Technical Information Report

AAMI TIR66: 2017/(R)2025

Guidance for the creation of physiologic data and waveform databases to demonstrate reasonable assurance of the safety and effectiveness of alarm system algorithms

AAMI
Advancing Safety in Health Technology

Guidance for the creation of physiologic data and waveform databases to demonstrate reasonable assurance of the safety and effectiveness of alarm system algorithms

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AAMI

Abstract: Provides guidance to manufacturers that change existing or create new alarm system algorithms as to how to create evidence that demonstrates a reasonable assurance of the safety and efficacy of the algorithm. This document also provides guidance to authorities having jurisdiction for the assessment of such evidence.

Keywords: electromedical equipment, waveforms

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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Glossary of equivalent standards

International Standards or Technical Reports 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.

www.aami.org/standards/glossary.pdf

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Committee representation

Association for the Advancement of Medical Instrumentation

Medical Device Alarms Committee

This AAMI Technical Information Report (TIR) was developed and approved by the AAMI Medical Device Alarms Committee.

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Foreword

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 TIR. “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 recommended practice are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE—This foreword does not contain provisions of the AAMI TIR66, *Guidance for the creation of evidence to demonstrate reasonable assurance of the safety and efficacy of ALARM SYSTEM algorithms* (AAMI TIR66:2017), but it does provide important information about the development and intended use of the document.

Introduction

Numerous studies have shown that the majority of ALARM CONDITIONS are clinically irrelevant ALARM CONDITIONS. There have been a number of attempts to develop improved ALARM SYSTEMS to increase clinical sensitivity and specificity. However, there is no established method for evaluating the performance of “expert" or "smart" ALARM SYSTEMS (INTELLIGENT ALARM SYSTEMS). These systems can use a multi-parameter approach to adjudicate a single-parameter ALARM CONDITION (e.g. use availability of valid pulse for suppression of false ECG asystole ALARM CONDITION). The expert ALARM SYSTEM can also be used to provide the OPERATOR with possible interpretations of physiologic and clinical data (e.g. “possible sepsis”, “possible pulmonary embolus”). This document provides guidance to manufacturers and describes how to create evidence that demonstrates a reasonable assurance of safety and effectiveness for changing existing, or creating new, ALARM SYSTEM algorithms. This document provides guidance to authorities having jurisdiction for the assessment of such evidence, which can be used as:

— a justification for IEC 60601-1 [42], subclause 4.5, to provide reasonable assurance of safety and effectiveness; and

— a justification for disclosures of performance of INTELLIGENT ALARM SYSTEMS as required by IEC 60601-1-8 [43], subclause 6.2.

Terms defined in Clause 3 of this document are in SMALL CAPITALS.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

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Guidance for the creation of physiologic data and waveform databases to demonstrate reasonable assurance of the safety and effectiveness of ALARM SYSTEM algorithms

1 Scope

This document is intended to define the nomenclature, ingredients, and principles for the development, annotation and use of physiologic waveform databases for developing and testing the performance of INTELLIGENT ALARM SYSTEM algorithms, and to test ALARM SYSTEMS incorporating such algorithms. This document also identifies issues that should be addressed in the design and development of these physiologic databases. It discusses many major pitfalls that should be avoided. Annexes that describe several publicly available databases in detail are included. The database profiles that are presented here are intended to serve as a guide in the design, development, acquisition and documentation of future physiologic databases that can be used in the development and evaluation of ALARM SYSTEMS and algorithms.

This document does not cover the use of databases beyond algorithm development and performance testing to ensure delivery of the stated ESSENTIAL PERFORMANCE.

NOTE It is expected that inter-device data fusion will be covered in interoperability standards being jointly developed by AAMI and Underwriters Laboratory (UL).

2 Normative references

ANSI/AAMI TIR 24:1999, *Acquisition and use of physiologic waveform databases for testing of medical devices*

3 * Terms and definitions

For the purposes of this document, the following definitions apply.

3.1
ALARM CONDITION
state of the ALARM SYSTEM when it has determined that a potential or actual HAZARDOUS SITUATION exists for which OPERATOR awareness or response is required

NOTE 1 An ALARM CONDITION can be invalid, i.e. a FALSE POSITIVE ALARM CONDITION.

NOTE 2 An ALARM CONDITION can be missed, i.e. a FALSE NEGATIVE ALARM CONDITION.

NOTE 3 Table 1 demonstrates the actionability consideration relationships of ALARM CONDITIONS.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012 [43], definition 3.1]

3.2
ALARM FATIGUE
condition that occurs when an OPERATOR is desensitized by the presence of excessive ALARM SIGNALS such that an inappropriate response to the ALARM SIGNAL occurs

NOTE 1 The source of excessive ALARM SIGNALS can be TRUE POSITIVE ALARM CONDITIONS, but are more likely to be from CLINICALLY NON-ACTIONABLE ALARM CONDITIONS.