

SLOVENSKI STANDARD
SIST EN ISO 11073-10418:2014/AC:2017
01-maj-2017

Zdravstvena informatika - Komunikacija osebnih medicinskih naprav - 10418. del: Specialne naprave - Monitor za mednarodno umerjeno razmerje (INR) - Tehnični popravek 1 (ISO/IEEE 11073-10418:2014/Cor 1:2016)

Health informatics - Personal health device communication - Part 10418: Device specialization - International Normalized Ratio (INR) monitor - Technical Corrigendum 1 (ISO/IEEE 11073-10418:2014/Cor 1:2016)

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Medizinische Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10418: Gerätespezifikation - Monitor für den international standardisierter Thromboplastinzeit-Quotient (INR) - Berichtigung 1 (ISO/IEEE 11073-10418:2014/Cor 1:2016)

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Informatique de santé - Communication entre dispositifs de santé personnels - Partie 10418: Spécialisation des dispositifs - Surveillance du rapport normalisé international (INR) - Rectificatif technique 1 (ISO/IEEE 11073-10418:2014/Cor 1:2016)

Ta slovenski standard je istoveten z: EN ISO 11073-10418:2014/AC:2016

ICS:

| | | |
|-----------|--|---|
| 11.040.01 | Medicinska oprema na splošno | Medical equipment in general |
| 35.240.80 | Uporabniške rešitve IT v zdravstveni tehniki | IT applications in health care technology |

SIST EN ISO 11073-10418:2014/AC:2017 en,fr,de

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EUROPEAN STANDARD

EN ISO 11073-10418

NORME EUROPÉENNE

October 2016

EUROPÄISCHE NORM

Octobre 2016

Oktober 2016

ICS 35.240.80

English version
Version Française
Deutsche Fassung

Health informatics - Personal health device communication - Part 10418:
Device specialization - International Normalized Ratio (INR) monitor -
Technical Corrigendum 1 (ISO/IEEE 11073-10418:2014/Cor 1:2016)

Informatique de santé - Communication
entre dispositifs de santé personnels - Partie
10418: Spécialisation des dispositifs -
Surveillance du rapport normalisé
international (INR) - Rectificatif technique 1
(ISO/IEEE 11073-10418:2014/Cor 1:2016)

Medizinische Informatik - Kommunikation
von Geräten für die persönliche Gesundheit -
Teil 10418: Gerätespezifikation - Monitor für
den international standardisierter
Thromboplastinzeit-Quotient (INR) -
Berichtigung 1 (ISO/IEEE 11073-
10418:2014/Cor 1:2016)

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This corrigendum becomes **effective on 19 October 2016** for incorporation in the official English version of the EN. <https://standards.iteh.ai/catalog/standards/sist/3635bffb-eceb-4b7b-b72b-7b70d793b4d9/sist-en-iso-11073-10418-2014-ac-2017>

Ce corrigendum prendra effet le 19 octobre 2016 pour incorporation dans la version anglaise officielle de la EN.

Die Berichtigung tritt am 19. Oktober 2016 zur Einarbeitung in die offizielle Englische Fassung der EN in Kraft.



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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Ref. No.: EN ISO 11073-10418:2016 E

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European foreword

The text of ISO/IEEE 11073-10418:2014/Cor 1:2016 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 11073-10418:2014/AC:2016 by Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

Endorsement notice

The text of ISO/IEEE 11073-10418:2014/Cor 1:2016 has been approved by CEN as EN ISO 11073-10418:2014/AC:2016 without any modification.

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**INTERNATIONAL STANDARD ISO/IEEE 11073-10418:2014
TECHNICAL CORRIGENDUM 1**

Published 2016-10-01

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION
INTERNATIONAL ELECTROTECHNICAL COMMISSION • МЕЖДУНАРОДНАЯ ЭЛЕКТРОТЕХНИЧЕСКАЯ КОМИССИЯ • COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE**Health informatics — Personal health device communication**
Part 10418:
**Device specialization — International Normalized Ratio (INR)
monitor****TECHNICAL CORRIGENDUM 1***Informatique de santé — Communication entre dispositifs de santé personnels — Partie 10418: Spécialisation des dispositifs — Surveillance du rapport normalisé international (INR)*

RECTIFICATIF TECHNIQUE 1

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Technical Corrigendum 1 to ISO/IEEE 11073-10418 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10418-2014/Cor 1:2015). 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.

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Health informatics—Personal health device communication

Part 10418: Device specialization— International Normalized Ratio (INR) monitor

Corrigendum 1

Sponsor

IEEE 11073™ Standards Committee

of the

IEEE Engineering in Medicine and Biology Society

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Approved 3 September 2015

IEEE-SA Standards Board

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Abstract: A normative definition of communication between personal telehealth International Normalized Ratio (INR) devices (agents) and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes) is established in this standard in a manner that enables plug-and-play interoperability. Work done in other ISO/IEEE 11073 standards is leveraged, including existing terminology, information profiles, application profile standards, and transport standards. The use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability is specified. A common core of functionality of INR devices is defined in this standard. In the context of personal health devices, the measurement of the prothrombin time (PT) that is used to assess the level of anticoagulant therapy and its presentation as the International Normalized Ratio compared to the prothrombin time of normal blood plasma is referred to in INR monitoring. Applications of the INR monitor include the management of the therapeutic level of anticoagulant used in the treatment of a variety of conditions. The data modeling and its transport shim layer according to IEEE Std 11073-20601™-2014 are provided by this standard, and the measurement method is not specified.

This standard corrects errors that have been identified in the IEEE Std 11073-10418-2011 to make it easier to implement the standard in an interoperable fashion.

Keywords: IEEE 11073™, IEEE 11073-10418™, IEEE 11073-20601™, ISO/IEEE 11073-10418, ISO/IEEE 11073-20601, International Normalized Ratio (INR) monitor, medical device communication, personal health devices

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