American National Standard

ANSI/AAMI 2700-2-1: 2022

Medical devices and medical systems—Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE): Part 2-1: Particular requirements for forensic data logging

AAMI
Advancing Safety in Health Technology

Medical devices and medical systems—Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE): Part 2-1: Particular requirements for forensic data logging

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Abstract: ANSI/AAMI 2700-2-1 is part of the AAMI 2700 family of standards to achieve safe integrated clinical environments (ICE) (ANSI/AAMI 2700-1). It was developed by the AAMI Interoperability Working Group (IOWG, SM-WG03) and is intended for use by medical device and platform manufacturers and system integrators. It provides requirements for the recording, storage, and playback of data to support safety, quality assurance, and forensic analysis for medical devices, applications, and platforms. This document supports safe and secure device interoperability by providing general functional, performance, security, and interoperability requirements of ICE data logging systems. It requires that logged data to be time-synchronized. Data may include patient waveform and parameters, images and video, configuration, settings, device capabilities of each ICE-connected device, and user and patient interactions with each device (e.g., button presses).

Keywords: data logging, forensic data logger, Integrated Clinical Environment, ICE, interoperability

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Committee representation

Association for the Advancement of Medical Instrumentation

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

Foreword

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The authors and the standards developing organization (SDO) shall not be held responsible for identifying any or all such patent rights.

This is the first edition.

The "ICE" family of standards has been proposed in ANSI/AAMI 2700-1 to consist of the following parts, under the general title *MEDICAL DEVICES and medical systems—Basic safety and essential performance of the patient-centric integrated clinical network environment (ICE).*

Part 1: General requirements and conceptual model, published as ANSI/AAMI 2700-1 (previously ASTM F2761-09 (13))

Part 2: Requirements for network control and equipment interface

Part 3: Requirements for device models

Part 4: Requirements for supervision

Part 5: Requirements for safe and reliable integration

Part 6: Particular requirements for the forensic DATA LOGGER – This standard (ANSI/AAMI 2700-2-1)

As the original standard was transitioned to an AAMI standard, the numbering system has been modified and updated. Particular Standards 2-6 are anticipated to be numbered as "AAMI 2700-2-n."

In this Standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples, and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN THIS STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In this standard, the conjunction "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- "shall" and "shall not" are used to express requirements;
- "should" and "should not" are used to express recommendations;
- "may" and "may not" are used to express permission;
- "can" and "cannot" are used as statements of possibility or capability;
- "might" and "might not" are used to express possibility;
- "must" is used for external constraints or obligations defined outside the document; "must" is not an alternative for "shall."

“Clauses, subclauses, and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).”

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the maintenance result date). At this date, the publication will be:

— reconfirmed;

— withdrawn;

— replaced by a revised edition; or

— amended.

The attention of Members is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended, or revised publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests.

Suggestions for improving this document are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of the ANSI/AAMI 2700-2-1:2022, *Medical devices and medical systems—Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE): Part 2-1: Particular requirements for forensic data logging* (ANSI/AAMI 2700-2-1:2022), but it does provide important information about the development and intended use of the document.

Introduction

Medical devices are essential for the practice of modern medicine. Many medical devices and single manufacturer multi-parameter monitoring systems currently have the capability to log settings and physiological and technical data to varying degrees. This data can include proprietary device performance metrics for technical troubleshooting and maintenance, and clinical data for patient care. Presently, DATA LOGs can be obtained from each individual device retrospectively when performing ADVERSE EVENT analysis, but even in the event that one device DATA LOG is fairly "complete," a single DATA LOG containing all the data from each of the MEDICAL DEVICES connected to the patient including data from the system used to connect the devices, is not available.

For example, in typical complex clinical environments (e.g., Operating Room, Intensive Care Unit, Emergency Department) obtaining the time-aligned integration of data streams from multiple devices – each with its own proprietary communication protocols and algorithms, time base, and physical interfaces – offers numerous challenges. An integrated time-aligned data logging capability is needed for the entire clinical environment in which the patient is being monitored or is receiving therapy – to include logging of network-communicated commands, user interaction with devices – such as keypresses, device connection and disconnection, physiologic and technical alarms, patient physiologic data, and other device status information. This contextually rich data source has an important role in the development of patient-centric data sets for developing smart and autonomous systems composed of applications including physiologic closed-loop control and real-time clinical decision support.

The availability of a DATA LOG is expected to provide enhanced retrospective analysis and mining capabilities of real time data from patient episodes, including:

a) Reconstruction of clinical workflow with respect to device operation and control.

b) Review of the sequence of events with common time-base time-stamped data.

c) Effective data analysis with associated patient ID.

d) Differentiation of manual user inputs (key press) from network transmitted commands (e.g., from an app).

e) Application of data science tools to analyze 'big data' sets.

These data logging capabilities are especially important in the risk management of automated or autonomous interoperable medical device systems.

ANSI/AAMI 2700-1:2019 *Medical devices and medical systems—Essential safety and performance requirements for equipment comprising the patient-centric INTEGRATED CLINICAL ENVIRONMENT (ICE)—Part 1: General requirements and conceptual model* (part 1 of this series of documents) established the general principles for the design, verification, and validation of a model-based integration system that enables the creation of an INTEGRATED CLINICAL ENVIRONMENT intended to facilitate cross-manufacturer medical device interoperability (heterogeneous interoperability), optionally including non-medical equipment.

This document is part 2-1 of the series, which focuses on the requirements for essential safety and performance of an ICE DATA LOGGER. Regulatory, technical, and clinical needs, particularly with respect to ADVERSE EVENT and incident reporting and investigation are influencing the development of this ICE system data logging standard, also known as the ICE DATA LOGGER. It is easily imagined that with the widespread availability of an integrated DATA STORE, opportunities for new and improved capabilities for real-time and retrospective clinical analytics, forensic data analysis of the ICE system and its components, quality assurance, and healthcare delivery organization and clinician credentialing will emerge.

This document is applicable to users and providers of data logging services and manufacturers of data loggers as described in ANSI/AAMI 2700-1, subclause 4.2.4, *Medical devices and medical systems—Essential safety requirements for equipment comprising the patient-centric INTEGRATED CLINICAL ENVIRONMENT (ICE)—Part 1: General requirements and conceptual model* (i.e., ICE standard).

Other parts of this standard series will focus on communication of patient data, requirements for safe local and remote medical device command and control, as well as other functionality necessary for the seamless creation of an INTEGRATED CLINICAL ENVIRONMENT. The approach defined and described by this series of standards for the INTEGRATED CLINICAL ENVIRONMENT (ICE) includes provisions for error resistance, and continual improvements in patient safety, treatment efficacy and workflow efficiency based on device interoperability and safe system integration.

Medical devices and medical systems—Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE): Part 2-1: Particular requirements for forensic data logging

1 Scope

This document provides general functional, performance, security, and interoperability requirements of ICE data logging systems including the recording and storage of data in support of forensic analysis of ICE systems. DATA LOGS, data logging, and data loggers can play an important role in maintaining and improving the basic safety and essential performance of INTEGRATED CLINICAL ENVIRONMENTS by enabling the forensic assessment of the ICE system and its components.

NOTE 1: In other industries, this type of data logger is referred to as a "black box recorder."

NOTE 2: The ICE data logger is not required to be capable of real-time clinical/patient monitoring.

NOTE 3: The ICE data logger is intended to provide a data store that can be used to assist in confirming that the ICE system and its components were operating as intended.

Clinical patient management is outside the scope of this standard.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

AAMI TIR71:2017 – *Guidance for logging of alarm system data*

ANSI/AAMI 2700-1:2019 (formerly ASTM F2761 09(2013)), *Medical devices and medical systems—Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE)—Part 1: General requirements and conceptual model*

ANSI/AAMI/IEC 62304:2006/Amd 1:2015, *Medical device software – Software life cycle processes*

ISO 14155:2011, *Clinical investigation of* medical devices *for human subjects -- Good clinical practice*

IEC 60601-1-8:2006, 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* Amendment 1:2012

IEC 80001-1:2012, *Application of risk management for IT-networks incorporating* medical devices

UL 2900-1:2017, *Standard for Safety, Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems*

