BSI Standards Publication

Health informatics - Device interoperability

Part 40101: Foundational - Cybersecurity - Processes for vulnerability assessment

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English Version

Health informatics - Device interoperability - Part 40101: Foundational - Cybersecurity - Processes for vulnerability assessment (ISO/IEEE 11073-40101:2022)

Informatique de santé - Interopérabilité des dispositifs - Partie 40101: Fondamentaux - Cybersécurité - Processus pour l'évaluation de la vulnérabilité (ISO/IEEE 11073-40101:2022)

Medizinische Informatik - Geräteinteroperabilität - Teil 40101: Grundlagen - Cybersicherheit - Prozess zur Schwachstellenanalyse (ISO/IEEE 11073-40101:2022)

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Full document details: BS EN ISO/IEEE 11073-40101:2022

Contents

Page

European foreword **3**

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Health informatics—Device interoperability

Part 40101: Foundational—Cybersecurity—Processes for vulnerability assessment

Developed by the

IEEE 11073 Standards Committee
of the
IEEE Engineering in Medicine and Biology Society

Approved 24 September 2020

IEEE SA Standards Board

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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.

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Contents

1. Overview 11
1.1 General 11
1.2 Scope 12
1.3 Purpose 12
1.4 Word usage 12

2. Definitions, acronyms, and abbreviations 13
2.1 Definitions 13
2.2 Acronyms and abbreviations 13

3. Risk management 13

4. Software of unknown provenance 14

5. Multi-component system vulnerability assessment 14

6. Threat modeling 14
6.1 General 14
6.2 Data flow diagram 15
6.3 STRIDE classification scheme 15

7. Scoring system 15
7.1 General 15
7.2 CVSS 15
7.3 eCVSS 16

8. Process for vulnerability assessment 17
8.1 Iterative vulnerability assessment 17
8.2 System context 17
8.3 System decomposition 20
8.4 Scoring 22
8.5 Mitigation 24
8.6 Iteration 24

Annex A (informative) Bibliography 25

Annex B (informative) STRIDE 26

Annex C (informative) embedded Common Vulnerability Scoring System 30
C.1 Overview 30
C.2 Scoring equations in pseudo code 35
C.3 Test vectors 36

Annex D (informative) Microsoft TMT2Excel Macro 37

Annex E (informative) Example insulin delivery device vulnerability assessment 40
E.1 General 40
E.2 System context 40
E.3 Threat model 41
E.4 Pre- and post-mitigation vulnerability assessment scores 42

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