



IEEE/UL Standard for Wireless Diabetes Device Security Assurance Evaluation: Connected Electronic Product Security Evaluation Programs

ULNORM.COM : Click to view the full PDF of UL 2621-1:2022

IEEE Engineering in Medicine and Biology Society

Developed by the
IEEE Engineering in Medicine and
Biology Standards Committee



IEEE Std 2621.1™-2022/UL 2621-1:2022

STANDARDS

IEEE/UL Standard for Wireless Diabetes Device Security Assurance Evaluation: Connected Electronic Product Security Evaluation Programs

Developed by the

Engineering in Medicine and Biology Standards Committee
of the
IEEE Engineering in Medicine and Biology Society

Approved 25 March 2022

IEEE SA Standards Board

ULNORM.COM : Click to view the full PDF of UL 2621-1 2022

Recognized as an American National Standard

Abstract: A framework for a connected electronic product security assurance evaluation program, with specific requirements and guidance relating to digital diabetes devices and solutions, such as insulin pumps is described 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

Copyright © 2022 by The Institute of Electrical and Electronics Engineers, Inc. and ULSE Inc.

UL's Standards for Safety and IEEE Standards are copyrighted by ULSE Inc. and IEEE respectively. Neither a printed nor electronic copy of a Standard should be altered in any way. All of UL's Standards for Safety and IEEE Standards and all copyrights, ownerships, and rights regarding those Standards shall remain the sole and exclusive property of ULSE Inc. and IEEE respectively.

All rights reserved. Published 13 May 2022. Printed in the United States of America.

IEEE is a registered trademark in the U.S. Patent & Trademark Office, owned by The Institute of Electrical and Electronics Engineers, Incorporated.

PDF: ISBN 978-1-5044-8580-7 STD25338
Print: ISBN 978-1-5044-8581-4 STDPD25338

IEEE prohibits discrimination, harassment, and bullying.

For more information, visit <https://www.ieee.org/about/corporate/governance/p9-26.html>.

No part of this publication may be reproduced in any form, in an electronic retrieval system or otherwise, without the prior written permission of the publisher.

Commitments for amendments

This Standard is issued jointly by the Institute of Electrical and Electronics Engineers, Inc. (IEEE) and ULSE Inc. (ULSE) Comments or proposals for revisions or any part of the standard may be submitted to IEEE and/or ULSE at any time. Revisions to this Standard will be made only after processing according to the Standards development procedures of IEEE and ULSE.

Comments or proposals for revisions on any part of the Standard may be submitted to ULSE Inc. at any time. Proposals should be submitted via a Proposal Request in ULSE's On-Line Collaborative Standards Development System (CSDS) at <https://csds.ul.com>.

Any person who would like to participate in evaluating comments or in revisions to an IEEE standard is welcome to join the relevant IEEE working group. You can indicate interest in a working group using the Interests tab in the Manage Profile & Interests area of the [IEEE SA myProject system](#).¹ An IEEE Account is needed to access the application.

Comments on IEEE standards should be submitted using the [Contact Us](#) form.²

Copyrights

IEEE draft and approved standards are copyrighted by IEEE under US and international copyright laws. They are made available by IEEE and are adopted for a wide variety of both public and private uses. These include both use, by reference, in laws and regulations, and use in private self-regulation, standardization, and the promotion of engineering practices and methods. By making these documents available for use and adoption by public authorities and private users, IEEE does not waive any rights in copyright to the documents.

UL's Standards for Safety are copyrighted by ULSE Inc. Neither a printed nor electronic copy of a Standard should be altered in any way. All of UL's Standards and all copyrights, ownerships, and rights regarding those Standards shall remain the sole and exclusive property of ULSE Inc.

To purchase UL Standards, visit ULSE's Standards Sales site at:

<http://www.shopulstandards.com/HowToOrder.aspx> or call toll-free 1-888-853-3503.

Important Notices and Disclaimers Concerning IEEE Standards Documents

IEEE Standards documents are made available for use subject to important notices and legal disclaimers. These notices and disclaimers, or a reference to this page (<https://standards.ieee.org/ipr/disclaimers.html>), appear in all standards and may be found under the heading "Important Notices and Disclaimers Concerning IEEE Standards Documents."

Notice and Disclaimer of Liability Concerning the Use of IEEE Standards Documents

IEEE Standards documents are developed within the IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Association (IEEE SA) Standards Board. IEEE develops its standards through an accredited consensus development process, which brings together volunteers representing varied

¹Available at: <https://development.standards.ieee.org/myproject-web/public/view.html#landing>.

²Available at: <https://standards.ieee.org/content/ieee-standards/en/about/contact/index.html>.