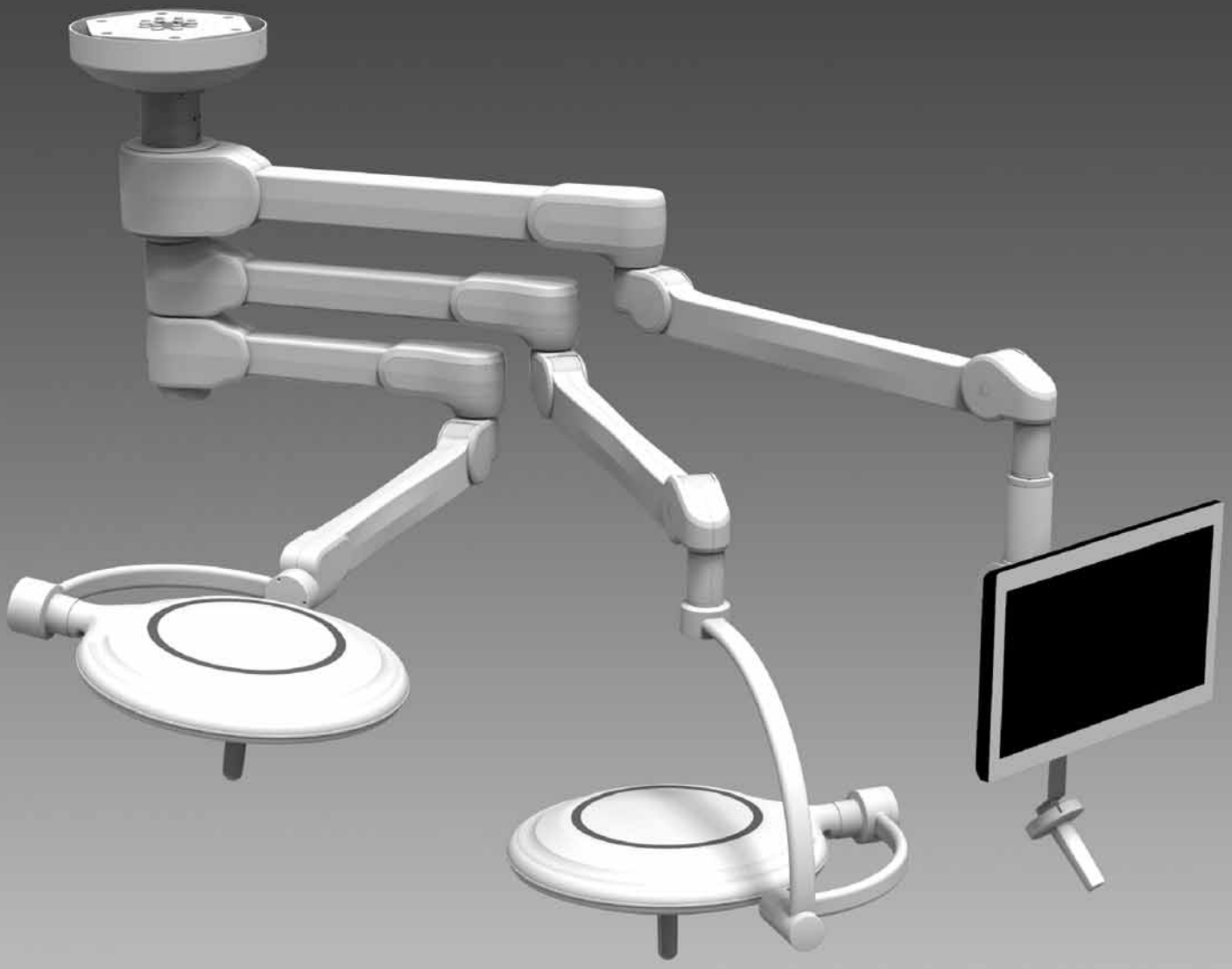


Operation Manual [English]

Claro™ Lights

ZIMMER BIOMET

Thank you very much for purchasing this ZIMMER BIOMET product. Please read this Operation Manual very carefully, abide by the safety notices and observe all operating and cleaning requirements.

For which appliances does this manual apply?

Claro™ Lights

Please do not hesitate to contact our Customer Service team

if you have any questions about the appliance and its installation, and also in service or warranty cases.

Distributor

Zimmer Surgicial, Inc.
200 West Ohio Avenue
Dover, Ohio 44622 USA
(800) 830-0970
www.ZimmerBiomet.com

Manufacturer

Ondal Medical Systems of America, Inc.
540 Eastpark Court, Suite A
Sandston, VA 23150 • USA

Ondal Medical Systems GmbH
Wellastraße 6
36088 Hünfeld
Germany

Notes on copyright and property rights

Copyright

- All rights reserved. This Operation Manual is protected by copyright law.
- Any other use than that regulated by law must be approved in writing by ZIMMER BIOMET.
- ZIMMER BIOMET does not take any liability for or in relation to the misuse of this information in the prohibited manner by any person or company.

Modifications and translations

Modifications to the appliance

- ZIMMER BIOMET products are subject to continuous further development. ZIMMER BIOMET reserves the right to modify the form, equipment and technology of the scope of supply without prior notice.

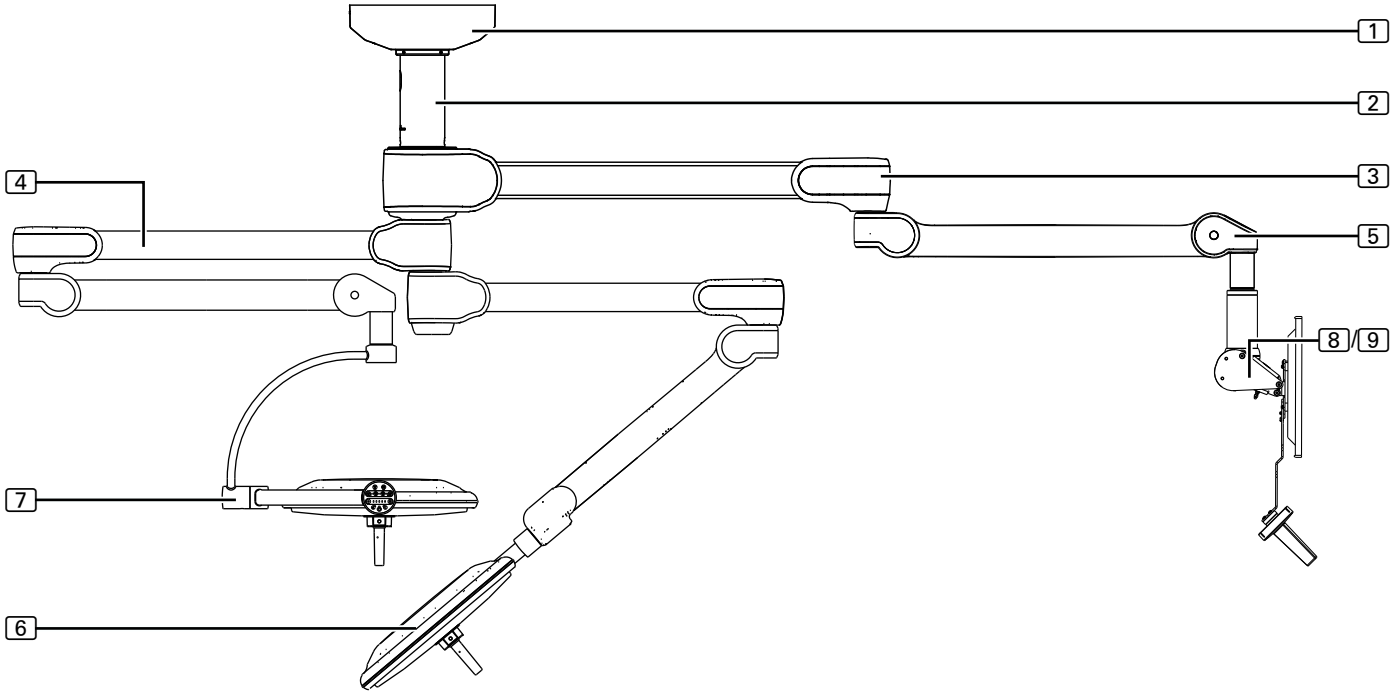
Modifications to the Operation Manual

- The content of this Operation Manual is subject to change without prior notice.

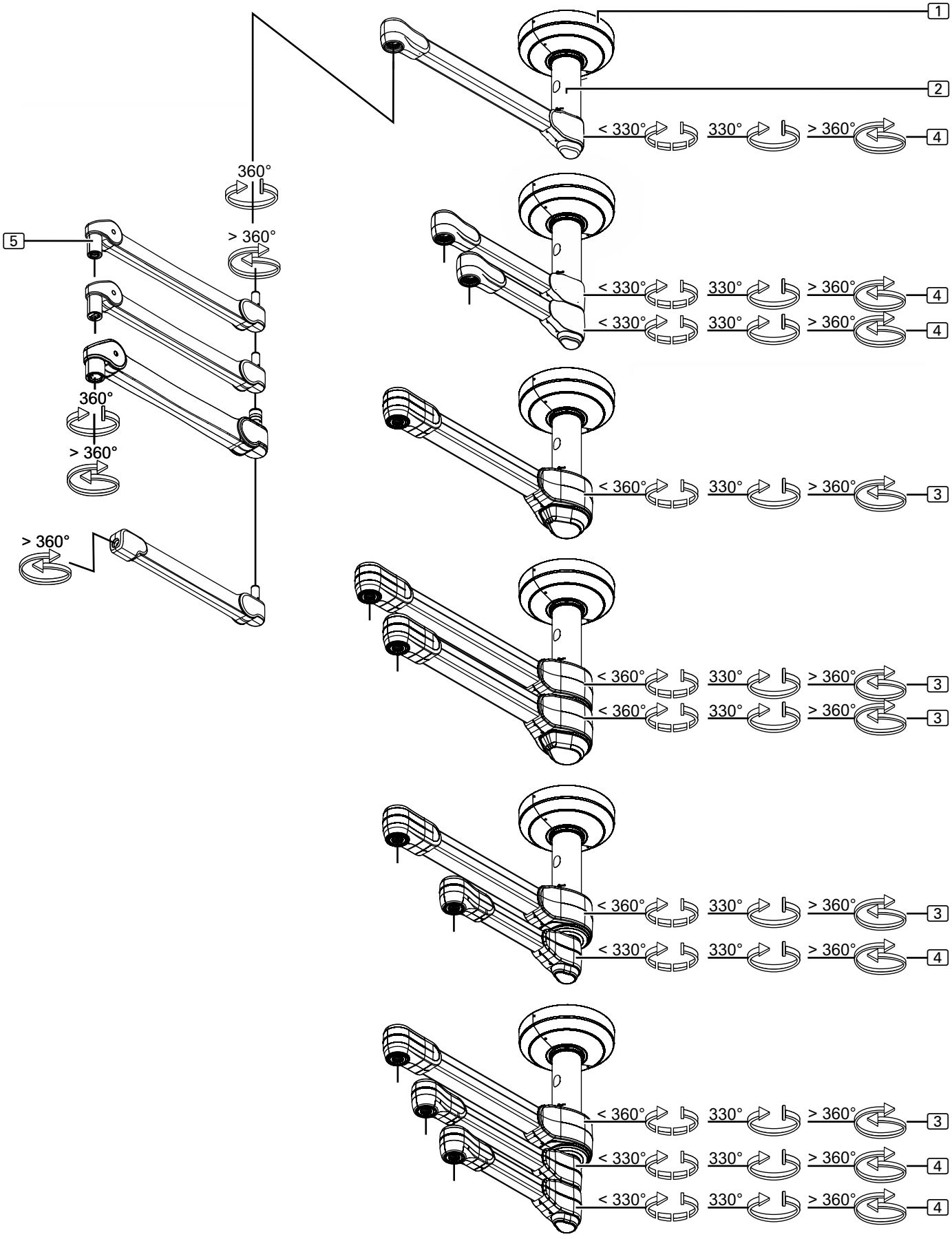
Trademarks

- All trademarks mentioned in this Operation Manual are the sole and exclusive property of the corresponding manufacturer.

Claro™ Lights



Versions of the pendant system



Device description

Canopy

Since the points for connecting the electrical cables of the pendant system are located under the canopy [1], the canopy [1] may only be removed by specialist personnel authorized by the operator.

Ceiling tube

The ceiling tube [2] compensates for different ceiling heights in order to ensure that the end device (e.g. flat screen, OR light, etc.) is positioned at the desired working height.

Extension arm

Depending on the version, the central axes are equipped with 1 to 3 extension arms [3]/[4] in different lengths.

Swivel ranges of the extension arms

Depending on the end device (e.g. flat screen, OR light, etc.) mounted, the extension arm [3]/[4] is configured for different swivel ranges:

Extension arm and spring arm with end stop (swivel range 330 degrees)

The extension arms [3]/[4] with one end stop have a swivel range of approximately 330 degrees as required for applications where the end device (e.g. flat screen) is powered via supply cables laid inside the extension arms [3]/[4] and the spring arm [5].
The end stop in the extension arms [3]/[4] and the spring arm [5] prevents these supply cables being sheared off.

Extension arm and spring arm without end stop (unrestricted swivel range)

The extension arms [3]/[4] without end stop are suitable for applications where the end device (e.g. OR light) is powered via internal plug couplings or where no internal cables are required. If equipped with an internal plug coupling, the extension arms [3]/[4] and the spring arm [5] can be rotated without restriction.

Central Axis C with optional comfort end stop (swivel range adjustable in graduations of 22.5 degrees)

In order to prevent the extension arm C [3] with spring arm [5] hitting walls or other components, the swivel range of the extension arm C [3] with comfort end stop can be reduced in increments of 22.5 degrees.

Central Axis S with optional comfort end stop (swivel range adjustable in graduations of 15 degrees)

In order to prevent the extension arm S [4] with spring arm [5] hitting walls or other components, the swivel range of the extension arm S [4] with comfort end stop can be reduced in increments of 15 degrees.

Spring arms

If equipped with an end stop, the spring arm [5] can be rotated 360 degrees horizontally; without an end stop, it can be rotated without restriction. The spring arm [5] can be moved up and down.

OR light

OR light with single yoke [6] and OR light with double yoke [7] is used to illuminate the surgical surface. It can optionally be equipped with a camera.

Monitor Carrier

The monitor carrier single [8] and monitor carrier dual [9] is used to support and position a flat screen.

Functional description

Extension arm

The extension arms [3]/[4] serve for the horizontal positioning of the end device (e.g. flat screen, OR light, etc.) on the specific spring arm [5]. The rotating motion can be restricted by an internal end stop.

Brakes on the extension arm

The extension arms [3]/[4] are equipped with 4 brakes which hold the extension arms [3]/[4] and the spring arm [5] in their set position.
For more detailed information on how to adjust the brake force, please contact your local ZIMMER BIOMET representative.

Spring arms

The spring arm [5] serve for the horizontal and vertical positioning of the end device (e.g. flat screen, OR light, etc.).

Vertical lift of the spring arms

In order to prevent collisions with the ceiling or other components, the vertical lift of the spring arm [5] can be restricted. The vertical lift is defined during installation.

Spring arm version

Identify the version of the spring arm [5] mounted according to the information on the product label. The product label is attached to the top side of the spring arm [5].
For more detailed information on how to adjust the vertical lift, please contact your local ZIMMER BIOMET representative.

Functioning of the spring in the spring arm

To facilitate the positioning of the end device (e.g. flat screen, OR light, etc.) a spring is mounted in the spring arm [5]. The spring compensates the weight of the end device (e.g. flat screen, OR light, etc.).

Adjusting the spring tension on the spring arm

If the spring arm [5] with the end device (e.g. flat screen, OR light, etc.) moves down or if a new end device is mounted, the spring tension of the spring arm [5] must be readjusted.

Spring arm version

Identify the version of the spring arm [5] mounted according to the information on the product label. The product label is attached to the top side of the spring arm [5].
For more detailed information on how to adjust the spring tension, please contact your local ZIMMER BIOMET representative.

Brakes on the spring arm

The spring arm [5] are equipped with brakes. The brakes hold the adaption and the end device (e.g. flat screen, OR light, etc.) in the set position.

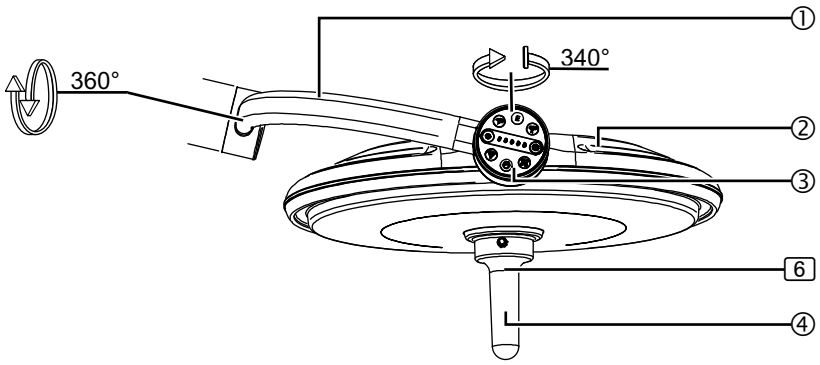
Spring arm version

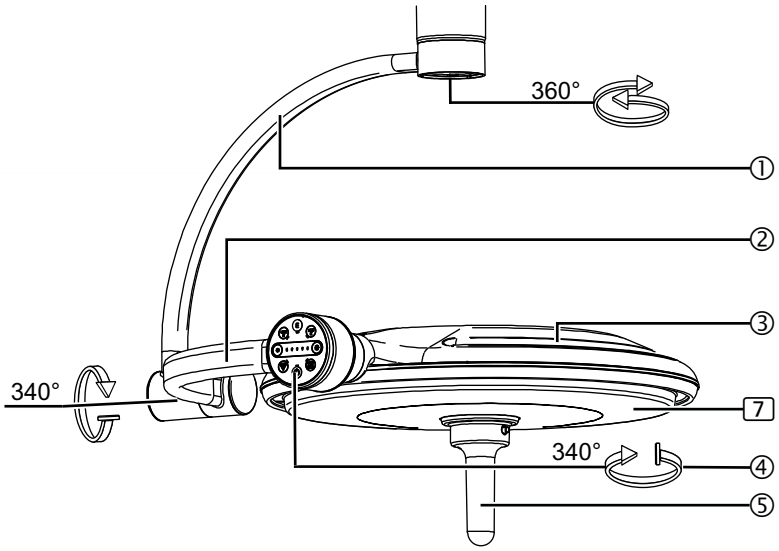
Identify the version of the spring arm [5] mounted according to the information on the product label. The product label is attached to the top side of the spring arm [5].
For more detailed information on how to adjust the brake force, please contact your local ZIMMER BIOMET representative.

Monitor Carrier

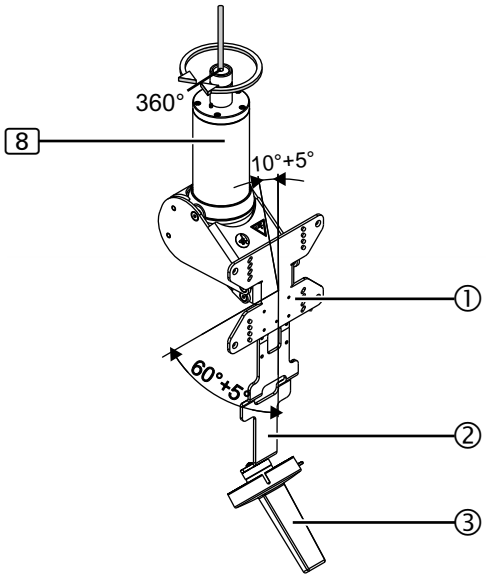
The monitor carrier single [8] and monitor carrier dual [9] can be tilted approx. 10° upwards and 60° downwards.

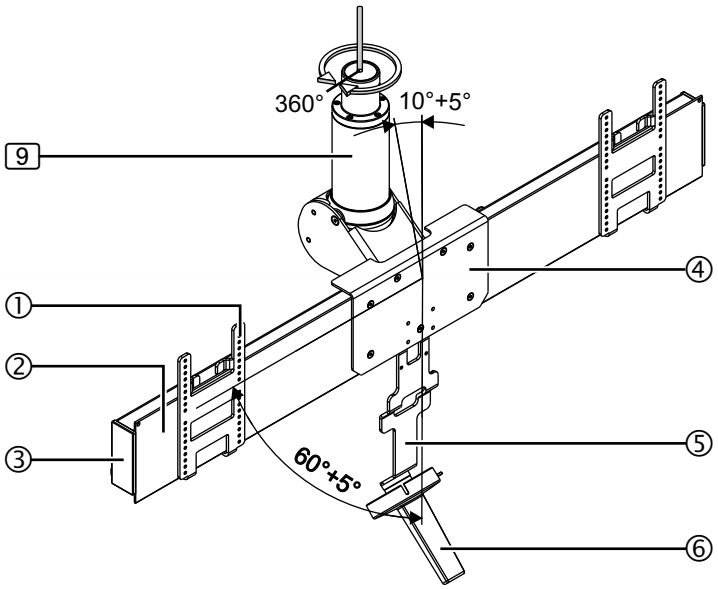
Versions of the OR lights





Versions of the Monitor Carrier





Device parts description

OR light with single yoke [6]

① Yoke
② Light head
③ Function control keyboard
④ Sterilizable handle

OR light with double yoke [7]

① External yoke
② Internal yoke
③ Light head
④ Function control keyboard
⑤ Sterilizable handle

monitor carrier single [8]

① Vesa interface plate
② Sterile handle connector
③ Sterilizable handle

monitor carrier dual [9]

① Vesa interface plates
② Rail
③ Rectangular plugs
④ Reinforcement panel
⑤ Sterile handle connector
⑥ Sterilizable handle

Part 1: General Information

1.1 Information for identification of the appliance

- This Operation Manual is intended solely for devices with the manufacturer's product label bearing the following information:

Device identification

  - Type designation: Claro™ Lights

1.2 How to identify the Operation Manual

Make sure you are using the latest version

- To ensure that you always have the latest version of these Operation Manual, every page bears a 7-digit identity number including the date of issue and the version number:

Identification of this Operation Manual

  - Edition: 1571192, Edition 2020-11, Version 0

- This identification is binding for the validity of the Operation Manual and must not be removed, regardless of the type of publication (printed form, electronic form or excerpts).

1.3 Identification of target groups

The groups of persons described below are mentioned in this Operation Manual.

1.3.1 Operator

The following natural persons or legal entities shall be considered as operators:

- All persons who use the product in a medical practice, hospital, etc. or hand over the appliance to third parties for use/application, and who have actual physical authority over the product during operation.
- The operator shall be liable for handing over a safe product and for instructing the user in the proper operation and normal use of the product.

1.3.2 User

The following persons shall be considered as users:

- Persons who, due to their professional qualification and instruction by the persons designated by the operator, are authorized to operate the product and to work with it.
- Users shall be fully responsible for the safe operation of the product in accordance with its intended purpose.

1.3.3 Qualified personnel

The following persons shall be considered as qualified personnel:

- Persons who underwent special professional training in the field of medicine or medical engineering.
- Persons who can assess their work and recognize the potential hazards involved on the basis of their professional experience and instruction in safety-relevant regulations.
- In States where the performance of tasks in the medical or medical engineering sector is subject to certification, qualified personnel must have obtained the corresponding certificate.

1.4 Notes for the operator

- Even though the product has been designed according to the state of the art and is safe to operate, it must be considered a potential source of danger, in particular when operated by insufficiently trained personnel or used improperly and not as prescribed.
- The product may only be operated, cleaned and disinfected by trained qualified personnel.
- For safety reasons, any operator actions or interventions exceeding this scope may only be carried out by ZIMMER BIOMET or companies authorized by ZIMMER BIOMET. As a prerequisite for the authorization of a company, its service technicians must have successfully participated in technical training organized by ZIMMER BIOMET. This authorization is granted for a limited period.
- All lengths (mm / inch) and angles (degrees) are approximate values and subject to production-related tolerances.

1.4.1 Initial commissioning

Validity

- This Operation Manual only applies after initial commissioning has been properly carried out.
- Prior to initial use, the product must be thoroughly cleaned and disinfected.
- The instruction for the proper installation of the product is included in the Installation Instructions applicable for the product.

1.4.2 Availability of this Operation Manual

Duty to inform

- Since this Operation Manual is an integral part of the product, it must always be kept near the product in order to be able to look up safety instructions and important information on use at any time.
- Do not pass on the product to any third party without valid Operation Manual. Based on the ID and version numbers, make sure you hand over an up-to-date and valid version of the Operation Manual together with the product.

1.4.3 Warranty

The warranty of ZIMMER BIOMET for the safety and operational reliability of the product is subject to the following conditions:

- The product is used exclusively as prescribed and operated as stipulated in the Operating Instructions.
- Only genuine spare parts or accessories and those specified and approved by ZIMMER BIOMET are used. The use of other parts may involve unknown risks and must be avoided in all cases.
- No structural alterations are made to the product. Unauthorised modifications or conversions to the product are not permitted for safety reasons.
- Inspections and maintenance are carried out at the specified time intervals.
- Initial commissioning has been carried out and the product has been released for operation by means of a declaration of acceptance.

1.5 Notes for the user

- All the steps described in this Operation Manual may only be carried out by qualified personnel who have been authorized and instructed by the operator.

1.5.1 Instruction on the product

Instruction

- The instruction must be carried out on the product immediately by ZIMMER BIOMET, by a company authorized by ZIMMER BIOMET.
- On completion of the instruction, an in service-form will be created and signed in order to document that the user has understood the special operator control actions required for normal use.

1.5.2 User's duty to inform and inspect

Duty to inform and inspect

- Read this Operation Manual carefully prior before useing the product for the first time. This ensures that you benefit from all the advantages of the product and prevents any risk of injury or damage.
- Prior to any use or transfer for use, the functional reliability and proper condition of the product must be inspected by the user.

Troubleshooting

- In case of special problems which are not sufficiently described in detail in this Operation Manual, contact your local ZIMMER BIOMET representative for your own safety.

1.5.3 Standards and directives

The product complies with the safety requirements of the following standards, laws and directives:

- FDA 21 CFR 820
- IEC 60601-1 Edition 3.1 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-2-41 - Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis

1.6 Intended purpose

- The light system is a medical device which is intended to be used by medical personnel to provide local surgical site illumination to any part of the patient's body for treatment and diagnosis. The light system is suitable to be used in the PATIENT AREA, with short term duration, active, non invasive for all types of surgical procedures. The clinical settings include, but are not limited to: The Operating Room, Labor and Delivery, Emergency Department, Trauma, Intensive Care Unit, Minor Procedure Room, etc. This is inclusive of all patients requiring surgical intervention.

1.6.1 Incorrect use

- The components have been adapted to each other and are safe to operate. Any other type of installation, and in particular the use of components from third-party manufacturers, is strictly prohibited because these components can be potential sources of danger.
- The combination of any other ZIMMER BIOMET product with the light system must be approved by ZIMMER BIOMET. If applicable, the conformity assessment must be repeated.

1.6.2 Contraindications

- The light system must not be used close to strong magnetic fields.
- No BF or CF application parts in accordance with IEC 60601-1 may be directly connected to the light system.

1.7 Ambient conditions

1.7.1 Ambient conditions for storage and transport

The following conditions apply to storage:

- Ambient temperature: -15°C (5°F) to +60°C (140°F)
- Relative humidity: 10% to 75%
- Atmospheric pressure: 500hPa to 1,060hPa
  (In original packing materials).

1.7.2 Ambient conditions for operation

- Ambient temperature: 10°C (50°F) to 40°C (104°F)
- Relative humidity: 30% to 75%
- Atmospheric pressure: 700hPa to 1,060hPa
  (This corresponds to a maximum operating altitude of 3,000m / 9842,52ft).

2.1 Structure of the safety instructions

2.1.1 Warnings of risk of injury

Important notes in this document are marked with graphic symbols and signal words. Signal words such as DANGER, WARNING or CAUTION describe the degree of risk of injury. The triangle symbols visually emphasize the degree of hazard.

⚠ DANGER

DANGER refers to a potential hazard with a high degree of risk which, if not avoided, will lead to death or severe injury.

⚠ WARNING

WARNING refers to a potential hazard with a medium degree of risk which, if not avoided, can lead to death or severe injury.

⚠ CAUTION

CAUTION refers to a potential hazard with a low degree of risk which, if not avoided, can lead to minor or moderate injury.

2.1.2 Warnings of damage to property

NOTICE

NOTICE refers to a potential hazard, which, if not avoided, will lead to damage to property.

2.1.3 Indication of additional information

NOTE

A NOTE provides additional information and useful tips for the safe and efficient use of the appliance.

2.2 Supplementary symbols used in the safety instructions

Electric shock hazard: warns of electric shock which can lead to severe injury or even death.

Risk of parts falling off: warns of parts falling off while carrying out mounting or dismantling work underneath the pendant system.

Sudden release of spring arm: warns that the spring arm may jump up suddenly while dismantling an adaption or an end device.

Risk of bruising: warns of the risk of bruising.

Explosion hazard: warns of the risks in combination with oxygen (see Chapter 2.7, “Risks in combination with oxygen”, on Page 25)

Danger of fire: warns of the risks in combination with oxygen (see Chapter 2.7, “Risks in combination with oxygen”, on Page 25)

2.3 Description of graphic symbols possibly used on the appliance and the package


Observe the Operation Manual: Read the Operation Manual carefully prior to installation of the pendant system. This ensures that you benefit from all the advantages of the pendant system and prevents any risk of injury or damage.

Observe the maximum load bearing capacity or maximum loading capacity (payload): warns of the risk of the appliance suddenly dropping because the maximum load bearing capacity or maximum loading capacity (payload) has been exceeded. The maximum value is indicated in kg or Nm.

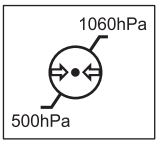
Risk of bruising: warns of the risk of bruising.

General note reminding the user to handle the pendant system with care.

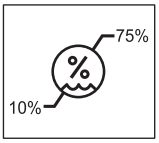
Environmentally friendly disposal: warns of damage to the environment caused by improper disposal of the pendant system (must not be disposed of as normal household waste).

Non-ionising electromagnetic radiation: warns that the high-frequency electromagnetic radiation generated by base transceiver stations and radio transmitters interferes with medical devices and electronic implants.

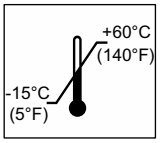
MEDICAL - GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK,
FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH
ANSI/AAMI ES 60601-1:2005/AMD1:2012;
IEC 60601-2-41:2009 / AMD1:2013;
CAN/CSA-C22.2 No. 60601-1:2014;
UL 60601-1;CAN/CSA-C22.2 No. 601.1
E346486



Atmospheric pressure: indicates the permissible atmospheric pressure values in a range from 500 hPa to 1060 hPa for transport and storage.

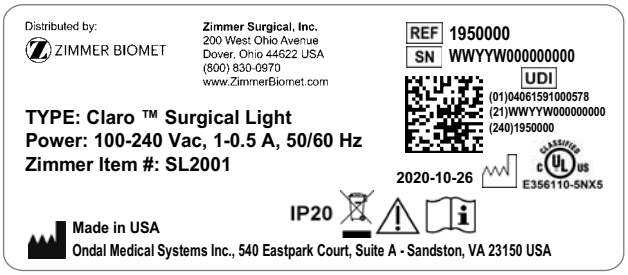


Relative humidity: indicates the permissible humidity values in a range from 10 % to 75 % for transport and storage.



Ambient temperature: indicates the permissible ambient temperature values in a range from -15 °C (5 °F) to +60 °C (140 °F) for transport and storage.

Figure 1: Information on the product label



Representation Only. May not be the latest revision.

2.4 Information on the product label

(See "Figure 1")

The information and illustrations serve as examples.
The information and illustrations on the product label can vary.

- The figure shows:
  – the information on the ClaroTM Lights product label.

- The ClaroTM Lights product label is located on the upper side of the top extension arm.

Unique Device Identifier

- The unique device identification system serves to identify medical devices from manufacturing through distribution to patient use.

Serial number

- The product label indicates the serial number (SN) of the light system.

Power supply

- The product label provides information on the power supply of the light system.

2.5 Overview of the most important safety instructions

The safety instructions in the following chapters must be adhered to.

2.5.1 Operation

⚠WARNING

Possibility of tissue dehydration and damage of overlapping light fields

In the event of overlapping lights, a temperature increase would ensue in the patient area with consequent risk of dehydration and tissue damage.

- In case of a reduction in blood flow with start of tissue dehydration, reduce light intensity.

Possibility of glare

If the light source is directed into the eyes of the patient and/or the operator, this can lead to glare and possible damage to the retina:

- Do not direct the light source into the patient's and/or operator's eyes.
- When Product use is restricted to the face (maxilla-facial surgery, plastic surgery, ear-nose-throat surgery) the patient's eyes must be covered with adequate protection.

Electromagnetic disturbance

To avoid any significant risk of reciprocal interference due to the presence of the Product during specific exams or treatments:

- use the information on Chapter 7, "EMC Declaration", on Page 43.

Risk of the light system dropping because the maximum load bearing capacity has been exceeded

If the maximum load bearing capacity has been exceeded, there is a risk that the light system or components of the light system may disengage from the fastening device and drop:

- The maximum loading capacity on the light system must not be exceeded!

Collision damage

In case of collision with other devices, walls or ceilings, the light system, the adaptions and end devices can be damaged and important patient care systems can fail:

- after a collision, the adaptions, end devices and the light system must be inspected for damage.
- in case of doubt, contact your supplier.

⚠WARNING

Checks to be made every time before use

To make sure the product is safe and provides a correct diagnosis, every time before use, the operator must check:

- The light has been correctly disinfected;
- The emitted light is stable and of adequate intensity;
- The swinging arm maintains its position;
- The light head maintains its Position;
- The light head shows no signs of physical damage and operates properly.

2.5.2 Mounting / dismantling

⚠WARNING

Electric shock hazard

To prevent the risk of electric shock, the light system may only be connected to a power supply network equipped with a protective conductor:

- The light system must be connected in such a way that it can be disconnected from the mains at all poles and at the same time and can be locked in the OFF position.

Electric shock hazard

Power supply cables are laid in the light system, the adaption and the end device. Contact with energized components presents a danger to life from electric shock. Prior to any installation/dismantling and setting up work, the light system must be disconnected from the mains:

- Disconnect all the poles from the mains and prevent the appliance from being switched back on again.
- Make sure that all the end devices (e.g. flat screen, OR light, etc.) connected via the light system are de-energized.

⚠WARNING

Sudden release of the spring arm

When dismantling the adaption or the end device from the spring arm, the spring arm can suddenly jump up and may cause serious injury:

- Before removing the adaption or end device, make sure that the vertical lift of the spring arm is restricted to the lowermost horizontal (0 degree) position.
- Check that the spring arm is safely locked in place. Once the spring arm has been fixed in its lowermost horizontal (0 degree) position, it must no longer be possible to move the spring arm upwards.

⚠WARNING

Risk of parts falling off

During all uninstallation and installation work, it must be ensured that no person is in the area underneath the light system.

2.5.3 Cleaning and disinfection

Cleaning

⚠WARNING

Risk of contamination and infection of the patient

Parts of the light system and the adaptions are made of plastic. Solvents can dissolve plastic materials. Strong acids, bases and agents with an alcoholic strength of more than 60 % can lead to the plastic materials becoming brittle. Detached particles can fall into open wounds. If liquid cleaning agents are allowed to penetrate the light system and the adaptions, excess cleaning liquid may drip into open wounds.

Disinfection

⚠CAUTION

Health hazard

Disinfectants can contain substances hazardous to health which, when in contact with the skin and eyes, can cause injuries or affect the respiratory organs when inhaled. Observe the protective measures:

- Observe the hygiene regulations.
- Adhere to the disinfectant manufacturer's instructions.
- Perform surface disinfection every working day and in case of contamination.

2.5.4 Incorrect use

⚠WARNING

Objects falling in the operating area

If anything is attached and/or suspended from the product, it may fall into the work area while the product is in use:

- Never place and/or hang anything on the Product.

If you hang on the product, it may be damaged or fall.

- Never hang on to the Product with your body weight.

Plastic parts or paint fall in the patient area

Collisions could cause the detachment of plastic parts or paint from the Product which could fall in the patient area.

- Avoid collisions between the arms of the light system as well as collisions between the light system and nearby equipment or walls.
- The use of after market, non-ZIMMER BIOMET accessories or parts such as disposable handles may fall off the light. Ensure that only ZIMMER BIOMET / Claro™ Lights genuine parts and accessories are utilized.

Overheating

Covering the light head can cause the light to overheat.

- To prevent overheating never cover the head of the Product during operation.

2.6 Warranty

⚠WARNING

Risk of product dropping

The light system is an adapted system with regard to the maximum load bearing capacity and maximum loading capacity (payload). Alterations to the light system can result in exceeding the permissible, total or maximum loading capacity of individual components. In this case, there is a risk of the light system or components of the light system disengaging from the product and dropping.

ZIMMER BIOMET warrants the functional reliability of the product only under the condition that:

- No structural alterations are made to the product. Unauthorised modifications or conversions to the product are not permitted for safety reasons.
- Only genuine spare parts or accessories and those specified and approved by ZIMMER BIOMET are used. The use of other parts may involve unknown risks and must be avoided in all cases.
- Inspections and maintenance are carried out at the specified time intervals.
- Related documents for dismantling, mounting and adjustment work to be carried out on the product are available from ZIMMER BIOMET on request.

2.7 Risks in combination with oxygen

⚠ DANGER

Oxygen explosion

Oxygen becomes explosive when in contact with oils, greases and lubricants. Compressed oxygen presents an explosion hazard:

- The Product is not suitable for use in explosion-risk areas.
- The Product is not suitable for use wherever there are inflammable mixes of anaesthetics with air, oxygen or N2O (laughing gas).
- Do not use any cleaning agents containing oil, grease or lubricants.

Danger of fire

Escaping oxygen is combustible:

- The Product is not suitable for use in oxygen rich environments and use is not intended in the presence of inflammable agents.
- Open fire, red hot objects and naked flames are not permitted when working with oxygen!

2.8 Disposal

RoHS conformity

- The light system complies with the requirements of the 2011/65/EC RoHS Directive (on the restricted use of certain hazardous substances in electrical and electronic equipment).
- To prevent environmental damage and personal injury, we request you to contact us or your authorized service partner if you intend to take the light system out of operation for the purpose of disposal.
- The light system must be disposed of at a suitable collection point for recyclable waste in accordance with country-specific regulations.
- The end of the useful life for the light system is 10 years under normal operating conditions, service parts are available for this period.
- Please contact your ZIMMER BIOMET authorized representative for disposal of the light system products or parts in accordance with current environmental regulations for medical products.
- The light system must be disposed of at a suitable collection point for recyclable waste in accordance with country-specific regulations.

⚠ WARNING

California Proposition 65:

This product may contain a chemical known to the State of California to cause cancer or birth defects or reproductive harm.

The light system is an adapted system with regard to the maximum load bearing capacity and the maximum loading capacity (payload).

Structural alterations

Alterations to the light system can result in exceeding the permissible, total load bearing capacity or maximum load bearing capacity of the individual components. In this case, there is a risk of the light system or components of the light system disengaging from the fastening device and dropping.

For this reason, structural alterations to the light system, including the replacement of the spring arms, adaptions and end devices, may only be carried out by ZIMMER BIOMET service technicians and authorized service personnel.

Initial commissioning

1. The light system must be properly installed. Instructions for installation are included in the scope of delivery of the product.
2. For commissioning following installation, proper initial commissioning must be carried out for the entire light system by an authorized ZIMMER BIOMET representative.

The following points must be observed during handover to the operator:

1. The light system must not be handed over and commissioned to the operator until it has been tested.
2. Install report: Handover must be documented in writing including confirmation by the operator.
3. In-service: In addition, the operator must be instructed in the functioning, operation, cleaning and disinfection of the light system during the handover procedure.
4. Biomed in-service: Furthermore, on handover, the operator must be instructed in the adjustments permitted according to the Operation Manual included in the scope of delivery.
5. On completion of the instruction, an in service-form will be created and signed in order to document that the operator/user has understood the special operator control actions required for normal use.

5.1 Safety instructions of Cleaning and Disinfection

⚠WARNING

Electric shock hazard

The appliances can carry electric current and must be treated with the utmost care during cleaning and disinfection:

- If a mains plug exists, pull out the mains plug.
- Do not apply spray cleaning and/or spray disinfection.
- Do not spray liquid into power sockets, gas sockets or appliance openings and prevent the penetration of liquids.
- Allow the light to cool down and only clean it when it is cold.

5.2 Cleaning

Follow the safety instructions

1. Follow the general safety instructions prescribed in Chapter 5.1, “Safety instructions of Cleaning and Disinfection”, on Page 28.

⚠WARNING

Risk of contamination and infection of the patient

Parts of the light system and the adaptions are made of plastic. Solvents can dissolve plastic materials. Strong acids, bases and agents with an alcoholic strength of more than 60% can lead to the plastic materials becoming brittle. Detached particles can fall into open wounds. If liquid cleaning agents are allowed to penetrate the light system and the adaptions, excess cleaning liquid may drip into open wounds.

Cleaning agents

Recommended cleaning agents
Use a mild soap solution or a regular dishwashing product.

General cleaning instructions

1. Wipe the surfaces of the appliances with a moderately moist cloth; add a mild soap solution (dishwashing product) if required.
2. Afterwards, carefully wipe the surfaces dry with a clean cloth.
3. Avoid directly spraying fluids onto the light and directly onto electrical components.

Cleaning instructions for the camera and the wall control

1. Wipe the surfaces of the appliances with a moderately moist cloth; add a mild soap solution (dishwashing product) if required.
2. Afterwards, carefully wipe the surfaces dry with a clean cloth.
3. Avoid directly spraying fluids onto the camera and the wall control.

5.3 Disinfection

Follow the safety instructions

1. Follow the general safety instructions prescribed in Chapter 5.1, “Safety instructions of Cleaning and Disinfection”, on Page 28.

⚠WARNING

The appliance is not suitable for sterilization

Avoid damage

- Make sure that no liquid penetrates the appliance while cleaning it.
- To prevent damage to plastic parts, refrain from using abrasives or alkaline, acidic or corrosive cleaning agents.
- Do not use bleaching agents on stainless steel parts.

Deploy trained technical specialists only and abide by national regulations.

- Cleaning/disinfection must be carried out by trained technical specialists only. The requirements of the national hygiene and disinfection committee must be complied with.

⚠CAUTION

Health hazard

Disinfectants can contain substances hazardous to health which, when in contact with the skin and eyes, can cause injuries or affect the respiratory organs when inhaled. Observe the protective measures:

- Observe the hygiene regulations.
- Adhere to the disinfectant manufacturer's instructions.
- Perform surface disinfection every working day and in case of contamination.

Disinfection method

Wiping disinfection is the standardized disinfection method prescribed for the light system. Hygiene regulations and related safety instructions for the disinfection methods to be applied must be defined by the operator.

- In case of contamination with potentially infectious material (e.g. blood, body secretion or excrement) the surfaces must be immediately and specifically disinfected.
- Make sure you apply the disinfectant in the correct concentration.
- For surface disinfection do not spray, but wipe, the surfaces.
- Wiped surfaces may only be used after the disinfectant has dried.

UV-disinfection

Surface disinfection of surfaces using UV-C radiation devices can cause damage to the transparent screen of the OR light. It can lead to a permature aging.

- DO NOT place the UV-C device directly under the OR light.

5.4 Sterilizing the handle of the light head

Frequency

The handles must be sterilized before use and can withstand up to 200 cycles.
The Operator must comply with the rules of the national commission for hygiene, disinfection and sterilization.

⚠WARNING

Possibility of damaging Product

The handpieces are made of plastic material resistant to heat and knocks (PSU - Polysulfone).
Handles that are cracked or deformed must be replaced immediately, because they could fall into the patient area.
Hand-piece fitting / removal:

- Press the hand-piece release button and remove it.
- Insert the handpiece in the support, following the guide provided until it is locked in position.

Sterilization

Clean and disinfect the handpieces in the traditional way before sterilization. They can be cleaned with a mid-alkaline detergent free of active chlorine. To disinfect the handpieces, we suggest using alcohol or aldehyde-based products. The disinfectants must be approved by the disinfectant manufacturer for use on polylsulfone (PSU). After disinfecting, rinse off the detergent residues with plenty of water.

The handpieces fit into a suitable sterilization pack (disposable sterilization pack, e.g., plastic/paper bags; single or double pack), before being sterilized.
The handpieces can withstand about 200 steam sterilization cycles in accordance with the following parameters:

- steam sterilization at 121°C (249,8°F) 1.3bar (18.9PSI) for 25 to 30 minutes
- steam sterilization at 134°C (273,2°F) 2.3bar (33.4PSI) for 4 minutes

Do not exceed a sterilization temperature of 134°C (273,2°F).
Strictly keep to the ISO 17665-1 standard.
When placing in the autoclave, make sure the open side of the handpieces is turned downwards. The handpieces must be free and not burdened by other material being sterilized.
Damaged handpieces must no longer be used.

5.5 Sterilizing the handle of the monitor carrier

The operator/user is responsible for cleaning and disinfecting.
The sterilizable handle must be cleaned, disinfected and sterilized before each application. This also applies to the first use after delivery. Thorough cleaning and disinfecting are indispensable requirements for effective sterilization of the sterilizable materials.

- Make sure that
  - validated methods are used for cleaning, disinfecting and sterilizing
  - the correct parameters are applied for the validated reprocessing
  - cleaning and disinfection is only carried out by trained staff
  - the devices used (cleaning and disinfection machine, sterilizer) are qualified and regularly tested and serviced employees wear the stipulated protective clothing

If possible, use a cleaning and disinfection machine for cleaning; see Chapter 5.5.3, “Mechanical cleaning and disinfection”, on Page 32.
Only apply manual cleaning (even if you are using an ultrasonic bath), if mechanical cleaning is not possible. In this case, bear in mind the significantly lower efficiency and reproducibility of the result.

NOTE: Mechanical and manual cleaning

Carry out pretreatment before mechanical or manual cleaning.

5.5.1 Pretreatment

- Rinse outside and inside of handle for at least 1 minute under running water (temperature < 35 °C / 95 °F).
- Remove all visible impurities manually with a clean, soft brush (or with a clean, soft, lint-free cloth). Never use metal brushes or steel wool.
- Soak handles in cleaning solution for the specified duration so that they are sufficiently covered and filled. The handles should not touch each other in the cleaning bath.
- Rinse outside and inside of handle again for at least 1 minute under running water.
- If you are using a combined agent for cleaning and disinfection, ensure that its effectiveness is explicitly verified (e.g. by VAH/DGHM or FDA/EPA or CE mark). Disinfection during pretreatment only contributes to the safety of the cleaning staff; it is not a substitute for disinfection after cleaning!

5.5.2 Cleaning agents

Neutral and enzymatic cleaning agents are recommended, but slightly alkaline cleaning agents may also be used.
Cleaning agents must always be suitable for cleaning of products made from plastic or metal.
Cleaning agents must be free of aldehydes (otherwise blood residues will accumulate).
The use of Surfanios and terralin® liquids is expressly prohibited.

- Observe the instructions from the manufacturers of the cleaning agents for correct application
  (e.g. concentration, temperature, soaking time and final rinse).
- Make sure that the pH values of cleaning agents and disinfectants are between 5.5 and 11.
- Make sure that the cleaning agents and disinfectants do not contain any of the following substances:
  - highly concentrated organic and mineral media
  - organic solvents (e.g. acetone, ether, alcohol, 2-ethoxyethanol, petroleum ether)
  - oxidants (e.g. peroxide)
  - halogens (chlorine, iodine, bromine)
  - aromatic, halogenated hydrocarbons

5.5.3 Mechanical cleaning and disinfection

Errors during mechanical disinfection in the cleaning and disinfection machine may lead to product damage. The cleaning and disinfection machine must fulfil the following requirements:

- Effectiveness explicitly verified (e.g. CE mark according to EN ISO 15883 or DGHM or FDA approval/clearance/registration)
- Thermal disinfection
  (A0 > 3,000 or at least 5 minutes hold time at 90 °C / 194 °F)
- Always suitable for plastic handles
- Filtered air for drying
- Regular maintenance and testing / setting
- Ensure the following aspects when you are choosing the cleaning agent:
  - The agent is suitable for the cleaning and disinfection of plastic handles; see Chapter 5.5.2, “Cleaning agents”, on Page 31.
  - Do not use acidic neutralising agents or rinsing aids.
  - Observe the data from the manufacturers of the cleaning agents in respect to concentration, temperature, soaking time and final rinse.
  - Follow the operating instructions of the manufacturer of the cleaning agent and disinfectant.

5.5.4 Manual cleaning and disinfection

- Ensure the following aspects when you are choosing the cleaning agent and disinfectant:
  - Suitable for cleaning and disinfection of products made from plastic or metal
  - A disinfectant with verified effectiveness (e.g. VAH/DGHM or FDA/EPA or CE mark) must be compatible with the cleaning agent you are using
  - Compatibility of the cleaning agent used for the handles; see Chapter 5.5.2, “Cleaning agents”, on Page 31.
  - Follow the operating instructions of the manufacturer of the cleaning agent and disinfectant.

Cleaning

- Soak handles in cleaning solution for the specified duration so that they are sufficiently covered and filled. The handles should not touch each other in the cleaning bath. Assist cleaning by carefully brushing with a soft brush.
- Take handles out of the cleaning bath and rinse with water at least 3 times for at least 1 minute.
- Inspect handles; see “Inspection, care and reprocessing”, on Page 33.

The cleaning validation was conducted with the cleaning agent Neodisher MediClean Forte® from Dr. Weigert.

Disinfection

- Soak handles in disinfecting solution for the specified duration so that they are sufficiently covered and filled. The handles should not touch each other in the disinfecting bath.
- Take handles out of the disinfection bath and rinse with water at least 5 times for at least 1 minute.
  Carry out the final rinse with demineralised water to prevent formation of stains and coating.
- Dry handles and protect against recontamination.

NOTE: Drying the handle

Always store the handle with the opening downwards for easier drying.

5.5.5 Sterilization

For sterile operation, the handle must be cleaned, disinfected and sterilized before each application.

NOTE: Service life of the handle

The sterilizable handle will become worn through use and sterilization. Wear is indicated by crack formation and discolouration.

– If you notice signs of wear, do not sterilize the handle again. It must be replaced.

NOTE: Damage to the handle

The handle must never be treated in a hot-air sterilizer, as it will lead to destruction!

– Do not expose the handle to temperatures > 142 °C (288 °F).
– Package the handle in a sterile barrier system according to ISO 11607 before sterilization.
– Sterilize the handle in accordance with a validated steam sterilization method at 134 °C (273.2 °F) / > 5 min or 121 °C (249.8 °F) / > 20 min, e.g. in a sterilizer according to EN 285 and ANSI/AAMI ST79, and validated according to ISO 17665-1. Also follow the operating instructions of the sterilizer.
– Make sure that the handle is not subject to mechanical loads during sterilization, as permanent deformations may occur otherwise.

Storage and transport

- Store sterilized products in sterilization packaging in a clean and dry place.
- Follow the procedures for sterile work defined in the hospital!

Inspection, care and reprocessing

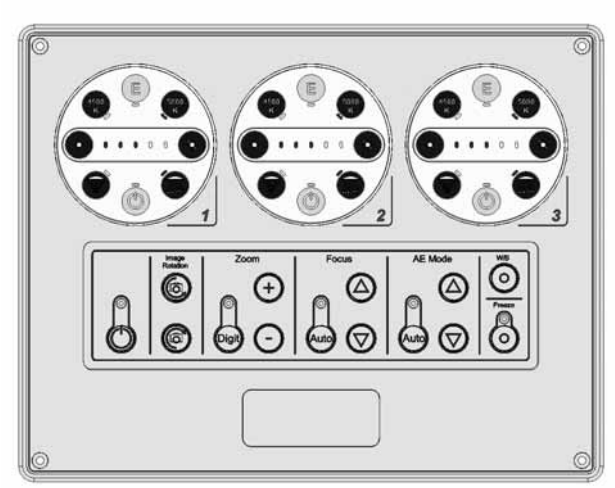
After treatment, inspect all products for crack formation, discolouration, damaged surfaces and impurities.

- Do not reuse damaged products.
- Clean and disinfect contaminated products again.
- Do not use instrument oil or grease.

The products can be reprocessed if they are not damaged.

Part 2: Claro™ Lights

Figure 2: Optional wall control



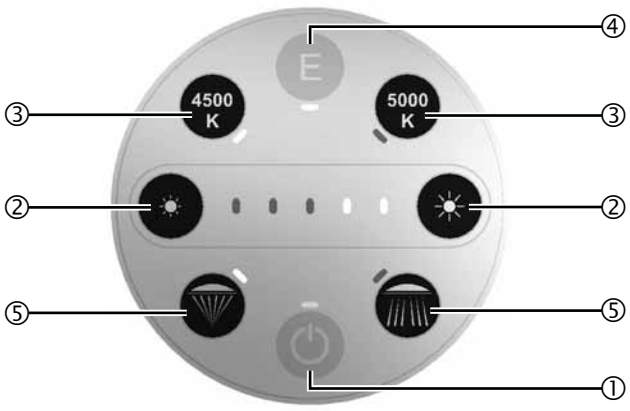
6.1 Description of operation

6.1.1 Keyboard

(See "Figure 2")

The capacitive keyboard with touch technology is located on the light head yoke and on the optional wall control. The wall control can come with an optional camera control keyboard. By touching with your finger on the surface of the keyboard, the following functions can be activated:

Figure 3: Keyboard



(See "Figure 3")

① Power button

- Turn the light on and off by pressing the power button. With the light off, the green LED indicates the presence of power voltage in the system;

② Sun symbol buttons

- Adjust light intensity by dragging your finger over the bar or touching the sun symbol buttons. The level of intensity achieved is indicated by means of 5 green or blue LEDs;

③ Color temperature buttons

- Select color temperature from among 2 values - 4500K and 5000K by pressing the buttons indicating the value.

④ “Endo-Led” function

- Enable the “Endo-Led” light function, using the button with the letter E. This function is only available when the light is off;

⑤ Light range adjustment

- Use the magnifying or reducing button to adjust the diameter of light.

6.1.2 Yoke keyboard

The light can also be controlled via the keyboard on the yoke. The yoke control keyboard is the same as the wall control keyboard.

Figure 4: Moving the product

6.1.3 Moving the product

(See "Figure 4")

The Product can be moved using the sterilizable handle or by means of the external contour.

Figure 5: Setting the light intensity

6.1.4 Setting the light intensity

(See "Figure 5")

By pressing the buttons on the keyboard, the previously described control functions can be enabled, or by pushing the sensors on the handle as previously indicated the light intensity can be adjusted.

Figure 6: Handle

6.1.5 Removing the handle

(See "Figure 6")

To remove the handle from the light head, simply press the handpiece release and remove it.

6.1.6 Installing the handle

(See "Figure 6")

To reinstall the handle, align it with the black support and slide it into place until it locks.

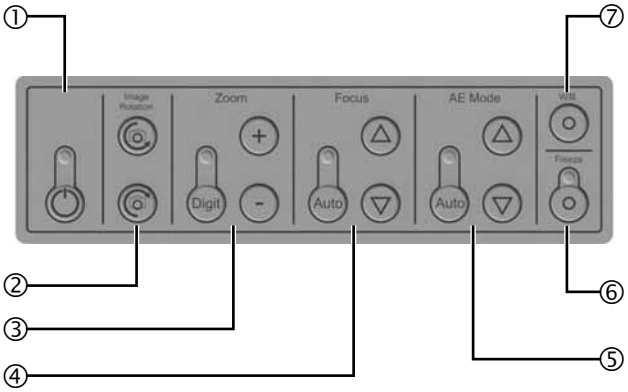
Figure 7: Camera

6.1.7 Optional camera

(See "Figure 7")

The camera uses a 1/2.8-type Exmor CMOS image sensor with Full HD (1080/60p) performance and achieves excellent zooming performance with a 30x optical zoom lens.
The camera only works with the camera ready light head. In order to use the camera, a camera ready light head must be present on the light system.

Figure 8: Camera keyboard



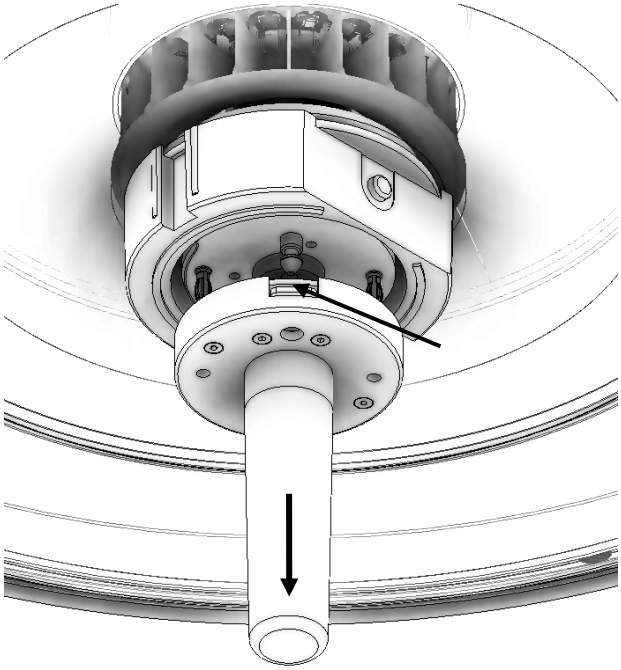
6.1.8 Optional camera control keyboard

(See "Figure 8")

The camera functions are managed by means of the membrane keyboard on the wall controller and are:

① Power button (on / off key)
② Image rotation
③ Zoom adjustment (digital and optical)
④ Focus adjustment (automatic and manual)
⑤ Exposure adjustment (automatic and manual)
⑥ Freeze image
⑦ White balance

Figure 9: Adapter

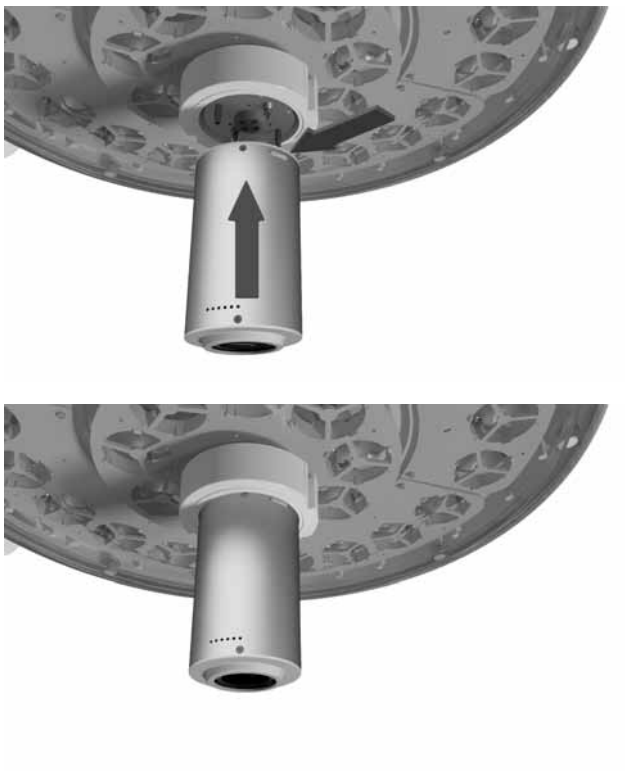


6.1.9 Removing the handle of the camera ready light head

(See "Figure 9")

If a handle is installed go to Chapter 6.1.5, “Removing the handle”, on Page 36 and remove it as described.
Then Press the lever of the adapter and remove it.

Figure 10: Camera installation

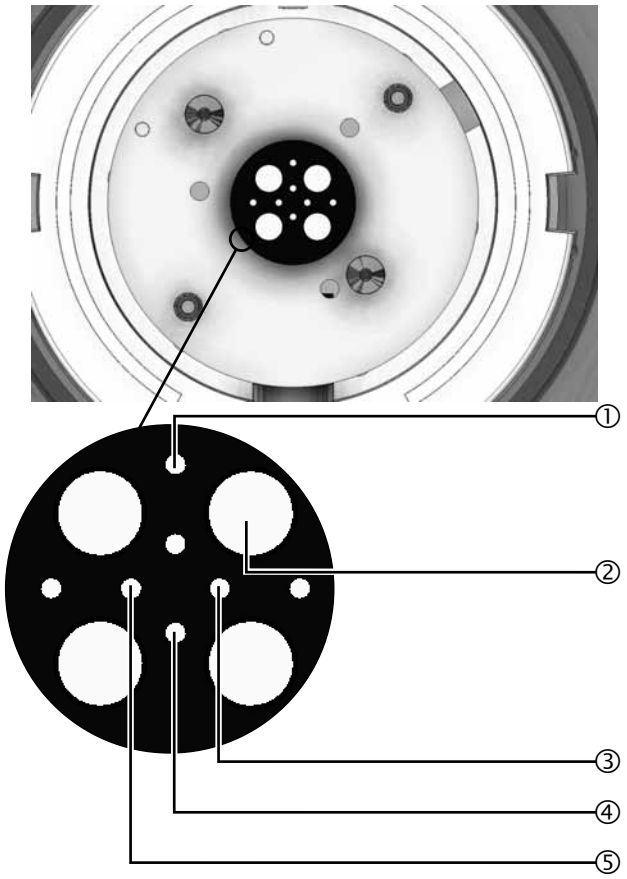


6.1.10 Camera installation

(See "Figure 10")

Align the camera with the support flange on the camera ready light head, in accordance with the shape of the connector and by matching the fixing pins with corresponding holes. See camera connection “Figure 11:” and “Figure 12:” on Page 39.
Press the lock lever, fit the camera up tight and release the lever.

Figure 11: Light head



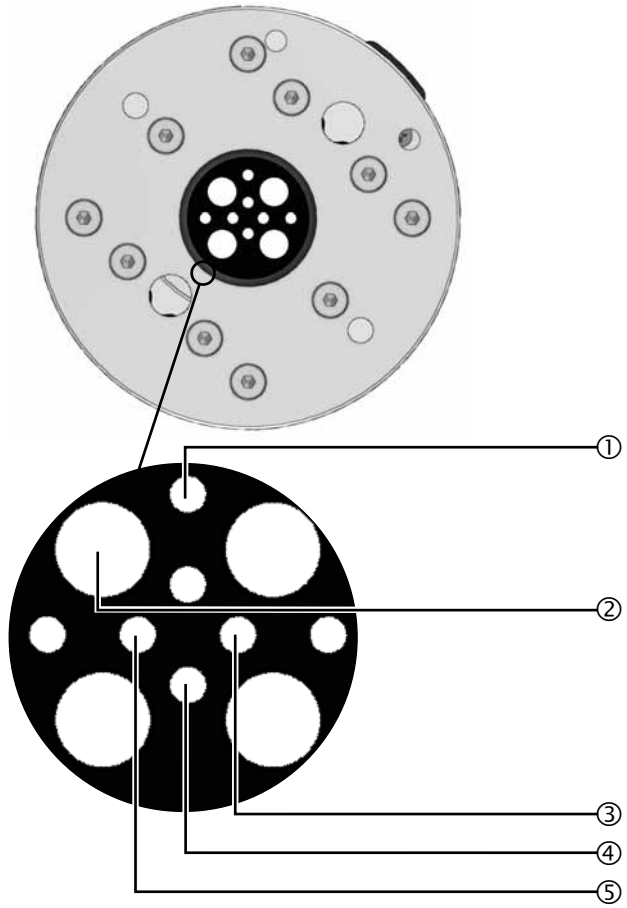
6.1.11 Camera connection light head side

(See "Figure 11")

The locating pins on the light head adapter must be aligned with the corresponding holes in the camera see “Figure 12:”.
Additionally the HD-SDI signal ② Pins in the light head adapter must be aligned with the corresponding pin in the camera connector.
The black adapter contains one active pin (the HD-SDI signal) and 3 empty holes.

Light head
① GND (0Vdc)
② HD-SDI signal
③ Rx communication
④ Tx communication
⑤ DC IN

Figure 12: Camera

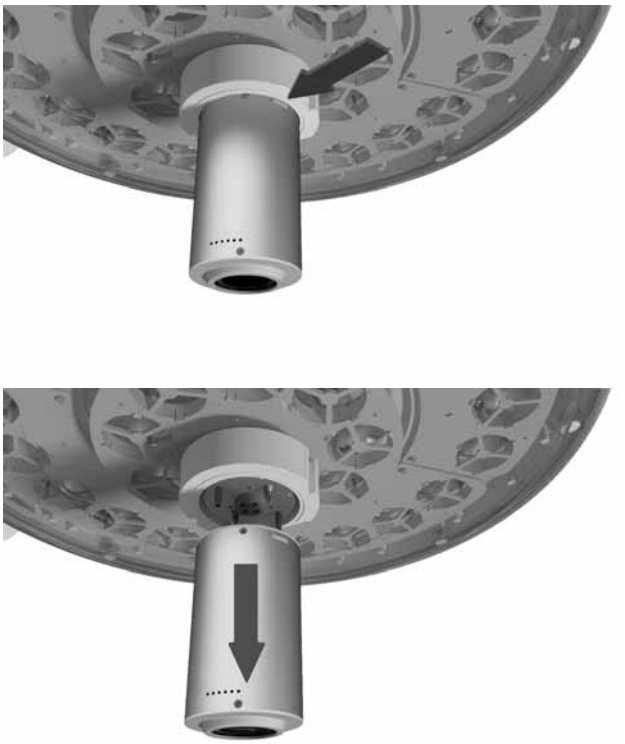


6.1.12 Camera connection camera side

(See "Figure 12")

Camera
① GND (0Vdc)
② HD-SDI signal
③ Rx communication
④ Tx communication
⑤ DC IN

Figure 13: Removing the camera



6.1.13 Removing the camera

(See "Figure 13")

To remove the camera body from the light head, press the lock lever with your finger and move the camera downwards.

Figure 14: Camera cover installation

6.1.14 Steriziable camera cover installation

(See "Figure 14")

To install the camera cover, align it with the camera body, insert it in the support, following the guide provided until it is locked in Position.

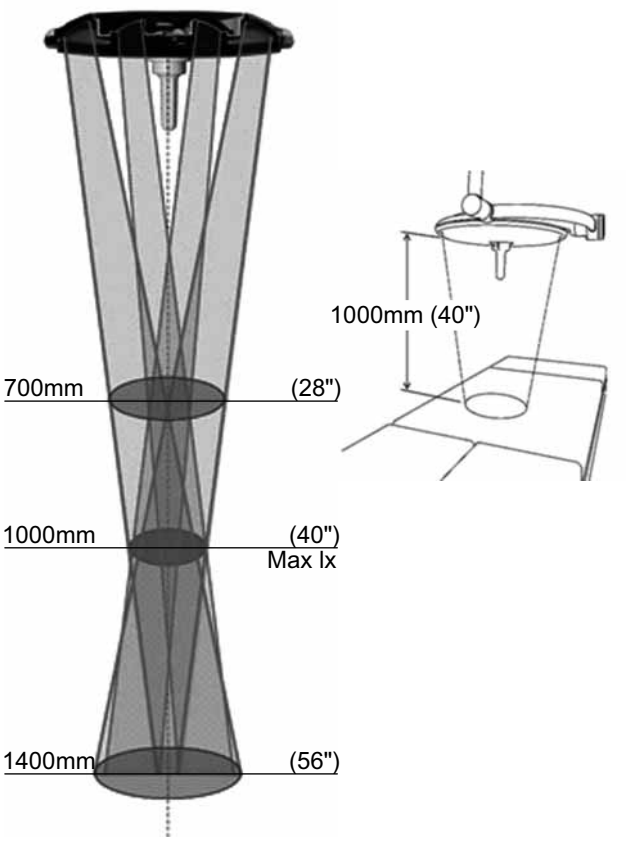
Figure 15: Removing the camera cover

6.1.15 Removing the steriziable camera cover

(See "Figure 15")

To remove the sterilizable camera cover from the light head, simply press the handpiece release and remove it.

Figure 16: Recommended work distance



6.1.16 Recommended work distance

(See "Figure 16")

To optimize light intensity (Max lx), the product is best used at a distance of 1000 mm (40").

The Product nevertheless also ensures a good light intensity at a distance between 700 mm (28") and 1400 mm (56").

The Product has been tested according to EN60601-1-2 standard to ensure correct electromagnetic compatibility.
Portable and mobile communication appliances can affect the product.
The product should not be used close to another device and if this is inevitable, the product must be checked to make sure it is working properly.
The use of accessories other than those supplied/recommended by the manufacturer could increase the level of emissions and lower the level of immunity of the appliance.
The Product has been designed to be used in the electromagnetic environments described below.
The Responsible Organization or Operator is responsible for making sure the Product is used in a compatible environment.

⚠WARNING

Possibility of interferences with nearby appliances

It could occur that if the Product is affected by radiations in the range of 80 MHz – 1 GHz or bursts, it will no longer respond to the commands both as regards the light and the camera.

- If this does occur, essential performance will in any case be ensured, but to restore normal operation it will be necessary to de-energize the master switch.

⚠WARNING

Possibility of interferences with nearby appliances

Immunity test	Compliance	Electromagnetic environment - directives
RF Emissions CISPR 11	Group 1	The Product only uses RF energy for internal operation. Consequently its RF emissions are very low and should not cause any interference to nearby electronic appliances.
RF Emissions CISPR 11	Class A	The Product is suitable for use in all environments except in domestic environments and those directly connected to a low-voltage public mains supply which supplies buildings used for domestic purposes, as long as the following precaution is followed. **Warning:** This Product is intended for use by professional health personnel only. This Product can cause radio-interference or disturb the operation of nearby appliances. Measures may have to be taken to reduce such disturbance, such as Product repositioning or shielding of premises.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Conforming	
NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radiofrequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.		

Immunity test	Test level to EN/IEC 60601-1-2	Conformity level	Electromagnetic environment - directives
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV at contact +/- 15 kV in air	+/- 8 kV at contact +/- 15 kV in air	Floors must be made of wood, concrete or ceramic tiles. If the floors are covered with synthetic material, relative humidity must at least be equal to 30%.
Rapid impulse electric transistors IEC 61000-4-4	+/- 2 kV For electric power lines +/- 1 kV For input/output lines	+/- 2 kV For electric power lines +/- 1 kV For input/output lines	Mains voltage quality should be that of a typical commercial or hospital environment.
Overvoltage IEC 61000-4-5	+/- 1 kV Between phases +/- 2 kV Between phases and earth	+/- 1 kV Between phases +/- 2 kV Between phases and earth	Mains voltage quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and variations on the power supply input lines IEC 61000-4-11	<5% U_T (drop >95% of U_T) For 0.5 cycles <40% U_T (drop = 60% of U_T) For 5 cycles <70% U_T (drop = 30% of U_T) For 25 cycles <5% U_T (drop >95% of U_T) For 5 s	<5% U_T (drop >95% of U_T) For 0.5 cycles <40% U_T (drop = 60% of U_T) For 5 cycles <70% U_T (drop = 30% of U_T) For 25 cycles <5% U_T (drop >95% of U_T) For 5 s	Mains voltage quality should be that of a typical commercial or hospital environment. If the Product user requires continued function during mains power supply interruptions, the Product should be supplied by a UPS unit or batteries.
Magnetic field at electrical mains frequency (50/60Hz) IEC 61000-4-8	30 A/m	30 A/m	The magnetic fields at mains frequency should have the characteristic levels of a typical locality in a commercial or hospital environment.
NOTE U_T mains voltage in AC before application of test level.			

Immunity test	Test level to EN/IEC 60601-1-2	Conformity level	Electromagnetic environment - directives
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Veff 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	3 Veff 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Products, included cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1,2\sqrt{P}$ 150 KHz to 80 MHz $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W), according to the transmitter manufacture and d is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance leave in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects an people.			

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [c] ± 5kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802-11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

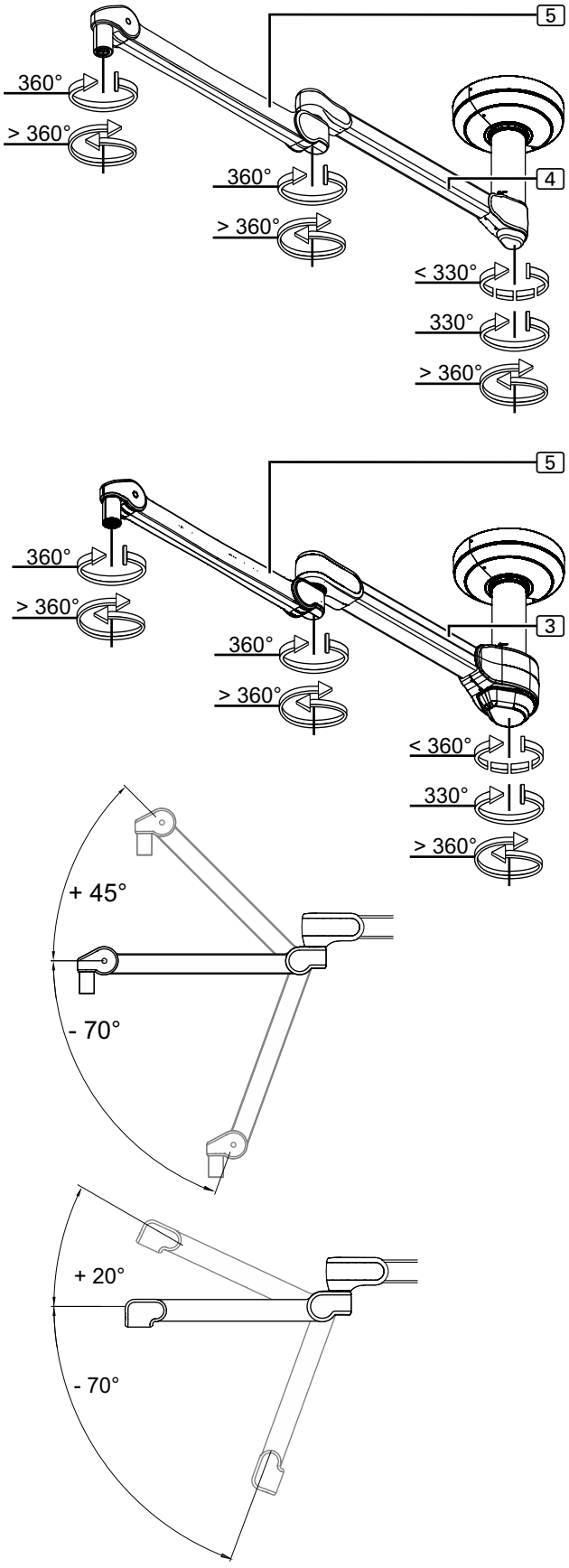
NOTE if necessary to achieve the IMMUNITY TES LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. the 1m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are include
[b] The carrier shall be modulated using a 50% duty cycle square wave signal.
[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Recommended separation distance between portable an mobile RF communications equipment and the Product			
The Product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Product as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz *d = 1,2√P*	**80 MHz to 800 MHz** *d = 1,2√P*	**800 MHz to 2.7 GHz** *d = 2,3√P*
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: at 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects an people.			

Part 3: Claro™ Lights Pendant System

Figure 17: Positioning the pendant system



8.1 Positioning the pendant system

(See "Figure 17")

The Figure illustrates the configuration example of the central axis.

The extension arm [3]/[4], spring arm [5] and the adaption with end device (e.g. flat screen, OR light, etc.) can be positioned easily.
The swivel range and the vertical lift can be restricted through internal end stops.

8.1.1 Swivelling the pendant system

(See "Figure 17")

NOTICE

Damage to the pendant system

To prevent damage to the pendant system:

- Do not hit the end stops hard,
- avoid collisions with other components.

- Slowly swivel the end device (e.g. flat screen, OR light, etc.).

– Depending on the individual version the swivel range ends at the internal end stops of the extension arm [3]/[4] and the spring arm [5].

8.1.2 Adjusting the height of the pendant system

(See "Figure 17")

NOTICE

Damage to the pendant system

If the end device (e.g. flat screen, OR light, etc.) is moved upwards, there is a risk that it collides with other components.

- Prior to adjusting the height, check for potential risks of collision.

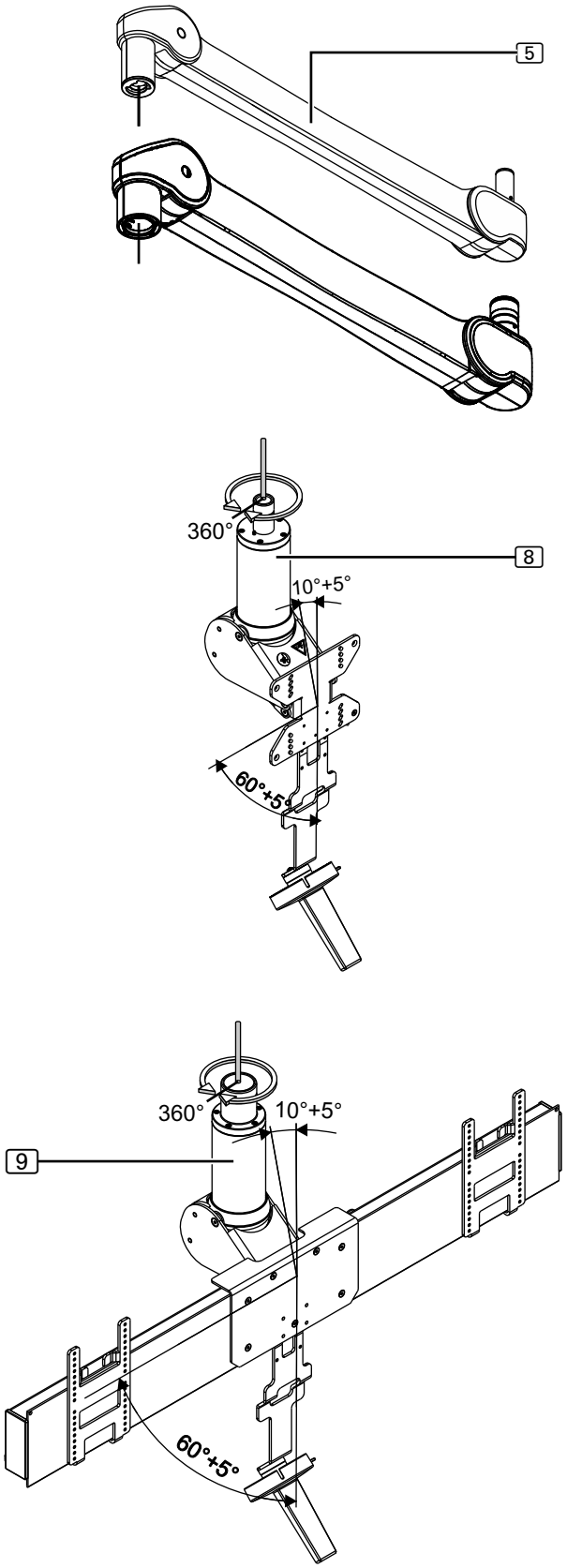
- Slowly adjust the height of the end device (e.g. flat screen, OR light, etc.).

– The height adjustment is restricted by the internal end stops of the spring arm [5].

If the extension arm [3]/[4], the spring arm [5], the adaption or the end device (e.g. flat screen, OR light, etc.) do not remain stable in the set position, the spring tension or brake force must be adjusted by a service technician. Contact your operator for this task.

Part 4: Claro™ Lights Monitor Carrier

Figure 18: Positioning the monitor carrier



9.1 Positioning the monitor carrier

(See "Figure 18")

The Figure shows a simplified illustration without flat screen.
The swivel range, the vertical lift and the tilting angle are restricted through internal end stops.

9.1.1 Swivelling the monitor carrier

(See "Figure 18")

NOTICE

Damage to the monitor carrier

To prevent damage to the monitor carrier and the flat screen:

- Do not hit the end stops hard;
- Avoid collisions with other components.

1. To swivel it, grab the monitor carrier [8]/ [9] by the handle or the frame of the flat screen.
2. Proceed slowly when swivelling the monitor carrier [8]/ [9].

- The swivel range is limited by the end stops of the spring arm [5].

9.1.2 Adjusting the height of the monitor carrier

NOTICE

Damage to the light system

If the monitor carrier is moved upwards, there is a risk that it collides with other components:

- Prior to adjusting its height, check for potential risks of collision.

- The height adjustment is limited by the internal end stops of the spring arm [5].

If the spring arm [5] or the screen do not remain stable in their set position, the spring tension or the brake force must be adjusted by a service technician. Contact your operator for this task.

9.1.3 Tilting the flat screen

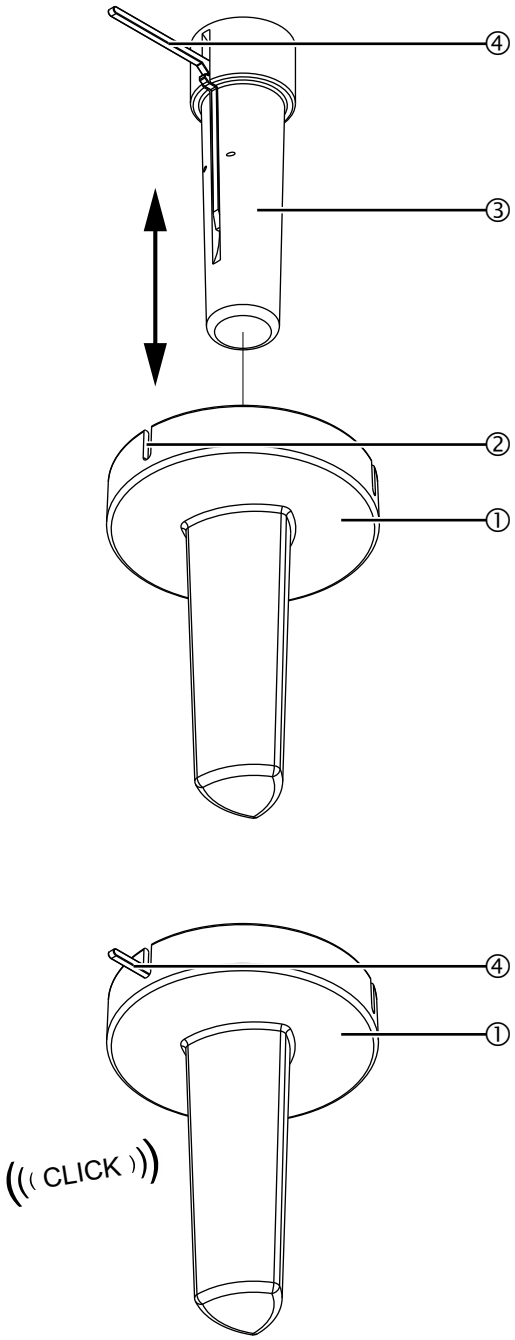
(See "Figure 18")

1. To tilt the flat screen, grab the monitor carrier [8]/ [9] by the handle or the frame of the flat screen and adjust the tilting angles as desired:

- Uppermost end stop positon: 10°+5°
- Lowest end stop postion: 60°+5

If the monitor does not remain stable in its set position or is not sufficiently flexible, the friction must be adjusted by a service technician. Contact your operator for this task.

Figure 19: Assembling/disassembling the sterilizable handle



9.2 Sterilizable handle of the monitor carrier

For sterile operation, the handle must be cleaned, disinfected and sterilized before each application.

9.2.1 Assembling/disassembling the sterilizable handle

(See 'Figure 19')

Before beginning an operation, the grip sleeve ① of the sterilizable handle must be disassembled for sterilization.

⚠WARNING

Risk of infection due to non-sterile handling

Sterilizable handle from ZIMMER BIOMET are supplied in non-sterile condition and must be sterilized before the first sterile application

- Improper sterilization or non-sterile handling of the handles may lead to serious health risks for patients.
- The operator/user is responsible for the cleaning, disinfection and sterilization of handles.
- Correspondingly approved sterilization packaging must be used for the sterilization, subsequent transport and storage, e.g. in accordance with EN 868, ISO 11607.
- National regulations must be strictly observed.

⚠WARNING

Risk of infection due to non-sterile handling

The guide on the grip holder is not sterile by design:

- This must be borne in mind when changing the sterilizable grip sleeve.

9.2.2 Disassembling the sterilizable grip sleeve

(See "Figure 19")

1. Loosen the grip sleeve ① by pressing on the guide ④ at the upper end of the grip holder ③ and pull it downwards.

9.2.3 Assembling the sterilizable grip sleeve

(See 'Figure 19')

2. Sterilize the grip sleeve ① of the sterilizable handle as per "Chapter 5.5" on Page 31.

NOTE: Cleaning and sterilization information

The cleaning and sterilization information in "Chapter 5.5" on Page 31 must be observed.

3. Slide the grip sleeve ① with one of the grooves ② into the guide ④ of the grip holder ③ until you hear it engage. A slight rotation to the left or right might be necessary for this step.

Part 5: Technical Data

General data	
Color	RAL 9010
Particular Standard	EN/IEC 60601-1 / 60601-2-41
Classification of Medical Device according to European Directive	Class I
Classification according to FDA for OR light	Class II
Approvals of the standard equipment	Product classified by UL
IP degree of protection	IP20
Operating conditions	Continuous operation
Handpiece steam sterilization	121°C (249,8°F) 1.3bar (18.9PSI) for 25 to 30 minutes 134°C (273,2°F) 2.3bar (33.4PSI) for 4 minutes
Mains power voltage insulation means	Outside the product (main switch) for ceiling versions
Technical details of light	
Diameter of light body [cm]	52 (21")
Light emission surface [cm^2]	736 (114")
Illumination Ec at 1 m -10% (d^1) [Lux]	160000
Illumination Ec at 1 m -10% (D^2) [Lux]	160000
Color temperature [K]	4,500 - 5,000
Color rendering index R_a [-]	96
R_9 [-]	>90
Light field diameter d_{50} [mm] (D)	124 (4.88")
Light field diameter d_{10} [mm] (D)	200 (7.87")
Lighting depth L1+L2 [mm] at 60% (4600K)	500 (19.69")
Lighting depth L1+L2 [mm] at 20%	1350 (53.15")
Max irradiance [W/m^2] (d)	580
Irradiance / Illumination [mW/m^2lx]	3.68
Max radiation in UV [W/m^2]	0.04
Ec 1 mask [Lux]	55,000
Ec 2 masks [Lux]	68,000
Ec with cylinder [Lux]	163,000
Ec with cylinder and 1 mask [Lux]	55,000
Ec with cylinder and 2 masks [Lux]	71,500
[1]d = with small diameter selected; [2]D = with big diameter selected	
All technical light measurements are to be deemed with a tolerance of ±6% for metrological and manufacturing reasons	

Essential performance	Distribution of minimum and adequate lighting (luminous flux emitted by the EM equipment shall not vary by more than 20% during use; the color temperature and color rendering index shall be stable and within the range 3000K-6700K and 85-100, respectively; E_c value shall be ≥ 40,000 lux and ≤ 160,000 lux).
	Limitation of energy in the operating field (UV-irradiance for wavelengths below 400 nm shall not exceed 10 W/m^2; and the total irradiance E_e in the lighted area shall not exceed 1000 W/m^2 at a distance of 1000 mm (40") ; Ec value shall be ≥ 40,000 lux and ≤ 160,000 lux; E_e/E_c ≤ 6 mV/m^2lx).

Power connection details of light	
Primary alternate voltage [Volt ac]	100 - 240
Frequency [Hz]	50 / 60
Absorbed power [VA]	60
Light source	No. 29 LED
Duration of LED diode light source [hr] (this figure can vary according to power peaks and operating frequency)	60,000
Light intensity control [%]	20-100
Technical details of pendant system	
Product labels	The Light System Claro™ Lights product label is located on the right side of the lowest extension arm (see Chapter 2.4, “Information on the product label”, on Page 20).
Noise level	Sound energy level 65db(A) (EN ISO 3746) not exceeded
Technical details of spring arms	
Product label	The product label is attached to the top side of the spring arm.
Maximum load bearing capacity:	
• springarm L21	1.5 - 21.0 kg
• springarm MD21	1.5 - 21.0 kg
• springarm MD40+	18 - 40 kg
• spring arm LCH17	20 - 176 Nm
Technical details of monitor carriers	
Product labels	The product labels is attached: •to the holding bracket of the monitor carrier
Approved flat screen size	up to 32"
Maximum loading capacity:	
• monitor carrier single	17.5 kg
• monitor carrier dual	35 kg
Electrical data	Depending on the customer-specific equipment (see product label)
Operating forces allowed when moving the flat screen	manual force for tilting <25N manual force for swivelling <20N

Adaptions	
Approved adaptions	• The components have been adapted to each other and are safe to operate. Any other type of installation, and in particular the use of components from third-party manufacturers, is strictly prohibited because these components can be potential sources of danger. • The combination of any other ZIMMER BIOMET product with the light system must be approved by ZIMMER BIOMET. If applicable, the conformity assessment must be repeated. • The maximum weight indicated on the product label of the light system must not be exceeded.

Combined medical products	
Read the Operating Instructions for combined medical products	• The monitor carrier is equipped with a flat screen from a third-party manufacturer. To prevent dangerous overload, which can damage or lead to a collapse of the light system, the maximum loading capacities specified in “Technical details of monitor carriers”, on Page 55 must be adhered to: – The party placing the device into operation is responsible for the validation of the overall system.

ZIMMER BIOMET

No. 1571192