ADVANCING HEALTHCARE TECHNOLOGY

HUTZ MEDICAL

INSTRUCTIONS FOR USE

Solaris II-LED 5000/7000

TABLE OF CONTENTS

1. GENERAL

1.1. Information on this Operating Manual

This User Manual enables safe and effective use of the Solaris 5000/7000. This User Manual is applicable to all Solaris II-LED 5000/7000 lights and it must be kept near the device and in a place, that is accessible to personnel at all times.

The personnel using the Solaris II-LED 5000/7000 should carefully read and understand this manual prior to commencing any work. The indispensable condition of working safely is compliance with all safety requirements and instructions given in this manual.

In addition, all local guidelines on the use of medical devices must be applied.

The aim of the illustrations in this manual is to provide basic understanding, even if the pictures differ from the actual version.

In addition to this manual, the manuals accompanying the installed components are also applicable. The spring arm must be mounted in the work steps in accordance with the accompanying assembly instructions and user manual of the manufacturer, Hutz Medical.

Any unauthorized modifications or conversions to the Solaris II-LED 5000/7000 are not permitted for the sake of safety. In case of unauthorized modifications or conversions, the manufacturer's warranty shall become null and void.

1.2. Symbol Description

Safety specifications

The safety specifications in this manual are identified with symbols.

The safety specifications are prefixed to certain phrases, which express the degree of danger.

In order to avoid accidents and damage to life and property and to ensure maximum safety of the patients, it is absolutely necessary to observe and follow the safety instructions and proceed with caution.

	**ELECTRIC SHOCK!** This combination of symbol and word warns of an electric shock. In the process, it may cause serious injuries or even death.
	**WARNING!** This combination of symbol and word refers to a potentially dangerous situation, which may cause serious or fatal injuries if not avoided.
	**FOLLOW THE USER MANUAL!** This symbol is placed on the labels and indicates that the user must observe and follow the user manual before use.
	**DATE OF MANUFACTURE!** This symbol is located on the model plate and indicates when the medical device was manufactured.
	**MANUFACTURER!** This symbol indicates the manufacturer of this medical device.
	**KEEP IN A DRY CONDITION!** This symbol is placed on the labels of outer packaging and indicates that the product should be protected from moisture during transport.

DISPOSAL INSTRUCTIONS!

This symbol indicates that the product should not be disposed of along with household waste.

Symbols in this user manual

For emphasis on procedural instructions, description of user manual results, bullets, directions and other elements, the following signs and visual marks are used in this user manual:

1. Depicts procedural instructions step-by-step.

→ Depicts a state or an automatic sequence as the result of an action.

▪ Depicts bullets and elements of a list without an established order.

Depicts references to chapters of this user manual.

[KEY] Depicts names of keys, knobs and other control elements

Position and illustration numbers of this document

The illustrations of this document can be numbered. In order to provide a clear assignment of picture and text, the item numbers are specified in the text according to the Figure number, for example: (Figure X/Y) where X is the Figure number and Y corresponds to the item number that is specified in the Figure.

1.3. Limitation of the Responsibility

All data and indications of this user manual are compiled in compliance with the applicable standards and regulations, and our knowledge from experience over many years.

We disclaim any responsibility and all warranty claims are null and void in case of damages that are attributable to:

- ignoring this user manual;
- any use other than that intended;
- operation by unqualified personnel;
- structural modifications that were implemented without authorization;
- technical modifications;
- use of defective or incorrectly repaired devices;
- use of unauthorized spare parts and accessories.

For special versions, options of additional orders or technical modifications of the latest generation, the real scope of supply may vary from the descriptions and representations illustrated here.

1.4. Protection of Intellectual Property

This user manual is protected by copyright and meant only for internal use.

It is prohibited to disclose this user manual to third parties, to reproduce it in any form - and even in extracts - or to evaluate or communicate its contents, unless for internal purposes, without the express written permission of the manufacturer.

Violations shall obligate to payment of compensation. We reserve the right to petition other complaints.

1.5. Warranty

The warranty provisions are furnished in the general terms and conditions of the manufacturer.

1.6. Customer Service

For technical information, our Sales employees are at your service.
Refer to the contact information on the last page.
Our employees, too, are always interested in new information and experiences arising from the use of our products, and which may contribute to the improvement of these products.

2. SAFETY

This paragraph provides an overview of the most important safety aspects on how to achieve optimum safety of patients and personnel and how to achieve a safe and trouble-free use of the equipment.

Failure to comply with the user manual and the safety information contained therein may lead to considerable damages.

2.1. Planned use

The system has been conceived and designed exclusively for the purpose described here. The exclusive purpose of Solaris II-LED 5000/7000 is the illumination of operation fields and medical treatment areas. The compliance with all indications in this user manual is part of the intended use. Any use that goes beyond the said or of other nature is considered to be inappropriate.

WARNING!

Risk due to inappropriate use!

The inappropriate use of the device can result in hazardous situations.
Inappropriate use denotes primarily:

- The use of the device beyond the treatment rooms and operating theatres that meet the medical purposes;
- The use of the device in theatres that have not been built according to the applicable guidelines for the construction of theatres with medical purposes and according to their standard.
- The use of the device in areas with risk of explosion.
- Use of a damaged unit.
- The use of the appliance by unqualified staff.
- The use of a device, on the arm or light fixture of which objects were hung or attached.

Rights of complaint for all damages resulting from an inappropriate use, from structural changes or from a modification of the Solaris II-LED 5000/7000 or examination light are excluded.

2.2. Responsibility of the Operating Unit

Operator
The operator is the person who uses the device on his own account for industrial or commercial purposes or who provides the device to third party for utilization/application and who assumes the legal responsibility of the device for the protection of the user, staff or any third party during the operation.

Duties of the Operator

The device is used in the medical field. For this reason, the operator is bound by the legal obligations of the country in which the device is used, inter alia, by those relating to the safety at work and the safety of the patient and the compliance with the hygiene regulations;
Before mounting the Solaris II-LED 5000/7000, the bearing capacity of the ceiling/wall is to be checked by a structural engineer and confirmed in a declaration of acceptance;
The electrical installation of the room in question must meet the requirements of the applicable national and international regulations;
The operator is obligated to be informed about all locally relevant laws that are valid at the time of use of the device and also about all the related standards and guidelines and is obligated to fulfill them;
The operator must be informed about the applicable guidelines on hygiene and prevention of accidents.

Personal Responsibility

- The operator must regulate and clearly define the relevant responsibility for the installation, operation, elimination of faults, maintenance and cleaning;
- It is the task of the operator to ensure that all the staff, who operate the unit, have read and understood this user manual. He must also train the staff in regular intervals and inform about existing risks;
- It is the task of the operator to ensure that the maintenance intervals and the technical inspections described in these user manuals are complied with;
- It is the task of the operator to ensure that components exclusively recognised and approved by the manufacturer are used for the device.

Technical safety checks

- The operator must ensure that the technical safety inspections are carried out in regular intervals;
- Technical safety inspections may be carried out exclusively by the employees of the manufacturer or by authorized and specialized skilled personnel;
- The maintenance and cleaning scheme drawn up by the authorized and qualified person with respect to the methodology of the applied measurements, results and other evaluations must be preserved until the next inspection.

The enclosed inspection schedule specifies the minimum test steps with interval specifications. No responsibility is assumed for lack of compliance with the inspections within the specified deadlines.

The manufacturer is not responsible for material damages or personal injuries that arise because the deadlines defined for the work and the implementation of technical safety inspections are not complied with.

Accident and Accident Reporting

- Malfunction or faults of the device that have caused personal injury must immediately be reported to the competent authority and the manufacturer.

The competent authority may require that the operator hands over the technical safety evaluation of the reported event to one of his experts and that the evaluation report is notified in writing to them.

- The technical safety evaluation must clarify the following points:

1. to what the event is to be attributed;
2. whether the device was in a fully functional state;
3. whether there is no more danger after elimination of the defect;
4. if you have heard of something new.

2.3. Combination with Other Devices

Use of incorrect or defective equipment can lead to risks for the staff and the patients, as well as to damages, malfunctions or a complete failure of Solaris II-LED 5000/7000.

2.4. Spare Parts

WARNING!

Risk of injury due to use of wrong spare parts!

Each component of Solaris II-LED 5000/7000 has a unique marking in the form of a model plate;

Use of incorrect or defective spare parts can lead to risks for the staff and the patients, as well as to damages, malfunctions or a complete failure of the device;

- Original spare parts of the manufacturer or spare parts authorized by him must be used;
- In case of doubt, always consult the manufacturer.

Loss of warranty

Use of unauthorized spare parts will cancel the right of warranty.

Spare parts can be purchased from an authorized distributor or directly from the manufacturer. Consult the address on the last page.

2.5. Personnel Requirements

2.5.1. Qualifications

In general, the medical devices must be set up, handled, cleaned and maintained by skilled personnel with the necessary training, expertise and the necessary experience.
People who have obtained their skills in medical technology as part of a specialized training with supporting documents are deemed as qualified personnel.

WARNING!

Risk of injury in case of inadequate qualification of the staff.

Operation of the device by unqualified personnel may result in situations that threaten the safety of patients and staff.

- All activities must be carried out by qualified personnel.

In these user manual, the required qualification is specified in order to exercise activities in various fields.

Electricians are capable, due to their technical training, knowledge and experience of the relevant standards and guidelines, to work on electrical installations as well as to detect and avoid potential risks to themselves and other people.
The electrician must follow legally valid guidelines and standards for the prevention of accidents.

Manufacturer

Some work can be done only by Hutz Medical, by staff trained explicitly by Hutz Medical or by a person or company that has been authorized by Hutz Medical. No other person is entitled to carry out this work. Please contact our technical service to have the respective tasks carried out; you will find the address on the last page.

Specialized Medical Personnel

The specialized medical personnel have been trained for the special area in which it operates. The specialized medical personnel are familiar with the contents of all important applicable guidelines and standards for the safe use of the device and can meet the requirements that are mentioned in the user manual.

Thanks to the instructions, which the specialized medical personnel must have received with this user manual, and also thanks to their specialized medical training and experience, the specialized medical personnel can implement their tasks and can discover, evaluate and avoid potential dangers for themselves and for the patient.

The specialized medical personnel must receive the necessary technical knowledge for proper use of the device and must be trained by the operator with respect to all guidelines of hygiene of the theatres of medical equipment and the use of medical products.

State Certified Technician / Specialization in Medical Technology
(collaborate in the development, manufacture and application of medical-technical devices)

The technician must have been trained by this for the work area and he must know the relevant standards and guidelines;
The technician can eliminate faults on basis of his technical training and experience and carry out maintenance work, which is assigned to him by the operator;
Only those people who are accepted as being reliable personnel should carry out the work.
Persons whose responsiveness is influenced by the use of drugs, alcohol or medication, will not be accepted.

In the selection of personnel, specific professional standards must be observed by the operator that are applicable at the place of application.

2.5.2. Unauthorized Persons

WARNING!

Risk of injury by unauthorized persons!

Unauthorized persons who do not comply with the indications specified here will not know the dangers of operating the device.

- The operation of the device by an unauthorized person must be avoided as guaranteed by the operator.

2.6. Requirements for Risk Management

In the next paragraph, other risks are mentioned that have been evaluated in a risk analysis. In order to reduce health risks and dangerous situations, the safety indications must be followed, which were put forward and are given in the following chapter of this user manual.

2.6.1. Hazards of electrical energy

Electric current

DANGER!

Mortal danger due to electric shock!

Upon contact with electrically conducting parts, there is a risk of instantaneous fatal injury from electric shock. Insulation damages in any component may be fatal.

- It must be possible to switch off the device by a main switch from all power supply networks with all poles;
- In case of insulation damage in a cable, the power supply must be interrupted immediately with the main switch of the operating theatre and the damage must be rectified;
- The repairs must always be carried out by specialized electricians;
- Fuses should neither be bypassed nor eliminated. When replacing fuses, it is necessary to comply with the correct amperage;
- Conductive parts must be protected from moisture. It could cause a short circuit;
- Before doing maintenance, cleaning or repair, the power supply must be switched off and covered such that the device cannot be switched on again;
- Connect the equipment only to a grounded power supply.

2.6.2. Hazard of increased temperatures

Drying up of wounds

WARNING!

Tissue damage due to drying up of wounds!

The superimposed light fields of various light fixtures with high light intensity produce a high temperature in the light field. This may damage tissues.

- When superimposing the light fields (2 lamps), it must be noted that the portion of energy may be higher.

2.6.3. Risk of overloading

Risk of injury due to overloading

WARNING!

Risk of injury due to overloading of individual parts

The support arm system and the terminal device constitute one system tuned to each other in the load capacity.

The placement of additional inappropriate loads on the spring arms, the cardan suspension or the light fixture produces an overload and may lead to fracture / crashing down of the support system, and the terminal device.

- Do not attach any additional loads to the spring arm, the cardan suspension or the lamp.

2.6.4. Risks of lack of hygiene

Risk of infection

WARNING!

In case of inadequate hygiene, cleaning and sterilization, there is a risk of infection.

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

- Clean and disinfect the device before each use;
- Clean and disinfect the device with general common disinfectants and cleaning agents based on alcohol. Do not use any caustic cleaning agents;
- Do not use abrasive cleaners;
- Follow the sterilization specifications;
- All locally applicable requirements regarding hygiene, disinfection and sterilization must be considered.

2.7. Safety Precautions

In case of interruption of the power supply via the main switch, the device must be immediately disconnected from the power supply. The operating theatre or the medical examination theatre must be equipped with a main switch, which ensures that the Solaris 5000/7000 is switched off with all poles from the supply networks.

WARNING!

Risk of fatal injury in case of unchecked reconnection!

An uncontrolled reconnection can cause serious or even fatal injuries.

- Before reconnection, ensure that all cleaning and maintenance work has been completed properly.

3. TECHNICAL SPECIFICATIONS

	Name	Solaris 5000	Solaris 7000
General data	Weight of the light fixture [kg]	14	18
	Dimensions [LxWxH] [mm]	586x597x55	679x708x55
	Service life of the lamp	>50,000	>50,000
	Rotation [°]	360	360
	Sterilisable handle	Standard	Standard
	IP protection class	42	42
	Housing	Aluminum	Aluminum
	Glass	Toughened safety glass	Toughened safety glass
Connection values	Nominal voltage [V]	24	24
	Voltage range [V]	20 to 32	20 to 32
	Current intake max. [A]	2.5	2.5
	Power intake nominal [A]	1.5	1.9
	Power intake [W]	35	45
Technical light properties	Light intensity at 1m distance [klx]	130	160
	Electronic dimming [klx]	40 to 130	40 to 160
	Light field diameter (D10) in 1m distance [mm]	150 to 280	170 to 300
	Electronic field adjustment	Yes	Yes
	Illumination intensity with tube and two masks, based on EC [%]	45	50
	Illumination intensity with standard tube, based on EC [%]	100	100
	Color rendering index Ra	96	96
	Red rendering index R9	96	96
	Depth of illumination L1 + L2 20 % [mm]	1000	900
	Depth of illumination (L1/L2) 60% [mm]	445	420
	Increase in temperature at head height	< 1°C	< 1°C

	Name	Solaris 5000	Solaris 7000
Technical light properties	Irradiance at 130/160 klx [W/m²]	480	520
	Color temperature [K]	4900	4900
	Luminous efficacy of radiation [lm/W]	290	290
Environmental conditions for the normal operation	Operating temperature [°C]	5 to 40	5 to 40
	Relative maximum humidity [%]	5 to 95	5 to 95
Environmental conditions temporary storage/ transport	Operating temperature [°C]	-10 to 40	-10 to 40
	Relative maximum humidity [%]	5 to 95 not condensing	5 to 95 not condensing
	Air pressure	700Pa to 1060 hPa	700Pa to 1060 hPa

Tolerance ±10 %; rights to technical changes reserved

3.1. Technical Specifications of the spring arm

The technical specifications of the spring arm are provided in the attached assembly instructions and the user manual of the manufacturer, Ondal Medical Systems GmbH, D-36088 Huehnfeld.

3.2. Model plate

Figure 1: Example of model plate Solaris II-LED 5000/7000

The model plate (Figure 1) is located on the cardan suspension and contains the following data:

▪ Article number: REF 80-000151	▪ Current intake: 1.5A
▪ Product name: Solaris II 5000	▪ Power intake: 35W
▪ Serial number: 123456789	▪ Manufacturer: Hutz Medical
▪ Nominal voltage: 24V DC	▪ Year of manufacture: 07-2015
▪ CE marking	

4. STRUCTURE AND FUNCTION

4.1. General overview

4.1.1. General overview of the ceiling versions

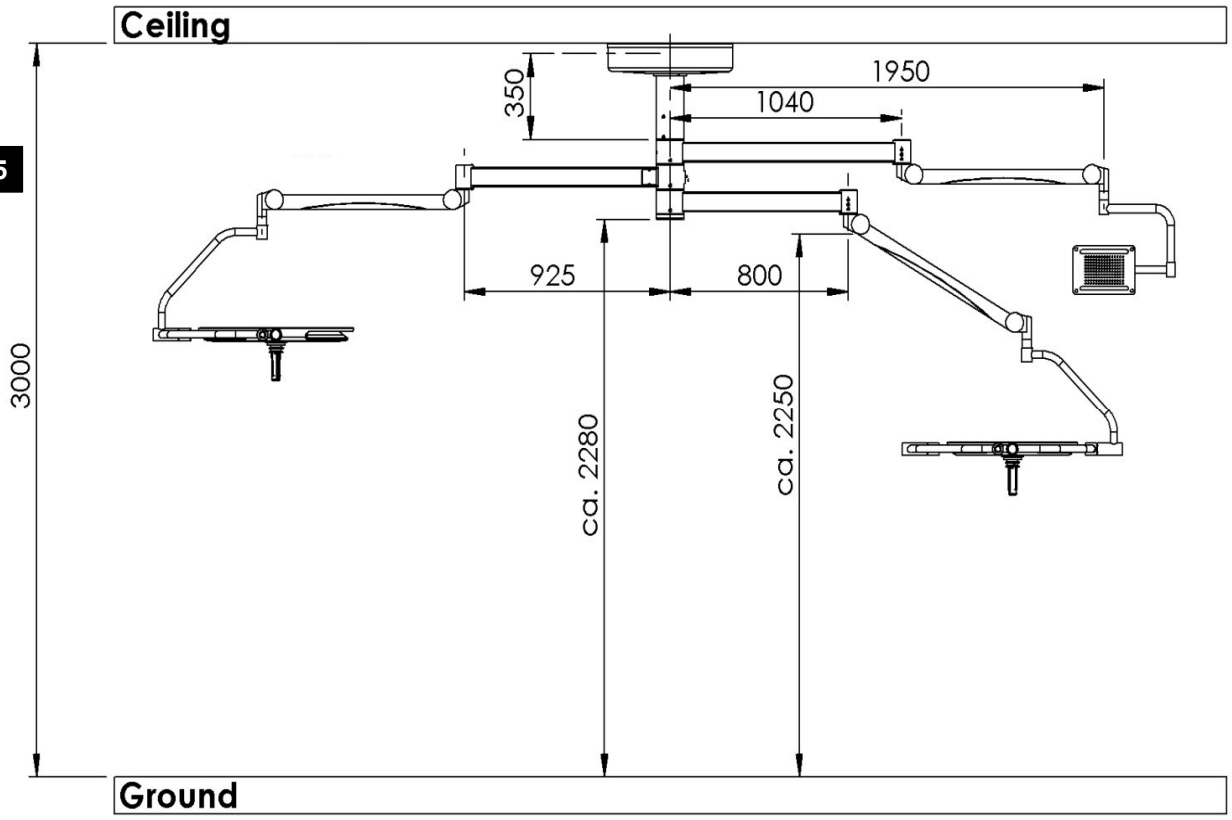

Figure 2: General overview of the ceiling version Solaris II-LED 5000/7000.

Position	Name
1	Light fixture
2	Light control panel
3	Sterile handle
4	Spring arm
5	Cardan suspension

4.1.2. General overview of the mobile version Solaris II-LED 5000/7000

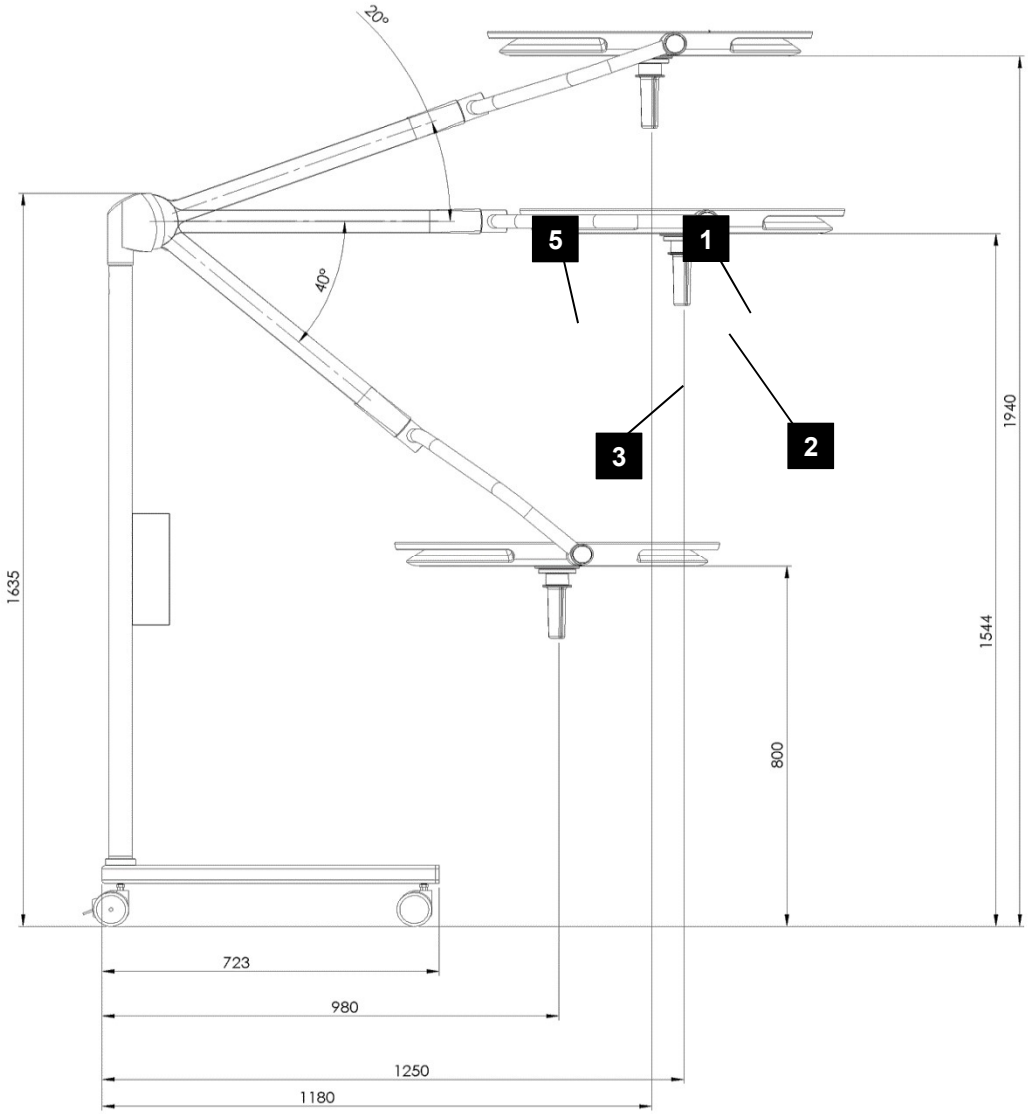

Figure 3: General overview of the mobile Solaris II-LED 5000/7000

Position	Name
1	Light fixture
2	Light control panel
3	Sterile handle
4	Spring arm
5	Cardan suspension

Position	Name
6	Mobile stand
7	Wheels
8	Brake
9	Power supply unit

The Solaris II-LED 5000/7000 on wheels (Figure 3) consists of the stand-, the spring arm- and the light fixture system. The rollers are equipped with brakes in order to prevent inadvertent movements of the device. The spring arm of the manufacturer Ondal Medical Systems GmbH, Wellastraße 6, 36088 Hünfeld can be adjusted in accordance with the optimum weight compensation. The mobile version Solaris II-LED 5000/7000 is powered by the power supply unit.

4.2. Brief description

The exclusive purpose of Solaris II-LED 5000/7000 in its various versions is the illumination of operation areas and areas of medical treatment. The mobile Solaris II-LED 5000/7000 is to be used for examination purposes. The mobility of the light fixture is guaranteed by a system which consists of a ceiling pipe, boom, spring arm, a cardan suspension and the light fixture. The Solaris II-LED 5000/7000 is controlled with the keys of the control panel on the light fixture to the right side of the cardan suspension. The light fixture is brought into position with the replaceable sterile handle.

The Solaris II-LED 5000/7000 with integrated camera module as an optional accessory is likewise controlled using the keys on the control panel on the light fixture to the right side of the cardan suspension. The camera focuses automatically on the basis of the present image content. The camera can be controlled both via the keypad of the control unit and "remotely" via various interfaces. Details about the operation of the camera system can be found in the corresponding user manual of the camera.

4.3. Description of design groups

4.3.1. Canopy and ceiling conduit

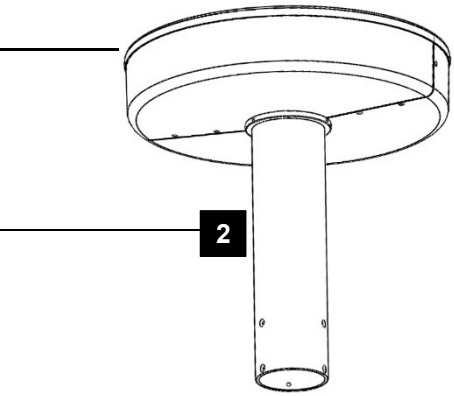

Figure 4: Canopy and ceiling tube

The boom system consisting of spring arm and lamp is mounted on the ceiling conduit (Figure 4/2). The canopy (Figure 4/1) obscures the hole in the ceiling drilled for mounting.

4.3.2. Central axis

Figure 5: Central axis

The central axis (Figure 5) is mounted on the ceiling conduit. The central axis consists of the central axis and booms.

4.3.3. Boom

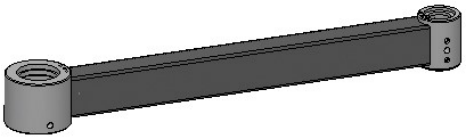

Figure 6: Boom

The boom (Figure 6) is available in various lengths. They serve as a support for the spring arms and thus also for the lamp.

4.3.4. Spring arm

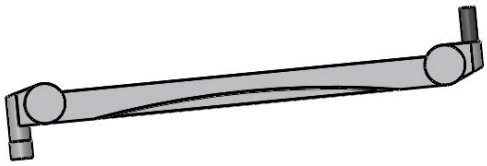

Figure 7: Spring arm

The spring arm (Figure 7) is attached to the central axis and allows the flexibility of the lamp. When adjusting the height stop, it must be ensured that a collision with terminals or the ceiling is not possible.

Please note carefully the enclosed assembly instructions and user manual for the spring arm of the manufacturer Ondal Medical Systems GmbH, Wellastraße 6, D-36088 Huenfeld.

4.3.5. Cardan suspension

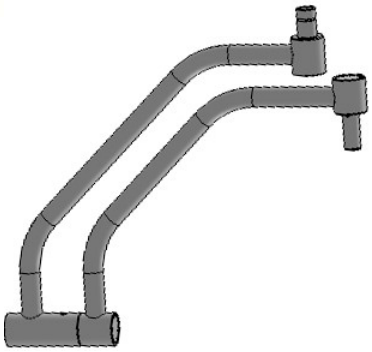

Figure 8: Cardan suspension

The cardan suspension (Figure 8) is attached to the spring arm and allows the light fixture to move in all degrees of freedom and in all possible directions.

4.3.6. Light fixture

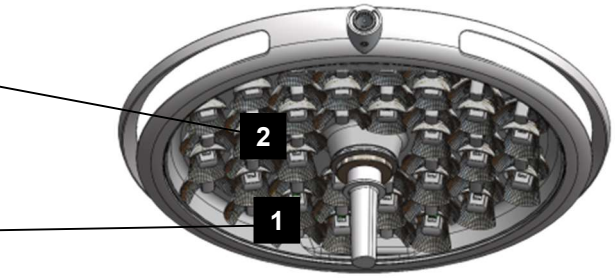

Figure 9: Light fixture

The light fixture (Figure 9) has a sterile handle (Figure 9/1) for manual positioning. With the capacitive touch control (Figure 9/2) the device can be turned on and off and the illumination intensity can be regulated.

4.3.7. Sterile handle

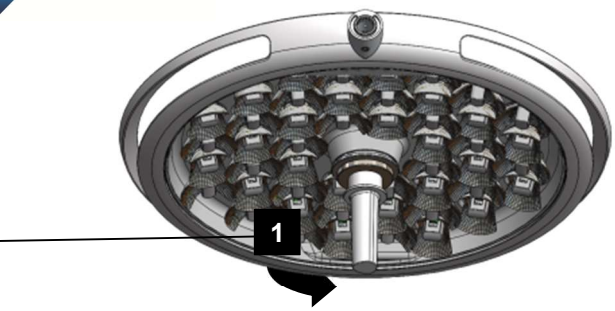

Figure 10: Sterile handle

By turning the sterile handle (Figure 10/1) the light field can be expanded or reduced.
The sterile handle can be taken out, which allows adequate cleaning and sterilization.
By turning the sterile handle clockwise, the light field is expanded and by turning the sterile handle counterclockwise the light field is reduced. The sterile handle can, together with the handle of the lamp unit, be removed and replaced by a camera.

4.3.8. Camera

Figure 11: Camera

The camera is controlled by the separate camera controller. The sterile camera handle (Figure 11/1) is removable in order to allow for proper disinfection and sterilization.

4.3.9. Mobile stand (only for mobile version Solaris II-LED 5000/7000)

The system consisting of spring arm and lamp is mounted on the mobile stand Solaris II-LED 5000/7000 (Figure 12). The wheels are designed to prevent electrostatic charges and are equipped with brakes to prevent inadvertent movement of the device.

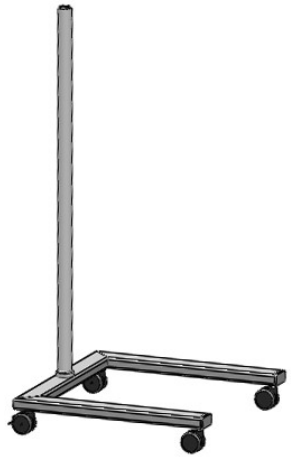

Figure 12: Mobile stand

4.4. Operation of Solaris II-LED 5000-7000

The touch controls (Figure 13) is integrated into the safety glass. By the [ON/OFF] keys, the device is turned on and off. The [MINUS] and [PLUS] keys are used to adjust the light intensity. The [AMBI] key is used to switch to endoscopic light.

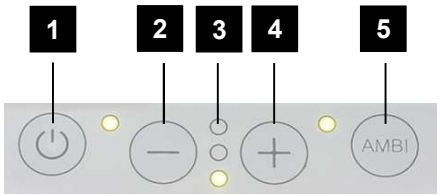

Figure 13: Touch control

Position	Name
1	[ON/OFF] Button with status display
2	[MINUS] Button for lighting
3	Dial illumination
4	[PLUS] Button for lighting
5	[AMBI] Integrated AMBI light for endoscopic operations

5. TRANSPORT, PACKAGING AND WAREHOUSING

The installation or the commissioning must be carried out exclusively by employees of the factory or by a person authorized by the manufacturer.

However, it may happen that the user or the personnel of the operator in connection with the installation and the subsequent use of the device assume the handling of the packages. In this case, the following instructions must be observed.

5.1. Safety Instructions for the transport

Improper transport

INSTRUCTION!

In case of improper transport, there is a risk of material damage!

Improper transport can lead to collapse or overturning of the pieces of luggage.
This can cause considerable material damages.

- When unloading the transported packages during delivery and during transport in the own company, you must proceed with caution and follow the symbols and indications on the packaging;
- Remove the packaging only shortly before the installation.

5.2. Transport inspection

Check the article immediately upon receipt, whether it is complete and whether they are damages due to transport.

If there are damages that are identified as damages due to transport, you must proceed as follows:

- Do not accept the delivery or only with appropriate annotation;
- Annotate the damage in the transport documentation or in the delivery note of the transport company;
- Immediately begin with the complaint formalities.

You can immediately complain about any defect that you find. Claims to redress can be asserted within the applicable complaint time. Please contact the address specified on the last page in case of damage.

5.3. Packaging

Regarding the packaging

The packages are packaged in cardboard boxes on a pallet in accordance with the provided transport conditions. For packaging, only environmentally friendly material is used.

Until the installation, the packaging must be protected against transport damage, corrosion and other damages in order to protect the various individual parts. Therefore, the packaging must not be destroyed and should be removed only shortly before the installation.

Handling of the packaging material

Dispose of the packaging material according to the legal and locally applicable regulations.

INSTRUCTION!

In case of improper disposal, there is a risk for the environment

Packaging materials are valuable raw materials that can be reused in many cases or processed and reused efficiently. Improper disposal of packaging materials can harm the environment.

- Dispose of packaging materials in harmony with the environment;

- Comply with the local disposal regulations. In this case, commission a specialized company with the disposal.

5.4. Packaging symbols

The following symbols are located on the packaging. Always follow the symbols for carrying out the transport.

	**Above** The arrowheads identify the upper part of the package. They must always be oriented upwards, otherwise the content may be damaged.
	**Fragile** Identifies packages, whose contents are fragile or sensitive. Be careful when handling the package, do not drop it or expose it to physical shocks.
	**Protect from moisture** Protect the packages from moisture and keep them dry.

5.5. Storage

Storage of the packages

The packages must be stored under the following conditions:

- Never store in open air;
- Store in a dry and dust-free place;
- Do not expose to aggressive agents;
- Protect them from the sun;
- Avoid mechanical shocks;
- Storage temperature between -10 and 40°C;
- Relative humidity: max. 95%;
- In case of a storage time of more than three months, the general condition of all pieces of luggage and their packaging are to be checked in regular intervals. If necessary, the preservative agent must be renewed or replaced.

6. INSTALLATION AND COMMISSIONING

6.1. General Instructions and Warnings

The installation and commissioning must be carried out exclusively by employees of the manufacturer or by a person authorized by the manufacturer.
When installing the spring arm, the enclosed assembly instructions and the user manual of the manufacturer Ondal Medical Systems GmbH, D-36088 Huehnfeld must be followed.
Before mounting the Solaris II-LED 5000/7000, the bearing capacity of the ceiling/wall is to be checked by a Structural Engineer and confirmed in a declaration of acceptance.

The electrical installation of the room in question must meet the requirements of the applicable national and international regulations.

WARNING!

Mortal danger in case of incorrect installation and erroneous commissioning!

Installation errors during the commissioning can cause danger to life and substantial material damages.

- The installation and commissioning must be carried out exclusively by employees of the manufacturer or by a person authorized by the manufacturer;
- To avoid the risk of electric shock, the lighting system may only be connected to a supply network with protective ground wire;
- In case of a later change in the installation location, consult with the manufacturer;
- The installation may not be done without authorization and the place of installation may not be changed upon own initiative.

7. APPLICATION

7.1. Safety Instructions in the application

Electric current

DANGER!

Mortal danger due to electric shock!

Upon contact with electrically conducting parts, there is a risk of instantaneous fatal injury from electric shock. Insulation damages in any component may be fatal.

- In case of insulation damage of a cable, the power supply must be immediately interrupted with the main switch of the operating theater and the damage is to be repaired;
- The repairs must always be carried out by electricians;
- Fuses should neither be bypassed nor eliminated. When replacing fuses, it is necessary to comply with the correct amperage;
- Conductive parts must be protected from moisture. It could cause a short circuit;
- Before doing maintenance, cleaning or repair, the power supply must be switched off and covered such that the device cannot be switched on again;
- Connect the equipment only to a grounded power supply;
- Power supply lines can be routed in the booms of the support arm system. Touching live parts may lead to a lethal electric shock. Before performing any assembly and maintenance work, disconnect the system from the power supply.

Improper operation

WARNING!

In case of improper operation, there is a risk of injury!

The improper operation can cause serious injuries and considerable material damages.

- All steps of operation must be performed according to the data and indications of this user manual;
- Before beginning the work, make sure that:
- a visual inspection of possible damages and cracks was carried out on the device;
- all hygiene standards have been met;
- nobody without authorization is located in the vicinity of the device.

Drying up of wounds

WARNING!

Tissue damage due to drying up of wounds!

The superposed light fields of various light fixtures with high light intensity produce a higher temperature in the light field. This can lead to damage to the tissue.

Risk of infection

WARNING!

In case of inadequate hygiene, cleaning and sterilization, there is a risk of infection.

Upon contact with parts that have not been cleaned or sterilized, there is a risk of infection;

- Clean and disinfect the device and the sterile handle before each use;
- Follow the sterilization specifications;
- All locally applicable requirements regarding hygiene, cleaning and sterilization must be considered.

Wound infection

⚠	WARNING! Risk of injury due to infection of wounds! If the light fixture or the sterile handle is damaged, loose or porous parts can fall into the wounds and can infect these. - Before each use of the device, carry out a visual inspection and a function check; - If the device shows external damages, it is not allowed to be put into operation; - Before each use of the device, check whether the sterile handle is securely fastened.

7.2. Changing the sterile handle

Figure 14: Detach the sterile handle

1. Press the knob (Figure 14/1) on the sterile handle.

Figure 15: Remove sterile handle

2. Remove the sterile handle from the inner handle of the lamp unit (Figure 15).

Install sterile handle

Figure 16: Install sterile handle

1. Make sure that the sterile handle has been properly cleaned and sterilized.

2. Position the sterile handle and turn until it locks in place (Figure 16).

3. Porous, defective sterile handles are to be disposed of immediately, as the sterility can no longer be reliably ensured.

7.3. Positioning of the light fixture Solaris II-LED 5000/7000

Depending on the intended field of use, the device must be correctly positioned before each start-up.

Positioning of the ceiling version

1. Bring the device under operation of the sterile handle to the desired position.

Positioning of the mobile version Solaris II-LED 5000/7000

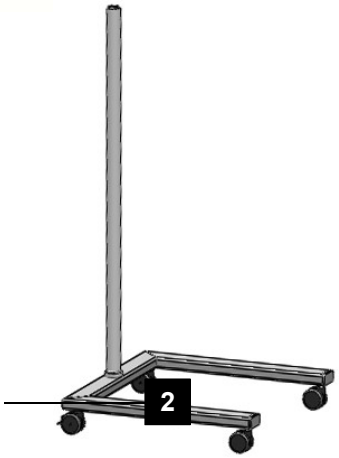

Figure 17: Wheels and brakes of the mobile stand

1. Bring the mobile stand in the desired position.

2. Apply the brakes (Figure 17/1) of the wheels. (Figure 17/2). For this, the brakes must be locked with the lever.

3. Bring the light fixture under operation of the sterile handle to the desired position.

7.4. Turn power supply on and off

Turn the power supply on

1. Turn on the OP main switch or, in case of the mobile version, insert the plug into the socket.

Turn off the power supply

1. Turn off the OP main switch or, in case of the mobile version, insert the plug into the socket.

Important condition: The OP-main switch is turned on or in case of the mobile version, the plug is in the live socket.

7.5. Turn touch-control on and off

Turn on device

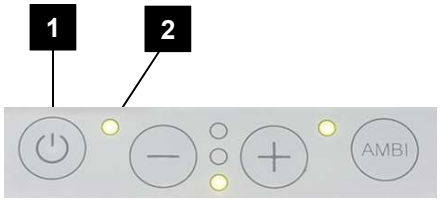

Figure 18: Button [ON/OFF]

Press the key [ON/OFF] (Figure 18/1) on the touch control of the light.

→ The surgical light turns on, green LED lights up (Figure 18/2).

The surgical light always begins the lighting process with the values of light field and illumination intensity set during the last use.

Turn off device

Press the key [ON/OFF] (Figure 18/1) on the touch control of the light again.
The surgical light will turn off.

7.6. Adjustment of the light field

The adjustment of the light field diameter is variable in 5 stages:

- FOCUS (reduced and adjusted to a light field set to a point);
- NORMAL (medium size light field);
- LARGE (medium size light field);
- LARGE (wide light field);
- Maximum (max. wide light field)

Expand light field

Figure 19: Light field adjustment - turn sterile handle clockwise

1. Turn the sterile handle clockwise (Figure 19) until the desired magnification of the light field is reached.

→ The Solaris II-LED 5000/7000 changes its light field.

Expand light field

Figure 20: Light field setting - turn sterile handle counterclockwise

1. Turn sterile handle counterclockwise until the desired reduction of the light field is reached.

7.7. Setting the lighting intensity

Increase the illumination intensity using the touch control

The light intensity can be adjusted in 8 steps. When viewing the LEDs, each 2 levels are indicated by one LED.

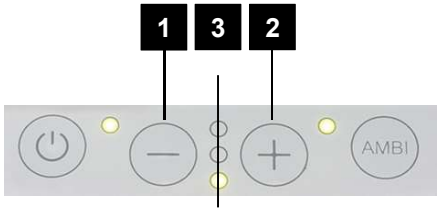

Figure 21: Setting the lighting intensity

1. Press the [PLUS] key (Figure 21/2) on the touch control of the light repeatedly or hold it down continuously until the desired illumination intensity is reached. The adjusted illumination intensity is indicated by green LED signal lights (Figure 21/3).

Reduce the illumination intensity using the touch control

1. Many a time press the key [MINUS] (Figure 21/1) on the touch control of the lamp or hold it down continuously until the desired decrease in the illumination intensity is reached. The adjusted illumination intensity is indicated by LEDs (Figure 21/3).

Increase the illumination intensity via the sterile handle

Figure 22: Increase the illumination intensity - rotate and hold sterile handle clockwise

1. Turn the sterile handle clockwise (Figure 22) and hold until the desired increased illumination intensity is reached.

Reduce the illumination intensity via the sterile handle

Figure 23: Reduce the illumination intensity - rotate and hold sterile handle counterclockwise

1. Turn the sterile handle counterclockwise (Figure 23) and hold until the desired reduced illumination intensity is reached.

8. SERVICING AND CLEANING

8.1. Safety instructions for Sevicing and Cleaning

Electric current

	**DANGER!** **Mortal danger due to electric shock!** Upon contact with electrically conducting parts, there is a risk of instantaneous fatal injury from electric shock. Insulation damages in any component may be fatal. - Electrical installation work must always be carried out by electricians; - For any type of maintenance work, cleaning and fault rectification, the power supply must be disconnected; - Keep conductive parts away from moisture and liquids. There may be a short circuit.

Poorly executed maintenance work

	WARNING! Risk of injury due to poorly executed maintenance work! Improper maintenance can cause serious injuries and considerable material damages. - Provide sufficient space for the assembly before beginning of work; - The assembly area must be in order and must be clean. - Loose and scattered components and tools evoke accidents. - Before a new start-up, you have to ensure: - that all maintenance work is carried out and completed in accordance with the data and instructions in this user manual.

8.2. Maintenance / Cleaning Schedule

The following paragraphs describe the maintenance work that is indispensable for optimal and trouble-free operation of the device.

If a high level of wear and tear is observed during regular inspections, the necessary maintenance intervals must be reduced based on the actual wear and tear.
In case of doubt with regard to the work and maintenance intervals, please contact the manufacturer (contact details on the last page).

Interval	Maintenance work	Staff
Annual	Carry out an overall inspection of the equipment	Operator
Monthly	Determine the braking force of the spring arm / mobile arm. ↳ *Chapter 8.4.2. "Adjustment of the braking force"*	Engineer / specialization in medical technology
	Examine the adjustment of the spring force ↳ *Chapter 8.4.1. "Adjustment of the spring force"*	Engineer / specialization in medical technology
	Examine the height stop ↳ *Chapter 8.4.3. "Adjustment of the height stop"*	Engineer / specialization in medical technology
After each operation	Replace the sterile handle with a clean and steam-sterilized sterile handle ↳ *Chapter 7.2. "Changing the sterile handle"*	Specialized medical personnel
	Clean and disinfect the device ↳ *Chapter 8.3.1. "Cleaning of device"* ↳ *Chapter 8.3.2. "Disinfection of the device"*	Specialized medical personnel
	Check whether the device shows external damages	Specialized medical personnel
	Check the proper functioning of the device	Specialized medical personnel
	Check whether the sterile handle is worn or damaged	Specialized medical personnel

8.3. Cleaning work

DANGER!

Mortal danger due to electric shock!

The cleaning of devices may only be performed by trained personnel. The operator is responsible for the compliance with national hygiene regulations. Upon contact with current-conducting parts or liquids, there is a risk of instantaneous fatal injury from electric shock;

- Before cleaning, disinfection or sterilization of the device, the power supply must be switched off using the main switch of the operating theatre. In the mobile version, - the plug must be pulled out of the live socket in addition;
- Secure the main switch or plug against an accidental power connection;
- Protect the device always against the ingress of liquid and never wet it for cleaning or disinfection;
- Always make sure that no cleaning agent or other liquids or moisture can penetrate into device openings or sockets.

For the safety of patients and staff and for the best possible care of the device, it must be cleaned and disinfected after each use.

8.3.1. Cleaning of device

INSTRUCTION!

Material damages caused by using inappropriate cleaning agents

Scraping or corrosive cleaning agents that dissolve the paint, can damage the surface of the device.

- Do not use cleaning agents that are abrasive or corrosive, that dissolve the paint or contain gasoline, aldehyde or large amounts of alcohol;
- Use the cleaning agent in such a way that no liquid can penetrate into the device;
- Clean the accessible parts only with neutral, surface-active soap solution.

1. Turn off power supply Chapter 7.4. "Turn power supply on and off".

2. Clean the device with a slightly damp cloth, however, never clean with any wet cloth. Finally, wipe dry with a clean, dry cloth.

8.3.2. Disinfection of the cleaning

WARNING!

Health risk due to disinfectants

Disinfectants can contain substances harmful to health.

- Always select and use disinfectants according to local guidelines of hygiene and function;
- Consult the recommendations and indications for the choice and application of disinfectants in the current provisions and guidelines for disinfection and protection from explosion.

INSTRUCTION!

Material damages due to spraying of disinfectants

The light fixtures are tested as per IP42; they can be sprayed over a large area with surface disinfectant.

- All components, including accessories and connecting cables must be disinfected with surface-active common disinfectants based on alcohol;
- Consult the recommendations and indications for the choice and application of disinfectants in the current provisions and guidelines for disinfection and protection from explosion.

INSTRUCTION!

Material damages caused by use of incorrect disinfectants

Disinfectants that contain the chloride, halide or too much alcohol can damage the surfaces and plastic parts of the device.
As standardized disinfection procedure for Solaris II-LED 5000/7000, the wiping disinfection is intended.

- Do not use disinfectants that contain chloride or halide;
- Use disinfectants with low alcohol content only;
- Dose the disinfectant in such a way that no liquid or moisture can penetrate into the device;
- Use wiped surfaces only after drying;
- After contamination with possible infectious materials (blood, secretions or other bodily excretions), an immediate cleaning and disinfection must be carried out;
- Consult the recommendations and indications for the choice and application of disinfectants in the current provisions and guidelines for disinfection and protection from explosion. Hygiene guidelines and appropriate safety measures for the disinfection method to be applied must be defined by the operator.

1. Turn off power supply Chapter 7.4. "Turn power supply on and off"

2. All components of the device including connecting cable must be disinfected by abrading

8.3.3. Cleaning and steam sterilization of the sterile handle

Clean the sterile handle

INSTRUCTION!

Material damages due to improper steam sterilization

Improper steam sterilization may damage the sterile handle and make the surface porous and fragile. Such damaged sterile handles can no longer be sterilized in a safe way and must be replaced immediately by new sterile handles.

- The steam sterilization should be carried out only under the following conditions:
- 20 minutes at 121° C and 1.3 bar;
- 4 minutes at 134° C and 2.3 bar;
- Never exceed the maximum temperature of 134°C;
- Always sterilize the sterile handle separately in containers suitable for sterilization;

The sterile handle has a service life of about 50 steam sterilization cycles.

Steam sterilization of the sterile handle

1. Place the sterile handle vertically and with the opening facing downwards into the container suitable for steam sterilization in the sterilizer.

2. Carry out the steam sterilization with the correct values of time, temperature and pressure.

8.4. Maintenance work

DANGER!

Mortal danger due to electric shock!

Upon contact with current-conducting parts, there is a risk of instantaneous fatal injury from electric shock.

- Before any maintenance work, the power supply of the device must be turned off with the main switch of the operating theater. In the mobile version, the plug must be pulled out of the live socket in addition;
- Secure the main switch or plug against an accidental power connection;
- Electrical installation work must always be carried out by electricians.

To ensure the safety of patients and staff and the best possible care of the device, it must be subjected to a regular and appropriate maintenance.

8.4.1. Adjusting the spring force of the ceiling version and the mobile version

When installing the spring arm, the enclosed installation instructions and the user manual of the manufacturer Ondal Medical Systems GmbH, D-36088 Huenfeld must be followed. Follow their safety instructions and requirements very accurately.

8.4.2. Adjustment of the braking force

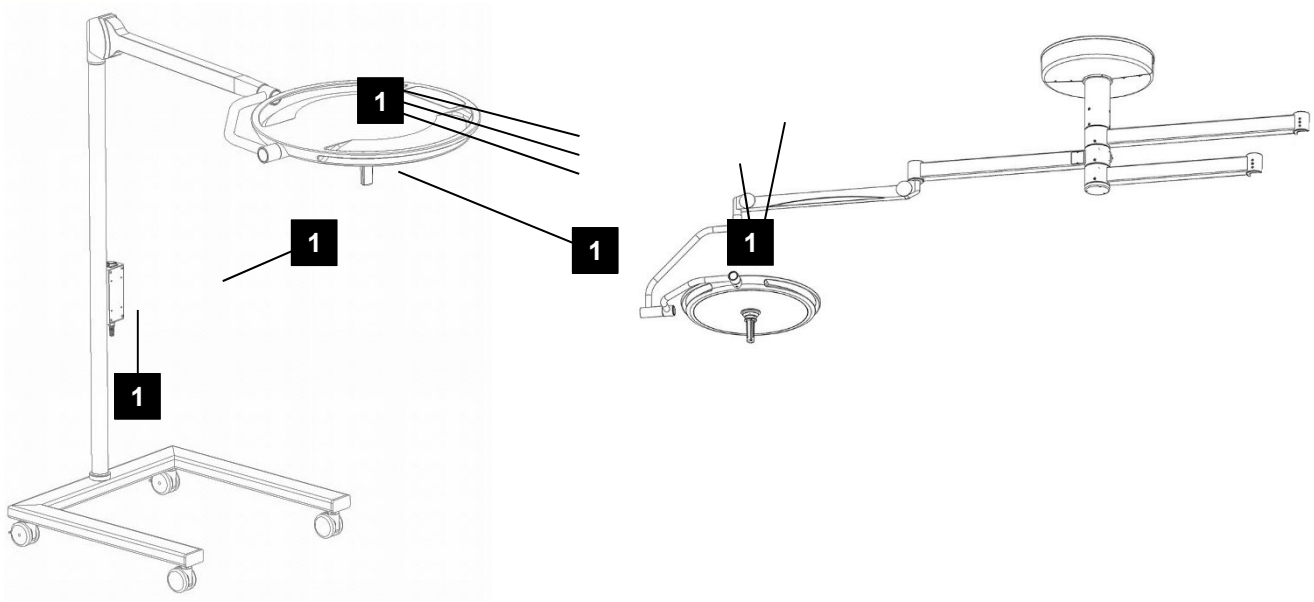

Figure 24: Positions of the brake screws

The component joints have brake screws (Figure 24/1) with which the braking intensity can be adjusted. If the device moves with difficulty or if it moves too easily in various positions, the braking force must be adjusted.

Special tool:

- Hexagonal Allen key with WAF 5

Figure 25: Adjustment of the brake screw using the example of cardan suspension

1. Insert Allen key (Figure 25) into the opening for adjusting the brake screw that should be adjusted.

2. Turn the Allen key clockwise to increase the braking force or turn in the opposite direction to reduce the braking force.

3. Remove the Allen key from the opening for adjustment.

8.4.3. Adjustment of the height stop

When adjusting the height stop, the enclosed installation instructions and the user manual of the manufacturer Hutz Medical must be followed.
Follow their safety instructions and requirements very accurately.

The spring arm has a height limit. When assembling, it must be adjusted in such a way that any collision with other components or with the ceiling is avoided.

9. FAULTS

In the following chapter, possible causes for faults and the necessary remedial tasks are described. If too many faults should occur, the maintenance intervals must be shortened in relation to the real stress. If faults occur, which cannot be remedied with the following indications, the manufacturer must be contacted.
Please find the address for the customer service on the last page.

9.1. Safety

Electric current

DANGER!

Mortal danger due to electric shock!

Upon contact with voltage-conducting parts, there is a risk of instantaneous fatal injury from electric shock. Insulation damages in any component may be fatal.

- Electrical installation work must always be carried out by electricians;
- For any type of maintenance work, cleaning and fault rectification, the power supply must be disconnected;
- Keep conductive parts away from moisture and liquids. There may be a short circuit.

Work done improperly for fault rectification

WARNING!

Risk of injury due to improper fault rectification!

Fault rectification work done incorrectly or improperly may cause serious injuries and considerable material damage.

- Before starting work, it must be ensured that sufficient space is available for installation;
- The assembly area must be in order and must be clean. Loose and scattered components and tools increase the risk of accidents;

Before a new start-up, you have to ensure:

- that all maintenance work is carried out and completed in accordance with the instructions in this user manual;
- that all covers and safety devices are installed and functioning properly.

9.2. Functional Error

No.	Error description	Cause	Solution	Person
	The lamp moves erratically upwards or downwards.	The spring force is set too high or too low in the spring arm.	Adjust the spring force. ↳ Chapter 8.4.1. "Adjustment of the spring force"	Engineer / specialization in medical technology
	It is difficult/too easy to move the light fixture	The braking force is set insufficiently / excessively	Adjust the braking force ↳ Chapter 8.4.2. "Adjustment of the braking force"	Engineer / specialization in medical technology
	The illumination intensity is insufficient / excessive	The illumination intensity has been set incorrectly	Adjust the illumination intensity ↳ Chapter 7.7. "Adjustment of the lighting intensity"	Medically specialized staff
	The light field is too small / too large.	The light field has been set incorrectly.	Adjust the light field ↳ Chapter 7.6. "Adjustment of the light field"	Medically specialized staff
	The sterile handles present cracks and are porous	Sterilization/cleaning has not been done properly.	Dispose of the porous handles. In the future, always perform the cleaning process in accordance with the user manual. ↳ Chapter 8.3.3. "Cleaning and steam sterilization of the sterile handle"	Medically specialized staff
	The device does not illuminate	The power supply is turned off	Turn on the power supply ↳ Chapter 7.4. "Turn power supply on and off"	Medically specialized staff
		The device has been switched off on the operating panel of the light	Turn on the device ↳ Chapter 7.5. "Turn the device on / off"	Medically specialized staff
		The power supply has been interrupted.	Check the voltage	Electrician with knowledge of medical devices
		The electronic system is damaged.	Contact the operator	Operator

9.3. Electromagnetic compatibility – Guidelines and manufacturer's declaration

Medical electrical devices are subject to special precautionary measure in terms of electromagnetic compatibility (EMC).
Portable and mobile radio frequency communications equipment can affect medical electrical equipment. The ME-device is designed for the operation in an electromagnetic environment as specified below. The user of the device should ensure that it is operated in such an environment.
The ME-device must not be used in the immediate vicinity of other devices or arranged as stacked with other devices.
If the operation in the vicinity of other devices or arranged as stacked with other devices is required, the ME-device should be observed in order to check its intended operation in this arrangement.
This ME-device is intended for use exclusively by medical professionals. This device can cause radio interference or can disrupt the operation of devices in the vicinity. It may be necessary to take appropriate remedial action, such as a new orientation, a new arrangement of the ME-device or the shielding.

Attention:
The use of other accessories, other converters and lines other than the accessories installed and approved by Hutz Medical can result in increased emissions or decreased noise immunity of the ME-device or ME-system.

Table 1 Guideline and manufacturer's declaration – Electromagnetic noise emissions		
All Solaris II-LED 5000/7000 models, irrespective of the mobile version Solaris II-LED 5000/7000 or ceiling-mounted, are meant for operation in an electromagnetic environment as specified below. The operator of Solaris II-LED 5000/7000 should ensure that the Solaris II-LED 5000/7000 is only operated in such an environment.		
Measurements of noise emissions	**Compliance**	**Electromagnetic environment - Guideline**
RF-emissions as per CISPR 11	Group 1	Solaris II-LED 5000/7000 use RF energy exclusively for its internal function. Therefore, the RF emissions are very low, and it is unlikely that nearby electronic devices will be disturbed.
RF-emissions as per CISPR 11	Class B	Solaris II-LED 5000/7000 is designed for use in all facilities, including domestic facilities and those, which are directly connected to the public supply network that also supplies buildings used for residential purposes.
Emissions due to higher harmonics according to IEC 61000-3-2	Class C	
Emissions due to voltage fluctuations/flicker according to IEC 61000-3-3	matches	
RF-emissions as per CISPR 15	matches	Solaris II-LED 5000/7000 is not suitable to be connected to other devices

Table 2 Guidelines and manufacturer's declaration – Electromagnetic noise immunity			
All Solaris II-LED 5000/7000 models, irrespective of the mobile version Solaris II-LED 5000/7000 or ceiling-mounted, are meant for operation in an electromagnetic environment as specified below. The operator of Solaris II-LED 5000/7000 should ensure that the Solaris II-LED 5000/7000 is only operated in such an environment.			
Noise immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environmental guidelines**
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should consist of wood or concrete or be furnished with ceramic tiles. If the floors are furnished with synthetic material, the relative humidity should be at least 30%.
Fast transient electrical disturbances/burst according to IEC 61000-4-4	± 2 kV power lines ± 1 kV for input and output lines	± 2 kV power lines ± 1 kV for input and output lines	The quality of the supply voltage should correspond to a typical business- or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV voltage line to line ± 2 kV voltage line to ground	± 1 kV voltage line to line ± 2 kV voltage line to ground	The quality of the supply voltage should be equivalent to that of a typical business or hospital environment.
Voltage dips, short term interruptions and fluctuations in the supply voltage according to IEC 61000-4-11,	<5% UT (> 95% cut in UT) for ½ a period <40% UT (> 60% cut in UT) for 5 periods <70% UT (> 30% cut in UT) for 25 periods <5% UT (> 95% cut in UT) for 5 sec.	<5% UT (> 95% cut in UT) for ½ a period <40% UT (> 60% cut in UT) for 5 periods <70% UT (> 30% cut in UT) for 25 periods <5% UT (> 95% cut in UT) for 5 sec.	The quality of the supply voltage should be equivalent to that of a typical business or hospital environment. If the user of Solaris II-LED 5000/7000 requires continuing functionality even during interruptions of the power supply, it is recommended to supply power to the Solaris II-LED 5000/7000 from an uninterruptible power supply or a battery.
Magnetic field at the supply frequency (50/60 Hz) as per IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields at power supply frequency should correspond to the typical values, as they are found in the business and hospital environment.
* Note: UT is the AC power supply voltage prior to application of the test level.			

Table 3

All Solaris 5000/7000 models, irrespective of the mobile version Solaris 5000/7000 or ceiling-mounted, are meant for operation in an electromagnetic environment as specified below. The operator of Solaris 5000/7000 should ensure that the Solaris 5000/7000 is only operated in such an environment.

Noise immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environmental guidelines**
Conducted RF disturbances according to IEC 61000-4-6 Radiated RF disturbances according to IEC 61000-4-3	3 V RMS value 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V RMS value 3V/m	Portable and mobile wireless devices should not be used closer to Solaris II-LED 5000/7000 models, including the cables, than the recommended safe distance calculated according to the equation applicable for the transmission frequency. $d = 3.5 / 3 \sqrt{P}$ 150 kHz to 80 MHz $d = 3.5 / 3 \sqrt{P}$ 80 MHz < 800 MHz $d = 7 / 3 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the nominal power of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended safety distance in meters (m). The field strength of stationary radio transmitters should be less than the compliance level b) at all frequencies in accordance with a site survey a) Interferences are possible in the vicinity of the devices bearing the following symbol. 

Remark 1: At 80 MHz and 800 MHz, the higher frequency range shall apply.
Remark 2: These guidelines may not apply in all situations.
The propagation of electromagnetic parameters is affected by absorption and reflection from structures, objects and human beings.

a) Field strengths of fixed transmitters, such as base stations of cellphones and fixed wireless devices, amateur radio stations, AM and FM radio broadcast and TV broadcast transmitter cannot be predicted theoretically and accurately in advance. In order to determine the electromagnetic environment of the stationary transmitters, a study of the electromagnetic phenomena of the site should be considered. If the measured field strength at the site, where the Solaris II-LED 5000/7000 is used, exceeds the above compliance level, the Solaris II-LED 5000/7000 should be observed in order to verify proper operation. If unusual performance characteristics are observed, additional measures may be necessary, such as changed orientation or another location for the Solaris II-LED 5000/7000, for example.

b) Over the frequency range from 150 kHz to 80 MHz, the field strengths should be less than [*U*1] V/m.

Table 4

Recommended safety distances between portable and mobile RF/telecommunications equipment and the Solaris II-LED 5000/7000.

The Solaris II-LED 5000/7000 is meant for operation in an electromagnetic environment in which the RF disturbances are controlled. The user of Solaris II-LED 5000/7000 can help in preventing electromagnetic interferences by maintaining a minimum distance between portable and mobile RF telecommunications equipment (transmitters) and the Solaris II-LED 5000/7000 – depending on the output power of the communication device as specified below.

Nominal power of the transmitter [W]	**Safety distance depending on the frequency of transmitter m**		
	150 kHz to < 80 MHz $d = 1.2\sqrt{F}$	**80 MHz to < 800 MHz** $d = 1.2\sqrt{F}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{F}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.74
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters, whose maximum nominal output is not specified in the above table, the recommended safety distance *d* in meters (m) can be determined using the equation that belongs to the respective column, where *P* is the maximum nominal power of the transmitter in watts (W) according to the specification of the transmitter manufacturer.

Remark 1: At 80 MHz and 800 MHz, the higher frequency range shall apply.
Remark 2: The guidelines may not apply in all cases.
The propagation of electromagnetic parameters is affected by absorption and reflection from structures, objects and human beings.

10. Warranty

Product name		
Article number		
Serial number		
Warranty period		1 year from the purchase date
Customer data	Name of the customer	
	Address of the customer	
	Name of the contact person	
	Telephone	
	Email	
Dealer		
Manufacturer		Hutz Medical 26 Henry Ford Road Neave Port Elizabeth 6000 enquiries@hutz.co.za www.hutz.co.za

11. DISASSEMBLY AND DISPOSAL

	Solaris II-LED 5000/7000 must be disposed of in accordance with the local regulations for recycling electrical and electronic equipment. Solaris II-LED 5000/7000 meets the requirements of the Directive 2002/95/EC RoHS (for restricting the use of certain hazardous materials in electrical and electronic equipment) The equipment should be disassembled only by employees of the manufacturer.

	**WARNING!** **Risk of fatal injury due to erroneous disassembly!** Errors during disassembly may cause dangerous situations and considerable material damage. - Assign the work of disassembly only to employees of the manufacturer; - Consult the manufacturer in case of subsequent change in the installation site; - Refrain from carrying out the work of disassembly independently and from changing the installation site.

Hutz Medical
26 Henry Ford Road
Neave
Port Elizabeth
Phone +27 (0)41 451 0964
Fax +27 (0)41 451 0977
enquiries@hutz.co.za

www.hutz.co.za

12. INSPECTION PLAN

Inspection plan for _____

System data

Supplier:	Date of installation:
	Serial number of Hutz Medical:
	Serial number of operator:
	Device location:

Important information

- The inspection work must be performed by trained service personnel.
- The test intervals must be complied with.
- This inspection plan is valid only in conjunction with the user manual for assembly instructions of Hutz Medical, which are to be consulted in addition for the inspections.
- After 10 years, the functional inspection must be carried annually.

The support arm must be checked for the following points in accordance with the intervals specified by Hutz Medical, by a company authorized by Hutz Medical or by personnel with appropriate qualificatios:

Visual inspection (must be done annually)

	1 i.O n.i.O	2 i.O n.i.O	3 i.O n.i.O	4 i.O n.i.O	5 i.O n.i.O	6 i.O n.i.O	7 i.O n.i.O	8 i.O n.i.O	9 i.O n.i.O	10 i.O n.i.O
The parts of the support system are without deformation*										
- The system is free from paint damages*										
- The plastic parts are present and in position*										
- The plastic parts do not have any cracks*										
- All model plates are present and legible										

Functional test (must be done every 2 years)

	2 i.O n.i.O	4 i.O n.i.O	6 i.O n.i.O	8 i.O n.i.O	10 i.O n.i.O
- Rotatability/stops (depending on the version) provided**					
- If necessary, re-grease horizontal and vertical joints smoothly					
- If necessary, readjust height stop correctly**					
- Check and grease the locking segment*					
- Locking ring in position and shape (boom/FA)*					
- If necessary, readjust load balancing / spring force correctly					
- Collision damages - all welded joints are free from cracks **					
- Test of protective conductor transfer resistance ** - applies only if live wires are installed					
- After 10 years, the lines and any installed hoses are to be checked and replaced if necessary **					

Confirmation of the inspection done

The work listed above was carried out including the necessary adjustment work and safety inspection:

1st year

_____ Date _____ Signature/Stamp

2nd year

_____ Date _____ Signature/Stamp

3rd year

_____ Date _____ Signature/Stamp

4th year

_____ Date _____ Signature/Stamp

5th year

_____ Date _____ Signature/Stamp

6th year

_____ Date _____ Signature/Stamp

7th year

_____ Date _____ Signature/Stamp

8th year

_____ Date _____ Signature/Stamp

9th year

_____ Date _____ Signature/Stamp

10th year

_____ Date _____ Signature/Stamp

* Damaged or deformed parts should be replaced. Please contact the supplier of the spring arm for this purpose.
** Should one of the marked points come up during the test, the spring arm must be shut down immediately as the best precautionary measure, in order to prevent further damages to human beings and equipment. Inform the supplier of the systems immediately.
The medical device logbook associated with each medical device and prescribed according to MPBetreibV (Regulations governing the installation, operation and use of medical devices) must be kept available on-site. Service and maintenance work and safety reviews must be documented in this medical device manual.
Test reports like this are to be filed in the respective medical device manual.

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USER MANUAL Solaris II-LED 5000/7000
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