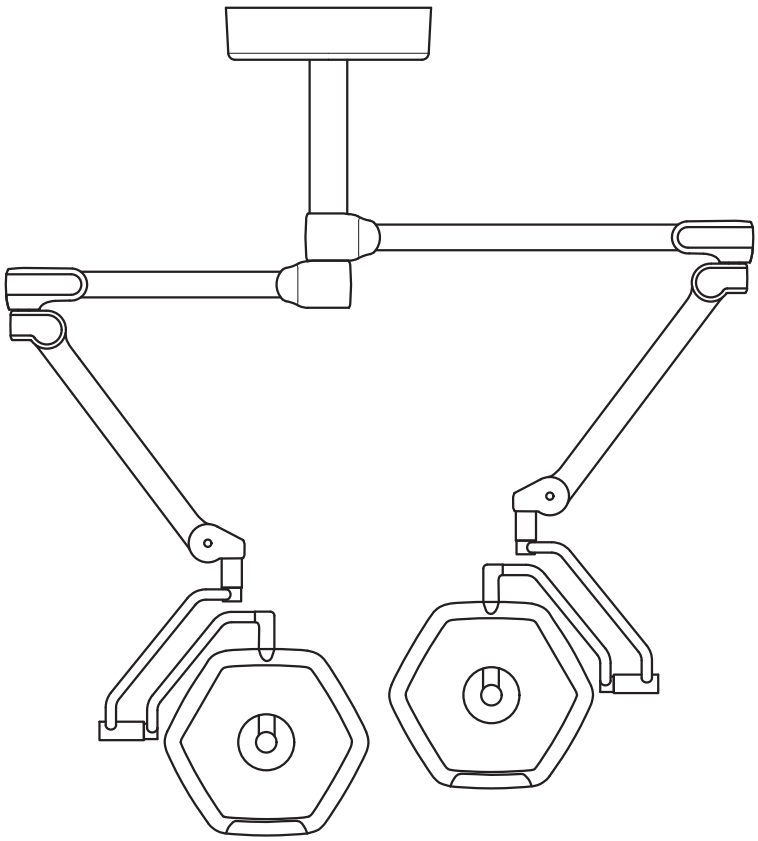
Instructions for use

iLED 7

Surgical light



Read the instructions for use carefully before using the product and keep it safe for future reference.

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en-US

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Manufacturer

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Baxter Medical Systems GmbH + Co. KG is a Baxter International Inc. company. The manufacturer is hereinafter referred to as Baxter.

Technical Customer Service

The contact details for the current Technical Customer Service hubs in the individual countries are listed on the Internet at www.hillrom.com.

Information about the document

Original instructions for use

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These instructions for use are included in paper form in the scope of the product supply.

This document applies to the following sales units:

Product designation	Part number
iLED 7 Ceiling Single	4068110
iLED 7 Mobile	4068120
iLED 7 Pendant	4068140
iLED 7 Ceiling Duo	4068210
iLED 7 Ceiling Trio	4068310
iLED 7 Ceiling Quad	4068410

Supporting documents

The products listed are individually combined with various Baxter products. Section 2.2 lists the compatible products along with their associated instructions for use. The instructions for use of all the products used then apply.

The following additional documents are available online under ois.hillrom.com/ois:

Product designation	Document number
Radio Information	7990103
SVHC list (Substances of Very High Concern)	–

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Basic information

After purchase, the product is handed over to the operator in an appropriate and professional manner. Handover is performed by someone authorized by the manufacturer and is documented using a handover protocol.

Check the packaging on delivery for damage sustained during transport. If damage is noticed before unpacking, contact the Technical Customer Service.

Before using the product, familiarize yourself with the settings options and how to operate the product. Observe the information notices on the product.

About the instructions for use

- These instructions for use contain important information about the safe and effective use of this product.
- The instructions for use are part of the product and must be complied with.
- Read the instructions for use carefully and fully before using the product. The instructions for use must be thoroughly understood. In the event of uncertainty or questions about the product, please contact the manufacturer.
- The instructions for use must also be handed over in the event of a change of location or personnel.
- The instructions for use must be kept where the product is used.
- The instructions for use must be easily accessible in full to all users of the product at all times.
- The figures in the instructions for use are highly simplified and are intended to provide a basic understanding.
- Residual dangers that may occur while using the product are identified in the document with a signal word. The safety measures required and potential consequences of failing to take these are listed. A corresponding signal word provides information about the severity of the danger:

Signal word	Meaning
DANGER	This signal word indicates a dangerous situation that will immediately lead to death or serious injury if no precautionary measures are taken.
WARNING	This signal word indicates a dangerous situation that may lead to death or serious injury if no precautionary measures are taken.
CAUTION	This signal word indicates a dangerous situation that may lead to moderate to slight injury if no precautionary measures are taken.
NOTICE	This signal word indicates a dangerous situation that may lead to material damage or damage to the environment if no precautionary measures are taken.

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Contents

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1 Usage specifications

1.1 Normal use

The surgical light system can have up to four support arms with up to three lamp heads. In addition to the lamp heads, other products can also be attached using a spring arm (e.g. VidiaPort spring arm with monitor holder and monitor).

It is possible to attach a camera, depending on the lamp head.

The surgical light can be moved in a sterile manner by using a sterile handle and be controlled in line with the version of the handle and the lamp head.

The specifications and guidelines of the manufacturer must always be adhered to.

1.2 Intended purpose

The product is used for visual illumination of the operating field or the patient.

1.3 Contraindication

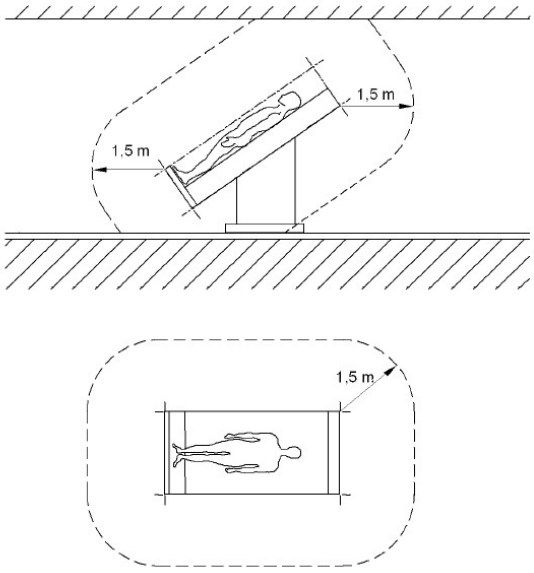
There are no known contraindications.

1.4 Patient definition

No limitations in terms of patient age, gender or other physiognomic features are imposed.

1.5 Patient environment

The measurements in the following image show the minimum extent of the patient environment in an unlimited environment.



1.6 Improper use

- The light suspension unit must not be exposed to additional loads.
- The surgical light may not be exposed to strong vibrations.
- The surgical light system must not be used for investigatory and diagnostic purposes.

1.7 User definition

The users must be authorized for the use and service of the product. Users can be sterile and non-sterile employees in the operating room, such as surgeons, nurses, cleaning personnel, as well as service, maintenance and hospital technicians.

1.8 Usage environment

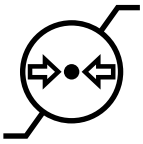
Temperature:	+10°C to +35°C / +50°F to +95°F
Air humidity:	30% to 75%
Atmospheric pressure:	70 kPa to 106 kPa / 10 psi to 15 psi
Operating altitude:	Up to 3,000 m / 9,843 ft above sea level

For integrated systems with RS232 interface, a maximum operating altitude of 2000 m / 6562 ft above sea level applies.

1.9 Ambient conditions for storage and transport

Temperature: -20°C to +40°C / -4°F to +104°F
A maximum storage temperature of +60°C / +140°F applies for the lamp head.

Air humidity: 5% to 95%



Atmospheric pressure: 50 kPa to 106 kPa / 7 psi to 15 psi

Fragile contents

Top

Keep dry

1.10 Service life

The service life with normal use is:

Product	Service life
Lamp head (without cover panel)	10 years
Support arm system	10 years
Wall Control Panel	5 years
Mobile Control 7,9 (third-party component)	2 years

2 Safety

2.1 Configuration

The configuration of a surgical light with the listed products was tested by Baxter and subjected to a compliance assessment.

- Various canopies
- Various central axes with booms

Spring arm

Product designation	Part number
L21, 3P Springarm	2077410
L21, 9P Springarm	2077411
LCH19, 3P Springarm	2077412
LCH19, 9P Springarm	2077413

Lamp head

Product designation	Part number
iLED 7	4047020

Handle adapter

Product designation	Part number
SLC Handle	2065726
Adaption Standard handle	2065945
Adaption disposable handle	2066135

Product designation	Part number
Handle sleeve flange type short	2079288
Handle sleeve flange type middle	2079289
Handle sleeve flange type long	2078603
Handle sleeve ring type short	2079287
Handle sleeve ring type long	2079336

Control module

Product designation	Part number
TR Wall Control	1992610
TR WallControl -striking front interface	2069207

Component

Product designation	Part number
RS232 Interface iLED 7	2065004

2.2 Combination with other products from Baxter

Baxter offers a wide variety of products for further equipping of the surgical light. Not all products are available in all countries. Detailed information can be obtained from the relevant representative offices of Baxter, which are represented worldwide. Contact details are available online at hillrom.com.

Use of the surgical light is permitted in combination with the following Baxter products. The products are described in separate instructions for use, which must be read carefully and in full. The document number of the instructions for use is listed in the column on the right.

Pre-assembly set

Product designation	Part number	Document number
Pre-Install Set iLED 7	4068051	7990000

Ceiling-mounted supply unit

Product designation	Part number	Document number
FCS 300 Electro Cube	1971846	7990082
FCS 700 Ceiling Supply Unit Solo/ TanPrep	4037210	7990001
TruPort Ceiling Mounted Support System		55000-00001
FCS 700 Ceiling Supply Unit TanAdd	4037220	7990001
TruPort Ceiling Mounted Support System		55000-00001
FCS 500 Ceiling Carrier ML Solo/ TanPrep	4037251	7990002
FCS 500 Ceiling Carrier ML TanAdd	4037252	7990002
FCS 500 Ceiling Carrier HL Solo/ TanPrep	4037261	7990002
FCS 500 Ceiling Carrier HL TanAdd	4037262	7990002

Camera

Product designation	Part number	Document number
TruVidia Wireless Camera	1940442	7990007
TruVidia Wireless Receiver	1940747	7990007

Support arm

Product designation	Part number	Document number
VidiaPort Springarm Bottom	4028150	7990089
VidiaPort Springarm Middle	4028152	7990089
VidiaPort Springarm Top	4028155	7990089

Sterilizable handle

Product designation	Part number	Document number
Sterilizable ALC Handle, 3 pcs	1660214	7990009
Sterilizable Central Handle, 3 pcs	4025708	7990009
Sterilizable Camera Handle, 3 pcs	4025709	7990009

2.3 Combination with products from other manufacturers

Use of the surgical light is permitted in combination with the following MAVIG products.

Product designation	Manufacturer part number	Part number
E-OT25B05 Portegra 2 radiation protection 76x60	E-OT25B05	2005395
FA102-TR spring arm	FA102-TR	1982310
E-OT54B01-TR Portegra 2 radiation protection 78x90	E-OT54B01-TR	2005442
FA402-TR spring arm	FA402-TR	1982311

The surgical light may be operated in combination with the following products.

Product designation	Part number
Mobile Control 7,9	2073425
Catalyst Case iPad Mini 5	2074252
Interface Converter SILEX SD-330AC	2076027

The surgical light is not designed for combination with products from other manufacturers (third-party products) and no compatibility tests have been carried out by Baxter. Exceptions are explicitly mentioned in these instructions for use. Baxter does not, however, exclude the combination of third-party products. If the operator intends to combine the surgical light with third-party products, the operator is responsible for this combination. Baxter accepts no responsibility for the combination of the surgical light with third-party products. The guarantee/warranty for products from Baxter may become void in the event of their combination with third-party products.

2.4 Operator's responsibility

The operator is the natural or legal person who operates the product himself for commercial or economic purposes or who leaves its operation to a third party. The operator bears the legal product responsibility for protecting personnel or third parties.

The medical device may only be operated and applied according to its intended purpose and the general rules of technology. Medical devices may only be used by persons who have the training or knowledge required to do this.

Instructions regarding the proper handling of the medical device must be provided. However, training is not required when the medical device is self-explanatory or instructions for a product with the same design have already been provided.

Interconnected medical products, as well as those combined with accessories, including software or other objects, may be operated and used only if they are suitable for use in this combination, taking into account their intended purpose and the safety of patients, users, employees or third parties.

Before the medical device is applied, the user must ensure that the product is operational and in an appropriate state and the user must further have read the instructions for use as well as other, attached, safety-relevant information and maintenance instructions.

The instructions for use and the instructions provided with the medical device must be stored in a way that ensures that the user can access the information required for using the medical device at any time.

The user and/or the patient must report any serious incidents related to the use of the medical device to the manufacturer and the relevant authorities of the member state of which the user and/or the patient is a resident.

2.5 Malfunction caused by other devices

There are no known functional failures of the surgical light due to other devices.

2.6 What to do in the event of a malfunction

In the event of a failure of the electrical functions of the surgical light, the surgical light is to be disconnected from the power supply and the Technical Customer Service notified.

2.6.1 Failure of the surgical light electrical functions

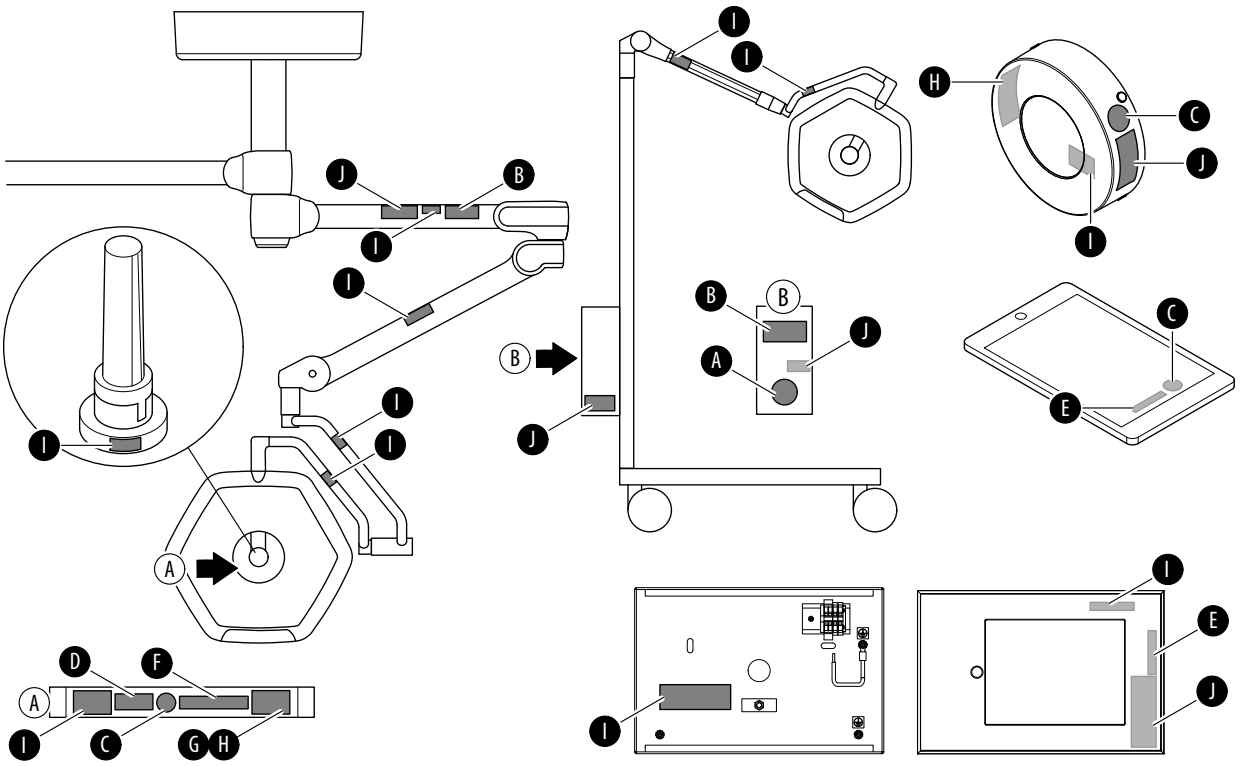
According to current state-of-the-art technology, failure of the surgical light cannot be completely ruled out, with the result that the electrical functions on the operating table are no longer available. In this rare case, stop using the surgical light and notify the Technical Customer Service.

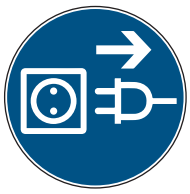
2.7 Information notices

2.7.1 Safety instructions

- The information notices on the product provide information about residual dangers during use, or provide additional useful information.
- The device label and all information notices must be present and be undamaged in the prescribed locations on the product. A damaged, illegible or missing device label / information notice must be replaced immediately.
- Observe the information notices on the product.
- The information notices must not be altered or removed.

2.7.2 Position and meaning



No.	Information notice	Meaning
[A]		Pull the mains power plug out of the socket before opening the housing.
[B]	Baxter	Manufacturer’s logo
[C]		Follow the instructions for use
[D]		Laser identification 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).
[E]		Current software version of the operating units
[F]		UL mark: device tested by Underwriter Laboratories Inc. for use in the USA and Canada

No.	Information notice	Meaning
[G]	–	PATENTS/PATENT hillrom.com/patents May be subject to one or more patents. See website address above. Hillrom companies are the holders of European, US and other patents, as well as pending patent applications.
[H]	Not available	–
[I]	Device label for the individual component	
[J]	Device label of the surgical light system	
		Manufacturer
UDI		Unique device identification (UDI), comprising: – Data Matrix Code – (01) Global Trade Item Number (GTIN) – (11) Date of manufacture (Year Month Day) – (21) Serial number – (240) Part number
REF		Baxter part number
SN		Serial number
MD		Medical product
CE		The device conforms to Regulation 2017/745/EU concerning medical devices.
		Caution! Follow the warnings in the instructions for use!
		The product must be disposed of at a suitable disposal facility for the recycling of electrical and electronic devices in accordance with the requirements of Directive WEEE II 2012/19/EU and country-specific regulations.
variable		Radio license For detailed information, refer to Document 7990103 (Radio Information).
		Date of manufacture

3 Overview

The surgical light can be individually combined from various Baxter products. The approved products are listed in Chapter 2.2.

The surgical light system is a modular system.

Different variants are available:

iLED7 Ceiling Single/Duo/Trio/Quad

- mounted on a ceiling mount
- combined with a maximum of 3 VidiaPort spring arms but a maximum of 4 support arms per central axis in total
- with at least 1 light head or a maximum of 3 light heads per central axis

iLED7 Pendant

- in combination with an FCS 500 monitor support or with a FCS 700/TruPort ceiling-mounted supply unit
- mounted on the Pendant Adapter of the FCS/TruPort

iLED7 Mobile

- mounted on a mobile frame

4 Description

iLED 7 surgical lights are available in the Single, Duo, Trio, Quad, Mobile and Pendant variants with different boom lengths and spring arms.

The Single, Duo, Trio, Quad and Pendant variants are ceiling-mounted versions with support arms.

With the iLED 7 Ceiling Single/Duo/Trio/Quad variants, the light head is attached to the ceiling in combination with a pre-assembly set and a VidiaPort support arm system. Single, double, triple and quadruple axes are available with S or C booms.

With the iLED 7 Pendant variant, the light head is attached to the ceiling in combination with an FCS/TruPort support arm system.

The Mobile variant is a mobile single light with a spring arm.

With the support arm system and with the mobile variant with the spring arm, the light head can be positioned as desired and precisely pointed at the wound area.

The surgical light is operated with the control on the lamp head or with a separate control module. The light system can be individually adjusted with the following functions:

- Light field size
- Lighting intensity
- ALC Plus (Adaptive Light Control Plus)
- Color temperature
- Shadow management
- Synchronization (not for Mobile variant)
- Radio connection and safe mode (not for Mobile variant)

The surgical light emits infrared light. The infrared radiation of the 3D sensor can interfere with the infrared radiation of other devices that communicate in the same wave length range. The essential functions of the surgical light are, however, not affected by the interference.

4.1 Overview of surgical light

4.1.1 iLED 7 Ceiling Trio surgical light system

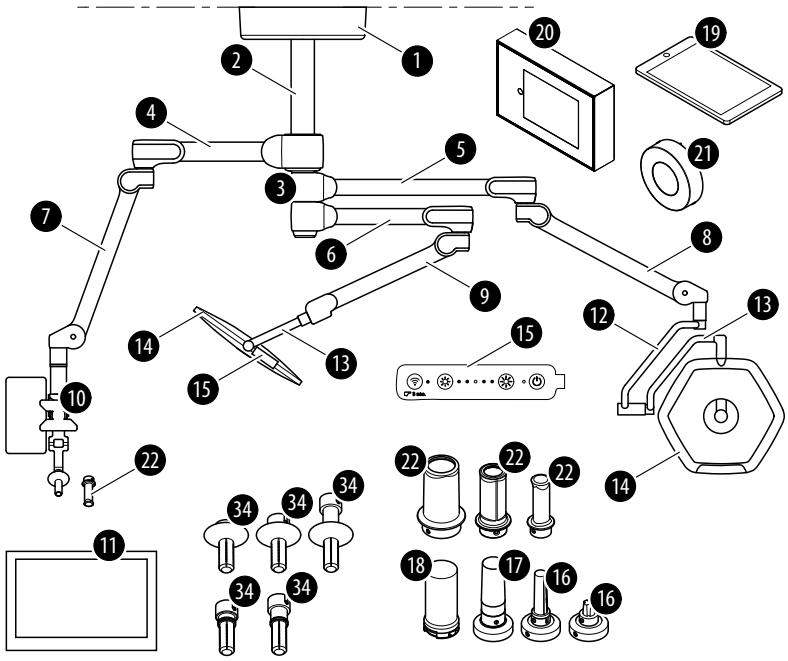
The iLED 7 Ceiling Trio surgical light system (example shown below) consists of the following components:

- the canopy [1]
- the ceiling conduit [2] (part of the Pre-Install Set iLED 7) and the central axis [3]
- a horizontally rotating upper C boom [4] on the central axis with a horizontally and vertically adjustable MD26+ spring arm [7] (VidiaPort Springarm Top)
- a horizontally rotating middle S boom [5] on the central axis with a horizontally and vertically adjustable L21 spring arm [8]
- a horizontally rotating lower S boom [6] on the central axis with a horizontally and vertically adjustable LCH19 spring arm [9]
- a monitor mount (VidiaPort monitor Holder Single) [10] on the upper boom for mounting a flat screen

– two horizontally rotating and vertically adjustable light heads [14]

In the example, the iLED 7 Ceiling Trio surgical light system is equipped with the following additional accessories of Baxter and the following third-party products:

– an SLC handle adapter [17] or handle adapter [16]
– a TruVidia Wireless camera [18] or a handle adapter [16]
– a sterilizable handle [22] for the monitor mount [10]
– a Handle sleeve [34] handle adapter and a sterile disposable handle/disposable sleeve for the monitor mount [10] (after prior conversion by a qualified service technician)
– a sterilizable handle [22] for the TruVidia camera system [18] or the handle adapter [16]
– a Handle sleeve [34] handle adapter and a sterile disposable handle/disposable sleeve for the Adaption disposable handle [16] handle adapter on the light head mount
– a sterilizable handle [22] for the SLC handle adapter [17] or the handle adapter [16]
– a Handle sleeve [34] handle adapter and a sterile disposable handle/disposable sleeve for the Adaption disposable handle [16] handle adapter on the light head mount
– a medical flat screen [11] (product from a third-party manufacturer)
– a Wall Control Panel [20]
– an RS232 interface [21]
– a Mobile Control 7,9 control module [19] (product from a third-party manufacturer)



[1] Canopy
[2] Ceiling conduit
[3] Central axis
[4] Upper C boom
[5] Upper S boom

[6] Lower S boom
[7] Spring arm
(MD26+)
[8] Spring arm
(L21)
[9] Low room height spring arm
(LCH19)
[10] Monitor mount
(VidiaPort Monitor Holder Single and VidiaPort Monitor Holder Box)
[11] Flat screen
[12] iLED 7 comfort bracket
[13] 1/4 bracket iLED 7
[14] Lamp head
[15] Control element
The functions available on the control are limited.
[16] Handle adapter
(Adaption Standard handle/Adaption disposable handle)
[17] SLC Handle Adapter
[18] TruVidia wireless camera
[19] Mobile Control 7,9
[20] Wall Control Panel
[21] RS232 interface
[22] Sterilizable handle
(Sterilizable ALC Handle, 3 pcs/Sterilizable Central Handle, 3 pcs/Sterilizable Camera Handle, 3 pcs)
[34] Disposable handle adapters
(Handle sleeve flange type short/Handle sleeve flange type middle/Handle sleeve flange type long/Handle sleeve ring type short/Handle sleeve ring type long)

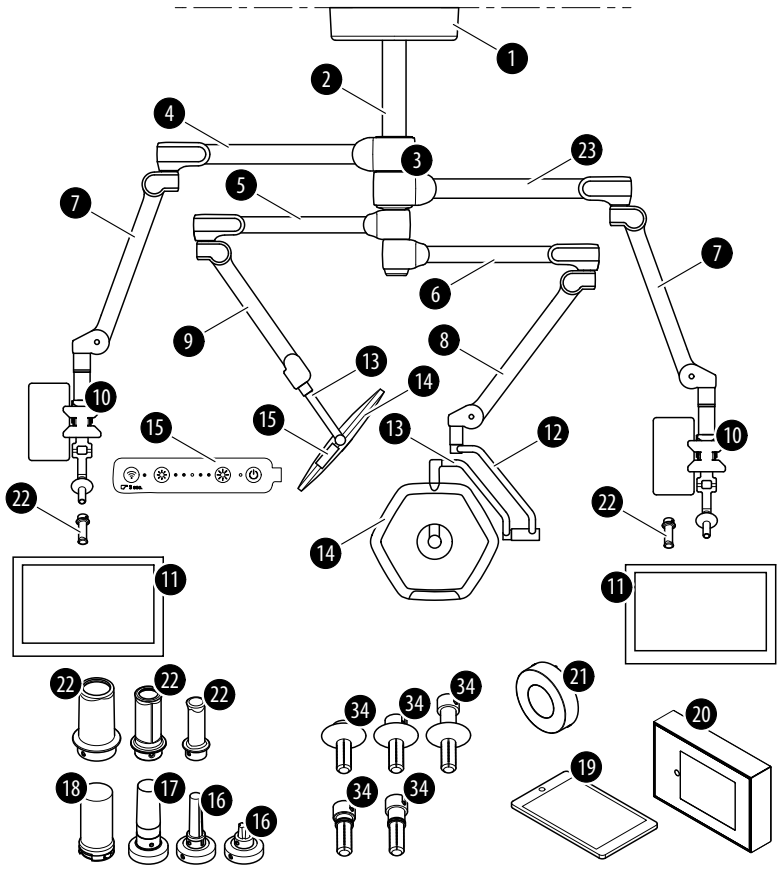
4.1.2 iLED 7 Ceiling Quad surgical light system

The iLED 7 Ceiling Quad surgical light system (example shown below) consists of the following components:

- the canopy [1]
- the ceiling conduit [2] (part of the Pre-Install Set iLED 7) and the central axis [3]
- a horizontally rotating upper C boom [4] on the central axis with a horizontally and vertically adjustable MD26+ spring arm [7] (VidiaPort Springarm Top)
- a horizontally rotating lower C boom [23] on the central axis with a horizontally and vertically adjustable MD26+ spring arm [7] (VidiaPort Springarm Middle)
- a horizontally rotating upper S boom [5] on the central axis with a horizontally and vertically adjustable LCH19 spring arm [9]
- a horizontally rotating lower S boom [6] on the central axis with a horizontally and vertically adjustable L21 spring arm [8]
- two monitor mounts (VidiaPort Monitor Holder Single) [10] on the C booms for mounting a flat screen each
- two horizontally rotating and vertically adjustable light heads [14]

In the example, the iLED 7 Ceiling Quad surgical light system is equipped with the following additional accessories of Baxter and the following third-party products:

- an SLC handle adapter [17] or handle adapter [16]
- a TruVidia Wireless camera [18] or a handle adapter [16]
- two sterilizable handles [22] for the monitor mounts [10]
- two Handle sleeve [34] handle adapters and two sterile disposable handles/disposable sleeves for the monitor mounts [10] (after prior conversion by a qualified service technician)
- a sterilizable handle [22] for the TruVidia camera system [18] or the handle adapter [16]
- a Handle sleeve [34] handle adapter and a sterile disposable handle/disposable sleeve for the Adaption disposable handle [16] handle adapter on the light head mount
- a sterilizable handle [22] for the SLC handle adapter [17] or the handle adapter [16]
- a Handle sleeve [34] handle adapter and a sterile disposable handle/disposable sleeve for the Adaption disposable handle [16] handle adapter on the light head mount
- two medical flat screen monitors [11] (products from third-party manufacturers)
- a Wall Control Panel [20]
- an RS232 interface [21]
- a Mobile Control 7,9 control module [19] (product from a third-party manufacturer)



[1] Canopy
[2] Ceiling conduit
[3] Central axis
[4] Upper C boom
[5] Upper S boom
[6] Lower S boom
[7] Spring arm
(MD26+)
[8] Spring arm
(L21)
[9] Low room height spring arm
(LCH19)
[10] Monitor mount
(VidiaPort Monitor Holder Single and VidiaPort Monitor Holder Box)
[11] Flat screen
[12] iLED 7 comfort bracket
[13] 1/4 bracket iLED 7
[14] Lamp head
[15] Control element
The functions available on the control are limited.
[16] Handle adapter
(Adaption Standard handle/Adaption disposable handle)
[17] SLC Handle Adapter
[18] TruVidia wireless camera
[19] Mobile Control 7,9
[20] Wall Control Panel
[21] RS232 interface
[22] Sterilizable handle
(Sterilizable ALC Handle, 3 pcs/Sterilizable Central Handle, 3 pcs/Sterilizable Camera Handle, 3 pcs)
[23] Lower C boom
[34] Disposable handle adapters
(Handle sleeve flange type short/Handle sleeve flange type middle/Handle sleeve flange type long/Handle sleeve ring type short/Handle sleeve ring type long)

4.1.3 iLED 7 Pendant surgical light system

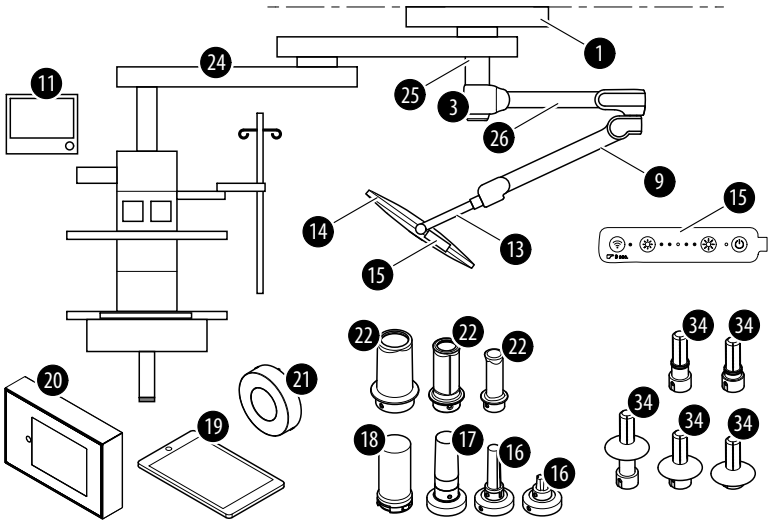
The iLED 7 Pendant surgical light system (example shown below) consists of the following components:

- the canopy [1]
- the FCS/TruPort ceiling-mounted supply unit [24] with a Pendant Adapter [25]
- a horizontally rotating S boom [26] on the Pendant Adapter [25] with a horizontally and vertically adjustable LCH19 spring arm [9]
- a rotating and vertically adjustable light head [14]

In the example, the iLED 7 Pendant surgical light system is equipped with the following additional accessories of Baxter and the following third-party products:

- an SLC handle adapter [17] or a TruVidia Wireless camera [18] or a handle adapter [16]
- a sterilizable handle [22] for the TruVidia camera system [18] or the SLC handle adapter [17] or the handle adapter [16]

- a Handle sleeve [34] handle adapter and a sterile disposable handle/disposable sleeve for the Adaption disposable handle [16] handle adapter on the light head mount
- a medical flat screen [11] (product from a third-party manufacturer)
- a Wall Control Panel [20]
- an RS232 interface [21]
- a Mobile Control 7,9 control module [19] (product from a third-party manufacturer)

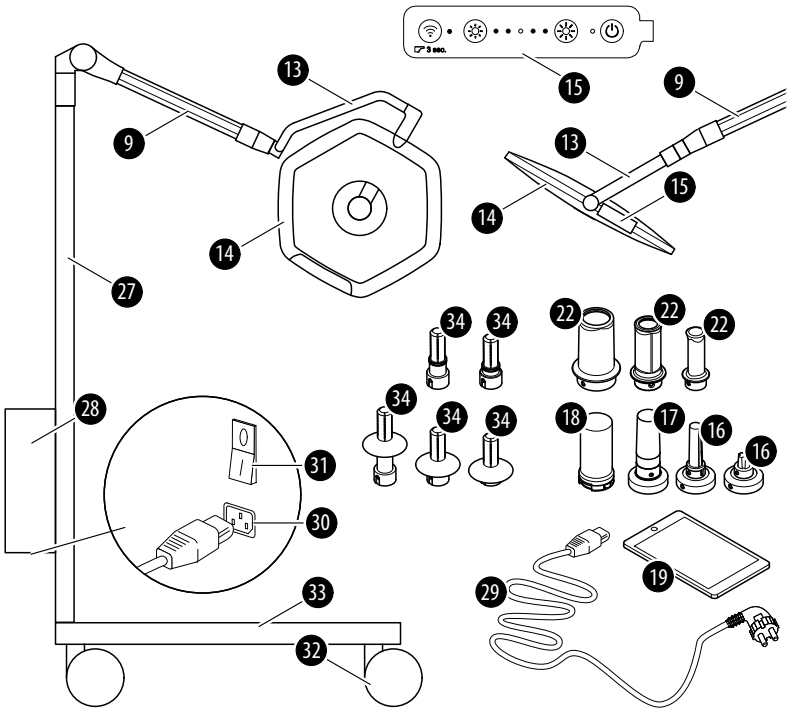


[1] Canopy
[3] Central axis
[9] Low room height spring arm (LCH19)
[11] Flat screen
[13] 1/4 bracket iLED 7
[14] Lamp head
[15] Control element
The functions available on the control are limited.
[16] Handle adapter
(Adaption Standard handle/Adaption disposable handle)
[17] SLC Handle Adapter
[18] TruVidia wireless camera
[19] Mobile Control 7,9
[20] Wall Control Panel
[21] RS232 interface
[22] Sterilizable handle
(Sterilizable ALC Handle, 3 pcs/Sterilizable Central Handle, 3 pcs/Sterilizable Camera Handle, 3 pcs)
[24] FCS 700 Ceiling Supply Unit ceiling-mounted supply unit / TruPort Ceiling Mounted Support System
[25] Pendant Adapter
(Light adaptation on the ceiling-mounted supply unit)
[26] Boom
[34] Disposable handle adapters
(Handle sleeve flange type short/Handle sleeve flange type middle/Handle sleeve flange type long/Handle sleeve ring type short/Handle sleeve ring type long)

4.1.4 iLED 7 Mobile

The mobile surgical light can be moved freely in any direction, as all 4 wheels are able to turn on their own axes. All 4 wheels can be braked. The parking brake allows the surgical light to be safely parked.

The Mobile Control 7,9 is available as a separate control module for the mobile surgical light.



[9] Low room height spring arm
(AC 2000 NRH mobil)
[13] 1/4 bracket iLED 7
[14] Lamp head
[15] Control element
The functions available on the control are limited.
[16] Handle adapter
(Adaption Standard handle/Adaption disposable handle)
[17] SLC Handle Adapter
[18] TruVidia wireless camera
[19] Mobile Control 7,9
[22] Sterilizable handle
(Sterilizable ALC Handle, 3 pcs/Sterilizable Central Handle, 3 pcs/Sterilizable Camera Handle, 3 pcs)
[27] Pedestal rod
[28] Power supply unit
[29] Mains power cable
[30] Connector socket for power cable
[31] On/Off switch (underside of the power supply unit)

[32] Wheel
[33] Stand foot
[34] Disposable handle adapters
(Handle sleeve flange type short/Handle sleeve flange type middle/Handle sleeve flange type long/Handle sleeve ring type short/Handle sleeve ring type long)

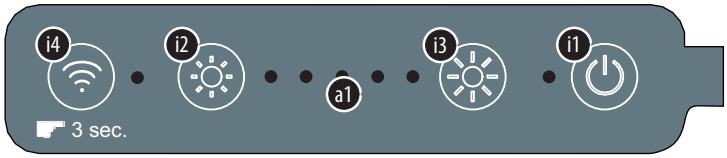
4.2 Overview of control modules

The control modules are used to set various functions of the surgical light. The control units available depend on the configuration of the surgical light.

Control units for the surgical light:

- Control element
- SLC handle adapter(Sterile Light Control)
- Mobile Control 7,9
- Wall Control Panel
- Operating interface of an external control module (OP integration systems using RS232 interface)

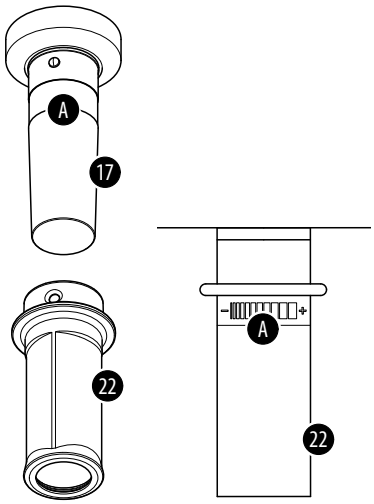
4.2.1 Operating element on the lamp head



[i1] Switching the surgical light function on and off
Status indicator on the button: The display lights up when the external power supply is switched on and the surgical light is in stand-by mode.
[i2] Reducing the lighting intensity function
[i3] Increasing the lighting intensity function
[i4] Safe mode
Status indicator on the button: The indicator lights up when the safe mode has been switched off.

[a1] Lighting intensity of display
(5 levels: Endo, 30%, 50%, 80%, 100%)

4.2.2 SLC handle adapter(Sterile Light Control)



The SLC sterilizable handle [17] can be optionally used to set one of the following functions of the surgical light:

- Lighting intensity (without Endo lighting intensity)
- Light field size
- Color temperature

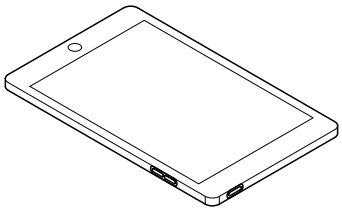
The function is set via the touch sensor [A] of the SLC handle adapter.

A sterilizable handle Sterilizable ALC Handle, 3 pcs (#1660214) [22] must be placed onto the SLC Handle Adapter to facilitate operation. This function is then set in a sterile manner.

The function of the handle adapter required by the user was adjusted during assembly of the surgical light. The preset function can be set by the Technical Customer Service.

Take note of the instructions for use of the sterilizable handle (see Chapter 2.1).

4.2.3 Mobile Control 7,9



The Mobile Control 7,9 (a product from a third-party manufacturer) is a mobile tablet unit with touch screen that is optimized for operation during surgery. The TruRemote control software is installed on the tablet unit and used to remotely operate the surgical light. The TruRemote software ensures that all functions of the surgical light are available. Adjustment is via the graphic user interface of the TruRemote software and the touchscreen.

The Mobile Control 7,9 cannot be sterilized and may only be used outside the sterile area.

The Mobile Control 7,9 may only be operated in a network approved for this purpose by Baxter.

Please note that the Mobile Control 7,9 must be charged daily. The Mobile Control 7,9 may only be charged from the charger provided and outside the patient environment. The Mobile Control 7,9 may not be used with the charger in place.

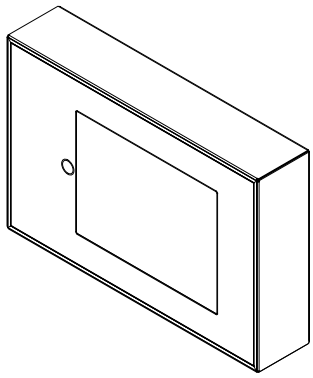
If the Mobile Control 7,9 is switched off and cannot be activated, the battery may be empty. Charge the control module as required. The Mobile Control 7,9 will start automatically after charging for some minutes.

The Mobile Control 7,9 control unit is only intended for operating the TruRemote software installed by Baxter and may not be equipped with additional software or apps from third-party manufacturers. Updates of the existing software are not permitted.

The Mobile Control 7.9 control module is a display and control device and must not be used for diagnostic purposes.

The safety housing #2074252 is recommended for safe handling of the Mobile Control 7,9.

4.2.4 Wall Control Panel

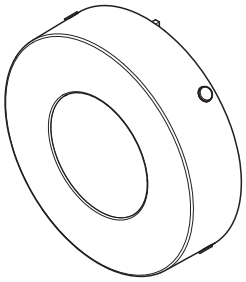


The Wall Control Panel is a tablet unit with touchscreen optimized for surgical use, mounted in a permanent frame on/in a wall and directly connected to the power supply. The TruRemote control software is installed on the tablet unit and used to remotely operate the surgical light. The TruRemote software ensures that all functions of the surgical light are available. Adjustment is via the graphic user interface of the TruRemote software and the touchscreen.

The Wall Control Panel control unit is intended exclusively for the use of the TruRemote software installed by Baxter and may not be equipped with additional software or apps from third -party manufacturers. Updates of the existing software are not permitted.

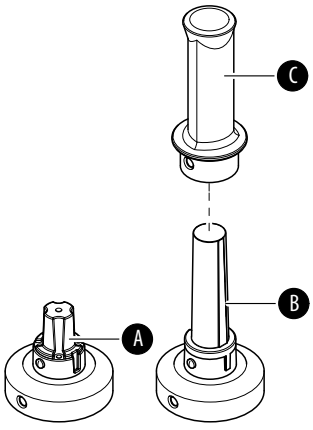
The Wall Control Panel control module is a display and control device and must not be used for diagnostic purposes.

4.2.5 Surgical Integration System



The optional iLED 7 RS232 interface makes it possible to integrate the surgical light into the system of a third-party manufacturer and to set selected functions of the surgical light via the user interface of an external control unit. Adhere to the reference manual with document number 55000-00029.

4.3 Handle adapter



The Adaption disposable handle [A] handle adapter is used to hold adapters (products from third-party manufacturers) to which sterile disposable handles are attached.

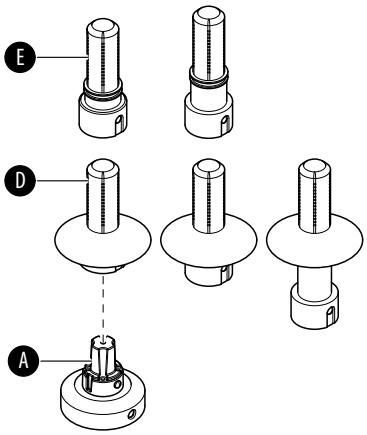
The Adaption Standard handle [B] handle adapter is used to attach the Sterilizable Central Handle [C].

The Adaption disposable handle [A] and Adaption Standard handle [B] handle adapters can also be used to compensate for the weight on the mount of the light head (camera interface), as a cover for the electrical connections, to act as a guide for a sterile or sterilizable handle [C] and to position the light head with an attached sterile handle.

If the TruVidia Wireless camera is disconnected from a light head with a camera or the SLC handle adapter is disconnected from a light head with SLC handle adapter, the Adaption disposable handle [A] or Adaption Standard handle [B] handle adapter must be attached to the mount of the light head.

A Handle sleeve flange or Handle sleeve ring handle adapter must be attached to use sterile disposable handles and disposable sleeves on the handle adapter.

The Handle sleeve flange and Handle sleeve ring handle adapters do not fit on the Adaption Standard handle [B]. The Adaption Standard handle [B] handle adapter needs to be



replaced by the Adaption disposable handle [A] handle adapter. Other handles need to be converted by a qualified service technician.

The Handle sleeve flange [D] or Handle sleeve ring [E] handle adapter is placed on the Adaption disposable handle [A] handle adapter or the handle converted by the service technician and is used to attach a sterile handle (disposable handle or disposable sleeve). The disposable handles and disposable sleeves are products from third-party manufacturers and may only be used once.

The handle adapter may only be used with a sterilizable or sterile handle.

4.4 Bulbs

The surgical light is equipped with LED light sources. The use of a multitude of LEDs provides high failure safety for the surgical light. Failures of up to 10 LEDs do not affect the basic functions of the surgical light and the surgical light remains operational. The surgical light may no longer be used when more than 10 LEDs of the surgical light fail.

4.5 Power supply

Ceiling-mounted version:

The ceiling-mounted version of the surgical light is permanently connected to the external power supply of the room and is only disconnected by means of the separate On/Off switch in the event of an emergency for cleaning or for service purposes.

Mobile pedestal version:

The mobile stand version of the surgical light is connected with the mains cable to the room's mains power network.

4.6 Setting options

4.6.1 Light field size

The light field size concerns the diameter of the light field. For the working distances of 80 cm to 130 cm (31.50 inch to 51.18 inch) commonly used in every surgical setting, 3 constant light field sizes (narrow – medium – wide) are available. If the working distance of the surgical light to the patient's wound area is changed manually, the surgical light automatically refocuses on the set light field.

When a narrow light field is set, the inner LED modules are switched off.

4.6.2 Lighting intensity

Lighting intensity concerns brightness and is measured in lux. Lighting intensity can be adjusted within a range of 30% to 100%. In addition, Endo lighting intensity can be selected. The Endo lighting intensity is a fixed-setting lighting intensity (< 10%) primarily intended for endoscopic surgery.

4.6.3 ALC Plus (Adaptive Light Control Plus) - automatic measurement of the working distance

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 facilitates optimal focusing of the light onto the wound surface and thus ensures optimal illumination of the wound area.

If the lamp head is repositioned during surgery, the distance between the lamp head and the wound area is automatically determined and the light field and lighting intensity are adapted/ optimized accordingly.

Notice: The function is only triggered when the working distance to the wound field of the patient is changed by moving the surgical light. Changing the patient’s position does not trigger automatic measuring and optimization of the lighting conditions.

For the automatic function, the working distance between the surgical light and wound area of the patient must be between 80 cm and 130 cm (31.50 inch and 51.18 inch).

4.6.4 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, for example during operations carried out at night.

Four color temperatures are available: 3500 K – 4000 K – 4500 K and 5000 K.

4.6.5 Shadow management

The sensor-controlled assistance system of the surgical light ensures consistent lighting conditions without disruptive shadows, even if the surgeon is working directly under the surgical light. The assistance system detects obstacles between the surgical light and the patient's wound area. Corresponding LED modules of the surgical light system are activated and deactivated by the assistance system. Even without any manually adjusted settings, the wound area is always illuminated as effectively as possible.

Where there are 3 surgical lights within a light system, shadow management can only be activated in 2 surgical lights.

4.6.6 Synchronization

The Synchronization function is used to balance the functions of all surgical lights within a single lighting system. When this function is activated, the current settings of the selected surgical light are automatically transferred to all other surgical lights in the lighting system. The following functions can be synchronously adjusted:

– Light field size

- Lighting intensity
- Color temperature
- ALC Plus
- Shadow management
- Switching on and off

The selection of the function to be synchronized can be adjusted by personnel trained in this work by Baxter. Adjustment of the selection must take place individually for every Mobile Control 7,9 and each Wall Control Panel in the operating room.

4.6.7 Safe mode

With the Safe mode button, ALC Plus, shadow management and radio communication via WLAN with the Mobile Control 7,9 or Wall Control Panel, for example in the event of a fault, can be interrupted. Pressing this button reboots the processing unit and enables safe mode.

While the surgical light is in safe mode, the green status LED on the operating panel is switched off.

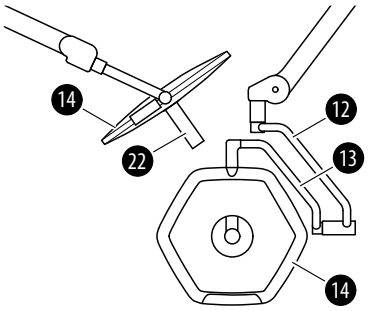
In safe mode, the following light parameters are set:

- Color temperature 4500 K
- Medium light field width
- Lighting intensity = level 3 = 50%
- SLC = OFF
- Sync = OFF
- ALC Plus = OFF
- Shadow management = OFF
- WLAN = OFF

When safe mode is exited, the light starts with the factory or customer-specific default settings.

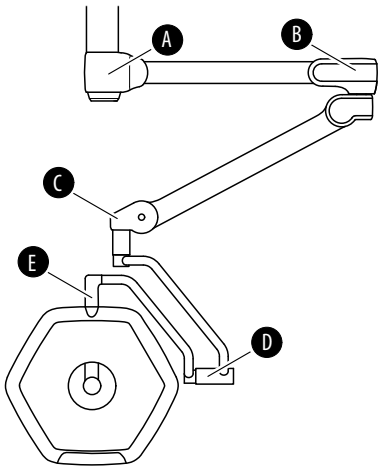
4.6.8 Operating range

The operating range of the surgical light is determined by the support arm system for the ceiling version. The operating range of the mobile surgical light is determined by the spring arm and can be placed at any position in the room due to its mobile stand foot. Within the operating range, the surgical light can be placed in any position and accurately pointed onto the wound field.



The surgical light is positioned in a sterile way using the sterilizable handle [22] or in a non-sterile way using the comfort bracket [12], the 1/4 bracket [13] or directly by grabbing the housing of the lamp head [14].

The hinge joints of the support arm system have been equipped with a friction brake. The friction brake transmits the friction from the brake screw to the pin of the support arm component, thus locking it in position. If the boom, the spring arm, the convenience bracket, the 1/4 bracket or the light head do not remain securely



in the set swivel position, or can only be moved with difficulty, the brake force must be adjusted by staff trained in this work by Baxter.

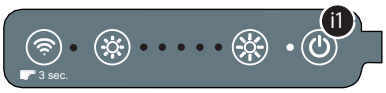
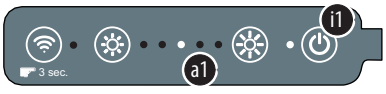
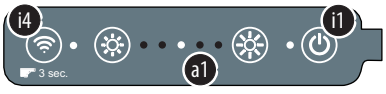
If the braking force needs to be adjusted on multiple support arm components, use the following sequence:

1. Brake screw [A] for the brake of the extension arm
2. Brake screw [B] for the brake of the spring arm
3. Brake screw [C] for the optional braking of the comfort bracket
4. Brake screw [D] for brake of the 1/4 bracket
5. Brake screw [E] for the braking of the light head

The weight of the support arm component is compensated by a spring installed in the spring arm. If the spring arm does not remain stable in the selected height position, the spring force must be adjusted by staff trained in this work by Baxter. If the spring arm creeps upwards, the spring force is too high. If the spring arm creeps downwards, the spring force is too low.

The swivel range of the spring arm upwards and downwards can be individually adjusted by staff trained in this work by Baxter. The swivel range can be limited up to a fully horizontal position.

4.7 Visual indicators and displays

Display	Status	Meaning
	No indicator is illuminated.	The external power supply of the surgical light is switched off.
	The indicator next to the [i1] key lights up.	The external power supply of the surgical light is switched on. The surgical light is switched off.
	The indicator next to the [i1] key and the middle indicator for lighting intensity [a1] light up.	The surgical light is illuminated, but is not connected to the Mobile Control 7,9 / the Wall Control Panel.
	The indicator next to the [i1] key and the middle indicator for lighting intensity [a1] light up, along with the [i4] indicator.	The surgical light is illuminated and can be controlled with the Mobile Control 7,9 / the Wall Control Panel.

4.8 TruRemote software

The Mobile Control 7,9 and Wall Control Panel control units are equipped with the TruRemote software and have a graphic user interface.

The Mobile Control 7,9 and Wall Control Panel can be used to operate up to 3 iLED 7 surgical lights in a single light system.

4.8.1 Page types

The TruRemote software has 4 different page types:

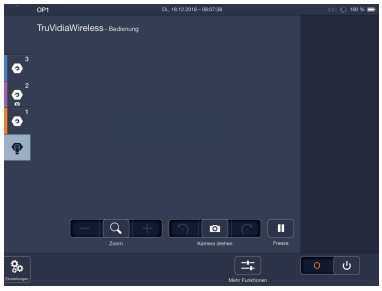
– The control screen for the surgical light, to operate a surgical light with several sub-pages

– The one-click page for rapid control of a surgical light on one side

  Only personnel trained in this work by Baxter may activate or deactivate the one-click page.

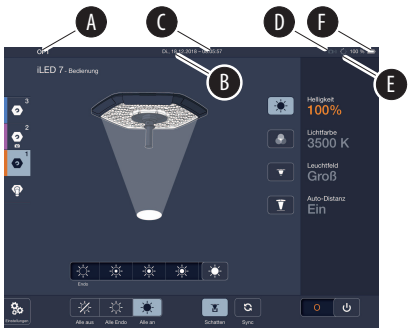
– The password-protected settings page for adjustment of the TruRemote Software

  Only personnel trained in this work by Baxter may adjust the TruRemote software.



– TruVidia Wireless control screen for operating a camera

4.8.2 Status bar



All pages have a status bar along their upper edge, with the following information:

– [A] Location
– [B] Date
– [C] Time
– [D] Icon showing the signal strength of the camera connection
– [E] Icon for connection status of the Mobile Control 7,9 / Wall Control Panel
– [F] Battery capacity of the Mobile Control 7,9

Icon signal strength

An icon for the signal strength of the camera connection is only displayed when a TruVidia Wireless Camera has been connected to the light system.

Icon	Meaning
	Signal strength 0 There is no connection between the TruRemote software and the receiver. The camera is turned off.
	Signal strength 1 There are many sources of interference in the room. The line of sight between the camera and the receiver is interrupted.
	Signal strength 2 There are sources of interference in the room. The line of sight between the camera and the receiver is impaired.
	Signal strength 3 There are minor sources of interference in the room.
	Signal strength 4 There is a very good connection between the receiver and the TruVidia Wireless Camera.

Connection status icons

Icon	Meaning
	The connection between the surgical light and Mobile Control 7,9/Wall Control Panel is established.
	The Mobile Control 7,9/the Wall Control Panel is not accepted by the surgical light.
	The login of the Mobile Control 7,9 / Wall Control Panel into the surgical light starts.
	The Mobile Control 7,9 / the Wall Control Panel is accepted by the surgical light.

4.8.3 Page configuration of control screen of surgical light

The surgical light control screen is divided up into the following areas:

- [A] Quick access bar
- [B] Header line with the name of the surgical light
- [C] Operating range with
  - [D] Diagram of the surgical light
  - [E] Functions of the surgical light
  - [F] Settings range for the functions
- [G] Information area
- [H] Action bar

Quick access bar

The quick access bar can be used to display the control screen of the desired surgical light or the TruVidia Wireless Camera.

Diagram of the surgical light

The surgical light diagram gives an immediate visual overview of the changes made to the settings of the surgical light.

Functions of the surgical light

The function area is used to select the functions of the surgical light (lighting intensity, color temperature, light field and ALC Plus).

Setting range for the functions

The desired settings option is exercised for the selected function in the settings range.

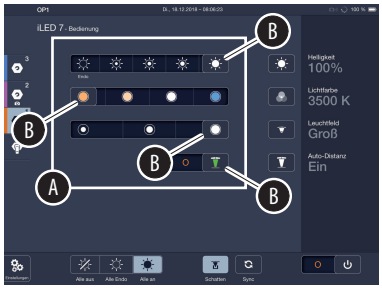
Information area

The information area shows the current settings for lighting intensity, the color temperature and the light field of the surgical light, as well as the status of the ALC Plus function.

Action bar

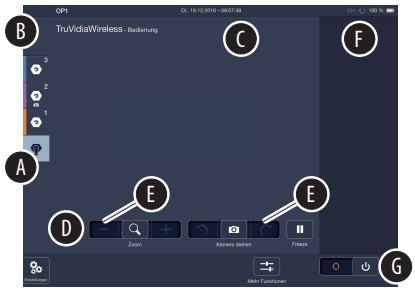
The action bar is used to select the functions that affect all surgical lights of the lighting system (switching off the surgical lights, Endo lighting intensity, switching on the surgical lights, shadow management, synchronization) and for switching the surgical light on or off.

4.8.4 One-Click page structure



The one-click page has a similar structure to the surgical light control screen. The difference lies in the operating range. Instead of the surgical light diagram, all functions and the setting ranges [A] for a surgical light are shown simultaneously and can be directly adjusted. The highlighted icons [B] show the current settings option for each function.

4.8.5 Page configuration of TruVidia Wireless control screen



The TruVidia Wireless light control screen is divided up into the following areas:

- [A] Quick access bar
- [B] Header line with the name of the camera
- [C] Operating range with
  - [D] Functions of the camera
  - [E] Setting ranges for the functions
- [F] Information area
- [G] Action bar

Camera functions

Camera functions are selected in the Functions area.

- Image rotation
- Scaling
- Storing a still image

Setting range for the functions

The desired settings option is exercised for the selected function in the settings range.

Action bar

The action bar is used to switch the camera on or off and to show other camera functions.

- Focusing
- Select exposure metering
- White Balance

5 Use

The surgical light has a multitude of functions that can be ergonomically controlled using the control unit. The SLC Handle Adapter can be operated in a sterile manner by using the sterilizable handle. All other control units are used in a non-sterile manner.

5.1 Safety instructions

When operating devices involved in the operation, always keep visual contact with the operation situation.

Electrical hazards:

Danger of electric shock
- No patient applied parts of type BF or CF in accordance with IEC 60601-1 may be directly connected to the surgical light system.
- Do not insert objects into device openings.
- Disconnect the surgical light system from the mains power supply before cleaning and service work.

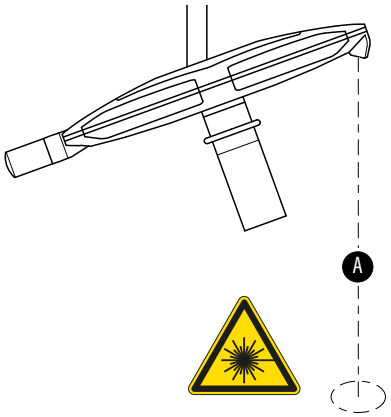
Risk of explosion posed by anesthetics

The surgical light is not suitable for operation in explosive areas. With a higher concentration of flammable mixtures, there is a risk of ignition under certain conditions.
- The surgical light may not be used in rooms or areas in which flammable mixtures of anesthetics with air or oxygen or N_2O (laughing gas) are used.

Risk to the patient if the power supply fails
- The power supply of the surgical light system may not be interrupted.

Risk of charge balancing
- To avoid electrostatic discharge between metallic parts of the device and the body of the patient, the user may not touch parts of the surgical light system, the Mobile Control 7,9 and the patient at the same time.

Optical radiation:



Risk due to laser beams

Prolonged visual contact with the laser beam might damage eyesight.
- Do not look directly into the laser beam [A].
- Close or protect the patient's eyes during surgery. For example with protective glasses with an optical density of at least 2, or that are designed according to protection level 6 EN 169.

Risk due to blue light

The blue light (400 nm to 780 nm) of the LEDs can fatigue the eyes or damage the retinas. The maximum radiation duration in the working range from 80 cm to 130 cm (31.50 inch to 51.18 inch) is 73 seconds.

- Do not look for a prolonged time into the switched-on light field of the surgical light.

Risk due to high lighting intensity

A high light intensity can cause burns in the wound area of the patient, dry out tissue (especially during long exposure times and reduced perfusion), and damage the eyes. The light intensity is high if light fields overlap or if there is direct contact with the emitted light.

- Position the light head so that the light fields do not overlap.
- Reduce the light intensity of the individual light heads.
- Do not look directly into the light field or surgical light.
- Close or protect the patient's eyes during surgery. For example with protective glasses with an optical density of at least 2, or that are designed according to protection level 6 EN 169.
- For patients with a thin or sensitive skin, for example with children, use additional skin protection.

Risk due to reduced light intensity

- If more than 10 LEDs fail on one light head, take the surgical light out of service and notify the Technical Customer Service.

Risk of interference

- In the event of interference between the surgical light and other devices, switch off the automatic shadow management and contact the manufacturer of the affected device.

Support arm system:

Danger due to overloading

Overloading the support arm system can result in severe malfunctions and the support arms, individual components or accessories may come loose from their mountings and crash.

- The maximum load capacities, specified in the technical data of the support arms, may not be exceeded. Observe the instructions for use with the document number 7990089.
- Only components and accessories authorized by Baxter may be used on the support arm system.

Danger due to uncontrolled movement on the support arm system

- Before MRI use, swivel the support arms, components and accessories away from the danger area of the strong magnetic field.
- If the spring arm moves upwards or downwards of its own accord, the spring force must be readjusted by trained personnel.
- If the surgical light or camera does not remain securely in the set position after a turning movement, the braking force must be readjusted by trained staff.

Risk of spring arm shooting up

Abrupt removal of loads may cause the spring arm to suddenly shoot up, resulting in serious injury.

- Flat screen monitors or other components must only be removed from the spring arm by the Technical Customer Service.

Contamination and infection:

Risk of infection for the patient

- Before using the products for the first time, they must first be cleaned and disinfected according to the hygiene specifications of the medical facility. Cleaning and disinfecting may be performed only by trained staff and using cleaning and disinfecting agents approved by Baxter.
- The sterile handle, handle adapter or the camera must not be removed during operation.
- After each surgical use, the support arm system must be cleaned and disinfected.
- Cleaning or servicing work may not be carried out during operation.

5.2 Inspections during operation

⚠ WARNING

Risk of contamination and infection

Loose or damaged parts may fall into the wound of the patient.

- Check the support arm system for loose parts at the comfort bracket, 1/4 bracket or light head.
- Check the support arm system for visible damage, particularly on the covers, lenses of the inner and outer LED ring, the 3D sensor, the control element and the sterilizable handles.

The following work steps must be completed before using the surgical light.

1. Check the Mobile Control 7,9 for visible damage and switch it on.
2. Check the charging status of the Mobile Control 7,9. Charge the control module as required.
3. Activate the Mobile Control 7,9 / the Wall Control Panel and unlock it.
4. Fit a handle adapter or a camera and a sterile handle to each surgical light.
5. Switch all surgical lights on.
6. Check the function of the Mobile Control 7,9 / Wall Control Panel.
7. Check the status display of safe mode. The display must light up to ensure that the full functionality of the surgical light is available.
8. Check the functionality of all control screens of the TruRemote software.
9. Check the surgical light for visible damage, particularly at the lens.

10. Check the sterilizable handle for visible damage and a secure fit on the lamp head.
11. Check the functionality of the surgical light with all control modules in use.

Immediately take a faulty surgical light or control module out of service, label it clearly as being defective and ensure it is not used again. If there is damage or a fault, notify the technical customer service.

Following any damage reported by a user, a functional check and a visual inspection must be carried out by personnel trained to perform these tasks by Baxter.

Weekly inspection

At least once a week, a functional check and a visual inspection must be carried out by personnel trained to perform these tasks by Baxter.

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

Annual inspection

The annual inspection must be performed by staff trained in this work by Baxter.

The annual inspection includes a visual inspection and functional inspection of the entire surgical light considering the following inspection points.

- Check the components of the lamp head and the support arm system for deformation
- Surface damage
- Check the support arm system and lamp head for paint damage
- Check plastic parts for cracks, brittle spots and clouding
- Check welds for cracks
- The surgical light must be checked for completeness of all plastic parts (such as covers and plugs)
- Check to ensure that device labels and information labels are legible.
- Check the LEDs for functionality
- Check the joints for functionality
- Check the position of the end stops
- Check the effect of the spring and brake forces
- Check the safe mode function

5.3 Selection of functions

The functions of the surgical light are set with the following control units:

- Control element
- SLC handle adapter (Sterile Light Control)
- Mobile Control 7,9
- Wall Control Panel
- Operating interface of an external control module (OP integration systems using RS232 interface)

The commands of the individual control modules are executed in the following sequence:

1. Control element
2. SLC handle adapter (Sterile Light Control)

3. Mobile Control 7,9
4. Wall Control Panel

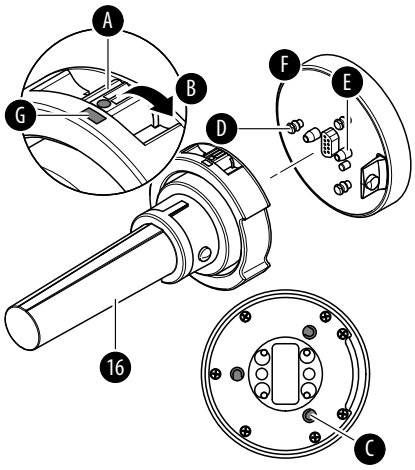
Simultaneous activation of keys on various control units leads to execution of functions in order of priority.

Any setting of the surgical light, irrespective of whether it is performed with the Mobile Control 7,9, the Wall Control Panel, the SLC handle adapter or directly at the control unit, will be simultaneously shown on the other control units and the corresponding control screen of the Mobile Control 7,9 and Wall Control Panel. The change is displayed in both the Information area and on the device display and the corresponding setting areas or operating options. The user always sees the current settings for the surgical light on all operating units.

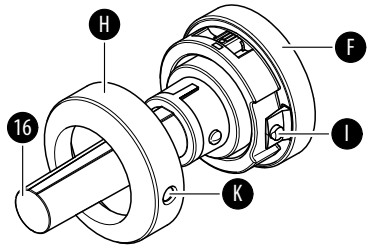
Multiple Mobile Controls 7,9 and Wall Control Panel units may be used in one room. Where the surgical light is operated with two Mobile Control 7,9 or Wall Control Panel units simultaneously, only the last operator input made to the surgical light will be executed.

5.4 Attaching the handle adapter

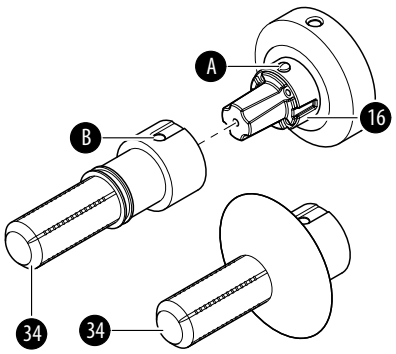
5.4.1 Adaption disposable handle/Adaption Standard handle



1. Slide the locking device of the bayonet lock [A] downwards into position [B] so that the three shut-off openings [C] of the base plate are released.
2. Align the handle adapter [16] so that the arrangement of the three bayonet pins [D] and the two centering pins [E] of the mount [F] on the camera bracket are aligned with the shut-off openings [C] in the base plate (the camera plug connector will then also be aligned).
3. Insert the handle adapter [16] on the mount [F] of the lamp head.
4. To secure it in place, slide the locking device of the bayonet lock [A] upwards so that the two red marking dots [G] are aligned.
5. **NOTICE!** Check the secure position of the handle adapter on the mount. After locking the bayonet lock, always make sure to check that the handle adapter is securely seated on the mount.
6. Slide the cover (metal ring) [H] onto the handle adapter [16] and the mount of the lamp head. Ensure that the plastic catch [I] of the mount [F] is correctly engaged in the securing hole [K] on the cover [H].



5.4.2 Handle sleeve flange/Handle sleeve ring



1. Attach the Adaption disposable handle handle adapter to the mount (see Chapter 5.4.1).
2. Push the Handle sleeve flange or Handle sleeve ring [34] handle adapter onto the Adaption disposable handle [16] handle adapter. Ensure that the plastic catch [A] of the Adaption disposable handle [16] handle adapter is correctly engaged in the locking hole [B] on the Handle sleeve [34] handle adapter.

5.5 Removing the handle adapter

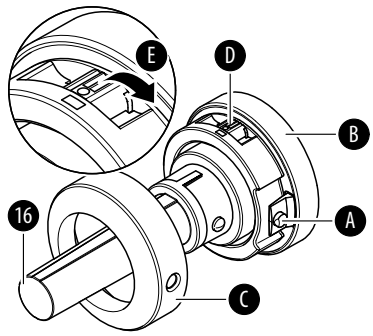
5.5.1 Adaption disposable handle/Adaption Standard handle

⚠ CAUTION

Danger of short circuit

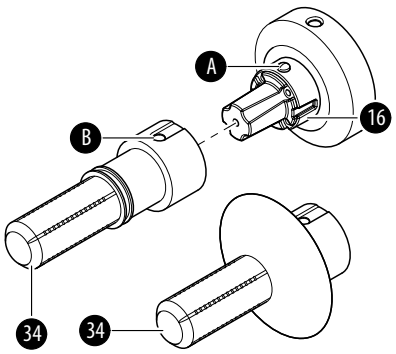
Liquid spilled onto the mount of the light head can cause a short circuit and interrupt the power supply for the surgical light system.

- The mount of the light head must always be covered by a camera or a handle adapter.



1. Remove the sterilizable handle from the handle adapter [16].
2. Press in the plastic catch [A] of the mount [B] and remove the cover [C] from the handle adapter [16].
3. Support the lamp head.
4. Slide the locking device of the bayonet lock [D] downwards into position [E] so that the three shut-off openings of the base plate are released.
5. Pull the handle adapter [16] off the mount [B] of the lamp head.

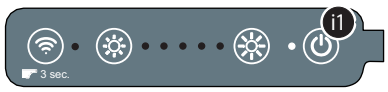
5.5.2 Handle sleeve flange/Handle sleeve ring



1. Remove the disposable handle/disposable sleeve from the Handle sleeve [34] handle adapter.
2. Press in the plastic catch [A] on the Adaption disposable handle [16] handle adapter and remove the Handle sleeve [34] handle adapter from the Adaption disposable handle handle adapter.

5.6 Connecting the power supply

5.6.1 Ceiling-mounted version



The power supply must be connected by specialized personnel with the necessary access authorization, knowledge and documentation to set up internal power supplies.

When there is no separate main switch in the room, the surgical light is in standby mode when the power supply is switched on. The indicator next to the [i1] key lights up.

Switch on the main switch if the room has a separate main switch. The indicator next to the [i1] key lights up. The surgical light is now in standby mode.

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

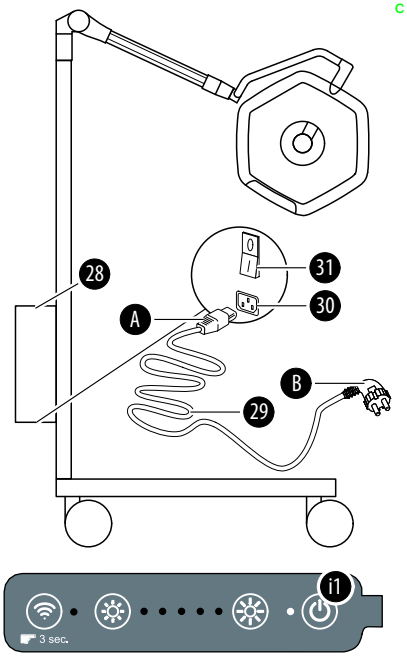
5.6.2 Mobile version

⚠ WARNING

Electric shock due to damaged electrical equipment

Touching live device parts can result in electrocution.

- The mobile surgical light system (Protection Class I) may only be connected to a properly earthed power socket.
- Check the plugs and mains power cable for damage before connecting to the mains power network.
- Do not connect the mobile surgical light to the mains power if plugs or mains power cable are damaged.
- If the above damage or further damage occurs, the surgical light is no longer safe to operate.
  - Label the surgical light system as defective.
  - Notify the Technical Customer Service.



c

1. Check the power supply cable [29] including plug [A] and [B] for integrity.
2. Plug the connector [A] of the mains power cable [29] into the power socket [30] of the mains supply [28].
3. Route the cable to the socket so that no one can trip or fall over it. Do not put the cable under strain.
4. **NOTICE!** The mains voltage at the shock-proof socket must correspond with the information on the device label. If in doubt, ask the responsible power supply company or a qualified electrician.
   Plug the connector [B] of the power supply cable into a protective contact socket in the room.
5. Switch on the mains power supply [28] at the switch [31] (Position I).
   The indicator next to the [i1] key lights up. The surgical light is now in standby mode.

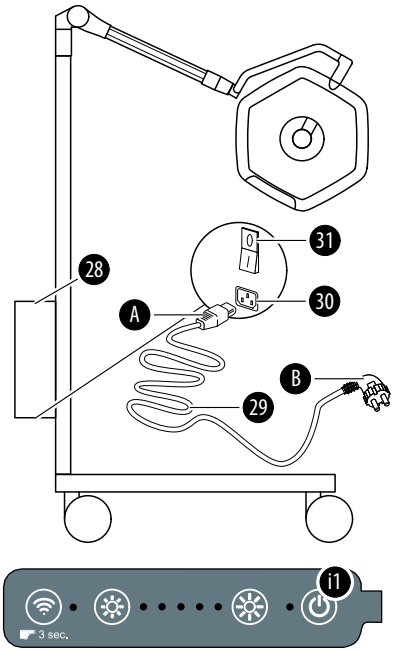
5.7 Disconnecting the power supply

5.7.1 Ceiling-mounted version

Only personnel trained in this work by Baxter may disconnect the surgical light from the power supply.

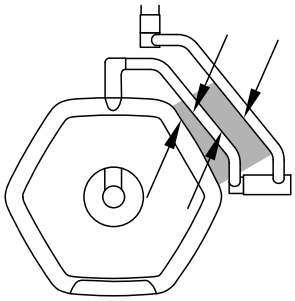
1. Switch off the surgical light on a control unit.
2. Switch off all products connected to the surgical light, such as the Mobile Control 7,9 or the TruVidia Wireless Camera.
3. Disconnect all poles of the surgical light from the power supply and secure it against being switched back on. The protective earth (PE) may not be disconnected.
   The indicator next to the [i1] key goes off.

5.7.2 Mobile version



1. Switch off the surgical light at the controls.
2. Switch off the mains power supply [28] at the switch [31] (Position 0).
   The indicator next to the [i1] key goes off.
3. Pull the power cable plug [B] [29] from the socket.
4. Pull the plug [A] out of the connection socket [30] on the power supply unit.
5. Wrap the power cable around the power supply unit.

5.8 Positioning the surgical light



⚠ CAUTION

Pinching hazard

When swiveling the lamp head, do not reach between the comfort bracket and the 1/4 bracket or between the 1/4 bracket and the lamp head.

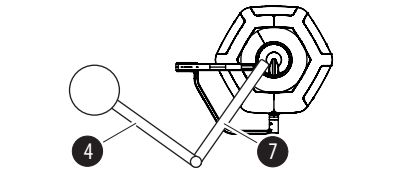
- Only position the lamp head using the sterile handle or at the non-sterile housing.

To prevent damage to the product, observe the following when positioning the surgical light:

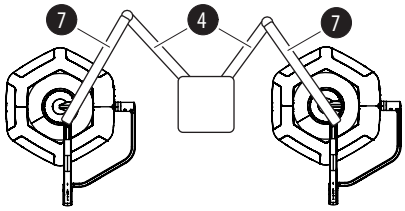
– When adjusting the product, take care not to hit the stops hard. Perform the setting slowly.
– Avoid collisions with other components.

- Depending on the variant, the swivel range and the vertical travel is limited by the internal end stops of the boom, the spring arm and the adaption.
- Remove any possible collision hazards before swiveling or height adjustment.

However, if there is still a collision with other devices, wall or ceiling, the product may be damaged and fail. After a collision, check the product immediately for possible damage and contact the operator if necessary.



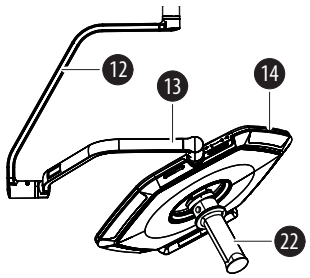
An individual surgical light is best moved when the boom [4] and the spring arm [7] form a “V”.



For a light system with several surgical lights, best mobility is achieved when the extension arms [4] and spring arms [7] form an “M”.

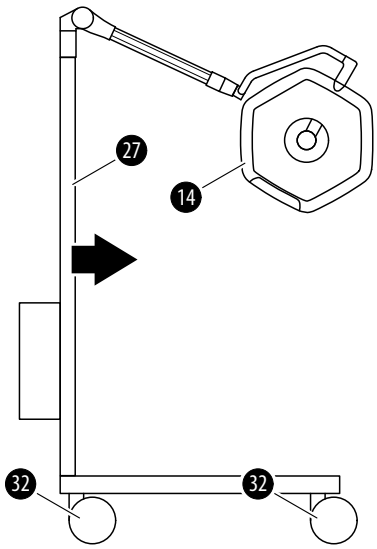
A collision between the surgical light and adjoining object may lead to material damage. Observe the operating range of the surgical light.

If the ALC Plus function is active, the distance to the wound field will be newly determined when the lamp head is moved. Distance is measured in an area around the centerline of the light field. Strongly structured wound fields or other objects in the measuring range may affect the distance measurement. When moving the surgical light, care must be taken to ensure that the light field is aligned with the wound area and that there are no interfering objects in the measuring range.



Hold the surgical light at the sterile handle [22], the comfort bracket [12], the 1/4 bracket [13] or light head [14] and move it to the desired position.

5.9 Moving the mobile surgical light

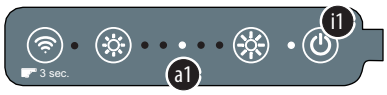


Do not exert excessive force onto the spring arm or the lamp head in the braked state, as this may cause the surgical light to tilt. Do not attach any additional loads to the spring arm.

1. Switch off the surgical light at a control module and disconnect it from the mains power (see Chapter 5.7). The power supply only needs to be disconnected when the surgical light is to be moved outside of its operating range. The operating range is determined by the length of the mains power cable.
2. Release the parking brake at all 4 wheels [32]. Push the latching mechanism upwards for this purpose.
3. Hold the surgical light at the stand pole [27] and push in the direction of travel together with the lamp head [14]. Tightly hold the surgical light at steps or on uneven ground and carefully move it past the obstacle.
4. Park the surgical light at the place of operation or the parking place in its braked state. To do this, release the locking mechanism at all 4 wheels [32].

5.10 Operating the surgical light with the control module and SLC handle adapter

5.10.1 Switching the surgical light on/off



The function is set on the controls of the surgical light.

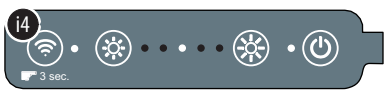
Switching on:

– Press the [i1] key.
  The surgical light starts with the standard setting or with the last parameters set. The desired option can be set by a service technician.
  The indicator next to the [i1] key and the indicator for lighting intensity [a1] light up.

Switching off:

– Press the [i1] key.

5.10.2 Establishing/disconnecting the radio connection



The function is set on the controls of the surgical light.

Establishing:

– Press the [i4] key.
  The indicator next to the [i4] key lights up.

Disconnecting:

– Press the [i4] key for 3 seconds.
  The indicator next to the [i4] key goes off.

5.10.3 Activating/deactivating safe mode

The function is set on the controls of the surgical light.

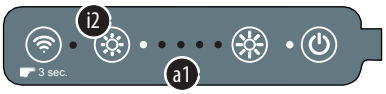
Activation:

1. Set the working distance between the surgical light system and the patient's wound area to 100 cm/39.37 inch.
2. Press the [i4] key for 3 seconds.
   The indicator next to the [i4] key goes off.

Deactivation:

– Press the [i4] key.
  The indicator next to the [i4] key lights up.

5.10.4 Adjusting the light intensity

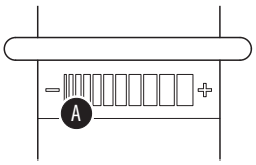


Reduce the lighting intensity:

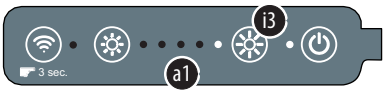
Controls on the surgical light:

– Press the [i2] key.
  On the indicator [a1], the corresponding LED of the current lighting intensity set lights up.

SLC handle adapter:



– Move a finger across the sterilizable handle from right to left, until the desired lighting intensity has been set via the touch sensor [A].
  The Endo lighting intensity cannot be set with the SLC handle adapter.

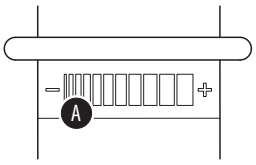


Increase the lighting intensity:

Controls on the surgical light:

– Press the [i3] key.
  On the indicator [a1], the corresponding LED of the current lighting intensity set lights up.

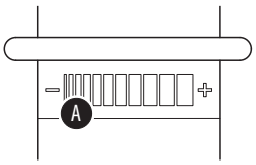
SLC handle adapter:



– Move a finger across the sterilizable handle from left to right until the desired lighting intensity has been set via the touch sensor [A].

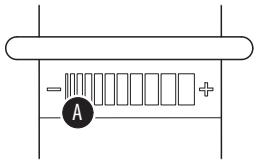
5.10.5 Setting the size of the light field

The function is set using the SLC handle adapter.



Narrow light field:

– Move a finger across the sterilizable handle from right to left, until the desired light field size has been set via the touch sensor [A].

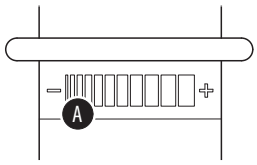


Wide light field:

– Move a finger across the sterilizable handle from left to right until the desired light field size has been set via the touch sensor [A].

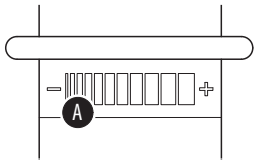
5.10.6 Setting the color temperature

The function is set using the SLC handle adapter.



Reduce color temperature:

– Move a finger across the sterilizable handle from right to left until the desired color temperature has been set via the touch sensor [A].

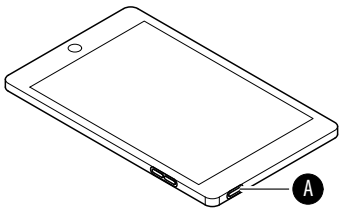


Increase color temperature:

– Move a finger across the sterilizable handle from left to right until the desired color temperature has been set via the touch sensor [A].

5.11 Operating the surgical light with the Mobile Control 7,9/ Wall Control Panel

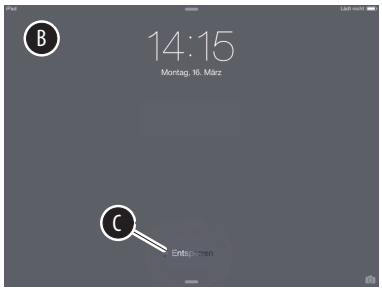
5.11.1 Setting the operating state of the Mobile Control 7,9



Switching on:

Press the On/Off switch [A] until the Mobile Control 7,9 is activated.

The Unlock screen [B] will be shown after a few seconds.



Switching to standby mode:

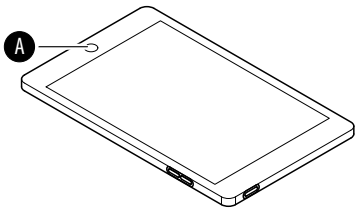
Briefly press the On/Off switch [A].

The display goes out and the Mobile Control 7,9 goes into standby mode.

Switching off:

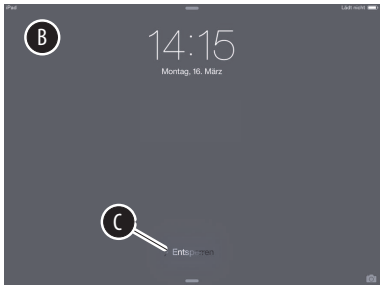
1. Press the On/Off switch [A] until the Unlock screen [B] is shown, with its slider [C] and red switch-off sign.
2. Slide the slider [C] to the right.
   The Mobile Control 7,9 will shut down and the display goes off.

5.11.2 Unlocking the Mobile Control 7,9 / Wall Control Panel



Unlocking:

1. Briefly press the Home button [A].
   The Unlocking screen [B] is displayed.



2. Slide the slider [C] to the right.

The control screen for the surgical light [D] is shown.

5.11.3 Switching the surgical light on/off

Switching individual surgical lights on:

In the action bar [A] of the TruRemote software, slide the slide control [B] to the right, from 0 to I.

The surgical light is shown in the operating range and the functions of the surgical light and the adjustment areas appear. In the information area, the current settings for the surgical light are displayed. The action bar shows functions for all surgical lights in the lighting system.

Switching all surgical lights on:

On the action bar [A], touch the icon [C] to switch all surgical lights in the lighting system on.

All surgical lights in the lighting system are switched on. The surgical light is shown in the operating range and the functions of the surgical light and the adjustment areas appear. In the information area, the current settings for the surgical light are displayed. The action bar shows functions for all surgical lights in the lighting system. The icon [C] has a white highlighted background.

Switching individual surgical lights off:

In the action bar [A] of the TruRemote software, slide the slide control [B] to the left, from I to 0.

The operating range shows the surgical light and its functions in gray. The settings areas are hidden. The information area is empty.

Switching all surgical lights off:

1. On the action bar [A], touch the icon [D] to switch all surgical lights in the lighting system off.
   A feedback window is displayed.
2. In the feedback window, touch the OK button to switch off the surgical light.
   All surgical lights in the lighting system are switched off. The operating range shows the surgical light and its functions in gray. The settings areas are hidden. The information area is empty. The icon [D] has a white glowing background.
   If the lighting system is not to be switched off, touch the Cancel button. The feedback window is closed and the control screen is active once more.

5.11.4 Operating the surgical light

1. Switch on the Mobile Control 7,9.
2. Activate the Mobile Control 7,9 / the Wall Control Panel and unlock it.
3. Mount a sterile handle on each surgical light.
4. Switch on all surgical lights of the lighting system at the relevant controls or in the action bar of the TruRemote software.
5. Position all surgical lights of the lighting system.
6. The handle adapter and, where available, the camera of the lamp heads should be pointed directly at the patient's wound area.
7. On the quick-access bar, touch the icon for the desired surgical light or the icon of the TruVidia Wireless Camera.
   The desired surgical light control screen or the TruVidia Wireless control screen will be shown.
8. In the functions area, touch the icon of the function to be set.
   In the settings area of the function, the settings options are displayed.
9. In the settings area of the function, touch the icon of the desired setting option.
   In the diagram of the surgical light, the change to the setting is visually displayed.
10. On the action bar, touch the function that is to be carried out for all surgical lights of the lighting system.
11. Switch the Mobile Control 7,9 / the Wall Control Panel to standby mode.
12. After surgery, switch off all surgical lights of the lighting system at the relevant controls or in the action bar of the TruRemote software.
13. Switch off the Mobile Control 7,9.
14. Connect the Mobile Control 7,9 to the charger for charging.

15. Remove all sterilizable handles/disposable handles/ disposable sleeves from the surgical lights.

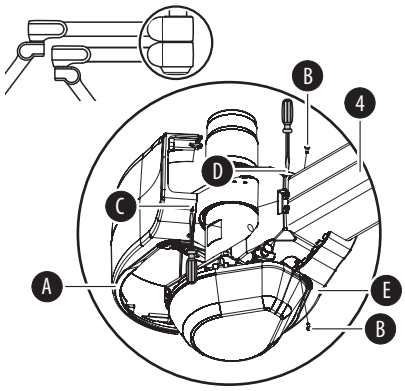
5.12 Adjusting the braking force at the boom and spring arm

The braking force should only be set by personnel who have been trained by Baxter in this work.

5.12.1 C boom

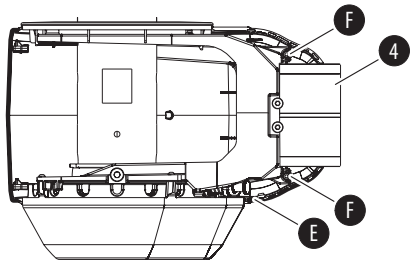
There are 2 opposing brake screws on each boom.

1. Switch off the surgical light at a control module and disconnect it from the mains power (see Chapter 5.7).
2. Remove the left back cover [A] from the boom [4].

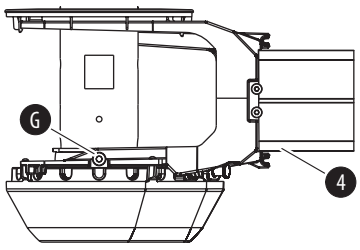


   a) Turn the boom so that the upper PT screw [B] is accessible.

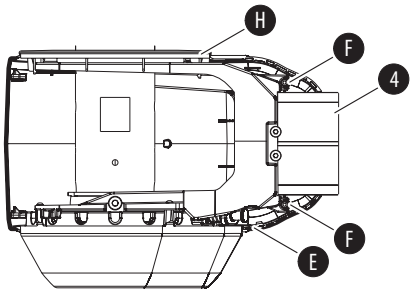
      For better access to the PT screw, remove the rear cover of the boom above it.
   b) Using a Torx T10 screwdriver, remove the upper and lower PT screw [B] on the left rear cover.
   c) Insert a suitable flathead screwdriver into the mounting opening [C] of the left rear cover.
   d) Press the flathead screwdriver slightly upwards and release the cover.
   e) Insert the flathead screwdriver into the mounting opening [D] of the right rear cover [E].
   f) Press the flathead screwdriver slightly downwards and release the cover.
   g) Carefully open the left rear cover at the joint between the two cover panels as far as possible and remove it from the boom.
3. Remove the right rear cover [A] from the boom [4].



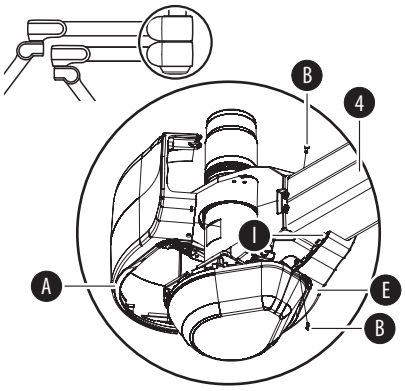
   a) Using a Torx T10 screwdriver, remove the upper and lower PT screw [F] on the right rear cover.
   b) Remove the right rear cover from the boom.



4. To adjust the brake force, alternately turn both opposite brake screws [G] by the same number of rotations with a Size 5 Allen key.
   – Increase the braking force:
     Turn the Allen key clockwise.
   – Reduce the brake force:
     Turn the Allen key in an anticlockwise direction.
5. Test the braking strength. The support arm component must be easily adjustable and remain steadily in the set swivel position.

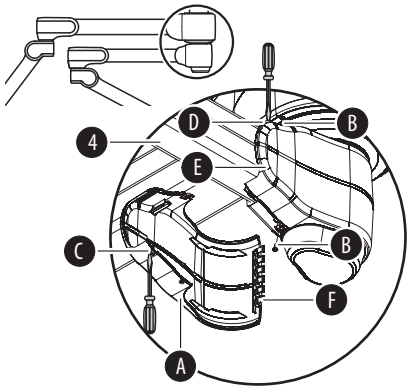


6. Install the right rear cover [E] on the boom [4].
   a) Position the right rear cover on the boom so that the upper cover [H] is inside the rear cover.
   b) Attach the right rear cover at the top and bottom to the boom with a PT screw [F] (Torx T10 screwdriver).



7. Install the left rear cover [A] on the boom [4].
   a) Turn the boom so that the hole for the upper PT screw [B] is accessible.
   b) At the joint between the two rear cover panels [A] and [E], insert the left cover into the catches [I] of the right cover and close it as if it was fitted on a hinge.
   c) Attach the left rear cover at the top and bottom to the boom with a PT screw [F] (Torx T10 screwdriver).
8. If necessary, install the rear cover of the boom above it.
9. Check the secure fit of the rear cover on the boom.
   – The covers on the boom must be connected to one another with the least possible gap.
   – The PT screws must be completely screwed in and may not protrude from the cover.

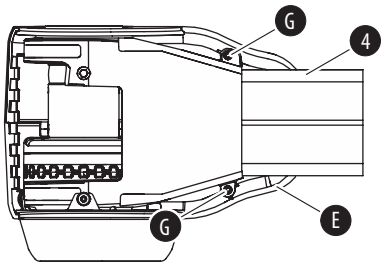
5.12.2 S boom



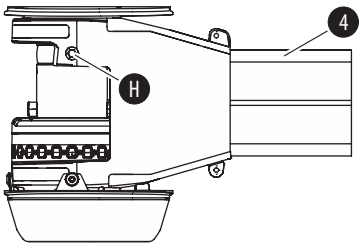
There are 2 opposing brake screws on each boom.

1. Switch off the surgical light at a control module and disconnect it from the mains power (see Chapter 5.7).
2. Remove the left back cover [A] from the boom [4].
   a) Turn the boom so that the upper PT screw [B] is accessible.

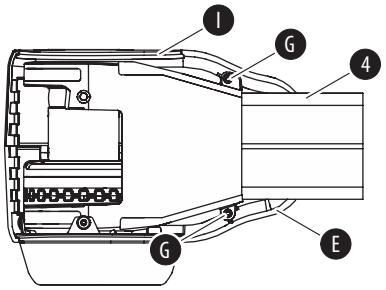
      For better access to the PT screw, remove the rear cover of the boom above it.
   b) Using a Torx T10 screwdriver, remove the upper and lower PT screw [B] on the left rear cover.
   c) Insert a suitable flathead screwdriver into the mounting opening [C] of the left rear cover.
   d) Press the flathead screwdriver slightly upwards and release the cover.
   e) Insert the flathead screwdriver into the mounting opening [D] of the right rear cover [E].
   f) Press the flathead screwdriver slightly downwards and release the cover.
   g) Carefully release the catches [F] of the left rear panel at the joint between the two cover panels.
   h) Remove the left rear cover from the boom.



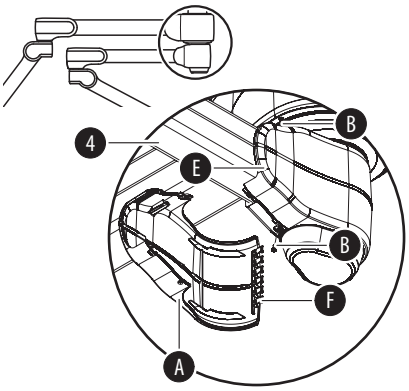
3. Remove the right rear cover [A] from the boom [4].
   a) Using a Torx T10 screwdriver, remove the upper and lower PT screw [G] on the right rear cover.
   b) Remove the right rear cover from the boom.



4. To adjust the brake force, alternately turn both opposite brake screws [H] by the same number of rotations with a Size 5 Allen key.
   – Increase the braking force:
     Turn the Allen key clockwise.
   – Reduce the brake force:
     Turn the Allen key in an anticlockwise direction.
5. Test the braking strength. The support arm component must be easily adjustable and remain steadily in the set swivel position.

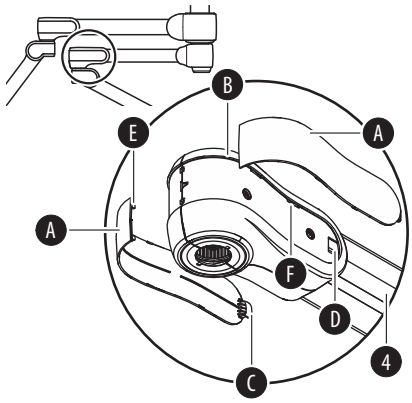


6. Install the right rear cover [E] on the boom [4].
   a) Position the right rear cover on the boom so that the upper cover [I] is inside the rear cover.
   b) Attach the right rear cover at the top and bottom to the boom with a PT screw [G] (Torx T10 screwdriver).



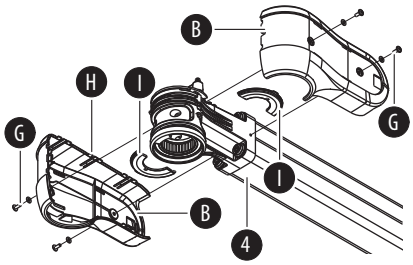
7. Install the left rear cover [A] on the boom [4].
   a) Turn the boom so that the hole for the upper PT screw [B] is accessible.
   b) At the joint between the two rear cover panels [A] and [E], insert the catches [F] of the left cover at an angle of 90 degrees into the catches of the right cover.
   c) Close the left rear cover as if it was fitted on a hinge.
   d) Attach the left rear cover at the top and bottom to the boom with a PT screw [F] (Torx T10 screwdriver).
8. If necessary, install the rear cover of the boom above it.
9. Check the secure fit of the rear cover on the boom.
   – The covers on the boom must be connected to one another with the least possible gap.
   – The PT screws must be completely screwed in and may not protrude from the cover.

5.12.3 Spring arm

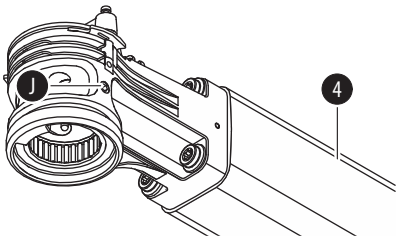


There are 2 opposing brake screws on each boom.

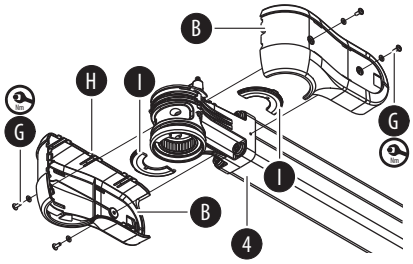
1. Switch off the surgical light at a control module and disconnect it from the mains power (see Chapter 5.7).
2. Remove the decor caps [A] of the socket cover [B].
   a) Lightly press in the right and left decor caps near the lugs [C] and pull the decor caps out of the openings [D].
   b) Carefully open the locking mechanisms [E] of the decor caps.
   c) Feed the right and left decor cap out of the mounts [F] and remove.



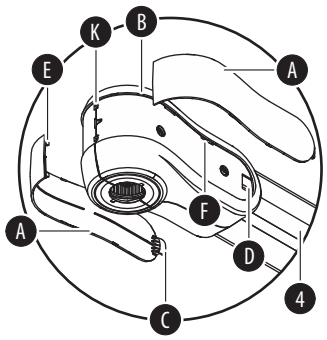
3. Remove the socket cover [B] from the boom [4].
   a) Using a Torx T10 screwdriver, remove 2 MLF screws and their washers [G] from each of the right and left socket covers.
   b) Carefully open the locking mechanisms [H] of the socket cover.
   c) Remove the right and left socket cover together with the optional faceplates [I] from the boom.



4. To adjust the brake force, alternately turn both opposite brake screws [J] by the same number of rotations with a Size 5 Allen key.
   – Increase the braking force:
     Turn the Allen key clockwise.
   – Reduce the brake force:
     Turn the Allen key in an anticlockwise direction.
5. Test the braking strength. The support arm component must be easily adjustable and remain steadily in the set swivel position.



6. Mount the socket cover [B] on the boom [4].
   a) Fasten the right socket cover together with the optional faceplate [I] with 2 MLF screws and washers [G] (Torx T10 torque screwdriver with a torque of 0.5 Nm/0.37 ft lb) on the boom.
   b) Position the left socket cover together with the optional faceplate [I] on the right socket cover so that all locking mechanisms [H] are pushed together and engage.
   c) Fasten the left socket cover with 2 MLF screws and washers [G] (Torx T10 torque screwdriver with a torque of 0.5 Nm/0,37 ft lb) on the boom.
7. Check the secure fit of the socket cover with the optional faceplates on the boom.
   – The covers on the boom must be connected to one another with the least possible gap.
   – Each socket cover must be attached with 2 MLF screws and washers.



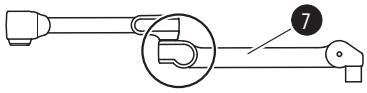
8. Install the decor caps [A] of the socket cover [B].
   a) Insert the right and left decor cap flush with the socket cover into the mounts [F], using light pressure.
   b) Push the lugs [C] of the decor caps into the recesses [D] of the socket cover and the locking mechanisms [E] into the mounts [K] until they engage.
9. Check the secure fit of the decor caps in the socket cover on the boom.
   – The decor caps must be connected to the socket cover with the least possible gap.

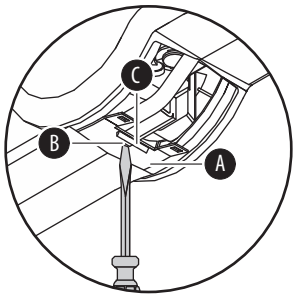
5.13 Setting the spring force of the spring arm

The spring force should only be set by personnel who have been trained by Baxter in this work.

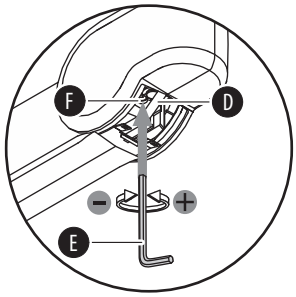
During adjustment work, make sure that any electrical cables in the spring arm remain routed in the center of the spring arm and do not slip underneath other components.

5.13.1 L21, LCH19 spring arm

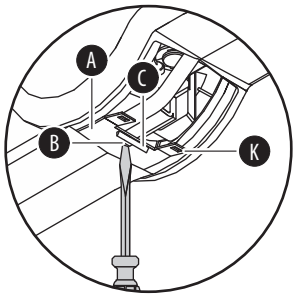




1. Switch off the surgical light at a control module and disconnect it from the mains power (see Chapter 5.7).
2. Open the lower faceplate [A].
   a) Insert a suitable flathead screwdriver into the opening [B].
   b) Slightly press the flathead screwdriver upwards and guide the locking hook [C] out of the rear spring arm cover.
   c) Push the faceplate towards the rear back into the side cover with the slot screwdriver.
3. Swivel the spring arm [7] 5 to 10 degrees upwards.
   The adjustment screw of the spring arm is relieved.

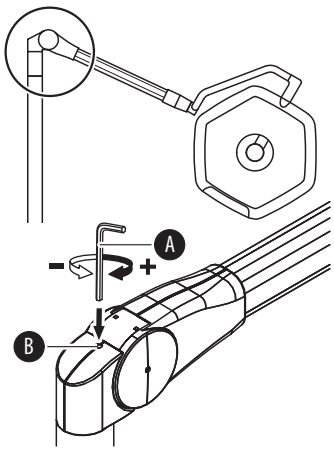


4. Carefully move any electrical cables [D] to the side and insert a Size 5 Allen key [E] into the adjustment opening [F].
5. Adjust the spring force.
   – If the spring arm drops, increase the spring force: Turn the Allen key in an anticlockwise direction.
   – If the spring arm rises, decrease the spring force: Turn the Allen key clockwise.
6. Test the spring strength. The support arm must remain stable in the set height position.



7. Close the lower faceplate [A].
   a) Manually pull the faceplate out of the side cover and insert the 2 catches [K] into the rear spring arm cover.
   b) Insert the flathead screwdriver into the opening [B], slightly press the faceplate upwards and guide the locking hook [C] into the rear spring arm cover.
8. Move the spring arm upwards and downwards. Check the secure fit of the upper and lower faceplate while doing so.
   – The locking hooks must engage with the rear spring arm cover.
   – The plates must slide easily in the lateral guides.

5.13.2 AC 2000 NRH mobil spring arm



1. Switch off the surgical light at a control module and disconnect it from the mains power (see Chapter 5.7).
2. Swivel the spring arm approx. 10 degrees upwards.
   The adjustment screw of the spring arm is relieved.
3. Insert a Size 5 Allen key [A] into the adjustment opening [B].
4. Adjust the spring force.
   - If the spring arm drops, increase the spring force:
     Turn the Allen key clockwise.
   - If the spring arm rises, decrease the spring force:
     Turn the Allen key in an anticlockwise direction.
5. Test the spring strength. The support arm must remain stable in the set height position.

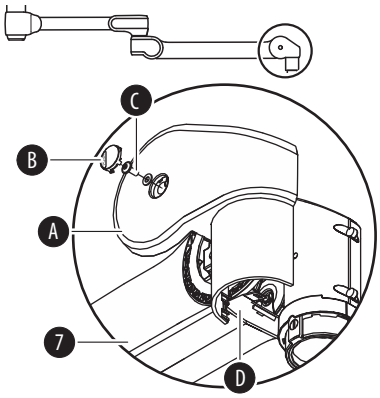
5.14 Adjusting the swivel range of the spring arm upwards and downwards

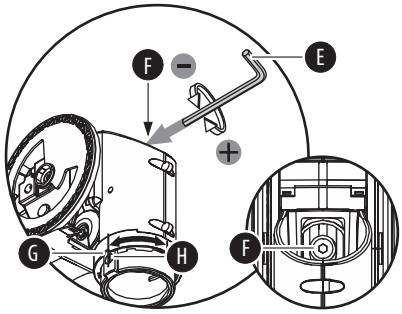
The swivel range should only be set by personnel who have been trained by Baxter for this work.

Set the swivel range in such a way that collision with the ceiling or adjacent objects is not possible.

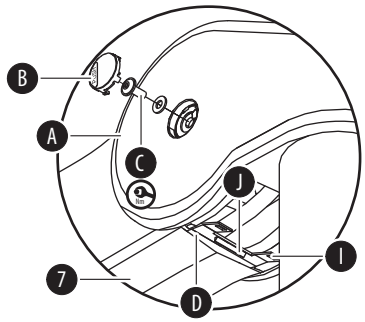
During adjustment work, make sure that any electrical cables in the spring arm remain routed in the center of the spring arm and do not slip underneath other components.

5.14.1 Spring arm L21



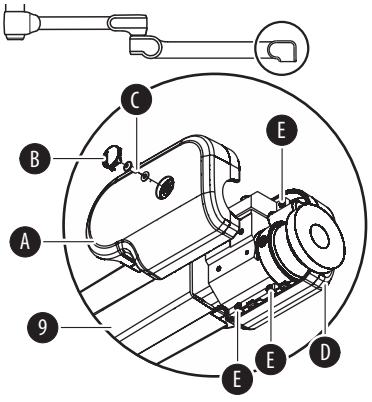


1. Switch off the surgical light at a control module and disconnect it from the mains power (see Chapter 5.7).
2. Pull the spring arm [7] down to relieve the setting screw.
3. Remove the front cover [A] from the spring arm [7].
   a) Press and remove the PUSH button [B] from the right and left front spring arm cover respectively.
   b) Using a Torx T10 screwdriver, remove 1 MLF screw and its washer [C] from each of the right and left front spring arm covers.
   c) Carefully unlock all catches at the joint between the two cover panels.
   d) Remove the front spring arm covers from the spring arm.
4. Manually push the upper and lower faceplates [D] into the side cover of the spring arm.
5. Insert a Size 5 Allen key [E] into the adjustment opening [F].
6. Adjust the swivel range.
   - Reducing the swivel range:
     Turn the Allen key in an anticlockwise direction.
   - Increasing the swivel range:
     Turn the Allen key clockwise.
7. Test the swivel range.

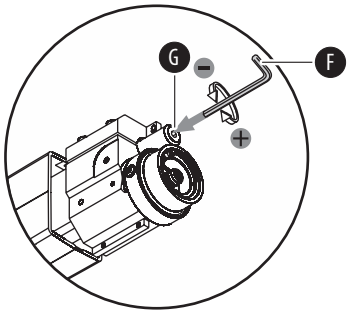


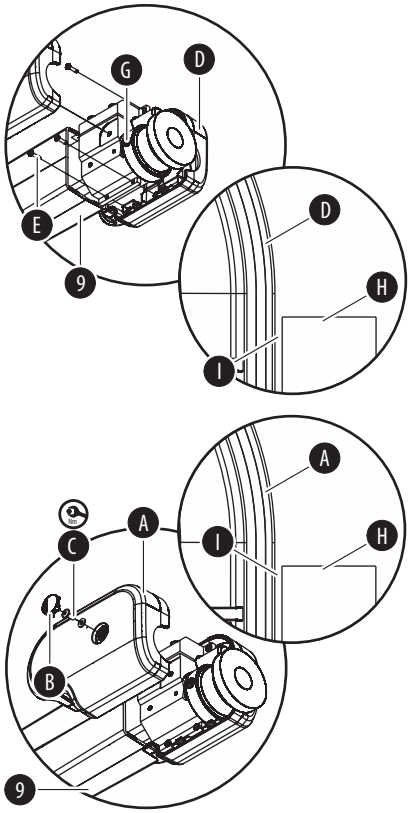
8. Mount the front cover [A] on the spring arm [7].
   a) Rotate the recess of the segment lock [G] over the optional brake screw or the brake screw opening [H].
   b) Position the right and left front spring arm covers on the spring arm so that, at the joint between the two front cover panels, all catches slide into one another and engage.
   c) Fasten the right and left front spring arm cover with one MLF screw and one washer [C] (Torx T10 torque screwdriver with a torque of 1 Nm/0.73 ft lb) each on the boom.
   d) Insert 1 PUSH-button [B] flush into each of the right and left front spring arm cover. The PUSH-button may not protrude from the cover.
9. Close the upper and lower faceplate [D].
   a) Manually pull the upper and lower faceplate out of the side cover in a forward direction and insert the 2 catches [I] into the front spring arm cover.
   b) Push the face plates further into the cover with a suitable flathead screwdriver, slightly press them upwards and guide the locking hooks [J] into the front spring arm cover.
10. Move the spring arm upwards and downwards. Check the secure fit of the upper and lower faceplate while doing so.
   – The locking hooks must engage with the front spring arm cover.
   – The plates must slide easily in the lateral guides.

5.14.2 Spring arm LCH19



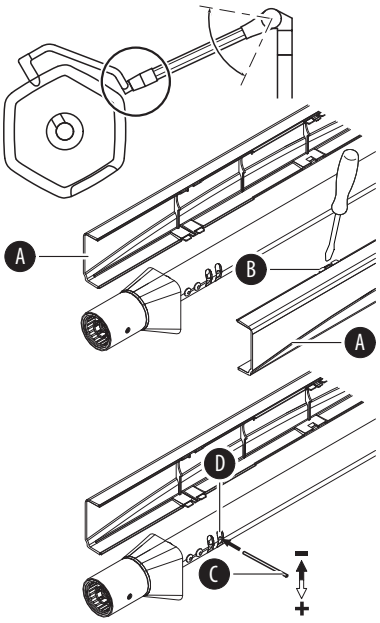
1. Switch off the surgical light at a control module and disconnect it from the mains power (see Chapter 5.7).
2. Pull the spring arm [9] down to relieve the setting screw.
3. Remove the left front cover [A] from the spring arm [9].
   a) Press and remove the PUSH-button [B] from the left front spring arm cover.
   b) Using a Torx T10 screwdriver, remove the MLF screw and its washer [C] from the left front cover.
   c) Carefully unlock the catches of the left front panel at the connecting edge between the two cover panels.
   d) Remove the left front cover from the spring arm.
4. Remove the right front cover [D] from the spring arm [9].
   a) Using a Torx T10 screwdriver, remove 3 PT screws [E] from the right front cover.
   b) Remove the right front cover from the spring arm.
5. Insert a Size 5 Allen key [F] into the adjustment opening [G].
6. Adjust the swivel range.
   – Reducing the swivel range:
   Turn the Allen key in an anticlockwise direction.
   – Increasing the swivel range:
   Turn the Allen key clockwise.
7. Test the swivel range.





8. Mount the front cover on the spring arm [9].
   a) Position the right front cover [D] on the spring arm so that there is a gap [I] between the connecting pin of the adaptation [H] and the cover.
   b) Attach the right front cover to the spring arm with 3 PT screws [E] (Torx T10 screwdriver).
   c) Position the left front cover [A] on the spring arm so that there is a gap [I] between the connecting pin of the adaptation [H] and the cover and so that, at the joint between the two front cover panels, all catches slide into one another and engage.
   d) Fasten the left front cover with 1 MLF screw and its washer [C] (Torx T10 torque screwdriver with a torque of 1 Nm / 0.73 ft lb) on the spring arm.
   e) Insert 1 PUSH-button [B] flush into the left front cover. The PUSH-button may not protrude from the cover.

5.14.3 AC 2000 NRH mobil spring arm

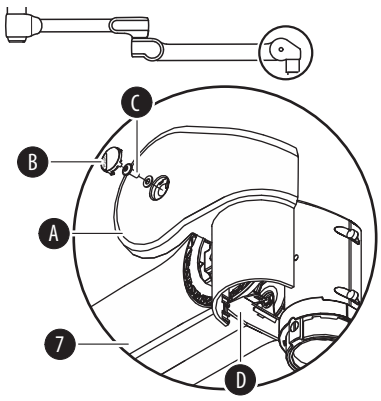


1. Switch off the surgical light at a control module and disconnect it from the mains power (see Chapter 5.7).
2. Separate the two cover halves [A] from each other and remove them. To do this, press the six tabs [B] on the cladding, using a slotted screwdriver.
3. Insert the pin [C] into setting opening [D] and set the swivel range.
   – Reduce the swivel range:
     Push the pin upwards.
   – Increasing the swivel range:
     Push the pin downwards.
4. Position the two cladding halves on the spring arm and press them together, so that the six tabs engage.
5. Check that the covers are securely attached.
6. Test the swivel range. Collisions must be avoided.

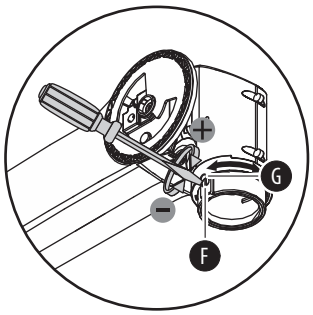
5.15 Adjusting the optional brakes on the spring arm

The braking force should only be set by personnel who have been trained by Baxter in this work.

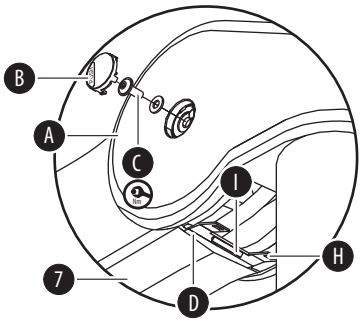
5.15.1 Spring arm L21



1. Switch off the surgical light at a control module and disconnect it from the mains power (see Chapter 5.7).
2. Remove the front cover [A] from the spring arm [7].
   a) Press and remove the PUSH button [B] from the right and left front spring arm cover respectively.
   b) Using a Torx T10 screwdriver, remove 1 MLF screw and its washer [C] from each of the right and left front spring arm covers.
   c) Carefully unlock all catches at the joint between the two cover panels.
   d) Remove the front spring arm covers from the spring arm.
3. Manually push the upper and lower faceplates [D] into the side cover of the spring arm.



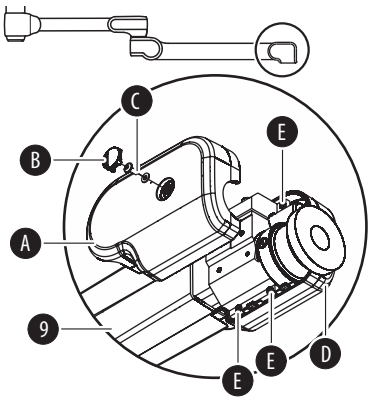
4. Adjust the brake [F] with a suitable flathead screwdriver.
   – Increase the braking force:
   Turn the flathead screwdriver clockwise.
   – Reduce the brake force:
   Turn the flathead screwdriver in an anticlockwise direction.
5. Test the braking strength. The support arm component must be easily adjustable and remain steadily in the set swivel position.



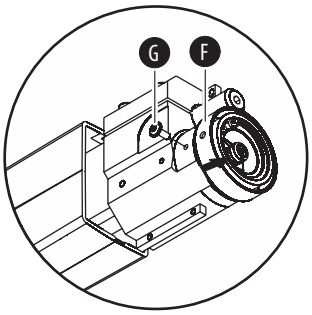
6. Mount the front cover [A] on the spring arm [7].
   a) Rotate the recess of the segment safety catch [G] over the optional brake screw.
   b) Position the right and left front spring arm covers on the spring arm so that, at the joint between the two front cover panels, all catches slide into one another and engage.
   c) Fasten the right and left front spring arm cover with one MLF screw and one washer [C] (Torx T10 torque screwdriver with a torque of 1 Nm/0.73 ft lb) each on the boom.
   d) Insert 1 PUSH-button [B] flush into each of the right and left front spring arm cover. The PUSH-button may not protrude from the cover.
7. Close the upper and lower faceplate [D].
   a) Manually pull the upper and lower faceplate out of the side cover in a forward direction and insert the 2 catches [H] into the front spring arm cover.
   b) Push the face plates further into the cover with a suitable flathead screwdriver, slightly press them upwards and guide the locking hooks [I] into the front spring arm cover.

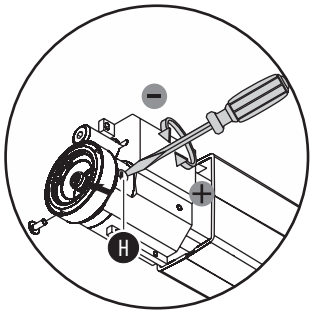
8. Move the spring arm upwards and downwards. Check the secure fit of the upper and lower faceplate while doing so.
   – The locking hooks must engage with the front spring arm cover.
   – The plates must slide easily in the lateral guides.

5.15.2 Spring arm LCH19

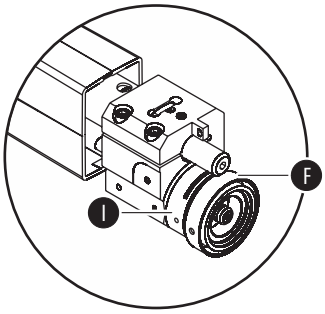


1. Switch off the surgical light at a control module and disconnect it from the mains power (see Chapter 5.7).
2. Remove the left front cover [A] from the spring arm [9].
   a) Press and remove the PUSH-button [B] from the left front spring arm cover.
   b) Using a Torx T10 screwdriver, remove the MLF screw and its washer [C] from the left front cover.
   c) Carefully unlock the catches of the left front panel at the connecting edge between the two cover panels.
   d) Remove the left front cover from the spring arm.
3. Remove the right front cover [D] from the spring arm [9].
   a) Using a Torx T10 screwdriver, remove 3 PT screws [E] from the right front cover.
   b) Remove the right front cover from the spring arm.
4. Move the segment safety catch [F].
   a) Using a Torx T10 screwdriver, remove 1 MLF screw [G] from the segment safety catch.
   b) Push the segment safety catch forwards until the brake screw [H] is accessible.

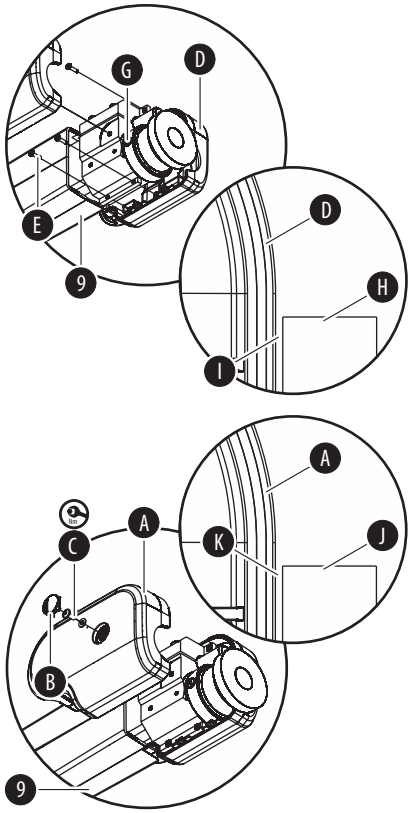




5. Adjust the brake [H] with a suitable flathead screwdriver.
   – Increase the braking force:
   Turn the flathead screwdriver clockwise.
   – Reduce the brake force:
   Turn the flathead screwdriver in an anticlockwise direction.
6. Test the braking strength. The support arm component must be easily adjustable and remain steadily in the set swivel position.

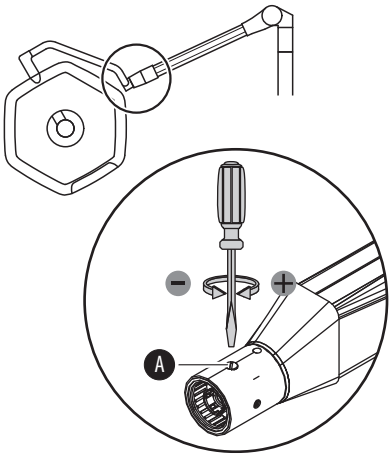


7. Move the segment safety catch [F].
   a) Push the segment safety catch backwards until it no longer protrudes over the mounting opening [I].
   b) Attach the segment safety catch to the spring arm using 1 MLF screw [G] (Torx T10 screwdriver).



8. Mount the front cover on the spring arm [9].
   a) Position the right front cover [D] on the spring arm so that there is a gap [K] between the connecting pin of the adaptation [J] and the cover.
   b) Attach the right front cover to the spring arm with 3 PT screws [E] (Torx T10 screwdriver).
   c) Position the left front cover [A] on the spring arm so that there is a gap between the connecting pin of the adaptation and the cover and so that, at the joint between the two front cover panels, all catches slide into one another and engage.
   d) Fasten the left front cover with 1 MLF screw and its washer [C] (Torx T10 torque screwdriver with a torque of 1 Nm/ 0.73 ft lb) on the spring arm.
   e) Insert 1 PUSH-button [B] flush into the left front cover. The PUSH-button may not protrude from the cover.

5.15.3 AC 2000 NRH mobil spring arm

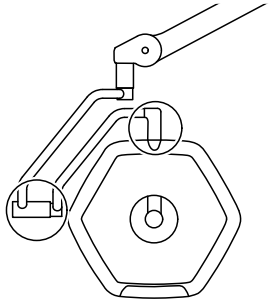


1. Switch off the surgical light at a control module and disconnect it from the mains power (see Chapter 5.7).
2. Use a suitable Phillips screwdriver to remove the locking screw on the retaining sleeve.
3. Turn the retaining sleeve until the brake screw becomes visible on the bottom.
4. Adjust the brake [A] with a suitable flathead screwdriver.
   – Increase the braking force:
     Turn the flathead screwdriver clockwise.
   – Reduce the brake force:
     Turn the flathead screwdriver in an anticlockwise direction.
5. Test the braking strength. The surgical light must be easy to adjust and remain steadily in the set swivel position.
6. Rotate the retaining sleeve back into the original mounting position and secure it with the locking screw.

5.16 Adjusting the brake force on the surgical light

The braking force should only be set by personnel who have been trained by Baxter in this work.

1. Switch off the surgical light at a control module and disconnect it from the mains power (see Chapter 5.7).



2. To adjust the brake force, alternately turn both opposite brake screws by the same number of rotations with a suitable flathead screwdriver.
   – Increase the braking force:
     Turn the flathead screwdriver clockwise.
   – Reduce the brake force:
     Turn the flathead screwdriver in an anticlockwise direction.
3. Test the braking strength. The light head must be easy to adjust and remain steadily in the set rotation position.

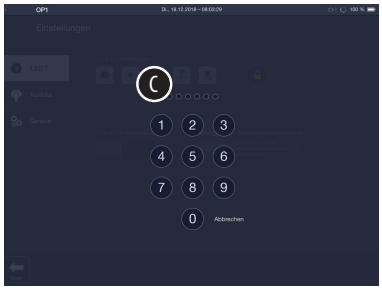
5.17 Adapting the TruRemote software

Adaptation of the TruRemote software may only be carried out by trained hospital technicians authorized by Baxter.

5.17.1 Opening the password-protected settings page

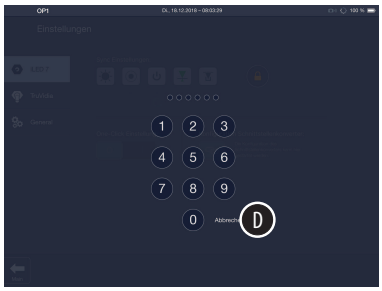
1. On the operating page, touch the Settings button [A].
   The password-protected adjustment screen will be shown as blocked.

2. Touch the lock icon [B] on the blocked, password-protected settings page.
   The login window is displayed.



3. Enter the six-digit number code provided to you when the surgical light was handed over or when training by the Baxter personnel took place.
   When entering each individual digit of the number code, a point in the code display [C] will fill up.

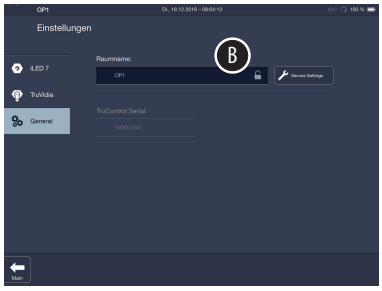
The password-protected settings page will be shown as unlocked.



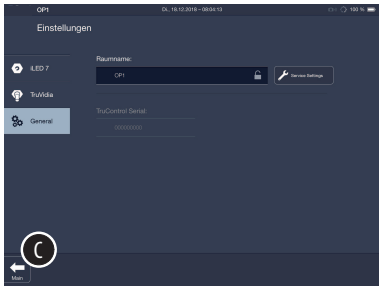
If the password-protected settings page does not unlock, the number code entered was incorrect. Enter the six-digit number code again or abort the process.
To do this, touch the Cancel button [D].
The operating page will be shown again.

5.17.2 Changing the name of the room

1. Open the password-protected settings page.
2. Touch the General icon [A] in the quick-access bar of the settings page.
   The general settings screen is displayed.



3. Touch the field [B] room name.
   A window with a keypad is shown.
4. Enter the new room name.



5. Touch the Main button [C].
   The change is saved.

The last operating page selected for the surgical light is displayed.

5.17.3 Defining the scope of synchronization

When this function is activated, the current settings of the selected surgical light are automatically transferred to all other surgical lights in the lighting system.

The following functions can be defined during synchronization:

- Light field size
- Lighting intensity
- ALC Plus
- Shadow management
- Switching on and off

The color temperature is always synchronously adjusted. This function cannot be deactivated during synchronization.

1. Open the password-protected settings page.

2. Touch the icon of the desired function in the Sync Settings area [A].
   If a function is activated, the icon will be shown in gray.
   If a function is deactivated, the icon will be shown in black.
3. Touch the Main button [B].
   The change is saved.
   When leaving the Settings page, a warning message appears that the settings must be adjusted separately for each control unit.

   The last operating page selected for the surgical light is displayed.

5.17.4 Activating/deactivating the one-click page

Activation:

1. Open the password-protected settings page.

2. Pull the slide controller [B] in the One-Click Settings area [A] to the right, from 0 to I.
3. Touch the Main button [C].
   The change is saved.
   When leaving the Settings page, a warning message appears that the settings must be adjusted separately for each control unit when several control units are used.

The One-click page will be shown.

Deactivation:

1. Open the password-protected settings page.

2. Pull the slide controller [B] in the One-Click Settings area [A] to the left, from I to 0.
3. Touch the Main button [B].
   The change is saved.

The control page for the surgical light is displayed.

5.18 Decommissioning

⚠ WARNING

Risk of infection

The product may be contaminated with infectious substances.

- The product must always be disinfected before temporarily or permanently taking it out of service.

Disconnect the surgical light from all mains power supply terminals (see Chapter 5.7), and secure it against being switched on again when temporarily or permanently taking the surgical light out of service. Disassembly of the surgical light in case of permanent decommissioning may only be carried out by qualified service technicians.

6 Cleaning and disinfection

⚠ WARNING

Risk of infection for the patient

- No cleaning work may be carried out during operation.

⚠ WARNING

Danger of electric shock

Contact with live parts may result in electric shock.

- Decommission the surgical light before cleaning and disinfecting it. See information in Chapter 5.7.
- Before cleaning and disinfection, take all products connected to the surgical light (for example, Mobile Control 7,9, TruVidia Wireless camera) out of service.
- Dose cleaning agents and disinfectants so that no fluid can enter into the joints or openings of the surgical light or parts of the support arm system.
- Do not insert objects into device openings.

⚠ WARNING

Improperly used cleaning agents or disinfectants can endanger patients or damage products.

Failure to comply with the specifications and directions in this section can lead to the risk of contamination or infection for patients or damage products. It also completely voids the warranty.

- Use wipe-down disinfection only as the disinfection method.
- The cloth used to clean / disinfect the device should only be damp, not wet.
- Dispense cleaning agents and disinfectants such as to ensure that no liquid can enter through joints or openings of the support arm system, the surgical light, the Mobile Control 7,9 or the Wall Control Panel.
- Only use surface disinfectants in the concentration specified by the manufacturer.
- Only use 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.
- The operator's hygiene guidelines must be complied with.

To avoid damage to surfaces, note the following:

- Do not use sharp, pointed or abrasive objects.
- Do not use abrasives or stripping agents.
- Do not use solvents, gasoline, or paint thinners, or alkaline, acidic, or aldehyde-containing cleaning agents.
- Do not use cleaning agents with glycol derivatives, phenols, phenol derivatives or quaternary compounds.
- To avoid damage to paint and corrosion, only use agents that are free of chlorides or halogenides.
- The operator's hygiene guidelines must be complied with.

NOTICE

The patient may be at risk or the product may be damaged when using unsuitable cleaning agents or disinfectants.

Non-compliance with cleaning or disinfection specifications voids all warranty claims. No liability is assumed for damage caused by inappropriate cleaning/disinfection agents. The warranty is valid only for undamaged surfaces.

Safe use of the surgical light system, the Mobile Control 7,9 and the Wall Control Panel requires regular cleaning and disinfection of these components with suitable cleaning agents or disinfectants after each surgical intervention.

The operator must meet the requirements of the national Commission for Hygiene and Disinfection.

The cleaning and disinfection of the surgical light system may only be performed by a hygiene specialist or a person instructed by the hygiene specialist.

Only agents or chemicals compatibility-tested and approved by Baxter may be used for cleaning and disinfecting. When using alternative cleaning agents and disinfectants, Baxter cannot confirm any material compatibility. Do not use agents that are not listed, as otherwise functional components may be altered or damaged.

Before actual disinfection, thorough cleaning of any visible impurities, such as body fluids, must be performed.

To clean heavy or stubborn dirt, use only a soft brush and mild cleaner or cleaning disinfectant. Disinfection can take place once all the visible contaminants have been removed.

After a risk of contamination of the product through potentially infectious material (e.g. blood, secretions or excrements) disinfect the surfaces immediately, especially where such material has built up.

Use only wipe-down disinfection as the disinfection method. Disinfection using UV light or steam is prohibited.

It is recommended to use the Mobile Control 7,9 after single wipe disinfection in a protective enclosure. The most suitable product is Catalyst Case iPad Mini 5 made by Catalyst, with part number 2074252.

The handles are sterilizable. Take note of the operating instructions for the handle.

6.1 Wipe-down disinfection

⚠ WARNING

Switching off the power supply

Contact with live parts may result in electric shock.

- Before cleaning and disinfection, the permanently connected ME device must be disconnected from all phases of the power supply grid. The ground conductor connection (PE) must remain intact.
- It must be possible to lock the power supply disconnector in the off position.
- For ME devices that are not permanently connected and have no power supply main switch, a suitable plug device to disconnect the ME device from the power supply grid will meet this requirement.
- Separate all electrical phases of these components according to Chapter 5.7:
  - Ceiling-mounted version
  - Mobile pedestal version
  - Lamp head or support arm system
- Ensure that no cleaning and disinfecting agents penetrate the lamp head or support arm system.
- Do not insert objects into device openings.

⚠ DANGER

Risk of fire or explosion due to disinfectants

Flammable or explosive atmospheres may be created when handling disinfectants due to the formation 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.

The disinfection procedure to be used for the lamp head, the support arm system, the Mobile Control 7,9 and the Wall Control Panel is wipe disinfection. The lamp head must be cool for cleaning and disinfection.

Only clean and disinfect the surgical light system, the Mobile Control 7,9 and the Wall Control Panel by wiping 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.

Applying too much fluid to the surface during disinfection leaves residue behind. 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. The regularity of cleaning depends on the frequency of disinfection, but should be carried out at least once a month.

Cleaning procedure

1. Disconnect the surgical light system from all power supply terminals and secure it against being switched back on. See Chapter 5.7.
2. Allow the device components to cool. Only clean or disinfect the surgical light system when it is cold.
3. Remove the TruVidia Wireless camera as required. The handle adapter #2065945 (Adaption Standard handle) or #2066135 (Adaption disposable handle) must be attached to the camera mount of the light head as a cover for the mount and as a compensation weight.
4. Moisten a cloth with cleaning agent or disinfectant.
5. Clean the surgical light system with the damp but not wet cloth.

6.2 Recommended disinfecting agents

Baxter recommends the following disinfecting agents for manual use:

Manufacturer	Product 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%

Comply with the hygiene guidelines of the product and the instructions of the disinfectant manufacturer.

The disinfectant information, regarding application concentrations and exposure time, must be followed.

The following disinfectants are permitted to disinfect the surfaces of the support arm system (ceiling conduit, central axis, boom and spring arms):

Preparation	Active ingredient
Meliseptol	Alcohols/aldehydes
Ethanol 60%	Alcohols
Chlorhexidine 0.5% in 70% ethanol	Chlorine-based
Chlorine 250 ppm in 1 liter of distilled water	Chlorine-based
Haemosol 1% in 1 liter of water	Guanidine derivative
Dismozon pure	Peroxide compounds

Preparation	Active ingredient
Incidin Extra N	Quaternary compounds, alkylamine derivative
Terralin protect	Quaternary compounds, glycol derivative

7 Troubleshooting

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

Error	Possible cause	Correction
Support arm		
The lamp head moves down or rises.	The spring force in the spring arm is too low or too high.	Adjust the spring force.
The lamp head movement is too hard or too easy.	The brake force is set too high or too low.	Adjust the brake force.
Optical Device / light technology		
Lighting intensity is too low.	Lighting intensity is set too low.	Increase the brightness.
		More than 10 LEDs are defective. Notify the Technical Customer Service.
Uneven light field	Lamp head is outside the working area.	Position the lamp head in the appropriate working area.
	Impact/effect on the surgical lights	Switch the lamp head off and on again.
The surgical light does not come on.	External power supply is switched off.	Switch on the external power supply.
	The lamp head has been switched off at the controls.	Press the On/Off button on the controls.
	The power plug of the mobile pedestal version is not plugged in.	Plug the power plug into the socket.
	The power supply unit of the mobile pedestal version is not switched on.	Press the On/Off switch on the power supply unit.
	Electronics are faulty.	Notify the Technical Customer Service.
	The local power supply is interrupted.	Check the local fuses and power supply.

Error	Possible cause	Correction
The automated distance measurement does not work (ALC Plus indicator flashes).	Failure of the sensor or repeated incorrect measurements.	– Deactivate ALC Plus function with the help of the Mobile Control 7,9, or – Deactivate ALC Plus function with the help of the secure mode, or – Disconnect the power to the surgical light system to force a restart.
Different color temperatures in the light field	The color temperature is only set on one lamp head.	Switch on the synchronization function.
Mobile Control 7,9 operation		
The surgical light cannot be operated with the Mobile Control 7,9.	Fault in the WLAN connection	Control lighting intensity using the controls on the lamp head.
	The Mobile Control 7,9 is faulty.	

8 Maintenance

⚠ WARNING

Do not carry out any maintenance work during surgery or while the device is in use.

The surgical light system must be serviced at least every 2 years after handover to the user. After ten years of operation, maintenance of the surgical light must be carried out annually.

Product maintenance or the exchange of components may only be carried out by qualified service technicians.

The contact details of service technicians can be obtained from the Technical Customer Service at Baxter.

Baxter recommends concluding a maintenance agreement, so that maintenance can be carried out promptly and reliably.

9 Repair

⚠ WARNING

Do not carry out any maintenance work during surgery or while the device is in use.

The products must be repaired only by qualified service technicians. The contact details of service technicians can be obtained from the Technical Customer Service at Baxter.

After each repair, an electrical safety inspection according to the criteria specified by Baxter must be carried out.

10 Spare parts

The wear parts may only be exchanged by staff trained in this work by Baxter.

Product designation	Part number
Service parts on the boom	
SP-ValiaS, braking screws M10	1946894
Service parts on the spring arm	
SP-VALiA, basic spring arms, M10 brake screws	1946909
Brake screw M12x1-21 mm	1378866
Wear parts on the iLED 7 1/4 bracket	
Brake screw M10x1-11 mm	4025239

11 Disposal

Within the European Union, the product is subject to Directive 2012/19/EU on Waste Electrical and Electronic Equipment and complies with the requirements in Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, amended by the Commission delegated directive 2015/863 of 31 March 2015 as regards the list of restricted substances (RoHS). The surgical light may not be disposed of via municipal collection points for waste electrical devices.

In countries outside the European Union (EU), the legal regulations applicable in the respective country must be observed.

If you have any questions about proper disposal, please contact the Technical Customer Service at Baxter, your local dealer, or the appropriate national authority.

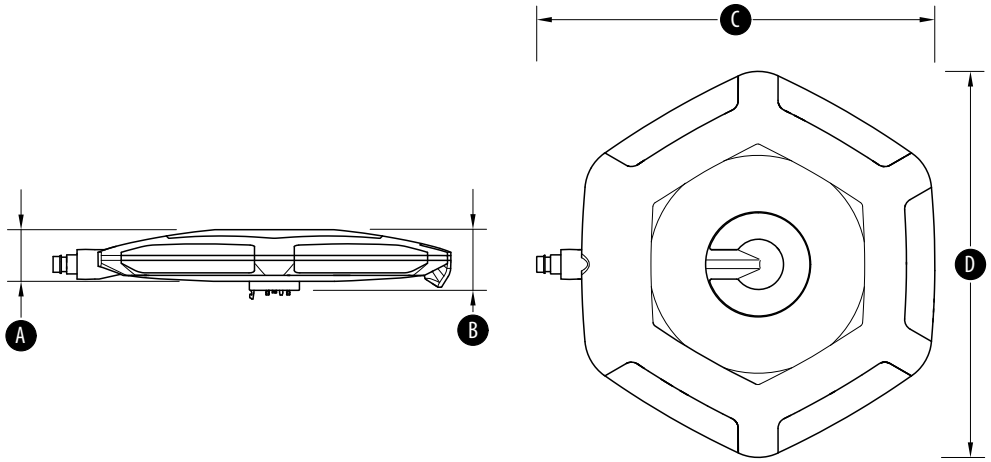
In addition to regional disposal, faulty or obsolete products can be returned to Baxter. Baxter will ensure environmentally sound disposal. Detailed information about returns is provided by the Technical Customer Service at Baxter.

12 Technical data

12.1 Surgical light accessories

Product designation	Equipment
Sterile Light Control (SLC)	Optional
Adaptive Light Control Plus (ALC Plus)	Present
Automatic shade management (available for a maximum of 2 surgical lights on a single ceiling pipe)	Present

12.2 Device data

Dimensions	
	
Height [A]	95.1 mm/ 3.74 inch
Height [B]	111.4 mm/ 4.39 inch
Width [C]	731.2 mm/ 28.79 inch
Width [D]	709.0 mm/ 27.91 inch

IP classification according to IEC 60529	
Lamp head	IP40
Support arm system	
VALiA	IP30
VISTA	IP10
Mobile Control 7,9 with Catalyst Case iPad Mini 5 (#2074252, product from a third-party manufacturer)	IP54
Wall Control Panel	IP42

Electrical data	
Supply voltage at the power supply unit	100–240 V AC 50/60 Hz
Supply voltage to the 24 V converter	22–32 V DC 22–26 V AC
Maximum power consumption for a surgical light	< 160 VA
Internal fuse (only mobile pedestal version)	2× T10 A

Electrical data	
Voltage at the fixed point on the ceiling	48 V
Classification according to the Act on Medical Devices (MPG)	1

Operating mode	
Surgical light system	Continuous operation

Lighting data All light technology values maximum +/- 10% tolerance			
Central lighting intensity at a distance of 0.8 m/1.0 m/1.3 m (31.50 inch/39.37 inch/51.18 inch)	160,000 lux		
Dimmable from/to	< 10% Endo 30% – 100%		
Light field size can be varied by changing the distance	16 cm – 30 cm / 6.30 inch – 11.81 inch		
Focusable light field size (d10) at 1.0 m/39.37 inch	Narrow	Medium	Wide
	approx. 16 cm/ 6.30 inch	approx. 20 cm/ 7.87 inch	approx. 25 cm/ 9.84 inch
Focusable light field size (d50) at 1.0 m/39.37 inch	Narrow	Medium	Wide
	approx. 10 cm/ 3.94 inch*1	approx. 12 cm/ 4.72 inch*1	approx. 14 cm/ 5.51 inch*1
	*1 The value d50 is subject to a tolerance of +/- 2 cm (+/- 0.79 inch).		
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/75.98 inch with ALC Plus		
Illumination depth (L1 + L2) at 60% Ec / EN ISO 60601-2-41 3rd Edition	1090 mm/42.91 inch with ALC Plus		
Average service life of the LEDs	> 60,000 hrs.		
Color temperature	3,500 K, 4,000 K, 4,500 K, 5,000 K		
Color rendition index Ra	Max. 97		
Color rendition index R9	Max. 96		
Color rendition index R13	Max. 99		

Lighting data All light technology values maximum +/- 10% tolerance	
Radiation strength (W/m^2) at a distance of 1.3 m / 51.18 inch	Approx. 623
Radiant flux density/lighting intensity (mW/m^2 lx)	Approx. 3.84

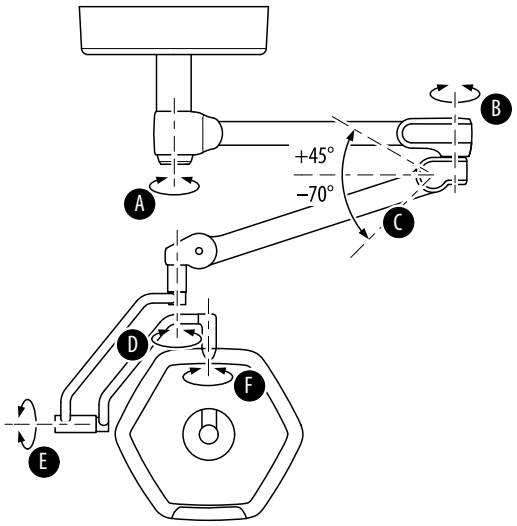
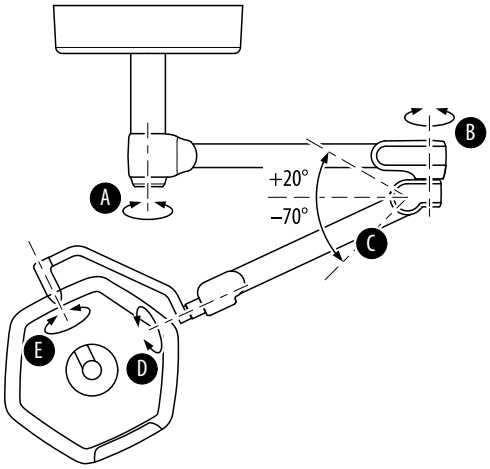
Mechanical Data	
Diameter of the lamp head	710 mm/ 27.95 inch
Illuminated area of the lamp head	3300 cm^2 / 511.50 $inch^2$
Light-emitting surface	1996 cm^2 / 309.38 $inch^2$
Area of the lamp head aperture	200 cm^2 / 31.00 $inch^2$
Weight of the lamp head (including comfort bracket and 1/4 bracket)	approximately 18.5 kg / 40.8 lbs

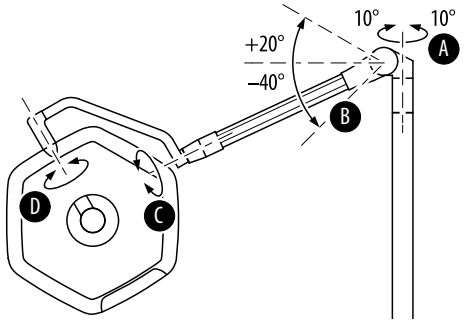
Specification of 3D sensor for distance measurement	
Maximum output power	108 mW
Wavelength	860 nm

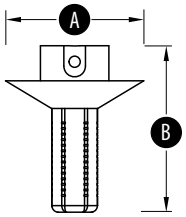
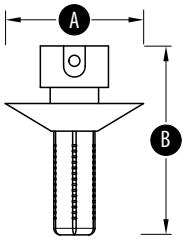
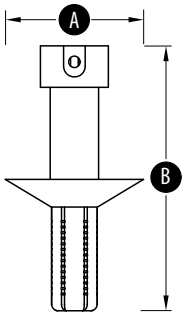
WLAN specification	
Wireless communication and mobile radio	IEEE 802.11a, 802.11b, 802.11g, 802.11n
Data rate	802.11b: 1, 2, 5.5, 11 Mbps 802.11g: 6, 9, 12, 18, 24, 36, 48, 54 Mbps 802.11n: MCS0 up to MCS7 with and without short GI
Internal frequencies	Dual-band (2.4 GHz or 5 GHz)

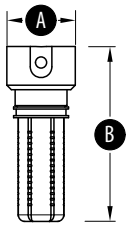
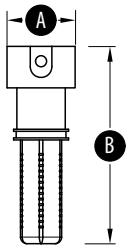
Internal frequencies	
2412–2484 MHz	802.11 b/g/n
4910–5825 MHz	802.11 a
800 MHz	Processor
480 MHz / 5 GHz	USB 2.0/3.0
16 MHz	Micro-controller

12.2.1 Support arm system swivel ranges

Joint		Swivel range
Ceiling-mounted version with L21 spring arm		
		
[A]	Ceiling conduit – Boom	Horizontal: > 360° (without stop)
[B]	Boom – Spring arm L21	Horizontal: > 360° (without stop)
[C]		Vertical: +45° to -70°
[D]	Spring arm L21 – iLED 7 comfort bracket	Horizontal: > 360° (without stop)
[E]	iLED 7 comfort bracket – 1/4 bracket iLED 7	Vertical: > 360° (without stop)
[F]	1/4 bracket iLED 7 – Lamp head	Vertical: > 360° (without stop)
Ceiling-mounted version with LCH19 spring arm (Version: Low room height)		
		
[A]	Ceiling conduit – Boom	Horizontal: > 360° (without stop)
[B]	Boom – Spring arm LCH19	Horizontal: > 360° (without stop)
[C]		Vertical: +20° to -70°
[D]	Spring arm LCH19 – 1/4 bracket iLED 7	Vertical: > 360° (without stop)
[E]	1/4 bracket iLED 7 – Lamp head	Vertical: > 360° (without stop)

Mobile pedestal version		
		
[A]	Pedestal rod – Spring arm AC 2000 NRH mobil	Horizontal: +10° to -10°
[B]		Vertical: +20° to -40°
[C]	Spring arm AC 2000 NRH mobil – 1/4 bracket iLED 7	Vertical: > 360° (without stop)
[D]	1/4 bracket iLED 7 – Lamp head	Vertical: > 360° (without stop)

Handle sleeve flange type short handle adapter		
	Diameter [A]	101.6 mm / 4.00 inch
	Length [B]	122.3 mm / 4.81 inches
Handle sleeve flange type middle handle adapter		
	Diameter [A]	101.6 mm / 4.00 inch
	Length [B]	138.8 mm / 5.46 inches
Handle sleeve flange type long handle adapter		
	Diameter [A]	101.6 mm / 4.00 inch
	Length [B]	194.6 mm / 7.66 inches

Handle sleeve ring type short handle adapter		
	Diameter [A]	50.3 mm / 1.98 inch
	Length [B]	128.5 mm / 5.06 inches
Handle sleeve ring type long handle adapter		
	Diameter [A]	50 mm / 1.97 inch
	Length [B]	145 mm / 5.71 inches

12.3 Electromagnetic compatibility

⚠ WARNING

Only operate the iLED 7 surgical light/Mobile Control 7,9/Wall Control Panel with the accessories specified

- The iLED 7 System/Mobile Control 7,9/Wall Control Panel may only be operated with the accessories indicated in the accompanying documentation. Operation with accessories, converters or cables other than those specified in the accompanying paperwork can lead to increased EMC emissions or reduced immunity of the iLED 7 System/Mobile Control 7,9/Wall Control Panel 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 the iLED 7 System/Mobile Control 7,9/Wall Control Panel determined according to emissions permit it to be used in the industrial sector and in hospitals (CISPR 11, Class A). When used in domestic situations (for which CISPR 11 Class B is normally required), iLED 7 System/ Mobile Control 7,9/Wall Control Panel may not provide adequate radio equipment protection. Where necessary, the user must take remedial measures such as the relocation or readjustment of the iLED 7 System/Mobile Control 7,9/Wall Control Panel.

NOTICE

Installing and operating the iLED 7 surgical light/Mobile Control 7,9/Wall Control Panel according to the EMC instructions

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

Key performance features

The key feature of the iLED 7 surgical light system is the provision of illumination and limitation of the energy over the operating area. Components such as the Wall Control Panel, Mobile Control 7,9 and interface converter do not feature any key performance characteristics as per this standard.

NOTICE

Do not stack the iLED 7 surgical light/Mobile Control 7,9/Wall Control Panel on top of or next to other devices.

- The iLED 7 surgical light system/Mobile Control 7,9/Wall Control Panel may not be stacked immediately next to or on top of other devices.

Guidelines and manufacturer's declaration – electromagnetic emissions		
The iLED 7 surgical light system/Mobile Control 7,9/Wall Control Panel is intended for use in the electromagnetic environment indicated below. The customer or user of the iLED 7 surgical light system/Mobile Control 7,9/Wall Control Panel must 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 7 surgical light 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 iLED 7 surgical light system is intended for operation in facilities other than private homes, provided that these facilities are directly connected to a public power supply network that also supplies buildings used for residential purposes.
Harmonic emissions as per EN/IEC 61000-3-2	Class A	
Voltage fluctuations / flickers in accordance with EN/IEC 61000-3-3	fulfilled	
HF emissions in accordance with CISPR 11	Class B	The Mobile Control 7,9 is suitable for use in all establishments including private homes and those directly connected to a public power supply network that also supplies buildings used for residential purposes.
Harmonic emissions as per EN/IEC 61000-3-2	Class B	
Voltage fluctuations / flickers in accordance with EN/IEC 61000-3-3	fulfilled	

Guidelines and manufacturer's declaration – electromagnetic immunity

NOTICE

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

Guidelines and manufacturer's declaration – electromagnetic immunity			
The iLED 7 surgical light system/Mobile Control 7,9/Wall Control Panel is intended for use in the electromagnetic environment indicated below. The customer or user of the iLED 7 surgical light system/Mobile Control 7,9/Wall Control Panel must ensure that it is operated in such an environment.			
Immunity testing	EN/IEC 60601-1 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	The floor should be made of wood or concrete, or should be covered with ceramic tiles. If a floor is covered with synthetic material, the relative humidity must be at least 30%.

Guidelines and manufacturer's declaration – electromagnetic immunity			
The iLED 7 surgical light system/Mobile Control 7,9/Wall Control Panel is intended for use in the electromagnetic environment indicated below. The customer or user of the iLED 7 surgical light system/Mobile Control 7,9/Wall Control Panel must ensure that it is operated in such an environment.			
Immunity testing	EN/IEC 60601-1 test level	Compliance level	Electromagnetic environment – guidelines
Electrical fast transient disturbances/ bursts in accordance with EN/IEC 61000-4-4	± 2 kV for mains power cables ± 1 kV for input and output lines 100 kHz repeat frequency	± 2 kV for mains power cables ± 1 kV for input and output lines 100 kHz repeat frequency	Mains power quality should correspond to a typical commercial or hospital environment.
Impulse voltages/ surges in accordance with EN/IEC 61000-4-5	± 1 kV voltage outer conductor – outer conductor ± 2 kV outer conductor – ground voltage	± 1 kV voltage outer conductor – outer conductor ± 2 kV outer conductor – ground voltage	Mains power quality should correspond to a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations as per EN/IEC 61000-4-11	0% U_T; 0.5 cycle[a)] 0% U_T; 1 cycle 70% U_T; 25/30 cycles[b)] 0% U_T; 250/300 cycles	0% U_T; 0.5 cycle[a)] 0% U_T; 1 cycle 70% U_T; 25/30 cycles[b)] 0% U_T; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the iLED 7 surgical light system/Mobile Control 7,9/ Wall Control Panel requires continued operation during interruptions in power supply, then it is recommended that the iLED 7 surgical light system/ Mobile Control 7,9/ Wall Control Panel be connected to an uninterruptible power supply or a battery.
Magnetic field at supply frequency (50/60 Hz) in accordance with EN/IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields for the network frequency should comply with values commonly found in commercial and hospital environments.
a) at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° b) at 0° Comment: U_T is the AC mains voltage prior to applying the test level.			

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

Portable and mobile RF communications equipment should not be used in the vicinity of the iLED 7 surgical light system/Mobile Control 7,9/Wall Control Panel, including cables, nor closer than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

NOTICE

The iLED 7 surgical light system/Mobile Control 7,9/Wall Control Panel 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 health care facility.

Immunity testing	EN/IEC 60601-1 test level	Compliance level
Conducted HF disturbance variables in accordance with EN/IEC 61000-4-6	iLED 7: 3 V 0.15 MHz – 80 MHz 6 V in the ISM band between 0.15 MHz and 80 MHz [a)] Mobile Control 7,9: 3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio frequency bands between 0.15 MHz and 80 MHz [a)+b)]	iLED 7: 3 V 0.15 MHz – 80 MHz 6 V in the ISM band between 0.15 MHz and 80 MHz [a)] Mobile Control 7,9: 3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio frequency bands between 0.15 MHz and 80 MHz [a)+b)]
Radiated HF disturbance as per EN/IEC 61000-4-3	iLED 7 System: 3 V/m Mobile Control 7,9: 10 V/m 80 MHz – 2.7 GHz	iLED 7 System: 3 V/m Mobile Control 7,9: 10 V/m 80 MHz – 2.7 GHz
a) = The ISM bands (ISM = industrial, scientific and medical) between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz. b) = 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 HF fields of wireless communications equipment

Table: Special frequencies

Test frequency (MHz)	Band (MHz)	Service	Modulation	Max. power (W)	Distance (m)	Immunity level (V/m)
385	380–390	TETRA 400	Pulse modulation 15 Hz	1.8	0.3	26
450	430 – 470	GMRS 460 FRS 460	Pulse modulation FM ± 5 kHz variation 1 kHz sine	2	0.3	28
720	704 – 787	LTE band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						

Test frequency (MHz)	Band (MHz)	Service	Modulation	Max. power (W)	Distance (m)	Immunity level (V/m)
1720 1845 1970	1700 – 1990	GSM 1.800 CDMA 1900 GSM 1900 DECT LTE band 1, 3, 4, 25 UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400 – 2570	Bluetooth WLAN 802.11 b/g/n RFID 2.450 LTE band 8	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

⚠ WARNING

Distance for portable RF communications equipment and its peripherals

- Do not use portable RF communication equipment (including peripherals such as antenna cables and external antennae) at a distance of less than 30 cm (11.81 inch) to the iLED 7 surgical light system/ Mobile Control 7,9/Wall Control Panel including its cables as specified by the manufacturer. Otherwise, the functionality of the system may be impaired!

EMC-related wireless characteristics of the iLED 7 surgical light system/Mobile Control 7,9/ Wall Control Panel

NOTICE

Interference caused by other devices

- The iLED 7 surgical light system/Mobile Control 7,9/Wall Control Panel may be subject to interference from other devices, even if these devices comply with the applicable CISPR-defined emission requirements. The table below may 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

12.4 SVHC (Substance of very high concern)

According to Article 33 of the REACH Regulation (EC) no. 1907/2006, the following products may contain components with reportable substances in concentrations exceeding 0.1 mass percent. A list of affected components will be provided by Baxter on request. The list can also be seen on the Internet at ois.hillrom.com/ois.

13 Product certification

13.1 European Union

The surgical light is a Class I medical device according to Regulation 2017/745/EU concerning medical devices, and is compliant with the version of this regulation in force at the time of product sale. Baxter declares the conformity of the surgical light with the essential safety and performance requirements according to Regulation 2017/745/EU concerning medical devices, Annex I. A conformity assessment procedure required for Class I devices shall be carried out in accordance with Article 52 (7), taking into account a quality management system in accordance with Annex IX, Chapter 1. Baxter certifies conformity by means of the CE marking.

The Trumpf Medical Wifi module, the Mobile Control 7,9 and the Wall Control Panel comply, under normal use, with the requirements of Directive 2014/53/EU regarding radio systems. The declaration of compliance can be requested using the contact details below.

13.2 USA/Canada

The surgical light was tested for the USA and Canada by Underwriter Laboratories Inc. UL/cUL classification with respect to electric shock, fire and mechanical hazards 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.

13.3 Ukraine

УкрСЕПРО: Це маркування підтверджує, що вироби, промарковані знаком відповідності, пройшли всі необхідні процедури підтвердження відповідності та підкоряються визначеним технічним керівництвам України.

Відповідність: Технічний регламент щодо медичних виробів, затверджений Постановою Кабінету міністрів України від 02 жовтня 2013 р. № 753

13.4 Serbia

Certificate / registration number: 515-02-03704-16-001

14 Radio license

Radio license information is listed in Document 7990103 (Radio information).

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