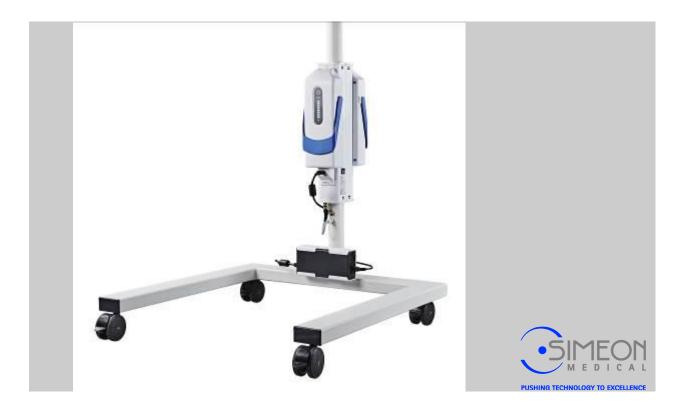
Instructions for Use

Mobile battery stand



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Before starting any work please read these Instructions for Use!

 S.I.M.E.O.N. Medical GmbH & Co. KG

 In Grubenäcker 18

 D-78532 Tuttlingen

 Telephone:
 +49 (0) 7461 90068-0

 Fax:
 +49 (0) 7461 90068-900

 E-mail:
 info@simeonmedical.com

 Internet:
 www.simeonmedical.com

Technical Service S.I.M.E.O.N. Medical GmbH & Co. KG Telephone: +49 (0) 7461 90068-888 E-mail: service@simeonmedical.com

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Instructions for Use Mobile battery stand

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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 5000/7000 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 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.
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.
	Forwarding of the Instructions for Use to a third party, its reproduction in any type or form – even if only partial – and the exploitation and/or dissemination of its contents are not allowed without written authorization from the manufacturer.
	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
- 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 noncompliance 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

A DANGER	Indicates a hazardous situation that, if not avoided, will result in death or serious injury.
	Indicates a hazardous situation that, if not avoided, could result in death or serious injury.
	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 Explanation of symbols

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

Max °C Min hPa ... hPa .. % REF SN IP20

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

Article number

Serial number

Class II

Protection type







Caution when using the product



Recyclable (Taiwan)

A1:2013



Federal Communications Commission Conformance (US)

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-



RoHS-conform as per 2011/65/EU



Protect from sunlight.



Direct current



Alternating current



Transport regulations for hazardous substances complied with



Underwriters Laboratory (UL) listed



Lithium Ion Recycling







TÜV Rheinland listed device for US and Canada.

Do not use the device if the packaging is damaged

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.

Under dismantling/disposal (in addition to the existing text): Batteries or accumulators must not be disposed of with household waste at the end of their service life. If batteries or accumulators contain mercury (Hg), cadmium (Cd) or lead (Pb), you will find the respective chemical symbol below the symbol of the crossed-out garbage can. You are legally obliged to return old batteries and accumulators after use. You can do this free of charge at a retail store or at another collection point near you. Addresses of suitable collection points can be obtained from your city or local government. Batteries or accumulators can be returned to the manufacturer.

Batteries may contain substances that are harmful to the environment and human health. Particular caution is required due to the special risks involved in handling lithium-containing batteries. The separate collection and recycling of old batteries and accumulators is intended to avoid negative effects on the environment and human health.

Please avoid generating waste from old batteries as much as possible, e.g. by giving preference to batteries with a longer service life or rechargeable batteries. Please avoid littering public spaces by not leaving batteries or battery-containing electrical and electronic devices lying around. Please explore ways to recycle a battery instead of disposing of it, such as reconditioning or repairing the battery.

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



MD





Unique Product Identifier, displays a carrier that contains information about a Unique Product Identifier (UDI).

Local Agent, EC = Agent in the European Union

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

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 use

Intended use	The mobile stand with battery serves to hold the Sim.LED 350/3500+/4500/450/500/700/5000/7000 lights, position them in the room in a non-sterile manner, and operate them in mains operation or, if the battery is being used, independently of the power grid in accordance with the intended use of the lights in question. The mobile battery stand can be used off-line for a limited period of time with the use of a battery.
	The concept of intended use also includes compliance with all specifications in these Instructions for Use and the separate Installation Instructions.
Usage restrictions	May only be used in environments with professional healthcare facilities (such as dental offices, operating theatres, etc.)
	Any use that exceeds the intended use, and any other kinds of uses, are considered to be incorrect uses.

NOTICE	The battery module is a consumable.

A DANGER	Danger due to incorrect use!
A DANOLIN	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 device as a mobile stand.

Claims of any type due to damage caused by misuse, alteration or modification of the mobile battery stand are excluded.

Any changes to this medical device are not allowed as a basic principle. Exceptions are only given to authorized technical specialists appointed by the manufacturer.

Electromagnetic compatibility As electri (EMC) examinat

As electric medical devices, systems which can hold surgical or examination 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 system. The operation of accessories, converters and cables on the system which the manufacturer has not expressly approved may increase the system's interference emissions or reduce its interference resistance.

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

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

Operational reliability

The main performance feature of the mobile battery stand is:

the mechanical connection to the light

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 together with the unit.
Technical safety inspections	The operator must allow technical safety inspections to be conducted biennial.
	Technical safety checks may only be conducted by the manufacturer's personnel, or by authorized specialists who have received written approval from the manufacturer.
	The protocol prepared by the authorized specialist, detailing the measurement procedures, measurement results, and other evaluations, must be kept until the next check.



No liability in the event of noncompliance with time limits!

Notification of accidents and damages

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

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 batteries contain lithium ions and must be disposed of in an environmentally friendly manner.

Dismantling should only be conducted by trained, skilled personnel.

The devices may be returned to the manufacturer.

A DANGER	Risk of death due to improper dismantling!
DANOLIN	Errors during dismantling may result in life-threatening situations and cause significant material damages.
	Only allow trained, qualified personnel to conduct dismantling.
	Unauthorized dismantling is prohibited.



2	Operation	
	Â	Read all instructions first before operating!
	Â	Operating is to be performed by properly trained and authorized personnel only!
	À	Do not drink any alcohol or take any drugs before or during the operating and follow the safety instructions carefully.
	\wedge	Prevent direct glare! Users, patients and third parties should avoid looking into the surgical light for long periods of time.



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.

A DANGER	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. For that reason, please note the following:
	The installation and initial start-up may only be conducted by the manufacturer's personnel or by persons authorized by the manufacturer.
	The second secon
A DANGER	Risk of injury due to electric shock! In order to avoid the risk of an electric shock, the lighting may only be connected to a power supply system with a ground connection!
	Risk of injury due to pinching!



Objects and body parts may be pinched when moving! Make sure that the entire movement area is free when the device is being moved!



2.2 Variants

The Mobile battery stand is available in available in different variants.

2.2.1 Mobile battery stand for surgical lights

The various type designations generally denote mobile battery stands with different numbers of batteries.



Mobile battery stand with single Mobile battery stand with dual battery battery

The mobile battery stands for surgical lights may exclusively be used to hold surgical lights. For details on compatible types of lights, see 🗞 *"Technical data", page 31*



2.2.2 Mobile battery stand for examination lights



Mobile battery stand with single battery

The mobile battery stands for examination lights may exclusively be used to hold examination lights. For details on compatible types of lights, see *"Technical data", page 31*:



2.3 Visual inspection of the mobile battery stand

Before switching on the mobile battery stand, make sure that it is undamaged and correctly plugged in.

If the device is used in battery mode, make sure that the batteries are fully charged. There is no danger when an intact mobile battery stand is used as intended.

♦ "Intended use", page 11.

However, damage to the mobile battery stand, battery or current supply could cause considerable risks:

ADANGER	Risk of death due to electric shock!
Z	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.
Electrical hazard.	In the event of insulation damages or electric cable defects, the lights must immediately be disconnected from the mains through the main switch in the operating room (wall- and ceiling-mounted versions; for mobile lamps, pull the power plug). Perform repairs! Never supply voltage to defective lights!
	Repairs may only be conducted by skilled electricians!
	Keep moisture away from live parts. Moisture could lead to a short-circuit.
	Before conducting any maintenance, cleaning or repairs, switch off the power supply and safeguard against reconnection.
	Before starting any work, ensure that:
	 a visual inspection for damage or cracks on the unit has been conducted.
	 all hygiene regulations have been adhered to
	 there are no unauthorized persons in the vicinity of the unit.
	Risk of infection due to improper hygiene, disinfection, or sterilization!
	There is a risk of infection upon contact with parts that have not been cleaned or disinfected.
	Clean and disinfect the unit before every use.
	Adhere to all standards on hygiene, disinfection and sterilization that are locally in effect.



Risk of injury due to contamination of wounds!
Damage to the mobile battery stand 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.



2.4 Operation of the mobile battery stand

2.4.1 Check charge level and attach battery module

NOTICEIf the remaining battery life is lower than 15 minutes, an acoustic signal will
sound every 10 seconds and the charging bar will light up orange. Please
replace the battery modules as quickly as possible or connect the mobile
stand to the power supply unit! Complete charging takes approx. 2.5 hours.
With 2 modules, this corresponds to approx. 5 hours.If the mobile battery stand is not used for a long period of time, the

If the mobile battery stand is not used for a long period of time, the charge level of the battery module must be checked after a maximum of 4 weeks. If the charge level is below 50%, the battery module must be fully charged again.



Check charge level

First, check whether the battery module is charged sufficiently by briefly pressing the standby button. The display graph will light up and indicate the current charge level. It is recommended to use only fully charged battery modules for ideal performance.



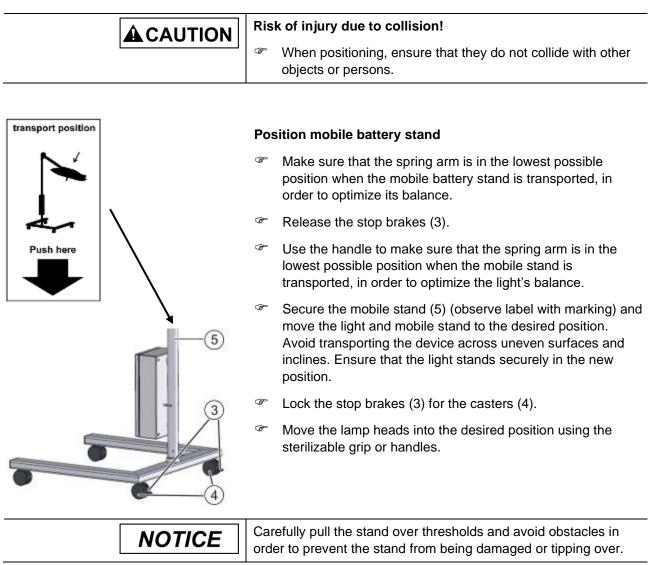
Attach battery module

Attach the battery module to the lower base and click it into place towards the center.

Attach second battery module (for mobile battery stands with dual batteries only)

Attach the second battery module to the lower base and click it into place towards the center.





2.4.2 Position mobile battery stand



2.4.3 Switching the mobile battery stand on/off



Switching the mobile battery stand on

- Hold the standby button down for approx. 2 seconds in order to turn the system on.
 - ➡ The standby button will blink and briefly light up blue and the charge bar will run from bottom to top one time. The system is ready for operation.

Switching on the light

Switch on and adjust the light according to the relevant instructions for use.

Switching off the mobile battery stand

- Hold the standby button down for approx. 5 seconds in order to turn the system on.
 - ➡ The standby button will go out and the charge bar will run from bottom to top one time. The system is turned off.

NOTICE	The battery modules must be switched off and charged after use.
--------	---

2.4.4 Connect external power supply (optional)



- An external power supply can be optionally connected in order to supply the light with mains voltage or charge the battery module.
 - Slide the power supply into the intended power supply holder and connect it to the battery module. Insert the mains plug into the socket.
 - ➡ The battery modules will be charged automatically; the charge bar will run from bottom to top.
 - If two battery modules are connected, they will both be charged up at the same time.



2.4.5 Remove battery module



Remove battery module

- Push the release button in order to remove the battery module
 - ➡ The battery modules can now be charged using the wall charging station
- ♦ "3.1 Wall charging station, page 25



Accessories

3 Accessories

3.1 Wall charging station

Intended use

The wall charging station accessory is for holding and charging individual batteries intended for this purpose by the manufacturer.



2x charging station *Item no.: 491-0016703*

4x charging station *Item no.: 491-0016702*

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. For that reason, please note the following:	
The installation and initial start-up may only be conducted by the manufacturer's personnel or by persons authorized by the manufacturer.	
 The second secon	



4	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.
	NOTICE	Do not conduct maintenance or service work while the devices are being used.
		Risk of death due to incorrect maintenance! Errors during maintenance may result in life-threatening situations and cause significant material damage. For that reason, please note the following: Image: The second



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	Check the braking power and adjust if necessary. Setting the braking power", page 30.	Operator's medical technicians
Monthly	Check the charge level of the battery module and fully charge it if necessary	Operator's medical technicians



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.
Unauthorized dismantling is prohibited.

Cleaning the unit 4.2.1

NOTICE	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 containing benzine or aldehyde.		
	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).		



DANGER	Risk of death due to electric shock!		
2111	There is an immediate risk of death due to electric shock when coming into contact with live parts.		
11	Before cleaning, disinfecting or sterilizing, also pull the power plug from the power outlet.		
ctrical ard.	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 or moisture is able to penetrate		

P Disconnect the power supply.

into the unit through openings.

^{CP} Wipe the unit using a moist - not wet - cloth.



4.2.2 Disinfecting the unit: Wiping disinfection

	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.	
NOTICE	Risk of material damages due to spray disinfectants!	
None	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 using a surface disinfectant.	
	You can find recommendations and information on the selection and use of disinfecting agents, in the most curren standards and guidelines on disinfection and explosion protection.	
NOTICE	Risk of material damages when using unsuitable disinfectants!	
	Chloride-, peroxide- and halide-containing disinfectants may corrode the unit's surfaces or plastic parts.	
	Do not use any chloride-, peroxide- or halide-containing disinfectants.	
	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 store has been been being being agents.	

Disconnect the power supply

protection.

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

standards and guidelines on disinfection and explosion



4.2.3 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.

- Insert the Allen key into the adjustment opening (1) of the brake screw to be adjusted.
- Turn the brake screw in a clockwise direction, using the Allen key, to increase the braking power. Turn the brake screw counter-clockwise to decrease it.
- Remove the Allen key from the adjustment opening.





Technical data

5 Technical data

5.1 Technical data Surgical light mobile battery stand

Mobile stand with a battery	Description	Valu	ies	
General information	Battery life at maximum intensity [h]			
	Sim.LED 450 SC/MC	5 / 4	1.2	
	Sim.LED 500 SC/MC	4/3	3.5	
	Sim.LED 700 SC/MC	3.5 /	3.5	
	Sim.LED 5000 SC/MC	3.2 /	4.3	
	Sim.LED 7000 SC/MC	3.2 /	3.6	
	Optional power supply			
	Supply voltage AC [V]	100 - 240		
	Mains frequency [Hz]	47 -	63	
	Current consumption [A]	2.5 -	1.2	
Operating conditions				
	Temperature range	5 – 40 °C	41 – 104 °F	
	Relative air humidity, maximum	75 %		
	Air pressure	700–1,060 hPa		
	Usage	Indoor Use		
	Pollution Degree	2		
	Overvoltage Category	II		

Technical specifications are subject to change; tolerance $\pm 10\%$

Mobile stand with two batteries	Description	Values
General information	Battery life at maximum intensity [h]	
	Sim.LED 450 SC/MC	10 / 8.4
	Sim.LED 500 SC/MC	8 / 7
	Sim.LED 700 SC/MC	7 / 7
	Sim.LED 5000 SC/MC	6.4 / 8.6
	Sim.LED 7000 SC/MC	6.4 / 7.2
	Optional power supply	
	Supply voltage AC [V]	100 - 240
	Mains frequency [Hz]	47 - 63

Technical data



Mobile stand with two batteries	Description	Values	
	Current consumption [A]	2.5 - 1.2	
Operating conditions			
	Temperature range	5 – 40 °C 41 – 104 °F	
	Relative air humidity, maximum	75 %	
	Air pressure	700–1,060 hPa	
	Usage	Indoor Use	
	Pollution Degree	2	
	Overvoltage Category	II	

Technical specifications are subject to change; tolerance ±10%

5.2 Technical data examination light mobile battery stand

Mobile stand with a battery	Description	Values
General information	Battery life at maximum intensity [h]	
	Sim.LED 350	8.6
	Sim.LED 3500+	14.5
	Sim.LED 4500	7.7
	Optional power supply	
	Supply voltage AC [V]	100 - 240
	Mains frequency [Hz]	47 - 63
	Current consumption [A]	2.5 - 1.2
Operating conditions		
	Temperature range	5-40 °C 41-104 °F
	Relative air humidity, maximum	75 %
	Air pressure	700–1,060 hPa
	Usage	Indoor Use
	Pollution Degree	2
	Overvoltage Category	I

Technical specifications are subject to change; tolerance ±10%

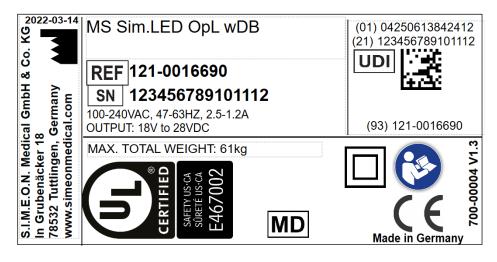




Technical data

5.3 Type plate

The type plate is located on the mobile stand.



It includes the following information:

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