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**ISO/IEEE
11073-10425**

**Health informatics — Device
interoperability —**

Part 10425:
**Personal health device
communication — Device
specialization — Continuous
Glucose Monitor (CGM)**

*Informatique de santé — Interopérabilité des dispositifs —
Partie 10425: Communication entre dispositifs de santé personnels
— Spécialisation des dispositifs — Glucomètre continu (CGM)*

**Third edition
2024-09**



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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;

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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.

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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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