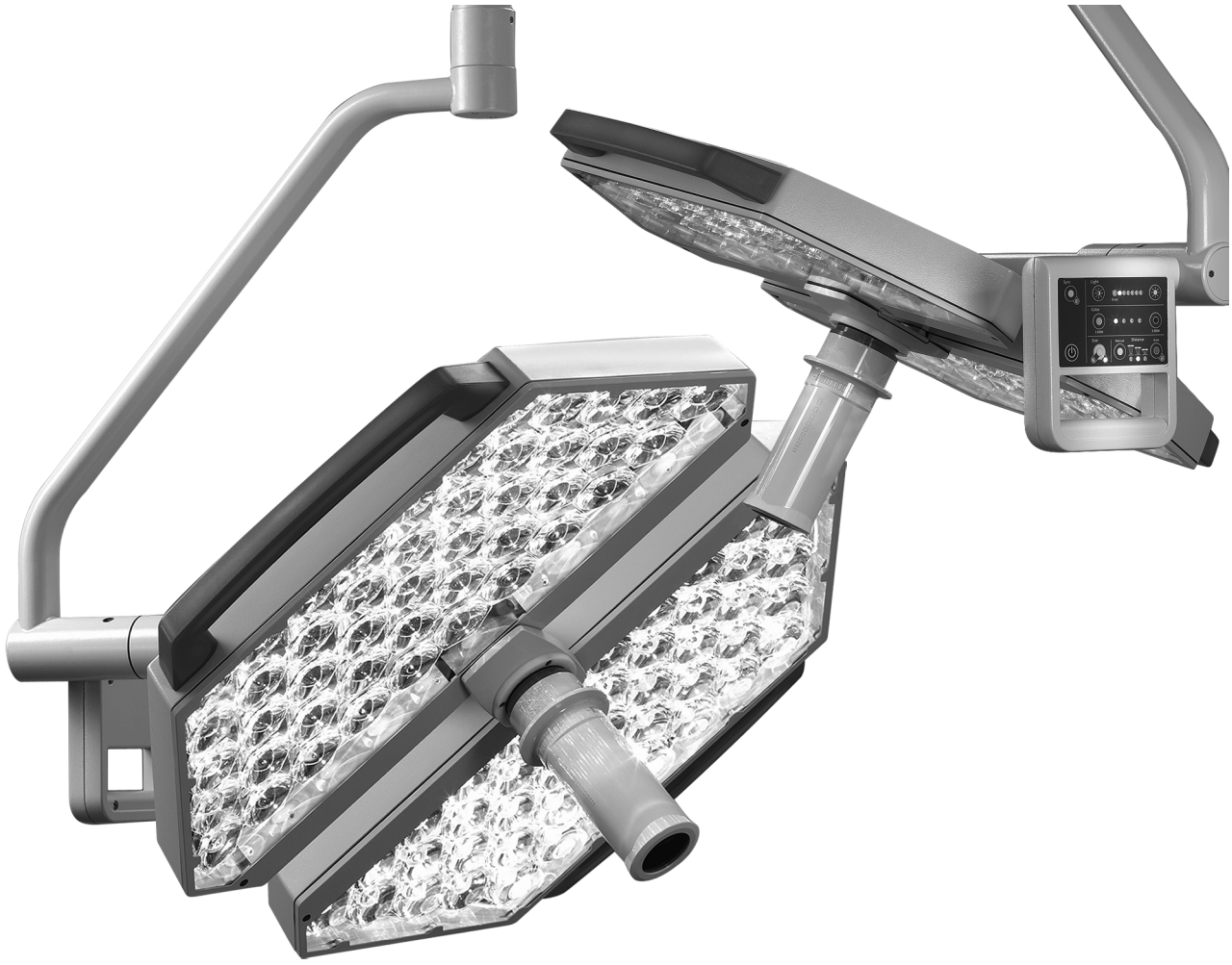
Trumpf Medical

Instruction manual

TruLight 5000/3000 lighting system



Read the instruction manual before using the product and store for later reference.

Englisch
en-GB

Enhancing outcomes for patients and their caregivers: Hill-Rom

for buying the new TruLight 5000/3000 lighting system. Please read through this instruction manual carefully and ensure adherence to all safety instructions and requirements regarding the operation and care of the device.

This instruction manual applies to

the TruLight 5000 and TruLight 3000 lighting systems:

- Implementation as an individual, small surgical light with a light head in stand, wall-mounted or ceiling-mounted versions.
- Implementation as surgical lighting system, including the combination of two to three surgical lights mounted on the ceiling.
- Optional equipment, such as light head with camera or laser.

Light head

For both machine versions – TruLight 5000 and TruLight 3000 – both the large light head (Ø 730 mm) as well as the small light head (Ø 640 mm) are available with various adjustments for the size of the field of illumination, light intensity and colour temperature.

Optional camera system

The operation of the optional camera system is described in the following instruction manual:

- TruVidia SD camera system and VidiaPort TFT support arm system,
- TruVidia HD camera system and VidiaPort TFT support arm system,
- TruVidia 3D camera system and VidiaPort TFT support arm system.

Manufacturer and distributor

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- Trumpf Medical will assume no liability whatsoever arising from or connected with the use of unapproved information by any person or company.

Modifications and translations

Modifications to the device

We constantly work on the further development of our products and reserve the right to make changes to the scope of delivery in terms of form, equipment and technology.

Changes to the instruction manual

- The content of the instruction manual can be changed at any time without prior notice.
- Please keep up to date on the current version of the instructions, e.g. using the TRUMPF Medical Online Information System (OIS) at regular intervals.

Translations

- The German-language version of this instruction manual shall be binding as regards translations into foreign languages.

1.1 Details for the identification of the system

This instruction manual is solely intended for systems with rating plates that show the following information:

System identification

- TruLight single 4038110
- TruLight mobile 4038120
- TruLight wall 4038130
- TruLight duo 4038210
- TruLight trio / quad 4038310

1.2 Details for identification of the instruction manual

Updated status of this instruction manual

To indicate the updated status of the instruction manual, all pages are marked with a 7-figure identification number and the status:

Identification of the instruction manual

- Material no.: 1756789
- Date of publication: 2017-09-06
- Document number: 55000-00011_002_01

This identification coding is binding for the validity of the instruction manual and must not be removed irrespective of the type of publication (in printed or electronic form, in full or excerpted).

1.3 Designation of groups of individuals

The following groups of individuals are named in this instruction manual.

1.3.1 Operator

An operator (e.g. a medical practice, hospital, etc.) is any natural or legal person who owns a device and is authorised to use it or by whose authority the device is used.

- The operator is obliged to provide a safe device and appropriately instruct the user regarding operation and proper use of the device.

1.3.2 User

Users are individuals who by their qualifications or an appropriate briefing by specialist personnel are authorised to operate and work with the device.

- Users are fully responsible for the safe application of the device for the purpose intended.

1.3.3 Specialist personnel

Specialist personnel means authorised individuals, generally employed by the operator, who:

- have acquired their knowledge by a technical education in the field of medical technology,
- can assess the work they carry out on the basis of professional experience and briefing about safety regulations, and can recognize possible hazards in their work.
- In countries where there is certification regarding performance of work in the field of medical technology, classification as specialist personnel requires the corresponding authorization.

1.4 Information for operators

Procedural guidelines

The device has been manufactured to the current state of technology and is operationally safe.

- The device can nevertheless be a source of danger, especially when it is operated by inadequately trained personnel or is used incorrectly or not for the purpose intended.

- The device may only be operated, cleaned, disinfected and maintained by qualified personnel.

1.4.1 Initial commissioning

Scope

This instruction manual is only valid after successful initial operation by the operator or an installer authorised by the manufacturer.

- The device must be thoroughly cleaned and disinfected before its first use.
- Once the device has been released for use, the information in this instruction manual will be binding for the user.

1.4.2 Availability of the instruction manual

Obligation to inform

The instruction manual is part of the device and must therefore be kept in a place in the immediate vicinity of the device to allow consultation regarding safety instructions and important operating information at any time.

- Never hand the device to third parties without the valid instruction manual. Ensure that the instruction manual provided with the device is valid by checking the identity and version number.

1.4.3 Guarantee

Guarantee

Trumpf Medical guarantees the safety and functionality of the device as long as the following conditions are met:

- the device is exclusively used for the purpose intended and is operated and maintained in accordance with the provisions of this instruction manual
- only original spare parts or accessories approved by Trumpf Medical are used
- no modifications are made to the device
- inspections and maintenance work are carried out at the time intervals specified
- an initial commissioning is carried out and the device is released for operation with a handover declaration

1.4.4 Maintenance and repair

The device or parts thereof may only be maintained or repaired by:

- Trumpf Medical Customer Service
- authorised service companies trained by Trumpf Medical
- the operator's service personnel when trained and authorised by Trumpf Medical

1.4.5 Service life of the device

Trumpf Medical products are designed in compliance with all safety and maintenance requirements for a service life of 10 years.

- This life span includes the functionality of the product when used according to the specifications in the instruction manual, a guaranteed service and the supply with spare parts.
- Trumpf Medical makes use of a quality management system certified in accordance with DIN EN ISO 13485 for all company processes.
- This guarantees:
  - Top quality
  - Easy operation
  - Functional design
  - Optimisation for the intended purpose

1.5 Date of manufacture

The rating plate indicates the date of manufacture of the device. The position of the rating plate on the device is shown in Chapter 4.1, page 24.

1.6 Delivery

Before installation, check the delivered components for completeness and for any possible transportation damage.

- To check the delivery, unpack all components and carry out visual inspection.
- The components can be identified on the basis of the order number on the delivery note and / or the order-specific dimension sheet.

1.6.1 Transportation damage

Damage claims

Claims for damage cannot be accepted unless Trumpf Medical is notified without delay. In the event of damage during transport or missing components, please send Trumpf Medical a report containing the following information:

Accompanying documents

- Damage record giving details of damage or defects.
- Primary serial number of the device or system or the serial numbers of the damaged components,
- Order number (shown on the delivery note and/or the order-specific dimension sheet)
- Name and address of the customer,
- Consignee.

1.6.2 Return address

Returns

In the event of a return, use the original packaging if possible.
Address returns to:
TRUMPF Medizin Systeme GmbH + Co. KG
Carl-Zeiss-Straße 7–9
07318 Saalfeld
Germany

1.7 Information for users

Note that the device may only be operated by persons who have had the corresponding instruction.

1.7.1 Training for use of the device

Instruction

Training must be carried out directly at the device by qualified staff of the operator or by an installer of the device who has been authorised by the manufacturer.

- At the end of the briefing, it must be documented that the user in question has understood the special operating measures necessary regarding use for the intended purpose.

1.7.2 Obligation of the user to inform and to inspect

Dealing with problems

The instruction manual must be carefully read before commissioning to prevent possible injuries and damage to goods.

- Check the functional capability and correct condition of the device before every application or handover for use.
- While the device is in use, do not fail to comply with the provisions of the instruction manual.
- Get the information you require from the operator’s technical service or from Trumpf Medical in the event of specific problems that are not treated in sufficient detail in this instruction manual.

1.8 Purpose of the device

1.8.1 Identification

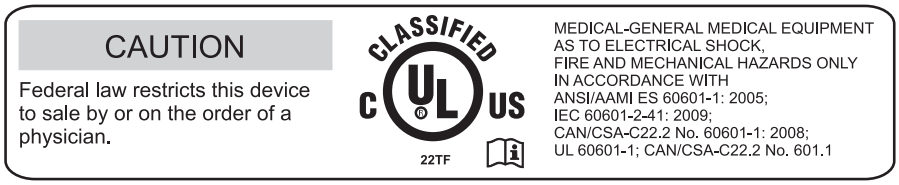
Conformity

The manufacturer declares that this product complies with the fundamental requirements according to MDD Appendix I and documents this by means of the CE and UL marking.

CE mark: This device is a Class I medical device as defined by the European Medical Device Directive (MDD).

UL mark (only NRTL region)

UL marking: device has been tested by Underwriter Laboratories Inc. for the USA and Canada with regard to electric shock and fire hazard as well as mechanical hazards.



1.8.2 Standards and Directives

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

MDD

- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

RoHS

- DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND COUNCIL dated 8 June 2011 to restrict the use of specific harmful substances in electrical and electronic devices
  - EN 50581 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Electrical safety

- EN 60601-1 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2 (IEC 60601-1-2) - Medical electrical equipment - Electromagnetic compatibility

1.8.3 Internationally applied standards

- UL 60601-1
- ANSI / AMI ES 60601-1
- CAN/ CSA-C22.2 No. 60601-1
- IEC 60601-1
- IEC 60601-1-2

1.8.4 Intended use

Intended use

The device is intended for use in a patient environment in hospitals or medical practices to illuminate a part of the patient with high light intensity for examination or surgical purposes.

The working range lies at a distance between 70 cm to 150 cm to the wound area. The device is suitable for continuous operation.
Application does not involve the patient; unintentional contact is possible.

Each use exceeding the aforementioned conditions is not considered to be intended use. Only the user or operator will be liable for any loss or damage arising as a result.

Cleaning

As part of daily clinical routine, the equipment is cleaned several times. This is most often done by turning around housing parts for wiping and drying that are usually facing down.

Single light

Definition: small surgical light

A small surgical light is a single lamp for use in operating theatres to support diagnoses or treatments that do not pose a risk to the patient due to interruptions by lighting failure (IEC 60601-2-41).

Surgical lighting system

Definition: Surgical lighting system

A surgical lighting system consists of two or multiple small surgical lamps and is usable without restrictions.

1.8.5 Special features

High light intensity

The light heads provide high light intensity to ensure good visual conditions for the surgeon.

Overlap of the light fields

- Visible light generates heat in the operating area, due to physical effects. High irradiation densities are generated when the light fields of several light heads overlap. This can cause drying of tissue and, particularly after prolonged exposure, reduced perfusion and tissue damage. The light intensity must be reduced when perfusion is reduced or the tissue starts to dry out.

Surgical interventions in the field of vision

- For operations in the field of vision with unprotected and open eyes, high levels of local light intensities of surgical lamps or direct visual contact with the laser beam may lead to damage to eyesight. The patient's eyes must be closed or protected as necessary (e.g. with safety goggles with an optical density of at least 2 or designed according to protection level 6 EN169).
- The laser used in the ALC plus function to measure distance is classified as a class 2 laser, and has the following specifications:
  - max. output power 0.95 mW
  - wave length -620-690 nm,
  - beam divergence 0.16 x 0.6 mRad
  - pulse duration 0.4 x 10 ^ -9 s
  - pulse refresh rate 320 MHz.

1.8.6 Improper use

Improper use

- Additional load on the light support is not permitted.
- The device may not be exposed to severe vibration.

Restriction

- The device is not suitable for operation in areas at risk of explosions
- The device should not be used in the vicinity of strong magnetic fields
- The device is not suitable for use in rooms or areas in which inflammable mixtures of anaesthetics with air or oxygen or laughing gas (N_20) are used.
- Mixtures of combustible anaesthetic vapours with oxygen or laughing gas may arise in the vicinity of the device in such a high concentration that ignition could occur under certain circumstances. The danger area according to EN 11197 lies in an area between 5 cm and 25 cm from the point of outflow or escape of the gas.

1.9 Ambient conditions for operation and storage

Various ambient conditions apply to the operation and temporary storage of the device.

1.9.1 Ambient conditions for operation

- Ambient temperature: 10°C to 40°C;
- Relative humidity: 30 % to 75 %;
- Air pressure: 700 hPa to 1060 hPa
- Operating height up to 3000 m above sea level

1.9.2 Ambient conditions for storage

- Ambient temperature: -15°C to 60°C;
- Relative humidity: 5 % to 95 %;
- Air pressure: 500 hPa to 1060 hPa

1.10 Combination with other medical devices

Observe the instruction manuals of combined medical devices

- The system can be combined with medical devices from other manufacturers (e.g. monitoring systems). The operation of the devices is described in the relevant instruction manual.
- Only medical devices approved in accordance with IEC 60601-1 or UL 60601-1 may be attached to the system. If a medical device is installed afterwards, the installation must be performed as specified in IEC 60601-1 and IEC 60601-1-1 or in accordance with the specifications provided by the manufacturer. Compliance with this standard must be ensured by the service technician responsible.
- No BF or CF Class application components according to IEC 60601-1 may be directly connected.
- Devices of third-party manufacturers in the patient environment must have safety levels equivalent to that of the TruLight 5000/3000 lighting systems.
- Devices of third-party manufacturers outside the patient environment must have safety levels appropriate for the devices and compliant with the relevant IEC or ISO safety standards.

1.11 Disposal

The device should be disposed of in accordance with the pertinent national regulations and at a suitable waste disposal point for the recycling of electrical and electronic devices.

RoHS conformity

- The device meets the requirements of Directive 2011/65/EU RoHS (restriction of the use of certain hazardous substances in electrical and electronic devices).

2.1 Structure of the safety instructions in this instruction manual

Important information is shown in this instruction manual by means of symbols and signal words.

2.1.1 Indicating risk of injury

Signal words such as DANGER, WARNING or CAUTION indicate the severity of the hazard. Various triangle symbols are used to add visual emphasis.

⚠DANGER

DANGER indicates an immediately dangerous situation in which non-compliance can cause death or serious injury.

⚠WARNING

WARNING indicates a potentially dangerous situation in which non-compliance may cause death or serious injury.

⚠CAUTION

CAUTION indicates a potentially dangerous situation in which non-compliance may cause minor injury.

2.1.2 Indicating damage to property

ATTENTION

ATTENTION indicates a potentially dangerous situation in which non-compliance may cause damage to property.

2.1.3 Indicating additional information

NOTE

NOTE provides you with additional information and helpful tips for safe and efficient use of the device.

2.2 Additional symbols for the safety information

Gas explosion: warns against the explosive ignition of gas mixtures.

Electric shock: warns against an electric shock, which can cause serious injury or even death.

The spring arm may bounce up: warns of the spring arm jumping up while dismantling the light head / flat screen.

Lighting system falling down: warns of a sudden downwards movement of the light system when it is exposed to additional load.

Patient eye protection: warns of damage to the patient's vision in examinations or surgery in the field of vision

Optical radiation: warns of possible damage to the retina by photobiologically active radiation (blue light of LEDs)

Risk of pinching: warns of pinching the fingers in the device.

Damage to surfaces: warns against damages to surfaces caused by unsuitable cleaning agents and disinfectants.

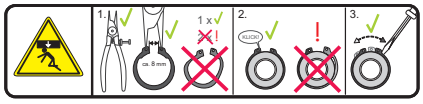
2.3 Symbols on the device

CE conformity mark: certifies that the device complies with the European Medical Device Directive (MDD).

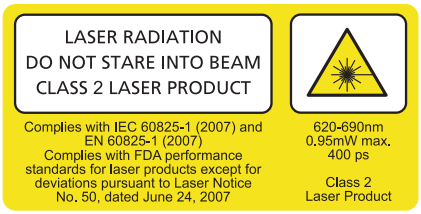
Comply with instruction manual: makes reference to this instruction manual.

UL marking: The device has been tested by Underwriter Laboratories Inc. for the USA and Canada. UL/cUL classification regarding electric shock, fire hazard and mechanical hazard only in accordance with UL 60601-1, 1st Edition, 2006-04-26, ANSI /AMI ES60601-1: 2005/(R) 2012 and CAN/CSA-C22.2 No. 60601-1: 2008.

Makes reference to the need for users to read through the instruction manual for important safety information, such as warnings and precautionary measures which it may not be possible to apply to the medical device for a range of reasons.



Installation / dismantling of the securing ring: Only to be performed by authorised service personnel. The detailed instructions relating to the installation / dismantling of a securing ring must be complied with.



Sensor marking: identifies the class of the laser product installed for distance measurement according to IEC 60825-1, Edition 2.0 (2007-03) and IEC 60825-1, Edition 3 (2014).

2.4 Overview of the most important safety instructions

Location requirements

⚠DANGER

Gas explosion

The lighting system is not suitable for use in an environment in which flammable mixtures of anaesthetics with oxygen or laughing gas in a high concentration are used.
Mixtures of combustible anaesthetic vapours with oxygen or laughing gas may arise in the vicinity of the device in a sufficiently high concentration that ignition may occur under certain circumstances.
The danger area according to EN 11197 lies in an area between 5 cm and 25 cm from the point of outflow or escape of the gas.

Strong magnetic fields

The support arm systems of the lighting systems must not be used in the vicinity of strong magnetic fields.

BF/CF Class application components

No BF or CF Class application components in accordance with IEC 60601-1 may be directly connected to the support arm systems of the lighting system.

⚠WARNING

Electric shock

The lighting system may only be connected to an appropriately earthed power supply with protective conductors in order to avoid the risk of an electric shock.

Electrostatic charge balance

⚠WARNING

Complications due to electrostatic discharge

To avoid complications due to electrostatic discharge between parts of the device and patients, the user must not touch parts of the surgical light and the patient at the same time.

Surgical interventions in the field of vision

⚠WARNING

Damage to vision

In case of surgery in the field of vision of the patient, the high light intensity by the light heads may cause eye fatigue or damage to vision:

- **The eyes of the patients must be closed, covered or protected, e.g. with protective goggles.**
- **Do not look directly into the light-emitting surface area of the light.**

Overlapping fields of illumination from several light heads

⚠WARNING

Damage to patient's tissue

Overlapping fields of illumination from several light heads with high intensity illumination may cause damage to tissue. In the event of incipient tissue dehydration:

- **Separate the fields of illumination from several light heads.**
- **Reduce the light intensity of the light heads.**

Contact with laser beams

⚠WARNING

Damage to vision

Direct contact with the laser beam may cause damage to vision:

- **Do not look directly into the laser beam**
- **Protect the patient's eyes:**
  The patient's eyes must be closed or protected as necessary (e.g. with safety goggles with an optical density of at least 2 or designed according to protection level 6 EN169).
- **Use of operating methods or procedures other than those stated in these instructions for use may result in dangerous radiation effects due to the laser.**

Light intensity of the light head

⚠CAUTION

LED failure

After failure of the tenth LED, the light head does not achieve the specified light intensity.

- **Take the lighting system out of service.**
- **Inform Trumpf Medical Customer Service. Exchanging a light head or repairs to the lighting system may only be performed by Trumpf Medial Customer Service or by service staff trained and authorised by Trumpf Medical.**

Additional loads

⚠WARNING

Crashing of the light system

Do not place any additional weight on the light system

Swivel movement of the light head

⚠WARNING

Risk of injury due to uncontrolled swivel movement

Uncontrolled movement of the spring arm may result when the spring force of the spring arm is not correctly adjusted.

Risk of jamming

When rotating the light head, the distance between the cardan joint and the light head changes:

- **Do not insert your fingers between the cardan joint and the light head when swivelling the light head.**

- **Only position the light head by using the sterile handle or the non-sterile handles (outer handles).**

Cleaning and disinfection

⚠ WARNING

Improperly used cleaning agents or disinfectants can pose a risk for patients or damage products

If the following information and instructions are not observed or complied with, this may result in a risk of contamination or infection for the patient or damage to the product. Furthermore, it would render any claim for damages void!

- **Use the wipe-over method only for disinfection.**
- **For cleaning and disinfection, only wipe with a damp but not wet cloth.**
- **Dispense cleaning agents and disinfectants so that no liquid can enter through joints or openings of the surgical light or parts of the support arm system.**
- **Use the surface disinfectant only at the concentration specified by the manufacturer.**
- **Only use disinfectants approved by the manufacturer for use with the following materials:**
  Polycarbonate (PC), polyamide (PA), acrylonitrile butadiene styrene copolymer (ABS), polystyrene (PS), polyurethane (PUR), polyphenylene sulphone (PPSU), polybutylene terephthalate (PBT) and silicones.
- **In the event of an increased layer formation of surface disinfectant, thorough cleaning must be performed.**
- **Due to the risk of surface damage:**
  - Do not use sharp, pointed or abrasive objects,
  - Do not use abrasive substances or agents which can remove material,
  - Do not use solvents, benzene, paint thinners, alkaline cleaning agents or cleaning agents containing acids or aldehydes,
  - Do not use agents with glycol derivatives, phenols, phenol derivatives or quaternary compounds,
  - To prevent paint or corrosion damage, only use agents that do not contain chlorides or halogenides.
- **It is essential that the hygiene instructions of the operator are observed.**

For more detailed information about cleaning and disinfection, see Chapter 9, page 60

Adjustments

⚠ CAUTION

Adjusting the device

The manufacturer guarantees the safety and proper working of the device only under the condition that the work of adjustment has been

done by an authorised hospital technician or a person with equivalent qualification.

Deinstallation for service purposes

⚠ WARNING

The spring arm may bounce up

When the light head/flat screen is removed before moving the spring arm to the top-most limit stop position, the spring arm will shoot up and can cause severe injuries:

- The light head/flat screen may therefore only be de-installed by Trumpf Medical Customer Service.

Commissioning

⚠ CAUTION

Initial commissioning prior to use

The light system must be handed to the user in a tested state after initial operation before it can be used in routine medical procedures.

- The initial operation includes functional and safety checks on the entire lighting system.
- Handover must be documented by a handover declaration.

3.1 The light head

The light head has a wide range of new functions that allow for ergonomic control using the control panel on the light head or using the optional wall-mounted control panel.

Operating modes of the non-sterile handles (optional)

The light heads are fitted with illuminated, non-sterile handles (outer handles). The following operating modes are available:

- Permanent illumination (factory setting),
- No illumination,
- Illumination when the light head is switched on,
- Illumination only when the light head is in stand-by mode
- Illumination in stand-by mode or when the ENDO-dimming of the light head is switched on.

The operating mode selected by the user can be configured by a service technician during assembly.

ENDO-dimming

ENDO-dimming is intended for endoscopic surgical procedures. ENDO-dimming switches the light head to less than 10 percent of the light intensity.

Light intensity

The light intensity can be set in the range from 40% to 100%. A reduction (dimming) of the light intensity does not change the colour temperature of the light.
The light intensity can be separately set for each light head.

Adaptive Light Control (ALC) (optional)

The newly developed Adaptive Light Control allows the light settings to be adapted to the new working distance when the position of the light head to the wound field is changed.
The three settings for a working distance of approximately 0.8 metres, 1.0 meter and 1.2 meters are selected on the control panel or the optional wall-mounted control panel.
The light head then automatically selects the optimum light setting for this working distance.

Adaptive Light Control plus (ALC plus) (optional)

Adaptive Light Control plus (ALC plus) enables the targeted electronic control of various LEDs in order to achieve optimum illumination of the wound area. The Adaptive Light Control plus automatically ensures even light intensity and higher light output for the first time. The distance between the light head and the wound area is automatically determined based on movement detection when the light head is moved during surgery. This allows accurate adaptation of the illumination at any time.

Sterile Light Control (SLC) (optional)

Simple swiping with a finger allows the light functions to be activated in a completely sterile way using the sterile handle.

Adjustable Color Temperature (optional)

The function Adjustable Color Temperature is used to increase the colour contrast in the wound area and provides a better perception of colour differences by the operating team.

TruVidia camera system (optional)

With the optional TruVidia camera system, a camera installed in the middle of the light head can be controlled using an optional control device. The two camera light heads TruLight 5310 and TruLight 5510 are fitted as standard with the ALC plus function, as soon as the camera module is fitted.

Please refer to the overview of light versions in the Technical Data chapter for detailed information on the availability of this option.

3.2 The LED light source

The light system is a future-proof light equipped with LEDs (Light Emitting Diodes).

Service life

LEDs have a very high service life, unlike conventional halogen or discharge lights.

Low heat generation

Further advantages of the LEDs are that they generate less heat by not emitting IR (infrared) radiation and cause less tissue damage by not emitting UV (ultraviolet) radiation.

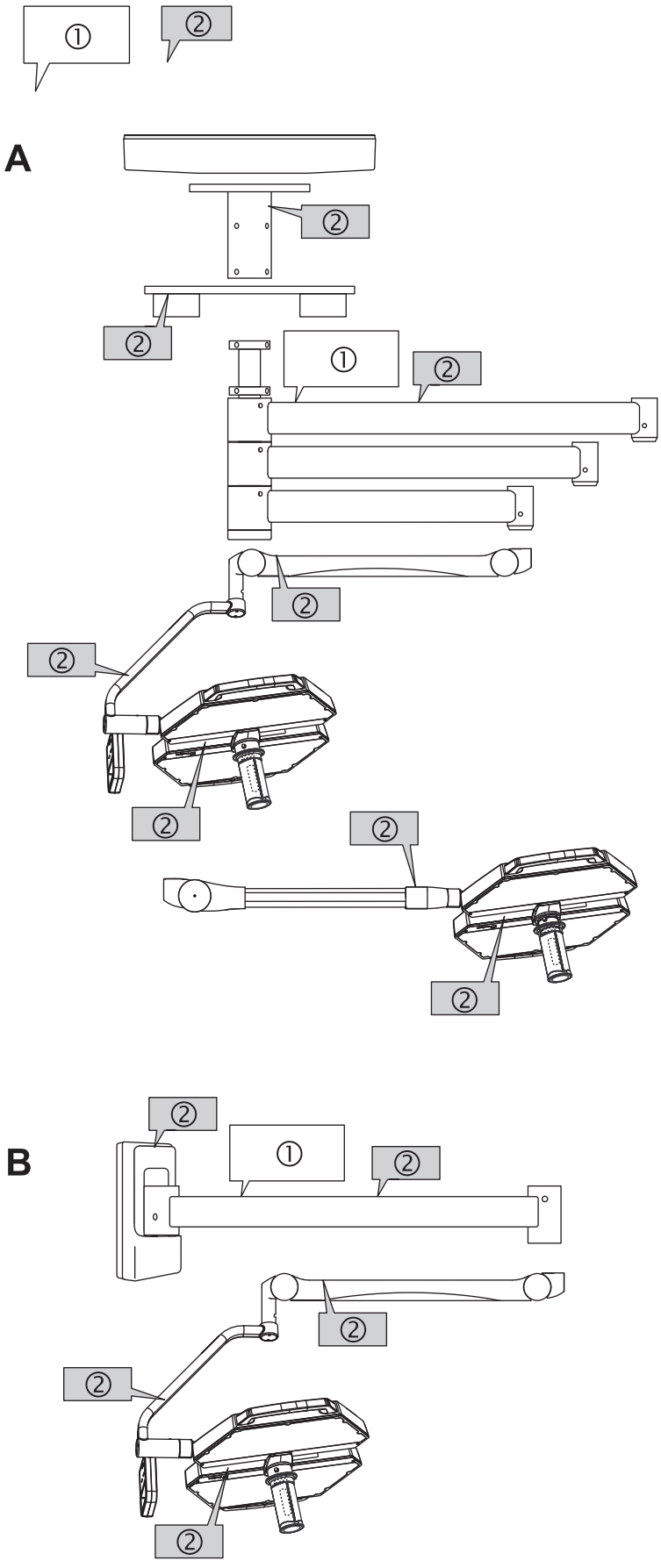
High failure safety

The use of a large number of LEDs makes the light head very resistant to failure. Failure of single LEDs does not affect the function of the light head.

3.3 Accessories

- Dock - Desk
  - Material no. 1839155: Dock - Desk
- WallControl Panel
  - Material no. 1992641: TCO Wall Control-Universal Front Interf.
  - Material no. 1956143: Wall Control -Preinstall Set, FLUSH
  - Material no. 1956144: Wall Control -Preinstall Set, SURFACE
- Control incl. Bumper
  - Material No. 1835274 TCO Control incl. Bumper
- OPL Interface Converter (optional)
  is needed to integrate the surgical light TruLight 5000/3000 in third party systems.
  - Material No. 1793338

Figure 1



4.1 Use of serial numbers

A light system is identified by its rating plate and serial numbers.

- The rating plate ① contains the specific device data and also the main serial number.
  The main serial number identifies a complete device order-specifically. The main serial number also enables components which do not have a serial number themselves to be identified by Trumpf Medical Customer Services, permitting the supply of the correct spare parts.
- The serial numbers ② identify the individual components of a device.

4.1.1 Position of the serial numbers on the ceiling-mounted version

A: Ceiling-mounted version

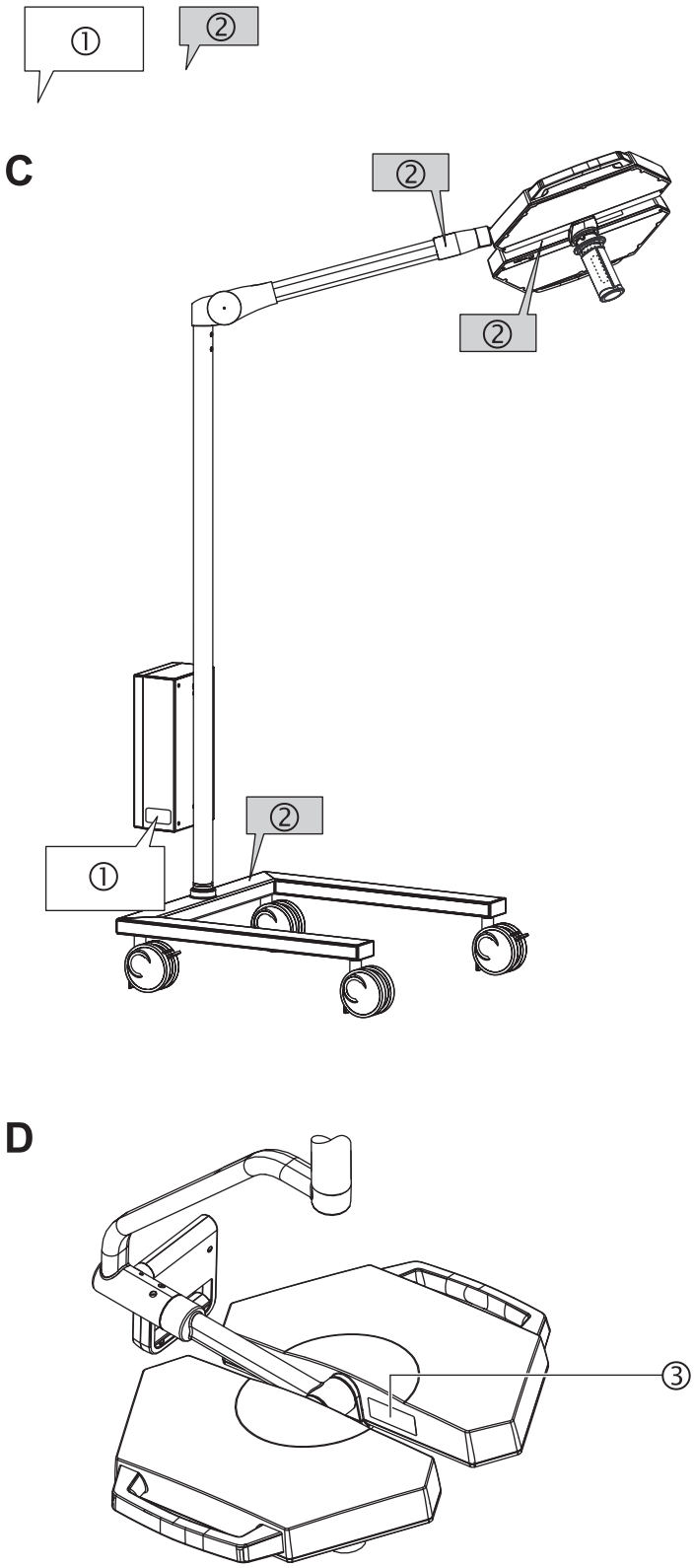
- The name plate ① with the main serial number is on the topmost beam.
- Serial numbers ② of the individual components are provided at:
  - Ceiling conduit
  - Interface plate
  - Boom
  - Spring arm
  - Quarter bracket
  - Light head

4.1.2 Position of the serial numbers on the wall-mounted version

B: Wall-mounted version

- The rating plate ① with the main serial number is on the topmost beam.
- Serial numbers ② of the individual components are provided at:
  - Wall support
  - Boom
  - Spring arm
  - Quarter bracket
  - Light head

Figure 2



4.1.3 Position of the serial numbers on the mobile stand version

C: Mobile stand version

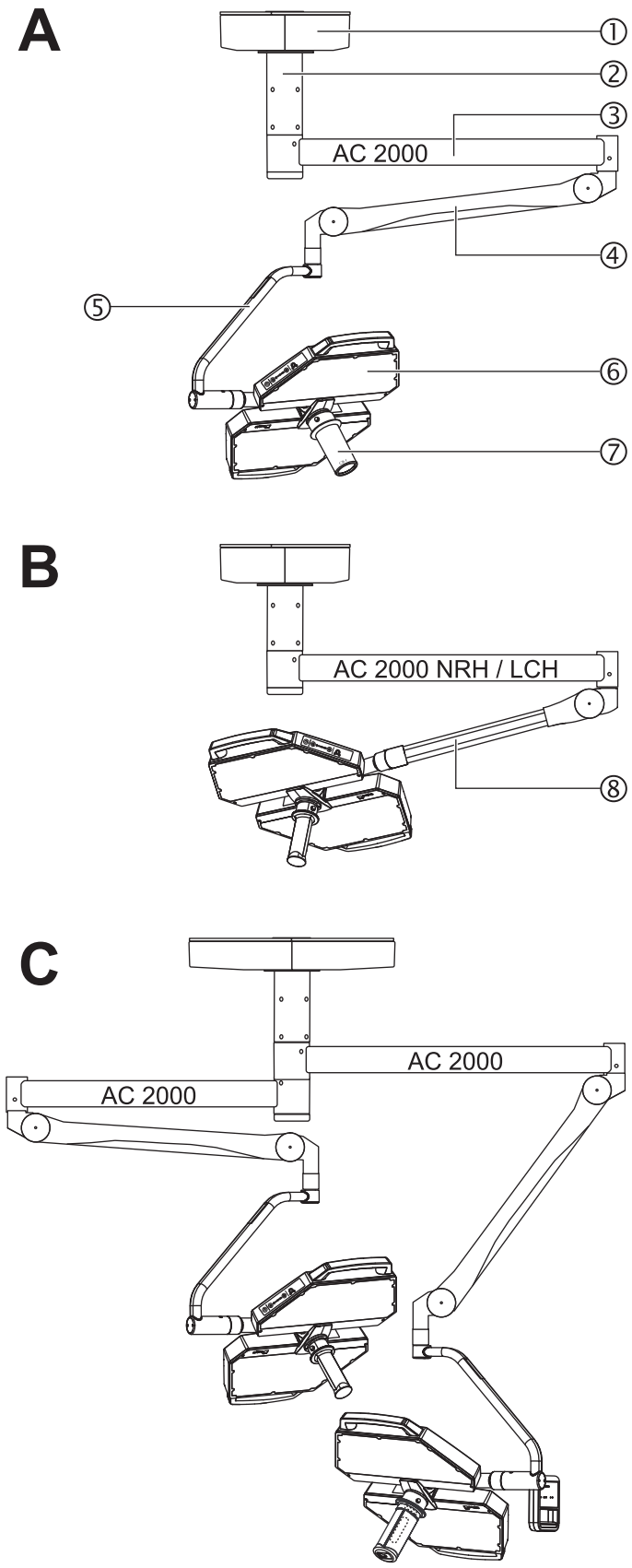
- The rating plate ① with the main serial number is on one side of the power adapter housing.
- Serial numbers ② of the individual components are provided at:
  - Boom
  - Light head
  - Stand base

4.1.4 Position of the laser marking

D: Light head with Adaptive Light Control plus (ALC plus)

- The laser marking ③ is provided in the suspension area of the light head housing.

Figure 3



5.1 Description of the ceiling-mounted version

5.1.1 Implementation of the ceiling-mounted version

Different models of the ceiling-mounted version of the lighting system are available:

- **A:** Surgical light as single light with a small light head on the AC 2000 type spring arm
- **B:** Surgical light as single light with a small light head on the AC 2000 spring arm LCH (Low Ceiling Height).
- **C:** Surgical lighting system as a combination of several large or small light heads on AC 2000 or AC 2000 LCH (Low Ceiling Height) spring arms.

5.1.2 Components of the ceiling-mounted version

The lighting system comprises of:

- Ceiling cover panel ①,
- Ceiling conduit ②,
- Boom ③,
- AC 2000 ④ or AC 2000 LCH (Low Ceiling Height) spring arm ⑧,
- Convenience bracket ⑤,
- Light head ⑥.

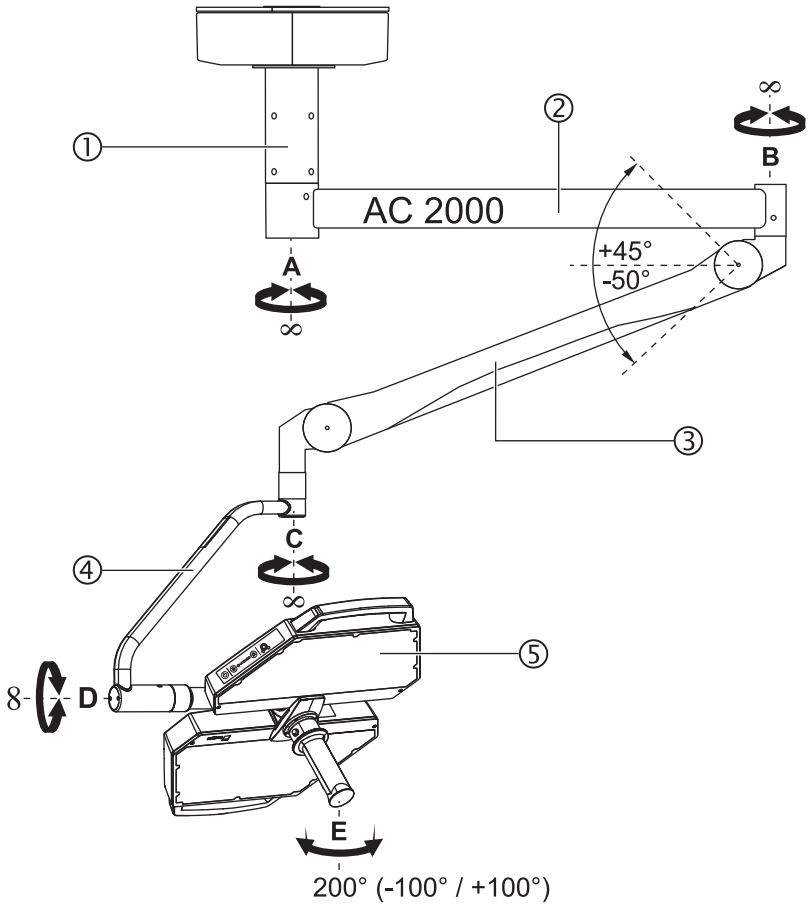
5.1.3 Camera on light head, optional

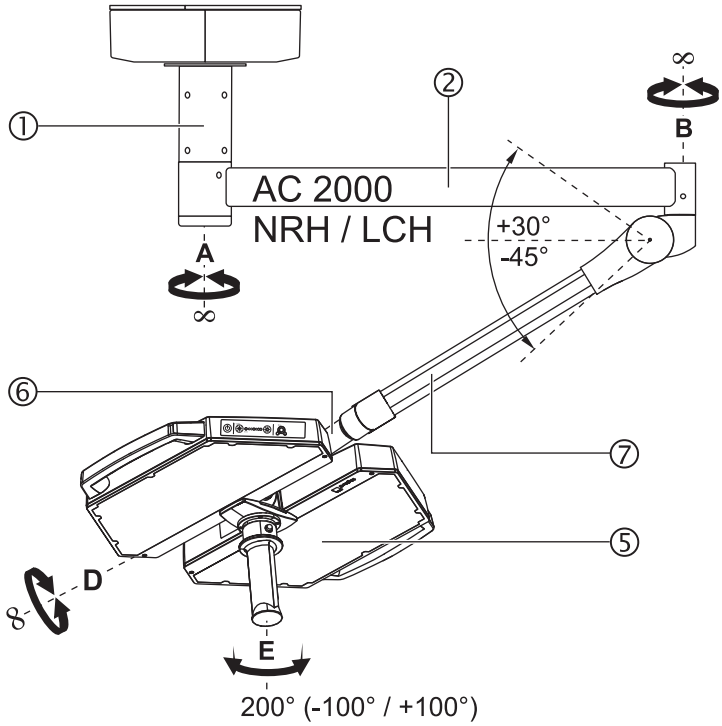
The light heads can be equipped with an optional camera ⑦ (see the Instruction Manual: TruVidia SD or TruVidia HD).

5.1.4 Size of the light heads

For both light head versions – TruLight 5000 and TruLight 3000 – both the large light head (Ø 730 mm) as well as the small light head (Ø 640 mm) are available with various adjustments for the size of the light field, light intensity and colour temperature (see functional specifications and overview of technical data).

Figure 4





5.1.5 Rotation / swivel ranges of the ceiling-mounted version

The horizontally rotatable boom ② together with the horizontal and vertically adjustable spring arm ③ or ⑦ facilitate stable positioning of the light head ⑤ within the activity range of the support arm system. Convenience bracket ④ facilitates accurate alignment of the light head onto the wound area.
The following rotation and swivel movements can be performed at the joints of the support arms when there is sufficient distance from neighbouring
walls and objects:

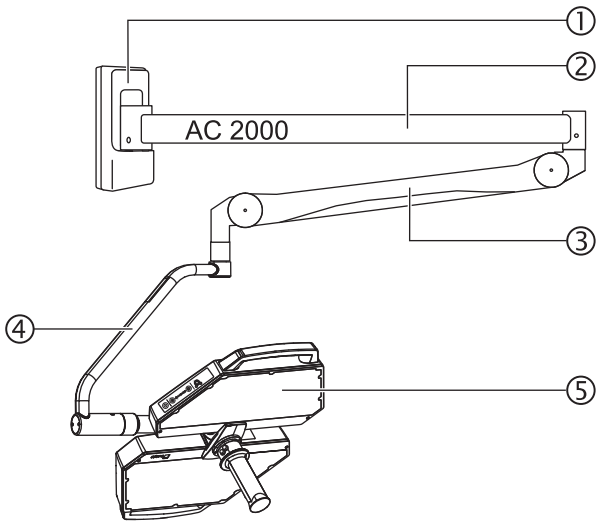
AC 2000 type spring arm

- Hinge **A**, boom ② at the ceiling conduit ①:
  Full horizontal rotation movement (> 360°)
- Hinge **B**, AC 2000 type spring arm ③ on the boom ②:
  Horizontal rotation movement (> 360°).
  Vertical swivel movement in the range: +45° to -50°
- Hinge **C**, convenience bracket ④ at the spring arm type AC 2000 ③:
  Full horizontal rotation movement (> 360°)
- Hinge **D**, light head on the convenience bracket ④:
  TruLight 3000: Full vertical rotation movement (> 360°)
  TruLight 5000: Limited rotation movement to position stop (< 420°)
- Hinge **E**, light head on cardan joint light head:
  Swivel movement (200°).

AC 2000 LCH type spring arm

- Hinge **A**, boom ② at the ceiling conduit ①:
  Full horizontal rotation movement (> 360°).
- Hinge **B**, AC 2000 LCH type spring arm ⑦ on the boom ②:
  Full horizontal rotation movement (> 360°).
  Vertical swivel movement in the range: +30° to -45°.
- Hinge **D**, light head on cardan joint light head ⑥:
  Full vertical rotation movement (> 360°).

Figure 5



- Hinge **E**, light head on cardan joint light head:
  Swivel movement (200°).

The swivelling ranges of the support arms are adjustable (see Chpt. 12).

5.2 Description of the wall-mounted version

5.2.1 Implementation of the wall-mounted version

Different models of the wall-mounted version of the lighting system are available:

- Surgical light as single light with a small light head on the AC 2000 type spring arm

5.2.2 Components of the wall-mounted version

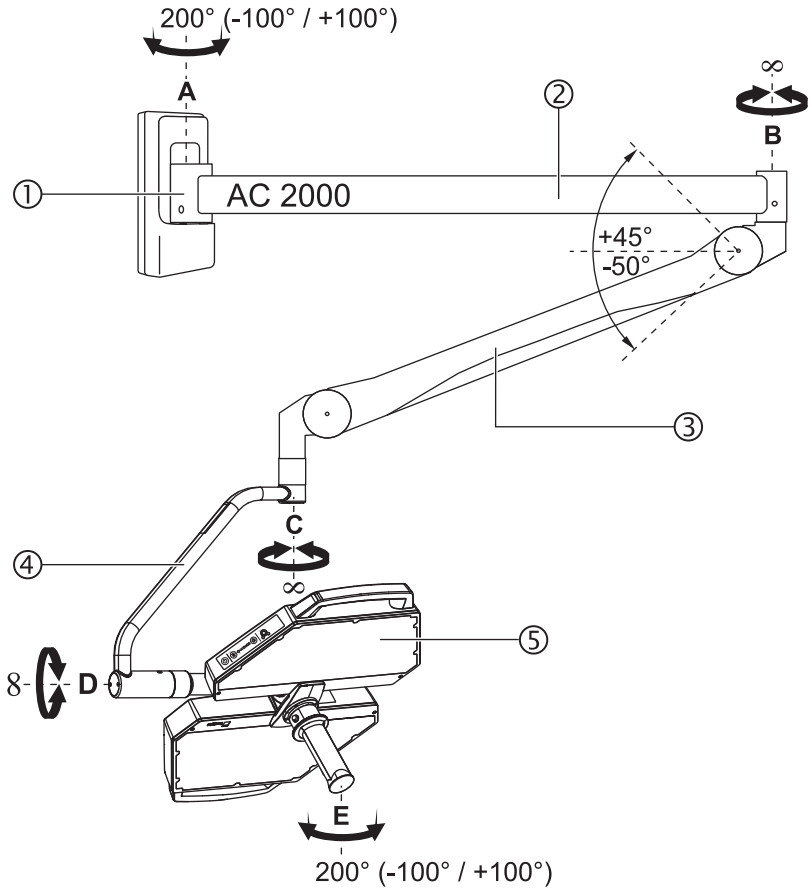
The lighting system comprises of:

- Wall support ①,
- Boom ②,
- AC 2000 ③ or AC 2000 LCH (Low Ceiling Height) spring arm,
- Convenience bracket ④,
- Light head ⑤.

5.2.3 Size of the light heads

For both light head versions – TruLight 5000 and TruLight 3000 – both the large light head (Ø 730 mm) as well as the small light head (Ø 640 mm) are available with various adjustments for the size of the light field, light intensity and colour temperature (see functional specifications and overview of technical data).

Figure 6



5.2.4 Rotary / swivel movement of the wall-mounted version

The horizontally rotatable boom ② together with the horizontal and vertically adjustable spring arm ③ facilitate stable positioning of the light head ⑤ within the activity range of the support arm system. Convenience bracket ④ facilitates accurate alignment of the light head onto the wound area.

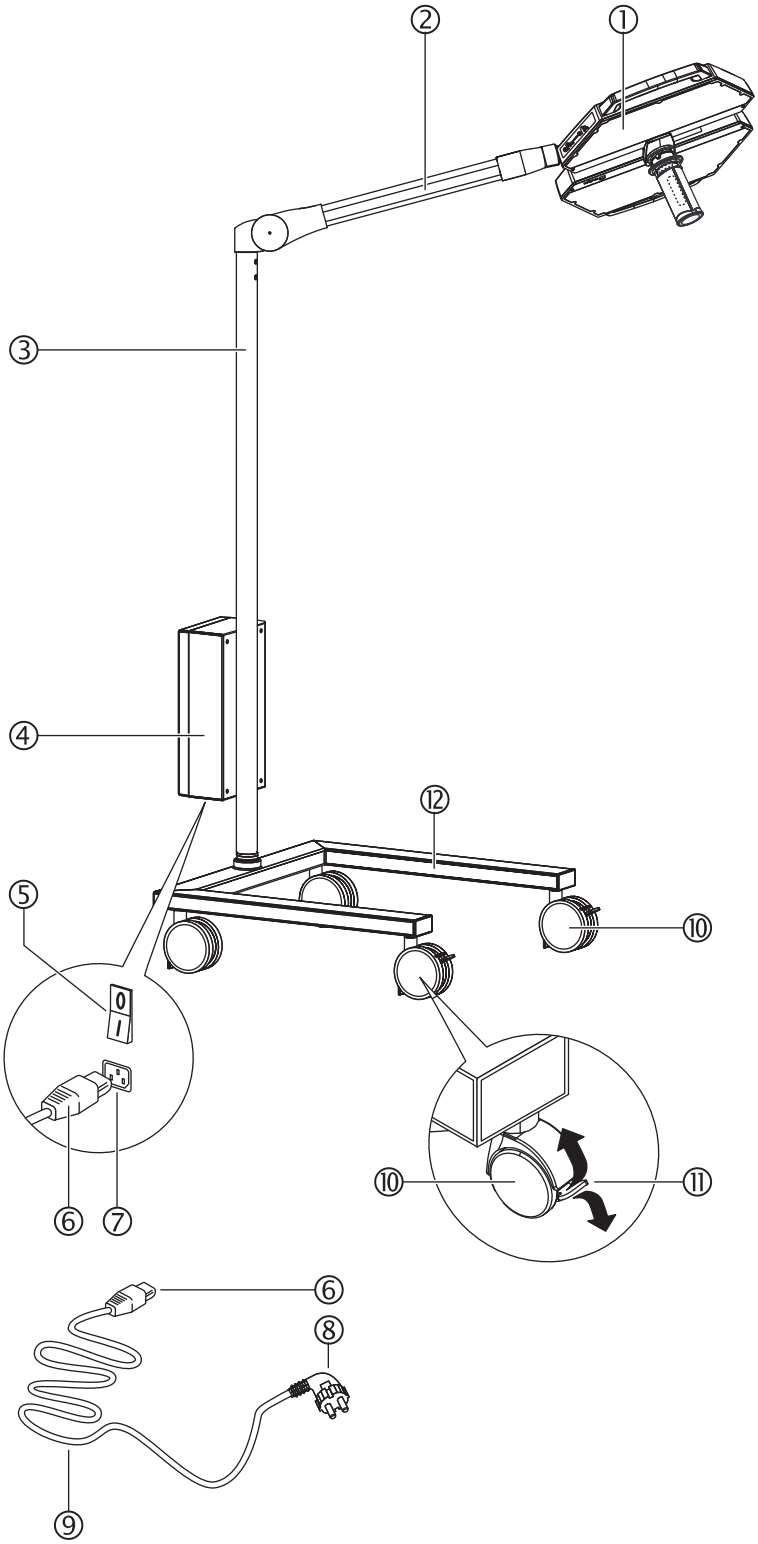
The following rotation and swivel movements can be performed at the joints of the support arms when there is sufficient distance from neighbouring walls and objects:

AC 2000 type spring arm

- Hinge **A**, boom ② at the wall support ①:
  Horizontal rotation movement (200°).
- Hinge **B**, AC 2000 type spring arm ③ on the boom ②:
  Full horizontal rotation movement (> 360°).
  Vertical swivel movement in the range: +45° to -50°.
- Hinge **C**, convenience bracket ④ at the spring arm type AC 2000 ③:
  Full horizontal rotation movement (> 360°).
- Hinge **D**, light head on the convenience bracket ④:
  TruLight 3000: Full vertical rotation movement (> 360°).
  TruLight 5000: Limited rotation movement to position stop (< 420°).
- Hinge **E**, light head on cardan joint light head:
  Swivel movement (200°).

The swivelling ranges of the support arms are adjustable (see Chpt. 12).

Figure 7



5.3 Description of mobile stand version

5.3.1 Implementation of the mobile stand version

The mobile stand version is available as an single light equipped with an AC 2000 LCH type spring arm.

5.3.2 Components of the mobile stand version

The mobile stand version consists of:

- Light head ①,
- AC 2000 LCH (Low Ceiling Height) type spring arm ②,
- stand rod ③,
- power supply housing ④ with mains cable ⑨. The power supply housing ⑦ contains components for the supply of electric power.
- Stand base ⑫, with four castors ⑩ (two of which are lockable ⑪),

5.3.3 Power supply of the mobile stand version

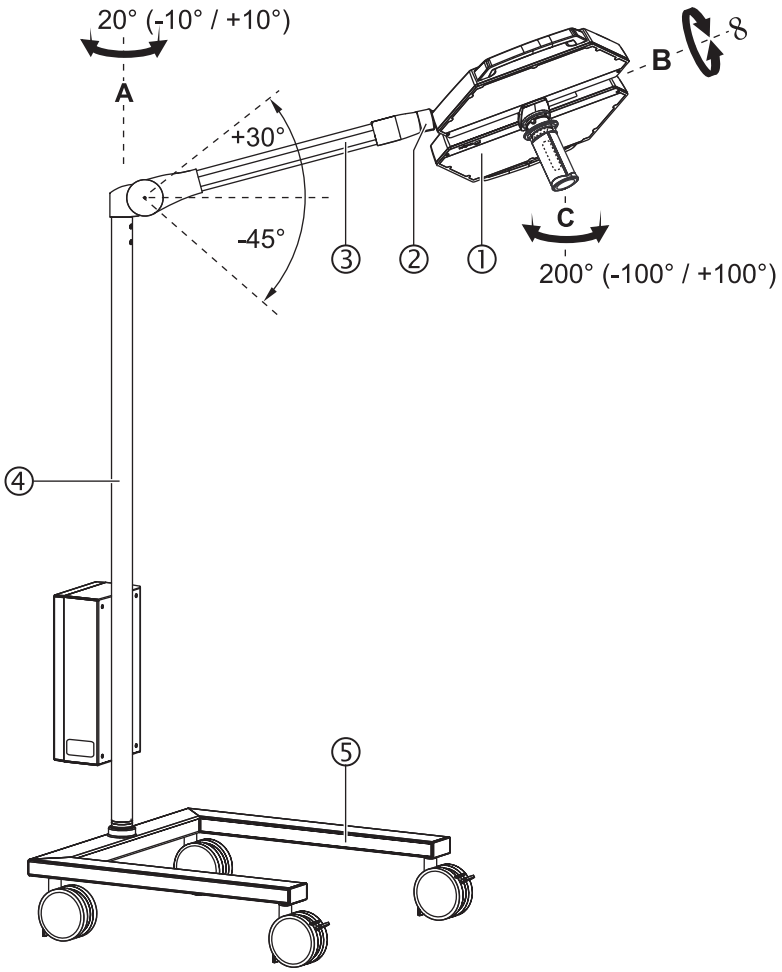
The power supply of the mobile stand version is provided at the power supply housing ④:

- by the mains cable with the IEC power connector ⑥ for connection to the IEC power socket ⑦ on the underside of the power supply housing,
  and
- with the earthed plug connector ⑧ for connection to a mains socket.
- Power unit ON/OFF switch ⑤ on the underside of the power supply housing for switching on or off.
  If the power supply unit is switched on, the power supply is on standby.

5.3.4 Size of the light heads

For both light head versions – TruLight 5000 and TruLight 3000 – both the large light head (Ø 730 mm) as well as the small light head (Ø 640 mm) are available with various adjustments for the size of the light field, light intensity and colour temperature (see functional specifications and overview of technical data).

Figure 8



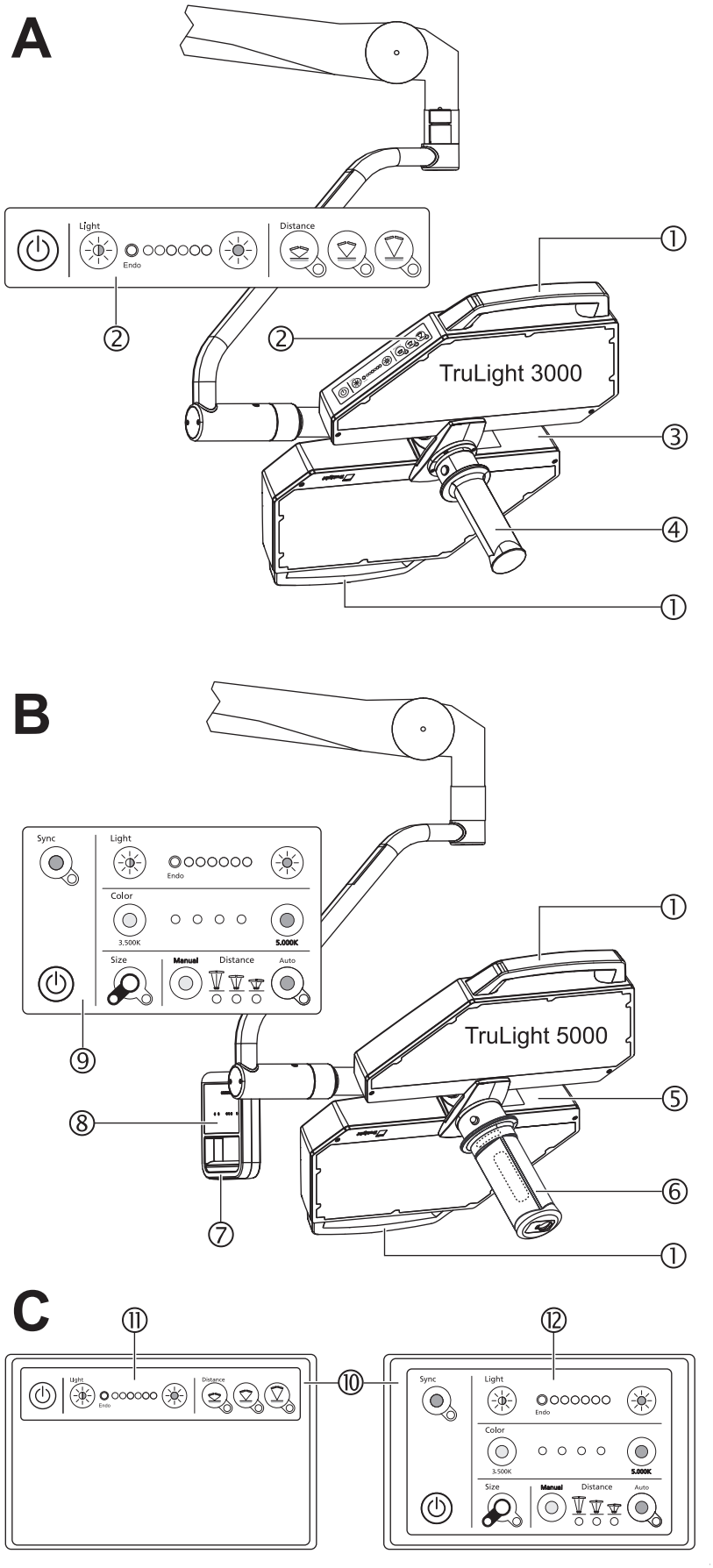
5.3.5 Rotating / swivel movement of the mobile stand version

The stand base ⑤ with castors facilitates unrestricted mobility. The horizontally and vertically adjustable AC 2000 LCH (Low Ceiling Height) type spring arm ③ on the stand rod ④ allows for stable positioning of the light head ① within the activity range of the stand. The cardan joint ② facilitates accurate alignment of the light head onto the wound area.

The following rotation and swivel movements can be performed at the joints of the support arms when there is sufficient distance from neighbouring
walls and objects:

- Hinge **A**, spring arm ③ on stand rod ④:
  Horizontal swivel movement in the range +10° to -10°.
  Vertical swivel movement in the range: +30° to -45°.
- Hinge **B**, light head on cardan joint ②:
  Full vertical rotation movement (> 360°).
- Hinge **C**, light head on cardan joint:
  Swivel movement (200°).

Figure 9



5.4 Functional specifications of the light head

5.4.1 Positioning the light head

Sterile positioning

The light head can be positioned with complete sterility using the sterile handle:

- sterile handle, standard version ④,
- sterile handle with function: Sterile Light Control (SLC) ⑥.

Non-sterile positioning (optional illuminated outer handles)

The light heads can be positioned with the non-sterile outer handles.

- TruLight 3000:
  - Outer handles ① on the light head ③.
- TruLight 5000:
  - Outer handles ① on the light head ⑤.
  - Outer handle ⑦ on the control unit ⑧.

TruLight 5000 light head versions are optionally equipped with illuminated non-sterile outer handles. The operating mode options for the outer handles are described in Chapter 3.1, page 22.

5.4.2 Operating the light heads

Sterile operation at the handle

The light intensity of the TruLight 5000 light version can be adjusted with the sterile handle using the *optional* Sterile Light Control (SLC) function ⑥.

Non-sterile operation at the control panels

The lighting function of light types TruLight 3000 and TruLight 5000 can be set at the non-sterile control panel ② or ⑨ on the light head or at the *optional* wall-mounted control panel ⑩:

- **A:** TruLight 3000 with control panel ② on the light head to adjust:
  - Light intensity;
  - Adaptive Light Control (ALC);
- **B:** TruLight 5000 with control panel ⑨ on the control unit ⑧ to adjust:
  - Light intensity;
  - Colour temperature;
  - Colour temperature synchronisation;
  - Size of light field;
  - Adaptive Light Control Plus (ALC plus);
- **C:** Both light types TruLight 5000 and

TruLight 3000 can be fitted with an *optional* wall-mounted control panel ⑩.

TruLight 3000, wall-mounted control panel ⑪

The wall-mounted control panel has the same range of functions as the corresponding control panel on the light head.

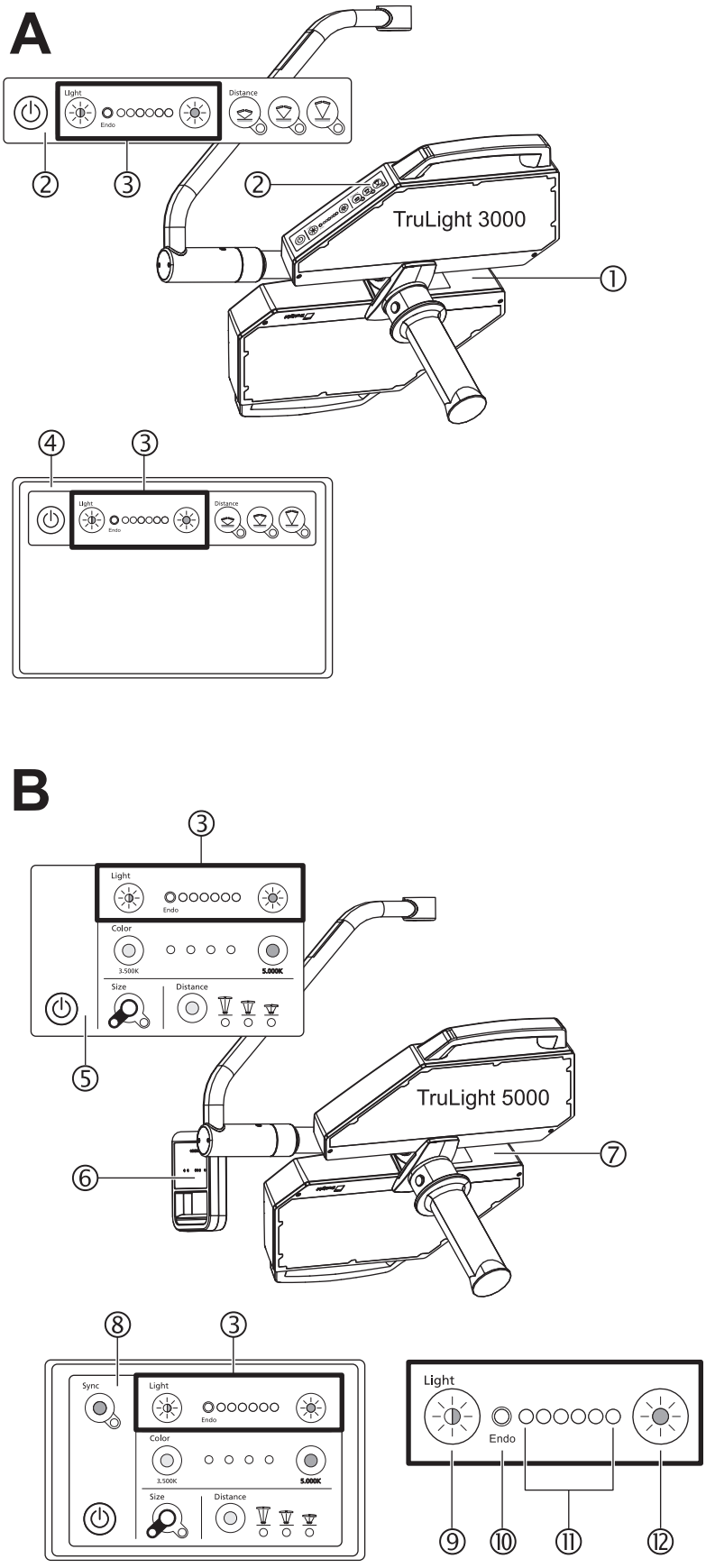
– Light intensity;
– Adaptive Light Control (ALC);

TruLight 5000, wall-mounted control panel ⑫

The wall-mounted control panel has the same range of functions as the corresponding control panel on the light head.

– Light intensity;
– Colour temperature;
– Colour temperature synchronisation;
– Size of light field;
– Adaptive Light Control Plus (ALC plus).

Figure 10



5.4.3 Controlling the light intensity

Non-sterile setting of the light intensity

The light intensity is set at the **Light** ③ control panel.

- **A:** for TruLight 3000 ① at the control panel ② for the light head or the optional wall-mounted control panel ④, or
- **B:** for TruLight 5000 ⑦ on the control panel ⑤ of the control unit ⑥, or on the optional wall-mounted control panel ⑧.

The intensity of illumination of the light head can be adjusted in 7 stages:

– < 10 % (Endo)

– 40 %–100 %

Reducing the light intensity:

- Press key ⑨ on the control panel.

→ The LED for the currently set light intensity ⑪ lights up.

Increasing the light intensity:

- Press key ⑫ on the control panel.

→ The LED for the currently set light intensity ⑪ lights up.

Endo-dimming

The light intensity level Endo-dimming ⑩ is intended as the light intensity for endoscopic operations.

Activating Endo-dimming:

- Press key ⑨ on the control panel until the Endo LED lights up.

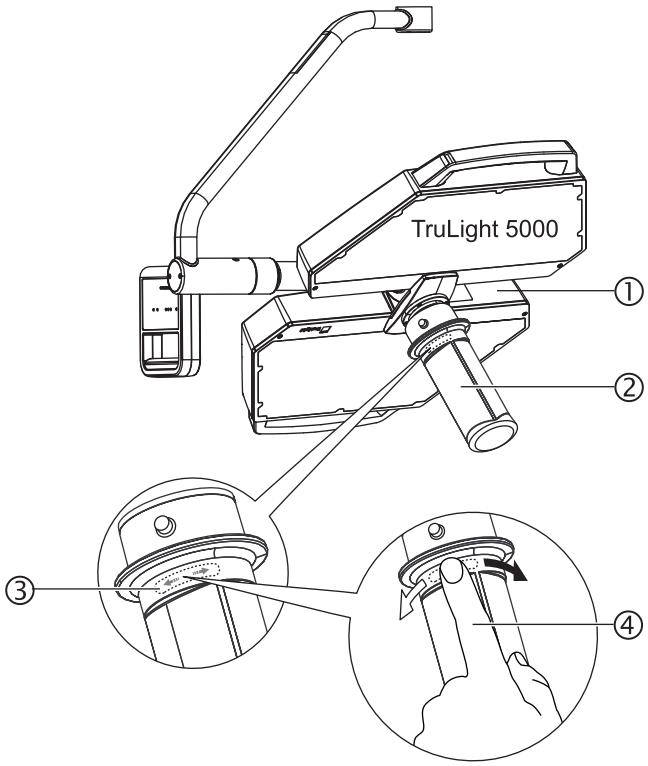
→ The light intensity is reduced to a value < 10 % of the maximum light intensity.

Deactivating Endo-dimming:

- Press key ⑫ on the control panel until the Endo LED goes out.

The light intensity is set to a value in the range of 40 %–100 % (indicated by the corresponding lit LED).

Figure 11



5.4.4 Sterile Light Control (SLC) function, optional

Sterile setting of the light intensity

With the *optional* sterile handle ② with Sterile Light Control (SLC), the light intensity of the TruLight 5000 ⑤ lamp can be adjusted with complete sterility.

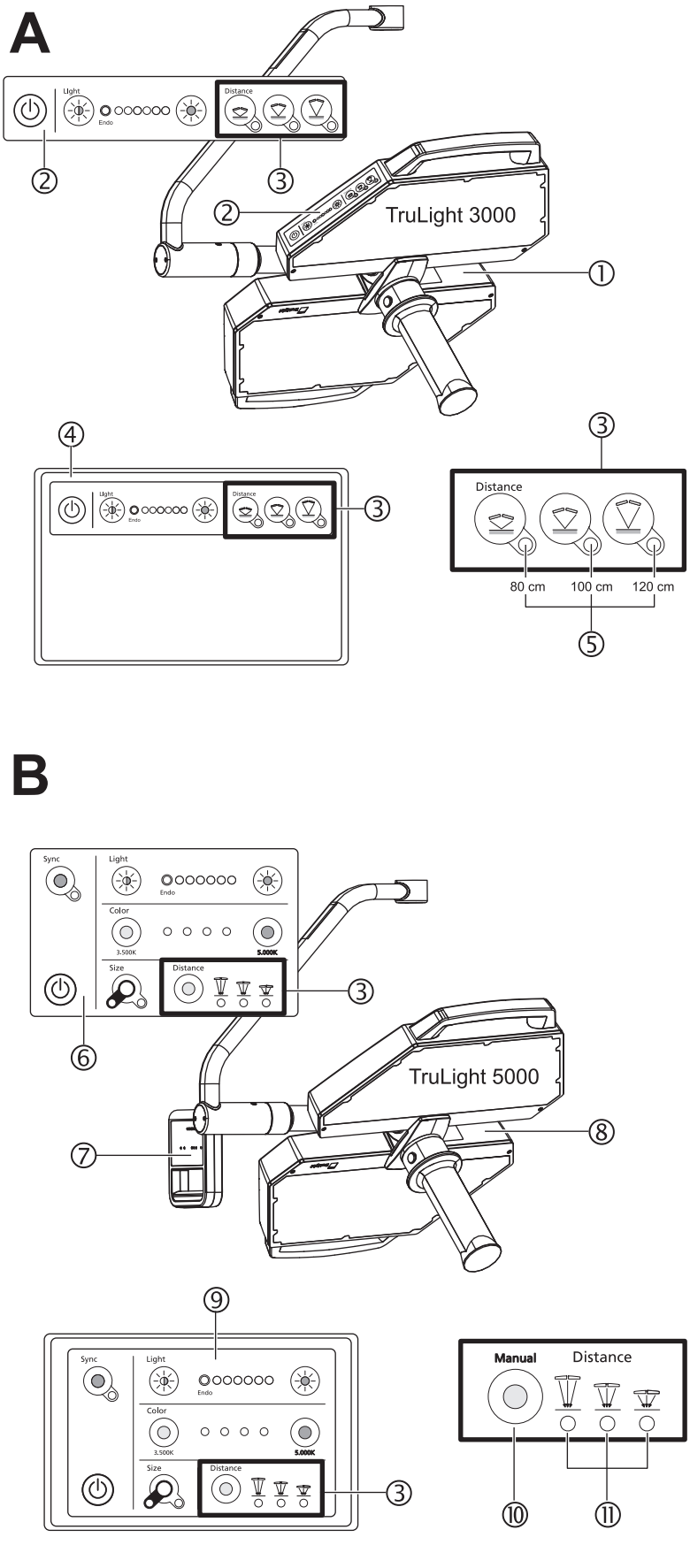
Adjusting the light intensity with Sterile Light Control

A touch sensor ③ is installed in the area below the collar of the sterile handle ②. This can be used to adjust the light intensity by a simple finger movement ④:

- **Increasing the light intensity:**
  Swipe the finger from left to right.
- **Reducing the light intensity:**
  Swipe the finger from right to left.

The functions can be assigned differently if this is required by the customer.

Figure 12



5.4.5 Adaptive Light Control (ALC) function, optional

Non-sterile adjustment of the light control

The Adaptive Light Control (ALC) function allows lighting settings of the two light types TruLight 3000 and TruLight 5000 to be manually adjusted to the new working distance, if the position of the light head to the wound area is changed.

- The three ALC settings ③ for an approximate working distance of 0.8 m, 1.0 m and 1.2 m are selected:
  - **A:** for TruLight 3000 ① on the control panel ② on the light head or the optional wall-mounted control panel ④,
    or
  - **B:** for TruLight 5000 ⑧ on the control panel ⑥ of the control unit ⑦, or on the optional wall-mounted control panel ⑨.

Adjusting the light intensity with Adaptive Light Control

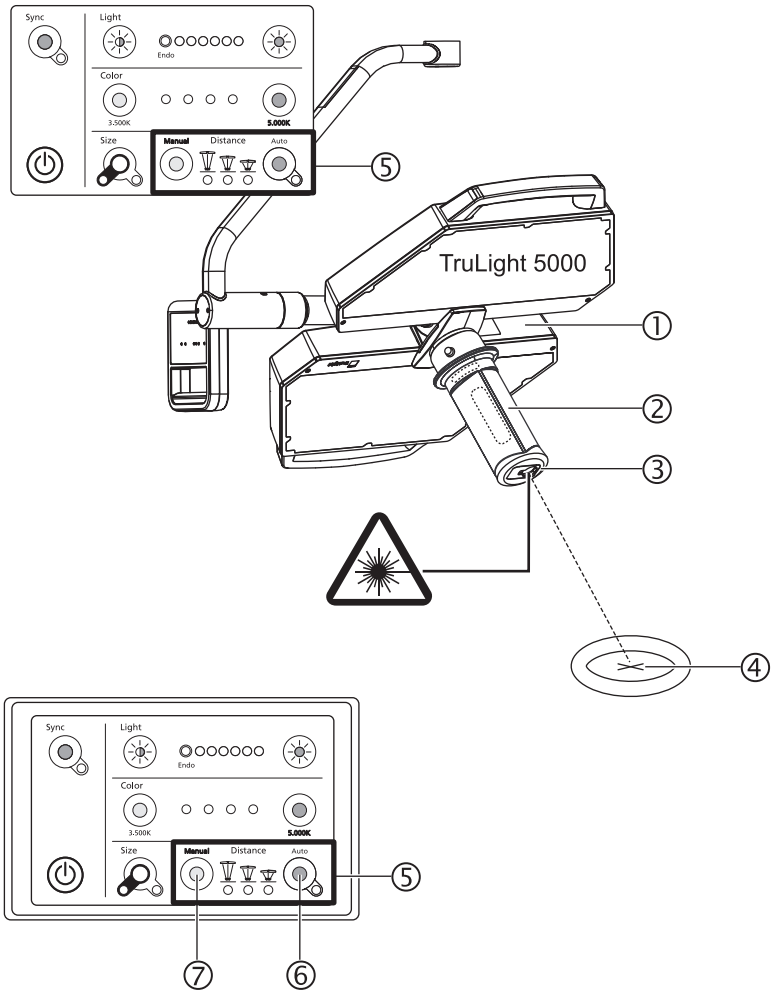
TruLight 3000

- Select the relevant key ⑤ on the control panel ③.
  The light head automatically selects an optimum LED setting for the light intensity.

TruLight 5000

- Press key ⑩ on the control panel until the LED ⑪ for the required distance level lights up.
  The light head automatically selects an optimum LED setting for the light intensity.

Figure 13



5.4.6 Adaptive Light Control plus (ALC plus) function, optional

The light model TruLight 5000 can be optionally fitted with the Adaptive Light Control plus (ALC plus) function.
Alongside the basic ALC function ⑤, the ALC plus function can automatically control various LED groups of the light modules depending on the distance of the light head ① to the wound area ④.

- The laser ③ for detecting the distance is installed in the handle adapter of the handle ②.
- If the light head is repositioned during surgery, a movement sensor activates the distance detection. The distance of the light head from the wound area is automatically detected with the aid of a laser beam.
- The light intensity is automatically adapted to the working distance on the basis of the measurement data.
- Switchover between automatic distance detection and manual adjustment of the distance is performed by pressing the keys **Auto** ⑥ or **Manual** ⑦.

⚠WARNING

Damage to vision

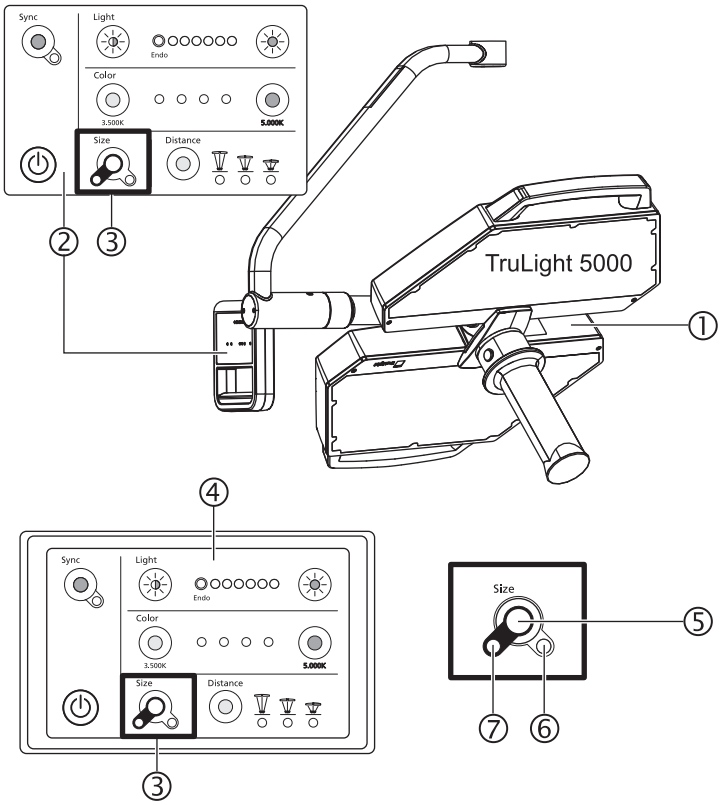
Direct contact with the laser beam may cause damage to vision:

- **Do not look directly into the laser beam**

Protect the patient's eyes:

- **The patient's eyes must be closed or protected (e.g. with safety goggles with an optical density of at least 2, or designed according to protection level 6 EN169).**

Figure 14



5.4.7 Controlling the light field

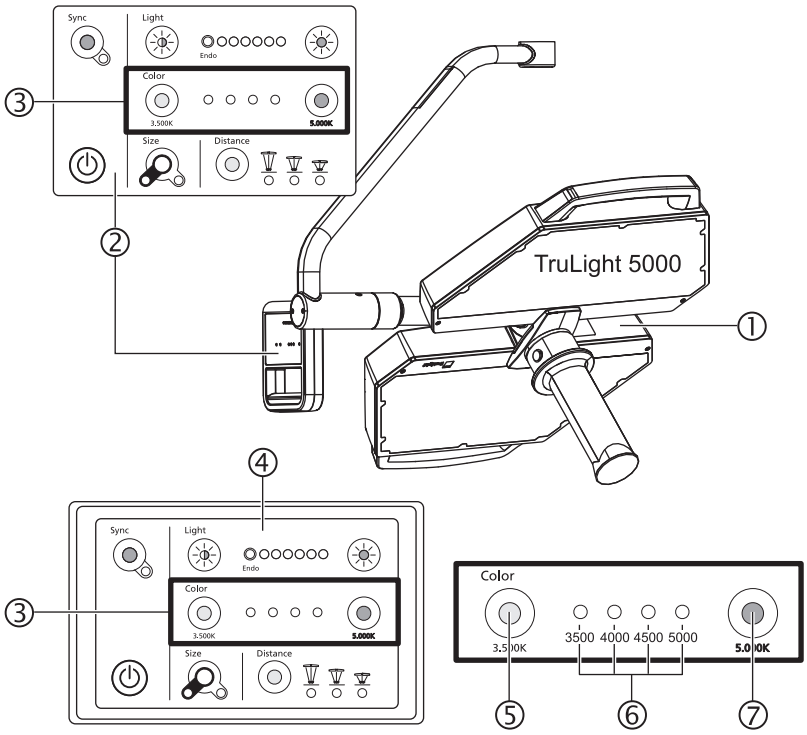
The TruLight 5000 light model is equipped with a function for setting the size of the light field ③:

- Narrow light field, Ø 16 cm at 1 m distance, for a short distance of the light head from the wound area,
- Broad light field, Ø 23 cm at 1 m distance, for a greater distance of the light head from the wound area,

Adjustment of the size of the light field is performed on the non-sterile control panel ② of the light head ① or on the relevant optional wall-mounted control panel ④.

- **Activating the narrow field:**
  - Press the key ⑤ in the **Size** section until the LED ⑦ lights up.
- **Activating the broad field:**
  - Press the key ⑤ in the **Size** section until the LED ⑥ lights up.

Figure 15



5.4.8 Controlling the colour temperature (optional)

The TruLight 5000 light models are equipped with a functionality for variable colour temperature ③. The value of the colour temperature can be manually adjusted in the range from 3500 K up to 5000 K in steps of 500 K.

The colour temperature is set in the non-sterile area on the control panels ② on the light head or on the corresponding optional wall-mounted control panel.

- **Increasing the colour temperature:**
  - Press key ⑦ in the **Color** section until the LED ⑥ for the required colour temperature lights up.
- **Reducing the colour temperature:**
  - Press key ⑤ in the **Color** section until the LED ⑥ for the required colour temperature lights up.

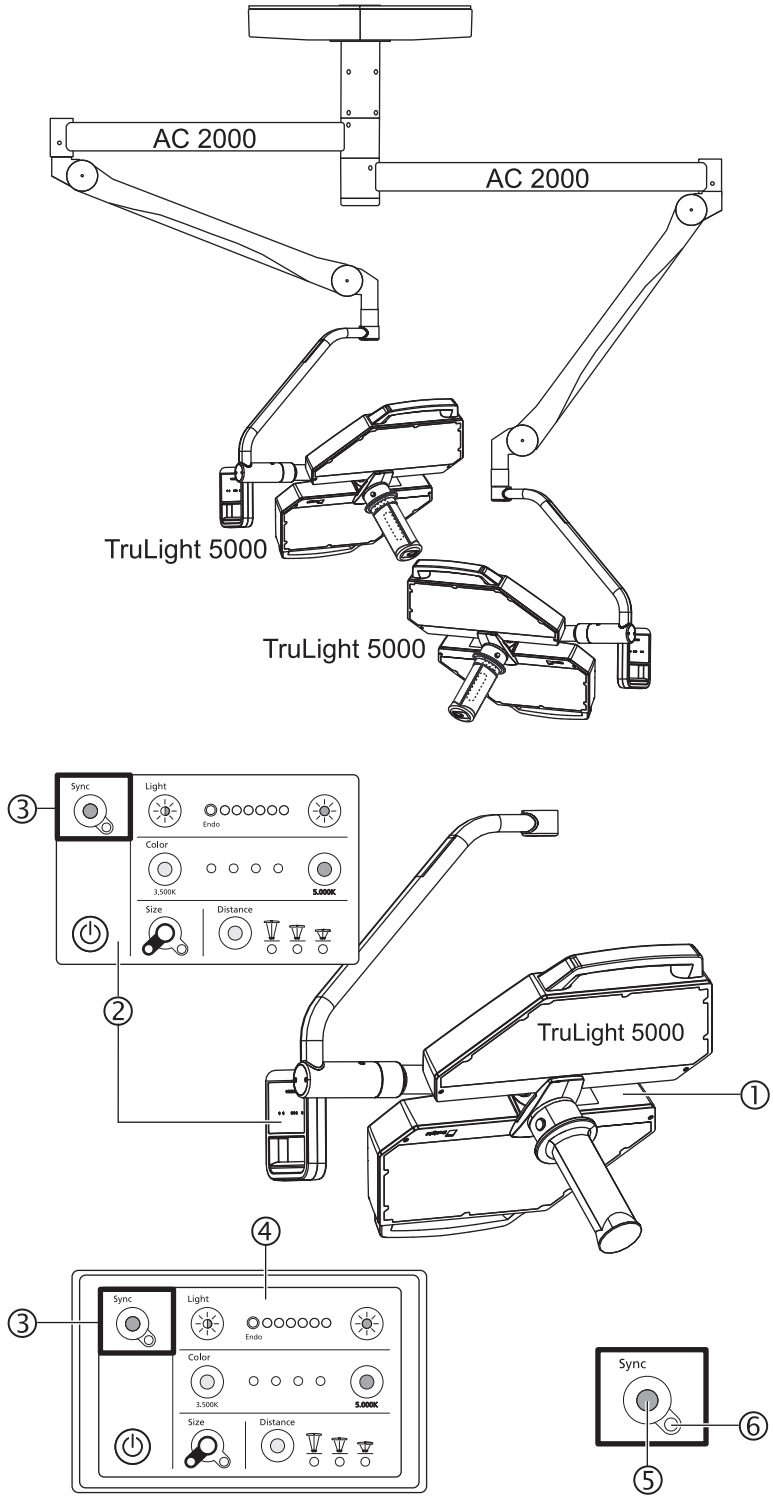
Mode of action of the colour temperature

The variable colour temperature function is used to increase the colour contrast in the wound area. The visual contrast behaviour of the colour temperature is as follows:

- For a wound area which is mainly blue in colour, a lower colour temperature (3500 K to 4000 K) increases the colour contrast and provides a better perception of colour differences by the operating team.
- For a wound area which is mainly red in colour, a higher colour temperature (4000 K to 4500 K) increases the colour contrast and provides a better perception of colour differences by the operating team.

For normal operations, a colour temperature in the range 4000 K to 4500 K should be initially selected.

Figure 16

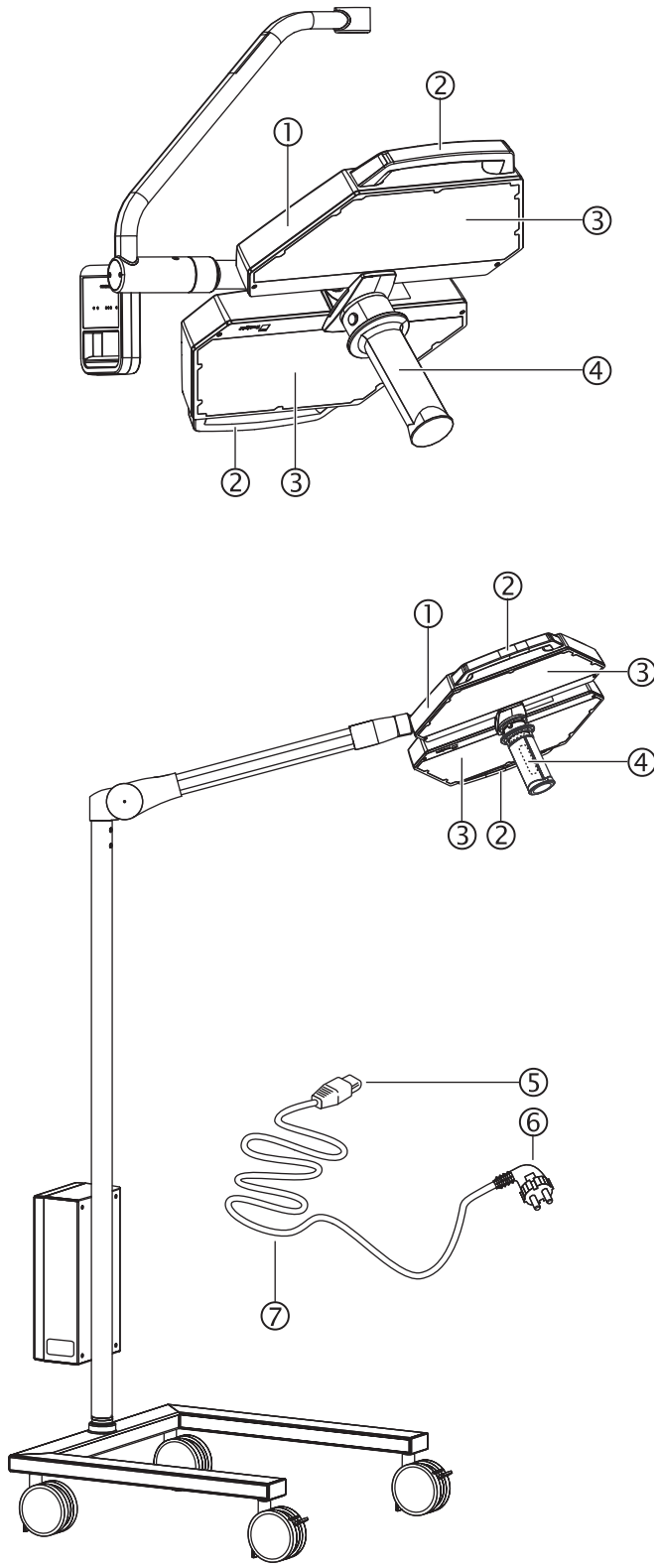


5.4.9 Synchronisation of the colour temperature

The TruLight 5000 light models ① are equipped with a functionality for colour temperature synchronisation ③.
For operating table lighting systems which consist of several lamps, the TruLight 5000 allows the synchronisation of the colour temperature of the individual light heads.
The synchronisation is set in the non-sterile area on the control panels ② on the light head or on the corresponding optional wall-mounted control panel.
For activation, the colour temperature value of the light head on which synchronisation is initiated is definitive.

- **Synchronising the colour temperature:**
  - Press key ⑤ in the **Sync** section,
  - the LED ⑥ lights up and indicates that the synchronisation is activated.
  - Synchronisation is deactivated if the colour temperature of a light head in the system is changed.

Figure 17



6.1 Checking the lighting systems

For all versions of the lighting system, a function test and a visual inspection should be carried out before use, or at least once per week.

⚠WARNING

Contamination and infection hazard for patients

Loose or damaged parts may fall into wounds. To ensure the safety of patients, check the components of the lighting system for the following points before each use:

- **Loose parts on the light head ①,**
- **Visible damage, in particular on the cover plates ③ of the light heads, the non-sterile outer handles ② and the sterile handles ④.**
- **Secure attachment of the sterile handles ④**

Electric shock

There is a risk of electric shock in the event of contact with damaged electrical components of the mobile stand version:

- **Do not connect the stand to the mains in the event of defective plug connectors ⑤ or ⑥ or damaged mains cables ⑦.**

The lighting system is no longer safe to use when the damage described above or other damage occurs:

- **Disconnect the lighting system by using the master switch installed in the building, or remove the safety connector.**
- **Ensure that the mains switch is not unintentionally switched on or that the safety connector is not unintentionally plugged in.**
- **Label the lighting system as DEFECTIVE!**
- **Inform Trumpf Medical Customer Service.**

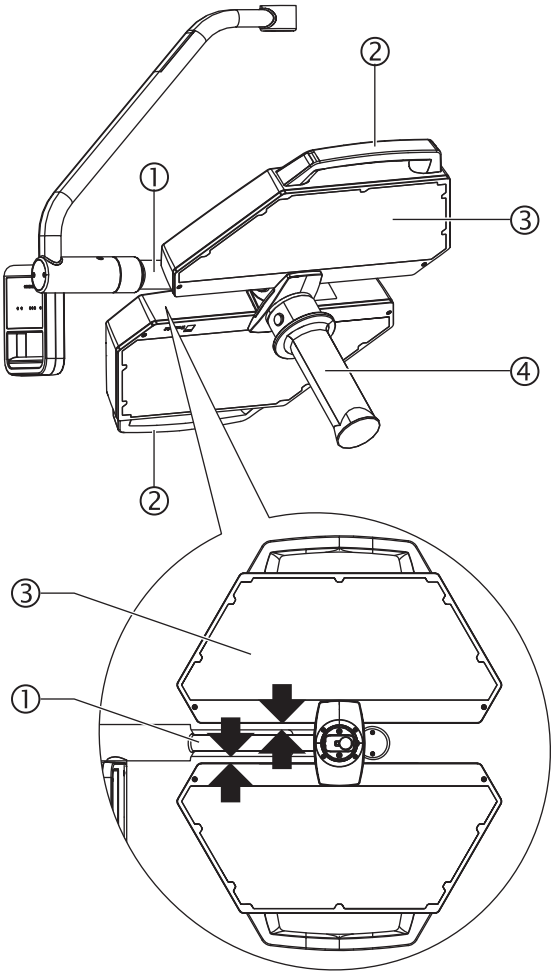
Strong magnetic fields

The support arm systems of the lighting systems must not be used in the vicinity of strong magnetic fields.

BF/CF Class application components

No BF or CF Class application components in accordance with IEC 60601-1 may be directly connected to the support arm systems of the lighting system.

Figure 18



6.2 Positioning of the lighting systems

The positioning function of the lighting system is safe to operate. Pinching injuries during positioning may nevertheless occur.

⚠ CAUTION

Risk of jamming

When rotating the light head, the distance between the cardan joint and the lighting module reduces:

- **Do not reach between the cardan joint rod ① and the lighting module ③ while rotating the light head.**
- **Only use the sterilisable handle ④ or the non-sterile outer handles ② to position the light head.**

6.2.1 Risks of collision during positioning

The lighting system has an impact-proof surface coating. Collisions may nevertheless damage the lighting system.

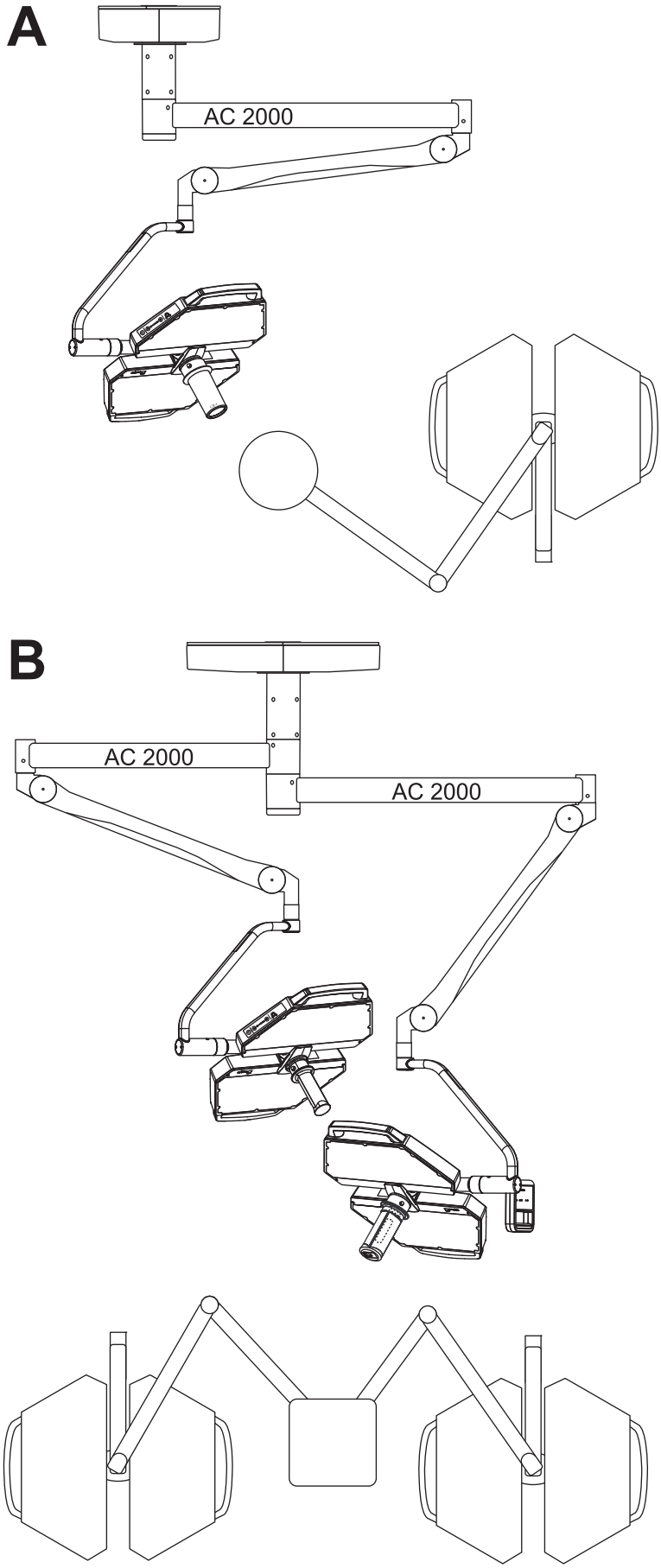
ATTENTION

Damage to the light head

The area of rotation of the lighting system may be restricted by other components or adjacent walls. A collision of the support arm or the light head may cause damage:

- **Avoid collisions with other objects or with adjacent walls.**
- **Before adjusting the height, make sure that there is sufficient distance from the ceiling and ensure that no other objects are located above the light head.**

Figure 19



6.2.2 Positioning the cover-mounted / wall-mounted version

Ceiling-mounted version of single light

A: Surgical light as single light with a light head on the AC 2000 type spring arm

- The best possible mobility of the support arms is a "V-type arrangement".

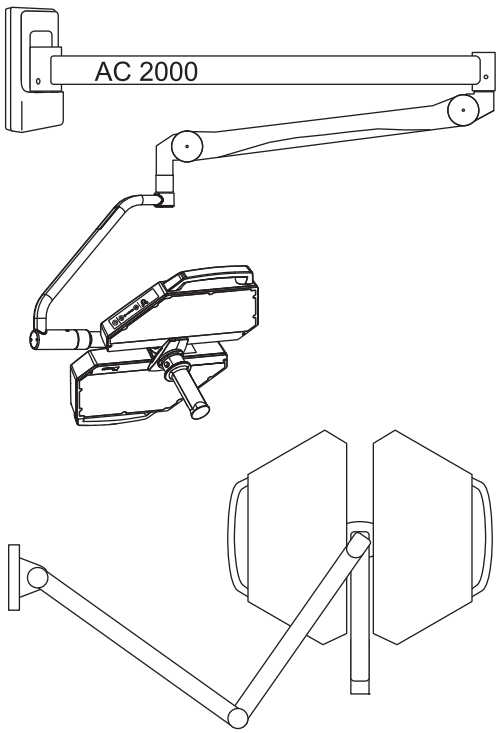
Ceiling-mounted lighting system

B: Surgical lighting system as a combination of several light heads on AC 2000 or AC 2000 LCH (Low Ceiling Height) type spring arms.

- The best possible mobility of the support arms is an "M-type arrangement".

Figure 20

C



Wall-mounted version single light

C: Surgical light as single light with a light head on an AC 2000 or AC 2000 LCH (Low Ceiling Height) type spring arm.

- The best possible mobility of the support arms is a "V-type arrangement”.

Working distance

Position the light head with the sterile handle or the outer non-sterile outer handles at a working distance of 70–150 cm from the wound area.

Adaptive Light Control plus (ALC plus), optional

In order to use the functionality of Adaptive Light Control plus effectively, the integrated distance measurement must make its measurement within the wound area. The sterile handle of the light head must therefore be adjusted so that the laser beam falls inside the wound area.

⚠WARNING

Damage to vision

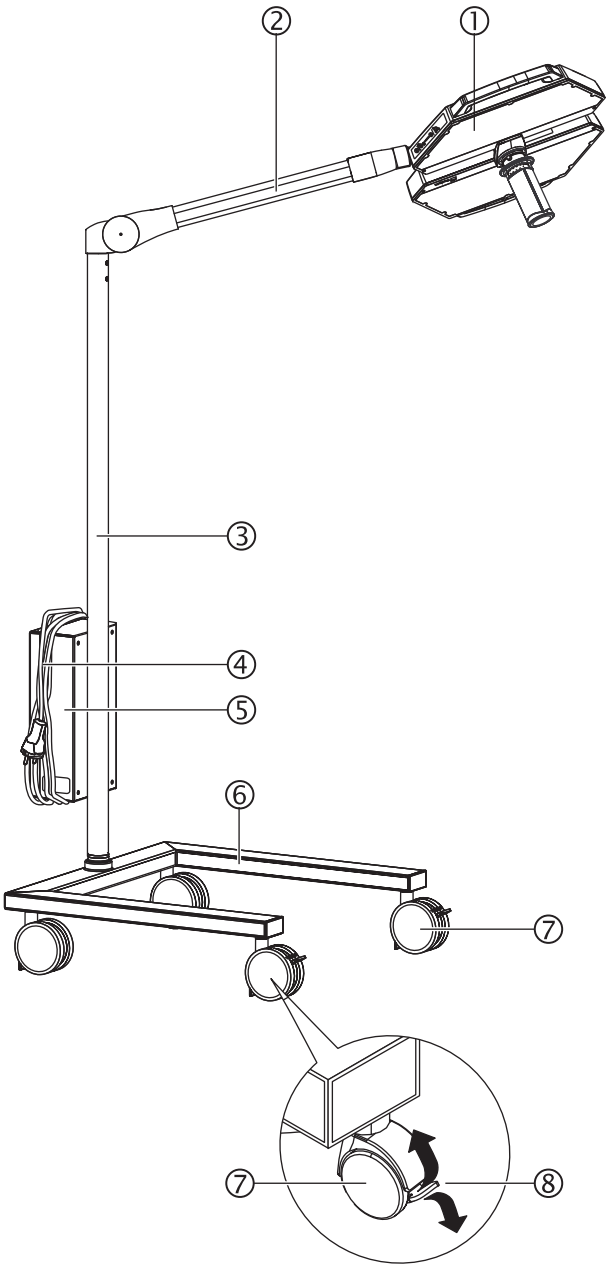
Direct contact with the laser beam may cause damage to vision:

- **Do not look directly into the laser beam**
- **Protect the patient's eyes:**
  The patient's eyes must be closed or protected as necessary (e.g. with safety goggles with an optical density of at least 2 or designed according to protection level 6 EN169).
- **Use of operating methods or procedures other than those stated in these instructions for use may result in dangerous radiation effects due to the laser.**

Switch the power supply to Standby

- Switch on the operating theatre master switch.
- Switch on light head (see chapter Operation).

Figure 21



6.3 Positioning the mobile stand version

The mobile stand version has a high tilting stability. The following, basic precautions must nevertheless be considered when positioning the mobile stand version.

ATTENTION

Tilting of the stand

The tilting stability of the mobile stand version can be at risk due to objects lying on the floor, uneven floors or the mains cable:

- **Always move the mobile stand to the place of operation with the light head pointing forwards.**
- **Do not drive over objects lying on the floor, uneven parts of the floor or the mains cable.**
- **Pull the mains plug out of the socket and roll up the mains cable ④ at the power supply housing ⑤ to move the stand.**

The pedestal might tilt when the castors ⑦ are locked and excessive force is exerted onto the spring arm ② or light head ①:

- **Avoid strong leverage onto the spring arm or the light head.**
- **Do not add additional loads to the spring arm.**

NOTE

Locking the stand base

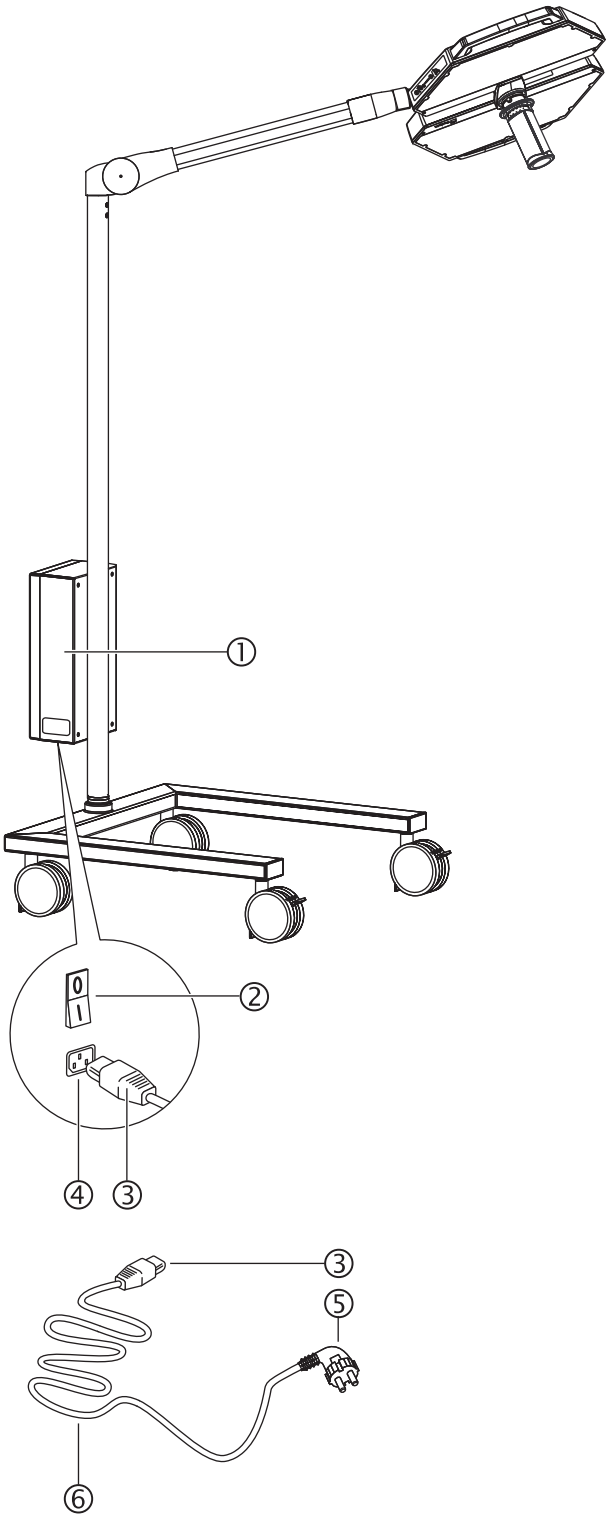
The two front castors ⑦ can be locked to immobilise the stand base ⑥.

- **Press the brakes ⑧ of both front castors downwards to lock them.**
- **Press the brakes ⑧ of both front castors upwards to unlock them.**

Positioning the stand

1. Release the brakes on the two front castors.
2. Grasp the stand by the stand rod ③ and move it with the light head ① in the direction of travel to the place of use.
3. Position the light head ① by using the sterile handle or the outer non-sterile outer handles at a working distance of 70–150 cm from the wound area.
4. Connect the mobile stand version to the mains.
5. Align the light head ① with the wound area using the non-sterile handle.

Figure 22



6.3.1 Connecting the mobile stand version to the mains

The power supply of the mobile stand version is established by a mains cable ⑥ with an IEC connector ③ and a safety connector ⑤.

⚠WARNING

Electric shock

There is a risk of electric shock in the event of contact with damaged electrical components:

- **Do not connect the lighting system to the mains in case of defective plug connectors ③/⑤ or in case of damaged mains cables ⑥.**
- **Label the device as DEFECTIVE and contact Trumpf Medical Customer Service.**

Earthing of the mains socket

In case of an electrical short circuit, earthing reduces the danger of electric shock:

- **The mobile stand version (Protection Class I) may only be connected to a properly earthed safety socket.**

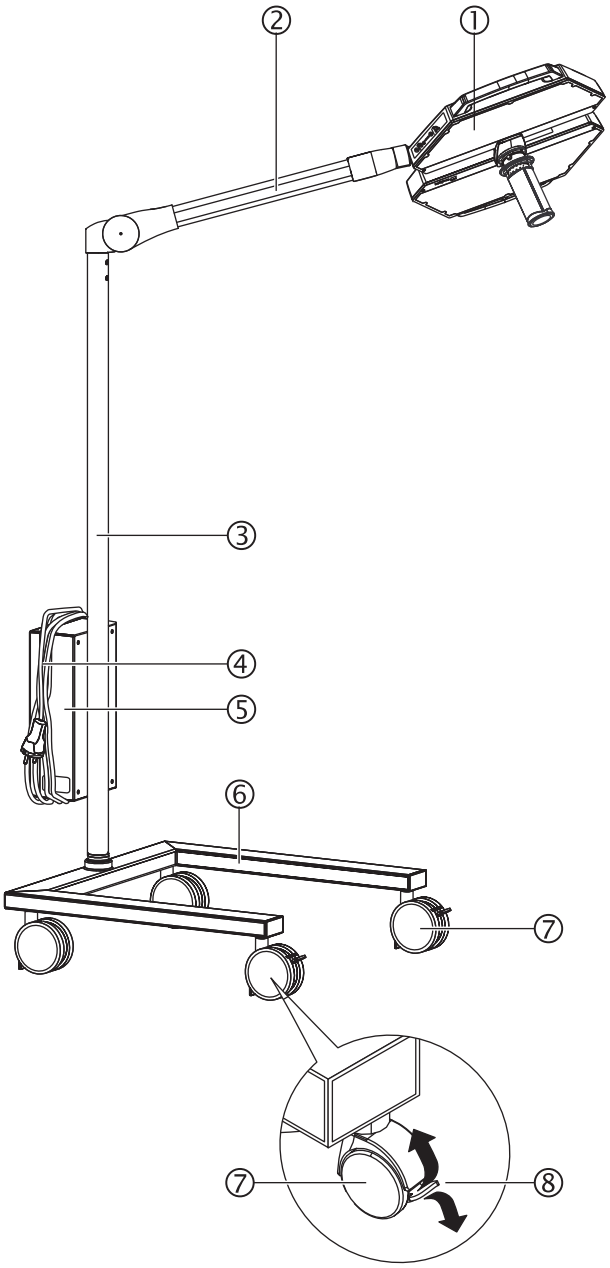
Connect the power supply to the mains

1. Check whether the mains voltage corresponds to the information on the name plate. Ask the local energy supply company or a specialist electrical company in cases of doubt.
2. Lay the mains cable ⑥ so that there is no danger of tripping and so that there is no strain on the cable.
3. Plug the IEC power connector plug connector ③ into the socket ④ on the underside of the power supply housing ①.
4. Insert the mains plug ⑥ into a correctly installed and earthed three-pin plug socket.

Switch the power supply to Standby

- Switch on the power supply unit with the ON/OFF switch ② on the power supply housing.
- Switch on light head (see chapter Operation).

Figure 23



7.1 Switching off the ceiling- and wall-mounted version

Disconnecting the power to the lighting system

- Switch off the operating theatre master switch.

→ The lighting system is disconnected from the power supply.

7.2 Switch off the mobile stand version

Switching the mobile stand version to a current-free state

- Switch off the power supply unit, position the switch in position 0 (see Chapter 6.3.1, page 46), pull the mains cable out of the safety socket.

→ The mobile lighting system is disconnected.

- Coil up the mains cable onto the power supply housing.

Storing the mobile stand version

- Store the mobile stand version at a storage place with suitable environmental conditions (see Chpt. 1.9.2).
- Lock the two front castors.

8.1 Working rules

Compliance with safety instructions

The safety instructions must be read and adhered to when using the lighting system to ensure that it is safely handled and to prevent harm to the patient.

8.2 Preparatory measures

Measures that should be considered before using the lighting system.

Checking the lighting system

Function test / visual inspection

A function test and a visual inspection should be carried out before use, or at least once per week.

⚠WARNING

Contamination and infection hazard for patients

Loose or damaged parts may fall into wounds. To ensure the safety of patients, check the components of the lighting system for the following points before each use:

- **Loose parts on light head,**
- **visible damage, in particular on the cover plates of the light head and the sterile handle,**
- **secure mounting of the sterilisable handle.**

Electric shock

There is a risk of electric shock in the event of contact with damaged electrical components of the mobile stand version:

- **Do not connect the lighting system to the mains in the event of damaged plug connectors or a damaged mains cable.**
- **Take the device out of service and label it as DEFECTIVE.**

LED failure

After failure of the tenth LED, the light head does not achieve the specified light intensity.

- **Take the lighting system out of service.**

Decommissioning

In the event of functional defects or damage which impair the operational safety of the lighting system, the device must be immediately taken out of service:

- **Disconnect the lighting system by using the master switch installed in the building, or remove the safety connector.**
- **Secure the master switch or the safety connector against accidental switch-on/plugging in.**
- **Label the lighting system as DEFECTIVE!**
- **Inform Trumpf Medical Customer Service.**

8.3 Measures to take when using the lighting system

Measures that should be considered while using the lighting system.

⚠WARNING

Risk of damage to vision due to high intensity illumination

In the event of surgery in the field of vision of the patient, the high intensity of illumination by the light heads may cause damage to vision:

- **Protect the patient's eyes (e.g. with safety goggles).**
- **Do not look directly into the light-emitting surface area of the light.**

Damage to patient's tissue

Overlapping fields of illumination from several light heads with high intensity illumination may cause damage to tissue.
In the event of incipient tissue dehydration:

- **Separate the fields of illumination from several light heads.**
- **Reduce the light intensity of the light heads.**

Damage to eyes due to laser beams

Direct contact with the laser beam may cause damage to vision:

- **Do not look directly into the laser beam**
- **Protect the patient's eyes:**
  The patient's eyes must be closed or protected as necessary (e.g. with safety goggles with an optical density of at least 2 or designed according to protection level 6 EN169).
- **Use of operating methods or procedures other than those stated in these instructions for use may result in dangerous radiation effects due to the laser.**

Complications due to electrostatic discharge with the mobile stand version

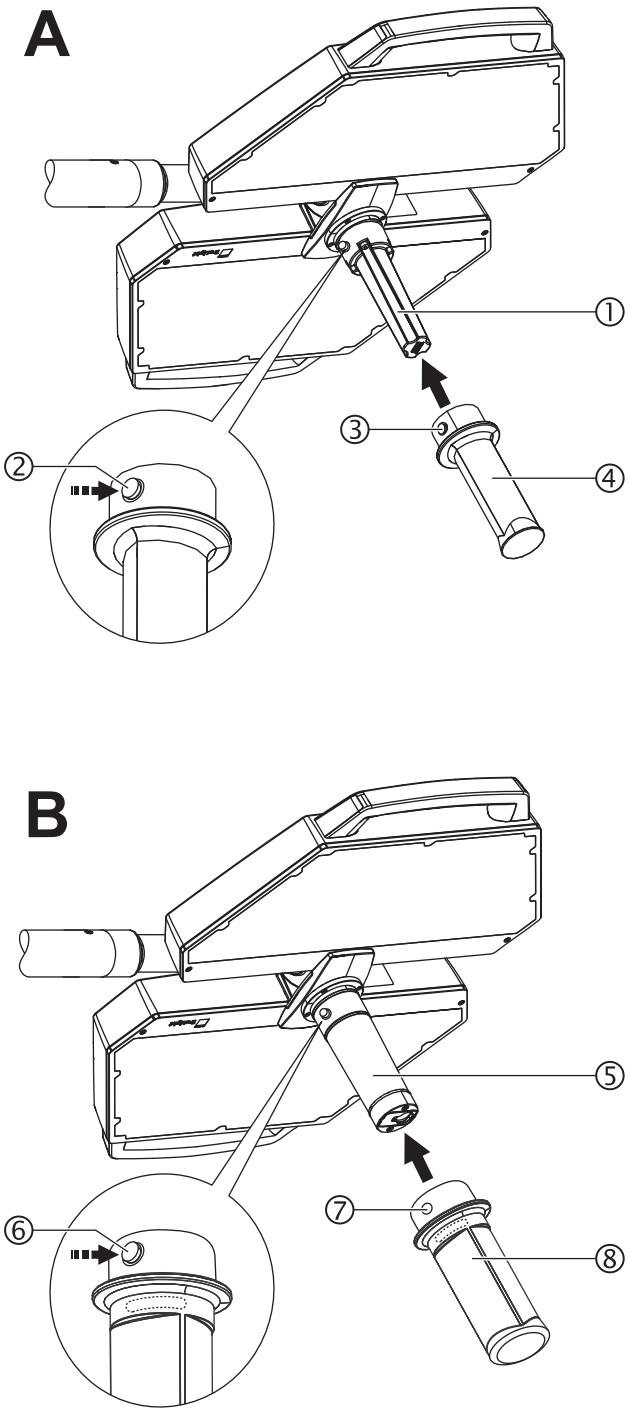
To avoid complications due to electrostatic discharge between parts of the device and patients, the user must not touch parts of the mobile stand version and the patient at the same time.

LED failure

After failure of the tenth LED, the light head does not achieve the specified light intensity.

- **Take the lighting system out of service.**
- **Inform Trumpf Medical Customer Service. Exchanging a light head or repairs to the lighting system may only be performed by Trumpf Medial Customer Service or by service staff trained and authorised by Trumpf Medical.**

Figure 24



8.4 Attaching the sterile handle

Sterile handle standard version

- **A:** Push the sterile handle ④ onto the handle adapter ① and press it upward until the ball latch ② engages audibly in the hole ③.
- Check the firm attachment of the sterile handle.

Sterile Light Control (SLC) handle, optional

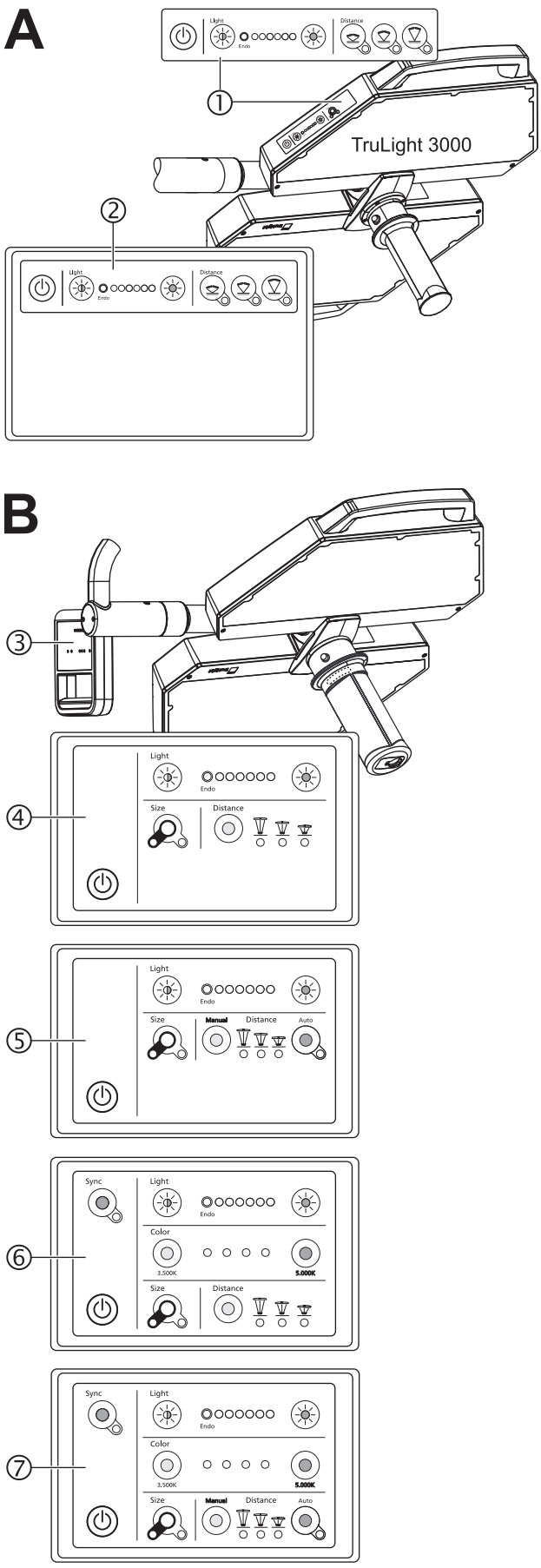
- **B:** Push the sterile handle ⑧ onto the handle adapter with distance detection ⑤ and press it upward until the ball latch ⑥ engages audibly in the hole ⑦.
- Check the firm attachment of the sterile handle.

Sterile handle for ceiling-mounted version with optional camera

The camera as well as the sterile handle for the camera must be coupled according to the following instruction manual:

- TruVidia SD camera system and VidiaPort TFT support arm system,
- TruVidia HD camera system and VidiaPort TFT support arm system,
- TruVidia 3D camera system and VidiaPort TFT support arm system.

Figure 25



8.5 Control panels of the lighting system

The control panels for the lighting functions area equipped with various control elements, depending on the scope of functions of the particular light.

A: TruLight 3000

- Control panel ① on the light head,
- Corresponding control panel ② on the optional wall-mounted control panel with the following equipment variants:
  - Light intensity
  - Adaptive Light Control

B: TruLight 5000

- Control panel on control unit ③,
- Corresponding control panels on the optional wall-mounted control unit ④-⑦ with various equipment variants.

- Version ④:
  - Light intensity
  - Adaptive Light Control
  - Size of light field

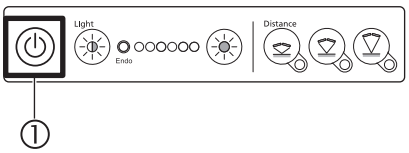
- Version ⑤:
  - Light intensity
  - Adaptive Light Control
  - Size of light field
  - Adaptive Light Control plus

- Version ⑥:
  - Light intensity
  - Adaptive Light Control
  - Size of light field
  - Adjustable Color Temperature
  - Colour temperature synchronisation

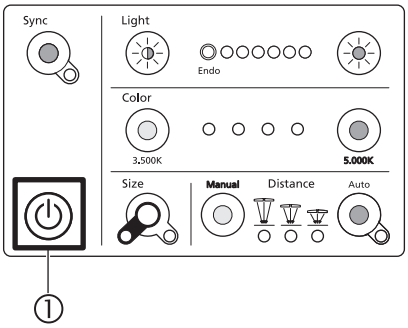
- Version ⑦:
  - Light intensity
  - Adaptive Light Control
  - Size of light field
  - Adjustable Color Temperature
  - Adaptive Light Control plus
  - Colour temperature synchronisation

Figure 26

TruLight 3000



TruLight 5000



8.6 Switching the light head on/off

The lighting system is switched on in two stages:

- Switch the power supply of the lighting system to standby,
- Switch on the light head

Switch the power supply to Standby

Ceiling-mounted and wall-mounted versions:

- Switch on the operating theatre master switch.

→ The power supply of the lighting system is in Standby.

Mobile stand version:

- Connect the mains cable and switch on the power supply. Set the switch to Position I (see Chapter 6.3.1, page 46),

→ The power supply of the mobile lighting system is in Standby.

Switching on the light head

- Press the ON / OFF button ①:

→ The two lighting modules ③ of the light head light up.

Switching off the light head

- Press the ON / OFF button ①.

→ The two lighting modules ③ of the light head go out.

8.7 Disconnecting the power to the lighting system

Ceiling-mounted and wall-mounted versions

- Switch off the operating theatre master switch.

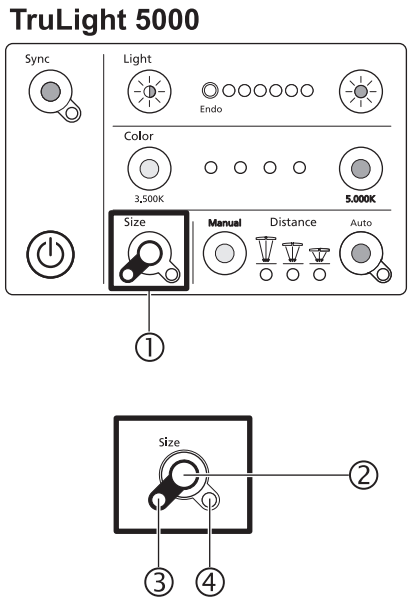
→ The lighting system is disconnected from the power supply.

Mobile stand version

- Switch off the power supply unit, position the switch in Position 0 (see Chapter 6.3.1, page 46), pull the mains cable out of the safety socket.

→ The mobile lighting system is disconnected.

Figure 27



8.8 Setting the size of the light field

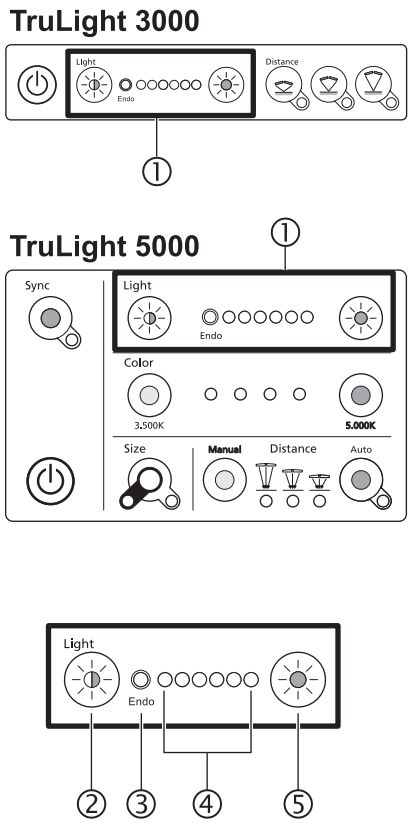
The TruLight 5000 light model is equipped with a function for setting the size of the light field ③:

- Narrow light field for a short distance of the light head from the wound area,
- wide light field for a short distance of the light head from the wound area,

Selecting the light field

- **Activating the narrow field:**
  - Press the key ② in the **Size** section until the LED ④ lights up.
- **Activating the broad field:**
  - Press the key ② in the **Size** section until the LED ③ lights up.

Figure 28



8.9 Setting the light intensity

Working distance

Position the light head with the sterile handle or the outer non-sterile outer handles at a working distance of 70 cm–150 cm from the wound area.

⚠ CAUTION

High light intensities with overlapping fields of illumination

When working with overlapping fields of illumination, high light intensities may accelerate tiring of the eyes.

- **Reduce the light intensity of the light heads.**

8.9.1 Non-sterile setting of the light intensity at the control panel

The light intensity is set at the **Light** ① control panel. The intensity of illumination of the light head can be adjusted in 7 stages:

– < 10 % (Endo)

– 40 %–100 %

Reducing the light intensity:

- Press key ② on the control panel.

→ The LED for the currently set light intensity ④ lights up

Increasing the light intensity:

- Press key ⑤ on the control panel.

→ The LED for the currently set light intensity ④ lights up

Endo-dimming

The light intensity level Endo-dimming ③ is intended as the light intensity for endoscopic operations.

Activating Endo-dimming:

- Press key ③ on the control panel until the Endo LED illuminates.

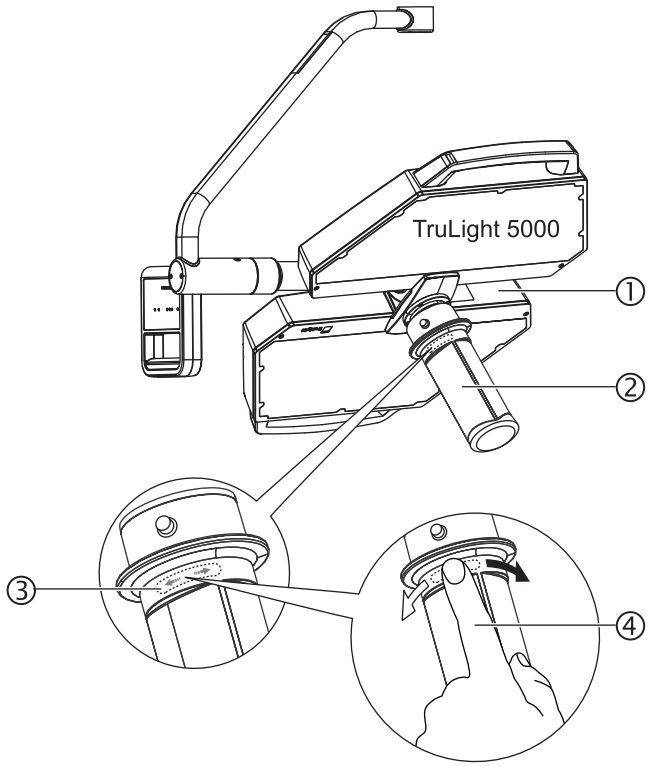
→ The light intensity is reduced to a value < 10 %.

Deactivating Endo-dimming:

- Press key ⑤ on the control panel until the Endo LED goes out.

→ The light intensity is set to a value in the range of 40 %–100 % (indicated by the corresponding lit LED).

Figure 29



8.9.2 Set the light intensity in the sterile area using the Sterile Light Control (SLC)

The light intensity can be set in the sterile area for the light model TruLight 5x20 ①.
The sterile handle ② with Sterile Light Control function can be used to set light intensity with simple finger movements ④. A touch sensor ③ is installed below the collar of the sterile handle to regulate the light intensity.

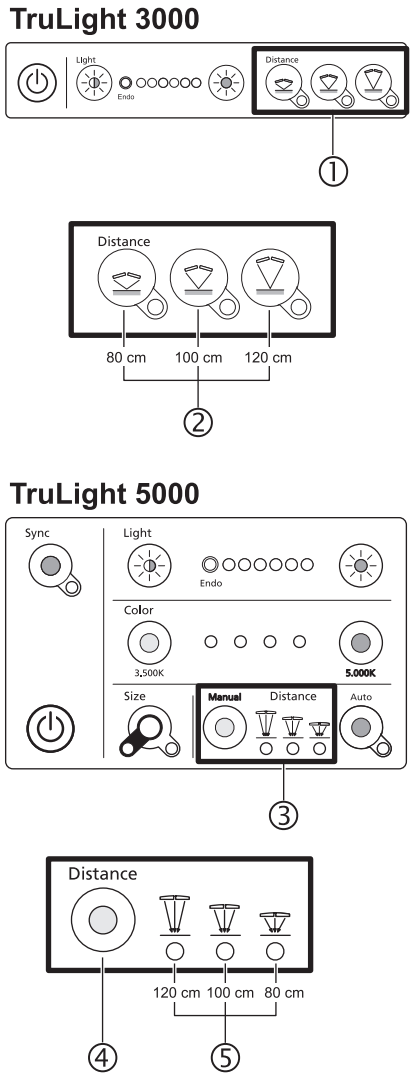
Increasing the light intensity:

- Swipe from left to right.

Reducing the light intensity:

- Swipe the finger from right to left.

Figure 30



8.9.3 Setting the light intensity to the working distance in the non-sterile area with Adaptive Light Control (ALC)

The Adaptive Light Control (ALC) function automatically adapts the light intensity when the position of the light head is changed relative to the wound area. Three distance levels can be selected with the ALC function ①:

- Long distance (approximately 120 cm);
- Medium distance (approximately 100 cm);
- Short distance (approximately 80 cm);

TruLight 3000

Setting distance levels:

- Select the relevant key ② on the control panel ①.

→ The light head automatically selects an optimum LED setting for the light intensity.

TruLight 5000

Setting distance levels:

- Press key ④ on the control panel until the LED ⑤ for the required distance level lights up.

→ The light head automatically selects an optimum LED setting for the light intensity.

8.9.4 Adjusting the light intensity with Adaptive Light Control plus (ALC plus)

Adaptive Light Control plus (ALC plus) has the same functionality as Adaptive Light Control (ALC), but also enables the targeted electronic control of various LEDs in order to achieve optimum illumination of the wound area.

⚠WARNING

Damage to vision

Direct contact with the laser beam may cause damage to vision:

- **Do not look directly into the laser beam**
- **Protect the patient's eyes:**
  Close the patient's eyes or protect them as necessary (e.g. with safety goggles with an optical density of at least 2 or designed according to protection level 6 EN169).
- **Use of operating methods or procedures other than those stated in these instructions for use may result in dangerous radiation effects due to the laser.**

NOTE

ALC plus function

The Adaptive Light Control plus (ALC plus) function is only available for light models TruLight 5x10 and TruLight 5x20.

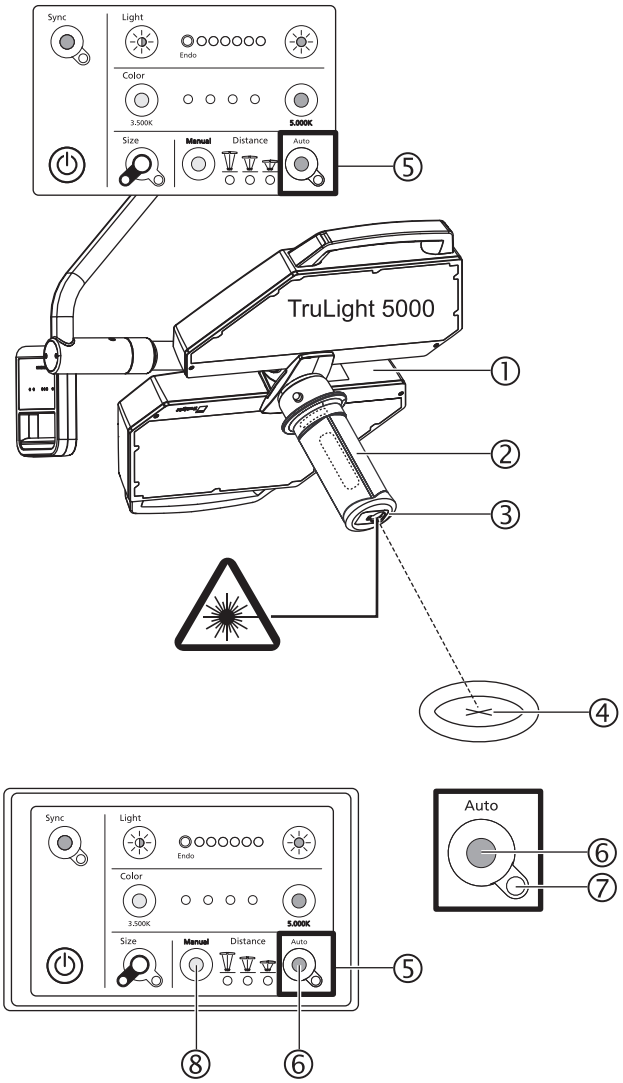
Camera system

Adjusting the light intensity for camera system with Adaptive Light Control plus (ALC plus)

The functionality of Adaptive Light Control plus (ALC plus) in the camera is based on evaluating image signals.

- If the light head is repositioned during surgery, the measuring mode of the camera is activated and automatically remeasures the distances between the light head and the wound area.
- The light intensity is automatically adapted to the working distance on the basis of the established measurement data (see also instruction manual: TruVidia SD or TruVidia HD).

Figure 31



Fine positioning Adaptive Light Control Plus (ALC plus)

To use Adaptive Light Control plus (ALC plus), point the light head precisely at the wound area ④ using the sterile handle ②.

Activating the ALC plus function:

1. Press the key ⑥ Auto.

→ The LED ⑦ lights up and indicates that ALC plus is activated.

2. Briefly readjust the position of the light head:

→ The laser beam is switched on automatically and measures the distance of the light head from the wound area ④ again.

→ The light intensity is immediately and precisely adapted to the working distance on the basis of the measurement data.

Deactivate the ALC plus function:

3. Press the key ⑥ Auto.

→ The LED ⑦ goes out and indicates that ALC plus is deactivated.

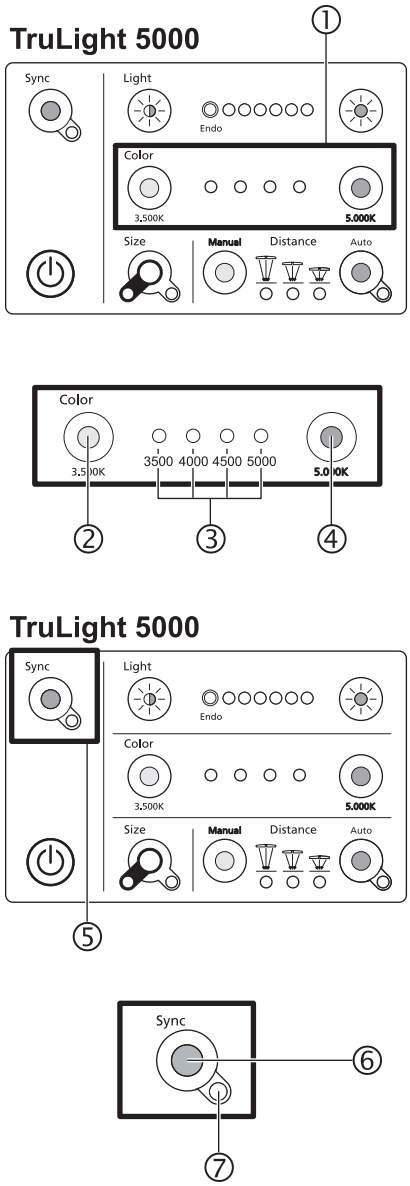
→ Only the functions of Adaptive Light Control (ALC) are now available.

NOTE

Manual/auto switchover

Switchover between automatic distance detection and manual adjustment of the distance is performed by pressing the keys Auto ⑥ or Manual ⑧.

Figure 32



8.9.5 Setting colour temperature

Only the light models TruLight 5000 have the Adjustable Color Temperature function (optional). The value of the colour temperature can be manually adjusted in the range from 3500 K up to 5000 K in steps of 500 K.

The colour temperature is set in the non-sterile area on the control panels ① on the light head or on the corresponding optional wall-mounted control panel.

- **Increasing the colour temperature:**
  - Press key ④ in the **Color** section until the LED ③ for the required colour temperature lights up.
- **Reducing the colour temperature:**
  - Press key ② in the **Color** section until the LED ③ for the required colour temperature flashes up.

Mode of action of the colour temperature

The Adjustable Color Temperature function is used to increase the colour contrast in the wound area. The visual contrast behaviour of the colour temperature is as follows:

- For a wound area which is mainly blue in colour, a lower colour temperature (3500 K to 4000 K) increases the colour contrast and provides a better perception of colour differences by the operating team.
- For a wound area which is mainly red in colour, a higher colour temperature (4000 K to 4500 K) increases the colour contrast and provides a better perception of colour differences by the operating team.

8.9.6 Synchronisation of the colour temperature

The TruLight 5000 light models are equipped with a functionality for colour temperature synchronisation.
For operating table lighting systems which consist of several lamps, the colour temperature of the individual light heads can thereby be synchronised.
The synchronisation setting is made in the non-sterile area on the control panels ⑤ on the light head or on the corresponding optional wall-mounted control panel.
For activation, the colour temperature value of the light head on which synchronisation is initiated is definitive.

- **Synchronising the colour temperature:**
  - Press key ⑥ in the **Sync** section,
  - the LED ⑦ lights up and indicates that the synchronisation is activated.
  - Synchronisation is deactivated if the colour temperature of a light head in the system is changed.

Regular cleaning and disinfection with suitable cleaning or disinfection agents is necessary for the safe use of the surgical light.

⚠WARNING

Electric shock

Touching live components may result in an electric shock.

- **Disconnect the device before cleaning and disinfection:**
- **Ensure that no cleaning or disinfectant fluids penetrate into the device or into the support arm system.**
- **Do not place any objects in the equipment openings.**

Ceiling-mounted and wall-mounted versions

- Switch off the operating theatre master switch.

→ The lighting system is disconnected from the power supply.

Mobile stand version

- Switch off the power supply unit, position the switch in Position **0** (see Chapter 6.3.1, page 46), pull the mains cable out of the safety socket.

→ The mobile lighting system is disconnected.

⚠WARNING

Improperly used cleaning agents or disinfectants can pose a risk for patients or damage products

If the information and instructions contained in this chapter are not observed or complied with, this may result in a risk of contamination or infection for the patient or damage to the product. Furthermore, it would render any claim for damages void!

- **Dispense cleaning agents and disinfectants such that no liquid can enter through joints or openings of the surgical lamp or parts of the support arm system.**
- **Use the surface disinfectant only at the concentration specified by the manufacturer.**
- **Only use disinfectants approved by the manufacturer for use with the following materials:**
  Polycarbonate (PC), polyamide (PA), acrylonitrile butadiene styrene copolymer (ABS), polystyrene (PS), polyurethane (PUR), polyphenylene sulphone (PPSU), polybutylene terephthalate (PBT) and silicones.
- **In the event of an excessive coating of surface disinfectant forming, carry out a thorough cleaning.**
- **Due to the risk of surface damage:**
  - Do not use sharp, pointed or abrasive objects,
  - Do not use abrasive substances or agents which can remove material,
  - Do not use solvents, benzene, paint thinners, alkaline cleaning agents or cleaning agents containing acids or aldehydes,
  - Do not use agents with glycol derivatives, phenols, phenol derivatives or quaternary compounds,
  - To prevent paint or corrosion damage, only use agents that do not contain chlorides or halogenides.

- **It is essential that the hygiene instructions of the operator are observed.**

9.1 Cleaning and disinfection

9.1.1 General

Performed by hygiene specialist staff

Cleaning and disinfection of the surgical lights may only be performed by a hygiene specialist or a person instructed by the hygiene specialist.

Only use recommended cleaning agents and disinfectants

For cleaning and disinfection you should only use agents and chemicals tested by and approved by Trumpf Medical with regard to their material compatibility in accordance with Chapter 9.1.3, page 62. If an agent is not included on the list it should not be used as otherwise functional components could be changed or damaged.

Basic cleaning before disinfection

Thorough cleaning of visible dirt, e.g. by body fluids, must be performed before the actual disinfection.

- Cleaning may not involve sharp, pointed or abrasive objects or scouring agents or agents containing material with abrasive effects, as this might damage the surfaces.
  Damaged surfaces can be penetrated and destroyed by chemical substances.
- Only soft brushes and mild detergents or cleaning disinfectants may be used to remove strong and persistent dirt. Disinfection may start after no more visible dirt can be found.

Only use wipe-over disinfection

Use the wipe-over method only for disinfection. Disinfection by UV irradiation or steaming is not permissible.

NOTE

Warranty claim

Failure to comply with cleaning or disinfection requirements will render any warranty claim void. No warranty is accepted for damage which is due to the use of unsuitable cleaning agents or disinfectants.

The warranty applies only to undamaged surfaces!

9.1.2 Wipe-over disinfection

Wipe-over disinfection is used to disinfect the light head and the support arm system. The light head may only be cleaned and disinfected when it is cold.

Only wipe with a damp cloth

For cleaning and disinfection, wipe the device components only with a damp but not wet cloth. Wiping should apply only a thin film of liquid and after wiping only a thin coherent film of moisture should remain. From the microbiological point of view, this moisture film is entirely sufficient. Liquid should not pool on the surface.

Avoid the build-up of a coating

If too much liquid is applied to the surface during disinfection, residues will be left on the product. To prevent the build-up of a coating of disinfectant residues, regular cleaning with a mild all-purpose cleaner is necessary.

Cleaning to be carried out at least monthly

The regularity of cleaning will depend on the frequency of disinfection but must be at least once a month.
Only clean the surgical light with a damp but not wet cloth.

Cleaning procedure

1. Disconnect the power supply from the mains.
2. Allow the light head to cool down. Only clean or disinfect the light head when it is cold.
3. Moisten a cloth with a drop of cleaning or disinfecting agent. Clean the surgical light with the damp but not wet cloth.

⚠WARNING

Risk of fire or explosion by disinfectants

Production of gases, fumes or mists when using disinfectants may create a combustible or explosive atmosphere.

- **Do not use highly flammable disinfectants.**
- **Do not disinfect large areas.**
- **Allow hot surfaces to cool down before disinfection.**
- **Where possible, completely isolate the room's electrical systems or ensure that no switching processes – especially automatic processes – are initiated or run whilst disinfection is in progress.**
- **After wipe-over disinfection, wait until the disinfectant has completely dried.**
- **Ensure the room is adequately ventilated.**

NOTE

Comply with national guidelines.

The operator must observe the requirements of the responsible national hygiene and disinfection board.

9.1.3 Recommended disinfectants

Trumpf Medical recommends the following disinfectants for manual application:

Manufacturer	Product designation
B. Braun Melsungen AG	Meliseptol
Various	70 % 2-propanol alcohol
Schülke & Mayr GmbH	Perform 0.5 %
Bode Chemie GmbH & Co. KG	Dismozon pure 0.75 %
Clorox Healthcare	Hydrogen peroxide cleaner disinfectant wipes
Kesla Pharma	Wofasteril 0.5 %

- The list of approved disinfectants is continually updated and is given in the 'OP lights instruction manual as a supplement' which can be downloaded in the OIS.

Material

The handles are made of heat- and impact-resistant polyphenylene sulfone (PPSU) plastic.

NOTE

Warranty claim

Failure to comply with the sterilisation requirements will render any warranty claim null and void.
No warranty is accepted for damage, which is due to the use of unsuitable sterilisation methods.

Comply with national guidelines.

The operator must observe the requirements of the responsible national hygiene and disinfection board.

10.1 Preparation

- Remove any surface dirt on the surgical light with a disposable cloth / paper towel.
- Remove coarse dirt from the handle immediately after use (within 2 hours).
- Store the handle for later cleaning in a container in which the dirt remains humid.
- Avoid situations in which the inner surface of the handle is dirtied or the cover panel is scratched.

10.2 Cleaning and disinfection

NOTE

Sterilisation faults lead to product damage

Product damage may result when the specifications and instructions provided below are not considered or adhered to. Furthermore, it would render any claim for damages void!

- **Do not use hot-air sterilisation for handles.**

10.2.1 Cleaning

The handles may be cleaned with mildly alkali cleaners without active chlorine. Trumpf Medical recommends neodisher mediClean (forte) at a concentration of 0.5 % (5 ml/l).

1. Pull the handle off the handle adapter.
2. Clean the handle with cleaning agent.
3. Thoroughly rinse off cleaning agents with water.

10.2.2 Disinfection

Use wipe-over or spraying as the method of disinfection. Trumpf Medical recommends products based on alcohol or aldehyde that are approved by the manufacturer for use on PPSU.

4. Disinfecting the handle.
5. Check the handle for material damage, cracks or deformation and exchange damaged handles.
6. Check the cover pane (where present) for firm attachment and exchange the handle as required.

A machine-based procedure (disinfector) according to DIN EN ISO 15883-1 is to be used for cleaning/disinfection. The effectiveness of the method used must be accepted in principle (e.g. be included in the list of the disinfectants and procedures checked and approved by the Robert Koch-Institute / DGHM) and must be validated in principle.
The effectiveness of other methods used (e.g. manual methods) must be proven in principle as part of the validation.
The Dario-D standard cleaning programme provided by the Miele company or programmes that adhere to the following time and temperature values can in principle be used for machine-based cleaning:

Phase	Temperature	Time
Pre-rinsing	20 °C	60 seconds
Cleaning	20 - 55 °C	300 seconds
Neutralisation	24 - 55 °C	60 seconds
Intermediate rinsing	20 - 24 °C	60 seconds
Disinfection	93 °C	300 seconds
Drying	100 °C	25 minutes

10.3 Sterilisation

10.3.1 General information

- The sterilisation methods must be validated in accordance with DIN EN ISO 17665-1 and DIN EN ISO 17665-2;
- Only use fractionated pre-vacuum;
- The temperatures may not exceed 135 °C.

⚠WARNING

Contamination and infection hazard for patients

Check handles after sterilisation for material damage, cracks or deformation, as detaching material particles may fall into the wounds.

- **Handles that are damaged, have undergone a maximum of 350 steam sterilisation cycles or are older than 1.5 years must immediately be exchanged.**

10.3.2 Steam sterilisation

Handles may be exposed to a maximum of 350 steam sterilisation cycles without damage when the following requirements are adhered to:

- Place the handles at an upright position with the open side pointing downwards and ensure that the pane of the ALC or camera handles are not in direct contact with the rinsing device (risk of scratching);
- Sterilise the handles individually in a packaging which is suitable for steam sterilisation;
- The sterilisation packaging must be large enough for the handle, so that the seal is not under tension;
- the maximum load of the steriliser may not be exceeded when several handles are sterilised in one sterilisation cycle.

Steam sterilisation at 132 °C (270 °F):

- Sterilisation time = 4 minutes,
- Drying time = 20 minutes.

Steam sterilisation at 135 °C (275 °F):

- Sterilisation time = 3 minutes,
- Drying time = at least 16 minutes

10.3.3 Sterilisation packaging

The handles are placed in a suitable sterilisation packaging (disposable sterilisation packaging, e.g. film/paper sterilisation bags; single or double packaging in accordance with DIN EN ISO 11607, suitable for steam sterilisation) and then sterilised.

7. Place the pre-cleaned and disinfected handle in the sterilisation packaging.
8. Sterilise the handle according to the specifications.
9. Check the sterilised handle for material damage, cracks or deformation and exchange damaged handles.
10. Check the cover pane (where present) for firm attachment and exchange the handle as required.

All devices are subject to wear and tear over time. The safety and function of the device must therefore be inspected after regular inspection and maintenance intervals. Repeat inspections must be carried out according to the specific national regulations. Trumpf Medical recommends taking out a service contract.

Technical Customer Service
Telephone: +49 3671 586-41911
Fax: +49 3671 586-41175
Service.wwo@trumpfmedical.com

11.1 Inspections during operation

Weekly inspection

A function test and visual inspection must be performed before each use of the lighting system in running medical operation, however at least once per week.

⚠WARNING

Contamination and infection hazard for patients

Loose or damaged parts may fall into wounds. To ensure the safety of patients, check the components of the lighting system for the following points before each use:

- **loose parts in the light heads,**
- **visible damage, in particular on the cover plate of the light head and the sterilisable handle,**
- **secure mounting of the sterilisable handle.**

Defective devices

Defective devices or functional units must be clearly labelled immediately and taken out of operation.
Contact Trumpf Medical Customer Service or an authorised service partner in the event of damage or faults.

11.2 Annual visual inspection

Annual visual inspection

A visual inspection of the hardware of the entire lighting system must be carried out annually by the operator's qualified technicians. In the visual inspection, in particular the following parts and components of the device must be examined for changes to the material:

- Deformation of components of the light head and the support system,
- Paint damage on the entire support arm system and on the light heads,
- missing plastic components and small parts, e.g. covers, plugs, etc.
- cracking and brittle plastic parts,
- legibility of type labels.

Damaged or deformed components must be replaced.

11.3 Maintenance every two years

Maintenance every two years

The device must only be serviced by the Trumpf Medical Customer Service, or authorised partners. The tests must be carried out every 2 years by qualified experts in accordance with the service manual.

ATTENTION

Observe the maintenance intervals

The device must be inspected for the following points:

- **Function test**
- **Electrical safety test**

Function test

In particular, the function test includes the following tests on the support arm system:

- Rotation of the support arms, adjustment of the stops; adjust as necessary;
- ease of movement of the joints; adjust as necessary;
- position of the height stops; adjust as necessary;
- attachment of the securing elements, grease as necessary;
- position and form of the securing rings on the boom and the spring arms;
- check the effect of the spring force; adjust as necessary;
- visual inspection for collision damage;
- visual inspection for cracks in the area of welds.

NOTE

Shortening of maintenance intervals

After 10 years of operation, the function test of the lighting system must be carried out annually.

Documentation according to MPBetreibV [German regulation for the operation of medical equipment]

According to the MPBetreibV, the performance of safety inspections as well as service and maintenance work must be documented in a medical product logbook.
This medical product logbook must be kept on site.

11.4 Repairs

Trumpf Medical will provide an appropriate replacement light head that can be replaced by trained technicians, when required (e.g. when a lamp fails). Installation of the light head is described in the installation instructions which are provided (see Chapter: Installation of the light unit onto the support arm system).

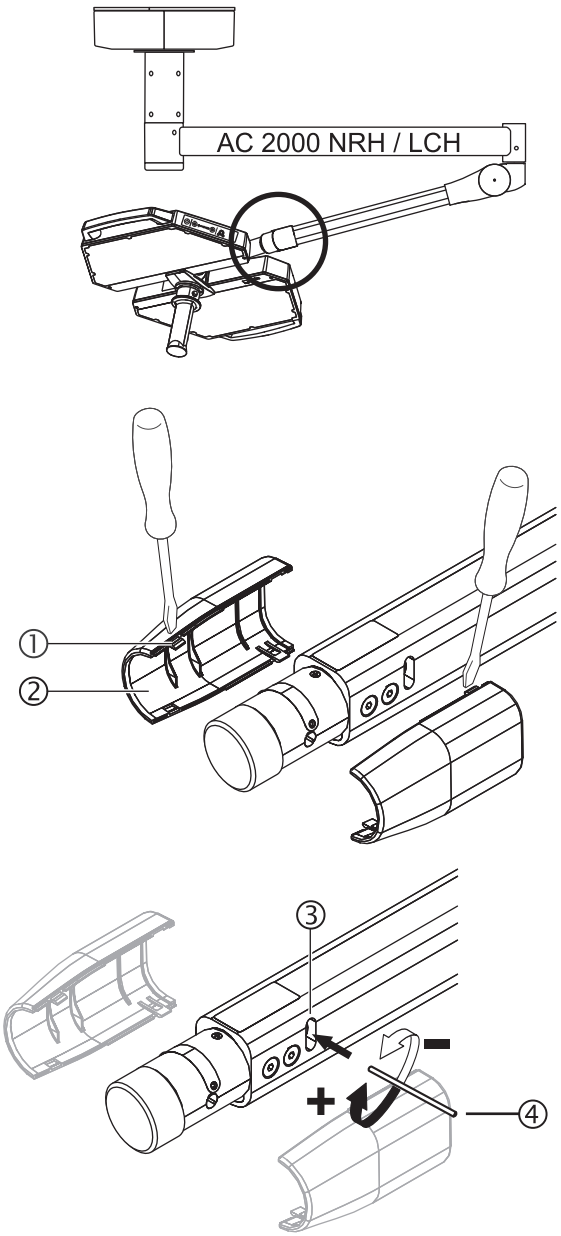
⚠WARNING

Incorrect repairs

Authorised service personnel

The device may only be repaired by Trumpf Medical Customer Service, trained and qualified service staff.

Figure 33



12.1 Setting spring arm swivel range type AC 2000 LCH

The vertical swivel movement may only be adjusted within the range of +30° (upwards) and -45° (downwards). The swivel range can be set so that the collision with the ceiling or with bordering objects can be avoided (the swivel range can be restricted down to the horizontal level).

12.1.1 Disconnecting the power to the lighting system

Ceiling-mounted version

1. Switch off the operating theatre master switch.

→ The lighting system is disconnected from the power supply.

2. Secure the master switch against accidental switch-on.

Mobile stand version

1. Switch off the power supply unit, position the switch in Position 0 (see Chapter 6.3.1, page 46), pull the mains cable out of the safety socket.

→ The mobile lighting system is disconnected.

2. Secure the mains plug against unintentional plugging-in.

12.1.2 Setting the swivel range

Removing the covers

1. Carefully press in and unlock the four lugs ① of the two halves of the cover ② with a suitable flat screwdriver.
2. Remove the two halves of the cover ②.

Adjusting the swivel range

3. Insert the attached pin ④ (Ø4 mm x 110 mm) into the hole of the adjusting nut in the adjustment opening ③.

Reducing the swivel range

- Turn the internally arranged adjusting nut to the right (clockwise).

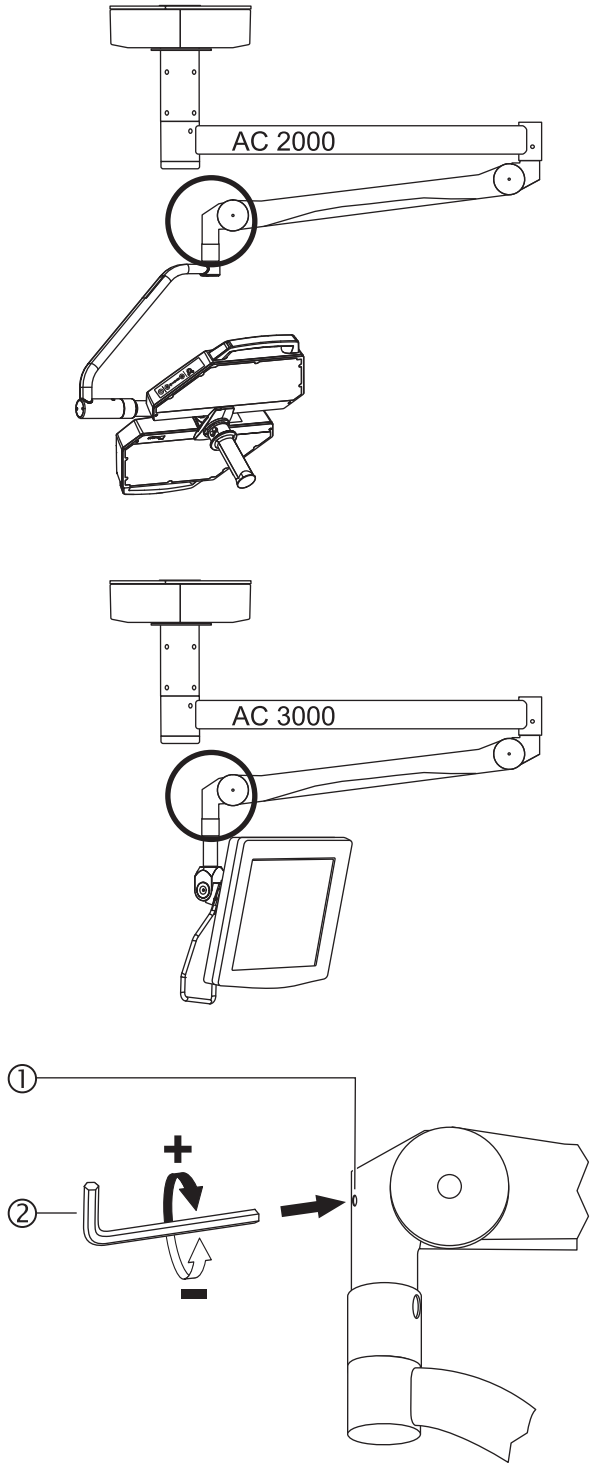
Increasing the swivel range

- Turn the internally arranged adjusting nut to the left (anti-clockwise).

Installing the covers

4. Place the halves of the cover ② on the spring arm and press the four lugs ① against the spring arm, so that they engage.
5. Check the firm attachment of the cover ②.
6. Carry out a function test of the swivel movement.

Figure 34



12.2 Setting spring arm swivel range type AC 2000 and type AC 3000

The vertical swivel movement may only be adjusted within the range of +45° (upwards) and -50° (downwards). The swivel range can be set so that the collision with the ceiling or with bordering objects can be avoided (the swivel range can be restricted down to the horizontal level).

12.2.1 Disconnecting the power to the lighting system

Ceiling-mounted and wall-mounted versions

1. Switch off the operating theatre master switch.

→ The lighting system is disconnected from the power supply.

2. Secure the master switch against accidental switch-on.

12.2.2 Setting the swivel range

1. Insert Allen key ② (5 mm) into the adjustment screw in the adjusting opening ①.
2. Pull down the spring arm to unload the adjustment screw.

Reducing the swivel range

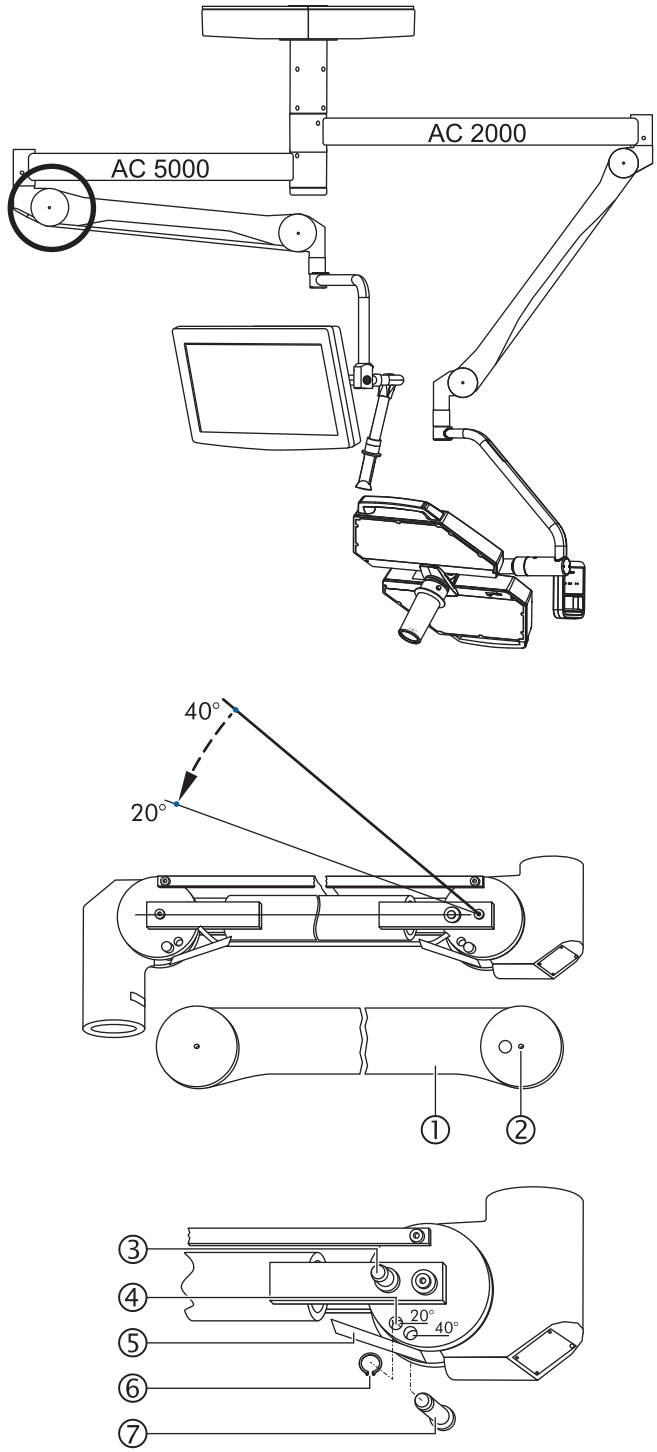
- Turn the adjustment screw to the left (anti-clockwise).

Increasing the swivel range

- Turn the adjustment screw to the right (clockwise).

3. Carry out a function test of the swivel movement.

Figure 35



12.3 Setting spring arm swivel range type AC 5000

The vertical swivel movement may only be adjusted within the range of +40° (upwards) and -40° (downwards). The swivel range can be set so that the collision with the ceiling or with bordering objects can be avoided (the swivel range can be restricted down to the horizontal level).

12.3.1 Disconnecting the power to the lighting system

1. Switch off the operating theatre master switch.

→ The lighting system is disconnected from the power supply.

2. Secure the master switch against accidental switch-on.

12.3.2 Removing the covers

3. Unscrew four cross section recess screws ② (M4 x 6 mm) and remove both the halves of the cover ①.

12.3.3 Setting the swivel range

1. Release the retaining pin ③.
2. Pull off the securing ring ⑥ and remove the stop pins ⑦ .
3. Insert stop bolts ⑦ into the required hole ④ (20° or 40°) and secure using the circlip ⑥.
4. Check for the secure fit of the circlip ⑥.

12.3.4 Installing the covers

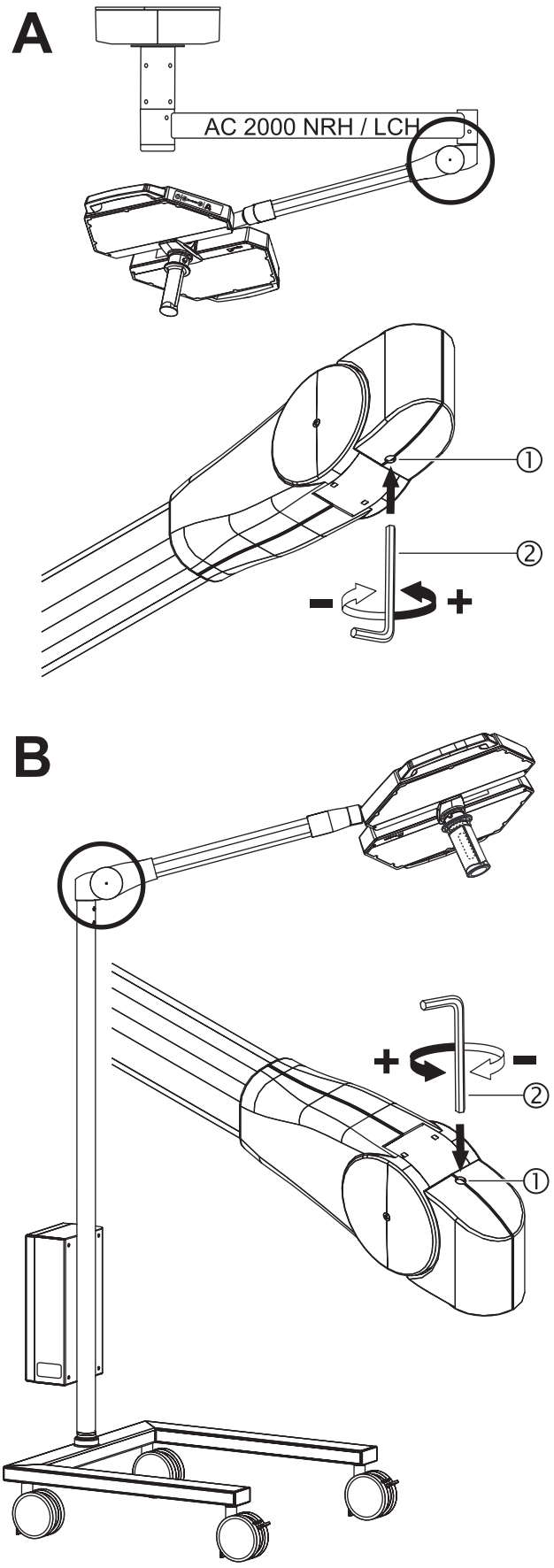
NOTE

Positioning the cover flaps

Make sure during installation of the halves of the cover ② that the four chrome-plated cover flaps ⑤ sit in the guides of the halves of the cover ②.

1. Insert cover flaps ⑤ in the guide of the cover halves ②.
2. Tightly screw both halves of the cover ② with four cross section screws ① (M4 x 6 mm).
3. Check the firm attachment of the cover ②.
4. Carry out a function test of the swivel movement.

Figure 36



12.4 Setting spring arm spring force type AC 2000 LCH

The weight of the light head is compensated by a spring which is installed in the spring arm. The spring force must be adjusted when the spring arm with the light head does not reliably stop at the height position selected after a swivel movement.

12.4.1 Disconnecting the power to the lighting system

Ceiling-mounted version

1. Switch off the operating theatre master switch.

→ The lighting system is disconnected from the power supply.

2. Secure the master switch against accidental switch-on.

Mobile stand version

1. Switch off the power supply unit, position the switch in Position 0 (see Chapter 6.3.1, page 46), pull the mains cable out of the safety socket.

→ The mobile lighting system is disconnected.

2. Secure the mains plug against unintentional plugging-in.

12.4.2 Adjusting the spring force

1. Insert Allen key ② (5 mm) into the adjustment screw in the adjusting opening ①.
2. Place the spring arm in a position approx. +10° or -10° to the horizontal in order to relieve the load on the adjustment screw.

A: Ceiling-mounted and wall-mounted versions

Reducing the spring force

- Turn the adjustment screw to the right (clockwise).

Increasing the spring force

- Turn the adjustment screw to the left (anti-clockwise).

B: Mobile stand version

Reducing the spring force

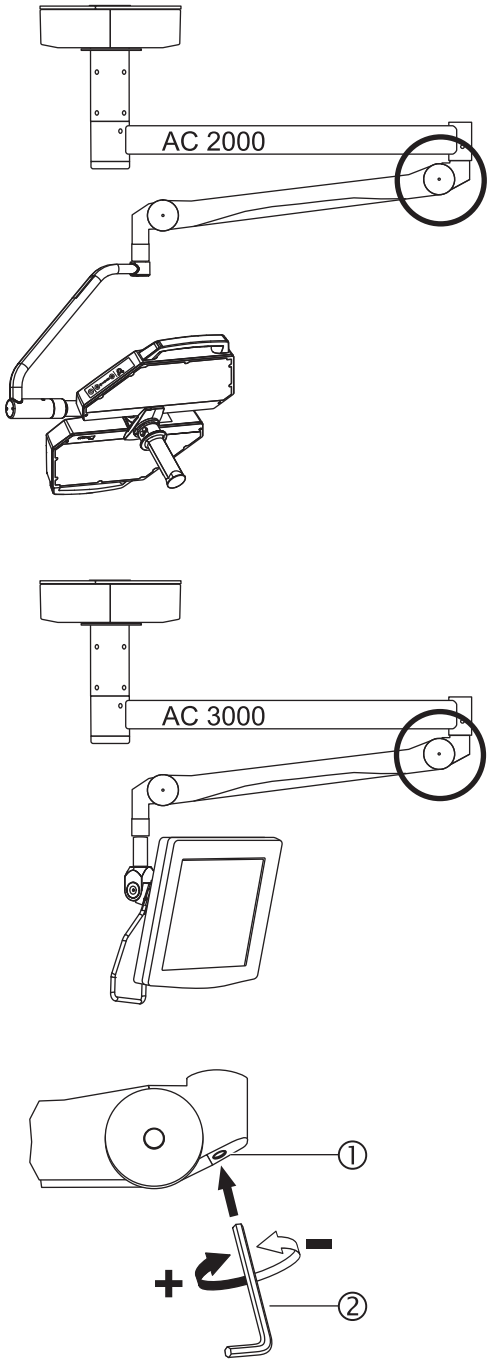
- Turn the adjustment screw to the left (anti-clockwise).

Increasing the spring force

- Turn the adjustment screw to the right (clockwise).

3. Carry out a function test of the spring force.

Figure 37



12.5 Setting spring arm spring force type AC 2000 and type AC 3000

The weight of the light head is compensated by a spring which is installed in the spring arm. The spring force must be adjusted when the spring arm with the light head does not reliably stop at the height position selected after a swivel movement.

12.5.1 Disconnecting the power to the lighting system

Ceiling-mounted and wall-mounted versions

1. Switch off the operating theatre master switch.

→ The lighting system is disconnected from the power supply.

2. Secure the master switch against accidental switch-on.

12.5.2 Adjusting the spring force

1. Place the spring arm in a position approx. +10° to the horizontal in order to relieve the load on the adjustment screw.
2. Turn the M5 threaded pin with Allen key ② (5 mm) in adjustment hole ①.

Reducing the spring force

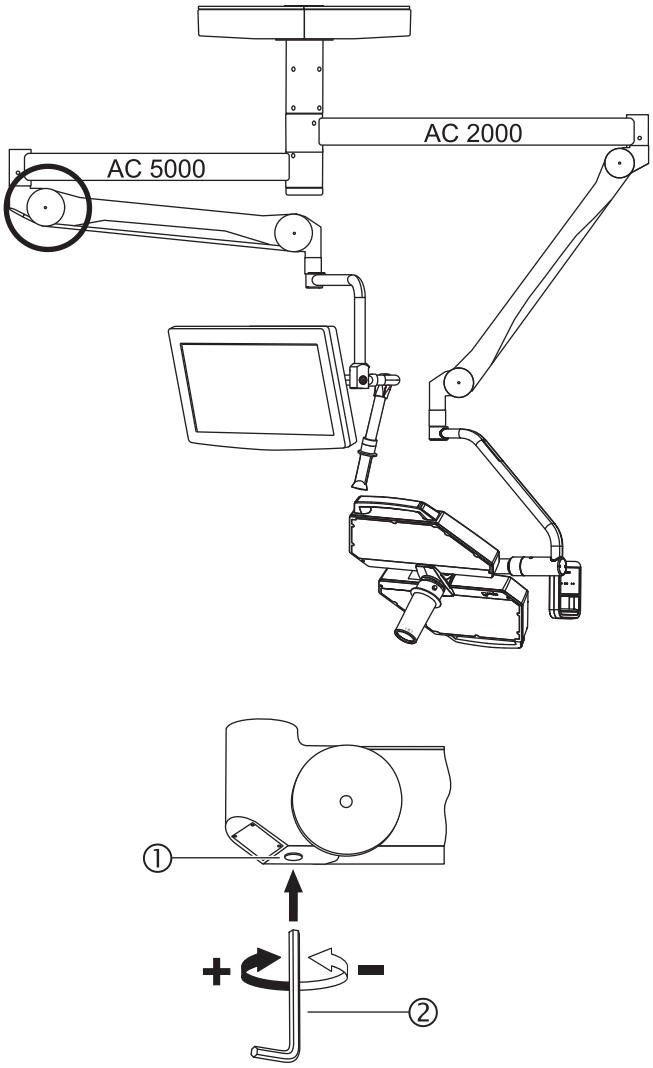
- Turn the adjustment screw to the left (anti-clockwise).

Increasing the spring force

- Turn the adjustment screw to the right (clockwise).

3. Carry out a function test of the spring force.

Figure 38



12.6 Setting the spring arm spring force type AC 5000

The weight of the light head is compensated by a spring which is installed in the spring arm. The spring force must be adjusted when the spring arm with the light head does not reliably stop at the height position selected after a swivel movement.

12.6.1 Disconnecting the power to the lighting system

Ceiling-mounted version

1. Switch off the operating theatre master switch.

→ The lighting system is disconnected from the power supply.

2. Secure the master switch against accidental switch-on.

12.6.2 Adjusting the spring force

1. Place the spring arm in a position approx. +10° to the horizontal in order to relieve the load on the adjustment screw.
2. Turn the M6 threaded pin with Allen key ② (6 mm) in adjustment hole ①.

Reducing the spring force

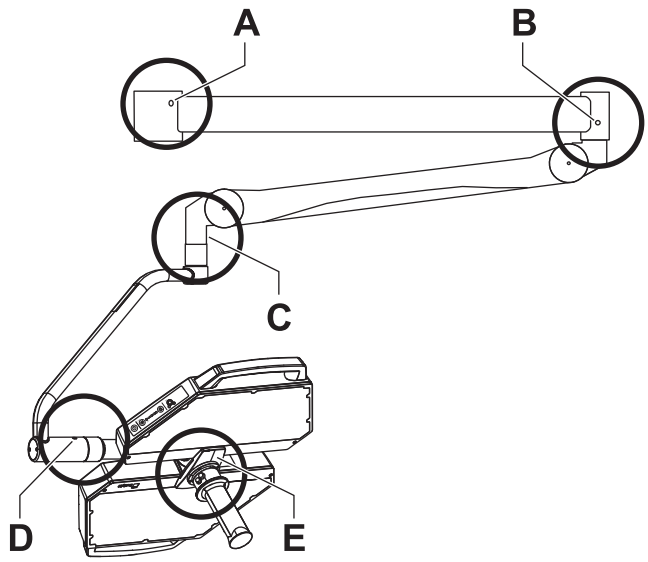
- Turn the adjustment screw to the left (anti-clockwise).

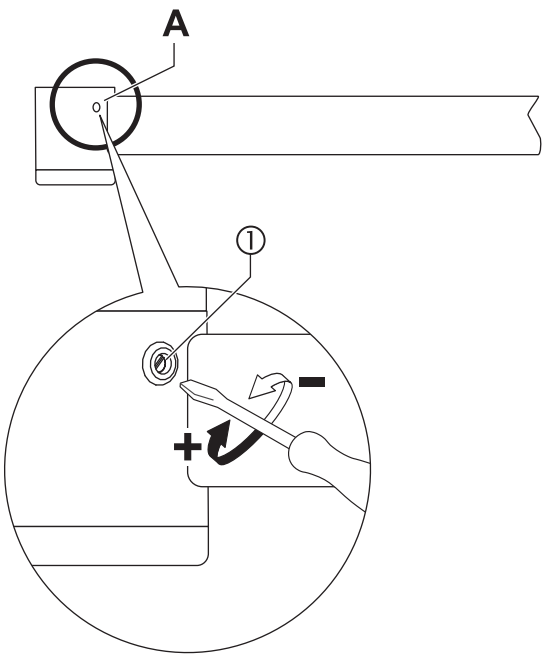
Increasing the spring force

- Turn the adjustment screw to the right (clockwise).

3. Carry out a function test of the spring force.

Figure 39





12.7 Adjusting the brake force of the friction brakes

If the boom, spring arm, convenience bracket or the light head do not remain stable in the position to which they are rotated, the braking force of the friction brake must be adjusted.
The friction brake acts through the friction force of the adjustment screw (slot-head screw (3)) on the relevant pin of the support arm components.
If the braking force of several support arm components needs to be adjusted, the brakes must be adjusted in the following sequence:

1. Friction brake A for boom;
2. Friction brakes B for spring arm;
3. Friction brake C for convenience bracket;
4. Friction brake D and E for the cardan joint light head;

ATTENTION

Screw types for the friction brakes

The brake screws are slot-head screws:
All other types of screw must not be loosened.

12.7.1 Disconnecting the power to the lighting system

Ceiling-mounted and wall-mounted versions

1. Switch off the operating theatre master switch.

→ The lighting system is disconnected from the power supply.

2. Secure the master switch against accidental switch-on.

Mobile stand version

1. Switch off the power supply unit, position the switch in Position **0** (see Chapter 6.3.1, page 46), pull the mains cable out of the safety socket.

→ The mobile lighting system is disconnected.

2. Secure the mains plug against unintentional plugging-in.

12.7.2 Adjusting the braking force for the boom

Adjusting friction brake **A**:

1. Adjust brake screw ① with a suitable slot-head screwdriver:

Reducing the braking force

- Turn the adjustment screw to the left (anti-clockwise).

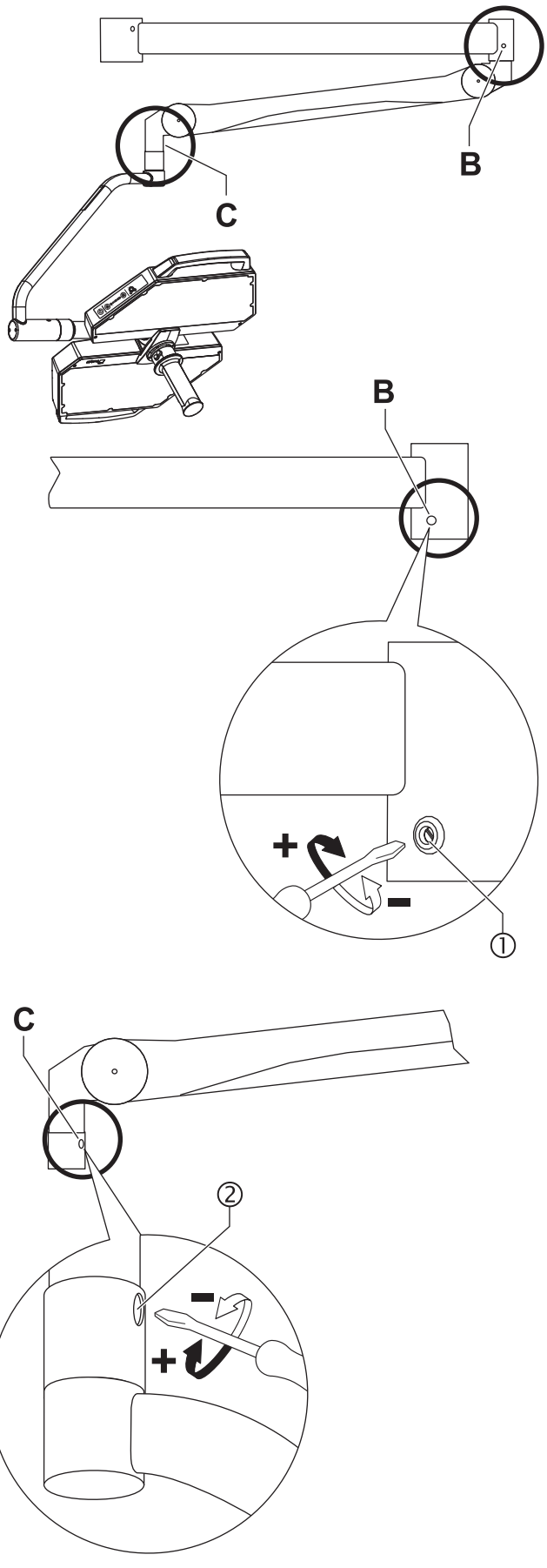
Increasing the braking force

- Turn the adjustment screw to the right (clockwise).

2. Carry out a function test of the braking force.

Brake screw type: 1378864

Figure 40



12.7.3 Adjusting the braking force for the spring arm

Adjusting friction brake **B**:

1. Adjust brake screw ① with a suitable slot-head screwdriver:

Reducing the braking force

- Turn the adjustment screw to the left (anti-clockwise).

Increasing the braking force

- Turn the adjustment screw to the right (clockwise).

2. Carry out a function test of the braking force.

Brake screw type: 1378857

12.7.4 Adjusting the brake of the convenience bracket on AC 3000

The braking force for the convenience bracket is only adjusted on the AC 3000 spring arm. Adjusting friction brake **C**:

1. Adjust brake screw ② with a suitable slot-head screwdriver:

Reducing the braking force

- Turn the adjustment screw to the left (anti-clockwise).

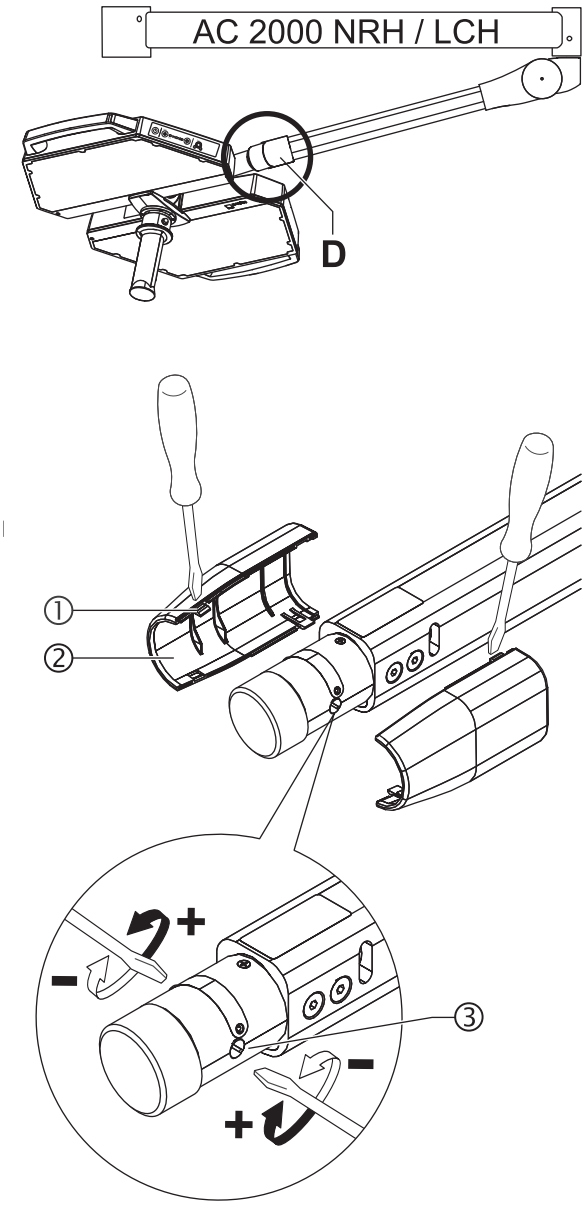
Increasing the braking force

- Turn the adjustment screw to the right (clockwise).

2. Carry out a function test of the braking force.

Brake screw type: 1378868

Figure 41



12.7.5 Adjusting the brake force of the cardan joint rod

Light head on the convenience bracket

Adjusting the friction brake **D** of the light head on the convenience bracket:

1. Adjust brake screw ① with a suitable slot-head screwdriver:

Reducing the braking force

- Turn the adjustment screw to the left (anti-clockwise).

Increasing the braking force

- Turn the adjustment screw to the right (clockwise).

2. Carry out a function test of the braking force.

Brake screw type: 4025239

Light head on AC 2000 LCH spring arm

Adjusting the friction brake **D** for the light head on AC 2000 LCH spring arm:

Removing the covers

1. Carefully press in and unlock the four lugs ① of the two halves of the cover ② with a suitable flat screwdriver.
2. Remove the two halves of the cover ②.

Adjusting the braking force

1. Adjust brake screw ③ with a suitable slot-head screwdriver on both sides:

Reducing the braking force

- Turn the adjustment screw to the left (anti-clockwise).

Increasing the braking force

- Turn the adjustment screw to the right (clockwise).

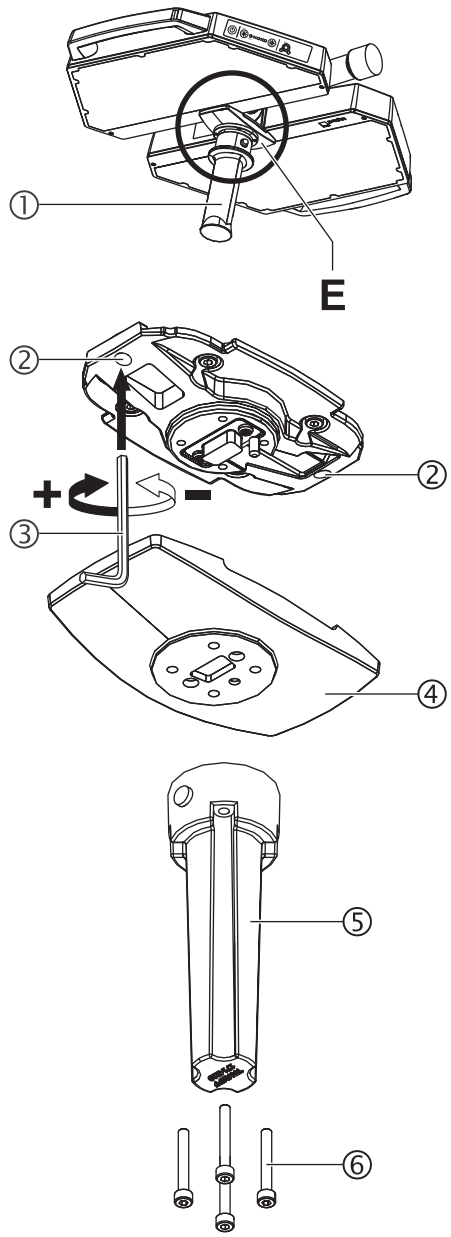
2. Carry out a function test of the braking force.

Installing the covers

3. Place the halves of the cover ② on the spring arm and press the four lugs ① against the spring arm, so that they engage.
4. Check the firm attachment of the cover ②.

Brake screw type: 1378866

Figure 43



12.7.6 Setting the braking force of the cardan joint axle on the standard light head

Adjusting the friction brake **E** for the light head on the handle attachment. If the friction brake can no longer be adjusted, an internal brake strip must be replaced by a service technician.

1. Pull the sterile handle ① off the handle adapter.
2. Unscrew the four Allen screws ⑥ (M4 x 30 mm) and remove the handle attachment ⑤.
3. Remove cover of the handle attachment ④.
4. Evenly turn the two M6 threaded pins with Allen key ③ (6 mm) in adjustment hole ②.

Reducing the braking force

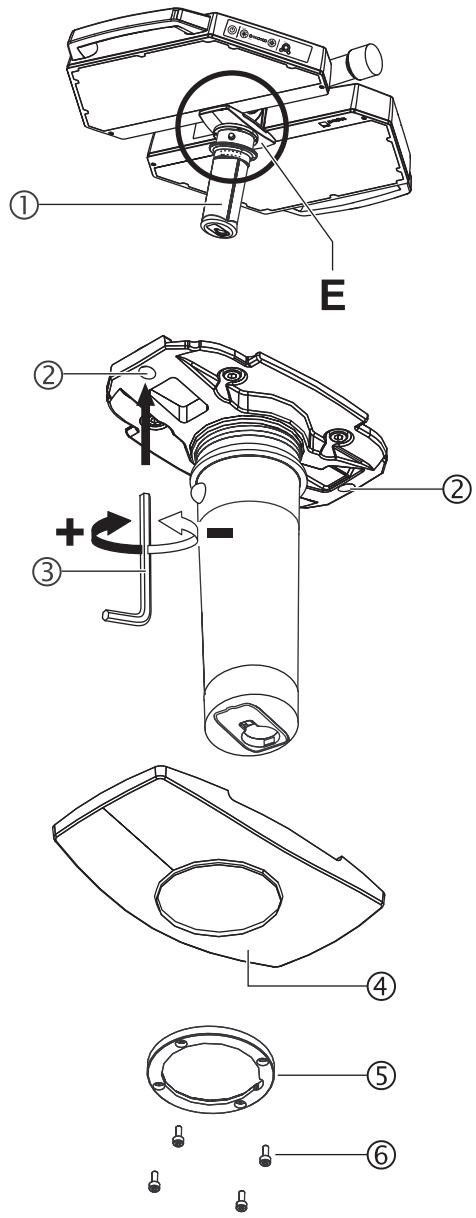
- Turn the adjustment screw to the left (anti-clockwise).

Increasing the braking force

- Turn the adjustment screw to the right (clockwise).

5. Put on the cover of the handle attachment ④. Put on the handle attachment ⑤ and fasten it with the four Allen screws ⑥.
6. Check the firm attachment of the components.
7. Put the sterile handle ① on the handle adapter.
8. Carry out a function test of the braking force.

Figure 44



12.7.7 Setting the braking force on the light head SLC / ALC plus

Adjusting the friction brake **E** for the light head on the handle attachment. If the friction brake can no longer be adjusted, an internal brake strip must be replaced by a service technician.

1. Pull the sterile handle ① off the handle adapter.
2. Unscrew the four Allen screws ⑥ (M4 x 15 mm).
3. Remove the securing ring ⑤.
4. Remove cover of the handle attachment ④.
5. Evenly turn the two M6 threaded pins with Allen key ③ (6 mm) in adjustment hole ②.

Reducing the braking force

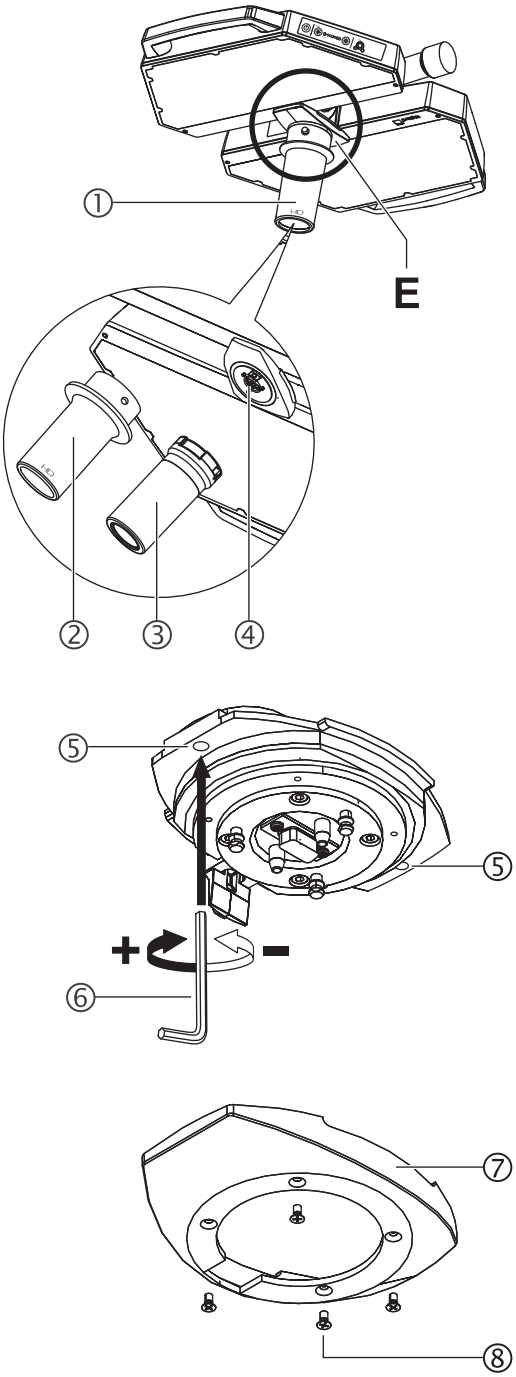
- Turn the adjustment screw to the left (anti-clockwise).

Increasing the braking force

- Turn the adjustment screw to the right (clockwise).

6. Put on the cover of the handle attachment ④.
7. Put on the securing ring ⑤.
8. Fasten the securing ring with the four Allen screws ⑥.
9. Check the firm attachment of the components.
10. Put the sterile handle ① on the handle adapter.
11. Carry out a function test of the braking force.

Figure 45



12.7.8 Setting the cardan joint axis braking force on the standard light head with camera

Adjusting the friction brake **E** for the light head on the handle attachment. If the friction brake can no longer be adjusted, an internal brake strip must be replaced by a service technician.

1. Pull the sterile handle ① off the camera.
2. Remove camera ② from camera mount ③ (See TruVidia SD/HD/3D instruction manual).
3. Unscrew the four countersunk screws with cross-heads ⑧ and remove the cover of handle attachment ⑦.
4. Evenly turn the M6 threaded pins with Allen key ⑥ (6 mm) in adjustment hole ⑤.

Reducing the braking force

- Turn the adjustment screw to the left (anti-clockwise).

Increasing the braking force

- Turn the adjustment screw to the right (clockwise).

5. Put on handle attachment cover ⑦ and screw in the four countersunk screws with cross-heads ⑧.
6. Check the firm fastening of handle attachment cover ⑦.
7. First couple on camera ③ and then put the sterile handle ① on the camera.
8. Carry out a function test of the braking force.

Handles and brake screws

Handles	Chapter	#
Sterilisable handle for light head; Plastic (pack of 3)	Chpt. 8.4	0337642
Sterilisable handle for camera; Plastic (pack of 3)	Instruction manual TruVidia SD/HD/3D	0337643
Sterilisable handle for Adaptive Light Control plus; (pack of 3)	Chpt. 8.4	1612088
Brake screws	**Chapter**	**#**
Brake screw with slot on AC 3000 type spring arm; M10 x 1 mm with 9 mm length (2 units)	Chpt. 12.7.4	1378868
Brake screw with slot at the spring arm type AC 2000 LCH (Low Ceiling Height); M12 x 1 mm with 21 mm length (2 units)	Chpt. 12.7.5	1378866
Brake screw with slot at the boom (brake of the boom); M12 x 1 mm with 30 mm length (2 units)	Chpt. 12.7.2	1378864
Brake screw with slot at the boom (brake of the spring arm); M12 x 1 mm with 16 mm length (2 units)	Chpt. 12.7.3	1378857
Brake screw with slot at the convenience bracket; M10 x 1 mm with 11 mm length (2 units)	Chpt. 12.7.5	4025239
Brake cleat with M6 threaded pins with 12 mm length on light head (2x); (light head brake)	Replacement by service technician only	1506935

NOTE

Recurrent faults

If a fault reoccurs or cannot be remedied, put the device out of service and contact Trumpf Medical Customer Service.

Causes of faults and fault removal

Error	Possible cause	Remedy	Chapter
Suspension / mobility			
Light head drops / rises	Spring force in spring arm is too strong / too weak	Adjusting the spring force	Chpt. 12.4 - Chpt. 12.6
Light head moves with difficulty / easily	Brakes too stiff / too loose	Adjust brakes	Chpt. 12.7.2 - Chpt. 12.7.5
Optical system / light technology			
Light intensity too low	Light intensity set too low	Increase light intensity	Chpt. 8.9
Inhomogeneous light field	The light head is outside the working area	Position the light head	Chpt. 8.6
The light does not light	Main switch in the operating theatre is switched off	Switch on the main switch	Chpt. 8.6
	Light head has been turned off at the control panel	Press the ON / OFF button	Chpt. 8.6
	Mains cable of the mobile stand version not plugged in	Plug mains cable into socket	Chpt. 8.6
	Power unit of the mobile stand version not switched on	Press the ON / OFF button on the power supply housing	Chpt. 8.6
	Defective electronics	Inform Trumpf Medical Customer Service	—
	Site power supply is interrupted	Check site fuses and power supply	—
Automatic distance measurement is not working (ALC plus display is flashing)	Software failure	Deactivate ALC plus and manually select the distance or disconnect from power supply and then reconnect	Chpt. 8.9.3
Different colour temperatures in the light field	Colour temperature is set on only one light head	Switch on the SYNC function	Chpt. 8.9.6
Sterilisable handle			
Handles are damaged or show cracks	End of service life has been reached	Replace handles	Chpt. 8.4
Life span of the sterilisable handles too short	Wrong sterilisation method	Check sterilisation method	Chpt. 11

15.1 Equipment versions for the light models

TruLight 3000 equipment versions

Product designation	TruLight 3300	TruLight 3500	TruLight 3510
Adaptive Light Control (ALC)	3	3	3
Camera	—	—	3
Outer handles not illuminated	3	3	3
Wall-mounted control panel	Optional	Optional	Optional

TruLight 5000 equipment versions

Product designation	TruLight 5300	TruLight 5310	TruLight 5320	TruLight 5500	TruLight 5510	TruLight 5520
Adaptive Light Control (ALC)	3	3	3	3	3	3
Sterile Light Control (SLC)	—	—	3	—	—	3
Adaptive Light Control Plus (ALC plus)	—	3	3	—	3	3
Camera	—	3	—	—	3	—
Outer handles illuminated	3	3	3	3	3	3
Wall-mounted control panel	Optional	Optional	Optional	Optional	Optional	Optional
Colour temperature can be set on control panel	Optional	Optional	Optional	Optional	Optional	Optional

15.2 Device data

TruLight 3000 electrical data

Electrical data	TruLight 3300	TruLight 3500	TruLight 3510
Mains adapter supply voltage	100 - 240 VAC 50/60 Hz	100 - 240 VAC 50/60 Hz	100 - 240 VAC 50/60 Hz
Supply voltage at the DC-DC converter	19 - 36 V DC 21.6–26.4 V AC	19 - 36 V DC 21.6–26.4 V AC	19 - 36 V DC 21.6–26.4 V AC
Light head power uptake (160,000 lux at a distance of 1.0 m)	65 VA		
Max. power uptake of total system	130 VA		150 VA
Internal fuse (mobile stand version only)	2 x T10 A		
Voltage at fixed point on ceiling	48 V		
Average Service Life of Light Source (LED)	> 60,000 hrs		
Classification according to MPG	1	1	1

TruLight 5000 electrical data

Electrical data	TruLight 5300	TruLight 53x0	TruLight 5500	TruLight 55x0
Mains adapter supply voltage	100 - 240 VAC 50/60 Hz	100 - 240 VAC 50/60 Hz	100 - 240 VAC 50/60 Hz	100 - 240 VAC 50/60 Hz
Supply voltage at the DC-DC converter	19 - 36 V DC 21.6–26.4 V AC	19 - 36 V DC 21.6–26.4 V AC	19 - 36 V DC 21.6–26.4 V AC	19 - 36 V DC 21.6–26.4 V AC
Light head power uptake (160,000 lux at a distance of 1.0 m)	65 VA			
Max. power uptake of total system	110 VA	140 VA	120 VA	160 VA
Internal fuse (mobile stand version only)	2 x T10 A			
Voltage at fixed point on ceiling	48 V			
Average Service Life of Light Source (LED)	> 60,000 hrs			
Classification according to MPG	1	1	1	1

TruLight 3000 lighting system technical data

Product designation	TruLight 33x0	TruLight 35x0
Light intensity at 1.0 m	140,000 lux	160,000 lux
Dimmable from/to	< 10% Endo; 40%–100%	< 10% Endo; 40%–100%
Variable light field size due to changes in distance	17 - 25 cm	17 - 25 cm
Light field diameter (d10) at 1.0 m	18 cm	18 cm
Light field diameter (d50) at 1.0 m	9.4 cm	9.5 cm
d50/d10 ratio	0.52	0.53
Radiant power (W/m)*:	587	616
Residual light intensity with 1 switch	81,200 lux 58%	108,800 lux 68%
Residual light intensity with 2 switches	61,600 lux 44%	75,200 lux 47%
Residual light intensity with tube	140,000 lux 100%	155,200 lux 97%
Residual light intensity with tube and 1 switch	81,200 lux 58%	104,000 lux 65%
Residual light intensity with tube and 2 switches	61,600 lux 44%	72,000 lux 45%
Illumination depth (L1 + L2) at 20% Ec / EN ISO 60601-2-41 2nd Edition	83 cm	75 cm
Illumination depth (L1 + L2) at 60% Ec / EN ISO 60601-2-41 3rd Edition	44 cm	41 cm
Colour rendering index Ra	94	93
Colour temperature	4.500 K	

* = at a distance of 0.9 m

TruLight 5000 lighting system technical data

Product designation	TruLight 53x0		TruLight 55x0	
Light intensity at 1.0 m	140,000 lux		160,000 lux	
Dimmable from/to	< 10% Endo; 40 %–100 %		< 10 % Endo; 40 %–100 %	
Variable light field size due to changes in distance	16 cm - 30 cm		16 cm - 30 cm	
Radiant power (W/m)*:	620		676	
	Narrow light field	**Wide light field (optional)**	**Narrow light field**	**Wide light field (optional)**
Light field diameter (d10) at 1.0 m	16 cm	23 cm	16 cm	23 cm
Light field diameter (d50) at 1.0 m	9.6 cm	12 cm	9 cm	11 cm
d50/d10 ratio	0.60	0.52	0.56	0.48
Residual light intensity with 1 mask	40,600 lux 29 %	81,200 lux 58 %	94,400 lux 59 %	121,600 lux 76 %
Residual light intensity with 2 masks	57,400 lux 41%	60,200 lux 43%	68,800 lux 43 %	78,400 lux 49 %
Residual light intensity with tube	140,000 lux 100 %	140,000 lux 100%	156,800 lux 98 %	150,400 lux 94 %
Residual light intensity with tube and 1 switch	40,600 lux 29 %	81,200 lux 58%	92,800 lux 58 %	112,000 lux 70 %
Residual light intensity with tube and 2 switches	57,400 lux 41 %	60,200 lux 43%	68,800 lux 43 %	72,000 lux 4 5%
Illumination depth (L1 + L2) at 20% EC / EN ISO 60601-2-41 2nd edition	94 cm	96 cm	95 cm	94 cm
Illumination depth (L1 + L2) at 60% EC / EN ISO 60601-2-41 3rd edition	51 cm	51 cm	60 cm	60 cm
Colour rendering index (Ra)	max. 96		max. 96	
Colour temperature (settable during initial installation)	3,500 K, 4,000 K, 4,500 K, 5,000 K			
Colour temperature (can be set on control panel)	Optional		Optional	

* = at a distance of 0.9 m

Mechanical data, light models 3000

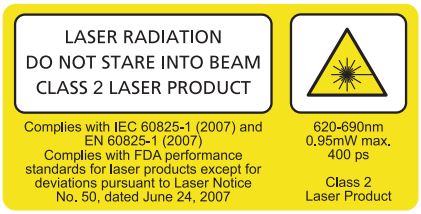
Mechanical data	TruLight 33x0	TruLight 35x0
Light head diameter	640 mm	730 mm
Distribution area of the light head	2100 cm^2	3100 cm^2
Light-emitting surface area	1332 cm^2	1892 cm^2
Weight of the light heads (incl. convenience and central bracket)	12.9 kg	17.2 kg

Mechanical data, 5xxxx light models

Mechanical data	TruLight 53x0	TruLight 55x0
Light head diameter	640 mm	730 mm
Distribution area of the light head	2100 cm^2	3100 cm^2
Light-emitting surface area	1332 cm^2	1892 cm^2
Weight of the light heads (incl. convenience and central bracket)	13.9 kg	17.2 kg

Performance specifications, Laser 5520/5320

Performance specifications	TruLight 5520	TruLight 5320
Max. output power	0.95 mW	0.95 mW
Wavelength	620-690 nm	620-690 nm
Beam divergence	0.16 x 0.6 mRad	0.16 x 0.6 mRad
Pulse duration	0.4 x 10 ^ -9 s	0.4 x 10 ^ -9 s
Pulse refresh rate	320 MHz	320 MHz



Sensor marking: identifies the class of the laser product installed for distance measurement according to IEC 60825-1, Edition 2 (2007-03) and IEC 60825-1, Edition 3 (2014).

15.3 EMC information

EMC notes

⚠WARNING

Operate the device only with the stated accessories.

The device may only be operated with the accessories stated in the accompanying documents. Operation with accessories, converters or cables other than those stated in the accompanying documents can lead to increased EMC emissions or reduced interference immunity of the device and with it to improper use.

Using the device

Use of the device directly adjacent to other devices or stacked with other devices should be avoided, as this can result in faulty operation. If this form of use is, however, necessary, this device and the other devices should be monitored to ensure they are working properly.

The lighting system is intended for use in the environment specified below. The customer or user of the device should ensure that it is operated in one of the environments as described.

Essential characteristics:

The key performance characteristics are the supply of illumination and the limiting of energy in the surgical area.

Measurement of interfering emissions	Compliance	Comments
RF emissions in accordance with CISPR 11	Group 1	The lighting system uses RF energy exclusively for its internal FUNCTION. Therefore, its' RF emission is very low and it is very unlikely that neighbouring devices are disturbed.
RF emissions in accordance with CISPR 11	Class A	The TruLight lighting system is suitable for use in establishments other than domestic and those connected directly to the PUBLIC LOW-VOLTAGE NETWORK that supplies buildings used for domestic purposes, providing the following warning is observed: REMARK The properties of this device determined by its EMISSIONS allows its use in industrial fields and in hospitals (CISPR 11, Class A). If used in a domestic setting (for which Class B is generally required in accordance with CISPR 11), this device may cause radio interference. The user may be required to take adequate measures, such as conversion or realignment of the device.
Harmonic Emissions as per IEC 61000-3-2	Class A	
Harmonic emissions from voltage fluctuations and flicker emissions as per IEC 61000-3-3	In compliance	

The recommendations in the instruction manual to preserve BASELINE SAFETY and ESSENTIAL PERFORMANCE PROPERTIES of the devices during its entire operating life must be observed. See Chapter 11 "Inspections, maintenance and repairs".

Guidelines and manufacturer's declaration - electromagnetic immunity

The lighting system is intended for use in the environment specified below. The customer or user of the device should ensure that it is operated in one of the environments as described. The support arm system may not execute any unintentional movements in cases of interference. Important EMC characteristics of the lighting systems:

Error/immunity test	IEC 60601 test level	Compliance level	Environment / guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Flooring should be made of wood or concrete or have ceramic tiles. If the floor is made with synthetic material, the relative humidity must amount to at least 30 %.
Rapid transient electrical interference variables/bursts as per IEC 61000-4-4	±2 kV for mains cables ±1 kV for input and output cables 100 kHz repetition rate	±2 kV for mains cables ±1 kV for input and output cables 100 kHz repetition rate	Mains power quality should be that of a typical commercial or hospital environment.
Surges as per IEC 61000-4-5	±1 kV outer conductor - outer conductor voltage ±2 kV outer conductor – ground wire	±1 kV outer conductor - outer conductor voltage ±2 kV outer conductor – ground wire	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage fluctuations of power supply as per IEC 61000-4-11	0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70 % UT; 25/30 cycles at 0° and 180° 0 % UT; 250/300 cycle Note: UT is the AC mains voltage prior to applying the test level.	0 % UT; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70 % UT; 25/30 cycles at 0° and 180° 0 % UT; 250/300 cycle Note: UT is the AC mains voltage prior to applying the test level.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the lighting system requires continued functioning even during power supply interruptions, it is recommended that the lighting system be supplied from an uninterruptible power source or battery.
Magnetic field with a supply frequency (50/60 Hz) as per IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields for the network frequency should comply with values commonly found in commercial and hospital environments.

Guidelines and manufacturer declaration - immunity to electromagnetic interference / portable and mobile radio devices

Portable and mobile RF communication device should be used no closer to any part of the insulating lighting system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended safety distance:

Immunity test	IEC 60601 test level	Compliance level	Environment / guidelines
Conducted RF noise as per IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in the ISM band between 0.15 MHz and 80 MHz [a]	3 V 0.15 MHz – 80 MHz 6 V in the ISM band between 0.15 MHz and 80 MHz [a]	$D = 1,2\sqrt{P}$
Conducted RF noise as per IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz (see special frequencies table)	3 V/m 80 MHz – 2.7 GHz (see special frequencies table)	$D = 1,2\sqrt{P}$ at: 80 MHz to 800 MHz * $D = 2,3\sqrt{P}$ at 800 MHz to 2.7 GHz *
[a] = The ISM radio bands (ISM = industrial, scientific and medical) between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz. The amateur radio frequencies between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz; 3.5 MHz to 4.0 MHz; 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 8.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.			

*With P as the rated output of the transmitter in watt (W) according to the details of the transmitter manufacturer and D as the recommended safety distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.

[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Explanation of [a] and [b]:

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasting and TV broadcasting cannot be predicted theoretically with accuracy. In order to determine the electro-magnetic environment with regard to the fixed transmitter, a study of the location should be considered. If the measured field strength at the location where the aforementioned devices are being used exceeds the compliance level given above, the lighting system should be kept under observation. Additional measures may be necessary, such as a changed orientation or a different location.

[b] The field strength should be lower than 3 V/m in the frequency range of 150 kHz to 80 MHz.

Notes:

At 80 MHz and 800 MHz, the higher value applies.

These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Immunity level of RF fields from wireless communication device

Table: Special frequencies

Test Frequency (MHz)	Band (MHz)	Service	Modulation	max. power (W)	Distance (m)	Immunity level (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	26
450	430 – 470	GMRS 460 FRS 460	Pulse modulation FM ±5 kHz variation, 1 kHz sine	2	0.3	28
720	704 – 787	LTE band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE band 5	Pulse modulation 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 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 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Controlled RF interference variables

The lighting system is intended for use in an electromagnetic environment where the RF disturbances are monitored. To prevent electromagnetic interference, maintain a minimum distance between the portable and mobile HF communications devices (transmitters) and the above-mentioned device according to the maximum output power of the communications equipment, as recommended below.

Rated output of transmitter/W	Safety distance for the transmission frequency		
	150 kHz to 80 MHz $D = 1,2\sqrt{P}$	80 MHz to 800 MHz $D = 1,2\sqrt{P}$	800 MHz to 2.7 GHz $D = 2,3\sqrt{P}$
0.01 0.1 1 10 100	0.12 0.38 1.2 3.8 12	0.12 0.38 1.2 3.8 12	0.23 0.73 2.3 7.3 23

For transmitters, whose maximum rated output is not indicated in the table above, the recommended safety distance D in metres (m) can be determined using the equation, which belongs to the respective column, whereby P is the maximum rated output of the transmitter in watts (W) according to the information of the transmitter manufacturer.

Notes:
At 80 MHz and 800 Hz, the higher frequency range applies. These guidelines may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

⚠WARNING

Distance for portable RF communication device and their peripherals

Do not use portable RF communication device (including peripherals such as antenna cables and external antenna) at a distance below 30 cm (12 inch) to the lighting system including its cables specified by the manufacturer. This can otherwise lead to a decline in the functionality of the system.

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55000-00011_002_01 – 1756789 – 2017-09-06