Instructions for Use

Sim.CAM

Dok-ID: 100-0016900 EN – V. 2.3

CO #003-01665

CE

Before starting any work please read these Instructions for Use!

S.I.M.E.O.N. Medical GmbH & Co. KG
In Grubenäcker 18
D-78532 Tuttlingen
Telephone: +49 (0) 7461 90068-0
Fax: +49 (0) 7461 90068-900
E-Mail: info@simeonmedical.com
Website: www.simeonmedical.com

Technical Service
S.I.M.E.O.N. Medical GmbH & Co. KG
Telefon: +49 (0) 7461 90068-888
E-Mail: service@simeonmedical.com

PUSHING TECHNOLOGY TO EXCELLENCE

Table of Contents

Table of Contents

1 General

1.1 Information on these Instructions for Use

These Instructions for Use enable the safe and efficient handling of the Sim.CAM.
The Instructions for Use are an integral part of the camera and must be stored near the unit, in a manner accessible to personnel, at all times.

Persons who handle the camera must have carefully read the instructions for use and understood their contents before starting any work. The basic requirement for safe operation is the adherence to all safety and handling instructions in this manual.

Furthermore, local regulations on the operation of medical equipment apply.

The illustrations in this manual are provided for basic understanding and could deviate from the actual design.

Symbols

☞ Indicates handling instructions.

⇨ Indicates a status or an automatic sequence as a result of a handling step

↳ *“Reference title”, page XX*

Is a cross-reference to a chapter in this document.

Copyright protection

These Instructions for Use are copyright-protected.

Forwarding of the Instructions for Use to a third party, its reproduction in any type or form – even if only partial – and the exploitation and/or dissemination of its contents are not allowed without written authorization from the manufacturer.

Infringements will be liable to compensation for damages.
We reserve the right to assert further claims.

Limitation of liability

All specifications and instructions in these Instructions for Use have been compiled under consideration of applicable norms and standards, the current state of the art, and our many years of knowledge and experience.

We will accept no liability, and the warranty and guarantee will become inapplicable in the event of damages resulting from:

- Non-observance of these Instructions for Use
- Non-adherence to the designated use / specific function.
- Use by non-qualified personnel
- Operation of the surgical lights by insufficiently trained personnel
- Modifications conducted independently
- Technical modifications
- Use of defective or improperly-repaired unit
- Use of unauthorized spare parts or accessories
- Use of the device with damaged packaging and/or non-compliance with the transport and storage conditions

The actual scope of delivery may deviate from the explanations or illustrations provided here in the case of special designs, the use of additional order options, or due to the most recent technical changes.

Contraindications

There are no known contraindications.

1.2 Symbol explanation

Safety information

Safety indications are identified in these Instructions for Use through symbols.

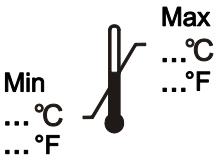
1.2.1 Safety symbols

DANGER	Indicates a hazardous situation that, if not avoided, **will** result in death or serious injury.
WARNING	Indicates a hazardous situation that, if not avoided, **could** result in death or serious injury.
CAUTION	Indicates a hazardous situation that, if not avoided, **could** result in **minor or moderate** injury.
NOTICE	Indicates information considered important, but not hazard-related (e.g. messages relating to property damages).

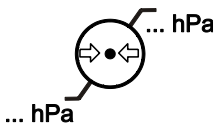
1.2.2 Symbol explanation

The following symbols can be found on the type plate and/or packaging. The symbols must always be observed.

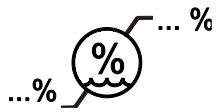
Follow the Instructions for Use



Specifications on minimum and maximum ambient temperature for storage and transportation



Specifications on minimum and maximum air pressure for storage and transportation



Specifications on minimum and maximum air humidity for storage and transportation

The arrows point towards the top side of the package. They must always point upwards; otherwise, the contents could be damaged.

This symbol identifies packages that contain breakable or sensitive contents.

Handle the package carefully, do not allow it to drop and do not subject it to any blows.

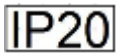
Protect the package from wetness and keep dry

Date of manufacture and manufacturer's address

Article number

Serial number

Protective grounding



Protection type

Medical Equipment – General Medical Equipment

AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2012), CAN/CSA-C22.2 No. 60601-1 (2014), IEC 60601-2-41:2009-A1:2013

CE mark of conformity

The symbol of the crossed-out wheeled bin means that the product must not be disposed of with household waste at the end of its useful life.

Indicates that the object in question is a medical device (DIN EN ISO 15223)

Unique Product Identifier, displays a carrier that contains information about a Unique Product Identifier (UDI).

Local Agent, EC = Agent in the European Union

Local authorized representative, CH = authorized representative in Switzerland

Distributor, indicates the company that sells the medical device locally.

Importer, indicates the company that imports or has imported the medical device locally.

1.3 Spare parts

Procure spare parts from your authorized dealer or directly from the manufacturer. For the address, see page 2.

⚠WARNING	**Risk of injury due to the use of incorrect spare parts!** The use of incorrect or defective spare parts may place personnel and patients at risk as well as cause damages, malfunctions, or a total breakdown of the unit. ☞ Only use original manufacturer spare parts or manufacturer-approved spare parts. ☞ In case of doubt, always contact the manufacturer.

1.4 Warranty provisions

The warranty provisions are contained in the manufacturer's General Business Terms and Conditions.

The manufacturer's warranty is voided if unauthorized spare parts are used.

1.5 Technical Service

Our Technical Service is available to provide technical information. For contact information, see page 2.

In addition, our personnel is always interested in hearing about new information and experiences that may arise from use of the product and that may be valuable for the improvement of our products.

1.6 Intended use

The Sim.CAM HD, HD/4K Wireless is an optional accessory that turns a patient's treatment or operation into a video. The video is used to document the treatment or operation process.

Usage restrictions

The video must not be used for visual control of a treatment or operation. The treating physician or surgeon must always have a direct view of the treatment or operation.

The Sim.CAM HD, HD/4K Wireless is not suitable for use in explosion-hazard or oxygen-rich environments. The Sim.CAM HD, HD/4K Wireless is only intended for use in operating and examination rooms.

Intended use

The Sim.CAM HD, HD/4K Wireless can be either integrated directly into the camera-ready light on the ceiling variant or attached to a separate arm.
The Sim.CAM HD, HD/4K Wireless is positioned using a sterile camera sleeve.
The Sim.CAM HD, HD/4K Wireless is operated using a remote control and/or wall control.
Intended use also includes compliance with all specifications in these instructions for use and the separate installation instructions.
The camera may only be operated by professional users.
Any use that exceeds the intended use, and any other kinds of uses, are considered to be incorrect uses.

⚠ DANGER	**Danger due to incorrect use!** Incorrect use of the unit may lead to dangerous situations. The following are especially considered to be incorrect uses: – Use of the unit in facilities that have not been built in compliance with applicable standards and guidelines regulating the construction of medical facilities. – Use of the unit in explosion-prone areas. – Use of a damaged unit. – Opening of the unit. – Use of the unit by unqualified personnel. – Use of the unit when objects are hanging from its extension arm, spring arm, or light head.

Claims of any type due to damages caused by misuse, alteration or modification of the surgical lights are excluded.

Any changes to this medical unit are fundamentally not allowed. Exceptions are only given to authorized technical specialists appointed by the manufacturer.

Electromagnetic Compatibility (EMC)

As electric medical devices, these lights are subject to special precautionary measures with regard to EMC. They must be installed and commissioned in accordance with the EMC instructions.

Mobile HF communication devices may affect the functioning of the camera. The operation of accessories, converters and cables on the camera which the manufacturer has not expressly approved may increase the cameras' interference emissions or reduce their interference resistance.

The camera may not be used in the immediate vicinity of other devices. If this cannot be avoided, the affected lights must be observed in order to make sure they are functioning reliably in this environment.

All necessary EMC measures must be conducted and observed during installation.

1.7 Incoming inspections

Inspect your delivery for completeness and integrity, immediately after receipt. Any transportation damages must be notified immediately.

1.8 Duties of the operator

Responsibility to instruct

The operator must inform himself of all applicable accident prevention and hygiene regulations and must additionally conduct a risk assessment in order to identify the risks posed by the particular work conditions at the site where the unit will operate. The regulations must be implemented in the form of instructions for operation of the unit.

During the entire time that the unit is in use, the operator must check whether the operating instructions that he prepared comply with current technical regulations. If necessary, they must be revised.

The operator must clearly establish and manage responsibilities in the areas of installation, operation, troubleshooting, maintenance, and cleaning.

The operator must ensure that all employees who handle the unit have read and understood these Instructions for Use. Furthermore, he must train personnel at regular intervals and inform them of all dangers. He must also place safeguards so that unauthorized persons do not use the unit.

The operator must ensure that all maintenance intervals and technical safety controls described in these Instructions for Use are adhered to.

The operator must ensure that only approved accessories and accessories released by the manufacturer are used together with the unit.

Technical safety controls

The operator must allow technical safety controls to be conducted biennial.

Technical safety controls may only be conducted by the manufacturer's personnel, or by authorized specialists who have received written approval from the manufacturer.

The protocol prepared by the authorized specialist, detailing the measurement procedures, measurement results, and other evaluations, must be kept until the next control.

No liability in the event of non-observance of time limits!

The manufacturer assumes no liability for personal or material damages if technical safety controls are not contracted and conducted within the time limits provided.

Notification of accidents and damages

All serious incidents which occur in connection with the product must be reported to SIMEON Medical and the competent authority of the country in which the incident took place.

Malfunctions or unit defects that lead to bodily injury must be immediately notified to the authorities in charge and to the manufacturer.

The authorities in charge may request that the operator submit the incident being notified to a technical safety evaluation by an authorized expert, at its own expense, and that the evaluation be submitted in writing to such authorities. The authorized expert will be selected in consultation with the authorities in charge.

The technical safety evaluation will include determinations on

- whereupon fault for the incident lies,
- whether the unit was in proper condition,
- whether any further danger exists following rectification of defects,
- whether new knowledge has been gained, calling for different or new precautionary measures.

1.9 Dismantling and disposal

The unit must be dismantled and undergo environmentally-sensible disposal.

Dismantling should only be conducted by trained, skilled personnel.

DANGER	**Risk of death due to improper dismantling!** Errors during dismantling may result in life-threatening situations and cause significant material damages. ☞ Dismantling should only be conducted by trained, skilled personnel. ☞ The manufacturer must also be involved when conducting unit relocations at a later time. ☞ Dismantling and relocations may not be conducted by independent parties.

1.10 Authorized representatives and importers

MedEnvoy Switzerland
Gotthardstraße 28
6302 Zug
Switzerland

2 Operation

	**Read all instructions first before operating!**
	**Operating is to be performed by properly trained and authorized personnel only!**
	**Do not drink any alcohol or take any drugs before or during the operating and follow the safety instructions carefully.**
	**Prevent direct glare! Users, patients and third parties should avoid looking into the surgical light for long periods of time**

2.1 Installation and initial start-up

The installation and initial start-up should be exclusively conducted by the manufacturer's personnel or by persons authorized by the manufacturer.

⚠ DANGER	**Risk of death due to faulty installation or faulty initial start-up!** Errors during the installation or initial start-up may result in life-threatening situations and cause considerable material damages. Thus, please note: ☞ The installation and initial start-up may only be conducted by the manufacturer's personnel or by persons authorized by the manufacturer. ☞ The manufacturer must also be involved when conducting unit relocations at a later time. ☞ Installation and relocations by independent parties are not allowed.

	**Risk of injury due to pinching!** When moving the extension arm, objects and fingers placed on it may be pinched! When moving the arm system, please make sure to place your grip on the equipment attached to the arm systems, and that the entire range of rotation is unobstructed!

2.2 Visual inspection of the camera

Before switching on the camera, ensure that it is undamaged and correctly plugged in.

There is no danger when an intact camera is used as intended, ↳ *"Intended use", page 11*.

Damages to the camera, current supply or mounting could cause significant risks, however:

⚠WARNING	**Risk of infection due to improper hygiene, disinfection, or sterilization!** There is a risk of infection upon contacts with parts that have not been cleaned, sterilized or disinfected. ☞ Clean and disinfect the unit before every use. ☞ Observe the instructions on sterilization. ☞ Adhere to all standards on hygiene, disinfection and sterilization that are locally in effect.

⚠WARNING	**Risk of injury due to contamination of wounds!** Damage to the camera or to the sterilizable handle can cause loose or porous parts to fall into wounds and contaminate them. ☞ Conduct a visual and functional inspection before each use of the lighting unit. ☞ Do not operate a damaged unit. ☞ Inspect the sterilizable handles for safe positioning before each use of the lighting equipment.

2.3 Camera Sim.CAM HD

2.3.1 Installing the camera

The camera can be attached to the lamp body in place of the handle unit.

Removing the handle unit

☞ Disconnect the power supply.

☞ Loosen the two knurled screws by turning them in a counterclockwise direction.

☞ Remove the handle unit.

Inserting the camera unit

☞ Plug the D-Sub connector found on the rear of the camera unit into the socket on the lamp body. In doing so, press in the entire unit firmly and uniformly.

☞ Tighten the camera unit with the knurled screws. To do so, turn the knurled screws in a clockwise direction.

☞ Slide the sterilizable camera handle (Item code 141-0017066) onto the camera unit and turn until the safety snaps audibly into position.

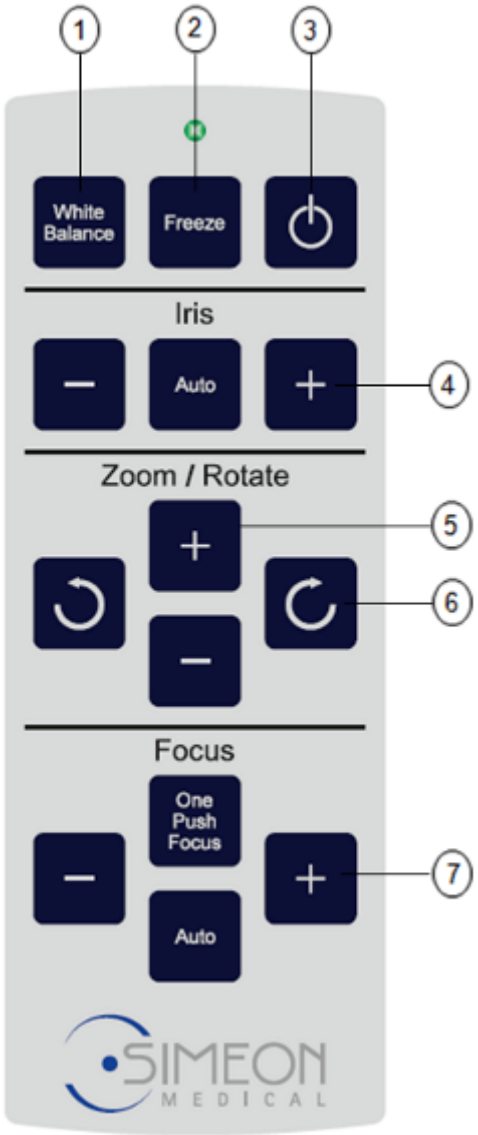
⇨ The camera unit is ready to use.

☞ Switch on the power supply once again.

2.3.2 Infrared remote control for Sim.CAM HD

The IR remote control has a membrane keypad with all control functions, and requires visual contact to the receiver, which is attached to the monitor bracket.

IR remote control operation and display elements



1 White Balance
2 Still Frame (Freeze)
3 Power on/off
4 Iris (brightness - Minus/Auto/Plus)
5 Zoom
6 Rotation (image positioning, motorized)
7 Focus (Minus/One Push/Auto/Plus)

Using the IR remote control

- ☞ Always point the IR remote control toward the receiver.
- ☞ Press the desired button.
- ☞ The function will be performed, and feedback will be displayed on the monitor.

2.3.3 Wall controls for Sim.CAM HD

Information about the wall controls for Sim.CAM HD Wireless can be found in chapter 2.5.2 Wall controls for Sim.CAM HD, Sim.CAM HD Wireless and Sim.CAM 4K Wireless, page 38.

2.3.4 Turning the camera on/off

Turning the camera on

Press the Camera on/off key on the remote control.

⇨ The camera will now begin transmitting the image signal to the receiver.

Turning the camera off

☞ Press the **Camera on/off key** on the remote control again.

⇨ The camera will now stop transmitting the image signal to the receiver.

2.3.5 Performing a white balance

NOTICE	Because of the manufacturer's pre-settings, a white balance should not be performed if it is not necessary. In order to adapt the camera's color control to the lighting conditions in the respective operating room, a white balance can be performed if needed.

☞ Position the unit in accordance with the intended working conditions.

☞ Turn on the camera.

☞ Hold a white sheet of paper at a distance of approx. 50 cm from the camera lens.

⇨ The monitor displays a fully white screen.

☞ Switch on the OR-light (max. intensity, largest light field, color temperature for MC light heads: 4500K) and focus on the white paper

☞ Press the **White balance** button on the camera control panel for approx. 3 seconds.

⇨ The white balance is performed automatically.

⇨ The process is completed after 5 seconds.

2.3.6 Image rotation

Electric rotation (non-sterile): Image positioning / reflection can be used to turn the camera inside the camera module in a clockwise or counterclockwise direction.

Sim.CAM HD 30x

The range of rotation is > 360°.

☞ Press and hold the rotation keys until the desired image position is achieved.

⇨ Rotation will continue as long as the key is pressed.

Sim.CAM HD 10x

Electric image rotation allows the camera image to be rotated 180° rapidly (=image reflection).

☞ Pressing the rotation buttons once rotates the image 180°

Pressing the Rotate key again will return the image to its original state.

Manual rotation (sterile): Alternatively, the entire camera module can be rotation (without end stop)

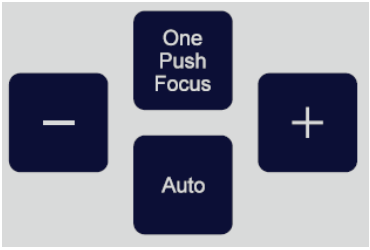
☞ Turn the camera handle to the right or left until the desired image position has been reached.

2.3.7 Zooming

The Zoom keys can be used to make the video image larger (+) or smaller (–). Depending on the camera type, the camera module allows enlargement of 1 to 10 (10x optical zoom) or 1 to 30 (30x optical zoom).

☞ Press and hold the zoom key (+) or (–) until the desired position has been reached.

2.3.8 Focusing



The Sim.CAM HD supports automatic focusing.

There is an option to deactivate the automatic function and to perform focusing manually.

Manual focusing

☞ Turn off the auto focus by pressing the **Auto** button.

☞ Press the **–** or **+** keys repeatedly until the camera image achieves the desired sharpness.

Focusing on a plane

☞ Press the **One Push Focus** button.

⇨ The camera's auto focus will be turned off

⇨ The camera focuses on the current plane

⇨ No new focusing occurs if e.g. the hands of the operator appear in the camera range.

2.3.9 Setting the brightness (Iris)

Automatic brightness adjustment

⇨ The image brightness is set automatically.

⇨ As soon as the camera is moved, the image brightness automatically resets.

Manual brightness adjustment

☞ Push the **+** key repeatedly in order to increase the brightness.

☞ Push the **–** key repeatedly in order to reduce the brightness.

2.3.10 Still frame (Freeze)

☞ Press the **Freeze** button.

⇨ A still image will be generated.

☞ In order to switch from still-frame mode back into normal mode, press the **Freeze** button once again.

2.4 Sim.CAM HD Wireless and Sim.CAM 4K Wireless

2.4.1 Pairing the camera and receiver

NOTICE	The camera and receiver are paired at the time of first installation. If the camera is to be used (for example) with another receiver in a different operating room, the pairing process must be completed first so that the image will appear on the screen. Pairing the camera and the receiver ensures that the transmission remains secure, as does the system's 60 GHz transmission technology, since the operating room walls completely absorb the radio signal.

- ☞ Switch on the monitor that the receiver is installed on and connected to.
- ☞ Attach the camera to the receiver and hold it in place.
- ☞ Press the red button on the receiver for two seconds.
  - ⇨ When the yellow LED starts blinking, the pairing process has begun, the pairing process takes approx. 2 minutes in total. The first part of the pairing process is the blinking of the yellow LED which takes approx. 30 seconds
  - ⇨ When the yellow LED starts "triple-blinking" the pairing process between receiver and camera has started. This takes between 30 to 45 seconds.
  - ⇨ Once the pairing process has finished, the receiver shows a stable blue LED light and the camera image will be shown on the monitor.
  - ⇨ The camera is now ready to use, and can be attached to the light head.
  - ⇨ After installing the camera into the light head it takes approx. 30 seconds until the booting process is finished. The receiver shows a stable blue light again and the camera image is displayed at the monitor.

2.4.2 Installing the camera

The camera can be attached to the lamp body in place of the handle unit.

Removing the handle unit

☞ Disconnect the power supply.

☞ Loosen the two knurled screws by turning them in a counterclockwise direction.

☞ Remove the handle unit.

Inserting the camera unit

☞ Plug the D-Sub connector found on the rear of the camera unit into the socket on the lamp body. In doing so, press in the entire unit firmly and uniformly.

☞ Tighten the camera unit with the knurled screws. To do so, turn the knurled screws in a clockwise direction.

☞ Slide the sterilizable camera handle (Item code 141-0017066) onto the camera unit and turn until the safety snaps audibly into position.

⇨ The camera unit is ready to use.

☞ Switch on the power supply once again.

2.4.3 Infrared remote control for Sim.CAM HD Wireless and Sim.CAM 4K Wireless

Information about the infrared remote control of the Sim.CAM HD Wireless can be found in chapter 2.5.1 Infrared remote control for Sim.CAM HD Wireless and Sim.CAM 4K Wireless, page 36.

2.4.4 Wall controls for Sim.CAM HD Wireless and Sim.CAM 4K Wireless

Information about the wall controls for Sim.CAM HD Wireless can be found in chapter 2.5.2 Wall controls for Sim.CAM HD, Sim.CAM HD Wireless and Sim.CAM 4K Wireless, page 38.

2.4.5 Turning the camera on/off

Turning the camera on

Press the Camera on/off key on the remote control.

⇨ The camera will now begin transmitting the image signal to the receiver.

Turning the camera off

☞ Press the **Camera on/off key** on the remote control again.

⇨ The camera will now stop transmitting the image signal to the receiver.

2.4.6 Performing a white balance

NOTICE	Because of the manufacturer's pre-settings, a white balance should not be performed if it is not necessary. In order to adapt the camera's color control to the lighting conditions in the respective operating room, a white balance can be performed if needed.

- ☞ Position the unit in accordance with the intended working conditions.
- ☞ Turn on the camera.
- ☞ Hold a white sheet of paper at a distance of approx. 50 cm from the camera lens.
  - ⇨ The monitor displays a fully white screen.
- ☞ Switch on the OR-light (max. intensity, largest light field, color temperature for MC light heads: 4500K) and focus on the white paper
- ☞ Press the **White balance** button on the camera control panel for approx. 3 seconds.
  - ⇨ The white balance is performed automatically.
  - ⇨ The process is completed after 5 seconds.

2.4.7 Image rotation

Electric rotation (non-sterile): Image positioning / reflection can be used to turn the camera inside the camera module in a clockwise or counterclockwise direction.

Sim.CAM HD Wireless 30x/4K Wireless

The range of rotation is > 360°.

☞ Press and hold the rotation keys until the desired image position is achieved.

⇨ Rotation will continue as long as the key is pressed.

Sim.CAM HD Wireless 10x

Electric image rotation allows the camera image to be rotated 180° rapidly (=image reflection).

☞ Pressing the rotation buttons once rotates the image 180°

Pressing the Rotate key again will return the image to its original state.

Manual rotation (sterile): Alternatively, the entire camera module can be rotation (without end stop)

☞ Turn the camera handle to the right or left until the desired image position has been reached.

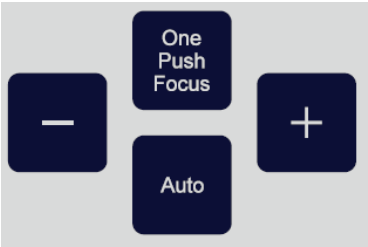
NOTICE	The transmitter is inside the camera housing. If the user's hand comes into direct contact with the sterile sleeve during manual rotation, and the transmitter is covered as a result, it can cause image transmission to be interrupted. If this happens, the last image will be frozen on the monitor. As soon as the radio transmission has been re-established, the current image will be displayed again.

2.4.8 Zooming

The Zoom keys can be used to make the video image larger (+) or smaller (–).The camera module allows enlargement of 1 to 30 (30x optical zoom).

☞ Press and hold the zoom key (+) or (–) until the desired position has been reached.

2.4.9 Focusing



The Sim.CAM HD Wireless supports automatic focusing.

There is an option to deactivate the automatic function and to perform focusing manually.

Manual focusing

☞ Turn off the auto focus by pressing the **Auto** button.

☞ Press the **–** or **+** keys repeatedly until the camera image achieves the desired sharpness.

Focusing on a plane

☞ Press the **One Push Focus** button.

⇨ The camera's auto focus will be turned off

⇨ The camera focuses on the current plane

⇨ No new focusing occurs if e.g. the hands of the operator appear in the camera range.

2.4.10 Setting the brightness (Iris)

Automatic brightness adjustment

⇨ The image brightness is set automatically.

⇨ As soon as the camera is moved, the image brightness automatically resets.

Manual brightness adjustment

☞ Push the **+** key repeatedly in order to increase the brightness.

☞ Push the **–** key repeatedly in order to reduce the brightness.

2.4.11 Still frame (Freeze)

☞ Press the **Freeze** button.

⇨ A still image will be generated.

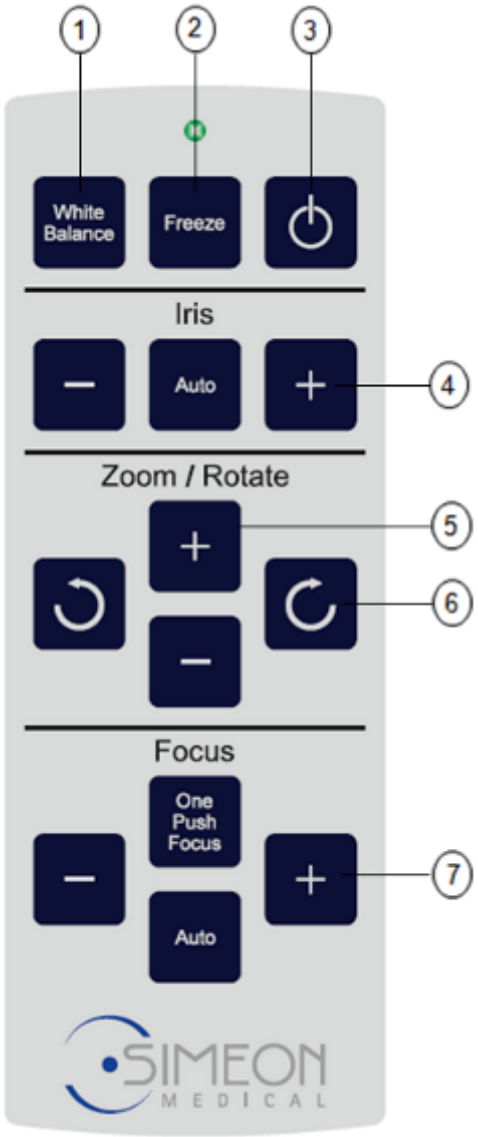
☞ In order to switch from still-frame mode back into normal mode, press the **Freeze** button once again.

2.5 System components

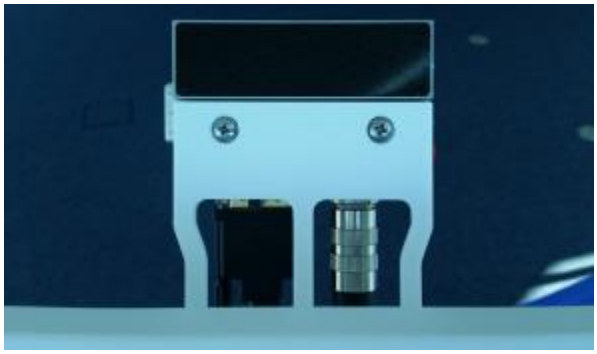
2.5.1 Infrared remote control for Sim.CAM HD Wireless and Sim.CAM 4K Wireless

The IR remote control has a membrane keypad with all control functions, and requires visual contact to the receiver, which is attached to the monitor bracket.

IR remote control operation and display elements



1 White Balance
2 Still Frame (Freeze)
3 Power on/off
4 Iris (brightness - Minus/Auto/Plus)
5 Zoom
6 Rotation (image positioning, motorized)
7 Focus (Minus/One Push/Auto/Plus)



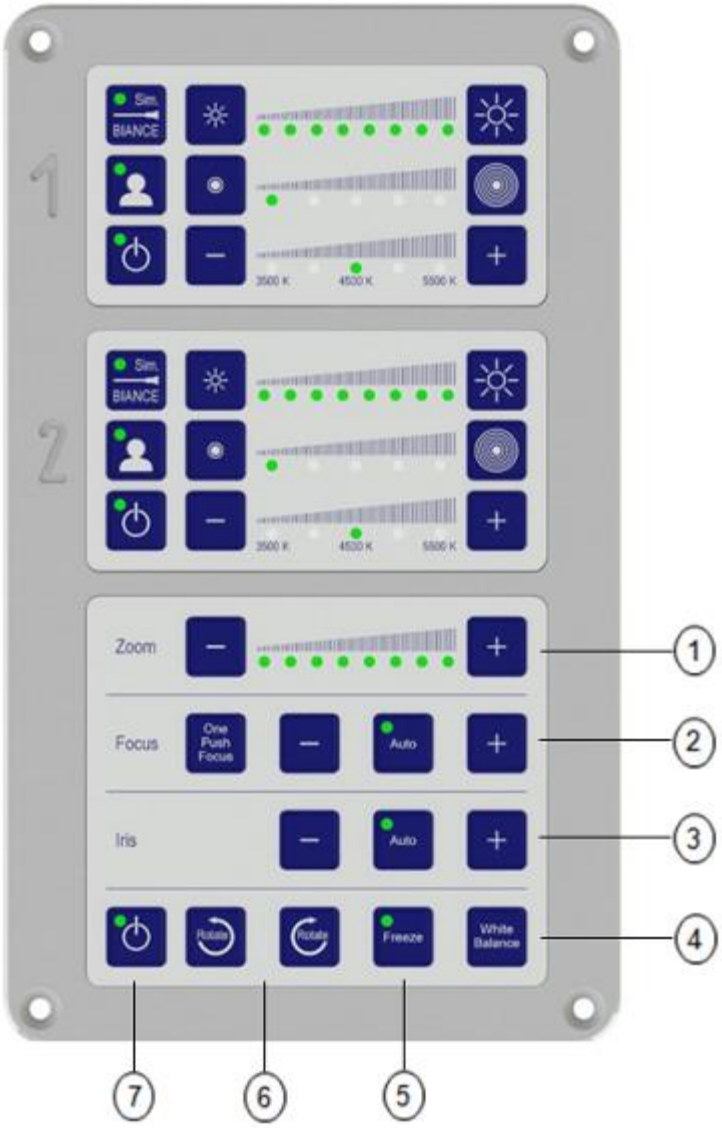
Using the IR remote control

- ☞ Always point the IR remote control toward the receiver (mounted onto the monitor bracket).
- ☞ Press the desired button.
- ☞ The function will be performed, and feedback will be displayed on the monitor.

2.5.2 Wall controls for Sim.CAM HD, Sim.CAM HD Wireless and Sim.CAM 4K Wireless

The cameras Sim.CAM HD, Sim.CAM HD Wireless and Sim.CAM 4K Wireless can also be operated using optional wall controls.

Wall control operation and display elements



1 Zoom
2 Focus (Minus/One Push/Auto/Plus)
3 Iris (Brightness – Minus/Auto/Plus)
4 White Balance
5 Still Frame (Freeze)
6 Rotation (image positioning, motorized)
7 Power on/off

3 Maintenance

	**Read all instructions first before maintenance!**
	**Maintenance is to be performed by properly trained and authorized personnel only!**
	**Do not drink any alcohol or take any drugs before or during the maintenance and follow the safety instructions carefully.**
DANGER	**Risk of death due to incorrect maintenance!** Errors during maintenance may result in life-threatening situations and cause significant material damages. Thus, please note: ☞ Maintenance may only be conducted by employees of the manufacturer or by persons authorized by the manufacturer.

3.1 Maintenance plan

The following sections describe the work that is required for the optimal and fault-free operation of the unit.

If increased wear is observed during regular inspections, shorten the required maintenance intervals in accordance with the actual signs of wear and tear. Contact the manufacturer if you have questions regarding maintenance work and intervals, contact information is found on page 2.

Interval	Maintenance work	Personal
After every operation	Exchange the sterilizable handle for a clean and steam-sterilized grip	Medical qualified personnel
	Clean and disinfect the unit ↳ *„Cleaning the* unit*“, page 41* ↳ „Disinfecting the unit: Wiping disinfection*“, page 42*	Medical qualified personnel
	Inspect the unit for exterior damages	Medical qualified personnel
	Test the unit for faultless function	Medical qualified personnel
	Inspect the sterilizable handle for wear and damages	Medical qualified personnel

4 Preparation

4.1 Cleaning the unit

NOTICE	**Material damages due to the use of improper cleaning agents!** Abrasive, corrosive, or paint-thinning cleaning agents may damage the surface of the unit. ☞ Do not use any abrasive, corrosive or paint-thinning cleaning agents. ☞ Do not use cleaning agents containing benzine or aldehyde. ☞ Always apply the cleaning agent in such a manner that no liquid is able to penetrate the unit. ☞ Only clean accessible parts using neutral, tenside-based cleaning agents (manual dishwashing liquid, neutral cleansers).
	**Risk of death due to electric shock!** There is an immediate risk of death due to electric shock when coming into contact with live parts. ☞ Switch off the power supply to the unit from the main switch in the operating room before cleaning, disinfecting or sterilizing. With mobile variants, also pull the power plug from the power outlet. ☞ Safeguard the main switch or power plug from unintended switching-on/plugging-in. ☞ Always protect the unit from splash water and never wet clean or wet disinfect it. ☞ Always ensure that no liquid or moisture is able to penetrate into the unit through openings.

☞ Disconnect the power supply.

☞ Wipe the unit using a moist – not wet – cloth.

4.2 Disinfecting the unit: Wiping disinfection

⚠WARNING	**Health risk due to disinfectant!** Disinfectants may contain agents hazardous to health. ☞ Always select and use disinfectants that comply with local hygienic and operating regulations. ☞ You can find recommendations and information on selecting and using disinfectants in the most current standards and guidelines on disinfection and explosion protection.
NOTICE	**Risk of material damages due to spray disinfectants!** Spray mist may cause short-circuits in the electrical installations and corrosion of the mechanical components. ☞ Do not use spray disinfectants. ☞ All components, including accessories and connecting cables, may only be disinfected by wiping using a surface disinfectant. ☞ You can find recommendations and information on selecting and using disinfectants in the most current standards and guidelines on disinfection and explosion protection.
NOTICE	**Risk of material damages when using unsuitable disinfectants!** Chloride-, peroxide- and halide-containing disinfectants may corrode the unit's surfaces or plastic parts. ☞ Do not use any chloride-, peroxide- or halide-containing disinfectants. ☞ Apply the disinfectant in such a manner that no moisture or liquid is able to penetrate the unit. ☞ You can find recommendations and information on selecting and using disinfectants in the most current standards and guidelines on disinfection and explosion protection.

☞ Disconnect the power supply

☞ All of the unit's components, including connecting cables, must undergo wiping disinfection.

4.3 Preparing the sterilizable handle

Products: 141-0017066 SteC Sim.CAM HD

WARNINGS	Only allow suitably trained medical personnel to conduct work.
Limitations in preparation	The sterilizable handles can undergo approx. 100 steam sterilization cycles if properly steam sterilized.

Pretreatment at the site of Use:	Remove heavy dirt with a disposable cloth/paper towel with low particulate release.
Storage and transport:	No special requirements. It is recommended to prepare the handles as soon as possible after use.
Preparation prior to cleaning	No special requirements. No disassembly necessary.
Automated cleaning	**Furnishings** Cleaner/disinfector: Miele PG8535 with standard furnishings with floor grilles, mesh basket and bottle rack *(It is recommended to use a cleaner/disinfector in accordance with ISO 15883.)* **Cleaning products** neodisher® MediClean Dr. Weigert # 510643/1114 **Cleaning instructions** For automatic cleaning, place the product into the cleaner/disinfector upright with the opening facing downwards. The automatic cleaning process is conducted with the following steps (based on the DES-VAR-TD program from Miele): • Rinsing 1 min (cold water) • Cleaning at 55°C (± 2 °C) for 5 min with neodisher® MediClean (0.3 % v/v) cleaning product • Neutralization with 1/3 cold water and 2/3 warm water for 1 min • Rinsing with 1/3 cold water and 2/3 warm water for 1 min • Thermal disinfection with A0-value > 3.000 • Drying: Do not exceed a temperature of 120°C
Manual cleaning: *(if automated cleaning is not possible)*	**Furnishings** Ultrasound bath: Bandelin RK510H **Cleaning products and material** Toothbrush (medium) Dr. Best neodisher® MediClean Dr. Weigert; # 534621/1115 **Cleaning instructions** Completely submerge the products in the ultrasound bath (filled with 0.5 % (v/v) neodisher® MediClean in demineralized water). Ultrasound treatment at 35 kHz for 10 min.

	Do not exceed the maximum temperature of 40 °C in the process! After the ultrasound treatment, remove any visible residue with the cleaning product and the toothbrush. Then rinse the product for 1 min in demineralized water (temperature 20°C - 25°C)
Manual disinfection:	The disinfectant solution should be used in accordance with the instructions on the label! **Manual disinfection** Sekusept® active Ecolab; # 4254FM6908, 4305FM5509 **Disinfection instructions** Completely submerge the product in the disinfectant solution Sekusept® active 3 % (w/v) (prepare the solution according to the manufacturer's instructions). Temperature: 20 °C ± 2 °C Time: 15 min Avoid air bubbles on the surface during the immersion bath! Then rinse the product completely for at least 3 min. in cold demineralized water.
Maintenance, inspection and testing:	Visually inspect all handles for damage, discoloration and wear.
Packaging:	A standardized, sterilizable system can be used. The bag must be large enough for the handle, so that the seal is not under tension.
Sterilization:	It is recommended to use damp heat (steam) for sterilization! **Furnishings** Steam autoclave: Systec HX-320 *(It is recommended to use a sterilizer in accordance with EN 285.)* Sterilization packaging: Brömeda, REF 68170912 **Sterilization instructions** Individually package the products Temperature of saturated steam: 134°C 3x fractionated pre-vacuum Sterilization time: 4 min Resulting half-cycle exposure time: 2 min Drying time: 10 min Improper steam sterilization may damage the sterilizable handles and make their surfaces porous and prone to cracks. Do not exceed the maximum temperature of 134 °C.
Storage:	No special requirements.
Additional information:	When sterilizing reusable handles in an autoclave cycle, it must be ensured that the maximum load for the sterilizer is not exceeded.

Contact to manufacturer:	**S.I.M.E.O.N. Medical GmbH & Co. KG** In Grubenäcker 18 78532 Tuttlingen GERMANY Telephone: +49 (0) 7461 90068-888 E-mail: service@simeonmedical.com

The instructions above were validated by S.I.M.E.O.N. Medical GmbH & Co. KG as being suitable for the preparation of a medical device for use in accordance with ISO 17664. The preparer assumes the responsibility for making sure that the preparation conducted achieves the desired results with the equipment, materials and personnel used in the preparation facility. This requires the validation and routine monitoring of the procedure.

5 Technical data

5.1 Technical data Sim.CAM HD

Sim.CAM HD	Sim.CAM HD 30x	Sim.CAM HD 10x
General information		
Expected operating life	15,000 h	15,000 h
Sensor	1/2.8" Exmor CMOS Sensor IMX-136	1/3' CMOS Sensor
Video signal	Full HD 1080i 50/60 Hz	Full HD 1080i 50/60 Hz
Resolution	1920 x 1080	1920 x 1080
Pixels	2,140,000 pixels	2,140,000 pixels
Aspect ratio	16:9	16:9
Minimum illumination	1,4 lx	0.4 lx
Recommended illumination	100 lx – 100,000 lx	100 lx – 100,000 lx
Signal to noise ratio S/N	> 50 dB	> 50 dB
Diaphragm	1/1 s - 1/10000 s (22 steps)	1/1 s - 1/10000 s (22 steps)
Focus distance	4.3 mm - 129 mm	3.3 mm - 33.0 mm
Zoom	30x optical zoom 12x digital zoom	10x optical zoom 16x digital zoom
Focus	Auto or manual	Auto or manual
Aperture	Auto or manual	Auto or manual
Minimum working distance	10 mm (wide), 1200 mm (tele)	10 mm (wide), 800 mm (tele)
Power supply	24 VDC ± 20 %	24 VDC ± 20 %
Power consumption	<8W	<8W
Image rotation	Electrical (stepless) and mechanical	Electrical (2 steps) and mechanical
Certificate	CE	CE
Protection class	I	I
Weight camera	1.4 kg	1.4 kg
Operating conditions		
Temperature range	5 – 40 °C / 41 – 104 °F	5 – 40 / 41 – 104 °F
Relative air humidity, maximum [%]	95 %	95 %
Air pressure [hPa]	700 – 1,060 hPa	700 – 1,060 hPa
Usage	Indoor Use	Indoor Use

Sim.CAM HD	Sim.CAM HD 30x	Sim.CAM HD 10x
Pollution Degree	2	2
Overvoltage Category	II	II

Technical specifications are subject to change: Tolerance ±10%

5.2 Technical data Sim.CAM HD Wireless

Sim.CAM HD	Sim.CAM HD Wireless 30x	Sim.CAM HD Wireless 10x
General information		
Expected operating life	15,000 h	15,000 h
Sensor	1/2.8" Exmor CMOS Sensor IMX-136	1/3' CMOS Sensor
Radio frequency	60 GHz	60 GHz
Video signal	Full HD 1080i 50/60 Hz	Full HD 1080i 50/60 Hz
Resolution	1920 x 1080	1920 x 1080
Pixels	2,140,000 pixels	2,140,000 pixels
Aspect ratio	16:9	16:9
Minimum illumination	1,4 lx	0.4 lx
Recommended illumination	100 lx – 100,000 lx	100 lx – 100,000 lx
Signal to noise ratio S/N	> 50 dB	> 50 dB
Diaphragm	1/1 s - 1/10000 s (22 steps)	1/1 s - 1/10000 s (22 steps)
Focus distance	4.3 mm - 129 mm	3.3 mm - 33.0 mm
Zoom	30x optical zoom 12x digital zoom	10x optical zoom 16x digital zoom
Focus	Auto or manual	Auto or manual
Aperture	Auto or manual	Auto or manual
Minimum working distance	10 mm (wide), 1200 mm (tele)	10 mm (wide) 800 mm (tele)
Power supply	24 VDC ± 20 %	24 VDC ± 20 %
Power consumption	9 W	<9 W
Image rotation	Electrical (stepless) and mechanical	Electrical (2 steps) and mechanical
Certificate	CE	CE
Protection class	I	I
Weight camera	1.4 kg	1.4kg

Sim.CAM HD	Sim.CAM HD Wireless 30x		Sim.CAM HD Wireless 10x	
Operating conditions				
Temperature range	5 – 40 °C	41 – 104 °F	5 – 40	41 – 104 °F
Relative air humidity, maximum	95 %		95 %	
Air pressure	700 – 1,060 hPa		700 – 1,060 hPa	
Usage	Indoor Use		Indoor Use	
Pollution Degree	2		2	
Overvoltage Category	II		II	

Technical specifications are subject to change: Tolerance ±10%

5.3 Technical data Sim.CAM 4K Wireless

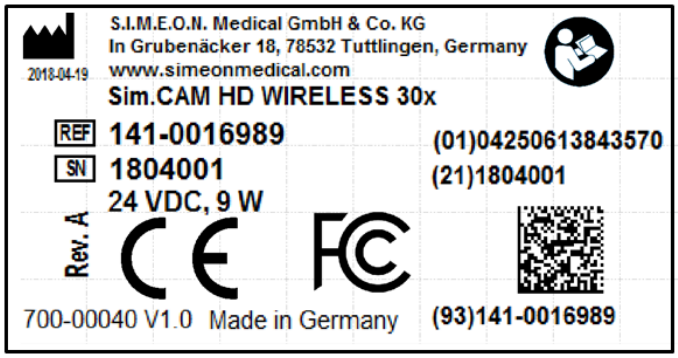
Sim.CAM 4K Wireless	Description	Values
General information		
	Expected operating life	15,000 h
	Sensor	1/2.5 Type “Exmor R” CMOS Sensor
	Radio frequency	60.16275 – 60.79725 GHz (Data/Control) 62.32275 – 62.95725 GHz (Data/Control) 60.48 – 62.64 GHz (Video)
	Video signal	4K 2160p 25/30 Hz
	Resolution	3840 x 2160
	Pixels	8,510,000 pixels
	Aspect ratio	16:9
	Minimum illumination	1.4 lx
	Recommended illumination	100 lx – 100,000 lx
	Signal to noise ratio S/N	> 50 dB
	Diaphragm	1/1 s - 1/10000 s (22 steps)
	Focus distance	4.3 mm - 129 mm
	Zoom	20x optical zoom 12x digital zoom
	Focus	Auto or manual
	Aperture	Auto or manual
	Minimum working distance	80 mm (wide), 800 mm (tele)
	Power supply	24 VDC ± 20 %

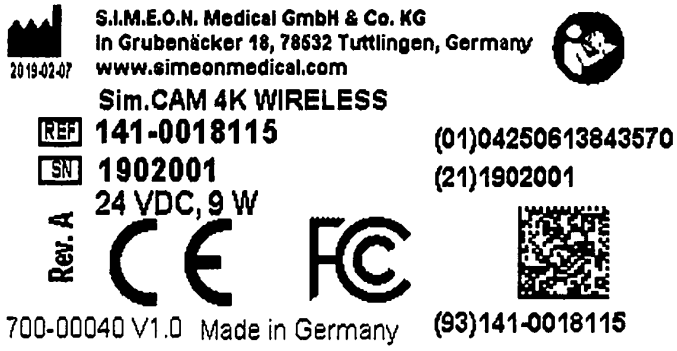
Sim.CAM 4K Wireless	Description	Values	
	Power consumption	9 W	
	Image rotation	Electrical and mechanical	
	Certificate	CE	
	Protection class	I	
	Weight camera	1.4 kg	
Operating conditions			
	Temperature range	5 – 40 °C	41 – 104 °F
	Relative air humidity, maximum	95%	
	Air pressure	700 – 1,060 hPa	
	Usage	Indoor Use	
	Pollution Degree	2	
	Overvoltage Category	II	

Technical specifications are subject to change: Tolerance ±10%

5.4 Type plate

The type plate can be found on the camera:





It includes the following information:

Manufacturer address, article number (REF), product name, serial number (SN), electrical power data, manufacturing month and year