

P11073-10418-2011/Cor 1

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Type of Project: Corrigendum to IEEE Standard 11073-10418-2011

PAR Request Date: 04-Apr-2013

PAR Approval Date: 14-Jun-2013

PAR Expiration Date: 31-Dec-2017

Status: PAR for a Corrigendum to an existing IEEE Standard

Root Project: 11073-10418-2011

1.1 Project Number: P11073-10418-2011/Cor 1

1.2 Type of Document: Standard

1.3 Life Cycle: Full Use

2.1 Title: Health informatics--Personal health device communication Part 10418: Device specialization--International Normalized Ratio (INR) monitor - Corrigendum 1

3.1 Working Group: Personal_Health_Device (EMB/11073/PHD)

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3.2 Sponsoring Society and Committee: IEEE Engineering in Medicine and Biology Society/IEEE 11073TM Standards Committee (EMB/11073)

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4.1 Type of Ballot: Individual

4.2 Expected Date of submission of draft to the IEEE-SA for Initial Sponsor Ballot: 04/2014

4.3 Projected Completion Date for Submittal to RevCom: 05/2015

5.1 Approximate number of people expected to be actively involved in the development of this project: 15

5.2.a. Scope of the complete standard: The scope of this standard is to establish 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) in a manner that enables plug-and-play interoperability. It leverages work done in other ISO/IEEE 11073 standards including existing terminology, information profiles, 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 functionality of INR devices.

In the context of personal health devices, INR monitoring refers to 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. Applications of the INR monitor include the

Changes in scope: The scope of this standard is to establish 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) in a manner that enables plug-and-play interoperability. It leverages work done in other ISO/IEEE 11073 standards including existing terminology, information profiles, 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 functionality of INR devices. In the context of personal health devices, INR monitoring refers to 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. 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 provides the data modeling and its transport shim layer

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5.2.b. Scope of the Proposed changes: So far, we have three items on the list of change request for 11073-10418:

- 1) The name of Table-17 shall be 'Context tester enumeration object attributes'. And the same applies to Figure 2 at Page 25.
- 2) The Device Alarms object shall be removed from Figure 1.
- 3) In Table C.1, the Reference ID and Medical Device Communications (MDC) nomenclature Code are wrong. They shall be changed to MDC_DEV_SPEC_PROFILE_INR and 4114

Above three items are the scope of this proposed change, but we don't preclude any further change request pop up during the developing process of this Corrigenda unless it requires a significant change to the technical content of the original 11073-10418 standard.

5.3 Is the completion of this standard dependent upon the completion of another standard: No

5.4 Purpose: This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices (agents) and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes). Interoperability is key to growing the potential market for these devices and to enabling people to be better informed participants in the management of their health.

5.5 Need for the Project: We have identified three errors of IEEE Std. 11073-10418-2011, that they have to be corrected immediately to ensure the implementers implement this standard in a correct way.

5.6 Stakeholders for the Standard: People who use personal health devices in home and mobile environments, personal health device vendors, personal health manager vendors, institutions that may ultimately receive data from these devices (e.g. hospitals, doctor offices, diet and fitness companies), payors (e.g. insurance companies), regulatory agencies, telemedicine consultants and businesses.

Intellectual Property

6.1.a. Is the Sponsor aware of any copyright permissions needed for this project?: No

6.1.b. Is the Sponsor aware of possible registration activity related to this project?: No

7.1 Are there other standards or projects with a similar scope?: No

7.2 Joint Development

Is it the intent to develop this document jointly with another organization?: No

8.1 Additional Explanatory Notes (Item Number and Explanation): The aforementioned standards in section 5.2.a, 5.2.b and 5.5 of this PAR request are:

IEEE Std 11073-20601a-2010 Application profile - Optimized Exchange Protocol, Amendment 1

IEEE Std 11073-10418-2011 Device specialization - International Normalized Ratio (INR) monitor