HEINE EN 200 | EN 200-1 diagnostic centre.

Diagnostic instruments located at your fingertips in a space-saving design.

Whether in a clinic or a practice – the HEINE EN 200 | EN200-1 can be customised to match your individual needs and can be equipped with a number of HEINE instruments, such as otoscopes, ophthalmoscopes and sphygmomanometers. The wall unit can also be expanded with thermometers of other manufacturers. Highest safety standards: The power supply and the EN 200 | EN200-1 have several built-in protections against electronic malfunctions.

DATA

Description	EN 200	EN 200-1
Catalogue number	X-095.12.250	X-095.12.252 (Single unit with one handle) X-095.12.251 (Extension unit with one handle)
Item included in following catalogue numbers	A-095.12.208 EN200/BETA400+BETA200 OPH./LED A-095.12.209 EN200/BETA200 LED OTO.+OPHTH. A-095.12.210 EN 200/K180 OPHTH.+ OTOSC./LED A-095.12.218 EN200/BETA400+200 OPH.KIT/LED A-095.12.219 EN200/BETA200 OTO./OPH.KIT/LED A-095.12.220 EN 200/K180 OPHTH.+ OTO.KIT/LED	K-010.28.252 EN200-1 SINGLE/DELTA 20 T/KIT
Date	April, 2024	

MECHANICAL

Weight product	ca. 905 g	ca. 410 g
Weight packing including product	ca. 960 g	ca. 550 g (X-095.12.252) ca. 450 g (X-095.12.251)
Dimensions product	ca. 180 x 234 x 99 mm (L x W x H)	ca. 195 x 120 x 105 mm (L x W x H)
Dimensions packing	ca. 230 x 353 x 107 mm (height x width x depth)	
Connections	AV-connector	
Imprints	Housing front: EN 200, HEINE made in Germany, HEINE logo Housing back: HEINE made in Germany, EN 200, CE, symbol, production date, UDI code, serial number, www.heine.com, data matrix code, manufacturer adress	Housing front: EN 200-1, HEINE made in Germany, HEINE logo Housing back: HEINE made in Germany, EN 200-1, power consumption, CE, symbol, production date, UDI code, serial number, www.heine.com, data matrix code
Enclosure rating	IP40	

ELECTRICAL

Power supply	External power supply	micro USB
Input	100 - 240 V~ | 50 - 60 Hz	4.6 - 5.4 V DC
Power consumption	<12 W, 2 - 6 W typ.	1200 mA max., 65 mA typ. (standby)
Output	1.6 V bis 3.6 V typ., <800 mA (<15 W limited current)	
Operation indicator	Green LED at wall unit	
Auto power down	15 min typ.	
Protection class	Class II	

GENERAL

Material	Plastic, metal	
REACH | RoHS	Conform	
Phthalate	Contains no phthalate	
Latex	Contains no latex	
Biocompatibility	Conform	
Surface	Plastic, polyurethan, metal	
Environmental conditions operation	+10 °C to +35 °C, 10 % to 75 % rel. humidity, 700 hPa to 1060 hPa	
Environmental conditions storage	+5 °C to +45 °C, 45 % to 80 % rel. humidity, 500 hPa to 1060 hPa	
Environmental conditions transport	-20 °C to +50 °C, 10 % to 90 % rel. humidity, 500 hPa to 1060 hPa	
Instructions for use **	Deutsch, English, Francais, Espanol, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Portugues *	
Operating elements	Wall unit has no operating elements, handles fitted with rheostat and instrument locking system (AV)	
Removable parts | accessories	All HEINE AV-instruments, tip dispenser, wall mount	All HEINE AV-instruments, USB cable short, USB cable long, E4-USB power supply
Maintenance	Device is maintenance-free	
Service	Device is service-free	
Patents	N/A	

HYGIENIC REPROCESSING

Procedure	Please see detailed description in the reprocessing procedure!

CODES

Customs code (tariff number)	90189084	
GTIN	04053755188611	04053755194803 (X-095.12.251) 04053755194810 (X-095.12.252)
Traceability	UDI Code	
Country of origin	DE	

REGULATORY

Product classification (EU)	Part of a medical device
Product classification (USA)	Class I | Class II, 510(k) excempt
Product classification (Canada)	Part of a medical device
UMDNS code	16-935
GMDNS code	16933
Regulation number (FDA)	886.1860 | 886.1945
Product code (FDA)	HMF | HJM

FULFILLS 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 60601-1-2	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 62304	Medical device software - Software life-cycle processes
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
EN 1041	Information supplied by the manufacturer of medical devices
ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 2248	Packaging; complete, filled transport packages; vertical impact test by dropping
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

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