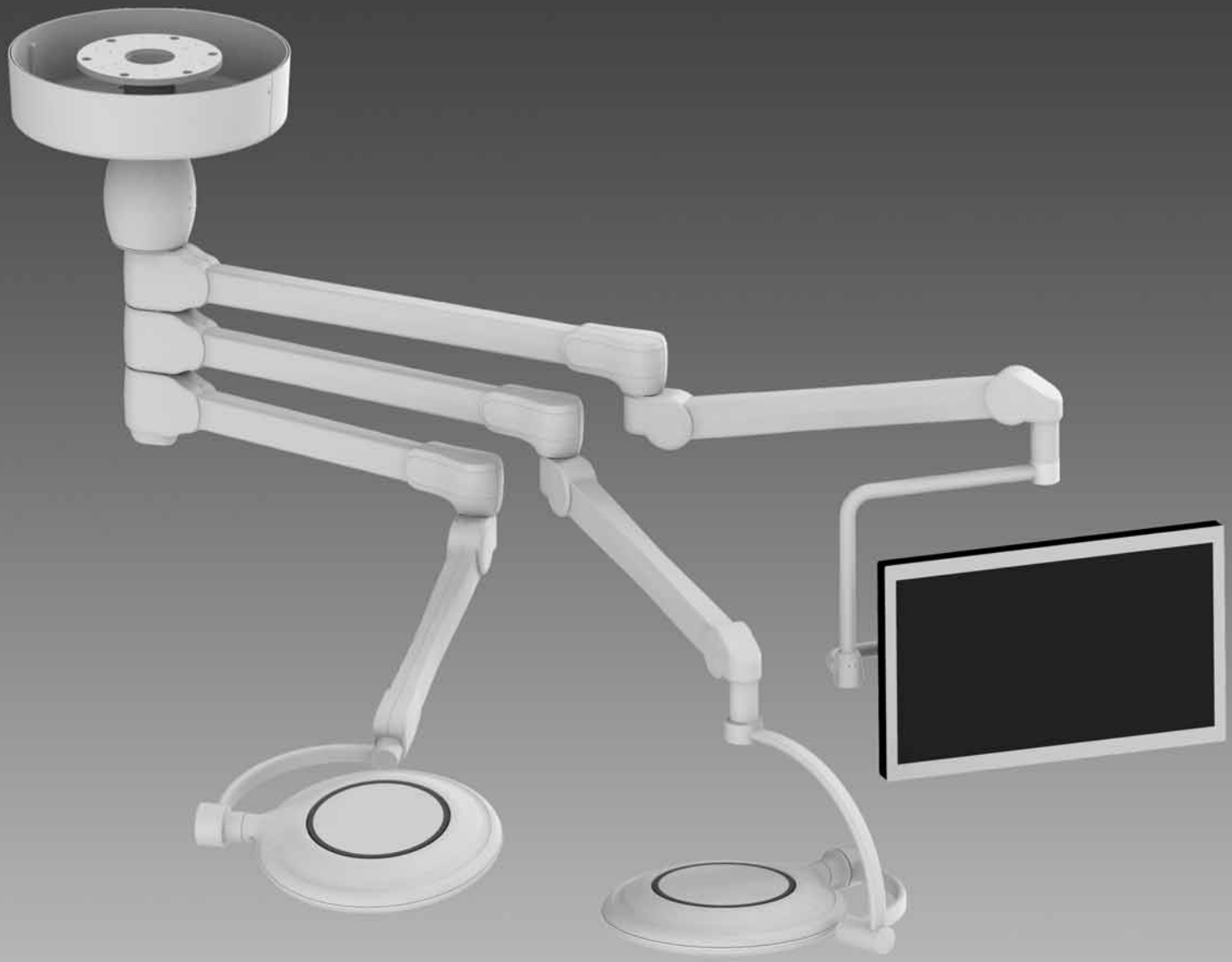

Operation Manual [English]

Light System DoVera DM520

SKYTRON®

Thank you very much for purchasing this SKYTRON 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?

Light System DoVera DM520

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

US - SKYTRON
5085 Corporate Exchange Blvd. S.E.
Grand Rapids, MI 49512 • USA
Phone: +1 / (616) 656-2900

Internet www.skytron.us
E-mail address info@skytron.us

Manufacturer

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

EC REP

Ondal Medical Systems GmbH
Wellastraße 6
36088 Hünfeld
Germany

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- Any other use than that regulated by law must be approved in writing by SKYTRON.
- SKYTRON 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

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

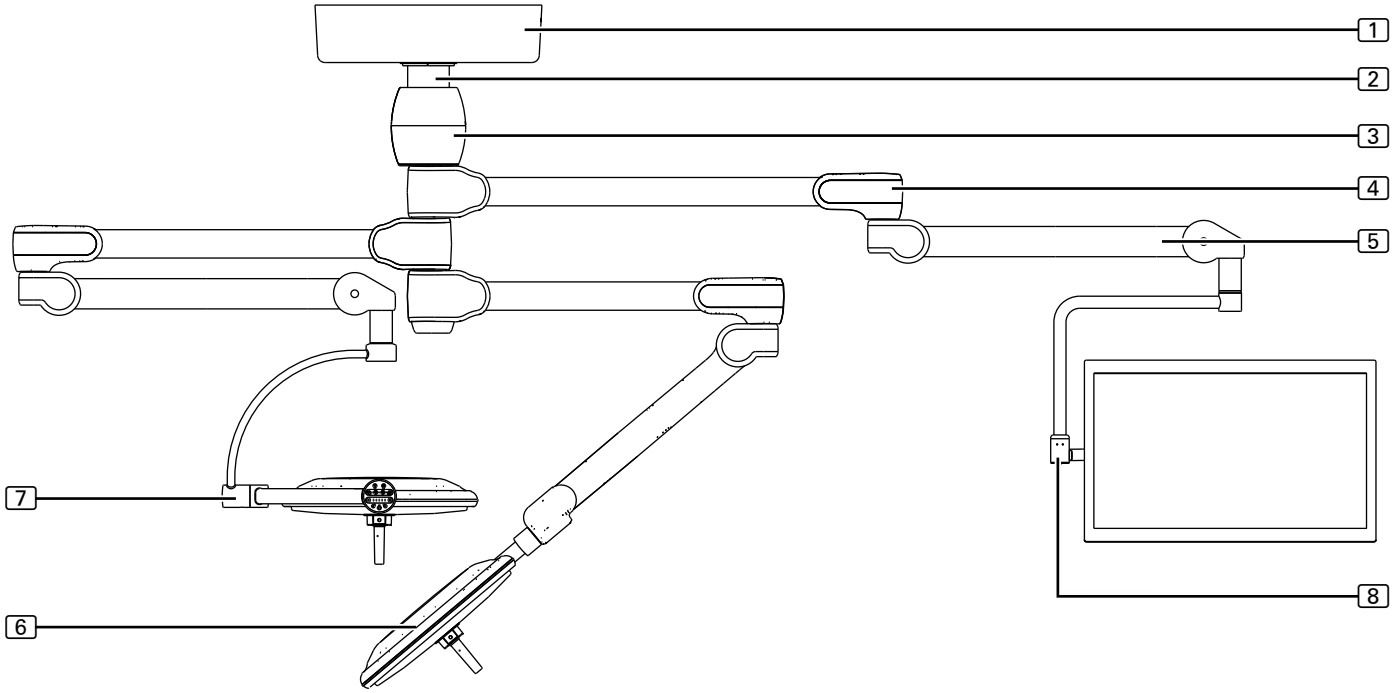
Modifications to the Operation Manual

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

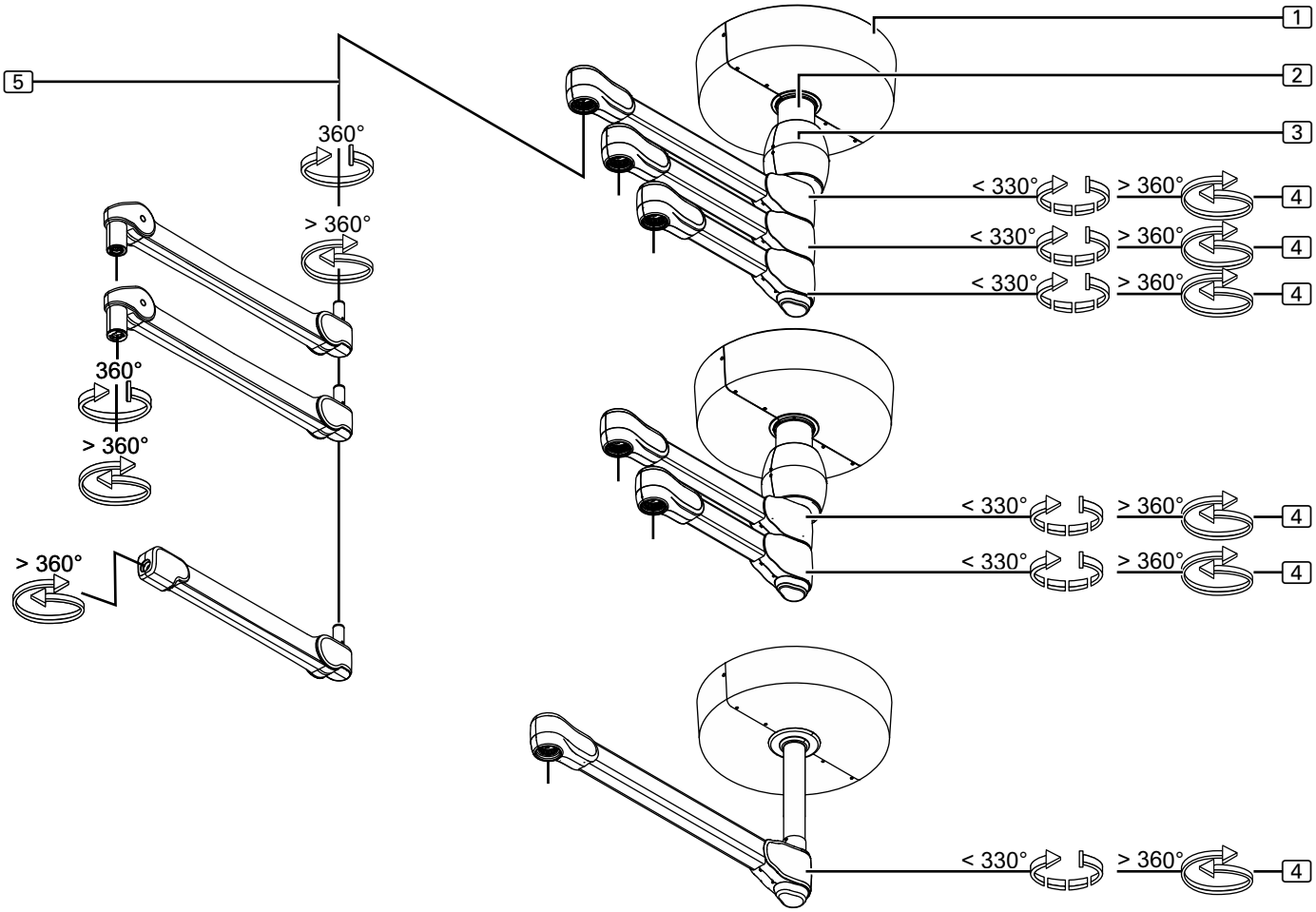
Trademarks

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

Light System DoVera DM520



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.

Rotating canopy

The end device on the top arm of a 2-fold or 3-fold system is a light with camera or a monitor, the internal cables for the end device are housed in the rotating canopy [3].

Extension arm

Depending on the version, the central axes are equipped with 1 to 3 extension arms [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 [4] is configured for different swivel ranges:

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

The extension arms [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 [4] and the spring arms [5].
The end stop in the extension arms [4] and the spring arms [5] prevents these supply cables being sheared off.

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

The extension arms [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 [4] and the spring arms [5] can be rotated without restriction.

Extension arm with a comfort end stop (swivel range adjustable in graduations of 15 degrees)

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

Spring arms

If equipped with an end stop, the spring arms [5] can be rotated 360 degrees horizontally; without an end stop, it can be rotated without restriction. The spring arms [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 [8] is used to support and position a flat screen.

Functional description

Extension arm

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

Brakes on the extension arm

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

Spring arms

The spring arms [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

Spring arm version

In order to prevent collisions with the ceiling or other components, the vertical lift of the spring arms [5] can be restricted. The vertical lift is defined during installation.
Identify the version of the spring arms [5] mounted according to the information on the product label. The product label is attached to the top side of the spring arms [5].
For more detailed information on how to adjust the vertical lift, please contact your local SKYTRON 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 arms [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

Spring arm version

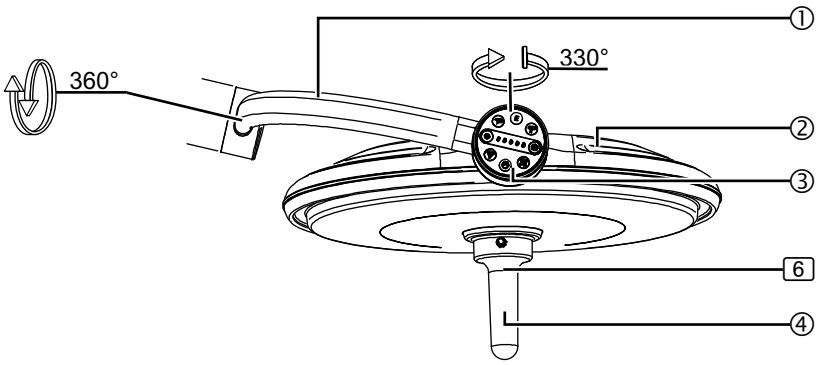
If the spring arm [5] with the end device (e.g. flat screen, OR light, etc.) moves down or if a new end device is mounted, the spring tension of the spring arm [5] must be readjusted.
Identify the version of the spring arm [5] mounted according to the information on the product label. The product label 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 SKYTRON representative.

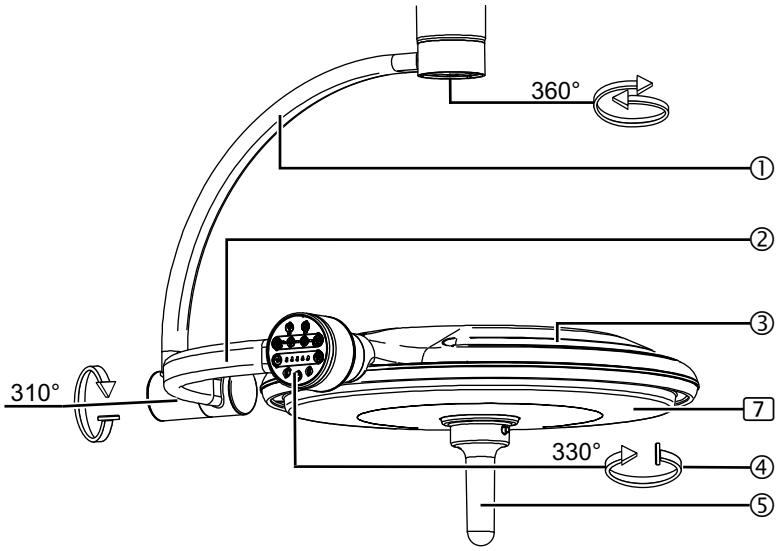
Brakes on the spring arm

Spring arm version

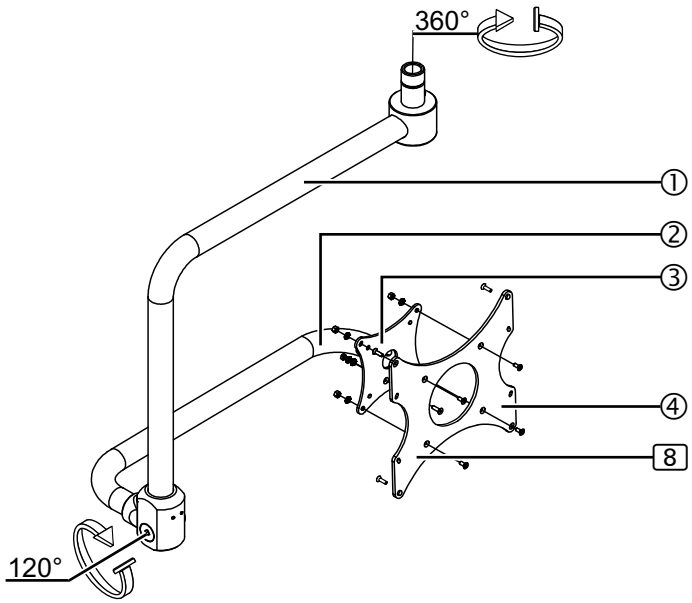
The spring arms [5] are equipped with brakes. The brakes hold the adaption and the end device (e.g. flat screen, OR light, etc.) in the set position.
Identify the version of the spring arm [5] mounted according to the information on the product label. The product label is attached to the top side of the spring arm [5].
For more detailed information on how to adjust the brake force, please contact your local SKYTRON representative.

Versions of the OR lights





Version 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 [8]

① Supporting tube,
② Monitor carrier,
③ Vesa interface,
④ Vesa adapter plate.

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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: Light System DoVera DM520

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: 1567030, Edition 2020-04, Version 1

- 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 appliance 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 appliance during operation.
- The operator shall be liable for handing over a safe appliance and for instructing the user in the proper operation and normal use of the appliance.

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 appliance and to work with it.
- Users shall be fully responsible for the safe operation of the appliance 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 appliance 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 appliance 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 SKYTRON or companies authorized by SKYTRON. As a prerequisite for the authorization of a company, its service technicians must have successfully participated in technical training organized by SKYTRON. 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 appliance must be thoroughly cleaned and disinfected.
- The instruction for the proper installation of the appliance is included in the Installation Instructions applicable for the appliance.

1.4.2 Availability of this Operation Manual

Duty to inform

- Since this Operation Manual is an integral part of the appliance, it must always be kept near the appliance in order to be able to look up safety instructions and important information on use at any time.
- Do not pass on the appliance 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 appliance.

1.4.3 Warranty

- Pay attention to the warranty requirements as described in the separate warranty document.

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 appliance

Instruction

- The instruction must be carried out on the appliance immediately by SKYTRON, by a company authorized by SKYTRON.
- 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 to installation of the appliance. This ensures that you benefit from all the advantages of the appliance and prevents any risk of injury or damage.
- Prior to any use or transfer for use, the functional reliability and proper condition of the appliance 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 SKYTRON representative for your own safety.

1.5.3 Standards and directives

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

- Medical Devices Act (MPG)
- FDA 21 CFR 820
- 93/42 EEC (Medical Device Directive)
- 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 SKYTRON product with the light system must be approved by SKYTRON. 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

Explosion hazard: warns of the improper use of oxygen (see Chapter 2.7, “Proper use of oxygen”, on Page 25).

Danger of fire: warns of the improper use of oxygen (see Chapter 2.7, “Proper use of oxygen”, on Page 25).

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.

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.

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

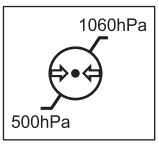
Environmentally friendly disposal: warns of damage to the environment caused by improper disposal of the pendant system (must not be disposed of as normal household waste).

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.

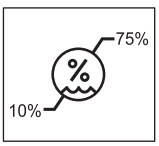
CE mark: The manufacturer declares that the products comply with the relevant regulations set forth in the applicable European Directives.

This symbol marks the product as a component approved by a "Nationally Recognized Testing Laboratory" which complies with both Canadian and US deviations from applicable standards.

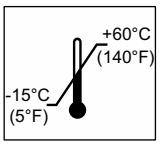
MEDICAL - GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH
ANSI/AAMI ES 60601-1:2005/AMD1:2012;
IEC 60601-2-41:2009 / AMD1:2013;
CAN/CSA-C22.2 No. 60601-1:2014;



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

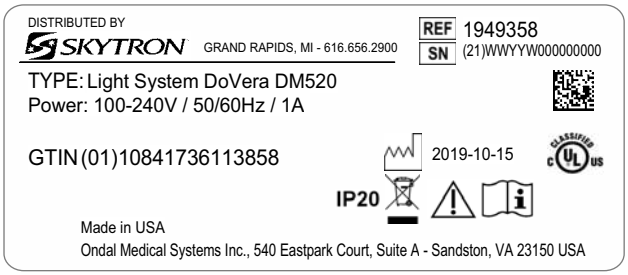


Relative humidity: indicates the permissible humidity values in a range from 10 % to 75 % for transport and storage.



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



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 Light System DoVera DM520 product label.

- The Light System DoVera DM520 product label is located on the right side of the lowest extension arm.

Global Trade Item Number

- The GTIN (01) is a global article number and is assigned by GS1. It serves for the exact identification of the product.

Serial number

- The product label indicates the serial number (SN/21) 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 40.

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-SKYTRON accessories or parts such as disposable handles may fall off the light. Ensure that only SKYTRON / DoVera 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

Light system 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 the individual components. In this case, there is a risk of the light system or components of the light system disengaging from the device and dropping.

2.7 Proper use of oxygen

⚠ DANGER

Oxygen explosion

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

- Make sure that the oxygen and gas outlet points are free from oily, greasy and lubricating materials!
- Do not use any cleaning agents containing oil, grease or lubricants.

Danger of fire

Escaping oxygen is combustible:

- 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 SKYTRON 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 SKYTRON 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 SKYTRON 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 Handle sterilization

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 132 °C (270 °F) 2.3 bar (33.4 PSI) for 4 minutes

Do not exceed a sterilization temperature of 132 °C (270 °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.

Part 2: Light System DoVera DM520

Figure 2: Optional wall control

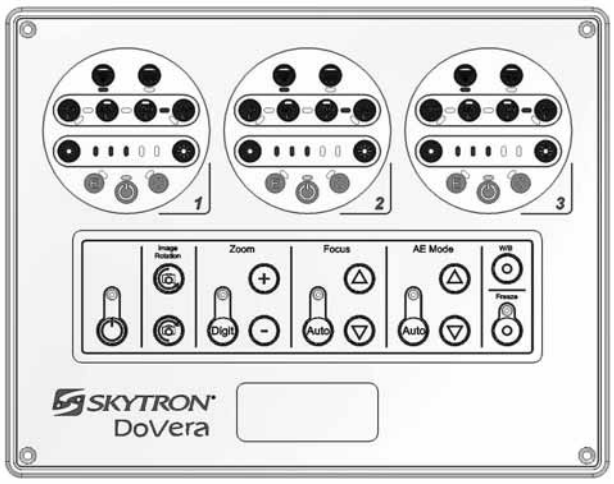


Figure 3: Keyboard

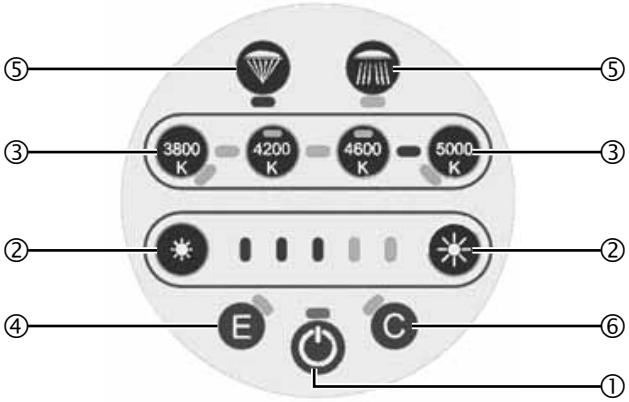


Figure 4: Capacitive control on handle

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:

(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 blue LEDs;

③ Color temperature buttons
- Select color temperature from among 7 values - 3800K, 4000K, 4200K, 4400K, 4600K, 4800K and 5000K by pressing the buttons indicating the value. Press the button twice to select intermediate values;

④ “Endoled” function
- Enable the “Endoled” 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 Courtesy light button
- Enable the courtesy light (also known as the ambient light) by pressing the C button.

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.

6.1.3 Capacitive control on handle

(See "Figure 4")

The same function of light intensity adjustment, button ② (see “Figure 3:”) on the keyboard, can be done through the sterilizable handle.
Touching the sensors on the handle will either increase or decrease the light intensity. The sensors are indicated by a lowered circle ⑦ and a raised circle ⑧ at the top of the handle, which allows you to adjust the intensity by feel. Press the circle once to incrementally change the intensity. Hold your finger or thumb on the circle to rapidly change the intensity. The lowered circle ⑦ decreases the intensity. The raised circle ⑧ increases the intensity.
The light intensity can be adjusted without losing sight of the working area.

Figure 5: Moving the product

6.1.4 Moving the product

(See "Figure 5")

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

Figure 6: Setting the light intensity

6.1.5 Setting the light intensity

(See "Figure 6")

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 7: Handle

6.1.6 Removing the handle

(See "Figure 7")

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

6.1.7 Installing the handle

(See "Figure 7")

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

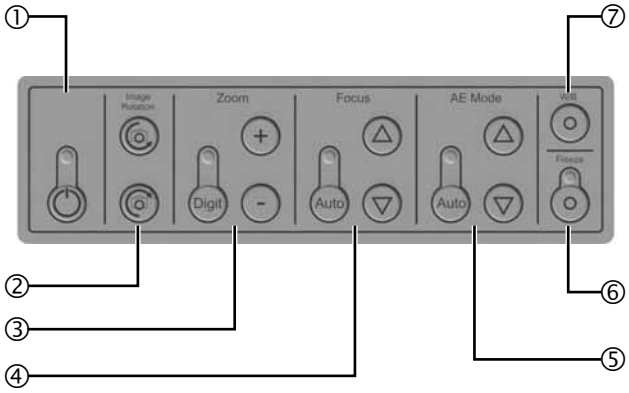
Figure 8: Camera

6.1.8 Optional camera

(See "Figure 8")

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 9: Camera keyboard



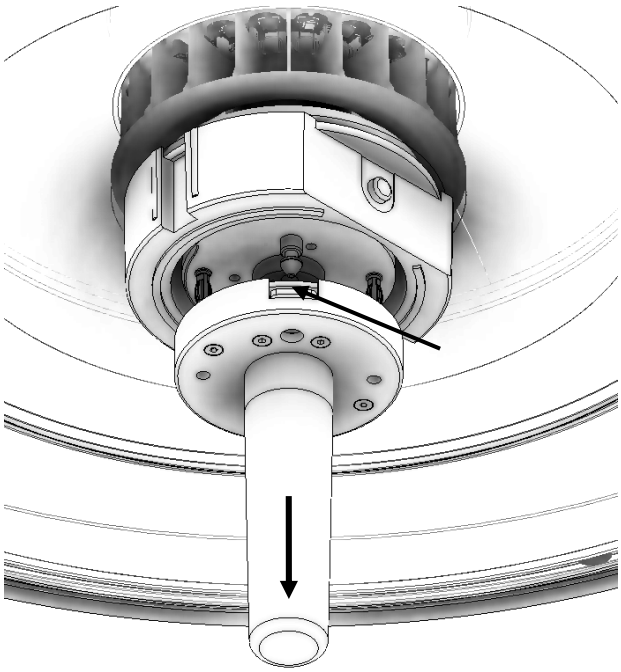
6.1.9 Optional camera control keyboard

(See "Figure 9")

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 10: Adapter

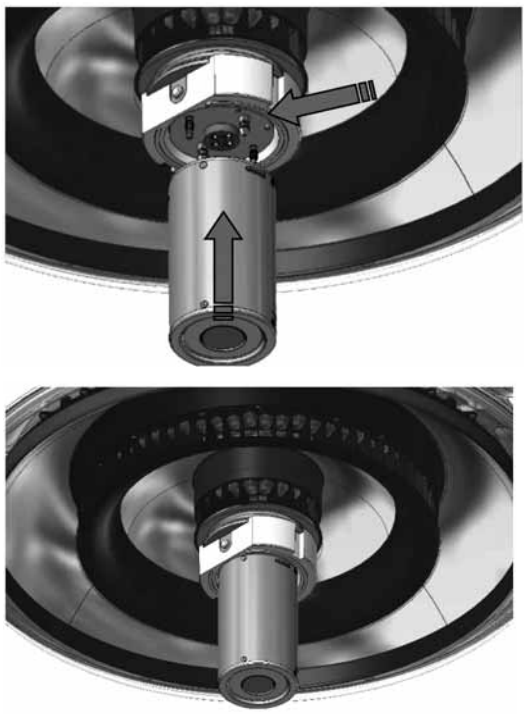


6.1.10 Removing the handle of the camera ready light head

(See "Figure 10")

If a handle is installed go to Chapter 6.1.6, “Removing the handle”, on Page 33 and remove it as described.
Then Press the lever of the adapter and remove it.

Figure 11: Camera installation

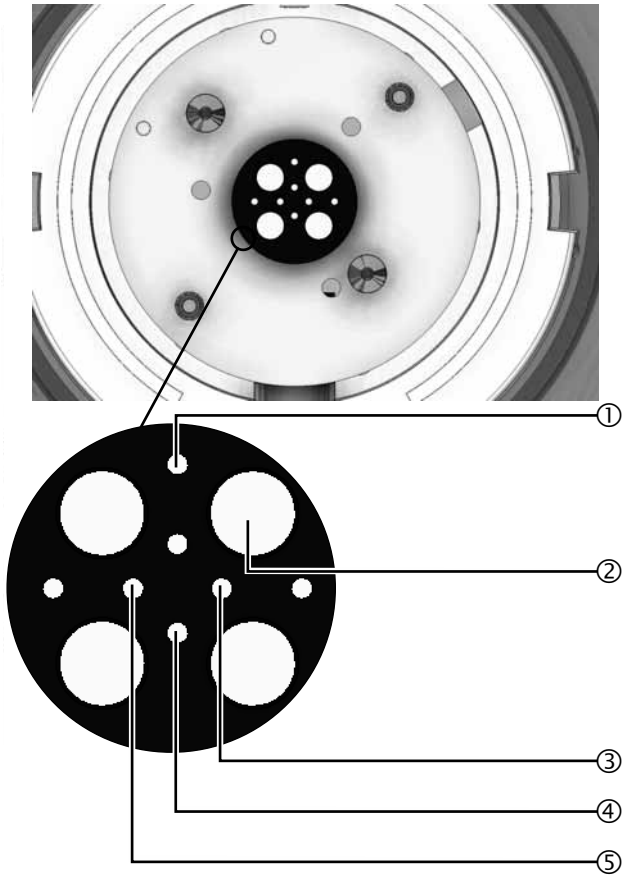


6.1.11 Camera installation

(See "Figure 11")

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 12:” and “Figure 13:” on Page 36.
Press the lock lever, fit the camera up tight and release the lever.

Figure 12: Light head



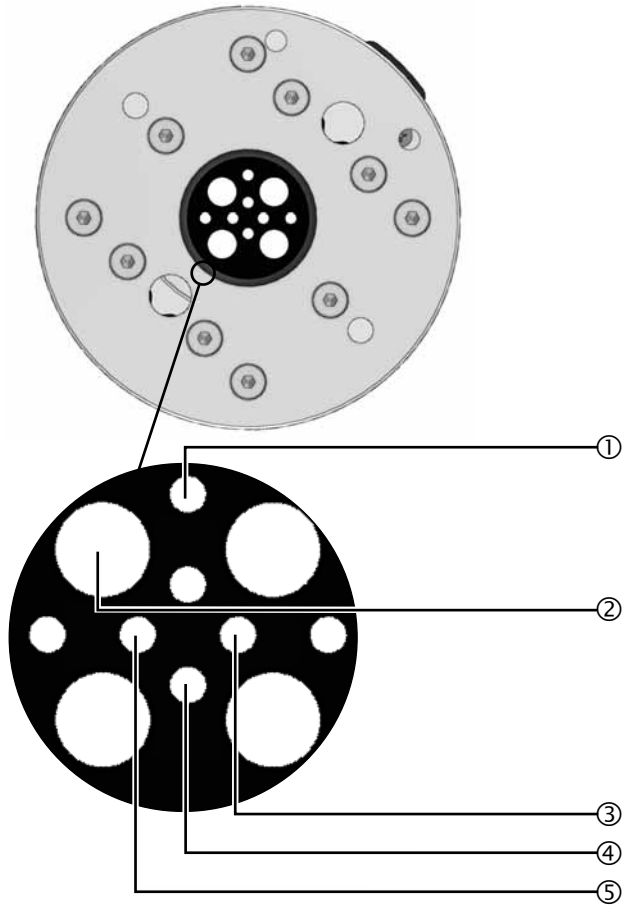
6.1.12 Camera connection light head side

(See "Figure 12")

The locating pins on the light head adapter must be aligned with the corresponding holes in the camera see “Figure 13:”.
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 13: Camera

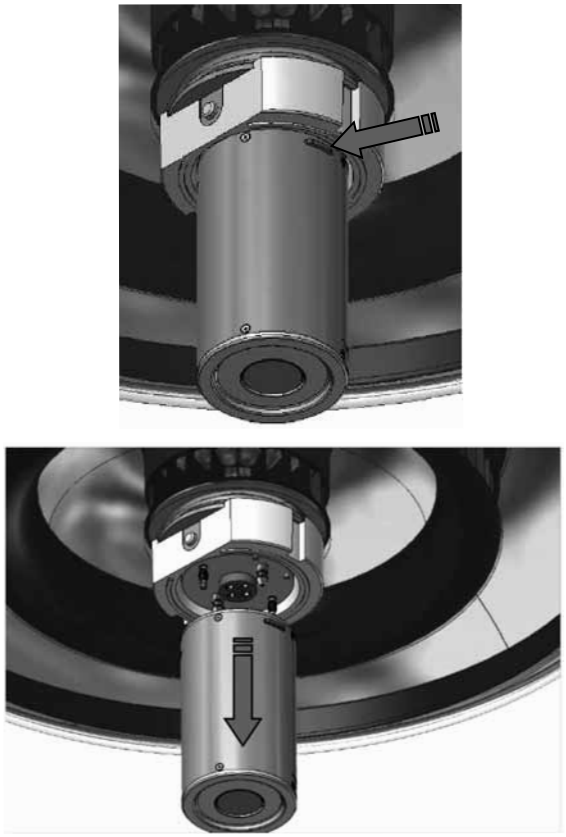


6.1.13 Camera connection camera side

(See "Figure 13")

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

Figure 14: Removing the camera



6.1.14 Removing the camera

(See "Figure 14")

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

Figure 15: Camera handpiece installation

6.1.15 Camera handpiece installation

(See "Figure 15")

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

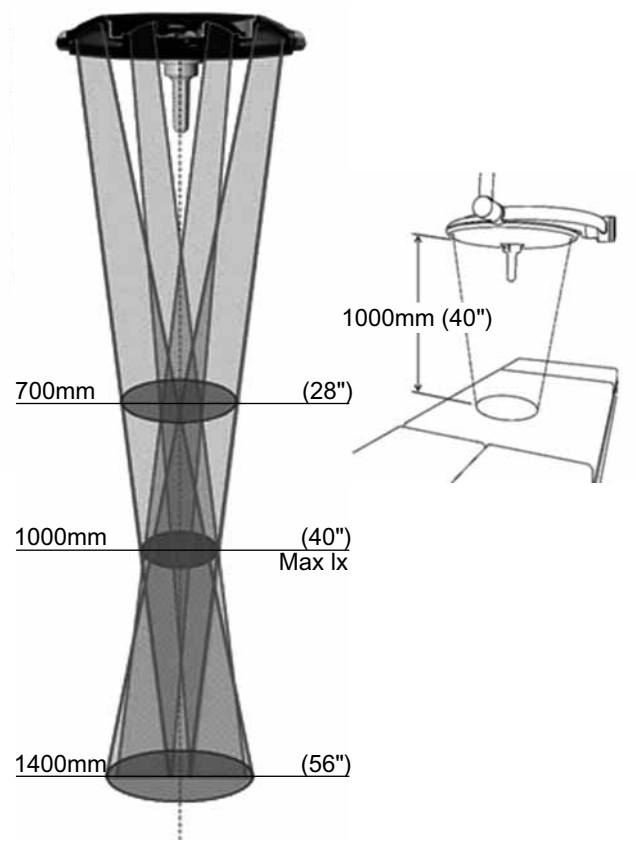
Figure 16: Removing the handpiece

6.1.16 Removing the handpiece

(See "Figure 16")

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

Figure 17: Recommended work distance



6.1.17 Recommended work distance

(See "Figure 17")

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	

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						

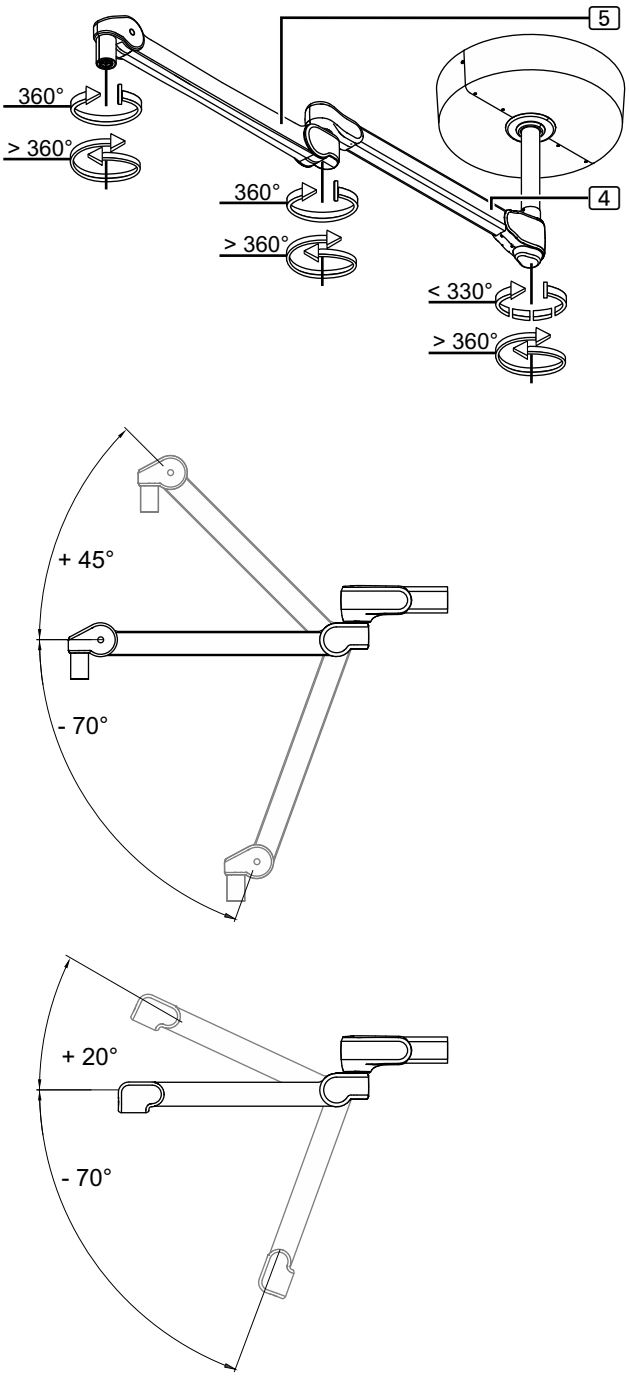
NOTE if necessary to achieve the IMMUNITY TES LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. the 1m test distance is permitted by IEC 61000-4-3.

[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: DoVera Pendant System

Figure 18: Positioning the pendant system



8.1 Positioning the pendant system

(See "Figure 18")

The Figure illustrates the configuration example of the central axis.

The extension arm [4], spring arm [5] and the adaptions 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 18")

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 [4] and the spring arm [5].

8.1.2 Adjusting the height of the pendant system

(See "Figure 18")

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.

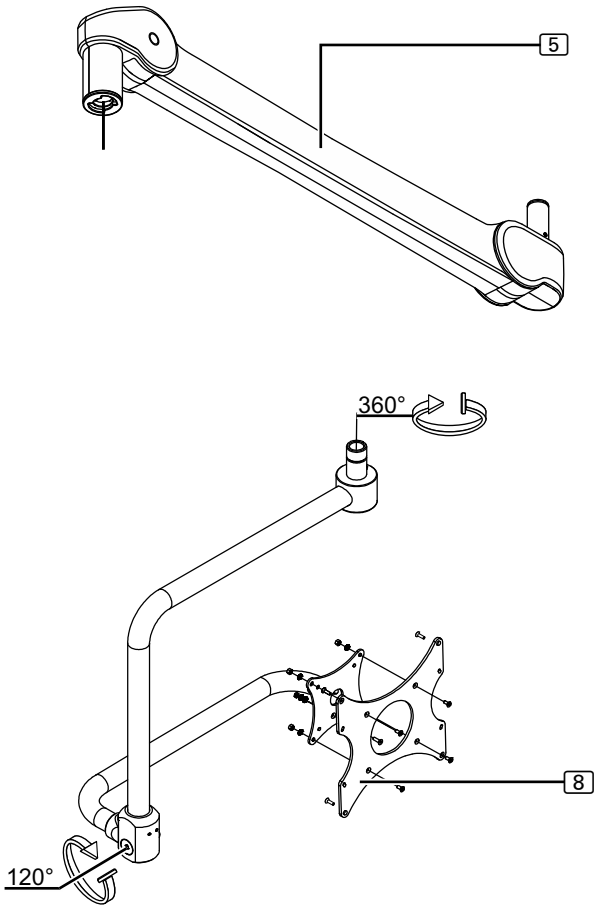
- Slowly adjust the height of the end device (e.g. flat screen, OR light, etc.).

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

If the extension arm [4], the spring arm [5], the adaptions 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 as described in the service manual.

Part 4: DoVera Monitor Carrier

Figure 19: Positioning the monitor carrier [8]



9.1 Positioning the monitor carrier

(See "Figure 19")

The swivel range and the vertical lift can be restricted through internal end stops.

9.1.1 Swivelling the monitor carrier

(See "Figure 19")

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] by the frame of the flat screen.
2. Proceed slowly when swivelling the monitor carrier [8].

- The swivel range is limited by the end stops of the monitor carrier [8].

9.1.2 Adjusting the height of the monitor carrier

NOTICE

Damage to the pendant 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 as described in the service instructions.

Part 5: Technical Data

General data	
Color	RAL 9010
Applicable European Directive	93/42/EEC and 2007/47/EC
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	132 °C (270 °F) 2.3 bar (33.4 PSI) 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]	1350 (210 ")
Illumination Ec at 1 m -10% (d^1) [Lux]	160000
Illumination Ec at 1 m -10% (D^2) [Lux]	160000
Color temperature [K]	3,800 - 4,000 - 4,200 - 4,400 - 4,600 - 4,800 - 5,000
Color rendering index R_a [-]	95
R_9 [-]	95
Light field diameter d_{50} [mm] (D)	82.5 (3.25")
Light field diameter d_{10} [mm] (D)	164 (6.45")
Lighting depth L1+L2 [cm] at 60% (4600K)	L1 = 231 mm (9.1"); L2 = 142 mm (5.6 ") L1 + L2 = 373 mm (14.7 ")
Max irradiance [W/m^2] (d) (3800K)	583,8
Irradiance / Illumination [mW/m^2lx]	3.8
Max radiation in UV [W/m^2]	0.002
Ec 1 mask [Lux]	69,000 (d) / 67,500 (D)
Ec 2 masks [Lux]	80,000 (d) / 72,000 (D)
Ec with cylinder [Lux]	165,000 (d) / 151,000 (D)
Ec with cylinder and 1 mask [Lux]	74,000 (d) / 74,000 (D)
Ec with cylinder and 2 masks [Lux]	85,000 (d) / 75,000 (D)
[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
Power input [W]	87
Power consumption OR light [W]	79
Light source	No. 84 LED
Duration of LED diode light source [hr] (this figure can vary according to power peaks and operating frequency)	60,000
Light intensity control [%]	25-100
Technical details of pendant system	
Product labels	The Light System DoVera DM520 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
• spring arm LCH17	20 - 176 Nm
Technical details of monitor carrier	
Product labels	The product labels are attached: •on the VESA interface of the monitor carrier, •on the VESA interface of the adapter plate.
Approved flat screen width/height	max. of 800/600 mm (32"/24")
Dead weight	4.5 kg
Maximum loading capcity	16.5 kg
Electrical data	Depending on the customer-specific equipment (see product label)
Operating forces allowed when swivelling the flat screen	During the swivel motion, make sure that the flat screen does not hit the end stops of the monitor carrier hard. The operating forces when traveling to the end stop must not exceed 20 N.

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 SKYTRON product with the light system must be approved by SKYTRON. If applicable, the conformity assessment must be repeated. • The party placing the appliance into operation is responsible for the validation of the overall system. A conformity assessment procedure shall be executed if required and a declaration in accordance with Article 12 of 93/42/EEC (Medical Device Directive, MDD) shall be provided. • 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 carrier”, on Page 51 must be adhered to: – The party placing the device into operation is responsible for the validation of the overall system. A conformity assessment procedure shall be executed if required and a declaration in accordance with Article 12 of 93/42/EEC (Medical Device Directive, MDD) shall be provided.

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