SVENSK STANDARD
SS-EN ISO 11073-20601:2016

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**Hälso- och sjukvårdsinformatik – Kommunikation med personlig utrustning för hälsovården –
Del 20601: Applikationstyp – Optimerat protokoll för datautbyte
(ISO/IEEE 11073-20601:2016, including Cor 1:2016)**

**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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The European Standard EN ISO 11073-20601:2016 has the status of a Swedish Standard. This document contains the official English version of EN ISO 11073-20601:2016.

This standard supersedes the Swedish Standard SS-EN ISO 11073-20601:2011, edition 1.

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EUROPEAN STANDARD

EN ISO 11073-20601

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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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.

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.

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.

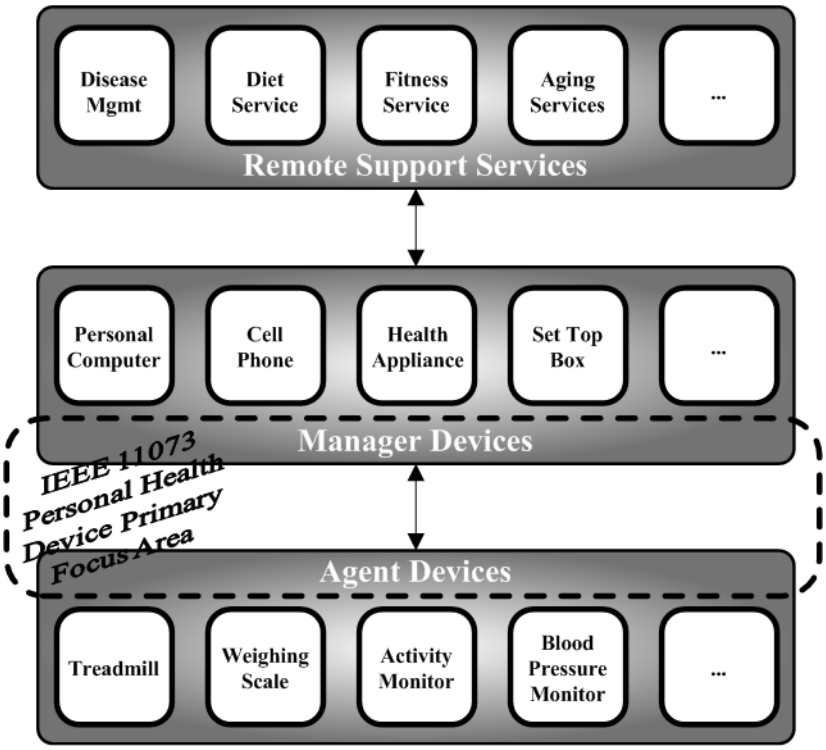

Figure 1—Overall context of work

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 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.

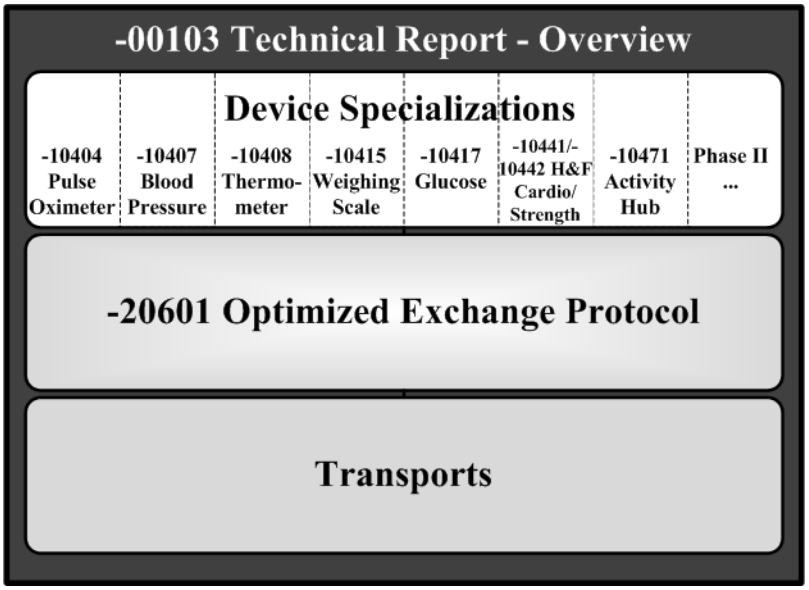

Figure 2—Document map

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