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AAMI Consensus Report

Basic Introduction to the
IEC 60601 Series

AAMI CR500:2019



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Basic Introduction to the IEC 60601 Series

Approved December 2019 by
AAMI

Abstract: This document provides information regarding concepts and principles that underlie the IEC 60601 series of standards. (The IEC 60601 series is defined in the Introduction.) This document is intended to clarify and to point out the importance of the series as well as to provide guidance to understanding and to implementing the series.

Key Words electromedical equipment, medical electrical equipment, medical electrical systems, basic safety, essential performance, risk management

AAMI Consensus Report

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- When variation in the development, implementation or use of a product or process exists
- When existing standards or other documents require additional context/clarification

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Rd, Suite 300, Arlington, VA 22203.

Published by

AAMI

901 N. Glebe Rd., Suite 300

Arlington, VA 22203

www.aami.org

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Printed in the United States of America

ISBN 978-1-57020-733-4

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Committee representation

Association for the Advancement of Medical Instrumentation

This AAMI Consensus Report (CR) was developed by an AAMI Task Group specially formed for this project. The members of the task group are listed below.

This CR was reviewed by the **AAMI Electrical Safety Committee** and the **AAMI Application of risk management to medical devices Working Group** and approved by the **AAMI Electrical Safety Committee**.

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NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Foreword

This consensus-driven document was proposed as new work and developed initially by employees of the U.S. Food and Drug Administration (FDA). A task group composed of representatives of manufacturers, testing laboratories, and accreditation bodies met with representatives from the FDA and finalized the document.

The Association for the Advancement of Medical Instrumentation (AAMI) administers the Secretariat for IEC Subcommittee (SC) 62A, "Common aspects of electrical equipment used in medical practice," and Subcommittee (SC) 62D, "Electromedical equipment."

AAMI also supports the U.S. TAG (technical advisory group) for the two SCs as well as Technical Committee (TC) 62, "Electrical equipment in medical practice."

As part of the consensus-driven process of the AAMI standards program, this document was circulated for comments to the AAMI Electrical Safety Committee and the AAMI Application of Risk Management to Medical Devices Working Group. This document was also balloted for approval by the AAMI Electrical Safety Committee, the primary group that adopts the IEC 60601-1 standard.

It is hoped that this document will be useful for users of the IEC 60601 series.

Suggestions for improving this document are invited. Comments and suggestions should be forwarded to the AAMI Standards Program, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

Introduction

This document explores how medical device manufacturers and their stakeholders—including FDA and other regulators—can best make use of the IEC 60601 series of safety standards to assure the safety of users/operators and patients. This document takes a holistic and pragmatic view of the subject, starting with an examination of the concepts and rationale underlying the development of the standards that comprise the 60601 series.

The IEC 60601 series constitutes a massive and complex body of work. The original standard, IEC 601, dates to 1977. This standard has been updated and now is in its 3rd edition. This edition has been adopted as an American National Standard, ANSI/AAMI ES60601-1, which runs over 400 pages. Eight *collateral* standards add requirements having general (horizontal) applicability to all medical electrical equipment (MEE) or medical electrical systems (MES) within the scope, covering such topics as alarm safety, radiation protection, and the use of medical equipment in the home and emergency medical service environments. The vertical or device-specific *particular* standards provide safety and performance requirements for specific types of medical electrical equipment or medical electrical systems. The general standard normatively references close to 50 ISO and IEC standards, and informatively references an additional 70-plus standards¹. In a subsequent section, we will go into greater detail about the structure and organization of the series.

IEC Technical Committee (TC) 62, *Electrical equipment in medical practice*, is responsible for the care and maintenance of the IEC 60601 series. Within TC 62, there are 4 subcommittees, with given responsibilities as outlined below. The subcommittees head up 80 or more working groups, maintenance teams, joint working groups, and advisory boards working on different aspects of the committee's program.

- SC 62A, "Common aspects of electrical equipment used in medical practice" (responsible for general and most of the collateral standards along with related documents for horizontal issues)
- SC 62B, "Diagnostic imaging equipment" (responsible for 60601-1-3 and particular standards and related documents in the subject matter of imaging equipment)
- SC 62C, "Equipment for radiotherapy, nuclear medicine and radiation dosimetry" (responsible for particular standards and related documents in the subject matter)
- SC 62D, "Electromedical equipment" (responsible for particular standards that have not been covered by the other three SCs)

Given the size and complexity of this body of work, it is a challenge to gain more than a superficial understanding of what the 60601 series of standards encompasses, let alone why it matters. Therefore, a key objective of this document is to provide stakeholders with sufficient information about the 60601 series to grasp its significance and value. At the same time, it is important to know what the 60601 series excludes, so that stakeholders can understand the role it plays in the broader context of assuring the safety and effectiveness of MEE/MESs.

¹ Normatively referenced standards are the basis for the associated requirements in 60601-1. Informative references are for information only.