HEINE QUALITY
MADE IN GERMANY

HEINE® EN200 BP

V-200.00.501

INTENDED USE

The EN200 BP is an automatic, non-invasive blood pressure monitor that can be used together with an inflatable cuff for repeated, indirect blood pressure measurement without arterial puncturing. This electrically powered ME DEVICE for indirect blood pressure measurement without arterial puncturing uses an automatic method to assess the blood pressure. The device is suitable for clinic environment.

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1 FIRST STEPS

1.1 SCOPE OF DELIVERY AND PACKAGING

First, check to ensure that the device is complete and that it does not display any damage. In case of doubt, do not start-up the device and contact your dealer or service centre.
Every device is identified by a unique serial number that is placed in a clearly visible position on the rear of the device.

Scope of delivery:

M-000.09.202	EN200 BP as single module
M-000.09.091	Coiled tubing EN200 BP
X-000.99.204	USB-cord
X-000.99.305	E4-USB Plug-in power supply with primary plug
	Instruction for use

M-000.09.201	EN200 BP for use with the EN 200 Wall Transformer
M-000.09.091	Coiled tubing EN200 BP
X-000.99.203	USB-cord
	Instruction for use

Accessories:

Quick Cuff (Reusable)

M-000.09.803	20,5 – 28 cm	Adult small
M-000.09.804	27 – 35 cm	Adult
M-000.09.805	34 – 43 cm	Adult large
M-000.09.806	42 – 54 cm	Adult XL

Quick Cuff Single Patient

M-000.09.813	20,5 – 28 cm	Adult small (10 pcs.)
M-000.09.814	27 – 35 cm	Adult (10 pcs.)
M-000.09.815	34 – 43 cm	Adult large (10 pcs.)

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WARNING: Keep packaging film out of the reach of children.
Risk of suffocation!

1.2 THE START SCREEN

The EN200 BP is equipped with an innovative touch screen. The entire navigation takes place by lightly touching the specific function icon on the display.

FUNCTION SYMBOLS


Switching on/off


Home: Go back to the main screen


Back: Go back one level


”BACK“ touch button (to go back one level)


”CANCEL“ touch button


”START“ touch button


”RESET“ touch button


”DOWN“ touch button

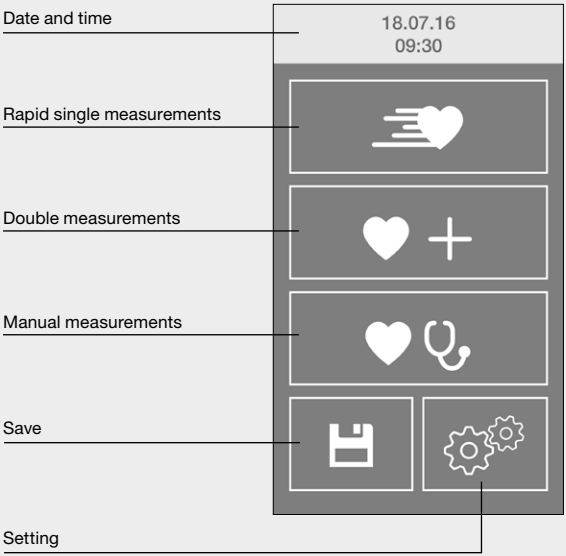

”UP“ touch button“


”CONFIRM“ touch button


”SAVE“ touch button


”TO DELETE“ touch button

START SCREEN



1.3 START-UP

1.3.1 ASSEMBLY AND DISASSEMBLY

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. There is a USB port on the rear side. 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.

5. 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.
6. Additionally, the lower screw can be fixed, in order to avoid the device from slipping off the mount. If you do fix the lower screw, please stick the enclosed identification plate visibly on the bottom of the housing.

For disassembly, remove the plug-in transformer from the mains socket, loosen the lower screw, push upwards and take it off the wall.

1.3.2 SETTING UP

One option is to connect the USB cable to the HEINE plug-in power supply, attach the primary adapter to the plug-in power supply until it latches into place, and then connect the primary adapter to the socket. The other option is to use the HEINE® EN200 wall transformer for power supply.

Primary plug

EU USA / Japan UK Australia

The device may only be operated with the supplied power supply unit. Use only original HEINE accessories.

1.3.3 SWITCHING YOUR UNIT ON AND OFF

To switch the device on, hold down the ⏻-button for about 1 seconds. The unit will switch itself off after around 2 minutes if no other buttons have been pressed in that time. On the start screen, it is also possible to switch off the unit by pressing and holding the ⏻-button for around 1 second.

1.3.4 INITIAL CONFIGURATION

Switch on the unit. You will be taken directly to the initial configuration menu when first switching on your device. This is where you can perform the following settings:

LANGUAGE
Set the language with the navigation buttons ∨ ∧ and confirm the entry with the confirmation button ✓.
This will also define the date and time format.

DATE
Set the current date using the navigation buttons ∨ ∧.
Confirm the entry using the button ✓.

TIME
Set the current time using the navigation buttons ∨ ∧.
Confirm the information entered using the confirm button ✓.

2 BLOOD PRESSURE MEASUREMENT

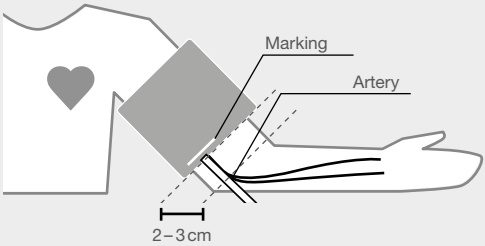
2.1 PRIOR TO MEASURING THE BLOOD PRESSURE

Selecting the right cuff size and the correct cuff position of the blood pressure cuff are critical for successful blood pressure measurement; this is the most common source of errors for inaccurate measurements.

CORRECT CUFF POSITION

IMPORTANT: THE CUFF SIZE MUST BE CORRECT!

The cuff for adults is suitable for an upper arm circumference of 27–35 cm.
Other cuff sizes can be selected for different arm circumferences.



- First insert the free end of the cuff air tube into the connection provided on the device.
- Open the sleeve and place it over the patient's bare left arm, above the elbow. Make sure that the arm is not affected by the hitching up of the sleeve in the event of tight-fitting clothing.
- The cuff must be positioned about 2 finger widths above the elbow with the tube pointing in the direction of the wrist. The cuff itself must not be twisted at all.
- The arrow printed on the cuff must be positioned over the brachial artery.
- Close the cuff so that it is close-fitting but not constricting.

PLEASE NOTE: The EN200 BP has an automatic switch-off function that is triggered if the device is not used for 2 minutes. As a result, take the time to calmly position the blood pressure cuff on the arm and then confirm that it has been positioned correctly. Then switch on your device and start the blood pressure measurement.

THE CORRECT MEASURING POSITION

Perform the measurement while seated. Pay attention to the following:

- Assume a comfortable sitting position
- Do not cross the legs
- Place the feet flat on the floor
- Support the back and arm
- Place the centre of the cuff at the height of the right atrium
- Relax the arm and place it on a table, for example
- Keep quiet and calm during the measurement: Do not move or talk, as this could affect the measurement values.

The following must be noted when taking the blood pressure:

- Seated measurement after 3 – 5 minutes of rest prior to the measurement
- At least two blood pressure measurements at an interval of 1 to 2 minutes in a seated position and additional confirmation measurements, if the first two measurements differ significantly. The averaging of the blood pressure values may be considered.
- Repeat the measurements in order to improve the accuracy for patients with arrhythmias, e.g. atrial fibrillation.
- The cuff must be positioned at heart height.
- For auscultatoric methods, pay attention to the disappearance of the Korotkoff sounds to identify the systolic and diastolic blood pressure (phase I and V).
- The blood pressure should be measured on both arms as part of an initial examination. The higher blood pressure value is the reference value.
- In order to detect orthostatic hypotension for older patients, diabetics or other common illnesses, the first measurement should take place while standing, after 1 and 3 minutes.
- For conventional blood pressure measurements, the heart rate should be detected by feeling for the pulse (at least 30 seconds) in a seated position after the second measurement.

THREE TYPES OF BLOOD PRESSURE MEASUREMENT USING THE EN200 BP

The individual measurement methods (”rapid single measurement“, ”double measurement“ and ”manual measurement“) perfectly complement each other and were developed based on the recommendations by the ESH and the daily requirements of everyday medical practice.

RAPID SINGLE MEASUREMENTS: Whether in the hospital or in the doctor’s office – each routine physical examination starts with a thorough measurement of blood pressure. The EN200 BP and accurately determines blood pressure with a fully automatic single measurement. The integrated memory documents up to 500 readings. These are then clearly displayed and available for further processing and analysis.

DOUBLE MEASUREMENTS: Accurate blood pressure measurement in routine practice is even more convenient in the double measurements mode. The measurement is fully automatic and the blood pressure value is calculated from the average of two single measurements in accordance with the ”Guidelines for the prevention, detection, diagnosis and treatment of arterial hypertension“ by the German Hypertension League. This scientifically based approach corresponds to the conventional understanding of correct medical blood pressure measurement.

MANUAL MEASUREMENTS supports the physician in his or her profession and is used for special groups of patients, such as pregnant mothers.
The measurement is taken by auscultation with the stethoscope; only the pumping and memory is performed by the EN200 BP.

BLOOD PRESSURE MEASUREMENT TERMINOLOGY

SYSTOLIC PRESSURE: ”Systole“ is the medical term for the phase of the pumping process in which the heart contracts and ejects blood.

DIASTOLIC PRESSURE: the diastolic blood pressure value represents the lowest pressure in the vascular system, a base pressure, to which the vessels are permanently exposed.

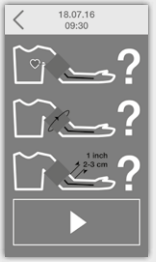
The MEAN ARTERIAL BLOOD PRESSURE is the mean blood pressure, i.e. the mean blood pressure independent of the systolic and diastolic fluctuations in the vascular system.

PULSE FREQUENCY: the pulse frequency refers to the number of pulses for a specific unit of time (generally 1 minute).

2.2 SINGLE MEASUREMENTS

PERFORMING THE SINGLE MEASUREMENTS

- Start your EN200 BP.
- The start screen appears in the display accompanied by an acoustic signal.
- Select the ”single measurement“ mode.



- Position the blood pressure measurement cuff on the left arm.
- A note on the screen asks you to double-check the position and size of the blood pressure cuff.
- Confirm this screen and perform the measurement by pressing the ”Start“-button [▶].

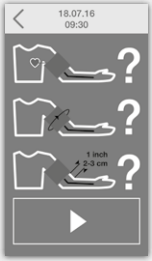
- The EN200 BP automatically slowly inflates the cuff to measure the blood pressure. The pressure display changes constantly during inflation.
- The device inflates the cuff until an adequate pressure for the measurement is reached. The device then slowly releases the air from the cuff and performs the measurement. The blinking ♥-symbol represents the pulse.
- You can terminate the measurement at any time by pressing the [×]-button.

- It displays the determined blood pressure value by indicating the systolic pressure, the diastolic pressure, the mean arterial blood pressure and the pulse.
- The EN200 BP automatically stores the measured values in the single measurement memory. The memory can be called up directly from this menu using the [💾]-icon.
- If you want to start another manual measurements, please press the <-Button.

2.3 DOUBLE MEASUREMENTS

PERFORMING THE DOUBLE MEASUREMENTS

- Start your EN200 BP.
- The start screen appears accompanied by an acoustic signal.
- Select the ”double measurements“ mode.



- Position the blood pressure measurement cuff on the left arm.
- A note on the screen asks you to double-check the position and size of the blood pressure cuff.
- Confirm this screen and perform the measurement by pressing the ”Start“-button [▶].

- The clock icon, which changes over time, appears in the display; the inflation process starts after 60 seconds. The patient should remain motionless and come to rest during this period in order to establish optimal measuring conditions.

- The EN200 BP automatically slowly inflates the cuff to measure the blood pressure. The pressure display changes constantly during inflation.
- The device inflates the cuff until an adequate pressure for the measurement is reached. The device then slowly releases the air from the cuff and performs the measurement. The blinking ♥-symbol represents the pulse.
- You can terminate the measurement at any time by pressing the [×]-button.

- The clock icon, which changes over time, once again appears in the display at the end of the first measurement.
- The second measurement starts after a further 60 seconds.

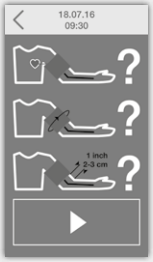
- Once the second measurement is complete, the blood pressure that has been calculated appears, showing the systolic pressure, diastolic pressure, mean arterial pressure and pulse rate.
- The EN200 BP automatically stores the measured values in the double measurement memory. The memory can be called up directly from this menu using the -icon.
- If you want to start another double measurement, press the <-button.

2.4 MANUAL MEASUREMENTS

PERFORMING THE MANUAL MEASUREMENTS

- Start your EN200 BP.
- The start screen appears accompanied by an acoustic signal.
- Select the measuring mode ”manual measurements”.

- Determine the point where the pumping should stop.



- Position the blood pressure measurement cuff on the left arm.
- A note on the screen asks you to double-check the position and size of the blood pressure cuff.
- Confirm this screen and perform the measurement by pressing the buttons ▶.

- The EN200 BP automatically slowly inflates the cuff to measure the blood pressure. The pressure display changes constantly during inflation.
- The device inflates the cuff until an adequate pressure for the measurement is reached. The device then slowly releases the air from the cuff and performs the measurement. The blinking ♥-symbol represents the pulse.
- You can terminate the measurement at any time by pressing the <-button.

- Use a stethoscope to determine the value for the SYSTOLE and save this in the display by tapping the ✓-button.
- The reading is shown in the display.

- Use a stethoscope to determine the value for the DIASTOLE and save this in the display by tapping the ✓-button.
- The reading is shown in the display.
- The device automatically deflates the cuff after confirming the DIASTOLE and displays the measurement result.

- It displays the determined blood pressure value by indicating the systolic pressure, the diastolic pressure, the mean arterial blood pressure and the pulse.
- The EN200 BP automatically stores the measured values in the double measurement memory. The memory can be called up directly from this menu using the 💾-button.
- If you want to start another manual measurement, please press the <-button.

2.5 ERROR MESSAGES

The device displays one of the following error images if no blood pressure result could be determined.

Internal device error: restart your device. If this error message is still displayed, please contact the manufacturer. This error image also appears if the measuring range limits are exceeded or not reached; the measurement does not provide a result.

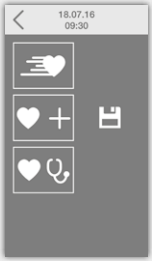
Cuff pressure: check the correct position and the correct size of the cuff and repeat the measurement.

Motion artefacts: muscle twitching, coughing, sneezing and mental activities such as speaking, listening and observing (TV) may distort the result of a blood pressure measurement. Repeat the measurement in total peace and quiet.

3 THE READINGS MEMORY

The unit memory of your EN200 BP is structured in a way that reflects the three measurement modes: single measurement, double measurement and manual measurement. Each provides 500 memory spaces.

- Start your EN200 BP.
- The start screen appears accompanied by an acoustic signal.
- Select the MEMORY MENU item.



- Select the measurement mode from which you would like to retrieve the measured values.

- The results of your last blood pressure measurement are displayed in a list in chronological order at the bottom of the screen. Use the left and right navigation buttons to scroll through the list.
- The top part of the screen provides a detailed display of the latest or selected blood pressure value, with the following additional information:
  - Date and time of measurement
  - Number of memory spaces (here: 1) of the total stored measurements (max. 500).
    The measurement results can be deleted separately via the button 🗑. Confirm the deleted value with the button ✓.

4 SETTINGS MENU ITEM

Device and system settings can be performed using the settings menu item. You are guided through the initial configuration menu step by step when first starting up your EN200 BP. You can subsequently change your individual information at any time.

- Start your EN200 BP.
- The start screen appears accompanied by an acoustic signal.
- Select the SETTINGS MENU item.

Setting options:
- Date
- Time
- Language selection

Proceed as described in 1.3.4

You can reset your device to factory default. This will delete the entire memory and the settings for language, date and time will be reset.

- Turn of the device.
- Switch on the device with the ⏻-button. During the start screen (HEINE logo with revision stand), simultaneously press the ⌂ and ‹ keys.
- As soon as the screen turns orange, release the buttons and press the ⌂-icon again.
- You are now in the ”Reset“ menu. By pressing the ↺-symbol, you will reset your device to the factory settings.
- Switch on the device and carry out the initial configuration (as described in chapter 1.3.4).

5 NOTES

5.1 PATIENT SAFETY

Indication: electronic blood pressure monitor to measure blood pressure using inflatable cuffs. It is intended for preventive use, for regular blood pressure checks performed by a doctor or qualified medical staff.

The EN200 BP is not intended for use with the following groups of people:

- No measurement for newborns, toddlers and children.
- Not suitable for people with relative and absolute contraindicators.
- Not suitable for patients with pre-eclampsia.
- Not suitable on the arm on the side of a mastectomy.

Relative contraindicators:
- Lymphoedema
- Partial or complete paralysis
- Arterial or venous vascular accesses (e.g. Viggo)

Absolute contraindicators:

- Dialysis shunt
- Fresh (OP) wounds (on the affected arm)
- Mastectomy (on the affected arm)
- The EN200 BP can be used for blood pressure measurement during pregnancy. However, pregnant mothers should pay attention to the necessary precautionary measures and their individual resilience. In the event of discomfort, such as pain in the upper arm or other complaints, during a measurement, press the [×]-button to immediately deflate the cuff. Loosen the cuff and remove it from the upper arm.

- When taking blood pressure measurements, remember that the daily values depend on many factors. For example, the following factors influence the blood pressure measurement in different ways:
  - Measuring point
  - Patient's posture (standing, sitting, lying)
  - Exertion
  - Patient's mental state
  - Smoking
  - Consumption of alcohol
  - Medication
  - Manual labour
- The following factors can influence the blood pressure measurement:
  - Arrhythmias
  - Premature atrial contractions
  - Ventricular or atrial fibrillation
  - Arteriosclerosis
  - Low blood circulation
  - Diabetes
  - Age
  - Pregnancy
  - Hypertension in pregnancy
  - Kidney disease
  - Patient movement, shaking or shivering
- The EN200 BP and HEINE original accessories are free of phthalates.
- The device must not be used to check the heart rate of patients with pace makers.
- The device must be kept out of reach of children – risk of injury!
- The operator should always be in the room during the measurement on the patient and have a good view of the measured values.

- Permanent cuff pressure, e.g. due to a bent cuff tube, may lead to circulatory disorders that may cause serious injury to the patient. If the cuff pressure remains, open the cuff fastener and switch the device off by pressing the ⏻-button.
- Press the ☒- or the ‹-button in order to terminate the inflation process. The EN200 BP immediately stops the inflation process, starts to discharge air.
- To manually deflate the cuff, pull the tube off at the device's connector. Makes sure that the tube is not bent, so that the cuff can be fully deflated.
- The cuff must not be applied to wounds or cuts as this involves a higher risk of infection.
- Please note! The positioning and inflation of the cuff on any limb for which an intravascular access or intravascular therapy or an arterio-venous (a.v.) shunt is present may lead to a temporary interruption and patient injury.
- Please note! The inflation of the cuff may lead to a temporary loss of function of a monitoring ME device used simultaneously on the same limb.
- Please note! The cuff tube may wrap around the neck and result in strangulation. Please only wear the cuff on the upper arm and ensure that the pressure tube cannot wrap around the neck.
- Please note! Check that the operation of the automatic, non-invasive blood pressure monitor does not impair the patient's blood circulation for an extended period of time. (The check may include the observation of the relevant limb.)
- Please be aware that the method of measurement involves the interruption of blood circulation for a short period. A break of at least one minute must be provided between multiple measurements. Measurements performed too frequently may injure the patient as a result of circulatory disorders.
- The results of the blood pressure measurement may also be influenced by extreme temperatures and humidity. Pay attention to the operating conditions.
- If multiple unexpected measurement values occur, please measure with an alternative device.
- The device is only intended for wall mounting and may only be used once it is mounted.

- 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.
- If liquid has been sprayed onto the device, send the device to your authorised HEINE sales partner or directly to the manufacturer for checks.
- Comply with the statutory provisions and the current state-of-theart when cleaning and disinfecting the device. Use the detergent and disinfectant recommended by the manufacturer to clean and disinfect the device. Clean and disinfect your device and accessories in line with the specifications in Chapter 5.3 Cleaning and maintaining the device and 5.4. Cleaning and maintaining the cuff.

5.2 OPERATION, MAINTENANCE AND CARE

- Metrological control (MTK): the device is calibrated by the manufacturer for a period of two years. The metrological control must take place in accordance with §11 MPBetreibV (Medical Device Operator Regulation) at least every two years and after repairs. The inspection is subject to a charge and may be performed by the manufacturer or an authorised maintenance service centre, in accordance with the Medical Device Operator Regulation. To perform the MTK, the "MTK Calibration Procedure" document must be requested from your authorized HEINE sales partner or the HEINE Customer Service.
- A regular, mandatory safety check (STK), at least every two years, is prescribed for this device pursuant to the MPBetreibV. In addition to the statutory requirements, the manufacturer prescribes a regular annual safety check; this must also be performed by an authorized service centre after every repair, change or modification of the system or device.
  Every safety check must be completed in full and consists of the following components: visual inspection, functional check, testing of the monitoring, safety, display and messaging systems, measurement of the key safety values, electrical test.
- Only use the device in accordance with its intended use defined in the instructions for use. The warranty expires if the device is used incorrectly.
- The compression or other mechanical restriction of the crosssection of connecting tubes must be avoided.

- The device may not be used together with HF surgery, x-rays and MRI.
- The device must not be operated near devices that emit powerful electrical radiation, such as radios, mobile telephones or microwave units.
- Do not repair the device yourself if faults occur.
- Only allow the manufacturer or authorised service centres to perform repairs. The device must be subjected to a further metrological control after a repair.
- Protect the device against moisture. Avoid further use if moisture should penetrate into the device. In this case, contact your dealer or inform us directly. In this case, the device must undergo a safety check (STK).
- If the device is exposed to adverse environmental conditions (e.g. high humidity in bathrooms), the likelihood of malfunctions must be clarified in each specific case. Please contact the manufacturer.
- Any modifications to the device are prohibited.
- The use of accessories, removable parts and materials that are not described in these instructions for use is prohibited. Only use original HEINE accessories.
- Over-stressing due to dust, fluff and exposure to light may damage the device. Please pay attention to the storage conditions.
- Should you forget to switch off the device, the device will automatically switch off after 2 min.

5.3 CLEANING AND MAINTAINING THE DEVICE

- Never use aggressive detergent or sturdy brushes.
- Clean the device using a soft cloth, which you moisten using a mild soap solution.
- Ensure that no water penetrates into the device. Only use the device once it is completely dry.
- Never expose the device to direct sunlight; protect it against dirt and moisture.
- Only inflate the cuff once it has been positioned on the upper arm.

5.4 CLEANING AND MAINTAINING THE CUFF

If the EN200 BP is used to perform measurements for different individuals, it is advisable to disinfect the cuff using spray or wipe disinfection. Please do not immerse the device and the connector in water.

- Spray disinfection: spray the cuff cover with detergent or disinfectant and allow the agent to take effect in line with the manufacturer's instructions. Then wipe with a dry cotton cloth if necessary.
- Wipe disinfection: moisten the cuff cover or a cloth with the detergent/ disinfectant. Then wipe down the cuff surface by applying a slight amount of pressure.

5.5 CLEANING AGENTS

Please only use clean and soft cotton cloths to support these cleaning methods. Recommended detergent for EN200 BP and the associated HEINE cuffs:

- Fugaten®-spray (Lysoform spray)
- Alternative: Esemfix® by Schülke; (foam cleaner)
- Promanum® pure by Braun
- Meliseptol® Foam pure by von Braun

5.6 DISPOSAL INFORMATION

This device must not be disposed of together with household waste.

Every user is obliged to dispose of all electrical or electronic devices at a collection point in their town or by returning them to a commercial dealer, regardless of whether they contain pollutants or not, so that they can be disposed of in an environmentally friendly manner.

6 WARRANTY AND REPAIR CONDITIONS

STATUTORY WARRANTY

In the event of a warranty claim, please contact your dealer, the service centre or the manufacturer directly. If you need to send in the device, please indicate the defect and provide a copy of the purchase receipt.
The following provisions apply for the statutory warranty:

- 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.heine.com.

- Defects due to material or production faults are removed free of charge within the warranty period.
- A warranty claim does not result in an extension of the warranty period, either for the device or for the replaced component.
- The following are excluded from any warranty claim:
  a. all damage caused as a result of incorrect handling, e.g. due to non-compliance with the instructions for use.
  b. damage due to repairs or interventions by the buyer or unauthorized third parties.
  c. transport damage that occurs en-route from the manufacturer to the user or if it is sent to the service centre.
  d. accessories that are subject to normal wear, such as batteries, cuffs, etc.
- No liability for direct or indirect consequential damages caused by the device is accepted if the damage to the device is identified as a warranty case.

7 INFORMATION ON LABELLING AND SAFETY

LAWS AND PROVISIONS RELATED TO THE PRODUCT

This device is designed in accordance with Medical Device Directive 93/42/EEC, Class IIa, and corresponds to protection class II. type BF pursuant to DIN EN 60601-1

DIN EN 60601-1:2013-12
General requirements for basic safety and essential performance

DIN EN 80601-2-30:2011-05
Particular requirements for the basic safety and essential performance of automated type non-invasive sphygmomanometers

DIN EN 60601-1-2:2007-12
Electromagnetic compatibility: the device complies with the standard's requirements for electromagnetic compatibility.

Other provisions: The accident prevention measures, provisions and requirements in the respective user's country apply for users outside the Federal Republic of Germany.

a. Legend – icons on the device

EN200 BP	Device name EN200 BP
SN:1441001243	Serial number on the rear of the unit
	Manufacturer
	Date of manufacture
	CE mark
	Icon for ”Type BF applied parts“
	Only to measure the blood pressure of adults. The device is not suitable for performing blood pressure measurements on newborns, toddlers and children.
	Pay attention to the instructions for use.

Separate collection of electrical and electronic devices, do not dispose of in household waste.

ATTENTION: risk of injury and damage to the device. Comply with the instructions.

The device corresponds to protection class II and has reinforced or double insulation. No protective earth connection.

IP22

The device protection class defines the degree of protection provided by the housing against contact, foreign objects and water.

b. Legend – icons in the instructions for use

Notes and warnings are identified by the following icons in the instructions for use and compliance must be ensured.

WARNING: these warnings must be complied with in order to avoid potential injuries to the user.

NOTE: information and tips on using the device.

c. Technical data

Name and model:	EN200 BP
Display system:	Digital display
Memory space:	500 per measuring mode
Measuring method:	Oscillometric
IP protection class:	IP22
Protection against contact and foreign:	Protected against finger (Ø 12 mm, L = 80 mm) Protected against solid foreign bodies (diameters over 12.5 mm)
Moisture protection:	Protected against water dripping at an angle: (angle up to 15° to the vertical)
Input:	5 V, 0.5 A
Power supply for single module:	Power supply: GTM41078-0605-USB Manufacturer: GlobTek Inc. Input: 100 – 240 Vac, 50 – 60 Hz, 0.3 A Output: 5 V, 1.2 A
Power supply for use with the EN 200 Wall Transformer:	Manufacturer: HEINE Optotechnik GmbH & Co. KG Input: 100 – 240 Vac, 50 – 60 Hz, 300 – 150 mA Output: typ. 5 V, 0.5 A
Nominal display of the result of the blood pressure value	
Measuring range for the systolic blood presssure:	60 – 230 mmHg
Measuring range for the diastolic blood presssure:	40 – 130 mmHg
Measuring range for the pulse:	30 – 220 beats / min.
Measurement range:	0 mmHg – 299 mmHg
Measuring range for the cuff pressure:	40 mmHg – 299 mmHg

Maximum measurement error for the static pressure:	± 3 mmHg
Maximum measurement error for the pulse value:	± 5 % of the value
Pressure generation:	Automatic, pump
Deflation:	Automatic
Automatic switch-off:	After about 2 minutes
Operating conditions:	+5 °C to +40 °C, 15 % – 93 % max. rel. humidity (non-condensing) 700 to 1060 hPa atmospheric pressue
Mode of operation:	The device is designed for continuous operation
Operating time:	Continuous operation
Transport and storage conditions:	-25 °C to +70 °C Up to 93 % max. rel. humidity (non-condensing) 700 to 1060 hPa atmospheric pressure
Dimensions:	Approx. 220 x 140 x 55 mm
Cuff:	Adult size: Ø 27 – 35 cm for adults with average upper arm circumferences
Weight:	470 g
	Subject to technical and design changes as a result of constant product improvements.

d. Manufacturer declaration on EMC (electromagnetic compatibility)

Electromagnetic disturbances – Requirements and tests	
The EN200 BP is intended for use in the electromagnetic environment specified below. The customer or the user of the EN200 BP 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 EN200 BP that have been determined to be essential to the performance:	No permanent loss of function due to component failure. The originally set software mode must be retained. The blood pressure measurement is not impaired.

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.

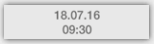
Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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 BP, including cables specified by the manufacturer. Otherwise, degradation of the performance of this EN200 BP could result.

A list of all cables, transducers and other accessories that are relevant for the EMC compliance:

Requirements applicable to all ME EQUIPMENT and ME SYSTEMS	CISPR 11	Class B Group 1
Emission Standards	CISPR 55011 IEC 61000-3-2	Class B Class A
Immunity Standards	IEC 61000-4-2; IEC 61000-4-3; IEC 61000-4-4; IEC 61000-4-5; IEC 61000-4-6; IEC 61000-4-8; IEC 61000-4-11	Passed

e. Icons in the display



Date and time display: If you have set your language to "German", the current data will be displayed in the top area of the display in the DD/MM/YY format, and time, in the 24-hour format. If you have set your language to "English", the current data will be displayed in the format YYYY/MM/DD, and time in the 12 hour format.

The file icon refers to the internal device memory.
No delete function – once all memory spaces are assigned, the oldest data record is overwritten.

The gear wheel icon refers to the system settings. This is where the initial configuration and subsequent modifications of the individual settings take place.

Calendar icon:
enter the current date

Clock icon:
enter the current time

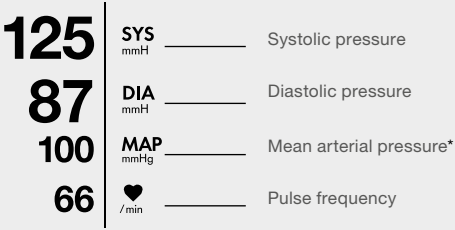
Language icon:
setting the language

f. Icons of blood pressure measurement

”Rapid single measurements“ mode

”Double measurements“ mode

”Manual measurements“ mode



*MAP = diastolic pressure+1/3 (systolic pressure – diastolic pressure)

SYS mmHg — Systolic pressure

DIA mmHg — Diastolic pressure

MAP mmHg — Mean arterial pressure

/min — Pulse frequency

Pulse

1. /500 — This icon appears in the results screen; the first number indicates the memory space in which the currently displayed blood pressure measurement value is stored; the second number is the total number of measurements stored (max. 500).