Instructions for use

Lucea 50-100

IFU 01741 EN 11 2023-04-06

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.

V11 06.04.2023

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
	**NOTICE**	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 Light types

Minor surgical light

Single light located in the patient's environment in an operating room and designed to facilitate treatment and diagnosis procedures which can be interrupted without compromising patient safety in the event of a light failure.

Surgical lighting system

Combination of several surgical lights designed to facilitate treatment and diagnosis operations and to be used in operating rooms. A surgical lighting system must be failsafe and must provide adequate central illumination to light the body of the patient locally even if an initial fault condition occurs.

Example: A combination of at least two minor surgical lights constitutes a surgical lighting system.

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 51].

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.

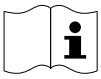
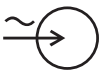
This service lifetime does not apply to consumables such as sterilisable handles.

This 10-year service lifetime applies subject to annual periodic checks being performed by personnel trained and approved by Getinge; see Maintenance schedule [⏩ Page 50]. 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

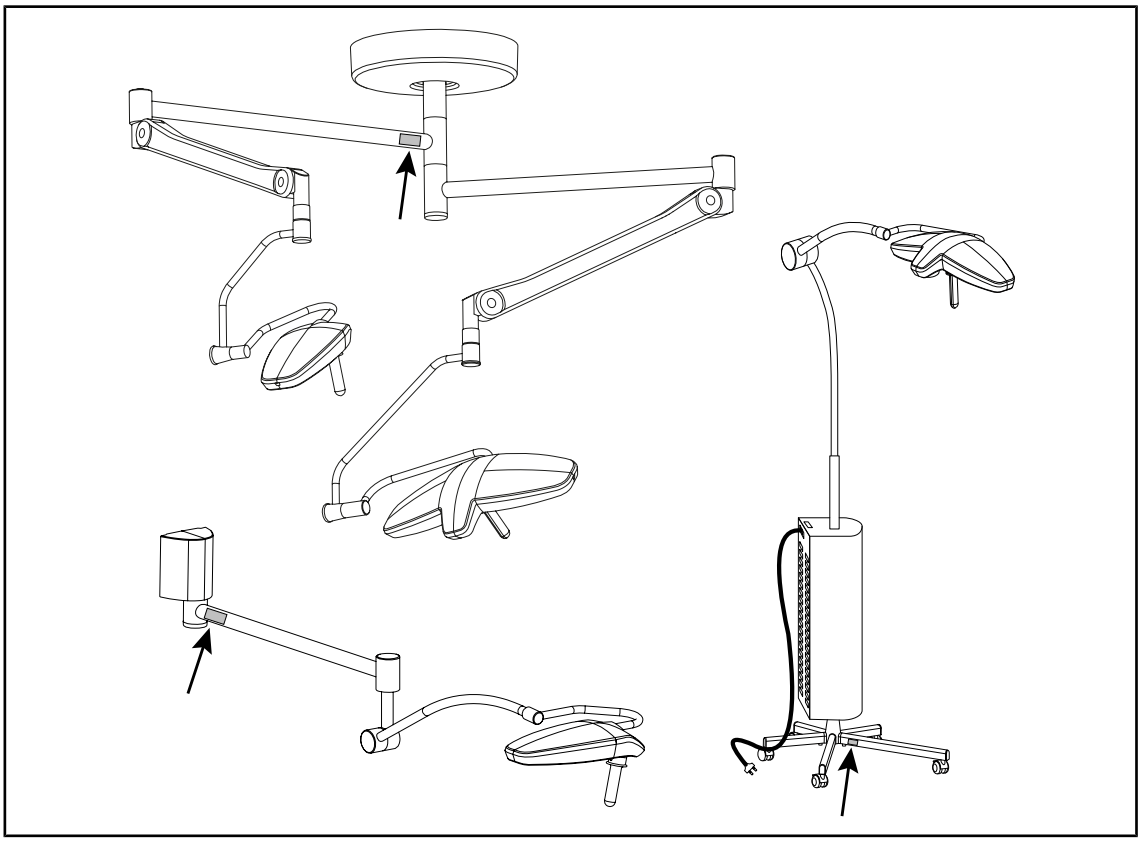


Fig. 1: Location of the product identification label

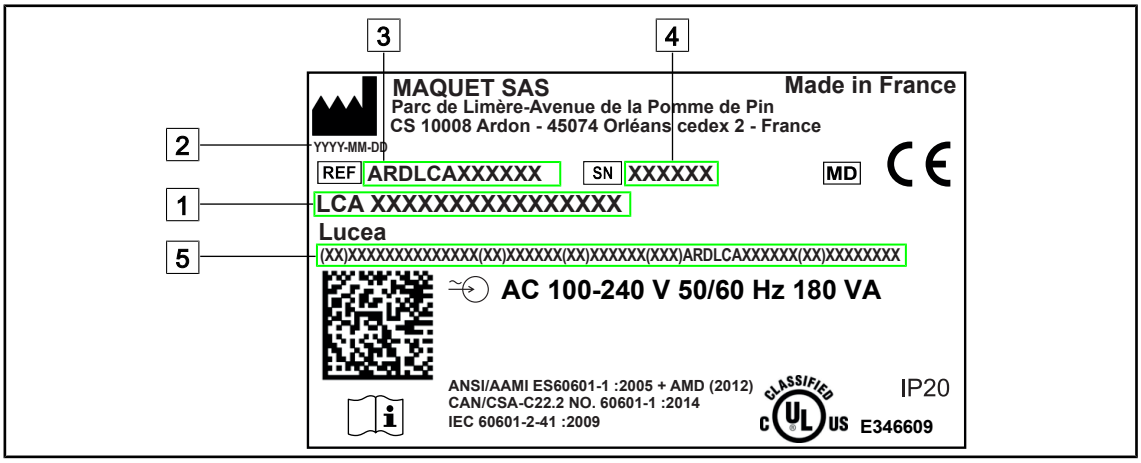


Fig. 2: Example label

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

1.9 Product overview

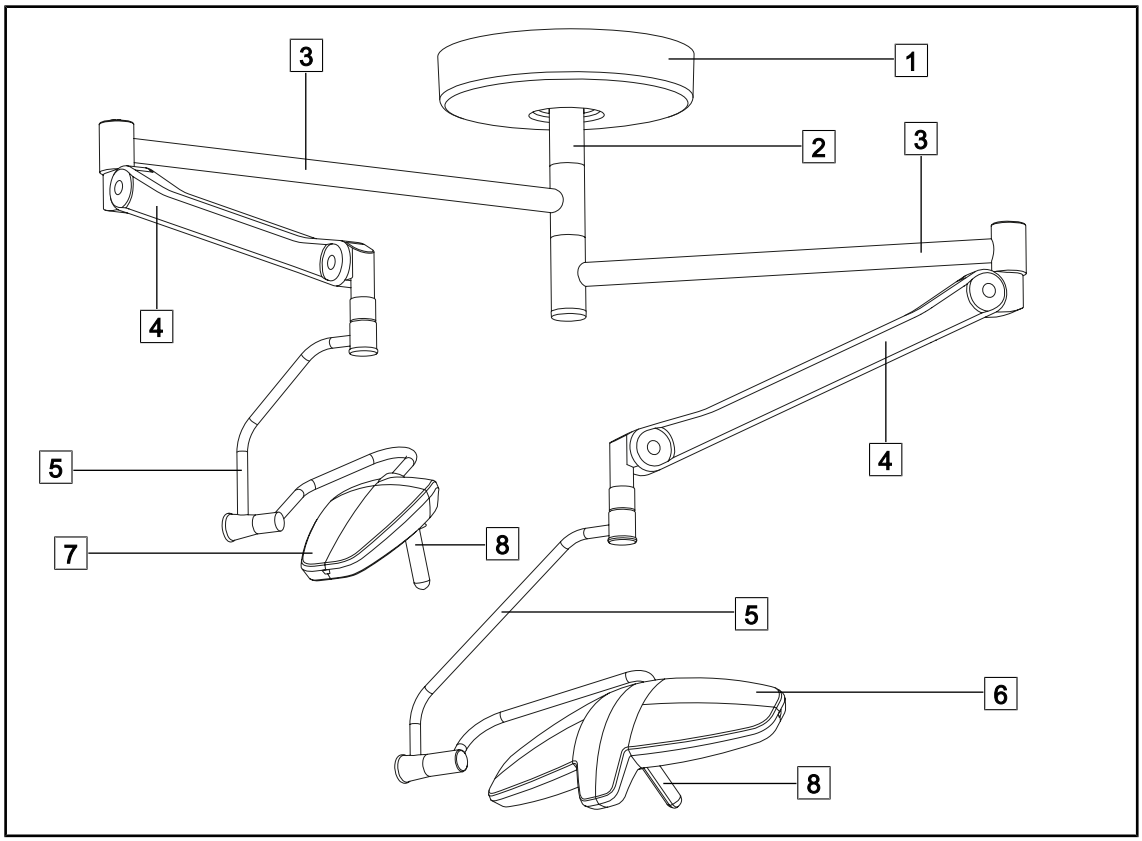


Fig. 3: Typical ceiling-mounted configuration

1	Ceiling cover	5	Double fork
2	Suspension tube	6	LUCEA* 100 lighthead
3	Extension arm	7	LUCEA 50 lighthead
4	DF spring arm	8	STG HLX sterilisable handle

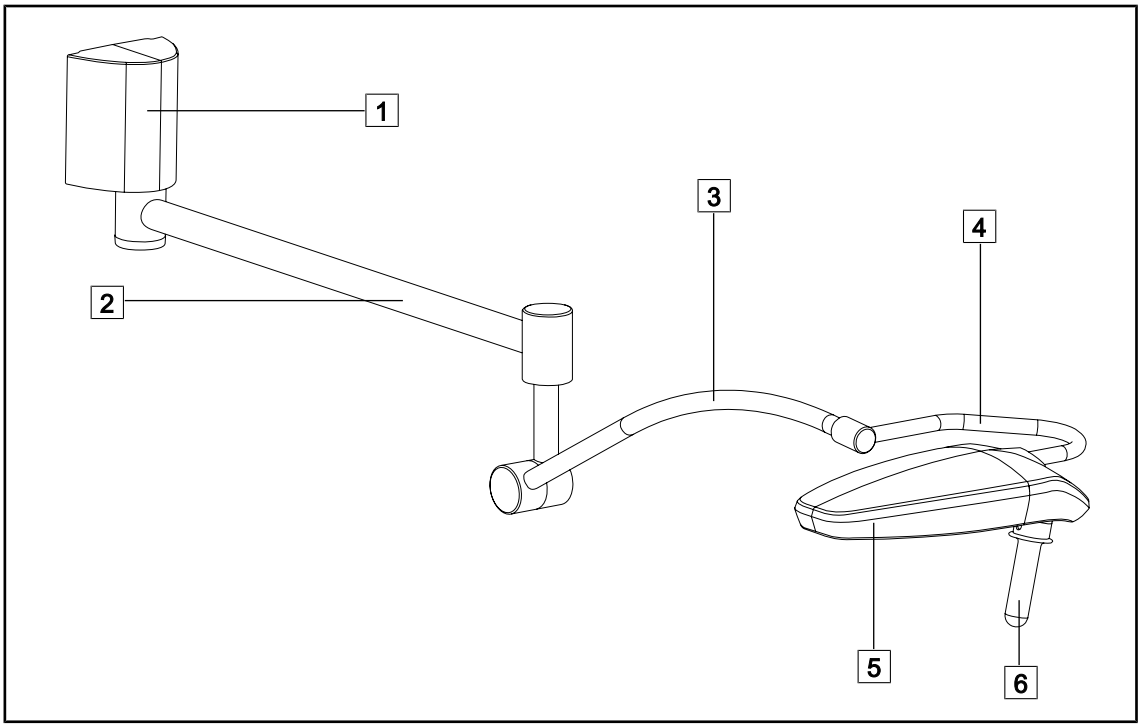


Fig. 4: Typical wall-mounted configuration

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

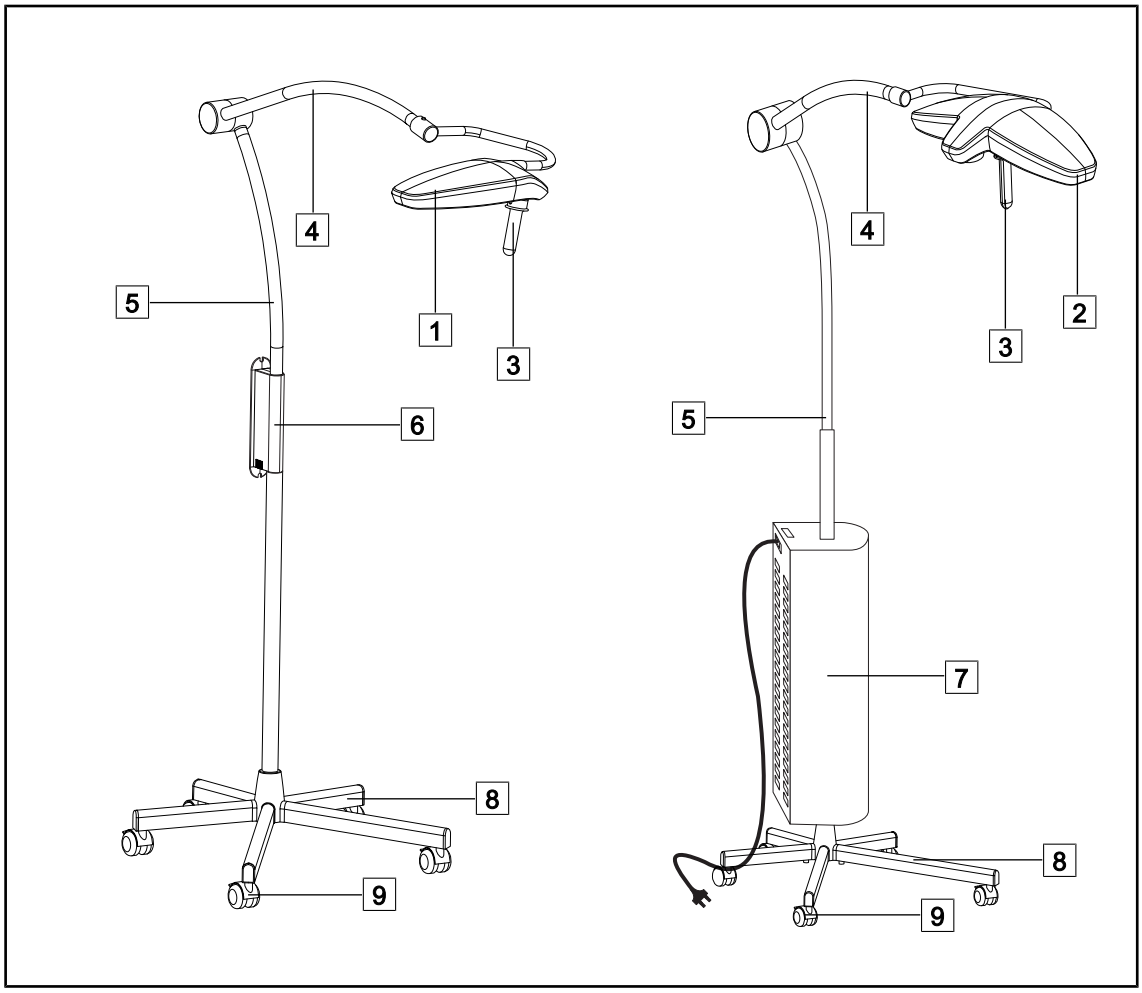


Fig. 5: Typical mobile configurations

1 LUCEA 50 lighthead
2 LUCEA 100 lighthead
3 STG HLX sterilisable handle
4 SF spring arm
5 Pole
6 Power supply without backup
7 Power supply with backup
8 Stand base
9 Casters

1.9.1 Components

1.9.1.1 Lightheads

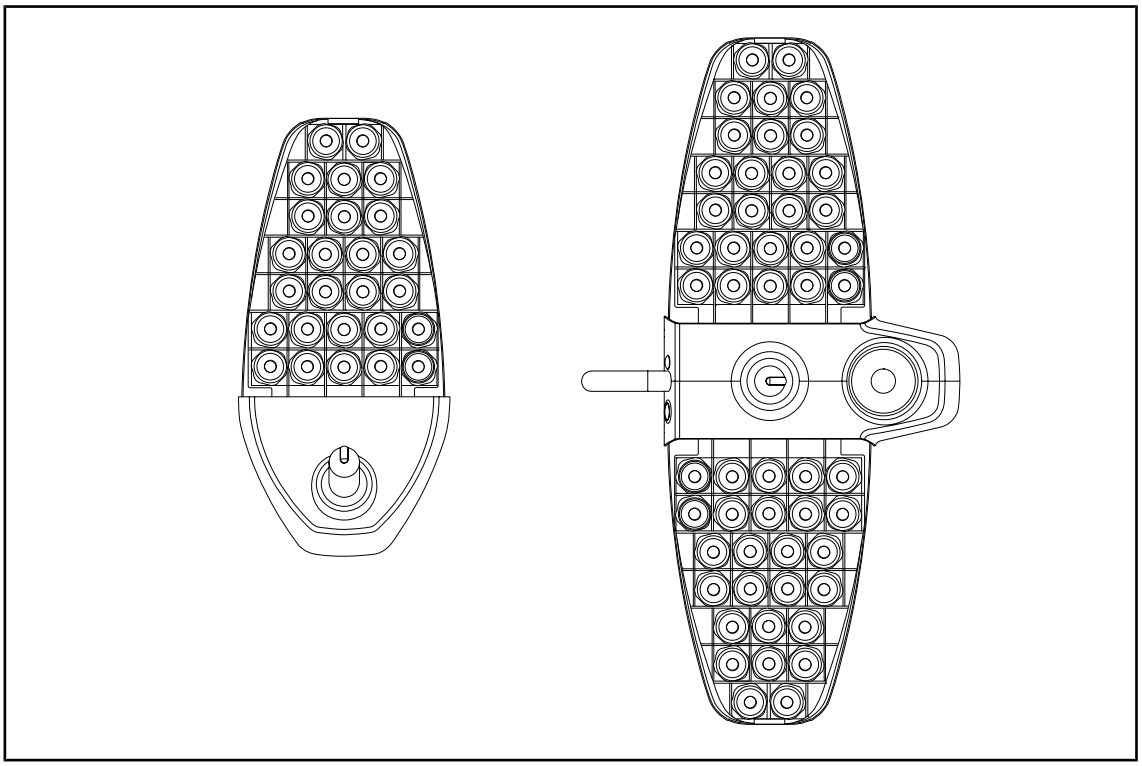


Fig. 6: LUCEA 50 and LUCEA 100 lightheads

Each lighthead comprises the following elements:

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

The LUCEA 100 lighthead features a system for varying the diameter of the light field by turning the sterilisable handle.

FSP function for better electronic management of illumination

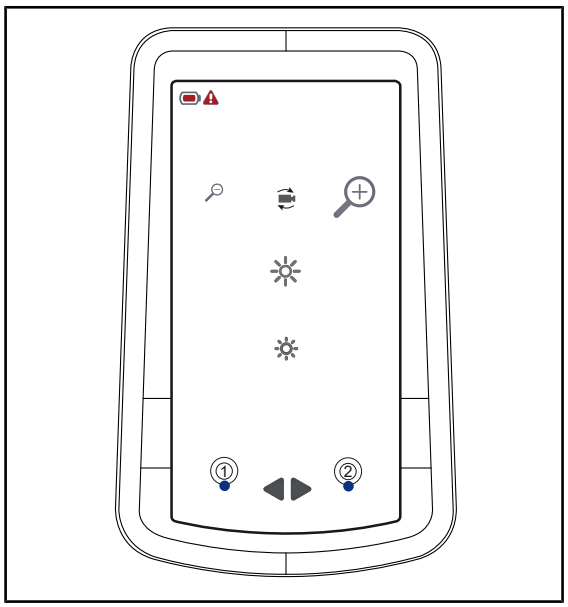
1.9.2 Accessories

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

NOTE

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 ANSI/AAMI ES60601-1:2005/(R)2012 CAN/CSA-C22.2 No. 60601-1:14 EN 60601-1:2006/A1:2013/ A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-2-41:2009+AMD1:2013 EN 60601-2-41:2009/ A11:2011/A1:2015	Medical electrical equipment – Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
IEC 60601-1-2:2014 EN 60601-1-2:2015	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

Tab. 4: Compliance with product standards

Reference	Title
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
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
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

Tab. 6: Environmental standards and regulations

Reference	Year	Title
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
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 Hazardeous 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

Tab. 7: Compliance with market standards

Country	Reference	Year	Title
Taiwan	TPAA 2018-01-31	2018	Taiwanese Pharmaceutical Affairs Act
UK	Act	2021	Medical Devices Regulations 2002 No. 618
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

LUCEA 50 and LUCEA 100 lightheads are surgical lights designed to illuminate the body of a patient during surgical operations, diagnostics and treatment.

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 Indications

The LUCEA 50-100 range is intended to be used for any type of surgery, treatment or examination requiring a specific type of lighting.

1.11.4 Inappropriate use

- Use of a damaged product (e.g. lack of maintenance).
- In a setting other than a professional healthcare environment (e.g. home care).
- Use of the mobile light on battery power (intended for emergency use only).

1.11.5 Contraindications

This product does not have any contraindications.

1.12 Primary purpose

The primary purpose of the LUCEA 50-100 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 58] chapter.

NOTE

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 burns
The high intensity of the light source results in a risk of burns to the eye if the user looks directly towards the lighthead.

The patient's eyes must be protected during facial surgery. Users must not look directly into the light source.

2.2.4 Infection

WARNING!

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

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

3 Control interfaces

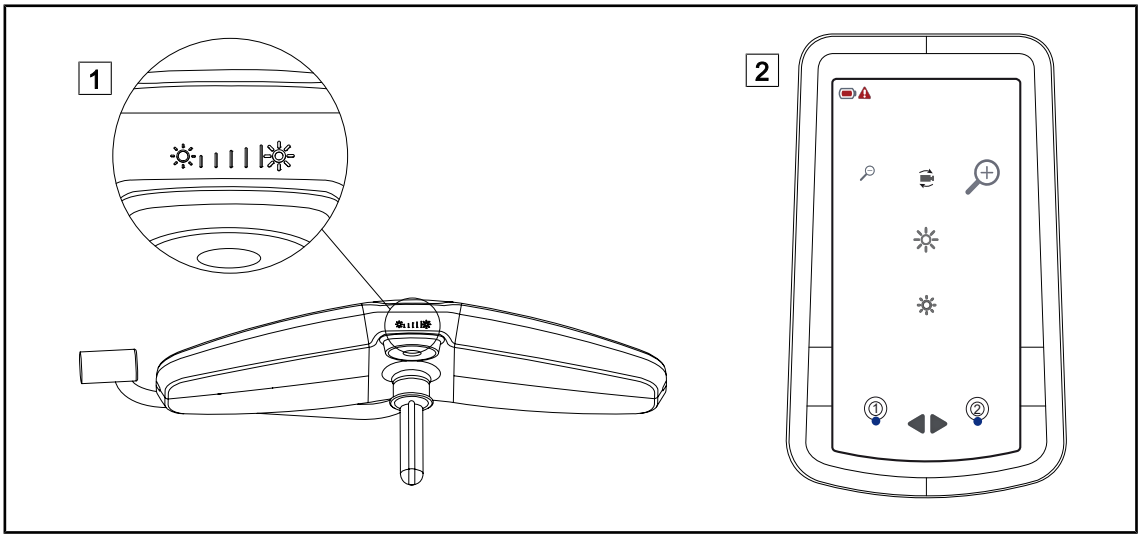


Fig. 8: LUCEA 50-100 control interfaces

1 Lighthead control keypad

2 Remote control

4 Use

4.1 Daily inspections before use

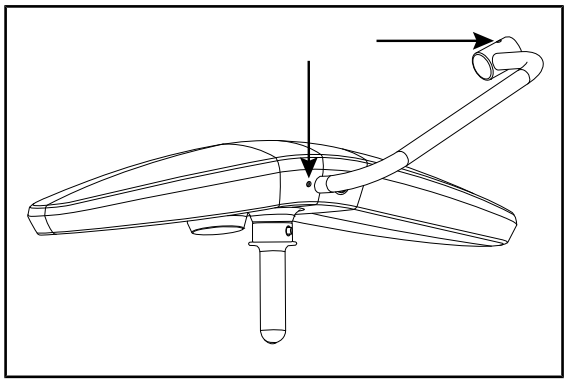


Fig. 9: Integrity of the lightheads

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. If a problem is noted, contact technical support.

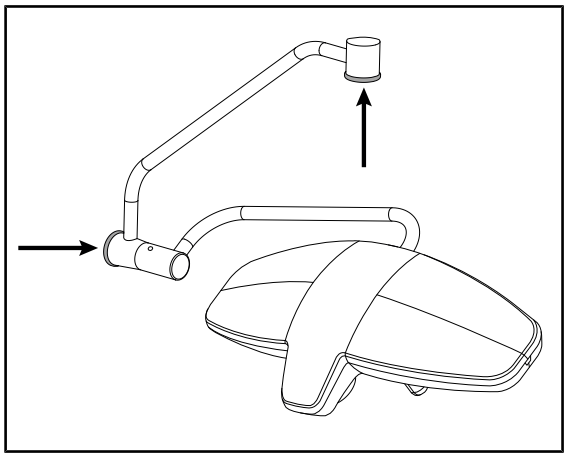


Fig. 10: DF fork plugs

Fork plugs (DF version only)

1. Check that the grey plugs are correctly installed.
2. If a problem is noted, contact technical support.

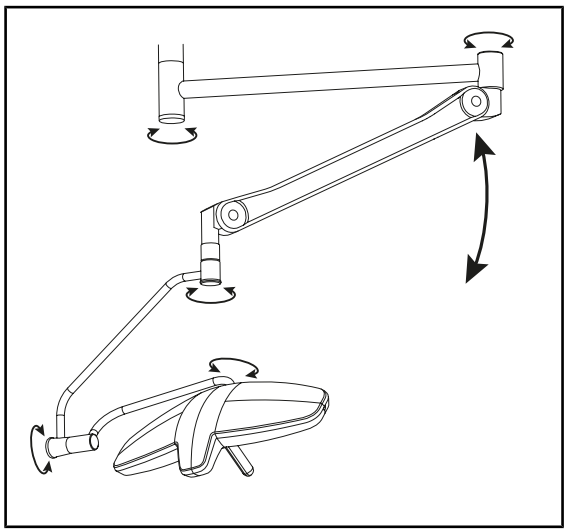


Fig. 11: Stability/drift

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.

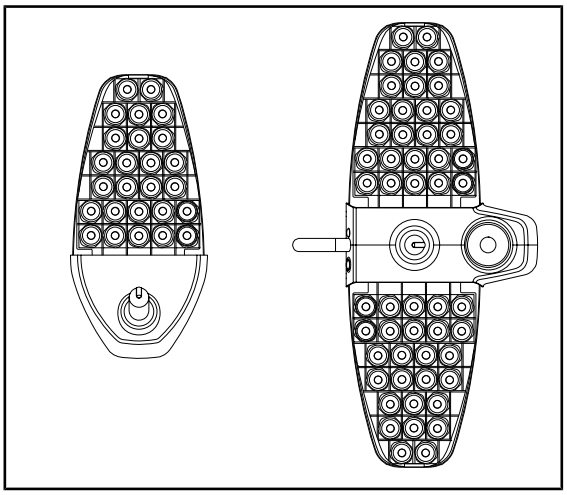


Fig. 12: Operation of LEDs

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.

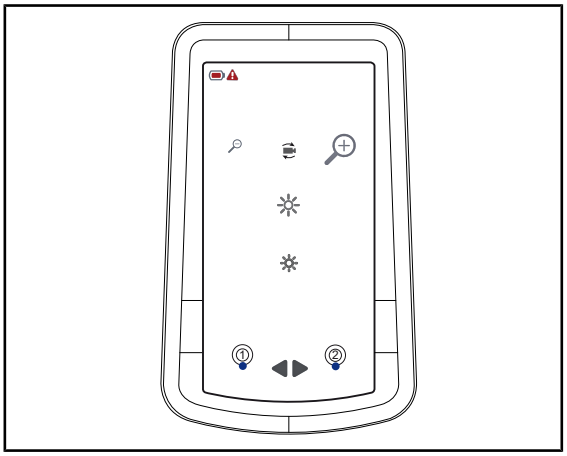


Fig. 13: Remote control

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.

The video camera compatible with the LUCEA 100 lightheads is no longer available since January 2019.

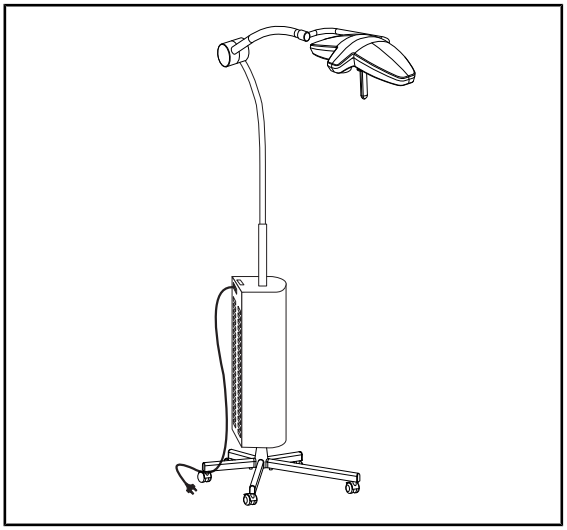


Fig. 14: Power lead for mobile version

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

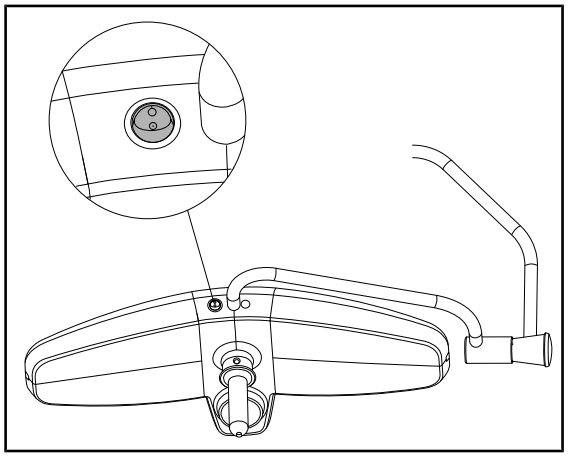


Fig. 15: Turning the lighthead on and off

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

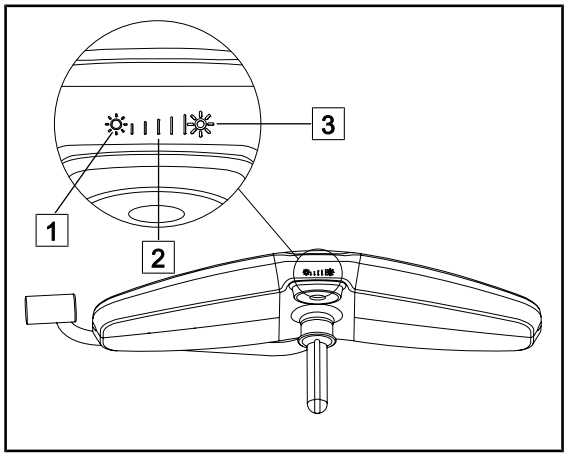


Fig. 16: Adjusting the illumination via the keypad

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].

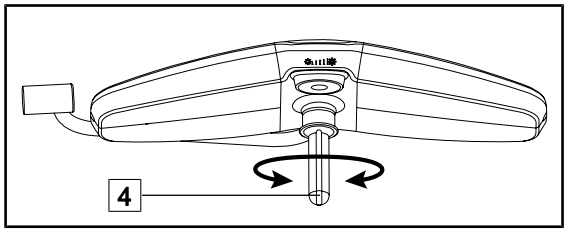


Fig. 17: Adjusting the light field diameter

Adjusting the light field diameter (on LUCEA 100 only)

1. Turn the handle [4] clockwise to enlarge the light field or counter-clockwise to reduce the light field.

4.2.2.2 From the remote control

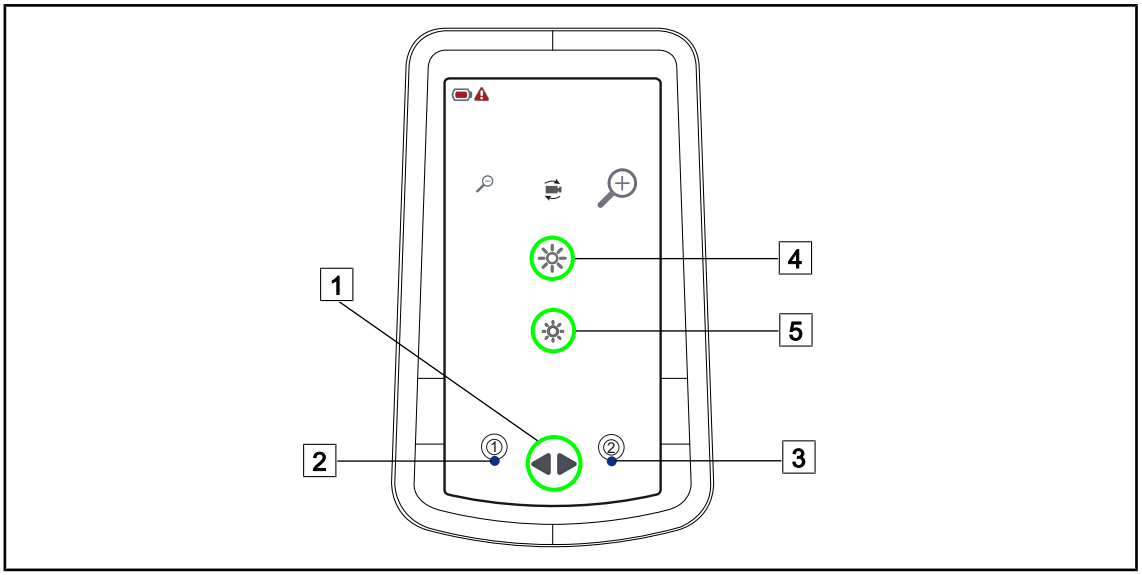


Fig. 18: Adjusting the illumination via the remote control

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 Controlling the camera (not sold since January 2019)

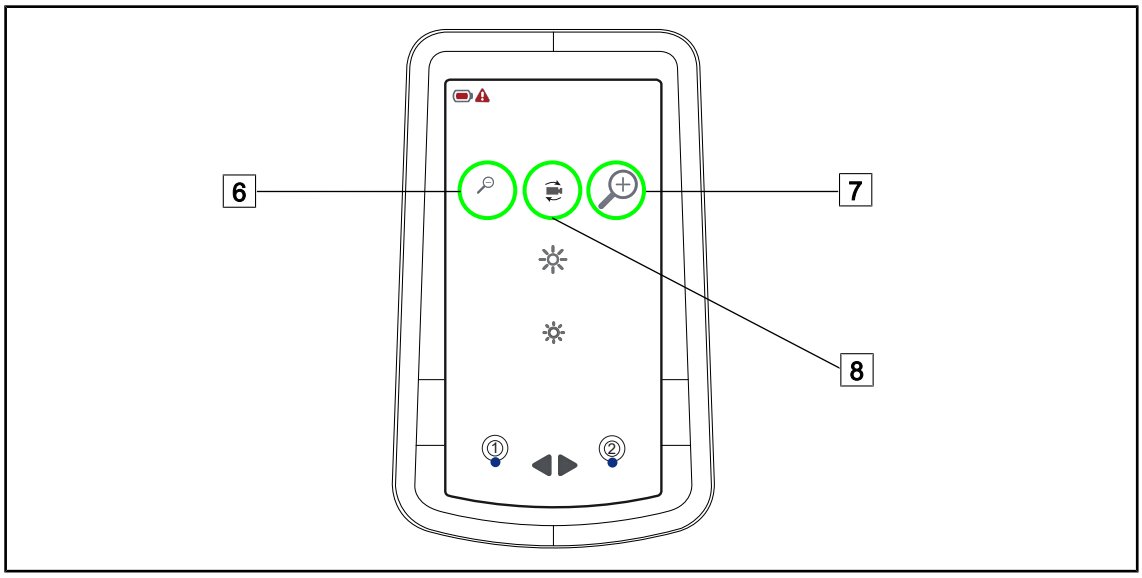


Fig. 19: Controlling the LUCEA 100 camera

Adjusting the camera zoom

1. Press **Increase Zoom** 7 or **Decrease Zoom** 6 to adjust the camera zoom.

Adjusting the image position

1. Press **Rotate camera** 8 to adjust the image position from 0° to 180°.

4.4 Positioning the light

4.4.1 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.

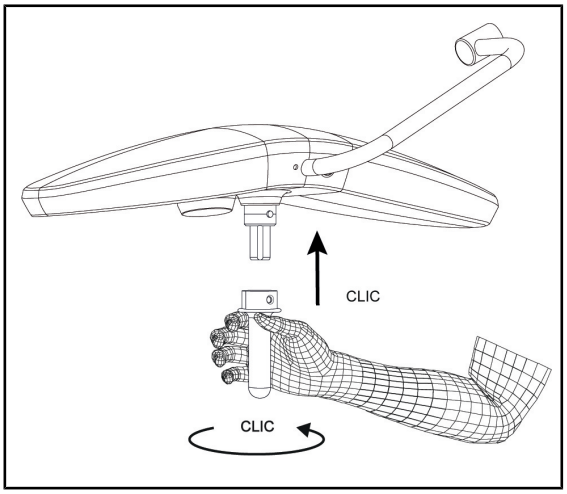


Fig. 20: Installing the sterilisable handle

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.

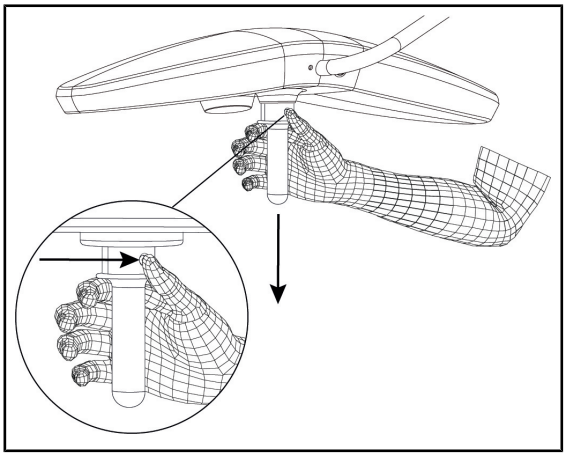


Fig. 21: Removing the sterilisable handle

Removing a sterilisable handle from the lighthead

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

4.4.2 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.

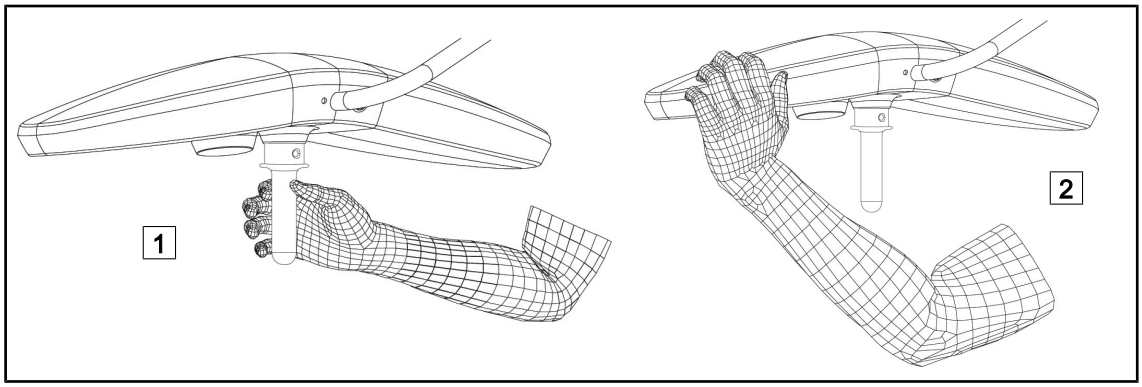


Fig. 22: Manoeuvring the lighthead

- 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

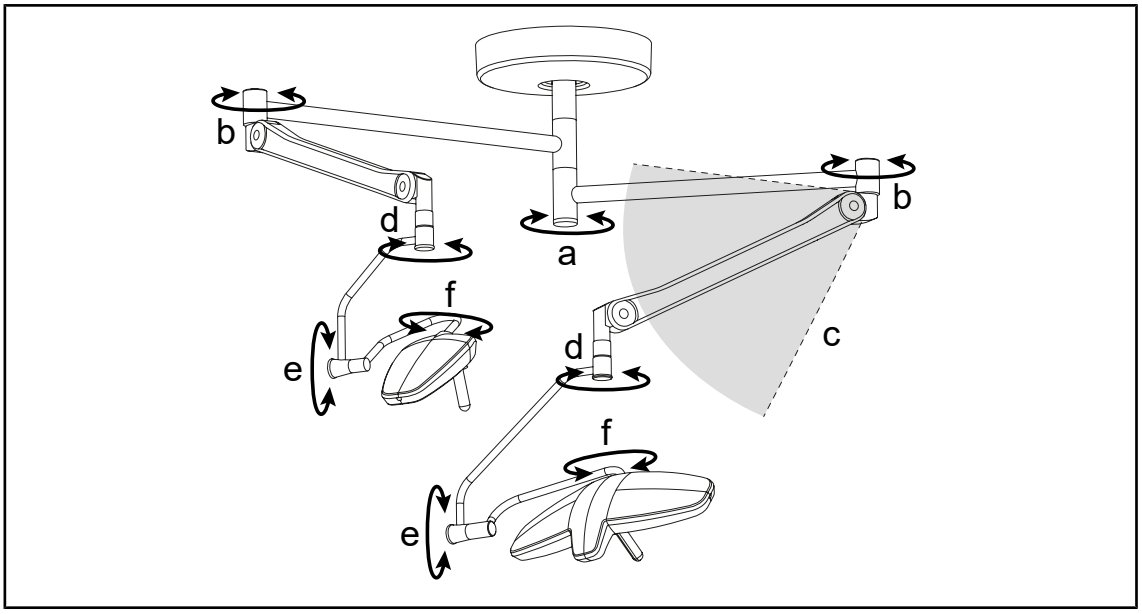


Fig. 23: Possible rotations of the DF ceiling-mounted light

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

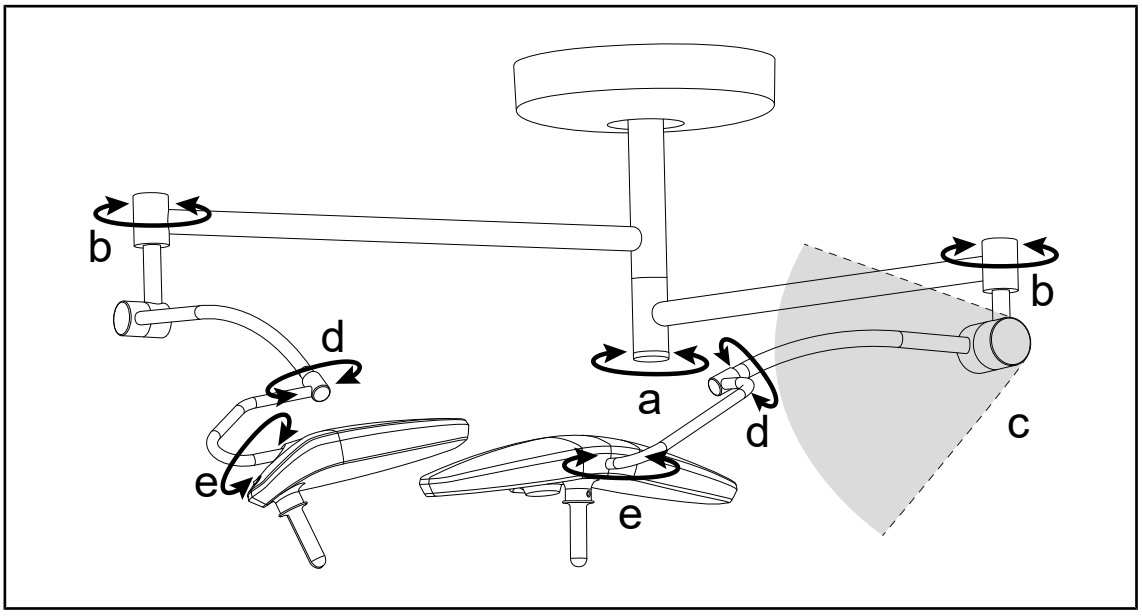


Fig. 24: Possible rotations of the SF ceiling-mounted light

a	b	c	d	e
infinite	infinite	+5° / -75° (LCA50) +10° / -90° (LCA100)	180°	320°

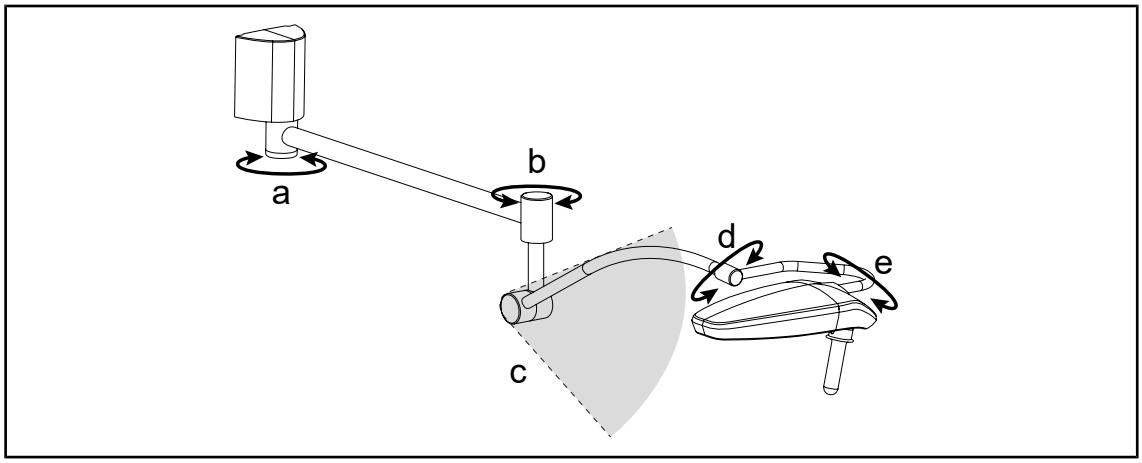


Fig. 25: Possible rotations of the wall-mounted light

a	b	c	d	e
180°	infinite	+5° / -75° (LCA50) +10° / -90° (LCA100)	180°	320°

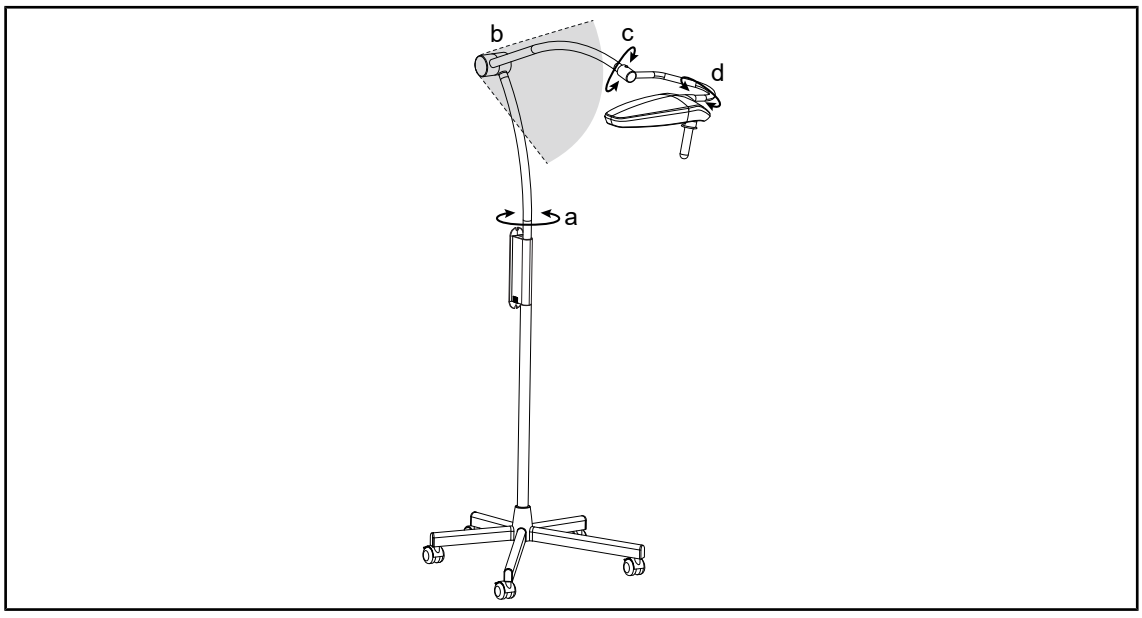


Fig. 26: Possible rotations of the mobile light

a	b	c	d
55°	+30° / -80° (LCA50) +10° / -85° (LCA100)	180°	320°

4.4.3 Pre-positioning examples

NOTE

To optimise shadow management, it is advisable to position the lightheads so that they are aligned with the surgeon.

Excisions, incisions, biopsies, sutures

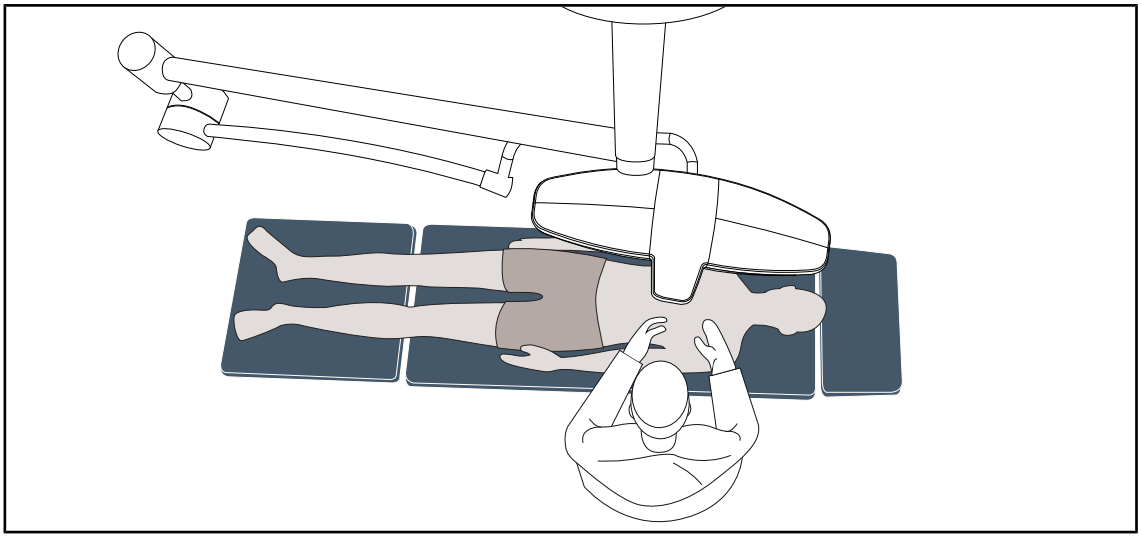


Fig. 27: Pre-positioning for excisions, incisions, biopsies, and sutures

- The lighting is positioned perpendicular to the area of interest, taking care not to obstruct the LEDs with the surgeon's head.
- In the event that the single-fork lighthead is controlled by the sterile team, it is preferable to position the fork on the side opposite to the operator.

ENT, neurology, stomatology, ophthalmology

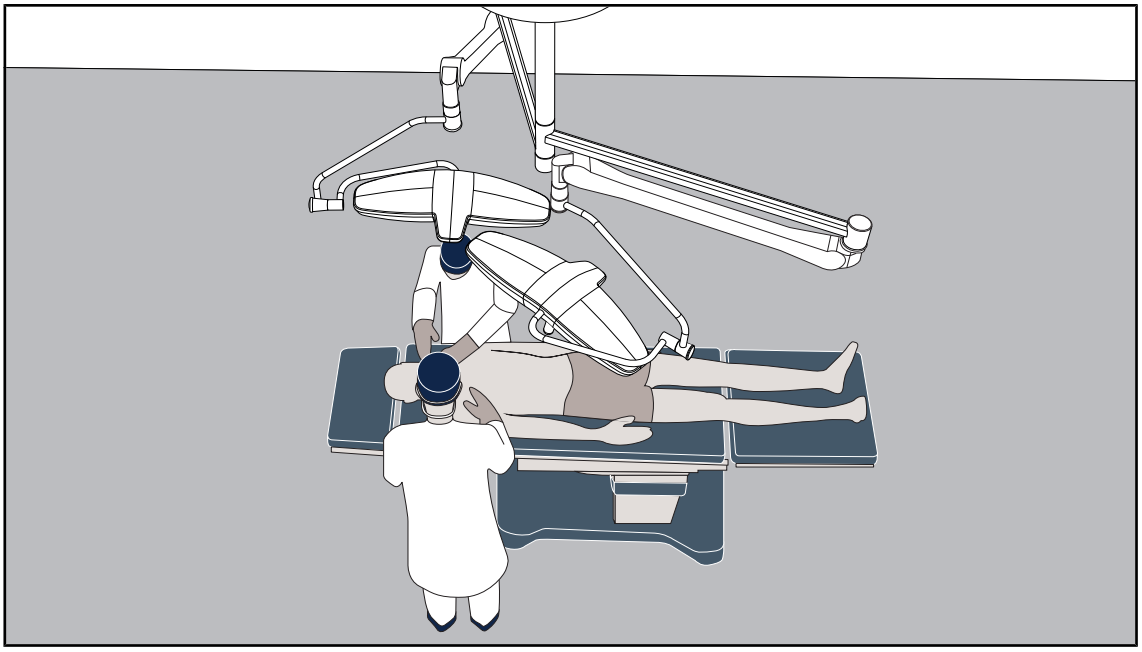


Fig. 28: Pre-positioning for ENT, neurology, stomatology, or ophthalmology

The lights should be positioned above the area of interest:

- The main lighthead must be perpendicular to the cavity, taking care not to obstruct the LEDs. This component provides in-depth vision.
- The secondary lighthead must also be tilted so as to point to the cavity. It should preferably be controlled so as to direct the light beam at different angles inside the cavity.

4.5 Remote control

4.5.1 Registering the remote control with the light

NOTE

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

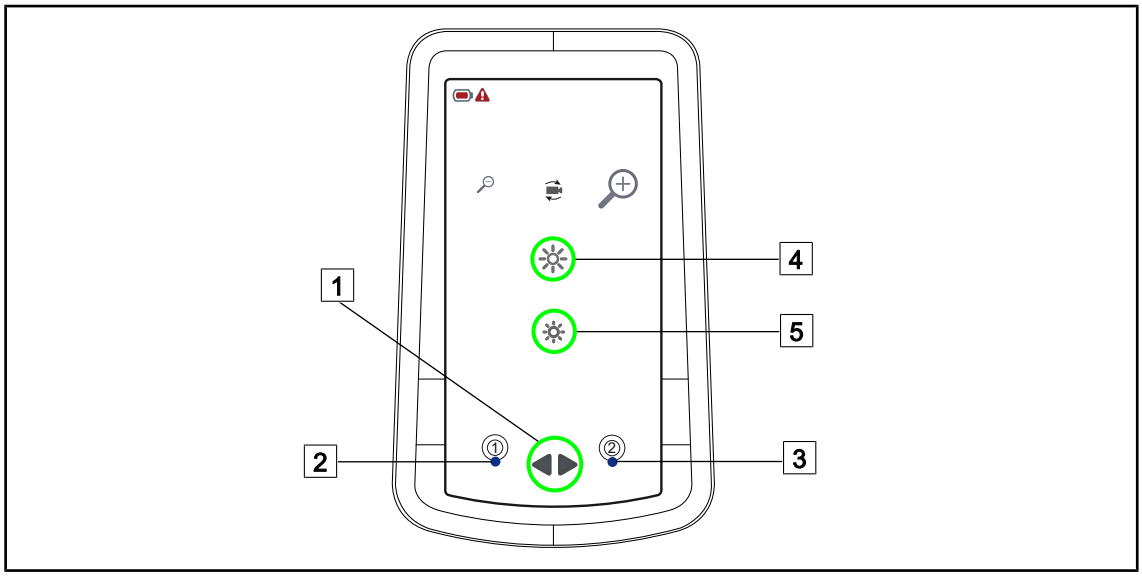


Fig. 29: Registering a remote control with a light

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.

4.5.2 Changing the remote control batteries

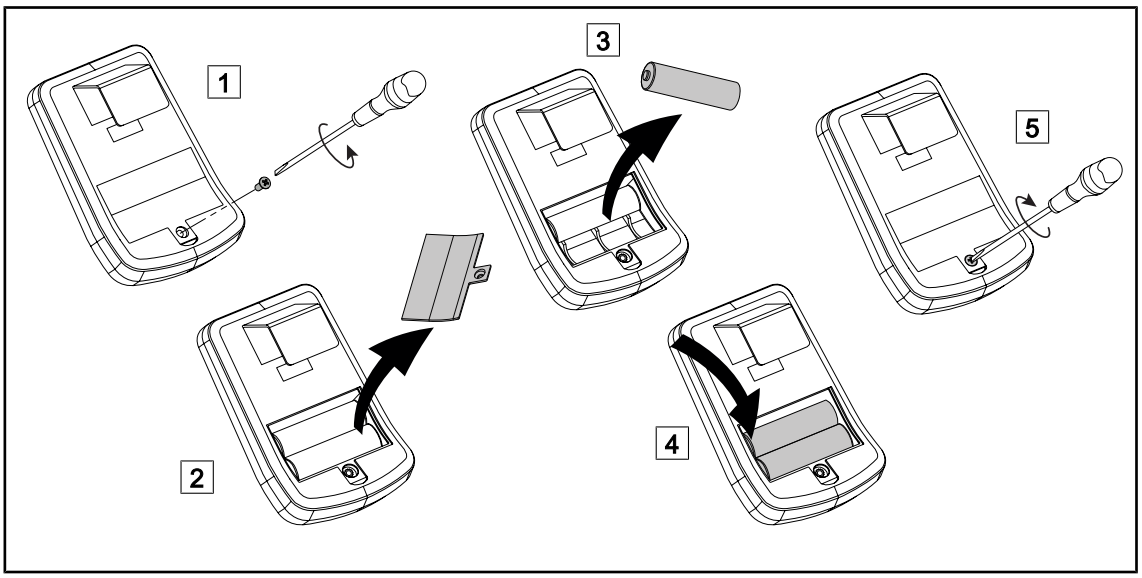


Fig. 30: Replacing the remote control batteries

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].

4.6 Mobile light

4.6.1 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.

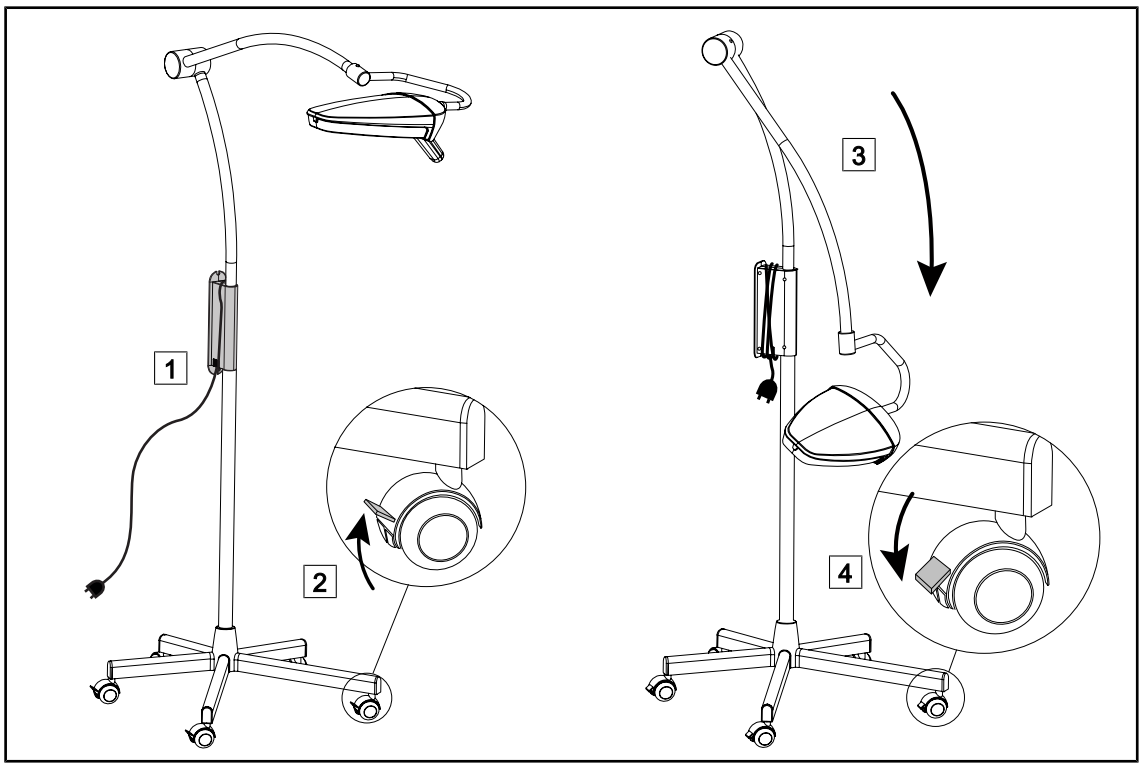


Fig. 31: Moving a mobile light

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.

4.6.2 Battery system operation

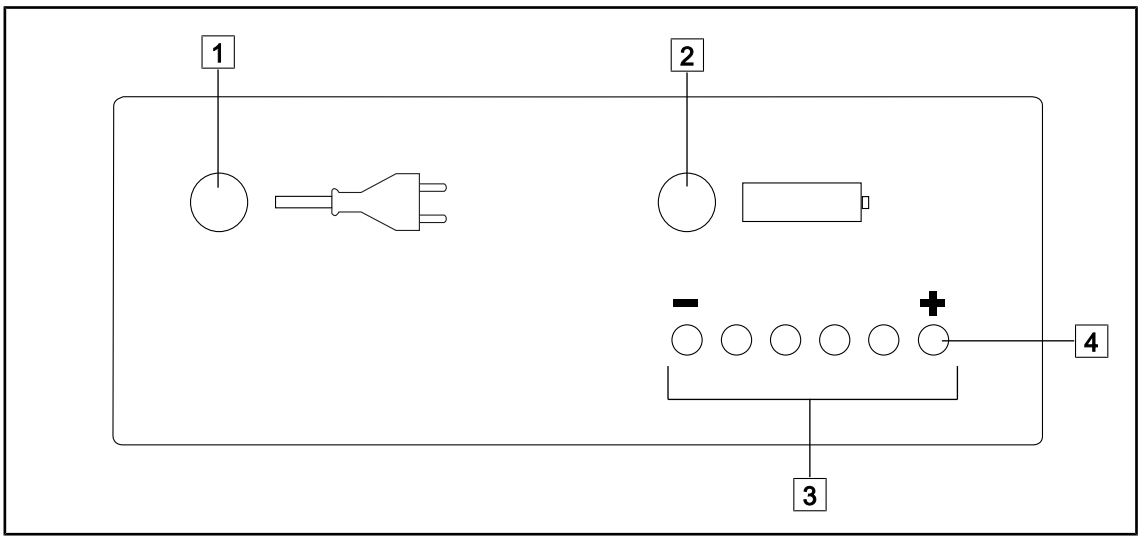


Fig. 32: Battery system indicators

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.

NOTE

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).

NOTE

If the batteries are fully charged, the LUCEA 50 can run on battery power for at least three hours and the LUCEA 100 for eight hours.

4.6.3 Battery state

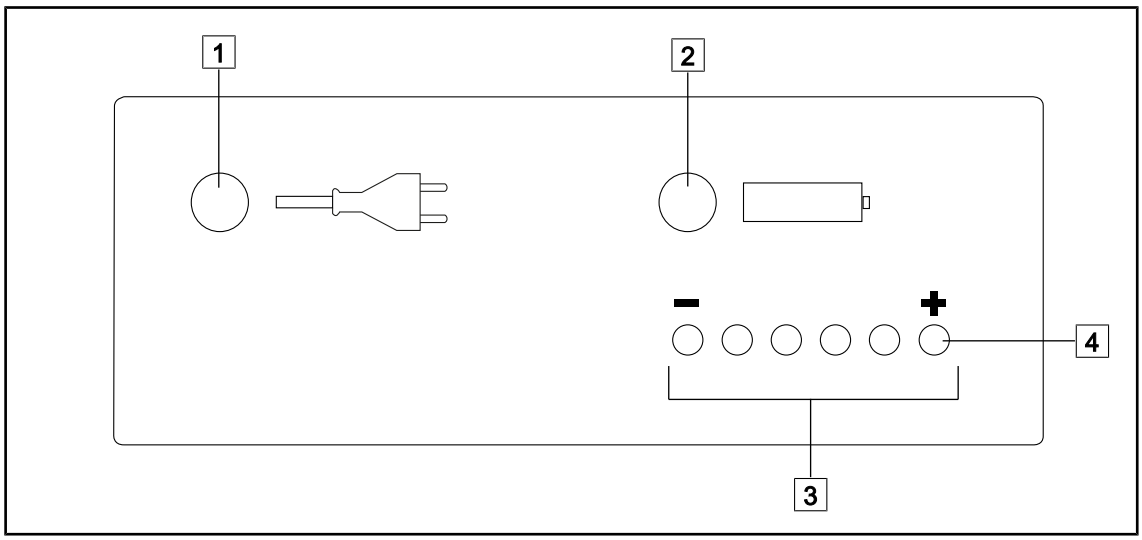


Fig. 33: Battery indicators

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 (LCA50) or 4 hours (LCA100)	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

4.6.4 Mobile light pre-positioning example

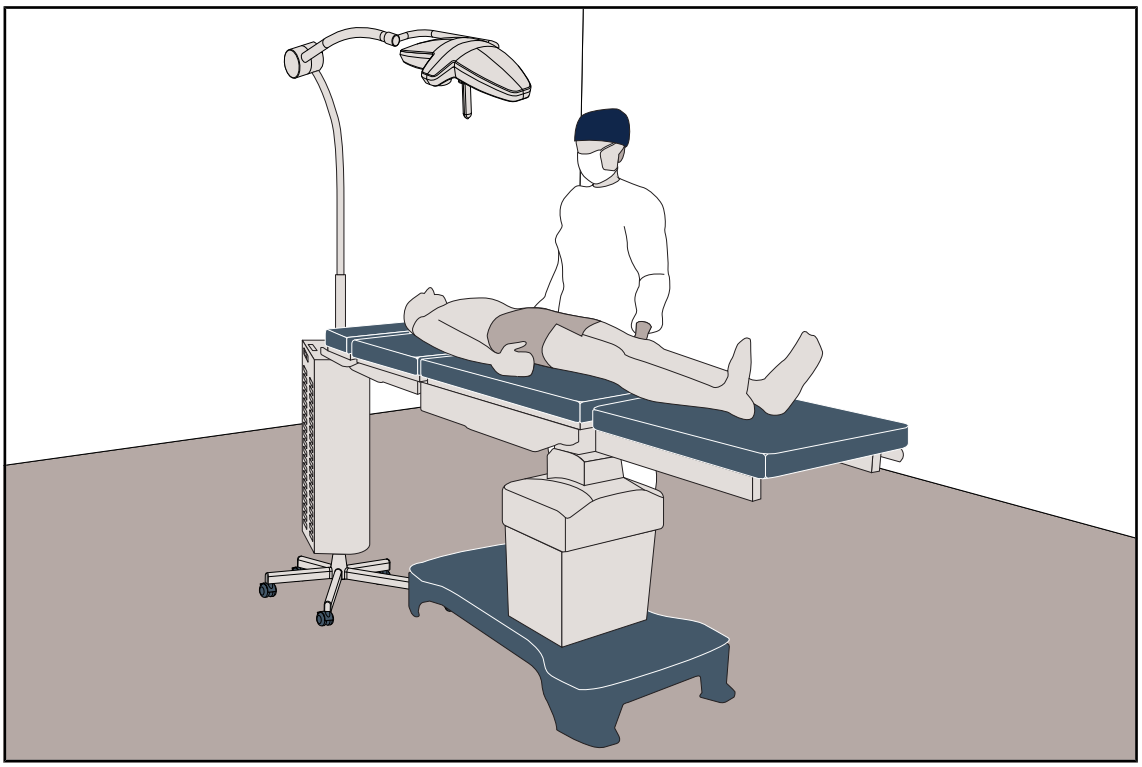


Fig. 34: LUCEA 100 mobile light pre-positioning example

- The mobile unit must be positioned so that the base and its wheels do not prevent the operating room personnel from moving around freely.
- Depending on the area of interest, the mobile unit can be installed on the head end or on the foot end of the operating table.
- The lighthead is positioned perpendicular to the area of interest.

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.

NOTE

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

NOTE

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 inspections should be performed as follows. During the guarantee period, maintenance and inspections 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.

8.1 Maintenance schedule

This table summarises the main maintenance steps to be performed during the product lifetime.

Description	Maintenance interval		
	1 year	3 years	6 years
General maintenance of the device	X		
All brakes on the device	X		
Suspension mounting screws			X
Spring arm locking screws			X
Spring arm safety segment			X
Batteries		X	

Tab. 17: Maintenance schedule

8.2 Contact

The contact details of your local Getinge representative can be found on **https://www.getinge.com/int/contact**.

9 Technical specifications

9.1 Optical specifications

Specifications	LUCEA 50	LUCEA 100	Tolerance
Nominal illumination	60,000 lx	120,000 lx	± 10 %
Diameter d10	22 cm		± 3 cm
Diameter d50/d10	0,55		± 0,05
Illumination depth at 20%	190 cm	105 cm	± 15%
Illumination depth at 60%	120 cm	55 cm	± 15%
Colour temperature	4 500 K		± 400 K
Colour rendering index (Ra)	96		± 4
Special colour rendering index (R9)	92		+10 / -20
Irradiance (Ee)	< 250 W/m²	< 500 W/m²	–
Radiant energy	3.9 mW/m²/lx		± 0.4
UV illumination	≤ 0.7 W/m²		–
FSP system	Yes		–

Tab. 18: Table of LUCEA 50-100 optical data

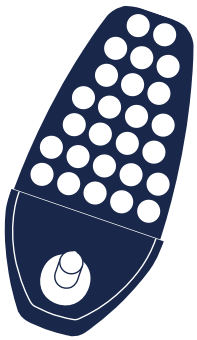
Specifications	LUCEA 50	LUCEA 100	Tolerance
With one mask	5%	42%	± 10
With two masks	58%	49%	± 10
At base of tube	100%	96%	± 10
With one mask, at base of tube	5%	38%	± 10
With two masks, at base of tube	58%	46%	± 10

Tab. 19: LUCEA 50-100 residual illumination

NOTE

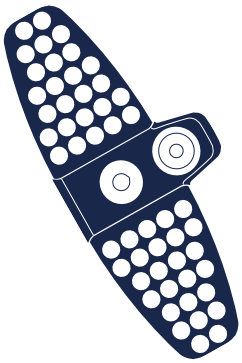
These values are measured with the small light field diameter.
The test value for the masks must necessarily remain above 0%.

LED Life Time
Certificate



Lucea 50

Lucea 100



IES LM-80 Test report for LED

According to **IES LM-80 standard**, lumen maintenance is the remaining luminous flux output (% of the initial output) at a selected operating time.

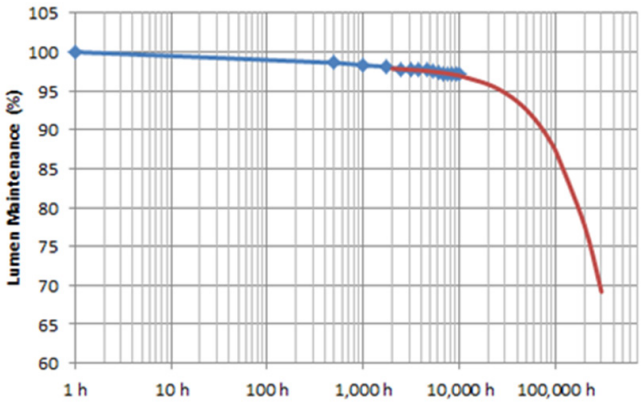
According to **IES TM-21 standard**, L70(D) is the lumen maintenance life expressed in hours where 70% of initial lumen output is maintained, with D the total duration time for the effective tests, in hours. ***The life projection is limited to 6 times the total duration of the effective tests.***

Chosen conditions for IES LM-80 Test:
Case Temperature: 85°C
Drive Current: 500 mA
Total Duration Time (D): 10,000 hours

Lumen Maintenance = 97.1 %

Average L70 Extrapolation following IES TM-21 method:

L70(10,000) ≥ 60,000 hours

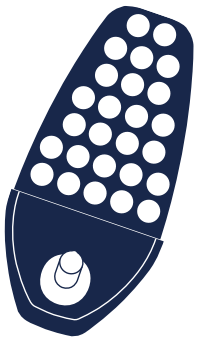


Extrapolation for LED in Cupola

According to the driving and thermal conditions in the cupola(s), the average L70 Life Projection following IES TM-21 method gives:

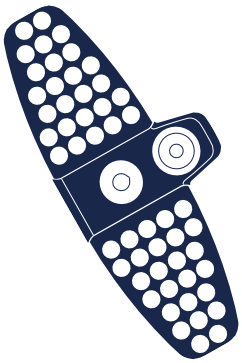
LED Projected Life Time: L70(10,000) ≥ 60,000 hours

EN 62471
Certificate



Lucea 50

Lucea 100



Measurements conditions

The irradiance measurements are performed at 1 meter, which is considered the working distance of the light.
The radiance measurements are performed with a field of view of 11 mrad, which is considered representative of the usual eye's exposure (several short time exposures).
The measurements are performed for an illuminance of 130,000 lux for Lucea 100 and 60,000 lux for Lucea 50.

The measurements and calculation are performed according to EN 62471. Only the worst values of each settings and cupolas are summarized below. Please note that the official Group limits may not be relevant for the specific use of surgical lights.

Measurements results for Artificial Optical Radiations

Irradiance results		
	Lucea 50	Lucea 100
E_H	250 $W.m^{-2}$	500 $W.m^{-2}$
E_S	7.82 10^{-6} $W.m^{-2}$	1.56 10^{-5} $W.m^{-2}$
E_{UVA}	0.184	0.368
E_{IR}	0.00	0.00

Radiance results		
	Lucea 50	Lucea 100
L_B 11 mrad	5,800 $W.m^{-2}.sr^{-1}$	5,800 $W.m^{-2}.sr^{-1}$
L_R 11 mrad	77,700 $W.m^{-2}.sr^{-1}$	77,700 $W.m^{-2}.sr^{-1}$

For Blue light risk, the EN 62471 classification is Risk Group 1.**
For all other risks, the EN 62471 classification is Exempt Group*.

Case of Eye Surgery: Maximum time allowed for a patient's eye under the cupola (positioned at the center of the light patch), depending upon Illuminance:

	Illuminance Settings	Time without any risk
Lucea 50	Maximum (60,000 Lux)	3 minutes
	Minimum (24,000 Lux)	7 minutes
Lucea 100	Maximum (120,000 Lux)	3 minutes
	Minimum (54,000 Lux)	7 minutes

**Exempt Group (RG 0): where no optical hazard is considered reasonably foreseeable, even for continuous, unrestricted use.*
***Risk Group 1 (RG 1): products are safe for most use applications, except for very prolonged exposures where direct ocular exposures may be expected*

9.2 Electrical characteristics

Specifications	Values
Supply voltage	100-240 Vac, 50/60 Hz
Power consumption, LUCEA 50 configuration	60 VA
Power consumption, LUCEA 100 configuration	120 VA
Power consumption, DUO L50/100	180 VA
Power consumption, DUO L50	120 VA
Power consumption, DUO L100	240 VA
Power consumption, L50 Mobile configuration, without batteries	60 VA
Power consumption, L100 Mobile configuration, without batteries	120 VA
Power consumption, L50 Mobile configuration, with batteries	145 VA
Power consumption, L100 Mobile configuration, with batteries	
Supply voltage	24 Vac, 50/60 Hz, 24 Vdc
Battery type	Lead gel
Minimum battery lifetime, LUCEA 50 mobile	3 hours
Minimum battery lifetime, LUCEA 100 mobile	8 hours
Charge time for Lucea 50 mobile batteries	3 hours
Charge time for Lucea 100 mobile batteries	15 hours
Fuses	7.5A - 32
240 Vac consumption	0,6 A
100 Vac consumption	1,33 A

Tab. 20: LUCEA 50-100 electrical specifications

9.3 Mechanical specifications

9.3.1 Light

Specifications	Values
Weight, LUCEA 50 mobile without batteries	11 kg
Weight, LUCEA 100 mobile without batteries	24 kg
Weight, LUCEA 50 mobile with batteries	22 kg
Weight, LUCEA 100 mobile with batteries	63 kg
Length of mains supply cable	2/4 m
Vertical reach of spring arm, LCA 50 Mobile	+30° / -80°
Vertical reach of spring arm, LCA 100 Mobile	+10° / -85°

Tab. 21: 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. 22: 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 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.

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.

NOTE

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

Type of test	Test methods	Range of frequencies	Boundaries
Measurement of conducted emissions on the main ports	EN 55011 GR1 CL A[2]	0.15 - 0.5 MHz	66 dBµV - 56 dBµV QP 56 dBµV - 46 dBµV A
		0.5 - 5 MHz	56 dBµV PQ 46 dBµV A
		5 - 30 MHz	60 dBµV PQ 50 dBµV A
Measurement of the radiated electromagnetic field	EN 55011 GR1 CL A[2]	30 - 230 MHz	40 dBµV/m PQ 10 m
		230 - 1000 MHz	47 dBµV/m PQ 10 m

Tab. 23: EMC declaration

Type of test	Test methods	Test level: Healthcare facility.
Electrostatic discharge immunity	EN 61000-4-2	Contact: ± 8kV Air: ± 2; 4; 8; 15 kV
Immunity to radiated 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: ± 1 kV - 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

Tab. 24: EMC declaration

[2] 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.

Type of test	Test methods	Test level: Healthcare facility.
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

Tab. 24: 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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