Directions for use

MACH LED 150F / 150 / 150FP

Dr. Mach **GmbH u. Co. KG, Floßmannstrasse 28, D-85560 Ebersberg**
Tel.: +49 (0)8092 2093 0, Fax +49 (0)8092 2093 50
Internet: www.dr-mach.com, E-Mail: info@dr-mach.de

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Dear customer!

Congratulations for acquiring our new light **MACH LED 150F / LED 150 / LED 150FP**.

The new light generation with LED technology supports your professionalism by innovative technology and design.

The advantages of the LED technology: a life-span of minimum 60.000 hours and an almost non-existent heat development in the surgeon's head area and in the wound field.

The advantages already provided by Dr. Mach's light technology with halogen and gas discharge lamps have been maintained: natural colour reproduction, exact illumination of the wound field and easy positioning of the light head.

All information quoted here relates only to the illuminant. Details of ceiling or wall installation can be found in the mounting instructions.

1. Safety instructions

Pay attention to the instructions for use when handling the lamp.

WARNING:

This device has not been designed for use in potentially explosive areas.
According to the Medical Device Regulation the light is classified under class I.

Store the light in its package for at least 24 hours in the respective room before mounting, in order to equal temperature differences.

Please read the instructions for use carefully to make the most of your lighting system and to avoid any damages to the device.

The lights may only be repaired and special assembly work may only be carried out on the reflector or sockets by Dr. Mach or a company that has been expressly authorized by Dr. Mach.

The manufacturer can only be made responsible for the safety of the light if repairs and alterations are carried out by the manufacturer himself or a company that guarantees to observe the safety regulations.

 No modification of the lamp is allowed!

The manufacturer cannot be made liable for personal or material damages if the light is operated inexpediently or incorrectly or used for purposes other than those for which it is intended.

The light is to be dismantled from the spring arm in reverse order to its assembly. This may only be carried out after the spring arm has been adjusted in height at horizontal position since the arm is under spring tension and can bounce up.

Make sure that the light is in perfect working order before every use.

Attention, external power supply!
The light works only with an external power supply 60VA.
The external power supply used with the light must be tested and validated according to IEC 60601-1.

Attention!
A main control switch must be installed for turning the system power-off. The switch must meet the requirements of the standard IEC 61058-1 regarding rated voltage peaks of 4kV.

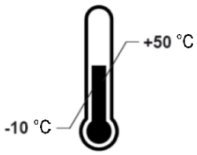

During the mounting of the lights the entire system (incl. the ceiling attachment) must be disconnected from mains!
A later dismounting of the lights from the spring arms or dismounting the sliding contacts inside the arms is to be done ONLY AFTER DISCONNECTING THE ENTIRE SYSTEM FROM MAINS.
Otherwise the electronic board will be damaged!

Symbols and notes used in this user manual:

This symbol means possible hazard sources. Please observe also the safety remarks and the hazard specifications mentioned in the mounting instructions and user manuals from Ondal company.

This symbol means possible hazard caused by electric current. Please observe also the safety remarks and the hazard specifications mentioned in the mounting instructions and user manuals from Ondal company.

This symbol refers to important mounting indications, useful information and operation hints.



Temperature range for transport and storage

Indication for disposal

CE- conformity mark

This way up

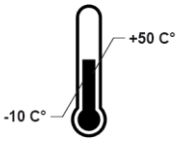
Keep dry

Fragile, Handle with care

Symbols and notes used on the device:

This symbol indicates to observe the user manual.

Indication on China RoHS / Pollution control Logo China



Temperature range for transport and storage

Indication for disposal

Serial number of the product

Article number of the product

Address of manufacturer / distributor of the product

Year of manufacture

CE- conformity mark

Quality control

This symbol indicates the certification mark of the TÜV.

2. Brief description of the light MACH LED 150F / 150 / 150FP

Mach LED 150F/150/150FP intended use:
The Mach LED 150F/150 lighting system is designed for illuminating an examination area at the hospital and doctor's practice.

Mach LED 150F/150/150FP indications for use:
The surgical light MACH LED 150F/150/150FP is intended to illuminate the surgical field and the patient's body with a high intensity, shadow-free and "cold" light.

Essential Performance:
The surgical light Mach LED 150F/150/150FP is intended to illuminate in depth and to restrict the energy on the operating field.

General product description:
- The Mach LED 150F/150/150FP lighting system is an examination light according to EN 60601-2-41, which is not fail-safe when used as a single light.
- The Mach LED 150F/150/150FP lighting system is designed to support therapy and diagnosis.
- The light is used in medical rooms (groups 0, 1 and 2 according to DIN VDE 0100-710 respectively HD 60364-7-710).
- This light system can be added to the ceiling mounted suspension system supporting the horizontal arms and spring arms, as well as a wall light or mobile light.
- The maintenance of the light must take place every two years.
- The electrical connection for the ceiling and wall lights is done by a fixed connection.

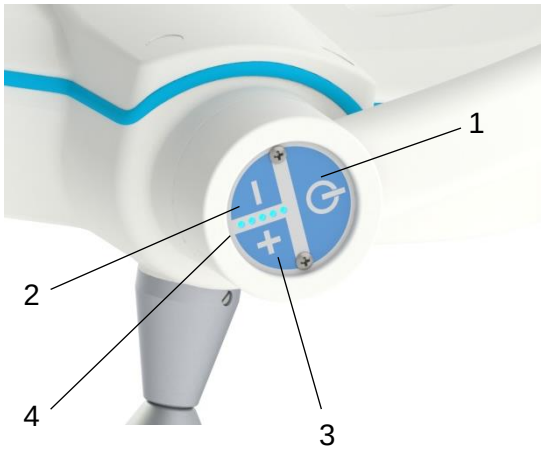
The examination light Mach LED 150F/150/150FP is available in following versions:
- Mach LED 150F with light intensity control and focusing function.
- Mach LED 150 with light intensity control and fixed-focus.
- Mach LED 150F with light intensity control, focusing function and sterilizable handle.
- Mach LED 150 with light intensity control, fixed-focus and sterilizable handle.
- Mach LED 150FP with light intensity control and focusing function.
- Mac LED 150FP with light intensity control, focusing function and sterilizable handle.

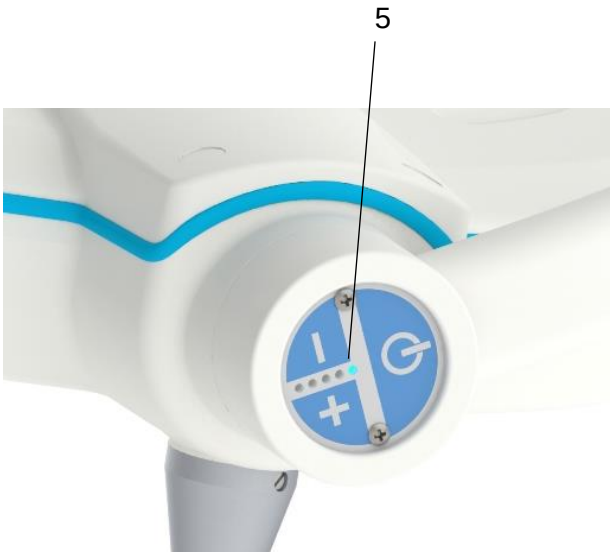
Accessory

The accessories for the Mach LED 150F/150/150FP lighting systems are as follows:

Camera module
Remote control for camera module
Single monitor yoke for flat panel monitors
Double monitor yoke for flat panel monitors
Instrument trays
24V DC battery backup support
Sterile handle sleeves

3. Operating the light MACH LED 150F / 150 / 150FP





3.1 ON/OFF switch

The push button **1** on the control panel turns the light **MACH LED 150F/150/150 FP** ON and OFF.

3.2 Light intensity control

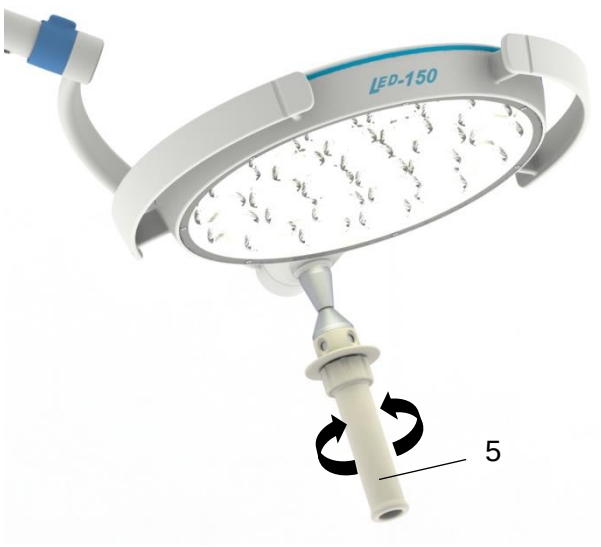
The lights Mach LED 150F/150/150 FP offer the facility of light intensity control.
The adjustment range of the light intensity is from 50 % to 100 %.
The light intensity can be adjusted according to the requirements of the surgeon / physician.

The light intensity can be decreased by pressing push button **2**.
The light intensity can be increased by pressing push button **3**.

The set light intensity is shown by the display **4**.

3.3 Endo – Light (Mach LED 150/150F/150FP with 4500 Kelvin)

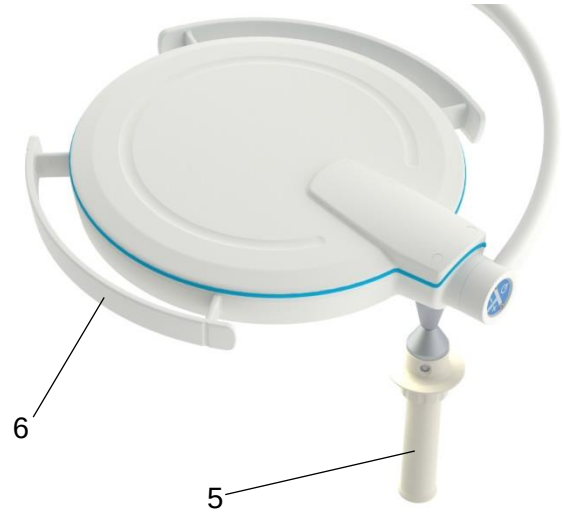
In case of endoscopic intervention the light of the OT- lamp with 4500 Kelvin (optional) can be dimmed.
The Endo mode is activated by repeated pressing of the – key, until only LED **4** is on. When pressing the – key again, LED **4** goes off and LED **5** turns on automatically.
The Endo mode is now active.
This mode can be deactivated by pressing the + key.



3.4 Focusing

The lamp-models Mach LED 150F/150FP have a focusing function. That means, you can either enlarge the diameter of the light field or bundle the light to a smaller area, depending on the circumstances.

To activate the function of focusing turn the handle **5** (see figure).



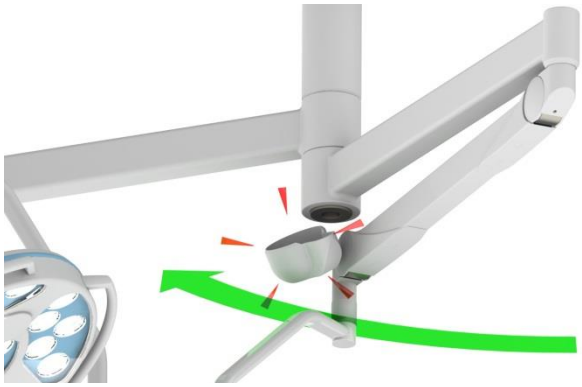
3.5 Positioning

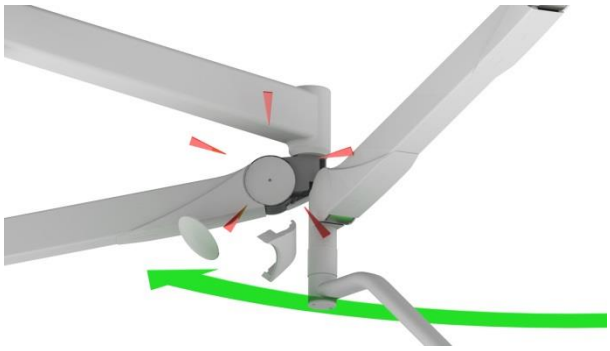
Use the handle **5** or the handle rail **6** to position the lamp.

Use the handle rail to position the lights before the operation.

Use the handle for positioning the light during the operation.

Remark:
Position the light only with the handle or the special designed parts on the light housing

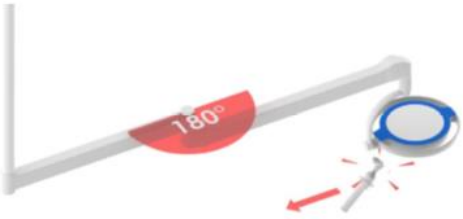


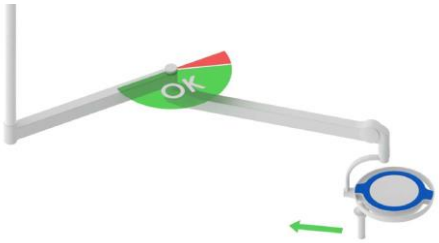


3.6 Danger of collision while positioning the lights

During positioning, eventual collisions between the lights, spring arms and other devices must be avoided.

Cover parts can get loose and fall down.





3.7 Addition to positioning the lamp

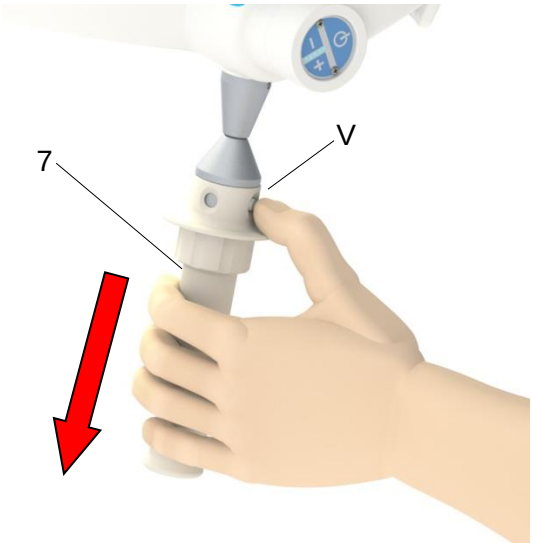
When the spring arm and extension arm are in a 180° position, the lamp head cannot be moved in the direction of the suspension axis.

A repeated force of > 25 N (according to EN 60601-2-41) at this angle can lead to damage.

This applies for all ceiling and wall mounted lamps (example in picture).

In order to be able to move the lamp in the direction of its suspension axis, the angle between the extension arm and spring arm must be < 180°.

4. Cleaning



4.1 Sterilizable handle

The light can be equipped against surcharge with the **sterilisable handle 7**. The handle sleeve is removable and sterilisable. Before using the first time and before every use the handle sleeve must be cleaned, disinfected and sterilised.

The handle sleeve must be removed for sterilisation:

- To remove press the lock **V** and pull off the sterilisable handle sleeve **7** while keeping the lock pressed.
- To attach, push on and slightly twist the handle until the lock **V** engages securely.

Handles often become unsterile during an operation. Therefore always keep additional handles available for exchange.

Cleaning / disinfection and sterilisation

Basics
Efficient cleaning / disinfection is an essential requirement for effective sterilisation of the handle.
Within the scope of responsibility for the sterility of the products it should be noted that only sufficiently validated equipment and product specific processes are used for cleaning / disinfection and that the validated parameters are complied with in every cycle.
In addition, the hospital / clinic hygiene regulations must be observed.

Remark:
The requirements of the national committees (standards and directives) for hygienics and disinfection must be observed.

Cleaning / disinfection
Cleaning and disinfection must be carried out immediately after use.
A mechanised process (disinfector) should be used for cleaning / disinfection. The efficiency of the process used must be recognised and validated in principle (e.g. listed under disinfectants and disinfection procedures tested and recognised by Robert-Koch-Institute / DGHM).
When using other procedures (e.g. a manual procedure), proof and process efficiency in principle must be provided within the scope of validation.
Proof in principle of the suitability of the handles for efficient cleaning / disinfection was provided using a cyclic cleaning system (Netsch-Bellmed T-600-IUDT/AN, programme 2 for small parts; code B).

It is not allowed to use agents / disinfectants, which contain the following substances, as these may cause changes in the material:

- High-concentration organic and inorganic acids
- Chlorinated hydrocarbons
- 2-ethoxyethanol

When cleaning / disinfecting, the following procedures must be followed:

	Process	Time (sec.)
Zone 1	Pre-rinse, external, cold, 10 – 15°C Washing, acidic, external 35°C Draining time Re-rinse, external approx. 80°C Draining time Re-rinse, external approx. 80°C Draining time	45 120 10 *10 *15 *15 15
Zone 2	Washing, alkaline, external, 93°C Draining time Re-rinse, external, acidic, 90°C Draining time Re-rinse, external 90°C Draining time	135 10 10 15 15 15
Zone 3	Drying, external 100 – 120°C	200
Zone 4	Drying, external 100 – 120°C	200
	Door open / close & transport (sluice discharge)	60
	Cycle time overall ca.	890 ≈ 15 minutes

* When occupying the disinfection zone (washing zone 2), the re-rinse and draining times will depend on the respective objects being washed therein!

Sterilisation

Only previously cleaned and disinfected handles may be sterilised.
The handles are placed in a suitable sterilisation pack (one-way sterilisation pack, e.g. foil / paper sterilisation bags, single or double pack) in accordance with DIN EN 868 / ISO 11607 for steam sterilisation and then sterilised.
Use only the sterilisation procedure listed below for sterilisation. Other sterilisation procedures (e.g. ethylene oxide, formaldehyde and low-temperature plasma sterilisation) are not permissible.

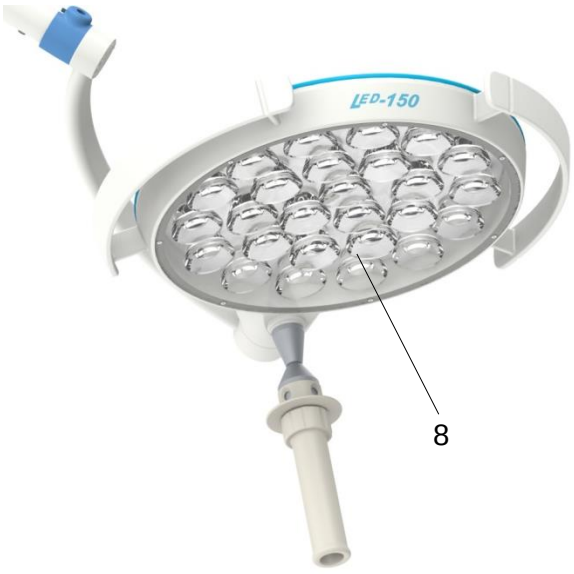
Steam sterilisation procedure
Validated in accordance with DIN EN 554/ISO 11134
Maximum sterilisation temperature 134°C

Proof in principle of the handles' suitability for effective sterilisation was provided using a fractional vacuum process (Euroselectomat 666 by MMM Münchner Medizin Mechanik GmbH, sterilising temperature 134°C, holding time 7 min.).
When applying other sterilization procedures, the suitability and effectiveness of the process must be validated.

Inspection / durability

The sterilisable handle sleeve must be disposed after 1000 sterilisation cycles or at the latest after 2 years and replaced with a new one.

The year of manufacture can be determined with the help of a stamping on the inner side of the handle sleeve (like shown in the photo). The stamping in the photo shows the number 12, which stands for the year 2012.



4.2 Lamp housing, protective disk and support system

The Dr. Mach light system has a high-quality surface, which can be cleaned with conventional cleaning agents.

The protective disk **8** is made of a high-quality plastic. Pay attention to the following during cleaning:

- Never wipe over the protective disk **8** with a dry cloth (always clean with a wet cloth).
- Wipe the protective disk **8** after cleaning with an antistatic, non-fluffy cloth.

5. Initial operation and Maintenance

Preventive maintenance of the light must take place every two years. This includes a technical and mechanical check-up.
Please observe also the mounting instructions and instructions for the carrying systems. These instructions can contain statements for different maintenance intervals.

Basis of the examination of the lighting and load-bearing systems forms the DGV V3 (formerly BGV-A3) in connection with the EN 62353.

Attention:
Set the height adjustment, if applicable, of the spring arm to horizontal position before dismounting the lamp. Please observe also the mounting instructions and instructions for the carrying systems.

 **Attention: During all maintenance work the light must be disconnected from mains and secured against resetting.**

5.1 Activity at initial operation and maintenance work

The following maintenance work / tests has / have to be done:
- check on defects in paint work;
- check on fissures at plastic parts;
- check on deformation of the suspension.
- check on loosened parts;
- check the connection between light and carrying system;
- check and grease the securing segment;
- check the faultless function of the light;
- perform the electrical safety tests

 For adjustments at the ceiling attachment please observe also the mounting instructions "**Ceiling attachment with heavy central axis**" or "**Ceiling attachment – wall attachment**" from Dr. Mach.

Remark:
Wiring diagrams, complete spare parts lists and maintenance manuals can be provided on request.
It is not allowed to exchange spare parts and make repair work while the light is in operation.
It is not allowed to touch parts below the housing cover and to touch the patient at the same time.

6. Troubleshooting

LED 150 in combination with the spring arm Acrobat 2000

1. <u>The light cannot be switched on after the installation:</u>

a.) Is the light connected to mains? →
Mobile light:
Plug the mains plug into the wall socket.
→ **Wall light or ceiling light**:
The power supply of the light must be connected to the electric circuit according to the included wiring diagram. You can check the correct connection by measuring the voltage at the primary side of the power supply.

b.) Is the securing segment installed between the light and the spring arm? →

Check if the securing segment is installed. In case the securing segment is not installed, install it according to the mounting instructions. (The securing segment is part of the accessories of the spring arm.)

c.) The light is connected to mains (a.) and the securing segment is installed correctly (b.), but the light cannot be switched on. →
Disconnect the light from the mains power supply for a short time:
Mobile light:
Unplug the mains plug from the wall socket.
Wall light or ceiling light:
Turn off the light on the wall switch or disconnect it from the electric circuit by pulling the mains fuse.
Reconnect the light to mains and switch on the light.

2. <u>The spring arm cannot be adjusted as required:</u>

a.) The light head is not yet mounted to the spring arm. →
Install the light to the spring arm according to the mounting instructions. After that the spring arm can be moved easier.

b.) The light head does not hold its position
and moves upwards →
and moves downwards
Adjust the spring force of the spring arm according to the mounting instructions. Please observe the below remark for adjusting the spring force.

<u>Remark for adjusting the spring force</u>
Please make sure, that the adjusting screw in the spring arm (see pictures below) is turned so far, until a resistance is noticeable! An overturn of the screw damages the spring arm irreversible!


Pull off the plastic cap at the rear joint of the spring arm.


View of the joint without plastic cap. The adjusting screw is positioned at the top.


Adjust the spring force with this screw according to the mounting instructions.

7. Data

7.1 Technical data

	Mach LED 150F	Mach LED 150	Mach LED 150FP
Central light intensity at a distance of 1 meter	110.000 Lux	110.000 Lux	130.000 Lux
Light field diameter d_{10}	187 mm	200 mm	172 mm
Light field diameter d_{50}	96 mm	113 mm	90 mm
Light intensity with one shadower	0 %	0 %	0 %
Light intensity with two shadowers	55 %	50 %	54 %
Light intensity on the ground of a normed tube	100 %	100 %	100 %
Light intensity on the ground of a normed tube with one shadower	0 %	0 %	0 %
Light intensity on the ground of a normed tube with two shadowers	55 %	50 %	54 %
Illumination depth 60%	900 mm	800 mm	840 mm
Colour rendering index R_a	96	96	96
Colour rendering index R_9	94	94	94
Max. radiation in field in a distance of 1 meter	379 W/m²	376 W/m²	459 W/m²
Max. radiation in field in a distance of 0,85 meters	454 W/m²	460 W/m²	541 W/m²
Focusable light field size	18-25 cm	19 cm (fixed focus)	17-24 cm
Colour temperature (Kelvin)	4500 K*	4500 K*	4500 K*
Electronic light intensity control at the light head (standard)	50-100 %	50-100 %	50-100 %
Temperature increase in head area	0,5 °C	0,5 °C	0,5 °C
Number of LED's	26	26	26
Life span of LED's	60.000 h	60.000 h	60.000 h
Working distance	70-140 cm	70-140 cm	70-140 cm
Diameter of the light head	40 cm	40 cm	40 cm
Height adjustment	118 cm	118 cm	118 cm

*Surcharge for a colour temperature of 4300 Kelvin.

Remark:
The technical data are subject to fluctuations. Due to manufacturing reasons the real values can slightly differ from the data mentioned above.
The values for R_a and R_9 can differ with approx ± 5%.
The values for the colour temperature can differ with approx ± 200K.

7.2 Electrical data

	Mach LED 150F	Mach LED 150	Mach LED 150FP
Power consumption	35 W	35 W	35 W
Operating voltage DC	24 V DC	24 V DC	24 V DC
Current	1,45 A	1,45 A	1,45 A

7.3 Information regarding the electrical installation

When turned ON, the examination light MACH LED 150F / 150 / 150FP is exposed to a current peak.
The examination light MACH LED 150F / 150 /150FP is delivered with a Dr. Mach power supply.
It is an electronic power supply with a wide-range input, input voltage 100 – 240V AC, 50 – 60Hz, output voltage 24V DC.
In case there is a switch-over relay needed for a emergency power supply on site, this switch over relay must be ordered separately at Dr. Mach.

In case of a power supply provided by the customer, the following points must be observed:

- The OT-light works with 24V DC (direct voltage).
- The direct voltage provided by the hospital must have a maximum undulation of 5%.

Warning!
The light is class I. equipment. In order to avoid the risk of an electric shock, the equipment must be connected to a mains supply with protective earth.

7.4 Weights

Light	Weight
Mach LED 150F	3,5 kg*
Mach LED 150	3,5 kg*
Mach LED 150FP	3,5 kg*

* without handle

7.5 Environmental conditions

Operation

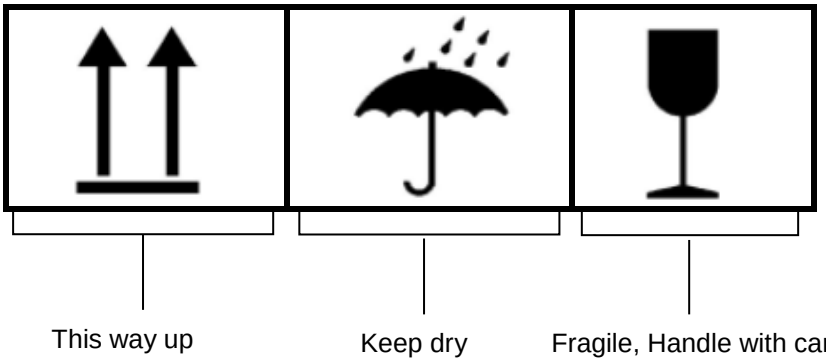
	Min.	Max.
Temperature	+10°C	+30°C*
Relative atmospheric humidity	30 %	75 %
Air pressure	700 hPa	1060 hPa

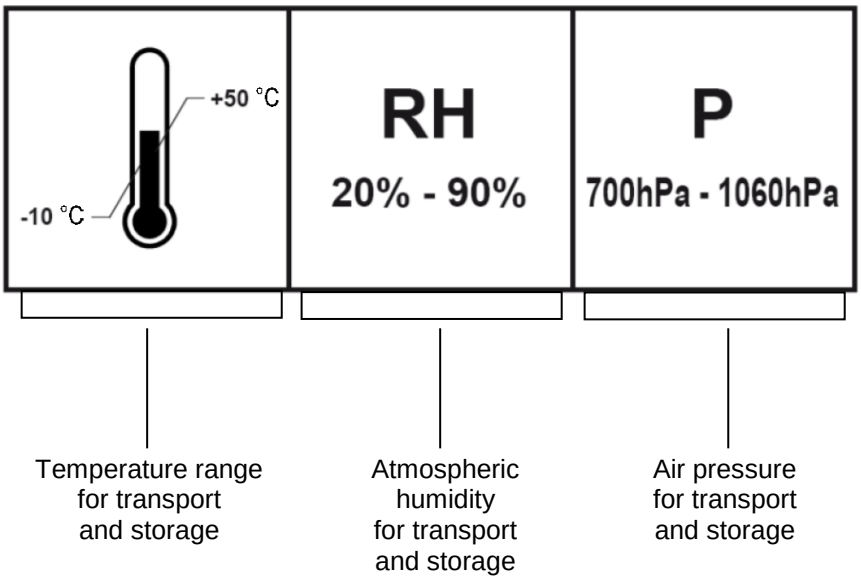
* in case of higher temperatures please contact us

Transport / storage

	Min.	Max.
Temperature	-10°C	+50°C
Relative atmospheric humidity	20 %	90 %
Air pressure	700 hPa	1060 hPa

References on the package





7.6 General remarks

When using more than one light at the same time (light combinations), due to the overlapping of the light fields of different lights, the total radiation intensity can exceed the value of 1000 W/m^2. This means a risk of higher heat development in the wound field.

When using more than one light at the same time (light combinations), due to the light fields overlapping of different lights the maximum permissible values for UV-radiation (< 400 nm) of 10 W/m² can be exceeded.

The test certificate for the electrical safety test can be requested when needed. Please provide the serial number of the respective light.

In case of a collective wiring of further lights or devices at installation, chapter 16 of the European standard EN 60601-1:2013 must be applied and eventually it has to be checked if the requirements are met.

The light must be tested according to EN 62353 at commissioning.

The polarity is very important for the installation of the light. In case the light does not function after installation, the polarity must be checked at the secondary side of the power supply.

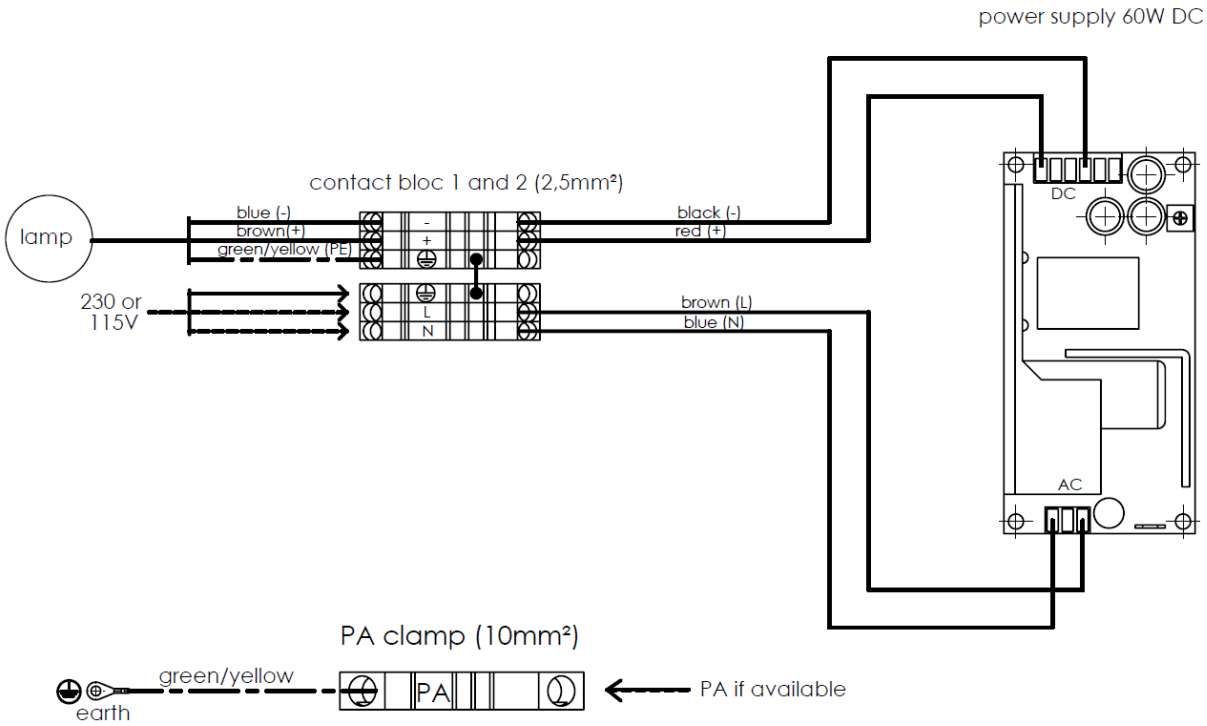
8. CE-mark

The products Mach LED 150F / 150 / 150FP comply with the standards 93/42/EEC for medical products of the European Community's Council.
Dr. Mach applies the standard EN 60601-2-41.
Dr. Mach GmbH is certified according to EN ISO 13485:2016 + AC:2016.

9. Disposal

The light doesn't contain any dangerous goods.
The components of the light should be properly disposed at the end of its shelf-life.
Make sure, that the materials are carefully separated.
The electrical conducting boards should be submitted to an appropriate recycling proceeding.
The rest of the components should be disposed according to the contained materials.

10. Wiring diagram for single attachments



power supply type: XP Power ECM60US24

11. Electromagnetic compatibility

The Dr. Mach OT- and examination lights are subject to special preventive measures regarding the electromagnetic compatibility and must be installed according to the EMC-instructions mentioned in the accompanying documents
The function of the OT- and examination lights can be affected by portable and mobile HF-communication or other HF-devices.
If the essential performance should be lost or degraded due to electromagnetic disturbances it is to be expected that the provisioning of the illumination, for a short time, is not ensured.
To ensure the basic safety and essential performance of the Mach LED 150/150F/150FP regarding electromagnetic disturbances during the expected service life, the maintenance has to be performed within the defined interval and according to the instructions in the technical service manual. Only spare parts specified by the legal manufacturer may be installed.

The Examination light Mach LED 150/150F/150FP has been tested under Professional healthcare facility environment.

The use of other equipment than the equipment mentioned in chapter 2. leads to an increased emission or to a reduced interference resistance of the device.

For the intended use of the OT-light MACH LED 150/150F/150FP it is required that the light MACH LED 150/150F/150FP is not mounted immediate and near to other devices or mounted together with other devices. If operating the light is obligatory near other devices or together with other devices, the functions of the light MACH LED 150/150F/150FP must be observed.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Mach LED 150/150F/150FP, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 2 – Emission limits per environment

Phenomenon	Professional healthcare facility environment [a)]	Home healthcare environment [a)]
Conducted and radiated RF emissions	Class B; Group 1 (according CISPR 11)	CISPR 11 [c), d)]
Harmonic distortion	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) See 8.9 of IEC 60601-1-2:2014 for information about the environments of intended use.

b) This test is not applicable in this environment unless the ME EQUIMENT and ME SYSTEMS used there will be connected to the public mains network and the power input is otherwise within the scope of the Basic EMC standard.

c) ME EQUIMENT and ME SYSTEMS intended for use in aircraft shall meet the RF emissions requirements of

ISO 7137. The conducted RF emissions test is applicable only to ME EQUIMENT and ME systems that are intended to be connected to aircraft power. ISO 7137 is identical to RTCA DO-160C:1989 and EUROCAE ED-14C:1989. The latest editions are RTCA DO-160G:2010 and EUROCAE ED-14G:2011. Therefore, use of

Section 21 (and category M) of a more recent edition, e.g. [39] or [40], should be considered.

d) Standards applicable to other modes or EM environments of transportation for which use is intended shall apply. Examples of standards that might be applicable include CISPR 25 and ISO 7637-2.

Table 4 – Enclosure port

Phenomenon	Basic EMC standard or test method	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV , ± 15 kV air	
Radiated RF EM fields [a)]	IEC 61000-4-3	3 V/m [f)] 80 MHz - 2,7 GHz [b)] 80 % AM at 1 kHz [c)]	10 V/m [f)] 80 MHz - 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 fields [d) e)]	IEC 61000-4-8	30 A/m [g)] 50 Hz or 60 Hz	

a) The interface between the patient physiological signal simulation, if used, and the ME EQUIMENT and ME SYSTEM shall be located within 0,1m of the vertical plane of the uniform field area in one orientation of the ME EQUIMENT and ME SYSTEMS.

b) ME EQUIMENT and ME SYSTEMS that intentionally receive RF electromagnetic energy for the purpose of their operation shall be tested at the frequency of reception. Testing may be performed at other modulation frequencies identified by the risk management process. This test assesses the basic safety and essential performance of an intentional receiver when an ambient signal is in the passband. It is understood that the receiver might not achieve normal reception during the test.

c) Testing may be performed at other modulation frequencies identified by the risk management process.

d) Applies only to ME EQUIMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

e) During the test, the ME EQUIMENT or ME SYSTEMS may be powered at any nominal input voltage, but with the same frequency as the test signal (see Table 1).

f) Before modulation is applied.

g) This test level assumes a minimum distance between the ME EQUIMENT or ME SYSTEM and sources of power frequency magnetic field of at least 15 cm. If the risk analysis shows that the ME EQUIMENT or ME SYSTEM will be used closer than 15 cm to sources of power frequency magnetic field, the immunity test level shall be adjusted as appropriate for the minimum expected distance.

Table 5 – Input a.c power PORT (1 of 2)

Phenomenon	Basic EMC standard	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrostatic fast 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 bands between 0,15 MHz and 80MHz [n)] 80 % AM at 1 kHz [e)]	3 V [m)] 0,15 MHz - 80 MHz 6 V [m)] in ISM and amateur radio 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; 25/30 cycles [h)] Single phase: at 0°	
Voltage interruptions [f) i) o) r)]	IEC 61000-4-11	0 % U_T; 25/30 cycles [h)]	

a) The test may be performed at any one power input voltage within the ME EQUIPMENT OR ME SYSTEM RATED voltage range. If the ME EQUIMENT OR ME SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.

b) All ME EQUIPMENT and ME SYSTEM cables are attached during the test.

c) Calibration for current injection clamps shall be performed in a 150.Ω system.

d) If the frequency stepping skips over an ISM or amateur band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.

e) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.

f) ME EQUIPMENT and ME SYSTEMS with a d.c. power input intended for use with a.c.-to-d.c. converters shall be tested using a converter that meets the specifications of the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM. The IMMUNITY TEST LEVELS are applied to the a.c. power input of the converter.

g) Applicable only to ME EQUIPMENT and ME SYSTEMS connected to single-phase a.c. mains.

h) E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz.

i) ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase shall be interrupted once for 250/300 cycles at any angle and at all phases at the same time (if applicable). ME EQUIPMENT and ME SYSTEMS with battery backup shall resume line power operation after the test. For ME EQUIPMENT and ME SYSTEMS with RATED input current not exceeding 16 A, all phases shall be interrupted simultaneously.

j) ME EQUIPMENT and ME SYSTEMS that do not have a surge protection device in the primary power circuit may be tested only at ± 2 kV line(s) to earth and ± 1 kV line(s) to line(s).

k) Not applicable to CLASS II ME EQUIPMENT and ME SYSTEMS.

Table 5 (2 of 2)

l) Direct coupling shall be used..

m) r.m.s., before modulation is applied.

n) The ISM (industrial, scientific and medical) bands 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 RATED input current less than or equal to 16 A / phase and ME EQUIPMENT and ME SYSTEMS with RATED input current greater than 16 A / phase.

p) Applicable to ME EQUIPMENT and ME SYSTEMS with RATED input current less than or equal to 16 A / phase.

q) At some phase angles, applying this test to ME EQUIPMENT with transformer mains power input might cause an overcurrent protection device to open. This can occur due the magnetic flux saturation of the transformer core after the voltage dip. If this occurs, the ME EQUIPMENT or ME SYSTEM shall provide BASIC SAFTEY during and after the test.

r) For ME EQUIPMENT and ME SYSTEMS that have multiple voltage settings or auto ranging voltage capability, the test shall be performed at the minimum and maximum RATED input voltage. ME EQUIPEMT and ME SYSTEMS with a RATED input voltage range of less than 25 % of the highest RATED input voltage shall be tested at one RATED input within the range. See table 1 Note c) for examples calculations.

Table 9 – Test specifications for enclosure port immunity to RF wireless communications equipment

Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [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 modulation [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 modulation [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 modulation [b] 217 Hz	2	0,3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5500						
5785						

NOTE If necessary to achieve the immunity test level, the distance between the transmitting antenna and the ME equipment or ME system may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.