

# Technical Information Report

## AAMI TIR44: 2012

Non-invasive blood  
pressure motion artifact -  
Testing and evaluation of  
NIBP device performance  
in the presence of motion  
artifact

## Non-invasive blood pressure motion artifact – Testing and evaluation of NIBP device performance in the presence of motion artifact

Approved 16 November 2012 by  
Association for the Advancement of Medical Instrumentation

**Abstract:** This report is intended to provide information on the sources and effects of artifact noise in non-invasive blood pressure measurement. The report also includes an overview of potential evaluation methods for the qualification and classification of device performance when varying levels of artifact noise are present during an NIBP cycle.

**Key words:** NIBP, non-invasive blood pressure, artifact noise, motion artifact, motion testing, simulated artifact noise

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## Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

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## Committee representation

### Association for the Advancement of Medical Instrumentation

#### Sphygmomanometer Committee

This AAMI Technical Information Report (TIR) was developed by the NIBP Motion Artifact Task Group under the auspices of the AAMI Sphygmomanometer Committee. Approval of the TIR does not necessarily mean that all committee members voted for its approval.

At the time this document was published, the **AAMI Sphygmomanometer Committee** had the following members:

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NOTE—Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

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## Foreword

This technical information report (TIR) was developed by the NIBP Motion Artifact Task Group under the auspices of the AAMI Sphygmomanometer Committee.

It is widely recognized that NIBP devices are used in environments where there are frequent occurrences of artifact noise during measurement. Existing standards provide methodology to evaluate the accuracy and performance of NIBP devices in a clinical environment without artifact noise. This gap between common device evaluation methodology and common use case was identified by the AAMI Sphygmomanometer Committee as an important issue to purchasers and users of NIBP devices.

The objective of this TIR is to provide an overview of the work done by the AAMI NIBP Motion Artifact Task Group to date and to serve as supporting information for the development of future US and/or international standards in the area of NIBP with regard to motion tolerance.

The concepts incorporated herein are not inflexible or static. They are reviewed periodically to assimilate new data and advances in technology.

As used within the context of this document, “should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the recommended practice. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22204-1633.

## Introduction

Healthcare is delivered in a wide variety of environments and clinical situations. Medical devices, in general, are required to perform safely and effectively in all of the environments in which they are intended for use. Some use environments are inherently favorable to medical device longevity and performance; others provide situations in which devices are challenged to perform effectively. One such challenge for the measurement of many physiological parameters is artifact that is either present along with the signal to be measured or induced by the patient, clinician, or healthcare environment directly to the device. Patient movement, either voluntary or involuntary, can mask a physiological signal to a degree that inhibits a medical device from providing an accurate reflection of the true physiologic parameter.

This technical information report provides information on the potential sources of motion artifact noise in manual and automated sphygmomanometers in common professional healthcare environments. While it is not possible to anticipate all potential sources of artifact in these environments, this report will identify general categories and types of artifact noise that are known to interfere with the physiologic signals normally interrogated to estimate blood pressure non-invasively.

The report also provides potential device evaluation strategies that can indicate a sphygmomanometer's performance when such common types of artifact noise are present. It is the hope of the AAMI Sphygmomanometer Committee that this work will eventually lead to standardized evaluation methods. These methods would provide clinicians with device performance information that is relevant to the particular environments in which they deliver healthcare and allow them to choose a device that has accurate and acceptable levels of accuracy and performance in those environments. It is a challenge to devise standardized test methods for NIBP devices because of the complexities of an accurate reference determination for a given subject and the varying types of proprietary technology employed by different manufacturers of sphygmomanometer devices.

# Non-invasive blood pressure motion artifact - Testing and evaluation of NIBP device performance in the presence of motion artifact

## 1 Scope

### 1.1 General

This technical information report (TIR) discusses the potential sources of motion artifact noise affecting manual and automated sphygmomanometers in common professional healthcare environments, as well as potential standardized device evaluation methods for determining the performance of these sphygmomanometers when artifact noise is present. Devices in the scope of this TIR include manual sphygmomanometers, oscillometric devices, auscultatory devices, and devices that utilize doppler ultrasound in the estimation of Systolic and Diastolic arterial blood pressure.

### 1.2 Exclusions

This TIR does not cover artifact noise that is not patient or motion induced. For example, radio frequency interference is outside the scope of this document and is adequately addressed in other US and international regulations.

## 2 Normative references

The following referenced documents are relevant for the application of this report and are standards publications that are currently utilized in the evaluation of NIBP devices:

ANSI/AAMI/IEC 80601-2-30:2009, *Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers*<sup>35</sup>

ANSI/AAMI/ISO 81060-1:2007, *Non-invasive sphygmomanometers -- Part 1: Requirements and test methods for non-automated measurement type*<sup>36</sup>

ANSI/AAMI/ISO 81060-2:2009, *Non-invasive sphygmomanometers -- Part 2: Clinical validation of automated measurement type*<sup>37</sup>.

BHS 1993, *The British Hypertension society protocol for the evaluation of blood pressure measurement devices*<sup>38</sup>

EN 1060-4:2004, *Non-invasive sphygmomanometers – Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers*

## 3 Terms and definitions

### ABPM

Ambulatory Blood Pressure Measurement

### ARTIFACT NOISE

Disturbances of the signals required to estimate blood pressure non-invasively. Noise includes perturbations in the cuff pressure signal, and acoustic disturbances in the subject limb or subject environment that interfere with Korotkoff sounds.