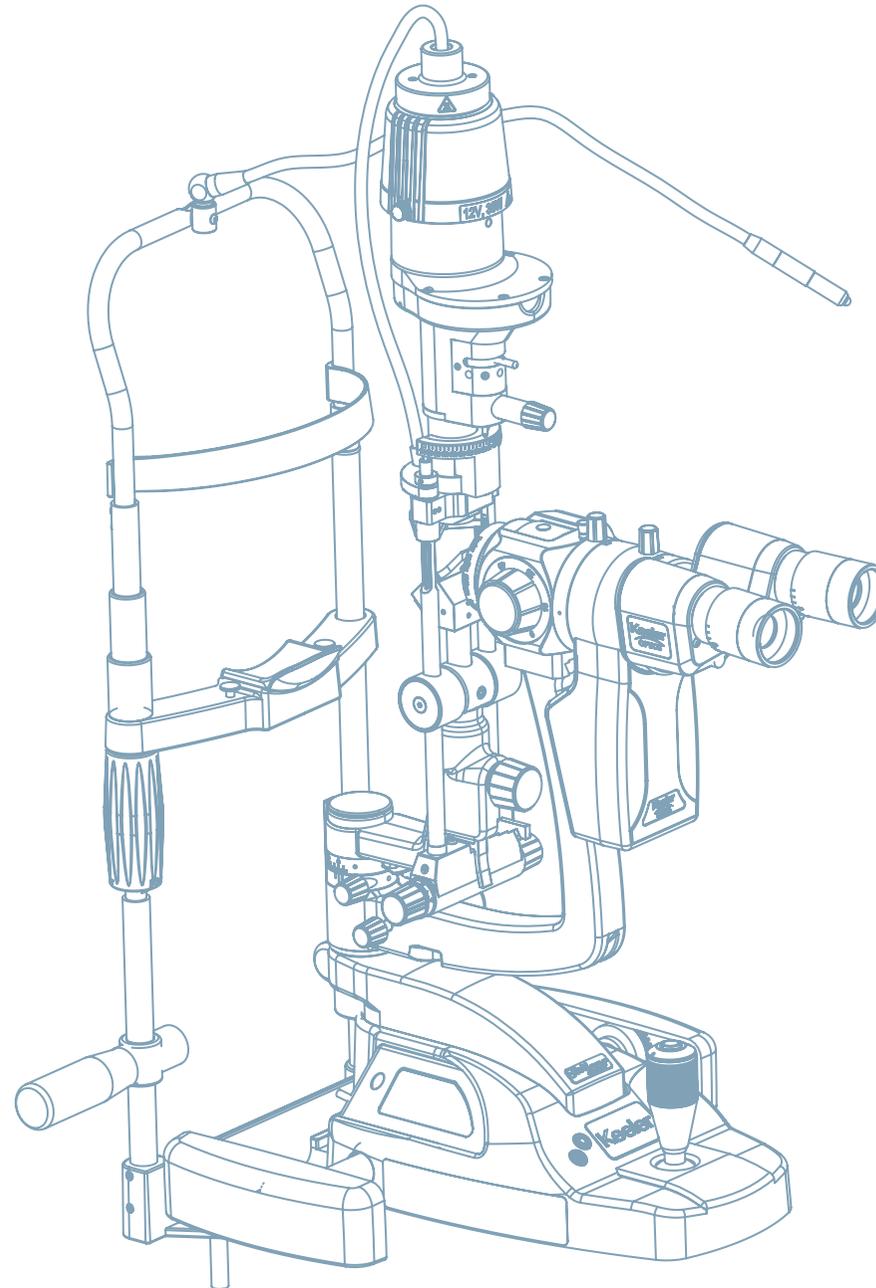


# SLIT LAMP

## INSTRUCTIONS FOR USE

Digital IFU supplement  
H Series



*Slitlamp*  
by Keeler

**Keeler**

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# CONTENTS

Please click on the contents to go straight to your chosen section or navigate by using the 'Next' and 'Back' buttons to the right. Clicking on 'Home' will bring you back to this page.

Introduction	2
Symbols used in these Instructions for Use and the Slit Lamp packaging	3
Indications for use Intended use/purpose of instrument Brief description of the instrument	4
Safety	5
Cleaning and disinfection instructions Transport, storage and working conditions	7
Installation and setup of digital unit	8
Controls	11
Electromagnetic emissions	12
Technical Specification	14
Contact, packaging and disposal Information	15

# 1 INTRODUCTION

Thank you for choosing this Keeler product.

These Instructions for Use are aimed solely at hardware installation on the slit lamp of the digital camera assembly (DCA), which to display captured images needs to be used in conjunction with CE compliant or FDA cleared imaging software installed on a medically approved PC. For detailed instructions on use of the Keeler Desktop Slit Lamp please refer to the Slit Lamp Manual EP59-70040.



**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.**

**This manual should be read in conjunction with the Keeler Slit Lamp IFU (EP59-70040). Contact your distributor if do not have a copy of this IFU.**

## 2 SYMBOLS USED IN THESE INSTRUCTIONS FOR USE AND THE PACKAGING OF THE UNIT:



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 its Packaging and instructions indicates it was put on the market place after August 2005 and this product shall not be treated as Household Waste



Operating Instructions



Exposure +



Exposure -



PC connection



Camera connection

### 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. The digital camera allows pictures to be captured of this pathology.

### 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 Digital Slit Lamp consists of multiple subassemblies; Illumination Tower; Observation System; XYZ Translation Base; Chinrest Assembly, Digital Camera Assembly and a Table Top with Power Supply and Accessory Drawer, (not applicable to the refraction stand unit)

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.

The digital module is fitted between the magnification drum and viewing optics and is used to capture an image of the patients pathology

**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: H-series - Safety Class II  
Application 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

### 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. In addition there is an infra red filter incorporated in the illumination system to reduce IR light levels.



**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 safety guideline after a period of 11 minutes when using the ancillary 90D lens and 45 minutes when not.**

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

## 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.
- 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 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.



- Bulbs can reach high temperatures in use – allow to cool before handling.



- Duty Cycle 50% in 6 mins 12V bulb unit only.



- 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.
- Care should be taken when handling halogen bulbs. Halogen bulbs can shatter if scratched or damaged.
- After removal of the bulb, do not touch the Slit Lamp bulb electrical contacts and patient simultaneously.
- 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 case the dust cover is used: risk of overheating.
- For indoor use only (protect from moisture).
- Electrical equipment can be affected by electromagnetic interference. If this occurs whilst using this equipment, switch the unit off and reposition.
- Do not touch accessible connectors and the patient simultaneously.
- Keeler digital DSL is not intended to be used with wireless technology. Do not plug a wireless dongle into USB port. It is advisable to disable wireless technology on the computer to prevent unauthorised access to the camera.
- Keeler digital DSL cannot be used in the vicinity of known sources of electromagnetic interference (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 leads and USB cables are 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: -40°C to +70°C

Storage: -10°C to +55°C



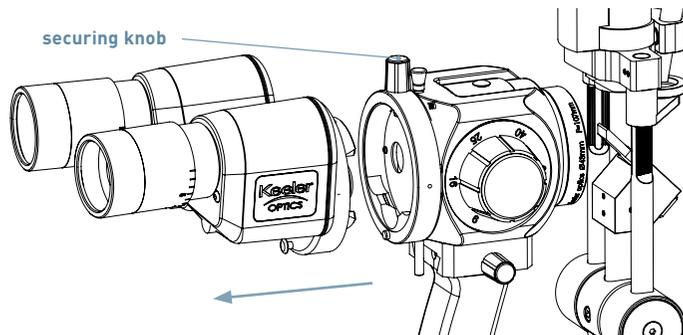
**Before use, the Slit Lamp should be allowed to adjust to the ambient room temperature for several hours. This is especially important when the unit has been stored or transported in a cold environment; this can cause severe condensation to develop on the optical elements.**

## 9 INSTALLATION OF DIGITAL UNIT

For 'Digital Ready' variants of the Keeler Slit Lamp a Digital Camera Assembly (DCA) must be purchased separately, contact Keeler or your local distributor for details.

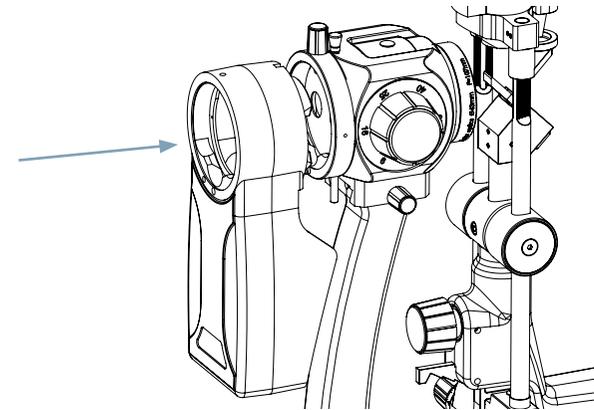
Set up the Slit Lamp as directed in the Instructions For Use (IFU) EP59-70040, Contact your distributor if you are unable to locate a copy of these Instructions.

- 1 Install the Digital Camera Assembly (DCA) - carefully remove the eyepiece assembly from the magnification block by unscrewing the securing knob at the same time as supporting the eyepieces. The eyepieces assembly is a dovetail type fit to the magnification block.

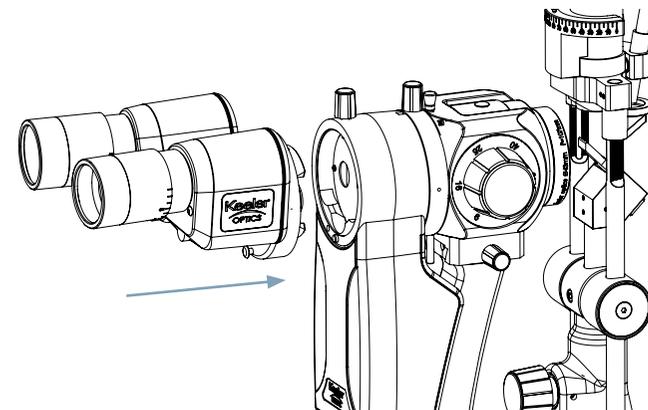


**Care must be taken to avoid getting any dirt or dust on any of the optical components.**

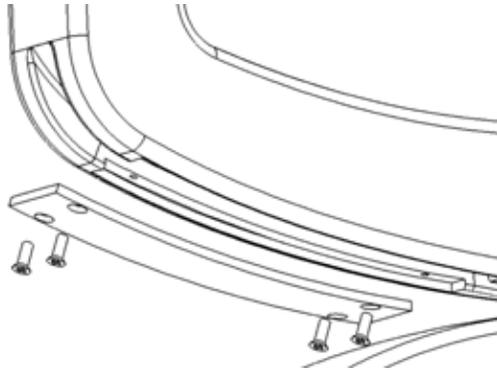
- 2 Fit the digital camera assembly to the rear of the magnification block and tighten the securing knob to hold it in place.



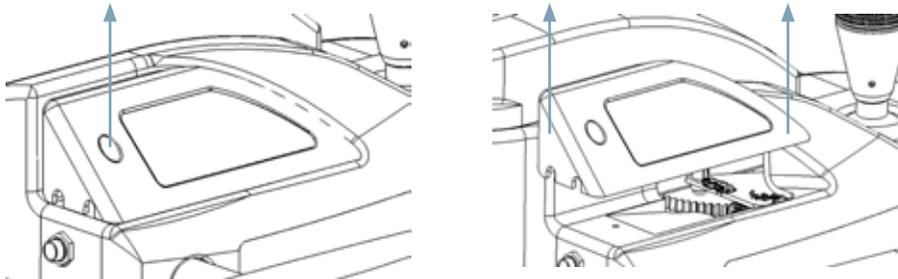
- 3 Re-fit the eyepiece assembly to the rear of the DCA and secure it by tightening the securing knob.



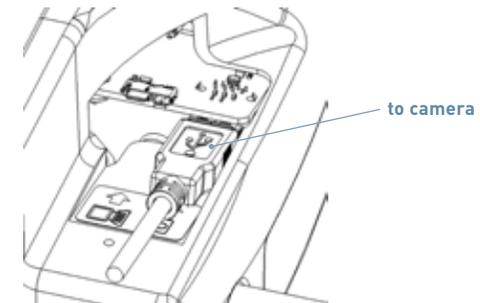
- 4 Rotate the swing arm to either side of the unit, and with a suitable philips screw driver remove the cable channel cover plate.



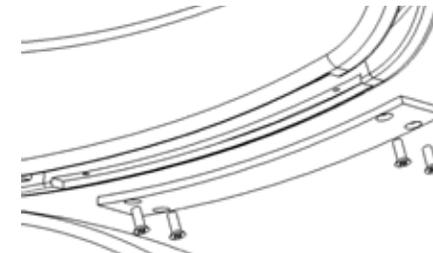
- 5 Remove the cover to the USB hub on the Slit Lamp base by undoing the small Phillips head screw and lifting off the cover.



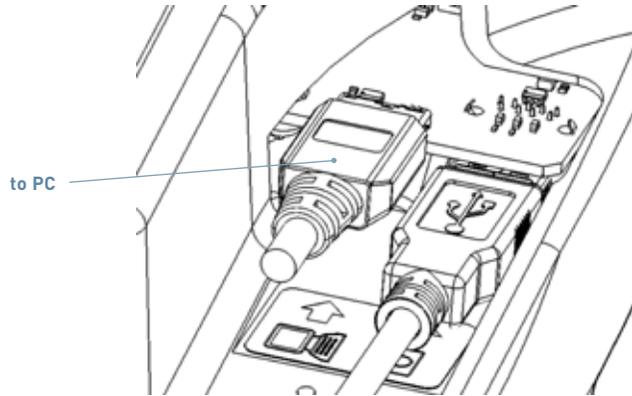
- 6 Connect the shorter USB cable (3020-P-7028) to the socket on the underside of the DCA and to the appropriate socket on the USB hub located on the Slit Lamp base. Ensure that there is plenty of slack at the USB hub end to allow Slit Arm rotation.



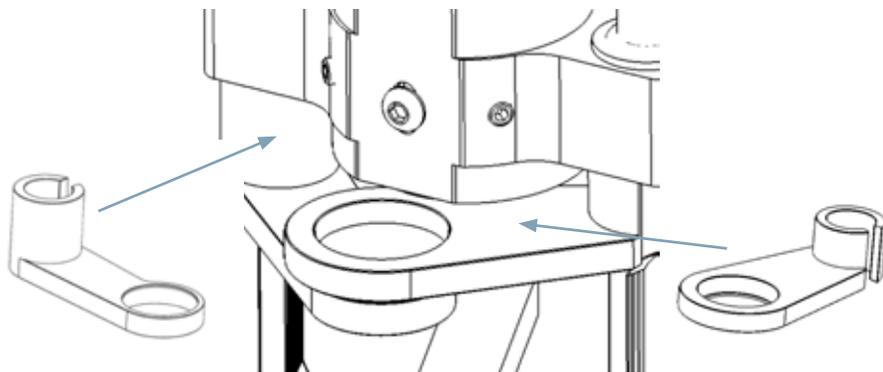
- 7 Route the cable in the groove in the Slit Lamp arm and replace the cover plate.



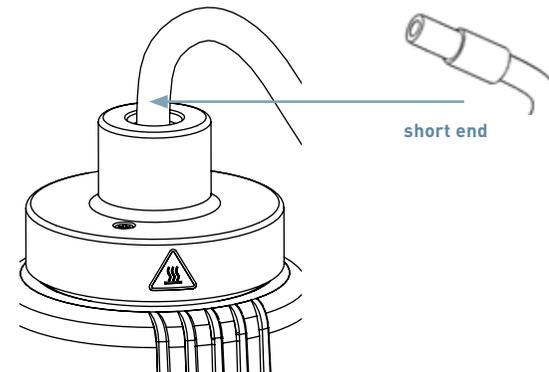
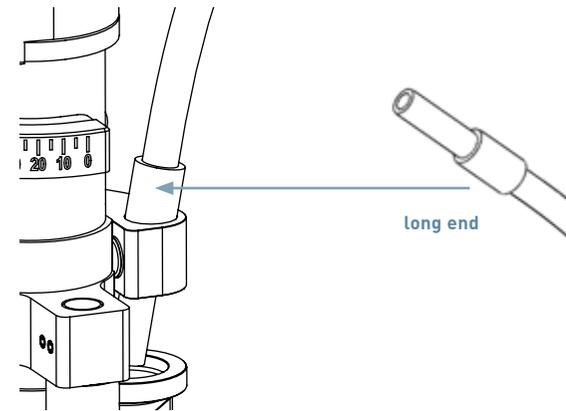
- 8 Connect the longer USB cable for connection to the PC to the hub and replace the USB hub cover plate, this secures the cables.



- 9 Clip the auxiliary diffuser and blue filter in place on the Slit Lamp tower upright posts, above the level of the mirror. Align the slot to the flattened post section.



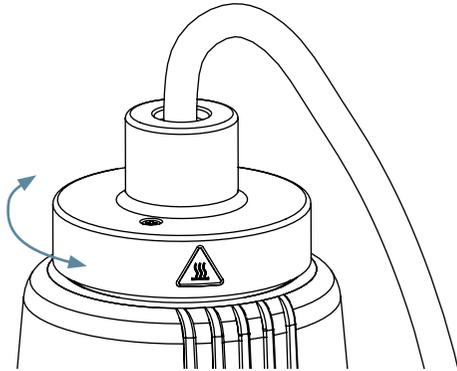
- 10 Fit the background illumination fibre optic cable, The short end to the top of the lamp housing, the long end to the fibre optic swing arm adjacent to the mirror.



- 11 If CE compliant or FDA cleared imaging software has been installed, connect the PC USB cable to the PC.

## 10 CONTROLS

### BACKGROUND ILLUMINATION ADJUSTMENT

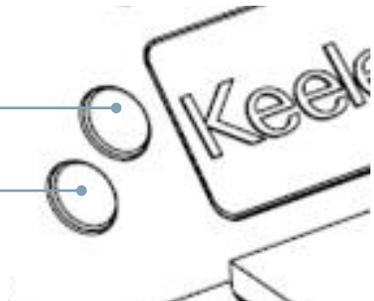


### EXPOSURE AND REVIEW BUTTONS

Pressing these buttons provides adjustment of the camera exposure

Increase exposure time (milliseconds)  
Review freeze frame images forwards

Decrease exposure time (milliseconds)  
Review freeze frame images backwards

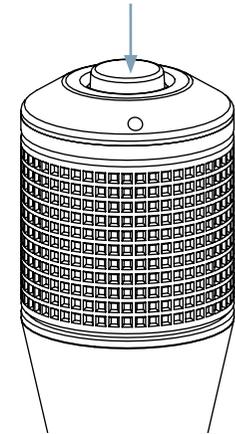


### CAPTURE BUTTON

Press once to 'freeze frame'

Use image review buttons to select best frame

Press again to capture selected frame



### KEYBOARD SHORTCUTS

Ctrl + Alt + :

F6 Left eye

F7 Right eye

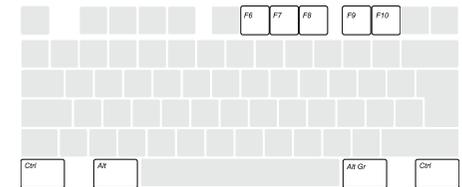
F8 Freeze frame / Trigger

F9 Longer exposure time

F9 Review freeze frame images forwards

F10 Shorter exposure time

F10 Review freeze frame images backwards



### DIGITAL ACCESSORIES/SPARES

USB Cable camera to hub 3020-P-7028

USB cable hub to PC 3020-P-7029

External illuminator 3020-P-5039

Auxiliary diffuser 3020-P-7034

Auxiliary blue filter 3020-P-7035

# 11 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 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.
Harmonic emissions IEC 61000-3-2	Class A	The Keeler Slit lamp is not intended for use in home environment.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

## 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 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 6100-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	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.
Electrical fast transient/burst. IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for power supply lines	± 2 kV for power supply lines ± 1 kV for power supply lines	Mains power quality should be that of a typical professional healthcare facility environment.
Surge. IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) for input/output line(s)	± 1 kV line(s) to line(s) ± 2 kV line(s) for input/output line(s)	Mains power quality should be that of a typical professional healthcare facility environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% $U_T$ {> 95% dip in $U_T$ } 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 $U_T$ } 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 instrument 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.

## 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 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.
			<b>Recommended separation distance</b>
Conducted RF IEC 61000-4-6	3 Vrms	3 V	$d = 1.2 \sqrt{p}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	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 <sup>1</sup> , should be less than the compliance level in each frequency range. <sup>2</sup>
			 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.

<sup>1</sup> 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.

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

## Recommended separation distances between 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 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)		
	50 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
0.01	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
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.

## 12 TECHNICAL SPECIFICATION

### DIGITAL SYSTEM CAMERA

<b>Camera</b>	Resolution 1600 x 1200 Pixel Class: 2 MPixel Sensor size: 1/1.8" Sensor Technology: CCD
<b>PC Specification</b>	Medically approved PC CPU: Intel Core 2 Duo 2.33GHz or higher Memory: 1Gb RAM or higher USB port: 2.0 or higher Hard disk speed 5200 rpm or higher Operating system: Microsoft Windows XP Service pack 3 or higher, Windows 7/8 32-Bit or 64 Bit
<b>Software requirements</b>	CE compliant or FDA cleared camera imaging software

### WEIGHT, PACKED (APPROX.)

<b>Slit Lamp with chinrest</b>	20.0Kg, 75 x 54 x 45cm W x D x H
<b>Table top with PSU &amp; Acc drawer</b>	5.2Kg, 51 x 42 x 15cm W x D x H

### PROTECTION AGAINST INGRESS IPx0

### CLASS II ME EQUIPMENT

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

### SYSTEM COMPONENTS

	Part number
<b>Slit Lamp 40HDi, Standard complete with Table Top</b>	3020-P-2004
<b>Slit Lamp</b>	3020-P-5030
<b>PSU</b>	3020-P-5020
<b>Slit Lamp 40HDi, Refraction stand unit</b>	3020-P-2001
<b>Slit Lamp</b>	3020-P-5030
<b>PSU</b>	3020-P-5020
<b>Slit Lamp 40HDi, Refraction Stand Unit (US Market only)</b>	3020-P-2014
<b>Slit Lamp</b>	3020-P-5030
<b>PSU</b>	3020-P-5020

### POWER SUPPLY

	Part number
<b>Power supply unit</b>	Switch Mode, (100V-240V input) +/- 10% multi plug compliant to EN60601-1 EN 61000-6-2, EN 61000-6-3
<b>Power supply output</b>	24V DC: 2.2 amps must be IEC/EN 60601 compliant
<b>Complies with</b>	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

### ENVIRONMENTAL

	Temperature	Humidity	Pressure
<b>Use</b>	+10°C to +35°C	30% to 90%	800 hpa to 1060 hpa
<b>Storage</b>	-10°C to +55°C	10% to 95%	700 hpa to 1060 hpa
<b>Transport</b>	-40°C to +70°C	10% to 95%	500 hpa to 1060 hpa

## 13 CONTACT, PACKAGING AND DISPOSAL INFORMATION

### MANUFACTURER

Keeler Limited  
Clewer Hill Road  
Windsor  
Berkshire  
SL4 4AA

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**Fax** +44 (0) 1753 827145

### USA SALES OFFICE

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**Tel** 1 610 353 4350

**Fax** 1 610 353 7814

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Andheri (East) Mumbai – 400072  
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**Fax** +91 (99303) 11090

### CHINA OFFICE

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1012B,  
KunTai International Mansion,  
12B ChaoWai St.  
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).**

EP59-70041

Issue 4

Keeler