



IEEE/UL Standard for Wireless Diabetes Device Security: Information Security Requirements for Connected Diabetes Solutions

IEEE Engineering in Medicine and Biology Society

Developed by the
IEEE Engineering in Medicine and
Biology Standards Committee



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STANDARDS

IEEE/UL Standard for Wireless Diabetes Device Security: Information Security Requirements for Connected Diabetes Solutions

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IEEE Engineering in Medicine and Biology Standards Committee
of the
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Abstract: A framework for a connected electronic product security evaluation program, with specific requirements and guidance relating to digital diabetes devices and solutions, such as insulin pumps is defined in this standard.

Keywords: assurance, diabetes, devices, evaluator, firmware, IEEE 2621.1™, protection profile, security, security target

The Institute of Electrical and Electronics Engineers, Inc.
3 Park Avenue, New York, NY 10016-5997, USA

ULSE Inc.
333 Pfingsten Road
Northbrook, IL 60062

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⁵ Available at: <https://standards.ieee.org/about/sasb/patcom/materials.html>.

Participants

At the time this IEEE standard was completed, the Healthcare Device Security Assurance Working Group had the following membership:

David Klonoff, *Chair*
David Kleidermacher, *Co-Chair*

Aiman Abdel-Malek
Carole C. Carey
Kong Chen
Sean Donahue
Anura Fernando
Brian Fitzgerald

Barry Ginsberg
Julia Han
Diana Pappas Jordan
Christopher Keegan
Kevin T Nguyen
Naomi Schwartz

Patricia Sena
Trisha Shang
Christine Sublett
Nicole Y Xu
Jennifer Y. Zhang
Margie Zuk

The following members of the individual Standards Association balloting group voted on this standard. Balloters may have voted for approval, disapproval, or abstention.

Pradeep Balachandran
Brian Blum
Carole C. Carey
Diego Chiozzi
Todd Cooper

Werner Hoelzl
Piotr Karocki
Edmund Kienast
David Kleidermacher
David Klonoff

Ting Li
Rajesh Murthy
Esteban Pino
Naomi Schwartz
Walter Struppler

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Edward A. Addy
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Yousef Kimiagar
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Thomas Koshy
John D. Kulick

Johnny Daozhuang Lin
Kevin Lu
Daleep C. Mohla
Andrew Myles
Damir Novosel
Annette D. Reilly
Robby Robson
Jon Walter Rosdahl

Mark Siira
Dorothy V. Stanley
Lei Wang
F. Keith Waters
Karl Weber
Sha Wei
Philip B. Winston
Daidi Zhong

*Member Emeritus

Introduction

This introduction is not part of IEEE Std 2621.2-2022/UL 2621-2:2022, IEEE/UL Standard for Wireless Diabetes Device Security: Information Security Requirements for Connected Diabetes Solutions.

Target of Evaluation (TOE) overview

Medical devices used for monitoring and managing diabetes provide therapeutic benefits to patients and effective treatment options for healthcare providers. These connected diabetes devices (CDDs) include blood glucose meters (BGMs) and continuous glucose monitors (CGMs) (see Figure 1), insulin pumps, and automated insulin dosing (AID) systems. The ever-increasing connectivity to other devices (such as smartphones, other CDDs, and cloud-based servers) allows patients, their families, and their healthcare providers to more closely monitor and manage their health and experience a concomitant increase in quality of life. At the same time, improperly secured CDDs present risks to the safety and privacy of the patient.

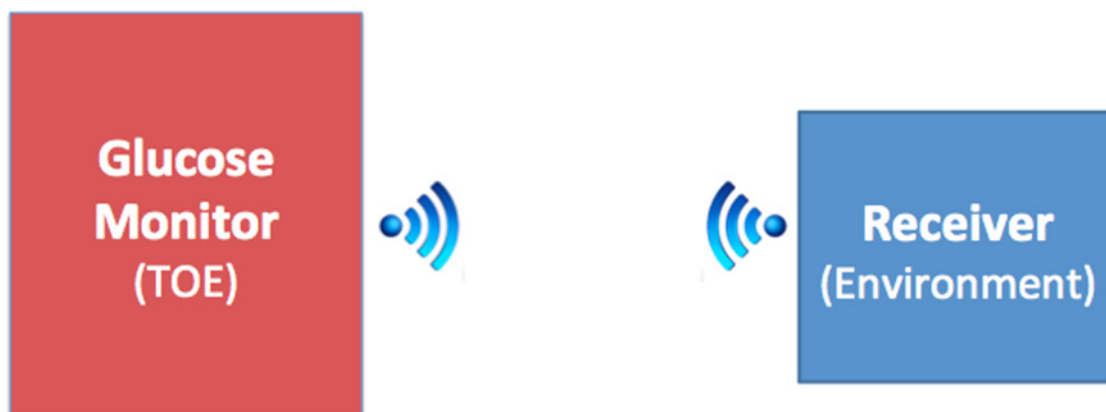


Figure 1—Network operating environment for a glucose monitor the Target of Evaluation

This standard specifies information security requirements for CDDs. A CDD in the context of this standard is a device composed of a hardware platform and its system software. For example, a BGM may include software for functions like analyzing blood samples to compute a blood glucose (BG) reading, displaying the BG reading, storing BG readings in local non-volatile memory, transferring BG readings to a PC via USB cable, managing user input peripherals (e.g., buttons) that configure operation of the monitor, and transmitting BG readings wirelessly to a receiver, such as an insulin pump or a smartphone.

Examples of a CDD that should conform to this standard include simple BGM, more sophisticated BGMs, e.g., with larger displays and audio functions, CGMs, remote controllers of other CDDs, and insulin pumps. An AID system Target of Evaluation (TOE) may be a single CDD from a single manufacturer or may be comprised of multiple evaluated CDDs from multiple manufacturers (example depicted in Figure 2):