

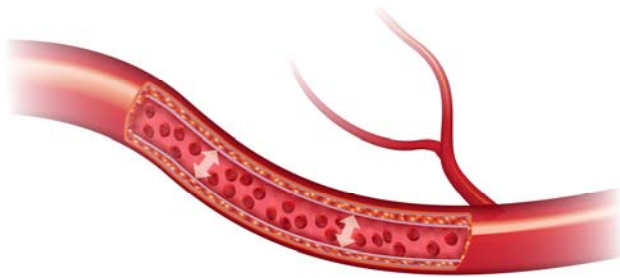
# White Paper

## Non-Invasive Blood Pressure (NIBP) Monitoring and Testing

### Blood pressure overall

#### *How is blood pressure generated?*

When the heart pumps blood into the arteries, the blood flows with a force pushing against the walls of the arteries. Blood pressure is the product of the flow of blood times the resistance in the blood vessels.



**Figure 1.** Generation of Human Blood Pressure

#### *Blood pressure interpretation*

Blood pressure is measured with a blood pressure cuff and recorded as two numbers, such as 120/80 mm Hg (millimeters of mercury). The top, larger number is called the systolic pressure. This is the pressure generated when the heart contracts (pumps). It reflects the pressure of the blood against arterial walls. The bottom, smaller number is called the diastolic pressure. This reflects the pressure in the arteries while the heart is filling and resting between heartbeats.

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Doctors have determined a normal range for both systolic and diastolic blood pressure after examining the blood pressure of many people. The following figures can be used as a guide for adult blood pressure:

1. Normal blood pressure: less than 120/80 mmHg
2. High/Normal: between 120/80 and 140/90 mmHg
3. High: equal to or more than 140/90 mmHg
4. Very high: equal to or more than 180/110

Individuals whose blood pressure is consistently higher than this norm are said to have high blood pressure, or hypertension. Uncontrolled high blood pressure is indirectly responsible for many deaths and disability resulting from heart attack, stroke, and kidney failure.

High blood pressure does not usually give warning signs. You can have high blood pressure and feel perfectly well. The only way to determine whether you have high blood pressure is to have it checked regularly. If a reading is high, your doctor will measure your blood pressure again on several separate occasions to confirm the level. Your doctor may also recommend you measure your blood pressure at home or have a 24-hour recording with a blood pressure monitor devices. This can also be useful if going to the clinic makes your blood pressure rise due to nervousness or anxiety.

## ***Blood pressure measurement***

Blood pressure can be measured using a variety of techniques, which can be classified into two major categories: invasive and non-invasive. The invasive approach inserts a catheter into an artery of a test subject. The catheter may contain a pressure transducer at its tip or it may be fluid-filled and couple the blood pressure through the fluid to an external transducer. The change of fluid pressure (blood pressure) in the subject's artery is measured invasively. This technique is also referred to as a direct measurement, because the parameter being measured is directly coupled to the transducer.

Non-invasive blood pressure measurement usually involves the use of an inflatable cuff wrapped around the limb of a test subject. The cuff is inflated and deflated at a controlled rate and physical parameters are observed. The auscultatory and oscillometric techniques are well known non-invasive methods. These methods are indirect because they do not couple directly to the artery. Modern NIBP monitors now use oscillometric technique to measure pressure.

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## NIBP monitoring technologies

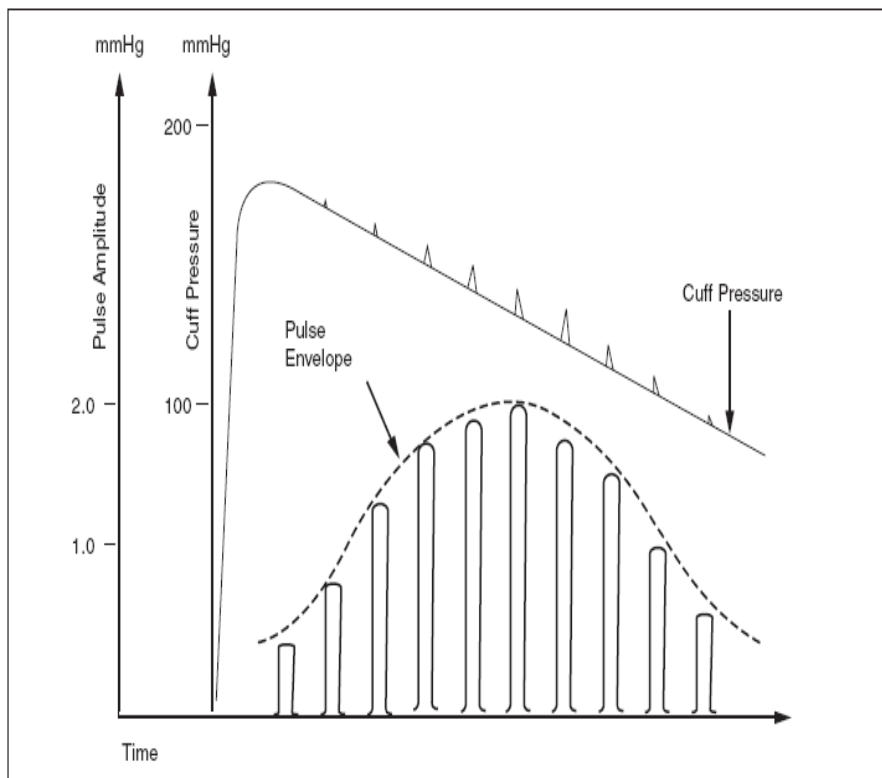
### *Oscillometric technique*

Unlike auscultatory technique, which uses K (Korotkov) sounds to determine blood pressure, the oscillometric technique monitors the changes in cuff pressure caused by the flow of blood through the artery. The monitor inflates the cuff to a pressure that occludes the artery. Even when the artery is occluded, the pumping of the heart against the artery can cause small pressure pulses in the cuff baseline pressure.

The monitor lowers cuff pressure at a controlled rate. As the cuff pressure decreases, blood starts to flow through the artery. The increasing blood flow causes the amplitude of the pressure pulses in the cuff to increase. These pressure pulses continue to increase in amplitude with decreasing cuff pressure until they reach maximum amplitude, at which point they begin to decrease with decreasing cuff pressure. The cuff pressure at which the pressure pulse amplitude is the greatest is known as Mean Arterial Pressure (MAP).

The manner in which the pulse amplitudes vary is often referred to as a pulse envelope. The envelope is an imaginary line that connects the peak of each pressure pulse and forms an outline. The shape of the envelope is observed by different monitors using a variety of techniques to determine the diastolic and systolic blood pressures.

### *Pulse amplitude*



**Figure 2.** Pulse Amplitude and Cuff Pressure

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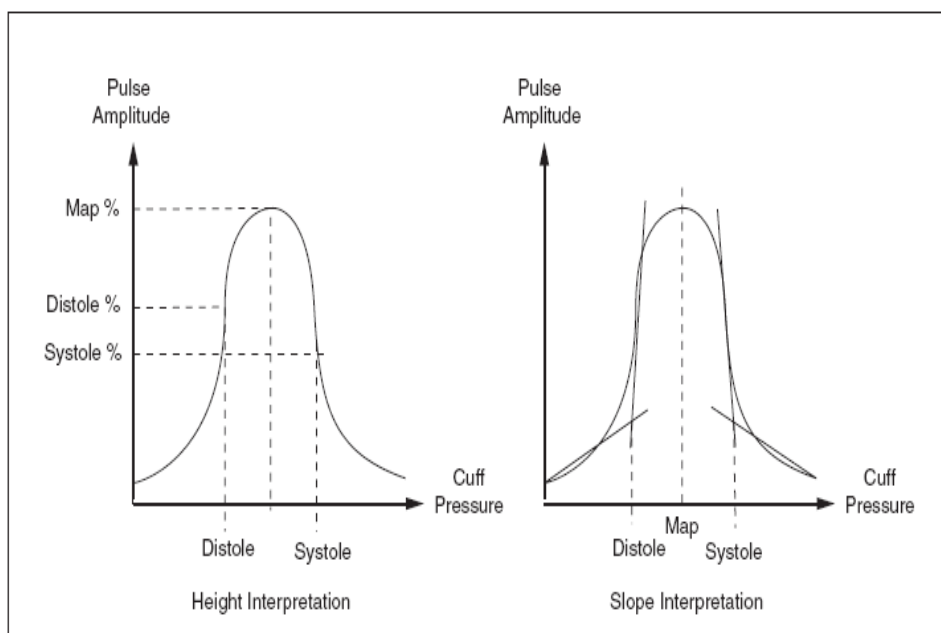
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The amplitude of the oscillometric pulses is quite small when compared to the static pressure in the cuff. As shown in Figure 2, these pulses appear as very small spikes on the cuff pressure waveform. They are depicted in amplified form with the cuff pressure stripped off to reveal how the amplitude varies as a function of cuff pressure. The peak pulse amplitude is 2 mmHg at a cuff pressure of 115 mmHg (MAP) in the example shown.

In general, the peak pulse amplitude is 1-3 % of the cuff pressure at which it occurs. Therefore, the monitor must be able to strip off the large static cuff pressure to measure the individual pulse. Because the pulses are so small, it is possible for artifact conditions to obscure the pulse. Patient motion and respiration are common artifacts that the monitor must reject. When the cuff pressure is quite high the pulse amplitude is small. As the cuff deflates, the pulse amplitudes increase to a maximum and then decrease to a minimum.

## ***BP determination***

The manner in which oscillometric pulses vary as a function of cuff pressure is open to interpretation. Height-based and slope-based algorithms are used to determine blood pressure based on pulse amplitudes. Figure 3 shows the same pulse envelope interpreted by these two different methods.



**Figure 3.** Height/Slope Interpretations for Determining BP from Pulse Amplitude Data

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## A. Height Method

The peak pulse amplitude is treated as MAP and normalized to a value of 100 %. The cuff pressure at MAP is the MAP pressure. Systole and diastole are fixed percentages based on MAP. The cuff pressure under diastole is the diastolic pressure and the cuff pressure under systole is the systolic pressure.

There is no standard to suggest what the percentages for systole and diastole should be or even that they should be fixed percentages. Manufacturers using height-based algorithms have performed their own clinical trials and drawn their own conclusions about what the percentages should be and whether they are fixed as a function of MAP pressure.

## B. Slope method

There are many methods employed to determine how many slopes should be drawn and what conclusions can be made about their intersection. As shown in Figure 3, the cuff pressure under the intersection of the slopes is treated as the systolic and diastolic pressures. There is no standard for slope algorithms, just as there is no standard for height algorithms.

## Testing a NIBP monitor by a simulator

The design of the NIBP parameter of a patient monitor is required to be proven to be safe and effective for use in the diagnosis, and treatment of disease states and underlying chronic conditions, and in the prescribing of medications and other therapies. This testing is governed by national and international standards for minimum performance and safety (e.g., AAMI/ANSI SP10, IEC 80601-1-2-30, etc.). The performance of NIBP monitors are required to be evaluated or tested during scheduled maintenance by the manufacturer. This performance testing is detailed in their recommended test procedure which is usually found in the Service Manual for the particular patient monitor model. The NIBP parameter can be tested using static pressure (e.g., generated by an inflation bulb and measured by a pressure meter, or similar more automated device) or dynamically (e.g., simulation using an NIBP patient simulator or analyzer).

Manufacturers of NIBP monitors that use the oscillometric technique have performed clinical trials to determine the correlation between both auscultatory techniques and invasive (arterial line) methods of measuring blood pressure to the oscillometric technique. The accuracy and repeatability of measurement claims are substantiated by the clinical testing and comparison/correlation across the methods of assessment used.

Patient simulators have been used to mimic the dynamic nature of patient NIBP because the input to the NIBP portion of the patient monitor is a signal that is quite repeatable, though may not be precisely clinically correct in its shape when compared with a live patient (whether healthy or with cardiovascular disease or chronic

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condition). This becomes somewhat of a mix between qualitative and true quantitative analysis of NIBP performance. It is assumed that if the NIBP measured by and displayed on the patient monitor matches the simulated Pulse Rate, Systolic/Diastolic, and MAP numerics, and if these fall within the accuracy range specified by the patient monitor manufacturer, then the performance must be acceptable. For this reason it is strongly suggested that more than one group of simulator settings, including both healthy and disease state-affected simulations, be included in the performance testing. Because the simulator produces a stable live subject response to the cuff during the measurement cycle, it is possible to determine the repeatability and agreement of these monitors.

The International Organization of Legal Metrology's international recommendation on non-invasive automated sphygmomanometers<sup>1</sup> describes a NIBP patient simulator as: "... is required in assessing stability of performance" of NIBP patient monitors.

Section A5.1.1 further details the simulator requirement: "Patient simulator for the auscultatory and/or oscillometric method, having additional deviations originating from the simulator of not more than 0.27 kPa (2 mmHg) for the mean value of the measurements and generating signals for blood pressure values of approximately systolic (120 mmHg) Diastolic (80 mmHg) pulse rate 70/min to 80/min."

Simulators that regenerate oscillometric waveforms can partially replace clinical trials for NIBP monitors if they include sufficient physiological and pathological oscillometric waveforms.

## Testing procedures

To perform the test, connect a hose and cuff to the NIBP monitor. Place the cuff around a piece of PVC pipe or other sturdy cylindrical object to simulate placement on a limb. Connect a piece of tubing to the pressure port on the BP Pump2. Connect a tee to this tubing and attach tubing and connectors. Connect the two legs of the tee between the hose and the cuff of the NIBP monitor.

**Figure 4** Test a NIBP monitor with the BP Pump2



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## *Physical condition*

Check the physical condition of the device to make sure device is clean and decontaminated and no physical damage to case, display, mounts, cart or components etc.

## *Leak test*

Test NIBP monitor, including cuff and tubing checks for air leaks. Place the NIBP monitor in service mode to perform the leak test. Select “Leak test” from BP Pump2. Press “SET UP” to change the test pressure set point. Use the number keys to enter a test pressure of 250 mmHg and then press “ENT.” Press the soft key labeled “START” on the analyzer to start the test. The test takes at least 30 seconds. The leak rate should be less than 15 mmHg/min.

## *Static pressure accuracy*

Monitor pressure in the NIBP test system with manometer capability. With the NIBP monitor in service mode, select “Static Pressure” on the BP Pump2. Press “SOURCE.” Set the test pressure on the analyzer to 200 mmHg. Start the test by pressing the “Start” key to start. Compare the pressure displayed on the NIBP monitor with the measured pressure displayed on the analyzer. The measured pressure should be within 3 mmHg of the displayed pressure.

## *Pressure relief test*

The pressure relief test is also called the “pop-off” test, which is an overpressure test that evaluates a NIBP monitor’s emergency release valve. Place the NIBP monitor into service mode. Select “Pressure Relief Test” on the BP Pump2 and set the test pressure to 380 mmHg. Press the “Start” key to start the test. Once the high-pressure relief valve is triggered on the NIBP monitor, the monitor will vent the pressure from the cuff.

## *Dynamic blood pressure testing*

Place the NIBP monitor into the normal operating mode. Select “STANDARD BP” on the BP Pump2. Press the soft key labeled “OPTIONS” on the BP Pump2 to cycle through the available preset blood pressure simulations including both normal and abnormal patient conditions.

Some variance on readings on the NIBP monitor is normal and acceptable. The ANSI Standard for Electronic or Automated Sphygmomanometers specifies the required efficacy of the blood pressure determination: “The mean difference of the paired measurements of the test system and the comparison system shall be  $\pm 5$  mmHg or less with a standard deviation of 8 mmHg or less.”<sup>2</sup>

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This means that variations in individual readings of 5, 6, or even 10 mmHg are normal and do not indicate the NIBP monitor or the simulator are malfunctioning. Some monitors are more repeatable than others, and repeatability is one measure of the overall quality of the monitor.

## *Test automation*

Automated NIBP performance testing can be accomplished by using Ansur testing automation software developed by Fluke Biomedical.

Ansur-automated BP Pump 2 is controlled remotely by a PC and test elements in a series of standardized tests called a test template. These test templates can be customized to fit a user's specific needs for different NIBP monitor makes/models. Within these test templates, each test element has specific functions and unique properties that can be applied and manipulated by the user as needed. Test results can be stored in and printed through a PC. The test template should include all steps mentioned above to determine the safe and effective performance of the NIBP device under test.

## **Summary**

Blood pressure is generated by blood flow with a force against the artery. Hypertension is a medical condition that may be diagnosed when a person's blood pressure is consistently recorded at the level of 140/90 mmHg or higher. Doctors need to measure a patient's blood pressure in several occasions and may advise a patient to undergo other tests such as ECG and exercise stress tests before diagnosing and/or treating a patient for hypertension.

NIBP device manufacturers conduct clinical studies on a large statistical sample of human patients for each of different patient conditions such as arrhythmia, motion, trauma, cardiac conduction path anomalies/blocks; etc to prove the safety and effectiveness for clinical use of their device designs for these dynamic conditions.

A patient simulator is used to evaluate the performance of NIBP monitors. NIBP accuracy is determined using static pressures, whether generated by an NIBP simulator or other pressure source that is traceable to national standards for metrology. These are calibration or specification verification tests. A well-designed simulator should mimic the dynamic nature of patient NIBP and produce a stable live subject response to the cuff during the measurement cycle, therefore it is possible to use a simulator to determine the repeatability and agreement of these monitors.

NIBP monitor performance testing can be conducted using Ansur testing automation software developed by Fluke Biomedical. Simulators such as the BP Pump 2 can be controlled remotely by a PC and test elements

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can be customized to fit a user's specific needs for different NIBP monitors. Test result can then be stored and printed through a PC.

## References

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2. ANSI/AAMI SP10-1992 Standard for Electronic or Automated Sphygmomanometers
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