P11073-10316

Submitter Email: jan.wittenber@gmail.com Type of Project: New IEEE Standard PAR Request Date: 22-Mar-2016 PAR Approval Date: 12-May-2016 PAR Expiration Date: 31-Dec-2020 Status: PAR for a New IEEE Standard Project Record: P11073-10316

1.1 Project Number: P11073-10316 **1.2 Type of Document:** Standard

1.3 Life Cycle: Trial Use

2.1 Title: Trial-Use Health Informatics - Point-of-Care Medical Device Communication - Device Specialization - Dialysis Device

3.1 Working Group: Point-of-Care Devices (EMB/11073/PoCD)

Contact Information for Working Group Chair

Name: John Rhoads

Email Address: john rhoads@acm.org

Phone: 617 868 5018

Contact Information for Working Group Vice-Chair

None

3.2 Sponsoring Society and Committee: IEEE Engineering in Medicine and Biology Society/IEEE 11073 Standards Committee

(EMB/11073)

Contact Information for Sponsor Chair

Name: Todd Cooper

Email Address: toddcooperafc@gmail.com

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Contact Information for Standards Representative

Name: Elliot Sloane

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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: 10/2017

4.3 Projected Completion Date for Submittal to RevCom

Note: Usual minimum time between initial sponsor ballot and submission to Revcom is 6 months.: 08/2018

5.1 Approximate number of people expected to be actively involved in the development of this project: 12

5.2 Scope: The scope of this project is medical device communication for dialysis medical devices, including renal intensive care devices. It will specialize definitions provided by other IEEE 11073 standards, including general data format standards, application profile standards, and transport standards. The project will define data model and semantics specifically related to dialysis devices.

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

- **5.4 Purpose:** The purpose of this project is to establish a normative definition of communication between dialysis devices and other medical devices and information systems in a manner that enables plug-and-play interoperability. By providing standardized communication for these devices, information from these systems will be more readily acquired and integrated into the healthcare enterprise information infrastructure, ultimately reducing the cost of implementing such systems and increasing the availability of this class of data.
- **5.5 Need for the Project:** Currently there is no standardized communication of information from dialysis medical devices. As a result, either the information is not available to information systems or it is provided using proprietary technology, which greatly limits the amount of information available, limits the systems that can actually consume the information, drives up the costs of the overall communication infrastructure, and lowers overall system quality.
- **5.6 Stakeholders for the Standard:** Renal (dialysis) care providers, dialysis device developers, healthcare informaticists, healthcare technology managers, health information technology specialists, healthcare and medical researchers.

Intellectual Property

 $\textbf{6.1.a. Is the Sponsor aware of any copyright permissions needed for this project?: } \\ No$

6.1.b. Is the Sponsor aware of possible registration activity related to this project?: Yes

If yes please explain: These devices utilize IEEE EUI-64 identifiers.

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: Section 5.2: ISO/IEEE 11073-10101:2004 Health informatics -- Point-of-care medical device communication -- Part 10101: Nomenclature:

IEEE STANDARD 11073-10101a-2015 - IEEE Standard Health informatics--Point-of-care medical device communication --Part 10101: Nomenclature Amendment 1: Additional Definitions

ISO/IEEE 11073-10201:2004 Health informatics -- Point-of-care medical device communication -- Part 10201: Domain information model

ISO/IEEE 11073-20101:2004 Health informatics -- Point-of-care medical device communication -- Part 20101: Application profiles -- Base standard

Section 7.3.b: This IEEE 11073 project should be processed in accordance with the ISO PSDO agreement, and the IEEE liaison with ISO/TC 215 Health Informatics.