WITHINGS

THE SCIENCE BEHIND

BPM Pro 2

Where insight meets precision

FDA Cleared

Why is it important to measure blood pressure?

Hypertension - Key Facts

- Hypertension — or high blood pressure — is a serious medical condition that significantly increases the risk of heart, brain, kidney and other diseases[1].
- The World Health Organization (WHO) reported an estimated 1.28 billion people worldwide with hypertension[1] and the American Heart Association reported 119.9 million hypertensive adults in the US[2].
- Globally, 1 in 4 men and 1 in 5 women have hypertension[1] (1 in 3 for both men and women in the US).
- 77.5% of people suffering from hypertension have uncontrolled hypertension[2].
- Hypertension is a major cause of premature death worldwide[1]. It's the primary or contributing cause of 685,875 deaths in the United States (2022)[3].
- One of the global targets of the WHO is to reduce the prevalence of hypertension by 33% by 2030 (baseline 2010)[1].

What is hypertension?

Blood Pressure (BP) is the force exerted by circulating blood against the walls of the body's arteries, the major blood vessels in the body. Hypertension is when blood pressure is too high.

Blood pressure is written as two numbers. The first (systolic) number represents the pressure in blood vessels when the heart contracts or beats. The second (diastolic) number represents the pressure in the vessels when the heart rests between beats.

According to the American Heart Association (AHA), hypertension is diagnosed if the systolic blood pressure is ≥ 130 mmHg and/or the diastolic blood pressure is ≥ 80 mmHg when it is measured on two different days at the doctor's office and averaged (see Figure 1). When measured at home, these thresholds are 125 mmHg and 75 mmHg.

For the European Society of Hypertension (ESH), hypertension is defined as a systolic blood pressure of ≥ 140 mmHg and/or a diastolic blood pressure of ≥ 90 mmHg when measured at the doctor's office (see Figure 1). When measured at home, these thresholds are 135 mmHg and 85 mmHg.

Hypertension is one of the most common chronic diseases in the world and is considered a major cardiovascular risk factor. In addition, it causes anomalies and stiffening of the arterial walls due to the permanent mechanical pressure exerted on them. Chronic hypertension increases the risk of stroke, coronary heart disease, heart failure, kidney failure, and cognitive disorders.

ESC/ESH - European guidelines - June 2018				ACC/AHA - American guidelines - November 2017			
Category	**Systolic (mmHg)**		**Diastolic (mmHg)**	**Category**	**Systolic (mmHg)**		**Diastolic (mmHg)**
Optimal	<120	and	<80	Normal	<120	and	<80
Normal	120-129	and	80-84	Elevated BP	120-129	and	<80
High Normal	130-139	or	85-89	Stage 1	130-139	or	80-89
Grade 1	140-159	or	90-99	Stage 2	≥140	or	≥90
Grade 2	160-179	or	100-109	Hypertensive crisis	≥180	or	≥120
Grade 3	≥180	or	≥110				

Figure 1. Hypertension classification chart for office measurements (compiled from references 3 and 4)

What are common symptoms of hypertension?

Hypertension is often called “the silent killer” because many people with hypertension are unaware of the problem, as it can have no warning signs or symptoms. For this reason, it is essential that blood pressure is measured regularly.

Symptoms can include early-morning headaches, nosebleeds, irregular heart rhythms, vision changes, and buzzing in the ears. Severe hypertension can cause fatigue, nausea, vomiting, confusion, anxiety, chest pain, and muscle tremors.

The only way to detect hypertension is to have a health professional measure blood pressure. Having blood pressure measured is quick and painless. Individuals can also measure their own blood pressure using automated devices.

Why is home blood pressure monitoring important?

The European Society of Hypertension[4] and American Heart Association[5] have stressed the major advantages of Home Blood Pressure Monitoring (HBPM) compared to office BP monitoring because:

- HBPM provides more reproducible BP data
- HBPM better predicts cardiovascular morbidity and mortality
- HBPM enables the diagnosis of white-coat effect (BP is elevated in the office but normal in real-life conditions) and masked hypertension (BP is normal in the office but elevated in real-life conditions) (see Figure 2)
- Patient self-monitoring has a beneficial effect on medication adherence and BP control, especially combined with education and counselling
- Smartphone applications may act as a memory aid to take BP measurements and act as a convenient way to store, review, and transmit BP data in a digital diary

Studies have shown that white-coat hypertension can account for up to 30-40% of people with an elevated office BP[4] and masked hypertension can occur in 14-30% of people with a normal office BP[5].

	Office/Clinic/Healthcare Setting	Home/Nonhealthcare/ABPM Setting
Normotensive	No hypertension	No hypertension
Sustained hypertension	Hypertension	Hypertension
Masked hypertension	No hypertension	Hypertension
White coat hypertension	Hypertension	No hypertension

Figure 2. BP pattern based on office and out-of-office measurements (from reference 4). ABPM indicates ambulatory blood pressure monitoring

How does BPM Pro 2 work?

BPM Pro 2 measures blood pressure using the oscillometric method during the inflation phase. This process consists of inflating a cuff around the arm in a controlled manner, until a pressure greater than the Systolic Blood Pressure (SBP) is reached, while recording the pressure oscillations that appear in the cuff due to the pulsating blood flow (see Figure 3). Because the measurement is done during the inflation phase, the pressure can be quickly released after the inflation in order to reduce the time during which the arm is compressed.

Using signal processing algorithms, BPM Pro 2 extracts these oscillations by separating the baseline (DC signal) and pulsatile (AC signal) components to obtain the so-called "oscillometric signal" (see Figure 4). The amplitudes of oscillations are computed and plotted against the baseline pressure, which forms the envelope of the signal (see Figure 5). The maximum amplitude of the envelope, called Mean Arterial Amplitude (MAA) is computed. The corresponding pressure is the Mean Arterial Pressure (MAP). Two thresholds—the Systolic (SA) and Diastolic (DA) Amplitudes—are computed using the measured MAA and systolic and diastolic ratios that have been predetermined on a calibration population during the product development phase. The intersections of these thresholds with the envelope at the high- and low-pressure sides give the Systolic Blood Pressure (SBP) and diastolic Blood Pressure (DBP) by reading on the x-axis.

Meanwhile, the Heart Rate (HR) is determined by analyzing the detected oscillations against time.

The results are then displayed on the device via an integrated LCD colored screen, together with color-coded feedback according to the 2017 American Heart Association classification: green for normal, yellow for elevated, orange for stage 1 hypertension, red for stage 2 hypertension and dark red for hypertensive crisis.

Data is sent to the care provider via cellular connection. If the cellular network is low, Bluetooth and Wi-Fi connectivities are also embedded in the product as fallback solutions.

BPM Pro 2 is compatible with two cuff sizes:

- regular cuff, for arm circumferences ranging from 8¾ to 16½ inches (22 cm to 42 cm)
- XL cuff, for 15¾ to 20½" arm circumferences (40 cm to 52 cm). This cuff also has a conical shape, to fit larger arms.

Using an appropriate cuff size and shape allows for an even compression of the arm artery, and thus a better accuracy of the Blood Pressure result. For large and conical arms, the distributed cuff pressure also helps improve the patient's comfort.

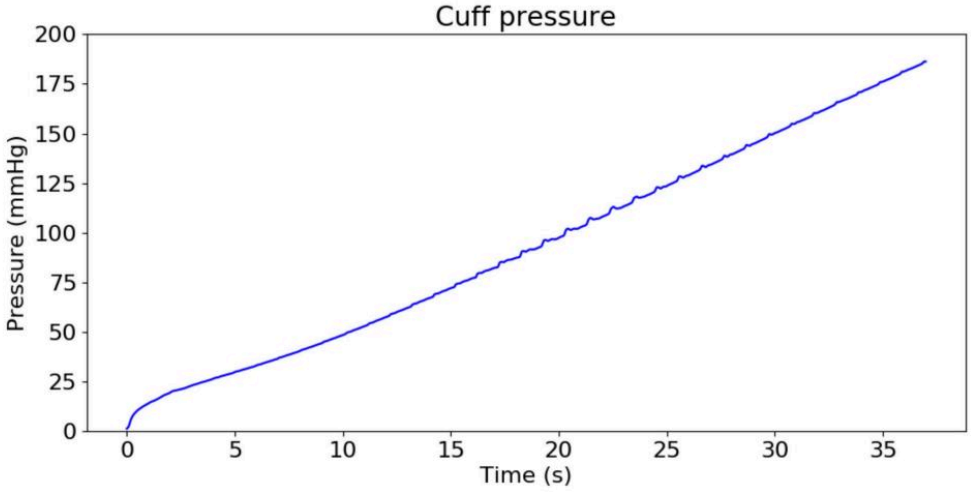

Figure 3. Raw cuff pressure signal

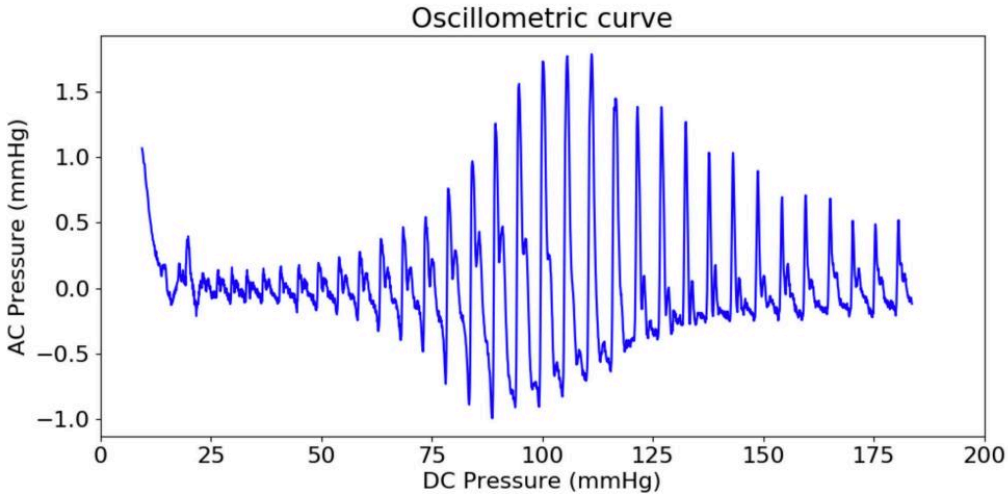

Figure 4. Oscillometric signal (DC pressure: baseline of the raw pressure. AC pressure: baseline-subtracted pressure)

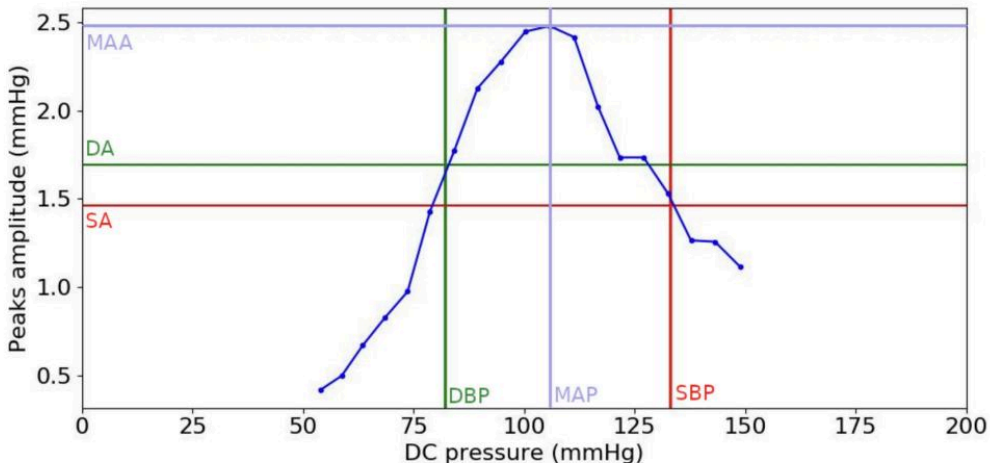

Figure 5. Envelope signal (MAA: Mean Arterial Amplitude, MAP: Mean Arterial Pressure, SA: Systolic Amplitude, SBP: Systolic Blood Pressure, DA: Diastolic Amplitude, DBP: Diastolic Blood Pressure)

Clinical validation

BPM Pro 2 has received FDA clearance for medical devices. It is still pending CE marking.

BPM Pro 2 performance of blood pressure measurement has been validated in a clinical trial on a population sample of 91 subjects, representative of the intended population: adults from the general population with an arm range of 22-42 cm (9 to 17 inches), and adults from the general population with an arm range of 40-52 cm (9 to 17 inches).

For each participant, 3 measurements were taken and compared with 3 measurements acquired for reference (by the auscultatory method), determined by two trained independent observers. The mean error is +0.20 mmHg for systolic blood pressure and +0.76 mmHg for diastolic blood pressure, and the standard deviation of the error is 2.96mmHg and 3.43mmHg, respectively.

These results are within the margin of acceptance defined by the internationally recognized evaluation standard of blood pressure monitors ISO 81060-2:2018+A1:2020, developed by the Association for the Advancement of Medical Instrumentation (AAMI)[5]. This standard defines how blood pressure monitors should be validated through a clinical study.

Subject requirements

The study must consist of a minimum of 85 subjects in order to ensure enough statistical power. At least 3 valid blood pressure determinations were taken for each subject with a minimum of 255 valid paired blood pressure determinations. Each pair was composed of a measurement using the reference sphygmomanometer and a measurement using the device under test (DUT).

The studied population were stratified according to the distributions specified in standard ISO 81060-2:2018+A1:2020, depending on gender, upper limb size and blood pressure values (measured with the reference sphygmomanometer).

Subject, reference, and observer preparation

Prior to taking the measurements, the subject was told to empty their bladder, sit comfortably, and relax for about 5 minutes. The subject was then placed in a comfortable position, with the back supported by the chair and the forearm resting on the table, while the bare mid-arm was at heart level. Their legs had to be uncrossed, their feet flat on the floor. The subject was told not to move, shake, or bend fingers during the measurement, and to avoid talking during and between measurements.

The reference determinations were taken by two observers using a double stethoscope and a reference sphygmomanometer that complied with ISO 81060-1 and with a maximum error of less than ±1 mmHg. The reference cuff was chosen to fit the subject based on arm circumference.

Observers were trained using a double stethoscope and a reference sphygmomanometer and have had sufficient practice in performing blood pressure determinations. Each observer's recording of the observations of the reference sphygmomanometer was not visible to the other observer. The readings of the device under testing were not visible to either of the observers.

The fifth (last) Korotkoff sound (K5) is used to determine the reference diastolic blood pressure. If the Korotkoff sound for determining DSP is not audible, the subject shall be excluded. Any pair of observers' determinations with a difference greater than 4 mmHg was excluded.

Measurement procedures

1. The observers performed a first reference blood pressure measurement using the reference sphygmomanometer and the double stethoscope. Once the measurement was done, the reference sphygmomanometer was removed.
2. After at least 60 seconds, the observers placed the DUT and performed the first DUT blood pressure measurement. The DUT was equipped with the cuff most adapted to the subject based on arm circumference. At the end of the measurement, the DUT was removed.
3. Steps 1 and 2 were repeated until four pairs of measurement were obtained. Between each cycle, a rest period of at least 60 seconds was observed.
4. The observers performed a fifth reference blood pressure measurement using the reference sphygmomanometer and the double stethoscope. Once the measurement was done, the reference sphygmomanometer was removed.

The first measurement pair was excluded from the statistical analysis. In the case where two measurements of the reference systolic blood pressure differed by more than 12 mmHg, or if two measurements of the reference diastolic blood pressure differed by more than 8 mmHg, the patient was excluded.

Statistical analysis

Criterion 1 - differences between observers' reference sphygmomanometer and DUT values, and the standard deviation (SD) of those differences:

For the systolic and diastolic blood pressures, the average value of the differences, xn, between the n individual paired measurements obtained with the DUT and the reference sphygmomanometer for all subjects shall be within or equal to ± 5.0 mmHg, with a standard deviation, sn, that is no greater than 8.0 mmHg.

Criterion 2 - standard deviation of the mean BP differences between the DUT and the reference sphygmomanometer per subject :

For the systolic and diastolic blood pressures for each of the m subjects, the standard deviation, sm, of the averaged paired measurements per subject obtained with the DUT and the reference sphygmomanometer shall be less than or equal to the value presented in Table 1 of EN ISO 81060-2:2018+A1:2020 (below) when calculated according to the formula below.

Maximum permissible standard deviation, s_m, as function of, $\bar{x}$ — mmHg

$\bar{x}_n$	0.0	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9
±0.	6.95	6.95	6.95	6.95	6.93	6.92	6.91	6.90	6.89	6.88
±1.	6.87	6.86	6.84	6.82	6.80	6.78	6.76	6.73	6.71	6.68
±2.	6.65	6.62	6.58	6.55	6.51	6.47	6.43	6.39	6.34	6.30
±3.	6.25	6.20	6.14	6.09	6.03	5.97	5.89	5.83	5.77	5.70
±4.	5.64	5.56	5.49	5.41	5.33	5.25	5.16	5.08	5.01	4.90
±5.	4.79	—	—	—	—	—	—	—	—	—

EXAMPLE For mean of ± 4.2 mmHg, the maximum permissible standard deviation is 5.49 mmHg.

Figure 6. Averaged subject data acceptance (criterion 2) in mmHg.

Results

A total of 91 subjects yielded a total of 272 valid paired measurements (3 per subject) and 6 subjects yielded 12 valid paired measurements (2 per subject). The subjects' distribution requirements (gender, upper limb size, blood pressure value), as defined by ISO 81060-2:2018+A1:2020 standard, were fulfilled.

The mean difference and standard deviation of systolic and diastolic blood pressure based on the analysis of Figure 7 met the requirements of criterion 1 and 2 of clause 5.2.4.1.2 of ISO 81060-2:2018+A1:2020.

BPM Pro 2 Clinical results	**Criterion 1**		**Criterion 2**
	Mean error	**Standard deviation**	**Standard deviation**
Acceptance limits	[-5;5]	≤8	sys ≤ 6.95 / dia ≤ 6.89
Systolic	0.2	2.96	2.46
Diastolic	0.76	3.43	2.83
Pass?	yes	yes	yes

Figure 7. Performance of BPM Pro 2

BPM Pro 2 passes all the criteria of the ANSI/AAMI/ISO 81060-2: 2013, EN ISO 81060-2 :2018+A1:2020 standard for the evaluation of blood pressure monitors.

Glossary

AAMI Association for the Advancement of Medical Instrumentation
ACC American College of Cardiology
AHA American Heart Association
BP Blood Pressure
BPM Blood Pressure Monitor
CE Conformité Européenne
DA Diastolic Amplitude
DBP Diastolic Blood Pressure
DUT Device Under Test
ESC European Society of Cardiology
ESH European Society of Hypertension
FDA Food and Drug Administration
HBPM Home Blood Pressure Monitoring
HR Heart Rate
MAA Mean Arterial Amplitude
MAP Mean Arterial Pressure
SA Systolic Amplitude
SBP Systolic Blood Pressure
WHO World Health Organization

References

1. World Health Organization, Hypertension, available online
2. Benjamin EJ, Virani SS, Callaway CW, et al. Heart Disease and Stroke Statistics-2018 Update: A Report From the American Heart Association. Circulation. 2018;137(12):e67-e492.
3. Williams B, Mancia G, Spiering W, et al. 2018 ESC/ESH Guidelines for the management of arterial hypertension: The Task Force for the management of arterial hypertension of the European Society of Cardiology and the European Society of Hypertension. J Hypertens. 2018;36(10):1953-2041.
4. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Hypertension. 2018;71(6):e13-e115.
5. ANSI/AAMI/ISO 81060-2:2013 Non-invasive sphygmomanometers–Part 2: Clinical investigation of automated measurement type.