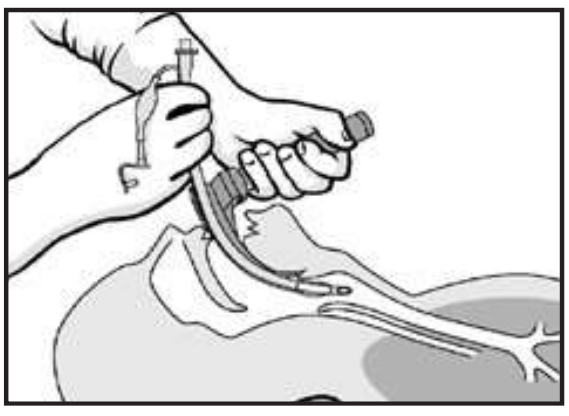
Dear Customer, thank you for choosing a KaWe product. Our products are known for their high quality and longevity. This KaWe product meets EC Standards 93/42/EWG (standards for medical products).

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.
This device may only be used properly as described here. Noncompliance with the generally applicable regulations and these instructions releases the manufacturer from liability for any resulting damages.

This device may only be used by authorized personnel!

This user's manual is applicable for all KaWe laryngoscope blades and handles as well as all sterile KaWe laryngoscope blades and handles.

Intended use:



Used for direct inspection of the larynx. The laryngoscopes are used mainly during intubation procedures by anesthesiologists, 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. Laryngoscopes consist of the three main parts: the handle, the blade and the light system (battery, lead, optical components), all of which must be compatible with each other.

Safety information:

Only use KaWe brand laryngoscope handles and lights.

⚠ 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!

⚠ Also refer to the user's manual for rechargeable batteries and chargers!

Risk of danger and information about possible hazards:

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

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 on the mucous membranes.

Frequent use for intubation can cause the lamp to become loose and therefore result in intermittent light supply failure. Therefore, check the lamp before each use to make sure that the bulb is firmly connected!

Operating instructions:

Instrument preparation measures: 1. Perform a visual inspection of all laryngoscope parts including batteries and rechargeable batteries for damage, impurities and compatibility. 2. Assemble all instrument parts and check for proper operation (light and mechanical operation). The laryngoscope may only be used on a patient after these measures have been completed and these tests have been successfully passed.

Single-use blade: before use, disinfect with a suitable cleaning agent.

Hygienic preparation:

The laryngoscopes must be clinically sanitized. 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 sterilization thereof. Proof of sufficient sterilization must be provided by the applying institution and may be verified, inter alia, by a standard soiling.

Cleaning preparation:

We recommend the blade be rinsed with running water or a mildly basic solution immediately after its use in order to prevent various kinds of residue (such as blood) from drying on it. Before a proper steam sterilization procedure may be performed, the blade must first be thoroughly cleaned! No disassembly is necessary. For laryngoscopes, remove the blade from the battery or charging handle.

Manual cleaning:

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.

Automatic cleaning:

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 %)

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 device following manufacturer 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 national regulations (EN / ISO 15883).

6. When the cycle is complete, remove the instruments from the machine and dry them. (The 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 sterilizer using suitable instrument stands or baskets is required.

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

Sterilization:

Fibre optic laryngoscope blade and handle

Max. temperature of steam sterilization: ..... 134°C
Max. contact time at temperature: .....5 min
Min. drying time: .....20 min

Handle: Remove the light before performing steam sterilization!

Type C – laryngoscope blade and handle

Max. temperature of steam sterilization: ..... 134°C
Max. contact time at temperature: .....5 min
Min. drying time: .....20 min

Note: The vacuum lamp may remain in the handle during the sterilization process and must be properly secured.

Single-use blades/handles – not sterile

Metal: The user is responsible for hygienic preparation of the blade! A typical clinical ethylene-oxide (E.O.) sterilization procedure can be performed under the following conditions:

Max. temperature of E.O. sterilization: .....65 °C

Max. contact time at temperature: ..... 6 h

Relative humidity of E.O. sterilization: .....40% . . . 65 %

Max. ethylene-oxide concentration: .....600 mg/l

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). Sterilization is not allowed!

Storage:

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

Ambient temperature:

-40°C to +70°C

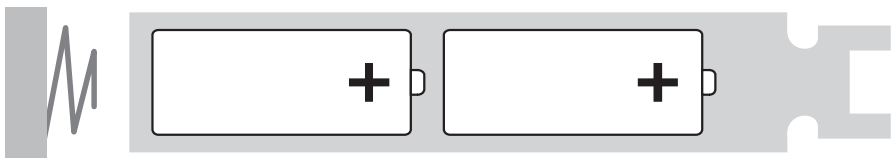
Relative humidity:

50 KPa-106 KPa

Storage and transport:

Place the instruments into a container filled with a suitable disinfecting agent directly after using them for treating a patient. Soaking the instruments prevents residual materials from drying on them (protein fixation). 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.

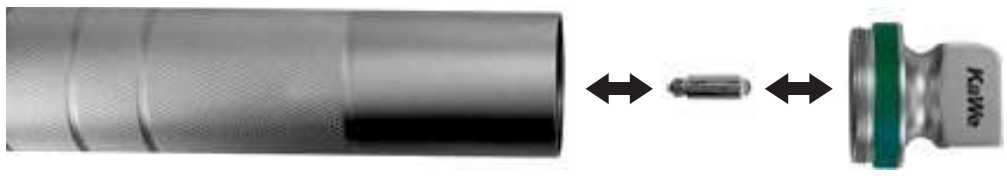
Inserting the batteries into the handle:



Maintenance and service:

Replacing the lamp on the F.O. laryngoscope handle:

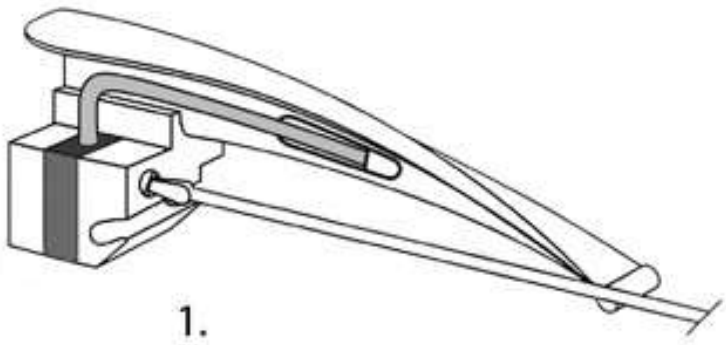
Proper operation of the laryngoscope is only guaranteed when the appropriate xenon or LED bulbs are used. Unscrew the head from the handle containing the batteries. Next, remove the lamp by pulling it out. Clean the glass bulb of the new lamp with alcohol if necessary. The glass bulb should be clean and free of fingerprints (free of grease). The new lamp must then be completely inserted into the handle until it touches the back of the opening.



Fibre optic light guide replacement:

Caution: Please note that the light cannot be replaced on the KaWe MEGALIGHT® blade with integrated fibre optics! Should the intensity of the emitted light decrease, please check the following four possible causes: 1. The handle batteries are low and need to be replaced, or the rechargeable battery must be fully charged. 2. The light source in the handle head must be cleaned or replaced. 3. Either the input or output of the fibre optic bundle must be cleaned and polished. 4. The light guide is damaged, for example at the tip of the fibre optic bundle.

The ends of the light guide must be cleaned with great care. Please use a soft, clean cloth to carefully clean the optical surface and avoid scratching it. If causes 1, 2 and 3 have been ruled out, then the light guide may need replacement.



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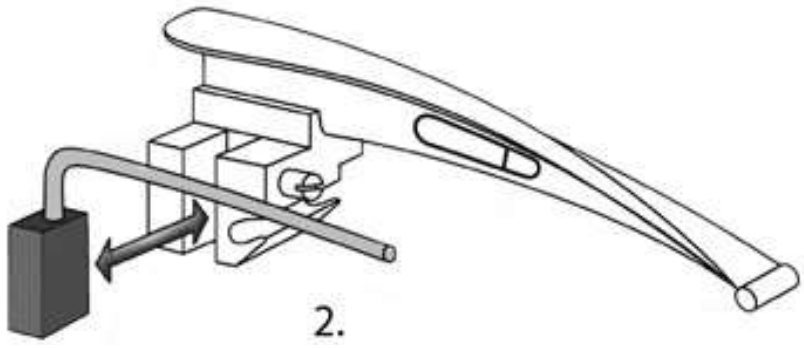

2.

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.
- Check to see if the green light guide holder is now loose.
- Do not attempt to completely remove the lock screw.
- As soon as the green light guide holder is loosened, slide the holder out of the slot. (Fig. 2)
- The light guide can now be detached and the curved fibre guide can be removed.
- 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.

Regularly check the integrity of the light guide. In order to ensure the long-term functionality of your product, follow the approved disinfection and sterilization procedures.

Replacing the bulb on conventional laryngoscope blades:

Detach the lamp from the blade by turning it counter clockwise. Clean the glass bulb of the new lamp with alcohol if necessary. The bulb should be free of fingerprints (free of grease). Screw in the new lamp with gasket all the way into the lamp socket! Before each use/intubation the user must check to ensure that the lamp is tightly fitted into the blade. Please only use original KaWe replacement lamps to ensure a good light quality.

Further instructions:

In order to prevent material damage, ensure that the blade is properly attached. Practice assembling the laryngoscopes by performing several “dry runs”. When using our LED illumination instruments, ensure that you use new and high-quality alkali batteries. A decrease in battery power leads to a reduction of the light intensity and in some cases causes the LED lights to flicker. Both of these circumstances are indications that the batteries should be replaced.

Frequent use for intubation can cause the lamp to become loose and therefore result in intermittent light supply failure. Therefore, check the lamp before each use to make sure that the bulb is firmly connected! Heed the instrument preparation instructions.

Information about material-related warranty limits:

Kirchner & Wilhelm selects materials for the production of their products very carefully, especially 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 serialization 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 sterilization 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 implied product warranty does not apply to the observable and removable superficial traces of corrosion and surface inhomogeneity found on the stainless steel.

Guarantee:

When used properly and with attention to our user's manual as well as when used with original parts, we guarantee this product for two years from the date of purchase (except for light sources and batteries). When used and stored properly, this product will serve you dependably for many years. Should you need further information or should your instrument require repair, please contact your dealer.

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Disposal:

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

Electric or electronic devices that are damaged or require disposal must be brought to a proper recycling centre.

Symbol key

	Manufacturer		CE conformity label
	Date of manufacturer		Do not dispose of batteries in household waste.
	Batch code		Separate disposal of electric and electronic devices
	Heed the user's manual		For one single use only
	Separate disposal of electric and electronic devices		Non-sterile
	Caution!		Does not contain latex

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Contact information:

Address or tel. no. of your dealer or dial +49 7141 68188-0