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**Ansi Aami Es60601 1 2005**

This consolidates the original text of ANSI/AAMI ES60601-1:2005 and its amendments. Keywords: electromedical equipment, electrical safety, essential performance . PREVIEW COPY. This is a preview edition of an AAMI guidance document and is intended to allow

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amendments Medical electrical  
equipment - Part 1: General  
requirements for basic safety and  
essential performance (IEC  
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ES60601-1:2005/(R)2012 and A1:2012,  
C1:2009/(R)2012 and A2:2010/(R)2012)  
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requirements for basic safety and  
essential performance. Baseline of  
requirements for the basic safety and  
essential performance of all medical

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electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment.

**ANSI/AAMI ES60601-1:2005 -  
Medical electrical equipment ...**

ANSI/AAMI ES60601-1:2005/C1:2009  
(R2012) and A2:2010 (R2012) Medical

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electrical equipment - Part 1: General requirements for basic safety and essential performance, Amendment. This amendment is identical to the following IEC 60601-1:2005 international documents: Corrigendum 1 and Corrigendum 2.

**ANSI/AAMI ES60601-1:2005/C1:2009**

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**ES60601-1:2005/(R)2012, Medical  
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ANSI AAMI ES60601-1:2005/(R)2012 and  
A1:2012, C1:2009/(R)2012 and  
A2:2010/(R)2012 (Consolidated Text)  
Medical electrical equipment - Part 1:

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General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

**Recognized Consensus Standards**

60601-1:2005 was approved by the American National Standards Institute (ANSI; i.e., ANSI/ AAMI ES60601-1:2005).<sup>2</sup> This article also

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refers to the international standards IEC 60601-1:2012 (edition 3 with Amendment 1), ISO 14971:2000, and ISO 14971:2007. Each of the following standards has been adopted as ANSI/AAMI U.S. national stand-

**Risk Management And IEC 60601-1:  
Assessing Compliance**



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The adoption of Amendment 1 to IEC 60601-1 as an amendment to an existing national standard, ANSI/AAMI ES60601-1:2005 was initiated by the AAMI Electrical Safety Committee. U.S. representatives played an active role in developing the IEC standard.

**American National Standard - The**

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**AAMI Store**

“FDA recognition of Edition 2:1988 (A1:1991+A2:1995) of IEC 60601-1 is hereby superseded by recognition of ANSI/AAMI ES60601-1:2005, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance.

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**Which 60601-1, 3rd ed. Standard  
Applicable for FDA ...**

ANSI/AAMI ES60601-1:2005/A2:2010/(  
R)2012 A2 applies to AAMI, only ....

ANSI/AAMI/ISO 15223-1:2012. Glossary  
of equivalent standards International  
Standards adopted in the United States  
may include normative references to  
other International Standards. For each

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International Standard that has been adopted by AAMI (and ANSI), the table below ...

### **AAMI Glossary of Equivalent Standards - MAFIADOC.COM**

The AAMI/American National Standard edition is identical to IEC 60601-1:2005 with the exception of a few requirements

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that have been modified to comply with the U.S. National Electrical Code and relevant standards of the National Fire Protection Association. Where deviations do occur, the original IEC text also is included for users' reference.

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(IEC 60601-1:2005, MOD ...**

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reaffirmed by AAMI. E.g., ANSI/AAMI/ISO 10993-4:2002/(R)2009 indicates that 109934, originally approved and - published in 2002, was reaffirmed without change in 2009. Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI;

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## **American National Standard - The AAMI Store**

This document includes ANSI/AAMI  
ES60601-1:2005/C1:2009 and ANSI/AAMI  
ES60601-1:2005/A2:2010. The changes  
made by these amendments are  
consolidated into the text of ES60601-1  
and the amendments are included at the  
end of the PDF for those who want to

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see exactly what was changed.

**AAMI ES60601-1:2005/(R)2012**

ANSI AAMI: ES60601-1:2005/(R)2012  
and A1:2012, C1:2009/(R)2012 and  
A2:2010/(R)2012 (Consolidated Text)  
Medical electrical equipment - Part 1:  
General requirements for basic safety  
and essential performance (IEC



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60601-1:2005, MOD) 04/04/2016:

General II (ES/ EMC) 19-16: ANSI AAMI:

HA60601-1-11:2015

## **Recognized Consensus Standards**

According to the recent publication of the US national version of the collateral standard for products intended for home use, ANSI/AAMI HA60601-1-11, the

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application of the standard does not apply to the nursing home environment. In the United States, nursing facilities are considered to be environments providing professional healthcare.

### **IEC 60601 - Wikipedia**

Note: The American National Standard versions of these documents are

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ANSI/AAMI/IEC ES60601-1:2005 and ANSI/AAMI/ISO 14971:2000, respectively. For the medical device manufacturer, there are also a series of collateral and particular standards that may apply to their device. Each of these standards is a part of the 60601 family and as the parent ...

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**Cleaning, Sterilization, and  
Biocompatibility Risk ...**

ANSI/AAMI ES60601-1:2012 Medical  
Electric Equipment, General  
Requirements for Safety and Essential  
Performance (CB Scheme) E314885  
IEC60601-1:2005, 3rd Edition +  
AM1:2012 Medical Electric Equipment,  
General Requirements for Safety and

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Es60601 1 2005 R 2012 A1 2012

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Essential Performance WD-SE-  
R-180524-A0 EN60601-1:2006 +  
A12:2014 IEC60601-1:2005, 3rd Edition  
+ AM1:2012

**eature • 2MOPP, 250VAC working  
oltage isolation • Clearance ...**

iec 60601 1:2005, iec 60601  
1:2005/amd1:2012 CAN/CSA-C22.2 NO.

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60601-1:08 +AM1 ANSI/AAMI  
ES60601-1:2005/(R)2012, AND C1:2009  
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