

Health informatics - Personal health device
communication - Part 10425: Device specialization -
Continuous glucose monitor (CGM) (ISO
11073-10425:2016)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11073-10425:2016 sisaldab Euroopa standardi EN ISO 11073-10425:2016 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11073-10425:2016 consists of the English text of the European standard EN ISO 11073-10425:2016.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 29.06.2016.	Date of Availability of the European standard is 29.06.2016.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

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English Version

Health informatics - Personal health device
communication - Part 10425: Device specialization -
Continuous glucose monitor (CGM) (ISO 11073-
10425:2016)

Informatique de santé - Communication entre
dispositifs de santé personnels - Partie 10425:
Spécialisation du dispositif - Glucomètre continu
(CGM) (ISO 11073-10425:2016)

Medizinische Informatik - Kommunikation von Geräten
für die persönliche Gesundheit - Teil 10425:
Gerätespezifikation - Kontinuierlicher Glukose-Monitor
(ISO 11073-10425:2016)

This European Standard was approved by CEN on 21 February 2016.

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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

The text of ISO/IEEE 11073-10425:2016 has been prepared by Technical Committee ISO/TC 215 “Health informatics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11073-10425:2016 by Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2016, and conflicting national standards shall be withdrawn at the latest by December 2016.

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Endorsement notice

The text of ISO/IEEE 11073-10425:2016 has been approved by CEN as EN ISO 11073-10425:2016 without any modification.

Introduction

This introduction is not part of IEEE Std 11073-10425-2014, Health informatics—Personal health device communication—Part 10425: Device Specialization—Continuous Glucose Monitor (CGM).

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 and describes a specific, interoperable communication approach for continuous glucose monitors (CGMs).^a 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).

^a Information on references can be found in Clause 2.

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Health informatics—Personal health device communication

Part 10425: Device Specialization— Continuous Glucose Monitor (CGM)

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1. Overview

1.1 Scope

This standard establishes a normative definition of communication between personal health continuous glucose monitor (CGM) devices (agents) and managers [e.g., cell phones, personal computers (PCs), 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 of communication functionality of CGM devices. In this context, CGM refers to the measurement of the level of glucose in the body on a regular (typically 5 minute) basis through a sensor continuously attached to the person.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices (PHDs) and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes). Interoperability is the 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 IEEE Std 11073-20601a[™] for an overview of the environment within which this standard is written.¹

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

This standard is based on IEEE Std 11073-20601a-2010 and ISO/IEEE 11073-20601:2010, which in turn draw information from both ISO/IEEE 11073-10201:2004 [B7] and ISO/IEEE 11073-20101:2004 [B8].² The medical device encoding rules (MDERs) used within this standard are fully described in ISO/IEEE 11073-20601:2010.

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, ISO/IEEE 11073-20601:2010, 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. 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 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 11073-20601:2010, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol.⁴

IEEE Std 11073-20601a-2010, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol—Amendment 1.^{5, 6}

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.⁷

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.

⁴ ISO/IEEE publications are available from the ISO Central Secretariat (<http://www.iso.org/>). ISO/IEEE publications are also available in the United States from The Institute of Electrical and Electronics Engineers (<http://standards.ieee.org/>).

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