

SVENSK STANDARD

SS-EN ISO 11073-10407:2011



Fastställt/Approved: 2011-03-28
Publicerad/Published: 2011-04-28
Utgåva/Edition: 1
Språk/Language: engelska/English
ICS: 35.240.80

**Hälsa- och sjukvårdsinformatik – Kommunikation med personlig utrustning för hälsovården –
Del 10407: Produkttyp – Blodtrycksmätare
(ISO/IEEE 11073-10407:2010)**

**Health informatics – Personal health device communication –
Part 10407: Device specialization – Blood pressure monitor
(ISO/IEEE 11073-10407:2010)**

This preview is downloaded from www.sis.se. Buy the entire standard via <https://www.sis.se/std-77353>

Standarder får världen att fungera

SIS (Swedish Standards Institute) är en fristående ideell förening med medlemmar från både privat och offentlig sektor. Vi är en del av det europeiska och globala nätverk som utarbetar internationella standarder. Standarder är dokumenterad kunskap utvecklad av framstående aktörer inom industri, näringsliv och samhälle och befrämjar handel över gränser, bidrar till att processer och produkter blir säkrare samt effektiviserar din verksamhet.

Delta och påverka

Som medlem i SIS har du möjlighet att påverka framtida standarder inom ditt område på nationell, europeisk och global nivå. Du får samtidigt tillgång till tidig information om utvecklingen inom din bransch.

Ta del av det färdiga arbetet

Vi erbjuder våra kunder allt som rör standarder och deras tillämpning. Hos oss kan du köpa alla publikationer du behöver – allt från enskilda standarder, tekniska rapporter och standardpaket till handböcker och onlinetjänster. Genom vår webbtjänst e-nav får du tillgång till ett lättnavigerat bibliotek där alla standarder som är aktuella för ditt företag finns tillgängliga. Standarder och handböcker är källor till kunskap. Vi säljer dem.

Utveckla din kompetens och lyckas bättre i ditt arbete

Hos SIS kan du gå öppna eller företagsinterna utbildningar kring innehåll och tillämpning av standarder. Genom vår närhet till den internationella utvecklingen och ISO får du rätt kunskap i rätt tid, direkt från källan. Med vår kunskap om standarders möjligheter hjälper vi våra kunder att skapa verklig nytta och lönsamhet i sina verksamheter.

Vill du veta mer om SIS eller hur standarder kan effektivisera din verksamhet är du välkommen in på www.sis.se eller ta kontakt med oss på tel 08-555 523 00.



Standards make the world go round

SIS (Swedish Standards Institute) is an independent non-profit organisation with members from both the private and public sectors. We are part of the European and global network that draws up international standards. Standards consist of documented knowledge developed by prominent actors within the industry, business world and society. They promote cross-border trade, they help to make processes and products safer and they streamline your organisation.

Take part and have influence

As a member of SIS you will have the possibility to participate in standardization activities on national, European and global level. The membership in SIS will give you the opportunity to influence future standards and gain access to early stage information about developments within your field.

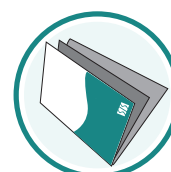
Get to know the finished work

We offer our customers everything in connection with standards and their application. You can purchase all the publications you need from us - everything from individual standards, technical reports and standard packages through to manuals and online services. Our web service e-nav gives you access to an easy-to-navigate library where all standards that are relevant to your company are available. Standards and manuals are sources of knowledge. We sell them.

Increase understanding and improve perception

With SIS you can undergo either shared or in-house training in the content and application of standards. Thanks to our proximity to international development and ISO you receive the right knowledge at the right time, direct from the source. With our knowledge about the potential of standards, we assist our customers in creating tangible benefit and profitability in their organisations.

If you want to know more about SIS, or how standards can streamline your organisation, please visit www.sis.se or contact us on phone +46 (0)8-555 523 00



Europastandarden EN ISO 11073-10407:2011 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 11073-10407:2011.

The European Standard EN ISO 11073-10407:2011 has the status of a Swedish Standard. This document contains the official version of EN ISO 11073-10407:2011.

**Förhållandet till övriga delar under samma huvudtitel -
Utdrag ur Förord i ISO/IEEE 11073-10407:2010/
Relations to other parts under the same general title -
Extract from the Foreword of ISO/IEEE 11073-10407:2010**

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: Domain information model
- Part 10404: Device specialization – Pulse oximeter
- Part 10407: Device specialization – Blood pressure monitor
- Part 10408: (Point-of-care medical device communication) Device specialization – Thermometer
- Part 10415: (Point-of-care medical device communication) Device specialization – Weighing scale
- Part 10417: Device specialization – Glucose meter
- Part 10471: (Point-of-care medical device communication) Device specialization – Independent living activity hub
- Part 20101: (Point-of-care medical device communication) Application profiles – Base standard
- Part 20601: (Point-of-care medical device communication) 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

© Copyright/Upphovsrätten till denna produkt tillhör SIS, Swedish Standards Institute, Stockholm, Sverige. Användningen av denna produkt regleras av slutanvändarlicensen som återfinns i denna produkt, se standardens sista sidor.

© Copyright SIS, Swedish Standards Institute, Stockholm, Sweden. All rights reserved. The use of this product is governed by the end-user licence for this product. You will find the licence in the end of this document.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Hälso- och sjukvårdsinformatik, SIS/TK 334.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

EN ISO 11073-10407

NORME EUROPÉENNE

EUROPÄISCHE NORM

March 2011

ICS 35.240.80

English Version

**Health informatics - Personal health device communication -
Part 10407: Device specialization - Blood pressure monitor
(ISO/IEEE 11073-10407:2010)**

Informatique de santé - Communication entre dispositifs de
santé personnels - Partie 10407: Spécialisation des
dispositifs - Moniteur de pression sanguine (ISO/IEEE
11073-10407:2010)

Medizinische Informatik - Kommunikation von Geräten für
die persönliche Gesundheit - Teil 10407:
Gerätespezifikation - Blutdruckmonitor (ISO/IEEE 11073-
10407:2010)

This European Standard was approved by CEN on 23 April 2010.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents	Page
Foreword.....	v
Introduction.....	vi
1. Overview	1
1.1 Scope.....	1
1.2 Purpose.....	1
1.3 Context.....	1
2. Normative references	2
3. Definitions, acronyms, and abbreviations	2
3.1 Definitions.....	2
3.2 Acronyms and abbreviations.....	3
4. Introduction to ISO/IEEE 11073 personal health devices	3
4.1 General.....	3
4.2 Introduction to IEEE 11073-20601 modeling constructs	4
5. Blood pressure monitor device concepts and modalities.....	5
5.1 General.....	5
5.2 Systolic and diastolic pressure	5
5.3 Mean arterial pressure	5
5.4 Pulse rate	5
6. Blood pressure monitor domain information model.....	6
6.1 Overview.....	6
6.2 Class extensions	6
6.3 Object instance diagram.....	6
6.4 Types of configuration	7
6.5 Medical device system object	7
6.6 Numeric objects	11
6.7 Real-time sample array objects	13
6.8 Enumeration objects.....	13
6.9 PM-store objects	15
6.10 Scanner objects	15
6.11 Class extension objects	15
6.12 Blood pressure monitor information model extensibility rules	15
7. Blood pressure monitor service model	15
7.1 General.....	15
7.2 Object access services	15
7.3 Object access event report services	16

8.	Blood pressure monitor communication model.....	17
8.1	Overview.....	17
8.2	Communication characteristics.....	17
8.3	Association procedure.....	17
8.4	Configuring procedure.....	19
8.5	Operating procedure.....	21
8.6	Time synchronization.....	21
9.	Test associations.....	21
9.1	General.....	21
9.2	Behavior with standard configuration.....	22
9.3	Behavior with extended configurations.....	22
10.	Conformance.....	22
10.1	Applicability.....	22
10.2	Conformance specification.....	22
10.3	Levels of conformance.....	23
10.4	Implementation conformance statements.....	23
	Annex A (informative) Bibliography.....	28
	Annex B (normative) Any additional ASN.1 definitions.....	29
	Annex C (normative) Allocation of identifiers.....	30
	Annex D (informative) Message sequence examples.....	31
	Annex E (informative) Protocol data unit examples.....	33

Foreword

The text of ISO/IEEE 11073-10407:2010 has been prepared by Technical Committee ISO/TC 215 “Health informatics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11073-10407:2011 by 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 September 2011, and conflicting national standards shall be withdrawn at the latest by September 2011.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO/IEEE 11073-10407:2010 has been approved by CEN as a EN ISO 11073-10407:2011 without any modification.

Introduction

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in IEEE Std 11073-20601^a and describes a specific, interoperable communication approach for blood pressure monitors. These standards align with and draw on the existing clinically focused standards to provide support for communication of data from personal health devices.

^aInformation on references can be found in Clause 2.

Health informatics — Personal health device communication —

Part 10407: Device specialization — Blood pressure monitor

IMPORTANT NOTICE: *This standard is not intended to ensure safety, security, health, or environmental protection in all circumstances. Implementers of the standard are responsible for determining appropriate safety, security, environmental, and health practices or regulatory requirements.*

This IEEE document is made available for use subject to important notices and legal disclaimers. These notices and disclaimers appear in all publications containing this document and may be found under the heading “Important Notice” or “Important Notices and Disclaimers Concerning IEEE Documents.” They can also be obtained on request from IEEE or viewed at <http://standards.ieee.org/IPR/disclaimers.html>.

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 communication between personal telehealth blood pressure monitor devices and compute engines (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, information models, application profile standards, and transport standards. 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 blood pressure monitors.

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 compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes). Interoperability is the key to growing the potential market for these devices and to enabling people to be better informed participants in the management of their health.

1.3 Context

See IEEE Std 11073-20601™ for an overview of the environment within which this standard is written.

This document, IEEE Std 11073-10407, defines the device specialization for the blood pressure monitor, being a specific agent type, and provides a description of the device concepts, its capabilities, and its implementation according to this standard.