

IEEE 11073 PHD Cybersecurity Paper and Pre-Standards Development Activity

Industry Connections Activity Initiation Document (ICAID)

Version: 0.3, 03 August 2017

IC17-013-01 Approved by the IEEE-SASB 28 September 2017

Instructions

- Instructions on how to fill out this form are shown in red. It is recommended to leave the instructions in the final document and simply add the requested information where indicated.
- **Shaded Text** indicates a placeholder that should be replaced with information specific to this ICAID, and the shading removed.
- Completed forms, in Word format, or any questions should be sent to the IEEE Standards Association (IEEE-SA) Industry Connections Committee (ICCom) Administrator at the following address: industryconnections@ieee.org.
- The version number above, along with the date, may be used by the submitter to distinguish successive updates of this document. A separate, unique Industry Connections (IC) Activity Number will be assigned when the document is submitted to the ICCom Administrator.

1. Contact

Provide the name and contact information of the primary contact person for this IC activity. Affiliation is any entity that provides the person financial or other substantive support, for which the person may feel an obligation. If necessary, a second/alternate contact person's information may also be provided.

Name: Nathaniel Hamming

Email Address: nathaniel.hamming@contractors.roche.com

Phone: +1 5069770743

Employer: HMT Consulting

Affiliation: Roche Diabetes Care GmbH

Name: Christoph Fischer

Email Address: christoph.fischer@ieee.org

Phone: +49 62175969723

Employer: Roche Diabetes Care GmbH

Affiliation: Roche Diabetes Care GmbH

2. Participation and Voting Model

Specify whether this activity will be entity-based (participants are entities, which may have multiple representatives, one-entity-one-vote), or individual-based (participants represent themselves, one-person-one-vote).

Individual-Based.

3. Purpose

3.1. Motivation and Goal

Briefly explain the context and motivation for starting this IC activity, and the overall purpose or goal to be accomplished.

The motivation of this activity is to address the process and capability of secure Plug & Play interoperability for Personal Health Devices (PHD), which the IEEE 11073-PHD series of standard is striving for. In order to maximize the possibility of receiving opinions from various stakeholders this team is open to everyone and interacts with various organizations in the personal connected health domain.

The mission of this activity is to build common ground about cybersecurity in the Personal Health Device community and create an "information security toolbox" appropriate for the IEEE 11073 PHD family of standards. The result of this work is collected in the "IEEE 11073 PHD Cybersecurity Whitepaper". It contains the background related to PHD cybersecurity, a detailed risk analysis of use cases specific to IEEE 11073 device types and the controls to be adopted for a future enhancement of the Optimized Exchange Protocol defined in IEEE Std 11073-20601. The whitepaper will serve as the basis for future standardization of secure Plug & Play interoperability in an open consensus standard by the IEEE 11073 PHD Working Group.

3.2. Related Work

Provide a brief comparison of this activity to existing, related efforts or standards of which you are aware (industry associations, consortia, standardization activities, etc.).

This work has already attracted attention and support from various relevant organizations, including: Personal Connected Health Alliance, Bluetooth SIG MedWG, AAMI / UL 2800 and ISO/IEC. Some of the existing and on-going standards in the domains of Cybersecurity, Health Software and Device Interoperability will be leveraged.

3.3. Previously Published Material

Provide a list of any known previously published material intended for inclusion in the proposed deliverables of this activity.

None.

3.4. Potential Markets Served

Indicate the main beneficiaries of this work, and what the potential impact might be.

The potential market is the Personal Connected Health market. Potential stakeholders are the 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.

4. Estimated Timeframe

Indicate approximately how long you expect this activity to operate to achieve its proposed results (e.g., time to completion of all deliverables).

This activity will have a relatively short lifespan as much of the ground work has been completed as a sub-group of EMB/11073/PHD Working Group. Now that the group was recently introduced to the Industry Connection Program, we would like to leverage Industry Connections to bring the project to successful completion, resulting in incubation of new standards and related products by facilitating collaboration among organizations and individuals on the topic of Personal Health Device Cybersecurity.

Expected Completion Date: 12/2018

IC activities are chartered for two years at a time. Activities are eligible for extension upon request and review by ICCom and the IEEE-SA Standards Board. Should an extension be required, please notify the ICCom Administrator prior to the two-year mark.

5. Proposed Deliverables

Outline the anticipated deliverables and output from this IC activity, such as documents (e.g., white papers, reports), proposals for standards, conferences and workshops, databases, computer code, etc., and indicate the expected timeframe for each.

Published documents that are intended to be widely accessed by the public to encourage future participation as part of standard projects, and to encourage adoption of current standards developed in this space.

6. Funding Requirements

Outline any contracted services or other expenses that are currently anticipated, beyond the basic support services provided to all IC activities. Indicate how those funds are expected to be obtained (e.g., through participant fees, sponsorships, government or other grants, etc.). Activities needing substantial funding may require additional reviews and approvals beyond ICCom.

None.

7. Management and Procedures

7.1. IEEE Sponsoring Committee

Indicate whether an IEEE sponsoring committee of some form (e.g., an IEEE Standards Sponsor) has agreed to oversee this activity and its procedures.

Has an IEEE sponsoring committee agreed to oversee this activity?: Yes

If yes, indicate the sponsoring committee's name and its chair's contact information.

Sponsoring Committee Name: EMB/11073
Chair's Name: Elliot Sloane
Chair's Email Address: ebsloane@gmail.com
Chair's Phone: +1 2158952690 (
 EMB/11073 General Committee Chair: Ken Fuchs
 GC Chair's Email Address: ken.fuchs@ieee.org
 GC Chair's Phone: +1 5083145652

This group is managed by the EMB/11073 Personal Health Devices Working Group
 Co-Chair's Name: Daidi Zhong
 Co-Chair's Email Address: daidi.zhong@ieee.org
 Co-Chair's Phone: +86-13696454858
 Co-Chair's Name: Michael Kirwan
 Co-Chair's Email Address: mkirwan@pchalliance.org
 Co-Chair's Phone: 9132078226

7.2. Activity Management

If no IEEE sponsoring committee has been identified in 7.1 above, indicate how this activity will manage itself on a day-to-day basis (e.g., executive committee, officers, etc).

N/A.

7.3. Procedures

Indicate what documented procedures will be used to guide the operations of this activity; either (a) modified baseline *Industry Connections Activity Policies and Procedures*, (b) Sponsor policies and procedures accepted by the IEEE-SA Standards Board, or (c) Working Group policies and procedures accepted by the Working Group's Sponsor. If option (a) is chosen, then ICCom review and approval of the P&P is required. If option (b) or (c) is chosen, then ICCom approval of the use of the P&P is required.

Working Group policy and procedures accepted by the Working Group's Sponsor
 --- WG P&P of IEEE 11073-PHD WG (2015)



IEEE 11073 PHD
 WG v1.0-full clear

8. Participants

8.1. Stakeholder Communities

Indicate the stakeholder communities (the types of companies or other entities, or the different groups of individuals) that are expected to be interested in this IC activity, and will be invited to participate.

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 (e.g., food and drug administration), telemedicine consultants and businesses.

8.2. Expected Number of Participants

Indicate the approximate number of entities (if entity-based) or individuals (if individual-based) expected to be actively involved in this activity.

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8.3. Initial Participants

Provide a list of the entities or individuals that will be participating from the outset. It is recommended there be at least three initial participants for an entity-based activity, or five initial participants (each with a different affiliation) for an individual-based activity.

Use the following table for an individual-based activity:

Individual	Contact Information	Employer	Affiliation
Beth Pumo	beth.pumo@kp.org	Kaiser Permanente	
Brian Ondiege	brian.ondiege@brunel.ac.uk	Brunel University	
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Catherine Li	catherine.li@fda.hhs.gov	FDA	
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