Instructions for use

PowerLED

IFU 01581 EN 2020-04-01

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.

End of production of the PowerLED 500 and PowerLED 700 lightheads

The PowerLED 500 and PowerLED 700 lightheads have been discontinued as of January 2020. Only the PowerLED 300 lighthead has been available for sale since that date; these instructions only cover currently sold products.

V 09 01.04.2020

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
DF	Double Fork
FSP*	Flux Stability Program
IFU	Instructions For Use
IP	Ingress Protection rating
K	Kelvin
LED	Light-Emitting Diode
lx	lux
N/A	Not Applicable
SF	Single Fork

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.

1.2.3 Definitions

1.2.3.1 Hazard levels

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

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

Tab. 1: Hazard levels of safety instructions

1.2.3.2 Indications

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

Tab. 2: Types of indication in the document

1.2.3.3 Groups of people

Users

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

Qualified personnel:

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

1.2.3.4 Light types

Minor surgical light

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

Surgical lighting system

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

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

1.3 Other documents relating to this product

- Technical manual (Ref. ARD01582)
- Installation Manual (Ref. ARD01584)

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 40].

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 the annual periodic checks being performed by personnel trained and approved by Getinge, see Maintenance schedule [⏩ Page 39]. 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).
	Follow the instructions for use (IEC 60601-1:2005).
	Follow the instructions for use (IEC 60601-1:1996).
	Manufacturer + manufacturing date
	Product code
	Product serial number
	Alternating current
	Direct current
	UL mark (Canada and United States)
	CE marking (Europe)
	Medical Device (MD) marking
	Do not discard with conventional waste.
	Standby
	Datamatrix identification code

1.8 Location and explanation of the device identification label

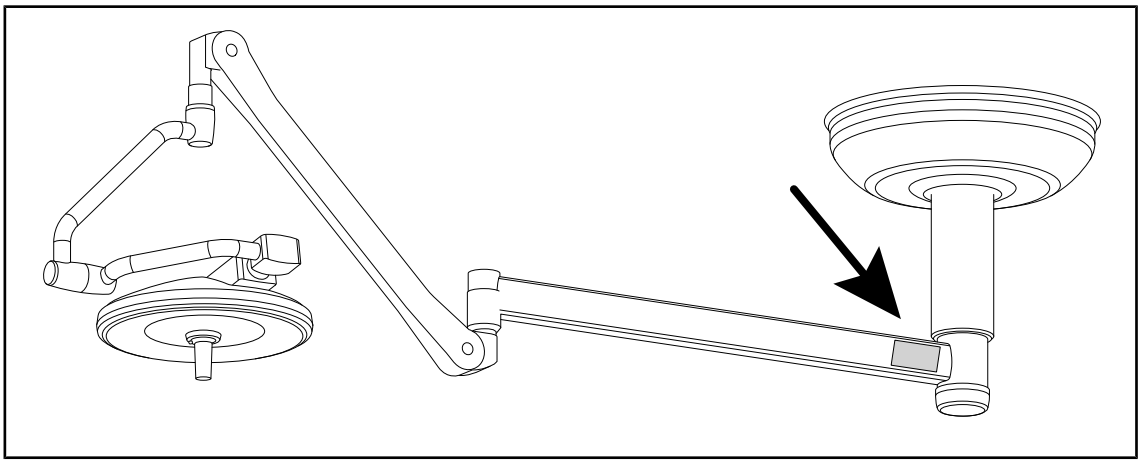


Fig. 1: Location of the product identification label

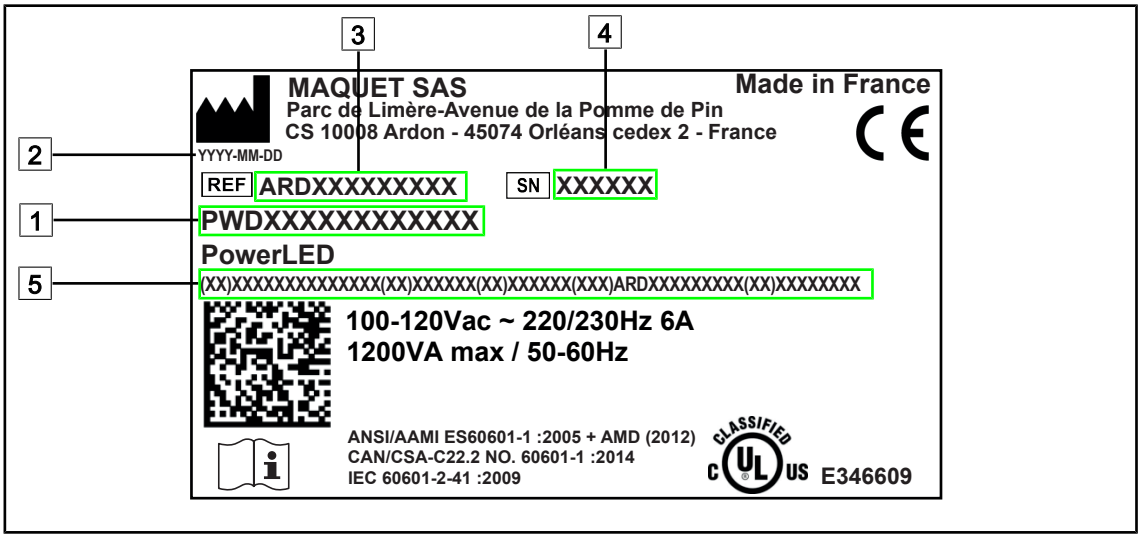


Fig. 2: Example label

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

1.9 Product overview

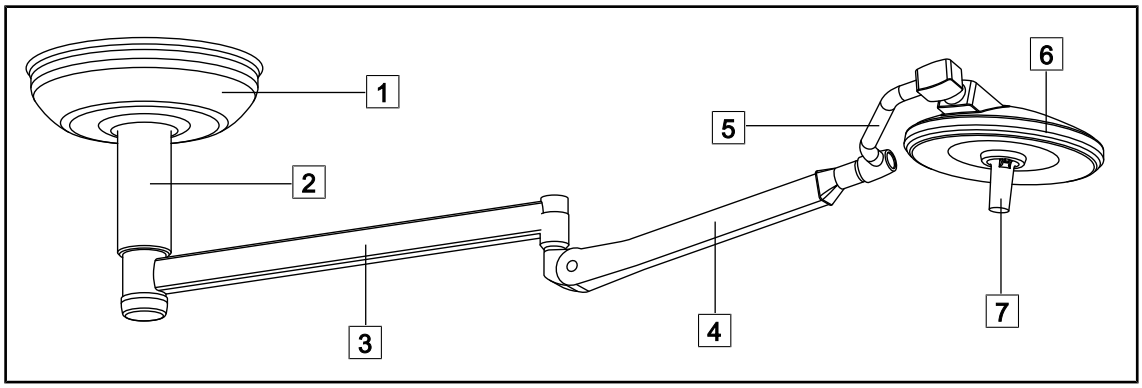


Fig. 3: Typical configuration: PWD30+SF K3

1 Ceiling cover
2 Suspension tube
3 Extension arm
4 SF spring arm
5 Single fork
6 PowerLED 300 lighthead
7 Sterilisable handle

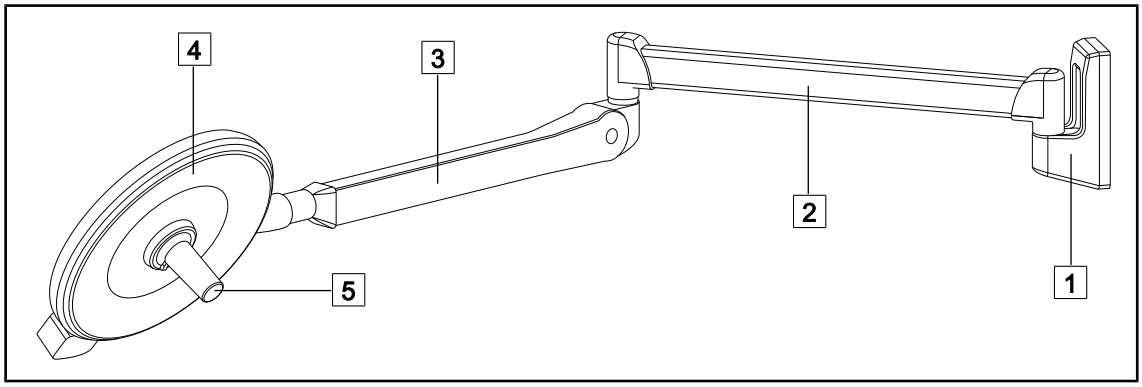


Fig. 4: Typical configuration: PWD30+SF W K3

1 Wall-mounted suspension arm
2 Extension arm
3 SF spring arm
4 PowerLED 300 lighthead
5 Sterilisable handle

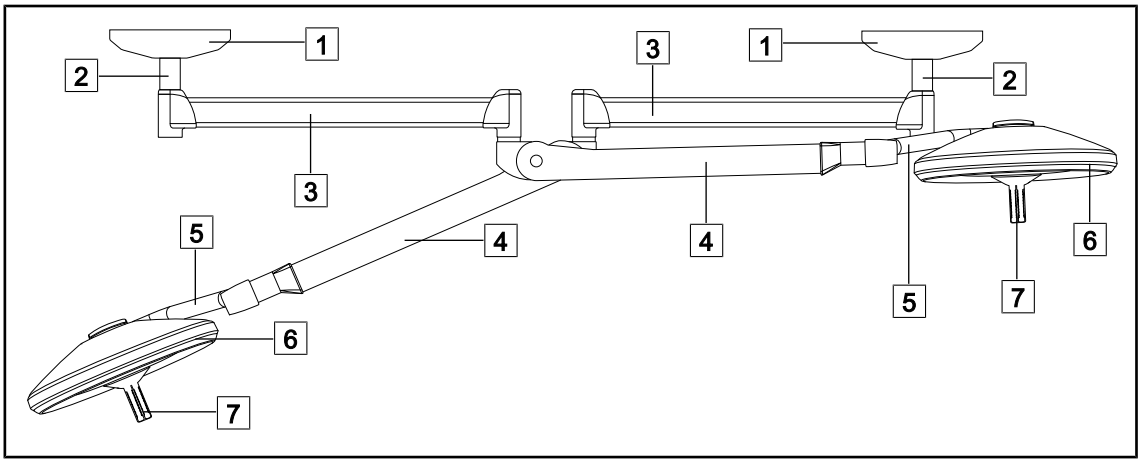


Fig. 5: Typical configuration: PWD30 DUAL NAVY SHIP

1 Ceiling cover
2 Suspension tube
3 Extension arm
4 SF spring arm
5 Single fork
6 PowerLED 300 lighthead
7 DEVON/DEROYAL handle mount**

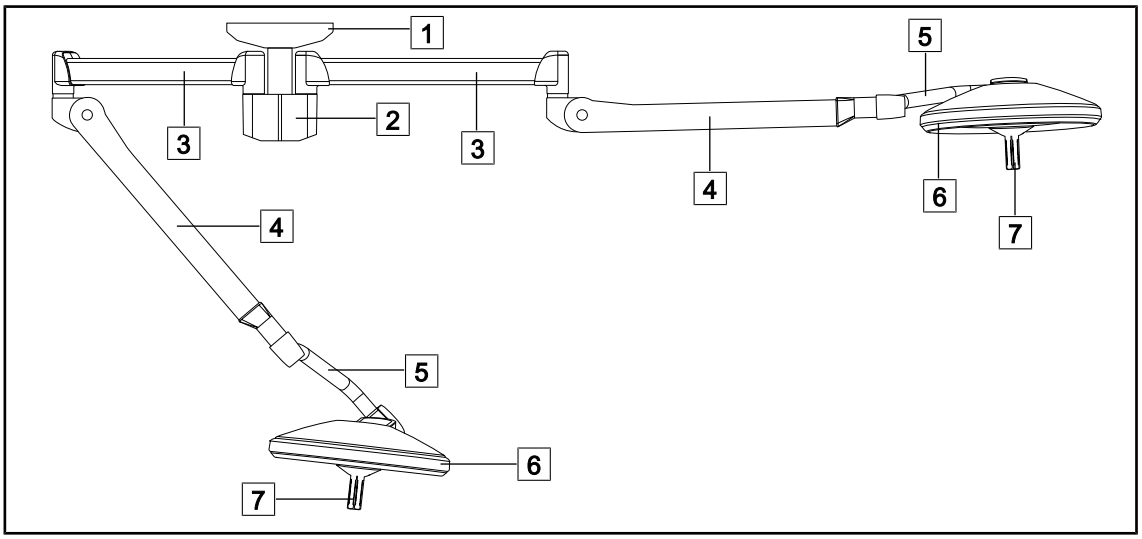


Fig. 6: Typical configuration: PWD33 S SHELTER

1 Ceiling cover
2 Suspension tube
3 Extension arm
4 SF spring arm
5 Single fork
6 PowerLED 300 lighthead
7 DEVON/DEROYAL handle mount

NOTE

This product can be mounted and dismounted inside an ISO SHELTER container. It is stored in a special carrying case.

1.9.1 Components

1.9.1.1 Lighthead

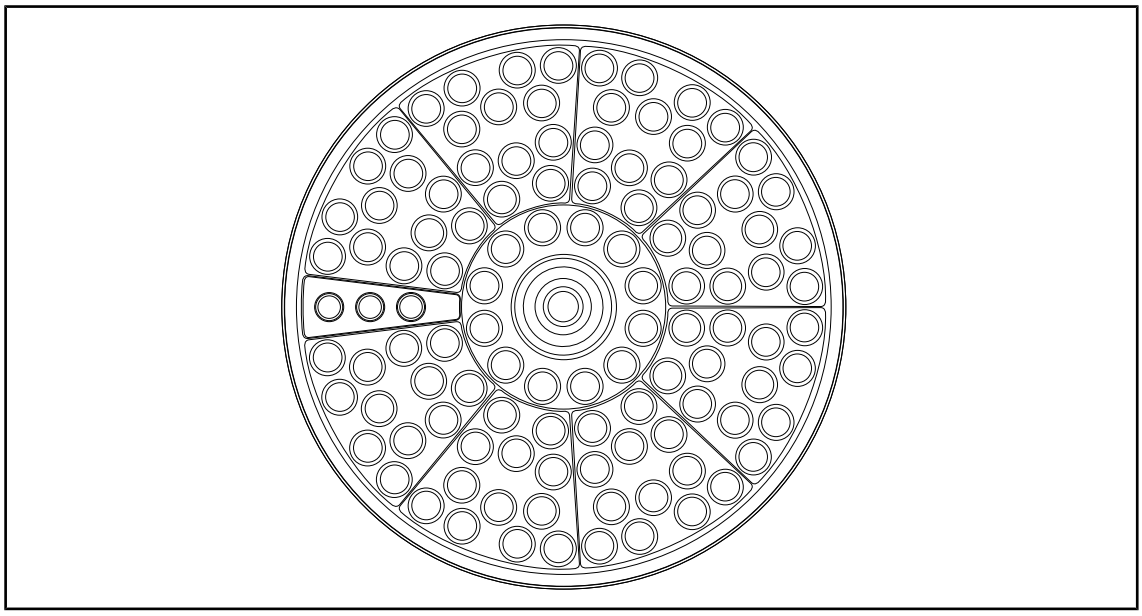


Fig. 7: PowerLED 300 lighthead

1.9.2 Accessories

Sterilisable handles

Illustration	Description	Code
	**Set of five PSX handles** These sterilisable handles are compatible with the PSX handle mount.	PSX 003

1.10 Standards applied

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

Standards	Year	Title
Directive 93/42/EEC	1993	Medical devices directive (Annex VII)
Directive 2014/53/EU	2014	Radio equipment directive
IEC 60601-1+A1 EN 60601-1+A1 IEC 60601-1+A1+A2+3 IEC 60601-1-1	2012 2013 1996 2000	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-4+A1	1999	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Collateral standard: Programmable electrical medical systems
ANSI/AAMI ES60601-1+A1	2005 + 2012	UL/cUL rating concerning electric shock, mechanical hazards and fire risks.
UL 60601-1		UL/cUL rating concerning electric shock, mechanical hazards and fire risks.
CSA CAN/CSA-C22.2 NO. 60601-1	2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (standard IEC 60601-1+A1:2012, with specific requirements for Canada)
IEC 60601-1-2 EN 60601-1-2 IEC 60601-1-2	2014 2015 2007	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6 EN 60601-1-6	2010 2010	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-2-41 EN 60601-2-41	2009 2009	Medical electrical equipment – Part 2-41: Particular requirements for the basic safety and essential performance of surgical luminaires and luminaires for diagnosis
IEC 62304 EN 62304/AC	2006 2008	Medical device software – Software life cycle processes
IEC 62311 EN 62311	2007 2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
IEC 62366 EN 62366	2007 2008	Medical devices – Application of usability engineering to medical devices
FCC Part 15	2008	Radio Frequency Devices
IEC 62471 EN 62471	2006 2008	Photobiological safety of lamps and lamp systems

Tab. 3: Compliance with product standards

Quality management:

Standards	Year	Title
EN ISO 13485 ISO 13485	2016 2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971 ISO 14971	2012 2007	Medical devices – Application of risk management to medical devices

Tab. 4: Compliance with quality management standards

RoHS:

Standards	Year	Title
EN 50581	2012	Assessment of electrical and electronic products with respect to the restriction of hazardous substances

Tab. 5: Compliance with RoHS standards

1.11 Information relating to intended use

1.11.1 Intended use

The PowerLED range is designed to illuminate the body of a patient during surgical operations, diagnostics or treatment.

1.11.2 Intended users

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

1.11.3 Inappropriate use

The device must be used:

- As a major light system (two lightheads) for all operations performed on patients, with or without risk.
- As a minor light system (one lighthead) only if the operation may be interrupted without endangering the patient’s life (e.g., diagnostic procedure).

Inappropriate use:

- Use of a damaged product (e.g., lack of maintenance).
- In a setting other than a professional healthcare environment (e.g., home care).

1.11.4 Contraindications

This product does not have any contraindications.

1.12 Primary purpose

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

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. 6: Environmental conditions for transport/storage

Environmental conditions for use

Ambient temperature	+10°C to +40°C
Relative humidity	20% to 75%
Atmospheric pressure	700 hPa to 1060 hPa

Tab. 7: Environmental conditions for use

2.2 Safety instructions

2.2.1 Safe use of the product

WARNING!

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

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

WARNING!

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

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

WARNING!

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

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

WARNING!

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

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

WARNING!

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

Do not use a damaged device.

2.2.2 Electrical

WARNING!

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

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

WARNING!

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

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

2.2.3 Optical

WARNING!

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

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

2.2.4 Infection

WARNING!

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

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

3 Control interface

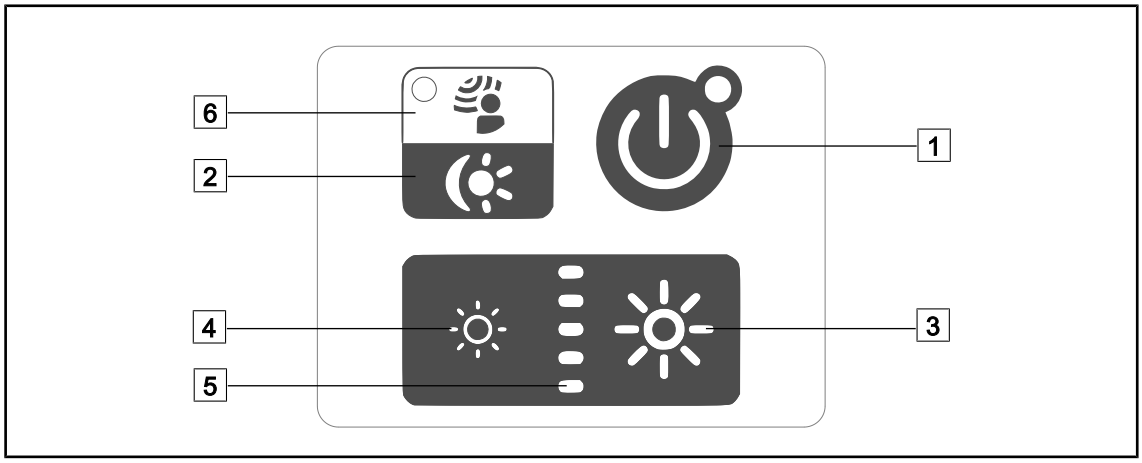


Fig. 8: Control keypad located on the lighthead fork

1 On/Off
2 Light mode
3 Increase illumination
4 Decrease illumination
5 Level indicator
6 AIM* (not available on PWD300)

4 Use

4.1 Daily inspections before use

NOTE

To ensure that the product used is compliant, various daily visual and functional inspections must be performed by trained personnel. It is recommended that records be kept of the results of these inspections, along with the date and signature of the person performing them.

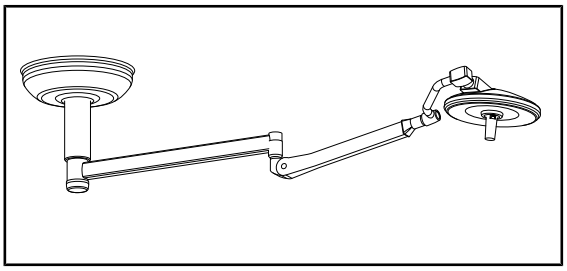


Fig. 9: Integrity of the device

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.

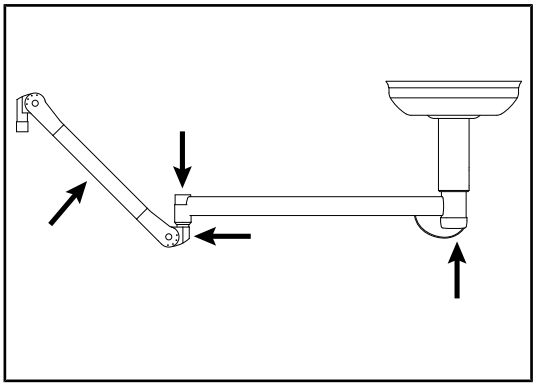


Fig. 10: Suspension covers

Suspension covers

1. Check that the spring arm covers are in the proper position and in good condition.
2. Check that the suspension covers, including the one beneath the central shaft, are in the proper position and in good condition.
3. If a problem is noted, contact technical support.

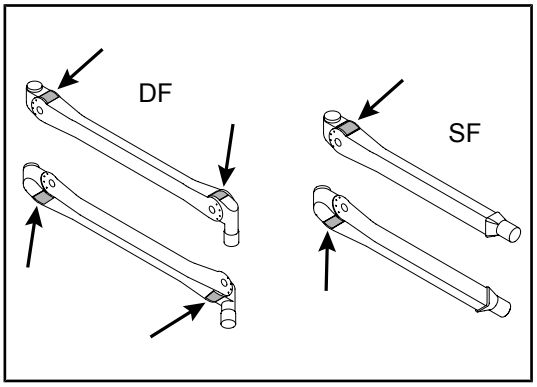


Fig. 11: Metal half-rings

Metal half-rings on spring arms

1. Check that the metal half-rings on the spring arms are in place in their slots.
2. If a problem is noted, contact technical support.

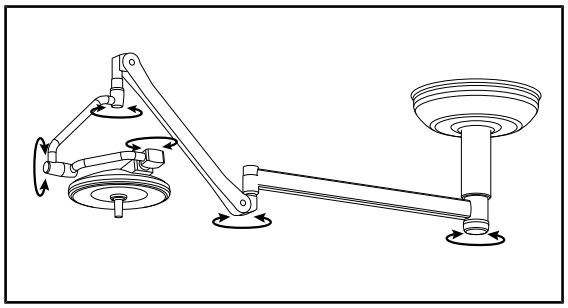


Fig. 12: Stability and drift of the system

Stability and drift of the system

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

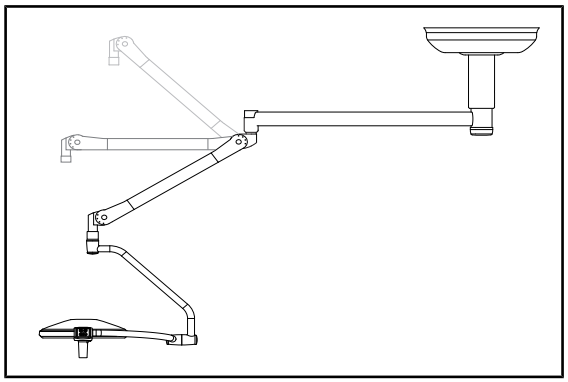


Fig. 13: Spring arm positioning

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.
3. If a problem is noted, contact technical support.

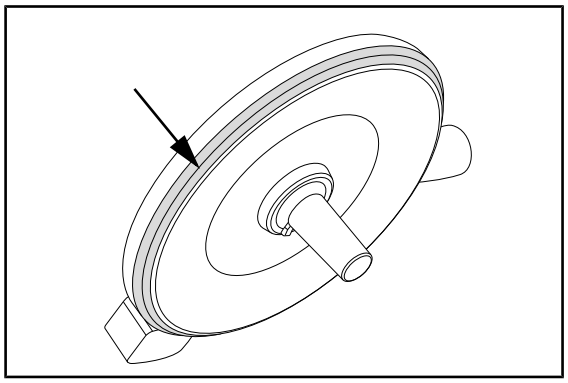


Fig. 14: Lighthead gaskets

Lighthead gaskets

1. Check that the lighthead gaskets are in the proper position and in good condition.
2. If a problem is noted, contact technical support.

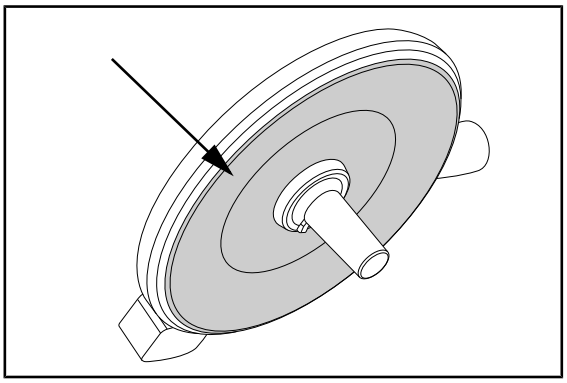


Fig. 15: Lighthead underside

Lighthead underside

1. Check that the underside is not damaged.
2. If a problem is noted, contact technical support.

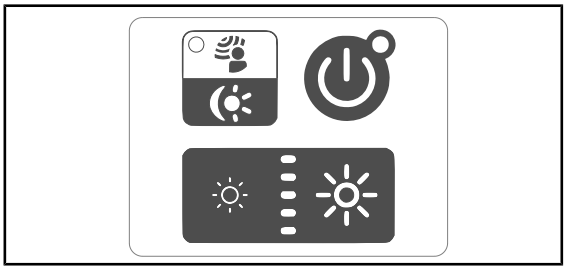


Fig. 16: Condition of lighthead keypad

Lighthead control keypad

1. Check that the lighthead control keypad is in good condition and in the proper position.
2. If a problem is noted, contact technical support.

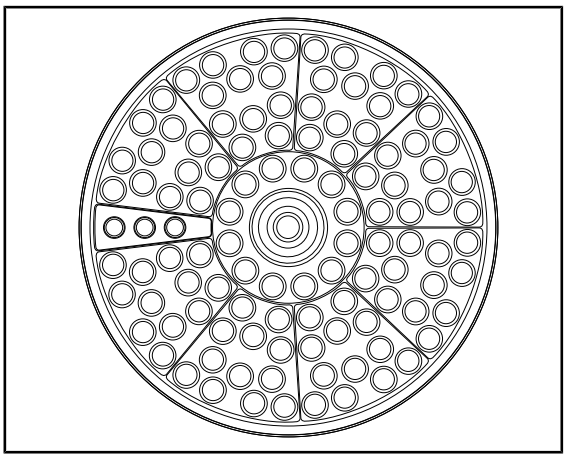


Fig. 17: Operation of LEDs

Operation of the LEDs

1. Press the ON/OFF button on the lighthead control keypad to turn on the light.
2. Check that 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.
3. Check that all the LEDs are operating.

For the attention of sterilisation personnel

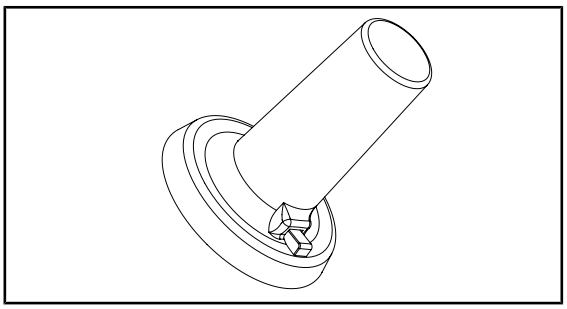


Fig. 18: Sterilisable handles

Integrity of sterilisable handles

1. After sterilisation, check that there are no cracks or soiling on the handle.
2. Also after sterilisation, check that the mechanism operates correctly.

4.2 Controlling the light

4.2.1 Turning the light on and off

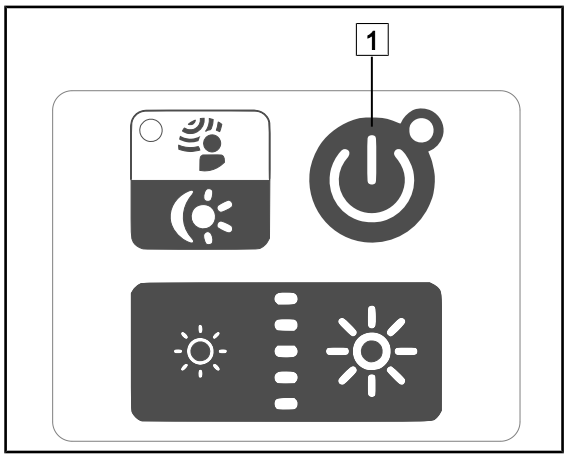


Fig. 19: Turning the light on and off

Turning on the lighthead

1. Press the **On/Off** 1 button to turn on the lighthead.
   - ➢ The LED sectors are turned on and the illumination level is set to the last value used when the light was turned off.

Turning off the lighthead

1. Press the **On/Off** 1 button and hold it until the lighthead turns off.

4.2.2 Adjusting the illumination

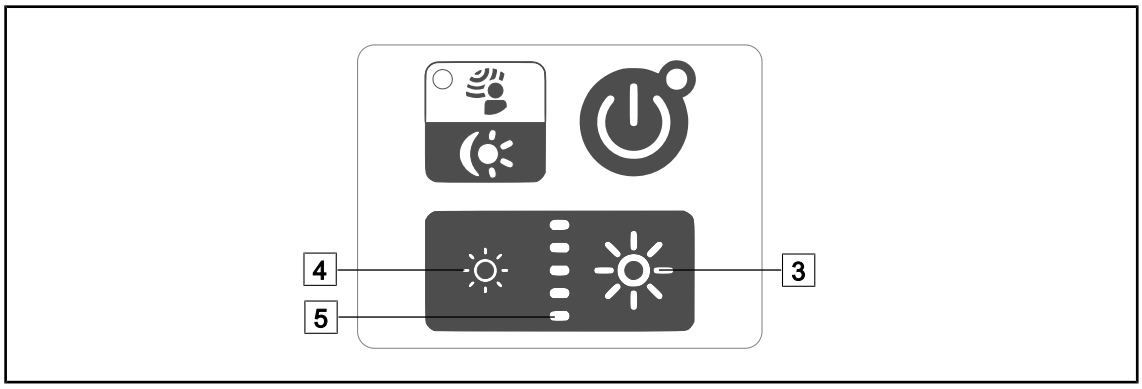


Fig. 20: Adjusting the illumination

Adjusting the light intensity

1. Press **Increase illumination** 3 to increase the light intensity level of the lighthead.
2. Press **Decrease illumination** 4 to decrease the light intensity level of the lighthead.

Enabling/disabling Boost mode

1. When the light intensity level is at 100%, press the **Increase illumination** 3 button until the last LED on the level indicator 5 starts flashing.
   - ➢ Boost mode is now enabled.
2. Press **Decrease illumination** 4 to disable Boost mode.
   - ➢ Boost mode is now disabled.

4.2.3 Ambient light

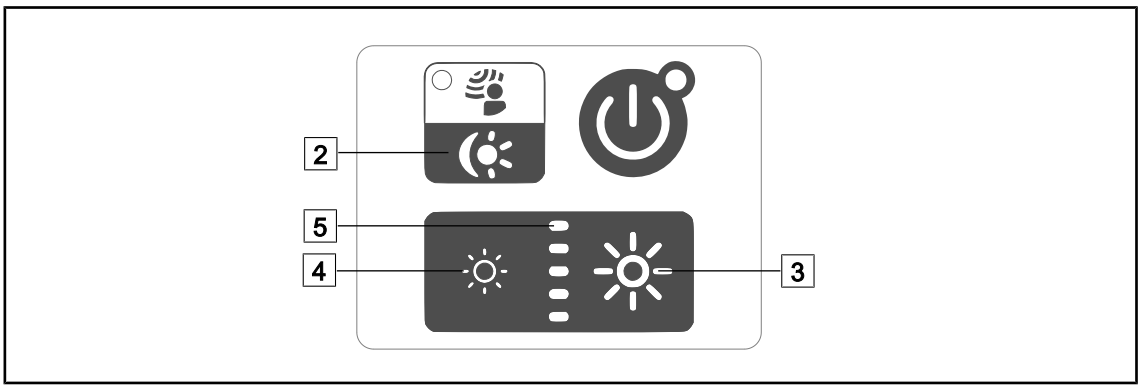


Fig. 21: Ambient light

Enabling/disabling the ambient light

1. Press **Light mode** [2] to enable the ambient light.
   - ➢ The ambient light mode is now enabled.
2. Press **Light mode** [2] again to disable the ambient light.
   - ➢ The ambient light mode is now disabled.

Adjusting the light intensity of the ambient light

1. Press **Increase illumination** [3] to increase the light intensity level of the ambient light.
2. Press **Decrease illumination** [4] to decrease the light intensity level of the ambient light.

4.3 Installing or removing a sterilisable handle

WARNING!

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

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

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.

PSX sterilisable handle

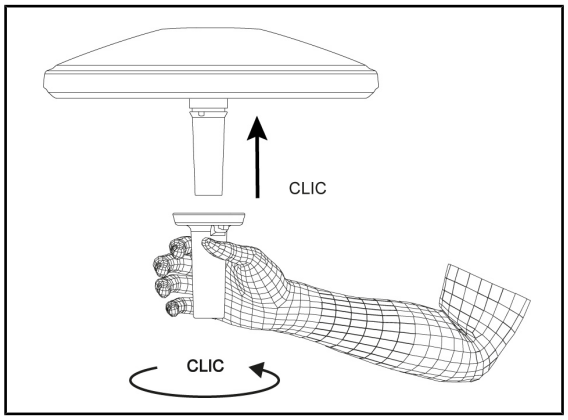


Fig. 22: Installing a PSX sterilisable handle

Installing a sterilisable handle on the lighthead

1. Inspect the handle and check for cracks or soiling.
2. Fit the handle to the mount.
   ➢ A click is heard.
3. Turn the handle until a second click is heard.
4. Check that the handle is firmly in place.
   ➢ The handle is now locked in place and ready for use.

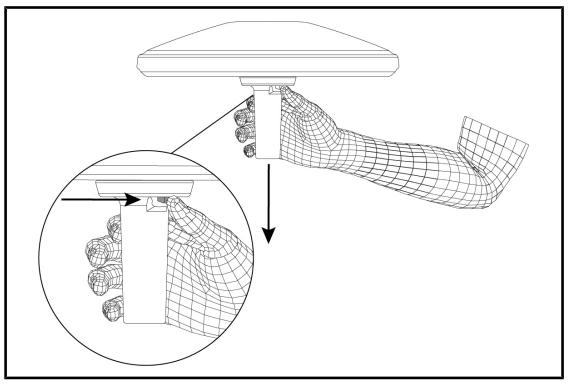


Fig. 23: Removing a PSX sterilisable handle

Removing the sterilisable handle from a lighthead

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

DEVON or DEROYAL handle

NOTE

Refer to the instructions supplied with the DEVON or DEROYAL handle.

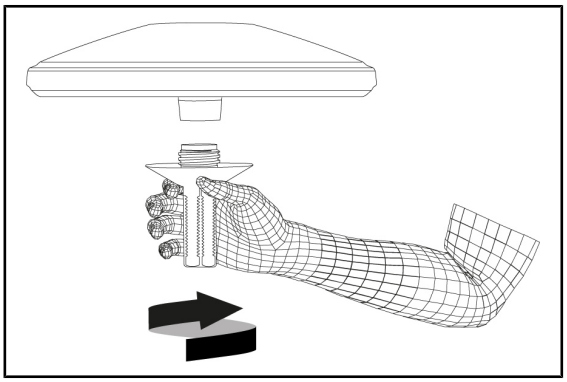


Fig. 24: Installing a DEVON or DEROYAL handle

Installing a DEVON or DEROYAL handle

1. Screw the handle fully onto the mount.
   ➢ The handle is now ready for use.

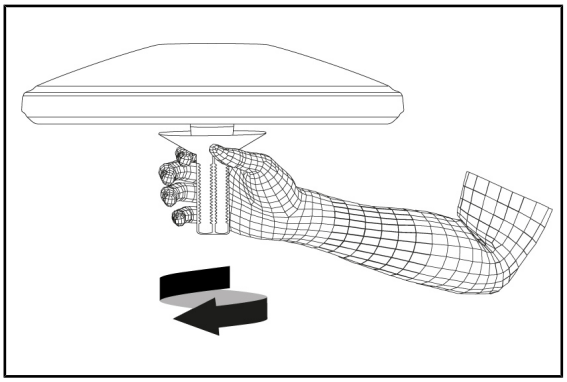


Fig. 25: Removing a DEVON or DEROYAL handle

Removing a DEVON or DEROYAL handle

1. Unscrew the handle from the handle mount.

4.4 Positioning the light

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.

4.4.1 Manoeuvring the lighthead

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.

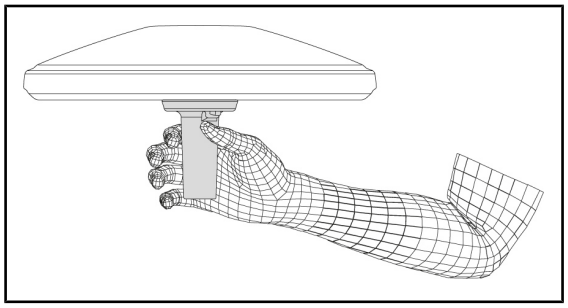


Fig. 26: Handling by sterile team

Instructions to sterile team

In order to move the lighthead, the sterile team must use the sterilisable handle to grab the lighthead.

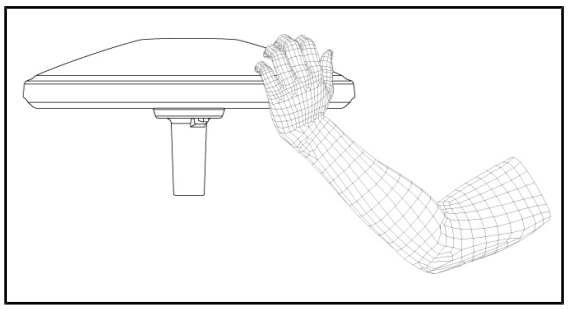


Fig. 27: Handling by non-sterile team

Instructions to non-sterile team

In order to move the lighthead, the non-sterile team must grab the lighthead itself.

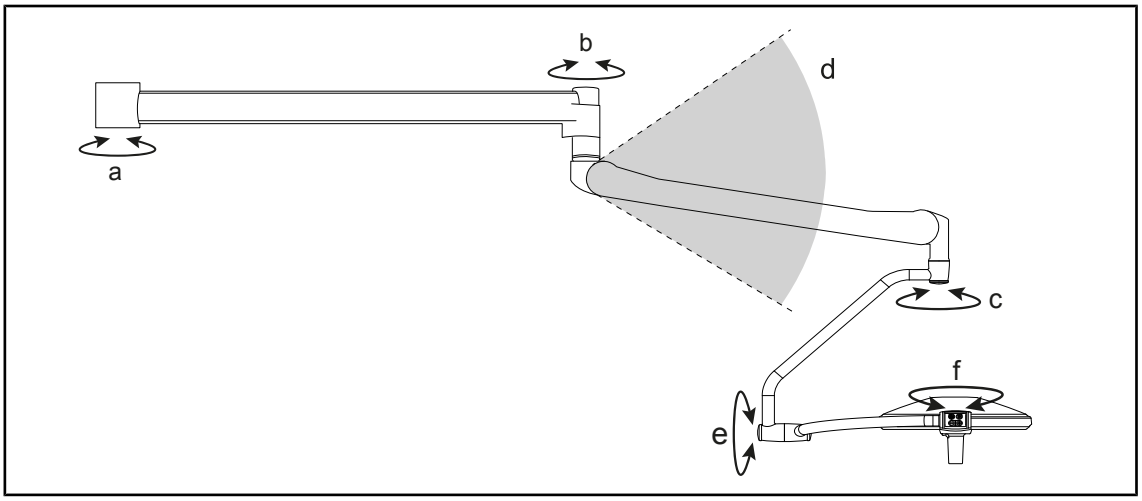


Fig. 28: Possible rotation angles with dual fork on SA suspension

a	b	c	d	e	f
infinite	infinite	infinite	+45° / -50°	210°	260°

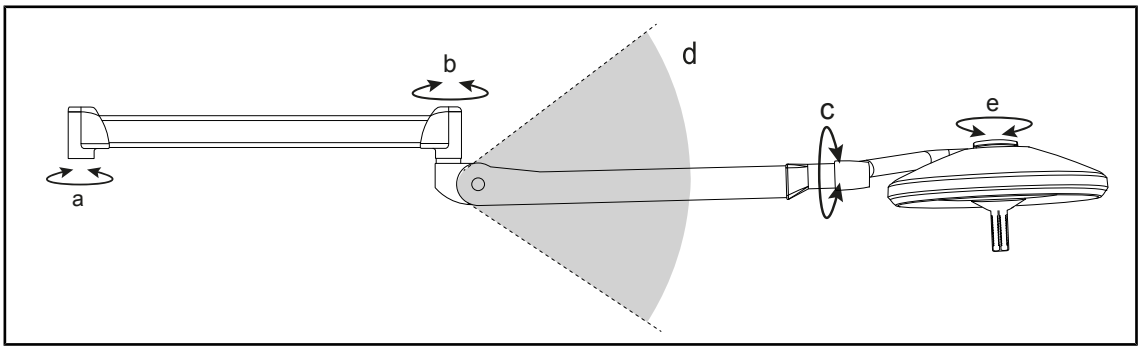


Fig. 29: Possible rotation angles on S suspension (SHELTER and DUAL NAVY SHIP)

a	b	c	d	e
infinite	infinite	infinite	+15° / -40°	260°

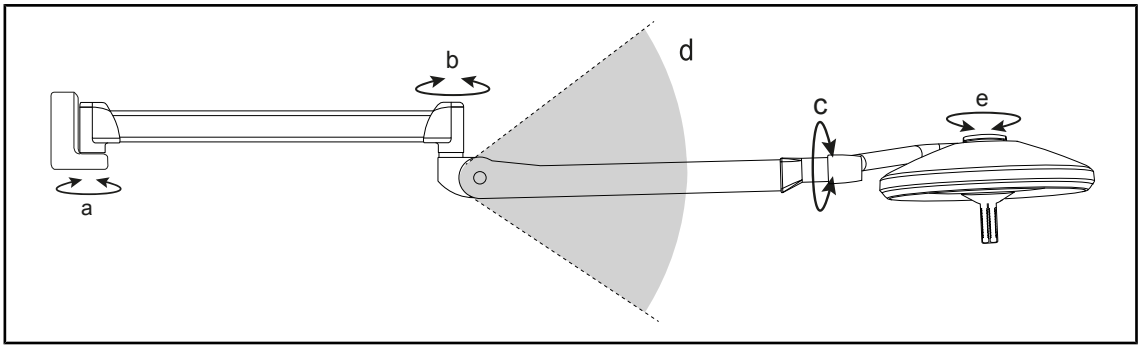


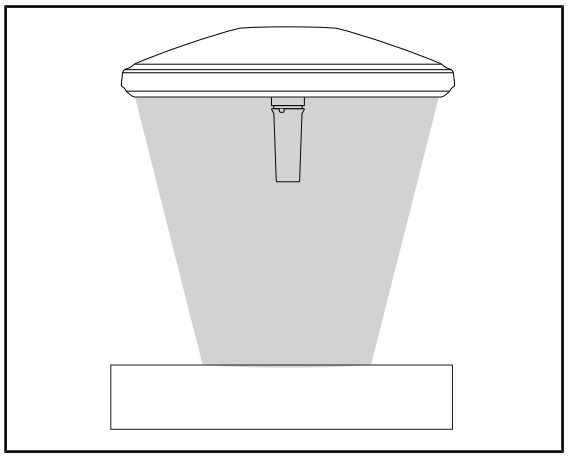
Fig. 30: Possible rotation angles on wall-mounted suspension

a	b	c	d	e
260°	infinite	infinite	+15° / -40°	260°

4.4.2 Pre-positioning

NOTE

Correctly positioning the light before each operation will limit the chances of it coming into contact with other objects.



The recommended distance between the underside of the lighthead and the surgical site is 1 meter.

Fig. 31: Pre-positioning the lighthead

4.5 Special case: PWD33 S SHELTER

NOTE

During installation, check that there is no damage to the slip rings, cables, brushes and connectors.

4.5.1 Installing the lighthead

WARNING!

Risk of electric shock or injury
The use of screws or spare parts other than those supplied by the manufacturer may damage the device.

Use only screws and spare parts supplied by the manufacturer.

WARNING!

Risk of injury
If the spring arm is not released before the component is removed, it may spring up abruptly and pose a safety hazard.

Before installing or uninstalling the component, adjust the top limit stop on the spring arm to the horizontal position. Set the spring arm in the horizontal position to remove the component.

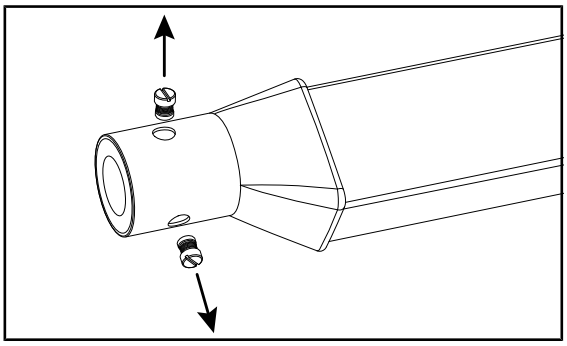


Fig. 32: Removing the brake screws

1. Remove the two brake screws from the spring arm.

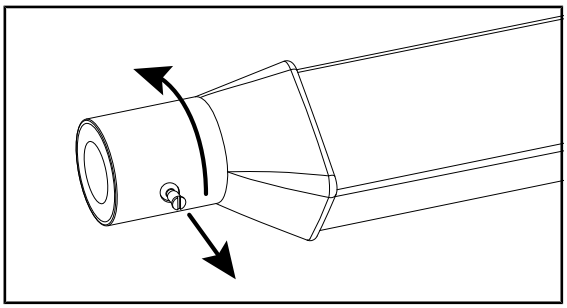


Fig. 33: Removing the mounting screws

1. Turn the ring by 90° and remove the first mounting screw.
2. Turn the ring by 180° and remove the second mounting screw.

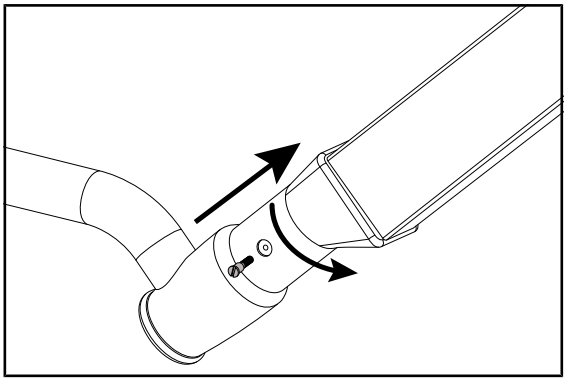


Fig. 34: Inserting the lighthead

1. Insert the lighthead hub in the spring arm.
2. Turn the ring by 90° and fit the first mounting screw.
3. Turn the ring by 180° and fit the second mounting screw.

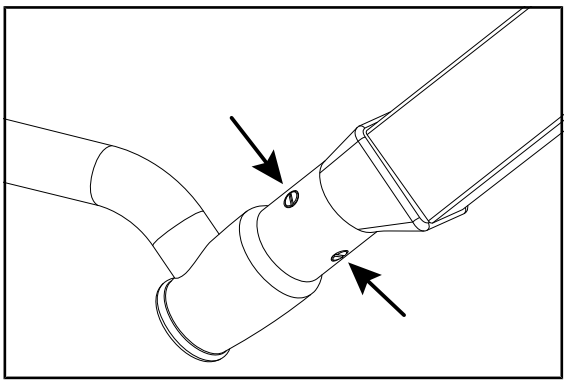


Fig. 35: Fitting the brake screws

1. Fit the two brake screws.

4.5.2 Fitting the power supply

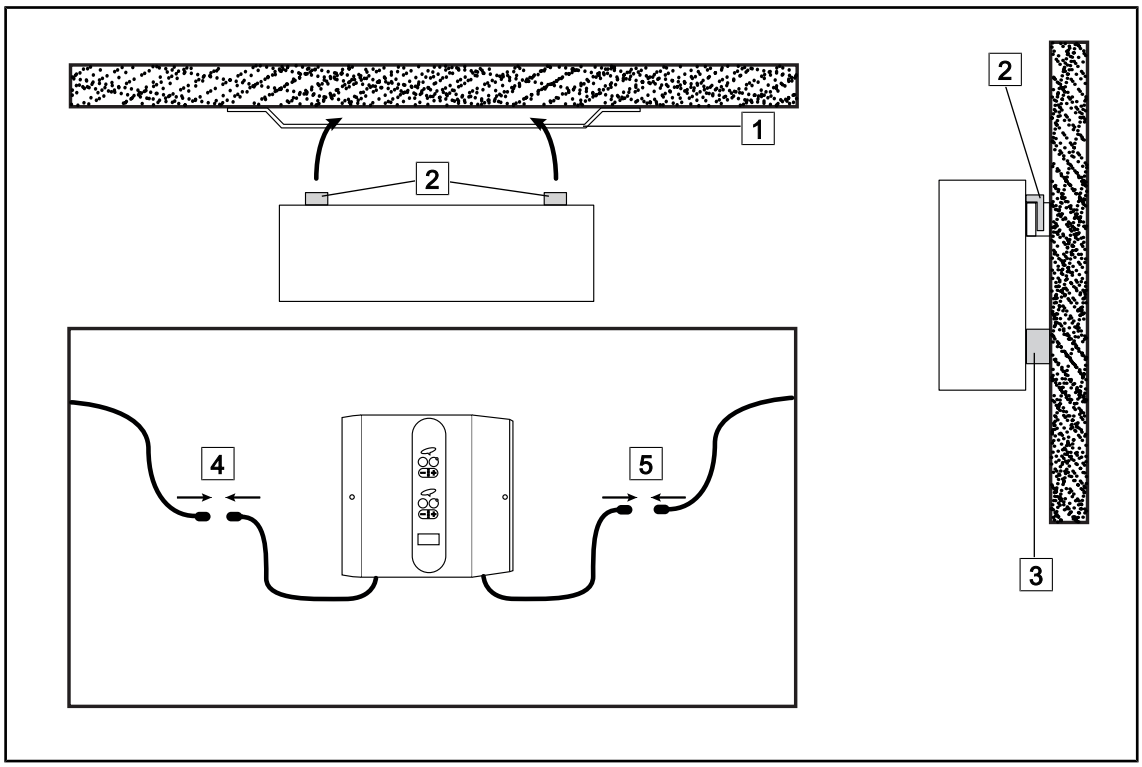


Fig. 36: Fitting the power supply

1. Install the power supply on its mount [1], making sure that the anchoring clamps [2] are positioned correctly, and that the bottom of the power supply is in contact with the special pads provided [3].
2. Connect the input cable to the power cable [4], making sure that the connectors are securely fastened.
3. Connect the output cable to the configuration cable [5], making sure that the connectors are securely fastened.

4.5.3 Disassembling the lightheads and power supply

WARNING!

Risk of injury
If the spring arm is not released before the component is removed, it may spring up abruptly and pose a safety hazard.

Before installing or uninstalling the component, adjust the top limit stop on the spring arm to the horizontal position. Set the spring arm in the horizontal position to remove the component.

NOTE

To remove the lightheads, refer to the Installing the lighthead [⏩ Page 29] section and proceed in the reverse order. Then store the lightheads in their respective slots in the carrying case.

NOTE

To remove the power supply, disconnect the two cables and release the power supply from its mount. Then store the power supply in its slot in the carrying case.

4.5.4 Securing the suspension

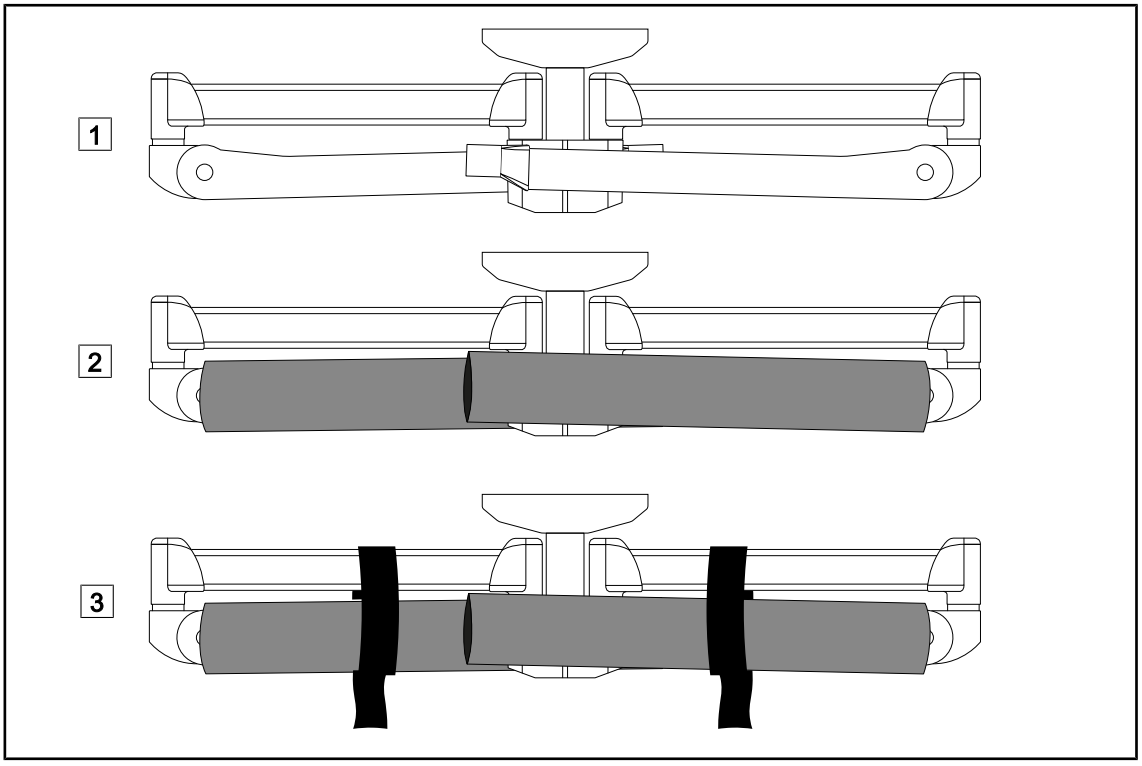


Fig. 37: Securing the suspension

1. Place the spring arms in the top position, wedged against the suspension tube on either side 1.
2. Place the protective tubes (USALM43548) around the two spring arms 2.
3. Firmly attach the spring arms to the corresponding extension arms using a strap 3.

5 Error messages and alarm indicators

Not applicable for this product.

6 Troubleshooting

Mechanical

Problem	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. 8: Mechanical anomalies and malfunctions

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
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

Tab. 9: Troubleshooting

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 paintwork 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.

7.1.1 Cleaning the device

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

7.1.2 Disinfecting the device

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

7.1.2.1 Disinfectants to be used

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

7.1.2.2 Permitted active substances

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

Tab. 10: Lists of active substances suitable for use

Examples of commercially available products tested

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

7.2 Cleaning and sterilising PSX and HLX sterilisable handles

7.2.1 Preparation for cleaning

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

7.2.2 Manual cleaning

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

7.2.3 Cleaning in a washer-disinfector

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

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

Tab. 11: Typical cleaning cycles in a washer-disinfector

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

7.2.4 Sterilisation

WARNING!

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

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

NOTE

PSX and HLX sterilisable handles are designed for autoclave sterilisation.

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

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

Tab. 12: Examples of steam sterilisation cycles

8 Maintenance

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

8.1 Maintenance schedule

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

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

Tab. 13: Maintenance schedule

8.2 Contact

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

9 Technical specifications

9.1 Optical specifications

Specifications	PowerLED 300	Tolerance
Nominal illumination	>110 000 lx	–
Illumination with Boost mode	160,000 lx	0/- 10%
Diameter d10	17 cm	± 3 cm
Diameter d50/d10	>0.6	± 0.05
Illumination depth at 20%	105 cm	± 10%
Illumination depth at 60%	55 cm	± 10 %
Colour temperature	3 800 K	± 400 K
Colour rendering index (Ra)	95	±5
Special colour rendering index (R9)	80	±15
Radiant energy	3.6 mW/m²/lx	±0.4
Irradiance (Ee)[2]	< 500 W/m²	–
UV illumination	≤ 0.7 W/m²	–
FSP system	Yes	–
Illumination in ambient light mode	< 500 lx	–

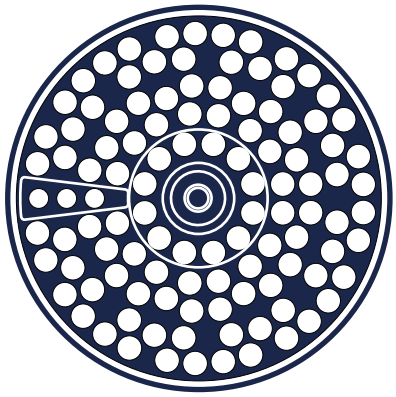
Tab. 14: PowerLED 300 optical data in accordance with the EN 60601-2-41 standard

Residual illumination	PowerLED 300	Tolerance
With one mask	28%	±10
With two masks	44%	±10
At base of tube	100%	±10
With one mask, at base of tube	28%	±10
With two masks, at base of tube	44%	± 10

Tab. 15: PowerLED 300 residual illumination in accordance with the EN 60601-2-41 standard

[2] For illumination less than 130,000 lux

LED Life Time
Certificate



PowerLED 300

IES LM-80 Test report for LED

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

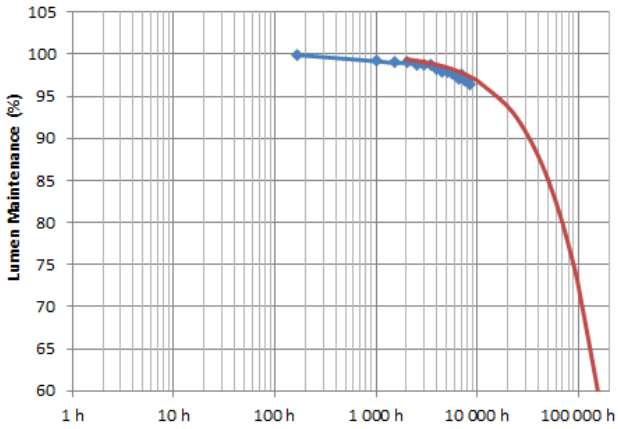
According to **IES TM-21 standard**, L70(D) is the lumen maintenance life expressed in hours where 70% of initial lumen output is maintained, with D the total duration time for the effective tests, in hours. ***The life projection is limited to 6 times the total duration of the effective tests.***

Chosen conditions for IES LM-80 Test:
Case Temperature: 85°C
Drive Current: 550 mA
Total Duration Time (D): 10,000 hours

Lumen Maintenance at L70 = 97.1 %

Average L70 Extrapolation following IES TM-21 method:

L70(10,000) ≥ 60,000 hours

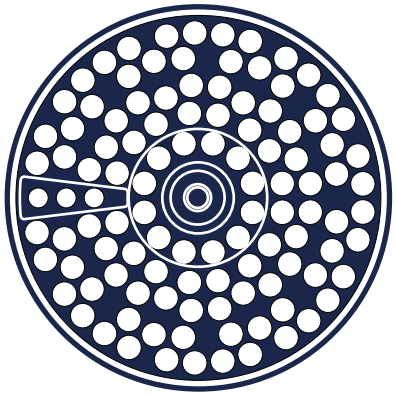


Extrapolation for LED in Cupola

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

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

EN 62471
Certificate



PowerLED 300

Measurements conditions

The irradiance measurements are performed at 1 meter, which is considered the working distance of the light.
The radiance measurements are performed with a field of view of 11 mrad, which is considered representative of the usual eye's exposure (several short time exposures).
The measurements are performed for an illuminance of 155,000 lux.

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

Measurements results for Artificial Optical Radiations

Irradiance results	
E_H	551 $W.m^{-2}$
E_S	3 10^{-6} $W.m^{-2}$
E_{UVA}	0.01
E_{IR}	0.4

Radiance results	
L_B 11 mrad	2,541 $W.m^{-2}.sr^{-1}$
L_R 11 mrad	37,528 $W.m^{-2}.sr^{-1}$

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

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

	Illuminance Settings	Time without any risk
PowerLED	Maximum (155,000 Lux)	7 minutes
	Minimum (60,000 Lux)	20 minutes

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

9.2 Electrical characteristics

Electrical specifications	PowerLED 300
Power supply input voltage	100-120 Vac / 220-230 Vac , 50/60 Hz
Power supply power rating	375 VA
Lighthead power rating	150 VA
Lighthead input	20 - 46 Vdc
Number of LEDs	108
Average service life of LEDs	60,000 hours

Tab. 16: Table of electrical specifications

9.3 Mechanical specifications

Mechanical specifications	PowerLED 300	Tolerance
Weight of single-fork lighthead	8.5 kg	±2%
Weight of dual-fork lighthead	10 kg	±2%
Lighthead diameter	45 cm	±0.5%

Tab. 17: Table of mechanical specifications

9.4 Other characteristics

Protection against electrical shocks	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	IP 20
Protection rating of the lightheads	IP 44
UMDNS code	12 282
GMDN code	12 282
CE marking year	2007

Tab. 18: Specifications relating to standards and regulations

9.5 EMC declaration

CAUTION!

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

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

CAUTION!

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

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

CAUTION!

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

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

CAUTION!

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

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

NOTE

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

Type of test	Test methods	Range of frequencies	Boundaries
Measurement of conducted emissions on the main ports	EN 55011 GR1 CL A[3]	0.15 - 0.5 MHz	66 dBµV - 56 dBµV QP 56 dBµV - 46 dBµV A
		0.5 - 5 MHz	56 dBµV PQ 46 dBµV A
		5 - 30 MHz	60 dBµV PQ 50 dBµV A
Measurement of the radiated electromagnetic field	EN 55011 GR1 CL A[3]	30 - 230 MHz	40 dBµV/m PQ 10 m
		230 - 1000 MHz	47 dBµV/m PQ 10 m

Tab. 19: EMC declaration

Type of test	Test methods	Test level: Healthcare facility.
Electrostatic discharge immunity	EN 61000-4-2	Contact: ± 8kV Air: ± 2; 4; 8; 15 kV
Immunity to radiated electromagnetic fields	EN 61000-4-3	80 MHz, 2.7 GHz 3 V/m Mod AM 80%/1 kHz
		Wireless RF frequencies 9 to 28 V/m Mod AM 80%/1 kHz
Immunity to fast electrical transients and bursts	EN 61000-4-4	AC: ± 2 kV - 100 kHz IO >3m: ± 1 kV - 100 kHz
Immunity to power source voltage surges	EN 61000-4-5	± 0.5; 1 kV diff. ± 0.5 kV, ± 1 kV, ± 2 kV common mode
Immunity to conducted interference due to electromagnetic fields	EN 61000-4-6	150 kHz, 80 MHz 3 Vrms Mod AM 80%/1 kHz
		ISM 6 Vrms Mod AM 80%/1 kHz
Immunity to voltage dips and short interruptions	EN 61000-4-11	0% Ut, 10 ms (0°; 45°; 90°; 135°; 180°; 225°; 270°; 315°) 0% Ut, 20 ms 70% Ut, 500 ms 0% Ut, 5 s

Tab. 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.

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.

Do not dispose of contaminated sterilisable handles as municipal waste.

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.

GETINGE

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