Technical Information Report

AAMI TIR75: 2019

Factors to consider when multi-vendor devices interact via an electronic interface: Practical applications and examples

AAMI

Advancing Safety in Health Technology

Factors to consider when multi-vendor devices interact via an electronic interface: Practical applications and examples

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AAMI

Abstract: Guidance on factors that manufacturers should consider when designing, testing, and monitoring interoperable medical devices.

Keywords: interoperability, connectivity, risk management

AAMI Technical Information Report

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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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Committee representation

Association for the Advancement of Medical Instrumentation
Interoperability Working Group

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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.

Foreword

This technical information report (TIR) was developed by the AAMI Interoperability Working Group under the auspices of the AAMI Software Standards Committee.

Manufacturers of medical devices that are intended to interoperate have the responsibility to manage the risks of this functionality. In many cases, there are unique factors that manufacturers should consider when designing, testing, and monitoring interoperable medical devices.

The objective of this TIR is to provide guidance to medical device manufacturers on assessing and managing the risks associated with interoperable medical devices.

NOTE—This foreword does not contain provisions of AAMI TIR75, *Factors to consider when multi-vendor devices interact via an electronic interface: Practical applications and examples* (AAMI TIR75), but it does provide important information about the development and intended use of the document.

Introduction

A number of factors impact the management of risks in a multi-vendor system of interoperating medical and non-medical devices. It would be useful if individual manufacturers could consider them in a common and consistent manner when developing or adding connectivity-based functionality to their products. Some factors are unique to connected products. This document provides a discussion of the context for important factors and questions that manufacturers should consider when designing, testing, installing, and maintaining connected medical devices. Consistent consideration of a structured set of factors can facilitate exchange of interoperability-related information, especially those factors impacting risks, among the stakeholders involved in development, deployment, and use of connected devices.

Failure can occur in the connection and connected functionality that impact the risk profile of a device in many ways, including issues of data quality, availability, authenticity, and integrity, as well as problems such as data blockage, backlogged data, and dropped data. Functionality that depends on connections includes command and control, remote access, remote software updates, and other functions controlled via connections. The factors described in this document are intended to shed light on how a manufacturer may better understand and plan for these risks. Evaluation of the impact of failure of connected functionality needs to include the potential to impact overall device functionality, not just the failure of connected functionality.

This technical information report is primarily intended to aid manufacturers as they design and develop products intended to interact with other devices via an electronic interface. It may also be useful as a reference when integrating devices from multiple vendors into a system via an electronic interface; maintaining a multi-vendor, interoperable system; auditing, inspecting, and evaluating the factors involved in an interoperable system; and selecting devices or systems for procurement or implementation.

Factors to consider when multi-vendor devices interact via an electronic interface: Practical applications and examples

1 Scope

1.1 General

This document is intended to assist stakeholders in considering risks associated with connectivity when designing, testing, installing, and maintaining devices that interact via an electronic interface. It identifies specific factors that should be considered as part of risk management activities. It also provides examples where these factors are used to identify causes, hazards, and hazardous situations related to interoperability. These factors can be relevant throughout the lifecycle of connected products.

This list of factors is not intended to be comprehensive. Instead, it is meant to direct design teams to think about common elements requiring dedicated attention when assessing the risk of the connected functionality of the medical device. These elements are referred to as, “Factors to Consider.”

This TIR applies to the following:

- devices with added or modified connectivity; and
- newly developed devices that are intended to connect via an electronic interface for the purposes of interoperability.

1.2 Exclusions

This TIR does not specifically consider the following:

- devices not connected by an electronic interface; and
- basic issues of medical device safety not directly related to data interoperability, e.g., electrical safety.

2 References

The following referenced documents are useful for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 14971, *Medical devices—Application of risk management to medical devices*

Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices—Guidance for Industry and Food and Drug Administration Staff. U.S. Food and Drug Administration. September 2017.

IEC 60601-1-8, *Medical electrical equipment—Part 1-8: General requirements for safety—Collateral standard: General requirements, test and guidance for alarm systems in medical electrical equipment and medical electrical systems*

3 Factors to consider

The interconnection of devices and systems in a healthcare setting presents the potential for significant innovation in healthcare, ranging from simple tracking of inventory to medical devices that interact autonomously to control functions that protect patients’ lives. However, incorporating an electronic interface into a medical device also poses risks that are typically not posed by an unconnected device.

