Instructions for use

Maquet PowerLED II

IFU 01811 EN 13 2024-09-24

GETINGE

Subject to technical changes.

The illustrations and technical specifications provided in this manual may, on account of future product developments, differ slightly from the actual product supplied.

V13 24.09.2024

Contents

1 Introduction

1.1 Preface

Your hospital has chosen Getinge's innovative medical technology. We thank you for the confidence you have shown in us.

Getinge is one of the world's leading suppliers of medical equipment for operating rooms, hybrid rooms, induction rooms, intensive care units and patient transport. Getinge always puts the needs of healthcare staff and patients first during the development of its products. Getinge provides solutions that respond to the safety, efficiency and economic constraints faced by hospitals.

Building on its experience in surgical lights, ceiling-mounted equipment management systems and multimedia solutions, Getinge focuses on quality and innovation to ensure that its solutions best meet the needs of patients and healthcare staff. Getinge surgical lights are world-renowned for their design and innovative features.

1.2 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 105].

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

- Installation recommendations (Ref. ARD01816)
- Installation manual (P/N ARD01814)
- Maintenance manual (P/N ARD01810)
- Repair manual (P/N ARD01812)
- Decommissioning instructions (P/N ARD01815)

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
DF	Double Fork
FSP*	Flux Stability Program
HD	High Definition
IFU	Instructions For Use
IP	Ingress Protection rating
K	Kelvin
LED	Light-Emitting Diode
LMD	Luminance Management Device
lx	lux
N/A	Not Applicable
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 1.

1.4.2.3 Actions and results

Actions to be performed by the user are listed with sequence numbers; the "➢" symbol is used to show the result of an action.

Example:

Prerequisites:

- The sterilisable handle must be compatible with the product.

1. Fit the handle to the mount.
   ➢ A click is heard.
2. Turn the handle until it locks into place with a second click.

1.4.2.4 Menus and buttons

Menu and button names are shown in **bold**.
Example:

1. Press the **Save** button.
   ➢ The changes are saved and the **Favourites** menu is displayed.

1.4.2.5 Hazard levels

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

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

Tab. 1: Hazard levels of safety instructions

1.4.2.6 Indications

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

Tab. 2: Types of indication in the document

1.4.3 Definitions

1.4.3.1 Groups of people

Users

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

Qualified personnel:

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

1.4.3.2 Light types

Minor surgical light

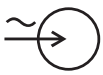
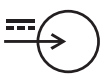
Single light located in the patient's environment in an operating room and designed to facilitate treatment and diagnosis procedures which can be interrupted without compromising patient safety in the event of a light failure.

Surgical lighting system

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

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

1.5 Symbols on the product and packaging

	Follow the instructions for use (IEC 60601-1:2012).		CE marking (Europe)
	Follow the instructions for use (IEC 60601-1:2005).		UL mark (Canada and United States)
	Follow the instructions for use (IEC 60601-1:1996).		UR mark (Canada and United States)
	Manufacturer + manufacturing date		Medical Device (MD) marking
	Product code		Unique device identification
	Product serial number		Packaging orientation
	AC input		Fragile, handle with care
	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
	Do not discard with conventional waste		Risk of hand injury

1.6 Product overview

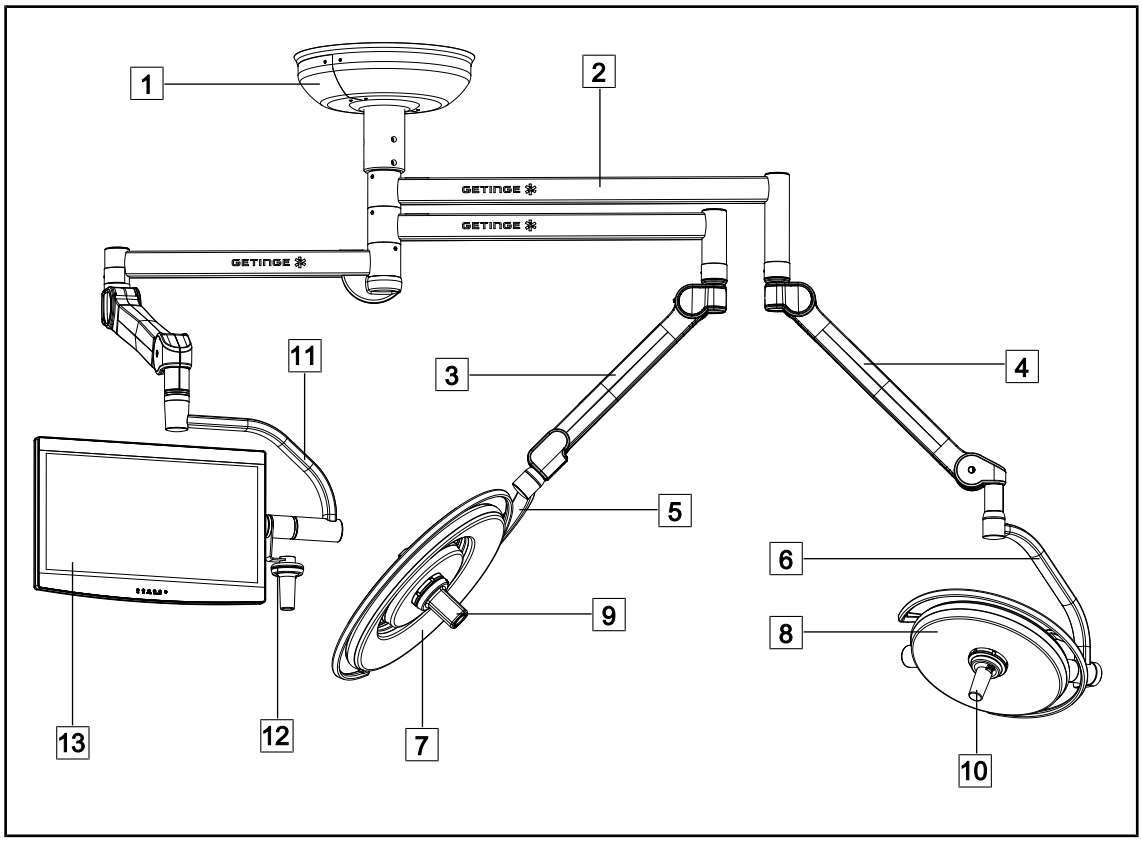


Fig. 1: Typical configuration

1. Ceiling-mounted cover
2. Suspension arm
3. SF spring arm
4. DF spring arm
5. Single fork
6. Dual fork
7. Maquet PowerLED II 700 lighthead
8. Maquet PowerLED II 500 lighthead
9. Camera
10. Sterilisable handle mount
11. Screen holder
12. Screen holder handle option
13. Monitor

1.6.1 Components

1.6.1.1 Lightheads

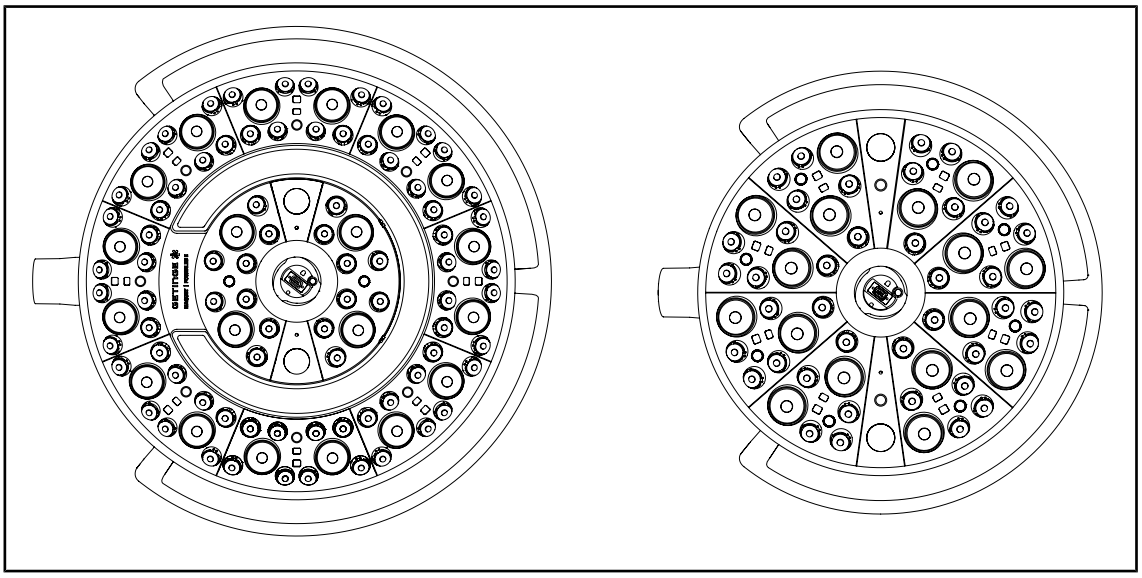


Fig. 2: Maquet PowerLED II 700 and Maquet PowerLED II 500 lightheads

Each lighthead comprises the following components:

- Handle mount and sterilisable handle
- Control keypad with antibacterial film
- Outer handle coated in antibacterial paint
- IP44 protection against dust and liquid ingress

Each lighthead includes the following functions:

- Boost mode
- Light field diameter variation
- AIM AUTOMATIC ILLUMINATION MANAGEMENT*
- ambient lighting with six selectable colours
- laser positioning assistance

NOTICE

If a configuration has several lightheads, these can be synchronised, i.e. the lightheads can be set to the same state and controlled simultaneously; see Synchronising the lightheads [⏩ Page 57]

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.

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

Boost mode

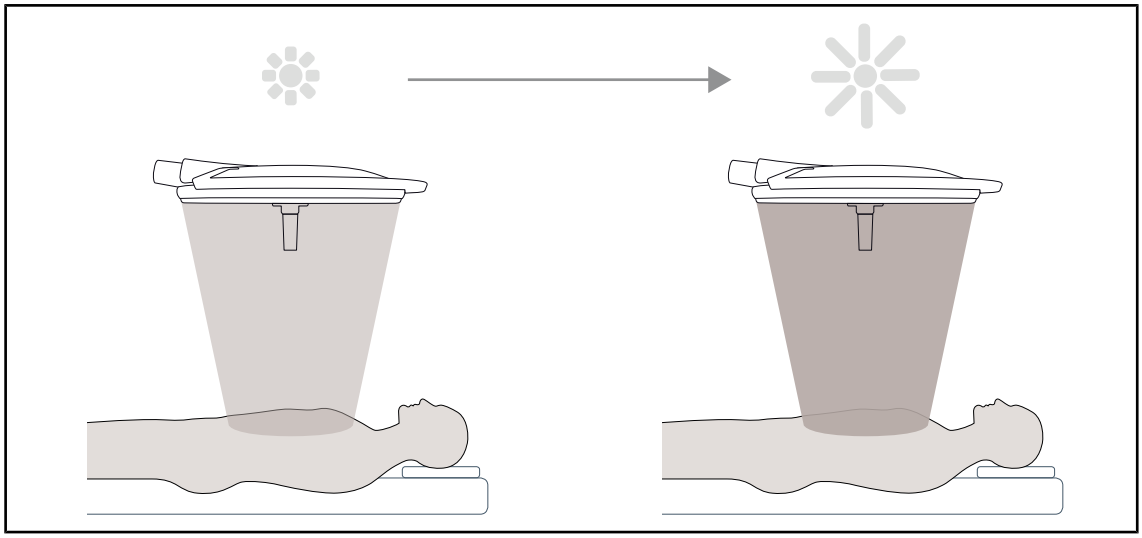


Fig. 3: Boost mode

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 necessary.

Light field diameter variation

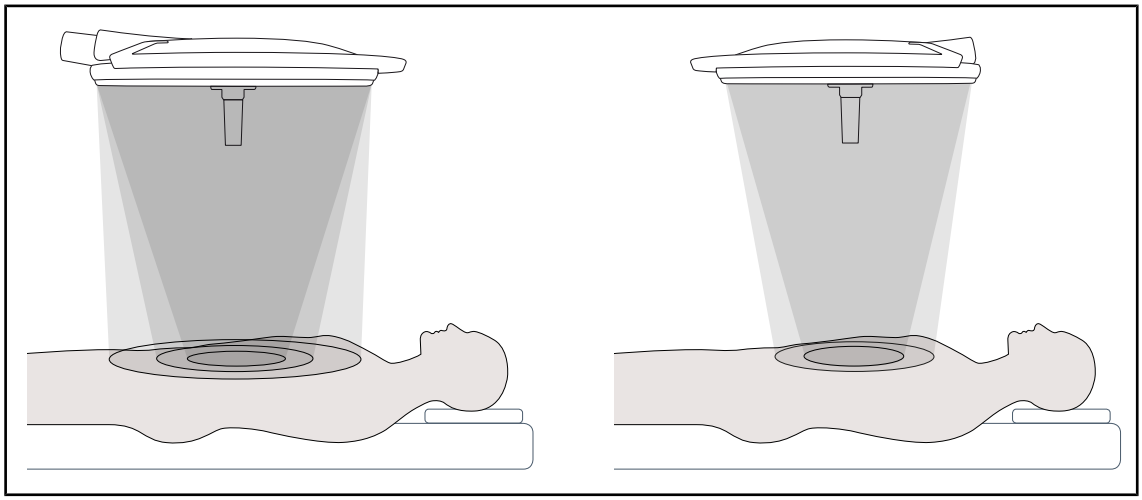


Fig. 4: Light field diameter variation

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).

AIM AUTOMATIC ILLUMINATION MANAGEMENT

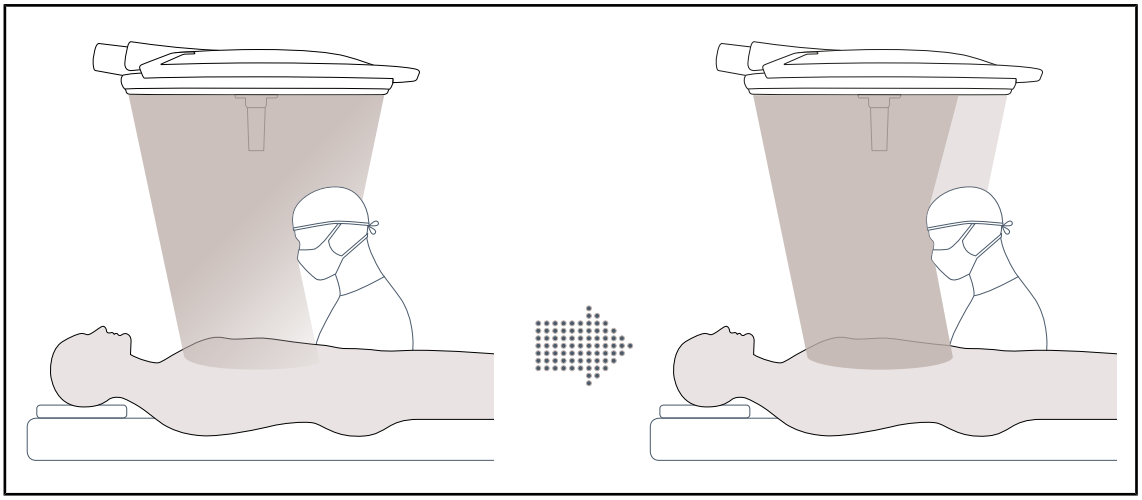


Fig. 5: Presence of one or two surgeons

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. Power is reduced in the obstructed LEDs and increased in the unobstructed LEDs in order to:

- Stabilize the illumination at the surgical site
- Allow freedom of movement for the surgical team
- Improve the surgeon's working conditions

Ambient light

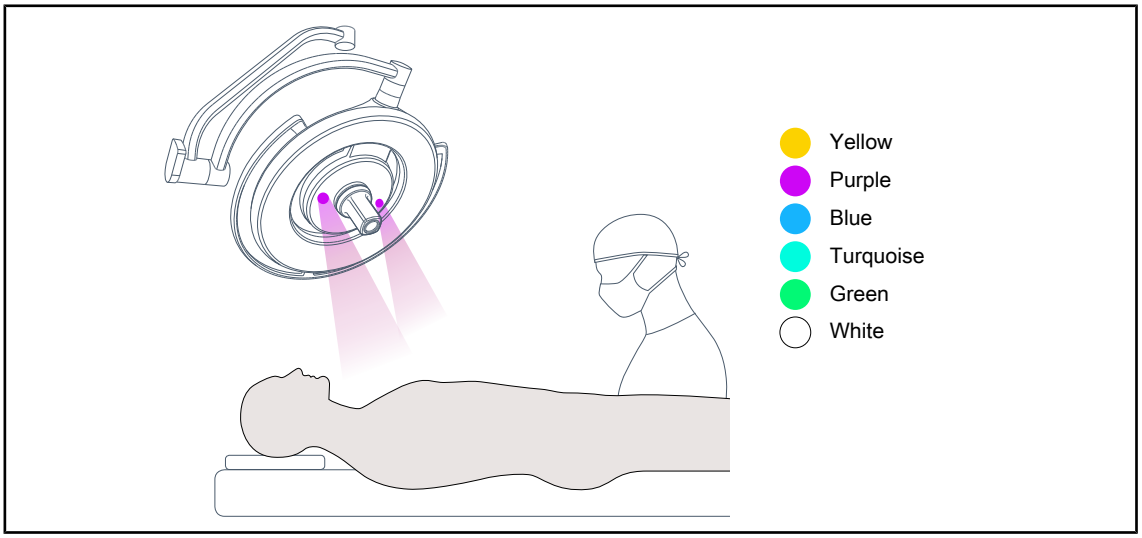


Fig. 6: Ambient light function

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

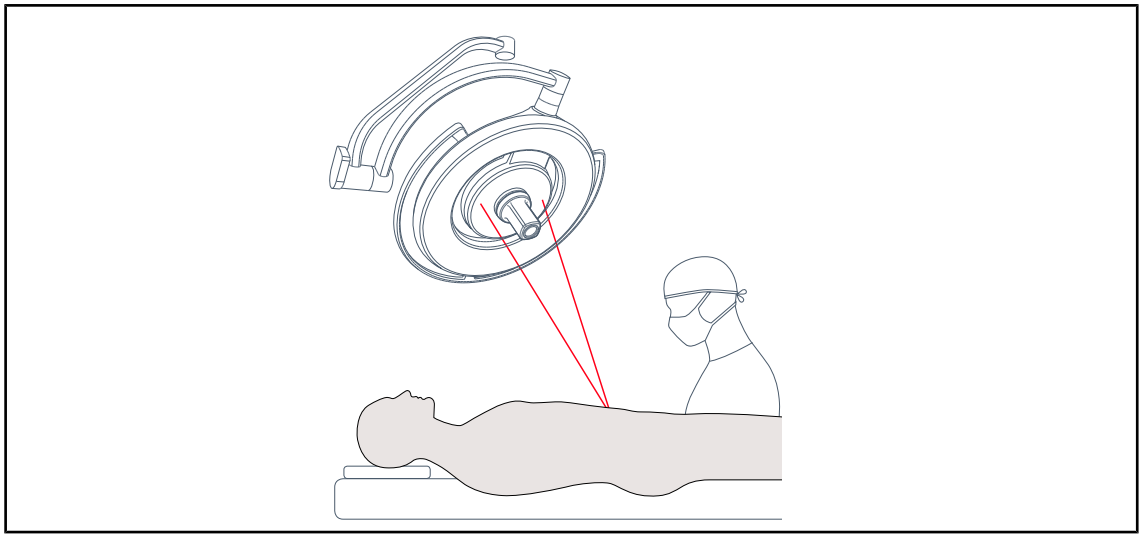


Fig. 7: Laser positioning assistance

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.

1.6.1.2 Screen holder built into the device

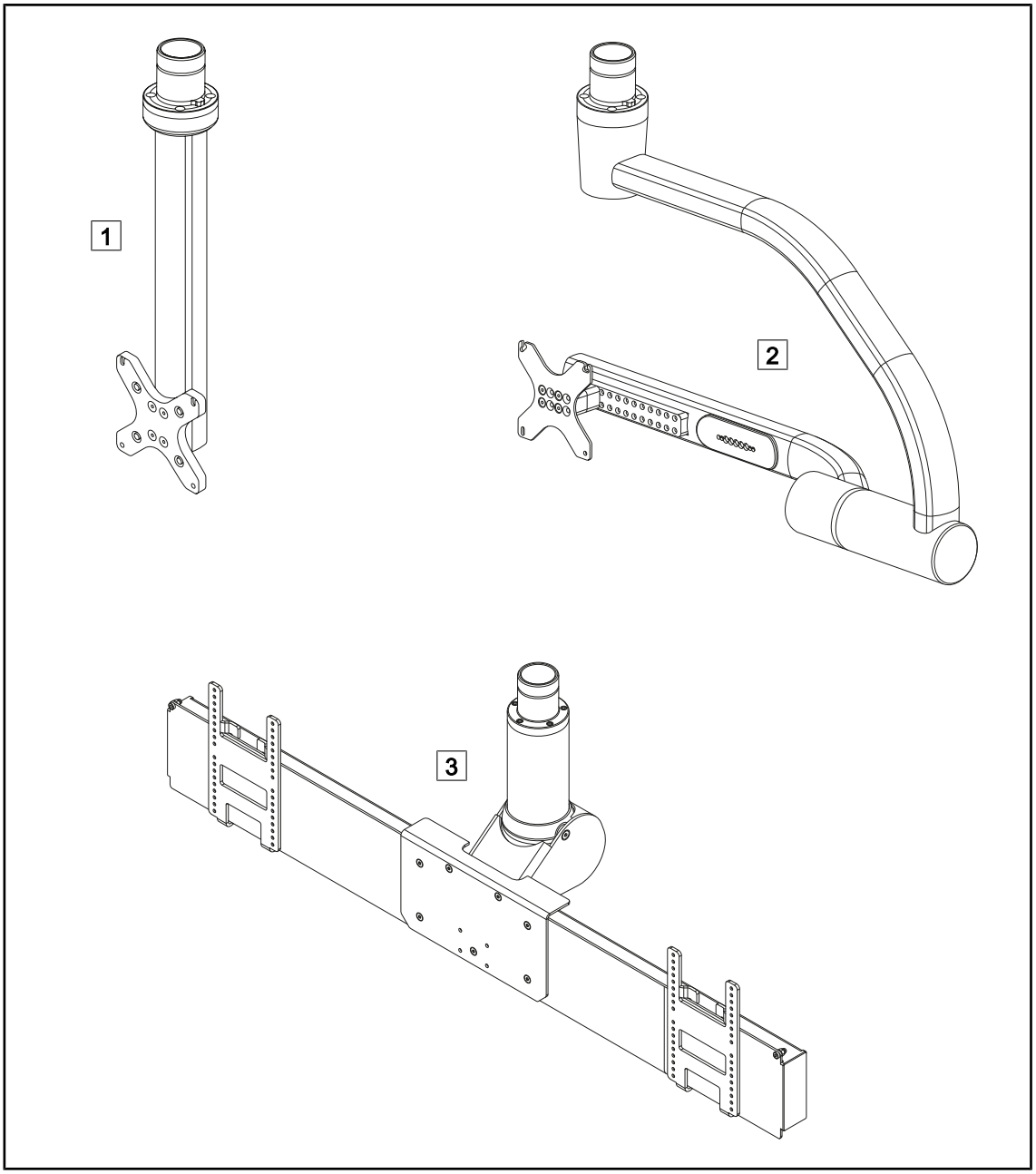
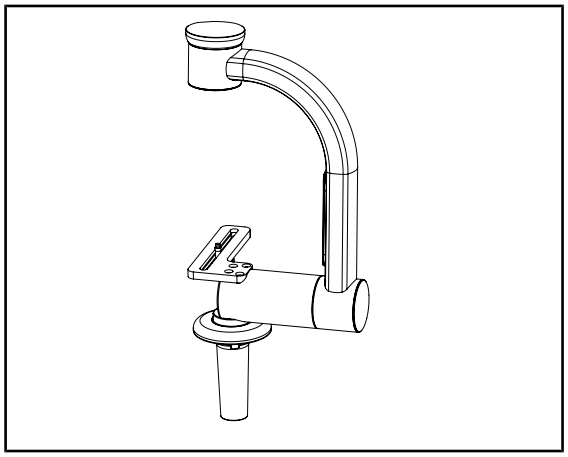


Fig. 8: Screen holders available with Maquet PowerLED II

1 FHS0 / MHS0
2 XHS0
3 XHD1

1.6.1.3 Monitor mount built into the device

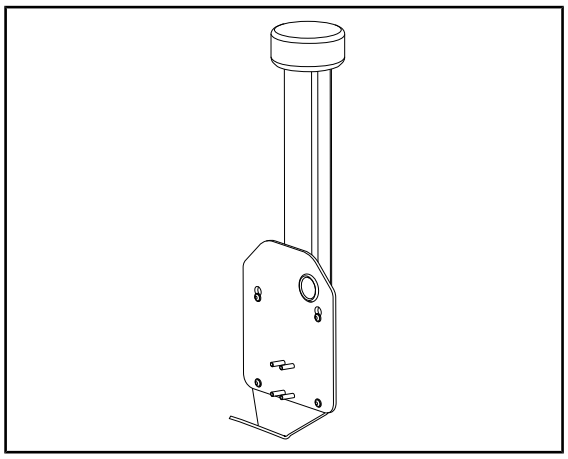
SC05 camera mount



This camera mount is intended to hold high-resolution medical cameras, and provides wide clearance to enable complex signal cables to be routed. A Kodak screw is used to mount the camera, which can be oriented in all directions in order to obtain views of the operating field from various angles.

Fig. 9: SC05 camera mount

CAMERA MOUNT PLATE



A PSX/HLX/DAX FH CAMERA MOUNT PLATE can be installed on the structure of an FHS0 or MHS0 screen holder. This camera mount is designed to accommodate high resolution medical video cameras that can be fitted to a 100x100 VESA interface. The mounted camera can be adjusted for optimum position, providing views of the operating field from various angles.

Fig. 10: CAMERA MOUNT PLATE

1.6.2 Options

1.6.2.1 Wall-mounted remote control panels

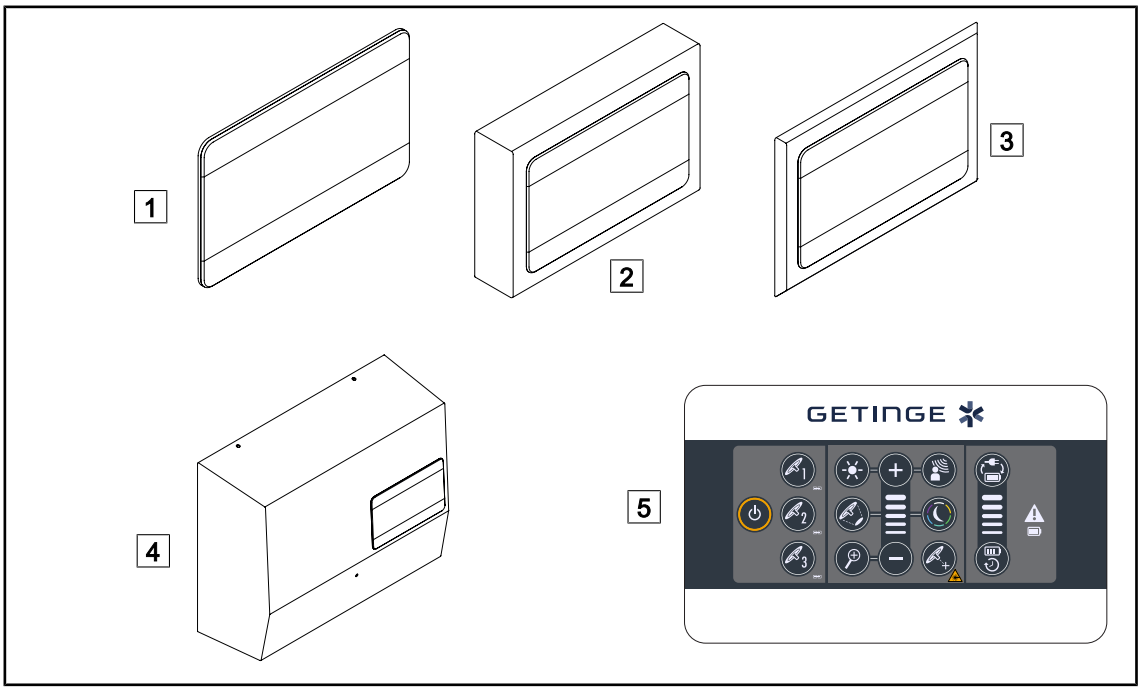


Fig. 11: Wall-mounted control keypads

1 Recessed version
2 Surface-mounted version
3 Recessed version with front panel
4 Power supply version
5 Wall-mounted control keypad

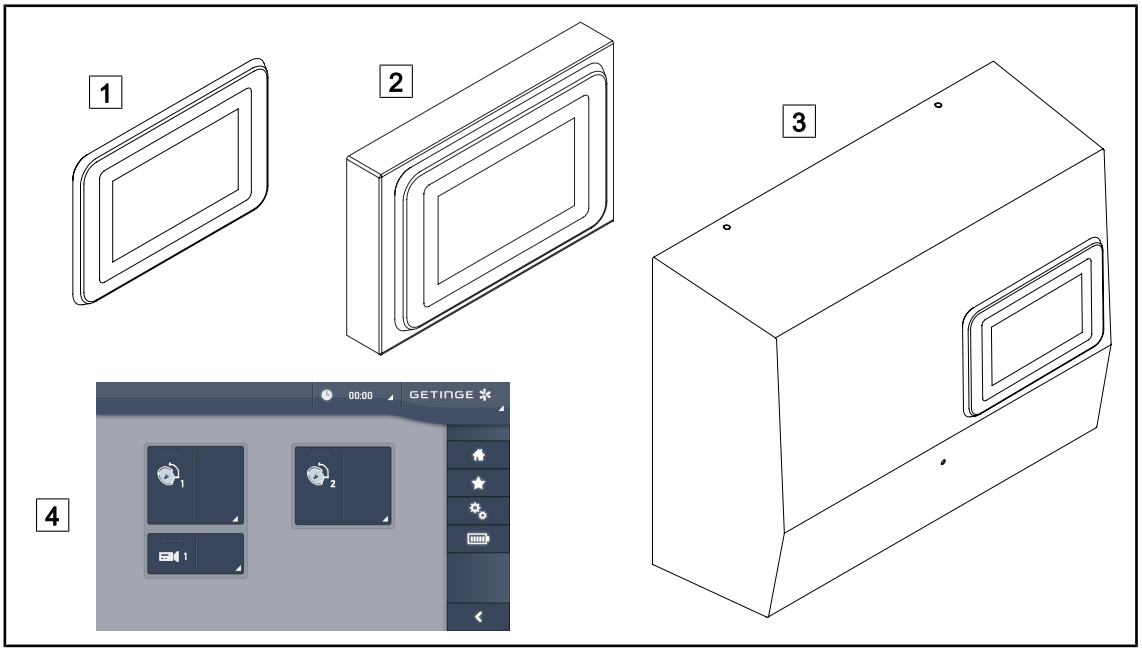


Fig. 12: Touchscreens

1 Recessed version
2 Surface-mounted version
3 Power supply version
4 Touchscreen control panel

1.6.2.2 Comfort Light*

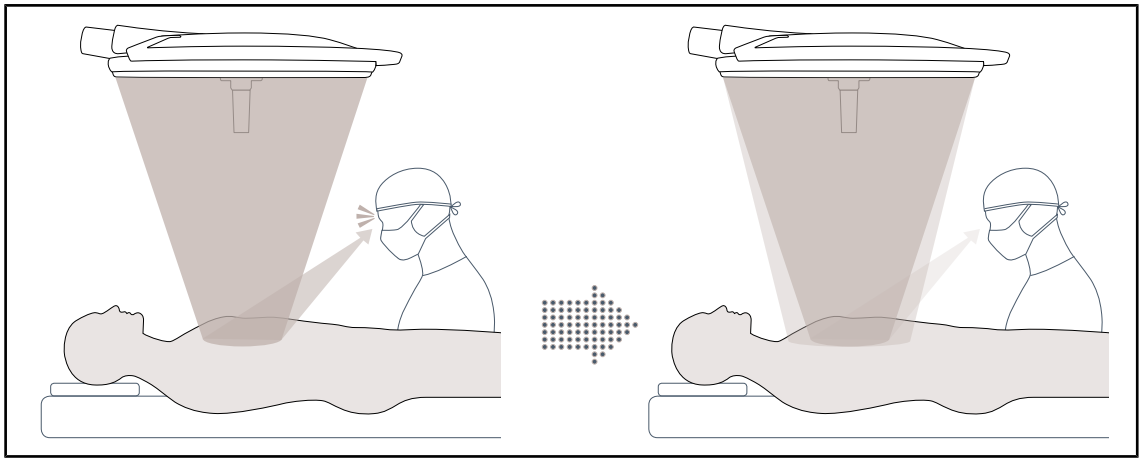


Fig. 13: Comfort light

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.

1.6.2.3 Video

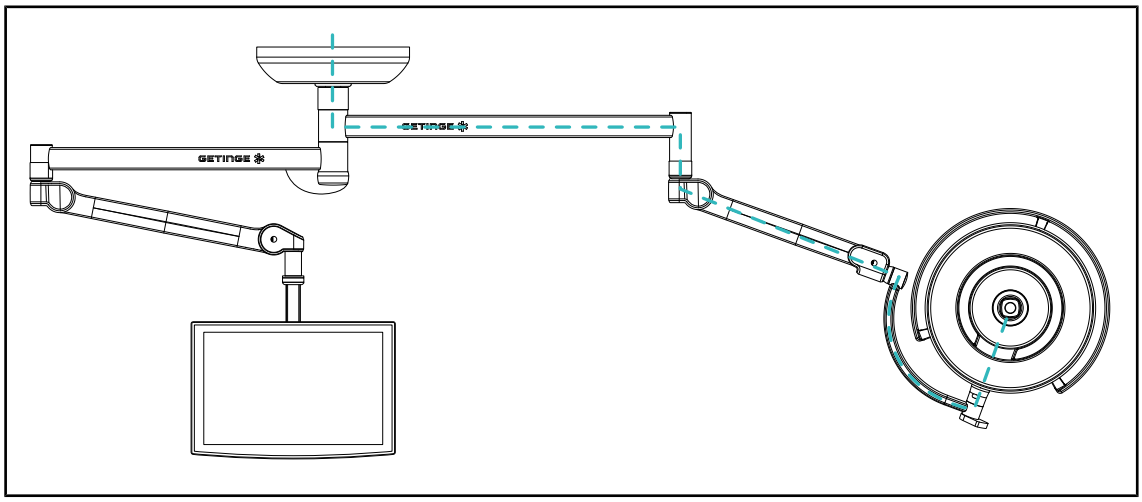


Fig. 14: FHD pre-wired configuration

For Full HD video pre-wiring, the location of the lighthead does not matter and the video signal from the camera can be replicated to two different screens.
For 4K video pre-wiring, the camera is installed on the lowest lighthead of the lighting configuration.

1.6.2.4 Colour temperature

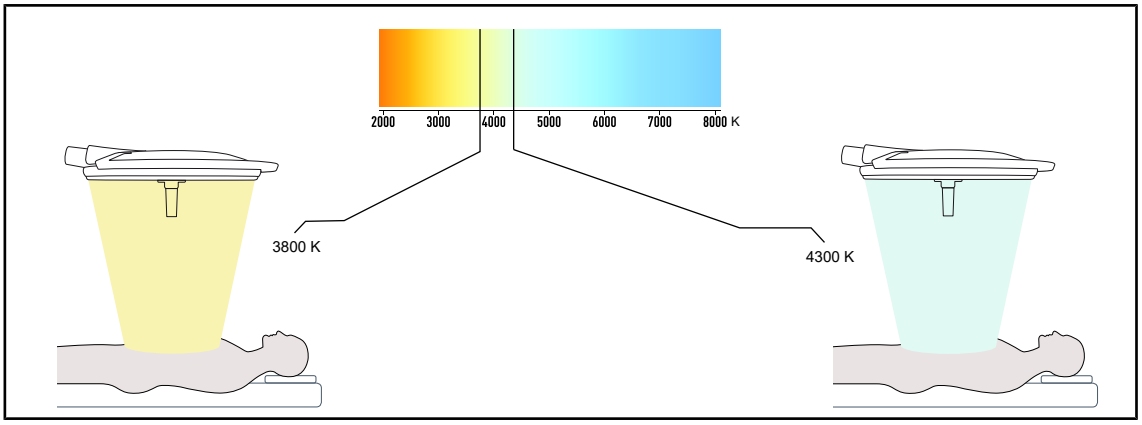


Fig. 15: Colour temperature 3800 K and 4300 K

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

1.6.2.5 Handle mounts

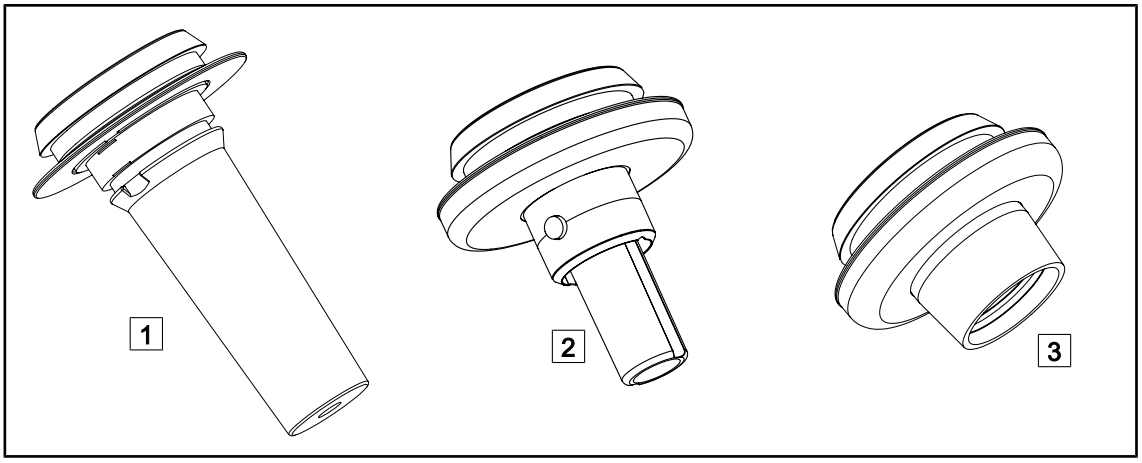


Fig. 16: Handle mounts for Maquet PowerLED II lightheads

1	Mount for STG PSX 01 handle	2	Mount for STG HLX 01 handle
3	Adapter for Devon® or Deroyal® disposable handle. Two versions are available: either with (DAX QL+ 001) or without (DAX QL+ 002) tilt (handle-adjusted light field diameter variation)		

1.6.2.6 Options for FHS0/MHS0

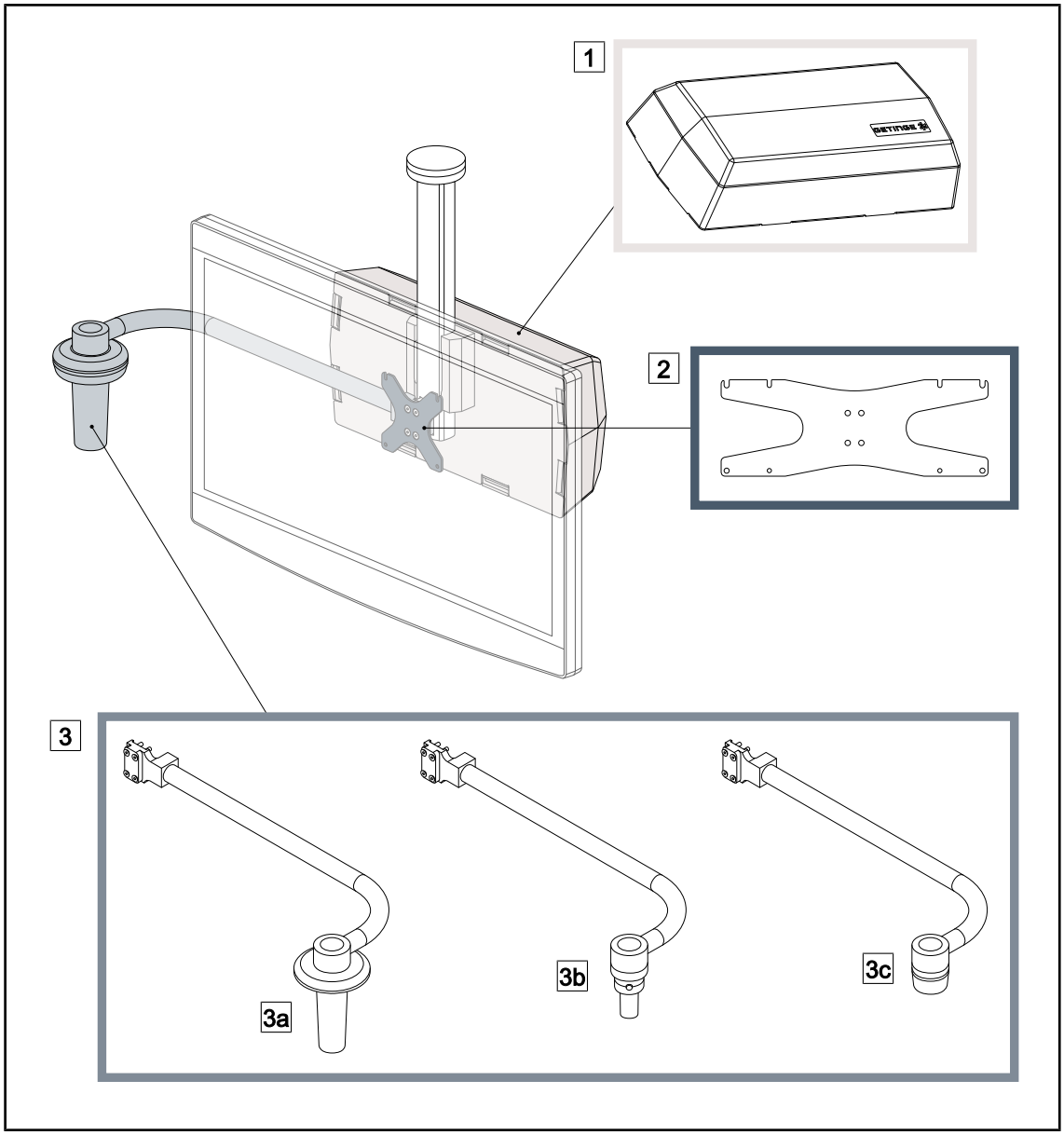


Fig. 17: Options for FHS0/MHS0

1 Rear Box
2 Screen holder plate MH
3 Handle option (three possibilities, mounts to the left or to the right of the screen)
3a PSX FH/MH handle mount
3b HLX FH/MH handle mount
3c DAX FH/MH handle mount

1.6.2.7 Options for XHS0

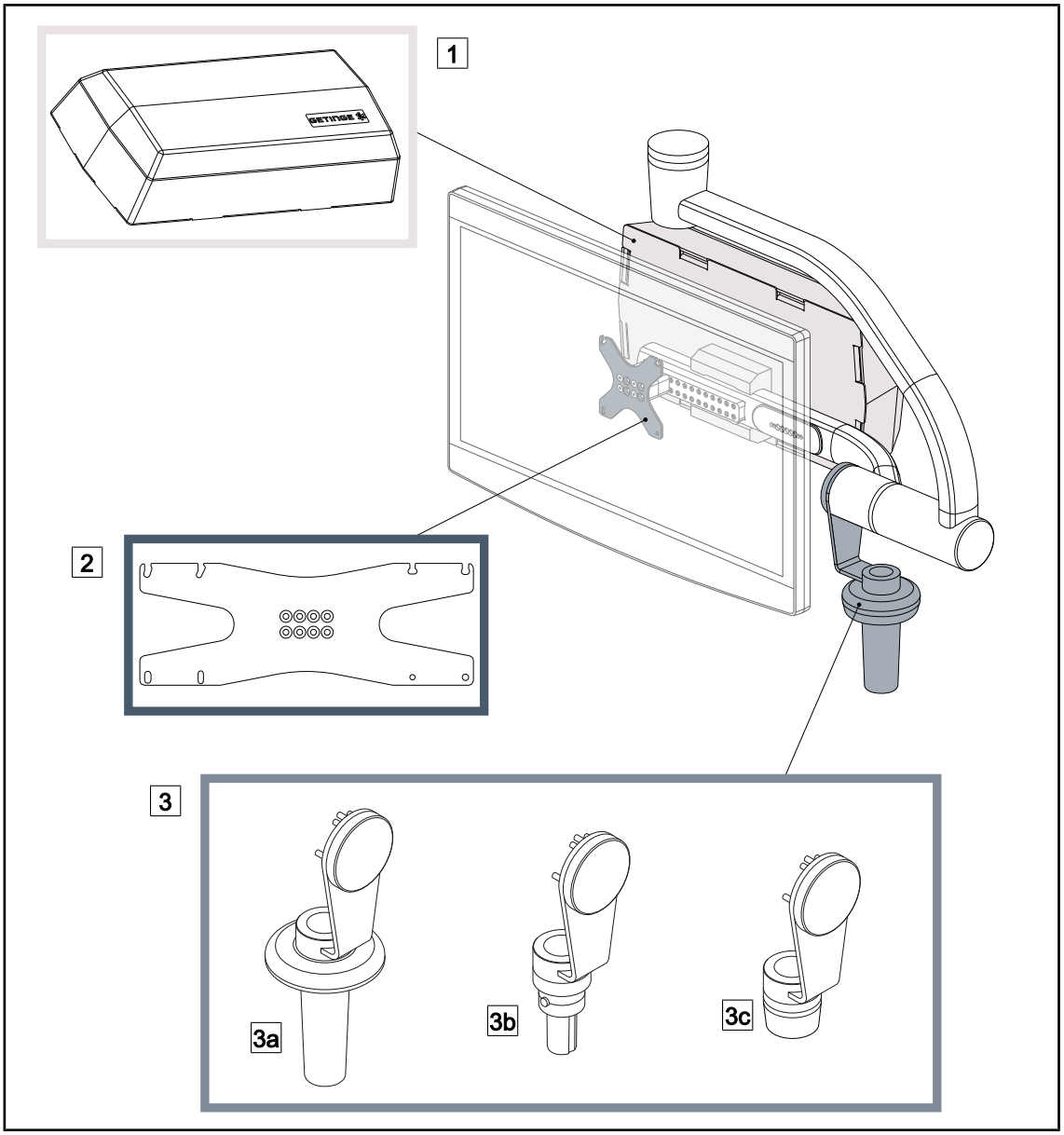


Fig. 18: Options for XHS0

1 Rear Box
2 Screen holder plate XH
3 Handle option (three possibilities)
3a PSX XH handle mount
3b HLX XH handle mount
3c DAX XH handle mount

1.6.2.8 Option for XHD1

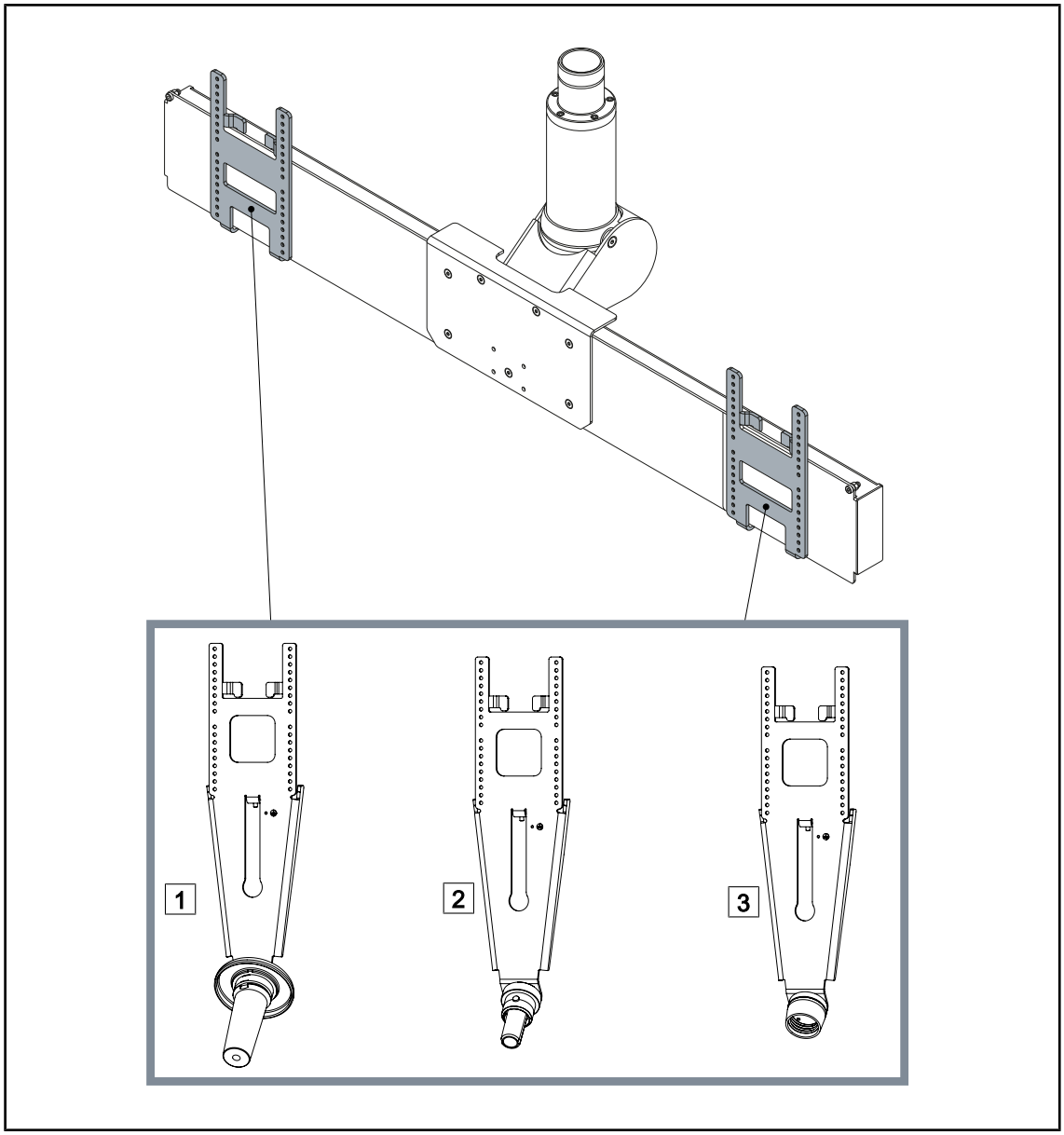


Fig. 19: Option for XHD1

1 Screen Holder Plate PSX XHD1
2 Screen Holder Plate HLX XHD1
3 Screen Holder Plate DAX XHD1

1.6.2.9 Options for camera mounts

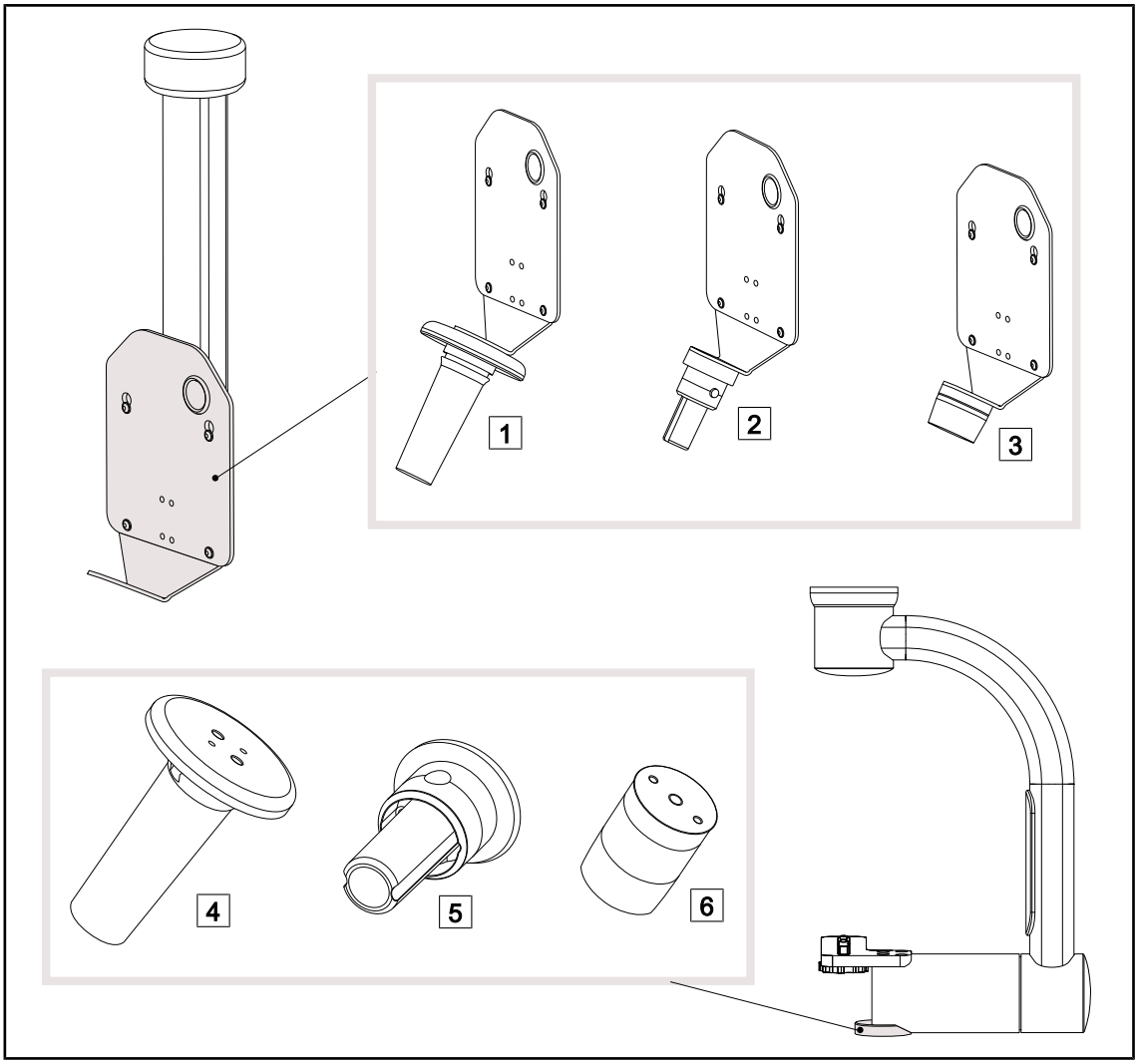


Fig. 20: Options available with camera mounts

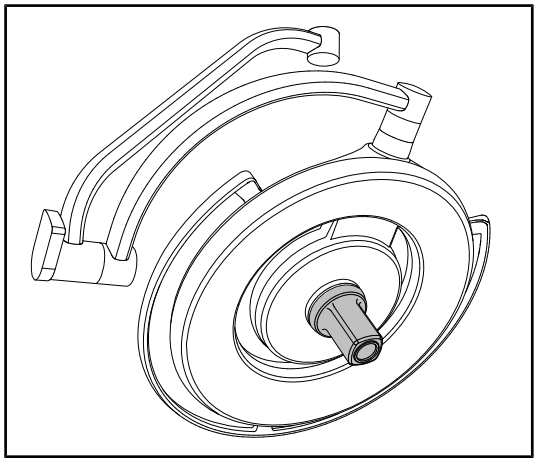
1 CAMERA MOUNT PLATE PSX FH
2 CAMERA MOUNT PLATE HLX FH
3 CAMERA MOUNT PLATE DAX FH
4 PSX handle mount for SC05
5 HLX handle mount for SC05
6 DEVON/DEROYAL® handle mount for SC05

1.6.3 Accessories

1.6.3.1 Cameras

NOTICE

The camera is designed to capture a perioperative view, which may be shared, saved or broadcast. It is not intended to be used for assistance during an operation or to establish a diagnosis.



The camera can be mounted in the centre of the lighthead using the Quick Lock system.

Fig. 21: Maquet PowerLED II 700 with camera

Wired cameras

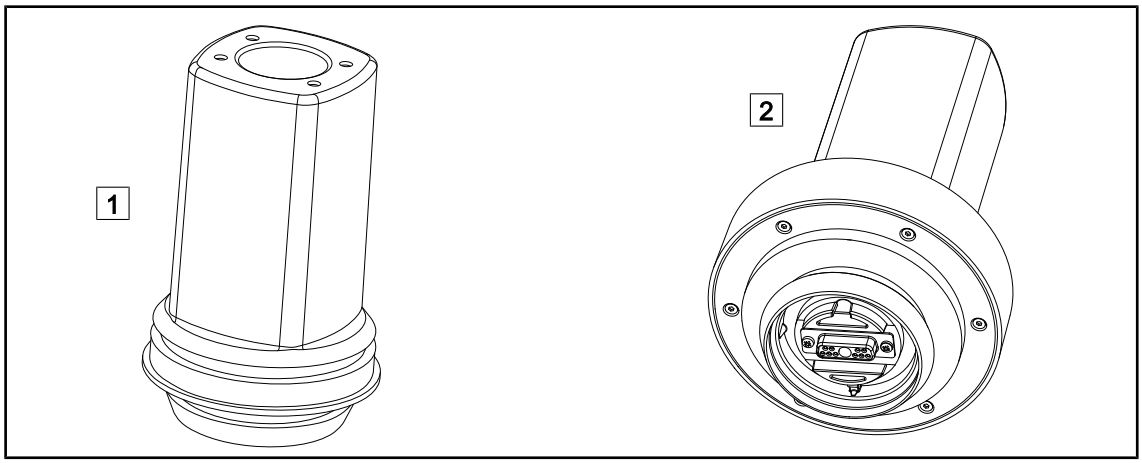


Fig. 22: OHDII FHD QL+ VP01 and OHDII 4K QL+ VP11 cameras

1 OHDII FHD QL+ VP01

2 OHDII 4K QL+ VP11

These cameras feature a quick lock system enabling it to be moved from one operating theatre to another, and offers genuine benefits for the surgical team. They ensure operating fluidity by keeping the surgical area clear during training phases, and facilitate monitoring of the surgeons' actions, enabling their needs to be better anticipated.

NOTICE

If two Full HD cameras are installed, two power adapters must be used.

NOTICE

Before installing a wired camera, make sure the lighthead is pre-wired for video. If the camera is installed on a lighthead that is not pre-wired for video, the camera will be detected, but no viewing of the video will be possible.

Overview of the Picture-in-Picture (PiP) and E-Pan Tilt options on the 4K camera

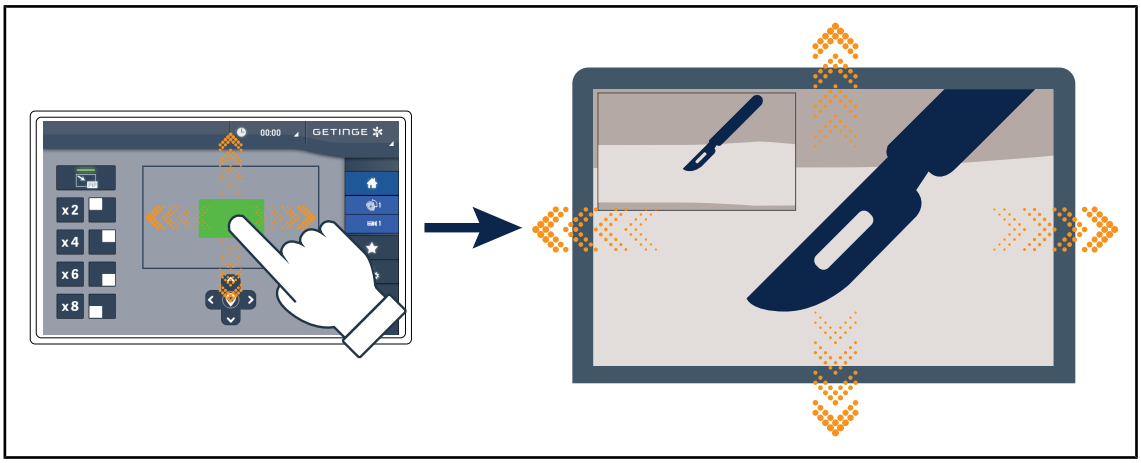


Fig. 23: Picture-in-Picture feature

The PiP function allows the user to zoom in on a specific area of the full screen image, while keeping the original image (wider field) embedded in a corner of the screen.

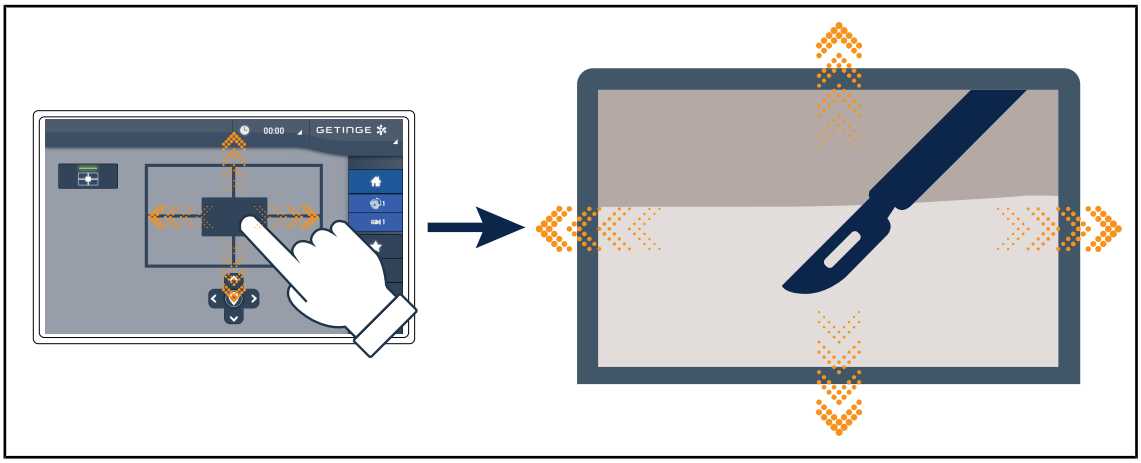


Fig. 24: E-Pan Tilt feature

The E-Pan Tilt function allows the user to focus on a region of interest, and move that area, without having to move the light or the camera.

1.6.3.2 Lead screens

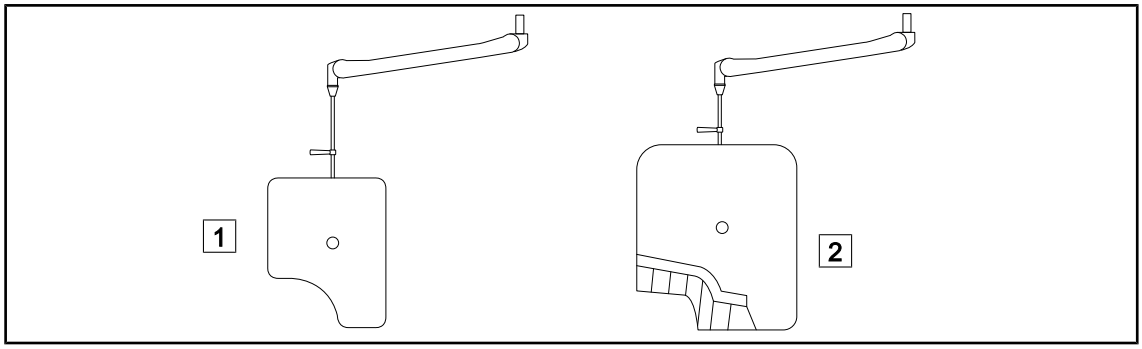


Fig. 25: Lead screens

1 Lead shield without radiation protection strips 2 Lead shield with radiation protection strips

1.6.3.3 LMD (with touchscreen control panel only)

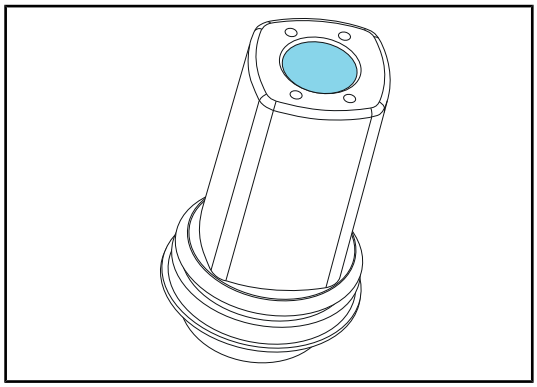


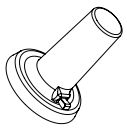
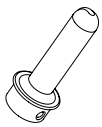
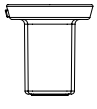
Fig. 26: LMD module

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.

NOTICE

The LMD system is compatible only with lightheads whose serial number is greater than 520000. If this is not the case, the LMD module flashes and does not operate.

1.6.3.4 Sterilisable handles

Illustration	Description	Part Number
	**Set of five STG PSX handles**	STG PSX 01
	**Set of five STG HLX handles**	STG HLX 01
	**STG PSX VZ sterilisable handle** For camera and LMD	STG PSX VZ 01

Tab. 3: Table of consumables

1.7 Product identification label

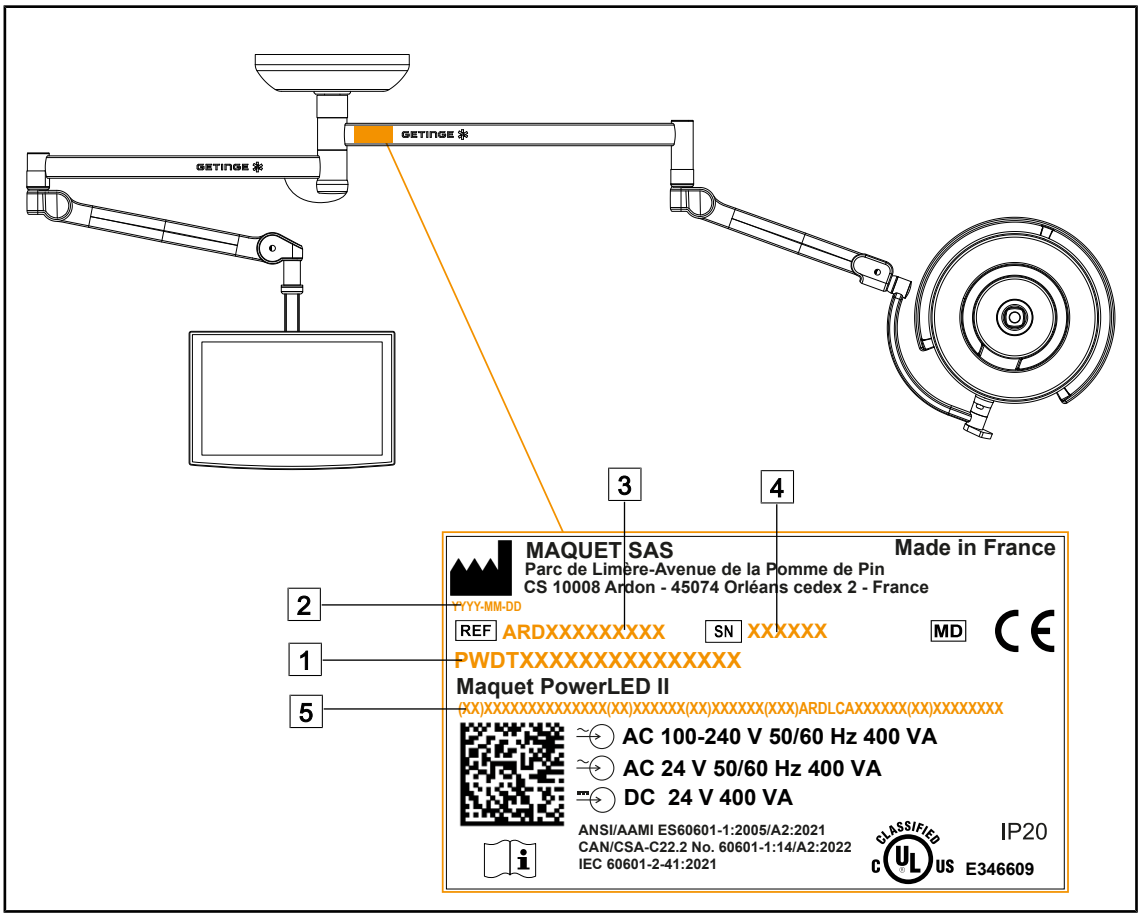


Fig. 27: Product identification label

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

1.8 Standards applied

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

Reference	Title
IEC 60601-1:2005+AMD1:2012+AMD2:2020 ANSI/AAMI ES60601-1:2005/A2:2021 CAN/CSA-C22.2 No. 60601-1:14/A2:2022 EN 60601-1:2006/A1:2013/A2:2021	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-2-41:2021 EN IEC 60601-2-41:2021	Medical electrical equipment – Part 2-41: Particular requirements for the safety of surgical luminaires and luminaires for diagnosis

Tab. 4: Compliance with product standards

Reference	Title
IEC 60601-1-2:2014+AMD1:2020 EN 60601-1-2:2015/A1:2021	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 EN 60601-1-6:2010/A1:2015/A2:2021	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-9:2007+AMD1: 2013+AMD2:2020 EN 60601-1-9:2008/A1:2014/A2:2020	Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for an environmentally friendly design
IEC 62366-1:2015+AMD1:2020 EN 62366-1:2015/A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
IEC 62304:2006+AMD1:2015 EN 62304:2006/A1:2015	Medical device software – Software life cycle processes
ISO 20417:2020 EN ISO 20417:2021	Medical devices - Information provided by manufacturer
ISO 15223-1:2021 EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be provided by manufacturer - Part 1: General requirements
EN 62471:2008	Photobiological safety of lamps and lamp systems
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. 4: 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

Tab. 5: Compliance with quality management standards

Reference	Year	Title
21 CFR Part 11	2023	Title 21--Food And Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter A -- General PART 11 - Electronic records, electronic signatures
21 CFR Part 820	2020	Title 21--Food And Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter H -- Medical Devices PART 820 - Quality System Regulation

Tab. 5: Compliance with quality management standards

Environmental standards and regulations:

Reference	Year	Title
Directive 2011/65/EU	2011	Limitation of the use of certain hazardous substances in electrical and electronic equipment
Directive 2015/863/EU	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 2018/851	2018	Directive amending Directive 2008/98/CE concerning waste
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. 6: Environmental standards and regulations

Country	Reference	Year	Title
Argentina	Dispocision 2318/2002	2002	Administración Nacional de Medicamentos, Alimentos y Tecnología Médica - Registro de productos Medicas - Reglamento
Australia	TGA 236-2002	2021	Therapeutic Goods (Medical Devices) Regulations 2002. Statutory Rules No. 236, 2002 made under the Therapeutic Goods Act 1989
Brazil	RDC 665/2022	2022	RDC n°665, 30 March 2022, Provides for the Good Manufacturing Practices for Medical Devices and Medical devices for In Vitro Diagnostis
Brazil	RDC 751/2022	2022	RDC No. 751, of September 15, 2022, which provides for risk classification, notification and registration regimes, and labeling requirements and instructions for use of medical devices.
Canada	SOR/98-282	2023	Medical Devices Regulations
China	Regulation 739	2021	Regulation for the Supervision and Administration of Medical Devices
EU	Regulation 2017/745/EU	2017	Medical Devices Regulations
Japan	MHLW Ordinance: MO No. 169	2021	Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-Vitro Diagnostics
South Korea	Act 14330	2016	Medical Device Act
South Korea	Decree 27209	2016	Enforcement Decree of Medical Act
South Korea	Rule 1354	2017	Enforcement Rule of the Medical Act
Switzerland	RS (Odim) 812.213	2020	Medical Devices Ordinance (MedDO) of 1 July 2020
Taiwan	TPAA 2018-01-31	2018	Taiwanese Pharmaceutical Affairs Act
UK	Act	2021	Medical Devices Regulations 2002 No. 618
USA	21CFR Part 7	2023	Title 21--Food And Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter A -- General PART 7 - Enforcement policy
USA	21CFR Subchapter H	2023	Title 21--Food And Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter H -- Medical Devices

Tab. 7: Compliance with market standards

1.9 Information relating to intended use

1.9.1 Intended use

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

1.9.2 Indications

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

1.9.3 Intended users

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

1.9.4 Inappropriate use

- Use as a secondary lighting system (a lighthead) if an interruption of the operation threatens the life of the patient.
- Use of a damaged product (e.g., lack of maintenance).
- In a setting other than a professional healthcare environment (e.g., home care).
- Use of the camera for assistance during an operation or to establish a diagnosis.
- Use of the screen holder or camera mount while carrying something other than a screen or a camera.
- Installation of a screen that is too heavy or too wide based on recommendations.

1.9.5 Contraindications

This product does not have any contraindications.

1.10 Primary purpose

The primary purpose of the Maquet PowerLED II 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, see Maintenance [⏩ Page 104]. After this time, if the device is still in use, an inspection must be carried out by personnel trained and approved by Getinge to ensure the continued safety of the device.

1.14 Instructions for reducing the environmental impact

To ensure optimum use of the device while limiting its impact on the environment, here are some rules to follow:

- Reduce power consumption by switching off the device when not in use.
- Position the device correctly so as not to have to compensate for poor positioning by increasing the lighting power.
- Follow the specified maintenance schedule in order to keep the level of environmental impact as low as possible.
- For questions relating to waste treatment and device recycling, refer to the Waste management chapter.
- Use the various options wisely to avoid needless power consumption.

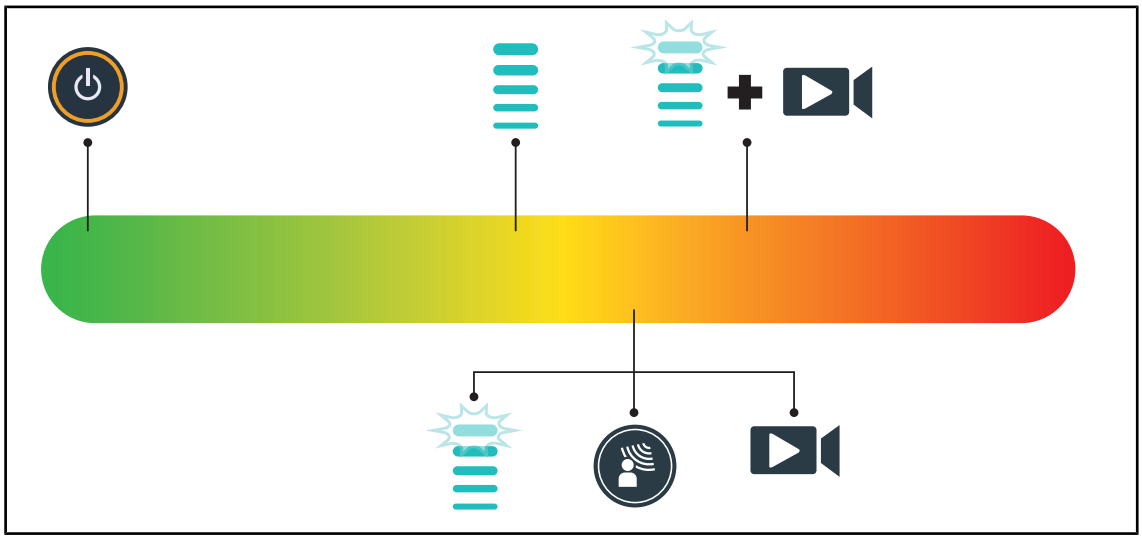


Fig. 28: Power consumption of device in operation

NOTICE

Power consumption for the device is provided in chapter 9.2, Electrical specifications.
The device does not contain hazardous substances in accordance with RoHS 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. 8: Environmental conditions for transport/storage

Environmental conditions for use

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

Tab. 9: Environmental conditions for use

NOTICE

For information regarding operation in electromagnetic environments; see EMC declaration [⏩ Page 112]

2.2 Safety instructions

2.2.1 Safe use of the product

WARNING!

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

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

WARNING!

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

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

WARNING!

Risk of injury
If the battery discharges too quickly, a lighthead may go out during a procedure.

Perform a battery lifetime test monthly to estimate the battery lifetime. Contact the Getinge technical department if a malfunction occurs.

WARNING!

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

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

WARNING!

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

Do not use a damaged device.

2.2.2 Electrical

WARNING!

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

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

WARNING!

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

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

2.2.3 Optical

WARNING!

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

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

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

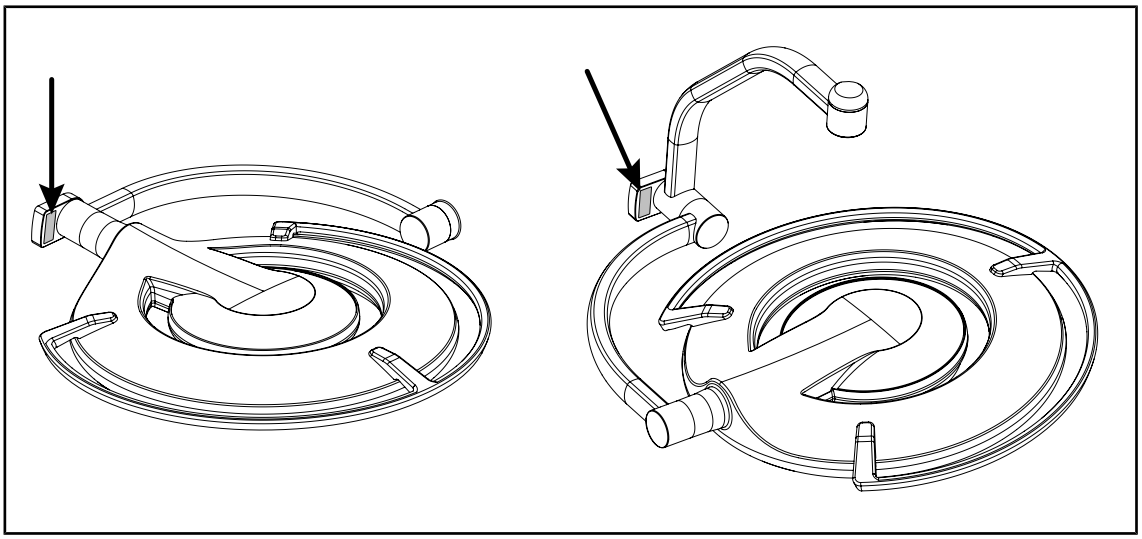
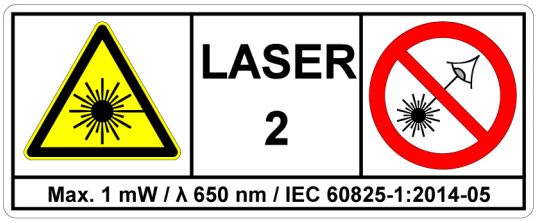


Fig. 29: Location of laser label

Label	Meaning
	**Laser radiation.** Do not look into the beam. Class 2 laser device.
	**Laser radiation.** Do not look into the beam. Class 2 laser device.

Tab. 10: Safety label on the product

3 Control interfaces

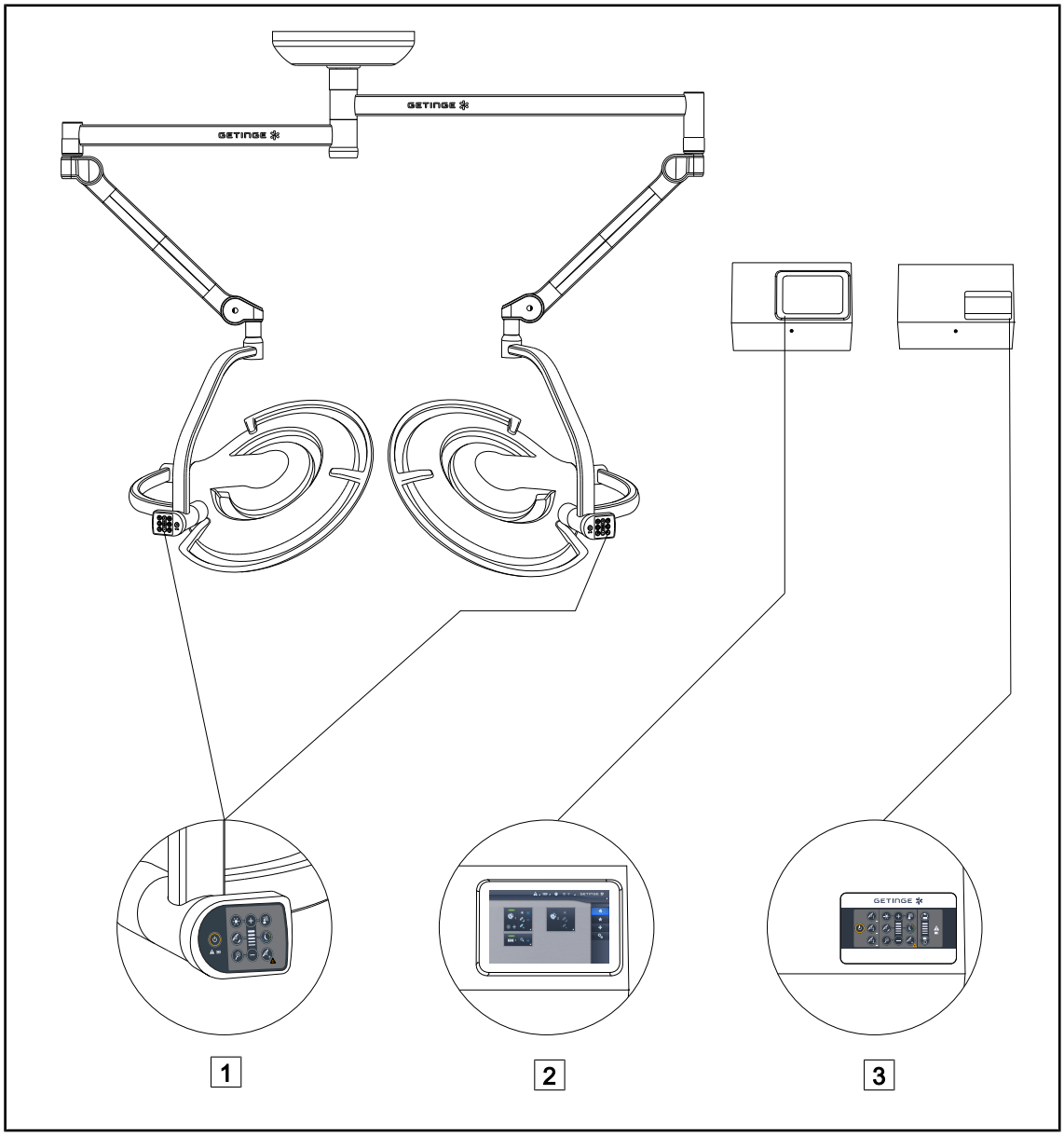


Fig. 30: PWD II control interfaces

1 Lighthead control keypad
2 Touchscreen control panel (optional)
3 Wall-mounted control keypad (optional)

NOTICE

The light can also be controlled via external control equipment provided by an integrator. Contact your Getinge representative for more information. Contact your Getinge representative for more information.

3.1 Lighthead control keypad

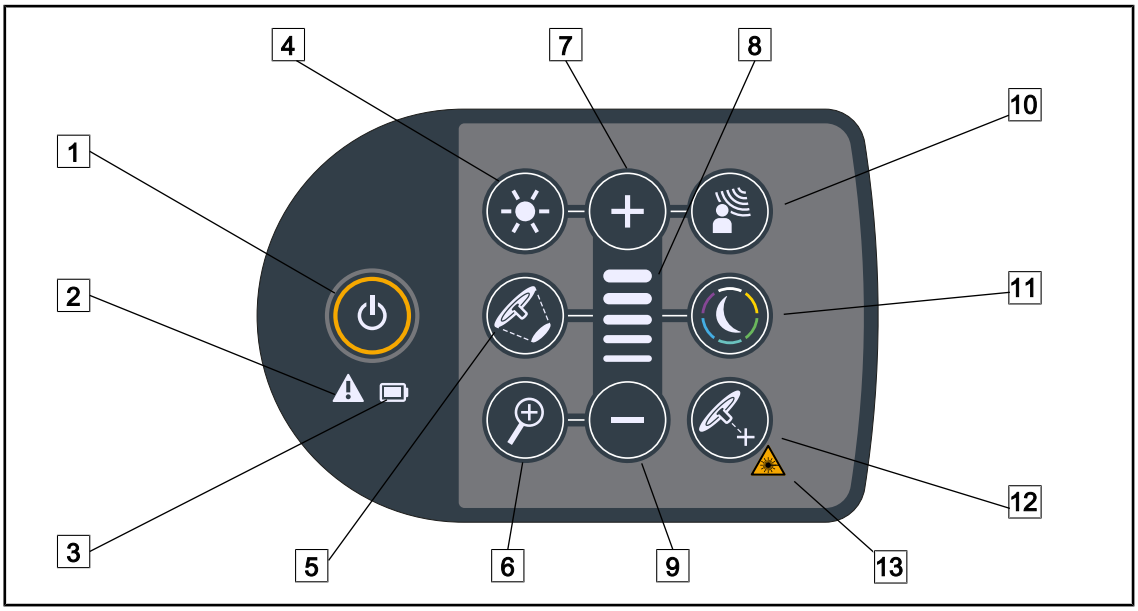


Fig. 31: Control keypad located on the lighthead fork

1 On/Off
2 Warning indicator
3 Battery indicator
4 Adjustment of illumination
5 Light field diameter variation
6 Camera zoom
7 Plus (increase the level)
8 Level indicator
9 Minus (reduce the level)
10 AIM
11 Ambient light mode
12 Laser positioning mode*
13 Laser safety symbol

3.2 Wall-mounted control keypad

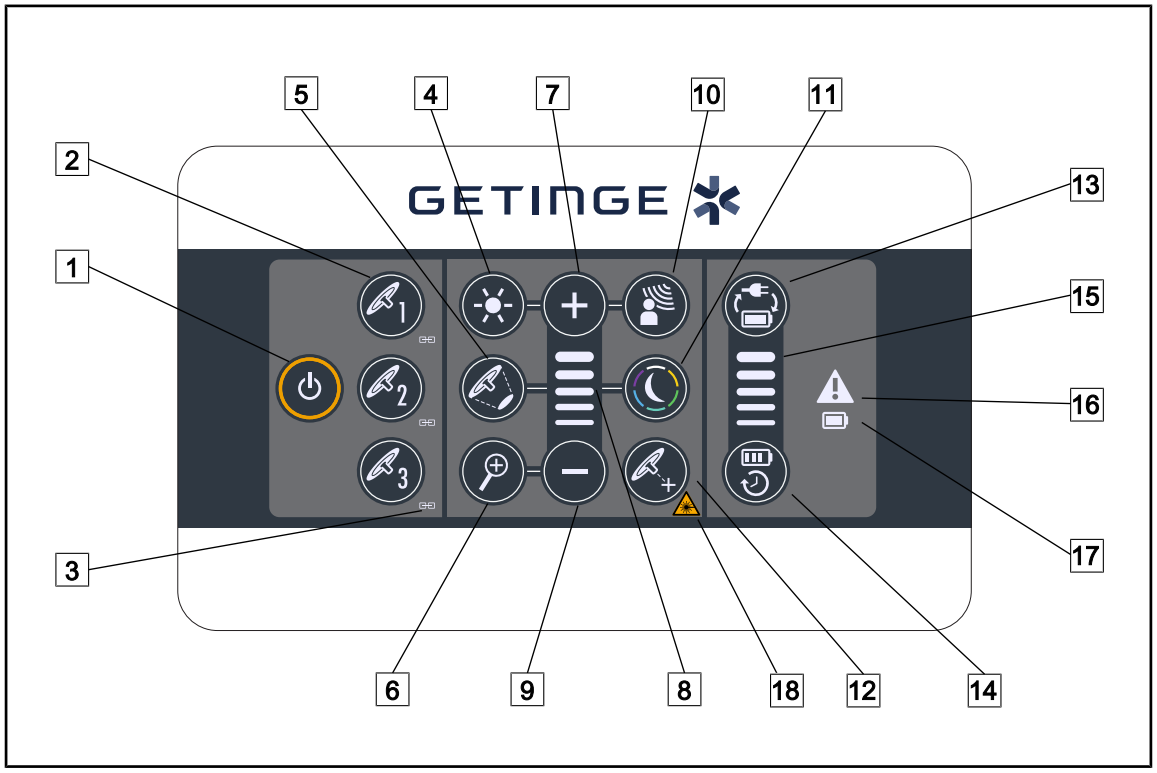


Fig. 32: Wall-mounted control keypad

1 On/Off
2 Lighthead options (1, 2 or 3)
3 Synchronisation indicator
4 Adjustment of illumination
5 Light field diameter variation
6 Camera zoom
7 Plus (increase the level)
8 Level indicator
9 Minus (reduce the level)
10 AIM
11 Ambient light mode
12 Laser positioning mode
13 Battery switchover
14 Battery capacity
15 Battery level indicator
16 Warning indicator
17 Battery indicator
18 Laser safety symbol

3.3 Touchscreen control panel

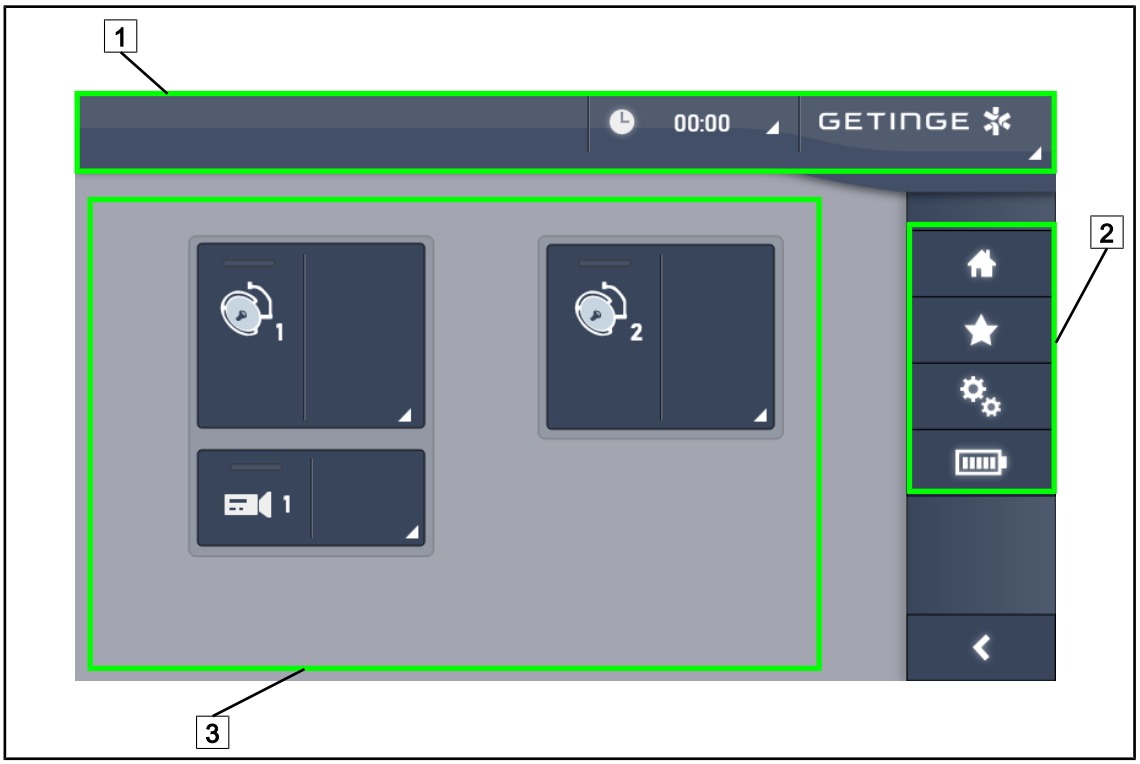


Fig. 33: Touchscreen control panel

1 Status bar
2 Menu bar
3 Active area

Ref.	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. 11: Touchscreen control panel information

Status bar

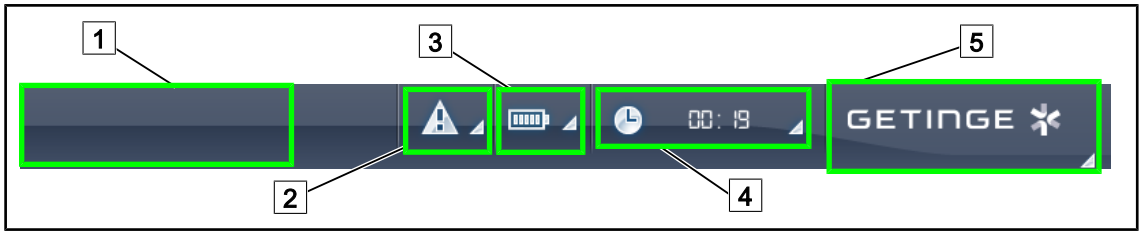


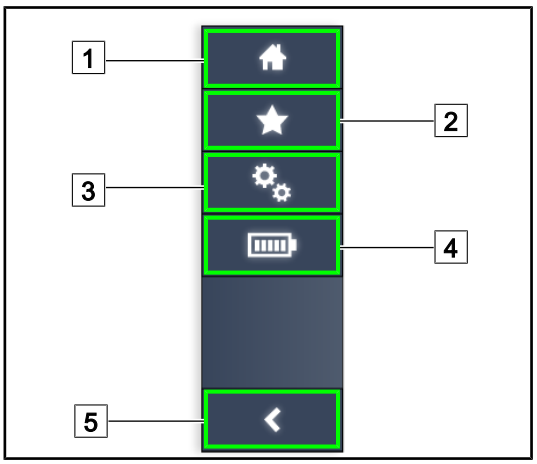
Fig. 34: Touchscreen control panel status bar

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

Ref.	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. ▪ Displayed only if a backup system is present.	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. 12: Touchscreen control panel status bar

Menu bar



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

Fig. 35: 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. 13: Touchscreen control panel status bar

4 Use

4.1 Daily inspections before use

NOTICE

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.

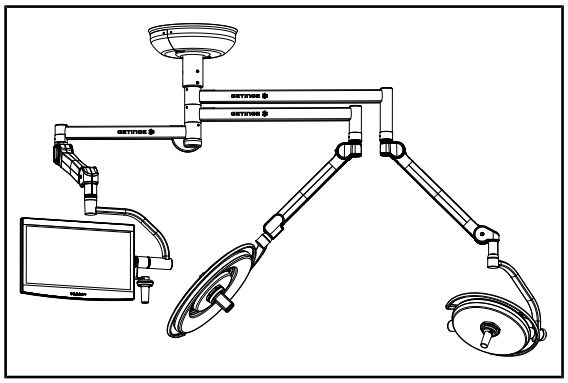


Fig. 36: Integrity of the device

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.

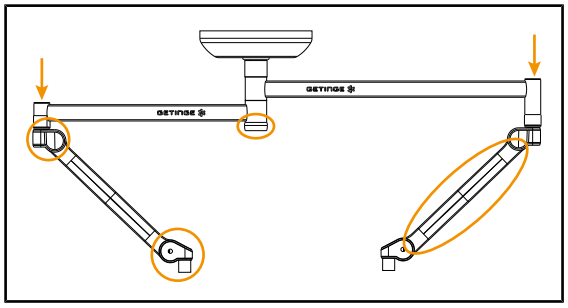


Fig. 37: Suspension covers

Suspension covers

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

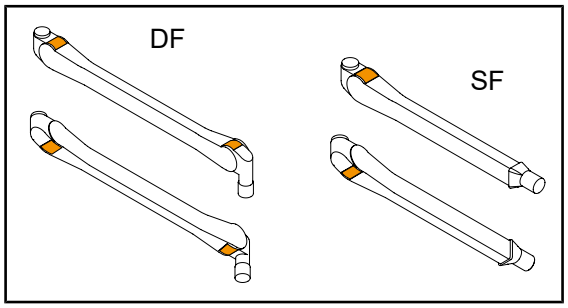


Fig. 38: Half-rings

Half-rings on spring arms

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

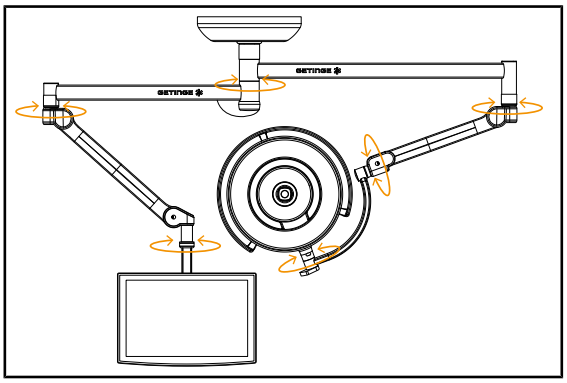


Fig. 39: Stability and drift

Stability and drift of the system

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

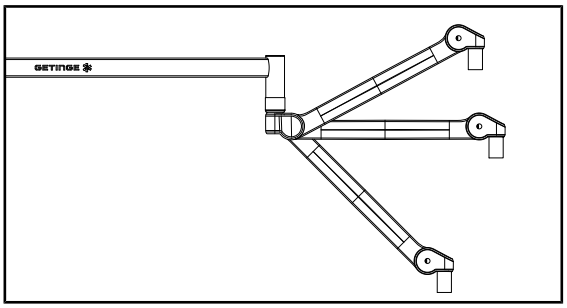


Fig. 40: Spring arm positioning

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.

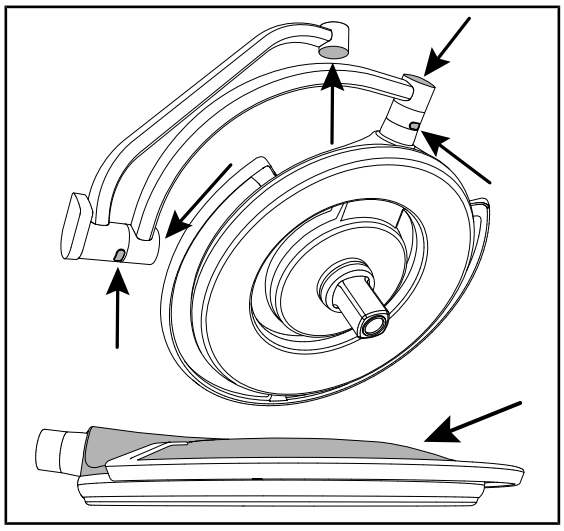


Fig. 41: Silicone caps and lighthead cover

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 are in the proper position and in good condition.
3. If a problem is noted, contact technical support.

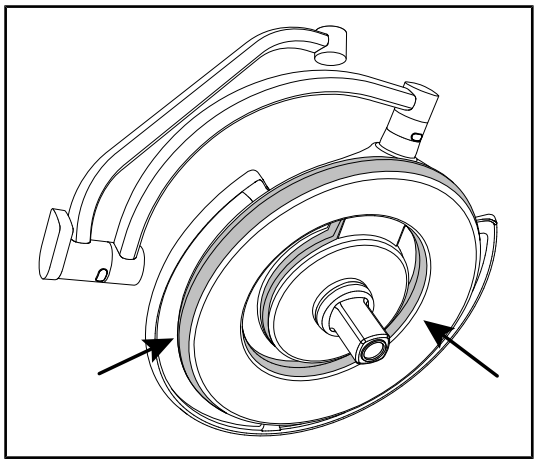


Fig. 42: Lighthead gaskets

Lighthead gaskets

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

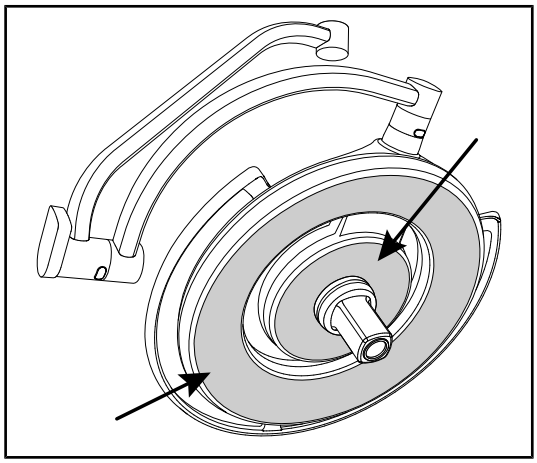


Fig. 43: Lighthead underside

Lighthead underside

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

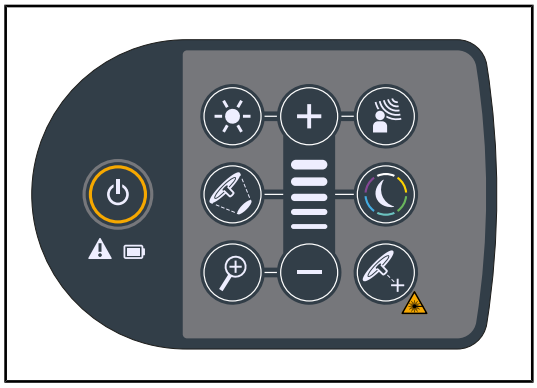


Fig. 44: Condition of lighthead keypad

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.

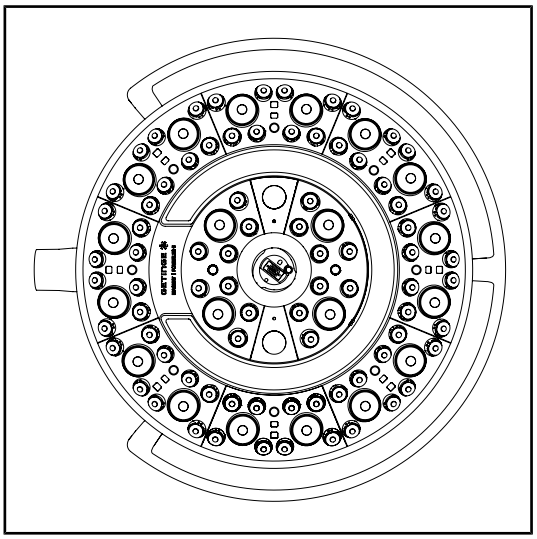


Fig. 45: Operation of LEDs

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 50].
4. Check that all the LEDs are operating.

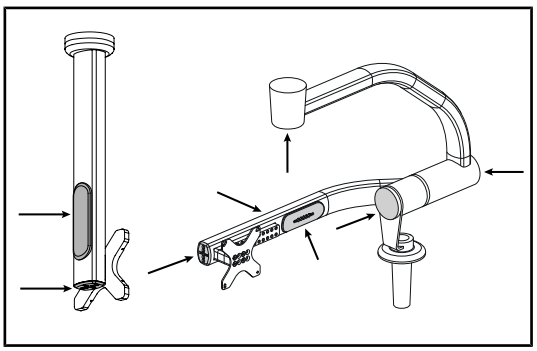


Fig. 46: Screen holder caps

Screen holder silicone caps and grommets

1. Check that the silicone caps on the screen holder are in the proper position and in good condition.
2. Check that the silicone grommets on the screen holder are in the proper position and in good condition.

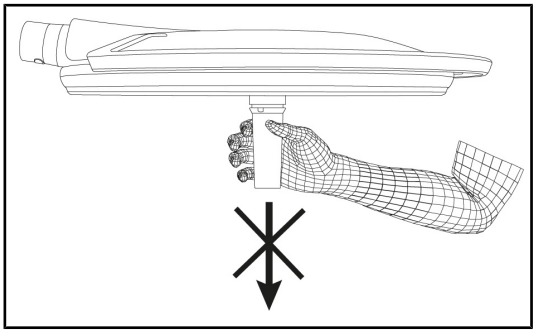


Fig. 47: Holding the handle mount

Holding the handle mount

1. Pull along the handle interface axis to ensure that it holds properly.

For the attention of sterilisation personnel

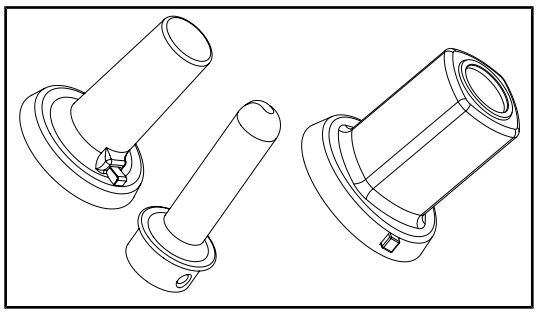


Fig. 48: Sterilisable handles

Condition of the sterilisable handles

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

NOTICE

If the device has a backup system, perform a battery backup test. To test from the wall-mounted control keypad, the lightheads must be turned off and the test start button must be backlit to enable the test to be started. To test from the touchscreen control panel, the battery icon must be displayed in the status bar.

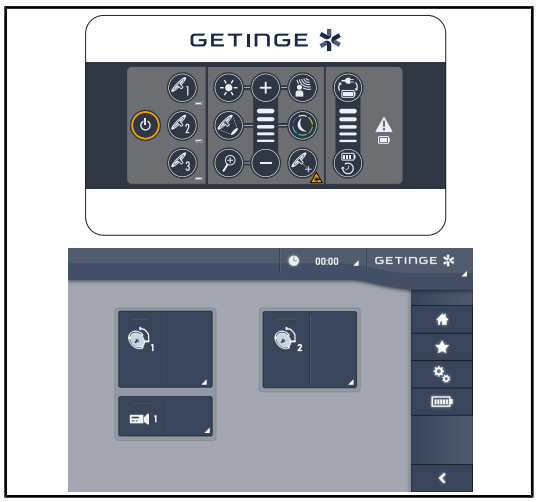


Fig. 49: Battery backup test

Battery backup test (only for a battery-backed system)

1. Perform a battery backup test via the wall-mounted control keypad (From the wall-mounted control keypad [⏩ Page 95]) or 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 From the lighthead or wall-mounted control keypad

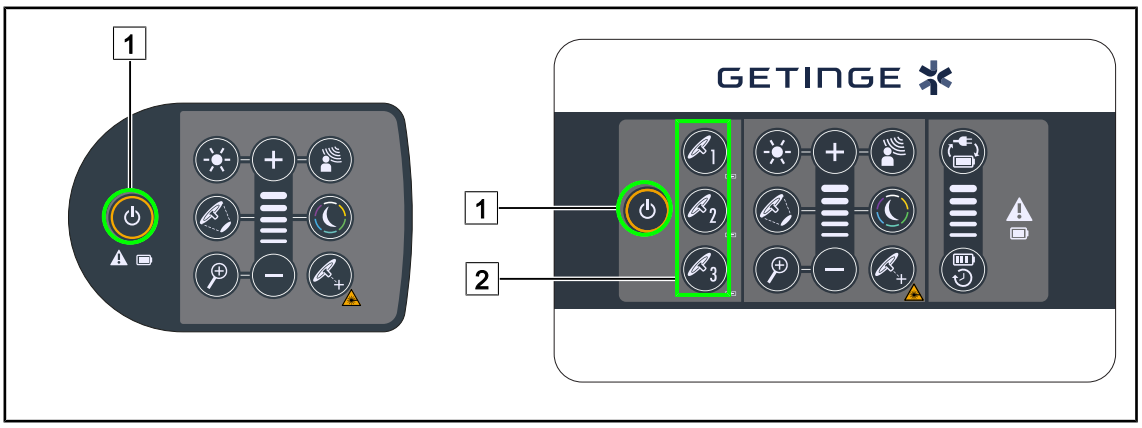


Fig. 50: Turning the light on and off via the keypads

Turning on the light, one lighthead at a time

1. On a wall-mounted control keypad, press the button [2] for the lighthead to be turned on, and hold it until the button is backlit.
2. Press the **On/Off** [1] button to turn on the lighthead.
   - ➢ The LED sectors are turned on in sequence, and the illumination level is set to the last value used when the light was turned off.

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

1. Press **On/Off** [1].
   - ➢ The LED sectors on all lightheads are turned on in sequence, and the illumination level is set to the last value used when the light was turned off.

Turning the light off via the lighthead keypad

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

Turning the light off via the wall-mounted keypad

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

4.2.1.2 From the touchscreen control panel

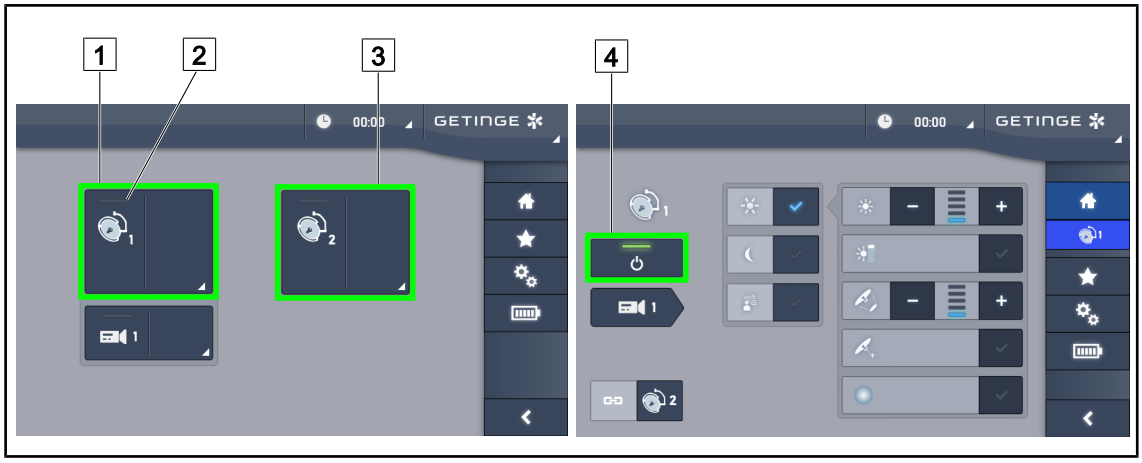


Fig. 51: Turning the light on and off via the touchscreen control panel

Turning on the light

1. Press the **Lighthead 1 active area** [1].
   - ➢ The **operation indicator** [2] is activated and lighthead 1 turns on.
2. Press the **Lighthead 2 active area** [3] and then the **Lighthead 3 active area** if available.
   - ➢ The entire light is now on.

Turning off the light

1. Press the **Lighthead 1 active area** [1].
   - ➢ The lighthead control page is displayed.
2. Press **Lighthead ON/OFF** [4].
   - ➢ Lighthead 1 and the lighthead 1 **operation indicator** are turned off.
3. Proceed in the same way for all lightheads that are on.
   - ➢ The entire light is now off.

4.2.2 Adjusting the illumination

4.2.2.1 From the lighthead or wall-mounted control keypad

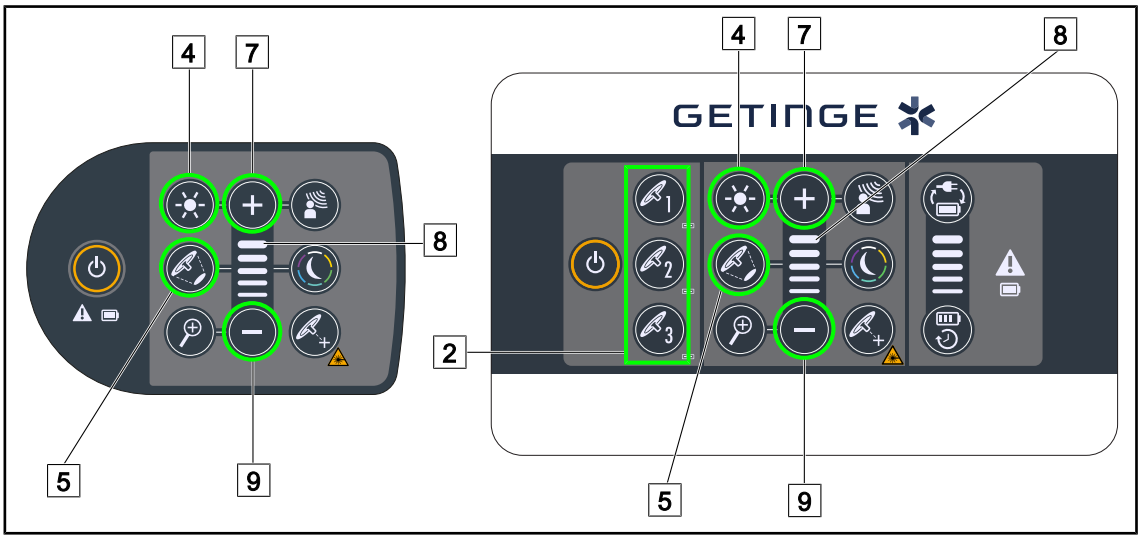


Fig. 52: Adjusting the illumination using the control keypads

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

Adjusting the light intensity

1. Press the **Intensity adjustment** 4 button.
   ➢ The button is backlit on the keypad.
2. Press **Plus** 7 to increase the light intensity level of the lighthead(s).
3. Press **Minus** 9 to decrease the light intensity level of the lighthead(s).

Enabling/disabling boost mode

1. When the light intensity level is at 100%, press the **Plus** 7 button until the last LED on the level indicator 8 starts flashing.
   ➢ Boost mode is now enabled.
2. To disable Boost mode, press **Minus** 9 or select AIM or Ambient Light 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(s).
3. Press **Minus** 9 to decrease the light field diameter of the lighthead(s).

NOTICE

The Maquet PowerLED II 700 lighthead has three light field diameter levels and the Maquet PowerLED II 500 lighthead has two.

4.2.2.2 From the touchscreen control panel

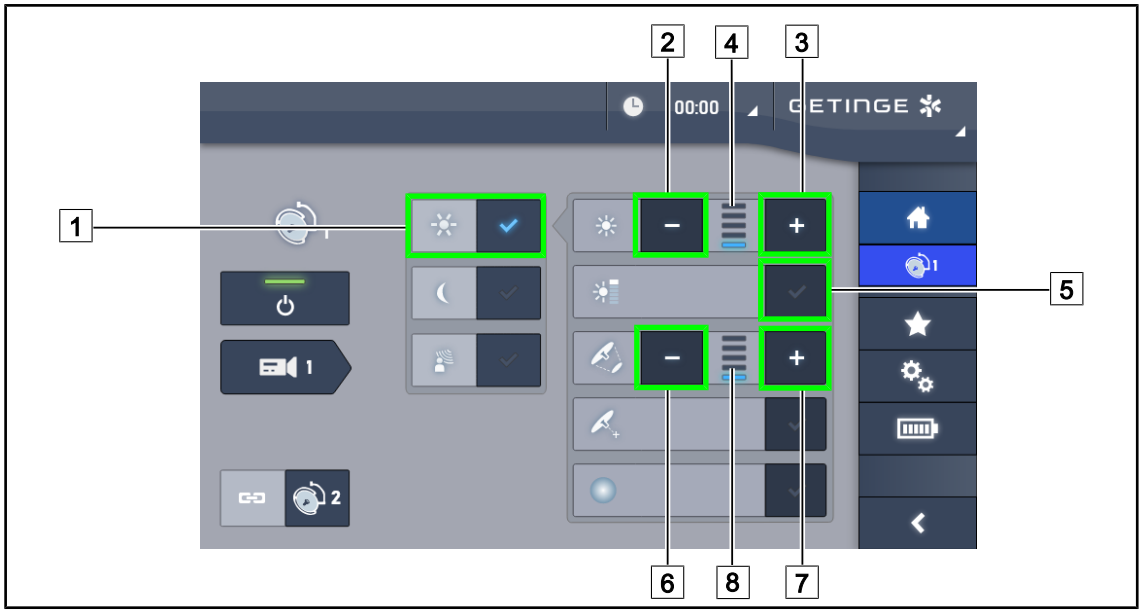


Fig. 53: Adjusting the illumination level via the touchscreen control panel

Adjusting the light intensity

1. From the lighthead page, press the **Illumination adjustment** 1 button.
   - ➢ When enabled, the button is blue.
2. Press **Increase intensity** 3 to increase the light intensity of the lighthead(s) 4.
3. Press **Decrease intensity** 2 to decrease the light intensity of the lighthead(s) 4.

Enabling boost mode

1. From the lighthead page, press the **Illumination adjustment** 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(s) concerned.

Adjusting the light field diameter

1. From the lighthead page, press the **Illumination adjustment** 1 button.
   - ➢ When enabled, the button is blue.
2. Press **Increase diameter** 7 to increase the light field diameter of the lighthead(s) 8.
3. Press **Decrease diameter** 6 to decrease the light field diameter of the lighthead(s) 8.

4.2.3 Ambient light

4.2.3.1 From the lighthead or wall-mounted control keypad

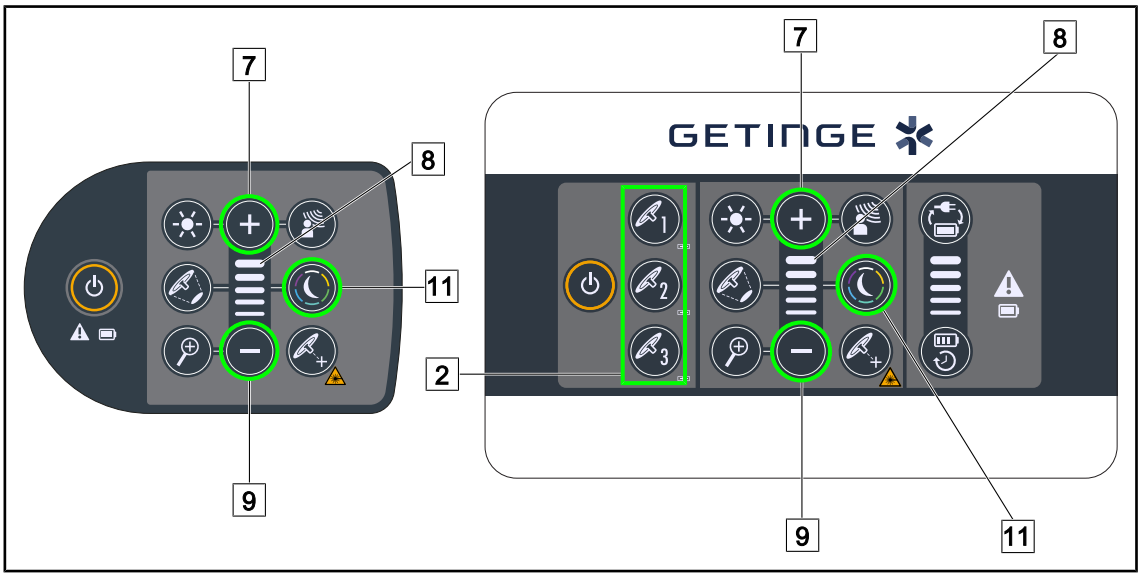


Fig. 54: Adjusting the ambient light via the keypads

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

Selecting the ambient light colour

1. Press **Ambient light mode** 11 until the button is backlit on the keypad.
   ➢ The ambient light is enabled with the last selected colour.
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(s) 8.
3. Press **Minus** 9 to decrease the light intensity level of the lighthead(s) 8.

4.2.3.2 From the touchscreen control panel

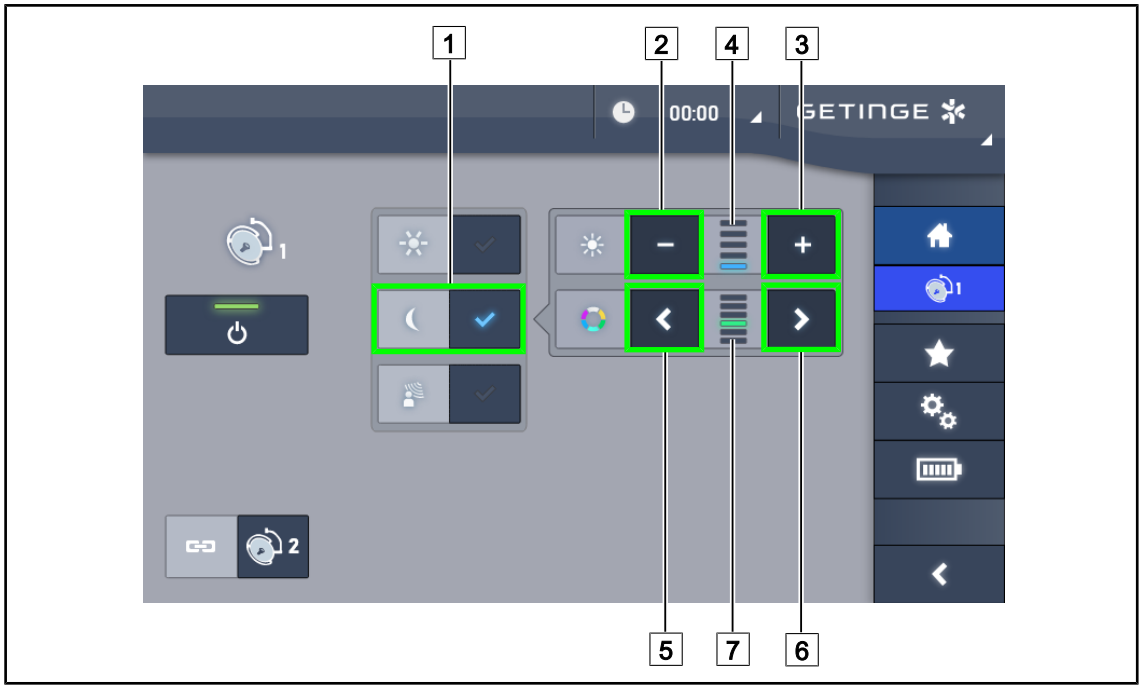


Fig. 55: Adjusting the ambient light via the touchscreen control panel

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(s) [4].
3. Press **Minus** [2] to decrease the light intensity level of the lighthead(s) [4].

4.2.4 AIM AUTOMATIC ILLUMINATION MANAGEMENT*

4.2.4.1 From the lighthead or wall-mounted control keypad

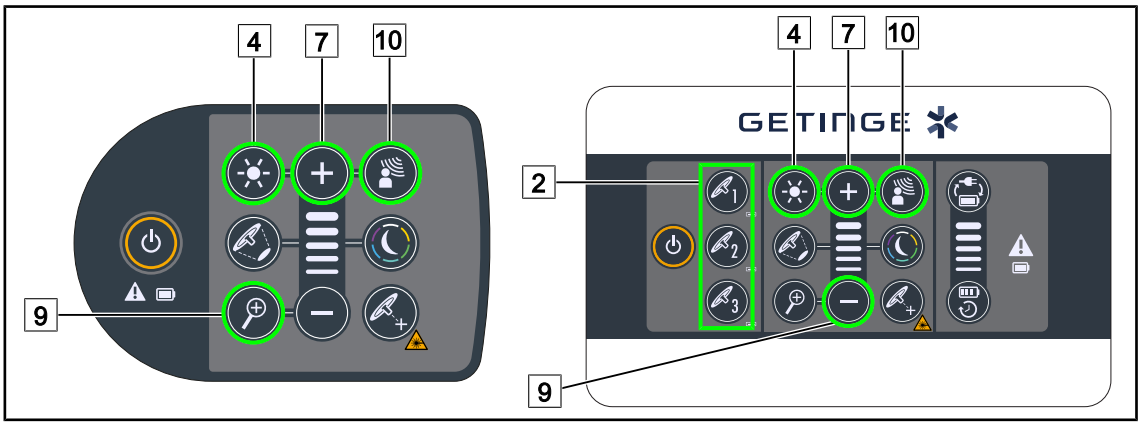


Fig. 56: AIM using the control keypads

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

Enabling/disabling AIM

1. Enable AIM by pressing the **AIM** [10] button.
   - ➢ The **AIM** [10] and **Illumination adjustment** [4] buttons are backlit on the keypad and AIM is enabled.
2. Disable AIM by pressing the **AIM** [10] button.
   - ➢ The **AIM** [10] button is no longer backlit on the keypad and AIM 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 lighthead(s).
2. When AIM mode is enabled, press **Minus** [9] to decrease the light intensity level of the lighthead(s).

NOTICE

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

4.2.4.2 From the touchscreen control panel

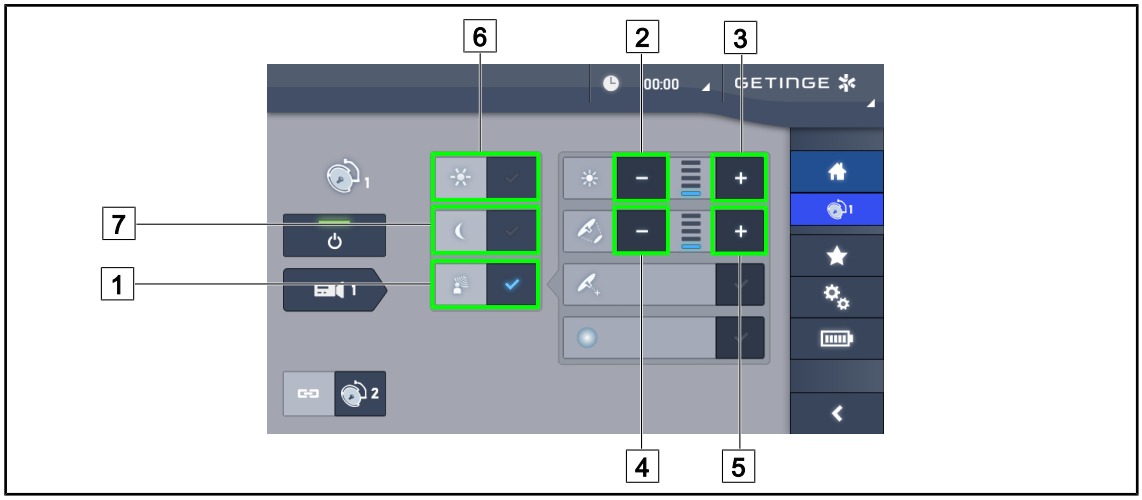


Fig. 57: AIM using the touchscreen control panel

Enabling/disabling AIM

1. Enable AIM by pressing the **AIM** 1 button.
   - ➢ The button is lit blue and AIM is enabled on the lighthead(s) concerned.
2. Disable the AIM by pressing **Illumination adjustment** 6 or **Ambient light mode** 7.
   - ➢ The button turns off and the selected mode button is backlit. AIM is then disabled on the lighthead(s) concerned.

Adjusting the light intensity with AIM

1. Press **Increase intensity** 3 to increase the light intensity of the lighthead(s).
2. Press **Decrease intensity** 2 to decrease the light intensity of the lighthead(s).

NOTICE

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

Adjusting the light field diameter with AIM

1. Press **Increase diameter** 5 to increase the light field diameter of the lighthead(s).
2. Press **Decrease diameter** 4 to decrease the light field diameter of the lighthead(s).

4.2.5 Comfort Light (available only with the touchscreen control panel)

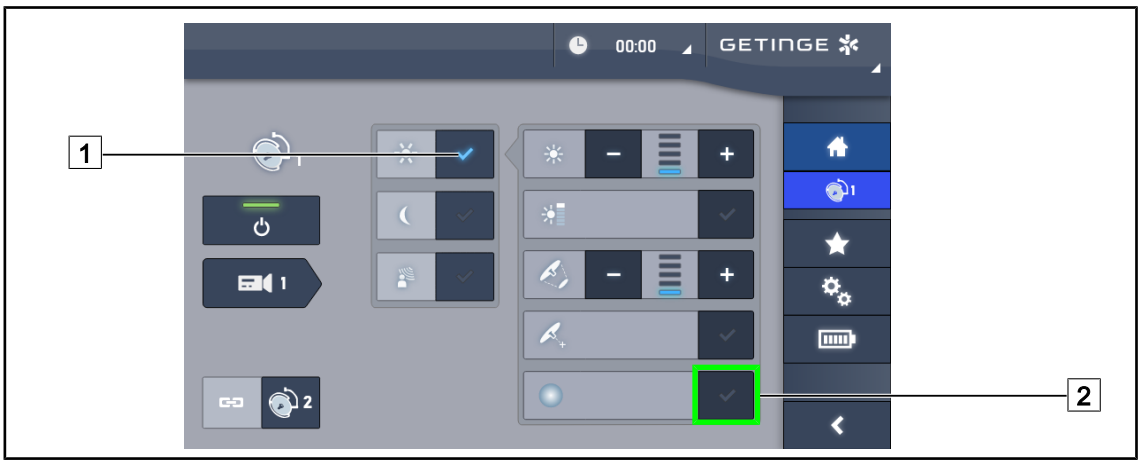


Fig. 58: Comfort Light

Prerequisites:

- Illumination adjustment mode is enabled [1].

1. Press **Comfort Light mode** [2].
   ➢ The button is lit blue and Comfort Light mode is enabled on the lighthead(s) concerned.
2. When Comfort Light mode is enabled, press the **Comfort Light mode** [2] button to disable it.
   ➢ The button turns off and Comfort Light mode is disabled on the lighthead(s) concerned.

4.2.6 Synchronising the lightheads

4.2.6.1 From the wall-mounted control keypad

Fig. 59: Synchronising the lightheads via the wall-mounted keypad

Synchronising the lightheads

1. Adjust one of the lightheads to the desired settings.
2. Press the button 1 for the lighthead to be synchronised and hold it until the button is backlit. Repeat this step to synchronise a third lighthead.
   - ➢ The lightheads are now synchronised and all changes on one lighthead will result in the same changes being applied to the other lighthead(s).

Desynchronising the lightheads

1. To desynchronise the desired lighthead(s), press the button 1 for the lighthead to be desynchronised and hold it until the button is no longer backlit, or modify the status of a lighthead using its local control keypad.
   - ➢ The lightheads are no longer synchronised.

NOTICE

Special case: To synchronise lightheads with ambient light mode, this mode must be active on the lightheads concerned before synchronisation.

4.2.6.2 From the touchscreen control panel

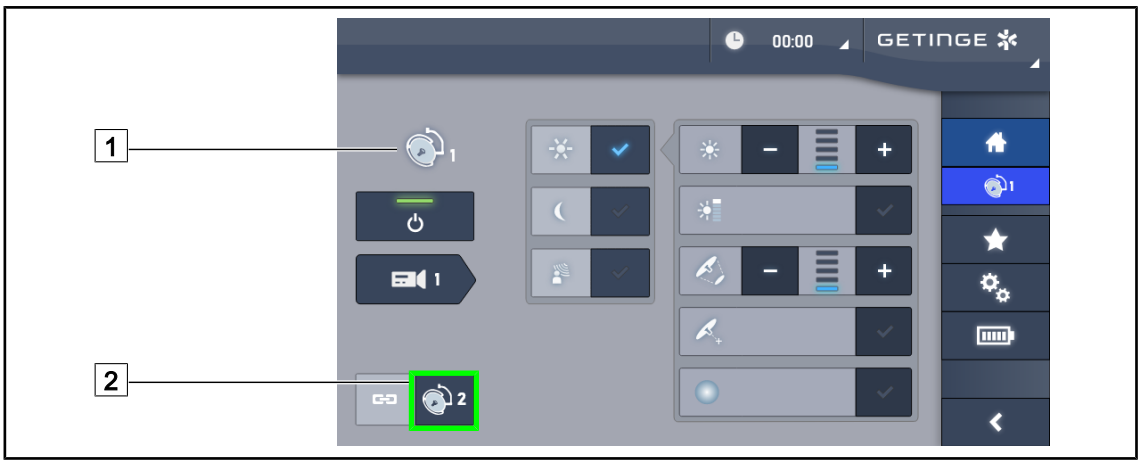


Fig. 60: Synchronising the lightheads

1. Configure one of the lightheads [1] to the desired settings.
2. Press **Synchronise** [2].
   - ➢ The lightheads are now synchronised and all changes on one lighthead will result in the same changes being applied to the other lighthead(s).
3. Press **Synchronise** [2] again to desynchronise the lightheads.
   - ➢ The lightheads are desynchronised.

NOTICE

Special case: To synchronise lightheads with ambient light mode, this mode must be active on the lightheads concerned before synchronisation.

4.2.7 LMD* (with touchscreen control panel only)

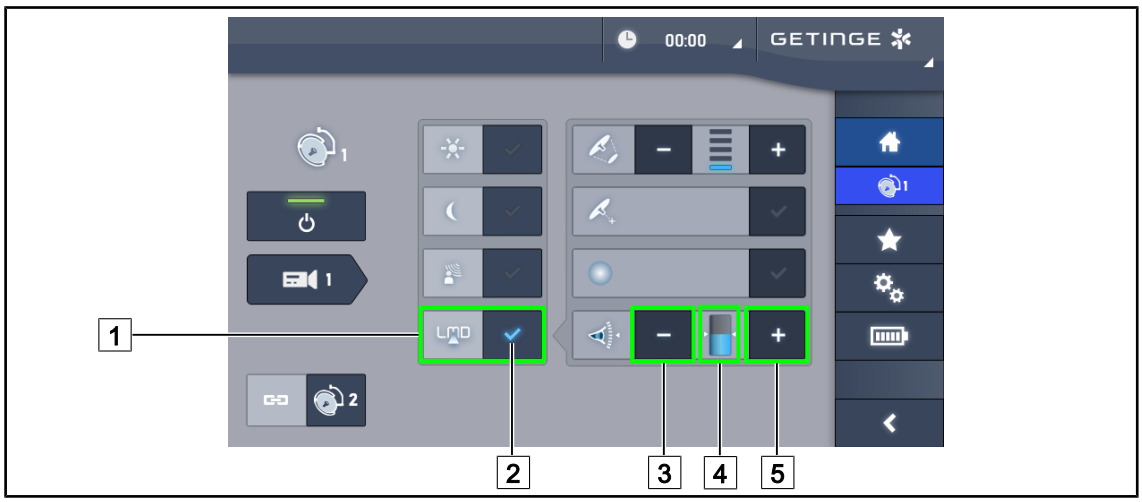


Fig. 61: LMD page

Enabling/disabling LMD mode

1. Set the desired light intensity that is comfortable for the surgeon.
2. Next press **LMD** [1].
   - ➢ The LMD indicator is lit blue [2] and LMD is enabled on the lighthead.
3. When LMD is enabled, press **LMD** [1] to disable it.
   - ➢ The LMD indicator [2] turns off and LMD is disabled on the lighthead.

Adjusting the luminance setpoint value

1. Press **Increase luminance** [5] to increase the luminance of the light.
2. Press **Decrease luminance** [3] to decrease the luminance of the light.
   - ➢ The luminance level of the light concerned varies as shown by the luminance level indicator [4].

NOTICE

If the lighthead is at its maximum level, the luminance cannot be increased and the **Plus** [4] button is shaded and inactive.
If the lighthead is at its minimum level, the luminance cannot be decreased and the **Minus** [3] button is shaded and inactive.

The luminance level indicator [5] 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. 14: Luminance levels

4.2.8 Presets (with touchscreen control panel only)

4.2.8.1 Selecting or storing a preset

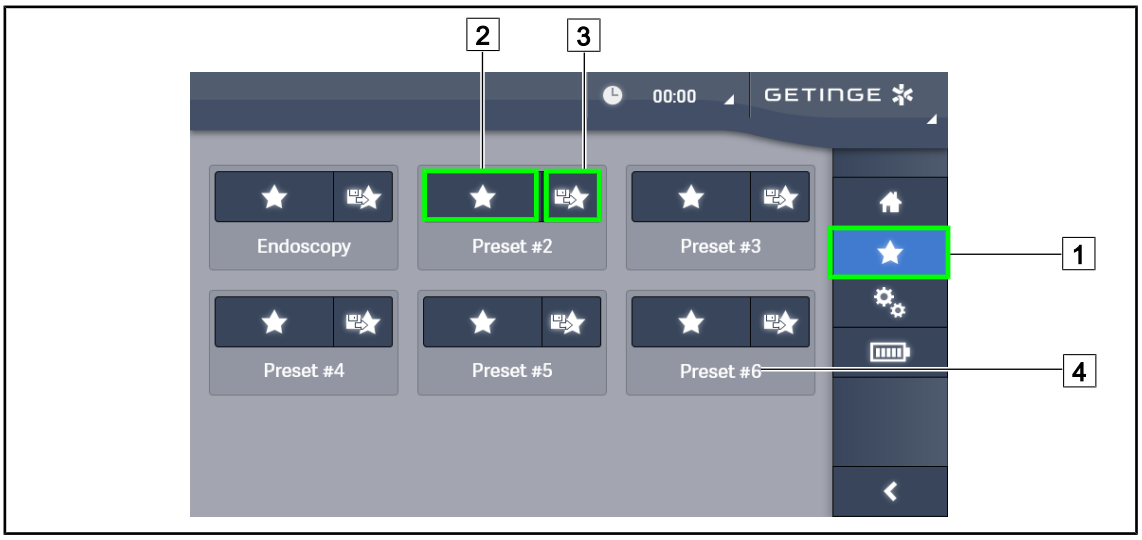


Fig. 62: Presets page

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. 63: 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

Applications	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. 15: Factory default lighthead presets

Applications	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	Large	Large
AIM	Enabled	Enabled	Enabled	Enabled	Enabled	Enabled
Auto laser	–	–	–	–	–	–
Comfort Light	Enabled	Enabled	Enabled	Enabled	Enabled	Enabled
Endo	–	–	–	–	–	–

Tab. 16: Factory default lighthead presets (continued)

Applications	Uro/ Gyneco	Laparotomy	Orthopaedic	ENT	Plastic surgery	Cardiac surgery
On/Off	–	ON	ON	–	ON	ON
Zoom	–	50%	50%	–	20%	50%
WB	–	Auto	Auto	–	Auto	Auto
Contrast	–	High	Medium	–	Standard	High

Tab. 17: Factory default camera presets

4.3 Installing or removing a sterilisable handle

WARNING!

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

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

WARNING!

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

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

4.3.1 Installing or removing an STG PSX 01 sterilisable handle

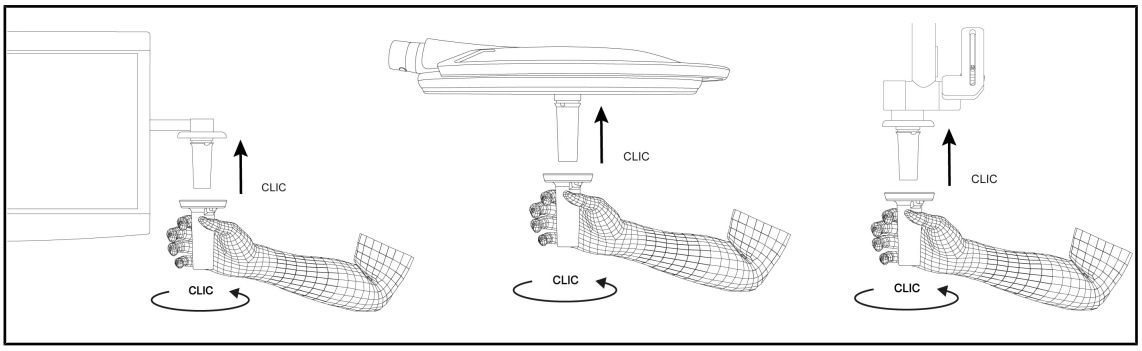


Fig. 64: Installing an STG PSX 01 sterilisable handle

Installing an STG PSX 01 sterilisable handle

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.

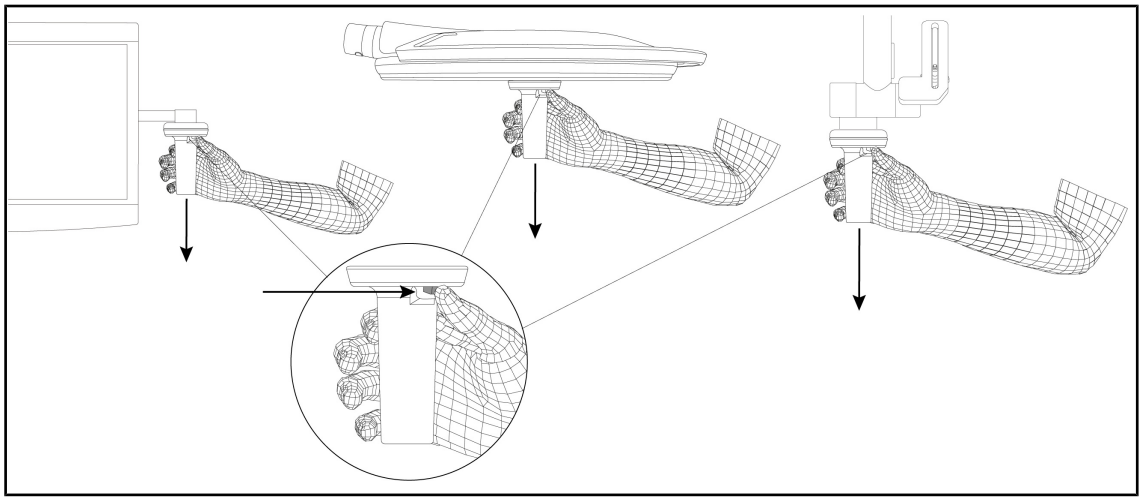


Fig. 65: Removing an STG PSX 01 sterilisable handle

Removing an STG PSX 01 sterilisable handle

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

4.3.2 Installing or removing an STG HLX 01 sterilisable handle

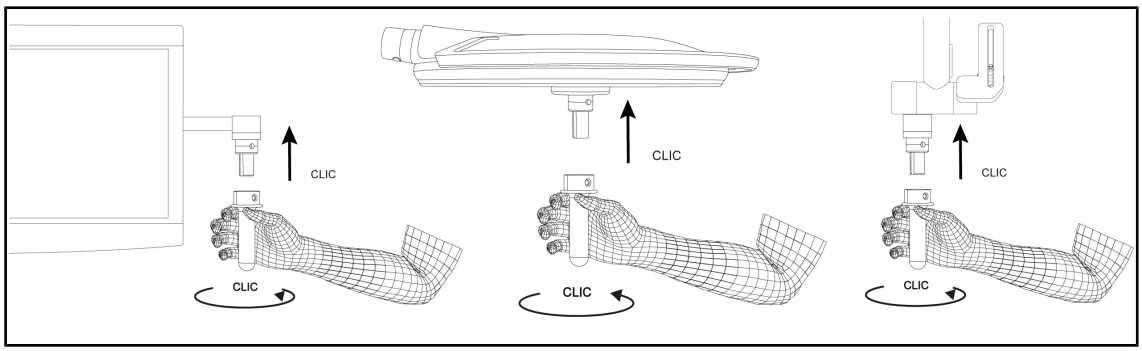


Fig. 66: Installing an STG HLX 01 sterilisable handle

Installing an STG HLX 01 sterilisable handle

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

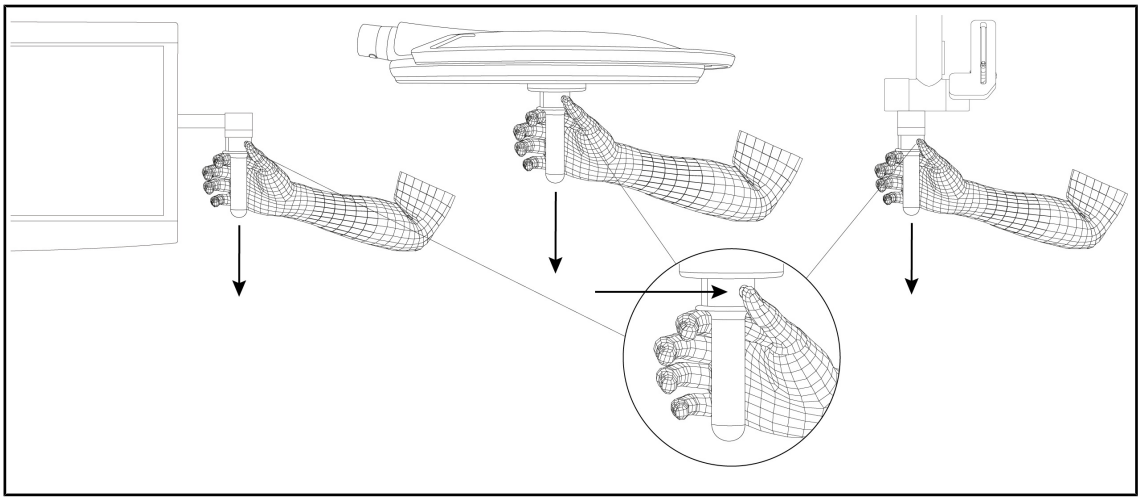


Fig. 67: Removing an STG HLX 01 sterilisable handle

Removing an STG HLX 01 sterilisable handle

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

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

NOTICE

Refer to the instructions supplied with the Devon or Deroyal handle.

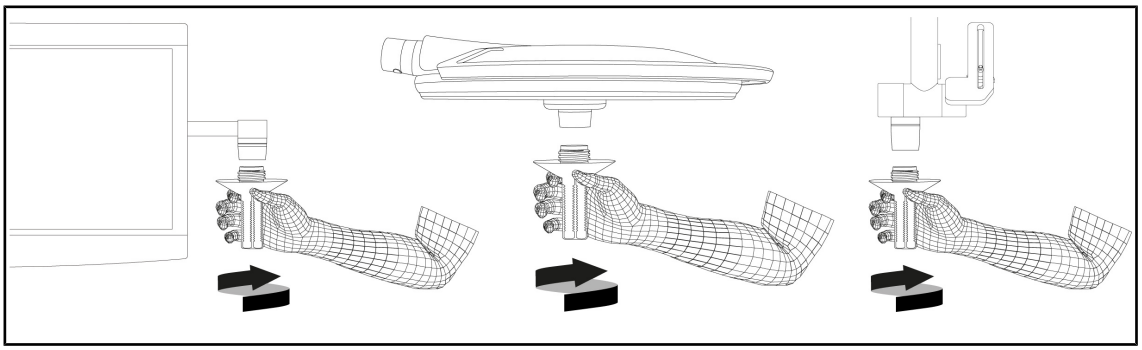


Fig. 68: Installing a DEVON® or DEROYAL® clip-on handle

Installing a DEVON® or DEROYAL® clip-on handle

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

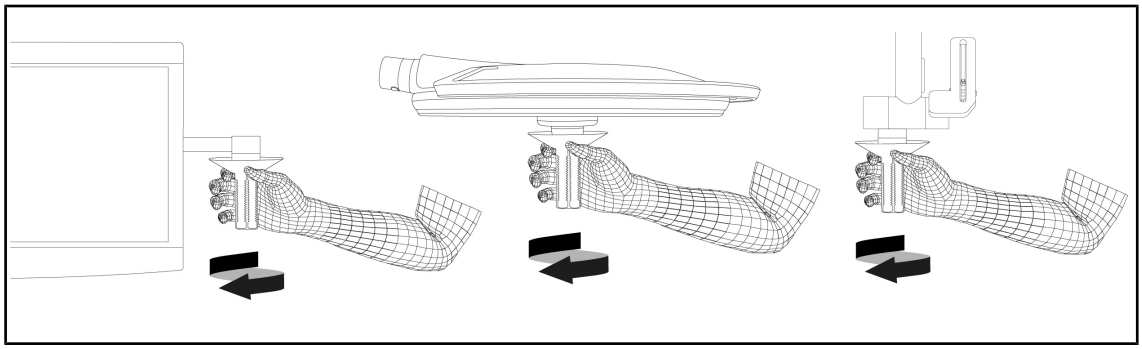


Fig. 69: Removing a DEVON® or DEROYAL® clip-on handle

Removing a DEVON® or DEROYAL® clip-on handle

1. Unscrew the handle from the handle mount.

4.3.4 Installing or removing an STG PSX VZ 01 sterilisable handle

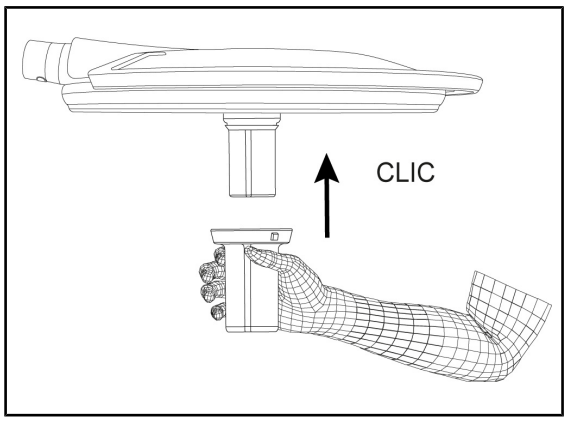


Fig. 70: Installing an STG PSX VZ 01 sterilisable handle

Installing an STG PSX VZ 01 sterilisable handle

1. Inspect the handle and check for cracks or soiling.
2. Fit the handle to the camera or LMD and turn until a click is heard.
3. Check that the handle is firmly in place.
   - ➢ The handle is now locked in place and ready for use.

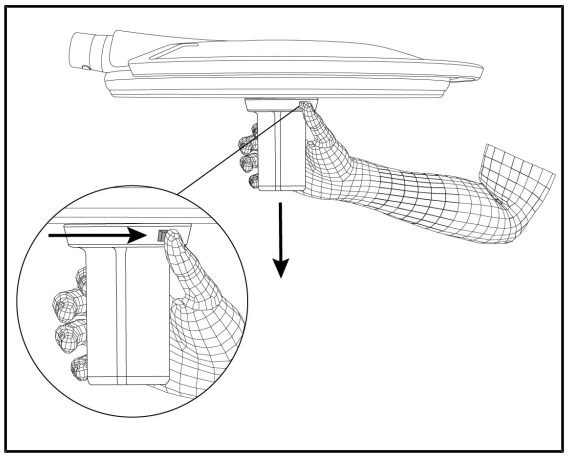


Fig. 71: Removing an STG PSX VZ 01 sterilisable handle

Removing an STG PSX VZ 01 sterilisable handle

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

4.4 Positioning the light

4.4.1 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

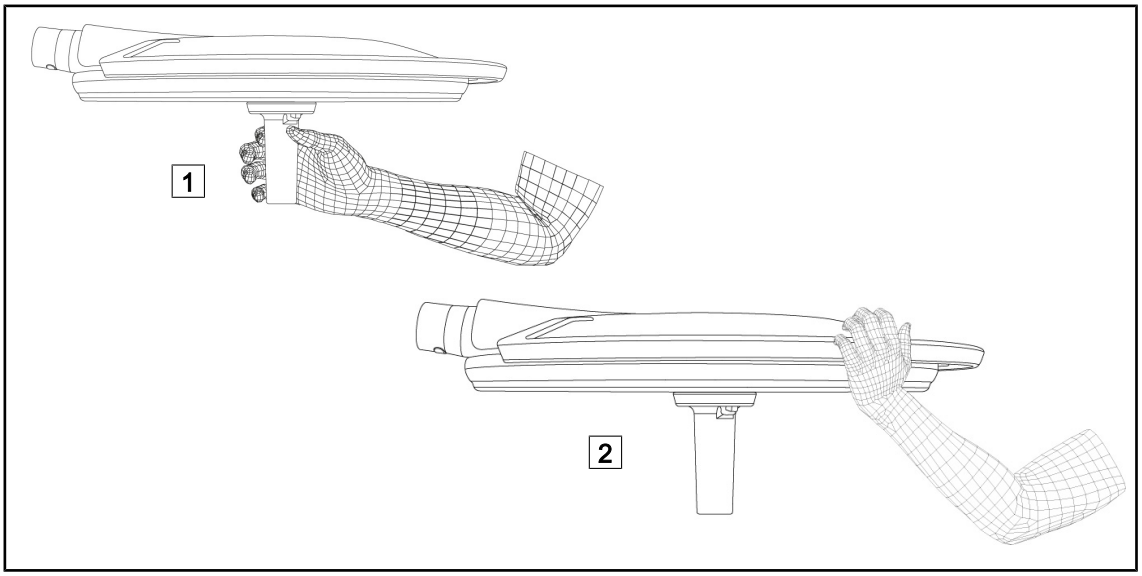


Fig. 72: Manoeuvring the lighthead

- 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

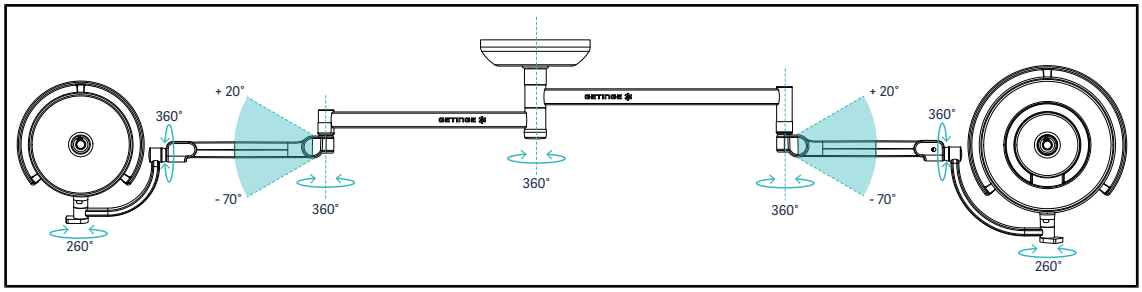


Fig. 73: Rotation angles with SAX suspension and SF arm

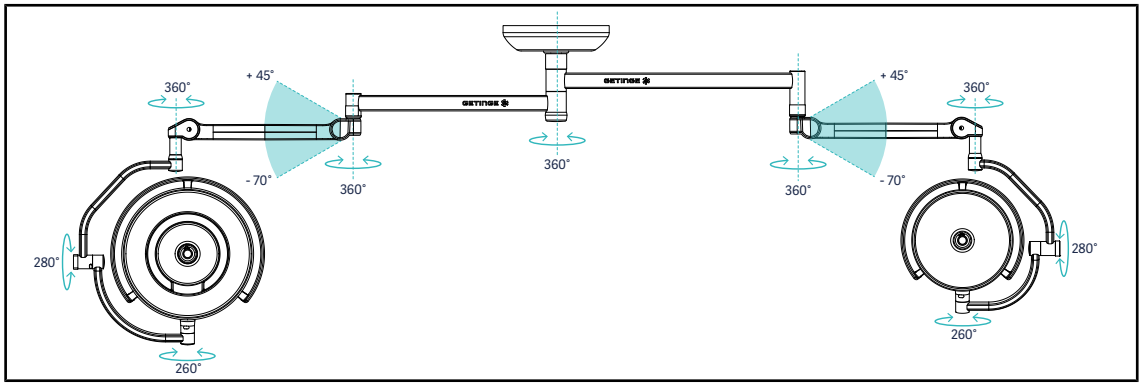


Fig. 74: Rotation angles with SAX suspension and DF arm

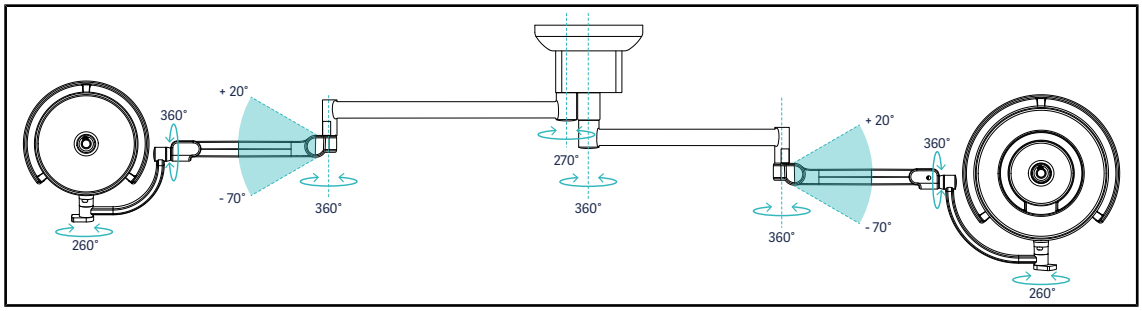


Fig. 75: Rotation angles with SATX suspension and SF arm

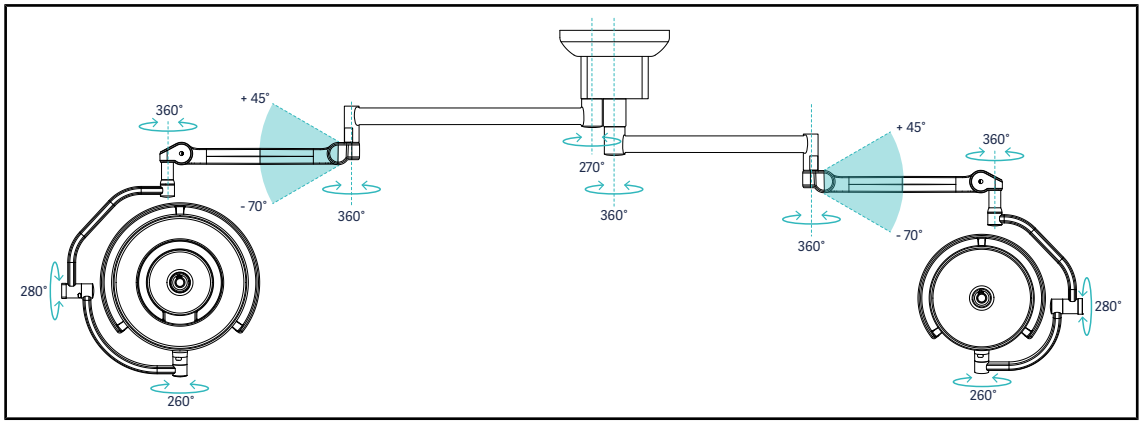


Fig. 76: Rotation angles with SATX suspension and DFarm

4.4.2 Laser positioning assistance

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.

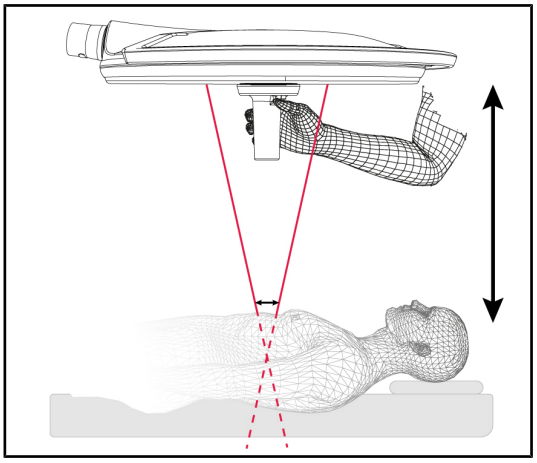


Fig. 77: Laser positioning

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.

4.4.2.1 From the lighthead or wall-mounted control keypad

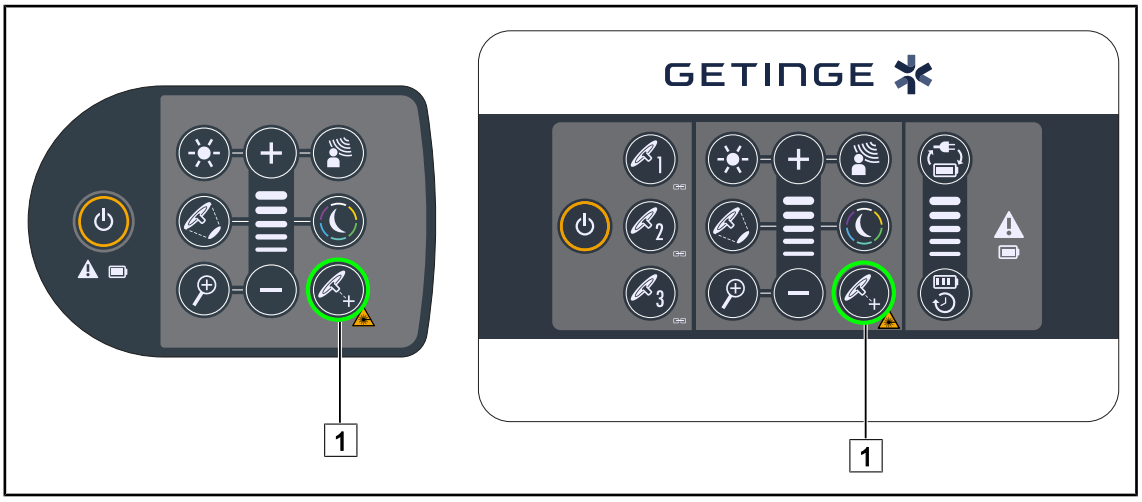


Fig. 78: Enabling the laser positioning assistance function via the keypads

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.

4.4.2.2 From the touchscreen control panel

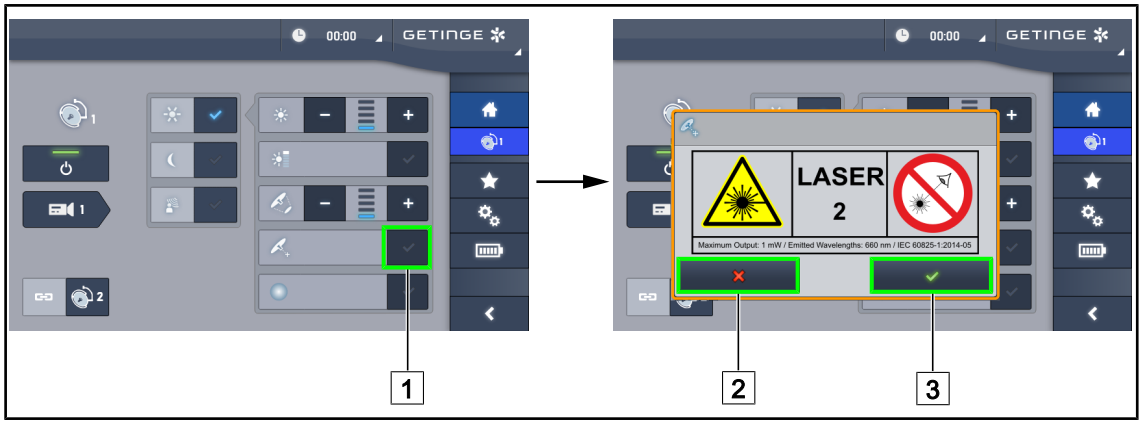


Fig. 79: Enabling the laser positioning assistance function via the touchscreen control panel

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.

4.4.3 Pre-positioning examples

General surgery, abdominal surgery, thoracic surgery

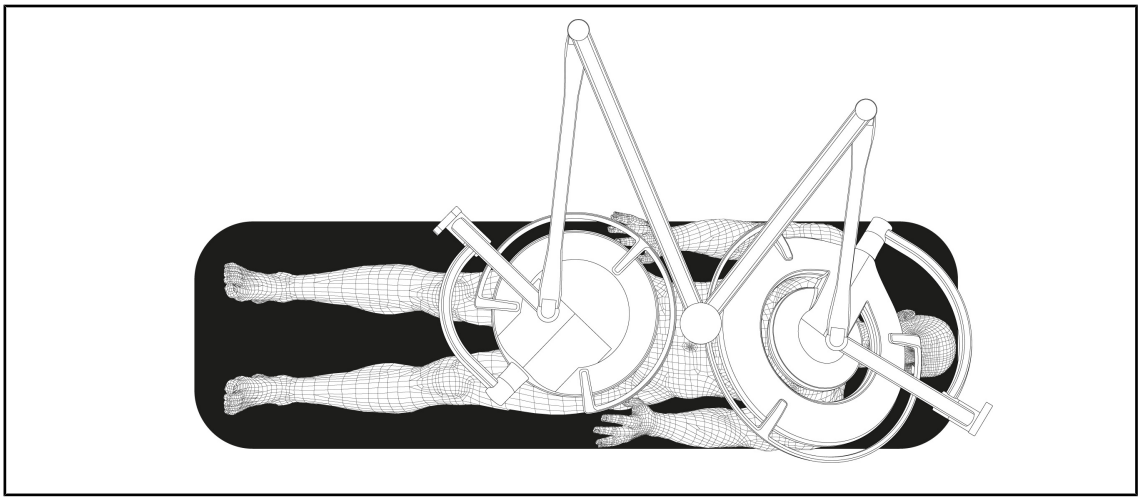


Fig. 80: Pre-positioning for general, abdominal or thoracic surgery

- The suspension arms and spring arms should be positioned opposite the person operating the lights, forming an M shape.
- Check beforehand that the lighthead controls will be accessible if needed for non-sterile personnel.
- The lights should be positioned above the operating table:
  - The main lighthead should be directly above the cavity.
  - The secondary lighthead can be manoeuvred more easily to target various points of interest.

Urology, gynaecology

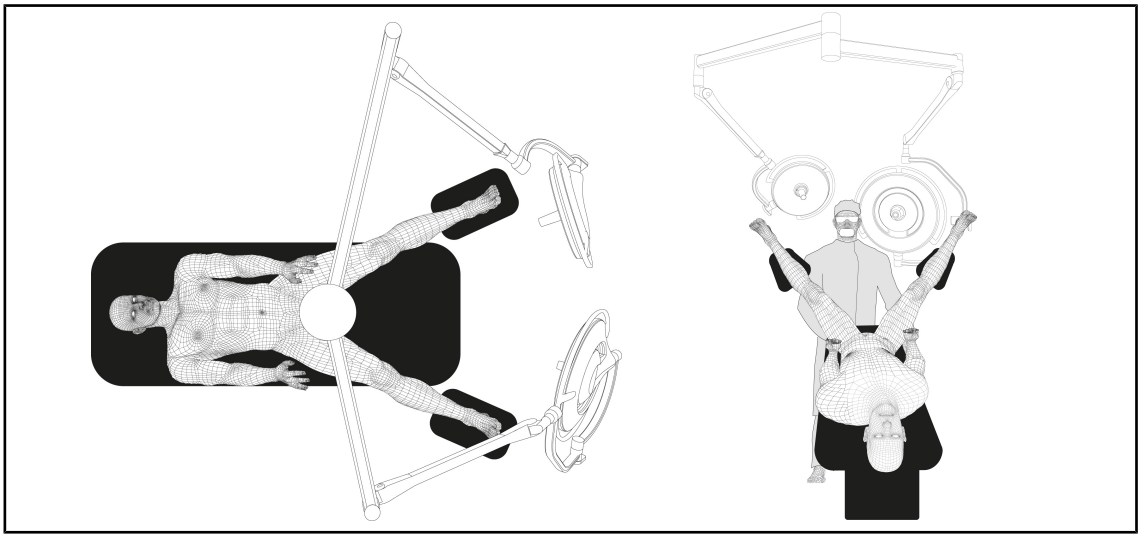


Fig. 81: Pre-positioning for urology or gynaecology

- The suspension arms and spring arms should be located either side of the table, to avoid cluttering the area above the patient and the surgeon’s head.
- The two lights should be located on either side of the surgeon’s shoulders.

ENT, neurology, maxillofacial, ophthalmology

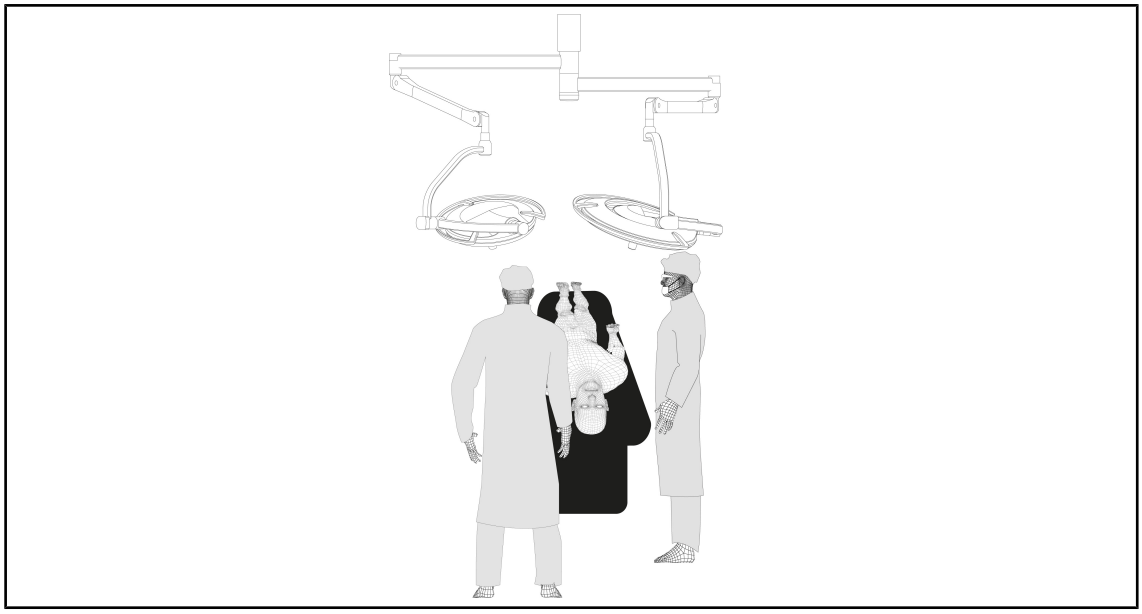


Fig. 82: Pre-positioning for ENT, neurology, maxillofacial or ophthalmology

- The lights should be positioned above the operating table:
  - The main lighthead should be directly above the cavity.
  - The secondary lighthead can be manoeuvred more easily to target various points of interest.

Plastic surgery

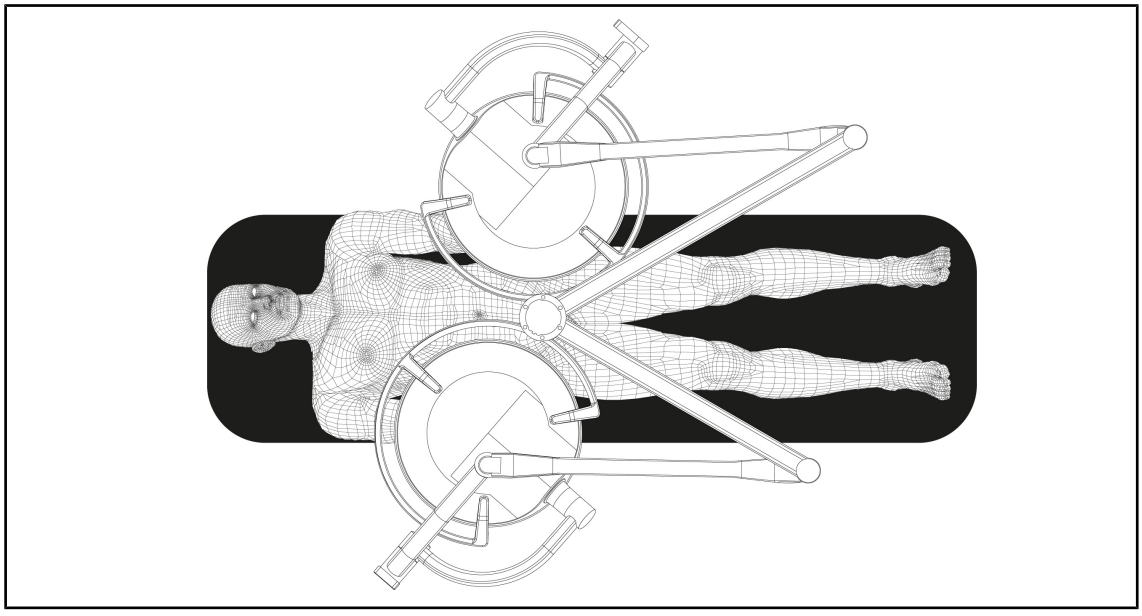


Fig. 83: Pre-positioning for plastic surgery

For plastic surgery, it is recommended to have two lightheads of the same size so as to ensure that exactly the same lighting is provided symmetrically.

4.5 Installing or removing a Quick Lock + device

WARNING!

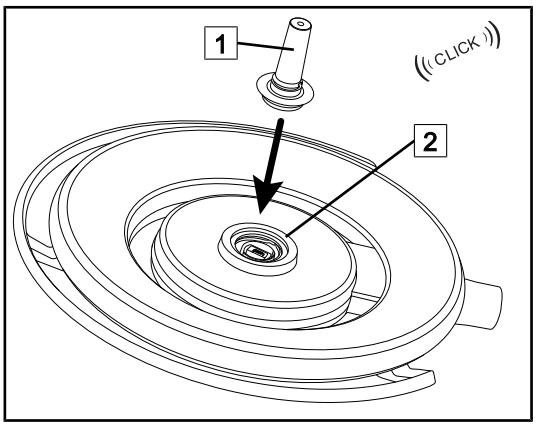
Risk of infection

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 Fitting the device to the lighthead

For the handle mount



- Turn the lighthead over to insert the handle mount
- Insert the handle mount 1 into the base 2 until it clicks.
- Check that the handle mount is fastened securely by moving the lighthead.
- The handle mount is installed.

Fig. 84: Install a handle mount

Camera and LMD

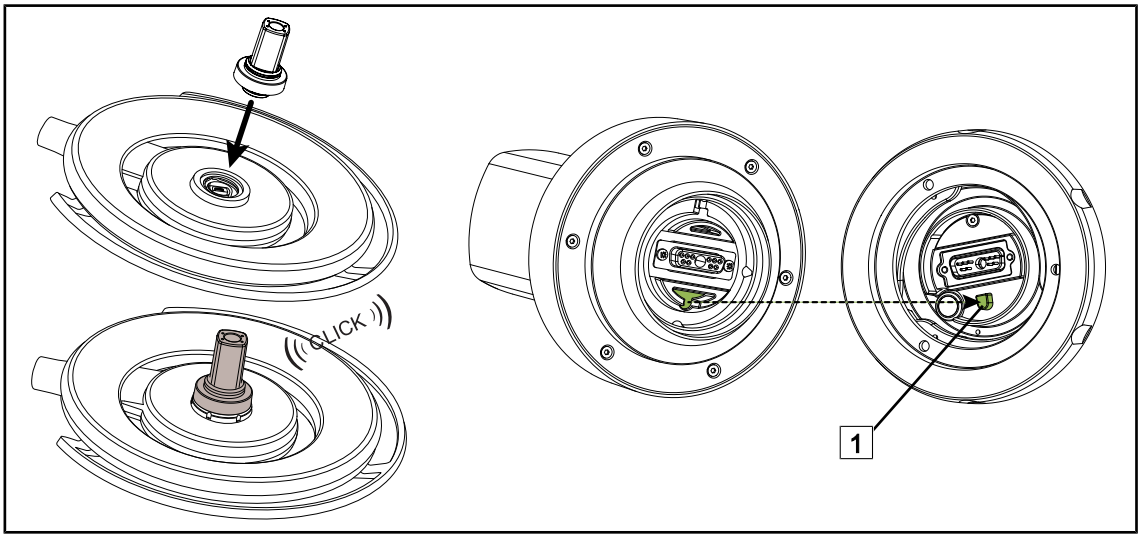


Fig. 85: Installing a Quick Lock + device

- Turn the lighthead over to install the Quick Lock + device.
- Rotate the camera so as to align it with the keyed slot on the base 1.
- Insert until it clicks.
- Check that the handle mount is fastened securely by moving the lighthead.
- The Quick Lock + device is installed.

4.5.2 Removing the Quick Lock + handle mount or camera

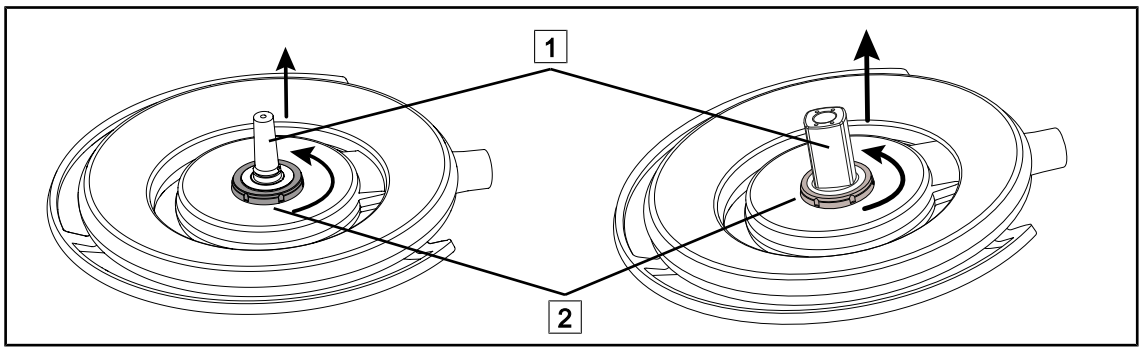


Fig. 86: Removing a Quick Lock + device

- Turn the lighthead over to remove the Quick Lock + device 1
- Turn the locking interface anticlockwise on the base 2.
- Remove the device 1.
- The Quick Lock + device is removed.

4.6 Using the camera

NOTICE

Before installing a camera on a lighthead, check that the lighthead is pre-wired for video.

4.6.1 Controlling the camera

4.6.1.1 From the lighthead or wall-mounted control keypad (zoom only)

NOTICE

When using the control keypads, the camera is turned on and off at the same time as the light.

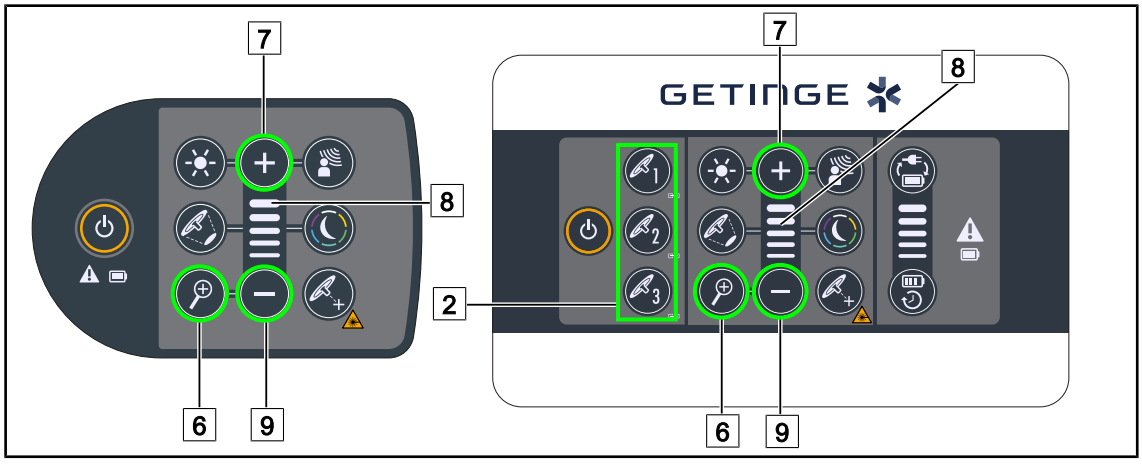


Fig. 87: Camera keypad controls

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

Adjusting the camera zoom

1. Press **Camera Zoom** 6.
2. Press **Plus** 7 or **Minus** 9 to modify the zoom level 8.

4.6.1.2 Control the FHD camera from the touchscreen control panel

NOTICE

When using the touchscreen control panel, the camera may be turned on or off independently of the light.

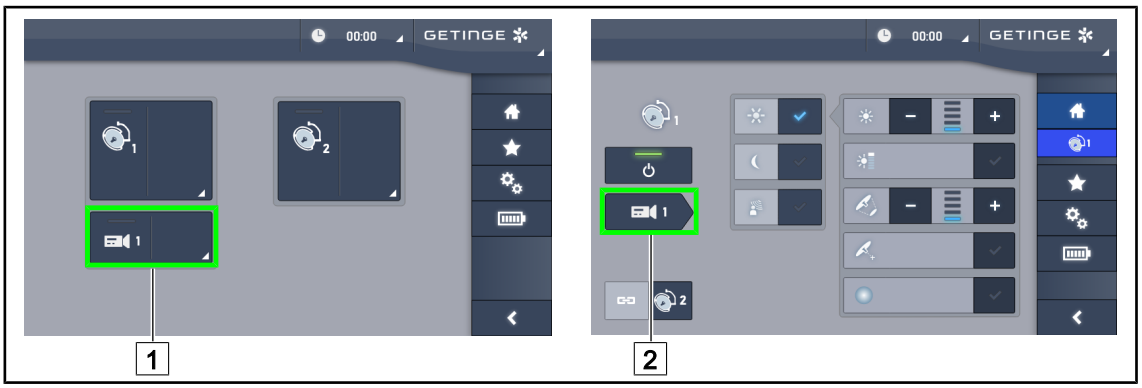


Fig. 88: Turn on the camera

Turning a camera on via the home page

1. Press the **Camera active area** [1] button.
   - ➢ The activated button is lit green and the image is displayed on the screen.
2. Press the **active Camera button** [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. 89: Camera page

Turning off the camera

1. From the camera page, press **Camera ON/OFF** [3] to turn off the camera.
   - ➢ The button light turns off and the camera is turned off.

Pausing the camera

1. Press the **Camera pause** [4] button to pause the camera.
   - ➢ The button is lit blue and the retransmitted image is frozen.
2. Press the **Camera pause** [4] button again to resume video transmission.

Fig. 90: Zoom control

Zooming in and out

1. Press the **Zoom button** [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.

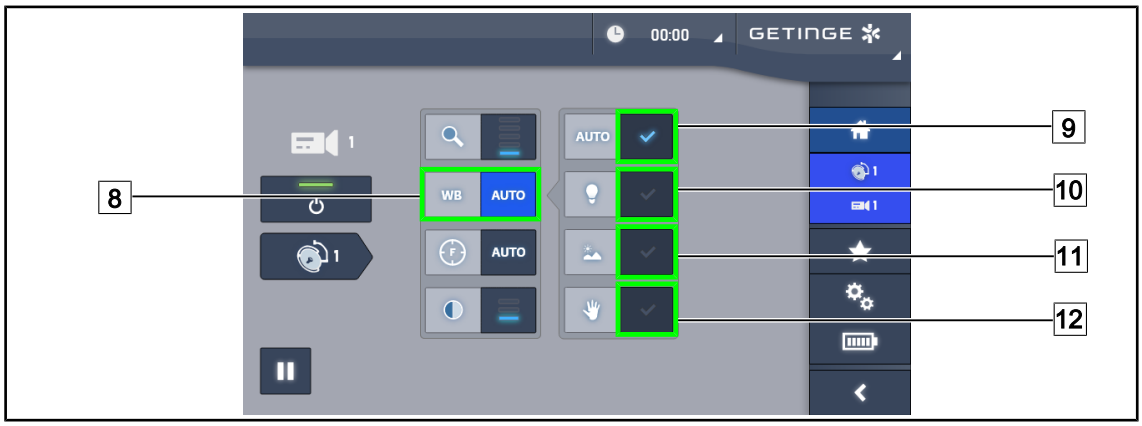


Fig. 91: White balance

Adjusting the white balance automatically

1. Press the **White Balance button** [8].
2. Press the **Automatic balance button** [9] to set the white balance automatically, or the **Artificial light button** [10] to set the white balance to 3200 K or the **Daylight button** [11] to set the white balance to 5800 K.
   - ➢ The selected button is lit blue and the white balance is applied.

Adjusting the white balance manually

1. Press the **White Balance button** [8].
2. Place a uniform white surface under the camera.
3. Press the **Manual balance button** [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 applied.

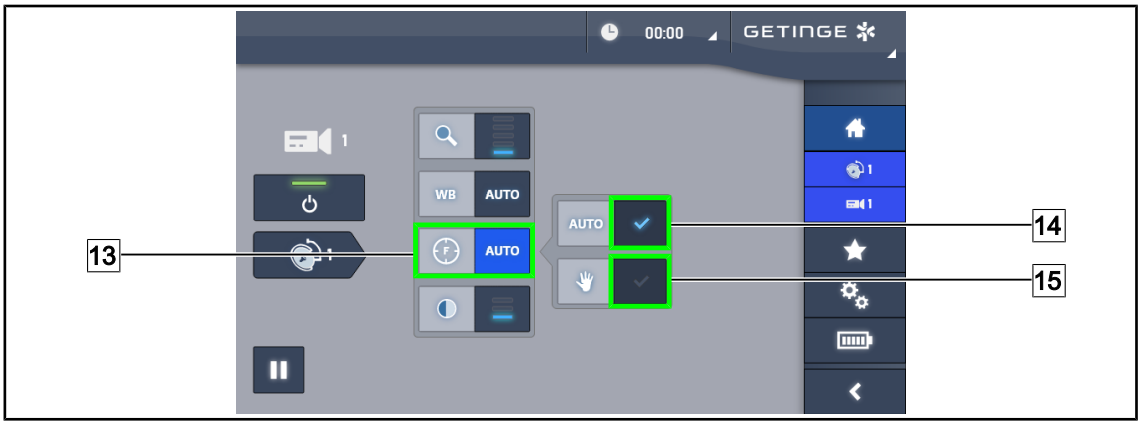


Fig. 92: Setting the focus

Setting the focus automatically

1. Press the **Focus button** 13 to access the focus adjustment menu.
2. Press the **Auto Focus button** 14.
   ➢ The button is lit blue and the camera focus is set to automatic.

Setting the focus manually

1. Press the **Focus button** 13 to access the focus adjustment menu.
2. Press the **Auto Focus button** 14.
   ➢ The button is lit blue and the camera focus is set to automatic.
3. Position the camera at the desired distance.
4. Press the **Manual Focus button** 15.
   ➢ The button is lit blue and the camera focus is fixed.

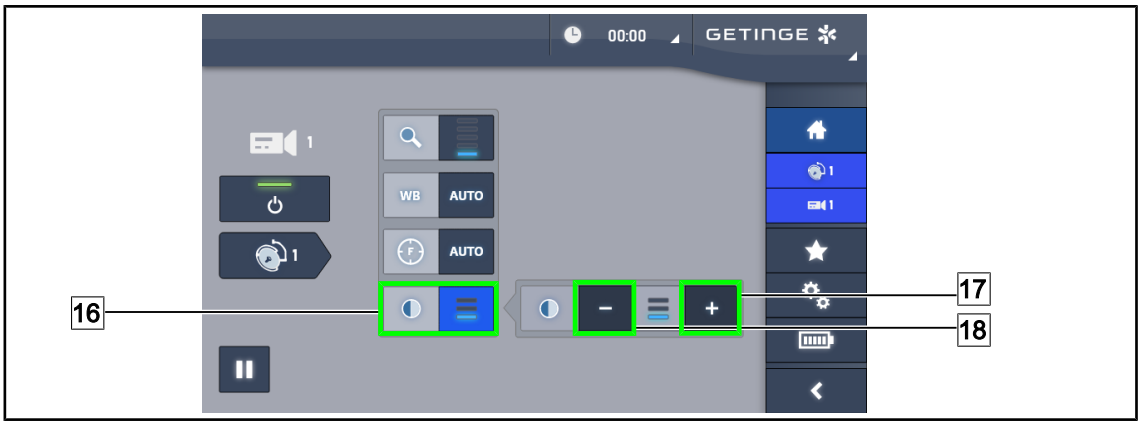


Fig. 93: Contrast adjustment

Adjusting the contrast

1. Press the **Contrast button** 16 to access the contrast adjustment menu.
2. Press the **Increase contrast** 17 or **Decrease contrast buttons** 18 to select one of the three contrast levels.

4.6.1.3 Control the 4K camera from the touchscreen control panel

NOTICE

When using the touchscreen control panel, the camera may be turned on or off independently of the light.

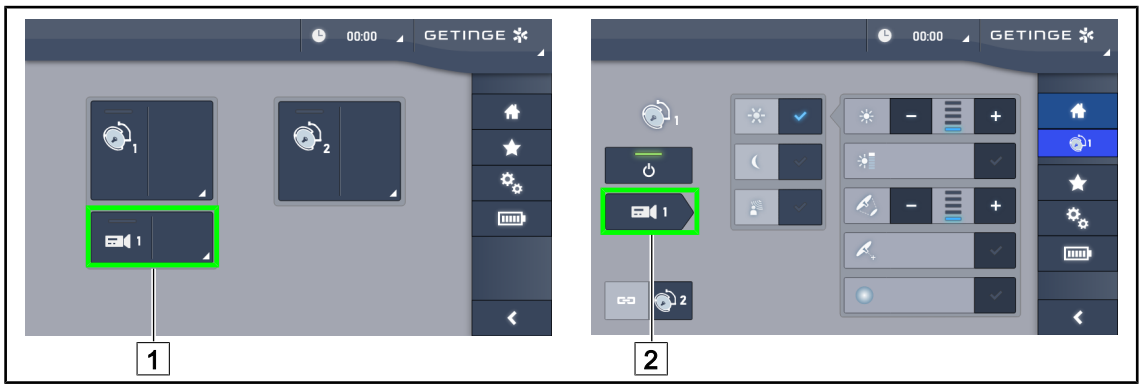


Fig. 94: Turn on the camera

Turning a camera on via the home page

1. Press the **Camera active area** [1] button.
   - ➢ The activated button is lit green and the image is displayed on the screen.
2. Press the **active Camera button** [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.

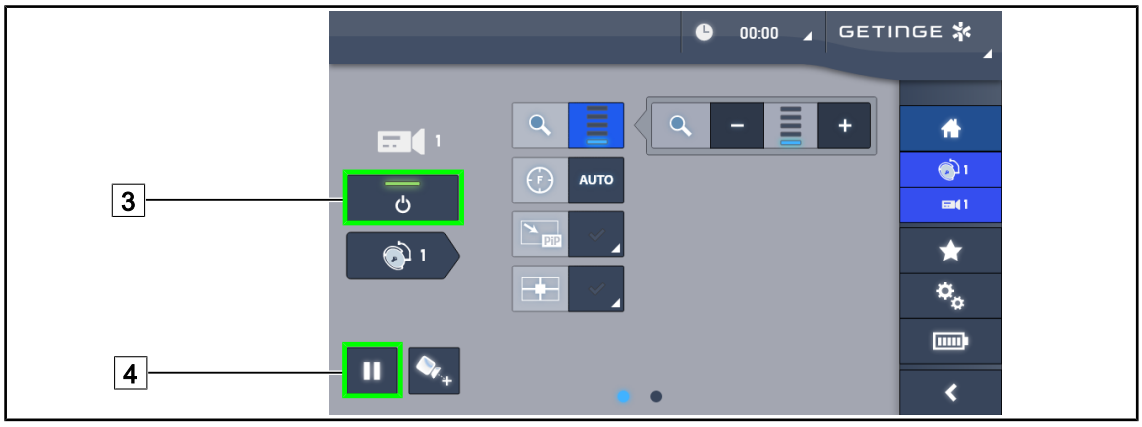


Fig. 95: Camera page

Turning off the camera

1. From the camera page, press **Camera ON/OFF** [3] to turn off the camera.
   - ➢ The button light turns off and the camera is turned off.

Pausing the camera

1. Press the **Camera pause** [4] button to pause the camera.
   - ➢ The button is lit blue and the retransmitted image is frozen.
2. Press the **Camera pause** [4] button again to resume video transmission.

Fig. 96: Positioning assistance

Enabling the camera positioning assistance

1. Press the **Positioning Assistance button** 34 to enable the camera positioning assistance.
   ➢ A green cross appears on the transmitted image for 20 seconds to help centring the image.

Fig. 97: Zoom control

Zooming in and out

1. Press the **Zoom button** 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.

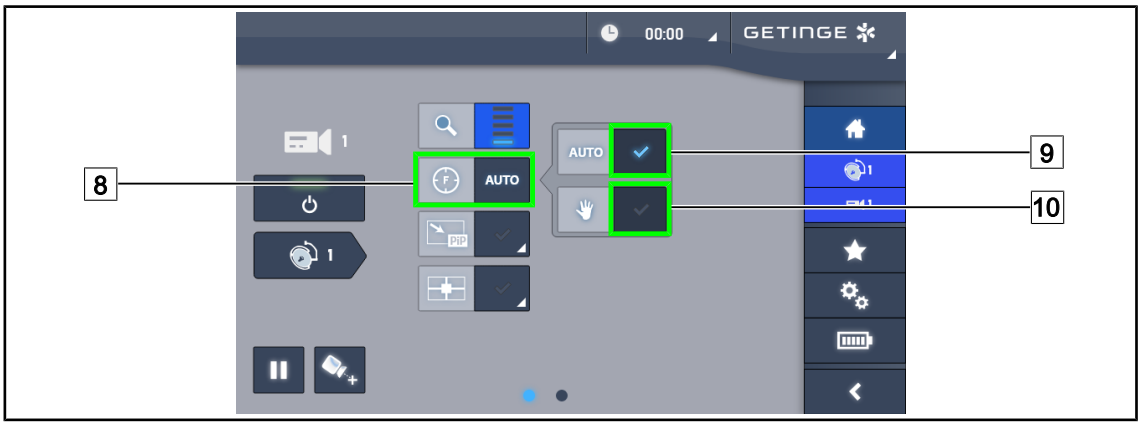


Fig. 98: Setting the focus

Setting the focus automatically

1. Press the **Focus button** 8 to access the focus adjustment menu.
2. Press the **Auto Focus button** 9.
   ➢ The button is lit blue and the camera focus is set to automatic.

Setting the focus manually

1. Press the **Focus button** 8 to access the focus adjustment menu.
2. Press the **Auto Focus button** 9.
   ➢ The button is lit blue and the camera focus is set to automatic.
3. Position the camera at the desired distance.
4. Press the **Manual Focus button** 10.
   ➢ The button is lit blue and the camera focus is fixed.

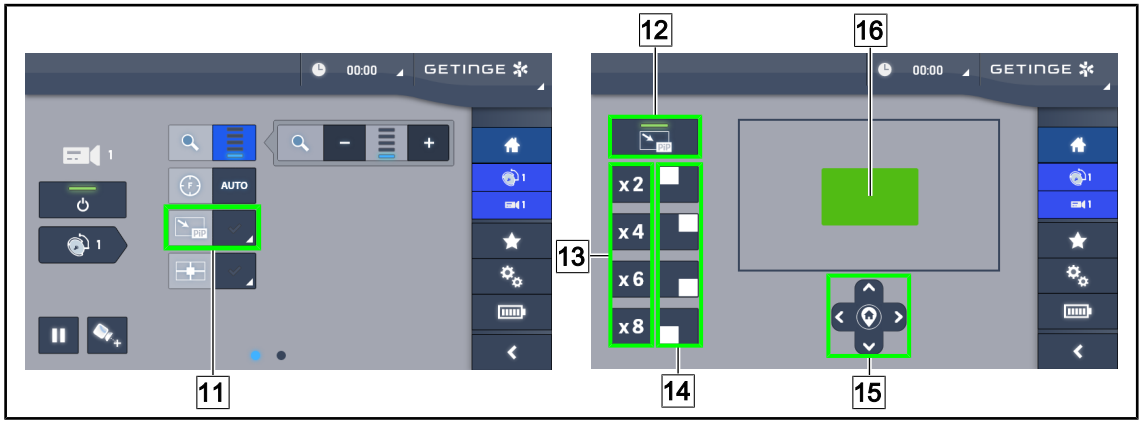


Fig. 99: Using the Picture-in-Picture

Enabling/disabling the Picture-in-Picture function

1. Press the **PiP button** 11 to enable the Picture-in-Picture function.
   ➢ The function settings page is displayed.
2. Press the **PiP OFF button** 12 to disable the Picture-in-Picture function.
   ➢ The function is disabled.

Using the Picture-in-Picture function

1. Press the **PiP button** 11 to access the function settings page.
2. Define the area to display using the green keypad 16 then refine if necessary using the directional keys 15. You can return to the centre of the image at any time by pressing the symbol in the centre of the directional keys 15.
3. Set one of the zoom values to apply to the selected area 13.
4. Define the corner of the screen in which the wide field image will be transmitted 14.

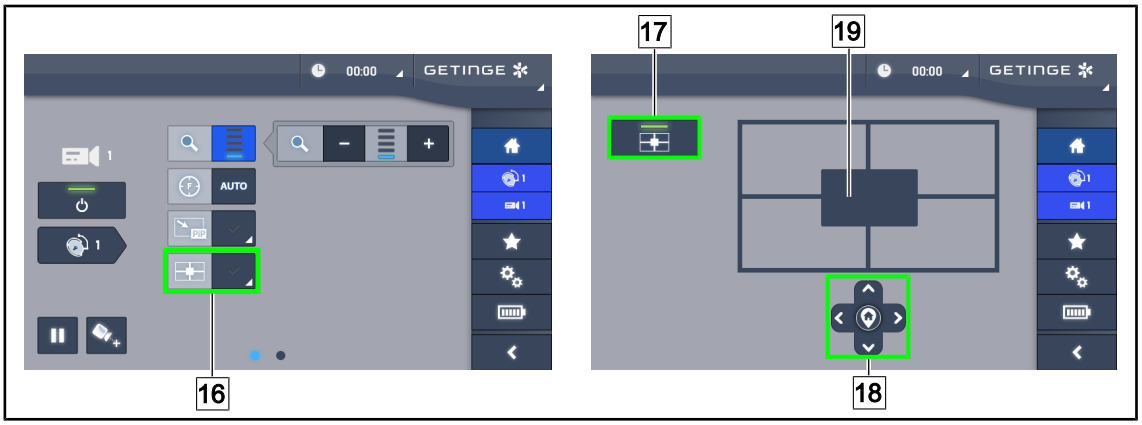


Fig. 100: Using the E-Pan Tilt

Enabling/disabling the E-Pan Tilt function

1. Press the **E-Pan button** 16 to enable the E-Pan Tilt function.
   ➢ The function settings page is displayed.
2. Press the **E-Pan OFF button** 17 to disable the E-Pan Tilt function.
   ➢ The function is disabled.

Using the E-Pan Tilt function

1. Press the **E-Pan button** 16 to access the function settings page.
2. Define the area to display using the directional keys 18 or the grey keypad 19. You can return to the centre of the image at any time by pressing the symbol in the centre of the directional keys 18.

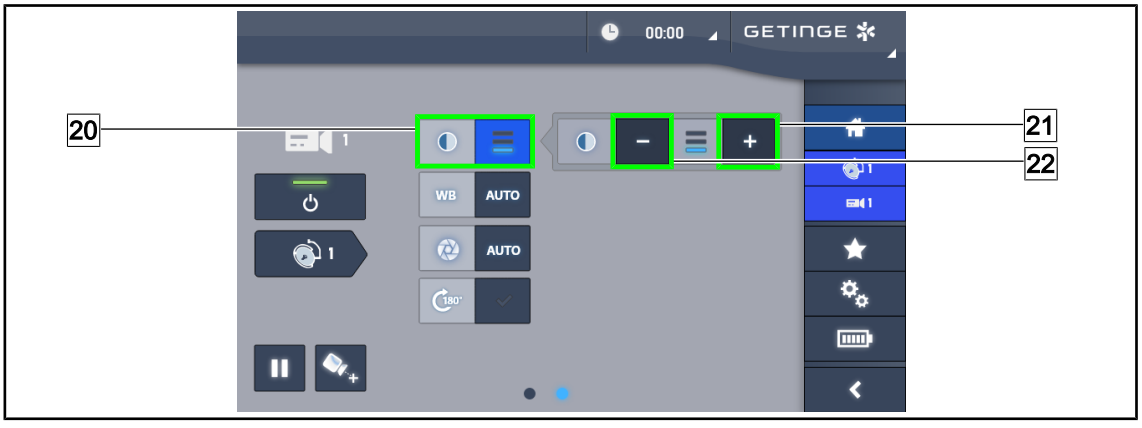


Fig. 101: Contrast adjustment

Adjusting the contrast

1. Switch to the second settings page.
2. Press the **Contrast button** 20 to access the contrast adjustment menu.
3. Press the **Increase contrast** 21 or **Decrease contrast buttons** 22 to select one of the three contrast levels.

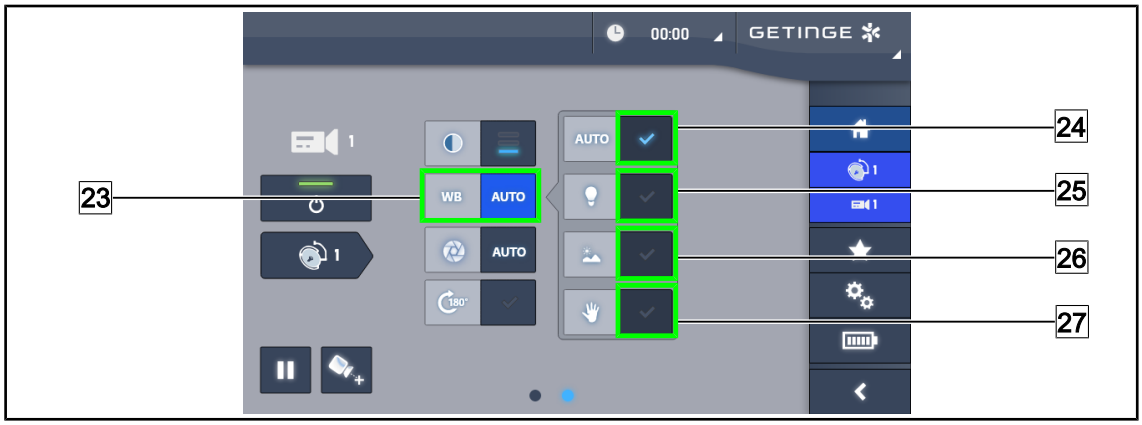


Fig. 102: White balance

Adjusting the white balance automatically

1. Press the **White Balance button** 23.
2. Press the **Automatic balance button** 24 to set the white balance automatically, or the **Artificial light button** 25 to set the white balance to 3200 K or the **Daylight button** 26 to set the white balance to 5800 K.
   - ➢ The selected button is lit blue and the white balance is applied.

Adjusting the white balance manually

1. Press the **White Balance button** 23.
2. Place a uniform white surface under the camera.
3. Press **Manual balance** 27 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 applied.

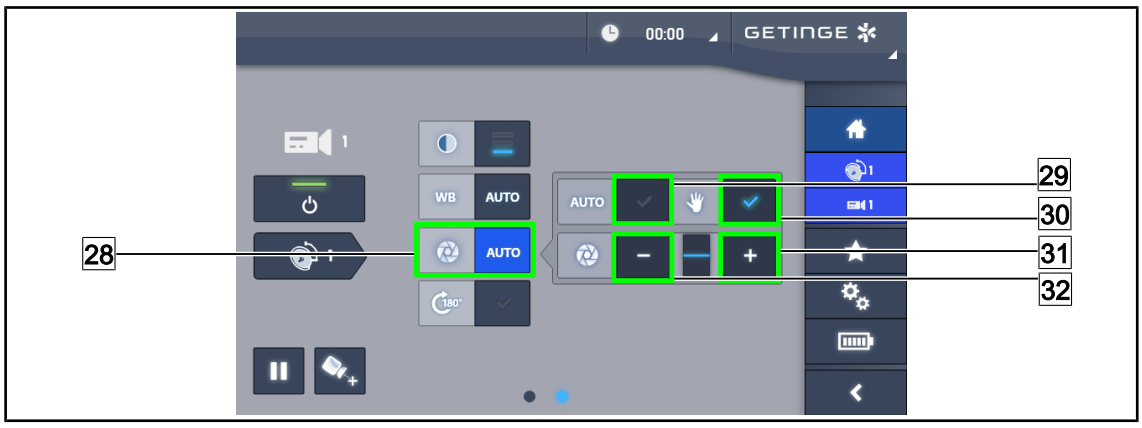


Fig. 103: Adjusting the exposure

Setting the exposure automatically

1. Press the **Exposure button** 28 to access the exposure adjustment menu.
2. Press the **Auto Exposure button** 29.
   - ➢ The button is lit blue and the camera focus is set to automatic.

Setting the exposure manually

1. Press the **Exposure button** 28 to access the exposure adjustment menu.
2. Press the **Manual Exposure button** 30.
3. Press the **Exposure Plus button** 31 to increase the exposure or on **Exposure Minus** 32 to decrease the exposure.

Fig. 104: Image rotation

Inverting the transmitted image

1. Press the **Rotate 180° button** 33 to rotate the transmitted image 180°.

4.6.2 Orienting the camera

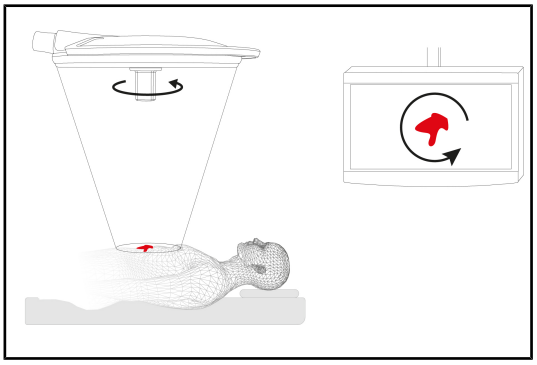


Fig. 105: Orienting the camera

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

1. Install a sterilisable handle on the camera (Installing or removing an STG PSX VZ 01 sterilisable handle [⏩ Page 65]).
2. Use the handle to rotate the camera.
   ➢ The image is rotated on the screen.

4.7 Positioning the screen holder

4.7.1 Handling and positioning the screen holder

WARNING!

Risk of infection
The sterilisable handle is the only sterilisable component of the device. The monitor, the screen holder and its accessories are not sterile and any contact with the sterile team results in a risk of infection for the patient.

During the operation, the screen, the screen holder and its accessories must never be touched by the sterile team and the handle must never be touched by non-sterile personnel.

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 injury
A wrong handling of XHD1 screen holder may result in a hand injury.

Respect safety indications on the product.

Handling of the screen holder by the sterile team

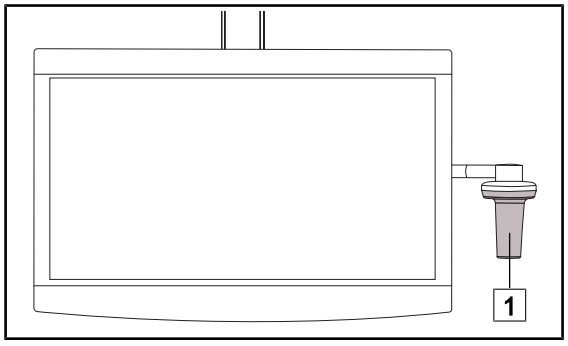


Fig. 106: Handling by sterile team

1. Move the device by grasping the sterilisable handle 1 or the DEVON or DEROYAL sterile handle.

Handling of the screen holder by the non-sterile team

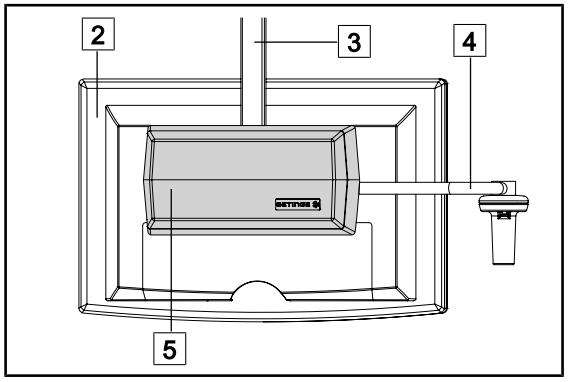


Fig. 107: Handling by the non-sterile team

1. Move the device by grasping the flat-panel monitor 2, the screen holder frame 3, the fork handle 4 or the rear box 5.

Positioning the screen holder

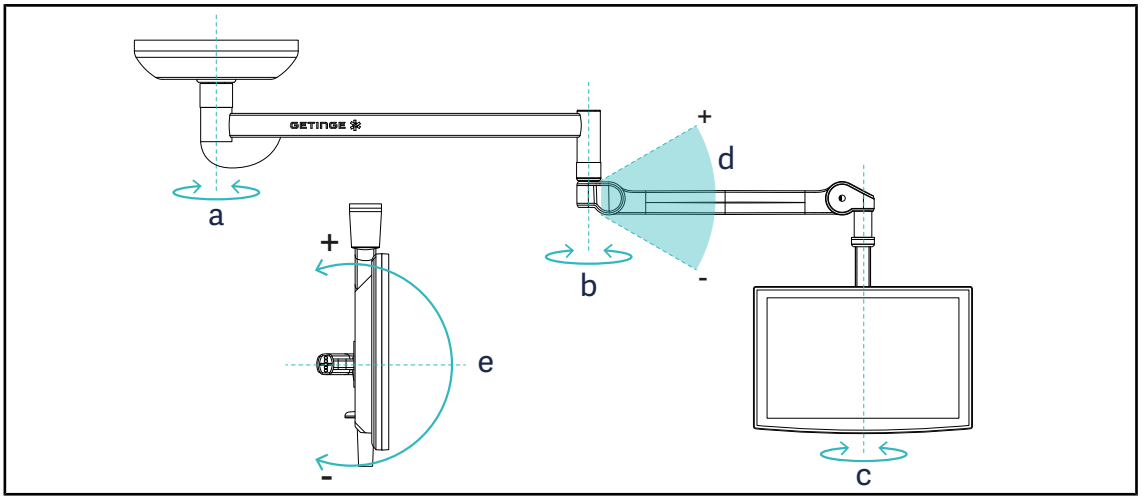


Fig. 108: Possible rotations on an SAX suspension

Screen holder	a	b	c	d	e
FHS0 / MHS0	330°	330°	315°	+45°/-70°	–
XHS0	330°	330°	315°	+45°/-70°	-45°/+90°
XHD1	330°	330°	330°	+45°/-70°	-60°/+10°
XO	360°	360°	360°	+45°/-50°	–

Tab. 18: Rotation amplitude values (in degrees) on a SAX suspension

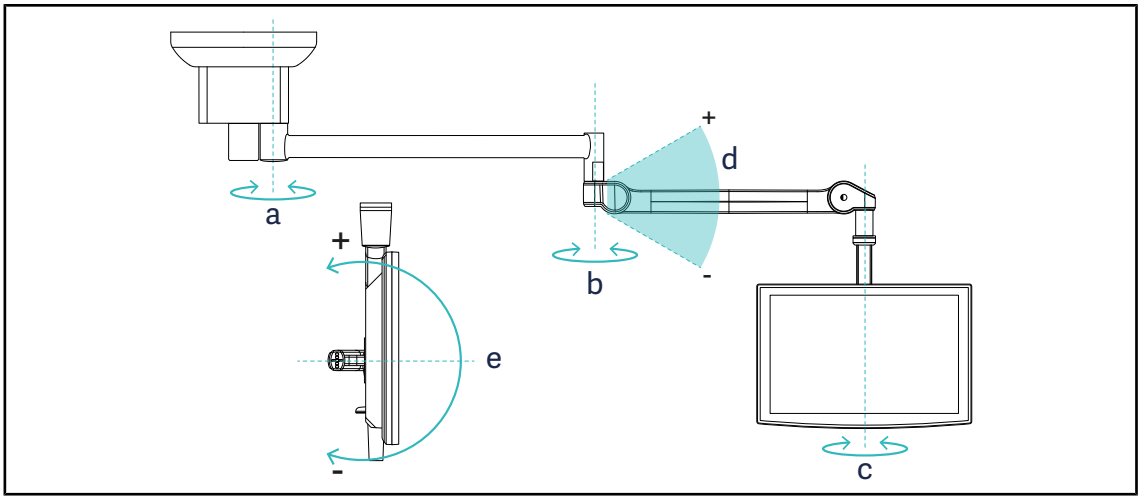


Fig. 109: Possible rotations on a SATX suspension

Screen holder	a	b	c	d	e
FHS0 / MHS0	270°	330°	315°	+45°/-70°	–
XHS0	270°	330°	315°	+45°/-70°	-45°/+90°
XHD1	270°	330°	330°	+45°/-70°	-60°/+10°

Tab. 19: Rotation amplitude values (in degrees) on a SATX suspension

4.7.2 Screen holder pre-positioning examples

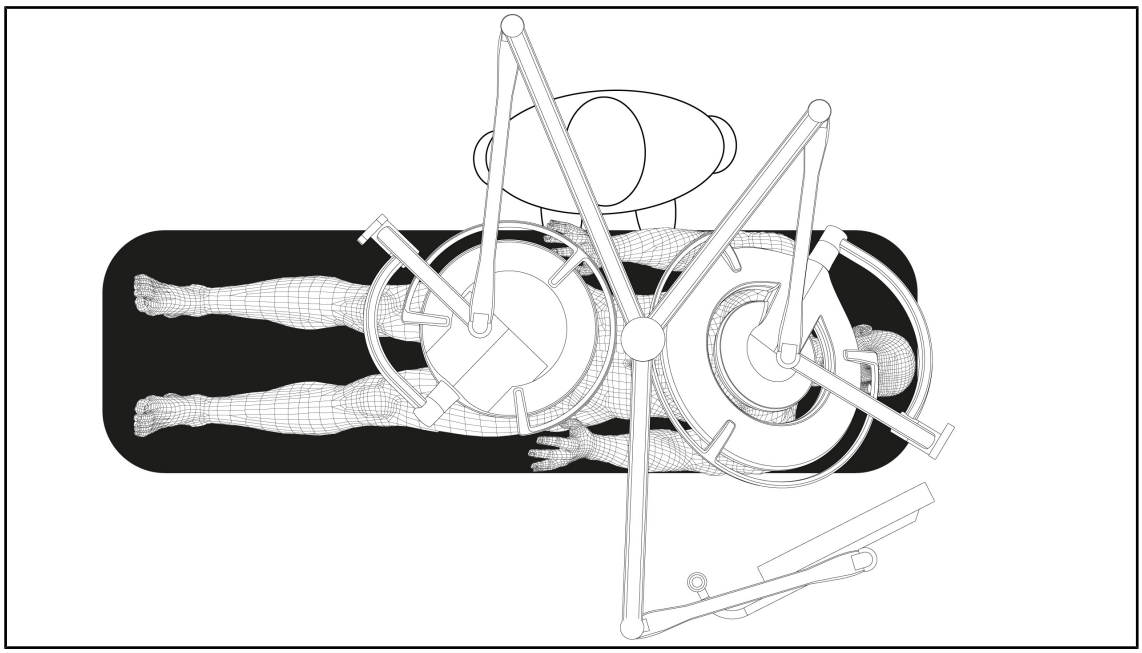


Fig. 110: Pre-positioning example for a triple configuration with screen holder

- The position of the screen depends on the type of surgery and the surgeon.
- It must be positioned such that the surgeon can see all of the information.
- It must be at a sufficient distance to avoid any contact with sterile personnel.

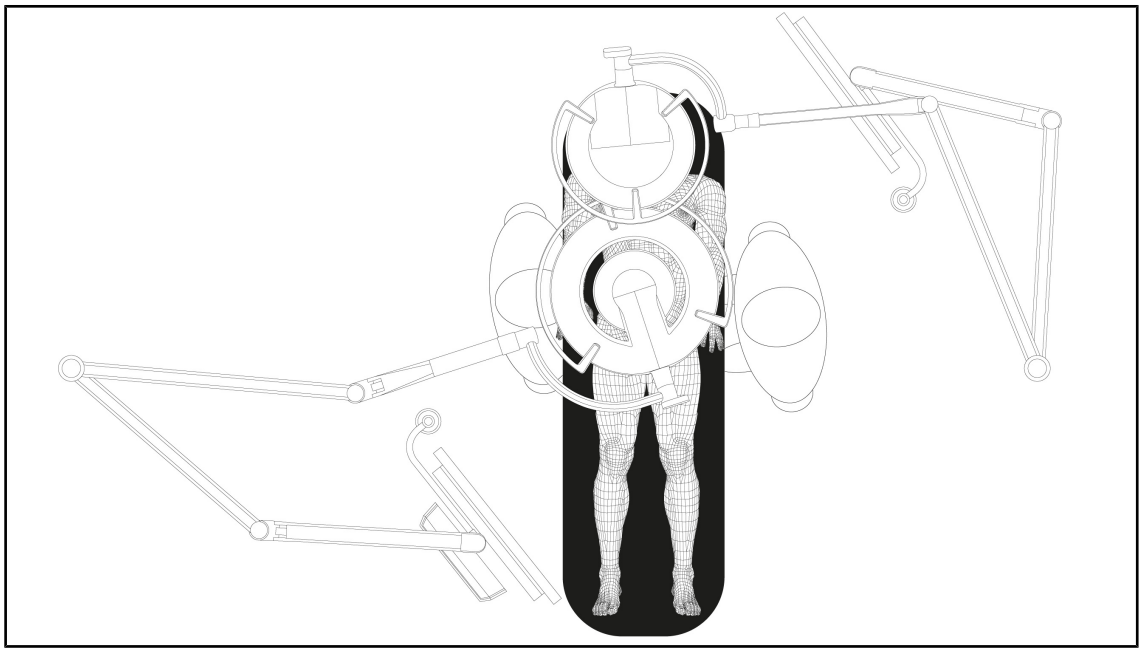


Fig. 111: Pre-positioning example for two double configurations with two screen holders

- The position of the screens depends on the type of surgery and the surgeon.
- They must be positioned such that the surgeon can see all of the information.
- They must be at a sufficient distance to avoid any contact with sterile personnel.

4.7.3 Screen control interface

NOTICE

Refer to the manufacturer's instructions provided with the screen to learn about all the features of the device.

4.8 Positioning the camera mount

4.8.1 Attaching a camera to the SC camera mount

NOTICE

Only medical video cameras compliant with IEC 60601-1 and featuring moulded detachable connectors and a 1/4’’ thread may be fitted on this mount. The choice of camera, cables and their routing through the mount remains under the responsibility of the customer.

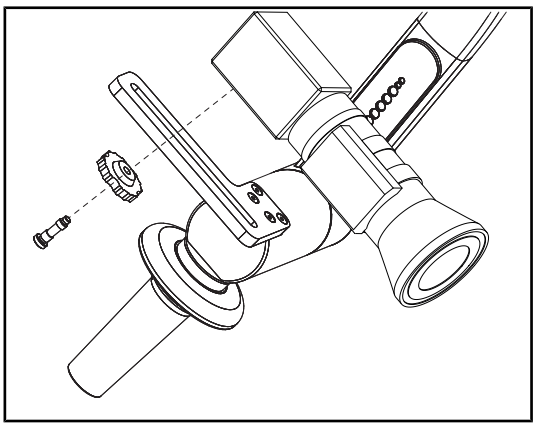


Fig. 112: Attaching the camera to the SC mount

1. Pass the screw through the hole in the mounting plate.
2. Place the camera on the mounting plate and tighten the screw fully.
3. Position the camera enclosure correctly relative to the mounting plate.
4. Turn the lock nut clockwise to fasten the camera in place.
5. Connect the cables after routing them through the suspension arm to the camera module.

4.8.2 Handling the camera mount

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.

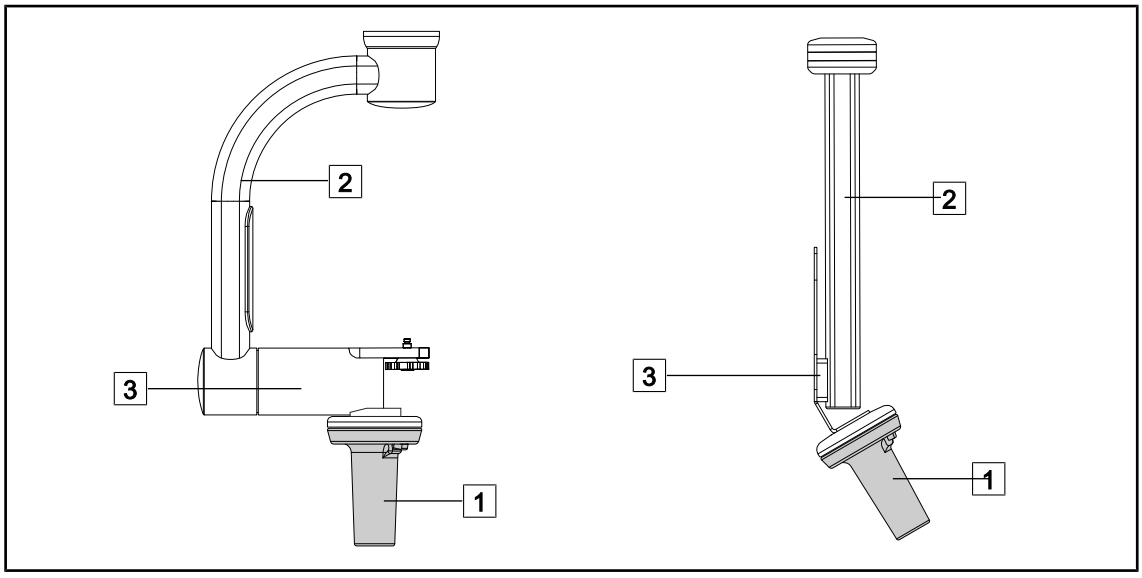


Fig. 113: Handling the camera mount

The camera mount can be manoeuvred in various ways:

- For sterile personnel: Using the sterile handle provided for this purpose 1.
- For non-sterile personnel: Using the fixed uprights 2 or the mount 3.

Degrees of rotation

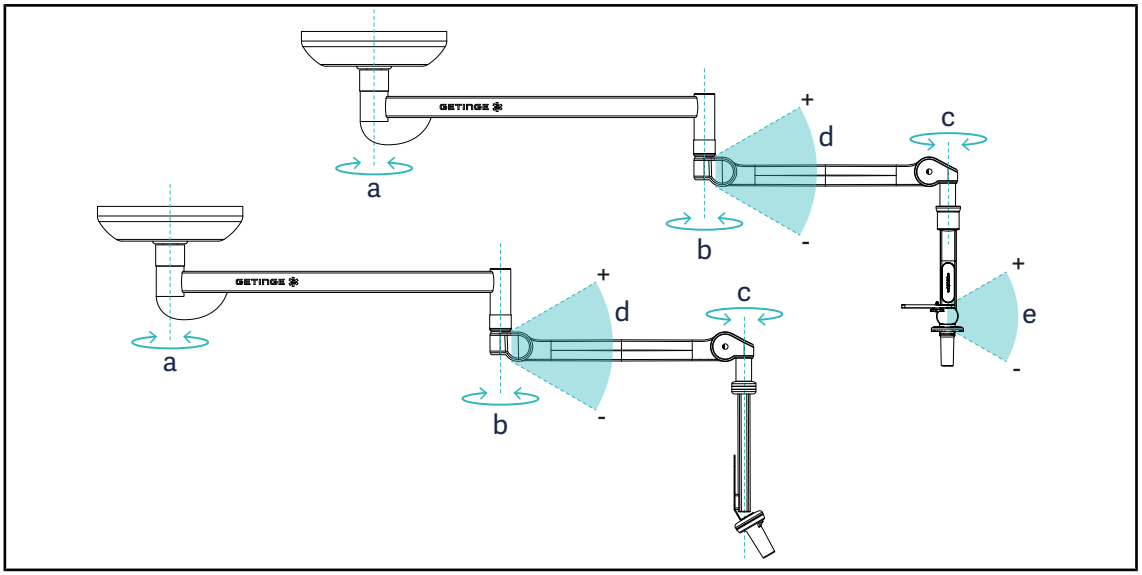


Fig. 114: Degrees of rotation of camera mounts

	a	b	c	d	e
SC05	SAX: 330° SATX: 270°	330°	315°	+45° / -70°	+15° / -105°
CAMERA MOUNT FH					–

4.8.3 Using the SC430-PTR camera

NOTICE

Please refer to the manual supplied with the camera to discover all of its features. Only the basic commands for a quick start are described below.

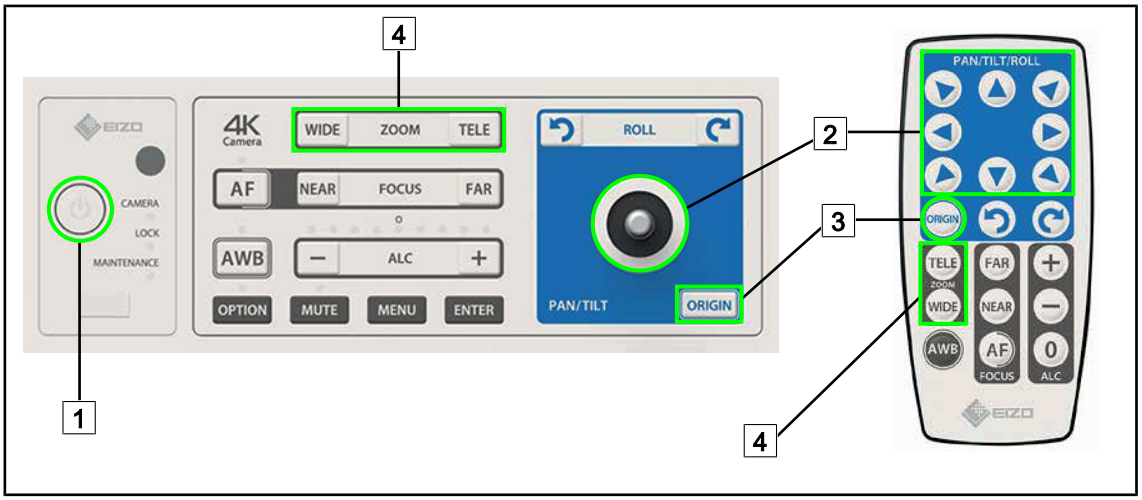


Fig. 115: Main commands of the SC430-PTR camera

1 On/Off
2 Camera motion
3 Home position
4 Zoom buttons

4.9 Settings and functions

Fig. 116: 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

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.

4.9.1 Screen brightness

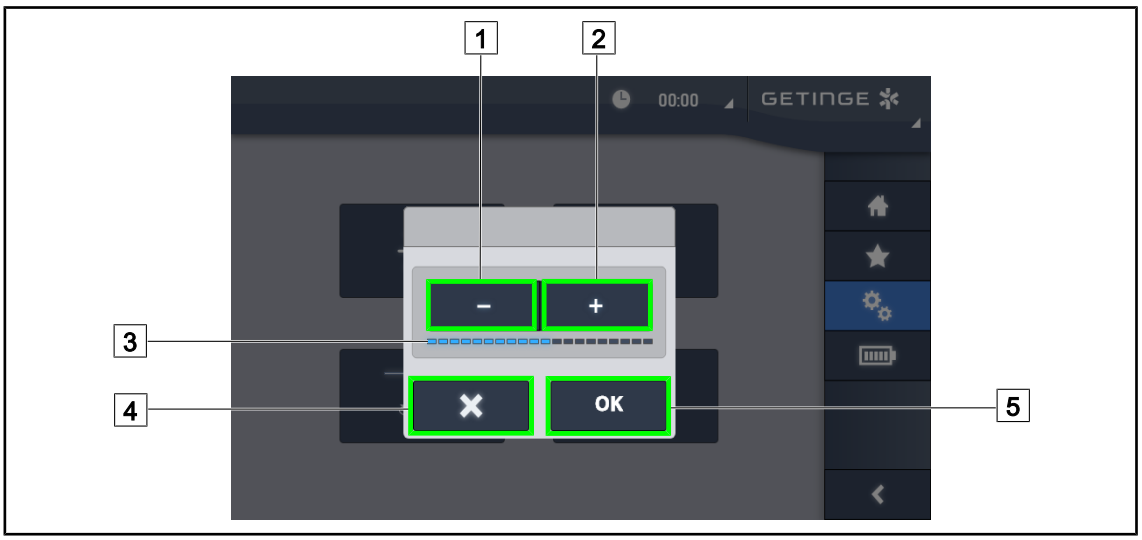


Fig. 117: Adjusting the screen brightness

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.

4.9.2 Date and time, and stopwatch/timer functions

Fig. 118: 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.

4.9.3 Tilt handle

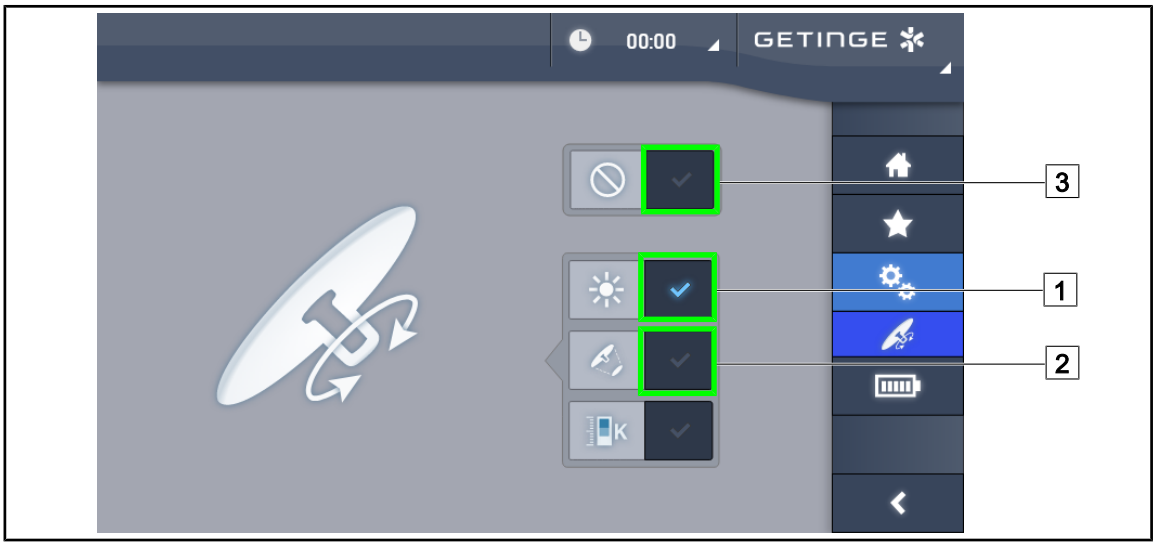


Fig. 119: Tilt handle configuration

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 **Disabled** [3] so that the Tilt handle is disabled and does not adjust any lighting parameters.

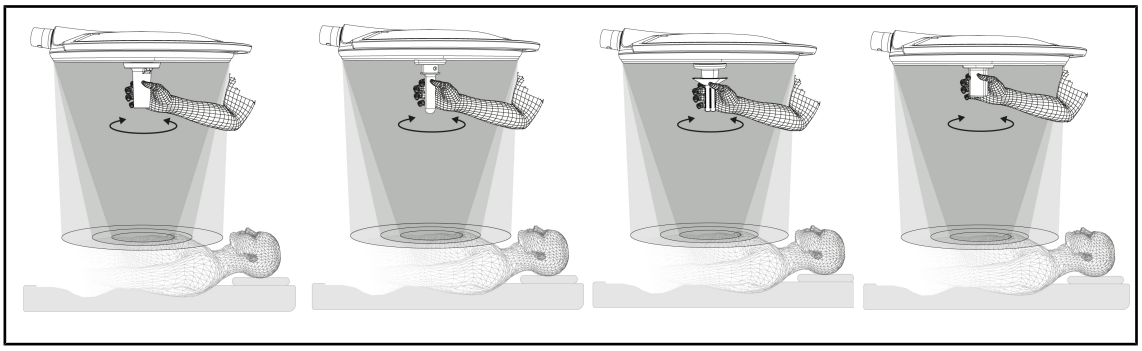


Fig. 120: Tilt handles

Adjusting the illumination using the tilt handle

1. Turn the handle to adjust the light intensity, light field diameter or colour temperature to the chosen setting.

NOTICE

The Tilt handle does not have limit stops.

4.9.4 Information

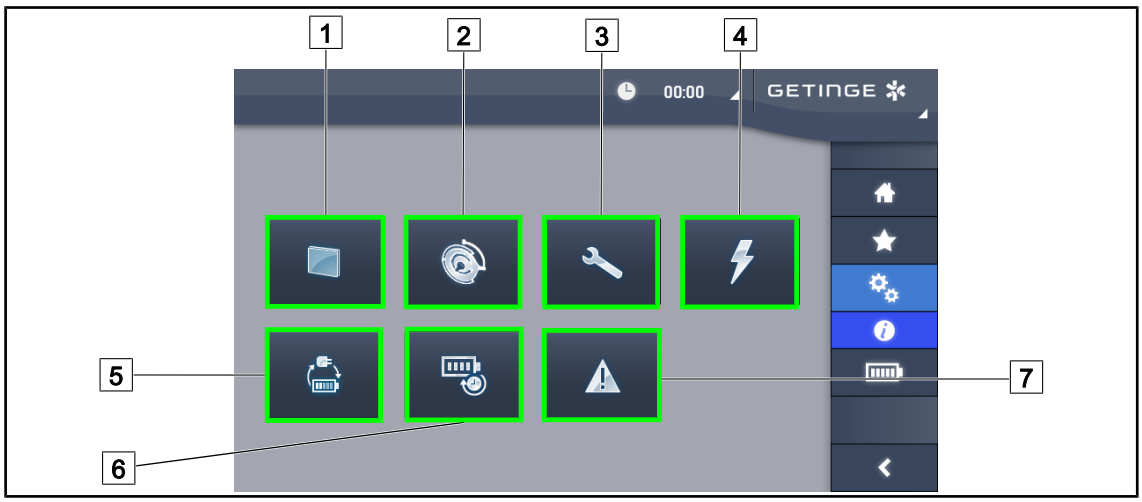


Fig. 121: Information page

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

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. 20: All information menus

4.10 Backup battery

NOTICE

When the backup power supply is triggered, Boost, AIM and Comfort Light modes are automatically disabled. They can be re-enabled later.

NOTICE

The batteries are charged only when the light is off.

4.10.1 LEDs

Indicators	Description	Meaning
	Orange battery indicator	Switchover to backup
	Flashing red indicator	Backup battery nearly discharged (with Getinge backup only)

Tab. 21: Lighthead keypad backup operation indicators

Indicators	Description	Meaning
	One LED lit red	External backup at a very low level (with Getinge backup only)
	Two LEDs lit red	External backup at a low level (with Getinge backup only)
	Three LEDs lit orange	External backup at a relatively low level (with Getinge backup only)
	Four LEDs lit green	External backup at a satisfactory level (with Getinge backup only)
	Five LEDs lit green	External backup at excellent level (with Getinge backup) **or** device on backup (with customer backup)
	The green LEDs are lit one by one	LEDs lit in chasing sequence: batteries charging (with Getinge backup only)

Tab. 22: Wall-mounted keypad backup operation indicators

Indicators	Description	Meaning
	Full orange battery	Switchover to backup
	Non-full orange battery	Remaining battery capacity (with Getinge backup only)
	Flashing red indicator	Backup battery nearly discharged (with Getinge backup only)

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

4.10.2 Performing battery tests

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.

4.10.2.1 From the wall-mounted control keypad

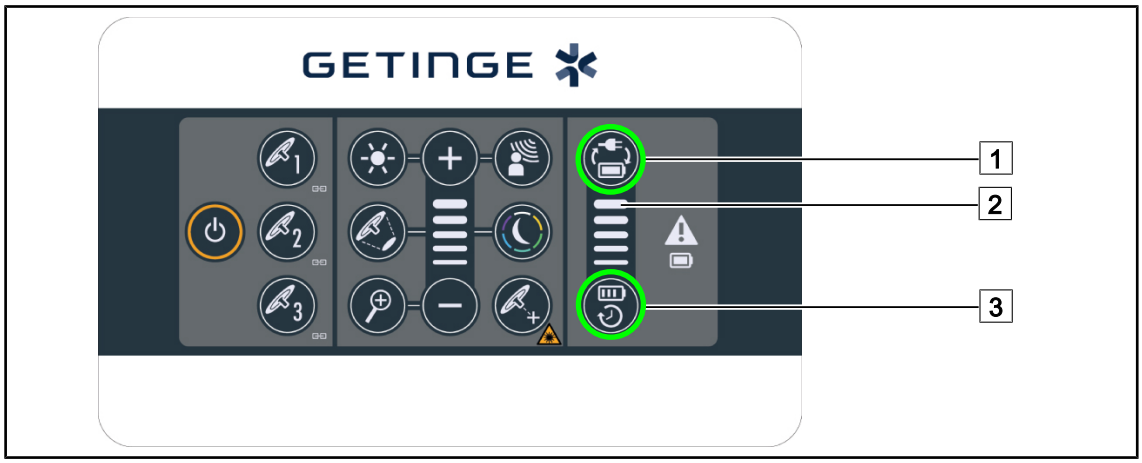


Fig. 122: Battery tests from the wall-mounted keypad

Running a battery backup test

1. Turn off the light.
2. Press **Battery backup test** [1].
   - ➢ If the test is successful, the battery level indicator [2] flashes green. If the test fails, the battery level indicator [2] flashes red.
3. If the test fails, contact the Getinge technical service department.
4. Press **Battery backup test** [1] again.
   - ➢ The battery level indicator [2] stops flashing. The light is on and ready for use.

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

1. Turn off the light.
2. Press **Battery lifetime test** [3].
   - ➢ If the test is successful, the battery level indicator [2] flashes green. If the test fails, the battery level indicator [2] flashes red.
3. If the test fails, contact the Getinge technical service department.
   - ➢ The light turns off when the test is complete.
4. Press **Battery lifetime test** [3] again.
   - ➢ The battery level indicator [2] stops flashing.

NOTICE

The battery lifetime test can be stopped at any time by pressing **Battery lifetime test** [3] again until the lightheads turn off.

4.10.2.2 From the touchscreen control panel

Fig. 123: 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** [1] in the menu bar.
   - ➢ The battery tests page is displayed.
3. Press **Battery lifetime test** [3] to start the test.
   - ➢ The date of the most recent battery lifetime test [7] and the battery lifetime [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** [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.

NOTICE

The battery lifetime test can be stopped at any time by pressing the cross [5].

5 Troubleshooting

5.1 Warning indicators

5.1.1 Indicators on the lighthead and wall-mounted 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 (only available with Getinge backup)	Powered from backup supply The batteries are almost totally discharged and 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 (only available with Getinge backup)	Powered from backup supply The batteries are almost totally discharged and the system will lose power in a few minutes.
	Battery charge indicator (only available with Getinge backup)	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
Drift of the system	Worn brake(s)	Have the brakes replaced by a trained technician
	Incorrect adjustment of the brake(s)	Have the brakes adjusted by a trained technician
Device too stiff to manoeuvre	Mechanical lock	Contact the Getinge technical department

Tab. 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

Tab. 30: Optical anomalies and malfunctions

Anomaly	Likely cause	Corrective action
A control button does not respond	The control keypad is defective	Contact the Getinge technical department
	Communication problem	Contact the Getinge technical department
	This function is not available on your device	N/A
No image after starting the camera	The camera is defective	Replace the camera
	The monitor is defective	Replace the monitor
	Other reason	Contact the Getinge technical department

Tab. 30: Optical anomalies and malfunctions

Touchscreen control panel error messages

The error messages on the touchscreen control panel 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

NOTICE

In all cases, please contact Getinge technical support.

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

[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.

NOTICE

Maquet Sterigrip sterilisable handles are designed for autoclave sterilisation.

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

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

Tab. 33: Example of a steam sterilisation cycle

7 Maintenance

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

Preventive maintenance	To be performed every year

Certain components must be replaced during the device’s service life. Check the Maintenance Manual for how frequently to do so. The Maintenance Manual mentions all of the electrical, mechanical, and optical checks to carry out, as well as which wear parts need to be periodically replaced to maintain the reliability and performance of the operating lighting system and guarantee safe operation.

NOTICE

The Maintenance Manual is available from your local Getinge representative. To find your local Getinge representative’s contact information, visit the website **https://www.getinge.com/int/contact/find-your-local-office**.

8 Technical specifications

8.1 Optical specifications

NOTICE

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

Specifications	Maquet PowerLED II 700	Maquet PowerLED II 500	Tolerance
Central Illumination ($E_{c,MI}$)	15,000 lx to 160,000 lx		–
Maximum Central Illumination ($E_{c,MI}$)[3]	160,000 lx		0 - 10%
Maximum central illumination ($E_{c,Ref}$)[4]	150,000 lx		±10%
Light field diameter d_{10}	13 / 20 / 27 cm	13 / 20 cm	± 2 cm
Light distribution d_{50}/d_{10}	0.56		± 0.06
Depth of illumination above 60 %	24 / 43 / 44 cm	38 / 53 cm	± 10 %
Colour temperature	Fixed: 3,800 K / 4,300 K		± 400 K
Colour rendering index (Ra)	96		±4
Special colour rendering index (R9)	90		±10
Specific colour rendering index (R13)	96		± 4
Special colour rendering index (R15)	95		± 5
Maximum irradiance (E_{total})[3]	550 W/m²		± 10 %
Irradiance at level 8 and below	< 350 W/m²		–
Heat to light ratio[3]	3.4 mW/m²/lx		± 0.4
UV illumination[3]	≤ 0.7 W/m²		–
FSP system	Yes		–
Illumination in ambient light mode	< 500 lx		–

Tab. 34: Maquet PowerLED II lightheads optical data in accordance with the IEC 60601-2-41:2021 standard

[3] Measured at Maximum Illuminance Distance (D_{MI}) of 95 cm / 37.4 inches (± 10%).

[4] Limited to 160,000 lx

Residual illumination[5]	Maquet PowerLED II 700	Maquet PowerLED II 500	Tolerance
With one mask	77 %	56%	± 10
With two masks	56 %	46%	± 10
With simulated cavity	87 %	100%	± 10
With one mask, with simulated cavity	64 %	56%	± 10
With two masks, with simulated cavity	45 %	46%	± 10

Tab. 35: 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	100 %	100%	± 10
Shadow dilution with two masks	100 %	75 %	± 10

Tab. 36: Specifications in AIM mode

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

Tab. 37: Laser specifications

Photobiological risk factors

WARNING!

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

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

WARNING!

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

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

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

8.2 Mechanical specifications

8.2.1 Light

Mechanical specifications	Maquet PowerLED II 700	Maquet PowerLED II 500	Tolerance
Mass of single fork lighthead	16.8 kg	12.3 kg	± 2%
Mass of double fork lighthead	18.4 kg	13.9 kg	± 2%
Lighthead diameter (including handle)	797 mm	637 mm	± 0.5%
Lighthead protection against dust and liquid ingress	IP44		–

Tab. 38: Table of mechanical specifications

8.2.2 Power supply

Specifications	Maquet PowerLED II	Tolerance
Dimensions of wall-mounted power supply	311 × 400 × 145 mm	± 2%

Tab. 39: WPS power supply mechanical specifications

8.2.3 Screen holder(s)

Screen holder	Maximum on-board weight on the holder	Maximum screen dimensions
FHS019	19 kg	809 x 518 mm (32")
MHS019	19 kg	
XHS016	16 kg	
XHS021	21 kg	
XHD127	27 kg	

Tab. 40: Mechanical specifications of the screen holders

NOTICE
For more information, refer to the Maquet PowerLED II installation instructions.

8.2.4 Mechanical compatibility

Device	Compatibility
Camera for SC05	Camera with 1/4'' screw thread weighing less than 5 kg
Screen for screen holder	VESA interface (16 kg max)

Tab. 41: List of compatible devices

8.3 Electrical characteristics

Electrical specifications	Maquet PowerLED II 700	Maquet PowerLED II 500
WPS input voltage	100-240 Vac, 50/60 Hz	
WPSXXX24 input voltage	24 Vac, 50/60 Hz or 24 Vdc	
Power	Single configuration: 200 VA Dual-lighthead configuration: 400 VA Triple-lighthead configuration: 600 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	
Compatible with Full HD video	Yes	
4K-compatible vidéo	Yes	
Battery charge time	14 hours (3H pack) / 7 hours (1H pack)	
Battery lifetime	>3 hours for Volista Dual (3H pack) >1 hours for Volista Dual (1H pack)	

Tab. 42: Table of electrical specifications (Class I appliance)

Electrical compatibility with other devices

Compatible electrical devices	Compatibility
External control device	RS232 / MaqBus / Dry contact

Tab. 43: Electrical compatibility table

8.4 Technical specifications of the cameras and receiver

Technical specifications of the OHDII FHD QL+ VP01 camera

Specifications	OHDII FHD QL+ VP01
Sensor	1/3” CMOS
Number of pixels	~2.48 Megapixels
Video standard	**1080i** / 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 x H) at 1 m from the underside (wide angle to telephoto)	865 x 530 mm to 20 x 12 mm
Anti-flicker	Yes
Focusing	**Auto** / Focus Freeze
White balance	Auto / Indoor / Outdoor / **Manual**
Contrast enhancement	Yes (3 levels)
Freeze	Yes
Presets	6
Transmission type	Wired
RS232 interface	Yes
Weight (without sterile handle)	460 g
Dimensions (without sterile handle) (Diam. x H)	93 x 150 mm

Tab. 44: Technical specifications of the OHDII FHD QL+ VP01 camera

VP01 RECEIVER technical specifications

Specifications	VP01 RECEIVER
Video input	RJ45 (owner)
Video output	3G-SDI
Weight (without/with mounting bracket)	230 g / 260 g
Dimensions with mounting bracket (L x W x H)	143 × 93 × 32 mm

Tab. 45: VP01 RECEIVER technical specifications

Technical specifications of the OHDII 4K QL+ VP11 camera

Specifications	OHDII 4K QL+ VP11
Sensor	1/2.5” CMOS
Number of pixels	8.29 Megapixels
Video standard	3840 x 2160p
Image refresh rate	25 fps / 29.97 fps
Format	3840 x 2160p
Shutter speed	1/1 to 1/10000 s
Wide viewing angle (diagonal/horizontal/vertical)	77.8° / 70.2° / 43.1°
Telephoto viewing angle (diagonal/horizontal/vertical)	4.7°/4.1°/2.3°
Signal to noise ratio	50 dB
Optical zoom (focal ratio)	x20
Digital zoom	x3
Total zoom	x60
Focal length (wide angle to telephoto)	f = 4.4 mm to 88.4 mm
Visible field (W x H) at 1 m from the underside (wide angle to telephoto)	875 x 480 mm to 25 x 15 mm
Anti-flicker	Yes
Focusing	**Auto** / Focus Freeze / One Push Trigger
White balance	Auto / Indoor / Outdoor / **Manual**
Contrast enhancement	Yes (3 levels)
Exposure	15 levels (-7 to +7)
Picture in Picture	X2 X4 X6 X8 (four-corner selection)
Electronic Pan Tilt	Yes
Positioning assistance	Yes
Freeze	Yes
Image electronic rotation	180°
Presets	6
Transmission type	Wired (Coaxial)
RS232 interface	Yes
Weight (without sterile handle)	780 g
Dimensions (without sterile handle) (Diam. x H)	124 x 181 mm

Tab. 46: Technical specifications of the OHDII 4K QL+ VP11 camera

8.5 Other characteristics

Protection against electrical shock	Class I
Medical device classification for Europe, Canada, Korea, Japan, Brazil & Australia	Class I
Medical device classification for USA, China & Taiwan	Class II
Protection rating for the device as a whole	IP 20
Protection rating of the lightheads	IP 44
EMDN code	Z12010701
GMDN code	12,282
CE marking year	2018

Tab. 47: 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 a high frequency generator (e.g. electrosurgical unit) adjacent to the device may affect its operation and performance.

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

CAUTION!

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

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

NOTICE

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

Test type	Test method	Range of frequencies	Boundaries
Measurement of conducted emissions on the main ports	EN 55011 GR1 CL A[6]	0.15 / 0.5 MHz	79 dBµV QP 66 dBµV A
		0.5 / 5 MHz	73 dBµV QP 60 dBµV A
		5 / 30 MHz	73 dBµV QP 60 dBµV A
Measurement of the radiated electromagnetic field	EN 55011 GR1 CL A[6]	30 / 230 MHz	40 dBµV/m PQ 10 m
		230 / 1000 MHz	47 dBµV/m PQ 10 m

Tab. 48: 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. 49: 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.

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

9 Waste management

9.1 Disposal of packaging

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

9.2 Product

Do not dispose of this device as unsorted municipal waste. Take it to a collection facility for value enhancement, recycling or re-use.

For full information relating to processing of the device once it is no longer in use, see the Maquet PowerLED II Decommissioning Instructions (ARD01815). Contact your local Getinge representative to obtain a copy of this document.

Do not dispose of contaminated sterilisable handles as municipal waste.

9.3 Electrical and electronic components

All electrical and electronic components used during the life of the product must be processed in an environmentally friendly manner, in line with applicable local standards.

Notes

GETINGE

Maquet SAS · Parc de Limère · Avenue de la Pomme de Pin · CS 10008 ARDON ·
45074 ORLÉANS CEDEX 2, France
Tel.: +33 (0) 2 38 25 88 88 Fax: +33 (0) 2 38 25 88 00

CE

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