

## OEM MAXNIBP<sup>®</sup> Frequently Asked Questions

<p>Why does the monitor sometimes inflate the BP cuff, then shortly thereafter reinflate the cuff?</p>	<ul style="list-style-type: none"> <li>- On an adult, MAXNIBP will typically pump to an initial pressure of about 150mm Hg (or 30 mm higher than the last systolic reading if the monitor is not cycled between patients).</li> <li>- If the patient's systolic pressure is higher than this initial pressure, after a few deflation "steps" MAXNIBP will sense that it has not pumped high enough and will reinflate the cuff about 30 mmHg.</li> </ul>
<p>How will I know if the monitor is experiencing motion artifact during a measurement? How is motion indicated?</p>	<ul style="list-style-type: none"> <li>- If motion is present during a measurement, MAXNIBP will either pause to wait for the disturbance to end, or re-inflate the cuff.</li> <li>- Repeated re-inflation during a measurement may be an indication of excessive motion.</li> <li>- If the disturbance is too great and/or motion is present for an extended period, the error message "MOTION" will be displayed.</li> </ul>
<p>Are there any other causes of repeated re-inflation during a NIBP measurement?</p>	<p>Although atypical, repeated re-inflation during a measurement may signal a problem with the module or monitoring system. Recommended troubleshooting steps include:</p> <ul style="list-style-type: none"> <li>- Check (listen) for air leaks</li> <li>- Check for integrity of : <ul style="list-style-type: none"> <li>• The BP cuff</li> <li>• The connections at both ends of the hose</li> <li>• The monitor itself</li> </ul> </li> </ul>
<p>Can an oscillometric NIBP simulator be used to determine accuracy of NIBP modules?</p>	<p>The main function of an oscillometric NIBP simulator is to dynamically reproduce the pressure profile of a live subject during a blood pressure measurement cycle. A common question that arises when using an NIBP simulator is, "why are the results produced by my blood pressure monitor different than the settings on the NIBP simulator?"</p> <p>NIBP module manufacturers use different criteria to calculate the systolic and diastolic pressure values; it is unreasonable to expect a single NIBP simulator to achieve universal agreement with all clinically approved oscillometric blood pressure monitors. To establish the absolute performance between an NIBP monitor and a particular NIBP simulator, an offset table must be employed.</p> <p>Non-invasive blood pressure simulators are excellent tools for verifying a host of safety and performance requirements that NIBP monitors (modules) approved for clinical use must meet. In the area of blood pressure simulation, it is not the absolute agreement between the oscillometric blood pressure monitor and an NIBP simulator that matters, but how repeatable the results produced by the monitor under test are when using the simulator</p>

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### Frequently Asked Questions (page 2)

<p>Can an oscillometric NIBP simulator be used to determine accuracy of NIBP modules? (con't)</p>	<p>A detailed discussion on this topic may be found by reviewing "Performance of the CAS Oscillometric Algorithm When Compared Against Various Commercially Available NIBP Simulators." This document may be found by visiting our website <a href="http://www.CASMED.com">www.CASMED.com</a> and selecting OEM NIBP Technology.</p>
<p>How does the MAXNIBP algorithm manage atrial fibrillation and arrhythmias?</p>	<p>Atrial fibrillation and arrhythmias are managed the same way that artifact is handled. If atrial fibrillation or an arrhythmia occurs it will corrupt the amplitude and/or timing of the oscillometric pressure pulse. If the detected pressure pulse does not agree with other pressure pulses at a fixed pressure step, then the pressure pulse is rejected and more pressure pulses are observed until the pressure pulse amplitude and timing meet the required criteria. If there are too many arrhythmias and the timing and amplitude of each pressure pulse varies widely, an error message will occur.</p>
<p>Do you conduct a quality check on the pulses before creating the oscillometric envelope?</p>	<p>Yes, at a fixed pressure step, the timing and the amplitude of each oscillometric pressure pulse are assumed to be relatively constant. If the amplitude or timing of a pressure pulse are outside the acceptable range, the pulse is rejected and additional pressure pulse samples are gathered. Once the pressure pulse amplitude and timing are accepted at a pressure step, this information is stored and is used during the post processing phase when the oscillometric envelope is created.</p>
<p>How does motion affect MAXNIBP Technology?</p>	<ul style="list-style-type: none"> <li>- Motion may affect the performance of a monitor with MAXNIBP, but it will not affect the accuracy of the BP reading.             <ul style="list-style-type: none"> <li>• MAXNIBP rejects motion artifact, thereby rejecting any signal with artifact.</li> </ul> </li> <li>- The monitor may take longer at each deflation step to match pulse amplitudes due to motion artifact rejection, thereby increasing the measurement time.</li> <li>- The monitor may have to re-pump to obtain more data.</li> </ul>

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### Frequently Asked Questions (page 3)

CLINICAL Q & A	
<p><b>Why is blood pressure measurement important?</b></p>	<p>- When measured as an average over a long period of time (weeks to months) blood pressure is an important factor for assessing your risk for:</p> <ul style="list-style-type: none"> <li>• heart attack</li> <li>• stroke</li> <li>• other complications such as kidney failure</li> </ul> <p>- While blood pressure by itself cannot determine whether you will or will not suffer any of these ailments, a very large body of scientific research has shown that high blood pressure (also known as hypertension) is a strong risk factor for developing a wide range of medical problems.</p>
<p><b>What is "blood pressure"?</b></p>	<p>- The average heart beats almost 90,000 times per day. With each beat, the heart expels blood into the arteries that carry blood to all parts of body, branching into smaller and smaller vessels along the way.</p> <p>- When the heart beats, it generates a force that is transferred to the blood. As blood leaves the heart, it carries this force with it into the arteries. This force pushes on the walls of the arteries and the arteries push back, helping to propel the blood forward into the body.</p> <p>- This force also causes pressure within the arteries called "blood pressure".</p> <p>- Blood pressure measurements consist of two numbers, systolic and diastolic. Systolic pressure is measured while the heart is contracting, and is the larger of the two numbers. Diastolic pressure is measured while the heart is relaxing, and is smaller than the systolic pressure. These two pressures are written together, like this: 120/80, and pronounced "120 over 80."</p> <p>- Both systolic and diastolic blood pressures are important determinants of cardiovascular risk, so both are used in evaluating overall blood pressure status.</p>
<p><b>What is normal blood pressure?</b></p>	<p>- For a long time, normal blood pressure was defined as 120/80 (systolic / diastolic). Recently, the American Heart Association changed the definition of normal blood pressure to "Less than 120 / Less than 80."</p> <p>- This redefinition was enacted due to ongoing research examining the long term health effects of varying blood pressures. In addition to redefining the normal value, the new American Heart Association guidelines changed the cutoff values for different stages of high blood pressure. These changes were also based on new research that more clearly demonstrates an increasing risk of heart attack and other illness as the blood pressure rises. The new American Heart Association guidelines define three levels of abnormal blood pressure values.</p>

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### Frequently Asked Questions (page 4)

<p><b>What is normal blood pressure? (con't)</b></p>	<p><b>Pre-hypertension</b> (120-139) / (80-89) is now considered to be “pre-hypertension” (or “Almost High Blood Pressure”). Clinicians are watching blood pressures in this range more carefully than in the past.</p> <p><b>Stage 1</b> (140/90) is the cutoff for Stage 1 Hypertension. Stage 1 Hypertension may or may not be treated with medicines, depending on lifestyle and other risk factors.</p> <p><b>Stage 2</b> Systolic pressures above (160), or Diastolic pressures above 100. Patients that fall into this category are classified as having Stage 2 Hypertension, a serious condition that warrants immediate medical treatment.</p>
<p><b>What are the risk factors for developing high blood pressure?</b></p>	<p>There are many variables that contribute to an individual’s risk for developing high blood pressure. These are collectively called “risk factors” and include:</p> <p><b>Age.</b> Being older than age 55 is an important risk factor. Simply stated, the odds of developing high blood pressure increase as we get older.</p> <p><b>Ethnicity.</b> Certain ethnic groups have a higher risk of developing high blood pressure than other groups.</p> <p><b>Gender.</b> At younger ages, women are less likely to develop high blood pressure than men. This risk equalizes later in life, but statistically, women are still less likely to develop high blood pressure, overall.</p> <p><b>Family History.</b> Having a family history of high blood pressure places you in a higher risk category for developing high blood pressure than someone with no family history of high blood pressure.</p> <p><b>Smoking.</b> Smoking is the number 1 controllable risk factor. Smoking is such a powerful risk factor for so many different human diseases that doctors are encouraged to ask every patient who smokes if they would like to quit - every time they visit the office!</p> <p><b>Activity Level / Exercise</b> A low exercise lifestyle leads to a weak heart, poor exercise tolerance, and obesity. All of which have been implicated in the development of high blood pressure.</p> <p><b>Diet.</b> While there is evidence that specific items, such as salt, can worsen high blood pressure in certain individuals, diet primarily impacts an individual’s weight which may ultimately increase the risk for high blood pressure.</p> <p><b>Medications and Street Drugs.</b> Certain medications can cause or worsen high blood pressure, as can a wide variety of street, or “recreational”, drugs, like cocaine, crack, and amphetamines (“speed”).</p> <p><b>Kidney Problems.</b> The kidneys are very important regulators of long term blood pressure. Damage to the kidneys - such as can occur from diabetes - almost invariably leads to high blood pressure.</p> <p><b>Other Medical Problems.</b> Hormone imbalances, certain anatomic abnormalities, tumors, and other medical problems can cause a type of high blood pressure known as secondary hypertension.</p>

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### *Frequently Asked Questions (page 5)*

Can certain variables affect the ability to obtain a blood pressure reading?

Blood pressure measurements can be affected by multiple factors. These include:

- o **Patient movement** (shivering, tremors, seizures, and flexing the arm in reaction to cuff pressure) may interfere with a blood pressure reading.
- o **External motion** such as bumping the patient or motion of the blood pressure cuff tubing will interfere with obtaining blood pressure reading.
- o **Very low blood pressures** such as those found in patients in shock, produce low pressure amplitudes that can be difficult to detect.
- o **Atrial fibrillation** or frequent premature beats may cause variations and difficulty getting precise readings since very early beats produce variable cardiac output.
- o **Arrhythmias** may affect pulse rate accuracy resulting in a longer time needed to complete a measurement.
- o **Operator error** including technique and cuff size may impact the accuracy of NIBP readings. Using a cuff that is too small may produce inaccuracy (high readings), and using a cuff that is too large may underestimate pressure and produce a low reading.
- o **Length of time between BP measurements** may impact the accuracy of a blood pressure reading. If the interval between measurements is too short, venous congestion may occur.

The following technique guidelines should be used when taking an NIBP measurement:

- Patient should be seated quietly, both feet flat on floor, back supported.
- Patient should rest for 2-3 minutes prior to the reading.
- Patient & Clinician should not speak during the reading.
- Clinician should support patient's arm, keeping cuff at heart height and impeding movement during the reading.
- Cuff should be positioned 1" above the elbow.
- Cuff should be wrapped around upper arm tightly enough for the 2-finger-test.
- Cuff and artery should be properly aligned.
- Cuff should not be placed over clothing.
- Cuff should be the proper size for the patient.

#### References:

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