SLOVENSKI STANDARD
oSIST prEN ISO/IEEE 110736-10425:2024

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Zdravstvena informatika - Interoperabilnost naprav 10425. del: Komunikacija osebnih medicinskih naprav - Specialne naprave - Stalno spremljanje ravni glukoze (ISO/IEEE FDIS 11073-10425:2024)

Health informatics - Device interoperability - Part 10425: Personal Health Device Communication - Device Specialization- Continuous Glucose Monitor (CGM) (ISO/IEEE FDIS 11073-10425:2024)

Medizinische Informatik - Interoperabilität von Geräten - Teil 10425: Kommunikation von Geräten für die persönliche Gesundheit - Gerätespezifikation - Kontinuierlicher Glukose-Monitor (ISO/IEEE FDIS 11073-10425:2024)

Informatique de santé - Interopérabilité des dispositifs - Partie 10425: Titre manque (ISO/IEEE FDIS 11073-10425:2024)

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Part 10425: Personal Health Device Communication — Device Specialization- Continuous Glucose Monitor (CGM)

ISO/TC **215**

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ISO/IEEE 11073-10425 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10425) and drafted in accordance with its editorial rules. It was adopted, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE, by Technical Committee ISO/TC 215, *Health informatics*.

This third edition cancels and replaces the second edition (ISO/IEEE 11073-10425:2019), which has been technically revised.

The main changes are as follows:

— updated Normative Reference to refer to IEEE Std 11073-20601-2019;
— updated version of this device specialization;
— updated the association details based on new version;
— updated the wording in 6.3 regarding the Observational;
— added some text to 6.12 to further elaborate the DIM extensibility rule;
— corrected the use condition of GET MDS at E.4.1;

— updated the text in 8.5.2 regarding attribute-id-list, in order to be compliant with 20601-V4;
— added 4.3, Compliance with other standards;
— removed the year in bibliography to represent the latest version;
— updated the bit example in E.4.3 by inserting the Mds-Time-Info into MDS;
— made the ISO/IEEE 11073-10101 as normative reference;
— updated the wording at 1.3 and 4.1 regarding the precedence of nomenclature between 10101, 20601, 104xx and this standard;
— updated the usage of nomenclature-version. Tied it with the corresponding protocol-version;
— updated the examples in Annex E using protocol-version4.

A list of all parts in the ISO 11073 series can be found on the ISO website.

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Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of the communication between continuous glucose monitor (CGM) devices and managers (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 and information models. 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.

Keywords: continuous glucose monitor, IEEE 11073-10425™, medical device communication, personal health devices

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Introduction

This introduction is not part of IEEE Std 11073-10425-2023, Health Informatics—Device Interoperability—Part 10425: Personal Health Device Communication—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 and describes a specific, interoperable communication approach for continuous glucose monitors (CGMs).[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.