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Health informatics - Personal health device communication - Part 10419: Device specialization - Insulin pump (ISO/IEEE 11073-10419:2019)

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This standard includes the English version of the European Standard.

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English Version

Health informatics - Personal health device communication - Part 10419: Device specialization - Insulin pump (ISO/IEEE 11073-10419:2019)

Informatique de santé - Communication entre dispositifs de santé personnels - Partie 10419: Spécialisation des dispositifs - Pompe à insuline (ISO/IEEE 11073-10419:2019)

Medizinische Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10419: Gerätespezifikation - Insulinpumpe (ISO/IEEE 11073-10419:2019)

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Contents

Page

European foreword..... 3

European foreword

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This corrected version of ISO/IEEE 11073-10419:2016 incorporates the following corrections:

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— *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*

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

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

ISO/IEEE 11073-10419:2016(E)

IEEE Std 11073-10419™-2015

Health informatics—Personal health device communication

Part 10419: Device Specialization—Insulin Pump

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Approved 16 February 2015

IEEE-SA Standards Board

ISO/IEEE 11073-10419:2016(E)

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

1. Overview 1
1.1 Scope 1
1.2 Purpose 2
1.3 Context 2

2. Normative references 2

3. Definitions, acronyms, and abbreviations 3
3.1 Definitions 3
3.2 Acronyms and abbreviations 4

4. Introduction to ISO/IEEE 11073 personal health devices 5
4.1 General 5
4.2 Introduction to ISO/IEEE 11073-20601 modeling constructs 6
4.3 Compliance with other standards 6

5. Insulin pump device concepts and modalities 7
5.1 General 7
5.2 Device types 8
5.3 Collected data 8
5.4 Stored data 14
5.5 Scheduled data 15

6. Insulin pump domain information model 15
6.1 Overview 15
6.2 Class extensions 15
6.3 Object instance diagram 15
6.4 Types of configuration 17
6.5 Profiles 18
6.6 Medical device system object 18
6.7 Numeric objects 21
6.8 Real-time sample array objects 35
6.9 Enumeration objects 36
6.10 PM-store objects 41
6.11 Schedule-store objects 46
6.12 Scanner objects 55
6.13 Class extension objects 55
6.14 Insulin pump information model extensibility rules 56

7. Insulin pump service model 56
7.1 General 56
7.2 Object access services 56
7.3 Object access event report services 58

8. Insulin pump communication model 59
8.1 Overview 59
8.2 Communications characteristics 59
8.3 Association procedure 60
8.4 Configuring procedure 61
8.5 Operating procedure 63
8.6 Time synchronization 64

9. Test associations 64
9.1 Behavior with standard configuration 64
9.2 Behavior with extended configurations 64

10. Conformance 64
10.1 Applicability 64
10.2 Conformance specification 65
10.3 Levels of conformance 65
10.4 Implementation conformance statements 66

Annex A (informative) Bibliography 71

Annex B (normative) Any additional ASN.1 definitions 72
B.1 Device status and insulin pump status bit mapping 72

Annex C (normative) Allocation of identifiers 74
C.1 General 74
C.2 Definitions of terms and codes 74
C.3 Systematic derivations of terms and codes 76

Annex D (informative) Message sequence examples 85

Annex E (normative) Schedule-store class 87
E.1 Schedule-store class 87
E.2 Schedule-segment class 91

Annex F (normative) Schedule class ASN.1 definitions 97
F.1 ACTION-method-related data types 97
F.2 Data types for new object attributes and object services 97
F.3 Data protocol definitions 100

Annex G (informative) The schedule-store concept 102
G.1 General 102
G.2 Schedule-store object hierarchy 103

Annex H (informative) Scedule communication model 107
H.1 Operating procedure 107

Annex I (informative) Protocol data unit examples 112
I.1 General 112
I.2 Association information exchange 112
I.3 Configuration information exchange 116
I.4 GET MDS attributes service 120
I.5 Data reporting 121
I.6 Disassociation 122

ISO/IEEE 11073-10419:2016(E)

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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