AAMI Tackles Alarm Management Standards

Jennifer Moyer

The Association for the Advancement of Medical Instrumentation (AAMI) Medical Device Alarms Standards Committee is dedicated to supporting the efforts to reduce unnecessary alarms in healthcare facilities by writing two technical information reports (TIRs) that provide guidance on alarm systems.

The committee recently completed work on a new TIR. AAMI TIR66, *Guidance for the creation of physiologic waveform databases to demonstrate reasonable assurance of the safety and effectiveness of alarm system algorithms* identifies issues that will assist with testing the performance of intelligent alarm system algorithms. The document defines the nomenclature, ingredients, and principles for the development, annotation, and use of physiologic waveform databases when designing and testing alarm systems that incorporate such algorithms. The database profiles outlined in the document are intended to serve as guidance for the design, development, acquisition, and documentation of future physiologic databases that can then be used in the development and evaluation of alarm systems and algorithms. Alarm condition actionability considerations were established to assist with the testing. AAMI TIR66 is now available for purchase.

The Medical Device Alarms Committee is also developing AAMI TIR71, *Guidance for logging of clinical and forensic alarm data*. This document is intended to provide guidance to manufacturers of devices that generate alarm signals and have a logging capability as to what information should be logged. This information should assist both manufacturers and clinicians with the identification of events that triggered the alarm signal and/or the failure mode that the device went into. The logged data would also compile alarm statistics that might be useful for the healthcare organization, as well as for manufacturer's postmarket surveillance use. This document is under development, and we anticipate that it will be published in mid-2017.

The AAMI Medical Device Alarms Standards Committee values additional clinical input. For more information regarding the committee's work or to join the committee, please contact me at **jmoyer@aami.org**. ■

About the Author

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Available AAMI Alarm Standards

- AAMI/TIR66:2017, *Guidance for the creation of physiologic waveform databases to demonstrate reasonable assurance of the safety and effectiveness of alarm system algorithms*
- ANSI/AAMI/IEC 60601-1-8+Amd 1, *Medical electrical equipment—Part 1-8: General requirements for basic safety and essential performance—Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
- AAMI/IEC TIR80001-2-5, *Application of risk management for IT-networks incorporating medical devices—Part 2-5: Guidance on distributed alarm systems*

Standards are available for purchase at **www.aami.org/store**.