

HEINE BETA[®] 200 LED Retinoscope

Polarisation filter:
Eliminates stray light and internal reflexes

For a very bright, readily visible fundus reflex: brilliant, precise streak image with a line width of typically 1.1 mm (ISO 12865 Standard < 1.5mm) and a line length of 35mm. Completely homogeneous and bright light for a precise, fast diagnosis.
LED working life typ. 50,000 hours.
Adjustable feel-good lighting for the patient: exclusive continuous brightness control between 100% and 3% (patented) with one-finger operation for glare-free light.

LED HQ
LED NOW IN HEINE QUALITY.



Dustproof housing

Brilliant, precise streak image

ParaStop for the precise selection of the parallel beam

Enclosed vergence sleeve prevents drift during examinations

Continuous brightness control

DATA	
Description	HEINE BETA200 LED Retinoscope
Catalogue number	C-008.15.353
Version / Date	Rev.00/03.11.2017
GENERAL	
Weight	90g
Dimensions product	129 x 37 x 43mm
Dimensions packaging	Case: 158 x 90 x 43mm Hard case BETA200 LED Retinoscope: 186 x 120 x 50mm Hard case BETA200 LED Diagnostic Set: 237 x 138 x 52mm
Materials	Metal, glass, plastic
REACH/RoHS	Conform
Phthalate	Product is phthalate free
Latex	Product is Latex free
Biocompatibility	The medical device does not have patient contact per intended use. Therefore the ISO 10993 is not applicable. All materials used are not toxic.
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
Instructions for use	Deutsch, English, Francais, Espanol, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Portugues
Operating elements	Single control for vergence and rotation, ParaStop: precise and easy selection of a parallel beam, detachable brow rest
Power supply	EN 100, EN200, BETA4 USB, BETA4 NT, BETA NT, BETA L, BETA SLIM (all with 3.5V only)
Continuous operation	Typ. 3.5h at maximum brightness with Li-ion L charging battery
Removable parts / accessories	Fixation cards
MECHANICAL DETAILS	
Connections	AV connection
Imprints and labels	Product name, ParaStop, HEINE made in Germany, CE, HEINE logo



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ELECTRICAL DETAILS	
Class	Internal power supply
Power Supply	3.0V – 3.7V
Power Consumption	400mA typ. at full brightness and nominal supply
OPTICAL	
Type	LED illumination (HQ)
Maintenance	Instrument does not require regular service. The LED can't be replaced by the user.
Light controlling	Rheostat (continuous brightness control)
Color temperature	Typ. 3500K
CRI	Typ. 80
Length of the streak (500mm working distance)	Typ. 35mm
Width of the streak (500mm working distance)	Typ. 1.1 mm
Working distance	500mm
Operating times:	Less than 3 minutes of each eye with a 15 minutes break until the next application
Medium life expectancy (LED)	>50,000h
Optical safety	Group 2 instrument according to ISO 15004-2
HYGIENIC REPROCESSING	
Procedure	Housing can be cleaned and disinfected manually (wipe clean and wipe disinfect). Please see detailed description in the user manual.
CODES	
Customs Code (tariff number)	90185090
GTIN	4053755191598 (also see http://files.heine.com/barcode)
Country of origin	Germany
REGULATORY	
Product classification (EU)	Class 1
Product classification (USA)	Class 1
Product classification (Canada)	Class 1
UMDNS Code	13-372
GMDNS Code	46784
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
Directive 93/42/EEC	Concerning 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
UN Transport Test	UN Transport Test, Section 38.3 lithium ion batteries / Part III
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 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 17664	Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable 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

