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Health informatics — Personal health device communication —

Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)

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Informatique de santé — Communication entre dispositifs de santé personnels —

Partie 10406: Spécialisation des dispositifs — Électrocardiographe de base (ECG) (ECG 1 à 3)

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Institute of Electrical and Electronics Engineers, Inc.
3 Park Avenue, New York • NY 10016-5997, USA
E-mail stds.ipr@ieee.org
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Foreword

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ISO/IEEE 11073-10406 was prepared by the IEEE 11073 Standards Comittee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10406-2011). It was adopted by Technical Committee ISO/TC 215, *Health informatics*, in parallel with its approval by the ISO member bodies, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE. IEEE is responsible for the maintenance of this document with participation and input from ISO member bodies.

ISO/IEEE 11073 consists of the following parts, under the general title *Health informatics — Personal health device communication* (text in parentheses gives a variant of subtitle):

— *Part 10101: (Point-of-care medical device communication) Nomenclature*

— *Part 10201: (Point-of-care medical device communication) Domain information model*

— *Part 10404: Device specialization — Pulse oximeter*

— *Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)*

— *Part 10407: Device specialization — Blood pressure monitor*

— *Part 10408: Device specialization — Thermometer*

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— *Part 10415: Device specialization — Weighing scale*

— *Part 10417: Device specialization — Glucose meter*

— *Part 10420: Device specialization — Body composition analyzer*

— *Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)*

— *Part 10471: Device specialization — Independant living activity hub*

— *Part 10472: Device specialization — Medication monitor*

— *Part 20101: (Point-of-care medical device communication) Application profiles — Base standard*

— *Part 20601: Application profile — Optimized exchange protocol*

— *Part 30200: (Point-of-care medical device communication) Transport profile — Cable connected*

— *Part 30300: (Point-of-care medical device communication) Transport profile — Infrared wireless*

— *Part 30400: (Point-of-care medical device communication) Interface profile — Cabled Ethernet*

— *Part 90101: (Point-of-care medical device communication) Analytical instruments — Point-of-care test*

— *Part 91064: (Standard communication protocol) Computer-assisted electrocardiography*

— *Part 92001: (Medical waveform format) — Encoding rules [Technical Specification]*

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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).

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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.

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1.3 Context

See IEEE Std 11073-20601a-2010[1] 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]

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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.

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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.
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3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary: Glossary of Terms & Definitions* should be consulted for terms not defined in this clause.[7]

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

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

3.1.3 device: A term used to refer to a physical apparatus implementing either an agent or a manager role.

3.1.4 electrode: An electrical sensor in contact with a specified part of the body. Two or more electrodes are used to detect heart action voltage. *See*: **lead**.

3.1.5 handle: An unsigned 16-bit number that is locally unique and identifies one of the object instances within an agent.

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3.1.6 lead: Commonly refers to two different things: It may be used to refer to the combination of an electrode and associated lead wire, used for a certain ECG recording. Alternatively, it may be used to refer to the signal obtained by tracing the voltage between two electrodes or linear combinations thereof. The latter definition is used throughout this standard.

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3.1.7 lead wire: A cable connected between an electrode and the agent device.

3.1.8 manager: A node receiving data from one or more agent systems. Some examples of managers include a cellular phone, health appliance, set top box, or computer system.

3.1.9 obj-handle: *See:* **handle.**

3.1.10 object: In object-oriented modeling, a particular instantiation of a class. The instantiation realizes attributes, methods, and events from the class.

3.1.11 personal health device: A device used in personal health applications.

3.1.12 personal telehealth device: *See:* **personal health device.**

3.2 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
DIM	domain information model
ECG	electrocardiogram or electrocardiograph
EKG	elektrokardiogramm (German)
EUI-64	extended unique identifier (64 bits)
ICS	implementation conformance statements

[7] *The IEEE Standards Dictionary: Glossary of Terms & Definitions* is available at http://shop.ieee.org/.

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MDC	medical device communication
MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
PDU	protocol data unit
PHD	personal health device
RT-SA	real-time sample array
VMO	virtual medical object
VMS	virtual medical system

4. Introduction to ISO/IEEE 11073 personal health devices

4.1 General

This standard and the remainder of the series of ISO/IEEE 11073 personal health device (PHD) standards fit in the larger context of the ISO/IEEE 11073 series of standards. The full suite of standards enables agents to interconnect and interoperate with managers and with computerized health-care information systems. See IEEE Std 11073-20601a-2010 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

IEEE Std 11073-20601a-2010 supports the modeling and implementation of an extensive set of personal health devices. This standard defines aspects of the basic ECG (1- to 3-lead ECG) device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD basic ECG (1- to 3-lead ECG) agent and a manager. This standard defines a subset of the objects and functionality contained in IEEE Std 11073-20601a-2010 and extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1). Nomenclature codes referenced in this standard, which are not defined in IEEE Std 11073-20601a-2010, are normatively defined in Annex C.

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4.2 Introduction to ISO/IEEE 11073-20601 modeling constructs

4.2.1 General

The ISO/IEEE 11073 series of standards, and in particular IEEE Std 11073-20601a-2010, is based on an object-oriented systems management paradigm. The overall system model is divided into three principal components: the domain information model (DIM), the service model, and the communication model. See IEEE Std 11073-20601a-2010 for a detailed description of the modeling constructs.

4.2.2 Domain information model

The DIM is a hierarchical model that describes an agent as a set of objects. These objects and their attributes represent the elements that control behavior and report on the status of the agent and data that an agent can communicate to a manager. Communication between the agent and the manager is defined by the application protocol in the IEEE Std 11073-20601a-2010.

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4.2.3 Service model

The service model defines the conceptual mechanisms for the data exchange services. Such services are mapped to messages that are exchanged between the agent and the manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined in ASN.1. The messages defined in IEEE Std 11073-20601a-2010 can coexist with messages defined in other standard application profiles defined in the ISO/IEEE 11073 series of standards.

4.2.4 Communication model

In general, the communication model supports the topology of one or more agents communicating over logical point-to-point connections to a single manager. For each logical point-to-point connection, the dynamic system behavior is defined by a connection state machine as specified in IEEE Std 11073-20601a-2010.

4.2.5 Implementing the models

An agent implementing this standard shall implement all mandatory elements of the information, service, and communication models as well as all conditional elements where the condition is met. The agent should implement the recommended elements, and it may implement any combination of the optional elements. A manager implementing this standard shall utilize at least one of the mandatory, conditional, recommended, or optional elements. In this context, "utilize" means to use the element as part of the primary function of the manager device. For example, a manager whose primary function is to display data would need to display a piece of data in the element in order to utilize it.

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4.3 Compliance with other standards

Devices that comply with this standard may also be required to comply with other domain- and device-specific standards that supersede the requirements of this standard with respect to issues including safety, reliability, and risk management. A user of this standard is expected to be familiar with all other such standards that apply and to comply with any higher specifications thus imposed. Typically, medical devices will comply with the IEC 60601-1:2005 0 base standards with respect to electrical and mechanical safety and any device-specific standard as might be defined in the IEC 60601-2 [B2] series of standards. Software aspects may apply through standards such as IEC 62304:2006/EN 62304:2006 [B3]. Devices that comply with this standard implement higher layers of network software and utilize lower layers as appropriate to the application. The requirements on performance of such applications and conformance are defined elsewhere and are outside the scope of this standard. Moreover, the use of any medical equipment is subject to risk assessment and risk management appropriate to the application. Some relevant examples are ISO 14971:2007 [B5] and IEC 80001-1:2010 [B4]. The requirements of such risk assessment and risk management and conformance are outside the scope of this standard.

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5. Basic ECG (1- to 3-lead ECG) device concepts and modalities

5.1 General

This clause presents the general concepts of basic ECG (1- to 3-lead ECG) devices. In general, an ECG device with associated lead wires and electrodes measures the electrical activity of the heart. More precisely, it measures the electrical potential differences between electrodes placed on the person's body, reflecting the sum of the electrical activities of muscle fibers. These electrical activities are related to the myocardial muscle but also include artifacts caused by electrical activities of other muscle fibers after movement. In the context of personal health devices in this family of standards, a basic ECG (1- to 3-lead ECG) is used for the purpose of acquiring and recording 1 to 3 channel (leads) electrocardiographic waveforms or analyzing the acquired signals to measure heart rate.

The electrical potential is measured by means of a system of conducting wires attached to a person using electrodes. The electrodes are placed on specific locations on the surface of the person's body. There are different lead measurement systems for placing the electrodes on the person's body.

5.2 ECG waveform

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ECG waveforms represent a continuous stream of measured electrical potential differences within a certain time period. ECG waveforms are typically used for cardiac rhythm monitoring.

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5.3 R-R interval

Figure 1 illustrates the basic ECG signal and specific waveforms that may occur, for example, during atrial depolarization (P wave), ventricular depolarization (QRS complex), and ventricular repolarization (ST-T wave). The R-R interval (interbeat interval) is an instantaneous measurement defined as the time between the maximums of two consecutive R-waves (early ventricular depolarization), and it is typically indicated in milliseconds or an internal oscillator count. The latter is used in order to simplify implementations or to support higher accuracy by avoiding round off errors and is referred to as ticks and defined as ticks per second in this standard. Conceptually the R-R interval measurement is implemented by means of a detector that registers the time instant of each individual R peak and subsequently calculates the interval in between them.

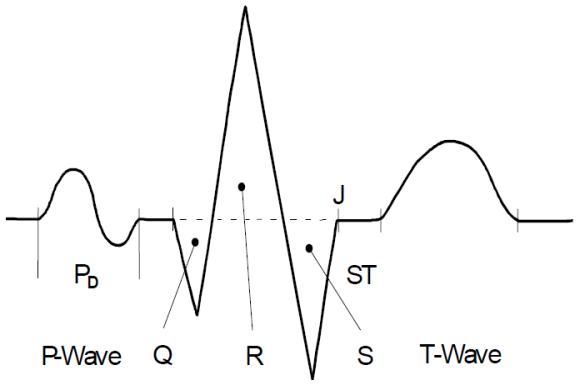

Figure 1—Basic form of ECG signal

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5.4 Heart rate

Heart rate is defined as the number of heartbeats per unit of time. Typically, this value is quoted as beats per minute, although often a period less than 1 min is used to determine the number of beats that have occurred, and the value is normalized. A heart rate measurement based on a single beat interval is termed the instantaneous heart rate. The instantaneous heart rate is defined as the inverse of a single R-R value, subject to a proper normalization factor accounting for the conversion from beats per millisecond to beats per minute. The instantaneous heart rate is often fluctuating and is therefore filtered (averaged) reducing higher frequency content for the purposes of display.

6. Basic ECG (1- to 3-lead ECG) domain information model

6.1 Overview

This clause describes the domain information model of the basic ECG (1- to 3-lead ECG).

6.2 Class extensions

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In this standard, no class extensions are defined with respect to IEEE Std 11073-20601a-2010.

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6.3 Object instance diagram

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The metric object instance diagram of the basic ECG (1- to 3-lead ECG) domain information model, defined for the purposes of this standard, is shown in Figure 2.

The objects of the DIM, as shown in Figure 2, are described in 6.6 through 6.11. This includes the medical device system (MDS) object (see 6.6), the numeric objects (see 6.7), the RT-SA objects (see 6.8), the enumeration objects (see 6.9), the PM-store objects (see 6.10), and the scanner objects (see 6.11). See 6.13 for rules for extending the basic ECG (1- to 3-lead ECG) information model beyond elements as described in this standard. Each clause that describes an object of the basic ECG (1- to 3-lead ECG) contains the following information:

- The nomenclature code used to identify the class of the object. One example where this code is used is the configuration event, where the object class is reported for each object. This allows the manager to determine whether the class of the object being specified is a numeric, real-time sample array, enumeration, scanner, or PM-store class.
- The attributes of the object. Each object has attributes that represent and convey information on the physical device and its data sources. Each object has a Handle attribute that identifies the object instance within an agent. Attribute values are accessed and modified using methods such as GET and SET. Attribute types are defined using ASN.1. The ASN.1 definitions for new attribute types specific to this standard are in Annex B, and the ASN.1 definitions for existing attribute types referenced in this standard are in IEEE Std 11073-20601a-2010.
- The methods available on the object.
- The potential events generated by the object. The data are sent to the manager using events.
- The available services such as getting or setting attributes.

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