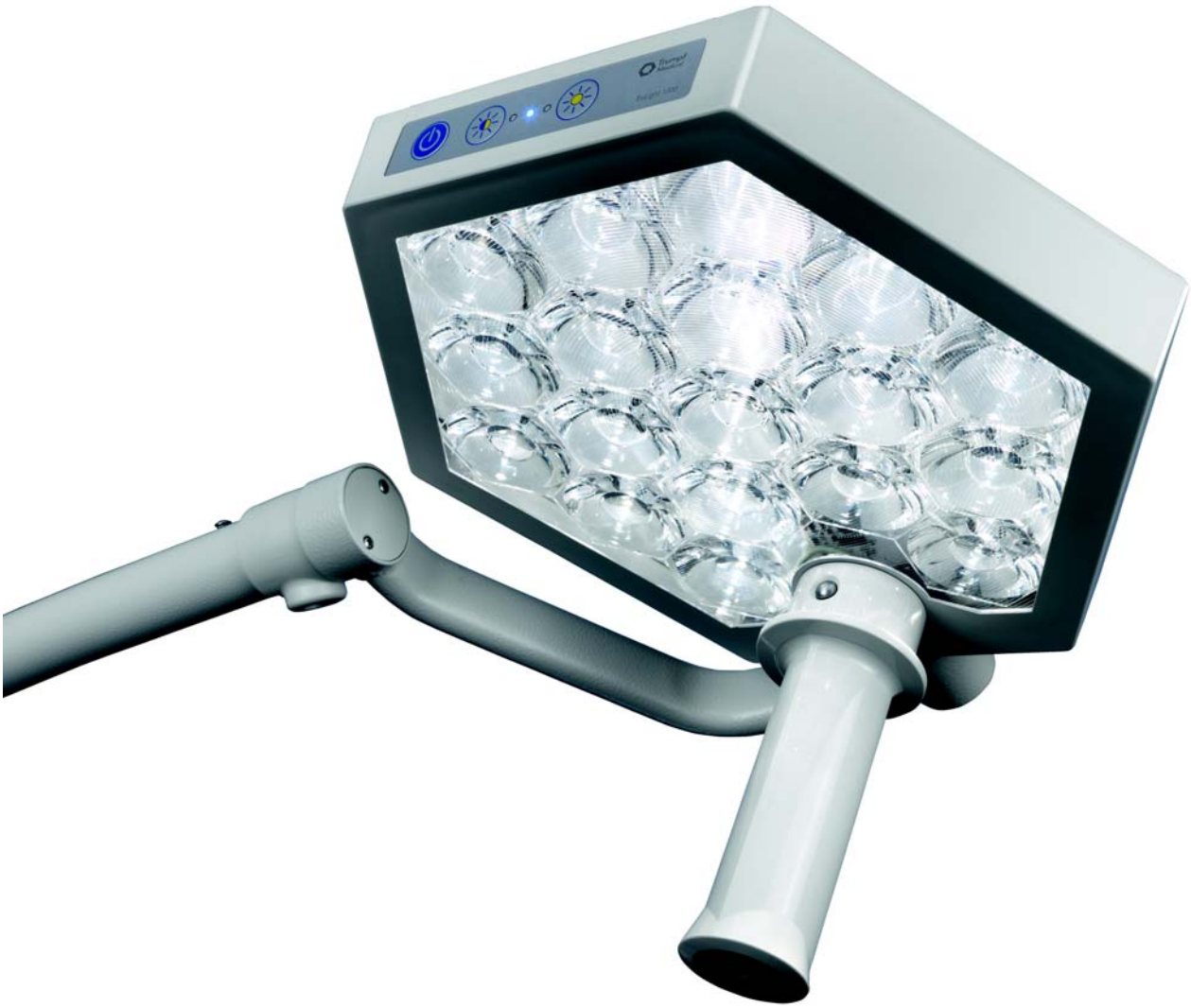
Trumpf Medical

Instruction manual

TruLight™ 1000 examination light



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

English
en-EN

Enhancing outcomes for patients and their caregivers: Hill-Rom

for buying the new TruLight™ 1000 lighting system. Please read through this instruction manual very carefully and ensure adherence to all safety instructions and requirements regarding the operation and care of the device.

This instruction manual applies to the following components:

Device versions

TruLight™ 1000 lighting system:

- Version with light head as ceiling-mounted version.
- Version with light head as wall-mounted version.
- Version with light head as mobile pedestal version.
- Version with a light head on TRUMPF Medizin Systeme GmbH + Co. KG ceiling-mounted supply unit.

Manufacturer and distributor	TRUMPF Medizin Systeme GmbH + Co. KG Carl–Zeiss–Straße 7–9 07318 Saalfeld Germany Telephone: +49 3671 586-0 Fax: +49 3671 586-41165 info@trumpfmedical.com www.trumpfmedical.com Trumpf Medical will hereinafter be used as a synonym for TRUMPF Medizin Systeme GmbH + Co. KG to improve readability.
Technical Customer Service	The contact data for the current sites of the technical customer service in the individual countries are provided on the Internet at www.trumpfmedical.com. In the following, technical Customer Service will be used as a synonym for Trumpf Medical Customer Service and for technicians of service operators authorised and trained by Trumpf Medical.

Original instruction manual on CD

This instruction manual is available in PDF format on the Trumpf Medical CD provided with the system. Please contact the technical customer service if you require a replacement CD.

Keep the instruction manual stored safely near the system

A printed version of the user manual should be kept easily accessible and near the system for reference purposes.

Copyright and property rights

Copyright

- Any use not currently regulated by law must be approved in writing by TRUMPF Medizin Systeme GmbH + Co. KG, hereinafter referred to as Trumpf Medical.
- 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.
- The German instruction manual is the original instruction manual.

Translations

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

1.1 Details for identification of the device

This instruction manual is solely intended for devices with device labels that show the following information:

Device identification

Descriptor / rating	Type	Material no.
TruLight™ 1000	TruLight™ 1000 pre-assembly set	4058051
TruLight™ 1000	TruLight™ 1000 ceiling	4058110
TruLight™ 1000	TruLight™ 1000 wall	4058120
TruLight™ 1000	TruLight™ 1000 mobile	4058130
TruLight™ 1000	TruLight™ 1000 pendant	4058140

1.2 Details for identification of the instruction manual

Up-to-dateness of this user 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.: 1695233
- Date of publication: 25/01/2018
- Document number: 55000-00012_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 user 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 appropriate training by specialised staff, are authorised to operate and work with the device.

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

1.3.3 Specialised staff

Specialised staff means authorised individuals, who are generally employed by the operator. They must

- have undertaken a course of technical training in the medical technology field,
- be able to use their professional experience and training regarding safety regulations to assess the work they perform and recognise potential hazards involved in that work.
- must have the appropriate certification to be classified as 'specialist personnel' (e.g. by Trumpf Medical certified medical technicians or Trumpf Medical sales employees) in countries requiring certification of personnel performing work in the medical technology field.

1.4 Information for operators

Procedural guidelines

The device has been manufactured with state-of-the-art technology and is operationally safe.

- The device can nevertheless be a source of danger, especially when it is operated by inadequately trained personnel or used incorrectly or for an unintended purpose.
- The device may only be operated, cleaned, disinfected and maintained by users that were trained by specialised staff.

1.4.1 Initial commissioning

Validity

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

- A full electrical safety test is required before initial commissioning.
- The operator must be instructed in the operation of the lighting system in accordance with the applicable instruction manual.
- Prior to being used for the first time, the device must be thoroughly cleaned and disinfected.
- 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 Exclusion of liability

Exclusion of liability

The warranty for the product by Trumpf Medical requires that:

- the device is exclusively used for the proper use 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 design 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:

- Technical customer service,
- authorised service companies trained by Trumpf Medical,
- the operator's service personnel when trained and authorised by Trumpf Medical.

After every maintenance or repair event, an electrical safety test must be performed.

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 lifespan 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 applies 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.

1.4.6 Date of manufacture

The device label indicates the date of manufacture of the device. The position of the device label on the device is shown in Chapter 4.1.

1.5 Delivery

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

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

The following applies to Japan: The mains connection wiring may only be used with the equipment supplied.

1.5.1 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 / 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.

1.5.2 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

1.6 Information for users

The device may only be operated by persons who have undergone appropriate training.

1.6.1 Training on the device

Training

Training of users 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 training, it must be documented that the user has understood the special operating procedures required for proper use.

1.6.2 Obligation of the user to inform and to inspect

Dealing with problems

The instruction manual must be read carefully 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.

1.7 Conformity

1.7.1 Identification

Conformity

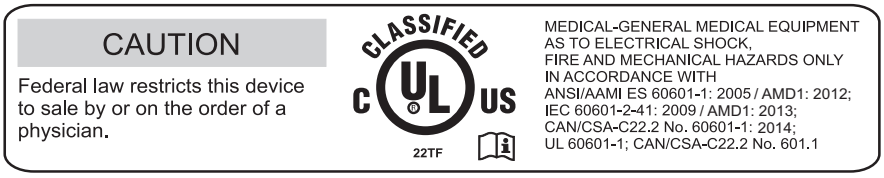
The manufacturer declares that this product conforms to the fundamental requirements according to MDD Appendix I and documents this by means of the CE and UL marking.

CE

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

UL mark

UL mark: device tested by Underwriter Laboratories Inc. for the USA and Canada with regard to shock and fire hazard and also mechanical endangerment.



1.7.2 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

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

Combination with other medical devices

- UL 60601-1
- EN 60601-1
- EN 60601-1-1

1.7.3 Proper use

Proper use

Lighting unit for the local illumination of the patient's body to support diagnoses or treatments which may be interrupted in case of light failure without hazard to the patient.

Working range

- The working range lies at a distance between 70 and 150 cm to the area being examined.
- The device is suitable for continuous operation.
- Each use exceeding the aforementioned conditions is considered to fall outside of the scope of proper use. Only the user or operator will be liable for any loss or damage arising as a result.

1.7.4 Special features

High light intensity

To ensure good visibility, the light head has a high light intensity.

Overlap of the light fields

- Visible light also generates heat in the examination area due to physical effects. The light intensity must be reduced when perfusion is reduced or the tissue starts to dry out.

Examinations in the field of vision

- For examinations in the facial area with unprotected and open eyes, high levels of local light intensities 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).

1.7.5 Improper use

Improper use

The examination light is not intended for use in operating theatres.

- 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 explosion.
- 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.
- The device should not be used in the vicinity of strong magnetic fields.
- 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 is formed in accordance with EN 11197 in an area between 5 cm and 25 cm from the point of outflow or escape of the gas.

1.8 Ambient conditions for operation and storage

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

1.8.1 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.

1.8.2 Ambient conditions for storage

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

1.9 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 subsequently, 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™ 1000 examination light.
- 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.

1.10 Disposal

The device must be disposed of in accordance with the requirements of directive WEEE II 2012 / 19 / EU and relevant national regulations 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 user manual

Important information is shown in this user 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 injuries.

⚠CAUTION

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

2.1.2 Indicating damage to property

ATTENTION

ATTENTION indicates a potentially dangerous situation, which, unless avoided, can lead to 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.

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 the conformity of the device with the European product directive (Medical Device Directive (MDD).

Follow the Instruction Manual: refers to this instruction manual.

UL mark: 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 may not be possible to apply to the medical device for a range of reasons.

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 is formed in accordance with EN 11197 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.

Examinations in the field of vision

⚠WARNING

Damage to vision

In case of examinations 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 protective glasses.**
- **Do not look directly into the light-emitting surface area of the light.**

Strong light fields

⚠WARNING

Damage to patient's tissue

High levels of illumination may cause damage to tissue. In cases of incipient tissue dehydration, reduce the intensity of illumination of the light head.

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 examination light and the patient at the same time.

Additional loads

⚠WARNING

Crashing of the light system

Do not place any additional weight on the light system.

Light intensity of the light head

⚠CAUTION

LED failure

After failure of the third LED, the light head no longer achieves the specified light intensity.

- **Take the lighting system out of service.**
- **Contact Technical Customer Service. Exchange of the light head or repairs on the lighting system may only be performed by the technical customer service.**

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 swivelling the light head, the distance between the quarter bracket and the light head changes:

- **Do not insert your fingers between the quarter bracket and the light head when rotating the light head.**
- **Only grasp the light head with the sterilisable handle.**

Cleaning and disinfection

⚠WARNING

Improperly used cleaning agents or disinfectants (see Chapter 8**) 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.**
- **To clean or disinfect the device, the cloth for wiping must be moist and not wet.**
- **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 halides.

- **Please refer to** Chapter 9 **for the sterilisation of handles.**
- **It is essential that the hygiene instructions of the operator are observed.**

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

If the light head is removed without first moving the spring arm to the highest limit position, the spring arm will shoot up and can cause severe injuries:

- **The light head may therefore only be de-installed by the technical 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

Operation

The light head is ergonomically adjusted via the non-sterile control panel on the light head.

Light intensity

The light intensity can be set in the range from 30 % to 100 %. A reduction (dimming) of the light intensity does not change the colour temperature of the light.

3.2 The LED light source

The light head is equipped with LED light sources.

Service life

LEDs have a very long 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 (infra-red) radiation and cause less tissue damage by not emitting UV (ultraviolet) radiation.

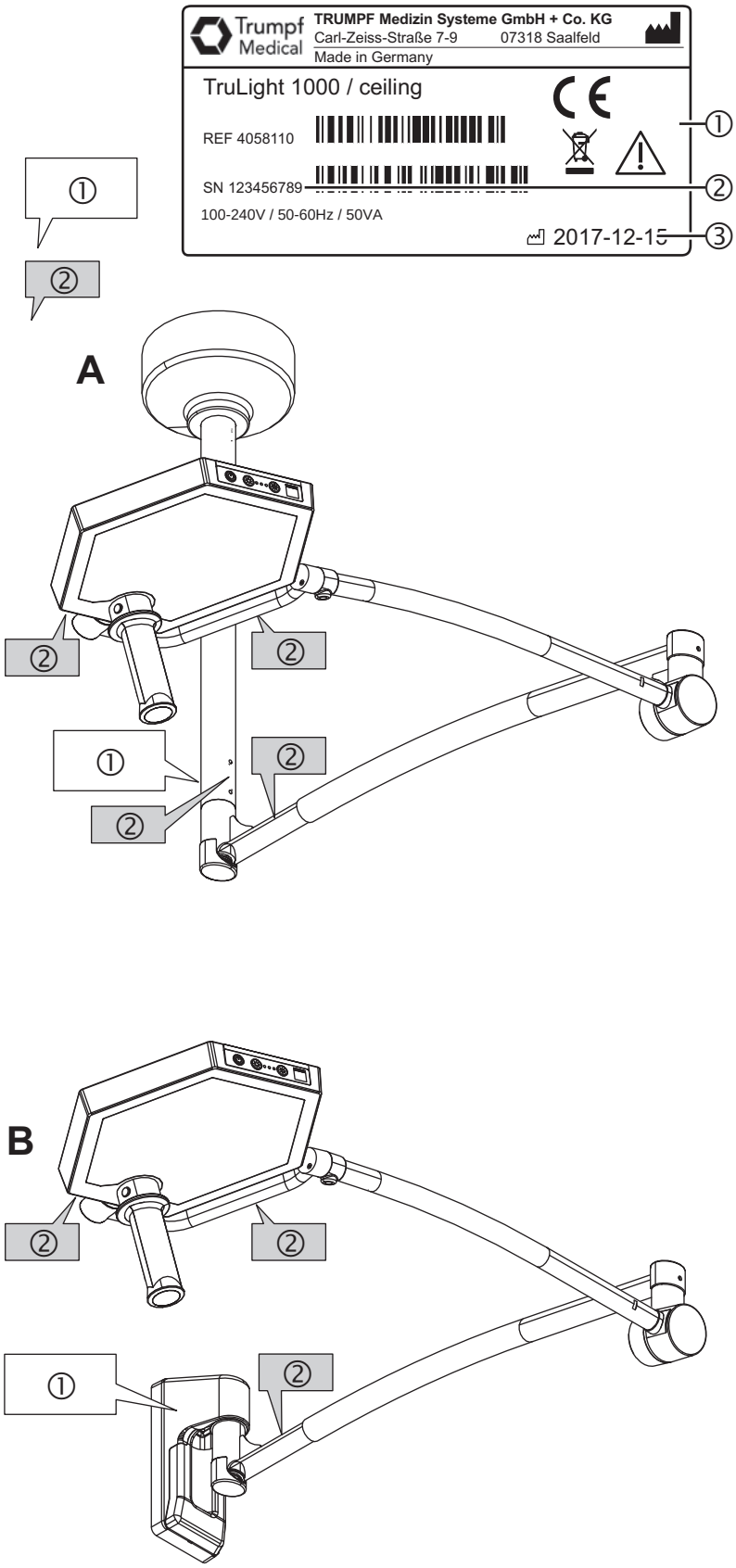
High failure safety

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.

Homogeneous colour temperature

The equipment of the light head with LEDs allows a homogeneous colour temperature in the range of 4,500 Kelvin.

Figure 1



4.1 Use of serial numbers and device labels

A light system is identified by its device label and serial numbers.

- The device label ① contains the specific device data and also the main serial number.
- The main serial number characterises an entire device in an order-specific manner. The main serial number also enables components which do not have a serial number themselves to be identified by the technical customer service permitting the correct spare parts to be supplied.
- The serial numbers ② identify the individual components of a device.

4.1.1 Markings on the ceiling-mounted version

A: Ceiling-mounted version

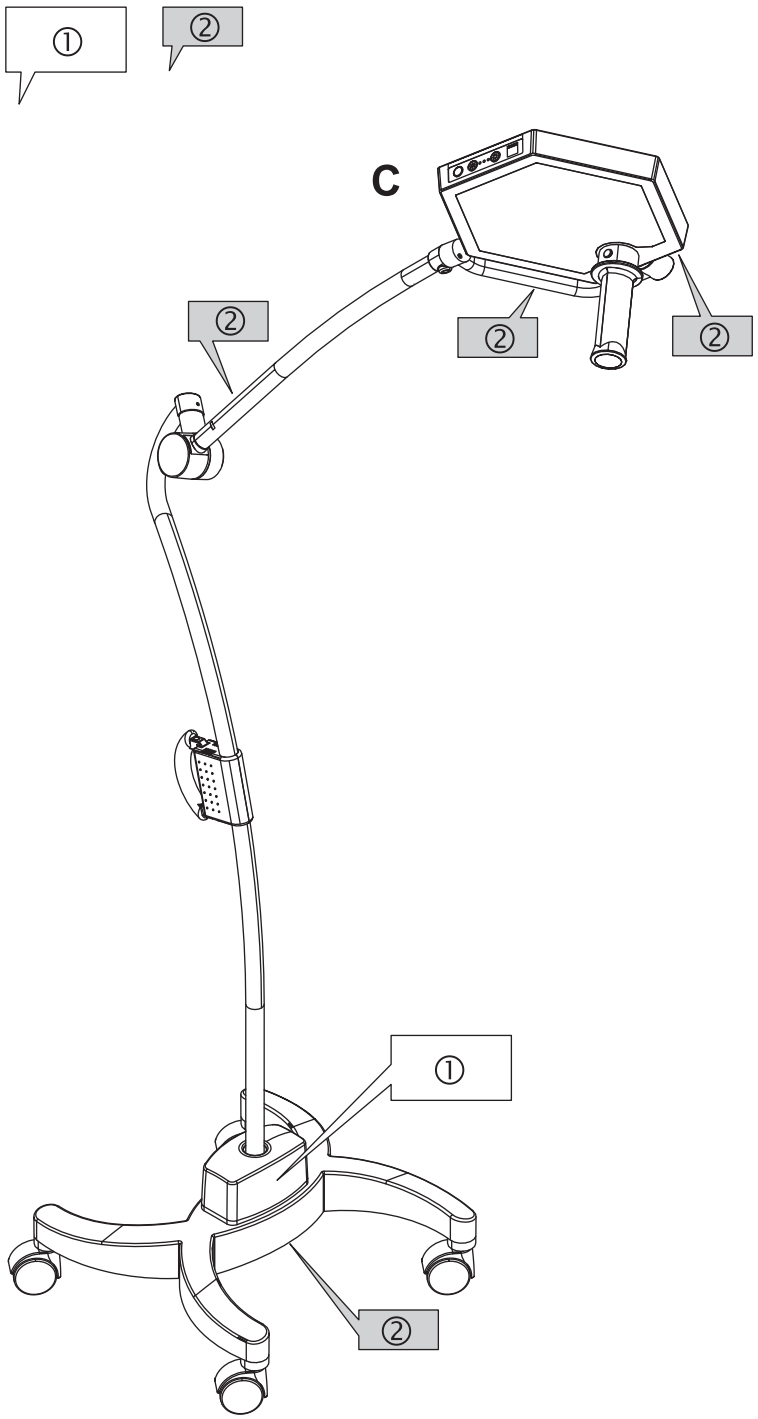
- The device label ① with the main serial number on the ceiling conduit.
- Serial numbers ② of the individual components are provided at:
  - Light head
  - Quarter bracket
  - Ceiling conduit
  - Boom with spring arm

4.1.2 Markings on the wall-mounted version

B: Wall-mounted version

- The device label ① with the main serial number on the cover of the wall support.
- Serial numbers ② of the individual components are provided at:
  - Light head
  - Quarter bracket
  - Boom with spring arm

Figure 2

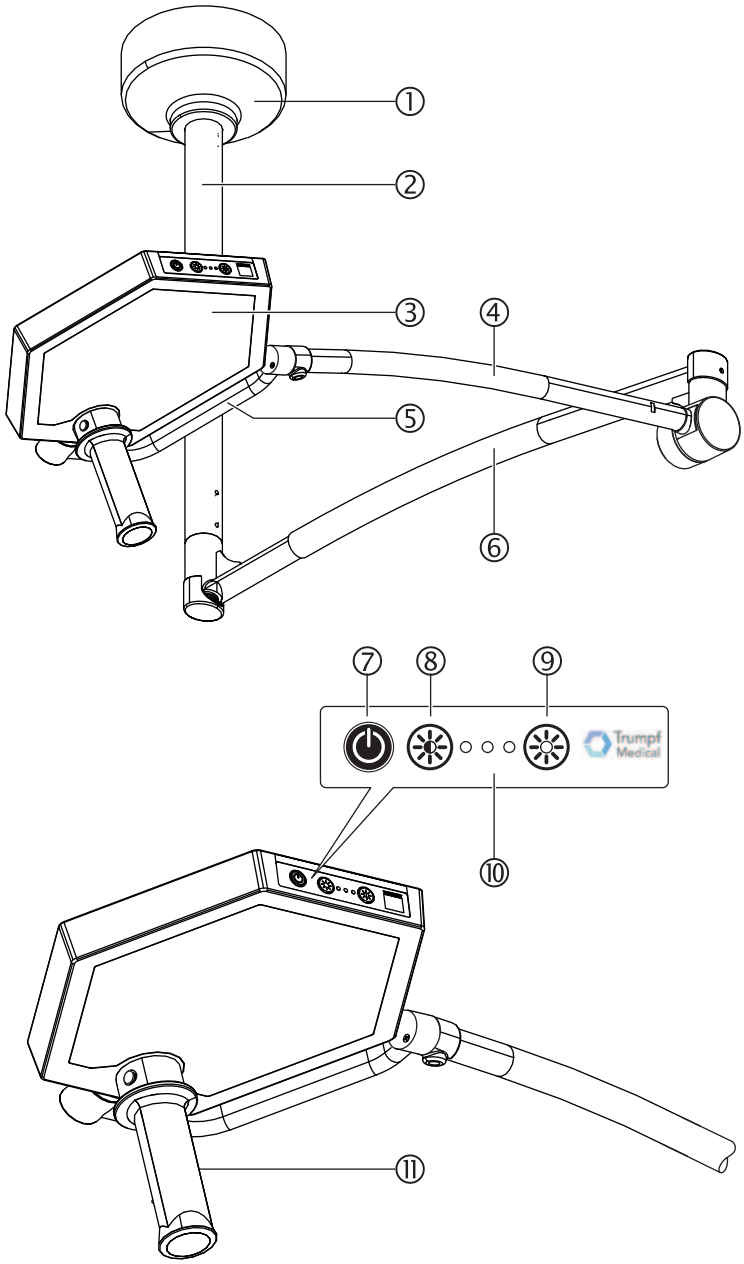


4.1.3 Markings on the mobile stand version

C: Mobile stand version

- Device label ① with the main serial number on the cover of the power supply unit.
- Serial numbers ② of the individual components are provided at:
  - Light head
  - Quarter bracket
  - Stand rod with spring arm
  - Stand base

Figure 3



5.1 Description of the ceiling-mounted version

Components of the ceiling-mounted version

The ceiling mounted version consists of:

- A single arm support arm system with a light head ③ on the quarter bracket ⑤.
- The support arm system comprises:
  - Canopy ①,
  - The central axis ② with the horizontal rotating boom ⑥,
  - The horizontally and vertically adjustable spring arm ④.

Power supply

Under the canopy ①, there is the ceiling fastening and the components for the power supply to the light system.

Light head control panel

Control panel ⑩ for switching the light head on / off and for adjusting the light intensity with:

- Key ⑦ for switching on / off,
- Key ⑧ for reducing the light intensity,
- Key ⑨ for increasing the light intensity.

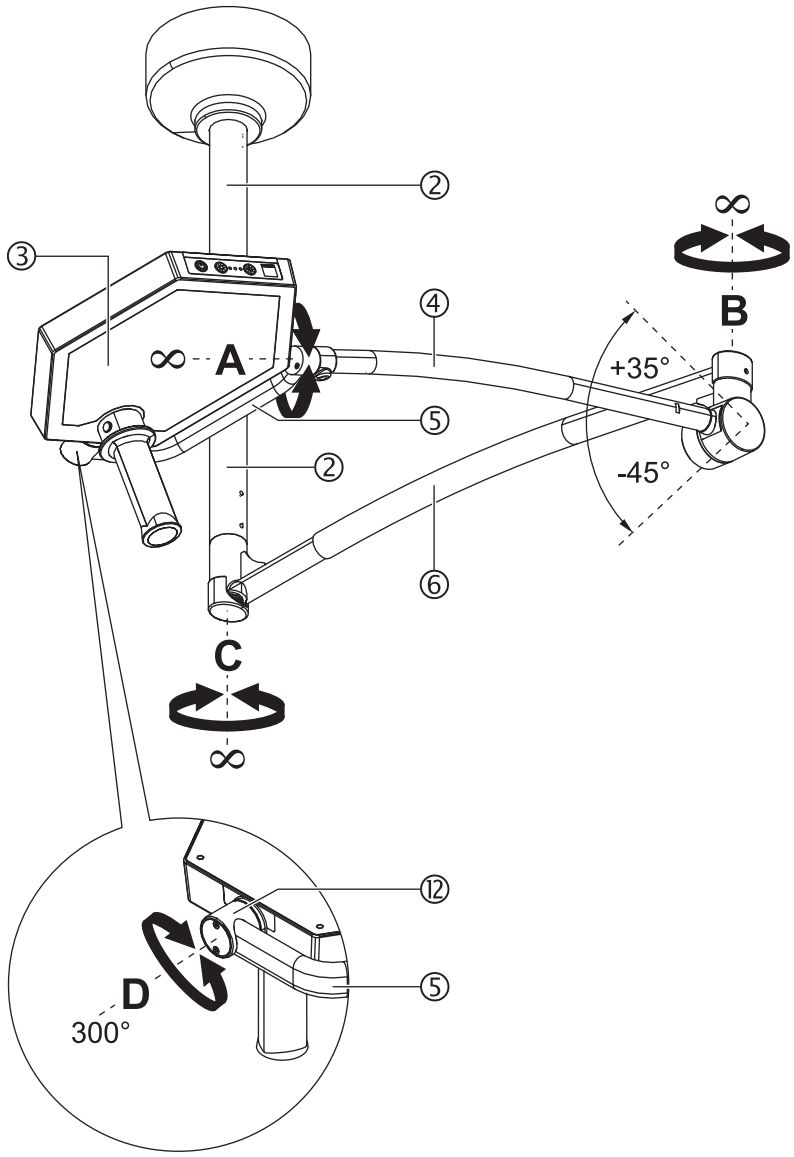
The light intensity can be adjusted in three stages:

- 30 %
- 60 %
- 100 %

Handle

Sterilisable handle ⑪ for sterile positioning of the light head.

Figure 4



5.2 Functional description of the support arm system, ceiling version

Mobility of the support arm system

The horizontally rotatable boom ⑥ together with the horizontal and vertically adjustable spring arm ④ facilitate stable positioning of the light head ③ within the activity range of the support arm system. The quarter bracket ⑤ facilitates accurate alignment of the light head onto the area to be examined.

Rotation / swivel ranges of the support arm system

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

- Boom ⑥ at the ceiling conduit ②, hinge **C**:
  Full horizontal rotation movement (>360°).
- Spring arm ④ on the boom ⑥, hinge **B**:
  Full horizontal rotation movement (>360°).
  Vertical swivel movement in the range: +35 ° to -45°.
- Quarter bracket ⑤ on the spring arm ④, hinge **A**:
  Full vertical rotation movement (>360°).
- Light head on axle bearing ⑫, hinge **D**:
  Vertical rotation movement 300°.

The rotation / swivel ranges are defined by the factory and may not be changed.

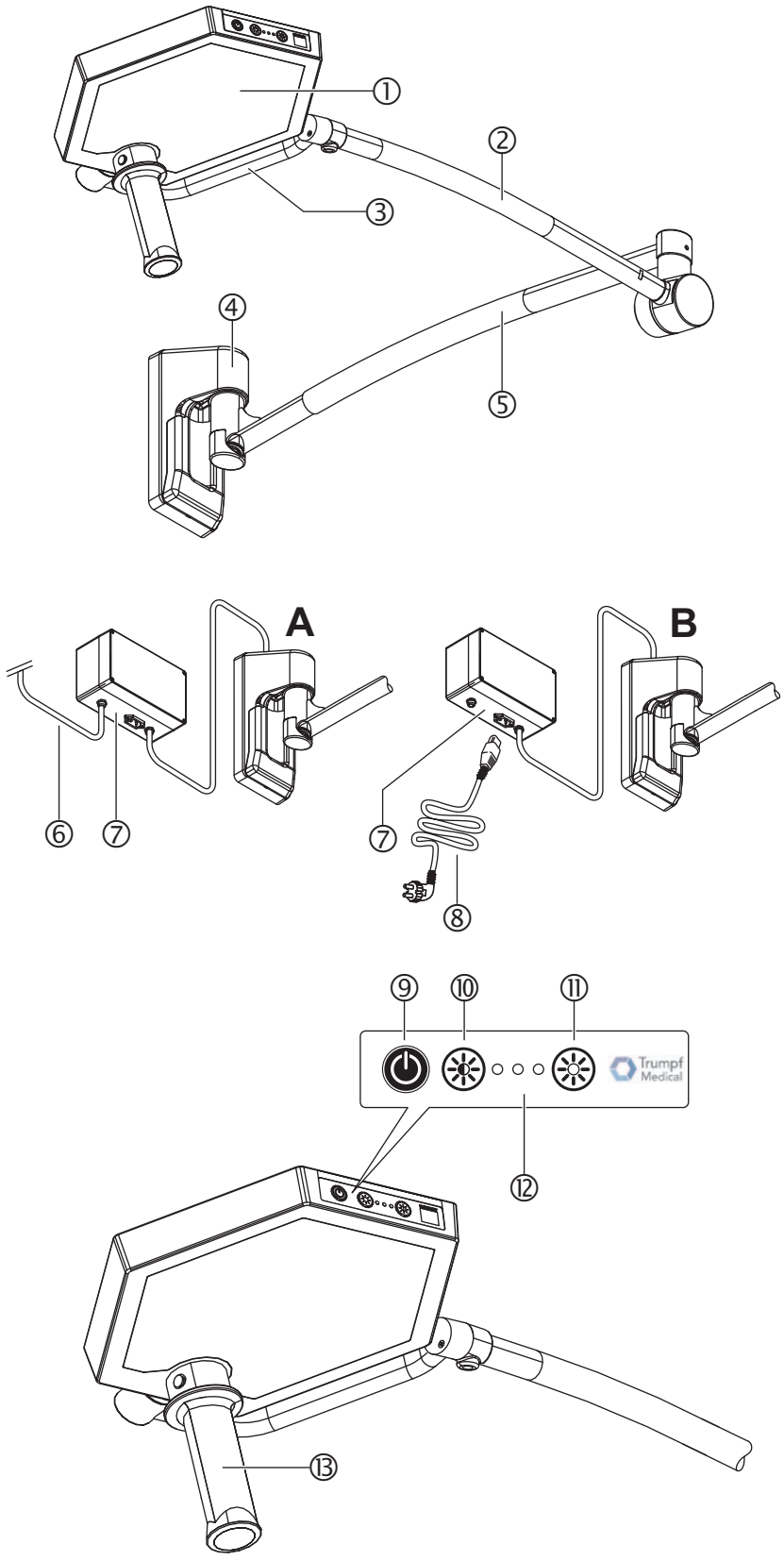
Spring force of the spring arm

The weight of the light head is compensated by a spring which is installed in the spring arm ④. The spring force must be readjusted if the spring arm with the light head sinks down of its own accord (see Chapter 11.1).

Braking force of hinges

The stabilisation of the support arms' horizontal rotating position in hinges **B** and **C**, as well as the stabilisation of the light head's vertical rotating position in hinges **A** and **D** is ensured through friction brakes in the relevant hinges.
The braking force can only be controlled on hinge **A** (see Chapter 11.3).

Figure 5



5.3 Description of the wall-mounted version

Components of the wall-mounted version

The wall-mounted version consists of:

- A two-arm support arm system with a light head ① on the quarter bracket ③.
- The support arm system comprises:
  - The wall support ④,
  - The horizontally rotating boom ⑤,
  - The horizontally and vertically adjustable spring arm ②.

Power supply

The power to the wall-mounted version can be supplied by three types of connection:

- **A:** Power supply box ⑦ with fixed connection, 100 V - 240 V ⑥,
- **B:** Power supply box ⑦, fed by a mains cable with cold-device plug, 100 V - 240 V ⑧.

Light head control panel

Control panel ⑫ for switching the light head on/off and for adjusting the light intensity with:

- Key ⑨ for switching on / off,
- Key ⑩ for reducing the light intensity,
- Key ⑪ for increasing the light intensity.

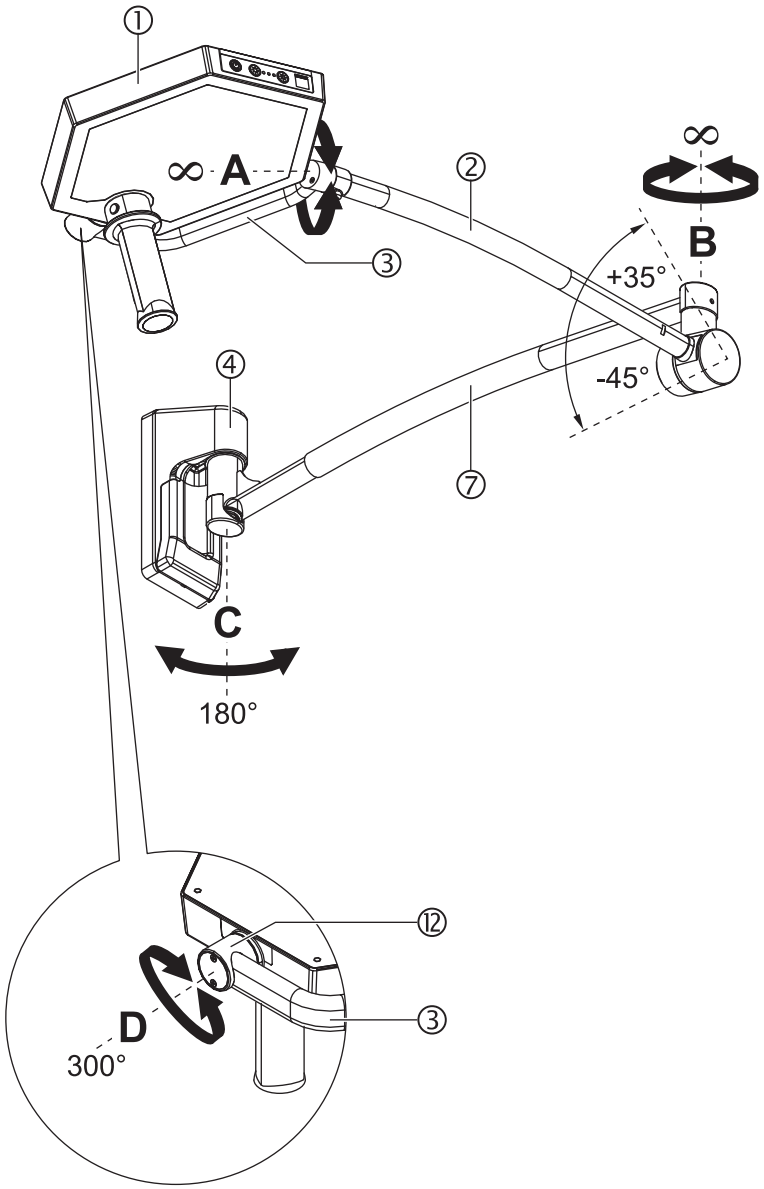
The light intensity can be adjusted in three stages:

- 30 %
- 60 %
- 100 %

Handle

Sterilisable handle ⑬ for sterile positioning of the light head.

Figure 6



5.4 Functional description of the support arm system, wall-mounted version

Mobility of the support arm system

The horizontally rotatable boom ⑦ together with the horizontal and vertically adjustable spring arm ② facilitate stable positioning of the light head ① within the activity range of the support arm system. The quarter bracket ③ facilitates accurate alignment of the light head onto the area to be examined.

Rotation / swivel ranges of the support arm system

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

- Boom ⑦ on the wall support ④, hinge **C**:
  Horizontal rotation movement (180 °).
- Spring arm ② on the boom ⑦, hinge **B**:
  Full horizontal rotation movement (>360°).
  Vertical swivel movement in the range: +35° to -45°.
- Quarter bracket ③ on spring arm ②, hinge **A**:
  Full vertical rotation movement (>360°),
- Light head on axle bearing ⑫, hinge **D**:
  Vertical rotation movement 300°.

The rotation / swivel ranges are defined by the factory and may not be changed.

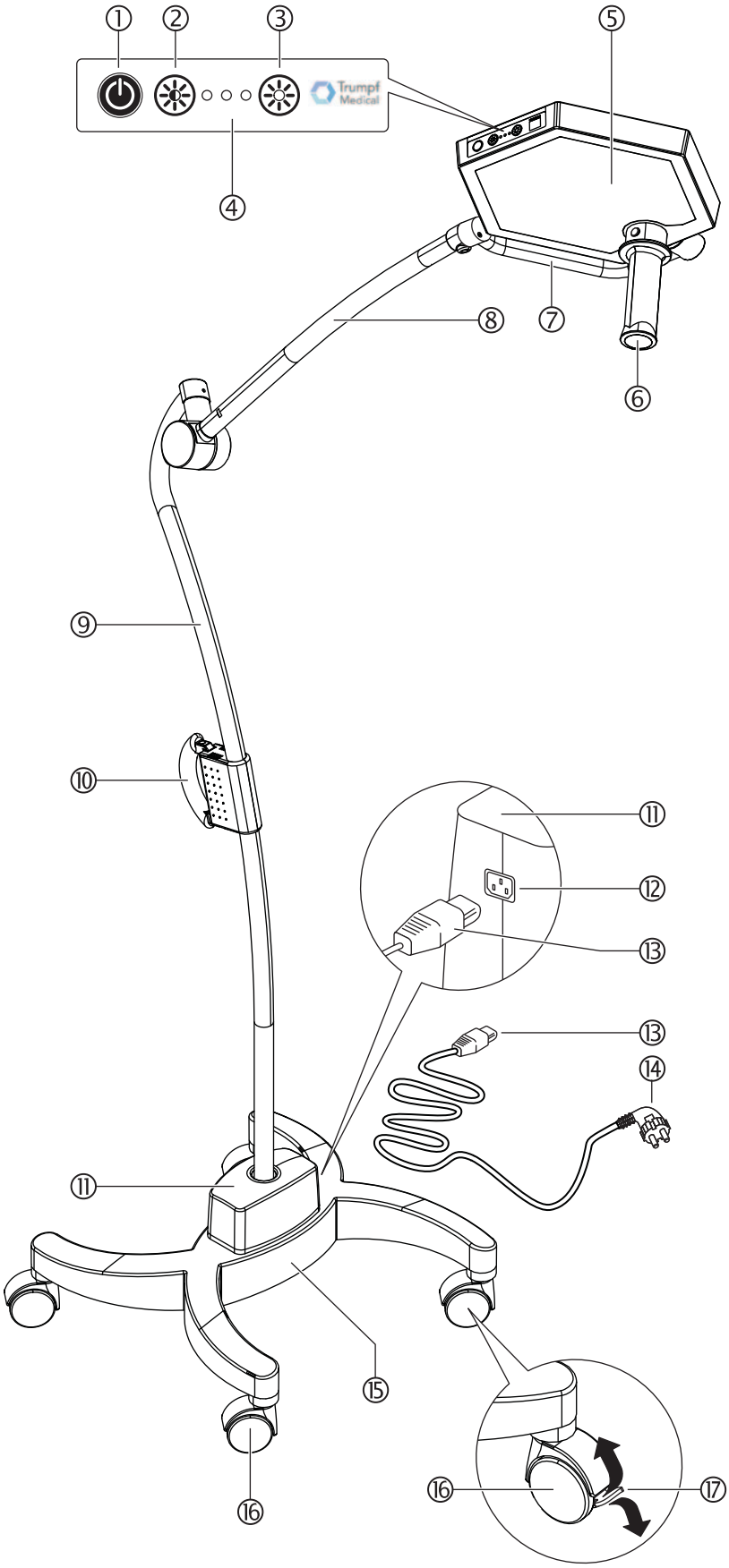
Spring force of the spring arm

The weight of the light head is compensated by a spring which is installed in the spring arm ②. The spring force must be readjusted if the spring arm with the light head sinks down of its own accord (see Chapter 11.1).

Braking force of hinges

The stabilisation of the support arms' horizontal rotating position in hinges **B** and **C**, as well as the stabilisation of the light head's vertical rotating position in hinges **A** and **D** is ensured through friction brakes in the relevant hinges.
The braking force can only be controlled on hinge **A** (see Chapter 11.3).

Figure 7



5.5 Description of mobile stand version

Components of the mobile stand version

The mobile stand version consists of:

- A single arm support arm system with a light head ⑤ on the quarter bracket ⑦.
- The support arm system comprises:
  - The stand base ⑮, with four rollers, the two front rollers ⑯ can be locked in place with a brake ⑰,
  - The stand rod ⑨ with handle ⑩ for moving the stand,
  - The power supply unit ⑪,
  - The horizontally and vertically adjustable spring arm ⑧,

Power supply

The power supply to the stand version is established at the power supply unit ⑪ with:

- The mains cable with cold-device plug ⑬ for connection to the cold-device socket ⑫ on the power supply (on the right-hand side) and the shockproof plug ⑭ for connection to a mains socket.
  Once the mains cable is connected, the power supply is on standby.

Light head control panel

Control panel ④ for switching the light head on / off and for adjusting the light intensity with:

- Key ① for switching on / off,
- Key ② for reducing the light intensity,
- Key ③ for increasing the light intensity.

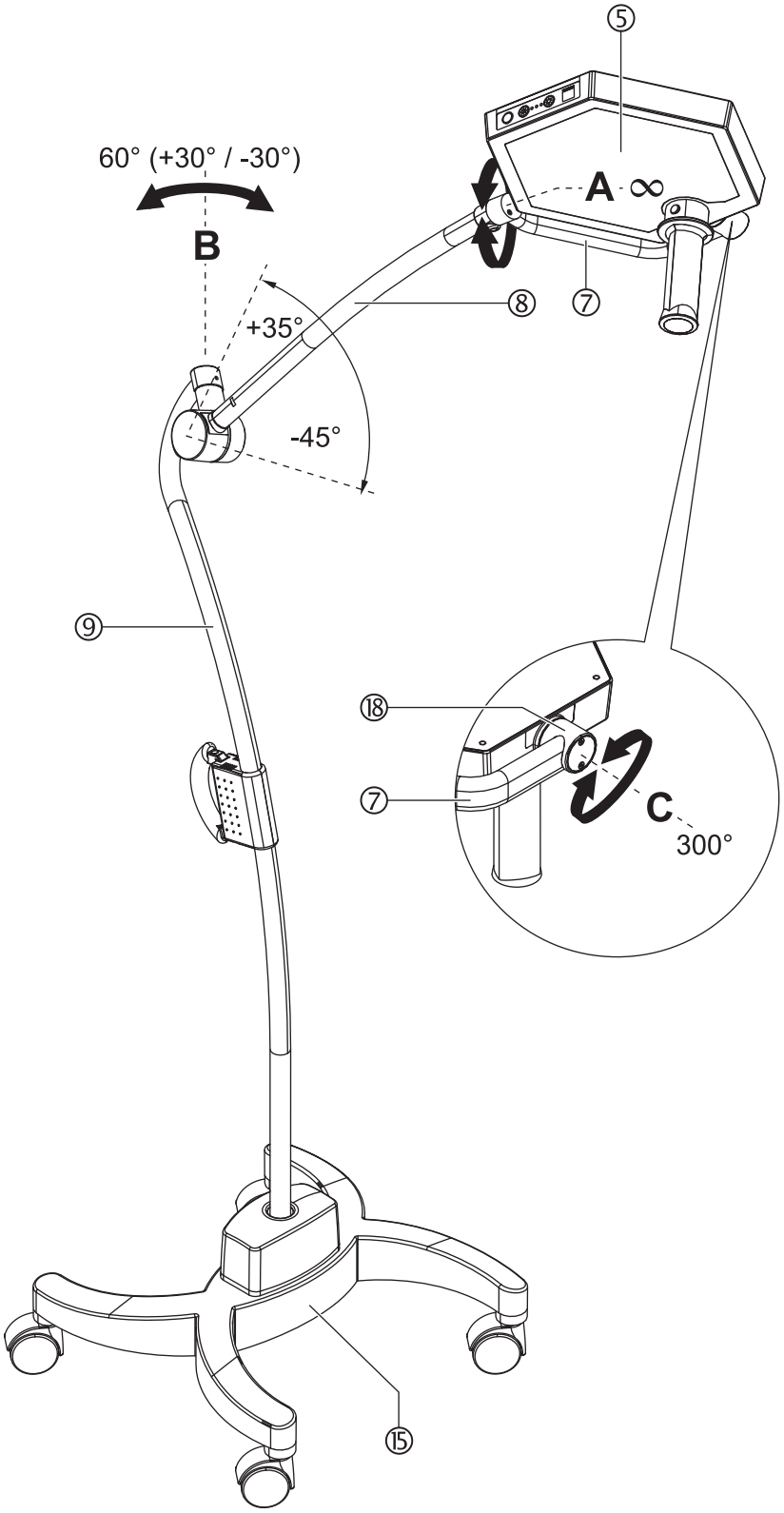
The light intensity can be adjusted in three stages:

- 30 %
- 60 %
- 100 %

Handle

Sterilisable handle ⑥ for sterile positioning of the light head.

Figure 8



5.6 Functional description of the support arm system, mobile stand version

Mobility of the support arm system

The stand base with castors ⑤ facilitates unrestricted mobility. The horizontally and vertically adjustable spring arm ⑧ on the stand rod ⑨ allows for stable positioning of the light head ⑤ within the activity range of the stand. The quarter bracket ⑦ facilitates accurate alignment of the light head onto the area to be examined.

Rotation / swivel ranges of the support arm system

The following movements can be performed with the support arms when there is sufficient distance from neighbouring walls and objects:

- Spring arm ⑧ on stand rod ⑨, hinge **B**:
  Horizontal rotation movement in the range:
  +30° to -30°.
  Vertical swivel movement in the range: +35° to -45°.
- Quarter bracket ⑦ on spring arm ⑧, hinge **A**:
  Full vertical rotation movement (>360°),
- Light head on axle bearing ⑱, hinge **C**:
  Vertical rotation movement 300°.

The rotation / swivel ranges are defined by the factory and may not be changed.

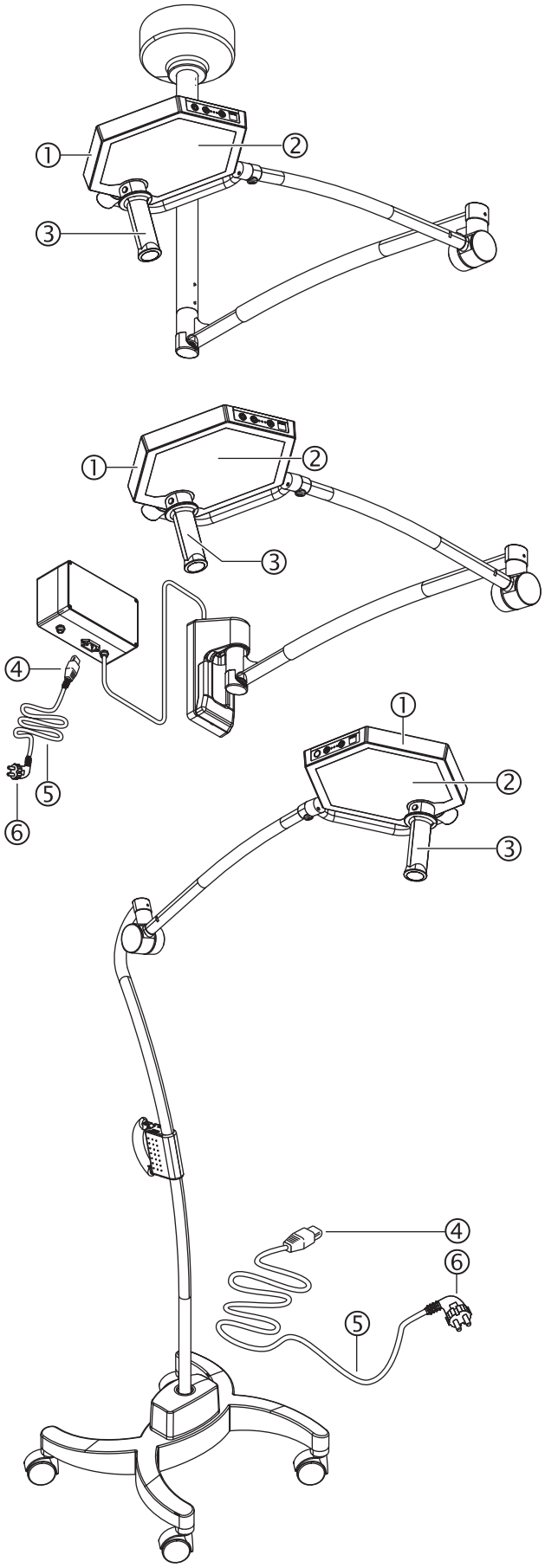
Spring force of the spring arm

The weight of the light head is compensated by a spring which is installed in the spring arm ⑧. The spring force must be readjusted if the spring arm with the light head sinks down of its own accord (see Chapter 11.1).

Braking force of hinges

The stabilisation of the support arm's horizontal rotating position in hinge **B**, as well as the stabilisation of the light head's vertical rotating position in hinges **A** and **C**, is ensured through friction brakes in the relevant hinges. The braking force can only be controlled on hinge **A** (see Chapter 11.3).

Figure 9



6.1 Checking the lighting system

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 control screen for the following points before each use:

- **Loose parts on light head ①,**
- **visible damage, in particular on the cover plates ② of the light head and the sterilisable handle ③,**
- **secure mounting of the sterilisable handle ③.**

Electric shock

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

- **Do not connect the lighting system to the mains in the event of defective plug connectors ④ or ⑥ or damaged mains cables ⑤.**

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.
- Secure the master switch or the safety connector against accidental switch-on / plugging in.
- Label the lighting system as DEFECTIVE!
- Inform Technical Customer Service.

⚠WARNING

Strong magnetic fields

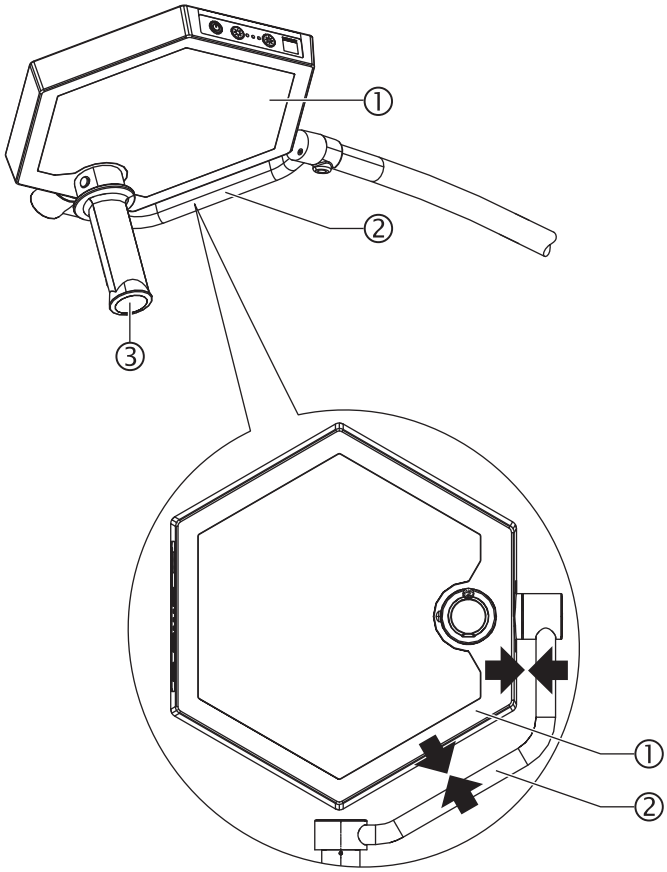
The support arm systems of the lighting systems must not be used in the vicinity of strong magnetic fields.

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 10



6.1.1 Danger of pinching when positioning the lighting system

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 quarter bracket and the light head reduces:

- **Do not insert your fingers between the quarter bracket ② and the light head when rotating the light head ①.**
- **Only position the light head with the sterilisable handle ③.**

6.1.2 Risks of collision during positioning

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

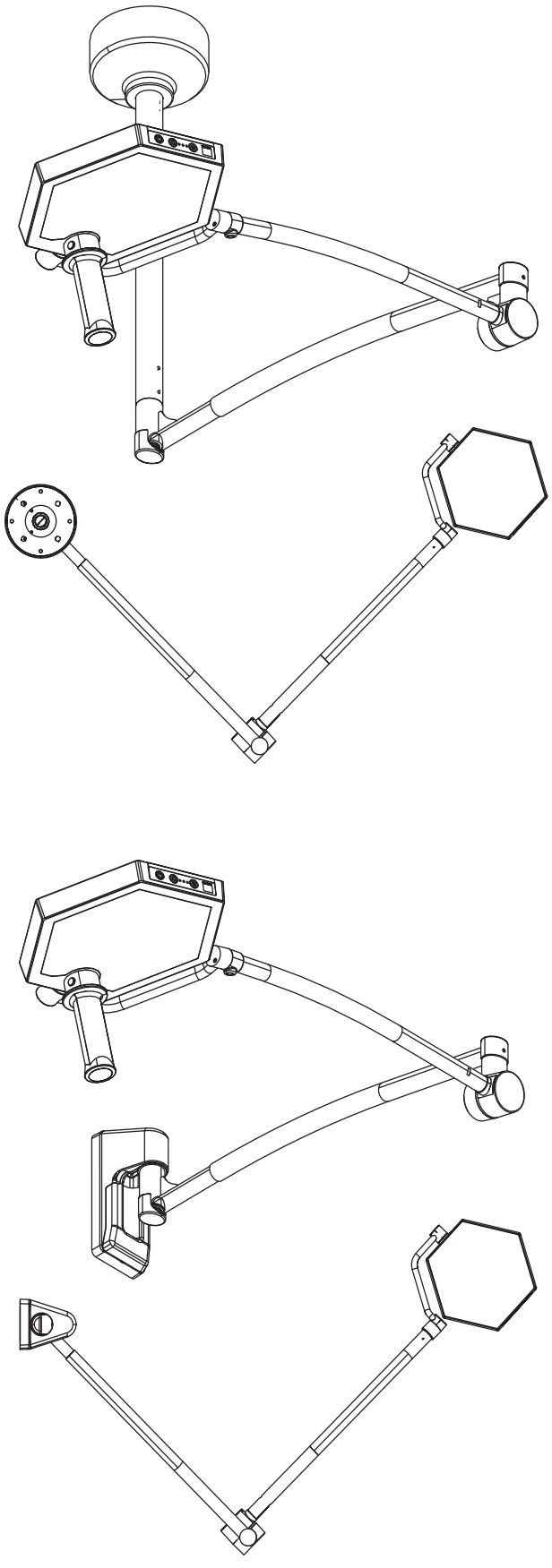
ATTENTION

Damage to the device

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 11



6.1.3 Positioning the cover-mounted / wall-mounted version

With the ceiling-mounted and wall-mounted version, the best mobility of the support arm is achieved in a “V-type arrangement”.

Working distance

Using the sterilisable handle, position the light head at a working distance of 70 – 150 cm from the area of the patient which is to be examined.

Examinations in the field of vision

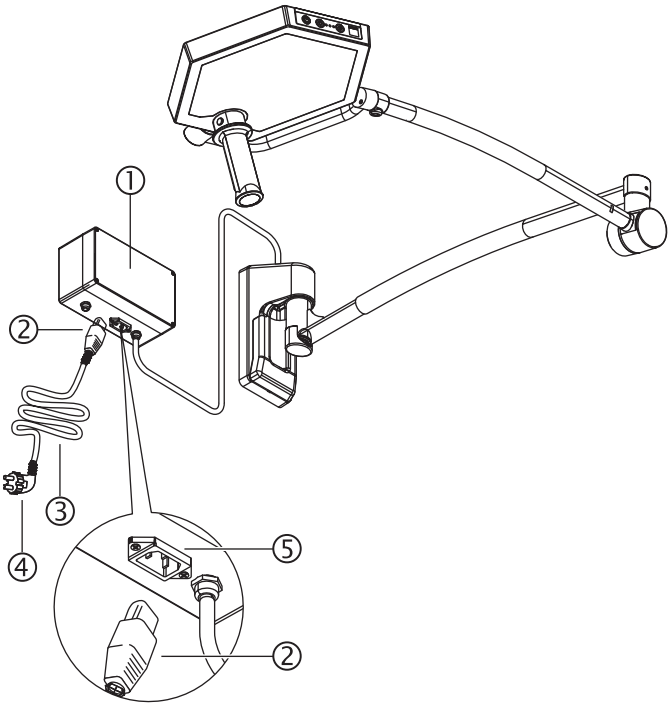
⚠WARNING

Damage to vision

In case of examinations 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 protective glasses.**
- **Do not look directly into the light-emitting surface area of the light.**

Figure 12



6.1.4 Power supply of wall-mounted version cable connection

The power supply of the wall-mounted version with cable connection is established by a mains cable ③ with a cold-device plug and a shockproof plug.

⚠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 the event of damaged plug connectors ② / ④ or a damaged mains cable ③.**
- **Label the device as DEFECTIVE and contact the technical customer service**

Connecting the lighting system

1. Check the cold-device plug ②, the mains plug ④ and the mains cable ③ for damage.
2. Route mains cable ③ from power supply box ① so that no tension forces are able to affect the cable.

⚠WARNING

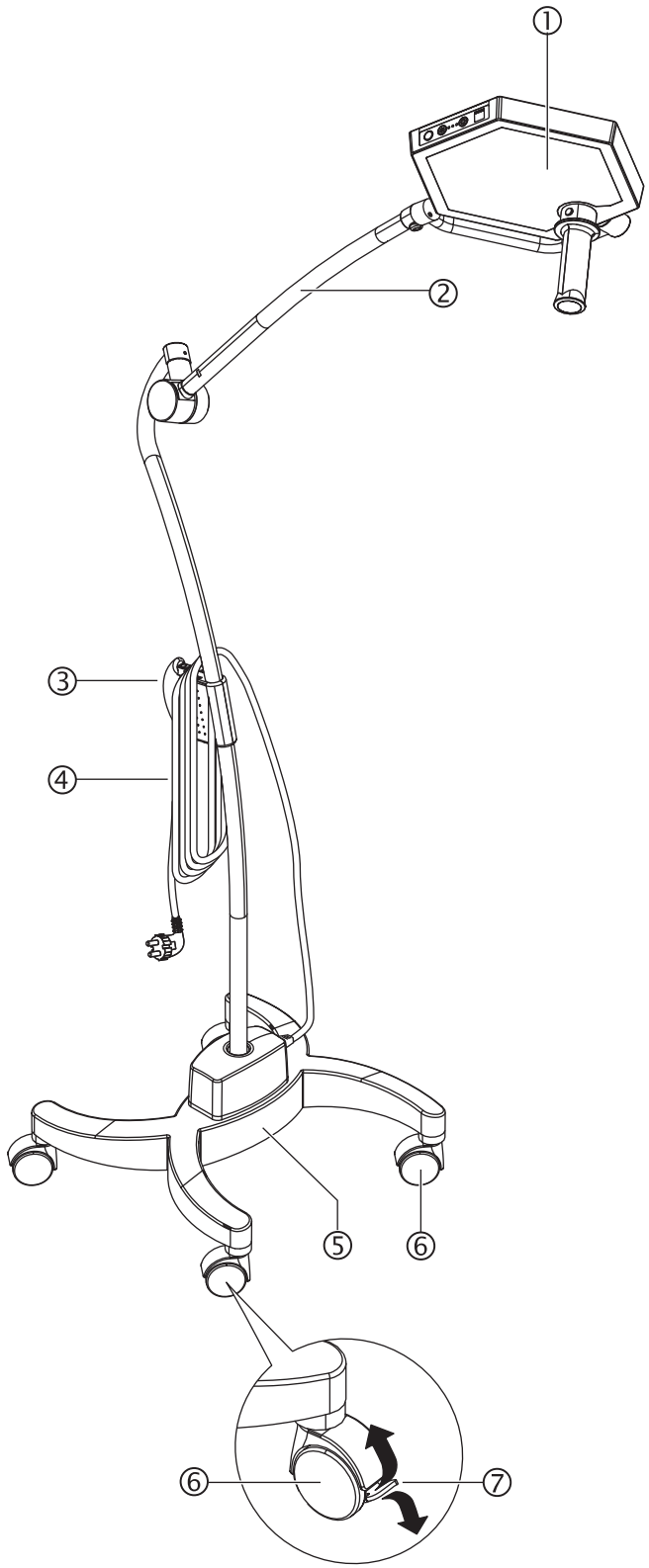
Electric shock

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

- **The wall-mounted version (protection class I) may only be connected to a properly earthed safety socket.**

3. Check whether the mains voltage corresponds to the information on the device label. Ask the local energy supply company or a specialist electrical company in cases of doubt.
4. Plug the cold-device plug ② into the cold-device socket ⑤ on the underside of the power supply box ①.
5. Insert the mains plug ④ into a correctly installed and earthed shockproof plug socket.
6. The device is switched to Standby.

Figure 13



6.1.5 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 ④:

- **Always move the mobile stand to the place of operation with the light head pointing in the direction of travel.**
- **Do not drive over objects lying on the floor, uneven parts of the floor, doorsteps or the mains cable.**
- **Pull the mains plug out of the socket and roll up the mains cable ④ on the stand handle ③ to move the stand.**

The stand might tilt when the castors ⑥ 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

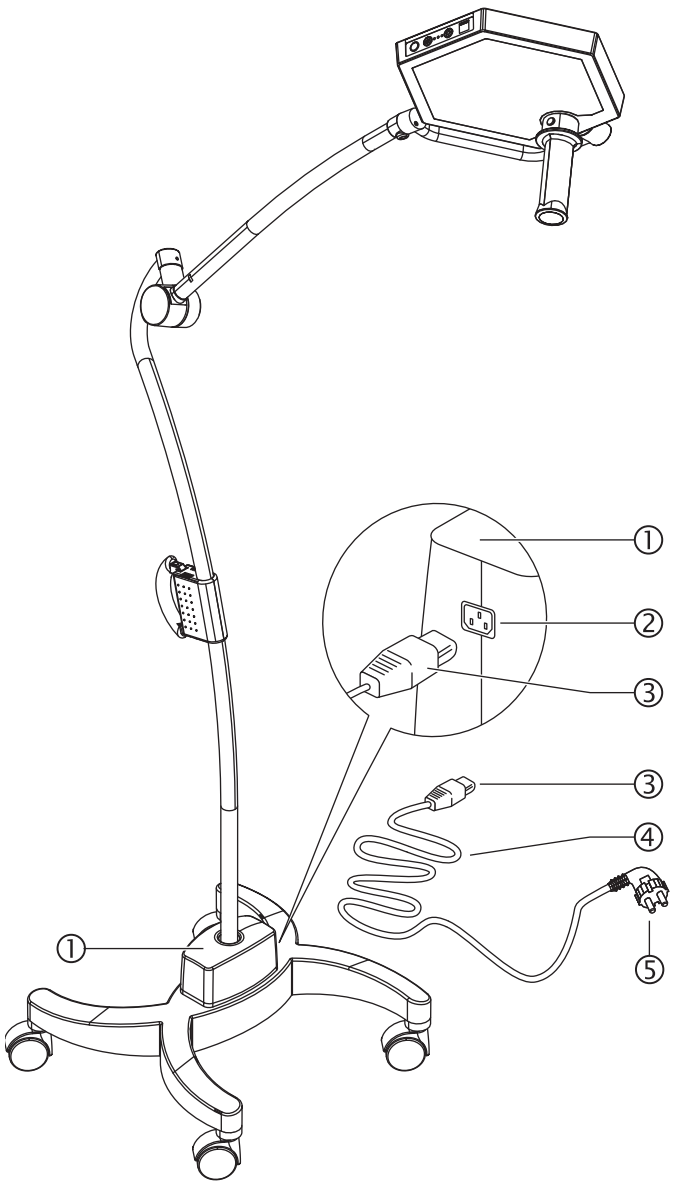
The two front castors ⑥ can be locked to immobilise the stand base.

- **Press the brakes ⑦ of both front castors downwards to lock them.**
- **Press the brakes ⑦ 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 handle ③ and move it with the light head ① in the direction of travel to the place of use.
3. Using the sterilisable handle, position the light head ① at a working distance of 70 - 150 cm from the area to be examined.
4. Connect the mobile stand version to the mains.

Figure 14



6.1.6 Power supply of the mobile stand version

The power supply of the mobile stand version is established by a mains cable ④ with cold-device plug and a safety connector.

⚠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 if the plug connectors ③ / ⑤ are damaged or if the mains cable ④ is damaged.**
- **Label the device as DEFECTIVE and contact the technical customer service**

Connecting the lighting system

1. Check the cold-device plug ③, the mains plug ⑤ and the mains cable ④ for damage.
2. Lay the mains cable ④ so that there is no danger of tripping and so that there is no strain on the cable.
3. Check whether the mains voltage corresponds to the information on the device label. Ask the local energy supply company or a specialist electrical company in cases of doubt.

⚠WARNING

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) must only be connected to a properly earthed shockproof plug socket.**

4. Plug the cold-device plug ③ into the cold-device socket ② on the right-hand side of the power supply unit ①.
5. Insert the mains plug ⑤ into a correctly installed and earthed shockproof plug socket.
6. The device is switched to Standby.

7.1 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.

7.2 Preparatory measures

Measures that should be considered before using the lighting system.

Checking the lighting system

Visual inspection

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 light head,**
- **Visible damage, in particular on the cover plates of the light head and the sterilisable 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 wall-mounted / 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 third LED, the light head no longer achieves the specified light intensity.

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

Decommissioning

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.**
- **Secure the master switch or the safety connector against accidental switch-on / plugging in.**
- **Label the lighting system as DEFECTIVE!**
- **Inform Technical Customer Service.**

Examinations in the field of vision

⚠WARNING

Damage to vision

In case of examinations 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 protective glasses.**
- **Do not look directly into the light-emitting surface area of the light.**

7.3 Measures to take when using the lighting system

Measures that should be considered while using the lighting system.

Strong light fields

⚠WARNING

Damage to patient's tissue

High levels of illumination may cause damage to tissue. In the event of incipient tissue dehydration:

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

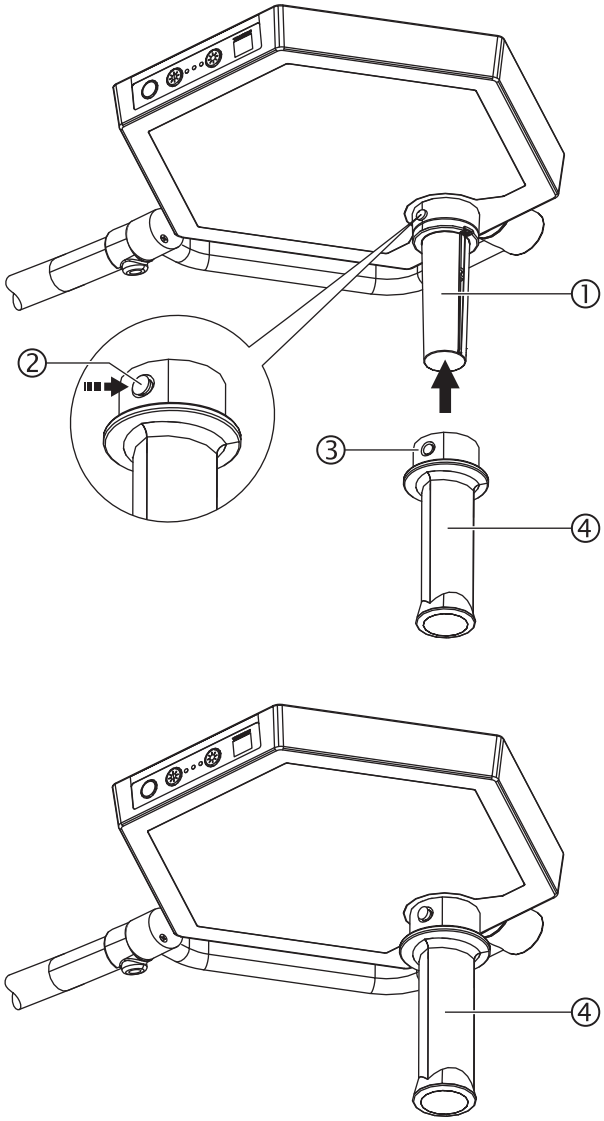
Electrostatic charge

⚠WARNING

Risk posed by electrostatic charge

To avoid risks due to electrostatic charge between parts of the device and patients, the user must not touch parts of the examination light and the patient at the same time.

Figure 15



7.4 Attaching / removing the sterilisable handle

The sterilisable handle ④ is fixed to the handle adapter ① with a ball latch ②.

⚠WARNING

Contamination and infection hazard for patients

Check the handle for damage to the material, cracks or deformations.

- **Loose particles of material may fall into the wound area.**
- **Do not use damaged handles.**

Improper use

Sterile positioning of the light head is only possible with the handle attached.

- **For medical purposes, only use light heads with the handle attached.**

Putting on the sterilisable handle

- Push the sterilisable 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 sterilisable handle.

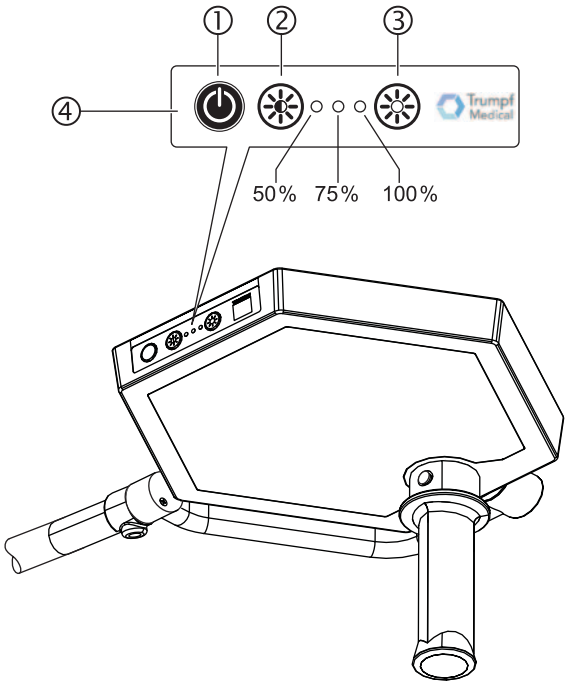
Removing the sterilisable handle

- Press in the ball latch ②.
- Pull the sterilisable handle ④ off the handle adapter ①.

7.5 Positioning the light head

- Using the sterilisable handle ④, position the light head at a working distance of 70 – 150 cm from the area of the patient which is to be examined.

Figure 16



7.6 Switching the light head on / off

The ceiling-mounted version of the lighting system is connected to the power supply via a fixed connection.

Establishing the voltage supply

Ceiling and wall-mounted version with fixed connection:

- Switch on the master switch in the examination room.

Wall-mounted version and mobile stand version with cable connection:

- Connect the power supply with the mains cable (see Chapter 6.1.4, Chapter 6.1.6).

→ The power supply of the device is in Standby mode.

Switching on the light head

- Press the ON / OFF button ① on the control panel ④.

→ The light head starts to light up.

Switching off the light head

- Press the ON / OFF button ① on the control panel ④.

→ The light head goes out.

Disconnecting the voltage supply

Ceiling and wall-mounted version with fixed connection:

- Switch off the operating theatre master switch.

→ The lighting system is disconnected from the power supply.

Wall-mounted version and mobile stand version with cable connection:

- Disconnect the mains plug (see Chapter 6.1.4, Chapter 6.1.6).

→ The lighting system is disconnected from the power supply.

7.7 Setting the light intensity

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

- 30 %
- 60 %
- 100 %

The light intensity which is currently set is indicated by the illuminated LED.

Reducing the light intensity:

- Press key ② on the control panel ④.

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

Increasing the light intensity:

- Press key ③ on the control panel ④.

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

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.**

⚠WARNING

Improperly used cleaning agents or disinfectants (see Chapter 8**) 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 halides.
- **Please refer to** Chapter 9 **for the sterilisation of handles.**
- **It is essential that the hygiene instructions of the operator are observed.**

8.1 Cleaning and disinfection

8.1.1 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 8.1.3, page 41. 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!

8.1.2 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. All poles of the operating lamp must be disconnected from the power supply and secured against switching on.
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 with 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.

8.1.3 Recommended disinfectants

Trumpf Medical recommends the following disinfectants for manual application:

Manufacturer	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 sulphone (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.

9.1 Preparation

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

9.2 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 dry-heat sterilisation for sterilisable handles.**

9.2.1 Cleaning

The sterilisable 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 sterilisable handle off the handle adapter.
2. Clean the sterilisable handle with cleaning agent.
3. Thoroughly rinse off cleaning agents with tap water.

9.2.2 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. Disinfect the sterilisable handle.
5. Check the sterilisable 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.

An automatic method using a machine (disinfector) should be used for cleaning / disinfection in accordance with DIN EN ISO 15883-1. The effectiveness of the method used must be generally accepted (e.g. be included in the list of the disinfectants and procedures checked and approved by the Robert Koch-Institute / DGHM) and must already be validated in principle.
When using other methods (e.g. manual methods), the effectiveness of the method must be verified in principle in the course of validation.
The Vario-TD 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

9.3 Sterilising handles for examination lights

Material

The handles are made of heat- and impact-resistant polyphenylene sulphone (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.

9.3.1 Preparation

- Remove coarse dirt from the sterilisable handle immediately after use (within 2 hours).
- Store the sterilisable handle for later cleaning in a container in which the dirt remains moist.
- Avoid situations in which the inner surface of the sterilisable handle is dirtied or the cover panel is scratched.

9.3.2 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 dry-heat sterilisation for sterilisable handles.**

Cleaning

The sterilisable 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 sterilisable handle off the handle adapter.
2. Clean the sterilisable handle with cleaning agent.
3. Thoroughly rinse off cleaning agents with tap water.

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. Disinfect the sterilisable handle.
5. Check the sterilisable 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.

An automatic method using a machine (disinfector) should be used for cleaning / disinfection in accordance with DIN EN ISO 15883-1. The effectiveness of the method used must be generally accepted (e.g. be included in the list of the disinfectants and procedures checked and approved by the Robert Koch-Institute / DGHM) and must already be validated in principle.
When using other methods (e.g. manual methods), the effectiveness of the method must be verified in principle in the course of validation.
The Vario-TD 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

9.3.3 Sterilisation

General information

- The sterilisation methods must be validated in accordance with EN ISO 17665-1 and 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 be immediately exchanged.**

Steam sterilisation

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

- Place the sterilisable handles in 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 sterilisable handles individually in packaging 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.

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

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

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

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

9.3.4 Sterilisation packaging

The sterilisable handles must be inserted into suitable sterilisation packaging (disposable sterilisation packaging, e.g. film / paper sterilisation bags; simple or double packaging according to EN ISO 11607, suitable for steam sterilisation) and subsequently sterilised.

1. Place the pre-cleaned and disinfected handle in the sterilisation packaging.
2. Sterilise the sterilisable handle according to the specifications.
3. Check the sterilised handle for material damage, cracks or deformation and exchange damaged handles.
4. 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.
We recommend that a service contract is concluded.

Service telephone

Technical Customer Service: Telephone: +49 3671 586-41911
Fax: +49 3671 586-41175

E-mail: Service.wwo@trumpfmedical.com

10.1 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 on the light head**
- **Visible damage, in particular on the cover plate of the light head and the sterile handle.**
- **Secure mounting of the sterilisable handle.**

Defective devices

Defective devices or functional units must be clearly labelled immediately and taken out of operation.
Inform the technical customer service in the event of damage or faults.

10.2 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.
- cracks and brittle plastic parts,
- Legibility of device labels.
- Damaged or deformed components must be replaced.

10.3 Maintenance every two years

Maintenance every two years: The device may only be maintained by the technical customer service.

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.

10.4 Repairs

Please contact the technical Customer Service team in the event of a fault.
You will receive an appropriate replacement light head that can be replaced by trained technicians, when required (e.g. if a lamp fails). For more information, see the installation instructions provided (see chapter: Installation of the light unit onto the support arm system).

ATTENTION

Incorrect repairs

Authorised service centres

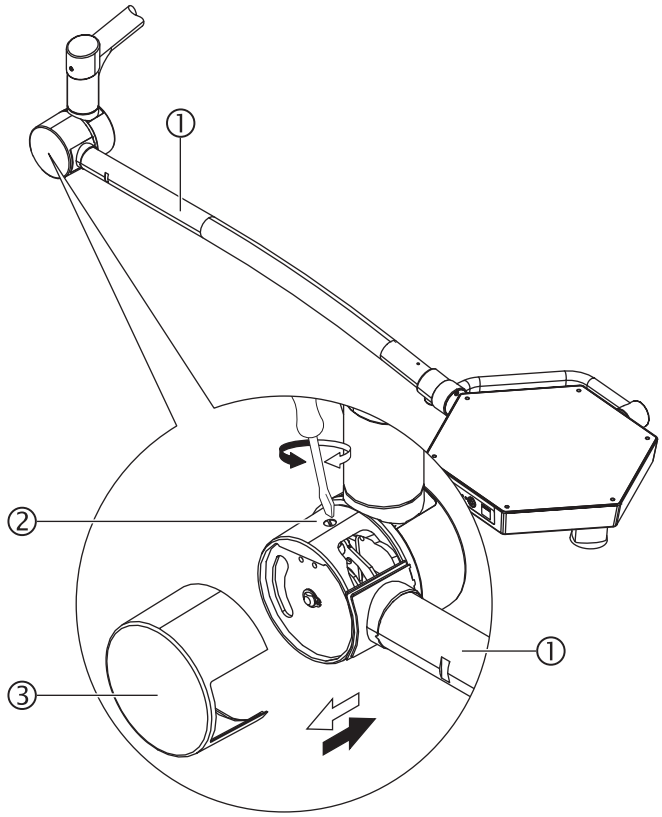
The device must only be repaired by the technical customer service or trained service staff.

Repeat test

Repeat test

After replacement of the light head (e.g. after failure of a lamp), a measurement is required (according to DIN EN 62353 - Repeat inspection and test after repairs to electrical medical devices).

Figure 17



11.1 Specifications

Adjustment work may only be performed by specialised technical staff of the operating company following appropriate hospital technician training by Trumpf Medical.

11.2 Adjusting the spring force on the spring arm

The weight of the light head is compensated by a spring which is installed in the spring arm ①. The spring force must be readjusted if the spring arm with the light head sinks down of its own accord.
The adjustment screw for setting the spring force is installed:

- In the ceiling and wall mounted version: on the joint between the boom and the spring arm,
- In the mobile stand version: on the joint between the stand rod and the spring arm.

1. Carefully lever off the cover cap ③ from the joint of the spring arm using a thin blade.
2. Swivel the spring arm ① to the top end position (+35°).

⚠ CAUTION

Uncontrolled rotation of the spring arm

Risk of injury due to uncontrolled rotation movement!

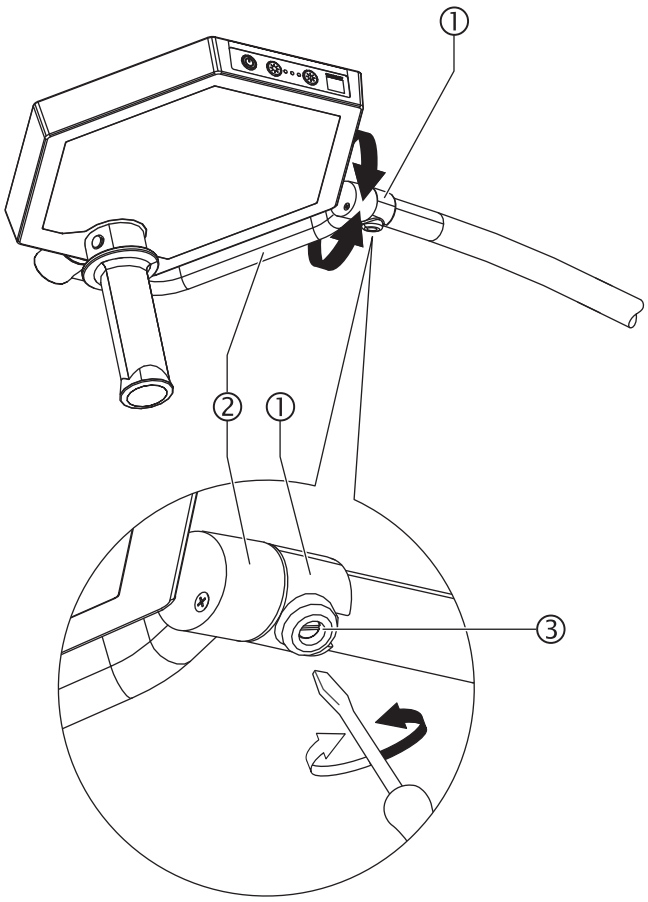
- **The spring arm may jump up if the spring force is set too high.**
- **If the spring force is reduced too far, the spring arm may slip down due to the weight of the light head.**
- **Carefully turn the adjustment screw while continuously monitoring the positional stability of the rotation movement.**

Damage to the adjustment mechanism

The adjustment mechanism can be damaged and the spring arm made unfit for use if the adjustment screw is screwed in too far.

3. Adjust the spring force by turning the slot-head screw ② with a screwdriver:
   – **Increasing the spring force:** Unscrew the slot-head screw ② anticlockwise.
   – **Reducing the spring force:** Screw in the slot-head screw ② clockwise.
4. Place the cover cap ③ on the joint and press it on.

Figure 18



11.3 Adjusting the brake force of the quarter bracket

If the light head does not remain stable in the vertical rotation position, the braking force for the rotation of the light head must be readjusted on the joint between the spring arm ① and the quarter bracket ②. The friction brake of the quarter bracket acts through the friction force of the adjustment screw (slot-head screw ③) on the quarter bracket pin.

1. Adjust the braking force by turning the slot-head screw with a screwdriver:
   – **Increasing the braking force:** Screw in the slot-head screw ③ clockwise.
   – **Reducing the brake force:** Unscrew the slot-head screw ③ anticlockwise.
2. Check the function of the friction brake in several positions of rotation.

Wearing parts may only be exchanged by specialised technical staff of the operating company following appropriate hospital technician training by Trumpf Medical.

Handles and brake screws

High-wear part	Chapter	#
Sterilisable handle for light head; plastic (pack of 3)	see Chapter 7.4	0337642
Brake screw with slot on the quarter bracket (light head brake); M10 x 1 mm with 11 mm length (2 units)	see Chapter 11.3	4025239

NOTE

Recurrent faults

If a fault recurs or cannot be remedied, put the device out of service and contact the technical 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	see Chapter 11.1
Light head moves with difficulty / easily	Brakes set too stiff / too loose.	Adjust brakes	see Chapter 11.3
Optical system / light technology			
Light intensity too low	Light intensity set too low	Increase light intensity	see Chapter 7.5
Inhomogeneous light field	The light head is outside the working area	Position the light head	see Chapter 7.7
The light does not light up	Main switch in the examination room is switched off	Switch on the main switch	see Chapter 7.6
	Light head has been turned off at the control panel	Press the ON / OFF button	see Chapter 7.6
	Mains cable of the mobile stand version not plugged in	Plug mains cable into socket	see Chapter 6.1.6
	Mains cable of the wall-mounted version not plugged in	Plug mains cable into socket	see Chapter 6.1.4
	Defective electronics	Inform Technical Customer Service	—
	Site power supply is interrupted	Check site fuses and power supply	—
Sterilisable handle			
Handles are damaged or show cracks	End of service life has been reached	Replace handles	see Chapter 7.4
Life span of the sterilisable handles too short	Wrong sterilisation method	Check sterilisation method	see Chapter 9.3.3

14.1 Device data

Electrical data

Designation	Electrical data
Connected voltage at the power supply unit	100 V AC - 240 V AC, 50 / 60 Hz
Max. power uptake of whole system	50 VA
Nominal frequency	50 / 60 Hz
Output current with 24 V secondary voltage	<1.25 A
Internal fuse (mobile stand version only)	M 2.0 A
Max. heat load of the light head	20 W
Average LED life span	>50,000 hrs
Classification according to MPG	Safety class: I Mode of operation: Suitable for continuous operation

Technical data for the lighting system

Designation	Technical data for the lighting sys-
Central lighting intensity at a defined distance (1 m)	80,000 Lux
Dimmable from / to	30 - 100 %
Focusable light field size d10 at 1 m distance	Approx. 160 mm
d50/d10 ratio	0.57
Colour temperature	4,500 K
Colour rendering index Ra	Ra 95
Colour rendering index R9	90
Total radiant power at a distance of 0.85 m	319 W/m2

Mechanical data

Designation	Mechanical data
Light head diameter	300 mm
Distribution area of the light head	340 cm2
Light-emitting surface area	240 cm2
Weight of the light head (incl. quarter bracket)	2.4 kg

14.2 EMC information

EMC notes

⚠WARNING

Operate the device only with the stated accessories.

TruLight™1000 may only be operated with the accessories stated in the accompanying documents. Operation with accessories, converters or conduits other than those stated in the accompanying documents can lead to increased EMC emissions or reduced interference immunity of the device and thus to improper use.

NOTE

Install or operate the device according to the EMC instructions

Medical electrical devices such as the TruLight™ 1000 are subject to specific precautionary measures regarding EMC and must be installed and operated in accordance with the EMC instructions stated in the accompanying documents.

NOTE

Do not stack the device with or next to other devices

TruLight™ 1000 must not be stacked immediately next to or on top of other devices.

Guidelines and manufacturer's declaration - electromagnetic immunity		
TruLight™ 1000 is intended for use in the ELECTROMAGNETIC ENVIRONMENT described below. The customer or user should ensure that the TruLight™ 1000 is operated in an environment as described.		
Emission measurements	**Compliance**	**ELECTROMAGNETIC ENVIRONMENT - guidelines**
RF emissions in accordance with CISPR 11	Group 1	TruLight™ 1000 uses RF energy exclusively for its internal FUNCTION. Therefore, its RF emission levels are very low, and it is unlikely that neighbouring electronic devices would be adversely affected.
RF emissions in accordance with CISPR 11	Class B	TruLight™ 1000 is suitable for use in all establishments, including residential areas and facilities that are directly connected to a PUBLIC POWER SUPPLY NETWORK which also supplies buildings that are used for residential purposes.
Harmonic emissions in accordance with EN / IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions in accordance with EN / IEC 61000-3-3	Fulfilled	

Guidelines and manufacturer's declaration - electromagnetic immunity

NOTE

Avoid environments with electromagnetic fields and interference above the given levels

Guidelines and manufacturer's declaration - ELECTROMAGNETIC IMMUNITY			
TruLight™ 1000 is intended for use in the ELECTROMAGNETIC ENVIRONMENT described below. The customer or user should ensure that the TruLight™ 1000 is operated in an environment as described.			
Immunity tests	**EN / IEC 60601-test level**	**Compliance level**	**ELECTROMAGNETIC ENVIRONMENT / guidelines**
Electrostatic discharge (ESD) according to EN / 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 out of synthetic material, the relative humidity must amount to at least 30 %.
Rapid transient electrical interference variables / bursts according to EN / IEC 61000-4-4	±2 kV for mains power cables 100 kHz repetition rate	±2 kV for mains power cables 100 kHz repetition rate	Mains power quality should be that of a typical commercial or hospital environment.
Surges according to EN / IEC 61000-4-5	±1 kV outer conductor - outer conductor voltage ±2 kV outer conductor – ground wire voltage	±1 kV outer conductor - outer conductor voltage ±2 kV outer conductor – ground wire voltage	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and fluctuations of power supply according to EN / IEC 61000-4-11	0 % UT; 0.5 cycle [a] 0 % UT; 1 cycle [b] 70 % UT; 25/30 cycles [b] 0 % UT; 250/300 cycle	0 % UT; 0.5 cycle [a] 0 % UT; 1 cycle [b] 70 % UT; 25/30 cycles [b] 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued functioning even during power supply interruptions, it is recommended that the device be supplied from an uninterruptible power source or battery.
Magnetic field with a supply frequency (50 / 60 Hz) according to EN / 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.
[a] at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° [b] at 0° Note: UT is the AC mains voltage prior to application of the test level.			

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

Portable and mobile RF communication devices should be used no closer to any part of the TruLight™ 1000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

NOTE

TruLight™ 1000 is not intended for use in the vicinity of HF surgical devices or in RF shielded rooms for MRI. It was only tested for interference immunity against radiated fields in the electromagnetic environment mentioned below, which corresponds to a professional or domestic healthcare environment.

Immunity test	EN / IEC 60601-1 test level	Compliance level
Conducted RF interference variables according to EN / IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in the ISM band and amateur radio bands between 0.15 MHz and 80 MHz [a])	3 V 0.15 MHz – 80 MHz 6 V in the ISM band and amateur radio bands between 0.15 MHz and 80 MHz [a])
Radiated RF disturbance variables according to EN / IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz	10 V/m 80 MHz – 2.7 GHz
[a]) = The ISM 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, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.		

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	27
450	430 – 470	GMRS 460 FRS 460	Pulse modulation FM ±5 kHz variation, 1 kHz sine	2	0.3	28
710	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

Recommended separation distances between portable and mobile RF communication equipment and TruLight™ 1000			
TruLight™ 1000 is intended for use in an ELECTROMAGNETIC ENVIRONMENT where the radiated RF disturbances are monitored. The customer or user can help to prevent electromagnetic interference by maintaining the minimum distances between the portable and mobile RF telecommunication equipment (transmitters) and TruLight™ 1000, as is recommended below corresponding to the maximum output power of the communication equipment.			
Nominal power of the transmitter W	**Safe distance according to transmission frequency m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 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. Note 1: To calculate the recommended safe distance from the transmitter in the frequency range of 80 MHz to 2.5 GHz, an additional factor of 10/3 was used to reduce the probability of interference caused by a mobile / portable communication instrument unintentionally introduced into the patient area. Note 2: These guidelines may not be applicable in all situations. The propagation of electromagnetic waves is affected by absorption and reflection by structures, objects and people. Note 3: At 80 MHz and 800 Hz, the higher frequency range applies.			

⚠WARNING

Distance for portable RF communication devices 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 TruLight™ 1000 including its cables specified by the manufacturer. This can otherwise lead to a decline in the functionality of the system.

TRUMPF Medizin Systeme GmbH + Co. KG
Carl-Zeiss-Straße 7-9
D-07318 Saalfeld
Telefon: +49 3671 586-0
Telefax: +49 3671 586-41165
E-Mail: info@trumpfmedical.com
www.trumpfmedical.com

55000-00012_002_01 – 1695233 – 25/01/2018