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Sundhedsinformatik – Interoperabilitet mellem enheder – Del 20601: Kommunikation med personligt sundhedsudstyr – Anvendelsesprofil – Optimeret udvekslingsprotokol

Health informatics – Device interoperability – Part 20601: Personal health device communication – Application profile – Optimized exchange protocol (ISO/IEEE 11073-20601:2022)

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English Version

Health informatics - Device interoperability - Part 20601: Personal health device communication - Application profile - Optimized exchange protocol (ISO/IEEE 11073-20601:2022)

Informatique de santé - Interopérabilité des dispositifs - Partie 20601: Communication entre dispositifs de santé personnels - Profil d'application - Protocole d'échange optimisé (ISO/IEEE 11073-20601:2022)

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European foreword

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Third edition
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Health informatics — Device interoperability —

Part 20601: Personal health device communication — Application profile — Optimized exchange protocol

Informatique de santé — Interopérabilité des dispositifs —

Partie 20601: Communication entre dispositifs de santé personnels — Profil d'application — Protocole d'échange optimisé

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This third edition cancels and replaces the second edition (ISO/IEEE 11073-20601:2016), which has been technically revised. It also incorporates the Technical Corrigendum ISO/IEEE 11073-20601:2016/Cor 1:2016.

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(Revision of IEEE Std 11073-20601-2014)

Health informatics—Personal health device communication

Part 20601: Application profile—Optimized Exchange Protocol

Developed by the

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

Approved 5 September 2019

IEEE SA Standards Board

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Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a common framework for making 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 is described in this standard. The protocol is optimized to personal health usage requirements and leverages commonly used methods and tools wherever possible.

Keywords: IEEE 11073-20601™, medical device communication, personal health devices

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Introduction

This introduction is not part of IEEE Std 11073-20601-2019, 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™ [B6][1] provides an overview of the personal health space and defines the underlying use cases and usage models.

— 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.

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

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Health informatics—Personal health device communication

Part 20601: Application profile—Optimized Exchange Protocol

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.

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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.

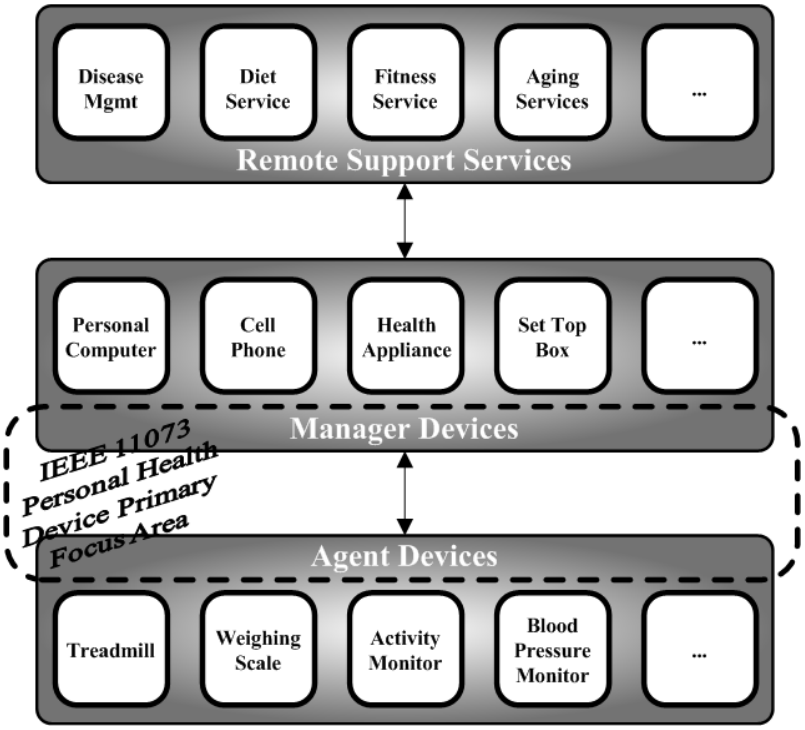

Figure 1—Overall context of work

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 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 the scope of this standard and the working group.

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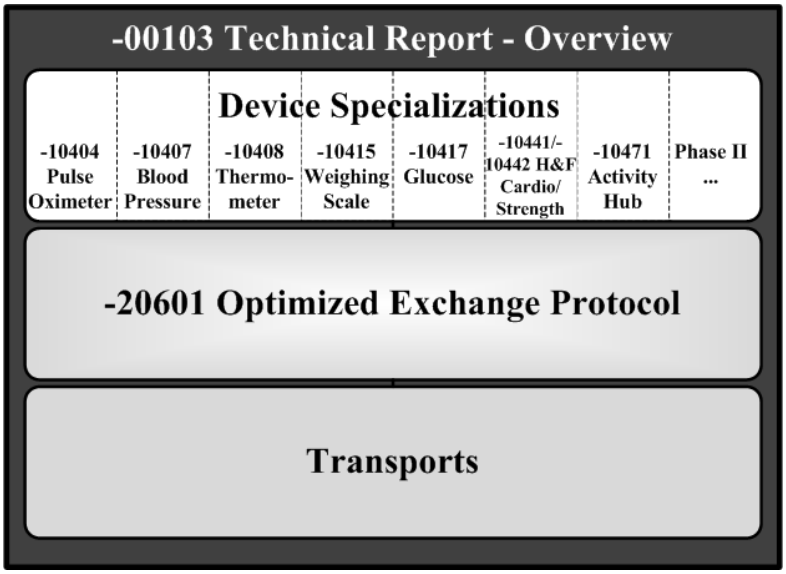

Figure 2—Document map

Above the transport layer is the Optimized Exchange Protocol. 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).

Two device specializations are defined by this document itself, “hydra” and “generic”. These two specializations are not covered in a separate IEEE 11073-104zz standard. These specializations are defined to support signaling of multi-function or generic agents and managers at the transport level. See 7.4.3.4 for more details.

Note that, in the medical device system (MDS) object defined in this specification, an agent can indicate the full list of supported specializations.

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IEEE Std 11073-00103™ [B6][2] technical report describes the overall personal health space with further definition of the underlying use cases and usage models.

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).

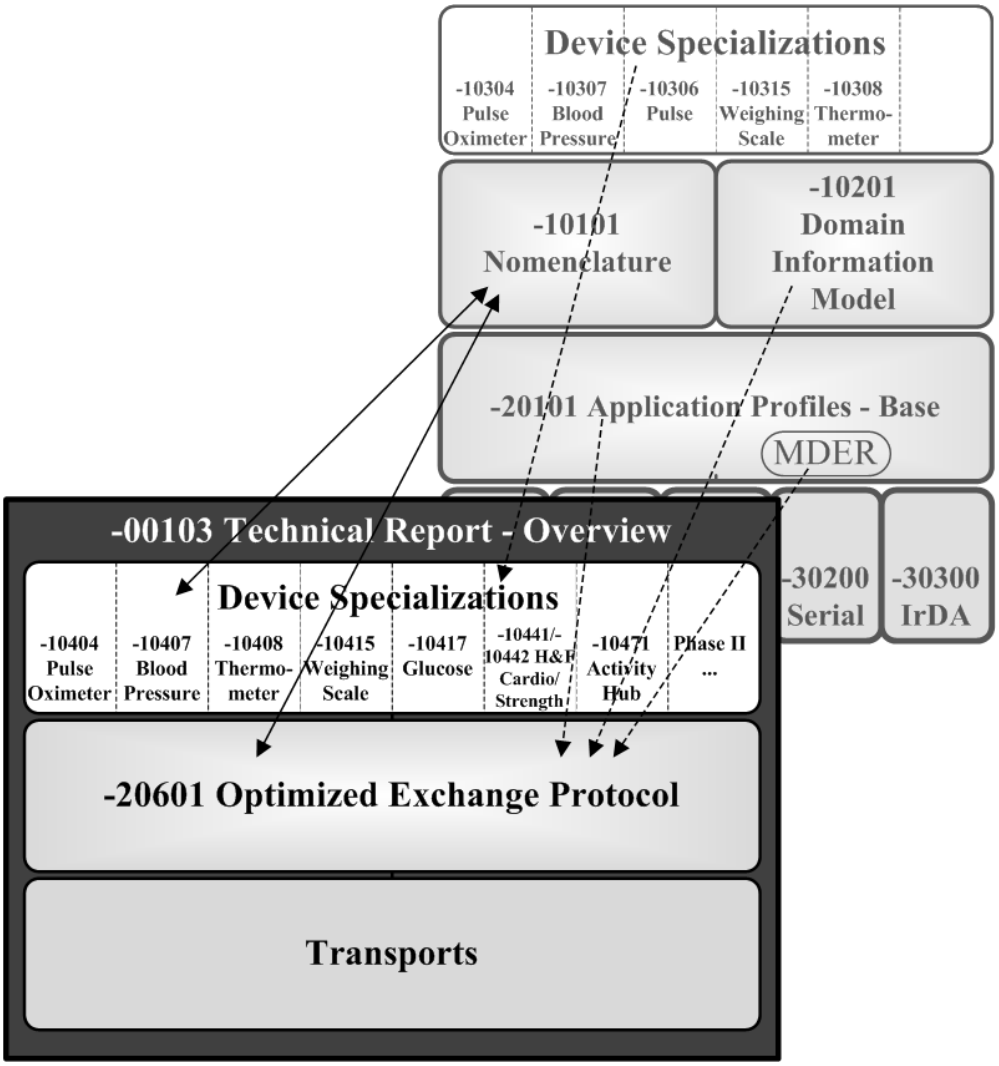

Figure 3—Relationship to other IEEE 11073 documents

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

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

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takes priority. Because of the reuse of constructs from these standards, some of the names appear to be more clinically focused (e.g., MDS instead of personal health device system); however, to maintain consistency, the traditional names have been preserved.

This standard reproduces relevant portions of IEEE Std 11073-1010.[3] Between this standard, IEEE Std 11073-10101, and IEEE 11073-104zz, all required nomenclature codes for implementation are documented. New codes may be defined in newer versions/revisions of each of these documents. In the case of a conflict, where one term code has been assigned to two separate semantic concepts with different RefIDs, in general the oldest definition that is in actual use should take precedence. The same policy applies when one RefID has two different code values assigned in different specifications. The resolution of such conflicts will be determined through joint action by the responsible working groups and other stakeholders, and any corrective actions will be published as corrigenda.

1.4 Word usage

The word *shall* indicates mandatory requirements strictly to be followed in order to conform to the standard and from which no deviation is permitted (*shall* equals *is required to*).[4,5]

The word *should* indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others; or that a certain course of action is preferred but not necessarily required (*should* equals *is recommended that*).

The word *may* is used to indicate a course of action permissible within the limits of the standard (*may* equals *is permitted to*).

The word *can* is used for statements of possibility and capability, whether material, physical, or causal (*can* equals *is able to*).

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 802®-2014, IEEE Standard for Local and Metropolitan Area Networks: Overview and Architecture.[6,7]

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

IEEE Std 11073-10101™, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.

[3] Information about normative references can be found in Clause 2.
[4] The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.
[5] The use of *will* is deprecated and cannot be used when stating mandatory requirements; *will* is only used in statements of fact.
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ISO/IEC 80000-13:2008, Quantities and units—Part 13: Information science and technology.[8, 9]

ITU-T Rec. X.667 (09/2004), 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.[10]

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

[9] 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/).

[10] ITU-T publications are available from the International Telecommunications Union (http://www.itu.int/).

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