

# Comparison of Wrist Watch Type Device (GT-103) and Oscillometric Device for Blood Pressure Measurement Following the AAMI/ESH/ISO Standards

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**Background:** Cuffless devices have been studied and developed in the past and in recent years products that employ photoplethysmography became available in the market. However, the vast majority of available product's accuracy have not yet been studied.

**Objective:** The main objective of this study was to compare a wristwatch device GT 103 to an oscillometric blood pressure device Omron HEM 7120 using the standards set by Association for the Advancement of Medical Instrumentation (AAMI) / The European Society of Hypertension (ESH) Working Group on Blood Pressure / International Organization for Standardization (ISO).

**Methods:** This is a cross sectional study involving blood pressure measurements of 85 individuals using the test device (GT 103) and the reference device (Omron HEM 7120). Demographic characteristics such as age, arm circumference, diagnosis of hypertension, and treatment status were also reported. Sequential blood pressure measurements followed the prescribed steps of AAMI/ESH/ISO. Paired measurements were statistically treated using the Paired T test. Mean differences of the paired measurements are reported in mean $\pm$ SD, and proportions of blood pressure differences at  $\pm 5$ mmHg,  $\pm 10$ mmHg, and  $\pm 15$ mmHg are also reported.

**Results:** The mean SBP difference of GT 103 and Omron 7120 was  $1.5\pm 20.5$ mmHg which is not significant ( $p=0.25$ ) and mean DBP difference of  $3\pm 12.6$  which is significant ( $p=0.00017$ ). The result is in accordance with the criterion 1 of ANSI/AAMI/ISO 81060-2:2013 standard requirements ( $\leq 5\pm 8$  mmHg), but did not fulfil the criterion 2 which requires an SD of less than or equal to 6.47 for SBP and less than or equal to 6.90 mmHg for DBP. The proportion of paired blood pressure readings within  $\pm 5$ mmHg,  $\pm 10$ mmHg, and  $\pm 15$ mmHg were 19.61%, 36.08%, 45.1% for SBP and 30.98%, 56.07%, 69.8% for DBP. This shows that SBP and DBP measurements did not meet the requirement of AAMI/ESH/ISO.

**Conclusions and Recommendations:** This study showed that GT 103 did not fulfill the requirements for acceptable device accuracy. The use of the device for blood pressure measurement is still not recommended by the researcher. Future studies of other similar devices can be done to ensure accuracy of blood pressure measurement.

**Key words:** Hypertension, cuffless, photoplethysmography

## INTRODUCTION

Current blood pressure measuring devices are cumbersome to operate and produce anxiety during cuff inflation. This results in increased blood pressure in many patients, even among the normotensive ones. To address this, researchers tried to develop technologies in cuffless blood pressure measuring devices. Accurate measurement of blood pressure is important to diagnose and manage hypertension. Due to this, validation protocols were made in the past to ensure devices in the market have acceptable accuracy. Criteria for acceptance are in the guidelines of Association for the Advancement of Medical Instrumentation/European

Society of Hypertension/International Organization for Standardization (AAMI/ESH/ISO) Collaboration Statement to guide researchers and to standardized testing. Through this, we had several devices in the market that are validated and are listed in the 2020 ISH Global hypertension guidelines.<sup>1</sup> However, available devices are still cuff-based. This is partly because the guidelines available are still for testing cuff-based devices. But in the past, researchers used the current criteria to test the accuracy of cuffless devices and yielded promising results. This study aims to compare a wristwatch type device (GT-103) with a validated oscillometric blood pressure measuring device following the protocol of AAMI/ESH/ISO. AAMI and ISO are 2 independent organizations

that develop and standardize devices for medical use while ESH is a medical organization with particular interest in hypertension. These 3 independent bodies collaborated to develop protocols for validating blood pressure measuring instruments that were used by past researches similar to this study. They recognized that the accurate measurement of blood pressure is an important criterion for the reliable diagnosis and efficient management of hypertension. Therefore, the evaluation and review of the accuracy of BP measuring devices is of great significance. Instead of the varying study designs from multiple organizations and studies, they organized with the same goal to establish a single validation protocol that has universal acceptance. The summary from AAMI/ESH/ISO presents nine key aspects of the study design. These are 1) device efficacy measure, 2) sample size, 3) cuff size, 4) general population and special population, 5) method of BP data collection, 6) reference BP measurement and validation procedure, 7) validation criteria and reporting, 8) validation of other BP monitors, 9) quality and reliability of validation study reports. The criteria used for this study is derived from the consensus described by AAMI/ASH/ISO.

Hypertension is prevalent both locally and internationally. It is still one of the leading causes of death globally according to ISH Global hypertension Practice Guidelines, with 10.4 million deaths per year.<sup>1</sup> In a study of Sison J, et al. (2007) called Presyon 3, it is estimated that hypertension has a prevalence of 28%.<sup>2</sup> This shows an increasing trend from its last estimate from Presyon 2 in 2007 with an estimated prevalence of 21%.<sup>3</sup> The prevalence rate keeps increasing with a 47% prevalence rate when a retrospective study was done among patients consulting at mobile clinics after the typhoon Haiyan.<sup>4</sup> Diagnosis of hypertension is still largely done by non-invasive means like an office blood pressure measurement using a cuff-based device or an ambulatory blood pressure that still utilizes an inflatable cuff. An ambulatory blood pressure is often needed to confirm diagnosis of hypertension and to detect white coat and masked hypertension. The direct effects of cuff inflation in blood pressure are also noted in several studies.<sup>5,6,7</sup> They found that there is a transient rise of <10mmHg in SBP. The exact mechanisms are still unknown. Another study by Skov-Madsen, et al. in 2008 showed that anxiety during cuff inflation may be a minor importance only, but the conclusions were based on heart rate changes but not in blood pressure.<sup>8</sup>

Advances in technology made cuffless blood pressure estimation possible. Photoplethysmography is one of these advances. This kind of technology involves light sensors to detect volume changes in the blood vessels. Through complex mathematical algorithms, devices that use this technology can estimate the blood pressure. Earlier versions of the use of photoplethysmography with cuffs placed at the finger was studied by Buclin, et al. (1999). Similar device was studied by Nitzan, et al. (2009) compared oscillometric sphygmomanometer with photoplethysmography and found out that their results are comparable and even better than the set standard by Association for the Advancement of Medical Instrumentation® (AAMI) at that time. He followed on this study in 2013 with a similar one by comparing photoplethysmography and Korotkoff sounds. They found out that the two techniques have comparable accuracy.<sup>9,10</sup> As technology advances, we start to see cuffless blood pressure monitoring technology. In a study published in 2014 by Ting Ma, a comparison between oscillometric

blood pressure and photoplethysmography combined with ECG showed promising results.<sup>11</sup> Databases of photoplethysmography readings provided successive research in the development of algorithms to estimate blood pressure using photoplethysmography alone. In the study of Xiaman and Mingshan (2016), their photoplethysmography BP estimations provided accurate results.<sup>12</sup> Further usage of databases of photoplethysmography readings allowed successive researchers to apply machine learning. Inclusion of information like age, sex, weight was included in the study of Kengo, et al. (2017). Inclusion of these features made their estimations better.<sup>13</sup> It is important to know that there are several algorithms developed for cuffless blood pressure measurement. These algorithms produce different degrees of accuracy which was shown by Khalid, et al. (2018) when they compared different algorithms. Newer studies show similar results when comparing two different software.<sup>14</sup> This highlights the importance of validation of new devices especially when they are using different software or algorithms. Recent studies use machine learning through a database of PPG databases which all showed promising results. However, they also utilized ECG recordings in their study to get the BP estimation.<sup>15,16,17</sup>

A lot of wearable devices have been developed in recent years. One of the technologies being developed is photoplethysmography that can be fitted in a wrist watch. One advantage of such devices is its convenience. Discomfort from inflating a cuff might also be eliminated because such devices do not use a cuff. Islam et al noted in their study positive reviews on the experience of users along with comparability of a cuffless device to a cuff-based blood pressure monitor.<sup>18</sup> There are new devices listed in the market every day that measure blood pressure by photoplethysmography. Some devices claim to be accurate and come with a heavy price tag. A lot of devices can be seen through online stores but with undisclosed accuracy. Not every device has been studied or released a validation study of their product. Here, we studied a device GT 103 if it can perform within the limits set by AAMI/ESH/ISO. Thus, a study like this is needed to evaluate the usability of such devices in the hypertensive population. This was reiterated in the study of Lee, et al. (2021) that more study is needed to evaluate these devices.<sup>19</sup>

## METHODS

### Study Design

This is a cross-sectional study comparing the blood pressure measurements of a wrist watch device GT 103 with an oscillometric blood pressure device Omron HEM 7120. This study included participants ages 24-72. Hypertensive and normotensive participants are both included with or without anti-hypertensive treatment. Participants were asked to wear the test device and the control device on their left arm while seated comfortably and arm supported.

### Study Setting and Sampling

The study proper was conducted in Healthway Family Clinic Green City, Imus, Cavite from April 12-30, 2021. A total of 85 subjects, as recommended by AAMI/ESH/ISO, were recruited in this study. All participants were Healthway Family Clinic patients and had undergone

physical examination before recruitment. Each participant consented to participate in the research. Inclusion criteria are as follows: Male or Female, at least 12 years of age, and with or without hypertension, treated or untreated. Excluded in this study are: pregnant, diagnosed with ESRD, age of 80 years or older, arm circumference of more than 42cm, and those with atrial fibrillation.

### Control and Test Device

The test device used in the study is GT 103, a smartwatch with several functions which include; blood pressure, heart rate, sleep monitor, pedometer, etc. GT 103 is one of the most common smartwatches available in public. It is very affordable and is convenient to use. The device displays measurements from the wearer on its screen. It is readily available from online stores. The device uses a light sensor located at the back of the device which is directed towards the user's wrist. It can also connect to the user's phone via an application and log heart rate and blood pressure. For the reference blood pressure, the oscillometric blood pressure device used was Omron HEM 7120 listed in the 2020 ISH Global Hypertension Practice Guidelines of validated devices. The oscillometric device was purchased last April 6, 2021 and was calibrated the same day at ACOSERVE Inc. in Pasig City, an authorized service center of OMRON.

### Data Gathering

After physical examination, each participant was asked to sit comfortably for at least 5 minutes before the start of the procedure, his/her back and arm supported with the middle of the upper arm at the heart level, legs uncrossed and feet flat on the floor. Talking and any other interference were prohibited throughout the entire procedure. The principal investigator served as the observer and recorded the measurements obtained. The sequential methods for measuring the BP are listed below with a 60 seconds interval after each measurement.

#### Initial BP measurements

1. Take reference BP measurement (R0)
2. Take test device BP measurement (T0)

#### Validation BP measurements for accuracy evaluation

3. Take first reference BP measurement (R1)
4. Take first test device BP measurement (T1)
5. Take second reference BP measurement (R2)
6. Take second test device BP measurement (T2)
7. Take third reference BP measurement (R3)
8. Take third test device BP measurement (T3)
9. Take fourth reference BP measurement (R4)

### Data Analysis

The primary outcome of the study is the comparison of the blood pressure measurements of the test device and reference device. This was done by getting the average of the first 2 BP measurements of

the control device (R1 and R2) and subtracting it from the first test device measurement (T1), then average of R2 and R3 subtracted from T2, and lastly average of R3 and R4 subtracted from T3. Results are reported in mean and standard deviation. Paired T-test was performed to compare the blood pressure measurements of the test and reference device. Secondary outcomes are the absolute BP differences within 5, 10, and 15mmHg and standard Bland-Altman scatter plots, and the demographics of the subjects that will be reported in mean and SD, and in frequency and percentages. A tolerable error of  $\leq 10$ mmHg with a probability of that error of at least 85% is considered acceptable. R0 and T0 are the initial BP measurements to check if the BP devices are functioning well, hence are not used in the data analysis.

### RESULTS

There were 85 subjects. The mean age is  $50.22 \pm 14.67$  and arm circumference of  $28.7\text{cm} (\pm 2.78)$ . Both are within the inclusion criteria of AAMI/ESH/ISO. The males comprise 36 individuals which is 42.35% of the total participants and females comprise 49 individuals which is 57.65% of the total number of subjects. The male and female composition in this study is within the limits of the general population. This study included both hypertensive and non-hypertensives. There are 44 (51.76%) participants who are hypertensives and 36 (81.82%) of them are receiving treatment, and 8 (18.18%) of the hypertensive participants are not receiving treatment. The remaining 41 (48.24%) participants are normotensive. There are a total of 340 reference blood pressure measurements done in this study. Of these 340 measurements, 9 (2.65%) SBP measurements are  $\geq 160$ mmHg, 65 (19.12%) SBP measurements are  $\geq 140$  to  $< 160$ mmHg, 238 (70%) are SBP  $> 100$  to  $< 140$ mmHg, and 28 (8.23%) are SBP  $\leq 100$ mmHg. Diastolic blood pressure measurements had 10 (2.94%) DBP  $\leq 60$ mmHg, 206 (60.59%) DBP  $> 60$  to  $< 85$ , 94 (27.65%) DBP  $\geq 85$ mmHg to  $< 100$ mmHg, and 30 (8.82%) DBP  $\geq 100$ mmHg. This fell short of what the AAMI/ESH/ISO characterized as the general population. Thus, the results in this study should be used with caution especially in making generalizations about the general population.

The mean SBP values measured by Omron HEM 7120 and GT 103 were  $125.7 \pm 17.6$ mmHg and  $124.2 \pm 9.6$ mmHg respectively. The mean difference of the devices was  $1.5 \pm 20.5$ mmHg which is not significant ( $p=0.25$ ). The mean DBP values were  $80.9 \pm 11.6$ mmHg for Omron HEM 7120 and  $77.9 \pm 5.2$ mmHg for GT 103. The mean difference of the DBP was  $3 \pm 12.6$  which is significant ( $p=0.00017$ ). The results are in accordance with the criterion 1 of ANSI/AAMI/ISO 81060-2:2013 standard requirements ( $\leq 5 \pm 8$  mmHg), but did not fulfill the criterion 2 which requires an SD of less than or equal to 6.47 for SBP and less than or equal to 6.90 mmHg for DBP.

The proportion of paired blood pressure readings within  $\pm 5$ mmHg,  $\pm 10$ mmHg, and  $\pm 15$ mmHg were 19.61%, 36.08%, 45.1% for SBP and 30.98%, 56.07%, 69.8% for DBP.

This shows that SBP and DBP measurements did not meet the requirement of AAMI/ESH/ISO which is tolerable error of  $\leq 10$ mmHg (using an individual's average of 3 BP readings versus a reference BP measurement method) and an estimated probability of that error of at least 85%

**Table 1.** Sample characteristics and reference blood pressure.

Demographics	
Age	50.22 years ± 14.67
Arm circumference (cm)	28.17cm ± 2.78
Sex	
Males	36 (42.35%)
Females	49 (57.65%)
Hypertensive	44 (51.76%)
Receiving treatment	36 (81.82%)
No treatment	8 (18.18%)
Normotensive	41 (48.24%)
Blood pressure	
SBP ≥ 160mmHg	9 (2.65%)
SBP ≥ 140 to < 160mmHg	65 (19.12%)
SBP >100 to <140mmHg	238 (70%)
SBP ≤ 100mmHg	28 (8.23%)
DBP ≥ 100mmHg	30 (8.82%)
DBP ≥ 85mmHg to <100mmHg	94 (27.65%)
DBP >60 to <85	206 (60.59%)
DBP ≤ 60mmHg	10 (2.94%)

**Table 2.** Comparison of oscillometric BP and GT 103.

	Mean difference	SD	p
SBP	1.5	±20.5	0.25
DBP	3	±12.6	0.00017

**Table 3.** Absolute systolic blood pressure differences in specified blood pressure cutoffs.

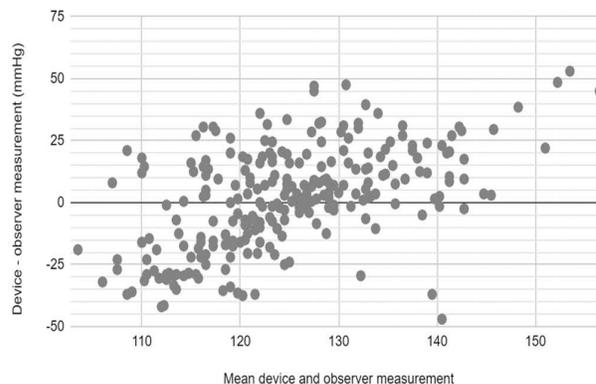
BP difference (SBP)	n (%)
5mmHg	50 (19.61%)
10mmHg	92 (36.08%)
15mmHg	115 (45.1%)

**Table 4.** Absolute diastolic blood pressure differences in specified blood pressure cutoffs.

BP difference (DBP)	n (%)
5mmHg	78 (30.98%)
10mmHg	142 (56.07%)
15mmHg	177 (69.8%)

The Bland-Altman scatter plots show an increasing blood pressure difference for both SBP and DBP when the measurements are on the extreme ends of the graph. Hence, there are more measurements outside the +/- 10mmHg range which is the tolerable error accepted by AAMI/ESH/ISO.

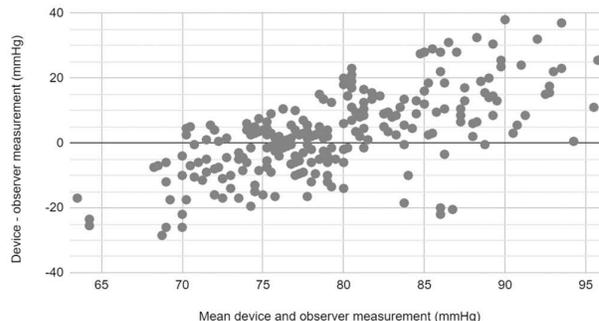
SBP



**Figure 1.** Bland-Altman scatterplot for Systolic Blood Pressure (SBP)

The x axis represents BPs in the systolic range 100 to 160 mmHg and diastolic range 30 to 140 mmHg. The y axis represents errors from -50 to +75 mmHg. Horizontal reference lines are drawn at 5 mmHg intervals from -50 to +75 mmHg. The mean of each device BP and its corresponding observer BP is plotted against their difference with a point. Vertical lines represent BP distribution boundaries.

DBP



**Figure 2.** Bland-Altman scatterplot for Systolic Blood Pressure (DBP)

The x axis represents BPs in the diastolic range 65 to 95 mmHg and diastolic range 30 to 140 mmHg. The y axis represents errors from -40 to +40 mmHg. Horizontal reference lines are drawn at 5 mmHg intervals from -40 to +40 mmHg. The mean of each device BP and its corresponding observer BP is plotted against their difference with a point. Vertical lines represent BP distribution boundaries.

## DISCUSSION

In this study we see that the SBP measurement of GT 103 and Omron HEM 7120 was not significantly different. However, DBP measurements were significantly different from the 2 devices. Only 36.08 % of the paired SBP measurements were within 10mmHg difference and 56.07% of the paired DBP measurements were within 10mmHg difference from the reference. The results suggest that the test device did not meet

the requirement for the device accuracy. This was contrary to past studies done using similar devices which showed acceptable accuracy. Previous study showed that a similar device, InBodyWATCH, showed good accuracy using the set criteria of AAMI/EST/ISO.<sup>20</sup> Acceptable accuracy was also reported using the T2 Mart blood pressure device, but their study design slightly differs from the AAMI/ESH/ISO validation methods.<sup>18</sup> The sample size for both studies utilized less than 85 samples. The study of Islam, et al. in particular, included only 20 participants, but with more blood pressure measurements compared to the validation method of AAMI/ESH/ISO. Another study by Kilian, et al. also showed promising results when they tested Somnotouch-NIBP using different software. However, there are also variations in their study design as well as the functionality of their device like an ECG which is not included in this study. It is also noteworthy to mention that in this study, only 1 observer was used using a calibrated oscillometric device. GT 103 is a relatively cheap device that is affordable even by a low-income patient. Finding a cheap device with acceptable accuracy may have a huge impact on the management of hypertension, patient awareness and lastly patient comfort. However, the result of the study did not meet the criteria of AAMI/ESH/ISO.

This study's strengths are inclusion of participants with diverse ranges of blood pressure, age, being tested in a real-life clinic, and testing a finished product (GT 103). The study followed the AAMI/ESH/ISO guide in validating blood pressure instruments and the reference device was calibrated prior to the study.

There were also limitations in this study. First, the test device's software is undisclosed and contacting the manufacturer cannot be done due to translation problems in the labels. It is worth mentioning that individual devices might use different software that can affect the blood pressure estimation of the device. Earlier studies on these types of devices resulted in different degrees of accuracy when using different software.<sup>15,16,17</sup> Another limitation is the restrictions during the COVID-19 pandemic. The researcher of this study is limited to include patients who visit the clinic for medical consultations only. Thus, the participants included did not fully meet the characteristics of the general population. Third, due to shortage of manpower, this study only had one observer measuring and recording the blood pressure measurements of the participants. Lastly, validation tools for cuffless devices are still not available. The researchers utilized what is currently available for cuff-based devices and followed previous research done to compare a cuffless device.<sup>14</sup>

#### CONCLUSION AND RECOMMENDATIONS

The result of the study showed that GT 103 did not fulfill the requirements for acceptable device accuracy. Thus, the use of the test device for measuring blood pressure is still not recommended by the authors. However, the conclusion in this study is not applicable to other devices and further study is warranted. This study may be used by the manufacturer to supplement the review of the accuracy and reliability of their device.

There are a lot of similar devices like GT 103 in the market. The opportunity to study cuffless blood pressure devices is huge. Similar devices that are cheap and have not been studied are also available and

may have a huge impact on the management of hypertension if proven accurate, especially to the majority of the population who cannot afford expensive devices.

Consequently, the universal standard established by the AAMI/ESH/ISO can also be used in testing other BP devices as it is the goal of this protocol to validate many BP devices for vast options of BP measurement that can accommodate a broad range of patient populations.

#### *Acknowledgments and Conflict of Interest Statement.*

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