

Welch Allyn® 13500 Insight™ Wireless LED Binocular Indirect Ophthalmoscope



Directions for use

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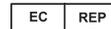
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Advancing Frontline Care™

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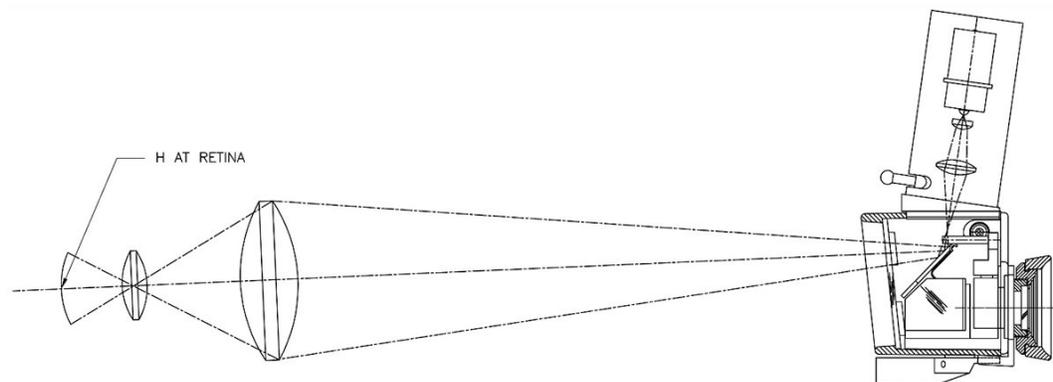
Overview

Indications for use

The Welch Allyn 13500 Wireless LED Insight Binocular Indirect Ophthalmoscope (Insight BIO) is a battery-powered device containing illumination and viewing optics intended for use by medical professionals to examine the cornea, aqueous, lens, vitreous, and the retina of the eye.

General operation and schematics

For illumination, the Welch Allyn Insight BIO uses a Light-Emitting Diode (LED). The following optical schematic highlights the traditional principles that govern how the device operates.



Unpacking the ophthalmoscope

Open the package and verify that all components listed below are included. If any component is missing, contact Welch Allyn immediately.

Item	Quantity
Insight BIO	1
Insight battery	2
Insight battery charger (USA, EU, UK plug)	1
Insight 0 diopter eyepiece lens	2
Insight directions for use	1
Insight wall mount	1

Accessories (available by order)

Part number	Description
13500S	Insight BIO kit complete with soft case
75360	Insight BIO rechargeable battery
13510	Insight BIO battery charger (USA, EU, UK plug)
13550	Insight BIO teaching mirror
13560	Insight BIO wall mount kit
13520	Insight BIO 2.0D eyepiece lenses (qty 2)
13530	Insight BIO 0.0D eyepiece lenses (qty 2)
13570	Insight BIO soft case
13540	Insight headband pad kit (all three pads)
13546	Insight BIO eye cups (qty 2)

Symbols and definitions

Documentation symbols



WARNING The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. Warning statements appear with a gray background in a black and white document but have a yellow background in color hard copies.



CAUTION The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.



Consult directions for use (DFU).
A copy of the DFU is available on this website.
A printed copy of the DFU can be ordered from Welch Allyn for delivery within 7 days.

Miscellaneous symbols



Fragile



Keep away from sunlight



This way up



Keep away from rain



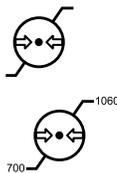
For indoor use only



Class II equipment



Humidity limitation



Atmospheric pressure limitation

	Temperature limit		Serial Number
	Product Identifier		Global Trade Item Number
	Reorder number		By prescription or order of physician
	Do not dispose of in trash, for batteries only		Do not dispose of in trash, for devices
	Rechargeable battery		Authorized Representative in the European Community
	Manufacturer		CE Mark for Class I equipment

Warnings and cautions

All users of the Insight BIO must read and understand all safety information presented in this manual before using the device.



WARNING The Welch Allyn 13500 Insight BIO is classified as a Group 2 instrument according to EN/ISO 15004-2:2007. The classification was performed together with a Ø54mm/20 Diopter Ophthalmoscopy loupe.



WARNING 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 10 minutes.



WARNING Because prolonged intense light exposure can damage the retina, the use of the Insight Binocular Indirect Ophthalmoscope for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. This device should be used with filters that eliminate UV radiation (<400 nm) and, whenever possible, filters that eliminate UV short wavelength blue light (<420 nm).



WARNING The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit. While no accurate optical radiation hazards have been identified for indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants and persons with aphakia or other eye disease/disorders may be at greater risk. The risk may also increase if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.



CAUTION Charge the Insight BIO only with the provided charger. Using any other charger could damage the instrument.



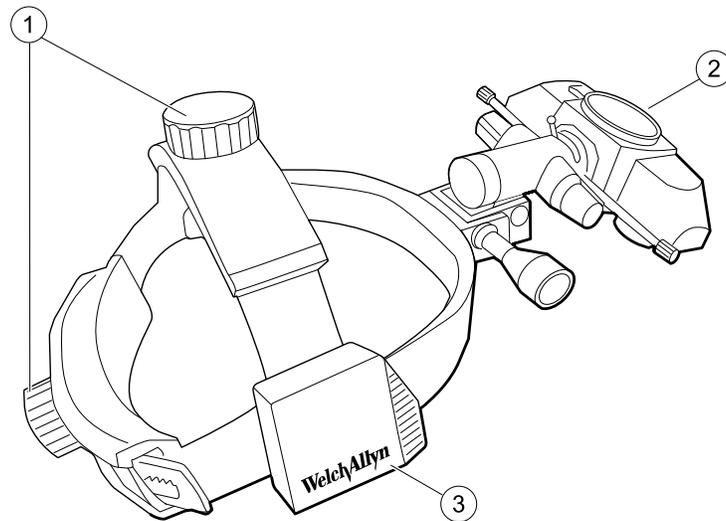
CAUTION Do not autoclave, immerse, excessively wet, or use germicidal cleaners other than those identified. Doing so will damage the instrument.



CAUTION United States Federal law restricts this device to sale, distribution, or use by or on the order of a physician or licensed healthcare professional.

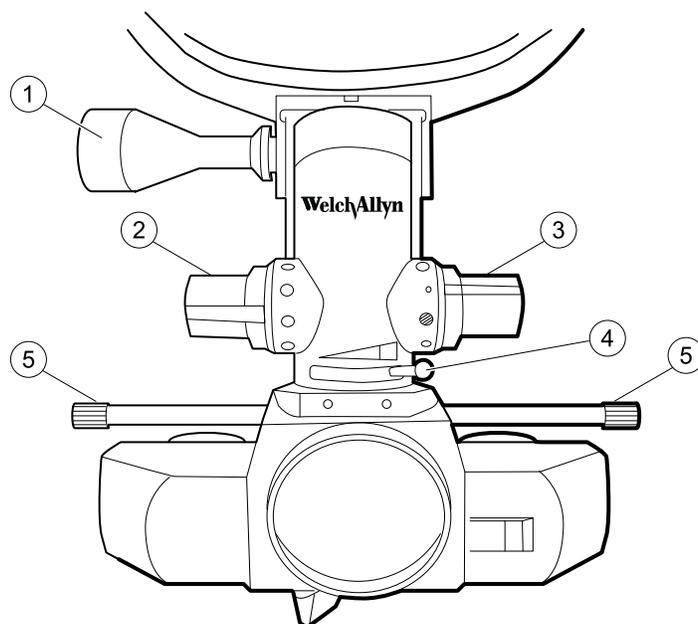
Controls, indicators, and connectors

Instrument top, right side view



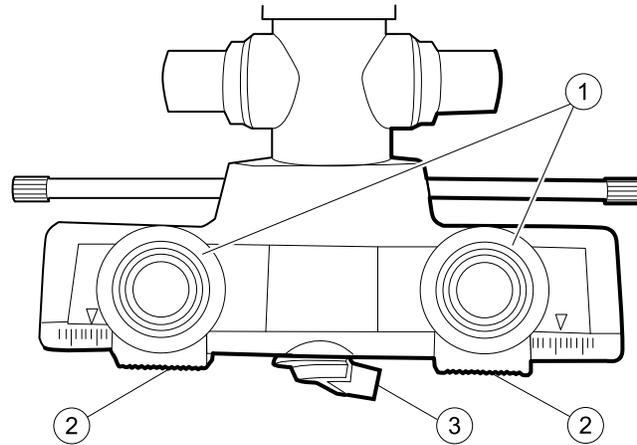
No.	Feature	Description
1	Headband adjustment knobs	Loosen or tighten fit of the headband.
2	Binocular	Provides illumination and viewing optics to examine the fundus (shown in OFF position).
3	Battery pack	Provides power to the binocular. Rechargeable with battery charger.

Binocular front view



No.	Feature	Description
1	Locking nut lever	Holds binocular in place. When unlocked, enables adjusting the binocular's position.
2	Filter selection control	Enables selection of neutral (none), red-free, amber, and cobalt blue filters.
3	Aperture selection control	Enables selection of small, medium, and large apertures as well as the diffuser.
4	Light output control	Enables selection of zero intensity (maximum dimming) to full intensity light output.
5	Tilt-mirror adjustment	Controls the vertical position of the light beam.

Binocular rear view



No.	Feature	Description
1	Eyepieces and lenses	Provide view of the fundus.
2	Inter-pupillary spacing adjustment controls	Enable manual adjustment of the space between the eyepieces.
3	Synchronized convergence and parallax adjustment control	Enables selection of wide or narrow settings to improve the view of the fundus.

Using the Insight BIO

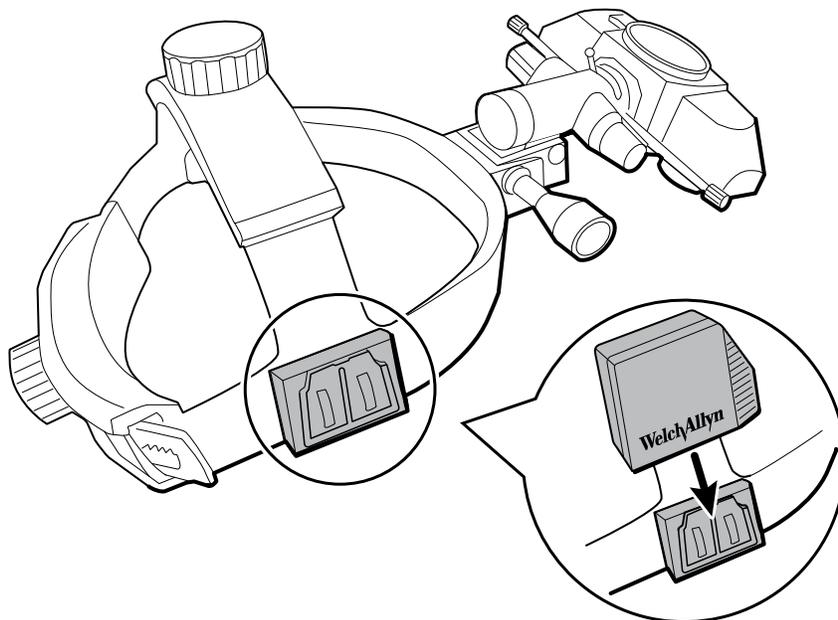
Attach the battery pack

The Insight BIO operates wirelessly with a rechargeable battery pack. Follow these instructions to set up the instrument.

1. Check the charge on the battery and recharge as needed. (See Maintenance.)

The charge LED on the battery charger block turns green when the battery is fully charged.

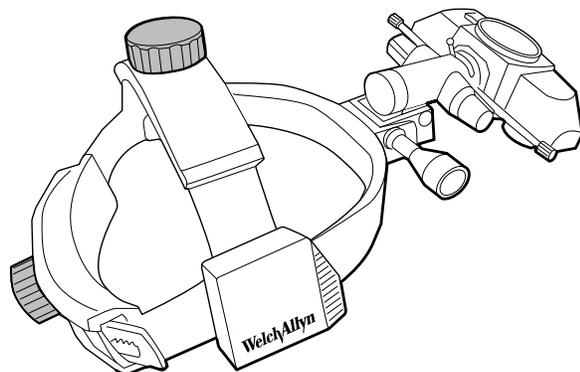
2. Place the binocular in the up/OFF position.
3. Locate battery connector on the headband.
4. Attach the battery pack.



Fit the instrument to your head

The knobs on the headband enable you to adjust the headband size. One knob is on the back of the instrument headband; the other is on the top of the headband strap.

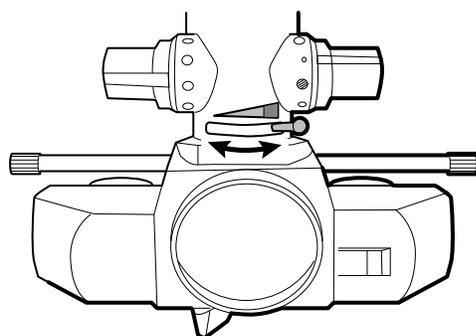
1. Loosen the headband to a circumference wider than your head.
2. Place the instrument on your head and tighten the top knob until the front of the headband is just above your eyebrow ridge.
3. Tighten the rear knob to a comfortable level.



Light output control

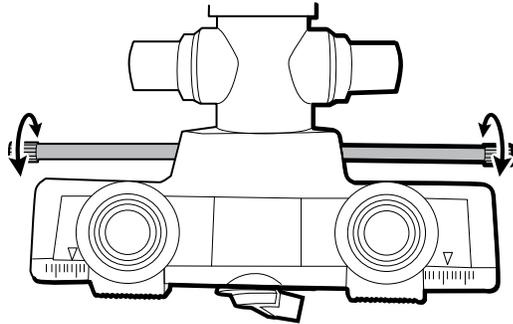
The LED light source constantly generates the same amount of light. The light output adjustment is gradual between substantially full and zero intensity, and is based on the relative position of two polarizer filters.

One of the filters is permanently affixed in the holder. You can rotate the other one with an adjustment control located on the front panel of the BIO module directly below the green-to-red intensity indicator graphic. By moving the control from left to right, you can adjust the light output to the desired level. When the two polarizer filters are aligned (the control is under the red and widest part of the graphic), the intensity level is at maximum. When the polarizer filter is perpendicular (at 90°) to the fixed polarizer filter (the control is under the green and narrowest part of the graphic), the intensity level is at minimum (maximum dimming).



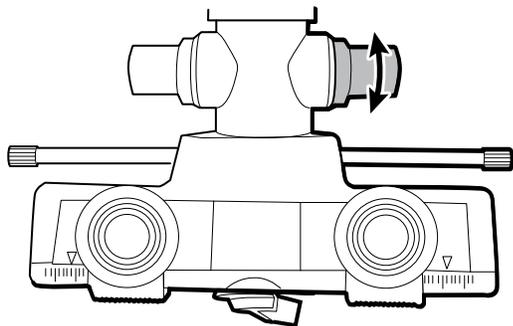
Light position controls

The BIO module also has a tilt-mirror adjustment that controls the vertical position of the light beam. For convenience, the controls are located on both sides of the device so that you can adjust the light beam when the instrument is on your head.

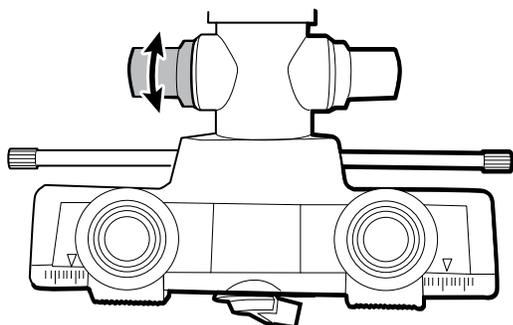


Filter and aperture controls

The Insight BIO is equipped with built-in filter and aperture controls. The control that selects between neutral (no filter), red-free, amber, and cobalt blue filters is located on the right side of the control arm when the instrument is on your head.



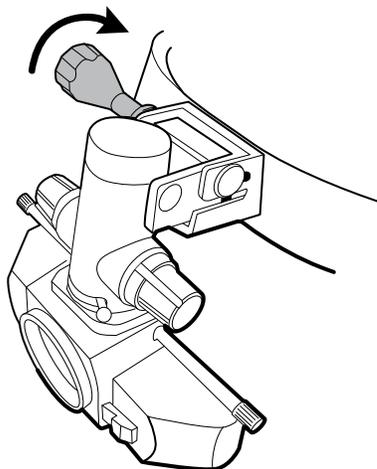
Similarly, the control that selects between small, medium, and large apertures and the diffuser is located on the left side of the control arm when the instrument is on your head.



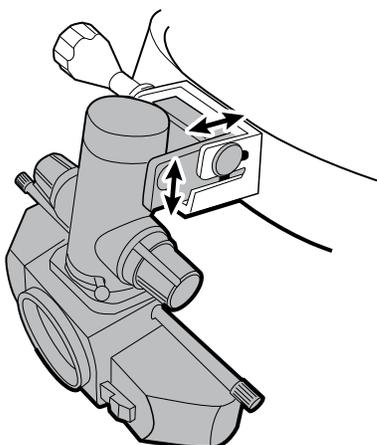
Module position controls

The Insight BIO module provides fine position adjustment controls to promote obtaining a superior view of the fundus and optimal comfort when using the instrument. The two-directional connection slots allow moving the BIO module up and down as well as closer and farther away from your face. The locking nut mechanism secures the BIO module in the desired position.

1. Place the Insight BIO module on your head.
2. Loosen the locking nut to adjust the position of the BIO module.



3. Put your hand in front of you at the approximate distance of the patient's eye.
4. Adjust the position of the module until you center the illumination spot on the palm of your hand.

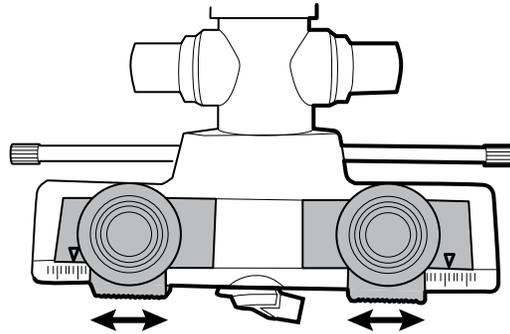


5. Tighten the locking nut to secure the module in place

Inter-pupillary spacing controls

Follow these instructions to manually adjust the inter-pupillary distance (spacing between the eyepieces) in the range of 49–74 mm:

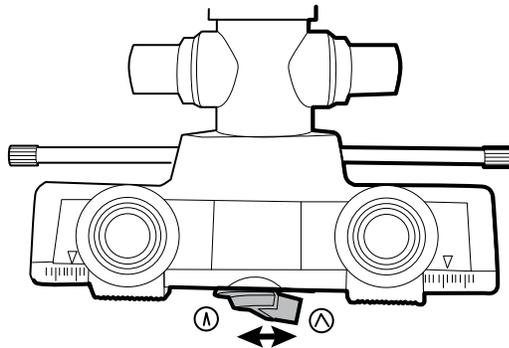
1. Close the left eye and adjust the eyepiece for the right eye by manually sliding it left and right until you center the illumination spot in your field of view.



2. Close the right eye and adjust the left eyepiece in the same fashion.
3. If necessary, re-adjust the position of the BIO module as described in the previous section.

Synchronized convergence and parallax controls

Using the control in the middle of the module's bottom panel, you can adjust for parallax and synchronized convergence and thus improve your ability to view the fundus. On patients with dilated pupils, use a wider distance to maximize stereopsis. On patients with smaller pupils, use a more narrow setting.

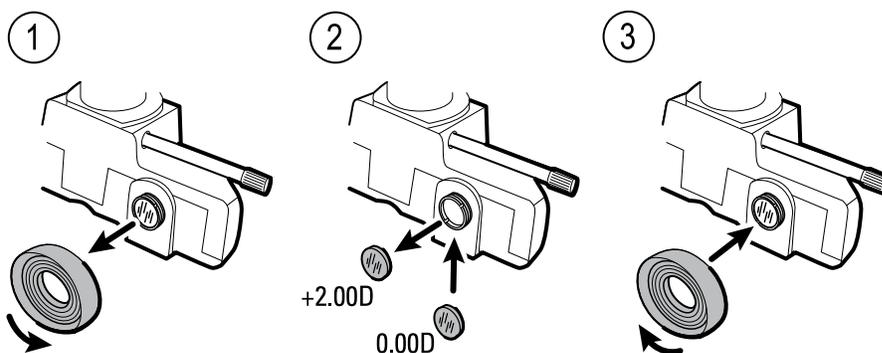


In practice, it's best to use the narrow setting first to obtain the fundus view. Then you can adjust for synchronized convergence and parallax by gradually moving the control as far as possible toward the wide setting without inducing a change in the image brightness or stability.

Lens options

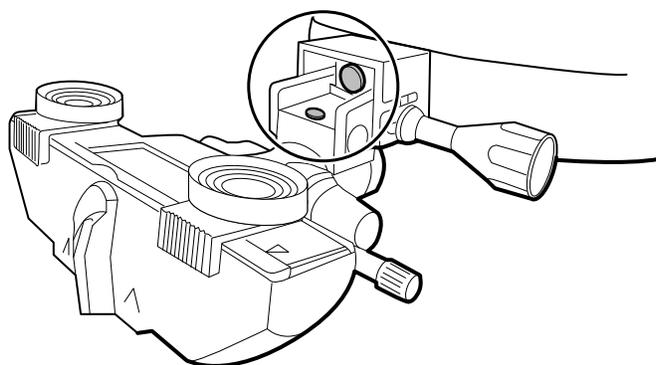
The Insight BIO is equipped with removable +2.00D lenses and an extra set of 0.00D lenses delivered with the product. These lens options enable you to view the fundus through lenses providing distance correction or standard lenses with no correction. Select the set of lenses that most closely matches any corrective lenses you normally wear.

To replace the +2.00D lenses, move to a reasonably dust-free environment, and follow the steps illustrated below:

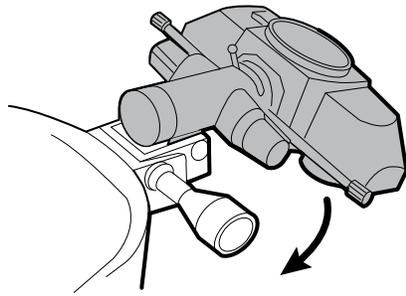


Power-on/power-off control

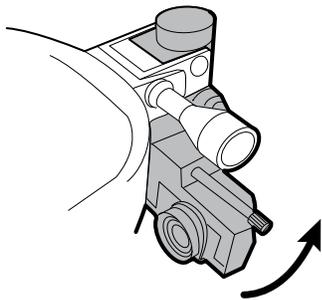
As shown below, the BIO module is connected directly to the headband with a pivot bracket mechanism. Two magnets built into this mechanism secure the module in operating position and also provide the electrical contacts which power-on/power-off the instrument.



To perform an examination, flip down the BIO module into operating position in front of your face. The magnets engage, connect the LED light source to the power source, and turn on the light.



After completing an examination, flip up the BIO module to disengage the magnets, disconnect power, and turn off the light.



Note The neodymium composition of the magnet guarantees a reliable electric contact for years.

Maintenance

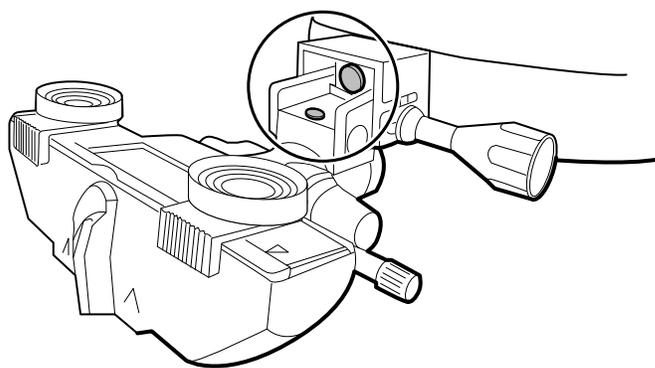
The Insight BIO does not require regular maintenance. Change the eyepiece lenses only in a reasonably dust-free environment. If you should require service on your product, please contact Welch Allyn.

Clean and disinfect the instrument



CAUTION Do not autoclave, immerse, excessively wet, or use germicidal cleaners other than those identified. Doing so will damage the instrument.

1. Remove the rechargeable battery from the Insight BIO headband.
2. Clean the Insight BIO's lens glass with a soft, lint-free cloth lightly dampened with 70% isopropyl alcohol. Do not excessively wet the lens glass.
3. Clean and disinfect the remaining surfaces of the Insight BIO with a soft cloth and 70% isopropyl alcohol or germicidal wipes labeled for healthcare equipment. Follow wipe manufacturer's instructions for appropriate use and contact time, and heed all warnings and cautions. Do not excessively wet the instrument or allow liquid to penetrate the optical unit.
4. Clean dirty on/off magnet contacts with cotton swab soaked in alcohol.



Charge the battery

You can charge the battery when it is disconnected from the Insight BIO and also when it is mounted on the Insight BIO headband.



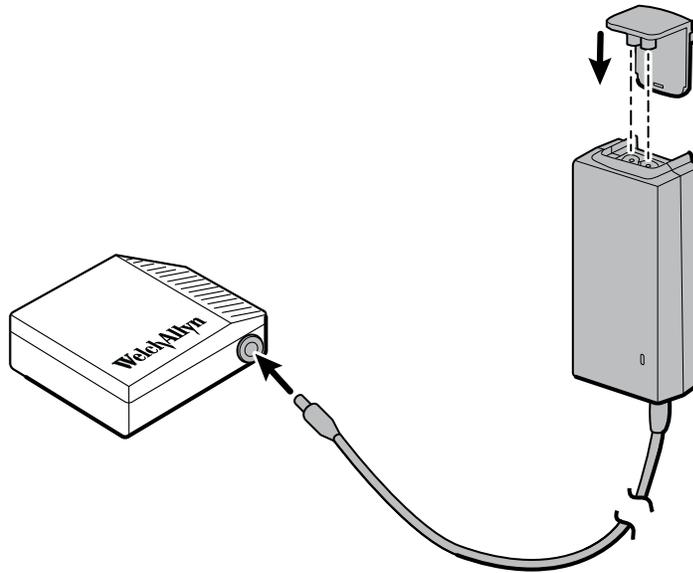
CAUTION The battery charger for the Insight BIO is for charging the # 75360 battery. Never use it for other purposes or on other manufacturers' batteries.



CAUTION Charge the Insight BIO battery only with the GlobTek #GTM91128L11CEL or Cell-Con #452241-LA30 charger. Never charge the #75360 battery with any other charger.

Note The battery charger for the Insight BIO comes with interchangeable prongs to fit power outlets in different regions of the world.

1. Attach the plug prongs that correspond to your AC power outlet as shown and plug the charger into an AC power outlet.



2. Connect the charger's output cord to the charge plug on the battery.

The LED charge status indicator on the charger block displays the following colors during recharging:

- Solid amber or red: Pre-charge
- Solid green: Charge complete
- None: No power to battery or fault condition

3. Unplug the charger from the battery and from the AC power outlet.
4. Store charged batteries appropriately (see Appendix).

Recharge time depends on the percent of charge remaining in the battery. Full charging takes approximately 3 hours. Charge current will terminate within 10 percent of bulk charge current. The battery charger's internal timer terminates charging 2-3 hours after the expected full charge time. A fully charged battery pack provides about 3 hours of uninterrupted use.

Specifications

Environmental specifications

Parameter	Temperature	Humidity
Operation	+5 °C to +40 °C	15% to 90%
Storage	+5 °C to +40 °C	15% to 95%
Transportation	-20 °C to +40 °C	15% to 90%

Rechargeable battery and charger specifications

Battery specifications

Characteristic	Specification
Manufacturer	GlobTek
Model	#BL2200F603451S2PZAL
Type	Lithium-ion
Output	3.7V 2200mAh (8.14Wh)
Estimated run time	3.5 hours (continuous)
Charger	Use only GlobTek #GTM91128L1CELE or Cell-Con #452241-LA30
Protection	Internal
Approvals	IEC 62133, CB Certificate # SE-74847 UN DOT 38.3 IATA 1.2m drop

Battery charger electrical specifications

Characteristic	Specification	Specification
Manufacturer	GlobTek	Mascot
Model	#GTM91128LI1CEL	Cell-Con #452241-LA30
Input voltage	100–240VAC	90–264VAC
Input frequency	50/60Hz	47–63Hz
Input current	< 1.5A RMS Max	1.3A +5/–7%
Charging voltage	1 cell: 4.2Vdc, +/1% Maximum	1 cell: 4.2V +.05V
Battery charging ambient temperature	0 °C to 35 °C	–25 °C to +40 °C
Plug prong type	USA: NEMA 1-15 EU: CEE 7/16 UK: BS 1363	USA: NEMA 1-15 EU: CEE 7/16 UK: BS 1363
LED charge status indicator	Solid Amber: Pre-charge Solid Green: Charge complete None: No power to battery or fault condition	Solid Red: Pre-charge Solid Green: Charge complete None: No power to battery or fault condition
Approvals	EN/IEC 60601-1:2005 UL 60601-1, 1st Edition CAN/CSA-C22.2 No. 601.1-M90, 2005	UL 60601-1 EN 60950 EN 60601-1 EN 60335-2-29

Default settings and setup

The Insight BIO is set up as follows when you first remove it from the package.

Control	Setting
Light output	Maximum
Aperture	Largest
Filter	Clear
Synchronized convergence and parallax	Wide
Attached lenses	+2.00D

Regulatory conformance

The 13500 Insight BIO conforms to the applicable requirements of the following standards:

- ISO 10943
- ISO 15004-1
- ISO 15004-2
- IEC 60601-1
- IEC 60601-1-2
- IEC 62366
- EN 1041
- EN 50581 (RoHS)
- 93/42/EEC

Guidance and manufacturer's declarations

EMC compliance

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment.

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this document.
- Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The instrument complies with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- Avoid using the instrument in extremely close proximity to other equipment.

Emissions and immunity information

Electromagnetic emissions

The 13500 Insight BIO is intended for use in the electromagnetic environment specified below. The customer or user of the 13500 Insight BIO should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The 13500 Insight BIO 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 13500 Insight BIO 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 IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity

The 13500 Insight BIO is intended for use in the electromagnetic environment specified below. The customer or the user of the 13500 Insight BIO 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	±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 ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	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 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	<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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 13500 Insight BIO requires continued operation during power mains interruptions, it is recommended that the 13500 Insight BIO be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	0,3 A/m	If image distortion occurs, it may be necessary to position the 13500 Insight BIO further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

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

Electromagnetic immunity

The 13500 Insight BIO is intended for use in the electromagnetic environment specified below. The customer or the user of the 13500 Insight BIO should assure that it is 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 13500 Insight BIO, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = (1,2) \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 1 GHz	3 V/m	$d = (1,2) \sqrt{P}$ 80 to 800 MHz

$$d = (2,3) \sqrt{P} \text{ 800 MHz to 2,5 GHz}$$

where P is the maximum output power rating of the transmitter in watts (W) and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b. Interference may occur in the vicinity of equipment marked with the following symbol:



Note1: 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.

^aField strengths from fixed transmitters, such as base stations for radio (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 13500 Insight BIO is used exceeds the applicable RF compliance level above, the 13500 Insight BIO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 13500 Insight BIO.

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

Recommended separation distances between portable and mobile RF communications equipment and the 13500 Insight BIO

The 13500 Insight BIO is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the 13500 Insight BIO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 13500 Insight BIO as recommended below, according to the maximum output power of the communications equipment.

Separation distance according to frequency of transmitter (m)

Rated max. output power of transmitter (W)	150 kHz to 80 MHz $d = (1.17) \sqrt{P}$	80 MHz to 800 MHz $d = (1.17) \sqrt{P}$	800 MHz to 2.5 GHz $d = (2.23) \sqrt{P}$
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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 80 MHz and 800 MHz, the separation distance for 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.

Appendix

Warranty

Welch Allyn warrants that the Insight Binocular Indirect Ophthalmoscope will be free of defects in workmanship or material for 10 years from the date of purchase. During this period, Welch Allyn will correct any such defects by repairing or replacing the product at its expense (excluding shipping costs). This warranty does not apply to defects caused by normal wear and tear; damage caused by accident, abuse, misuse, neglect, fire or other external cause, or during shipping; or damage caused by use outside of manufacturer's published guidelines, service performed by anyone other than Welch Allyn or its authorized agent, or modifications to alter functionality or capability without the express written authorization of Welch Allyn.

This warranty does not cover consumable parts, such as headband pads and eye cups.

Welch Allyn warrants the battery, charger, teaching mirror, and eyepiece lenses for 1 year from the date of purchase.

THIS LIMITED WARRANTY IS PROVIDED INSTEAD OF ANY OTHER IMPLIED PRODUCT QUALITY WARRANTIES AND IT IS THE SOLE WARRANTY OF THE PRODUCT.

Register your product

Choose one of the registration options below:

- Enter product information on the website: www.welchallyn.com/warranty
- Call the customer service phone number for your region to register your product within 30 days of original purchase, which will validate the product warranty

Visit www.welchallyn.com/about/company/locations.htm to find the customer service phone number for your region.

Welch Allyn will use your information only to contact you in case of a safety alert or recall for this product. We will not sell, rent, or share your personal information.

Battery disposal/recycling

Recycle the Lithium-ion battery according to local or national regulations.

Short-term storage

The Insight BIO can be conveniently stored on the Wall Mount or with the Soft Case accessories. Flip up the optical unit to the “Off” position. Then place the BIO’s rear cushion on the horizontal part of the Wall mount.



CAUTION Maintain the environmental storage conditions identified within the specifications during storage.



CAUTION To put the Insight BIO away for storage, disconnect the battery from the Insight BIO device and store the battery in the Soft Case away from other metal objects. Short-term storage on the Wall Mount does not require removing the battery pack.

Long-term storage

Follow these steps to store the Insight BIO for an extended period:

1. Disconnect battery from device and store battery in a location that meets environmental specifications and is free from other metal objects, intense sunlight, and moisture.
 - a. Charge batteries to 30–50% of capacity for long-term storage. We recommend that batteries be charged at least once every six months to prevent over-discharge.
 - b. Charged batteries will remain charged for several months if left unused.
2. As with the battery, store the Insight BIO in a location that meets environmental specifications and is free from other metal objects, intense sunlight, and moisture.

