Instructions for use

LUCEA 10-40

IFU 01701 EN 13 2024-10-01

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.

V13 01.10.2024

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. ARD01700)
- Repair manual (Ref. ARD01702)
- Installation manual (Ref. ARD01704)
- Decommissioning instructions (Ref. ARD01705)

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 32].

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.

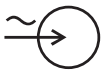
This service lifetime does not apply to consumables such as sterilisable handles.

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

1.8 Location and explanation of the device identification label

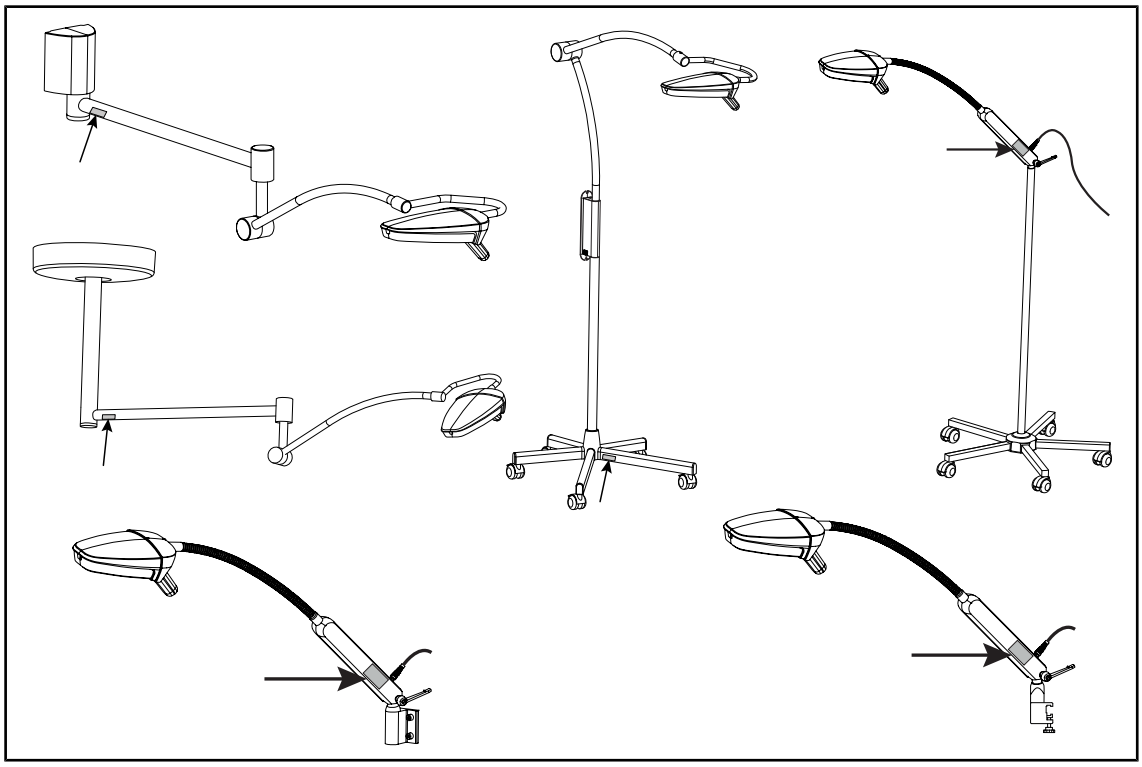


Fig. 1: Location of the product identification label

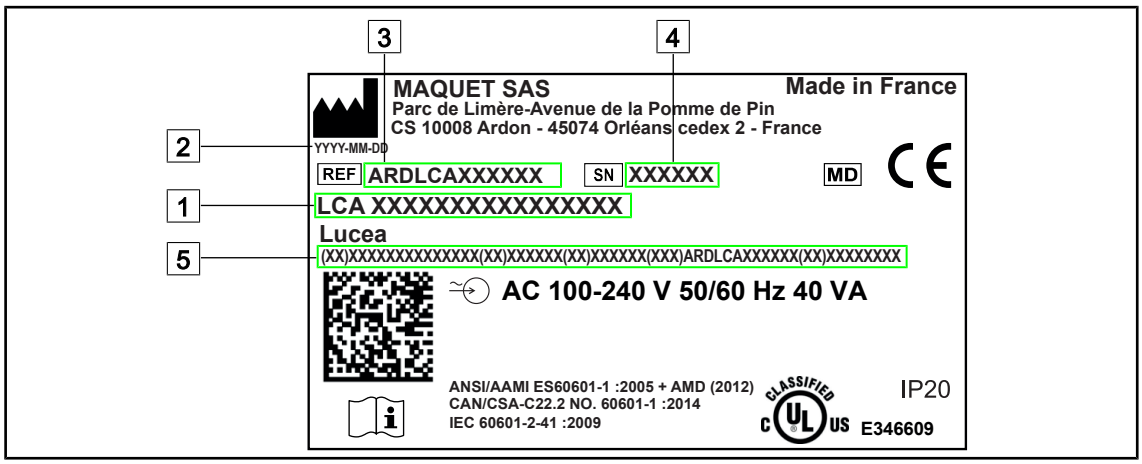
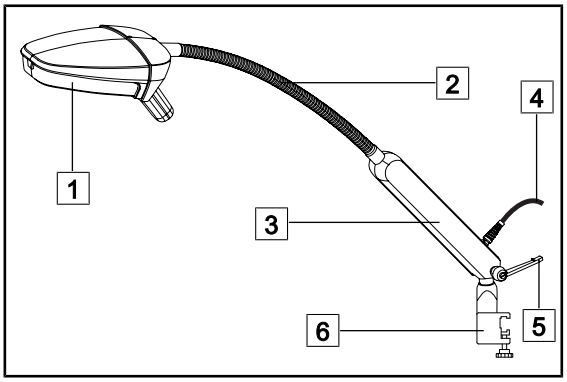


Fig. 2: Example label

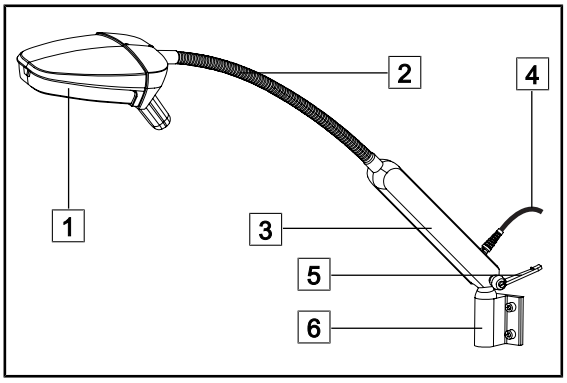
1 Product name
2 Manufacturing date
3 Product code
4 Serial No.
5 Unique device identifier (UDI)

1.9 Product overview



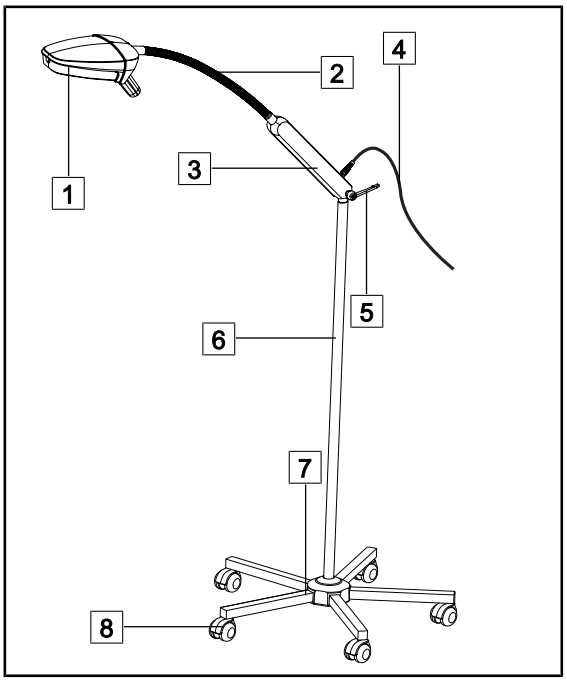
1 LUCEA 10 lighthead
2 Flexible fork
3 Power supply block
4 Power supply cable
5 Fastening handle
6 Rail mounting bracket

Fig. 3: Rail-mounted LUCEA 10



1 LUCEA 10 lighthead
2 Flexible fork
3 Power supply block
4 Power supply cable
5 Fastening handle
6 Wall bracket

Fig. 4: Wall-mounted LUCEA 10



1 LUCEA 10 lighthead
2 Flexible fork
3 Power supply block
4 Power supply cable
5 Fastening handle
6 Pole
7 Mobile base
8 Casters with brakes

Fig. 5: LUCEA 10 mobile

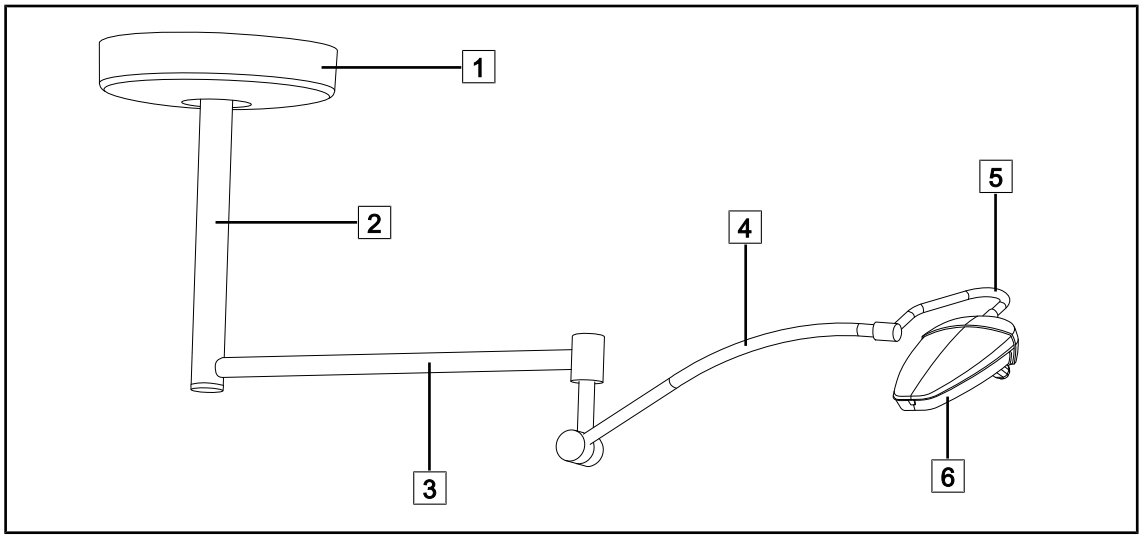


Fig. 6: Ceiling-mounted LUCEA 40

1 Ceiling cover
2 Suspension tube
3 Extension arm
4 Spring arm
5 Fork
6 LUCEA 40 lighthead

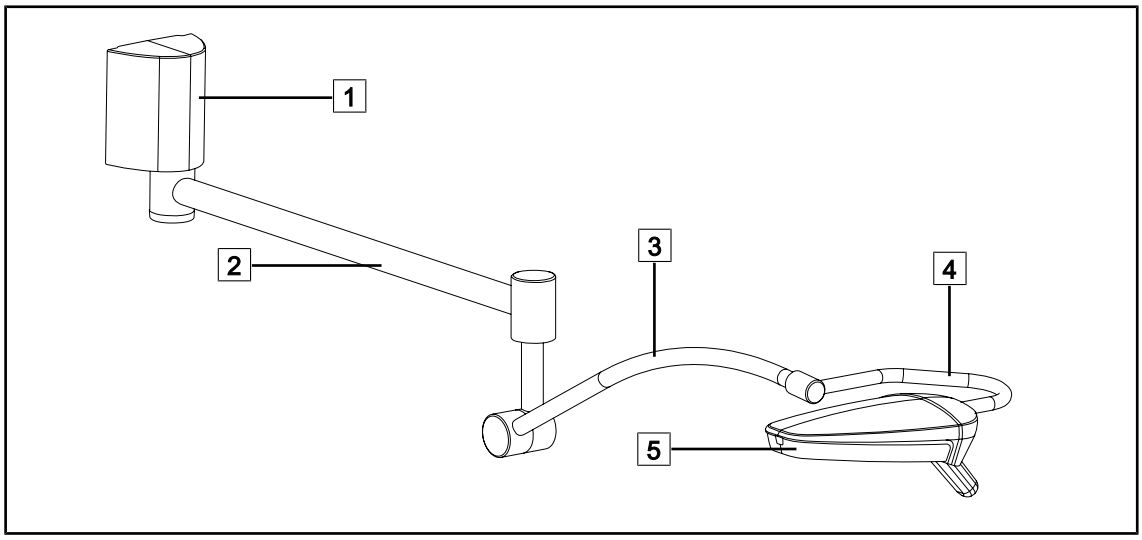


Fig. 7: Wall-mounted LUCEA 40

1 Wall bracket
2 Extension arm
3 Spring arm
4 Fork
5 LUCEA 40 lighthead

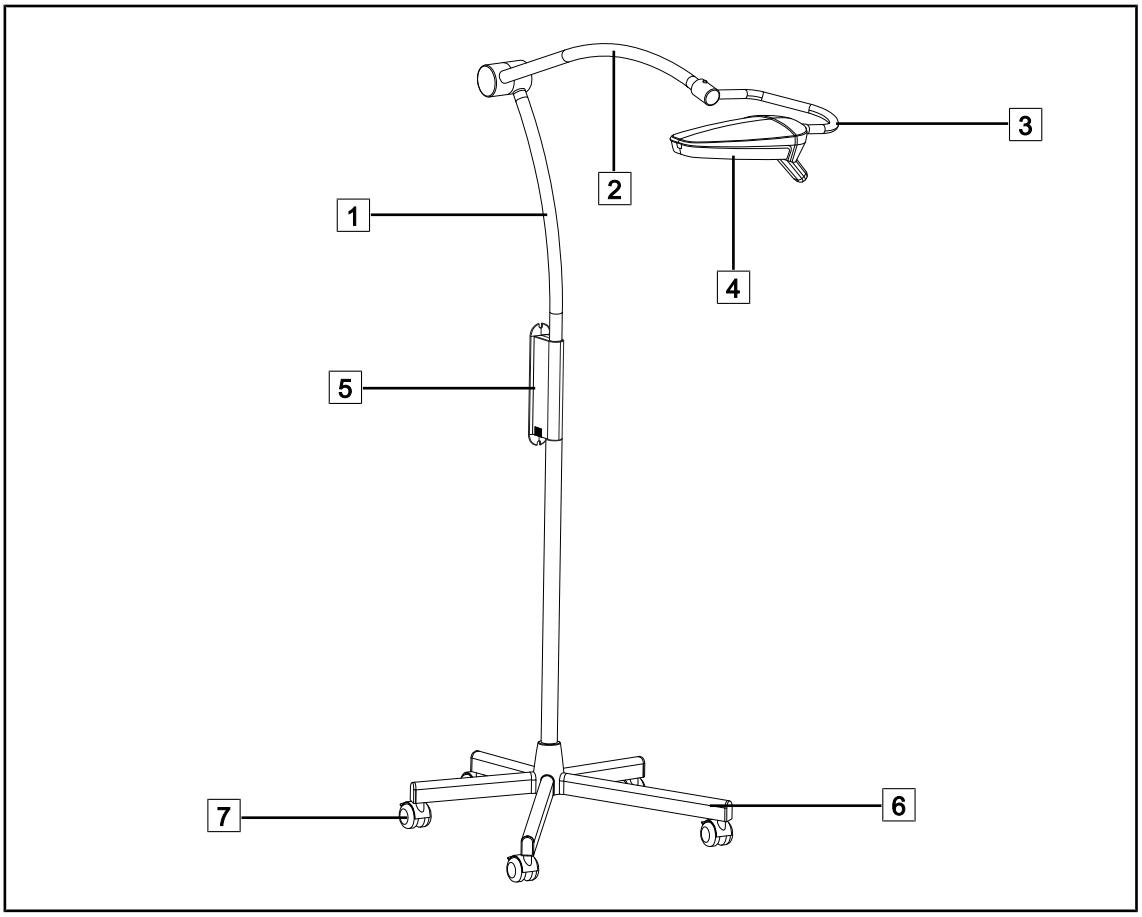


Fig. 8: LUCEA 40 mobile

1 Pole
2 Spring arm
3 Fork
4 LUCEA 40 lighthead
5 Power supply
6 Stand base
7 Casters with brakes

1.9.1 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.

Article	Name	Part number	Length
POWER CORD C7 EUR	Lucea 10 power supply cable for Europe	5 686 02 901	3.5 m
POWER CORD C7 GBR	Lucea 10 power supply cable for the UK	5 686 02 904	3.5 m
POWER CORD C7 US JPN	Lucea 10 power supply cable for the USA and Japan	5 686 02 900	3.5 m
POWER CORD C7 BRA	Lucea 10 power supply cable for Brazil	5 686 02 902	2 m
POWER CORD C7 AUS	Lucea 10 power supply cable for Australia	5 686 02 905	2 m

Tab. 3: Lucea 10 power supply cables

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

Tab. 4: Lucea 40 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
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
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. 5: Compliance with product standards

Quality management:

Reference	Year	Title
ISO 13485 EN ISO 13485	2016 2016	ISO 13485:2016 EN ISO 13485:2016 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	2023	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. 6: 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
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 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. 7: 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	2021	Therapeutic Goods (Medical Devices) Regulations 2002. Statutory Rules No. 236, 2002 made under the Therapeutic Goods Act 1989
Brazil	RDC 665/2022	2022	Resolution RDC n°665, 30 March 2022, Provides for the Good Manufacturing Practices for Medical Devices and Medical devices for In Vitro Diagnostis
Brazil	RDC 751/2022	2022	RDC No. 751, of September 15, 2022, which provides for risk classification, notification and registration regimes, and labeling requirements and instructions for use of medical devices.
Canada	SOR/98-282	2023	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
USA	21CFR Part 7	2023	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	2023	Title 21--Food And Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter H -- Medical Devices

Tab. 8: Compliance with market standards

Other information (for China only)

适用规格型号：Lucea 10 rail version; Lucea 10 desk version; Lucea 10 mobile version; Lucea 10 wall version, Lucea 40 mobile version, Lucea 40 Ceiling-mounted version
产品名称：手术辅助照明灯
规格型号：见标签
序列号：见标签

生产日期：见标签
性能结构及组成：通常由光源、灯架等组成。预期供手术辅助照明用，为不具备自动防故障功能的照明灯具，不能单独用于手术。不具有无影效果。
预期用途：用于手术室手术辅助照明。
备案号：国械备20151610号
产品技术要求编号：国械备20151610号
备案人/生产企业名称：MAQUET SAS 迈柯唯股份有限公司
备案人注册地址：Parc de Limere-Avenue de la Pomme de Pin, CS 10008 Ardon 45074 ORLEANS CEDEX 2 FRANCE
生产地址：Parc de Limere-Avenue de la Pomme de Pin, CS 10008 Ardon 45074 ORLEANS CEDEX 2 FRANCE
售后服务单位/代理人名称：迈柯唯（上海）医疗设备有限公司
售后服务单位/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
售后服务单位/代理人电话：800 820 0207

1.11 Information relating to intended use

1.11.1 Intended use

The LUCEA 10-40 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 10-40 examination light is to illuminate the examination site or region of interest 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 37] 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. 7) 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. 9: 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. 10: Environmental conditions for use

2.2 Safety instructions

2.2.1 Safe use of the product

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 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 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 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.

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.

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.

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.

3 Control interfaces

This product does not have a control interface.

4 Use

4.1 Daily inspections before use

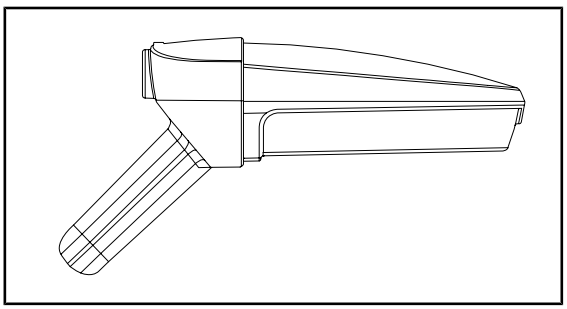


Fig. 9: Integrity of the device

Integrity of the device

1. Check that the device has not suffered any impact damage.
2. Check for any chipped or missing paint.
3. If a problem is noted, contact technical support.

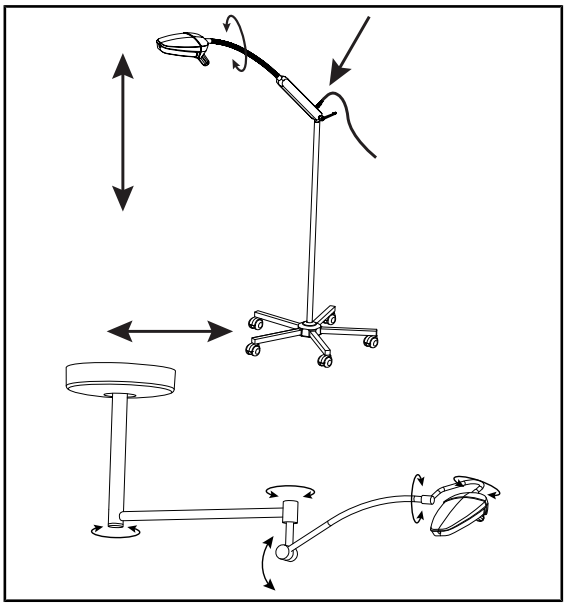


Fig. 10: Stability of the light

Stability of the light

1. Manipulate the device, moving it several times in order to rotate all of the mechanisms.
   - ➢ The entire system should move easily and smoothly.
2. Check that the mains connector on the power supply enclosure is correctly connected and that the mains cable is in good condition.
3. If a problem is noted, contact technical support.

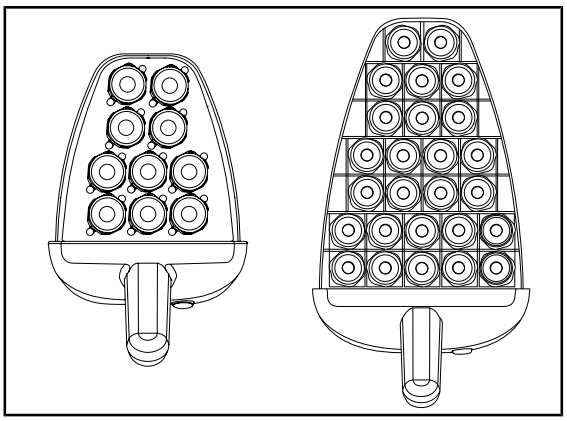


Fig. 11: Operation of LEDs

Operation of the LEDs

1. Press the ON/OFF button on the lighthead control keypad to turn on the light.
2. Check that all the LEDs are operating.
3. If a problem is noted, contact technical support.

4.2 Positioning the light

Lucea 10 Mobile and Lucea 10 Wall-Mounted

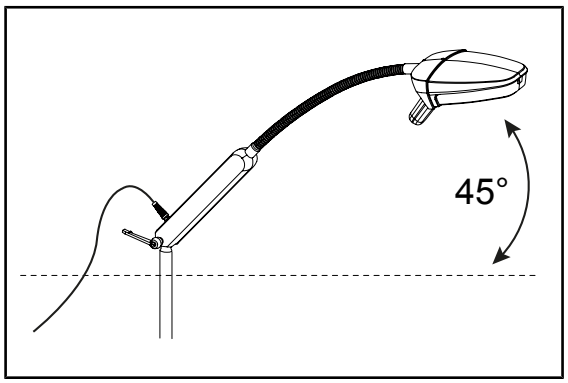


Fig. 12: Positioning the Lucea 10

1. Connect the power outlet.
2. Check that the fastening handle is properly tightened.
3. For the mobile version, lock the brakes by lowering the levers on the casters.
4. To facilitate use, position the power supply enclosure at an angle of at least 45°.

Lucea 10 Rail-Mounted

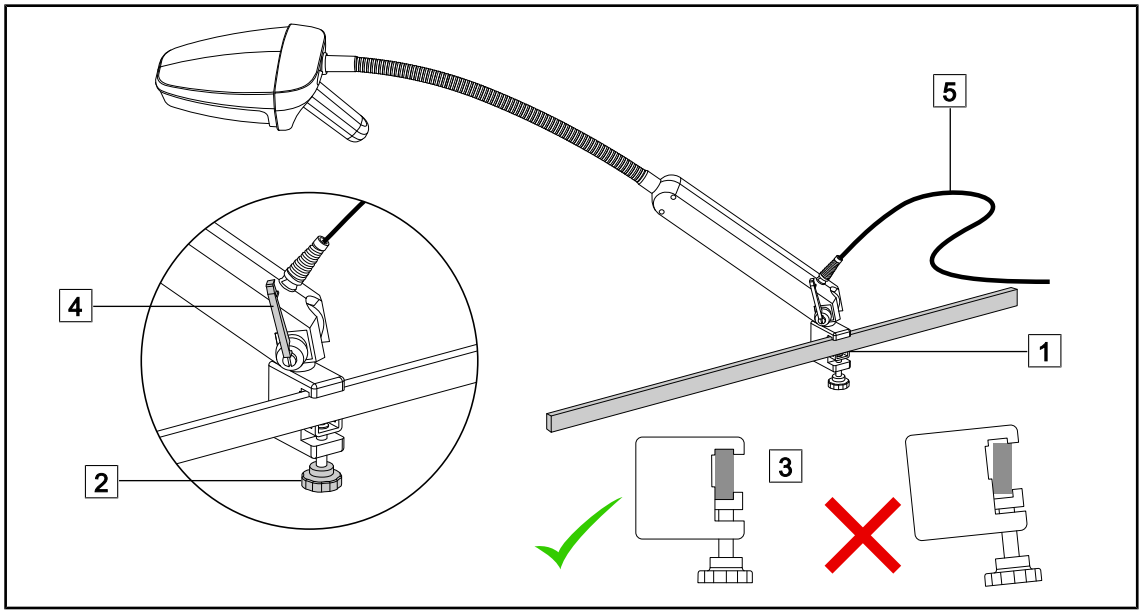
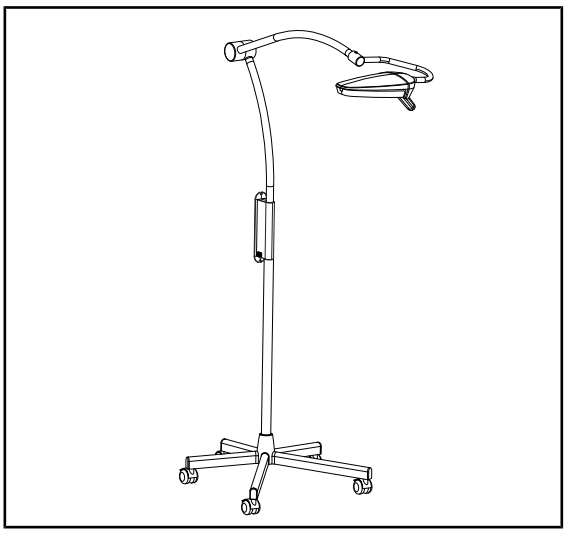


Fig. 13: Installing the Lucea 10 on the rail

1. Place the bracket on the rail [1].
2. Tighten the knob [2] ensuring the correct positioning of the bracket on the rail [3].
3. Tighten the handle [4] until a slight resistance is felt when moving the light.
4. Connect the power outlet.
5. To facilitate use, position the power supply enclosure at an angle of at least 45°.

Lucea 40 Mobile



1. Connect the power outlet.
2. Lock the brakes by lowering the levers on the casters.

Fig. 14: Positioning the Lucea 40

4.3 Turning the light on and off

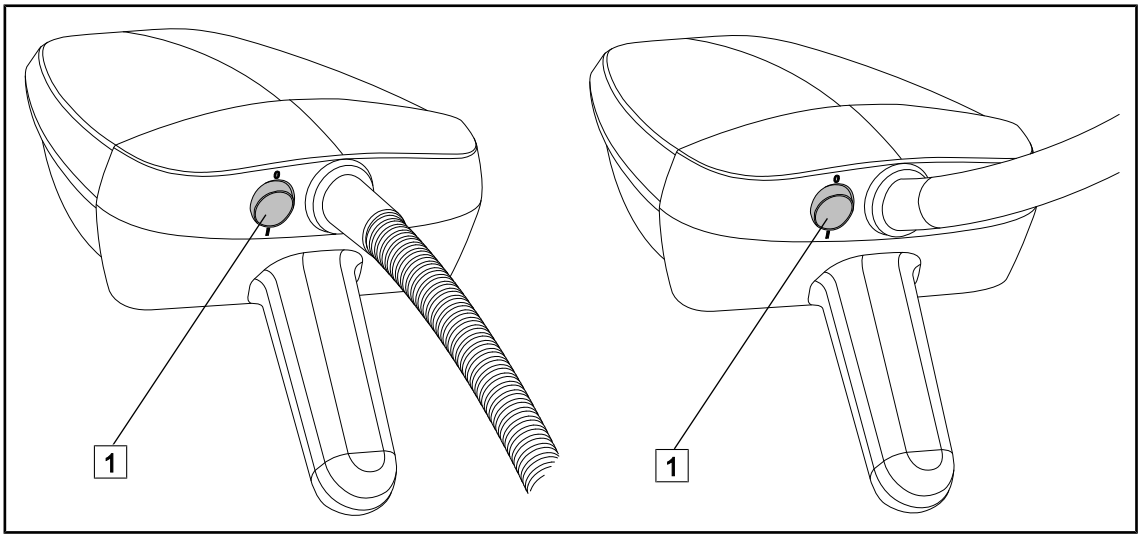


Fig. 15: Turning the light on and off

Turning the light on and off

1. Press the switch located at the rear of the lighthead [1] to turn on the light.
2. Press the switch located at the rear of the lighthead [1] again to turn off the light.

4.4 Manoeuvring the lighthead

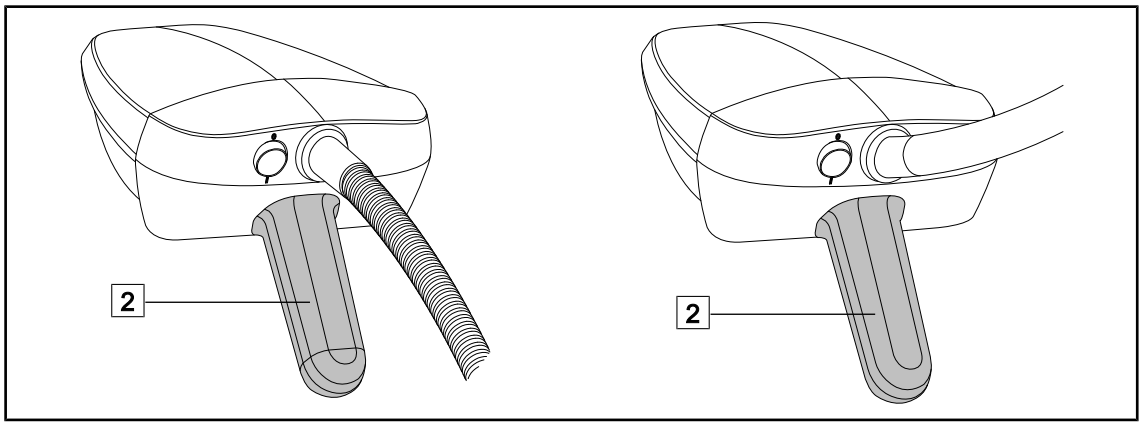


Fig. 16: Manoeuvring the lighthead

1. Use the handle 2 to position the lighthead in order to illuminate the examination area.

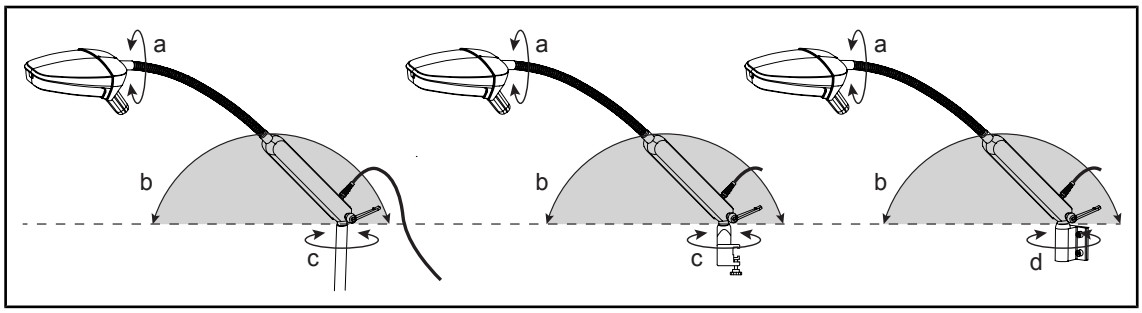


Fig. 17: Rotation of the Lucea 10

a	b	c	d
300°	180°	Infinite	160°

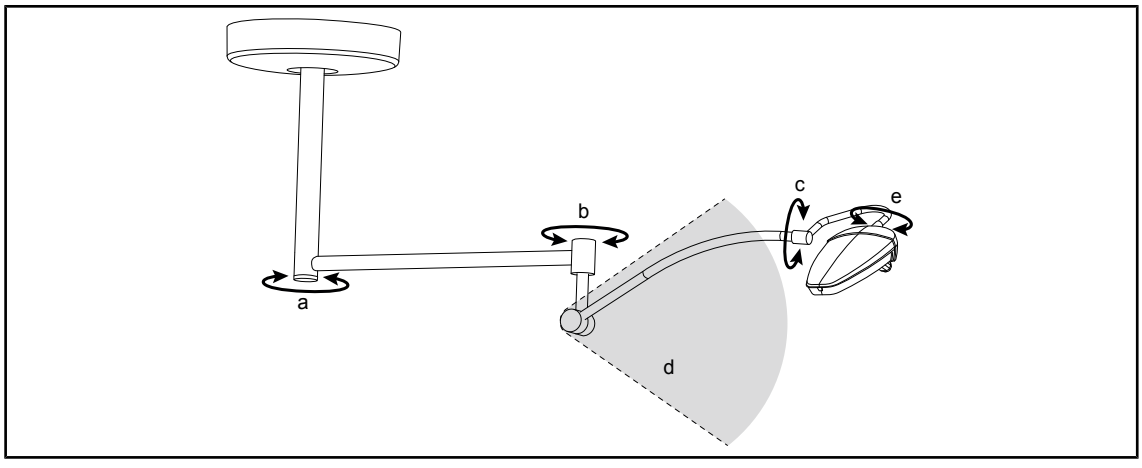


Fig. 18: Rotation of the ceiling-mounted Lucea 40

a	b	c	d	e
Infinite	Infinite	180°	+45° / -50°	300°

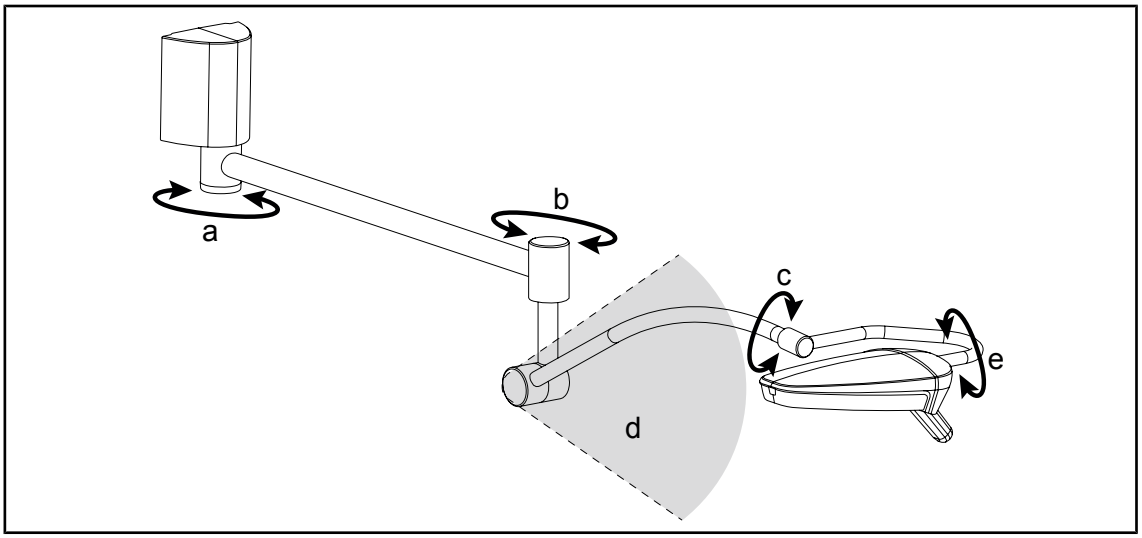


Fig. 19: Rotation of the wall-mounted Lucea 40

a	b	c	d	e
180°	infinite	180°	+45° / -50°	290°

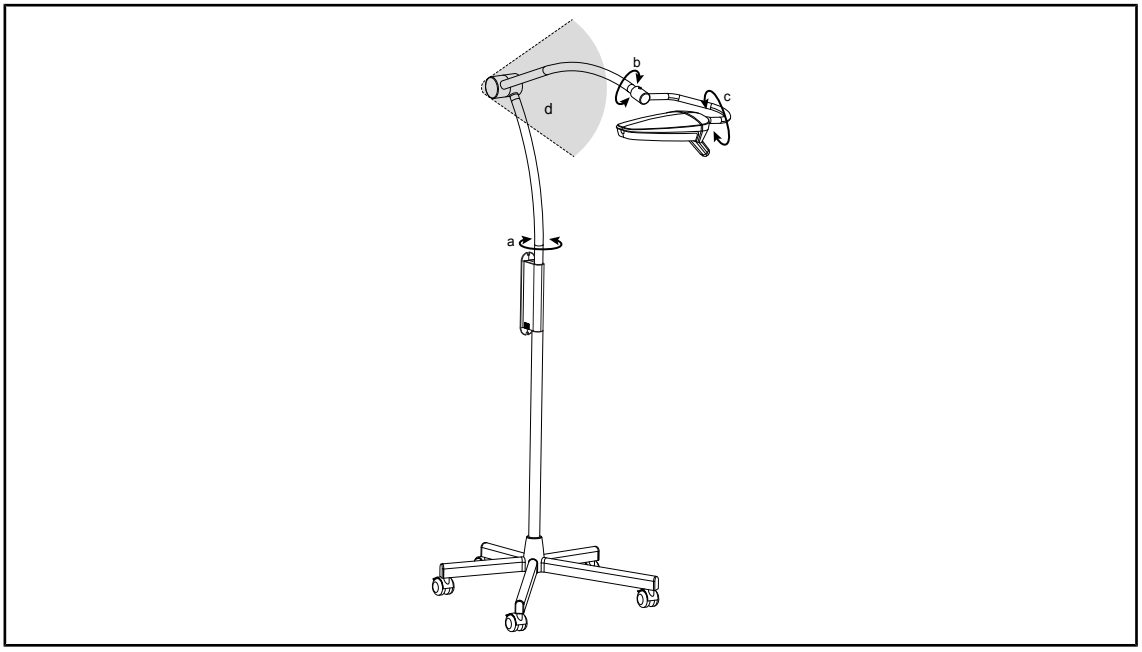


Fig. 20: Rotation of the Lucea 40 mobile

a	b	c	d
55°	180°	290°	+65° / -45°

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
	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 electronic circuit board does not communicate with the LED board.	Contact the Getinge technical department

Tab. 11: Troubleshooting

Mechanical components

Problem	Likely cause	Corrective action
The lighthead drifts	Suspension tube not vertical	Contact the Getinge technical department
	Ceiling structure unstable	Contact the Getinge technical department
Lighthead or suspension arm too loose or too stiff to manoeuvre	Fork brake incorrectly adjusted	Contact the Getinge technical department
Device too stiff to manoeuvre	Mechanical lock	Contact the Getinge technical department

Tab. 12: Mechanical anomalies and malfunctions

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. 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.
2. 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. 13: Lists of active substances suitable for use

Examples of commercially available products tested

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

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 50 cm (19.7 inches).

Specifications	LUCEA 10	Tolerance
Maximum Central Illumination ($E_{c,MI}$)[1]	< 100 000 lx	–
Maximum Central Illumination ($E_{c,Ref}$)	> 50 000 lx	–
Light field diameter d_{10}	11 cm	± 3 cm
Maximum Central Illumination at 80 cm (31.5 in)	> 10 000 lx	–
Light field diameter d_{10} at 80 cm (31.5 in)	18 cm	± 3 cm
Colour temperature	4,500 K	± 450 K
Colour rendering index (Ra)	96	±4
Special colour rendering index (R9)	90	± 10
Specific colour rendering index (R13)	90	± 10
Specific colour rendering index (R15)	90	± 10
Maximal total Irradiance (E_{Total})[1]	< 350 W/m²	–
Heat to light ratio[1]	3,9 mW/m²/lx	± 0.4
UV illumination[1]	≤ 0,7 W/m²	–

Tab. 14: Lucea 10 optical specifications

[1] Measured at Maximum Illuminance Distance (D_{MI}) of 35 cm / 13.8 inches (± 7)

NOTICE

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

Specifications	LUCEA 40	Tolerance
Maximum Central Illumination ($E_{c,MI}$)[2]	< 90 000 lx	–
Maximum Central Illumination ($E_{c,Ref}$)	> 40 000 lx	–
Light field diameter d_{10}	22 cm	± 3 cm
Colour temperature	4,500 K	± 450 K
Colour rendering index (Ra)	96	±4
Special colour rendering index (R9)	90	± 10
Specific colour rendering index (R13)	90	± 10
Specific colour rendering index (R15)	90	± 10
Maximal total Irradiance (E_{Total})[2]	< 350 W/m²	–
Heat to light ratio[2]	3,9 mW/m²/lx	± 0.4
UV illumination[2]	≤ 0,7 W/m²	–

Tab. 15: Lucea 40 optical specifications

9.2 Electrical characteristics

Specifications	LUCEA 10	LUCEA 40
Supply voltage	100-240 V AC/50-60 Hz	100-240 V AC/50-60 Hz
Nominal voltage	40 V	48 V
Rated power	14 VA	40 VA

Tab. 16: LUCEA 10-40 electrical characteristics

9.3 Mechanical specifications

Specifications	LUCEA 10	LUCEA 40
Lighthead weight	0.8 kg	1.85 kg
Lighthead dimensions	223 × 175 mm	337 × 214 mm
Sterilisation and disinfection methods	Not applicable	
Operating mode	Continuous operation	

Tab. 17: LUCEA 10-40 mechanical characteristics

[2] Measured at Maximum Illuminance Distance (D_{MI}) of 62 cm / 24.4 inches (± 7)

9.4 Other characteristics

Specifications	LUCEA 10	LUCEA 40
Protection against electrical shock	Class II	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 for non-mobile versions	12276	
GMDN code for mobile versions	36843	
EMDN code for non mobile versions	Z12010701	
EMDN code for mobile versions	Z12010702	
CE marking year	2009	

Tab. 18: Other characteristics of the LUCEA 10-40

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.

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
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. 19: 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

Tab. 20: 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	Test level: healthcare facility
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. 20: EMC declaration

9.5.1 FCC Part 15 (USA only)

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

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, contact your local Getinge representative.

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.

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