



UL 2800-1-1

STANDARD FOR SAFETY

Risk Concerns for Interoperable Medical Products

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UL Standard for Safety for Risk Concerns for Interoperable Medical Products, UL 2800-1-1

First Edition, Dated June 10, 2022

Summary of Topics

This is the First Edition of ANSI/AAMI/UL 2800-1-1, the Standard for Risk Concerns for Interoperable Medical Products.

The new requirements are substantially in accordance with Proposal(s) on this subject dated November 5, 2021.

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AAMI
AAMI 2800-1-1
First Edition



Underwriters Laboratories Inc
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Standard for Risk Concerns for Interoperable Medical Products

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Commitment for Amendments

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This ANSI/UL Standard for Safety consists of the First Edition. The most recent designation of ANSI/AAMI/UL 2800-1-1 as an American National Standard (ANSI) occurred on June 10, 2022. ANSI approval for a standard does not include the Cover Page, Transmittal Pages, Title Page (front and back), or the Preface.

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

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Preface

This is the joint AAMI/UL Standard for Risk Concerns for Interoperable Medical Products, AAMI/UL 2800-1-1. It is the first edition of AAMI 2800-1-1 and the first edition of UL 2800-1-1.

This Joint Standard was prepared by the Joint Committee for Medical Device Interoperability, JC 2800. The standard was formally approved by the Joint Committee and the efforts and support of the Joint Committee are gratefully acknowledged.

This standard has been approved by the American National Standards Institute as an American National Standard.

AAMI/UL Joint Committee for Medical Device Interoperability, JC 2800

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1 Introduction

1.1 The AAMI/UL 2800 series of standards covers the interoperability of medical products. AAMI/UL 2800-1 is the general standard that specifies a baseline set of requirements for assuring safe and secure interoperability for interoperable medical systems. The requirements in the AAMI/UL 2800-1 standard are supplemented by the requirements in additional AAMI/UL 2800 standards. These additional standards are intended to be used in conjunction with the general standard and applied as needed. While this introduction applies to all of the AAMI/UL 2800 series of standards, the scope section of each additional standard describes what is covered by that standard.

1.2 Multiple stakeholders may participate in the development, deployment, assembly, and operation of a medical system with interoperable elements. Such a system, referred to as an interoperable medical system, should minimize patient risks, maintain clinical effectiveness, ensure timely and adequate access to data while protecting its security, and enable adequate provision of care. In order to facilitate alignment of stakeholders around these aims, the AAMI/UL 2800 series of standards establishes a baseline set of requirements for assuring safe and secure interoperability.

1.3 Each stakeholder will need to determine the specific level and manner in which interoperability will be specified and assured for its interoperable medical products. However, a specific system may be developed, assembled, deployed, and operated through a range of processes undertaken by multiple stakeholders. Specific activities in these processes assure interoperability. In order for stakeholders to collectively accomplish this, the processes need to be linked effectively.

1.4 Effective linkage of processes across multiple stakeholders is a core focus of the AAMI/UL 2800 series of standards. This first requires that each stakeholder adequately assesses and manages safety and security vulnerabilities of its interoperable medical products. Secondly, it requires that each stakeholder understands and conforms with interoperability aspects of disclosed specifications of an interoperable medical product which it acquires or with which it interoperates, including the consequent safety and security characteristics. Finally, it requires that each stakeholder clearly communicates to the other stakeholders the information required to assure interoperability.

1.5 The requirements in the AAMI/UL 2800 series of standards are intended to apply to medical devices, as well as other connected infrastructure elements, and interoperable medical systems constructed from these. The AAMI/UL 2800 series of standards is intended to be used by individual stakeholders.

1.6 The AAMI/UL 2800 series of standards employ a lifecycle process approach to organizing requirements. In addition to a set of broad management functions, the standards provide for a set of interoperability planning, realization, deployment, and monitoring activities. These activities also incorporate cross-cutting requirements for security and risk management. The standards recognize that a given organization may be responsible for only a part of the full range of activities required for an interoperable medical system. Furthermore, the organization's interoperable medical products may provide only a specific or limited functionality. To accommodate this, the standards provide for flexibility in the scope, sequence, and interaction of these activities. Finally, the standards provide requirements and supplementary guidance on key clinical and engineering properties of an interoperable medical system that are essential to assuring safe and secure interoperability and provide guidance on lifecycle activities.

1.7 The requirements provide a baseline for assuring safe and secure interoperability throughout the lifecycle of the interoperable medical system. In order to meet these requirements, a set of lifecycle processes needs to be established. It is anticipated that many organizations in the interoperability ecosystem will also have requirements for formal quality and risk management processes, as well as those related to specific aspects of product development, such as usability, software development, electrical and biological safety. The lifecycle processes in the AAMI/UL 2800 series of standards may be integrated into the organization's processes previously established for meeting quality and risk management and product-specific requirements.