

# HEINE BETA X

## Ophthalmoscope



### DATA

Description	HEINE BETA X Ophthalmoscope
Catalogue number	C-130.28.330
Items included	HEINE BETA X Ophthalmoscope, hard case, USB-C-cable with IEC 60601-1 approved power supply and country adapters
Document release date	March, 2025

### MECHANICAL

Weight product	150 g
Weight battery	22 g
Weight packaging (including product)	775 g
Dimensions product	200 x 48 x 31 mm
Dimension packaging	221 x 63 x 216 mm
Connections	USB-C port
Imprints	front: HEINE logo, BETA X, icon: on   off; back: HEINE made in Germany, icons: different apertures and filters, focusCONTROL F   C; side: USB-C, 5 V, 500 mA, MD, production year, CE, serial number, www.heine.com, datamatrix code

### ELECTRICAL

Power supply	Li-ion cell (internal battery)
Input	5 V DC, 500 mA
Power consumption	max. 1 W
Operating time	typ. 240 min. with 100 % brightness
Charging time	typ. 160 min.
Automatic switch-off function	turns off after 5 min.
Protection class	charging: II; operating: internally powered

### OPTICAL

Type	HEINE LED illumination (HQ)
Magnification	ca. 15x for emmetropic patient
Diopter	+38 D to -36 D
Optical system	AOS+ (Aspherical Optical System)
Colour temperature	typ. 3 500 K
Color rendering index (CRI)	typ. CRI 93
Field of view	9° with largest aperture
Working distance	fundus: ≈20 mm, cornea: ≈50 mm
Pupil size	min. 2 mm; opt. ≥4 mm
Filters	red-free, polarisation, blue
Apertures	7 luminous field apertures with separate red-free and polarisation filter: cobalt blue filter, fixation star with polar coordinates, large spot, small spot, pinhole, slit, hemispot
Focus switch	HEINE focusCONTROL: switch between anterior (C: cornea) and posterior segment (F: fundus) of the eye

Classification according to ISO 10942	group A
Classification according to IEC 62471	risk group 2 (moderate risk)
Optical safety according to ANSI Z80.36	group 2
Optical safety according to ISO 15004-2	group 2

#### GENERAL

Material	anodized aluminium, plastic, glass
REACH   RoHS	conform
Phthalate	contains no phthalate
Latex	contains no latex
Biocompatibility	conform
Environmental conditions operation	temperature: + 10 °C to +35 °C, relative humidity: 10 % 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: 10 % to 90 %, air pressure: 500 hPa to 1060 hPa
Instructions for use *	Deutsch, English, Francais, Espanol, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Portugues
Operating elements	illumination control wheel, diopter adjustment wheel, aperture wheel, filter switch, focusCONTROL switch
Display	indirect illuminated index of refraction
Maintenance	device is maintenance-free
Service	device is service-free   change of rechargeable battery

#### HYGIENIC REPROCESSING

Procedure	please see detailed description for the reprocessing procedure online at <a href="http://www.heine.com">www.heine.com</a>
-----------	---

#### CODES

Customs code (tariff number)	90185090
GTIN	4053755203031
Traceability	UDI code
Country of origin	Germany

#### REGULATORY

Product classification (EU)	class I
Product classification (USA)	class II, 510(k) exempt
Product classification (Canada)	class I
UMDNS code	12-817
GMDN code	46786
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
IEC 60601-1	Medical electrical equipment: general requirements for basic safety and essential performance
ISO 10993-1	Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process
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
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 10942	Ophthalmic instruments - direct ophthalmoscopes
IEC 62471	Photobiological safety of lamps and lamp systems
IEC 62304	Medical device software - software life-cycle processes
IEC 62133-2	Secondary cells and batteries containing alkaline or other non-acid electrolytes - safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - part 2: lithium systems
UN transport test	UN transport test, section 38.3 lithium ion batteries   part III
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 17664-2	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 (94/62/EC) packaging   packaging waste	Packaging and packaging waste, German registration no. DE 5329703000126
Directive (2011/65/EU) ROHS	Restriction of the use of certain hazardous substances in electrical and electronic equipment
Directive (2012/19/EU) WEEE	Waste of electrical and electronic equipment
Regulation (1907/2006) REACH	Registration, evaluation, authorization and restriction of chemicals

\*) further languages on request