

Technical Document - ODocs nun Ophthalmoscope

Product Description

The oDocs nun ophthalmoscope is designed and made to be used in a general office, clinics or home environment. It is designed for the observation of the cornea, lens, vitreous humor and the retina. Pathological conditions of the eye can be directly observed through this ophthalmoscope.

Please read this technical document (this document) carefully before using the product.

Features of the product

- Non-mydratic (works for pupils as small as 2 mm)
- Wide view angle (30° FOV at pupil size 4mm)
- Dynamic focus (+20D to -20D)
- Universal smartphone compatibility (Androids and iPhones)
- Filter enhancement (yellow, red-free, blue)
- Rechargeable lithium-ion battery
- Can be used with or without a smartphone

System Identification Data

Product Name	Portable Ophthalmoscope / Model : WFE-02S
Brand Name	nun
Parent company	ODOCS EYE CARE LIMITED
Manufacturer	WikiOptics, Inc.
EU representative	JaviTech e.K.
Eu representative Address	Sachsenhausener Str.16, 65824 Schwalbach a. Ts., Germany
Medical device class	Class 1 (Annex IX Rule 12)
GMDN code and term	GMDN Code: 46788 Term (P-Term): Indirect monocular ophthalmoscope, battery-powered
CE labelling	Registered
Allowed device combination	Androids or IOS phone; acceptable length 55-94 mm
Current document status:	Document version 1.1.1 dated 2020-12-30

Product Specifications

Dimension & Weight

Name/Category	Length (mm)	Width (mm)	Height (mm)	Weight (g)
Nun ophthalmoscope body	125	42	155	280
Nun ophthalmoscope with box	335	80	285	1140

Optical specification

Field of view (FOV) :30 degrees with pupil size of 4mm
Diopter: -20D to +20D (manual focus)
Light source: Red-free and cobalt-blue; visible light illumination is built-in UV and IR filters.
Image format: JPEG
Image sensor: 13Mp
Image resolution: 4208x3120
USB connectivity: Mini USB2.0

Rechargeable battery

3.6V 3500mAh protection circuit 18650

Waterproof grade

IPX0: This product is NOT protected from any penetration of water.

Operating Environment

- Operating temperature: 0°C~45°C
- Storage temperature (non-operating): -20°C~ 55°C
- Operating humidity: 30%~ 90%
- Storage humidity: 10%~ 95%
- Operating & Storage Atmospheric pressure: 800hPa~ 1060hPa

DC power supply (for charging)

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

Scope of Delivery

Delivered Package Content

oDocs Eye Care package delivery is entirely annotated in the oDocs nun ophthalmoscope packing list. Delivered components including:

	Body of ophthalmoscope, 'nun'
	Smartphone Adaptor
	DC power Supply & Plug
	Micro USB Power Cable
	User Manual

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

Composition of the fundus camera body



- A: Filter Adjustment Wheel
- B: Focus Adjustment Wheel
- C: Light Intensity Adjustment Wheel
- D: 5-PIN Charging Port
- E: Battery Status Indicator (LED)

Standards

The product is approved by the Therapeutic Goods Administration (TGA) and MedSafe. The nun-IR WFC-01 complies with the following standards:

IEC60601-1: 2012

IEC 60601-2: 2007

EN62304

EN62366

IEC62133: 2012

ELECTROMAGNETIC COMPATIBILITY

- This device has been tested and found to comply with the limits for medical devices to the IEC60601-1-2(Edition4.0):2014.
- Electromagnetic Interference – Although this equipment conforms with the intent of the directive 2014/108/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.

WARRANTY : 12 months

Technical Assistant/ Application Support

oDocs Eye Care Ltd. offers a comprehensive warranty and service support program. Highly qualified representatives from our service and customer support departments are available to support you to solve operational questions.

Company Name	oDocs Eye Care Limited
NZBN	9429041414613
Entity Status	Registered
Business Type	NZ Limited Company
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