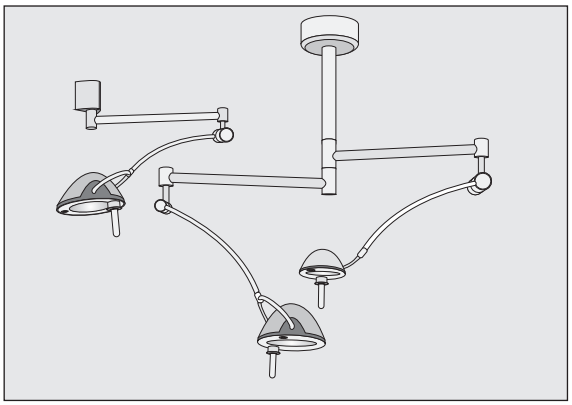
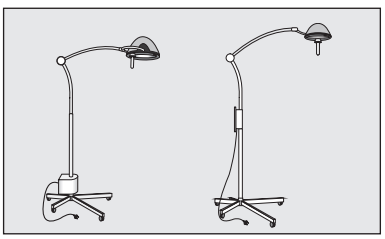
MAQUET
GETINGE GROUP

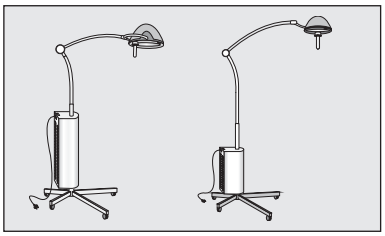
BLUELINE

Ceiling, wall-mounted or mobile surgical light

User's manual EN







BLUELINE NU 0136102 EN Ed2B

17 January 2013

CONTENTS

QUALITY STANDARDS COMPLIANCE

Certification of MAQUET SAS's quality system

LNE/G-MED certifies that the quality system developed by MAQUET SAS for design, implementation, sales, installation and after-sales service of surgical lights complies with the requirements of the following international standards:

• ISO 9001:2000

• NF EN ISO 13485:2004.

CE labelling/intended use

Compliance with the requirements of Directive 93/42/EEC relating to medical devices has been assessed and approved by LNE/G-MED. The BLUELINE range of surgical lights belongs to Class I in accordance with Annex IX of Directive 93/42/EEC.

This range includes single or dual ceiling-mounted, single wall-mounted and mobile light units with or without battery-backed power supply.

WARNINGS

Changes or modifications not expressly approved by MAQUET SAS could void the user's authority to operate the equipement.

Light energy can potentially dry tissue, in particular if several surgical lights are used together.

Certain light wavelengths may be incompatible with certain pathologies.


Do not use in an MRI room.


The underside of the lighthead becomes hot during use. Do not touch the underside when adjusting the position of the lighthead.


Do not use the unit in the presence of inflammable anaesthetic gases.


Do not look directly at the light source due to its high intensity.


In the event of a power failure, only lightheads connected to a backup power supply system will remain operational.


After each sterilisation and before re-using the sterilisable handle:

- Check that there are no cracks.
- Check that the handle operates correctly on the light.


Before an operation, check that the sterilisable handle is in place on its mount.


To guarantee aseptic conditions the sterilisable handle should be touched only by the surgical team during an operation.


Take care when moving the mobile light to avoid any risk of it toppling over. Pay particular attention to objects on the floor, steps and the light's power cable.


BLUELINE MOBILE and HOSPITAL lights have an automatic voltage selection mechanism for supply voltages from 100 to 230 V. Only connect BLUELINE MOBILE or HOSPITAL lights to correctly installed power outlets.


When changing a blown bulb:

- Switch off the power supply and leave the lighthead to cool.
- Only use the recommended model of MAQUET bulb.
- Handle bulbs carefully, using gloves or a cloth.
- Never touch bulbs with bare hands. Grease on bulbs shortens their life.


Do not change bulbs during an operation.


The unit is designed to operate with the cover closed. When conducting maintenance, take appropriate precautions to avoid touching surfaces marked as hot.


Dismantling certain elements may affect operation and safety. For example:

- Servicing the electrical power supply.
- Servicing the suspension arm and balance system.
- Servicing the optical system of lightheads equipped with filters designed to eliminate radiation not visible to patients. Surgical lights must never be used without these filters.


Fumigation methods are unsuitable for disinfecting the unit and must not be used.


It may be necessary to press the On/Off switch to turn the light back on following a power cut.

To avoid any risk of an electric shock, class I devices must be connected to a power supply system which is earthed.

Do not touch the patient and non-sterile parts of the system at the same time.

Do not pull on the power supply lead to disconnect the mobile

The connection to the electrical outlet must remain accessible (mobile versions only).

Disconnect the batteries if the device is not scheduled to be used for more than three months (mobile versions only).

SYMBOLS USED IN THE MANUAL

Symbol	Meaning
	**Mandatory:** may affect patient or user safety
	**Recommendation:** risk of damage to device or accessories
	**CE mark:** The device complies with the requirements of European Directive 93/42/EEC on medical devices.
	**Medical equipment** classified with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1 and UL 60601-2-41 and CSA C22.2 No. 601-M90
	**Environment:** information relating to recycling

SYMBOLS USED ON THE DEVICE

Symbol	Meaning
	**Caution** Follow the instructions for use
	**R**ead the documents supplied with unit carefully
	Manufacturer
	**Caution**: Hot surface.
	**Caution**: Spring arm enabled
~	Alternating current
	Bulb failure in BLUE 80 lighthead
	Class II protection (BLUE 30 MOBILE only)
IPS	Internal power supply (BLUE HOSPITAL only)
	Comply with the applicable handling precautions for products that are sensitive to electrostatic discharges.
CE	**CE mark:** The device complies with the requirements of European Directive 93/42/EEC on medical devices.
	**Medical equipment** classified with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1 and UL 60601-2-41 and CSA C22.2 No. 601-M90
	This equipment must not be disposed of with household waste as it is subject to separate collection for value enhancement, reuse or recycling.
	Identifies the year and week of manufacture
	Do not use any cleaning solutions containing alcohol

1 INTRODUCTION

Dear user,

Thank you for choosing the BLUELINE surgical light.

MAQUET has designed this product line to ensure the most comfortable working conditions for surgical teams and optimal safety conditions for patients.

The BLUELINE surgical light is the result of on-going contacts with customers and the experience of our engineering and design team. The BLUELINE surgical light features the following characteristics:

- Easy handling.
- Precise positioning.
- Compact balance system.
- Aerodynamic shape.

The BLUELINE surgical light is suitable for examination rooms, medical practices, outpatient consulting areas and operating theatres (BLUE 80 only).

Safety instructions

Note that some operations should only be performed by persons with appropriate qualifications:

- **The surgical light may be used by trained medical staff only**.
- Although the technology used in this device ensures complete safety, risks may nonetheless arise if it is used by unqualified staff, if it is not used correctly or if it is used for a purpose for which it was not designed.
- **The device must be cleaned by specialised personnel.**

Please read these instructions carefully before using your surgical light to ensure that you are aware of all its advantages and to protect yourself and others against the consequences of incorrect use.

Please follow these instructions to train your staff in using the surgical light safely and with all necessary care.

This surgical light should not be used for purposes for which it was not designed, as set out in this user's manual. Any other use may result in danger to users and/or damage to the device or its environment.

For safety reasons, do not alter or adapt the device in any way without MAQUET's approval.

For your own safety, please contact us if you encounter any problems that are not explained in sufficient detail in this document.

MAQUET may alter the contents of this user's manual without notice.

Transport and storage

- Ambient temperature: -10°C to +60°C
- Relative humidity: 20 to 75%
- Atmospheric pressure: 500 to 1060 hPa
- Store only in enclosed or covered rooms.
- Do not subject to strong vibrations.

Conditions of use

- Ambient temperature: +10°C to +40°C
- Relative humidity: 30 to 75%
- Atmospheric pressure: 700 to 1060 hPa

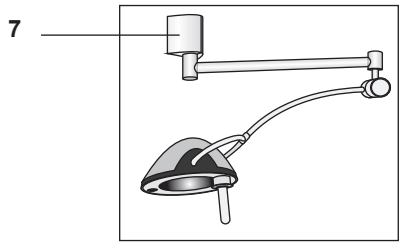
- This device is not designed for operation in explosion hazard areas.
- The device is intended for continuous use.
- BLUELINE surgical lights must be installed and commissioned in accordance with the EMC information provided pages 27 to 30.
- Portable and mobile RF communication devices may affect the correct operation of the device.

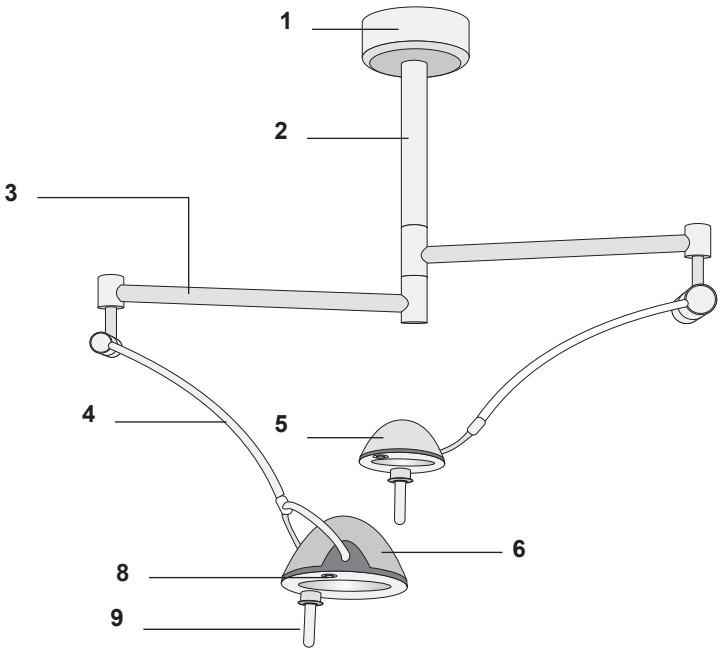
NOTE (for USA only): This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the installation and user manual, may cause harmful interference to radio communication. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

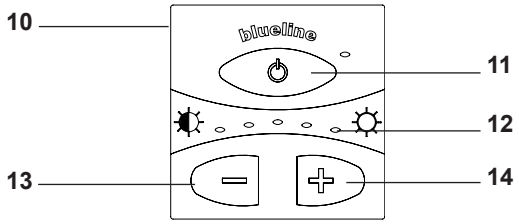
Maintenance

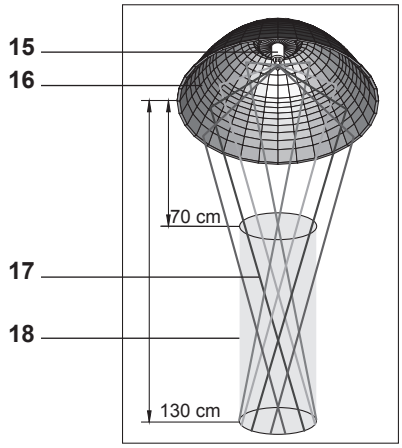
- The MAQUET warrantee, as well as the safety and correct operation of the device can only be guaranteed if:
  - All inspection, maintenance and repair work is performed by MAQUET engineers or trained and authorized technical support technicians.
  - Exclusive use is made of original accessories, consumables and spare parts.

Ceiling and wall-mounted BLUELINE surgical light

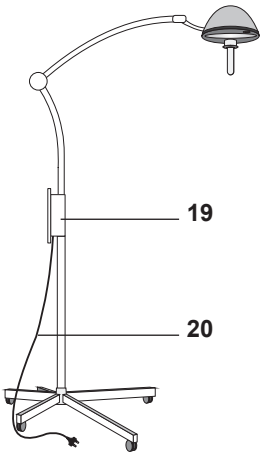


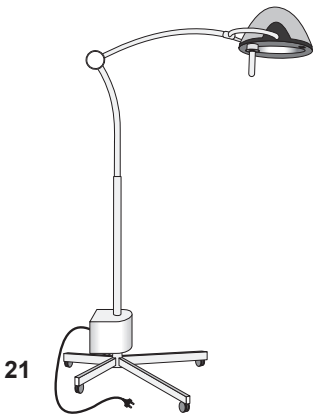




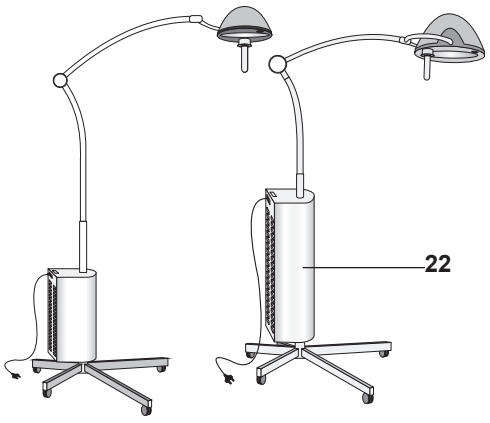


BLUELINE MOBILE





BLUELINE HOSPITAL



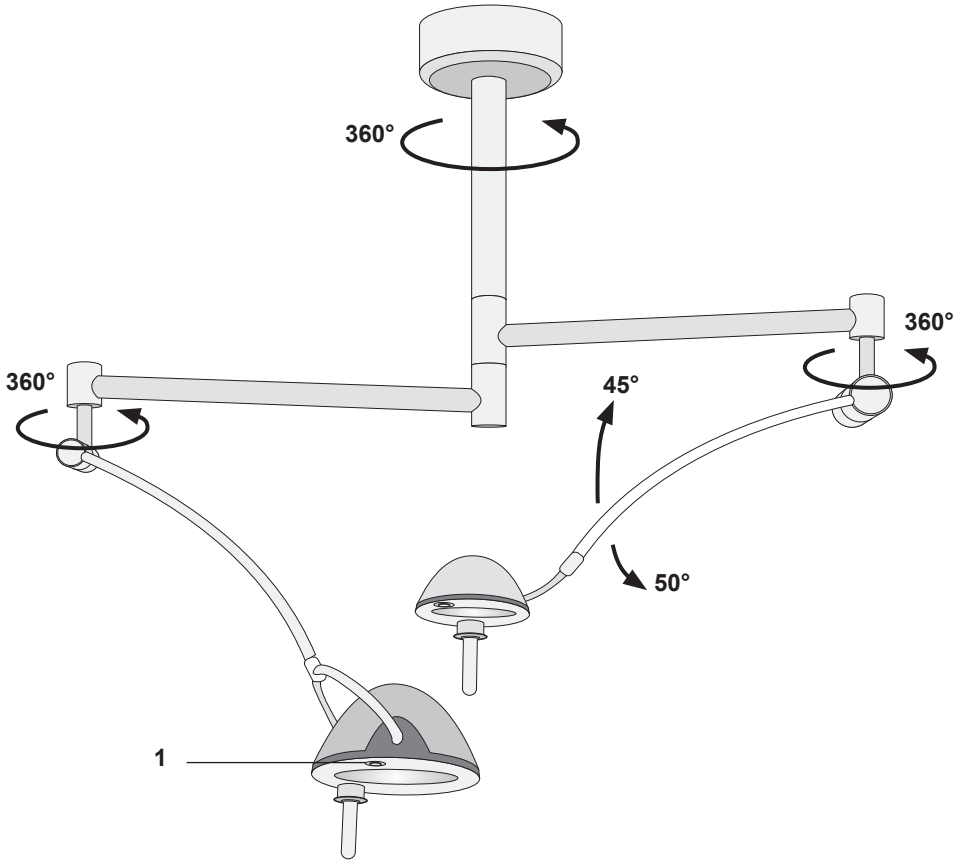
2 DESCRIPTION

The BLUELINE surgical light enables surgical procedures to be carried out in optimal working conditions.

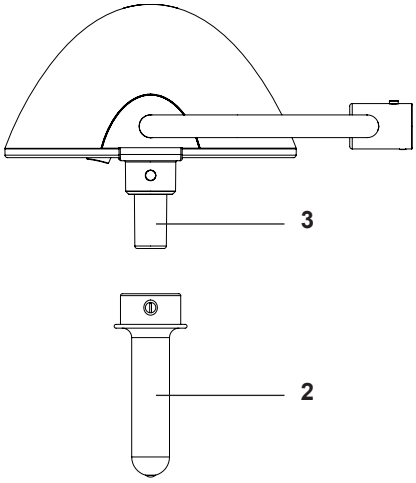
- Light is produced by an IRC halogen lamp (15) adapted to the optical system.
- The light concentrated by the reflector (16) generates a cascading series of light spots (17) beneath the BLUELINE lighthead.
- This technique results in a near-cylindrical light field (18) with a uniform light distribution between 70 cm and 130 cm from the lighthead.
- Depending on the chosen version the lighthead produces an illumination of 35,000 lux (BLUE 30) or 90,000 lux (BLUE 80).
- Optional wall dimmer available (10).

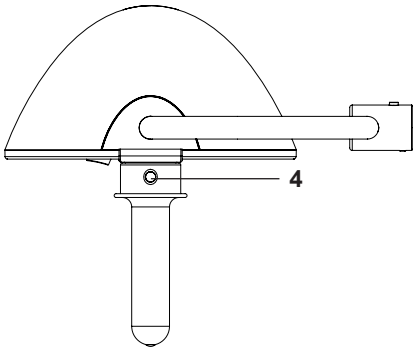
1 Ceiling mount and cover
2 Suspension tube
3 Main arm
4 Spring arm
5 BLUE 30 or 80 satellite lighthead
6 BLUE 30 or 80 main lighthead
7 Wall-mounted version with mounting point
8 On / Off switch
9 Sterilisable handle
10 Optional dimmer
11 Dimmer on/off button
12 Light intensity indicator
13 Light intensity adjustment button (less)
14 Light intensity adjustment button (more)
15 IRC halogen lamp
16 Reflector
17 Cascading series of light spots
18 Cylindrical light field
19 Power supply housing
20 Connection cable
21 Brakes
22 Batteries for emergency power supply

Positioning the light



Installing the sterilisable handle





3 USING CEILING OR WALL-MOUNTED BLUELINE LIGHTS

3.1 Positioning the BLUE ceiling-mounted light

The underside of the lighthead becomes hot during use. Do not touch the underside when adjusting the position of the lighthead.

It is important to pre-position the light before starting surgery in order to minimise subsequent handling. Setting an initial position appropriate for the operation reduces potential interactions with any obstacles (IV stands, pendants, etc.).

The degree of freedom of the main arms and spring arms (360° horizontally, 95° vertically) enables optimal three-dimensional movement of the lighthead.

The lower shell should be located at a distance of between 70 and 130 cm above the surgical site for optimal illumination.

Do not use the surgical light suspension arm to suspend or lift objects. Do not hang on the light.

Do not turn the lighthead upside down during use as this may result in overheating.

3.2 Turning on the light

Do not use the unit in the presence of inflammable anaesthetic gases.

Do not look directly at the light source due to its high intensity.

The manufacturer's warranty is only valid if the recommended power supplies are used.

In the event of a power failure, only lightheads connected to a backup power supply system will remain operational.

- Use the ON/OFF switch (1) to turn the unit on or cut off the power supply.

It may be necessary to press the ON/OFF switch to turn the light back on following a power cut.

3.3 Installing the sterilisable handle

After each sterilisation and before re-using the sterilisable handle:

- Check that there are no cracks.
- Check that the handle operates correctly on the light.

Before an operation, check that the sterilisable handle is in place on its mount.

To guarantee aseptic conditions the sterilisable handle should be touched only by the surgical team during an operation.

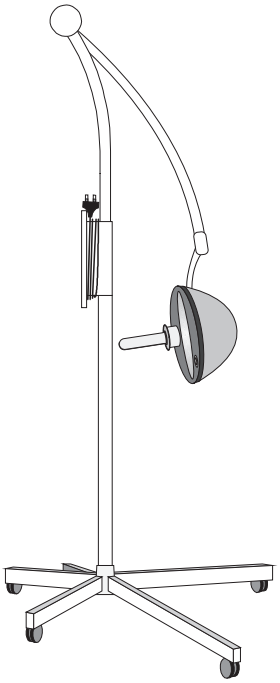
Installing the handle

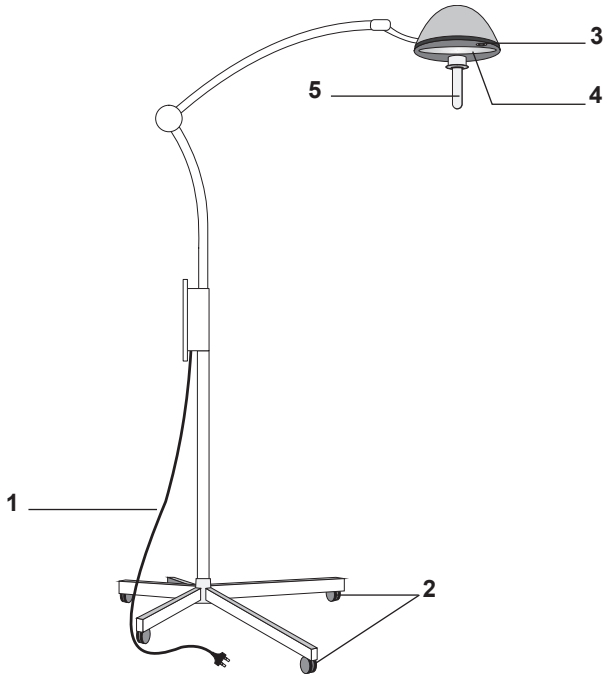
Insert the sterilisable handle (2) on its mount (3). An audible click confirms that the handle is correctly in place.

Removing the handle

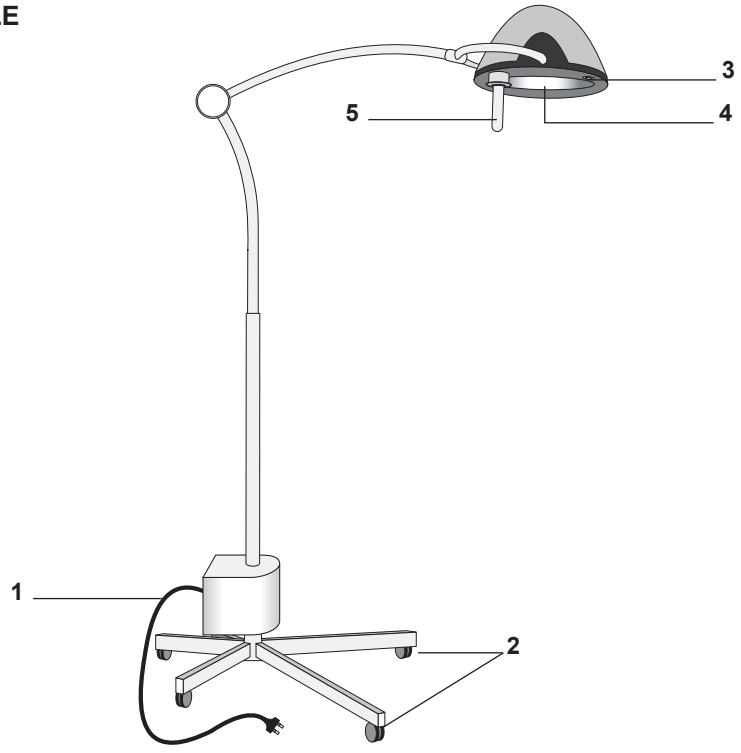
To remove the sterilisable handle (2) from the lighthead, hold down the push button (4) and pull the handle downwards away from its mount.

BLUE 30 MOBILE





BLUE 80 MOBILE



4 USING THE BLUELINE MOBILE

4.1 Moving the surgical light

Take care when moving the mobile light to avoid any risk of it toppling over. Pay particular attention to objects on the floor, steps and the light's power cable.

- Wind the power supply cable (1) loosely around the power supply housing.
- Release the brake at the base (2) by raising the black levers on the casters.
- Tilt the lighthead (3) downwards.
- Move the light to the desired location

4.2 Turning on the light

The BLUELINE MOBILE light has an automatic voltage selection mechanism for supply voltages from 100 to 230 V. Only connect the BLUELINE MOBILE light to correctly installed power outlets.

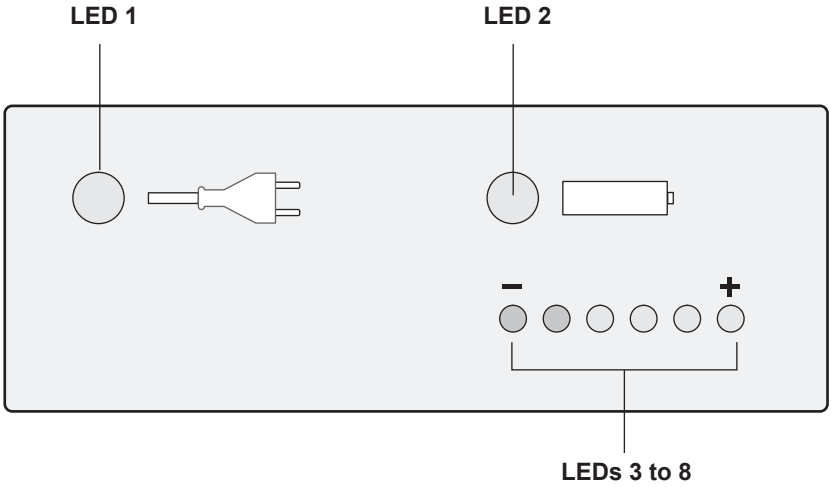
- Plug the cable into the power outlet (1).
- Apply the brake at the base (2) by pressing the black levers on the casters. Raise these levers to release the brake.
- Use the power switch (3) to turn on the light.

The lighthead heats up during use. Do not touch the underside (4) when adjusting the position of the lighthead.

- Use the sterilisable handle (5) to change the position of the lighthead. See section 3.3.
- The lower shell should be located at a distance of between 70 and 130 cm above the surgical site for optimal illumination.

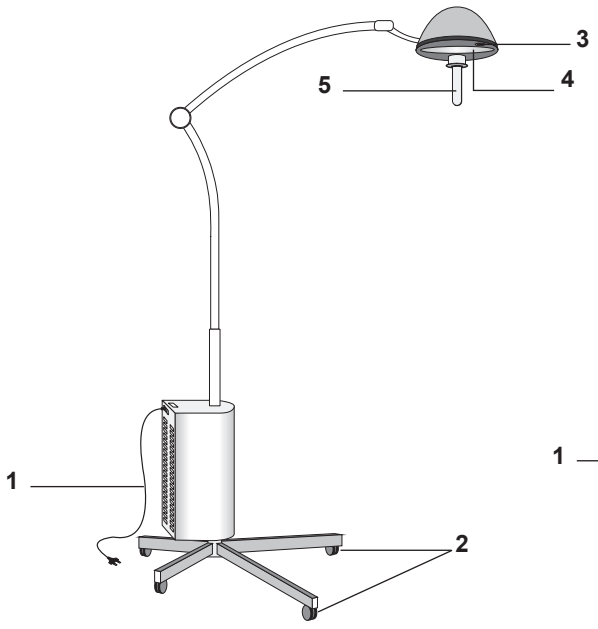
Do not turn the lighthead upside down during use as this may result in overheating.

Do not look directly at the light source due to its high intensity.

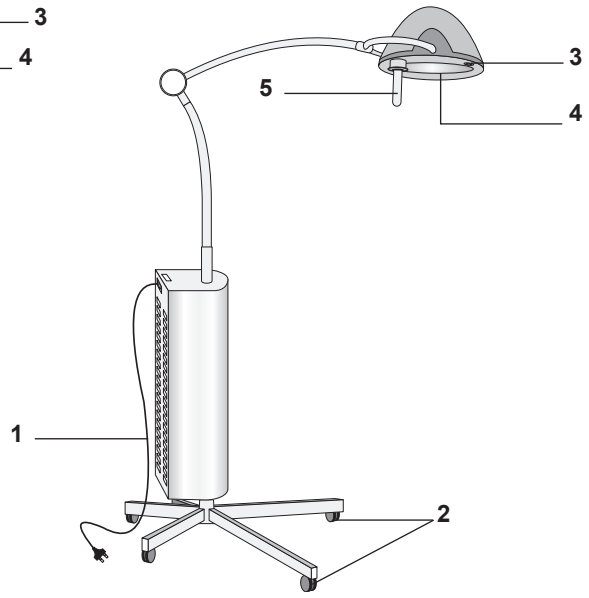


LED 1	Mains operation: LED green
	Batteries too low: LED red
LED 2	Battery operation: LED yellow
LEDs 3 to 8	Battery charge level:
	Batteries charging: LEDs 3 to 8 chasing
	Batteries charged: LED 8 flashing
	Batteries low: LED 4 flashing
	Deep discharge: LED 3 steady red

BLUE 30 HOSPITAL



BLUE 80 HOSPITAL



5 USING BLUELINE HOSPITAL LIGHTS

5.1 Mains and battery operation

5.1.1 Mains operation

- During operation, the LED marked with a power plug symbol (LED 1) is green.
- While the batteries are charging, LEDs 3 to 8 are chasing.
- When the batteries are fully charged, LED 8 flashes.
- The minimum battery charging times are 90 minutes for the BLUE 30 and 4 hours for the BLUE 80.

5.1.2 Battery operation

- The light is powered by batteries in the event of a power failure. The batteries then discharge gradually. Fully charged batteries provide power for 3 hours of light for the BLUE 30 and 8 hours for the BLUE 80. During battery operation, LED 2 is lit yellow.
- The battery charge level is shown by LEDs 3 to 8. As the batteries discharge the indicator moves from (+) towards (-).
- When the batteries are too low, an alarm sounds and LED 1 is lit red.
- The light cuts itself off automatically after the alarm (to protect against deep discharge).

5.2 Start up

- Check the charge of the batteries (see section 5.3 on page 16).

Take care when moving the mobile light to avoid any risk of it toppling over. Pay particular attention to any objects on the floor, any steps, as well as the light's power cable.

The BLUELINE HOSPITAL light has an automatic voltage selection mechanism for supply voltages from 100 to 230 V. Only connect the BLUELINE HOSPITAL light to correctly installed power outlets.

- Plug the cable into the power outlet (1).
- Apply the brake at the base (2) by pressing the black levers on the casters. Raise these levers to release the brake.
- Use the power switch (3) to turn on the light.

The lighthead heats up during use. Do not touch the underside (4) when adjusting the position of the lighthead.

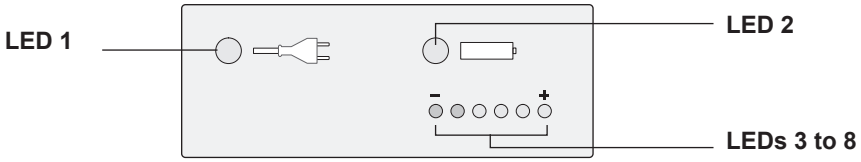
- Use the sterilisable handle (5) to change the position of the lighthead. See section 3.3.
- The lower shell should be located at a distance of between 70 and 130 cm above the surgical site for optimal illumination.

Do not turn the lighthead upside down during use as this may result in overheating.

Do not look directly at the light source due to its high intensity.

5.3 Checks to be carried out each time the BLUELINE HOSPITAL is used

To ensure that the surgical light will operate correctly in the event of a power failure it must be checked before each use.



Check	Mains LED 1	Battery LED 2	Charging LEDs 3 to 8	Comments
Plug the light into the power outlet and turn it on	LED green	off	LEDs 3 to 8 chasing	Batteries charging
			LED 8 flashing	Batteries completely charged
Disconnect the power outlet (the light should remain on)	off	LED orange	One of the LEDs 3 to 8 is lit (showing battery charge level)	Battery operation

5.4 Test of the BLUELINE HOSPITAL batteries' autonomy

To ensure that the surgical light will operate correctly in the event of a power failure it must be checked at least once a year during the preventive maintenance visit.

Check	Mains LED 1	Battery LED 2	Charging LEDs 3 to 8	Comments
Turn off the light and charge the batteries for at least 14 hours	LED green	off	LEDs 3 to 8 chasing	Batteries charging
			LED 8 flashing	Batteries completely charged
Turn on the light	LED green	off	LEDs 3 to 8 chasing	Batteries charging
			LED 8 flashing	Batteries completely charged
Disconnect the power supply (the light should remain on)	off	LED yellow	One of the LEDs 3 to 8 is lit (showing battery charge level)	Battery operation
BLUE 30: After 1 hours' battery operation	off	LED yellow	One of the LEDs 3 to 8 is lit (showing battery charge level)	Battery operation
BLUE 80: After 4 hours' battery operation				
Connect the power supply	LED green	off	LEDs 3 to 8 chasing	Batteries charging

5.5 Troubleshooting

Operation	Anomaly	Likely cause	Corrective action
On power outlet (light on)	LED 1 not lit green	Electronic fault	Call MAQUET technical department
	LED 2 not lit yellow	Power fuse missing or blown	Change the fuse
	LED 1 flashes red	Charging circuit safety fuse fault	Change the fuse (quick-blow automotive type, 7.5 A/32 V)
	No chasing of LEDs 3 to 8 LED 8 not lit	Electronic fault	Call MAQUET technical department
On batteries (light on)	LED 2 not lit yellow	Electronic fault	Call MAQUET technical department
	None of LEDs 3 to 8 lit	Electronic fault	Call MAQUET technical department
	Light goes out when the power outlet is disconnected	Battery fault or batteries incorrectly connected	Check the connections and change the batteries if necessary
		Charging circuit safety fuse fault	Change the fuse (quick-blow automotive type, 7.5 A/32 V)
		Electronic fault	Call MAQUET technical department
	LED 4 flashing	Batteries low	Charge batteries
	LED 3 lit red LED 1 lit red	Batteries close to deep discharge	Charge batteries immediately

☞ To know if the batteries are completely discharged or down, disconnect the power supply. None of the LEDs should be lit.

BLUE 30

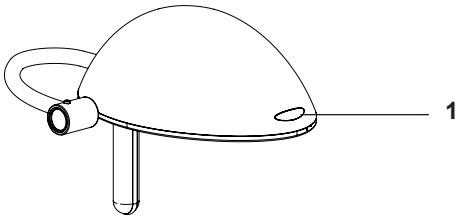


Figure 1

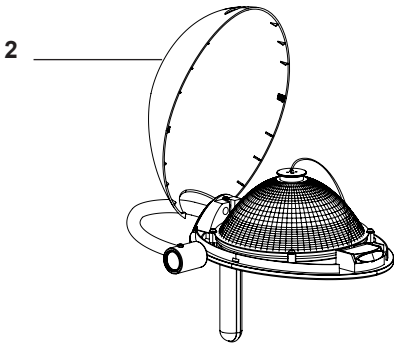


Figure 2

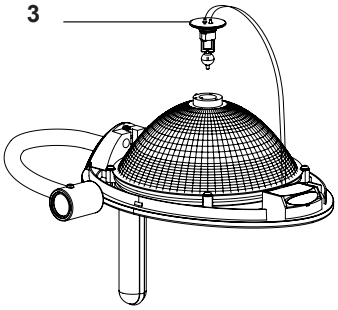


Figure 3

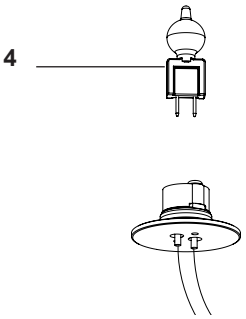


Figure 4

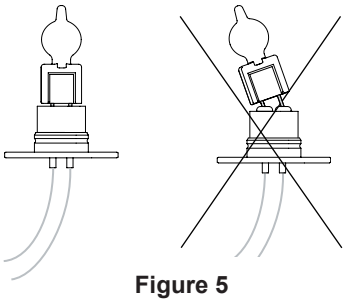


Figure 5

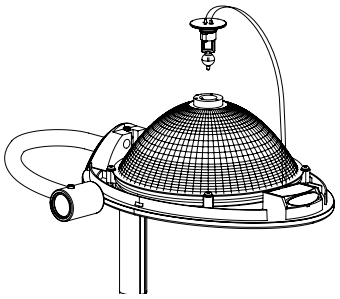


Figure 6

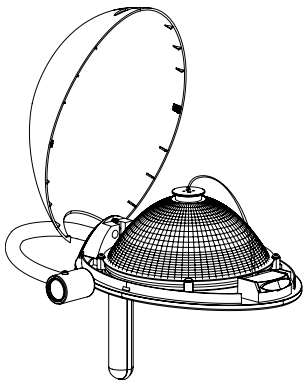


Figure 7

6 CHANGING THE BULB

6.1 BLUE 30 lighthead

When changing a blown bulb:

- Switch off the power supply and leave the lighthead to cool for 25 minutes.
- Only use MAQUET bulbs.
- Handle bulbs carefully, using gloves or a cloth.
- Never touch bulbs with bare hands. Grease on bulbs shortens their life.

Do not change bulbs during an operation.

The unit is designed to operate with the cover closed. When conducting maintenance, take precautions to avoid touching surfaces marked as hot with the following symbol:

To avoid failures during operations, we recommend changing the bulbs on a preventive basis every 1000 hours.

Figures 1 and 2

- Press the locking tab (1) and raise the casing of the failed bulb (2).

Figure 3

- Remove the bulb holder (3), taking care not to knock the hot bulb against any surfaces.

Figure 4

- Take the failed bulb (4) and remove it from the holder.
- Take the new bulb and remove it from its packaging.

Figure 5

- Insert the bulb pins into the bulb holder as far as they can go.
- Check that the bulb is correctly seated.

The bulb does not go in all the way. Do not push beyond the stop.

Figure 6

- Replace the bulb holder (3) and check that the locking tab clicks audibly into place.

Figure 7

- Close the cover and check that the locking tab clicks audibly into place.

Check that the cover is correctly in place.

BLUE 80

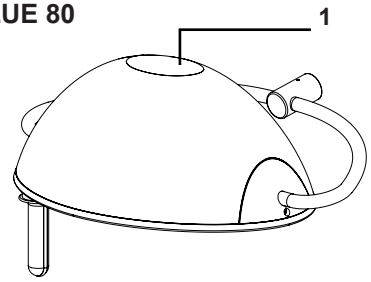


Figure 1

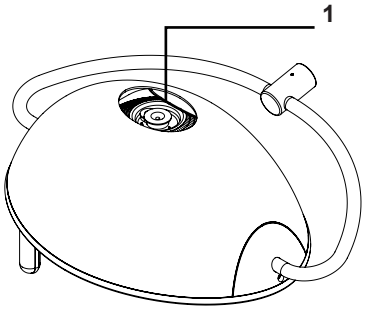


Figure 2

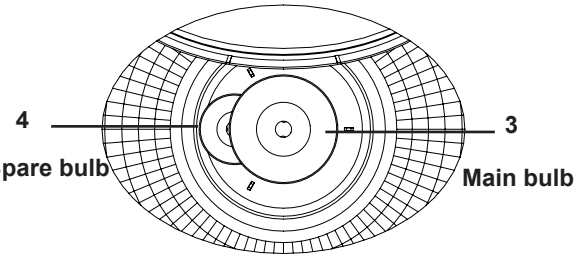


Figure 3

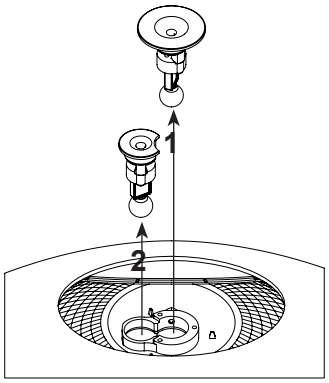


Figure 4

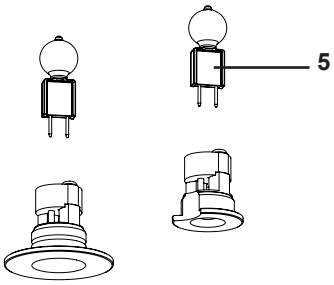


Figure 5

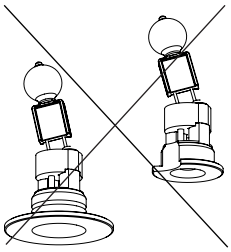


Figure 6

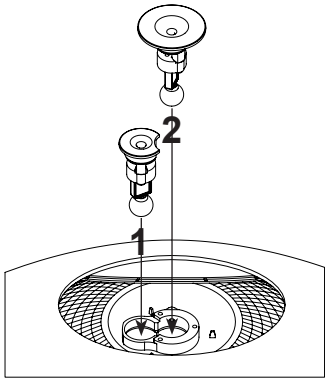


Figure 7

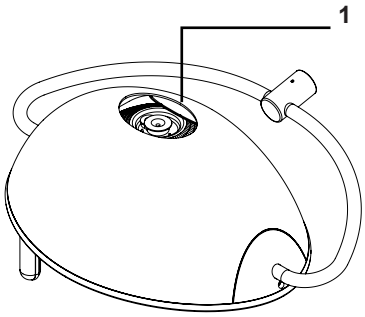


Figure 8

6.2 BLUE 80 lighthead

When changing a blown bulb:

- Switch off the power supply and leave the lighthead to cool for 25 minutes.
- Only use MAQUET bulbs.
- Handle bulbs carefully, using gloves or a cloth.
- Never touch bulbs with bare hands. Grease on bulbs shortens their life.

Do not change bulbs during an operation.

The unit is designed to operate with the cover closed. When conducting maintenance, take precautions to avoid touching surfaces marked as hot with the following symbol:

To avoid failures during operations, we recommend changing the bulbs on a preventive basis every 1000 hours.

The yellow indicator on the underside of the Blue 80 lighthead is lit if the spare bulb is activated. To avoid a total failure of the surgical light, change the main bulb as soon as possible.

Figures 1 and 2

- Push the cover in slightly (1) and slide it sideways.

Figures 3 and 4

- First remove the main bulb holder (3), then the spare bulb holder (4), taking care not to knock the hot bulb against any surfaces.

Figure 5

- Take the failed bulb (5) and remove it from the holder.
- Take the new bulb and remove it from its packaging.
- Insert the bulb pins into the bulb holder as far as they can go.

The bulb does not go in all the way. Do not push beyond the stop.

Figure 6

- Check that the bulb is correctly seated.

Figure 7

- Replace the spare bulb holder first, then the main bulb holder, checking that the locking tab clicks audibly into place in each case.

Figure 8

- Close the cover (1) and check that it is correctly in place.

7 CLEANING / DISINFECTION / STERILISATION

Users must contact their hospital's sanitary specialists. Use only the recommended products and procedures. Should there be any doubt concerning the compatibility of active agents to be used, contact your local MAQUET customer service department.

7.1 Cleaning and disinfecting the surgical light

☞ Check that the power is switched off and the light has cooled down before starting cleaning.

7.1.1 General instructions concerning cleaning, disinfection and safety:

- Remove the sterilisable handles.
- Clean the unit with cloth moistened with surface detergent, in line with the manufacturer's recommended dilution, length of application and temperature.
- Use a cloth to rinse the unit with clean water and wipe dry.
- Disinfect uniformly using a cloth moistened with a disinfectant, in line with the manufacturer’s recommendations.
- Use a cloth to rinse with clean water in order to remove residues (in particular products containing aldehydes, quaternary ammonium or surfactants).
- Wipe with a dry cloth.
- Make sure that all liquid cleaning products used have been thoroughly wiped off.

7.1.2 Examples of recommended products

Getinge USA product: TEC QUAT 256

Anios products: SURFA’SAFE; HEXANIOS G + R at 0.5% ; ANIOSYME P.L.A; SALVANIOS pH 10; ANIOS DDSH.

Schülke & Mayr products: Antifect Plus.

7.1.3 Examples of prohibited products

☞ Solutions containing glutaraldehyde, phenol, iodine, bleach, alcohol or chloride ions must not be used.

⚠ Fumigation methods are unsuitable for disinfecting the unit and must not be used.

7.2 Cleaning and sterilising the handles

7.2.1 Before cleaning

- Use a soft cloth immediately after use to wipe away soiling from the handle surface.
- Store handles in a place that keeps them moist to make further cleaning easier.
- Take care to store them in such a way that the inside does not get soiled.

7.2.2 Cleaning

- Soak the handles in a detergent solution.[1]
- Soak for 15 minutes to allow the solution to act, then clean by hand with a soft brush and a lint-free cloth.
- During cleaning, check regularly that the handles are fully clean and that no soiling remains on the inside or outside.
- If any soiling remains, repeat cleaning or use an ultrasonic cleaning process.
- Rinsing: Rinse thoroughly in clean water to completely eliminate the detergent solution.
- Drying: Wipe with a clean lint-free cloth.

[1] Never soak the handles in enzyme-based detergents as they may damage the handle material; rinse thoroughly if these detergents are used.

7.2.3 Disinfection

Handles may be disinfected by machine (Clean MAQUET) and rinsed at a maximum temperature of 93°C. Typical recommended cycles:

Stage	Temperature	Time
Pre-wash	18 - 35°C	60 sec
Wash	46 - 50°C	300 sec
Neutralisation	41 - 43°C	30 sec
Wash 2	24 - 28°C	30 sec
Rinse	92 - 93°C	600 sec
Dry		20 min

7.2.4 Sterilisation

After cleaning, the handles must be steam sterilised as set out below:

Country	Sterilisation cycle	Temperature [°C]	Time [min]	Drying [min]
USA & Canada	Prevacuum[2]	132 - 135	10	16
France	ATNC (Prion) (Prevacuum)	134	18	
Other countries	Prevacuum	Comply with national regulations		

- Check that each handle is clean before continuing the process.
- Wrap the handles with sterilisation wrapper material (double wrapper or equivalent).
  Handles may also be placed in paper or plastic sterilisation bags[3], for easier identification and reuse.
- Place the handles on steriliser trays with the opening downwards.[4]
- Package with biological and/or chemical indicators for monitoring the sterilisation process, in accordance with applicable regulations.
- Run the sterilisation cycle according to the steriliser manufacturer's instructions.

☞ To ensure correct sterilisation do not allow any soiling to penetrate inside the handle.

☞ Handles are guaranteed for no more than 350 sterilisation cycles with the above sterilisation parameters.

- Dispose of sterilisable handles in the same way as other hazardous products in a hospital environment.

[2] This handle is made of a porous material.

[3] Possible sterilisation bag suppliers:
Medical Action Industries
SBW Medical
Baxter International

[4] For air removal and faster drying.

8 MAINTENANCE

8.1 Preventive maintenance

To preserve your surgical light's original performance and reliability, annual maintenance and inspections should be performed as follows:

- by a MAQUET technician or MAQUET-approved distributor during the guarantee period,
- by a MAQUET technician or MAQUET-approved distributor or by the hospital's technical maintenance department outside the guarantee period. (Contact your distributor to apply for the required technical training.)

8.2 First level maintenance

8.2.1 Daily inspection (user)

- Check that the bulbs operate correctly.
- Check that the sterilisable handle clicks and locks in place correctly, if not replace it.
- Check the arm position.
- If a backup power supply is installed, check that the light would operate correctly if a power cut were to occur.
- On the BLUE HOSPITAL:

  - check the charge of the batteries and the backup switchover (see section 5.3).

  - recharge the batteries once every three months if the device is not used.

8.2.3 Annual inspection (must be performed by an authorised technician):

- Check that the limit stops are in place.
- Check and tighten the brakes.
- Check the bulb holder and replace if necessary.
- Check that the limit stops are in place on the lightheads.
- On the BLUE HOSPITAL, check the autonomy of batteries and the automatic switch to battery operation (see paragraph 5.4).

Safety items

Check the following points

- Attachment screws on suspension tube correctly tightened, seals in position.
- Arm(s) correctly mounted.
- All covers and caps installed.

WARNING

Spring arm to be changed every six years (wearing part).

Other checks

- Nominal illumination: see technical data.
- Earth continuity: max. 0.1 Ohm
- Condition of thermal filter.
- Suspension tube vertical.
- Balancing system adjusted correctly.
- Sterilisable handle locking mechanism.

Dismantling certain elements may affect operation and safety. For example:

- Servicing the electrical power supply.
- Servicing the suspension arm and balance system.
- Servicing the optical system of lightheads equipped with filters designed to eliminate radiation not visible to patients. Surgical lights must never be used without these filters.

Contact the authorised MAQUET after-sales service department for this type of inspection.

9 GENERAL CHARACTERISTICS
(IN ACCORDANCE WITH STANDARD IEC 60 601-2-41 AND IEC 60 601-1)

Specifications		Unit	BLUE 30	BLUE 80
Nominal illumination*		lx ± 10%	35,000	90,000
Nominal voltage		V AC+DC	22.8	22.8
Maximum power		W	40	80
Colour temperature		K ± 6%	4600	4600
Colour rendering index		N/A	> 85	> 85
R9 specific index		N/A	30 ±5	20 ±5
Illumination depth at 20%		cm (inches)	186 (73)	159 (63)
Illumination depth at 60%		cm (inches)	150 (59)	120 (47)
Diameter d10		cm (inches) ±10%	17 (6.7)	16 (6.3)
Diameter d50		cm (inches) ±10%	10 (3.9)	10 (3.9)
Shadow dilution	With one mask	%	0%	6%
	With two masks	%	62%	49%
	At base of tube	%	100%	100%
	With one mask, at base of tube	%	0%	6%
	With two masks, at base of tube	%	62%	49%
Irradiance (Ee)*		W/m^2	140	360
Electrical classification		N/A	Protection class I (except Blue 30 mobile version of class II)	Protection class I
Degree of protection against harmful ingress of water		N/A	Ordinary	Ordinary
Methods of sterilization or disinfection		N/A	See section 7	See section 7
Mode of operation		N/A	Continuous operation	Continuous operation

* Values measured during certification:
BLUE 30: 38,400 lx / 139 W/m^2
BLUE 80: 85,500 lx / 305 W/m^2

10 ACCESSORIES

Accessories	Part number
BLUE sterilisable handle	5 679 17 999
Pack of 1 spare bulb for BLUE 30 - 22,8 V	5 690 05 995
Pack of 1 spare bulb for BLUE 80 - 22,8 V	5 690 05 996
Pack of 10 spare bulbs for BLUE 30 - 22,8 V	5 690 05 997
Pack of 10 spare bulbs for BLUE 80 - 22,8 V	5 690 05 998

11 EMC DECLARATION

(IN ACCORDANCE WITH STANDARD EN 60601-1-2, NOVEMBRE 2001 EDITION)

Table 201 - Guidance and Manufacturer's Declaration - Electromagnetic Emissions

BLUELINE surgical lights are intended for use in the electromagnetic environment specified below. BLUELINE customers or users should ensure that they are used in such an environment.

Immunity test	Compliance	Electromagnetic environment — directives
RF emissions CISPR 11	Group 1	BLUELINE lights use RF energy only for their internal functions. Their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	BLUELINE lights are suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations and flicker emissions IEC 61000-3-3	Not applicable	

Table 202 - Guidance and manufacturer's declaration - electromagnetic immunity

BLUELINE surgical lights are intended for use in the electromagnetic environment specified below. BLUELINE customers or users should ensure that they are used in such an environment..

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% V_T (dip > 95% of V_T) for 0.5 cycles 40% V_T (dip = 60% of V_T) for 5 cycles 70% V_T (dip = 30% of V_T) for 25 cycles < 5% V_T (dip = 95% of V_T) for 5 cycles	< 5% V_T (dip > 95% of V_T) for 0.5 cycles 40% V_T (dip = 60% of V_T) for 5 cycles 70% V_T (dip = 30% of V_T) for 25 cycles < 5% V_T (dip = 95% of V_T) for 5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the BLUELINE requires continuous operation during mains interruptions, it is recommended that it be powered from an uninterruptible power supply.
Power frequency (50/60 Hertz) magnetic fields IEC 61000-4-8	3 A	3 A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: V_T is the voltage of the AC supply network before applying the test level.

Table 204 - Guidance and manufacturer's declaration - electromagnetic immunity

BLUELINE surgical lights are intended for use in the electromagnetic environment specified below. BLUELINE customers or users should ensure that they are used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V rms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V rms 3 V/m 	Portable and mobile RF communications equipment should be used no closer to any part of the BLUELINE, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = [\frac{3.5}{V1}]\sqrt{P} = 1.17\ \sqrt{P}$ $d = [\frac{3.5}{E1}]\sqrt{P}$ from 80 MHz to 800 MHz = $1.17\ \sqrt{P}$ $d = [\frac{7}{E1}]\sqrt{P}$ from 800 MHz to 2.5 GHz = $2.34\ \sqrt{P}$ where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic syrvey on site[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: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BLUELINE is used exceeds the applicable RF compliance level above, the BLUE 30/80 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BLUELINE.

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

Table 206 - Recommended separation distance between portable and mobile RF communication devices and BLUELINE lights.

The BLUELINE is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BLUELINE can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BLUELINE as recommended below, according to the maximum output power of the communications equipment.

Maximum rated output power of transmitter W	**Separation distance depending on transmitter frequency 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	0.24
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.70	11.70	23.40

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12 TROUBLESHOOTING

Anomaly	Likely cause	Corrective action
• Lighthead does not turn on.	• Faulty or missing bulb.	• Cut off the power supply and replace the bulb(s).
	• Power cut.	• Check if other devices on the same supply network are operating.
	• Other reason.	• Call MAQUET technical department.
• Light flickers.	• Contact problem.	• Call MAQUET technical department.
• Illumination too bright/too dim.	• Supply voltage incorrect.	• Have an electrician check the power supply.
		• Check the bulb and replace if necessary.
• Bulb service life too short.	• Non-compliant bulbs used, or voltage surges occur.	• Check that the bulbs recommended by MAQUET are used.
		• Have an electrician check the power supply.
• Unnatural colours.	• Unsuitable bulb(s) used.	• Replace the bulb(s).
• Light spot is not round	• Unsuitable bulb(s) used.	• Check the bulb and replace if necessary.
	• Incorrect bulb position.	• Check the position of the bulb.
	• Main bulb faulty.	• Check the bulb and replace if necessary.
• Sterilisable handle does not fit properly in its mount.	• Sterilisation parameters (temperature, time) exceeded.	• Check the operation of the handle and in particular the locking mechanism (audible click).
	• Maximum service life exceeded / handle deformed.	• Replace the handle.
• Lighthead drifts.	• Suspension tube not vertical.	• Check the tube verticality and ceiling structure.
	• Ceiling structure unstable.	• Call MAQUET technical department.
• Lighthead too loose or too rigid to manoeuvre.	• Brake incorrectly adjusted.	• Adjust the balancer.
	• Insufficient lubrication.	• Call MAQUET technical department.

CE

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