

HEINE EN 200-1 Wall Transformer



DATA	
Description	EN200-1 Wall Transformer
Catalogue number	X-095.12.247 WALLTRANSFORMER EN200-1 W/O PL
Item included in following catalogue numbers	K-010.28.252 EN200-1 SINGLE/DELTA 20 T/KIT; X-095.12.251 WALLTRANSF. EN200-1/EXTENSION; X-095.12.252 WALLTRANSFORMER EN200-1/SINGLE
Date	January 23, 2019

MECHANICAL	
Weight	0.415kg
Dimensions product	ca. 195 x 120 x 105 mm (Hight x Breadth x Depth)
Connections	AV-connector
Imprints	Housing front: EN200-1, HEINE made in Germany, HEINE logo Housing back: type palte with CE-symbol, production date, serial number, data matrix code, www.heine.com, power consumption
Protection class	IP40

ELECTRICAL	
Power supply (micro-USB)	4.75 V – 5.25 V DC
Power consumption	1200 mA max.
Power consumption (standby)	65 mA typ.
Power output (AV)	1.6 V bis 3.6 V typ., <800mA (<15W limited current)
Operation indicator	Green LED at wall unit
Auto power down	15 min typ.
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 *
Removable parts/ accessories	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	Housing can be cleaned and disinfected manually (wipe clean and wipe disinfect). Please see detailed description in the accompanying documents

* further languages on request



CODES	
Customs code (tariff number)	90189084
Country of origin	Germany

REGULATORY	
Product classification (EU)	Class I
Product classification (USA)	Class I / Class II, 510(k) exempt
Product classification (Canada)	Class I
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
Directive 93/42/EEC	European directive for 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	On the restriction of the use of certain hazardous substances in electrical and electronic equipment
Directive (2012/19/EU) WEEE	On the waste of electrical and electronic equipment
Regulation (1907/2006) REACH	Registration, evaluation, authorization and restriction of chemicals

