

# **SLOVENSKI STANDARD**

## **SIST EN ISO 11073-10425:2019**

**01-junij-2019**

**Nadomešča:**

**SIST EN ISO 11073-10425:2017**

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**Zdravstvena informatika - Komunikacija osebnih medicinskih naprav - 10425. del:  
Specialne naprave - Stalno spremljanje ravni glukoze (ISO/IEEE 11073-10425:2019)**

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) (ISO/IEEE 11073-  
10425:2019)

**Ta slovenski standard je istoveten z: EN ISO 11073-10425:2019**

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**ICS:**

|           |   |  |
|-----------|---|--|
| 11.040.55 | Diagnostična oprema                             | Diagnostic equipment                         |
| 35.240.80 | Uporabniške rešitve IT v<br>zdravstveni tehniki | IT applications in health care<br>technology |

**SIST EN ISO 11073-10425:2019**

**en,fr,de**

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 11073-10425**

April 2019

ICS 35.240.80

Supersedes EN ISO 11073-10425:2016

English Version

**Health informatics - Personal health device  
communication - Part 10425: Device specialization -  
Continuous glucose monitor (CGM) (ISO/IEEE 11073-  
10425:2019)**

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

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**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

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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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INTERNATIONAL  
STANDARDISO/IEEE  
11073-10425Second edition  
2019-03

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**Health informatics — Personal health  
device communication —**

Part 10425:

**Device specialization — Continuous  
glucose monitor (CGM)**

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

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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.

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## ISO/IEEE 11073-10425:2019(E)

**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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