

WelchAllyn

PanOptic™ Ophthalmoscope

118 Series



CE

Operating
Instruction
Manual

This product is protected by the following US patents: 6,065,837; 6,390,625; 6,409,341; 6,527,390; U.S. Pub. No. US20020097379; other patents pending.

AU App. No. 16331/100; AU App. No. 2001263366; CA App. No. 2,352,148; CA App. No. 2,409,596; PRC App. No. 99813584.4; EP App. No. 99959085.4; EP App. No. 01937653.2; JP App. No. 2000-583418.

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Symbols



Attention. Read Operating Manual for Cautions and Instructions for Use.



TYPE BF – Indicates this is a product with Type BF applied parts (the patient eyecup).



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.

Warnings and Cautions



CAUTION: To minimize lamp housing temperatures, on-time should not exceed 2 minutes with off-time not less than 10 minutes.



CAUTION: No acute optical radiation hazards are identified for ophthalmoscopes. However, Welch Allyn recommends limiting the intensity of the light directed into the patient's eye to the minimum level that is necessary for diagnosis. Infants, aphakes, and persons with diseased eyes are at a greater risk. The risk is also increased if the examined person has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source within the previous 24 hours. This will apply particularly if the eye has had exposure to retinal photography. The intended use of this device is for routine ophthalmic exams on the order of typically less than 60 seconds per eye. Although there is a benefit versus risk factor in any medical procedure, these more complicated exams should not exceed a three minute exam time in 24 hours. Significant use of this device beyond its intended use is not recommended; it may cause harm to the eyes.



Use only PanOptic Patient Eyecups (part number 118092) with this product.



CAUTION: Federal Law restricts this device to sale by or order of a physician.



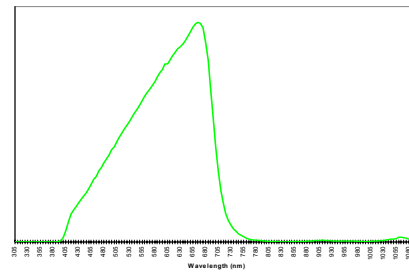
CAUTION: Spectrally weighted photochemical radiance L_B and L_A give a measure of the potential hazard that exists for a beam of light to cause photochemical damage to the retina. L_B gives the measure for eyes in which a crystalline lens is not in place. L_A gives this measure either for eyes in which the crystalline lens has been removed (aphakes) and has not been replaced by a UV-blocking lens or for the eyes of very young children.

The value stated for this ophthalmoscope gives a measure of hazard potential when the instrument is operated at maximum intensity and maximum aperture. Values of L_B or L_A over $684\text{mW}/(\text{cm}^2\cdot\text{sr})$ are considered high.

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. For instance, at a radiance level of $684\text{mW}/(\text{cm}^2\cdot\text{sr})$, a 3-minute exposure would produce a retinal exposure dose level at the recommended limit. If the value of radiance were reduced to $342\text{mW}/(\text{cm}^2\cdot\text{sr})$, twice that time (i.e. 6 minutes) is needed to reach the recommended limit. The recommended exposure dose is based on calculations using the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values for Chemical Substances and Physical Agents (1995-1996 Edition).



The 118 Series Ophthalmoscope has spectrally weighted photochemical radiances at maximum intensity and maximum aperture of $.281\text{ W}/(\text{cm}^2\cdot\text{sr})$ for L_B and $.300\text{ W}/(\text{cm}^2\cdot\text{sr})$ for L_A (aphake). The relative spectral output of the device is shown below.

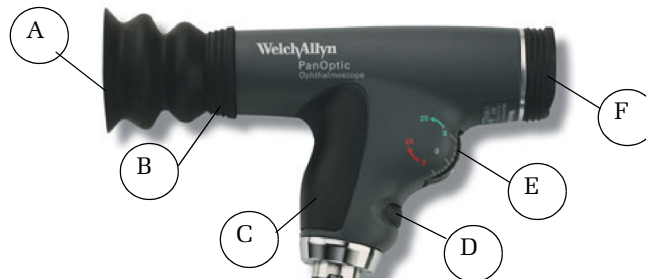


The **PanOptic™** Ophthalmoscope

Transparency of the cornea, lens and vitreous humor permits the practitioner to directly view arteries, veins, and the optic nerve of the retina.

Direct observation of the structures of the fundus through a PanOptic Ophthalmoscope may show disease of the eye itself or may reveal abnormalities indicative of disease elsewhere in the body. Among the most important of these are vascular changes due to diabetes or hypertension and swelling of the optic nerve head due to papilledema or optic neuritis. In this sense, the eye serves as a window through which many valuable clinical evaluations may be made.

When a preliminary diagnosis of an imminently dangerous eye condition, such as acute (angle-closure) glaucoma or retinal detachment, is made by the examiner, prompt referral to an eye specialist may prevent irreversible damage. Or, when distressing but less urgent conditions, such as visual impairment due to cataract or vitreous floaters, are recognized, the patient can be reassured and referred.

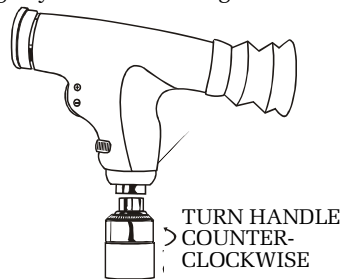


A Patient Eyecup	D Aperture/Filter Dial
B Patient's Side	E Focusing Wheel
C Soft Grip Handle	F Practitioner's Side Brow Rest

Set-up Instructions

Attaching the **PanOptic** Ophthalmoscope head to a Welch Allyn Power Source

Align cutouts in the PanOptic Ophthalmoscope base with lugs on power source. (The PanOptic Ophthalmoscope fits all 3.5v Welch Allyn power sources.) Push in slightly and turn 90 degrees.



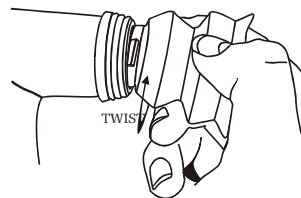
Attaching the Patient Eyecup to **PanOptic**



Use only PanOptic Patient Eyecups (part number 118092) with this product.

Insert eyecup into the patient's side of the instrument. Push and twist in one motion until you feel the two "lock" together.

See "Accessory and Replacement Parts List" on page 19 to reorder new PanOptic Patient Eyecups.

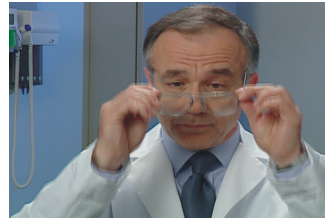


Attaching Corneal Viewing Lens to **PanOptic** (Model 11820 only)

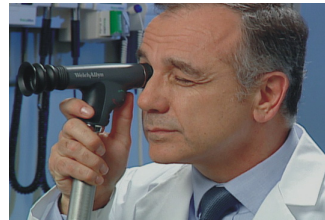
Insert Corneal Viewing Lens into patient's side of the instrument. Push and twist in one motion until you feel the two "lock" together as shown on page 5, except replacing Patient Eyecup with the Corneal Viewing Lens. Verify that the line on the lens housing is aligned with the top seam of the PanOptic instrument

Conducting an Examination with the **PanOptic** Ophthalmoscope

1. To examine the right eye, stand or sit to the patient's right side.
2. Remove Spectacles (preferred, but not required).



3. Look through the scope (from the doctor's side) with your thumb on the focusing wheel. Focus the scope on an object roughly 15 feet away. (This procedure will make any adjustments for your own eye's corrective needs.)
4. Start with the small aperture (green line position on the aperture dial).

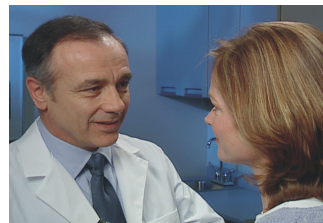


5. Turn the scope on (using any Welch Allyn 3.5V power source). Adjust light intensity rheostat to desired position.



You are now ready to begin the examination:

6. Examiner should be positioned approximately 15 degrees to the temporal side of the patient.
7. Instruct the patient to look straight ahead at a distant object.
8. Begin from about 6 inches away, looking through the scope and shining the light at the patient's eye while looking for the red retinal reflex.
9. Rest your left hand on the patient's forehead. (optional)

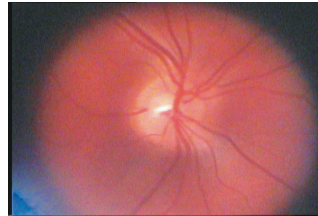


10. Slowly follow the red reflex toward the patient and into the pupil. Get as close as possible for the optimum view (the eyecup should contact the patient's brow).
11. Once you have a stable view of the fundus rotate the focusing wheel until you have a crisp view of the optic disc and the vessels surrounding it.

Note: For the largest view, compress the eyecup halfway against the patient's brow. This enables the user to view the entire optic disc plus many surrounding vessels (about 25° field of view) at one time.



12. Examine the optic disc for clarity of outline, color, elevation and condition of the vessels. Follow each vessel as far to the periphery as you can. To locate the macula, focus on the disc, then move the light approximately one (1) disc diameter temporally. You may also have the patient look at the light of the ophthalmoscope, which will automatically place the macula in full view. Examine for abnormalities in the macular area. The red-free filter facilitates viewing of the center of the macula, or the fovea.
13. To examine the extreme periphery instruct the patient to:
- A look up for examination of the superior retina
 - B look down for examination of the inferior retina
 - C look temporally for examination of the temporal retina
 - D look nasally for examination of the nasal retina.



This routine will reveal almost any abnormality that occurs in the fundus.

14. To examine the left eye, repeat the procedure outlined above. However, unlike traditional ophthalmoscopy, a unique feature of PanOptic is that the examiner does not have to switch to his/her left eye. The practitioner can use either eye to examine either patient eye because of the greater working distance between patient and practitioner. This permits those who are strongly dominant in one eye to always use that eye in the fundus exam.



Apertures and Filters

There is a wide range of practical apertures and filters to select from: small spot, large spot, micro spot, slit aperture, red-free filter, cobalt blue filter (optional), and half-moon aperture (optional).

1. **Small Aperture:** Provides easy view of the fundus through an undilated pupil. Always start the examination with this aperture and proceed to micro aperture if pupil is particularly small and/or sensitive to light. This position is the “Home” position on the aperture dial and is denoted by the green marking. 
2. **Large Aperture:** Standard aperture for dilated pupil examination of the eye. 
3. **Micro Spot Aperture:** Allows easy entry in very small, undilated pupils. 
4. **Slit Aperture (Models 11810, 11820 only):** Helpful in determining various elevations of lesions, particularly tumors and edematous discs. 
5. **Red-Free Filter (Model 11810, 11820 only):** This filter excludes red rays from the examination field: this is superior to ordinary light in viewing slight alterations in vessels, minute retinal hemorrhages, ill-defined exudates and obscure changes in the macula. The nerve fibers become visible and the observer may note the disappearance of such fibers, as in optic nerve atrophy. The background appears gray, the disc appears white, the macula appears yellow, the fundus reflex is intense and the vessels appear almost black. This filter is also used to help distinguish veins from arteries; veins stay 

relatively blue, but oxygenated arterial blood makes arteries appear blacker. This greater contrast makes differentiation easier for the examiner.

6. **Cobalt Blue Filter (Model 11820 only):** In conjunction with fluorescein dye applied topically to the cornea and an add-on magnifying lens (included), this filter is helpful in detecting corneal abrasions and foreign bodies. In this way, it can be used as a surrogate to a Woods Light.
7. **Half-Moon Aperture (11810 Only):** Provides a combination of depth perception and field-of view.

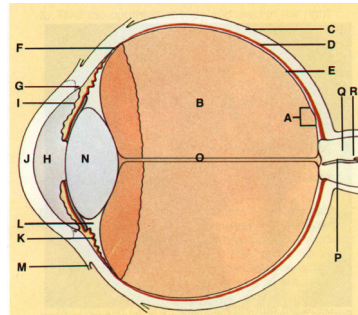


The Eye

In addition to examination of the fundus, the PanOptic Ophthalmoscope is a useful diagnostic aid in studying other ocular structures. The light beam can be used to illuminate the cornea and the iris for detecting foreign bodies in the cornea and irregularities of the pupil.

The practitioner can also easily detect lens opacities by looking at the pupil through an add-on corneal viewing lens. In the same manner, vitreous opacities can be detected by having the patient look up and down, to the right and to the left. Any vitreous opacities will be seen moving across the pupillary area as the eye changes position or comes back to the primary position.

- A) Macula
- B) Vitreous humor
- C) Sclera
- D) Choroid
- E) Retina
- F) Ora Serrata
- G) Canal of Schlemm
- H) Anterior chamber
- I) Iris
- J) Cornea
- K) Ciliary body
- L) Zonule (Suspensory Ligament)
- M) Conjunctiva
- N) Lens
- O) Hyaloid canal
- P) Central retinal vein
- Q) Optic nerve
- R) Central retinal artery

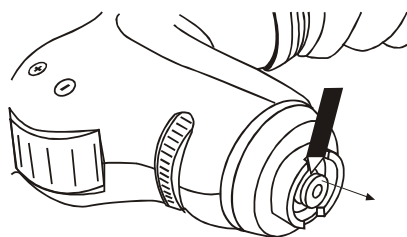


Lamp Replacement Instructions

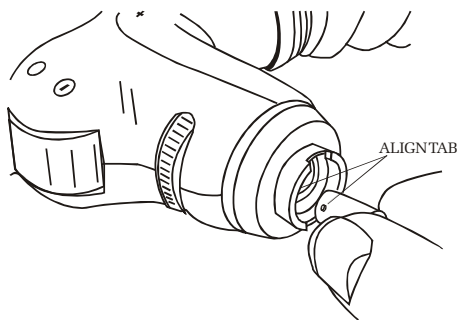
Lamp Replacement Caution: Halogen lamps are pressurized to provide maximum efficiency and illumination. Mistreatment may cause shattering. Protect lamp surface against abrasion and scratches. Verify power is off when replacing lamp. Dispose of lamp with care.



CAUTION: Lamps may be hot. Lamp should be allowed to cool before removal. **Use only Welch Allyn model 03800 lamp with this product**



Use your fingernail or a small prying instrument to remove the lamp from the ophthalmoscope head base.



To insert the new lamp, align tab on lamp with notch in the base of the ophthalmoscope head and push inward until firmly seated.

Cleaning and Repair Instructions

Cleaning and repairs (with exception of the lamp replacement) beyond what is specified in the “**general cleaning instructions**” section should be performed at the factory.

General Cleaning Instructions

NOTE: Excess solution entering the optical assembly could damage internal components. Use caution to ensure cloth is not saturated with solution.

This is a precision optical instrument. Please follow these specific cleaning requirements:

- **Do not use any solvent based cleaners on the lenses. Use only the supplied cleaning cloth on the lenses.**
- **The PanOptic Ophthalmoscope is Non-sterilizable.**
- **Disinfect housing using soft cloth moistened with alcohol.**
- **Clean the Patient Eyecup by any of the following methods:**
 1. **Soft cloth/cotton swab moistened with alcohol.**
 2. **Soaking in gluteraldehyde based solutions (i.e. Cidex OPA).**

NOTE: For disinfection time / procedure requirements it is recommended that you follow the directions of the specific brand you are using.

3. **Autoclaving.**
- **Do not use acetone based products or other harsh chemicals.**

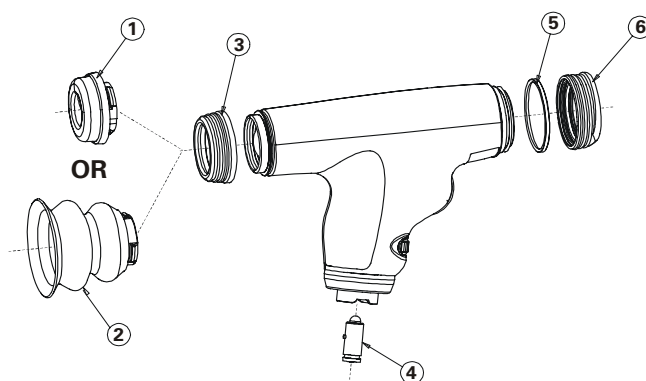
No other preventative maintenance is necessary for this product.

Troubleshooting

Trouble Area	Possible Cause	Corrective Action
No Light output	Aperture dial is in-between positions Lamp burned out. Wrong lamp/ incorrect Welch Allyn lamp/non-Welch Allyn lamp. The battery handle has completely discharged.	Rotate the aperture dial. Replace the lamp using Welch Allyn part number 03800. Replace lamp using Welch Allyn part number 03800. Charge the handle, check the battery, and/or the charger.
Spot is not centered.	The aperture dial is not centered.	Move aperture dial to the full detent position.
Not achieving full or expected view.	Unit is not in proper operating position.	Ensure that the eyecup is slightly compressed during the procedure.

Trouble Area	Possible Cause	Corrective Action
Can not obtain sharp focus/hazy view.	The lenses are dirty.	Clean the lenses with the provided cleaning cloth.
Dim Light Output	Lamp pin not engaged in slot	Insert the lamp with pin firmly seated in slot.
	Film on Optics	Clean the lenses with the provided cleaning cloth.
	The handle is not fully charged.	Charge the handle, check the battery and/or the charger
Glare in view	Fingerprints or dirt on the objective (Patient's Side) lens	Clean the objective (Patient's Side) lens with the provided cleaning cloth.
Cannot attach to power handle.	Lamp is not fully inserted.	Insert the lamp with pin firmly seated in slot.

Accessory and Replacement Parts List



Item No.	Description	Product #
1	Corneal Viewing Lens (model no. 11820 only)	11875
2	Patient Eyecups (Package of five (5) each 118092)	11870
3	Patient's Side Bumper	118051
4	Lamp	03800
5	Chrome Ring	118027
6	Practitioner's Side Brow Rest	118052
7	Cleaning Cloth (not shown)	11873

Service and Warranty Information

Service

For customers in North America, please return instruments requiring service to a Welch Allyn Technical Service Department listed below or to an authorized Welch Allyn distributor.

Technical Service Department

USA:

Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0220 USA
Telephone: 800-669-9771
Fax: 315-685-4653

Canada:

Welch Allyn, Ltd. - Canada
160 Matheson Blvd. E., Unit #2
Mississauga, Canada L4Z 1V4
Phone: 905-890-0004
Fax: 905-890-0008

For customers outside of North America, return your unit to a local, authorized Welch Allyn distributor or to your nearest Welch Allyn service center.

Welch Allyn, Ltd. – UK
Cublington Road
Aston Abbots, Buckinghamshire
England HP22 4ND
Phone: 011-44-1296-689905
Fax: 011-44-1296-682104

Welch Allyn France
814 rue Charles de Gaulle
77100 Mareuil les Meaux
France
Phone: 011-33 1 60 06 33 66
Fax: 011-33 1 60 09 67 97

Welch Allyn, GmbH PSC
Zollerstrasse 2-4
72417 Juningen, Germany
Phone: 011-49-7477-927173
Fax: 011-49-7477-927193

Welch Allyn, LTD - Singapore
300 Beach Road #25-08
The Concourse
Singapore 199589
Phone: 011-65-291-0882
Fax: 011-65-291-5780

Welch Allyn China Service Center
Room 708, 227 Huang Pi Road, North
Central Plaza
Shanghai 200003, China
Phone: 011-86-21-6327-9631
Fax: 011-86-21-6327-9632

Welch Allyn, Ltd. - Australia
Metro Center Unit 5
38 South Street
Rydalmere NSW 2116, Australia
Phone: 011-(612) 9638-3000
Fax: 011-(612) 9638-3500

For service in Latin America and the Caribbean region, contact:

MD International
11300 N.W. 41st Street
Miami, FL 33178 USA
Phone: 1-305-669-9003
Fax: 1-305-669-1971

PanOptic Ophthalmoscope Warranty

Welch Allyn, Inc. warrants the No. 11810, 11820 PanOptic Ophthalmoscope to be free of original defects in material and workmanship and to perform in accordance with manufacturer's specifications for a period of one year from the date of purchase. If this instrument or any component thereof is found to be defective or at variance with the manufacturer's specifications during the warranty period, Welch Allyn will repair or replace the instrument or component(s) at no cost to the purchaser.

This warranty only applies to instruments purchased new from Welch Allyn or its authorized distributors or representatives. The purchaser must return the instrument directly to Welch Allyn or an authorized distributor or representative and bear the costs of shipping.

This warranty does not cover breakage or failure due to tampering, misuse, neglect, accidents, modification or shipping, and is void if the instrument is not used in accordance with manufacturer's recommendations or if repaired or serviced by other than Welch Allyn or a Welch Allyn authorized representative.

No other express or implied warranty is given.

Specifications

Model Number

11810 PanOptic Ophthalmoscope without Cobalt Blue Filter
11820 PanOptic Ophthalmoscope with Cobalt Blue Filter and
Add-on Corneal Viewing Lens

Dimensions

5.125"L x 1.4"W x 3.750"H without eyecup
Eyecup 1.45"L

Weight

.48 lbs without eyecup
.50 lb with eyecup

Approvals

EN60601-1
IEC 60601-1-2
CAN/CSA-C22.2 No. 601.1-M90
UL 2601-1, Second Edition, 1997

Equipment Classification

IPXØ Equipment not protected against the ingress of water.



Equipment not suitable for use in the presence of a flammable anesthetic.

Environment

Transport/ -20°C - 49°C, 95% Rh max, 500hPa - 1060 hPa,
Storage: altitude

Operating: 10°C - 49°C, 95% Rh max, 500 hPa - 1060 hPa,
altitude

CAUTION: Federal Law restricts this device to sale by or order of a physician.



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Printed in U.S.A.

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