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# Standards and Guidance for Wireless in Healthcare

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# Summary

- Existing standards and guidance can help assure EMC in healthcare
- Standards and guidance are evolving
- Management of EMC/EMI/wireless is (still) needed

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# Topics

- EMI problem reports
- Standards
- Guidance
- Summary

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# EMI Problem Reports

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# EMI Problem Reports

- Medical device electromagnetic interference (EMI) problems continue to be reported
  - Most involve implanted pacemakers, ICDs, and neurostimulators
- Please report medical device EMI problems to MedWatch at  
<http://www.fda.gov/medwatch/>

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# Sources of EMI problem information

- FDA mandatory problem reports
- FDA voluntary problem reports
- FDA regulatory actions
- 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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# Example EMI problem reports

- Implantable pulse generator for Parkinson's
  - MDR # 1181002, received 29 September 2008

The 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 21 February 2006

The 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.

# Example EMI problem reports (cont'd)

- Infusion pump

- MDR # 736554, Received 19 June 2006

The facility reported a pump that stopped infusing during patient use. The pump was infusing heparin, at which time the patient's family member used a cell phone in close proximity to the pump. The pump then stopped infusing. There was no patient injury or medical intervention according to the hospital rep.

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# Example EMI Recalls

- Processing Module for in vitro diagnostics
- Recall Z-0415-2007, 7 February 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

# 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/cfMAUDE/search.CFM> or

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
- Recall database

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/medicaldevicesafety/recalls.cfm> or

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/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%).

## 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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## Software problem with an electronic medical record system

- In October 2008 after installation of a patch, the US Veteran's Administration reported that when switching from a patient's record to a second patient's record, the first patient's information could still be displayed, possibly impacting patient care decisions. The problem occurred intermittently. It has since been corrected. It is unknown if incorrect data were entered into patients' records. No adverse patient outcomes were reported.

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# Standards

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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
- Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards, issued 17 September 2007

<http://www.fda.gov/cdrh/osel/guidance/321.html>

# Standards

- 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
    - 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, Application of risk management to information technology (IT) networks incorporating medical devices
- IEC 62304, Medical device software - Software life cycle processes

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# IEC 60601-1-2:2007

## Radiated RF immunity requirements

- Life-supporting equipment: 10 V/m
- Equipment that is not life-supporting: 3 V/m
- 80 MHz – 2.5 GHz

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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, etc. [see std for list]
- 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

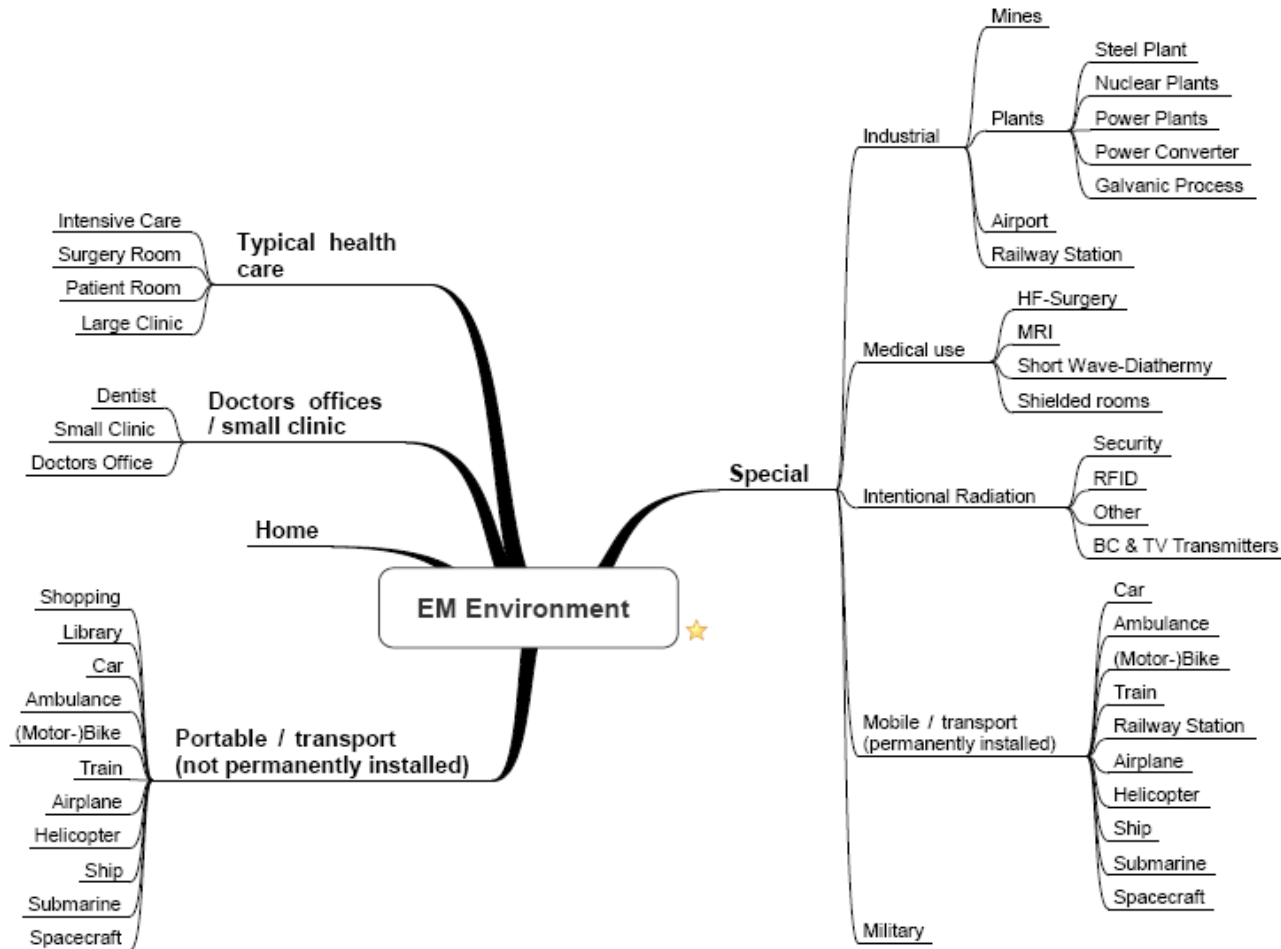
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# Draft new standard to replace IEC 60601-1-2 (IEC 6XXXX)

- Title: MEDICAL ELECTRICAL EQUIPMENT – Electromagnetic compatibility and safety with regard to electromagnetic disturbances – requirements and tests
- Safety and performance requirements
- Recognizes that portable transmitters and other wireless equipment can no longer be prohibited from the patient vicinity because it has become essential to the efficient provision of healthcare.

# IEC 6XXXX (subject to change) (cont'd)

## ■ Classification of medical use environments



# IEC 6XXXX (subject to change) (cont'd)

- Immunity test levels for safety
  - Typical healthcare: 10 V/m
  - Doctor's office / small clinic: 10 V/m
  - Home: 20 V/m
  - Portable / transport: 30 V/m
  - Special – TBD
  - Close-distance: 2 W at 1 or 2 cm
- Simplification of labeling requirements
  - Less guidance required

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IEC 6XXXX (subject to change) (cont'd)

## Additional immunity tests

- Low-frequency magnetic field
- HF surgery equipment immunity

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# Guidance

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# Guidance

- As required by IEC 60601-1-2
- FDA/CDRH
  - EMC/EMI
  - Wireless medical devices
  - Medical software
- AAMI TIR 18:1997, Guidance on electromagnetic compatibility of medical devices for clinical/biomedical engineers— Part 1: Radiated radio-frequency electromagnetic energy

## 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
- 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

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# 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**

# 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/cdrh/emc/emc-in-hcf.html>
  - ❑ **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/cdrh/osel/guidance/1618.html>

- 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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# Example recommendations and guidance

- AAMI TIR 18:1997 – Guidance on EMC for Biomedical/Clinical Engineers
  - 14 summary recommendations
  - Background information
  - Model EMC/EMI policy
  - Second edition under development
    - Update
    - Wider target audience
    - To include conducted EMC and ESD
    - To acknowledge the benefits of wireless

# Example recommendations and guidance

- ANSI C63.18:1997 - On-Site, Ad Hoc Test Method
  - Test method
  - Introduction to EMI
  - Recommendations for mitigation of EMI
  - Second edition under development
    - Update
    - Wider target audience
    - Alternative test methods
    - Use of field strength meter

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# Summary

- Existing standards and guidance can help assure EMC in healthcare
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Secretary, IEC SC62A MT23

