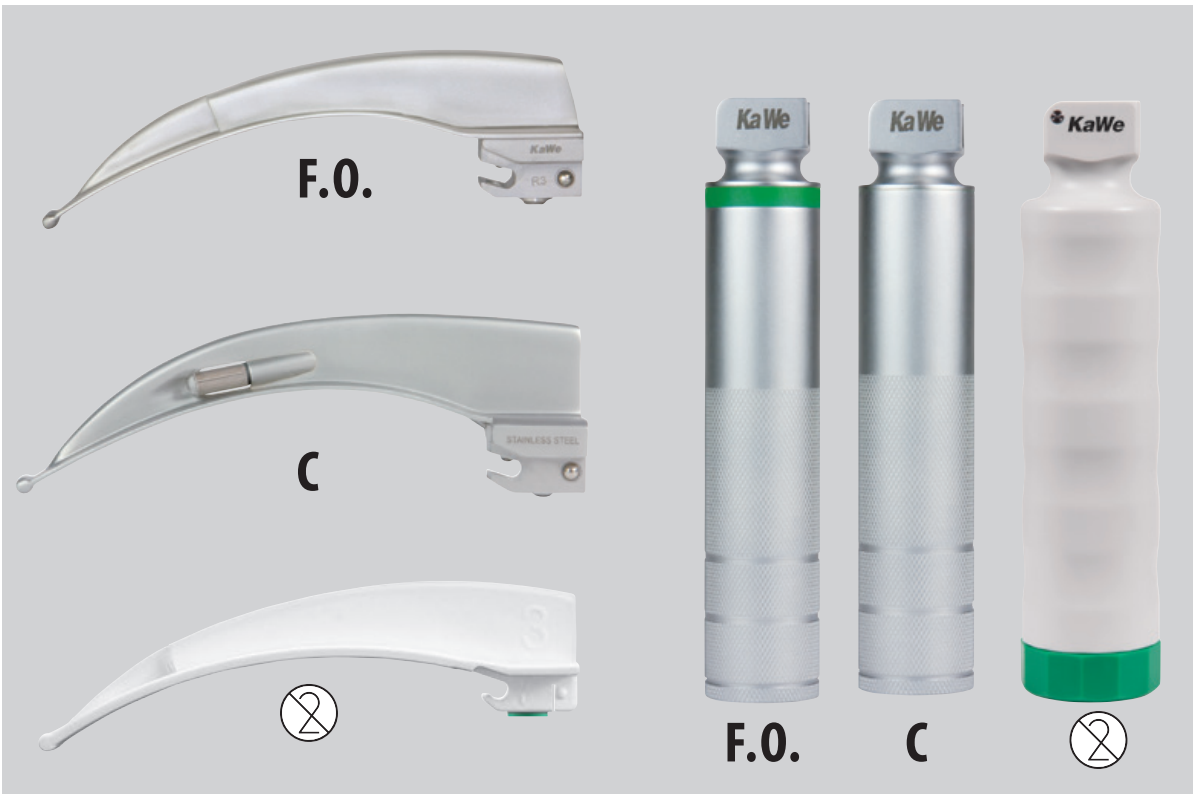
de	Gebrauchsanweisung	Laryngoskope
en	User‘s manual	Laryngoscopes
fr	Mode d’emploi	Laryngoscopes
it	Istruzioni per l’uso	Laringoscopi
es	Instrucciones de empleo	Laringoscopios
pt	Manual de operação	Laringoscópios
ru	Руководство по применению	Ларингоскопы



CE

MEDIZINTECHNIK seit 1890 KaWe

Please read this user's manual thoroughly and carefully before using this product and heed the given care instructions. Familiarize yourself fully with the proper operation of this device before attempting to use it. Save this user's manual for future reference and pass it on to the next user of this device.

For questions about the connection and/or operation of this device, please contact customer service. (See back for manufacturer address.)

These user instructions apply to all KaWe laryngoscope blades and handles. KaWe laryngoscopes comply with ISO 7376 and meet the provisions of EU Regulation 2017/745 (Medical Device Regulation). They classified as Class I medical products and can be categorized into three groups:

FO Fibre optics models

C Conventional

Disposable models

Illustrations of all models can be found on the front of this user's manual. The differences between the models are described in this manual. The other variances (battery operation, battery operation, light intensity, etc.) are not described in great detail here, since there is no significant difference in their operation.

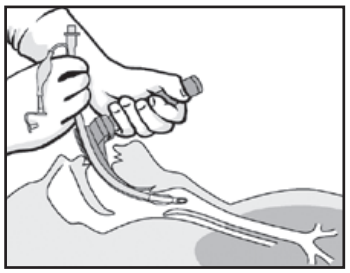
1. Symbols in user's manual and on product packaging

	Safety instructions or warning	CE	CE conformity label
	Manufacturer & if applicable date of manufacture		Applied part Type B
	Date of manufacture		Bring used batteries to proper collection facility
LOT	Batch code		Single-use only
	Heed user's manual	NON STERILE	Non-sterile
	Separate collection of electrical / electronic equipment and rechargeable batteries	LATEX	Does not contain latex

	Store in dry conditions		Temperature range limits
	Humidity, limit		GOST-R certification of goods imported into Russia
MD	Medical product	UDI	UDI Data Carrier

2. Purpose and intended use

Laryngoscopes consist of the three main parts: the handle, the blade and the light system, all of which must be compatible with each other. The corresponding spatula installed is the working element of the laryngoscope.



This device may only be used by authorized personnel after professional training.

The laryngoscopes are used mainly during intubation procedures by anaesthesiologists, to secure airways in intensive care units and during the oral intubation of accident victims. This kind of intubation is performed with an endotracheal tube, for example.

The observation of all instructions in this user's manual as well as relevant regulations and guidelines are also part of the intended use of this product. Any other use is not considered the intended use and the manufacturer is not liable for any resulting damages.

3. ⚠ Safety instructions / contraindications

- In order to prevent infection resulting from patient cross-contamination, the laryngoscope blades and handles are only to be used after they have been professionally cleaned and or disinfected.
- This product is not to be used near strong magnetic fields (such as MRI machines).
- The lights in these laryngoscopes can, in rare cases cause heat-related irritation of the mucous membranes.
- Frequent use for intubation can cause the light to become loose and therefore result in intermittent light supply failure. Therefore, check the light system before each use to make sure that the lamp is firmly connected!
- Do not use the device in flammable or explosive environments (e.g., oxygen or anesthetics).
- When working with KaWe laryngoscopes, electromagnetic compatibility precautions must be observed.

- The operation of KaWe laryngoscopes can be interfered by mobile HF telecommunication equipment.
- In case of damage (e.g., leakage), batteries and rechargeable batteries must be rejected.
- The F.O. disposable laryngoscope handles (REF 03.41022.721) with the remark „Batteries included“ on the label, contain a permanently installed button cell for power supply. The battery compartment cannot AND must not be opened.

Single-use blades and handles are only intended for one single use and must therefore be disposed of immediately after being used on a patient!

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.

Risks and indications of possible hazards

Risk of injury to anatomical structures such as the mucus membranes, lips, teeth, Adam's apple, vocal cords and epiglottis.

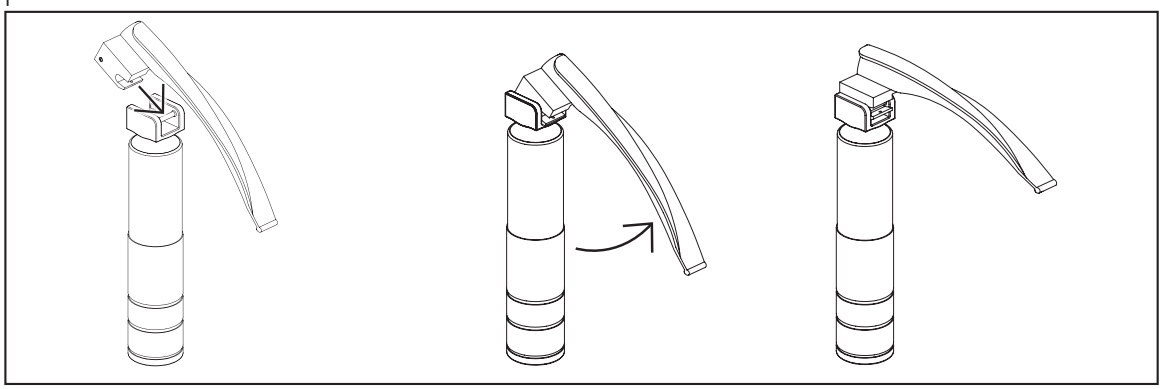
Materials used

These laryngoscopes are made of stainless steel or recyclable plastic (polycarbonate). Allergic reactions are therefore not to be expected.

4. Assembly

1. Place the blade on the blade receptacle on the handle and snap it into place.
2. Fold up the blade and snap it into place.

Check the fit to make sure it is secure. Make sure that the blade is securely engaged to prevent material damage. Perform a few "dry runs" of assembling the instrument before using it on a patient.



5. Pre-use preparatory measures

1. Check the assembled laryngoscope for damage, impurities and compatibility.
2. Check the light to ensure that it is in the proper position, is firmly attached and fully functional.

A loose-fitting light can become detached from the blade during intubation and be swallowed by the patient. **Choking hazard!**

3. Check the charge status and the function of the batteries.

If these tests have been successfully passed and hygienic preparation has been carried out, the laryngoscope can be used on patients.

Note: The complete functionality of the laryngoscope must be checked before each use!

6. Hygienic preparation

Before use

Remove batteries and the lamp from the handle before hygienic preparation (see Sec. 8)

Single-use blade: disinfect with a suitable agent.

Metal blades and handles: are to be sterilised if possible before their first use.

The laryngoscopes must be clinically sanitised. This is to be carried out in accordance with institutionally established standards. The user is responsible for the hygienic preparation of the blade, namely the cleaning, disinfection and / or sterilisation thereof. Proof of sufficient sterilisation must be provided by the applying institution and may be verified, inter alia, by a standard soiling.

After use – cleaning preparation

Single-use blades and handles are only intended for one single use and may therefore not be cleaned or prepared for reuse!

After using the blade, immediately rinse it with running water or a mildly basic solution in order to prevent various kinds of residue (such as blood) from drying on it.

It is recommended that the instruments be prepared for reuse no later than an hour after they have been used. Transport the instruments to the location at which they are to be cleaned in a covered instrument tray.

Mechanical cleaning in a washer/disinfector (WD)

In accordance with the recommendations from the Robert Koch Institute (RKI), mechanical cleaning is the preferred method for preparing the instruments for use. Manual preparation is not recommended. For laryngoscopes, remove the blade from the battery or charging handle. No further disassembly is required.

For mechanical cleaning, use one of the following cleaning agents:

- CM 310 (Maquet), cleaning agent (neodisher®FA forte 0.4%/neodisher®Z 0.2%)
- G7828 (Miele), cleaning agent (Mucapur®XL 0.4 %/Mucapur®Z 0.15 %)
- WD 390 (Belimed), cleaning agent (Mucapur®AF 0.5 %/Mucapur®Z 0.1 %)
- PG 8582 (Miele), cleaning agent (neodisher® MediClean forte 0.6 %/neodisher® Z 0.1%)

1. Thoroughly rinse the instruments with running water immediately before placing them into the machine so that residual cleaning/disinfection agents that may still be on the instruments are kept out of the machine.
2. Place the instruments in a suitable instrument stand.
3. Place the instrument stand into the machine such that they are not directly hit by the spray.
4. Place the cleaning agent into the machine in accordance with the manufacturer's instructions.
5. Start the Vario TD cycle with thermal disinfection. The thermal disinfection procedure is carried out under consideration of the A_0 value and EN / ISO 15883 regulations.
6. When the cycle is complete, remove the instruments from the machine and dry them. (RKI recommends the use of pressurized air). When drying instrument stands, take special care to dry the hard-to-reach areas.
7. Visually inspect the instruments with a magnifying glass to check for damaged parts and cleanliness. (In our experience, a magnifier with 8-times magnification is the optimal tool for performing such visual inspections.) If residual contaminants are still visible after completion of the mechanical preparation procedure, repeat the cleaning and disinfection procedure until no contaminants are evident on the instruments.

If only mechanical preparation methods are to be used (without provable disinfection), a final thermal disinfection procedure in a steam steriliser using suitable instrument stands or baskets is required.

Sterilisation

Thorough cleaning beforehand is a prerequisite for proper steam sterilisation!

FO - laryngoscope blade and handle (reusable)

Max. temperature of steam sterilisation: ..... 134°C
Max. contact time at temperature / Min. drying time: ..... 5 min / 20 min
Number of cycles (plastic base, „Economy" models): .....approx. 2000
Number of cycles (stainless steel base):..... approx. 4000

Handle: Remove the light before performing steam sterilisation!

Typ C - laryngoscope blade and handle (reusable)

Max. temperature of steam sterilisation: ..... 134°C
Max. contact time at temperature / Min. drying time: ..... 5 min / 20 min
Number of cycles (plastic base, „Economy" models): .....approx. 2000
Number of cycles (stainless steel base):..... approx. 4000

Note: The vacuum lamp may remain in the handle during the sterilisation process and must be properly secured. After sterilization, check the correct fit and function of the lamp.

Single-use blades/ single-use handles

a) Metal:

The user is responsible for hygienic preparation of the blade! A typical clinical ethylene-oxide (EO) sterilisation procedure can be performed under the following conditions:

Max. temperature of EO sterilisation: ..... 65 °C
Max. contact time at temperature: ..... 6 h
Relative humidity of EO sterilisation: .....40% to 65 %
Max. ethylene-oxide concentration: ..... 600 mg/l

b) Plastic:

The user is responsible for the hygienic preparation of the blade! The plastic blades can be disinfected prior to use with a suitable cleaning agent (alcohol, for example). These may not be sterilised!

Note: For disposable handles, only wipe disinfection with a damp, not wet, cloth is allowed.

7. Transportation and storage

Store the instruments such that they are protected from dust, moisture and contaminants.

Ambient temperature:

Reusable laryngoscopes

	Temperature	Relative humidity	Air pressure
Operation	+10°C to +35°C	30% to 70%	700 hPa to 1060 hPa
Storage	-10°C to +50°C	10% to 90%	500 hPa to 1060 hPa
Transport			

Disposable laryngoscopes

	Temperature	Relative humidity	Air pressure
Operation	+10°C to +35°C	30% to 70%	700 hPa to 1060 hPa
Storage & Transport (Metal)	+10°C to +40°C	10% to 70%	500 hPa to 1060 hPa
Storage & Transport (Plastic)	+15°C to +25°C		

Service life:

- Disposable devices: 3 years
- Reusable devices:
  - Plastic base („Economy“ models): 5 years
  - Stainless steel base: 8 years

8. Maintenance and service

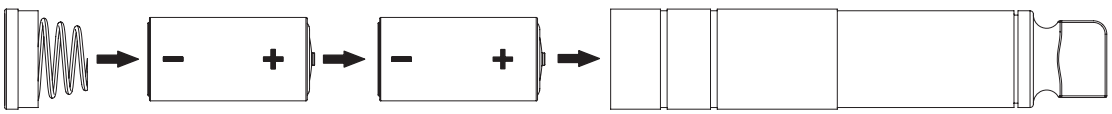
Replacing the battery

Check the charge status of the batteries regularly. Decreasing battery voltage (due to consumption) leads to reduced light intensity and possible flickering of the LEDs. In both cases,

the batteries must be replaced. When replacing the batteries, only use new, high-quality alkaline batteries (or fully charged batteries).

Note: In the F.O. disposable laryngoscope handle (REF 03.41022.721), the battery (button cell) is permanently installed and cannot be replaced.

a) Handle medium & large (batteries: 2x Baby C) / handle small (batteries: 2x Mignon AA)



b) REF-Nr. 03.41000.741, 03.41020.741, 03.41030.741 (Batteries: 2x Mignon AA)

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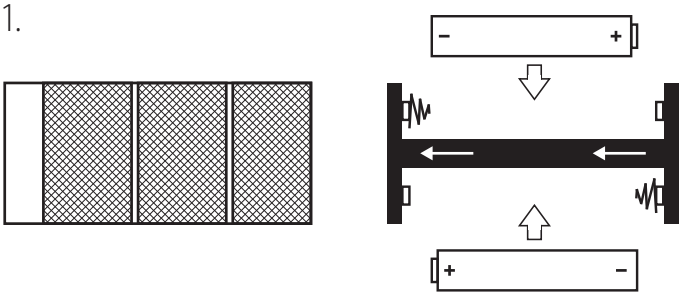

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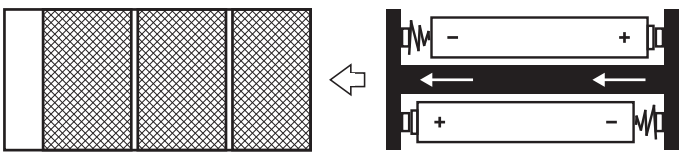


In addition, follow the instructions given in the user's manual for the batteries and chargers!

Replacing the light

Proper operation of the laryngoscope is only guaranteed when the appropriate xenon or LED lamp are used.

FO laryngoscope handle:

1. Unscrew the head from the handle containing the batteries.
2. Remove the defective light.
3. Clean the glass bulb of the new light with alcohol. The glass bulb must be clean and free of fingerprints (free of grease)!
4. Insert the new light completely into the handle until it touches the back of the opening.

5. Screw the head back onto the handle.

Conventional laryngoscope blade (type C):

1. Detach the light from the blade by turning it counter clockwise.
2. Clean the glass bulb of the new light with alcohol. The glass bulb must be clean and free of fingerprints (free of grease)!
3. Screw the new lamp with gasket completely in until it touches the back of the light socket.

Before each use/intubation the user must check to ensure that the light is securely attached to the blade.

Replacing the light guide (only for FO laryngoscope)

Please note that the light guide on the KaWe MEGALIGHT blade with integrated fibre optics cannot be replaced!

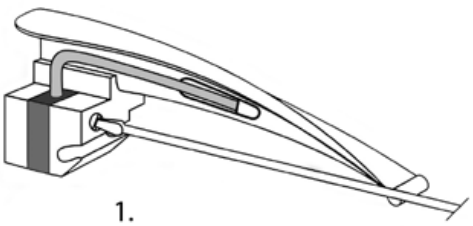
Check the integrity of the light guide frequently. To maintain long-term functionality of this product, follow the approved disinfection and / or sterilisation procedures.

If the light intensity is insufficient, check the following causes:

1. Check the charge status of the handle battery / rechargeable battery and, if necessary, fully charge or replace it.
2. If necessary, clean or replace the light source in the handle head.

3. If necessary, carefully clean and polish the input and output of the optical fibres (optical lenses). Use a soft, clean cloth to avoid scratching the surface.
4. Check the optical fibre for damage, for example at the tip of the fibre optic bundle.

If causes 1, 2 and 3 have been ruled out and cause 4 applies, then the light guide may need replacement.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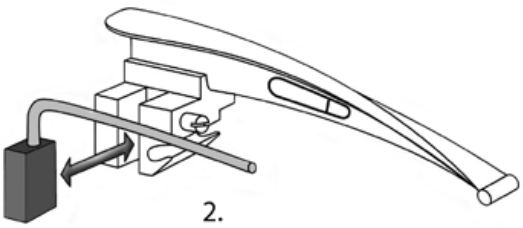
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Procedure:

- Use an approx. 2mm wide flathead screwdriver.
- Find the lock screw on the laryngoscope blade. (Fig. 1)
- Loosen the screw by turning it to the left with the screwdriver but do not completely remove it.
- Check to see if the green light guide holder is now loose.
- As soon as the green light guide holder is loosened, slide the holder out of the slot. (Fig. 2)
- Detach the light guide and remove the curved fibre guide.
- Select a new light guide.
- Do not touch either end of the light guide.
- Insert the light guide carefully into the preformed opening in the laryngoscope blade. Do not apply any pressure to the light guide or bend it.
- Insert the green light guide holder into the metal slot on the underside of the blade.
- Adjust the green base of the light guide holder so that it is level with the base of the blade.
- Carefully tighten the screw until the light guide holder is tightly fastened.
- Carefully polish the input and output areas of the newly-inserted light guide.
- Test the light output intensity.

9. Accessories and replacement parts

Accessories and spare parts can be found in our catalogue at
https://www.kawemed.com/download/broschueren or at your specialist dealer.

10. Disposal

Disposal/recycling instructions are printed on the device itself as well as on the packaging.

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

Please note that the F.O. disposable laryngoscope handle contains a permanently installed button cell and may need to be disposed of separately.

11. Appendix

Guarantee & 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. LED lights are guaranteed for 5 years from the date of purchase. Should you need further information or should your instrument require repair, please contact your dealer.

Material-related warranty restrictions

KIRCHNER & WILHELM attaches great importance to the material selection of the products. This applies especially for our stainless steel products. These materials are carefully selected to ensure that the required hygienic standards are met and mechanical stability, which is required for high-quality durable clinical instruments, is ensured. Our stainless steel surfaces are easy to clean and compatible with a wide range of clinical disinfecting agents and serialisation methods. There is however, no such thing as stainless steel that is completely corrosion free and homogeneous with regard to its visible microstructure. Small temporary but superficial corrosion spots can occur – especially in connection with cleaning, disinfection and sterilisation procedures. These spots can usually be removed by polishing the stainless steel surface and do not pose any medical threat for the patient or the user. Inhomogeneous stainless steel surfaces can expose tiny grains with a circumferential steel orientation. These are production-related surface irregularities that have no effect on the mechanical stability and durability and pose no danger to either the user or the patient. The product warranty does not apply to the observable and removable superficial traces of corrosion and surface inhomogeneity found on the stainless steel.

Contact information
Contact your specialist dealer or the manufacturer (address on the back).

Basic UDI-DI
4030155KaWe03SN

Instructions for service personnel and patients
In case of problems during the device use, it is necessary to immediately contact the manufacturer and the competent authorities of the relevant member state of the Union, in which the service personnel or the patient are located.