Instructions for use

Maquet Orchide

IFU 04661 EN 02 2021-08-09

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.

V02 09.08.2021

Contents

1 Introduction

1.1 Preface

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

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

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

1.2 Information about this document

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

Please note:

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

1.2.1 Abbreviations

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

1.2.2 Symbols used in this manual

1.2.2.1 Cross-references

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

1.2.2.2 Reference numbers

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

1.2.2.3 Actions and results

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

Example:

Prerequisites:

- The sterilisable handle must be compatible with the product.

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

1.2.2.4 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.

1.2.3 Definitions

1.2.3.1 Hazard levels

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

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

Tab. 1: Hazard levels of safety instructions

1.2.3.2 Indications

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

Tab. 2: Types of indication in the document

1.2.3.3 Groups of people

Users

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

Qualified personnel:

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

1.3 Other documents relating to this product

- Installation Manual (P/N ARD04664)

1.4 Liability

Modifications to the product

The product must not be modified in any way without the prior written consent of Getinge.

Compliant use of the device

Getinge may not be held liable for any direct or indirect damage that results from actions not set out in this user's manual.

Installation and maintenance

Installation, maintenance and decommissioning operations must be performed by trained personnel, approved by Getinge.

Training on the device

Training must be provided directly on the device by personnel approved by Getinge.

Compatibility with other medical devices

Only medical devices approved in accordance with IEC 60601-1 or UL 60601-1 should be installed on the system.

The compatibility data is detailed in the chapter entitled Technical specifications [⏩ Page 39].

The compatible accessories are detailed in the chapter concerned.

In the event of an incident

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

1.5 Expected service lifetime

The expected service lifetime of the product is 10 years.

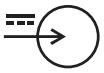
This service lifetime does not apply to consumables such as sterilisable handles.

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

1.6 Warranty

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

1.7 Symbols on the product and packaging

	Follow the instructions for use (IEC 60601-1:2012)		Product serial number
	Follow the instructions for use (IEC 60601-1:2005).		Medical Device (MD) marking
	Follow the instructions for use (IEC 60601-1:1996).		Unique device identification
	Manufacturer + manufacturing date		CE marking (Europe)
	Product code		Direct current input

1.8 Location and explanation of the device identification label

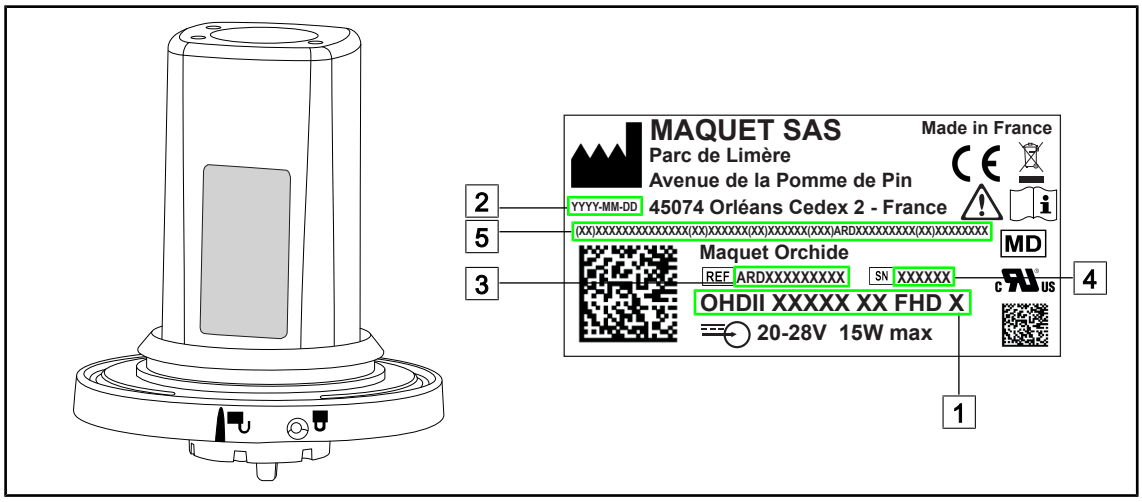


Fig. 1: Product identification label

1 Product name
2 Manufacturing date
3 Product code
4 Serial number
5 Unique device identifier (UDI)

1.9 Product overview

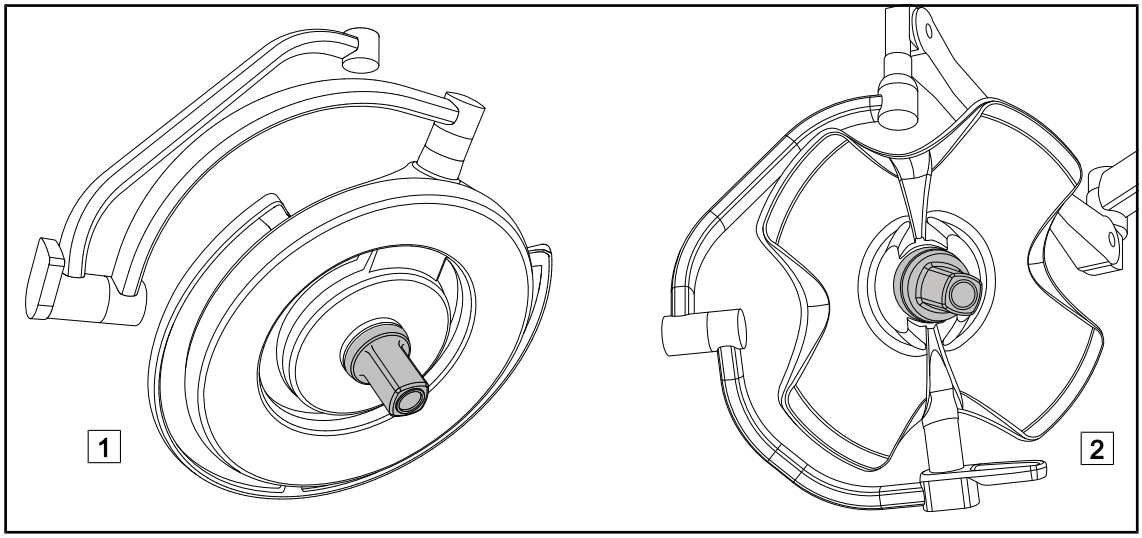


Fig. 2: Maquet Orchide cameras

NOTE

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.

1.9.1 Components

NOTE

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.

1.9.1.1 Cameras with wired video system

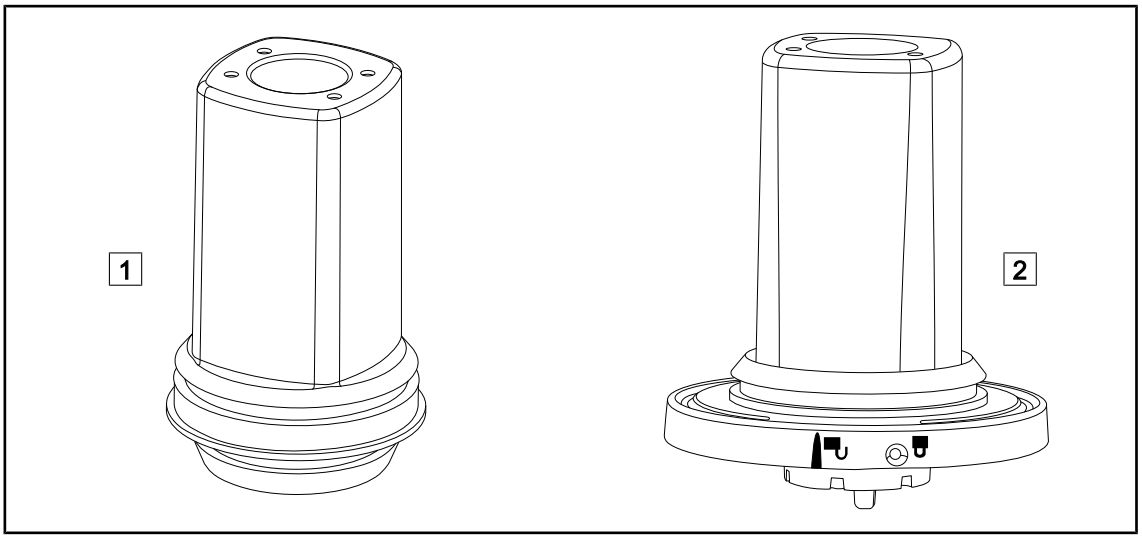


Fig. 3: Cameras with wired video system

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

2 OHDII FHD QL+ VP01 (for Volista lighthead)

These Full HD cameras, which can be moved from one operating theatre to another using the QL et QL+ systems, offer genuine benefits for the surgical team. They ensure operating fluidity by keeping the surgical area clear during training phases, and facilitate monitoring of surgeons' actions, enabling their needs to be better anticipated.

The OHDII FHD QL+ VP01 camera can only be installed on a Maquet PowerLED II lighthead pre-wired for video.

The OHDII FHD QL VP01 camera can only be installed on a pre-wired Volista lighthead pre-wired for video.

NOTE

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

NOTE

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". 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.

1.9.1.2 Camera with wireless video system (only on Volista)

OHDII FHD QL AIR03/04 E/U

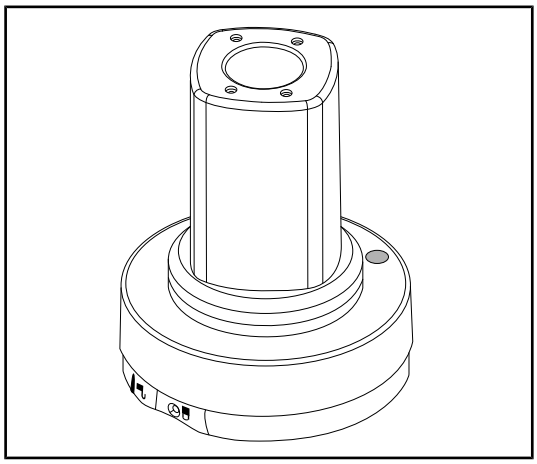


Fig. 4: OHDII FHD QL AIR03/04 E/U camera

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

NOTE

For optimal use of the system, do not use more than two cameras within a radius of 10 m, and do not position a camera more than 10 m away from its receiver.

NOTE

For the technical specifications of the wireless system, refer to the user instructions supplied with the product or to the complete manual available on the supplier's website.

1.9.2 Accessories

Illustration	Description	Part number
	**STG PSX VZ sterilisable handle** This handle is compatible with all cameras.	STG PSX VZ 01

Tab. 3: Maquet Orchide accessories table

1.10 Standards applied

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

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

Tab. 4: Compliance with product standards

Quality management:

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

Tab. 5: Compliance with quality management standards

Environmental standards and regulations:

Standards	Year	Title
Directive 2011/65/UE RoHS2	2011	Limitation of the use of certain hazardous substances in electrical and electronic equipment
Directive 2015/863 RoHS3	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
REACH regulation No. 190	2006	Registration, evaluation and authorization of chemical substances, as well as the restrictions applicable to these substances
Prop. 65	1986	The Safe Drinking Water and Toxic Enforcement Act of 1986
Chinese RoHS		China order No. 39, Administration of the Control and Electronic Information Products

Tab. 6: Environmental standards and regulations

1.11 Information relating to intended use

1.11.1 Intended use

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

1.11.2 Intended users

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

1.11.3 Inappropriate use

- 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.

1.11.4 Contraindications

This product does not have any contraindications.

1.12 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.

1.13 Clinical benefit

Maquet Orchide cameras are medical devices. When used appropriately, they will:

- Broadcast live surgical operations to the medical team in the operating room.
- Document the patient record (video).

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 [⏩ Page 43] 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. 7: Environmental conditions for transport/storage

Environmental conditions for use

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

Tab. 8: 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 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 infection
A maintenance or cleaning operation may result in contamination of the surgical site.

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

WARNING!

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

Do not use in an MRI environment.

WARNING!

Risk of 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.

3 Control interfaces

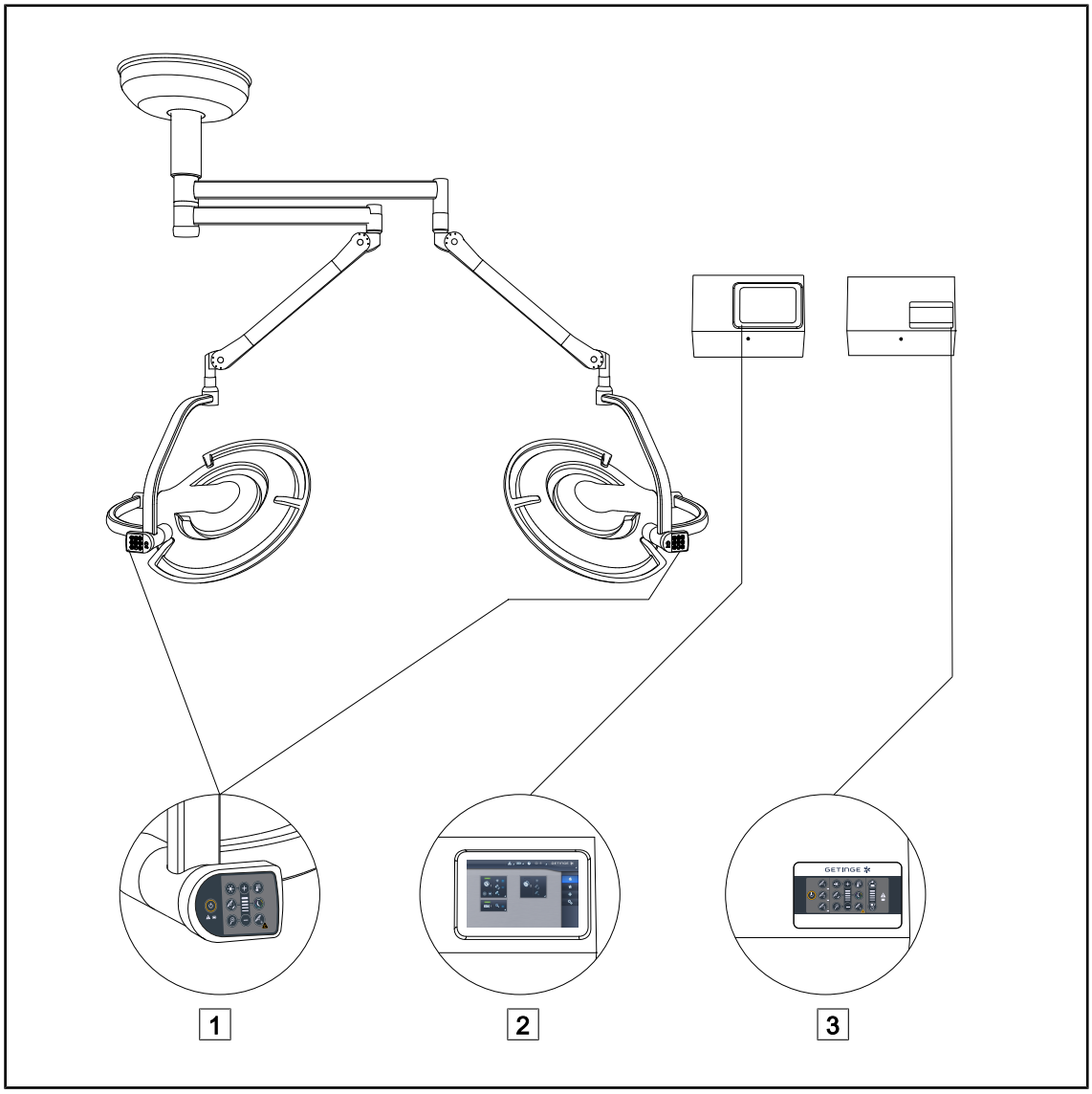


Fig. 5: Maquet PowerLED II control interfaces

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

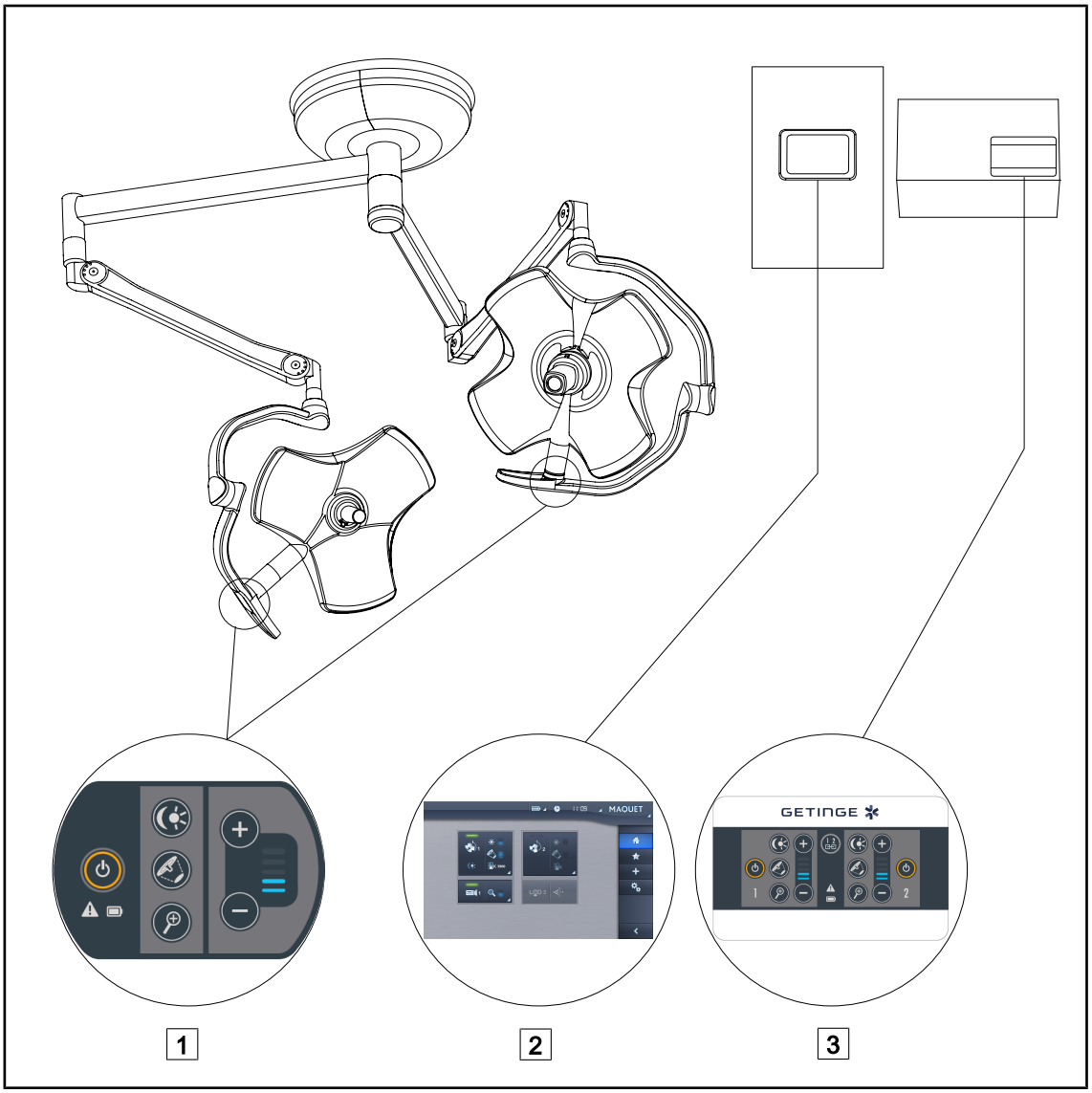


Fig. 6: Volista control interfaces

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

4 Use

4.1 Daily inspections before use

NOTE

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

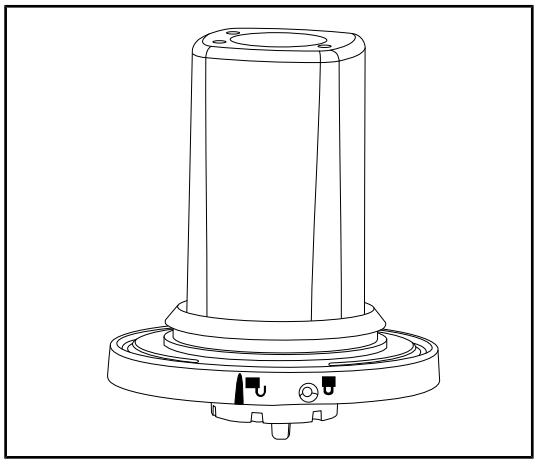


Fig. 7: Integrity of the device

Integrity of the device

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

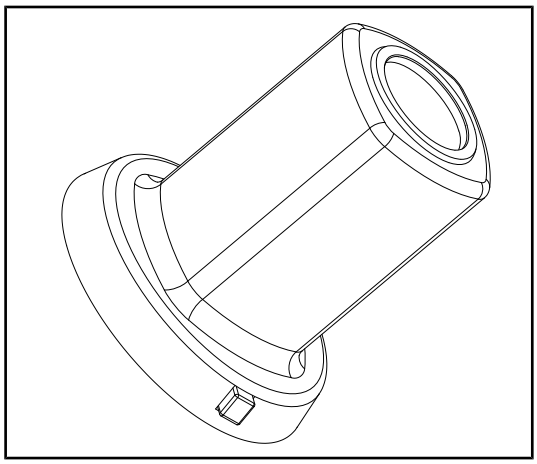


Fig. 8: Sterilisable handles

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

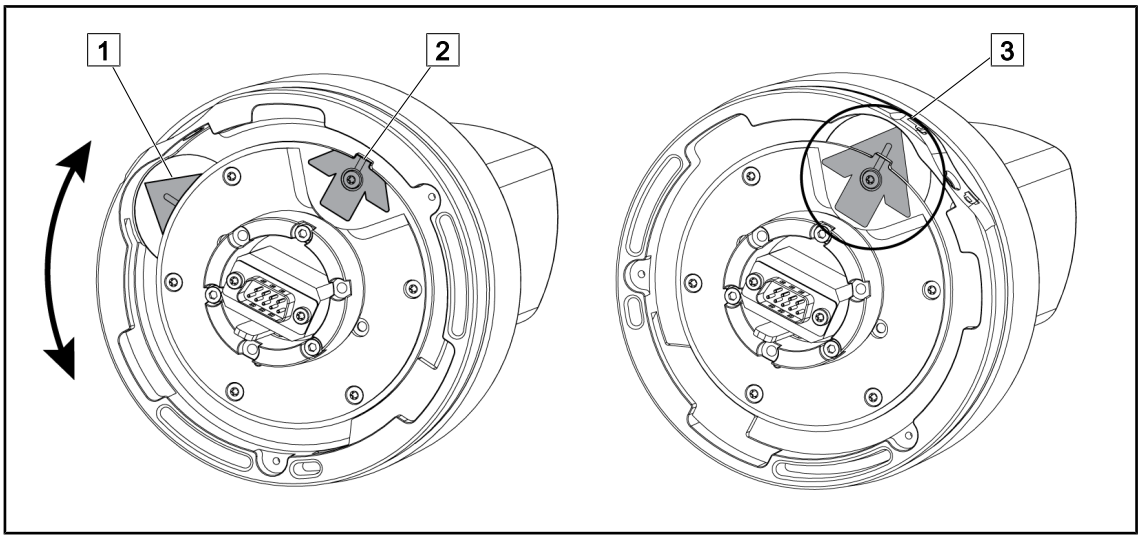


Fig. 9: Pre-positioning the camera

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

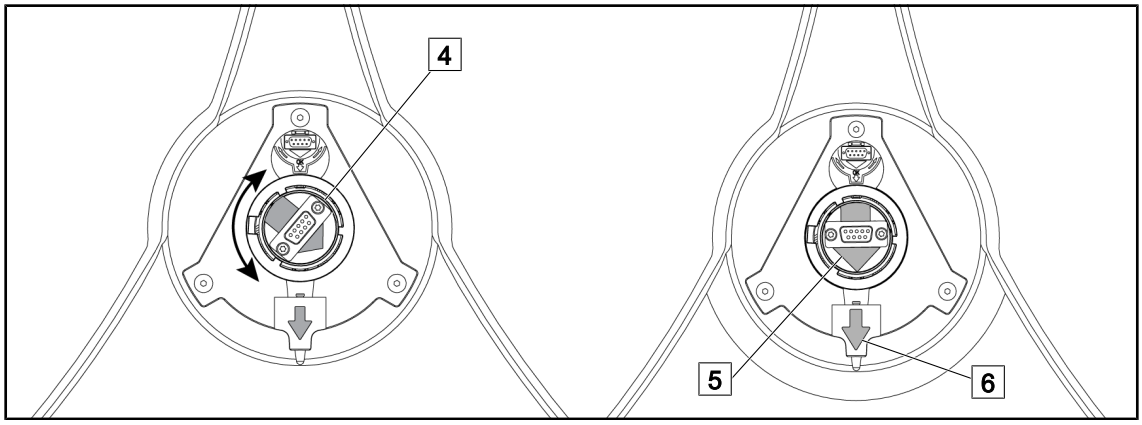


Fig. 10: Pre-positioning the lighthead

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

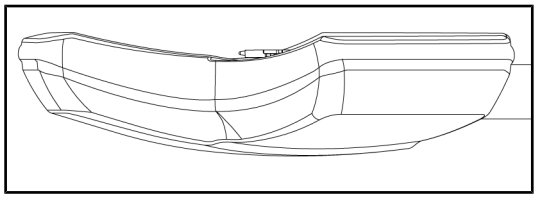


Fig. 11: Positioning the lighthead

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

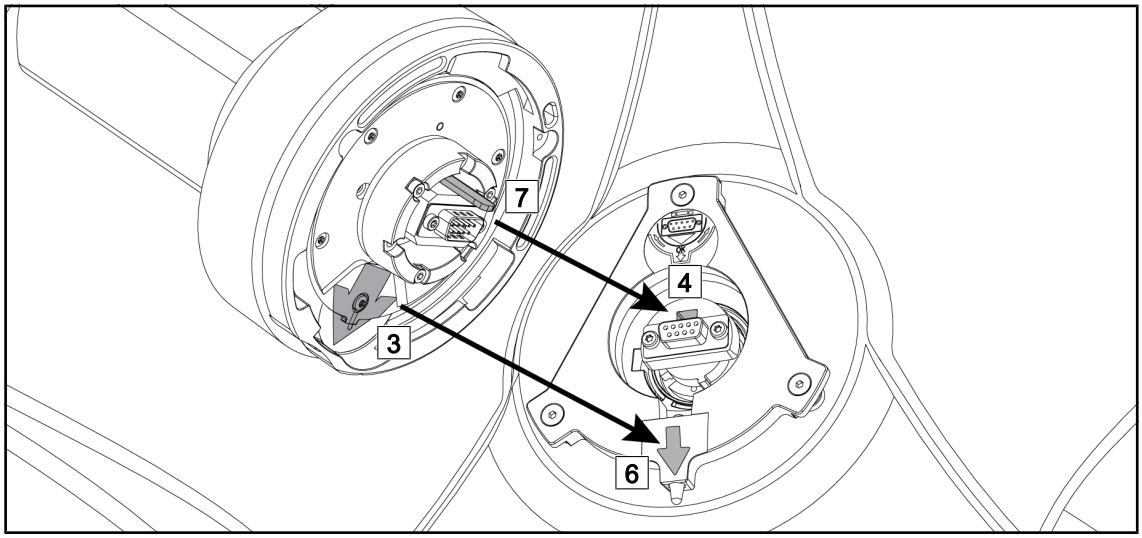


Fig. 12: Instructions for installing the Quick Lock system

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

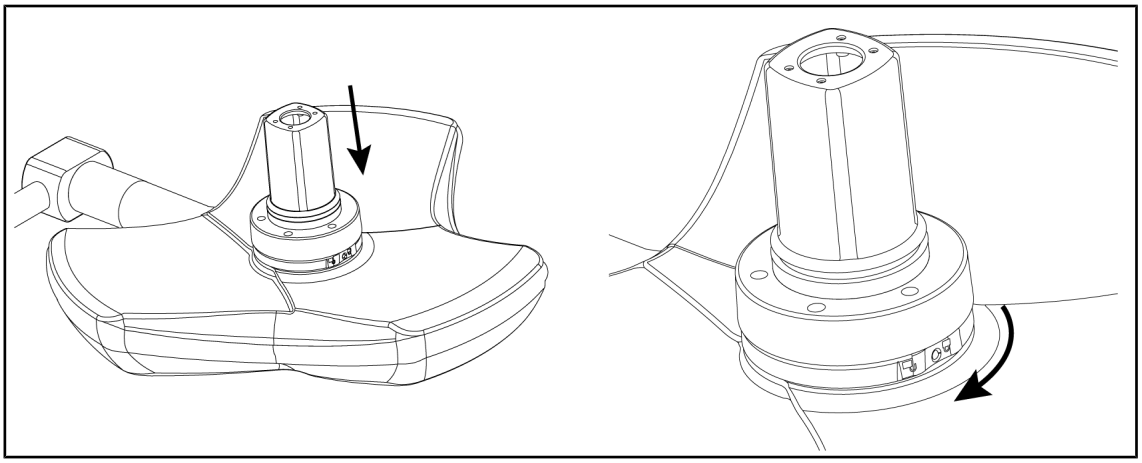


Fig. 13: Presenting the camera against the lighthead

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.

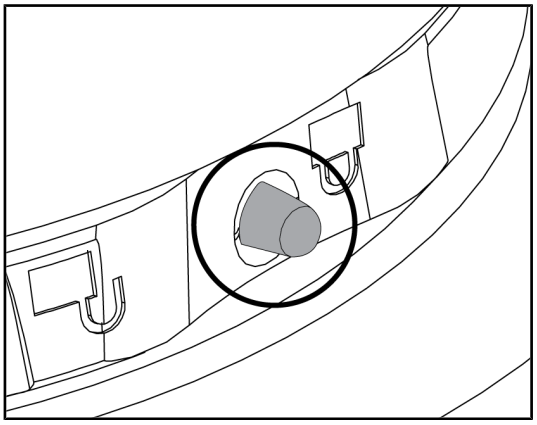


Fig. 14: Locking the camera in place on the lighthead

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

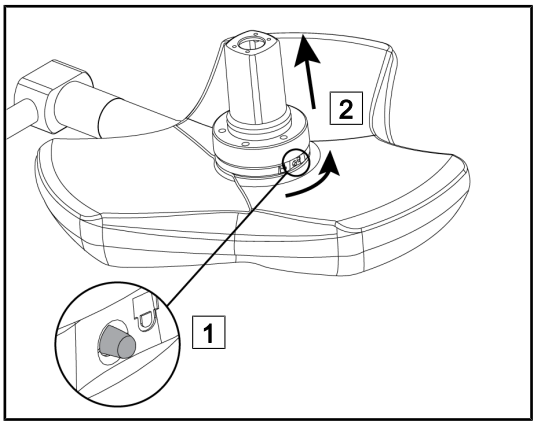


Fig. 15: Removing the lighthead

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

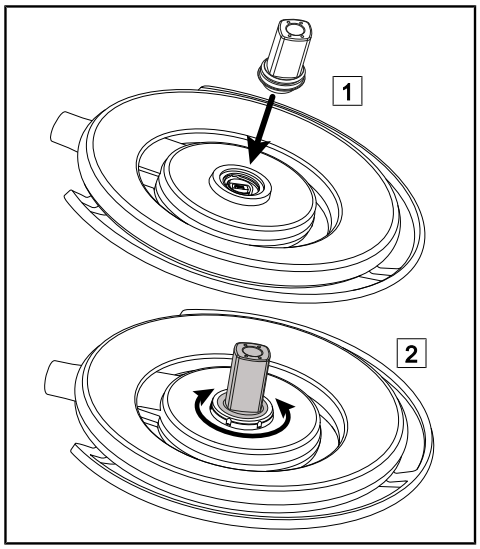


Fig. 16: Installing a QL+ camera

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

4.3.2 Removing the device

NOTE

Turn the lighthead over so that the underside is facing the ceiling, in order to remove the camera.

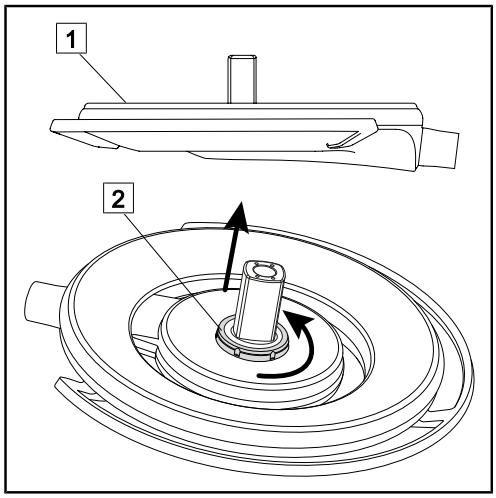


Fig. 17: Removing a Quick Lock device

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.

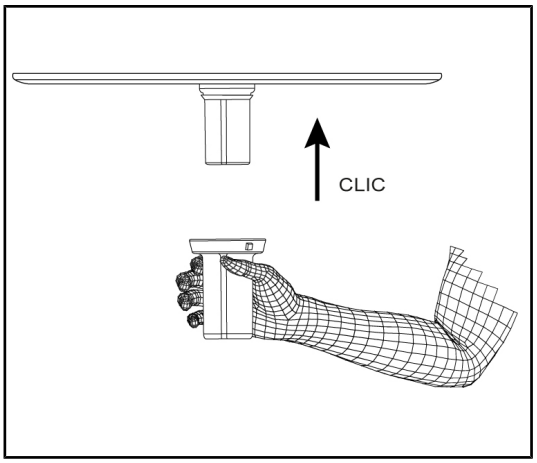


Fig. 18: Installing a sterilisable handle for use with a camera

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.

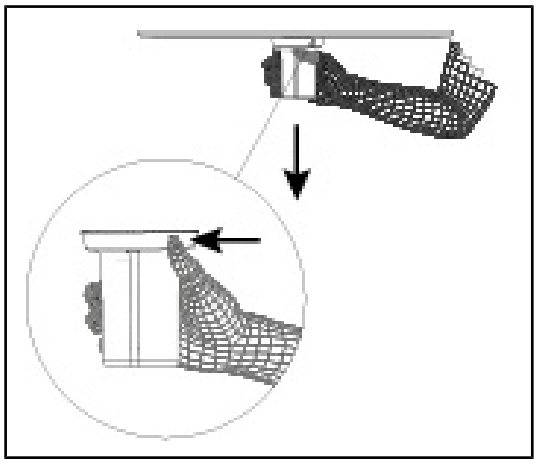


Fig. 19: Removing a sterilisable handle for use with a camera

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

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

4.5 Wired video system

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

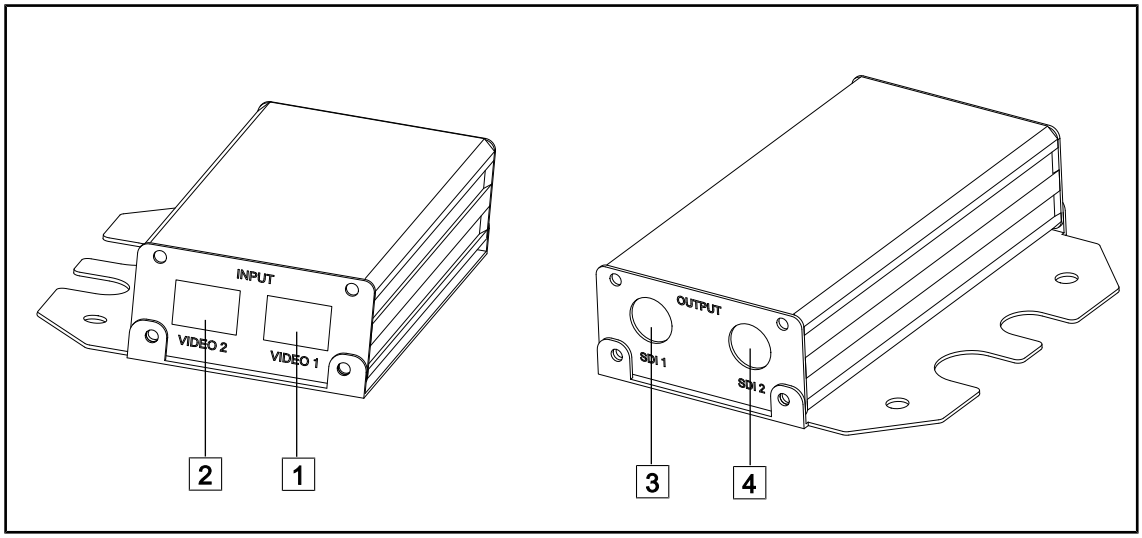


Fig. 20: Wired video system

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

NOTE

If two wired cameras are installed, two power adapters must be used. Contact the Getinge technical department if necessary.

4.6 Wireless video system (on Volista lighthead only)

CAUTION!

Risk of malfunction of the device
The presence of other wireless devices nearby may affect the quality of the transmitted image.

The user must refer to the instructions for the wireless system in order to learn its conditions of use.

CAUTION!

Risk of malfunction of the device
The use of wireless accessories other than those supplied or specified by the manufacturer can affect the operation and performance of the device.

Use only the wireless accessories specified by Getinge.

NOTE

For optimal use of the system, do not use more than two cameras within a radius of 10 m, and do not position a camera more than 10 m away from its receiver.

4.6.1 Registering the camera

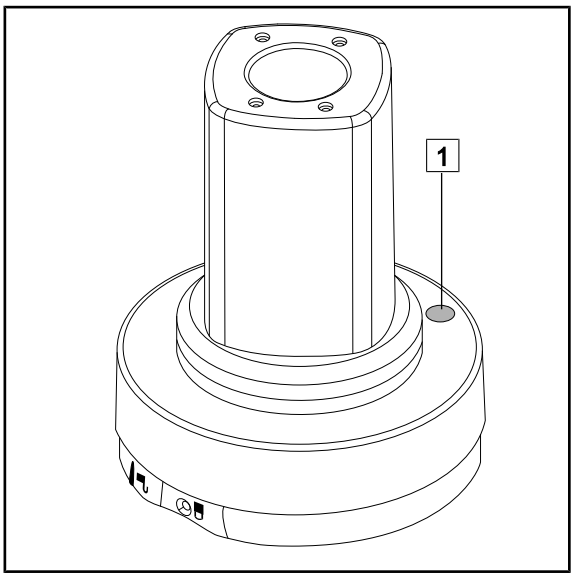


Fig. 21: Wireless camera

To pair the camera with its wireless system, refer to the manufacturer's instructions supplied with the wireless device. During the pairing process, press the camera transmitter button 1 to enable camera detection during the signal search phase.

4.6.2 Switching on the registered system

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

4.7 Controlling the camera

4.7.1 From the lighthead control keypad (zoom only)

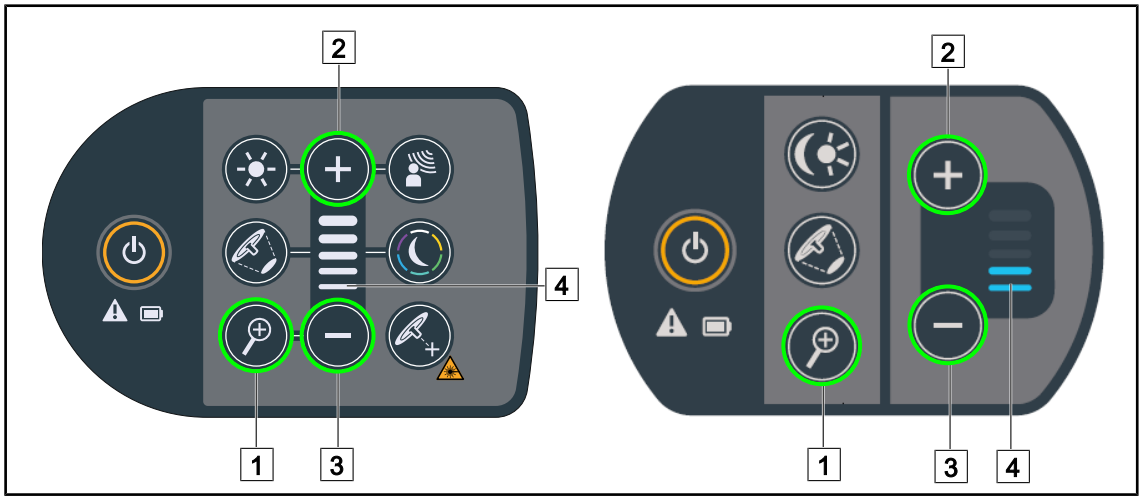


Fig. 22: Controlling the camera using the lighthead control keypads

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)

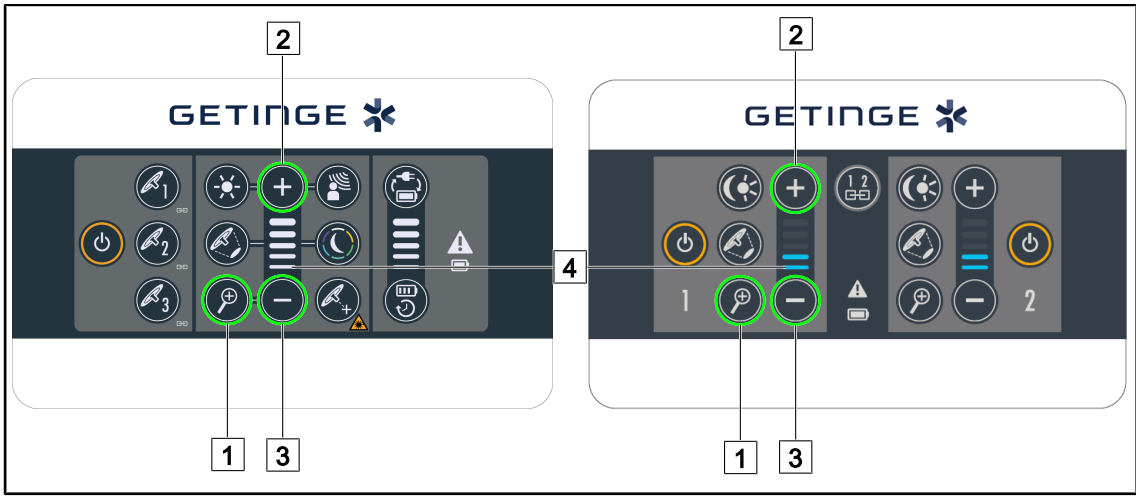


Fig. 23: Controlling the camera using the wall-mounted control keypads

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.

4.7.3 From the touchscreen control panel

NOTE

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

Fig. 24: Turning the camera on via the touchscreen control panel

Turning a camera on via the home page

1. Press the **Camera active area** 1 button.
   - ➢ The button is lit green and the image is displayed on the screen.
2. Press the **Camera active area** 1 again to access the camera page.

Turning the camera on via the lighthead page

1. From the lighthead page, press the **Camera shortcut** 2.
   - ➢ The camera page is displayed and the camera is turned on.

Fig. 25: Camera page

Turning off the camera

1. From the camera page, press **Camera ON/OFF** 3 to turn off the camera.
   - ➢ The button and the camera are turned off.

Pausing the camera

1. Press **Camera pause** [5] to pause the camera.
   ➢ The button is lit blue and the retransmitted image is frozen.
2. Press **Camera pause** [5] again to resume video transmission.

Access the lighthead page directly by pressing the **Lighthead shortcut** [4].

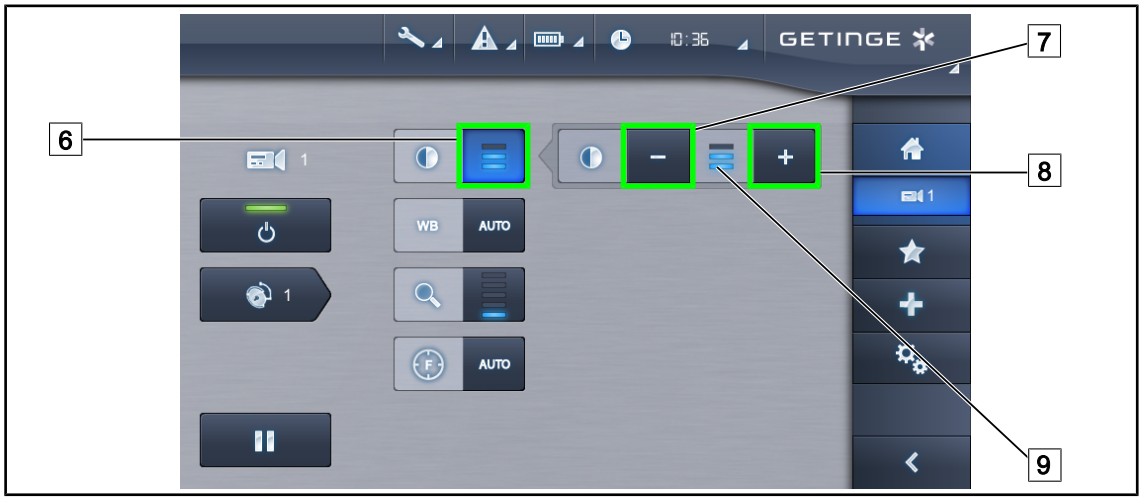


Fig. 26: Contrast adjustment

Adjusting the contrast

1. Press **Contrast** [6] to access the contrast adjustment menu.
2. Press **Increase contrast** [8] or **Decrease contrast** [7] to select one of the three contrast levels [9].

Fig. 27: White balance control

Adjusting the white balance automatically

1. Press **White balance** 10.
2. Press **Automatic balance** 11 to set the white balance automatically or **Artificial light** 12 to set the white balance to 3200 K or **Daylight** 13 to set the white balance to 5800 K.
   ➢ The selected button is lit blue and the white balance is set.

Adjusting the white balance manually

1. Press **White balance** 10.
2. Place a uniformly white target under the camera.
3. Press **Manual balance** 14 twice to set the white balance on the basis of the target under the camera.
   ➢ The selected button is lit blue and the white balance is set.

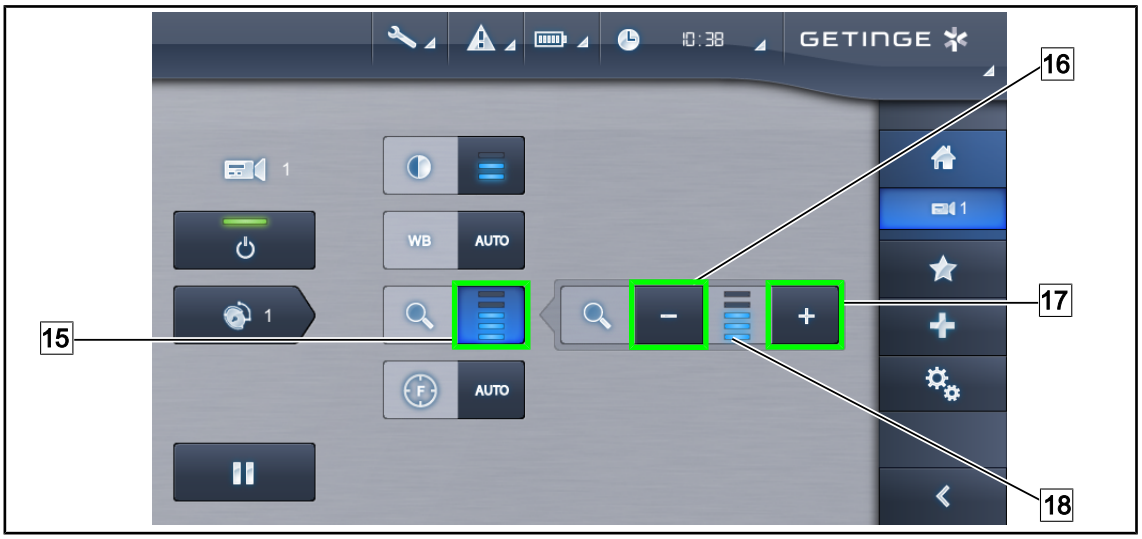


Fig. 28: Zoom control

Zooming in and out

1. Press **Zoom** 15 to access the zoom adjustment menu.
2. Press **Zoom in** 17 or **Zoom out** 16 to adjust the size of the image on screen 18 in real time.

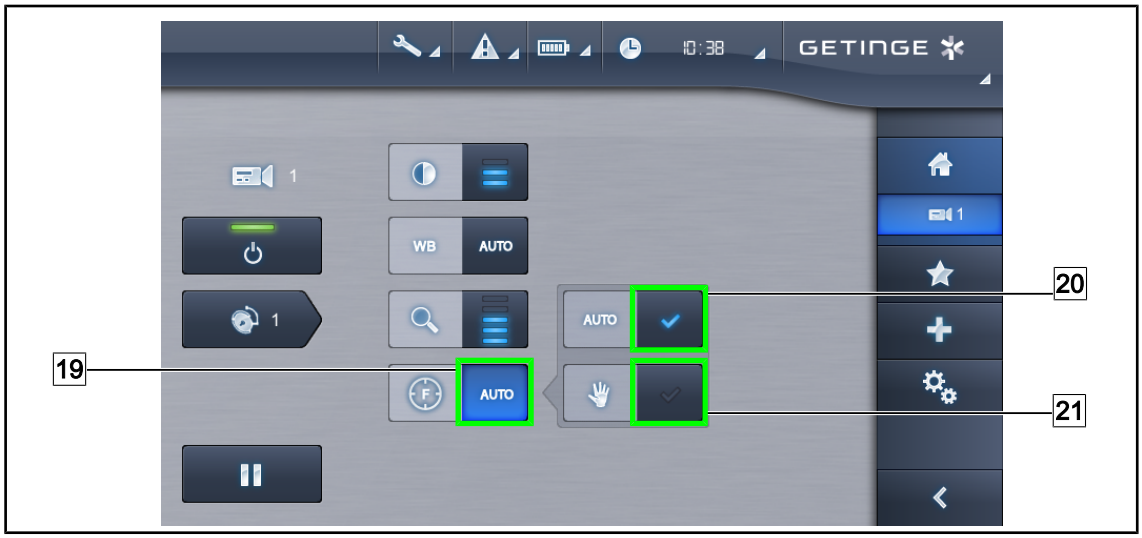


Fig. 29: Setting the focus

Setting the focus automatically

1. Press **Focus** 19 to access the focus adjustment menu.
2. Press **Auto Focus** 20.
   - ➢ The button is lit blue and the camera focus is automatic.

Setting the focus manually

1. Press **Focus** 19 to access the focus adjustment menu.
2. Press **Auto Focus** 20.
   - ➢ The button is lit blue and the camera focus is automatic.
3. Position the camera at the desired distance.
4. Press **Manual Focus** 21.
   - ➢ The button is lit blue and the camera focus is fixed.

5 Error messages and alarm indicators

Not applicable for this product.

6 Troubleshooting

Problem	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
No image after setting up the OHDII VP01 QL FHD or OHDII VP01 QL+ FHD camera	The camera is not on a light-head pre-wired for video for a wired camera.	Install the camera on a light-head pre-wired for video.
No image after starting the OHDII AIR03 QL FHD camera	Communication problem	1. Check on the touchscreen control panel whether the camera is on 2. Disconnect and reconnect the receiver power cable 3. Re-register the camera 4. Contact the Getinge technical department
Image lost for more than 20 seconds with the OHDII AIR03 QL FHD camera	Interference with another system	1. The system should reset itself within around 20 seconds 2. Modify the zoom level 3. Contact the Getinge technical department

Tab. 9: Troubleshooting and mechanical failures

7 Cleaning / Disinfection / Sterilisation

WARNING!

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

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

7.1 Cleaning and disinfecting the system

WARNING!

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

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

WARNING!

Risk of infection
Certain cleaning products or procedures may damage the 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.

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.

7.1.1 Cleaning the device

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

7.1.2 Disinfecting the device

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

7.1.2.1 Disinfectants to be used

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

7.1.2.2 Permitted active substances

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

Tab. 10: Lists of active substances suitable for use

Examples of commercially available products tested

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

7.2 Cleaning and sterilising Maquet Sterigrip sterilisable handles

7.2.1 Preparation for cleaning

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

7.2.2 Manual cleaning

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

7.2.3 Cleaning in a washer-disinfector

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

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

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

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

7.2.4 Sterilisation 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.

NOTE

Maquet Sterigrip sterilisable handles are designed for autoclave sterilisation.

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

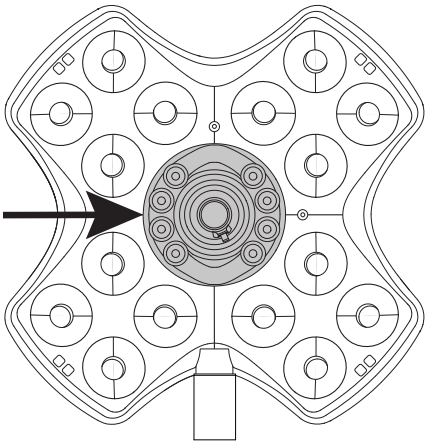
Sterilisation cycle	Temperature (°C)	Time (min)	Dry (min)
ATNC (Prion) Prevacuum	134	18	–

Tab. 12: Example of a steam sterilisation cycle

8 Maintenance

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

8.1 Monthly inspections

Illustration	Action
	**Absence of particles** 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. 2. If a problem is noted, contact technical support.

Tab. 13: Monthly visual and functional inspections

8.2 Contact

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

9 Technical specifications

9.1 Electrical specifications of cameras and receivers

Electrical specifications of cameras

Specifications	OHDII VP01 QL+ FHD	OHDII VP01 QL FHD	OHDII AIR03 QL FHD E/U
Sensor	1/3” CMOS		
Number of pixels	~2.48 Megapixels		
Video standard	**1080i** / 1080p	1080i	1080p
Image refresh rate	**50** / 60 Hz	**50** / 60 Hz	**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 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 [2]	**Auto** / Focus Freeze		
White balance[2]	Auto / Indoor / Outdoor / **Manual**		
Contrast enhancement[2]	Yes (3 levels)		
Image freeze[2]	Yes		
Preset[2]	6		
Transmission type	Wired	Wired	Wireless
RS32 interface	Yes		
Weight (without sterile handle)	460 g	820 g	790 g
Dimensions (without sterile handle) (Diam. x H)	93 x 150 mm	129 x 167 mm	132 x 198 mm

Tab. 14: Electrical specifications of cameras

[2] via touch screen only

VP01 RECEIVER technical specifications

Specifications	VP01 RECEIVER
Video input	RJ45 (proprietary)
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. 15: VP01 RECEIVER technical specifications

AIR03/04 SYSTEM E/U technical specifications

Specifications	AIR03/04 SYSTEM E/U
Video output	HDMI 1.4
Weight (without/with mounting bracket)	220 g / 340 g
Dimensions with mounting bracket (L x W x H)	156 × 117 × 61 mm
Transmission frequencies	see below

Tab. 16: AIR03/04 SYSTEM E/U technical specifications

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

AIR04 SYSTEM E/U transmission frequencies:
UE/US zone: Central frequency of transmission channels in accordance with the ETSI EN 301 893 and FCC Sec. 15.407 standards: 5.190 GHz, 5.230 GHz, 5.270 GHz, 5.310 GHz, 5.510 GHz, 5.550 GHz and 5.670 GHz

Electromagnetic compatibility of the device

Device	Description	Supplier
Wireless HDMI video transmission system	EXT-WHD-1080P-SR	GEFEN**
	VE819	ATEN**

NOTICE

The technical specifications of the AIR03 and AIR04 wireless systems are described in the documentation available on the GEFEN and ATEN websites.

9.2 EMC declaration

CAUTION!

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

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

CAUTION!

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

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

CAUTION!

Risk of malfunction of the device
The use of 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.

NOTE

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

Type of test	Test methods	Range of frequencies	Boundaries
Measurement of conducted emissions on the main ports	EN 55011 GR1 CL A[3]	0.15 - 0.5 MHz	66 dBµV - 56 dBµV QP 56 dBµV - 46 dBµV A
		0.5 - 5 MHz	56 dBµV PQ 46 dBµV A
		5 - 30 MHz	60 dBµV PQ 50 dBµV A

Tab. 17: EMC declaration

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

Type of test	Test methods	Range of frequencies	Boundaries
Measurement of the radiated electromagnetic field	EN 55011 GR1 CL A[3]	30 - 230 MHz	40 dBµV/m PQ 10 m
		230 - 1000 MHz	47 dBµV/m PQ 10 m

Tab. 17: EMC declaration

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

Tab. 18: EMC declaration

10 Waste management

10.1 Disposal of packaging

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

10.2 Product

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

For full information relating to processing of the device once it is no longer in use, contact your local Getinge representative.

10.3 Electrical and electronic components

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

GETINGE

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