

# Operating Manual K-L.E.D. System with charger

# Binocular loupes



#### **INTRODUCTION**

Thank you for purchasing the Riester K-L.E.D. Headlamp.

The product has been designed and manufactured to ensure that you will enjoy many years of trouble free and safe use. Please follow the User Instructions to ensure optimum performance.

The headlamp has been designed to be used in dental and surgical environments, to illuminate areas under examination by the

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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.

#### 2. SAFETY

Device classification CE Regulation 93/42 EEC: Class I

FDA: Class I

Carefully read this Instruction Section before using your Riester 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 Riester 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



Caution:



Use only genuine Riester approved parts and accessories or device safety and performance may be compromised.

Use only Riester 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. Do not hold magnifying glasses or any other optical system in front of the light. For indoor use only (protect from moisture).

When replacing lithium battery pack, turn K-LED 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.

# 3. K-L.E.D. HEADLAMP WITH SINGLE BATTERY PACK

# **DESCRIPTION OF THE PRODUCT**

- **A** Rechargeable Battery Pack
- B Power Supply and Adaptors
  C Battery Charger
  D LED Light Source
  E Connector



Before using the product, please check that the above parts are included.

# CHARGING THE SINGLE BATTERY PACK

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

Green LED Charging storage unit powered

O No yellow LED Battery charged

Flashing yellow LED Top-up charge

Solid yellow LED Rapid charge

## **Battery pack**

—————Flashing LED Battery requires charging.

# Charging cycle

The battery will take approximately 3 hours to fully charge.



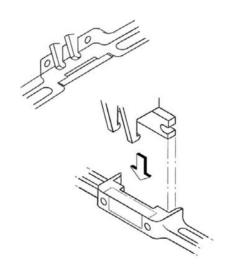


## 4. FITTING THE K-L.E.D. HEADLAMP TO YOUR LOUPE FRAME

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



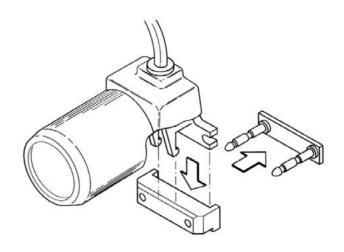
2. Attach the LED light to the loupe bar. Ensure that the LED light is fitted correctly and held securely in position, as shown.



**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.



**4.** If the LED light is to be used on its own without loupes, attach the Light to the Spacer bar as shown.



**5.** Attach the cable to the frame sides using the cable clips provided.



**6.** Connect the LED light lead into the connector port on top of the battery pack.



#### 5. CLEANING INSTRUCTIONS

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

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, nonshedding 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 nonshedding cloth.
- **d** Safely dispose of used cleaning materials.
- e Do not operate LED light until thoroughly dry.

#### 6. TECHNICAL INFORMATION

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

Power supply rating:12V : 2.5ampsOperation:ContinuousClassification:Class II equipment

Type B protection against shock

Transport, storage and operating conditions			
	Transport	Storage	Operation
Temperature range	-40°C	-10°C	+10°C
	to +70°C	to +55°C	to +35°C
Relative	10%	10%	30%
humidity	to 95%	to 95%	to 74%

#### **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 abd 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.

#### 7. ANNEX I - EMC STATEMENT AND GUIDELINES

The Riester K-LED 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.

Guidance and manufacturer's declaration – electromagnetic immunity					
The Riester K-LED 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	± 6 kV contact	± 6 kV contact	Floors should be wood, concrete or ceramic tile.		
discharge (ESD).	± 8 kV air	± 8 kV air	If floors are covered with synthetic material, the relative		
IEC 61000-4-2			humidity should be at least 30%.		
Electrical fast	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or		
transient/burst.	± 1 kV for input/output lines	N/A	hospital environment.		
IEC 61000-4-4					
Surge.	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or		
IEC 61000-4-5	± 2 kV line(s) to earth	N/A	hospital environment.		
Voltage dips, short	<5% U <sub>™</sub>	<5% <i>U</i> ⊤	Mains power quality should be that of a typical commercial or		
interruptions and	(> 95% dip in $U_T$ ) for 0.5 cycles	(> 95% dip in $U_T$ ) for 0.5 cycles	hospital environment.		
voltage variations on	40% U <sub>T</sub>	40% <i>U</i> T	If the user of the Riester K-LED charger requires continued		
power supply input	(60% dip in $U_{\rm T}$ ) for 5 cycles	(60% dip in $U_T$ ) for 5 cycles	operation during power mains interruptions, it is recommended		
lines.	70% <i>U</i> <sub>T</sub>	70% <i>U</i> T	that the charger be powered from an uninterruptible power		
IEC 61000-4-11	(30% dip in $U_T$ ) for 25 cycles	(30% dip in $U_T$ ) for 25 cycles	supply.		
	<5% U <sub>™</sub>	<5% U <sub>T</sub>			
	(>95% dip in $U_T$ ) for 5 s	(>95% dip in $U_{\rm T}$ ) for 5 s			
Power frequency	3 A/m	3 A/m	Power frequency magnetic fields should be at a level		
(50/60 Hz) magnetic			characteristic of a typical location in a typical commercial or		
field. IEC 61000-4-8			hospital environment.		

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

The Riester K-LED and char	rgers are intended for use	in the electromagnetic env	vironment specified below. The customer or user should assure that they are use	
in such an environment.	Bero are interraca for acc	the electromagnetic em		
Emissions test		Compliance	Electromagnetic environment - guidance	
Single / double charger only	RF emissions CISPR 11		The Riester K-LED 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	The Riester K-LED chargers are suitable for use in all establishments, including domestic establishments and those directly connected to the	
Harmonic emissions IEC 61000-3-2 Voltage fluctuations / flicker emissions IEC 61000-3-3		Class A	public low-voltage power supply network that supplies buildings used for domestic purposes.	
		Complies		

The Riester K-LED is considered to be inherently EMC benign<sup>1</sup>, and therefore is not covered by the statements in this section

<sup>&</sup>lt;sup>1</sup> Refer to section 1.1.4 of the Guide for the EMC Directive 2004/108/EC (published 21st May 2007).

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

The Riester K-LED 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
			Portable and mobile RF communications equipment should be used no
			closer to any part of the Riester K-LED or chargers, including cables, than the
			recommended separation distances calculated from the equation applicable
			to the frequency of the transmitter.
			Recommended separation distance
			d = 1.2 √ p
Conducted RF	3 Vrms	3 V	
IEC 61000-4-6	150 kHz to 80 MHz		d = 1.2 √ p 80MHz to 800 MHz
			d = 2.3 √ p 800MHz to 2.5GHz
Radiated RF	3 V/m	3 V/m	Where p is the maximum output power rating of the transmitter in watts(W)
IEC 61000-4-3	80MHz to 2.5GHz		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 following symbol:

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 Riester K-LED / charger is used exceeds the applicable RF compliance level above, the Riester K-LED / 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 Riester K-LED / charger.

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

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

The Riester K-LED and charger are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Riester K-LED / charger can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Riester K-LED / charger as recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Separation distance according to frequency of transmitter			
output power of	m			
transmitter	150 kHz to 80MHz	80MHz to 800MHz	800MHz to 2.5GHz	
l w	d = 1.2√ p	d = 1.2√ p	d = 2.3√ 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.

