

Keeler K-LED II

Headlamp

Instructions for use



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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.

K-LED II is a registered trademark of Keeler Ltd 2012.

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2. Introduction

Thank you for purchasing the Keeler K-LED II Headlamp

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.

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

Please read and follow these instructions carefully.

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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



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



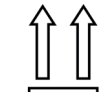
Trip hazard



Optical radiation hazard



Hot surface



This way up



Keep dry



Fragile



Material suitable for recycling

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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 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 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



LED's 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

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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 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

- 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

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5. K-LED II Headlamp and charging units

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



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6. 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, as shown.

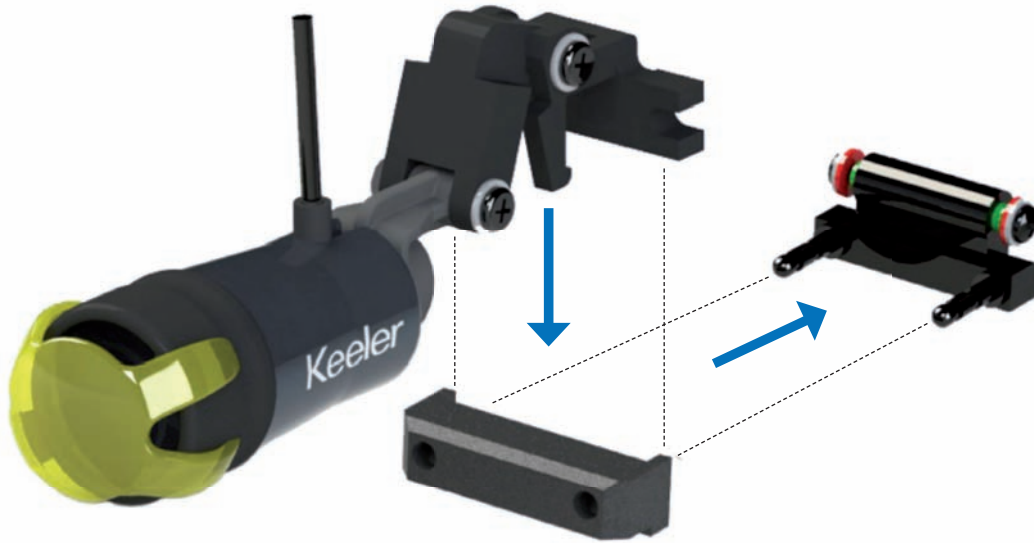


- 3 Re-attach the loupes and LED light to the frame hinge by holding the loupe bar as before.

Locate the hinge pins into the loupe bar holes and push the loupes onto the hinge.

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6. Fitting the K-LED II Headlamp to your loupe frame



- 4 If the LED light is to be used on its own without loupes, attach the Light to the Adaptor PD bar as shown. Attach the cable to the frame using the Velcro strap provided.



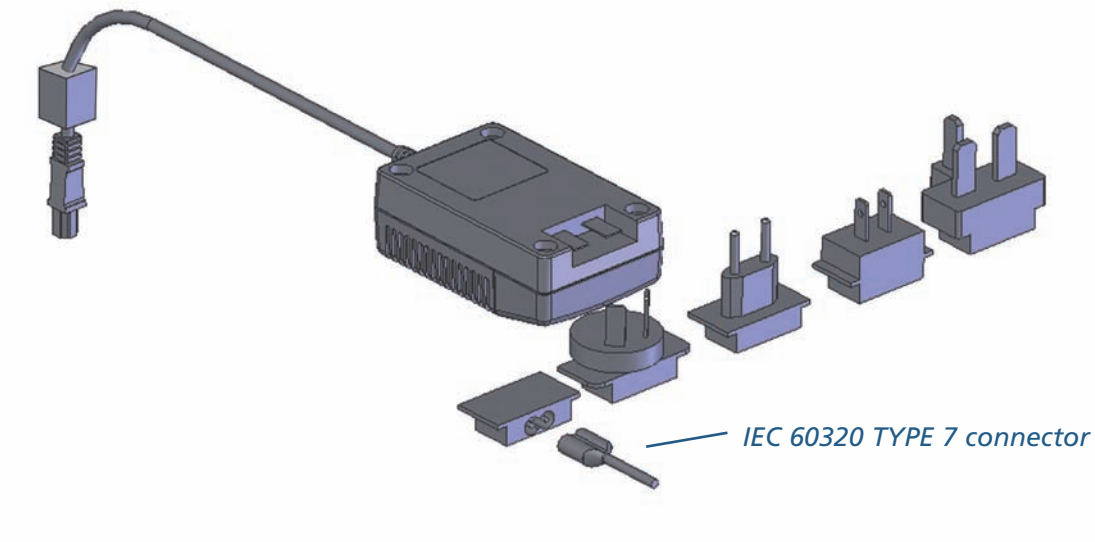
- 5 Connect the LED light lead into the connector port on top of the battery pack.

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7. K-LED II 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).



7. K-LED II charger and storage units

Power up the charger and storage unit by plugging it in to a mains outlet. The green LED shows the unit is powered.

Turn the battery pack off, and place into the charging well as shown.

A yellow LED indicates the battery pack's charge state.



Double charger storage unit



Single charger storage unit

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7. 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
- **No yellow LED** Battery charged
- ☀ **Flashing yellow LED** Top-up charge
- **Solid yellow LED** Rapid charge

Battery pack

- ☀ **Flashing LED** Battery requires charging

Belt clip

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

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.



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8. 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

- 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
- Ensure that excess solution does not enter the instrument. Use caution to ensure cloth is not saturated with solution
- Surfaces must be carefully hand-dried using a clean non-shedding cloth
- Safely dispose of used cleaning materials
- Do not operate LED until thoroughly dry

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9. Specifications and electrical ratings

Input mains data: 100-240V – 50/60Hz
700mA

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 +55°C | +10°C to +35°C |
| Relative humidity | 10% to 95% | 10% to 95% | 30% to 75% |

10. Annex I – EMC statement and guidelines

The Keeler K-LED II and chargers are medical electrical instruments. These instruments require special care concerning electromagnetic compatibility (EMC). This section describes the suitability in terms of electromagnetic compatibility of these instruments. When installing or using these instruments, 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.

10. Annex I – EMC statement and guidelines

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|--|
| The Keeler K-LED II and chargers are intended for use in the electromagnetic environment specified below. The customer or the user should assure that they are 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 K-LED II charger 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.


10. Annex I – EMC statement and guidelines

| Guidance and manufacturer's declaration – electromagnetic emissions | | | |
|---|-----------------------|-----------------|--|
| The Keeler K-LED II and chargers are intended for use in the electromagnetic environment specified below. The customer or user should assure that they are used in such an environment. | | | |
| Emissions test | | Compliance | Electromagnetic environment - guidance |
| Single / double charger only | RF emissions CISPR 11 | Group 1 | The Keeler K-LED II chargers use RF energy only for their internal function. Therefore, the 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 | |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | | Complies | |

The Keeler K-LED II is considered to be inherently EMC benign¹, and therefore is not covered by the statements in this section.

¹ Refer to section 1.1.4 of the Guide for the EMC Directive 2004/108/EC (published 21st May 2007).

10. Annex I – EMC statement and guidelines

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|-----------------------------|------------------|--|
| The Keeler K-LED II and chargers are intended for use in the electromagnetic environment specified below. The customer or user should assure that they are 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 | <p>Portable and mobile RF communications equipment should be used no closer to any part of the Keeler K-LED II or chargers, including cables, than the recommended separation distances calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance $d = 1.2 \sqrt{p}$</p> <p>$d = 1.2 \sqrt{p}$ 80MHz to 800 MHz $d = 2.3 \sqrt{p}$ 800MHz to 2.5GHz</p> <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey¹, should be less than the compliance level in each frequency range.²</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p> |
| 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 K-LED II / charger is used exceeds the applicable RF compliance level above, the Keeler K-LED II / charger 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 K-LED II / charger.

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

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10. Annex I – EMC statement and guidelines

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

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

11. Spare parts and accessories

The following spares and accessories are available from the distributor:

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

12. 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.

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13. 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).



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