

# Instruction Manual iLED<sup>®</sup> 7 Lighting system



Read the instruction manual carefully before using the product and keep it safe for future reference.







for purchasing the new iLED<sup>®</sup> 7 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 is valid for the following components:

iLED<sup>®</sup> 7 lighting systems:

- Designed as a single surgical light with a lamp head in ceiling-mounted or mobile version
- Designed as a surgical lighting system with a combination of two to three surgical lights in ceiling-mounted version

Control system for the iLED<sup>®</sup> 7 lighting system:

- External control units Control and WallControl Panel
- TruRemote operating software

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

• TruVidia<sup>®</sup> Wireless camera system and VidiaPort TFT support arm system



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	Below, Trumpf M GmbH + Co. KG ir	edical is used as a synonym for TRUMPF Medizin Systeme n order to facilitate easier reading.
Technical Customer Service	The contact deta individual countr www.trumpfmed Technical custom Customer service trained service p	ils for the current Technical Customer Service hubs in the ies can be found on the Internet at lical.com. her service is used as a synonym for Trumpf Medical e and for technicians authorized by Trumpf Medical and roviders.



Original instruction manual for the iLED® 7 lighting system

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### Supporting documents

Designation	Document number	Material no.
TruVidia <sup>®</sup> Wireless camera system instruction manual DE	55000-00030	2022461
RH interface converter iLED <sup>®</sup> 7 DE / EN	55000-00029	2068523
EPC iLED <sup>®</sup> 7 DE / EN	55000-00038	2025701
SM iLED <sup>®</sup> 7 DE	55000-00006	2015531
IA iLED <sup>®</sup> 7 DE	55000-00005	1971385
VidiaPort holder Duo instruction manual	55000-00033	1836570
VidiaPort holder Single instruction manual	55000-00033	1836569



Designator / rating	Туре	Item No.	
This document applies to the following sales units:			
iLED <sup>®</sup> 7 For the position of the serial numbers, see Chapter 5.1.	iLED <sup>®</sup> 7 single	4068110	
iLED® 7 / mobile	iLED <sup>®</sup> 7 mobile	4068120	
iLED® 7 / iLED® 7 iLED® 7 / VidiaPort 2000 iLED® 7 / VidiaPort 3000 iLED® 7 / VidiaPort 5000 VidiaPort 2000 / iLED® 7 VidiaPort 3000 / iLED® 7 VidiaPort 5000 / iLED® 7	iLED® 7 duo	4068210	
iLED® 7 / iLED® 7 / iLED® 7 VidiaPort 2000 / iLED® 7 / iLED® 7 VidiaPort 3000 / iLED® 7 / iLED® 7 VidiaPort 5000 / iLED® 7 / iLED® 7 iLED® 7 / iLED® 7 / VidiaPort 2000 iLED® 7 / iLED® 7 / VidiaPort 3000 iLED® 7 / iLED® 7 / VidiaPort 5000 VidiaPort 2000 / iLED® 7 / VidiaPort 2000 VidiaPort 2000 / iLED® 7 / VidiaPort 2000 VidiaPort 2000 / iLED® 7 / VidiaPort 2000 VidiaPort 3000 / iLED® 7 / VidiaPort 2000 VidiaPort 5000 / iLED® 7 / VidiaPort 2000 VidiaPort 5000 / iLED® 7 / VidiaPort 2000 VidiaPort 5000 / iLED® 7 / VidiaPort 2000 iLED® 7 / iLED® 7 / iLED® 7 / VidiaPort 5000 VidiaPort 5000 / iLED® 7 / VidiaPort 5000 VidiaPort 2000 / iLED® 7 / VidiaPort 2000 iLED® 7 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 2000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 2000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 2000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 2000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 2000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 2000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 2000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 2000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 2000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 2000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 3000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 3000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 3000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 3000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 3000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 3000 / iLED® 7 / iLED® 7 / VidiaPort 3000 VidiaPort 5000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 5000 / iLED® 7 / iLED® 7 / VidiaPort 2000 VidiaPort 5000 / iLED® 7 / iLED® 7 / VidiaPort 3000 VidiaPort 5000 / iLED® 7 / iLED® 7 / VidiaPort 3000 VidiaPort 5000 / iLED® 7 / iLED® 7 / VidiaPort 3000 VidiaPort 5000 / iLED® 7 / iLED® 7 /	iLED® 7 trio / quad	4068310	



Original instruction manual on CD	This instruction manual can be found in PDF form on the CD enclosed with the system from Trumpf Medical. Please contact Trumpf Medical Customer Service if you need to request a replacement CD.
Keep the instruction manual with the system	For reference purposes, a printout of this instruction manual must be kept in an easily accessible location, near the system.
Copyright	<ul> <li>Notes on copyright and property rights</li> <li>All rights reserved. These instruction manual are protected by copyright law.</li> <li>Any other use than that regulated by law must be approved in writing by TRUMPF Medizin Systeme GmbH + Co. KG.</li> <li>TRUMPF Medizin Systeme GmbH + Co. KG accepts no liability for any damage arising from the non-permitted use of the information set out in these instructions by other persons or companies.</li> <li>iLED<sup>®</sup> is a registered trademark of TRUMPF Medizin Systeme GmbH + Co. KG.</li> </ul>
	Modifications and translations
Modifications to the device	Since our products are subject to continuous further development, we reserve the right to modify the form, equipment and technology of our scope of delivery.
Modifications to the instruction manual	• The content of this instruction manual is subject to change without prior notice.
Translations	<ul> <li>The German instruction manual is the original instruction manual.</li> <li>The German language version of this instruction manual shall be binding.</li> </ul>
Tansidtions	• The German language version of this instruction manual shall be binding

• The German language version of this instruction manual shall be binding with respect to translations into foreign languages.



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Structure of the safety information in this instruction



1.1

manual

#### Important notes in this instruction manual are marked with graphic symbols and signal words. Signal word DANGER In the safety information, the signal words are WARNING located in the title field with the color CAUTION background. ATTENTION They follow a specific hierarchy and, in NOTE conjunction with the warning symbol, indicate the severity of the hazard or the type of information. Warning symbols In safety information, the warning symbols are located in the title field with the colored background, to the left of the signal word. Safety information with warning symbols indicates a risk of personal injury. Follow the safety information to reduce the risk of injuries or death. Safety instructions without warning symbols indicate risk of material damage. Pictogram The pictograms in the safety information are intended to clearly depict the imminent hazard. Example: Danger of explosion 1.1.1 Identification of physical harm DANGER refers to an immediate hazard, which, if not avoided, will lead to death or severe injury. WARNING refers to a potential hazard which, if not avoided, can lead to death or severe injury. CAUTION refers to a potential hazard, which, if not avoided, can lead to minor or slight injury. 1.1.2 Warnings of damage to property **ATTENTION** refers to a potential hazard, which, if not avoided, can lead to ATTENTION damage to property. 1.1.3 Identification of additional information NOTE provides additional information and useful tips for the safe and efficient NOTE use of the device.





## **1.2** Graphic symbols used in the safety instructions

Gas explosion: warns of the ignition of explosive mixtures of gases

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



**Sudden release of spring arm:** warns of the risk of the spring arm suddenly jumping up when dismantling the lamp head/flat screen

**Lighting system crashing:** warns of the risk of the lighting system suddenly crashing due to additional loads



**Optical radiation:** warns of potential damage to the retina caused by photobiological radiation (blue light from the LEDs)



Pinch hazard: warns of the risk of catching fingers in the device

**Damage to surfaces:** warns of damage to surfaces caused by improper cleaning agents and disinfectants

- 1.3 Graphic symbols on the device
- 1.3.1 General notes

**CE conformity marking:** shows the device's conformity with the guidelines of the European Medical Device Directive (MDD)

Follow the instruction manual: refers to this instruction manual



**UL mark:** device tested by Underwriter Laboratories Inc. for use in the USA and Canada. UL/cUL classification with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, 1st Edition, 04-26-2006 and, ANSI/AAMI ES60601-1: 2005/(R) 2012 and CAN/CSA-C22.2 No. 60601-1: 2008

**HF transmitter:** the ME device contains a HF (high-frequency) transmitter emitting non-ionizing radiation



Refers to the need for the user to consult the instruction manual for important safety-related information such as warnings and precautionary measures which, for a variety of reasons, cannot be attached to the medical product itself.



**Assembly / dismantling of the safety ring:** To be performed only by Technical Customer Service. The more detailed instructions relating to the assembly / dismantling of a safety ring must be complied with.



**IP40 IP code:** Protection class of the lamp head through the housing according to EN 60529:1991+A1:2000+A2:2013

First digit "4" = protected against solid foreign bodies with a diameter of 1.0 mm and greater

Second digit "0" = no protection against water

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

#### 1.3.2 Radio identification

#### **European Union**

The Trumpf Medical Wi-fi module, the Control and the WallControl Panel comply, based on proper use, with the fundamental requirements and other relevant provisions of Directive 2014/53/EU regarding radio systems. The declaration of compliance can be requested using the contact details below.

The device is assigned to class B. It can cause interference in residential buildings. The user must take appropriate measures accordingly.

#### **National restrictions**

This device is suitable for use without restriction in homes and offices in all EU countries (and in other countries in which EU Directive 2014/53/EU applies).

Country	Restriction	Reason / comment
Bulgaria	None	For outdoor operation and for public purposes, a permit is generally required.
France	Outdoor operation is limited to 10 mW EIRP in the frequency range from 2454 - 2483.5 MHz military radio-location.	The 2.4 GHz band was redivided a few years ago in order to allow the relaxed regulation currently in place. Complete implementation occurred in 2012.
Italy	None	For operation outside proprietary premises, a permit is generally required.
Luxembourg	None	For mains feed and the provision of the service, a permit is generally required (not for the bandwidth).
Norway	Restriction must be complied with.	This sub-section does not apply to the geographical area in a radius of 20 km from the center of Ny-Ålesund.
Russian Federation	None	May only be used in buildings.



Complies with IEC 60825-1, Ed 2 (2007) and IEC 60825-1, Ed 3 Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice 50, June 24, 2007





USA

## FCC ID Trumpf Medical Wi-fi module: XF6-RS9113DB FCC ID interface converter: N6C-SDMAN

This device has been tested and complies with the thresholds for digital devices of class B according to Part 15 of the FCC provisions. These thresholds are intended to ensure adequate protection from interference with domestic use. The device generates and uses high-frequency radiation and may possibly emit high-frequency radiation. If the device is not installed and operated exactly in accordance with the instructions, radio interference may occur. It cannot be guaranteed, however, that no interference will occur with any given installation. Switching the device off and on again will determine whether it is the source of any interference to radio or TV reception. To remedy the fault, the user should then carry out one or more of the following steps:

- Realign or reposition the receiving antenna
- Increase the distance between the device and the radio or TV
- Connect the device to a socket that is not on the same circuit as the radio or TV
- Contact the dealer or an experienced radio / TV engineer

#### Canada

#### IC ID Trumpf Medical Wi-fi module: 8407A-RS9113DB

#### IC ID interface converter: 4908B-SDMAN

This device complies with the FCC regulations according to Part 15 and the license-free RSS standards from Industry Canada. Operation is subject to the following two conditions:

(1) This device must not cause any harmful interference.

(2) This device must be able to absorb receiving interference, including interference that may cause undesired operation.

#### Australia / New Zealand

In terms of electrical safety, EMC and the radio frequency spectrum, the product complies with the regulatory requirements relating to products that are destined for the Australian and New Zealand market.

#### Israel

The iLED<sup>®</sup> 7 lighting system for Israel is exclusively limited to the use of the lower 5 GHz band (5130 – 5350 MHz).

#### Taiwan

本產品符合低功率電波輻射性電機管理辦法 第十二條、第十四條等條文規定 1. 經型式認證合格之低功率射頻電機,非經許可,公司、商號或使用者均不得 擅自變更頻率、加大功率或變更原設計之特性及功能。

This device was approved in accordance with its type as a low-frequency electrical device without express permission from the authorities. The company, the business or user must not voluntarily change the frequency, increase the output or modify the functions and characteristics of the original design.

 低功率射頻電機之使用不得影響飛航安全及干擾合法通信;經發現有干擾現 象時,應立即停用,並改善至無干擾時方得繼續使用。 前項合法通信,指依電信法規定作業之無線電通信。

Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This digital Class A apparatus complies with Canadian ICES-003.





#### 低功率射頻電機須忍受合法通信或工業、科學及醫療用電波輻射性電機設備之 干擾。

The use of low-frequency electrical equipment must impair neither flight safety nor legal communication. If radio interference occurs, the use of the device must be stopped immediately and the cause of the interference remedied before use of the device may continue.

Legal communication includes radio transmission in accordance with the Telecommunications Act.

Low-frequency electrical equipment should be able to tolerate interference from installations for legal communication and from electrical equipment for industrial, commercial and medical applications.

#### Qatar

The iLED<sup>®</sup> 7 lighting system produced and configured for Qatar is limited in the production facility exclusively to the use of the 2.4 GHz band (2400 - 2435 MHz).

### Singapore

Complies with IMDA standards [N1312-17]

#### **United Arab Emirates**

TRA REGISTERED No: ER54166/17

Jordan TRC/SS/2017/101



ESD – 1714802C



TAC No. 9.405/2017

#### Japan

The mains connection cable must be used exclusively with the equipment supplied.

#### 1.4 Pictograms on the packaging



**Keep dry:** The package must be protected from moisture or high ambient humidity and must be covered with tarpaulin when outside.

**Top:** The package must be transported, handled and stored such that the arrows point upward at all times. Rolling, flipping, tilting at a severe angle or tipping are prohibited.









**Moisture limit:** Displays the permissible moisture range for the storage or transport of the package. The upper or lower limit must not be exceeded.

Atmospheric pressure limit: Displays the permissible atmospheric pressure range for the storage or transport of the package. The upper or lower limit must not be exceeded.

**Permissible temperature range:** Displays the permissible temperature range for the storage or transport of the package. The upper or lower limit must not be exceeded.

**Fragile contents:** The package is fragile. It should be handled with care and must not be dropped, tied up or similar.

**Non-sterile:** Indicates a medical product that has not undergone a sterilization procedure.

🗥 DANGER

#### 1.5 Overview of the most important safety instructions

Location requirements



Gas explosions due to anesthetics

The lighting system is not suitable for use in environments containing high concentrations of

inflammable mixtures of anesthetics with oxygen or nitrous oxide. If such high concentrations of flammable mixtures of anesthetics with oxygen or nitrous oxide occur in the device's environment, there is a risk of ignition under certain conditions. In accordance with EN ISO 11197, the hazardous area includes an area between 5 cm and 25 cm from the gas leak point.

Strong magnetic fields

The support arm systems for the lighting system should not be used near strong magnetic fields.

#### Application parts type BF / CF

No application parts of type BF or CF in accordance with IEC 60601-1 should be connected directly to the lighting system's support arm systems.

#### 



To avoid electric shock hazard, the lighting system may

**Electric shock hazard** 

be connected only to an appropriately grounded power supply with ground wires.



## Electrostatic charge balancing Complications due to charge balancing To avoid complications due to electrostatic charge balancing between metallic device parts and the patient, the user must not touch the surgical light, the Control or the Dock desk and the patient at the same time. Operations in the field of vision Damage to eyesight In the event of operations involving the patient's field of vision, high lighting intensities of the surgical lights and the blue light of the LEDs can lead to eye fatigue or even damage to the eyes: Always close the patient's eyes, cover them or protect them with e.g. goggles. • Do not use the iLED<sup>®</sup> 7 surgical light for operations involving the patient's field of vision under anesthesia with open eyes. • Do not look directly into the light aperture.

Overlapping fields of illumination of several lamp heads

#### 

Tissue damage to the patient

Overlapping fields of illumination of several lamp heads with high lighting intensities can cause tissue damage. With the early onset of tissue dehydration:

- Separate the overlapping fields of illumination of multiple lamp heads
- Reduce the lighting intensity of the lamp heads

Eye safety

## 



Impairment of vision

After prolonged direct visual contact with the sensor, eyesight may be damaged:

- Do not look directly into the sensor.
- Protect the patient's eyes the patient's eyes must be closed or protected.

The performance of operations or procedures other than those specified in this instructions manual may lead to hazardous radiation effects by the sensor.





Photobiological safety (eye safety)

The surgical light is classified in risk group 2 (medium risk) according to the IEC 62471 standard and therefore

extends beyond the "Free group". The risk to the retina from blue light (400 nm to 780 nm) occurs when the thresholds of risk group 2 relating to retinal danger are significantly exceeded by blue light.

• During operation, do not look into the lamp for a prolonged period (maximum radiation duration in the working range from 0.8 - 1.3 m = 73 s).

Lighting intensity of the lamp head

#### 

#### Failure of the LED

After failure of the tenth LED, the lamp head no longer reaches the specified lighting intensity.

- Take the lighting system out of service.
- Contact Technical Customer Service. The replacement of the bulb or repairs to the lighting system must only be carried out by Technical Customer Service.

#### Additional loads

#### **A**WARNING



Support arm system crashing

Overloading may cause the support arm system or the end device to become detached from the fixture and to fall to the ground.

• The maximum load capacity specified in the technical data must not be exceeded.

Swivel motion of the lamp head



Risk of injury due to uncontrolled swivel motion

If the spring tension of the spring arm has not been correctly adjusted, there is a risk of injury due to uncontrolled swivel motions of the spring arm.



Pinch hazard

When swiveling the light there is a risk that fingers may become trapped between the light and the cardan joint:

- When swiveling the lamp head, do not place fingers between the cardan joint and the lamp head.
- Only position the lamp head using the sterile hand grip or using the non-sterile lamp head housing.



#### Installation / replacement

#### **WARNING**

Installation only by Technical Customer Service

The iLED<sup>®</sup> 7 lighting system may only be installed by Technical Customer Service since otherwise the correct function of the iLED<sup>®</sup> 7 cannot be guaranteed.

**Replacement of components by Technical Customer Service** 

All connected components must only be replaced by Technical Customer Service.

Use / Operation

#### WARNING

Do not use the Control / WallControl Panel for findings or diagnosis

The Control /WallControl Panel is purely a display and control device.

 Do not use the Control / WallControl Panel for findings or diagnosis.

Do not use the Control over the area of the operation

During medical use, do not use the non-sterile Control over the sterile operation area, as otherwise contamination or danger of infection may result for the patient.

Only use the Control in a sterile, disposable sleeve

In a sterile environment, only use the Control in a sterile, disposable sleeve. Do not place the sterile Control on the nonsterile Dock desk.

Service, maintenance, system configuration

While in operation, no service or maintenance work, system configurations, or modifications may be carried out on the Control, WallControl Panel and Dock desk, as otherwise harm or danger to the user and patient may result.



**Check room allocation** 

Before using the Control / WallControl Panel, ensure that the Control / WallControl Panel is allocated to the correct room, since otherwise damage or danger can occur to the user and patient.

• Check the room allocation in the status bar of the TruRemote operating software. See Chapter 10.4.2.

#### Maintain visual contact

When operating devices involved in the operation, always maintain visual contact with the operation in order to recognize and prevent incorrect control actions.

#### ATTENTION

#### **Charging the Control**

To prevent damage to the Control, please note the following:

- the Control can only be charged on the Dock desk,
- and the Control must be charged on the Dock desk every 1.5 days at the latest,
- the Dock desk can only be used to charge the Control. Other devices may not be charged on the Dock desk.

#### ΝΟΤΕ

#### Booting up the system

The processing unit in the lamp head requires around one minute to start up. After this, the system is fully ready for use and operation. Basic functions such as light ON / OFF and lighting intensity, however, are available immediately.

#### Network

#### 

#### **Control network**

The Control may only be operated in a network with devices which have been explicitly approved by Trumpf Medical.

Components may only be replaced by authorized personnel

All connected components may only be replaced by Trumpf Medical personnel, or by personnel authorized or trained by Trumpf Medical.



#### Software

#### **WARNING**

Only use the original software from Trumpf Medical

Do not use any software other than the original software from Trumpf Medical, as this can impair the safety, effectiveness and functionality of the system and can therefore lead to increased risk for the user and the patient.

Do not install any other software or updates

Do not install any auxiliary or application programs or updates on the Control, as this can impair the safety, effectiveness and functionality of the system and can therefore lead to increased risk for the user and the patient.

#### Hardware

#### 

Do not damage the plastic components of the Control

Do not open or damage the bumper or display film of the Control, as otherwise there is a danger of contamination of the patient or injury to the user. Only use the Control with the bumper and in accordance with the proper use.

Malfunctions of the system or the control devices

If the Control does not work or does not work correctly, take the following steps:

- On the lamp head control element, actuate the relevant button and activate safe mode in order to interrupt communication (WLAN) with the Control.
  - The surgical light can continue being operated using the control element.
  - ALC plus, Sync, shadow management and SLC are deactivated.
  - The status LED on the control unit is off.
- To restore the radio connection via WLAN and to communicate with the Control, press the safe mode button again.
- Charge the Control on the Dock desk.

Sterile disposable sleeves

#### **WARNING**

Risk of contamination and infection of the patient

The requirements of the properties and use of a sterile disposable sleeve for the Control must be specified in the operator's hygiene guidelines.



Handling sterile, disposable sleeves

Sterile, disposable sleeves must not be damaged and must not be reused or used after the expiry of the maximum storage period.

- Replace sterile disposable sleeves after use or if they become damaged.
- Dispose of used, damaged or expired disposable sleeves.

Cleaning and disinfection

#### 



Risk of fire or explosion due to disinfectants

Flammable or explosive atmospheres may arise when handling cleaning and disinfecting agents due to the occurrence of gases, vapors or mists. The following measures

must be taken in order to avoid flammable or explosive atmospheres:

- Do not use any highly flammable alcohol-based disinfecting agents.
- Do not perform any large-scale disinfections.
- Allow hot surfaces, including inside devices, to cool before disinfecting.
- Completely disconnect the electrical installations in the room, where possible, and ensure that no switching can take place while disinfecting, especially automatically.
- After wiping with disinfectant, wait until the disinfecting agent is completely dry.

#### WARNING

Risk to the patient or danger of material damage from incorrectly used cleaning agents or disinfectants

Non-compliance with the specifications and directions in these instructions for use (see Chapter 11) can lead to risk of contamination or infection for patients or product damage. It also completely voids the warranty.

- Only use a wipe-down disinfectant to disinfect the device.
- The cloth used to clean and disinfect the device should only be damp, not wet.
- Dose cleaning agents and disinfectants such that no fluid can enter into the joints or openings of the OR lights or parts of the pendant system.
- Use surface disinfectants only in the concentration specified by the manufacturer.
- Use only disinfectants approved by the manufacturer for use on the following materials:



Polycarbonate (PC), polyamide (PA), acrylonitrile-butadienestyrene copolymer (ABS), polystyrene (PS), polyurethane (PUR), polyphenylsulfone (PPSU), polyvinyl chloride (PVC), polybutylene terephthalate (PBT), and silicones.

- In the event of increased build-up of surface disinfectant, conduct a thorough basic cleaning.
- To avoid damage to surfaces:
  - Do not use sharp, pointed or abrasive objects
  - Do not use abrasives or agents that strip away material
  - Do not use solvents, gasoline, paint thinners, or alkaline, acidic or aldehyde-containing cleaning agents
  - Do not use cleaning agents with glycol derivatives, phenols, phenol derivatives or quaternary compounds
  - Only use agents without chlorides or halides
- The operator's hygiene guidelines must be complied with.

#### Adjustments

#### 

#### Performing settings

The manufacturer guarantees the safety and proper function of the system only under the condition that settings are performed by an authorized hospital technician or by a person with comparable qualifications.

#### Dismantlement for service

#### WARNING



Sudden release of spring arm

If the lamp head / flat screen (for video display) is disassembled without first having put the spring arm in

the uppermost end stop position, the spring arm will spring up and may cause serious injuries:

• The lamp head / flat screen must therefore only be disassembled by Technical Customer Service.

#### Commissioning

#### 

Initial commissioning prior to use

Prior to use for medical operation, the system must be subjected to initial commissioning in a tested state before being handed over to the operator.

- Initial commissioning comprises the functional test and safety inspection of the complete lighting system.
- Handover must be documented by means of a declaration of acceptance.



#### 2.1 Groups of individuals

This instruction manual refers to the following groups of individuals:

- Operators
- Users
- Qualified staff

#### 2.1.1 Operators

An operator (e.g. medical office, hospital, etc.) is any individual person or legal entity that owns and operates the device or on whose behalf the device is operated.

• The operator is obliged to provide a safe device and instruct the user adequately in the operation of the device and its proper use.

#### 2.1.2 Users

Users are persons who, due to their qualifications or appropriate training by qualified staff, are entitled to operate and work with the device.

 Users are fully responsible for the safe operation of the device and for ensuring that it is only used for its proper use.

#### 2.1.3 Qualified staff

Qualified staff are authorized persons who are generally employees of the operator. They must

- have acquired their skills through professional training within the medical-technical sector
- be able to assess their job and recognize the potential hazards involved on the basis of their professional experience and instruction in the safety-relevant regulations
- be able to demonstrate the appropriate certificate for classification as qualified staff (e.g. medical technician certified by Trumpf Medical or Trumpf Medical sales staff) in countries in which jobs in the medicaltechnical field require certification.

#### 2.2 Information for operators

Procedural guidelines T

The device is designed according to state-of-the-art technology and is safe to operate.

- However, use of this appliance may still constitute a hazard. In particular, if it is used by staff without sufficient training or if not used properly and in accordance with its intended purpose.
- The device may only be operated, cleaned, disinfected and maintained by qualified staff.

#### 2.2.1 Initial commissioning

Validity

- These instruction manual are only valid after the device has been properly commissioned by the installation engineer authorized by the manufacturer.
  - A complete electrical safety check must be carried out before initial commissioning (see also Chapter 12).
  - The operator must be instructed in the operation of the lighting system according to the currently valid instruction manual.



- Prior to its first use, the device must be thoroughly cleaned and disinfected.
  - Once the device has been released for operation, the instructions in this instruction manual are binding for the user.

#### 2.2.2 Availability of the instruction manual

Duty to supply information Th

The instruction manual is an integral part of the device and must therefore be kept in a place close to the device as a ready reference for safety instructions and other important information when required.

• Please do not pass on the device to third parties without the instruction manual. Using the identity number and version number as a reference, ensure that the latest valid instruction manual is supplied with the device.

#### 2.2.3 Disclaimer of liability

Disclaimer of liability

The Trumpf Medical product warranty requires that:

- The device is used exclusively as prescribed for its proper use and is operated and maintained as stipulated in this instruction manual
- Only original spare parts and accessories authorized by Trumpf Medical are used
- No structural alterations are made to the device
- Checks and maintenance work are carried out at the specified intervals by trained and authorized qualified staff
- Initial commissioning has been carried out and the device has been released for operation by means of a declaration of acceptance

#### 2.2.4 Maintenance and Repair

Maintenance and repair work on this device or on parts thereof must be carried out by:

- Trumpf Medical customer service
- Authorized service companies trained by Trumpf Medical
- Operator service personnel that have been trained and authorized by Trumpf Medical
- After each episode of maintenance or repair, an electrical safety check must be carried out as defined in Chapter 12.

Service life

Ten years



	Axis system	len years
	Preassembly set	Ten years
	Control	Two years
	WallControl Panel	Five years
	Dock desk	Ten years
	<b>2.2.6 Date of production</b> The production date of the device can location of the device label on the dev	be found on the device label. For the ice, see Chapter 5.1.
	2.3 Delivery	
	<ul> <li>Since the scope of delivery varies from delivery paperwork to check that the c damage in transit.</li> <li>The components can be identified slip and/or the dimension sheet sp</li> </ul>	customer to customer, please use the order is complete and that there is no by the order number on the packing ecific to the order.
	2.3.1 Damage in transit	
Damage claims	Damage claims can only be asserted if immediately. In case of damage in tran including the following information, m	Trumpf Medical is notified isit or shortages, a damage report, ust be forwarded to Trumpf Medical:
Accompanying documents	<ul> <li>Damage report providing information on the damage and / or faults</li> <li>Main serial number of the device/system or serial numbers of the damaged components</li> </ul>	
	<ul> <li>Order number (as specified on the dimension sheet)</li> <li>Name and address of the custome</li> </ul>	shipping note and / or order-specific r
	• Recipient of the delivery	
Returns	<b>2.3.2 Address for returns</b> To return an item, use the original pack Returns must be sent to the following TRUMPF Medizin Systeme GmbH + Co Carl-Zeiss-Straße 7-9 07318 Saalfeld Germany	kaging. address: . KG
	2.4 Notes for users	
	The device must only be operated by p training.	persons who have had appropriate

Component

Lamp head

## 2.2.5 Service life of all components in the iLED® 7 lighting system



#### 2.4.1 Training on the device

- Training All user training must be hands-on at the device and carried out by qualified staff of the operator or the installation engineer authorized by the manufacturer.
  - On completion of the training, it must be documented that the user has understood the special operating measures required for correct use of the device for its proper use.

#### 2.4.2 Information and inspection commitment of the user

Carefully read the instruction manual prior to initial use in order to avoid potential injuries and property damage.

- The user must check that the device is fully functional and in perfect condition before it is used or rented out. See Chapter 12.1.
- The instructions in this instruction manual must be complied with when using the device.
- If you encounter specific problems not covered in sufficient detail by this instruction manual, please request the necessary information from the operator's technical service department or from Trumpf Medical.

#### 2.5 Compliance

#### 2.5.1 Marking

Compliance The manufacturer declares the compliance of this product with the fundamental requirements as defined in Appendix I to 93/42/EEC and a complete quality assurance system as detailed in Appendix VII.

CE mark: This device is a Class I medical device in accordance with the directive specified above and as defined in Appendix IX. The quality assurance system is subject to regular monitoring by the specified center in accordance with Appendix II Section 5.

- UL mark The device has been tested by Underwriter Laboratories Inc. for the USA and Canada: UL/cUL
- (NRTL region only) Classification with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, 1st Edition, 04-26-2006 and ANSI /AAMI ES60601-1: 2005/AMD1:2012 and CAN/CSA-C22.2 No. 60601-1:2014



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

#### 2.5.2 Standards and directives

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

- DIRECTIVE 93/42/EEC OF THE COUNCIL of June 14, 1993 regarding medical products
  - EN 980
  - EN 1041
  - EN 15223-1
  - EN 60601-1



- EN 60601-1-2
- EN 60601-2-41
- EN 17764
- EN 0825-1 / IEC 60825
- EN 62471 / IEC 62471
- EN 60950
- POHS DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND THE COUNCIL dated June 8, 2011 on the restriction of use of certain hazardous substances in electrical and electronic equipment
  - EN 50581 Technical documentation for the assessment of electrical and electronic equipment in relation to the restriction of hazardous substances
- Particle Participation Partial Partial Partial Participation Partial Part
  - EN 300328
  - EN 301893
  - EMC Directive, 2014/30/EU Electromagnetic compatibility (of electrical and electronic products) for electrical measurement, control and laboratory devices
    - EN 301489-1
    - EN 301489-17
  - FCC provisions as per the requirements of the FCC Provisions and Regulations set out in 47 CFR Chapter 1, Sections 2 (Edition 1-10-13) and 15 (Edition 1-10-13). The following sub-sections apply:
    - Sub-section 15

#### 2.5.3 Internationally applied standards

- UL 60601-1
- ANSI/AAMI ES60601-1
- CAN/CSA-C22.2 No. 60601-1
- IEC 60601-1:2005/AMD1:2012
- IEC 60601-1-2

#### 2.5.4 Proper use

Proper useThe device is intended for use in a patient environment and is used to<br/>illuminate an examination and surgical area on the patient with high lighting<br/>intensity in a hospital or medical practice.<br/>The working range is at a distance of between 70 and 150 cm from the wound<br/>area.Use in medical operationThe device is suitable for continuous operation.<br/>Application to the patient is not intended, but accidental contact is possible.<br/>The following, described functions are to be implemented in the device to<br/>upgrade its functionality:<br/>

The size of the field of illumination must be adjustable



• The color temperature must be adjustable and the adjustment method optimally selectable

Any use exceeding the conditions specified above shall be considered as improper use. The user or operator is exclusively responsible for any damage arising from incorrect use.

#### 2.5.5 Improper use

Improper use

- The lighting system must not be used for investigatory and diagnostic purposes.
- The lighting system must not be configured during ongoing operation.
- The Control / WallControl Panel is exclusively intended for the use of the TruRemote operating software installed by Trumpf Medical and must not be equipped with additional software or apps from third party manufacturers. Updates of the existing software are not permitted.
- The light suspension unit must not be exposed to additional loads.
- The system must not be exposed to severe shocks.

#### Restriction

• The system is not suitable for operation in explosive areas. • The system must not be used near strong magnetic fields.

The system is not suitable for use in rooms or areas with flammable mixtures of anesthetics with air, oxygen or nitrous oxide (N2O). If such high concentrations of flammable mixtures of anesthetic vapors with oxygen or nitrous oxide occur in the environment of the device, there is a risk of ignition under certain conditions. In accordance with EN ISO 11197, the hazardous area includes an area between 5 cm and 25 cm from the gas leak point.

#### 2.5.6 Application

Cleaning	The lighting system is cleaned multiple times as part of everyday operating room operations. This is most commonly done by swiveling the housing parts facing downwards to wipe and dry them.
Definition: Surgical lights	A surgical light is designed for use in operating rooms for supporting diagnosis or treatment which, in the event of interruption by light failure, does not pose any risk for the patient (EN 60601-2-41).

#### 

#### Do not interrupt the power supply

The iLED<sup>®</sup> 7 lighting system is connected to a special power supply system. An interruption to the power supply can result in an unjustifiable risk for the patient.



Definition: Surgical light system	A surgical light system consists of two or more surgical lights and is therefore failure-safe. It can be used without restriction within the scope of its correct use.	
Operation	<ul> <li>The surgical lights can be operated in two ways</li> <li>Via an integrated control element attached to each light (restricted function)</li> <li>Via a Control or WallControl Panel, each of which is equipped with a tablet unit (with pre-installed TruRemote operating software)</li> </ul>	
	<b>Control element on the lamp head</b> Key functions of the light can be controlled directly with the integrated control element.	
	Control / WallControl Panel	
	The mobile Control consists of a tablet unit with touchscreen optimized for use in operating rooms and a plastic sleeve pulled over it (bumper) as impact protection. The underside of the tablet unit features a recess which fits the Dock desk, the charging station of the Control, perfectly. The WallControl Panel comprises a tablet unit with a fixed frame for attachment to or within a wall. It must be directly connected to the power supply and does not need to be charged. The tablet unit is the surgical light's external control panel. All of the surgical light's functions can be controlled or adjusted using the TruRemote operating software.	
	<ul> <li>iLED® 7 RS 232 interface (optional)</li> <li>The iLED® 7 RS 232 interface allows third-party integrators to integrate the iLED® 7 surgical light into their system and control selected functions.</li> <li>The iLED® 7 RS 232 interface converts wire-mediated RS 232 signals into wireless TCP/IP signals. This ultimately allows the user to wirelessly adjust the settings of the iLED® 7 surgical light via the third-party system.</li> <li>A WallControl Panel is required for the integration of the iLED® 7 RS 232 interface.</li> </ul>	
	<ul> <li>For details of integrators, see the ILED® / Interface converter</li> <li>reference manual document number 55000-00029</li> </ul>	
High lighting intensity	<b>2.5.7</b> Special conditions To ensure good viewing conditions for the surgeon, the lamp head has high lighting intensities.	
Overlapping of the field of illumination	According to the laws of physics, visible light also produces heat in the operating area. If the fields of illumination of more than one lamp head overlap, high illumination levels are created, which may lead to tissue dehydration and, especially with longer periods of exposure and reduced blood circulation, to tissue damage. In case of reduced blood circulation or any symptoms of tissue dehydration, the lighting intensity must be reduced.	
Automatic distance measurement: Adaptive Light Control plus (ALC plus)	The 3D sensor used for distance measurement for the ALC plus function is classified as a laser of laser class 1 according to EN / IEC 60825-1:2007 Ed 2 and EN / IEC 60825-1:2014 Ed 3. The laser also complies with the performance standards of the US FDA with the exception of deviations that are listed in the Laser Note No. 50 dated January 24, 2007. The 3D sensor has	

the following outputs:



- Max. output 108 mW
   The output was measured with an ambient light of 200 lux on a white screen which fills the camera's field of view at a distance of 20 cm.
- Wavelength 860 nm

#### 2.6 Ambient conditions for operation and storage

Different ambient conditions apply for the operation and interim storage of the device. See Chapter 2.5.5 regarding the restriction of ambient conditions.

#### 2.6.1 Ambient conditions for operation

- Ambient temperature: +10 °C to +35 °C
- Relative humidity: 30% to 75%
- Atmospheric pressure: 700 hPa to 1060 hPa
- Operating altitude: Up to 3000 m above sea level

For integrated systems with interface converter, a maximum operating altitude of 2000 m above sea level applies.

#### 2.6.2 Ambient conditions for storage

- Ambient temperature:
  - Surgical light
     -20 °C to +40 °C

A maximum storage temperature of +60 °C applies for the lamp head.

- Relative humidity: 5% to 95%
- Atmospheric pressure: 500 hPa to 1060 hPa

#### 2.7 Combination with other medical devices

The lighting system can be equipped with medical products of other manufacturers which are approved according to IEC 60601-1. The (newly) resulting combination of medical products must be mapped according to Article 12 of Directive 93/42/EEC and its compatibility must be declared. This must be ensured by the operator.

#### 2.8 Combination with non-medical devices

- The system can be a combination of medical products and non-medical devices.
- This means that the system manufacturer must classify the combination of devices independently and subject it to a corresponding compliance assessment process as defined in Article 11 of Directive 93/42/EEC.



#### 2.9 Disposal



- The system must be disposed of at a suitable disposal point for the recycling of electrical and electronic devices in accordance with the requirements of Directive WEEE II 2012/19/EU and country-specific regulations.
- RoHS compliance
- The device complies with the requirements of standard EN 50581 and the 2011/65/EU RoHS Directive (on the restricted use of certain hazardous substances in electrical and electronic equipment).

	3.1 The lamp head
	The iLED <sup>®</sup> 7 surgical light features settings for lighting intensity, color temperature, field of illumination size, shadow management and synchronization (Sync), as well as the automatic Adaptive Light Control plus (ALC plus) function. The light can be operated using an operating element on the lamp head, on the Control Planel or via the optional starile hand grip (with SLC)
	Optionally, settings configured to switch on the light can be saved or the light can always be switched on with the last lighting situation set. These settings are defined when the lighting system is installed.
Lighting intensity	<b>Lighting intensity</b> Aside from ENDO dimming, the lighting intensity can be set from 30% to 100%. A reduction (dimming) in lighting intensity does not alter the color temperature.
ENDO dimming	The lighting intensity can be adjusted separately for each lamp head. ENDO dimming has been designed for endoscopic procedures. ENDO dimming turns the lamp head down to less than 10% lighting intensity.
Adaptive Light Control plus (ALC plus)	<b>Functions</b> ALC plus is enabled thanks to the 3D sensor and allows the targeted electrical and mechanical control of various LED groups to ensure optimal illumination of the wound area. ALC plus automatically ensures a consistent lighting intensity and higher lighting power. If the lamp head is moved during the surgery, the movement detector automatically measures the distance of the light from the wound area. This allows precise adjustment of the lighting at all times. ALC plus can be disabled in the Control's graphical user interface.
Reduced operating element Safe mode	<ul> <li>Operation</li> <li>The operating element on the lamp head allows the light to be switched on and off and the lighting intensity adjusted, see Chapter 9.</li> <li>With the Safe mode button, ALC plus, shadow management and radio communication via WLAN with the Control or WallControl Panel, for example in the event of a fault, can be interrupted. Pressing this button reboots the processing unit and enables safe mode.</li> <li>While the surgical light is in safe mode, the green LED on the operating panel is switched off.</li> <li>In safe mode, the following light parameters are set: <ul> <li>Color temperature 4500 K</li> <li>Medium field of illumination width</li> <li>Lighting intensity = step 3 = 50%</li> <li>SLC = OFF</li> <li>Sync = OFF</li> <li>ALC plus = OFF</li> <li>Shadow management = OFF</li> <li>WLAN = OFF</li> </ul> </li> <li>When safe mode is exited, the light starts with the factory or customer-specific default settings.</li> </ul>
Control / WallControl Panel	The Control / WallControl Panel allows all settings / functions to be controlled intuitively and ergonomically via a graphical user interface. See Chapter 10.


Sterile hand grip with Sterile Light Control (SLC) (optional)	Using the horizontal slider on the sterile hand grip of the light or TruVidia <sup>®</sup> Wireless camera, the lighting intensity (without Endo function), color temperature and size of the illumination field can be controlled in a sterile manner. The function can be set up by Technical Customer Service during installation.	
	Control / WallControl Panel	
Operating system	The operating system of the Control / WallControl Panel is restricted to basic functions and is optimized for the TruRemote operating software. For safety reasons, no additional software or apps from third party suppliers may be installed on the Control / WallControl Panel and no updates of existing programs may be performed.	
Device controller	The surgical light can be intuitively and ergonomically operated/controlled using the graphical user interface of the TruRemote operating software on the touchscreen of the Control / WallControl Panel.	
Graphical user interface	The TruRemote operating software features an intuitively operated graphical user interface with clearly structured function areas and distinctive icons, displays and buttons. The clear and easy to learn operation of the various functions allows an excellent level of process safety and the easy integration of all operating room staff in the operation process.	
	TruVidia® Wireless camera system (optional)	
	The optional TruVidia <sup>®</sup> Wireless camera system allows a TruVidia <sup>®</sup> Wireless video camera mounted in the center of the lamp head to be controlled. The radio-controlled TruVidia <sup>®</sup> Wireless camera system can also be controlled using the Control / WallControl Panel. See the separate instruction manual for the TruVidia <sup>®</sup> Wireless camera system (document number 55000-00030).	
	3.2 The LED illuminant	
	The lighting system is equipped with LED illuminants.	
Service life	Unlike conventional halogen or discharge lamps, LEDs are characterized by a very long life span.	
Low heat output	Another advantage of LEDs is their low heat output thanks to the lack of IR (infra-red) radiation and tissue-damaging UV (ultra-violet) radiation.	
High reliability against failure	The large number of LEDs gives the lamp head high failsafe operation. The failure of a single LED does not affect the function of the lamp head.	



The following technical terms and abbreviations are used in this instruction manual:

Арр	Abbreviation for application (TruRemote control software)
Control element	Control panel membrane at the operating lamp
Touchscreen	Touch-sensitive control screen
Control	Light, portable tablet unit with touchscreen
WallControl Panel	Tablet unit with touchscreen permanently installed on a wall
LED	Abbreviation for Light Emitting Diode
lcon	Pictogram
OP	Operation
WLAN	Abbreviation for Wireless Local Area Network
SLC	Abbreviation for Sterile Light Control
Sync	Synchronization function
IR	Abbreviation for infrared
ALC	Abbreviation for Adaptive Light Control
NRTL	National Recognized Testing Laboratory
LCH	Abbreviation for low ceiling height
#	Item / material number





## 5.1 Use of serial numbers

A lighting system is identified through its device label and serial numbers.

- The device label ① includes the specific device data
  - the manufacturer whose contact details are listed alongside
  - REF = article number
  - SN = serial number

 $^{(1)}$ 

3

-(2)

(4)

and the main serial number. The main serial number represents the order-specific identification of an entire device. The main serial number also identifies components without separate serial numbers and thus enables the delivery of suitable spare parts by Technical Customer Service.

- IP class ③
- The serial numbers (2) identify the individual components of a device.
- The production date of the device ④.
- 5.1.1 Position of the serial numbers on the ceiling-mounted version
- A: Ceiling-mounted version
- The device label ① with the main serial number on the topmost extension arm.
- The serial numbers 2 of the individual components are marked on the:
  - Ceiling pipe
  - Interface plate
  - Extension arm
  - Spring arm
  - Comfort bracket, ¼ bracket
  - Lamp head





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





#### 5.1.2 Position of the serial numbers on the mobile pedestal version

B: Mobile pedestal version

- The device label (1) with the main serial number on the side of the power pack housing.
- The serial numbers (2) of the individual components are marked on the:
  - Spring arm
  - ¼ bracket
  - Lamp head
  - Stand foot

#### Position of the sensor detection (laser) 5.1.3

C: Lamp head with Automatic Adaptive Light Control plus (ALC plus) function

• Sensor detection (3) is attached in the area of the mounting on the housing of the lamp head.







# 5.1.4 Position of the serial numbers on the Control

The device label (1) / (3) with the serial number (2) of the control is located on the back.

# 5.1.5 Position of the serial numbers on the WallControl Panel

The serial number of the WallControl Panel (5) must be looked up by technical personnel in the TruRemote operating software

# 5.1.6 Position of the serial numbers on the Dock desk

The device label 4 with the serial number of the Dock Desk is located on the underside of the housing.

#### 5.2 Scope of delivery iLED<sup>®</sup> 7

- Lamp head iLED<sup>®</sup> 7 with video camera connection and control element
- Control (welded-in tablet unit with bumper) and / or optional WallControl Panel
- Dock desk with power pack cable
- TruRemote operating software (installed on Control / WallControl Panel)
- RS 232 interface iLED® 7 (8) (optional) with
  - Device label (6)
  - Serial number 7
- Position of the RS 232 interface device label iLED<sup>®</sup> 7
   (9)
- Position of the RS 232 interface radio label iLED<sup>®</sup> 7
   10







# 6.1 Components of the iLED<sup>®</sup> 7 lighting system

The lighting system consists of the following components: Hardware

# il ED<sup>®</sup> 7 Jamp boad

- iLED<sup>®</sup> 7 lamp head 2 with video camera connection and integrated operating element 1
- External operating components
  - Control ③
  - WallControl Panel (optional) 6
- Dock desk ④ (Control charging station with power pack)
- iLED<sup>®</sup> 7 RS 232 interface (5) (optional)

#### Software

The TruRemote operating software ⑦ is used to control and adjust the surgical light.

## 6.1.1 Hardware

#### Lamp head

The iLED® 7 lamp head 2 features an integrated operating element (restricted functions), a 3D sensor for distance measurement and a connection for a TruVidia® Wireless camera system. The lamp head 2 can be mounted with or without a comfort bracket and ¼ bracket onto various support arm systems as a

- ceiling-mounted version or
- mobile pedestal version

#### Dock desk

The Dock desk ④ is placed in the non-sterile area and is used as a storage location and charging station for the non-sterile Control ③. The Control is placed exactly onto the shape of the Dock desk and is then charged automatically.

It is impossible to overcharge the Control.

The Dock desk is connected to the hospital's power supply via a power pack.

#### Control

The Control ③ comprises a welded-in tablet unit, over which a plastic sleeve (bumper) is pulled as impact protection. The underside of the tablet unit fits precisely onto the Dock desk ④, on which the high-performance batteries can be wirelessly charged after they are placed on it. It is impossible to overcharge the Control. The Control ③ has a high-resolution touchscreen ③.



The tablet unit and the bumper can be disinfected but not sterilized.

#### WallControl Panel

The WallControl Panel (6) comprises a tablet unit with a high-resolution touchscreen, which is built into a sturdy frame. It is either secured with the frame onto the wall or integrated into a recess in the wall. The WallControl Panel is directly connected to the hospital's power supply and does not need to be charged. The WallControl Panel (6) can be disinfected, but not sterilized. See Chapter 11.5.

#### 6.1.2 TruRemote operating software

All of the functions and settings can be operated / adjusted using the graphical user interface (GUI) of the TruRemote operating software ⑦ on the Control / WallControl Panel.







## 6.2 Ceiling-mounted version

# 6.2.1 Ceiling-mounted version designs

The lighting system is available in various designs as a ceiling-mounted version: A: Surgical light as a single light on spring arm AC 2000.

**B**: Surgical light system in combination with multiple lamp heads on spring arm AC 2000.

#### 6.2.2 Components of the ceilingmounted version

The lighting system comprises:

- Ceiling paneling (1)
- Ceiling pipe (2)
- Extension arm ③
- Spring arm AC 2000 ④
- Comfort bracket and ¼ bracket (5)
- iLED<sup>®</sup> 7 lamp head 6

# 6.2.3 Optional camera on the lamp head

The lamp head can be equipped with an optional camera ⑦ (see TruVidia<sup>®</sup> Wireless camera system instructions for use).





# 6.2.4 Rotational / swivel range of the ceiling-mounted version

The horizontally rotating extension arm (2), together with the horizontally and vertically adjustable spring arm (3), allows stable positioning of the lamp head (6) with the support arm system's range of action. The comfort bracket (4) and ¼ bracket (5) allow precise alignment of the lamp head with the wound area.

Provided that there is sufficient distance to adjacent walls or objects, the following rotating / swiveling motions can be carried out at the articulations with the support arms.

## Spring arm type AC 2000

- Articulation A extension arm (2) on the ceiling pipe (1): Full horizontal rotational movement > 360°
- Articulation B spring arm type AC 2000 ③ on the extension arm
   ②:
  - Horizontal rotational movement
     > 360°
  - Vertical swivel movement in the range from +45° to -50°
- Articulation **C** comfort bracket ④ on spring arm AC 2000 ③:
  - Full horizontal rotational movement > 360°
- Articulation **D** comfort bracket ④ on ¼ bracket ⑤:
  - Full vertical rotational movement
     > 360°
- Articulation E lamp head 6 on ¼ bracket 5:
  - Full vertical rotational movement > 360°





#### Spring arm type AC 2000 NRH

- Articulation A extension arm (2) on the ceiling pipe (1):
  - Full horizontal rotational movement > 360°
- Articulation B spring arm type
   AC 2000 NRT ③ on the extension arm ②:
  - Full horizontal rotational movement > 360°
  - Vertical swivel movement in the range from +30° to -45°
- Articulation D ¼ bracket (5) on spring arm type AC 2000 NRH (3):
  - Full vertical rotational movement
     > 360°
- Articulation E lamp head (6) on ¼ bracket (5):
  - Full vertical rotational movement
     > 360°

The swivel ranges of the support arms can be adjusted by the technical personnel, see Chapter 13.3.





### 6.3 Mobile pedestal version

# 6.3.1 Designs of the mobile pedestal version

The mobile pedestal version is designed as a single light and equipped with an AC 2000 NRH spring arm.

#### NOTE

The mobile pedestal version of the iLED<sup>®</sup> 7 is used as a single light for the local illumination of an examination or operation area on the patient. See 2.5.4.

# 6.3.2 Components of the mobile pedestal version

The mobile pedestal version comprises:

- iLED<sup>®</sup> 7 lamp head ①
- ¼ bracket (2)
- AC 2000 NRH spring arm (3)
- Stand rod ④
- Power pack housing (5) with mains cable (10) (the power pack housing (5) contains the components of the electrical supply)
- Stand foot (13) with 4 casters (11) (2 of which have a locking mechanism (12))

# 6.3.3 Power supply to the mobile pedestal version

The power supply to the mobile pedestal version is established at the power pack housing (5):

- Through the mains cable with the IEC plug 7 for connection to the IEC socket 8 on the underside of the power pack housing
   and
- with the shockproof connector (9) for connection to a mains power socket
- Switch the power pack on and off at the ON / OFF switch 6 on the underside of the power pack housing

If the power pack is switched on, the light is set to standby.







### 6.3.4 Rotational / swivel movements of the mobile pedestal version

The mobile stand foot (6) ensures unlimited mobility. The horizontally and vertically adjustable AC 2000 NRH spring arm (low room height) (4) on the stand rod (5) allows stable positioning of the lamp head (2) with the stand's range of action. The rotational joints (1) / (3) on the ¼ bracket allow precise alignment of the lamp head (2) with the wound area.

Provided that there is sufficient distance to adjacent walls or objects, the following rotating / swiveling motions can be carried out at the articulations:

- A spring arm ④ on the stand rod ⑤:
  - Horizontal rotational movement in the range from +10° to -10°
  - Vertical swivel movement in the range from +30° to -45°
- B ¼ bracket ③ on the spring arm
  ④: Full vertical rotational movement
  > 360°
- C lamp head 2 on the ¼ bracket
   (1): Full vertical rotational movement
   > 360°





#### 6.4 Non-sterile positioning of the lamp head

The lamp head can be positioned in a nonsterile manner via the housing (1) and at the brackets (2).

In order not to impair the function of the 3D sensor (3), this is not suitable as a touchpoint for repositioning.

# 6.5 Sterile positioning of the lamp head

The lamp head (2) can be positioned in a sterile manner using sterile hand grips:

- Sterile single-use hand grip
- Sterile standard hand grip (3)
- Optional sterile hand grip with horizontal slider ④ and the Sterile Light Control (SLC) function

# 6.6 Non-sterile operation on the operating element

The following functions can be set on the non-sterile operating element (1) on the lamp head (2):

- Surgical light on / off (5)
- Lighting intensity (6)
- Safe mode (7)

## On / Off

Switch for switching the surgical light on and off.

#### Lighting intensity

The lighting intensity (6) of the lamp head can be adjusted using 5 levels:

- ENDO
- 30%
- 50%
- 80%
- 100%

#### Radio connection / safe mode

The light is set to the default settings (color temperature 4500 K, medium field of illumination width, lighting intensity level 3 / 50%), the ALC plus, Sync, shadow



management and SLC functions are deactivated and the PC is restarted.

The status LED lights up once the surgical light is in normal operating mode. In safe mode, the status LED does not light up.

#### 6.6.1 States of the operating element

The operating interface can have the following states:

- Light is off, no power = light is switched off at the main switch ①
- Light is in standby mode and in safe mode = light is off (2)
- Light is on, but is not connected to the Control (external control) (3) (the LED of the radio connection / safe mode button is off)
- Light is on, is shining and can connect to the Control (external control) ④

# 6.7 Non-sterile operation with TruRemote operating software

The TruRemote operating software, which is installed on the external Control and WallControl Panel operating units, contains the graphical user interface for the control of

- up to three iLED<sup>®</sup> 7 lights
- a TruVidia<sup>®</sup> Wireless video camera in one operating room. The control of the TruVidia<sup>®</sup> Wireless video camera is described in a separate instruction manual.

The following functions are available:

- Setting the setting ranges of one surgical light on one operating screen
- Setting the setting ranges of all surgical lights on one operating screen (one-click screen)
- Switch all lights on or off simultaneously and set them to the ENDO lighting intensity
- Synchronize all lights to the settings of the light currently being used (Sync)

The scope of the synchronization function can be set by the hospital technician, together with activation of the one-click screen. See Chapter 10.4.

Figure 13







#### 6.8 Control sequence

The Control / WallControl Panel is secondary in priority to the operating element, i.e. if an operating element and the Control / WallControl Panel are operated simultaneously, only the control inputs from the operating element will be actioned.

Several Controls and WallControl Panels can be used in a single room. If a device is operated with two Control / WallControl Panels simultaneously, only the most recent control input is executed.

Any change to the settings of the devices, regardless of whether this is made with the Control / WallControl Panel or directly on an operating element, is simultaneously displayed on the corresponding device control screen of the Control / WallControl Panel.

The change is displayed in both the Information area as well as in the image of the device and in the corresponding control areas or operating options. See Chapter 10.4.3.

The user always sees the current setting of the surgical light on the Control / WallControl Panel if the corresponding control screen is open.

## 6.9 Sterile operation with the hand grip

One of the following functions can be set in a sterile manner with simple finger movements on the optional sterile hand grip with horizontal slider ④ and Sterile Light Control (SLC):

- Lighting intensity (other than Endo setting)
- Color temperature
- Field of illumination size

The functions that can be operated are defined during the commissioning stage.

#### 6.9.1 Sterile Light Control (SLC), optional use

In the area below the collar of the sterile hand grip (2) is a touch sensor (3), with which the lighting intensity can be controlled with simple finger movements (4). To allow precise control, only swipe one finger over the surface of the sensor. Contact with two fingers simultaneously or grasping the grip may result in malfunction.



#### NOTE

Assignment of the hand grip

At the customer's request, the functions can also be assigned differently.

Safe mode

In safe mode, SLC is disabled.





## 7.1 Checking the lighting system

Each lighting system must be subjected to a function check before use or at least once a week, and to a visual inspection by the operator's technical personnel.

## **A**WARNING

Risk of contamination and infection of the patient

Loose or damaged parts are at risk of falling into wounds. To ensure patient safety, the lighting system components must be checked for the following points prior to each use:

- Loose parts on the comfort bracket, ¼ bracket ① or on the lamp head
- Visible damage, particularly on the:
  - Cover panels (2)

3 (5)

4

- Cover plates ③ of the internal and external LED ring
- 3D sensor (5)
- Operating element 6
- Sterile hand grips ④
- Secure positioning of the sterile hand grips ④

## **Regular function check**

Before every use of the surgical light, check its function and the accidental activation of the safe mode button (6), since otherwise full functionality will not be available.



Electric shock hazard

There is a risk of electric shock when in contact



with damaged electrical components of the mobile pedestal version:

- If the plugs ⑦ / ⑧ or mains cables ⑨ are damaged, do not connect the stand to the power supply.
- If the damage mentioned above or further damage occurs, the light is no longer safe to operate:
  - Label the lighting system as FAULTY!
  - Contact Technical Customer Service.

#### Strong magnetic fields

The support arm systems for the lighting system should not be used near strong magnetic fields.

## 7.2 Positioning the lighting system

Positioning the lighting system is safe and reliable. Despite this, pinching injuries can occur when the lighting system is being positioned.

## 



Pinch hazard When the lamp head is being

swiveled, the distance between the two brackets or the lower bracket and the lamp head reduces:

- When swiveling the lamp head, do not place fingers between the comfort bracket
  1) and the ¼ bracket 2) or between the ¼ bracket 2) and the lamp head 3.
- For sterile positioning of the lamp head, only touch the lamp head at the sterilizable hand grip (4).

Figure 16







# 7.2.1 Risk of collision while positioning

The lighting system features impactresistant housing parts and surface coatings. Despite this, collisions can cause damage to the lighting system.

### ATTENTION

#### Damage to the lamp head

The lamp head's swivel range can be restricted by other components or adjacent walls. A collision involving the support arms or lamp head can result in damage:

- Avoid collisions with other objects or adjacent walls.
- Before adjusting the height, check that there is sufficient ceiling clearance and ensure that there are no other objects positioned above the lamp head.
- 7.2.2 Positioning the ceilingmounted version

#### Single light ceiling-mounted version A: Surgical light as a single light with a lamp head on the AC 2000 spring arm:

 The best possible mobility of the support arm is ensured by a "V" arrangement.

# Lighting system ceiling-mounted version

**B:** Surgical lighting AC 2000 or AC 2000 NRH.

 The best possible mobility of the support arms is ensured by an "M" arrangement.



# 2 3 (4) (5) 6 ହ

#### 7.2.3 Taking the ceiling-mounted version out of service

- 1. Disconnect the lighting system from the power by switching off the main switch in the operating room.
  - The lighting system is disconnected from the mains.

#### 7.3 Commissioning the mobile pedestal version

#### 7.3.1 Positioning the mobile pedestal version

The mobile pedestal version is well secured against tilting. Despite this, the following basic measures must be taken into consideration when positioning the mobile pedestal version.

## **ATTENTION**

## Tipping of the stand

The safety of the mobile pedestal version against tipping can be endangered by rolling over objects on the floor, uneven flooring or mains cables:

- Always move the pedestal with the lamp head pointing in the direction of travel to its place of use.
- Do not roll over any objects lying on the floor, uneven flooring or mains cables.
- To move the pedestal, disconnect the mains cable plug from the socket and coil the mains cable (4) on the power pack housing (5).

When the casters (7) are locked, any excess force on the spring arm or lamp head can cause the pedestal to tip over:

- Avoid strong leverage forces on the spring arm or lamp head.
- Do not attach any additional loads to the spring arm.

# NOTE

Locking the pedestal foot

2 of the 4 casters (7) can be fixed in position to lock the pedestal foot (6).

• To engage the locking mechanism (8), push down on the two front casters (7).

Figure 18



• To release the locking mechanism (8), push the two front casters (7) upwards.

### 7.3.2 Positioning the pedestal

- 1. Release the locks on the front two casters.
- 2. Grip the pedestal on the stand rod (3), hold the spring arm in place and move to the place of use with the lamp head (1) facing forwards.
  - If there are steps, uneven flooring etc., keep a particularly firm grip of the pedestal and spring arm / surgical light and carefully overcome the obstacle.
- 3. After positioning the mobile pedestal version, lock the brakes on the two front casters.
- Position the lamp head ① using the sterile hand grip at a working distance of 70 to 150 cm from the wound area.
- 5. Connect the mobile pedestal version to the mains power supply.
- 6. Align the lamp head ① with the wound area using the housing.







# 7.3.3 Connecting the mobile pedestal version to the mains power supply

The mobile pedestal version is supplied with power via a mains cable 6 with an IEC plug 3 and an earthed plug 5.

## WARNING



Electric shock hazard

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

- If the plugs ③ / ⑤ or mains cables ⑥ are damaged, do not connect the lighting system to the mains power supply.
- Label the device as FAULTY and notify Technical Customer Service.

#### Earthing the socket

Electrical earthing reduces the risk of electric shock in the event of an electrical short circuit:

- The mobile pedestal version (protection class I) may only be connected to a properly earthed protective contact socket.
- 1. Check that the mains voltage matches the details specified on the device label. If in doubt, ask the responsible power supply company or a qualified electrician.
- 2. Route the mains cable (6) so that no trip hazards can occur and no strain forces can impact on the cable.
- 3. Connect the IEC plug (3) to the socket (4) on the underside of the power pack housing (1).
- Connect the mains plug (6) to a correctly installed and earthed protective contact socket.
- 5. Switch on the power pack using the ON / OFF switch
  (2) on the power pack housing, i.e. by moving it to position I.
- 6. Switch on the lamp head. See Chapter 9.1.





# 7.3.4 Taking the mobile pedestal version out of service

- Disconnect the mobile pedestal version from the power supply by switching off the ON / OFF switch on the underside of the power pack housing 2, i.e. by moving it to position 0.
- 2. Disconnect the mains cable (1) from the earthed socket.
  - The mobile lighting system is switched off.
- 3. Coil the mains cable ① around the power pack housing ②.
- 4. Park the mobile pedestal version in a storage location with suitable ambient conditions (see Chapter 2.6.2).
- Fix the front two casters (3) in position with the locking mechanism (4).





#### 7.4 Dock desk

## 7.4.1 Selecting the location of the Dock desk

The Dock desk (1) must

- stand on a straight, level surface
- stand in a location in which neither the Dock desk

   nor the Control lying on it can inadvertently be knocked down.

#### ATTENTION

Do not operate the non-sterile Dock desk in the sterile operating area.

1. Set up the Dock desk (1) in a suitable location.

# 7.4.2 Connecting the Dock desk to the power supply

The Dock desk (1) is connected to the hospital's power supply via a power pack. The power pack is equipped with a special flanged plug (2) for connection to the Dock desk (1) and a power pack with a plug for connection to a socket.

- 1. Plug the flanged plug (2) into the corresponding socket on the Dock desk (1) according to the white marking.
- 2. Thread the mains cable ④ into the three cable holders ③ and guide it out of the cable opening ⑤ on the Dock desk ①.
- 3. Plug the mains unit adapter into a power socket.

## **WARNING**

Testing the components of the device

Contact with live device components may lead to fatal electric shock.

- Check plug and power cable for damage prior to connection to the mains power supply.
- Do not connect damaged plugs or cables to the mains.





## **WARNING**

Checking the mains power supply

- Before connecting to the mains power supply, check that the voltage values of the power supply correspond with the information shown on the device label of the Dock desk.
- If the voltage (V) and maximum current (A) information are not the same, the mains unit must not be connected to the power supply.

#### 7.4.3 Replacing the Dock desk power pack

- 1. Pull the mains unit adapter out of the power socket.
- Unthread the mains cable ④ from the cable opening ⑤ and the three cable holders ③.
- 3. Pull the flanged plug 2 out of the socket on the Dock desk 1.
- 4. Clearly label the power pack (e.g. "Faulty") and take it out of service.
- 5. Connect a new power pack.





## 7.5 Control / WallControl Panel

# 7.5.1 Removing bumpers / putting bumpers on the Control

#### NOTE

The bumper is a wear part with a maximum service life of six months.

 Bumpers must be replaced when damaged or after their service life has expired.

#### A: Removing the bumper

- At one corner ①, pull the bumper ③ diagonally outwards and downwards over the corner of the welded-in tablet unit ②.
- Pull down the adjacent corner of the bumper (3) diagonally outwards over the corner of the welded-in tablet unit (2).
- Pull down another corner of the bumper ③ diagonally outwards over the corner of the weldedin tablet unit ② and remove the tablet unit ② from the bumper ③.

#### B: Putting on the bumper

- 1. Slide the welded-in tablet unit (2) from above into one corner (4) of the bumper (3).
- 2. Slip the edge of the adjacent corner of the bumper
  ③ over the corresponding corner of the tablet unit
  ②.
- Slip the corners of the bumper ③ one after the other over the corresponding corners of the tablet unit ②.
- 4. Align the bumper ③ so that it sits perfectly on the tablet unit ②.





#### 7.5.2 Charging the Control

The underside (3) of the Control (1) fits the Dock desk (4) perfectly.

- 1. Place the Control (1) on the Dock desk (4).
  - A signal sounds and the Control 1 is charged automatically.

#### NOTE

#### Use of the Control while charging

The Control can also be used while charging, i.e. while it is on the Dock desk.

#### 7.5.3 Switching the Control On / Off

To switch off, press and hold the On / Off switch (2) until the slider with the red switch-off sign is displayed. Push the slider control to the right.

To switch on, press and hold the On / Off switch (2) until the Apple logo is displayed. A few seconds later, the Unlock screen (6) appears.

#### **Control standby**

Briefly pressing the On / Off switch ② sets the Control / WallControl Panel to standby.

#### Unlocking the Control / WallControl Panel

After switching on / activating, the Control (1) / WallControl Panel (5) must be unlocked before the TruRemote operating software can be started. To do this, move the Unlock slider (7) to the right.

# This function of the Control / WallControl Panel cannot be switched off!

#### **Energy-saving mode**

The WallControl Panel (5) darkens after around one to two minutes if the screen is not used. To reactivate the display, touch the touchscreen.

To operate the Control / WallControl Panel using the TruRemote operating software, see Chapter 10.



#### NOTE

#### **Storing the Control**

Place the non-sterile Control on the Dock desk in the non-sterile area.

Use of the Control while charging

The Control can be used while charging, i.e. while it is on the Dock desk.

The Control is not responding

If the Control has switched off and cannot be activated, the batteries may be discharged. Charge the Control on the Dock desk. After a few minutes, the Control will restart automatically.

#### ATTENTION

**Charging the Control** 

To prevent damage to the Control, please note the following:

- The Control can only be charged on the Dock desk
- The Control must be charged on the Dock desk every 1.5 days at the latest.

#### **Operating safety**

For safety reasons, check the components of the Control for the following prior to every use:

- The Dock desk is secure
- The Control is adequately charged
- Visible damage, especially abrasion of the plastic surfaces or loose parts
- Correct function of the operating unit including the TruRemote operating software

#### 7.6 Inspections

#### 7.6.1 Before commissioning

Repeat electrical inspection and function test

Before commissioning, the first electrical safety inspection as described in Chapter 12 must be performed and the hardware and software must be tested to make sure they are functioning properly.

Follow the safety information

The safety information in Chapter 1 must be followed for the safe use of the Control / WallControl Panel and the Dock desk.



## 7.7 Handing over of the organization system

Handover and training

After checking the installation, the lighting system is handed over to the operator's responsible operating personnel through hands-on training on the system's devices. After training has been completed, it must be documented that the operating personnel understand the operation of the system in line with its proper use. See Chapter 2.5.4.



	8.1	Introduction
	Variou lightir • Pr	us steps must be carried out before and after every use of the surgical og system. These include: rescribed steps
	• Us	ser-specific configuration
	8.2	Work rules
Follow the safety information	For th patier and co	e safe operation of the lighting system and to protect yourself and its from harm, the safety information set out in Chapter 1 must be read omplied with whenever the lighting system is used.
	8.3	Prescribed steps
	Befor	e or after an operation
Visual inspection for damage	1. Cł fo	neck the Control, the bumper and the Dock desk (incl. the power pack) r damage.
	-	Dispose of any damaged bumpers and put on new ones.
	-	Label any damaged tablet units or Dock desks, notify Technical
		Customer Service and obtain replacements.
Cleaning and disinfection	2. Se	e Chapter 11
Charging the Control	3. Pl	ace the Control on the Dock desk and charge it fully.
	Befor	e every operation
	1. Ao iLl	ctivate the Control / WallControl Panel and operating page of the ED® 7 TruRemote operating software.
Function test	2. Cł	neck the function of the Control / WallControl Panel.
	3. Cł so	neck the function of all operating pages of the TruRemote operating ftware.
	4. Cł	neck the lighting system:
	-	Function test
	-	Visual inspection
Troubleshooting	5. In	case of malfunctions:
	-	Check the room allocation in the status bar.
	-	Charge the Control.
		Awarning

Risk of contamination and infection of the patient

Loose or damaged parts are at risk of falling into wounds. To ensure patient safety, the lighting system components must be checked for the following points prior to each use:

- Loose parts in the lamp head
- Visible damage, particularly on the cover plates of the lamp head and on the sterilizable hand grip
- The sterilizable hand grip is securely in place



Do not use damaged Controls in medical settings

- Take the Control out of service.
- Do not position a non-sterile Control over the sterile operation area during medical use.
- Replace damaged devices or parts (bumpers, Dock desk or power pack/cable) immediately.

#### **Operating safety**

For safety reasons, check the components of the Control for the following prior to every use:

- The Dock desk is secure
- The Control is adequately charged
- Visible damage, especially abrasion of the plastic surfaces or loose parts



**Electric shock hazard** 

There is a risk of electric shock when in contact with damaged electrical components of the mobile pedestal

version:

- If the plugs or mains cable are damaged, the lighting system must not be connected to the power supply.
- Take the device out of service and label it FAULTY.

Taking the lighting system out of operation

If functional defects or damage occur that impair the operational safety of the lighting system, the device must be taken out of service:

- Disconnect the lighting system from the power supply at the master switch or withdraw the grounding plug.
- Secure the master switch or grounding plug against unintentional switch-on / plugging.
- Label the lighting system as FAULTY!
- Contact Technical Customer Service.

#### WARNING



Eye injuries caused by excessive lighting intensity

During operations near the patient's field of vision, high lighting intensity settings on the lamp head can damage the patient's eyesight:

- Protect the patient's eyes (e.g. with safety goggles).
- Do not look directly into the light aperture.





## 

Impairment of vision

After prolonged direct visual contact with the sensor, the eyesight may be damaged:

- Do not look directly into the sensor.
- Protect the patient's eyes the patient's eyes must be closed or protected.
- The performance of operations or procedures other than those specified in this instructions manual may lead to hazardous radiation effects by the sensor.

### **WARNING**

Complications due to charge balancing

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







## 8.4 User-specific configuration

# 8.4.1 Coupling the grip adapter / camera

- Slide the locking device of the bayonet lock downwards into position (1) so that the three shut-off openings (12) of the base plate (13) are released.
- 2. Align the grip adapter camera ④ /
  ⑥ or camera ③ so that the arrangement of the three bayonet pins ⑨ and the two centering pins ⑪ of the mount ② are aligned with the shut-off openings ⑫ in the base plate ③ of the lamp head ① (alignment of the camera plug connector then also matches up).
- Connect the grip adapter (4) / (6) or camera (3) to the mount (2) on the lamp head (1).
  - To secure it in place, slide the locking device of the bayonet lock upwards into position E so that the two red marking dots align.



#### ATTENTION

Check the secure position of the grip adapter / camera

After locking the bayonet lock, make sure to check that the grip adapter / camera is securely in place on the mount.

Only use the grip adapter / camera with the sterile hand grip!

#### Grip adapter only:

- 4. Slide the cover (metal ring) (8) onto the grip adapter (4) / (6) and the mount (2) of the lamp head (1).
  - Ensure that the plastic catch (5) on the mount
     (2) is correctly engaged in the securing hole (7) on the cover (8).
- Push the sterile hand grip (18) onto the camera (16) so that the locking lever (15) of the camera (16) audibly engages in the securing hole (17) of the hand grip (9).
- 6. If necessary, adjust the braking force on the spring arm with the help of the operator's technical personnel. See Chapter 13.5.







# 8.4.2 Decoupling the grip adapter / camera

- Before removing the grip adapter (18)
   / camera (16), remove the sterile hand grip (see Chapter 8.4.4).
- Press the locking lever (15) of the grip adapter (18) / camera (16) in and remove the cover / sterile hand grip from the camera.

## ATTENTION

#### **Decoupling procedure**

Do not decouple the grip adapter, camera or sterilizable hand grip during an operation, during ongoing use or in the area of the operation.

#### Grip adapter only:

Press the plastic catch (5) on the mount (2) in and pull the cover (8) off the hand grip (4) / (6).

### Grip adapter and camera:

- 4. Hold the lamp head (1) still.
- 5. Slide the bayonet lock downwards into position (1) so that the three shut-off openings (2) on the base plate (3) are released.
- 6. Remove the grip adapter (4) / (6) or camera (3) from the mount (2) on the lamp head (1).

## Camera only:

- 7. Carefully set down the camera ③.
- If necessary, adjust the braking force on the spring arm with the help of the operator's technical personnel. See Chapter 13.5.

## 

## Short circuit

If liquids come into contact with the camera connection, the short circuit will switch the lamp head or power pack off.




The camera connection must always be covered by a camera or grip adapter.

- 8.4.3 Fitting the sterile hand grip (camera / grip adapter)
- Slide the standard sterile hand grip

   or Sterile Light Control (SLC) hand grip
   onto the camera or slide the grip adapter
   / 5 so that the locking lever
   / 6 of the camera / grip adapter audibly engages in the hand grip's securing hole
   / 7.
- 2. Check that the sterile hand grip is securely in place.
- 8.4.4 Removing the sterile hand grip (camera / grip adapter)

Push the locking lever (2) / (6) of the camera / grip adapter in and pull off the hand grip (4) / (8).





- 9.1 Switching the lamp head on / off
- 9.1.1 Putting the power supply in standby mode

### **Ceiling-mounted version**

- 1. Switch on the main switch in the operating room.
  - The power supply to the lighting system is set to standby.
  - The LED 1 next to button 2 ON / OFF lights up.

### Mobile pedestal version

- 1. Connect the mains cable to the hospital's power supply.
- 2. Switch on the power pack by moving the switch to position I (see Chapter 7.3.3).
  - The power supply to the mobile lighting system is set to standby.

### 9.1.2 Switching on the lamp head

- Press button (2) ON / OFF on the operating element (3) of the lamp head (4).
  - The light illuminates with the default setting or the last lighting intensity set, depending on which option was set during commissioning by Technical Customer Service.
  - The LED lighting intensity button

     next to button
     ON / OFF and LED
     light up.

### 9.1.3 Switching the lamp head off

- 1. Press the ② ON / OFF button.
  - The light goes off.
  - ► LED ① lights up.



9.1.4

### system

**Disconnecting the lighting** 

### **Ceiling-mounted version**

- 1. Switch off the main switch in the operating room.
  - The lighting system is disconnected from the mains. No LEDs remain lit up on the operating element.

### Mobile pedestal version

- Switch off the power pack by moving the switch to position **0** (see Chapter 7.3.4).
- 2. Disconnect the mains cable from the earthed socket.
  - The mobile lighting system is switched off.

## 9.2 Adjusting the lighting intensity

### 

High lighting intensity with overlapping fields of illumination

When working with overlapping fields of illumination from multiple lamp heads, high levels of intensity can accelerate eye fatigue and tissue dehydration.

• Reduce the lighting intensity of the lamp heads.

The lighting intensity of the lamp head can be adjusted using 5 levels:

• ENDO - 30 - 50 - 80 - 100%

### Increase the lighting intensity:

- Press button (3) on the operating element (4) until the required lighting intensity is achieved.
  - With each press, the corresponding LED 2 of the current level set lights up.

### Reduce the lighting intensity:

- Press button 1 on the operating element 4 until the required lighting intensity is achieved.
  - With each press, the

Figure 30







corresponding LED ② of the current level set lights up.

## 9.3 Activating and deactivating the radio connection / safe mode

- To interrupt the connection with the Control, for example in the event of a malfunction, press button ① for three seconds.
  - ▶ LED ② goes out.
- 2. To restore the connection with the Control, press button (1) again.
  - ► LED (2) lights up.
  - The light can again be operating using the Control.

### ΝΟΤΕ

### Effects of safe mode

Safe mode disconnects the communication connection (WLAN) to the Control and restarts the internal processing unit. Shadow management, ALC plus, Sync and SLC functions are disabled and the light is switched to its default settings. Shadow management, ALC plus, Sync and SLC are reactivated when safe mode is disabled, and the radio connection to the Control is restored.





## 9.3.1 Adjusting the lighting intensity in a sterile manner with the Sterile Light Control (SLC)

Below the collar (1) of the sterile hand grip (2) is a touch sensor (3), with which the preset function, e.g. lighting intensity, can be controlled by simple finger movements (4).

### Increase the lighting intensity:

1. On the horizontal slider (3), swipe a finger (4) from left to right.

### Reduce the lighting intensity:

2. On the horizontal slider (3), swipe a finger (4) from right to left.

### 9.4 Light functions

The light functions described below can only be set using the TruRemote operating software. See Chapter 10.7.

### 9.4.1 Adaptive Light Control plus (ALC plus)

The ALC plus function allows lighting intensity to be automatically adjusted when the position of the lamp head relative to the wound area changes. ALC plus allows optimum focusing of the light on the wound surface and therefore ensures optimized illumination of the wound area.

If the lamp head is repositioned during surgery, the distance of the lamp head to the wound area is automatically determined and the field of illumination and lighting intensity are adapted / optimized accordingly. To set the ALC plus function.

### 9.4.2 Diameter of the field of illumination

For distances of 0.8 to 1.3 meters commonly used in everyday surgical settings, three constant field of illumination sizes (narrow - medium - wide) are available. If the working distance to the operating field is changed manually, the iLED<sup>®</sup> 7 automatically refocuses on the set field of illumination.

When a narrow field of illumination is set, the inner, fixed LED modules are switched off.

### 9.4.3 Shadow management

The sensor-controlled assistance system of the iLED<sup>®</sup> 7 ensures consistent lighting conditions without disruptive shadows, even if the surgeon is working directly under the surgical light. It detects obstacles between the light and wound area and activates or deactivates corresponding LED modules. Even without any manually adjusted settings, the wound area is always illuminated as effectively as possible.

### 9.4.4 Setting the color temperature



The user can make contrasts as visible as possible by changing the color temperature. At the same time, a higher color temperature allows low-fatigue working and supports the ability to concentrate, e.g. during operations carried out at night.

There are four color temperatures available (3500 - 4000 - 4500 and 5000 K).

### 9.4.5 Lamp head synchronization (Sync)

When this function is activated, the following situations are set synchronously for all lamp heads in the system (max. three lamp heads):

- Lighting intensity
- Field of illumination size
- Color temperature
- ALC plus status
- Shadow management status
- On / Off

The choice of synchronized functions can be set by Technical Customer Service.



### 10.1 Introduction

The following functions are available:

- Setting the setting ranges of one surgical light on one operating screen
- Setting the setting ranges of all surgical lights on one operating screen (one-click screen)
- Switch all lights on or off simultaneously and set them to the Endo lighting intensity
- Synchronize all lights to the settings of the light currently being used (Sync)

The scope of the synchronization function can be set by the hospital technician, together with activation of the one-click screen. See Chapter 10.3.

### 10.1.1 Conditions for operation

A device can only be operated if it is switched on and connected to the power supply. In addition, it must be licensed for the operating room, recognized by the system and must be located in the same operating room as the Control / WallControl Panel that is intended for the control of the device. The radio connection must also be active and of sufficient strength.

**10.2 Operating the Control / WallControl Panel** Installation / replacement

### **WARNING**

### Check room allocation

Before using the Control / WallControl Panel, ensure that the Control / WallControl Panel is allocated to the correct room, since otherwise damage or danger can occur to the user and patient.

• Check the room allocation in the status bar of the TruRemote operating software. See Chapter 10.4.2.

### **10.2.1** Unlocking the Control / WallControl Panel

After switching on / activating, the Control / WallControl Panel 1 must be unlocked before the TruRemote operating software can be started. To do this, slide the Unlock slider 3 to the right on the touchscreen 2.

This function of the Control / WallControl Panel cannot be switched off!

### 10.2.2 Energy-saving mode

The Control / WallControl Panel darkens after around one to two minutes if the screen is not used. To reactivate the display, touch the touchscreen.

### 10.2.3 Operating safety

For safety reasons, the following points should be checked before any of the components are used:

- The Dock desk is secure
- The Control is adequately charged
- Check for visible damage, especially abrasion of the plastic surfaces or loose parts.











## 10.3 Adjusting the settings (hospital technicians only)

### 10.3.1 Opening the settings screen

- 1. To call up the settings screen ③ from a control screen, tap the **Settings** icon.
  - The settings screen is displayed.

The settings options (1) are locked and must be unlocked with a login.

- 1. To edit the settings, tap the padlock icon 2.
  - ► A login window ③ is displayed.
- 2. Using the number pad (5), enter the six-digit numerical code (which was provided at handover or product training).
  - With each number input, a dot appears in the code display (4).
  - If the code has been entered correctly, the page unlocks.
  - If the code is incorrect, the code display 4
     clears and the code must be re-entered with the number pad 5.
- or

### Tap the Cancel button (6) and end the process.

### 10.3.2 Changing the room name

- 1. Tap the **Room name** field ⑦.
  - The keyboard appears.
- 2. Change the room name.
- 3. Tap the **Main** button 10.
  - ► The change is saved.
  - If necessary, log in for further adjustments!

### 10.3.3 Defining the scope of synchronization

The Synchronization (Sync) function sets the values of the lights being used currently on all of the Trumpf Medical lights present in the operating room and adapts automatically to each change while the function is active.

To do this, it is defined for the Control in question which of the setting ranges are to be adjusted for all surgical lights. The icons correspond to those on the control screen. The following can be synchronized:

- Lighting intensity
- Field of illumination size
- Lights On / Off

The color temperature is always synchronized and cannot be deactivated.

- 1. Activate (gray) or deactivate (black) the required functions (8) by tapping them.
- 2. Tap the Main button 🛈.



### Figure 35- Partial repetition Fig. 30



The change is saved. If necessary, log in for further adjustments!

#### NOTE

Making the settings for each Control

The Sync settings areas must be defined individually for each Control / WallControl Panel used in the operating room.

### 10.3.4 Enabling / disabling the one click screen

For power users, the one-click screen can be displayed instead of the operating screen, so that all settings can be changed on a single page.

- 1. To activate the one click screen function, tap the **One click setting** field (9).
  - A tick appears in the field (9).
  - Next time a light's control screen is opened, it is displayed.
- To deactivate the one click screen function, tap the One click setting field (9).
  - The tick disappears, and field (9) is empty.
  - Next time a light's control screen is opened, the control screen is displayed again.

## 10.3.5 Calling the control screens from a settings screen

- 1. To call up a control screen on the settings screen, tap the Main button (10).
  - The control screen (2) of the last surgical light selected (4) is displayed.





## 10.4 Structure of the TruRemote operating software

If an iLED<sup>®</sup> 7 surgical light is connected, the control screen of the iLED<sup>®</sup> 7 surgical light ① always opens when an external operating unit is switched on. The quick-access bar can be used to open the control screen of the TruVidia<sup>®</sup> Wireless camera system. If a TruVidia<sup>®</sup> Wireless video camera is connected to another Trumpf Medical surgical light (not iLED<sup>®</sup> 7), the TruVidia<sup>®</sup> Wireless control screen appears. See the separate TruVidia<sup>®</sup> Wireless camera system instructions for use.

## 10.4.1 Graphical user interface of the iLED<sup>®</sup> 7 surgical light

The graphical user interface of the iLED<sup>®</sup> 7 is comprised of four different screen types:

- A control screen (1) for each iLED $^{\circ}$  7 surgical light
- An optional one-click screen (2) on which all operating areas for all lights can be displayed
- A settings screen ③, password-protected
- An operating screen for controlling a TruVidia<sup>®</sup>
   Wireless video camera ④. For operation, see the separate TruVidia<sup>®</sup> Wireless camera system instruction manual





## **10.4.2** Screen structure - all screen types Status bar

All screens have a status bar (6) at the top with important general information, displays and functions:

- Location (e.g. operating room 1) (2)
- Date and time ③
- Signal strength of the video radio connection (only if a TruVidia<sup>®</sup> Wireless video camera is connected)

lcon	Meaning
<b>(</b> 0,0)	Signal strength 0 = no connection / device is switched off
	Signal strength 1 = many sources of interference are present / line-of- sight connection between the camera and receiver is interrupted
<b>(</b> • <b>)</b>	Signal strength 2 = sources of interference are present / line-of- sight connection between the camera and receiver is impaired
<b>(</b> • <b>)</b>	Signal strength 3 = minor sources of interference are present
<b>(</b> )	Signal strength 4 = very good connection

• Status indicator (4),

lcon	Meaning
$\circ \circ \circ$	Establishing a connection
0	Control not accepted
	Login starts
۲	Control logged in

• Charge status (% and icon) of the Control (5).





### 10.4.3 Screen structure - control screen

The control screen (3) is divided up into the following areas:

- Quick-access bar ① a click on the icon opens the control screen for one surgical light or for the TruVidia<sup>®</sup> Wireless video camera, if present
- Header containing the name of the device 2

   (surgical light or TruVidia<sup>®</sup> Wireless video camera)
- Light image ④
- Action area (5)
- Settings areas for
  - Lighting intensity 6
  - Color temperature (8)
  - Size of the field of illumination 9
  - ALC plus active / not active status ①
     With each change of the settings options ①, the light image ④ adapts to the modified selection.
- Information area ⑦ with the current settings for brightness, color temperature, field of illumination and ALC plus in written form
- Settings options for settings areas (1)
- Action bar 12 to 18 with the following functions:
  - Switch the surgical light On / Off (12)
  - Synchronization (Sync) (3) of all surgical lights present
  - Activate shadow management (14)
  - Switch all surgical lights on (15)
  - Switch all surgical lights off 17
  - Set all surgical lights to the Endo brightness 16
  - Call up the settings screen (18), password protected





### 10.4.4 Screen structure - One-click screen

The one click screen has a similar structure to the control screen, but here instead of the stylized light image, all of the settings options for the settings ranges (1) are displayed. This allows the surgical lights to be operated more quickly. It therefore shows the current settings of the surgical light as a highlight in the respective image icon.





## 10.5 Calling up other screens from a control screen

After starting the operating software, the iLED<sup>®</sup> 7 control screen (2) of the first surgical light (4) (if multiple are present) is displayed.

### 10.5.1 Opening other control screens

- 1. To call up another control screen, tap the relevant device (3) in the quick-access bar (1).
  - The selected control screen is displayed.

### 10.5.2 Opening the settings screen

- 1. To call up the settings screen ③, tap the Settings icon (5).
  - The settings screen (6) is displayed.

## 10.6 Calling the control screens from a settings screen

- To call up a control screen 2 on a settings screen
   (6), tap the Main icon 7.
  - ► The control screen ② of the last surgical light selected ④ is displayed.
- To call up another control screen, tap the relevant device (3) in the quick-access bar (1) on the left at the edge of the light control screen (2).
  - The selected control screen is displayed.





### 10.7 Operating the light

### 10.7.1 Switching on the light

The light can only be operated if it is switched on.

- 1. To switch the light on, move the slider (6) to the right to position I.
  - The image of the light ① illuminates and shows the last settings which were used in the settings area ②, the settings options ④ and the information area ③.

### 10.7.2 Switching off the light

- 1. To switch the light off, move the slider (5) to the left to position **0**.
  - The image of the light ① no longer illuminates; the Information area ③ is empty, the settings options ④ disappear and the settings areas ② are grayed out.







### 10.7.3 Adjusting the light

- 1. Switch on the light as described in Chapter 9.1.
  - The image of the light illuminates and the information area shows the last setting in writing.
- 2. Select the setting area (5) by tapping the icon (1)/(2)/(6)/(7).
  - The corresponding settings options (4)/(5)/(9)/
     (8) are displayed. The settings areas are:
- Lighting intensity ①
   Five setting levels ⑤:
   Endo, 30, 50, 80 and 100%
- Color temperature (2)
   Four color variants (4):
   3500 4000 4500 5000 K
- Field of illumination 6
   Three settings versions 9:
   Narrow medium wide
- ALC plus ⑦ On / Off
- 3. Select the settings option 1/2/6/7 by tapping it.
  - ► The change to the settings option is indicated visually in the image of the light ④/(5)/(8)/(9) and in text form in the information area 10.

### 10.7.4 Activating shadow management

- 1. Tap the **Shadow** button (12).
  - The light adjusts automatically to what is happening in the operating room and darkens partial areas of the light.

### NOTE

### More than two lamp heads

If three iLED<sup>®</sup> 7 lamp heads are present in a single system, shadow management is only available on two of the three lamp heads. The button for the third lamp head is not present.





### 10.7.5 Synchronizing all lights

- 1. Tap the **Sync** (1) button.
  - On all lights, the settings ranges specified on the settings screen are adjusted to the values of the surgical light currently being used.
  - While the Sync function (11) is active, each change of the settings of the "control light" is automatically adjusted on all of the other lights.

### **Only with ENDO brightness**

- If, when the brightness is being synchronized, All Endo (14) is selected or if this is selected during the synchronization process, a feedback window appears asking whether all lights really are to be set to the Endo lighting intensity.
- 2. Tap the OK or Cancel button as necessary.

### 10.7.6 Switching all lights on

- 1. Tap the All on button (15).
  - All surgical lights present are switched on.

### 10.7.7 Switch all lights off

- 1. Tap the **All off** button (13).
  - A feedback window appears asking whether all lights really are to be switched off.
- 2. Tap the **OK** or **Cancel** button as necessary.
  - All surgical lights present are switched off.

### 10.7.8 Setting all lights to Endo lighting intensity

- 1. Tap the All Endo button (14).
  - All surgical lights are switched to Endo.
  - If necessary, log in for further adjustments!



### 10.7.9 Operating the one-click screen

The one-click screen (1) displays all settings areas (3) and their settings options (2).

- 1. Switching on the lights, see Chapter 9.1.
  - The last settings are displayed in the settings options (2) and in the information area (4).
- 2. Select the settings area required (2) by tapping the icon (5)-(8).
  - The settings areas are:
- Lighting intensity (12)
   Five setting levels:
   Endo, 30, 50, 80 and 100%
- Color temperature 11
   Four color variants:
   3500 4000 4500 5000 K
- Field of illumination ①
   Three setting versions:
   Narrow medium wide
- ALC plus (9) On / Off

Or execute point 3. directly

- 3. Select the settings option 2 by tapping the corresponding icons in the individual settings options.
  - The change is displayed in the settings options
     (9)-(12) with highlighting (frame with gray background) and in writing in the information area (4).



### 11.1 General

For the safe operation of the surgical lights, it is essential to regularly clean and disinfect them with suitable cleaning agents and disinfectants.

### WARNING



Switching off the power supply

Contact with live parts may result in an electric shock.

- Before cleaning and disinfecting them, disconnect the following system components from the power supply

   lamp heads or support arm system
  - Dock desk
- Ensure that no cleaning and disinfecting agents penetrate the lamp head or support arm system.
- Do not insert objects into device openings.

### NOTE

Follow national directives

The operator must meet the requirements of the national hygiene and disinfection committee.

Ceiling-mounted version

- 1. Switch off the main switch in the operating room.
  - ► The lighting system is disconnected from the mains.

### Mobile pedestal version

- 1. Switch off the power pack by moving the switch to position **0**. See Chapter 7.3.4.
- 2. Disconnect the mains cable from the earthed socket.
  - The mobile lighting system is switched off.

### WARNING

Improperly used cleaning or disinfecting agents can endanger patients or damage products

Non-compliance with the specifications and directions in this chapter can lead to risk of contamination or infection for patients or damage products. It also completely voids the warranty.

- Dose cleaning agents/disinfectants such that no fluid can enter into the joints or openings of the OR lights or parts of the pendant system.
- Use surface disinfectants only in the concentration specified by the manufacturer.
- Use only disinfectants approved by the manufacturer for use on the following materials: Polycarbonate (PC), polyamide (PA), acrylonitrile-butadiene-



styrene copolymer (ABS), polystyrene (PS), polyurethane (PUR), polyphenylsulfone (PPSU), polyvinyl chloride (PVC), polybutylene terephthalate (PBT), and silicones.

- In the event of increased build-up of surface disinfectant, conduct a thorough basic cleaning.
- To avoid damage to surfaces:
  - Do not use sharp, pointed or abrasive objects
  - Do not use abrasives or agents that strip away material
  - Do not use solvents, gasoline, paint thinners, or alkaline, acidic or aldehyde-containing cleaning agents
  - Do not use cleaning agents with glycol derivatives, phenols, phenol derivatives or quaternary compounds
  - Use only agents without chlorides or halogenides to avoid damage to paint and corrosion
- The operator's hygiene guidelines must be complied with.

### 11.2 Recommended disinfecting agents

Trumpf Medical recommends the following disinfecting agents for manual use:

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

The list of recommended disinfectants is regularly supplemented. The latest version can be requested from Trumpf Medical as "Cleaning supplement, disinfection & sterilization - surgical lights".

### 11.3 Cleaning and disinfection of the surgical lighting system

### 11.3.1 General

Only a hygiene specialists or those instructed by them may clean and disinfect the OR lights.

Only those agents or chemicals compatibility-tested and approved by Trumpf Medical may be used for cleaning and disinfecting as specified in Chapter 11.2. Do not use agents that are not listed, otherwise functional components may be altered or damaged.

Before the actual disinfection, thoroughly clean any visible impurities such as bodily fluids.

- Do not use any sharp, pointed or abrasive objects, abrasives or stripping agents, otherwise surfaces may be damaged.
- Chemical substances could infiltrate and destroy damaged surfaces.
- To clean heavy or stubborn soil, use only a soft brush and mild cleaner or

To be performed by hygiene specialists Use only approved cleaning and disinfecting agents

Basic cleaning prior to disinfection



cleaning disinfectant. Disinfection can take place once all the visible contaminants have been removed.

NOTE

### Wipe-down disinfection only

y Use only a wipe-down disinfectant to disinfect the device. Disinfection using UV light or steam is prohibited.

### Warranty

Non-compliance with cleaning and disinfection specifications voids all warranty claims. No liability is assumed for damage caused by cleaning/disinfecting with inappropriate cleaning/disinfecting agents.

### The warranty is valid only for undamaged surfaces.

### 11.3.2 Wipe-down disinfection

A wipe-down disinfectant is to be used to disinfect the lights head and pendant systems. The lamp head must be cool for cleaning and disinfection.

Wipe with moist cloth only To clean and disinfect the components of the device, wipe them with a damp but not wet cloth. Apply only a thin liquid film, wipe, and leave behind only a thin, cohesive film of moisture. This moist film has sufficient microbiological effect. The fluid does not need to remain on the surface.

# Avoid build-up Applying too much fluid to the surface during disinfection leaves behind residue. This can lead to incorrect measurements, especially on the sensor cover plate. To prevent build-up of disinfectant residue, a mild all-purpose cleaner should be used for regular cleaning.

Clean at least once per month The regularity of cleaning depends on the frequency of disinfection, but should be carried out at least once a month.

Clean OR lights only with a damp but not wet cloth.

### **Cleaning procedure**

- 1. Disconnect the surgical light from the power supply and secure it against being switched back on.
- 2. Allow the lamp heads to cool. Lamp heads should only be cleaned / disinfected when cool.
- 3. Moisten a cloth with some cleaning or disinfecting agent. Wipe the OR lights using the moist, not wet, cloth.

### **A**DANGER



Risk of fire or explosion due to disinfectants

Flammable or explosive atmospheres may arise when handling cleaning and disinfecting agents due to the occurrence of gases, vapors or mists.

- Do not use any highly flammable disinfecting agents.
- Do not perform any large-scale disinfections.
- Allow hot surfaces to cool prior to disinfection.



- Completely disconnect the electrical installations in the room, where possible, and ensure that no switching can take place while disinfecting, especially automatically.
- After wiping with disinfectant, wait until the disinfecting agent is completely dry.
- Ensure that the room is adequately ventilated.

### **11.4** Sterilization of OR light hand grips

Material The hand grips are made of polyphenylsulfone (PPSU), a heat-resistant, shock-resistant plastic.

### NOTE

### Warranty

Non-compliance with sterilization specifications voids all warranty claims.

No liability is assumed for damage caused by use of inappropriate sterilization methods.



### 11.4.1 Preparation

- Remove heavy soil on the sterilizable hand grip immediately after use (within 2 hours).
- For later cleaning, store the sterilizable hand grip in a retaining device where the soil will remain moist.
- Avoid situations that soil the inner surface of the sterilizable hand grip or scratch the cover plate.

### 11.4.2 Cleaning and disinfection

### NOTE

Sterilization errors damage products

Non-compliance with the following specifications and instructions can cause damage to products. It also completely voids the warranty.

• Do not use hot-air sterilization for sterilizable hand grips.

### Cleaning

The sterilizable hand grips can be cleaned using mildly alkaline cleaning agents that do not contain active chlorine. Trumpf Medical recommends a 0.5% (5ml/L) concentration of neodisher mediClean (forte).

- 1. Remove the sterilizable hand grip from the grip adapter.
- 2. Clean the sterilizable hand grip with the cleaning agent.
- 3. Rinse off the cleaning agent thoroughly with faucet water.

### Disinfecting

Use a wipe-down or spray disinfectant. Trumpf Medical recommends products with an alcohol or aldehyde base that are approved by the manufacturer for use on PPSU.

- 1. Disinfect the sterilizable hand grip.
- 2. Check the sterilizable hand grip for material damage, cracks, or deformations and replace damaged hand grips.
- 3. Check that the cover plate (if present) is seated securely and replace the sterilizable hand grip if necessary.

A mechanical process (disinfector) compliant with EN ISO 15883-1 should be used for cleaning/disinfection. The effectiveness of the process used must always be approved in principle (e.g., included in the list of tested and approved disinfecting agents and processes by the Robert Koch Institute/DGHM) and have already been thoroughly validated.

If another process is used (e.g. manual), its principle of effectiveness must be proven through validation. For machine cleaning, the Vario-TD standard cleaning program from Miele can be used, or other programs that adhere to the following time and temperature values:

Phase	Temperature	Time
Prerinsing	20 °C	60 s
Cleaning	20 - 55 °C	300 s
Neutralization	24 - 55 °C	60 s



Interim rinsing	20 - 24 °C	60 s
Disinfecting	93 °C	300 s
Drying	100 °C	25 min

### 11.4.3 Sterilization

### **General instructions**

- Sterilization processes must be validated according to EN ISO 17665-1 and EN ISO 17665-2;
- use only fractionated prevacuum;
- do not exceed temperatures of 135 °C.

### **WARNING**

Risk of contamination and infection of the patient

After sterilization, check hand grips for material damage, tears or deformations; flaking particles can fall into wounds.

• Immediately replace hand grips that are damaged, have undergone a maximum of 350 steam sterilization cycles, or are older than 1.5 years.

### Steam sterilization

Sterilizable hand grips can undergo up to 350 steam sterilization cycles without damage as long as the following requirements are met:

- Position sterilizable hand grips upright with the open side down, making sure that the plate of the ALC or camera hand grips are not sitting directly on the rinsing device (danger of scratching);
- Sterilize sterilizable hand grips individually in packaging suitable for steam sterilization;
- The sterilization packaging has to be large enough for the hand grip without placing any tension on the seal;
- If sterilizing more than one hand grip in one sterilization cycle, do not exceed the maximum load of the sterilizer.

### a) Steam sterilization at 132 °C (270 °F):

- Sterilization time = 4 min
- Drying time = 20 min

### b) Steam sterilization at 135 °C (275 °F):

- Sterilization time = 3 min
- Drying time = at least 16 min

### 11.4.4 Sterilization packaging

The sterilizable hand grips are placed in suitable sterilization packaging (disposable sterilization package, e.g., foil/paper sterilization pouches; single or double packaging per EN ISO 11607, suitable for steam sterilization) and then sterilized.

- 1. Place precleaned and disinfected hand grip in sterilization packaging.
- 2. Sterilize the sterilizable hand grip according to the specifications.
- 3. Check the sterilized hand grip for material damage, cracks, or



deformations and replace damaged hand grips.

4. Check that the cover plate (if present) is seated securely and replace the sterilizable hand grip if necessary.

## 11.5 Cleaning, disinfection and sterilization of external control units

For the safe operation of the Control, WallControl Panel, bumper and the Dock desk, it is essential to clean and disinfect the hardware components regularly with suitable cleaning agents or disinfectants.

### 11.5.1 Cleaning and disinfection

Wipe-down disinfection is to be used to disinfect the Control, WallControl Panel, bumper and Dock desk.

### **WARNING**

Improperly used cleaning or disinfecting agents can endanger patients or damage products

- Never position the non-sterile Control / WallControl Panel above the sterile operating area during medical use.
- Only use a wipe-down disinfectant to disinfect the device. To clean and disinfect the components of the device, wipe them with a damp but not wet cloth.
- Dose cleaning agent/disinfectant such that no fluid flows into the joints or openings of the device.
- Use surface disinfectants only in the concentration specified by the manufacturer.
- Use only disinfectants approved by the manufacturer for use on the following materials:
- Polycarbonate (PC), polyamide (PA), acrylonitrile-butadienestyrene copolymer (ABS), polystyrene (PS), polyurethane (PUR), polyphenylsulfone (PPSU), polyethylene terephthalate (PET), and silicones.
- In the event of increased build-up of surface disinfectant, conduct a thorough basic cleaning.
- To avoid damage to surfaces:
  - do not use sharp, pointed or abrasive objects;
  - do not use abrasives or agents that strip away material;
  - do not use solvents, gasoline, paint thinners, or alkaline, acidic or aldehyde-containing cleaning agents;
  - do not use cleaning agents with glycol derivatives, phenols, phenol derivatives or quaternary compounds;
  - use only agents without chloride or halides to avoid damage to paint and corrosion.
- The operator's hygiene guidelines must be complied with.



Use only approved cleaning and disinfecting agents

Wipe-down disinfection only

### 11.5.2 General

Only those agents or chemicals compatibility-tested and approved by Trumpf Medical may be used for cleaning and disinfecting as specified in Chapter 11.2. Do not use agents that are not listed, otherwise functional components may be altered or damaged.

Use only a wipe-down disinfectant to disinfect the device. Disinfection using UV light or steam is prohibited.

### NOTE

**Disclaimer of liability** 

Non-compliance with cleaning and disinfection specifications voids all warranty claims. No liability is assumed for damage caused by cleaning/disinfecting with inappropriate cleaning/ disinfecting agents.

The warranty is valid only for undamaged surfaces.

### 11.5.3 Wipe-down disinfection

Wipe-down disinfection is used as the disinfection method.

Wipe with moist cloth onlyTo clean and disinfect the components of the device, wipe them with a damp<br/>but not wet cloth. Apply only a thin liquid film, wipe, and leave behind only a<br/>thin, cohesive film of moisture. This moist film has sufficient microbiological<br/>effect. The fluid does not need to remain on the surface.

Avoid build-up Applying too much fluid to the surface during disinfection leaves residue behind on the device. To prevent build-up of disinfectant residue, a mild all-purpose cleaner should be used for regular cleaning.

## Clean at least once per month The regularity of cleaning depends on the frequency of disinfection, but should be carried out at least once a month.

### 11.5.4 Sterilization

The Control / WallControl Panel and its components, the Dock desk and its accessories must not be sterilized.

The Control (tablet unit with bumper) must be packed in a sealable, sterile, disposable sleeve for use in sterile areas.

The WallControl Panel, the Dock desk and its accessories are only used in the non-sterile area.



Δ



	<u>کا</u> WARNING	
	Do not carry out any maintenance work during surgery or while the device is in use	
	All equipment is subject to wear over time. As a result, the safety and proper functioning of your device must be checked at regular inspection and maintenance intervals. Electrical repeat inspections must be carried out according to country-specific regulations. Trumpf Medical recommends concluding a service contract.	
	Service phone number	
Trumpf Medical Field Service	Phone: +49 3671 586-41199 (24-hour service hotline for Germany) Fax: +49 3671 586-41175	
E-mail	Service@trumpfmedical.com	
	12.1 Inspections during operation	
	<ul> <li>12.1.1 Defective or damaged devices or accessories</li> <li>Defective or damaged Controls, WallControl Panels, bumpers or Dock desks must be immediately clearly labeled, taken out of service and replaced.</li> <li>Operate surgical lights directly on the operating panel.</li> <li>If there is damage or a fault, notify Technical Customer Service.</li> </ul>	
Inspection before and after use	<ul> <li>The user is required to check the device for visible damage before and after every use. This can be integrated into the cleaning procedure, for example. The following damage must be reported to the operator's technical personnel: <ul> <li>Loose parts on the lighting system</li> <li>Visible damage to the lighting system, particularly on the cover plate of the lamp head and on the sterilizable hand grip</li> <li>Insecure fastening of the sterilizable hand grip</li> <li>Functional restrictions, for example on the arm system or in the operating units.</li> </ul> </li> <li>The charge level of the external operating units (Control / WallControl Panel) must also be checked and, if necessary, increased by charging at the Dock desk.</li> </ul>	
	<b>WARNING</b>	
	Risk of contamination and infection of the patient	
	<ul> <li>Loose or damaged parts on the lamp head or lighting system are at risk of falling into wounds. To ensure patient safety, the lighting system components must be checked for the following points prior to each use:</li> <li>Loose parts in the lamp heads</li> <li>Visible damage, particularly on the cover plate of the lamp head and on the sterilizable hand grip</li> </ul>	

• The sterilizable hand grip is securely in place



**Operating safety** 

For safety reasons, check the components of the Control for the following prior to every use:

- The Dock desk is secure
- The Control is adequately charged
- Visible damage, especially abrasion of the plastic surfaces or loose parts
- Correct function of the Control, Dock desk and TruRemote operating software
- Condition of the bumper (wear part with service life of six months)

Faulty devices or accessories

Defective devices and function units must be immediately marked clearly and removed from operation. If there is damage or a fault, notify Technical Customer Service.

Weekly inspection by technical personnel

At least once per week and following any reports of damage by a user, a functional and visual inspection must be carried out by technical personnel.

If there is damage or a fault, notify Technical Customer Service.

Faulty devices or accessories

Defective devices and function units must be immediately marked clearly and removed from operation.

### 12.2 Annual visual inspection

Annual visual inspection

A visual inspection of the entire lighting system must be performed by qualified operator personnel once a year. In particular, the following device parts and components must be checked for material deteriorations during this visual inspection:

- Deformation of the components of the lamp head and the support arm system
- Defects in paintwork on the entire support arm system and on the lamp heads
- Missing plastic components / small parts, e.g. covers, plugs, etc.
- Crack formation, clouding or other surface damage (e.g. scratches) on the 3D sensor cover
- Embrittlement of plastic parts
- Readability of the device labels
- Readability of the safety notices
- Turning ability of the support arms
- Position of the stops, correcting if necessary.
- Effect of the spring force, see Chapter 16.2.



- Visual inspection for collision damage
- Visual inspection for cracks in the area of the welded joints
- Test the Safe mode button regularly.

### **12.3** Two-year maintenance

Two-year maintenance

The device must only be maintained by Technical Customer Service. The inspections must be carried out at least every two years. The equipment must be tested as regards the following:

- Maintenance
- Electrical safety inspection, with the testing specifications for performance of the electrical repeat inspection being available from Trumpf Medical.

### NOTE

### Shorter maintenance intervals

• After 10 years in operation, the functional inspection on the lighting system must be repeated once a year.

Documentation in accordance with Medical Devices Operators Ordinance (MPBetreibV)

The safety inspections, service and maintenance work performed in accordance with MPBetreibV must be documented in a Medical Device Book.

This book must be available on site.





### 13.1 Introduction

Adjustments should only be made by the operator's trained technical personnel and only following suitable hospital engineer training provided by Trumpf Medical.

## 13.2 Adjusting the swivel range of the mobile pedestal version's spring arm

The vertical swivel movement can be adjusted in a range from +30° (upwards) to -45° (downwards). Adjust the swivel range in such a manner that collisions with the ceiling or other components are ruled out (the swivel range can be restricted up to the horizontal level).

### 13.2.1 Disconnect the mobile pedestal version

- Switch off the power pack by moving the switch to position 0. See Chapter 7.3.4. Disconnect the mains cable from the earthed socket.
  - The mobile lighting system is switched off.
- 2. Ensure that the power plug is safeguarded against being inadvertently plugged in again.

## **13.2.2** Adjusting the swivel range Removing the cover panels

- Carefully press in the two halves of the cover panel
   at the six clips ① using a compatible slotted screwdriver and unlock them.
- 2. Remove the halves of the cover panel (2).

### Adjusting the swivel range

3. Insert the attached pin (5) (Ø 4 mm x 110 mm) into the pierced adjusting nut in the adjustment opening (4) of the spring arm (3).

### Reducing the swivel range

• Push the internal adjusting nut upwards using the pin.

### Extending the swivel range

• Push the internal adjusting nut downwards using the pin.

### Fitting the cover panel

- 4. Position the two halves of the cover panel (2) on the spring arm and push the six clips (1) against the spring arm until they engage.
- 5. Check that the cover panel 2 is seated securely.
- 6. Check the function of the swivel movement.







## 13.3 Setting the swivel ranges of the spring arm support arm system

The vertical swivel movement can be adjusted in a range from +45° (upwards) to -50° (downwards). Adjust the swivel range in such a manner that collisions with the ceiling or other components are ruled out (the swivel range can be restricted up to the horizontal level).

### 13.3.1 Adjusting the swivel range

- 1. Insert the hexagon wrench (2) (size 5) into the setting screw in the adjustment opening (1).
- 2. Pull the spring arm down to relieve the setting screw.

### Reducing the swivel range

• Turn the setting screw clockwise, to the right.

### Extending the swivel range

- Turn the setting screw anti-clockwise, to the left.
- 3. Check the function of the swivel movement.





### 13.4 Setting the spring force of the spring arm

The weight of the lamp head is compensated by a spring installed in the spring arm. If the spring arm with the lamp head does not remain stable in the selected height position during a swivel movement, the spring force needs to be readjusted.

### Only the mobile pedestal version

- Switch off the power pack by moving the switch to the 0 position (see Chapter 7.3.4), disconnect the mains cable from the earthed socket.
  - ► The mobile lighting system is switched off.
- 2. Ensure that the power plug is safeguarded against being inadvertently plugged in again.

### All versions

- 3. Insert the hexagon wrench (2) (size 5) into the setting screw in the adjustment opening (1).
- 4. Position the spring arm approximately +10° relative to the horizontal in order to relieve the setting screw in the spring arm.

### 13.4.1 Ceiling-mounted version

### To reduce the spring force

• Turn the setting screw clockwise, to the right

### To increase the spring force

• Turn the setting screw anti-clockwise, to the left.

### 13.4.2 Mobile pedestal version

### To reduce the spring force

- Turn the setting screw anti-clockwise, to the left.
- To increase the spring force
  - Turn the setting screw clockwise, to the right.
- 5. Check the function of the spring force.







## **13.5** Setting the braking force of the support arm system friction brakes

If the extension arm, spring arm, comfort bracket, ¼ bracket or lamp head do not remain stable in the set swivel position during a swivel movement, the braking force of the friction brake needs to be readjusted. The friction brake acts on the relevant pins of the support arm components by using friction from the setting screw (slotted screw ③). If the braking force needs to be adjusted on multiple support arm components, adjust the brakes in the following sequence:

- 1. Friction brake A for extension arm
- 2. Friction brake **B** for spring arm
- 3. Friction brake **C** for comfort bracket and **D** for ¼ bracket / lamp head

### ATTENTION

Friction brake screw types

The brake screws are designed as slotted screws. No other type of screw should be loosened.

## **13.5.1** Disconnecting the lighting system Ceiling-mounted version

1. Switch off the main switch in the operating room.

- The lighting system is disconnected from the mains.
- 2. Ensure that the main switch is safeguarded against being inadvertently switched back on.

### Mobile pedestal version

- Switch off the power pack by moving the switch to the 0 position (see Chapter 7.3.4), disconnect the mains cable from the earthed socket.
  - The mobile lighting system is switched off.
- 2. Ensure that the power plug is safeguarded against being inadvertently plugged in again.

## 13.5.2 Setting the braking force for the extension arm

Adjust the friction brake A:

1. Adjust the brake screw ① using a suitable slotted screwdriver:

### Reduce the braking force

• Turn the brake screw to the left, anti-clockwise.

### Increase the braking force

- Turn the brake screw to the right, clockwise.
- 2. Check the function of the braking force.



Figure 49 B В (1 Brake screw type: 1378864

## **13.5.3** Setting the braking force for the spring arm Adjust the friction brake **B**:

1. Adjust the brake screw ① using a suitable slotted screwdriver:

### Reduce the braking force

• Turn the setting screw anti-clockwise, to the left.

### Increase the braking force

- Turn the setting screw clockwise, to the right.
- 2. Check the function of the braking force.

Brake screw type: 1378857




#### Figure 50



## 13.5.4 Setting the braking force for the lamp head on the comfort bracket or ¼ bracket

### Adjust the friction brake C for the comfort bracket

1. Adjust the brake screw (2) using a suitable slotted screwdriver:

#### Reduce the braking force

• Turn the setting screw anti-clockwise, to the left.

#### Increase the braking force

- Turn the setting screw clockwise, to the right.
- 2. Check the function of the braking force.

Brake screw type: 4025239

### 

1. Adjust the brake screw ① using a suitable slotted screwdriver:

#### Reduce the braking force

• Turn the setting screw anti-clockwise, to the left.

#### Increase the braking force

- Turn the setting screw clockwise, to the right.
- 2. Check the function of the braking force.

Brake screw type: 4025239



Figure 51



### 13.6 Setting the friction brake of the spring arms (mobile pedestal version, NRH of the ceiling-mounted systems)

Adjust the friction brake **D** for the lamp heads on the spring arm AC 2000 NRH:

### Adjusting the brake force

1. Adjust the brake screw (2) on both sides using a suitable slotted screwdriver (1):

### Reduce the braking force

• Turn the setting screw anti-clockwise, to the left.

### Increase the braking force

- Turn the setting screw clockwise, to the right.
- Check the function of the braking force.

Brake screw type: 1378866



### Hand grips, brake screws and external components

Wear parts should only be replaced by the operator's trained technical personnel and only following suitable hospital engineer training provided by Trumpf Medical.

Hand grips	Chapter	# (article / material number)
Sterilizable hand grip for lamp head; Plastic (pack of three)		0337642
Sterilizable hand grip for camera; Plastic (pack of three)	TruVidia <sup>®</sup> Wireless Instruction Manual	0337643
Sterilizable hand grip for Adaptive Light Control plus (pack of three)		1604969
Brake screws	Chapter	#
Slotted brake screw on spring arm AC 2000 NRH; M12 x 1 mm with 2 mm length (two pieces)		1378866
Slotted brake screw on extension arm (extension arm brake); M12 x 1 mm with 30 mm length (two pieces)		1378864
Slotted brake screw on extension arm (spring arm brake); M12 x 1 mm with 16 mm length (two pieces)		1378857
Slotted brake screw on comfort bracket; M10 x 1 mm with 11 mm length (two pieces)		4025239
External components	Chapter	#
Replacement battery. The expected service life is six months (please contact Technical Customer Service)		
Bumper (impact protection). The expected service life is six months		1854744. bumper (pack of three)
Case (welded sleeve of the tablet unit). The expected service life is one year		
Dock desk: Replacement power pack Dock desk. The expected service life is five years		Country-specific material number upon request



### NOTE

#### **Error repetition**

If an error recurs or cannot be resolved, take the device out of service and notify Technical Customer Service

### **Causes and remedies**

Error	Possible cause	Remedy	Chapter
Mounting / mobility			
Lamp head falls / rises	Spring force in the spring arm too low / too high	Adjust the spring force	Chapter 13.5.3
Lamp head is difficult / too easy to move	Brakes are set too firmly / lightly.	Adjust the brakes	Chapter 13.4, Chapter 13.5
Optical system / lighting t	echnology		
Lighting intensity too low	Lighting intensity is set too low	Increase the brightness	Chapter 9.2
Uneven field of illumination	Lamp head is outside the work area	Position the lamp head	Chapter 7.2, Chapter 7.3.1
	Shock / impact on the light	Switch the lamp head off and on again	Chapter 9.1
The light does not illuminate	The main switch in the operating room is switched off	Switch the main switch on	_
	The lamp head has been switched off at the control element	Press the ON / OFF switch	Chapter 9.1
	The mains cable of the mobile pedestal version is not plugged in	Plug the mains cable into the socket	_
	The power pack of the mobile pedestal version is not switched on	Press the ON / OFF switch on the power pack housing	Chapter 7.3.3
	Electronics are faulty	Contact Technical Customer Service	_
	The local voltage supply is interrupted	Check the local fuses and power supply	-



Automatic distance detection does not work	Failure of the sensor or repeatedly incorrect measurements	<ol> <li>Disable the ALC plus function using the Control or</li> <li>Disable the ALC plus function using safe mode (press the button on the lamp head) or</li> <li>Disconnect the power to the lighting system to force a restart</li> </ol>	
Different color temperatures in the field of illumination	The color temperature is only set on one light	Switch on the Sync function	See Chapter 10.7.5
Operation Control			
The light cannot be operated with the Control	Fault in the WLAN connection	Control lighting intensity using the control element on the lamp head	

Sterilizable hand grip			
Hand grips are damaged or exhibit cracks	The end of their useful life has been reached	Replace the hand grips	
Service life of the sterilizable hand grips is too short	Unapproved sterilization method	Use the sterilization method in this manual	



### 16.1 Equipment of the surgical light

Designation	Equipment
Sterile Light Control (SLC)	Optional
Adaptive Light Control Plus (ALC plus)	$\Box$
Automatic shadow management (available for max. two lights in one system)	

### 16.2 Device data

#### IP classification according to IEC 60529

Designation	Values
Lamp head	IP40
Axis system	IP20
Control	IP67
WallControl Panel	IP42

#### Electrical data

Designation	Values
Supply voltage on the power supply pack	100 - 240 VAC 50 / 60 Hz
Max. power consumption of one light	< 160 VA
Internal fuse (only mobile pedestal version)	2 × T10 A
Voltage at the fixed point on the ceiling	48 V
Classification in accordance with MPG	1

### **WARNING**

Only operate the device with the specified accessories

The device must only be operated with the accessories specified in the accompanying paperwork. Operation with accessories, converters or cables other than those specified in the accompanying paperwork can lead to increased EMC transmissions or reduced resistance of the device to interference.



# Light technology data<sup>1</sup>

Designation	Values		
Central lighting intensity at 0.8 / 1.0 / 1.3 m distance	160,000 lux		
Dimmable from/to	< 10% Endo, 30% - 100%		
Field of illumination size variable by changing the distance	16 cm - 30 cm		
Focusable field of illumination size	Narrow	Medium	Wide
(d10) at 1.0 m (100 cm)	Approx. 16 cm	Approx. 20 cm	Approx. 25 cm
Central lighting intensity at 1.0 m	160,000 lux	•	
d50 / d10 ratio	≥ 0.5		
Residual lighting intensity with one shade	92% 147,200 lux		
Residual lighting intensity with two shades	68% 108,800 lux		
Residual lighting intensity with lens barrel	98% 156,800 lux		
Residual lighting intensity with lens barrel and one shade	91% 145,600 lux		
Residual lighting intensity with lens barrel and two shades	66% 105,600 lux		
Illumination depth (L1 + L2) at 20% Ec / EN ISO 60601-2-41 2nd Edition	1930 mm with	n ALC plus	
Illumination depth (L1 + L2) at 60% Ec / EN ISO 60601-2-41 3rd Edition	1090 mm with	ALC plus	
Average service life of the LED	> 60,000 h		
Color temperature	3,500 K, 4,000	) K, 4,500 K, 5,000	К
Color rendition index Ra	Max. 97		
Color rendition index R9	Max. 96		
Color rendition index R13	Max. 99		
Radiant flux density (W/m <sup>2</sup> ) <sup>2</sup>	Approx. 623		
Radiant flux density / lighting intensity (mW/m <sup>2</sup> lx)	Approx. 3.84		

1 = All light technology values max. + / - 10% tolerance 2 = At a distance of 1.30 m



### **Mechanical Data**

Designation	Values
Diameter of the lamp head	710 mm
Flow surface of the lamp head	3300 cm <sup>2</sup>
Light-emitting surface	1996 cm <sup>2</sup>
Area of the lamp head aperture	200 cm <sup>2</sup>
Weight of the lamp head (including comfort and quarter brackets)	approx. 15.5 kg

### Specification of 3D sensor for distance measurement

Designation	Values
Max. output power	108 mW
Wavelength	860 nm



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

#### WLAN specification

Designation	Values
Wireless communication and mobile radio	IEEE 802.11a, 802.11b, 802.11g, 802.11n
Data rate	802.11b: 1, 2, 5.5, 11 Mbps 802.11g: 6, 9, 12, 18, 24, 36, 48, 54 Mbps 802.11n: MCS0 up to MCS7 with and without short GI
Internal frequencies	Dual-band (2.4 or 5 GHz)

Internal frequencies (MHz)	Description
2412 - 2484 MHz	802.11 b/g/n
4910 - 5825 MHz	802.11 a
800 MHz	Processor
480 MHz / 5 GHz	USB 2.0 / 3.0
16 MHz	Micro-controller



### **16.3** EMC information

#### **EMC** notes

### **WARNING**

#### Only operate the device with the specified accessories

The device must only be operated with the accessories specified in the accompanying paperwork. Operation with accessories, converters or cables other than those specified in the accompanying paperwork can lead to increased EMC transmissions or reduced resistance of the device to interference and therefore to incorrect operation.

There are no specified precautions for maintaining basic safety in relation to EMC over the expected operational service life.

The properties of this device determined by emissions allow its use in the industrial sector and in hospitals (CISPR 11, Class A). When used in domestic situations (for which CISPR 11 normally Class B is required), this device may not provide adequate protection from radio services. The user must, if necessary, take remedial measures such as the relocation or realignment of the device.

#### NOTE

Install and operate the device in accordance with the EMC notes

Medical electrical equipment is subject to particular safety measures in relation to EMC and must be installed and operated in accordance with the EMC notes set out in the accompanying paperwork.



### 16.3.1 iLED® 7 lighting system

NOTE

Do not stack the device with or next to other devices

The iLED<sup>®</sup> 7 lighting system must not be arranged in a stacked manner immediately next to or with other devices.

#### **Key features**

The key feature is the provision of illumination and limitation of the energy over the operative field.

#### Guidelines and manufacturer's declaration - ELECTROMAGNETIC EMISSIONS

The iLED<sup>®</sup> 7 lighting system has been designed for operation in one of the ELECTROMAGNETIC ENVIRONMENTS described below. The customer or user of the iLED<sup>®</sup> 7 lighting system should ensure that it is operated in such an environment.

Emissions measurements	Compliance	ELECTROMAGNETIC ENVIRONMENT - guidelines
HF emissions in accordance with CISPR 11	Group 1	The iLED <sup>®</sup> 7 lighting system uses HF energy only for its internal FUNCTIONING. Therefore its HF emissions levels are very low and it is improbable that neighboring devices would be affected by interference.
HF emissions in accordance with CISPR 11	Class B	The iLED <sup>®</sup> 7 lighting system is suitable for operation in all facilities including private homes and those
Harmonic emissions as per EN / IEC 61000-3-2	Class A	NETWORK that also supplies buildings used for residential purposes.
Voltage fluctuations / flickers in accordance with EN / IEC 61000-3-3	satisfied	F - F



### Guidelines and manufacturer's declaration - electromagnetic immunity

### Guidelines and manufacturer's declaration - ELECTROMAGNETIC IMMUNITY

The iLED<sup>®</sup> 7 lighting system has been designed for operation in one of the ELECTROMAGNETIC ENVIRONMENTS described below. The customer or user of the iLED<sup>®</sup> 7 lighting system should ensure that it is operated in such an environment.

Immunity tests	EN / IEC 60601 test level	Compliance level	ELECTROMAGNETIC ENVIRONMENT - guidelines
Static electricity discharge (ESD) according to EN / IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be made from wood or concrete or covered with ceramic tiles. If a floor is covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient disturbances/bursts in accordance with EN / IEC 61000-4-4	±2 kV for power lines ±1 kV for input and output lines	±2 kV for power lines ±1 kV for input and output lines	The supply voltage quality should correspond to that in a typical business or hospital environment.
Impulse voltages / surges in accordance with EN / IEC 61000-4-5	±1 kV outer conductor - outer conductor voltage ±2 kV outer conductor - ground voltage	±1 kV outer conductor - outer conductor voltage ±2 kV outer conductor - ground voltage	The supply voltage quality should correspond to that in a typical business or hospital environment.
Voltage dips, short inter- ruptions and voltage variations on power supply input lines pursuant to EN / IEC 61000-4-11	< 5% UT For 1/2 periods (> 95% drop) 40% UT For five periods (60% drop) 70% UT For 25 periods (30% drop) < 5% UT For 5 s (> 95% drop)	< 5% UT For 1/2 periods (> 95% drop) 40% UT For five periods (60% drop) 70% UT For 25 periods (30% drop) < 5% UT For 5 s (> 95% drop)	The supply voltage quality should correspond to that in a typical business or hospital environment. If the iLED® 7 lighting system user requires uninterrupted functionality even in case of voltage interruptions, we recommend you supply the iLED® 7 lighting system via an uninterruptible power supply (UPS) or a battery.
Magnetic field with a supply frequency (50/ 60 Hz) as per EN / IEC 61000-4-8	3 A/m	3 A/m	Magnetic fields for the network frequency should comply with values commonly found in commercial and hospital environments.
comment.			

UT is the supply voltage prior to applying the test levels.



The iLED<sup>®</sup> 7 lighting system satisfies the following EN / IEC 60601-1-2:2014 test level with the specified compliance levels; the customer or user of the iLED<sup>®</sup> 7 lighting system should ensure that it is being used in such an environment.

Interference immunity test	EN / IEC 60601-1 test level	Compliance level		
Static electricity 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		
Electrical fast transient disturbances/bursts in accordance with EN / IEC 61000-4-4	±2 kV 100 kHz repeat frequency	±2 kV 100 kHz repeat frequency		
Impulse voltages / surges in accordance with EN / IEC 61000-4-5	See table above			
Voltage dips, short interruptions and voltage variations on power supply input lines pursuant to EN / IEC 61000-4-11	0% UT; 0.5 cycle a) 0% UT; 1 cycle 70% UT; 25/30 cycles b) 0% UT; 250/300 cycles b)	0% UT; 0.5 cycle a) 0% UT; 1 cycle 70% UT; 25/30 cycles b) 0% UT; 250/300 cycles b)		
Magnetic field with a supply frequency (50/60 Hz) as per EN / IEC 61000-4-8	30 A/m	30 A/m		
a) at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° b) at 0°				
Comment: UT is the supply voltage prior to applying the test levels.				

### Guidelines and manufacturer's declaration - electromagnetic immunity / portable and mobile radio units

### Distance for portable RF communications equipment and its peripherals

Do not use portable RF communications equipment (including peripherals such as an antenna cable and external antennas) at a distance of less than 30 cm (12 in) from the lighting system, including its cables that have been specified by the manufacturer. Otherwise, the system's functionality can be impaired.

### NOTE

The iLED<sup>®</sup> 7 lighting system is not designed for use close to HF surgical equipment. It has been tested in regard to interference immunity exclusively against radiated fields in the electromagnetic environment set out below, which corresponds to a professional healthcare facility or domestic environment for healthcare.



### Guidelines and manufacturer's declaration - ELECTROMAGNETIC IMMUNITY

The iLED<sup>®</sup> 7 lighting system has been designed for operation in one of the ELECTROMAGNETIC ENVIRONMENTS described below. The customer or user of the iLED<sup>®</sup> 7 lighting system should ensure that it is operated in such an environment.

Immunity tests	EN / IEC 60601 test level	Compliance level	ELECTROMAGNETIC ENVIRONMENT - guidelines
			Portable and mobile radio units must not be used at a dis- tance from the iLED <sup>®</sup> 7 lighting system, including cables, less than the recommended separation distance calculated on the basis of the transmission frequency equation.
Conducted HE	3 V effective value 150 kHz to 80 MHz	3 V effective value	<b>Recommended safe distance:</b> d = 1.2√P
disturbance	3 V/m		d = 1.2√P - 80 MHz to 800 MHz
variables as per EN / IEC 61000-	80 MHz to 2.5 GHz	3 V/m	d = 2.3√P - 800 MHz to 2.5 GHz
4-6 Radiated HF disturbance variables in accordance with			P is the nominal rating of the transmitter in watts (W) as per the transmitter manufacturer's data and d is the recommended safe distance in meters (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> is less than the COMPLIANCE LEVEL. <sup>b</sup>
4-3			Interference may occur in the vicinity of equipment marked with the following symbol:
			(((••)))

#### Note 1:

For 80 MHz and 800 MHz, the higher frequency range applies.

Note 2:

These guidelines might not be applicable in all situations. The propagation of electromagnetic waves is influenced by the absorptions and reflections of buildings, objects and human beings.

<sup>a</sup> = The field strength of stationary transmitters e.g. the base stations of cell phones and mobile land radio services, amateur radio stations, AM and FM radio and TV broadcasting transmitters cannot be precisely predetermined theoretically. In order to determine the electromagnetic environment with regard to stationary HF transmitters, a study of the location is recommended. If the determined field strength at the location of the iLED<sup>®</sup> 7 lighting system exceeds the compliance level specified above, the iLED<sup>®</sup> 7 lighting system must be observed to ensure its normal operation in each place of use. If unusual characteristics are observed, it may be necessary to take additional measures such as reorienting or relocating the iLED<sup>®</sup> 7 lighting system.

 $^{\rm b}$  The field strength in the 150 kHz to 80 MHz frequency range should be less than 1 V/m.



The iLED<sup>®</sup> 7 lighting system satisfies the following EN / IEC 60601-1-2:2014 test level with the specified compliance levels; the customer or user of the iLED<sup>®</sup> 7 lighting system should ensure that it is being used in such an environment.

Interference immunity test	EN / IEC 60601-1 test level	Compliance level		
Conducted HF disturbance variables as per EN / IEC 61000-4-6	3 V 0.15 MHz – 80 MHz	3 V 0.15 MHz – 80 MHz		
	σv	σv		
	In the ISM band between 0.15 MHz	In the ISM band between 0.15 MHz		
	and 80 MHz a)	and 80 MHz a)		
Radiated HF disturbance variables	10 V/m	10 V/m		
as per EN / IEC 61000-4-3	80 MHz – 2.7 GHz	80 MHz – 2.7 GHz		

<sup>a</sup> = 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 bands 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 levels for RF fields of wireless communications equipment

Table: Special frequencies

Test Fre- quency (MHz)	Band (MHz)	Service	Modulation	max. Power (W)	Distance (m)	lmmu- nity 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	Pulse modulation 18 Hz	2	0.3	28
870		IEIRA 800 IDEN 820	320			
930		CDMA 850 LTE band 5				
1720	1700 -	GSM 1800	Pulse modulation 217 Hz	2	0.3	28
1845	1990	CDMA 1900 GSM 1900				
1970		DECT LTE band 1, 3, 4, 25 UMTS				



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 -	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500	5800					
5785						

### Controlled HF disturbance variables

#### Recommended separation distances between portable and mobile HF communication devices and the

The iLED<sup>®</sup> 7 lighting system has been designed for operation in an ELECTROMAGNETIC ENVIRONMENT in which radiated HF disturbance variables are controlled. The customer or user of the iLED<sup>®</sup> 7 lighting system can help to prevent electromagnetic interference by complying with the minimum distances between portable and mobile HF telecommunications equipment (transmitters) and the iLED<sup>®</sup> 7 lighting system, as recommended below in accordance with the communications equipment's maximum output.

Rated output of the transmitter W	Separation distance according to transmission frequency m			
	150 kHz to 80 MHz d = 1.2√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5 GHz d = 2.3√P	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitters with a nominal power not found in the table above, the distance can be calculated using the equation for the respective column, where P is the nominal power of the transmitter in watts (W) according to the transmitter manufacturer's data.

#### Note 1:

To calculate the recommended separation distance of transmitters in the frequency range from 80 MHz to 2.5 GHz, an additional factor of 10/3 is used in order to reduce the likelihood that a mobile / portable communications device unintentionally brought into the PATIENT area will cause any interference.

### Note 2:

These guidelines might not be applicable in all situations. The propagation of electromagnetic waves is influenced by the absorptions and reflections of buildings, objects and human beings.

#### EMC-relevant wireless properties of the lighting system

NOTE

#### Interference caused by other devices

The iLED<sup>®</sup> 7 lighting system can experience interference from other devices, even if these devices comply with the CISPR-defined transmission requirements applicable to them.



The table below can be subject to country-specific restrictions.

Table: WLAN properties

Bandwidth	20 MHz or 40 MHz
Frequencies	2412 MHz – 2484 MHz 4910 MHz – 5825 MHz
Modulation	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS
Transmission power	18 dBm

### 16.3.2 WallControl Panel

ΝΟΤΕ

The WallControl Panel must not be arranged in a stacked manner immediately next to or with other devices.

Guidelines and manufacturer's declaration - ELECTROMAGNETIC EMISSIONS

The WallControl Panel has been designed for operation in one of the ELECTROMAGNETIC ENVIRONMENTS described below. The customer or user of the WallControl Panel should ensure that it is operated in such an environment.

Emissions measurements	Compliance	ELECTROMAGNETIC ENVIRONMENT - guidelines
HF emissions in accordance with CISPR 11	Group 1	The WallControl Panel (iLED <sup>®</sup> 7 control system) uses HF energy only for its internal FUNCTIONING. Therefore its HF emissions levels are very low and it is improbable that neighboring devices would be affected by interference.
HF emissions in accordance with CISPR 11	Class A	The properties of this device determined by its TRANSMISSIONS allow its use in the industrial sector
Harmonic emissions as per EN / IEC 61000-3-2	Class A	and in hospitals (CISPR 11, Class A). When used in a domestic setting (for which according to CISPR 11 Class B is usually required),
Voltage fluctuations / flickers in accordance with EN / IEC 61000-3-3	satisfied	this device may not provide adequate protection from radio services. The user must, if necessary, take remedial measures such as the relocation or realign- ment of the device.



### Guidelines and manufacturer's declaration - electromagnetic immunity

NOTE

### Avoid environments with electromagnetic fields and interference stronger than those listed below

#### Guidelines and manufacturer's declaration - ELECTROMAGNETIC IMMUNITY

The WallControl Panel (iLED<sup>®</sup> 7 control system) has been designed for operation in one of the ELECTROMAGNETIC ENVIRONMENTS described below. The customer or user of the WallControl Panel (iLED<sup>®</sup> 7 control system) should ensure that it is operated in such an environment.

Immunity tests	EN / IEC 60601 test level	Compliance level	ELECTROMAGNETIC ENVIRONMENT - guidelines
Static electricity 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	Floors should be made from wood or concrete or covered with ceramic tiles. If a floor is covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transient disturbances/bursts in accordance with EN / IEC 61000-4-4	±2 kV for power lines ±1 kV for input and output lines 100 kHz repeat frequency	±2 kV for power lines ±1 kV for input and output lines 100 kHz repeat frequency	The supply voltage quality should correspond to that in a typical business or hospital environment.
Impulse voltages / surges in accordance with EN / IEC 61000-4-5	±1 kV outer conductor - outer conductor voltage ±2 kV outer conductor - ground voltage	±1 kV outer conductor - outer conductor voltage ±2 kV outer conductor - ground voltage	The supply voltage quality should correspond to that in a typical business or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines pursuant to EN / IEC 61000-4-11	0% UT; 0.5 cycle <sup>a)</sup> 0% UT; 1 cycle 70% UT; 25/30 cycles <sup>b)</sup> 0% UT; 250/300 cycles <sup>b)</sup>	0% UT; 0.5 cycle <sup>a)</sup> 0% UT; 1 cycle 70% UT; 25/30 cycles <sup>b)</sup> 0% UT; 250/300 cycles <sup>b</sup>	The supply voltage quality should correspond to that in a typical business or hospital environment.
Magnetic field with a supply frequency (50/ 60 Hz) as per 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.
<sup>a)</sup> at 0°, 45°, 90°, 135°, 180 <sup>b)</sup> at 0° Comment: UT is the suppl	)°, 225°, 270° and 315° y voltage prior to applyin	g the test levels.	



Guidelines and manufacturer's declaration - electromagnetic immunity / portable and mobile radio units

**WARNING** 

Distance for portable RF communications equipment and its peripherals

Portable and mobile radio units must not be used at a distance from the WallControl Panel (iLED<sup>®</sup> 7 control system), including cables, less than the recommended protection ratio calculated on the basis of the transmission frequency equation.

### NOTE

The WallControl Panel (iLED<sup>®</sup> 7 control system) lighting system is not designed for use close to HF surgical equipment. It has been tested in regard to interference immunity exclusively against radiated fields in the electromagnetic environment set out below, which corresponds to a professional healthcare facility for healthcare.

Interference immunity test	EN / IEC 60601-1 test level	Compliance level		
Conducted HF disturbance variables as per EN / IEC 61000-4-6	3 V 0.15 MHz – 80 MHz	3 V 0.15 MHz – 80 MHz		
	6 V In the ISM band between 0.15 MHz and 80 MHz a)	6 V In the ISM band between 0.15 MHz and 80 MHz a)		
Radiated HF disturbance variables as per EN / IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz	10 V/m 80 MHz – 2.7 GHz		
$a^{3}$ = The ISM bands (ISM = industrial, scientific and medical) between 0.15 MHz and 80 MHz are 6.765 MHz to				

<sup>a</sup> = 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 bands 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 levels for RF fields of wireless communications equipment

Table: Special frequencies

Test Fre- quency (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
75						
780						
810	800 – 960	GSM 800/900	Pulse modulation 18 Hz	2	0.3	28
870		IEIRA 800 IDEN 820				
930		CDMA 850 LTE band 5				
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 HF disturbance variables**

Recommended separation distances between portable and mobile HF communication devices and the WallControl Panel

The WallControl Panel (iLED<sup>®</sup> 7 control system) has been designed for operation in an ELECTROMAGNETIC ENVIRONMENT in which radiated HF disturbance variables are controlled. The customer or user of the WallControl Panel (iLED<sup>®</sup> 7 control system) can help to prevent electromagnetic interference by complying with the minimum distances between portable and mobile HF telecommunications equipment (transmitters) and the WallControl Panel (iLED<sup>®</sup> 7 control system), as recommended below in accordance with the communications equipment's maximum output.

Rated output of the transmitter	Separation distance according to transmission frequency (m)			
(W)	150 kHz to 80 MHz d = 1.2√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5 GHz d = 2.3√P	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitters whose maximum rated power is not indicated in the table above, the recommended separation distance D in meters (m) can be determined by means of the equation assigned to the corresponding column; P represents the maximum rated power of the transmitter in watts (W) in accordance with the transmitter manufacturer's specifications.

Note 1:

To calculate the recommended separation distance of transmitters in the frequency range from 80 MHz to 2.5 GHz, an additional factor of 10/3 is used in order to reduce the likelihood that a mobile / portable communications device unintentionally brought into the patient area will cause any interference. Note 2:

These guidelines might not be applicable in all situations. The propagation of electromagnetic waves is influenced by the absorptions and reflections of buildings, objects and human beings. Note 3:

For 80 MHz and 800 Hz, the higher frequency range applies.

### **WARNING**

Distance for portable RF communications equipment and its peripherals

Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) at a distance of less than 30 cm (12 in) from the WallControl Panel (iLED<sup>®</sup> 7 control system), including its cables, that have been specified by the manufacturer. Otherwise, the system's functionality can be impaired.



### EMC-relevant wireless properties of the WallControl Panel (iLED® 7 control system)

NOTE

Interference caused by other devices

The WallControl Panel (iLED<sup>®</sup> 7 control system) can experience interference from other devices, even if these devices comply with the CISPR-defined transmission requirements applicable to them.

The table below can be subject to country-specific restrictions.

Table: WLAN properties

Bandwidth	20 MHz or 40 MHz
Frequencies	2412 MHz – 2484 MHz 4920 MHz – 5825 MHz
Modulation	OFDM with BPSK, QPSK, 16-QAM and 64-QAM 802.11b with CCK and DSSS
Wi-Fi transmission power	18 dBm for 802.11b DSSS 17 dBm for 802.11g/n OFDM 15 dBm for 802.11a/g/n OFDM



Accessories	<ul> <li>TruVidia<sup>®</sup> Wireless Video Camera</li> </ul>	1940442
	<ul> <li>TruVidia<sup>®</sup> Wireless Receiver</li> </ul>	1940747
	<ul> <li>WallControl -Preinstall Set FLUSH</li> </ul>	1956143
	<ul> <li>WallControl -Preinstall Set SURFACE</li> </ul>	1956144
	<ul> <li>WallControl-Universal Front Interf.</li> </ul>	1956146
	<ul> <li>Control incl. bumper</li> </ul>	1992609
	– Dock-Desk	1839155
	<ul> <li>iLED<sup>®</sup> 7 RS 232 interface config</li> </ul>	2065004
Components	– iled® 7	4047000
	– iled® 7	4047020
	<ul> <li>iLED<sup>®</sup> 7 preassembly set</li> </ul>	4068051
	– Axis 1f ZA 850, 3p	1470954
	– Axis 2f ZA 850/1000, 3p/3p	1470957
	– Axis 2f ZA 850/1000, 3p/STOP	1470958
	<ul> <li>Axis 3f ZA 700/850/1000, 3p/3p/STOP</li> </ul>	1470959
	– Axis 1f ZA 1150, 3p	1470960
	<ul> <li>Axis 3f ZA 700/850/1000, STOP/3p/3p</li> </ul>	1470966
	<ul> <li>Axis 3f ZA 700/850/1000, 3p/3p/3p</li> </ul>	1470967
	<ul> <li>Axis 3f ZA 700/850/1000, STOP/3p/STOP</li> </ul>	1470969
	<ul> <li>Axis 2f ZA 1000/1150, STOP/3p</li> </ul>	1470997
	– Axis 2f ZA 1000/1150, 3p/STOP	1470999
	– Axis 1f ZA 1000, 3p	1471346
	<ul> <li>Axis 2f ZA 850/1000. STOP/7P</li> </ul>	1529528
	– Axis 1f ZA 700. 3p	1561452
	- Axis 1f SlimLine 750. 3p + AC2	1622050
	– Axis 1f ZA 1750. 3p	1622052
	<ul> <li>Axis 2f ZA 1600-1750. Stop-3p</li> </ul>	1623198
	– Axis 1f ZA 1600. 3p	1623236
	<ul> <li>Axis 2f ZA 1450-1600. Stop-3p</li> </ul>	1623250
	<ul> <li>Axis 2f ZA 1450-1600, 3p-3p</li> </ul>	1623254
	<ul> <li>Axis 2f ZA 1150-1300, Stop-3p</li> </ul>	1623255
	- Axis 2f ZA 1150-1300, 3p-3p	1623260
	- Axis 1f ZA 1300. 3p	1623261
	- Axis 4f 7A 700-1000/1150 STP/3n/3n/STP	1631605
	- Axis 1f 7A 1450 3n	1633538
	- Axis 2f SlimLine $800/950 - 3n/3n$	1650050
	- Axis 4f 7A 700-1150 3n/3n/3n/STOP	1694913
	<ul> <li>Axis 17 Z4 700 1100, 50, 50, 50, 50, 50, 50, 50, 50, 50,</li></ul>	1804366
	- Axis 2f 7A 850/1000 STOP/3n	0281812
	- Axis 1f  M/1 = 600,  STOP + FA AC2	0381180
	- Avis 1f WL 600, STOL FTA AC2	0204403
	- Avis 2f 7A 850/1000/1150  2n/2n/2n	0304430
	-  Avic 2f 7A 850/1000/1150 $2n/2n/2n/2000$	0300047
	$= A_{X13} S1 2A S50/1000/1150, SP/SP/S10P$ $= A_{X13} S1 2A S50/1000/1150 ST0P/3n/3n$	0300049
	- AXIS SI ZA 65U/1UUU/115U, SI UP/3P/3P	0380823

# 17.1 iLED<sup>®</sup> 7 components and accessories



<ul> <li>Axis 3f ZA 850/1000/1150, STOP/3p/STOP</li> </ul>	0386854
<ul> <li>Axis 2f ZA 1000/1150, 3p/3p</li> </ul>	0387058
– FA AC2000 3p, 12-18kg	1471010
<ul> <li>FA AC2000 NRH 3p, 12-18kg</li> </ul>	1471012
<ul> <li>FA AC2000 NRH mobile 3p 12-18kg</li> </ul>	0384021
<ul> <li>iLED<sup>®</sup> 7 ¼ bracket compact cpl.</li> </ul>	1987401
<ul> <li>iLED<sup>®</sup> 7 comfort bracket compact cpl.</li> </ul>	1987403
<ul> <li>230V OPL control cabinet section cpl.</li> </ul>	1937988
<ul> <li>– 24 V iLED<sup>®</sup> 7 control cabinet section cpl</li> </ul>	1938216
<ul> <li>230V/230V OPL control cabinet section cpl.</li> </ul>	1943610
<ul> <li>24V/24V iLED<sup>®</sup> 7 control cabinet section cpl</li> </ul>	1943622
<ul> <li>– 230V/24V iLED<sup>®</sup> 7 control cabinet section cpl</li> </ul>	1943623
<ul> <li>Control cabinet section cover cpl</li> </ul>	1982041
<ul> <li>Mounting housing for SSP single</li> </ul>	1536239
<ul> <li>Mounting housing for SSP double1536240</li> </ul>	
<ul> <li>Canopy control cabinet section cover plate</li> </ul>	1998751
<ul> <li>Sterilizable central hand grip</li> </ul>	4023312
<ul> <li>Sterilizable camera hand grip</li> </ul>	1580889
<ul> <li>Sterilizable ALC hand grip</li> </ul>	1583966
<ul> <li>Disposable hand grip adapter</li> </ul>	2066135
<ul> <li>iLED<sup>®</sup> 7 standard hand grip adapter / TL</li> </ul>	2065945
<ul> <li>SLC hand grip cpl.</li> </ul>	2065726
<ul> <li>Sterilizable ALC hand grip, pack of 3</li> </ul>	1660214
<ul> <li>Sterilizable central hand grip, pack of 3</li> </ul>	4025708
<ul> <li>Sterilizable camera grip, pack of 3</li> </ul>	4025709
<ul> <li>Control bumper</li> </ul>	1835271
<ul> <li>Control bumper pack (3 pcs)</li> </ul>	1887193
<ul> <li>SteriTablet 240x340 mm</li> </ul>	1881617
<ul> <li>FA AC2000 stop 3.5-7 kg</li> </ul>	1471018
<ul> <li>FA AC2000 stop 6-11 kg</li> </ul>	1471016
<ul> <li>FA AC2000 stop 12-18 kg</li> </ul>	1471011
<ul> <li>FA AC3000 stop, 12-18 kg</li> </ul>	4024214
– FA AC3000 stop (17-26 kg)	1419354
<ul> <li>FA AC3000 stop 23-30 kg</li> </ul>	4025574
<ul> <li>FA AC5000 stop max 15 kg</li> </ul>	4025575
<ul> <li>FA AC5000 stop 15-32 kg</li> </ul>	4024215
<ul> <li>FA102-TR/FA AC2000MAVIG Portegra2 6-11 kg</li> </ul>	1982310
<ul> <li>FA402-TR/FA AC2000MAV. Portegra2 12-18 kg</li> </ul>	1982311
<ul> <li>VidiaPort holder 2000, single monitor</li> </ul>	1714801
<ul> <li>VidiaPort holder 3000, single monitor</li> </ul>	1714802
<ul> <li>VidiaPort holder 3000, duo monitor</li> </ul>	1714803
<ul> <li>VidiaPort holder 5000, duo monitor</li> </ul>	1714804
<ul> <li>VidiaPort holder 5000, single monitor</li> </ul>	1714805
<ul> <li>VidiaPort bracket 2000, VESA 100, with</li> </ul>	6003784
<ul> <li>Power supply extension cable</li> </ul>	1713291
<ul> <li>Earthing cable for VidiaPort monitor holder</li> </ul>	1774337
-	



<ul> <li>VidiaPort adapter cpl</li> </ul>	2020629
<ul> <li>GTP8 adapter VidiaPort 2000</li> </ul>	0377609
<ul> <li>GTP8 adapter VidiaPort 3000</li> </ul>	0377610
<ul> <li>E-OT25B05 Portegra2 radiation protector 76x60</li> </ul>	2005395
<ul> <li>E-OT54B01 Portegra2 radiation protector 78x90</li> </ul>	2005442
<ul> <li>– 19" FSN medical display</li> </ul>	1812820
<ul> <li>26" HD FSN medical display</li> </ul>	1844095
<ul> <li>– 24" FSN medical display</li> </ul>	1975566
<ul> <li>32" High-Bright LED medical display</li> </ul>	2068217

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