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Vantage Plus LIO Instructions For Use

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Published in the UK 2012

Introduction

Thank you for purchasing the Keeler Vantage Plus Laser Indirect Ophthalmoscope (LIO) – Keeler Type Reference 1205L.

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 LIO.

Please read and follow these instructions carefully.

1 Symbols


Manufacturer's name and address


Mandatory action sign


Follow Instructions for Use


Optical radiation hazard


Warning: Dangerous Voltage


Trip Hazard


Hot surface


General warning sign


Type B Applied Part


Non-ionizing radiation


Keep dry

REF Reference Number

SN Serial Number


Date of manufacture


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


This way up


Material suitable for recycling


Fragile


The symbol on the Product or on it's Packaging and instructions indicates it was put on the market place after August 2005 and this product shall not be treated as Household Waste


Operating Instructions


Symbol for humidity limitations


Symbol for temperature limitations


Caution symbol

2 Safety

Device classification

CE Regulation 93/42 EEC: Class IIb
FDA: Class II
IEC/EN Standard 60601-1: Safety Class II

The LIO is intended for use by a medical professional trained in the use of ophthalmic laser equipment and procedures.

The LIO is intended for use in photocoagulating ocular tissue in the treatment of diseases of the eye.

The LIO has no applied parts (parts which may contact the patient).

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

- This device must only be used by clinicians trained in the use of ophthalmic laser devices
- This device is designed for safe use with a laser of specific wavelength. Check the markings on the top of the LIO (near the optical fiber connection) and ensure they match those on the connected Laser.
- The LIO contains safety filters to reduce reflected laser light to safe levels for users. Always look through the ophthalmoscope when the therapy beam is activated. Do not look over the ophthalmoscope when the therapy beam is activated.
- Test prior to use
- In order to minimise risk of patient movement during operation, ensure patient has been adequately prepared
- Minimise all possible distractions prior to commencement of treatment
- Ensure the headband is secure to remove the risk of movement during treatment
- Ensure the fiber optic cable is routed carefully and has enough slack to prevent tugging or snagging during treatment
- All attending personnel must wear laser safety glasses matching the operating wavelength of the laser
- 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, Dispose of batteries in line with local environmental regulations
- 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
- 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
- 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 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
- At product end of life dispose of in accordance with local environmental guidelines (WEEE)
- Ensure the equipment is positioned in such a way that it can be disconnected from the mains easily
- The LIO is intended to be used with the LIO LED only (PN 1012-P-5305). Any other light source used with the LIO will not function.
- The LIO is intended to be used with the laser wavelength specified on the top of the head unit only.
- The LIO is intended to be used with the LIO docking station only (PN 1945-P-5012).
- After removal of the LED do not touch the LED contacts and the patient simultaneously. Do not touch the contacts on the batteries, contacts on the rear side of headband battery pack and the contacts on the charging dock station and the patient simultaneously.
- No modification of this equipment is allowed.

- Remove the battery pack from the LIO if the equipment is unlikely to be used for a extended period of time, this will reduce the likelihood of leakage from the battery.

- No other equipment apart from the LIO and spare battery should be mounted onto the charging dock when fixed to the wall to prevent the likelihood of the charging dock from falling.

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

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

Route charger power cords and fiber optic cable safely to eliminate risk of tripping or damage to equipment

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

Do not exceed maximum recommended exposure time

The LIO should only be used with an approved laser system which emits a therapeutic laser beam with a wavelength of 532nm. The use of any other wavelength laser beam could lead to over exposure of the therapeutic beam to the user.

Operator shall be informed also to not touch the contact of the batteries, contacts on the rear side of the ophthalmoscope intended to be connected to the charging dock and the contacts of the charging dock station and the patient simultaneously

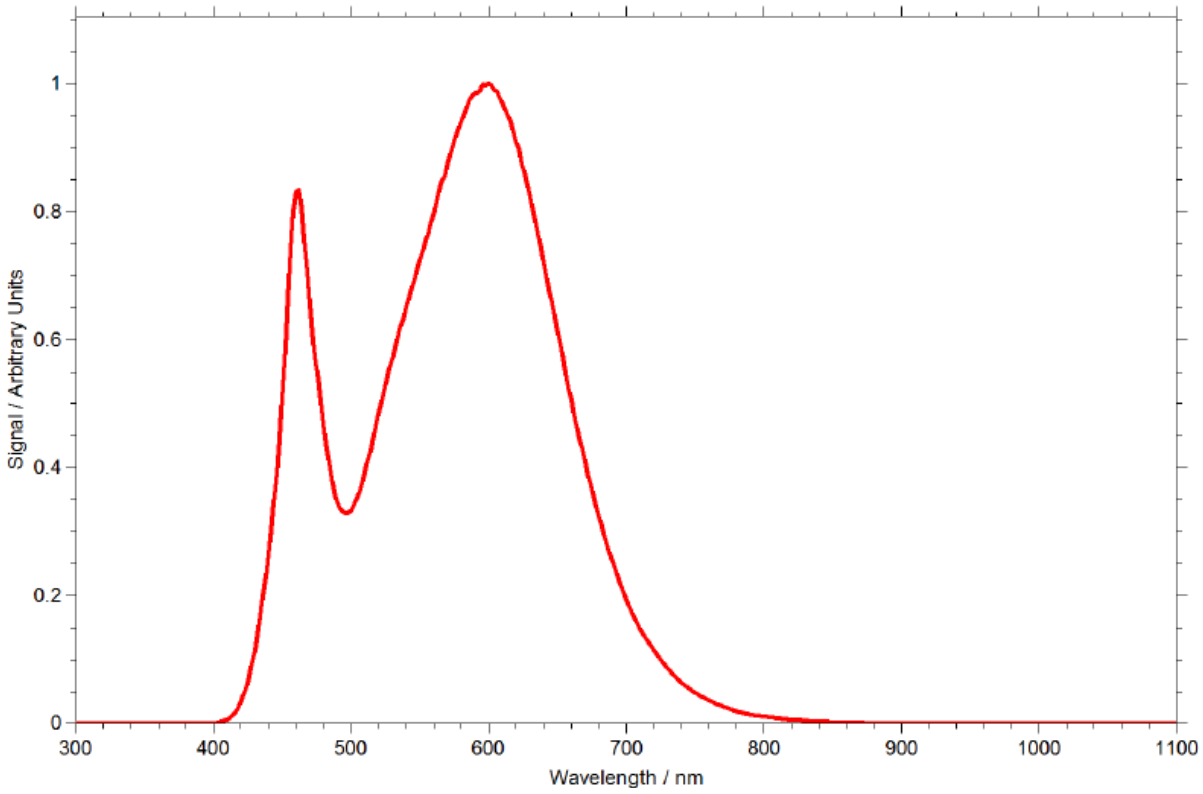
Safety considerations – Illumination

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 to 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 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.

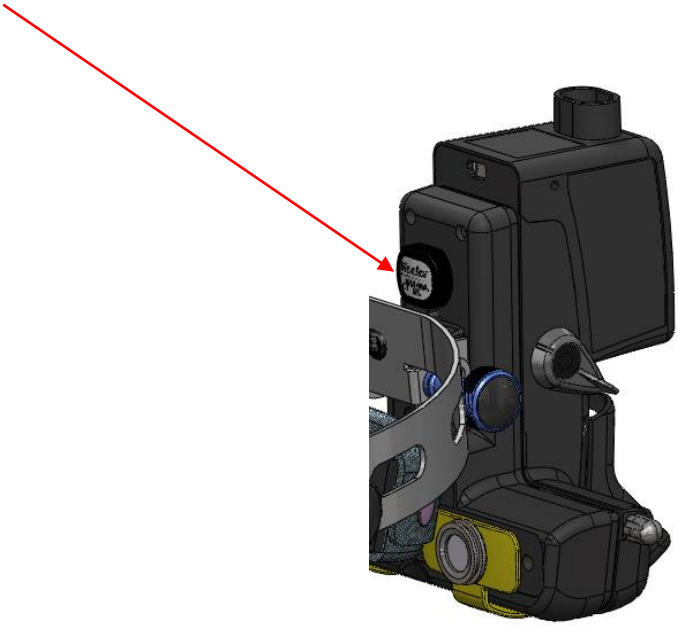
Safety considerations

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 60 minutes using a ancillary 20D lens.



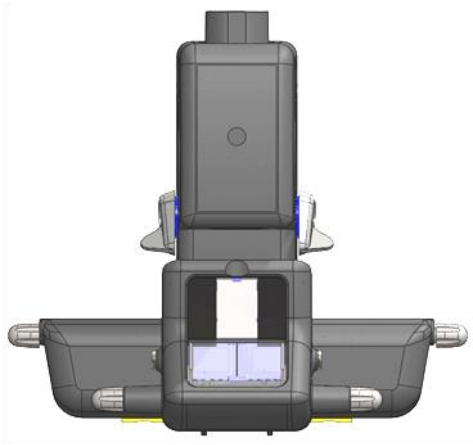
Relative spectral output of LED light source

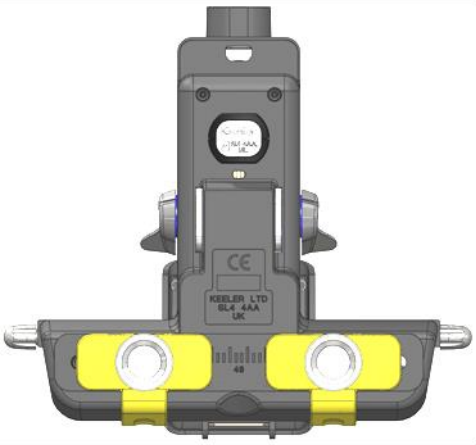
Under some single fault conditions the temperature of the surface shown below could get hot and there is a possible risk of a burn if touched.

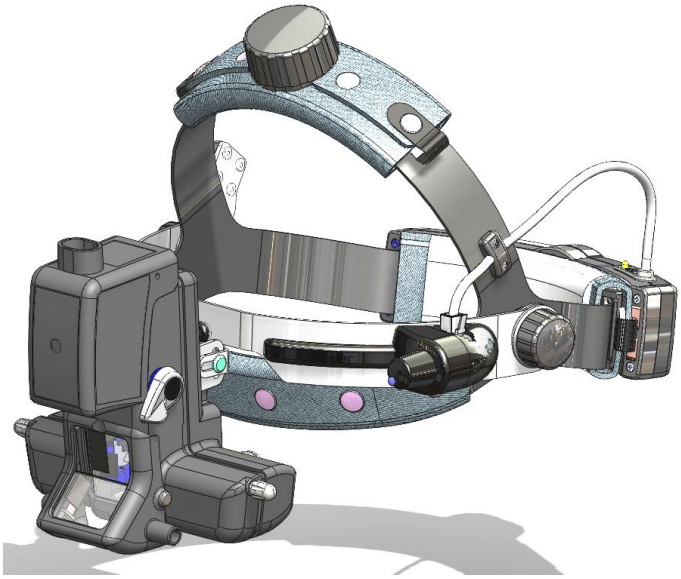


3 Setting up and using the Vantage Plus LIO

The Vantage Plus LIO is designed to connect to an ophthalmic laser. An optical system projects an aiming and treatment laser beam delivered from a laser via a fiber optic cable. The user can adjust the angle of projection of the laser by approximately +/- 3 degrees. The illumination patch is separately adjustable.







3.1 Adjusting the headband

Comfortable Fit

Adjust the size (fig.1) and the height (fig.2), so that the instrument is supported comfortably around and on top of the head.

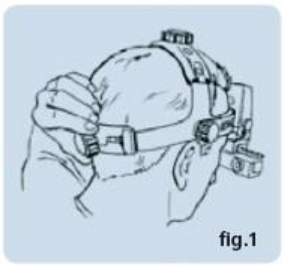


fig.1

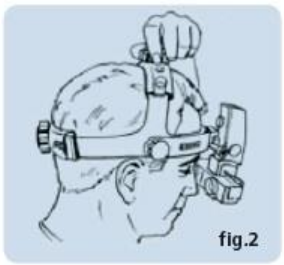
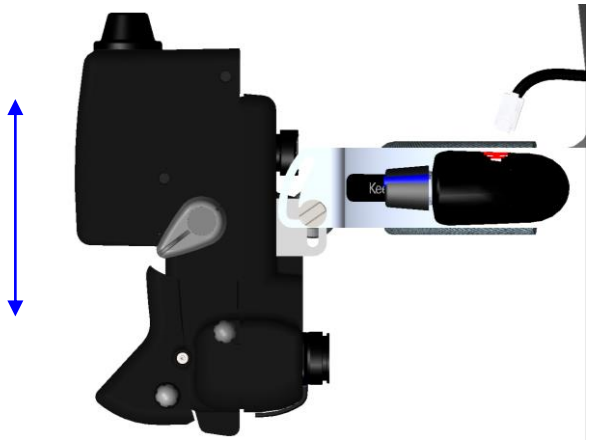


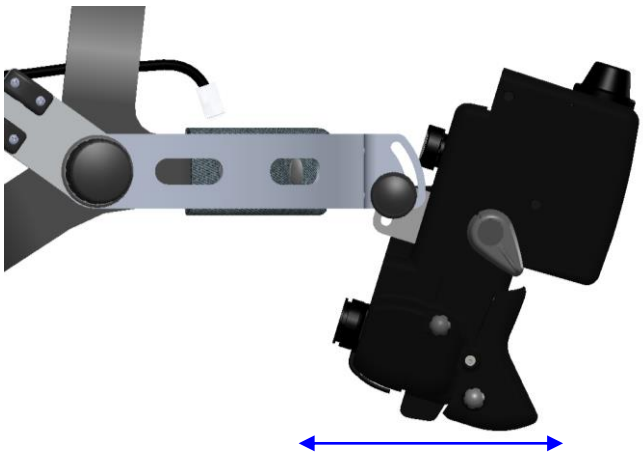
fig.2

Ophthalmoscope Angle Alignment

For vertical alignment of the eyepieces and binocular block, adjust the height of the Metal Outer Brow Bar if necessary by using the brow band tension knobs located on the sides of the headset.



Position the Binocular Block as close to the eyes or spectacles as possible for maximum field of view. Slightly loosen the ophthalmoscope angle knob to allow for adjustment and tighten when in position as in.



3.2 Interpupillary Distance Setting Control

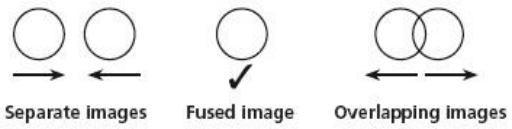
Because the eyes are dissociated, particular care must be taken to ensure the optics (eyepieces) are set properly in front of each eye.

Always set the Aperture Selection to the large light patch for this exercise.

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 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.

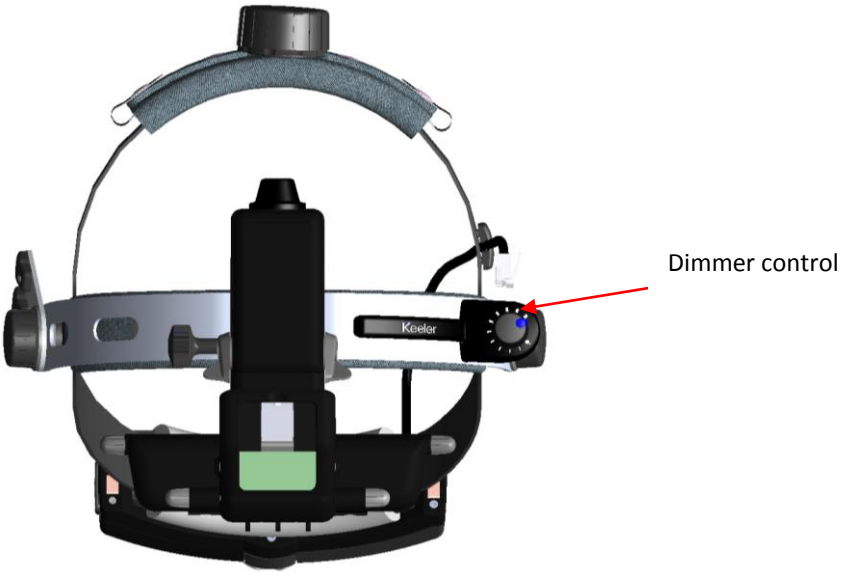
3.3 Obtaining a fused image

Ensure that a singular, fused image is obtained as follows:



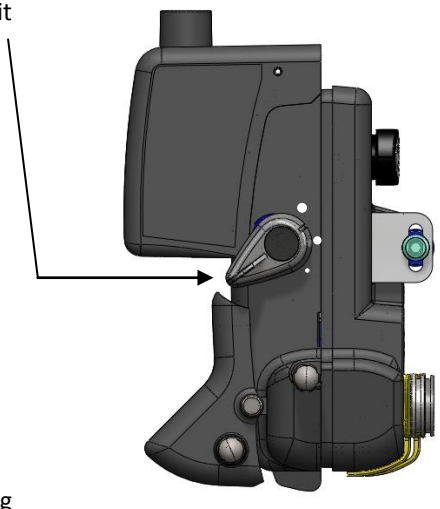
3.4 Head Dimmer Switch

Turn the illumination on by rotating the headband dimmer in an anti clockwise direction.



3.5 Setting the Aperture

Select different apertures by rotating the leaver on left side of the unit



The Vantage Plus LIO has three light apertures which offer maximum Stereopsis. When you select the aperture, the illumination and Viewing mirrors automatically adjust for maximum stereopsis.

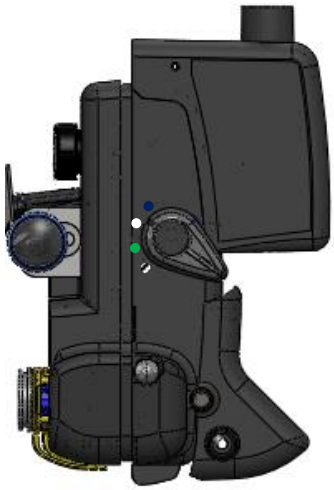
Large
The large, round, homogeneous patch is suitable for routine examinations through fully dilated pupils. In this position the mirror remains in the forward position and the optics are diverged.

Intermediate
The intermediate patch is designed to reduce reflections when entering a partially or poorly dilated pupil (3mm). It is also ideal for closer inspection of particular fundal areas. The mirror and optics stag in the mid position.

Small
This light patch is ideally for small, undilated pupils. The mirror moves back and the optics automatically converge.

3.6 Filter Selection

Select different filters by rotating the leaver on the right side of the unit:



Blue Circle
Cobalt blue filter for fluorescein angioscopy.

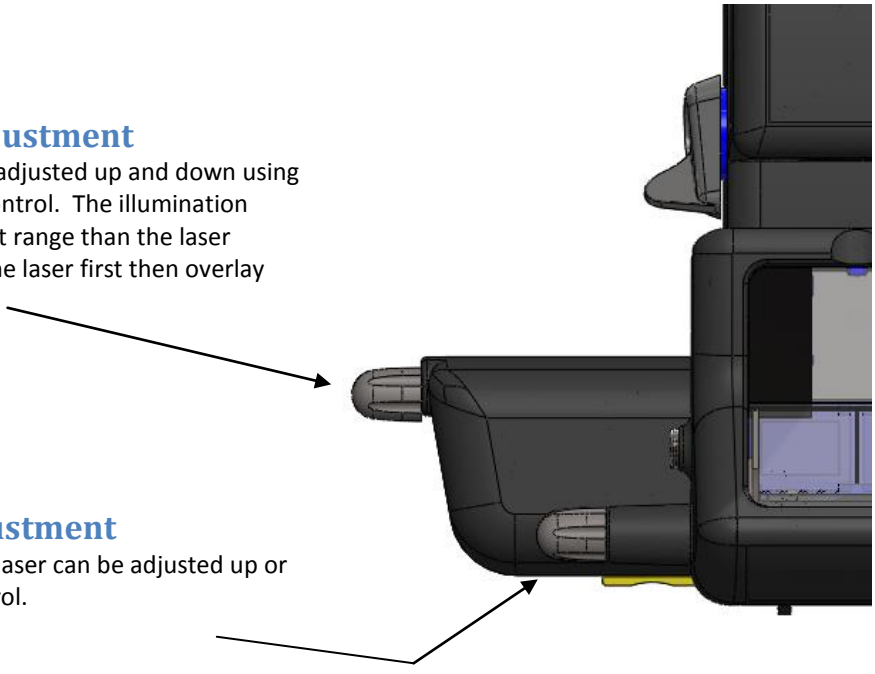
White Circle
Clear light – Select the clear with no filter when inspecting a specific pathology and a brighter, whiter light is desired.

Green Circle
Red Free filter – this filter reduces the red light, so blood will appear black, silhouetted against a dark background.

Diffuser
This unique extra wide beam of diffused light permits a more relaxed technique during more challenging fundus examinations. Beginners may also find this aperture particularly helpful since the alignment between the headset, the condensing lens and the pupil, in order to achieve a full lens image, is not as critical as with the conventional beam.

3.7 Illumination adjustment

The illumination patch can be adjusted up and down using the illumination adjustment control. The illumination control has a larger adjustment range than the laser control so it is best to adjust the laser first then overlay the illumination.

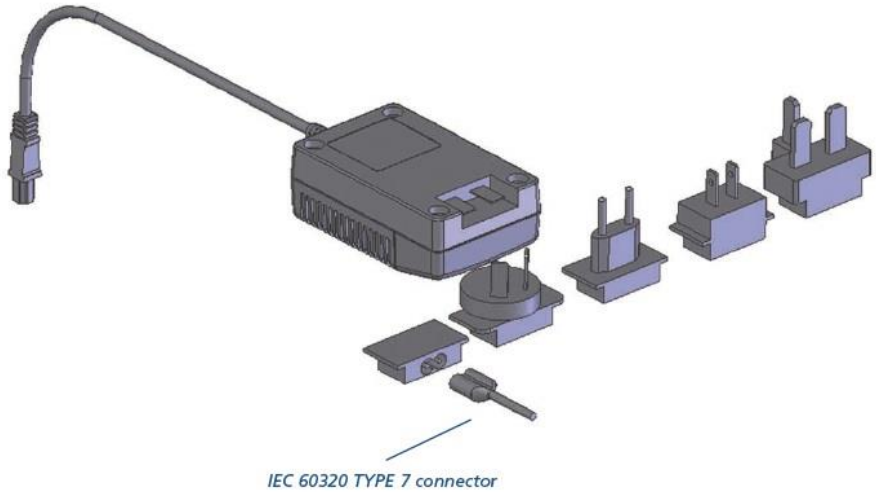


3.8 Laser angle adjustment

The angle of projection of the laser can be adjusted up or down the front mounted control.

3.9 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).



4 Slimeline Lithium Charger

Charging

1. Replace the blanking plate with the appropriate mains adapter, and connect plug on the cable to power input socket on charger

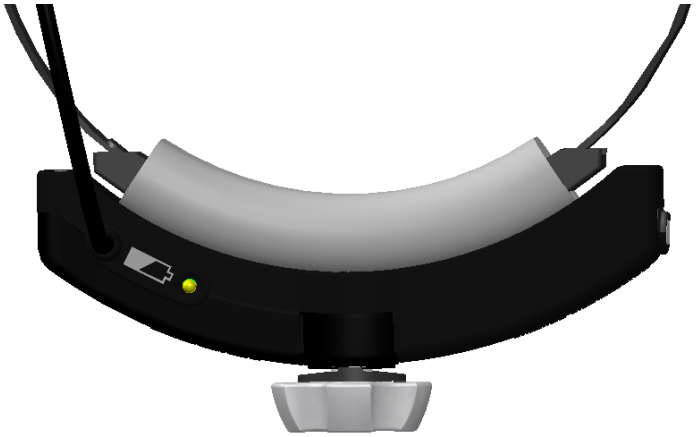
   Switch on the charger by plugging it into the mains outlet.

2. Place your spare battery pack or headset into the charger as shown. Check that the headset is securely mounted into the docking station to ensure the headset does not fall.

3. Ensure that the LIO is turned off during the charging process

Headband Battery Holder

Flashing LED – Battery requires charging.



Charging Station

No indicator – Battery is fully charged.

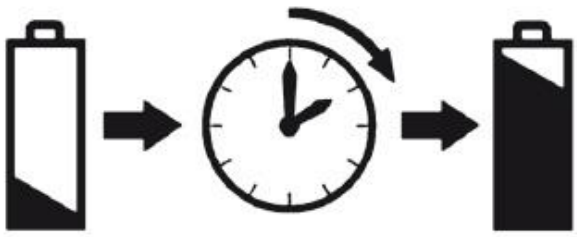
Flashing indicator – Top up Charge.

Solid indicator – Rapid Charge.

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

Direction arrow on charger indicates which battery is being charged.

Charging Cycle



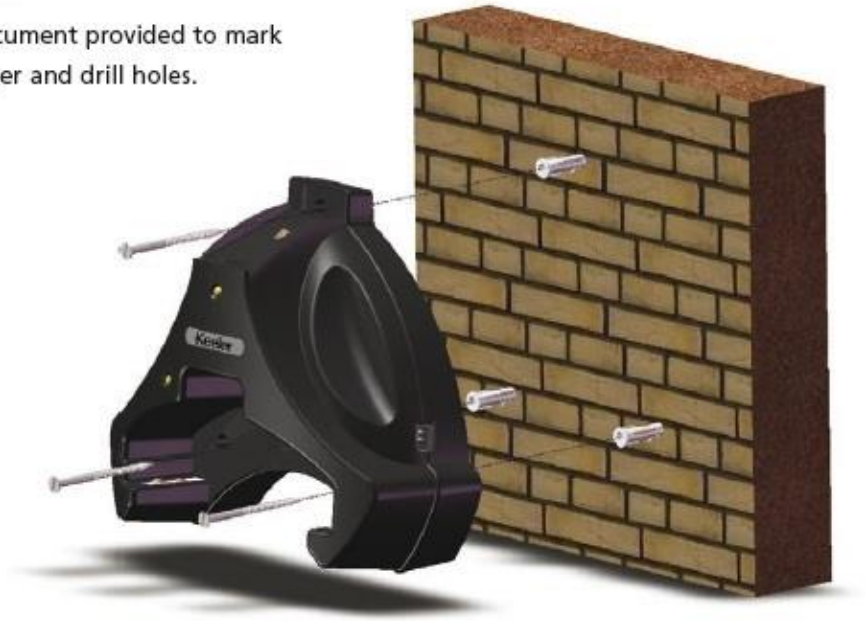
The battery attached to the indirect will take approximately 2 hours to fully charge.

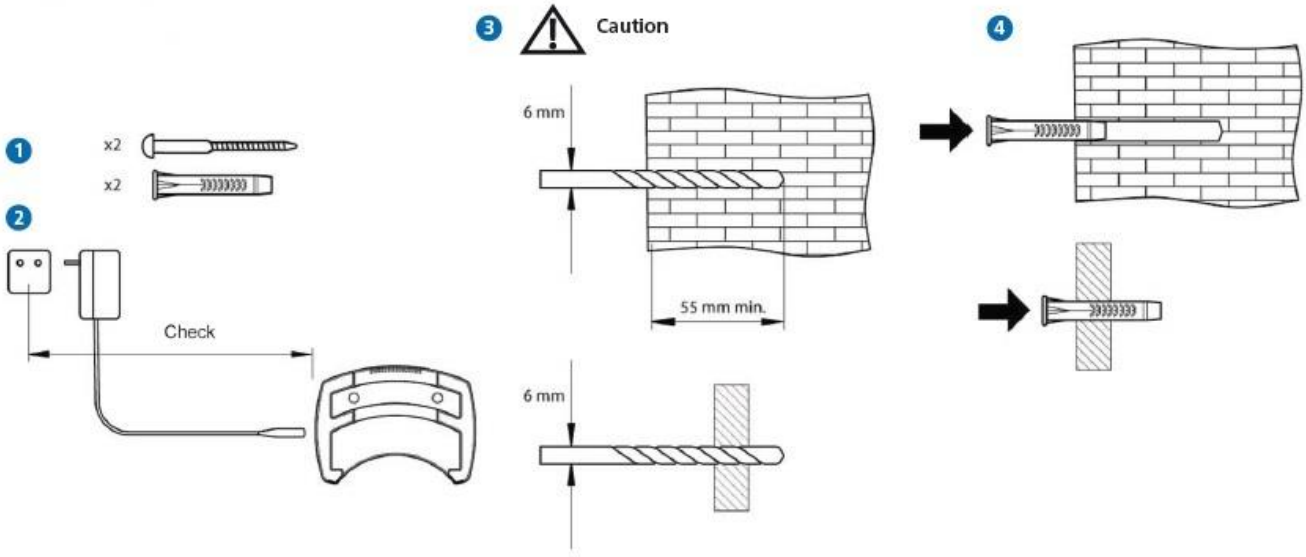
The battery will last approximately 2 hours on full power.

The spare battery will take 4 hours to charge.

Wireless charger – Wall mounting

Use template document provided to mark position of charger and drill holes.

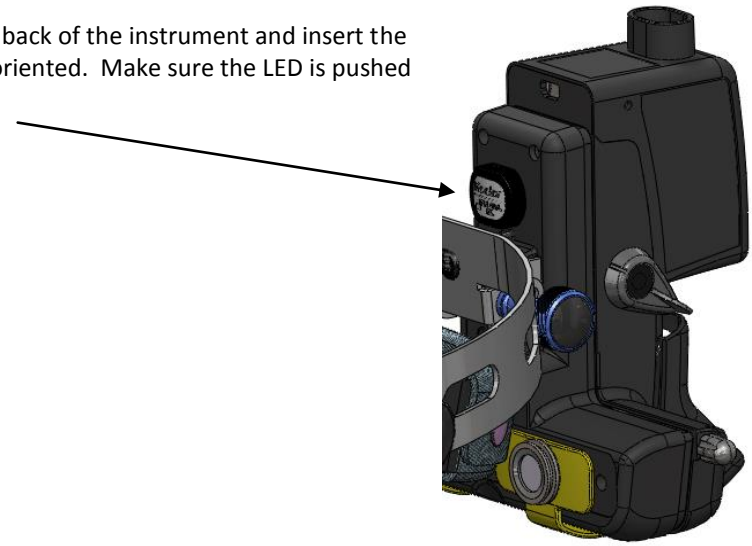




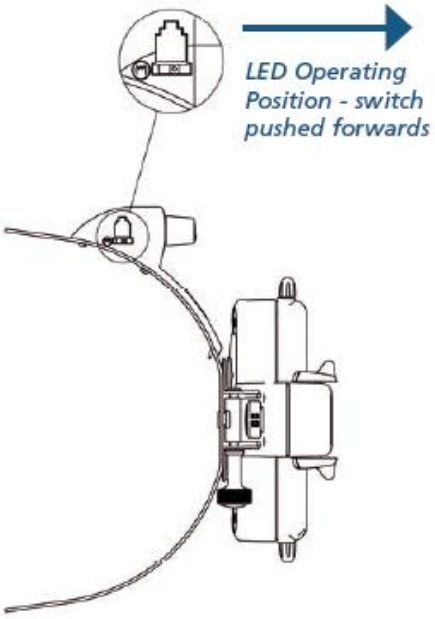
5 LED replacement

Caution, the LED may get hot during prolonged use.

Allow the LED to cool. Remove the LED from the back of the instrument and insert the new LED ensuring the alignment key is properly oriented. Make sure the LED is pushed all the way into the unit.



Note that the LIO should only be used with the LIO LED (PN 1012-P-5305). Ensure that the red switch on the rheostat is in the direct shown in the figure below. The symbol shown on the rheostat indicates a bulb light source.



6 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

7 Specifications and electrical ratings

The Keeler LIO and laser system combine to become a Medical Electrical system and therefore this system is required to comply with IEC 60601-1 standard.

7.1 Power supply

The LIO, the Power supply (EP29-32777) with its charging dock (1945-P-5012) together constitute a Medical Electrical system as defined in EN60601-1:2006.

Input mains data: 100-240V – 50/60Hz
700mA
Power supply rating: 12V : 2.5amps (PSU only)
Operation: Continuous
Classification: Class II equipment (charging dock & PSU only)
IP rating: IPX0

The LIO is internally powered

The Power Supply Unit (PSU) has been evaluated for use in a Pollution Degree 2 and overvoltage category II environment and a maximum altitude of 2000 m

7.2 Transport, storage and working conditions

The following ambient condition limits are recommended for the LIO, for transport and storage it is recommended that the LIO is kept in its original manufacturers packaging.

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%

7.3 Ophthalmoscope Technical Specifications

Illumination Intensity	3500 Lux +/-500*
Illumination patch sizes	20/40/60mm +/-10%*
Interpupillary adjustment	48 to 76mm
Ophthalmoscope filters	Red free, Blue and diffused
Net weight	<800g (including Fiber optical cable)

*Measurements taken at 440mm from the front surface of the LIO

8 Annex I – EMC statement and guidelines

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 Keeler LIO 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 LIO 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.

Guidance and manufacturer's declaration – electromagnetic emissions			
The Keeler LIO 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 LIO 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 Keeler LIO chargers 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.
Harmonic emissions IEC 61000-3-2		**Class A**	
Voltage fluctuations / flicker emissions IEC 61000-3-3		**Complies**	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Keeler LIO 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80MHz to 2.5GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Keeler LIO or chargers, including cables, than the recommended separation distances calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{p}$ $d = 1.2 \sqrt{p}$ 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: 

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 LIO charger is used exceeds the applicable RF compliance level above, the Keeler LIO / 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 LIO / 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 Keeler LIO / charger

The Keeler LIO 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 LIO / charger can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Keeler LIO / charger as recommended below, according to the maximum output power of the communications equipment.

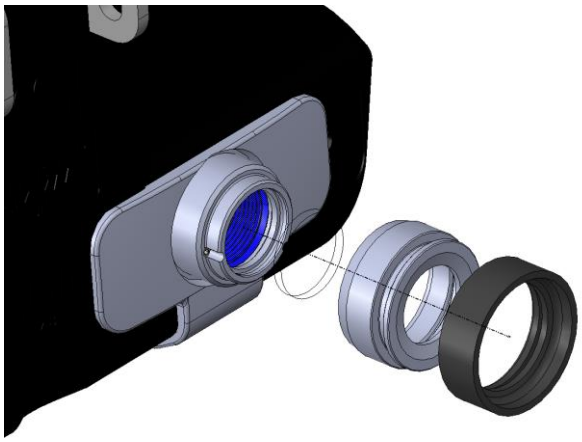
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80MHz $d = 1.2\sqrt{p}$	80MHz to 800MHz $d = 1.2\sqrt{p}$	800MHz to 2.5GHz $d = 2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

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.

9 Spare parts and accessories

Rubber Eyecaps

Rubber eyecaps are provided to protect spectacles and have been manufactured in rubber to avoid any abrasions. To use simply fit over the eyecaps.



Plano lenses

The unit is supplied with +2 dioptre lenses. Plano lenses are provided in the accessory kit.

Scleral depressors

Scleral depressors are available to view the ora serrata.

Fiber optic cable

A replacement fiber optic cable is available but this must be fitted by an authorised service engineer.

Spare Part List

Rubber Eyecaps	EP39-53799
Plano Lenses	EP39-53748
Large Scleral depressor	1201-P-6067
Small Scleral depressor	1201-P-6075
LED	1012-P-5305
Fiber optic cable	1205-P-8000
Lens Cloth	2199-P-7136
Charging dock	1945-P-5012
Battery pack	1919-P-5338
Wall pad	EP39-22706
Wall mount template	EP59-49005
Rawbloc wall plug (qty 3)	EP79-06498
Rubber foot (qty 3)	EP79-09496
Wood screw (qty 3)	SP90-82000
Power Supply Unit	EP29-32777

10 Warranty, Service & Maintenance

10.1 Warranty

Contact your laser manufacturer for details of your warranty plan.

Warranty will be conditional on routine maintenance and will not cover mechanical issues caused as a result of lack of routine maintenance, poor use, incorrect transport or inappropriate storage conditions.

10.2 Routine maintenance

Routine maintenance should be carried before use of the LIO to ensure the highest level of clinical effectiveness. The following tasks should be conducted before use:-

- Ensure that the front projection mirrors and windows are free from dust and debris to ensure a clear visual image of the eye. These mirrors windows can be cleaned as per the instructions provided in section 6.
- Ensure that both eyepieces are free from dust and debris to ensure clear visual image of the eye.
- Ensure that the fiber optic cable has no snags or sharps bends.
- Check for damage to any wiring or the fiber optic cable. If any damage is noticed contact a authorised representative.

Apart from routine maintenance there are no user serviceable parts – servicing must only be performed by authorised representative. Please refer all service requests to laser manufacturer.