EN

Handbook

Mach LED 300

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CE

Contents

Congratulations on acquiring a new Mach LED 300 operating light!

With the Mach LED 300, you have a premium product from Dr. Mach, which is perfectly matched in design and function, which combines all the advantages of LED technology with innovative new features and satisfies the highest **quality, functionality and safety** of operating lights in professional environments - **high-tech "Made in Germany**"!

Easy positioning
of the light body

Long lifetime of the LEDs
(at least 60,000 hours)

Precise illumination of the wound area

Wide depth of focus
(with SC-variants additionally electronic focusing)

Changeable light colour
with excellent
perfect colour reproduction

Integrated **camera** or additional
spot light
(Camera and spot cannot be combined)

Hardly noticeable heat development

Optimal flow properties

The Mach LED 300 is available in the following equipment variants:

	Focussing (electronic and mechanical)	Focussing (mechanical only)	Adjustung the colour temperature	Brightness adjustment	Sterilisable handle	Spot (improved depth illumination)	Camera preparation	Hand-held remote radio control
Mach LED 300DF SC KV	✔	-	-	✔	✔	-	✔	-
Mach LED 300DF SC KV radio	✔	-	-	✔	✔	-	✔	✔
Mach LED 300DF SC Spot	✔	-	-	✔	✔	✔	-	-
Mach LED 300DF SC Spot radio	✔	-	-	✔	✔	✔	-	✔
Mach LED 300MC KV	-	✔	✔	✔	✔	-	✔	-
Mach LED 300MC KV radio	-	✔	✔	✔	✔	-	✔	✔

MC: Multicolour; **SC**: Single colour; **DF**: Dual focus (electronic and mechanical focusing); **KV**: Camera preparation

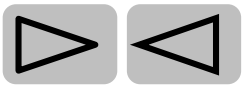
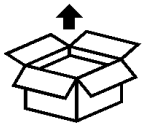
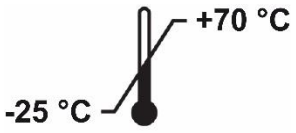
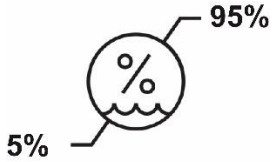
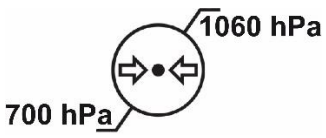
An installation with one or more Mach LED 300 operations lights can be extended by further products from Dr. Mach or our sales partner, for example lights of a different type, monitor carriers, camera systems or additional operating options.

1 Pictograms and advice in these document

	This symbol indicates possible sources of danger. Also heed the safety instructions and specific dangers in the associated fitting instructions and instructions for use.
	This symbol indicates important information and tips about usage.
	Information about disposal of the device
	CE Conformity symbol

2 Pictograms and advice on the equipment and on the packaging

	This symbol tells the user to observe the instructions for use.
	Serial number of the product
	Part number of the product
	Address of the product's manufacturer or distributor
	Date of manufacture and country of manufacture
	CE conformity symbol
	This symbol indicates that this is a medical device

	Unique device identifier (ID) of the product
	Reference to China RoHS / pollution control logo
	Positioning arrows
	Information about disposal of the device
	Fragile, Handle with care
	Keep dry
	Opening from the top
	Temperature range for transport and storage
	Atmospheric humidity for transport and storage
	Air pressure for transport and storage

3 Instructions for safe use

3.1 Safety instructions

	Pay attention to the instructions for use when handling the light
	To avoid the risk of an electric shock, this device must only be connected to a supply network that has a protective earthing conductor
	A primary-side ON/OFF switch to isolate the system from the supply network must be provided on site. The switch must meet the requirements of IEC 61058-1 for nominal voltage peaks of 4kV.
	This device is not designed for operation in environments enriched with oxygen.
	The light may only be used for the intended purpose. Otherwise, the manufacturer will not be liable for personal injury or damage to property.
	The light is equipped with a sterilisable handle at the factory and must only be used with this handle.
	Changes to the light are prohibited and will invalidate the manufacturer's certificate of conformity and all warranty claims.
	Use only the mains units (or transformers) approved or supplied by the manufacturer. Non-observance will void the conformity of the product and release the manufacturer from any claims under warranty.
	Installation, maintenance and repair work may only be carried out by the manufacturer or by specially trained staff.
	Maintenance must be carried out on the light at least every two years.
	Additional equipment that is connected to medical electrical equipment, must conform to the relevant IEC- or ISO standards (e.g. IEC 60950 or IEC 62368 for data processing equipment). Moreover, all configurations must meet the requirements for medical electrical systems (see Section 16 of the latest version of IEC 60601-1). Anyone who connects additional equipment to medical electrical equipment, is configuring a medical system and is therefore responsible for ensuring that the system meets the requirements for medical electrical systems. In case of doubt, contact your local representative or our technical customer services.

	The simultaneous use of several lights to illuminate a wound area may result in the maximum allowed energy input being exceeded (1,000 W/m²) and thus excessive heat development. It is the user's responsibility to ensure that the maximum allowed limit is not exceeded.
	The unprotected human eye can be damaged by direct light. Do not look directly into the light beam of the lamp. Do not point the light beam at the patient's unprotected eye continuously.
	When positioning the light body, there is a risk of injury (e.g. crushing) and collisions with other objects (inventory) or walls.
	Parts that fall off could injure the patient or lead to an infection of the wound area!
	Do not remove the rating plate or the warning labels!
	It is forbidden to carry out servicing or repair activities whilst the light is in use.

3.2 Intended user

The Mach LED 300 is a Class I medical device and may only be operated by trained medical staff.

3.3 Information and obligation of the user to check the product

Pay attention to the instructions for use when handling the lamp. These Instructions for use are part of the product and must therefore be stored in a place close to the product in order for the safety instructions and important information to be consulted at any time.

Make sure that the light is in satisfactory working order before every use. If there is obvious damage, unusual operating conditions, etc., the lamp must not be used.

3.4 Download of documents

The Instructions for Use and further documents on the light head can be found online at the following link:

https://dr-mach.de/login/mach-led-300.html

3.5 Intended use / contra-indications

The Mach LED 300 operating light is designed to illuminate an operating site in medical facilities (e.g. in a laboratory, hospitals or doctor's practice) with focussed, low-glare, shadow-free light. It enables the user to perform a diagnosis or carry out medical interventions. The Mach LED 300 light is an operating light that is not fail-safe when used as a single light. It is not intended for use in areas where explosions are likely although it is permissible to use it in the vicinity of HF surgical equipment.

Permanent illumination of the open human eye should be avoided when illuminating the face area.

3.6 Essential performance

The essential performance is to provide the illumination in depth and to restrict the energy on the operating light.

3.7 Accessories

The following accessories are available for the Mach LED 300 examination light:

- sterilisable handle (one handle is included)
- hand radio operation for remote control of the light

3.8 Environmental conditions for operation

Ambient temperature:	+5°C to +40°C
Relative air humidity	30% to 75% RH
Air pressure:	700 hPa to 1060 hPa

3.9 Reporting obligations

Every serious incident which has occurred in connection with the product must be reported to the manufacturer and the competent authority.

4 Installation

The light may only be installed, maintained or repaired by the manufacturer or by specially trained staff.

5 Putting into operation

5.1 Check before use

Every time before the light is used, the following points should be checked:

- Damage to the surface (for example the coating)
- Crack
- Deformation or damage
- Loose parts
- Faulty function

The light must not be put into operation if any of the deficiencies listed above are noticed. In this case please inform your competent service and maintenance partner.

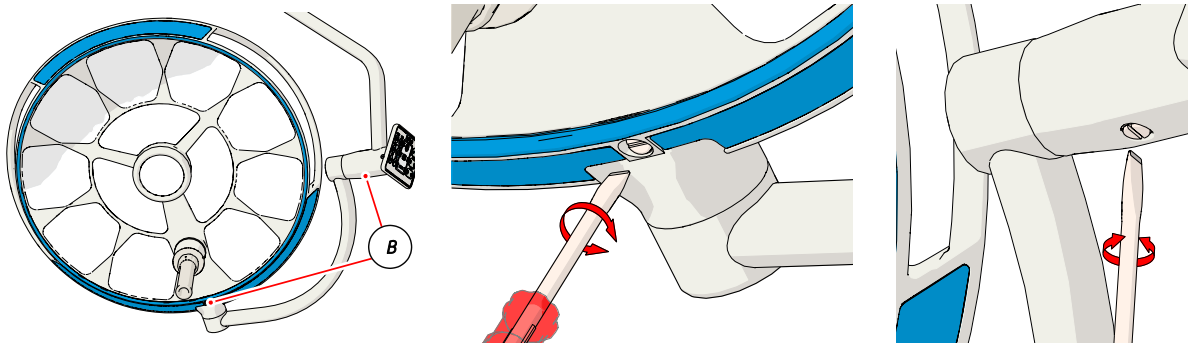
⚠	Parts that fall off could injure the patient or lead to an infection of the wound area.

5.2 Adjusting the brake

The Mach LED 300 surgical light is equipped with two brakes **(B)**, one on the lamp body near the handle and another on the suspension near the control panel.

If a light is difficult to move or does not retain its position by itself, the braking forces can be adjusted to remedy this. The brake screws can be adjusted by one turn to the left (easy) or right (more difficult) using a large (slotted) screwdriver.

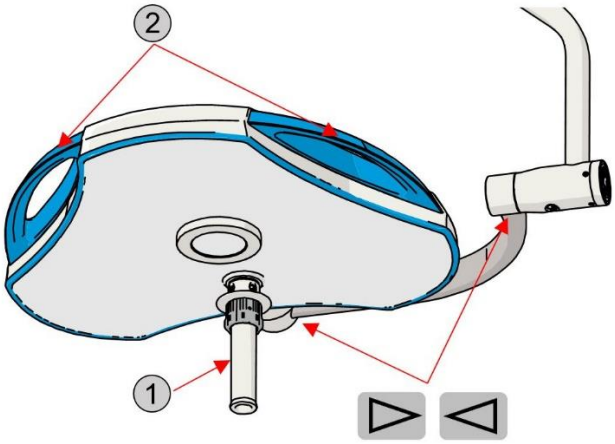
⚠	Parts that fall off could injure the patient or lead to an infection of the wound area.



(Illustrations of a typical example)

6 Operation of the light

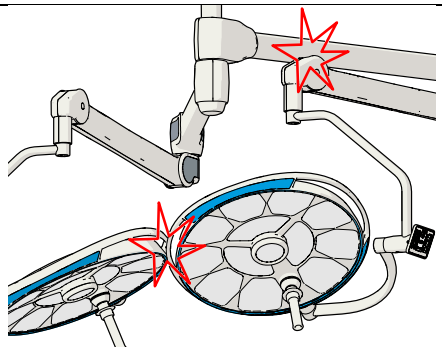
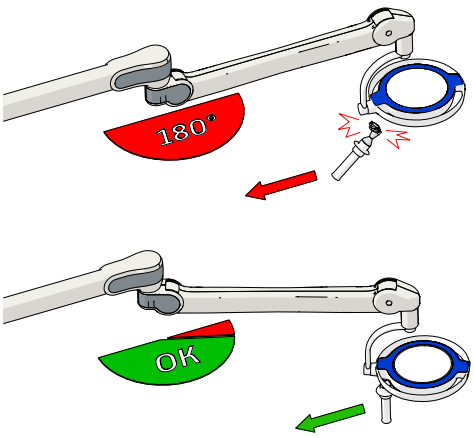
6.1 Positioning



Use the sterile handle **(1)** or both hand rails **(2)** (unsterile) to position the light body. The handle can be removed for sterilisation.

Due to the internal wiring, the joints on the light have stops and cannot be turned completely freely.

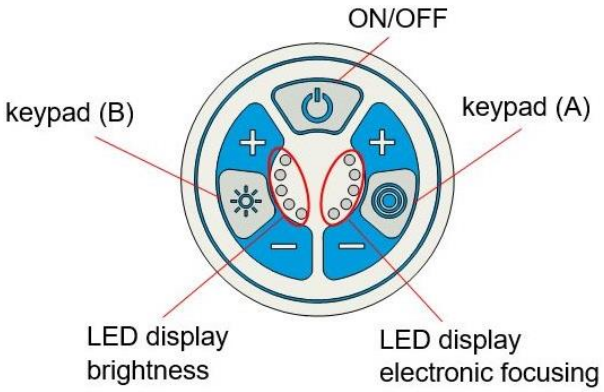
To ensure maximum rotability of the lamp, the two position arrows on the joints must be aligned.

⚠	To ensure sterility, a previously sterilised sterile handle must be used each time the light is used
⚠	When positioning the spring arms, collisions between lights, booms, spring arms and other objects should be avoided. This is because parts of the light and covers may be loosened or damaged. (Illustration of a typical example) 
⚠	In the 180° position of the spring arm and bracket, the light cannot be moved in the direction of the suspension axis. Repeated force may cause damage at this angle. To be able to move the light in the direction of the suspension axis, the angle between bracket and spring arm should be < 180°. (Illustration of a typical example) 

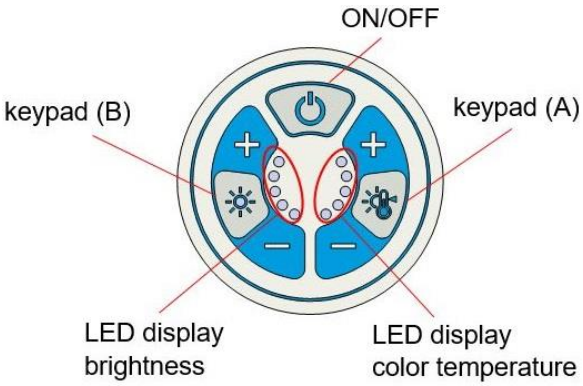
6.2 Functions

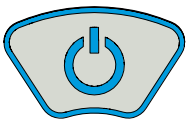
6.2.1 Functions on the control panel

Mach LED 300DF SC



Mach LED 300MC





ON/OFF switch of the light

To turn off the lamp, the ON/OFF button must be pressed **for at least one second**. If the light is switched off by this button, it is in standby mode and the upper LED of the LED brightness display flashes slowly.

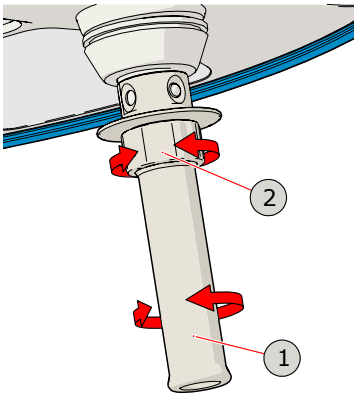
Adjustment of the brightness

Turn on endoscopic mode

Regulation of electronic focusing

Adjusting the colour temperature

6.2.2 Functions on the handle



The handle consists of two elements (handle and ring) that can be rotated. The handle **(1)** is used to regulate the mechanical focusing.

The ring **(2)** of the handle can have the following functions:

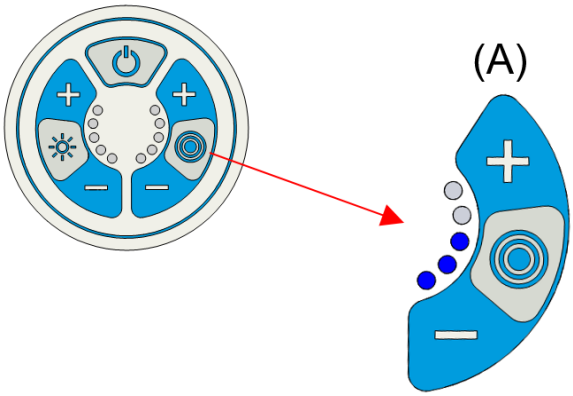
- electronic focusing
  (enlargement or reduction of the light field, only in SC versions)

- adjusting the colour temperature
  (only in MC versions)

6.2.3 Focussing

Mechanical focusing via the handle

The examination light MACH LED 300 offers mechanical focussing as a standard feature. In mechanical focusing the three outer LED units can be swivelled. This allows the projected light field to be enlarged or reduced.



Electronic focusing on the control panel

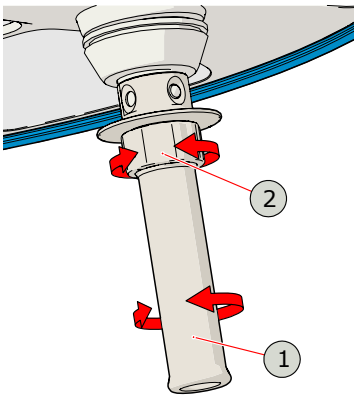
Only available in SC versions of Mach LED 300

The electronic focusing has 5 levels, which are indicated by 5 LEDs on the control panel.

Pressing the **minus key** on the keypad **(A)** reduces the size of the light field in steps. Pressing the **plus key** on the keypad **(A)** increases the size of the light field in steps.

If only the lowest LED lights up, this corresponds to the smallest electronically focusable light field.

If all five LEDs light up, this corresponds to the largest electronically focusable light field.



Focusing on the handle

The size of the light field can be adjusted by turning the sterilisable handle **(1)**.

The electronic focusing can also be changed by means of the ring **(2)** of the handle.

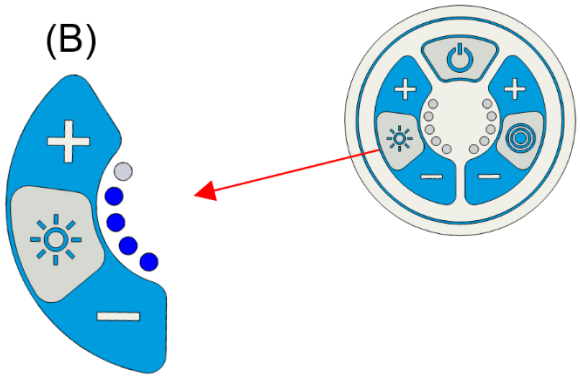
Turning the ring on the handle clockwise increases the light field by one step; turning the ring on the handle counter-clockwise decreases the light field by one step.

The set electronic focusing can be read on the corresponding LED display on the operator panel.

Only available in SC versions of Mach LED 300

6.2.4 Adjustment of the brightness

The desired brightness can be set before surgery. It is recommended to start with a lower brightness and then increase it over time. As standard, the brightness can be adjusted between 28% and 100% in 5 steps.



Adjustment of the brightness on the control panel

The brightness has 5 levels, which are indicated by 5 LEDs on the control panel.

Pressing the **minus key** on the keypad **(B)** reduces the brightness in steps. Pressing the **plus key** on the keypad **(B)** increases the brightness in steps.

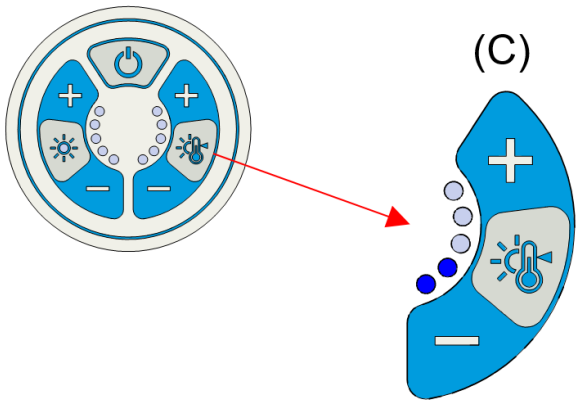
If only the lowest LED lights up, this corresponds to the smallest adjustable brightness.

If all five LEDs are lit, this corresponds to the highest adjustable brightness.

6.2.5 Adjustment of the colour temperature

Only available in MC versions of the Mach LED 300

The colour temperatures of **3750, 4000, 4250, 4500 and 4750 K (Kelvin)** can be set on the standard light (3750 K warm red light, 4750 K cold blue light). This allows the user to select the optimal light colour temperature for the particular type of tissue and structure of the wound area.



Adjusting the colour temperature via the touch panel

The 5 selectable colour temperatures are indicated by 5 LEDs on the operator panel.

Pressing the **minus key** on the keypad **(C)** reduces the colour temperature in steps. Pressing the **plus key** on the keypad **(C)** increases the colour temperature in steps.

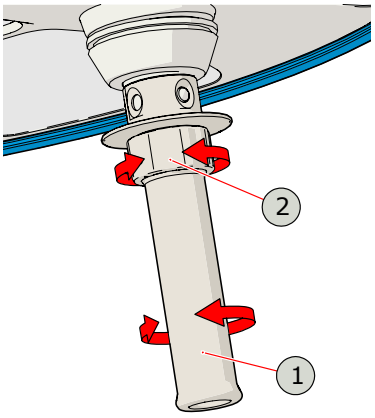
If only the lowest LED lights up, this corresponds to a colour temperature of 3750 K.

If two LEDs are lit – 4000 K.

If three LEDs are lit – 4250 K.

If four LEDs are lit – 4500 K.

If all 5 LED lights up, this corresponds to a colour temperature of 4750 K.



Adjusting the colour temperature by means of the handle (ring (2))

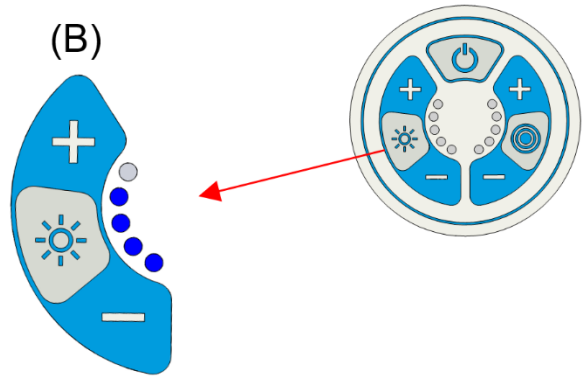
The size of the light field can be adjusted mechanically by turning the sterilisable handle **(1)**.

The colour temperature can also be changed by means of the ring **(2)** of the handle. Turning the ring on the handle clockwise increases the colour temperature by one step; turning the ring on the handle counter-clockwise decreases the colour temperature by one step.

The set colour temperature can be read on the corresponding LED display on the operator panel.

6.2.6 Endoscopic mode

The light emitted by the examination light can be dimmed for endoscopic surgery. When the function is active, the brightness of the examination light is reduced to approximately 5%.



Activation of the endoscopic mode on the control panel

The endoscopic mode is activated by pressing the **minus key** of the keypad **(B)** several times until only the bottom LED is lit.

After pressing the **minus key** of the keypad **(B)** again several times, the bottom LED goes out and the top LED lights up automatically – now the lamp is in endoscopic mode.

The function can be cancelled again by pressing the **plus key** on the keypad **(B)**.

6.2.7 Synchronisation of the settings

The Mach LED 300 light can optionally be equipped with the synchronisation function for lamp combinations in conjunction with a hand held radio remote control.

The synchronisation of several examination lights enables the doctor to transfer the brightness, colour temperature, electronic focussing or endoscopic mode set on one examination light to another examination light.

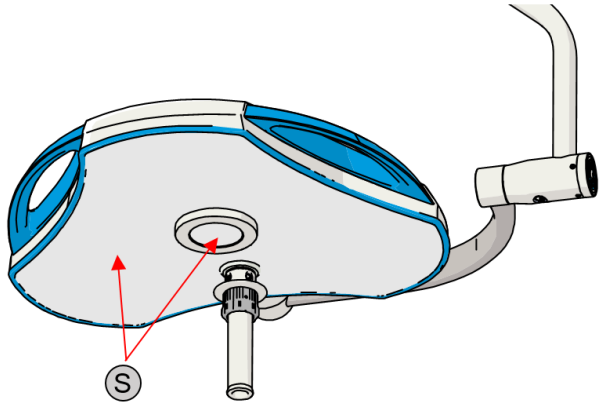
For more details, see the hand held radio remote control manual for the Mach LED 300.

7 Cleaning and disinfecting

Cleaning and disinfecting work must only be done by trained staff. The respective requirements must be observed for all cleaning and disinfection work.

7.1 Light body and protective screens

The light body and the protective screen can be cleaned and disinfected with many common/commercially available materials. **Do not use cleaning agents or disinfectants containing active substances based on biguanides or phenols.**



Furthermore, only cleaning agents approved for polycarbonate (PC) may be used to clean the protective screen **(S)**. To protect against mechanical damage, always use a damp cloth (never a dry one) to wipe the protective screen and after cleaning, wipe with an anti-static agent (lint-free cloth).

7.1 Sterilisable handle

7.1.1 Basic principles

The light comes with a handle that can be sterilised by steam. The handle must be cleaned/disinfected before each use. This applies in particular to the first use after delivery, as all handles are supplied non-sterile (cleaning and disinfection as well as sterilisation after removal of the protective transport packaging). Effective cleaning and disinfection is an essential prerequisite for effective sterilisation.

If desired, the sterilisable handle can also be used in combination with a sterile disposable coating. For more information, please contact Dr. Mach.

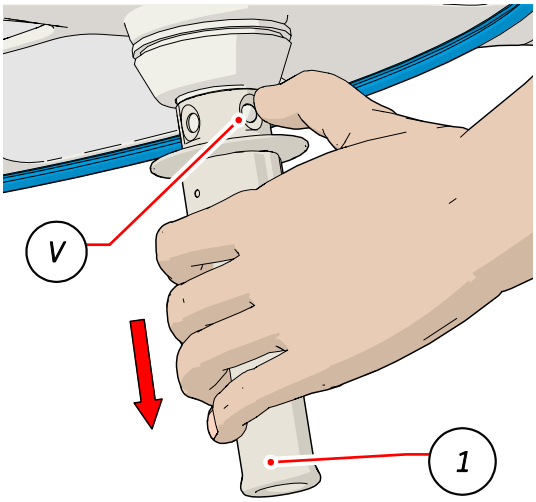
Handles can be processed up to 200 times, if they are undamaged, handled with care and not contaminated, before they have to be disposed of and replaced. The manufacturers decline all liability if this advice is disregarded.

Within the scope of your responsibility for ensuring the sterility of the handles used, please ensure

- that only methods which have been sufficiently validated specifically with regard to the equipment and products are used for the cleaning/disinfection and sterilisation,
- that the equipment used (disinfectors, sterilisers) are regularly maintained and tested and
- that the validated parameters are complied with in every cycle.

⚠	Please also observe the legal regulations applicable in your country as well as the hygiene regulations of the hospital. This applies particularly to the different guidelines with regard to effective prion inactivation (not applicable for the USA), which may call for the use of cleaning agents with proven effectiveness against prions as well as sterilisation with more intensive parameters.

The handle has to be removed to carry out sterilisation:



To remove the handle, press the lock button **V** and, keeping it pressed, pull the handle **(1)** downwards.

To fit the handle (**1)**, hold it gently in the hand and push it on with a slight twist until the lock button **V** engages positively in the four openings of the handle.

⚠	Before installing the handle, check it for visible damage, fouling and the specified manufacturing date. Do not use damaged or dirty handles or handles that are more than two years old.
⚠	Check the handle for a firm fit (clicking sound) after plugging it in, if necessary, with a tensile test. A handle that suddenly drops down can present a risk to safety.

☞ During an operation the handle often becomes unsterile so keep additional handles available for fitting.

7.1.2 Cleaning / disinfecting

7.1.2.1 Basics

A mechanical method (RDG - cleaning and disinfection equipment) should be used for cleaning and disinfection, if possible. Due to the significantly lower efficacy and reproducibility, a manual procedure – also using an ultrasonic bath – should only be used when a mechanical procedure is not available. (The use of a manual cleaning and disinfection process requires additional product and process-specific development and validation of the specific manual processing procedure under the sole responsibility of the operator).

	Do not clean any of the handles with metal brushes or steel wool.

7.1.2.2 Material resistance

When selecting the cleaning agents and disinfectants, ensure that they do not contain the following components:

- organic, mineral and oxidising acids (pH value should not be less than 5.5)
- strong alkaline solutions (pH value should not exceed 11, neutral/enzymatic or weak alkaline cleaning agents are recommended)
- organic solvents (e.g. alcohols, ether, acetone, petroleum ether)
- oxidizing agents (e.g. hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons

When choosing detergents, please also bear in mind that corrosion inhibitors, neutralising agents and/or rinsing agents may leave problematic residues on the handles.

7.1.2.3 Pre-treatment before cleaning and/or disinfection

Coarse contamination must be removed from the handles immediately after use of the light (within 2 hours at most):

Sequence:

1. Rinse the handle for at least one minute under running water (temperature < 35 C/95°F). Move any moving parts to and fro at least three times when pre-rinsing.
2. Place the handles such that they are fully immersed in the pre-cleaning bath for the predetermined reaction time (ultrasonic bath, activated by ultrasound). When doing so, make sure the handles do not touch one another.
3. Then remove the handles from the precleaning bath and flush. This should be done at least three times thoroughly (at least one minute) with water (Move moving parts back and forth at least three times during flushing).

	When choosing the cleaning agent make sure: - it is fundamentally suitable for cleaning metal or plastic instruments, - that it is suitable for ultrasound cleaning (no generation of foam), - that it is compatible with the handles (see section "Material resistance")
	The cleaning or cleaning- and disinfecting agent manufacturer's specifications on concentrations, temperatures and reaction times and instructions about final rinsing, must be adhered without fail. Use only freshly made solutions and only sterile or nearly sterile (max. 10 microbes/ml) and low endotoxin water (max. 0.25 endotoxin units/ml) (e.g. purified or highly purified water) and to dry use only a soft, clean and lint-free cloth and/or filtered air.
	If you use a detergent and disinfectant for pre-cleaning, please ensure that it is aldehyde-free (otherwise fixation of blood contamination), has a proven effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), is suitable for disinfecting instruments made of metals and plastics and is compatible with the handles (see section "Material resistance"). Please note that the disinfectant used during pretreatment only serves to protect personnel and cannot replace the disinfection step to be performed later, after cleaning.

7.1.2.4 Mechanical cleaning/Disinfection (RDG - cleaning and disinfection equipment)

When selecting the disinfector it should be ensured

- that the disinfector fundamentally complies with DIN EN ISO/ANSI AAMI ST15883 and has proven efficacy (e.g. DGHM or FDA approval/clearance/registration or CE marking),
- that, if possible, a tested thermal disinfection program (A_0 value $\geq$ 3000 or – in case of older equipment – at least 5 minutes at 90°C/194°F) is used (in the case of chemical disinfection, the risk of disinfectant residues on the handles),
- that the disinfector manufacturer's program used is suitable for the handles,
- that the program used has a sufficient number of rinse cycles (at least three degradation steps after the cleaning (or neutralisation, if used) or guide value control is recommended to effectively prevent residues of detergent),
- that only sterile or nearly sterile (max. 10 microbes/ml) and low-endotoxin (max. 0,25 endotoxin units/ml) water (e.g. purified or highly purified water) is used for final rinsing,
- that the air used for drying is filtered (oil-free and low in microbes and particles), and
- that the disinfector is regularly maintained and checked.

When selecting the cleaning agent system to be used, it should be ensured that

- it is fundamentally suitable for cleaning metal or plastic instruments,
- provided no thermal disinfection is used – and in addition a disinfectant with proven efficacy (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is used and that this is compatible with the cleaning agent used, that the program used has a sufficient number of rinse cycles (at least two degradation steps after the disinfection) or guide value control is recommended to effectively prevent residues of disinfectant) and
- that the chemicals used are compatible with the handles (see section "Material resistance").

The concentrations, temperatures and contact times of the cleaning agent and any disinfectant specified by the manufacturer and instructions about final rinsing must be strictly observed.

Sequence:

1. Use a standard basket with a locating net to place the handles into the disinfector. In doing so, make sure the handles do not touch one another
2. Start the program.
3. Remove the handles from the disinfector when the program has ended.
4. Check and pack the handles straight after removal, if possible (see sections "Checking", "Maintenance" and "Packing", possibly after further final drying in a clean place).

Proof in principle of the handles' suitability for effective mechanical cleaning and disinfection was provided by an independent, governmentally accredited and recognised test laboratory (§ 15 (5) MPG) using an ultrasonic device of the SONOREX series at 35 kHz (BANDELIN electronic, Berlin) for pre-cleaning, the disinfector G 7836 CD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the Neodisher mediclean forte pre-cleaning and cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg). Here, the above-described method was taken into consideration and also worst-case aspects were applied in relation to the guidelines of the detergent manufacturer.

7.1.2.5 Inspection

Inspect all handles after cleaning or cleaning/disinfection for corrosion, damaged surfaces, illegible markings, chipping, dirt, discolouration and ease of movement, and discard damaged handles . Handles which are still contaminated must be cleaned and disinfected once more.

7.1.2.6 Packaging

Please pack the handles in single-use sterilisation packaging (single or double packaging material), that meets the following requirements (material/process):

- DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA-Clearance)
- Suitable for steam sterilisation (temperature resistance up to at least 142°C (288°F), sufficient permeability to steam)
- Sufficient protection of the handles and of the sterilisation packaging against physical damage.

7.1.3 Steam sterilisation

	Only the steam sterilization process may be used for sterilization, other methods such as lightning sterilization, hot air sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization as well as plasma sterilization are not permitted.

- Fractionated vacuum method with sufficient drying of the product:
  - at least three vacuum steps
  - The less effective gravitation method may be used only if the fractionated vacuum method is not available. It requires far longer sterilisation times, and also equipment-, procedure- parameter- and product specific process development and validation must be performed under the sole responsibility of the user.
  - The actual drying time required is directly dependent on the parameters, which are the sole responsibility of the user (loading configuration and density, sterilizer condition, etc.) and must therefore be determined by the user. Nevertheless, drying times should never be less than 20 minutes
- Steam-steriliser according to DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- Validated according to DIN EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))
- Maximum sterilisation temperature 138°C (280°F; plus tolerance according to DIN EN ISO 17665)
- Sterilisation time (exposure time at the sterilisation temperature):

Country	Fractionated vacuum method	Gravitation method
USA	4 minutes at 132°C (270°F), drying time at least 20 minutes	Not recommended
Germany	5 minutes at 134°C (270°F) or 18 minutes for prion inactivation (not relevant for the USA)	Not recommended
Other countries	At least 3 minutes at 132°C (270°F) / 134°C (273°F) or 18 minutes for prion inactivation (not relevant for the USA)	Not recommended

Proof in principle of the handles' suitability for effective steam sterilisation was provided by an independent, governmentally accredited and recognised (§ 15 (5) MPG) test laboratory using the HST 6x6x6 steam sterilizer (Zirbus technology GmbH, Bad Grund) and using the fractionated vacuum method. Here, typical conditions in clinics were taken into consideration as well as the method described above.

	The handles must not be exposed to temperatures above 142°C (288°F).

After sterilisation, the handles must be stored dry and dust free in the sterilisation packaging.

8 HD Wireless Camera (optional)

The models of the Mach LED 300 luminaire that do not have a spot can be equipped with an HD wireless camera (at the factory or as a retrofit kit).

This HD wireless camera is designed exclusively for installation in the Mach LED 300, installation in other Dr. Mach lights or independent operation is not possible.

Standard scope of delivery of the HD wireless camera:

- Camera
- Control unit (infrared remote control)
- Radio receiver
- Wall bracket for radio receiver
- Device connection cable
- HDMI cable (10 m)

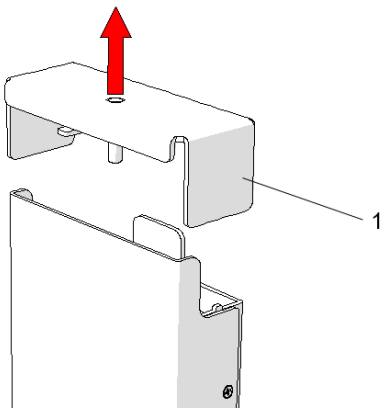
The camera, which is permanently installed in the luminaire body, is always precisely aligned with the center of the light field, so the camera is positioned with the luminaire.

The functions of the camera are controlled with a control device (infrared remote control). The radio receiver has an HDMI output to which a monitor, distributor or recording device, etc. can be connected using the HDMI cable (10 m) included in the scope of delivery.

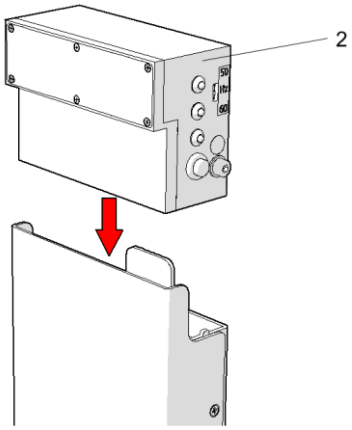
8.1 Mounting preparation

	Before installation, switch off all devices (disconnect lights, monitors, recording devices, etc. from the power supply)!

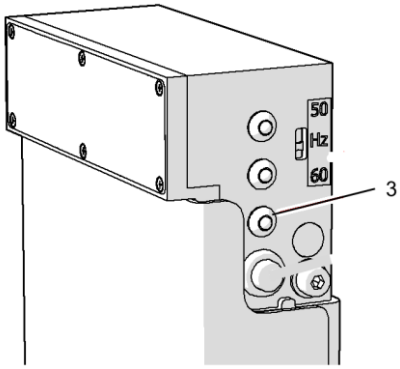
8.2 Connection of the radio receiver



Pull off the top cover **1** of the wall bracket upwards



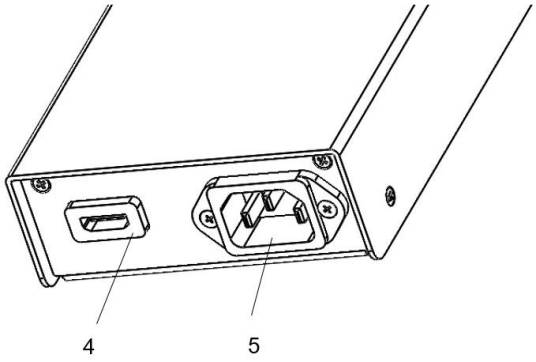
Place the radio receiver **2** on the wall bracket (the radio receiver is now supplied with power through the wall bracket).



The radio receiver is now in the so-called **configuration mode.**

The green status LED **3** flashes steadily for about one minute.

After one minute the radio receiver is in **normal operating mode** (the green LED **3** flashes briefly).



Connect the monitor or another compatible device (recording device, splitter etc.) to the HDMI port **4** on the wall bracket using the HDMI cable.

Connect the power cord to connection **5**.

8.3 Pairing

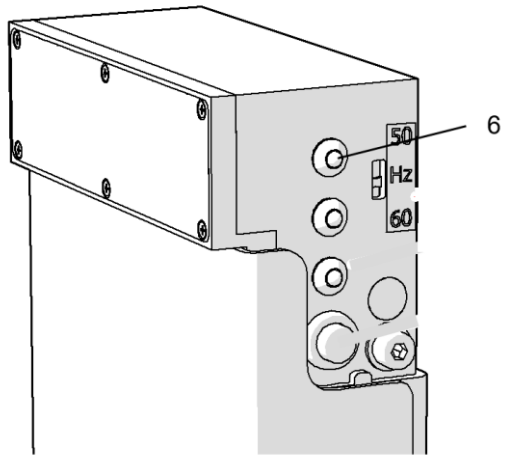
In order for the camera (transmitter) to communicate with the correct receiver, the two devices must be paired. Pairing is triggered wirelessly via the control device (remote control).

Only one camera can be paired with a single radio receiver at a time.

In order to be able to carry out the pairing, the radio receiver in the wall bracket and the light including the camera must be supplied with voltage.

There must be no obstacles between the radio receiver and the camera during pairing

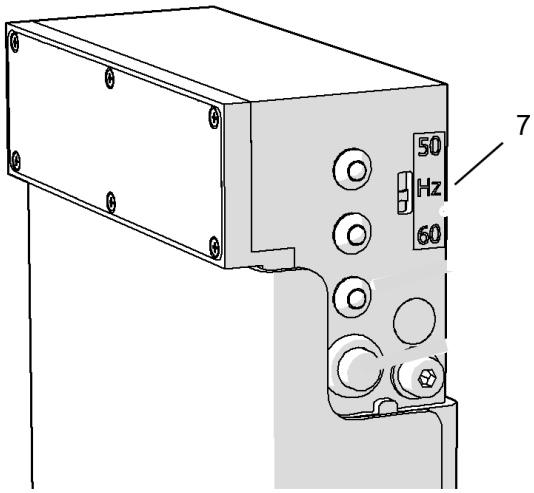
1. Switch off the camera with the control device (remote control) using the ON / OFF button or switch to standby (standby is indicated by the permanently lit yellow LED in the camera)
2. Press and hold the red button on the radio receiver for at least 5 seconds. If the radio receiver is in pairing mode, this is indicated by the yellow LED flashing rapidly.
3. On the control unit (remote control, pointed at the camera), press the Freeze button five times in succession within 15 seconds. Once the camera has established a connection with the radio receiver, the yellow LED in the camera flashes - pairing starts.
4. Pairing takes a few minutes. Once the pairing is complete, the yellow LED in the camera lights up again permanently and the blue LED on the radio receiver also lights up permanently.
5. Switch on the camera via the control device (remote control). If an image is displayed on the monitor, the pairing was successful, if no image is displayed on the monitor, repeat pairing.



The status of the radio connection is indicated by the blue LED **6**.

- LED lights up continuously: the radio connection is stable and active
- LED flashes quickly: the radio connection is established, but the picture cannot be shown on the monitor. Please check the monitor cable.
- LED flashes slowly: no radio connection established.

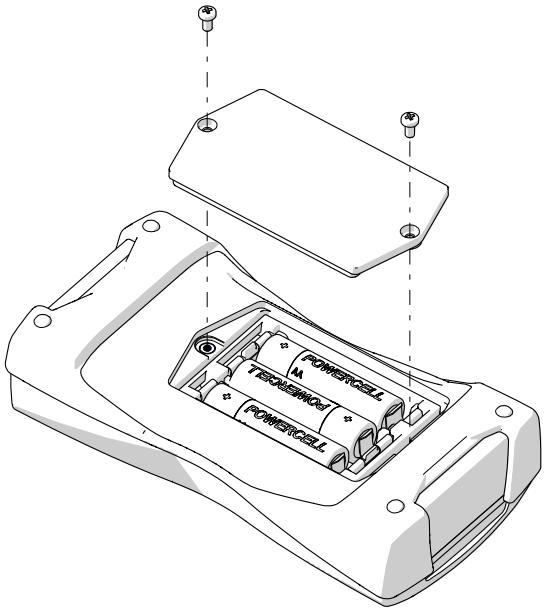
8.4 Setting the frame rate



The image frequency can be set to 50 Hz or 60 Hz using switch **7** on the radio receiver (the standard setting of the camera system is 50 Hz).

Slide the switch up or down for the desired frame rate.

8.5 Control of the camera

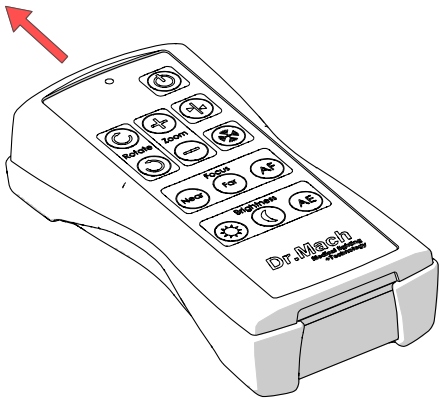


Inserting the batteries

- Loosen the fastening screws and remove the cover on the back of the device.
- Insert batteries (3x type AA 1.5 V) (observe polarity)
- Reattach the cover and secure it with the screws.

NOTE: Always replace all batteries!

The batteries may at the end of their lifetime not be disposed of in the normal household waste, but must be given to a point of sale or to a collection point for the recycling of electrical devices.



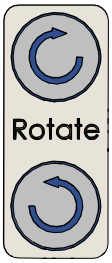
Point the remote control towards the camera and make sure that there are no optical barriers between the camera and the remote control.

ON/OFF button

This button is used to turn the camera on and off.

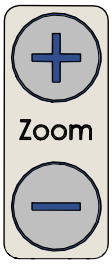
When the power supply of the light with camera is switched on again, it takes approx. 20 seconds until the camera is booted up and ready for use.

The camera is then initially in stand-by mode and a black image is transmitted. A yellow LED next to the front lens of the camera lights up and signals that the camera is supplied with voltage and is in standby. If the camera is switched on, the video image is transmitted and the status LED goes out.



ROTATION (Rotate)

Use this button to rotate the camera image 180 degrees.



ZOOM

The image scale is changed with the ZOOM key. The focal length can be continuously adjusted from 3.2 mm to 33.6 mm (10x zoom).

The zoom process continues as long as the button is pressed. As soon as the end of the optical zoom range is reached when zooming in, the zooming process is stopped. If the + button is then pressed again, the image is digitally enlarged up to 16 times. If the - key is now pressed, the digital zoom is first reduced before the optical zoom is reduced.

White balance

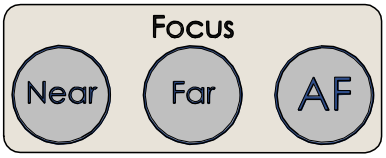
This function is used to adapt the color temperature to the existing environment.

The following steps must be carried out to carry out a white balance:

1. Adjust and align the surgical light.
2. Place a white paper in the beam of light.
3. Align the camera and zoom the image until the sheet fills the video image.
4. The automatic white balance is started by pressing the White Balance button once. The process is completed after 5 seconds at the latest.

Freeze frame

With the Freeze button, the system is able to freeze the current video image as a still image.



FOCUSSING (FOCUS)

After switching on the power supply of the camera, the automatic focusing is activated.

By pressing the **AF** button, the automatic focus can be switched on or off as required.

With the **Near** and **Far** buttons, the manual focus can be adjusted accordingly to objects that are closer or more distant. The process continues as long as the button is pressed.

EXPOSURE (Brightness)

After switching on the power supply of the camera, the automatic exposure control is activated.

This function determines the automatic brightness of the video image based on the optical impression.

If necessary, the automatic exposure control can be switched on or off by pressing the **AE** button.

With the "Sun" and "Moon" buttons, the brightness of the video image can be increased or decreased manually step by step.

9 Maintenance

To ensure safe and reliable operation of the surgical light, it must be serviced regularly. A visual inspection of the light must be carried out at least annually, and an additional functional test must be carried out at least every two years. Maintenance activities must only be carried out by the manufacturer, Dr. Mach GmbH & Co KG or by persons authorized and trained by Dr. Mach GmbH & Co KG. Details about maintenance can be found in the maintenance manual of Mach LED 300 (available by download, link section 3.4) as well as in the maintenance protocol (see annex).

The light is designed to have a life-span of 10 years. To ensure reliable operation beyond the estimated life-span, the light needs to be given a functional test annually as part of the service work.

The maintenance interval of the support system may deviate from the above. The relevant information can be found in the respective manufacturer's instructions for use or maintenance instructions.

10 Faults

10.1 Electrical faults

The following steps are to be executed if an error occurs:

- Disconnect the lamp from the power supply for about 30 seconds (light is voltage-free). Disconnection from the power supply is done by the ON/OFF switch installed by the customer. Switching the lamp off and on by means of the touch panel is not sufficient.
- Take the radio receiver (optional) out of the wall bracket and reinsert it after 30 seconds.
- If the error is still present, please contact our technical services.

11 Technical data

11.1 Light body

Type of device	Operating light
Protection class/-type	I
Class (acc. to directive 93/42/EU)	I
IP protection class	IP 42
Input voltage	24-30 V DC
Power consumption	32 W max. (spot version) 37 W max. (camera/camera preparation)
Current	1,3 A max. (spot version) 1,6 A max. (camera/camera preparation)
Radio interference suppression	EN 55011 (CISPR 11) EN 60601-1-2 (IEC 60601-1-2)
Temperature (transport and storage)[1]	-25 °C to +70 °C
Relative humidity (transport and storage)	5 % RH to 95 % RH
Air pressure (transport and storage)	700 hPa to 1060 hPa
Operating time	Continuous operation possible
Weight of light including accessories	max. 12 kg
Expected life [2]	10 years

[1] Ambient conditions for light body and power supply.

[2] At the end of the expected (designed) service life, the lamp must be serviced more frequently for safe operation

11.2 Mains power supply

The LED 300 examination light is operated with a Dr. Mach 200 W power supply. As an alternative, the Dr. Mach 190 W power supply can be used.

Power supply 200 W	
Input voltage (primary)	100-240V AC, 50/60 Hz
Current consumption (primary)	7.1 A max.
Output voltage (secondary)	28 V DC
Output power (secondary)	200 W maximum

Power supply 190 W (alternative)	
Input voltage (primary)	100-240V AC, 50/60 Hz
Current consumption (primary)	6.6 A max.
Output voltage (secondary)	28 V DC
Output power (secondary)	190 W maximum

11.3 Wireless receiver power supply unit (wall bracket) (optional)

Power supply 15 W	
Input voltage (primary)	100-240 V AC, 50/60 Hz
Power consumption (primary)	0,4-0,2 A max.
Output voltage (secondary)	12 V DC
Output power (secondary)	15 W max.

11.4 HD wireless camera (optional)

Image sensor	1/3-type CMOS
Effective Number of Pixels	4000K pixels
Aspect ratio	HD 16:9
Signal system	HD 1080i/60, 1080i/50
Lens	10x optical zoom, 16x digital zoom, f=3.3 mm (wide) to 33.0 mm (tele) F1.8 to F3.4
Horizontal angle of view	59,9° (wide) to 2,1° (tele) (1080i mode)
Minimum illumination	0.5 lx
Minimum object distance	10 mm (wide) to 800 mm (tele)
Camera operation switch	Zoom tele, Zoom wide
White balance	Auto (using OT-light)
Focus system	Full Auto, Manual
Electronic shutter	1/1 sec to 1/10.000 sec (22 steps)
Camera control	via Remote Control

11.5 Radio parameters (camera radio system, optional)

Radio channel LRP 1 [1]	Operating mode: send / receive Frequency range: 60.16275 - 60.79725 GHz Transmission power: 14.6 dBm eirp Modulation: BPSK
Radio channel LRP 2 [1]	Operating mode: send / receive Frequency range: 62,32275 – 62,95725 GHz Transmission power: 14,6 dBm eirp Modulation: BPSK
Radio channel MRP [1]	Operating mode: send Frequency range: 60,48 – 62,64 GHz Transmission power: 24,0 dBm eirp Modulation: QPSwK
Radio channel HRP [1]	Operating mode: send Frequency range: 60,48 – 62,64 GHz Transmission power: 24,2 dBm eirp Modulation: QPSK and 16-QAM

12 Lighting technical data

	Mach LED 300DF SC	Mach LED 300DF SC Spot	MACH LED 300MC
Central light strength (distance 1 m) [1]	160,000 lux	160,000 lux	160,000 lux
Light field diameter d_{10}	174 mm	173 mm	184 mm
Light field diameter d_{50}	89 mm	89 mm	104 mm
Residual light intensity with one shadower	42%	34%	44%
Residual light intensity with two shadowers	42%	53%	44%
Residual light intensity on the ground of a normed tube	100%	100%	100%
Residual light intensity on the ground of a normed tube and a switch	42%	34%	44%
Residual light intensity on the ground of a normed tube and two shadowers	42%	53%	44%
Illumination depth 20%	883 mm	1560 mm	915 mm
Illumination depth 60%	449 mm	634 mm	510 mm
Colour rendering index R_a (type)	95	95	97
Colour rendering index R_9 (type)	92	92	97
Max. radiation strength in the field (distance 1 m)	559 W/m²	585 W/m²	574 W/m²
Radiation strength in the field (distance 0.90 m)	611 W/m²	-	674 W/m²
Radiation strength in the field (distance 0.88 m)	-	616 W/m²	-
Focusable light field size	17 - 27 cm	17 - 25 cm	18 - 30 cm
Colour temperature (Kelvin)	4500K	4500K	3750, 4000, 4250, 4500, 4750 K
Temperature increase in the head area	0.5°C	0.5°C	0.5°C
Luminous efficacy (efficiency)	286 lm/W	274 lm/W	279 lm/W
Number of LEDs	36	37	36
Working distance	70 - 150 cm	70 - 150 cm	70 - 150 cm
Diameter of light body	55 cm	55 cm	55 cm
Life-span of LEDs	60,000 hours	60,000 hours	60,000 hours
Height adjustment	118 cm	118 cm	118 cm

All technical data are subject to certain fluctuations. For production reasons, the actual values have a tolerance of ± 10%. The values for the colour temperature can have deviations of ± 200 K.

[1] according to IEC 60601-2-41, the maximum illumination intensity must not exceed 160,000 lux. The measurement tolerance is therefore only -5%.

13 Hints and tables concerning electromagnetic compatibility

Medical electrical equipment is subject to special precautionary measures with regard to electromagnetic compatibility (EMC). It may only be installed and put into service in accordance with the EMC instructions in the accompanying documents. The Mach LED 300 examination light has been tested for use in professional equipment of the health care system.

The functioning of the OP and examination lights can be affected by portable and mobile HF communications equipment.

Should a loss or limitation of the essential performance characteristics occur due to electromagnetic interference, one can expect the provision of illumination to be temporarily not guaranteed.

To ensure the basic reliability and essential performance characteristics of the Mach LED 300 with regard to electromagnetic interference during the anticipated period of use, the maintenance work must be performed within the specified intervals and in accordance with the instructions in the Technical Service Manual. Only spare parts expressly approved by Dr. Mach may be installed.

	The lamp is suitable for use with an RF surgical device. There must be a distance of at least 50 cm between the surgical light, including the suspension system, and the RF electrode cables.
	Portable and mobile HF communications equipment can affect medical electrical equipment and must not be used within 30 cm of the light, including the cable.
	The use of this equipment immediately next to other equipment or with other equipment in stacked form should be avoided since this may result in faulty operation. Should use in the aforementioned manner nevertheless be necessary, this device and the other equipment should be kept under observation to ensure that they are working properly.
	The use of different accessories, converters or cables to those that the manufacturer of this device has stipulated or made available may result in increased electromagnetic interference or reduced immunity to electromagnetic interference and to faulty operation.
	Furthermore, the light must not be operated if the housing, cable or electromagnetic shielding is damaged.

Table 2 (IEC 60601-1-2) - ambient limits and error messages

Phenomenon	Professional health care facility environment [a]	Home healthcare environment authority [a]
Conducted and radiated interference emission	Class B, Group 1 (acc. to CISPR 11)	CISPR 11 [cd]
Distortion due to harmonics	See IEC 61000-3-2 [b]	See IEC 61000-3-2
Voltage fluctuations and flicker	See IEC 61000-3-3 [b]	See IEC 61000-3-3

[a]) Regarding information about the environment categories of use as intended, see 8.9 (IEC 60601-2-41)

[b]) These tests do not apply for this environment unless the ME-GERAT light used therein is connected to the public supply network and its input power is within a range that is in the range of application of the cited basic EMC standard.

[c] ME-GERAT and ME-SYSTEMS intended for use in aircraft must meet the requirements on interference emissions according to ISO 7137. A measurement of the conductor-borne interference emissions is required only if the ME-EQUIPMENT and ME-SYSTEMS concerned are intended for connection to the aircraft's on-board supply network. The norm ISO 7137 is identical to the specifications RTCA DO-130C:1989 and EUROCAE ED-14C:1989. The latest editions of these specifications are the RTCA DO-160G:2010 and the EUROCAE ED-14G:2011. For this reason, section 21 (and category M) of a more recent edition, e.g. [39] or [40], should be observed.

[d] The pertinent norms shall be used for other applicable operating situations or other EM environments in transportation, insofar as use as intended of the ME-GERAT and ME-SYSTEMS is envisaged there. Possibly relevant norms include the CISPR 25 and ISO 7637-2 with a

Table 4 (IEC 60601-1-2) - Covering

phenomenon	Basic EMC standard or test procedure	Immunity test level	
		Professional health care facility environment a	Home healthcare environment
Discharge of static electricity	IEC 61000-4-2	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV , ± 15 kV air	
RF electromagnetic fields [a]	IEC 61000-4-3	3 V/m [f] 80 MHz to 2.7 GHz [b)] 80% AM at 1 kHz [c)]	10 V/m [f] 80 MHz to 2.7 GHz [b)] 80% AM at 1 kHz [c)]
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See table 9	
Rated power frequency magnetic Measuring frequencies [d e]	IEC 61000-4-3	30 A/m [g] 50 Hz or 60 Hz	

[a)] The interface between the simulator for the physiological patient signal, where used, and the ME-GERAT or ME-SYSTEMS must be arranged within a distance of 0.1 m to the vertical plane of the uniform field. The simulator must be aligned in a direction with the ME-EQUIPMENT or ME-SYSTEM.

[b)] ME-GERAT and ME-SYSTEMS which receive electromagnetic HF energy for the purposes of their operation as intended, must also be tested for the received frequency. The test can also be carried out with other modulation frequencies defined by the risk management process. This test rates the basic safety and essential performance characteristics of an ME GERAT of this type intended for reception in the presence of ambient signals in its receive frequency range. It is to be assumed that normal reception conditions for the receiver, where applicable, are not reached during this test.

[c] The test can also be carried out with other modulation frequencies defined in the risk management process.

[d] Applies only for ME-GERAT with magnetically sensitive components or circuitry.

[e] In the test the ME-GERAT can be supplied with one of the nominal input voltages provided, however the pertinent mains frequency must correspond to that of the test signals (see Table 1).

[f] Level before use of modulation.

[g] This test level assumes a minimum separation between ME-GERAT or ME-SYSTEM and mains frequency magnetic field sources of 15 cm. If the risk analysis indicates that the ME-GERAT or ME-SYSTEM when used comes closer than 15 cm to the mains frequency magnetic field sources, the immunity test level must be altered appropriate to the anticipated minimum separation.

Table 5 (IEC 60601-1-2) - Alternating current GATE for the supply unit

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVEL	
		Professional facilities for health care	Home healthcare environment
Fast electrical transients/bursts [a l o]	IEC 61000-4-4	± 2 kV 100kHz repetition frequency	
Surges [a b j k o] line to line	IEC 61000-4-5	± 0.5 kV, ± 1 kV	
Surges [a b j o] line to ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV ± 2 kV	
Conducted disturbances induced by RF fields [c d o]	IEC 61000-4-6	3 V [m] 0.15 MHz - 80 MHz 6 V [m] in ISM frequency bands Between 0.15 MHz and 80 MHz [n] 80% AM at 1 kHz [e.]	3 V [m] 0.15 MHz - 80 MHz 6 V [m] in ISM and amateur radio frequency bands between 0.15 MHz and 80MHz [n] 80% AM at 1 kHz [c)]
Voltage dips [f p r]	IEC 61000-4-11	0 % U_T; 0.5 cycle [g)] at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° [q]	
		0 % U_T; 1 cycle and 70% U_T; 250/300 cycle [h] Single phase at 0 degrees	
Voltage interruptions [f i o r]	IEC 61000-4-11	0% U_T; 250/300 cycles [h]	

[a] The test can be carried out with any mains input voltage in the range of the ASSESSMENT VALUES for the mains voltage of the ME-GERAT or ME SYSTEM. If the ME-EQUIPMENT or ME-SYSTEM is tested at a mains input voltage, no further tests with other voltages are necessary.

[b] All lines of the ME-EQUIPMENT and ME-SYSTEM must be attached when performing the test.

[c] The calibration of the current feeder tongs must be done in a 150 Ω system.

[d] If the frequency steps skip over an ISM or amateur radio band, an additional test frequency must be used within the latter. This applies for any ISM or amateur radio band within the stipulated frequency range.

[e] c) The test can also be carried out with other modulation frequencies defined in the RISK MANAGEMENT PROCESS.

[f] ME-EQUIPMENT and ME-SYSTEMS with a d.c. input supply that are intended for operation with a converter with a.c. input and d.c. output, must be tested with a converter that complies with the specifications of their MANUFACTURER. The IMMUNITY TEST LEVELS must be applied at the a.c. input of the converter.

[g] Applies only for ME-EQUIPMENT and ME-SYSTEMS intended for connection to single phase a.c. networks.

[h] Specifications separated by a forward slash such as 10/12, signifies 10 cycles at 50Hz or 12 cycles at 60Hz mains frequency.

[i] ME-EQUIPMENT and ME-SYSTEMS with a RATED input current under 16 A per phase must be interrupted once for 250/300 cycles at any arbitrary angle and with all phases simultaneously (where applicable). ME-EQUIPMENT and ME-SYSTEMS with battery backup must pick up the mains operation again after the test . With ME-EQUIPMENT and ME-SYSTEMS with a RATED input current less than or equal to 16A, all phases must be interrupted.

[j] ME-EQUIPMENT and ME SYSTEMS without transient protection devices in the primary circuit need to be tested only with ± 2 kV between the supply line(s) and earth and with ± 1 kV between the separate supply units.

[k] Not applicable for ME-EQUIPMENT and ME SYSTEMS of PROTECTION CLASS II.

[l] Direct coupling must be used

[m] Effective value before modulation is used.

[n] The ISM bands (i.e. frequency bands used for industrial, scientific and medical purposes) 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, 14MHz 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 MHz to 54.0 MHz.

[o] Applicable to ME-EQUIPMENT and ME-SYSTEMS with a RATED input current less than or equal to 16 A per phase and to ME-EQUIPMENT and ME-SYSTEMS with a RATED input current greater than 16 A per phase.

[p] Applicable to ME-EQUIPMENT and ME-SYSTEMS with a RATED input current of less than or equal to 16 A per phase.

[q] With ME-GERAT fitted with a mains input transformer, the carrying out of this test at some phase angles may cause the high-current protection device to trip and switch off. Such an event may occur due to magnetic saturation of the transformer's core after a voltage dip. Should this occur, the BASIC SAFETY of the ME-EQUIPMENT or ME-SYSTEM must be ensured during and after the test.

[r] With ME-EQUIPMENT and ME-SYSTEMS that have a multitude of possible mains voltage settings or else are equipped with an automatic mains voltage selector, the tests with mains voltage values must be carried out with the smallest and greatest RATED VALUE for mains input voltage that make up less than 25% of the highest mains input voltage falling in the range of the RATED VALUE. Tests must be done with a mains input voltage that lies in this range. For corresponding example calculations, refer to Table 1 remark c).

Table 9 IEC 60601-1-2)- Test specifications for the NOISE IMMUNITY and SHEATHING against wireless communication equipment

Test fre-quency (MHz)	Frequency band [a] (MHz)	Radio service [a]	Modulation [b]	Maximum power (W)	Distance m)	IMMUNITY TEST LEVEL (V/m)
385	380 - 390	TETRA 400	Pulse modula-tion [b] 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM [c] ± 5 kHz devia-tion 1 kHz sine	2	0.3	28
710	704 -787	LTE Band 13, 17	Pulse modula-tion [b] 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 modula-tion [b] 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 modula-tion [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modula-tion [b] 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modula-tion [b] 217 Hz	0.2	0.3	9
5500						
5785						

REMARK: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME-EQUIPMENT or ME-SYSTEM can be reduced to 1 metre.
The 1 metre test distance is permitted by IEC 61000-4-3.

[a] For some radio services only the frequencies for the radio link from the mobile communications device to the base station (uplink) are included in the table.

[b] The carrier must be modulated with a square-wave signal at a 50% duty cycle.

[c] As an alternative to frequency modulation (FM), pulse modulation with a 50% duty cycle at 18 Hz can be used because, whilst not the actual modulation, it would nevertheless constitute the worst case.

14 Disposal

The light does not contain any harmful substances.

The components of the light should be disposed of appropriately at the end of the product's life.

Take care that the material is carefully separated.

The electrical circuit boards should be recycled appropriately. The housing of the light and the remaining light components should be disposed of according to the materials they contain.

Dr. Mach **GmbH & Co. KG**
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85560 Ebersberg, GERMANY

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Dr. Mach maintenance protocol

Documentation of the maintenance work on the light (the maintenance intervals are to be found in the latest version of the accompanying documents)

Please <u>also</u> observe the maintenance protocol of the manufacturer's maintenance instructions of the suspension arm system.

Please contact us if you have any questions about the maintenance of the products. You can reach us on telephone number +49 8902 2093-0.

Manufacturer:	Dr. Mach GmbH & Co KG Flossmannstr. 28 (D) 85560 Ebersberg		Customer/Address:	
Light:	Type:		Inventory No.:	
	Serial No.:			
Inspector:			Person to contact at the customer's:	

No.	**Activity**	**Checked** (yes, no, nn=not necessary)	**Result** (OK, F=Fault, H=Advice)
1.	**Visual inspection (yearly)**		
1.1	**Luminaire / Monitor suspension**		
1.1.1	Checking for external damage (damaged paintwork, cracks, deformation and clearances)		
1.1.2	Checking all parts are tightly fastened		
1.1.3	Checking that type plate and stickers are present and legible		
1.2	**Suspension (ceiling, wall, stand)**		
1.2.1	Checking for external damage (damaged paintwork, cracks, deformation and clearances)		
1.2.2	Check that all parts are tightly fastened (particularly those of the ceiling suspension; open air-handling ceiling if necessary)		
1.2.3	Checking that type plate and stickers are present and legible		

2.	**Function check (every 2 years)**		
2.1	**Protective conductor test for devices of protection class I** (see also EN 62353/VDE 0751 section 5.3.2)		
2.1.1	Measurement of protective contact of plug to accessible conductive parts of the device for devices with a non-detachable mains connection cable (max. 0.3Ω)		
2.1.2	Measurement of protective contact connection of the device to accessible conductive parts of the device for non-detachable devices (max. 0.3Ω)		
2.2.	**Leakage current measurement** (see also EN 62353/VDE 0751 section 5.3.4)		
2.2.1	Direct measurement of the earth leakage current of the entire device with placement on an insulated surface (max. 0.5mA)		
2.2.2	Leakage current measurement of lamp head (if 2.1.1 is not possible) (maximum 0.3 mA)		
2.3	**Light head**		
2.3.1	Checking of illuminated field		
2.3.2	Functional testing of all operating elements		
2.3.3	Checking ease of movement of the light head		
2.3.4	Checking the stops of the light suspension		
2.3.5	Check coupling for sterile Handle Check sterile handle is firmly seated		
2.3.6	Checking of brake screw on light head		
2.4	**Video system**		
2.4.1	Checking operation of the camera		
2.4.2	Checking the image transfer		
2.4.3	Functional testing of all operating elements		
2.5	**Monitor suspension**		
2.5.1	Checking ease of movement of the monitor suspension		

2.5.2	Checking the stops of the monitor suspension		
2.5.3	Check coupling for sterile Handle Check sterile Handle is firmly seated		
2.6	**Suspension**		
	Note: **For the maintenance work on the suspension, the instructions for use of the manufacturer of the suspension arm system must also be observed and the corresponding servicing log of the suspension arm system must be completed.**		
2.6.1	Checking of **securing segments**		
2.6.2	Checking of the suspension arm system (**see maintenance protocol of the manufacture**)		
2.6.3	Checking the screw connection between ceiling suspension device and suspension arm system		
3.	**Documentation of maintenance / archiving of documents**		
Notes / Remarks:			

Date:	**Name Inspector:**	**Sign Inspector:**