

P11073-10425

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Type of Project: Revision to IEEE Standard 11073-10425-2014

PAR Request Date: 29-Jul-2016

PAR Approval Date: 22-Sep-2016

PAR Expiration Date: 31-Dec-2020

Status: PAR for a Revision to an existing IEEE Standard

Root Project: 11073-10425-2014

1.1 Project Number: P11073-10425

1.2 Type of Document: Standard

1.3 Life Cycle: Full Use

2.1 Title: Health Informatics--Personal Health Device Communication - Part 10425: Device Specialization--Continuous Glucose Monitor (CGM)

Changes in title: Health ~~informatics~~Informatics--Personal ~~health~~Health ~~device~~Device ~~communication~~Communication - Part 10425: Device Specialization--Continuous Glucose Monitor (CGM)

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 11073 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: 01/2019

4.3 Projected Completion Date for Submittal to RevCom

Note: Usual minimum time between initial sponsor ballot and submission to Revcom is 6 months.: 10/2020

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

5.2 Scope: This standard establishes a normative definition of communication between personal health continuous glucose monitor (CGM) devices (agents) and managers [e.g., cell phones, personal computers (PCs), personal health appliances, 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 communication functionality of CGM devices. In this context, CGM refers to the measurement of the level of glucose in the body on a regular (typically 5 minute) basis through a sensor continuously attached to the person.

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 (PHDs) and compute engines (e.g., cell phones, personal computers, personal health appliances, and set top boxes). Interoperability is the 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: To enrich the functionalities of this standard and to resolve the known issues, in order to better support the needs of our stakeholders.

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 (e.g. food and drug administration), 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: For Section 5.2: The 'ISO/IEEE 11073' mentioned in 5.2 refers to the standard family created by IEEE 11073 Personal Health Device WG, including IEEE Std 11073-20601(-2008,-2010 and -2014) and a group of Device Specializations whose project numbers start with 'IEEE11073-104'.

IEEE Std 11073-20601-2008, Health informatics Personal health device communication- Application profile Optimized Exchange Protocol
IEEE Std 11073-20601a-2010, Health informatics Personal health device communication- Application Profile Optimized Exchange Protocol Amendment 1

IEEE Std 11073-20601-2014, Health informatics Personal health device communication- Application Profile Optimized Exchange Protocol
IEEE Std 11073-20601-2014/Cor 1-2015, Health informatics Personal health device communication- Application Profile Optimized Exchange Protocol Corrigendum 1

IEEE Std 11073-10404-2008, Health informatics Personal health device communication- Device specialization Pulse Oximeter

IEEE Std 11073-10406-2011, Health informatics Personal health device communication- Device specialization- Basic

Electrocardiograph(ECG) (1 to 3-lead ECG)

IEEE Std 11073-10407-2008, Health informatics Personal health device communication- Device specialization- Blood Pressure Monitor

IEEE Std 11073-10408-2008, Health informatics Personal health device communication- Device specialization- Thermometer

IEEE Std 11073-10415-2008, Health informatics Personal health device communication- Device specialization- Weighing Scale

IEEE Std 11073-10417-2009, Health informatics Personal health device communication- Device specialization- Glucose meter

IEEE Std 11073-10417-2011, Health informatics Personal health device communication- Device specialization- Glucose meter

IEEE Std 11073-10417-2015, Health informatics Personal health device communication- Device specialization- Glucose meter

IEEE Std 11073-10418-2010, Health informatics Personal health device communication- Device specialization- International Normalized Ratio (INR) monitor

IEEE Std 11073-10418-2011/Cor 1-2015, Health informatics Personal health device communication- Device specialization- International Normalized Ratio (INR) monitor Corrigendum 1

IEEE Std 11073-10419-2015, Health informatics Personal health device communication- Device specialization- Insulin Pump

IEEE Std 11073-10420-2010, Health informatics Personal health device communication- Device specialization- Body composition analyzer

IEEE Std 11073-10421-2010, Health informatics Personal health device communication- Device specialization- Peak expiratory flow monitor (peak flow)

IEEE Std 11073-10424-2014, Health informatics Personal health device communication- Device Specialization- Sleep Apnoea Breathing Therapy Equipment (SABTE)

IEEE Std 11073-10425-2014, Health informatics Personal health device communication- Device Specialization- Continuous Glucose Monitor (CGM)

IEEE Std 11073-10441-2008, Health informatics Personal health device communication- Device specialization- Cardiovascular Fitness and Activity Monitor

IEEE Std 11073-10441-2013, Health informatics Personal health device communication- Device specialization- Cardiovascular Fitness and Activity Monitor

IEEE Std 11073-10442-2008, Health informatics Personal health device communication- Device specialization- Strength fitness equipment

IEEE Std 11073-10471-2008, Health informatics Personal health device communication- Device specialization- Independent living activity hub

IEEE Std 11073-10472-2010, Health informatics Personal health device communication- Device specialization- Medication monitor