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KaWe MASTERLIGHT HL / LED





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Dear buyer! Thank you for choosing a KaWe product. Our products are known for high quality and durability. Our lamps comply with the provisions of Regulation EU 2017/745 (European Regulation on Medical Devices), whereby they are classified as class 1 medical products.

Please read these instructions thoroughly and carefully before attempting to use this product and heed the given instructions for the care of the product!

Advantages of LED technology: a bulb life of at least 50,000 hours, very bright light and hardly any noticeable heat build-up on the surgeon's forehead or on the area of the patient's body that is being examined. The advantages of KaWe's conventional illumination technology with halogen bulbs have been maintained: natural colour reproduction, exact illumination of the treatment area and easy positioning of the lamp body.

1. SAFETY INSTRUCTIONS

When handling the light, the instructions given in the User's Manual must be followed.

WARNING : This device is not intended for use in areas in which explosions may occur.

Please read these instructions thoroughly and carefully and familiarise yourself fully with this product before using it in order to benefit from all the advantages of the lamp system and to avoid the possibility of damaging it.

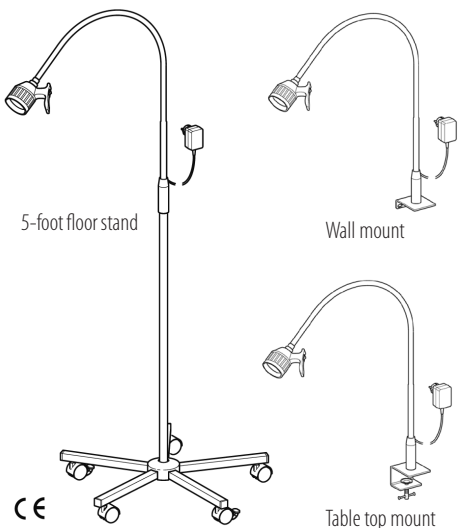
Maintenance work on the lamp, especially assembly, is only to be carried out by authorised personnel.

The safety of the lamp is only guaranteed by the manufacturer if repairs and changes are performed by the manufacturer itself or by a location that guarantees that the safety rules will be followed.

WARNING: The lamp may not be modified in any way!

The manufacturer is not responsible for damage to persons or other objects if the lamp is used incorrectly or for a non-intended purpose. The KaWe MASTERLIGHT HL / LED cannot be combined with any other devices.















Prior to each use, check the lamp to ensure that it is in perfect working order.



General instructions

- All KaWe floor lamps come equipped with all of the parts required for assembly and connection.
- Mounting is carried out on the stand, on the wall or on the table.
- Due to packaging requirements, the five-footed base of the stand comes unassembled. The stand post is always delivered as one piece and needs only to be connected to the base with the fastening screw, which is found on the bottom of the post.
- The lamp includes an integrated power cable and shock-proof plug.
- The type of outlet used must be installed in a manner that complies with IEC and VDE 0100-710 requirements.

Symbol key:

	Manufacturer & date of manufacture
	UDI Data Carrier
	Lot code
	Please follow the User's Manual (color: blue)
	Caution! During assembly and when replacing bulb
	Temperature limit
	Separate disposal of electric and electronic devices
	CE conformity mark
	MEDICAL DEVICE
	Air humidity limitation
	Device safety class: II
	Fragile
	Keep dry
	Electromagnetic field warning

► 2. SHORT DESCRIPTION OF THE LAMP

KaWe MASTERLIGHT HL / LED

Intended use:

The lamps serve as illumination during the treatment and diagnosis process in hospitals or doctors' offices. They illuminate the work area and the patient's body with a shadow-free, cold, high power light.

Application:

The lamps can only be used by authorized trained personnel!

Group of patients with indications for use:

All patient groups



► 3. LIST OF INCLUDED PARTS

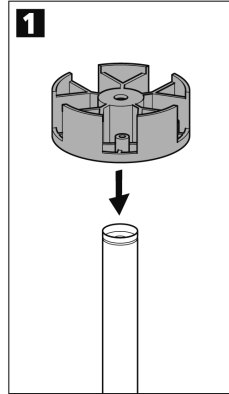
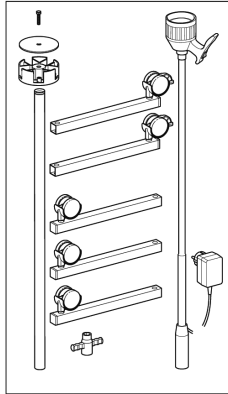
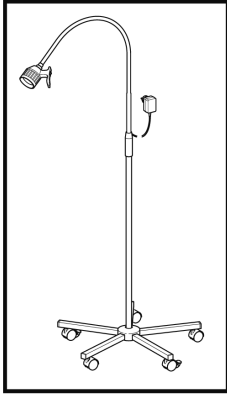
- 1x floor stand mounting block
- 2x feet with locking castors
- 3x feet without locking castors
- 1x stand post
- 1x stand cap
- 1x fillister head screw with washer
- 1x flat spanner
- Lamp body with arm
- User's manual

Information for users and patients:

All serious incidents involving this device must be immediately reported to the manufacturer and the competent authorities of the respective Member State in which the user and/or patient is located.

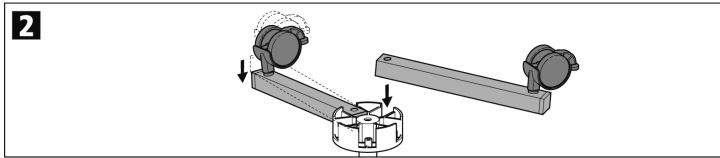
3.1 Assembly instructions: 5-foot-floor stand

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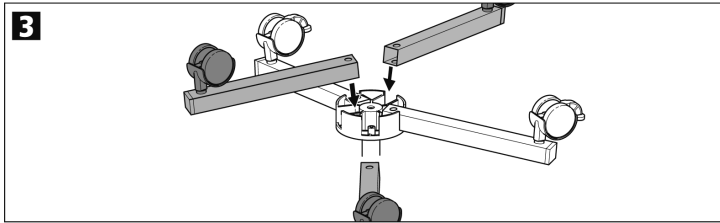


Mounting parts

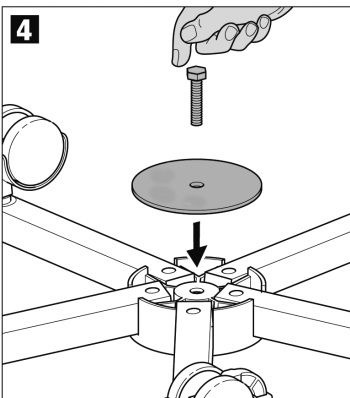
1. Attach the block.



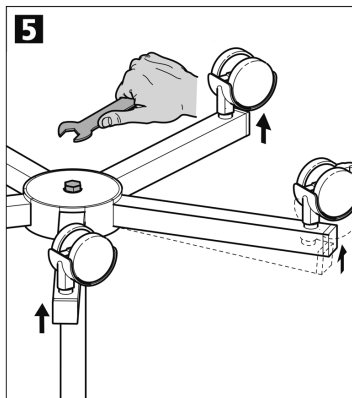
2. Attach two foot pieces with brake rollers opposite one another.



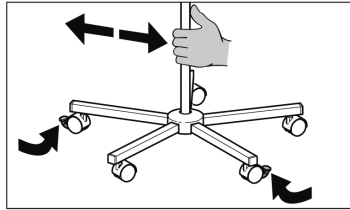
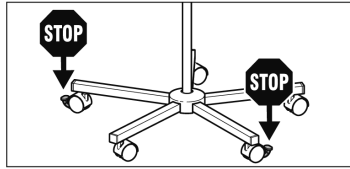
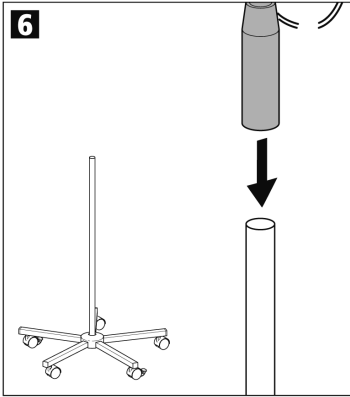
3. Attach three foot pieces without brake rollers.



4. Screw in hexagon head screw.



5. Tighten the hexagon head screw.

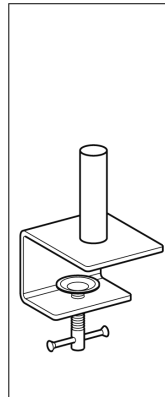
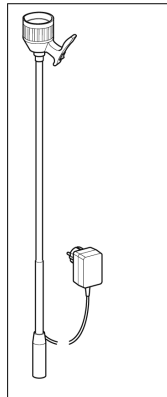
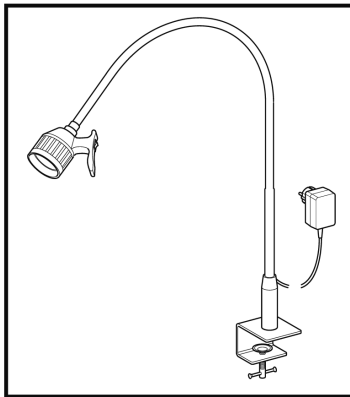


6. Push the upper part of the examination lamp onto the floor stand post.

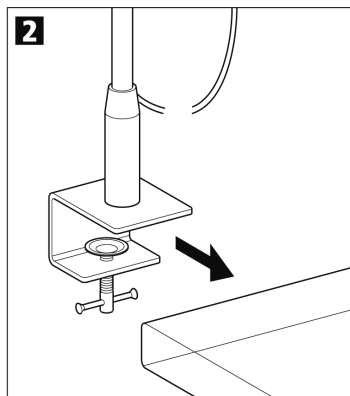
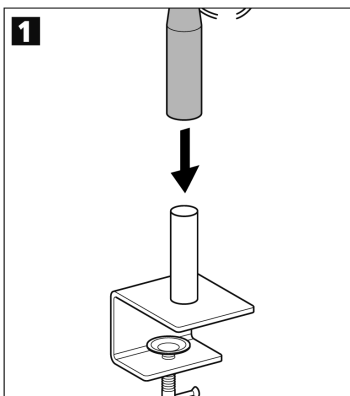
Lock the brake rollers.
Loosen the brake rollers to move the examination lamp.



3.2 Assembly instructions: table top mount



Mounting parts

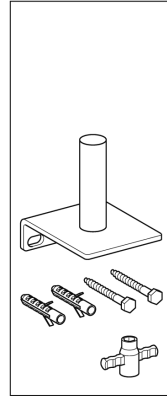
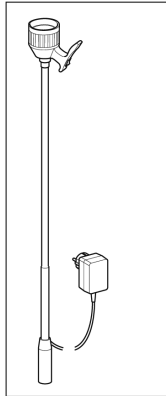
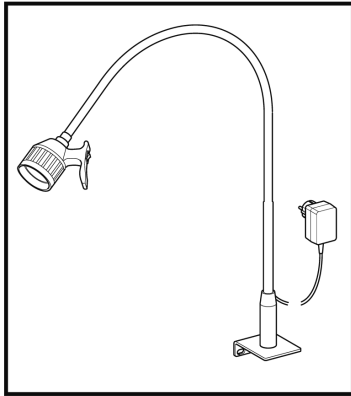


1. Push upper part of examination lamp onto table clamp.

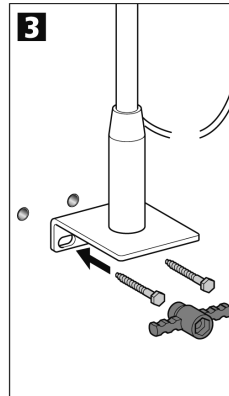
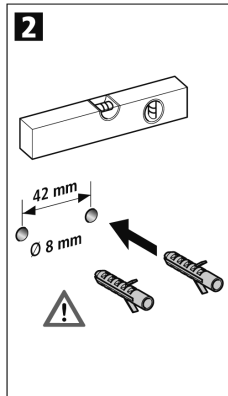
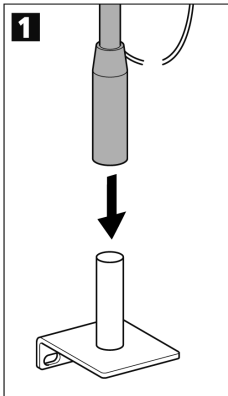
2. Fasten examination lamp to the table top.

3.3 Assembly instructions: wall mount

en



Mounting parts

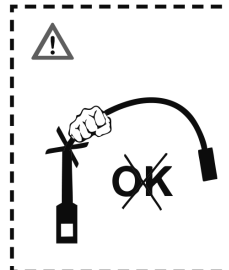
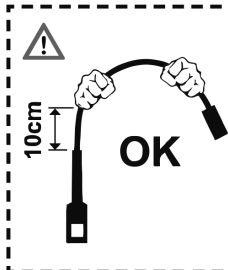
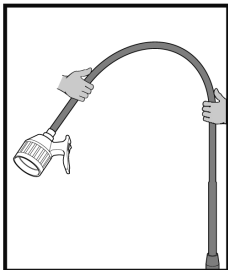


1. Push upper part of examination lamp onto the wall bracket.

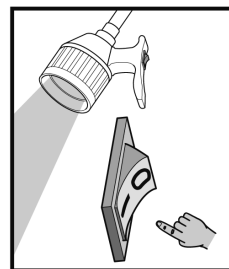
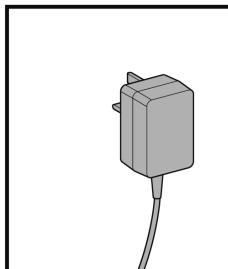
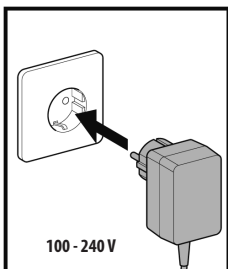


2. Use caution when drilling! Check the wall for electric lines, gas and water conduits.

3. Affix examination lamp to the wall.

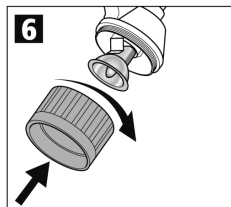
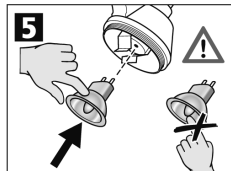
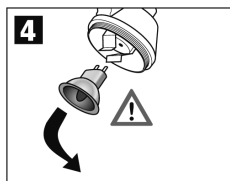
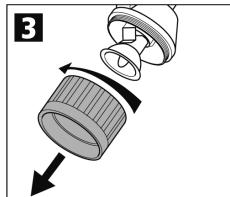
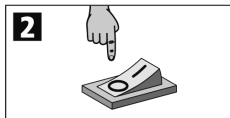
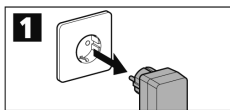
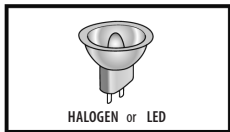


Adjust position of light with both hands.



Electric supply (EU / GB)

Turn ON - I -
Turn OFF - 0 -



3.4 Replacing the bulb

1. Disconnect the power plug.
2. Set switch to - 0 -.
3. Unscrew the ring.



4. Remove defective bulb only after it has cooled down.
5. Insert new bulb.
6. Screw the ring back on.



► 4. CLEANING

Before cleaning, turn off the lamp. Unplug the power cord and allow the lamp head to cool.

4.1 Floor stand: The surface of the floor stand can be kept clean by wiping it gently with a damp cloth. Any common cleaning agent may be used. For disinfection, we recommend a solution that is either dissolved in water or **max. 20% alcohol**.

4.2 Light body: The lamp is made with a high quality surface material. The surface of the light can be easily kept clean by wiping it with a damp cloth and any common cleaning agent. Only use disinfecting agents with an alcohol content of **less than 20%**.

4.3 Examination lamp: **1.** The examination lamp is resistant to disinfectants, abrasion, urine and blood. **2.** The examination lamp is to be wiped with a damp cloth and alcohol-based surface disinfectant. **3.** Clean dirty castors in order to avoid static charge. **4.** Do not use agents containing acids.

► 5. TECHNICAL DATA

Max. height: approx. 211 cm
 Lamp arm pivoting range: approx. 82 cm
 Diameter of floor stand base: approx. 70 cm
 Weight: approx. 4.7 kg
 Supply voltage: 100 - 240 Volt
 Halogen: 12 V / 35 W / 5 A max.
 Life of the halogen bulb: ≥ 1,000 h
 LED: 12 V / ca. 7 W / 0.8 A max.
 Life of the LED lamp: approx. 50,000h
 Beam angle HL / LED: 8° / 24°

Colour temperature ca.: HL: 3200K/LED: 4000K
 Illumination intensity (HL) at a distance of 30 cm ca. 44,000 Lux
 Illumination intensity (LED) at a distance of 30 cm ca. 31,000 Lux
 Light spot size (at a working distance of 0.5m) ca. 100 mm

Note: The technical data are subject to certain fluctuations, especially with regard to the product life, color temperature and illumination intensity. The floor stand model should be placed on level surfaces.

Information: The examination lamp is not water proof! National board requirements (standards and directives) for hygiene and disinfection must be followed.

► 6. MAINTENANCE

After being used for a longer period of time, the KaWe MASTERLIGHT HL / LED lamp screws must be tightened. The lamp is to be serviced and checked at least every two years.

Information: The halogen lamp can become hot during use!

When servicing and or checking the unit, turn it off and disconnect the plug. Insure that the lamp cannot be turned back on.

6.1 Regular maintenance: The structural system of the lamp is to be checked/serviced every two years: **1.** Cracks in plastic parts **2.** Functionality test **3.** Electrical safety test **4.** Structural system check.



► 7. ELECTRICAL INSTALLATION INFORMATION

The KaWe MASTERLIGHT HL / LED lamp comes with a power adaptor.

Caution! The power adaptor is a protection class II unit.

7.1 Environmental conditions

	Operation	
	Min.	Max.
Temperature	+10° C	+40° C*
Relative humidity	30 %	75 %
Air pressure	700 hPa	1060 hPa

*for higher temperatures, please consult manufacturer

	Transport/Storage	
	Min.	Max.
Temperature	-10° C	+50° C
Relative humidity	30 %	75 %
Air pressure	700 hPa	1060 hPa

7.2 Important information

If multiple lamps are used at once, the total irradiance may exceed 1,000 W/m² due to superposition of the luminous fields. As a result, there is a risk that the illuminated field may become very hot. The superposition of the luminous fields of multiple lights may cause the limit values for UV radiation (<400 nm) of 10 W/m² to be exceeded.

If other lights or appliances are connected together during installation, section 16 of EN 60601-A1:2012 applies and if necessary, the compliance with the requirements is to be verified. KaWe examination lamps are subject to special safety measures with regard to electromagnetic compatibility. The function of KaWe examination lamps can be influenced by high-frequency communication devices. (Heed the following tables.)

► 8. BASIC UDI-DI

4030155KaWe10SK

► 9. DISPOSAL



At the end of its product life, the lamp's components are to be disposed of properly. Ensure that the materials are sorted carefully according to type. The electrical circuit boards are to be disposed of at an appropriate recycling centre. The lamp's housing and the rest of the components should be disposed of according to their type of material.

► 10. TABLES

These KaWe examination lights are subject to special safety measures with regard to EMC requirements and must be installed in accordance with the enclosed EMC instructions. The functionality of these KaWe examination lights can be influenced by portable and mobile HF communication devices.

Guidelines and manufacture declaration – Electromagnetic emissions

The KaWe MASTERLIGHT HL / LED is designed to be used in the types of electromagnetic environments listed below. The customer or user is responsible for ensuring that this device is used in such an environment.

Emissions Measurement	Conformity	Electromagnetic environment – Guidelines
Type-CISPR 11 – high-frequency emissions	Group 1	The KaWe MASTERLIGHT HL / LED uses high-frequency energy solely for its internal OPERATION. Its high-frequency emissions are therefore very low and it is unlikely that any nearby electronic equipment will be adversely effected.
Type-CISPR 11 – high-frequency emissions	Class B	The KaWe MASTERLIGHT HL / LED is designed for use in all facilities including living spaces that are directly connected to a public low-voltage power supply network that also supplies power to buildings used for domestic purposes.
Harmonic oscillations according to IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions according to IEC 61000-3-3	Complies	

Guidelines and Manufacturer Declaration – Electromagnetic Interference Immunity

The KaWe MASTERLIGHT HL / LED is designed to be used in the types of environments listed below.

The customer or user of the KaWe MASTERLIGHT HL / LED is responsible for ensuring that this device is used in such an environment.

Interference immunity test	IEC 60601-test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6kV contact discharge ± 8 kV air discharge	± 6kV contact discharge ± 8 kV air discharge	The flooring should be wood or concrete or be covered with ceramic tile. If the floor material is a non-conductive, synthetic material, the relative humidity of the air must be at least 30%.
Fast transient electrical disturbances/ bursts according to IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input and output lines => not applicable	± 2kV for power supply lines ± 1kV for input and output lines => not applicable	The quality of the mains supply voltage should be the same as that of a typical commercial or hospital environment.
Surges according to IEC 61000-4-5	± 1 kV differential mode voltage ± 2 kV common mode voltage	± 1 kV differential mode voltage ± 2 kV common mode voltage	The quality of the mains supply voltage should be the same as that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines according to IEC 61000-4-11	< 5 % UT (>95 % dip in the UT) for a ½ period 40 % UT (60 % dip in the UT) for 5 periods 70 % UT (30 % dip in the UT) for 25 periods < 5 % UT (>95 % dip in the UT) for 5 seconds	< 5 % UT (>95 % dip in the UT) for a ½ period 40 % UT (60 % dip in the UT) for 5 periods 70 % UT (30 % dip in the UT) for 25 periods < 5 % UT (>95 % dip in the UT) for 5 seconds	The quality of the mains supply voltage should be the same as that of a typical commercial or hospital environment. If the user of the KaWe MASTERLIGHT HL / LED requires continued operation during power interruptions, it is recommended that the KaWe MASTERLIGHT HL / LED be powered from an uninterruptable power supply or a battery.
Magnetic field with a power frequency of (50/60 Hz) according to IEC 61000-4-8	3 A/m	30 A/m	Magnetic fields with their line frequencies should be the same as those typical of commercial and hospital environments.


Note: Ut is the mains voltage prior to application of the test level.



Guidelines and Manufacturer Declaration – Electromagnetic Interference Immunity

The KaWe MASTERLIGHT HL / LED is designed to be used in the types of environments listed below. The customer or user of the KaWe MASTERLIGHT HL / LED is responsible for ensuring that this device is used in such an environment.



Interference immunitytest	IEC 60601-test level	Compliance level	Electromagnetic environment – guidelines
Conducted HF-interference according to IEC 61000-4-6	3 V 150 kHz to 80 MHz	3 V	<p>Portable and mobile HF communications equipment should be used no closer to the KaWe MASTERLIGHT HL / LED (including its power cords) than the recommended separation distance. The separation distance is calculated using various equations depending on the transmission frequency.</p> <p>Recommended separation distance: $d = 1.2\sqrt{P}$</p> <p>$d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz</p> <p>$d = 2.3\sqrt{P}$ for 800 MHz to 2.5 GHz</p>
Radiated HF-interference according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p>“P” is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. “d” is the recommended separation distance in meters (m). Field strengths from fixed transmitters, as determined by an electromagnetic survey of site “a” are less than the COMPLIANCE LEVEL in each frequency range.</p> <p> Interference may occur in the vicinity of equipment marked with the following symbol.</p>

Note 1: For 80 MHz and 800 MHz, the larger of the two values applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted with accuracy in theory. It is recommended that in order to assess the electromagnetic environment caused by fixed HF transmitters, an electromagnetic site survey should be conducted. If the measured field strength at the location at which the KaWe MASTERLIGHT HL / LED is used exceeds the applicable compliance level stated above, the equipment should be checked at each of its locations of use in order to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the KaWe MASTERLIGHT HL / LED.

b: For frequencies ranging from 150 kHz to 80 MHz, the field strength is less than 3 V/m.

Recommended Separation Distances Between Portable and Mobile HF Communications Equipment and the KaWe MASTERLIGHT HL / LED

The KaWe MASTERLIGHT HL / LED is intended for use in an electromagnetic environment in which radiated HF disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference by ensuring that the minimum distance (shown below) between communications equipment (transmitters) and the KaWe MASTERLIGHT HL / LED is maintained. The minimum distance is dependent on the maximum output power and the frequency of the communications equipment.



Rated Power Output of Transmitter (W)	Separation Distance According to Transmitter Frequencies (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance can be determined using the equation applicable to the frequency of the transmitter. P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: For 80 MHz and 800 MHz, the larger of the two values applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

► 11. WARRANTY

The warranty is two years after the sale, provided that the device was operated as intended and according to this User's Manual (except for illumination sources, batteries and rechargeable batteries). If you have any questions, or your device requires repair, please contact your supplier.