

Zdravotnícka informatika. Komunikácia zdravotníckeho prístroja na mieste zdravotnej starostlivosti. Časť 10103: Názvoslovie: Implantovateľné pomôcky srdca (ISO/IEEE 11073-10103: 2014).

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Health informatics - Point-of-care medical device communication - Part 10103: Nomenclature - Implantable device, cardiac (ISO/IEEE 11073-10103:2013)

Táto norma obsahuje anglickú verziu európskej normy.

This standard includes the English version of the European Standard.

Obsahuje: EN ISO 11073-10103:2013, EN ISO 11073-10103:2014/Cor. Feb.:2014, ISO/IEEE 11073-10103:2014

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## EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

## EN ISO 11073-10103

December 2013

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## **English Version**

Health informatics - Point-of-care medical device communication - Part 10103: Nomenclature - Implantable device, cardiac (ISO/IEEE 11073-10103:2014)

Informatique de santé - Communication entre dispositifs médicaux sur le site des soins - Partie 10103: Nomenclature - Dispositif implantable, cardiaque (ISO/IEEE 11073-10103:2014)

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## **Foreword**

This document (EN ISO 11073-10103:2013) 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.

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EN ISO 11073-10103:2013

Reference:

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It has been brought to our attention that this document, issued on 2013-12-18, requires modification.

ISO/CS initially notified CCMC that this project would be published in December 2013. CCMC published the EN ISO in December 2013 however ISO/CS failed to notify CCMC that they had postponed their publication to February 2014. The date of the ISO 11073-10103:2014 is updated in the EN ISO text, not the EN ISO year of publication which remains 2013. Additionally the implementation dates are recalculated against the publication date of the ISO text.

Please find enclosed the updated English and French versions.

INTERNATIONAL STANDARD

## 11073-10103

First edition 2014-03-01

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## Health informatics — Point-of-care medical device communication —

Part 10103:

Nomenclature — Implantable device, cardiac

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

Partie 10103: Nomenclature — Dispositif implantable, cardiaque



## ISO/IEEE 11073-10103:2014(E)

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## **Foreword**

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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

### ISO/IEEE 11073-10103:2014(E)

- 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 Independent 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 10103: Nomenclature—Implantable device, cardiac

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New York, NY 10016-5997 USA Health informatics—Point-of-care medical device communication

# Part 10103: Nomenclature—Implantable device, cardiac

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Approved 14 May 2012

**IEEE-SA Standards Board** 

Abstract: The base nomenclature provided in IEEE 11073 to support terminology for implantable cardiac devices is extended in this standard. Devices within the scope of this nomenclature are implantable devices such as pacemakers, defibrillators, devices for cardiac resynchronization therapy, and implantable cardiac monitors. The discrete terms necessary to convey a clinically relevant summary of the information obtained during a device interrogation are defined in this nomenclature. To improve workflow efficiencies, cardiology and electrophysiology practices require the management of summary interrogation information from all vendor devices and systems in a central system such as an Electronic Health Records (EHR) system or a device clinic management system. To address this requirement, the Implantable Device, Cardiac (IDC) Nomenclature defines a standard-based terminology for device data. The nomenclature facilitates the transfer of data from the vendor proprietary systems to the clinic EHR or device clinic management system.

**Keywords:** cardiac resynchronization therapy (CRT), codes, follow-up, home monitoring, IEEE 11073-10103, implantable cardioverter defibrillator (ICD), implantable devices, medical device communication, nomenclature, pacemaker, remote follow-up, remote monitoring, terminology

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### Introduction

This introduction is not part of IEEE Std 11073-10103-2012, Health informatics—Point-of-care medical device communication—Part 10103: Nomenclature—Implantable device, cardiac.

This standard enables and standardizes the reporting of discrete data elements associated with implantable cardiac device interrogations (observations) to enterprise-based applications (e.g., clinical information systems). Currently, no such standardization exists, typically resulting in the reports being managed as paper documents and not electronically.

Given the lack of standardization in this domain, information retrieved from implantable cardiac devices is transmitted and stored in centralized health records using vendor proprietary methods, or in many cases, it is managed as paper documents. By standardizing the terminology used to describe the settings and measurements of these devices, both the ordering and follow-up reporting can be integrated more easily with health care applications, such as electronic health records, order entry systems, and electronic patient records. This integration will result in greater access to critical patient information and automated verification that clinical orders have been completed in a timely fashion, ultimately resulting in increased quality of care and patient safety.

Subject domain experts provided the requirements for the nomenclature. Subject domain experts are represented by members of the Heart Rhythm Society (HRS), which is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders.

This standard is a distinct and standalone partition within the IEEE 11073-10101 nomenclature. It is meant to be a self-contained and comprehensive nomenclature for information pertaining to implantable cardiac devices.

NOTE—The XML Schema, XSLT transforms and XML data files contained in Annex H are available at the following URL: <a href="http://standards.ieee.org/downloads/11073/11073-10103-2012/">http://standards.ieee.org/downloads/11073/11073-10103-2012/</a>.

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## Health informatics—Point-of-care medical device communication

# Part 10103: Nomenclature—Implantable device, cardiac

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## 1. Overview

## 1.1 Scope

This standard extends the base nomenclature provided in ISO/IEEE 11073-10101:2004<sup>1</sup> to support terminology for implantable cardiac devices. Devices within the scope of this nomenclature are implantable devices such as pacemakers, defibrillators, devices for cardiac resynchronization therapy, and implantable cardiac monitors. This nomenclature defines the discrete terms necessary to convey a clinically relevant summary of the information obtained during a device interrogation. The nomenclature extensions may be used in conjunction with other IEEE 11073 standard components (e.g., ISO/IEEE 11073-10201 [B2]<sup>2</sup>) or with other standards, such as Health Level Seven International (HL7).

<sup>&</sup>lt;sup>1</sup> Information on references can be found in Clause 2.

<sup>&</sup>lt;sup>2</sup> The numbers in brackets correspond to those of the bibliography in Annex I.

## STN EN ISO11073-10103: 2014

IEEE Std 11073-10103-2012

Health informatics—Point-of-care medical device communication Part 10103: Nomenclature—Implantable device, cardiac

## 1.2 Purpose

ISO/IEEE 11073-1010' :2014(E)

This standard addresses the need for an openly defined, independent standard for representing information collected from industry-wide implantable cardiac devices. A broader intent is to enable a standards-based exchange of implantable cardiac device information between vendor's proprietary interrogation systems and clinic electronic medical record systems.

#### 1.3 Audience

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

- Cardiologist or electrophysiologist physicians
- Heart failure physicians
- Heart and device clinic specialists or staff
- Primary care physicians
- Clinic information technologists
- Clinic information system vendor engineers
- Implantable cardiac device vendor engineers
- Regulatory and quality management agencies

### 1.4 Context

This nomenclature has been developed within the context of the broader 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.

ISO/IEEE 11073-10101:2004, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.<sup>3</sup>

The Unified Code for Units of Measure (UCUM), version 1.8.<sup>4</sup>

## koniec náhľadu – text ďalej pokračuje v platenej verzii STN

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