HEINE BETA® 200 LED retinoscope.

DATA

Description	HEINE BETA 200 LED retinoscope 2.5 V	HEINE BETA 200 LED retinoscope 3.5 V
Catalogue number	see catalogue or price list	
Document release date	June, 2024	

MECHANICAL

Weight	90 g
Weight packaging (including product)	200 g
Dimensions product	129 x 37 x 43 mm
Dimensions packaging	case: 158 x 90 x 43 mm hard case BETA 200 LED retinoscope: 186 x 120 x 50 mm hard case BETA 200 LED diagnostic set: 237 x 138 x 52 mm
Connections	AV connection
Imprints	product name, ParaStop, HEINE made in Germany, CE, HEINE logo, datamatrix code, serial number, www.heine.com

GENERAL

Materials	metal, glass, plastic	
REACH | RoHS	conform	
Biocompatibility	conform	
Surface	metal, glass, plastic	
Environmental conditions operation	temp.: +10°C to +35°C, relative humidity: 30 % - 90 %, air pressure: 800hPa to 1060hPa	
Environmental conditions storage	temp.: -10°C to +55°C, relative humidity: 10 % - 95 %, air pressure: 700hPa to 1060hPa	
Environmental conditions transport	temp.: -40°C to +70°C, relative humidity: 10 % - 95 %, air pressure: 500hPa to 1060hPa	
Durability	5 years warranty	
Instructions for use*	Deutsch, English, Français, Español, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Português	
Operating elements	light intensity control, single control for vergence and rotation, ParaStop for precise and easy selection of a parallel beam, detachable brow rest	
Power supply	HEINE battery handles (2.5 V)	HEINE rechargeable handles (3.5 V), HEINE EN 200 wall transformator
Accessories	fixation cards	

ELECTRICAL

Input voltage	1.8 V - 3.2 V	3.0 V - 3.7 V
Power consumption	typ. 373 mA at full brightness and 3.2 V	max. 400 mA typ. at full brightness and nominal supply
Protection class	internally powered	charging: II, operating: internally powered

OPTICAL

Type	LED (HQ) illumination (2.5 V | 3.5 V)
Light controlling	rheostat (continuous brightness control)
Color temperature	typ. 3000 K
Length of the streak (500 mm distance)	typ. 35 mm
Width of the streak (500 mm distance)	typ. 1.1 mm
Working distance	500 mm
Medium life expectancy (LED)	> 50,000 h
Classification according to ISO 15004-2	group 2

HYGIENIC REPROCESSING

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

CODES

Customs code (tariff number)	90185090
GTIN	4053755119967 (2.5 V); 4053755191598 (3.5 V)
Traceability	UDI-code
Country of origin	Germany (DE)

REGULATORY

Product classification (EU)	class I
Product classification (USA)	class 1, 510(k) exempt
Product classification (Canada)	class I
UMDNS code	13-372
GMDN code	32712
Regulation number (FDA)	886.1780
Product code (FDA)	HKM

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 12865	ophthalmic instruments - retinoscopes
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 the 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

*) further languages on request

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