# HEINE BETA® 200 LED Retinoscope


**DATA**

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|---|---|---|
| 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 | August, 2025 | |

**MECHANICAL**

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|---|---|
| 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<br>Hard case BETA 200 LED retinoscope: 186 x 120 x 50 mm<br>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 |
| Protection class | IP40 |

**GENERAL**

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|---|---|---|
| Materials | metal, glass, plastic | |
| REACH \| RoHS | conform | |
| Biocompatibility | conform | |
| Surface | metal, glass, plastic | |
| Environmental conditions operation | +10 °C to +35 °C, 30 % to 90 % relative humidity, 700 hPa to 1060 hPa | |
| Environmental conditions storage | -10 °C to +55 °C, 10 % to 95 % relative humidity, 700 hPa to 1060 hPa | |
| Environmental conditions transport | -40 °C to +70 °C, 10 % to 95% relative humidity, 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 | 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 Transformer |
| Accessories | Fixation cards | |

**ELECTRICAL**

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|---|---|---|
| Input voltage | 1.8 V - 3.2 V | 3.0 V - 3.7 V |
| Power consumption | typ. 390 mA at full brightness and nominal supply | |
| Protection class | internally powered | charging: II, operating: internally powered |

## OPTICAL

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|---|---|
| Type | HEINE LED illumination (HQ) |
| 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 |
| Classification according to ISO 15004-2 | group 2 |

## HYGIENIC REPROCESSING

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

## CODES

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| Customs code (tariff number) | 90185090 | |
| GTIN | 4053755119967 | 4053755191598 |
| Traceability | UDI-code | |
| Country of origin | Germany (DE) | |

## REGULATORY

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| 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 |

## FULFILS THE REQUIREMENTS OF DIRECTIVES & STANDARDS

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|---|---|
| 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 |

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| 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 17664-2 | 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 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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