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To ebsloane@villanova.edu

cc Norma Davis/STDS/STAFF/US/IEEE, douglas.p.bogia@intel.com

bcc

Subject Approval of Project - P11073-10472

01 October 2007

Elliot Sloane
Villanova University
800 Lancaster Avenue
Villanova, PA 19085
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Re: P11073-10472 - Standard for Health informatics - Personal health device communication - Device specialization – Medication Monitor

Dear Elliot:

I am pleased to inform you that on 27 September 2007 the IEEE-SA Standards Board approved the above referenced project until 31 December 2011 with the agreed parenthetical statement added to Item 5.3. A copy of the file can be found on our website at <http://standards.ieee.org/board/nes/projects/11073-10472.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"

Rosters can be submitted in any format to the NesCom Administrator (nescom-admin@ieee.org). Please forward this list to the NesCom Administrator via e-mail at nescom-admin@ieee.org no later than 26 December 2007.

Or, for your convenience, you can manage your standards development roster in myProject. Instructions are as follows:

- Go to myProject - <https://development.standards.ieee.org/my-site>
- Login using your IEEE Web Account username and password.
- Once logged into myProject, go to "Manage Committees"
- Drill down to the project by clicking the (+) on the left to expand each level. The actual project will be highlighted in yellow
- Click "Manage Committees" for that project. A list of individuals enrolled in the

Committee/Project will appear. On this screen you can assign whether a person is a Participant, a Non-Voting Member or a Voting Member of the project group. You may also view contact information for that individual.

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 questions, please contact the NesCom Administrator via e-mail at nescom-admin@ieee.org or via telephone at +1 732 562 3806.

Sincerely,

NesCom Admin
Standards Activities
Email: nescom-admin@ieee.org

PAR Request Date: 02 August 2007**PAR Approval Date:** 27 September 2007**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.:** **11073-10472****1.2 Type of Document:** Standard**1.3 Life Cycle:** Full-Use**1.4 Is this document in ballot now?** No**2.1 Title**

Standard for Health informatics - Personal health device communication - Device specialization – Medication Monitor

3.1 Working Group Name[11073 WG - Personal health device - PHD](#)**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:** January 2008**4.3 Projected Completion Date for Submittal to RevCom:** May 2008**5.1 Approximate number of people expected to work on this project:** 30

5.2 Scope: 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, 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 medication monitors. In this context, medication monitors are defined as devices that have the ability to determine and communicate (to a manager) measures of a user's adherence to a medication regime.

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 system standard to define the generic aspects of a device. (P11073-20601 - Standard for Health Informatics - Personal Health Device Communication - Application Profile - Optimized Exchange Protocol)

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 managers (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 differs sufficiently from other ISO/IEEE 11073 point of care medical devices to require derivative standards 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 medication monitoring devices. For end users, this standard addresses a market need to provide interoperability among personal telehealth devices and managers that interact with the collected information.

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), payers (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? No

If yes, please explain:

Sponsor Organization:

Project/Standard Number:

Project/Standard Date: 0000-00-00

Project/Standard Title:

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: