

HEINE GAMMA® G5, G7, GP, XXL LF



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

General Conditions of Warranty

Instead of the usual 2-year guarantee, we guarantee the HEINE GAMMA® G5/GP Sphygmomanometers except for accessories (outer cuff and inflator) for a period of 5 years and the HEINE GAMMA® G7/XXL LF for a period of 10 years, both periods to run from the date of delivery from our factory. For the outer cuff and inflator a 2-year guarantee applies from the date of delivery from the factory.

We guarantee the proper function of the unit provided it is used as intended by the manufacturer and according to the instructions for use. Any faults or defects which occur during the guarantee period will be repaired free of charge provided they are caused by faults in material, design or workmanship. In the case of a complaint of a defect in the product during the guarantee period, the buyer must prove that any such defect was present at the time the product was delivered. The usual legal guarantee and warranty do not apply to incorrect use, the use of non-original HEINE parts or accessories. Also excluded are repairs or modifications made by persons not authorised by HEINE or cases where the customer does not follow the instructions supplied with the product. Any modification of a HEINE product with parts or additional parts which do not conform to the original HEINE specification will invalidate the warranty for the correct function of the product and further invalidate any warranty claims which result from such a change or modification. Further claims, in particular claims for damage not directly related to the HEINE product, are excluded.

For repairs, please contact your supplier, who will return the goods to us or our authorized agent.



For U.S. only:

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).



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

Intended Use

HEINE GAMMA® G aneroid sphygmomanometers are exclusively designed for measuring blood pressure at the upper arm or thigh on healthy skin.

OPERATE

Fitting the cuff

Fit the cuff so that the lower edge is about 2-3 cm above the elbow (or about 5 cm above the knee). Locate the special mark over the artery. The white index mark should be located in the marked index area.

Measurements

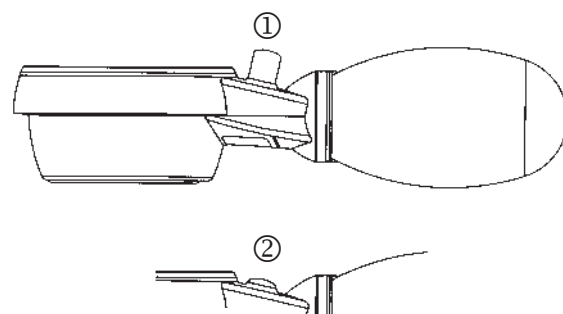
GAMMA G5, G7, XXL LF

Close the air release valve by turning to the right. Pump up the cuff to a value approximately 30 mmHg greater than the expected systolic pressure. Open the valve slowly and regulate the air release to 2 – 3 mmHg per second. After the measurement, open the valve entirely in order to quick-release the air from the cuff.

GAMMA GP

Press the button to close the valve completely ①. Pump up the cuff to a value approximately 30 mmHg greater than the expected systolic pressure. Open the valve slowly and regulate the rate of air release to 2 – 3 mmHg per second. After the measurement, open the valve completely in order to quick-release the air from the cuff ②.

Please note: It is not possible to pump up the cuff with the button in position ②.



Changing the position of the spoon (GAMMA G5, G7, GP)

The spoon is normally set for right-handed use. If you wish to inflate the cuff with the left hand, the spoon can be re-positioned for left-handed use:

- Remove the ball from the instrument with a twisting and pulling motion.
- Loosen the two screws near the air intake but do not screw them out completely.
(A special tool is supplied with GAMMA G7 for this purpose).
- Rotate the base of the spoon through 180° and re-tighten the screws.
- Grip the neck of the ball and push it back onto the air intake with a twisting motion. If necessary moisten the air intake to ease fitting.

HYGIENIC CLEANING / PROCESSING

The following recommendations must be followed in procedures in hospitals / practises with regard to national hygienic guidelines and / or legal requirements.

Manual Cleaning

Clean all accessible surfaces by wiping with a damp cloth (water, pH-neutral, light alkaline detergent). The cuff could be hand washed at 30 °C after removing the bladder.

Manual Disinfection

Do a cleaning disinfection of all accessible surfaces by wiping with a damp cloth. For disinfection only those products which are approved for use on medical devices made of plastic and aluminium alloy (GAMMA G7) may be use. The manufacturer's recommendations must be followed.

Sphygmomanometer:

Liquid must not penetrate the device. Disinfection by spraying and soaking is not allowed.

Cuff / Bladder:

Cuff and Bladder are released to for a disinfection by spraying and soaking.

Machine Cleaning / Ultrasonic Cleaning / Sterilisation

Sphygmomanometer, cuff and bladder are not permitted for these procedures as they will lead to damage of the components.

Maintenance

This product does not require regular maintenance.

Service

This product does not require regular service.

Technical specification

Range:	0 – 300 mmHg
Accuracy:	± 3 mmHg
<i>Environmental conditions:</i>	
Normal Use:	0°C to +40°C
Storage:	-34°C to +70°C
Relative humidity:	≤ 85%

Note calibration: A calibration check should be carried out at the latest every two years by the manufacturer or an authorized service technician.

Applicable standards:

DIN EN 1060: "Non-invasive sphygmomanometers"

Part 1: General requirements, and

Part 2: Supplementary requirements for mechanical sphygmomanometers

ANSI/AAMI SP9: 1994




ANSI/AAMI/ISO 81060-1:2007

Disposal

















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

General Notes and Warnings

-  Check the correct operation of the product at regular intervals. Do not use the equipment if it shows visible signs of damage.
- Protect the instrument from impact or shocks (do not drop) and protect from moisture and dirt. Avoid damaging the cuff with pointed objects such as needles or scissors.
Do a regular inspection of the devices and its components regarding to its function. Do not use the sphygmomanometer if fit is defective in any way. Do not expose the sphygmomanometer to direct sunlight for long periods of time.
 - Do not take your blood pressure for more than 2 minutes!
Wait for at least 2 minutes before taking a repeat measurement !
Accurate performance of the sphygmomanometer can only be guaranteed if original HEINE G-series latex-free cuffs are used. The use of other cuffs is done so entirely at the liability of the user.
A rectangular label is attached to the back of the instrument which carries a year-mark. This shows the year in which the instrument should be re-calibrated.
Please refer to the enclosed assembly instructions.
-  This product is a precise optical instrument. Please handle this product with care and store it in a clean place.
- All components of this sphygmomanometer are latex-free, the inflation bulb is also phthalate-free.
-  This product is not allowed to be entered or used in strong magnetic fields like MRI scanners.

Explanation of utilized symbols

The following symbols are used on the device or on the packaging:

	The CE mark indicates that the product complies with the European medical device directive 93/42/EEC.
	Catalogue- or reference number
	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
	Please read and follow the instructions for use and keep them for future reference (background color blue; foreground color white)
	Fragile, handle with care!
	Keep dry
	Interference may occur in the vicinity of equipment marked with the following symbol
	“Grüner Punkt” (country-specific)