SLOVENSKI STANDARD
SIST EN ISO 11073-10472:2013

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Zdravstvena informatika - Komunikacija osebnih medicinskih naprav - 10472. del: Specialne naprave - Naprava za nadzor jemanja zdravil (ISO 11073-10472:2012)

Health Informatics - Personal health device communication - Part 10472: Device specialization - Medication monitor (ISO 11073-10472:2012)

Medizinische Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10472: Gerätespezifikation - Medikamentenmonitoring (ISO 11073-10472:2012)

Informatique de santé - Communication entre dispositifs de santé personnels - Partie 10472: Spécialisation de dispositif - Moniteur de médication (ISO 11073-10472:2012)

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35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

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Health Informatics - Personal health device communication - Part 10472: Device specialization - Medication monitor (ISO 11073-10472:2012)

Informatique de santé - Communication entre dispositifs de santé personnels - Partie 10472: Spécialisation des dispositifs - Moniteur de surveillance de médication (ISO 11073-10472:2012)

Medizinische Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10472: Gerätespezifikation - Medikamentenmonitoring (ISO 11073-10472:2012)

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Foreword

This document (EN ISO 11073-10472:2012) 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of an identical text or by endorsement, at the latest by May 2013, and conflicting national standards shall be withdrawn at the latest by May 2013.

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INTERNATIONAL STANDARD

ISO/IEEE 11073-10472

First edition
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Health informatics — Personal health device communication —

Part 10472: Device specialization — Medication monitor

Informatique de santé — Communication entre dispositifs de santé personnels —
Partie 10472: Spécialisation de dispositif — Moniteur de médication

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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 contained in its standards.

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ISO/IEEE 11073-10472 was prepared by the IEEE 11073 Standards Comittee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10472-2010). 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 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*

Introduction

This introduction is not part of IEEE Std 11073-10472-2012, Health Informatics—Personal health device communication—Part 10472: Device specialization—Medication monitor.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between medication monitoring devices and managers (e.g., cell phones, personal computers, personal health appliances, 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 information models. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting ambiguity in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for medication monitors. In this context, medication monitors are defined as devices that have the ability to determine and communicate (to a manager) measures of a user's adherence to a medication regime.

Health informatics — Personal health device communication —

Part 10472: Device specialization — Medication 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.

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 medication monitoring devices and managers (e.g., cell phones, personal computers, personal health appliances, 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 information models. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting ambiguity in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for medication monitors. In this context, medication monitors are defined as devices that have the ability to determine and communicate (to a manager) measures of a user's adherence to a medication regime.