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
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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.

ICS 35.240.80 **Ref. No. ISO/IEEE 11073-10418:2014/Cor.1:2016(E)**

Published in Switzerland

IEEE Std 11073-10418™-2011/Cor 1-2015
(Corrigendum to
IEEE Std 11073-10418-2014)

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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PDF: 978-0-7381-9993-1 STD20426
Print: 978-0-7381-9994-8 STDPD20426

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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.

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Contents

Health informatics—Personal health device communication

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

Corrigendum 1

NOTE—The editing instructions contained in this corrigendum define how to merge the material contained therein into the existing base standard and its amendments to form the comprehensive standard.

The editing instructions are shown in ***bold italic***. Four editing instructions are used: change, delete, insert, and replace. ***Change*** is used to make corrections in existing text or tables. The editing instruction specifies the location of the change and describes what is being changed by using ~~strikethrough~~ (to remove old material) and underscore (to add new material). ***Delete*** removes existing material. ***Insert*** adds new material without disturbing the existing material. Insertions may require renumbering. If so, renumbering instructions are given in the editing instruction. ***Replace*** is used to make changes in figures or equations by removing the existing figure or equation and replacing it with a new one. Editing instructions, change markings, and this NOTE will not be carried over into future editions because the changes will be incorporated into the base standard.

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:

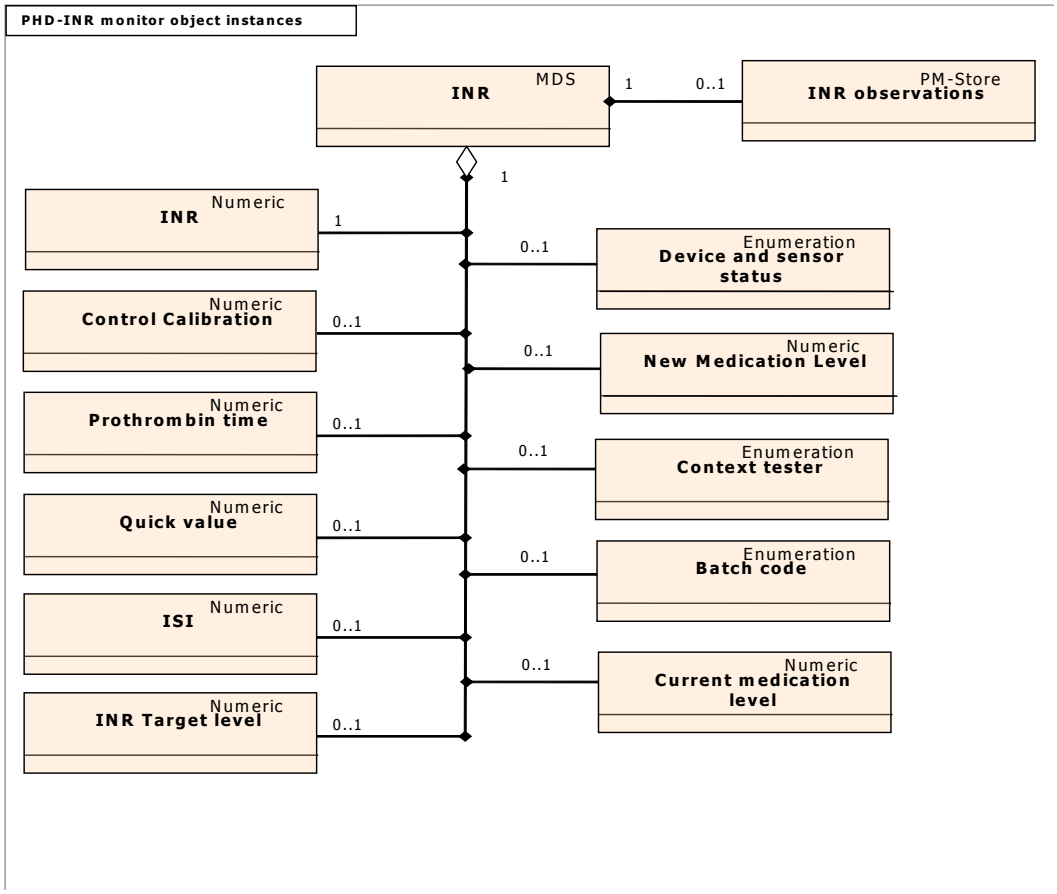

Figure 1—INR monitor—domain information model

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:

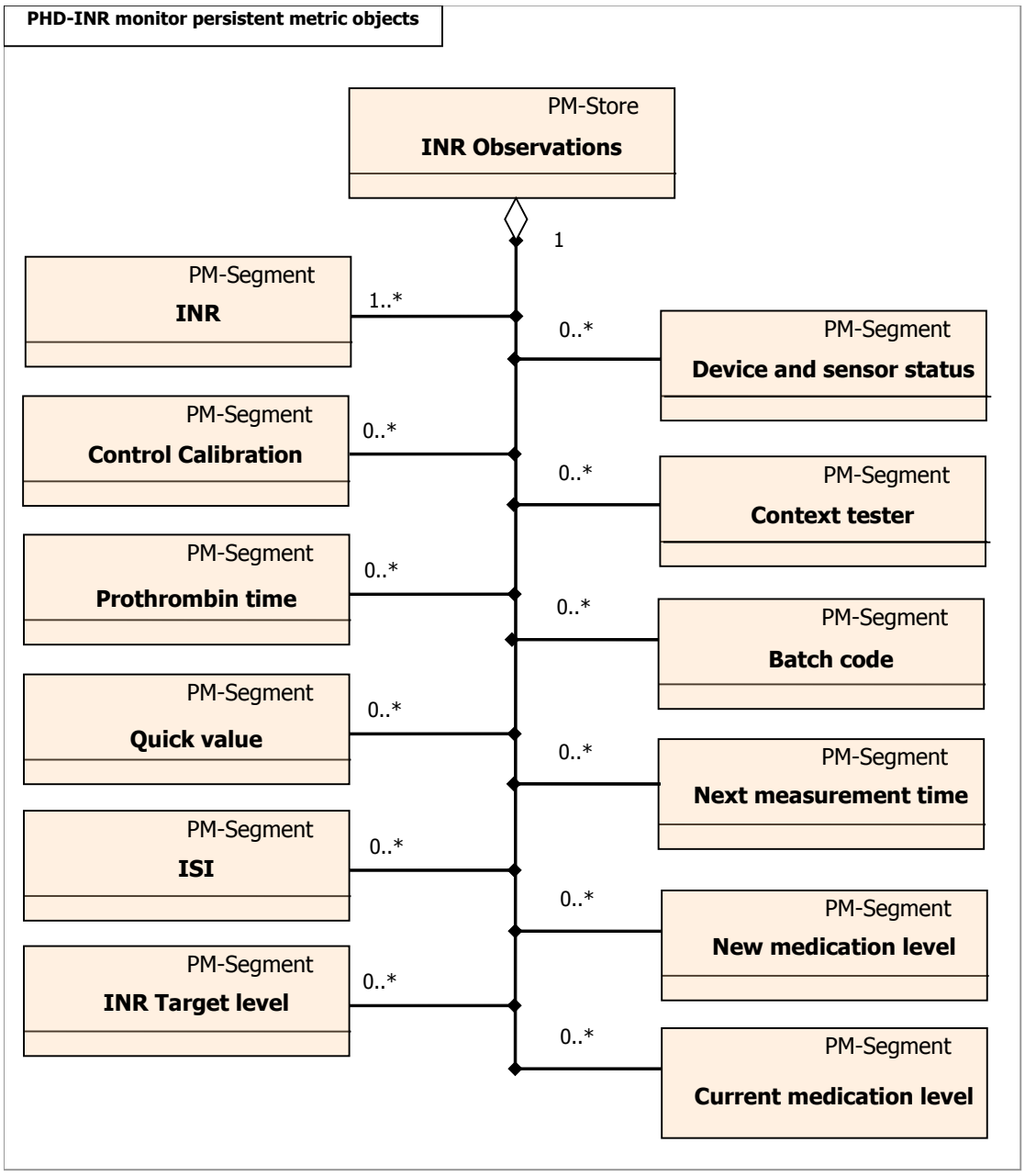

Figure 2—INR monitor—persistent metric store model

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	411~~8~~4

Change the number after Table C.5 as shown:

```
/**********************************************************************************
* From Infrastructure (MDC_PART_INFRA) (8)
**********************************************************************************/
#define MDC_DEV_SPEC_PROFILE_COAG          411~~8~~4  /*                              */
```