EN ISO 11073-10425

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Health informatics — Personal health device communication

Part 10425: Device specialization — Continuous glucose monitor (CGM)

(ISO/IEEE 11073-10425:2019)

Medizinische Informatik — Kommunikation von Geräten für die persönliche Gesundheit — Teil 10425: Gerätespezifikation — Kontinuierlicher Glukose-Monitor
(ISO/IEEE 11073-10425:2019)

Informatique de santé — Communication entre dispositifs de santé personnels — Partie 10425: Spécialisation du dispositif — Glucomètre continu (CGM)
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National Foreword

For the present ÖNORM EN ISO no German translation is envisaged.

Therefore, the English version has been implemented in Austria and made available to all users of the standard.

EUROPEAN STANDARD EN ISO 11073-10425

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European foreword

This document (EN ISO 11073-10425:2019) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with 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of an identical text or by endorsement, at the latest by October 2019, and conflicting national standards shall be withdrawn at the latest by October 2019.

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The text of ISO/IEEE 11073-10425:2019 has been approved by CEN as EN ISO 11073-10425:2019 without any modification.

Second edition
2019-03

Health informatics — Personal health device communication —

Part 10425: Device specialization — Continuous glucose monitor (CGM)

Informatique de santé — Communication entre dispositifs de santé personnels —

Partie 10425: Spécialisation du dispositif — Glucomètre continu (CGM)

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted (see www.iso.org/directives).

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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 11073-10425-2017) 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 second edition cancels and replaces the first edition (ISO/IEEE 11073-10425:2016), which has been technically revised.

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

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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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