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Health informatics - Point-of-care medical device communication - Part 10102: Nomenclature - Annotated ECG (ISO/IEEE 11073-10102:2014)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Obsahuje: EN ISO 11073-10102:2014, ISO/IEEE 11073-10102:2014

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EUROPÄISCHE NORM

EN ISO 11073-10102

March 2014

ICS 35.240.80

English Version

Health informatics - Point-of-care medical device communication - Part 10102: Nomenclature - Annotated ECG (ISO/IEEE 11073-10102:2014)

Informatique de santé - Communication entre dispositifs médicaux sur le site des soins - Partie 10102: Nomenclature - ECG annoté (ISO/IEEE 11073-10102:2014)

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Contents

Page

Foreword

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INTERNATIONAL STANDARD

ISO/IEEE 11073-10102

First edition
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Health informatics — Point-of-care medical device communication —

Part 10102: Nomenclature — Annotated ECG

Informatique de santé — Communication entre dispositifs médicaux sur le site des soins

Partie 10102: Nomenclature — ECG annoté

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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 00103: Overview*

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

— *Part 10102: (Point-of-care medical device communication) Nomenclature — Annotated ECG*

— *Part 10103: (Point-of-care medical device communication) — Nomenclature — Implantable device, cardiac*

— *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*

— *Part 10415: Device specialization — Weighing scale*

— *Part 10417: Device specialization — Glucose meter*

— *Part 10418: Device specialization — International Normalized Ratio (INR) monitor*

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

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

— *Part 10441: Device specialization — Cardiovascular fitness and activity monitor*

— *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*

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Health informatics—Point-of-care medical device communication

Part 10102: Nomenclature—Annotated ECG

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Health informatics—Point-of-care medical device communication

Part 10102: Nomenclature—Annotated ECG

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Approved 5 December 2012

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ISO/IEEE 11073-10102:2014(E)

Abstract: The base IEEE 11073 -10101 Nomenclature is extended by this st andard to provide support for ECG annotation terminology. It ma y be used eit her in conjunction with other IEEE 11073 standards (e.g., ISO/IEEE 11073-10201:2001) or independently with other standards. The major subject areas addressed by the no menclature include ECG beat annotations, wave component annotations, rhythm annotations, and noise annotations. Additional "global" and "per-lead" numeric observation identifiers, ECG lead systems, and additional ECG lead identifiers also are defined.

Keywords: annotated ECG, annotation s, arrhythmias, cardiac rhythm, codes, ECG lead s, ECG lead systems, ECG m easurements, home monitori ng, IEEE 11073-10102 ™, medical device communication, nomenclature, pacemaker, patient monitoring, remote monitoring, terminology

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Introduction

This introduction is not part of IEEE Std 11073-10102-2012, Health informatics—Point-of-care medical device communication—Nomenclature—Annotated ECG.

This standard extends the base ISO/IEEE 11073-10101:2004[a] nomenclature to provide support for electrocardiogram (ECG) annotation terminology. The major subject areas addressed by the nomenclature include ECG beat annotations, wave component annotations, rhythm annotations, and noise annotations. It also defines additional “global” and “per-lead” numeric observation identifiers, ECG lead systems, and additional ECG lead identifiers. The nomenclature extensions may be used in conjunction with other IEEE 11073 standard components (e.g., ISO/IEEE 11073-10201:2004 [B19][b]) or independently with other standards.

[a] Information on references can be found in Clause 2.

[b] The numbers in brackets correspond to those in the bibliography in Annex E.

Contents

Health informatics—Point-of-care medical device communication

Part 10102: Nomenclature—Annotated ECG

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1. Overview

1.1 Scope

This standard extends the base ISO/IEEE 11073-10101:2004[1] to provide support for ECG annotation terminology. Major subject areas addressed by the nomenclature include ECG beat annotations, wave component annotations, rhythm annotations, and noise annotations. It also defines additional "global" and "per-lead" numeric observation identifiers, ECG lead systems, and additional ECG lead identifiers. The nomenclature extensions may be used in conjunction with other IEEE 11073 standard components (e.g., ISO/IEEE 11073-10201:2004 [B19][2]) or independently with other standards.

1.2 Purpose

This standard provides a unified and comprehensive terminology for ECG annotation semantics, making it suitable for medical device data exchange that requires inclusion of ECG annotations. This standard consolidates numerous other standard and nonstandard terminologies that are in current use, resulting in the harmonization of how ECG annotation information is identified, enabling interoperability, and providing information exchange at the application level.

[1] Information on references can be found in Clause 2.

[2] The numbers in brackets correspond to those of the bibliography in Annex E.

Currently, many terminologies and protocols, both standard and vendor specific, are used to manage and exchange ECG annotation information. As a result, protocol converters and translators are required to integrate systems and applications, typically with some degree of semantic loss and noninteroperability. This standard provides a single terminology that is capable of supporting applications that require ECG annotations, including evaluation of patient condition (e.g., reviewing ECG data at the point-of-care or remotely) as well as clinical research (e.g., electronically submitting clinical drug trial evidence supporting the efficacy of a new medication). In addition to incorporating ECG annotations into an ISO/IEEE 11073-based information stream acquired at the bedside, the underlying nomenclature can also be used in other persistent and communication standards [e.g., Health Level Seven International (HL7) V2 and V3, and Digital Imaging and Communications in Medicine (DICOM)] for use by various applications, including clinical information systems, electronic patient records, and clinical research.

1.3 Audience

The audience for this document is those who work with monitoring and diagnostic ECG information in the context of systems integration. This may include but is not limited to the following roles:

- Cardiologist or electrophysiologist physicians
- Heart and device clinic specialists or staff
- Primary care physicians
- Clinic information technologists
- Clinic information system vendor engineers
- Academic and clinical research scientists
- Regulatory and quality management agencies
- Clincal trial and research results reporting
- Medical device and system development engineers

The following clinical applications are facilitated by this interoperability enabled by this standard. This may include but is not limited to the following activities:

- Clinical trial and research results reporting [HL7 annotated electrocardiogram (aECG), Clinical Data Interchange Standards Consortium (CDISC), and others]
- Transfer of ECG data in an interoperable manner [DICOM, HL7, IEEE 11073, Integrating the Healthcare Enterprise Patient Care Devices (IHE PCD), and other communication protocols]
- Algorithm development and performance evaluation
- Sophisticated real-time data exchange with option to retrospectively review and correct data

1.4 Context

This nomenclature has been developed within the context of the broader ISO/IEEE 11073 Health Informatics—Point-of-Care Medical Device Communication standards. Its goal is to be consistent with existing 11073 standards and information models.

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.

ANSI/AAMI EC71-2001, Standard Communications Protocol for Computer Assisted-Electrocardiography.[3]

ISO/IEEE 11073-10101:2004, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.[4]

[3] ANSI publications are available from the American National Standards Institute (http://www.ansi.org/).
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