Instructions for use

Maquet Rolite

GETINGE ✳

Copyright

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.

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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 or UL 60601-1 should be installed on the system.

The compatibility data is detailed in the chapter entitled Technical specifications [▸ Page 95].

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.

1.3 Other documents relating to this product

- Repair manual (Ref. ARD01832)
- Maintenance manual (Ref. ARD01833)
- Installation manual (Ref. ARD01834)

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

AIM	Automatic Illumination Management
EMC	Electromagnetic compatibility
FSP*	Flux Stability Program
HD	High Definition
IFU	Instructions For Use
K	Kelvin
LED	Light-Emitting Diode
LMD	Luminance Management Device
lx	lux
N/A	Not Applicable
QL(+)	Quick Lock(+)
SF	Single Fork
WB	White Balance

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 $\boxed{1}$.

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
ℹ	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

1.4.3 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   Type of light

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.

Example: A mobile light (Maquet Rolite*) is a minor surgical light.

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 minor 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).	C E	CE marking (Europe)
	Follow the instructions for use (IEC 60601-1:2005).	c(UL)us CLASSIFIED	UL mark (Canada and United States)
	Follow the instructions for use (IEC 60601-1:1996).		Do not discard with conventional waste
	Manufacturer + manufacturing date	MD	Medical Device (MD) marking
REF	Product code	UDI	Unique device identification
SN	Product serial number		Packaging orientation
	AC input		Fragile, handle with care
	DC input		Keep away from the rain
	DC output		Temperature range for storage
	Standby		Humidity range for storage
	Laser radiation.		Ambient pressure range for storage
	Equipotential grounding connector		Swivel legs locked into position for use
	Caution: Non-insulated live parts inside the device.		Risk of toppling: Do not push the mobile light or lean on it when the casters are locked.
	Place yourself on the lighthead side when moving the light on sloped surfaces. Only pull the light behind you when moving it on sloped surfaces. Turn the light so that the batteries are towards the bottom of the slope.		Push the Rolite mobile light to move it. Do not pull the light behind you. The lighthead arm must be folded away before moving the Rolite mobile light.

1.6   Product overview
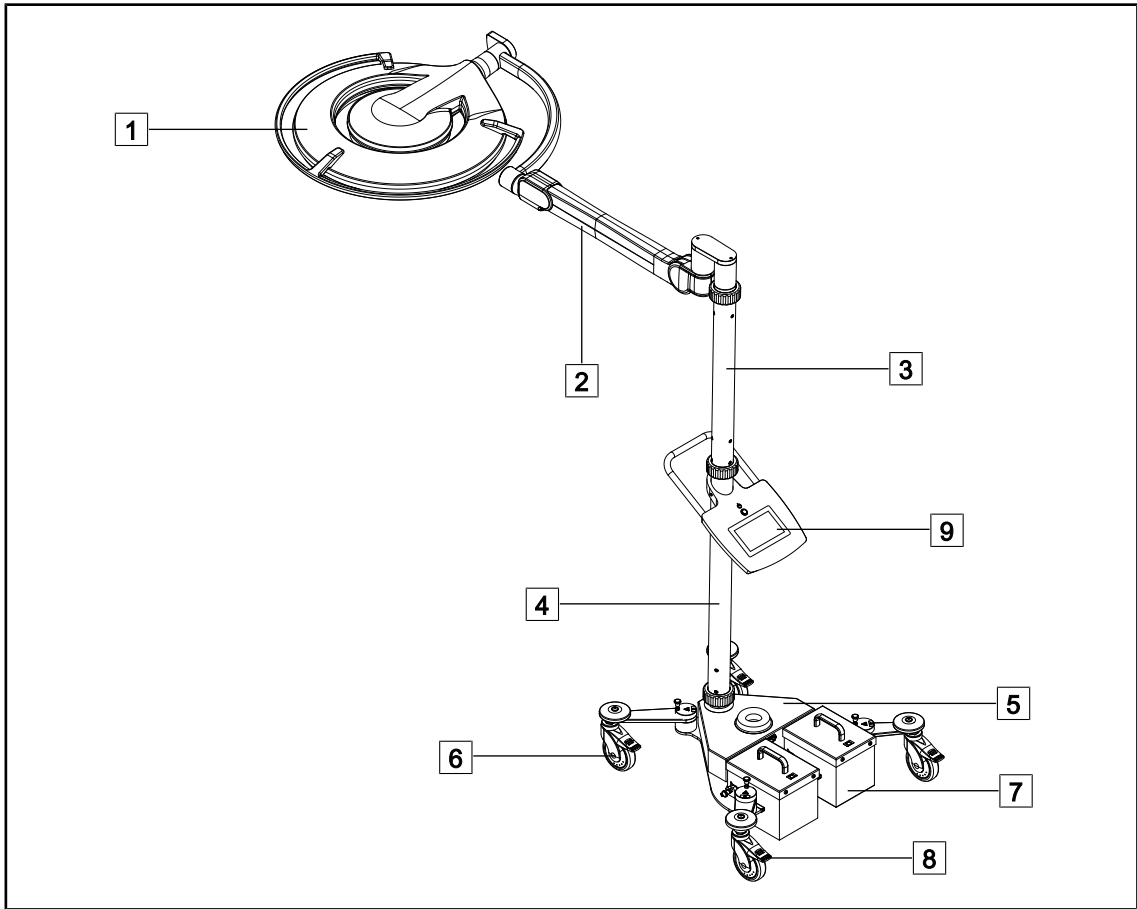
Fig. 1:   Overview of the Maquet Rolite PowerLED II

1	Lighthead	6	Swivel casters
2	Spring arm	7	Batteries
3	Top pole	8	Caster brakes
4	Bottom pole	9	Control interface
5	Stand base		

Functions	Volista VCSII	Volista VSTII	Maquet PWDII
Boost mode	✔	✔	✔
Light field diameter variation	✔	✔	✔
Ambient light	✔	✔	✔
AIM mode	�’✘	✔	✔
Laser positioning system	✘	✘	✔
Antimicrobial film for lighthead control keypad	✘	✘	✔
Colour temperature selected at time of order	✘	✘	✔
Variable colour temperature	✔	✔	✘
Volista VisioNIR	✘	✔	✘
Comfort Light*	✘	✘	✔
Camera with remote control functionalities	✔	✔	✘
QL+ handle mounts with Tilt	✘	✘	✔
QL handle mounts with Tilt	✔	✔	✘
Sterilisable handles	✔	✔	✔
LMD	✘	✔	✔
Power supply cables	✔	✔	✔

Tab. 3:   Available functions and accessories on the various lightheads

1.6.1 Components

1.6.1.1 Lightheads
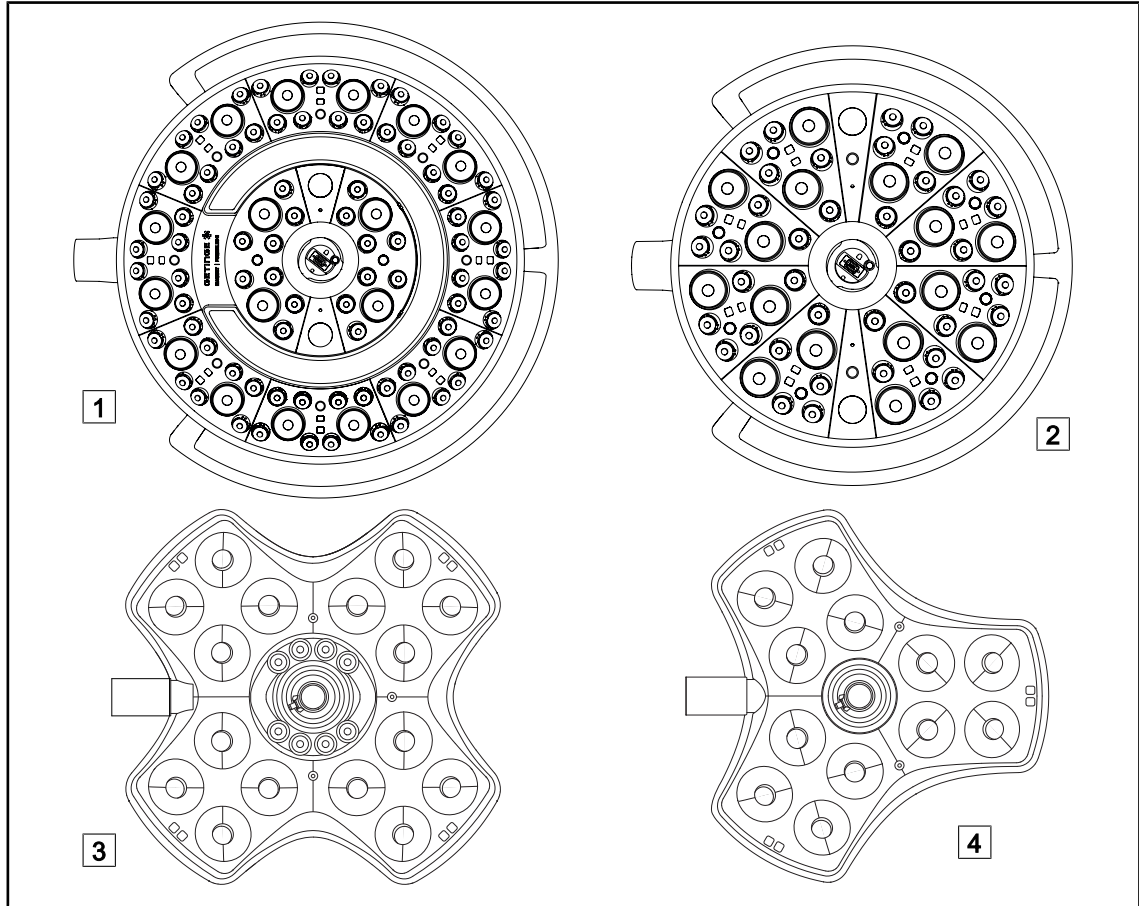
Fig. 2:   Available lightheads for Maquet Rolite

1	Maquet PowerLED II 700 lighthead	3	Volista VSTII/VCSII 600 lighthead
2	Maquet PowerLED II 500 lighthead	4	Volista VSTII/VCSII 400 lighthead
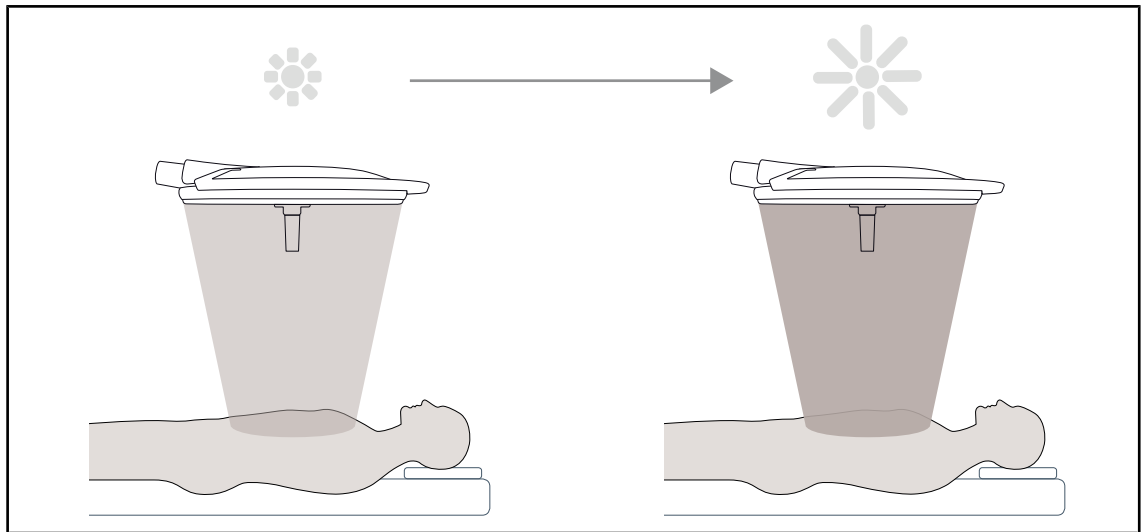
Boost mode

Fig. 3:   Boost mode

Boost mode (spare lighting capacity) enables the illumination to be set to the maximum level when required by surgical conditions. Boosting the illumination level is unnecessary under normal conditions; this mode is activated only when required.

Light field diameter variation
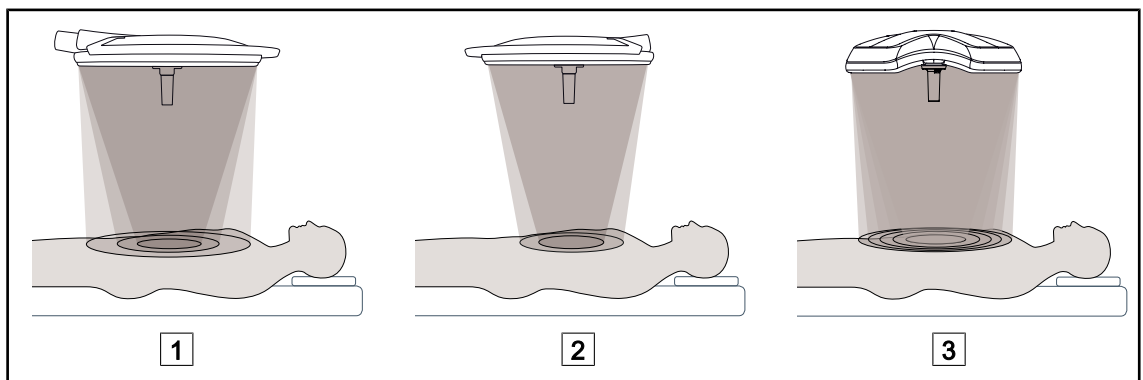
Fig. 4:   Light field diameter variation

| 1 | Maquet PowerLED II 700 | 3 | Volista VSTII VCSII 400 + 600 |
| 2 | Maquet PowerLED II 500 | | |

The light field diameter variation function can be used to adjust the size of the light field so that it matches the dimensions of the incision. The Maquet PowerLED II lighting system provides three diameter settings on the Maquet PowerLED II 700 (small, medium and large) and two settings on the Maquet PowerLED II 500 (small and medium). The Volista lighting system enables the diameter to be set to one of five levels.

AIM mode (on Maquet PowerLED II and Volista VSTII only)
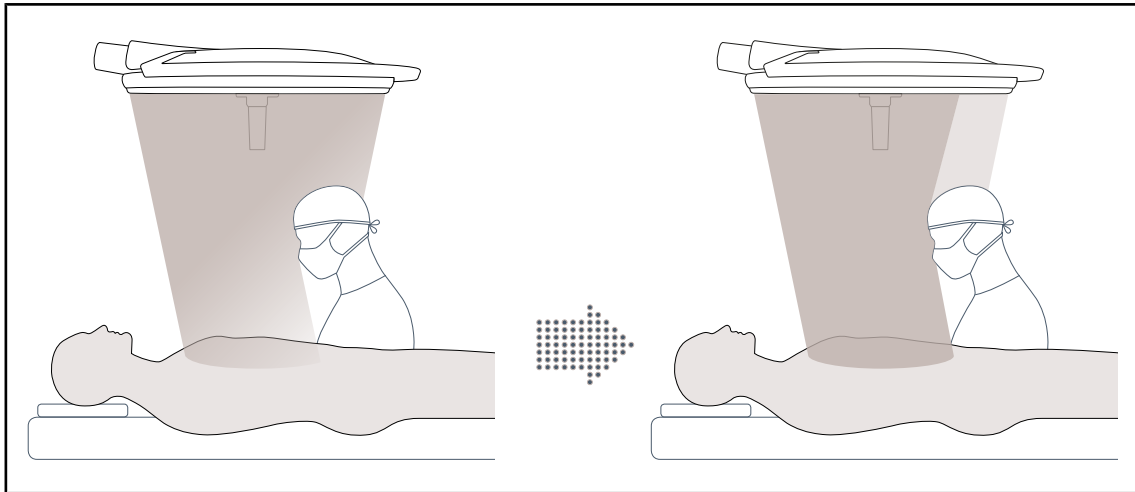
Fig. 5:   Presence of one or two surgeons

This function automatically compensates for the loss of illumination due to the presence of obstacles (surgeons' head or shoulders) between the lighthead and the surgical site. Illumination is reduced in the obstructed LEDs and increased in the unobstructed LEDs to ensure that:

• Illumination is stable at the surgical site
• The surgeon's movements are unrestricted
• The surgeon's working conditions are improved

Ambient light
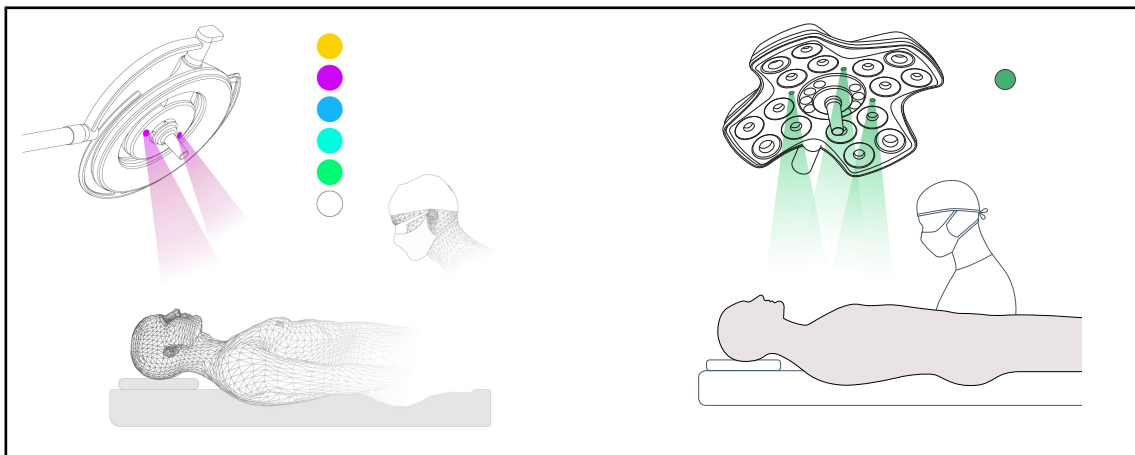
Fig. 6:   Ambient light

Multi-coloured ambient lighting enhances contrast to enable easier viewing of monitors during minimally invasive procedures. It provides the surgical team and the anaesthetist with minimal lighting during minimally invasive procedures. It also creates a calm atmosphere to welcome patients, thereby minimising stress.

Laser positioning assistance function (on Maquet PowerLED II only)
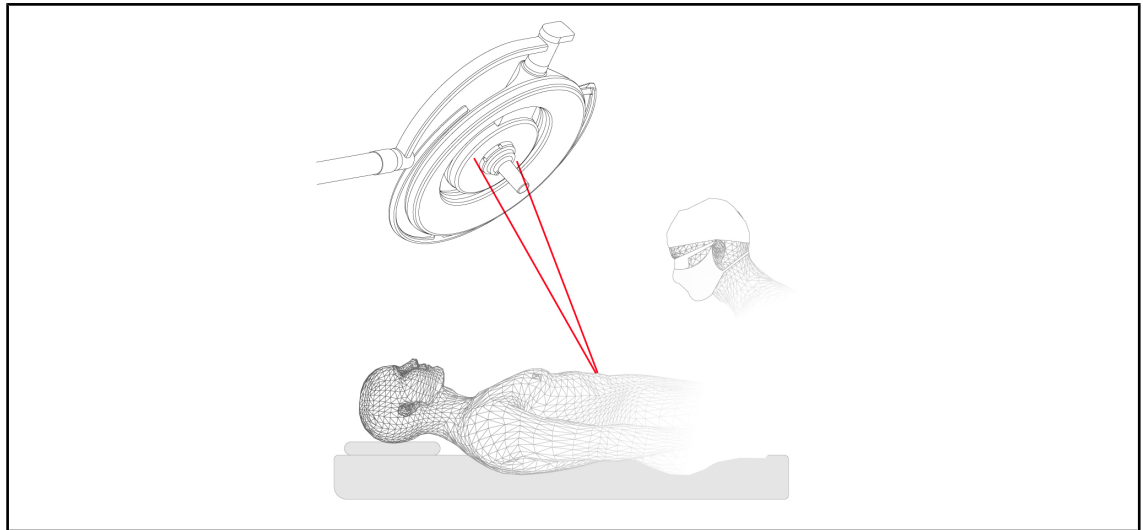
Fig. 7:   Laser positioning assistance on Maquet PowerLED II

This function enables the surgical light to be ideally positioned relative to the incision. Surgeons can then work under optimum conditions, with maximum illumination of the area of interest.

> ⚠️ **WARNING!**
>
> **Risk of injury**
> **Prolonged exposure to laser light may result in eye damage.**
>
> **Do not direct a laser beam into the patient's unprotected eyes. Users must not look directly into the laser beam.**

Antimicrobial film on the lighthead control keypad (on Maquet PowerLED II only)

PVC film and paint containing silver ions are incorporated on the most used areas of the lightheads (keyboards, external handle) to ensure antibacterial[1] efficacy between two cleaning operations. Silver ions may be released during cleaning operations or in the presence of humidity. These ions come into contact with bacteria, blocking their metabolism and/or interrupting their multiplication mechanism, resulting in their elimination.

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[1]   ISO 22196:2011 reduction greater than LOG 2 against Staphylococcus aureus and Escherichia coli.

1.6.2 Options

1.6.2.1 Maquet PowerLED II options

Comfort Light*
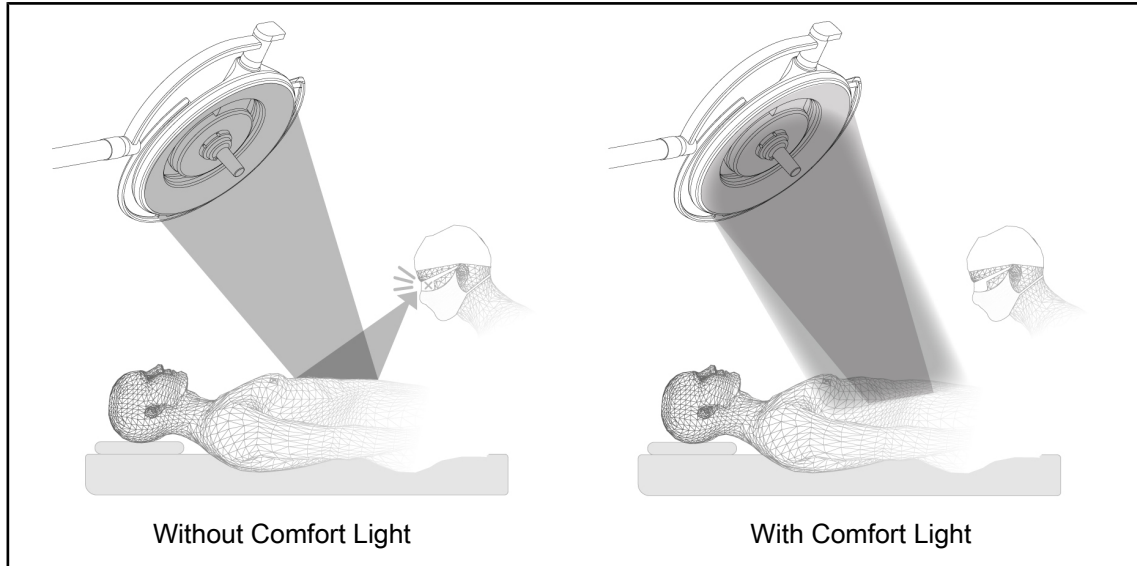
Fig. 8:   Comfort light

This function forms a low-intensity light field around the main surgical site. The reduced contrast resulting from this additional peripheral lighting enhances the comfort and visual performance of the surgical team, in particular by reducing perceived glare.

Colour temperature
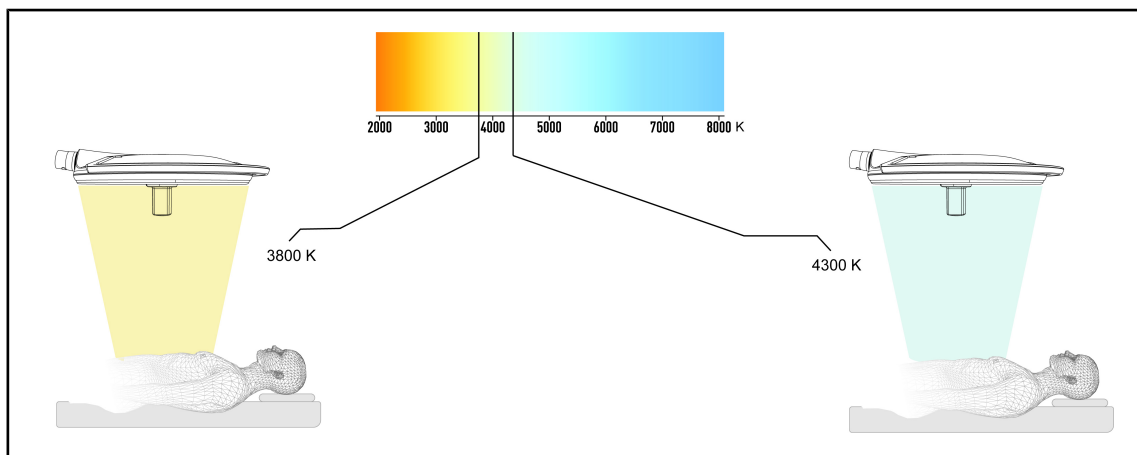
Fig. 9:   Colour temperature 3800 K and 4300 K

The Maquet PowerLED II surgical light is available in two colour temperature versions: 3800 K and 4300 K.

1.6.2.2 Volista options

Variable colour temperature

The VSTII surgical light features three colour temperatures: 3900 K, 4,500 K and 5,100 K. The VCSII surgical light features three colour temperatures: 3900 K, 4,200 K and 4,500 K.
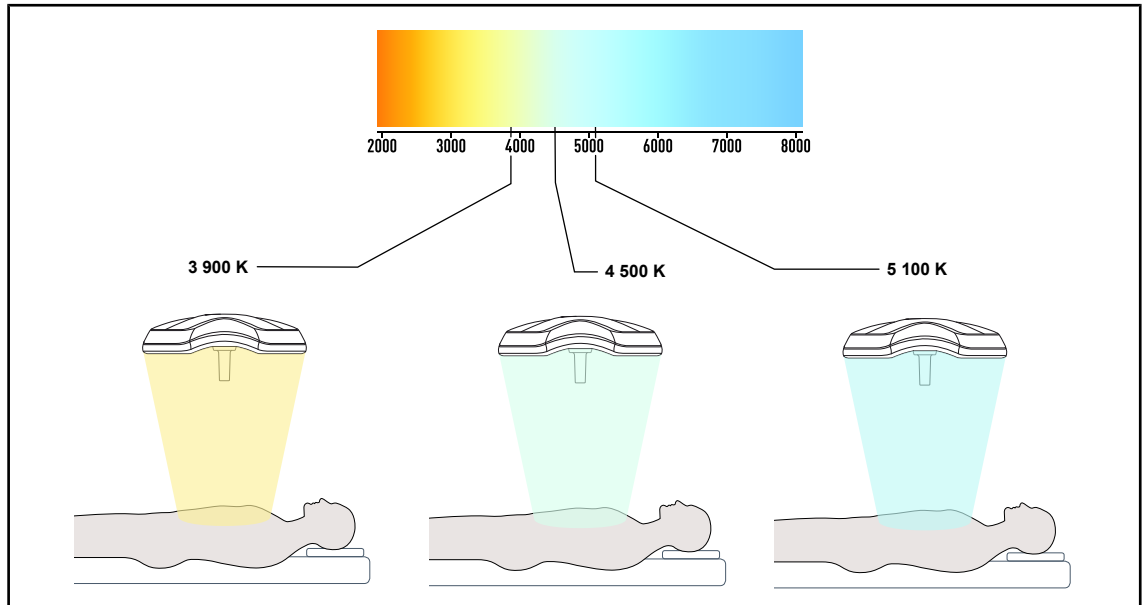
Fig. 10: Colour temperature

Volista VisioNIR (VSTII only)
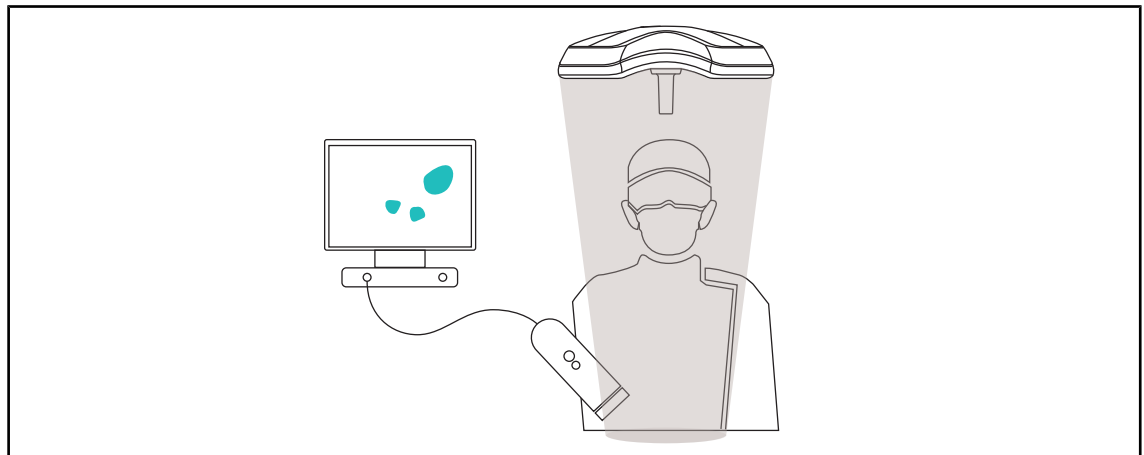
Fig. 11: Volista VisioNIR function

The Volista VisioNIR function is used to filter out the residual near-infrared rays from the LED spectrum in order to keep them at very low levels. Volista VisioNIR is suitable for use with near-field infrared cameras, without disturbing the signal transmitted to the monitor. Volista VisioNIR can be used during surgery using ICG (indocyanine green), as well as by taking advantage of the natural property of certain tissues, which emit fluorescent light following stimulation (autofluorescence). In this case, the detection area of the fluorescence camera must have a wavelength greater than 740 nm (see Table 35).

ⓘ NOTE

It is recommended to first test the NIR imaging system and the fluorescent dye with the Volista VisioNIR function in order to optimise the settings.

1.6.3 Accessories

1.6.3.1 Camera with wireless system OHDII FHD QL AIR03/E/U (only on Volista lightheads)
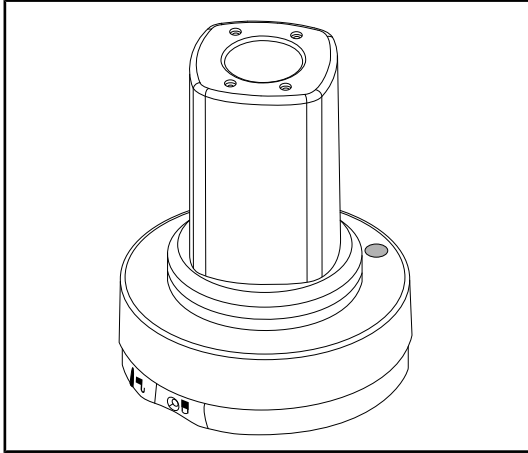
Fig. 12: OHDII FHD QL AIR03E/U camera

This camera features a QL system enabling it to be moved from one operating theatre to another, and offers genuine benefits for the surgical team. It ensures operating fluidity by keeping the surgical area clear during training phases, and facilitates monitoring of surgeons' actions, enabling their needs to be better anticipated.

ⓘ NOTE

The system consists of a USB-powered camera with HDMI output, to which a wireless system can be interfaced. A camera fitted with a Gefen wireless system is available from Getinge. A different wireless system can also be used instead, following approval by Getinge. Please contact a Getinge representative for more information on that option.

1.6.3.2 QL+ handle mounts (only on Maquet PowerLED II)
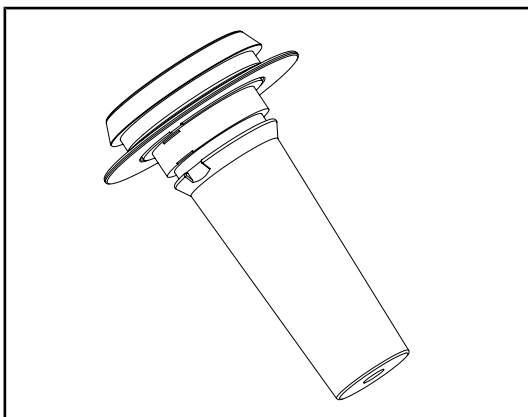
The handle mount can be fitted in the centre of the lighthead using the QL+ system. It is designed to receive a STG PSX sterilisable handle.

Fig. 13: Mount for STG PSX sterilisable handle
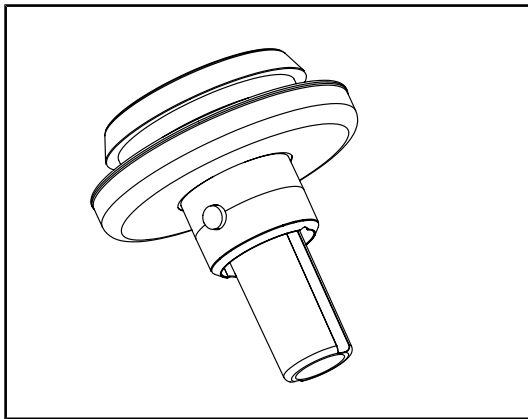
Fig. 14:   Mount for STG HLX sterilisable handle

The handle mount can be fitted in the centre of the lighthead using the QL+ system. It is designed to receive a STG HLX sterilisable handle.
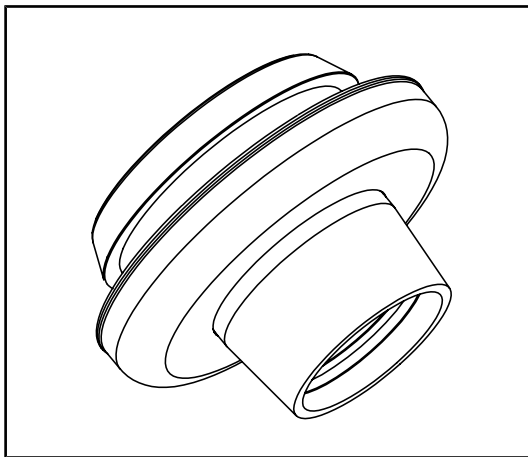
Fig. 15:   Adapter for Devon/Deroyal handles

The adapter for Devon/Deroyal handles can be fitted in the centre of the lighthead using the QL+ system. It is designed to receive a Devon® or Deroyal® disposable handle. Two versions are available: with or without TILT function (light field diameter variation using the handle)

1.6.3.3   QL handle mounts (only on Volista)
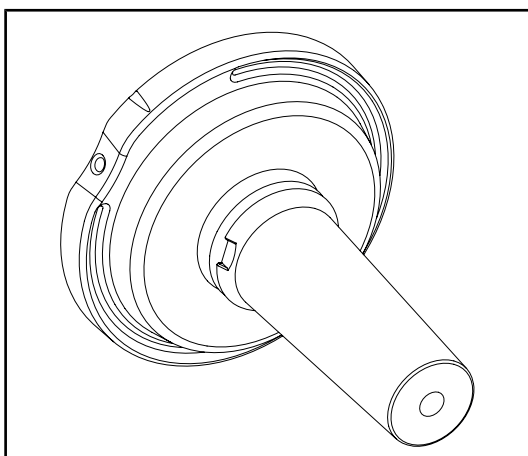
Fig. 16:   Mount for STG PSX sterilisable handle

The handle mount can be fitted in the centre of the lighthead using the QL system. It is designed to receive a STG PSX sterilisable handle.

The handle mount can be fitted in the centre of the lighthead using the QL system. It is designed to receive a STG HLX sterilisable handle.

Fig. 17:   Mount for STG HLX sterilisable handle
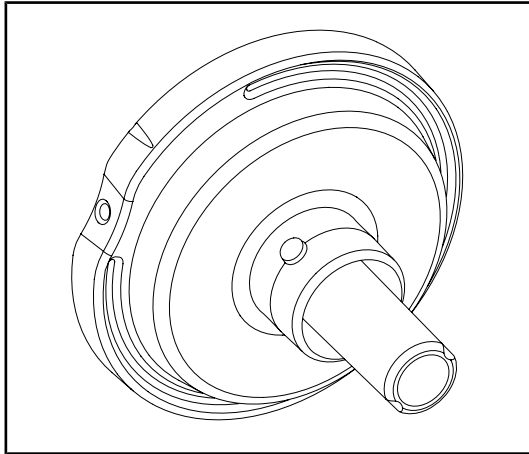
This adapter for disposable handles can be fitted in the centre of the lighthead using the QL system. It is designed to receive a Devon® or Deroyal® disposable handle.
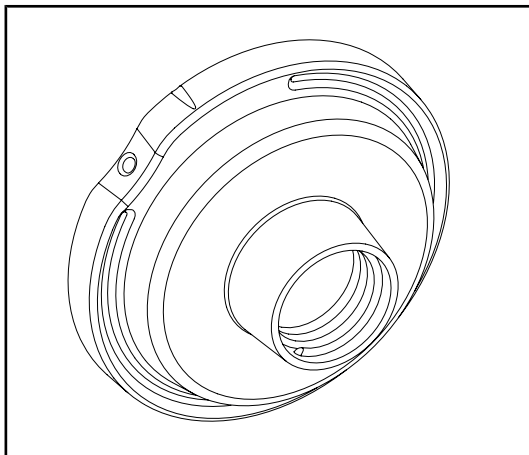
Fig. 18:   Adapter for disposable handle with Tilt

1.6.3.4   LMD (on Maquet PowerLED II et Volista VSTII only)
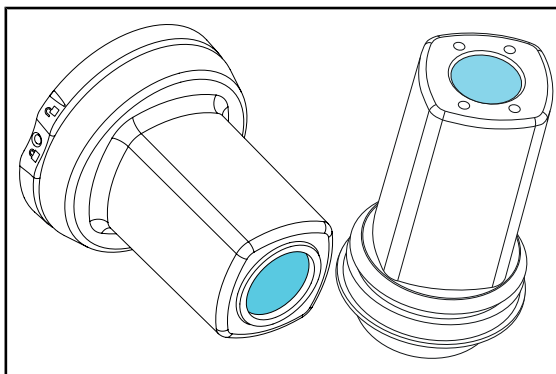
The LMD system (Luminance Management Device) adjusts the illumination perceived by the surgeon's eye. This innovation is designed to maintain optimal visual acuity and avoid problems relating to vision adjustments in the event of brightness variations. Surgeons thus have the same level of illumination when looking at dark cavities or light tissue.

Fig. 19:   LMD module

1.6.3.5 Power supply cables

Item	Description	Reference	Length
POWER CORD EUR	Power cord for Europe	5,686 04,960	4m
POWER CORD GBR	Power cord for the UK	5,686 04,961	4m
POWER CORD US	Power cord for the US	5,686 04,967	4m
POWER CORD BRA	Power cord for Brazil	5,686 04,963	4m
POWER CORD CHE	Power cord for Switzerland	5,686 04,965	4m
POWER CORD AUS	Power cord for Australia	5,686 04,964	4m
POWER CORD ITA	Power cord for Italy	5,686 04,962	4m
POWER CORD ARG	Power cord for Argentina	5,686 04,968	2 m

Tab. 4: Power supply cables

1.7　Device identification label
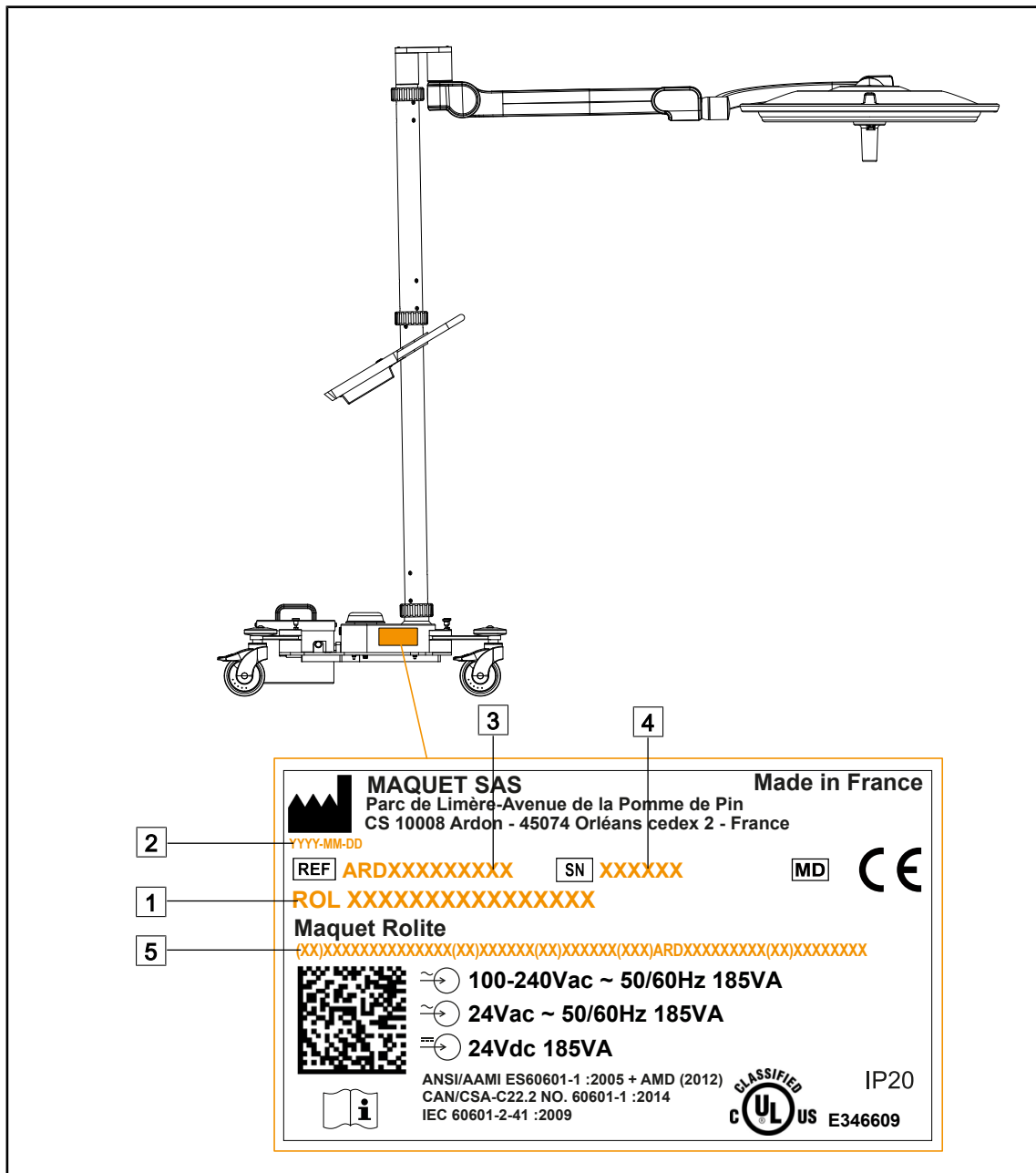
Fig. 20:　Location of the product identification label

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

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 ANSI/AAMI ES60601-1:2005/(R)2012 CAN/CSA-C22.2 No. 60601-1:14 EN 60601-1:2006/A1:2013/A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-2-41:2009+AMD1:2013 EN 60601-2-41:2009/A11:2011/A1:2015	Medical electrical equipment – Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis
IEC 60601-1-2:2014 EN 60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 EN 60601-1-6:2010/A1:2015/A2:2021	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-9:2007+AMD1:2013+AMD2:2020 EN 60601-1-9:2008/A1:2014/A2:2020	Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for an environmentally friendly design
IEC 62366-1:2015+AMD1:2020 EN 62366-1:2015/A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 62304:2006+AMD1:2015 EN 62304:2006/A1:2015	Medical device software – Software life cycle processes
ISO 20417:2021 EN ISO 20417:2021	Medical devices - Information provided by manufacturer
ISO 15223-1:2021 EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be provided by manufacturer - Part 1: General requirements
EN 62471:2008	Photobiological safety of lamps and lamp systems
IEC 62311:2019 EN 62311:2020	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz – 300 GHz)
IEC 60825-1:2014 EN 60825-1:2014	Safety of laser products – Part 1: Equipment classification and requirements
Ordinance 384/2020	INMETRO Certification - Compliance assessment requirements for equipment under Health Surveillance

Tab. 5:   Compliance with product standards

Quality management:

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

Tab. 6: Compliance with quality management standards

Environmental standards and regulations:

Reference	Year	Title
Directive 2011/65/EU	2011	Limitation of the use of certain hazardous substances in electrical and electronic equipment
Directive 2015/863	2015	Directive amending Annex II of Directive 2001/65/EU of the European Parliament and of the Council as regards the list of substances subject to limitation
Directive 2016/585/EU	2016	Exemption for lead, cadmium, hexavalent chromium and PBDEs on medical devices
Directive 2017/2102	2017	Limitation of the use of certain hazardous substances in electrical and electronic equipment
IEC 63000	2022	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
Regulation 1907/2006	2006	Registration, evaluation and authorization of chemical substances, as well as the restrictions applicable to these substances
US California Proposition 65 Act	1986	The Safe Drinking Water and Toxic Enforcement Act of 1986
Directive 94/62/EC	1994	Packaging and Waste Management
SJ/T 11365-2006	2006	Administrative Measure on the Control of Pollution caused by Electronic Information Products Chines RoHS (Restriction of Hazardous Substances)

Tab. 7: Environmental standards and regulations

Market standards:

Country	Reference	Year	Title
Argentina	Dispocision 2318/2002	2002	Administración Nacional de Medicamentos, Alimentos y Tecnología Médica - Registro de productos Medicas - Reglamento
Australia	TGA 236-2002	2019	Therapeutic Goods (Medical Devices) Regulations 2002. Statutory Rules No. 236, 2002 made under the Therapeutic Goods Act 1989
Brazil	RDC 665/2022	2022	GMP Requirements for Medical Devices and IVDs
Brazil	RDC 185/2001	2001	Technical regulation about the registration of medical products at ANVISA, as well as its alteration, revalidation, or cancellation
Canada	SOR/98-282	2021	Medical Devices Regulations
China	Regulation 739	2021	Regulation for the Supervision and Administration of Medical Devices
EU	Regulation 2017/745/EU	2017	Medical Devices Regulations
Japan	MHLW Ordinance: MO No. 169	2021	Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-Vitro Diagnostics
South Korea	Act 14330	2016	Medical Device Act
South Korea	Decree 27209	2016	Enforcement Decree of Medical Act
South Korea	Rule 1354	2017	Enforcement Rule of the Medical Act
Switzerland	RS (Odim) 812.213	2020	Medical Devices Ordinance (MedDO) of 1 July 2020
Taiwan	TPAA 2018-01-31	2018	Taiwanese Pharmaceutical Affairs Act
UK	Act	2021	Medical Devices Regulations 2002 No. 618
USA	21CFR Part 7	2017	Title 21--Food And Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter A -- General PART 7 - Enforcement policy
USA	21CFR Subchapter H	-	Title 21--Food And Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter H -- Medical Devices

Tab. 8:   Compliance with market standards

1.9 Information relating to intended use

1.9.1 Intended use

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

1.9.2 Intended users

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

1.9.3 Inappropriate use

- Use as a major light system (two or three lightheads) for all operations performed on patients, with or without risk.
- Use of a damaged product (e.g., lack of maintenance).
- In a setting other than a professional healthcare environment (e.g., home care).
- Use of the camera for assistance during an operation or to establish a diagnosis.

1.9.4 Contraindications

This product does not have any contraindications.

1.10 Primary purpose

The primary purpose of the Maquet Rolite 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 [» Page 106] chapter.
- Use the various options wisely to avoid needless power consumption.
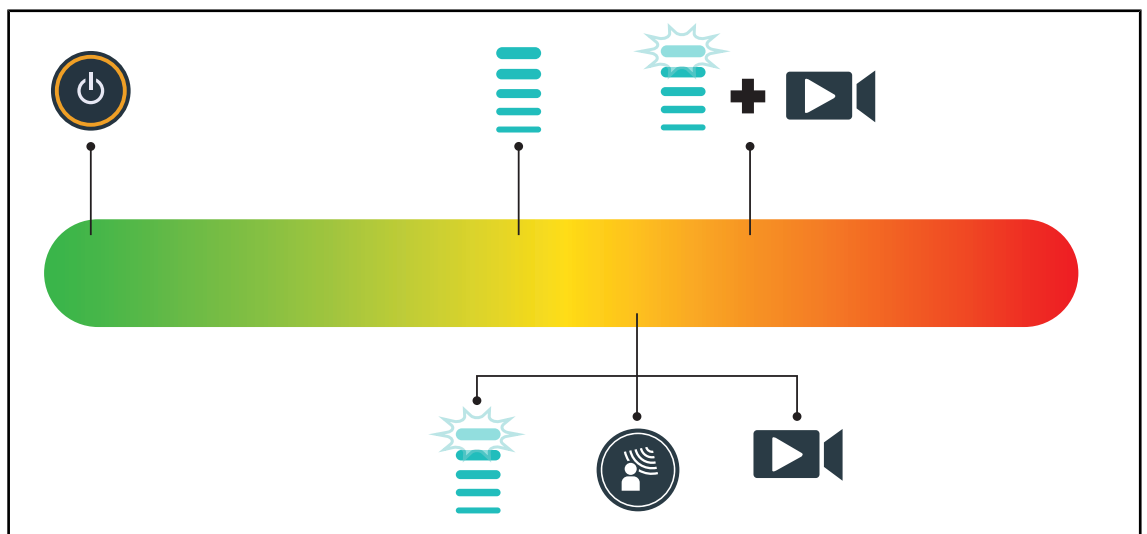
Fig. 21:   Power consumption of device in operation

ℹ **NOTE**

Power consumption for the device is provided in chapter 9.2, Electrical specifications.
The device does not contain hazardous substances in accordance with RoHS directive (see Tab. 5) and Reach regulation.

---

2 Safety-related information

2.1 Environmental conditions

Environmental conditions for transport and storage

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

Tab. 9:   Environmental conditions for transport/storage

Environmental conditions for use

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

Tab. 10:   Environmental conditions for use

2.2 Safety instructions

2.2.1 Safe use of the product

WARNING!

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

Do not use in an MRI environment.

WARNING!

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

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

WARNING!

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

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

WARNING!

Risk of injury
The mobile light may tip over if not handled properly.

Push the mobile light to move it. Never pull the light behind you except on a slope.

⚠️ **WARNING!**

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

Never lean on the mobile light.

⚠️ **WARNING!**

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

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

⚠️ **WARNING!**

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

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

⚠️ **WARNING!**

Risk of injury
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.

2.2.2 Electrical

CAUTION!

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

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

WARNING!

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

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

WARNING!

Risk of electric shock
A user may be electrocuted if the device is not connected to the mains supply.

If the light is not connected to the mains supply, link the grounding connector on the device to a grounding terminal in the room.

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

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

2.3 Safety labels on the product
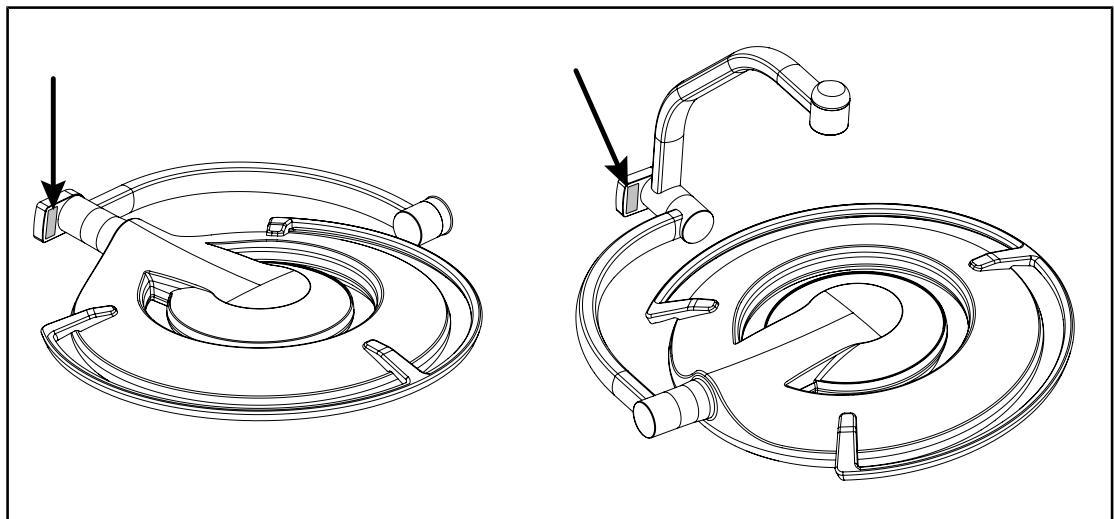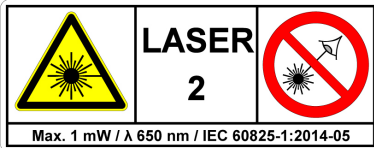
Fig. 22: Location of laser label

Label	Meaning
LASER 2 Max. 1 mW / λ 650 nm / IEC 60825-1:2014-05	**Laser radiation (only on Maquet PowerLED II)** Do not look into the beam. Class 2 laser device.
LASER RADIATION DO NOT STARE INTO BEAM CLASS 2 LASER PRODUCT Max. 1mW, 650nm, IEC60825-1:2014. Complies with 21 CFR 1040.10 and 1040.11, except for deviation pursuant to Laser Notice No.50, dated June 24, 2007	**Laser radiation (only on Maquet PowerLED II)** Do not look into the beam. Class 2 laser device.
	Risk of toppling: Do not push the mobile light or lean on it when the casters are locked.
	Push the Rolite mobile light to move it. Do not pull the light behind you. The lighthead arm must be folded away before moving the Rolite mobile light.
	Place yourself on the lighthead side when moving the light on sloped surfaces. Only pull the light behind you when moving it on sloped surfaces. Turn the light so that the batteries are towards the bottom of the slope.

Tab. 11: Safety label on the product

3 Control interfaces
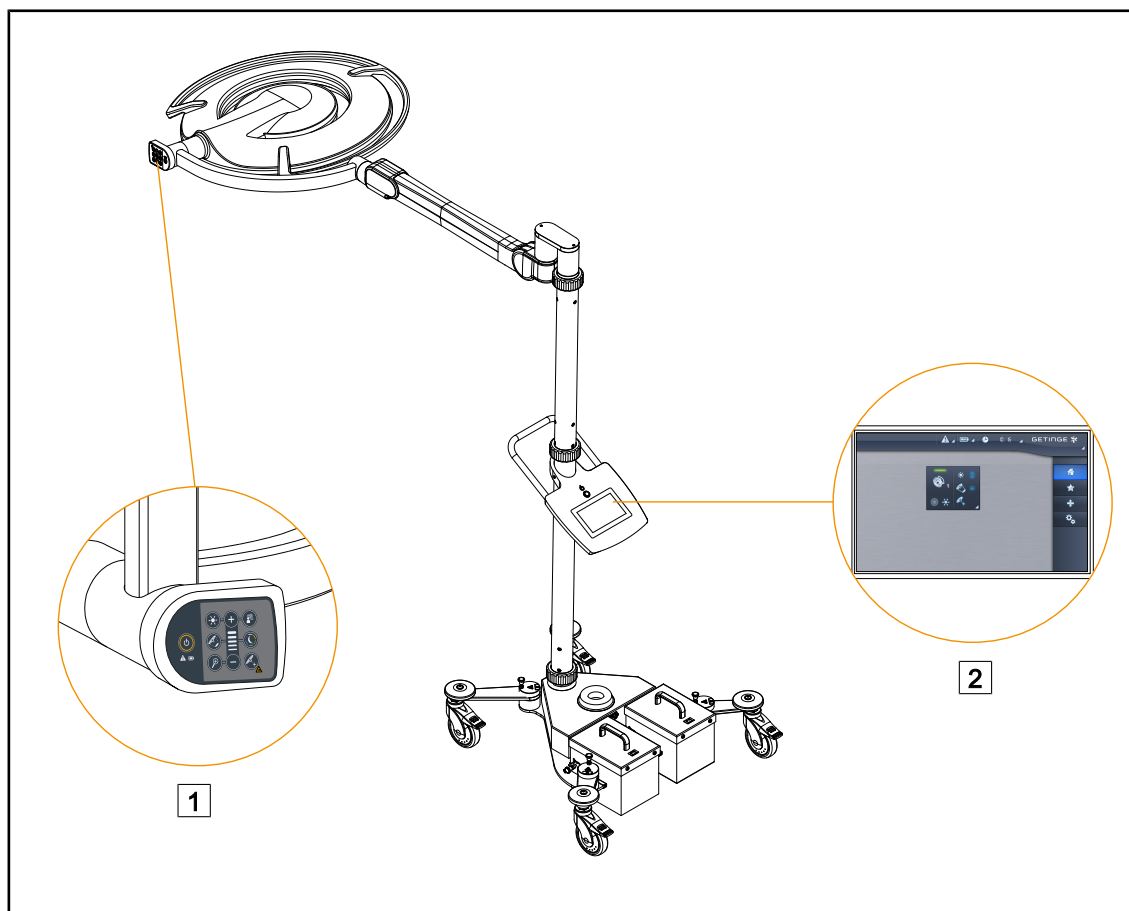
Fig. 23:   Control interfaces

| 1 | Lighthead control keypad | 2 | Touchscreen control panel |

3.1 Lighthead control keypads
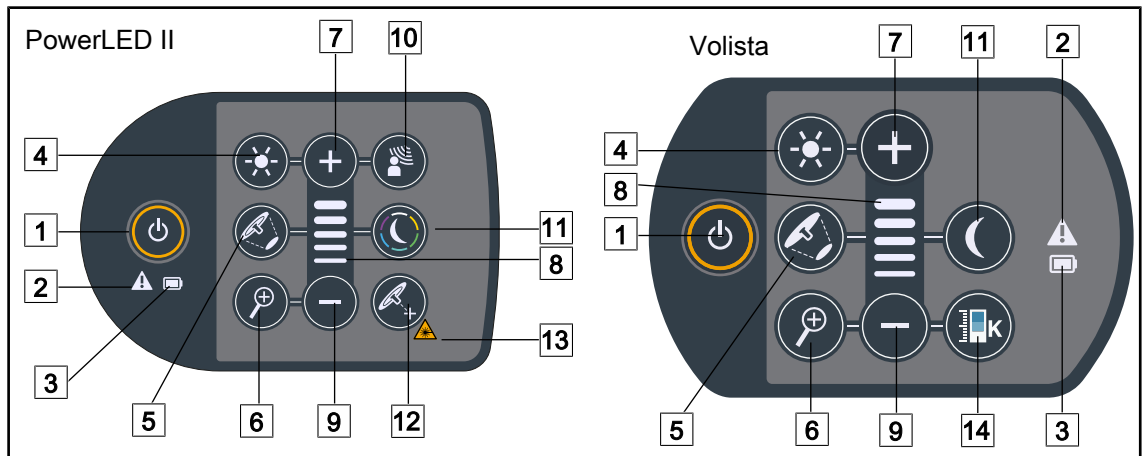
Fig. 24:   Control keypads located on the lighthead forks

1	On/Off	8	Level indicator
2	Warning indicator	9	Minus (reduce the level)
3	Battery indicator	10	AIM mode
4	Adjustment of illumination	11	Ambient light mode
5	Light field diameter variation	12	Laser positioning mode*
6	Camera zoom (not operational on PowerLED II)	13	Laser safety symbol
7	Plus (increase the level)	14	Colour temperature variation

3.2 Touchscreen control panel
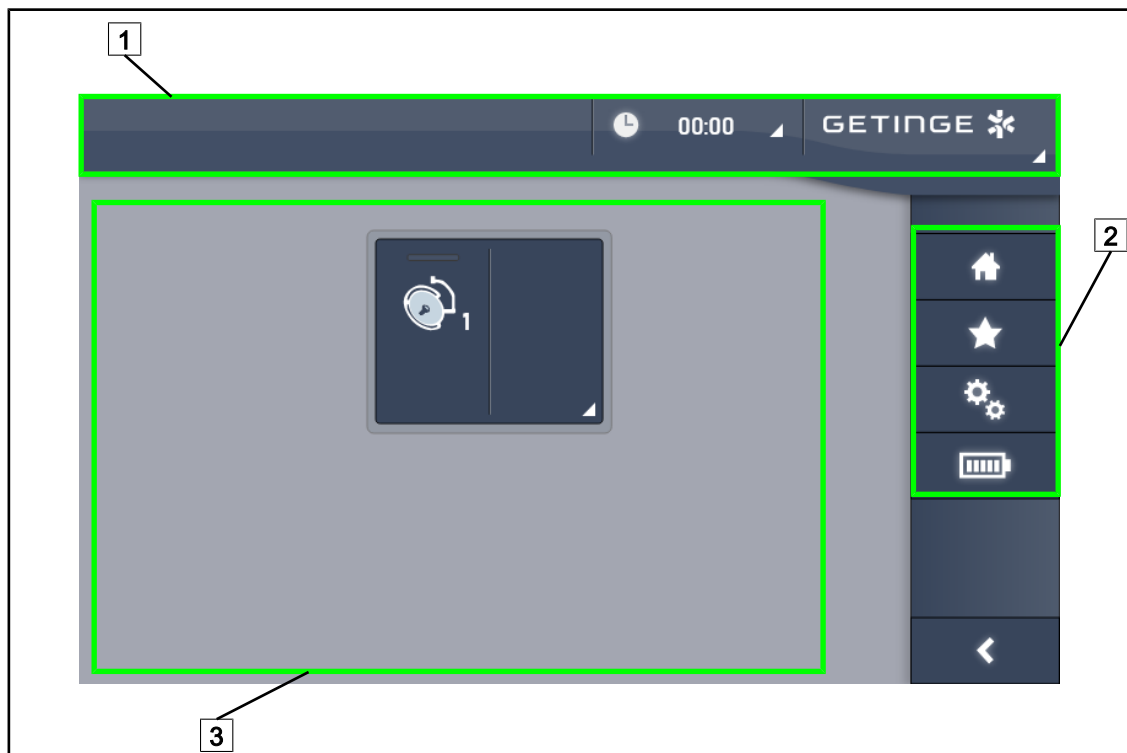
Fig. 25: Touchscreen control panel

| 1 | Status bar | 3 | Active area |
| 2 | Menu bar | | |

No.	Description
1	Area of the screen used to display the fault indicator, battery indicator, time, Getinge logo and customer logo.
2	Area of the screen used to access the menus: home screen, presets, functions and settings.
3	Area of the screen used to control the device.

Tab. 12: Touchscreen control panel information

Status bar
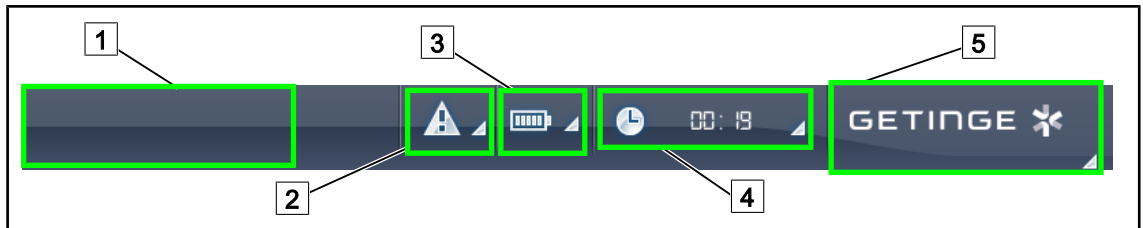
Fig. 26:   Touchscreen control panel status bar

1	Location for customer logo (optional)	4	Clock
2	Fault indicator	5	Getinge logo
3	Battery indicator		

No.	Description	Possible actions
1	Customer logo	The customer can have its facility's logo displayed in this location. Contact the technical department for this.
2	▪ Indicates a system fault. ▪ Displayed only if a system fault has occurred.	Press the **fault indicator** icon to view the faults.
3	▪ Indicates the battery status. For more information, see the dedicated section Indicators shown on the touchscreen control panel [» Page 87] ▪ Visible only when the backup system is used (e.g., not plugged into an electrical outlet)	Press the **battery indicator** icon to view the status of the batteries.
4	Shows the time	Press the **clock** icon to access the date and time settings.
5	Getinge logo	▪ Press the **Getinge logo** to access product maintenance information. ▪ Press the **Getinge logo** a second time to access a menu reserved for Getinge technicians and qualified personnel, see Groups of people.

Tab. 13:   Touchscreen control panel status bar

Menu bar

1	Home screen
2	Favourites
3	Settings
4	Battery tests
5	Return

Fig. 27: Touchscreen control panel menu bar

Part No.	Description	Possible actions
1	Page giving access to all commands and information.	Press the **home** icon to return to the home page.
2	User-defined presets.	Press the **Presets** icon to go to the page showing all saved settings.
3	Configurable settings and configuration-related information	Press the **Settings** icon to access the settings page and information about the configuration.
4	Battery tests	Press the **Battery Tests** icon to access the backup tests page.
5	Return	Press the **return** button to return to the previous screen.

Tab. 14: Touchscreen control panel status bar

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.
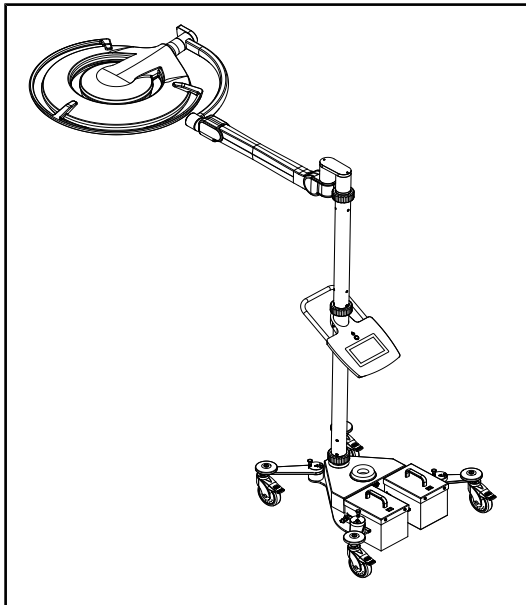
Fig. 28: Integrity of the device

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.
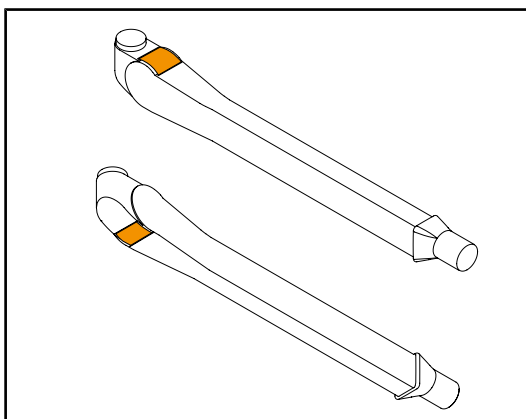
Fig. 29: Inspection of spring arm half-rings

Half-rings on spring arms

1. Check that the half-rings on the spring arm are in place in their slot.
2. If a problem is noted, contact technical support.
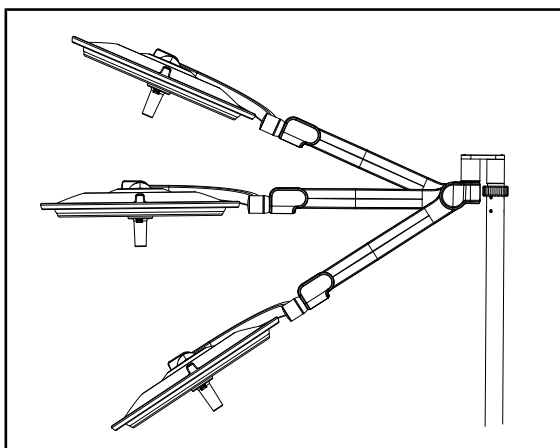
Fig. 30:   Spring arm positioning

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.
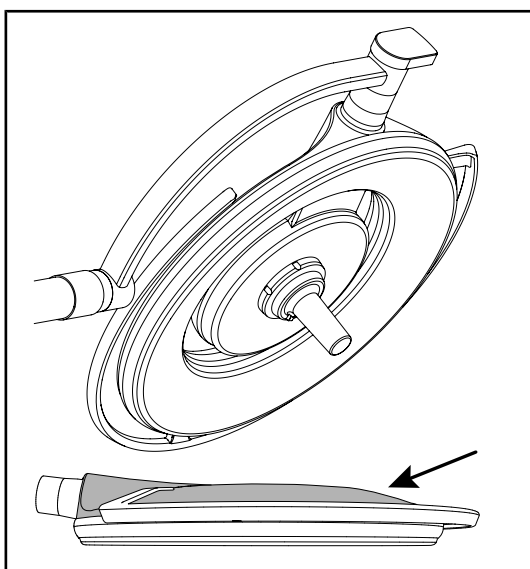
Fig. 31:   Inspection of caps and covers

Silicone caps and lighthead cover

1.   Check that the lighthead caps are in the proper position and in good condition.

2.   Check that the lighthead cover is in the proper position and in good condition.

3.   If a problem is noted, contact technical support.
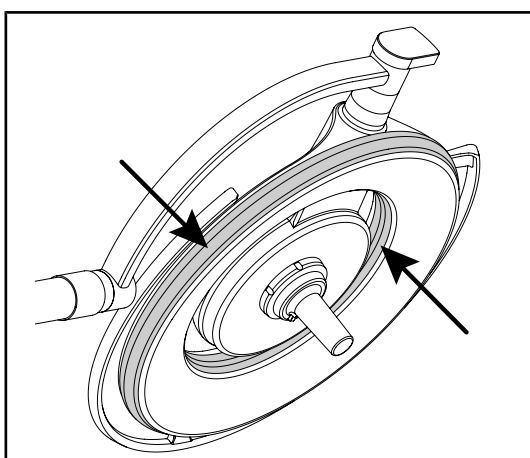
Fig. 32:   Inspection of lighthead gaskets

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.
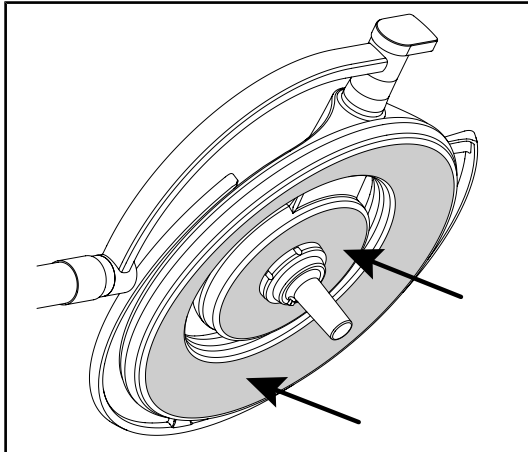
Fig. 33: Inspection of underside

Lighthead underside

1. Check that the underside is not damaged (scratches, stains, etc.)

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

Fig. 34: Condition of lighthead keypad

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 for 5 seconds.

   ➢ All buttons and warning indicators are backlit.

3. If a problem is noted, contact technical support.
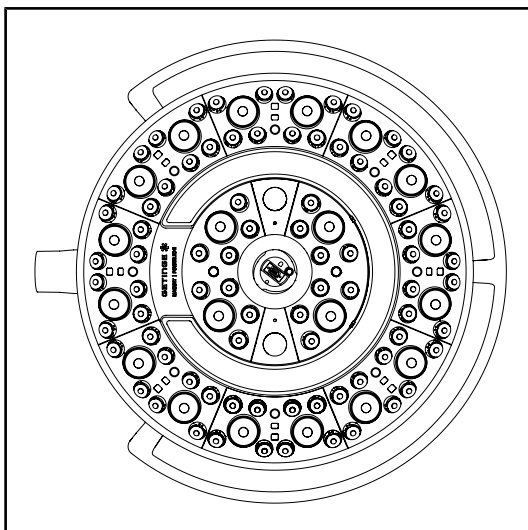
Fig. 35: Operation of LEDs

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. Turn on the light, selecting the largest light field diameter (such that all LEDs are lit); see Adjusting the illumination [» Page 44].

4. Check that all the LEDs are operating.
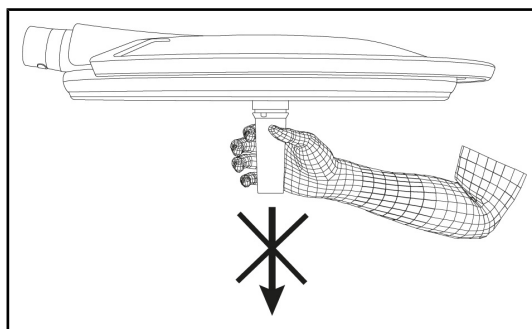
Fig. 36:   Holding the handle mount

Fig. 37:   Battery test

Lighthead handle interface

1. Remove the handle mount in place (Removing the device).

    ➢ Check that it can be removed easily.

2. Reinstall the handle mount on the lighthead (Fitting the device to the lighthead).

    ➢ Check that it can be installed smoothly and that the handle mount is properly installed.
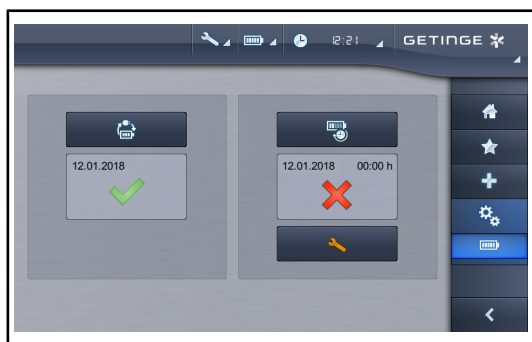
Backup fail test (only for a battery-backed system)

1. Conduct a battery failover test via the touchscreen control panel (From the touchscreen control panel).

2. If the test fails, contact technical support.

4.2   Controlling the light

4.2.1   Turning the light on and off

4.2.1.1   Turning on the mobile light
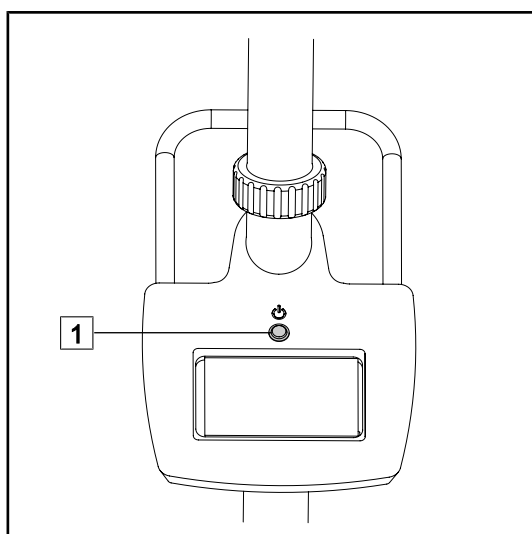
Fig. 38:   Turning on the light

1. Press the On/Off button 1 on the mobile light to turn on the device.

4.2.1.2   From the lighthead control keypad
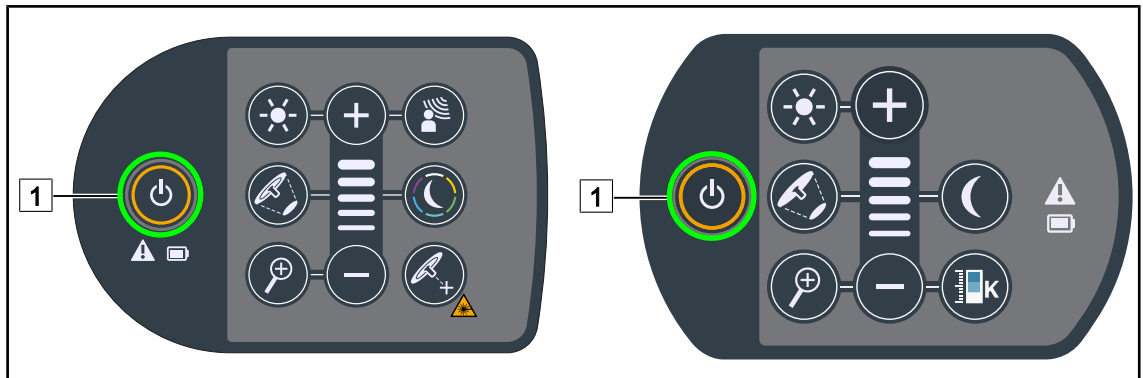
Fig. 39:   Turning the light on and off via the lighthead keypad

1. Press the **On/Off** 1 button to turn on the lighthead.

   ➢ The light turns on, setting the illumination level to the last value used when the light was turned off.

2. Press the **On/Off** 1 button again until the keypad turns off.

   ➢ The lighthead turns off when the button is released.

4.2.1.3   From the touchscreen control panel
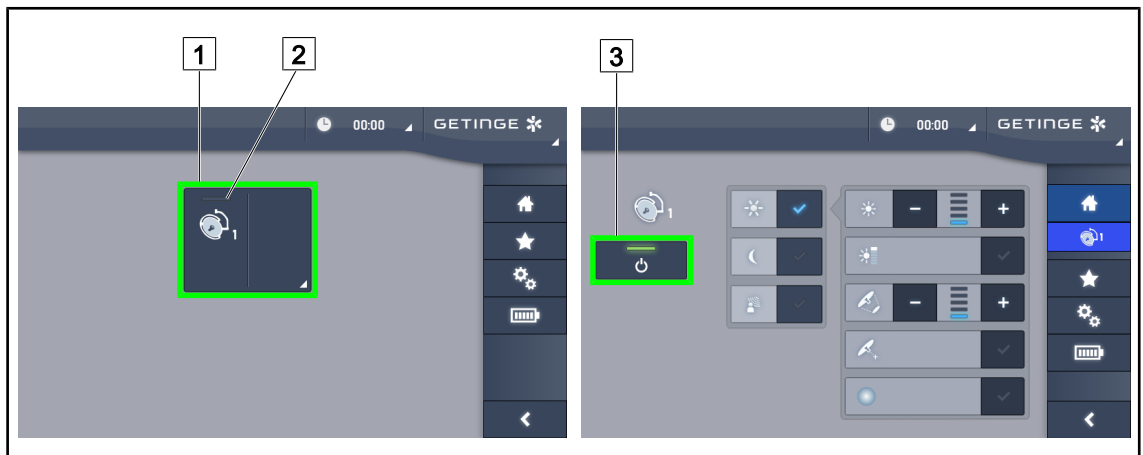
Fig. 40:   Turning the light on and off via the touchscreen control panel

Turning on the light

1. Press the **Lighthead active area** 1.

   ➢ The **operation indicator** 2 is activated and the lighthead turns on.

Turning off the light

1. Press the **Lighthead active area** 1.

   ➢ The lighthead control page is displayed.

2. Press **Lighthead ON/OFF** 3.

   ➢ The lighthead and the **operation indicator** are turned off.

   ➢ The light is now off.

4.2.2 Adjusting the illumination

4.2.2.1 From the lighthead control keypad
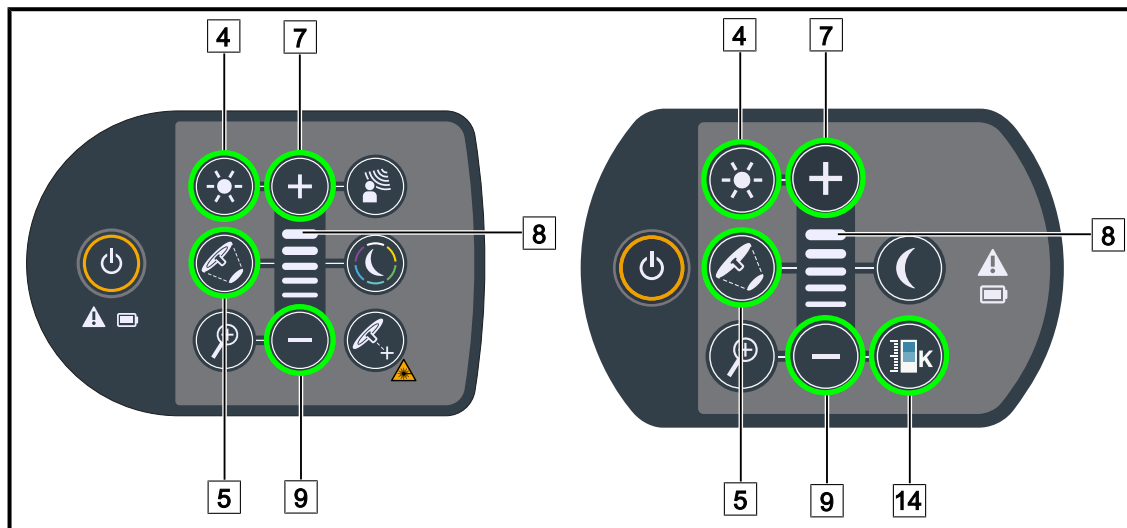
Fig. 41:   Adjusting the illumination level using the lighthead control keypad

Adjusting the light intensity

1. Press the **Light intensity adjustment** 4 button.

    ➢ The button is backlit on the keypad.

2. Press **Plus** 7 to increase the light intensity level of the lighthead.

3. Press **Minus** 9 to decrease the light intensity level of the lighthead.

Enabling/disabling boost mode

1. When the light intensity level is at 100%, press and hold the **Plus** 7 button until the last LED on the level indicator 8 starts flashing.

    ➢ Boost mode is now enabled.

2. Press **Minus** 9 to disable Boost mode.

    ➢ Boost mode is now disabled.

Adjusting the light field diameter

1. Press the **Light field diameter variation** 5 button.

    ➢ The button is backlit on the keypad.

2. Press **Plus** 7 to increase the light field diameter of the lighthead.

3. Press **Minus** 9 to decrease the light field diameter of the lighthead.

Adjusting the colour temperature

1. Press **Colour Temperature** 14

    ➢ The button is backlit on the keypad.

2. Press **Plus** 7 to select a warmer colour temperature.

3. Press **Minus** 9 to select a colder colour temperature.

4.2.2.2 From the touchscreen control panel
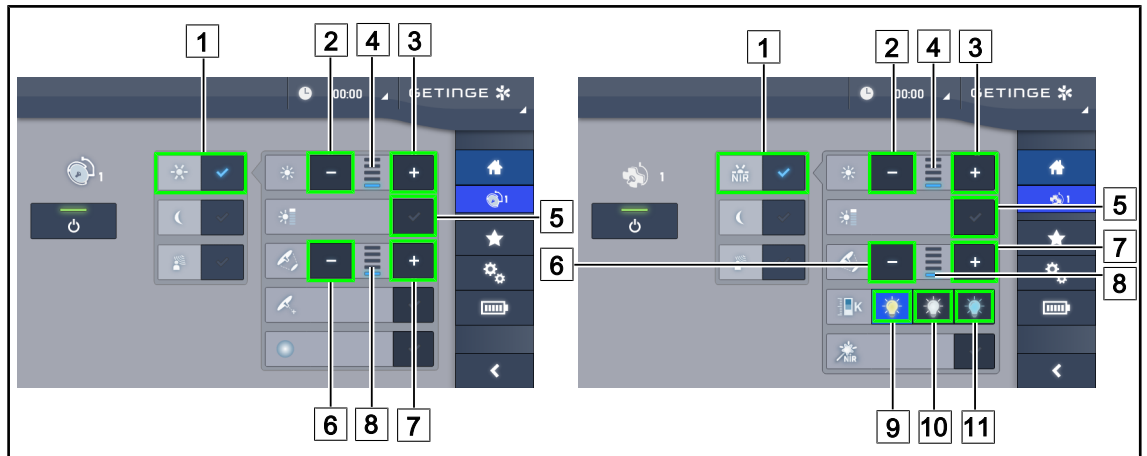
Fig. 42: Adjusting the illumination level via the touchscreen control panel

Adjusting the light intensity

1. From the lighthead page, press the **Standard mode** 1 button.

   ➢ When enabled, the button is blue.

2. Press **Increase intensity** 3 to increase the light intensity level of the lighthead.

3. Press **Decrease intensity** 2 to decrease the light intensity level of the lighthead.

Enabling boost mode

1. From the lighthead page, press the **Standard mode** 1 button.

   ➢ When enabled, the button is blue.

2. Press **Boost mode** 5.

   ➢ The Boost mode button is lit blue and the last bar on the illumination level indicator 4 flashes. Boost mode is now enabled on the lighthead.

Adjusting the light field diameter

1. From the lighthead page, press the **Standard mode** 1 button.

   ➢ When enabled, the button is blue.

2. Press **Increase diameter** 7 to increase the light field diameter of the lighthead 8.

3. Press **Decrease diameter** 6 to decrease the light field diameter of the lighthead 8.

Adjusting the colour temperature

1. From the lighthead page, press **3900K** 9, **4500K** 10 or **5100K** 11 to select the desired colour temperature.

   ➢ The button is lit blue and the selected colour temperature is enabled on the lighthead.

4.2.3 Ambient light

4.2.3.1 From the lighthead control keypad
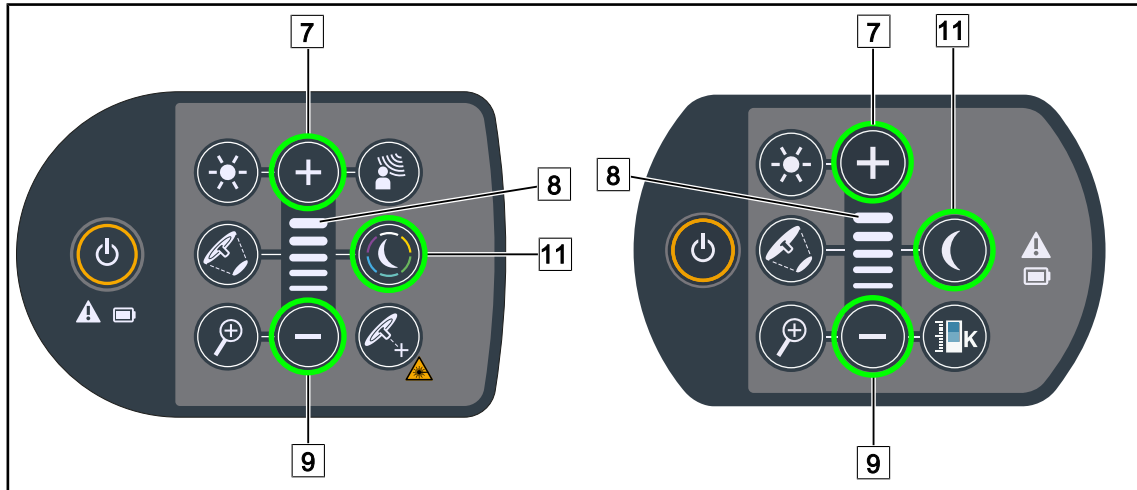
Fig. 43:   Adjusting the ambient light via the lighthead keypad

Maquet PowerLED II

Selecting the ambient light colour

1. Press **Ambient light mode** 11.

    ➢ The button is backlit on the keypad.

2. Press **Ambient light mode** 11 again to select the desired colour. The cycle of colours is as follows: white, yellow, green, turquoise, blue and then purple.

Adjusting the light intensity of the ambient light

1. Press **Ambient light mode** 11.

    ➢ The button is backlit on the keypad.

2. Press **Plus** 7 to increase the light intensity level of the lighthead 8.

3. Press **Minus** 9 to decrease the light intensity level of the lighthead 8.

For Volista

Enabling ambient light mode

1. Press **Ambient light mode** 11.

    ➢ The button is backlit on the keypad.

Adjusting the illumination level of the ambient light

1. Press **Ambient light mode** 11.

    ➢ The button is backlit on the keypad.

2. Press **Plus** 7 to increase the illumination level of the lighthead 8.

3. Press **Minus** 9 to decrease the illumination level of the lighthead 8.

4.2.3.2 From the touchscreen control panel
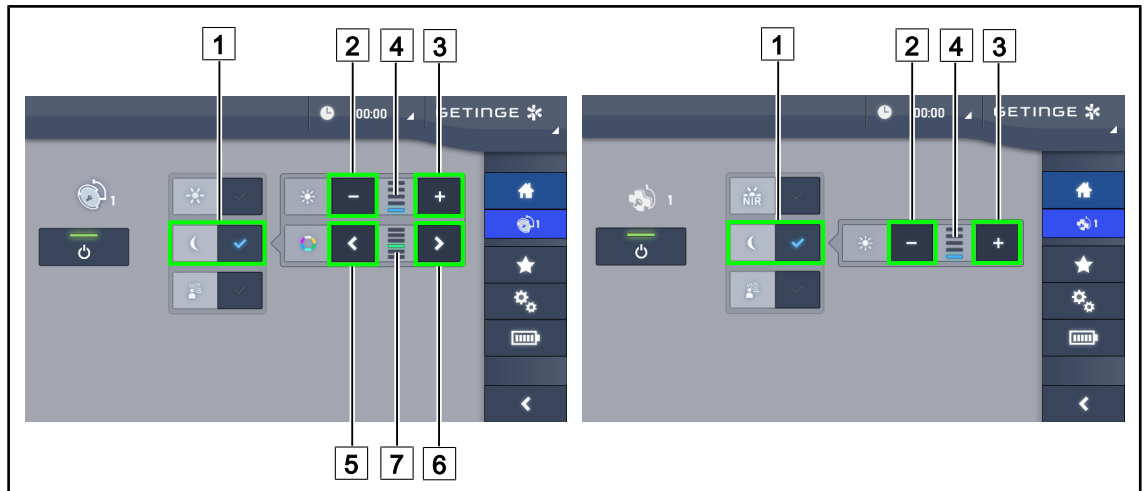
Fig. 44:   Adjusting the ambient light via the touchscreen control panel

For Maquet PowerLED II

Selecting the ambient light colour

1. From the lighthead page, press the **Ambient light mode** 1 button.

   ➢ When enabled, the button is blue.

2. Press **Previous** 5 or **Next** 6 to select the desired colour 7 . The cycle of colours is as follows: white, yellow, green, turquoise, blue and then purple.

Adjusting the light intensity of the ambient light

1. From the lighthead page, press the **Ambient light mode** 1 button.

   ➢ When enabled, the button is blue.

2. Press **Plus** 3 to increase the light intensity level of the lighthead 4 .

3. Press **Minus** 2 to decrease the light intensity level of the lighthead 4 .

For Volista

Enabling ambient light mode

1. From the lighthead page, press the **Standard/Ambient light** 1 button.

   ➢ When enabled, the button is blue.

Adjusting the light intensity of the ambient light

1. From the lighthead page, press the **Standard/Ambient light** 1 button.

   ➢ When enabled, the button is blue.

2. Press **Plus** 3 to increase the light intensity level of the lighthead 4 .

3. Press **Minus** 2 to decrease the light intensity level of the lighthead 4 .

4.2.4 AIM

4.2.4.1 From the lighthead control keypad (only with Maquet PowerLED II)
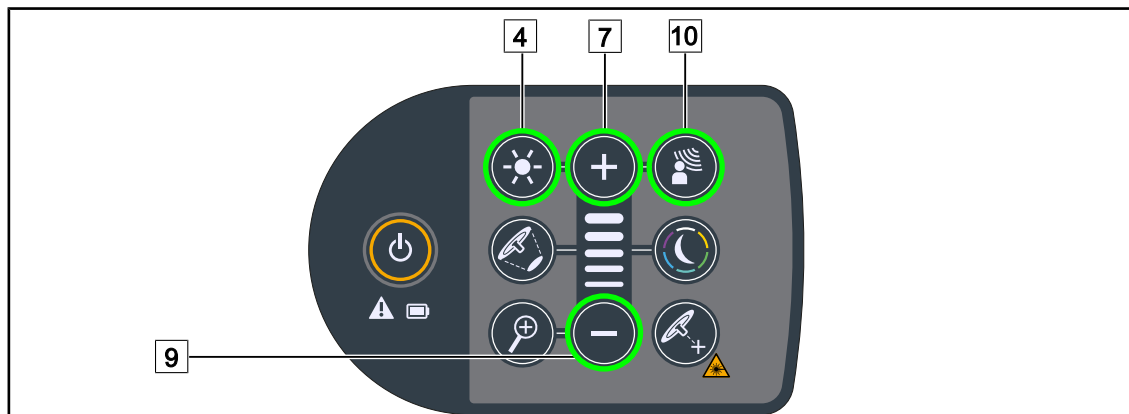
Fig. 45:   AIM mode via the lighthead control keypad

Enabling/disabling AIM mode

1. Enable AIM by pressing the **AIM mode** [10] button.

    ➢ The **AIM mode** [10] and **Illumination adjustment** [4] buttons are backlit on the keypad and AIM mode is enabled.

2. Disable AIM by pressing the **AIM mode** [10] button.

    ➢ The **AIM Mode** [10] button is no longer backlit on the keypad and AIM mode is disabled.

Adjusting the light intensity with AIM

1. When AIM mode is enabled, press **Plus** [7] to increase the light intensity level of the light-head.

2. When AIM mode is enabled, press **Minus** [9] to decrease the light intensity level of the light-head.

---

i **NOTE**

Boost mode is not available when AIM mode is enabled. In this case, the light has 10 illumination levels.

4.2.4.2 From the touchscreen control panel
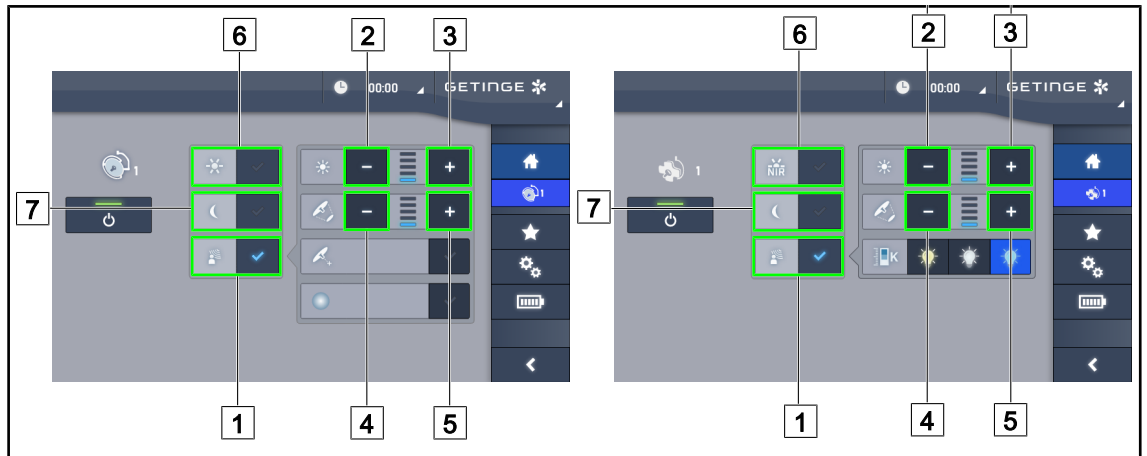
Fig. 46:   AIM mode using the touchscreen control panel

Enabling/disabling AIM mode

1. Enable AIM by pressing the **AIM mode** 1 button.

    ➢ The button is lit blue and AIM mode is enabled on the lighthead.

2. Disable the AIM function by pressing **Illumination adjustment** 6 or **Ambient light mode** 7.

    ➢ The AIM button turns off and the selected mode button is backlit. AIM mode is disabled on the lighthead.

Adjusting the light intensity with AIM

1. Press **Increase intensity** 3 to increase the light intensity level of the lighthead.

2. Press **Decrease intensity** 2 to decrease the light intensity level of the lighthead.

ⓘ   **NOTE**

Boost mode is not available when AIM mode is enabled; in this mode, the system features 10 illumination levels for Maquet PowerLED II and 5 illumination levels for Volista.

Adjusting the light field diameter with AIM

1. Press **Increase diameter** 5 to increase the light field diameter of the lighthead.

2. Press **Decrease diameter** 4 to decrease the light field diameter of the lighthead.

4.2.5 Volista VisioNIR* (on VSTII only)
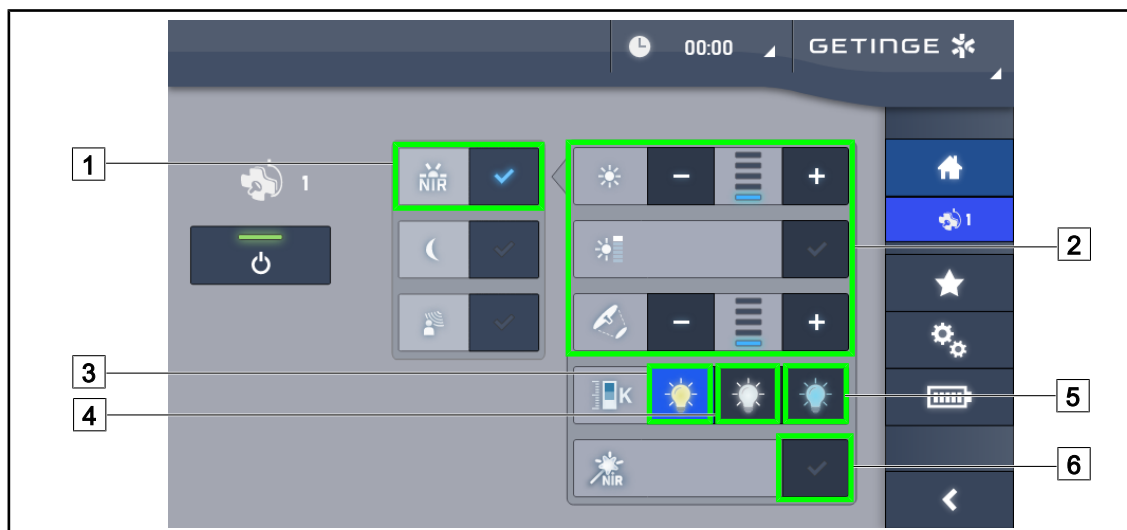
Fig. 47:   VisioNIR

Adjust the illumination of the lighthead in Volista VisioNIR mode

1. From the lighthead page, press the **Volista VisioNIR Mode** 1 button.

   ➢ The button turns blue when enabled.

2. Activate Boost mode, adjust the light intensity or light field diameter in the same way as in Standard mode 2 Adjusting the illumination.

Adjusting the colour temperature

1. From the lighthead page, press **3900 K** 3 , **4500 K** 4 or **5100 K** 5 to select the desired colour temperature.

   ➢ The button is lit blue and the selected colour temperature is enabled on the lighthead.

Enabling/disabling the VisioNIR Boost function

1. Press **VisioNIR Boost** 6 to enable the VisioNIR Boost function.

   ➢ The button turns blue when enabled.

2. Press **VisioNIR Boost** 6 to disable the VisioNIR Boost function.

---

i **NOTE**

When a fluorescence camera is used with indocyanine green, in most cases the Volista VisioNIR lighthead exhibits little disturbance in the fluorescence signal in Standard mode. For a weak signal, or to improve contrast on the screen, the VisioNIR Boost function can be used to optimise the settings (see Table 35). The lightheads are then automatically set to the 5100K colour temperature, and the central ring LEDs on the Volista 600 are turned off.

4.2.6 Comfort Light* (option available on Maquet PowerLED II only)

Fig. 48:   Comfort Light

Prerequisites:

- The Standard or AIM mode is enabled 1 .

1. Press **Comfort Light** 2 .

   ➢ The button is lit blue and the Comfort Light is enabled on the lighthead.

2. When the Comfort Light is enabled, press **Comfort Light** 2 to disable it.

   ➢ The button turns off and the Comfort Light is disabled on the lighthead.

4.2.7 LMD* (on Maquet PowerLED II et Volista VSTII only)
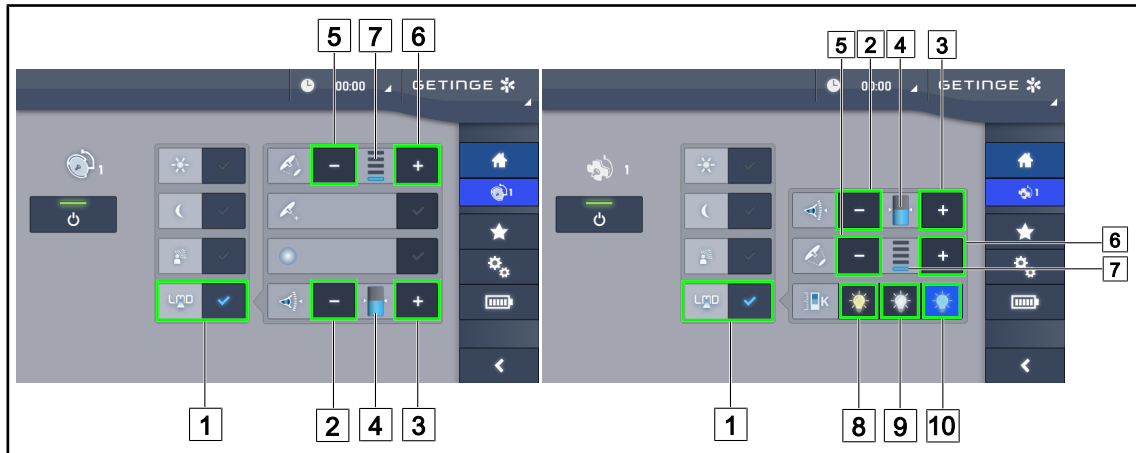
Fig. 49:   Controlling the LMD

Enabling/disabling LMD mode

1. Set the desired light intensity that is comfortable for the surgeon.

2. Next press **LMD** 1.

   ➢ The button is lit blue and the LMD is now enabled.

3. When LMD is enabled, press **LMD** 1 to disable it.

   ➢ The button turns off and the LMD is now disabled.

Adjusting the luminance setpoint value

1. Press **Increase luminance** 3 to increase the luminance of the lighthead 4.

2. Press **Decrease luminance** 2 to decrease the luminance of the lighthead 4.

Adjusting the light field diameter with LMD

1. Press **Increase diameter** 6 to increase the light field diameter of the lighthead 7.

2. Press **Decrease diameter** 5 to decrease the light field diameter of the lighthead 7.

Adjusting the colour temperature with LMD enabled

1. With LMD enabled, press **3900K** 8, **4500K** 9 or **5100K** 10 to select the desired colour temperature.

   ➢ The button is lit blue and the selected colour temperature is enabled on the lighthead.

> **ℹ** **NOTE**
>
> If the lighthead is at its maximum level, the luminance cannot be increased and the **Plus** 3 button is shaded and inactive.
> If the lighthead is at its maximum level, the luminance cannot be increased and the **Minus** 2 button is shaded and inactive.

The luminance level indicator 4 provides a visual indication that the stored luminance level is maintained:

	The setpoint value is achieved.
	The lighthead is at its minimum and the luminance remains above the set value (orange gauge above the reference value).
	The lighthead is at its maximum and the light remains below the set value (orange gauge below the reference value).

Tab. 15:   Luminance levels

4.2.8   Presets

4.2.8.1   Selecting or storing a preset
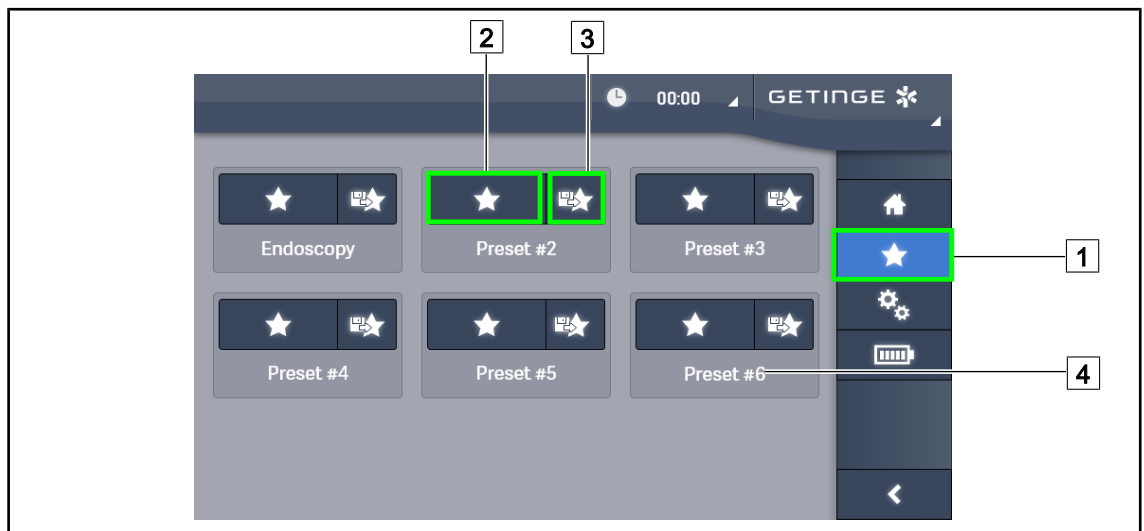
Fig. 50:   Presets page

Applying a preset

1. Press **Presets** 1 to access the Presets page.

    ➢ The presets page is displayed.

2. Press the **Apply preset** 2 button for the desired preset name 4 corresponding to of the six saved presets.

    ➢ The selected preset is applied.
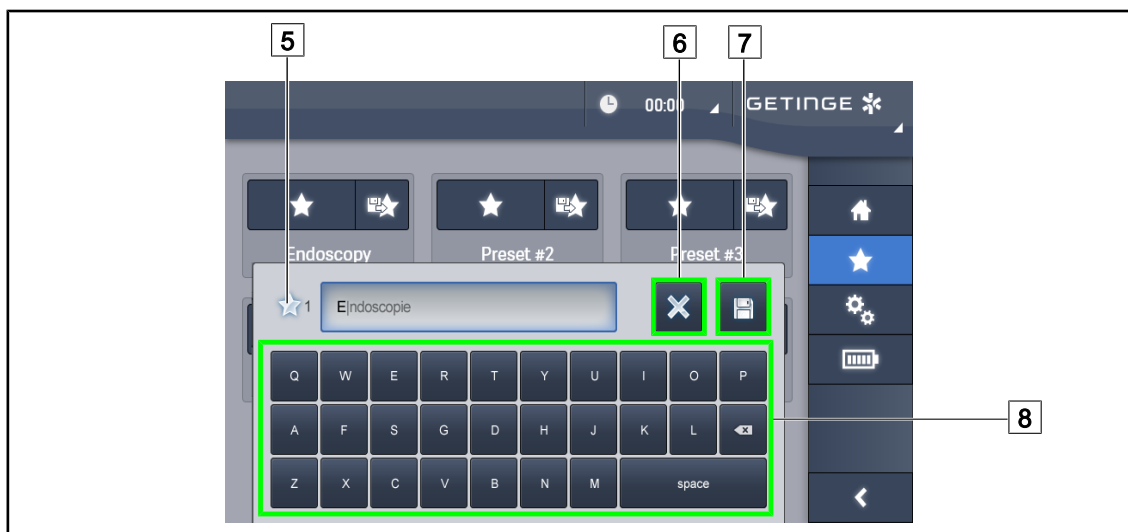
Fig. 51:   Store preset

Storing a preset

1. Adjust the light settings to the configuration desired for the preset.

2. Press **Store preset** ⎡3⎤.

    ➢ The preset data entry window is displayed (see opposite) showing the selected preset ⎡5⎤.

3. Use the keypad ⎡8⎤ to enter the preset name.

4. Press **Save preset** ⎡7⎤ to store the preset. Changes can always be cancelled by pressing **Cancel changes** ⎡6⎤.

    ➢ A pop-up window is displayed to confirm that the preset has been stored, before returning to the presets page.

4.2.8.2   Factory presets

Applica-tions	Uro/Gyneco		Laparotomy		Orthopaedic	
	PWDII 500	**PWDII 700**	**PWDII 500**	**PWDII 700**	**PWDII 500**	**PWDII 700**
Illumination	80%	80%	100%	100%	60%	60%
Light field diameter	Small	Small	Medium	Large	Medium	Medium
AIM	–	–	Enabled	Enabled	–	–
Auto laser	–	–	–	–	–	–
Comfort Light	Enabled	Enabled	Enabled	Enabled	Enabled	Enabled
Endo	–	–	–	–	–	–

Tab. 16:   Maquet PowerLED II factory default lighthead presets

Applica-tions	ENT		Plastic surgery		Cardiac surgery	
	PWDII 500	**PWDII 700**	**PWDII 500**	**PWDII 700**	**PWDII 500**	**PWDII 700**
Illumination	60%	60%	100%	100%	100%	100%
Light field diameter	Small	Small	Medium	Large	Medium	Large
AIM	Enabled	Enabled	Enabled	Enabled	Enabled	Enabled
Auto laser	–	–	–	–	–	–
Comfort Light	Enabled	Enabled	Enabled	Enabled	Enabled	Enabled
Endo	–	–	–	–	–	–

Tab. 17:   Maquet PowerLED II factory default lighthead presets (cont.)

Applications	Illumination	Light field diameter	Colour temperature
Urology/gynaecology	80%	Small	4500
Laparotomy	100%	Large	3900
Orthopaedic	60%	Medium	5,100
ENT	60%	Small	4,500
Plastic surgery	100%	Small	5,100
Cardiac	100%	Small	3,900

Tab. 18:   Volista factory default lighthead presets

Applications	Zoom	WB	Contrast
Laparotomy	50%	Auto	High
Orthopaedic	50%	Auto	Medium
Plastic surgery	20 %	Auto	Standard
Cardiac	50%	Auto	High

Tab. 19:   Factory default camera presets (only on Volista)

4.3 Positioning the light

4.3.1 Moving the mobile light

⚠️	**WARNING!** **Risk of electric shock** **If the outlet is not disconnected properly, damage to the power supply cable may occur and live parts may become accessible.** **Do not pull on the power lead to disconnect the mains outlet.**
⚠️	**WARNING!** **Risk of injury** **The mobile light may tip over if not handled properly.** **Push the mobile light to move it. Never pull the light behind you except on a slope.**
⚠️	**WARNING!** **Risk of inconvenience during use** **If the mobile light is not properly positioned, it may move in an uncontrolled manner.** **Position the light by following the steps set out, to ensure that it is properly stable.**
⚠️	**WARNING!** **Risk of injury** **The mobile light may tip over if a person leans on it.** **Never lean on the mobile light.**
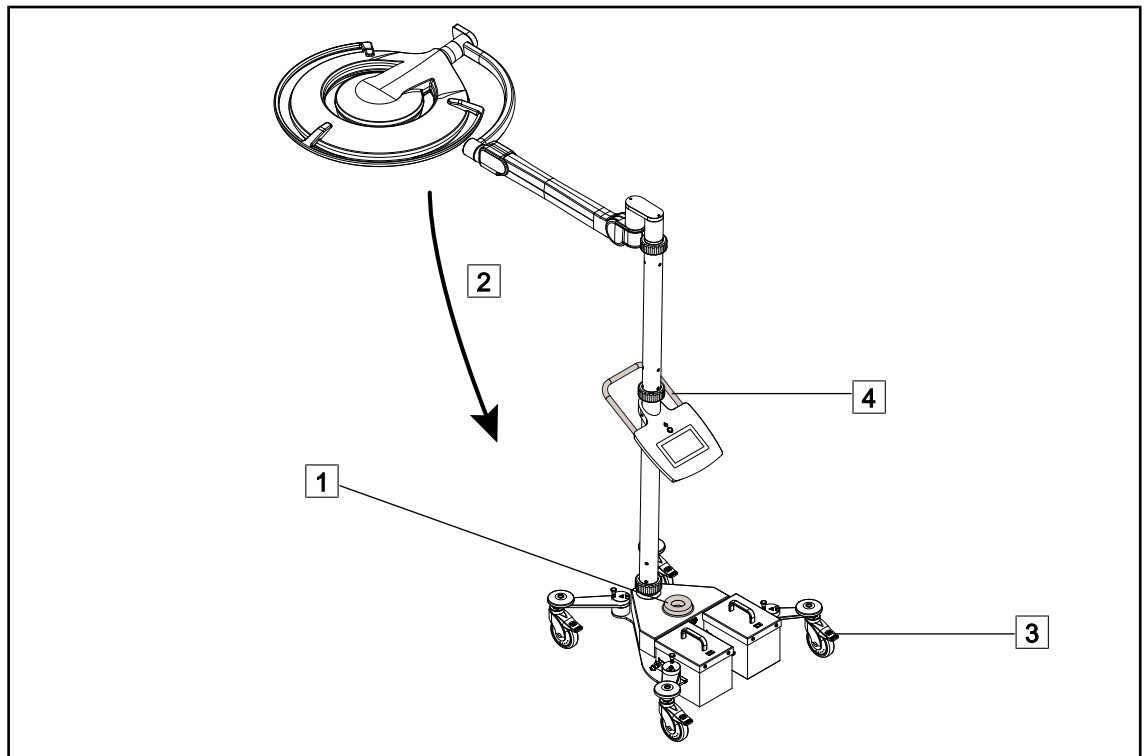
Fig. 52:   Moving the light

1. Make sure that the lighthead is switched off and that the mobile light is not plugged into the mains supply.

2. Wind the power cable around the cable reel on the base $\boxed{1}$.

3. Fold the spring arm $\boxed{2}$ in as far as possible to reduce the reach of the unit.

4. Release the caster brake pedals $\boxed{3}$ by pulling them up, before attempting to move the mobile light.

5. Grasp the handle on the bottom pole $\boxed{4}$ and push the device on its casters.

6. After moving the light to its new location, lock it in place by pushing down on the brake pedals on the rear casters $\boxed{3}$.

4.3.2 Fitting the sterilisable 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.

4.3.2.1 Installing and removing a STG PSX sterilisable handle on the lighthead
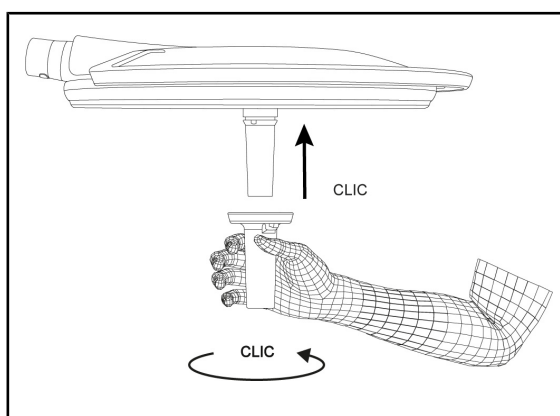
Fig. 53:   Installing the STG PSX sterilisable handle

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. 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.
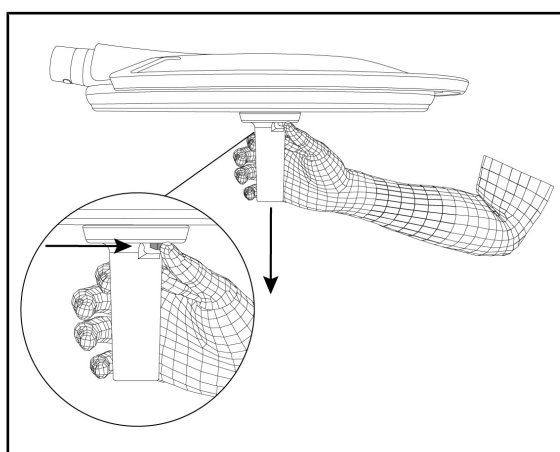
Fig. 54:   Removing the STG PSX sterilisable handle

Removing the sterilisable handle from a lighthead

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

4.3.2.2 Installing and removing a STG HLX sterilisable handle on the lighthead
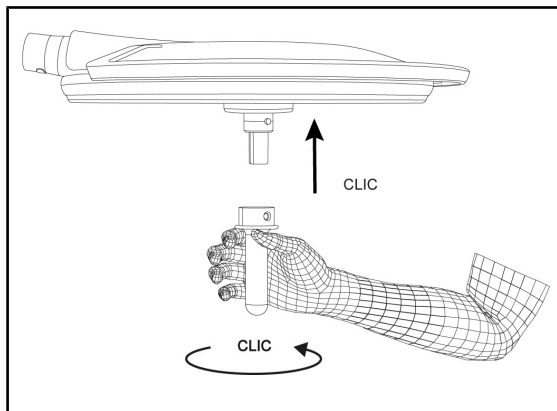
Fig. 55:   Installing the STG HLX sterilisable handle

Installing a sterilisable handle on the light-head

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.

4. Check that the handle is firmly in place.

    ➢ The handle is now locked in place and ready for use.
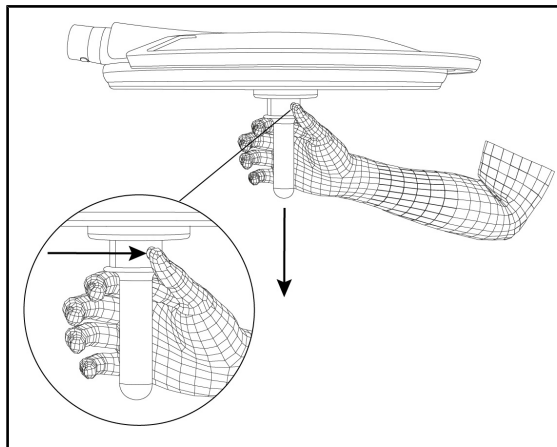
Fig. 56:   Removing the STG HLX sterilisable handle

Removing the sterilisable handle from a lighthead

1. Press the locking button.

2. Remove the handle.

4.3.2.3   Installing and removing DEVON® or DEROYAL® handles®**

ℹ **NOTE**

Refer to the instructions supplied with the Devon or Deroyal handle.
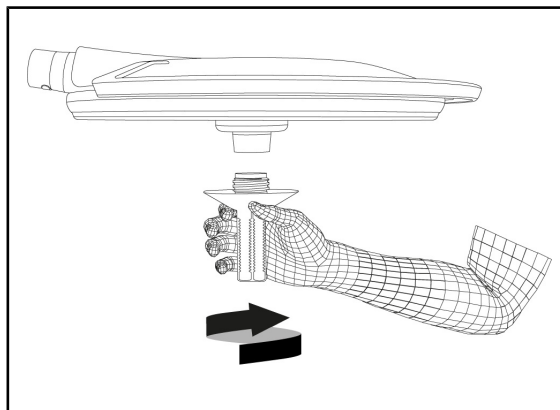
Fig. 57:   Installing a Devon or Deroyal handle

Installing a Devon or Deroyal handle on the lighthead

1. Screw the handle fully onto the mount.

    ➢ The handle is now ready for use.
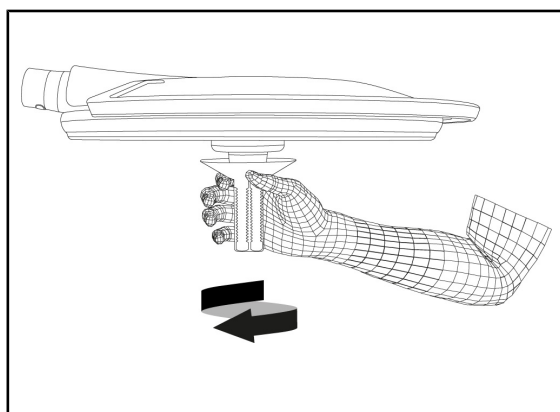
Fig. 58:   Removing a Devon or Deroyal handle

Removing a Devon or Deroyal handle from a lighthead

1. Unscrew the handle from the handle mount.

4.3.2.4 Installing and removing the STG PSX VZ sterilisable handle
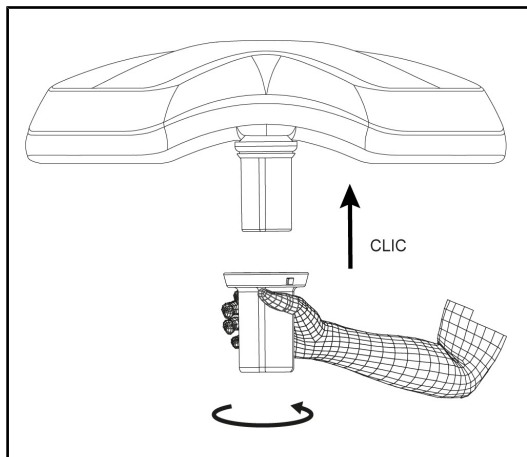
Fig. 59:   Installing the STG PSX VZ sterilisable handle

Installing a sterilisable handle for use with a camera on the lighthead

1. Inspect the handle and check for cracks or soiling.

2. Fit the handle to the mount.

   ➢ A click is heard.

   ➢ The handle is now locked in place and ready for use.
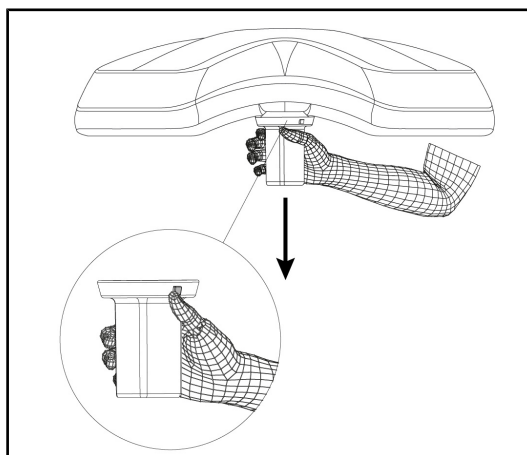
Fig. 60:   Removing the STG PSX VZ sterilisable handle

Removing a sterilisable handle for use with a camera from a lighthead

1. Press the locking button.

2. Remove the handle.

4.3.3 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.**

Manoeuvring the lighthead
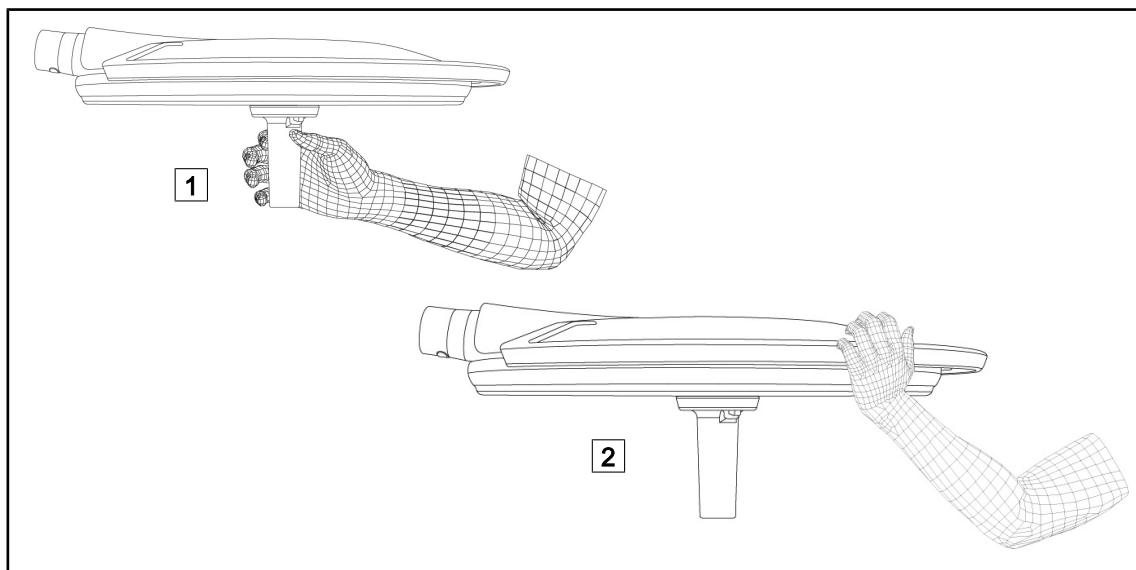
Fig. 61:   Manoeuvring the lighthead

- 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 handling the lighthead either directly or using its outer handle 2 .

Light rotation angles
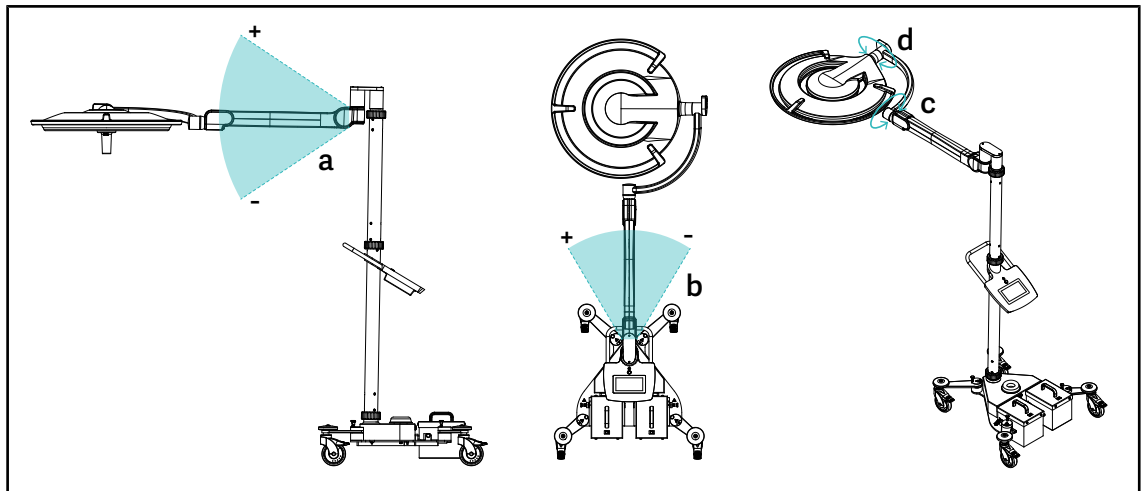
Fig. 62:   Maquet Rolite rotation angles

a	b	c	d
+15° / -15°	+20° / -70° (PWDII et Volista VSTII) +45° / -45° (Volista VCSII)	360°	260° (PWDII) 330° (Volista)

Tab. 20:   Maquet Rolite rotation angles

Overall height of lighting system
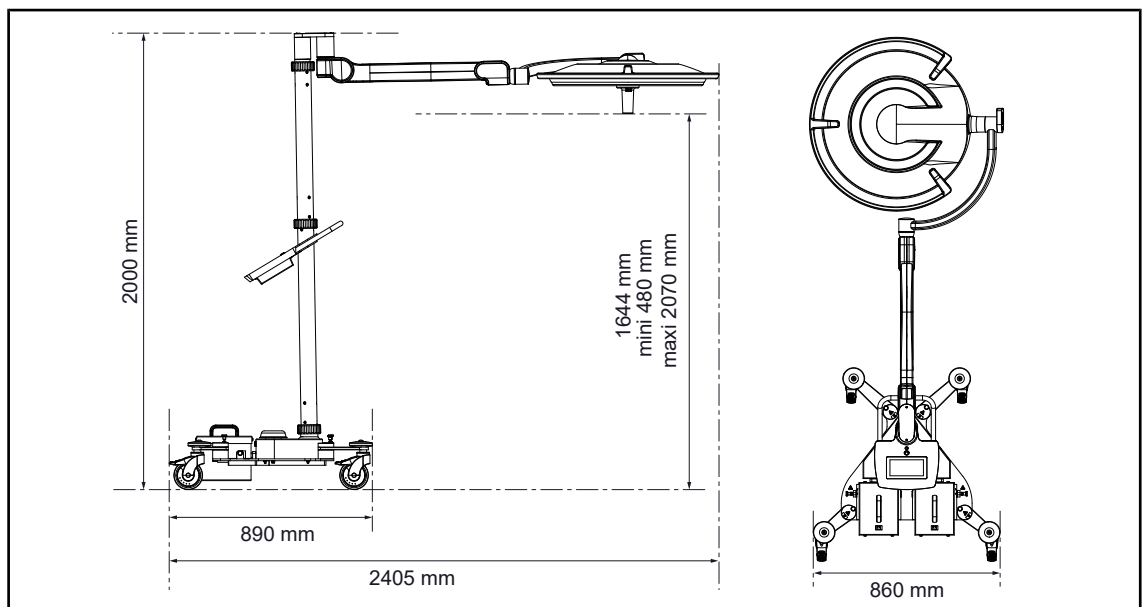
Fig. 63:   Overall height of Maquet Rolite lighting system

4.3.4 Laser positioning assistance (on Maquet PowerLED II only)

⚠️ **WARNING!**

Risk of injury
Prolonged exposure to laser light may result in eye damage.

Do not direct a laser beam into the patient's unprotected eyes. Users must not look directly into the laser beam.
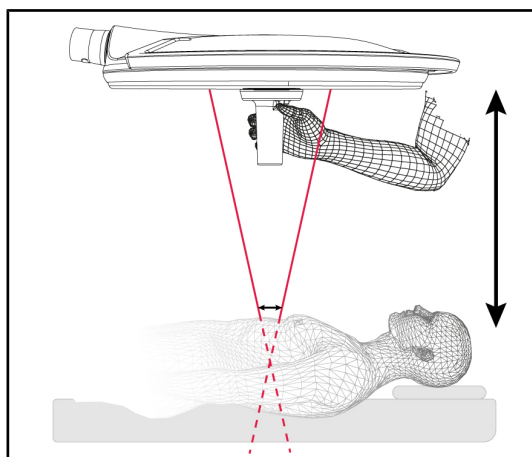
To determine the optimal lighthead position, the positioning assistance system (see below) can be enabled. Two laser beams then appear in the light field. The lighthead should then be lowered or raised to bring the two laser beams closer together.

Fig. 64:   Laser positioning

4.3.4.1 From the lighthead control keypad

Fig. 65:   Enabling the laser positioning assistance function via the keypad

1.   Press the **Laser** 1 button and hold it until it flashes.

   ➢ The light output level is reduced and two laser dots appear for 20 seconds.

2.   Position the lighthead so as to bring the two dots closer together.

   ➢ The lighthead is then at the optimum distance from the area to be illuminated.

3.   Press the **Laser** 1 button again to turn off the laser manually before the 20 seconds have elapsed.

4.3.4.2 **From the touchscreen control panel**
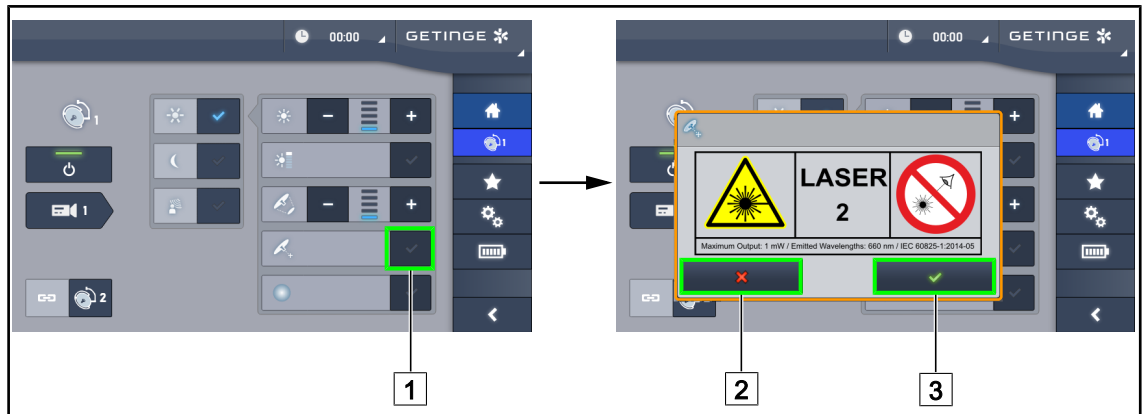
Fig. 66: Enabling the laser positioning assistance function via the touchscreen control panel

1. From the lighthead page, press the **Laser** ⊡1 button.

   ➢ A pop-up window is displayed.

2. Press **Enable Laser** ⊡3 to engage the positioning assistance function or **Cancel Laser** ⊡2 to return to the lighthead page.

   ➢ The light output level is reduced and two laser dots appear for 20 seconds.

3. Position the lighthead so as to bring the two dots closer together.

   ➢ The lighthead is then at the optimum distance from the area to be illuminated.

4.3.5 Pre-positioning examples
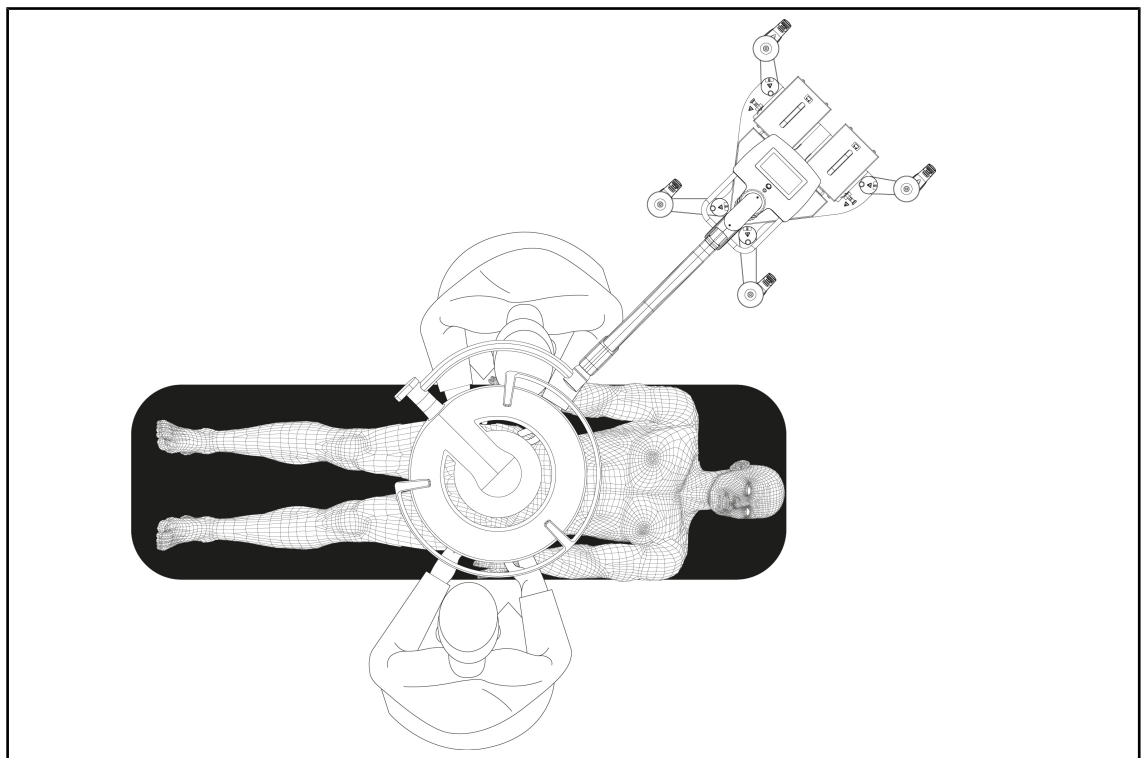
Fig. 67: Maquet Rolite pre-positioning

4.3.6 Storing the mobile light

When the mobile light is not in use, the following recommendations should be followed for storage.
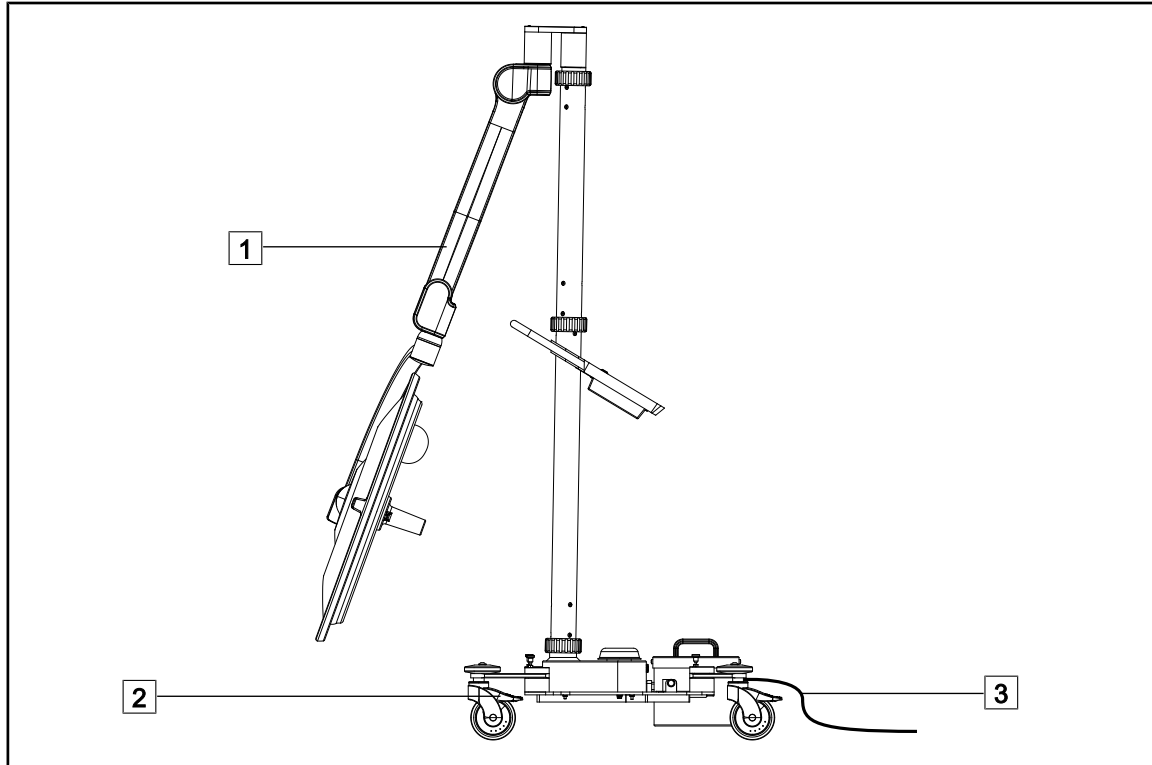
Fig. 68:   Parking position

1. Lower the spring arm fully $\boxed{1}$.

2. Lock the device in position on the floor by pressing the caster brakes $\boxed{2}$.

3. If batteries are fitted, connect the cable $\boxed{3}$ to the mains supply to charge the batteries, making sure that the lighthead is turned off.

ℹ NOTE

The estimated battery charging time is approximately 14 hours.

ℹ NOTE

The batteries will discharge when the product is stored. Connect the device to the mains supply regularly to charge the batteries, and check the battery level before use.

4.4 Installing/removing a QL+ device

⚠️ **WARNING!**

Risk of infection
The installation or removal of a handle mount or a camera during an opera-tion may cause particles to fall onto the surgical site.

The installation or removal of a Quick Lock device must be performed out-side the operating area.

4.4.1 Fitting the device to the Maquet PowerLED II lighthead

For handle mounts
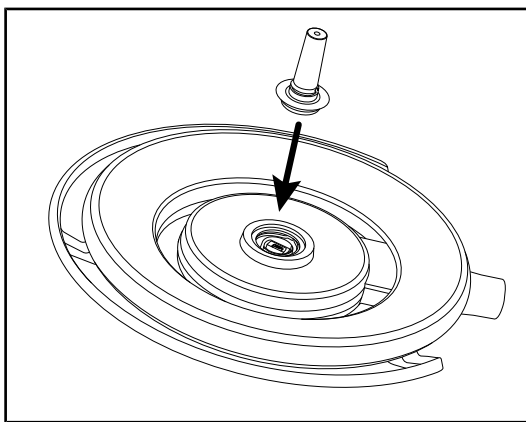
Fig. 69:   Installing a QL+ device

1. Insert the QL+ device in the slot at the centre of the lighthead until it locks into place.
2. Move the lighthead to check that the QL+ device is firmly attached.
   ➢ The QL+ device is installed.

For the LMD
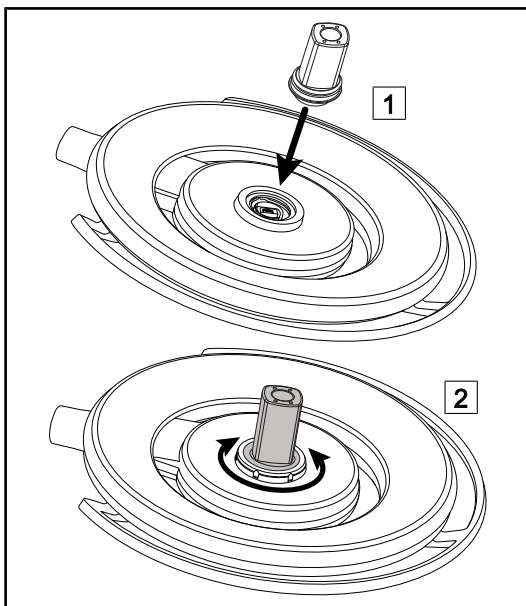
Fig. 70:   Installing a QL+ device

1. Insert the QL+ device in the slot at the centre of the lighthead ⬚1.
2. Rotate the accessory until it clicks ⬚2.
3. Move the lighthead to check that the QL+ device is firmly attached.
   ➢ The QL+ device is installed.

4.4.2 Removing the device

> **ⓘ NOTE**
> Turn the lighthead over so that the underside is facing the ceiling, in order to re-move the handle mount.
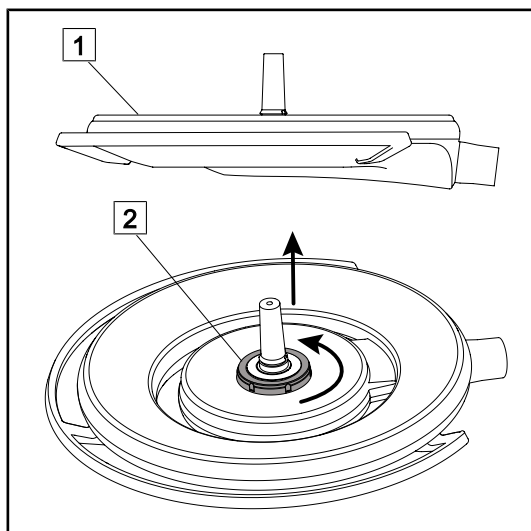
Fig. 71:   Removing a Quick Lock device

1. Turn the lighthead over so that the under-side is facing the ceiling ⎡1⎤.

2. Once the lighthead is turned over, rotate the locking interface ⎡2⎤ anti-clockwise and then remove the Quick Lock device whilst holding the locking interface ⎡2⎤.

   ➢ The Quick Lock device is removed.

4.5   Installing/removing a QL device

⚠️ **WARNING!**
Risk of injury
If the handle mount or camera are not installed, live parts may be accessible.

Technicians should turn off the equipment before installing or removing Quick Lock accessories on a lighthead.

⚠️ **WARNING!**
Risk of infection
The installation or removal of a handle mount or a camera during an operation may cause particles to fall onto the surgical site.

The installation or removal of a Quick Lock device must be performed outside the operating area.

4.5.1   Pre-positioning the device

4.5.1.1   On camera and LMD QL
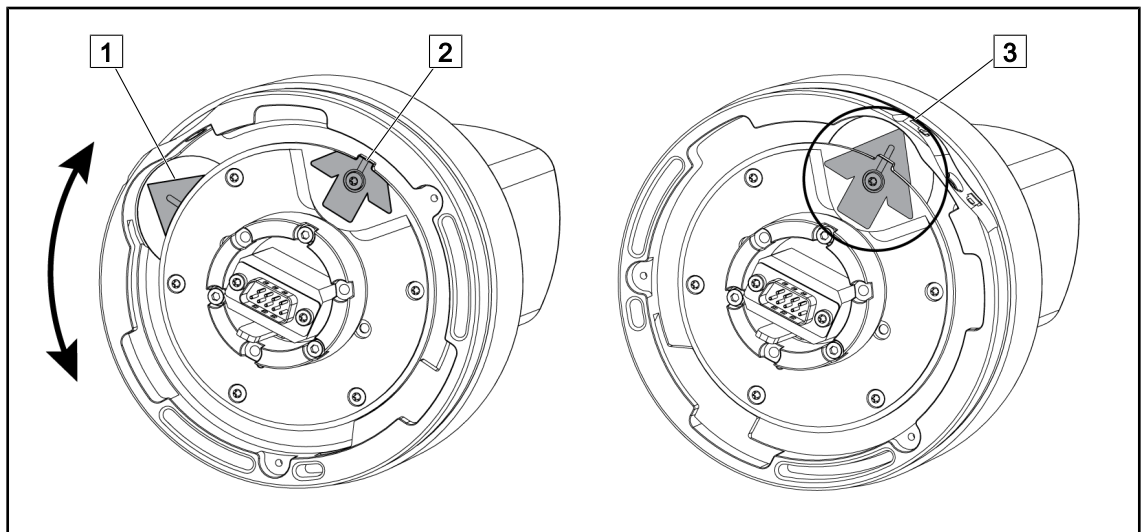
Fig. 72:   Pre-positioning the Quick Lock camera

1. Rotate the baseplate ⟨1⟩ to align with the tip ⟨2⟩ and form a green arrow ⟨3⟩.

    ➢ The camera is ready to be positioned.

4.5.1.2 On the lighthead
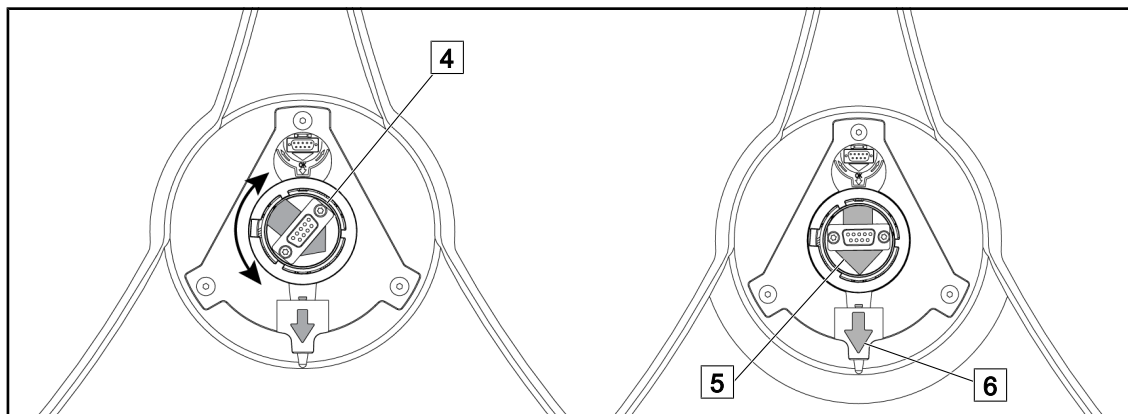
Fig. 73:   Pre-positioning the lighthead

1. In the centre of the lighthead, orient the connector 4 so that the two green arrows 5 and 6 are aligned.

    ➢ The lighthead is ready to receive the camera.

4.5.2   Fitting the device to the lighthead
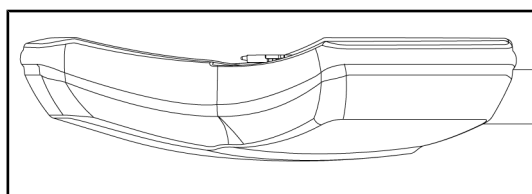
Fig. 74:   Positioning the lighthead

1. Position the lighthead with the underside facing the ceiling.

    ➢ This facilitates installation of the camera on the lighthead.
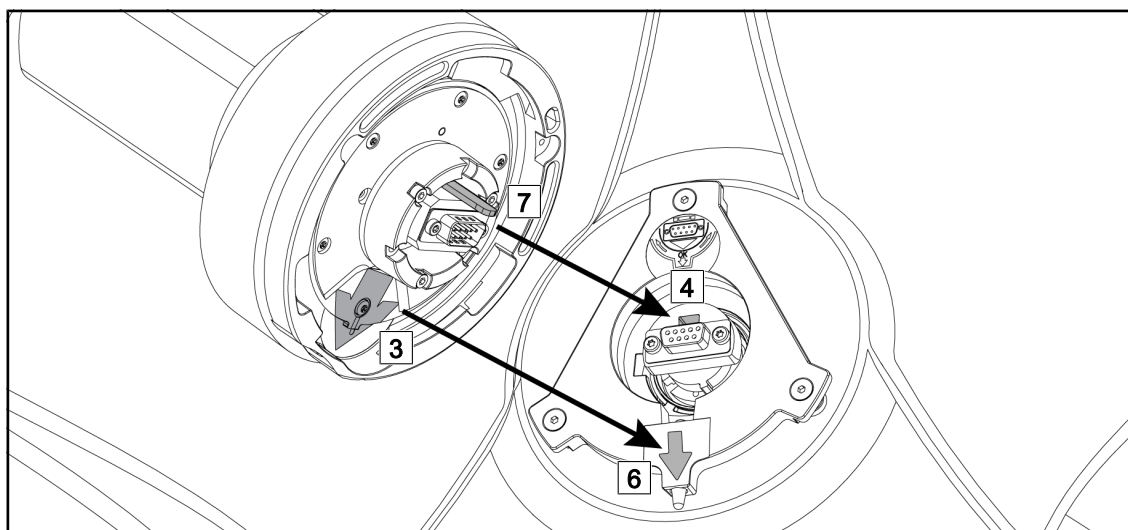
Fig. 75:   Instructions for installing the Quick Lock system

1. Present the camera with the pin 7 opposite the slot 4.

2. Place the two arrows 3 and 6 opposite each other.
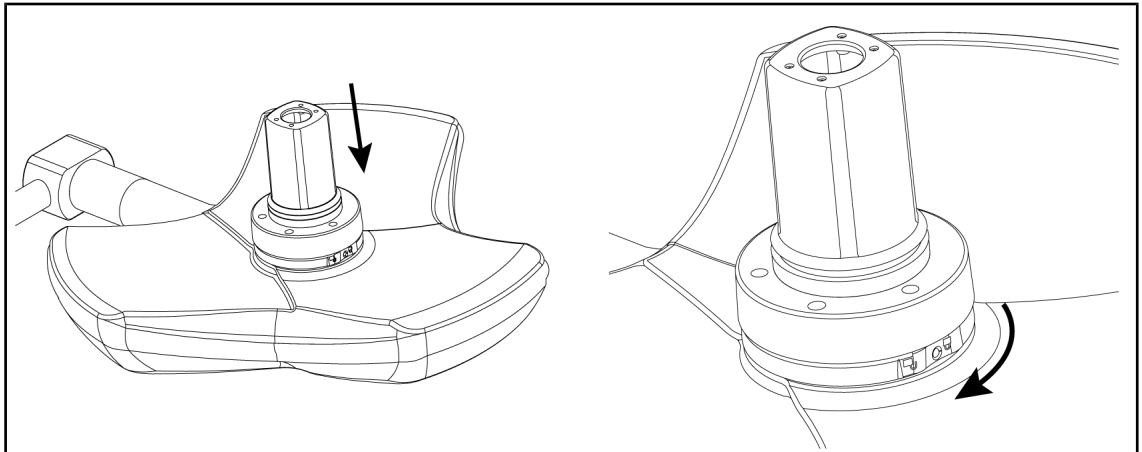
Fig. 76:   Presenting the camera against the lighthead

1. Insert the camera into the lighthead such that the camera base plate is fully flush against the underside.

2. Using both hands, turn the camera base plate clockwise until it clicks into place.
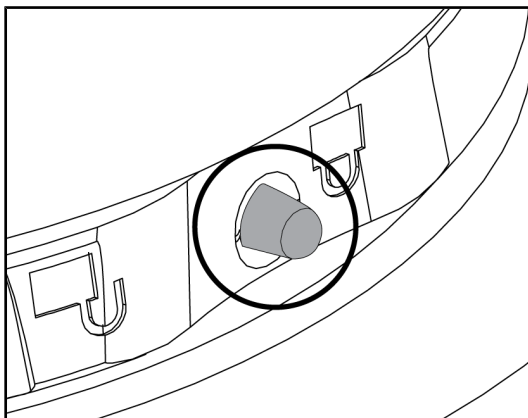
Fig. 77:   Locking the camera in place on the lighthead

1. Check that the camera is correctly in place and that the locking button protrudes correctly from its recess.

2. Move the lighthead using the handle, to check that the system is correctly in place.

3. Check that the camera assembly turns freely through 330°.

   ➢ The device is installed.

4.5.3   Removing the device
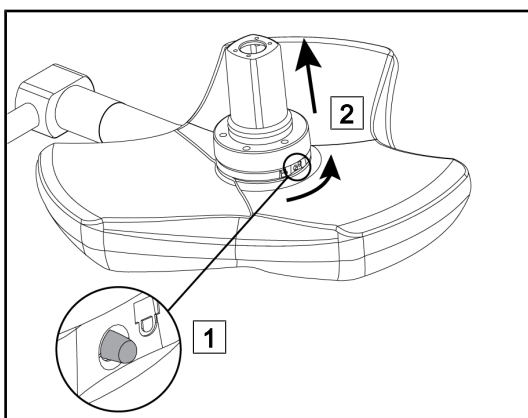
Fig. 78:   Removing the lighthead

1. Press the locking button.

2. Keep the button 1 pressed and, using two hands, rotate the base of the device anticlockwise.

3. Remove the Quick Lock camera by pulling upwards 2.

   ➢ The device is removed.

4.5.4 Quick Lock handle mount
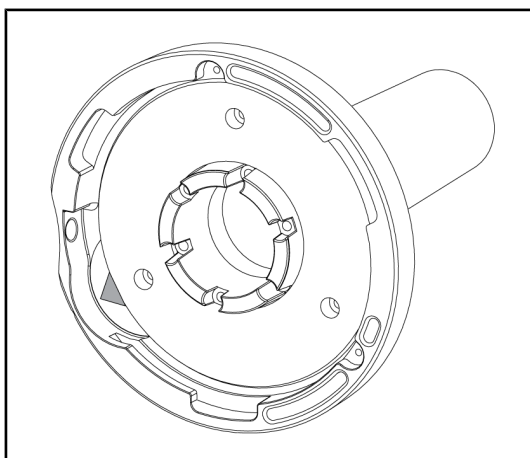
Fig. 79:   Quick Lock handle mount

1. The positioning steps are the same as for the camera.
2. The green arrows must be aligned and the connector positioned correctly.
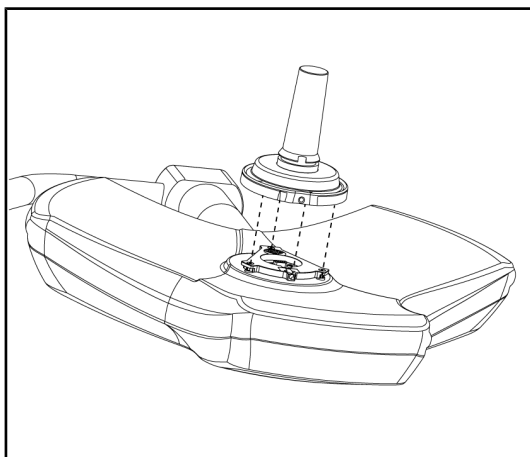
Fig. 80:   Presenting the handle

1. Align the green arrows to insert the handle (there is no pin on the handle).
2. As for the camera, rotate the base of the handle clockwise and then check that the lock is correctly engaged.

    ➢ The handle mount is installed.

4.6 Using the camera

> **NOTE**
>
> The OHDII AIR03 QL FHD camera with wireless system requires a pairing step during the first use, and an intermediate procedural step during subsequent uses. Getinge offers a camera version pre-fitted with a GEFEN® wireless transmission key; refer to the instructions supplied with the wireless system or see the Wireless video system [» Page 73] section.

4.6.1 Wireless video system

> ⚠ **CAUTION!**
>
> **Risk of malfunction of the device**
> **The presence of other wireless devices nearby may affect the quality of the transmitted image.**
>
> **The user must refer to the instructions for the wireless system in order to learn its conditions of use.**

> ⚠ **CAUTION!**
>
> **Risk of malfunction of the device**
> **The use of wireless accessories other than those supplied or specified by the manufacturer can affect the operation and performance of the device.**
>
> **Use only the wireless accessories specified by Getinge.**

4.6.1.1 Commissioning and registration
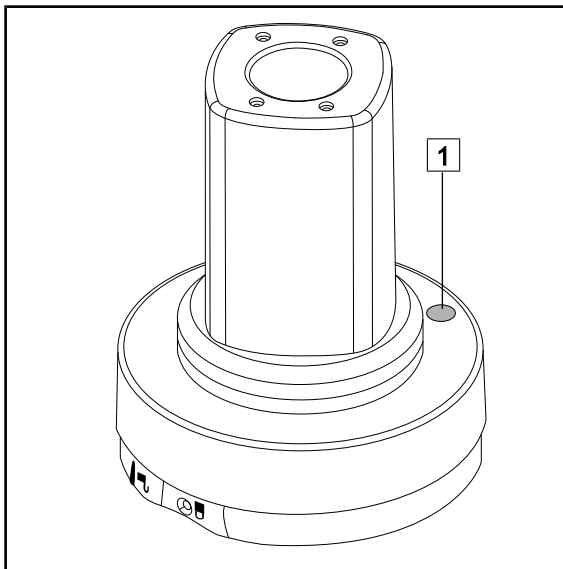
Fig. 81:   AIR03 video system

1	Camera registration button	5	USB port
2	Sender button	6	HDMI connector
3	OK button	7	Infra-red port
4	Power connector	8	Infra-red sensor
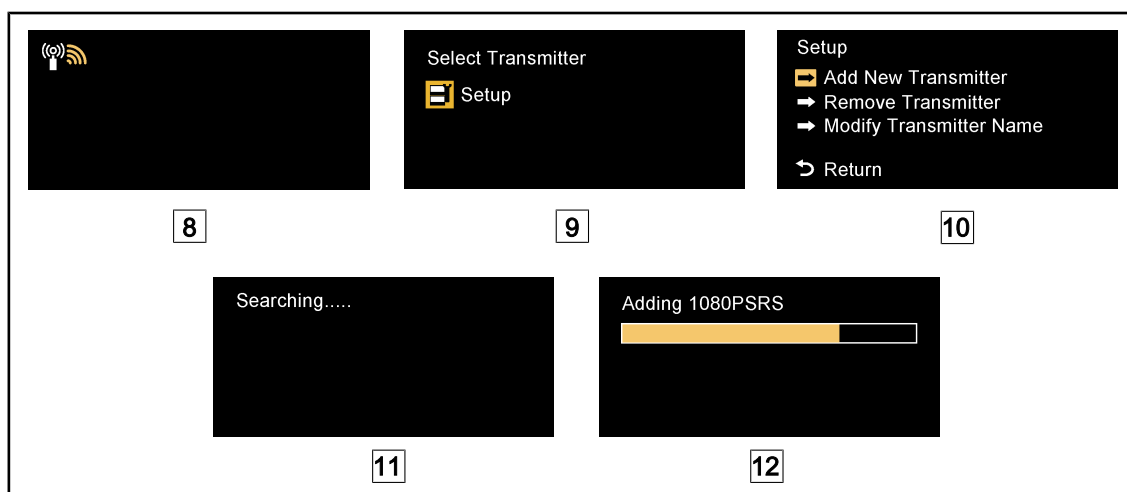
Fig. 82:   Initial registration of AIR03

1. Turn the configuration on.

    ➢ The display shown in ⑧ appears on the screen.

2. Press the **Sender** button on the remote control ② and then press **OK** ③ to enter the **Setup** ⑨ menu.

    ➢ The **Setup** menu is displayed ⑩.

3. Select **Add New Transmitter** using the **OK** ③ button.

    ➢ The search process starts ⑪.

4. Press and hold the registration button on the camera base ① for five seconds and then release it.

    ➢ Once the signal has been detected, the registration procedure is performed automatically and the message "Adding 1080PSRS" is displayed on the screen ⑫.

5. Once registration is complete, the actual image is displayed.

4.6.1.2   Switching on the registered system

Fig. 83:   OHDII AIR03 QL FHD connected

Once the camera is turned on, the receiver automatically connects to the camera with which the receiver was paired. A message appears when connecting to indicate the channel and the resolution.

ⓘ   **NOTE**

If the AIR03 camera used is not the last one that was registered, and if it has never been registered to this receiver, proceed as described above for registration. If the camera has already been registered to this receiver, proceed with the registration procedure until the message "Source already listed" is displayed, and then wait for 30 seconds for the image to appear. The receiver can store up to eight transmitters. If the memory is full, use the "Remove transmitter" function in the **Setup** menu.

4.6.2 Controlling the camera

4.6.2.1 From the lighthead control keypad
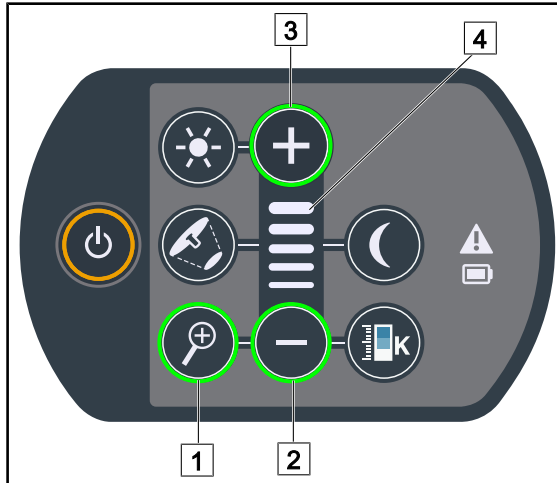
Fig. 84:   Controlling the camera from the keypad

Adjusting the camera zoom

1. Press **Camera Zoom** 1.

2. Press **Plus** 3 or **Minus** 2 to modify the zoom level.

    ➢ The camera zoom level varies as shown by the level indicator for the selected function 4.

4.6.2.2 From the touchscreen control panel

> **i** **NOTE**
>
> When using the touchscreen control panel, the camera may be turned on or off independently of the light.
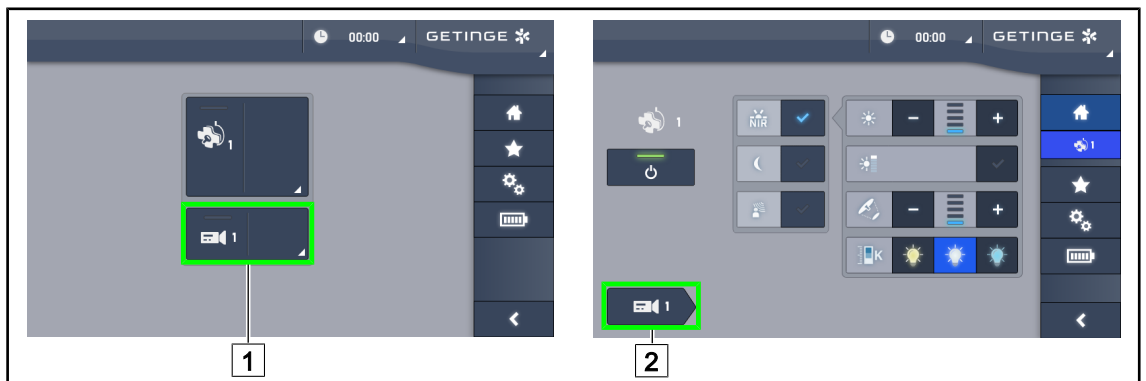
Fig. 85:   Turn on the camera

Turning a camera on via the home page

1. Press the **Camera active area** 1 button.

    ➢ The button is lit green and the image is displayed on the screen.

2. Press the **Camera active area** 1 again to access the camera page.

Turning the camera on via the lighthead page

1. From the lighthead page, press the **Camera shortcut** 2.

    ➢ The camera page is displayed and the camera is turned on.
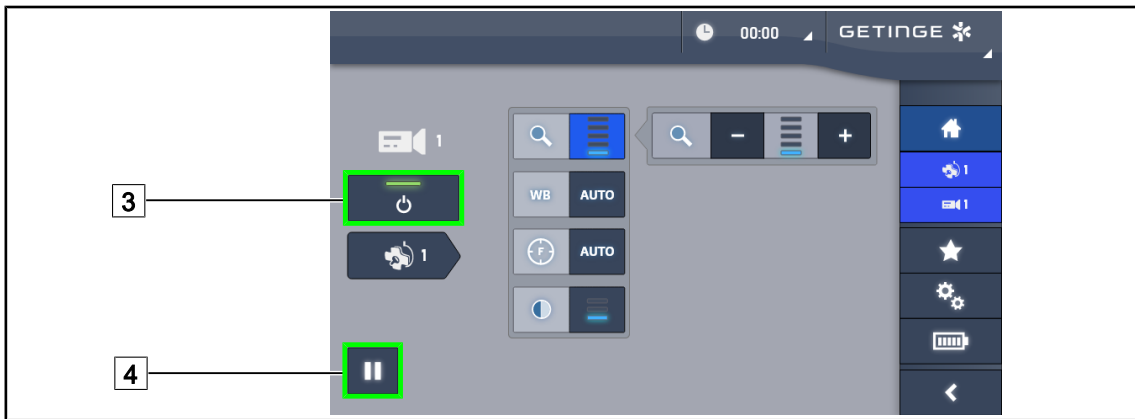
Fig. 86:   Camera page

Turning off the camera

1. From the camera page, press **Camera ON/OFF** 3 to turn off the camera.

    ➢ The button and the camera are turned off.

Pausing the camera

1. Press **Camera pause** 4 to pause the camera.

    ➢ The button is lit blue and the retransmitted image is frozen.

2. Press **Camera pause** 4 again to resume video transmission.

Fig. 87:   Zoom control

Zooming in and out

1. Press **Zoom** 5 to access the zoom adjustment menu.

2. Press **Zoom in** 6 or **Zoom out** 7 to adjust the size of the image on screen in real time.

Fig. 88:   White balance

Adjusting the white balance automatically

1. Press **White balance** 8 .

2. Press **Automatic balance** 9 to set the white balance automatically or **Artificial light** 10 to set the white balance to 3200 K or **Daylight** 11 to set the white balance to 5800 K.

    ➢ The selected button is lit blue and the white balance is set.

Adjusting the white balance manually

1. Press **White balance** 8 .

2. Place a uniform white surface under the camera.

3. Press **Manual balance** 12 twice to set the white balance on the basis of the target under the camera.

    ➢ The selected button is lit blue and the white balance is set.
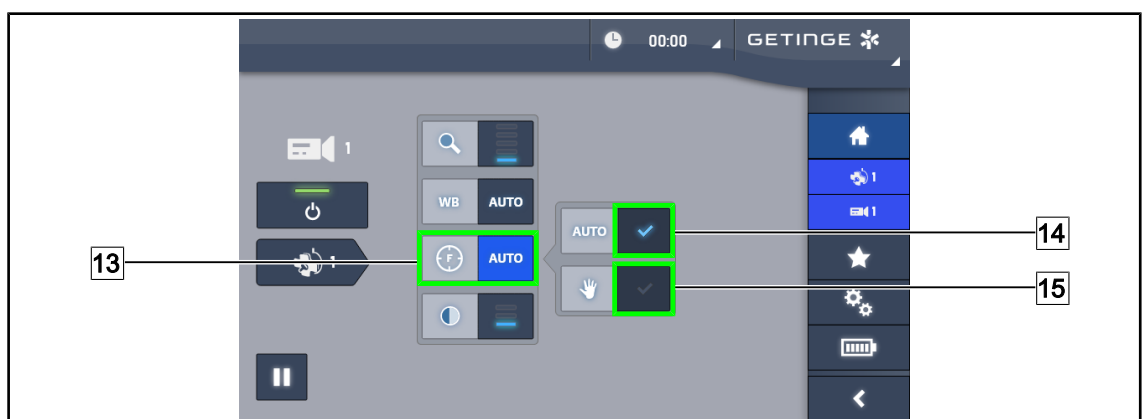
Fig. 89:   Setting the focus

Setting the focus automatically

1. Press **Focus** 13 to access the focus adjustment menu.

2. Press **Auto Focus** 14 .

    ➢ The button is lit blue and the camera focus is automatic.

Setting the focus manually

1. Press **Focus** 13 to access the focus adjustment menu.

2. Press **Auto Focus** 14.

   ➢ The button is lit blue and the camera focus is automatic.

3. Position the camera at the desired distance.

4. Press **Manual Focus** 15.

   ➢ The button is lit blue and the camera focus is fixed.

Fig. 90:   Contrast adjustment

Adjusting the contrast

1. Press **Contrast** 16 to access the contrast adjustment menu.

2. Press **Increase contrast** 17 or **Decrease contrast** 18 to select one of the three contrast levels 9.

4.6.3   Orienting the camera
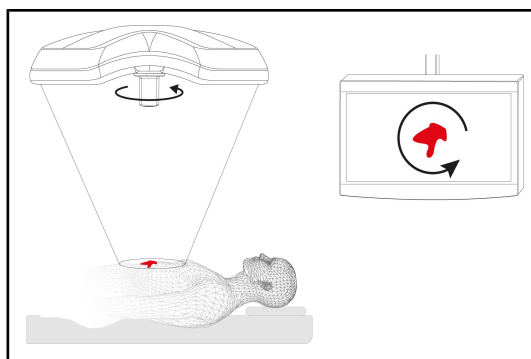
Fig. 91:   Orienting the camera

Optimise the orientation of the image on screen to suit the observer's position

1. Install a handle on the camera. Installing and removing a sterilisable handle for use with cameras on the lighthead

2. Use the handle to rotate the camera.

   ➢ The image is rotated on the screen.

4.7 Settings and functions

Fig. 92:   Touchscreen control panel settings page

Adjusting the screen brightness

1. Press **Settings** 1 in the menu bar.

    ➢ The Settings page is displayed (see above).

2. Press **Screen Brightness** 2 .

    ➢ The brightness setting page is displayed.

Setting the date and time and using the stopwatch/timer

1. Press **Settings** 1 in the menu bar.

    ➢ The Settings page is displayed (see above).

2. Press **Date/Time** 3 .

    ➢ The page for date and time settings and stopwatch/timer functions is displayed.

Adjusting the tilt handle (on Volista only)

1. Press **Settings** 1 in the menu bar.

    ➢ The Settings page is displayed (see above).

2. Press **Tilt Handle** 4 .

    ➢ The tilt handle adjustment page is displayed.

Accessing configuration information

1. Press **Settings** 1 in the menu bar.

    ➢ The Settings page is displayed (see above).

2. Press **Information** 5 .

    ➢ The configuration information page is displayed.

4.7.1   Screen brightness
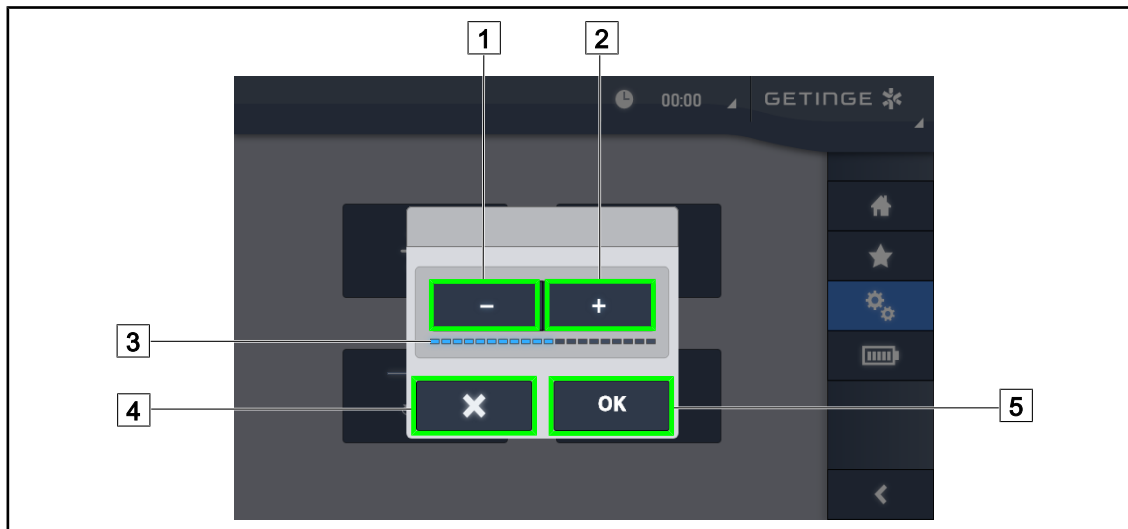
Fig. 93:   Adjusting the screen brightness

1. Press **Plus** 2 to increase the brightness of the touchscreen control panel or **Minus** 1 to decrease the brightness.

    ➢ The screen brightness varies as shown by the brightness level indicator 3 .

2. Press **OK** 5 to confirm the brightness changes, or **Cancel** 4 to cancel the changes in progress.

    ➢ The configured brightness is stored and applied.

4.7.2 Date and time, and stopwatch/timer functions
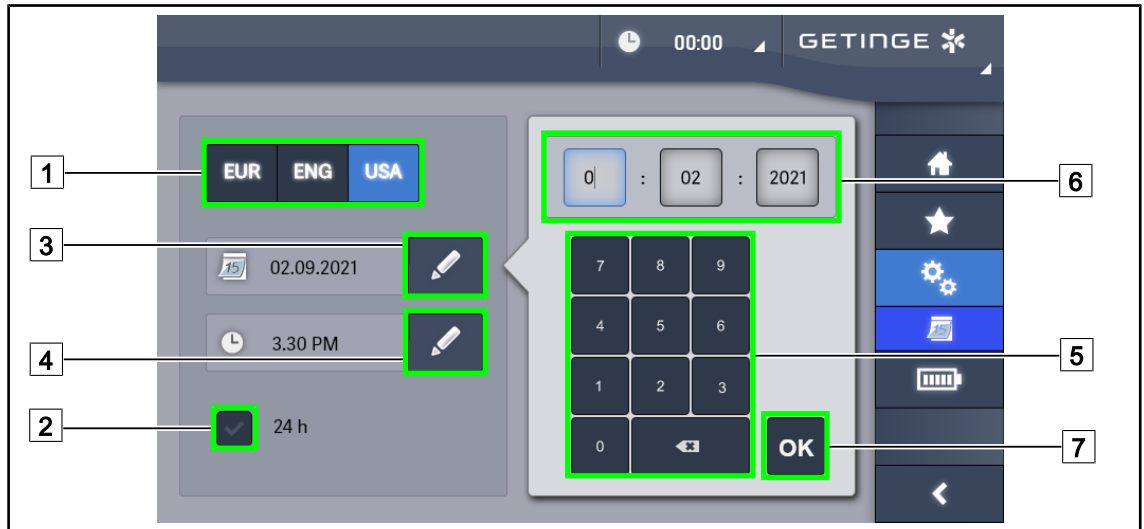
Fig. 94:   Date and time settings

Defining the date and time format

1. Press **Date Format** [1] to choose the desired date display format. European, English or American date format can be set.

   ➢ The selected format is shown with a blue background.

2. Press **Time Format** [2] to choose the desired time display format.

   ➢ If the button is selected, times are displayed in 24h format; if not, 12h format is used.

Changing the date

1. Press **Edit Date** [3].

   ➢ A data entry window is displayed.

2. Press the field to be modified: day, month or year [6].

   ➢ The selected field is shown with a blue border.

3. Use the keypad [5] to enter the desired value and then press **OK** [7] to confirm the changes.

   ➢ The data entry window closes and the changes take effect.

Changing the time

1. Press **Edit time** [4].

   ➢ A data entry window is displayed.

2. Press the field to be modified: hours or minutes [6].

   ➢ The selected field is shown with a blue border.

3. Use the keypad [5] to enter the desired value and then press **OK** [7] to confirm the changes.

   ➢ The data entry window closes and the changes take effect.

4.7.3 TILT handle

Fig. 95: Tilt handle configuration (on Volista only)

Configuring the tilt handle

1. Press **Illumination** [1] so that the Tilt handle can be used to adjust the light intensity level of the lighthead.

2. Press **Light Field Diameter** [2] so that the tilt handle can be used to adjust the diameter of the light field of the lighthead.

3. Press **Colour Temperature** [3] so that the tilt handle can be used to adjust the colour temperature of the lighthead(s).

4. Press **Disabled** [4] so that the Tilt handle is disabled and does not adjust any lighting parameters.
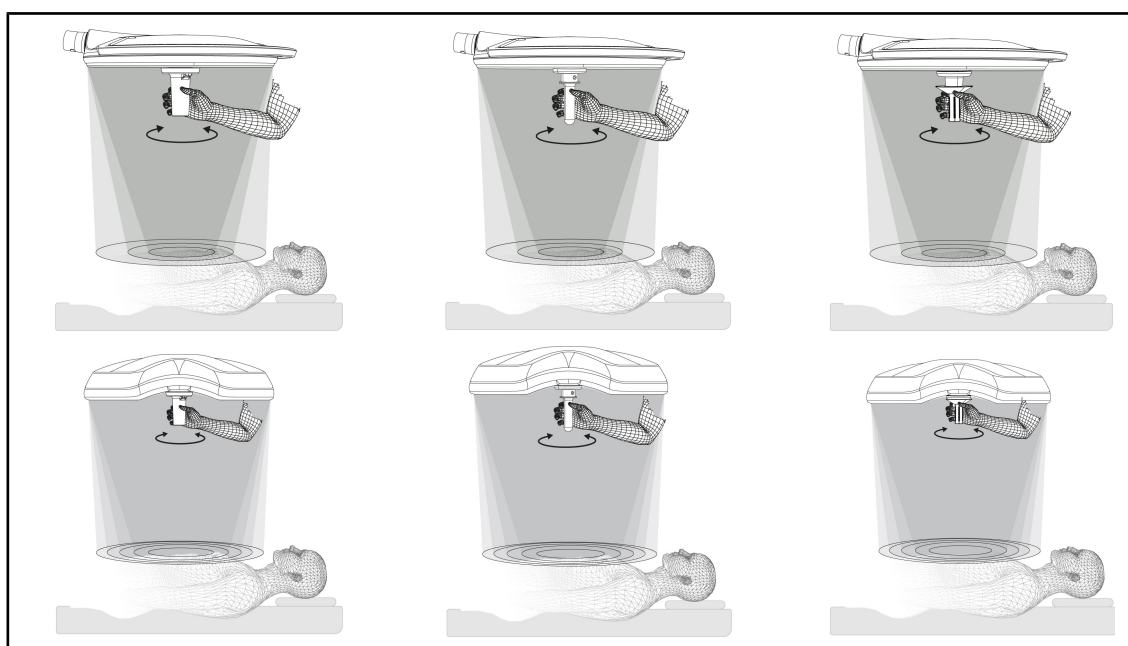
Fig. 96: TILT handles

Adjusting the light field diameter (or choosen parameter on Volista only) using the tilt handle

1. Turn the handle to increase or decrease the light field diameter.

ℹ **NOTE**
The TILT handle does not have limit stops.

4.7.4   Information
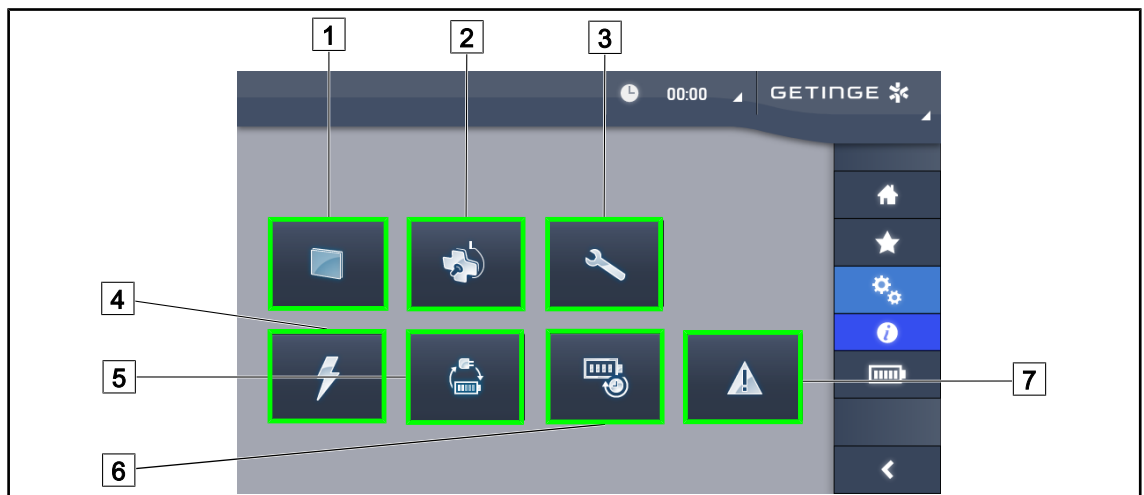
Fig. 97:   Information page

1	Touchscreen control panel	5	Battery backup
2	Lightheads	6	Battery lifetime
3	Maintenance	7	Faults
4	Power supply		

Part No.	Possible action
1	Press the **Touchscreen control panel** button to display the software version and update date, the touchscreen control panel reference, serial number and date of installation.
2	Press **Lightheads** to display information about the lighthead(s) installed: product reference, serial number, options available, usage hours.
3	Press **Maintenance** to display the dates on which maintenance was performed and the Getinge contact details.
4	Press **Power supply** to display a history of power cuts.
5	Press **Battery Backup** to display a history of battery backup tests.
6	Press **Battery lifetime** to display a history of battery lifetime tests.
7	Press **Faults** to display a history of faults.

Tab. 21:   All information menus

4.8 Backup battery

4.8.1 LEDs

Indicators	Description	Meaning
	Orange battery indicator	Backup power supply on
	Flashing red indicator	Cut-out imminent

Tab. 22:   Lighthead keypad backup operation indicators

Indicators	Description	Meaning
	Full orange battery	Backup power supply on
	Non-full orange battery	Remaining battery lifetime
	Flashing red indicator	Cut-out imminent

Tab. 23:   Backup operation indicators on the touchscreen control panel

4.8.2 Performing the battery test

⚠️ **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.

4.8.2.1 From the touchscreen control panel

Fig. 98:   Battery test

Running a battery backup test

1. Turn off the light.

2. Press **Battery Tests** 1 in the menu bar.

   ➢ The battery tests page is displayed.

3. Press **Battery backup test** 2 to start the test.

   ➢ The date of the most recent battery backup test 6 is updated and a green tick is displayed if the test was successful. If the test fails, however, a red cross and a **Maintenance Information** 4 button are displayed.

4. If the test fails, press **Maintenance information** 4 to access the maintenance information page, and then call the Getinge technical service department.

Running a battery lifetime test (only with a Getinge backup)

1. Turn off the light.

2. Press **Battery Tests** $\boxed{1}$ in the menu bar.

   ➢ The battery tests page is displayed.

3. Press **Battery lifetime test** $\boxed{3}$ to start the test.

   ➢ The date of the most recent battery lifetime test $\boxed{7}$ and the battery lifetime $\boxed{8}$ are updated, and a green tick is displayed if the test was successful. If the test fails, however, a red cross and a **Maintenance Information** $\boxed{4}$ button are displayed.

4. If the test fails, press **Maintenance information** $\boxed{4}$ to access the maintenance information page, and then call the Getinge technical service department.

ℹ NOTE

The battery lifetime test can be stopped at any time by pressing the cross $\boxed{5}$.

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5 Troubleshooting

5.1 Warning indicators

5.1.1 Indicators on the lighthead control keypads

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

Tab. 24: Warning indicators

Indicator	Description	Meaning
▭	Indicator off	Powered from mains
▬	Orange indicator	Powered from backup supply
▬	Flashing red indicator	Powered from backup supply The battery level is very low, the system will lose power in a few minutes.

Tab. 25: Battery indicators

5.1.2 Indicators shown on the touchscreen control panel

Indicator	Description	Meaning
▭	Battery fully charged	Configuration powered from mains, shown only when on mains
▬	Orange indicator	Powered from backup supply The number of bars indicates the battery level.
▭	Flashing red indicator	Powered from backup supply The batteries are almost totally discharged and the system will lose power in a few minutes.
▬	Battery charge indicator	System charging

Tab. 26: Battery indicators

Indicator	Description	Meaning
–	Indicator off	No fault
⚠	Warning indicator	Faulty system

Tab. 27: Warning indicators

Indicator	Description	Meaning
–	Indicator off	Maintenance up to date
	Maintenance indicator	Annual maintenance needed

Tab. 28:   Maintenance indicators

5.2   Potential failures and troubleshooting

Mechanical

Anomaly	Likely cause	Corrective action
The sterilisable handle does not click into place correctly	The locking mechanism is damaged	Replace the handle
Device too stiff to manoeuvre	Mechanical lock	Contact the Getinge technical department

Tab. 29:   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	A

Tab. 30:   Optical anomalies and malfunctions

The error messages on the touchscreen control panel for Maquet PowerLED II are formed as follows:

PWD2 A B C D, where:

A	Faulty lighthead (700 or 500)
B	Address of faulty lighthead (1, 2, or 3)
C	Fault type
D	Faulty component

The error messages on the touchscreen control panel for Volista are formed as follows:

A: B (C) where

A	Component concerned (e.g. Volista 600 1, Power Supply, etc.)
B	Fault type (e.g. Communication failure, Option failure, etc.)
C	Faulty element (e.g. Power 2, Backup, etc.)

Example error message on the touchscreen control panel: Volista 600 1: Option failure (Backup)

ℹ NOTE

In all cases, please contact Getinge technical support.

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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 ▪ 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. 31:   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[2] 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.

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. 32: Typical cleaning cycles in a washer-disinfector

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[2] 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.

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.

ℹ️ **NOTE**

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. 33:   Example of a steam sterilisation cycle

7 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.

7.1 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		
Spring arm safety segment			X
Batteries		X	

Tab. 34:   Maintenance schedule

7.2 Contact

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

8 Technical specifications

8.1 Optical specifications

8.1.1 Optical specifications for Maquet PowerLED II lightheads

Specifications	Maquet PowerLED II 700	Maquet PowerLED II 500	Tolerance
Illumination	15,000 lux to 160,000 lx		–
Nominal illumination (Level 10)	130,000 lx		±10%
Illumination with Boost mode (Level 11)	160,000 lx		0/-10%
Central illumination (AIM enabled) [3]	130,000 lx		±10%
Diameter d10 [4]	13 / 20 / 27 cm	13 / 20 cm	±2 cm
Diameter d50/d10	0.56		±0.06
Illumination depth at 60%	24 / 43 / 44 cm	38 / 53 cm	±10%
Fixed colour temperature [5]	3,800 K / 4,300 K		±400°K
Colour rendering index (Ra)	96		±4
Special colour rendering index (R9)	90		±10
Special colour rendering index (R15)	95		±5
Radiant energy	3.5 mW/m²/lx		±0.4
Irradiance (Ee)[4]	< 500 W/m²		–
UV illumination	≤ 0.5 W/m²		–
FSP system	Yes		–
Illumination in ambient light mode	< 500 lx		–

Tab. 35:   Table of optical data for Maquet PowerLED II 700 and Maquet PowerLED II 500 lightheads

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[3] For all light field diameters

[4] In nominal mode

[5] The colour temperature is selected at the time of order

Residual illumination	Maquet PowerLED II 700	Maquet PowerLED II 500	Tolerance
With one mask [6]	77%	56%	±10
With two masks [6]	56%	46%	±10
At base of tube [6]	87%	100%	±10
With mask, at base of tube [6]	64%	56%	±10
With two masks, at base of tube [6]	45%	46%	±10

Tab. 36:   Residual illumination for Maquet PowerLED II 700 and Maquet PowerLED II 500 lightheads

AIM specifications	Maquet PowerLED II 700	Maquet PowerLED II 500	Tolerance
Nominal illumination (AIM enabled)	130,000 lx		±10%
Shadow dilution with one offset mask [6]	100%	100%	±10
Shadow dilution with two masks [6]	100%	80%	±10

Tab. 37:   Specifications in AIM mode

Laser specifications	Values
Wavelength	650 nm
Beam divergence	0.58 mrad
Maximum power output	1 mW

Tab. 38:   Laser specifications

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[6] Optical values measured with the largest light field diameter

8.1.2 Optical properties of VSTII lightheads

Specifications	VSTII 600 and 400 lightheads	Tolerance
Illumination [78]	10,000 lux to 160,000 lx	–
Nominal illumination (Level 5)[78]	130,000 lx	±10%
Illumination in Boost mode (Level 6)[78]	160,000 lx	0 - 10%
Diameter d10[8]	20 - 25 cm	±15%
Diameter d50/d10[78]	0.55	±0.05
Illumination depth L1+L2 at 60%[8]	50 cm	±10%
Colour temperature	Fixed: 3900ºK Variable: 3900ºK - 4500ºK - 5100ºK	±400ºK
Colour rendering index (Ra)	95	±5
Special colour rendering index (R9)	90	+10/-20
Special colour rendering index (R15)	95	±5
Radiant energy	3.3 mW/m²/lx	±0.5
Irradiance (Ee)[9]	< 500 W/m²	–
UV illumination	≤ 0.7 W/m²	–
FSP system	Yes	–
Illumination in ambient light mode	< 500 lx	–

Tab. 39:   VSTII lighthead optical data in accordance with the EN 60601-2-41 standard.

Residual illumination	VSTII 600	VSTII 400	Tolerance
With one mask[78]	55%	40%	±10
With two masks[78]	50%	45%	±10
At base of tube[78]	100%		±10
With one mask, at base of tube[78]	55%	40%	±10
With two masks, at base of tube[78]	50%	45%	±10

Tab. 40:   Volista lighthead residual illumination in accordance with the EN 60601-2-41 standard

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[7]   Measured with small light field and fixed colour temperature

[8]   Measured at 4500ºK with variable colour temperature

[9]   In nominal mode

Specifications	VSTII 600	Tolerance	Representation
Nominal illumination, Ec (AIM mode enabled)[78]	130,000 lx	±10%	
Shadow dilution with one offset mask[78]	86%	±10	
Shadow dilution with two offset masks[78]	58%	±10	

Tab. 41: AIM mode specifications on VSTII 600

Specifications	VSTII 400	Tolerance	Representation
Nominal illumination, Ec (AIM mode enabled)[78]	130,000 lx	±10%	
Shadow dilution with one offset mask[78]	77%	±10	
Shadow dilution with two offset masks[78]	50%	±10	

Tab. 42: AIM mode specifications on VSTII 400

> **NOTE**
>
> The R9 colour rendering index applies to only one end of the spectrum, above 650 nm, in which the sensitivity of the eye is reduced. Therefore, above a value of 50 points, there is no longer any impact on colour discrimination by the surgeon. An increase in R9 is necessarily accompanied by an increase in radiant energy.

Irradiance in near-infrared wavelengths of the ranges relevant to fluorescence imaging

	Volista fixed colour temperature	Volista variable colour temperature	Volista VisioNIR Boost
Irradiance in the 710-800 nm range	≤ 35 W/m²	≤ 12 W/m²	**≤ 1.25 W/m²**
Irradiance in the 800-870 nm range	≤ 2.1 W/m²	≤ 0.25 W/m²	**≤ 0.03 W/m²**

Tab. 43: Irradiance in near-infrared wavelengths

8.1.3 Optical specifications for VCSII lightheads

Specifications	VCSII 600 and 400 lightheads	Tolerance
Illumination	from 10,000 lx to 160,000 lx	–
Nominal illumination (level 5)	130,000 lx	± 10 %
Illumination with Boost mode (level 6)	160,000 lx	0/- 10%
Diameter d10	20 - 25 cm	± 15 %
Diameter d50/d10	0,55	± 0.05
Illumination depth at 60%[10]	52 cm	± 10 %
Colour temperature	Fixed : 4200 K Variable : 3900 K / 4200 K / 4500 K	± 400 K
Colour rendering index (Ra)	95	± 5
Special colour rendering index (R9)	90	+10/-20
Special colour rendering index (R15)	95	± 5
Radiant energy	3.3 mW/m²/lx	± 0.5
Irradiance (Ee) [11]	< 500 W/m²	–
UV illumination	< 0.7 W/m²	–
FSP system	Yes	–
Illumination in ambient light mode	< 500 lx	–

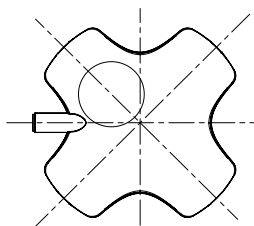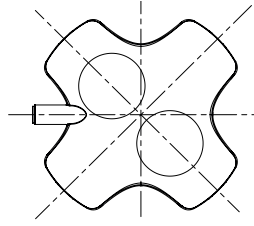Tab. 44: VCSII lighthead optical data in accordance with the EN 60601-2-41 standard

Residual illumination	VCSII 600	VCSII 400	Tolerance
With one mask [10]	60 %	55 %	± 10
With two masks [10]	50 %	45 %	± 10
At base of tube [10]	100 %		± 10
With one mask, at base of tube [10]	60 %	55 %	± 10
With two masks, at base of tube [10]	50 %	45 %	± 10

Tab. 45: Volista lighthead residual illumination in accordance with the EN 60601-2-41 standard
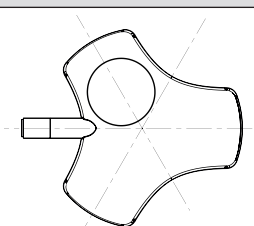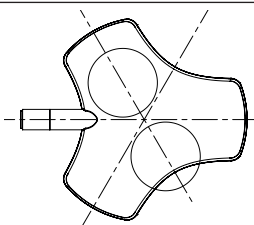
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[10] Measured at 4200°K with small light field

[11] In nominal mode

8.2 Electrical characteristics

8.2.1 Maquet PowerLED II

Electrical specifications	Maquet PowerLED II 700	Maquet PowerLED II 500
Input voltage	100-240 Vac, 50/60 Hz	
Power	185 VA	
Lighthead power rating	110 VA	80 VA
Lighthead input	20 - 28 Vdc	
Number of LEDs	100	56
Average service life of LEDs	60,000 hours per TM-81:2012 standard 55,000 hours per TM-81:2016 standard	
Battery charge time	14 hours	
Battery pack capacity	8 hours minimum	
Battery type	Lead gel	

Tab. 46:   Table of electrical specifications for Maquet PowerLED II

8.2.2 Volista VSTII

Specifications	Volista VSTII 600	Volista VSTII 400
Input voltage	100-240 Vac, 50/60 Hz	
Power	185 VA	
Lighthead power rating	90 VA	60 VA
Lighthead input	20 - 28 Vdc	
Average service life of LEDs	60,000 hours per TM-81:2012 standard 55,000 hours per TM-81:2016 standard	
Battery charge time	14 hours	
Battery pack capacity	8 hours minimum	
Battery type	Lead gel	

Tab. 47:   Volista VSTII lighthead power consumption

8.2.3 Volista VCSII

Specifications	Volista VCSII 600	Volista VCSII 400
Input voltage	100-240 Vac, 50/60 Hz	
Power	185 VA	
Lighthead power rating	70 VA	70 VA
Lighthead input	20 - 28 Vdc	
Average service life of LEDs	60,000 hours per TM-81:2012 standard 55,000 hours per TM-81:2016 standard	
Battery charge time	14 hours	
Battery pack capacity	8 hours minimum	
Battery type	Lead gel	

Tab. 48:   Volista lighthead power consumption

8.3 Mechanical specifications

8.3.1 Maquet PowerLED II

Mechanical specifications	Maquet PowerLED II 700	Maquet PowerLED II 500
Weight of single-fork lighthead	16.8 kg	12.3 kg
Lighthead diameter (including handle)	797 mm	637 mm

Tab. 49:   Table of mechanical specifications

8.3.2 Volista

For Volista VCSII

Specifications	Volista VCSII 600	Volista VCSII 400
Weight of single-fork lighthead	13.5 kg	11.5 kg
Lighthead diameter	700 mm	630 mm

Tab. 50:   VCSII light mechanical specifications

For Volista VSTII

Specifications	Volista VSTII 600	Volista VSTII 400
Weight of single-fork lighthead	14 kg	13 kg
Lighthead diameter	700 mm	630 mm

Tab. 51:   VSTII light mechanical specifications

8.4 Technical specifications of the camera and receiver

Technical specifications of the camera

Specifications	OHDII FHD QL AIR03 E/U
Sensor	1/3" CMOS
Number of pixels	~2.48 Megapixels
Video standard	1080p
Image refresh rate	**50** / 60 Hz
Format	16:9
Shutter speed	1/30 to 1/30000 s
Wide viewing angle (diagonal)	68°
Telephoto viewing angle (diagonal)	6.7°
Signal to noise ratio	> 50 dB
Optical zoom (focal ratio)	x10
Digital zoom	x6
Total zoom	x60
Focal length (wide angle to telephoto)	f = 5.1 to 51 mm
Visible field (W × H) at 1 m from the underside (wide angle to telephoto)	865 x 530 mm to 20 x 12 mm
Anti-flicker	Yes
Focus [12]	**Auto** / Focus Freeze
White balance[12]	Auto / Indoor / Outdoor / **Manual**
Contrast enhancement[12]	Yes (3 levels)
Image freeze[12]	Yes
Preset[12]	6
Transmission type	Wireless
RS232 interface	Yes
Weight (without sterile handle)	790 g
Dimensions (diam. x h) (without sterile handle)	132 x 198 mm

Tab. 52: Technical specifications of the camera

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[1] via touch screen only

[2]

AIR03 SYSTEM E/U technical specifications

Specifications	AIR03 SYSTEM E/U
Video output	HDMI 1.4
Weight (without mounting bracket)	220 g
Dimensions with mounting bracket (L x W x H)	156 × 117 × 61 mm
Transmission frequencies	see below

Tab. 53:   AIR03 SYSTEM E/U technical specifications

AIR03 SYSTEM E/U transmission frequencies:
UE zone: Central frequency of transmission channels in accordance with ETSI EN 301 893:
5.190 GHz and 5.230 GHz
USA zone: Central frequency of transmission channels in accordance with the FCC 15.407
standard: 5.190 GHz, 5.230 GHz, 5.755 GHz and 5.795 GHz

Electromagnetic compatibility of the device

Device	Description	Supplier
Wireless HDMI video transmission system	EXT-WHD-1080P-SR	GEFEN**

NOTICE

The technical specifications of the AIR03 wireless system are detailed in the documentation available on the GEFEN manufacturer's website.

8.5   Other characteristics

Protection against electrical shock	Class I
Medical device classification for Europe, Canada, Korea, Japan, Brazil, Australia, Switzerland and United Kingdom	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
EMDN code	Z12010702
GMDN code	36843

Tab. 54:   Specifications relating to standards and regulations

8.6   EMC declaration

⚠️ **CAUTION!**

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

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

⚠️ **CAUTION!**

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

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

⚠️ **CAUTION!**

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

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

⚠️ **CAUTION!**

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

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

ℹ️ **NOTE**

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

Test type	Test method	Range of frequencies	Boundaries
Measurement of conducted emissions on the main ports	EN 55011 GR1 CL A[13]	0.15 / 0.5 MHz	79 dBµV QP 66 dBµV A
		0.5 / 5 MHz	73 dBµV QP 60 dBµV A
		5 / 30 MHz	73 dBµV QP 60 dBµV A

Tab. 55:   EMC declaration

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

Test type	Test method	Range of frequencies	Boundaries
Measurement of the radiated electromagnetic field	EN 55011 GR1 CL A[13]	30 / 230 MHz	40 dBµV/m PQ 10 m
		230 / 1000 MHz	47 dBµV/m PQ 10 m

Tab. 55:   EMC declaration

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

Tab. 56:   EMC declaration

8.6.1   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, contact your local Getinge representative.

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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