DR.MACH
GERMAN MED-LIGHT SOLUTIONS

Mach LED 6MC

CH REP

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Congratulations on acquiring a new MACH LED 6MC operating light.

Please read these Instructions for use very carefully.

1. Instructions for safe use

1.1 Intended user

The Mach LED 6MC 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 handbook with detailed information on how to deal with a fault, a list of accessoires and further tips on how to use the light can be found online at the following link:

https://dr-mach.de/login/mach-led-6mc.html

1.4 Intended use / contra-indications

The Mach LED 6MC operating light is designed to illuminate an operating site in medical facilities (e.g. in a laboratory, in 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 6MC light is an operating light that is not failsafe 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.

1.5 Technical data

Class of protection	I	
IP protection class	IP 54 (light body without camera preparation) IP 53 (light body with camera preparation)	
Input voltage (power supply)	100-240 V AC, 50/60 Hz	
Input voltage (light body)	24-30 V DC	
Power consumption / Current	Standard 140.000 Lux	Optional 160.000 Lux
	66 W / 2,7 A max. (without KV)	75 W / 3,1 A max. (without KV)
	89 W / 3,3 A max. (without KV, mit S)	94 W / 3,9 A max. (without KV, mit S)
	65 W / 2,7 A max. (withKV, without S)	78 W / 3,2 A max. (with KV, without S)
	75 W / 3,1 A max. (with KV, with S)	87 W / 3,6 A max. (with KV, with S)
	75 W / 3,1 A max. (with camera, without S)	87 W / 3,6 A max. (with camera, without S)
	84 W / 3,5 A max. (with Kamera, with S)	95 W / 3,9 A max. (with Kamera, with S)
Operating time	Continuous operation possible	
Expected life [(1)]	10 years	

KV: camera preparation; **S**: shade management

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 6MC	**Mach LED 6MC KV [a]**
Central light intensity (distance 1 m)	140,000 lux (optional 160,000 lux)	140,000 lux (optional 160,000 lux)
Light field diameter d10	180 mm	180 mm
Light field diameter d50	103 mm	103 mm
Residual light intensity (one shadower)	50%	50%
Residual light intensity (two shadowers)	45% [b] 58% [c]	41% [b] 53% [c]
Residual light intensity (normed tube)	100%	100 %
Residual light intensity (normed tube, one shadower)	50%	50 %
Residual light intensity (normed tube, two shadowers)	45% [b] 58% [c]	41 % [b] 53 % [c]
Illumination depth (20%)	2000 mm	1680 mm
Illumination depth (60%)	1050 mm	1010 mm
Radiation intensity in the field (distance 1 m)	518 W/m^2 558 W/m^2 [d]	500 W/m^2 567 W/m^2 [d]
Max. radiation intensity in the field (distance 0.69 m)	723 W/m^2 757 W/m^2 [d]	673 W/m^2 763 W/m^2 [d]

[a] KV refers to the model with camera preparation, the lighting specifications have been determined for a light with a built-in camera.

[b] Without shade management system

[c] With shade management system (optional)

[d] Mach LED 6MC with 160,000 lux (optional)

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:	+5°C to +40°C
Relative air humidity:	30% to 75% RH
Air pressure.	700h Pat o 1060h Pa

1.9 Reporting obligations

Every serious incident which has 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.

SN	Serial number of the product
REF	Part number of the product
	Address of the manufacturer
DE	Date of manufacture and country of manufacture
CE	EC conformity symbol
MD	This symbol indicates that this is a medical device.
UDI	Unique device identifier (ID) of the product
Laserstrahlung Nicht in den Strahl blicken! / Laser radiation Do not stare into the beam! / Rayonnement laser Ne regarde pas dans le rayon! / Laser Klasse 2 Laser class 2 Laser classe 2 IEC 60825-1:2014 P < 1 mW λ = 650 nm	LASER CLASS 2 The lamp can be equipped with a laser.
50	Reference to China RoHS / pollution control logo
TÜV SÜD C US	NRTL Test mark The lamp is tested by a 'Nationally Recognized Testing Laboratory'
	Positioning arrows
	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.
	Pay attention to the instructions for use when handling the lamp.
	Warning: 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 sterilizable 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
	It is forbidden to carry out servicing or repair activities whilst the lamp is in use.
	Lights with the camera preparation equipment may only be used with the camera or camera bay cover installed.
	Simultaneous touching of parts on the luminaire and the patient is not permitted.
	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.
	Do not allow the laser beam to enter the eyes of the patient or user. The eyelid closing reflex of patients, in particular, may be impaired by this.
	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.

4. Operating the Mach LED 6MC light


ON/OFF switch of the light
(To turn off the lamp, press and hold the (ON/OFF) button for one second.)


Activates or deactivates the depth light


Activates or deactivates the shade management system


Activates or deactivates the laser (press for one second to activate)


Transfers the adjustments of light intensity, colour temperature, focus, shade management and Endo-mode to other lights (optional)


Activation or deactivation of Endo-mode (reduced light for endoscopy applications)


Regulation of the electronically adjustable light field size


Adjusts the light intensity


Adjusts the colour temperature


The handle symbol shows which function is currently being operated via the ring on the handle


Shows the relative size of the adjusted light field


Shows the light intensity

3750 K

Shows the light temperature in Kelvin

Indicates an error with error code and description

5. 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 or phenols.** Cameras must be removed and the camera bay cover put on prior to cleaning and disinfection.

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.

6. Faults

In the event of unusual operating conditions or a fault message displayed on the display, 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, stating the error code.

7. Information on electromagnetic compatibility

Medical electrical equipment is subject to special precautionary measures with regard to electromagnetic compatibility (EMC). They may only be installed and put into service in accordance with the EMC instructions in the accompanying documents. The Mach LED 6MC operating light has been tested for use in professional equipment of the health care system.

	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 RF 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.

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

8. 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.

Félicitations pour votre achat du scialytique Mach LED 6MC !

Veuillez lire attentivement le présent mode d’emploi.

1. Consigne pour un fonctionnement sûr

1.1 Utilisateur prévu

Le scialytique Mach LED 6MC est un dispositif médical de classe I et ne doit être utilisé que par du personnel médical instruit à son utilisation.

1.2 Obligation d’information et de contrôle de l’utilisateur

Il est indispensable de lire le présent mode d’emploi avant de manipuler le scialytique. Le présent mode d’emploi fait partie du produit et doit par conséquent être conservé dans un endroit situé à proximité direct permettant de consulter à tout moment les consignes de sécurité et les informations importantes relatives à son usage.

Avant chaque utilisation, s'assurer que le scialytique est en parfait état. En cas de dommages visibles, de fonctionnements inhabituels, etc. le scialytique ne doit pas être utilisé !

1.3 Disponibilité du manuel

Ce mode d’emploi et un manuel détaillé avec des informations détaillées sur la façon de traiter un défaut, une liste d'accessoires et d'autres conseils pour une utilisation optimale de la lumière peuvent être consultés en ligne sur le lien suivant :

https://dr-mach.de/login/mach-led-6mc.html

1.4 Usage conforme / contre-indications

Le scialytique Mach LED 6MC est destiné à éclairer un site opératoire dans des établissements médicaux (par ex. dans un laboratoire , dans un hôpital ou un cabinet médical) par un éclairage focalisé, anti-éblouissant et sans zones d’ombre. Il permet à l’utilisateur d’établir un diagnostic ou de réaliser des interventions médicales. Le scialytique Mach LED 6MC est une lampe opératoire qui, en tant que luminaire individuel, n’est pas infaillible. Il n’est pas destiné à être utilisé dans des zones à risque d’explosion, l’utilisation à proximité d’appareils chirurgicaux HF est autorisée.
En cas d’éclairage dans la zone du visage, un éclairage prolongé en direction de l'œil humain ouvert doit être évité.

1.5 Caractéristiques techniques

Classe de protection	I	
Degré de protection IP	IP 54 (corps de lampe sans préparation pour une caméra) IP 53 (corps de lampe avec préparation pour une caméra)	
Tension d’entrée (bloc d’alimentation)	100-240 V AC, 50/60 Hz	
Tension d’entrée (corps de lampe)	24-30 V DC	
Puissance absorbée / Intensité	Standard 140.000 Lux	Optionnel 160.000 Lux
	66 W / 2,7 A max. (sans KV)	75 W / 3,1 A max. (sans KV)
	89 W / 3,3 A max. (sans KV, avec S)	94 W / 3,9 A max. (sans KV, avec S)
	65 W / 2,7 A max. (avec KV, sans S)	78 W / 3,2 A max. (avec KV, sans S)
	75 W / 3,1 A max. (avec KV, avec S)	87 W / 4,1 A max. (avec KV, avec S)
	75 W / 3,1 A max. (avec caméra, sans S)	87 W / 3,6 A max. (avec caméra, sans S)
	84 W / 3,5 A max. (avec caméra, avec S)	95 W / 3,9 A max. (avec caméra, avec S)
Durée de service	Fonctionnement continu possible	
Durée de vie prévue [1]	10 ans	

KV : préparation caméra ; **S** : système de gestion des ombres

[1] À la fin de la durée de vie prévue (prédéfinie), le scialytique doit faire l’objet d’une maintenance à des intervalles plus fréquents pour garantir un fonctionnement sûr (consulter le manuel pour de plus amples détails).

1.6 Caractéristiques de l'éclairage

	Mach LED 6MC	Mach LED 6MC KV [a]
Intensité lumineuse au centre (distance d’1 m)	140 000 Lux (optionnel 160 000 Lux)	140 000 Lux (optionnel 160 000 Lux)
Diamètre du champ d’éclairage d10	180 mm	180 mm
Diamètre du champ d’éclairage d50	103 mm	103 mm
Intensité lumineuse résiduelle (un ombrage)	50 %	50 %
Intensité lumineuse résiduelle (deux ombrages)	45 % [b] 58 % [c]	41 % [b] 53 % [c]
Intensité lumineuse résiduelle (tube standardisé)	100 %	100 %
Intensité lumineuse résiduelle (tube standardisé, un ombrage)	50 %	50 %
Intensité lumineuse résiduelle (tube standardisé, deux ombrages)	45 % [b] 58 % [c]	41 % [b] 53 % [c]
Profondeur d’éclairage (20 %)	2000 mm	1680 mm
Profondeur d’éclairage (60 %)	1050 mm	1010 mm
Intensité du rayonnement dans le champ (distance 1 m)	518 W/m^2 558 W/m^2 [d]	500 W/m^2 567 W/m^2 [d]
Intensité du rayonnement max. dans le champ (distance 0,69 m)	723 W/m^2 757 W/m^2 [d]	673 W/m^2 763 W/m^2 [d]

[a] KV désigne la variante avec préparation pour une caméra, les caractéristiques de l'éclairage ont été calculées pour une lampe avec caméra intégrée.

[b] sans système de gestion des ombres

[c] avec système de gestion des ombres (en option)

[d] Mach LED 6MC avec 160.000 Lux (en option)

Vous trouverez dans le manuel un aperçu complet des caractéristiques techniques et de l'éclairage.

1.7 Installation/maintenance/réparation

Le scialytique doit être installé, maintenu en état ou réparé par le fabricant ou du personnel spécialement qualifié. Une maintenance doit être effectuée au moins tous les deux ans !

1.8 Conditions environnementales de service

Température ambiante : +5 °C à +40 °C
Humidité relative de l’air : 30 % à 75 % RH
Pression de l’air : 700 hPa à 1060 hPa

1.9 Obligation de déclaration

Tous les événements graves survenant en corrélation avec le produit doivent être déclarés au fabricant et à l’autorité compétente.