



**SLOVENSKI STANDARD**  
**SIST EN ISO/IEEE 11073-40102:2022**

**01-julij-2022**

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**Zdravstvena informatika - Interoperabilnost naprav - 40102. del: Temeljno -  
Kibernetska varnost - Sposobnosti za ublažitev (ISO/IEEE 11073-40102:2022)**

Health informatics - Device interoperability - Part 40102: Foundational - Cybersecurity -  
Capabilities for mitigation (ISO/IEEE 11073-40102:2022)

iTeh STANDARD PREVIEW  
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Informatique de santé - Interopérabilité des dispositifs - Partie 40102: Fondamentaux -  
Cybersécurité - Capacités d'atténuation (ISO/IEEE 11073-40102:2022)

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**ICS:**

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology
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**SIST EN ISO/IEEE 11073-40102:2022**      **en,fr,de**



EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO/IEEE 11073-  
40102**

March 2022

ICS 35.240.80

English Version

**Health informatics - Device interoperability - Part 40102:  
Foundational - Cybersecurity - Capabilities for mitigation  
(ISO/IEEE 11073-40102:2022)**

Informatique de santé - Interopérabilité des dispositifs  
- Partie 40102: Fondamentaux - Cybersécurité -  
Capacités d'atténuation (ISO/IEEE 11073-40102:2022)

Medizinische Informatik - Geräteinteroperabilität - Teil  
40102: Grundlagen - Cybersicherheit - Möglichkeiten  
zur Schadensbegrenzung (ISO/IEEE 11073-  
40102:2022)

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**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

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## European foreword

This document (EN ISO/IEEE 11073-40102:2022) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 "Health informatics" the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2022, and conflicting national standards shall be withdrawn at the latest by September 2022.

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# INTERNATIONAL ISO/IEEE STANDARD 11073-40102

First edition  
2022-03

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## Health informatics — Device interoperability —

### Part 40102: Foundational — Cybersecurity — Capabilities for mitigation

*Informatique de santé — Interopérabilité des dispositifs —  
Partie 40102: Fondamentaux — Cybersécurité — Capacités  
d'atténuation*

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## Foreword

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ISO/IEEE 11073-40102 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-40102-2020) and drafted in accordance with its editorial rules. It was adopted, under the "fast-track procedure" defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE, by Technical Committee ISO/TC 215, *Health informatics*.

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## Health informatics—Device interoperability

# Part 40102: Foundational—Cybersecurity— Capabilities for mitigation

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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**ISO/IEEE 11073-40102:2022(E)**

**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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