



BSI Standards Publication

Health informatics — Personal health device communication

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

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National foreword

This British Standard is the UK implementation of ISO/IEEE 11073-10425:2019. It supersedes BS EN ISO 11073-10425:2016, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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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)

**IEEE**

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

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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 11073-10425-2017, 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 11073-20601:2016 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.

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Contents

1. Overview	12
1.1 Scope	12
1.2 Purpose	12
1.3 Context	12
2. Normative references.....	13
3. Definitions, acronyms, and abbreviations	13
3.1 Definitions	13
3.1 Acronyms and abbreviations	14
4. Introduction to ISO/IEEE 11073 personal health devices (PHDs)	15
4.1 General	15
4.2 Introduction to ISO/IEEE 11073-20601 modeling constructs	15
4.3 Compliance with other standards.....	16
5. Glucose monitoring concepts and modalities	16
5.1 General	16
5.2 Device types	17
5.3 CGM agent-to-manager communication	18
5.4 Collected data	19
5.5 Stored data	20
6. Continuous glucose monitor (CGM) domain information model (DIM)	20
6.1 Overview	20
6.2 Class extensions.....	21
6.3 Object instance diagram	21
6.4 Types of configuration.....	22
6.5 Profiles.....	23
6.6 MDS object.....	23
6.7 Numeric objects.....	26
6.8 Real-time sample array objects.....	36
6.9 Enumeration objects	36
6.10 PM-store objects	40
6.11 Scanner objects	44
6.12 Class extension objects	44
6.13 CGM information model extensibility rules.....	44
7. CGM service model.....	45
7.1 General	45
7.2 Object access services.....	45
7.3 Object access event report services	47
8. CGM communication model	47
8.1 Overview	47
8.2 Communication characteristics.....	47
8.3 Association procedure	48
8.4 Configuring procedure.....	49
8.5 Operating procedure	51
8.6 Time synchronization	51
9. Test associations.....	51
9.1 Behavior with standard configuration.....	51
9.2 Behavior with extended configurations	52

This is a preview of "BS ENISO/IEEE 11073-...". [Click here to purchase the full version from the ANSI store.](#)

10. Conformance	52
10.1 Applicability	52
10.2 Conformance specification	52
10.3 Levels of conformance	53
10.4 Implementation conformance statements (ICSs)	53
Annex A (informative) Bibliography	59
Annex B (normative) Any additional ASN.1 definitions	60
B.1 PHD DM status, CGM status, and measurement status bit mappings	60
B.2 Numeric extension for measurement confidence	61
B.3 Capability-mask	62
B.4 State-flag	62
Annex C (normative) Allocation of identifiers	64
C.1 General	64
C.2 Definitions of terms and codes	64
C.3 Systematic derivations of terms and codes	66
Annex D (informative) Message sequence examples	69
Annex E (informative) Protocol data unit examples	71
E.1 General	71
E.2 Association information exchange	71
E.3 Configuration information exchange	74
E.4 GET MDS attributes service	77
E.5 Data reporting	79
E.6 Disassociation	79
Annex F (informative) Revision history	80

This is a preview of "BS ENISO/IEEE 11073-...". [Click here to purchase the full version from the ANSI store.](#)

Health informatics—Personal health device communication

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

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, 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, 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 ISO/IEEE 11073-20601:2016 for an overview of the environment within which this standard is written.²

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.

² Information on references can be found in Clause 2.