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, 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

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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.), TM1, dust cover, CW1, CC1, E4-USBC, rechargeable battery
Maintenance	Change of paddings, change of eyepieces
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	
Directive 93/42/EEC or Regulation (EU) 2017/745	European directive for medical devices or 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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