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Health informatics—Device interoperability

Part 40102: Foundational—Cybersecurity—Capabilities for mitigation

IEEE Engineering in Medicine and Biology Society

Developed by the
IEEE 11073™ Standards Committee

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Approved 24 September 2020

IEEE SA Standards Board

Abstract: For Personal Health Devices (PHDs) and Point-of-Care Devices (PoCDs), a security baseline of application layer cybersecurity mitigation techniques is defined by this standard for certain use cases or for times when certain criteria are met. The mitigation techniques are based on an extended confidentiality, integrity, and availability (CIA) triad and are described generally to allow manufacturers to determine the most appropriate algorithms and implementations. A scalable information security toolbox appropriate for PHD/PoCD interfaces is specified that fulfills the intersection of requirements and recommendations from the National Institute of Standards and Technology (NIST) and the European Network and Information Security Agency (ENISA). A mapping of this standard to the NIST cybersecurity framework; IEC TR 80001-2-2; and the Spoofing, Tampering, Repudiation, Information Disclosure, Denial of Service, and Elevation of Privilege (STRIDE) classification scheme is defined.

Keywords: cybersecurity, IEEE 11073-40102™, medical device communication, mitigation techniques, Personal Health Devices, Point-of-Care Devices

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Introduction

This introduction is not part of IEEE Std 11073-40102-2020, Health informatics—Device interoperability—Part 40102: Foundational—Cybersecurity—Capabilities for mitigation.

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 [B20]) 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 [B20]).
— *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 [B13]).[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 capability 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 a security baseline of application layer cybersecurity mitigation techniques for certain use cases or for times when certain criteria are met. This standard provides a scalable information security toolbox appropriate for PHD/PoCD interfaces, which fulfills the intersection of requirements and recommendations from the National Institute of Standards and Technology (NIST) and the European Network and Information Security Agency (ENISA). This standard maps to the NIST cybersecurity framework [B15]; IEC TR 80001-2-2 [B8]; and the Spoofing, Tampering, Repudiation, Information Disclosure, Denial of Service, and Elevation of Privilege (STRIDE) classification scheme. The mitigation techniques are based on an extended confidentiality, integrity, and availability (CIA) triad and are described generally to allow manufacturers to determine the most appropriate algorithms and implementations.

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

Contents

Health informatics—Device interoperability

Part 40102: Foundational—Cybersecurity—Capabilities for mitigation

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 PHDs/PoCDs may be required to support application layer end-to-end information security. PHD/PoCD data exchange may be conducted over an untrusted transport. Also, a requirement may exist for multiple access control levels (e.g., restricted read access, restricted write access, full read access, full write access, full control access). Most PHDs/PoCDs have limited resources (e.g., processing power, memory, energy). Current standardized PHD/PoCD data exchange assumes the exchange is secured by other means, such as secure transport channel. This assumption requires that manufacturers define solutions by, for example, extensions or using mechanisms on the transport layer. Such solutions limit the usage of PHD/PoCD data exchange standards and restricts interoperability.

This standard is based on the PHD Cybersecurity Standards Roadmap findings (IEEE white paper [B10]) and defines a security baseline of application layer cybersecurity mitigation techniques for PHD/PoCD interfaces.[2] The mitigation techniques address an extended confidentiality, integrity, and availability (CIA) triad and allow manufacturers to implement the most appropriate algorithms. The mitigation techniques are not dependent on a specific risk management process. Instead they are applicable to any approach, including the vulnerability assessment described in IEEE Std 11073-40101™ [B9]. In Figure 1, IEEE Std 11073-40101 is depicted by the top row, and this standard is depicted by the bottom row.

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