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REVIEW PAPER

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Evaluating the impact of motion artifact on noninvasive blood pressure devices

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Abstract

Most automated sphygmomanometers use oscillometric algorithms. Motion, either patient-based or environmental, will affect the ability of a device to record an accurate blood pressure (BP). Members of the Association for the Advancement of Medical Instrumentation (AAMI) Sphygmomanometer Committee have been studying this problem for more than a decade. The AAMI TIR44 was the first publication to address the challenges of motion tolerance. The concepts described in TIR44 have led to the development of a draft of ISO 81060-4, a new standard for testing devices for which the manufacturer wishes to claim motion tolerance. The current ISO 81060-2 addresses both stress testing and 24-hour ambulatory BP monitoring. Recent publications have reported on testing of devices in response to voluntary and involuntary patient motion. The ISO 81060-4 will address testing in the presence of patient transport by ground, fixed-wing, and rotary (helicopter) ambulances. The protocol will utilize noise profiles recorded under those three conditions. The profiles will be digitally stored on a library with free access. The proposed testing will be performed using patient simulators introducing the noise library files into known BP oscillometric envelopes. The specifications of the data capture and playback devices are specified, as is the evaluation statistical testing. The authors expect that the final draft will be published in 2020.

1 | THE PROBLEM

The impact of motion artifact on the accuracy of oscillometric blood pressure (BP) determinations was recognized early in the development of the technology.[1] Motion artifact creates noise in the oscillometric data by generating pressure signals in the cuff that interfere with the processing of the patient's pulses. Noise sources interfering with the noninvasive blood pressure (NIBP) determination process include noise generated by the patient and noise generated by the environment around the patient. Since noise interferes with the NIBP determination process, a method to evaluate its influence is needed. For decades, the industry and Association for the Advancement of Medical Instrumentation (AAMI) Sphygmomanometer Committee members have recognized this need.

The first document developed on this topic was the AAMI technical information report (TIR) 44:2012, published in 2012.[2] Its intent was to summarize and communicate the findings of the motion artifact task group, which consisted of a subgroup of BP measurement experts from the AAMI Sphygmomanometer Committee. The TIR44 document summarizes the task group's multi-year effort to understand the characteristics and impact of different types of motion artifact on automated BP device readings. The TIR44 includes descriptions and sources of different types of artifact noise, including those induced by voluntary patient movement, involuntary

patient movement, and noise and vibrations induced into the measurement system from medical transport vehicles. The report also discusses the frequency content amplitude and effect of artifact noises on common methods of automated BP measurement. The TIR44 outlines some strategies for standardized device testing to determine the device's tolerance to artifact noise and serves as supporting information for the ongoing International Organization for Standardization (ISO) work described in this paper.

2 | NOISE SOURCES

One of the challenges inherent in any NIBP procedure is the fact that the NIBP determination process accumulates data at different pressures as the cuff pressure is changed across the range of expected systolic and diastolic BP values. Motion artifact, or noise, interferes with the information used by the device to estimate the BP of the patient. The occurrence of noise is mostly random with respect to the pressure pulses being acquired during the NIBP determination attempt; thus, the noise may affect the process in variable ways depending on its timing relative to the execution of the device's attempt.[3] If the noise occurs near systolic and diastolic BP levels, it can have an impact on those values. If the noise levels occur near mean arterial pressure, then the entire process can be compromised due to the inaccurate positing of the estimated BP envelope. There are two categories of noise that interfere with the NIBP determination process: noise generated by the patient and noise generated by the environment. Manufacturers of NIBP devices have dealt with noise in various ways. Most rely on filters to remove the noise before the signal is processed. These filters are effective in reducing the effect of noise that differs in frequency content from the oscillometric signal. However, simple filters are not able to remove noise that has overlapping frequency content with the oscillometric signal.[4] Some have used advanced signal processing techniques to qualify the oscillometric pulses to work through periods of noise. Some use a combination of techniques to address the challenges. Many of these techniques are proprietary to the medical device.[5] Because this noise interferes with the NIBP determination process, a method to evaluate its influence is needed.

3 | PATIENT-GENERATED NOISE

AHA guidelines require the subject/patient to be still during determinations; however, this may not always be possible or practical. There has been a recent study evaluating the impact of voluntary patient motion.[6] In that study, a protocol was described to assess NIBP device accuracy during voluntary patient-induced motion, where, during inflation/deflation cycles, the subjects perform forearm pronation/supination. Some other examples of voluntary patient motion include patient arm movement during the BP reading, flexing muscles in response to the squeezing of the cuff, and hand motions while talking or filling out forms during the cycle. Another study used a bench test procedure, similar to that being developed by the AAMI Sphygmomanometer Committee, to evaluate noise tolerance and to evaluate the effect of involuntary patient motion, such as tremor, on NIBP results.[7]

The results of these articles show promising optimism that patient-induced noise's effect on NIBP determination results can be evaluated. This highlights the need for a standardized method to evaluate the impact of noise on NIBP accuracy.

4 | ENVIRONMENTAL NOISE

Environmental noise also affects NIBP determination accuracy. The patient environment can be rather challenging during 24-hour ambulatory BP estimations, patient transport, or exercise stress testing. The noise sources in the environment cause changes in the cuff pressure being processed by the NIBP device. However, these pressure changes are not related to either the NIBP device's attempt to control cuff pressure, or the patient's pulses translated into the cuff. The NIBP device must be able to disregard the impact of the noise in order to provide accurate NIBP values. The ISO 81060-2 Standard already has procedures for stress testing and 24-hour ambulatory BP monitoring. The effect of patient transport noise on NIBP determinations is the focus of the current work in the ISO 81060-4 draft.

5 | EVALUATION OF DEVICES UTILIZED DURING PATIENT TRANSPORT

The AAMI and ISO have recognized the need to validate devices for patient transport. In response to this issue, several AAMI Sphygmomanometer Committee members are developing the ISO 81060-4 document, a protocol for the validation of automated oscillometric NIBP devices that wish to claim motion tolerance during patient transport. The ISO 81060-4 work item is the first attempt to establish an accepted procedure to evaluate oscillometric-based device performance in the presence of transport noise. The procedures being developed focus on a repeatable method to stress a device's performance adequately in the presence of noise.

AAMI committee members studying transport-induced artifact initially investigated whether the noise signals could be recorded using a human subject placed on a shake table. After visits to Fort Rucker, Alabama, where the US army has such a device, the members concluded that the administrative procedures needed to gain access to the shake table would be too complex. An inquiry to the University of Iowa, which has a similar piece of equipment, was also unsuccessful due to a lack of funding. It became apparent that the manufacturers of each device wanting to claim transport capability would have to contract individually with these sites and schedule the necessary number of subjects to fully evaluate the device for the multiple noise protocols. In addition to these issues, the difficulty of obtaining the true reference BP values under artifact conditions meant that an alternative approach needed to be developed.

The AAMI committee members then began investigating the use of simulators to introduce artifact signals into the oscillometric envelope generated during NIBP estimation. While patient simulators cannot be used to assess device accuracy, they are very useful in measuring repeatability of performance. Patient simulator signals without artifact are used to establish the baseline performance of the device and then compared with results obtained when artifact signals are merged with those same patient simulator signals. The proposed approach compares performance without noise versus performance with noise; therefore, it only examines the impact of the artifact on device performance. The BP device evaluation challenges addressed by the ISO 81060-4 draft are shown in Table 1.

6 | NOISE RECORDING AND PLAYBACK SYSTEMS

To reproduce the recorded transport noise, a playback device and the noise data file (ie, recorded artifact signals) are needed. The noise playback device requirements for bandwidth, amplitude, duty cycle, resolution sampling rate, and length of noise files are specified in the ISO 81060-4 draft. A system is also required to record the artifact signals in the noise data files. The recording system includes a cuff mandrel test fixture and a data acquisition system to save the data on a storage device. Similarly, the recording device utilized during transport (ground, rotary, and fixed-wing ambulances) must fulfill requirements for bandwidth, range (mm Hg), atmospheric pressure adjustment, resolution, sampling rate, and length of recording, also specified in the ISO 81060-4 draft.

AAMI committee members custom-built and tested the recording device and a cuff mandrel fixture to capture the noise signals experienced in the transport environment. The recording device acquires multiple pressure and accelerometer signals for each noise recording. Importantly, the setup included three pressure sensors mounted in the X, Y, and Z planes. The data are needed to assure an FDA review team that there were no artifact signals produced by the NIBP device's transducer during testing that are incremental to the artifact signals generated in the cuff. Because of the minimal mass of the current state-of-the-art transducers, this is highly unlikely. Some pilot data have been collected that confirm the lack of artifact arising from the transducers (Paul Matsumura, personal communication). The mandrel fixture consists of a PVC pipe wrapped with a specific foam material, around which a BP cuff was wrapped. This is mounted such that the cuff wrapped around the PVC mandrel has freedom to move during motion recording. Specifics are given in the full document and are beyond the scope of this publication.

7 | NOISE PLAYBACK DEVICE

The AAMI committee members are currently working with a simulator manufacturer to develop a playback device, which is essential to perform the required testing. The noise playback device will be commercially available. The committee believes most device manufacturers interested in performance during transport, or in general performance in the presence of noise, will purchase this playback device.

8 | NOISE DATABASE

The AAMI committee is creating a noise file database specifically for use with this test procedure. In cooperation with the Marshfield Clinic Health System, AAMI, Marshfield City Administration, Marshfield Fire and Rescue, Marshfield, Wisconsin, and LifeLink

TABLE 1 BP device evaluation challenges addressed by the ISO 81060-4 draft

Clinical Issues	Technical Issues	Technical Solutions
BP measurement devices need to be clinically validated utilizing a procedure and protocol that properly predicts the device's performance on the entire patient population and assures that all BP devices are evaluated with the same level of rigor.	It is not trivial to get a "gold standard" BP measurement to use as the correct BP when measuring the error of a device. The patient population has diverse attributes that can be challenging for a device design, including BP level, heart rate, arm size, BMI, and mild to severe heart rhythm variations.	The current version of ANSI/AAMI/ISO 81060-2 provides a comprehensive, expert informed, time-tested protocol for evaluating the accuracy of a BP device on stable patients at rest. The protocol is a balance between the practical limitations of a clinical study and subject requirements that result in repeatable evaluations
Motion artifact such as the type that is generated from a transport vehicle can have an impact on the accuracy of a BP device but may give no indication that the resultant BP reading has been affected by artifact noise.	There has been no protocol or standardized test method to objectively and repeatably evaluate a BP device's accuracy in the presence of artifact noise.	The draft standard of ISO 81060-4 aims to augment the 81060-2 protocol with further bench testing that evaluates the BP device's ability to measure in the presence of artifact noise
Motion artifact can cause a BP device to act erratically, pump the cuff to unnecessarily high pressures, take a prolonged time to estimate the BP, or result in an error code.	There has been no protocol or standardized test method to objectively and repeatably evaluate a BP device's behavior and ability to estimate BP in the presence of artifact noise	The draft standard of ISO 81060-4 outlines a procedure that will yield device behavior results as the device is presented with a standardized set of motion artifact simulations.

TABLE 2 Summary of test procedure steps from the 81060-4 draft

Procedure Step	Intention of the procedure step
Perform the clinical accuracy protocol described in ANSI/AAMI/ISO 81060-2	Establishes the BP device's clinical accuracy on stable, resting patients
Download standardized set of noise files from the AAMI-hosted noise library	Standardized noise files assure that the performance of different BP devices is evaluated equally.
Preload a noise file into the noise playback device	Set up the noise playback device
Connect the BP simulator equipment to the device under test as depicted in the 81060-4 draft	Assure a standardized setup
Configure the BP simulator to one of the predetermined BP values	Assure a standardized set of BP simulations
Perform and record the device readings	Establish baseline performance with no noise present
Connect the BP simulator and noise playback device to the device under test as depicted in the 81060-4 draft	Prepare to perform the same set of BP determinations with added artifact noise. Note: the BP simulation and noise playback functionality may be integrated into a single piece of test equipment.
Configure both the BP simulator and the noise playback simulator to one of the predetermined combinations	Assure a standardized set of BP + noise simulations
Perform and record the device readings	Measure the performance with noise present
Gather a set of device readings for each predetermined combination listed in the 81060-4 draft	Assure a consistent set of noise artifact challenges. This set of challenges is intended to represent a realistic subset of the artifact noise spectrum.
Compare and analyze the groups of device readings according to the instructions and specifications detailed in 81060-4 draft.	The results analysis will indicate the impact of artifact noise on the BP device reading accuracy and device behavior

III (a private helicopter and fixed-wing patient transport system headquartered in Minneapolis, Minnesota), an agreement was reached whereby the various transport vehicles obtain recordings during non-patient transport operations. Their interest, consistent with the interest of all medical personnel performing patient transport, both private and the Armed Forces is, of course, to be able to have the best assessment of the patient's status on the way to definitive care facilities. The noise files recorded in these transport vehicles contain environmental noise only, with no patient signal present. They come from actual recordings in patient transport vehicles, including ground ambulances, rotary aircraft, and fixed-wing aircraft.

The AAMI committee also recognized that a device manufacturer might choose to add noise files to the testing process to make additional claims (eg, watercraft transport). A manufacturer would then need to record those signals and have them added to the database. A manufacturer could also generate proprietary noise files to improve the robustness of the device. While these possibilities exist, the committee does not expect that manufacturers will quickly add to the initial noise database.

We believe that the ISO 81060-4 Standard will be finalized and the noise file database will be available in the near future. The AAMI has agreed to host the library. The noise file database will be available at no charge on the AAMI website.

9 | NOISE TESTING

Any device to be tested for motion tolerance during transport must have already passed clinical accuracy testing to the ISO 81060-2 Standard. The ISO 81060-4 Standard procedures must then be followed to qualify the device for use in transport situations.

The reference performance level is actually an average of multiple iterations using patient simulator signals only. Numerous patient simulator settings are used to assess a broad reference performance expectation for the device.

There are multiple noise files for each noise category (ie, transport vehicle type). Each noise file is to be used to assess the device's overall performance with noise. The device is again used with each simulator setting but this time with one of the noise files also being added to the signals processed by the device. This process continues until the device has been evaluated with each patient simulator setting and with each of the noise files added. This step of the testing presents a combined signal containing both the oscillometric pulses and the noise signals to the device being evaluated. A summary of test procedure steps from the 81060-4 draft is shown in Table 2.

The proposed procedure also includes numerous requirements for the gain and amplitude of test signals, so that they are a “true test” of motion tolerance. If the introduced artifact signals are much greater than patient signals, then the device under test (DUT) algorithm may not be able to produce a valid reading. If the artifacts are small relative to the patient signals, then there should be no effect on the DUT algorithm for patient transport.

Finally, all the results will be analyzed and evaluated to the pass/fail criteria present in the ISO 81060-4 draft.

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CONFLICTS OF INTEREST

There are no conflicts of interest to report for any of the authors.

AUTHOR CONTRIBUTIONS

All authors (Bruce Alpert, David Quinn, Bruce Friedman, Paul Matsumura, Richard Dart, and Robert Donehoo) took part in the concept, writing and critical reading of the original paper, the response to the reviewer's comments, and the revised submission.

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