Spectra Iris

Indirect Ophthalmoscope

Instructions for use

Keeler

Next

Contents

Page

1. **Copyright and trademarks** 3
2. **Introduction** 4
3. **Symbols** 5
4. **Safety** 6
   - *Device classification*
   - *Warnings*
   - *Cautions* 7
   - *Safety considerations* 8
5. **Setting up and using the Spectra Iris** 9
   - *Description of the product*
   - *Fitting the Spectra Iris to the frame* 10
   - *Frame adjustments* 11
   - *Aperture Lever* 12
   - *Filter selection control*
   - *Mirror angle control*
   - *Interpupillary distance setting control* 13

Page

6. **Chargers, battery packs and power supply** 14
   - *Power supply assembly*
   - *Charging the battery pack* 15
   - *Charge time / belt clip* 16
7. **Cleaning instructions** 17
8. **Specifications and electrical ratings** 18
   - *Electrical specifications*
   - *Transport, storage and operation*
9. **Annex I – EMC statement and guidelines** 19
10. **Spare parts and accessories** 24
11. **Warranty** 25
12. **Contact and disposal information** 26

Click on the headings above to go directly to that section.

Use the buttons on the right to navigate the document.

Clicking 'Home' from any page brings you back to this contents page.

Keeler

1. Copyright and trademarks

The information contained within this manual must not be reproduced in whole or in part without the manufacturer's prior written approval.

As part of our policy for continued product development we reserve the right to make changes to specifications and other information contained in this document without prior notice.

Spectra Iris is a registered trademark of Keeler Ltd 2012.

Published in the UK 2012.

2. Introduction

Thank you for purchasing the Keeler Spectra Iris Indirect Ophthalmoscope.

We have taken the greatest care in the design, development and manufacture of this product to ensure that you get many years of trouble free service. However, it is important that you read the descriptions, installation and operating instructions carefully prior to installing or using your new indirect ophthalmoscope.

Please read and follow these instructions carefully.

Keeler

3. Symbols

Read user instructions for warnings, cautions and additional information

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

Consult instructions for use

Double insulated

Manufacturer's name and address

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

Type B protections against shock

Mandatory action sign

Follow instructions for use

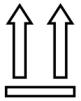
High voltage

Trip hazard

Optical radiation hazard

Hot surface

Non-ionizing radiation



This way up

Keep dry

Fragile

Material suitable for recycling

4. Safety

Device classification

CE Regulation 93/42 EEC: Class I
FDA: Class II

Carefully read this Instruction Section before using your Keeler product. For your own safety and that of your customers observe all cautionary information provided in this section. The following information is intended to highlight potential safety hazards that can be associated with misuse, or damage.

Warnings and cautions


Warning


- Check your Keeler product for signs of transport / storage damage prior to use
- Do not use if the product is visibly damaged, and periodically inspect for signs of damage
- Do not use in the presence of flammable gases / liquids, or in an oxygen rich environment
- 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
- US Federal law restricts this device to sale by or order of a physician or practitioner


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


Route power cords safely to eliminate risk of tripping or damage to equipment


Bulbs / LED's can reach high temperatures in use – allow to cool before handling


Do not exceed maximum recommended exposure time


After removal of the bulb / LED do not touch the bulb / LED contacts and the patient simultaneously

4. Safety

Caution

- 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 10
- 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 indirect off and attach new pack
- Remove batteries 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
- Care should be taken when handling halogen bulbs. Halogen bulbs can shatter if scratched or damaged
- 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

- Dispose of batteries in line with local environmental regulations
- At product end of life dispose of in accordance with local environmental guidelines (WEEE)

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

4. Safety

Safety considerations

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. Many ophthalmic instruments illuminate the eye with intense light. The decision about the intensity of the light level to use in any procedure must be made on a case to case basis. In each case, the clinician must take a risk benefit judgement about the intensity of light to be used. Use of insufficient intensity may result in inadequate visualization and in adverse effects more serious than retinal photic damage. Further, despite all efforts taken to minimise the risk of retinal damage, damage may still occur. Retinal photic injury is a possible complication of the need to use bright light clearly visualize ocular structure during delicate ophthalmic surgical procedure.

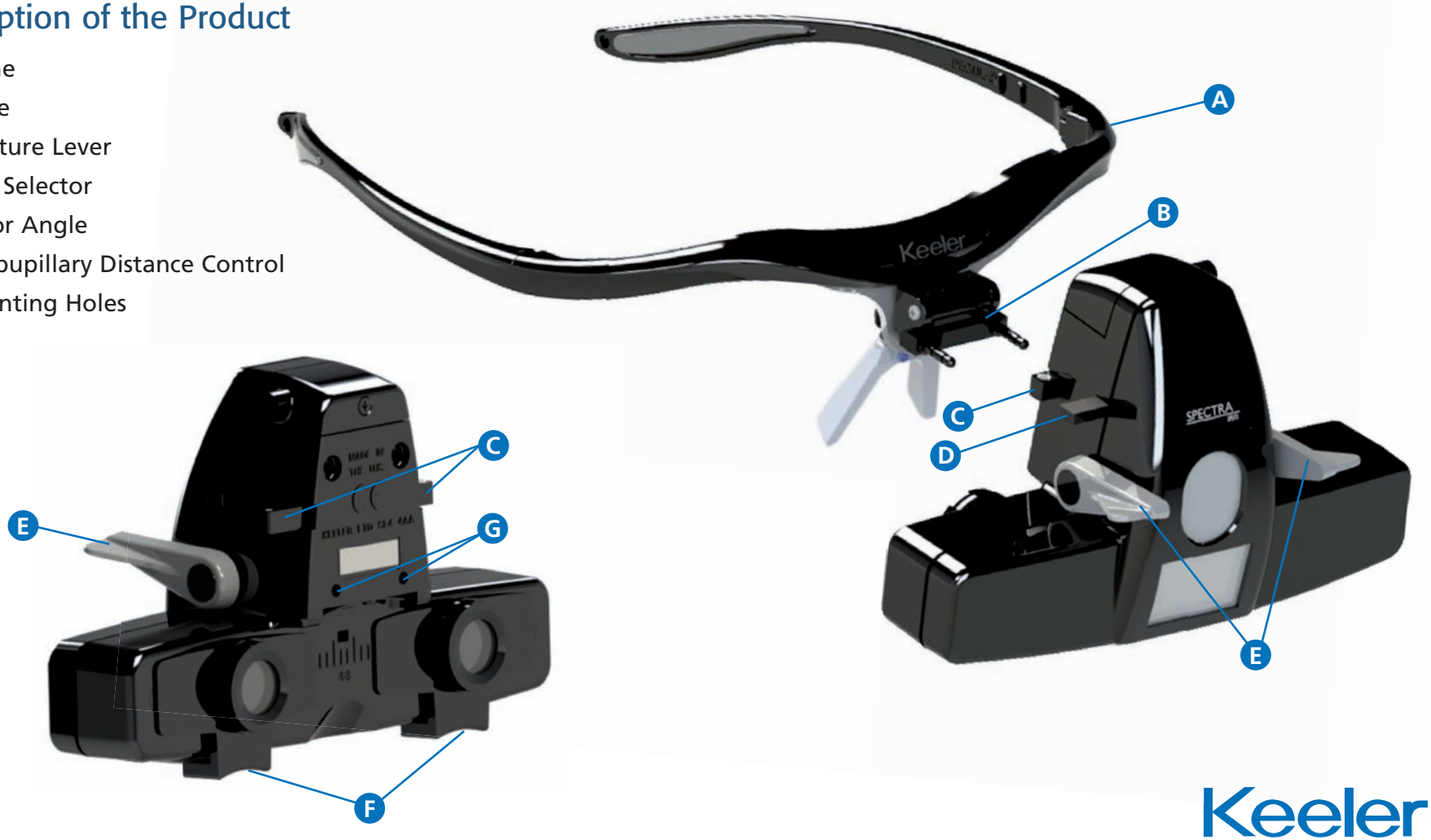
While no visible retinal lesions have been identified for ophthalmic instruments, it is recommended that illumination levels be set to the minimum level necessary to perform the diagnostic function. Young children and persons with diseased eyes may be at a higher risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using an intense visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.

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 guidelines after 27 minutes.

5. Setting up and using the Spectra Iris

Description of the Product

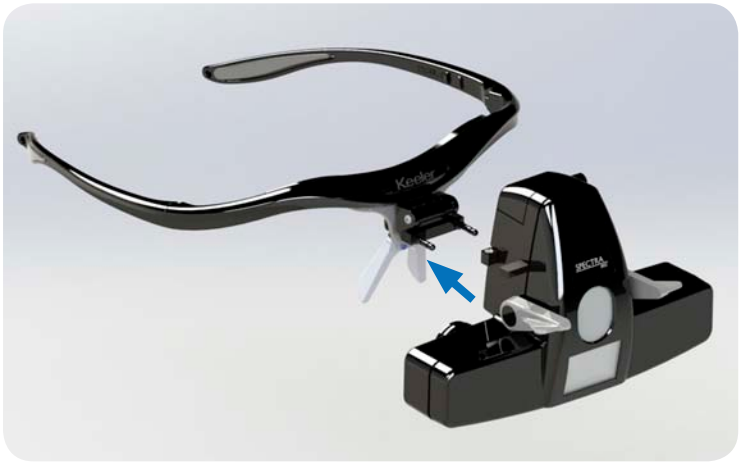
A Frame
B Hinge
C Aperture Lever
D Filter Selector
E Mirror Angle
F Interpupillary Distance Control
G Mounting Holes



Keeler

5. Setting up and using the Spectra Iris

Frame (A)



1. Fit the Spectra Iris head unit into the frame (A) via the pin mounting system as shown.

2. The prescription lens frame (if required) is fitted as shown.

Prescription lens frame in correct position

5. Setting up and using the Spectra Iris

Frame (A)

3. The nose bridge is fitted by sliding into the slot as shown.

4. 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.

5. 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.

Keeler

5. Setting up and using the Spectra Iris

Filter selection control (D)

By sliding the lever (D) in direction of the arrows, different filters may 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 angioscopy.

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.

Aperture lever (C)

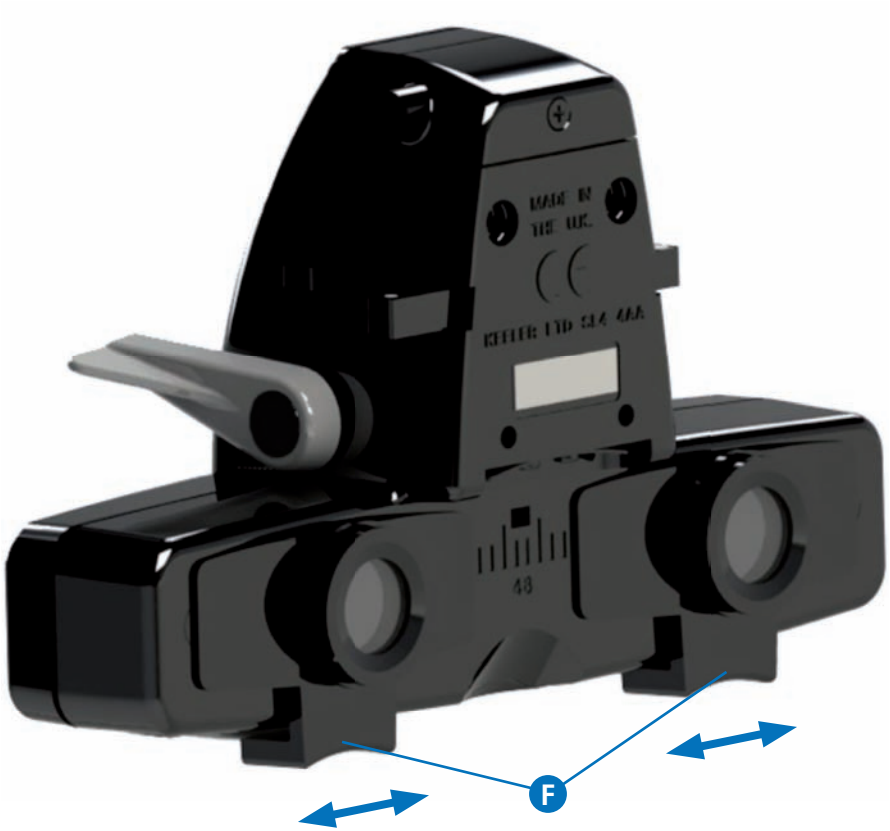
By sliding the lever (C) in direction of the arrows, the size of the aperture can be adjusted. Slide to the right to increase aperture size, to the left to decrease. Refer to the white dots located on the top of the lever, as per image right.

5. Setting up and using the Spectra Iris

Interpupillary Distance Setting Control (F)

Because the eyes are dissociated, particular care must be taken to ensure the optics (eyepieces) are set properly in front of each eye.

Place an object, perhaps the thumb, 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.

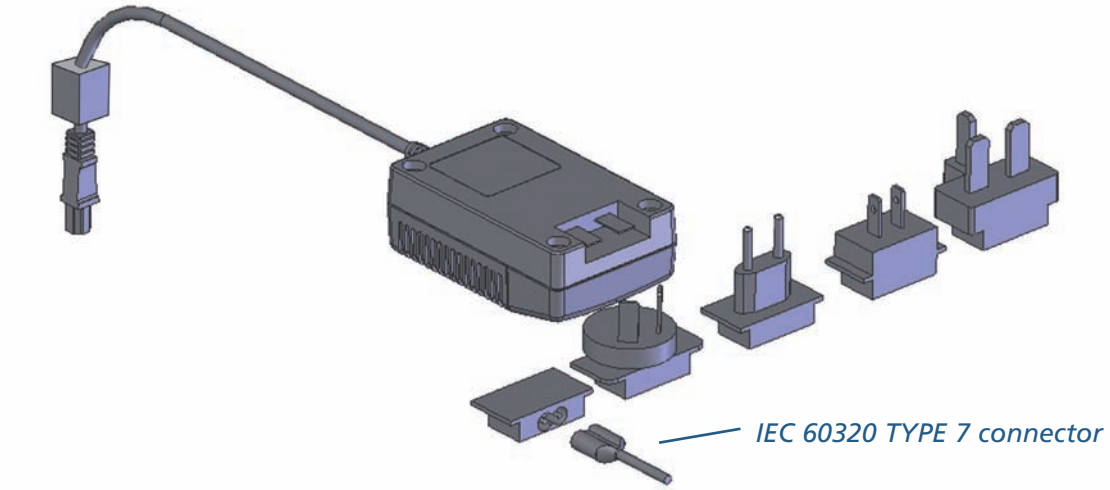


Keeler

6. Charger – power supply assembly

Set Plug

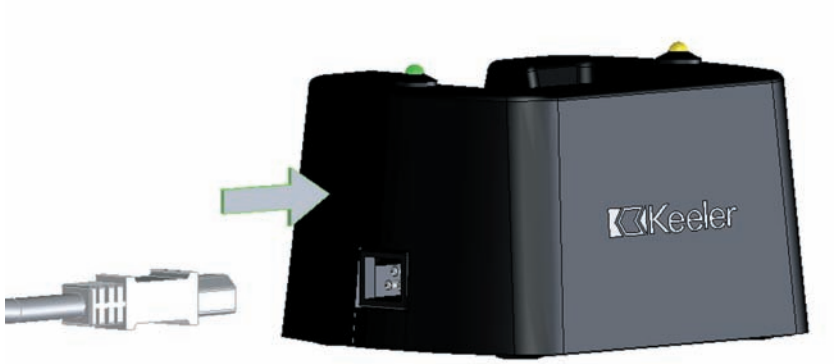
Replace the blanking plate with the appropriate mains plug adaptor if required, or use IEC 60320 TYPE 7 connector (not supplied).



6. Charger – lithium battery

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

●	**Green LED**	Charging storage unit powered
○	**No yellow LED**	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. Charger – lithium battery

Charge 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 into socket as shown.

Belt Clip

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

Keeler

7. Cleaning

- Only manual non-immersion cleaning as described should be used for this instrument

- Do not autoclave or immerse in cleaning fluids

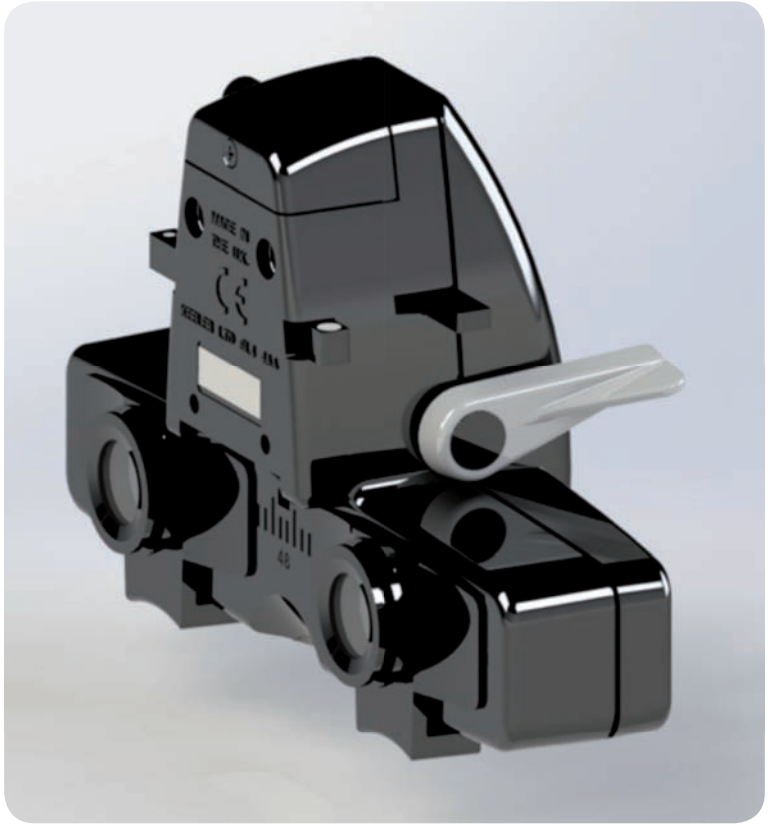
Always disconnect power supply from source before cleaning

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. Specifications and electrical ratings

Input mains data: 100-240V – 50/60Hz
Power supply rating: 12V : 2.5amps
Operation: Continuous
Classification: Class II equipment
Type B protection against shock

Transport, storage and operating conditions			
	Transport	**Storage**	**Operation**
Temperature range	-40°C to +70°C	-10°C to +35°C	+10°C to +35°C
Relative humidity	10% to 95%	10% to 95%	30% to 75%

9. Annex I – EMC statement and guidelines

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 this instrument, resulting in malfunctioning.

9. Annex I – EMC statement and guidelines

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 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 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) N/A	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 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 cycles 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 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.
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 commercial or hospital environment.

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

9. Annex I – EMC statement and guidelines

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="4">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.</td></tr>
<tr><th colspan="2">Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td rowspan="2">Charger only</td><td>RF emissions CISPR 11</td><td>Group 1</td><td>The Keeler Spectra Iris 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.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class B</td><td rowspan="3">The Keeler Spectra Iris is 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.</td></tr>
<tr><td colspan="2">Harmonic emissions IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td colspan="2">Voltage fluctuations / flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
<tr><td>Indirect Ophthalmoscope only</td><td>RF emissions CISPR 15</td><td>Complies</td><td>The Keeler Spectra Iris is not suitable for interconnection with other equipment.</td></tr>
</table>

9. Annex I – EMC statement and guidelines

Guidance and manufacturer's declaration – electromagnetic immunity			
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.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	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. **Recommended separation distance** $d = 1.2 \sqrt{p}$ $d = 1.2 \sqrt{p}$ 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 following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3 V/m	

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.

[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 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.

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

9. Annex I – EMC statement and guidelines

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 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	0.37	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 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.

10. Spare parts and accessories

The following accessories are supplied with the product:

Part Number	Description
1919-P-5215	Lithium battery pack
1941-P-5385	Single lithium charger (includes EP29-32777 power supply)
2199-P-7136	Lens cloth
2199-P-7582	Neck cord
2415-P-7001	Instructions for Use CD

The following accessories are available from the distributor:

Part Number	Description
1201-P-6067	Large thimble depressor for Scleral Indentation
1201-P-6075	Small thimble depressor for Scleral Indentation
1205-P-7000	Spectra teaching mirror
1941-P-5350	KLED / Spectra double charger
3412-P-7002	Spectra carrying case

Contact Keeler, who can supply a choice of Volk Lenses depending on magnification and field of view.

11. 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 that batteries are covered by this warranty statement for 1 year only.

12. Contact and disposal information

Keeler Limited
Clewer Hill Road
Windsor
Berkshire SL4 4AA
England

Freephone: 0800 521 251
Tel: +44 (0)1753 857177
Fax: +44 (0)1753 827145

Keeler Instruments Inc.
456 Parkway
Broomall
PA 19008,
USA

Toll Free: 1 800 523 5620
Tel: 610 353 4350
Fax: 610 353 7814

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).

CE

EP59-19156 Issue B

Keeler