

# Spectra Iris

Indirect Ophthalmoscope

INSTRUCTIONS FOR USE



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	Consult instructions for use		General warning sign
	Date of manufacture		Warning: Electricity
	Manufacturer's name and address		Warning: Floor level obstacle
	Country of manufacture		Warning: Non-ionizing radiation
	Waste Electrical and Electronic Equipment (WEEE) recycling		Warning: Optical radiation
	This way up		Warning: Hot surface
	Keep dry		Conformité Européene
	Fragile		Type B applied part
	Do not use if package is damaged		Class II equipment
	Temperature limit		Atmospheric pressure limitation
	Authorised representative in the European Community		Humidity limitation
	Use-by date		Serial number
	Catalogue number		Medical device
	Translation		

The Keeler Spectra Iris is 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

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

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## 1. INDICATIONS FOR USE

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.**

### Intended use / purpose of instrument

The Spectra Iris is indicated for examining the fundus; specifically the posterior segment where a wider field of view is needed in order to aid in the screening and diagnosis of retinal pathology including, but not limited to, lesions such as choroidal melanomas, papilloedema, retinopathy of prematurity, glaucomatous disc cupping, diabetic retinopathy, hypertensive retinopathy, retinal detachments and also help the practitioner to better understand where the lesion is located on the retina in relation to anatomical features such as the disc.

## 2. SAFETY

### 2.1 PHOTOTOXICITY



**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 safety guideline after 3 hours 24 minutes. Testing was completed with a 20D, 55mm diameter Volk lens.**



**While no acute optical radiation hazards have been identified for slit lamps, we recommend keeping the intensity of the light reaching the patient's retina to the minimum possible for the respective diagnosis. Children, people with aphakia and people suffering from eye conditions are most at risk. An increased risk may also occur if the retina is exposed to the same or a similar device with a visible light source within 24 hours. This applies, in particular, if the retina has been photographed with a flashbulb in advance.**

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

### 2.2 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. The use of other accessories may result in increased electromagnetic emissions or reduced electromagnetic immunity of the device and may lead to incorrect operation.

Observe the following precautions in order to ensure safe operation of the Spectra Iris.

**WARNINGS**

- Do not use if the product is 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 fluids.
- Do not disassemble or modify the battery. There are no serviceable parts inside.
- Do not dispose of battery in fire, puncture or short circuit.
- Do not use a battery that is deformed, leaking, corroded or visually damaged. Handle a damaged or leaking battery with care. If you come into contact with electrolyte, wash exposed area with soap and water. If it contacts the eye, seek medical attention immediately.



- Do not fit mains power adapter into a damaged mains outlet socket.



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



- Do not exceed maximum recommended exposure time.



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



- After removal of the LED do not touch the LED contacts and the patient simultaneously.

**CAUTION**

- Refraction stand variants or adaptors should only be used in combination with EN/IEC 60601-1 and EN/IEC 60601-1-2 compliant power supplies and devices.
- Use only genuine Keeler approved parts and accessories or device safety and performance may be compromised.
- Use only Keeler approved batteries, chargers and power supplies as per the accessories listed in section 8.
- 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).
- When replacing lithium battery pack, turn Spectra Iris off and attach new pack.
- Remove battery pack when device may not be used for prolonged periods.
- Do not charge battery in any environment where the temperature may exceed 40°C or fall below 0°C.
- There are no user serviceable parts inside. Contact authorised service representative for further information.
- Ensure battery orientation is correct, or personal injury / damage to equipment may occur.
- Ensure device is securely held in docking station to minimise risk of injury or damage to equipment.
- Follow guidance on cleaning / routine maintenance to prevent personal injury / damage to equipment.



- Switch off the electrical supply and disconnect from the mains electrical supply before cleaning and inspection.



- At product end of life dispose of in accordance with local environmental guidelines (WEEE).

- Dispose of batteries in line with local environmental regulations.

Note: Lithium Ion batteries contain no toxic heavy metals such as mercury, cadmium or lead.

## 2.3 CONTRAINDICATION

There is no restriction to patient population this device can be used with other than those outlined in the contra-indications stated below.

Whilst BIO using a head mount can be performed through an undiluted pupil, the field of view and magnification can be greatly compromised; therefore, pupillary dilation using mydriatics is recommended in practice. Optometrists regularly perform pupil dilation to comprehensively examine the ocular fundus as part of a comprehensive eye health examination where clinically indicated. Furthermore, in order to gain a more peripheral view of the retina, scleral indentation is performed as an adjunct to BIO when using a head mount.

## 3. CLEANING AND DISINFECTION INSTRUCTIONS



**Always disconnect power supply from source before cleaning.**

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

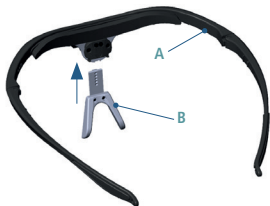
1. Wipe the external surface with a clean absorbent, non-shedding cloth dampened with a de-ionised water / detergent solution (2% detergent by volume) or water / isopropyl alcohol solution (70% IPA by volume). Avoid optical surfaces.

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.

## 4. SETTING UP AND USING THE SPECTRA IRIS

### 4.1 FRAME (A), NOSE BRIDGE (B)

1. The nose bridge is fitted by sliding into the slot as shown.
2. As the nose bridge slides into the slot a sprung catch will engage with the dimples on the nose bridge. This is to allow a range of adjustment to suit the users requirements.



3. The prescription lens frame (if required) is fitted.
4. The prescription lens frame (if required) and shield are fitted as shown below.



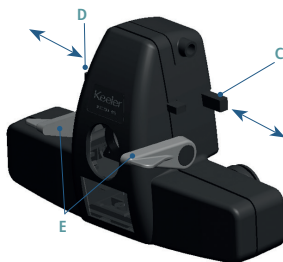
Prescription lens frame in correct position

- Fit the Spectra Iris head unit into the frame (A) via the pin mounting system.
- Once the desired position has been confirmed this can be locked more securely in position by gently tightening the screws circled.



**Please note: Care must be taken not to overtighten the screws during this process, or the equipment may be damaged.**

#### 4.2 APERTURE LEVER (C)






By sliding the lever (C) in direction of the arrows, the size of the aperture can be adjusted. Slide to the right to increase aperture size, to the left to decrease. Refer to the white dots located on the top of the lever, as per image below.



#### 4.3 FILTER SELECTION CONTROL (D)

By sliding the lever (D) in direction of the arrows, different filters can be selected.

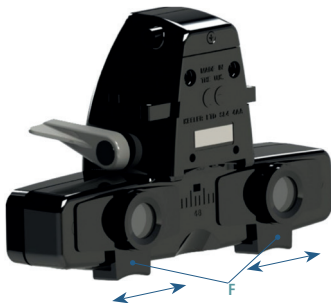
-  **Clear** Select the clear with no filter when inspecting a specific pathology and a brighter, whiter light is desired.
-  **Green** Red-free filter reduces the red light, so blood will appear black, silhouetted against a dark background.
-  **Blue** Cobalt blue for fluorescein angiography.

#### 4.4 MIRROR ANGLE CONTROL (E)

The light is positioned vertically into the field of view by rotation of the levers (E) located either side of the binocular block.

#### 4.5 INTERPUPILLARY DISTANCE SETTING CONTROL (F)

Place an object approximately 40cm from the face and centre it horizontally in the light patch. Then, close one eye. Using the thumb and forefinger of the opposite hand, slide the P.D.Control (F) of the open eye (located directly under each eyepiece) so that your object moves into the centre of the field, keeping the object in the centre of the light patch. Repeat for the other eye.



### 5. CHARGER – POWER SUPPLY ASSEMBLY

#### 5.1 SET PLUG

Replace the blanking plate with the appropriate mains plug adaptor if required, or use IEC 60320 TYPE 7 connector (not supplied).

### 6. CHARGER – LITHIUM BATTERY

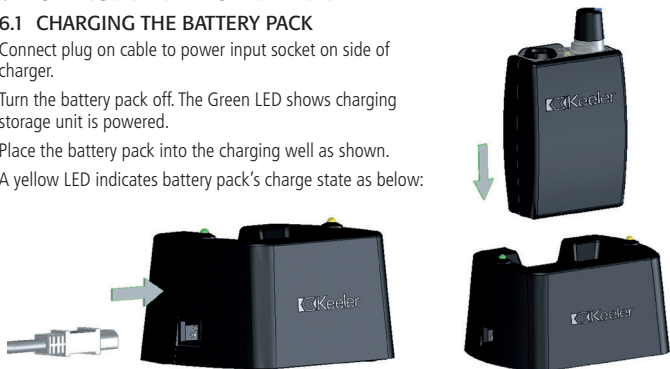
#### 6.1 CHARGING THE BATTERY PACK

Connect plug on cable to power input socket on side of charger.





Turn the battery pack off. The Green LED shows charging storage unit is powered.

Place the battery pack into the charging well as shown.

A yellow LED indicates battery pack's charge state as below:



## Charging the battery pack

-  **Green LED**                      Charging storage unit powered
-  **No LED light**                      Battery charged
-  **Flashing yellow LED**              Top-up charge
-  **Solid yellow LED**                      Rapid charge

The battery pack can be used at any time during the charging cycle and will resume charging when battery pack is placed back in the charger.


## 6.2 CHARGING TIME

The battery will take approximately 3 hours to fully charge. The battery will last approximately 4 hours on full power.

Turn the illumination on by rotating the dimmer control knob in an anti-clockwise direction.

A yellow LED indicates battery pack's charge state as below:



-  **Flashing yellow LED**  
Battery requires charging

Insert connector in socket as shown. To remove the lead pull in the direction of the arrows on the connector do not twist or unscrew

## 6.3 BELT CLIP

The belt clip can be used for those who prefer to carry the unit on a belt.

## 7. SPECIFICATIONS AND ELECTRICAL RATINGS

The Keeler Spectra Iris 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 these instruments, resulting in malfunctioning.

Keeler Spectra Iris and K-LED are designed with similar electrical systems and therefore share EMC characteristics and cautions.

### 7.1 ELECTROMAGNETIC EMISSIONS

#### Guidance and manufacturer's declaration – electromagnetic emissions

The Keeler Spectra Iris 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
K-LED/ Spectra Only	RF emissions CISPR 11	Group 1	The Keeler Spectra Iris and K-LED use 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	
Harmonic emissions IEC 61000-3-2		Class A	The Keeler Spectra Iris and K-LED are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions IEC 61000-3-3		Complies	
Charger only	RF emissions CISPR 14-1	Complies	The Keeler Spectra Iris and K-LED is not suitable for interconnection with other equipment.

### 7.2 ELECTROMAGNETIC IMMUNITY

#### Guidance and manufacturer's declaration – electromagnetic immunity


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

Immunity test	IEC 55015 Test level	Compliance level	Electromagnetic environment – guidance
K-LED/Spectra Only			
Electrostatic discharge (ESD). IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 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%.

Immunity test	IEC 55015 Test level	Compliance level	Electromagnetic environment – guidance
Power frequency (50/60 Hz) magnetic field. IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at a level characteristic of a typical location in a typical commercial or hospital environment.
<b>Charger only</b>			
Electrical fast transient/burst. IEC 61000-4-4	± 1 kV for power supply lines ± 1 kV for input/output lines	± 1 kV for power supply lines N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge. IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% $U_T$ (> 95% dip in $U_T$ ) for 0.5 cycles 40% $U_T$ (60% dip in $U_T$ ) for 10 cycles 70% $U_T$ (30% dip in $U_T$ ) for 25 cycles	<5% $U_T$ (> 95% dip in $U_T$ ) for 0.5 cycles 40% $U_T$ (60% dip in $U_T$ ) for 10 cycles 70% $U_T$ (30% dip in $U_T$ ) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Keeler Spectra Iris requires continued operation during power mains interruptions, it is recommended that the charger be powered from an uninterruptible power supply.

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

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
<b>Charger only</b>			Portable and mobile RF communications equipment should be used no closer to any part of the Keeler Spectra Iris, including cables, than the recommended separation distances calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 230 MHz	3 V	
<b>Spectra/K-LED only</b>			<b>Recommended separation distance</b>
Radiated RF IEC 61000-4-3	10V/m 80MHz to 2.7GHz	10 V/m	$d = 1.2 \sqrt{p}$ $d = 1.2 \sqrt{p}$ 80MHz to 800MHz $d = 2.3 \sqrt{p}$ 800MHz to 2.7GHz 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).

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
			<p>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>.</p> <p> Interference may occur in the vicinity of equipment marked with the this symbol.</p>

Note 1: At 80MHz and 800MHz, the higher frequency range applies.

Note 2: 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 Spectra Iris is used exceeds the applicable RF compliance level above, the Keeler Spectra Iris 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 Spectra Iris.

<sup>2</sup> Over the frequency range 150kHz to 230 MHz, field strengths should be less than 3 V/m.

### 7.3 RECOMMENDED SAFE DISTANCES

#### Recommended separation distances between portable and mobile RF communications equipment and the Keeler Spectra Iris.

The Keeler Spectra Iris is intended for the use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Keeler Spectra Iris can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Keeler Spectra Iris 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 230MHz $d = 1.2\sqrt{p}$	80MHz to 800MHz $d = 1.2\sqrt{p}$	800MHz to 2.7GHz $d = 2.3\sqrt{p}$
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: 1 At 80MHz and 800MHz, the higher frequency range applies.

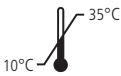

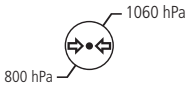
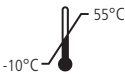
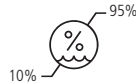


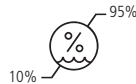
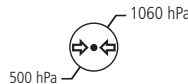
Note 2: These guide lines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## 7.4 TECHNICAL SPECIFICATIONS

### Power Supply

<b>Input mains data:</b>	100-240V – 50/60Hz
<b>Power supply rating:</b>	12V : 2.5amps
<b>Operation:</b>	Continuous
<b>Classification:</b>	Class II equipment Type B applied part

### Environmental Conditions:

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

## 8. SPARE PARTS AND ACCESSORIES

Item	Part Number
Teaching Mirror	1202-P-7205
Battery pack	1919-P-5282
Charger	1941-P-5414
Volk 20D Black Condensing Lens	2105-K-1159
Lens Cloth	2199-P-7136
Neck cord	2199-P-7582
Spectra Iris Carry Case	3412-P-5354

## 9. WARRANTY

No user serviceable parts – all preventative maintenance and servicing must only be performed by authorised Keeler representatives.

Your Keeler product is guaranteed for 3 years and will be replaced, or repaired free of charge subject to the following:

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

**Please note:**

Batteries are covered by this warranty statement for 1 year only.

## 10. 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.**

## Contact



### Manufacturer

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