Technical Information Report

AAMI TIR18:2010

Guidance on electromagnetic compatibility of medical devices in healthcare facilities

Association for the Advancement
of Medical Instrumentation

AAMI Technical Information Report

AAMI TIR18:2010
(Revision of AAMI TIR18:1997)

Guidance on electromagnetic compatibility of medical devices in healthcare facilities

Approved 8 March 2010 by
Association for the Advancement of Medical Instrumentation

Abstract: This AAMI Technical Information Report (TIR) provides information, guidance, and general recommendations regarding electromagnetic compatibility (EMC) of medical devices and the use of RF wireless technology in healthcare facilities to promote patient safety. It is intended to provide a broad range of information about EMC of medical devices for clinical and biomedical engineers and other technical personnel; healthcare administrators, including heads of hospital departments; medical staff; and healthcare associations. The information herein will help healthcare organizations evaluate their electromagnetic (EM) environment and implement actions needed to minimize electromagnetic interference (EMI) problems and manage the EM environment, including wireless RF sources. Although this TIR focuses on healthcare facilities, the home environment is briefly addressed. Management of the electromagnetic environment and management of medical devices for EMC are discussed, as are the following subjects: assessment of the electromagnetic environment; investigation and reporting of EMI problems; selected case studies in EMI problems; site selection, design, and construction of new facilities; a model EMC and wireless policy and guidance for developing EMC and wireless policies; and principles of electromagnetic energy and interference mechanisms. Definitions of terms and a bibliography are also provided.

Keywords: ad hoc testing, cellular telephones, conducted immunity, electromagnetic compatibility, electromagnetic disturbance, electromagnetic interference, electrostatic discharge, EMC, EM disturbance, EMI, ESD, mobile communications, mobile telephones, radiated immunity, wireless local area network (LAN)

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203.

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NOTE—Following each section cited below is a code to indicate which of the following readers should pay particular attention to that section. An acronym/abbreviation will be used for convenience:

Healthcare administrators, including hospital heads (ADMIN)
Patient safety/risk management personnel (PSRM)
Clinical/biomedical engineers and other technical personnel (TECH)
Medical staff (MED)
Healthcare associations (HCA)
All readers (ALL)

Figures

Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation. The code in the US column, "(R)20xx" indicates the year the document was officially reaffirmed by AAMI. E.g., ANSI/AAMI/ISO 10993-4:2002/(R)2009 indicates that 10993-4, 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; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005 Technical Corrigendum 1 and 2	ANSI/AAMI ES60601-1:2005 and ANSI/AAMI ES60601-1:2005/A2:2010 ANSI/AAMI ES60601-1:2005/C1:2009 (amdt)	Major 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 DF80:2003/(R)2010	Major technical variations
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004/(R)2009	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80601-2-30:2009 and Technical Corrigendum 1	ANSI/AAMI/IEC 80601-2-30:2009 and ANSI/AAMI/IEC 80601-2-30:2009/ C1:2009 (amdt) – consolidated text	Identical (with inclusion) C1 Identical to Corrigendum 1
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
IEC/TR 62354:2009	ANSI/AAMI/IEC TIR62354:2009	Identical
IEC/TR 80002-1:2009	ANSI/IEC/TR 80002-1:2009	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005/(R)2010	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2010	Identical
ISO 7199:2009	ANSI/AAMI/ISO 7199:2009	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-1:2009	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
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ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002/(R)2008 ANSI/AAMI BE78:2002/A1:2006/(R)2008	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
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ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:2010	ANSI/AAMI/ISO 10993-16:2010	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical

International designation	U.S. designation	Equivalency
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006/(R)2010	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006/(R)2010	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006/(R)2010	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006/(R)2010	Identical
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ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006/(R)2010	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
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ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
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ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
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ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
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ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
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ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
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ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical (with inclusions)
ISO/TS 17665-2:2009	ANSI/AAMI/ISO TIR17665-2:2009	Identical
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ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical
ISO 81060-2:2009	ANSI/AAMI/ISO 81060-2:2009	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Electromagnetic Compatibility Committee

This technical information report (TIR) was developed by the AAMI Electromagnetic Compatibility Committee. Approval of this TIR does not necessarily mean that all committee members voted for its approval.

At the time this document was published, the **AAMI Electromagnetic Compatibility Committee** had the following members:

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

Foreword

The electromagnetic (EM) environment in modern healthcare facilities can be extremely variable, particularly as a result of the tremendous growth in radiofrequency (RF) wireless communications such as cellular telephones, wireless personal digital assistants (PDAs), and wireless local area networks (LANs). Electromagnetic compatibility (EMC) is the ability of a system or medical device to function satisfactorily in its electromagnetic environment without introducing intolerable EM disturbance to anything in that environment. Thus, EMC of medical devices must be an integral part of all health care wherever active medical devices and systems are deployed. Healthcare organizations must actively manage their equipment and RF wireless technology to ensure EMC and mitigate the risks of electromagnetic interference (EMI).

This edition of the TIR reflects the continuous efforts of concerned medical device users, healthcare professionals, regulators, and medical device manufacturers to disseminate information and recommendations for control of EMI caused by EM disturbance from a variety of sources. The first edition was developed by the AAMI Electromagnetic Compatibility Committee in response to interest and inquiries from clinical and biomedical engineers regarding the risks of radiated EMI that might be caused by RF transmitters (e.g., portable cellular telephones) and what could be done to mitigate those risks. It was inspired in part by Paperman, et al. (1994). This new edition focuses on updating the original information and recommendations and on distinguishing important points for consideration by both engineering/technical and nontechnical personnel who use and manage electrical and electronic systems in healthcare facilities.

The objective of this TIR is to convey important information about the potential risks of EMI and RF wireless technology and what can be done to reduce those risks while deploying increasingly sophisticated medical systems. A primary objective is to help clinical and biomedical engineers and other technical personnel assess the electromagnetic environment in individual healthcare facilities, implement actions needed to minimize EMI problems, promote EMC, and, thus, promote the safety of patients and staff. In addition, this TIR is intended to raise awareness about the risks and concerns surrounding EMC and RF wireless technology in healthcare facilities. To this end, the new edition of the TIR has been rearranged to make it easier for non-engineers to find and understand the recommendations for EMC and RF wireless technology. These recommendations are aimed at promoting understanding and communication among the vital components of the healthcare organization, including administrators, medical staff, risk managers, security personnel, physical plant staff, and patients.

This TIR includes specific recommendations regarding how to assess and manage the electromagnetic environment for EMC, recognize and report EMI incidents, and promote communication about EMC and RF wireless technology deployment and use. In addition, the TIR

a) describes a model EMC and wireless policy that can be tailored to meet the needs of an individual healthcare facility;

b) provides background information on electromagnetic energy and interference mechanisms;

c) discusses what might be done to promote EMC for existing equipment and facilities as well as for new equipment and facilities; and

d) includes case studies to illustrate the types of EMI problems that can occur.

Readers should pay particular attention to the sections noted in the table of contents as being of interest according to their role in the healthcare organization.

As used within the context of this document, “should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the technical information report. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203.

NOTE—This foreword does not contain provisions of the AAMI Technical Information Report, *Guidance on electromagnetic compatibility of medical devices in healthcare facilities* (AAMI TIR18:2010), but it does provide important information about the development and intended use of the document.

Guidance on electromagnetic compatibility of medical devices in healthcare facilities

1 Introduction and scope

Because the performance of electronic medical devices can be disrupted by electromagnetic (EM) energy, patient safety can potentially be put at increased risk because of the effects of electromagnetic interference (EMI). EMI is caused by an EM disturbance, which can be in the form of radiated disturbance (radio waves propagating through the air); conducted disturbance (radio waves induced on power or signal wires); AC power-line transients, surges, sags, and dropouts; and electrostatic discharge (ESD). Radiofrequency (RF) sources that emit various EM disturbances have proliferated in modern society, including healthcare facilities, creating the potential for EMI with electronic medical devices. Sources of EM disturbance include any product or device that uses electricity or can carry an electrical charge. Systems that can emit EM disturbances include, but are not limited to, the following:

a) Cellular telephones and other wireless communication devices
b) Two-way radios
c) Wireless barcode systems
d) Radiofrequency identification (RFID) systems
e) Security systems
f) Fire alarm systems
g) Nurse call systems
h) Heating, ventilation and air-conditioning (HVAC) systems
i) Motor controllers, including elevators and copiers
j) Medical devices

Concerns arise because the EM disturbance exposure might exceed the immunity designed into medical devices and systems and because some electronic medical devices currently in use have not been tested for immunity to EM disturbances. The risks faced by even those devices that comply with EMC standards seem to be increasing as the number of radio transmitter sources, including RF wireless technology, is dramatically increasing within and outside healthcare facilities. Numerous EMI incidents have been reported in the literature.

2 Definitions and abbreviations

For purposes of this TIR, the following definitions and abbreviations apply.

NOTE 1—Throughout this TIR, “cell phone” is used interchangeably with “mobile phone.” The preferable usage is “mobile phone” because “mobile phone” is the term commonly used internationally.

NOTE 2—References in brackets are the source of the definition.

2.1 ANSI: American National Standards Institute.

2.2 ASHE: American Society for Healthcare Engineering.

2.3 BP: Blood pressure.

2.4 CCU: Critical care unit.

2.5 CDMA: Code division multiple access.

