

HEINE BETA[®] 200S LED and BETA[®] 200 LED ophthalmoscopes



DATA

Description	HEINE BETA 200 200S LED ophthalmoscope
Catalogue number	see catalogue or price list
Version Date	Rev.04 07.05.2024

GENERAL

Product variants	BETA 200 LED ophthalmoscope	BETA 200S LED ophthalmoscope
Material	synthetics, metal, glas	
REACH RoHS	compliant	
Biocompatibility	compliant	
Surface	synthetics, metal, glas	
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, filter switch	
Display	indirect illuminated index of refraction	
Power supply	HEINE rechargeable handles (3,5 V), HEINE battery handles (2,5 V), HEINE EN200 wall transformer	
Accessories	n/a	
Patents	n/a	

MECHANICAL

Weight	73 g 114 g (incl. packaging)	75 g 116 g (incl. packaging)
Dimensions product	98 x 48 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: BETA 200 LED, HEINE Logo, CE	examiner-sided: BETA 200S LED, HEINE Logo, CE
	patient-sided: Symbols, HEINE made in Germany	
	AV connector: data matrix code, SN, www.heine.com	

ELECTRICAL - RECHARGEABLE HANDLES

Input voltage	3.0 - 3.7 V DC
Current consumption	max. 350 mA
Operation time	ca. 7 h using fully loaded Li-ion L rechargeable battery (X-007.99.383)
Safety class	internal power supply
Fuse	n/a

ELECTRICAL - BATTERY HANDLES

Input voltage	1.8 V - 3.2 V
Current consumption	typ. 373 mA at full brightness and 3,2 V
Operation time	n/a
Safety class	internal power supply
Fuse	n/a

OPTICAL

Type	LED illumination (HQ) 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	
Apertures	6 luminous field apertures with separate red-free filter: Slit, fixation star with polar coordinates, cobalt blue filter, large spot, small spot, hemispot	7 luminous field apertures with separate red-free filter: Cobalt blue filter, fixation star with polar coordinates, large spot, small spot, pinhole, slit, hemispot
Lens diopter	27 lens 27 diopter steps (-35 D to +40 D)	28 lens 74 single-diopter steps (-36 D to +38 D)

HYGIENIC REPROCESSING

Procedure	Please see detailed description in the reprocessing procedure
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CODES

Customs code	90185090	90185090
EAN GTIN	4053755119981 (BETA 200 LED 2,5 V) 4053755182534 (BETA 200 LED 3,5 V)	4053755120000 (BETA 200S LED 2,5 V) 4053755182541 (BETA 200S LED 3,5 V)

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	On medical devices
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

**) further languages on request