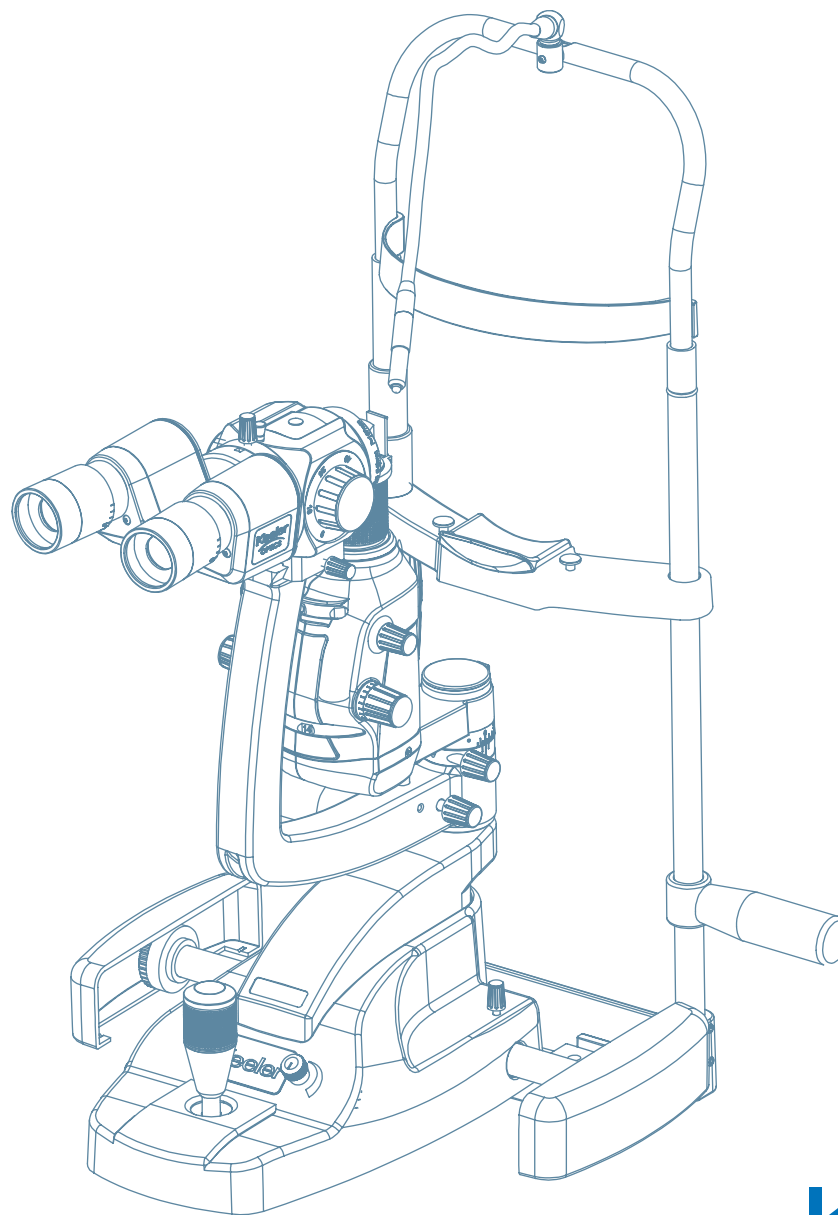


KSL-Z

SLIT LAMP

INSTRUCTIONS FOR USE

Z Series



Keeler

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1 INTRODUCTION

Thank you for choosing this Keeler product.



Please read this manual carefully before using your Keeler Slit Lamp, this will ensure the safety of the patient and ensure you get the best performance from this precision optical device.

2 SYMBOLS USED IN THESE INSTRUCTIONS FOR USE AND ON THE DEVICE AND PACKAGING



Manufacturer's name and address



Mandatory action sign



Follow Instructions for Use



Optical radiation hazard



Warning: Dangerous Voltage



Trip Hazard



Hot surface



General warning sign



Type B Applied Part



Non-ionizing radiation



Keep dry



Reference Number



Serial Number



Date of manufacture



The CE mark on this product indicates it has been tested to and conforms with the provisions noted within the 93/42/EEC Medical Device Directive



This way up



Material suitable for recycling



Fragile



The symbol on the Product or on it's Packaging and instructions indicates it was put on the market place after August 2005 and this product shall not be treated as Household Waste



Class II Equipment



RoHS Compliant

3 INDICATIONS FOR USE

This Keeler Slit Lamp is an AC-powered slit lamp biomicroscope and is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affects the structural properties of the anterior eye segment.

This device is intended to be used only by suitably trained and authorised healthcare professionals.



Caution: Federal Law restricts this device to sale by or on the order of a physician or practitioner.

4 INTENDED USE / PURPOSE OF INSTRUMENT

The Slit Lamp is an instrument consisting of a light source that can be focused to shine a thin sheet (slit) of light into the eye. It is used in conjunction with a biomicroscope. The lamp facilitates an examination of the anterior segment, or frontal structures and posterior segment, of the human eye, which includes the eyelid, sclera, conjunctiva, iris, natural crystalline lens, and cornea. The binocular Slit Lamp examination provides stereoscopic magnified view of the eye structures in detail, enabling anatomical diagnoses to be made for a variety of eye conditions.

5 BRIEF DESCRIPTION OF THE INSTRUMENT

This Keeler Slit Lamp can either be mounted onto a custom table top supplied by Keeler or can be mounted on a third parties table top (refraction unit) by suitably trained technicians.

The Keeler Slit Lamp consists of 5 assemblies; Illumination Tower; Observation System; XYZ Translation Base; Chinrest Assembly and a Table Top with Power Supply and Accessory Drawer.

The light intensity is controlled by a variable rheostat located on the XYZ Translation Base. There are a number of selectable filters allowing the user to control the characteristics of the examination light. Many ophthalmic instruments illuminate the eye with intense light. The light intensity on the Keeler Slit Lamp is continuously adjustable from maximum to zero.

The Keeler Slit Lamp is designed and built in conformity with EC Directive 93/42/EEC and the ISO 9000 and ISO 13485 series of quality standards.

The 'CE' (European Community) mark attests that the Keeler Slit Lamp complies with the provisions of the EC Directive 93/42/EEC.

**Classification: CE Regulation 93/42 EEC: Class I
FDA: Class II
IEC/EN Standard 60601-1 : Safety Class II
Applied part : Type B
Operation mode: continuous operation**

Production processes, testing, start-up, maintenance, and repairs are conducted in strict conformity with the applicable laws and international reference standards.

6 SAFETY

6.1 PHOTO TOXICITY



Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. This device should be used with filters that eliminate UV radiation (< 400 nm) and, whenever possible, filters that eliminate short-wavelength blue light (<420 nm).

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

While no acute optical radiation hazards have been identified for slit lamps, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.

It is well established that exposure of the eye to intense light sources for extended periods of time poses a risk of retinal **photic injury/ocular damage**.

Many ophthalmic instruments illuminate the eye with intense light. The light intensity on the Keeler Slit Lamp is continuously adjustable from maximum to zero.



CAUTION- The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage.

Exposure to light from this instrument when operated at maximum intensity will exceed the recommended maximum exposure (RME) of 2.2J/cm², unless additional action is taken by the user to minimise exposure, after 70 seconds. The risk of retinal injury at an exposure of 2.2J/cm² is not high, but because some patients may be more susceptible than others, caution is advised if this radiant exposure value is exceeded. However, because of significant risk of injury at exposures exceeding 10 J/cm², the user should avoid exposures longer than 5.3 mins when using the ancillary 90D lens.

Keeler Ltd shall on request, provide the user with a graph showing the relative spectral output of the instrument

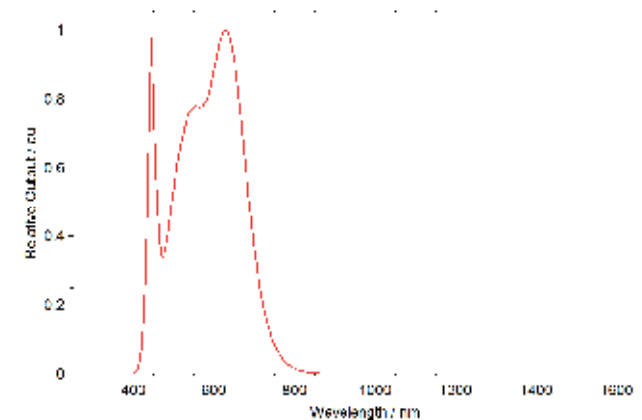


Figure 1. Relative Spectral output Keeler Slit Lamp Z-series

6.2 WARNINGS AND CAUTIONS

Observe the following prescriptions in order to ensure safe operation of the instrument

WARNINGS

- Never use the instrument if visibly damaged and periodically inspect it for signs of damage or misuse.
- Check your Keeler product for signs of transport / storage damage prior to use.
- Do not use in the presence of flammable gases / liquids, or in an oxygen rich environment.
- This product should not be immersed in fluid.
- Repairs and modifications to the instrument must be made only by the specialized technicians of the manufacturer's Technical Service Centre or by personnel trained and authorised by the manufacturer. The manufacturer declines any and all responsibility for loss and/or damages resulting from unauthorised repairs; furthermore, any such actions will invalidate the warranty.



- Route power cords safely to eliminate risk of tripping or damage to user.



- Before any cleaning of the instrument or the base unit ensure the power lead is disconnected.



- Do not exceed maximum recommended exposure time.
- Should the instrument suffer shocks (for example, should it accidentally fall), and the optical system or the illumination system are damaged it may be necessary to return the instrument to the manufacturer for repair.

- The owner of the instrument is responsible for training personnel in its correct use.
- Ensure the instrument or instrument table is placed on a level and stable surface.
- Use only genuine Keeler approved parts and accessories or device safety and performance may be compromised.
- Shut down after every use. In cases where the dust cover is used: risk of overheating.
- For indoor use only (protect from moisture).
- Electrical equipment can be affected by electromagnetic interference, for example videostream may freeze for one minute or more. If this occurs whilst using this equipment, switch the unit off and reposition. Essential performance is determined as continuous videostream which cannot be interrupted for longer than one minute.
- Do not touch accessible connectors and the patient simultaneously.
- The Keeler Slit Lamp should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary the Keeler Slit Lamp should be observed/monitored to verify normal operation in the configuration in which it will be used.
- The Keeler Slit Lamp cannot be used in the vicinity of sources known to cause electromagnetic disturbance (magnetic resonance imaging, computed tomography, radio-frequency identification, metal detectors, electronic article surveillance and other electromagnetic security systems). Do not bring the Keeler digital Slit lamp into magnetic resonance environment.

7 CLEANING AND DISINFECTION INSTRUCTIONS



Before any cleaning of the instrument or the base unit, ensure the power lead is disconnected.

Only manual non-immersion cleaning as described should be used for this instrument. Do not autoclave or immerse in cleaning fluids. Always disconnect power supply from source before cleaning.

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

8 TRANSPORT, STORAGE AND WORKING CONDITIONS

The following ambient condition limits are recommended for the Keeler Slit Lamp, for transport and storage it is recommended that the Slit Lamp is kept in its original manufacturers packaging.

WORKING ENVIRONMENT

+10°C to +35°C

30% to 75% relative humidity

TRANSPORT AND STORAGE CONDITIONS

Transport: -10°C to +60°C

Storage: -10°C to +55°C

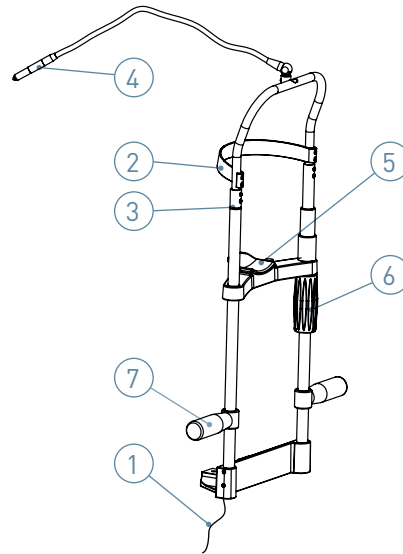


Before use, the Slit Lamp should be allowed to adjust to the ambient room temperature for several hours. This is especially important when the unit has been stored or transported in a cold environment; this can cause severe condensation to develop on the optical elements.

9 NAMES OF CONTROLS AND COMPONENTS

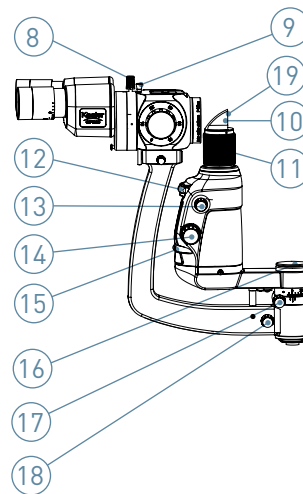
HEADREST ASSEMBLY

1. Fixation light cable
2. Forehead rest band
3. Patient's eye height marker
4. Fixation light
5. Chinrest
6. Chinrest height adjuster
7. Patient grab handles

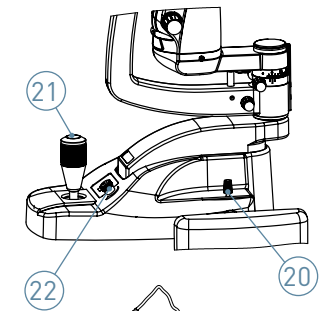


KSL-Z SERIES

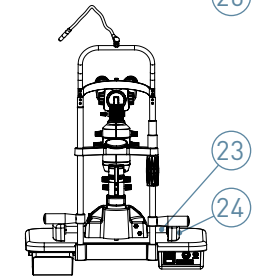
8. Eyepiece assembly securing knob
9. Yellow filter knob (up = out)
10. Illumination prism
11. Slit offset by rotating prism housing
12. Filter control wheel
13. Slit rotation knob
14. Slit width control knob
15. Aperture control wheel
16. Test bar & tonometer plate hole and cover
17. Illumination arm locking knob
18. Microscope arm locking knob
19. Diffuser



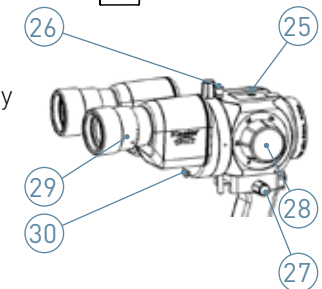
20. Joystick base locking knob
21. Joystick control (X Y Z movement)
22. Illumination control rheostat



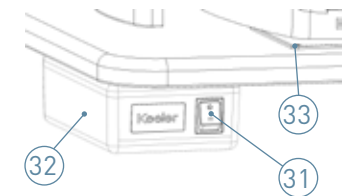
23. Axle
24. Runner covers



25. Z type tonometer mounting hole
26. Yellow filter knob (up = out)
27. Lock for securing magnification body
28. Magnification change drum
29. Eyepieces – adjustable for PD and dioptré correction
30. Breath shield securing knob



31. Main power switch
32. Power supply unit
33. Glide plate



10 ASSEMBLY

Your Keeler Slit Lamp has been designed to fit on to an electric insulated medical table base or on to an electric insulated and fire resistant medical table top, e.g. a Refraction Stand or Combi Unit.

Take care when unpacking your Slit Lamp that you do not accidentally damage or discard any of the contents.



Leave the Slit Lamp in the packing for several hours after delivery before unpacking to reduce the risk of condensation forming.

Keeler Slit Lamps can be fitted to most Refraction Stands / Combi units. Keeler recommends that this be carried out by suitably trained technicians to ensure performance and safety are not compromised.



The Refraction Stand, Combi Unit or table leg must be 60601-1 3rd edition compliant

If you are fitting or have fitted your Slit Lamp to a medical or Keeler table leg/base ensure it is situated on a firm and level floor.

If the table leg/base has castors ensure the following before moving it to another location:

- a) The table is at its lowest position
- b) The power cord is removed
- c) The slit lamp arm and base locking knobs are tightened
- d) The Runner covers are securely located
- e) The system is moved by grasping it at its lowest practical point.

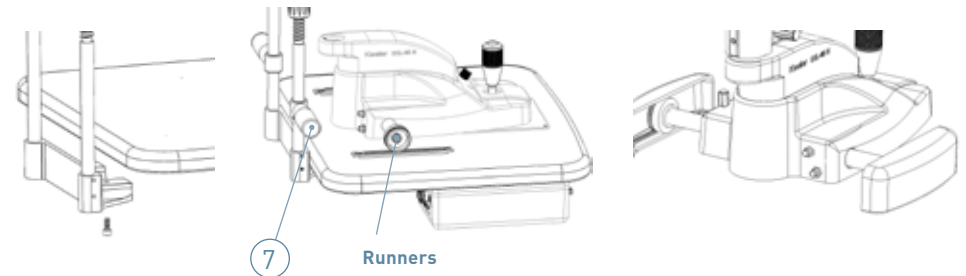
10.1 TABLE TOP AND BASE ASSEMBLY PROCEDURE

- 1 Attach the Slit Lamp table top to your table leg using the M6 x 20mm CAP head fasteners and washers. Note that the power supply and accessory drawer should face the operator.



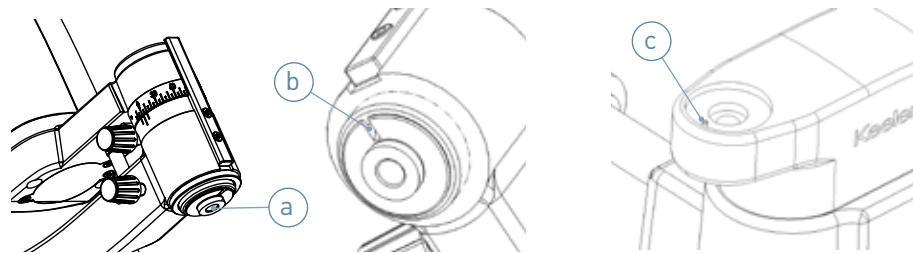
The security of the fitment of the table top to the table leg is critical for patient and Slit Lamp safety

- 2 Using the wrench provided, fit the Headrest Assembly to the tabletop using the hex bolts and washers. The Headrest Assembly locates on the underside of the tabletop. Take care not to over tighten the hex bolts.
- 3 Attach the Patient Grab Handles (7) to the Headrest Assembly.
- 4 Place the Slit Lamp base on the Runners. Ensure that the wheels are in line with each other. Check that the guide wheels are tight.
- 5 Fit the Runner covers to the Runners by gently sliding them inwards, towards each other.

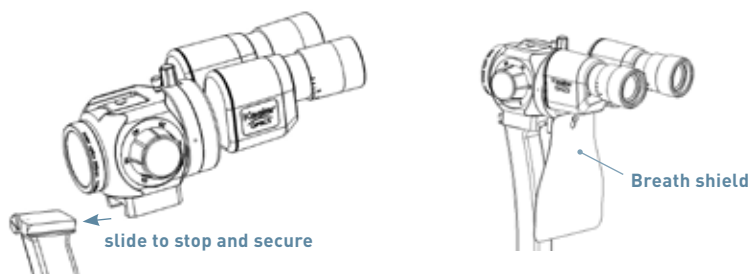


10.2 ILLUMINATION TOWER ASSEMBLY PROCEDURE

- 1 Remove the hex bolt (a) from the base of the Illumination tower, and then place the illumination tower on the Slit Lamp base with the base notch (b) and pin(c) aligned. Attach the tower to the base using the hex bolt removed earlier and tighten using the wrench provided.



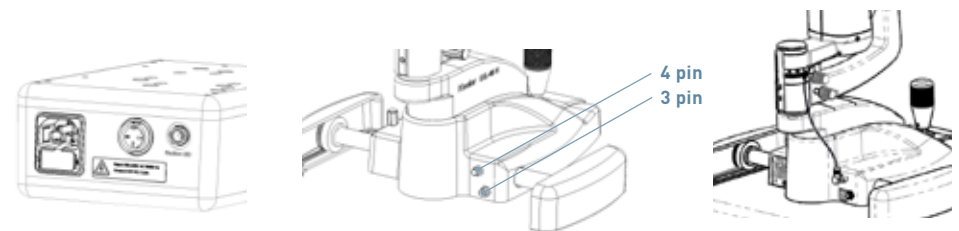
- 2 Carefully fit the microscope body to the arm – ensuring it is pushed to the stop. Tighten using the securing knob on the side.



- 3 Attach the breath shield to the pin on the rear of the magnification assembly.

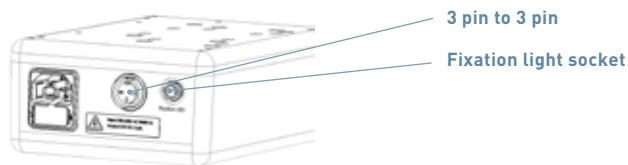
10.3 CABLE ATTACHMENT PROCEDURE

- 1 Connect the power cables
 - a) Chinrest fixation light cable to power supply unit
 - b) (3 pin) cable from power supply unit to slit lamp base assembly
 - c) (4 pin) main lamp cable from bottom of the illumination assembly to the slit lamp base assembly.
 - d) Ensure cables are routed to allow free movement of the XYZ base and to be clear of the patients.



If your Slit Lamp was not supplied with a transformer (Part #3020-P-5040), make sure that the power connection is compatible with the specifications in this manual and is connected by a qualified technician to an available and suitable power supply, see section 15.5 Power Supply

- 2 If the Keeler Slit Lamp is used with a power supply or cables other than those supplied, this may result in increased emissions or decreased immunity of the Keeler Slit Lamp in relation to EMC performance. Neither the power supply nor the cables provided with the Keeler Slit Lamp should be used on other equipment. To do so may result in increased emissions or decreased immunity of the other equipment in relation to EMC performance.
- 3 Connect the mains power to the Slit Lamp transformer using the power lead provided.



- 4 To isolate from the mains supply unpug the mains plug from the wall socket. Ensure that the product is positioned so that it is easily accessible.

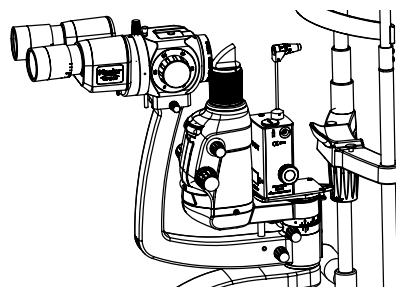
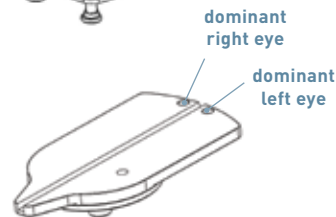
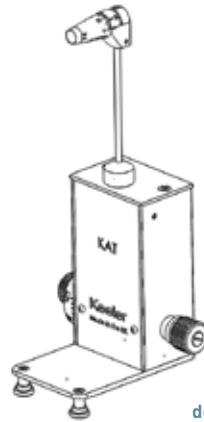


Only a hospital grade 3-conductor electrical power supply cable must be used. For USA and Canada: Detachable power supply cord set, UL listed, type SJE, SJT or SJO, 3-conductor, not smaller than 18 AWG. Plug, cable and ground lead connection of the socket have to be in perfect condition

10.4 FITTING APPLANATION TONOMETERS, T TYPE AND Z TYPES

KEELER APPLANATION TONOMETER (T-TYPE)

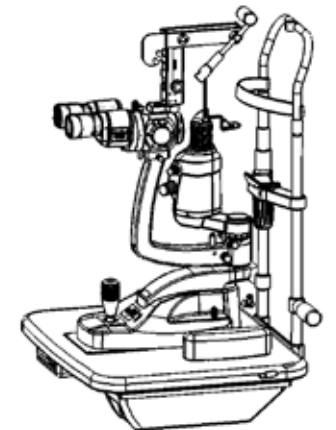
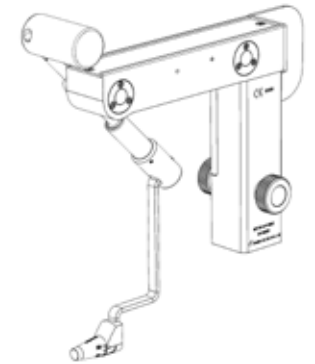
- Position the guide plate in the tonometer/test bar support hole on the slit lamp.
- Lift Tonometer out of the packaging and assemble it by inserting the pin on its base into one of the two possible openings (for right or left eye) on the horizontal guide plate above the slit lamp axis. These positions are related to the microscope optics and observation can be made either through the right or the left eye-piece.
- The tonometer will slip easily onto the support plate; stability is assured by the locking pins.
- To obtain an image as clear and as free of reflexes as possible, the angle between the illumination and the microscope should be about 60° and the slit diaphragm should be fully opened.
- When not in use the Tonometer should be removed from the Slit Lamp and placed securely back in the packaging or a suitable location..



APPLANATION TONOMETER 'KEELER FIXED' (Z-TYPE)

This instrument is for those who wish the tonometer to remain permanently on the slit lamp.

- Mount the plate for the tonometer onto the microscope body using the securing screw.
- Mount the Tonometer onto the mounting post ensuring the grub screws are loose.
- Swing the Tonometer arm forward in front of the microscope for examination. Rotate the Tonometer body until the prism is in the centre of the view through the eyepiece. Carefully tighten the two retaining grub screws in turn until the Tonometer is secure on the mount and the prism is in the centre of view.
- To obtain an image as clear and as free of reflexes as possible, the angle between the illumination and the microscope should be about 60° and the slit diaphragm should be fully opened.
- When not in use the tonometer arm should be swung up against the protection plate



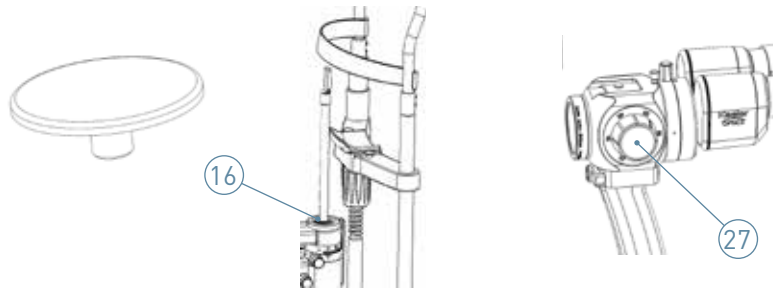
11 INSTRUCTIONS FOR USE

11.1 SETTING THE BINOCULARS

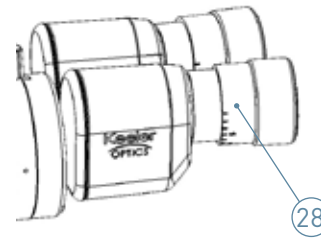


It is vital that the binoculars are optimised for the user's optical correction in order to obtain focused binocular images.

- 1 Remove the Test Bar locating hole cover plate (16) and place the test bar focus in the test bar location hole at the base of the microscope arm. To access the location hole first remove the cover. The test bar should be set with the flat projection face towards the Slit Lamp Microscope. The illumination and the microscope should be in the zero degrees position.
- 2 Turn on the Slit Lamp, and set the slit to full width (14), set the magnification to x16 (27).



- 3 Adjust the eyepieces pupillary distance by holding both eyepiece bodies and rotating them inwards or outwards until they are correct for your PD.
- 4 Turn both eyepieces (28) to maximum plus (+) correction.



- 5 Close one eye, and with the other eye look through the microscope slowly turning the open eye eyepiece towards the minus (-) position until the image of the test bar is in focus. Stop.
- 6 Repeat the above process for the other eyepiece.
- 7 Make a note of the positions of the eyepieces so that you can set them quickly if the Slit Lamp has been used by another clinician.
- 8 Note – younger examiners are recommended to compensate for their ability to accommodate by further adjusting the eyepieces by minus one (-1) or minus two (-2) dioptres.

11.2 PREPARING THE PATIENT AND USING THE SLIT LAMP



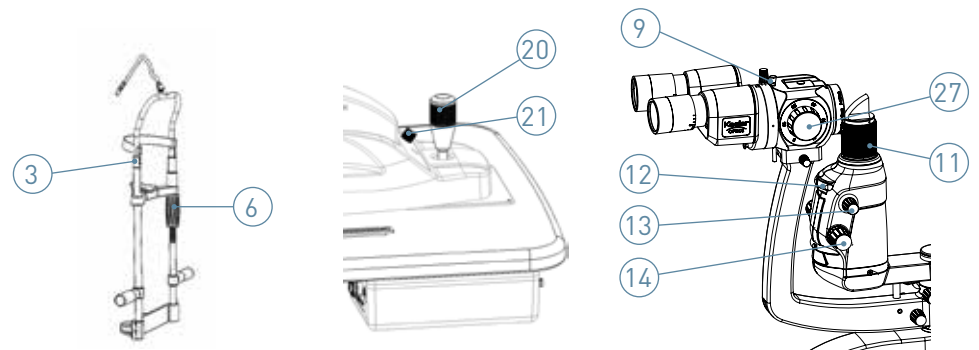
Parts of the slit lamp coming in to contact with the patient should be cleaned in accordance with these instructions prior to the examination. Keeler recommends the use of disposable hygienic chinrest tissues on the Chinrest before the patients place their chin on it.



Never use the instrument if visibly damaged and periodically inspect it for signs of damage or misuse.

- 1 The patient should be as comfortable as possible and with the patient in the chinrest adjust the chinrest height (6) so that the patient's eyes are level with the height marking (3) on the chinrest support.
- 2 Focus the eyepieces using the test bar as described earlier, and if you have not already done so set them to your interpupillary distance by holding both eyepiece bodies and rotating them inwards or outwards until they are correct for your PD.
- 3 Switch on the illumination, making sure the rheostat (21) is set to a low level to minimise the patient's exposure to light hazard.
- 4 Rotate the joystick (20) until the light beam is at eye level.
- 5 Holding the joystick vertical, move the slit Lamp base towards the patient until the slit beam appears focused on the patient's cornea.

- 6 Adjust slit width (14), magnification (27), slit rotation (13) & slit angle etc. as required to perform the examination.
- 7 To offset the slit for sclerotic scatter or retro illumination, rotate the illumination prism assembly (11) to the left or right as desired.
- 8 When using the blue filter (12) the user may wish to insert the yellow barrier filter (9). The yellow barrier filter is out when the knob is up, in when it is down.
- 9 When the examination is complete, set the rheostat to a low level and switch off the Slit Lamp.



Shut down after every use. In case the dust cover is used: risk of overheating.

12 DESCRIPTION OF FILTERS, APERTURES AND MAGNIFICATIONS

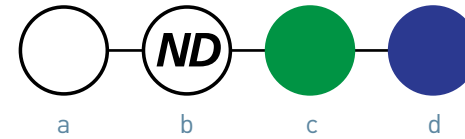
STEREO MICROSCOPE

Eyepieces	12.5x
Dioptic adjustment	+/- 8D
PD range 8° converging eyepieces	49mm – 77mm
PD range 0° parallel eyepieces	38mm – 85mm
Convergent angle of optical axis	13°

Magnification system

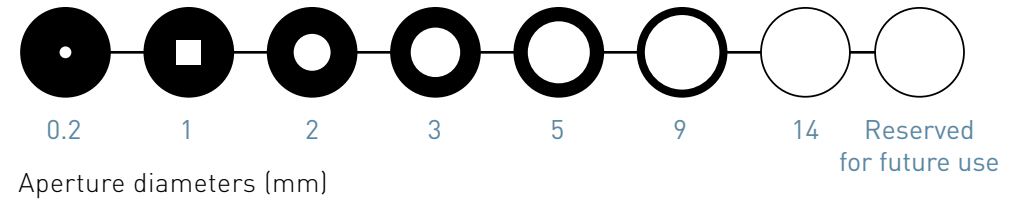
5 step drum	3 step drum	Magnification	Field of view
✓	×	6.3x	34mm
✓	✓	10x	22mm
✓	✓	16x	14mm
✓	✓	25x	8.5mm
✓	×	40x	5.5mm

FILTERS



- a Clear
- b Neutral Density
- c Red Free
- d Blue

APERTURES



13 ROUTINE MAINTENANCE



The maintenance outlined below should only be carried out once the main power cable has been disconnected. If you have any problems that are not covered by the procedures described below, contact Keeler Ltd or your local supplier.

13.1 LED SYSTEMS

LED's typically have a life exceeding 10,000 hours of continuous use and therefore can be considered as a non-consumable item that will not require changing by a user.

Whilst this is a significant life expectancy we suggest that the Slit Lamp is always switched off between examinations to conserve energy and LED life.

In the unlikely event of an LED failure please contact Keeler or your local distributor for guidance on the replacement procedure.

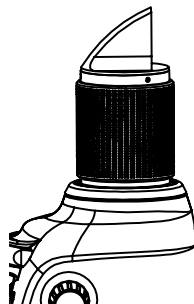
13.2 REGULARLY INSPECT THE DEVICE FOR DAMAGE OR DIRT

Routinely clean as per section 7 Cleaning Instructions.

13.3 CLEANING THE ILLUMINATION PRISM

The prism should be cleaned with a soft clean lens cloth.

Care must be taken to keep the objective and the eyepiece lenses clean – use only soft clean lens cloths to clean optical surfaces.



13.4 ELECTRICAL CONNECTIONS

Routinely check all electrical connections, cables and connectors.

13.5 OPTICS

The optics should be wiped clean of any loose dirt or debris with a suitable dust brush then cleaned with a soft dry lens cloth, washed linen or other non abrasive lens cleaning material.

13.6 AXLE AND MECHANICAL PARTS

If the Slit Lamp becomes hard to move on the glide plate, the plate should be cleaned with a lightly oiled cloth or silicon polish. The axle should be cleaned only with dry lint free cloths.

14 WARRANTY = 3 YEARS

The Keeler Z-Series Slit Lamps are guaranteed for three years (3) against faulty workmanship materials or factory assembly. Warranty is on a Return To Base (RTB) basis at the cost of the customer and may be void if the Slit Lamp has not been regularly serviced.

The manufacturers warranty and terms and conditions are detailed on the Keeler UK website http://www.keeler.co.uk/terms_and_conditions.htm

The mirror, main illumination lamp and general 'wear and tear' are excluded from our standard warranty.



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.

15 SPECIFICATIONS AND ELECTRICAL RATINGS

The Keeler Slit Lamp is a medical electrical instrument. The instrument requires special care concerning electromagnetic compatibility (EMC). This Section describes its suitability in terms of electromagnetic compatibility of this instrument. When installing or using this instrument, please read carefully and observe what is described here.

Portable or mobile-type radio frequency communication units may have an adverse effect on this instrument, resulting in malfunctioning.

15.1 ELECTROMAGNETIC EMISSIONS

Guidance and manufacturer's declaration – electromagnetic emissions

The Keeler Slit Lamp is intended for use in the electromagnetic environment specified below. The customer or user of the Keeler SLit Lamp should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Keeler Slit Lamp uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Keeler Slit lamp is suitable for use in a professional healthcare facility environment. The Keeler Slit lamp is not intended for use in home environment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

15.2 INTERFERENCE IMMUNITY

Guidance and manufacturer's declaration – electromagnetic immunity

The Keeler Slit Lamp is intended for use in the electromagnetic environment specified below. The customer or user of the Keeler Slit Lamp should ensure that it is used in such an environment.


Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD). IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst. IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines N/A	Mains power quality should be that of a typical professional healthcare facility
Surge. IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical professional healthcare facility
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical professional healthcare facility environment. If the user of the Keeler Slit Lamp requires continued operations during power mains interruptions, it is recommended that the Keeler Slit Lamp be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field. IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at a level characteristic of a typical location in a typical professional healthcare facility environment.

Note: U_T is the a. c. mains voltage prior to application of the test level.

15.3 ELECTROMAGNETIC IMMUNITY

Guidance and manufacturer's declaration – electromagnetic immunity

The Keeler Slit Lamp is intended for use in the electromagnetic environment specified below. The customer or user of the Keeler Slit Lamp should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Keeler Slit Lamp, including cables, than the recommended separation distances calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 V	$d = 1.2 \sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m 150kHz to 280MHz	3 V/m	$d = 1.2 \sqrt{p}$ 80MHz to 800 MHz $d = 2.3 \sqrt{p}$ 800MHz to 2.5GHz
			Where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ¹ , should be less than the compliance level in each frequency range. ²  Interference may occur in the vicinity of equipment marked with the this symbol.

Note: At 80MHz and 800MHz, the higher frequency range applies. These guide lines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

¹ Field strengths from fixed transmitters, such as base stations (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Keeler Slit Lamp is used exceeds the applicable RF compliance level above, the Keeler Slit Lamp should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the Keeler Slit Lamp.

² Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3 V/m.

15.4 RECOMMENDED SAFE DISTANCES

Recommended separation distances between portable and mobile RF communications equipment and the Keeler Slit Lamp

The Keeler Slit Lamp is intended for the use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of the Keeler Slit Lamp can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Keeler Slit Lamp as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80MHz $d = 1.2 \sqrt{p}$	80MHz to 800MHz $d = 1.2 \sqrt{p}$	800MHz to 2.5GHz $d = 2.3 \sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80MHz and 800MHz, the separation distance for the higher frequency applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

15.5 TECHNICAL SPECIFICATIONS

OPTICAL SYSTEM

Binoculars type	Galilean 8° converging Galilean 0° parallel
Magnification	Drum change x6.3, x10, x16, x25 & x40 x10, x16 & x25
Eyepiece	x12.5
Field of view	34, 22, 14, 8.5 and 5.5 mm 22, 14 & 8.5mm
PD range	8° converging eyepieces, 49 – 77mm 0° parallel eyepieces, 38 – 85mm
Objective lens focal distance	107mm
Objective lens convergence angle	13°

SLIT PROJECTION SYSTEM & BASE

Slit Width	0 – 14mm continuously variable
Slit Length	14mm
Aperture diameters	0.2, 1mm square, 2, 3, 5, 9, 14 and reserved
Filters	Clear; red free; neutral density; blue;
Slit rotation	360° continuous, detents at 0° and 180°
Base travel	25mm Z-axis, 107mm X-axis, 110mm Y axis
Horizontal fine adjustment	12mm
Table top dimensions	405 x 500mm
Fixation lamp	LED
Light source	LED

WEIGHT, PACKED (APPROX.)

Slit Lamp complete	25Kg, 90 x 58 x 45cm W x D x H
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PROTECTION AGAINST INGRESS IPx0

CLASS II ME EQUIPMENT

Insulation between mains parts and the functional earth provide at least two means of protection.

WEIGHT, PACKED (APPROX.)

LED output power	240k Lux
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POWER SUPPLY

Power supply unit	Switch mode, (100V-240V input) +/- 10% multi plug compliant to EN60601-1 EN 61000-6-2, EN 61000-6-3
Power supply output	12V DC: 2.5 amps must be IEC/EN 60601 compliant
Complies with	Electrical Safety (Medical) BS EN 60601-1 Electromagnetic compatibility EN 60601-1-2 Ophthalmic instruments - Fundamental requirements and test methods ISO 15004-1 Ophthalmic instruments - Optical radiation hazard ISO 15004-2

When the Slit Lamp is connected to the power supply together they constitute a Medical Electrical System as defined in EX 60601-1:2006.

The power supply forms a part of ME equipment.

FUSE RATINGS AND QUANTITY

2.5 amp anti-surge
Fuse current 2.5A
Voltage rating V AC 250V
Breaking capacity 1500Amps
Blow characteristic: Time Delay

ENVIRONMENTAL

	Temperature	Humidity	Pressure
Use	+10°C to +35°C	30% to 90%	800 hpa to 1060 hpa
Storage	-10°C to +55°C	10% to 95%	700 hpa to 1060 hpa
Transport	-10°C to +60°C	10% to 95%	500 hpa to 1060 hpa

APPLIED PARTS

Chinrest
Forehead rest
Grab handles

16 ACCESSORIES AND SPARES

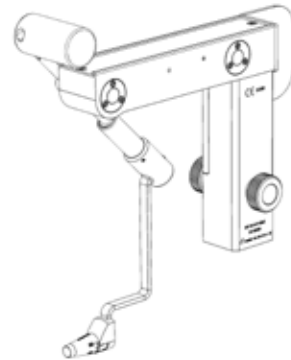
Part name	Part number
Test bar	EP39-80243
	
Dust cover	EP39-80273
Chinrest papers	3104-L-8200
Joystick rubber	EP39-70369
	
Fuse 2.5 amp anti-surge	EP79-80103

SUPPLIED WITH YOUR SLIT LAMP

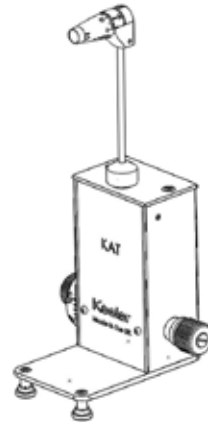
Part name	Part number
Mains Cables – EU	MIS138
Mains Cables – Brazil	3020-P-7007
Mains Cables – Japan	3020-P-7008
Mains Cables – UK	MIS100
Mains Cables – USA	3020-P-7016
Mains Cables – Australia	3020-P-7022
Mains Cables – China	3020-P-7023

ADDITIONAL ACCESSORIES

Part name	Part number
Tonometer Z type	2414-P-2010



Tonometer T type	2414-P-2032
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17 CONTACT, PACKAGING AND DISPOSAL INFORMATION

MANUFACTURER

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Clewer Hill Road
Windsor
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SL4 4AA
UK

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Chao Yang District,
Beijing, 10020
China

Tel +86 (10) 51261868

Fax +86 (10) 58790155

DISPOSAL OF OLD ELECTRICAL AND ELECTRONIC EQUIPMENT

(Applicable in the European Union and other European Countries with separate Collection Systems).



This Symbol on the Product or on its Packaging and instructions indicates that it was put on the market place after August 2005 and 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.

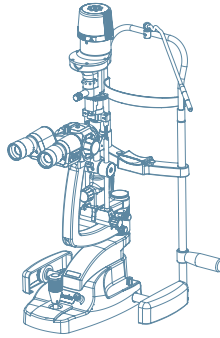
If you need more information on the collection reuse and recycling then please contact B2B Compliance on 01691 676124 (+44 1691 676124). (UK only).

EP59-70043

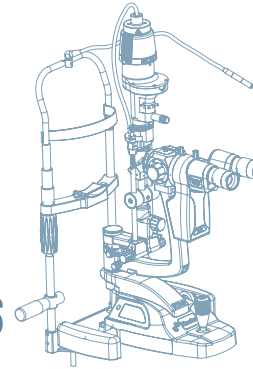
Issue 5

TECHNICAL SPECIFICATIONS

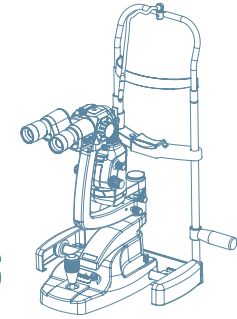
K SERIES



Q SERIES
DIGITAL



Z SERIES



Illumination type	H-type tower illumination		Z-type lower illumination
Binoculars type	Galilean converging binoculars 8° or Galilean 0° parallel		
Eyepiece	12.5x		
Magnification selection	3 or 5 steps by drum rotation		
Magnification ratio Field of view	6x 34mm (5 steps only) 10x 22mm 16x 14mm 25x 8.5mm 40x 5.5mm (5 steps only)		
Interpupillary distance (PD range)	49-77mm		8° converging eye piece: 49-77mm 0° parallel eye piece: 38-85mm
Slit width	0-12mm continuously variable		0-14mm continuously variable
Slit length	0.2, 2, 3, 5, 9 & 12mm circle (1-12mm continuously variable), 1mm square		0.2, 2, 3, 5, 9 & 14mm circle, 1mm square and reserved
Filters	blue, red-free, yellow, clear, neutral density, diffuser IR heat absorbing permanently installed		blue, red-free, yellow, clear, neutral density, diffuser
Slit angle	0-180° continuous		360° continuous
Base travel	107mm X-axis, 110mm Y-axis, 25mm Z-axis		
Fixation lamp	red LED		
Illumination lamp	LED or 6V, 20W halogen lamp	LED or 12V, 30W halogen lamp	LED
Applanation Tonometer	2414-P-2030 KAT T-type 2414-P-2040 KAT R-type 2414-P-2032 DKAT T-type, digital 2414-P-2042 DKAT R-type, digital		2414-P-2010 DKAT, Z-type, digital 2414-P-2032 DKAT, T-type, digital

	EC Declaration of Conformity- Desktop Slit Lamps	Revision: 08
		Review Date: 04/12/2019

Manufacturer: Keeler Ltd.

Address: Clewer Hill Rd., Windsor, Berkshire, SL4 4AA
United Kingdom

Device Name: Keeler Slit Lamp (H-Series, Z series)

Device Classification: Class I

GMDN Classification Code(s) 35148


I, the undersigned, hereby declare that the medical devices specified above and bearing CE marking, conform to the applicable provisions of the Medical Devices Directive (MDD) 93/42/EEC and the transpositions of this amended Directive into national law of the countries of sale.

Keeler hereby certifies that the part numbers listed are in compliance with EU Directive 2011/65/EU (RoHS)

This declaration of conformity is issued under the Sole Responsibility of the manufacturer on the basis of:

- i. Quality Management System Certificate No: LRQ 0943149/E Issued by Lloyds Register Quality Assurance
- ii. Technical File demonstrating conformity with the essential requirements of this Directive and maintained according to MDD Annex VII for devices classified as Class I under MDD Annex IX
- iii. Each device being released to market in accordance with records certifying compliance with applicable product specifications and procedures.

Full Name: Moria Zigman
Position: Senior Regulatory Affairs Officer

Signature: 
Date: 04/12/2018

Keeler Ltd Clewer Hill Road Windsor Berkshire SL4 4AA Tel: +44 (0) 1753 857177 Email: info@keeler.co.uk
Fax: +44 1753 827145 (Customer Services) Fax: +44 (0) 1753 830247 (Manufacturing) **Website:** www.keeler.co.uk

Registered in England No.408759 Registered office: Clewer Hill Road Windsor Berkshire SL4 4AA VAT No. GB 349 0761 40

Description	Part number
SLH 5XC 6V TBL	3020-P-2000
SLH 5XC 12V Di REF	3020-P-2001
SLH 5XC 6V TBL 6V LEG	3020-P-2002
SLH 5XC 6V REF	3020-P-2003
SLH 5XC 12V Di TBL	3020-P-2004
SLH 5XC LED REF	3020-P-2006
SLH 5XC LED TBL	3020-P-2007
SLH 5XC LED Di TBL LEG	3020-P-2008
SLH 5XC LED Di REF ST	3020-P-2009
SLH 5XC LED Di TBL	3020-P-2010
SLH 5XC 6V TBL USA	3020-P-2012
SLH 5XC LED TBL USA	3020-P-2013
SLH 5XC 12V Di TBL USA	3020-P-2014
SLH 5XC LED Di TBL USA	3020-P-2015
SLH 5XC 12V DiR REF	3020-P-2016
SLH 5XC 12V DiR TBL	3020-P-2017
SLH 5XC 12V DiR TBL USA	3020-P-2018
SLH 5XC LED DiR REF	3020-P-2019
SLH 5XC LED DiR TBL	3020-P-2020
SLH 5XC LED DiR TBL USA	3020-P-2021
DSL DIGITAL CAMERA KIT	3020-P-2022
SLZ 3XP REF	3020-P-2023
SLZ 3XP TBL	3020-P-2024
SLZ 3XP TBL USA	3020-P-2025
SLZ 3XP Di REF	3020-P-2026
SLZ 3XP Di TBL	3020-P-2027

SLZ 3XP Di TBL USA	3020-P-2028
SLZ 3XP DiR REF	3020-P-2029
SLZ 3XP DiR TBL	3020-P-2030
SLZ 3XP DiR TBL USA	3020-P-2031
SLZ 5XP REF	3020-P-2032
SLZ 5XP TBL	3020-P-2033
SLZ 5XP TBL USA	3020-P-2034
SLZ 5XP Di REF	3020-P-2035
SLZ 5XP Di TBL	3020-P-2036
SLZ 5XP Di TBL USA	3020-P-2037
SLZ 5XP DiR REF	3020-P-2038
SLZ 5XP DiR TBL	3020-P-2039
SLZ 5XP DiR TBL USA	3020-P-2040
SLZ 3XC REF	3020-P-2041
SLZ 3XC TBL	3020-P-2042
SLZ 3XC TBL USA	3020-P-2043
SLZ 3XC Di REF	3020-P-2044
SLZ 3XC Di TBL	3020-P-2045
SLZ 3XC Di TBL USA	3020-P-2046
SLZ 3XC DiR REF	3020-P-2047
SLZ 3XC DiR TBL	3020-P-2048
SLZ 3XC DiR TBL USA	3020-P-2049
SLZ 5XC REF	3020-P-2050
SLZ 5XC TBL	3020-P-2051
SLZ 5XC TBL USA	3020-P-2052
SLZ 5XC Di REF	3020-P-2053

SLZ 5XC Di TBL	3020-P-2054
SLZ 5XC Di TBL USA	3020-P-2055
SLZ 5XC DiR REF	3020-P-2056
SLZ 5XC DiR TBL	3020-P-2057
SLZ 5XC DiR TBL USA	3020-P-2058
SLH 5XC LED Di – Plate System	3020-P-2082
SLH 3XC LED REF	3020-P-2089
SLH 3XC LED TABLE	3020-P-2090
SLH 3XC LED Di REF	3020-P-2092
SLH 3XC LED Di TABLE	3020-P-2093
SLH 3XC LED DiR REF	3020-P-2095
SLH 3XC LED DiR TABLE	3020-P-2096
SLH 3XP LED REF	3020-P-2098
SLH 3XP LED TABLE	3020-P-2099
SLH 3XP LED Di REF	3020-P-2101
SLH 3XP LED Di TABLE	3020-P-2102
SLH 3XP LED DiR REF	3020-P-2104
SLH 3XP LED DiR TABLE	3020-P-2105
SLH 3XC LED - PLATE SYSTEM	3020-P-2139

Accessories

Description	Part number
Spare bulb	1030-P-7152
Spare bulb	1030-P-7160
Volk Digital Lens Set	2105-L-2010
Tonometer T-Type	2414-P-2030
Keeler Applanation Tonometer (R-Type)	2414-P-2040

DSL User Instruction CD	2415-P-7028
DSL Camera Kit	3020-P-2022
Base Assembly	3020-P-5007
Chinrest Assembly	3020-P-5036
Mains Cable – Brazil	3020-P-7007
Mains Cable – Japan	3020-P-7008
Power Supply to Slit Lamp Base Cable	3020-P-7011
Refraction Stand Cable kit	3020-P-7014
Mains Cable – USA	3020-P-7016
Mains Cable – Australia	3020-P-7022
Mains Cable – China	3020-P-7023
USB A to USB Mini B 0.5m Cable	3020-P-7028
USB 3A to USB 3 Micro B (3m)	3020-P-7029
Kapture Software	1205-P-7012
Keeler Kapture Lite Licence	3020-P-7036
Keeler Kapture Lite Video Licence	3020-P-7037
Keeler Kapture Digital Licence	3020-P-7038
Keeler Kapture Digital Pro Licence	3020-P-7039
Keeler FA Licence	3020-P-7040
Chinrest Papers	3104-L-8200
Chinrest Papers – Single (pk 500)	3104-L-8201
Joystick Rubber	EP39-70369
DSL Illumination Projection Mirror - Long	EP39-80052
Linear Gear Rack	EP39-80173
Linear Gear Rack Cover	EP39-80174
DSL Splash Guard	EP39-80242
DSL Test/Setting Bar	EP39-80243
DSL Illumination Projection Mirror - Small	EP39-80250
DSL Dust Cover	EP39-80273
DSL Table Template	EP39-80324

DSL Digital X-Y Pad	EP39-80364
DSL Digital Left/ Right Label	EP39-80365
Mains Cable – EU	MIS138
Mains Cable – UK	MIS100

EC Certificate Production Quality Assurance System: Certificate GB20/965237

The management system of

Keeler Ltd

Clewer Hill Road, Windsor, Berkshire, SL4 4AA, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex V

For the following products

**Applanation Tonometer to aid diagnosis
and measurement of intraocular pressure**

**Disposable Applanation Tonometer Cone
for use in testing of intraocular pressure**

Disposable Cryo Probe for use with Ophthalmic Surgery Devices

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 28 February 2020 until 30 September 2022
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 08 September 2009
and first certified by SGS Belgium NV since 28 February 2020

Certification is based on reports numbered GB/PC/ 240569

Authorised by

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp, Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5008 - Certificate CE1639 Annex V, EN rev. 01

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Certificate GB19/964765

The management system of

Keeler Ltd

Clewer Hill Road, Windsor, Berkshire, SL4 4AA, UK

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016



For the following activities

**Design, Development and manufacture, distribution & service
of Optometric and Ophthalmic medical devices and equipment.**

This certificate is valid from 02 December 2019 until 31 October 2022
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 04 September 2022

Issue 1. Certified since 10 September 1995

Authorised by

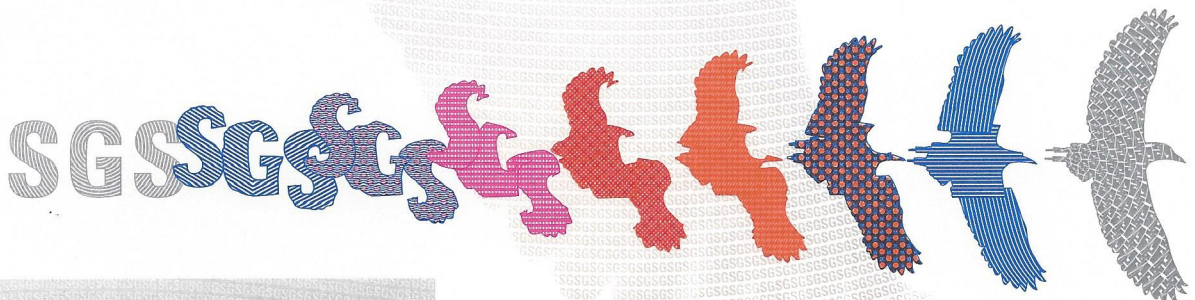
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HC SGS 13485 2016 0118

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