

Technical Document - ODocs nun IR

Product Description

The oDocs nun IR is a medical device under the category fundus camera. The nun-IR uses an Android smartphone as a view finder to view and assess subject's retina.

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

Features of the product

- Hand-held Fundus camera with increased portability and high resolution.
- Video and still photography functions enable recording video for dynamic signs, such as Spontaneous venous pulsation.
- Infrared illumination (IR Mode)
- Non-mydrriatic.
- Field-of-view (FOV) of 45-55 degrees.
- Manual focus of -20D to +20D.
- Mobile friendly with Android smartphone
- Rubber eye-cup to enable better adjustment between the camera and the patient's eyes.
- Rechargeable battery.

System Identification Data

| | |
|-----------------------------------|---|
| Product Name | Fundus Camera |
| Brand Name | nun IR |
| 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) |
| CE labelling | Registered |
| Allowed device combination | Android phone recommended by the oDocs Eye Care Ltd. |
| Current document status | Document version 1.1.1 dated 2020-12-30 |

We declare that the medical device described hereafter; Fundus camera / WFC-01 has been classified as Class I (Annex IX Rule 12) and conforms with the essential requirements and provisions of Council Directive MDD 93/42/EEC (Medical Device Directive).

Product Specifications

Dimension & Weight

| Name/Category | Length (mm) | Width (mm) | Height (mm) | Weight (g) |
|------------------------|-------------|------------|-------------|------------|
| Cradle | 224.6 | 79.7 | 87.9 | 224 |
| Nun IR camera body | 223.4 | 66.4 | 187 | 531 |
| Nun IR camera with box | 360 | 122 | 260 | 2340 |

Optical specification

Field of view (FOV) : >45°(Hor.), >40°(Ver.),

Diopter: -20D to +20D (manual focus)

Light source: Infrared LEDs for focus,

Natural White LEDs for flash, Fixation 7

LEDs for fixation target

Image format: JPEG

Image sensor: 13Mp

Image resolution: 4208x3120

USB connectivity: Mini USB2.0

User's smartphone environment for running nun-IR app

OS: Android 5.0 over

CPU: Quad-core 1.6GHz over

RAM: 2.0GB over

Display: 5.1inch display, 1080x1920 over

Rechargeable battery

3.6V 3500mAh 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 (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

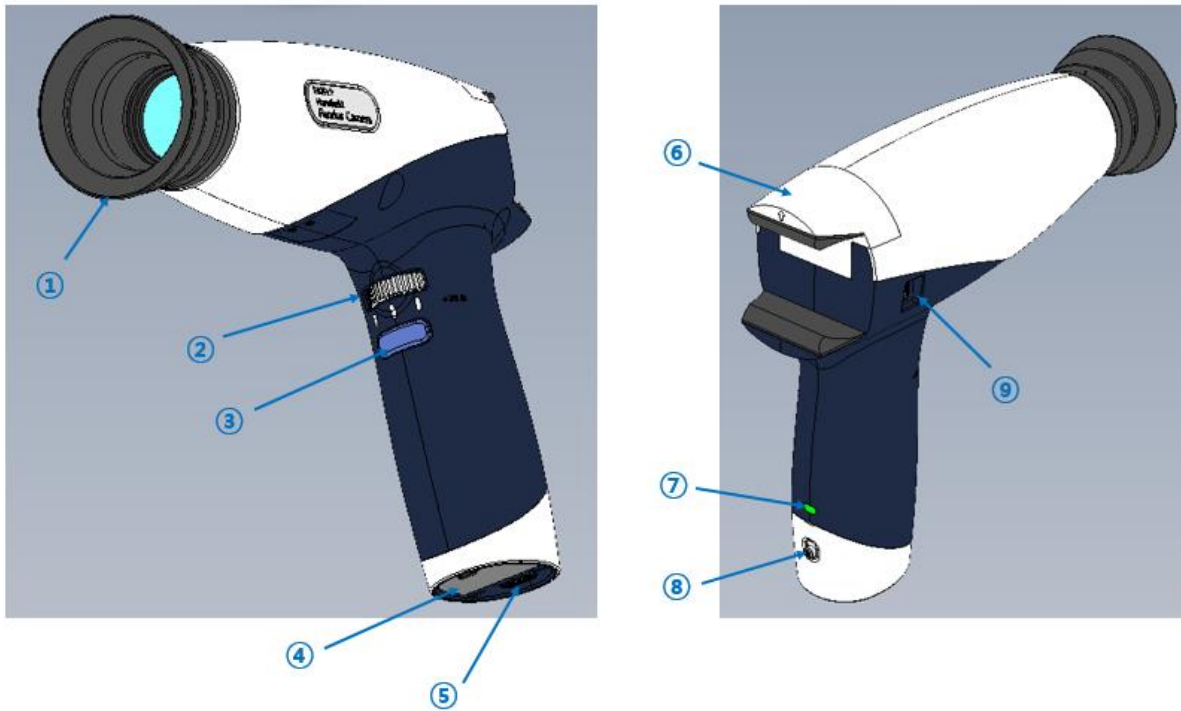
Delivered Package Content

oDocs Eye Care package delivery is entirely annotated in the oDocs nun IR packing list.

Delivered components including:

| | |
|---|--|
|  | Body of the oDocs nun IR fundus camera |
|  | Cradle for battery charging |
|  | Eye Cup |
|  | DC power supply & plug |
|  | Mini USB power cable |
|  | OTG cable |
|  | OTG gender adapter |
| / | User Manual (Download at home page) |

Composition of the fundus camera body



| No. | Item | Description |
|-----|--------------------------|--|
| 1 | Eyecup | External light interception, the pupil tracking function |
| 2 | Diopter | -20D to +20D focus adjustment |
| 3 | Shot button | Retina image capture |
| 4 | Battery cover | Cover to replace the battery |
| 5 | DC power terminal | DC power terminal for lithium-ion battery charging |
| 6 | Smartphone holder | Universal holder |
| 7 | Charging indicator | Another LED lighting when charging, Green LED lighting when charging is complete |
| 8 | Main power on/off switch | Main body power on/off switch |
| 9 | USB mini B type port | Data interface between smartphone and medical device |

Standards

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

| | |
|--------------|-------------------------|
| IEC60601-1-6 | 2010 |
| IEC60601-1 | 2012 (EN60601-1:2013) |
| IEC60601-1-2 | 2014 (EN60601-1-2:2015) |
| ISO15004-2 | 2007 |
| ISO10940 | 2009 |
| ISO10993-1 | 2009 |
| IEC62133-2 | 2017 |
| EN62304 | |

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 |
| Telephone Number | +64 27 268 6464 |
| Email Address | product@odocs-tech.com |



ODOCS
eye care

