

OEM MAXNIBP[®] *Motion Artifact Testing & Performance*

Are NIBP modules tested for performance during motion artifact?

Non-invasive blood pressure (NIBP) devices approved for clinical use must be tested to demonstrate compliance to one of the standards that exist for this purpose. Typically, the devices are tested against an auscultatory reference following the established protocols of either the Association for the Advancement of Medical Instrumentation (AAMI) or the British Hypertension Society (BHS). Whichever protocol is used to clinically validate an NIBP device, the movements of all study subjects are kept to an absolute minimum.

It should be noted that, although NIBP devices are validated clinically, this testing may not accurately represent the performance of the device when operated in the presence of motion artifact such as during patient transport or when the patient may be subject to motion.

[To date, a standard for validating the performance of an NIBP device in the presence of motion artifact does not exist.]

In a recent scientific statement from the American Heart Association (2009), authors suggested that “careful selection of equipment ... is essential for accurate recording.” Authors also noted that “monitors should be able to tolerate some subject movement without giving excessive error readings.”¹

To avoid a costly mistake in your medical device product design, it is critical to obtain demonstrated performance characteristics of the NIBP module in the presence of motion artifact. The performance evaluation should report on the specific effects and degree to which motion artifact influences the ability to obtain a blood pressure measurement.

Essential to the NIBP module performance evaluation is utilizing commercially available test equipment and strict adherence to a detailed engineering test plan to ensure repeatability, traceability and accuracy of the test result.

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The selected test equipment (simulator) should allow motion and tremor artifact to be superimposed onto the oscillometric blood pressure signal in a controlled, repeatable manner to replicate the vibration that would result from patient transport (road conditions) and tremor artifact associated with muscular activity such as that from Parkinson's disease or shivering.

In comparison to the baseline measurement, analysis of the data recorded during the performance evaluation will provide the evidence necessary to determine the NIBP module's ability to provide accurate, reliable measurements under harsh motion conditions. The influence that noise generates during blood pressure measurement, and the ability to manage the interference, can be determined by comparing the standard deviation of each NIBP module at various artifact settings.

When assessing an NIBP module for performance in a clinical setting, a number of variables should be considered prior to purchasing.

In the face of varying degrees of motion artifact, non-invasive blood pressure technologies may be differentiated and objectively rated using the following criteria:

- o Measurement accuracy
- o Number of completed readings
- o Percentage of completed readings
- o The ability to obtain an accurate measurement
- o The length of time required for a measurement
- o A comparison of the standard deviation from the baseline

CASMED's Non-Invasive Blood Pressure Technology Motion Artifact Comparative Study may be reviewed by clicking on this link: [Motion Artifact Study](#)

Reference:

1. Ambulatory Blood Pressure Monitoring in Children and Adolescents: Recommendations for Standard Assessment. A Scientific Statement From the American Heart Association. Elaine Urbina, MD et al. Dallas, TX: Hypertension: Journal of the American Heart Association, August 4, 2008, 52, Vol. 2008. 433-451.