INSTRUCTIONS FOR USE

MIMSAL

MD

SUPPORTS AND STANDS FOR

MIMLED 600

MIMLED 1000

VALID FROM MAY 2016

MIMSAL

TABLE OF CONTENTS

1 INFORMATION ON SAFE USE

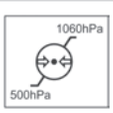
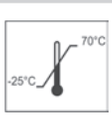
1.1 PICTOGRAPH LEGEND

In the Instructions for Use, important information is marked by symbols. The pictographs have the following meaning:

1.1.1 Symbols used in the Operating Instructions

SYMBOL	DESCRIPTION
	**DANGER!** Serious or even fatal injuries will certainly result from the non-observance.
	**WARNING!** Serious or even fatal injuries may result from the non-observance.
	**CAUTION!** Moderate to slight injuries or property damage may result from the non-observance.
	**NOTE!** Here hints and useful information are given

1.1.2 Other pictographs

SYMBOL	DESCRIPTION
	**FOLLOW INSTRUCTIONS FOR USE:** Please read these Instructions for Use carefully before you firstusethesupportsystem.This will allow you to get all of the advantages which the support system offers and avoid possible injury and property damage.
	**OBSERVE MAXIMUM PAYLOAD:** This warns against exceeding the approved maximum payload on the support arm system, an adaptation as well as using an end device other than MIMLED 600 or the MIMLED 1000 .
	**AIR PRESSURE:** This shows the allowed air pressure values from 500 hPa to 1060 hPa for transport and storage.
	**HUMIDITY:** This shows the allowed humidity values from 10% to 75% for transport and storage.
	**AMBIENT TEMPERATURE:** This shows the allowed ambient temperatures from -25 °C to 70 °C for transport and storage.

SYMBOL	DESCRIPTION
	**RISK OF TIPPING:** The device can take a maximum payload of 2.9 kg. If the maximum payload is exceeded, the device may tip over, fall onto people and cause serious injury. Do not climb or lean on the stand. Do not attach other loads to the device.
	**RELOCATION:** Before moving (arrow 2) device stand, make sure that the spring arm is in the lowest position (arrow 1). • Make sure that the lockable castors are unlocked. • Pay attention to bumps, door sills, steps on wheel chair entrances or other obstructions. • Make sure you use an appropriate vehicle speed so that it is possible to stop and and avoid collision at any time. Pay attention to steep flooring.

2 GENERAL SAFETY INFORMATION

Please also refer to the special safety instructions in the following chapters.

2.1 STANDARDS AND GUIDELINES

The device meets the safety requirements the following standards, laws and directives:

- Medical Device Act (MPG in Germany);
- EN 60601-1: Medical Electrical Equipment – Part1: General requirements for basic safety and essential performance.

2.2 SPECIFIC PURPOSE

- The devices are exclusively used to support and position the MIMLED 600 and MIMLED 1000 light heads as well as supply the devices with power.
- The devices are suitable for continuous operation.
- The devices are not suitable for the field of home care

2.3 IMPROPER USE

- The devices must not be loaded with additional weights in addition to the light body.

2.4 CONTRAINDICATION

- The support arm system should not be located in the vicinity of strong magnetic fields.
- Only lights of type MIMLED 600 and MIMLED 1000 may be con-nected to the support arm system.

2.5 OPERATION AND STORAGE CONDITIONS

Different environmental conditions apply for the operation of the device and its intermediate storage.

ENVIRONMENTAL CONDITIONS FOR THE STORAGE AND TRANSPORT	
The following storage conditions apply for up to 15 weeks after the date of delivery:	
Ambient temperature:	-25 °C to 70 °C
Relative humidity (non-condensing):	10% to 75%
Air pressure:	500 hPa to 1060 hPa

AMBIENT CONDITIONS FOR OPERATION	
Ambient temperature:	10 °C to 40 °C
Relative humidity (non-condensing):	30% to 75%
Air pressure:	700 hPa to 1060 hPa

2.6 CLEANING AND DISINFECTION

CLEANING

WARNING – RISK OF INFECTION AND CONTAMINATION FOR PATIENTS
Parts of the support arm system and the adaptations are made of plastic. Solvents can etch plastics. Strong acids, alkalis and media with more than 60% alcohol can cause embrittlement of the plastics.
Damaged parts can fall into open wounds.
If cleaning fluid penetrates into the support system and the adaptations, excess solution could get into open wounds.

DISINFECTION

WARNING – HEALTH HAZARD
Disinfectants can contain harmful substances which, in contact with skin and eyes, may cause injury or damage to the respiratory system through inhalation. Adhere to protective measures:

- Observe hygiene guidelines.
- Observe the disinfectant manufacturer's instructions.
- Perform surface disinfection each working day and in case of contamination (see also section "Cleaning and disinfection").

3 USE OF THE LIGHTWEIGHT SUPPORT

NOTE – QUALIFICATION OF PERSONNEL
The device shall be operated only by medical professionals in the hospital and in the doctor's office.

3.1 COMPONENTS OF THE SUPPORTS

CEILING MODEL	WALL MODEL	STAND MODEL
Slab bearing pads	Plug-in power supply	Spring arm
Spacer tube	Wall bearing pads	Stand tube
Cantilever arm	Cantilever arm	Stand base
Spring arm	Spring arm	Castors
Operating instructions	Operating instructions	Operating instructions
Instructions for installation	Instructions for installation	Instructions for installation

3.2 USE

NOTE
Because of the risk of tipping of the stand device, make sure that no objects lying on the ground or the connecting cable are run over. Move the stand device to the place of use and lock the existing lockable castors in position.

INSTALLATION/DISMANTLING:

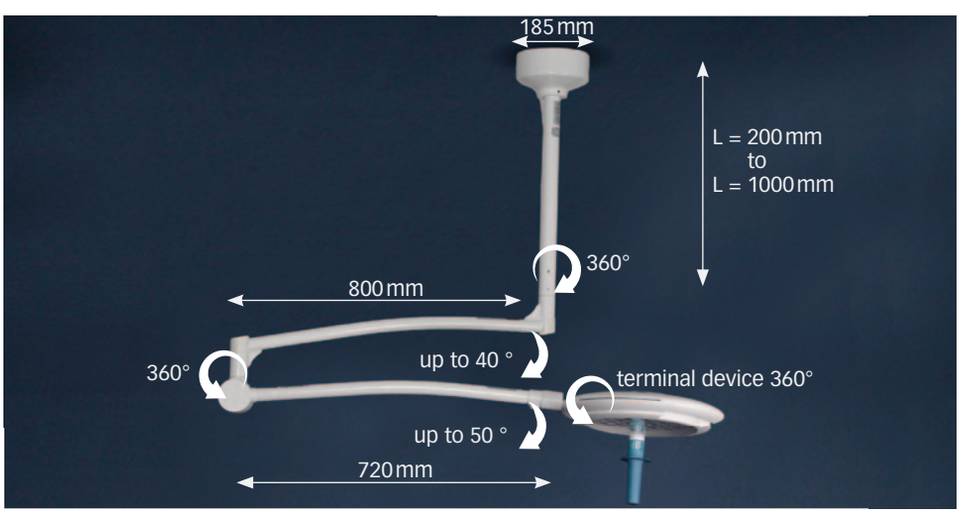
CAUTION – ELECTRIC SHOCK
To avoid risk of electric shock, the device may only be connected to supply mains with a protective earth conductor.

The device must be connected so that it can be completely (all poles) and, at the same time, disconnected from the mains.

WARNING – ELECTRIC SHOCK
In case of contact with damaged electrical parts, there is a danger of electrical shock. With damaged power cables or plugs, do not connect the device to the mains and immediately contact the Service Department.

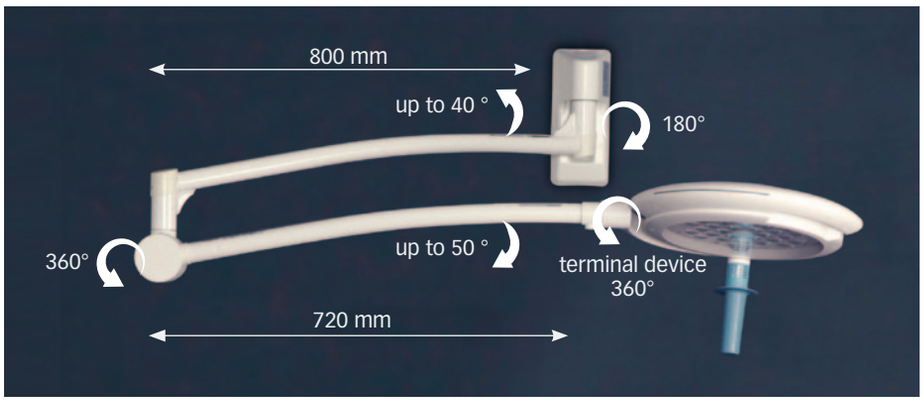
- Check mains plug and connecting cable for damage.
- To avoid the possibility of electric shock, the mains plug should only be plugged into to a properly installed socket with an earthing contact.

Combination with medical devices:
The spring arm is only to be equipped with end devices of the systems MIMLED 600 and MIMLED 1000 . For the information required for the operation of the light heads please refer to the appropriate instructions for use “Minor surgical lights MIMLED 600 and MIMLED 1000 ”.

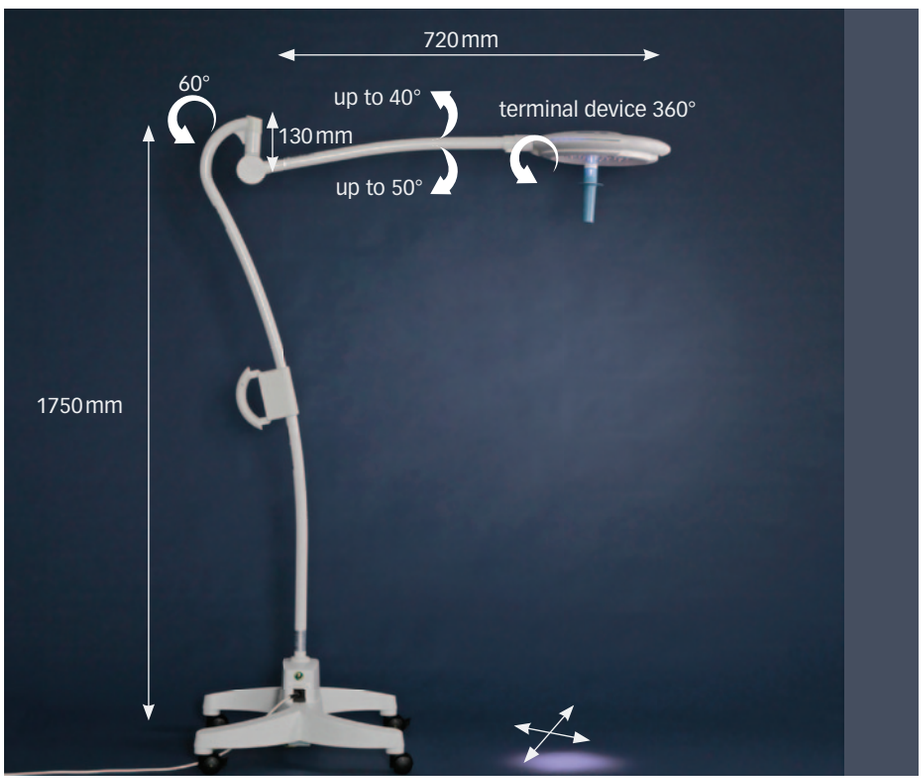


SWIVEL RANGE CEILING

WALL



MOBILE STAND



3.3 DISPOSAL

WARNING – ABRUPT RELEASE OF THE SPRING TENSION
A pre-tensioned spring in the spring arm is mounted which during dismantling of the spring arm, could release its energy suddenly leading to serious injuries.
Do not remove the spring arm for disposal.

For proper disposal of the system, please contact an authorised disposal business. You can obtain their address from your environmental officer or at your local municipality.

NOTE
Do not dispose of the product with the normal household waste.

WARNING
Perform all procedures for disinfection or sterilisation before decommissioning in order to avoid contamination of the environment.

4 CLEANING AND DISINFECTION

4.1 GENERAL SAFETY INSTRUCTIONS

WARNING – ELECTRIC SHOCK
The devices can conduct power and is to be treated with caution during cleaning and disinfection.
- If there is a mains cord, please disconnect it.
- Do not use spray cleaning and/or spray disinfection. Do not spray or allow any liquid to penetrate in sockets or device openings.

4.2 CLEANING

OBSERVE SAFETY INSTRUCTIONS
Observe the general safety instructions according to Section 2

RECOMMENDED CLEANING OF SUPPORTS AND STANDS
- Use a mild soap solution commercially available washing-up liquid as a cleaning agent.
- Wipe surfaces of the light heads with a lightly dampened cloth, if necessary, use some mild soap solution (washing-up liquid).
- Finally dry the exterior by wiping with a soft, clean cloth (use an ASC™ antistatic cloth, if necessary)

4.3 DISINFECTION

OBSERVE SAFETY INSTRUCTIONS
Observe the general safety instructions according to Section 5.1

DISINFECTION PROCEDURES

Disinfection wipes are to be used as a standardised disinfection procedure for the support arm system of MIMLED 600 and MIMLED 1000 . The operator must establish hygiene guidelines and appropriate security measures for the disinfection procedures.

RCOMMENDATION
The verifiedandvalidateddisinfectantMELISEPT OL® from the manufacturer Braun Melsungen is recommended.

Surfaces to be disinfected every working day!
After the contamination with potentially infectious material (e.g. blood, secretions or excrement), areas are to be immediately and specificallydisinfected.

Observe the instructions for application from the disinfectant manufacturer! (Concentration for application and contact times)

Contact your hygiene expert for the coordination of the disinfectants and disinfection procedures in connection with your in-house requirements concerning the current hygiene status!
Disinfect according to the in-house hygiene schedule!
Observe the hygiene guidelines!

Do not spray, but wipe for surface disinfection!

Use disinfected areas only when the disinfectant has dried!

Use disinfected areas only after the disinfectant is dry!

Do not sterilise! If sterilisation should be mandatory (e.g. administrative requirement), make sure to consult the manufacturer.

WARNING – HEALTH HAZARD
- Disinfectants may contain hazardous substances which may cause injuries after contact with skin or eyes, or may damage the respiratory system when inhaled. Observe the measures for protection:
- Follow the instructions of the disinfectant manufacturer!
- Observe the hygiene guidelines!

5 INSPECTION AND MAINTENANCE

Medical products shall be subject to regular maintenance and inspection cycles. This is essential for compliance with safety requirements. The manufacturer of the medical device is responsible for the definition of regular measures to ensure this. The operator is responsible for the implementation of defined measures

For all maintenance and audit work, switch the light to stand-by and unplug and disconnect the light from the mains. Secure the light against reconnection.

WARNING – DANGER OF INJURY
The support arm is spring loaded and can snap up during the removal of the light head – danger of injury!

5.1 RECURRING INSPECTIONS AND MAINTENANCE

NOTE – INSPECTIONS
The operator shall check and service all support systems for the following points:

DIN EN 62353 is to be observed for the periodic inspections (see “Inspection schedule” in the annex).

Every six months:
- Deformation of the support system
- Cracks in the plastic parts
- Paint damages

Annually:
- Extended check of the support system such as e.g. holding force of the spring arm, Check mounting bolt at the bottom of mobile stand foot and tighten, if necessary.
- Extended functional check, such as free movement of the joints
- Inspect and lubricate locking segment as in Section „Lubricate locking segment“ of the instructions for use of the holding systems.
- Electric safety inspection

In the event of any faults or damage, please contact your supplier.

Your supplier has been informed and trained regarding the scope and contents of the maintenance work.

For the inspection and maintenance work of the light head please observe the Instructions for Use for “Minor surgical lights MIMLED 600 and MIMLED 1000 “.

6 MAINTENANCE

NOTE – QUALIFICATION OF PERSONNEL
Maintenance must be performed by a hospital technician (or comparably qualified personnel).

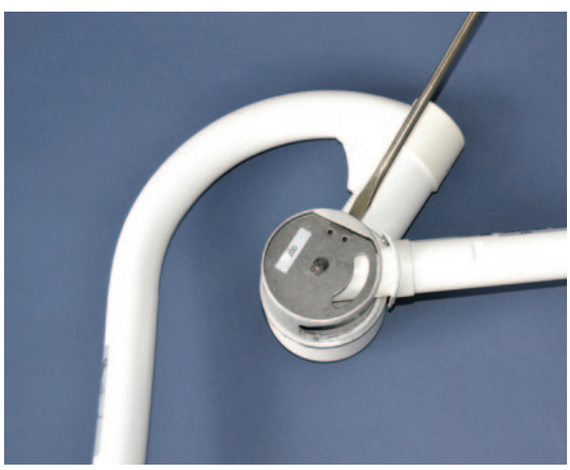
6.1 SETTING THE SPRING FORCE

As with any technical component, springs are subject to natural wear. Thus the spring force can decrease after extended operation and must be readjusted.
Adjust spring force so that the spring arm with the end device remains in any desired position.

CAUTION – DESTRUCTION OF THE SPRING ARM:
The adjusting of the spring force is done in the upper end position.

1. Remove the left joint cover on the spring arm in the direction of the end device. Carefully pry the joint cover out of the groove in the spring arm joint with a narrow flat-blade screwdriver.

2. Position end device in the upper end position.



3. Insert flat-blade screwdriver into the hole.

4. Adjust the spring force.

5. Install and snap joint cover into place.

CAUTION: DESTRUCTION OF THE SPRING ARM
If the brake screw is tightened too much, the spring arm will be destroyed. Only tighten the brake screw carefully under repeated monitoring of the braking force control.

If the spring arm lowers – the spring force is too low:
- The adjusting screw must be rotated to the left (counter clockwise).

If the spring arm rises – the spring force is too high:
- The adjusting screw must be rotated to the right (clockwise).

For the ceiling and wall mount, use the same approach – see figures below and see also the respective installation instructions.

Left joint cover on ceiling model

Left joint cover on ceiling model.

6.2 LUBRICATE LOCKING SEGMENT

- Dismantle end device according to Section "End device dismantling"
- Check locking segment (see figure) for a minimum thickness of 1.5 mm and replace if necessary.
- Lubricate locking segment, e.g. with Microgleit GP 360.
- Mount end device according to Section „Lubricate end device".

Locking segment

7 DISMANTLING AND REASSEMBLY FOR SERVICING

7.1 DISMANTLE END DEVICE

NOTE – QUALIFICATION OF PERSONNEL
The dismantling/reassembly must be performed by a hospital technician (or comparatively qualified personnel).

The spring arm is subject to high spring force. If the end device is not removed in the top spring arm position, the spring arm will snap up and can cause serious injury.
Only remove the terminal when the spring arm is in the top position.

DISMANTLE END DEVICE

1. Place spring arm in the top position.
2. Loosen and remove screw on plastic sleeve.

3. Rotate plastic sleeve 180° so that the locking segment is visible.
4. Remove locking segment with a small screwdriver while holding the terminal firmly.

5. Remove terminal from the support while holding the spring arm firmly.
6. Replace protection cap.

7. Allow spring arm to slowly move upwards.

keep Locking segment carefully.

7.2 INSTALL END DEVICE

NOTE – QUALIFICATION OF PERSONNEL
The dismantling/assembly must be performed by a hospital technician (or comparatively qualified personnel).

INSTALL END DEVICE ON THE MOBILE STAND

1. Unplug mains plug and secure against reconnection.
2. Remove protective cap from the spring arm opening.

WARNING – DANGER OF INJURY
The spring arm which is pressed downwards can snap back up and cause injury. During the installation of the end device, no people should be located within the swivel range of the spring arm.

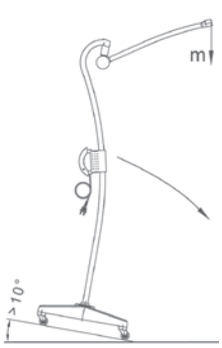
3. Push the plastic sleeve on the arm so that the two slots are covered.

4. Insert the terminal's swivel arm end (remove protective grease cover before).

5. Insert the locking segment completely into the slot so that the locking segment is guided into the groove.

6. Rotate plastic sleeve by 180° and tighten the screw.
7. Check secure seating of the end device.

Locking segment



CAUTION – DAMAGE TO THE DEVICE
After the installation of the end device, perform tilt test according to DIN EN 60601-1.

Use the same procedure with ceiling and wall mounting regarding installation and dismantling.

8 EQUIPOTENTIAL BONDING CONDUCTOR

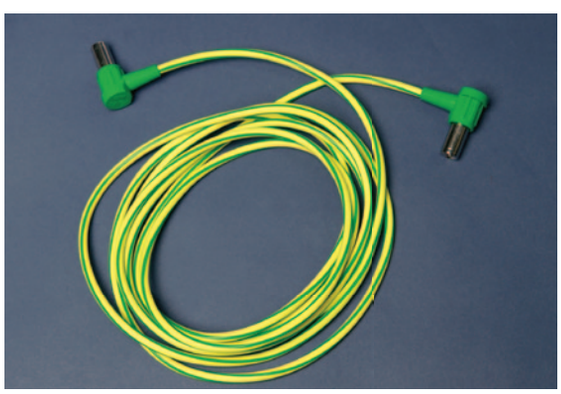
An equipotential bonding cable is an additional conductor (accessory; not included in the scope of delivery), which establishes a direct connection between the electrical device and the potential equalising bus bar of the electrical installation. The mobile light on the mobile stand as well as the wall-mounted lights have an equipotential bonding connector on the housing of the mobile stand or on the wall mounting so that possible differences in voltage which can occur as voltage sources, are avoided in the patient environment; also in connection with the parallel use of other devices. Such voltage sources can cause currents over the body resistance, which not only flow over the patient but can also affect doctors and nurses or even endanger them. Currents flowing through such active medical devices can lead to malfunctions.

In rooms used for Class 2 medical purposes, all external conductive parts within the patient environment are (electrically connected with each other and) connected to the earthing conductor busbar in addition to the protective measures according to DIN VDE 0100 Part 410. This means protective bonding conductors must be connected to a potential equalizing busbar.

In particular when using the lights in connection with critical procedures such as e.g. examinations near the heart and procedures to the heart, it must be ensured that the value for the maximum permissible contact voltages of 10 mV is not exceeded ($\Delta u \leq 10mV$). On the side of the lights, this is supported e.g. by the existing equipotential bonding connector in connection with the equipotential bonding conductor (see accessories).

In ceiling-mounted lamps, a protective bonding conductor must be connected for installation in medical rooms of Class 2 with the respective ceiling slabs, as listed in the corresponding instructions for installation.

Equipotential bonding connector on mobile stand with equipotential bonding cable



Equipotential bonding conductor

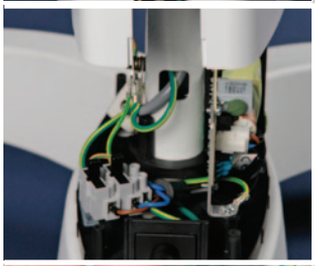
9 REPLACEMENT OF FUSES

WARNING – ELECTRIC SHOCK
For all maintenance work on the device, disconnect the power supply, pull out the mains plug and secure against being switched on again.

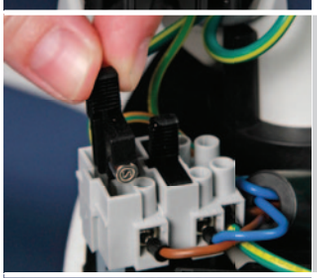
CAUTION – DAMAGE TO THE DEVICE
Only the specified screws may be used!

A. Replace the fuses on the mobile stand in accordance with the following operations:

1. Loosen cross-head screw but do not remove.

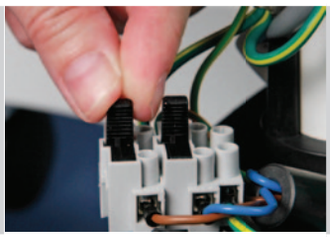


2. Loosen clamping ring, seal and housing but do not pull out completely.



3. Remove defective fuse.

4. Replace defective fuse.



5. Insert new fuse.

6. Slide down clamping ring, seal and housing.

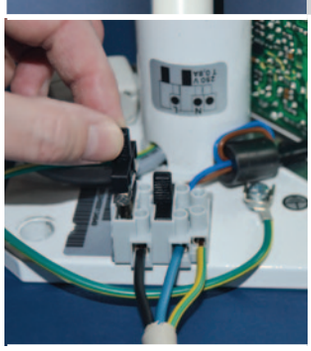
7. Tighten Cross-head screw.

NOTE – REPLACEMENT OF THE CONNECTION LINE
The connection cable must only be replaced by an authorised mechanic.

information on request on the replaceable components can be delivered.

B. Ceiling mount bracket

1. Loosen the three threaded screws with a screwdriver.
2. Pull canopy down.



3. Remove and replace defective fuse.
4. Insert new fuse.
5. Pull canopy back upwards and tighten the three threaded screws with a screwdriver.

10 ELECTRICAL AND OTHER TECHNICAL DATA

LIGHT HEAD	MIMLED 600	MIMLED 1000
Nominal voltage	24 V DC ± 10%	24 V DC ± 10%
Nominal current	1.1 A @ 24V max.	1.4 A @ 24V max.
Protection class	IP42	IP42
TOTAL SYSTEM	**MIMLED 600**	**MIMLED 1000**
Power consumption	25W	33W

	CEILING MODEL	WALL MODEL	MOBILE LIGHT
Protection class	Primary 250 V; T 800mA L; 5x20 mm		Primary 250 V; T 800mA L; 5x20 mm Secondary 250 V; M 2A L; 5x20 mm
Designed for continuous	I	II	I
Designed for continuous	X	X	X
Nominal voltage	100-230VAC	100-230VAC	100-230VAC
Nominal frequency	50/60 Hz	50/60 Hz	50/60 Hz
Maximum possible power consumption of power pack	60W	70W	60W

TABLE 1: TECHNICAL DATA

11 ELECTROMAGNETIC COMPATIBILITY

Despite of all measures there may be interferences and/or EMC problems. Therefore, please observe the following tables!

More information on electromagnetic compatibility:

- Medical devices are subject to special precautions regarding EMC and must be installed and commissioned according to the EMC information contained in the operating and installation instructions.
- Portable and mobile HF communication equipment may affect medical electrical devices.
- The use of stands and mounting systems that do not come from deliveries, as well as their components (such as spring arms and brackets), or the use of accessories such as power supply units and electric lines other than those described in the operating and installation instructions may result in increased emissions or decrea-sed immunity of the lighting systems, and is therefore not permitted.
- The parts shown in the sections of the instructions for use for „small surgical lights“ entitled „Scope of delivery“ and „Mounting system and accessories“ and their accessories must only be used in combination with the MIMLED 600 and the MIMLED 1000 systems.
- The operation of the parts (or their individual components or accessories) presented in the sections of the instructions for use for „small surgical lights“ entitled „Scope of delivery“ and „Mounting system and accessories“ in combination with devices than other than the MIMLED 600 and the MIMLED 1000 systems may lead to increased emission or decreased immunity of the device.
- Comply with the advice given in instructions for use for „small surgical lights“ on the subject of EMC and
- Comply with the advice given in instructions for use for „small surgical lights“ on the subject of significant performance characteristics.

11.1 INTERFERENCE EMISSIONS

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

MIMLED 600 and MIMLED 1000 are intended for operation in the electromagnetic environment as specifi ed below. The customer or the user of MIMLED 600 and MIMLED 1000 should ensure that it is used in the specifi c environment.

Emission measurement	Compliance	Electromagnetic environment – guidelines
HF emissions according to CISPR 11	Group 1	The MIMLED 600 and MINOR SUR-GICAL LIGHTS 100 000 LX use HF energy only for internal functions. Therefore, the HF emissions are very low and it is unlikely that nearby electronic devices will be disturbed.
HF emissions according to CISPR 11	Class B	
High frequency emis-sions according to IEC 61000-3-2	Class A	MIMLED 600 and MIMLED 1000 are intended for use in all facilities in-cluding residential establishments and those directly con-nected to the PUBLIC VOLTAGE SUPPLY NETWORK which supplies buildings used for residential purposes.
Aussendungen von Spannungsschwankungen nach IEC 61000-3-3	Complies	

11.2 INTERFERENCE IMMUNITY

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

MIMLED 600 and MIMLED 1000 are intended for operation in the ELECTROMAGNETIC ENVIRONMENT specified below.
The customer or the user of MIMLED 600 and MIMLED 1000 should ensure that it is used in the specific environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidelines
Electrosta-tic dischar-ge (ESD) according to EN 61000-4-2	air ±8 kV contact ±6 kV	air ±8 kV contact ±6 kV	Floors should be made of wood, concrete or ceramic tile. If the floor is covered with a synthetic material, the relative humidity must be at least 30%.
Burst accor-ding to EN 61000-4-4	Power supply ±2 kV Input and output lines ±1 kV	Power supply ±2 kV Not applicable	The quality of the supply voltage should be that of a typical business and hospital environment.
Surge accor-ding to EN 61000-4-5	±1 kV voltage external conductor-external conductor ±2 kV voltage external conductor-earth conductor		The quality of the supply voltage should be that of a typical business and hospital environment.

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

Voltage dips, short interruptions, an voltage variations on power supply input lines according to IEC 61000-4-11	<5% UT (>95% dip of the UT) for ½ cycle 40% UT (60% dip in the UT) for 5 cycles 70% UT (30% dip in the UT) for the 25 cycles <5% UT (>95% dip in the UT) for 5 seconds		Line power quality should be that of a typical business and hospital environment. If the user of the MIMLED 600 or the MIMLED 1000 requires continued operation during power supply interruptions. it is recommended that MIMLED 600 and MIMLED 1000 be powered from an uninterruptible power supply (UPS) or a battery.
Magnetic field with the supply frequency (50/60Hz) according to IEC 61000-4-8	3A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

REMARK: UT is the network alternating voltage prior to application of test levels

GUIDELINES AND MANUFACTURER DECLARATION – ELECTROMAGNETIC IMMUNITY

MIMLED 600 and MIMLED 1000 are intended for operation in the specified electromag-netic environment specified below.
The customer or the user of MIMLED 600 and MIMLED 1000 should ensure that it is used in such an environment.

Interference immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Radiated RF disturbance variables according to EN 61000-4-3	80MHz – 2.5GHz, 3V/m	80MHz – 2.5GHz, 10V/m	Portable and mobile communications equipment should not be used in closer proximity to MIMLED 600 and MIMLED 1000 including the cable used than the recommended safety distance which is calculated from the equation applicable to the transmitter frequency.
Conducted disturbance variables according to EN 61000-4-6	150kHz – 80MHz 3Vrms	150kHz – 80MHz 10Vrms	**Recommended separation distance:** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.34\sqrt{P}$ for 800 MHz to 2.5 GHz Where P is the rated output of the transmitter in watts (W) according to the information of the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixedRFtr ansmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol. 

GUIDELINES AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

NOTE 1 With 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not be applicable in all cases. Electromagnetic radiation is affected through absorption and reflection of structures, objects and people.

a The field strengths of stationary transmitters, such as, e.g. the base station of wireless telephones mobile radios, amateur radio stations, AM and FM radios and TV transmitters cannot theoretically be accurately predetermined. In order to determine the ELECTROMAGNETIC ENVIRONMENT with regard to the stationary transmitters, a survey of the electromagnetic phenomena on site should be considered. If the measured field strengths at the site used on MIMLED 600 and MIMLED 1000 exceeds the above-mentioned COMPLIANCE LEVEL, MIMLED 600 and MINOR SUR-GICAL LIGHTS 100 000 LX should be observed to verify intended function. If unusual performance charac-teristics are observed, additional measures may be required, such as, e.g. a modified alignment or another location of MIMLED 600 and MIMLED 1000 .

b The field strengths should be less than 3V/m over the frequency range of 150kHz to 80MHz.

11.3 RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF TELECOMMUNICATION EQUIPMENT AND THE DEVICE (NOT LIFE-SUPPORTING)

THE RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF TELE-COMMUNICATION DEVICES AND MIMLED 600 AS WELL AS MIMLED 1000

MIMLED 600 / MIMLED 1000 is intended for use in an electro-magnetic environment where radiated RF interferences are controlled. The customer or the user of MIMLED 600 / MIMLED 1000 can help to avoid electromagnetic distur-bances by maintaining a minimum distance between portable and mobile RF telecommunication equipment (transmitters) and MIMLED 600 / MIMLED 1000 – as specified below according to the output power of the telecommunication equipment

RATED OUTPUT OF THE TRANSMITTER (W)	SEPARATION DISTANCE ACCORDING TO THE TRANSMITTER FREQ. (M)		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.34\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output not given in the above table, the recommended separation distance d in meters (m) can be estimated using the equation in the respective column where P is the maximum rated output of the transmitter in watts (W) according to the manufacturer's specifications.

NOTE 1: With 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not be applicable in all cases. Electromagnetic radiation is affected through absorption and reflection of structures, objects and people.

Revised: 1.0 valid from 10 Dec. 2013

INSPECTION PLAN HOLDING FIXTURE SYSTEM

System data

Supplier _____ Date of installation _____

Serial number _____

Series/Inventory number Operator _____

Device location _____

Important information

- The inspection must be performed by trained service personnel.
- The inspection intervals must be observed
- This inspection is only valid in connection with the Installation and Instructions for Use which should be used as a supplement to the inspections.

The support arm system is to be checked according to the intervals specified below for the following points by personnel with the appropriate qualifications:

(Operating time in years)

Visual inspection (is to be carried out each year)	**1**		**2**		**3**		**4**		**5**		**6**		**7**		**8**		**9**		**10**	
	ok O	n.o. O	ok O	n.o. O	ok O	n.o. O	ok O	n.o. O	ok O	n.o. O	ok O	n.o. O	ok O	n.o. O	ok O	n.o. O	ok O	n.o. O	ok O	n.o. O
The parts of the support system are not deformed**																				
The system is free of paint damage*																				
The plastic parts are available and in position*																				
he plastic parts are free of cracks*																				
All type plates are present and legible																				

(Operating time in years)

Functional check (is to be carried out each year)	**1**		**2**		**3**		**4**		**5**		**6**		**7**		**8**		**9**		**10**	
	ok O	n.o. O	ok O	n.o. O	ok O	n.o. O	ok O	n.o. O	ok O	n.o. O	ok O	n.o. O	ok O	n.o. O	ok O	n.o. O	ok O	n.o. O	ok O	n.i. O
Free rotation/stops is given (depending on version)**																				
Horizontal and vertical joints move smoothly, lubricate if necessary*																				
Height stop mechanism positioned correctly, if necessary readjust**																				
Check and lubricate locking segment*																				
Snap ring in position and form (cantilever arm/FA)*																				
Load balancing/spring force is correct, readjust if necessary																				
Collision damage - All welded joints are free of cracks**																				
Check protective earth transfer resistance** (only applies if current-carrying lines are installed).																				
Check fastening srew at the bottom of the stand and tighten it if necessary**																				

Confirmation of the inspections carried out

The above listed work was performed including the necessary adjustment work and safety check:

1st year		6th year	
Date	Signature/stamp	Date	Signature/stamp
2nd year		7th year	
Date	Signature/stamp	Date	Signature/stamp
3rd year		8th year	
Date	Signature/stamp	Date	Signature/stamp
4th year		9th year	
Date	Signature/stamp	Date	Signature/stamp
5th year		10th year	
Date	Signature/stamp	Date	Signature/stamp

* Damaged or deformed components should be replaced as a precaution. Please contact the supplier of the system.

** If one of the points marked during the audit is objected to, the system should be immediately shut down as a precautionary measure to exclude further damage to people and equipment. Immediately inform the supplier of the system.

The medical products logbook associated with each medical device and specified according to the MPBetreibV is to be kept on-site. Service and maintenance work as well as safety checks are to be documented in this medical products logbook. Audit reports such as these are to be filed in the respective medical products logbook.

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