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QM-GAP-0020D



User's Manual MASTERLIGHT LED 1000

Dear customer, congratulations on your purchase of the new KaWe examination light. The innovative technology and design of this new generation of LED examination lights will help you to keep your professional edge.

Advantages of LED technology: a lamp life of at least 40,000 hours and hardly any noticeable heat build-up near the doctor's head or on the area of the patient's body that is being examined. The advantages of conventional illumination technology with halogen and gas-discharge light bulbs have been maintained: natural colour reproduction, exact illumination of the treatment area and easy positioning of the light.

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<u>1. SAFETY INFORMATION</u>

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

CAUTION: This device is not intended for use in areas in which explosions may occur. This lamp is classified as a class 1 device according to the medical products law.

Prior to assembly, store the KaWe examination light in its packaging in the room in which it will be used for at least 24 hours in order to compensate for transport-related temperature fluctuations.

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. Repair and maintenance work on the KaWe examination light is only to be carried out by us or by a location expressly authorised by us to perform such work.

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

The KaWe examination light may not be modified in any way!

The manufacturer is not responsible for damage to persons or other objects if the KaWe examination light is used incorrectly or for a non-intended purpose. Disassembly of the light body from the spring arm is to be carried out in reverse order of assembly and may only be carried out after the arm has been raised to its maximum height and is in a horizontal position.

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

General information

- All KaWe examination lights are delivered with all of the parts required for assembly and connection.
- In order to reduce the packaging volume, the five-footed base of the floor stand comes disassembled. The stand post is always assembled as one piece and must only be attached to the base with its lower fastening screw.
- The KaWe examination light (stand post or cross arm) is equipped with an integrated power cord and safety plug.
- The electrical outlet used must be installed according to IEC and VDE 0107 regulations.
- Check to see if there is a Schuko electrical outlet within the operating range of the light.

Symbol key:

\wedge	Caution!
Ŧ	This symbol informs of important assembly instructions, useful information and user's tips
1	Temperature limit
X	Separate disposal of electric and electronic devices
€€	Complies with relevant EU guidelines
3	Heed the User's Manual
	Protection class II
ଡ଼ୖୢ	GOST-R certification for exports to Russia
Ť	Keep dry
Ø	Humidity, limit
~~	Date of manufacture
	Manufacturer
SN	Series number
REF	Product reference number

Non-ionizing radiation

<u>2. SHORT DESCRIPTION OF THE</u> <u>KaWe EXAMINATION LIGHT</u>

Information about intended use: The KaWe examination lights were developed to illuminate the area of the patient's body being examined during medical examinations in hospitals and doctors' practices.

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Main function: The KaWe examination light serves to illuminate an area of a patient's body that is to be examined with high-power, shadow-free light.

General product description

- This is a KaWe examination light as described in EN 60601-2-41, which as individual luminaries, are not failsafe.
- The KaWe examination light is intended to aid in treatment and diagnosis.
- The KaWe examination light is used in areas used for medical reasons (group 0, 1 and 2 according to DIN VDE 0100-710 and HD 60364-7-710).
- The lights are mounted on a stand.
- The KaWe examination lights are to be serviced every 2 years.
- The light is powered via an electrical cord and plug

▶ <u>3. ASSEMBLY INSTRUCTIONS</u>

Parts included:

- 1x Stand mounting block
- 2x Foot piece with lockable castors
- 3x Foot pieces without lockable castors
- 1x Stand post
- 1x Stand cap
- 1x Fillister head screw M8 with washer
- 1x Flat spanner wrench
- Light body with arm
- User's manual for the MASTERLIGHT LED 1000



1. Put on the mounting block.

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2. Insert the two foot pieces with lockable castors across from one another.



3. Insert the three foot pieces with non-locking castors.



4. Screw in the hexagon head screw.



5. Tighten the hexagon head screw.

► 4. USER'S MANUAL



Adjust to desired height.



Engage the brake on the lockable castors.



 ${}\bigstar{}\rightarrow$ To move the lamp, release the brakes on the castors.

4.2 Operating the light

4.2.1 ON/OFF switch

The KaWe examination light is turned OFF and ON by pressing on the switch ${\bf 16}$ on the light body.



4.2.2 Positioning

To adjust the position of the light arm, use the clamping lever **17** on the cross arm. The light body can be moved in the shown direction. The flexible joint **G** holds the light body in the desired position.



Caution! Positioning the KaWe examination light at an angle of less than 90° is not allowed as this may damage the flexible hose connection.



5. CLEANING

5.1 Stand

The surface of the floor stand can be easily kept clean by wiping it with a damp cloth. Any common cleaning agents may be used.

5.2 Light body

The surface of the KaWe examination light is made of a high-quality material that can be cleaned by wiping it with a cloth and conventional liquid cleaning agents.



5.3 Protective screen

The protective screen **20** is made of a high-quality plastic. Pay attention to the following during cleaning:

- Always clean the screen **20** with a wet cloth (never clean with a dry cloth!).
- The protective screen **20** is to be wiped with an anti-static agent using a lint-free cloth.

► 6. FIRST USE AND MAINTENANCE

7. TECHNICAL DATA

The KaWe examination light is equipped with a clamping lever between the cross arm and the stand post. After assembly, this clamping lever may need to be adjusted.

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The KaWe examination light is to be serviced and checked at least every two years.

Note: Before conducting any maintenance or tests on the KaWe examination light, unplug it from the electrical outlet and ensure that it will not be plugged in again until the work has been completed.

6.1 Procedure for first use and maintenance

Inspect the KaWe examination light (especially for the following):

- Paint defects
- Cracks in plastic parts
- Deformation of the support system
- Loose parts
- Check the connection between the examination lamp and support system.
- Inspect and grease the mechanism securing the arm to the stand
- Proper operation
- Electrical safety



6.2 Adjusting the arm

adjust the clamping lever

If the light body is hard to move or does not stay in the desired position, the braking action of the clamping lever between the cross arm and the stand post must be adjusted.

7.1 Photometric data
Central illumination intensity

at a distance of 0.5 meters	35,000 Lux
Central illumination intensity at a distance of 1 meter	7,800 Lux
Light spot diameter d_{10} at a distance of 0.5 m	100 mm
Light spot diameter d ₁₀ at a distance of 1 m	163 mm
Light spot diameter d _{so} at a distance of 0.5 m	61 mm
Light spot diameter d _{so} at a distance of 1 m	116 mm
Residual illumination intensity with one shutter	0 %
Residual illumination intensity with two shutters	72 %
Residual illumination intensity at the bottom of a normed tube	100%
Residual illumination intensity at the bottom of a normed tube and one shutter	0 %
Residual illumination intensity at the bottom of a normed tube and two shutters	72 %
Illumination depth 60 %	1230 mm
Colour rendering index CRI	95
Colour rendering index R ₉	94
Light spot diameter at a distance of 0.5 m	10 cm
Light spot diameter at a distance of 1 m	16 cm
Colour temperature (Kelvin)	4000 K
Number of LEDs	3
Max. irradiation intensity in the field at a distance of 1.0 m	29 W/m ²
Max. irradiation intensity in the field	205 W/m ²
Working lifespan of the LEDs	40.000 h
Diameter of the light body	12 cm
Heat build-up near the head	0.5 °C

Note: The technical data are subject to certain deviations. Due to production-related reasons, the actual values can vary slightly from the above-named values. The values for R can deviate by approx. \pm 5%. The colour temperature values can deviate by approx. \pm 200K.

7.2 Electrical data

Power input	7W
Operating voltage	12V DC
Amperage	0.30A

7.3 Technical data for stand

Stand Base	Number of feet	5
	Foot length	310 mm
	Castor diameter	approx. 50 mm
Stand post	Length	1.400 mm
	Telescoping	no
	Power cord connec-	yes
	tion	
Light arm + Light body	Assembly	 Light arm with light body preassembled Light arm on floor stand

7.4 Electrical installation information

The KaWe examination light is exposed to a current peak when it is switched on and is therefore equipped with a power adapter.

Warning! This light is a Protection Class II device. To avoid the risk of electric shock, this unit must be connected to a grounded electrical outlet.

7.5 Weights

Examination light	Weight
MASTERLIGHT LED 1000	5.0 kg*

* with 5-foot base

7.6 Environmental conditions

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

* for higher temperatures please contact us

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

Instructions on the packaging

–10° C	20% - 90%	700hPa - 1060hPa
∕ ^{+50°C}	RH	Р
storage	storage	storage
during transport and	transport and	transport and
Temperature range	Humidity during	Air pressure during

7.7 Important information

If multiple KaWe examination lights 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 KaWe examination lights may cause the limit values for UV radiation (<400 nm) of 10 W/m^2 to be exceeded.

The report on the factory test for electrical safety can be obtained upon request. The only requirement is the serial number of the KaWe examination light for which the protocol is desired. If other KaWe examination lights or other pieces of equipment are connected together during installation, section 16 of EN 60601-1:2013 applies and if necessary, the compliance with the requirements is to be verified.

Before initial operation, the installation must be inspected in accordance with EN 62353.

▶ 8. CE-LABEL

CE This KaWe examination light complies with guidelines 93/42/ EWG (guidelines for medical products from the council of the European communities). The applicable standard is EN 60601-2-41. The company KaWe GmbH + Co. KG is certified according to DIN EN ISO 13485·2012 + AC·2012

9. DISPOSAL

At the end of the product's life, the components of the KaWe examination light 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 housing and the rest of the components of the KaWe examination light should be disposed of according to their type of material.

10. ELECTROMAGNETIC COMPATIBILITY TABLES AND INFORMATION

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

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Guidelines and Manufacturer Declaration – Electromagnetic Emissions

Guidelines and Manufacturer Declaration – Electromagnetic Emissions						
The KaWe examination lamp is designed to be used in the types of environments listed below. The customer or user of the examination lamp is responsible for ensuring that this device is used in such an environment.						
Emissions Measurement	Conformity	Electromagnetic environment – guidelines				
Harmonic oscillations according to IEC 61000-3-2	Class C	The KaWe examination lamp is designed for use in all facilities includ- ing living spaces that are directly connected to a public low-voltage				
Voltage fluctuations / flicker emissions according to IEC 61000-3-3	Complies	power supply network that also supplies power to buildings used for domestic purposes.				
Type-CISPR 15-1 high frequency emissions	Complies	The KaWe examination lamp is not designed to be connected to any other type of device.				

Table 10.2

Guidelines and Manufacturer Declaration – Electromagnetic Interference Immunity

Guidelines and Manufacturer Declaration – Electromagnetic Interference Immunity

The KaWe examination lamp is designed to be used in the types of environments listed below.

The customer or user of the KaWe examination lamp 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	\pm 6kV contact discharge \pm 8 kV air discharge	\pm 6kV contact discharge \pm 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	\pm 2kV for power supply lines \pm 1kV for input and output lines	\pm 2kV for power supply 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	\pm 1 kV differential mode voltage \pm 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 inter- ruptions and voltage variations on power supply input lines according to IEC 61000-4-11	< 5 % U _T (>95 % dip in the U _T) for a ½ period 40 % U _T (60 % dip in the U _T) for 5 periods 70 % U _T (30 % dip in the U _T) for 25 periods < 5 % U _T (>95 % dip in the U _T) for 5 seconds	< 5 % U _T (>95 % dip in the U _T) for a ½ period 40 % U _T (60 % dip in the U _T) for 5 periods 70 % U _T (30 % dip in the U _T) for 25 periods < 5 % U _T (>95 % dip in the U _T) 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 examination lamp requires continued operation during power interruptions, it is recommended that the KaWe examination lamp 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 : U_T is the mains voltage prior to application of the test level.					

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Guidelines and Manufacturer Declaration – Electromagnetic Interference Immunity

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The KaWe examination lamp is designed to be used in the types of environments listed below. The customer or user of the KaWe examination lamp 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
Conducted HE-interference	3.V		Portable and mobile HF communications equipment should be used no closer to the KaWe examination lamp (including its power cords) than the recommended separation distance. The separation distance is calculated using various equations depending on the transmission frequency.
according to IEC 61000-4-6	150 kHz to 80 MHz	3 V	Recommended separation distance: $d = 1.17 \sqrt{P}$
Radiated HF-interference according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.17\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.34\sqrt{P}$ for 800 MHz to 2.5 GHz "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
			Interference may occur in the vicinity of equipment marked with the following symbol.

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 examination lamp 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 examination lamp.

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

Table 9.4

Recommended Separation Distances between Portable and Mobile HF Communications Equipment and the device or system

Recommended Separation Distances Between Portable and Mobile HF Communications Equipment and the KaWe examination lamp

The KaWe examination lamp 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 examination lamp is maintained. The minimum distance is dependent on the maximum output power and the frequency of the communications equipment.

	Separation Distance According to Transmitter Frequencies (m)				
Rated Power Output of Transmitter (W)	150 kHz to 80 MHz $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz d = 1.17 \sqrt{P}	800 MHz to 2.5 GHz $d = 2.34\sqrt{P}$		
0.01	0.12	0.12	0.23		
0.10	0.37	0.37	0.74		
1	1.17	1.17	2.33		
10	3.69	3.69	7.38		
100	11.67	11.67	23.33		

For transmitters with a maximum rated output not specified in the above table, the recommended separation distance (d) can be determined in meters (m) using the equation for each column, where the maximum rated power (P) of the transmitter is in watts (W) as given by 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.

▶ <u>11. WARRANTY</u>

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.