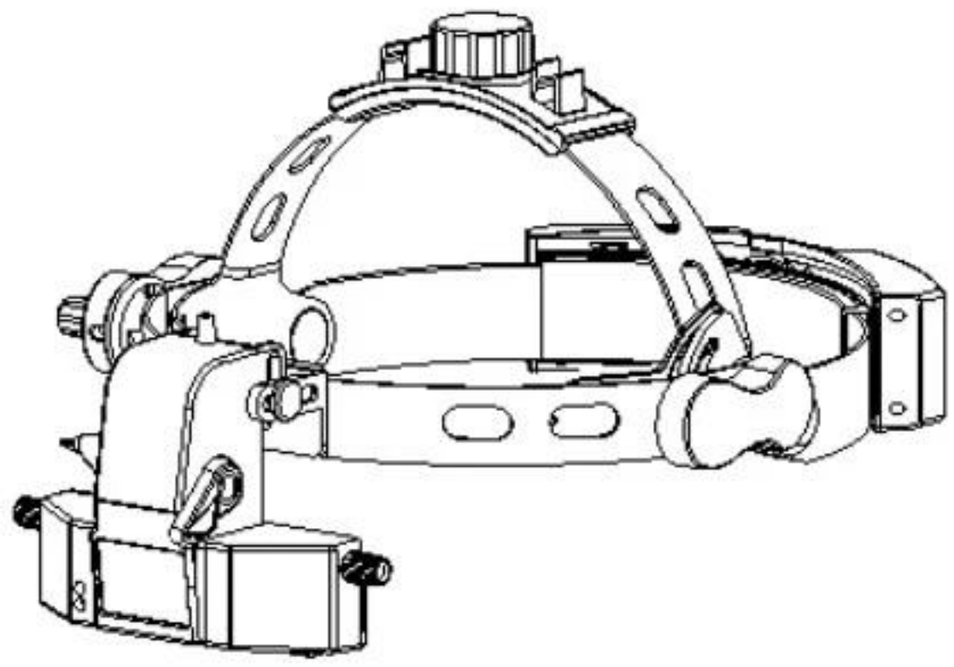
Eli Ezer Binocular Indirect Ophthalmoscope

EZ-BIO-2600 H



CE 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.

US Ophthalmic LLC

Thank you for purchasing this product. To prevent damage to your product or injury to yourself or to others, read the following safety precaution in their entirety before using this equipment. Keep these safety instructions where all those who use the product will read them.

Symbols:

Consult User's Guide

Internal electrical power source

Class Ⅱ

Cautions

1. **Read User's Guide for Cautions and instructions for use.**
2. **Do not use this instrument in damp rooms. Do not expose the instrument to water splashes, dripping water or sprayed water.**
3. **Do not shine the light directly into the patient's eyes.**
4. **Never scratch the glass cover with fingers or any other hard materials.**
5. **Please ensure that the control is in the off position when the examination has been completed.**
6. **This product must not be used in the presence of flammable gases.**
7. **Please use special certificated power adapter.**
8. **Federal law restricts this device to sale or order of a physician.**

1. Purpose and Features of the Product

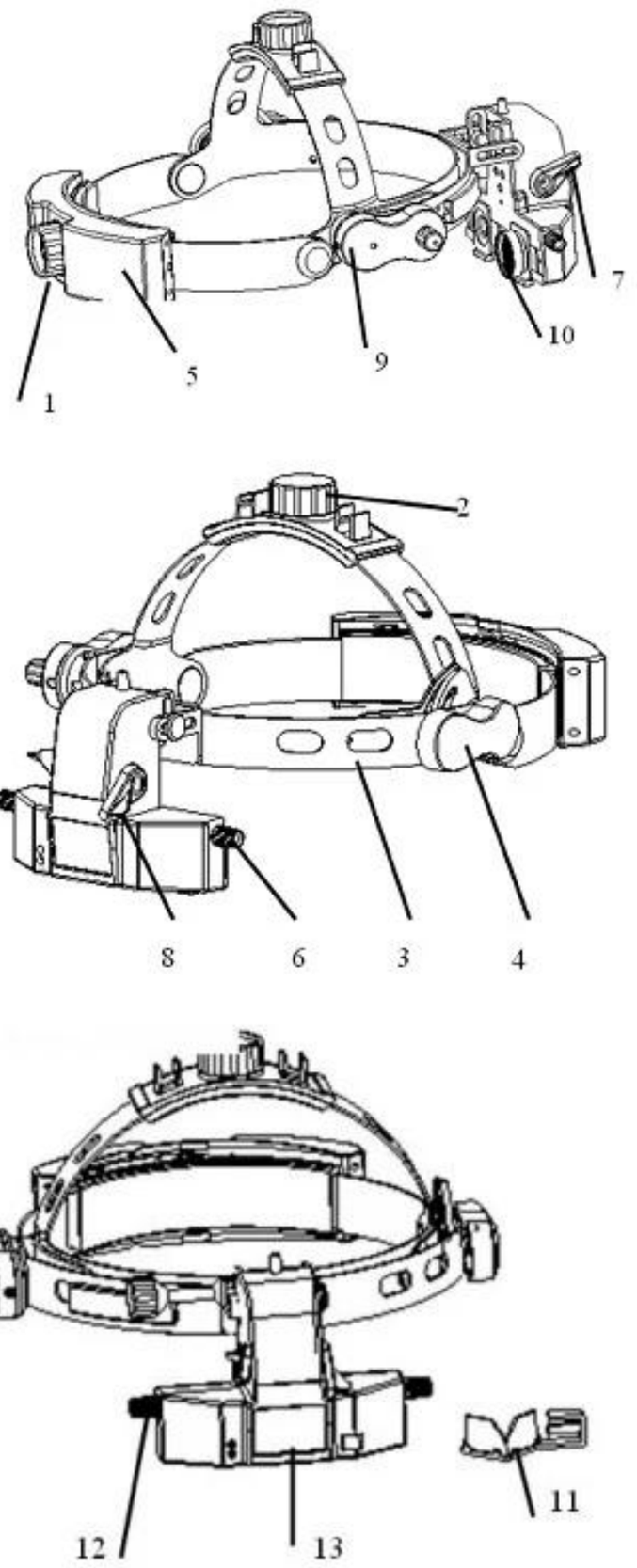
1.1 Purpose

The indirect Ophthalmoscope is battery powered device for medical professionals, containing illumination and viewing optics intended to examine the media, cornea, aqueous, lens, vitreous and the retina of the eye.

1.2 Features

- ◆ LED light source: One of the brightest, longest lasting lamps available in the BIO.
- ◆ Designed for maximum user comfort and performance. Its headband is ergonomically shaped to match the contours of the head and to provide improved stability and the most comfortable, natural fit available in a BIO. The optics are small and lightweight so you will experience even greater balance during use.
- ◆ Convergence Control for Small Pupil Capability.
- ◆ Diffuser Filter for Enhanced Peripheral Viewing of the Retina
- ◆ Smart design, convenient for mobile diagnosis.

1.3 Components



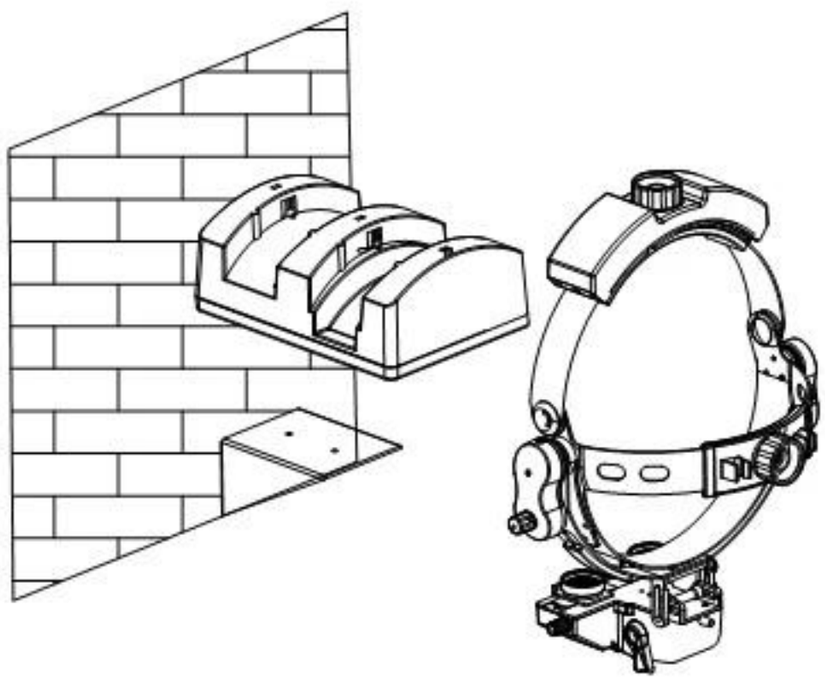
No.	Name
1	Headband Size Adjustment Knob
2	Headband Height Adjustment Knob
3	Metal Outer Brow Band
4	Lcckíng Knob
5	Lithium Battery
6	Mirror Angle Control
7	Filter Lever

8	Aperture Lever
9	Head Dimmer Switch
10	Optics of Eyepiece
11	Teaching mirror
12	Ophthalmoscope Angle Knob
13	Front Window

2. Mounting and Operating Instructions

2.1 Mounting Instructions

Make two expansion screw holes in the wall according to the supplied bracket label paper, and then tap into the expansion screw sleeve. Install the charging seat on the bracket as shown below.



2.2 Operating Instructions

Warning: No modification of this equipment is allowed.

Warning: Do not modify this equipment without authorization of the manufacturer.

Warning: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

Adjust the size and the height, so that the instrument is supported comfortably around and on top of the head.

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.

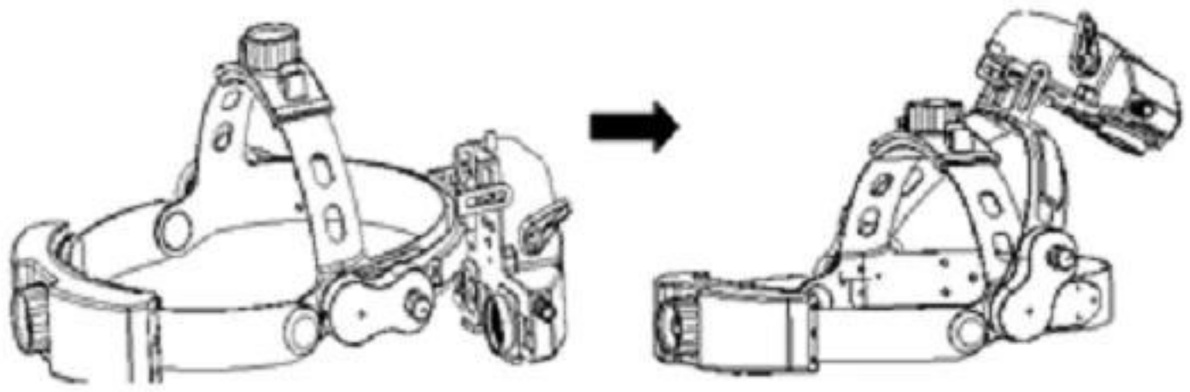
Connect the BIO to the battery adaptor. Rotate the brightness control knob to select the required brightness.

Inter papillary Distance Setting Control. 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.

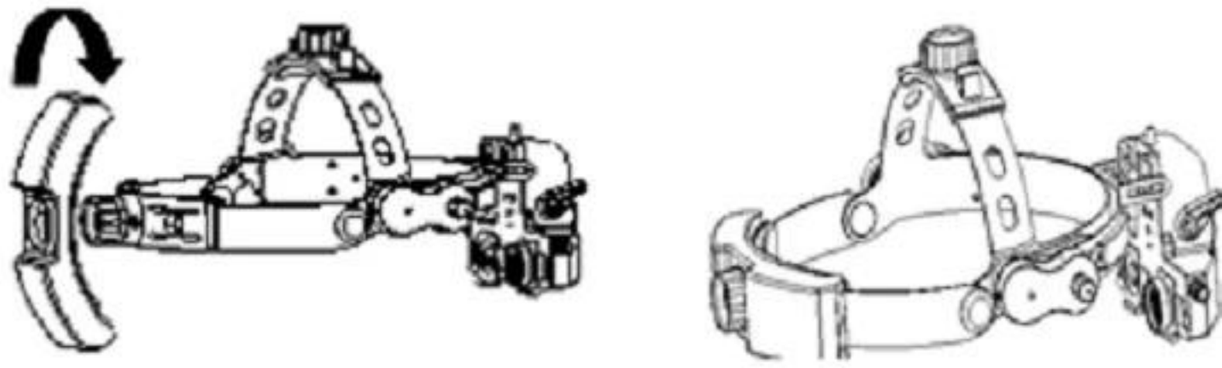
The light is positioned vertically into the upper two thirds of the field of view by rotating the spindle (7) located on either side of the binocular block.

- Small aperture: Provides easy view of the fund us through anundilated pupil.
- 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 stay in the mid position.
- Large aperture: Standard aperture for dilated pup and general examination of the eye.
- Cobalt Blue Filter: Blue filter used with fluorescein dye ermits easy viewing of small lesions, abrasions, and foreign objects.
- Red-free filter: Excludes red rays from examination field for easy identification of veins, arteries, and nerve fibers.
- Polarizing filter: eliminate corneal glare and reflection and can be used with any aperture.
- Teaching Mirror: The optional teaching mirror can be slid onto the fixture of the optics.

The Metal Outer Brow Band swivels and can be fixed into the following positions by means of the position lock (upwards for the rest position, down for working positions. To release the over band, press the position locking knob and rotate it.



Fit the battery to the headband, and rotate until it was locked. Then connect the short cable to the battery adaptor



3. Maintenance

3.1 Battery charging and replacing

During charging the LEDs operate sequentially, in use they remain switched on. If the LEDs remain switched off, the unit is non-operational or the battery is switched off. The number of illuminated or sequentially-switched LEDs indicates the state of charge of the Li-ion battery. The state of charge is shown whether an instrument is connected or not.

The Yellow LED indicated a fully-charged battery. If only the yellow LED illuminated, the battery must be recharged by means of the desk charger。.

Caution：Please use the appropriate battery. The battery should never be placed in municipal waste. Please check local regulations for disposal of batteries.

Caution：The adapter is specified as a part of indirect ophthalmoscope.

Warning：Replacement by inadequately trained personnel could result in a hazard (such as excessive temperatures, fire or explosion).

3.2 Cleaning and sterilization

◆ The outer surface of the instrument may be cleaned with wet cloth，the remaining stains can be cleaned off with the mixture of 50% alcohol and 50% distilled water. Do not wipe with any corrosive detergent lest that the surface should be damaged.

◆ Cleaning the lenses: Mirror-cleaning paper or a drop of liquid solvent (50% alcohol and 50% aether) may be used to clean the lens, blow it carefully. If there is dust stained on the lens, blow them with a blow ball or brush them with a dust pen.

Caution：Be careful to prevent the solvent into the instrument.

Caution: Dispose of old batteries safely.
Please contact the local environmental protection depa rtment to disposal of li-ion battery.

4. Technical Specification

Optical specifications	
PD Range	46–74 mm.
Illumination in 200mm working distance	≥2000 lx
Aperture	Large aperture, small aperture intermediate aperture Diffuser aperture Cobalt blue filter Red free filter Yellow filter Polarizing filter
Illumination angle	±4°
Weight	
Headlight (including head band)	400g
Electrical specifications	
Illumination source	LED
Rated voltage	7.4V rechargeable Li-ion battery
Battery Run-time	Not less than 7 hours continuous run-time on a fully charged battery.
Electrical Safety	Complying with EN60601−1 EN60601−1−2 Protection: Internal electrical power source IPX0
Charger	
Input voltage	12 VDC
Input power	⩽24VA
maximum charge time	⩽ hrs
Electrical Safety	Complying with EN60601−1 EN60601−1−2 Protection: Class Ⅱ IPX0
Adapter	
Type	UE15WCP1-120200SPA
Manufacture	Fuhua Electronic Co.,Ltd
Input voltage	100 VAC − 240 VAC 50 Hz / 60 Hz
Input power	⩽ 24 VA
Output	12 VDC/2 A
Electrical Safety	Complying with EN60601−1 EN60601−1−2 Protection: Class Ⅱ IP20
Environment requirements		
Operation	Environment Temperature	+10 ℃ - +40 ℃
	Relative Humidity	30% - 75%
	Atmospheric Pressure	700 hPa - 1060 hPa
Shipping	Common conveyance	
Storage	Environment Temperature	-40 ℃ - +55 ℃
	Relative Humidity	10% - 90%
	Atmospheric Pressure	500 hPa - 1060 hPa

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5. EMC (electromagnetic compatibility)

When using the device, the EMC precautions specified below must be observed.

• Only use spare parts approved by zumax for this device.

• Do not use any portable or mobile RF communication equipment in the vicinity of the device as this may impair the device's function.

• Do not use a mobile phone in the vicinity of the equipment because the radio interference can cause the equipment to malfunction. The effects of radio interference on medical equipment depend on a number of various factors and are therefore entirely unforeseeable.

• Please note the EMC guidelines on the following pages.

Warning: The indirect ophthalmoscope should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the MEEQUIPMENT or MESYSTEM should be observed to verify normal operation in the configuration in which it will be use.

Warning: Use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER of The indirect Ophthalmoscope as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of The indirect ophthalmoscope.

Electromagnetic interferenc

Guidance and manufacturer's declaration – electromagnetic emissions		
The indirect ophthalmoscope is intended for use in the electromagnetic environment specified below. The customer or the user of The indirect Ophthalmoscope should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The indirect Ophthalmoscope 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.
RF emissions CISPR 11	Class B	The indirect Ophthalmoscope 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.
Harmonic emissions IEV 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity for ME equipment and ME systems

Guidance and manufacturer's declaration – electromagnetic immunity			
The indirect Ophthalmoscope is intended for use in the electromagnetic environment specified below. The customer or the user of The indirect Ophthalmoscope 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	± 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 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	N/A	Internal electrical power source
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	N/A	Internal electrical power source
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 cycle 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	N/A	Internal electrical power source
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels 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.			

Electromagnetic immunity for non-life-supporting ME equipment and ME systems

<table>
<tr><td colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">The indirect Ophthalmoscope is intended for use in the electromagnetic environment specified below. The customer or the user of The indirect Ophthalmoscope should assure that it is used in such an environment.</td></tr>
<tr><td>IMMUNITY test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td></td><td></td><td></td><td>Portable and mobile RF communications equipment should be used no closer to any part of the indirect Ophthalmoscope , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td></tr>
<tr><td>Conducted RF
EN 61000-4-6</td><td>3 Vrms
150 kHz~80 MHz</td><td>N/A</td><td>nternal electrical power source</td></tr>
<tr><td>Radiated RF
IEC
61000-4-3</td><td>3 V/m
80 MHz~2.5 GHz</td><td>3V/m</td><td>$d=1.2\sqrt{P}$ 80 MHz~800 MHz
$d=2.3\sqrt{P}$ 800 MHz~2.5 GHz
where P is the output power rating of the transmitter in watts (W) according to the transmitter manufacturer's specifications and d is the recommended safety distance in meters(m).
Field strengths from stationary RF transmitters, as determined by a site survey[a], should be less than the compliance level in all frequency ranges.[b]
Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, 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.</td></tr>
<tr><td colspan="4">a Field strengths of stationary transmitters such as base stations for mobile telephones and mobile land radio equipment, amateur radio stations, AM and FM radio broadcast and TV broadcast transmitters cannot be theoretically predicted accurately. To assess the electromagnetic environment with respect to stationary RF transmitters, a site study of the electromagnetic phenomena should be considered. If the measured field strength in the location where the device is used exceeds the compliance levels indicated above, the device should be monitored to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ME equipment or ME system.
b Field strengths should be less than 3 V/m over the frequency range from 150 kHz to 80 MHz.</td></tr>
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