EESTI STANDARD

EVS-EN ISO 11073-20701:2020

Health informatics - Device interoperability - Part 20701: Point-of-care medical device communication - Service oriented medical device exchange architecture and protocol binding (ISO/IEEE 11073-20701:2020)

EESTI STANDARDIKESKUS **EVS**
ESTONIAN CENTRE FOR STANDARDISATION

EVS-EN ISO 11073-20701:2020

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11073-20701:2020 sisaldab Euroopa standardi EN ISO 11073-20701:2020 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11073-20701:2020 consists of the English text of the European standard EN ISO 11073-20701:2020.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 01.04.2020.	Date of Availability of the European standard is 01.04.2020.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN ISO 11073-20701

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English Version

Health informatics - Device interoperability - Part 20701: Point-of-care medical device communication - Service oriented medical device exchange architecture and protocol binding (ISO/IEEE 11073-20701:2020)

Informatique de santé - Interopérabilité des dispositifs - Partie 20701: Communication entre dispositifs médicaux sur le site des soins - Architecture d'échange orientée services entre dispositifs médicaux et liaison par protocole (ISO/IEEE 11073-20701:2020)

Medizinische Informatik - Kommunikation patientennaher medizinischer Geräte - Teil 20701: Service-Orientierte Architektur und Protokoll für Medizingeräte-Kommunikation (ISO/IEEE 11073-20701:2020)

This European Standard was approved by CEN on 18 February 2020.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 11073-20701:2020) 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 October 2020, and conflicting national standards shall be withdrawn at the latest by October 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO/IEEE 11073-20701:2020 has been approved by CEN as EN ISO 11073-20701:2020 without any modification.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

ISO/IEEE 11073-20701 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-20701-2018) 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*.

A list of all parts in the ISO/IEEE 11073 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This introduction is not part of IEEE Std 11073-20701-2018, Health Informatics—Point-of-care medical device communication—Part 20701: Service-Oriented Medical Device Exchange Architecture and Protocol Binding.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. They provide automatic and detailed electronic data capture of patient vital signs information and device operational data. The primary goals are to:

— Provide real-time plug-and-play interoperability for medical devices

— Facilitate the efficient exchange of vital signs and medical device data, acquired at the Point-of-Care (PoC), in all health care environments

"Real-time" means that data from multiple devices can be retrieved, time correlated, and displayed or processed in fractions of a second. "Plug-and-play" means that all the clinician has to do is to make the connection—the Participants automatically detect, configure, and communicate without any other human interaction.

"Efficient exchange of medical device data" means that information that is captured at the PoC (e.g., patient vital signs data) can be received, parsed, and interpreted by many different types of applications without unnecessary loss of information. The standards are especially targeted at acute, surgical, and continuing care devices, such as patient monitors, ventilators, infusion pumps, ECG devices, endoscopic camera system, insufflators, endoscopic light sources, dissectors, etc. They comprise a family of standards that can be bound to one another to provide optimized connectivity for devices at the Point-of-Care.

Within the context of the ISO/IEEE 11073 family of standards for PoC medical device communication, this standard defines an architecture for service-oriented distributed PoC medical devices and medical IT systems. It defines a binding of the Participant, Discovery, and Communication Model defined in IEEE Std 11073-10207 to the profile for transport over Web Services defined in IEEE Std 11073-20702. Moreover, a binding to Network Time Protocol (NTP) and Differentiated Services (DiffServ) is defined to satisfy time synchronization and transport Quality of Service requirements.

Contents

Health informatics—Point-of-care medical device communication

Part 20701: Service-Oriented Medical Device Exchange Architecture and Protocol Binding

1. Overview

1.1 Scope

The scope of this standard is a service-oriented medical device architecture and communication protocol specification for distributed system of Point-of-Care (PoC) medical devices and medical IT systems that need to exchange data or safely control networked PoC medical devices. It identifies the functional components, their communication relationships as well as the binding of the components and communication relationships to protocol specifications.

1.2 Purpose

This standard defines an architecture for service-oriented distributed PoC medical devices and medical IT systems. It describes a binding of the Participant and Communication model as defined in IEEE Std 11073-10207™ to Medical Devices Communication Profile for Web Services (MDPWS) as defined in IEEE Std 11073-20702™ for transport over Web Services.[1] Moreover, a binding to the Network Time Protocol (NTP) and Differentiated Services (DiffServ) is specified for time synchronization and transport Quality of Service requirements.

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so each referenced document is cited in text and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

IEEE Std 11073-10207-2017, IEEE Health informatics—Point-of-care medical device communication—Part 10207: Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication. [2, 3]

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[1] Information on references can be found in Clause 2.
[2] IEEE publications are available from the Institute of Electrical and Electronics Engineers (http://standards.ieee.org/).

IEEE Std 11073-20701-2018
Health informatics—Point-of-care medical device communication
Part 20701: Service-Oriented Medical Device Exchange Architecture and Protocol Binding

IEEE Std 11073-20702-2016, IEEE Health informatics—Point-of-care medical device communication—Part 20702: Medical Devices Communication Profile for Web Services.

IETF RFC 1305, Network Time Protocol (Version 3) Specification, Implementation and Analysis, D. Mills, March 1992. Available at https://tools.ietf.org/html/rfc1305.

IETF RFC 1769, Simple Network Time Protocol (SNTP), D. Mills, March 1995. Available at https://tools.ietf.org/html/rfc1769.

IETF RFC 2474, Definition of the Differentiated Services Field (DS Field) in the IPv4 and IPv6 Headers, K. Nichols et al., December 1998. Available at https://tools.ietf.org/html/rfc2474.

IETF RFC 2475, An Architecture for Differentiated Services, S. Blake et al., December 1998. Available at https://tools.ietf.org/html/rfc2475.

IETF RFC 4330, Simple Network Time Protocol (SNTP) Version 4 for IPv4, IPv6 and OSI, D. Mills, January 2006. Available at https://tools.ietf.org/html/rfc4330.

IETF RFC 5227, IPv4 Address Conflict Detection, S. Cheshire, July 2008. Available at https://tools.ietf.org/html/rfc5227.

IETF RFC 5246, The Transport Layer Security (TLS) Protocol Version 1.2, T. Dierks et al., August 2008. Available at https://tools.ietf.org/html/rfc5246.txt.

IETF RFC 5905, Network Time Protocol Version 4: Protocol and Algorithms Specification, D. Mills et al., June 2010. Available at https://tools.ietf.org/html/rfc5905.

ISO/IEEE Std 11073-10101:2004, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.[4]

3. Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause.[5]

ALERT: Synonym for the combination of patient-related physiological alarms, technical alarms and equipment user advisory signals.

NOTE 1—Patient-related physiological alarms as well as technical alarms are ALARM SIGNALs indicating the presence of ALARM CONDITIONs. An ALERT CONDITION is an ALARM CONDITION if the priority is LOW PRIORITY, MEDIUM PRIORITY, or HIGH PRIORITY and where the origin is a Physiological or Technical. See IEC 60601-1-8:2006+AMD1:2012 [B3].[6, 7]

NOTE 2—Equipment user advisory signals are INFORMATION SIGNALs indicating the presence of conditions that are not ALARM CONDITIONs. An ALERT CONDITION is not an ALARM CONDITION if the priority is neither LOW PRIORITY nor MEDIUM PRIORITY nor HIGH PRIORITY. See IEC 60601-1-8:2006+AMD1:2012 [B3].

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[3] The IEEE standards or products referred to in Clause 2 are trademarks owned by the Institute of Electrical and Electronics Engineers, Incorporated.
[4] ISO/IEEE publications are available from the International Organization for Standardization (http://www.iso.org/) and the Institute of Electrical and Electronics Engineers (http://standards.ieee.org/).
[5] *IEEE Standards Dictionary Online* is available at: http://dictionary.ieee.org.
[6] The numbers in brackets correspond to those of the bibliography in Annex C.
[7] Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement this standard.