




























Keeler K-LED II

Headlamp

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 K-LED II 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

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

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

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1. INDICATIONS FOR USE

Indications for Use/Intended Use

The K-LED II Headlamp has been designed to be used in dental and surgical environments, to illuminate areas under examination by the user.

The K-LED II is intended to be used at working distances in the range 340mm to 500mm.

The K-LED II is intended to be used only by suitably trained and authorised healthcare professionals.

2. SAFETY

2.1 WARNINGS AND CAUTIONS

Please note that the proper and safe functioning of our instruments is only guaranteed if both the instruments and their accessories are exclusively from Keeler Ltd. 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 K-LED II Headlamp.



WARNINGS

- Check your Keeler product for signs of transport / storage damage prior to use.
- Never use the product if visibly damaged and periodically inspect it for signs of damage or misuse.
- Do not shine directly into a person's eye. Do not stare into the light when in use. May be harmful to eyes.
- Do not hold magnifying glasses or any other optical system in front of the light.
- 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 on the order of a physician or practitioner.
- This device is intended to be used only by suitably trained and authorised healthcare professionals.



- 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.



- LED's can reach high temperatures in use – allow to cool before handling.



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 11.
- Ensure the equipment is positioned in such a way that it can be disconnected from the mains easily.
- 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 K-LED II 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 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.

2.2 CONTRAINDICATION

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

The K-LED II may produce discomfort in some photophobic patients due to the high illumination.

3. 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.

1. Wipe the external surface with a clean absorbent, non-shedding cloth dampened with a de-ionised water / detergent solution (2% detergent by volume) or water / isopropyl alcohol solution (70% IPA by volume). Avoid optical surfaces.
2. Ensure that excess solution does not enter the instrument. Use caution to ensure cloth is not saturated with solution.
3. Surfaces must be carefully hand-dried using a clean non- shedding cloth.
4. Safely dispose of used cleaning materials.
5. Do not operate LED until thoroughly dry.

4. K-LED II HEADLAMP AND CHARGING UNITS

4.1 DESCRIPTION OF THE PRODUCT

- A** Power supply and adaptors
- B** Rechargeable battery pack
- C** Single charger storage unit
- D** Double charger storage unit
- E** LED light source
- F** Connector



Note: Loupes shown in this image are not sold with the product.

5. FITTING THE K-LED II HEADLAMP TO YOUR LOUPE FRAME



1. To remove the loupes from the frame, hold the loupe bar between your thumb and forefinger of one hand and pull away from the hinge held in your other hand.



2. Attach the LED light to the loupe bar. Ensure that the LED light is fitted correctly and held securely in position.



3. Re-attach the loupes and LED light to the frame hinge by holding the loupe bar as before. Locate the hinge pins into the loupe bar holes and push the loupes onto the hinge.



4. If the LED light is to be used without loupes, attach the light to the adaptor PD bar. Attach the cable to the frame using the strap provided.



5. Connect the LED light lead into the connector port on top of the battery pack. To remove the lead pull in the direction of the arrows on the connector do not twist or unscrew.

6. K-LED II CHARGER POWER SUPPLY ASSEMBLY

6.1 SET PLUG

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

7. K-LED II CHARGER AND STORAGE UNITS

1. Power up the charger and storage unit by plugging it in to a mains outlet. The green LED shows the unit is powered.
2. Turn the battery pack off, and place into the charging well.
3. A yellow LED indicates the battery pack's charge state.



Double charger storage unit



Single charger storage unit

8. K-LED II BATTERY PACK CHARGING CYCLE

The battery pack can be used at any time during the charging cycle and will automatically resume charging when replaced in the charging well.

The battery pack can be left in the charger storage unit when it is not being used. The charger will automatically stop charging the battery pack when fully charged.

Charging the battery pack

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

Battery pack



Flashing yellow LED

Battery requires charging

Belt clip

A clip is provided to allow the user to wear the battery pack on a belt.

8.1 CHARGING CYCLE

Single charger storage unit

The battery will take approximately 2 hours to fully charge.



Double charger storage unit

The battery will take approximately 2 hours to fully charge in charging well 1 and approximately 4 hours to fully charge in charging well 2.



9. SPECIFICATIONS AND ELECTRICAL RATINGS

The Keeler KLED II and charger 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.

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

9.1 ELECTROMAGNETIC EMISSIONS

Guidance and manufacturer's declaration – electromagnetic emissions

The Keeler Spectra Iris/K-LED is intended for use in the electromagnetic environment specified below. The customer or user should ensure 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.

9.2 ELECTROMAGNETIC IMMUNITY

Guidance and manufacturer's declaration – electromagnetic immunity

The Keeler Spectra Iris/K-LED 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 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%.
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.
Charger only			
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.

Immunity test	IEC 55015 Test level	Compliance level	Electromagnetic environment – guidance
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/K-LED 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
Charger only			Portable and mobile RF communications equipment should be used no closer to any part of the Keeler Spectra Iris/K-LED, 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 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). 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 .
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 230 MHz	3 V	
Spectra/K-LED only			Interference may occur in the vicinity of equipment marked with the this symbol.
Radiated RF IEC 61000-4-3	10V/m 80MHz to 2.7GHz	10 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/K-LED is used exceeds the applicable RF compliance level above, the Keeler Spectra Iris/K-LED 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/K-LED.

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

9.3 RECOMMENDED SAFE DISTANCES

Recommended separation distances between portable and mobile RF communications equipment and the Keeler Spectra Iris/K-LED

The Keeler Spectra Iris/K-LED are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Keeler Spectra Iris/K-LED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Keeler Spectra Iris/K-LED 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.



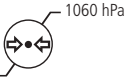


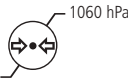


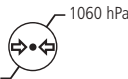
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9.4 TECHNICAL SPECIFICATIONS

Power Supply

Input mains data:	100-240V – 50/60Hz 700mA
Power supply rating:	12V : 2.5amps
Operation:	Continuous
Classification:	Class II equipment Type B applied part
Working distance:	340-500mm

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

10. SPARE PARTS AND ACCESSORIES

Item	Part Number
Power supply	EP29-32777
Yellow filter cap	EP39-57298
Battery pack	1919-P-5215
Twin charger	1941-P-5350
Single charger	1941-P-5385
Adaptor PD Bar	2001-P-7027

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:

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

12. PACKAGING AND DISPOSAL INFORMATION

Disposal of old electrical and electronic equipment



This symbol on the product or on its packaging and instructions indicates that this product shall not be treated as household waste.

To reduce the environmental impact of WEEE (Waste Electrical Electronic Equipment) and minimise the volume of WEEE entering landfills we encourage at product end of life that this equipment is recycled and reused.

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

Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of your Member State.

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