



# STARTING

Thank you for purchasing the oDocs nun ophthalmoscope. Please read the user manual carefully before using the product.

Keep the manual in a safe place for future reference.

## CAUTIONS

- (1) The contents of the user manual is the copyright of oDocs Eye Care and WIKIOPTICS. It is prohibited to copy or amend all or part of the contents without permission.
- (2) For an updated digital version, you can find them on our main website. [www.odocs-tech.com](http://www.odocs-tech.com)
- (3) Please contact oDocs Eye Care or WIKIOPTICS if you are in doubt with the contents in this document.
- (4) You will be liable for any injury or damages caused by this product for failure to comply with the written instructions provided in this manual.

## TERMS OF USE

The oDocs nun ophthalmoscope is designed and made to be used in a general office, clinics or home environment. The terms of use are as follows.

- Operating temperature: 0 degree Celsius to + 45 degree Celsius
- Storage temperature : -20 degree Celsius to + 55 Degree Celsius
- Operating humidity: 30% to 90%
- Storage humidity: 10% to 95%
- Operating and storage atmospheric pressure: 800pa to 1060hpa

# CAUTIONS FOR SAFETY

Please read the “CAUTIONS FOR SAFETY” carefully before using this product and use the product properly for preventing a user or another person from being harmed.

**WARNING** : It is possible for a patient to be harmed if the examiner fails to comply with the operating instructions.

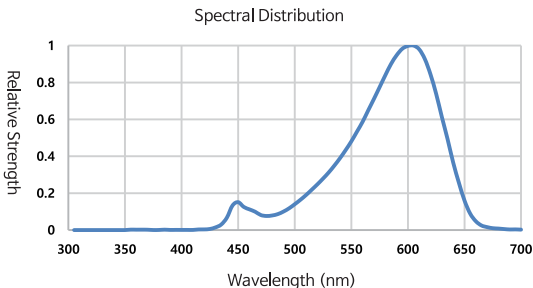
## WARNING & CAUTIONS

Risk of severe optical radiation harm can occur if used inappropriately. This product should only be used by a trained clinician. It is recommended that the light exposure duration should not be more than 60 seconds per eye.

It is prohibited to use this product for any cumulative duration of 3 minutes or more in a 24 hour block. Failure to comply may result in serious retinal injury.

Harmful optical wavelengths such as ultraviolet (UV) and infrared (IR) are filtered out.

The spectral distribution falls within the visible light spectrum



# CAUTIONS FOR SAFETY



## CAUTIONS

Unless the instructions for operating are followed carefully, this product is possible to fail or be broken.

### **SAFETY & CAUTIONS REGARDING TO USING THE PRODUCT, RECHARGEABLE BATTERY AND DC POWER SUPPLY**

It is not appropriate to use this product at a place where a flammable anaesthetic is used.

Please handle product with care, impacts may damage the product

Keep the product away from strong magnets.

Do not disassemble or remodel the battery pack.

Please use only the original battery pack.








Please do not charge a battery pack beyond the temperature range of 0 and 45 degree.

If the battery is fully charged, please unplug the DC power supply.

Do not expose the battery pack to a temperature beyond the range of -20 degree and 55 degree.

Do not discard the battery in open space with variable temperature due to risk of fire.

# SYMBOLS

	Increase brightness
	This symbol identifies a safety note. Ensure you understand the function of this control before using it. Control function is described in the appropriate service manual.
	This symbol indicates to follow instructions for use.
	This indicates the year of manufacture/production
	This indicates the manufacturer.
	Authorized Representative in the European Community.
	Class II equipment
	This symbol indicates to handle the fragile device with care
	This symbol indicates to keep the device away from sunlight
	This symbol indicates to keep the device dry
	This symbol indicates the humidity limitation for operation, transport and storage
	This symbol indicates the temperature limitation for operation, transport and storage
	Conforms with the Waste Electrical and Electronic Equipment Directive(2002/96/EC). At the end of useful life, dispose of all waste according to local requirements, or contact agent for device. The product is designated for separate collection at an appropriate collection point. Do not dispose of in normal waste stream.

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## **CHAPTER 1- HOW TO USE**

# **PURPOSE OF USE AND USAGE OF PRODUCT**

The oDocs nun is a medical device under the category ophthalmoscope.

It is designed for the observation of the cornea, lens, vitreous humor and the retina.

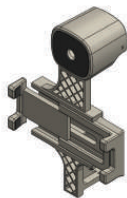
When used as instructed, pathological conditions of the eye can be directly observed through this ophthalmoscope.

Clinical diagnosis or diagnoses can only be made by a trained and certified clinician.

# CHAPTER 1- HOW TO USE Package Contents



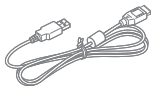
1. Body of ophthalmoscope,  
'nun'



2. Smartphone Adaptor



3. DC power Supply & Plug



4. Micro USB Power Cable



5. User Manual

Any ones of those components may be changed without notice for enhancing the performance or quality of the product.



## CHAPTER 1- HOW TO USE COMPOSITION OF BODY



- A: FILTER ADJUSTMENT WHEEL
- B: FOCUS ADJUSTMENT WHEEL
- C: LIGHT INTENSITY ADJUSTMENT WHEEL
- D: 5-PIN CHARGING PORT
- E: BATTERY STATUS INDICATOR(LED)

## CHAPTER 1- HOW TO USE FEATURES OF PRODUCT



### COMPATIBLE WITH GLASSES

- 20mm comfortable working distance

### WIDE FIELD OF VIEW

- 30 degree with pupil size of 4mm

### MANUAL FOCUS ADJUSTMENT

- Refractive error correction : +20D to -20D

### COLOR FILTER

- Red-free and cobalt-blue

### VISIBLE LIGHT ILLUMINATION

- Built-in UV and IR filters

## CHAPTER 1- HOW TO USE

# EXAMINATION OF THE RETINA PREPARATION STEP BEFORE EXAMINING

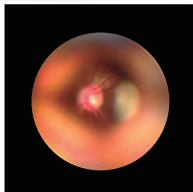
1. A clinician shall observe an eye with the non ophthalmoscope. A finger should be placed on the focus adjustment wheel. If is possible to use the ophthalmoscope while wearing glasses. To begin, set the focus at an object less than 3 metre away. This is to correct any refractive errors of the observe's eye by turning the focus adjustment wheel.
2. The color filter should be set at the white line to provide a bright yellow illumination.
3. Turn on the illumination by turning the dial at the bottom of the device. You can adjust the light intensity accordingly.



## ? NOTES

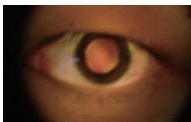
It is recommended to use the ophthalmoscope under dim-light conditions.

It is possible to use it in undilated patients. Non-mydratiac viewing angle is 15 degree.



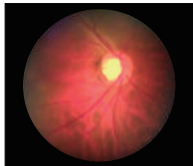
## CHAPTER 1- HOW TO USE EXAMINATION OF THE RETINA EXAMINING PROCEDURE

4. The examiner should be sitting at around 15 degree to the side of the patient.
5. The patient is then instructed to stare at an object in the distance.
6. With the device turned on, start at a distance 15cm from the patient and locate the red reflex
7. The focus can be adjusted in order to achieve a clear image of the retina.
8. The optimal distance between the device and the patient is around 15mm. The maximal field of view can only be achieved at this distance.



## CHAPTER 1- HOW TO USE EXAMINATION OF THE RETINA

9. When examining the retina, start with the optic disc and the blood vessels. The macula is located temporal to the optic disc. The patient can be instructed to look at the light in order to bring the macula into the centre of the view. Optical filters can be used at this stage to enhance the view of certain structures within the eye.



10. To observe the peripheral retina, the patient will have to follow the following instructions.
- Superior region of the retina : Instruct the patient to look up.
  - Inferior region of the retina: Instruct the patient to look down.
  - Temporal region of the retina: Instruct the patient to look away from the nose.
  - Nasal region of the retina: Instruct the patient to look towards the nose.



### ? NOTES

It is recommended to use this product in a dark or dim-light condition.

Ensure the ophthalmoscope is turned off after using it.

Keep the ophthalmoscope in the product case safely after cleaning it.

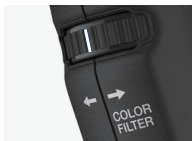


## CHAPTER 1- HOW TO USE

# EXAMINATION OF THE CORNEA

### PREPARATION STEP BEFORE EXAMINING

1. Set the focus wheel to the red mark.
2. Turn on the light.
3. Position the ophthalmoscope around 6 to 8 cm away from the patient's eye. The cornea should be in focus.
4. For fluorescein examination, cobalt blue filter can be used.



#### NOTES

It is recommended to use this product in a dark or dim-light condition.

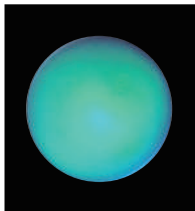
Ensure the ophthalmoscope is turned off after using it.

Keep the ophthalmoscope in the product case safely after cleaning it.



## CHAPTER 1- HOW TO USE COLOR FILTER

### SELECTION OF A COLOR FILTER



#### **Red-free filter**

Designed to filter out the red saturation of the retina. Highly effective for observing microaneurysm, and retinal vasculature.

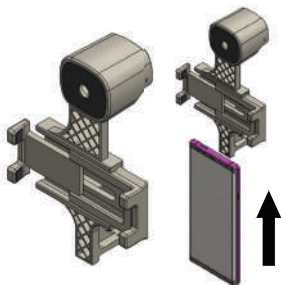


#### **Cobalt-blue filter**

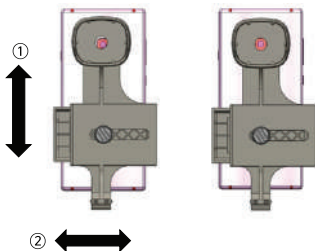
It is commonly used to excite fluorescein instilled on the surface of the eye. Highly effective for observing cornea epithelial defects.

## CHAPTER 1- HOW TO USE SMARTPHONE ADAPTOR USE GUIDE

1. Adjust the adaptor's mount so the smartphone can be inserted.

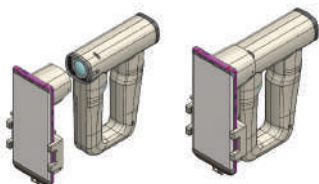


2. Turn the adaptor around so you can manually align the camera of the smartphone.
3. The visual axis of the camera has to be in the center of the aperture.
4. Fasten the knob to secure the smartphone in place.





## CHAPTER 1- HOW TO USE SMARTPHONE ADAPTOR USE GUIDE

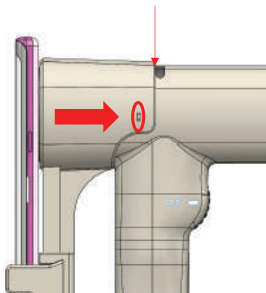


5. The smartphone adaptor can now be attached onto the observer eye piece of the non ophthalmoscope.

Example of good condition image



6. You will hear a “Click” when the sides are locked in place.
7. Turn on your phone’s camera, you can choose either still images or video.



## CHAPTER 1- HOW TO USE

# WASHING & REPAIRING

### REPAIRING

The product can be repaired by an authorized agent or its headquarters.

### WASHING FOR CONTINUOUS USE

#### Lens

Please do not use any detergent-based solvent for washing the lens. You can use an optical brush or micro-fibre cloth

#### Housing

Please clean the housing with low-level or medium level disinfected medical cloth or isopropyl alcohol for disinfection

#### After cleaning

Please inspect the product for any damages. In the case that a damage is found, please stop using it and contact WIKIOPTICS or ODOCS EYE CARE.



### CAUTIONS

Do not soak the entire product in any solvent

Do not sterilize the product at a high temperature or pressure

Product is not waterproof

# CHAPTER 1- HOW TO USE PRODUCT SPECIFICATIONS

## ■ Dimensions

[L] 125mm x [W] 42mm x [H] 155mm

## ■ Weight

Ophthalmoscope, 'nun': 280g

## ■ Rechargeable battery

3.6V 2500mAh protection circuit 18650

## ■ Waterproof grade

IPXØ: This product is NOT protected from any penetration of water.

## ■ Operating environment

Operating temperature : 0°C - +45°C

Storage temperature : -20°C - +55°C

Operating Humidity : 30% - 90%

Storage Humidity : 10% - 95%

Atmospheric pressure : 800 hpa - 1060 hpa(operating & storage)

## ■ The product lifetime

1 years

## ■ DC Power Supply (Rechargeable)

IEC60601-1 Medical power supply, compliant with 2MOPP

- Model name : GTM46101-1005-USB

- Input: 100-240V, 50-60Hz, 0.3A

- Output: DC 5.0 V, 2.0A

The medical device is class II equipment / Internal electrical power source equipment

## **CHAPTER 1- HOW TO USE**

# **HOW TO CHARGE AND REPLACE THE BATTERY, DC POWER SUPPLY AND MICRO USB POWER CABLE**

## **HOW TO CHARGE THE BATTERY**

- Please connect the USB charging cable into the micro USB port.
- Please maintain the state that the power is 'Off' by turning the light intensity adjustment wheel of the ophthalmoscope toward the end of the left.
- Please start charging the battery by connecting the charger cord into a socket.
- While the battery is being charged, the LED light maintains in green, but when the charging is completed, the green light turns off.
- When charging is completed, please unplug the charger before using the ophthalmoscope.

## **HOW TO REPLACE BATTERY**

When the rechargeable battery cannot be recharged any longer, please replace that as follows.

- Please detach the battery cover first.
- Please pick out the battery by pulling up the battery hold strap.
- Please insert a new 3.6 V 2500mAh protection circuit 18650 battery into the compartment in order for each pole of the battery to be matched to the same of the compartment.
- Please fix the battery cover with the guide hole.
- Please check the operation status of the ophthalmoscope with adjusting the light intensity adjustment wheel.

## **HOW TO REPLACE THE DC POWER SUPPLY MICRO USB CABLE**

When the DC power supply and micro USB power cable are no longer available, please replace them as follows.

- Micro USB power cable can be replaced by purchasing another new micro USB power cable.
- DC power supply must be purchased with our product or IEC60601-1 medical power supply, compliant with 2MOPP(Type A USB integral jack or with micro USB cable).

## CHAPTER 1- HOW TO USE CALIBRATION AND SERVICE

- The accuracy of this ophthalmoscope has been carefully tested and designed to last long.
- Periodic inspections are recommended every two years to ensure proper operation and accuracy of the ophthalmoscope.
- If you have any questions or problems, please contact the place of purchase or head office.
- Preventive inspections to ensure continuous safe use follow as;
  - Before using the ophthalmoscope, check the light on/off status and turn the light intensity adjustment wheel to the left or right for safety check and adjust the focus adjustment wheel to check the focus status.



### **1. The light is not operated or is dim.**

- 1) Please place the filter adjustment wheel to its original position by turning it around.
- 2) Please check whether the LED light is 'On' or 'Off'.
- 3) If the light intensity adjustment wheel is turned around to the left, the light becomes dimmer. So, please turn it around to the right.
- 4) The battery might be fully discharged. If the battery is discharged, please charge the battery again with the DC power supply.

### **2. Lighting is not shaped in a small ring.**

- 1) The filter adjustment wheel may not be positioned in the center.
- 2) Please place the filter adjustment wheel to its original position by turning it around.

#### **?** NOTES

- Please check whether there is an error or not in the process of connecting, setting or operating once more before repairing it. If there is a problem even after checking such points, please consult with the customer service center.

## CHAPTER 2- TROUBLE SHOOTING GUIDE

# PROBLEMS



### **3. It looks smaller than the viewing angle, '30°'.**

- 1) Please check whether the distance between the patient and the ophthalmoscope is maintained at around 15mm.
- 2) Please adjust the focus by using the focus adjustment wheel.

### **4. A Clear Image cannot be seen or some flash is seen.**

- 1) The lens might be contaminated.
- 2) Please clean the lens with a clean and soft cloth.

## CHAPTER 3- ELECTROMAGNETIC COMPATIBILITY

# EMC

- Electromagnetic Interference – Although this equipment conforms with the intent of the directive 20014/108/EC in relation to Electromagnetic Compatibility(EMC), all electrical equipment may produce interference. If interference is suspected, move equipment away from sensitive devices or contact the manufacturer.
- Portable and mobile RF communications equipment can effect medical electrical equipment.
- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information in the following tables.
- The following tables document compliance levels and guidance from the IEC 60601-1-2 2007 Standard, for the electromagnetic environment in which the WFE-02S Unit should be used a clinical environment.



# CHAPTER 3- ELECTROMAGNETIC COMPATIBILITY

## EMC

Guidance and manufacturer's declaration – electromagnetic emissions		
The REF WFE-02S is intended for use in the electromagnetic environment specified below. The customer or the user of the REF WFE-02S should assure that it is used such an environment.		
Emissions test	Compliance	Electromagnetic environment -
RF emissions CISPR 11	Group 1	The REF WFE-02S 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 A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Complies	
	[See 5.2.2.1 c) and Figure 1]	The REF WFE-02S 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.
	[See 5.2.2.1 c) and Figure 1]	The REF WFE-02S is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:  Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It such as re-orienting or relocating the REF WFE-02S or shielding the location.
	[See 5.2.2.1 c) and Figure 1]	The REF WFE-02S is suitable for use in all establishments other than domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR14-1	Complies	The REF WFE-02S is not suitable for interconnection with other equipment.
RF emissions CISPR 15		The REF WFE-02S is not suitable for interconnection with other equipment.


## CHAPTER 3- ELECTROMAGNETIC COMPATIBILITY

# EMC

Guidance and manufacturer's declaration – electromagnetic immunity			
The REF WFE-02S is intended for use in the electromagnetic environment specified below. The customer or the user of the REF WFE-02S 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	± 6kV contact ± 8kV air	± 6kV contact ± 8kV 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 IEC61000-4-4	± 2kV for power supply lines ± 1kV for input/output line(s)	± 2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to lines(s) ± 2kV line(s) to earth	± 1kV line(s) to lines(s)	Main 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% UT (>95% dip in UT ) for 0.5 cycle 40% UT (60% dip in UT ) for 5 cycles	< 5% UT (>95% dip in UT ) for 0.5 cycle 40% UT (60% dip in UT ) for 5 cycles	Main power quality should be that of a typical commercial of hospital environment. If the user of the REF WFE-02S requires continued operation during power mains interruptions, it is recommended that the REF WFE-02S be powered
	70% UT (30% dip in UT ) for 25 cycles <5% UT (>95% dip in UT ) for 5 s	70% UT (30% dip in UT ) for 25 cycles <5% UT (>95% dip in UT ) for 5 s	from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

## CHAPTER 3- ELECTROMAGNETIC COMPATIBILITY

# EMC

Guidance and manufacturer's declaration – electromagnetic immunity			
The REF WFE-02S is intended for use in the electromagnetic environment specified below. The customer or the user of the REF WFE-02S should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
<p>Conducted RF IEC61000-4-6</p> <p>Radiated RF IEC61000-4-3</p>	<p>3Vrms 150kHz to 80MHz</p> <p>3V/m 80MHz to 2.5GHz</p>	<p>3Vrms 150kHz to 80MHz</p> <p>3V/m 80MHz to 2.5GHz</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the REF WFE-02S, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = [3.5 \sqrt{V^2 P}] \sqrt{P}$ $d = [3.5 \sqrt{E^2 P}] \sqrt{P} \text{ 80M to 800MHz}$ $d = [7 \sqrt{E^2 P}] \sqrt{P} \text{ 80M to 2.5GHz}$ <p>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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup> Interference may occur in the vicinity of equipment marked with the following</p>
			<p>symbol : </p>
<p>NOTE 1 At 80MHz and 800MHz, the higher frequency range applies.</p> <p>NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically survey should be considered. If the measured field strength in the location in which the REF WFE-02S is used exceeds the applicable RF Compliance level above, the REF WFE-02S should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the REF WFE-02S.</p> <p>b Over the frequency range 150kHz to 80MHz, field strengths should be than <math>[V] \sqrt{m}</math>.</p>			

## CHAPTER 3- ELECTROMAGNETIC COMPATIBILITY

# WARRANTY STATEMENT

This product is manufactured based on the standard procedures for product management and inspection process that are defined by WIKIOPTICS, Inc. It is promised that the product bought by you shall be repaired free of charge only in case that the one is newly purchased at the head office of WIKIOPTICS, an exclusive sales agency or a branch, the warranty period is not expired and the product had been normally used in accordance with the user manual before it is broken.

If a charged repair item is occurred even within the warranty period, the relevant additional expense might be charged.

This warranty statement shall not be reissued, so please keep it well not to be lost.

When you request a repair, please show this warranty statement without missing.

The battery and all kinds of accessories other than the ophthalmoscope are consumables.

## FREE-OF-CHARGE REPAIRING

- Only in case that a problem is occurred to the product bought by you under the normal use within the warranty period from the date of purchasing.

## CHARGED REPAIRING

- In case that the warranty period is expired or there is no warranty statement.
- In case of a failure due to a mistake or negligence while using the product (dropping, flooding, an Impact, a damage or excessive operation)
- In case of a failure due to the abnormality of operating power or an inferiority of a connected device,
- In case of a failure due to the use of an accessory which is not provided or authorized by WIKIOPTICS, Inc.
- In case of a failure due to the disassembling or remodeling at your discretion,
- In case of a failure due to the repairing at a place other than the head office of WIKIOPTICS or an authorized service center.
- In case of a failure due to an act of God, such as, a fire, an earthquake and flooding, etc.

Model name		Ophthalmoscope (Model No. _____ )	
Lot no.			
Client	Name		
	Tel.		
	Address		
Date of purchasing (warranty period: ophthalmoscope= 1 year, battery= 6months, accessory =3months)			
Sales agency	Branch name		
	Tel.		
	Address		

## CHAPTER 3- ELECTROMAGNETIC COMPATIBILITY A/S SERVICE REQUEST FORM

Model name		
Date of purchasing		
Description of failure 1		
Description of failure 2		
Description of failure 3		
Name		
Contact info.	Tel.:	Cell Phone:
Address for product registration		
Comments		
<b>Contact information</b> ODocs Eye Care Limited 36 Murano Street, Waverley, Dunedin 9013, New Zealand Website: <a href="http://www.odocs-tech.com">www.odocs-tech.com</a> Address of customer service center: Rm. 205, U-Tower, 120, Heungdeokjungang-ro, Giheung-gu, Yongin-si, Gyeonggi-do, 16950, Korea		



### New Zealand Sponsor

oDocs Eye Care Limited  
36 Murano Street,  
Waverley, Dunedin 9013, New Zealand

### Australia Sponsor

Access-2-Healthcare Australia Pty Ltd  
12 Turnberry Grove, Melbourne,  
VIC 3939, Australia



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