

SLOVENSKI STANDARD
oSIST prEN ISO/IEEE 11073-10406:2026
01-september-2026

Zdravstvena informatika - Interoperabilnost naprav - 10406. del: Komunikacija osebnih medicinskih naprav, specialne naprave, osnovni elektrokardiograf (EKG) (od 1- do 3-odvodni EKG) (ISO/IEEE FDIS 11073-10406:2026)

Health Informatics - Device Interoperability - Part 10406: Personal health device communication, device specialization, basic electrocardiograph (ECG) (1- to 3-lead ECG) (ISO/IEEE FDIS 11073-10406:2026)

Medizinische Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10406: Gerätespezifikation - Basiselektrokardiogramm (EKG) (EKG mit 1 bis 3 Ableitungen) (ISO/IEEE FDIS 11073-10406:2026)

Informatique de santé - Communication entre dispositifs de santé personnels - Partie 10406: Spécialisation des dispositifs - Électrocardiographie de base (ECG) (ECG 1 à 3) (ISO/IEEE FDIS 11073-10406:2026)

Ta slovenski standard je istoveten z: prEN ISO/IEEE 11073-10406

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

oSIST prEN ISO/IEEE 11073-10406:2026 en,fr,de

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FINAL DRAFT International Standard

ISO/IEEE FDIS 11073-10406

Health Informatics — Device Interoperability —

Part 10406:
**Personal health device
communication, device
specialization, basic
electrocardiograph (ECG) (1- to
3-lead ECG)**

ISO/TC 215

Secretariat: **ANSI**

Voting begins on:
2026-07-14

Voting terminates on:
2026-12-01

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Published in Switzerland

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This second edition cancels and replaces the first edition (ISO/IEEE 11073-10406:2012), which has been technically revised.

The main changes are as follows:

- added support for Base-Offset-Time;
- defined new standard configuration 0x259;

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- updated Normative Reference, to refer to ISO/IEEE 11073-20601;
- updated version of this device specialization;
- updated the association details based on new version;
- updated the wording in 6.3 regarding the Observational;
- updated the examples in 8.4.2 and Annex E, to indicate the support of BaseOffsetTime;
- updated the qualifier in MDS and other objects to recommend BaseOffsetTime. Also updated the description of the qualifiers in 6.5;
- added some text to 6.12 to further elaborate the DIM extensibility rule;
- corrected the use condition of GET MDS at E.4.1;
- updated the text in 8.5.2 regarding attribute-id-list, in order to be compliant with 20601-V4;
- added Clause 3.4 --- Compliance with other standards;
- removed the year in bibliography to represent the latest version;
- extended Table 1 to specify qualifier details for all possible configurations;
- updated the bit example in E.4.3, by inserting the Mds-Time-Info into MDS;
- made the ISO/IEEE 11073-10101 as normative reference;
- updated the wording at 1.3 and 4.1 regarding the precedence of nomenclature between 10101, 20601, 104xx and this standard;
- updated the usage of nomenclature-version. Tied it with the corresponding protocol-version.

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IEEE Std 11073-10406™-2023
(Revision of IEEE Std 11073-10406-2011)

Health Informatics—Device Interoperability

Part 10406: Personal Health Device Communication—Device Specialization— Basic Electrocardiograph (ECG) (1- to 3-lead ECG)

Developed by the

IEEE 11073™ Standards Committee
of the
IEEE Engineering in Medicine and Biology Society

Approved 15 February 2023

IEEE SA Standards Board

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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 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 is established in this standard. Appropriate portions of existing standards including ISO/IEEE 11073 terminology and IEEE 11073-20601 information models are leveraged. The use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability is specified. A common core of communication functionality for personal telehealth basic ECG (1- to 3-lead ECG) devices is defined. 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).

Keywords: 1- to 3-lead ECG, basic electrocardiograph, ECG, IEEE 11073-10406™, medical device communication, personal health devices

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PDF:	979-8-8557-0178-4	STD26518
Print:	979-8-8557-0179-1	STDPD26518

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ISO/IEEE 11073-10406:2026(en)**Introduction**

This introduction is not part of IEEE Std 11073-10406-2023, Health Informatics—Device Interoperability—Part 10406: Personal Health Device Communication—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).

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