HEINE BETA® 400 LED and BETA® 200 LED F.O. Otoscopes

DATA

Description	HEINE BETA 200 | 400 LED F.O. Otoscope
Catalogue number	see catalogue or price list
Document release date	April 02, 2025

GENERAL

Product variants	BETA 200 LED F.O. Otoscope	BETA 400 LED F.O. Otoscope
Material	metal, synthetics, glass	
REACH | RoHS	compliant	
Biocompatibility	compliant	
Surface	metal, synthetics, glass	
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	swivelling viewing window	folding viewing window
Power supply	HEINE Rechargeable Handles (3.5 V), HEINE Battery Handles (2.5 V), HEINE EN 200 Wall Transformer	
Accessories	HEINE AllSpec Disposable Tips, Reusable Tips, Insufflation Bulb	
Patents	n/a	DE 10 2013 208 382; US 9,579,014 B2

MECHANICAL

Weight	87 g	90 g
Weight packing including product	128 g	131 g
Dimensions product	74 x 35 x 47 mm (height x width x depth)	
Dimensions packaging	108 x 42 x 68 mm (length x height x depth)	
Connections	AV for rechargeable handle, bayonet for tip, fitting for insufflation tube	
Imprints	BETA 200 LED	BETA 400 LED
	HEINE made in Germany, symbol (application part BF), CE, data matrix code, SN, www.heine.com	
Enclosure rating	IP40	

ELECTRICAL - RECHARGEABLE HANDLE

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)
Protection class	charging: II; operating: internally powered
Fuse	n/a

ELECTRICAL - BATTERY HANDLE

Input voltage	1.8 V - 3.2 V
Current consumption	typ. 373 mA at full brightness and 3.2 V
Operation time	n/a
Protection class	internally powered
Fuse	n/a

OPTICAL

Type	LED illumination (HQ) 3.5 V | 2.5 V	
Luminous flux** (without | with 5 mm tip)	typ. 17.5 lm | typ. 7.5 lm	
Colour temperature	3500 K +/- 500 K	
Colour rendering index	typ. CRI 92	
Classification according to IEC 62471	exempt	
Magnification	3x	4,2x

HYGIENIC REPROCESSING

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

CODES

Customs code	90189084	90189084
EAN | GTIN	4053755182565	4053755182558

REGULATORY

Product classification (EU)	class I
Product classification (USA)	class I, 510(k) exempt
Product classification (Canada)	class I
UMDNS code	12-849
GMDN code	12849
Regulation number (FDA)	874.4770
Product code (FDA)	ERA

FULLFILLS 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 60601-2-18	Medical electrical equipment - part 2-18: particular requirements for the basic safety and essential performance of endoscopic equipment
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
IEC 62471	Photobiological safety of lamps and lamp systems
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 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

**) at 3.7 V supply voltage

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