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**Zdravotnická informatika – Komunikační zařízení pro osobní
zdravotní péči –
Část 10418: Specializovaná zařízení – Komunikační zařízení INR**



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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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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.



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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.

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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.

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

Published 2016-10-01



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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

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.

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

Approved 3 September 2015

IEEE-SA Standards Board

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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Introduction

This introduction is not part of IEEE Std 11073-10418™-2011/Cor 1-2015, Health informatics—Personal health device communication—Part 10418: Device specialization—International Normalized Ratio (INR) monitor—Corrigendum 1.

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, 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 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 personal telehealth INR devices. In this context, 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 (INR) compared with the PT 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.

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

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Health informatics—Personal health device communication

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

Corrigendum 1

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5. INR monitor device concepts and modalities

Delete the following subclause as shown:

~~5.9 Device alarm conditions~~

~~This provides information on any device specific alarm conditions.~~

Change the following index of subtitles and renumber as shown:

~~5.10~~ 5.9 INR value out of bounds

~~5.11~~ 5.10 Extended capabilities

~~5.12~~ 5.11 Target level for INR

~~5.13~~ 5.12 Current level of medication

~~5.14~~ 5.13 Recommended new level of medication

~~5.15~~ 5.14 Context information

6. International Normalized Ratio monitor domain information model

6.5 Object instance diagram

Replace Figure 1 with the following figure:

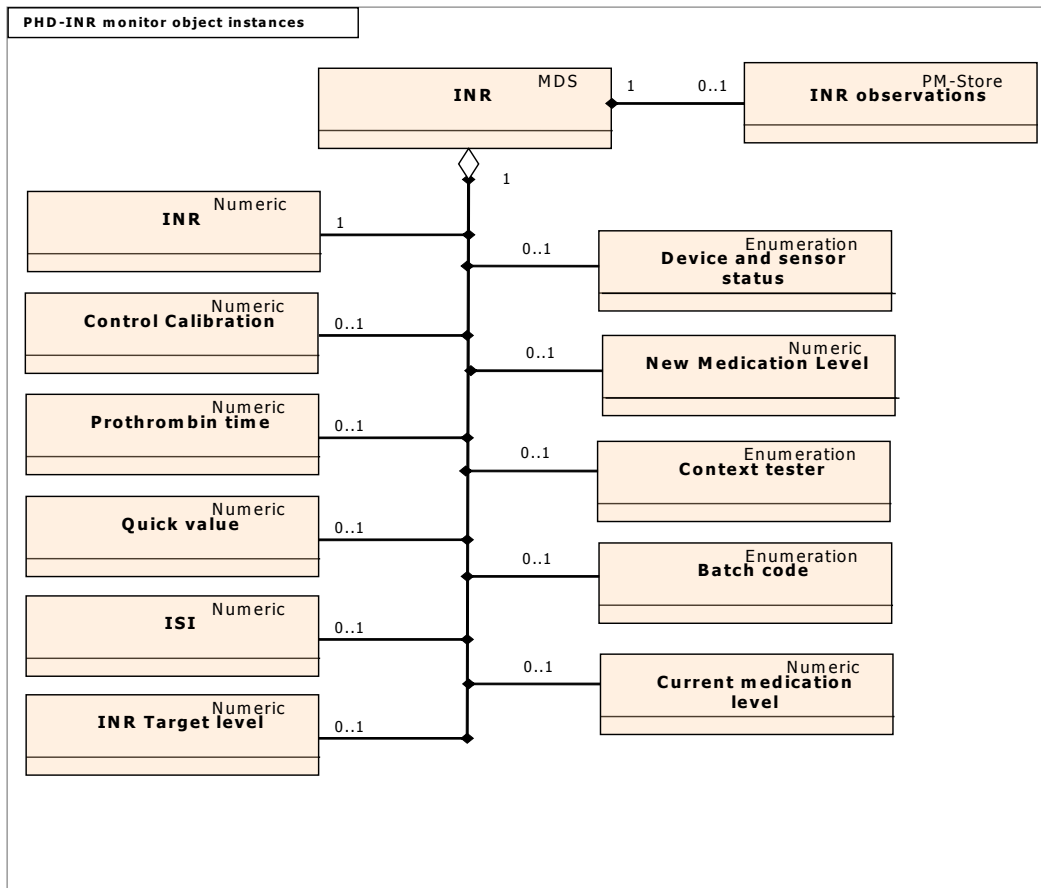


Figure 1—INR monitor—domain information model

6.8 Enumeration objects

6.8.1 Device and sensor status

Change the title of Table 17 as shown:

Table 17—Context tester ~~Device and sensor status~~ enumeration object attributes

6.9 PM-Store objects

6.9.2 Persistent store model

Replace Figure 2 with the following figure:

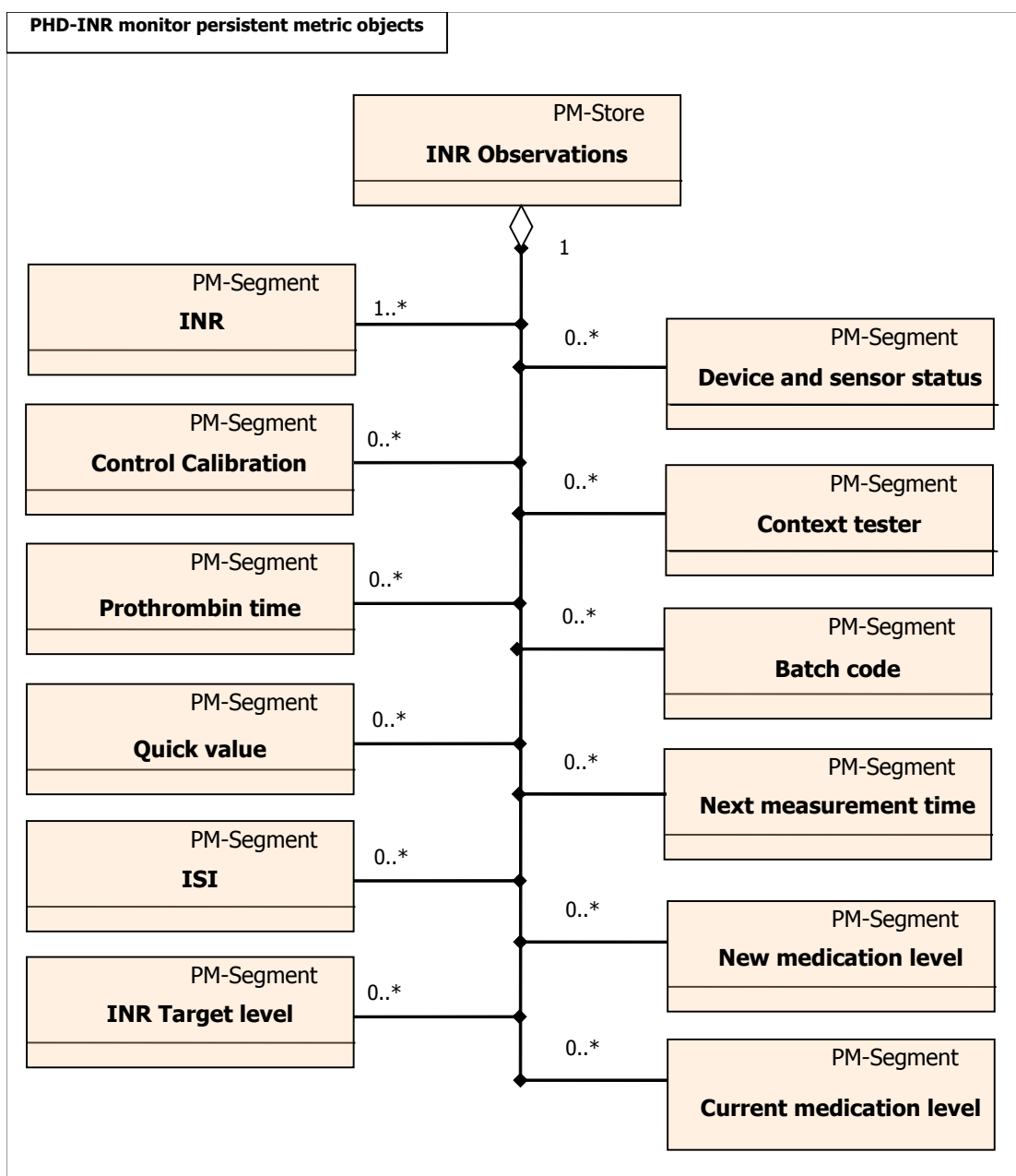


Figure 2—INR monitor—persistent metric store model

Annex C

(normative)

Allocation of identifiers

Change the number in Table C.1 as shown:

Table C.1—Device profiles nomenclature and codes

Systematic name	Common term	Reference ID	Code
Profile Device Coagulation	International Standardized Ratio	MDC_DEV_SPEC_PROFILE_COAG	41184

Change the number after Table C.5 as shown:

```

/*****
* From Infrastructure (MDC_PART_INFRA) (8)
*****/
#define MDC_DEV_SPEC_PROFILE_COAG      41184 /* */
    
```

U p o z o r n ě n í : Oznámení o změnách, opravách a nově vydaných normách jsou uveřejňována ve Věstníku Úřadu pro technickou normalizaci, metrologii a státní zkušebnictví.

Vaše názory, podněty a připomínky týkající se technických norem a zájmu o možnou účast v procesech technické normalizace lze zaslat na e-mailovou adresu info@agentura-cas.cz.

ČSN EN ISO 11073-10418 OPRAVA 1



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