Instructions for use

Maquet Equipment

IFU 01821 EN 15 2025-01-21

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.

V15 21.01.2025

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

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

The compatibility data is detailed in the chapter entitled Technical specifications [⏩ Page 50].

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

- Maquet Equipment Installation Instructions (P/N 01824)
- Maquet Equipment Maintenance Instructions (P/N 01820)
- Maquet Equipment Uninstalling Instructions (P/N 01825)
- Maquet Equipment Installation Recommendations (P/N 01826)

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

The terms **system** and **device** refer to the monitor mount and all its accessories.

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)		Hand-pinching hazard
	Follow the instructions for use (IEC 60601-1:2005).	MD	Medical Device (MD) marking
	Follow the instructions for use (IEC 60601-1:1996).	UDI	Unique device identification
	Manufacturer + manufacturing date		Packaging orientation
REF	Product code		Fragile, handle with care
SN	Product serial number		Keep away from the rain
	Do not discard with conventional waste		Temperature range for storage
CE	CE marking (Europe)		Humidity range for storage
c UL us	UR mark (Canada and United States)		Ambient pressure range for storage
	Non sterile product		

1.6 Product overview

1.6.1 Screen holders

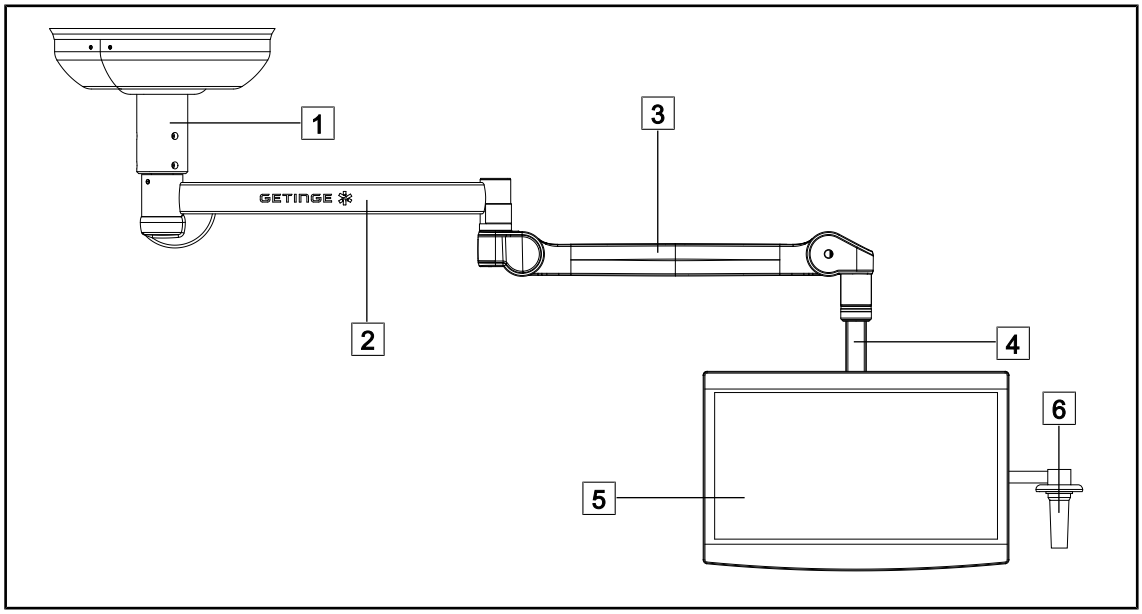


Fig. 1: Configuration of a single screen holder on a SAX suspension (e.g., EQTMHS019 12)

1 Suspension tube
2 Suspension arm
3 Spring arm
4 Single screen holder
5 Monitor
6 Handle mount (optional)

1.6.1.1 Components

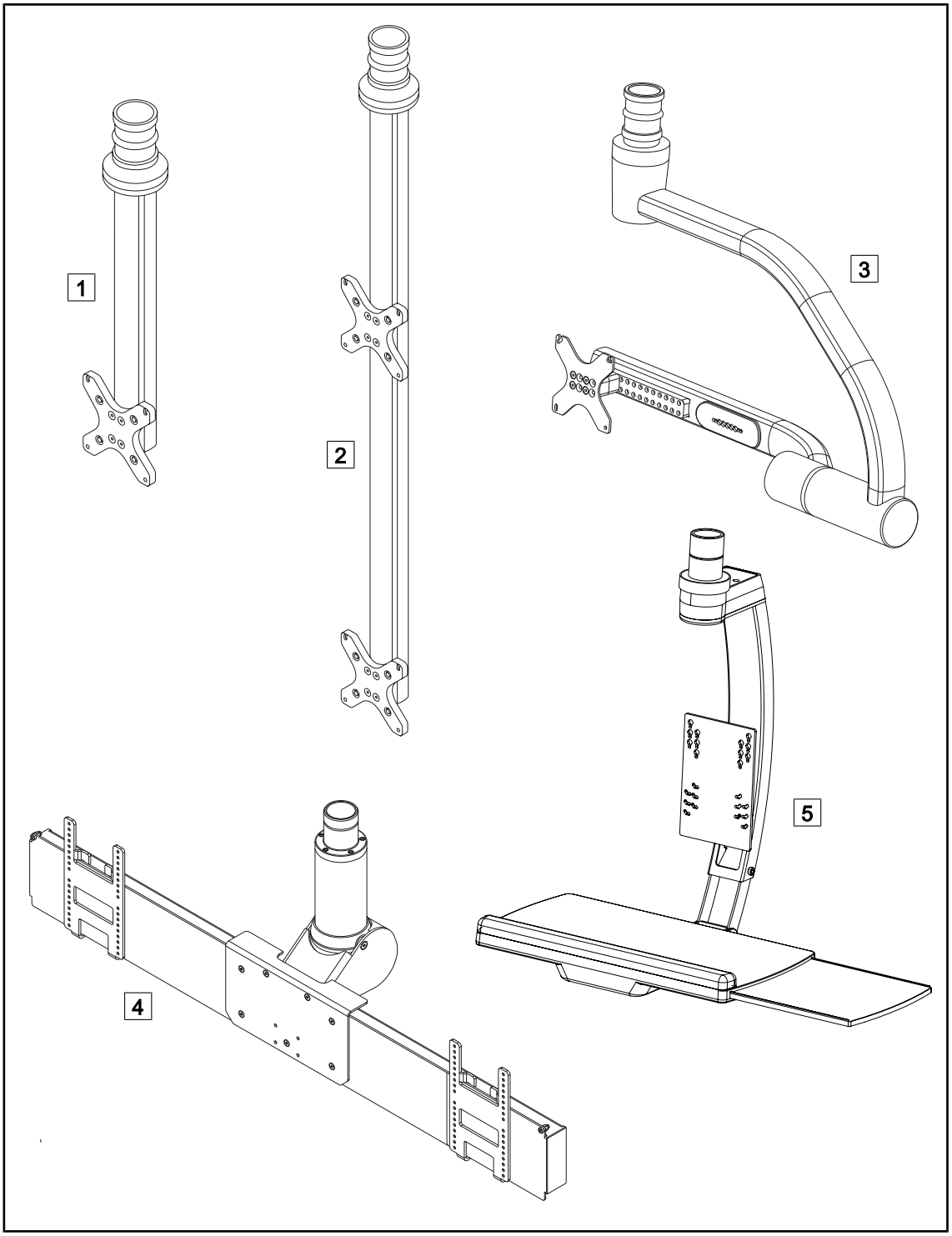


Fig. 2: Screen holders available in the Maquet Equipment range

1 FHS0 / MHS0
2 MHD2
3 XHS0
4 XHD1
5 SPC 12

1.6.1.2 Options for FHS0/MHS0/MHD2

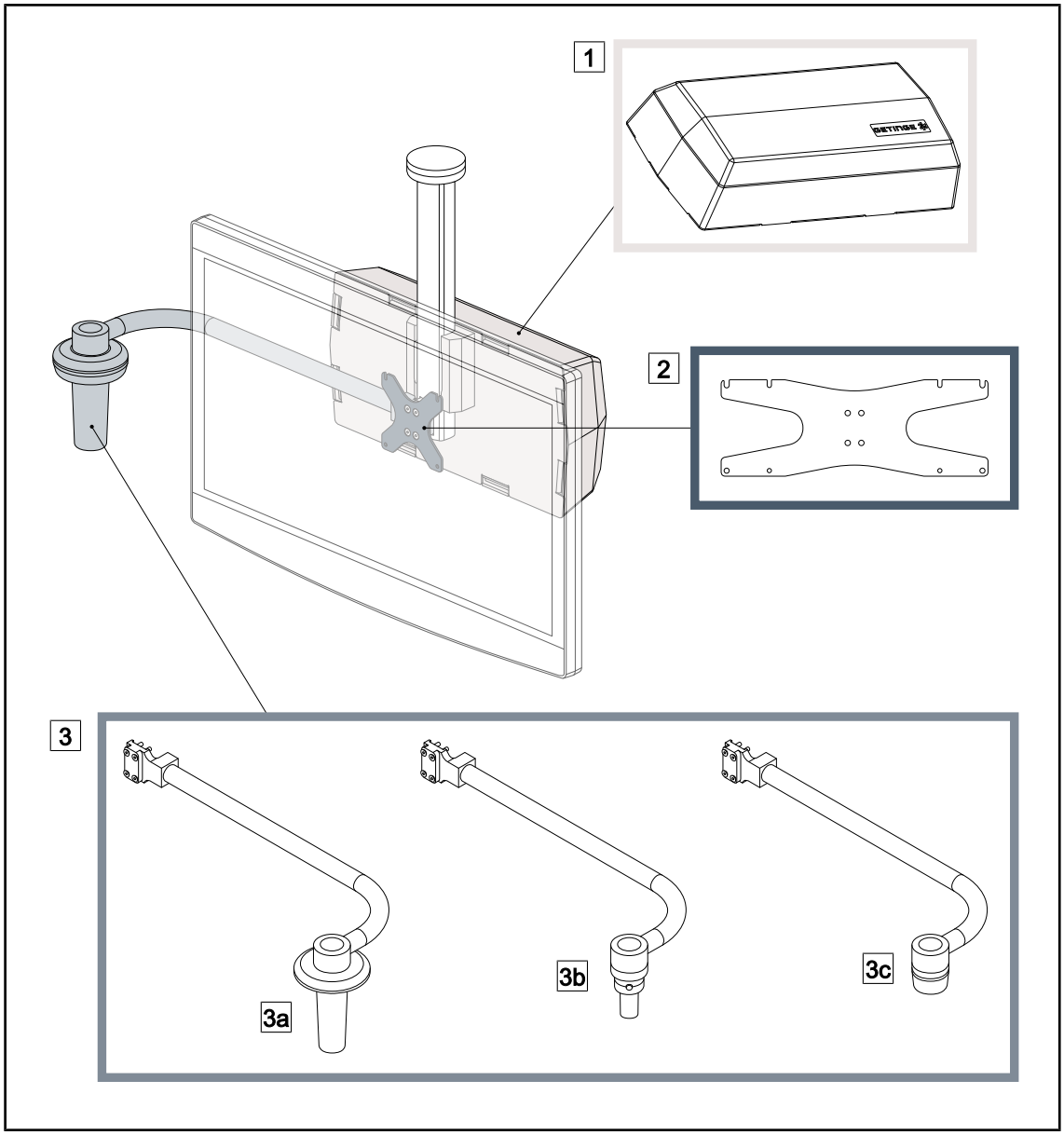


Fig. 3: Options for MHS0/MHD2

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

1.6.1.3 Options for XHS0

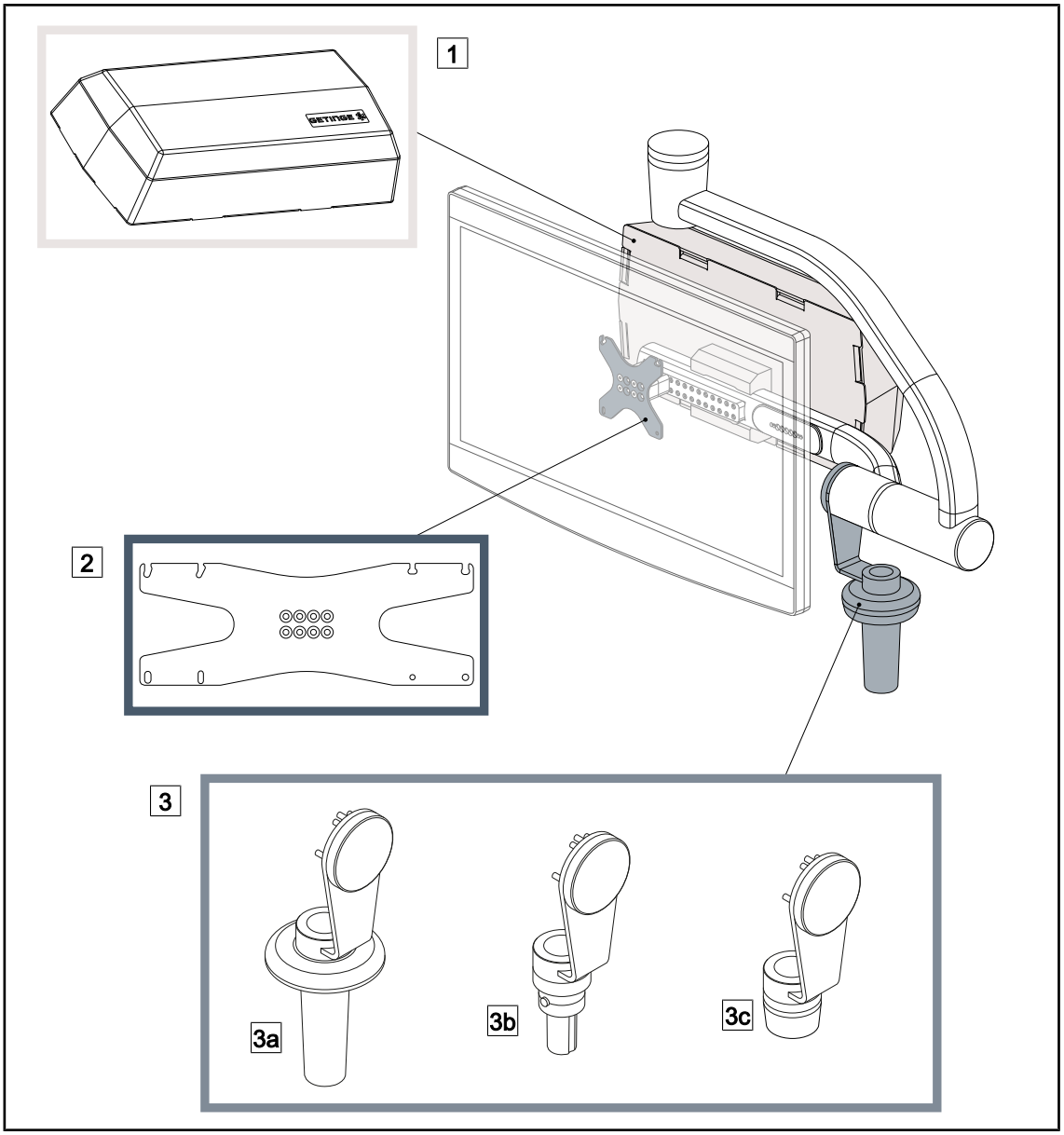


Fig. 4: Options for XHS0

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

1.6.1.4 Option for XHD1

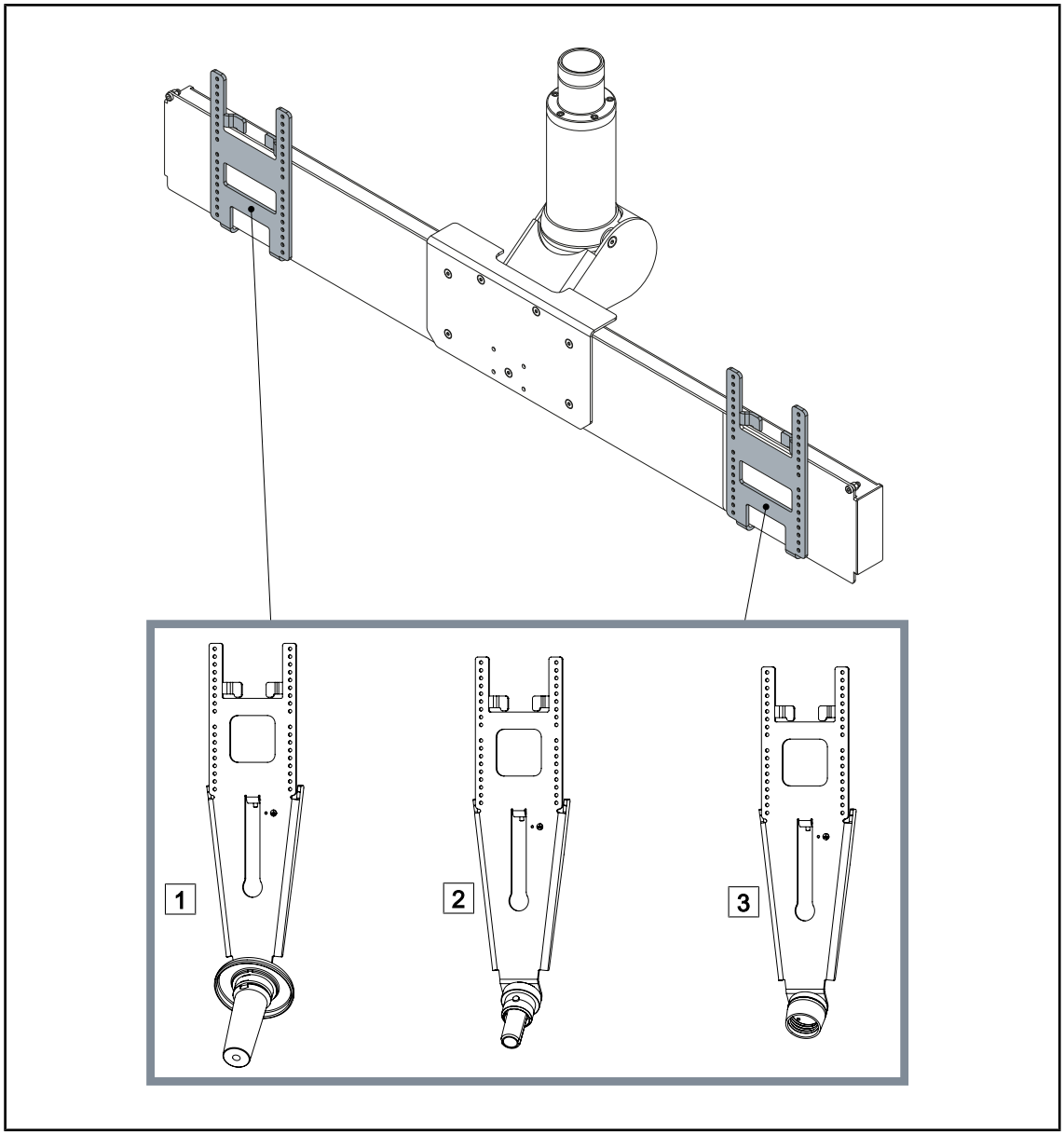
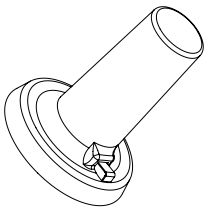
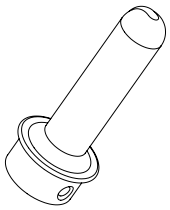


Fig. 5: Option for XHD1

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

1.6.1.5 Accessories for monitor mounts

Sterilisable handles

Illustration	Description	Part Number
	**Set of five STG PSX handles**	STG PSX 01
	**Set of five STG HLX handles**	STG HLX 01

1.6.2 Camera mounts

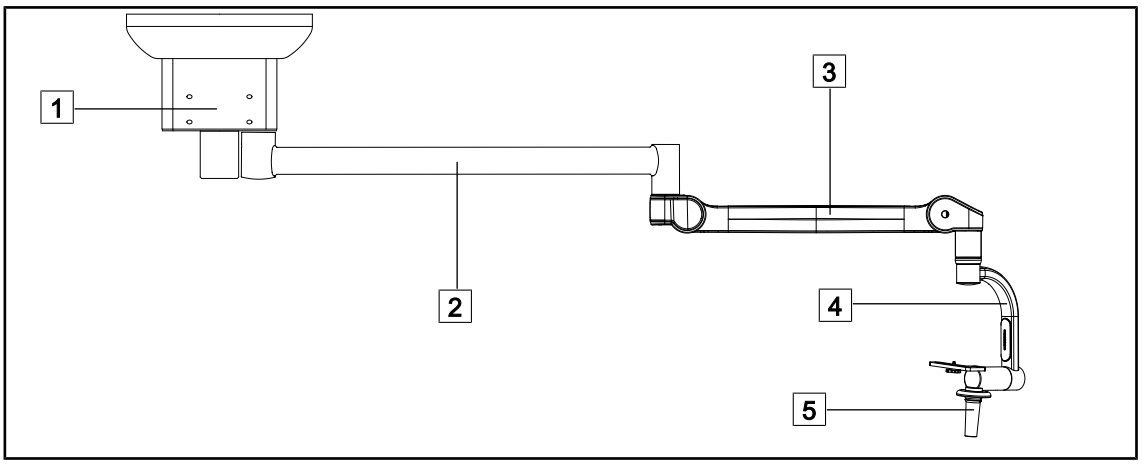
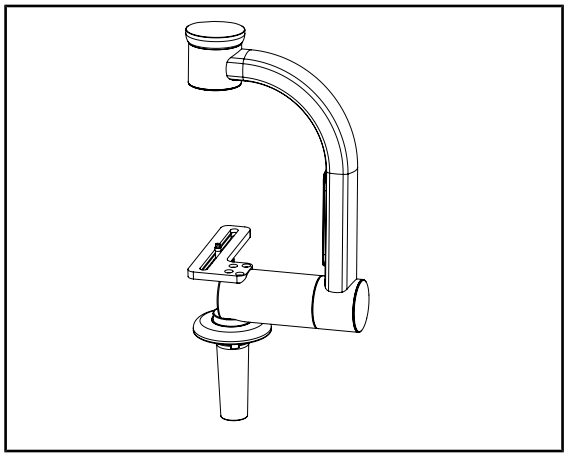


Fig. 6: Configuration of a SC05 camera mount on SATX suspension

1 Suspension tube
2 Suspension arm
3 Spring arm
4 SC05 camera mount
5 Sterilisable handle

1.6.2.1 Components

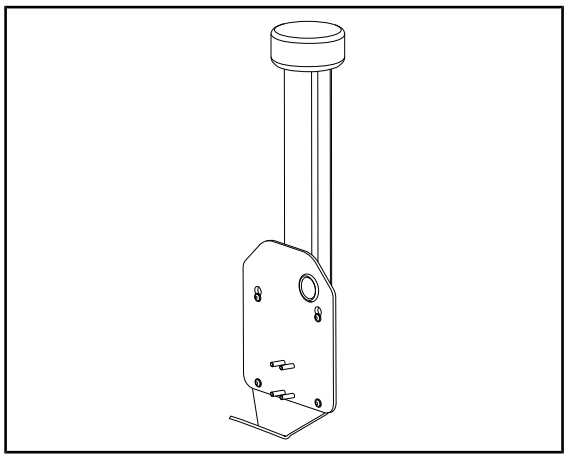
SC05 camera mount



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

Fig. 7: SC05 camera mount

FHS0 fitted with a camera mount



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

Fig. 8: CAMERA MOUNT PLATE

1.6.2.2 Options for camera mounts

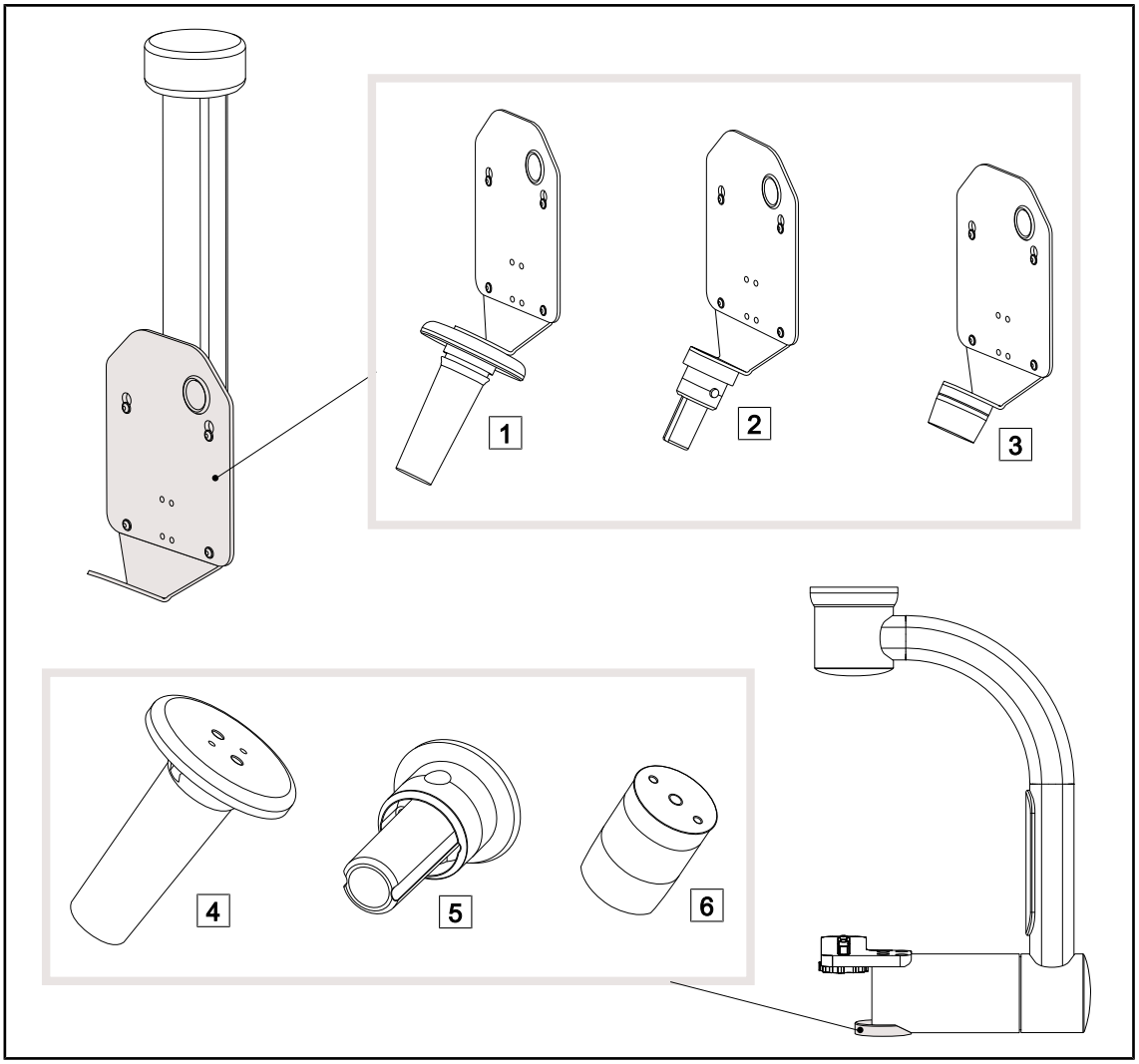
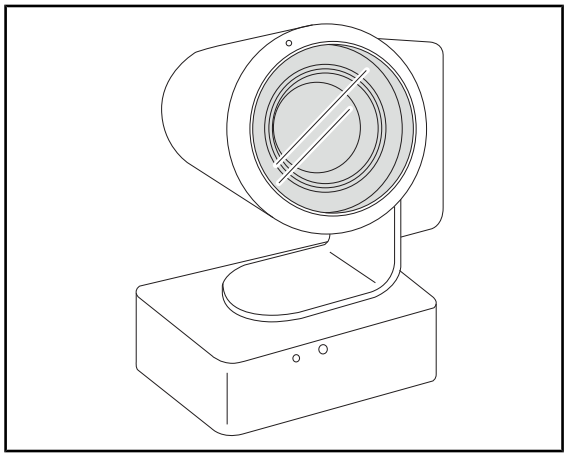


Fig. 9: Options available with camera mounts

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

1.6.2.3 Accessories for camera mounts

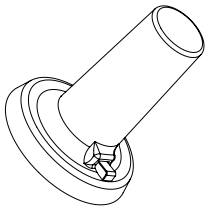
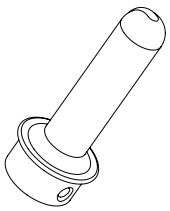
SC430-PTR camera



This camera can be secured to the camera mount using a VESA 100x100 bracket. It facilitates monitoring of surgeons' actions, enabling their needs to be better anticipated. It also ensures operating fluidity by keeping the surgical area clear during training phases.

Fig. 10: EIZO camera

Sterilisable handles

Illustration	Description	Reference
	**Set of five STG PSX handles**	STG PSX 01
	**Set of five STG HLX handles**	STG HLX 01

Tab. 3: Sterilisable handles available for camera mounts

1.6.3 Mounts for compatible devices

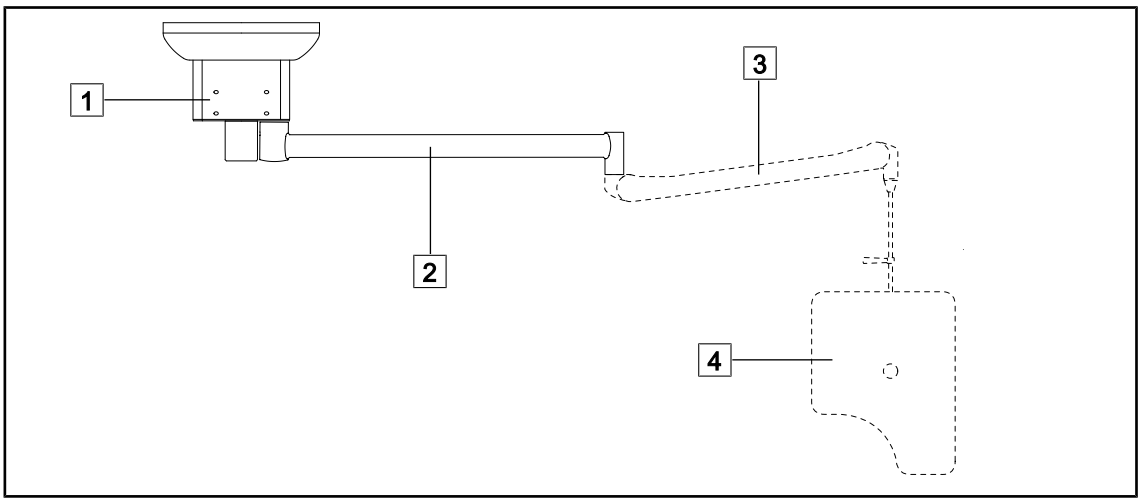


Fig. 11: Configuration of a lead shield holder

1 Suspension tube
2 Suspension arm
3 Spring arm (optional)
4 Lead shield (optional)

1.6.3.1 Lead screens

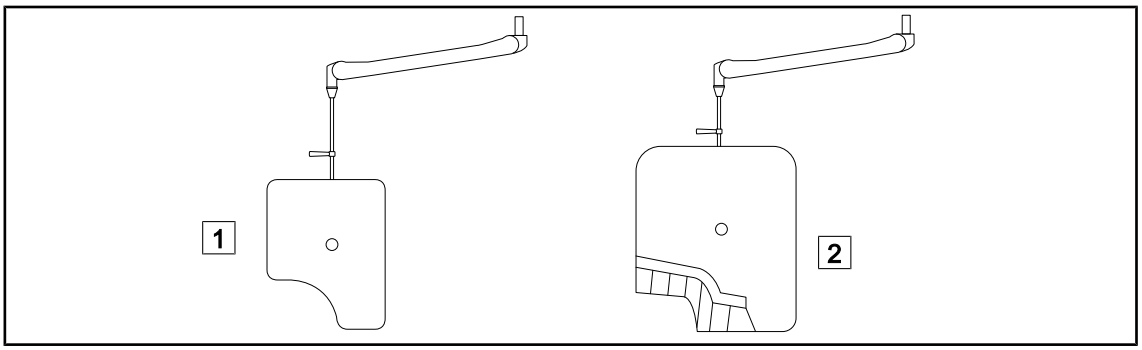


Fig. 12: Lead screens

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

1.6.4 Cable guide solution

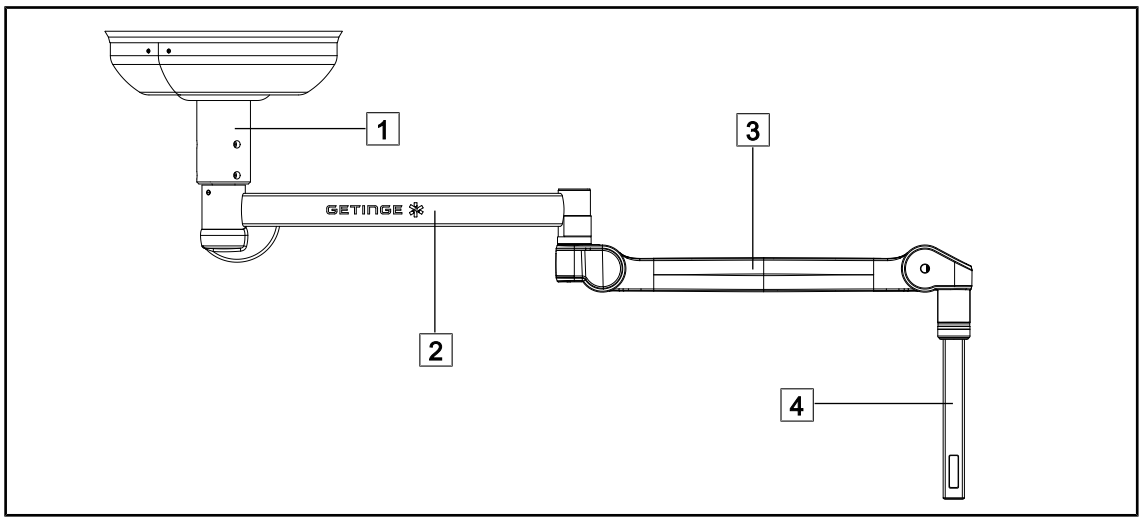


Fig. 13: Configuration of a cable guide on a SAX arm

1 Suspension tube
2 Suspension arm
3 Spring arm
4 Cable guide

1.7 Product identification label

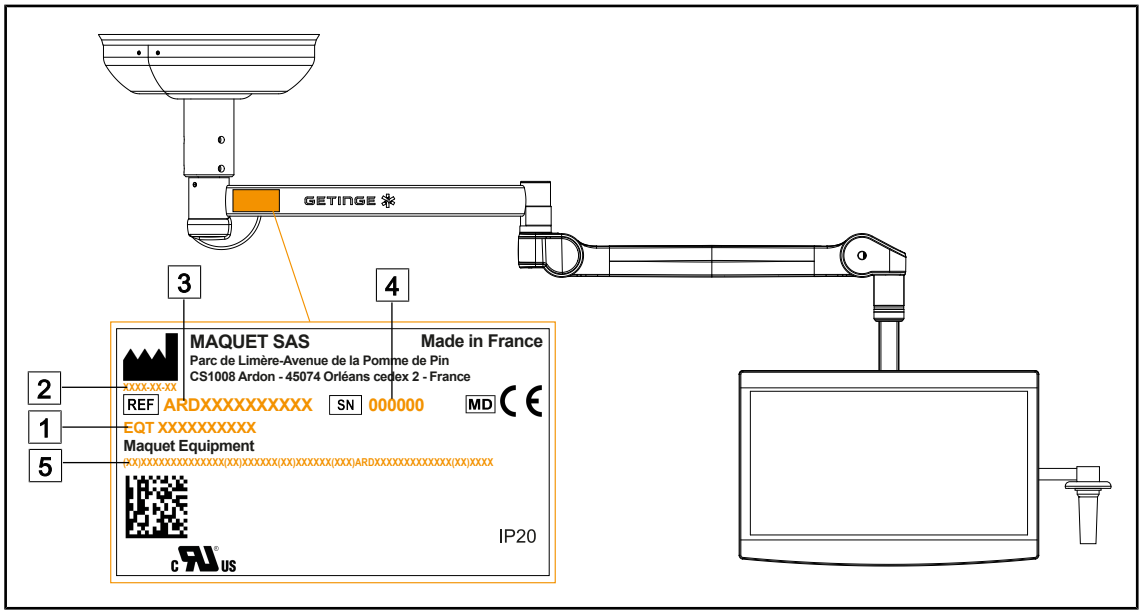


Fig. 14: Identification label

1 Product name
2 Manufacturing date
3 Product code
4 Serial number
5 UDI identification

1.8 Standards applied

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

Reference	Title
IEC 60601-1:2005+AMD1:2012+AMD2:2020 ANSI/AAMI ES60601-1:2005/A2:2021 CAN/CSA-C22.2 No. 60601-1:14 + A2:22 EN 60601-1:2006/A1:2013/A2:2021	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 EN 60601-1-6:2010/A1:2015/A2:2021	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-1-9:2007+AMD1: 2013+AMD2:2020 EN 60601-1-9:2008/A1:2014/A2:2020	Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for an environmentally friendly design
IEC 62366-1:2015+AMD1:2020 EN 62366-1:2015/A1:2020	Medical devices – Part 1: Application of usability engineering to medical devices
ISO 20417:2021 EN ISO 20417:2021	Medical devices - Information provided by manufacturer
ISO 15223-1:2021 EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be provided by manufacturer - Part 1: General requirements

Tab. 4: Compliance with product standards

Quality management:

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

Tab. 5: Compliance with quality management standards

Environmental standards and regulations:

Reference	Year	Title
Regulation 1907/2006	2006	Registration, evaluation and authorization of chemical substances, as well as the restrictions applicable to these substances
US California Proposition 65 Act	1986	The Safe Drinking Water and Toxic Enforcement Act of 1986
Directive 2018/851	2018	Directive amending Directive 2008/98/CE concerning waste
Directive 94/62/EC	1994	Packaging and Waste Management

Tab. 6: Environmental standards and regulations

Country	Reference	Year	Title
Argentina	Dispocision 2318/2002	2002	Administración Nacional de Medicamentos, Alimentos y Tecnología Médica - Registro de productos Medicas - Reglamento
Australia	TGA 236-2002	2021	Therapeutic Goods (Medical Devices) Regulations 2002. Statutory Rules No. 236, 2002 made under the Therapeutic Goods Act 1989
Canada	SOR/98-282	2023	Medical Devices Regulations
EU	Regulation 2017/745/EU	2017	Medical Devices Regulations
Switzerland	RS (Odim) 812.213	2020	Medical Devices Ordinance (MedDO) of 1 July 2020
Taiwan	TPAA 2018-01-31	2018	Taiwanese Pharmaceutical Affairs Act
UK	Act	2021	Medical Devices Regulations 2002 No. 618
USA	21CFR Part 7	2023	Title 21--Food And Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter A -- General PART 7 - Enforcement policy
USA	21CFR Subchapter H	2023	Title 21--Food And Drugs Chapter I--Food and Drug Administration Department of Health and Human Services Subchapter H -- Medical Devices

Tab. 7: Compliance with market standards

1.9 Information relating to intended use

1.9.1 Intended use

The mounts for the Maquet Equipment range are designed to hold medical devices or accessories so as to ensure safe and ergonomic use during diagnostic or treatment operations.

1.9.2 Indications

The Maquet Equipment range is intended to be used for any type of surgery requiring a flat screen to view the surgical procedure or a camera to record activities on the surgical site.

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).
- Do not use for any purposes other than supporting a compatible medical device.
- Do not install a device that is too heavy or too wide.

1.9.5 Contraindications

This product does not have any contraindications.

1.10 Primary purpose

The main purpose of the Maquet Equipment range devices is to hold medical devices or accessories.

1.11 Clinical benefit

Flat screens, cameras, lead screens and other devices are frequently used during surgery. The products in the Maquet Equipment range are designed to accommodate medical devices and accessories. When used appropriately, they will:

- Allow optimal positioning of a medical device or medical device accessory.
- Allow workspace management within the operating room while minimizing the risk of contamination.

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 [⏩ Page 52] 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. 8: Environmental conditions for transport/storage

Environmental conditions for use

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

Tab. 9: Environmental conditions for use

2.2 Safety instructions

2.2.1 Safe use of the product

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

Do not use a damaged device.

2.2.2 Infection

WARNING!

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

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

3 Control interfaces

This product does not have a control interface.

4 Use

4.1 Installing or removing a sterilisable handle

WARNING!

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

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

WARNING!

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

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

4.1.1 Installing or removing an STG PSX sterilisable handle

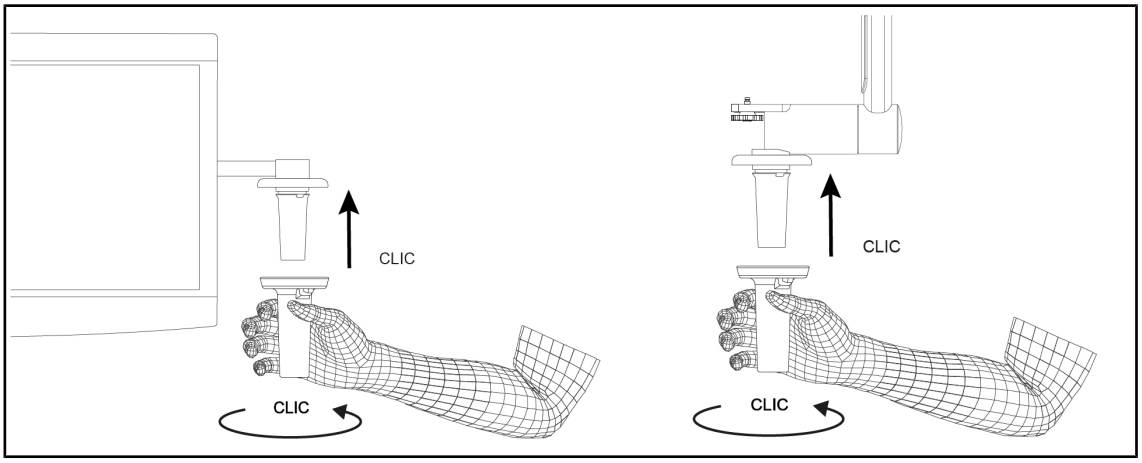


Fig. 15: Installing a STG PSX sterilisable handle

Installing a STG PSX sterilisable handle

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

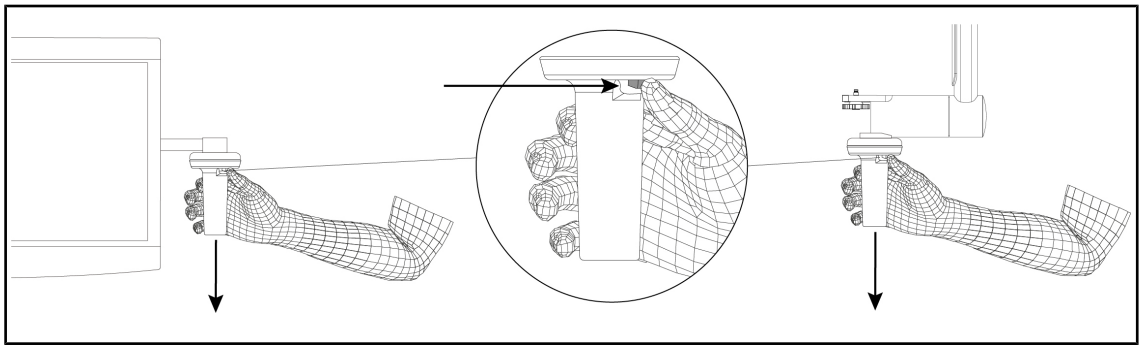


Fig. 16: Removing the STG PSX sterilisable handle

Removing an STG PSX sterilisable handle

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

4.1.2 Installing or removing an STG HLX sterilisable handle

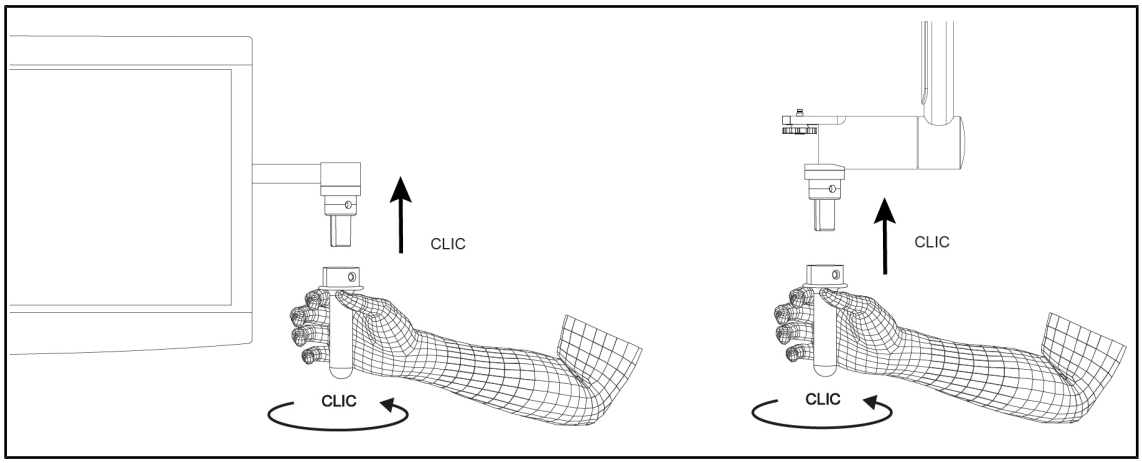


Fig. 17: Installing the STG HLX sterilisable handle

Installing an STG HLX sterilisable handle

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

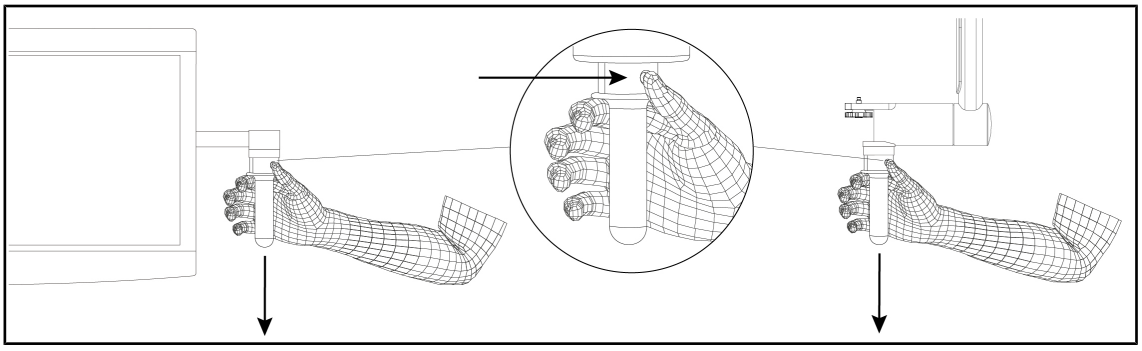


Fig. 18: Removing the STG HLX sterilisable handle

Removing an STG HLX sterilisable handle

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

4.1.3 Installing and removing a DEVON® or DEROYAL®** handle

NOTICE
Refer to the manual provided by the supplier of the medical device.

Screw-on version

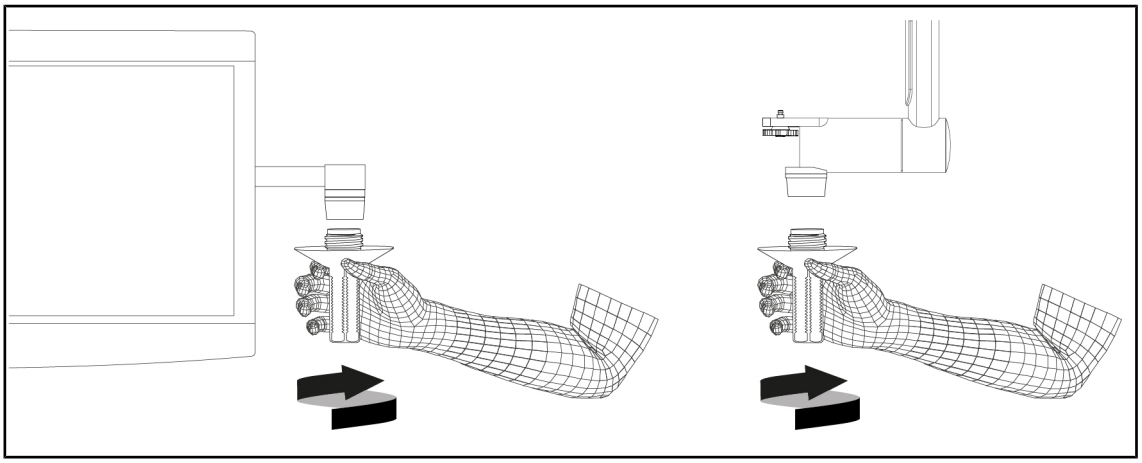


Fig. 19: Installing a DEVON® or DEROYAL® screw-on handle

Installing a screw-on handle on the adapter

1. Screw the handle into place.
   - ➢ The handle is now ready for use.

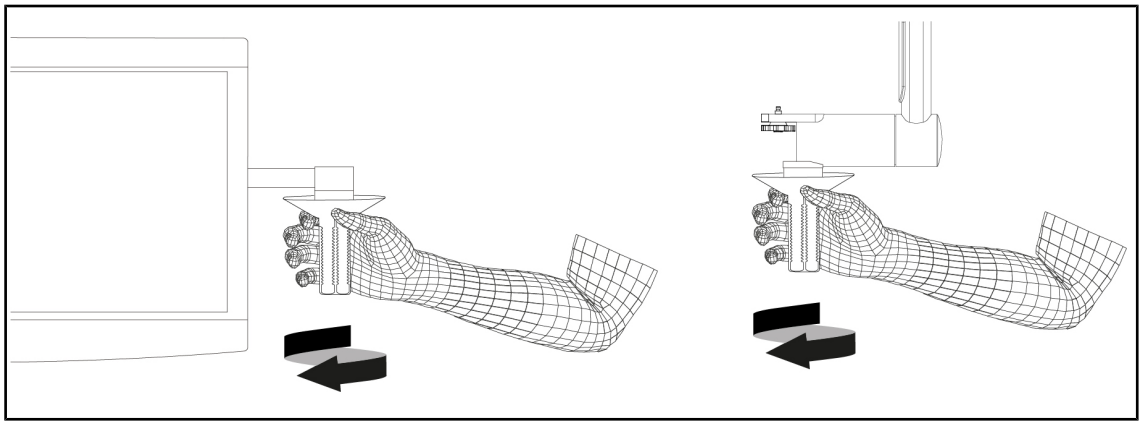


Fig. 20: Removing a DEVON® or DEROYAL® screw-on handle

Removing a screw-on handle after use

1. Unscrew the handle.

Clip-on version

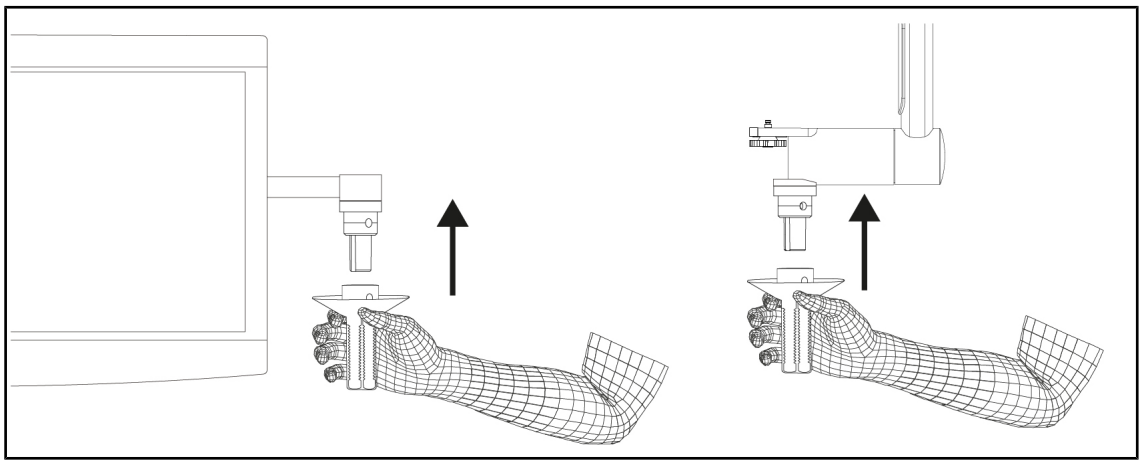


Fig. 21: Installing a DEVON® or DEROYAL® clip-on handle

Installing a DEVON® or DEROYAL® clip-on handle

1. Fit the handle to the mount.
2. Rotate the handle until its rotation is locked.
   - ➢ The locking button pops out of its housing.
3. Check that the handle is firmly in place.
   - ➢ The handle is now ready for use.

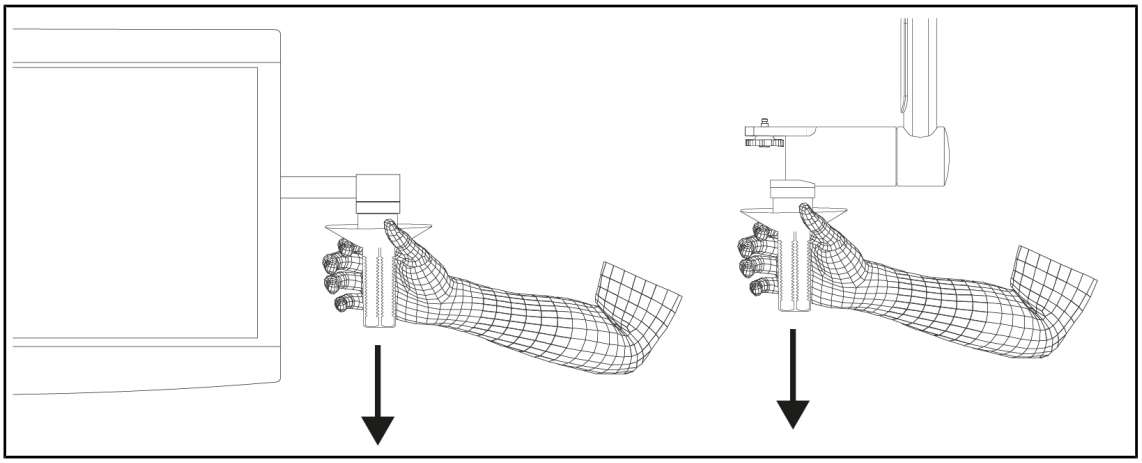


Fig. 22: Removing the handle

Removing a DEVON® or DEROYAL® clip-on handle

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

4.2 Use of screen holders

4.2.1 Daily visual and functional inspections for screen holders

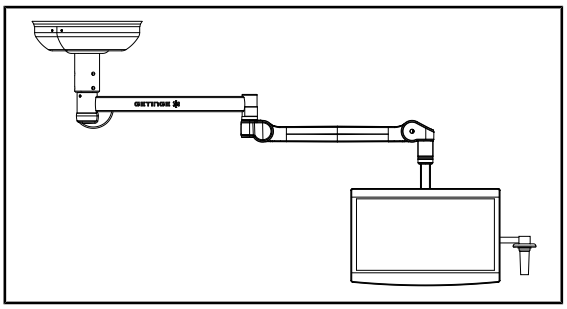


Fig. 23: Integrity of the device

Integrity of the device

1. Check that the device has not suffered any impact damage.
2. Check for any chipped or missing paint.
3. If a problem is noted, contact technical support.

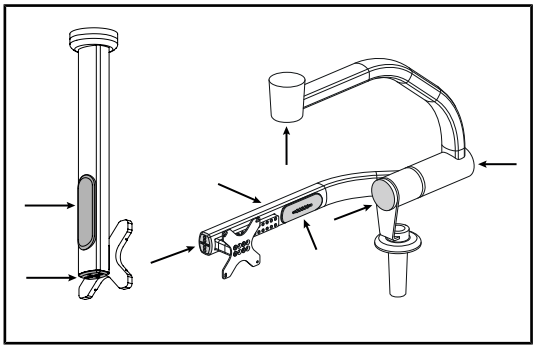


Fig. 24: Screen holder caps

Silicone caps or plastic covers on the screen holder

1. Check that the silicone caps on the screen holder are in the proper position and in good condition.
2. Check that the silicone grommets on the screen holder are in the proper position and in good condition.
3. If a problem is noted, contact technical support.

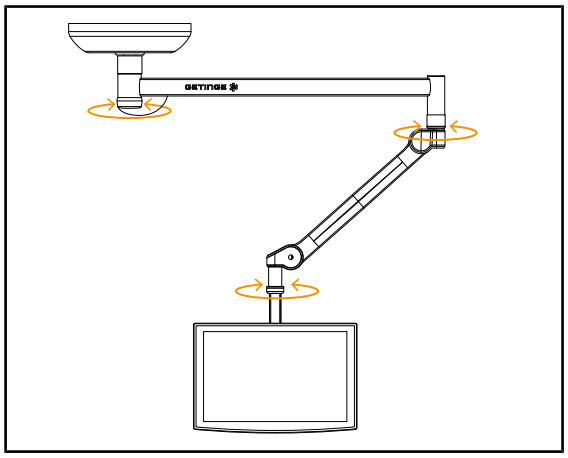


Fig. 25: Stability/drift

Stability and drift of the system

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

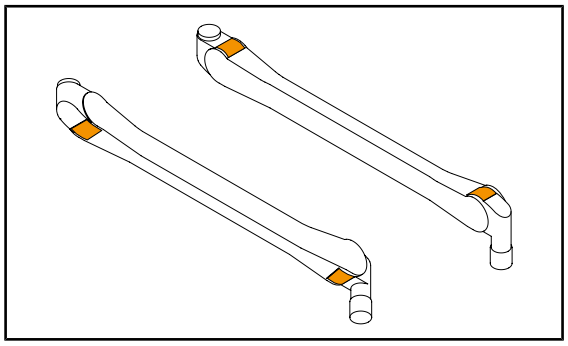


Fig. 26: Inspection of the half-rings

Half-rings on spring arms

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

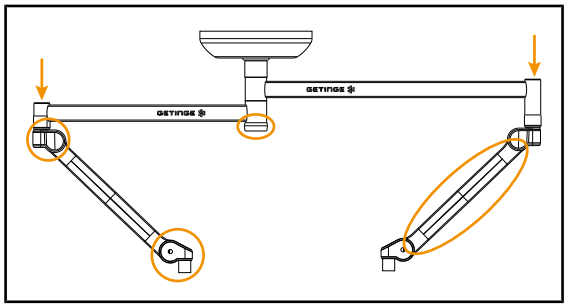


Fig. 27: Inspection of the covers

Covers

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

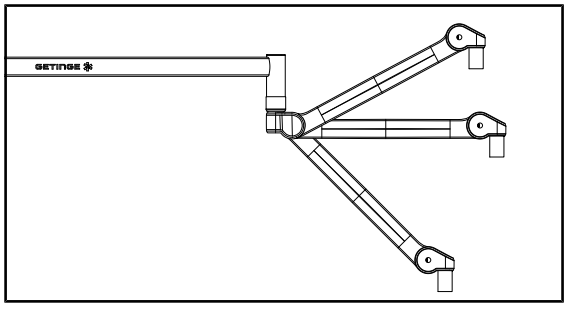


Fig. 28: Spring arm positioning

Spring arm positioning

1. Place the spring arm in its lowest position, horizontally and finally in its highest position.
2. Check that the spring arm remains in each of these positions.
3. If a problem is noted, contact technical support.

For the attention of sterilisation personnel

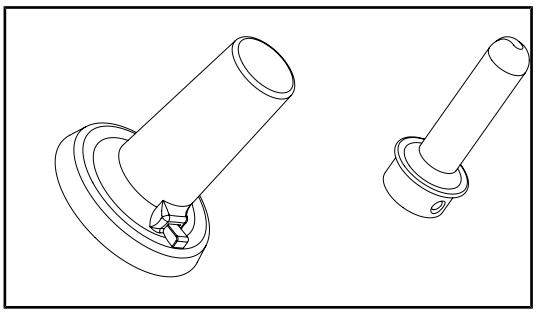


Fig. 29: Sterilisable handles

Condition of the sterilisable handles

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

4.2.2 Handling and positioning the screen holder

WARNING!

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

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

WARNING!

Risk of infection or tissue reaction
A collision between the device and another item of equipment may result in particles falling onto the surgical site.

Pre-position the device before the patient arrives. Move the device carefully to avoid a collision.

WARNING!

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

Respect safety indications on the product.

Handling of the screen holder by the sterile team

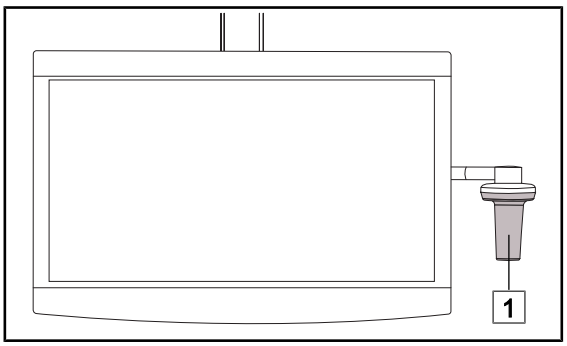
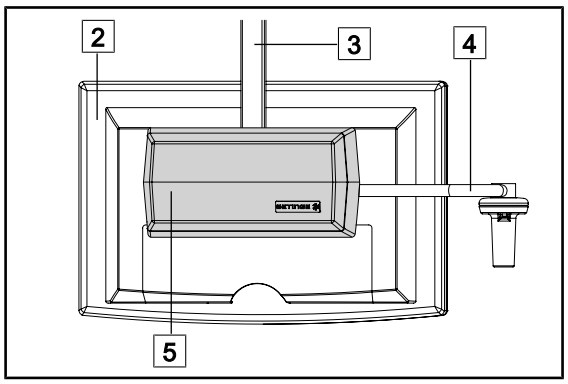


Fig. 30: Handling by sterile team

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

Handling of the screen holder by the non-sterile team



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

Fig. 31: Handling by the non-sterile team

Positioning the screen holder

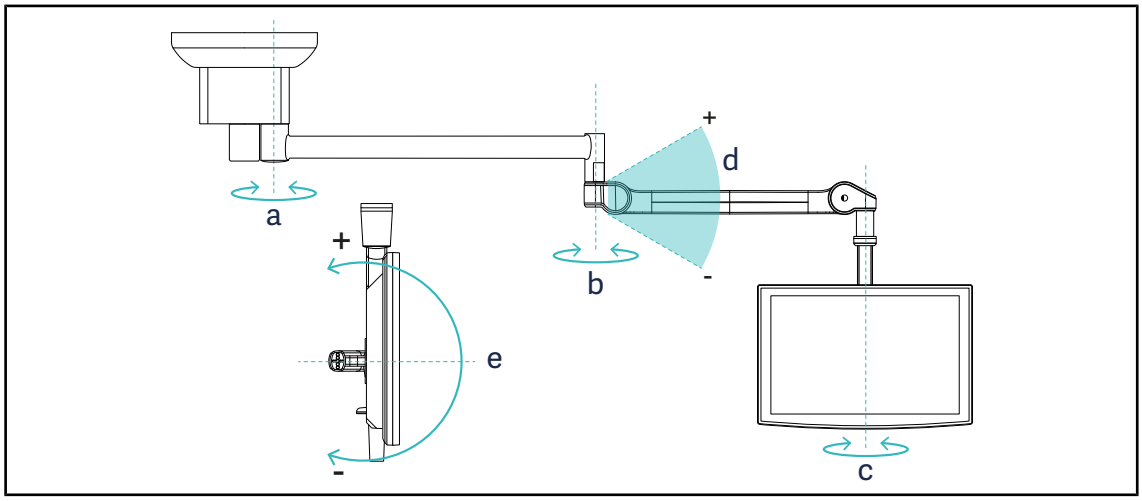


Fig. 32: Possible rotations on a SATX suspension

Screen holder	a	b	c	d	e
FHS0/MHS0/MHD2	270°	330°	315°	+45°/-70°	–
XHS0	270°	330°	315°	+45°/-70°	-45°/+90°
XHD1	270°	330°	330°	+45°/-70°	-60°/+10°
SPC 12	270°	330°	270°	+45°/-70°	–
XO	270°	360°	360°	+45°/-50°	–

Tab. 10: Rotation amplitude values (in degrees) on a SATX suspension

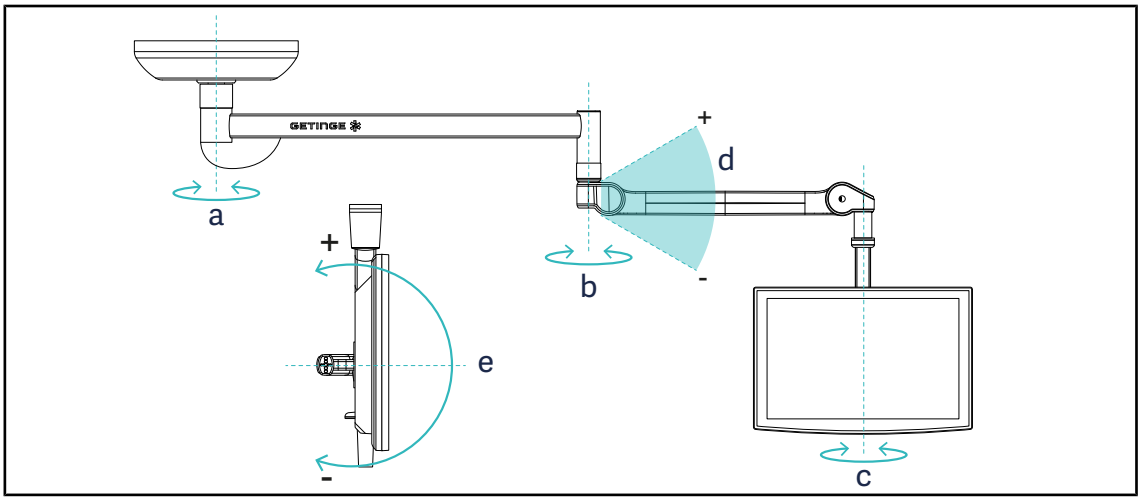


Fig. 33: Possible rotations on an SAX suspension

Screen holder	a	b	c	d	e
FHS0/MHS0/MHD2	330°	330°	315°	+45°/-70°	–
XHS0	330°	330°	315°	+45°/-70°	-45°/+90°
XHD1	330°	330°	330°	+45°/-70°	-60°/+10°
SPC 12	330°	330°	270°	+45°/-70°	–
XO	360°	360°	360°	+45°/-50°	–

Tab. 11: Rotation amplitude values (in degrees) on a SAX suspension

4.2.3 Screen control interface

NOTICE

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

4.2.4 Screen holder pre-positioning examples

SATELITE configuration on flange parallel to operating table

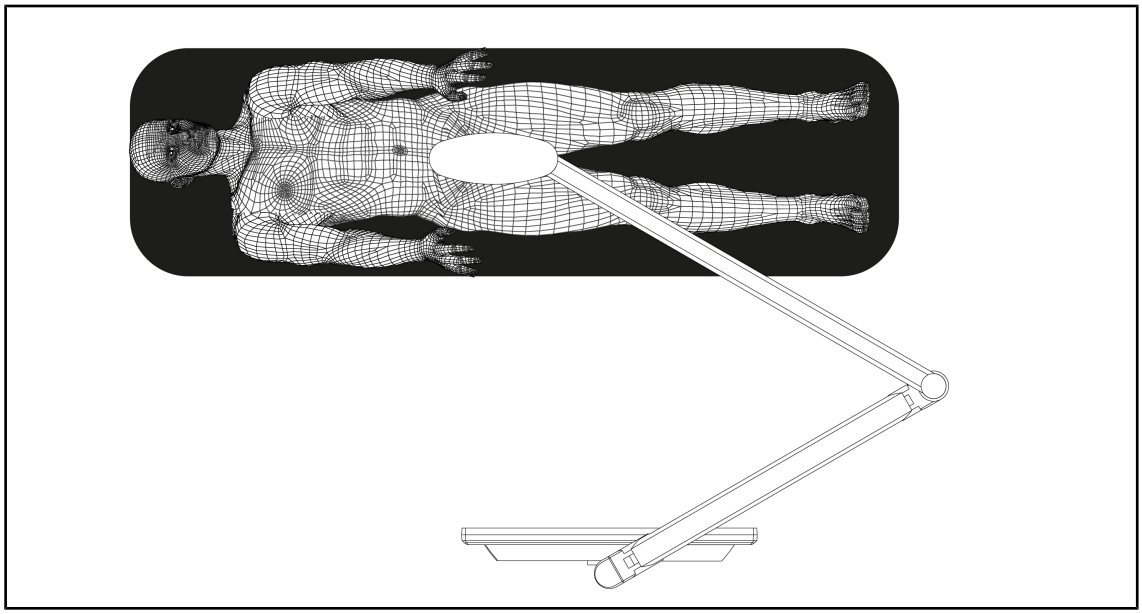


Fig. 34: SATELITE configuration on flange parallel to operating table

- Place the suspension arm - spring arm junction on the patient's feet side at the beginning of the operation.
- The monitors are moved around the table, not above the surgical site.

SATELITE configuration on flange perpendicular to operating table

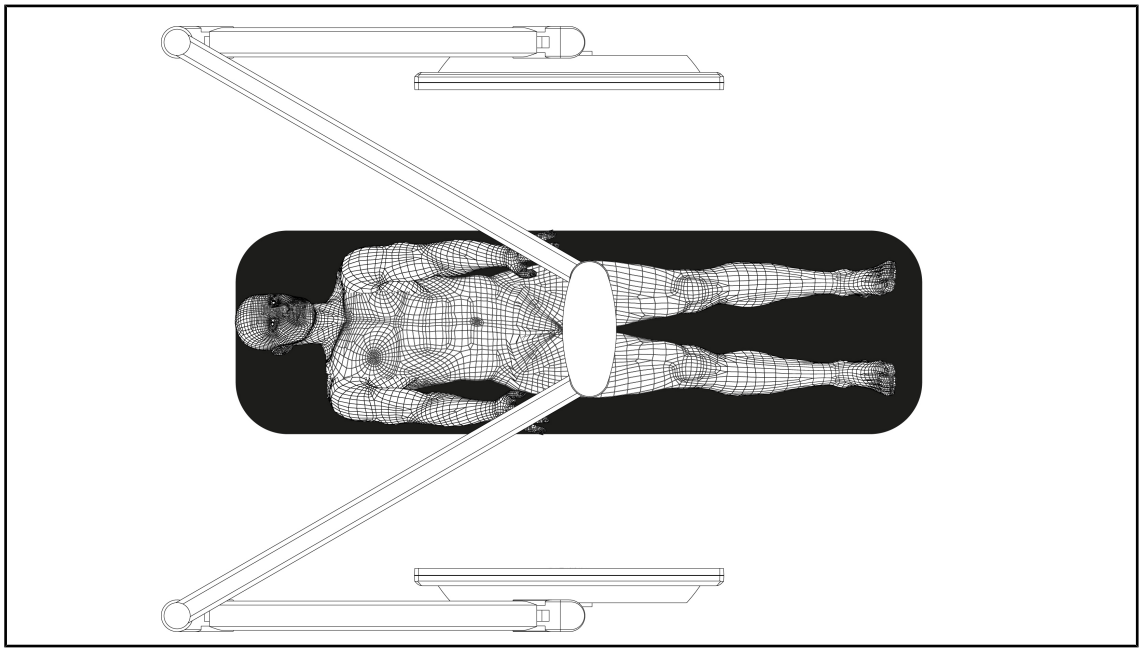


Fig. 35: SATELITE configuration on flange perpendicular to operating table

- Place the suspension arm - spring arm junction on the patient's head side at the beginning of the operation.
- The monitors are moved around the table, not above the surgical site.

4.3 Use of camera mounts

4.3.1 Visual and functional inspections for camera mounts

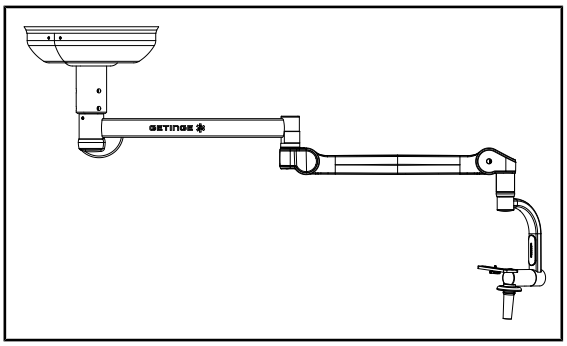


Fig. 36: Integrity of the device

Integrity of the device

1. Check that the device has not suffered any impact damage.
2. Check for any chipped or missing paint.
3. If a problem is noted, contact technical support.

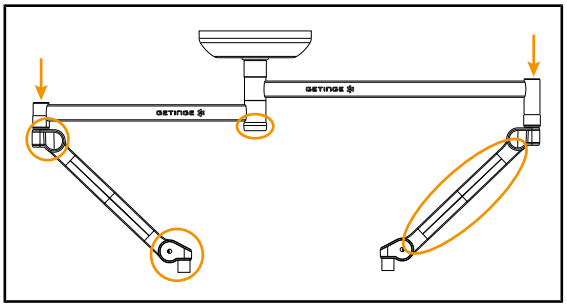


Fig. 37: Inspection of the covers

Covers

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

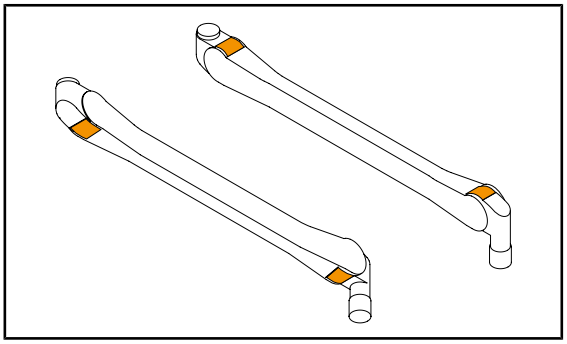


Fig. 38: Inspection of the half-rings

Half-rings on spring arms

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

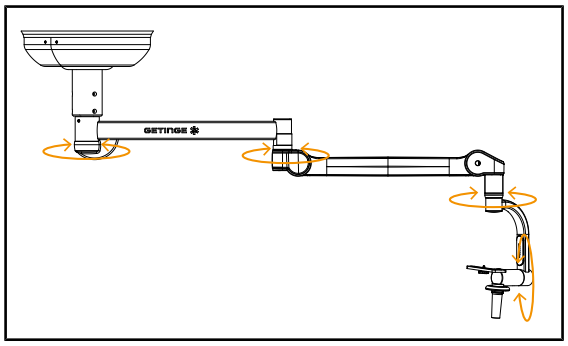


Fig. 39: Stability/drift

Stability and drift of the system

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

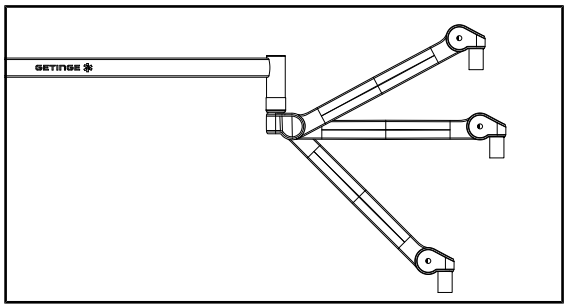


Fig. 40: Spring arm positioning

Spring arm positioning

1. Place the spring arm in its lowest position, horizontally and finally in its highest position.
2. Check that the spring arm remains in each of these positions.
3. If a problem is noted, contact technical support.

For the attention of sterilisation personnel

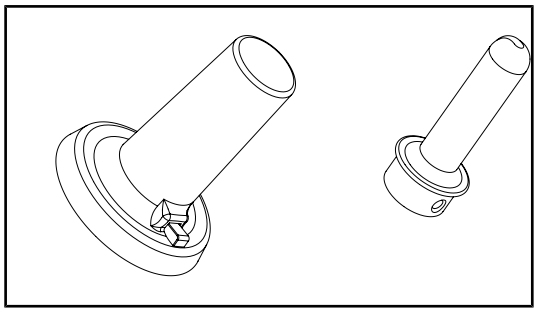


Fig. 41: Sterilisable handles

Condition of the sterilisable handles

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

4.3.2 Attaching a camera to the SC camera mount

NOTICE

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

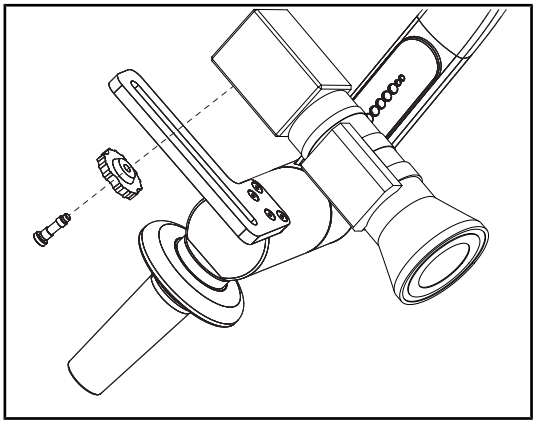


Fig. 42: Attaching the camera to the SC mount

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

4.3.3 Handling the camera mount

WARNING!

Risk of infection or tissue reaction
A collision between the device and another item of equipment may result in particles falling onto the surgical site.

Pre-position the device before the patient arrives. Move the device carefully to avoid a collision.

WARNING!

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

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

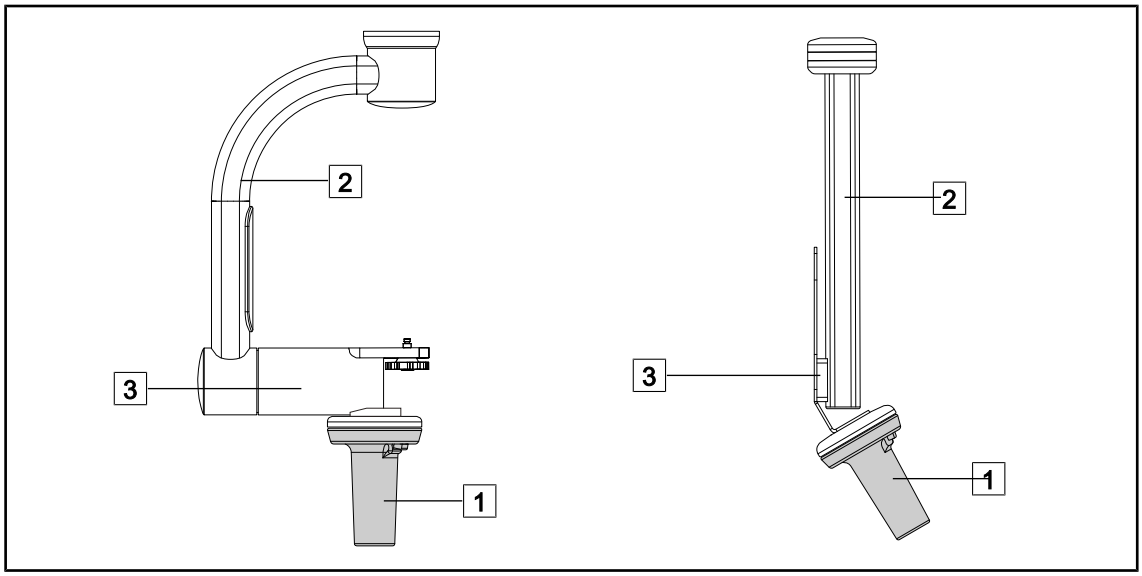


Fig. 43: Handling the camera mount

The camera mount can be manoeuvred in various ways:

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

Degrees of rotation

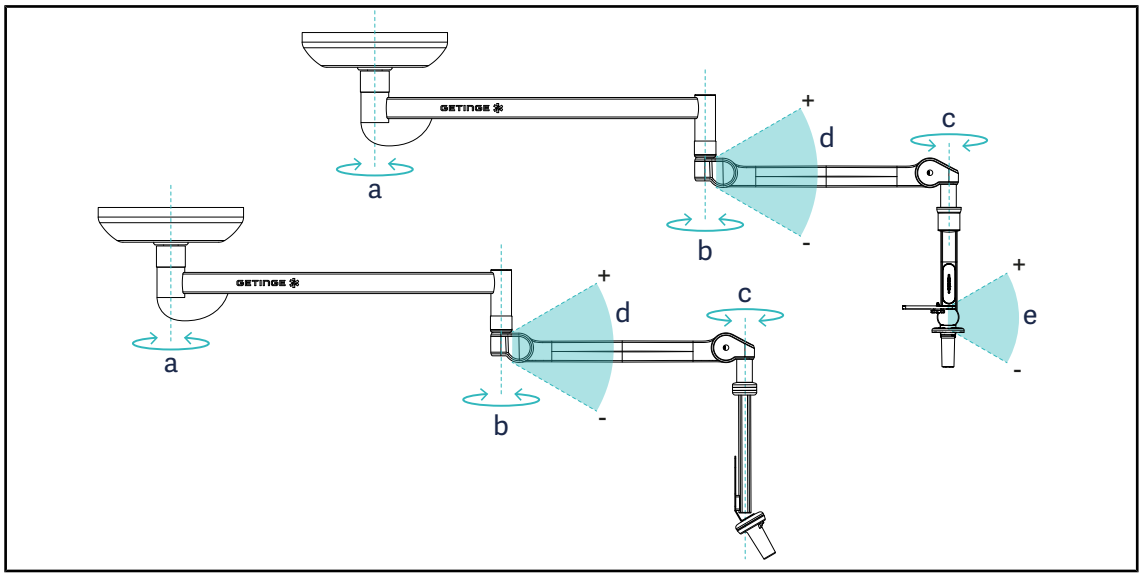


Fig. 44: Degrees of rotation of camera mounts

	a	b	c	d	e
SC05 CAMERA MOUNT FH	SAX: 360° SATX Shaft 1: 360° SATX Shaft 2/3: 270°	360°	360°	+45° / -70°	120°

4.3.4 Using the SC430-PTR camera

NOTICE

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

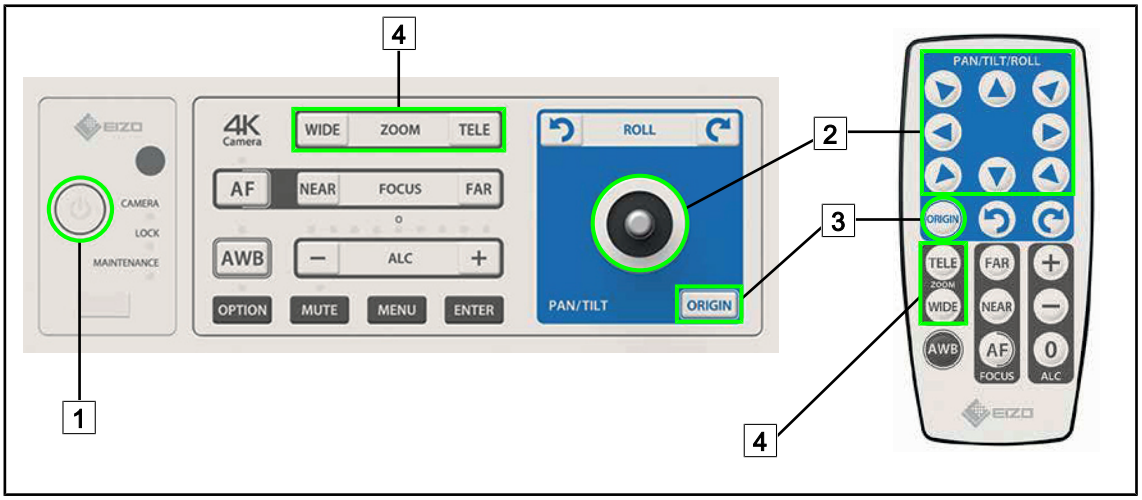


Fig. 45: Main commands of the SC430-PTR camera

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

4.4 Use of compatible devices

NOTICE

For all information regarding the use of compatible devices with the XO mounts, please refer to the instructions provided with the device.

4.5 Using the cable guide solution

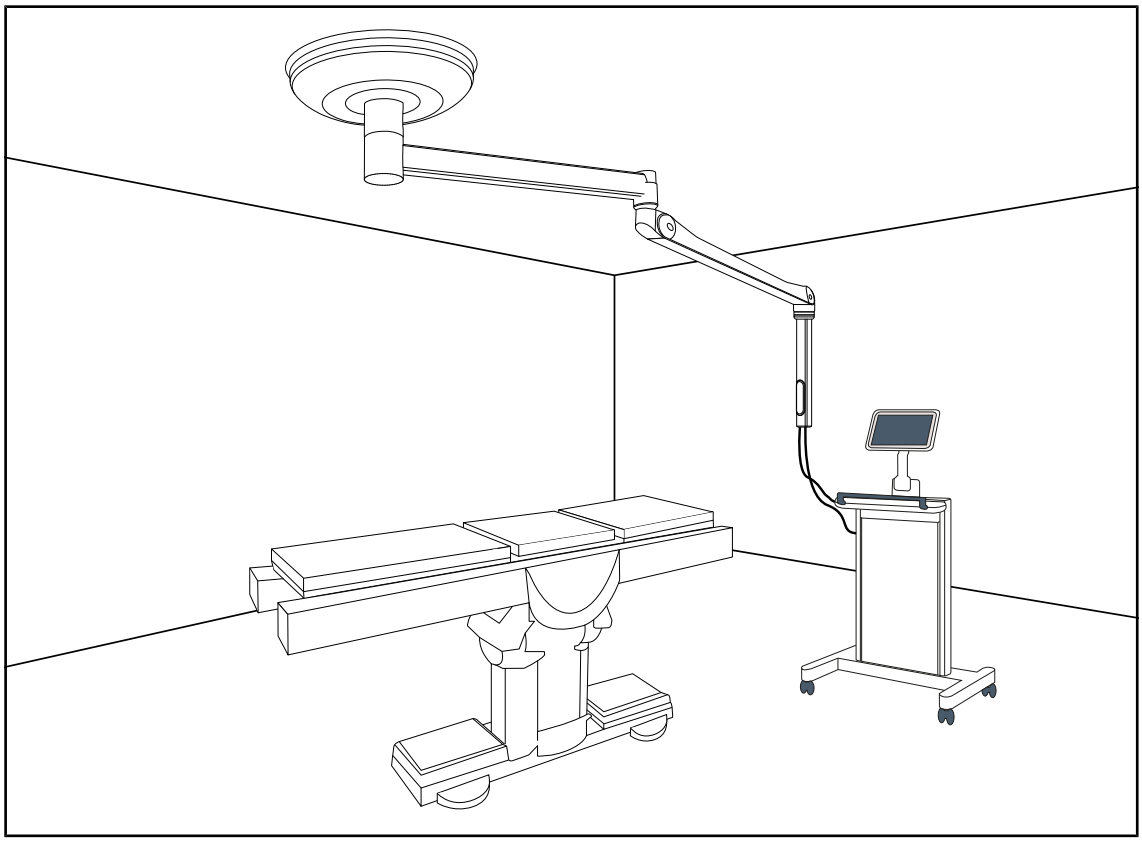


Fig. 46: Using the cable guide solution

The cable guide allows the cables to be moved freely in the operating room according to the needs of the surgical team or medical staff.

When using the cable guide, it is advisable to lock the spring arm in a vertical position. This makes it easier to position the vertical tube above the control unit and reduces the risk of damage to the cable.

5 Troubleshooting

Not applicable to this product

6 Cleaning / Disinfection / Sterilisation

WARNING!

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

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

6.1 Cleaning and disinfecting the system

WARNING!

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

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

WARNING!

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

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

WARNING!

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

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

General instructions concerning cleaning, disinfection and safety

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

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

6.1.1 Cleaning the device

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

6.1.2 Disinfecting the device

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

6.1.2.1 Disinfectants to be used

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

6.1.2.2 Permitted active substances

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

Tab. 12: 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[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.

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. 13: 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.

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. 14: Example of a steam sterilisation cycle

7 Maintenance

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

Preventive maintenance	To be performed every year

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

NOTICE

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

8 Technical specifications

8.1 Mechanical specifications

8.1.1 Screen holder(s)

Monitor mount	Maximum on-board weight on monitor mount	Maximum monitor dimensions
FHS019	19 kg	809 × 518 mm (32”)
MHS019		
MHS035	35 kg	1037 × 640 mm (42”)
MHD237	37 kg	809 × 518 mm (32”)
XHS016	16 kg	
XHS021	21 kg	
XHD127	27 kg	
SPC 12	12 kg (Tray: 3 kg max)	531 × 299 mm (24”)

Tab. 15: Mechanical specifications of the monitor mount

8.1.2 Suspension arms and spring arms

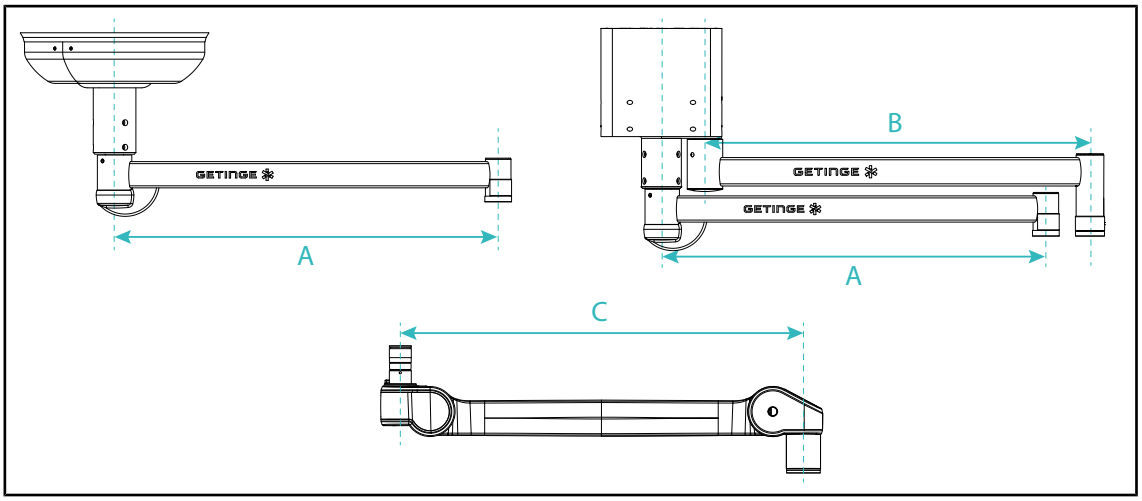


Fig. 47: Dimensions of suspension arms and spring arms

SAX (A) suspension arm	SATX (B) suspension arm	Spring arm (C)
850 mm (≈ 33.5 in) 1050 mm (≈ 41.5 in) 1250 mm (≈ 49 in) 1450 mm (≈ 57 in) 1650 mm (≈ 65 in)	1350 mm (≈ 53 in) 1550 mm (≈ 61 in)	920 mm (≈ 36 in)

Tab. 16: Possible dimensions of suspension arms and spring arms

8.1.3 Mechanical compatibility

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

Tab. 17: List of compatible devices

8.2 Other characteristics

Protection against electrical shock	Class I
Medical device classification: Europe, USA, Canada, Australia & Taiwan	Class I
Protection rating for the device as a whole	IP 20
GMDN code	32288 / 32245
EMDN code	Z12010799
CE marking year	2018

Tab. 18: Specifications relating to standards and regulations of the Maquet Equipment range

9 Waste management

9.1 Disposal of packaging

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

9.2 Product

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

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

9.3 Electrical and electronic components

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

Notes

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