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Health informatics—Device interoperability

Part 40101: Foundational—Cybersecurity—Processes for vulnerability assessment

IEEE Engineering in Medicine and Biology Society

Developed by the
IEEE 11073™ Standards Committee

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IEEE SA Standards Board

Abstract: For Personal Health Devices (PHDs) and Point-of-Care Devices (PoCDs), an iterative, systematic, scalable, and auditable approach to identification of cybersecurity vulnerabilities and estimation of risk is defined by this standard. The standard presents one approach to iterative vulnerability assessment that uses the Spoofing, Tampering, Repudiation, Information Disclosure, Denial of Service, and Elevation of Privilege (STRIDE) classification scheme and the embedded Common Vulnerability Scoring System (eCVSS). The assessment includes system context, system decomposition, pre-mitigation scoring, mitigation, and post-mitigation scoring and iterates until the remaining vulnerabilities are reduced to an acceptable level of risk.

Keywords: cybersecurity, embedded Common Vulnerability Scoring System, IEEE 11073-40101™, medical device communication, Personal Health Devices, Point-of-Care Devices, STRIDE, vulnerability assessment

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Introduction

This introduction is not part of IEEE Std 11073-40101-2020, Health informatics—Device interoperability—Part 40101: Foundational—Cybersecurity—Processes for vulnerability assessment.

Users of Personal Health Devices (PHDs) and Point-of-Care Devices (PoCDs) have implicit expectations on convenience, connectivity, accessibility, and security of data. For example, they expect to connect PHDs/PoCDs to their mobile devices and dashboards, view the data in the cloud, and easily share the information with clinicians or care providers. In some cases, the users themselves are taking action to build connections between PHDs/PoCDs, mobile devices, and the cloud to create the desired system. While many manufacturers are working on solving PHD/PoCD connectivity challenges with proprietary solutions, no standardized approach exists to provide secure plug-and-play interoperability.

The ISO/IEEE 11073 PHDs/PoCDs family of standards, Bluetooth Special Interest Group profiles and services specifications, and the Continua Design Guidelines (PCHAlliance [B7]) were developed to specifically address plug-and-play interoperability of PHDs/PoCDs (e.g., physical activity monitor, physiological monitor, pulse oximeter, sleep apnoea breathing therapy equipment, ventilator, insulin delivery device, infusion pump, continuous glucose monitor). In this context, the following terms have specific meanings:

- *Interoperability* is the ability of client components to communicate and share data with service components in an unambiguous and predictable manner as well as to understand and use the information that is exchanged (PCHAlliance [B7]).
- *Plug and play* are all the user has to do to make a connection—the systems automatically detect, configure, and communicate without any other human interaction (ISO/IEEE 11073-10201 [B5]).[1]

Within the context of *secure* plug-and-play interoperability, cybersecurity is the process and capability of preventing unauthorized access or modification, misuse, denial of use, or the unauthorized use of information that is stored on, accessed from, or transferred to and from a PHD/PoCD. This standard describes the process part of cybersecurity for transport-independent applications and information profiles of PHDs/PoCDs. These profiles define data exchange, data representation, and terminology for communication between agents (e.g., pulse oximeters, sleep apnoea breathing therapy equipment) and connected devices (e.g., health appliances, set top boxes, cell phones, personal computers, monitoring cockpits, critical care dashboards).

For PHDs/PoCDs, this standard defines an iterative, systematic, scalable, and auditable approach to identification of cybersecurity vulnerabilities and estimation of risk. This standard presents one approach to iterative vulnerability assessment that uses the Spoofing, Tampering, Repudiation, Information Disclosure, Denial of Service, and Elevation of Privilege (STRIDE) classification scheme and the embedded Common Vulnerability Scoring System (eCVSS). The assessment includes system context, system decomposition, pre-mitigation scoring, mitigation, and post-mitigation scoring and iterates until the remaining vulnerabilities are reduced to an acceptable level of risk.

[1] The numbers in brackets correspond to the numbers of the bibliography in Annex A.

Contents

Health informatics—Device interoperability

Part 40101: Foundational—Cybersecurity—Processes for vulnerability assessment

1. Overview

1.1 General

Many Personal Health Devices (PHDs) and Point-of-Care Devices (PoCDs) provide vital support for people living with chronic disease or experiencing a life-threatening medical event. Cybersecurity attacks on vulnerable devices may lead to the alteration of prescribed therapy (e.g., sleep apnoea breathing therapy, insulin therapy) or to information disclosure that results in insurance or identity fraud or in direct or indirect patient harm. Companies subject to a successful cybersecurity attack may suffer financial harm and a negative reputation.

Manufacturers of regulated PHDs/PoCDs are required to address cybersecurity vulnerabilities through a detailed risk analysis of use cases specific to the device. Of the various approaches to vulnerability assessment, some are not repeatable, scalable, systematic, and auditable. Both manufacturers and regulatory bodies may benefit from a common approach to vulnerability assessment based on threat modeling capable of analyzing PHDs/PoCDs across domains and described in a trusted open consensus standard. Likewise, patients, providers, and payers benefit from consistent and sufficient information provided in PHD/PoCD labeling.

This standard is based on the PHD Cybersecurity Standards Roadmap findings (IEEE white paper [B4]) and presents a repeatable, scalable, systematic, and auditable approach to vulnerability assessment.[2] While a specific approach is provided, any comparable approach is appropriate and will be compatible with the mitigations found in IEEE Std 11073-40102™ [B3]. In Figure 1, this standard is depicted by the top row, and IEEE Std 11073-40102 is depicted by the bottom row.

[2] The numbers in brackets correspond to the numbers of the bibliography in Annex A.