

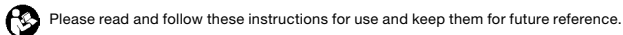
## ➤ HEINE GAMMA® G5, XXL LF



CE 0297




# HEINE GAMMA® G5, XXL LF





## Intended Use

The HEINE GAMMA® sphygmomanometers are intended for use for non-invasive, non-automated blood pressure measurements by qualified medical personnel. The devices are non-sterile, intended for multiple use and may only come into contact with intact skin. The HEINE GAMMA® blood pressure cuffs are available in various sizes ranging from small infants to large adults.

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

## Warnings and Safety Information

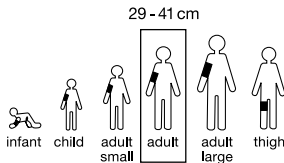
 **CAUTION!** Indicates potential hazardous situations. Ignoring the corresponding instructions may lead to dangerous situations of mild to moderate extent. (Background color, yellow; Foreground color, black for color print, or black in light-gray background.)

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

## Setting up

### Appropriate cuff size

To prevent measurement errors, the correct cuff size must be selected. To do this, measure the circumference of the patient's arm and select the appropriate HEINE cuff. The relevant arm circumference is indicated on the cuff as follows: (Example)  
(See also under "Accessories")



### Changing the cuff

To attach the cuff, attach the cuff tube to the nozzle on the measuring device.  
To change the cuff, detach the tube from the nozzle by turning slightly.

### Disassembly of the cuff

The cuff consists of a sleeve and an inflatable bladder. For hygienic reprocessing, the inflatable bladder can be taken out of the sleeve. To do this, first remove the bellows from the air tube and for the XXL size, also from the measuring unit. After this, withdraw the inflatable bladder sideways out of the sleeve:

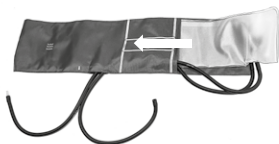


When reassembling, take note that you first need to thread in the tube / tubes (A) and then insert the inflatable bladder with the long side first into the sleeve (B).

(A)



(B)



## Operation

### 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.

- Do not take your blood pressure for more than 2 minutes!
- Wait for at least 2 minutes before taking a repeat measurement!

### Measurements

Let the patient relax for approx. 5 min. before you start the measurement. During the measurement, the patient should not talk if possible and should sit relaxed without crossing their legs. The back and arm should be supported.

The indicator on the scale should be at zero. To prevent measurement errors, the measured value should be read vertically to the measuring scale.

Pump the cuff approximately 30 mmHg above the expected systolic pressure. The artery is now compressed and no flow sounds should be heard.

The pulse-synchronous sounds which can be heard when the pressure is slowly released in the cuff are called Korotkoff sounds.

Use the K5 sound for measurements in adults and the K4 sound for children aged 3-12 years.

If Korotkoff sounds can be heard in adults or pregnant patients with a vented cuff, use the K4 sound as well for the measurement.

Open the valve to release the pressure. The pressure should go down at a speed of 2-3 mmHg per second. When sounds can be heard again, blood is flowing through the vessel again in the systole of the heart (Systolic / top pressure). Let the pressure slowly go down until the sound disappears (Diastolic / bottom pressure). Now there is no compression of the vessel and blood flows through again free from turbulence and sounds. At the end of the measurement, open the valve fully to quickly release the air from the cuff.

### GAMMA G5, XXL LF

Close the air release valve by turning to the right. Pump the cuff by pressing the bulb and release the air from it by opening the valve (3).



GAMMA XXL LF



GAMMA G5

### Changing the position of the spoon (GAMMA G5)

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.
- If necessary, moisten the air intake to ease fitting.
- 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.

### 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



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 for the sphygmomanometer*

Clean and disinfect the Sphygmomanometers manually (wipe clean and wipe disinfect).

#### Recommended agents

Cleaning agent, if necessary: enzymatic (e.g. Cidezyme® by ASP®)

Disinfectant agent: quaternary ammonia compounds (e.g. Sani-Cloth® AF3 by PDI®, Sani-Cloth® HB by PDI®)

#### *Procedure for the blood pressure cuff*

Clean and disinfect the blood pressure cuffs and tubes manually (wipe or immersion cleaning and disinfection).

The cuff sleeve can be hand-washed at max. 30 °C after removing the inflatable bladder.

#### Recommended agents

Cleaning agent, if necessary: enzymatic (e.g. Cidezyme® by ASP®)

Disinfectant agent: a combination of alcoholic and quaternary ammonia compounds (e.g. SUPER Sani-Cloth® by PDI®)

### Maintenance

The instruments do not require maintenance.

### Service

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

The reference measuring device must be traceable to a national/international standard.



A rectangular label is attached to the back of the instrument which displays a year-mark. This indicates the year in which the instrument should be reinspected.

## General Warnings



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

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.

Protect the instrument from impact or shocks (do not drop) and protect from moisture and dirt.

Avoid damaging the cuff, tube and bulb with pointed objects such as needles or scissors.

Do not expose the sphygmomanometer to direct sunlight for long periods of time.

This product is not allowed to be entered or used in strong magnetic fields like MRI scanners.

## 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](http://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.

The components of this sphygmomanometer are not made with natural rubber latex.

The inflation bulb is also phthalate-free.

Please refer to the enclosed assembly instructions.

## Disposal



Disinfect the product before disposal. Please observe the relevant state-specific disposal regulations.

## Accessories

### Cuffs for GAMMA G5

name	size / cm	circumference / cm	order number
infant	6x28	8-13	M-000.09.700-166
child	10x34	13-20	M-000.09.702-166
adult small	14x53	20-29	M-000.09.704-166
adult	14x58	29-41	M-000.09.619-166
adult large	17x70	35-47	M-000.09.706-166
thigh	20x86	41-59	M-000.09.615-166

### Cuffs for GAMMA XXL LF














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infant	6x28	8-13	M-000.09.701-166
child	10x34	13-20	M-000.09.703-166
adult small	14x53	20-29	M-000.09.705-166
adult	14x58	29-41	M-000.09.629-166
adult large	17x70	35-47	M-000.09.631-166
thigh	20x86	41-59	M-000.09.625-166

### Technical specification

Environmental conditions for operation	+10 °C to +40 °C 15 % to 85 % 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 45 % to 80 % rel. humidity 500 hPa to 1060 hPa
Measuring range	0 - 300 mmHg
Accuracy of the pressure indicator	± 3 mmHg

## 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 order 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
	Pressure limitation for storage and transport
	Fragile, handle with care!
	Keep dry!
	Follow instructions for use! (Background color, blue; Foreground color, white for color print, or white on black background.)

**Manufacturer**



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