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Part 10419: Device specialization — Insulin pump

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Partie 10419: Spécialisation des dispositifs — Pompe à insuline

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This second edition cancels and replaces the first edition (ISO 11073-10419:2016), which has been technically revised.

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Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of communication between personal telehealth insulin pump devices and compute engines (e.g., cell phones, personal computers, personal health appliances, set top boxes), in a manner that enables plug-and-play interoperability, is established in this standard. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. The standard defines a common core of communication functionality for personal telehealth insulin pump devices.

Keywords: IEEE 11073-10419™, insulin pump, medical device communication, personal health devices

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Introduction

This introduction is not part of IEEE Std 11073-10419-2017, Health informatics—Personal health device communication—Part 10419: Device Specialization—Insulin Pump.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in ISO/IEEE 11073-20601:2016 and describes a specific, interoperable communication approach for insulin pumps.[1] These standards align with, and draw on, the existing clinically focused standards to provide support for communication of data from clinical or personal health devices (PHDs).

[1]Information on references can be found in Clause 2.

Contents

Health informatics—Personal health device communication

Part 10419: Device Specialization—Insulin Pump

1. Overview

1.1 Scope

This standard establishes a normative definition of communication between personal telehealth insulin pump devices (agents) and managers (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability. It leverages work done in other ISO/IEEE 11073 standards including existing terminology, information profiles, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments, restricting optionality in base frameworks in favor of interoperability. This standard defines a common core functionality of personal telehealth insulin pump devices.

In the context of personal health devices (PHDs), an insulin pump is a medical device used for the administration of insulin in the treatment of diabetes mellitus, also known as continuous subcutaneous insulin infusion (CSII) therapy.

This standard provides the data modeling according to ISO/IEEE 11073-20601 and does not specify the measurement method.

1.2 Purpose

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

1.3 Context

See ISO/IEEE 11073-20601:2016 for an overview of the environment within which this standard is written.[2]

[2] Information on references can be found in Clause 2.

This standard defines the device specialization for the insulin pump, being a specific agent type, and provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on ISO/IEEE 11073-20601:2016, which in turn draw information from both ISO/IEEE 11073-10201:2004 [B8] and ISO/IEEE 11073-20101:2004 [B9].[3] The medical device encoding rules (MDER) used within this standard are fully described in ISO/IEEE 11073-20601:2016.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B6] and ISO/IEEE 11073-10101a:2015 [B7] and adds new nomenclature codes for the purposes of this standard. Among these standards and ISO/IEEE 11073-20601:2016, all required nomenclature codes for implementation are documented.

NOTE—In this standard, ISO/IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize ISO/IEEE 11073-20601, where zz can be any number from 01 to 99, inclusive.[4]

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used; therefore, 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.

ISO/IEEE 11073-20601:2016, Health informatics—Personal health device communication—Part 20601: Application Profile—Optimized Exchange Protocol.[5]

See Annex A for all informative material referenced by this standard.

3. Definitions, acronyms, and abbreviations

3.1 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.[6]

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

artificial pancreas: A system combining diabetes devices to provide similar functionality as a pancreas. Examples include linking a continuous glucose monitor to an insulin pump to automatically reduce or increase insulin infusion based upon specified thresholds of measured interstitial glucose.

basal insulin: Insulin required to cover the basic insulin needs of the body.

basal rate: Rate of continuously delivered insulin to cover the basic insulin needs of the body.

[3] The numbers in brackets correspond to the numbers of the bibliography in Annex A.
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