MEDIZINTECHNIK seit 1890
KaWe

User's Manual:
med.lux Pen / Cliplight LED / KaWe DIALIGHT XL / Diagnostic light, white / Diagnostic lamp, LED

Dear buyer, we are grateful to you for choosing KaWe products Our products are of high quality and long-lasting. This KaWe device complies with the provisions of Regulation EU 2017/745 (European Regulation on Medical Devices), whereby it is classified as a medical product of class 1.

Please carefully consider this instruction and read all the provisions prior to use. Follow the maintenance recommendations. Prior to use, please carefully consider the maintenance procedure.

Keep the User's manual, so you can refer to it again in the future, and pass it on to the next user of the device.

Application:

Only qualified medical professionals can use the diagnostic light.

Group of patients with indications for use: All

Intended use:

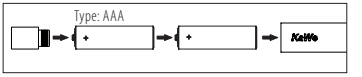
A diagnostic tool for illuminating the studied areas, for example, the oral cavity and the skin surface.

The „Cliplight LED", „Diagnostic Light, LED" and „med.lux Pen" models are tested in compliance with EN 62471 and are additionally suitable for quick eye examinations (pupillary reflex).

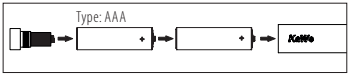
Operation:

med.lux Pen: Before the first use, remove the plastic battery insulator between the battery and the contact surface. Switch the light on and off by pressing the push-button switch at the end of the clip.

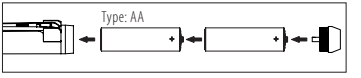
Unscrew the metal lamp bracket to replace the batteries.



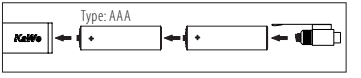
Cliplight LED: Switch on by pressing the clamp until contact occurs with the metal ring on the pin. Unscrew the metal lamp bracket to replace the batteries.



KaWe DIALIGHT XL: Switch on and off by moving the slider switch. Unscrew the upper part from the handle to replace the lamp or batteries.



Diagnostic light, white and Diagnostic lamp, LED: Switch the light on and off by pressing the black push-button switch at the end of the clip. Unscrew the upper part of the clip to replace the lamp or batteries.



Time of application: The models DIALIGHT XL and the "diagnostic light, white" are designed for intermittent use. The maximum operation time totals 1 minute. There shall be 10-minute pauses between the applications.

Improper use of the device/contraindications for use:

Any other use of use outside the above intended use shall be considered improper. The manufacturer is not responsible for damage resulting from such use.

DIALIGHT XL and the „diagnostic lamp, white" can not be used for eye examination!

Warnings:

- If the diagnostic light is visibly damaged, it should be removed from clinical use.
- If the light falls, it may break.
- Never immerse diagnostic lights in liquid.
- Avoid direct contact of the diagnostic lights with the tongue or mucosa.
- The device should not be used in strong magnetic fields (MRI).
- Do not use the device in flammable or explosive environment (for example, oxygen or anesthetics).
- Diagnostic lights, like any electrical diagnostic devices,are subject to special precautions regarding electromagnetic compatibility.
- Use only original KaWe accessories and spare parts.

The light coming from these devices is potentially harmful. The risk of eye damage increases with the duration of radiation. Exposure to radiation projected by these devices running at maximum intensity for longer than 7.6 hours will exceed the reference hazard value.

An error may cause extensive heat posing a threat of burn injury. In case of strong heating, immediately turn off the device and do not use it again.

Technical data:

Working distance:	15 cm
Risk group in compliance with ISO 15004-2:	2*
Classification as per EN 62471	exempt group*

** relates to the „Cliplight LED", „Diagnostic Light, LED" and „med.lux Pen" models only*

Please contact the manufacturer for a graphic representation of the relative spectral distribution (305 - 1100 nm) at maximum light intensity and maximum aperture (see overleaf for the address).

Secondary treatment limitations:

No special requirements. The service life of the product is usually defined based on the degree of wear and use-related damage. Prompt secondary processing of the tool is recommended after its application.

Transportation and storage:

Keep the tool away from dust, humidity and contamination during storage and transportation.

Ambient temperature:

Operation: from +10 °C to +35 °C
Storage: -10 °C to +45 °C
Transportation: -20 °C to +50 °C

Relative air humidity:

30 % to 75 %

Cleaning:

Clean the light surface with a damp or wet cloth.

Disinfection:

The light surface can be disinfected with an alcohol-soaked cloth.

Sterilization:

Sterilization is not possible.

Control and functional check:

Before each use, check the diagnostic light for faultless operation. Do not use the device if damage is found.

Make sure the moving parts are firmly fixed.

Disposal:

The product should be disposed of at a separate collection point for electrical appliances and electronics.

General accessories:

To find out more about the products, visit our homepage: www.kawemed.com.

Manufacturer:

KIRCHNER & WILHELM GmbH + Co. KG
Eberhardstrasse 56 | Germany, 71679 Asperg

Manufacturer's contact details:

Dealer's address or phone number: +49 7141 68188-0.

Basic UDI-DI:

4030155KaWe1202Z7

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.

Warranty:

The warranty for the device totals two years from the date of purchase with proper handling and following the operation manual (the warranty does not cover lamps/ rechargeable batteries). If you have any additional questions or need repair, please, contact your dealer.

Symbols:

	Safety instructions or warnings
REF	Article number
LOT	Factory number, batch
	Manufacturer & date of manufacture
	Please follow the User's manual
	Store in a dry place
CE	CE conformity mark
	Electric/electronic devices and used batteries shall be disposed separately
MD	Medical device
UDI	UDI Data Carrier

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