2. SAFETY INSTRUCTIONS

2.1 Intendend use

The luminaire Dmed® OPTICLUX Hand is an examination luminaire. It is intended to illuminate the body of a patient locally up to a distance of approx. 15 cm from the treating surface in order to support the dermatological diagnosis and treatment. The diagnosis can be interrupted at any time due to a light failure without endangering the patient. The luminaire is not intended for use in operating rooms.

In addition, the Dmed® OPTICLUX Hand can also be used in the medical environment of a laboratory or during industrial quality control.

2.2 User profiles

Medical Specialist

Are all persons who have completed medical training and work in their trained professional field.

Cleaning specialist

Is familiar with national and workplace hygiene regulations.

Electrician

He is trained in electronics and electrical engineering and knows the relevant standards and regulations.

Qualified specialist

Due to his technical training, knowledge and experience as well as knowledge of the regulations, he is able to carry out the assembly / disassembly.

2.3 Safety manual

- ► Operation by health professionals
- ► This manual is part of the product and must be stored and made available to all future users.
- ► All work on the luminaire (including repairs) must be done only by qualified professionals.
- ► The luminaire may not be altered or tampered with. Only approved original parts may be used. Any use other than that intended, using original parts, can change technical parameters and cause life-threatening hazards.
- ► Operation in combustible or explosion-prone areas is prohibited. The luminaire's power supply is a potential ignition source.
- ► The luminaire must be used only in dry, dust-free rooms.
- ► The luminaire should not be left on without supervision.
- ► Do not use a damaged luminaire. Defective cord locations also represent a potential hazard. Do not place the cord near heat sources or sharp edges.
- ► **Eye damage:** Never look directly into the light cone.
- ► Replace damaged glass before operating the luminaire again.
- ► The luminaire must not be covered when operational.
- ► The ventilation openings (if present) must always be kept clear during operation!
- ► The luminaire must not be operated near external heat sources that exceed the luminaire's maximum ambient temperature.
- ► Always store the hand magnifying lamp in the protective cover when not in use. Attention: (Fire and burn hazard)
- ► The luminaire must not be used outside the specified ambient conditions.
- ► Do not use with medical devices that may react sensitively to a light spectrum within the visible range (such as pulsating light and/or light with a high illumination intensity).
- ► The luminaire may only be used for the intended use described here.
- ► The manufacturer cannot be held responsible for any damages resulting from use deviating from the intended use, or failure to observe the safety instructions and warnings.
- ► During an examination in which the eyes may come into contact with UV light (Wood light version only), the user must advise the patient to keep his or her eyes closed.
- ► The luminaire is intended to last 10 years (not including the battery).
- ► When using several lights simultaneously, the total illuminance Ee in the light field 1000W/m² must not be exceeded during operation.
- ► When using several lamps simultaneously, the maximum UV illuminance Euv < 10W/m² must not be exceeded during operation.

2.4 Warning levels

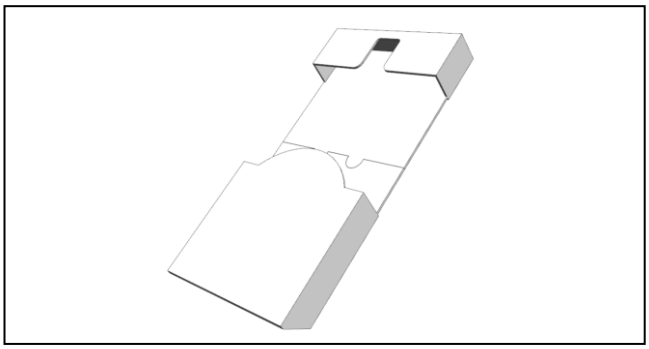
⚠ **DANGER**
Warning of hazards that can result in **death or serious injury** if instructions are not followed.

⚠ **WARNING**
Warning of hazards that can result in **injury** if instructions are not followed.

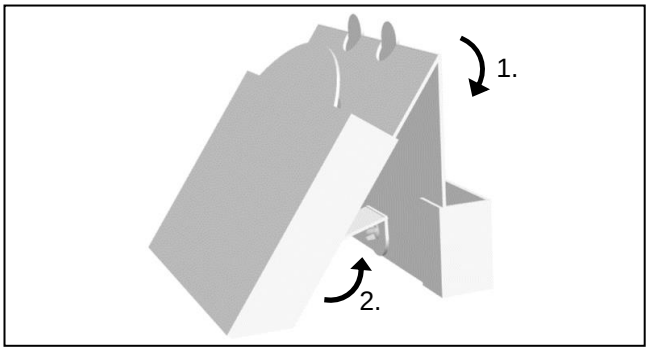
CAUTION
Warning of hazards that can cause **material damage** if instructions are not followed.

3. ASSEMBLY / SETUP

3.1 Holder instructions

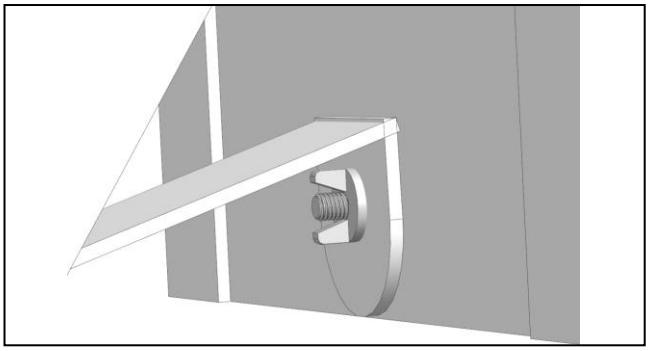


► The supplied packaging is folded into a holder.

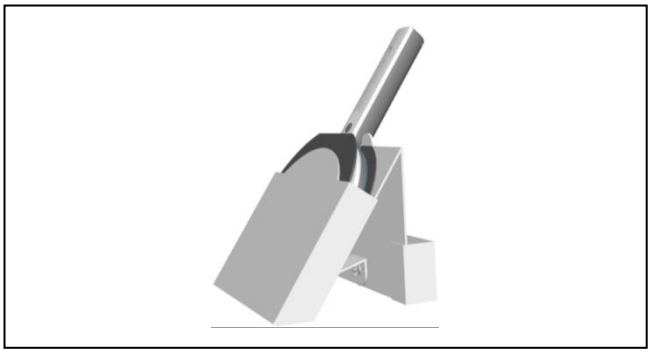


► 1. Fold the packaging once in the middle

► 2. Detach the strap from the bottom and fold it upward.



► Insert the fastening screw (included) into the tab's hole and tighten it.



► If the hand magnifying lamp is placed in the holder, it must always be protected in the felt case.

4. OPERATION

4.1 Hazard warnings

DANGER

Death hazard from electric shock

► The device must not be operated or used if it shows defects that may endanger patients, operating personnel or third parties. Visually inspect and function test before using.

► Use only an original charger or one tested according to EN 60601-1 or EN 60950.

► If the power cable shows damage, immediately replace it with a new one.

► The connection voltage and frequency must match the data on the type plate.

WARNING

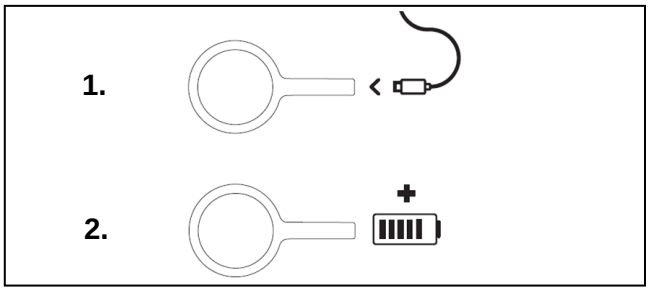
Eye injury warning

► This product may emit dangerous radiation. Never look directly into the light cone.

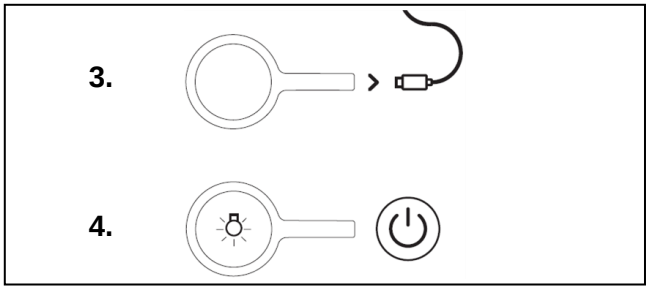
► The radiation emitted by this product conforms to the exposure limit value for reducing the risk of photobiological hazards based on IEC 62471.

4.2 First operation

When delivered, the luminaire is in a battery-saving transport mode.



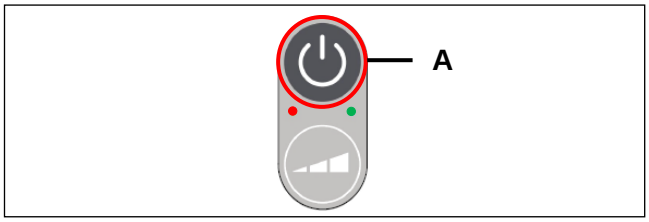
To deactivate the transport mode, the luminaire must be completely charged once before first use.



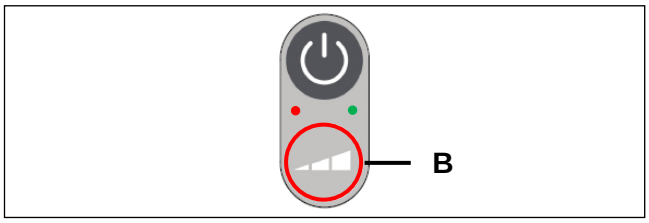
CAUTION

► During the charging process, the hand magnifying lamp is in battery-saving status and cannot be turned on.

4.3 Operating the OPTICLUX Hand 10-1 DL

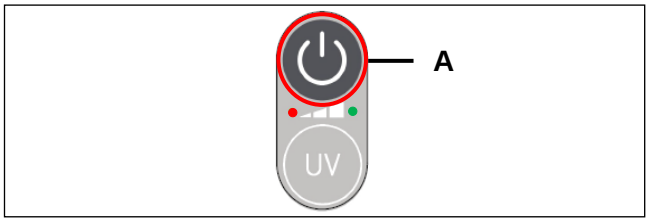


► Press button (A) once to turn on or off.

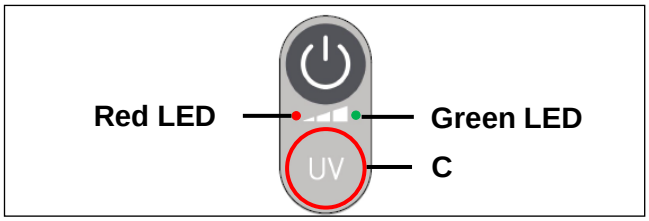


► To dim, press and hold button (B).

4.4 Operating the OPTICLUX Hand 10-2 UV



► Press button (A) once to turn on or off.
► To dim, press and hold button (A).



► Pressing the UV button (C) switches between the two modes (daylight or Wood light).

4.5 Status display LEDs

GREEN LED – CHARGING STATUS	
LED on	Charging process active
LED flashes	Charge low
LED does not turn on	Charging process finished / inactive
During the charging process, the hand magnifying lamp is in battery saving status and **cannot** be turned on.	

RED LED – ERROR DISPLAY	
LED does not turn on	No error present
LED flashes	Error present — contact service

5. CLEANING

DANGER

Death hazard from electric shock

► Before disinfection cleaning, switch off the power connection and secure against unintentional activation.

CAUTION

Material damage due to incorrect cleaning

► The luminaire is designed only for wipe disinfection.
► For cleaning, use only products that do not impair operation of the luminaire.
► For cleaning, do not use solvent-based, chlorine-based or abrasive detergents, because they can crack plastic parts and cause other damage.
► The cleaning agents must be approved for use on plastics such as PC, PMMA, PA and ABS.
► Concentrated disinfectant can damage the luminaire.
► For concentration and application times, check the information provided with the product used.
► The wrong cloth may cause scratches.

RECOMMENDED DISINFECTANTS

► Bacilol 30 Foam
► Dismozon Plus
► Kohrsolin Extra
► Lysoformin
► Mediclean
► Meliseptol Foam Pure
► Microbac Tissuses
► Mikrozid Sensitive Liquid
► Terralin PAA
► Terralin Protect
► Virex Tb
► CaciCide 1
► Gemicidal Bleach
► Hexaquart XL

CAUTION

Dirt reduces the light strength

► Clean the cover regularly to keep it clear.
► Only wipe cleaning allowed.

► Clean the lens with a nonabrasive cleaning cloth (such as an eyeglass cloth) and a suitable cleaning agent (see “Recommended disinfectants”).

CAUTION

► To minimize the risk of disease transmission, in addition to complying with this operating manual, you must also comply with the applicable occupational health and safety regulations and the requirements of authorities responsible for hygiene and disinfection.

6 SAFETY INSPECTIONS

DANGER

Death hazard from electric shock

► Unplug the charger and turn off the luminaire.
► The charger and charging cable must be checked at least once a year for damage.

CAUTION

► Maintenance and repairs can only be performed by qualified technical personnel.
► The corresponding user profile is in Section 1 Safety instructions.

EVERY YEAR

► Check the charger and charging cable for damage and replace if necessary.
► Check for deformations and cracks in the plastic parts.
► Check for loose parts.

7. REPAIRS

DANGER

Death hazard from electric shock and fire

► For service, the luminaire must be unplugged from the power supply before removal.
► Only original parts are to be used for all repairs.
► Damaged batteries must never be reused.

7.1 Disposal

Do not discard the luminaire with household waste. Follow local regulations and take the luminaire to a disposal site or hand it over to a dealer with an appropriate service department.

The products listed above are over 95% recyclable. For a high percentage of the used materials to either be physically reused or used for energy after the end of their life cycle, the luminaires have been designed with recycling in mind.

The battery contains materials subject to monitoring.

The battery must be separated from the rest of the product and disposed of separately according to national regulations.

Before disposal, the battery must be completely drained and the contacts must be insulated.

8 ADDITIONAL INFORMATION

The luminaire itself is maintenance free.

Additional documents may be requested from the manufacturer for this product.

Using this luminaire does not pose a risk to other equipment.

To save energy, the luminaire should be switched on only when it is actually needed.

Any serious incident that has occurred with the product must be reported to the manufacturer or their representative and the responsible authorities of the member state in which the user is located.

9. TROUBLESHOOTING

Fault	Possible cause	Correction	User profile
The luminaire doesn’t go on	Dead battery	Fully charge the battery	All
Luminaire can’t be charged	No power supply	Check voltage, check all connections	Qualified electrician
Luminaire can’t be charged	Charger / charging cable defective	Replace charger / charging cable	All
Luminaire doesn’t go on, red LED flashes	Defective electronic component	Contact manufacturer’s service department	Only by manufacturer’s service department

10. TECHNICAL DATA

Electrical data:	
Rated input voltage for charger	100-240V
Frequency range	50-60Hz
Maximum power consumption charging process **OPTICLUX Hand 10-1 DL / 10-2 UV**	 6.5 VA – 10.5 VA
Charging current for charger	0.06 A
Charger secondary side	5VDC
Photometric values*:	
Central illumination intensity E_v at 15 cm distance (380 – 780nm, 6500K)	8,000 lx
Central irradiance E_e at 15 cm (0.5 feet) distance (315 – 400nm, Wood light)	7.1 W/m^2
Light field diameter d10 at 15 cm distance	Ø = 30 cm
Color temperature	6500 K
Color rendering index Ra	95
Color rendering index R9	90
Total irradiance Ee at max. intensity	<25 W/m^2
	* -10% / +20% tolerance
Ambient conditions for transport, storage and operation:	
Ambient temperature (storage and transport)	< 1 month: -20°C to +50°C < 3 months: -20°C to +40°C < 1 year: -20°C to +20°C
Ambient temperature (operation)	+10°C to +35°C
Rel. humidity (non-condensing) (storage and transport)	max. 70%
Rel. humidity (non-condensing) (operation)	max. 70%
Weight:	
OPTICLUX Hand 10-1 DL / OPTICLUX Hand 10-2 UV	0.6 kg
Operating mode:	
Operating mode	Continuous operation
Classification:	
OPTICLUX Hand 10-1 DL / OPTICLUX Hand 10-2 UV	Protection class II
Degree of protection according to IEC 60529	IP 20
Classification according to EU REGULATION 2017/745 (MDR), article 51 U.S. FDA Device Class	Class I Class I
Electrical safety testing and EMC according to:	IEC 60601-1; IEC 60601-1-2
Blue light hazard according to IEC 62471	RG 1 (low risk)
Life cycle	
Life cycle of white LEDs	50,000h L80/B50
Life cycle UV LEDs	30,000 h L70/B50
Battery life	> 500 charging cycles (capacity decrease approx. 20%)

11. ELECTROMAGNETIC COMPATIBILITY (EMC)

Electrical medical devices are subject to special precautionary measures regarding electromagnetic compatibility. This device can be affected by other electrical devices.

This device was tested with accessories from the accessory list for electromagnetic compatibility. Other accessories can be used only if the electromagnetic compatibility is not interfered with. Use of noncompliant accessories can cause amplified electromagnetic emissions or decreased electromagnetic interference resistance in the device.

⚠ WARNING

Hazard due to inadequate safety distance

If high-frequency mobile communication devices are used to close to this device, malfunctions can occur that may endanger the patient.

A safety distance of at least 0.3 m (1 foot) must be maintained.

Electromagnetic environment

The device is only to be used in environments indicated in the “Intended use” section of the operating manual.

The medical device is intended only for operation in the electromagnetic environment indicated below.

Emissions	Correspond to	Electromagnetic environment
HF emissions EN 55011 (CISPR 11) Radiated: 30 MHz to 1 GHz Conducted: 150 kHz to 30 MHz	Class B, Group 1	The medical device is intended for use in all facilities, including residential buildings and facilities that are directly (without a transformer) connected to the same low voltage network as the residential building.
Emissions from Harmonics (IEC 61000-3-2)	Class A	
Emissions from Voltage fluctuations/flickering (IEC 61000-3-3)	Requirement is met.	

Immunity against	Test level and electromagnetic environment to be maintained	Electromagnetic environment
Electrostatic discharge (IEC 61000-4-2)	Contact discharge: ± 8 kV Air discharge: ± 15 kV	Floors made of wood, concrete or ceramic tile. For a synthetic floor covering, the relative humidity should be at least 30%.
Rapid transient electrical disturbances/ bursts (IEC 61000-4-4)	Power cable: ± 2 kV Longer signal input lines/signal output lines: ± 1 kV	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Impulse voltage/surges (IEC 61000-4-5)	Voltage: External conductor against external conductor: ± 1 kV External conductor against ground cable: ± 2 kV	
Voltage dips and brief interruptions in the power supply (IEC 61000-4-11)	30% to 100%, 10 ms to 5 s, various phase angles	
Magnetic field at the supply frequency (IEC 61000-4-8)	50 Hz and 60 Hz: 30 A/m	Devices with unusually strong line-frequency magnetic fields (transformer stations, etc.) should not be operated near the medical device.
Emitted HF disturbance (IEC 61000-4-3)	80 MHz to 2.7 GHz: 10 V/m	Near equipment marked with the following symbol, disturbances are possible: 
Conducted HF interference (IEC 61000-4-6)	150 kHz to 80 MHz: 3 V_{rms} ISM and amateur radio bands: 6 V_{rms}	