Keeler EP59 Loupe Frame Instruction Manual

Keeler
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EP59 Loupe Frame
Instruction Manual

	Consult instructions for use		General warning sign
	Date of manufacture	CE	Conformité Européene
	Manufacturer's name and address		Temperature limit
GB	Country of manufacture	EC REP	Authorised representative in the European Community
	Waste Electrical and Electronic Equipment (WEEE) recycling	REF	Catalogue number
	This way up	LOT	Batch code
	Keep dry		Atmospheric pressure limitation
	Fragile	%	Humidity limitation
	Do not use if package is damaged	A→文	Translation

The Keeler Loupe Frame is designed and built-in in conformity with Directive 93/42/EEC, Regulation (EU) 2017/745, and ISO 13485 Medical Devices Quality Management Systems.
Classification:
CE: Class I
FDA: Class II

This IFU is also available on the Keeler UK and Keeler USA websites.

Contents

INDICATIONS FOR USE

Intended use/purpose of the instrument
The Keeler Loupes and Frames are intended for use in various clinical settings including but not limited to users in dental practices, ophthalmology clinics, operating theatres, hospitals, veterinary practices, private consulting rooms, and surgical environments, and used by trained students and experienced professionals.
WARNINGS AND CAUTIONS
Please note that the proper and safe functioning of our instruments is only guaranteed if both the instruments and their accessories are exclusively from Keeler Ltd.
Observe the following precautions in order to ensure the safe operation of the Loupe Frame.

 **WARNINGS**

- Please note that the proper and safe functioning of our instruments is only guaranteed if both the instruments and their accessories are exclusively from Keeler Ltd.
- Check your Keeler product for signs of transport/storage damage prior to use.
- Do not use it if the product is visibly damaged and periodically inspect it for signs of damage or misuse.
- US Federal Law restricts this device to sale by or on the order of a physician or practitioner.
- This device is intended to be used only by suitably trained and authorized healthcare professionals.
- This product should not be immersed in fluids.

 **CAUTION**

- Use only genuine Keeler-approved parts and accessories or device safety and performance may be compromised.
- The product has been designed to function safely when at an ambient temperature between +10°C and +35°C.

- Keep out of the reach of children.
- To prevent condensation from forming, allow the instrument to come to room temperature before use.
- For indoor use only (protect from moisture).
- There are no user-serviceable parts inside. Contact the authorized service representative for further information.
- Failure to carry out recommended routine maintenance as per the instructions in this IFU may reduce the operational lifetime of the product.
- At product end of life dispose of in accordance with local environmental guidelines (WEEE).

CONTRAINDICATION
There is no restriction to the patient population this device can be used other than those outlined in the contraindications stated below.
The Keeler Loupe and Frame restrict the user's field and depth of view, forcing them to adopt awkward head-neck postures in order to see clearly.

CLEANING AND DISINFECTION INSTRUCTIONS

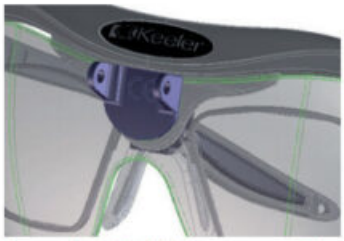
Only manual non-immersion cleaning as described should be used for this instrument. Do not autoclave or immerse in cleaning fluids.

1. Wipe the external surface with a clean absorbent, non-shedding cloth dampened with a de-ionized water/detergent solution (2% detergent by volume) or water/isopropyl alcohol solution (70% IPA by volume). Avoid optical surfaces.
2. Ensure that excess solution does not enter the instrument. Use caution to ensure the cloth is not saturated with the solution.
3. Surfaces must be carefully hand-dried using a clean non-shedding cloth.
4. Safely dispose of used cleaning materials.

SETTING UP AND USING THE LOUPE FRAME

1. Fit the Loupe unit to the frame via the pin mounting system as shown.

2. The protective shield is fitted by pushing the Shield into position as shown.



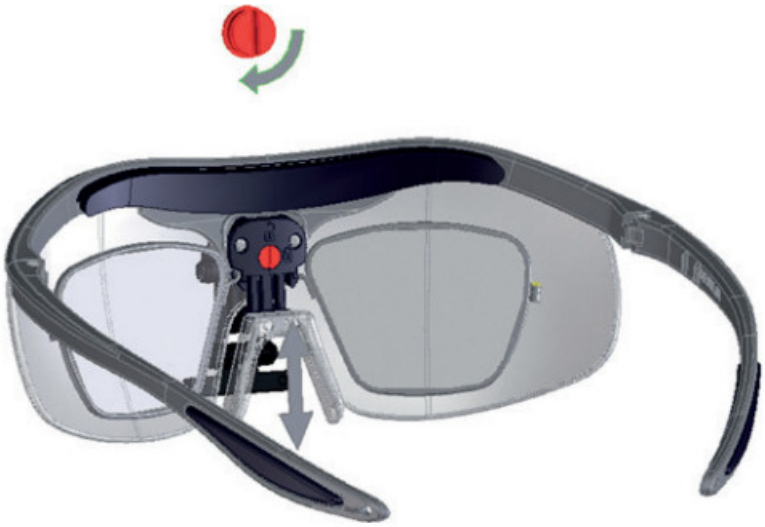
Protective shield in correct position

3. The Prescription Lens Frame is fitted if required as shown.

Protective shield in correct position

4. To adjust the nose bridge, turn the locking cam to a position as shown to release the Nose Bridge. The Nose Bridge can then be slid to the required position.

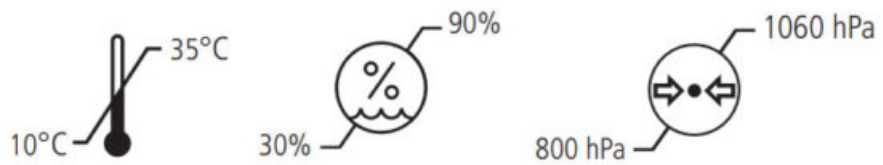
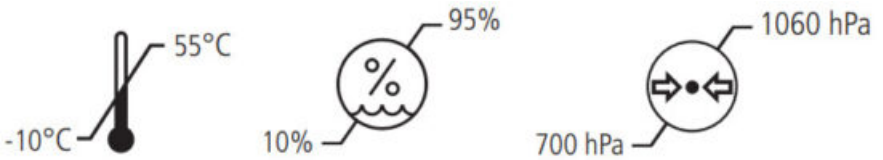
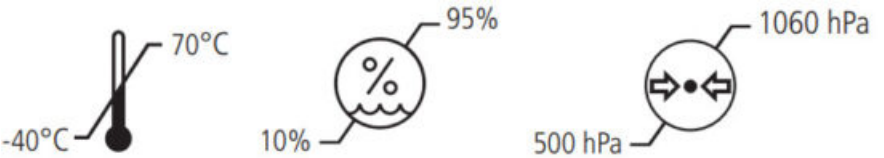
5. Lock the Nose Bridge in position by turning the locking cam to a position as shown.



6. To securely fit the frame to the user's head, slide the toggle indicated to a comfortable position

TECHNICAL SPECIFICATIONS

Environmental Conditions:

USE		
		
	Shock (without packing)	10 g, duration 6 ms
STORAGE CONDITIONS		
		
TRANSPORT CONDITIONS		
		
	Vibration, sinusoidal	10 Hz to 500 Hz: 0.5g
	Shock	30 g, duration 6 ms
	Bump	10 g, duration 6 ms

SPARE PARTS AND ACCESSORIES

Item	Part Number
Headband for surgical Loupes	2199-P-7259
Head strap	2199-P-7523
Hi-tech lens cloth in the wallet	2199-P-7136

WARRANTY

No user-serviceable parts – all preventative maintenance and servicing must only be performed by authorized Keeler representatives.
Your Keeler product is guaranteed for 3 years and will be replaced, or repaired free of charge subject to the following:

- Any fault due to faulty manufacture.
- The instrument and accessories have been used in compliance with these instructions.
- Proof of purchase accompanies any claim.

PACKAGING AND DISPOSAL INFORMATION

Disposal of old electrical and electronic equipment

This symbol on the product or on its packaging and instructions indicates that this product shall not be treated as household waste.
To reduce the environmental impact of WEEE (Waste Electrical Electronic Equipment) and minimize the volume of WEEE entering landfills we encourage at the product's end of life that this equipment is recycled and reused.

If you need more information on the collection reuse and recycling then please contact B2B Compliance on 01691 676124 (+44 1691 676124). (the UK only).
Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of your Member State.

Contact

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Documents / Resources

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