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

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**Förhållandet till övriga delar under samma huvudtitel - Utdrag ur Förord i ISO 11073-10406:2012/
Relations to other parts under the same general title - Extract from the Foreword of
ISO 11073-10406:2012**

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*
- 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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EUROPEAN STANDARD

EN ISO 11073-10406

NORME EUROPÉENNE

EUROPÄISCHE NORM

December 2012

ICS 35.240.80

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 - Électrocardiogramme 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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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.