

First edition
2012-12-01

**Health informatics — Personal health
device communication —**

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

*Informatique de santé — Communication entre dispositifs de santé
personnels —*

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



Reference number
ISO/IEEE 11073-10406:2012(E)



© IEEE 2012



COPYRIGHT PROTECTED DOCUMENT

© IEEE 2012

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO or IEEE at the respective address below.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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

Published in Switzerland

This is a preview of "ISO/IEEE 11073-10406...". [Click here to purchase the full version from the ANSI store.](#)

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

This is a preview of "ISO/IEEE 11073-10406...". [Click here to purchase the full version from the ANSI store.](#)

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

This is a preview of "ISO/IEEE 11073-10406...". [Click here to purchase the full version from the ANSI store.](#)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

IEEE Standards documents are developed within the IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Association (IEEE-SA) Standards Board. The IEEE develops its standards through a consensus development process, approved by the American National Standards Institute, which brings together volunteers representing varied viewpoints and interests to achieve the final product. Volunteers are not necessarily members of the Institute and serve without compensation. While the IEEE administers the process and establishes rules to promote fairness in the consensus development process, the IEEE does not independently evaluate, test, or verify the accuracy of any of the information or the soundness of any judgments contained in its standards.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is called to the possibility that implementation of this standard may require the use of subject matter covered by patent rights. By publication of this standard, no position is taken with respect to the existence or validity of any patent rights in connection therewith. ISO/IEEE is not responsible for identifying essential patents or patent claims for which a license may be required, for conducting inquiries into the legal validity or scope of patents or patent claims or determining whether any licensing terms or conditions provided in connection with submission of a Letter of Assurance or a Patent Statement and Licensing Declaration Form, if any, or in any licensing agreements are reasonable or non-discriminatory. Users of this standard are expressly advised that determination of the validity of any patent rights, and the risk of infringement of such rights, is entirely their own responsibility. Further information may be obtained from ISO or the IEEE Standards Association.

ISO/IEEE 11073-10406 was prepared by the IEEE 11073 Standards Committee 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*

This is a preview of "ISO/IEEE 11073-10406...". [Click here to purchase the full version from the ANSI store.](#)

- *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]*

This is a preview of "ISO/IEEE 11073-10406...". [Click here to purchase the full version from the ANSI store.](#)

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).