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06 December 2006

Elliot Sloane
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Re: P11073-10417 - Health informatics - Personal health device communication - Device specialization
- Glucose meter

Dear Elliot:

I am pleased to inform you that on 06 December 2006 the IEEE-SA Standards Board approved the above referenced project until 06 December 2010. A copy of the file can be found on our website at <http://standards.ieee.org/board/nes/projects/11073-10417.pdf>.

Now that your project has been approved, please forward a roster of participants involved in the development of this project. This request is in accordance with the IEEE-SA Operations Manual, Clause 5.1.2i under Duties of the Sponsor which states:

"Submit annually to the IEEE Standards Department an electronic roster of individuals participating on standards projects"

For your convenience, an Excel spreadsheet for your use has been posted on our website at <http://standards.ieee.org/guides/par/roster.xls>. Please forward this list to me via e-mail at s.hampton@ieee.org no later than 06 March 2007.

Please visit our website, IEEE Standards Development Online (<http://standards.ieee.org/resources/development/index.html>), for tools, forms and training to assist you in the standards development process. Also, we strongly recommend that a copy of your draft be sent to this office for review prior to the final vote by the working group to allow for a quick review by editorial staff before sponsor balloting begins.

If you should have any further questions, please contact me at +1 732 562 6003 or by email at s.hampton@ieee.org.

Sincerely,

Sherry Hampton
Administrator, Governance
Standards Activities
Phone +1 732 562 6003
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CC: Douglas.P.Bogia@intel.com

PAR Request Date: 06 August 2006**PAR Approval Date:** 06 December 2006**PAR Signature Page on File:** Yes**Type of PAR:** New IEEE Standard**Status:** PAR for a New IEEE Standard**Root Project:****1.1 Project No.:** **P11073-10417****1.2 Type of Document:** Standard**1.3 Life Cycle:** Full-Use**1.4 Is this document in ballot now?** No**2.1 Title**

Health informatics - Personal health device communication - Device specialization - Glucose meter

2.1 Amendment/Corrigenda Title**3.1 Working Group Name** [Health Informatics - Personal health device - Device Specialization - Glucose meter](#)**Working Group Chair**
[Bogia, Douglas](#)
Phone: 503-456-5031
Email: Douglas.P.Bogia@intel.com**Working Group Vice Chair****3.2 Sponsor** [IEEE Engineering in Medicine and Biology Society 11073 Committee \(EMB/11073\)](#)**Sponsor Chair**
[Sloane, Elliot](#)
Phone: 610-519-6432
Email: ebsloane@villanova.edu**Name of Standards Liaison Representative (if applicable)****3.3 Joint Sponsor****4.1 Type of Ballot:** Individual**4.2 Expected Date of Submission for Initial Sponsor Ballot:** March 2007**4.3 Projected Completion Date for Submittal to RevCom:** December 2007**5.1 Approximate number of people expected to work on this project:** 45

5.2 Scope: Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal telehealth glucose meter devices and compute engines (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, information models, 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 communication functionality for personal telehealth glucose meters.

5.3 Is the completion of this document contingent upon the completion of another document? Yes

This device specialization standard depends on the device specialization common framework for personal telehealth systems standard to define the generic aspects of a device.

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

5.5 Need for the Project: The applications for personal telehealth devices differ sufficiently from other ISO/IEEE 11073 point of care medical devices so as to require derivative standards tailored to address the particular needs of the personal telehealth market. Implementers of this standard will have a clear definition of what is required to implement a glucose meter device. For end users, this standard addresses a market need to provide interoperability among personal telehealth devices and compute engines that interact with the collected information.

5.6 Stakeholders for the Standard: Stakeholders are people who use personal health devices in home and mobile environments, personal health device vendors, personal health compute engine 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.

6.1.a. Has the IEEE-SA policy on intellectual property been presented to those responsible for preparing/submitting this PAR prior to the PAR submittal to the IEEE-SA Standards Board? Yes Presented Date: 2006-07-25

If no, please explain:

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

If yes, please explain:

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

If yes, please explain:

7.1 Are there other standards or projects with a similar scope? Yes

If yes, please explain:

A related standard is the CLSI POCT1 standard which includes devices such as glucose meters and blood gas analyzers; however, this standard is primarily focused on clinical settings, addressing devices which used to be located in clinical laboratories but then migrated out to the patient's bedside, sending results back to the lab. It does not address non-clinical personal health devices, nor does it include the specific information profiles for these devices that is needed for plug-and-play interoperability. Finally, this standard is one of a set of personal health device specialization standards which leverages the ISO/IEEE 11073 device communication framework - which is mostly out of scope for POCT1 interfaced devices.

Sponsor Organization: CLSI

Project/Standard Number: POCT1-A2

Project/Standard Date: 2006-00-00

Project/Standard Title: Point-of-Care Connectivity; Approved Standard

7.2 Is there potential for this standard (in part or in whole) to be adopted by another national, regional, or international organization? ? Yes

Technical Committee Name and Number: ISO TC215 WG7

Contact person: [Melvin Reynolds](#)

Contact person Phone Number: 44-1989-763-120

Contact person Email Address: MelvinR@AMS-Consulting.co.uk

7.3 Will this project result in any health, safety, security, or environmental guidance that affects or applies to human health or safety? Yes

This standard specifies interoperable data exchange for personal health devices.

7.4 Additional Explanatory Notes:

Please reference P11073-10400: Health informatics - Personal health device communication - Device specialization - Common framework

8.1 Sponsor Information:

Is the Scope of this project within the approved scope/definition of the Sponsor's Charter? Yes

If no, please explain: