

Keeler Loupes

Magnification Systems



















INSTRUCTIONS FOR USE



Keeler
– A world without vision loss –

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

The Keeler Loupes are designed and built 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

The information contained within this manual must not be reproduced in whole or part without the manufacturer's prior written approval. As part of our policy for continued product development we the manufacturer reserve the right to make changes to specifications and other information contained in this document without prior notice.

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

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1. INDICATIONS FOR USE

Intended use / purpose of 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.

It is important that if you normally wear spectacles, your prescription is fitted into the Loupe frames. Guidance notes for your optician are included, see Optician guidance notes, page 11. Please take these notes with you to your optician should you require prescription lenses to be fitted.

1.1 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 safe operation of the Loupes.



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 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 authorised 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 instrument to come to room temperature before use.
- For indoor use only (protect from moisture).
- There are no user serviceable parts inside. Contact authorised 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).
- Correctly fitted Loupe can help reduce back and neck pain. Spend a few moments ensuring your Loupes are at the optimal angle to suit you.

1.2 CONTRAINDICATION

There is no restriction to patient population this device can be used with 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.

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



- A Nose Pads
- B Telescope Locking Knobs
- C Telescope
- D PD Bar
- E Hinge
- F Hinge Pins
- G Hinge Tightening Screws

2. CLEANING AND STERILISATION INSTRUCTIONS



Under no circumstances should the telescopes be autoclaved or immersed in any form of cleaning fluid.

Only non-immersion cleaning as described below should be used for Keeler Loupes.

1. Wipe the external surface with a clean absorbent, non-shedding cloth dampened with a de-ionised 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 cloth is not saturated with solution.
3. Surfaces must be carefully hand-dried using a clean non-shedding cloth.
4. Safely dispose of used cleaning materials.
5. The optical surfaces of the Loupes are treated with an anti-reflective coating and should only be cleaned with the lens cloth provided.

The cleaning and sterilisation of the Loupe Flip Lever, protective and 1D caps, can be accomplished as follows:



Re-useable flip lever, protective and 1D caps should not be re-used if visibly contaminated with fluids or blood.

6. Manually clean all surfaces of the units using a suitable brush and de-ionised water/detergent solution (2% detergent by volume). Ensure all crevices are accessed. The glass lens may need to be carefully removed from the silicone rubber holder to achieve cleaning. Solution can be heated to no more than 35°C.
7. Carefully examine to ensure that all visible contamination has been removed.
8. Safely dispose of used cleaning materials.
9. Sterilize using a validated steam sterilizer complying with BS 3970 or equivalent standard. Operating cycle conditions as below: 134-138°C sterilizing temperature at 2.25 bar operating pressure for minimum of 3 minutes hold time.



Following cleaning and/or sterilisation processes inspect the device to ensure all visible soil has been removed and the device operates as intended and is suitable for its intended use. Do not use if damaged. Dispose of safely.

The useful life of the device is determined by the wear and damage during use.

For more extensive cleaning, service or repair, the Loupes may be returned to your authorised Keeler distributor or to Keeler directly.

3. YOUR LOUPE SPECIFICATION

When you receive your new Keeler Surgical Loupes please check that the contents are as ordered:

- The magnification and working distance of the Loupes is marked on the Loupe bar (e.g. 3.5x 42cm /16").
- The frame size is marked on the inside of the frame arm.
- As well as a pair of Loupes and a Frame, a full loupe outfit will comprise of the following additional components:
 - Loupe Flip Lever, Head Strap
 - Lens cloth
 - Case

4. SETTING UP AND USING YOUR LOUPES

The aim in using Keeler Surgical Loupes is to achieve a clear, circular, binocular view (Fig. 1) at your chosen magnification and working distance without any shadows or double images.

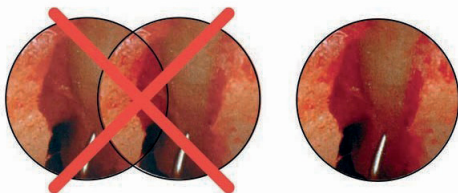


Fig.1

To achieve the best from your Keeler Loupes, they must be correctly aligned both horizontally and vertically with your visual axis (Figs. 2 and 3).

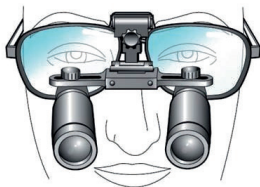


Fig.2

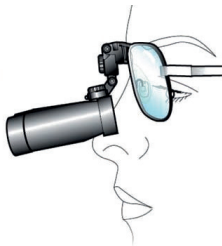


Fig.3

To obtain this, your Loupes may require some minor adjustments. The most common are:

Adjustment

Vertical alignment (height) =
(Fig 4 & 5)

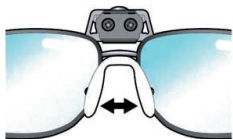


Fig.4

Method

Pinch or open frame pads



Fig.5

Horizontal alignment (PD) =

Slightly loosen locking knobs
(interpupillary distance) and slide
telescope along bar (Fig. 6)

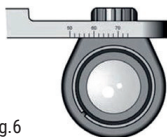


Fig.6

Look through your Loupes at a target that is the correct working distance away. Look through first with one eye closed and adjust the alignment until a perfect image appears. Repeat this with the other eye. Alternate closing the left and right eye to check binocularity and make fine adjustments. Once you are satisfied that you have the best possible image, tighten the telescope locking knobs.

Important: All Keeler Surgical Loupes are accurately aligned and set for precise binocular vision. Under no circumstances should adjustment be made by rotating or holding the telescopes, as this may cause the telescopes to misalign and create double vision.

The corrective actions outlined below should be followed for poorly aligned Loupes.

Image Quality	Telescope Position	Action
	Too high	Open frame pads
	Too low	Pinch frame pads
	Too far left	Slide telescope to the right in the direction of the shadow
	Too far right	Slide telescope to the left In the direction of the shadow

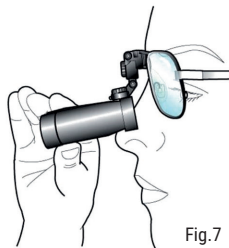


Fig.7

Adjust the angle and height of your Loupes by adjusting the hinge (Fig. 7).

4.1 HOW TO ADJUST LOUPES FITTED TO A HEADBAND

If you have ordered your Keeler Loupes for fitting to a Headband, the following notes will help you to set up the Loupes correctly.

- Put the Headband on and position centrally on your head with the padded band just above your eyebrows, adjusting both top and back bands for security and comfort.
- Position the telescopes in approximately the correct position in front of your eyes. Slightly loosen both adjustment knobs so that the telescopes can be moved easily. Vertically align each telescope. (Fig. 8).
- Align each telescope as outlined earlier by sliding along the bar. (Fig. 6)

Note: If you are using your Loupes in conjunction with a fiber-optic headlamp, first adjust the Loupes as described above. The light may then be adjusted to illuminate the specific area you are viewing through your Loupes.

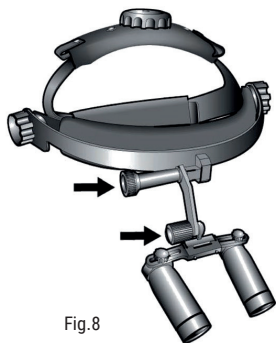


Fig.8

4.2 HOW TO FIT AND REMOVE LOUPES FROM A FRAME OR HEADBAND

Keeler Loupes allow you to easily fit or remove them from a Frame or Headband. This allows you to switch between Loupes of different magnifications without having to purchase an additional Frame.

- To fit Keeler Loupes to the hinge, hold the Loupe PD bar and push the Loupes onto the hinge pins through the holes on the PD bar. To remove, hold the Loupe PD bar and hinge and wriggle the Loupes away from the pins. (Fig. 9)



Fig.9

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



UNDER NO CIRCUMSTANCES SHOULD THIS BE DONE BY HOLDING THE TELESCOPES.

- If your Loupe Frames are fitted with prescription lenses, you may find it necessary to position your Loupes on the front stop of the Loupe pins to prevent the telescope from touching the lenses, particularly when the curvature of high-powered lenses prevent the Loupes from being angled fully downward.

4.3 HOW TO FIT THE LOUPE 'FLIP UP' LEVER

Keeler Surgical Loupes are mounted on a specially designed hinge, permitting the telescopes to be flipped up out of view when not required (Fig. 10).

To avoid touching the non-sterile Loupes, a sterilisable Loupe Flip Lever is provided with each pair of Loupes (spares are also available). When magnification is required again, the Loupes may be returned to their original preset working angle. The Loupe Flip Lever is fitted by pushing onto the Loupe bar (Fig. 11) and removed by twisting off.



Fig.10

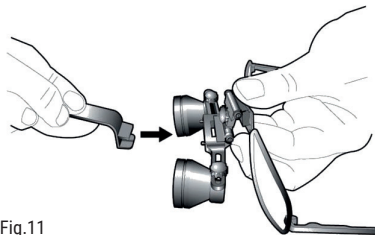


Fig.11

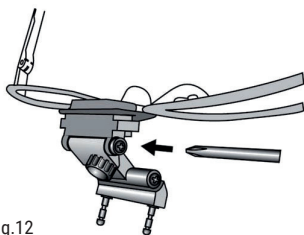


Fig.12

Over a period of time the hinge tension may slacken slightly and require adjustment. Using a small crosshead or Phillips screwdriver, adjust the hinge screw to the required tension as shown (Fig. 12).

4.4 THE LOUPE HEAD STRAP

Keeler Surgical Loupes are supplied with the Head Strap already fitted (spares are available). The use of the Head Strap is strongly recommended for added security and to ensure that the Loupes are close to your eyes for the widest field of view. Simply fit the Head Strap over the ends of the Loupe side arms. When wearing the Loupes use the toggle to tighten the strap.

4.5 FRAME ADJUSTMENTS

The length of the Loupe side arms may be altered by bending the end section to provide a comfortable fit. A qualified optician should do any other adjustments required to the Frame.

4.6 PROTECTIVE AND +1D CAPS

All Keeler Loupes are supplied with protective caps. These are designed to be a push fit. We recommend these be worn at all times to help protect the lenses.

+1D lens caps can be ordered separately. They reduce the working distance and are useful if you need to work in two different positions. They are also a push fit.

5. WARRANTY

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.


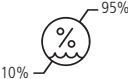
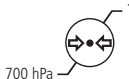

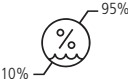
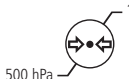


The manufacturer declines any and all responsibility and warranty coverage should the instrument be tampered with in any manner or should routine maintenance be omitted or performed in manners not in accordance with these manufacturer's instructions.

There are no user serviceable parts in this instrument. Any servicing or repairs should only be carried out by Keeler Ltd. or by suitably trained and authorised distributors. Service manuals will be available to authorised Keeler service centres and Keeler trained service personnel.

6. ENVIRONMENTAL CONDITIONS:

USE	
Shock (without packing)	10 g, duration 6 ms

USE	
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

7. ACCESSORIES AND SPARES

Item	Part Number
+1D lens cap for Galilean Loupes (pair)	2112-P-8057
Protective caps for Galilean Loupes (pair)	2112-P-8049
+1D lens cap for Hi Res Galilean Loupes (pair)	2112-P-8073
Protective caps for Hi Res Galilean Loupes (pair)	2112-P-8065
+1D lens cap for Panoramic Loupes (pair)	2113-P-7001
Protective caps for Panoramic Loupes (pair)	2113-P-7000
Loupe Flip Lever (pack of 7)	2199-P-7216

8. OPTICIAN GUIDANCE NOTES

The set of Keeler Surgical Loupes have been supplied to your customer with Plano lenses fitted. We hope that the following notes on lens fitting and frame adjustments will help you, help your customer obtain the best from their Loupes.

There are two types of binocular telescopes used in Keeler Loupes:

- Galilean based on a Galilean optical system.
- Panoramic based on a Keplerian telescope system incorporating a roof prism.

8.1 PRESCRIPTION FITTING

First establish the following facts:

1. The type of Loupe (i.e., Galilean, or Panoramic).
2. The magnification.
3. The working distance or focal length (noted on the loupes).
4. Your customers interpupillary distance, taking the working distance / focal length of the Loupe into consideration.

It is important to fit the frame as close as possible to the eyes so that your customer can obtain the widest field of view.

Any distance prescription should be fitted with centers to coincide with the Loupe IPD setting.

If fitting bifocals, care should be taken to fit the bifocal segment either below or above the rim of the telescope (Fig. 12, page 9) never in between. If the near vision ADD is more than +2D the bifocal segment should be fitted below the lower rim of the telescopes to avoid shortening the focal length of the telescopes and causing double vision.

Note: Varifocals are not suitable for fitting to Keeler Loupes.

In most cases the Bifocal ADD should be the same as the normal prescription. However, some surgeons prefer the ADD to be of a power that produces a working distance similar to that of the Loupe telescopes. This avoids constant accommodation as they alternatively look through the Loupe and alongside for orientation. Others prefer a weaker ADD for easier focusing onto surgical instruments outside the operative area. Discuss this matter with your customer to ascertain which option is best suited to their needs.

Note: All lenses should be plastic.

Once your customers Loupes have been glazed, it may be necessary to place the Loupes on the front stop of the Loupe pins to prevent the telescopes from touching the lenses, particularly where the curvature of high-powered lenses prevent the Loupes from being angled fully downwards.

8.2 CORRECT FITTING OF KEELER LOUPES

When you have glazed your customers correction into the Loupe Frame, we would be grateful if you could offer further assistance to help them 'set up' the Loupes correctly so that they can obtain the best from them. Full fitting instructions are given on Setting up and using your Loupes, page 6.

9. 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 minimise the volume of WEEE entering landfills we encourage at product 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). (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.

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