INSTRUCTIONS FOR USE

MIMSAL

MD

MIMLED 600

MIMLED 1000

VALID FROM MAY 2016

MIMSAL

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SYMBOL LEGEND

SYMBOL	DESCRIPTION
	**WARNINGS** general and specific
	**INFORMATION** for users and third parties (engineers, technicians)
	**HINT** Handling/activity which is to be implemented

TABLE 1: Symbol legend

Please keep the instructions for use/installation instructions carefully near the equipment!

1 WARNING AND SAFETY INSTRUCTIONS

- Make sure before each use that the lamp is in proper technical condition.
- Caution, the light works exclusively with the power supply integrated in the suspension/stand or the power supply provided with the wall mounting.
- Disconnection from the mains:
  With wall mounted and mobile systems, the lights can be disconnected from the power line by pulling the mains plug out of the socket.
  In ceiling mounted systems, a separate switch for full power shut-off during construction work shall be provided to be able to disconnect the device from the mains!
- The MIMLED 600 as well as thMIMLED 1000LX are not equip-ped with a fail-safe power supply or an electrical storage medium as minor surgical lights. The light will not operate in the event of an outage in the facility's power supply or disconnection from the mains.
- Only connect the device to a power grid with a connected earth conductor.
- This device is not intended for use in explosive areas.
- If several lights are operated together, make sure that the total irradiance intensity of 1000 W/m2 will not be exceeded in order to avoid excessive heat build-up in the wound area.
- Do not bring near strong magnetic fields such as MRI systems.
- Do not use in oxygen-enriched atmospheres.
- Do not use in the presence of flammable anaesthetic gases.
- As minor surgical lights, the MIMLED 600 as well as the MIMLED 1000 are not designed for use in a dental work environment (there are separate normative rules for the light field of a dental lamp in dentistry) – excepting oral and maxillofacial surgery and implantology
  (observe radiation spectrum when processing polymers!)
- For handling of the light, the Instructions for Use (Light head/holding fixture) should be taken into account.
- Store the light for at least 24 hours prior to assembly in its packaging in the room where it will be installed so that any temperature fluctuations are compensated for.
- The assembly, repair and maintenance work on the product may only be done by qualified personnel – see also instructions for ceiling and wall installation and the mobile stand.
- The manufacturer is only responsible for the safety of the light if repairs and alterations have been carried out by themselves or a company who can guarantee that the safety regulations have been observed and only uses genuine replacement parts.
- The manufacturer declines all liability for injury to persons and damage to components due to improper use or incorrect operation.
- During the installation/ dismantling of the minor surgical lights, the entire system must be completely disconnected from the mains (incl. holding fixture)!
- Only the support and mobile stand delivered together with the MINOR SURGICAL LIGHTS LAMP are to be used.
- Stand-by mode: The lights can be switched on or in the standby mode using control elements on the light head.
- 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 together with the MIMLED 600 | 1000
- The use of stands and mounting systems that do not come, 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 decreased immunity of the lighting systems, and is therefore not permitted.

Definition of minimum operating quality and essential performance

- Brief flickering or switching-off of the light for less than one second is allowed, as any examination, diagnosis or treatment will not be affected.
- In the event of short interruptions of the power supply, the light turns off and has to be switched on again manually by the operator if necessary.

2 TARGET GROUP

These Instructions for Use (including the Instructions for Use for the holding fixture system) are oriented to medical staff who use, clean, disinfect and sterilise the MIMLED 600 or the MIMLED 1000. The Installation instructions on the holding fixture system are directed to qualified and trained technical staff.

SPECIFIC PURPOSE

The MIMLED 600 | 1000 can be applied for the examination of patients as well as for small surgical procedures in surgery and operating rooms (of groups 0, 1 and 2). A system consists of light head in combination with a provided holding fi xture (mobile stand; ceiling fi xture or wall fi xture).

3 SHORT DESCRIPTION

3.1 LIGHT HEAD

The The MIMLED 600 and the TheMIMLED 1000 are designed for the examination of patients as well as for smaller surgical procedures in rooms used in the medical classes 0, 1 and 2. When using the lights in connection with critical procedures, such as e.g. examinations near the heart and proce-dures of the heart, it must be ensured that the value for the maximum permissible contact voltage of 10 mV is not exceeded ($\Delta u \leq 10mV$). On the light-side, this is supported through, e.g. the existing equipotential bonding connec-tors which are to be connected with equipotential bonding cable to the corresponding equipotential bonding bus bars (see also Section “Equipotential bonding cable).

As minor surgical lights, the The MIMLED 600 as well as the The MIMLED 1000 are not equipped with a fail-safe power supply or an electrical storage medium. The function of the light will be interrupted in the event of an outage in the room‘s power supply or disconnection from the mains.

If the user of the MIMLED 600 or the MIMLED 1000 requires continued use of the light even in the event of a power outage, the energy supply must come from an uninterruptible power supply (UPS).

The operation of the minor surgical light is done using a control panel on the upper side of the light head or on the grip on the bottom of the device. The product family of minor surgical lights is available in the variants 60,000 lux and 100,000 lux.

The MIMLED 600

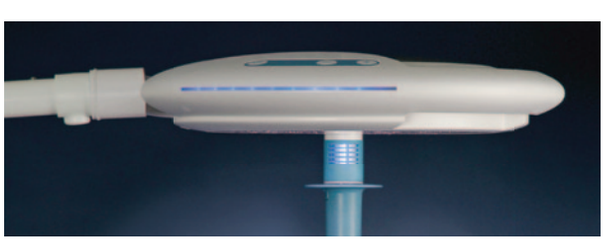
The The MIMLED 600 was desig-ned on the basis of LED-technology and has a compact, fl at light head.

In the grip area, there is a light indicator LED which displays the intensity in five levels.

FIGURE 1: Light head for the MIMLED 600

The MIMLED 1000

The The MIMLED 1000 is identi-cal despite higher illumination and just as compact as the The MIMLED 600 .



The light includes a standard blue sterilisable grip as well as an additional indicator LED bar on the housing for the intensity display in ten levels.

FIGURE 2: Light head for the MIMLED 1000

3.2 HOLDING FIXTURE SYSTEMS AND ACCESSORIES

The light head is positioned using the holding fixture system and the joints integrated in the light head and the holding fixture system and supplied with power using a power supply pack.

Connection only to mains power supply with protective earth!

The installation instructions enclosed regarding the installation of the holding fixture system must be observed.

No changes or modifications may be made to the product!

Despite all precautions, interference or EMC problems can occur. Therefore, please observe the corresponding tables on Page 26ff!

STAND

The stand devices delivered together with MINOR SURGICAL LIGHTS are suitable to hold and position lightweight lighting fixtures.

The light heads of the MIMLED 600 and/or MIMLED 1000 are designed in such a compact way that these can also be used as mobile lamps.

The Instructions for Use and Installation instructions are enclosed with the product.

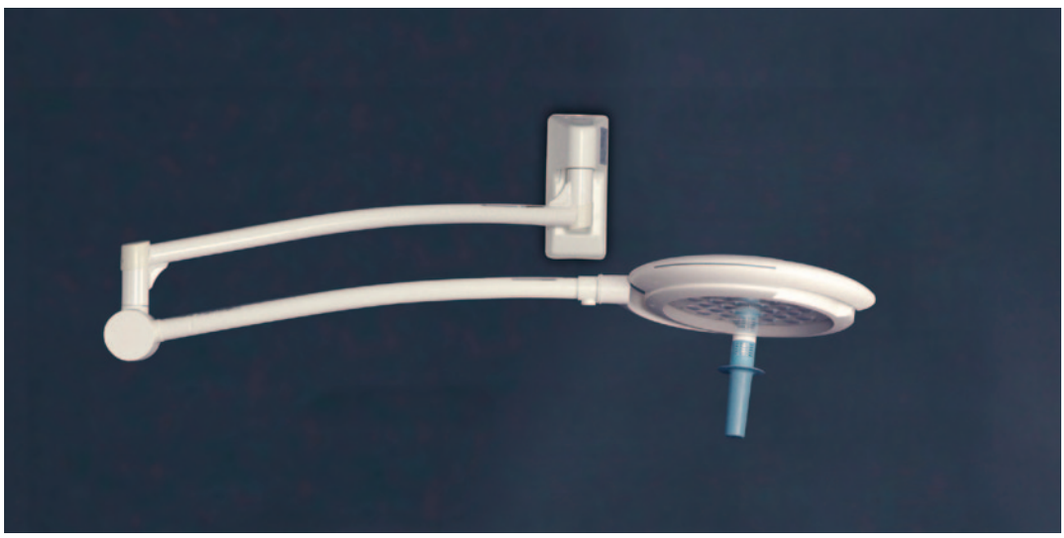
CEILING HOLDER

The ceiling holder devices delivered together with MINOR SURGICAL LIGHTS is suitable for holding and positioning lightweight lighting fixtures.

The light heads of the MIMLED 600 and/or MIMLED 1000 are de-signed in such a compact way that these can be ideally positioned by means of the ceiling holder.

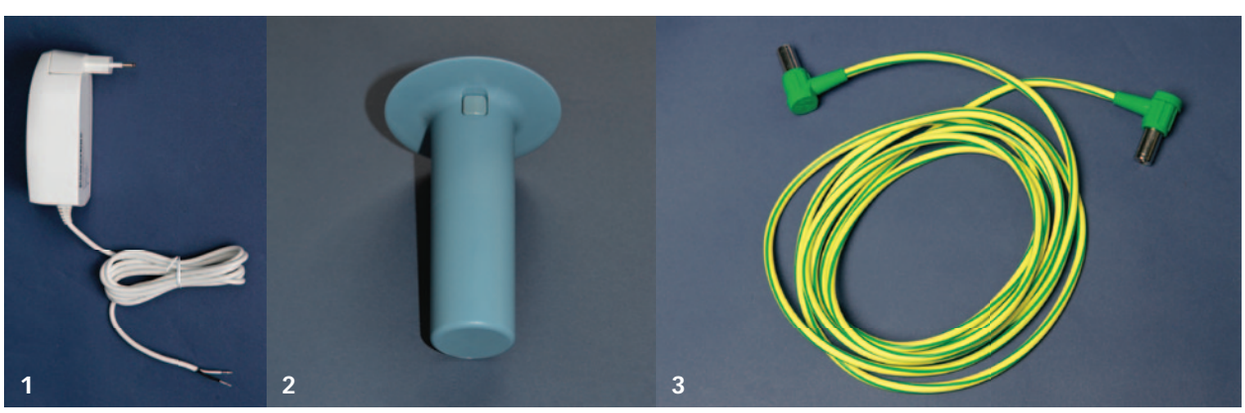
The Instructions for Use and Installation instructions are enclosed with the product.

WALL HOLDER



The light heads of the MIMLED 600 and/or MIMLED 1000 are designed in such a compact way that these can be ideally positioned by means of the wall holder.

The Instructions for Use and Installation instructions are enclosed with the product.



1	Medline EXM 80 for the wall holder
2	Blue “Sterigriff” forthe MIMLED 1000 which is not delivered in sterile condition. This must be disinfected and sterilised prior to first use according to the description in Section “Cleaning/ Disinfection/Sterilisation”. Article no. 4500.04-020
3	Equipotential bonding cable for mobile stands and wall mounting Article no. 4510.30000

FIGURE 3: Schematic representation for the approved holding systems and power supply pack for wall installation

4 OPERATION

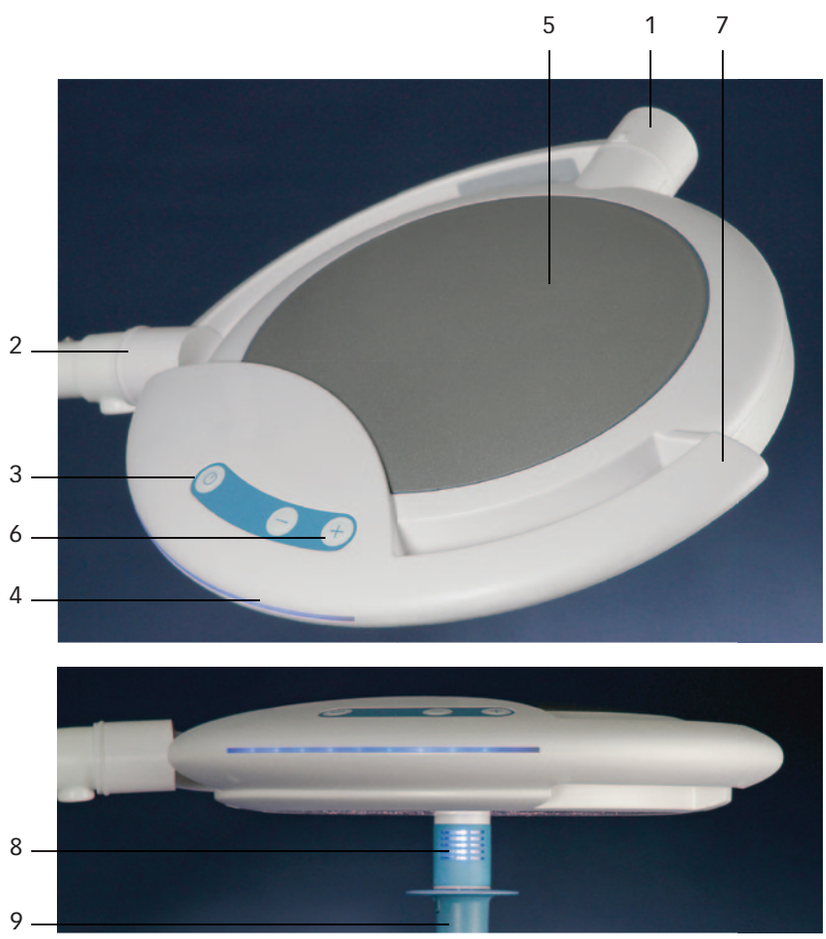
4.1 INSPECTION BEFORE EACH USE

- Check system for any visible deformation. If this is discovered, immediately contact the service department.
- Ensure that the system has the hygiene status required for the application.
- Prior to each start-up, the entire device is to be checked for its functionality. The device is to be moved in all of its degrees of freedom and the main function including control is to be checked.
- If a light should become too stiff or it does not hold its position, the holding forces must be adjusted for support and stands according to the Instructions for Use.
- Check the grip for cracks!

Do not operate the light if there is any doubt of the electrical safety or the static and dynamic stability.

4.2 OPERATION OF THE LIGHT HEAD

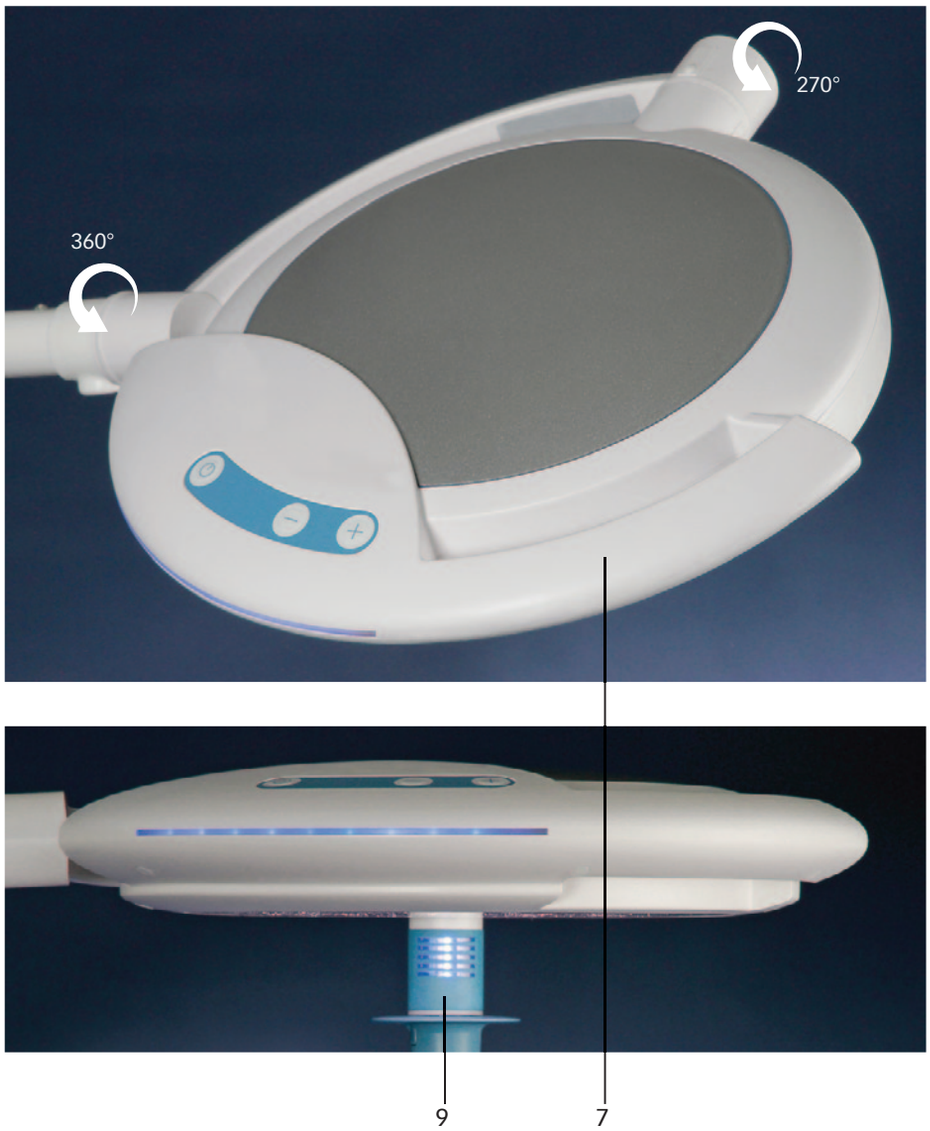
The simple and ergonomic operation concept of the MIMLED 600 or the MIMLED 1000 allows for intuitive operation by the user. The control elements for ON and OFF switching and for brightness regulation are integrated into the upper side of the light head. The grip allows for brightness regula-tion by turning the grip.



1	270° joint
2	360° Joint/interface holding fixture system
3	Stand-by/ON switch
4	Brightness intensity display (not applicable with MIMLED 600)
5	Cooling element
6	Brightness regulation
7	Lateral grip strip
8	Brightness intensity display

FIGURE 4: Control elements of light head

4.3 POSITIONING AND SWIVEL RANGE



The grip strip (position 7) is for the non-sterile use and positioning of the light head.

The sterilisable grip (position 9) also allows for both positioning of the light head and brightness adjustment of the light during the procedure.

LIGHT HEAD

The light head is connected via a holder to the holding fixture system.
The holder of the light head makes it possible to turn the light in its holder by approximately 270°.

STAND HOLDER

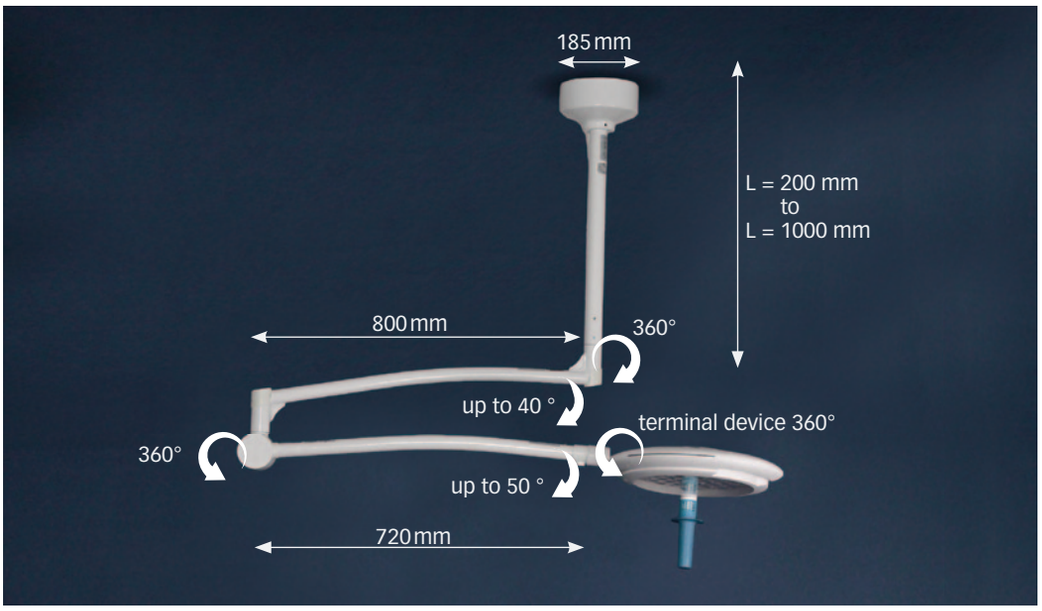
The holder of the stand mounting for connection to the light head makes it possible to rotate the light head by 360° around the in the horizontal axis.

The swivel arm of the stand holder is positioned vertically and with the swivel joint, allows for turning movements of 60° around the vertical axis.

The stand is only to be used on level and firm flooring.

After positioning the stand, lock both stand castors with brakes.

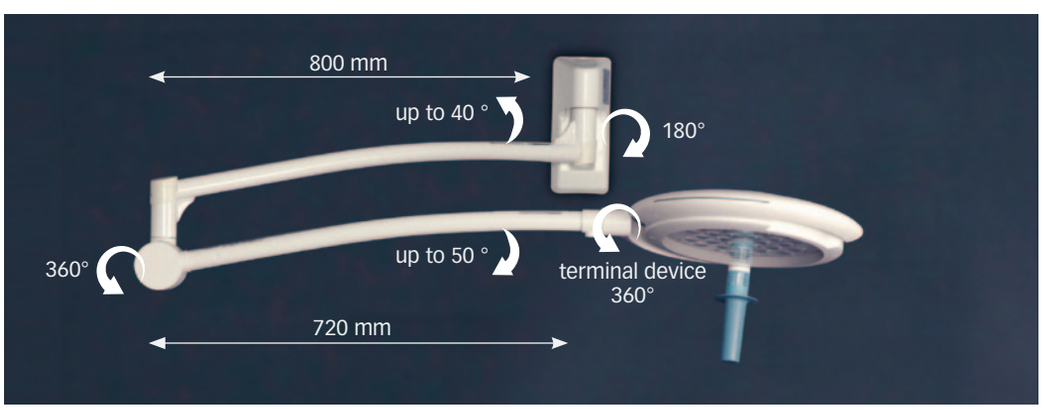
CEILING MOUNTING



The holder of the ceiling mounting for connection to the light head makes it possible to rotate the light head by 360° around the horizontal axis.

The cantilever arms of the ceiling mounting are positioned vertically and makes turning movements of 2 x 360° possible over the swivel joints in the horizontal axis.

WALL MOUNTING



The holder of the wall mounting for connection to the light head makes it possible to rotate the light head by 360° and in the vertical axis.

The cantilever arm of the wall mounting is positioned vertically and with the swivel joints, allows for turning movements of 360° between the cantilever arms and 180° on the wall around the vertical axis.

Do not attach any additional loads to the light head or stand/mounting.

FIGURE 5: The positioning of the light head and degree of freedom of the holder systems

4.4 ON/OFF SWITCHING OF THE LIGHT

Function standby is ensured if the power supply of the holder system is connected to the mains by means of the mains connecting cable.

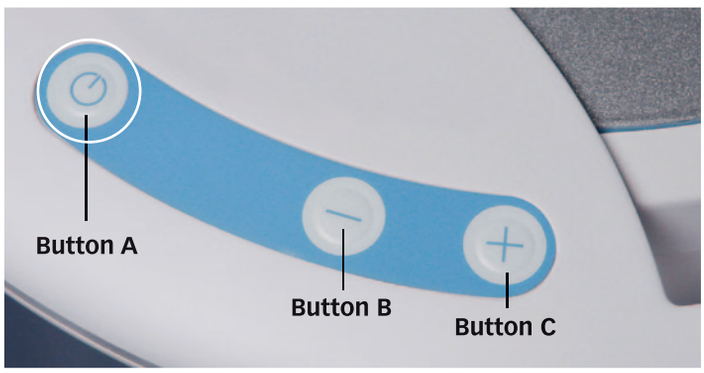


FIGURE 6: ON/OFF switch

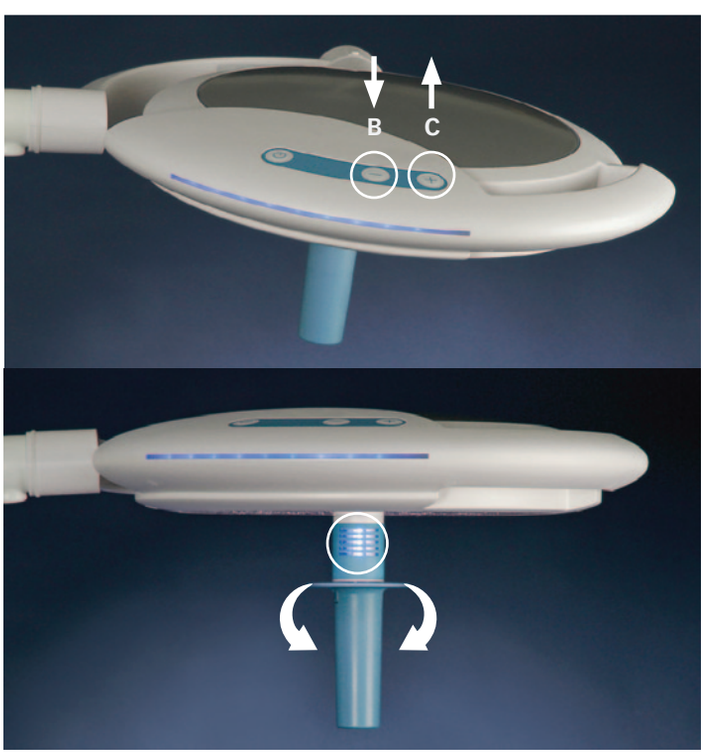
The minor surgical light is switched on or back into the standby mode with the ON/OFF button (Button A) on the membrane control panel.

The brightness display on the light head of MIMLED 1000 pul-ses in standby mode with the lowest order indicator LED.

MIMLED 600 does not have a brightness display on the light head.

4.5 BRIGHTNESS REGULATION

The minor surgical lights offer a brightness regulation between 10% and 100% via the two following functions:



In ten steps by pressing the + and – buttons (Button C and Button B in Figure 7) on the control unit on the top of the housing.

The illumination can be increased (+) or reduced (-) by activation of the C and B button.

Between approx. 10% and 100% in ten steps by regulation via the grip on the bottom of the light head, while the indicator lights on the grip display five steps (see Figure 7).

By turning the grip counter-clockwise, the illumination can be increased or, in the clockwise direction, reduced.

FIGURE 7: Brightness regulation

4.6 DISPLAY OF THE ILLUMINATION LEVEL

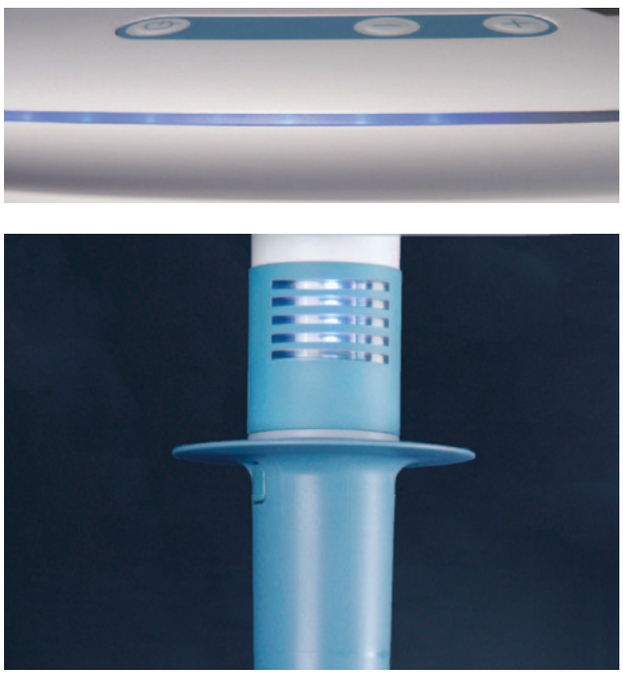


FIGURE 8: Display of the illumination levels

The lateral indicator LEDs of MIMLED 1000 visualise the current setting of the illumi-nation in ten steps.

MIMLED 600 does not have lateral brightness indication on the lamp head.

Both MIMLED 600 and MIMLED 1000 have an illumination display in the holder of the grip and therefore allow the user to immediately assess the current bright-ness with the simple display segmentation.

The indicator strip on the grip visualises the current brightness in five steps. The lowest order indicator LED pulses in standby mode.

4.7 REMOVAL AND REPLACEMENT OF THE GRIP

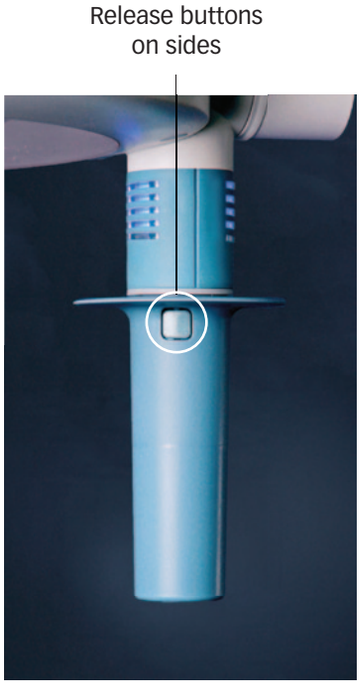


FIGURE 9: Sterilisable grip

MIMLED 600 | 1000

The grip must be removed for cleaning and disinfection:

- To remove, press the two release buttons on the sides and pull the grip off downwards.
- To reassemble, slide the grip on until the release buttons on the sides securely snap in and lock.

Only the blue grip of MIMLED 1000 can be sterilized. Before sterilization, at first clean and disinfect as described in section "Cleaning/Disinfection/Sterilisation"!

During surgery, the grips often become unsterile. Therefore, keep at hand several grips of article no. 4500.04-020 for replacement.

5 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.

FIGURE 10: Equipotential bonding connector on mobile stand

FIGURE 11: Equipotential bonding connector on mobile stand with equipotential bonding cable

6 CLEANING/DISINFECTION/STERILISATION OF THE STERILISABLE GRIP

The cleaning of the medical-technical facilities in the medical and especially in the surgical environment is determined through institutional-specific hygiene plans and procedures, coordinated to the in-house circumstances and the required hygiene status in general. The cleaning and disinfection procedures and disinfectants described here gave been developed and validated by professional societies and correspond to the conventional market standards.

Should different requirements exist in your workplace, please contact our customer service or your hygiene expert in this respect.

Only suffic ient device or product-specificproceduresforcleaning,disinfectionandsterilisationensuretheactual sterilisation of the parts (as with the blue, sterilisable grip). The prerequisite is that the validated parameters for each cycle are to be strictly complied with. The other hygiene provisions of the operator of the medical equipment (e.g. hospital) are to be additionally observed.

6.1 STERILISABLE GRIP (ALSO KNOWN AS “STERIGRIFF”)

Both MIMLED 600 and MIMLED 1000 are standardly equipped with a blue sterilisable grip (Sterigriff). The removable grip is steam-sterilisable up to 134 °C.

The blue sterilisable grip must be sterilised before the first use and before each use.

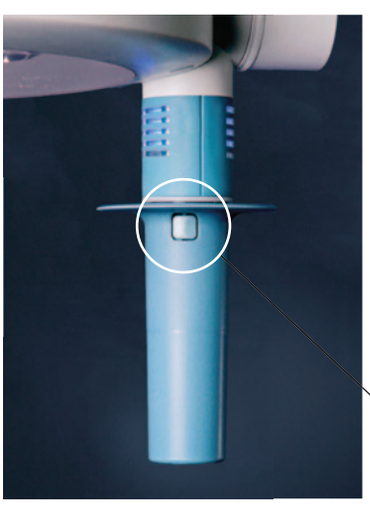


FIGURE: 12: “Sterigriff” sterilisable grip`

The grip must be removed for sterilisation:
To remove, press the two release buttons on the sides and pull the sterilisable grip off downwards.

To reassemble, slide the grip on until the release buttons on the sides audibly snap in and lock.

During surgery, the grip often becomes unsterile. Therefore keep several grips handy for replacement (article no. 4500.04-020).

6.2 CLEANING/DISINFECTION BASICS

Effective cleaning/disinfection is a mandatory prerequisite for effective and proper use of the blue grip as part of the device's use in the medical environment.

Contamination of the work area/risk of infection:

Poor or missing implementation of the procedures for cleaning, disinfection / sterilisation may lead to contamination of workspace/users/patients/third parties (observe the hygiene guidelines and manufacturer instructions!)

6.3 DISINFECTION

The blue grip must be disinfected and cleaned immediately after use. A mechanical cleaning/disinfection procedure should be used (disinfector).
The following mechanical procedure was validated for the effective cleaning/disinfection of the "Sterigriff" handle using the WE 290 cleaning and disinfection unit by Belimed, programme 1 (instruments alkaline):

Pre-cleaning:	3 min. pre-rinsing
Cleaning:	5 min. at 48°C, then rinse 2 min. cold and rinse with purified water
Disinfection:	5 min. at 93°C
Drying:	15 min. at 95°C
Cleaning agent:	Mediclean forte, Dr Weigert

6.4 STERILISATION

Sterilisation of the blue sterilisable grip must only be done with already cleaned and disinfected hand grips.
Sterilisation of the blue Sterigriff is validated with the following mechanical procedures and parameters:

Sterigriff packed in paper/laminate

Class B steriliser Lisa 522, serial number 08-0794, W&H

Sterilisation procedure: Fractionated pre-vacuum method

Temperature: 134°C

Dwell time: 18 min.

Only steam sterilisation! Not suitable for gamma rays, ethylene dioxide, and other procedures not associated with steam sterilisation!
If another sterilisation procedure than the described procedure will be used, the suitability and basic effectiveness of the procedure must be demonstrated as part of a validation.

6.5 INSPECTION/SERVICE LIFE

Before reusing, the grips must be checked for damage and replaced as required.
The grips may be cleaned/disinfected, sterilised and re-used a maximum of 1000 times.

The operator shall be responsible if the grips will be used more than 1000 times.

7 HOLDING FIXTURE SYSTEM

The small MIMLED 600 and/or MIMLED 1000 is designed for use in conjunction with the lightweight holder system. The holder system has been adapted to the MINOR SURGICAL LIGHTS.

Please observe the safety notes of the Instructions for Use of the holding fixture systems when cleaning!

For disinfection, please observe the safety notes of the Instructions for Use of the holding fixture system!

The requirements of the Instructions for Use enclosed to the holder fixture and mobile deliveries must be observed. The requirements for the selection of cleaning agents and procedures for cleaning and disinfecting shall apply accordingly.

7.1 CLEANING

When cleaning, please observe the following:

Recommended cleaning of the holder and stand
- Use a mild soap solution or customary detergents as a cleaning agent.
- Wipe the surface of the lamp head 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 (antistatic) cloth (e.g. with a ASC™ antistatic cloth).

7.2 DISINFECTION

The wipe disinfection procedure is to be used for the support arm's standard disinfection procedures.
The operator must establish hygiene guidelines and appropriate safety measures for the disinfection procedures to be used.

RECOMMENDATION:
The verified and validated disinfectant MELISEPTOL® from the manufacturer B. Braun Melsungen is recommended as a disinfectant.

Surface disinfection needs to be done every working day!
After contamination by potentially infectious material (e.g. blood, secretion or excrements) immediately disinfect the surfaces selectively!

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

For disinfection, please observe the safety notes of the Instructions for Use for the light heads!

Please contact your hygiene expert to coordinate the disinfectants and procedures in connection with your in-house requirements regarding the current level of hygiene! Disinfect according to the internal disinfection schedule! Observe the hygiene guidelines!

For surface disinfection, do not spray, but wipe!

Only use disinfected areas if the disinfectant is dry!

Do not sterilise! Should sterilisation be mandatory (e.g. due to administrative directive), it is essential 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!

8 MAINTENANCE

Medical devices 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.

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

Comply with the manufacturer's installation/dismantling instructions when carrying out maintenance work (see the installation instructions enclosed to the mounting fixture systems).

Comply with the manufacturer's instructions for use when performing any measures for repair.
(See Annex "Inspection")

8.1 HOLDING FIXTURE SYSTEMS

All holding systems are to be checked by the operator for the following points:

ELECTRIC SHOCK
For all inspections, disconnect the device from the mains.

A Recurring inspections:
DIN EN 62353 is to be observed when doing 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, checking of the lock screw at the bottom side of the stand foot and retightening, if necessary.
- Extended functional check, such as free movement of the joints
- Check and grease (e.g. with Microgleit GP 360) the locking segment according to section “Lubricate locking segment” in the instructions for the support systems.
- Electric safety check.

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.

8.2 LIGHT HEAD

The following inspections/maintenance must be performed every year:

- Check for cracks, deformation in plastic parts and seals
- Electric safety check
- Extended operational check
- Paint damage

9 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.

NO dismantling of the spring arms or hinge joints. The spring arms and joints contain, in part, pre-tensioned springs which during improper dismantling, could release their tension suddenly.

Information: Do not dispose of the product with normal household waste.

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

10 DATA

10.1 PHOTOMETRIC DATA FOR MIMLED 600 AND MIMLED 1000

MIMLED 600	
Central illumination at a distance of one meter [lx]	60,000
Light fielddiameterD_{10} [mm]	190
Light distribution D_{50}/D_{10}	≥ 0.56
Depth of illumination [mm]	≥ 960
Colour rendering index R_a*	≥ 94
Colour temperature [K]*	4,500
Electronic brightness control on the light head	Standard dimming range between 10% and 100% in ten stages
Electronic brightness control on the grip	Standard dimming range between 10% and 100% in ten stages, with approx. five stages being visualised on the grip.
Light fielddiameterD_{50} [mm]	110
Special colour rendering index R_9*	≥ 92
Total irradiance E_e [W/m²]	260
Shadow dilution without shutter [%]	100
Shadow dilution with one shutter [%]	Approx. 0
Shadow dilution with two shutters [%]	58
Shadow dilution at the bottom of a standardised tube [%]	100
Shadow dilution at the bottom of a standardised tube and one shutter [%]	Approx. 0
Shadow dilution at the bottom of a standardised tube and one shutter [%]	58
Service life [h]	Approx. 50,000

TABLE 2: Photometric data according to DIN EN 60601-2-41 for MIMLED 600

MIMLED 1000	
Central illumination at a distance of one meter [lx]	100,000
Light field diameter D_{10} [mm]	190
Light distribution D_{50}/D_{10}	≥ 0.56
Depth of illumination [mm]	≥ 960
Colour rendering index R_a*	≥ 94
Colour temperature [K]*	4,500
Electronic brightness control on the light head	Standard dimming range between 10% and 100% in ten stages
Electronic brightness control on the grip	Standard dimming range between 10% and 100% in ten stages, with approx. five stages being visualised on the grip.
Light field diameter D_{50} [mm]	110
Special colour rendering index R_9*	≥ 92
Total irradiance E_e [W/m²]	390
Shadow dilution without shutter [%]	100
Shadow dilution with one shutter [%]	Approx. 0
Shadow dilution with two shutters [%]	56
Shadow dilution at the bottom of a standardised tube [%]	100
Shadow dilution at the bottom of a standardised tube and one shutter [%]	Approx. 0
Shadow dilution at the bottom of a standardised tube and one shutter [%]	56
Service life [h]	Approx. 50,000

TABLE 3: Photometric data according to DIN EN 60601-2-41 for MIMLED 1000

The technical data is subject to certain fluctuations. For product-technical reasons, the actual values may slightly differ from the values listed above.

* The values for R_a/R_9 may deviate by approximately ± 5%.
The values for the colour temperature may deviate by approx. ± 250 K.

10.2 ELECTRICAL AND/OR OTHER TECHNICAL DATA

LIGHT HEAD	MIMLED 600	MIMLED 1000
Nominal voltage	24 V DC ± 10%	24 V DC ± 10%
Nominal current	1.1 A @ 24 V max.	1.4 A @ 24 V max.
Protection class	IP42	IP42

TOTAL SYSTEM	MIMLED 600	MIMLED 1000
Power consumption	25W	33W

	CEILING MODEL	WALL MODEL	MOBILE LAMP
Fuse type	Primary 250 V; T 800mA L; 5x20 mm		Primary 250 V; T 800mA L; 5x20 mm Secondary 250 V; M 2A L; 5x20 mm
Protection class	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	60W	70W	60W

TABLE 4: Technical data

10.3 ENVIRONMENTAL CONDITIONS

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

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

TABLE 5: Environmental conditions

10.4 ELECTROMAGNETIC COMPATIBILITY

10.4.1 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 MIMLED 1000 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 emissions 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.
Voltage fluctuation emissions according to IEC 61000-3-3	Complies	

10.4.2 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**
Electrostatic discharge (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 according 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 according 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 ELECTROMAGNETIC ENVIRONMENT specified below. The customer or the user of MINOR SUR-GICAL LIGHTS 60 000 LX 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	80 MHz – 2.5 GHz, 3V/m	80 MHz – 2.5 GHz, 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	150 kHz – 80 MHz 3Vrms	150 kHz – 80 MHz 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 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 SURGI-CAL 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 150 kHz to 80 MHz.

10.4.3 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 | 1000 is intended for use in an electromagnetic environment where radiated RF interferences are controlled. The customer or the user of MIMLED 600 | 1000 can help to avoid electromagnetic disturbances by maintaining a minimum distance between portable and mobile RF telecommunication equipment (transmitters) and MIMLED 600 | 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 FOR THE LIGHT HEAD OF MIMLED 600 AND MIMLED 1000

Inspection plan for the light head

Supplier _____ Date of installation _____

Serial number _____

Series/inventory no. 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 light head is to be checked according to the intervals specified below for the following points by personnel with the appropriate qualifications:

(Operating time in years)

View/function 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.o. O
The plastical parts are free of cracks*																				
The lamp shade is free of paint damage*																				
The seals are free of cracks*																				
The function is correct*																				
The electrical safety is completely functional																				

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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INSPECTION PLAN HOLDING FIXTURE SYSTEM

Inspection plan for the lightweight support system

Supplier _____ Date of installation _____

Serial number _____

Series/inventory no. 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 delivered 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 half-yearly)	**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*																				
The plastic parts are free of cracks*																				
All type plates are present and legible																				

(Operating time in years)

Functional check (is to be carried out half-yearly)	**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
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 (extension 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.

BRIEFING LOG
INSTRUCTIONS CONCERNING MIMLED 600 AND/OR MIMLED 1000

System data

Supplier _____ Date of installation _____

Serial number _____

Series/Inventory no. Operator _____

Device location _____

Briefing employee: _____

Important information

- The briefing must be carried out by authorised personnel
- The briefing includes operation as well as instructions for the proper use of the small surgical light

Declaration:

The operator assures that the briefing and the information for the proper use of the minor surgical light has been received.

_____ _____

Place, date Signature/stamp (Operator)

NOTES:

MIMSAL TRADE S.L.
C/ Mollet 17, Pol. Ind. Palou Nord
08401 - GRANOLLERS (Barcelona)

Telf. +34 930 139 860
mimsal@mimsal.com
www.mimsal.com