# HEINE OMEGA 600 Indirect Ophthalmoscope


| DATA | |
|---|---|
| **Description** | OMEGA 600 Binocular Indirect Ophthalmoscope |
| **Catalogue number** | C-008.33.610 |
| **Item included in following catalogue numbers** | C-008.33.612, C-008.33.613, C-008.33.614 |
| **Date** | December 10, 2020 |

| MECHANICAL | |
|---|---|
| **Weight product** | 475 g |
| **Weight battery** | 21 g |
| **Weight packing including product** | Cardboard box: 1.2 kg |
| **Dimensions product** | 320 x 300 x 200 mm |
| **Dimensions packing** | 255 x 190 x 410 mm |
| **Connections** | USB Type C port, charging port for wall charger CW1 |
| **Imprints** | *Front*: HEINE logo, OMEGA 600; *Back*: HEINE made in Germany, MD, production date, CE, serial number, www.heine.com, datamatrix code, distance scale; *Sides*: symbols for filters, apertures, pupillary size, adjustment lock; *Headband*: HEINE - Made in Germany, brightness scale, power indicator, 5V-1.2A |

| ELECTRICAL | |
|---|---|
| **Power supply** | Li-Po cell (internal battery) |
| **Input** | USB 2.0 Type C: 5 V, 1.2 A |
| **Power consumption** | 6 W |
| **Operating time, standard battery** | typ. 4 h |
| **Operating time, standard battery (boost mode)** | typ. 1.5 h |
| **Avg. working time before charging **** | Up to 8 hrs |
| **Charging time, standard battery** | typ. 1.5 h |
| **Protection class** | charging: class II; operating: internally powered |

| OPTICAL | |
|---|---|
| **Type** | HEINE LED illumination (HQ) |
| **Optical system** | Aspherical illumination optics |
| **Illuminance** | typ. 560 lx at 400 mm distance |
| **Illuminance boost mode** | typ. 1 380 lx at 400 mm distance |
| **Color temperature** | typ. 3 000 K |
| **Color rendering index (CRI)** | min. 90 |
| **Medium life expectancy (LED)** | > 60 000 h |
| **Antireflection coating** | Front window $R_{avg}$ < 0.2 % optimized for LED |
| **Working distance** | 400 mm |
| **Illuminated field (large spot)** | 400 mm distance (housing front) Ø 62.5 ± 2.5 mm |
| **Illuminated field (medium spot)** | 400 mm distance (housing front) Ø 33 ± 2 mm |
| **Illuminated field (small spot)** | 400 mm distance (housing front) Ø 16.5 ± 1.5 mm |
| **Field of view with 16D lens** | typ. 43° |
| **Field of view with 20D lens** | typ. 53° |
| **Field of view with 30D lens** | typ. 63° |
| **Filters** | Red-free, cobalt blue, yellow |
| **Apertures** | 3 sizes + diffuser |
| **Brightness control** | Continous between 3 % and 100 % (boost: 100 % to 245 %) |
| **Vertical adjustment** | Vertical adjustment of illumination between -4° and +7° |
| **Stereoscopic adjustment technology** | For use in dialated and undialated pupils |
| **Diopter** | Exchangeable 0D and +2D eyepiece |
| **Optical safety according to ISO 15004-2** | Group 2 |

| GENERAL | |
|---|---|
| **Material** | Plastic, metal, glass, synthetic leather |
| **REACH/RoHS** | Conform |
| **Phthalate** | Contains no phthalate |
| **Latex** | Contains no latex |
| **Biocompatibility** | Conform |
| **Surface** | Plastic, metal, glas, synthetic leather |
| **Environmental conditions operation** | +10 °C to +35 °C, 30 % to 75 % rel. humidity, 700 hPa to 1060 hPa |
| **Environmental conditions storage** | +5 °C to +45 °C, 45 % to 80 % rel. humidity, 500 hPa to 1060 hPa |
| **Environmental conditions transport** | -20 °C to +50 °C, 45 % to 80 % rel. humidity, 500 hPa to 1060 hPa |
| **Instructions for use** | Deutsch, English, Francais, Espanol, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Portugues * |
| **Operating elements** | Height adjustment, width adjustment, adjustment lever, brightness control, filter selection lever, aperture selection lever, illumination height adjustment, stereoscopic adjustment lever, eyepieces, flip-up of optics unit |
| **Removable parts/ accessories** | Brightness control, eyepieces (0 dpt. / +2 dpt.), TM2, dust cover, CW1, CC1, E4-USBC, rechargeable battery |
| **Maintenance** | Change of paddings, change of eyepieces, changing the position of the brightness control |
| **Service** | Change of rechargeable battery |
| **Patents** | N/A |

| HYGIENIC REPROCESSING | |
|---|---|
| **Procedure** | Please find detailed description for the reprocessing procedure online at WWW.HEINE.COM |

| CODES | |
|---|---|
| **GTIN** | 4053755198382 |
| **Customs code (tariff number)** | 90185090 |
| **Country of origin** | DE |
| **Traceability** | UDI Code |

| REGULATORY | |
|---|---|
| **Product classification (EU)** | Class I |
| **Product classification (USA)** | Class II, 510(k) exempt |
| **Product classification (Canada)** | Class I |
| **UMDNS code** | 12-818 |
| **GMDN code** | 46790 |
| **Regulation number (FDA)** | 886.1570 |
| **Product code (FDA)** | HLI |

| Fulfills the Requirements of Directives & Standards | |
|---|---|
| **Regulation (EU) 2017/745** | Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices |
| **ANSI Z80.36** | Ophthalmics - Light Hazard Protection for Ophthalmic Instruments |
| **EN 1041** | Information supplied by the manufacturer of medical devices |
| **ISO 10943** | Ophthalmic instruments - Indirect ophthalmoscopes |
| **ISO 10993-1** | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| **ISO 13485** | Medical devices - Quality management systems - Requirements for regulatory purposes |
| **ISO 14971** | Medical devices - Application of risk management to medical devices |
| **ISO 15004-1** | Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic |
| **ISO 15004-2** | Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection |
| **ISO 15223-1** | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements |
| **ISO 17664** | Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices |
| **ISO 22248** | Packaging; complete, filled transport packages; vertical impact test by dropping |
| **IEC 60601-1** | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| **IEC 60601-1-2** | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance -Collateral standard: Electromagnetic disturbances - Requirements and tests |
| **IEC 60601-1-6** | Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability |
| **IEC 60601-1-9** | Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design |
| **IEC 62133-2** | Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications |
| **IEC 62304** | Health software - Software life cycle processes |
| **IEC 62366-1** | Medical devices - Part 1: Application of usability engineering to medical devices |
| **UN Transport Test** | UN Transport Test, Section 38.3 lithium ion batteries / Part III |
| **Directive (2011/65/EU) ROHS** | Restriction of the use of certain hazardous substances in electrical and electronic equipment |
| **Directive (2012/19/EU) WEEE** | Waste of electrical and electronic equipment |
| **Regulation (1907/2006) REACH** | Registration, evaluation, authorization and restriction of chemicals |

*) further languages on request

**) based on average illumination intensity and energy consumption



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