HEINE QUALITY
MADE IN GERMANY

:· HEINE® EN 200

CE

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HEINE® EN200

Please read and follow these instructions for use and keep them for future reference.

Intended Use

The HEINE® EN200 Wall Transformer is a two–channel, dimmable 3.5 V power supply with a 5 V output for medical HEINE Diagnostic Instruments. It should only be operated by qualified medical personnel within a professional health facility.

Federal law restricts this device to sale by or on the order of a Physician or Practitioner!

Warnings and Safety Information

CAUTION! Indicates potential hazardous situations. Ignoring the corresponding instructions may lead to dangerous situations of mild to moderate extent. (Background color, yellow; Foreground color, black for color print, or black in light-gray background.)

NOTE! Indicates valuable advice in terms of set up, operation, maintenance or repair, as applicable. Notes are important, but not related to hazardous situations.

Assembly/Disassembly

To ensure all-pole disconnection from the mains at all times, the ME device must be installed so that the switch mode power supply is accessible and disconnectable.

Before mounting the device, check whether you need to use a special wall plug for the subsurface of your wall and whether the subsurface exhibits sufficient load-bearing capacity for the mechanical stress.

The wall plugs supplied with the product are universal wall plugs and suitable for most building materials (e.g. concrete, solid brick, brick).

1. Hold the drill template horizontally in place on the desired position and mark the drill holes. Drill a hole of at least 40 mm deep using a Ø 6 mm drill.
2. Fit wall plugs.
3. Use a suitable screwdriver to tighten the two upper screws with a distance of approx. 3 mm to the wall.
4. Hang the device – disconnected from the mains – on the two screw heads, press firmly and push downwards. Check to make sure that the device is correctly positioned on both screw heads.
5. Screw in the two lower screws.

To disassemble, disconnect the device from the mains first, loosen the two lower screws, push upwards and take off the wall.

USB connector

The device has an USB interface on its rear side as power supply for additional medical diagnostic instruments from HEINE.

Connect the HEINE USB cord and run the cable via the housing canal to the outside on the left or right hand side. To do so, press the cable into the clamping hubs, which act as strain relief.

Setting up

USA primary plug

The device may only be operated with the mains voltage specified on the nameplate of the power supply.

- Attach the primary plug to the plug-in transformer until it engages.
- Connect the device to the mains with the plug-in transformer. The green indicator light on the EN200 illuminates.

Connecting instruments

The HEINE® EN200 cable handles are fitted with HEINE automatic connectors for use with all similarly equipped HEINE instruments.

- Hold the handle in one hand and insert the instrument connector into the guides in the handle head.
- Push the instrument into the handle until it locks in place with an audible "click".
- Instruments can be locked to prevent unauthorized removal by using the enclosed Allen wrench according to fig. 1.
- To unlock, the screw may only be unscrewed so far until the connector can be turned.
- The instrument is ready for operation when taken off the unit.
- To adjust the brightness of the instrument activate the adjustment ring on the handle.
- Both handles can be simultaneously used independent of each other.
- To remove the instrument turn the upper conical ring to the right and pull the instrument off.

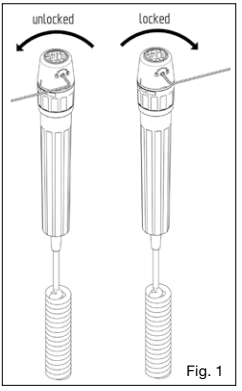

Fig. 1

The device enters power saving mode, if the handles are taken off the unit and are not used for more than 15 minutes.
The handles are activated by adjusting the brightness or by placing the handle back and taking it off the unit again.

The setting up and operation of the HEINE instrument heads are described in a separate instruction of use.

Hygienic Reprocessing

Instructions on hygienic reprocessing must be adhered to, based on national standards, laws and guidelines.

Classification according to KRINKO: non-critical

Spaulding Classification USA: non-critical

⚠ Before reprocessing, disconnect the device from the power source.

In the event of suspected contamination, carry out hygienic reprocessing of the instrument.

The described reprocessing measures do not replace the specific rules applicable for the establishment.

Only the reprocessing agents and procedures called out in this instruction for use are approved.

The reprocessing is to be carried out by persons with adequate hygienic expertise.

Observe the instructions of the manufacturer of the reprocessing media.

Procedure

Cleaning and disinfection

Clean and disinfect the device manually (wipe clean and wipe disinfect).
When wiping the handles, hold them down to prevent the ingress of liquid.
Ensure that the instrument is completely dry after reprocessing before you use it again.

Recommended agents

Cleaning agent, if necessary: enzymatic (e.g. Cidezyme® by ASP®)
Disinfectant agent: hydrogen peroxide (e.g. PREempt™ Wipes, Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes) or Quaternary Ammonium compounds (e.g. Super Sani-Cloth Germicidal Disposable Wipe).

Maintenance

The EN200 and the power supply are maintenance free.

Service

The device has some components serviceable by the end user.

General Warnings

Check the correct operation of the device before use! Do not use the device if there are visible signs of damage.

The power supply must not be opened (risk of electrical hazard).

Use power supply in dry environment only. Avoid splashing water. Do not immerse in liquids.

Do not use the device in fire- or explosive risk area (e.g. oxygen saturated or anaesthetic environments).

The device must not be placed near strong magnetic fields, e.g. MRI units.

Do not modify the device.

Use only original HEINE parts, spare parts, accessories and power sources.

Repairs shall only be carried out by qualified persons.

General Notes

The warranty for the entire product is invalidated if non-genuine HEINE products or non-original parts are used and if repairs or modifications are made to the device by persons not authorized by HEINE. For more information, please visit www.midmark.com.

The expected life cycle, when the device is normal used and the warning and safety information as well as the maintenance instructions are observed, is up to 10 years.
Beyond this period, the product may continue to be used if it has been determined to be in safe and good condition.

Disposal

The product must be recycled as separated electrical and electronic devices. Please observe the relevant state-specific disposal regulations.

Electromagnetic disturbances – Requirements and tests	
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such environments.	
Statement for the operational environments:	Inside hospitals except for: near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances are high.
Performance features of the ME system that have been determined to be essential to the performance	None
Warning ⚠	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the EN200, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
A list of all cables, transducers and other accessories that are relevant for the EMC compliance	None
Test	**Compliance**
RF emissions CISPR11	Group 1 Class B
Harmonic Emissions	Passed
Voltage Fluctuations/Flicker	Passed

Technical specifications

Environmental conditions for operation	+10 °C to +35 °C 10 % to 75 % rel. humidity 700 hPa to 1060 hPa
Environmental conditions for storage	+5 °C to +45 °C 45 % to 80 % rel. humidity 500 hPa to 1060 hPa
Environmental conditions for transport	-20 °C to +50 °C 10 % to 90 % rel. humidity 500 hPa to 1060 hPa
Main Power Supply	100 – 240 V AC / 50 – 60 Hz
Current consumption	300 – 150 mA
Output (USB)	typ. 5 V
Output (AV)	typ. 1.6 V – 3.6 V
Class	II
Protection Class	IP 40
Dimensions	180 x 234 x 99 mm
Weight	940 g

Explanation of utilized symbols
The following symbols are used on the device or on the packaging:

CE	The CE mark indicates that the product complies with the European medical device directive 93/42/EEC.
REF	Catalogue- or order number
SN	Serial number
	Manufacturer
	Date of manufacture
	Product bearing this symbol may not be disposed of together with general household waste, but instead requires separate disposal according to local provisions. (European Waste Electrical and Electronic Equipment Directive, WEEE)
	Temperature limits in °C for storage and transport
	Temperature limits in °F for storage and transport
	Humidity limitation for storage and transport
	Pressure limitation for storage and transport
	Instructions for use

	Alternating current (AC)
	Fragile, handle with care!
	Keep dry!
	Follow instructions for use! (Background color, blue; Foreground color, white for color print, or white on black background.)
	For indoor use only.
	UL Recognized Component Mark (for USA and Canada).
	Class II equipment
	Brightness intensity scale
	Lock mechanism

Manufacturer

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