



FDA/CDRH Experience with EMC Problem Reports, Standards, and Guidance

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SPEED BUMP DAVE COVERLY



Inquiring minds want to know...

- Have there been many safety events due to EMI for Medical Devices in the past? Why did they occur?
- What are the procedures and/or standards used by the FDA to ensure that EMI does not create a safety risk? Are these U.S.-only standards or are International standards also used?
- Are medical devices becoming more complex due to the addition of more electronics and software? If so, what is the FDA doing about this trend?
- What standards does the FDA use for the software aspects of safety?
- For Medical Device safety, how many electronics and EMC engineers does the FDA have? Is the staff keeping up with changes in the electronics?

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FDA medical device regulation - by degree of risk

- Class I
 - Low risk (examples: tongue depressors, band-aids)
 - General controls: registration, listing, Quality System, GMP
- Class II
 - Medium risk (examples: physiological monitors, infusion pumps, imaging systems)
 - General controls, sometimes special controls, plus clearance (substantial equivalence – 510(k)), design controls, etc.

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FDA medical device regulation - by degree of risk (cont'd)

- Class III
 - High risk, new, or not yet classified (examples: implantable pacemakers and defibrillators)
 - General controls, special controls, premarket approval
 - Clinical studies might be required before approval
 - Clinical studies might be required after approval
 - Annual reports might be required

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Have there been many safety events due to EMI for Medical Devices in the past? Why did they occur?

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Sources of medical device EMI problem information

- FDA mandatory problem reports
- FDA voluntary problem reports
- FDA regulatory actions (e.g. recalls)
- Professional contacts
 - Device and system professionals
 - EMC engineers and consultants
 - Hospital engineers
 - Trade and professional organizations
 - Consensus standards groups
- Published literature

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Study of EMI adverse events reported to FDA, January 1994 to March 2005

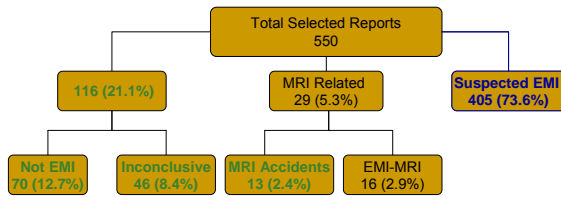
- Chapter 20: Exploring Methods for Analyzing Surveillance Reports on Electromagnetic Interference with Medical Devices
 - S. Lori Brown, Nilsa Loyo-Berrios, Michèle G. Bonhomme, Donald M. Witters, Nancy A. Pressly, and Jeffrey L. Silberberg
 - in Medical Device Epidemiology and Surveillance John Wiley & Sons Ltd., 2007
 - S. Lori Brown, Roselie A. Bright, Dale R. Tavis, editors

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EMI adverse events study, January 1994 to March 2005: Study methods



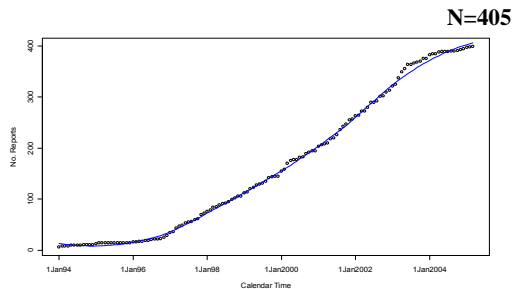
Adverse events study slides courtesy Michèle Bonhomme

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Cumulative Frequency of Monthly EMI Reports in MAUDE: Jan 1994 to Mar 2005

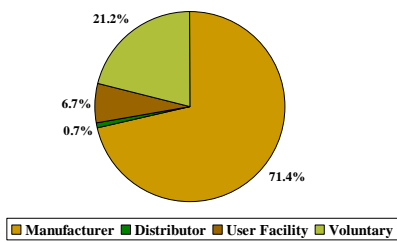


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EMI adverse events study, January 1994 to March 2005: Report source

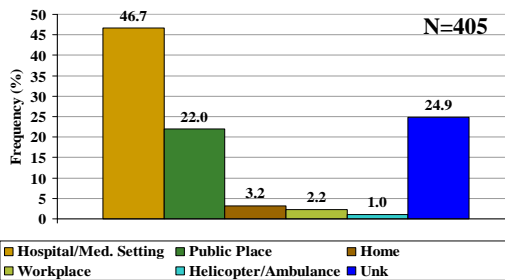


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EMI adverse events study, January 1994 to March 2005: Event location



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Examples of Event Descriptions

Hospital

During a breast surgery, the doctor was using the 9900 electrosurgery generator and the patient's pacemaker stopped working. Cardiopulmonary resuscitation (CPR) was used to resuscitate the patient.

The doctors claimed they 'were misled' by the pacemaker synch, which seemed like an 'R' complex on a pt's waveform that had ventricular fibrillation with pacing. During above situation the monitor gave HR readings and did not alarm for ventricular fibrillation or asystole.

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Examples of Event Descriptions

Public Place

The patient walked through the theft detector at a university library, and received a shock that knocked him to the floor. The implanted device [implanted spinal cord stimulator] was reset to "0" by the shock. The patient sustained no known injury. The device was reprogrammed and it is functioning properly. The library has been investigating this event and the health care provider stated that the security system was reportedly 'set too high'.

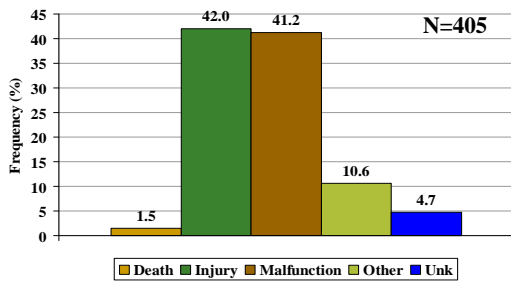
The device manufacturer reported that while a female patient (age unknown) was being transported by helicopter, "the patient's pacing was intermittently interrupted by radio frequency interference. The patient subsequently died".

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EMI adverse events study, January 1994 to March 2005: Event type

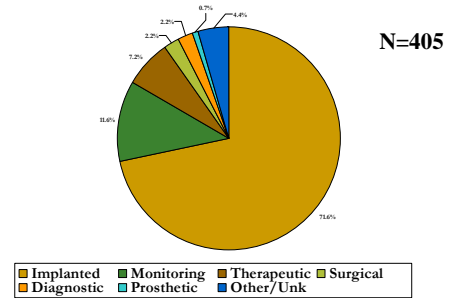


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EMI adverse events study, January 1994 to March 2005: Victim by device type

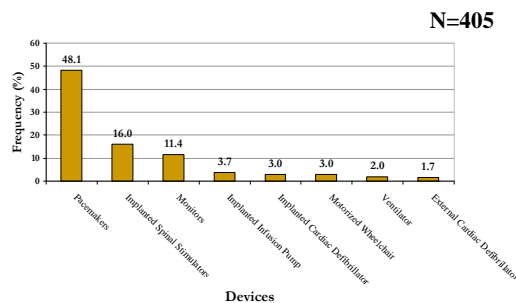


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EMI adverse events study, January 1994 to March 2005: Devices affected

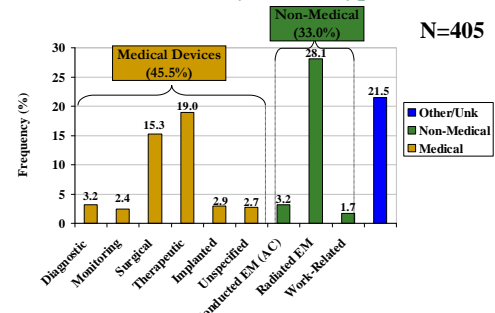


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EMI adverse events study, January 1994 to March 2005: Sources by device type



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Example EMI problem reports

- Implantable pulse generator for Parkinson's
 - MDR # 1181002, received September 29, 2008The patient experienced a loss of therapeutic effect after receiving electrocautery to his / her face for dermatologic reasons. The dermatologist had not been advised of the existence of the implantable device.

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Example EMI problem reports (cont'd)

- Infusion pump
 - MDR # 679280, Received February 21, 2006The facility reported an infusion pump with over infusion. Reportedly a displayed rate changed during pt infusion. The pt's cell phone rang and the nurse at the bedside noticed that rate of pitocin was displayed at 120ml/hr rather than the prescribed rate of 20 ml/hr. The change was noticed in less than one minute and there was no harm to the pt. A new pump was put on the pt. According to the hosp. rep, the event history did not show any buttons being pressed for the rate change.

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We suspect that medical device EMI incidents are underreported

- EMI can be transient
- EMI is difficult to recognize and confirm, esp. for untrained personnel,
- EMI might not even be suspected as the cause of an equipment problem, might be reported as something else
- Caregivers focus on achieving their treatment goals and not on reporting equipment problems
 - Find work-arounds and move on
- EMI problems in hospitals are often solved under private contract and might not be reported

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Examples of possible EMI problems that were not attributed to "EMI"

- **DBS and hybrid car interference**
 - Patient with deep brain stimulator for Parkinson's disease developed unusual symptoms possibly related to stimulator malfunction while riding in a hybrid car.
 - See letter to the editor: Chen, C and H. Bronte-Stewart, <http://onlinelibrary.wiley.com/doi/10.1002/mds.22739/full>
- **ICD and LVAD interaction**
 - Interaction between a patient's LVAD and an ICD or CRTD can prevent device programming and result in device replacement.

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Example EMI Recalls

- Processing Module for in vitro diagnostics
 - Recall Z-0415-2007, February 7, 2007
- Re-designed temperature controller board has been identified as being susceptible to EMI in the laboratory. This can cause a board reset condition, stopping temperature control function of the board. Situation does not stop analyzer operation and does not generate an error condition alerting operator when condition occurs.

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Example EMI Recalls (cont'd)

- Date Recall Initiated: March 17, 2008
- Recall Number: Z-1902-2008
- Product: Model X extracorporeal blood circulation system
- Reason for Recall: Use of Model Y Electrocautery Unit on the patient can cause Model X to stop pumping and alarm

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FDA Databases

- MAUDE - Manufacturer and User Facility Device Experience Database
 - Includes mfr., user facility, & voluntary problem reports
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/MAUDE/search.CFM> or
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/MAUDE/TextSearch.cfm>
- Recall database
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/Topic/medicaldevicesafety/recalls.cfm> or
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf/RES/res.cfm>

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Published EMI Studies

- van Lieshout EJ, van der Veer SN, Hensbroek R, Korevaar JC, Vroom MB, Schultz MJ. Interference by new-generation mobile phones on critical care medical equipment, Crit Care. 2007;11(5):R98.
- van der Togt, R., E. J. van Lieshout, et al. (2008). Electromagnetic interference from radio frequency identification inducing potentially hazardous incidents in critical care medical equipment. JAMA 299(24): 2884-90.

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Published EMI Studies (cont'd)

- Seidman S, Ruggera P, Brockman R, Lewis B, and Shein M. Electromagnetic Compatibility of Pacemakers and Implantable Cardiac Defibrillators Exposed to RFID Readers. International Journal of Radio Frequency Identification Technology and Applications, Volume 1, Number 3, 2007:237-246.

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van Lieshout et al.

- A total of 61 medical devices in 17 categories (27 different manufacturers) were tested and demonstrated 48 incidents in 26 devices ; 16 were classified as hazardous, 20 as significant and 12 as light. The GPRS-1 signal induced the most EMI incidents, the GPRS-2 signal induced fewer and the UMTS signal induced the least. The median distance between antenna and medical device for EMI incidents was 3 cm (range 0.1 to 500 cm). One hazardous incident occurred beyond 100 cm (in a ventilator with GPRS-1 signal at 300 cm).

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van der Togt et al.

- In 123 EMI tests (3 per medical device), RFID induced 34 EMI incidents: 22 were classified as hazardous, 2 as significant, and 10 as light. The passive 868-MHz RFID signal induced a higher number of incidents (26 incidents in 41 EMI tests) compared with the active 125-kHz RFID signal (8 incidents in 41 EMI tests). The passive 868-MHz RFID signal induced EMI in 26 medical devices.

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Seidman et al.

- *Implantable Pacemaker Reaction to RFID*
- At least one reaction was observed in 21 of the 22 pacemakers tested. While being exposed to each of the two 134 kHz RFID readers a pacemaker reaction was observed for 34 of the 44 possible tests (77%). While being exposed to each of the four 13.56 MHz RFID readers a pacemaker reaction was observed for 21 of the 88 possible tests (24%).

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Seidman et al. (cont'd)

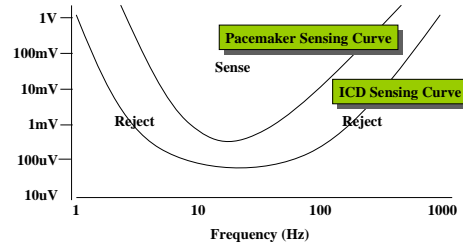
- *Implantable Cardioverter Defibrillator Reaction to RFID*
- At least one reaction was observed in 18 of the 19 ICDs that were tested. While being exposed to the two 134 kHz RFID readers an ICD reaction was observed for 27 of the 38 possible tests (71%). While being exposed to the four 13.56 MHz RFID readers an ICD reaction was observed for 8 of the 76 possible tests (11%).

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Pacemaker and ICD Sensing Characteristics



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Why do medical safety events occur due to EMI?

- A variety of reasons; including
 - Equipment in use (e.g. old equipment) does not comply with EMC standards
 - Applicable EMC standards might not adequately represent a particular phenomenon, combinations of phenomena, or a particular use environment
 - EM conditions occur that exceed the immunity of the medical device
 - The equipment could not be hardened further due to physical or physiological limitations

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Why do medical safety events occur due to EMI? (cont'd)

- A variety of reasons; including (cont'd)
 - New systems (e.g. non-medical) are deployed and interactions are not anticipated
 - Security systems
 - RFID
 - Rare or transient events occur, against which the equipment was not hardened
 - It is not feasible to test for every possible electromagnetic interaction

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What are the procedures and/or standards used by the FDA to ensure that EMI does not create a safety risk? Are these U.S.-only standards or are International standards also used?

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Procedures

- Premarket review
 - Clearance (Class II)
 - Premarket approval (Class III)
 - Usually includes checking for compliance with guidance (e.g. FDA guidance documents) and national and/or International standards, including voluntary consensus standards "recognized" by FDA
- Postmarket surveillance

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FDA/CDRH participation in development of voluntary consensus standards

- 240 representatives
- 30 standards development organizations
- 500 standards activities

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Standards Recognition

- Declaration of conformity to consensus standards recognized by FDA can be used in regulatory submissions
 - In general, FDA does not require or enforce the use of any particular consensus standard. However, once a claim is made, the mfr is bound by it.
- Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards, issued September 17, 2007

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077274.htm>

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Standards Recognition (cont'd)

- In general, there are conditions to recognition
 - Posted on FDA/CDRH website ("Supplementary information, Extent of recognition")
 - FDA guidances usually take precedence

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Example stds applicable to med devices

- IEC 60601-1-2 – EMC of medical electrical equipment and medical electrical systems
- EMC requirements of particular standards
 - IEC 60601-2-X
 - IEC 61326-2-6 – EMC of in-vitro diagnostic medical equipment
 - ISO standards
 - ISO 7176-21 – Powered wheelchairs and mot. scooters
 - ISO 9919 – Pulse oximeters (soon to be 80601-2-61)
 - ISO 14708-3 – Implantable neurostimulators
- ETSI radio equipment standards

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Standards (cont'd)

- AAMI PC69, Active implantable medical devices— Electromagnetic compatibility— EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators
- IEEE 802.11x, 802.15x
- IEC 80001-1, Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities
- IEC 62304, Medical device software - Software life cycle processes

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Testing to EMC standards does not guarantee prevention of EMI

- Compliance usually demonstrated by "type testing"
 - only one prototype is tested
 - production units can vary
 - device EMC characteristics can change with design changes, age, servicing
- Immunity pass/fail criteria
 - interpretation
 - most permit some performance degradation

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Testing to EMC standards does not guarantee prevention of EMI (cont'd)

- Radiated RF immunity test levels in many standards can be exceeded by RF transmitters at close range
- Allowances (e.g. in IEC 60601-1-2)
 - RF receivers exempt in passband
 - Manufacturer can justify a lower immunity test level
 - Example – ultrasound system “complies”
Radiated RF immunity: 3 V/m - 46 dB = 0.015 V/m
(general test level - mfr adjustment = resulting immunity)

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Testing to EMC standards does not guarantee prevention of EMI (cont'd)

- Disturbance test signals
 - are applied one phenomenon at a time
 - are simplified models
 - represent an estimate of the use EM environment
- Impractical to test all possible conditions of actual use
 - (changing) ambient EM environment
 - limited test time, \$\$
 - device operating modes, conditions

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Testing to EMC standards does not guarantee prevention of EMI (cont'd)

- Designing for worst possible EM environment generally not feasible
 - Field strengths very close to antenna of (even relatively low-power) portable transmitters can be very high
- However, important contribution to QA
 - Can detect significant, reproducible problems

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Medical devices that complied with IEC 60601-1-2 but ...

- Infusion pumps
 - Overinfusion of epinephrine caused by cell phone
- Defibrillator
 - Unintended synchronization to two-way radios found in ad hoc testing

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Guidance

- As required by IEC 60601-1-2
- FDA/CDRH
 - EMC/EMI
 - Wireless medical devices
 - Medical software
- AAMI TIR 18:2010, Guidance on electromagnetic compatibility of medical devices in healthcare facilities

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Guidance (cont'd)

- ANSI C63.18:1997, Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio-Frequency Transmitters
 - Ed. 2 nearing publication
- ISO TR 21730, Health informatics — Use of mobile wireless communication and computing technology in healthcare facilities — Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devices

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Guidance (cont'd)

- IEEE 11073-00101, Health Informatics - Point-of-Care Medical Device Communication - Technical Report – Guidelines for the Use of RF Wireless Technology
- ECRI Institute recommendations

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Example of guidance required by IEC 60601-1-2:2007

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Recommended separation distances between portable and mobile RF communications equipment and the Model 006

The Model 006 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 006 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 006 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table
For EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

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Separation distance guidance summary

- 150 kHz to 800 MHz $d = 1.2\sqrt{P}$
- 800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
- Recommendation for life-supporting equipment includes 3.3x additional margin
 - Test level is higher but separation distance recommendation is the same

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Example recommendations and guidance

- FDA/CDRH – for EMC/EMI in healthcare facilities
<http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/ElectromagneticCompatibilityEMC/ucm116566.htm>
 - Make use of available resources
 - Assess the electromagnetic environment
 - Manage
 - Coordinate
 - Educate
 - Establish and implement written policies and procedures
 - Report EMI problems

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Example recommendations and guidance

- FDA guidance - RF Wireless Technology in Medical Devices (January 2007)
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077210.htm>
 - For industry, systems and service providers, consultants, FDA staff, and others
 - Issues
 - Wireless coexistence
 - Performance
 - Quality of service
 - Data integrity
 - Security
 - EMC

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Are medical devices becoming more complex due to the addition of more electronics and software?

- Yes. They have been since at least the 1970s.

If so, what is the FDA doing about this trend?

- Significant changes in the technology of a medical product must be cleared by FDA
- Staff members attend professional meetings and give and receive professional development training
- Staff members participate in the development of national and International standards

What standards does the FDA use for the software aspects of safety?

- IEC 62304:2006, Medical device software – Software life cycle processes
- ISO 14971:2007, Application of risk management to medical devices
- IEC 80001-1:2010, Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities

What standards does the FDA use for the software aspects of safety? (cont'd)

- FDA guidances
 - Off-The-Shelf Software Use in Medical Devices, September 9, 1999
 - General Principles of Software Validation, January 11, 2002
 - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005
 - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, January 14, 2005

For Medical Device safety, how many electronics and EMC engineers does the FDA have?

■ Electronics Engineer	16
■ Electrical Engineer	9
■ Research Engineer	1
■ Staff Fellow	1
■ Visiting Scientist	4
■ Supervisory Electronics Engineer	2
■ Supervisory Electrical Engineer	1
■ Supervisory Research Electronics Engineer	1
	Total 35

Note 1 Out of a total of approximately 8800 FDA employees
 Note 2 There are far more Bioengineers and Physicists

For Medical Device safety, how many (electronics and) EMC engineers does the FDA have?

- Less than 10 EMC engineers
- Is the staff keeping up with changes in the electronics?
 - Trying

Summary

- FDA controls medical device risk with
 - Premarket review
 - Postmarket surveillance and enforcement
 - Standards (national and International)
 - Guidance (FDA and non-FDA)
 - Staff professional development

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Appendix

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Main Committee and Subcommittees

- IEC Technical Committee 62
 - Electrical equipment in medical practice
- Subcommittee 62A
 - Common aspects of electrical equipment used in medical practice
- Subcommittee 62B
 - Diagnostic imaging equipment
- Subcommittee 62C
 - Equipment for radiotherapy, nuclear medicine and radiation dosimetry
- Subcommittee 62D
 - Electromedical equipment

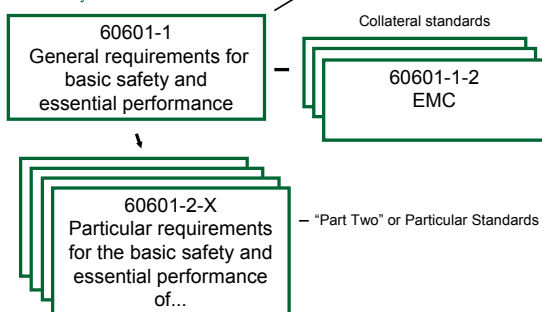
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The IEC 60601 (Third Edition)

Family of Standards



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IEC 60601-1:2005 Scope

- Basic safety and essential performance of medical electrical equipment and medical electrical systems
- Excludes IVD and implants

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Definitions from 60601-1:2005

- **BASIC SAFETY**
freedom from unacceptable RISK directly caused by physical HAZARDS
- **ESSENTIAL PERFORMANCE**
performance necessary to achieve freedom from unacceptable RISK
NOTE - ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

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Essential Performance ≠ Functional Safety

- **ESSENTIAL PERFORMANCE**
performance necessary to achieve freedom from unacceptable RISK
NOTE - ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.
- **functional safety**
part of the overall safety relating to the EUC and the EUC control system which depends on the correct functioning of the E/E/PE safety-related systems, other technology safety-related systems and external risk reduction facilities

EUC = equipment under control

E/E/PE = electrical/electronic/programmable electronic

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IEC 60601-1-2:2007

Immunity compliance (pass/fail) criteria

- Under the test conditions specified in 6.2, the ME EQUIPMENT or ME SYSTEM shall be able to provide the BASIC SAFETY and ESSENTIAL PERFORMANCE. The following DEGRADATIONS, if associated with BASIC SAFETY and ESSENTIAL PERFORMANCE, shall not be allowed:
 - Component failures, false alarms, etc.
- The ME EQUIPMENT or ME SYSTEM may exhibit DEGRADATION of performance (e.g. deviation from MANUFACTURER'S specifications) that does not affect BASIC SAFETY or ESSENTIAL PERFORMANCE

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62A/509/DC – Deficiencies in the current edition of IEC 60601-1-2

- Circulated September 2005
- Purpose
 - to describe recognized problems with IEC 60601-1-2
 - to ask the national committees to support MT23 in its plan to make appropriate corrections.

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62A/509/DC Background

- EMC requires that equipment continue to perform its intended functions in the presence of EM phenomena
 - 60601-1 requires only that the product remain safe (freedom from unacceptable RISK)
- Recognized and accepted by other IEC committees that EMC and EM safety are two separate and distinct issues

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62A/509/DC Background

- Distinction is clearly made in IEC TS 61000-1-2:2001:
Whether a test on the influence of an EM phenomenon on the behaviour of an equipment should be included in an EMC standard (or clause) or in a safety standard (or clause) is dependent on the approval criterion

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62A/509/DC Background

- During or after the test the equipment must continue to operate as intended
 - should be included in an EMC immunity standard (or clause) of a product (product family).
- During or after the test no unsafe situation is allowed (performance may be degraded)
 - should be included in a safety standard (or clause).
- For products with safety functions the immunity levels may be chosen to be higher than in the generic standards for that environment.

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- The IMMUNITY TEST LEVELS specified in 60601-1-2 were selected for EMC of performance in the normal use environment and may not be appropriate for safety requirements, i.e. they may not provide an adequate margin to assure the safety of ME EQUIPMENT and ME SYSTEMS.
- IEC 60601-1-2 does not specify EMC requirements for performance that is not ESSENTIAL PERFORMANCE but that the user or purchaser can reasonably expect from the EQUIPMENT.

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62A/509/DC Proposed Solutions

- MT23 proposed changes to IEC 60601-1-2 to correct these shortcomings.
- MT23 recommended that an IEC New Work Item Proposal (NWIP) for a Medical EMC performance standard be developed to address satisfactory functional performance as required by ISO 16142 Essential Principle A.3, MDD Essential Requirement I.3, and other national regulatory requirements for effectiveness of medical devices. The requirements of this new standard would be very similar to those of the 2nd (and 3rd) edition(s) of IEC 60601-1-2.

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IEC 60601-1-2 Edition 4

- 62A/509/DC approved January 2006
- Draft NP circulated for ballot August 6, 2009 as IEC 62A/672/NP
- Ballot closed December 4, 2009
 - Did not pass
 - 326 comments received (67 pages)
 - CD2 in preparation

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