

Mach LED 150

DE	deutsch Gebrauchsanweisung	FI	suomi Käyttöohjeet	SE	svenska Bruksanvisning
EN	english User manual	HU	magyar Használati utasítás	SK	slovenčina Návod na použitie
FR	français Mode d'emploi	HR	hrvatski Uputa za uporabu	SL	slovenščina Navodila za uporabo
IT	italiano Istruzioni per l'uso	LT	lietuvių Naudojimo instrukcijos		
ES	español Manual de instrucciones	LV	latviešu Lietošanas instrukcija		
BG	български език Инструкция за употреба	NL	nederlands Gebruikershandleiding		
CS	Česky Návod k použití	NO	Norsk Bruksanvisning		
DA	dansk Brugsanvisning	PL	wersja polska Instrukcja obsługi		
EL	Ελληνικά Οδηγίες χρήσης	PT	português Manual de instruções		
ET	eesti Kasutusjuhend	RO	română Manual de utilizare		



MedEnvoy Switzerland
Gotthardstrasse 28
6302 Zug, SWITZERLAND



Congratulations on acquiring a new Mach LED 150 operating light.

Please read these Instructions for use very carefully.

1. Instructions for safe use

1.1 Intended user

The Mach LED 150 is a Class I medical product and may only be operated by trained medical staff.

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

1.3 Availability of the instructions for use

These instructions for use and a detailed manual with further tips on how to use the light can be found online at the following link:

<https://dr-mach.de/login/mach-led-150.html>



1.4 Intended use / contra-indications

The Mach LED 150 operating light is designed to illuminate an operating site in medical facilities (e.g. in a laboratory, in hospitals or doctor's practice) with focused, low-glare, shadow-free light. It enables the user to perform a diagnosis or carry out medical interventions. The Mach LED 150 light is an operating light that is not fail-safe when used as a single light. This device is not designed to operate in areas which are subject to explosions.

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

1.5 Technical data

Class of protection	I
IP protection class	IP 42
Input voltage (power supply)	100-240 V AC, 50/60 Hz
Input voltage (light body)	24 V DC
Power consumption	24 W 29 W (Mach LED 150 MC P)
Current	1.0 A max. 1,2 A max. (MC P)
Examination time	Continuous operation possible
Expected life ¹	10 years

¹ At the end of the expected (designed) service life, the lamp must be serviced more frequently for safe operation (see the manual for details).

1.6 Lighting technical data

	Mach LED 150F	Mach LED 150	Mach LED 150FP	Mach LED 150MC	Mach LED 150MC P
Central illuminance (distance 1 m)	110.000 Lux	110.000 Lux	130.000 Lux	110.000 Lux	130.000 Lux
Light field diameter d10	163 mm	187 mm	157 mm	206 mm	205 mm
Light field diameter d50	85 mm	104 mm	83 mm	113 mm	112 mm
Residual light intensity (one shadower)	0 %	0 %	0 %	0 %	0 %
Residual light intensity (two shadowers)	52 %	46 %	53 %	46 %	45 %
Residual light intensity (normed tube)	100 %	100 %	100 %	100 %	100 %
Residual light density (normed tube, one shadower)	0 %	0 %	0 %	0 %	0 %
Residual light density (normed tube, two shadowers)	52 %	46 %	53 %	47 %	46 %
Depth of illumination (20%)	1800 mm	1544 mm	1800 mm	1755 mm	1740 mm
Depth of illumination (60%)	822 mm	803 mm	814 mm	855 mm	870 mm
Radiation intensity in the field (distance 1 m)	439 W/m ²	406 W/m ²	489 W/m ²	393 W/m ²	471 W/m ²
Radiation intensity in the field (0,78 m)	572 W/m ²	551 W/m ²	591 W/m ²	583 W/m ²	695 W/m ²

For a complete overview of technical and lighting specifications, refer to the manual.

1.7 Installation/Maintenance/Repair

The lamp may only be installed, maintained or repaired by the manufacturer or by specially trained staff. Maintenance must be carried out at least every two years

1.8 Environmental conditions for operation

Ambient temperature: +10°C to + 30°C
 Relative air humidity: 30% to 75% RH
 Air pressure: 700 hPa to 1060 hPa

1.9 Reporting obligations

All serious incidents which have occurred in connection with the product must be reported to the manufacturer and the competent authority.

2. Images on the device



This symbol indicates that the instructions for use must be followed.



Serial number of the product



Part number of the product



Address of the manufacturer



Date of manufacture and country of manufacture



EC conformity symbol



This symbol indicates that this is a medical device



Unique device identifier (ID) of the product



NRTL Test mark
The lamp was tested by a 'Nationally Recognized Testing Laboratory'



Reference to China RoHS / pollution control logo



Instruction for disposal of the device

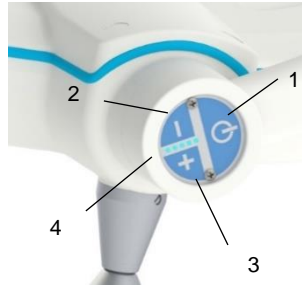
3. Safety instructions

	This symbol indicates possible sources of danger. Please also note the safety instructions and the hazard specification in the associated installation and operating instructions for the support arm system.
	The instructions for use must be observed for safe handling of the lamp
	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 4 kV.
	This device is not designed for operation in environments enriched with oxygen.

	The lamp may only be used for the intended purpose. Otherwise, the manufacturer will not be liable for personal injury or damage to property.
	The lamp 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/m ²) 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 lamp is in use.
	Simultaneous touching of parts on the luminaire and the patient is not permitted.

4. Operating the Mach LED 150 light

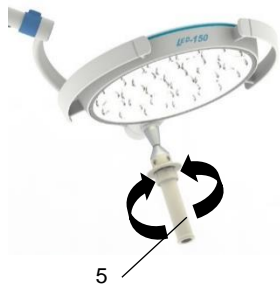


ON/OFF switch of the light (to switch off, hold for one second) (1)

Adjust the brightness in six levels between 50 and 100% (2 and 3) (lowest level = endoscopy light)

Display of the set brightness (4), the uppermost LED will flash in Standby

If only the top LED lights up, the light is in endoscopy mode

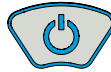


Focus the light field by turning the handle (5)



Position the lamp body using the handle (5) or the handle bar (6)

5. Operating the Mach LED 150MC light



Switching the light on/off (to turn off the light, press and hold the (ON/OFF) button for one second).



Adjusting the brightness
Switching on the endoscopy mode



Adjusting the colour temperature

6. 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 (details can be found in the manual).

Housing/protective screen

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

Furthermore, only cleaning agents approved for polycarbonate (PC) may be used to clean the protective screen. 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).

Sterilisable handle

The handle must be cleaned/disinfected before each use. It can be steam sterilised (max. 200 sterilisation cycles for max. 5 minutes at a max. temperature of 134°C); details can be found in the manual.





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.




7. Faults

In the event of unusual examination conditions, the lamp must not be used, as safe operation cannot be guaranteed. For troubleshooting, disconnect the lamp from the mains for about 30 seconds. In the event of continuous faults, a suitably trained service technician must be contacted.

8. Information on 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 150 and Mach 150MC operating light are intended for use in professional healthcare facilities.

	The emission characteristics of this device permit its use in industrial and hospital environments (CISPR 11, Class A). When used in a residential environment (which usually requires Class B according to CISPR 11), this device may not provide adequate protection of radio services. The user may need to take remedial action such as relocating or reorientating the device.
	Portable and mobile RF communications equipment can affect medical electrical equipment and must not be used within 30 cm of the light, including the cable.
	The light is suitable for use in conjunction with an RF surgical device. A minimum distance of 50 cm must be maintained between the surgical light, including its suspension system, and the RF electrode cables.
	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.
	To avoid adverse effects on patients and operators due to electromagnetic interference, lights must not be operated outside of their intended EMC environment.

Additional information on electromagnetic compatibility can be found in the manual.

9. 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 other components should be disposed of according to the materials they contain.