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Es60601 1

2005 R 2012

A1 2012

Medical

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2005 r 2012 a1
2012 medical, it is

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Es60601 2005

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1 2005 r 2012 a1

2012 medical as a

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Ansi Aami Es60601

1 2005

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Includes

ANSI/AAMI ES606
01-1:2005/C1:2009
and ANSI/AAMI ES
60601-1:2005/A2:2
010. 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

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those who want to
see exactly what
was changed.

ANSI/AAMI

ES60601-1:2005

(IEC

60601-1:2005,

MOD) - Medical ...

ANSI/AAMI

ES60601-1:2005

Medical electrical

equipment, Part 1:

General

Online Library

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requirements for
basic safety and
essential
performance.

Baseline of
requirements for
the basic safety and
essential
performance of all
medical electrical
equipment used by
or under the
supervision of
qualified personnel

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ES60601-1:2005
in the general
medical and patient
environment.

Medical

ANSI/AAMI

ES60601-1:2005 -

Medical electrical

equipment ...

ANSI/AAMI

ES60601-1:2005

(R2012) with

amendments

Medical electrical

equipment - Part 1:

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General 60601 1 2005

requirements for
basic safety and
essential

performance (IEC
60601-1:2005,
MOD)

(Consolidated
Text) (includes
ANSI/AAMI ES606
01-1:2005/(R)2012
and A1:2012,
C1:2009/(R)2012
and

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A2:2010/(R)2012)

Document includes
amendments.

Medical

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ES60601-1:2005

(R2012) with

amendments -

Medical ...

ANSI/AAMI

ES60601-1:2005

(R2012) (IEC

60601-1:2005

MOD) Medical

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electrical equipment

- Part 1: General
requirements for

basic safety and
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performance

(contains

C1:2009/(R)2012

and

A2:2010/(R)2012

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Text))

ANSI/AAMI

Page 11/38

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ES60601-1:2005
(R2012) (IEC
60601-1:2005 MOD

Medical

ANSI/AAMI

ES60601-1:2005,

Medical electrical

equipment - Part 1:

General

requirements

for basic safety and

essential

performance,

Amendment 1

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(2012. Amendment
by Association for
the Advancement of
Medical

Instrumentation,
02/09/2006. This
document is an
amendment. View
the base document.

AAMI ES60601-1:2
005/A1:2012 &
C1:2009/(R)2012 &
A2:2010/(R ...

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AAMI-ES60601-1

Medical electrical
equipment-Part 1:
General

requirements for
basic safety and
essential
performance ...

January 1, 2005

Medical electrical
equipment-Part 1:
General

requirements for
basic safety and

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Essential 1 2005

performance ...
(ANSI/AAMI/IEC
60601-2-27),...

This document is
referenced by:
TIR50 - Post-
market surveillance
of use ...

AAMI - ES60601-1
- Medical electrical
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es60601-1:2005
(r2012) (iec
60601-1:2005 mod)

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ANSI/AAMI ES606
01-1:2005/Amendm
ents - Medical
electrical ...

ansi/aami es60601-
1:2005/c1:2009
(r2012) and
a2:2010 (r2012)

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ANSI/AAMI ES606
01-1:2005/C1:2009
- Medical electrical

...

ANSI AAMI: ES606
01-1:2005/(R)2012
and A1:2012,
C1:2009/(R)2012
and
A2:2010/(R)2012
(Consolidated

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Text) Medical
electrical equipment
- Part 1: General
requirements for
basic safety and
essential
performance (IEC
60601-1:2005,
MOD) 09/17/2018:
General II (ES/
EMC) 19-8: ANSI
AAMI IEC:
60601-1-2:2014

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Recognized 2005 Consensus 2012 Standards

The 60601 related standards were updated to align with the transition period of ANSI/AAMI ES60601-1 std along with other changes of importance as noted below. In a future

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blog post we may discuss Recognition List 032 and the Cyber-security standards.

FDA Extends AAMI

ES 60601-1

Transition Date to

31 Dec ' 13 ...

2013 ANSI/AAMI

ES60601-1:2005 &

A1:2012 sub clause

11.2.2.1 b) 3) says,

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ES60601-1:2005
R 2012 A1 2012
Medical

“ The cause of the hazardous situation is: a leak occurs and is not detected, some time later an electrical failure occurs ...

IEC/ES60601-1

“ Medical Electrical Equipment, Oxygen-Rich ...

ANSI AAMI ES606
01-1:2005/(R)2012

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and A1:2012, 2005

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

60601-1:2005,

MOD)

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Es60601 1 2005
Recognized
Consensus
Standards

The adoption of IEC
60601-2-27 as a
revision of
ANSI/AAMI
EC13:2002 was
initiated by the
AAMI / (R) 2007
ECG/Cardiac
Monitor and
Diagnostic ECG

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Working Group of
the AAMI ECG
Committee. U.S.
representatives
played an active
role in developing
the IEC standard.

American National
Standard - The
AAMI Store

“ FDA recognition of
Edition 2:1988 (A1:
1991 + A2:1995) of

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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.

Which 60601-1, 3rd

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ed. Standard 2005

Applicable for FDA

iii
Medical

The
AAMI/American
National Standard
edition is identical
to IEC
60601-1:2005 with
the exception of a
few requirements
that have been
modified to comply
with the U.S.

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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.

ANSI/AAMI ES606
01-1:2005/(R)2012
(IEC

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ES60601-1:2005

MOD ...

The committee is seeking user and general interest members to participate in the U.S. adoption AAMI ES60601-1:2005/A amendment 2, Medical electrical equipment – Part 1: General requirements for

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ES60601-1:2005
basic safety and
essential
performance,
Amendment 2.

Standards Monitor

Online | AAMI

ANSI/AAMI

ES60601-1:2005

and ANSI/AAMI ES

60601-1:2005/A2:2

010 : ANSI/AAMI E

S60601-1:2005/C1:

2009 (amdt) Major

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60601-1-2:2005

technical variations
: C1 Identical to
Corrigendum 1 & 2
IEC

60601-1-2:2007

ANSI/AAMI/IEC

60601-1-2:2007 :

Identical IEC

60601-2-2:2009 :

ANSI/AAMI/IEC

60601-2-2:2009

Identical : IEC

60601-2-4:2002

ANSI/AAMI

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DF80:2003/(R)201

0 : Major ...

Medical
Technical

Information Report

- The AAMI Store

reaffirmed by

AAMI. E.g.,

ANSI/AAMI/ISO 10

993-4:2002/(R)200

9 indicates that

109934, originally

approved and -

published in 2002,

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was reaffirmed
without change in
2009. Other
normatively
referenced
International
Standards may be
under consideration
for U.S. adoption by
AAMI;

American National
Standard - The
AAMI Store

Page 34/38

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ANSI/AAMI HA606

01-1-11-2015

MEDICAL

ELECTRICAL

EQUIPMENT - Part

1-11: General

requirements for

basic safety and

essential

performance -

Collateral Standard:

Requirements for

medical electrical

equipment and

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medical electrical
systems used in the
home healthcare
environment

ANSI/AAMI HA606

01-1-11-2015 -

MEDICAL

ELECTRICAL

EQUIPMENT ...

In 2005, the third
edition of IEC
60601-1 was
published. It was

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the result of a comprehensive review of the second edition (dating from 1988). Some key changes are: the outline and the numbering scheme of the clauses and subclauses were changed, risk management was made much more

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relevant and the
concept of essential
performance was
added.

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