HEINE OMEGA 500 LED Indirect Ophthalmoscope

DATA

Description	HEINE OMEGA 500 LED Indirect Ophthalmoscope
Catalogue number	see catalogue or price list
Document release date	August, 2025

MECHANICAL

Weight product	470 g (instrument without power source)
Weight packaging (including product)	1.305 kg (instrument without power source)
Dimensions product	142 mm x 96 mm x 54 mm
Dimensions packaging	400 mm x 200 mm x 260 mm (paperboard box)
Connections	see power supply
Imprints	HEINE logo, OMEGA 500, HEINE MADE IN GERMANY, serial number, data matrix code, www.heine.com, scales, symbols for apertures and filters, label for pupil adjustment, CE, symbols for on | off and brightness adjustment (HC 50L)

ELECTRICAL

Power supply	EN 50, EN 50m, mPack, mPack UNPLUGGED, EN 50 UNPLUGGED, plug-in transformer OMEGA 500 and HC 50L
Input	6 V
Power consumption	1 W
Operating time	typ. 13 h with mPack; typ. 7 h with mPack UNPLUGGED
Protection class	Charging: II; Operating: internally powered using the mPack or mPack UNPLUGGED II using the plug-in transformer

OPTICAL

Type	HEINE LED illumination (HQ)
Light controlling	HC 50L
Colour temperature	typ. 4 000K
Color rendering index (CRI)	CRI > 90
Illuminance	typ. 500 lx at 400 mm distance
Luminous flux	typ. 1.3 lm
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
Lightening Direction	vertical adjustable from -4.5° to ≥ 7.5° (occular level)
Convergence and parallax adjustment	parallel adjustment possible
Pupil size	1 mm
Filters	cobalt blue, red-free, yellow filter and diffusor
Diopter	+2 dpt or 0 dpt lenses in oculars
Optical safety according to ISO 15004-2	group 2

GENERAL

Material	used material for OMEGA: aluminium, synthetic material, steel, brass, silicate glasses used material for cushions: synthetic leather, 1 mm thick, black
REACH | RoHS	conform
Phthalate	contains no phthalates that require declaration
Latex	contains no latex
Biocompatibility	conform
Surface	aluminium black coated, synthetic material matt black and anthracite grey, brass and steel blackened
Environmental conditions operation	+5 °C to +35 °C, 30 % to 90 % rel. humidity, 800 hPa to 1060 hPa
Environmental conditions storage	-20 °C to +55 °C, 10 % to 95 % rel. humidity, 700 hPa to 1060 hPa
Environmental conditions transport	-40 °C to +70 °C, 10 % to 95 % rel. humidity, 500 hPa to 1060 hPa
Instructions for use *	Deutsch, English, Français, Español, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Português
Operating elements	headband height, distance adjustment knob, headlight adjustment knob, flip-up functionality, filter control, aperture control, control locks, synchronized convergence and parallax adjustment lever, brightness adjustment (HC 50L)
Removable parts | accessories	scleral depressor (small | large), A.R. Loupes, LED module, teaching mirror, eyecups, dust cap (see more details in the catalogue or price list)
Maintenance	lamp replacement
Service	device is service-free

HYGIENIC REPROCESSING

Procedure	please see detailed description for the reprocessing procedure online at www.heine.com

CODES

Customs code (tariff number)	90185090
GTIN	4053755153756 (C-008.33.535, with mPack UNPLUGGED) 4053755153732 (C-008.33.533, with mPack)
Traceability	UDI code
Country of origin	Germany

REGULATORY

Product classification (EU)	class I
Product classification (USA)	class 2, 510(k) exempt
Product classification (Canada)	class I
UMDNS code	12-818
GMDN code	46790
Regulation number (FDA)	886.1570
Product code (FDA)	HLJ

FULFILS THE REQUIREMENTS OF DIRECTIVES & STANDARDS

ISO 13485	Medical devices - quality management systems - requirements for regulatory purposes
Regulation (EU) 2017/745	European regulation for medical devices (MDR)
IEC 60601-1	Medical electrical equipment: 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
ISO 14971	Medical devices - application of risk management to medical devices
IEC 60601-1-6	Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability
IEC 62366-1	Medical devices - part 1: application of usability engineering to medical devices

DIN EN 15004-1	Ophthalmic instruments - fundamental requirements and test methods - part 1: general requirements applicable to all ophthalmic instruments
DIN EN 15004-2	Ophthalmic instruments - fundamental requirements and test methods - part 2: light hazard protection
ANSI Z80.36	Ophthalmics - light hazard protection for ophthalmic instruments
ISO 10943	Ophthalmic instruments - indirect ophthalmoscopes
IEC 62304	Medical device software - software life-cycle processes
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
ISO 17664-2	Processing of health care products – information to be provided by the medical device manufacturer for the processing of medical devices part 2: non-critical medical devices
ISO 10993-1	Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process
ISO 2248	Packaging; complete, filled transport packages; vertical impact test by dropping
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

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