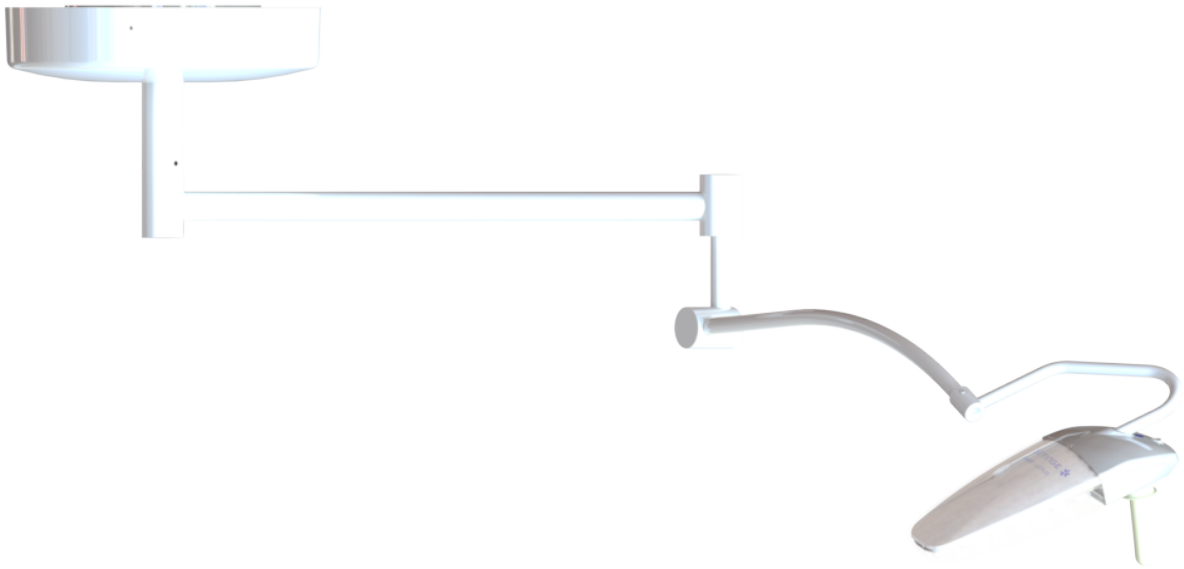


Instructions for use

Lucea 50-100
Lucea 50

IFU 01741 EN 12 2024-09-30

GETINGE

Subject to technical changes.

The illustrations and technical specifications provided in this manual may, on account of future product developments, differ slightly from the actual product supplied.

V12 30.09.2024

Contents

1 Introduction

1.1 Preface

Your hospital has chosen Getinge's innovative medical technology. We thank you for the confidence you have shown in us.

Getinge is one of the world's leading suppliers of medical equipment for operating rooms, hybrid rooms, induction rooms, intensive care units and patient transport. Getinge always puts the needs of healthcare staff and patients first during the development of its products. Getinge provides solutions that respond to the safety, efficiency and economic constraints faced by hospitals.

Building on its experience in surgical lights, ceiling-mounted equipment management systems and multimedia solutions, Getinge focuses on quality and innovation to ensure that its solutions best meet the needs of patients and healthcare staff. Getinge surgical lights are world-renowned for their design and innovative features.

1.2 Information about this document

This user's manual is intended for day-to-day users of the product, staff supervisors and hospital authorities. It is intended to familiarise users with the design, safety features and operation of the product. The manual is organised and divided into several separate chapters.

Please note:

- Please read the user's manual thoroughly and in full before using the product for the first time.
- Always proceed in line with the instructions in the user's manual.
- Keep this manual close to the equipment.

1.2.1 Abbreviations

EMC	Electromagnetic compatibility
IFU	Instructions For Use
IP	Ingress Protection rating
K	Kelvin
LED	Light-Emitting Diode
lx	lux
N/A	Not Applicable

1.2.2 Symbols used in this manual

1.2.2.1 Cross-references

References to other pages of the manual are identified by the "⏩" symbol.

1.2.2.2 Reference numbers

Reference numbers in illustrations and text are shown in a square box 1.

1.2.2.3 Actions and results

Actions to be performed by the user are listed with sequence numbers; the "➢" symbol is used to show the result of an action.

Example:

Prerequisites:

- The sterilisable handle must be compatible with the product.

1. Fit the handle to the mount.
   ➢ A click is heard.
2. Turn the handle until it locks into place with a second click.

1.2.2.4 Menus and buttons

Menu and button names are shown in **bold**.
Example:

1. Press the **Save** button.
   ➢ The changes are saved and the **Favourites** menu is displayed.

1.2.3 Definitions

1.2.3.1 Hazard levels

The text in safety instructions describes types of risk and how to avoid them. Safety instructions are classified into the following three levels:

Symbol	Hazard level	Meaning
	**DANGER!**	Indicates a direct and immediate risk that may be fatal or cause very serious injuries potentially leading to death.
	WARNING!	Indicates a potential risk that may cause injuries, health hazards or serious material damage leading to injuries.
	CAUTION!	Indicates a potential risk that may cause material damage.

Tab. 1: Hazard levels of safety instructions

1.2.3.2 Indications

Symbol	Indication type	Meaning
	**NOTE**	Additional assistance or useful information not relating to risks of injuries or risks of material damage.
	**ENVIRONMENT**	Information relating to recycling or to appropriate disposal of waste.

Tab. 2: Types of indication in the document

1.2.3.3 Groups of people

Users

- Users are persons who are authorised to use the device, either by virtue of their qualifications or as a result of receiving training from a qualified person.
- Users are responsible for the safe use of the device and for ensuring that it is used as intended.

Qualified personnel:

- Qualified personnel are persons who have acquired knowledge through specialised training in medical technology or due to their professional experience and knowledge of the safety rules relating to the tasks performed.
- In countries where certification is required to exercise a medico-technical profession, personnel must hold the necessary authorisation in order to be considered as qualified.

1.2.3.4 Type of light

Diagnostic light

Device used to locally illuminate the patient's body in order to facilitate diagnostic or treatment operations that can be interrupted without endangering the patient if the light fails. It is not intended for use in operating rooms.

1.3 Other documents relating to this product

- Maintenance manual (Ref. ARD01740)
- Repair manual (Ref. ARD01742)
- Installation manual (Ref. ARD01744)
- Decommissioning instructions (Ref. ARD01745)

1.4 Liability

Modifications to the product

The product must not be modified in any way without the prior written consent of Getinge.

Compliant use of the device

Getinge may not be held liable for any direct or indirect damage that results from actions not set out in this user's manual.

Installation and maintenance

Installation, maintenance and decommissioning operations must be performed by trained personnel, approved by Getinge.

Training on the device

Training must be provided directly on the device by personnel approved by Getinge.

Compatibility with other medical devices

Only medical devices approved in accordance with IEC 60601-1 or UL 60601-1 should be installed on the system.

The compatibility data is detailed in the chapter entitled Technical specifications [▸▸ Page 45].

The compatible accessories are detailed in the chapter concerned.

In the event of an incident

Any serious incident occurring in connection with the device must be notified to the manufacturer and the relevant authority of the member state in which the user and/or patient is based.

1.5 Expected service lifetime

The expected service lifetime of the product is 10 years.

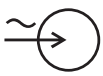
This service lifetime does not apply to consumables such as sterilisable handles.

This 10-year service lifetime applies subject to annual periodic checks being performed by personnel trained and approved by Getinge; see Maintenance schedule. After this time, if the device is still in use, an inspection must be carried out by personnel trained and approved by Getinge to ensure the continued safety of the device.

1.6 Warranty

For details of warranty conditions, please contact your local Getinge representative.

1.7 Symbols on the product and packaging

	Follow the instructions for use (IEC 60601-1:2012)		Risk of toppling: Do not push the mobile light or lean on it when the casters are locked.
	Follow the instructions for use (IEC 60601-1:2005).		CE marking (Europe)
	Follow the instructions for use (IEC 60601-1:1996).		UL mark (Canada and United States)
	Manufacturer + manufacturing date		Medical Device (MD) marking
	Product code		Unique device identification
	Product serial number		Packaging orientation
	AC input		Fragile, handle with care
	Operation		Keep away from the rain
	Stopped		Temperature range for storage
	Do not discard with conventional waste		Humidity range for storage
	Equipotential grounding connector		Ambient pressure range for storage

1.8 Location and explanation of the device identification label

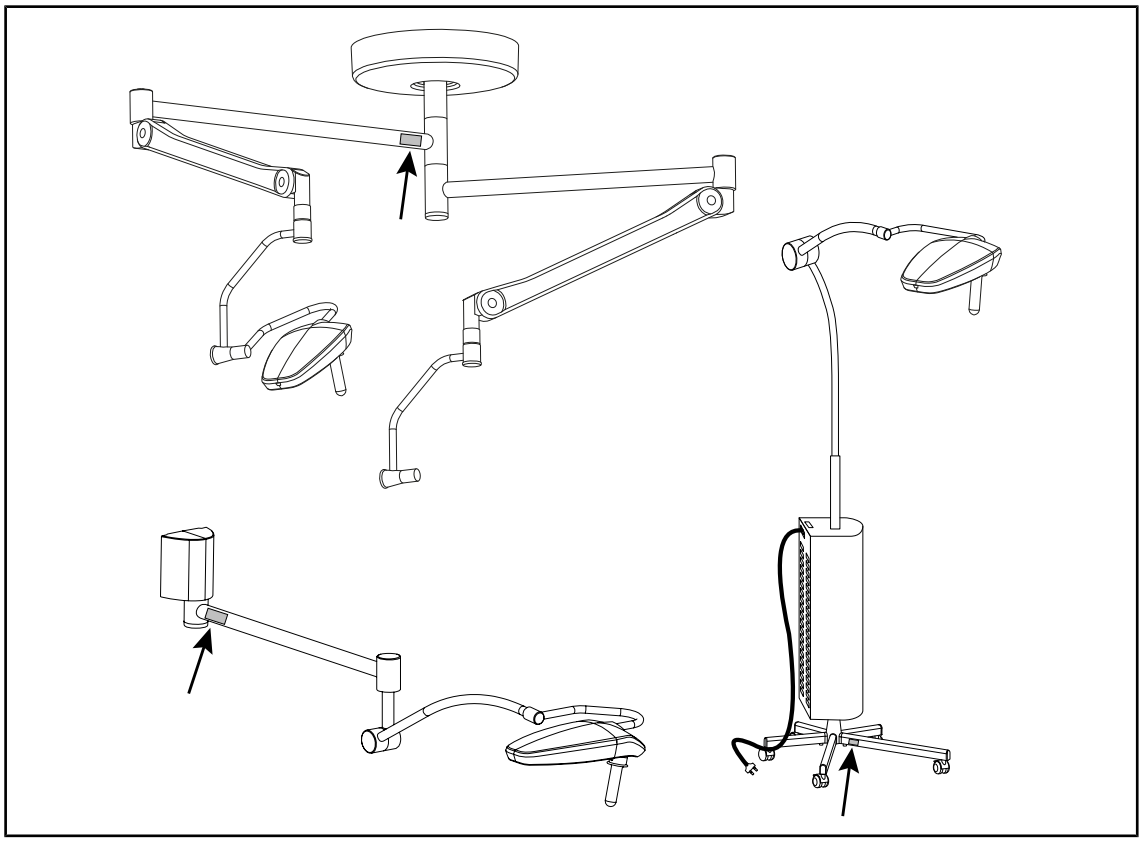


Fig. 1: Location of the product identification label

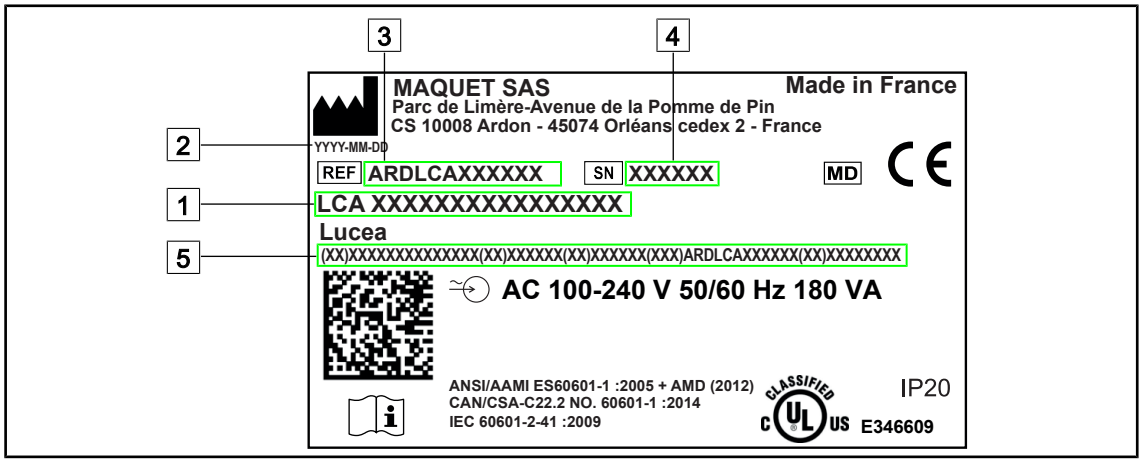


Fig. 2: Example label

1 Product name
2 Manufacturing date
3 Product code
4 Serial No.
5 Unique device identifier (UDI)

1.9 Overview

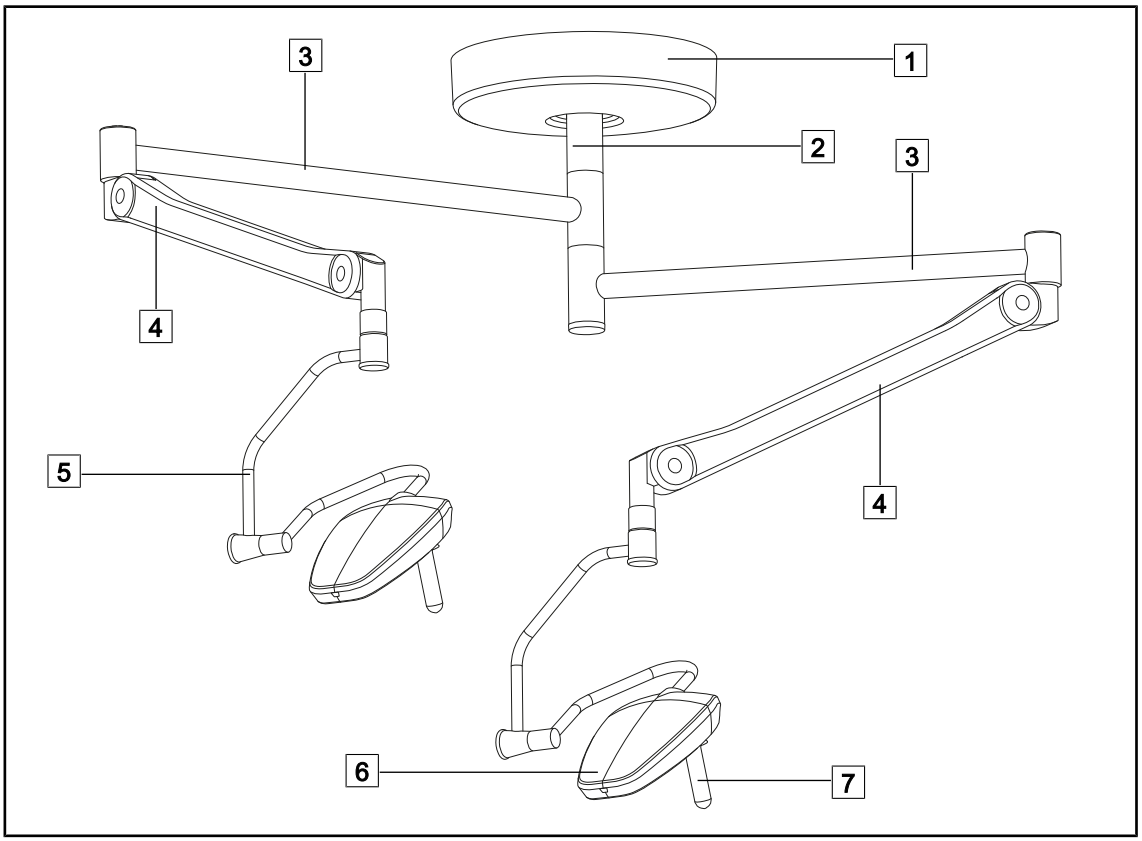


Fig. 3: Typical ceiling-mounted configuration

1 Ceiling-mounted cover
2 Suspension tube
3 Suspension arm
4 DF spring arm
5 Dual fork
6 LUCEA 50 lighthead
7 STG HLX sterilisable handle

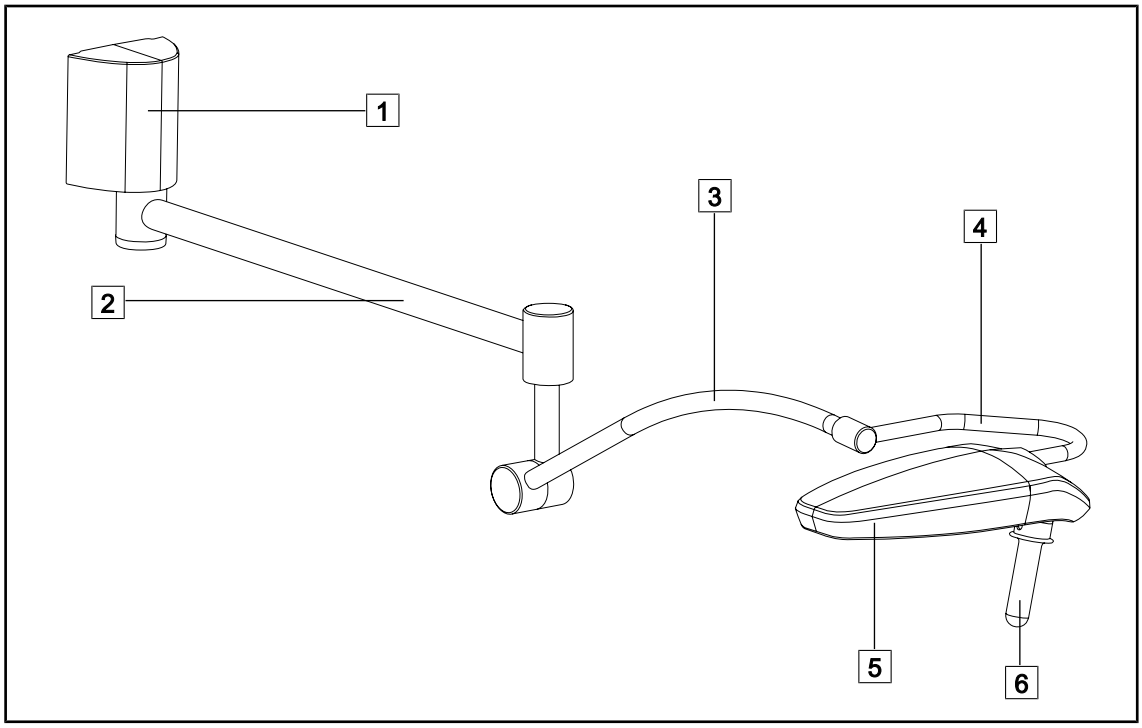


Fig. 4: Typical wall-mounted configuration

1 Wall bracket
2 Extension arm
3 SF spring arm
4 Single fork
5 LUCEA 50 lighthead
6 STG HLX sterilisable handle

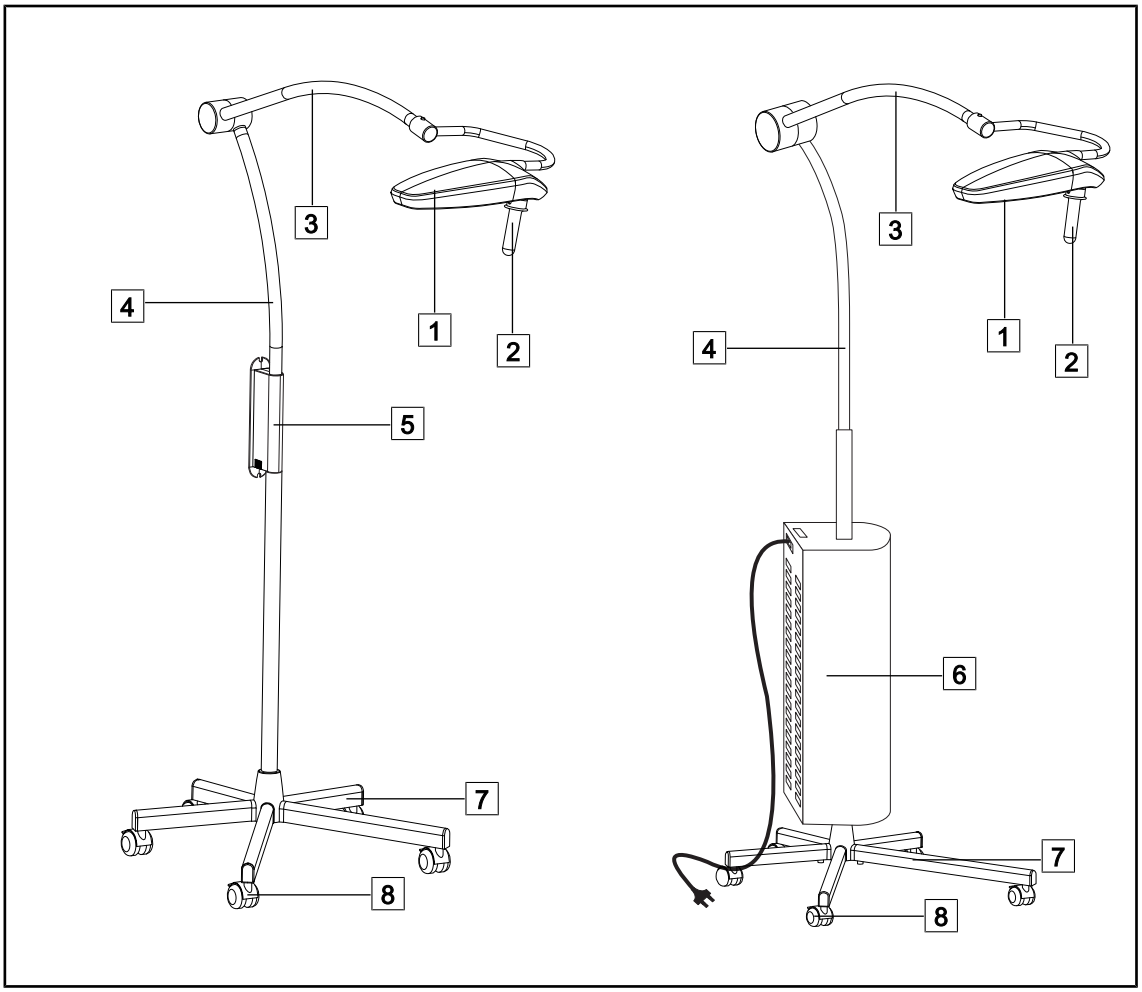


Fig. 5: Typical mobile configurations

1 LUCEA 50 lighthead
2 STG HLX sterilisable handle
3 SF spring arm
4 Pole
5 Power supply without backup
6 Power supply with backup
7 Stand base
8 Casters

1.9.1 Components

1.9.1.1 Lighthead

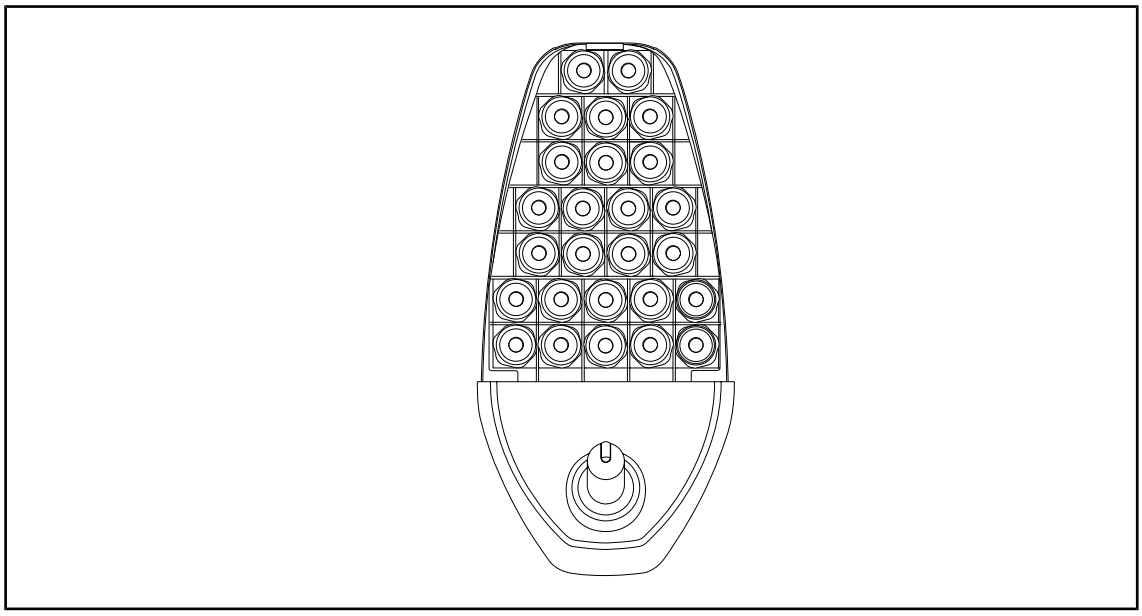


Fig. 6: LUCEA 50 lighthead

Each lighthead comprises the following elements:

- On/Off button
- A dimmer to vary the light intensity
- Sterilisable handle

FSP function for better electronic management of illumination

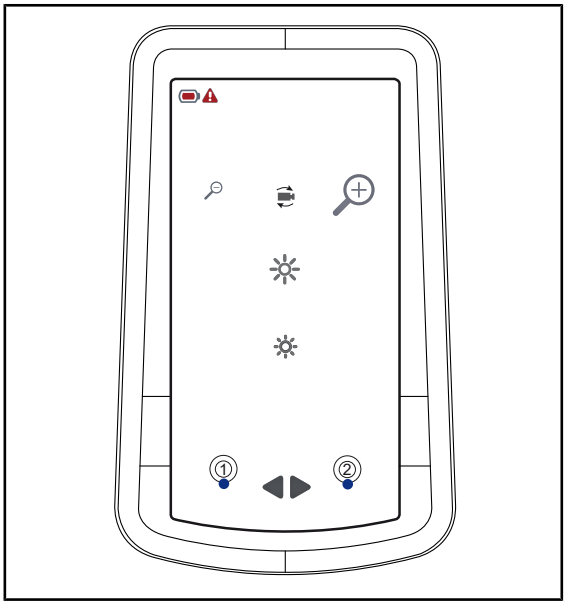
1.9.2 Accessories

CAUTION!

Risk of malfunction of the device
The use of accessories, transducers or cables other than those supplied or recommended by the manufacturer of this device may cause increased electromagnetic emissions or a decreased immunity of this device, and may result in improper operation.

Use only accessories and cables supplied or specified by the manufacturer.

Remote control



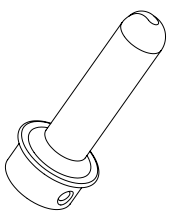
This remote control enables the light to be controlled at a distance, as needed by the surgeon, from anywhere in the operating room.

Fig. 7: LUCEA remote control

NOTICE

The remote control has a range of 10 m.

Sterilisable handle

Illustration	Description	Code
	**Set of five STG HLX handles**	STG HLX 01

Power supply cables, mobile version

Item	Description	Part number	Length
POWER CORD EUR	Power supply cable for Europe	5 686 04 960	4m
POWER CORD EUR	Power supply cable for the UK	5 686 04 961	4m
POWER CORD US	Power supply cable for the US	5 686 04 967	4m
POWER CORD BRA	Power supply cable for Brazil	5 686 04 963	4m
POWER CORD JPN	Power supply cable for Japan	5 686 04 966	4m
POWER CORD CHE	Power supply cable for Switzerland	5 686 04 965	4m
POWER CORD AUS	Power supply cable for Australia	5 686 04 964	4m
POWER CORD ITA	Power supply cable for Italy	5 686 04 962	4m
POWER CORD ARG	Power supply cable for Argentina	5 686 04 968	2 m

Tab. 3: Power supply cables

1.10 Standards applied

The device complies with the safety requirements of the following standards and directives:

Reference	Title
IEC 60601-1:2005+AMD1:2012+AMD2:2020 ANSI/AAMI ES60601-1:2005/A2:2021 CAN/CSA-C22.2 No. 60601-1:14/A2:2022 EN 60601-1:2006/A1:2013/A2:2021	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-2-41:2021 EN IEC 60601-2-41:2021	Medical electrical equipment – Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
IEC 60601-1-2:2014+AMD1:2020 EN 60601-1-2:2015/A1:2021	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 EN 60601-1-6:2010/A1:2015/A2:2021	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-9:2007+AMD1:2013+AMD2:2020 EN 60601-1-9:2008/A1:2014/A2:2020	Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for an environmentally friendly design
IEC 62366-1:2015+AMD1:2020 EN 62366-1:2015/A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 62304:2006+AMD1:2015 EN 62304:2006/A1:2015	Medical device software – Software life cycle processes
ISO 20417:2020 EN ISO 20417:2021	Medical devices - Information provided by manufacturer

Tab. 4: Compliance with product standards

Reference	Title
ISO 15223-1:2021 EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be provided by manufacturer - Part 1: General requirements
EN 62471:2008	Photobiological safety of lamps and lamp systems
IEC 62311:2019 EN 62311:2020	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz – 300 GHz)
Ordinance 384/2020	INMETRO Certification - Compliance assessment requirements for equipment under Health Surveillance

Tab. 4: Compliance with product standards

Quality management:

Reference	Year	Title
ISO 13485 EN ISO 13485	2021 2021	ISO 13485:2016 / A11:2021 EN ISO 13485:2016/A11:2021 Medical devices – Quality management systems – Requirements for regulatory purposes
ISO 14971 EN ISO 14971	2019 2019	ISO 14971:2019 EN ISO 14971:2019 Medical devices – Application of risk management to medical devices
21 CFR Part 11	2022	Title 21--Food And Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter A -- General PART 11 - Electronic records, electronic signatures
21 CFR Part 820	2020	Title 21--Food And Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter H -- Medical Devices PART 820 - Quality System Regulation

Tab. 5: Compliance with quality management standards

Environmental standards and regulations:

Reference	Year	Title
Directive 2011/65/EU	2011	Limitation of the use of certain hazardous substances in electrical and electronic equipment
Directive 2015/863	2015	Directive amending Annex II of Directive 2001/65/EU of the European Parliament and of the Council as regards the list of substances subject to limitation
Directive 2016/585/EU	2016	Exemption for lead, cadmium, hexavalent chromium and PBDEs on medical devices
Directive 2017/2102	2017	Limitation of the use of certain hazardous substances in electrical and electronic equipment

Tab. 6: Environmental standards and regulations

Reference	Year	Title
IEC 63000	2022	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
Regulation 1907/2006	2006	Registration, evaluation and authorization of chemical substances, as well as the restrictions applicable to these substances
US California Proposition 65 Act	1986	The Safe Drinking Water and Toxic Enforcement Act of 1986
Directive 2018/851	2018	Waste management
Directive 94/62/EC	1994	Packaging and Waste Management
SJ/T 11365-2006	2006	Administrative Measure on the Control of Pollution caused by Electronic Information Products Chines RoHS (Restriction of Hazardous Substances)

Tab. 6: Environmental standards and regulations

Country	Reference	Year	Title
Argentina	Dispocision 2318/2002	2002	Administración Nacional de Medicamentos, Alimentos y Tecnología Médica - Registro de productos Medicas - Reglamento
Australia	TGA 236-2002	2019	Therapeutic Goods (Medical Devices) Regulations 2002. Statutory Rules No. 236, 2002 made under the Therapeutic Goods Act 1989
Brazil	RDC 665/2022	2022	GMP Requirements for Medical Devices and IVDs
Brazil	RDC 185/2001	2001	Technical regulation about the registration of medical products at ANVISA, as well as its alteration, revalidation, or cancellation
Canada	SOR/98-282	2022	Medical Devices Regulations
China	Regulation 739	2021	Regulation for the Supervision and Administration of Medical Devices
EU	Regulation 2017/745/EU	2017	Medical Devices Regulations
Japan	MHLW Ordinance: MO No. 169	2021	Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-Vitro Diagnostics
South Korea	Act 14330	2016	Medical Device Act
South Korea	Decree 27209	2016	Enforcement Decree of Medical Act
South Korea	Rule 1354	2017	Enforcement Rule of the Medical Act
Switzerland	RS (Odim) 812.213	2020	Medical Devices Ordinance (MedDO) of 1 July 2020
Taiwan	TPAA 2018-01-31	2018	Taiwanese Pharmaceutical Affairs Act
UK	Act	2021	Medical Devices Regulations 2002 No. 618

Tab. 7: Compliance with market standards

Country	Reference	Year	Title
USA	21CFR Part 7	2022	Title 21--Food And Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter A -- General PART 7 - Enforcement policy
USA	21CFR Subchapter H	2022	Title 21--Food And Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter H -- Medical Devices

Tab. 7: Compliance with market standards

Other information (for China only)

产品名称：手术无影灯
规格型号：见标签
医疗器械注册证编号：国械注进20192010303
产品技术要求编号：国械注进20192010303
产品组成：由灯头（含发光二极管灯泡、调光器、灯罩）、电源箱、支架、手术灯头吊臂、摄像头（选配，后缀带V的型号适用）及其遥控器（选配，后缀带V的型号适用）组成。
适用范围：该产品为吊顶式安装，供医疗单位作医用手术照明用。
禁忌症：无。
生产日期：见标签
使用期限：10年
注册人/生产企业名称：Maquet SAS 迈柯唯股份有限公司
注册人/生产企业住所：Parc de Limère Avenue de la Pomme de Pin CS 10008 Ardon 45074 Orléans Cedex 2-FRANCE
生产地址：Parc de Limère Avenue de la Pomme de Pin CS 10008 Ardon 45074 Orléans Cedex 2-FRANCE
代理人名称：迈柯唯（上海）医疗设备有限公司
代理人住所：中国上海自由贸易试验区美盛路56号2层227室
代理人联系方式：800-820-0207
修订日期：见本说明书第二页

1.11 Information relating to intended use

1.11.1 Intended use

The LUCEA 50 lighthead is a medical examination light. It is designed to provide the additional light needed for close-up visual examinations.

1.11.2 Intended users

- The device may be operated only by medical staff who have read this manual.
- The device must be cleaned by qualified personnel.

1.11.3 Inappropriate use

- This light is not intended for use during surgical operations.
- This light must not be used if it is damaged (e.g. lack of maintenance).
- This light must not be used in a setting other than a professional healthcare environment (e.g. home care).

1.11.4 Contraindications

This product does not have any contraindications.

1.12 Primary purpose

The primary purpose of the LUCEA 50 surgical light is to illuminate the surgical site whilst minimising the associated heat energy.

1.13 Clinical benefit

Surgical and examination lights are considered as complementary to invasive and non-invasive treatment or diagnosis, and are essential to surgeons and healthcare staff for optimal vision.

The assistance they provide during surgical and examination procedures demonstrates their indirect clinical benefit. LED surgical lights offer several advantages over other technologies (e.g. incandescent lighting).

When used appropriately, LED surgical lights will:

- Improve workspace comfort and visual performance by focusing the light where surgeons and healthcare staff need it, while decreasing the heat released.
- Provide shadow management, which allows the medical staff to concentrate on surgery or diagnosis.
- Offer improved lifespan, thereby reducing the risk of partial malfunction during surgery.
- Provide steady illumination throughout their use.
- Ensure accurate colour rendering of the various tissues illuminated.

1.14 Instructions for reducing the environmental impact

To ensure optimum use of the device while limiting its impact on the environment, here are some rules to follow:

- Reduce power consumption by switching off the device when not in use.
- Position the device correctly so as not to have to compensate for poor positioning by increasing the lighting power.
- Follow the specified maintenance schedule in order to keep the level of environmental impact as low as possible.
- For questions relating to waste treatment and device recycling, refer to the Waste management [⏩ Page 50] chapter.

NOTICE

Power consumption for the device is provided in chapter 9.2, Electrical specifications.
The device does not contain hazardous substances in accordance with RoHS standards (see Tab. 6) and Reach regulation.

2 Safety-related information

2.1 Environmental conditions

Environmental conditions for transport and storage

Ambient temperature	-10°C to +60°C
Relative humidity	20% to 75%
Atmospheric pressure	500 hPa to 1060 hPa

Tab. 8: Environmental conditions for transport/storage

Environmental conditions for use

Ambient temperature	+10 °C to +40 °C
Relative humidity	20% to 75%
Atmospheric pressure	500 hPa to 1060 hPa

Tab. 9: Environmental conditions for use

2.2 Safety instructions

2.2.1 Safe use of the product

WARNING!

Risk of injury
An incorrectly positioned metal half-ring on the spring arm may result in a cutting hazard.

If a metal half-ring on the spring arm comes out of its slot, contact your technical department.

WARNING!

Risk of injury
If the battery discharges too quickly, a lighthead may go out during a procedure.

Perform a battery lifetime test monthly to estimate the battery lifetime. Contact the Getinge technical department if a malfunction occurs.

WARNING!

Risk of tissue reaction
Light is a form of energy that, on account of certain wavelengths emitted, may not be suitable for certain pathologies.

The user must be aware of the risks of using the light on subjects who are intolerant to UV and/or infrared light, and on photosensitive subjects.
Before a procedure, please ensure that the light is compatible with this type of pathology.

WARNING!

Risk of drying of tissue or burns
Light is a form of energy that can cause tissue to dry, particularly if light beams from more than one lighthead are superimposed.

The user must be aware of the risks relating to exposure of open wounds to a light source of too great an intensity. The user must be vigilant and must adjust the level of illumination to suit the patient concerned, particularly during a lengthy procedure.

WARNING!

Risk of injury
The mobile light may tip over if a person leans on it.

Never lean on the mobile light.

WARNING!

Risk of injury
Intense magnetic fields can cause the light to malfunction or move unexpectedly.

Do not use in an MRI environment.

WARNING!

Risk of burns
This device is not explosion-proof. Sparks, which would not normally be hazardous, may cause fires in oxygen-enriched atmospheres.

Do not use the device in environments rich in flammable gases or oxygen.

WARNING!

Risk of injury/infection
The use of a damaged device may lead to a risk of injury for users or a risk of infection for patients.

Do not use a damaged device.

2.2.2 Electrical

CAUTION!

Risk of malfunction of the device
The use of accessories, transducers or cables other than those supplied or recommended by the manufacturer of this device may cause increased electromagnetic emissions or a decreased immunity of this device, and may result in improper operation.

Use only accessories and cables supplied or specified by the manufacturer.

WARNING!

Risk of electric shock
Anyone not trained in installation, maintenance or decommissioning operations is exposed to the risk of injury or electric shock.

Installation, maintenance and decommissioning of the device or components of the device must be performed by a Getinge technician or a Getinge-trained service technician.

WARNING!

Risk of injury
If a power cut occurs in the middle of an operation, the lightheads will go out if the lighting system does not have a backup supply.

The hospital must comply with applicable standards on premises for medical use and must have a backup power system.

2.2.3 Optical

WARNING!

Risk of injury
This product emits possibly hazardous optical radiation. Eye injury may occur.

Do not stare at the light emitted from the surgical luminaire. The patient's eyes must be protected during facial surgery.

2.2.4 Infection

WARNING!

Risk of infection
A servicing or cleaning operation may result in contamination of the surgical site.

Do not perform servicing or cleaning operations when the patient is present.

3 Control interfaces

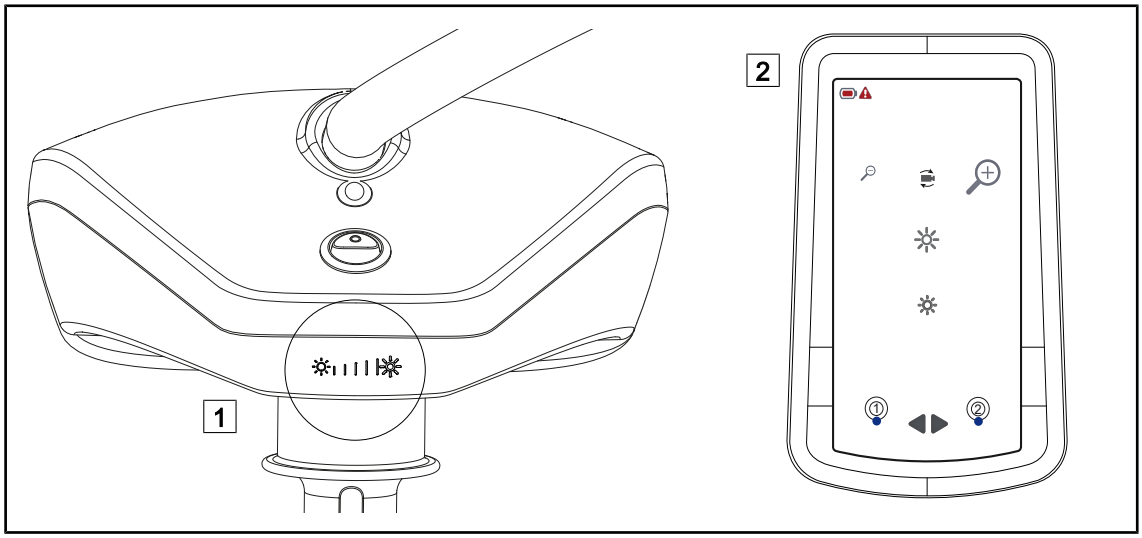


Fig. 8: LUCEA 50-100 control interfaces

1 Lighthead control keypad

2 Remote control

4 Use

4.1 Daily inspections before use

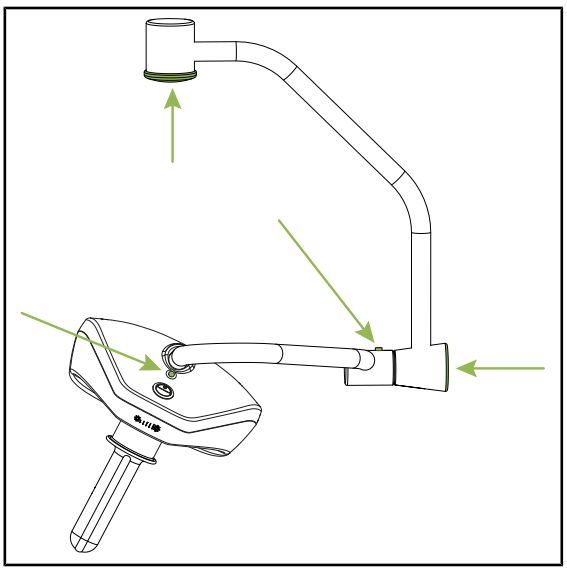


Fig. 9: Integrity of the lightheads

Integrity of the lightheads, brake screw cap and mounting screws

1. Check the lightheads for chipped paint, impact marks, any other damage, loose covers, etc.
2. Check that the cap protecting the brake screw is properly seated.
3. Check that all the mounting screws are present.
4. Check that the grey plugs are correctly installed (DF version only)
5. If a problem is noted, contact technical support.

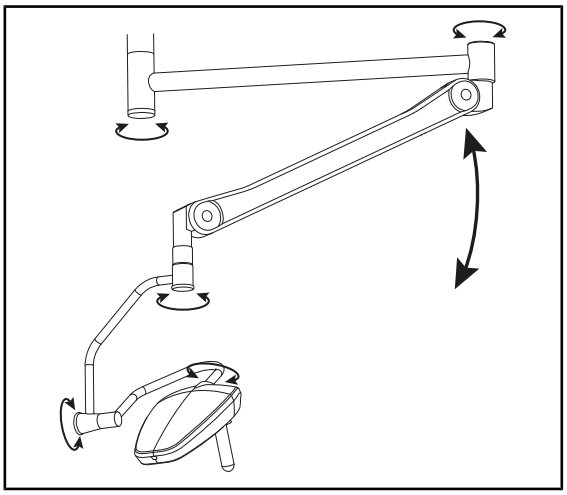


Fig. 10: Stability/drift

Stability and drift of the system

1. Operate the device, making several movements in order to swivel the extension arms, the spring arms and the lightheads.
   - ➢ The entire system should move easily and smoothly.
2. Place the system in various positions.
   - ➢ The entire system should remain in the selected position, without any drift.
3. If a problem is noted, contact technical support.

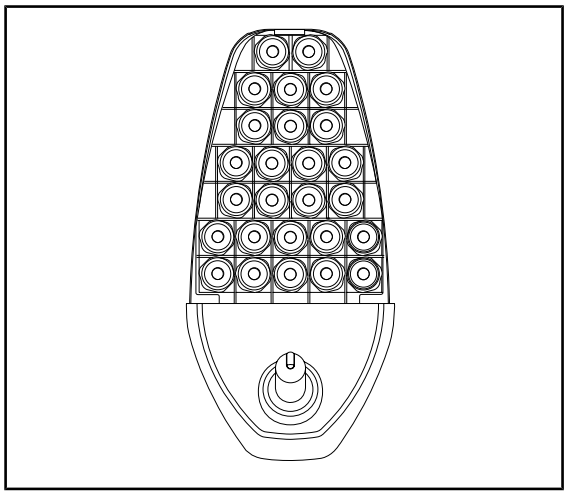


Fig. 11: Operation of LEDs

Operation of the LEDs

1. Check whether the LEDs operate correctly, by pressing the On/Off button on the lighthead.
2. If a problem is noted, contact technical support.

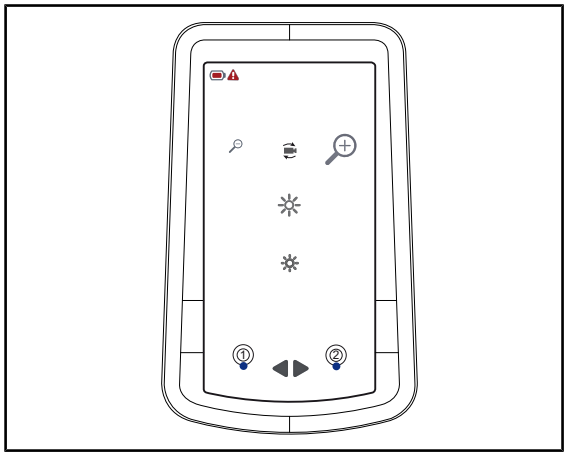


Fig. 12: Remote control

Remote control (option)

1. Check that the remote control operates correctly.
2. Check the state of the batteries.
3. Check the lighthead selection function.
4. If a problem is noted, contact technical support.

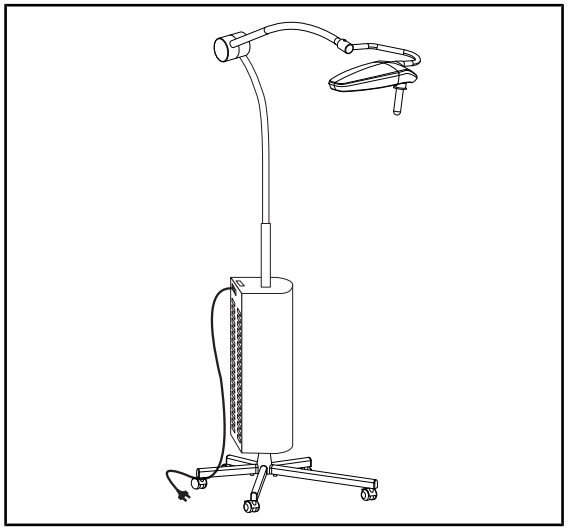


Fig. 13: Power lead for mobile version

Power lead (mobile version only)

1. Check that the power lead is not damaged.
2. Check that the IEC mains connector on the power supply enclosure cover is correctly connected
3. If a problem is noted, contact technical support.

4.2 Controlling the light

4.2.1 Turning the light on and off

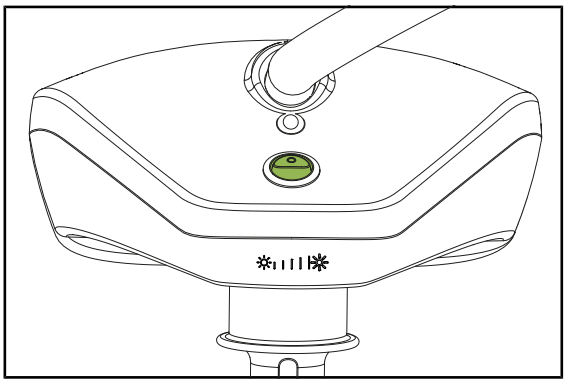


Fig. 14: Turning the lighthead on and off

1. Press the On/Off button to turn on the lighthead.
   - ➢ All of the LEDS turn on, at the last illumination level used when the light was turned off.
2. Press the On/Off button again to turn off the lighthead.
   - ➢ All of the LEDs turn off.

4.2.2 Adjusting the illumination

4.2.2.1 From the lighthead control keypad

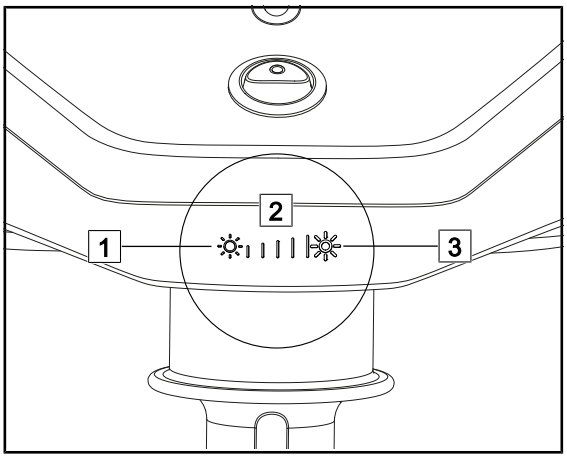


Fig. 15: Adjusting the illumination via the keypad

Adjusting the light intensity

1. Press **Increase intensity** 3 to increase the light intensity level of the lighthead.
2. Press **Decrease intensity** 1 to decrease the light intensity level of the lighthead.
   - ➢ The illumination level on the lighthead is shown by the LED 2.

4.2.2.2 From the remote control

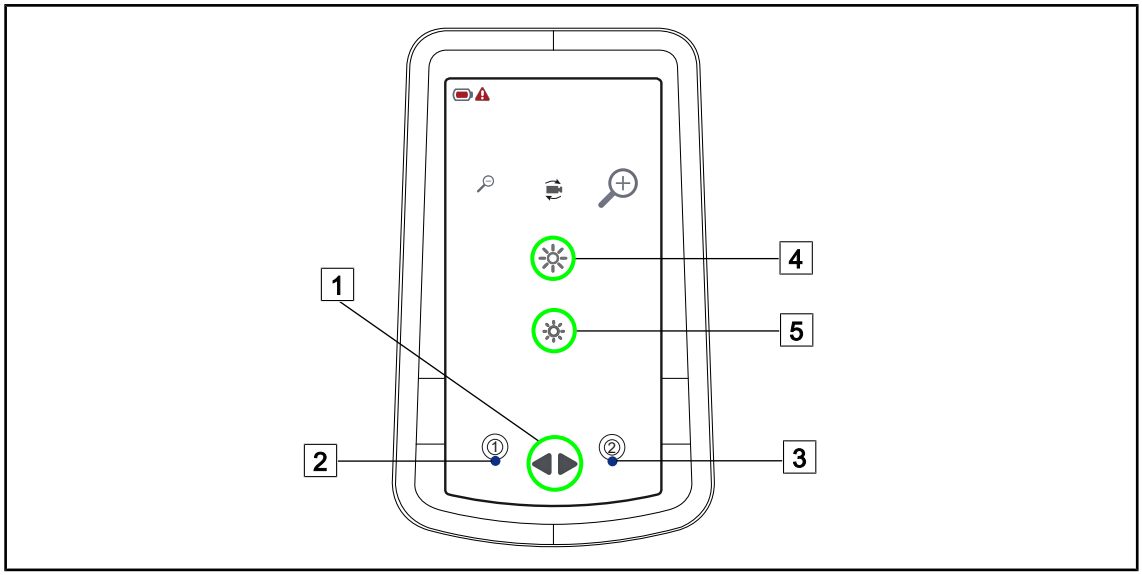


Fig. 16: Adjusting the illumination via the remote control

Select the lighthead(s)

1. Press **Select lighthead** [1] once to control lighthead 1.
   - ➢ The lighthead 1 LED [2] on the remote control is lit.
2. Press **Select lighthead** [1] twice to control lighthead 2.
   - ➢ The lighthead 2 LED [3] on the remote control is lit.
3. Press **Select lighthead** [1] three times to control the two lightheads.
   - ➢ The LEDs for the two lightheads [1] and [2] are lit on the remote control.

Adjusting the light intensity

1. After selecting the lighthead(s), press **Increase intensity** [4] to increase the light intensity level of the lighthead(s).
2. After selecting the lighthead(s), press **Decrease intensity** [5] to decrease the light intensity level of the lighthead(s).

4.3 Positioning the light

4.3.1 Installing/removing the sterilisable handle

WARNING!

Risk of infection
If the sterile handle is not in good condition, there is a risk that particles could fall from it into the sterile environment.

After each sterilisation and before using a sterilisable handle again, check that there are no cracks.

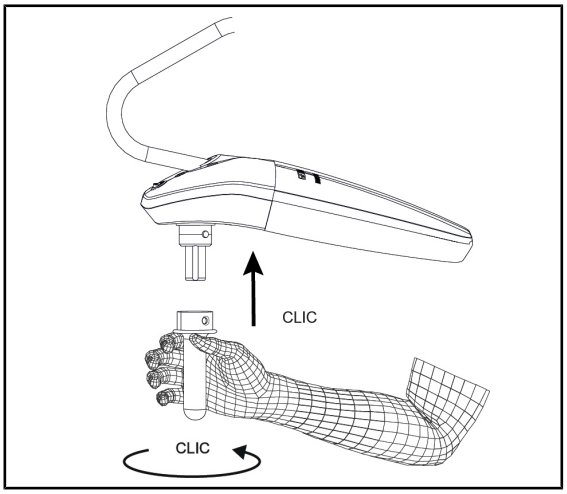


Fig. 17: Installing the sterilisable handle

Installing a sterilisable handle on the lighthead

1. Inspect the handle and check for cracks or soiling.
2. Fit the handle to the mount.
3. Rotate the handle until its rotation is locked.
   - ➢ The locking button pops out of its housing.
4. Check that the handle is firmly in place.
   - ➢ The handle is now locked in place and ready for use.

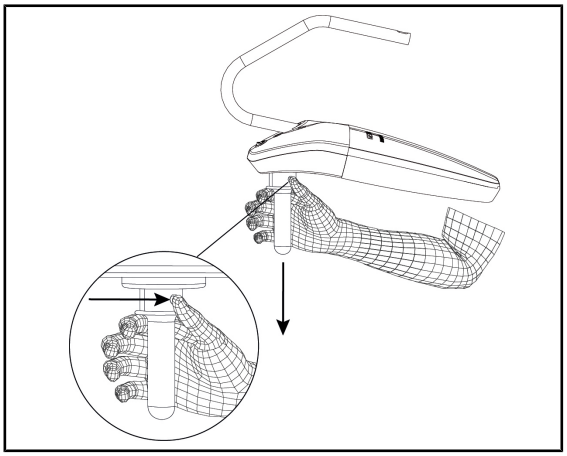


Fig. 18: Removing the sterilisable handle

Removing a sterilisable handle from the lighthead

1. Press the locking button.
2. Remove the handle.

4.3.2 Manoeuvring the lighthead

WARNING!

Risk of infection or tissue reaction
A collision between the device and another item of equipment may result in particles falling onto the surgical site.

Pre-position the device before the patient arrives. Move the device carefully to avoid a collision.

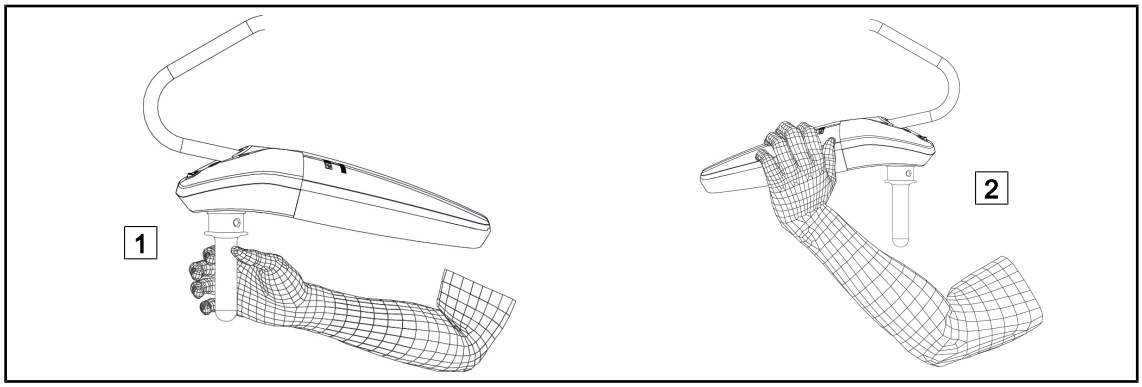


Fig. 19: Manoeuvring the lighthead

- The lighthead can be manoeuvred in various ways:
  - For sterile personnel: using the sterile handle provided for this purpose in the centre of the lighthead 1.
  - For non-sterile personnel: by holding the lighthead 2 directly.

Light rotation angles

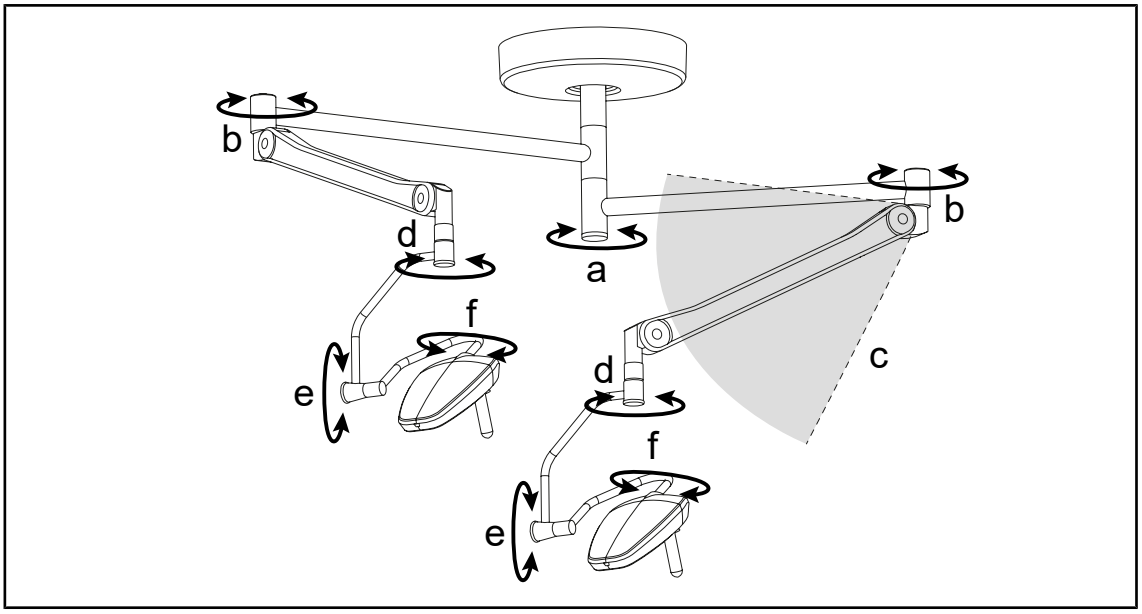


Fig. 20: Possible rotations of the DF ceiling-mounted light

a	b	c	d	e	f
infinite	infinite	+45° / -50°	infinite	180°	320°

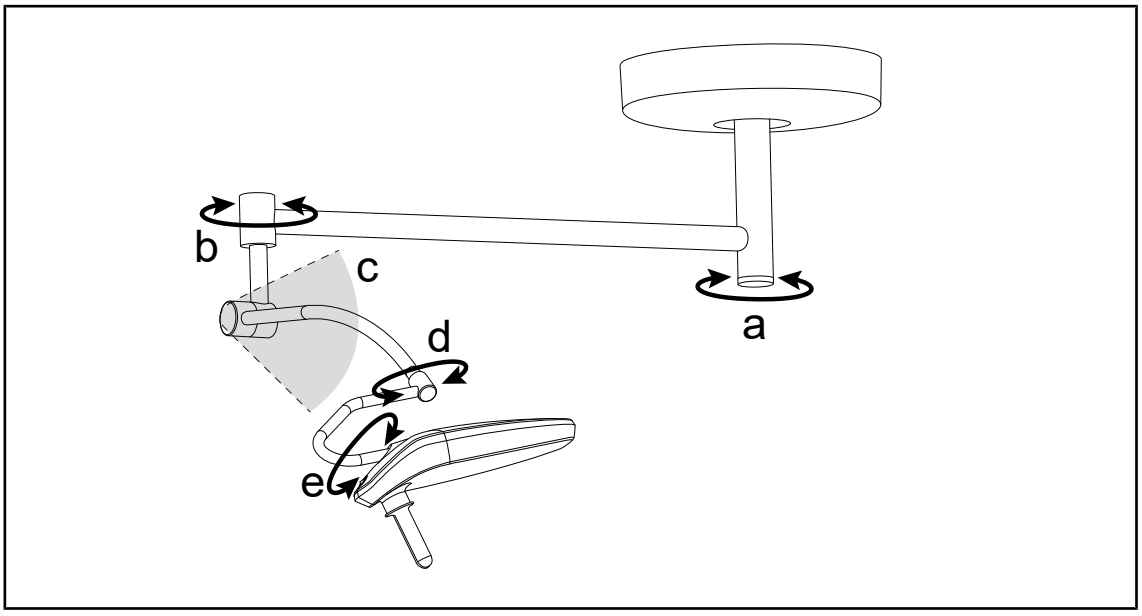


Fig. 21: Possible rotations of the SF ceiling-mounted light

a	b	c	d	e
infinite	infinite	+5° / -75°	180°	320°

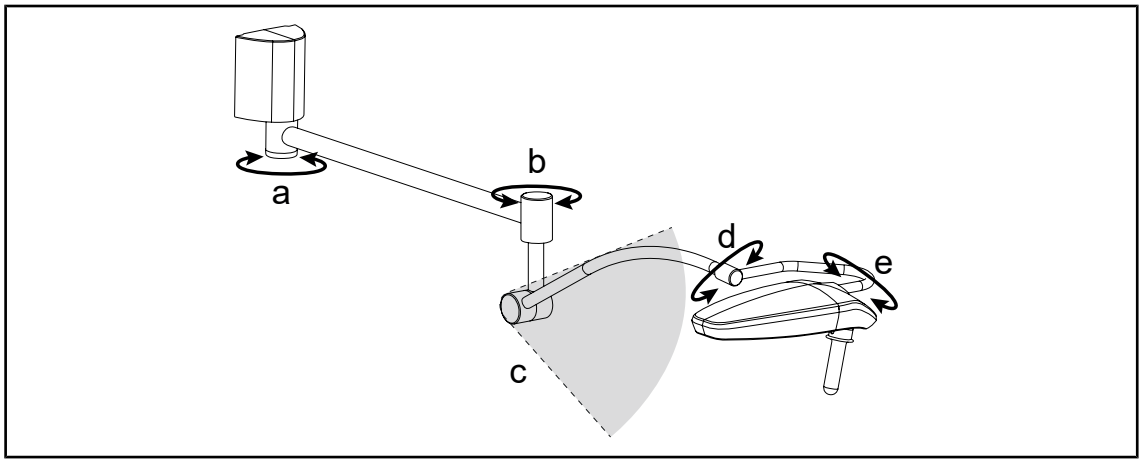


Fig. 22: Possible rotations of the wall-mounted light

a	b	c	d	e
180°	infinite	+5° / -75°	180°	320°

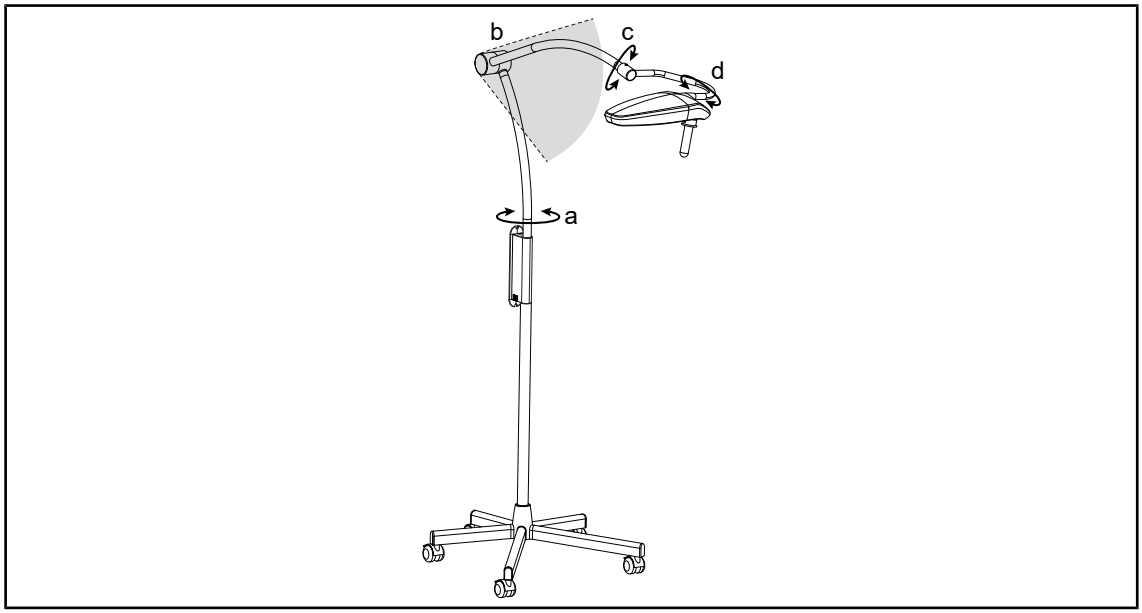


Fig. 23: Possible rotations of the mobile light

a	b	c	d
55°	+30° / -80°	180°	320°

4.4 Remote control

4.4.1 Registering the remote control with the light

NOTICE

The remote control can only be registered with a single light, and should not be used at a distance of more than 10 metres.

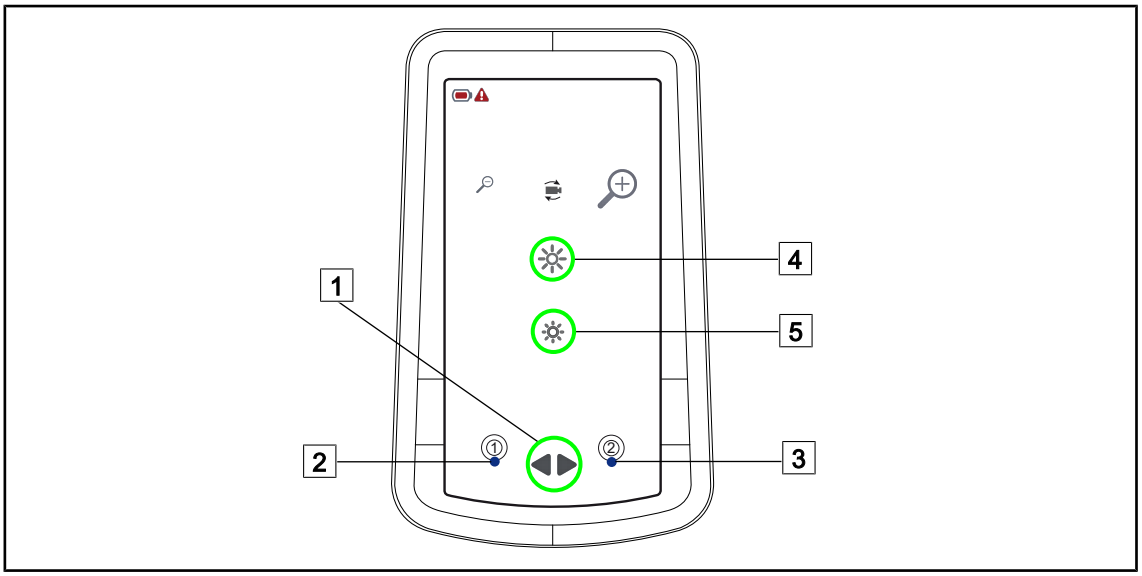


Fig. 24: Registering a remote control with a light

Registering the remote control with the first lighthead

1. Press **Select lighthead** [1].
2. Simultaneously press **Increase intensity** [4] and **Decrease intensity** [5] and hold until the lighthead dimmer LEDs flash.
3. Press **Increase intensity** [4] or **Decrease intensity** [5] and hold until the lighthead dimmer LEDs stop flashing.
   ➢ The remote control is registered with the lighthead.
4. To test that registration has been successful, check that the lighthead responds to the remote control.

Registering the remote control with the second lighthead

1. Proceed in the same way as for the first lighthead.
2. Test that the lighthead selection function on the remote control operates correctly.

4.4.2 Changing the remote control batteries

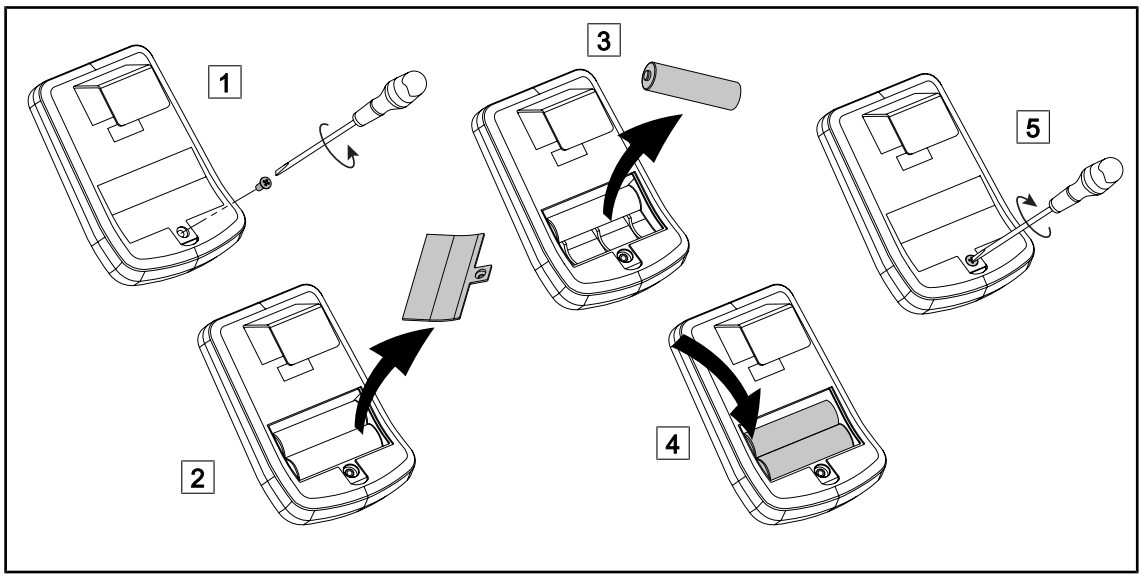


Fig. 25: Replacing the remote control batteries

1. Use a screwdriver to remove the screw that holds the battery cover in place [1].
2. Lift off the cover [2].
3. Remove the batteries [3].
4. Insert the new batteries, paying attention to the polarity [4].
5. Replace the cover and the attachment screw [5].

4.5 Mobile light

4.5.1 Moving a mobile light

WARNING!

Risk of electric shock
If the outlet is not disconnected properly, damage to the power supply cable may occur and live parts may become accessible.

Do not pull on the power lead to disconnect the mains outlet.

WARNING!

Risk of inconvenience during use
If the mobile light is not properly positioned, it may move in an uncontrolled manner.

Position the light by following the steps set out, to ensure that it is properly stable.

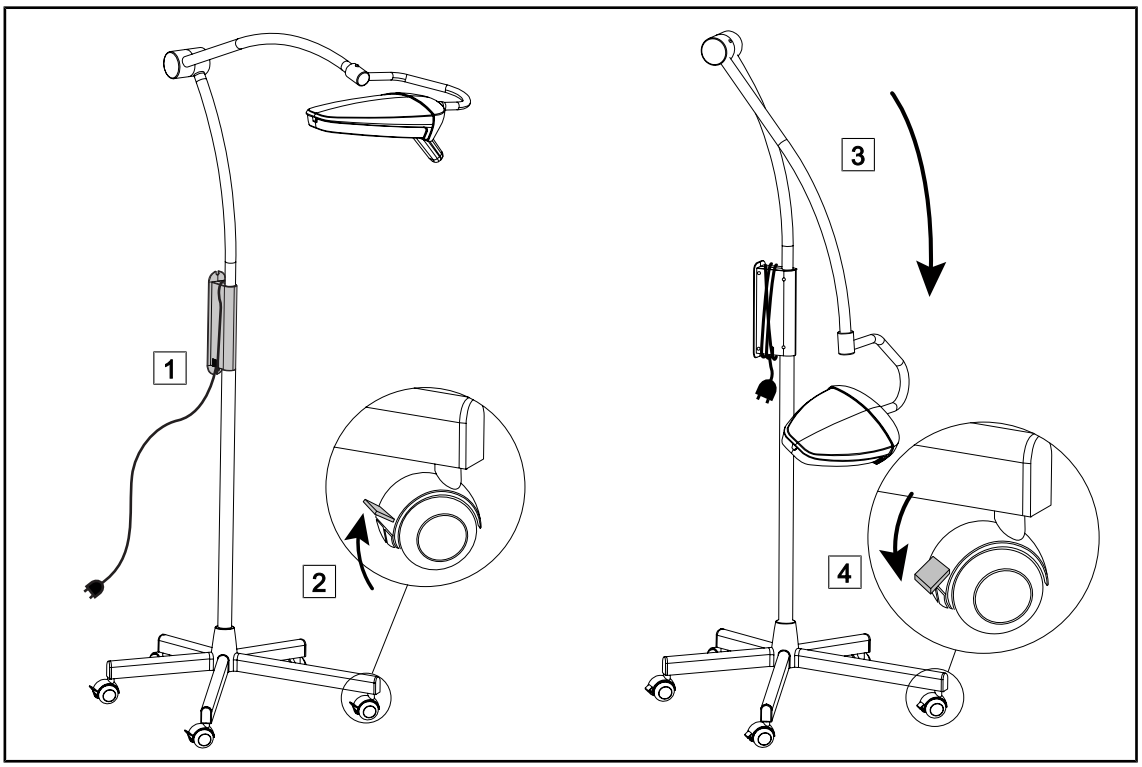


Fig. 26: Moving a mobile light

1. Wind the power lead around the power supply enclosure [1].
2. Release the brakes by raising the levers on the casters [2].
3. Lower the lighthead and then move the stand to the desired location [3].
4. Upon reaching the desired location, lock the brakes by pushing down the levers on the casters [4].
5. Plug the power lead into the mains outlet.

4.5.2 Battery system operation

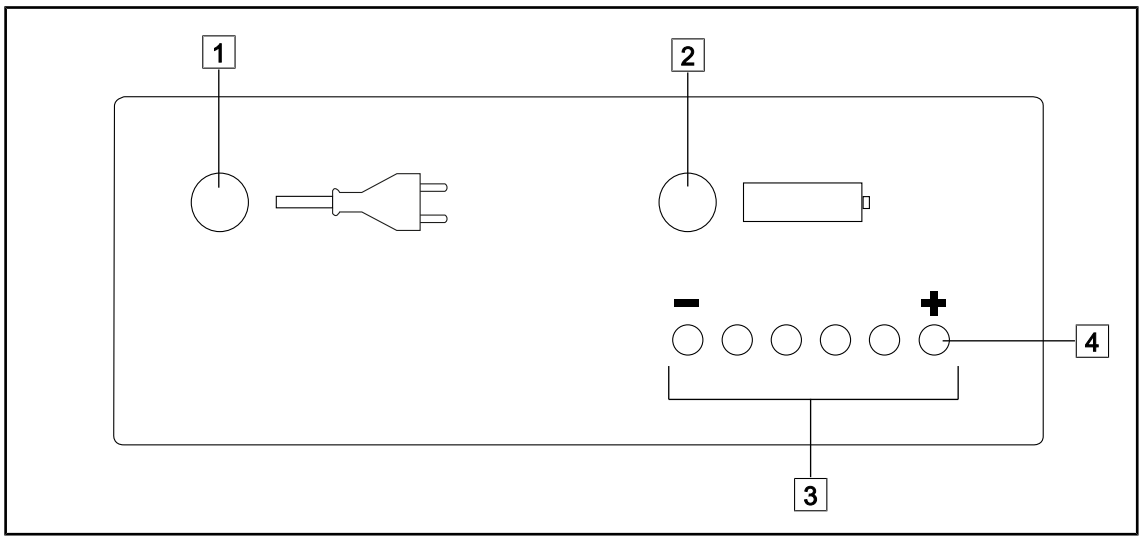


Fig. 27: Battery system indicators

Operation when the mobile light is connected to the mains

- When operating on mains power, the LED with the plug icon [1] is green.
- While the batteries are charging, LEDs 3 to 8 [3] scroll.
- Once the batteries are fully charged, LED 8 [4] starts flashing.

NOTICE

It takes at least 10 hours to fully charge the batteries.

Operation when the mobile light is on battery power

- When operating on battery power, the LED with the battery icon [2] is green.
- If a power cut occurs, the lighting runs on battery power, and the batteries thus gradually discharge.
- The charge in the batteries is indicated by LEDs 3 to 8 [3]. As the batteries run down, the indicator moves from (+) towards (-).
- When the batteries are discharged, an alarm signal sounds and LED 2 [2] turns red.
- The light shuts off automatically after the alarm signal sounds (to protect the batteries against deep discharge).

NOTICE

If the batteries are fully charged, the LUCEA 50 can run on battery power for at least three hours

4.5.3 Battery state

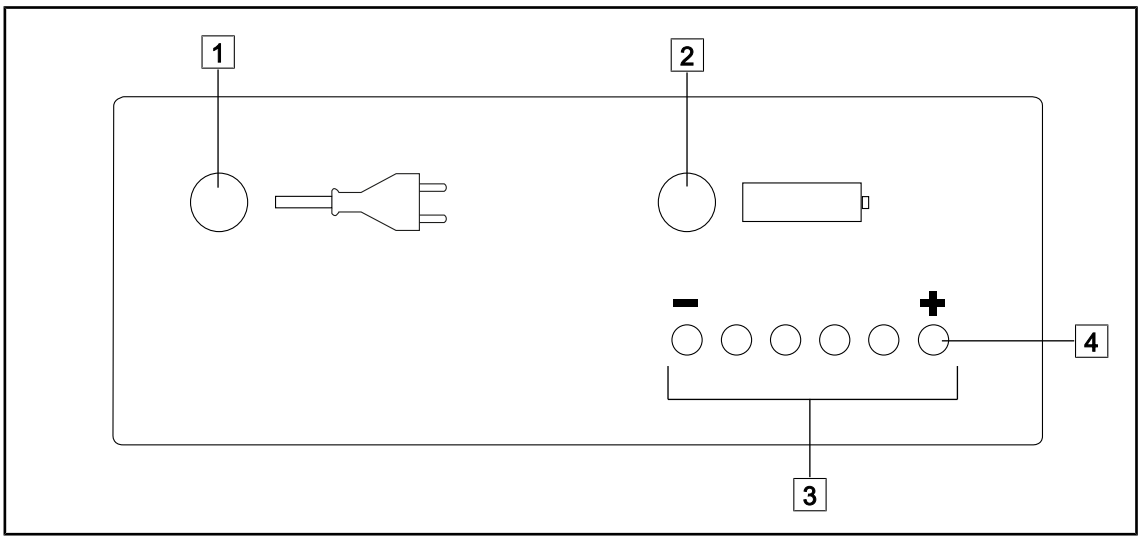


Fig. 28: Battery indicators

Check	Mains LED 1	Battery LED 2	LEDs 3 to 8 3	Meaning
Turn off the light	Green	Off	Scrolling LEDs	Batteries charging
			LED 8 flashes 4	Batteries completely charged
Turn on the light	Green	Off	Scrolling LEDs	Batteries charging
			LED 8 flashes 4	Batteries completely charged
Disconnect the mains power outlet (the light remains on)	Off	Yellow	One of LEDs 3 to 8 is lit (battery charge level)	Operation on batteries
After 1 hour	Off	Yellow	One of LEDs 3 to 8 is lit (battery charge level)	Operation on batteries
Connect the power outlet	Green	Off	Scrolling LEDs	Batteries charging

Tab. 10: Battery lifetime test

5 Error messages and alarm indicators

Not applicable for this product.

6 Troubleshooting

Electronics/Optics

Problem	Likely cause	Corrective action
The lighthead does not turn on.	Power cut	Contact your facility's technical services
	Does not switch over to backup	Contact the Getinge technical department
	Other reason	Contact the Getinge technical department
The lighthead does not turn off.	Communication problem	Contact the Getinge technical department
An LED does not come on.	The LED board is defective	Contact the Getinge technical department
The remote control does not operate the light	Registration problem	Re-register the remote control
	Battery level low	Replace the batteries

Tab. 11: Troubleshooting

Mechanical components

Problem	Likely cause	Corrective action
The sterilisable handle does not click into place correctly	Sterilisation parameters (temperature, time) exceeded	Check the operation of the handle and in particular the locking mechanism (audible click)
	Its maximum service life has expired or the handle is twisted or bent.	Replace the handle
The lighthead drifts	Suspension tube not vertical	Contact the Getinge technical department
	Ceiling structure unstable	Contact the Getinge technical department
	Locking screw incorrectly adjusted.	Contact the Getinge technical department
Lighthead moves too easily or is difficult to move.	Locking screw incorrectly adjusted.	Contact the Getinge technical department
	Other reason	Contact the Getinge technical department

Tab. 12: Mechanical anomalies and malfunctions

Mobile light with battery backup

Problem	Likely cause	Corrective action
The mobile light is on, running on the mains supply		
LED 1 not lit green	Electronic fault	Contact the Getinge technical department
LED 2 lit yellow	Mains fuse missing or blown	Contact the Getinge technical department
LED 1 flashes red	Charging circuit safety fuse fault	Contact the Getinge technical department
LEDs 3 to 8 not scrolling; LED 8 not lit	Electronic fault	Contact the Getinge technical department
The mobile light is on, running on battery power		
LED 2 not lit yellow	Electronic fault	Contact the Getinge technical department
None of LEDs 3 to 8 are lit	Electronic fault	Contact the Getinge technical department
The light goes out when the power outlet is disconnected	Batteries faulty or incorrectly connected	Contact the Getinge technical department
	Charging circuit safety fuse fault	Contact the Getinge technical department
	Electronic fault	Contact the Getinge technical department
LED 4 flashes	Batteries discharged	Recharge the batteries
LED 3 lit red	Batteries almost totally discharged	Recharge the batteries urgently
LED 1 lit red	Batteries almost totally discharged	Recharge the batteries urgently

Tab. 13: Troubleshooting the mobile light with battery backup

7 Cleaning / Disinfection / Sterilisation

WARNING!

Risk of infection
Cleaning and sterilisation procedures vary considerably from one healthcare institution to another and depending on local regulations.

Users must contact their hospital's sanitary specialists. The recommended products and procedures must be applied.

7.1 Cleaning and disinfecting the system

WARNING!

Risk of equipment damage
The ingress of liquid inside the device during cleaning may adversely affect its operation.

Do not clean the device under running water or spray a solution directly onto the device.

WARNING!

Risk of infection
Certain cleaning products or procedures may damage the enclosure of the device, which may result in particles falling onto the surgical site during an operation.

Disinfectants containing glutaraldehyde, phenol or iodine must not be used. Fumigation methods are unsuitable for disinfecting the unit and must not be used.

WARNING!

Risk of burns
Certain parts of the device remain hot after use.

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

General instructions concerning cleaning, disinfection and safety

In standard use, the level of treatment required for cleaning and disinfection of the device is low-level disinfection. The device is classified as non-critical with a low infectious risk. However, depending on the infectious risk, intermediate or high-level disinfection may be envisaged.

The responsible body must follow the national requirements (standards and guidelines) for all matters of hygiene and disinfection.

7.1.1 Cleaning the device

1. Remove the sterilisable handle.
2. Wipe the equipment with a cloth moistened with a surface cleaner. Follow the manufacturer's dilution instructions, application time and temperature recommendations. Use a slightly alkaline universal cleaner (soap solution) containing active substances such as detergents and phosphates. Do not use abrasive products, as these could damage the surfaces.
3. Remove the cleaner using a cloth moistened with water and then wipe with a dry cloth.

7.1.2 Disinfecting the device

Wipe evenly with a cloth soaked in disinfectant. Follow the manufacturer's recommendations.

7.1.2.1 Disinfectants to be used

- Disinfectants are not sterilising agents. They result in a qualitative and quantitative reduction in the microorganisms present.
- Use only surface disinfectants containing combinations of the following active substances:
  - Quaternary ammoniums (bacteriostatic for Gram – and bactericidal for Gram +, variable activity on enveloped viruses, no action on non-enveloped viruses, fungistatic, no sporicidal action)
  - Guanidine compounds
  - Alcohols

7.1.2.2 Permitted active substances

Class	Active substances
Low level of disinfection	
Quaternary ammonium	▪ Didecyl dimethyl ammonium chloride ▪ Alkyl dimethyl benzyl ammonium chloride ▪ Dioctyl dimethyl ammonium chloride
Biguanides	▪ Polyhexamethylene biguanide hydrochloride
Intermediate level of disinfection	
Alcohols	▪ Propan-2-ol
High level of disinfection	
Acids	▪ Sulfamic acid (5%) ▪ Malic acid (10%) ▪ Ethylene diamine tetraacetic acid (2.5%)

Tab. 14: Lists of active substances suitable for use

Examples of commercially available products tested

- ANIOS product®** : Surfa'Safe®**
- Other products: 20% or 45% isopropyl alcohol

7.2 Cleaning and sterilising STG HLX sterilisable handles

7.2.1 Preparation for cleaning

To prevent any soiling from drying out, soak the handles in a detergent-disinfectant bath containing no aldehydes, immediately after use.

7.2.2 Manual cleaning

1. Immerse the handles in a detergent solution[1] for 15 minutes.
2. Wash using a soft brush and a lint-free cloth.
3. Check that the handles are perfectly clean, with no remaining soiling. If not, use an ultrasound cleaning process.
4. Rinse thoroughly with clean water to fully eliminate the detergent solution.
5. Leave to air dry or wipe the handle with a dry cloth.

7.2.3 Cleaning in a washer-disinfector

Handles may be cleaned in a washer-disinfector and rinsed at a maximum temperature of 93°C. Typical recommended cycles:

Step	Temperature	Time
Pre-wash	18-35°C	60 sec
Wash	46-50°C	5 min
Neutralisation	41-43°C	30 sec
Wash 2	24-28°C	30 sec
Rinse	92-93°C	10 min
Dry	air dry	20 min

Tab. 15: Typical cleaning cycles in a washer-disinfector

[1] The use of non-enzymatic detergents is recommended. Enzymatic detergents may damage the handles. Never soak the handles in these detergents for prolonged periods. Rinse thoroughly.

7.2.4 Sterilisation

WARNING!

Risk of infection
A sterilisable handle that has exceeded the recommended number of sterilisation cycles is at risk of falling from its mount.

With the above sterilisation parameters, STG PSX sterilisable handles are guaranteed for no more than 50 uses, and STG HLX sterilisable handles for no more than 350 uses. Please do not exceed the recommended number of cycles.

NOTICE

STG PSX sterilisable handles are not compatible with the LUCEA 50-100.

NOTICE

STG HLX sterilisable handles are designed for autoclave sterilisation.

1. Check that the handle is not soiled or cracked.
   - ➢ If the handle is soiled, return it to the cleaning circuit.
   - ➢ If the handle has one or more cracks, it is unusable and must therefore be disposed of in accordance with the applicable protocols.
2. Place the handles on the steriliser tray using one of the following three methods:
   - ➢ In a sterilisation wrapper (double wrapper or equivalent).
   - ➢ In a paper or plastic sterilisation bag.
   - ➢ With no wrapper or bag, with the locking button facing down.
3. Package with biological and/or chemical indicators for monitoring the sterilisation process, in accordance with applicable regulations.
4. Run the sterilisation cycle according to the steriliser manufacturer's instructions.

Sterilisation cycle	Temperature (°C)	Time (min)	Dry (min)
ATNC (Prion) Prevacuum	134	18	–

Tab. 16: Example of a steam sterilisation cycle

8 Maintenance

To preserve your device’s original performance and reliability levels, annual maintenance and inspection operations must be performed. During the warranty period, maintenance and inspection operations must be performed by a Getinge technician or a Getinge-approved dealer. After this period, maintenance and inspections may be performed by a Getinge technician, a Getinge-approved dealer or a hospital technician trained by Getinge. Please contact your dealer to undergo the technical training required.

Preventive maintenance	To be performed every year

Certain components must be replaced during the device’s service life. Check the Maintenance Manual for how frequently to do so. The Maintenance Manual mentions all of the electrical, mechanical, and optical checks to carry out, as well as which wear parts need to be periodically replaced to maintain the reliability and performance of the operating lighting system and guarantee safe operation.

NOTICE

The Maintenance Manual is available from your local Getinge representative. To find your local Getinge representative’s contact information, visit the website **https://www.getinge.com/int/contact/find-your-local-office**.

9 Technical specifications

9.1 Optical specifications

NOTICE

Values measured at a reference distance (D_{REF}) of 1 meter / 39.4 inches).

Specifications	LUCEA 50	Tolerance
Central Illumination ($E_{c,Ref}$)	15,000 lx to 60,000 lx	–
Maximum Central Illumination ($E_{c,MI}$)[2]	< 120,000 lx	–
Maximum Central Illumination ($E_{c,Ref}$)	60,000 lx	± 10 %
Light field diameter d_{10}	22 cm	± 3 cm
Light distribution d_{50}/d_{10}	0.58	± 0.05
Depth of illumination above 60 %	120 cm	± 15 %
Correlated Colour temperature	4 500 K	± 400 K
Colour rendering index (Ra)	96	±4
Special colour rendering index (R9)	92	± 10
Specific colour rendering index (R13)	95	± 5
Specific colour rendering index (R15)	95	± 5
Maximal total Irradiance (E_{Total})[2]	< 470 W/m²	–
Heat to light ratio[2]	3,9 mW/m²/lx	± 0.4
UV illumination[2]	≤ 0,7 W/m²	–
FSP system	Yes	–

Tab. 17: Optical specifications for LUCEA 50 lighthead

Specifications	LUCEA 50	Toler-ance
With one mask	5%	± 10
With two masks	58%	± 10
With simulated cavity	100%	± 10
With one mask, with simulated cavity	5%	± 10
With two masks, with simulated cavity	58%	± 10

Tab. 18: LUCEA 50 residual illumination

[2] Measured at Maximum Illuminance Distance (D_{MI}) of 62 cm / 24.4 inches (± 10%).

NOTICE

The test value for the masks must necessarily remain above 0%.

WARNING!

Risk of injury
This product emits possibly hazardous optical radiation. Eye injury may occur.

Do not stare at the light emitted from the surgical luminaire. The patient's eyes must be protected during facial surgery.

WARNING!

Risk of injury
This product emits optical radiation which may cause harm to the user or patient.

The optical radiation emitted by this product complies with exposure limits for reducing the risk of photobiological hazards in IEC60601-2-41.

9.2 Electrical characteristics

Specifications	Values
Supply voltage	100-240 Vac, 50/60 Hz
Power consumption, LUCEA 50 configuration	60 VA
Power consumption, DUO L50	120 VA
Power consumption, L50 Mobile configuration, without batteries	60 VA
Power consumption, L50 Mobile configuration, with batteries	145 VA
Supply voltage	24 Vac, 50/60 Hz, 24 Vdc
Battery type	Lead gel
Minimum battery lifetime, LUCEA 50 mobile	3 hours
Charge time for Lucea 50 mobile batteries	3 hours
Fuses	7.5A - 32
240 Vac consumption	0,6 A
100 Vac consumption	1.33 A

Tab. 19: LUCEA 50 electrical specifications

9.3 Mechanical specifications

9.3.1 Light

Specifications	Values
Weight, LUCEA 50 mobile without batteries	11 kg
Weight, LUCEA 50 mobile with batteries	22 kg
Length of mains supply cable	2/4 m
Vertical reach of spring arm, LCA 50 Mobile	+30° / -80°

Tab. 20: Mechanical specifications of mobile lights

9.4 Other characteristics

Protection against electrical shock	Class I
Medical device classification for Europe, Canada, Korea, Japan, Brazil & Australia	Class I
Medical device classification for USA, China & Taiwan	Class II
Protection rating for the device as a whole	IP20
Protection rating of the lightheads	IP20
GMDN code	12282 / 36843
EMDN code	Z12010701 / Z12010702
CE marking year	2011

Tab. 21: Specifications relating to standards and regulations

9.5 EMC declaration

CAUTION!

Risk of malfunction of the device
If the device is used in conjunction with other equipment, its operation and performance may be affected.

Do not use the device alongside other equipment or stacked with other equipment except after observing the normal operation of the device and the other equipment.

CAUTION!

Risk of malfunction of the device
The use of accessories, transducers or cables other than those supplied or recommended by the manufacturer of this device may cause increased electromagnetic emissions or a decreased immunity of this device, and may result in improper operation.

Use only accessories and cables supplied or specified by the manufacturer.

CAUTION!

Risk of malfunction of the device
The use of hand-held RF communications equipment (including antenna cables and external antennas) alongside the device or specified cables may affect the operation and performance of the device.

Do not use hand-held RF communications equipment at within 30 cm of the device.

CAUTION!

Risk of malfunction of the device
The use of a high frequency generator (e.g. electrosurgical unit) adjacent to the device may affect its operation and performance.

If anomalous operation is observed, adjust the position of the lightheads until the interference ceases.

CAUTION!

Risk of malfunction of the device
The use of the device in an unsuitable environment may affect its operation and performance.

Do not use this device except in a professional healthcare facility.

NOTICE

Electromagnetic interference may result in temporary extinction or temporary flickering of the light, which will recover its initial settings once the interference has ceased.

Test type	Test method	Range of frequencies	Boundaries
Measurement of conducted emissions on the main ports	EN 55011 GR1 CL A[3]	0.15 / 0.5 MHz	79 dBµV QP 66 dBµV A
		0.5 / 5 MHz	73 dBµV QP 60 dBµV A
		5 / 30 MHz	73 dBµV QP 60 dBµV A

Tab. 22: EMC declaration

[3] The emission characteristics of this device enable it to be used in industrial areas and hospital settings (Class A as defined in CISPR 11). If used in a residential environment (for which class B defined in CISPR 11 is normally required), this device may not provide sufficient protection for radio frequency communication services. The user may need to take corrective measures, such as relocating or re-orienting the device.

Test type	Test method	Range of frequencies	Boundaries
Measurement of the radiated electromagnetic field	EN 55011 GR1 CL A[3]	30 / 230 MHz	40 dBµV/m PQ 10 m
		230 / 1000 MHz	47 dBµV/m PQ 10 m

Tab. 22: EMC declaration

Test type	Test method	Test level: healthcare facility
Electrostatic discharge immunity	EN 61000-4-2	Contact: ±8 kV Air: ±2; 4; 8; 15 kV
Immunity to radiated RF electromagnetic fields	EN 61000-4-3	80 MHz, 2.7 GHz 3 V/m Mod AM 80%/1 kHz
		Wireless RF frequencies 9 to 28 V/m Mod AM 80%/1 kHz
Immunity to fast electrical transients and bursts	EN 61000-4-4	AC: ±2 kV - 100 kHz IO >3m: ±1kV - 100 kHz
Immunity to power source voltage surges	EN 61000-4-5	±0.5; 1 kV diff. ±0.5 kV, ±1 kV, ±2 kV common mode
Immunity to conducted interference due to electromagnetic fields	EN 61000-4-6	150 kHz, 80 MHz 3 Vrms Mod AM 80%/1 kHz
		ISM 6 Vrms Mod AM 80%/1 kHz
Immunity to voltage dips and short interruptions	EN 61000-4-11	0% Ut, 10 ms (0°; 45°; 90°; 135°; 180°; 225°; 270°; 315°) 0% Ut, 20 ms 70% Ut, 500 ms 0% Ut, 5 s
Harmonic current emissions	EN 61000-3-2	Class A
Voltage variations, voltage fluctuations, and flicker in public low-voltage power supply networks	EN 61000-3-3	Compliant

Tab. 23: EMC declaration

10 Waste management

10.1 Disposal of packaging

All packaging stemming from the use of the device must be processed in an environmentally friendly manner, with recycling in mind.

10.2 Product

Do not dispose of this device as unsorted municipal waste. Take it to a collection facility for value enhancement, recycling or re-use.

For full information relating to processing of the device once it is no longer in use, see the LUCEA 50-100 decommissioning instructions (ARD01745). Contact your local Getinge representative to obtain a copy of this document.

10.3 Electrical and electronic components

All electrical and electronic components used during the life of the product must be processed in an environmentally friendly manner, in line with applicable local standards.

Notes

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