Validation of Heine Gamma G7 (G5) and XXL-LF aneroid devices for blood pressure measurement

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Objective To determine the accuracy of the Gamma G7 (and G5 model) and XXL-LF aneroid sphygmomanometers developed by the Heine Company.

Design Device evaluations were performed using the new protocol of the European Society of Hypertension. Monitor performance was assessed in relation to participants' sex, age, arm circumference, and systolic and diastolic blood pressures.

Methods The two sphygmomanometers were assessed in two different samples according to European Society of Hypertension requirements, which are based on four zones of accuracy differing from the mercury standard by 5, 10, 15 mmHg, or more.

Results Both sphygmomanometers passed all three phases of the protocol for systolic blood pressure and diastolic blood pressure. Mean blood pressure difference between Gamma G7 sphygmomanometer and observers was − 0.4 ± 3.3 mmHg for systolic blood pressure and − 0.5 ± 2.6 mmHg for diastolic blood pressure. Mean differences for the Gamma XXL-LF sphygmomanometer were − 0.3 ± 3.7 and − 1.0 ± 2.6 mmHg, respectively. In multivariable analyses, the SBP discrepancies between both aneroid sphygmomanometers and observers were unrelated to age, sex, arm circumference and systolic blood pressure. For diastolic blood pressure, a borderline relationship was found only for arm circumference (*P*=0.057) with the Gamma G7 device.

Conclusions These data show that the Heine Gamma G7 and Gamma XXL-LF aneroid sphygmomanometers satisfy the new recommended ESH accuracy levels for both SBP and DBP. Their performance is uniform across subgroups of participants with different clinical characteristics. *Blood Press Monit* 12:29–33 © 2007 Lippincott Williams & Wilkins.

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Introduction

The future of mercury sphygmomanometry for blood pressure (BP) measurement is seriously threatened because of concerns about mercury toxicity [1,2]. Thus, the mercury sphygmomanometer is destined to disappear from clinical practice in the next few years. Many reliable automated devices are available today, which might replace the traditional technique. The BP measurement based on Korotkoff sounds, however, represents a mainstay of BP assessment in clinical practice and many doctors are reluctant to quit the auscultatory technique. This has increased the interest of doctors and manufacturers for mercury-independent devices such as the aneroid sphygmomanometers [3,4], devices that combine manual blood pressure measurement with electronic pressure detection [5], or sphygmomanometers that are based on the mercury technique but replace the mercury column with an electronic transducer and display [6]. Although BP measurement with aneroid devices is based on the same principles as mercury sphygmomanometry, aneroid sphygmomanometry can introduce a variety of errors that may differ from those encountered with the use of mercury devices [7,8]. Many aneroid sphygmomanometers are available in the market, but only a few have passed clinical tests following international protocols [3,4]. Recently, the Heine Company developed two models of aneroid sphygmomanometer, the Gamma G7 (and G5 which has marginal differences) and the Gamma XXL-LF. This paper reports on the accuracy of these sphygmomanometers evaluated according to the protocol of the Working Group on Blood Pressure Monitoring of the European Society of Hypertension (ESH) [9].

Methods
Subjects

For each sphygmomanometer, 33 participants (18 men) with the range of BP required by the ESH rules were included in the protocol (Table 1). For the Heine Gamma G7 sphygmomanometer, mean ± SD age was 51 ± 21 years, lying systolic BP (SBP) was 145 ± 22 mmHg (range 102–178), diastolic BP (DBP) was 90 ± 17 mmHg (range 58–129) and arm circumference was 29 ± 3 cm

Table 1 Device validation table for the Heine Gamma G7 aneroid sphygmomanometer

Phase 1 (n=15)	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade
Required One of Achieved	25	35	40	
SBP	37	45	45	Passed
DBP	41	45	45	Passed
Phase 2.1 (n=33)	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade
Required Two of Achieved	65	80	95	
SBP	89	98	99	Passed
DBP	93	98	99	Passed
Phase 2.2 (n=33)	2/3 ≤ 5 mmHg	0/3 ≤ 5 mmHg		Grade
Required Achieved	≥ 22	≤ 3		
SBP	31	0		Passed
DBP	32	0		Passed

DBP, diastolic blood pressure; SBP, systolic blood pressure,.

(range 23–34). In 25 patients, arm circumference was ≤ 32 cm and the standard cuff was used. In eight patients, arm circumference was > 32 cm and the large cuff was used. For the Heine Gamma XXL-LF sphygmomanometer, mean age was 54 ± 21 years, lying SBP was 141 ± 25 mmHg (range 94–174), DBP was 88 ± 15 mmHg (range = 60–112) and arm circumference was 28 ± 4 cm (range 20–36). In 26 patients arm circumference was ≤ 32 cm and in seven patients it was > 32 cm, and appropriate cuffs were used. All participants agreed to participate in the protocol and gave informed consent.

Devices
Both devices are aneroid sphygmomanometers. Their measuring range spreads over 0–300 mmHg. Their standard cuff is suitable for circumferences of arm ranging over 22–32 cm. Cuffs for larger arms are also available (see Appendix). The Gamma G7 is a standard portable aneroid sphygmomanometer. The Gamma G5 is identical to the G7 model except for its shape and weight (see Appendix). Thus, the validation should be extended to the G5 as well, even though the G7 was the only model tested in the present study. The Gamma XXL-LF sphygmomanometer is an aneroid professional model provided with a larger screen and an easy to read scale. It is available in wall mount, rail mount, table mount, and wheeled stand options.

Device validation
Observer training was achieved before the validation process. Sequential same-arm measurements were performed. Observers took BP measurement with a mercury sphygmomanometer at the left arm using adult cuff,

whose bladders had to cover at least 80% of the circumferences of the arm. Only a discrepancy of smaller than 4 mmHg between the two observers was accepted, otherwise the measurement was repeated. Before starting comparative readings, the two observers took a BP measurement and the mean of these two values was used to determine the BP class in which the participant was allocated. Large size cuffs were used in the participants with arm circumference > 32 cm (see also Appendix).

The discrepancy between the reading provided by the sphygmomanometer and the mean of observer's measurements was allocated in four zones of accuracy [9]. The first three zones (zone 0, 1 and 2) include discrepancies ≤ 5, ≤ 10 and ≤ 15 mmHg, respectively. The fourth zone (zone 3) includes all measurements.

Data are mean ± SD. Pearson's test was used for correlations. Predictors of the discrepancy between observer and device measurements were included in linear multivariable regression analyses. Only $P < 0.05$ was considered as statistically significant.

Results
Gamma G7 sphygmomanometer
In the first phase (Table 1), the analysis was performed in a group of 15 participants (eight men): three measurements were taken for each participant for a total of 45 BP readings. For SBP, 37, 45 and 45 sphygmomanometer measurements fell in zones 0, 1 and 2, respectively. For DBP, 41, 45 and 45 measurements fell in zones 0, 1 and 2, respectively. As the ESH protocol requires at least 25, 33, and 40 measurements in zones 0, 1, and 2, respectively, this phase was passed. In the second phase, the analysis was performed in all 33 participants. The device gave 89, 98 and 99 successful measurements for SBP, and 93, 98 and 99 successful measurements for DBP, falling in zones 0, 1 and 2, respectively. According to ESH rules, this phase requires at least 60, 75 and 90 measurements, in zones 0, 1 and 2, respectively, and was, thus, successfully completed.

Gamma XXL-LF sphygmomanometer
In the first phase (Table 2), for SBP, 37, 44 and 45 sphygmomanometer measurements fell in zones 0, 1 and 2, respectively. For DBP 42, 45 and 45 measurements fell in zones 0, 1 and 2, respectively. In the second phase, the corresponding figures were 86, 98 and 99 successful measurements for SBP, and 93, 98 and 99 successful measurements for DBP, falling in zones 0, 1, and 2, respectively. Thus, both phases were successfully completed.

The second part of phase 2 (phase 2.2) of ESH protocol was also passed by both sphygmomanometers. This part

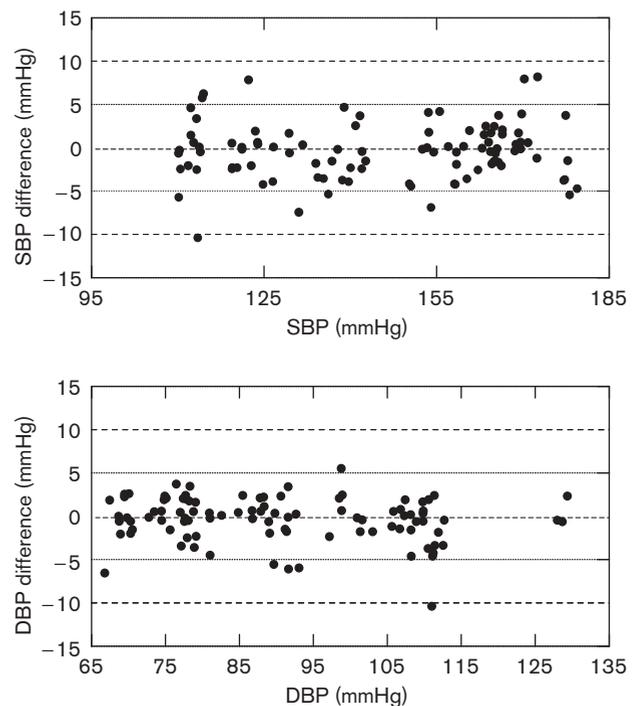**Table 2** Device validation table for the Heine Gamma XXL aneroid sphygmomanometer

Phase 1 (n=15)	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg	Grade
Required				
One of	25	35	40	
Achieved				
SBP	37	44	45	Passed
DBP	42	45	45	Passed
Phase 2.1 (n=33)	**≤ 5 mmHg**	**≤ 10 mmHg**	**≤ 15 mmHg**	**Grade**
Required				
Two of	65	80	95	
Achieved				
SBP	86	98	99	Passed
DBP	93	98	99	Passed
Phase 2.2 (n=33)	**2/3**	**0/3**		**Grade**
	≤ 5 mmHg	**≤ 5 mmHg**		
Required	≥ 22	≤ 3		
Achieved				
SBP	29	1		Passed
DBP	33	0		Passed

DBP, diastolic blood pressure; SBP, systolic blood pressure.
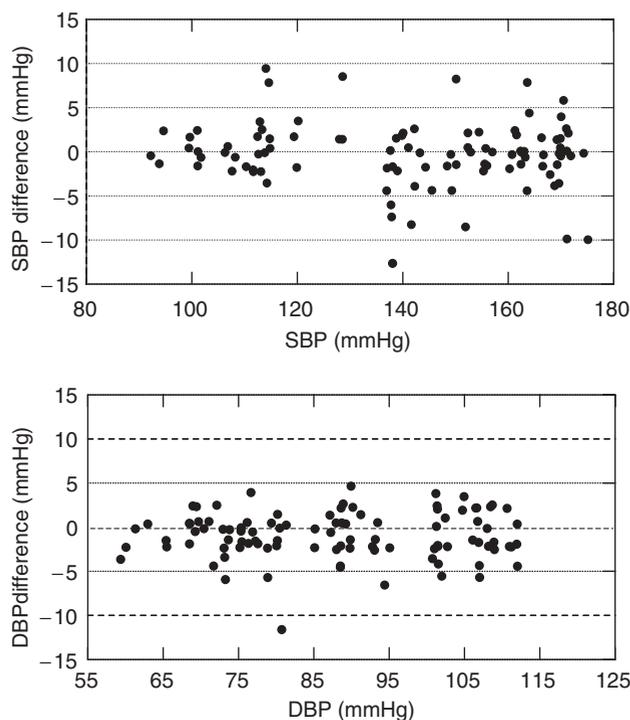
Fig. 1

Plot of the systolic (upper plot) and diastolic (lower plot) observer – Gamma G7 aneroid sphygmomanometer blood pressure differences. The *x*-axis represents the mean of the device and observer measurements. The *y*-axis represents the difference between the device and observer measurements. A positive value indicates that the observer's measurement is greater than the device measurement.

requires that in at least 22 participants two measurements of their three comparisons fall in zone 0, and that in no more than three participants all measurements fall in zones 1, 2 or 3. For the Gamma G7 sphygmomanometer, these figures were 31 and 0 participants, respectively, for SBP, and 32 and 0 participants, respectively, for DBP. For the Gamma XXL-LF sphygmomanometer, the corresponding figures were 29 and 1 participant, respectively, for SBP, and 33 and 0 participants, respectively, for DBP.

Both aneroid sphygmomanometers slightly underestimated observer-measured BP. For the Gamma G7 sphygmomanometer, the observer–device disagreement was − 0.4 ± 3.3 mmHg for SBP and − 0.5 ± 2.6 mmHg for DBP (Fig. 1). For the Gamma XXL-LF sphygmomanometer, the observer–device disagreement was − 0.3 ± 3.7 mmHg for SBP and − 1.0 ± 2.6 mmHg for DBP (Fig. 2). A close correlation was, however, found between BP measured with the mercury and the aneroid sphygmomanometers for both the Gamma G7 (SBP, $r = 0.97$ and DBP, $r = 0.95$; $P < 0.001$ for both) and the Gamma XXL-LF (SBP, $r = 0.98$ and DBP, $r = 0.98$; $P < 0.001$ for both) devices.

The predictive value of several clinical variables for the observer–sphygmomanometer discrepancy was tested in univariate and multivariable regression analyses. For SBP, no relationship between the absolute or relative sphygmomanometer–observer BP difference was found with age, sex, SBP, DBP and arm circumference with both sphygmomanometers. For DBP, a borderline relationship was found between the absolute measurement discrepancy and arm circumference at multivariable analysis with the

Gamma G7 sphygmomanometer ($P = 0.057$). No relationship was found between DBP discrepancies and the other clinical variables with both devices.

Discussion

Goal of Health Systems worldwide is to maintain a mercury-free environment in the near future [1,2]. Aneroid sphygmomanometers may be a reliable alterative to mercury sphygmomanometers for doctors who wish to use the auscultatory technique in clinical practice. Few aneroid devices, however, have been validated up to now [3,4]. The results of the present study demonstrate that both Gamma G7 and Gamma XXL-LF aneroid sphygmomanometers provide accurate and reliable BP measurements across a wide spectrum of participants with different clinical characteristics. The performance of the two Heine devices was comparable to that of the Maxi Stabile 3 aneroid device that achieved an A grade for both SBP and DBP according to a modified British Hypertension Society protocol [3]. In comparison with the Accoson Greenlight 300, which was tested with the ESH protocol [5], the Heine devices showed a similar performance for SBP and a slightly better performance for

Fig. 2

Plot of the systolic (upper plot) and diastolic (lower plot) observer–Gamma XXL-LF aneroid sphygmomanometer blood pressure differences. The x-axis represents the mean of the device and observer measurements. The y-axis represents the difference between the device and observer measurements. A positive value indicates that the observer's measurement is greater than the device measurement.

DBP. In the present study, both the absolute and the relative discrepancies between observer and device were totally unrelated to age, sex, and the level of SBP and DBP. A weak association was found between the observer–device discrepancy and arm circumference for DBP, but the relationship did not attain the level of statistical significance. To validate the Heine sphygmomanometers, we used the recently published protocol of the ESH [9]. It classifies the differences between test and control measurements according to whether these lay within 5, 10 or 15 mmHg, or are over 15 mmHg apart. The final grading is based on the number of differences falling into these categories. It can be seen that, in the present study, both devices easily met the ESH standard, as all but two observer–device discrepancies were included within 10 mmHg. We observed a tendency for the Heine devices to slightly underestimate the BP obtained with the mercury sphygmomanometer, but differences for SBP and DBP were all within 1 mmHg, and the standard deviations of the observer–device discrepancies were well within the AAMI requirement of a standard deviation of less than 8 mmHg [10]. A possible limitation of our study is that the Heine devices were tested in

participants with arm circumference < 37 cm, and thus our results may not apply to participants with larger arms.

We conclude that the Heine Gamma G7 (with extension to G5) and Gamma XXL-LF aneroid sphygmomanometers are accurate devices that may replace the traditional mercury sphygmomanmeter in clinical practice. It should, however, be borne in mind that our validation study was performed in new devices and that some components of aneroid manometers are subject to fatigue [11]. That is why it has been recommended to calibrate aneroid manometers every 6 months [12]. Progress in metal components and manufacturing processes has led to improved performance of these devices throughout the years [13]. According to recent results obtained in a large variety of aneroid sphygmomanometers used at the University of Michigan, for an accuracy standard of ± 3 mmHg the error rate was 4.4% as compared with the 33–46% of previous studies [14]. This led the authors to conclude that accurate aneroid sphygmomanometers can be used as an alternative to mercury manometers provided calibration is performed on a yearly basis. Thus, the user of aneroid devices should be aware that at least yearly maintenance and calibration should be performed also when using validated models.

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Appendix

In this appendix, the basic information of the devices is reported, following the suggestions of the ESH protocol [5].

Device identification: Heine Gamma Xxl-Lf, Heine Optotechnik GMbH & Co. KG, Herrsching am Ammersee, Germany.

The above device is a portable aneroid sphygmomanometer (140$W \times$ 173$H \times$ 72D mm). Its measuring range spreads over 0–300 mmHg for BP. The standard cuff is suitable for circumferences of arm ranging over 22–32 cm. The large adult cuff fits a 33.3–51.0 cm range. Cuffs below 22 cm = infant: 8–13 cm, child: 14–21 cm, special neonate: 7–10 cm.

Dimensions: *W*: 140 mm $\times$ *H*: 173 mm $\times$ *D*: 72 mm, excluding cuff.

Weight: 312 g, excluding cuff and packaging.

List of components: Device including its cuff, inflation tube, Wall/Desk or Wheel stand mounting parts and instruction manual.

Costs: Range from €135 00 (desk type) to €300 00 (IV pole with wheels).

Device identification: Heine Gamma G7 and G5, Heine Optotechnik GmbH & Co. KG, Herrsching am Ammersee, Germany.

These devices from Heine Gamma G series are portable aneroid sphygmomanometers (185$W \times$ 75$H \times$ 38D mm). For both models, measuring range spreads over 0–300 mmHg for BP. Cuffs are identical for both models and are suitable for circumferences of arm ranging over 22–32 cm. Large adult cuffs are available that fit a 33.3–51.0 cm range. Cuffs below 22 cm = infant: 8–13 cm, child: 14–21 cm, special neonate: 7–10 cm.

Costs: Range from €80 00 to €110 00.

Dimensions: *W*: 185 mm $\times$ *H*: 75 mm $\times$ *D*: 38 mm; excluding cuff. Weight = 134 g G5, 180 g G7, excluding cuff and packaging.

List of components: Device including its cuff, carrying etui and instruction manual.

G7 and G5 models differ for weight and frame materials, color and shape. The manometer, the mounting of the manometer, the airflow system, the control valve, the insufflation bulb and all the technical elements that can influence the measurement and accuracy of the blood pressure unit are identical.

All devices

Compliance with standard: All devices conform to the European Medical Device Directive 93/42 EEC.

They meet the Essential Requirements of the Medical Device Directive 93/42 EC, Annex 1 and bear therefore the CE 0123–mark.

Validation studies: European norm: EN1060, Part 1 & 2.

Instructions for use, care and maintenance: These are reported in detail in the instruction manual.

Power supply: Manual device.

Service facilities: Heine Optotechnik GmbH & Co. KG, Herrsching am Ammersee, Germany.

Method of BP measurement: Indirect/aneroid; based on 'Korotkoff' sounds.

Factors affecting accuracy: Human error.

Operator training requirements: The products must be used by trained personnel. The instrumentation does not require specific expertise because it is very easy to operate.