

OPTYSE™

LENS FREE OPHTHALMOSCOPE



REF: OPT / REF: OPT-B2

A User's Guide

CE

Caution: USA federal law restricts this device to sale by, or on the order of a Physician or Practitioner.

Symbols**Definitions****REF**

Catalogue Number

LOT

Lot Number



YYYY-MM

Manufactured on Year-Month



YYYY-MM

Use by Date



Read complete User's Guide prior to using device



Recommended storage and environmental conditions of use

Symbols

Definitions



If not disposed of properly, batteries can be harmful.



Table of Contents

- 1. Intended Use**
- 2. Kit Components**
- 3. The Optyse™ Lens Free Ophthalmoscope**
- 4. Mode of Operation**
- 5. Safety**
- 6. Maintenance**
- 7. Storage**
- 8. Technical Services**
- 9. Optyse™ Figures**

Optyse™ Lens Free Ophthalmoscope

A User's Guide

1. INTENDED USE

The Optyse™ Lens Free Ophthalmoscope is a direct ophthalmoscope intended to be used to examine the fundus or the inside of the back of the eye.

2. KIT COMPONENTS

This kit contains the following:

- The Optyse™ Lens Free Ophthalmoscope with bulb
- Two AAA Batteries
- Pouch to carry Optyse™
- User's Guide
- Diagrams for User's Guide
- REF:OPT-B2 : 2 bulbs

3. THE OPTYSE™ LENS FREE OPHTHALMOSCOPE

The Optyse™ Lens Free Ophthalmoscope is the invention of Mr Roger Armour, a retired surgeon who worked within the UK's national health care system for over 40 years. The Optyse™ was designed to simplify the technique of retinal examination by removing the lenses and special adjustments that are required in standard direct ophthalmoscopes. As there are no lenses in the Optyse™ that correct for the subject's or examiner's eyesight, the subject and the examiner may wear their spectacles or contact lenses during the examination.

Please refer to Section 4, Mode of Operation, and the Procedural Notes (5-6).

4. MODE OF OPERATION

Please read the following Procedural Notes prior to performing an examination.

PROCEDURAL NOTES:

1. *OPTYSE™ DIAGRAM*

Please refer to **Figures 1** and **2** to become familiar with the parts of the Optyse™. In **Figure 1** the Protective Cover is Closed shielding the Optical Head and in **Figure 2** the Protective Cover is Open exposing the Optical Head.

2. *CONDITION*

Upon receipt of your Optyse™ Lens Free Ophthalmoscope please visually inspect the device for any obvious defects. If the device is damaged in any way please contact your local distributor or Ophthalmos Ltd. Contact details are provided in **Section 8**.

3. *BATTERIES*

The Optyse™ is internally powered by two AAA batteries. The batteries have been provided separately; you will need to follow the directions in **Section 6A** to correctly insert the batteries into the Optyse™. *Please note that it is recommended that these batteries are removed when the device is unlikely to be used over a period of time.*

4. PUPIL DILATION

The subject's pupils may be dilated unless contraindicated. You should warn the subject that this process may affect their vision, that they should not drive until their vision has returned to normal, and caution them about any potential side-effects from this procedure.

Warning: *The risk of precipitating acute glaucoma is extremely small, and then only in subjects with severe hypermetropia (i.e. they wear glasses with convex lenses for distance viewing) and in elderly subjects with hypermetropia (because of increased bulk of the lens in their eye).*

Marked pain in the eye and prolonged blurred vision for more than 3 hours after dilating drops have been used should be assessed by an eye care professional with facilities for measuring intra-ocular pressure.

5. EXAMINER'S USE OF CORRECTIVE LENSES

If you normally wear glasses or contact lenses for reading it is recommended that they are removed before using the Optyse™. If you normally wear glasses or contact lenses for distance viewing (i.e. you are myopic or short-sighted) then you should wear these while using the Optyse™.

6. SUBJECT'S USE OF CORRECTIVE LENSES

If the subject normally wears glasses or contact lenses then they should keep these on during the examination, as an improved image should be obtained.

Please note that a slight reduction in the field of view may be seen if both the examiner and the subject wear glasses.

IF YOU ARE NOT GETTING A CLEAR VIEW DURING THE EXAMINATION, PLEASE TRY USING THE OPTYSE™ WITH AND WITHOUT GLASSES OR CONTACT LENSES.

GENERAL OPERATION:

- Open the Optyse™ by rotating the Protective Cover 180° so that it snaps into position over the Battery Compartment at the bottom of the device (see **Figures 1** and **2**).
- Please refer to **Figure 3** for the position of the Sight Hole during the examination and for a representation of the flow of light from the Optyse™ into the subject's eye.
- Holding the Optyse™ in your hand, use your thumb to push the pale blue Switch upward into the **ON** position. It should click into position and the bulb should light (see **Figure 4ii**).
- Examine the subject's eyes using standard ophthalmic procedures.

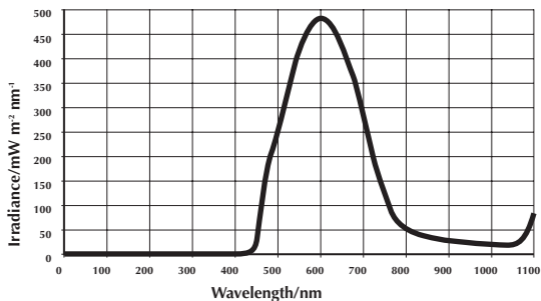
- After the ophthalmic examination, push the pale blue Switch downward into the **OFF** position. It should click into position and the bulb will go out (see **Figure 4i**).
- Return the Protective Cover from the bottom of the device to its original position by rotating it 180° until it snaps into position and covers the Optical Head.

If your Optyse™ fails to operate or causes you any concerns, please contact your local distributor.

5. SAFETY

The relative spectral output of the Optyse™ between 305 nm and 1100 nm indicates that this device is comparable with other ophthalmoscopes:

Spectral Irradiance at 10mm of Optyse™ Lens Free Ophthalmoscope



Spectrally weighted photochemical source radiance data for the Optyse™

Phakic $L_B = 10.1$

Aphakic $L_A = 9.9$

Because prolonged intense light exposure can damage the retina, the use of an ophthalmoscope for ocular examination should not be unnecessarily prolonged. The brightness of the bulb supplied with the Optyse™ should not exceed what is needed to provide clear visualisation of the target structures. The prism, within the Optyse™, is made of material that minimises UV radiation (<400 nm) and short-wavelength blue light (<420 nm).

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of the radiance were reduced by half, twice the time would be needed to reach the maximum exposure limit. 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 is the radiance that gives the measure for the eyes in which the crystalline lens is in place. L_A is the radiance that 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 Optyse™ has a set light intensity and no apertures. Therefore, the values stated are a measure of hazard potential during normal operation incorporating a new light source and batteries. A value of L_B or L_A over 80mW/(cm² sr) is considered high for beams that wholly fill a dilated pupil.

While no acute optical radiation hazards have been identified for direct ophthalmoscopes, it is recommended that the intensity of light directed into the subject's eye be limited to the minimum level that is necessary for diagnosis. Infants, aphakes, and those with diseased eyes

will be at greater 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 a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.

6. ROUTINE MAINTENANCE

A. REMOVING AND REPLACING THE BATTERIES

The Optyse™ uses 2 AAA, 1.5 volt batteries. For optimal performance Ophthalmos Ltd recommends the use of Duracell AAA batteries, which on average provide approximately 4 hours of continuous use. If the bulb appears dimmer than normal (and you have checked that the small prism in the optical head is clean) then consider replacing the batteries. Replacement batteries can be purchased from your local supplier.

1. First check that the Optyse™ is switched off by ensuring that the pale blue Switch is in the **OFF** position (**Figure 4i**).
2. Hold the Optical Head in one hand and place the flat surface of your thumb and index finger on the two Side Clips.
3. Firmly press the Clips to release these and gently move the Optical Head from side to side to detach it from the Battery Compartment (**Figure 5**).

Note: *Once the Optical Head becomes detached, the top battery may pop out of the Battery Compartment.*

4. Remove the batteries by turning the Battery Compartment upside down.
5. Insert replacement batteries in the orientation shown in **Figure 6**.
6. Reassemble the Optyse™ by gently pressing the two Side Clips (**X** and **Y**) around the top battery as shown in **Figure 7** and then slowly inserting these Clips into the Battery Compartment until they lock into place.

Note: *The Optical Head and Battery Compartment fit together in one orientation - there is a small semi-circle projection on the Sight Hole side of the Optical Head (labelled as **N** in **Figure 8**) that must be aligned with the notch in the Battery Compartment (labelled as **O** in **Figure 8**).*

Note: *Flat or used batteries should be disposed of safely as per local requirements.*

B. REMOVING AND REPLACING THE BULB

The Optyse™ uses a miniature 2.5 volt bulb as its light source. If the bulb fails to operate or you notice that the light has become less bright, first check that the batteries are functioning correctly. If the batteries are working properly, consider replacing the bulb. Replacement bulb units can be ordered from your local distributor.

1. Open the Optyse™ by following the directions described in **Section 6A, Steps 1-3**.

2. On the Sight Hole side of the Optical Head there is a small white Disc (**Q**) that holds the Bulb Unit (**P**) in position (see **Figure 9**). Pull the Disc that is on the unnotched side slightly towards the outer casing and lift the Bulb Unit out of the Optical Head by pushing it up from under the unnotched side.
3. Insert a replacement Bulb Unit, taking care to orientate it correctly (see **Figure 9**).
4. Reassemble the Optyse™ by gently pressing the Side Clips (**X** and **Y**) around the top battery as shown in **Figure 7** and then slowly insert these Clips into the Battery Compartment as described in **Section 6A, Step 6**.

Note: *Used bulb units should be disposed of safely as per local requirements.*

C. CLEANING AND DISINFECTING

Ensure that the Optyse™ is switched off by checking that the pale blue Switch is in the **OFF** position (**Figure 4i**). The Optyse™ may be cleaned by wiping the external casing with a damp cloth. Care should be taken to avoid debris building up around the pale blue Switch as this may affect the operation of the Optyse™.

If, during use, the prism in the Optical Head of the Optyse™ becomes dusty, remove dust by gently blowing. However, care should be taken to prevent dust from building up on the prism by replacing the cover over the Optical Head immediately following use.

If gently blowing on the prism fails to remove the dust, or you require further advice on how best to clean your Optyse™, then please contact local distributor.

If required, the Optyse™ can be disinfected by wiping all external surfaces with a 70% alcohol solution.

D. CAUTIONS

Do not immerse the Optyse™ in water. If the device comes in contact with water, dry it immediately.

Do not subject the unit to excessive: force, shock, dust, temperature or humidity. Such treatment may result in malfunction, shorter electronic life span, damaged batteries, or distorted parts.

Do not tamper with the device's internal components (except as described in **Section 6A, B and C**). Doing so may cause damage. The Optyse™ contains no user-serviceable parts.

Ophthalmos Ltd recommends the use of Duracell AAA batteries for optimum performance.

Do not mix new and old batteries as the old batteries may leak.

The content of this document is subject to change.

7. RECOMMENDED STORAGE AND ENVIRONMENTAL CONDITIONS OF USE

Conditions of Use:

Temperature: +10°C to 35°C (50°F to 95°F)

Relative Humidity: 30% to 75%

Storage Conditions:

Temperature: -10°C to 55°C (14°F to 131°F)

Relative Humidity: 10% to 95%

8. TECHNICAL SUPPORT

Please contact your local distributor, Altomed.

Telephone: 0191 519 0111

9. OPTYSE™ FIGURES

Refer to User's Guide Diagrams.