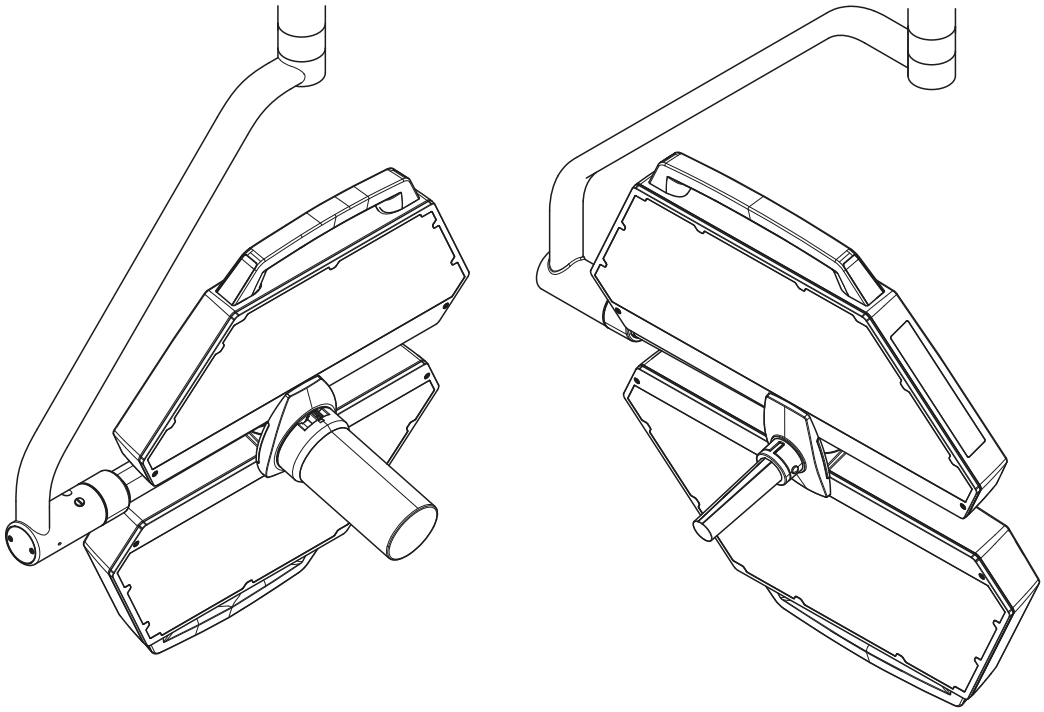
Instructions for use

TruLight 5000 / 3000

Surgical light



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

ENGLISH
en-US

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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

Document number: 7990005
Language ID: 030
Version: 05
Part number: 2078240
Date of publication: 2023-01-19

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
TruLight 5000 / 3000 Ceiling Single	4038110
TruLight 5000 / 3000 Mobile	4038120
TruLight 5000 / 3000 Wall	4038130
TruLight 5000 / 3000 Pendant	4038140
TruLight 5000 / 3000 Ceiling Duo	4038210
TruLight 5000 / 3000 Ceiling Trio	4038310
TruLight 5000 / 3000 Ceiling Quad	4038410

Supporting documents

The products listed are individually combined with various Baxter products. Chapter 2.1 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
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

- This 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	The signal word indicates a dangerous situation that will immediately lead to death or serious injury if no precautionary measures are taken.
WARNING	The signal word indicates a dangerous situation that may lead to death or serious injury if no precautionary measures are taken.
CAUTION	The signal word indicates a dangerous situation that may lead to moderate to slight injury if no precautionary measures are taken.
NOTICE	The 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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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 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.

1.6 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.

1.7 Usage environment

⚠ DANGER

Risk of explosion posed by anesthetics

If high concentrations of flammable mixtures of anesthetic vapors with oxygen or nitrous oxide occur in the environment for use of the surgical light, there is a risk of ignition under certain conditions. According to EN ISO 11197, the danger zone is formed in a range between 5 cm/1.97 inch and 25 cm/ 9.84 inch from the point where the gas leaks or escapes.

- The surgical light is not suitable for operation in explosive areas. The surgical light is not suitable for use in rooms with inflammable mixtures of anesthetics with air or oxygen or N_2O (nitrous oxide).

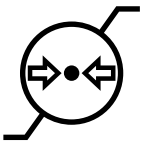
Temperature:	+10 °C to +40 °C / 50 °F to 104 °F
Air humidity:	30% to 75%
Atmospheric pressure:	70kPa to 106 kPa / 10 psi to 15 psi

The surgical light may not be used near strong magnetic fields.

1.8 Ambient conditions for storage and transport

Temperature: -15 °C to +60 °C / 5 °F to 140 °F

Air humidity: 5% to 95%



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

Fragile contents

Top

Keep dry

1.9 Service life

With normal use, the service life is 10 years.

2 Safety

2.1 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 TruLight 5000 / 3000	4038051	7990000

Ceiling-mounted supply unit

Product designation	Part number	Document number
TruPort Solo / Tandem preparation	4037210	7990001
TruPort Tandem addition	4037220	7990001
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 HD 2000	2072249	7990006
TruVidia HD 5000	2072520	7990006
TruVidia HD 7500	2072521	7990006

Support arm

Product designation	Part number	Document number
VidiaPort Springarm Bottom	4028150	7990008
VidiaPort Springarm Top	4028155	7990008
VidiaPort Springarm Middle	4028152	7990008

Sterilizable handle

Product designation	Part number	Document number
Sterilizable ALC Handle	1660214	7990009
Sterilizable Central Handle	4025708	7990009

2.2 Combination with products from other manufacturers

The surgical light is not designed for combination with products from other manufacturers (third-party products) and where no compatibility tests have been carried out by Baxter. Baxter does not, however, exclude combination with 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 combination with third-party products.

2.3 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.

Instruction regarding the proper handling of the medical device is required. 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.

Medical devices connected to each other as well as medical devices connected to accessories including software, or other objects, may only be operated and used when the specific combination is suitable with regard to its intended purpose and the safety of the 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 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.

2.4 Malfunction caused by other devices

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

2.5 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.

2.5.1 Failure of the surgical light electrical functions

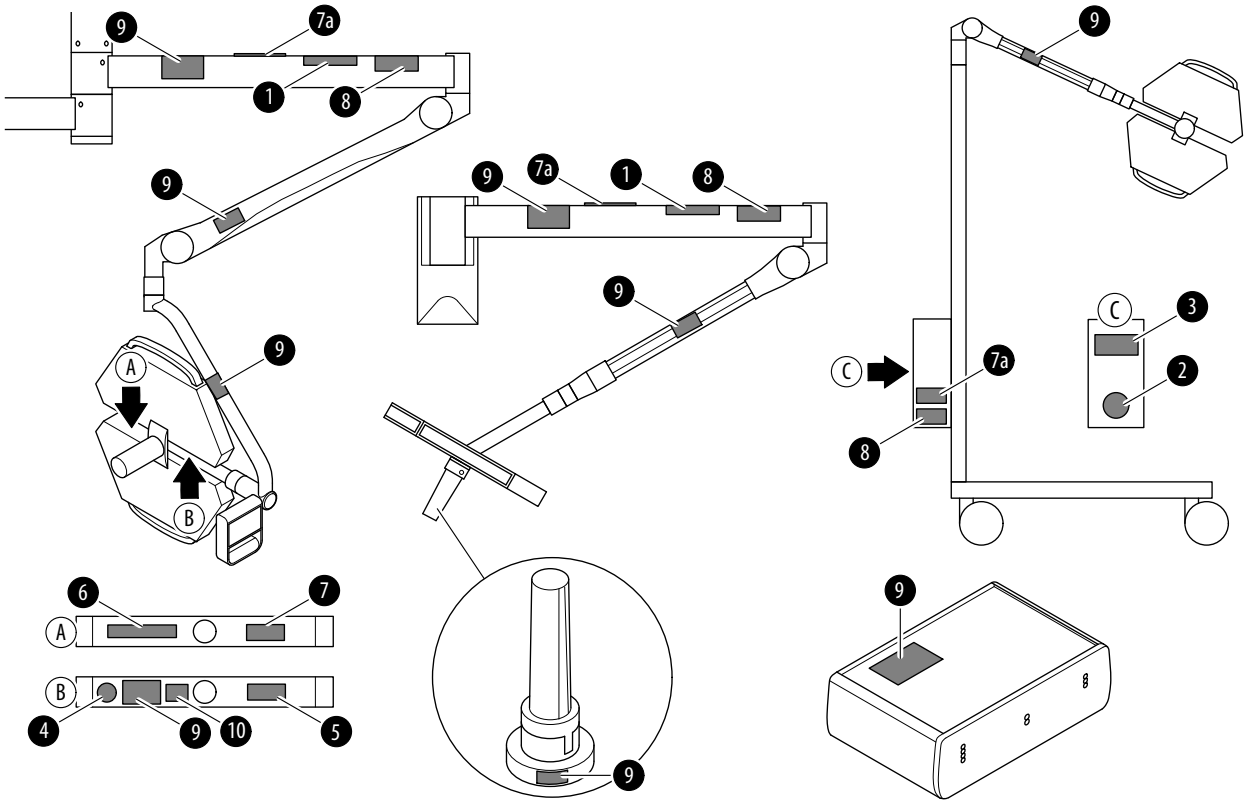
According to current state-of-the-art technology, failure of the surgical light cannot be completely ruled out, with the result that the electrical functions on the operating table are no longer available. In this rare case, stop using the surgical light and notify the Technical Customer Service.

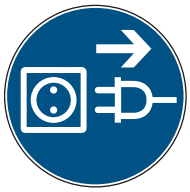
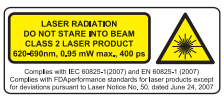
2.6 Information notices

2.6.1 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.

2.6.2 Position and meaning

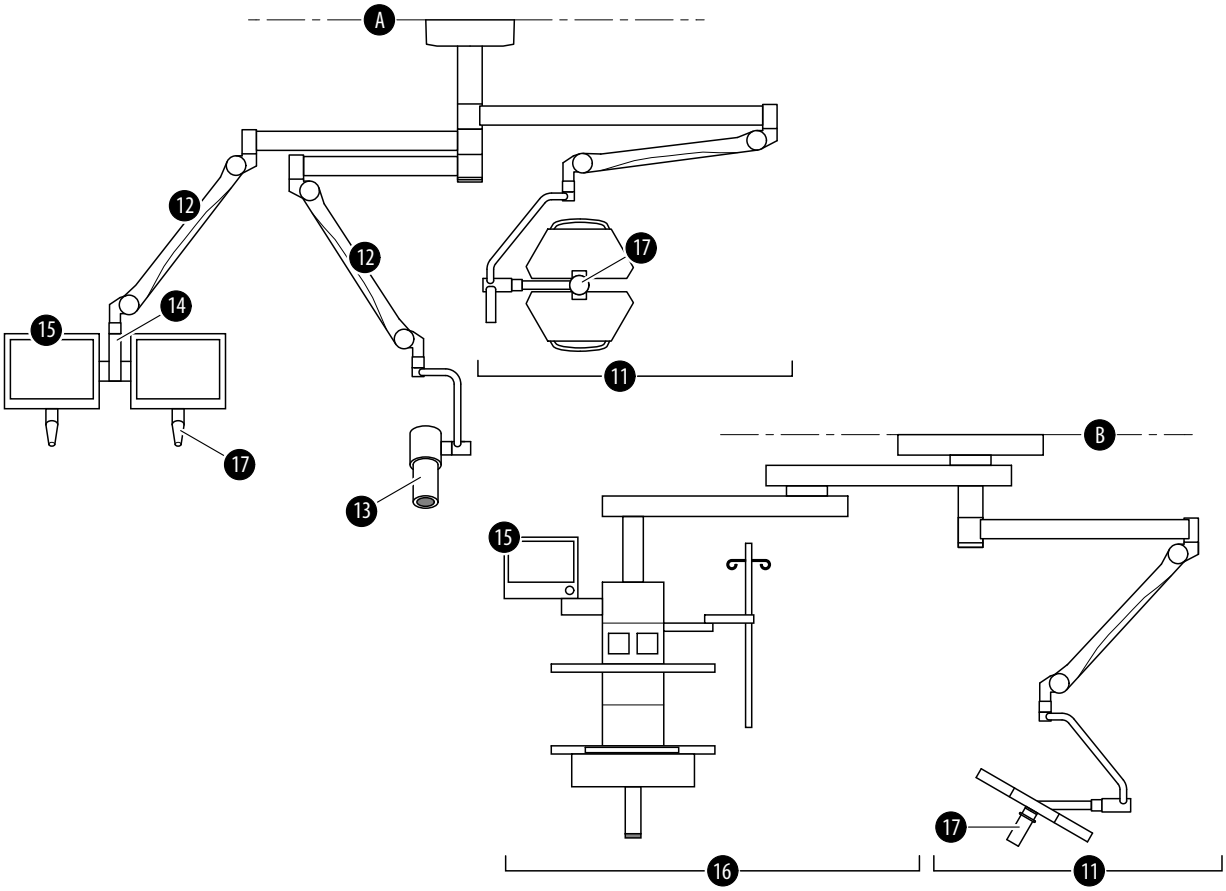


No.	Information notice	Meaning
[1]		Note to the service technician for mounting the circlip on the spring arm (connection to the extension arm)
[2]		Pull the mains power plug out of the socket before opening the housing.
[3]	Baxter	Manufacturer's logo
[4]		Follow the instructions for use
[5]		Laser identification Class of the installed laser product for distance measurement according to EN/IEC 60825-1:2007
[6]		UL mark: device tested by Underwriter Laboratories Inc. for use in the USA and Canada

No.	Information notice	Meaning
[7]	–	PATENTS / PATENT www.hillrom.com/patents May be covered by one or more patents. See above Internet address. The Hillrom companies are the proprietors of European, US, and other patents and pending patent applications.
[7a]	Not available	–
[8]	Device label of the surgical light system	
[9]	Device label for the individual component	
[10]	Additional device label (TruLight 5xxx)	
		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.
		Date of manufacture

3 Summary

The surgical light can be custom combined using various Baxter products. The approved products are listed in Chapter 2.1.



[A] Ceiling version of the surgical light (for example, Solo)
[B] Ceiling version of the surgical light on a ceiling-mounted supply unit (pedestal)
[11] Surgical lights
[12] VidiaPort support arm
[13] TruVidia HD camera
[14] VidiaPort monitor holder
[15] Flat screen
[16] Ceiling-mounted supply unit (FCS 700 Ceiling Supply Unit)
[17] Sterilizable handle

4 Description

4.1 Overview of surgical light

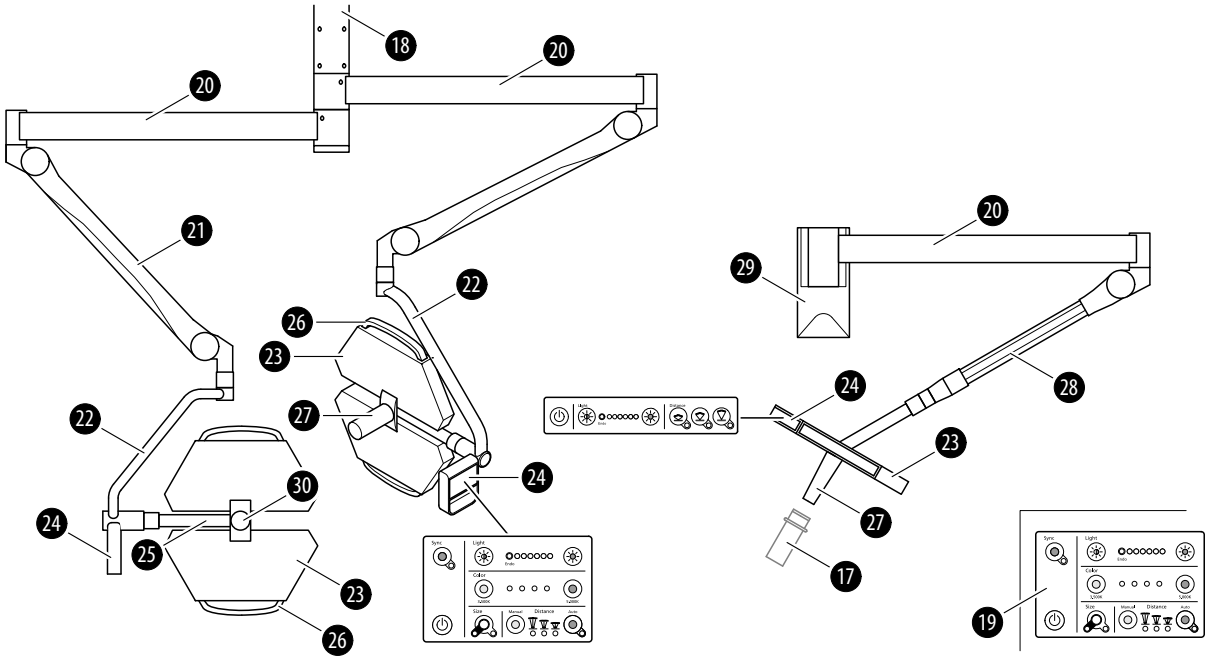
4.1.1 Ceiling and wall-mounted versions:

The lamp head is mounted using a support arm system to the ceiling or a wall. The support arm system can be used to turn the lamp head in any direction and to align it accurately with the wound field. The surgical light is operated via the controls on the lamp head or via the separate wall control panel (optional). The light system can be individually adjusted with the following functions:

Function	TruLight	
	3000	5000
Light field size	–	x
Lighting intensity	x	x
ALC (Adaptive Light Control)	x	x
ALC Plus (Adaptive Light Control Plus)	–	x
Color temperature	–	x
Synchronization	–	x

Ceiling-mounted version
(for example, Ceiling Duo)

Wall-mounted version



[17] Sterilizable handle
[18] Ceiling conduit
TruLight 5000 / 3000 Pendant: Light adjustment on the ceiling-mounted supply unit
[19] Control panel at the wall control panel
(Example TruLight 5x20)

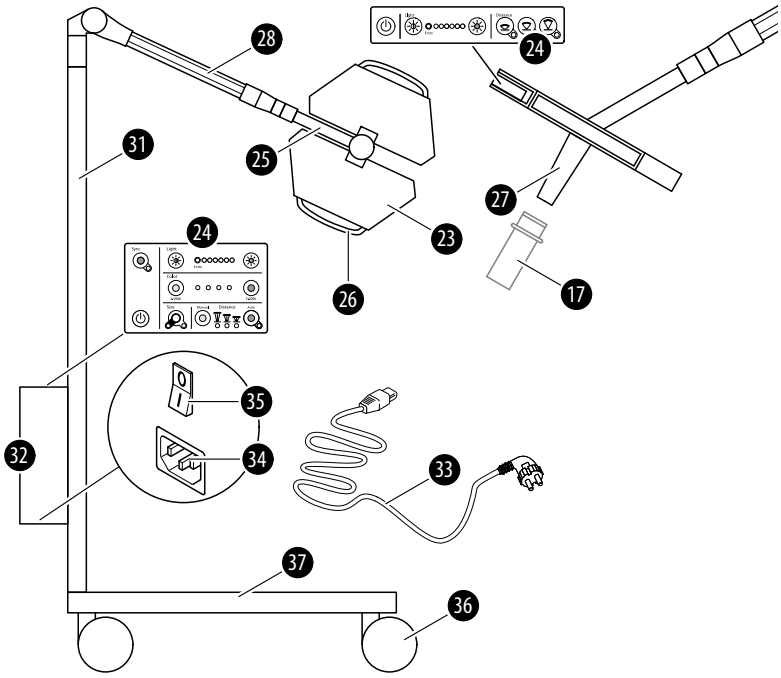
[20] Extension arm
[21] Spring arm
[22] Comfort strap
[23] Lamp head
[24] Control element
Depending on the version at the comfort strap or the lamp head.
The functions available on the controls depend on the functional scope of the surgical light.
[25] Transmission joint
[26] Non-sterile side handle (illuminated for TruLight 5000)
[27] Handle adapter (holder for the sterilizable handle)
for TruLight 5x20 with ALC Plus (laser measuring unit)
[28] Spring arm type AC 2000 NRH (Version: Low room height)
[29] Wall bearing
[30] Camera holder

4.1.2 Mobile version

The mobile surgical light is a mobile individual lamp head with spring arm. The surgical light can be moved freely in any direction, since the 4 wheels are all able to rotate on their own axes. Two wheels arranged diagonally on the stand foot can be braked. The parking brake allows the surgical light to be safely parked.

The lamp head is attached to a spring arm. The spring arm can be used to turn the lamp head in any direction and to align it accurately with the wound field. The surgical light is operated with the controls on the lamp head or the power supply unit. The light system can be individually adjusted with the following functions:

Function	**TruLight**	
	3000	**5000**
Light field size	–	x
Lighting intensity	x	x
ALC (Adaptive Light Control)	x	x
ALC Plus (Adaptive Light Control Plus)	–	x
Color temperature	–	x
Synchronization	–	x



[17] Sterilizable handle
[23] Lamp head
[24] Control element
The functions available on the controls depend on the functional scope of the surgical light.
The functional scope of the controls on the lamp head can be more limited than the functional scope of the controls on the power supply unit.
[25] Transmission joint
[26] Non-sterile side handle (illuminated for TruLight 5000)
[27] Handle adapter (holder for the sterilizable handle)
[28] Spring arm type AC 2000 NRH (Version: Low room height)
[31] Pedestal rod
[32] Power supply unit
[33] Mains power cable
[34] Connector socket for power cable
[35] On/ Off switch (underside of the power supply unit)
[36] Wheel
[37] Stand foot

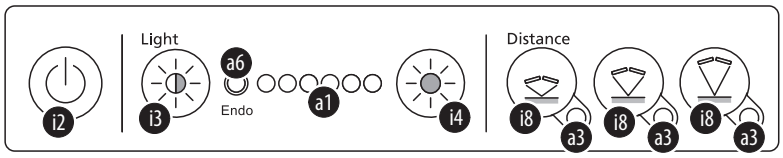
4.2 Summary of control modules

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

- Control element
- Sterilizable ALC Handle (#1660214)
- Wall control panel
  The wall control panel is used for external control of the surgical light.
- User interface of an external control unit (operating integration systems)

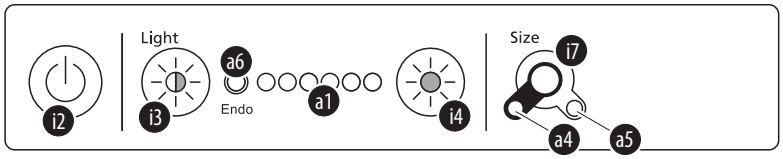
The control units available depend on the configuration of the surgical light.

4.2.1 Controls at the TruLight 3000 lamp head



[i2] Switching the surgical light function on and off
[i3] Reducing the lighting intensity function
[i4] Increasing the lighting intensity function
[i8] ALC (Adaptive Light Control) function - setting the working distance
(80 cm/31.50 inch; 100 cm/39.37 inch; 120 cm/47.24 inch)
Status indicator on the button: The indicator lights up when the distance is switched on.
[a1] Lighting intensity indicator (Endo < 10%, 6 steps: 50% - 100%)
[a6] Endo indicator
The indicator lights up when the Endo lighting intensity is switched on.
[a3] Working distance indicator
(3 steps from left to right: 80 cm/31.50 inch; 100 cm/39.37 inch; 120 cm/47.24 inch)

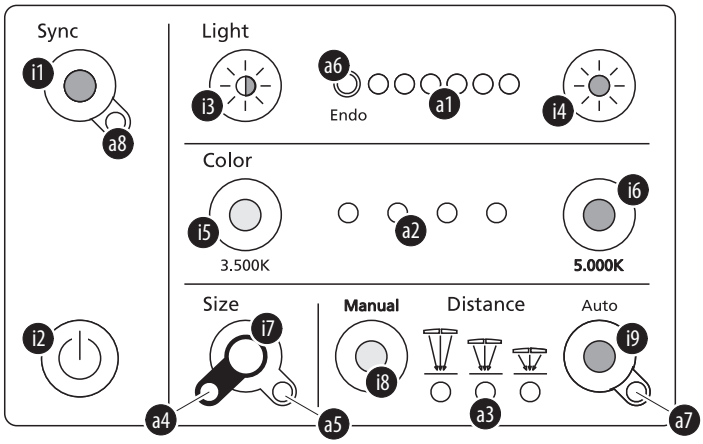
4.2.2 Controls at the TruLight 5000 lamp head



[i2] Switching the surgical light function on and off
[i3] Reducing the lighting intensity function
[i4] Increasing the lighting intensity function
[i7] Synchronize color temperature (optional)
[a1] Lighting intensity indicator (Endo < 10%, 6 steps: 50% - 100%)
[a4] Narrow light field indicator
The indicator lights up when the narrow light field is switched on.
[a5] Wide light field indicator
The indicator lights up when the wide light field is switched on.
[a6] Endo indicator
The indicator lights up when the Endo lighting intensity is switched on.

4.2.3 Controls at the TruLight 5000 comfort strap

The functions on the controls available for adjusting the lighting depend on the functional scope of the surgical light. The following overview is based on the maximum equipment level.

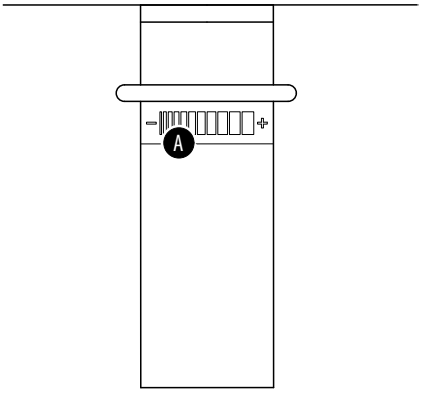


[i1] Color temperature synchronization function (optional)
[i2] Switching the surgical light function on and off
[i3] Reducing the lighting intensity function
[i4] Increasing the lighting intensity function
[i5] Reduce color temperature function (optional)
[i6] Synchronize color temperature (optional)
[i7] Setting the light field size function
[i8] ALC (Adaptive Light Control) function - setting the working distance
[i9] ALC Plus (Adaptive Light Control Plus) - automatically setting the working distance (optional)
[a1] Lighting intensity indicator (Endo < 10%, 6 steps: 50% - 100%)
[a2] Color temperature indicator (4 levels: 3500 K/4000 K/ 4500 K/5000 K)
[a3] Working distance indicator
(3 steps from left to right: 120 cm/47.24 inch; 100 cm/ 39.37 inch; 80 cm/31.50 inch)
[a4] Narrow light field indicator
The indicator lights up when the narrow light field is switched on.
[a5] Wide light field indicator
The indicator lights up when the wide light field is switched on.
[a6] Endo indicator
The indicator lights up when the Endo lighting intensity is switched on.
[a7] ALC Plus (Adaptive Light Control Plus) indicator
The indicator lights up when the ALC Plus function is switched on.
[a8] Color temperature synchronization indicator (optional)
The indicator lights up when the synchronization is switched on.

4.2.4 Wall control panel

The functional scope of the wall control panel corresponds to that of the controls on the surgical light. An exception to this is the Low Room Height version of the TruLight 5000 surgical light. Due to the design of the Low Room Height version, the controls on the lamp head have a more limited functional scope. The full functional scope for the Low Room Height version of the surgical light is only available on the wall control panel.

4.2.5 Sterilizable ALC Handle



The sterilizable ALC handle is only available for the TruLight 5x20 surgical light.

This handle can be used to set one of the following functions whilst maintaining surgical light sterility:

- Light field size
- Lighting intensity
- Color temperature

A contact sensor is attached below the collar for this purpose [A]. The user-specified option for the handle was set for the surgical light during installation. The preset function can be set by the Technical Customer Service.

Please take note of the instructions for use of the handle (see Chapter 2.1).

4.2.6 Operating Integration System

The optional RS232 interface (interface converter) facilitates the integration of the surgical light into the system of a third-party manufacturer and setting the surgical light functions through the user interface of an external control unit. Adhere to the reference manual with document number 55000-00020.

4.3 Illuminant

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.

4.4 Power supply

Ceiling and wall-mounted version:

The ceiling and wall version of the surgical light is firmly attached to the external power sources of the room and are only disconnected from mains power during emergencies, for cleaning purposes and for service work. The surgical light does not have its own devices for disconnecting from the power supply. Thus the power supply facility can only be disconnected by the customer.

Mobile pedestal version:

The mobile pedestal version (safety class I) may only be connected to a protective contact socket. The mobile stand version of the surgical light is connected with the mains cable to the room's mains power network.

4.5 Setting options

4.5.1 Light field size

The light field size function is only available for the TruLight 5000 surgical light.

The light field size concerns the diameter of the light field. At constant working distance, the user may decide between a narrow and a wide light field, depending on the size of the wound field.

4.5.2 Lighting intensity

Lighting intensity concerns brightness and is measured in lux. Lighting intensity can be adjusted within a range of 50% to 100%. In addition, Endo lighting intensity can be selected. Endo lighting intensity is a permanently set lighting intensity (<10%) for endoscopic operations. Some of the LEDs are deactivated with these settings.

Reducing or increasing the lighting intensity does not change the color temperature.

4.5.3 ALC (Adaptive Light Control)

The ALC (Adaptive Light Control) function optimizes light adjustment as a function of the working distance from the surgical light to the wound field of the patient. For a fast, optimized light setting of the surgical light, it is possible to manually select between the 3 typical working distances of 80 cm/31.50 inch, 100 cm/39.37 inch and 120 cm/47.24 inch. The LEDs of the surgical light are selectively controlled to guarantee optimal illumination of the wound field.

4.5.4 ALC Plus (Adaptive Light Control Plus) - automatic

The ALC Plus (Adaptive Light Control Plus) function is optional and only available for the TruLight 5000 surgical light.

The ALC Plus (Adaptive Light Control Plus) function automatically optimizes the light setting after the working distance to the wound field of the patients has been changed by moving the surgical light. The function automatically ensures consistent lighting intensity and higher lighting power.

When the lamp head is moved while the ALC Plus function is activated, a movement sensor triggers a new measurement of the working distance to the wound field of the patient. The laser measuring unit in the handle determines the working distance to the wound field of the patient. The distance measurement is made at one point in the center of the light field. The light setting of the surgical light is optimized automatically based on these measuring data. The LEDs of the surgical light are selectively controlled to guarantee optimal illumination of the wound field.

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 position of the patient does not trigger automatic measurement of the working distance.

4.5.5 Color temperature

The color temperature function is only available for the TruLight 5000 surgical light.

The color temperature function is used to increase color contrast in the wound area. The visual contrast behavior of the color temperature has the following effect:

- When the wound area is mainly of a bluish color, a low color temperature (range 3500 K to 4000 K) increases color contrast and leads to improved perception of the differences by the user.
- When the wound area is mainly of a reddish color, a high color temperature (range 4000 K to 4500 K) increases color contrast and leads to improved perception of the differences by the user.

Under normal surgical conditions, color temperature should be set to a range of 4000 K to 4500 K at the start of an operation.

Color temperature can be set within the range of 3500 K to 5000 K in steps of 500 K.

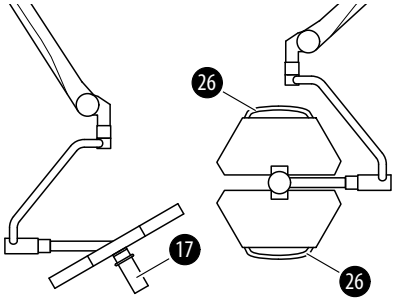
4.5.6 Synchronization

The function is only available for the TruLight 5000 surgical light.

During synchronization, the color temperature for the surgical light on which the function was selected is transferred to the other surgical lights.

4.5.7 Operating range

The operating range for the ceiling and wall versions of surgical lights is determined by the support arm system. 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 spring force in the spring arms keeps the lamp head stable at the desired height position. The swivel range of the spring arm upwards or downwards can be individually adjusted. The set position for rotational movement is maintained by the braking strength of the individual joints.



The surgical light can be positioned using the sterilizable handle [17] or the non-sterile side handles [26].

4.6 Illuminated side handles

The illuminated side handles on the lamp head are only available for the TruLight 5000 surgical light.

The light system is available with the following options:

- The side handle is permanently lit up (delivery state ex factory).
- The side handle is not lit up.
- The side handle lights up when the surgical light is switched on.
- The side handle is permanently lit up when the external power supply is connected (stand-by operation).
- The side handle is lit up when Endo lighting intensity is switched on.

The user's preferred option was set during installation of the surgical light.

5 Use

The surgical light has a multitude of functions that can be ergonomically controlled using the control unit. Operation using the ALC handle permits use in a sterile manner. All other control units are used in a non-sterile manner.

5.1 Safety instructions

Commissioning:

⚠ DANGER

Risk of explosion posed by anesthetics

If high concentrations of flammable mixtures of anesthetic vapors with oxygen or nitrous oxide occur in the environment of the surgical light, there is a risk of ignition under certain conditions. According to EN ISO 11197, the danger zone is formed in a range between 5 cm/1.97 inch and 25 cm/ 9.84 inch from the point where the gas leaks or escapes.

- The surgical light is not suitable for operation in explosive areas. The surgical light is not suitable for use in rooms with inflammable mixtures of anesthetics with air or oxygen or N_2O (nitrous oxide).

⚠ CAUTION

Electric shock

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

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. After the handover, the surgical light must be cleaned and disinfected according to the hygiene directives and specifications of Baxter.

The surgical light may only be used with the components and accessories approved by Baxter.

Functionality:

⚠ CAUTION

Reduced lighting intensity

In the event that more than 10 LEDs should fail, the lamp head will no longer achieve the given lighting intensity.

- Check the surgical light before use to ensure it is functional and intact.
- If more than 10 LEDs are out of service, switch off the surgical light and inform the Technical Customer Service.

The surgical light may not be used with damaged components and accessories.

Adhere to the maintenance recommendation to ensure the basic safety and major performance characteristics of the surgical light throughout its entire lifespan.

Load limit:

⚠ WARNING

Crashing of support arm system

The support arm system may not be exposed to additional stress. Overload may lead to significant malfunction. Overload may cause the support arms, individual components or accessories to detach from their holders and drop down.

- The support arms of the surgical light may not be used as a storage facility.
- Do not lean on the support arms, individual components or accessories.
- The maximum load on the various support arms may not be exceeded (see information in the technical data of the instructions for use of the support arms).

⚠ WARNING

Sudden release of spring arm

Abrupt removal of loads may cause sudden release of the spring arm together with serious injury.

- Flat screens or other devices on the spring arm must only be removed by Technical Customer Service.

Control:

⚠ WARNING

Risk to the retina due to visual radiation

(photobiological safety / eye safety)

The surgical light is classified in risk group 2 (medium risk) according to the IEC 62471 standard and therefore extends beyond the “Free Group”. The risk to the retina from blue light (400 nm to 780 nm) occurs when the thresholds of risk group 2 relating to retinal danger are significantly exceeded by blue light. The blue light (400 nm to 780 nm) of the LEDs may tire or damage the eyes.

- Do not look for a prolonged time into the switched-on light field of the surgical light. The maximum radiation duration in the workplace from 0.8 m to 1.3 m / 31.50 inch to 51.18 inch is 73 seconds.

⚠ WARNING

Charge balancing

- To avoid complications due to electrostatic charge balancing between metallic device parts of the surgical light and the patient, the user may not touch the surgical light and the patient at the same time.

The working distance when using the automated functions is 80 cm to 120 cm/31.50 inch to 47.24 inch. The lighting intensity and working distance must be manually adjusted when the ALC Plus function is deactivated.

The distance measurement of the ALC Plus function is only triggered when the lamp head is moved. If, for example, the operating table with the patient is moved, the lighting situation will not be adjusted.

The mobile pedestal version of the surgical light may only be connected to an appropriately earthed power socket with protective conductors.

5.2 Installation of the wall and ceiling versions

The surgical light must be installed by qualified service technicians at the place of installation. The mounting of the surgical light is described in the installation manual.

The surgical light must be cleaned and disinfected before using it for the first time.

5.3 Inspections during operation

Before and after each use, the user must perform a functional test and visual inspection of the surgical light.

A functional test and visual inspection of the surgical light by personnel trained for this work by Baxter must be performed at least once a week and following a damage report by a user.

⚠ WARNING

Risk of contamination and infection of the patient

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

- Loose parts in the lamp heads
- Visible damage, particularly on the cover plate of the lamp head, plastic parts, paint surfaces and sterilizable handle
- Secure attachment of the sterilizable handle

Immediately deactivate a defective surgical light, mark it clearly as defective and secure it against re-operation. If there is damage or a fault, notify the technical customer service.

Annual inspection

The annual inspection should only be carried out by personnel who have been trained by Baxter in this work.

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

- Check the components of the lamp head and the support arm system for deformation
- Check the support arm system and lamp head for paint damage
- Check plastic parts for cracks, brittle spots and clouding
- Check welds for cracks
- Check the surgical light for completeness in terms of plastic parts (e.g. covers and plugs).
- Check to ensure that device and information labels are legible.
- Check the LEDs for functionality
- Check the joints for functionality
- Check the position of the end stops
- Verify the effect of the spring force

5.4 Selection of functions

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

- Controls on the lamp head, comfort strap or power supply unit (mobile stand version)
- Sterilizable ALC Handle
- Wall control panel
- User interface of an external control unit (operating integration systems)

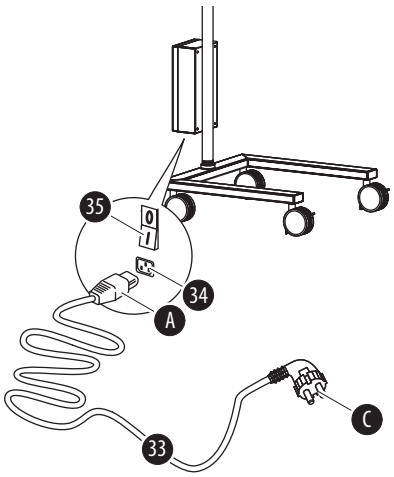
Any setting of the surgical light is shown simultaneously on the other control units. The current setting of the surgical light is always visible on all control units.

5.5 Connecting the power supply

5.5.1 Ceiling and wall-mounted versions:

The power supply must be connected by specialized personnel with the necessary access authorization, knowledge and documentation to set up internal power supplies. When power is supplied, the surgical light is in standby-mode.

5.5.2 Mobile version



⚠ WARNING

Electric shock in the event of a short circuit

- The mobile pedestal version (safety class I) may only be connected to a protective contact socket. Electrical earthing reduces the risk of electric shock in the event of an electrical short circuit.

1. Check the mains power line [33] including plugs [A] and [C] for integrity.
2. Push power connection plug [A] of the power cable into the connection socket [34] on the power supply unit.
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 [C] of the mains power cable into a grounded power socket in the room.
5. Switch on the power supply unit at the switch [35] (Position I).
   The power supply for the surgical light is in standby-mode.

5.6 Disconnecting the power supply

5.6.1 Ceiling and wall-mounted versions:

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

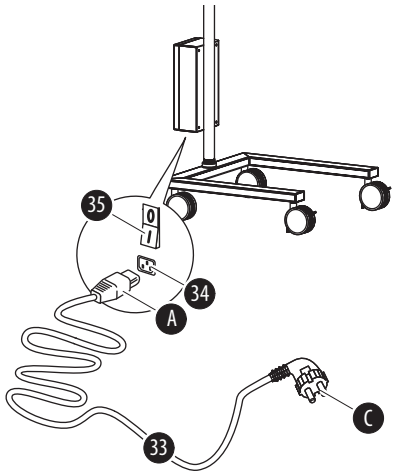
⚠ WARNING

Danger of electric shock

- Contact with live parts may result in electric shock.

1. Switch off the surgical light on a control unit.
2. 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.

5.6.2 Mobile version



1. Switch off the surgical light at the controls.
2. Switch off the power adapter at the switch [35] (Position 0).
3. Pull the plug [C] of the mains cable out of the socket.
4. Pull the plug [A] out of the connection socket [34] on the power supply unit.
5. Wrap the power cable around the power supply unit.

5.7 Switching on the surgical light

Press the [i2] button on the controls.

The surgical light starts with the preset parameters or the last set of parameters used. The desired option can be set by a service technician.

5.8 Switching off the surgical light

Press the [i2] button on the controls.

5.9 Positioning the surgical light

⚠ CAUTION

Too high lighting intensity

A too high lighting intensity can cause burns in the wound, dry out tissue (especially with long exposure time and reduced blood circulation), or harm the eyes. A too high lighting intensity occurs when light fields overlap, or the distance from the working area is too short.

- Overlapping light fields will separate when repositioning the lamp head.
- In case of overlapping light fields, reduce the light intensity of individual lamp heads and/or increase the distance from the work area.
- Do not look directly into the light field or surgical light.
- Always close, cover or protect the patient's eyes (for example, with goggles - optical density at least 2 or designed according to safety class 6 EN 169).
- The surgical light is not intended for surgery in the facial area or under anesthesia with open eyes.

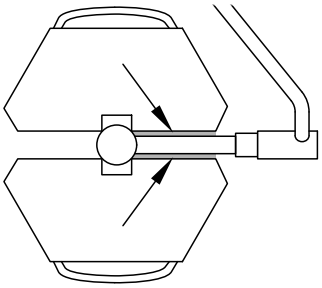
⚠ CAUTION

Uncontrolled movement of the joint

- If the spring arm moves up or down by itself, the spring strength will need to be re-adjusted.
- The brake force needs to be readjusted if the lamp head does not stably remain in the set position.

⚠ CAUTION

Pinching hazard



When swiveling the lamp head, do not place fingers between the transmission joint and the lamp head.

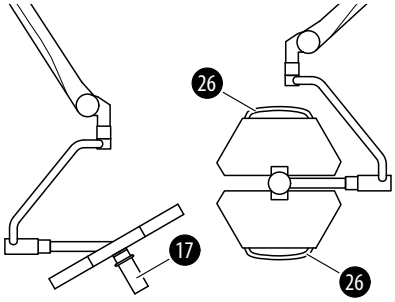
- Only touch the surgical light at the handle or at the side handles.

⚠ CAUTION

Risk of collision of lamp heads

The swivel range of the surgical light could be limited by other components or walls. Collision with objects in the vicinity might damage goods.

- Take note of the swivel range of the surgical light and avoid collisions.
- Before adjusting the height, check that there is sufficient ceiling clearance and ensure that there are no objects positioned above the lamp head.



Hold the surgical light at the handle [17] or the side handles [26] and move it to the desired position.

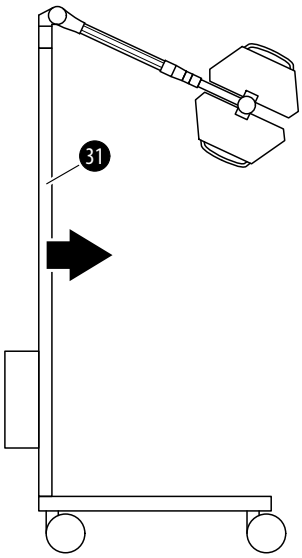
If the ALC Plus function is active, the distance to the wound field will be newly determined when the lamp head is moved. When moving the surgical light, take care to ensure that the light field is aligned with the wound field and that there are as few interfering objects as possible within the measuring range.

5.10 Moving the mobile pedestal version

NOTICE

Risk of tipping over

- 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.
- Avoid traveling over irregular surfaces or power supply cables.
- Pull the power cable out of the socket and wrap it around the power supply unit before the surgical light is moved outside of its operating range.



1. Switch off the surgical light on a control unit and disconnect it from the mains power. 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 on the front wheels. Push the latching mechanism upwards for this purpose.
3. Hold the surgical light at the stand rod [31] and push it with the lamp head in the driving direction.
   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. Press the latching mechanism at both wheels downwards for this purpose.

5.11 Adjusting the lighting

5.11.1 Adjusting the light intensity

⚠ WARNING

High lighting intensity

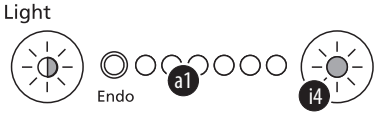
A too high lighting intensity can cause burns in the wound, dry out tissue (especially with long exposure time and reduced blood circulation), or harm the eyes. A too high lighting intensity occurs when light fields overlap, or the distance from the working area is too short.

- Overlapping light fields will separate when repositioning the lamp head.
- In case of overlapping light fields, reduce the light intensity of individual lamp heads and/or increase the distance from the work area.
- Do not look directly into the light field or surgical light.
- Always close, cover or protect the patient's eyes (for example, with goggles - optical density at least 2 or designed according to safety class 6 EN 169).
- The surgical light is not intended for surgery in the facial area or under anesthesia with open eyes.

Reduce the lighting intensity:

Controls on the surgical light or a wall control panel:

– Press the [i3] key.
  The corresponding LED for the currently set lighting intensity [a1] lights up.



Increase the lighting intensity:

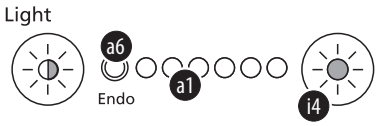
Controls on the surgical light or a wall control panel:

– Press the [i4] key.
  The corresponding LED for the currently set lighting intensity [a1] lights up.

Switching on the Endo lighting intensity:

Controls on the surgical light or a wall control panel:

– Press the [i3] button until the Endo [a6] status indicator lights up.

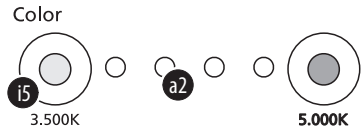


Switching off the Endo lighting intensity:

Controls on the surgical light or a wall control panel:

– Press the [i4] button until the Endo [a6] status indicator goes off. The LED for the actually set lighting intensity [a1] lights up.

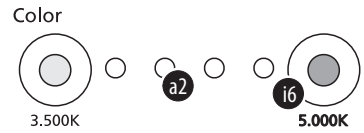
5.11.2 Set color temperature



Reduce color temperature:

Controls on the surgical light or a wall control panel:

– Press the [i5] button until the appropriate color temperature [a2] indicator lights up.

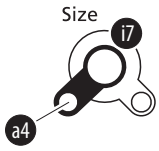


Increase color temperature:

Controls on the surgical light or a wall control panel:

– Press the [i6] button until the appropriate color temperature [a2] indicator lights up.

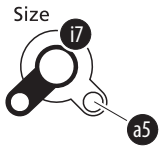
5.11.3 Set size of light field



Narrow light field:

Controls on the surgical light or a wall control panel:

– Press the [i7] button until the indicator [a4] lights up.



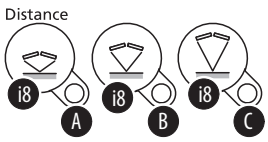
Wide light field:

Controls on the surgical light or a wall control panel:

– Press the [i7] button until the indicator [a5] lights up.

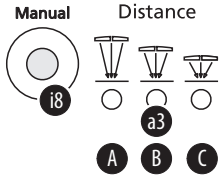
5.11.4 Adjusting the ALC (Adaptive Light Control)

The function is set on the controls or the wall control panel.



Controls on the lamp head:

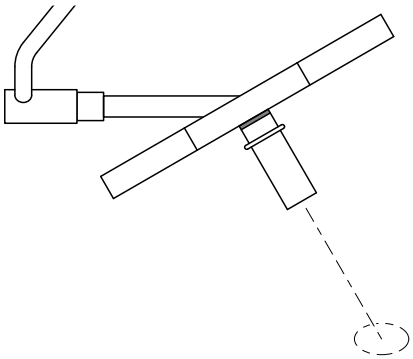
Press the corresponding key [i8]. The status indicator next to the [i8] key lights up (near 80 cm/31.50 inch [A], middle 100 cm/ 39.37 inch [B], far 120 cm/47.24 inch [C]).



Controls on the comfort strap:

Press the [i8] key until the respective working distance indicator [a3] lights up (near 80 cm/31.50 inch [A], middle 100 cm/ 39.37 inch [B], far 120 cm/47.24 inch [C]).

5.11.5 Adjusting the ALC Plus (Adaptive Light Control Plus)



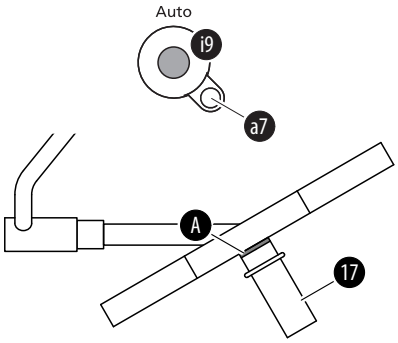
⚠ WARNING

Damage to eyesight

Prolonged visual contact with the laser beam might damage eyesight.

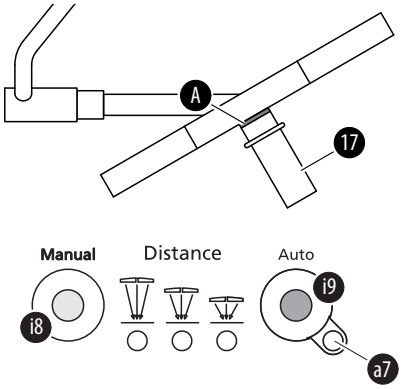
- Do not look directly into the laser beam.
- Always close, cover or protect the patient's eyes (for example, with goggles - optical density at least 2 or designed according to safety class 6 EN 169).

The function is set on the controls or the wall control panel.



Switching on the ALC Plus function:

1. Press the [i9] key.
   The [a7] status indicator next to the [i9] button lights up and a blue ring [A] lights up above the handle [17].
2. Point the handle [17] of the lamp head exactly onto the wound field of the patient. Interfering objects in the measuring range for the working distance must be avoided to prevent incorrect adjustments.



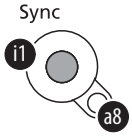
Switching off the ALC Plus function:

Press the [i8] button or the [i9] button.

The [a7] status indicator next to the [i9] button goes off and the blue ring [A] above the handle [17] goes off. The working distance from the surgical light to the wound field of the patient can be manually adjusted.

5.11.6 Synchronizing the color temperature

The function is set on the controls or the wall control panel.



Synchronizing the color temperature:

Press the [i1] key. The status indicator [a8] next to the [i1] key lights up.

Stopping the synchronization:

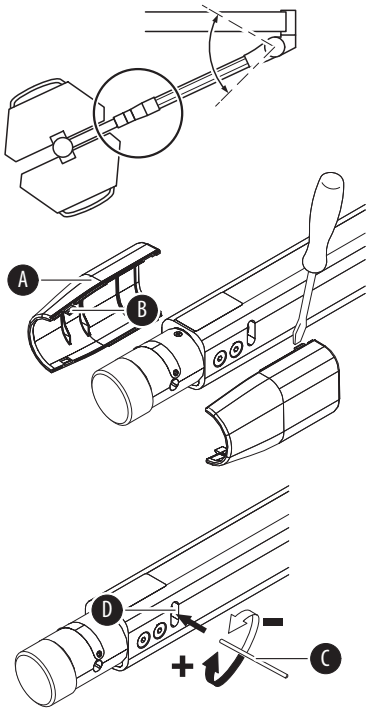
Press the [i1] key. The indicator [a8] next to the [i1] button goes out.

5.12 Adjusting the swivel range of the spring arm up and down

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

5.12.1 Spring arm type AC 2000 NRH (Version: Low room height)

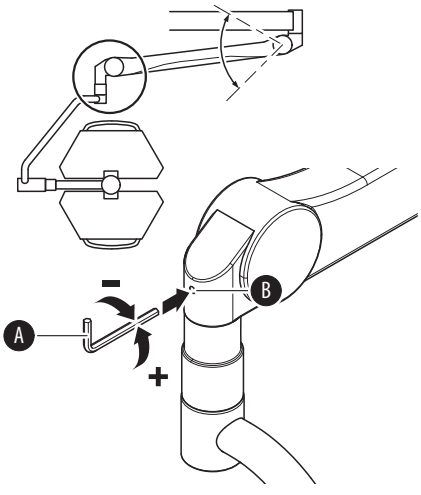
Set the swivel range in such a way that collision with the ceiling or adjacent objects is not possible. The swivel range can be limited to horizontal.



1. Switch off the surgical light on a control unit and disconnect it from the mains power.
2. Separate the two cover halves [A] from each other and remove them. Press in the four lugs [B] of the cover with a slotted screwdriver.
3. Insert the attached pin [C] into the adjustment opening [D] and set the swivel range.
   The swivel range is lowered by turning clockwise, and raised by turning counter-clockwise.
4. Place the two cover halves onto the spring arm and press them together so that the four lugs latch.
5. Check that the covers are securely attached.
6. Test the swivel range. Collisions must be avoided.

5.12.2 Spring arm

Set the swivel range in such a way that collision with the ceiling or adjacent objects is not possible. The swivel range can be limited to horizontal.



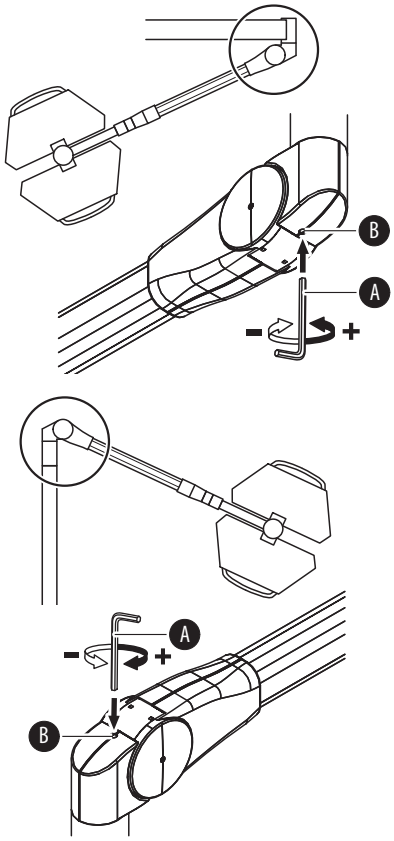
1. Switch off the surgical light on a control unit and disconnect it from the mains power.
2. Pull the spring arm down to relieve the setting screw.
3. Insert a hexagon wrench [A] with size 5 in the adjustment opening [B] and set the swivel range.
   The swivel range is lowered by turning clockwise, and raised by turning counter-clockwise.
4. Test the swivel range.

5.13 Adjusting the spring force

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

5.13.1 Spring arm type AC 2000 NRH (Version: Low room height)

The weight of the lamp head 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 needs to be readjusted.

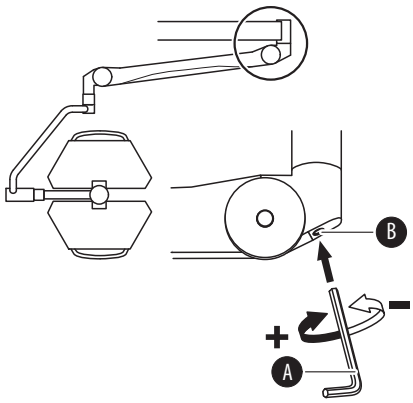


1. Switch off the surgical light on a control unit and disconnect it from the mains power.
2. Position the spring arm at approx. +10 or -10° relative to the horizontal in order to relieve the setting screw.
3. Insert a hexagon wrench [A] with size 5 in the adjustment opening [B] and set the swivel range.
   Ceiling and wall-mounted version:
   The spring strength is lowered by turning clockwise, and raised by turning counter-clockwise.

   Mobile pedestal version:
   The spring force is increased by turning in a clockwise direction and reduced by turning in an anticlockwise direction.
4. Test the spring strength. The support arm must remain stable in the set height position.

5.13.2 Spring arm

The weight of the lamp head 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 needs to be readjusted.



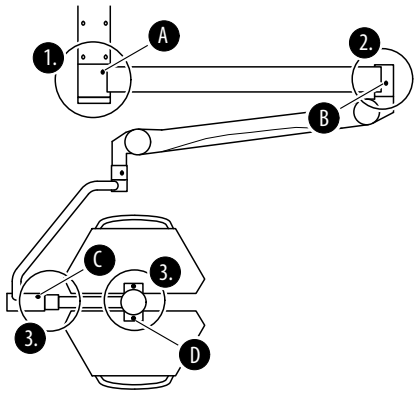
1. Switch off the surgical light on a control unit and disconnect it from the mains power.
2. Position the spring arm at approx. +10 or -10° relative to the horizontal in order to relieve the setting screw.
3. Insert a hexagon wrench [A] with size 5 in the adjustment opening [B] and set the swivel range.
   The spring strength is lowered by turning clockwise, and raised by turning counter-clockwise.
4. Test the spring strength. The support arm must remain stable in the set height position.

5.14 Setting the brake force

5.14.1 Overview

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

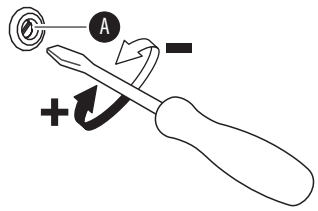
The joints are equipped with a friction brake. The friction brake acts on the pins of the support arm components by using friction from the setting screw. If the extension arm, spring arm, comfort strap or lamp head do not remain firmly in their set rotary positions, the braking force must be readjusted.



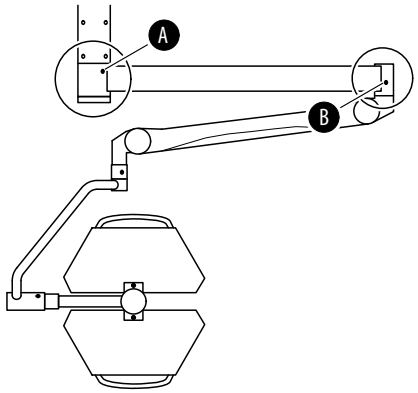
If the braking force needs to be adjusted on multiple support arm components, use the following sequence:

1. Set the friction brake for the extension arm (brake screw [A] at the extension arm).
2. Set the friction brake for the spring arm (brake screw [B] at the extension arm).
3. Set the friction brake for the transmission joint (brake screw [C] and lamp head (brake screw [D])).

5.14.2 Braking force for extension arm and spring arm

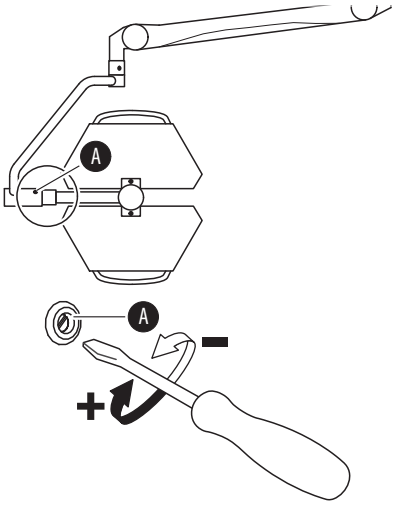


1. Switch off the surgical light on a control unit and disconnect it from the mains power.
2. Adjust the brake screw [A] with a slotted screw driver. The braking strength is raised by turning clockwise, and lowered by turning anti-clockwise.
3. Test the braking strength. The support arm components must remain stable in the set rotational position.



Item	Product designation	Part number
[A]	Brake screws on the extension arm (extension arm brake)	1378864
[B]	Brake screw at the extension arm (spring arm brake)	1378868

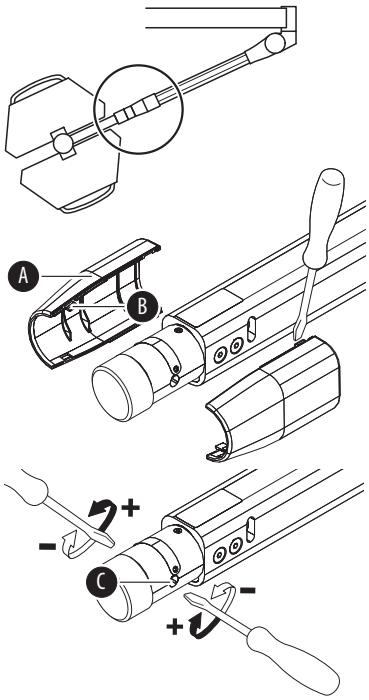
5.14.3 Brake force for the transmission joint



Spring arm:

1. Switch off the surgical light on a control unit and disconnect it from the mains power.
2. Adjust the brake screw [A] with a slotted screw driver.
   The braking strength is raised by turning clockwise, and lowered by turning anti-clockwise.
3. Test the braking strength. The support arm components must remain stable in the set rotational position.

Product designation	Part number
Brake screw on the comfort strap	4025239

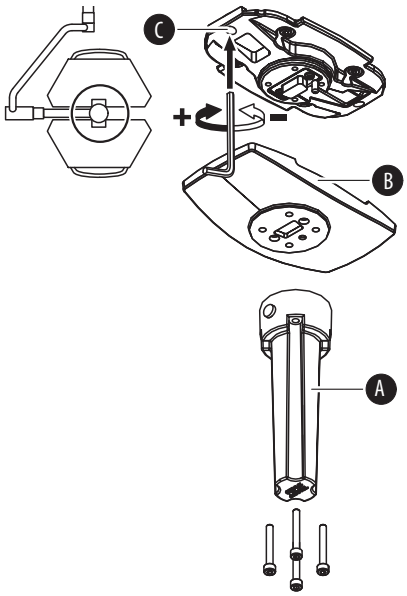


Spring arm type AC 2000 NRH (Version: Low room height):

1. Switch off the surgical light on a control unit and disconnect it from the mains power.
2. Separate the two cover halves [A] from each other and remove them. Press in the four lugs [B] of the cover with a slotted screwdriver.
3. Adjust the brake screw [C] on both sides evenly with a slotted screwdriver.
   The braking strength is raised by turning clockwise, and lowered by turning anti-clockwise.
4. Test the braking strength. The support arm components must remain stable in the set rotational position.
5. Place the two cover halves onto the spring arm and press them together so that the four lugs latch.
6. Check that the covers are securely attached.

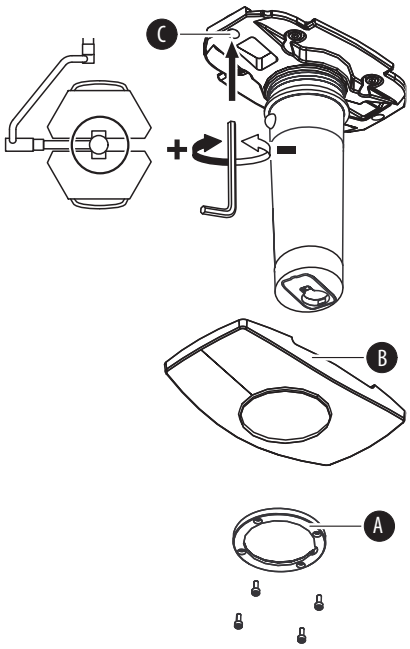
Product designation	Part number
Brake screw on the spring arm type AC 2000 NRH	1378866

5.14.4 Brake force on the lamp head



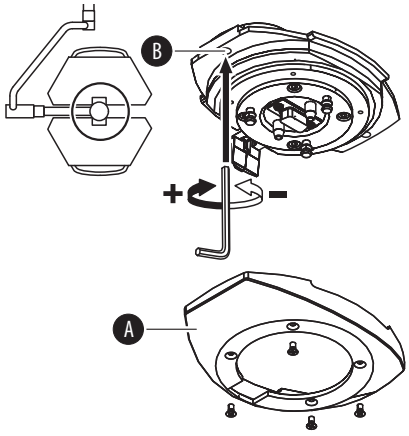
Lamp head with standard handle:

1. Switch off the surgical light on a control unit and disconnect it from the mains power.
2. Remove the sterilizable handle from the handle adapter.
3. Remove the grip attachment [A] (4 Allen screws M4x30 mm/ 1.18 inch).
4. Remove the cover of the handle attachment [B].
5. Adjust the two set screws [C] with a hexagonal wrench (wrench size 6).
   The braking strength is raised by turning clockwise, and lowered by turning anti-clockwise.
   If the force can no longer be adjusted, the internal brake strip must be replaced by a qualified service technician.
6. Attach the cover of the handle attachment [B].
7. Attach the grip attachment [A] (4 Allen screws M4x30 mm/ 1.18 inch).
8. Slide on the sterilizable handle.
9. Check all mounted parts for firm and correct attachment.
10. Test the braking strength. The lamp head must remain stable in the set rotational position.



Lamp head with ALC Plus function:

1. Switch off the surgical light on a control unit and disconnect it from the mains power.
2. Remove the sterilizable handle from the handle adapter.
3. Remove the retaining ring [A] (4 Allen screws M4x15 mm/ 0.59 inch).
4. Remove the cover of the handle attachment [B].
5. Adjust the two set screws [C] with a hexagonal wrench (wrench size 6).
   The braking strength is raised by turning clockwise, and lowered by turning anti-clockwise.
   If the force can no longer be adjusted, the internal brake strip must be replaced by a qualified service technician.
6. Attach the cover of the handle attachment [B].
7. Attach the retaining ring [A] (4 Allen screws M4x15 mm/ 0.59 inch).
8. Slide on the sterilizable handle.
9. Check all mounted parts for firm and correct attachment.
10. Test the braking strength. The lamp head must remain stable in the set rotational position.



Lamp head, TruVidia HD camera:

1. Switch off the surgical light on a control unit and disconnect it from the mains power.
2. Pull the sterilizable handle off the camera.
3. Remove the camera from the camera holder.
4. Remove the cover of the handle attachment [A] (4 countersunk cross-headed screws).
5. Adjust the two set screws [B] with a hexagonal wrench (wrench size 6).
   The braking strength is raised by turning clockwise, and lowered by turning anti-clockwise.
   If the force can no longer be adjusted, the internal brake strip must be replaced by a qualified service technician.
6. Remove the handle attachment cover [A] (4 flat-head screws with cross-slits).
7. Attach the camera to the camera mount.
8. Slide on the sterilizable handle.
9. Test the braking strength. The lamp head must remain stable in the set rotational position.

5.15 Decommissioning

For temporary or permanent decommissioning, completely disconnect the surgical light from the mains power network (see Chapter 5.6) and secure it against switching on. Disassembly of the surgical light in case of permanent decommissioning may only be carried out by qualified service technicians.

6 Cleaning and disinfection

⚠ WARNING

Danger of electric shock

Contact with live parts may result in electric shock.

- Take the surgical light out of service before cleaning and disinfecting it. See information in Chapter 5.6.
- Take all components connected to the surgical light (e.g. wall control panel, TruVidia HD camera) out of service before cleaning and disinfecting them.
- 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.

- 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.
- 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), polyethylene terephthalate (PET), 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.

NOTICE

The surgical light may be damaged when inappropriate cleaning or disinfecting agents are used.

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.

For safe use of the surgical light, regular cleaning and disinfection with suitable cleaning agents and disinfectants is required.

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

Only hygiene specialists or those instructed by them may clean and disinfect the surgical light.

Only those 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, otherwise functional components may be altered or damaged.

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

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.

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

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

6.1 Wipe-down disinfection

⚠ WARNING

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.

Use wipe-down disinfection to disinfect the lamp head and the support arm system. The lamp head must be cool for cleaning and disinfection.

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

Applying too much fluid to the surface during disinfection leaves residue behind. 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.

Clean surgical light only with a damp but not wet cloth.

Cleaning procedure:

1. Completely disconnect the surgical light from the mains power supply and secure it against switching on.
2. Allow lamp heads to cool. Only clean/disinfect the lamp head when it is cold.
3. Moisten cloth with a little cleaning agent or disinfectant. Wipe surgical light only with a 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 pure 0.75%
Clorox Healthcare	Hydrogen peroxide cleaner disinfectant wipes
Kesla Pharma	Wofasteril 0.5%

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 arms		
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.
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.
The automated distance measurement does not work (ALC Plus indicator flashes).	Software failure	Deactivate ALC Plus and select the distance manually or disconnect the voltage supply and switch it back on again.
Different color temperatures in the light field	The color temperature is only set on one lamp head.	Switch on the synchronization function.

8 Maintenance

⚠ WARNING

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

The surgical light must be maintained every 2 years after handover to the user. After 10 years in operation, maintenance of the surgical light must be performed 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.

An electrical safety check must be carried out after each repair.

10 High-wear parts

Product designation	Part number
Brake screws The brake screws may only be replaced by personnel that have been trained by Baxter in this kind of work.	
Brake screw at the extension arm (spring arm brake) M10x1 mm/0.04 inch with 9 mm/0.35 inch length (two pieces)	1378868
Brake screw on the spring arm type AC 2000 NRH M12x1 mm/0.04 inch with 21 mm/0.83 inch length (two pieces)	1378866
Brake screws on the extension arm (extension arm brake) M12x1 mm/0.04 inch with 30 mm/1.18 inch length (two pieces)	1378864
Brake screw on the comfort strap M10x1 mm/0.04 inch with 11 mm/0.43 inch length (two pieces)	4025239
Brake strip Replacement may only be performed by qualified service engineers. The contact details of service technicians can be obtained from the Technical Customer Service at Baxter.	
Brake rod with M6 set screws with 12 mm/0.47 inch length on the TruLight 5xx0 lamp head (two pieces) (Lamp head brake)	2002781

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 old 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 Device data

12.1.1 TruLight 3000

Product designation	TruLight		
	3300	3500	3510
Equipment			
Adaptive Light Control (ALC)	x	x	x
TruVidia HD camera	–	–	x
Side handles, not illuminated	–	–	–
Wall control panel	Optional	Optional	Optional
Electrical data			
Supply voltage at the power supply unit	100–240 V AC 50/60 Hz	100–240 V AC 50/60 Hz	100–240 V AC 50/60 Hz
Supply voltage to the DC-DC converter	22–32 V DC 22–26 V AC	22–32 V DC 22–26 V AC	22–32 V DC 22–26 V AC
Maximum power consumption of the overall system	130 VA	130 VA	150 VA
Internal fuse (only mobile pedestal version)	2 x T10 A	2 x T10 A	2 x T10 A
Voltage at the fixed point on the ceiling	48 V	48 V	48 V
Average service life of the bulb (LED)	> 60,000 hrs.	> 60,000 hrs.	> 60,000 hrs.
Classification according to the Act on Medical Devices (MPG)	1	1	1

Lighting data All light technology values maximum +/- 10% tolerance	TruLight	
	33x0	35x0
Light intensity with 1.0 m/39.37 inch	140,000 lux	160,000 lux
Dimmable from/to	< 10% Endo; 50% - 100%	< 10% Endo; 50% - 100%
Light field size can be varied by changing the distance	17–25 cm / 6.69–9.84 inch	17–25 cm / 6.69–9.84 inch
Light field diameter (d10) at 1.0 m/39.37 inch	18 cm/7.09 inch	18 cm/7.09 inch
Light field diameter (d50) at 1.0 m/39.37 inch	11 cm/4.33 inch	11 cm/4.33 inch
d50/d10 ratio	0.61	0.61
Radiation intensity (W/m) at a distance of 0.9 m/ 35.43 inch	587	616
Residual lighting intensity with one switch	81,200 lux 58%	108,800 lux 68%
Residual lighting intensity with two switches	61,600 lux 44%	75,200 lux 47%
Residual lighting intensity with lens barrel	140,000 lux 100%	155,200 lux 97%
Residual lighting intensity with lens barrel and one switch	81,200 lux 58%	104,000 lux 65%

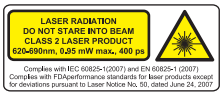
Lighting data All light technology values maximum +/- 10% tolerance	**TruLight**	
	33x0	**35x0**
Residual lighting intensity with lens barrel and two switches	61,600 lux 44%	72,000 lux 45%
Illumination depth (L1 + L2) at 20% Ec / EN ISO 60601-2-41 2nd Edition	83 cm/32.68 inch	75 cm/29.53 inch
Illumination depth (L1 + L2) at 60% Ec / EN ISO 60601-2-41 3rd Edition	44 cm/17.32 inch	41 cm/16.14 inch
Color rendition index Ra	94	93
Color temperature	4,500 K	
Mechanical Data		
Lamp head diameter	640 mm/25.20 inch	730 mm/28.74 inch
Flow surface of the lamp head	2100 cm²/ 325.50 inch²	3100 cm²/ 480.50 inch²
Light-emitting surface	1332 cm²/ 206.46 inch²	1892 cm²/ 293.26 inch²
Weight of the light head (including comfort and central handles)	13.6 kg / 29.98 lbs	16.4 kg / 36.16 lbs

12.1.2 TruLight 5000

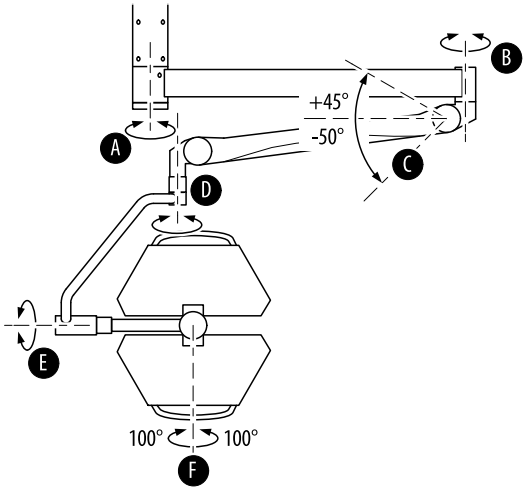
Product designation	**TruLight**					
	5300	**5310**	**5320**	**5500**	**5510**	**5520**
Adaptive Light Control (ALC)	x	x	x	x	x	x
Sterile Light Control (SLC)	–	–	x	–	–	x
Adaptive Light Control Plus (ALC Plus)	–	x	x	–	x	x
TruVidia HD camera	–	x	–	–	x	–
Side handles, illuminated	x	x	x	x	x	x
Wall control panel	Optional	Optional	Optional	Optional	Optional	Optional
Color temperature, adjustable on the controls	Optional	Optional	Optional	Optional	Optional	Optional

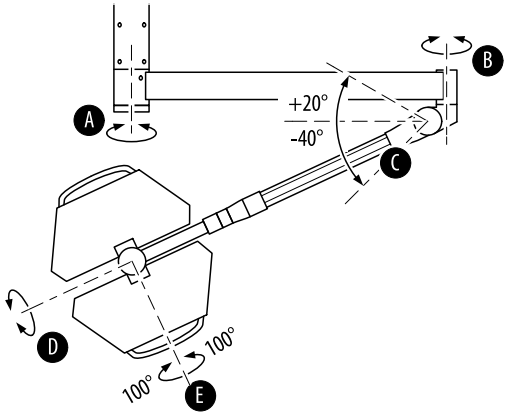
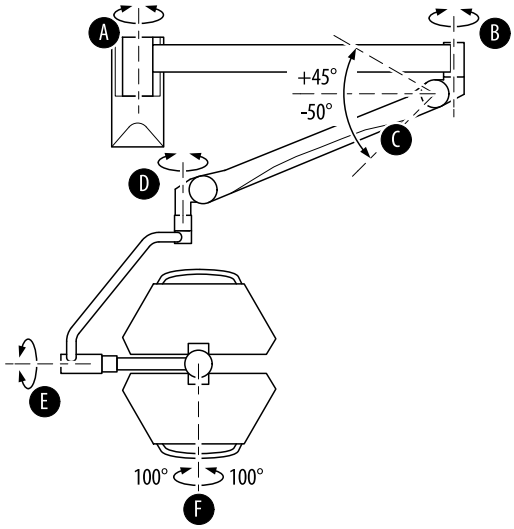
Electrical data	**TruLight**			
	5300	**53x0**	**5500**	**55x0**
Supply voltage at the power supply unit	100–240 V AC 50/60 Hz	100–240 V AC 50/60 Hz	100–240 V AC 50/60 Hz	100–240 V AC 50/60 Hz
Supply voltage to the DC-DC converter	22–32 V DC 22–26 V AC	22–32 V DC 22–26 V AC	22–32 V DC 22–26 V AC	22–32 V DC 22–26 V AC
Maximum power consumption of the overall system	110 VA	140 VA	120 VA	160 VA
Internal fuse (only mobile pedestal version)	2 x T10 A	2 x T10 A	2 x T10 A	2 x T10 A
Voltage at the fixed point on the ceiling	48 V	48 V	48 V	48 V
Average service life of the bulb (LED)	> 60,000 hrs.	> 60,000 hrs.	> 60,000 hrs.	> 60,000 hrs.
Classification according to the Act on Medical Devices (MPG)	1	1	1	1

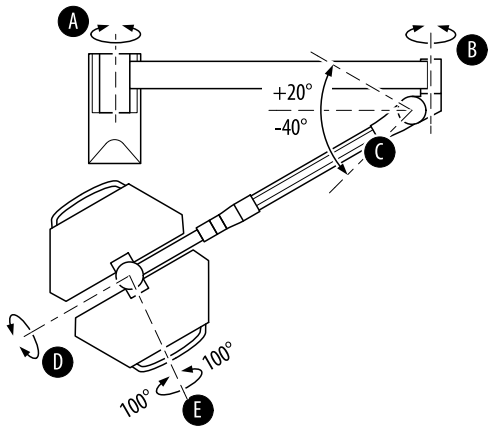
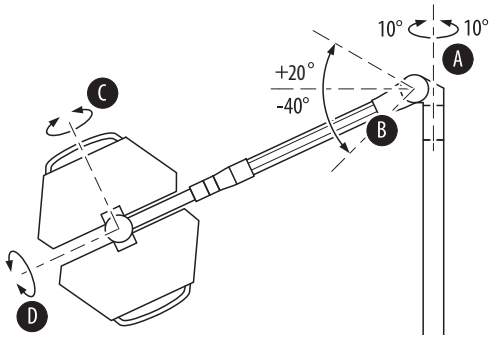
Lighting data All light technology values maximum +/- 10% tolerance	**TruLight**			
	53x0		**55x0**	
Light intensity with 1.0 m / 39.37 inch	140,000 lux		160,000 lux	
Dimmable from/to	< 10% Endo; 50% - 100%		< 10% ENDO; 50% - 100%	
Light field size can be varied by changing the distance	16 cm - 30 cm / 6.30–11.81 inch		16 cm - 30 cm / 6.30–11.81 inch	
Radiation intensity (W/m) at a distance of 0.9 m / 35.43 inch	620		676	
	Light field			
	Narrow	Wide (optional)	Narrow	Wide (optional)
Light field diameter (d10) at 1.0 m / 39.37 inch	17 cm/ 6.69 inch	24 cm/ 9.45 inch	17 cm/ 6.69 inch	24 cm/ 9.45 inch
Light field diameter (d50) at 1.0 m / 39.37 inch	10 cm/ 3.94 inch	13 cm/ 5.12 inch	10 cm/ 3.94 inch	13 cm/ 5.12 inch
d50/d10 ratio	0.59	0.54	0.59	0.54
Residual lighting intensity with one shade	40,600 lux 29%	81,200 lux 58%	94,400 lux 59%	121,600 lux 76%
Residual lighting intensity with two shades	57,400 lux 41%	60,200 lux 43%	68,800 lux 43%	78,400 lux 49%
Residual lighting intensity with lens barrel	140,000 lux 100%	140,000 lux 100%	156,800 lux 98%	150,400 lux 94%
Residual lighting intensity with lens barrel and one shade	40,600 lux 29%	81,200 lux 58%	92,800 lux 58%	112,000 lux 70%
Residual lighting intensity with lens barrel and two shades	57,400 lux 41%	60,200 lux 43%	68,800 lux 43%	72,000 lux 45%
Illumination depth (L1 + L2) at 20% Ec / EN ISO 60601-2-41 2nd Edition	94 cm/ 37.01 inch	96 cm/ 37.80 inch	95 cm/ 37.40 inch	94 cm/ 37.01 inch
Illumination depth (L1 + L2) at 60% Ec / EN ISO 60601-2-41 3rd Edition	51 cm/ 20.08 inch	51 cm/ 20.08 inch	60 cm/ 23.62 inch	60 cm/ 23.62 inch
Color rendition index (Ra)	Max. 96		Max. 96	
Color temperature (adjustable during initial installation)	3,500 K 4,000 K 4,500 K 5,000 K		3,500 K 4,000 K 4,500 K 5,000 K	
Color temperature (adjustable at the controls)	Optional		Optional	
Mechanical Data				
Lamp head diameter	640 mm/25.20 inch		730 mm/28.74 inch	
Flow surface of the lamp head	2100 cm^2/325.50 $inch^2$		3100 cm^2/480.50 $inch^2$	
Light-emitting surface	1332 cm^2/206.46 $inch^2$		1892 cm^2/293.26 $inch^2$	
Weight of the light head (including comfort and central handles)	14 kg/30.86 lbs		16.8 kg/37.04 lbs	

Performance specifications for laser	TruLight	
	5520	5320
 The single-beam laser is also classified as a laser in Laser Class 2 according to IEC 60825-1:2007. The laser complies with the performance standards of the US FDA with the exception of deviations that are listed in the Laser Note No. 50 dated January 24, 2007.		
Maximum output power The output power was measured with an ambient light of 200 lux on a white screen, which fills the camera's field of view at a distance of 20 cm/7.87 inch.	0.95 mW	0.95 mW
Wavelength	620–690 nm	620–690 nm
Beam divergence	0.16 x 0.6 mRad	0.16 x 0.6 mRad
Pulse duration	0.4 x 10 ^ -9 sec.	0.4 x 10 ^ -9 sec.
Pulse repeat rate	320 MHz	320 MHz

12.1.3 Support arm system swivel ranges

Joint		Swivel range
Type AC 2000 ceiling-mounted version with spring arm		
		
[A]	Ceiling conduit – Extension arm	Horizontal: > 360° (without stop)
[B]	Extension arm – Spring arm	Horizontal: > 360° (without stop)
[C]		Vertical: +45° to -50°
[D]	Spring arm – Comfort strap	Horizontal: > 360° (without stop)
[E]	Type Comfort strap – Lamp head TruLight 3000	Vertical: > 360° (without stop)
	Type Comfort strap – Lamp head of TruLight 5000	Vertical: < 420° (with end stop)
[F]	Lamp head – Transmission joint	200° (-100°/+100°)

Joint		Swivel range
Type AC 2000 NRH ceiling-mounted version with spring arm (Version: Low room height)		
		
[A]	Ceiling conduit – Extension arm	Horizontal: > 360° (without stop)
[B]	Extension arm – Spring arm	Horizontal: > 360° (without stop)
[C]		Vertical: +20° to -40°
[D]	Spring arm – Lamp head	Horizontal: > 360° (without stop)
[E]	Lamp head – Transmission joint	200° (-100°/+100°)
Type AC 2000 wall-mounted version with spring arm		
		
[A]	Wall bearing – Extension arm	Horizontal: 200°
[B]	Extension arm – Spring arm	Horizontal: > 360° (without stop)
[C]		Vertical: +45° to -50°
[D]	Spring arm – Comfort strap	Horizontal: > 360° (without stop)
[E]	Type Comfort strap – Lamp head TruLight 3000	Vertical: > 360° (without stop)
	Type Comfort strap – Lamp head of TruLight 5000	Vertical: < 420° (with end stop)
[F]	Lamp head – Transmission joint	200° (-100°/+100°)

Joint		Swivel range
Type AC 2000 NRH wall-mounted version with spring arm (Version: Low room height)		
		
[A]	Wall bearing – Extension arm	Horizontal: 200°
[B]	Extension arm – Spring arm	Horizontal: > 360° (without stop)
[C]		Vertical: +20° to -40°
[D]	Spring arm – Lamp head	Horizontal: > 360° (without stop)
[E]	Lamp head – Transmission joint	200° (-100°/+100°)
Mobile pedestal version		
		
[A]	Pedestal rod – Spring arm type AC 2000 NRH (Version: Low room height)	Horizontal: +10° to -10°
[B]		Vertical: +20° to -40°
[C]	Spring arm type AC 2000 NRH (Version: Low room height) – Lamp head	Vertical: > 360° (without stop)
[D]	Lamp head – Transmission joint	200° (-100°/+100°)

12.2 Electromagnetic compatibility

⚠ WARNING

Only operate the device with the specified accessories

- The device must be operated only with the accessories specified in the accompanying documentation. Operation with accessories, converters or cables other than those specified in the accompanying paperwork can lead to increased EMC transmissions or reduced resistance of the device to interference and therefore to incorrect operation. There are no specified precautions for maintaining basic safety in relation to EMC over the expected operational service life.
- The properties of this device, determined according to its emissions, allow it to be used in the industrial sector and in hospitals (CISPR 11, Class A). When used in domestic situations (for which CISPR 11 normally Class B is required), this device may not provide adequate protection from radio services. The user must, if necessary, take remedial measures such as the relocation or realignment of the device.
- The use of the surgical light immediately next to other devices or with other devices in a stacked arrangement should be avoided, as this may lead to faulty operation. If, nevertheless, it becomes necessary to use it with other devices, the surgical light and other devices should be monitored to ensure that they work appropriately.

NOTICE

Install and operate the device in accordance with 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 performance characteristics of the surgical light are:

– the provision of lighting

– the limitation of energy radiated onto the operating field

Guidelines and manufacturer's declaration – electromagnetic immunity

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

Guidelines and manufacturer's declaration – electromagnetic emissions		
The surgical light has been designed for operation in electromagnetic environments as described below. The customer or user of the surgical light must ensure that it is used in such an environment.		
Emissions measurements	Compliance	Electromagnetic environment – guidelines
HF emissions in accordance with CISPR 11	Group 1	The device 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 TruLight 5000 and the TruLight 3000 system are 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	In compliance	

Guidelines and manufacturer's declaration – electromagnetic immunity

Guidelines and manufacturer's declaration – electromagnetic immunity			
The device has been designed for operation in one of the electromagnetic environments described below. The customer or user of the device should ensure that it is used in such an environment. The support arm system may not move unintentionally or cause interference.			
Immunity testing	IEC 60601-1 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	The floor should be made of wood or concrete, or should be covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical disturbance variables/burst in accordance with 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 as per 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 on power supply input lines pursuant to 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 device user requires uninterrupted functionality even in case of power interruptions, we recommend supplying the device via an uninterruptible power supply or a battery.
Magnetic field with a supply frequency (50/60Hz) as per IEC 61000-4-8	30 A/m	30 A/m	Magnetic fields for the network frequency should comply with values commonly found in commercial and hospital environments.
a) at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° b) at 0° and 180° 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 radio units must not be used at a distance from the device, including cables, that is less than the recommended separation distance calculated according to the transmission frequency equation.

Immunity testing	IEC 60601-1 test level	Compliance level	Environment - guidelines
Conducted HF in accordance with IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in the ISM band between 0.15 MHz and 80 MHz[a)]	3 V 0.15 MHz – 80 MHz 6 V in the ISM band between 0.15 MHz and 80 MHz[a)]	D=1.2√P
Radiated HF disturbance variables as per IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz (see Special Frequencies table)	3 V/m 80 MHz – 2.7 GHz (see Special Frequencies table)	d=1.2√P at: 80 MHz – 800 MHz[b)] d=2.3√P at: 800 MHz – 2.7 GHz[b)]

a) = The ISM bands (ISM = industrial, scientific and medical) between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz. The amateur radio 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.

b) P is the nominal rating of the transmitter in watts (W) as per transmitter manufacturer data and d is the recommended safe distance in meters (m). According to an on-site inspection [c)], the field strength of stationary radio transmitters at all frequencies must be less than the compliance level.

d) Interference may occur in the vicinity of equipment marked with the following symbol:

Explanation to c) and d)

c) The field strength of stationary transmitters including the base stations of cellphones and mobile land mobile radios, amateur radio stations, AM and FM radio and TV broadcasting transmitters cannot be precisely predetermined theoretically. In order to determine the electromagnetic environment with regard to the fixed transmitter, a study of the location should be considered. If the field strength measured at a site where the above-mentioned equipment is used exceeds the above conformity levels, the device should be monitored. Additional measures may be required, e.g. changing the unit's alignment or location.

d) The field strength in the 150 kHz to 80 MHz frequency range should be less than 3 V/m.

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

Immunity levels for RF 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 18 Hz	1.8	0.3	26
450	430 – 470	GMRS 460 FRS 460	Pulse modulation FM ± 5 kHz variation 1kHz sine	2	0.3	28
720	704 – 787	LTE band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE band 1, 3, 4, 25 UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Controlled HF disturbance variables

Recommended separation distances between portable and mobile HF communication devices and the surgical light			
The device has been designed for operation in an electromagnetic environment in which radiated HF interference variables are controlled. The customer or user of the device mentioned above can help to prevent electromagnetic interference by complying with the minimum distances between portable and mobile HF telecommunications equipment (transmitters) and the device mentioned above, as recommended below in accordance with the communications equipment's maximum output power.			
Nominal transmitter power (W)	Separation distance according to transmission frequency (m)		
	150 kHz – 80 MHz d = 1.2√P	80 MHz – 800 MHz d = 1.2√P	800 MHz – 2.7 GHz d = 2.3√P
0.01 0.1 1 10 100	0.12 0.38 1.2 3.8 12	0.12 0.38 1.2 3.8 12	0.23 0.73 2.3 7.3 23
For transmitters whose rated power is not indicated in the table above, the recommended separation distance d in meters (m) can be determined by means of the equation assigned to the corresponding column; P represents the maximum rated power of the transmitter in watts (W) in accordance with the transmitter manufacturer's specifications. Note 1: These guidelines might not be applicable in all situations. The propagation of electromagnetic waves is influenced by the absorptions and reflections of buildings, objects and human beings. Note 2: At 80 MHz and 800 MHz, the higher frequency range applies.			

⚠ 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 device, including its cables as specified by the manufacturer. Otherwise, the functionality of the system may be impaired.

The surgical light is intended for use near high-frequency surgical equipment. The major performance characteristics of the surgical light are not affected.

12.3 SVHC (Substance of very high concern)

According to article 33 of the REACH regulation (EC) no. 1907/2006, components contained in the products contain reportable substances in concentrations exceeding 0.1 mass percent. The list with the affected components is provided by Baxter upon 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.

13.2 USA/Canada

The surgical light was tested for the USA and Canada by Underwriter Laboratories Inc. UL/cUL classification with respect to risk of electric shock, fire and mechanical endangerment as per ANSI/AAMI ES60601-1 (2005, 3rd ed.) and
CAN/CSA C22.2 No. 601.1 - M 90.

13.3 Ukraine

Це маркування підтверджує, що вироби, промарковані знаком відповідності, пройшли всі необхідні процедури підтвердження відповідності та підкоряються визначенимтехнічним керівництвам України.

Відповідність: Технічний регламент щодо медичних виробів, затверджений Постановою Кабінету міністрів України від 02 жовтня 2013 р. N° 753

13.4 Serbia

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

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