



## ANSI/AAMI SP10 Report

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**The UFIT<sup>®</sup> measurement of blood pressure meets all performance requirements of ANSI/AAMI SP10:2002 as an automated sphygmomanometer.**

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## List of Abbreviations

AAMI	Association for the Advancement of Medical Instrumentation
ANSI	American National Standards Institute, Inc.
BP	Blood pressure
DIA	Diastolic blood pressure
K1	First Korotkoff sound
K5	Fifth Korotkoff sound
mmHg	Millimeters of mercury
PRA	Pulse rate average
PRV	Pulse rate variability
SD	Standard deviation
SYS	Systolic blood pressure

## 1 Abstract

Blood pressure (BP) is a vital sign, and its measurement is a standard clinical procedure. Blood pressure is typically represented with two numbers: systolic blood pressure (SYS) and diastolic blood pressure (DIA). UFIT<sup>®</sup> measurement of BP has been validated based on its performance with respect to the auscultatory method. ANSI/AAMI SP10:2002 has set well defined requirements for the performance of an automated sphygmomanometer that uses the auscultatory method as the reference standard. Data collection has been performed in compliance with these requirements, and has met all observer and participant requirements. The current production release of the hemodynamic unit, HU21010 version 1.61, used in conjunction with the UFIT<sup>®</sup> hardware device, exceeds all system accuracy requirements for measurement of BP.

## 2 Background of Blood Pressure Measurement

Blood pressure is the pressure exerted by blood on the walls of blood vessels. Blood and blood vessels are components of the circulatory system, functions of which include the supply of energy (e.g., heat), oxygen, and nutrients to tissues. In order to facilitate this, BP exists in all blood vessels, from major arteries and veins to capillaries, and varies throughout the body.

During a ventricular systole, the left ventricle contracts to eject oxygenated blood into the aorta for systemic circulation. The maximum arterial pressure is usually achieved during this period and is defined as SYS. During the ventricular diastole, the left ventricle relaxes as the left atrium fills it with oxygenated blood from the pulmonary veins. This period is usually associated with the lowest arterial pressure and is defined as DIA. Thus, the SYS and DIA define the maximum and minimum, respectively, of an arterial blood pressure pulse. This pulse (Figure 2.1) travels as a pressure wave through the arterial system.

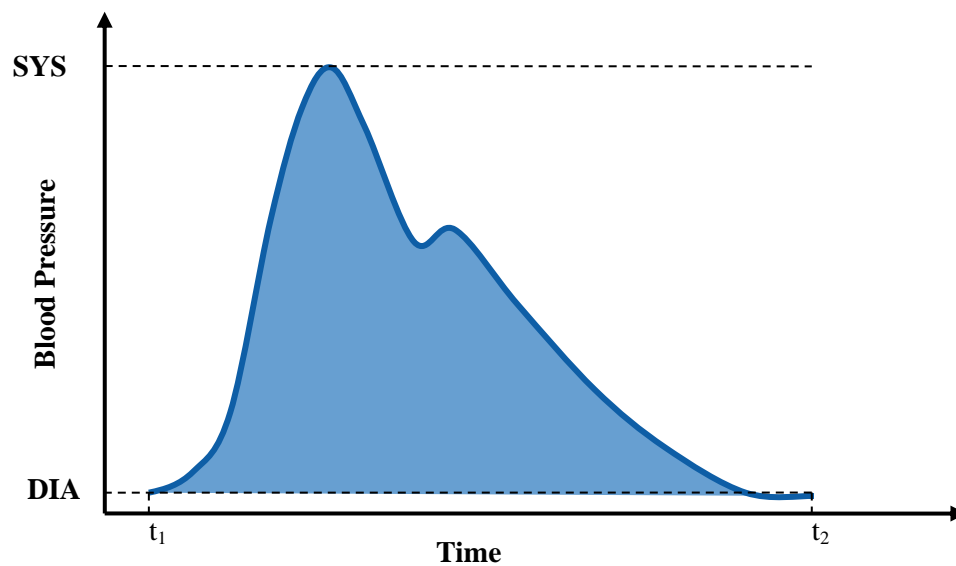


Figure 2.1: Example of arterial blood pressure pulse.

Blood pressure can be measured directly from within the artery; however, this invasive technique carries physical risks, and its use is limited to special circumstances. More commonly, BP is measured indirectly and non-invasively. In contrast to direct BP measurement, indirect techniques, such as the auscultatory method, do not measure BP for each heartbeat; rather, they make a single measurement of BP that spans the duration of the reading. These techniques are sensitive to various factors, including the cuff size, cuff placement, body position, and the height of the measurement site with respect to the heart. It is extremely important to adhere to the instructions pertaining to proper BP measurement in order to ensure the most accurate results.

The auscultatory method is considered the standard for non-invasive BP measurement. In this method, a cuff is inflated around the upper arm to occlude the brachial artery. As the cuff deflates, turbulent blood flow creates sounds, known as Korotkoff sounds, which can be heard using a stethoscope placed next to the cuff. The first Korotkoff sound (K1) corresponds to the first sound heard, and occurs when the cuff pressure, which is determined in units of millimeters of mercury (mmHg) by a manometer connected to

the cuff, is approximately equal to SYS. The fifth Korotkoff sound (K5) corresponds to when the sounds disappear, and occurs when the cuff pressure is approximately equal to DIA. The auscultatory method is limited to the measurement of SYS and DIA, and is prone to measurement errors, such as the observer's hearing acuity and interpretation of sounds, and the external noise level.

Automatic BP measurement devices typically use variations of the oscillometric method. This method was first introduced by Marey in 1876. Marey's experiment was to place the forearm and hand in a transparent, sealed, fluid-filled chamber to which a counter-pressure was applied. He observed that the pressure recordings exhibited a specific oscillation pattern as the counter-pressure was reduced.

The principle of the oscillometric method is that as the cuff deflates from a pressure above SYS to a pressure below DIA, the changes in characteristics of the arterial walls due to the counter-pressure form an oscillatory envelope (pulse amplitude profile), rising first to a maximum as the counter-pressure (which is applied by the cuff) falls, and returning to a steady state as the counter-pressure decreases further (Figure 2.2). Measurement of SYS and DIA using the oscillometric method is usually performed using proprietary algorithms that empirically correlate to the auscultatory method. Automatic BP measurement devices, such as the UFIT<sup>®</sup>, gain acceptance by complying with standards that dictate BP measurement accuracy with respect to the auscultatory method, such as ANSI/AAMI SP10 [1].

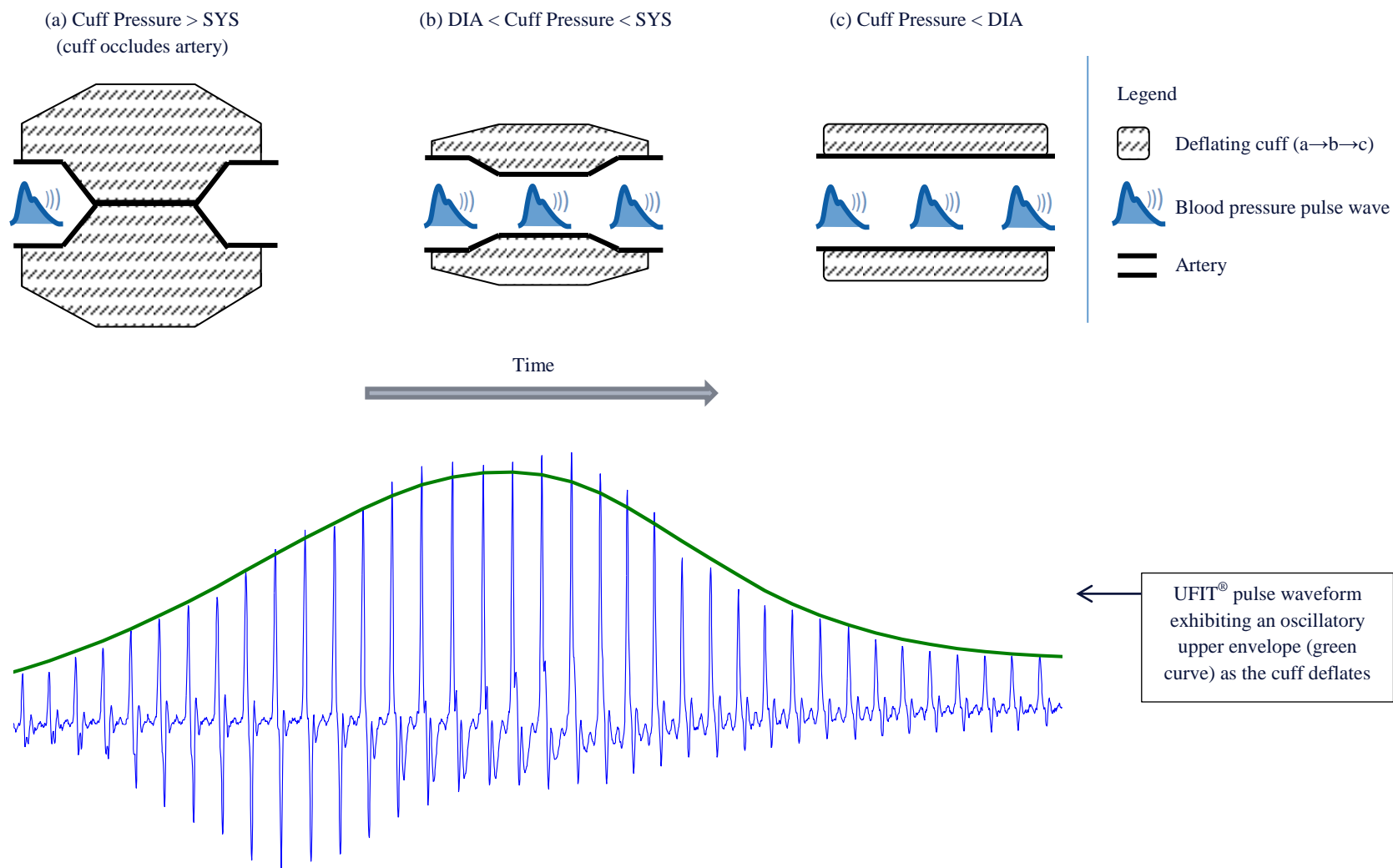


Figure 2.2: The principle of the oscillometric method.

### 3 Scope

This report is valid with reference to the current production release of the hemodynamic unit: HU21010 version 1.61. Data collection and system performance are carried out and assessed, respectively, in accordance with ANSI/AAMI SP10:2002. Refer to [1] for further information.

## 4 Data Collection

Data collection was performed in order to collect reference values for SYS and DIA. The reference standard used was the auscultatory method. With regards to Korotkoff sounds, K1 was used to indicate the reference SYS, and K5 was used to indicate the reference DIA. Data collection was performed simultaneously by two observers that have been trained in the auscultatory method. The observers were also trained in the proper use of the test device (UFIT<sup>®</sup>). The observers were blind to each other's measurements as well as to the test measurements.

Participants were asked to relax for 10-15 minutes prior to data collection in order to reduce temporal variations in hemodynamics during the session. Following this period, a minimum of 3 reference and 3 test measurements were taken alternately, with 1 minute rest periods between measurements. Participants whose UFIT<sup>®</sup> readings exhibited significant movement artifacts or high pulse rate variability (PRV) were excluded from this study.

In total, 87 participants were included in the study, with 354 readings/observations. Each participant contributed a minimum of 3 observations.

### 4.1 Participant Demographics

This section reports participant demographics, including age, gender, wrist circumference, and pulse rate. Reference SYS and DIA distributions and reported Korotkoff disturbances, as measured by the observers, are also reported.

#### Age

All participants were 12 years of age or older at the time of data collection.

#### Gender

Table 4.1 presents the number of participants categorized by gender.

Gender	Count
Male	52 of 87 (59.8 %)
Female	35 of 87 (40.2 %)

Table 4.1: Participant gender.

#### Wrist Circumference

The test device is designed for use with a single size wrist cuff. Table 4.2 presents the number of participants categorized by wrist circumference. Table 4.3 presents the descriptive statistics of the wrist circumference. Figure 4.4 presents the distribution of the wrist circumference. Note that in this figure, bin  $i$  covers the range from bin  $i$  to bin  $i+1$ .

Wrist Circumference [cm]	Count
$13.5 \leq \text{Wrist Circumference} < 18.25$ <sup>1</sup>	52 of 87 (59.8 %)
$18.25 \leq \text{Wrist Circumference} \leq 23$ <sup>1</sup>	35 of 87 (40.2 %)

<sup>1</sup> SP10 Requirement: Greater than or equal to 40 %.

Table 4.2: Participant wrist circumference.

Statistic	Wrist Circumference [cm]
Mean	17.6
Standard Deviation	2.2
Median	17.0
Interquartile Range	3.0
Minimum	13.5
Maximum	23.0
Range	9.5

Table 4.3: Descriptive statistics of participant wrist circumference.

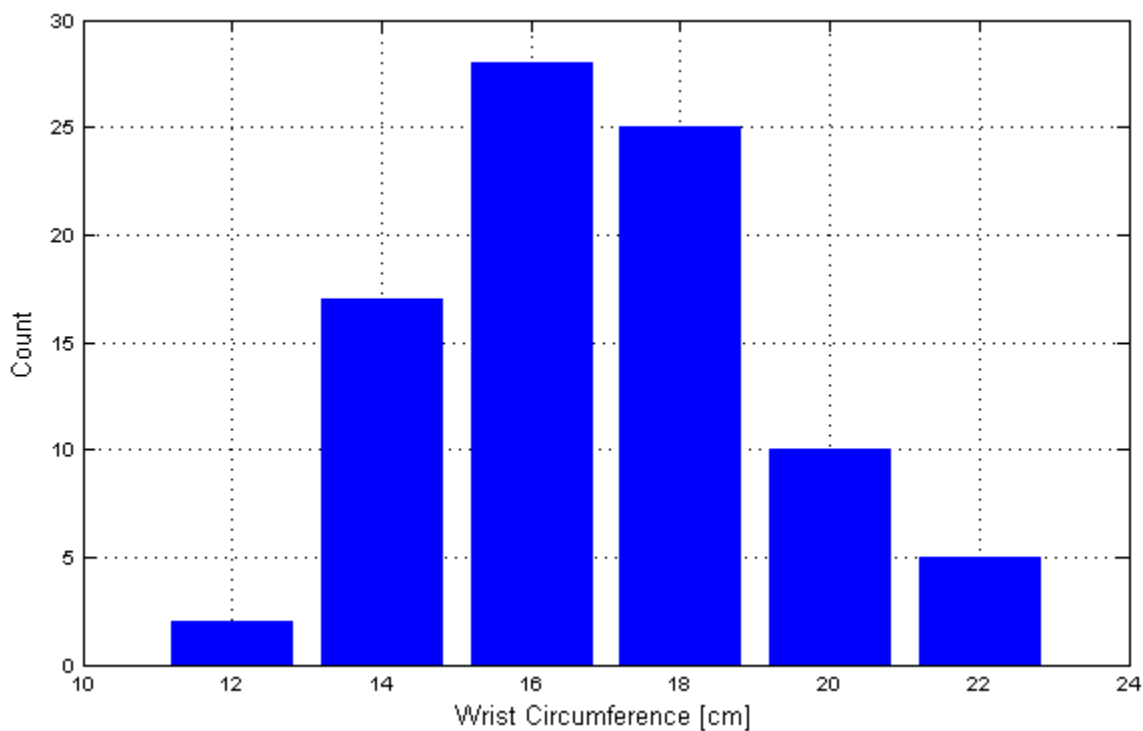


Figure 4.4: Distribution of participant wrist circumference.

## Pulse Rate

Pulse rate was measured based on the UFIT<sup>®</sup> readings, which provided the pulse waveforms. Table 4.5 presents the descriptive statistics of the pulse rate average (PRA) and PRV. Figures 4.6 and 4.7 present the distribution of the PRA and PRV, respectively. Note that in these figures, bin  $i$  covers the range from bin  $i$  to bin  $i+1$ .

Statistic	PRA [/min]	PRV [%]
Mean	74.5	3.9
Standard Deviation	13.0	2.1
Median	73.0	4.0
Interquartile Range	18.0	3.0
Minimum	48.0	1.0
Maximum	117.0	13.0
Range	69.0	12.0

Table 4.5: Descriptive statistics of observed PRA and PRV.

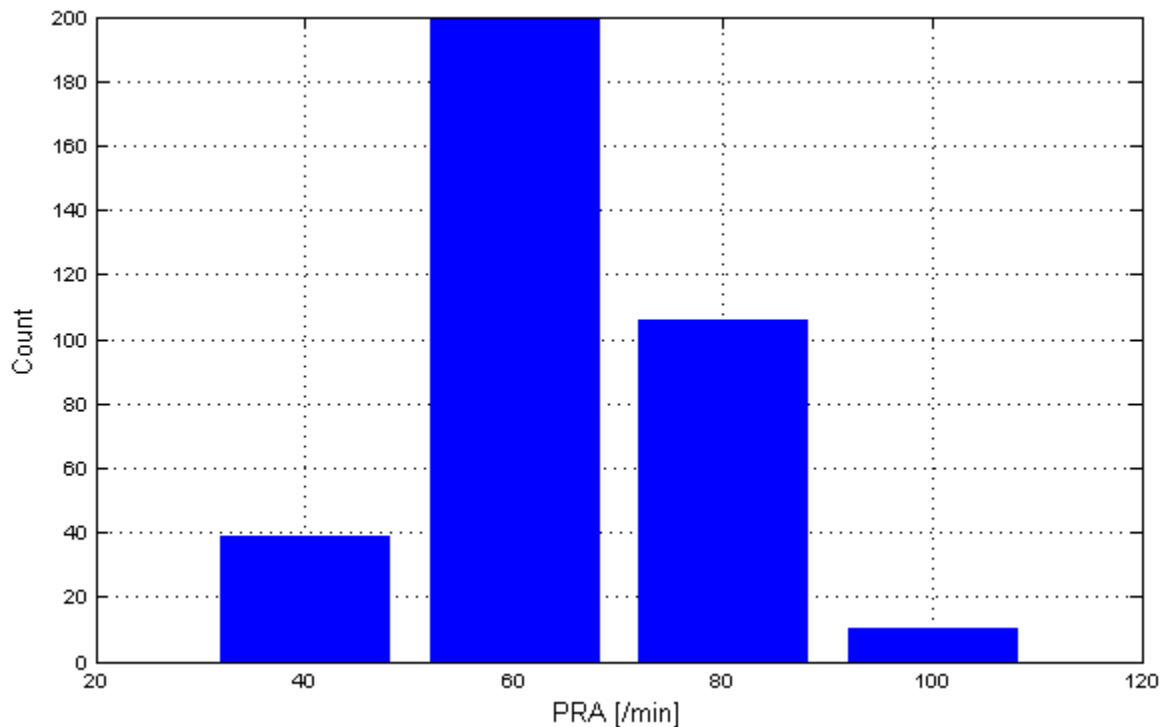


Figure 4.6: Distribution of observed PRA.

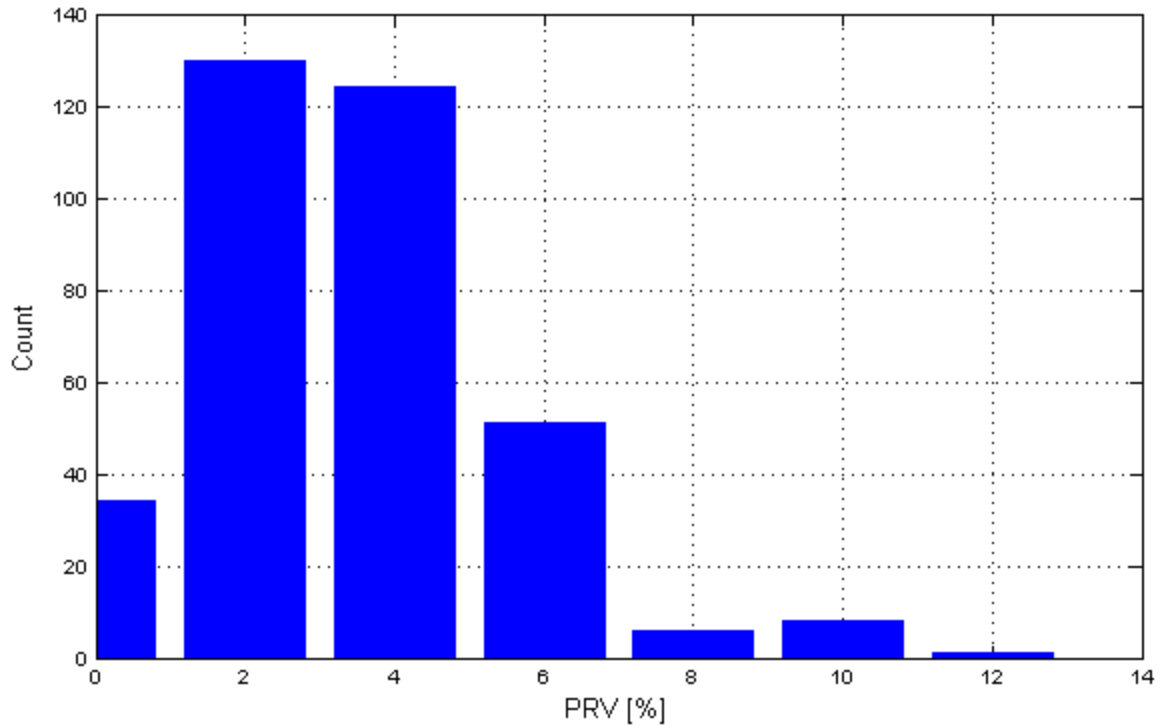


Figure 4.7: Distribution of observed PRV.

## Systolic and Diastolic

Table 4.8 presents the number of observations categorized by the reference SYS and DIA. These are calculated by the average of each simultaneous pair of measurements by the observers. Table 4.9 presents the descriptive statistics. Figures 4.10 and 4.11 present the distribution of the reference SYS and DIA, respectively. Note that in these figures, bin  $i$  covers the range from bin  $i$  to bin  $i+1$ .

BP Interval [mmHg]	Count
Reference SYS < 100 <sup>1</sup>	70 of 354 (19.8 %)
Reference SYS > 160 <sup>1</sup>	48 of 354 (13.6 %)
Reference DIA < 60 <sup>1</sup>	68 of 354 (19.2 %)
Reference DIA > 100 <sup>1</sup>	36 of 354 (10.2 %)

<sup>1</sup> SP10 Requirement: Greater than or equal to 10 %.

Table 4.8: Reference SYS and DIA.

Statistic	Reference SYS [mmHg]	Reference DIA [mmHg]
Mean	120.7	73.4
Standard Deviation	26.1	14.9
Median	111.5	70.0
Interquartile Range	27.0	17.0
Minimum	79.0	47.0
Maximum	212.0	120.0
Range	133.0	73.0

Table 4.9: Descriptive statistics of reference SYS and DIA.

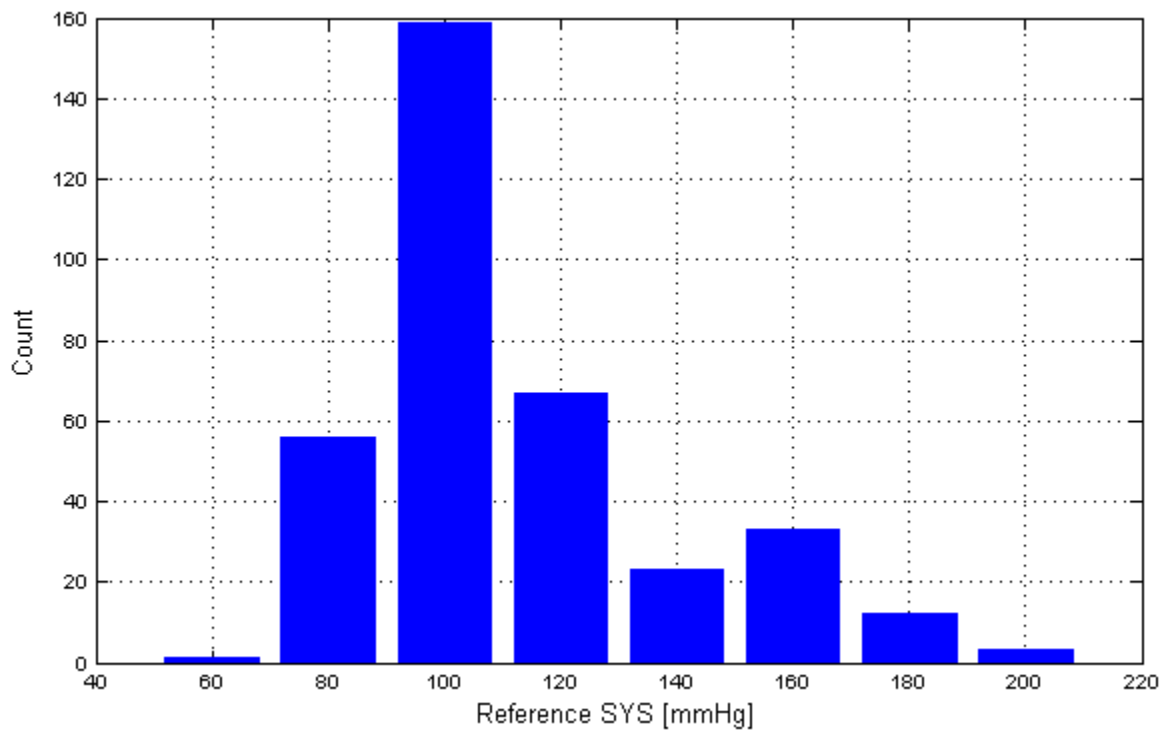


Figure 4.10: Distribution of reference SYS.

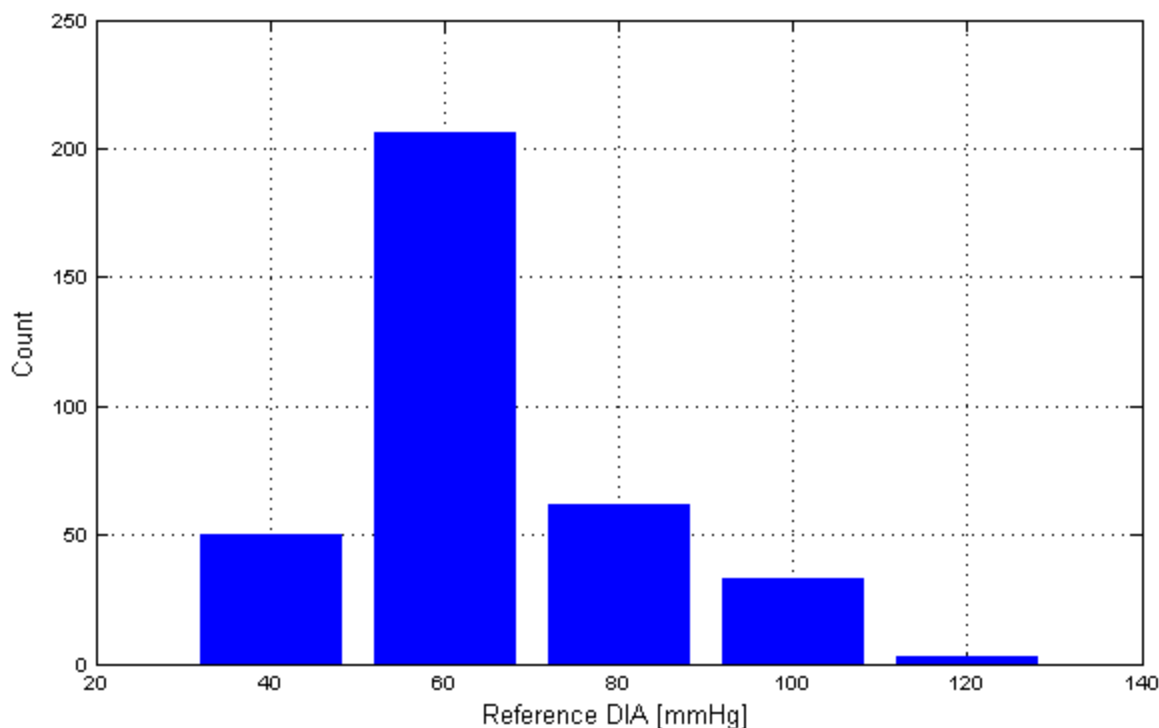


Figure 4.11: Distribution of reference DIA.

## Korotkoff Disturbances

Observers were asked to note instances in which certain factors that may affect the accuracy of the auscultatory method were present. These included the existence of an auscultatory (Korotkoff) gap, the disappearance of K5, and an arrhythmic heart rate. All observations included in the study did not present any of these factors, with the exception of a single case that presented an auscultatory gap. In this single instance, however, both observers had noted the correct K1 and K5, and the reference SYS and DIA met the requirements of the inter-observer differences.

## 4.2 Inter-Observer Differences

In order to reduce test device errors that may be due to observer disagreements, observations in which the inter-observer differences were significant were not included in the study. Table 4.12 displays a summary of the differences between observers' recordings of SYS and DIA.

<b>Observer 1 – Observer 2</b>	<b>SYS</b>	<b>DIA</b>
<b>Number of Observations</b>	354	354
<b>Range<sup>1</sup> [mmHg]</b>	79 – 212	47 – 120
<b>Difference within <math>\pm 10</math> mmHg<sup>2</sup></b>	354 of 354 (100 %)	354 of 354 (100 %)
<b>Difference within <math>\pm 5</math> mmHg<sup>3</sup></b>	352 of 354 (99.4 %)	347 of 354 (98.0 %)
<b>Difference greater than <math>\pm 5</math> mmHg</b>	2 of 354 (0.6 %)	7 of 354 (2.0 %)
<b>Difference greater than <math>\pm 10</math> mmHg</b>	0 of 354 (0 %)	0 of 354 (0 %)
<b>Mean [mmHg]</b>	0.1	-0.1
<b>SD [mmHg]</b>	1.9	2.0
<sup>1</sup> Corresponding to the range of average observer 1 and 2 SYS and DIA values.		
<sup>2</sup> SP10 Requirement: Equal to 100 %.		
<sup>3</sup> SP10 Requirement: Greater than or equal to 90 %.		

Table 4.12: Summary of differences between observers' recordings of SYS and DIA.

## 5 System Performance

The performance of the system within the scope of this report (refer to Chapter 3) was evaluated in terms of the accuracy. Accuracy is determined by the agreement between the test device measurement and that of the auscultatory reference. Test device measurements are provided by the UFIT<sup>®</sup>, and reference measurements are provided by the observers.

### 5.1 Accuracy

ANSI/AAMI SP10 requires that, when the auscultatory method is used as the reference standard, accuracy data be evaluated by two methods. This section presents the results of these analyses.

#### Method 1 Accuracy: Individual Paired Measurements

This method of evaluation of accuracy is based on the differences between each individual test measurement and the average of each simultaneous pair of recordings by the observers. For example, for a single *observation*, if the test SYS = 120 mmHg, observer 1 SYS = 123 mmHg, and observer 2 SYS = 125 mmHg, then the error is given by  $(123+125)/2 - 120 = 4$  mmHg. In this method, the number of error calculations equals the number of observations.

The results of method 1 accuracy are provided in Table 5.1.

**The test device has passed all method 1 accuracy requirements of ANSI/AAMI SP10:2002.**

Individual Paired Reference <sup>1</sup> – Test	SYS	DIA
Number of Participants <sup>2</sup>	87	87
Number of Observations <sup>3</sup>	354	354
Range [mmHg] <sup>4</sup>	86 – 216	52 – 118
Mean [mmHg] <sup>5</sup>	0.0	0.1
SD [mmHg] <sup>6</sup>	7.3	6.0
Difference within ± 5 mmHg	198 of 354 (55.9 %)	226 of 354 (63.8 %)
Difference within ± 10 mmHg	304 of 354 (85.9 %)	329 of 354 (92.9 %)
Difference within ± 15 mmHg	343 of 354 (96.9 %)	349 of 354 (98.6 %)
Difference greater than ± 5 mmHg	156 of 354 (44.1 %)	128 of 354 (36.2 %)
Difference greater than ± 10 mmHg	50 of 354 (14.1 %)	25 of 354 (7.1 %)
Difference greater than ± 15 mmHg	11 of 354 (3.1 %)	5 of 354 (1.4 %)

<sup>1</sup> Reference is given by the average of each simultaneous pair of recordings by the observers.  
<sup>2</sup> SP10 Requirement: Greater than or equal to 85 participants.  
<sup>3</sup> SP10 Requirement: Greater than or equal to 255 observations.  
<sup>4</sup> Corresponding to the range of average reference and test SYS and DIA values.  
<sup>5</sup> SP10 Requirement: Less than or equal to ± 5 mmHg.  
<sup>6</sup> SP10 Requirement: Less than or equal to 8 mmHg.

Table 5.1: Method 1 Accuracy: Summary of differences between individual paired measurements.

## Method 2 Accuracy: Averaged Paired Measurements

This method of evaluation of accuracy is based on the differences between each participant's averaged test and reference measurements. For example, for a single *participant*, if the average of that participant's three test SYS = 120 mmHg, and the average of the three averages of observer 1 and observer 2 SYS = 124 mmHg, then the error is given by  $124 - 120 = 4$  mmHg. In this method, the number of error calculations equals the number of participants.

The results of method 2 accuracy are provided in Table 5.2.

**The test device has passed all method 2 accuracy requirements of ANSI/AAMI SP10:2002.**

Averaged Paired Reference <sup>1</sup> – Test <sup>2</sup>	SYS	DIA
Number of Participants <sup>3</sup>	87	87
Number of Observations <sup>4</sup>	261	261
Number of Paired Observations Per Participant <sup>5</sup>	3	3
Mean [mmHg] <sup>6</sup>	0.3	0.2
SD [mmHg] <sup>7</sup>	6.90	5.20

<sup>1</sup> Reference is given by the per participant average of the average of each simultaneous pair of recordings by the observers.  
<sup>2</sup> Test is given by the per participant average of the test measurements.  
<sup>3</sup> SP10 Requirement: Greater than or equal to 85 participants.  
<sup>4</sup> SP10 Requirement: Greater than or equal to 255 observations.  
<sup>5</sup> SP10 Requirement: Exactly 3 paired observations contributed per participant.  
<sup>6</sup> SP10 Requirement: Less than or equal to  $\pm 5$  mmHg.  
<sup>7</sup> SP10 Requirement: For mean in the range of  $\pm 0.5$  mmHg, SD must be less than or equal to 6.93 mmHg.

Table 5.2: Method 2 Accuracy: Summary of differences between averaged paired measurements.

## 6 Conclusion

ANSI/AAMI SP10:2002 has set well defined requirements for the performance of an automated sphygmomanometer that uses the auscultatory method as the reference standard. Data collection has been performed in compliance with these requirements, and has met all observer and participant requirements. The current production release of the hemodynamic unit, HU21010 version 1.61, used in conjunction with the UFIT<sup>®</sup> hardware device, exceeds all system accuracy requirements.

## 7 References

- [1] *Manual, electronic, or automated sphygmomanometers*, ANSI/AAMI SP10, 2002.