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

BETA 200: 3 x magnification
BETA 400: 4.2 x magnification.

Patented, unique, stepless dimming from 3 % to 100 % with practical one-finger operation.

All metal housing and scratch resistant glass lenses.

Fiber Optic Illumination. Ensures homogeneous, very bright illumination and an unobstructed view of the ear canal and tympanum.

LED HQ
LED NOW IN HEINE QUALITY.

DATA	
Description	HEINE BETA 200 / 400 LED F.O. Otoscope
Catalogue Number	B-008.11.500, B-008.11.400
Version / Date	V03 / 16.10.2018

GENERAL		
Product variants	BETA 200 LED F.O. Otoscope	BETA 400 LED F.O. Otoscope
Material	metal, synthetics, glas	
REACH/RoHS	compliant	
Phthalate	product is phthalate free	
Latex	product is latex free	
Biocompatibility	compliant	
Surface	metal, synthetics, glas	
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	
Guarantee	5 years	
Instructions for use	Deutsch, English, Français, Español, Italiano, Svenska, Nederlands, Português, Dansk, Suomi *	
Operating elements	swivelling viewing window	folding viewing window
Power Supply	HEINE rechargeable handles (3,5 V), HEINE EN200 wall transformer, HEINE EN200-1 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 / 128 g (incl. packaging)	90 g / 131 g (incl. packaging)
Dimensions product	74 x 35 x 47 mm³ (height x width x depth)	
Dimensions packaging	108 x 42 x 68 mm³ (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	
Protection class	IP40	

ELECTRICAL	
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)
Safety class	internal power supply
Fuse	n/a

OPTICAL		
Type	LED illumination (HQ) 3.5V fixed in the instrument	
Luminous flux (without / with 5 mm tip)**	typ. 17.5 lm / typ. 7.5 lm	
Illuminance* (with 5 mm tip)**	typ. 380.000 lx	
Color temperature	3500 K +/- 500 K	
Color rendering index	typ. CRI 92	
Lifetime	typ. 100.000 h	
Classification according to IEC 62471	Exempt	
Magnification	3x	4,2x

* further languages on request
** at 3.7 V supply voltage
*** calculated

HYGIENIC REPROCESSING	
Procedure	Wipe cleaning and wipe disinfection with agents recommended in the instructions for use. Please consider the detailed information in the accompanying documents!

CODES		
Customs Code	90189084	90189084
EAN/GTIN	4053755182565	4053755182558
HIBC	+E229B0081150000019	+E229B0081140000018

Regulatory	
Product classification (EU)	Class I
Product classification (USA)	Class 1
Product classification (Canada)	Class I
UMDNS code	12-849
GMDNS code	12849
Regulation number (FDA)	874.4770
Product code (FDA)	ERA

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 60601-2-18	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 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 Waste Electrical and Electronic Equipment
Regulation (1907/2006) REACH	Registration, Evaluation, Authorization and Restriction of Chemicals