

[Email This Letter](#)

09 May 2007

Elliot Sloane
Villanova University
800 Lancaster Avenue
Villanova, PA 19085
ebsloane@villanova.edu

Re: P11073-00101 - Health informatics - Point-of-care medical device communication - Technical report - Guidelines for the use of RF wireless technology

Dear Elliot:

I am pleased to inform you that on 07 May 2007 the IEEE-SA Standards Board approved the above referenced project until 31 December 2007. A copy of the file can be found on our website at <http://standards.ieee.org/board/nes/projects/11073-00101.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 05 August 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
FAX +1 732 875 0695
Email: s.hampton@ieee.org

CC: ejm037@motorola.com BCC: s.hampton@ieee.org, t.t.lee@ieee.org

PAR Request Date: 15 March 2007**PAR Approval Date:** 07 May 2007**PAR Signature Page on File:** Yes**Type of PAR:** Modification to Approved PAR**Status:** Modification to a Previously Approved PAR P11073-00101, 14 August 2003**Root Project:** New Project**1.1 Project No.:** **11073-00101****1.2 Type of Document:** Guide**1.3 Life Cycle:** Full-Use**1.4 Is this document in ballot now?** Yes**2.1 Title**

Health informatics - Point-of-care medical device communication - Technical report - Guidelines for the use of RF wireless technology

3.1 Working Group Name [Engineering in Medicine and Biology](#)**Working Group Chair**[Morrissey, Joseph](#)

Phone: +1 954 723 5008

Email: ejm037@motorola.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:** August 2006**4.3 Projected Completion Date for Submittal to RevCom:** August 2007**5.1 Approximate number of people expected to work on this project:** 20

5.2 Scope: This document provides guidance for using radio-frequency (RF) wireless communication technologies for IEEE 11073™ point-of-care medical devices that exchange vital signs and other medical device information using shared information technology (IT) infrastructure. Use cases specific to these technologies are evaluated and key functional and performance criteria are identified, including quality of service (QoS) management, privacy and security, co-existence with other RF wireless technologies, environmental requirements (EMI/EMC), and power management. Guidelines are provided for each of these areas. Technologies include but are not limited to IEEE 802.11™ and IEEE 802.15™. Use case environments include traditional clinical settings, as well as personal (home- and mobile-) healthcare. The intent of the guidance document is to be global with respect to wireless spectrum and equipment, although working group participation and expertise have favored detail of scenarios from the US. Importantly, this guidance document will not be periodically updated, but instead will act as a source of information for follow-on IEEE 11073 RF wireless transport standards that will supersede it. These IEEE 11073 RF wireless transport standards will detail the use of specific wireless networked technology for the purpose of transporting medical data. Periodic updates will be performed on the IEEE 11073 standards only.

Old Scope: This project provides guidance on the usage of radio-frequency (RF) wireless communication technologies for IEEE 1073 point-of-care medical devices that exchange vital signs and other medical device information using shared information technology (IT) infrastructures. Use cases specific to these technologies are evaluated and key functional and performance criteria are identified, including quality of service (QoS) management, privacy and security, co-existence with other RF wireless technologies, environmental requirements (EMI/EMC), and power management. Guidelines are provided for each of these areas. Technologies include but not be limited to IEEE 802.11 and 802.15. Use case environments include traditional clinical settings, as well as homecare and mobile.

5.3 Is the completion of this document contingent upon the completion of another document? No

5.4 Purpose: In recent years there has been rapid growth of RF technology to support wireless communication and data transport, as evidenced by the growing use of personal communication devices (e.g., mobile phones, WiFi enabled laptop computers). The incorporation of RF technology into PoC medical devices for wireless data transport has the potential to offer significant benefits to healthcare, although there are many issues that need to be understood and managed in order to ensure data transfer to computer servers, healthcare professionals, terminal data collection units, or other medical devices is accurate, efficient and reliable. Specific recommendations are aimed at different stakeholder groups that make up the audience for this guidance document including healthcare providers, medical device manufacturers / vendors, wireless equipment manufacturers / vendors, and relevant agency groups. The different functionality and operating environment of medical devices is addressed, ranging from core hospital equipment providing complex waveform and other physiological data to single parameter, low data rate sensors worn in a mobile health scenario. Further, patients, healthcare workers, medical equipment, and medical data move across different areas of the healthcare topology and necessitate that data track in a seamless and managed manner. Quality of Service (QoS) requirements (e.g., priority, throughput, latency) can vary significantly across different medical data types (e.g., alarms, real time wave forms, chart data, asset tracking, e-prescriptions), and simultaneous transport of different data types on a shared IT infrastructure are considered for the design of appropriate solutions. Other issues associated with operation on standardized "open" networks are security and privacy. Coexistence becomes a significant issue as a growing number of medical devices from multiple manufacturers, perhaps using multiple technologies (e.g., IEEE 802.15.1(tm) with IEEE 802.11b(tm)), start to crowd the RF spectrum and compete for bandwidth and channel access. Other issues considered include EMI/EMC, cost, power consumption, and technology configurability. Several factors influence the performance of the wireless system itself, including whether it operates on a shared IT network (e.g., WLAN, WWAN) or simply maintains a point-to-point connection. The former example is especially important when considering the operation of multiple medical devices from different

Old Purpose: The development and use of RF wireless technologies is increasing at a very rapid rate; however, there are many issues that need to be properly understood and managed in order to ensure that the medical device systems which use them can operate in a safe and effective manner. This is especially the case when devices from different manufacturers and with widely varying quality of service requirements are expected to provide reliable and consistent services using a shared IT infrastructure (e.g., a single 802.11b wireless LAN), such as real-time waveform delivery and alarm notifications. Additional problems arise when different communication systems use technologies which have difficulty co-existing, and thus result in a degradation in the quality of service that can be provided. By analysing the use cases that include IEEE 1073 devices using RF wireless communications interfaces, and by providing guidelines for the management of the performance requirements and issues that are identified, reliability and safety can be significantly improved.

manufacturers, each with different QoS requirements. An overall effort to promote plug-and-play (PnP) operability between commercially available medical devices and wireless systems (i.e., IEEE, ISO, ANSI, ITU-R, ITU-T), is supported in this guidance document, as well as in follow-on IEEE 11073 profile standards. As private homes are increasingly outfitted with wireless networks, and home- and mobile- management of healthcare and chronic conditions becomes increasingly common, additional issues may emerge. Recommendations provided in this document are not prescriptive, but instead offer general guidance aimed at the different stakeholders to facilitate design and management of wireless medical data transport to support the necessary QoS and performance requirements as well as co-exist in a complex environment with other wireless traffic. Likewise, exercises and comparisons included in this document are not intended to endorse any particular medical device, wireless technology, or data exchange format, but to offer examples for reference and comparison. Ultimate solutions will vary greatly depend greatly on healthcare needs, resources, sizes, and environments.

5.5 Need for the Project: To provide guidance and highlight potential issues associated with the rapidly increasing use of wireless technology in medical devices, and wireless links and networks to transport medical information

5.6 Stakeholders for the Standard: The stakeholders include medical device manufacturers, wireless device manufacturers, wireless equipment vendors, healthcare enterprise, FDA.

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: 2007-03-21

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

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

Use of this standard may result in a reduction of problems that degrade a system's ability to communication, which in turn can result in more reliable provision of the functions provided by the communication capability, and ultimately increased patient safety and quality of care. For example, a device alert condition may incur a significant delay in reporting due to difficulties getting access to a wireless LAN, or real-time waveform information may not be delivered in time for displays due to reduced QoS.

7.4 Additional Explanatory Notes:

As the project evolved, it was necessary to improve and further define the scope and purpose to accurately reflect the effort and the desired technical guidance.

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: