HEINE K180 LED ophthalmoscope.

DATA

Description	HEINE K180 LED ophthalmoscope
Catalogue number	see catalogue or price list
Document release date	June, 2024

GENERAL

Product variants	HEINE K180 LED ophthalmoscopes 2.5 V | 3.5 V
Material	plastic, metal, glass
REACH | RoHS	conform
Biocompatibility	conform
Surface	plastics, metal, glass
Environmental conditions operation	temperature: +10 °C to +35 °C, relative humidity: 30 % to 75 %, air pressure: 700 hPa to 1060 hPa
Environmental conditions storage	temperature: +5 °C to +45 °C, relative humidity: 45 % to 80 %, air pressure: 500 hPa to 1060 hPa
Environmental conditions transport	temperature: -20 °C to +50 °C, relative humidity: 45 % to 80 %, air pressure: 500 hPa to 1060 hPa
Durability	5 years warranty
Instructions for use***	Deutsch, English, Français, Español, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Português
Operating elements	lens wheel, aperture wheel
Display	indirect illuminated index of refraction
Power supply	HEINE rechargeable handles (3.5 V), HEINE battery handles (2.5 V), HEINE EN 200 wall transformer
Accessories	n/a

MECHANICAL

Weight	45 g
Weight packaging (including product)	101 g
Dimensions product	90 x 46 x 28 mm (height x width x depth)
Dimensions packaging	108 x 42 x 68 mm (length x height x depth)
Connections	AV for rechargeable handle
Imprints	examiner-sided: K180 LED, HEINE logo, CE
	patient-sided: symbols, HEINE made in Germany
	AV connector: data matrix code, SN, www.heine.com

ELECTRICAL - RECHARGEABLE HANDLE

Input voltage	3.0 - 3.7 V DC
Current consumption	max. 350 mA
Operation time	approx. 7 h using fully loaded Li-ion L rechargeable battery (X-007.99.383)
Protection class	charging: II, operating: internally powered

ELECTRICAL - BATTERY HANDLE

Input voltage	1.8 V - 3.2 V
Current consumption	typ. 373 mA at full brightness and 3.2 V
Operation time	n/a
Protection class	internally powered

OPTICAL

Type	LED (HQ) illumination 3.5 V | 2.5 V
Luminous flux*	typ. 0.4 lm
Illuminance** (in 200 mm distance)	typ. 600 lx +/- 150 lx
Color temperature	3500 K +/- 500 K
Color rendering index	typ. CRI ≥ 90, high R9
Lifetime	typ. 42,000 h
Classification according to ISO 10942	group B
Classification according to ISO 15004-2	group 2
Aperture wheel 1	slit, red-free filter, fixation star with polar coordinates, large spot, small spot
Aperture wheel 2	slit, red-free filter, cobalt blue filter, large spot, small spot
Lens | diopter	27 lens | 27 diopter steps (-35 D to +40 D)

HYGIENIC REPROCESSING

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

CODES

Customs code	90185090
GTIN	4053755120017 (K180 LED 2.5 V); 4053755202232 (K180 LED 3.5 V)
	4053755120031 (K180 LED M.BF 2.5 V); 4053755202249 (K180 LED M:BF 3.5 V)
Traceability	UDI-code
Country of origin	Germany (DE)

REGULATORY

Product classification (EU)	class I
Product classification (USA)	class 2, 510(k) exempt
Product classification (Canada)	class I
UMDNS code	12-817
GMDNS code	12817
Regulation number (FDA)	886.1570
Product code (FDA)	HLJ

FULFILLS 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
ISO 15004-1	ophthalmic instruments – fundamental requirements and test methods – part 1: general requirements applicable to all ophthalmic instruments
ISO 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 10942	ophthalmic instruments - direct ophthalmoscopes
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 10993-1	biological evaluation of medical devices - part 1: evaluation and testing within a risk management process
ISO 17664	processing of health care products - information to be provided by the medical device manufacturer for the processing of medical devices
ISO 2248	packaging; complete, filled transport packages, vertical impact test by dropping
Directive (2011/65/EU) ROHS	on the restriction of the use of certain hazardous substances in electrical and electronic equipment
Directive (2012/19/EU) WEEE	on waste electrical and electronic equipment
Regulation (1907/2006) REACH	registration, evaluation, authorization and restriction of chemicals
Directive (94/62/EC) packaging | packaging waste	packaging and packaging waste, German registration no. DE 5329703000126

*) at 3.7 V supply voltage
**) calculated
***) further languages on request

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