| de   | Gebrauchsanweisung          | 2 |
|------|-----------------------------|---|
| en   | User's Manual               | 2 |
| fr   | Mode d'emploi               | 2 |
| (it) | Istruzioni per l'uso        | 2 |
| es   | Instrucciones de empleo 4   | 2 |
| pt   | Manual de operação          | 2 |
| ru   | Руководство по применению 6 | 2 |



# MASTERLIGHT LED 2000





## User's Manual – MASTERLIGHT LED 2000

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 50,000 hours and hardly any noticeable heat build-up near the surgeon'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.

## ► TABLE OF CONTENTS

| 1.    | Safety information                              | .page 12 |
|-------|---|----------|
| 2.    | Short description of the KaWe examination light | .page 13 |
| 3.    | Assembly instructions                           | page 13  |
| 3.1   | Stand assembly                                  | page 14  |
| 4.    | User's manual                                   | page 14  |
| 4.1   | Base  | page 14  |
| 4.2   | Stand post                                      | .page 14 |
| 4.3   | Operating the light                             | page 14  |
| 4.3.1 | ON/OFF switch                                   | page 14  |
| 4.3.2 | Positioning                                     | page 14  |
| 4.3.3 | Electronc brightness control                    | page 15  |
| 5.    | Cleaning  | page 15  |
| 5.1   | Stand   | .page 15 |
| 5.2   | Light body                                      | page 15  |
| 5.3   | Protective screen                               | page 15  |
|       |   |          |

| 6.  | First use and maintenance page 15               |
|-----|---|
| 6.1 | Procedure for first use and maintenance page 15 |
| 6.2 | Adjusting the arm page 16                       |
| 7.  | Technical datapage 16                           |
| 7.1 | Photometric data page 16                        |
| 7.2 | Electrical datapage 16                          |
| 7.3 | Electrical installation information page 16     |
| 7.4 | Weights page 16                                 |
| 7.5 | Environmental conditionspage 16                 |
| 7.6 | Important informationpage 17                    |
| 8.  | CE-labelpage 17                                 |
| 9.  | Disposalpage 17                                 |
| 10. | Electromagnetic compatibility tablespage 18     |
| 11. | Warranty page 21                                |
|     |   |

## ▶ <u>1. SAFETY INFORMATION</u>

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. 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 floor lamps come equipped with all of the parts required for assembly and connection.
- 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 (stand post or horizontal arm) contains 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.
- Ensure that the work area containing the light is equipped with a Schuko-type (two pinned, earthed) outlet.

#### Symbol key:

 $\wedge$ 

Non-ionizing radiation

| yiiiboi i |  |
|-----------|--|
| $\wedge$  | Caution!   |
| T         | This symbol informs of important assembly instructions, useful information and user's tips |
| X         | Temperature limit  |
| X         | Separate disposal of electric<br>and electronic devices                                    |
| CE        | Complies with relevant EU guidelines   |
| ®         | Heed the User's Manual   |
|           | Protection class II  |
| ଡ଼ୖୢ      | GOST-R certification for exports to Russia   |
| Ť         | Keep dry   |
| [@]       | Humidity, limit  |
| $\sim$    | Date of manufacture  |
| ***       | Manufacturer   |
| SN        | Series number  |
| REF       | Product reference number   |

## 2. SHORT DESCRIPTION OF THE KaWe EXAMINATION LIGHT

**Information about intended use:** This KaWe examination light was 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 provide an excellent depth of illumination.

### 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 diaqnosis.
- 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 light can be mounted on a floor stand, on the wall, on a table, on supply tracks, on round and square posts, and with a mounting plate.
- The KaWe examination light is to be serviced every 2 years.
- The light is powered via an electrical cord and plug

## ► <u>3. ASSEMBLY INSTRUCTIONS</u>

#### Parts included:

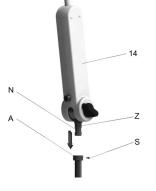
- 1x 5-foot stand with castors
- 1x Stand post
- 1x Filister head screw M8 with washer
- 1x Flat spanner wrench
- Light body with arm
- User's manual for the MASTERLIGHT LED 2000

#### 3.1 Stand assembly

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- Remove the screw and washer.
- Insert the stand post into the wheel brace

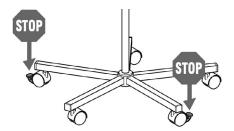
Make sure that the pin Z on the botton of the power supply housing 14 is completely inserted into the receptacle A, so that the locking screw S engages in the provided groove N.



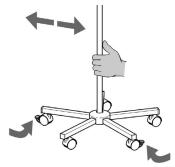
## ▶ <u>4. USER'S MANUAL</u>

### 4.1 Base

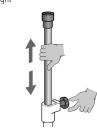
- Engage the brake on the lockable castors
- Secure the brakes on the locking castors.



• To move the light, release the brakes on the castors



# **4.2 Stand post**Adjust to desired height



4.3 Operating the light

## 4.3.1 ON/OFF switch

The KaWe examination light is turned OFF and ON by pressing on the switch **16** on the light body.



#### 4.3.2 Positioning

To adjust the position of the light arm, use the clamping lever **17** on the transformer houseing. Adjust the position of the light body using the hand grip **18**. 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.



# 4.3.3 Electronic brightness control

The KaWe examination light is equipped with electronic brightness control.



The brightness can be selected using the control panel **19** on the transformer houseing as follows:

- Pressing the button Intensity + : increased brightness;
- Pressing the button Intensity : decreased brightness.

# ▶ <u>5. CLEANING</u>

## 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. Should disinfection be necessary, the use of an agent that is either dissolved in water or max. 20% alcohol is recommended.

## 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 **22** is made of a high-quality plastic and is to be cleaned with luke-warm water and a soft viscose sponge. Pay attention to the following during cleaning:

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- Always clean the screen **22** with a wet cloth (never clean with a dry cloth!).
- The protective screen **22** is to be wiped with an anti-static agent using a lint-free cloth.



## ► <u>6. FIRST USE AND MAINTENANCE</u>

The KaWe examination light is equipped with a clamping lever on the tranformer housing. After assembly, this clamping lever may need to be adjusted.

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

## 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
- Check the connection between the examination lamp and support system.
- 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 must be adjusted.





## 7. TECHNICAL DATA

#### 7.1 Photometric data

| Central illumination intensity<br>at a distance of 0.5 meters                   | 60,000 Lux |
|---|------------|
| Central illumination intensity at a distance of 1 meter                         | 14,000 Lux |
| Light spot diameter $d_{10}$ at a distance of 0.5 m                             | 103 mm     |
| Light spot diameter $d_{10}^{}$ at a distance of 1 m                            | 228 mm     |
| Light spot diameter $d_{50}$ at a distance of 0.5 m                             | 60 mm      |
| Light spot diameter $d_{50}$ at a distance of 1 m                               | 103 mm     |
| Residual illumination intensity with one shutter                                | 0 %        |
| Residual illumination intensity with two shutters                               | 78 %       |
| 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 | 78 %       |
| Illumination depth 60 %   | 1180 mm    |
| Colour rendering index CRI  | 95         |
| Colour rendering index R <sub>9</sub>   | 94         |
| Max. irradiation intensity in the field at a distance of 1.0 m                  | 51W/m²     |
| Max. irradiation intensity in the field at a distance of 0.3 m                  | 330 W/m²   |
| Light spot size   | 10 cm      |

| Colour temperature (Kelvin)  | 4000 K   |
|------------------------------|----------|
| Heat build-up near the head  | 0.5 °C   |
| Number of LEDs               | 7        |
| Working lifespan of the LEDs | 40,000 h |
| Diameter of the light body   | 22 cm    |

#### 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<sub>a</sub> can deviate by approx.  $\pm$  5%. The colour temperature values can deviate by approx.  $\pm$  200K.

### 7.2 Electrical data

| Power input       | 10 W    |
|-------------------|---------|
| Operating voltage | 24 V DC |
| Amperage          | 0,42 A  |

## 7.3 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 I device. To avoid the risk of electric shock, this unit must be connected to a ground-ed electrical outlet.

## 7.4 Weights

| Examination Lamp     | Weight  |
|----------------------|---------|
| MASTERLIGHT LED 2000 | 6.0 kg* |

\* with 5-foot stand

#### 7.5 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

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

#### Instructions on the packaging

| +50° C            | <b>RH</b><br>20% - 90% | <b>P</b><br>700hPa - 1060hPa |
|-------------------|------------------------|------------------------------|
| Temperature range | Humidity during        | Air pressure during          |
| during transport  | transport and          | transport and                |
| and storage       | storage                | storage                      |

## 7.6 Important information

If multiple KaWe examination lights are used at once, the total irradiance may exceed 1,000 W/m<sup>2</sup> 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  $10 \text{ W/m}^2$  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 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

# ▶ <u>8. CE-LABEL</u>

**C C** 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 KIRCHNER & WILHELM GmbH + Co. KG is certified according to DIN EN ISO 13485:2012.

# ▶ <u>9. DISPOSAL</u>

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.

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## 10. ELECTROMAGNETIC COMPATIBILITY TABLES

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 light can be influenced by portable and mobile HF communication devices.

# $\Lambda$ The use of other accessories will result in increased emissions or decreased immunity of the unit.

A For the intended operation of the KaWe examination light, it is necessary that the light not be placed directly next to or stacked together with other equipment. If the lamp must be used directly next to or while stacked with other equipment, the KaWe examination light is to be closely monitored.

#### Table 10.1

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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 A The KaWe examination lamp is designed for use in all facili ing living spaces that are directly connected to a public low |  |
| 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<br>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<br>immunity test  | IEC 60601-<br>test level  | Compliance<br>level   | Electromagnetic environment –<br>guidelines  |  |
|--|---|---|--|--|
| Electrostatic<br>discharge (ESD)<br>according to   | $\pm$ 6kV contact discharge   | $\pm$ 6kV contact discharge   | The flooring should be wood or<br>concrete or be covered with ceramic tile.<br>If the floor material is a non-conductive,  |  |
| IEC 61000-4-2  | $\pm$ 8 kV air discharge  | $\pm$ 8 kV air discharge  | synthetic material, the relative humidity of the air must be at least 30%.   |  |
| Fast transient electrical<br>disturbances/ bursts according<br>to IEC 61000-4-4  | $\pm2\text{kV}$ for power supply lines  | $\pm2\text{kV}$ for power supply lines  | The quality of the mains supply voltage should be the same as that of a typical commercial or hospital environment.  |  |
|  | $\pm$ 1kV for input and output lines  | Not applicable  |  |  |
| Surges according to<br>IEC 61000-4-5   | $\pm$ 1 kV differential mode voltage  | $\pm$ 1 kV differential mode voltage  | The quality of the mains supply voltage<br>should be the same as that of a typical<br>commercial or hospital environment.  |  |
|  | ± 2 kV common mode<br>voltage   | ± 2 kV common mode<br>voltage   |  |  |
| Voltage dips, short inter-<br>ruptions<br>and voltage variations<br>on power supply input lines<br>according to IEC 61000–4–11 | < 5 % U <sub>T</sub><br>(>95 % dip in the U <sub>T</sub> )                                  | < 5 % U <sub>T</sub><br>(>95 % dip in the U <sub>T</sub> )                                  |  |  |
|  | for a ½ period<br>40 % U <sub>τ</sub><br>(60 % dip in the U <sub>τ</sub> )<br>for 5 periods | for a ½ period<br>40 % U <sub>1</sub><br>(60 % dip in the U <sub>1</sub> )<br>for 5 periods | The quality of the mains supply voltage<br>should be the same as that of a typical<br>commercial or hospital environment.<br>If the user of the KaWe examination lamp<br>requires continued operation during |  |
|  | 70 % U $_{\rm T}$<br>(30 % dip in the U $_{\rm T}$ )<br>for 25 periods                      | 70 % U $_{\rm T}$<br>(30 % dip in the U $_{\rm T}$ )<br>for 25 periods                      | power interruptions, it is recommended<br>that the KaWe examination lamp be<br>powered from an uninterruptable power<br>supply or a battery.   |  |
|  | $< 5 \% U_{T}$<br>(>95 % dip in the U <sub>T</sub> )<br>for 5 seconds                       | < 5 % U <sub>T</sub><br>(>95 % dip in the U <sub>T</sub> )<br>for 5 seconds                 |  |  |
| Magnetic field with a power<br>frequency of (50/60 Hz)<br>according to IEC 61000-4-8   | 3 A/m   | 30 A/m  | Magnetic fields with their line<br>frequencies should be the same as those<br>typical of commercial and hospital<br>environments.  |  |

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#### 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<br>level           | Compliance<br>level | Electromagnetic environment – guidelines  |
|---|-----------------------------------|---------------------|---|
| Conducted HF-interference<br>according to IEC 61000-4-6<br>Radiated HF-interference | 3 V<br>150 kHz to 80 MHz<br>3 V/m | 3 V<br>3 V/m        | Portable and mobile HF communications equipment should<br>be used no closer to the KaWe examination lamp (including<br>its power cords) than the recommended separation distance.<br>The separation distance is calculated using various equations<br>depending on the transmission frequency.<br>Recommended separation distance:<br>$d = 1.17\sqrt{P}$<br>$d = 1.17\sqrt{P}$ for 80 MHz to 800 MHz  |
| according to IEC 61000-4-3  | 80 MHz to 2.5 GHz                 |                     | d = 2.34√P for 800 MHz to 2.5 GHz<br>"P" is the maximum output power rating of the transmitter<br>in watts (W) according to the transmitter manufacturer.<br>"d" is the recommended separation distance in meters (m).<br>Field strengths from fixed transmitters, as determined by<br>an electromagnetic survey of site "a" are less than the<br>compliance level in each frequency range.<br>Interference may occur in the vicinity of equipment marked<br>with the following symbol. |

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

Note 2: These quidelines 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 10.6

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<br>(m) |                                       |                                       |  |  |
|--|---|---------------------------------------|---------------------------------------|--|--|
| Rated Power Output<br>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.

## 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.

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