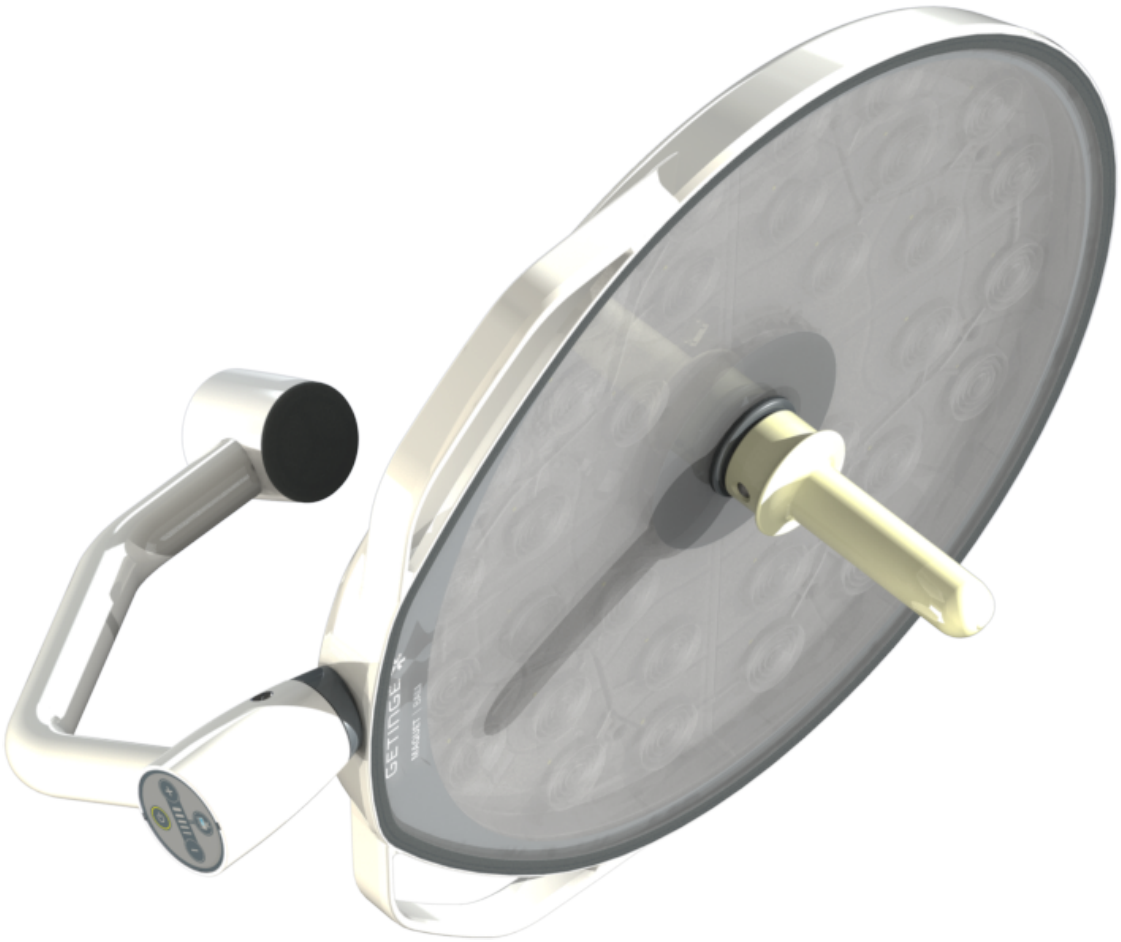


Instructions for use

# Maquet EZEA

IFU 01841 EN 06 2026-01-22

**Subject to technical changes**

In the event of future product developments, the illustrations and technical specifications provided/applied in this manual may differ slightly from the current product supplied.

V06 22.01.2026

# 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 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 should be installed on the system.

The compatibility data is detailed in the chapter entitled Technical specifications.

The compatible accessories are detailed in the corresponding chapter.

**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.

## 1.3 Other documents relating to this product

- Maquet EZEA Installation Recommendations (Ref. ARD01846)
- Maquet Ezea Installation Manual (Ref. ARD01844)
- Maquet EZEA Maintenance Instructions (Ref. ARD01840)
- Maquet EZEA Repair Instructions (Ref. ARD01842)
- Maquet EZEA Decommissioning Instructions (Ref. ARD01845)

## 1.4 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.

### 1.4.1 Abbreviations

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

### 1.4.2 Symbols used in this manual

#### 1.4.2.1 Cross-references

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

#### 1.4.2.2 Reference numbers

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

#### 1.4.2.3 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.

#### 1.4.2.4 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.

#### 1.4.2.5 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

#### 1.4.2.6 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

### 1.4.3 Definitions

#### 1.4.3.1 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.

### 1.4.3.2 Light types

**Surgical lighting**

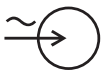
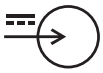
Lighting system which emits a light beam that can be directed independently of other light beams, to provide illumination for surgical operations. A surgical light cannot be designed to be single-fault safe by itself. However, when used in conjunction with another surgical light, the resulting surgical lighting system must be made single-fault safe.

**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: Two mobile lights, or one mobile light used in conjunction with another surgical light (ceiling-mounted surgical light or single wall-mounted light), form a surgical lighting system.

## 1.5 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). |  | Legal representative of the country concerned |
|  | Manufacturer + Manufacturing date |  | CE marking (Europe) |
|  | Product code |  | UL marking (Canada and United States) |
|  | Product serial number |  | UR marking (Canada and United States) |
|  | AC input |  | Packaging orientation |
|  | DC input |  | Fragile, handle with care |
|  | DC output |  | Keep away from rain |
|  | Standby |  | Temperature range for storage |
|  | Do not discard with conventional waste |  | Humidity range for storage |
|  | Medical Device (MD) marking |  | Ambient pressure range for storage |

## 1.6 Product overview

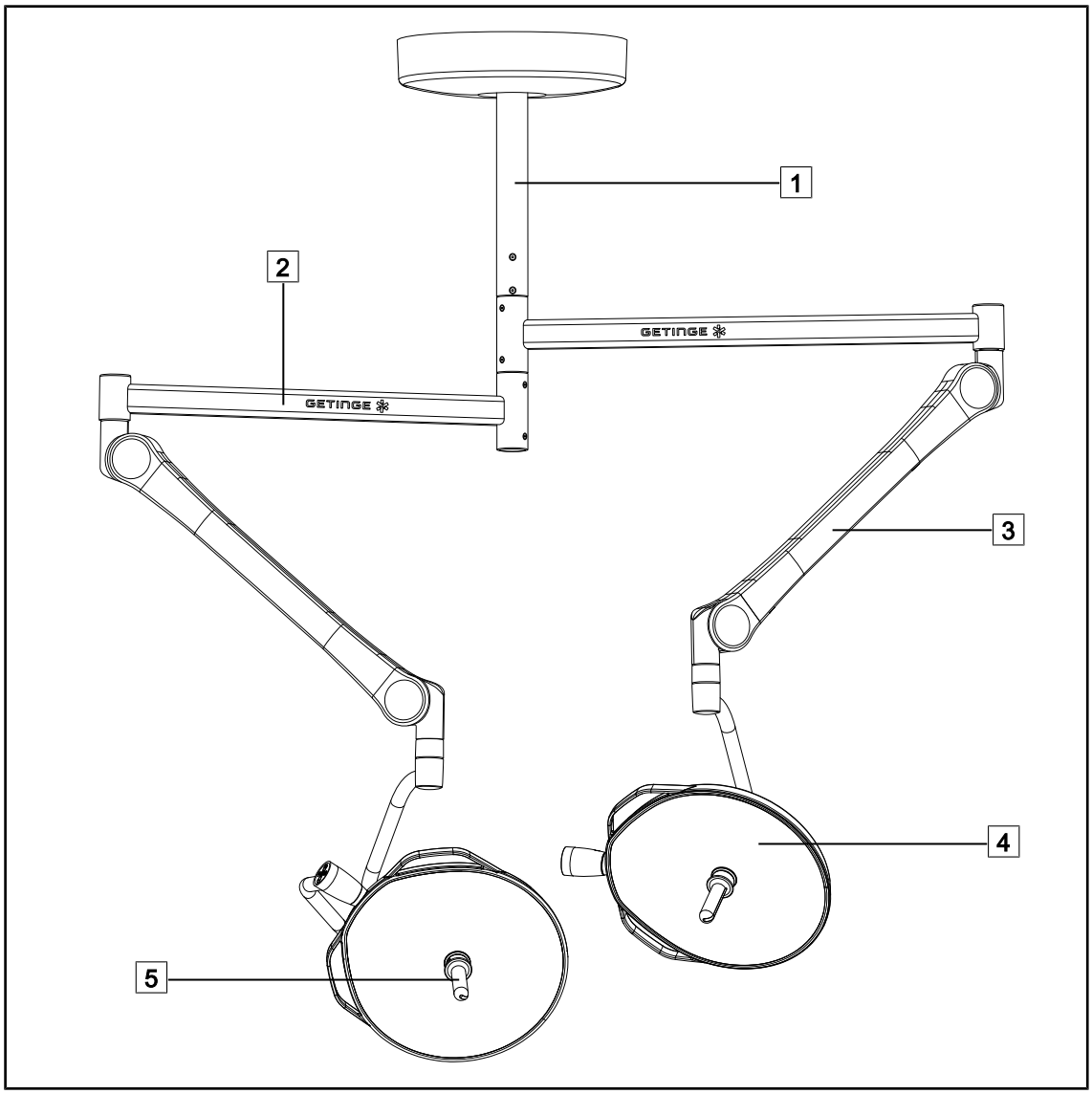



Fig. 1: Overview of a Maquet EZEA ceiling-mounted dual configuration

1 Suspension tube
2 Suspension arm
3 Spring arm
4 EZEA 300
5 Sterilisable handle

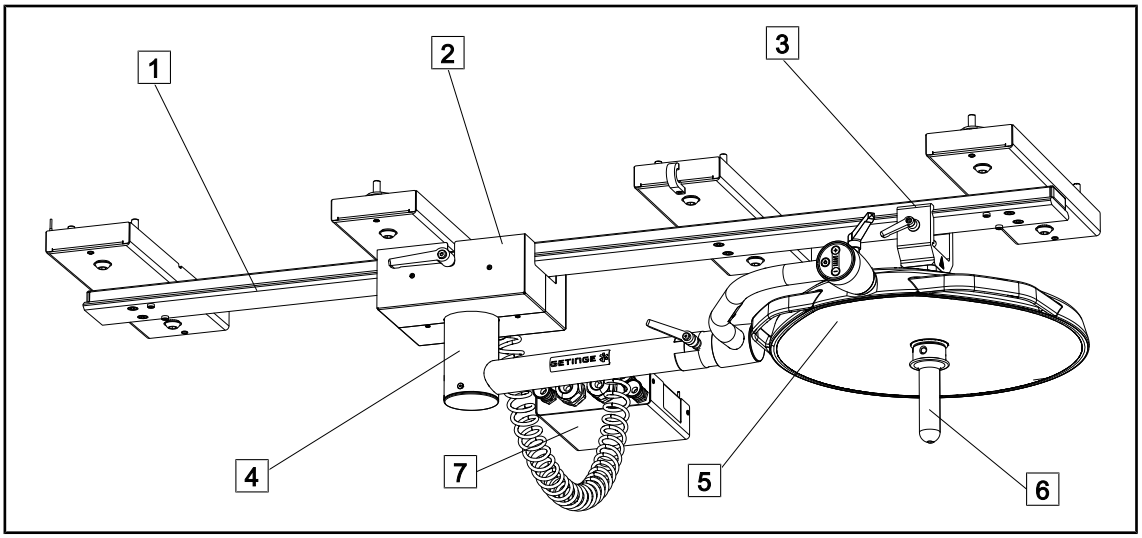



Fig. 2: Overview of a Maquet EZEA SHIP configuration

1 Rail anchor plate
2 Cart
3 Parking dock
4 Fixed suspension
5 EZEA 300
6 Sterilisable handle

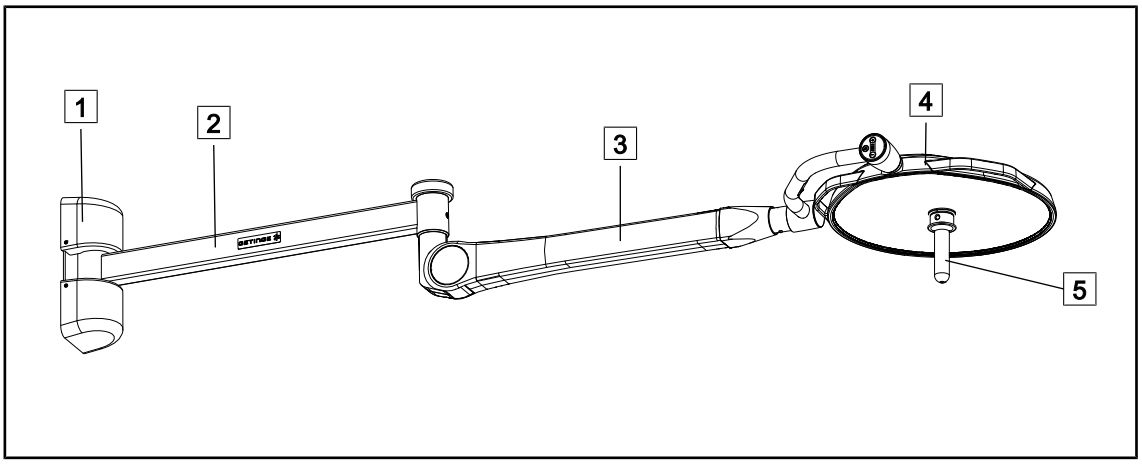



Fig. 3: Overview of a Maquet EZEA WALL configuration

1 Wall bracket
2 Suspension arm
3 Spring arm
4 EZEA 300
5 Sterilisable handle

### 1.6.1 Lightheads

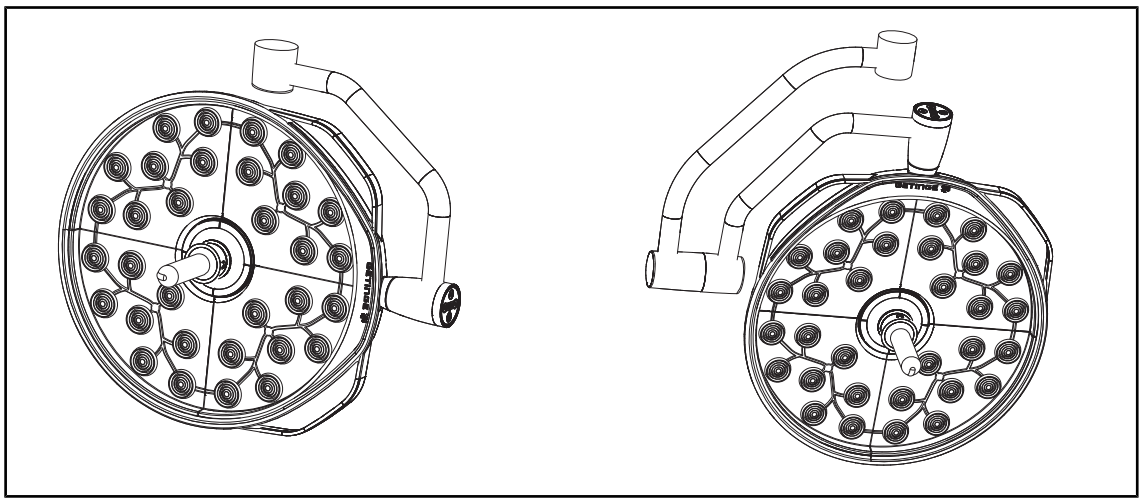


Fig. 4: Maquet EZEA 300 lightheads

Each lighthead comprises the following components:

- One handle mount for sterilisable handles (not included in configuration)
- One control keypad
- Two external handles
- IP44 protection against dust and liquid ingress

Each lighthead includes the following functions:

- Careview function
- Ambient light
- Light colour variation (optional)

**WARNING!**

**Risk of tissue drying or burns.**
**Light is a form of energy that can potentially cause injury to the patient (e.g. drying of tissues, burning of the retina), particularly in the event of superimposed light beams from several lightheads, or lengthy surgical interventions.**

**The user must be aware of the risks relating to exposure of open wounds to a light source with excessively high intensity. The user must be vigilant and must adjust the illumination level according to the patient examined, particularly during a lengthy procedure.**

### 1.6.1.1 Basic functions

#### Careview

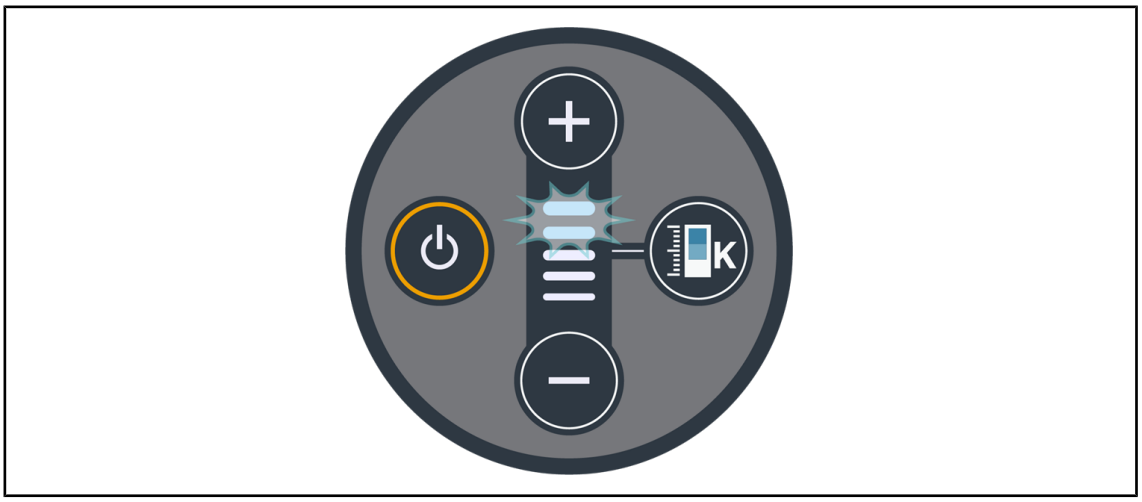



Fig. 5: Careview indication, levels 4 and 5

Maquet EZEA lightheads display visual information on the keypad via two flashing LEDs, drawing the user's attention to the superimposed light fields. Indeed, light is a form of energy that, at high-intensity levels, can dry out tissues. The IEC 60601-2-41 standard provides for a maximum of 700 W/m² acceptable level for a given area, hence the importance of informing the user that this limit can potentially be exceeded. The light beams of two lightheads can be superimposed, but when the two lightheads display a flashing intensity level, the user must be vigilant.

#### Ambient light

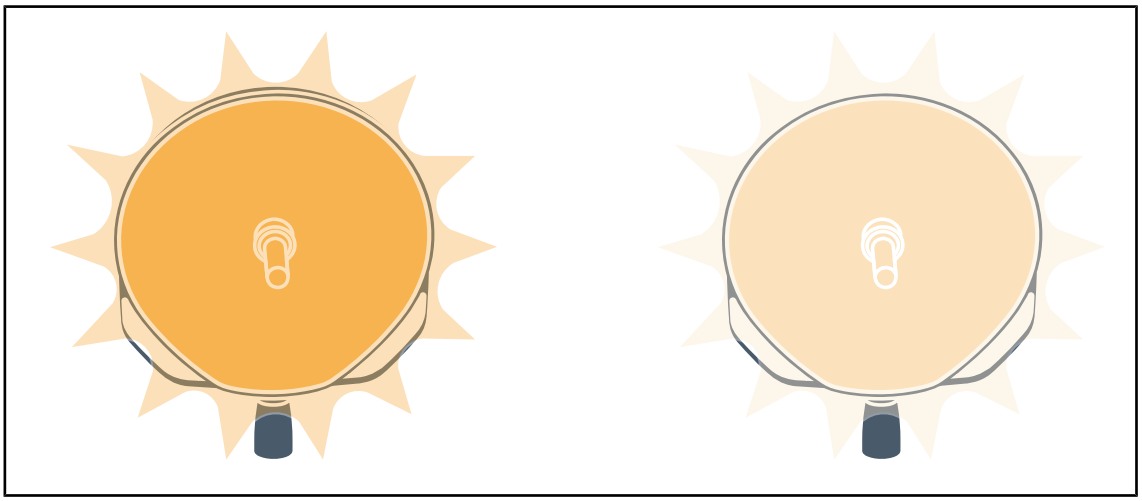


Fig. 6: Ambient light function

The ambient light function provides the surgical team and the anaesthetist with minimal lighting during minimally invasive procedures.

### 1.6.1.2 Options

#### Variable colour temperature

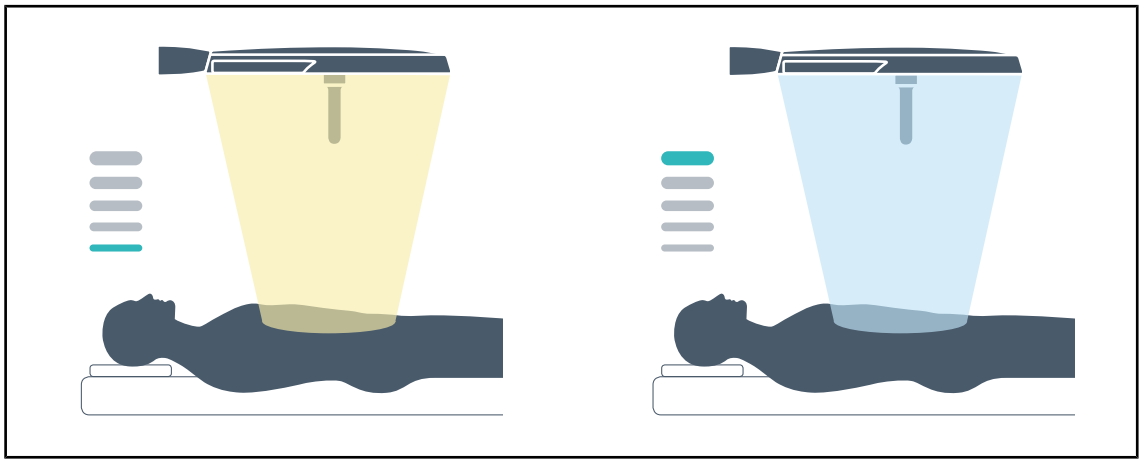


Fig. 7: Colour temperature

Light colour variation, available as an option, allows the surgical team to choose between a warm white: 4100K, and a cool white: 4600K, to suit viewing preferences.

#### Wall-mounted remote control panels

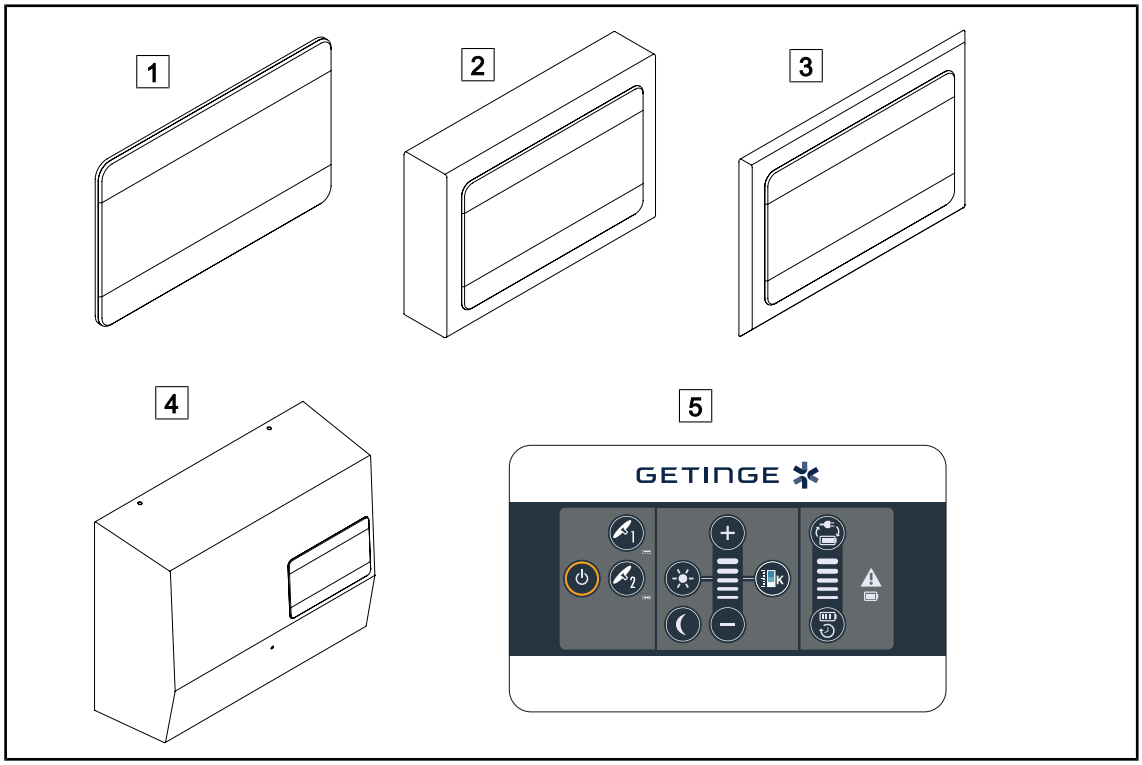
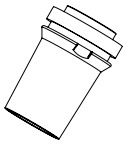



Fig. 8: Available wall-mounted control keypads

1 Flush-mounted version
2 Surface-mounted version
3 Flush-mounted version with front panel
4 Power supply assembly version
5 Control keypad

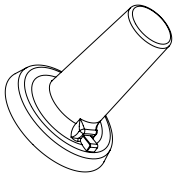
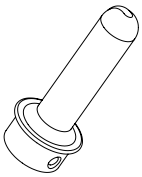
### 1.6.1.3 Accessories

#### Handle mounts

| Illustration | Description | Part number |
|---|---|---|
|  | Adapter for mounting an STG PSX-type sterilisable handle on a Maquet EZEA lighthead | PSX 003 handle mount |

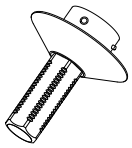
Tab. 3: Handle mounts

#### Sterilisable handles

| Illustration | Description | Part number |
|---|---|---|
|  | Set of five STG PSX handles | STG PSX 01 |
|  | Set of five STG HLX handles | STG HLX 01 |

Tab. 4: Sterilisable handles

#### Adapter for disposable handles

| Visual | Description | Reference |
|---|---|---|
|  | Adapter for mounting a disposable handle | DEVON HANDLE LI-TEX 3600-104 |

Tab. 5: Adapter for disposable handles

## 1.7 Product identification label

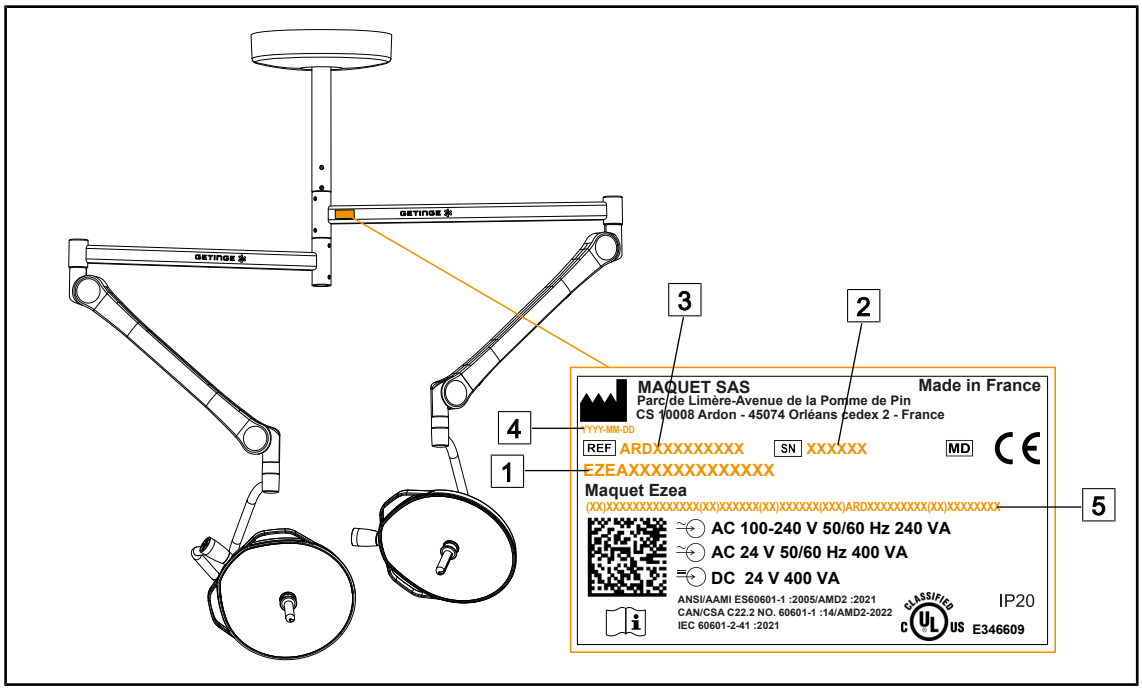



Fig. 9: Location and description of the product identification label

1 Product name
2 Serial number
3 Product code
4 Manufacturing date
5 UDI identification

## 1.8 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<br>ANSI/AAMI ES60601-1:2005/A2:2021<br>CAN/CSA-C22.2 No. 60601-1:14/A2:2022 | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance |
| 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<br>EN 60601-1-2:2015/A1:2021<br>ANSI/AAMI/IEC 60601-1-2:2014/A1:2021<br>CSA C22.2 No. 60601-1-2:16 (R2021) | 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 | Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability |

Tab. 6: Compliance with product standards

| Reference | Title |
|---|---|
| IEC 60601-1-9:2007+AMD1: 2013+AMD2:2020 | 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 | Medical devices – Part 1: Application of usability engineering to medical devices |
| IEC 62304:2006+AMD1:2015 | Medical device software – Software life cycle processes |
| ISO 20417:2020 | Medical devices - Information provided by manufacturer |
| ISO 15223-1:2021/A1:2025 | 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 | Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz – 300 GHz) |

Tab. 6: Compliance with product standards

Quality management:

| Reference | Year | Title |
|---|---|---|
| ISO 13485 | 2016 | ISO 13485:2016<br>Medical devices – Quality management systems – Requirements for regulatory purposes |
| VSTII 14971 | 2019 | ISO 14971:2019<br>Medical devices – Application of risk management to medical devices |
| ISO 14001 | 2024 | ISO 14001:2015/A1:2024<br>Environmental management systems - Requirements with guidance for use |
| 21 CFR Part 11 | 2023 | Title 21--Food And Drugs<br>Chapter I--Food and Drug Administration Department of Health and Human Services<br>Subchapter A -- General<br>PART 11 - Electronic records, electronic signatures |
| 21 CFR Part 820 | 2020 | Title 21--Food And Drugs<br>Chapter I--Food and Drug Administration Department of Health and Human Services<br>Subchapter H -- Medical Devices<br>PART 820 - Quality System Regulation |

Tab. 7: Compliance with quality management standards

Environmental standards and regulations:

| Country | Reference | Version | Title |
|---|---|---|---|
| EU | ROHS Directives | 2011 | DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011on the restriction of the use of certain hazardous substances in electrical and electronic equipment |
| | | 2015 | COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015, amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances |
| | | 2016 | COMMISSION DELEGATED DIRECTIVE (EU) 2016/585 of 12 February 2016 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices or electron microscopes |
| | | 2017 | DIRECTIVE (EU) 2017/2102 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 November 2017 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment |
| Worldwide | IEC 63000: | 2022 | Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances |
| EU | REACH Regulation | 2006 | REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and REACH - Restriction of Chemicals (REACH), amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC |
| USA _ California | US California Proposition 65 Act | 1986 | HEALTH AND SAFETY CODE - HSC DIVISION 20. MISCELLANEOUS HEALTH AND SAFETY PROVISIONS CHAPTER 6.6. Safe Drinking Water and Toxic Enforcement Act of 1986 |
| China | SJ/T 11365-2006 | 2006 | ACPEIP - Administrative Measure on the Control of Pollution caused by Electronic Information Products, China RoHS (Restriction of Hazardous Substances) |

Tab. 8: 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 |
| Bosnia and Herzegovina | Act | 2008 | Medicinal products and medical devices act of Bosnia and Herzegovina (“Official Gazette of BiH, No. 58/08”) |
| Brazil | RDC 665/2022 | 2022 | Resolution RDC No. 665, of March 30, 2022, provides for the good manufacturing practices for medical devices, and medical devices for in vitro diagnosis |
| Brazil | RDC 751/2022 | 2022 | RDC No. 751, of September 15, 2022, which provides for risk classification, notification and registration regimes, and labelling requirements and instructions for use of medical devices |
| Brazil | Ordinance 384/2020 | 2020 | INMETRO Certification - Compliance Assessment Requirements for Equipment under Health Surveillance Regimen - Consolidated. |
| Canada | SOR/98-282 | 2024 | Medical Devices Regulations |
| China | Regulation 739 | 2021 | Regulation for the Supervision and Administration of Medical Devices |
| Colombia | Decree 4725 | 2005 | DECRETO NÚMERO 4725 DE 2005 (Diciembre 26) por el cual se reglamenta el régimen de registros sanitarios, permiso de comercialización y vigilancia sanitaria de los dispositivos médicos para uso humano. |
| EU | Regulation 2017/745/EU | 2017 | REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC |
| India | Rule | 2017 | Medical Device Rules, 2017 |
| Indonesia | Regulation 62 | 2017 | Regulation of the minister of health of the republic of Indonesia number 62 of 2017 on product license of medical devices, in vitro diagnostic medical devices and household health products |
| Israel | Law 5772-2012 | 2012 | The Medical Equipment Law, 5772-2012 |
| Japan | MHLW Ordinance: MO No. 169 | 2021 | Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-Vitro Diagnostics |
| Kenya | Act | 2002 | The Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya |

Tab. 9: Compliance with market standards

| Country | Reference | Year | Title |
|---|---|---|---|
| Malaysia | Act 737 | 2012 | Medical Device Act 2012 (Act 737) |
| Montenegro | Law 53/09 | 2009 | Law of Montenegro on Medical Devices (2009) |
| Morocco | Law 84-12 | 2012 | Law No. 84-12 relative to medical devices |
| New Zealand | Regulation 2003/325 | 2003 | Medicines (Database of Medical Devices) Regulations 2003 (SR 2003/325) |
| Saudi Arabia | Regulation | 2017 | “Medical Device Interim Regulation” issued by the Board of Directors of the Food and Drug Authority (1-8-1429) dated 29/12/1429 H and amended by Saudi Food and Drug Authority Board of Directors decree No. (4-16-1439) dated 27/12/2017 |
| Serbia | Law 105/2017 | 2017 | Law on Medicinal Products and Medical Devices, “Official Gazette of the Republic of Serbia,” No. 105/2017 |
| 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 | Act | 2020 | Taiwanese Medical Device Act |
| Thailand | Act 2562 | 2019 | Medical Device Act (No. 2) B.E. 2562(2019) |
| UK | Act | 2021 | Medical Devices Regulations 2002 No. 618 |
| USA | 21CFR Part 7 | 2023 | Title 21--Food And Drugs<br>Chapter I--Food and Drug Administration Department of Health and Human Services<br>Subchapter A -- General<br>PART 7 - Enforcement policy |
| USA | 21CFR Subchapter H | - | Title 21--Food And Drugs<br>Chapter I--Food and Drug Administration Department of Health and Human Services<br>Subchapter H -- Medical Devices |
| Vietnam | Decree 98/2021 | 2021 | Decree No. 98/2021/ND-CP November 8, 2021 of the Government on the management of medical equipment |

Tab. 9: Compliance with market standards

## 1.9 Information relating to intended use

### 1.9.1 Intended use

Maquet EZEA surgical lights are designed to illuminate the body of a patient during surgical operations, diagnostics or treatment.

### 1.9.2 Indications

The Maquet EZEA range is intended to be used for any type of surgery, treatment or examination requiring a specific type of lighting.

### 1.9.3 Intended users

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

### 1.9.4 Inappropriate use

- Use as a surgical lighting system (a lighthead) if an interruption of the operation threatens the life of the patient.
- Use of a damaged product (e.g., lack of maintenance).
- In a setting other than a professional healthcare environment (e.g., home care).

### 1.9.5 Contraindications

This product does not have any contraindications.

## 1.10 Primary purpose

The primary purpose of the Maquet EZEA surgical light is to illuminate the surgical site whilst minimising the associated thermal energy.

## 1.11 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.

## 1.12 Warranty

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

## 1.13 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 the annual periodic checks being performed by personnel trained and approved by Getinge. 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.

## 1.14 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 chapter.

**NOTICE**

Power consumption for the device is listed in the Electrical Specifications chapter. The device complies with the European ROHS directive 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. 10: 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. 11: Environmental conditions for use

## 2.2 Safety instructions

### 2.2.1 Safe use of the product

**WARNING!**

**Risk of injury**
**A battery lifetime test fully discharges the batteries.**

**Do not perform an operation immediately after a battery lifetime test. Allow time for the batteries to charge.**

**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 tissue drying or burns.**
**Light is a form of energy that can potentially cause injury to the patient (e.g. drying of tissues, burning of the retina), particularly in the event of superimposed light beams from several lightheads, or lengthy surgical interventions.**

**The user must be aware of the risks relating to exposure of open wounds to a light source with excessively high intensity. The user must be vigilant and must adjust the illumination level according to the patient examined, particularly during a lengthy procedure.**

**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.**

**WARNING!**

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

**Do not use in an MRI environment.**

### 2.2.2 Electrical

**WARNING!**

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

**Installation, maintenance, repair and uninstallation of the device or its components must be carried out by a Getinge technician or a service technician trained by Getinge.**

**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 the use of premises for medical use and must have a backup power supply system.**

### 2.2.3 Optical

**WARNING!**

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

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

**WARNING!**

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

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

### 2.2.4 Infection

**WARNING!**

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

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

# 3 Control interfaces

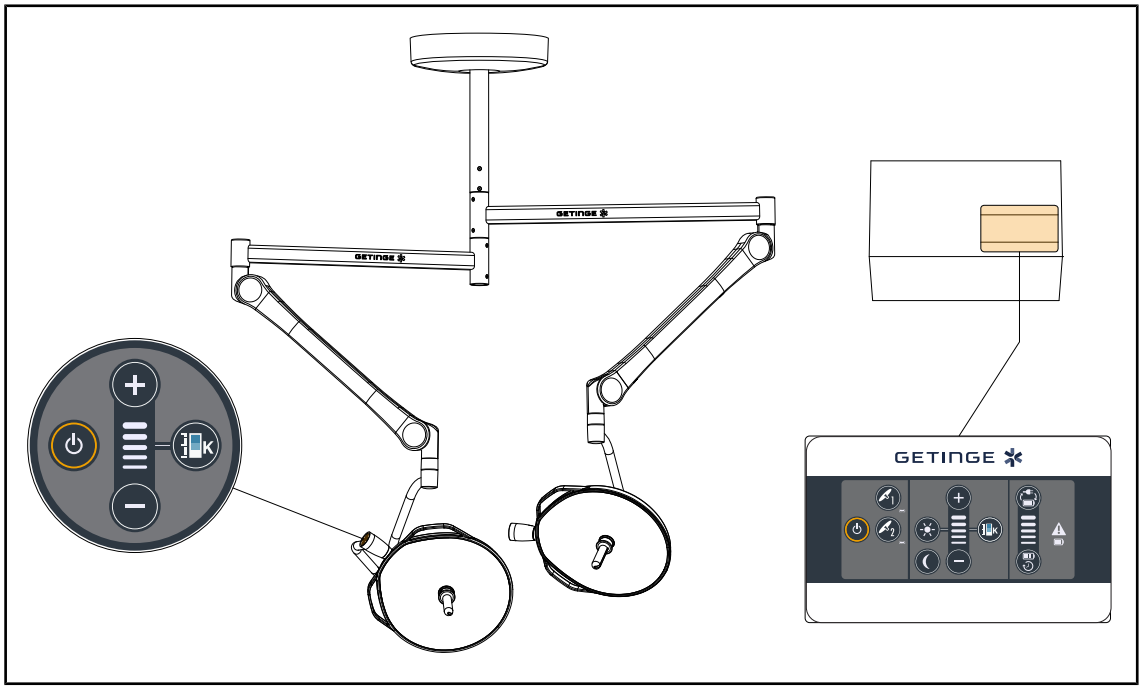



Fig. 10: Location of control interfaces

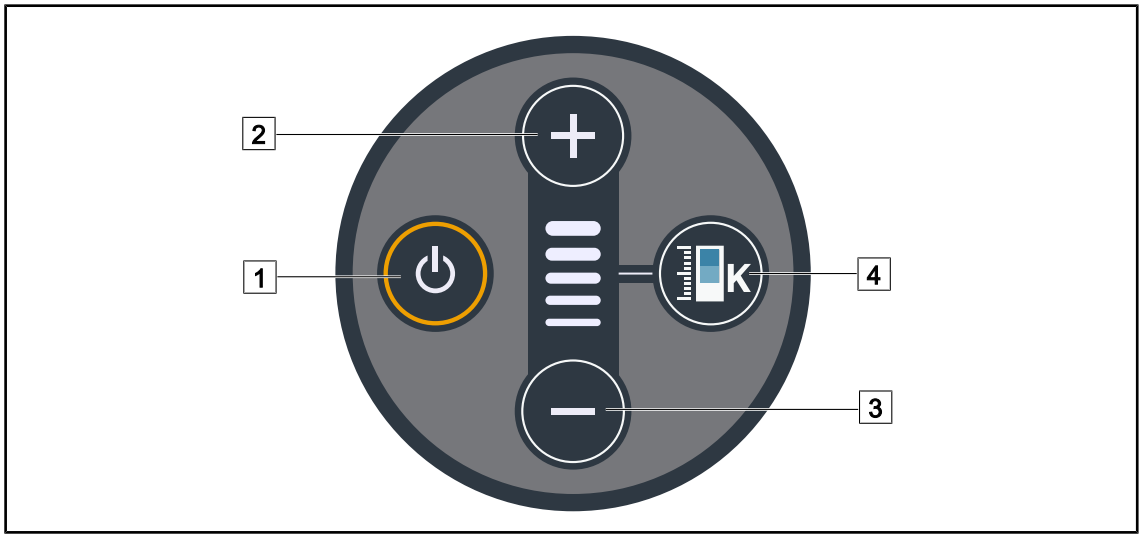



Fig. 11: Lighthead control keypad

1 On/Off
2 Plus (increase the level)
3 Minus (reduce the level)
4 Colour temperature variation (option)

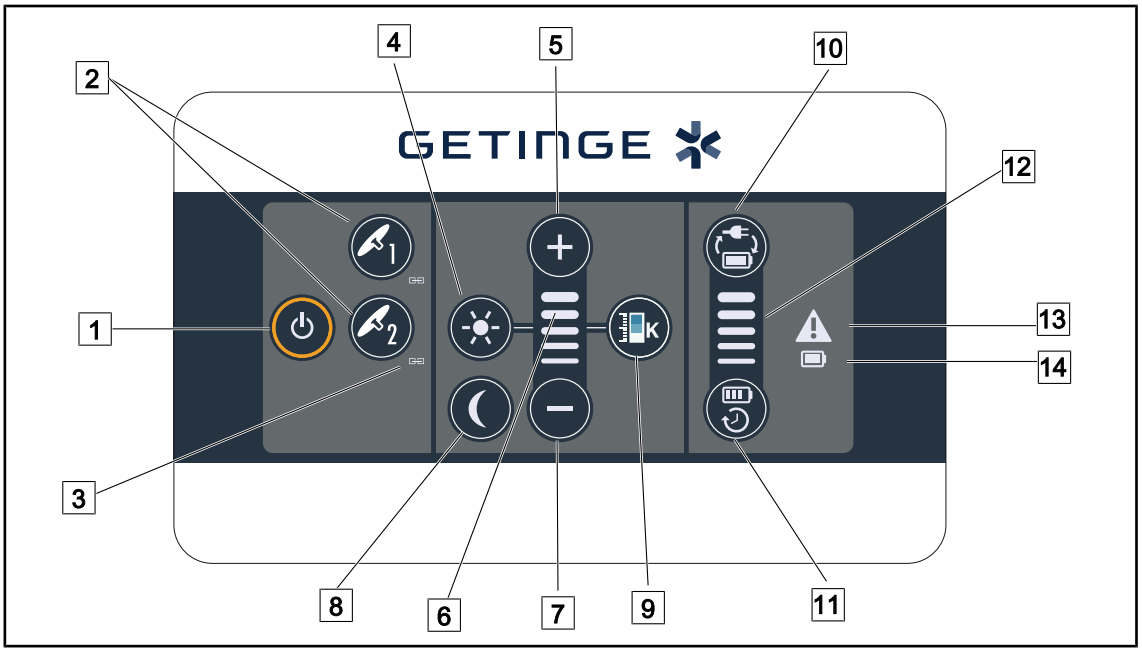



Fig. 12: Wall-mounted control keypad

1 On/Off
2 Lighthead selection (1 or 2)
3 Synchronisation indicator
4 Adjustment of illumination
5 Plus (increase the level)
6 Level indicator
7 Minus (reduce the level)
8 Ambient lighting mode
9 Colour temperature variation (option)
10 Battery switchover (option)
11 Battery life (option)
12 Battery level indicator (option)
13 Warning indicator
14 Battery indicator

## 3.1 Alarm indicators (on wall-mounted unit only)

| Indicator | Description | Meaning |
|---|---|---|
| | Indicator off | No defects |
| | Orange indicator | Faulty configuration (e.g. defective board, communication failure, other faults); backup battery level too low. |

Tab. 12: Warning indicators

| Indicator | Description | Meaning |
|---|---|---|
| | Indicator off | Powered from mains |
| | Orange indicator | Powered by backup supply |
| | Flashing red indicator | Powered by backup supply<br>The batteries are nearly depleted, and the system may shut down in a few minutes. |

Tab. 13: Battery indicators

# 4 Use

## 4.1 Daily inspections before use

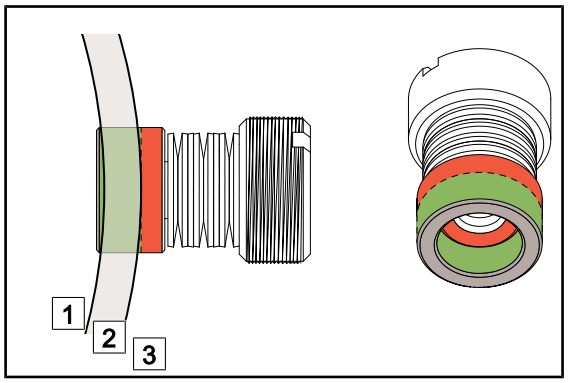
**NOTICE**

In order to ensure proper use of the product, visual and functional inspections must be carried out daily by a trained person. It is recommended that records be kept of the results of these inspections, along with the date and signature of the person performing them.

### Brake inspection

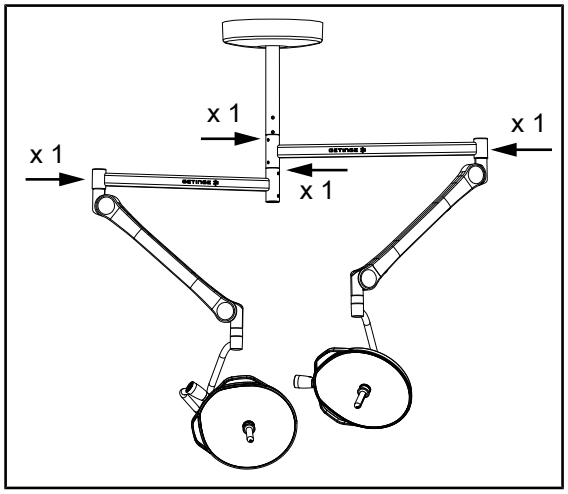
**NOTICE**

**It is normal for a newly installed brake to require readjustment after two to six months of use in order to compensate for wear.**



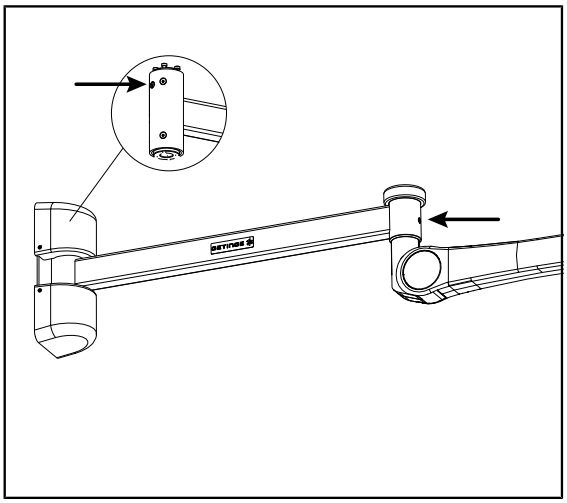

- Break-in zone 1
- Zone of use 2
- Wear zone 3

Fig. 13: Wear on brakes



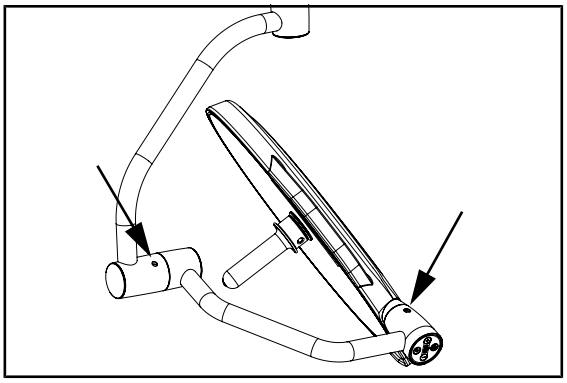

- Tighten screw to increase braking
- Loosen screw to reduce braking

Fig. 14: Suspension brake adjustments



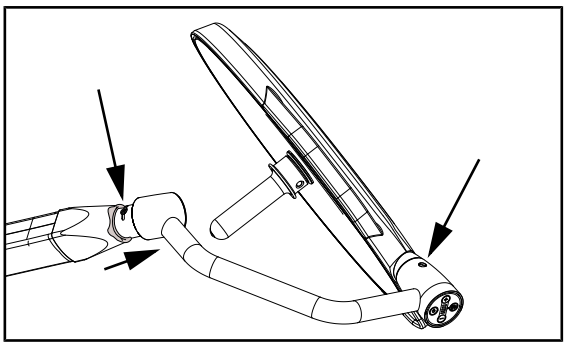
- Tighten screw to increase braking
- Loosen screw to reduce braking

Fig. 15: WALL suspension brake adjustments



- Adjust the brake on the intermediate and main yoke
  - Tighten screw to increase braking
  - Loosen screw to reduce braking

Fig. 16: Adjusting the DF lighthead brakes



- Adjust the brake on the spring arm and the main yoke
  - Fold the silicone sleeve back towards the spring arm
  - Tighten screw to increase braking
  - Loosen screw to reduce braking
  - Unfold the silicone sleeve while covering the end of the spring arm cover towards the lighthead.

Fig. 17: Adjusting the SF lighthead brakes

## General inspections

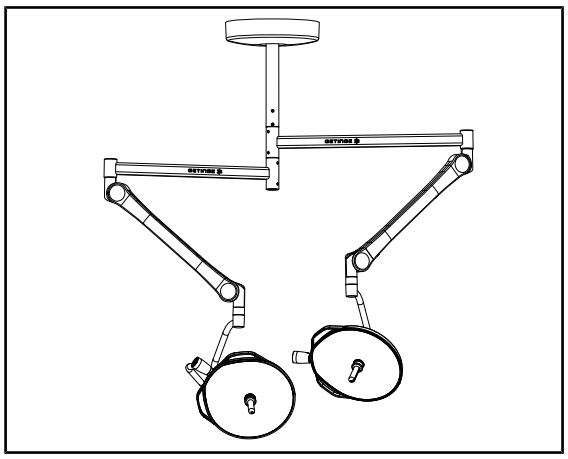


Fig. 18: Integrity of the device

### Integrity of the device

1. Check that the device has not suffered any impact damage.
2. Check for any chipped or missing paint.

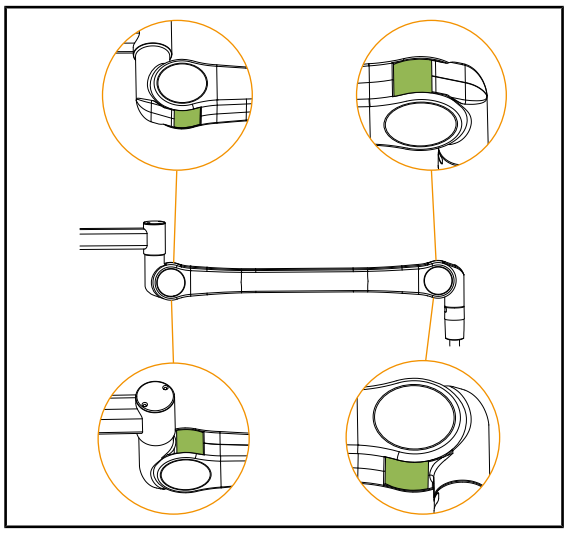


Fig. 19: Inspection of the spring arm tabs

### Half-rings on spring arms

1. Check that the tabs on the spring arms are fitted correctly in their slots.

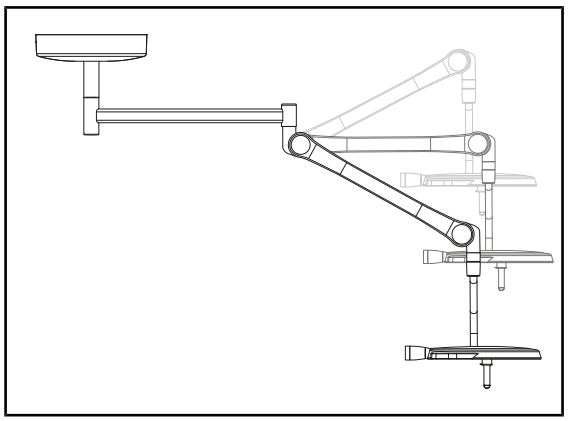


Fig. 20: Spring arm positioning

### Spring arm positioning

1. Place the spring arm in its lowest position, horizontally and finally in its highest position.
2. Check that the spring arm remains in each of these positions.

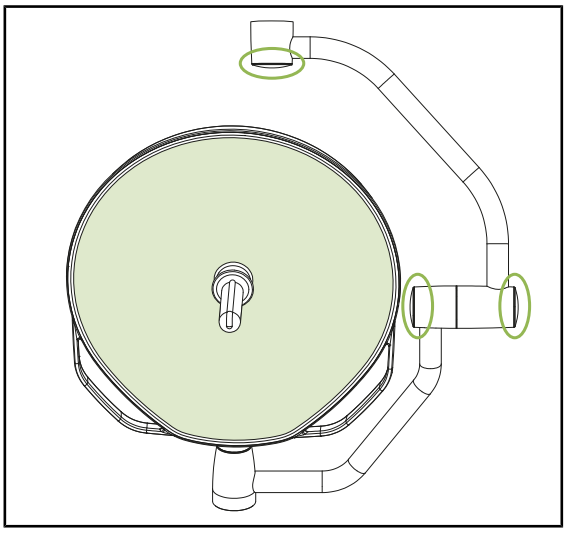


Fig. 21: Lighthead underside and fork cap

**Silicone caps and lighthead cover**

1. Check that the fork caps are properly positioned.
2. Check that the underside is not damaged (scratches, stains, etc.).

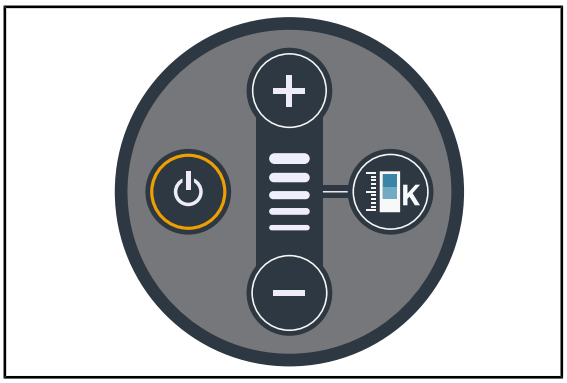


Fig. 22: Lighthead control keypad condition and operation

**Lighthead control keypad**

1. Check that the lighthead control keypad is in good condition and in the proper position.
2. Press the ON/OFF button on the lighthead control keypad to turn on the light.
3. Check that the lighthead responds to keypad commands by adjusting the illumination of the lighthead from the minimum to the maximum setting.
   - ➢ The light intensity varies depending on the selected level.
4. Check that all the LEDs are operating.

**NOTICE**

**After-sales service kits are available on the spare parts platform LinkOne**

The LinkOne platform is accessible on the GetingeOnline portal:
**https://swp-linkone.getingegroup.local/**

## 4.2 Controlling the light

### 4.2.1 Turning the light on and off

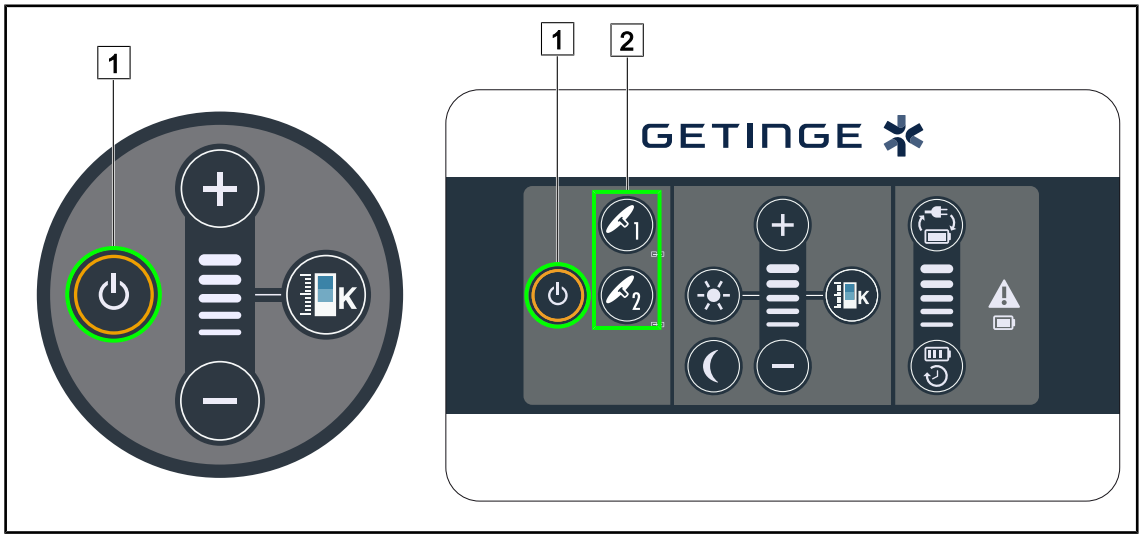



Fig. 23: Turning the light on and off

**Turning on the light, one lighthead at a time**

1. On a wall-mounted control keypad, press the button [2] for the lighthead to be turned on, and hold it until the button is backlit.
2. Press the **On/Off** [1] button to turn on the lighthead.
   - ➢ The LED sectors are turned on in sequence, and the illumination level is automatically set to Level 3, recommended to start the operation.

**Turning on the entire light system (via the wall-mounted control keypad only)**

1. Press **On/Off** [1].
   - ➢ The LED sectors on all lightheads are turned on in sequence, and the illumination level is set to Level 3, recommended to start the operation.

**Turning the light off via the lighthead keypad**

1. Press the **On/Off** [1] button and hold it until the keypad turns off.
   - ➢ The LED sectors on the lighthead are turned off in sequence once the button is released.

**Turning the light off via the wall-mounted keypad**

1. Press the button [2] for the lighthead to be turned off and hold it until the button is backlit.
2. Press the **On/Off** [1] button and hold it until the lighthead button turns off.
   - ➢ The LED sectors on the lighthead are turned off in sequence once the button is released.

## 4.2.2 Adjusting the illumination

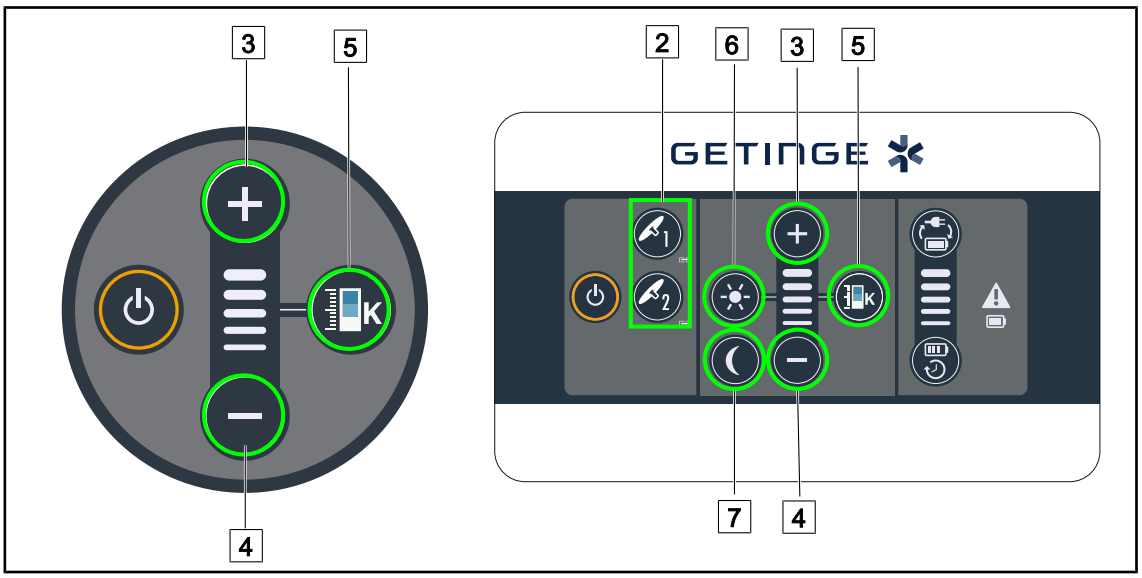



Fig. 24: Adjusting the illumination

*For the wall-mounted control keypad, first select the lighthead* 2 *to be adjusted.*

**Adjusting the light intensity**

1. On the wall-mounted keypad, press the **Sun** 6 button to adjust the illumination level of the lighthead(s).
2. Press **Plus** 3 to increase the light intensity level of the lighthead(s).
3. Press **Minus** 4 to decrease the light intensity level of the lighthead(s).

**NOTICE**

Careview: Levels 4 and 5 flash in order to maintain user vigilance when several light fields are superimposed.

**Enable/disable the ambient light via the lighthead keypad**

1. On the lighthead press **Minus** 4 until the first LED of the level indicator flashes.
   ➢ Ambient lighting is now enabled.
2. Press **Plus** 3 to disable ambient lighting.
   ➢ Ambient lighting is now disabled.

**Enable/disable the ambient light via the wall-mounted keypad**

1. On the wall-mounted keypad press the **Moon** 7 button until the first LED of the level indicator flashes.
   ➢ Ambient lighting is now enabled.
2. Press the **Sun** 6 button to disable ambient lighting.
   ➢ Ambient lighting is now disabled.

**Adjusting the colour temperature (option)**

1. Press **Colour Temperature** [5]
   ➢ The button is backlit on the keypad.
2. Press **Plus** [3] to select a colder colour temperature.
3. Press **Minus** [4] to select a warmer colour temperature.
4. Press **Colour Temperature** [5] on the lighthead, or select the Sun [6] button on the wall-mounted keypad to exit the colour temperature variation mode.

## 4.2.3 Synchronising the lightheads

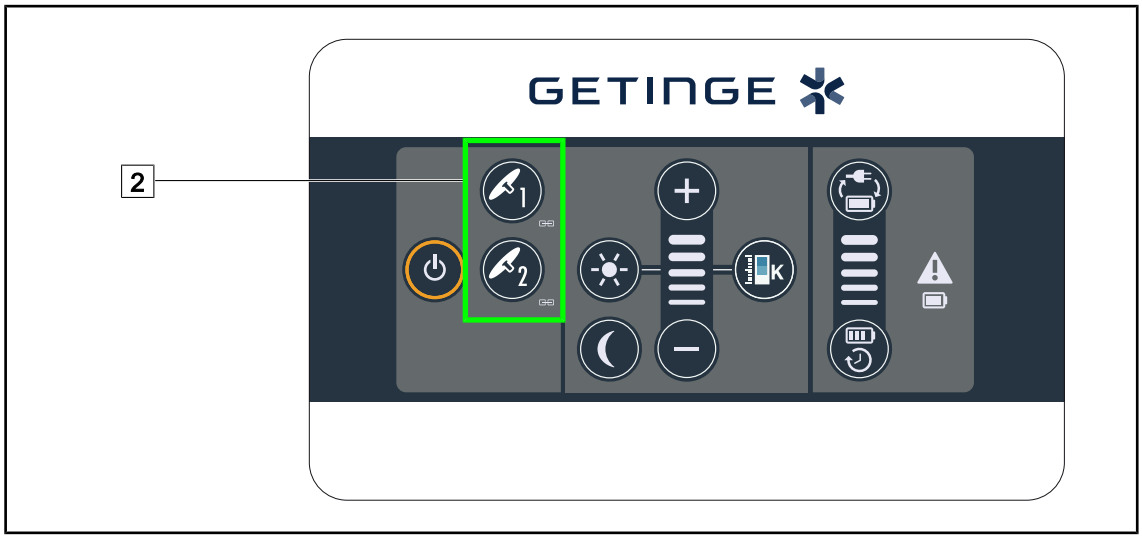



Fig. 25: Synchronising the lightheads via the wall-mounted keypad

**Synchronising/desynchronising the lightheads**

1. Adjust one of the lightheads to the desired settings.
2. Press the button [2] for the lighthead to be synchronised and hold it until the button is backlit.
   ➢ The lightheads are now synchronised and all changes on one lighthead will result in the same changes being applied to the other lighthead.
3. To desynchronise the desired lighthead, press the button [2] for the lighthead to be desynchronised and hold it until the button is no longer backlit, or modify the status of a lighthead using its local control keypad.
   ➢ The lightheads are no longer synchronised.

## 4.3 Positioning the light

### 4.3.1 Installing and removing the sterilisable handle

**STG HLX handle**

**WARNING!**
**Risk of infection**
**The sterilisable handles are the only parts of the device that can be sterilised. Any contact by the sterile team with another surface results in a risk of infection. Any contact by non-sterile personnel with these handles results in a risk of infection.**

**During the procedure, the sterile team must handle the device using the sterilisable handles. On an HLX handle, the locking button is not sterile. Non-sterile personnel must not come into contact with the sterilisable handles.**

**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.**

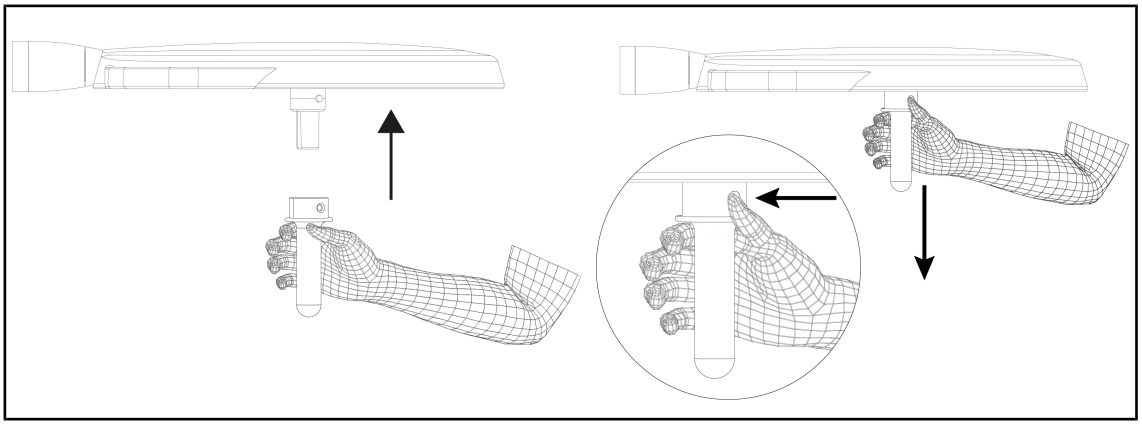


Fig. 26: Installing or removing the STG HLX sterilisable handle

**Installing an STG HLX sterilisable handle**

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

**Removing the STG HLX sterilisable handle**

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

### STG PSX handle

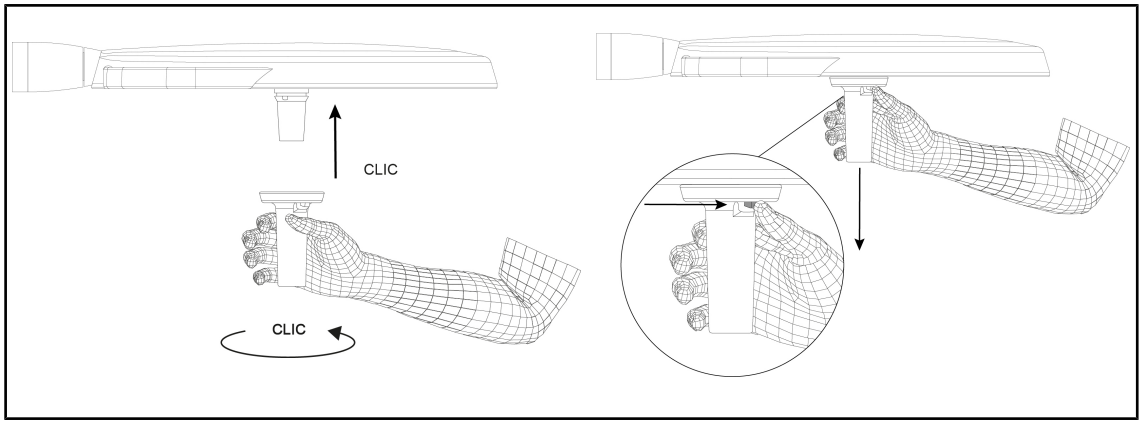



Fig. 27: Installing or removing the STG PSX sterilisable handle

#### Installing a sterilisable handle on the lighthead

1. Inspect the handle and check for cracks or soiling.
2. Insert the handle on the mount.
   - ➢ A click is heard.
3. Rotate the handle until its rotation is locked.
   - ➢ The handle is now locked in place and ready for use.

#### Removing the sterilisable handle from a lighthead

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

### 4.3.2 Manoeuvring the lighthead

**WARNING!**

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

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

**WARNING!**

**Risk of infection**
**The sterilisable handles are the only parts of the device that can be sterilised. Any contact by the sterile team with another surface results in a risk of infection. Any contact by non-sterile personnel with these handles results in a risk of infection.**

**During the procedure, the sterile team must handle the device using the sterilisable handles. On an HLX handle, the locking button is not sterile. Non-sterile personnel must not come into contact with the sterilisable handles.**

**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.**

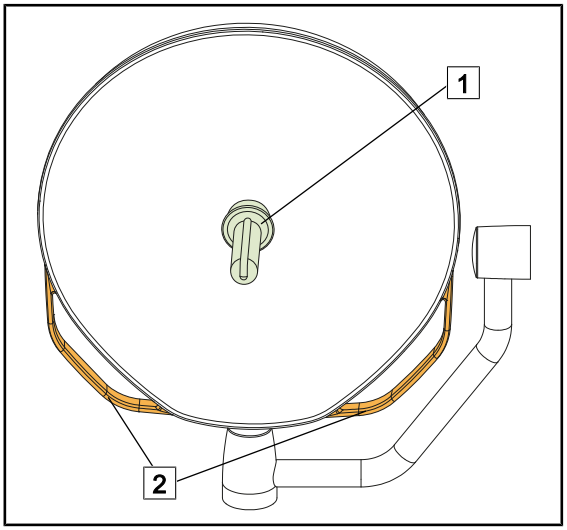



Fig. 28: Manoeuvring the lighthead

- 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 external handles of the lighthead [2].

### Special case - Maquet EZEA SHIP

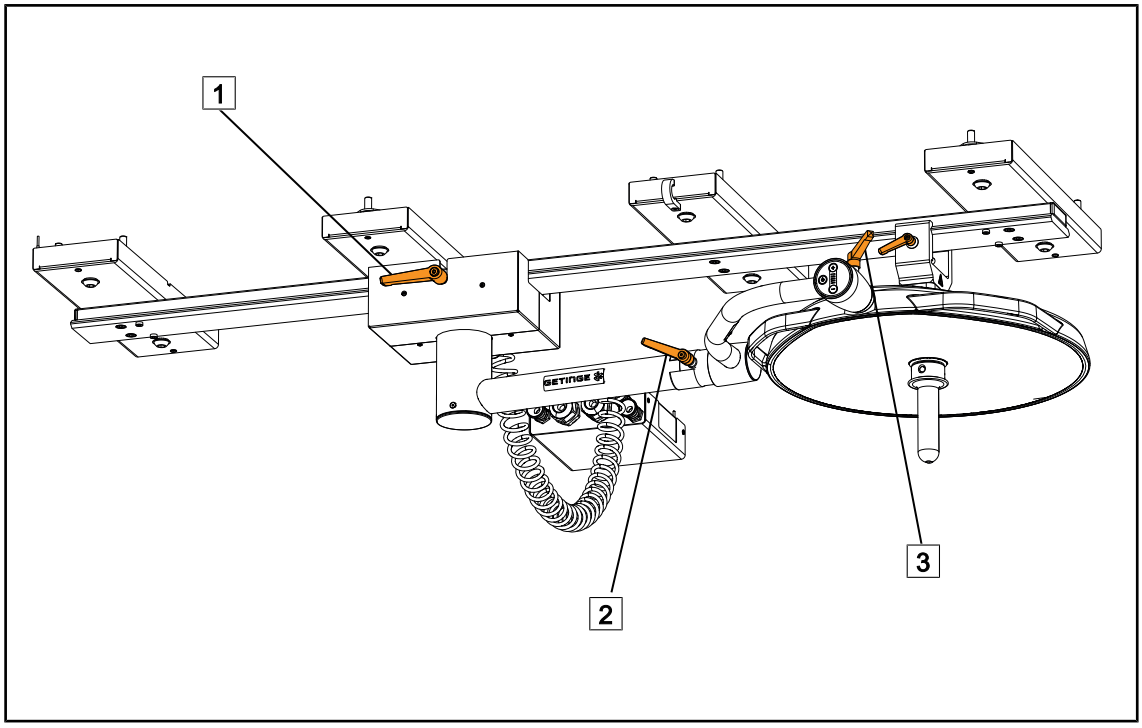



Fig. 29: Manoeuvring the Maquet EZEA SHIP configuration.

- Non-sterile personnel can manoeuvre the Maquet EZEA SHIP configuration in different ways in order to move it:
  - By unscrewing the threaded indexing lever 1, to slide the unit laterally on the rail.
  - By unscrewing the brake handle 2 to adjust the angle on the fixed suspension.
  - By unscrewing the brake handle 3 to adjust the angle on the fork.

### Light rotation angles

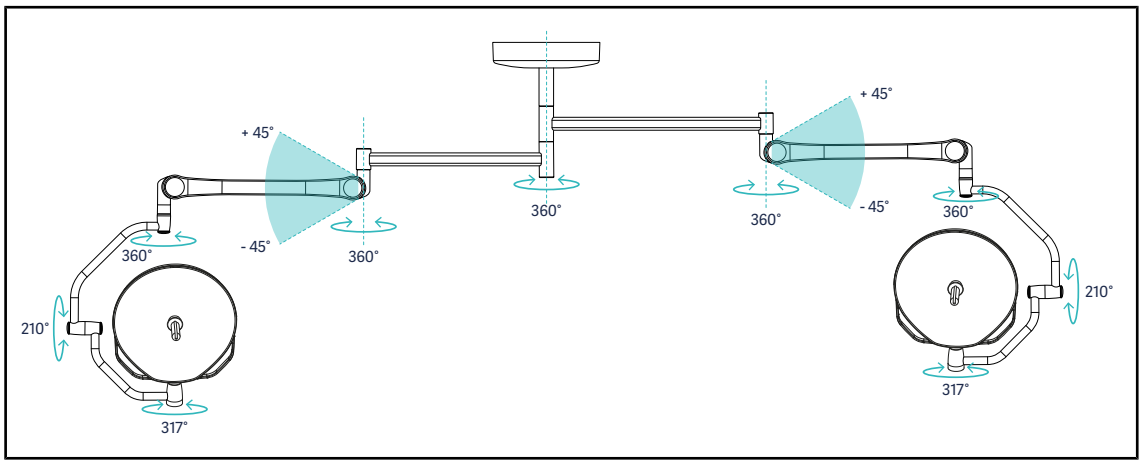



Fig. 30: Possible rotations of an EZEA DF dual configuration on SB suspension

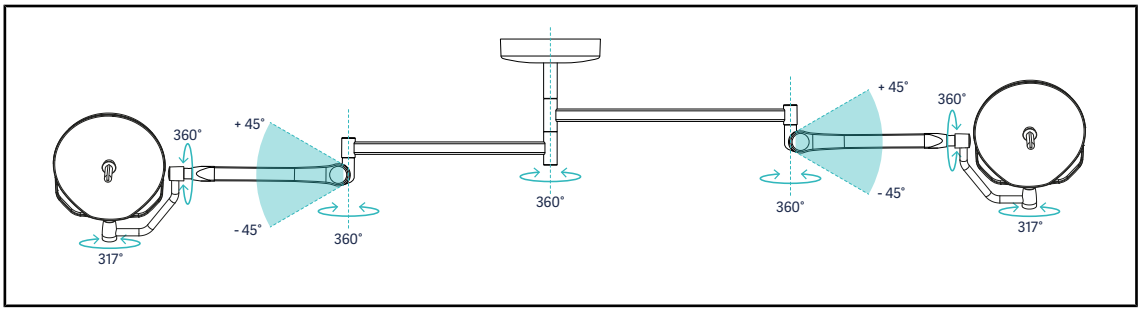



Fig. 31: Possible rotations of an EZEA SF dual configuration on SB suspension

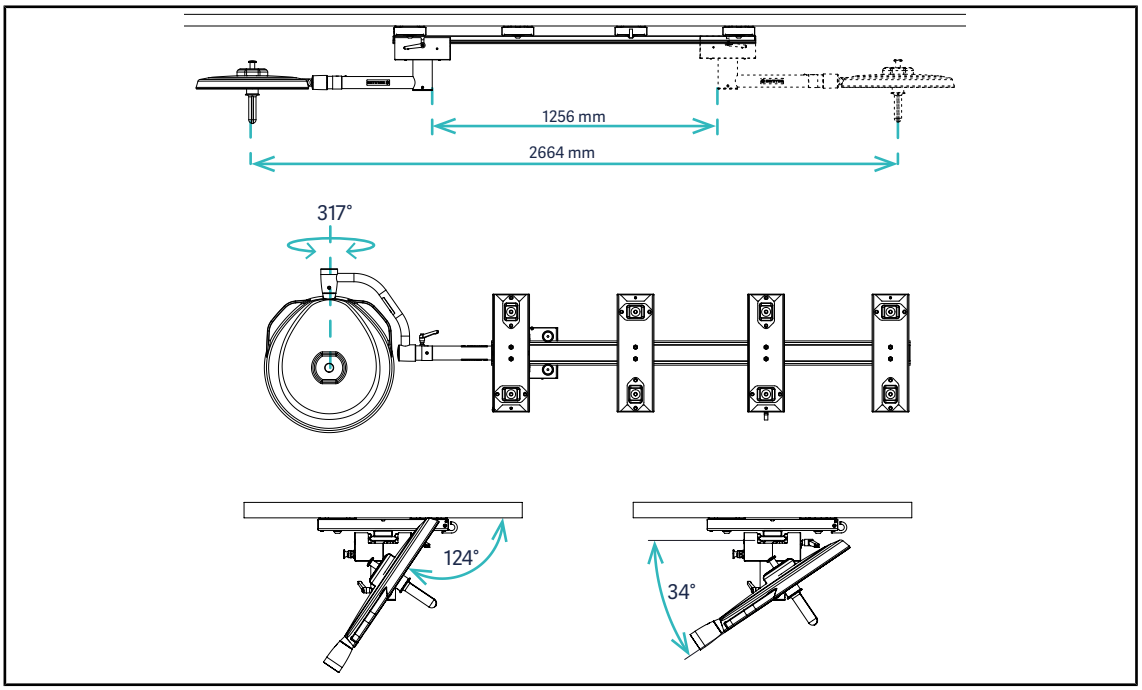



Fig. 32: Possible rotations and dimensions of a Maquet EZEA SHIP configuration

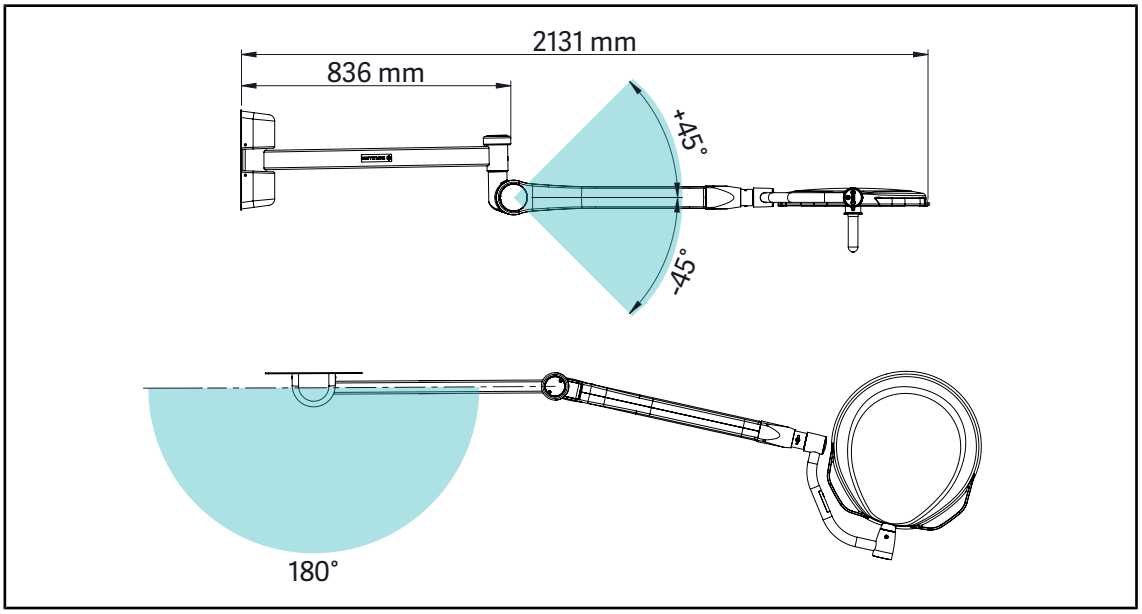



Fig. 33: Possible rotations and dimensions of a Maquet EZEA WALL configuration

### 4.3.3 Pre-positioning examples

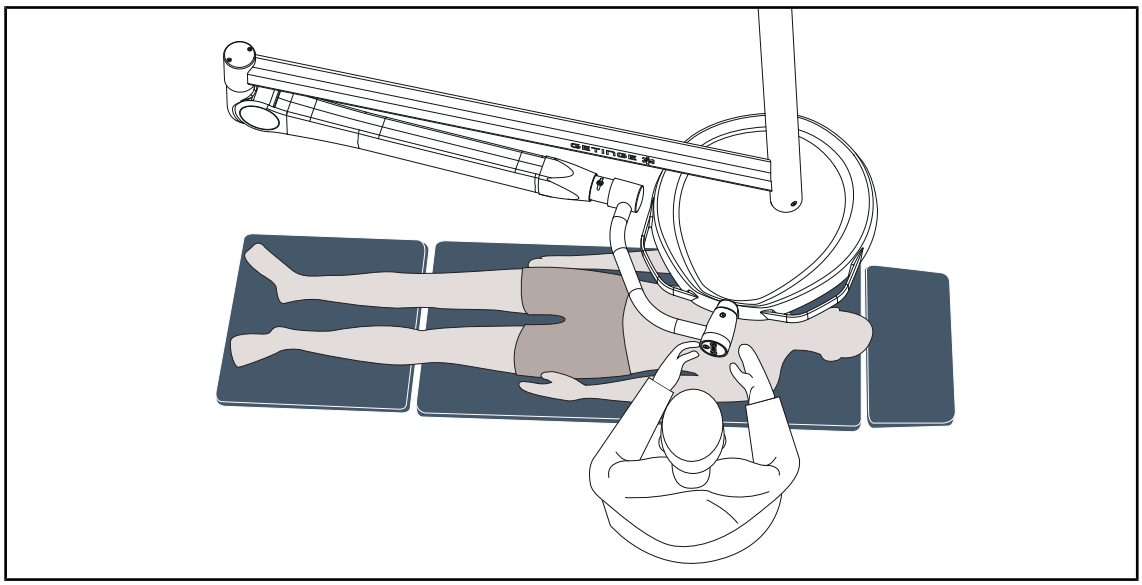


Fig. 34: Example of Maquet EZEA single configuration pre-positioning

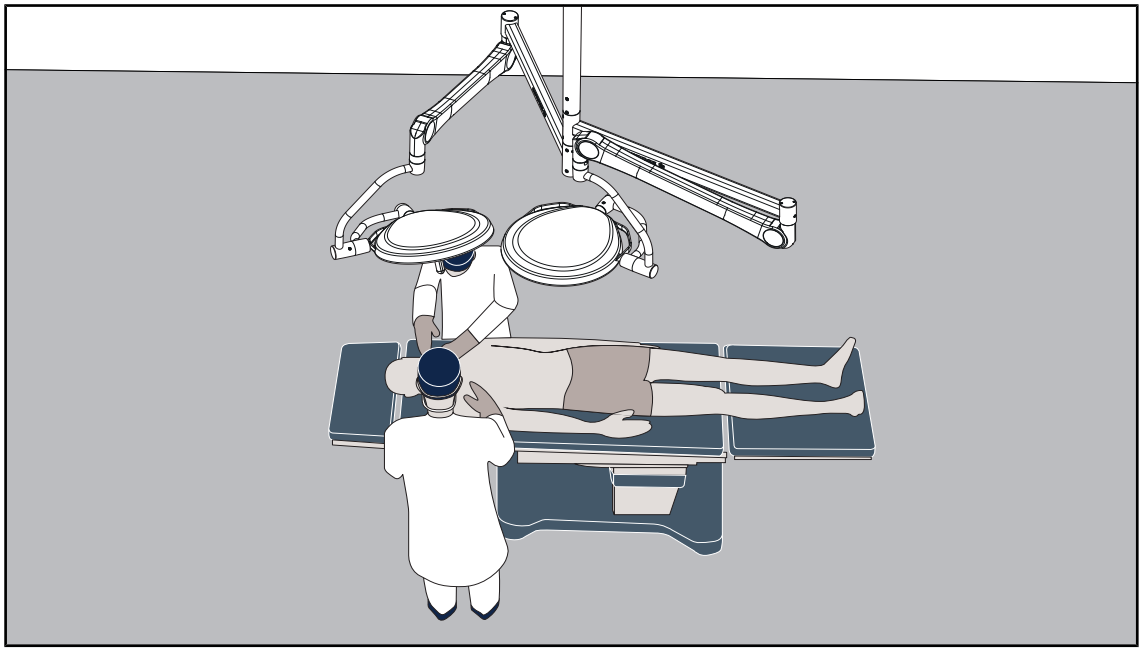


Fig. 35: Example of Maquet EZEA dual configuration pre-positioning

Surgical lighting should be placed above the surgical site, so as to direct the light volume into the area of interest:

- In case of a dual configuration, one lighthead is positioned perpendicular to the area ofinterest, while the other serves as a mobile auxiliary light source to illuminate at various angles.
- Lighting should be placed at a distance to cover the area ofinterest and minimize collisions, at the appropriate level so that the surgeon can operate comfortably. The optimal lighting distance is between 1.0 and 1.3 m.
- Lighting should be placed so as not to obstruct the movement of the surgical team or equipment.

### 4.3.4 EZEA SHIP special case (Transport)

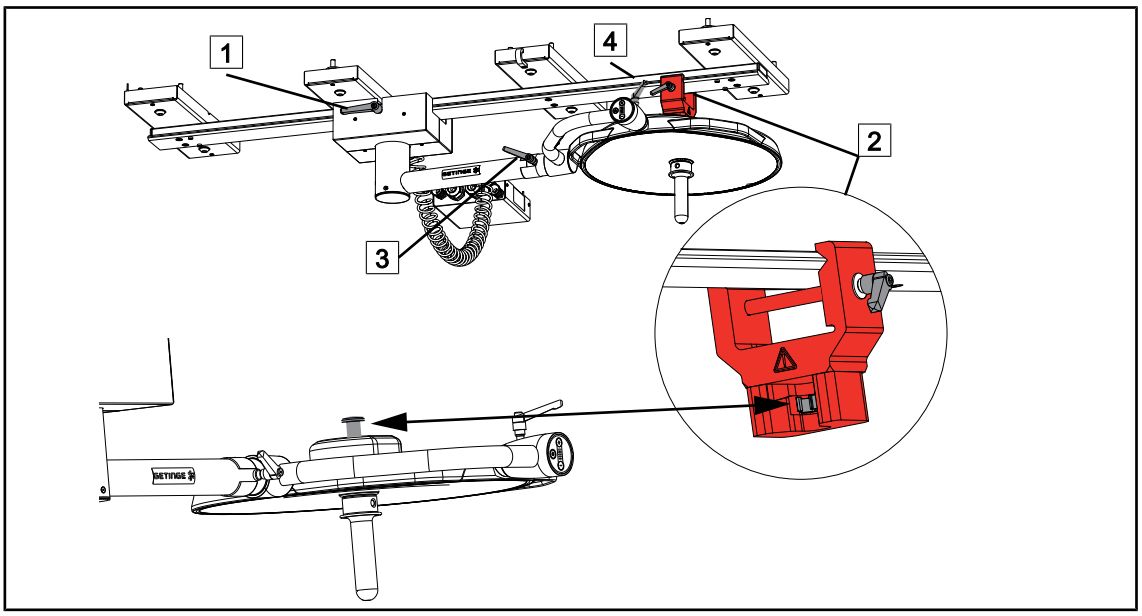



Fig. 36: Unlocking or locking the Maquet EZEA SHIP configuration.

**Unlock to use the unit, or lock to move the Maquet EZEA SHIP configuration.**

- Unlocking to use the unit:
  - Unscrew the indexing lever [1] by at least two turns to release the cart, then move the cart laterally on the rail to release the lighthead from the parking dock.
  - Unscrew the indexing lever [2] and remove the parking dock from the rail.
  - Turn the suspension tube to position the lighthead then tighten the indexing lever [1] to lock the cart and rotation.
- Locking to move the unit:
  - Unscrew the brake handle [4] to adjust the angle on the fork and position the lighthead horizontally, then tighten to lock.
  - Unscrew the brake handle [3] to adjust the angle on the fixed suspension and position the lighthead horizontally, then tighten to lock.
  - Unscrew the lever [1] to position the lighthead above the rail.
  - Insert the parking dock onto the rail, then tighten the indexing lever [2].
  - Move the lighthead laterally to insert it into the parking dock then tighten the indexing lever [1] to lock the cart.

## 4.4 Perform battery tests via the wall-mounted control keypad

**WARNING!**
**Risk of injury**
**A battery lifetime test fully discharges the batteries.**
**Do not perform an operation immediately after a battery lifetime test. Allow time for the batteries to charge.**

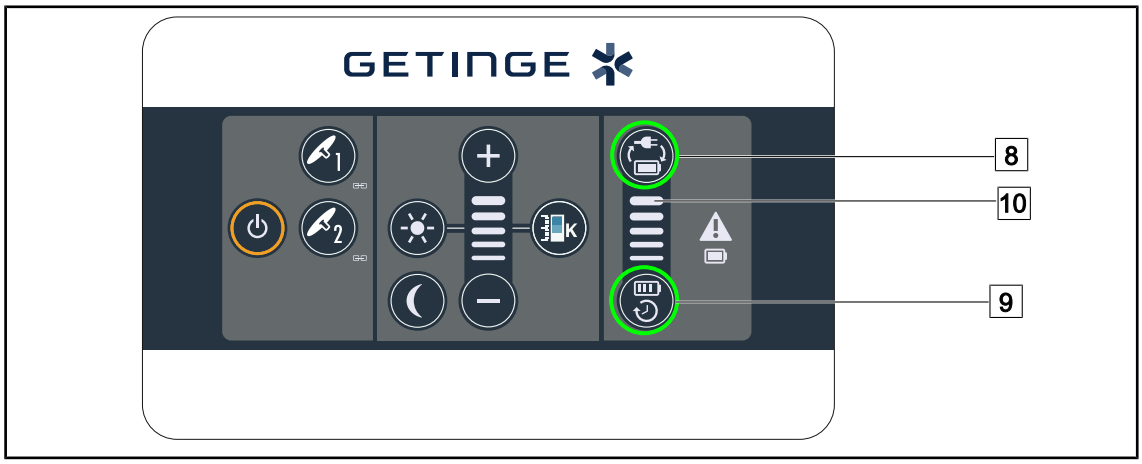



Fig. 37: Conducting battery tests

**Running a battery backup test**

1. Turn off the light.
2. Press **Scale test** [8].
   - ➢ If the test is successful, the battery level indicator [10] will flash green. If the test fails, the battery level indicator [10] flashes red.
3. If the test fails, contact the Getinge technical service department.
4. Press **Switchover test** [8] again and hold it down until the button goes out.
   - ➢ The light remains on at Level 3 and the system is ready for use.

**Running a battery life test (only with a Getinge backup)**

1. Turn off the light.
2. Press **Battery life test** [9] and hold it down until the button is backlit.
   - ➢ If the test is successful, the battery level indicator [10] will flash green. If the test fails, the battery level indicator [10] flashes red.
3. If the test fails, contact the Getinge technical service department.
   - ➢ The light turns off when the test is complete.
4. Press **Battery life test** [9] again and hold it down until the button goes out.

**NOTICE**
The battery life test can be stopped at any time by pressing **Battery life test** [9].

**The batteries are guaranteed for a period of 3 years.**

# 5 Troubleshooting

### Mechanical

| Anomaly | Likely cause | Corrective action |
|---|---|---|
| The sterilisable handle does not click into place correctly | The locking mechanism is damaged | Replace the handle |
| Drift of the system | Worn brake(s) | Have the brakes replaced by a trained technician |
| | Incorrect adjustment of the brake(s) | Have the brakes adjusted by a trained technician |
| Device too stiff to manoeuvre | Mechanical lock | Contact the Getinge technical department |

Tab. 14: Mechanical anomalies and malfunctions

### Electronics/Optics

| Anomaly | 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 |
| A group of LEDs or one LED does not come on | The LED board is defective | Contact the Getinge technical department |
| The light flickers | The LED board is defective | Contact the Getinge technical department |
| A control button does not respond | The control keypad is defective | Contact the Getinge technical department |
| | Communication problem | Contact the Getinge technical department |
| | This function is not available on your device | N/A |

Tab. 15: Optical anomalies and malfunctions

# 6 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.**

## 6.1 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.

### 6.1.1 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.

## 6.1.2 Disinfecting the device

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

### 6.1.2.1 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

### 6.1.2.2 Permitted active substances

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

Tab. 16: Lists of active substances suitable for use

**Examples of commercially available products tested**

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

## 6.2 Cleaning and sterilising Maquet Sterigrip sterilisable handles

### 6.2.1 Preparation for cleaning

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

### 6.2.2 Manual cleaning

1. Immerse the handles in a detergent solution 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.

**NOTICE**

The use of non-enzymatic detergents is recommended. Enzymatic detergents may damage various materials. Never soak parts in these detergents for prolonged periods; rinse thoroughly.

### 6.2.3 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. 17: Typical cleaning cycles in a washer-disinfector

### 6.2.4 Sterilisation of the Maquet Sterigrip handles

**WARNING!**

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

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

**NOTICE**

Maquet Sterigrip 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. 18: Example of a steam sterilisation cycle

# 7 Maintenance

To maintain the device's initial performance and reliability, maintenance and inspection operations must be carried out every 10 years. During the warranty period, maintenance and inspection work must be carried out by a Getinge technician or a Getinge-approved distributor. Beyond this period, maintenance and inspection operations may be carried out by a Getinge technician, a Getinge-approved distributor, or a hospital technician trained by Getinge. Please contact your dealer to undergo the technical training required.

| | |
|---|---|
| Preventive maintenance | To be performed every 10 years |

Certain components must be replaced during the device's service life. Check the Maintenance Manual to find out when this should be done. 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 the contact details for your local Getinge representative, please visit **https://www.getinge.com/int/contact/find-your-local-office**.

# 8 Technical specifications

## 8.1 Optical specifications

**NOTICE**

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

The maximum illumination distance ($D_{MI}$) is equal to the reference distance ($D_{REF}$) of 1 metre (39.4 inches) ± 10%.

| Specifications | EZEA 300 | Tolerance |
|---|---|---|
| Central illumination ($E_{c,MI}$) | 40,000 lux to 160,000 lx | – |
| Maximum central illumination ($E_{c,MI}$) = ($E_{c, Ref}$) | 160,000 lx | 0/- 10% |
| Light field diameter $d_{10}$ | 22 cm | ± 10% |
| Light distribution $d_{50}/d_{10}$ | 0.6 | ± 0.06 |
| Depth of illumination above 60% | 70 cm | ± 10% |
| Colour temperature | Fixed: 4300 K<br>Variable: 4100 K/4600 K | ± 400 K |
| Colour rendering index (Ra) | 95 | ± 5 |
| Special colour rendering index (R9) | 90 | +10 / - 20 |
| Special colour rendering index (R13) | 96 | ± 4 |
| Special colour rendering index (R15) | 95 | ± 5 |
| Maximum irradiance ($E_{total}$ | 608 W/m² | ± 10% |
| Irradiance at level 3 and below | < 350 W/m² | – |
| Heat/light ratio | 3.8 mW/m²/lx | ± 0.3 |
| UV illumination | ≤ 0.7 W/m² | – |
| FSP system | Yes | – |
| Illumination in ambient light mode | 12,000 lx | ± 7 klx |

Tab. 19: EZEA 300 lighthead optical data in accordance with IEC 60601-2-41

| Residual illumination | EZEA 300 | Tolerance |
|---|---|---|
| With one mask | 35% | ±10 |
| With two masks | 45% | ±10 |
| With simulated cavity | 100% | ±10 |
| With one mask, with simulated cavity | 35% | ±10 |
| With two masks, with simulated cavity | 45% | ±10 |

Tab. 20: EZEA 300 lighthead residual illumination in accordance with the EN 60601-2-41 standard

### Photobiological risk factors

**WARNING!**

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

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

**WARNING!**

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

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

## 8.2 Mechanical specifications

### Suspension arms and spring arms

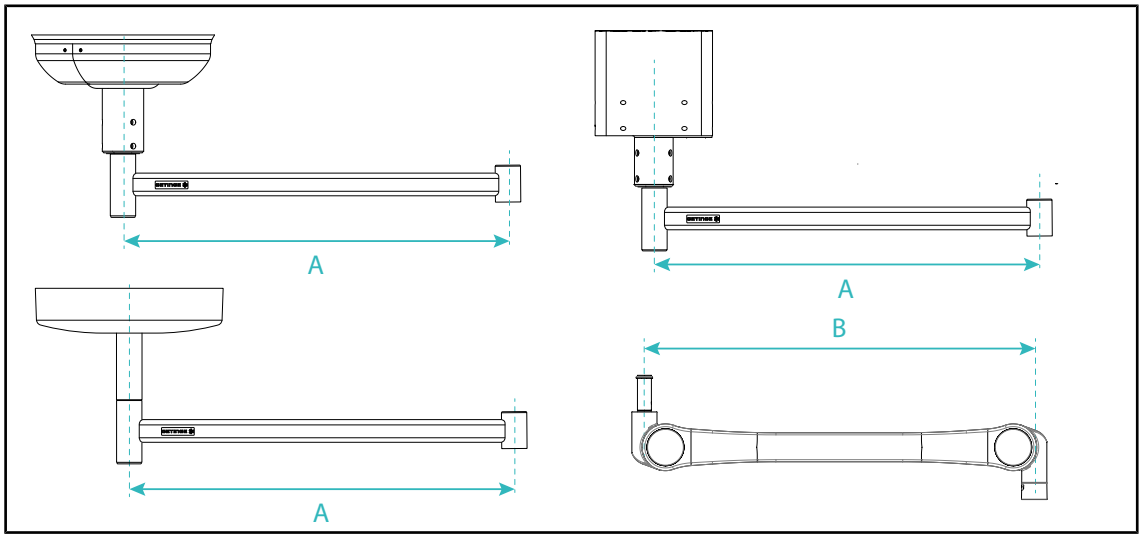



Fig. 38: Dimensions of suspension arms and spring arms

| SB (A) suspension arm | Spring arm (B) |
|---|---|
| 850 mm (≈ 33.5 in)<br>1000 mm (≈ 39.5 in)<br>1150 mm (≈ 45 in) | SF on SB suspension: 792 mm (≈ 31.2 in)<br>DF on SB suspension: 910 mm (≈ 35.8 in) |

Tab. 21: Table of possible dimensions of suspension arms and spring arms

### Lighthead

| Specifications | EZEA 300 | EZEA 300 SHIP | EZEA 300 CLS |
|---|---|---|---|
| Weight of single-fork lighthead | 6.3 kg | 6.8 kg | 7 kg |
| Weight of dual-fork lighthead | 7.4 kg | N/A | N/A |
| Diameter of lighthead (including handle) | 511.4 mm | 511.4 mm | 511.4 mm |

Tab. 22: Table of lighthead mechanical specifications

### Power supply

| Characteristics | EPS power supply |
|---|---|
| Dimensions of EPS wall-mounted unit (H x W x D) | 310 x 400 x 145 mm |
| Dimensions of battery pack unit (EPS MB) (H x W x D) | 310 x 400 x 145 mm |
| Weight of EPS 10 | 3.5 kg |
| Weight of EPS 20 | 4 kg |
| Weight of 1H -240 V battery pack unit (EPS MB1) (with batteries) | 10 kg |
| Weight of 3H -240V battery pack unit (EPS MB3) (with batteries) | 20 kg |

Tab. 23: Wall-mounted EPS power supply mechanical characteristics

| Characteristics | EPS power supply |
|---|---|
| Dimensions of EPS 10 ceiling-mounted enclosure (H x W x D) | 72.7 x 236 x 240 mm |
| Dimensions of EPS 20 ceiling-mounted enclosure (H x W x D) | 72.7 x 408.5 x 240 mm |
| Weight of EPS 10 ceiling-mounted unit | 1.5 kg |
| Weight of EPS 20 ceiling-mounted unit | 3 kg |

Tab. 24: Ceiling-mounted EPS power supply mechanical characteristics

| Characteristics | WPS 24 power supply |
|---|---|
| Dimensions of WPS 10 ceiling-mounted enclosure (H x W x D) | 72.7 x 236 x 240 mm |
| Dimensions of WPS 20 ceiling-mounted enclosure (H x W x D) | 72.7 x 408.5 x 240 mm |
| Weight of WPS 10 ceiling-mounted unit | 3 kg |
| Weight of WPS 20 ceiling-mounted unit | 6 kg |

Tab. 25: Ceiling-mounted WPS power supply mechanical characteristics

## 8.3 Electrical specifications

| Electrical specifications | EZEA 300 |
|---|---|
| EPS input voltage | 100-240 Vac, 50/60 Hz |
| Power | Single configuration: 120 VA<br>Dual configuration: 240 VA |
| Lighthead power rating | 80 VA |
| Lighthead input | 20 - 28 Vdc |
| Average service life of LEDs | ≥ 60,000 hours per TM-21:2012 standard<br>≥ 55,000 hours per TM-21:2016 standard |
| Battery charge time | 16 hours (3H pack) / 5 hours (1H pack) |

Tab. 26: Table of electrical specifications for EPS power supply

| Electrical specifications | EZEA 300 |
|---|---|
| WPS 24 input voltage | 24 Vac or 24 Vdc, 50/60 Hz |
| Power | Single configuration: 200 VA<br>Dual configuration: 400 VA |
| Lighthead power rating | 80 VA |
| Lighthead input | 20 - 28 Vdc |
| Average service life of LEDs | ≥ 60,000 hours per TM-21:2012 standard<br>≥ 55,000 hours per TM-21:2016 standard |

Tab. 27: Table of electrical specifications for WPS power supply

## 8.4 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 & Taiwan | Class II |
| Protection rating for the device as a whole | IP 20 |
| Protection rating of the lightheads | IP 54 |
| EMDN code | Z12010701 |
| GMDN code | 12 282 |
| CE marking year | 2023 |

Tab. 28: Specifications relating to standards and regulations

## 8.5 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.**

**NOTICE**

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[1] | 0.15 - 0.5 MHz | 66 dBµV - 56 dBµV QP<br>56 dBµV - 46 dBµV A |
| | | 0.5 - 5 MHz | 56 dBµV PQ<br>46 dBµV A |
| | | 5 - 30 MHz | 60 dBµV PQ<br>50 dBµV A |
| Measurement of the radiated electromagnetic field | EN 55011 GR1 CL A[1] | 30 - 230 MHz | 40 dBµV/m PQ 10 m |
| | | 230 - 1000 MHz | 47 dBµV/m PQ 10 m |

Tab. 29: EMC declaration

[1] 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. |
|---|---|---|
| Electrostatic discharge immunity | EN 61000-4-2 | Contact: ± 8kV<br>Air: ± 2; 4; 8; 15 kV |
| Immunity to radiated electromagnetic fields | EN 61000-4-3 | 80 MHz, 2.7 GHz<br>3 V/m Mod AM 80%/1 kHz |
| | | Wireless RF frequencies<br>9 to 28 V/m Mod AM<br>80%/1 kHz |
| Immunity to fast electrical transients and bursts | EN 61000-4-4 | AC: ± 2 kV - 100 kHz<br>IO >3m: ± 1 kV - 100 kHz |
| Immunity to power source voltage surges | EN 61000-4-5 | ± 0.5; 1 kV diff.<br>± 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<br>3 Vrms Mod AM 80%/1 kHz |
| | | ISM<br>6 Vrms Mod AM 80%/1 kHz |
| Immunity to voltage dips and short interruptions | EN 61000-4-11 | 0% Ut, 10 ms<br>(0°; 45°; 90°; 135°; 180°; 225°; 270°; 315°)<br>0% Ut, 20 ms<br>70% Ut, 500 ms<br>0% Ut, 5 s |

Tab. 30: EMC declaration

### 8.5.1 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.

# 9 Waste management

## 9.1 Disposal of packaging

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

## 9.2 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 Maquet EZEA Decommissioning Instructions (ARD01845). Contact your local Getinge representative to obtain a copy of this document.

Do not dispose of contaminated sterilisable handles as municipal waste.

## 9.3 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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