

**Health informatics - Personal health device
communication - Part 10406: Device specialization -
Basic electrocardiograph (ECG) (1- to 3-lead ECG)
(ISO/IEEE 11073-10406:2012)**

EESTI STANDARDI EESSÕNA

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See Eesti standard EVS-EN ISO 11073-10406:2012 sisaldab Euroopa standardi EN ISO 11073-10406:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11073-10406:2012 consists of the English text of the European standard EN ISO 11073-10406:2012.
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English Version

Health informatics - Personal health device communication -
Part 10406: Device specialization - Basic electrocardiograph
(ECG) (1- to 3-lead ECG) (ISO/IEEE 11073-10406:2012)

Informatique de santé - Communication entre dispositifs de
santé personnels - Partie 10406: Spécialisation des
dispositifs - Électrocardiographie de base (ECG) (ECG 1 à
3) (ISO/IEEE 11073-10406:2012)

Medizinische Informatik - Kommunikation von Geräten für
die persönliche Gesundheit - Teil 10406:
Gerätespezifikation - Basiselektrokardiogramm (EKG)
(EKG mit 1 bis 3 Ableitungen) (ISO/IEEE 11073-
10406:2012)

This European Standard was approved by CEN on 30 November 2012.

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Foreword

This document (EN ISO 11073-10406:2012) 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of an identical text or by endorsement, at the latest by June 2013, and conflicting national standards shall be withdrawn at the latest by June 2013.

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Endorsement notice

The text of ISO/IEEE 11073-10406:2012 has been approved by CEN as a EN ISO 11073-10406:2012 without any modification.

Contents

1. Overview	1
1.1 Scope	1
1.2 Purpose	1
1.3 Context	2
2. Normative references	2
3. Definitions, acronyms, and abbreviations	3
3.1 Definitions	3
3.2 Acronyms and abbreviations	3
4. Introduction to ISO/IEEE 11073 personal health devices	4
4.1 General	4
4.2 Introduction to ISO/IEEE 11073-20601 modeling constructs	4
4.3 Compliance with other standards	5
5. Basic ECG (1- to 3-lead ECG) device concepts and modalities	6
5.1 General	6
5.2 ECG waveform	6
5.3 R-R interval	6
5.4 Heart rate	7
6. Basic ECG (1- to 3-lead ECG) domain information model	7
6.1 Overview	7
6.2 Class extensions	7
6.3 Object instance diagram	7
6.4 Types of configuration	8
6.5 Profiles	9
6.6 Medical device system object	11
6.7 Numeric objects	15
6.8 Real-time sample array objects	18
6.9 Enumeration objects	19
6.10 PM-store objects	22
6.11 Scanner objects	29
6.12 Class extension objects	32
6.13 Basic ECG (1- to 3-lead ECG) information model extensibility rules	32
7. Basic ECG (1- to 3-lead ECG) service model	32
7.1 General	32
7.2 Object access services	32
7.3 Object access event report services	35
8. Basic ECG (1- to 3-lead ECG) communication model	35
8.1 Overview	35
8.2 Communications characteristics	36
8.3 Association procedure	36
8.4 Configuring procedure	38
8.5 Operating procedure	39
8.6 Time synchronization	40

9. Test associations	40
9.1 Behavior with standard configuration	40
9.2 Behavior with extended configurations	41
10. Conformance	41
10.1 Applicability	41
10.2 Conformance specification	41
10.3 Levels of conformance	42
10.4 Implementation conformance statements	42
Annex A (informative) Bibliography	47
Annex B (normative) Any additional ASN.1 definitions	48
Annex C (normative) Allocation of identifiers	49
Annex D (informative) Message sequence examples	50
Annex E (informative) Protocol data unit examples	52

Introduction

This introduction is not part of IEEE Std 11073-10406-2011, Health informatics—Personal health device communication—Part 10406: Device specialization—Basic electrocardiograph (ECG) (1- to 3-lead ECG).

Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between personal basic electrocardiograph (ECG) devices and managers (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 and IEEE 11073-20601 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 for personal telehealth basic ECG (1- to 3-lead ECG) devices. Monitoring ECG devices are distinguished from diagnostic ECG equipment with respect to including support for wearable ECG devices, limiting the number of leads supported by the equipment to three, and not requiring the capability of annotating or analyzing the detected electrical activity to determine known cardiac phenomena. This standard is consistent with the base framework and allows multifunction implementations by following multiple device specializations (e.g., ECG and respiration rate).

Health informatics — Personal health device communication —

Part 10406:

Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)

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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 the communication between personal basic electrocardiograph (ECG) devices and managers (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 and IEEE Std 11073-20601 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 for personal telehealth basic ECG (1- to 3-lead ECG) devices. Monitoring ECG devices are distinguished from diagnostic ECG equipment with respect to including support for wearable ECG devices, limiting the number of leads supported by the equipment to three, and not requiring the capability of annotating or analyzing the detected electrical activity to determine known cardiac phenomena. This standard is consistent with the base framework and allows multifunction implementations by following multiple device specializations (e.g., ECG and respiration rate).

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices and managers (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 11073-20601a-2010¹ for an overview of the environment within which this standard is written.

This standard defines the device specialization for the basic ECG (1- to 3-lead ECG), being a specific agent type, and it provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on IEEE Std 11073-20601a™-2010 and ISO/IEEE 11073-20601:2010, which in turn draw information from both ISO/IEEE 11073-10201:2004 [B7]² and ISO/IEEE 11073-20101:2004 [B8]. The medical device encoding rules (MDERs) used within this standard are fully described in ISO/IEEE 11073-20601:2010.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 0 and adds new nomenclature codes for the purposes of this standard. Among this standard, ISO/IEEE 11073-20601:2010, and IEEE Std 11073-20601a-2010, all required nomenclature codes for implementation are documented.

NOTE 1—IEEE Std 11073-20601a-2010 is an amendment to ISO/IEEE 11073-20601:2010. It contains new material and corrections and does not copy the content of ISO/IEEE 11073-20601:2010. Throughout this standard, a reference to IEEE Std 11073-20601a-2010 refers to the document that is obtained after applying this new material and corrections to ISO/IEEE 11073-20601:2010.³

NOTE 2—In this standard, ISO/IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601a-2010, where zz can be any number from 01 to 99, inclusive.

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 11073-20601a™-2010, Health informatics—Personal health device communication—Application profile—Optimized Exchange Protocol—Amendment 1.^{4,5}

ISO/IEEE 11073-20601:2010, Health informatics—Personal health device communication—Application profile—Optimized Exchange Protocol.⁶

See Annex A for all informative material referenced by this standard.

¹ Information on references can be found in Clause 2.

² The numbers in brackets correspond to those of the bibliography in Annex A.

³ 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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