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STN	**Zdravotnícka informatika. Osobné komunikačné zdravotné zariadenie. Časť 10419: Špecializácia zariadenia. Inzulínová pumpa (ISO/IEEE 11073-10419: 2016).**	**STN EN ISO 11073-10419** 84 8037

Health informatics - Personal health device communication - Part 10419: Device specialization - Insulin pump (ISO/IEEE 11073-10419:2016)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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NORME EUROPÉENNE

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EN ISO 11073-10419

June 2016

ICS 35.240.80

English Version

Health informatics - Personal health device communication - Part 10419: Device specialization - Insulin pump (ISO/IEEE 11073-10419:2016)

Informatique de santé - Communication entre dispositifs de santé personnels - Partie 10419: Spécialisation du dispositif - Pompe à insuline (ISO/IEEE 11073-10419:2016)

Medizinsche Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10419: Gerätespezifikation - Insulinpumpe (ISO/IEEE 11073-10419:2016)

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European foreword

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Part 10419: Device specialization — Insulin pump

Informatique de santé — Communication entre dispositifs de santé personnels

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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 10102: (Point-of-care medical device communication) Nomenclature: Annotated ECG*

— *Part 10103: (Point-of-care medical device communication) Nomenclature: Implantable device, cardiac*

— *Part 10201: (Point-of-care medical device communication) Domain information model*

— *Part 10404: Device specialization — Pulse oximeter*

— *Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)*

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

— *Part 10408: Device specialization — Thermometer*

— *Part 10415: Device specialization — Weighing scale*

— *Part 10417: Device specialization — Glucose meter*

— *Part 10418: Device specialization — International Normalized Ratio (INR) monitor*

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— *Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)*

— *Part 10471: Device specialization — Independant living activity hub*

— *Part 10472: Device specialization — Medication monitor*

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

— *Part 20601: 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*

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— *Part 91064: (Standard communication protocol) Computer-assisted electrocardiography*

— *Part 92001: (Medical waveform format) — Encoding rules [Technical Specification]*

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. Appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards are leveraged. The use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability are specified. A common core of communication functionality for personal telehealth insulin pump devices is defined.

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 11073-10419-2015, 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 11073-20601:2010[1] and describes a specific, interoperable communication approach for insulin pumps. 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.

[1]For information on references, see Clause 2.

Contents

Health informatics—Personal health device communication

Part 10419: Device Specialization—Insulin Pump

1. Overview

1.1 Scope

The scope of this standard is to establish 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, 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 the ISO/IEEE 11073-20601 standard, and does not specify the measurement method.

1.2 Purpose

This standard addresses the need for an openly defined, independent standard that support information exchange to and from personal health devices and compute engines (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 heath.

1.3 Context

See IEEE Std 11073-20601™-2014[1] for an overview of the environment within which this standard is written.

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 IEEE Std 11073-20601-2014, which in turn draw information from both ISO/IEEE 11073-10201:2004 [B7][2] and ISO/IEEE 11073-20101:2004 [B8]. The medical device encoding rules (MDERs) used within this standard are fully described in IEEE Std 11073-20601-2014.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B6] and adds new nomenclature codes for the purposes of this standard. Among this standard and IEEE Std 11073-20601-2014, all required nomenclature codes for implementation are documented.

NOTE 1—IEEE Std 11073-20601-2014 is a revision of ISO/IEEE 11073-20601:2010 (and its amendment IEEE Std 11073-20601a). It contains new material and corrections and does not copy the content of ISO/IEEE 11073-20601:2010. Throughout this standard, a reference to IEEE Std 11073-20601-2014 refers to the document that is obtained after applying this new material and corrections to ISO/IEEE 11073-20601:2010.[3]

NOTE 2—In this standard, ISO/IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601-2014, where zz can be any number from 01 to 99, inclusive.

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so that 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 11073-20601-2014, Health informatics—Personal health device communication—Application Profile—Optimized Exchange Protocol.[4,5]

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

[1] Information on references can be found in Clause 2.
[2] The numbers in brackets correspond to those of the bibliography in Annex A.
[3] Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.
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