

**Health informatics -
Personal health device communication -
Part 10417: Device specialization - Glucose meter
(ISO/IEEE 11073-10417:2017)**

EESTI STANDARDI EESSÕNA**NATIONAL FOREWORD**

See Eesti standard EVS-EN ISO 11073-10417:2017 sisaldab Euroopa standardi EN ISO 11073-10417:2017 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11073-10417:2017 consists of the English text of the European standard EN ISO 11073-10417:2017.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
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English Version

**Health informatics - Personal health device
communication - Part 10417: Device specialization -
Glucose meter (ISO/IEEE 11073-10417:2017)**

Informatique de santé - Communication entre
dispositifs médicaux sur le site des soins - Partie
10417: Spécialisation des dispositifs - Glucomètre
(ISO/IEEE 11073-10417:2017)

This European Standard was approved by CEN on 8 October 2016.

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European foreword

This document (EN ISO 11073-10417:2017) 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of an identical text or by endorsement, at the latest by November 2017 and conflicting national standards shall be withdrawn at the latest by November 2017.

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Endorsement notice

The text of ISO/IEEE 11073-10417:2017 has been approved by CEN as EN ISO 11073-10417:2017 without any modification.

Introduction

This introduction is not part of IEEE Std 11073-10417™-2015, Health informatics—Personal health device communication—Part 10417: Device Specialization—Glucose Meter.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in IEEE Std 11073-20601-2015^a and describes a specific, interoperable communication approach for glucose meters. 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.

^aFor information on references, see Clause 2.

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Health informatics—Personal health device communication

Part 10417: Device Specialization— Glucose Meter

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1. Overview

1.1 Scope

Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal telehealth glucose meter devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards, including ISO/IEEE 11073 terminology, information models, 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 for personal telehealth glucose meters.

1.2 Purpose

This standard addresses the need for an openly defined, independent standard that support information exchange to and from personal health devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes). Interoperability is key to growing the potential market for these devices and enabling people to be better informed participants in the management of their health.

1.3 Context

See IEEE Std 11073-20601™-2014¹ for an overview of the environment within which this standard is written.

This standard defines the device specialization for the insulin pump, being a specific agent type, and provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on IEEE Std 11073-20601™-2014² which in turn draws information from both ISO/IEEE 11073-10201:2004 [B3]³ and ISO/IEEE 11073-20101:2004 [B4]. The medical device encoding rules (MDERs) used within this standard are fully described in Annex F of IEEE Std 11073-20601-2014.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B2] and adds new nomenclature codes for the purposes of this standard. Among this standard and IEEE Std 11073-20601-2014, all required nomenclature codes for implementation are documented.

NOTE—In this standard, ISO/IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601-2014, where zz can be any number from 01 to 99, inclusive.⁴

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so that each referenced document is cited in text and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

IEEE Std 11073-20601-2014, Health informatics—Personal health device communication—Application Profile—Optimized Exchange Protocol.^{5, 6}

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause.⁷

agent: A node that collects and transmits personal health data to an associated manager.

class: In object-oriented modeling, it describes the attributes, methods, and events that objects instantiated from the class utilize.

¹ Information on references can be found in Clause 2.

² ISO/IEEE publications are available from the ISO Central Secretariat, 1, ch. de la Voie-Creuse, Case postale 56, CH-1211, Geneva 20, Switzerland (<http://www.iso.ch/>). ISO/IEEE publications are also available in the United States from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854-4141, USA (<http://standards.ieee.org/>).

³ The numbers in brackets correspond to those of the bibliography in Annex A.

⁴ Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.

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⁷ *IEEE Standards Dictionary Online* subscription is available at:

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