Instructions for use

# Maquet Orchide

IFU 04661 EN 07 2025-06-17

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.

V07 17.06.2025

# 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**

This system must only be installed on medical devices approved in accordance with IEC 60601-1.

The compatibility data is detailed in the chapter entitled Technical specifications [⏩ Page 47].

The compatible accessories are detailed in the corresponding chapter.

**In the event of an incident**

Any serious incident occurring in connection with the device must be notified to the manufacturer and the relevant authority of the member state in which the user and/or patient is based.

## 1.3 Other documents relating to this product

- Installation manual (Ref. ARD04664)
- Decommissioning instructions (Ref. ARD04665)

## 1.4 Information about this document

This user's manual is intended for day-to-day users of the product, staff supervisors and hospital authorities. It is intended to familiarise users with the design, safety features and operation of the product. The manual is organised and divided into several separate chapters.

**Please note:**

- Please read the user's manual thoroughly and in full before using the product for the first time.
- Always proceed in line with the instructions in the user's manual.
- Keep this manual close to the equipment.

### 1.4.1 Abbreviations

| | |
|---|---|
| EMC | Electromagnetic compatibility |
| HD | High Definition |
| IFU | Instructions For Use |
| N/A | Not Applicable |
| QL(+) | Quick Lock(+) |

### 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.

## 1.5 Symbols on the product and packaging

| | | | |
|---|---|---|---|
| | Follow the instructions for use (IEC 60601-1:2012) | | Giteki marking (Japan) |
| | Follow the instructions for use (IEC 60601-1:2005). | | ACMA marking (Australia) |
| | Follow the instructions for use (IEC 60601-1:1996). | CE | CE marking (Europe) |
| | Manufacturer + date of manufacture | | Direct current input |
| REF | Product code | | Packaging orientation |
| SN | Product serial number | | Fragile |
| MD | Medical Device (MD) marking | | Moisture sensitive |
| UDI | Unique device identification | | Temperature range for storage |
| XX REP | Authorized Representative | | Humidity range for storage |
| FC | FCC marking (USA) | | Ambient pressure range for storage |

Tab. 3: Symbols on the product and packaging

## 1.6 Product overview

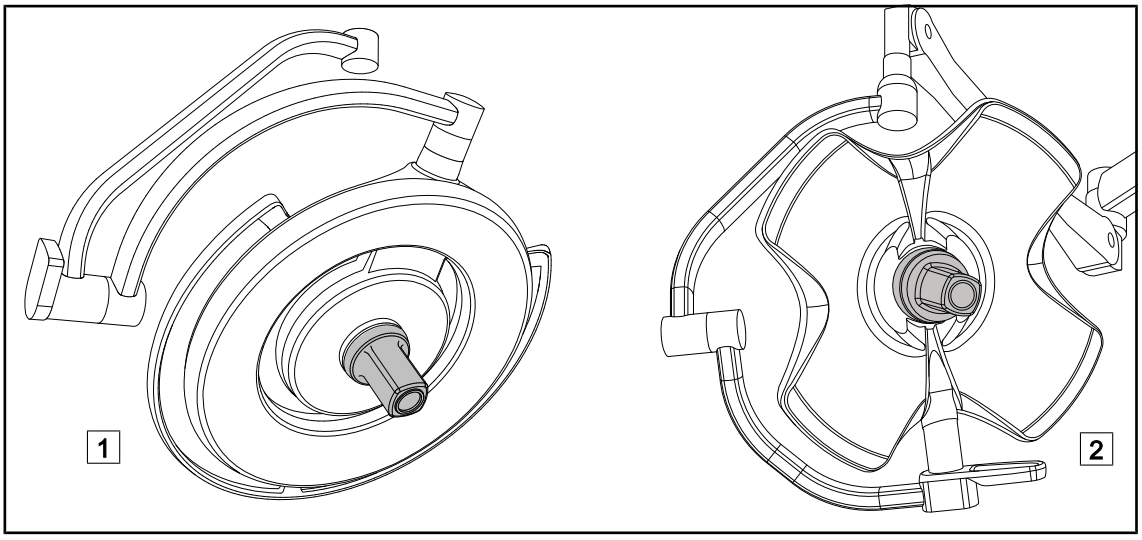



Fig. 1: Maquet Orchide cameras

**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 at the centre of the Maquet PowerLED II* lighthead 1 using the QL + system, or at the centre of the Volista lighthead 2 using the QL system.

## 1.6.1 Components

### 1.6.1.1 Cameras with wired video system

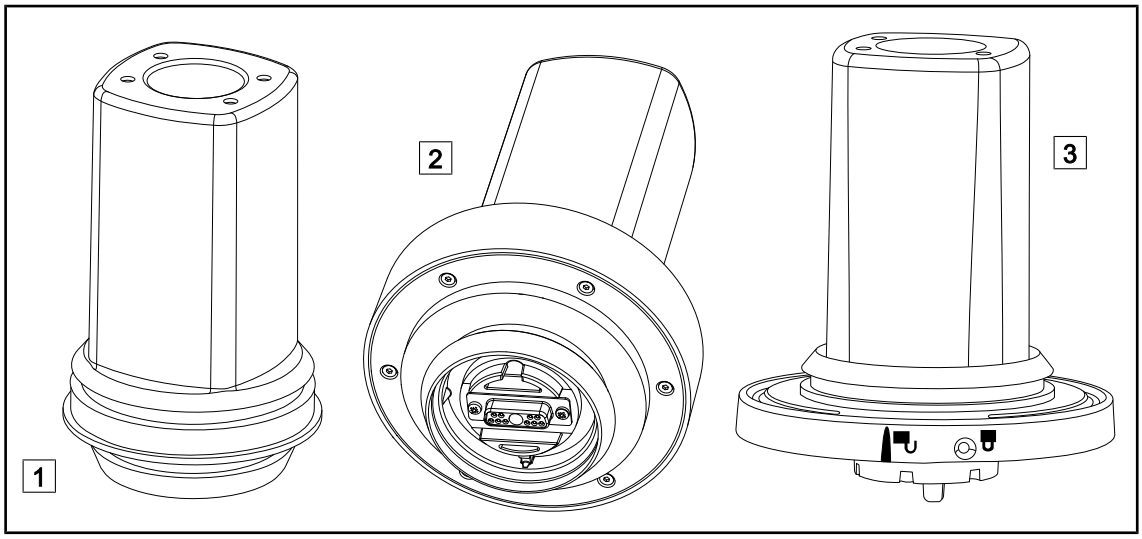



Fig. 2: Cameras with wired video system

1 OHDII FHD QL+ VP01 (for Maquet PowerLED II lighthead)

2 OHDII 4K QL+ VP11 (for Maquet PowerLED II lighthead)

2 OHDII FHD QL+ VP01 (for Volista lighthead)

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.

The OHDII FHD QL+ VP01 and OHDII 4K QL+ VP11 cameras can only be installed on a pre-wired FHD ("H6" in lighthead part number) or 4K ("HC3" in lighthead part number) Maquet PowerLED II lighthead.

The OHDII FHD QL VP01 camera can only be installed on a Volista lighthead that is pre-wired for video ("H6" in lighthead part number).

**NOTICE**

If two FHD wired cameras are installed, two power adapters must be used.

**NOTICE**

Before installing a wired camera, make sure the configuration is pre-wired for video by checking the configuration label. The label must bear the indication "VP" (FHD) or "VP4K" (4K). If the camera is installed on a lighthead that is not pre-wired for video, the camera will be detected and can be turned on, 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**

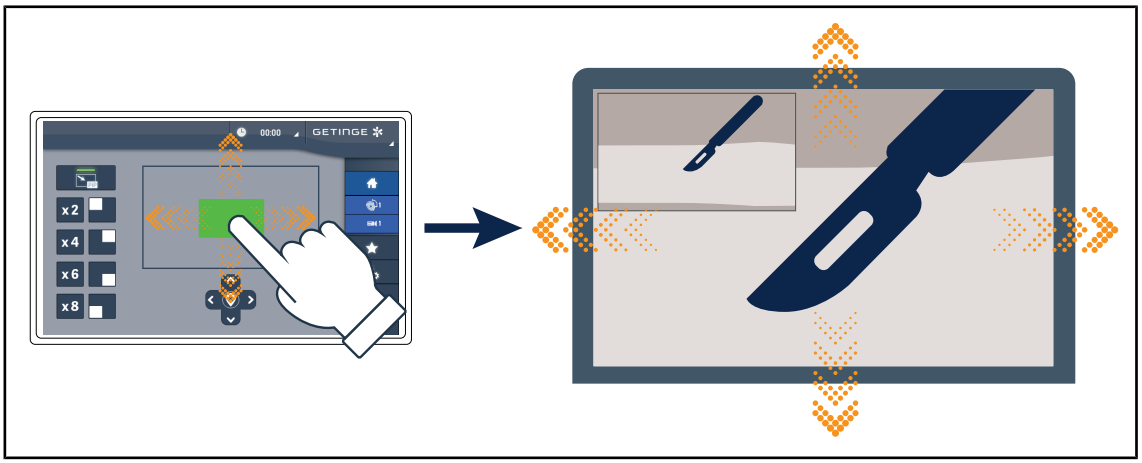



Fig. 3: Picture-in-Picture feature

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.

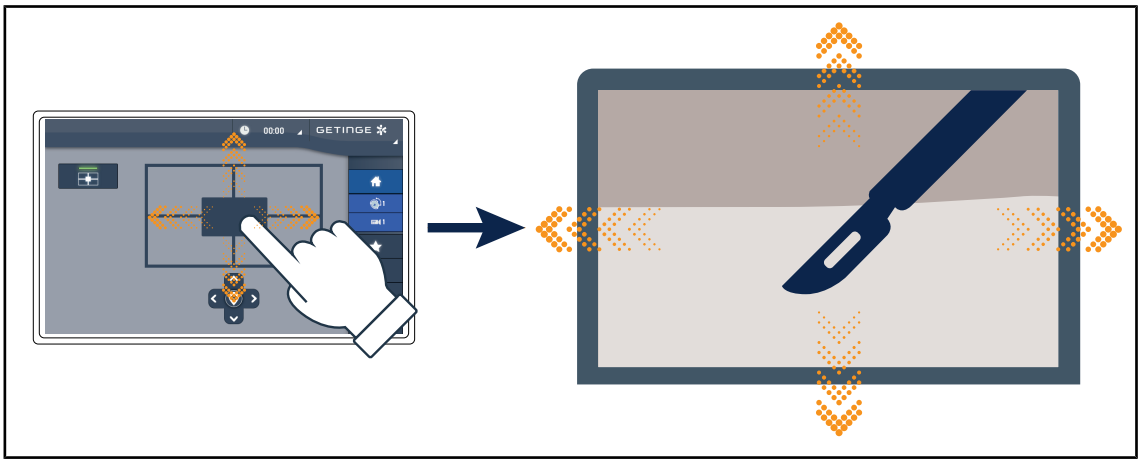



Fig. 4: E-Pan Tilt feature

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.

#### 1.6.1.2 Camera with wireless video system (only on Volista)

**OHDII FHD QL AIR05 + receiver**

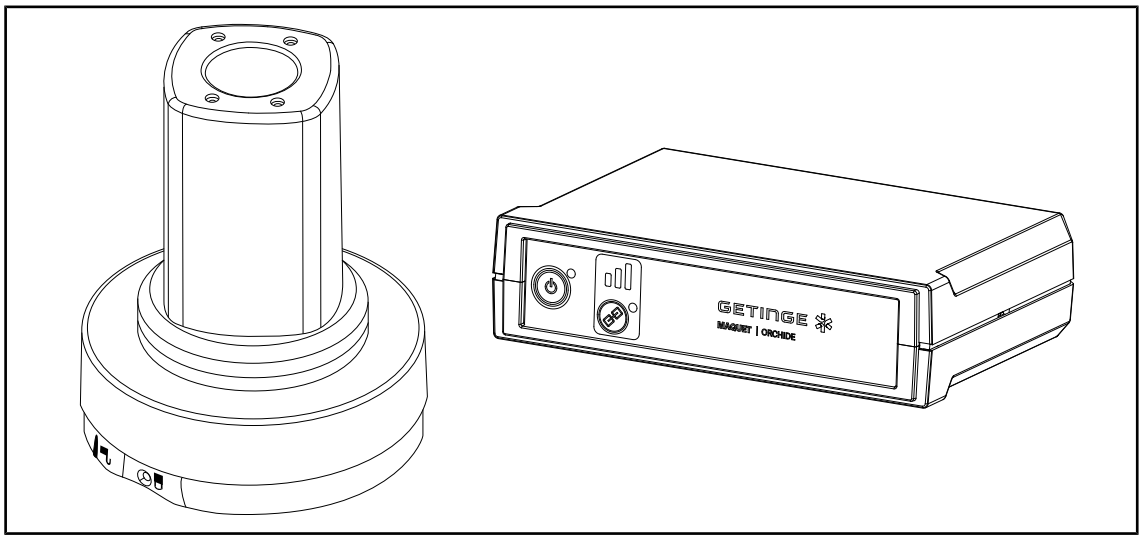



Fig. 5: OHDII FHD QL AIR05 camera + receiver

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

### 1.6.2 Accessories

| Illustration | Description | Part number |
|---|---|---|
|  | **STG PSX VZ sterilisable handle**<br>This handle is compatible with all cameras. | STG PSX VZ 01 |

Tab. 4: Maquet Orchide accessories table

## 1.7 Device identification label

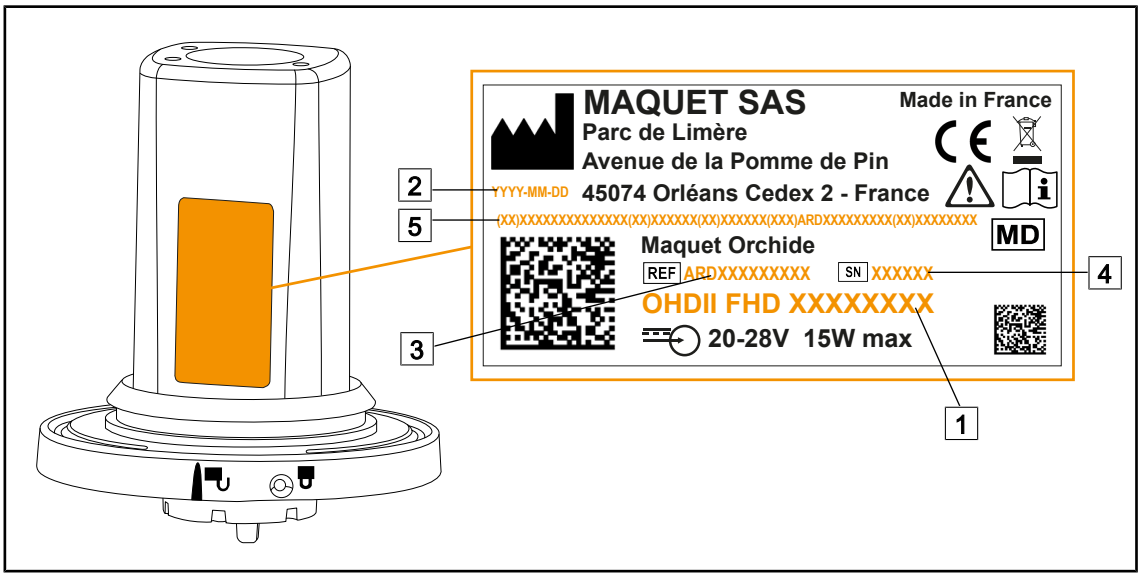



Fig. 6: Product identification label

1 Product name
2 Manufacturing date
3 Product code
4 Serial number
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<br>ANSI/AAMI ES60601-1:2005/A2:2021<br>CAN/CSA-C22.2 No. 60601-1:14 + A2:22 | Medical electrical equipment – Part 1: General requirements for basic safety and essential performance |
| IEC 60601-1-2:2014+AMD1:2020<br>ANSI/AAMI/IEC 60601-1-2:2014/A1:2021<br>CSA C22.2 No. 60601-1-2:16 (R2021)<br>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 | 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 | Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for an environmentally friendly design |
| IEC 62366-1:2015+AMD1:2020 | Medical devices – Part 1: Application of usability engineering to medical devices |
| IEC 62304:2006+AMD1:2015 | Medical device software – Software life cycle processes |

Tab. 5: Compliance with product standards

| Reference | Title |
|---|---|
| IEC 62311:2019 | Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz – 300 GHz) |
| ISO 20417:2020 | Medical devices - Information provided by manufacturer |
| ISO 15223-1:2021 | Medical devices - Symbols to be used with information to be provided by manufacturer - Part 1: General requirements |

Tab. 5: Compliance with product standards

| Reference | Title |
|---|---|
| 47 CFR Part 15 | Title 47--Telecommunications<br>Chapter I--Federal Communications Commission<br>Subchapter A -- General<br>PART 15 - Radio frequency devices |
| Directive 2014/53/EU | RED Directive |
| Radio Act 2014 | Japan Radio Act (Act No 131 of 1950) |
| Safety Code 6 2014 | Limits of Human Exposure to Radiofrequency Electromagnetic Energy in the Frequency Range from 3 kHz to 300 GHz |

Tab. 6: Radio standards and regulations

Quality management:

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

Tab. 7: Compliance with quality management standards

Environmental standards and regulations:

| Country | Reference | Version | Title |
|---|---|---|---|
| EU | ROHS Directives | 2011 | DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011on the restriction of the use of certain hazardous substances in electrical and electronic equipment |
| | | 2015 | COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015, amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances |
| | | 2016 | COMMISSION DELEGATED DIRECTIVE (EU) 2016/585 of 12 February 2016 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead, cadmium, hexavalent chromium, and polybrominated diphenyl ethers (PBDE) in spare parts recovered from and used for the repair or refurbishment of medical devices or electron microscopes |
| | | 2017 | DIRECTIVE (EU) 2017/2102 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 November 2017 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment |
| Worldwide | IEC 63000: | 2022 | IEC 63000:2016/A1:2022 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances |
| EU | REACH Regulation | 2006 | REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and REACH - Restriction of Chemicals (REACH), amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC |
| USA _ California | US California Proposition 65 Act | 1986 | HEALTH AND SAFETY CODE - HSC DIVISION 20. MISCELLANEOUS HEALTH AND SAFETY PROVISIONS CHAPTER 6.6. Safe Drinking Water and Toxic Enforcement Act of 1986 |
| China | SJ/T 11365-2006 | 2006 | ACPEIP - Administrative Measure on the Control of Pollution caused by Electronic Information Products Chines RoHS (Restriction of Hazardous Substances) |

Tab. 8: Environmental standards and regulations

Market standards and regulations

| Country | Reference | Year | Title |
|---|---|---|---|
| Australia | TGA 236-2002 | 2021 | Therapeutic Goods (Medical Devices) Regulations 2002. Statutory Rules No.236, 2002 made under the Therapeutic Goods Act 1989 |
| EU | Regulation 2017/745/EU | 2017 | Medical Devices Regulations |
| Malaysia | Act 737 | 2012 | Medical Device Act 2012 (Act 737) |
| Morocco | Law 84-12 | 2012 | Law No. 84-12 relative to medical devices |
| New Zealand | Regulation 2003/325 | 2003 | Medicines (Database of Medical Devices) Regulations 2003 (SR 2003/325) |
| Saudi Arabia | Regulation | 2017 | Medical Device Interim Regulation, decree No. (4-16-1439) dated 27/12/2017 |
| Serbia | Law 105/2017 | 2017 | Law on Medicinal Products and Medical Devices No. 105/2017 |
| South Korea | Act 14330 | 2016 | Medical Device Act |
| South Korea | Decree 27209 | 2016 | Enforcement Decree of Medical Act |
| South Korea | Rule 1354 | 2017 | Enforcement Rule of the Medical Act |
| Switzerland | RS (Odim) 812.213 | 2020 | Medical Devices Ordinance (MedDO) of 1 July 2020 |
| Thailand | Act 2562 | 2019 | Medical Device Act (No. 2) B.E. 2562 (2019) |
| UK | Act | 2021 | Medical Devices Regulations 2002 No. 618 |
| USA | 21CFR Part 7 | 2023 | Title 21--Food And Drugs<br>Chapter I--Food and Drug Administration Department of Health and Human Services<br>Subchapter A -- General<br>PART 7 - Enforcement policy |
| USA | 21CFR Subchapter H | 2024 | Title 21--Food And Drugs<br>Chapter I--Food and Drug Administration Department of Health and Human Services<br>Subchapter H -- Medical Devices |

Tab. 9: Compliance with market standards

## 1.9 Information relating to intended use

### 1.9.1 Intended use

The Maquet Orchide product range is designed to capture a view of the surgical site.

### 1.9.2 Indications

The Maquet Orchide range is intended to be used for any type of surgery or treatment for which activities on the surgical site must be recorded.

### 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 of a damaged product (e.g., lack of maintenance).
- In a setting other than a professional healthcare environment (e.g., home care).
- Use of the camera for assistance during an operation or to establish a diagnosis.

### 1.9.5 Contraindications

This product does not have any contraindications.

## 1.10 Primary purpose

The primary purpose of the Maquet Orchide range of cameras is to capture a view of the surgical site, while being compatible with the illumination intensity of the surgical lights.

## 1.11 Clinical benefit

Maquet Orchide cameras are medical devices that provide a video stream that can be used to:

- Broadcast live surgical operations in the operating room.
- Archive or document patient records.

## 1.12 Warranty

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

## 1.13 Expected service lifetime

The expected service lifetime of the product is 10 years.

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

This 10-year service lifetime applies subject to the annual periodic checks being performed by personnel trained and approved by Getinge. After this time, if the device is still in use, an inspection must be carried out by personnel trained and approved by Getinge to ensure the continued safety of the device.

## 1.14 Instructions for reducing the environmental impact

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

- Reduce power consumption by switching off the device when not in use.
- 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.

# 2 Safety-related information

## 2.1 Environmental conditions

**Environmental conditions for transport and storage**

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

Tab. 10: Environmental conditions for transport/storage

**Environmental conditions for use**

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

Tab. 11: Environmental conditions for use

## 2.2 Safety instructions

### 2.2.1 Safe use of the product

**WARNING!**

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

**Installation, maintenance, repair 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 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.**

**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.**

**WARNING!**

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

**Do not use a damaged device.**

**WARNING!**

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

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

# 3 Control interfaces

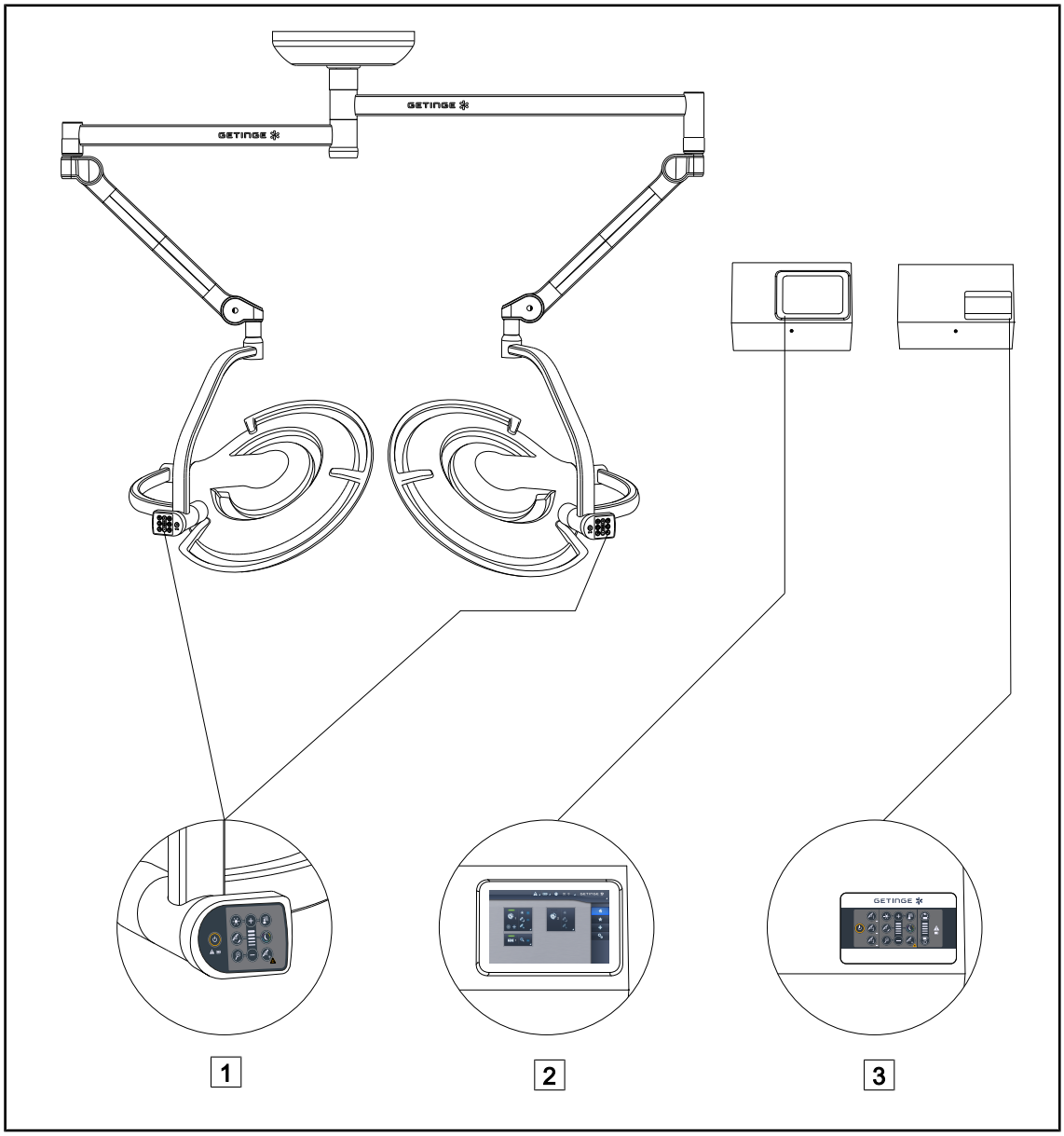



Fig. 7: Maquet PowerLED II control interfaces

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

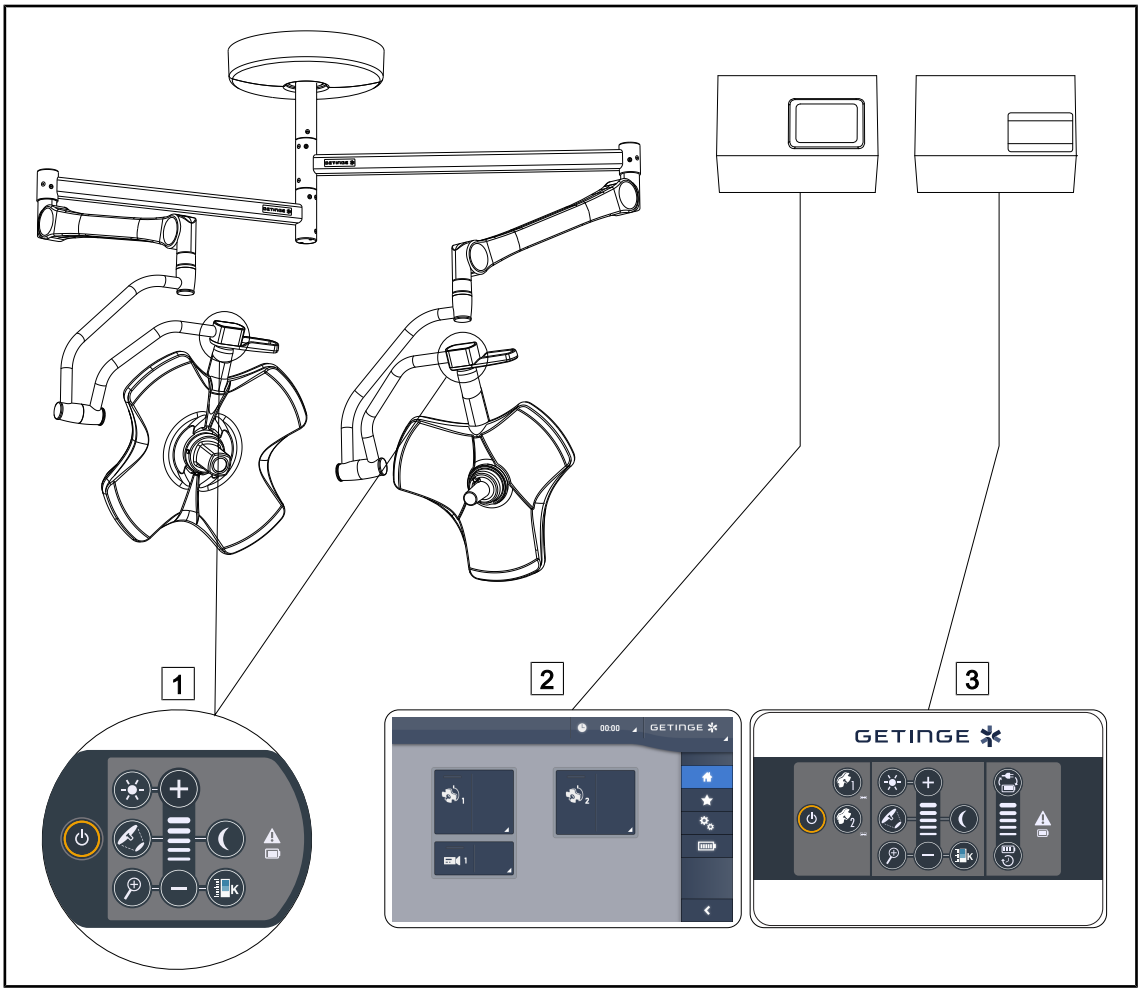



Fig. 8: Volista control interfaces

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

# 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.

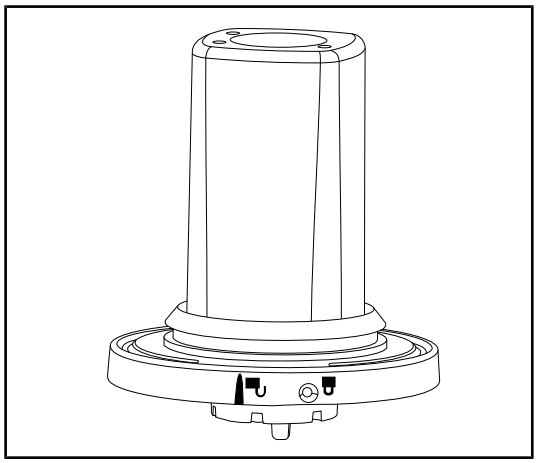


Fig. 9: Integrity of the device

**Integrity of the device**

1. Check that the device has not suffered any impact damage.
2. If a problem is noted, contact technical support.

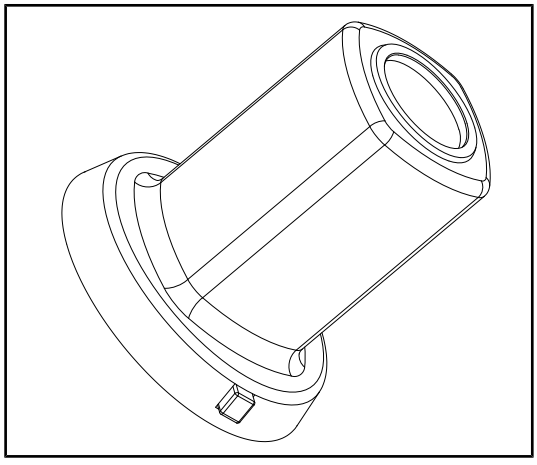


Fig. 10: Sterilisable handles

**Integrity of sterilisable handles**

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

## 4.2 Installing/removing a QL camera on a Volista lighthead

**WARNING!**

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

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

**WARNING!**

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

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

### 4.2.1 Pre-positioning prior to installation

**On the camera**

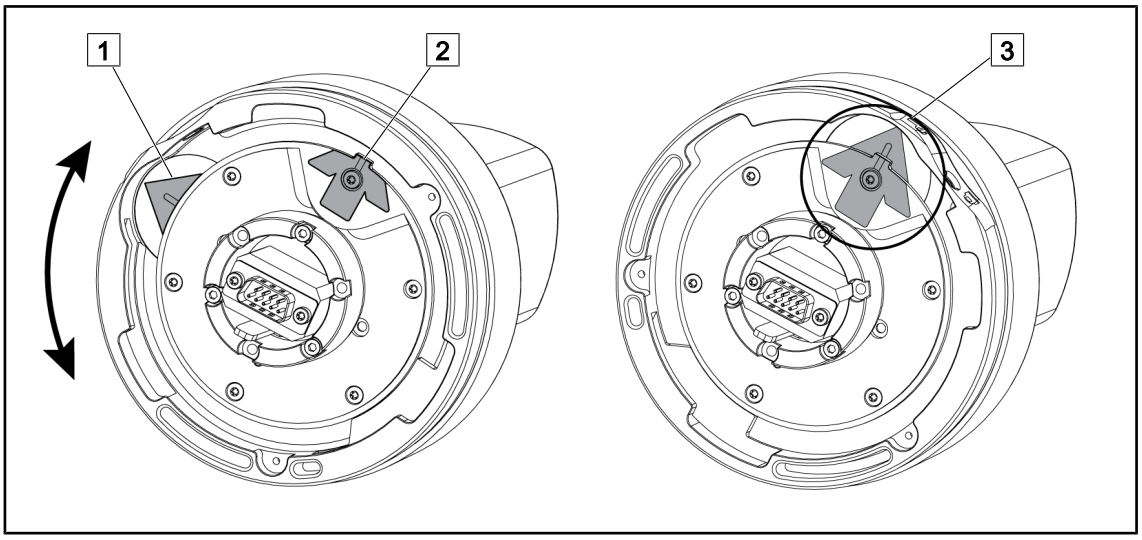



Fig. 11: Pre-positioning the camera

1. Rotate the baseplate [1] to align with the tip [2] and form a green arrow [3].
   ➢ The camera is ready to be positioned.

**On the lighthead**

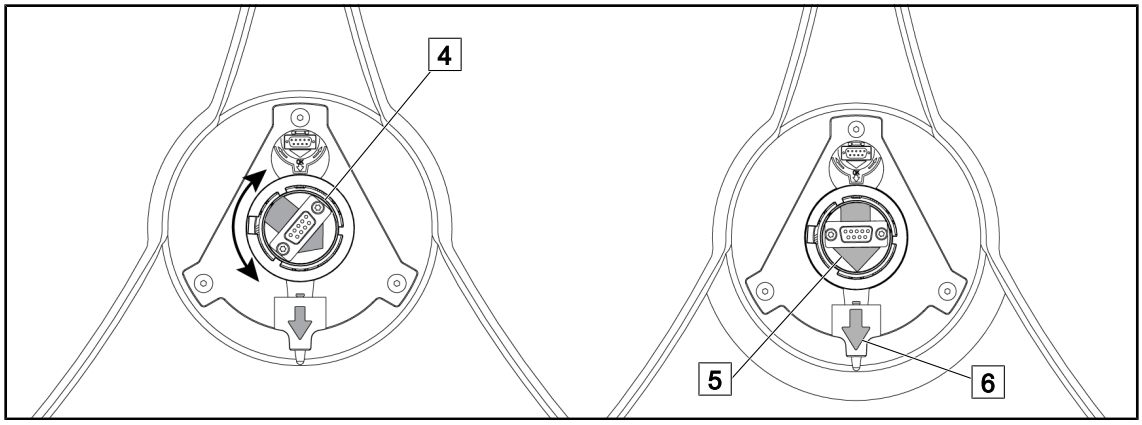



Fig. 12: Pre-positioning the lighthead

1. In the centre of the lighthead, orient the connector 4 so that the two green arrows 5 and 6 are aligned.
   - ➢ The lighthead is ready to receive the camera.

## 4.2.2 Fitting the device to the lighthead

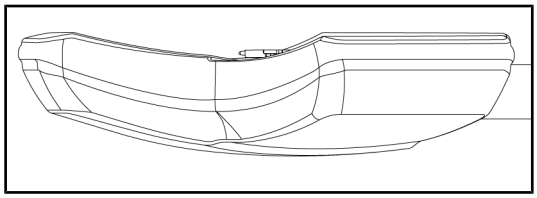


Fig. 13: Positioning the lighthead

1. Position the lighthead with the underside facing the ceiling.
   - ➢ This facilitates installation of the camera on the lighthead.

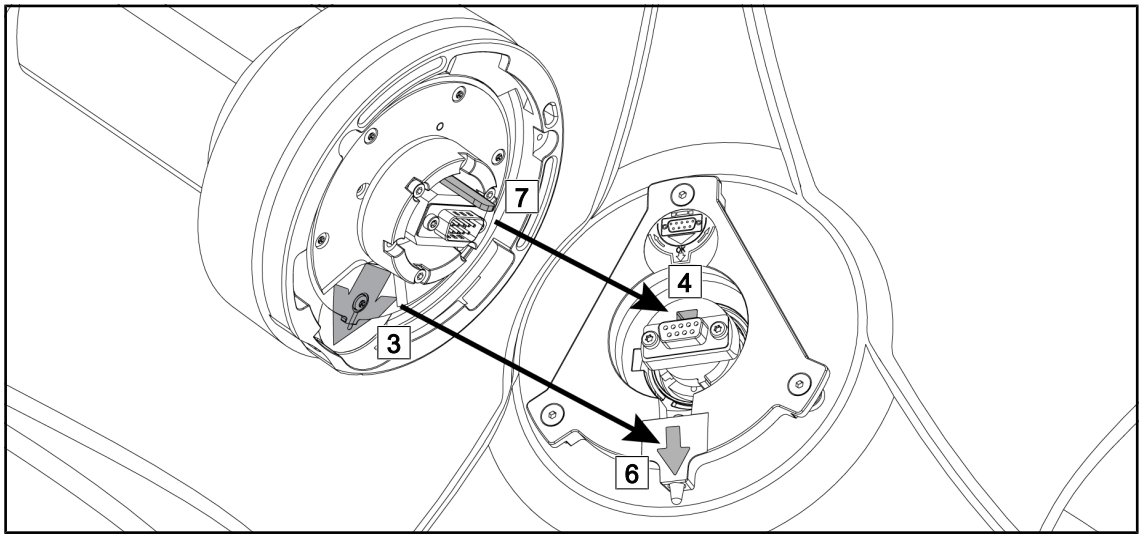



Fig. 14: Instructions for installing the Quick Lock system

1. Present the camera with the pin 7 opposite the slot 4.
2. Place the two arrows 3 and 6 opposite each other.

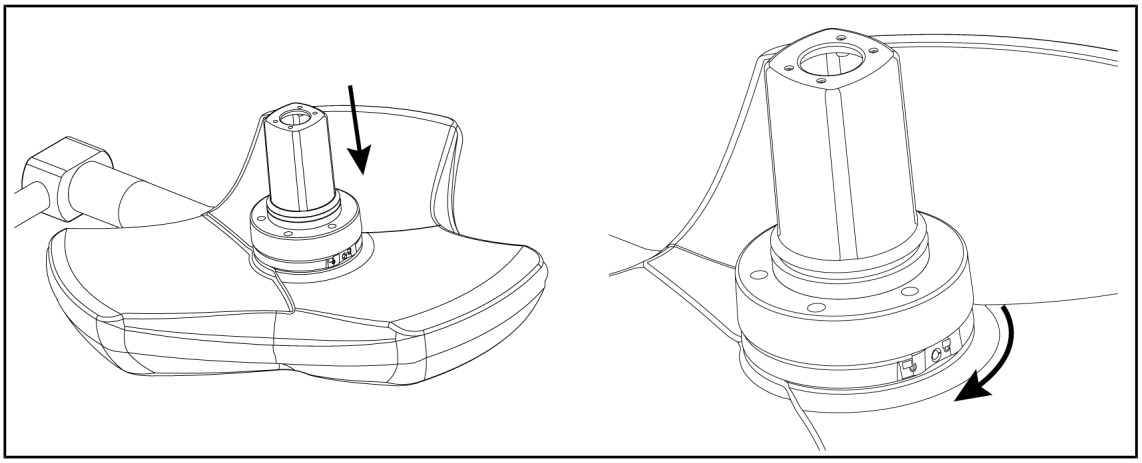


Fig. 15: Presenting the camera against the lighthead

1. Insert the camera into the lighthead until the camera base plate is fully flush against the underside.
2. Using both hands, turn the camera base plate clockwise until it clicks into place.

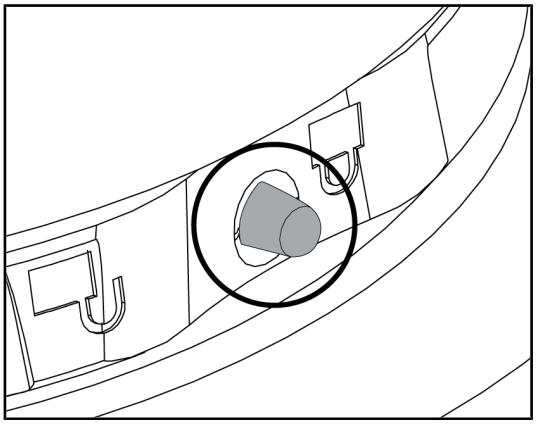


Fig. 16: Locking the camera in place on the lighthead

1. Check that the camera is correctly in place and that the locking button protrudes correctly from its recess.
2. Move the lighthead using the handle, to check that the system is correctly in place.
3. Check that the camera subassembly turns freely through 330°.

   ➢ The device is installed.

### 4.2.3 Removing the device

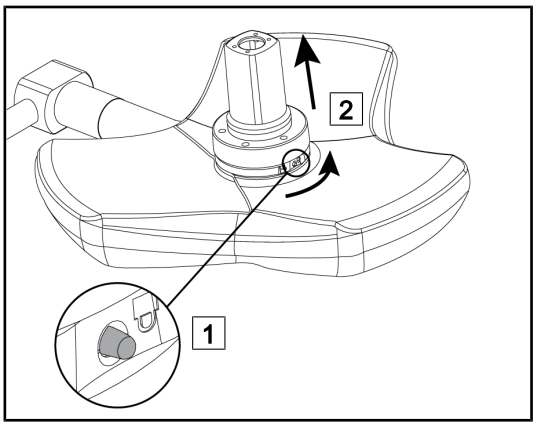



Fig. 17: Removing the lighthead

1. Press the locking button.
2. Keep the button [1] pressed and, using two hands, rotate the base of the device anticlockwise.
3. Remove the Quick Lock camera by pulling upwards [2].

   ➢ The device is removed.

## 4.3 Installing/removing a QL+ camera on a Maquet PowerLED II lighthead

**WARNING!**

**Risk of infection**

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

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

### 4.3.1 Mounting the camera on the lighthead

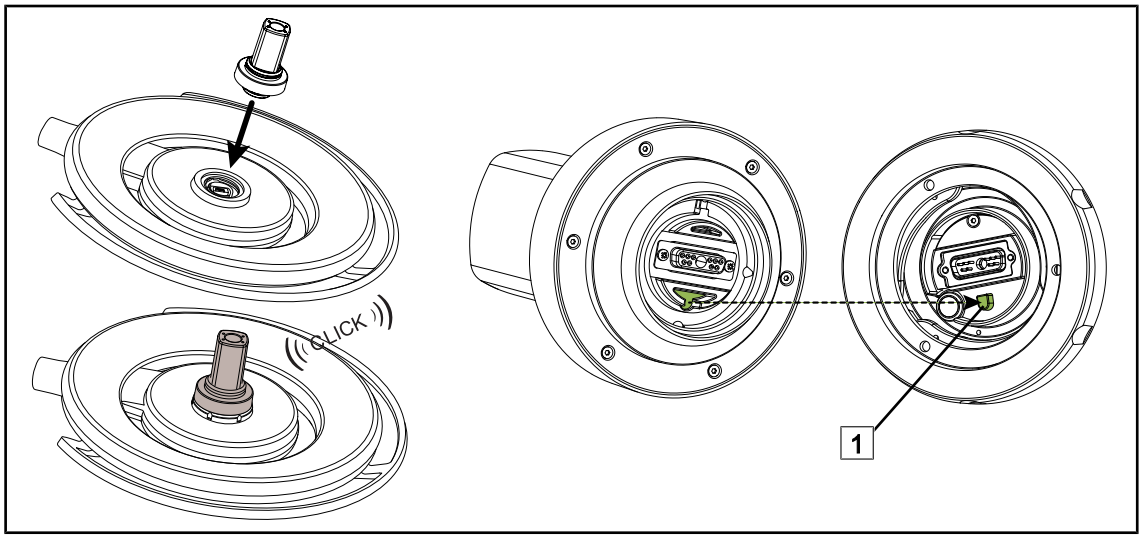



Fig. 18: Installing a Quick Lock + device

- 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.

### 4.3.2 Removing the camera from the lighthead

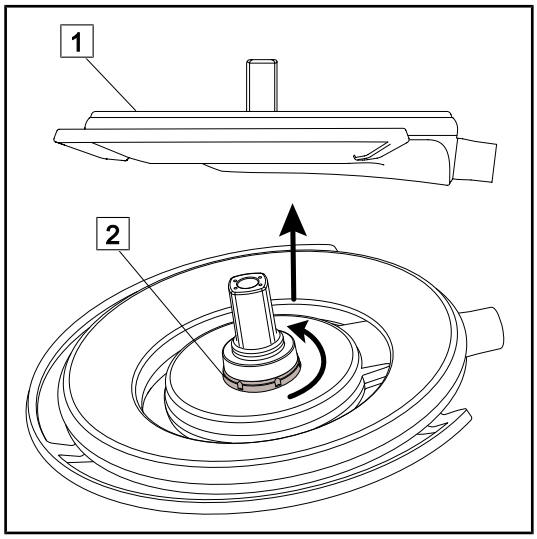



Fig. 19: Removing a Quick Lock device

1. Turn the lighthead over so that the underside is facing the ceiling 1.
2. Once the lighthead is turned over, rotate the locking interface 2 anti-clockwise and then remove the camera whilst holding the locking interface 2.

   ➢ The camera has been removed.

## 4.4 Installing and removing the 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.**

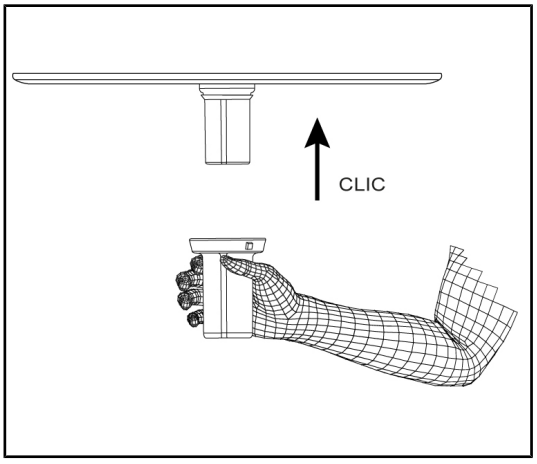



Fig. 20: Installing a sterilisable handle for use with a camera

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

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

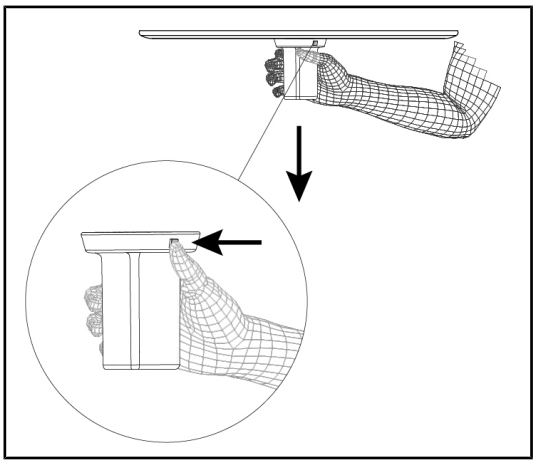


Fig. 21: Removing a sterilisable handle for use with a camera

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

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

## 4.5 FHD wired video system

This receiver placed in the false ceiling makes it possible to convert the camera signal, conveyed through the suspension, to the 3G-SDI output.

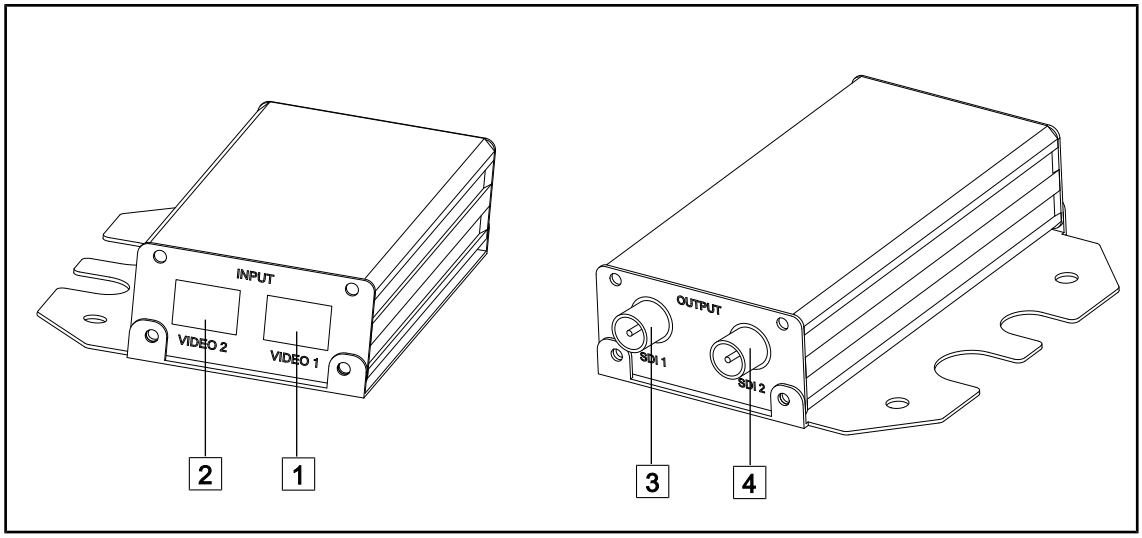



Fig. 22: Wired video system

1 Video input #1
2 Video input #2
3 3G-SD1 video output #1
4 3G-SD1 video output #2

**NOTICE**

If two wired cameras are installed to transmit two separate images, two receivers must be used. Contact the Getinge technical department if necessary.

## 4.6 Wireless video system (on Volista lighthead only)

**NOTICE**

For optimal use of the system, do not use two cameras on the same configuration, and do not position a camera more than 3m away from its receiver.

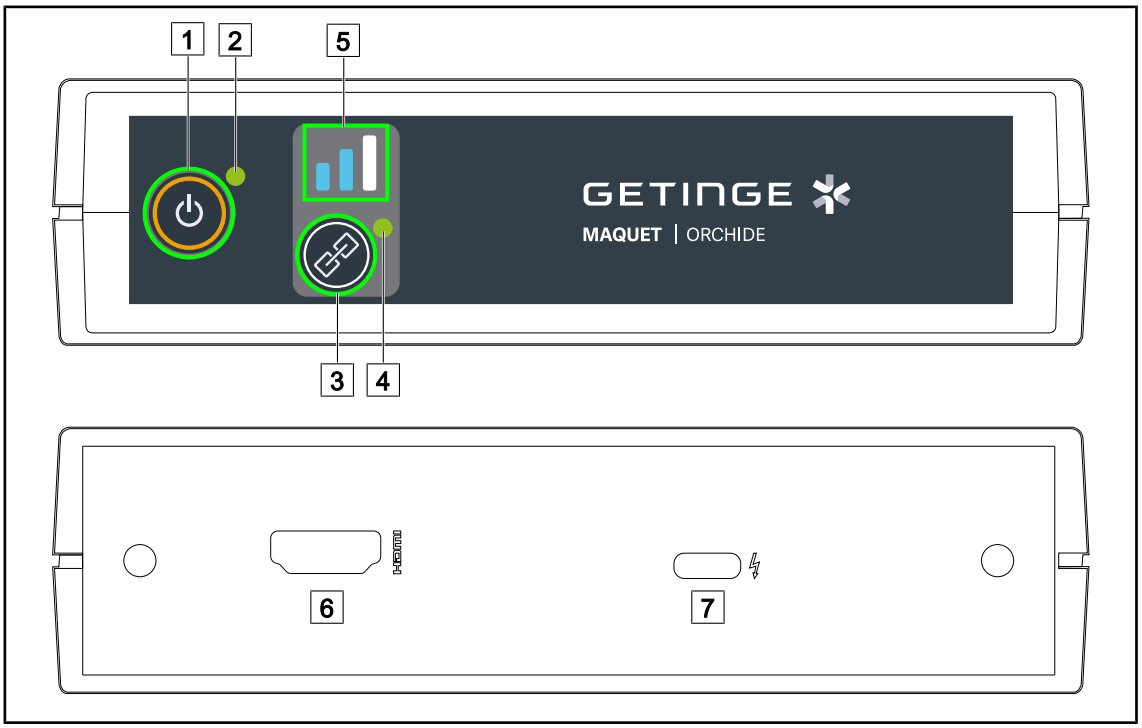



Fig. 23: Wireless video receiver system

1 On/Off button
2 Power indicator
3 Pairing button
4 Pairing indicator
5 Signal indicator
6 HDMI connector
7 USB-C port

**Turning the receiver on and off**

- Press the **On/Off button** 1 to turn on the receiver; the power indicator 2 lights up in green.
- Press the **On/Off button** 1 until the power indicator 2 is off to turn off the receiver.

After five minutes of idle time, the receiver goes into standby mode and the power indicator 2 flashes. It restarts automatically when a camera is detected.

**Pairing a camera automatically (auto mode enabled by default)**

- Turn on the camera and receiver.
- The pairing indicator 4 flashes quickly while the system searches for the camera.
- The pairing indicator 4 flashes slowly during pairing.
- Once the pairing indicator 4 is lit solid green, the camera is paired.
- If the pairing indicator 4 is lit red, pairing has failed. In this case, check that the camera is powered on and restart the pairing using the pairing button.

| | | | |
|---|---|---|---|
| | Risk of image loss | | Weak signal |
| | Average signal | | Good signal |

Tab. 12: Signal strength

People and objects in the operating environment (personnel, other devices, operating room configuration) can impact the signal strength. The signal strength can be improved by moving the camera and/or receiver.

**NOTICE**

The system has two pairing modes:

- Automatic: The receiver will automatically pair with any camera that is on and available.
- Manual: Pairing with any new camera that is on and available will happen only after starting the procedure using the pairing button.

### Pairing a camera

- Once the receiver is in manual mode, press the **pairing button** 3 until the pairing indicator 4 flashes quickly in green.
- Once the camera is found, the pairing indicator 4 will flash more slowly during pairing, then turn solid green once pairing is complete.

### Changing the pairing mode: Manual or Automatic

- The receiver must already be paired with a camera.
- Press the **pairing button** 3 until a bar on the signal indicator 5 starts flashing in blue. If the flashing bar is the smallest on the left, the receiver is in manual pairing mode; if the flashing bar is the largest on the right, the receiver is in automatic pairing mode.


Fig. 24: Auto/Manual Mode

**NOTICE**

With two cameras installed, the switchover is not automatic when one of the cameras is switched off in Manual mode. Press the pairing **button** 3 to switch to the active camera.

### Restoring the factory settings

Press the **On/Off button** 1 for 5 seconds to reset the receiver to its factory settings.

### Recommended positioning of the device

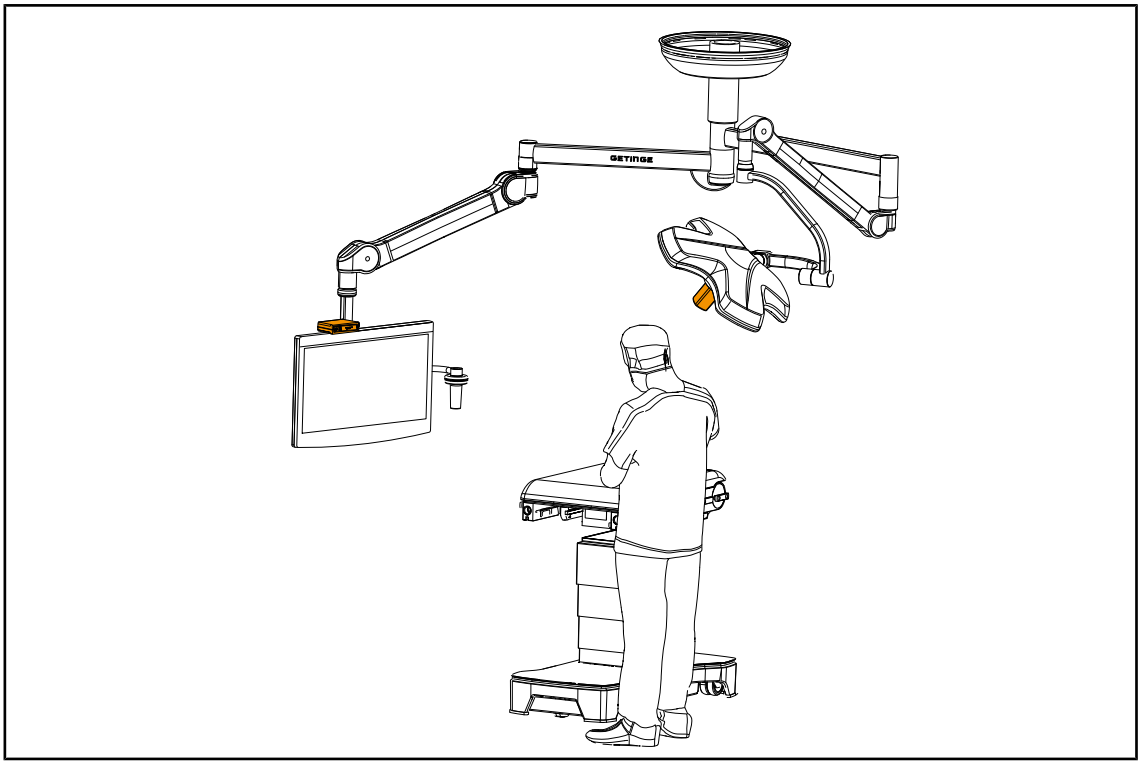


Fig. 25: Positioning when the surgeon is looking at the screen

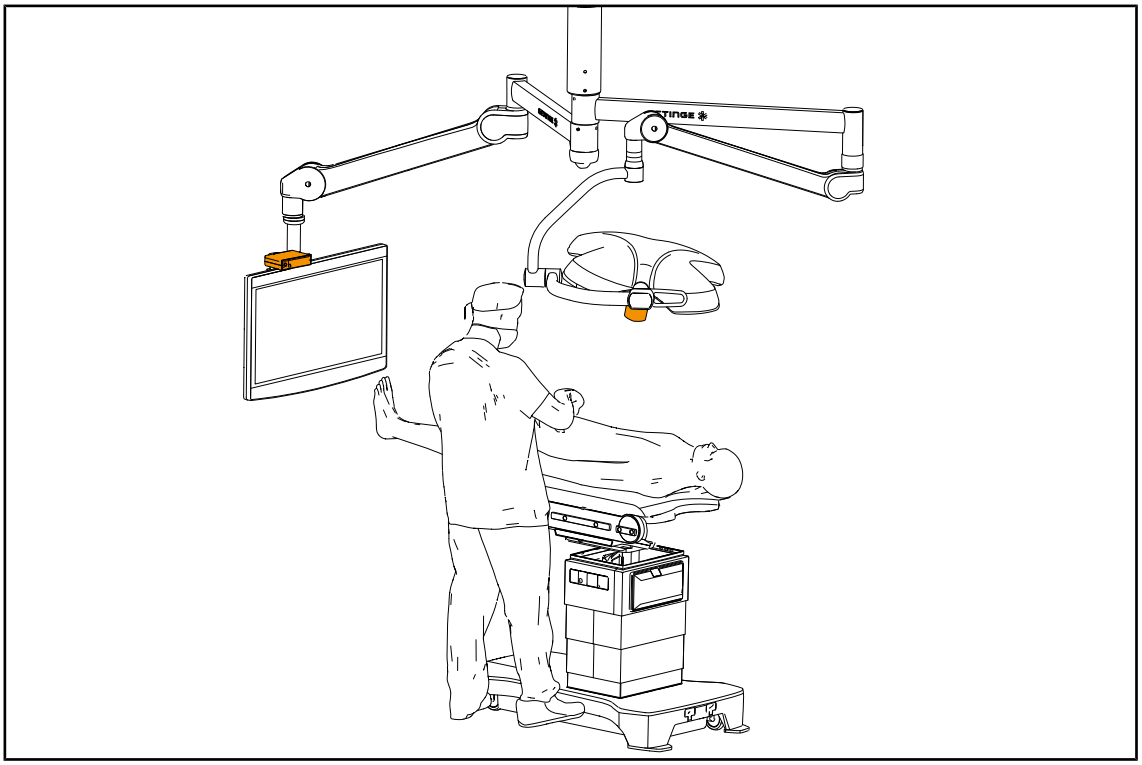


Fig. 26: Positioning when the screen is not intended for the surgeon

## 4.7 Controlling the camera

### 4.7.1 From the lighthead control keypad (zoom only)

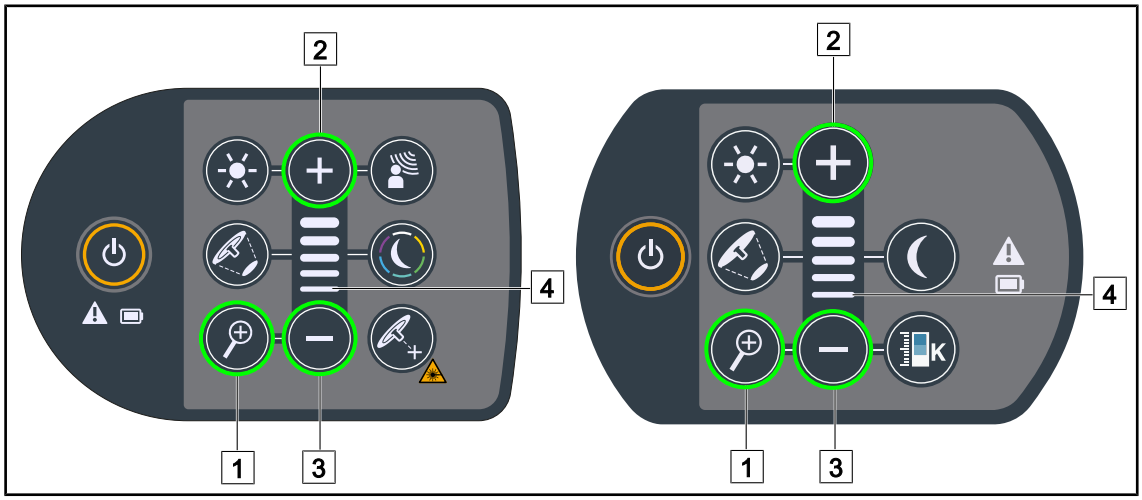



Fig. 27: Controlling the camera using the lighthead control keypads

**Adjusting the camera zoom**

1. Press **Camera Zoom** [1].
2. Press **Plus** [2] or **Minus** [3] to modify the zoom level.
   ➢ The level indicator [4] varies according to the zoom level setting on the camera.

### 4.7.2 From the wall-mounted control keypad (zoom only)

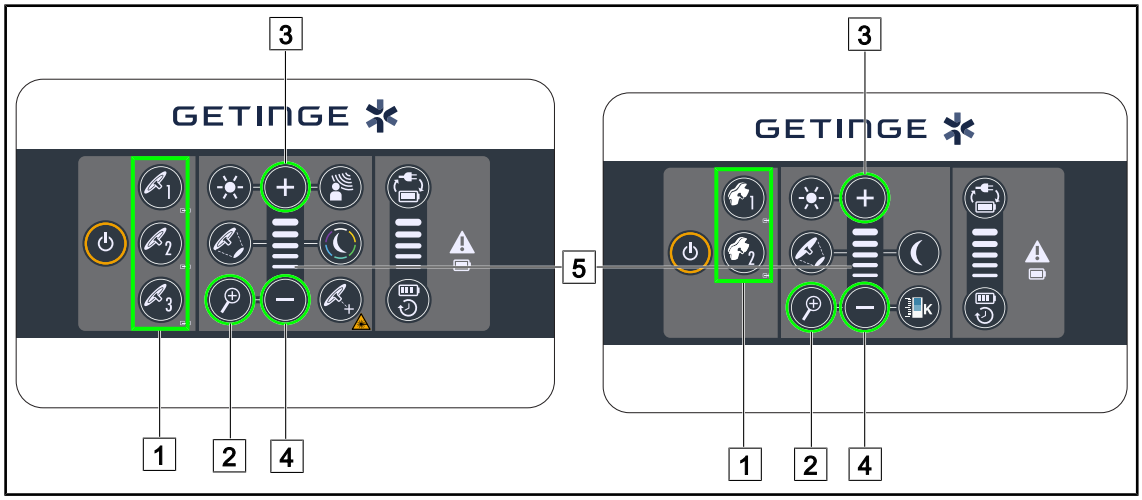



Fig. 28: Controlling the camera using the wall-mounted control keypads

*Begin by selecting the lighthead to be adjusted* [1].

**Adjusting the camera zoom**

1. Press **Camera Zoom** [2].
2. Press **Plus** [3] or **Minus** [4] to modify the zoom level.
   ➢ The level indicator [5] varies according to the zoom level setting on the camera.

### 4.7.3 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.

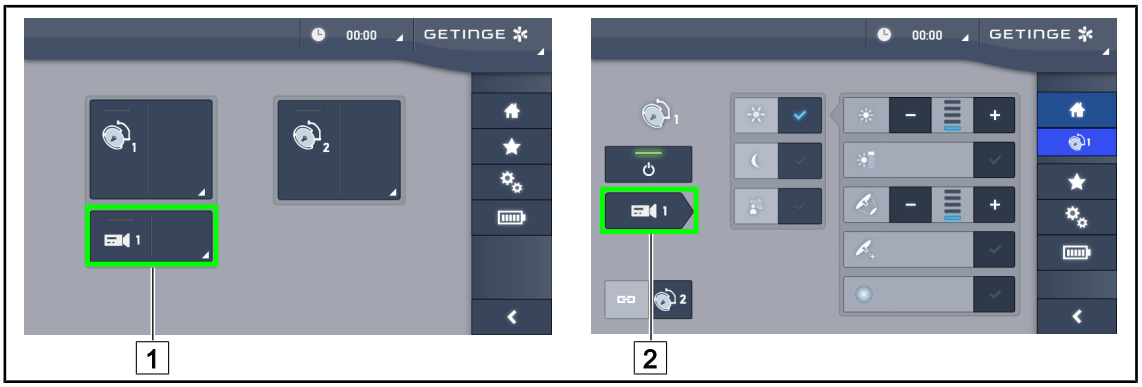



Fig. 29: Turn on the camera

**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. 30: 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. 31: 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.

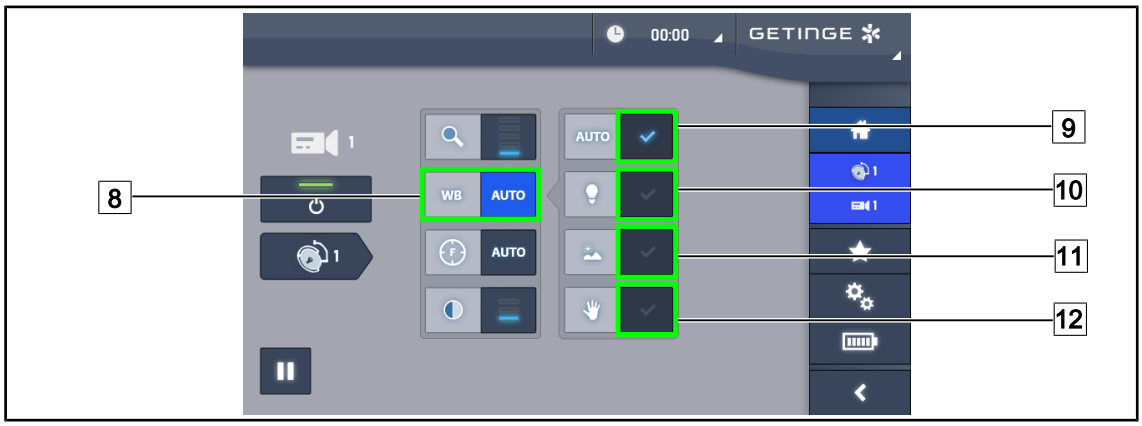



Fig. 32: White balance

### 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.

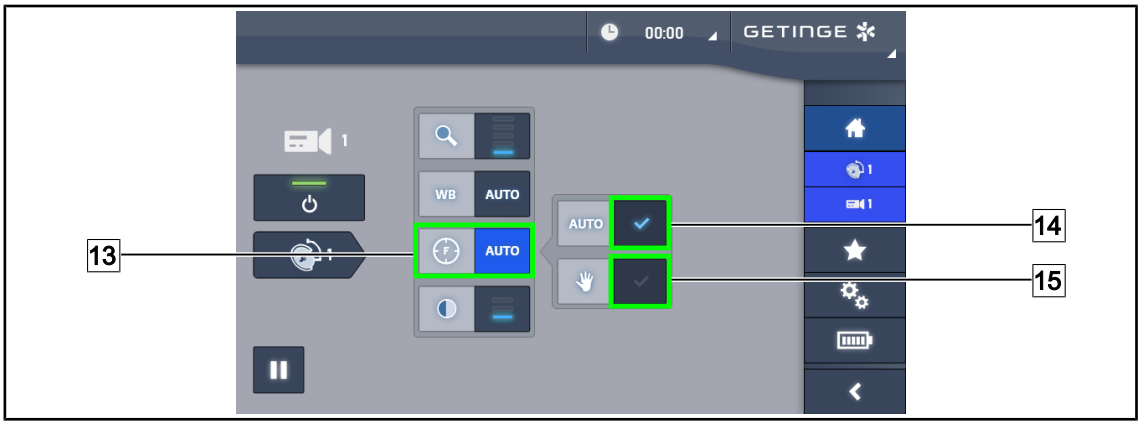



Fig. 33: Setting the focus

### 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.

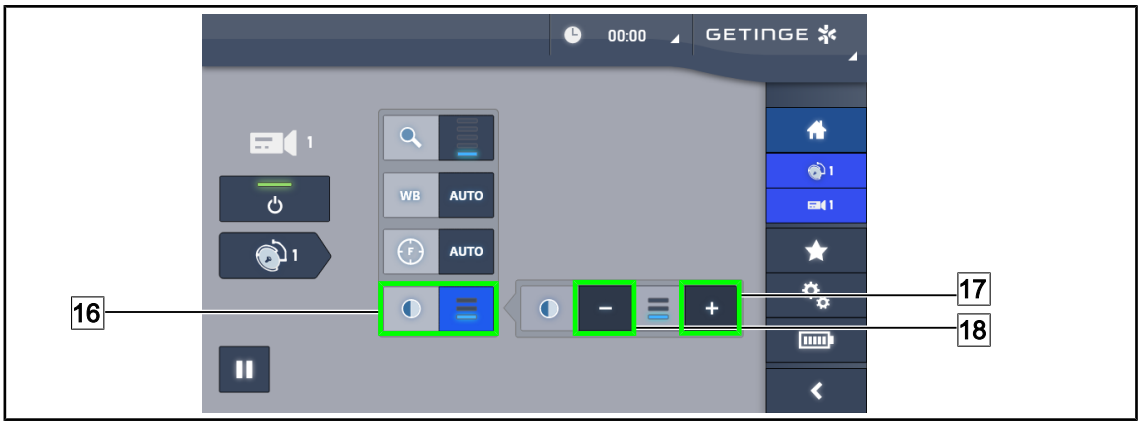



Fig. 34: Contrast adjustment

### 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.

## 4.7.4 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.

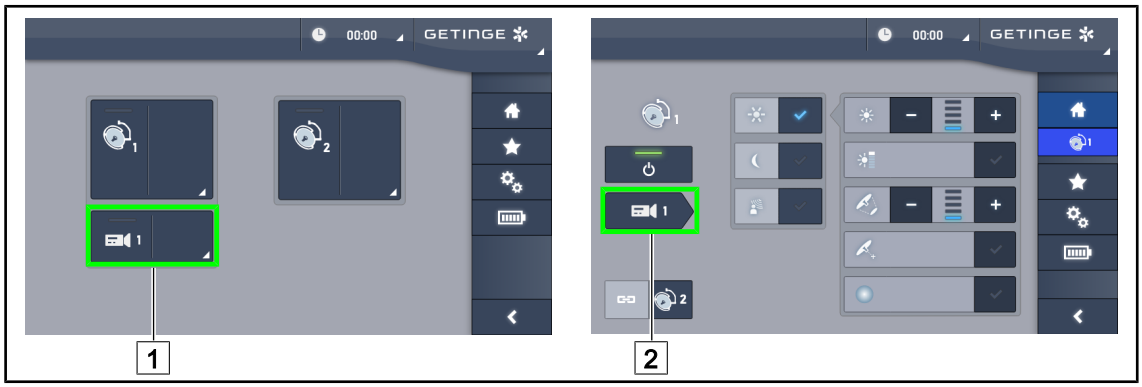



Fig. 35: Turn on the camera

### 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.

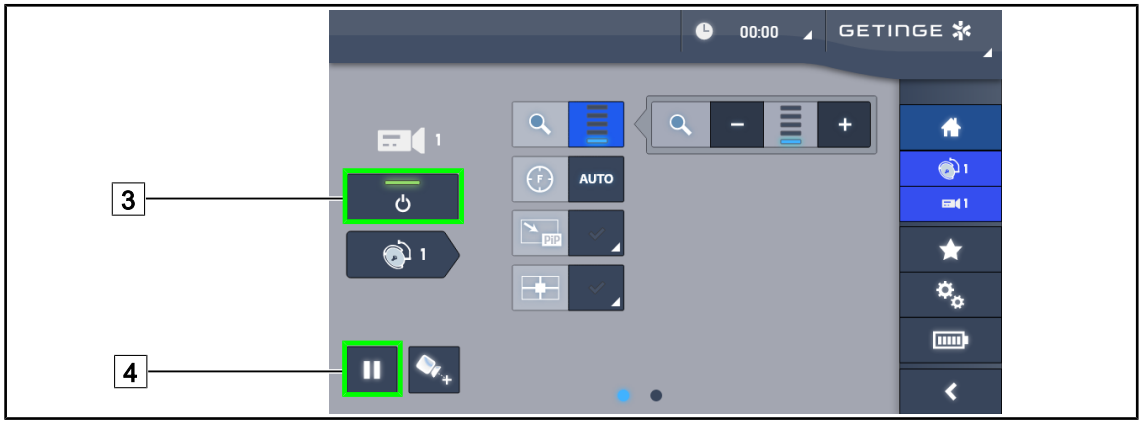



Fig. 36: Camera page

### 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. 37: 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. 38: 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.

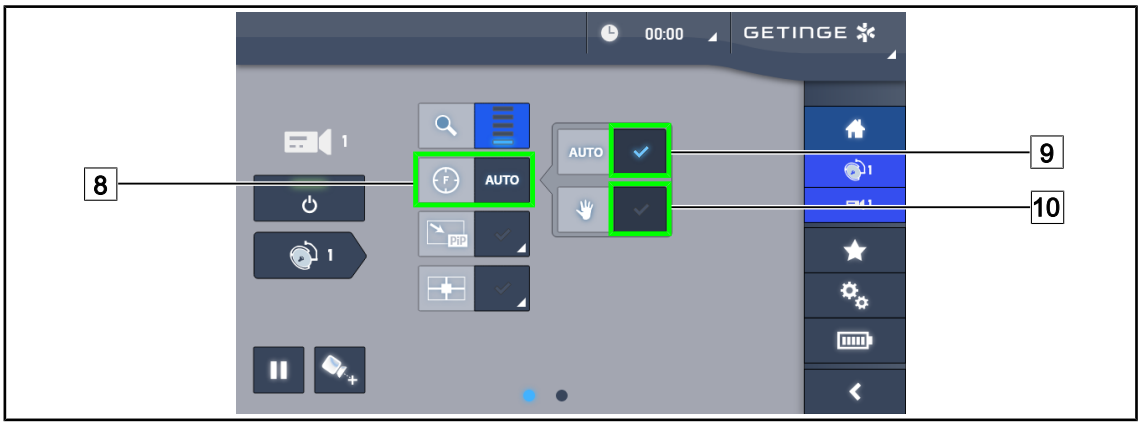



Fig. 39: Setting the focus

### 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.

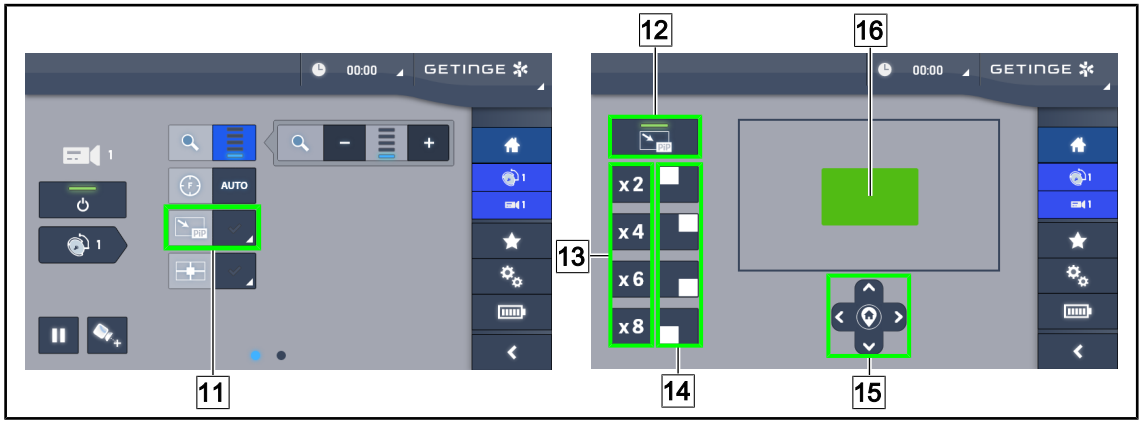



Fig. 40: Using the Picture-in-Picture

### 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.

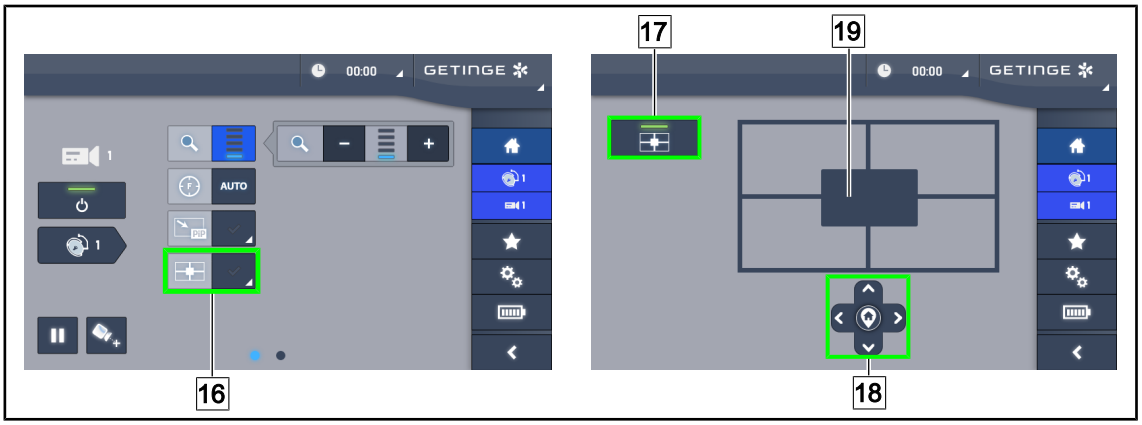



Fig. 41: Using the E-Pan Tilt

### 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.

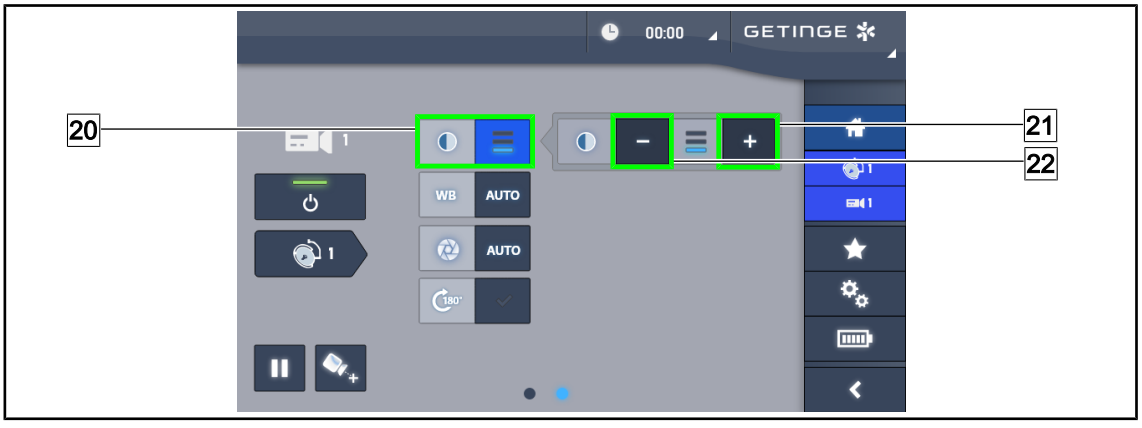



Fig. 42: Contrast adjustment

### 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.

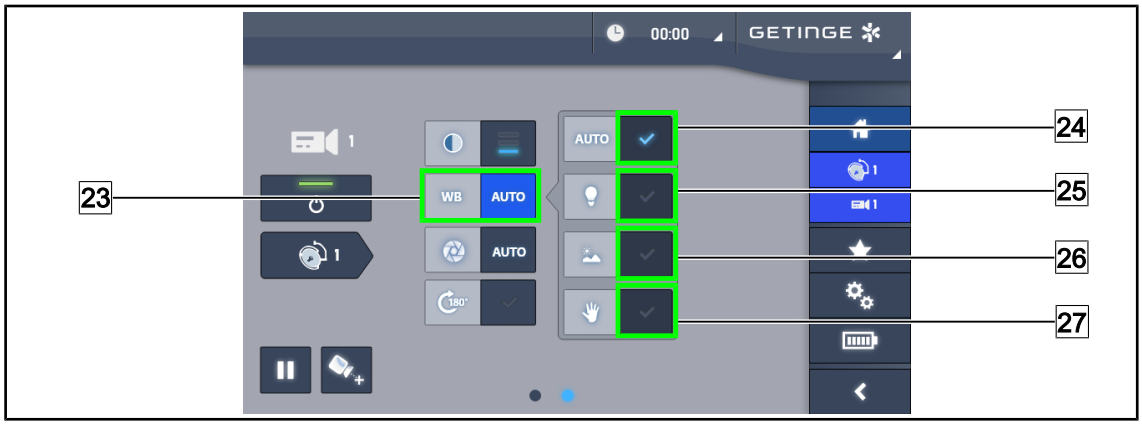



Fig. 43: White balance

### 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.

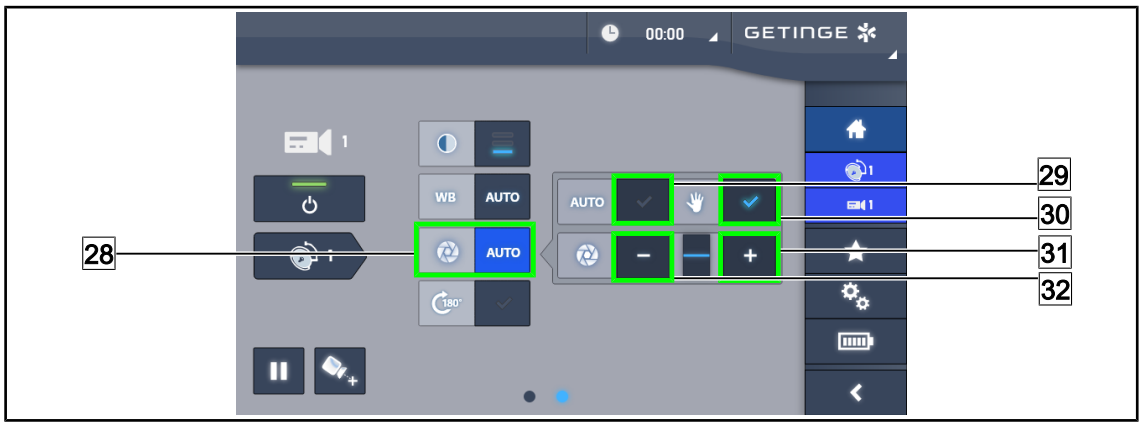



Fig. 44: Adjusting the exposure

### 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. 45: Image rotation

### Inverting the transmitted image

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

# 5 Troubleshooting

### OHDII FHD QL VP01 / OHDII FHD QL+ VP01

| Anomaly | Likely cause | Corrective action |
|---|---|---|
| The sterilisable handle does not click into place correctly | The locking mechanism is damaged | Replace the handle |
| 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 |
| | The camera is not on a light-head pre-wired for video. | Install the camera on a light-head that is pre-wired for video (‘H6’ marked on label). |

Tab. 13: Anomalies and malfunctions OHDII FHD QL VP01 ou OHDII FHD QL+ VP01

### OHDII FHD QL AIR05

| Anomaly | Corrective action |
|---|---|
| Receiver cannot be switched on | 1. Check that the receiver power cable is properly connected<br>2. If the cable is connected, check for the presence of voltage<br>3. If voltage is present and the problem persists, contact Getinge technical service |
| No image after switching on and Getinge logo does not appear on screen after 1 minute | 1. Check that the monitor is powered on and lights up<br>2. Check that the HDMI cable is properly connected to the monitor<br>3. If the cables are connected, check that voltage is present<br>4. If voltage is present and the problem persists, contact Getinge technical service |
| No image and red pairing indicator | 1. Pairing problem: re-pair the system in manual mode (see Wireless video system (on Volista lighthead only) [⏩ Page 28] section)<br>2. If the problem persists, contact Getinge technical service |
| No image and green pairing indicator (no signal indicator) | 1. Outside the camera's transmission range, reorient the camera to produce a signal of 1 or 2 bars.<br>2. If the problem persists, contact Getinge technical service |

Tab. 14: Anomalies and malfunctions OHDII FHD QL AIR05

# 6 Cleaning / Disinfection / Sterilisation

**WARNING!**

**Risk of infection**
**Cleaning and sterilisation procedures vary considerably from one healthcare institution to another and depending on local regulations.**

**Users must contact their hospital's sanitary specialists. The recommended products and procedures must be applied.**

## 6.1 Cleaning and disinfecting the system

**WARNING!**

**Risk of equipment damage**
**The ingress of liquid inside the device during cleaning may adversely affect its operation.**

**Do not clean the device under running water or spray a solution directly onto the device.**

**WARNING!**

**Risk of infection**
**Certain cleaning products or procedures may damage the enclosure of the device, which may result in particles falling onto the surgical site during an operation.**

**Disinfectants containing glutaraldehyde, phenol or iodine must not be used. Fumigation methods are unsuitable for disinfecting the unit and must not be used.**

**WARNING!**

**Risk of burns**
**Certain parts of the device remain hot after use.**

**Check that the power is switched off and the light has cooled down before starting cleaning.**

**General instructions concerning cleaning, disinfection and safety**

In standard use, the level of treatment required for cleaning and disinfection of the device is low-level disinfection. The device is classified as non-critical with a low infectious risk. However, depending on the infectious risk, intermediate or high-level disinfection may be envisaged.

The responsible body must follow the national requirements (standards and guidelines) for all matters of hygiene and disinfection.

### 6.1.1 Cleaning the device

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

## 6.1.2 Disinfecting the device

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

### 6.1.2.1 Disinfectants to be used

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

### 6.1.2.2 Permitted active substances

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

Tab. 15: Lists of active substances suitable for use

**Examples of commercially available products tested**

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

## 6.2 Cleaning and sterilising Maquet Sterigrip sterilisable handles

### 6.2.1 Preparation for cleaning

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

### 6.2.2 Manual cleaning

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

**NOTICE**

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

### 6.2.3 Cleaning in a washer-disinfector

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

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

Tab. 16: Typical cleaning cycles in a washer-disinfector

### 6.2.4 Sterilisation of the Maquet Sterigrip handles

**WARNING!**

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

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

**NOTICE**

Maquet Sterigrip sterilisable handles are designed for autoclave sterilisation.

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

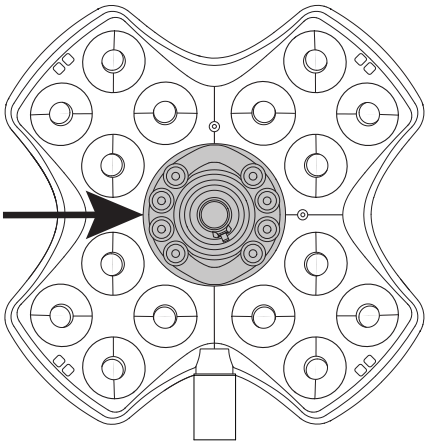
| Sterilisation cycle | Temperature (°C) | Time (min) | Dry (min) |
|---|---|---|---|
| ATNC (Prion) Prevacuum | 134 | 18 | – |

Tab. 17: Example of a steam sterilisation cycle

# 7 Maintenance

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

## 7.1 Monthly inspections

| Illustration | Action |
|---|---|
|  | **Absence of particles**<br>1. Check that there are no particles which could cause friction in the Quick Lock interface; remove any dust from the areas concerned on the camera/handle and the lighthead.<br>2. If a problem is noted, contact technical support. |

Tab. 18: Monthly visual and functional inspections

## 7.2 Contact

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

# 8 Technical specifications

## 8.1 Electrical specifications of cameras and receivers

**Electrical specifications of cameras**

**NOTICE**

The default specifications of the camera are highlighted in bold in the table.

| Specifications | OHDII FHD QL+ VP01 | OHDII FHD QL VP01 | OHDII FHD QL AIR05 |
|---|---|---|---|
| Sensor | 1/3” CMOS | | |
| Number of pixels | ~2.48 Megapixels | | |
| Video standard | **1080i** / 1080p | **1080i** / 1080p | 1080p |
| Image refresh rate | **50** / 60 fps | | |
| 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 tele-photo) | f = 5.1 to 51 mm | | |
| Visible field (W × H) at 1 m from the underside (wide angle to telephoto) | 865 x 530 mm to 20 x 12 mm | | |
| Anti-flicker | Yes | | |
| Focus [1] | **Auto** / Focus Freeze | | |
| White balance[1] | Auto / Indoor / Outdoor / **Manual** | | |
| Contrast enhancement[1] | Yes (3 levels) | | |
| Image freeze[1] | Yes | | |
| Preset[1] | 6 | | |
| Transmission type | Wired | Wired | Wireless |
| RS32 interface | Yes | | |
| Weight (without sterile handle) | 460 g | 820 g | 850 g |
| Dimensions (diam. x h) (without sterile handle) | 93 x 150 mm | 129 x 167 mm | 132 x 198 mm |

Tab. 19: Electrical specifications of cameras

[1] via touch screen only

### Technical specifications of the OHDII 4K QL+ VP11 camera

**NOTICE**

The default specifications of the camera are highlighted in bold in the table.

| Specifications | OHDII 4K QL+ VP11 |
|---|---|
| Sensor | 1/2.5” CMOS |
| Number of pixels | 8.29 Megapixels |
| Video standard | 2160p |
| Image refresh rate | 25 fps / 29.97 fps |
| Format | 16:9 |
| 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 × H) at 1 m from the underside (wide angle to telephoto) | 875 x 480 mm to 25 x 15 mm |
| Anti-flicker | Yes |
| Focus [1] | **Auto** / Focus Freeze / One Push Trigger |
| White balance[1] | Auto / Indoor / Outdoor / **Manual** |
| Contrast enhancement[1] | Yes (3 levels) |
| Exposure[1] | 15 levels ( -7 to +7) |
| Picture-in-Picture[1] | X2 X4 X6 X8 (four-corner selection) |
| Electronic Pan Tilt[1] | Yes |
| Positioning assistance[1] | Yes |
| Image freeze[1] | Yes |
| Electronic image rotation[1] | 180° |
| Preset[1] | 6 |
| Transmission type | Wired (Coaxial) |
| RS232 interface | Yes |
| Weight (without sterile handle) | 780 g |
| Dimensions (diam. x h) (without sterile handle) | 124 x 181 mm |

Tab. 20: Technical specifications of the OHDII 4K QL+ VP11 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. 21: VP01 RECEIVER technical specifications

**Technical specifications of the AIR05 receiver**

| Specifications | AIR05 RECEIVER |
|---|---|
| Video output | HDMI 1.4 |
| Weight (without/with mounting bracket) | 400 g / 1200 g |
| Dimensions of receiver | 155 × 105 × 40 mm |
| Transmission frequency | 60 GHz |
| Input voltage | 5V, 2A |

Tab. 22: AIR05 RECEIVER technical specifications

## 8.2 Radio specifications

| | |
|---|---|
| Wireless standard | Frequency 60 GHz (WiHD) |
| Frequency range | 59.40 GHz to 63.72 GHz |
| Channel index | Channel 2 (60.48 GHz)<br>Channel 3 (62.64 GHz) |
| Bandwidth per channel | 1.76 GHz |
| Signal range | 10 m |
| Maximum number of devices per room | 2 |
| Pairing encryption | AES 128 bits |
| Camera FCC identifier | UK2-SII-SK63102 |
| Camera IC identifier | 6705A-SIISK63102 |
| Camera Giteki identifier | 007-AA0107 |
| Receiver FCC identifier | UK2-SII-SK63101 |
| Receiver IC identifier | 6705A-SIISK63101 |
| Receiver Giteki identifier | 007-AA0106 |

Tab. 23: Radio specifications

## 8.3 Other characteristics

| | |
|---|---|
| Medical device classification for USA, Europe, Korea, UK, Switzerland, Australia, Morocco, New Zealand, Serbia, Thailand and Turkey | Class I |
| Medical device classification for Saudi Arabia | Class A |
| EMDN code | Z12020405 |
| GMDN code | 32265 |
| CE marking year | 2021 |

Tab. 24: Specifications relating to standards and regulations

## 8.4 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.**

**NOTICE**

Electromagnetic disturbance may cause a temporary loss of image.

| Test type | Test method | Range of frequencies | Boundaries |
|---|---|---|---|
| Measurement of conducted emissions on the main ports | EN 55011 GR1 CL A[2] | 0.15 / 0.5 MHz | 79 dBµV QP<br>66 dBµV A |
| | | 0.5 / 5 MHz | 73 dBµV QP<br>60 dBµV A |
| | | 5 / 30 MHz | 73 dBµV QP<br>60 dBµV A |
| Measurement of the radiated electromagnetic field | EN 55011 GR1 CL A[2] | 30 / 230 MHz | 40 dBµV/m PQ 10 m |
| | | 230 / 1000 MHz | 47 dBµV/m PQ 10 m |

Tab. 25: EMC declaration

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

| Test type | Test method | Test level: healthcare facility |
|---|---|---|
| Electrostatic discharge immunity | EN 61000-4-2 | Contact: ±8 kV<br>Air: ±2; 4; 8; 15kV |
| Immunity to radiated RF electromagnetic fields | EN 61000-4-3 | 80 MHz, 2.7 GHz<br>3 V/m Mod AM 80%/1 kHz |
| | | Wireless RF frequencies<br>9 to 28 V/m Mod AM<br>80%/1 kHz |
| Immunity to fast electrical transients and bursts | EN 61000-4-4 | AC: ±2 kV - 100 kHz<br>IO >3m: ±1kV - 100 kHz |
| Immunity to power source voltage surges | EN 61000-4-5 | ±0.5; 1 kV diff.<br>±0.5 kV, ±1 kV, ±2 kV common mode |
| Immunity to conducted interference due to electromagnetic fields | EN 61000-4-6 | 150 kHz, 80 MHz<br>3 Vrms Mod AM 80%/1 kHz |
| | | ISM<br>6 Vrms Mod AM 80%/1 kHz |
| Immunity to voltage dips and short interruptions | EN 61000-4-11 | 0% Ut, 10 ms<br>(0°; 45°; 90°; 135°; 180°; 225°; 270°; 315°)<br>0% Ut, 20 ms<br>70% Ut, 500 ms<br>0% Ut, 5 s |
| 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. 26: EMC declaration

## 8.5 Radio approval

**WARNING!**

**Risk of increased tissue temperature**
**Prolonged exposure close to the wireless camera may cause a sensation of localised heat.**

**Maintain a minimum distance of 9.2cm from the camera to ensure safe use.**

This device meets the requirements of the Radio Equipment Directive (RED) 2014/53/EU.

The licence-exempt transceiver contained in this device complies with FCC Part 15. Operation is authorized subject to the following two conditions:

- This device may not cause interference.
- This device must accept any interference received, including interference that may cause undesired operation.

# EU Declaration of Conformity (RED)

**Form ID : FR03-SOP-45054-E rev1**

**Doc ID:** EU DoC_AIR05Receiver **Revision:** A

## EU DECLARATION OF CONFORMITY FOR RADIO EQUIPMENT

**acc. to Article 18 of Directive 2014/53/EU on Radio Equipment**

**Name and Address of the Manufacturer:**

Maquet SAS
Parc de Limère
Avenue de la Pomme de Pin
CS 10008 Ardon
45074 Orléans cedex 2- France

On our sole responsibility, we hereby declare that the product(s)

**Product- / Trade Name:** AIR05 Receiver

**Reference-No.:** ARD568803989

comply with the relevant provisions of the following Regulation(s) and Directive(s):

- **Directive 2014/53/EU on Radio Equipment**

**Conformity Assessment Procedure:** acc. to Module A of Directive 2014/53/EU

**Standards applied:**

- IEC 62368-1:2014 - Audio/video, information and communication technology equipment Part 1: Safety – Requirements
- ETSI EN 301 489-1 v2.2.3 - ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility
- ETSI EN 301 489-3 v2.3.2 - ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz; Harmonised Standard for ElectroMagnetic Compatibility
- EN 55035: 2017 /A11:2020 - Electromagnetic compatibility of multimedia equipment – Immunity requirements
- EN 55032:2015/ AC:2016/ A11:2020/ A1:2020 - Electromagnetic compatibility of multimedia equipment - Emission requirements
- EN 302 567 v2.1.1 - Multiple-Gigabit/s radio equipment operating in the 60 GHz band; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

- **Directive 2011/65/EU on the restriction of the use of certain substances in electrical and electronic equipment**

This declaration of conformity is valid from date of issue until 5 years.

Ardon, March 17, 2025

**Pascal JAY**, Quality and Regulatory Compliance Director
Signed on behalf of Maquet SAS

**Maquet SAS**
Parc de Limère
Avenue de la Pomme de Pin
CS 10008 Ardon
45074 Orléans cedex 2, France

GETINGE

**Doc ID:** EU DoC_OHD
**Revision:** K

# EU DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

**acc. to Article 19 of Regulation (EU) 2017/745 on Medical Devices**

| | |
|---|---|
| **Name and Address of the Manufacturer:** | Maquet SAS<br>Parc de Limère<br>Avenue de la Pomme de Pin<br>CS 10008 Ardon<br>45074 Orléans cedex 2- France |
| **Single Registration Number:** | FR-MF-000002926 |

On our sole responsibility, we hereby declare that the product(s)

| | |
|---|---|
| **Product- / Trade Name:** | **Maquet Orchide** |
| **Intended Purpose:** | Designed to capture a view of the surgical site (see TFS_OHD_G). |
| **Reference-No.:** | See Annex I |
| **Basic UDI-DI** (acc. to Part C of Annex VI)**:** | 3700712421236R5 |
| **Classification** (acc. to Annex VIII)**:** | Class I |

comply with the relevant provisions of the following Regulation(s) and Directive(s):

- **Regulation (EU) 2017/745 on Medical Devices**

| | |
|---|---|
| **Conformity Assessment Procedure:** | acc. to Annex II and III of Regulation (EU) 2017/745 |
| **Common Specifications used:** | NA |

- **Directive 2011/65/EU on the restriction of the use of certain substances in electrical and electronic equipment**

Template: SOP-0402-B rev4

**Maquet SAS**
Parc de Limère
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45074 Orléans Cedex 2
France

- **Directive 2014/53/EU on Radio Equipment (only for references in Annex II)**

| | |
|---|---|
| **Conformity Assessment Procedure:** | acc. to Module A of Directive 2014/53/EU |
| **Standards applied:** | • IEC 62368-1:2014 - Audio/video, information and communication technology equipment Part 1: Safety – Requirements<br>• EN 62311:2020 - Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz- 300 GHz)<br>• ETSI EN 301 489-1 v2.2.3 - ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility<br>• ETSI EN 301 489-3 v2.3.2 - ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz; Harmonised Standard for ElectroMagnetic Compatibility<br>• EN 302 567 v2.1.1 - Multiple-Gigabit/s radio equipment operating in the 60 GHz band; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU |

This declaration of conformity is valid for a maximum of 5 years from the date of issue.

Ardon, May 21, 2025

**Pascal JAY,** Quality and Regulatory Compliance Director
Signed on behalf of Maquet SAS



**Maquet SAS**
Parc de Limère
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## ANNEX I

The products can be delivered in the following variants (Maquet Orchide references) associated with the Basic UDI-DI 3700712421236R5:

| Reference-No. | Product- / Trade Name | UDI-DI (GTIN) |
|---|---|---|
| ARD568803935 | OHDII FHD QL VP01 | 03700712415761 |
| ARD569204944 | OHDII FHD QL+ VP01 | 03700712412340 |
| ARD567704998 | OHDII 4K QL+ VP11 | 03700712421632 |
| ARD568803969 | OHDII FHD QL AIR05 | 03700712434298 |

## ANNEX II

The following product contains a Radio part.

| Reference-No. | Product- / Trade Name | UDI-DI (GTIN) |
|---|---|---|
| ARD568803969 | OHDII FHD QL AIR05 | 03700712434298 |



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# 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 Orchide Decommissioning Instructions (ARD04665). Contact your local Getinge representative to obtain a copy of this document.

## 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.

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IFU 04661 EN 07 2025-06-17