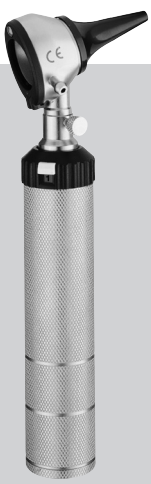
de	Gebrauchsanweisung	Otoskope
en	User's Manual	Otoscopes
fr	Instruction d'utilisation	Otoscopes
it	Istruzioni per l'uso	Otoscopi
es	Manual de instrucciones	Otoscopios
pt	Manual de usuário	Otoscópios
ru	Инструкция по применению	Отоскопы



KaWe EUROLIGHT

KaWe COMBILIGHT

KaWe PICCOLIGHT

MEDIZINTECHNIK seit 1890 KaWe

de Bitte lesen Sie diese Gebrauchsanweisung vor der Benutzung sorgfältig und vollständig durch und beachten Sie die Pflegehinweise.

en Please read this User's Manual thoroughly and carefully before attempting to use this product and heed the given care instructions.

fr Lisez ce mode d'emploi attentivement et entièrement avant d'utiliser l'appareil et respectez les consignes d'entretien.

it Si prega di leggere attentamente queste istruzioni per l'uso prima di utilizzare lo strumento e di seguire i consigli per la manutenzione.

es Por favor, lea con atención las presentes instrucciones de empleo en su totalidad y siga las indicaciones referentes al cuidado del aparato.

pt Antes de utilizar este produto pela primeira vez, favor de ler com muita atenção todo este manual de operação e observar as indicações relativas à manutenção.

ru Перед использованием следует полностью и внимательно прочитать настоящее руководство по применению и соблюдать указания по уходу!

Contents

1. Symbols used in this User's Manual and on the product package 13

2. Purpose and intended use 13

3. ⚠ Safety guidelines / contraindications 13

4. Assembly and service 14
- EUROLIGHT / COMBILIGHT 14
- PICCOLIGHT 15

5. Preparation for use 15

6. Sanitary preparation 15
- Manual/automated cleaning 15
- Disinfection 15
- Sterilization 16

en

7. Storage and transport 16
- Ambient temperature 16
- Relative air humidity 16

8. Service and maintenance 16
- Battery change 16
  - EUROLIGHT / COMBILIGHT 16
  - PICCOLIGHT 16
- Lamp change 17
  - EUROLIGHT F.O. / COMBILIGHT F.O. / PICCOLIGHT F.O. 17
  - PICCOLIGHT C 17
  - EUROLIGHT C / COMBILIGHT C 17

9. Accessories and spare parts 17

10. Disposal 19

11. Annex 19
- Warranty 19
- Contact details 19

Dear customer, thank you for choosing a KaWe product. Our otoscopes comply with the provisions of Regulation (EU) 2017/745 (European Regulation on Medical Devices) and, according to this Regulation, are classified as Class I medical products.

Please read this User's Manual and follow it. Keep this User's Manual in case you need to read it again.

Before using the device, please thoroughly read and understand the service procedure and follow the care instructions.

If you feel any uncertainty regarding the device connection or service, please do not hesitate to contact our customer support service (see the manufacturer's address on the back of the page).

KaWe otoscopes are divided into three groups

- EUROLIGHT With metal handle and head
- COMBILIGHT With metal handle and plastic head
- PICCOLIGHT With plastic handle and head

You can find the relevant images on the front page of this User's Manual. This User's Manual takes into account the differences between models. Each model may be equipped with Standard (S) of Fiber optic (F.O.) illumination type. Other options (battery/rechargeable battery power, illumination power, etc.) are not specifically covered herein, because there are no notable differences in their servicing.

1. Symbole in der Gebrauchsanweisung und auf der Verpackung

	Safety instructions and warnings
REF	Item No.
LOT	Manufacturer's number, lot number
	Manufacturer & date of manufacture
	Please follow this User's Manual
	Store in dry conditions
	Single-use only
CE	CE conformity mark
	Separate collection of electrical / electronic equipment and rechargeable batteries
MD	Medical device
	Temperature range limits
	Air humidity limits
UDI	UDI Data Carrier

2. Purpose and intended use

The otoscope with an attached ear funnel is designed for medical examination of the external auditory canal up to the ear drum. Following all instructions detailed herein, as well as all important guidelines and requirements also qualifies as proper use. Any other use of the device is not its intended use, and the manufacturer disclaims any liability that may arise as a result of such unintended use.

Otoscopes are used to diagnose and monitor different diseases and functional disorders in the areas of the outer ear, auditory canal, ear drum and inner ear.

- This device is recommended for use in adult patients, children and infants.
- Only authorized and trained professionals may use the device!

3. ⚠ Safety guidelines / contraindications

- Check the device for proper functioning before each use. Do not use the device if the device is damaged.
- Do not use the device without an ear funnel!
- Using the device on damaged tissue is not recommended!
- Using the device on damaged tissue is not recommended!
- In case of malformations of outer or inner ear which may cause the examination to end in an injury, using the device is not allowed.

- Choose the ear funnel size for each patient individually to avoid damaging the ear or the auditory canal.
- Keep the device out of strong magnetic fields (MRI).
- Do not shine the light from the device directly into eyes!
- Like all electrical diagnostic devices, KaWe otoscopes are subject to special electromagnetic compatibility precautions.
- Mobile high frequency telecommunications equipment may interfere with KaWe otoscopes' function.
- Reusable ear funnels shall be sterilized before use!
- Use only original KaWe spare parts and components.

⚠ In the event of an error, increased heat build-up can occur, which can lead to the risk of burns. In case of intense heating, turn the handle off immediately.

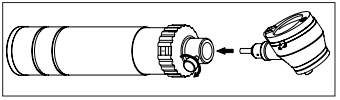
⚠ Disposable ear funnels are single-use only and to be disposed of immediately after use.

en

4. Montage & Bedienung

EUROLIGHT- / COMBILIGHT-Modelle

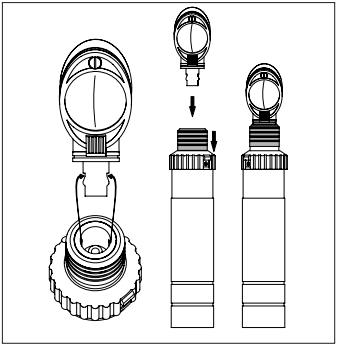
1. Insert the battery or the rechargeable battery into the



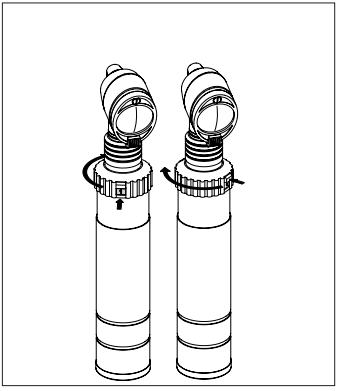
handle. Check for correct polarity and for correct lamps (2.5 V or 3.5 V)! Also follow the instructions of Section 8: Maintenance and Service.

2. C10 options: Push the head all the way down, hold it in place and tighten the screw. Check the screw groove on the head.

C30 / F.O.30 options: Push the head all the way down, hold it in place and tighten the screw. Check the grooves!



3. Turning the lamp on: Press on the latching switch and turn the illumination regulator to the left.

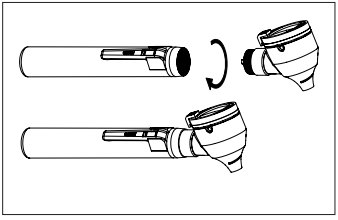


To turn the lamp off, turn the regulator back to its starting position (0). The illumination intensity changes gradually.

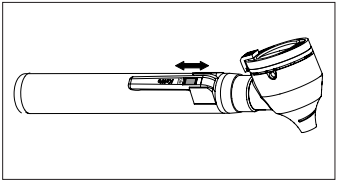
4. Battery/rechargeable battery change: see Section 8: Maintenance and Service.
5. **Note:** You can charge rechargeable batteries (NiMH, Li-Ion) inside the handle using MedCharge 4000 charger. Please follow a separate User's Manual for MedCharge 4000 Charger.

PICCOLIGHT

1. Insert batteries (2x Mignon AA 1.5 V batteries / LR6) into the handle. Check the polarity! Also follow instructions in Section 8: Maintenance and Service.
2. Screw the head onto the handle.



3. Use the sliding switch to turn the lamp on or off.



4. You can change batteries/rechargeable batteries by unscrewing the head from the handle. Also follow instructions in Section 8: Maintenance and Service.

Duration of operation

The devices are not intended for continuous operation, the maximum duration of one use is 1 minute with a 10 minutes pause between uses.

5. Preparation for use

1. Check the assembled otoscope for damage, impurities and compatibility. Check that the moving parts (i.e. magnifying glass frame, plug junctions) move smoothly.
2. Check that the lamp is well secured and functions properly.
3. Check the battery charge.

If all those checks have been successful, you can now use the otoscope to examine a patient after sanitizing it and attaching a new ear funnel.

6. Sanitary preparation

Disposable ear funnels are single-use only and therefore are not to be cleaned or re-used!

Clean reusable ear funnels immediately after use to prevent impurities from drying up.

Manual / automated cleaning

Otoscope (head and handle)

Protect the device from moisture!
Never allow the otoscope to come into contact with fluids and ensure that liquids do not penetrate the housing.

The exterior surface of the device can be cleaned with a damp, soft and lint-free cloth. Simple cleaning and or disinfection with an alcohol-based surface disinfecting agent is sufficient.

- Do not sterilize the device!
- Do not use abrasive cleaning agents!
- The magnifying glass is only to be cleaned with glass cleaner!

No automated cleaning possible/required!

Ear funnel (reusable)

Cleaning can be carried out under running water or with a 70:30 isopropyl alcohol solution.

Other accessories (see section 9)

Cleaning can be carried out under running water or with a 70:30 isopropyl alcohol solution.

Disinfection

Otoscope (head and handle)

The otoscope can be disinfected by wiping it with a cloth dampened with alcohol (e.g. isopropyl). Avoid moisture from getting on the device!

Ear funnel (reusable)

Disinfect reusable ear funnels with a suitable disinfectant (i.e. Helipur®). Follow the concentrations and reaction times indicated by disinfectant manufacturer.

en

Other accessories (see section 9)

The products can be disinfected by immersing them in a suitable disinfectant (e.g. Sekusept). Refer to the disinfectant manufacturer's instructions for concentrations and exposure times.

Sterilization

Only the following parts can be sterilized:
- Reusable ear funnel
- Lamp support (WITHOUT lamp!)
- Nose spreader speculum
- spatula holder
- Finoff lamp
- Laryngeal mirror, straight (WITHOUT mirror head!)

Proper steam sterilization can only be done after sufficient pre-cleaning!

en

Maximum hot steam sterilization temperature: .....134 °C
Minimum hot steam sterilization time: .....3 Min.

7. Storage & transport

Store and transport the device in clean conditions free of dust and moisture.

Ambient temperature:

Storage: -10 °C to +45 °C
Transport: -20 °C to +50 °C
Operation: +5 °C to +35°C

Relative air humidity:

30 % - 75 %

8. Maintenance and service

Any damaged parts (i.e. reusable ear funnels) must be discarded and replaced!

In case the illumination intensity is low, check for the following causes:

1. Check the battery/chargeable battery charge. If necessary, replace or recharge the battery.
2. Clean or replace the lamp.

If reasons 1 and 2 above are ruled out, it is possible that the device has to be repaired or replaced. Contact your supplier.

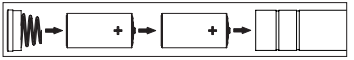
Battery change

Check the battery charge regularly. Reduced battery voltage (caused by wear) leads to diminishing illumination and in some cases to blinking LED lamps. In both cases replacing the batteries is recommended. Use high quality alkaline batteries or fully charged rechargeable batteries to replace the old ones.

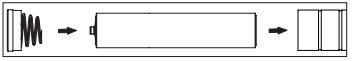
Please follow the User's Manual for the rechargeable batteries or charger devices!

EUROLIGHT / COMBILIGHT

a) battery (2x Baby C type batteries / LR14)

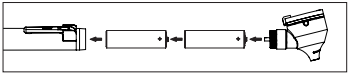


b) rechargeable battery



PICCOLIGHT

(Batteries: 2x Mignon AA / LR6)

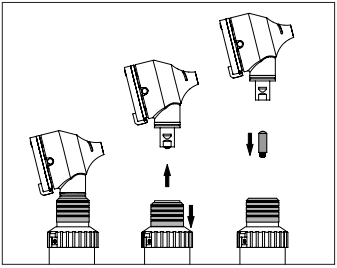


Lamp change

Satisfactory operation of the device with the best illumination power can only be guaranteed with the use of original KaWe replacement lamps.

EUROLIGHT F.O. / COMBILIGHT F.O. / PICCOLIGHT F.O.

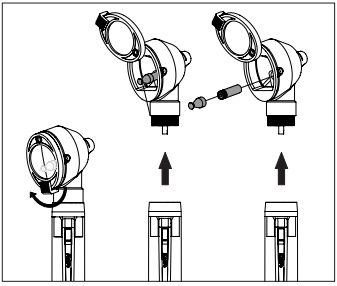
1. Remove the head from the handle. To do that, press the corrugated bushing down.



2. Pull the lamp from the bottom of the head.
3. Clean the bulb of the replacement lamp with alcohol. The glass bulb should be clean and free of fingerprints (grease spots).
4. Push the lamp all the way into the head.

PICCOLIGHT C

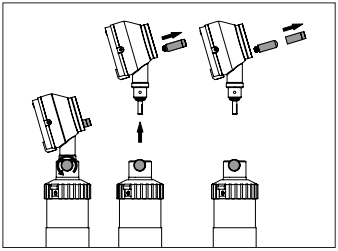
1. Swing the magnifying glass up and grasping the adapter, pull out the lamp.



2. Detach the lamp by unscrewing it from the adapter.
3. Clean the bulb of the replacement lamp with alcohol. The glass bulb should be clean and free of fingerprints (grease spots).
4. Screw the new lamp onto the adapter.
5. Push the lamp together with the adapter fully back into the slot.

EUROLIGHT C / COMBILIGHT C

1. Unscrew the lamp from the otoscope head.

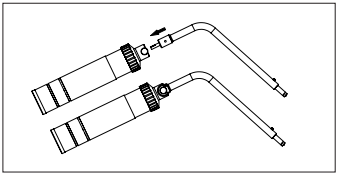


2. Remove the black plastic bushing from the lamp carefully.
3. Clean the bulb of the replacement lamp with alcohol. The glass bulb should be clean and free of fingerprints (grease spots).
4. Screw a replacement lamp into the head and cover it with plastic bushing..

9. Accessories and spare parts

- **Disposable ear funnels:**
  anthracite, Ø 2.5 mm / 4.0 mm
  black, Ø 2.5 mm / 4.0 mm
- **Reusable ear funnels:**
  black, Ø 2.0 mm / 2.5 mm / 3.0 mm / 3.5 mm / 4.0 mm / 4.5 mm / 5.0 mm / 9.0 mm*
  ** Only for EUROLIGHT C*

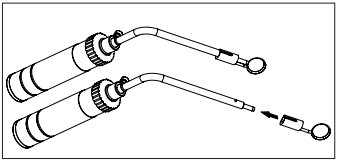
- **Lamp support 2.5 V**



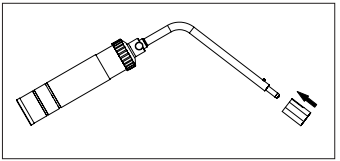
Replace the lamp the same way it is done with EURO-/ COMBILIGHT C.

en

• **Set of laryngeal mirrors**

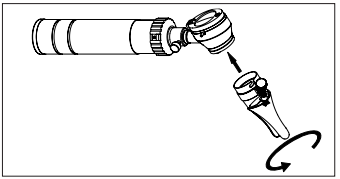


• **Spatula holder**



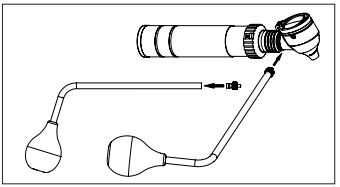
en

• **Nose spreader speculum**



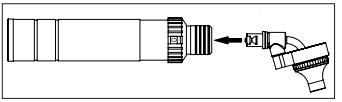
Turn the regulator screw to open or close.

• **Ball with adapter for pneumatic tests**



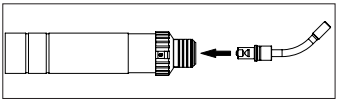
Adapter is required only for EURO-/COMBILIGHT F.O. and PICCOLIGHT models.

• **Nose lamp**



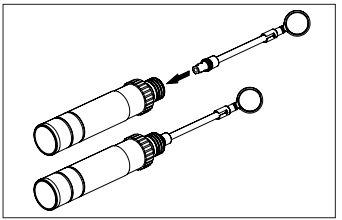
Replace the lamp the same way it is done with EURO-/ COMBILIGHT F.O.

• **Finoff lamp, XL**



Replace the lamp the same way it is done with EURO-/ COMBILIGHT F.O.

• **Laryngeal mirror, straight**



Replace the lamp by removing the mirror head and unscrewing the lamp.

You can find other accessories and spare parts in our product catalogue at https://www.kawemed.com or ask your supplier.

10. Disposal

Dispose of the device according to local regulations. Icons on the device and the package contain information on disposal requirements.

Defective and/or recyclable electrical / electronic devices and rechargeable batteries must be transferred to a designated waste collection point for recycling.

User and patient instructions

Please inform the manufacturer and the competent authorities of the relevant member state where the user and/or patient is located immediately about any serious product-related incidents.

11. Annex

Warranty

When used properly and with attention to our user's manual as well as when used with original parts, we warranty this product for two years from the date of purchase.

If you have any questions, or your device requires repair, please contact your supplier.

Contact details

Please contact your supplier or the manufacturer (the address is provided on the back of the page).

Basic UDI-DI

4030155KaWe0101XR