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EMC for Functional Safety

a report by
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This article describes the problems associated with 'electromagnetic compatibility (EMC) for functional safety' for medical and healthcare equipment and introduces a procedure for dealing with them.[1,2]

Introduction

Electronic technologies are increasingly used in medical equipment that has an impact on safety. Unfortunately, all electronic technologies are inherently prone to suffering inaccuracy, errors in operation or damage, due to electromagnetic interference (EMI).

The electromagnetic (EM) environment that equipment is exposed to is generally becoming more 'polluted', due to increased use of wired datacommunications, wireless communications, digital processing and solid-state power conversion, so existing designs are more likely to suffer errors or failures due to EMI.

The internal feature sizes of the integrated circuits and transistors used in electronic equipment are continually decreasing, while their speeds are increasing and operating voltages falling. New designs are therefore more likely to suffer errors or failures due to EMI.

Software runs on electronic circuits, so when they suffer from EMI the software can also be affected by errors or malfunctions, causing the equipment controlled by the software to suffer as a result.

Existing standards for the safety and EMC of medical equipment do not deal adequately with EMC for functional safety and there are increasing pressures on manufacturers to shorten design/development timescales and reduce prices.

The overall result, as shown in *Figure 1*, is that patients and others are exposed to increasing safety risks and medical manufacturers and healthcare providers are exposed to higher financial risks.

Medical Equipment, Risk Analysis and EMC

In the EU, medical equipment is covered by one of the following:

- Medical Device Directive (MDD), 93/42/EEC;
- Active Implantable Medical Devices Directive, 90/385/EEC; and
- In-Vitro Diagnostics Directive, 98/79/EEC.

All three have similar 'essential requirements', for example:

- 'General – Equipment must not compromise the clinical condition or health/safety of users'; and

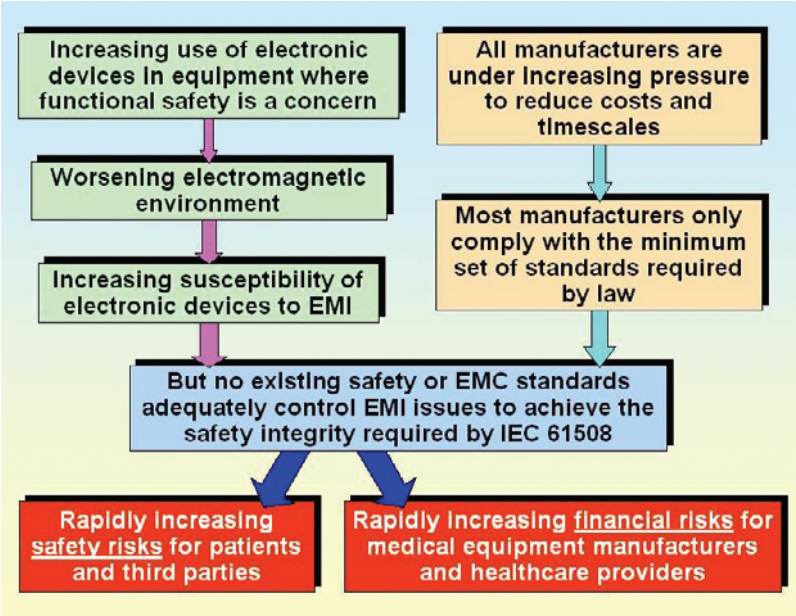
- 'Specific – Equipment must be designed and manufactured as far as possible to minimise risks due to reasonably foreseeable EM threats (influences).'

Compliance with all three directives is usually achieved by applying the EN 60601 series of standards – EU 'harmonised' versions of the International Electrotechnical Commission (IEC) 60601 series. Countries outside the EU also often base their medical safety standards on the IEC 60601 series. The base standard is IEC/EN 60601-1, and the others in the series add to or modify its requirements.

EMC issues for medical equipment are covered by IEC/EN 60601-1-2, although standards in the IEC/EN 60601-2-x series may add to, or modify its requirements, although they all rely solely on normal immunity testing methods, shown in this article to be inadequate for achieving functional safety over a lifecycle or complying with the directives' 'essential requirements'. In fact, the tests used in IEC/EN 60601-1-2 are almost identical to those in standards used for compliance with the EMC directive, which specifically do not cover safety issues.

1. *Institution of Electrical Engineers, "IEE Guide to EMC and Functional Safety", (September 2000), http://www.iee.org/Policy/Areas/Emc/index.cfm*
2. *Institution of Electrical Engineers training course, "EMC for Functional Safety".*

Figure 1: Increasing Risks Due to the Increasing Likelihood of EMI



Hazard and risk assessment is becoming a requirement of standards listed under the three medical directives. EN 14971:2001 addresses the 'Application of risk management to medical devices'. PD IEC TR 62296: 2003 'Considerations of unaddressed safety aspects in the Second Edition of IEC60601-1 and proposals for new requirements' includes a risk-based approach and has influenced the 3rd Edition of IEC 60601-1 (to be published during 2005, be 'EU harmonised' and replace the second edition during 2007).

Once the third edition of IEC/EN 60601-1 is published, it is likely that medical regulatory agencies will expect manufacturers to assess the EM environment that their equipment is to operate in and test accordingly. This may mean going beyond the EMC requirements in the IEC/EN 60601 series. They may also require manufacturers to define zones and separation distances for some situations.[3]

No medical safety standards yet employ the correct approach to functional safety, as described in IEC 61508.[4] This omission increases health risks and increases the likelihood of exposure to financial risks for manufacturers and healthcare providers, particularly under the state-of-the-art requirement in product liability legislation.

Post-market surveillance by manufacturers should cover new EM threats, such as new radio systems, introduction of new technology (e.g., personal digital assistants (PDAs) for doctors) to maintain the functional safety of their products and systems over their lifecycle.[5]

The Normal Approach to EMC is Inadequate

Safety standards employ well-proven safety engineering design and verification techniques that take into account foreseeable faults, environment, environmental extremes, ageing, use and misuse for the whole lifecycle of the equipment.

The normal approach to EMC never uses the word 'foreseeable' and is based solely on applying a set of EMC performance tests to a new item of equipment. This is not an appropriate methodology where safety is concerned.[6,7]

Normal immunity testing is too simplistic. For example:

- The radio frequency (RF) modulation frequency can be critical – but only 1kHz and 0.5Hz are used.
- In real life, equipment is subjected to multiple EM threats simultaneously (e.g., a radiated field plus a conducted mains transient), but normal EMC testing only applies one threat at a time, which overestimates the equipment's real-life immunity.[8]

Real-life EM exposure might not be tested. Normal immunity tests ignore foreseeable EM threats, for example:

- Close proximity of mobile radio transmitters (warning signs cannot stop all cellphone use).
- Almost all EM threats below 150kHz and above 2.5GHz.

3. *Philips T, "Is the EU Underplaying the Device Interference Problem?",* Clinica, *Issue 1 (21 June 2004);113: p. 8. http://www.clinica.co.uk*
4. *"Functional safety of electrical/electronic/programmable electronic safety-related systems", (in seven parts),* IEC 61508.
5. *Philips T, "Existing Products: How Far Should Firms Go In Evaluating New Risks?",* Clinica, *Issue 1, (23 August 2004);122: p. 6.*
6. *Brown S J, Radasky W A, "Functional Safety and EMC", IEC Advisory Committee on Safety (ACOS) Workshop VII, Frankfurt am Main, Germany (9–10 March 2004).*
7. *Armstrong K, "Why EMC Immunity Testing is Inadequate for Functional Safety", IEEE International EMC Symposium, Santa Clara, (9–13 August 2004). (Also:* Conformity Magazine, *pp. 15–23 (March 2005), downloadable via: http://www.conformity.com)*
8. *Mardiguian M, "Combined Effects of Several, Simultaneous, EMI Couplings", IEEE International EMC Symposium, Washington DC (21–25 August 2000), ISBN 0-7803-5680-2, pp. 181–184.*

- The ±6kV (approximately) overvoltages that occur on normal low-voltage AC supplies.

Compatibility levels may be too low. Each EM threat varies statistically and normal immunity tests use 'compatibility levels' that covers most of their range, but 'most' might not be good enough for some applications.[6]

Foreseeable faults are not addressed. The following examples of commonplace faults can badly affect the performance of shielding, filtering or surge suppression:

- poor connections, short circuits;
- missing or damaged conductive gaskets; and
- missing or loose fixings.

Foreseeable effects of the physical environment are ignored. For example:

- Filters can be badly affected by high temperatures, supply voltages and load currents.[9]
- Mounting stresses, shock, vibration, temperature extremes, exposure to liquids, conductive dusts, etc., can all degrade the performance of shielding and filtering – as can ageing due to temperature cycling, humidity, corrosion, wear and tear, etc.

Only a representative sample is tested, but the EMC performance of supposedly identical products can vary significantly if their design did not take account of the effects of foreseeable tolerances in components and variations in assembly.

Maintenance, repair, refurbishment and upgrades, etc., are ignored. Cleaning and maintenance may, for example, require the opening or removal of doors or panels that provide shielding. Real equipment is also subjected to repair, refurbishment, modifications and upgrades. The normal approach ignores the degraded EMC performance that can result.

Performance criteria might not be acceptable for systems. It is usual to assume that if all of the units comprising a system pass their EMC tests, the system will have good EMC, but performance criteria considered acceptable when testing an individual unit (e.g., a direct current (DC) power supply) might not be acceptable in a system.[6]

Safety Requires Good EMC Techniques in Design, Assembly and Maintenance

Achieving safety over the lifetime of equipment requires the use of good EMC techniques in design, assembly, quality assurance (QA) and maintenance – in the same way that well-proven safety design methods are required for all other safety issues, including software.[4]

EMC testing is necessary for verifying EMC design, but normal test methods may be inadequate (as previously mentioned) and special test methods may be required.[2]

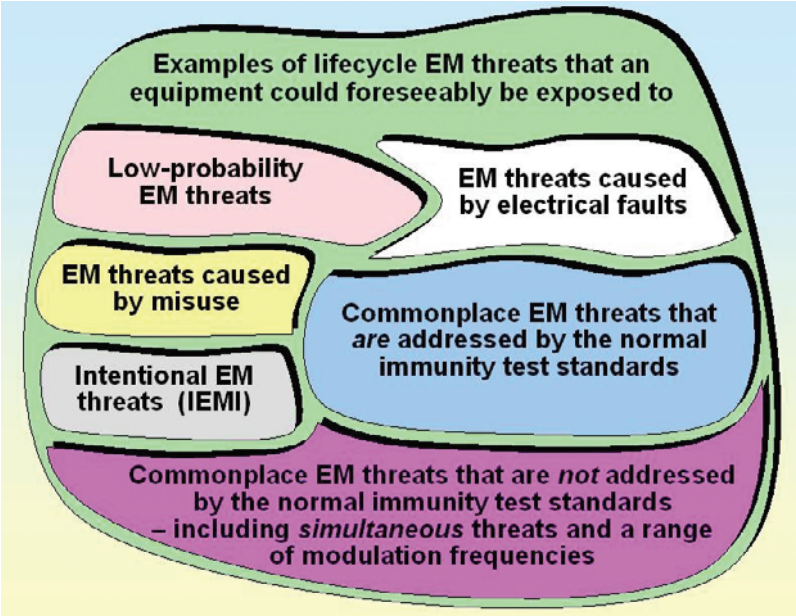
How EMC Should be Controlled for Functional Safety

IEC 61508[4] is the basic standard on functional safety. It covers EMC threats but does not say how they should be dealt with. The Institution of Electrical Engineers (IEE)[1,2] recommend using the approach summarised in below:

- What foreseeable EM threats could the equipment be exposed to? An 'EM threat assessment' is performed for the foreseeable EM environment of an equipment's operational site(s), taking into account low-probability EM threats over its lifecycle (see *Figure 2*).[10]
- What could the EM threats foreseeably affect? Electromechanical devices can malfunction and be damaged. Analogue and power conversion circuits can suffer errors or be damaged. Digital circuits, programmable devices and software can change operational modes, malfunction, or be damaged. Data can be corrupted or lost. All these possibilities should be considered in a hazards analysis and risk assessment.
- Foreseeable effects of equipment emissions. Normal EMC emissions standards do not protect nearby radio receivers or other sensitive circuits. Some permit extremely high emissions from some medical equipment at specified frequencies – enough to seriously interfere with electronics, so the foreseeable effects on existing equipment of the emissions from any new equipment should be considered.
- What are the reasonably foreseeable functional safety implications of the previously mentioned points? This should take into account the severity of the safety hazards, their probabilities (risks) and

9. *Beck F, Sroka J, "EMC Performance of Drive Application Under Real Load Condition", Schaffner EMV AG application note (11 March 1999).*
10. *Armstrong K, "Assessing an Electromagnetic Environment", http://www.cherryclough.com*

Figure 2: Some Foreseeable EM Threats



the number of people exposed. The approach used by the IEC should be followed, remembering that EM threats have statistical variations. Errors and failures due to EMI are systematic, not random and this affects how they must be treated in the equipment's design.

- What actions are needed to achieve the required level of safety? Five kinds of actions are needed, carried out in the following order:

  – Hazard and risk reduction by design. Design so that the hazards are less severe, the risk is reduced and fewer people are exposed.

  – EMC risk-reduction by design. Electrical and electronic devices, circuits and software that could have a safety impact should be designed to be sufficiently reliable over their lifecycle. This should take into account the foreseeable EM, physical and climatic environments, plus use/misuse, wear-and-tear and ageing, etc.

  – Verification of the design techniques employed. Verification, including EMC testing, that proves the design meets the requirements derived from the previously mentioned actions. Special immunity test techniques may be required.

  – Maintenance of safety performance in serial manufacture, maintenance, repair. A QA system should control all of the aspects of manufacture that could affect any EM-related safety issues. Sample-based EMC testing will generally be required during series manufacture.

  – Change control. A QA system should control EMC-related safety issues during modifications and upgrades.

- What documentation is required to show due diligence? Project records should show that previously mentioned steps were carried out in full and that the required EMC performance was determined and 'designed-in' for all safety-related areas from the start of a project and verified at the end.

Conclusion

The normal approach to EMC – applying IEC/EN 60601-1-2 and similar immunity test standards – cannot give confidence that adequate levels of functional safety will be maintained over the lifecycle of equipment.

Instead, good EMC design practices are required to address the equipment's real-world EM, physical, climatic, use or misuse and 'wear-and-tear' environments and design verification may require special immunity tests. ■