

**Health informatics - Personal health device
communication - Part 20601: Application profile -
Optimized exchange protocol (ISO/IEEE 11073-
20601:2016, including Cor 1:2016)**

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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 10.08.2016.	Date of Availability of the European standard is 10.08.2016.
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ICS 35.240.80

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EUROPEAN STANDARD

EN ISO 11073-20601

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2016

ICS 35.240.80

Supersedes EN ISO 11073-20601:2011

English Version

**Health informatics - Personal health device
communication - Part 20601: Application profile -
Optimized exchange protocol (ISO/IEEE 11073-
20601:2016, including Cor 1:2016)**

Informatique de santé - Communication entre
dispositifs de santé personnels - Partie 20601: Profil
d'application - Protocole d'échange optimisé (ISO/IEEE
11073-20601:2016, y compris Cor 1:2016)

Medizinische Informatik - Kommunikation von Geräten
für die persönliche Gesundheit - Teil 20601:
Anwendungsprofil - Optimiertes
Datenübertragungsprotokoll (ISO/IEEE 11073-
20601:2016, einschließlich Cor 1:2016)

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COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

This document (EN ISO 11073-20601:2016 including Cor 1:2016) 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of an identical text or by endorsement, at the latest by February 2017, and conflicting national standards shall be withdrawn at the latest by February 2017.

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The text of ISO/IEEE 11073-20601:2016 including Cor 1:2016 has been approved by CEN as EN ISO 11073-20601:2016 without any modification.

Introduction

This introduction is not part of IEEE Std 11073-20601-2014, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol.

ISO and IEEE 11073 standards enable communication between medical devices and external computer systems. This standard and corresponding IEEE 11073-104zz standards address a need for a simplified and optimized communication approach for personal health devices, which may or may not be regulated devices. These standards align with, and draw upon, the existing clinically focused standards to provide easy management of data from either a clinical or personal health device.

This document addresses a need for an openly defined, independent standard for converting the collected information into an interoperable transmission format so the information can be exchanged between agents and managers.

Other closely related standards include the following:

- IEEE Std 11073-00103-2012 [B5]^a provides an overview of the personal health space and defines the underlying use cases and usage models.
- ISO/IEEE 11073-10101 [B16] documents the nomenclature terms that can be used.
- ISO/IEEE 11073-10201:2004 [B17] documents the extensive domain information model (DIM) leveraged by this standard.
- ISO/IEEE 11073-104zz standards define specific device specializations. For example, ISO/IEEE 11073-10404 [B18] defines how interoperable pulse oximeters work.
- ISO/IEEE 11073-20101:2004 [B21] defines the medical device encoding rules (MDER) used in this standard.

^a The numbers in brackets correspond to the numbers of the bibliography in Annex K.

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Health informatics—Personal health device communication

Part 20601: Application profile— Optimized Exchange Protocol

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1. Overview

1.1 Scope

Within the context of the ISO/IEEE 11073 personal health device standard family, this standard defines an optimized exchange protocol and modeling techniques to be used by implementers of personal health devices to create interoperability between device types and vendors. This standard establishes a common framework for an abstract model of personal health data available in transport-independent transfer syntax required to establish logical connections between systems and to provide presentation capabilities and services needed to perform communication tasks. The protocol is optimized to personal health usage requirements and leverages commonly used methods and tools wherever possible.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes). Interoperability is key to growing the potential market for these devices and enabling people to be better informed participants in the management of their health.

1.3 Context

Figure 1 shows categories and typical devices supporting the personal health space. Agents (e.g., blood pressure monitors, weighing scales, and pedometers) collect information about a person (or persons) and transfer the information to a manager (e.g., cell phone, health appliance, or personal computer) for collection, display, and possible later transmission. The manager may also forward the data to remote support services for further analysis. The information is available from a range of domains including disease management, health and fitness, or aging independently applications.

The communication path between agent and manager is assumed to be a logical point-to-point connection. Generally, an agent communicates with a single manager at any point in time. A manager may communicate with multiple agents simultaneously using separate point-to-point connections.

The overlay shows the focus area of the IEEE 11073™ Personal Health Devices Working Group. The primary concentration is the interface and data exchange between the agents and manager. However, this interface cannot be created in isolation by ignoring the remainder of the solution space. Remaining cognizant of the entire system helps to move data reasonably from the agents all the way to the remote support services when necessary. This path may include converting the data format, exchange protocols, and transport protocols across different interfaces. Much of the standardization effort is outside of the scope of the Personal Health Devices Working Group; however, aligning all standardization efforts allows data to flow seamlessly through the overall set of systems.

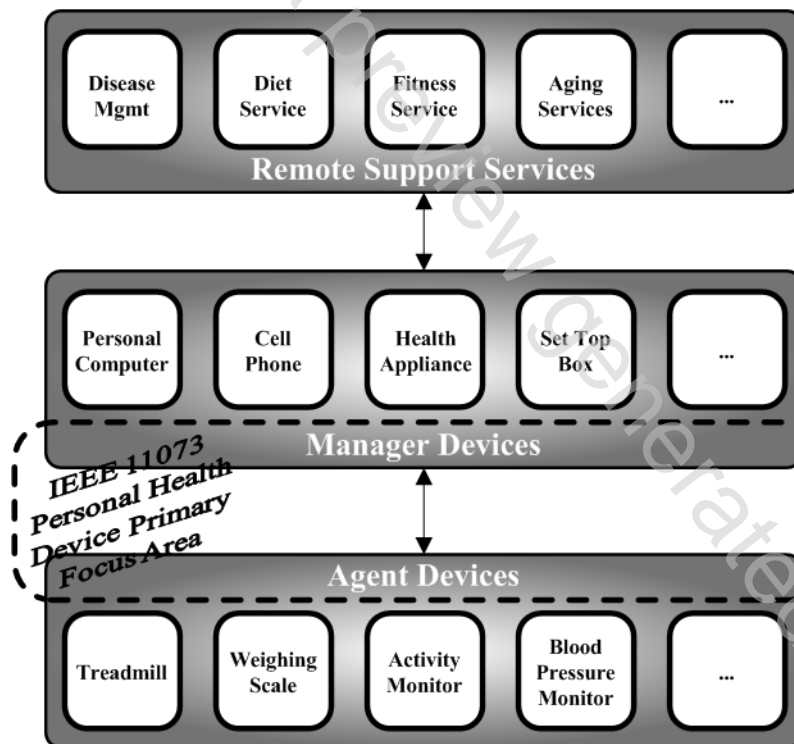


Figure 1—Overall context of work

Figure 2 shows a hierarchical view of the architecture of an agent or manager superimposed with a view of the related standards. The application layers are, for the most part, not specific to any particular transport. Where necessary, this standard identifies assumptions that require direct support by a transport or a “shim” layer above the transport. This approach allows support for various transports. The definition of the transports is outside of the scope of this standard and the working group.

Above the transport layer is the Optimized Exchange Protocol (described in this standard). This protocol consists of two aspects: the application layer services and the definition of the data exchange protocol between agents and managers. The application layer services provide the protocol for connection management and reliable transfer of actions and data between agent and manager. The data exchange protocol defines the commands, agent configuration information, data format, and overall protocol. The Optimized Exchange Protocol provides the basis to support any type of agent. For a specific device type, the reader is directed to the device specialization for that agent to understand the capabilities of the device and its implementation according to this standard. The device specialization indicates which aspects of this standard to comprehend and where further information to implement the device is found.

Above the exchange protocol are device specializations that describe specific details relative to the particular agent (e.g., blood pressure monitor, weighing scale, or pedometer). The specializations describe the details of how these agents work and act as a detailed description for creating a specific type of agent. Additionally, they provide reference to a related standard for further details. The standard numbers reserved for device specializations range from IEEE Std 11073-10401 through IEEE Std 11073-10499, inclusive. When the collection of standards is being referenced, the term *IEEE 11073-104zz* is used where *zz* could be any number in the range from 01 to 99, inclusive.

Some device specializations describe broad categories of device types (e.g., the IEEE 11073-10441™ model device types that promote cardiovascular activity such as step counters or exercise cycles). Other device specializations have a narrow focus on a single device type (e.g., IEEE 11073-10408™ model thermometers). Specializations that address one or more device types may also define *profiles*. A profile further constrains the model defined in a specialization to increase interoperability (e.g., the step counter profile utilizes a limited portion of IEEE 11073-10441 modeling).

The IEEE Std 11073-00103-2012 [B5]¹ technical report describes the overall personal health space with further definition of the underlying use cases and usage models.

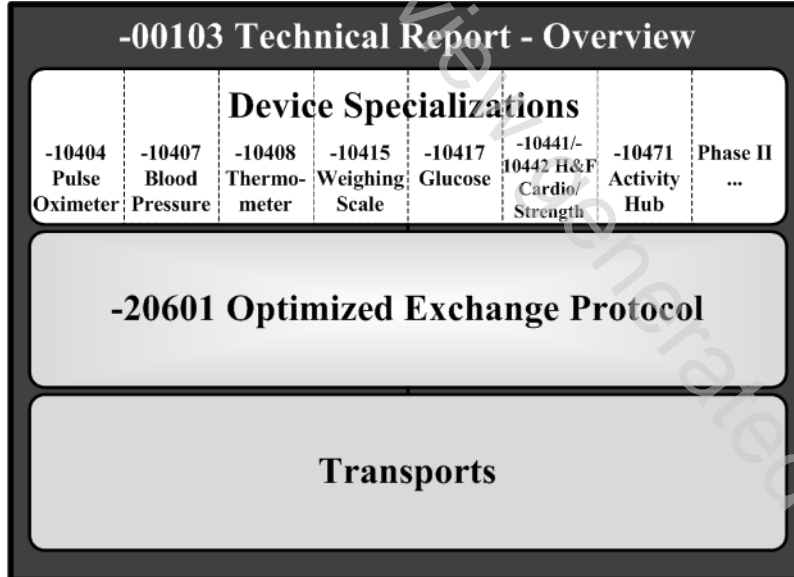


Figure 2—Document map

¹ The numbers in brackets correspond to the numbers of the bibliography in Annex K.

The personal health device specializations are not being created independently of all other standards. There are a number of existing standards generated for clinical environments upon which these standards draw. Figure 3 shows the relationship to the remainder of the IEEE 11073 documents. There are two types of relationships:

- Drawing ideas and/or content from the other documents (dashed lines)
- Leveraging information from the other document and introducing new content into that document to support this standard (solid lines)

This standard imports information from ISO/IEEE 11073-10201:2004 [B17] and ISO/IEEE 11073-20101:2004 [B21] as normative annexes. If there is a discrepancy between these standards, this standard takes priority. Because of the reuse of constructs from these standards, some of the names appear to be more clinically focused [e.g., medical device system (MDS) instead of personal health device system]; however, to maintain consistency, the traditional names have been preserved.

This standard replicates relevant portions of ISO/IEEE 11073-10101 [B16] and incorporates new nomenclature codes.

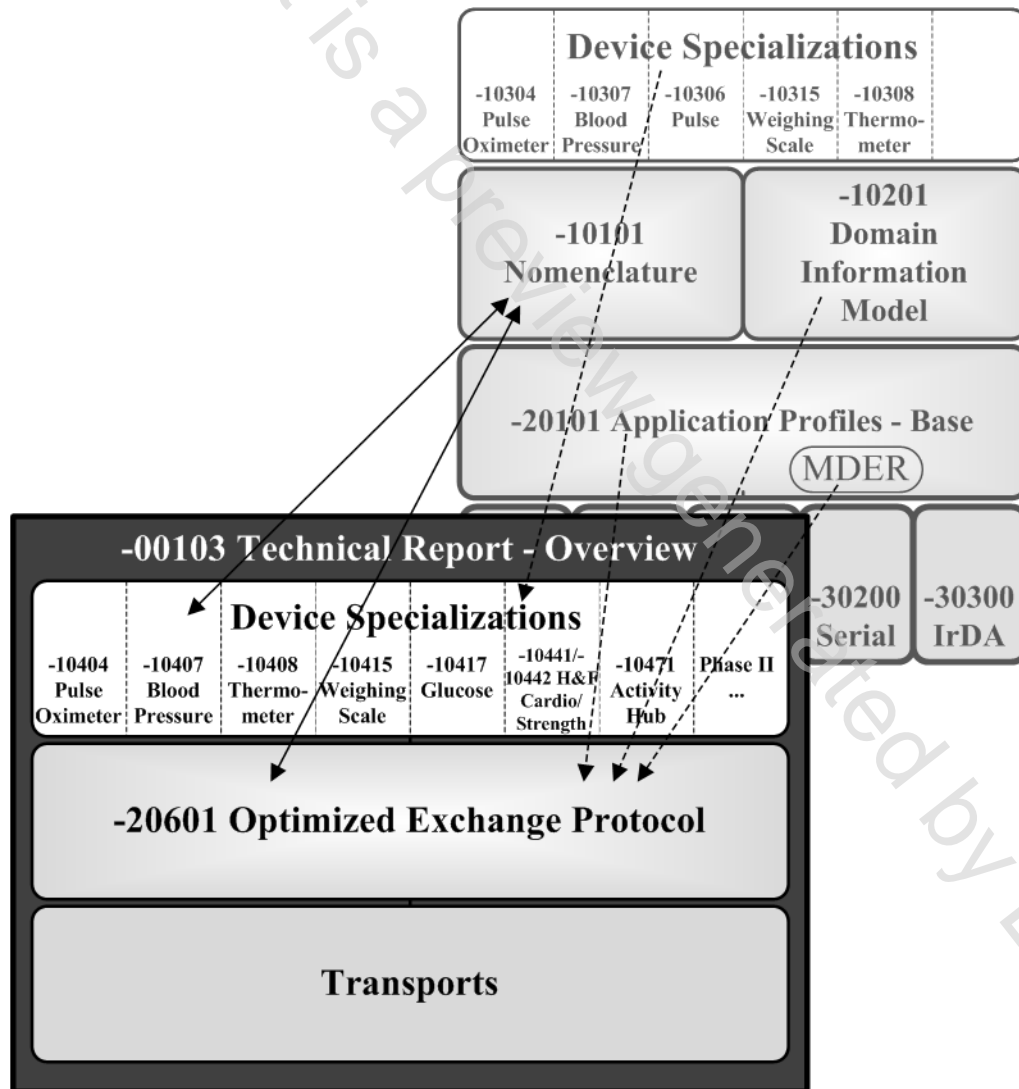


Figure 3—Relationship to other IEEE 11073 documents

2. Normative references

The following referenced documents are indispensable for the application of this standard (i.e., they must be understood and used; therefore, each referenced document is cited in the text and its relationship to this standard 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 802[®]-2014, IEEE Standard for Local and Metropolitan Area Networks: Overview and Architecture.^{2,3}

IEEE Std 1541[™]-2002 (Reaff 2008), IEEE Standard for Prefixes for Binary Multiples.

ISO/IEC 80000-13:2008, Quantities and units — Part 13: Information science and technology.^{4,5}

ITU-T Rec. X.667 (Sept. 2004), Information technology — Open Systems Interconnection — Procedures for the operation of OSI Registration Authorities: Generation and registration of universally unique identifiers (UUIDs) and their use as ASN.1 object identifier components.⁶

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For this standard, the following terms and definitions apply. *The IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause.⁷

agent: A node that collects and transmits personal health data to an associated manager.

attribute: Data representing a property of an object. Attributes, together with actions, define an object.

AttributeChangeSet: The set of attribute value changes that represents an atomic update of an object. The medical device system (MDS) or scanner is notified when an AttributeChangeSet is completed. Collections of these AttributeChangeSets are mapped by the MDS or scanner into one of the ObservationScan structures in a scan event report that is sent to the manager. The manager updates its object with the set of attribute value changes contained in the ObservationScan before deriving any semantic behavior.

compute engine: *See: manager.*

confirmed: An application-level, completion notification service mechanism. For EVENT REPORT services (i.e., the data plane), confirmation allows the agent to know when the manager has “accepted responsibility” for a piece of data so that the agent can delete that piece of data. For the ACTION, GET, and SET services (i.e., the control plane), confirmation allows the manager to know when the agent has “completed” the requested transaction.

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⁴ This standard cancels and replaces sections 3.8 and 3.9 of IEC 60027-2 (2005).

⁵ ISO/IEC publications are available from the International Organization for Standardization (<http://www.iso.ch/>). ISO/IEC publications are also available in the United States from Global Engineering Documents (<http://global.ihs.com/>). Electronic copies are available in the United States from the American National Standards Institute (<http://www.ansi.org/>).

⁶ ITU-T publications are available from the International Telecommunications Union (<http://www.itu.int/>).

⁷ *The IEEE Standards Dictionary Online* subscriptions are available at http://www.ieee.org/portal/innovate/products/standard/standards_dictionary.html