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Health informatics — Point-of-care medical device communication —

Part 20601: Application profile — Optimized exchange protocol

Informatique de santé — Communication entre dispositifs médicaux sur le site des soins —

Partie 20601: Profil d'application — Protocole d'échange optimisé

Reference number
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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.

IEEE Standards documents are developed within the IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Association (IEEE-SA) Standards Board. The IEEE develops its standards through a consensus development process, approved by the American National Standards Institute, which brings together volunteers representing varied viewpoints and interests to achieve the final product. Volunteers are not necessarily members of the Institute and serve without compensation. While the IEEE administers the process and establishes rules to promote fairness in the consensus development process, the IEEE does not independently evaluate, test, or verify the accuracy of any of the information contained in its standards.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO/IEEE 11073-20601 was prepared by the 11073 Committee of the Engineering in Medicine and Biology Society of the IEEE (as IEEE Std 11073-20601-2008). It was adopted by Technical Committee ISO/TC 215, *Health informatics*, in parallel with its approval by the ISO member bodies, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE. Both parties are responsible for the maintenance of this document.

ISO/IEEE 11073 consists of the following parts, under the general title *Health informatics — Personal health device communication (text in parentheses gives a variant of subtitle)*:

— *Part 10101: (Point-of-care medical device communication) Nomenclature*

— *Part 10201: Domain information model*

— *Part 10404: Device specialization — Pulse oximeter*

— *Part 10407: Device specialization — Blood pressure monitor*

— *Part 10408: (Point-of-care medical device communication) Device specialization — Thermometer*

— *Part 10415: (Point-of-care medical device communication) Device specialization — Weighing scale*

— *Part 10417: Device specialization — Glucose meter*

— *Part 10471: (Point-of-care medical device communication) Device specialization — Independant living activity hub*

— *Part 20101: (Point-of-care medical device communication) Application profiles — Base standard*

— *Part 20601: (Point-of-care medical device communication) Application profile — Optimized exchange protocol*

— *Part 30200: (Point-of-care medical device communication) Transport profile — Cable connected*

— *Part 30300: (Point-of-care medical device communication) Transport profile — Infrared wireless*

Introduction

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:

— ISO/IEEE P11073-00103 [B8][a] provides an overview of the personal health space and defines the underlying use cases and usage models.

— ISO/IEEE 11073-10101 [B12] documents the nomenclature terms that can be used.

— ISO/IEEE 11073-10201:2004 [B13] documents the extensive domain information model (DIM) leveraged by this standard.

— ISO/IEEE 11073-104zz standards define specific device specializations. For example, ISO/IEEE P11073-10404 [B9] defines how interoperable pulse oximeters work.

— ISO/IEEE 11073-20101:2004 [B14] 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.

Health informatics — Point-of-care medical device communication —

Part 20601:
Application profile — Optimized exchange protocol

1. Overview

1.1 Scope

Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard defines 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. The protocol is optimized to personal health usage requirements and leverages commonly used methods and tools wherever possible.

1.2 Purpose

This document addresses a need for an openly defined, independent standard for converting the information profile into an interoperable transmission format so the information can be exchanged to and from personal telehealth devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes).

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 ensure that data can reasonably move 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.

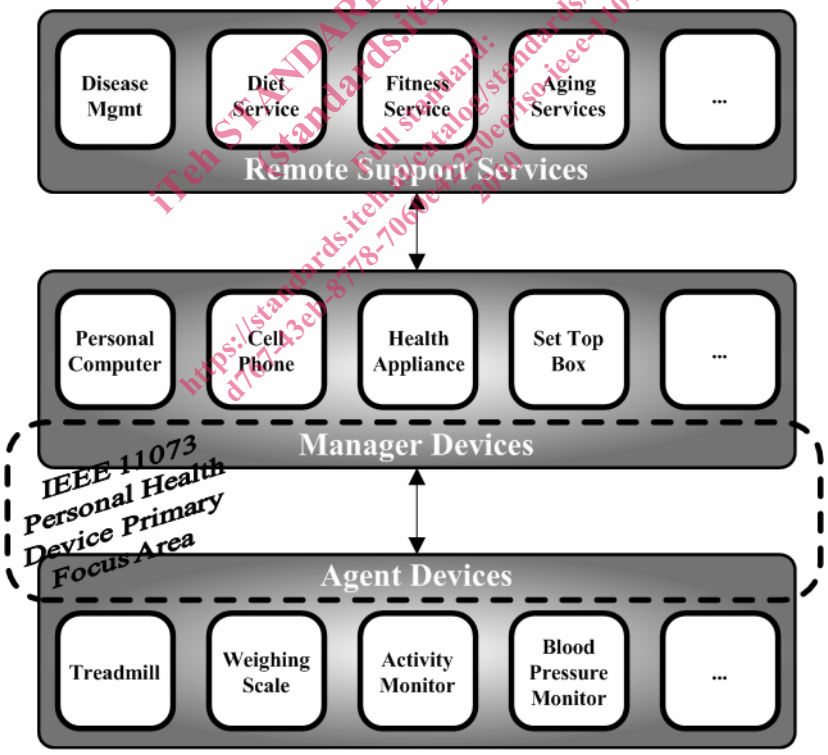

Figure 1 —Overall context of work

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 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.

The ISO/IEEE P11073-00103 [B8][1] technical report describes the overall personal health space with further definition of the underlying use cases and usage models.

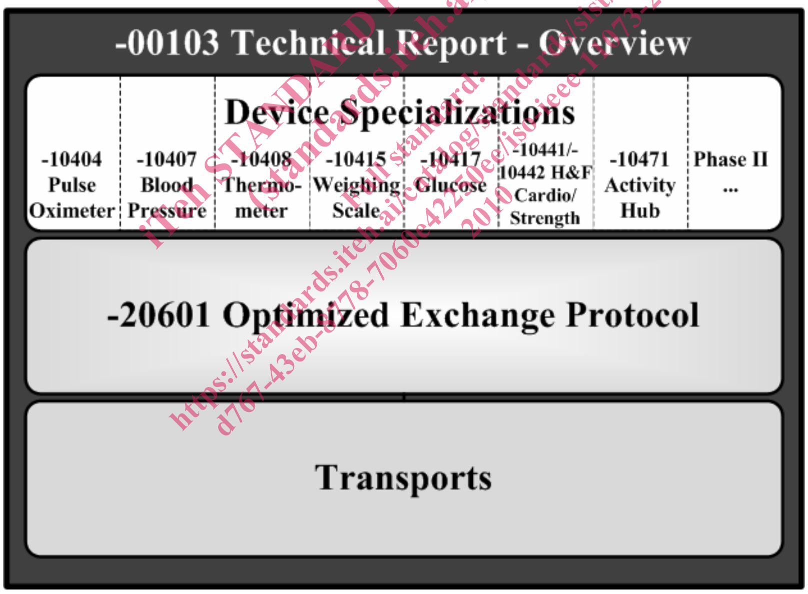

Figure 2 —Document map

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:

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

— 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 [B13] and ISO/IEEE 11073-20101:2004 [B14] 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 [B12] and incorporates new nomenclature codes.

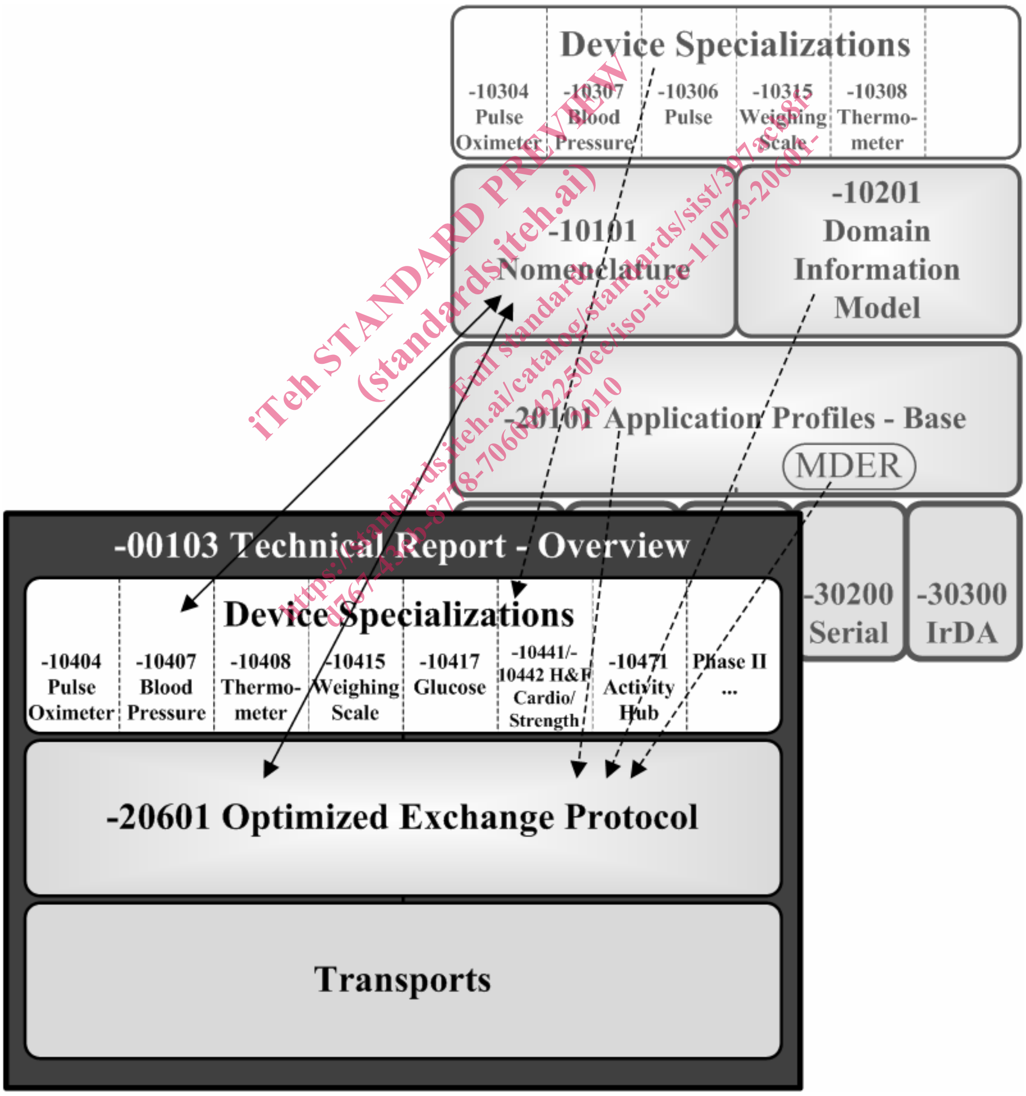

Figure 3 —Relationship to other IEEE 11073 documents

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®-2001, IEEE Standard for Local and Metropolitan Area Networks: Overview and Architecture.[2]

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.[3]

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this standard, the following terms and definitions apply. *The Authoritative Dictionary of IEEE Standards* [B6] should be referenced for terms not defined in this clause.

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

3.1.2 compute engine: *See:* **manager**.

3.1.3 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 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.

3.1.4 device: A physical device implementing either an agent or manager role.

3.1.5 handle: An unsigned 16-bit number that is locally unique and identifies one of the object instances within an agent.

3.1.6 manager: A node receiving data from one or more agent systems. Examples of managers include a cellular phone, health appliance, set top box, or computer system.

3.1.7 personal health device: A device used in personal health applications.

3.1.8 personal telehealth device: *See:* **personal health device**.

3.2 Acronyms and abbreviations

ASCII	American Standard Code for Information Interchange[4]
ASN.1	Abstract Syntax Notation One
APDU	application protocol data unit

[2] IEEE publications are available from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854, USA (http://standards.ieee.org/).
[3] ITU-T publications are available from the International Telecommunications Union, Place des Nations, CH-1211, Geneva 20, Switzerland/Suisse (http://www.itu.int/).
[4] Note that throughout this standard the term ASCII is used to mean the character set as defined in ISO/IEC 646 (1991) [B7].