PRESENTED BY

INTERFERENCE TECHNOLOGY®

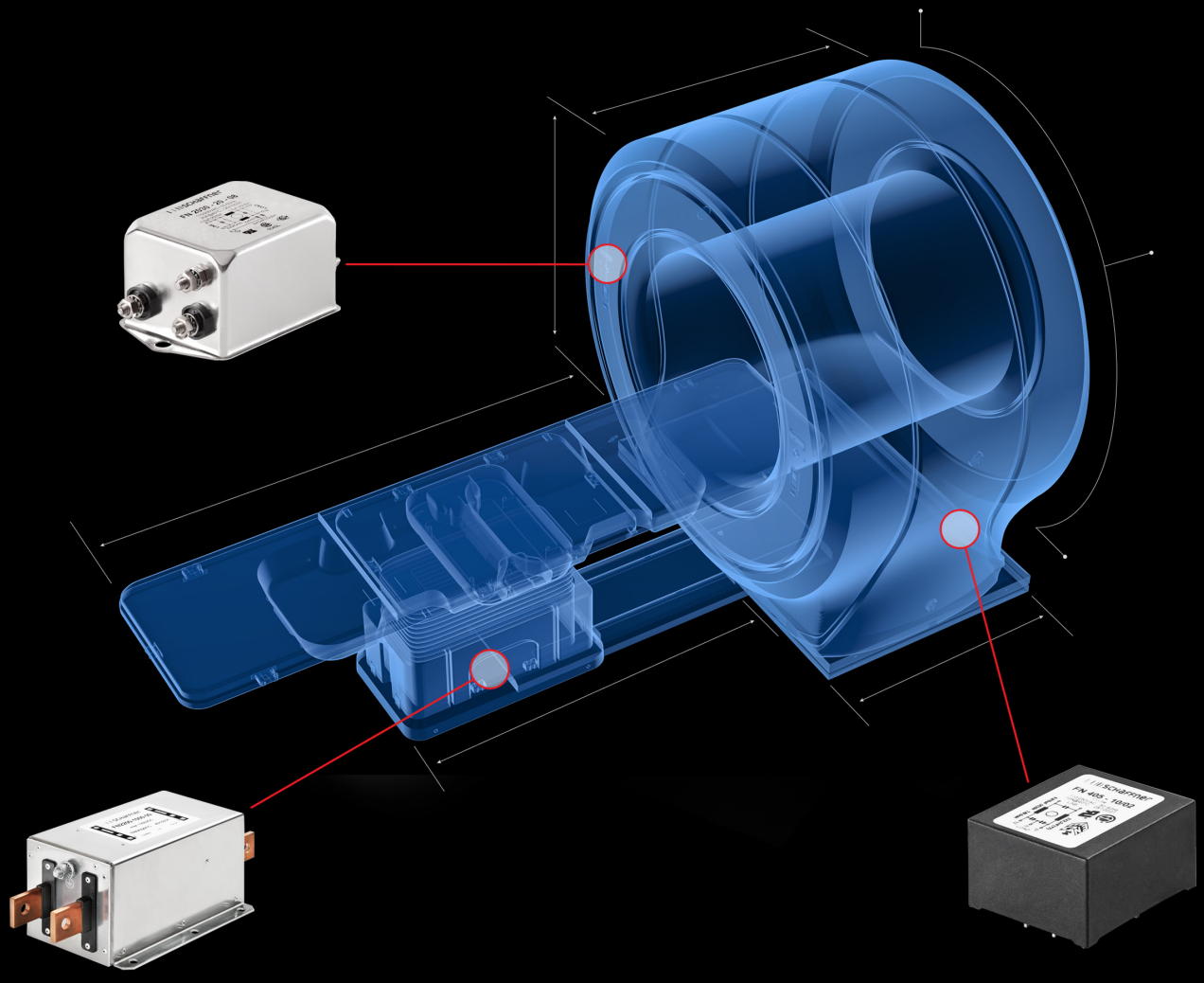
2020 MEDICAL EMC GUIDE

TABLE OF CONTENTS

Lives depend on reliable medical equipment.

RELIABLE MEDICAL EQUIPMENT DEPENDS ON SCHAFFNER.

Technological advancements like wireless, Bluetooth, and microprocessors means improved life-saving medical devices. **It also means greater risk of EMI issues.**



Protection Against Conducted and Radiated Emissions

Incorporating a Schaffner EMC filter into your product design, ensures the most reliable and efficient path to achieving **IEC-60601 compliance** – *and prevents the unthinkable*.

PCB FILTERS | IEC INLET FILTERS / POWER ENTRY MODULES | SINGLE-PHASE FILTERS | 3-PHASE FILTERS | CHOKES | AND MORE

Contact Us Now

Request a **FREE** product sample and learn how Schaffner can help make your medical device design compliant.

1.800.367.5566 | usasales@schaffner.com | www.schaffnerusa.com

---

schaffner
shaping electrical power

SCHAFFNER EMC INC. | 52 Mayfield Avenue, Edison, New Jersey 08837

INTRODUCTION

Darryl P. Ray
Darryl Ray EMC Consulting, LLC
Darryl.ray@Dray-emc.com

As with all devices in the electronics industry, the world of medical devices has been changing rapidly. Medical devices are now smaller, cheaper, more complicated, and more sensitive than ever before. In the past, many medical devices would experience significant susceptibilities in the presence of electromagnetic fields from nearby cellular phones and other mobile transmitting devices. The typical solution was the manufacturer would place a warning statement in the instructions for use advising the user to keep mobile communication devices far away (or turn them off) from the medical device. Those days are behind us, as the world now expects medical devices to operate properly while in the presence of mobile communications equipment.

Technology always outpaces standards and regulations. For external medical electrical equipment and systems, the main EMC standard utilized is IEC 60601-1-2. It was extensively revised in 2014 (becoming the fourth edition) and became mandatory for new device submittals in the U.S. and for all devices sold to the European Union, both starting January 1, 2019. The fourth edition is significantly different than its predecessors in that that it is a based solely on the safety of the medical device using an often-misunderstood concept of essential performance. The fourth edition addresses interference from nearby mobile transmitting devices and other environments. The immunity test levels are significantly increased in some cases. The fourth edition does not, however, address the overall performance/effectiveness (also referred to as the efficacy) of the device while exposed to electromagnetic disturbances. To address the efficacy concerns, IEC TR 60601-4-2 was published in 2016.

Per the fourth edition, risk management is now tightly connected with medical device EMC design and testing requirements with a focus on safety. This is an area that many test labs may not be able to adequately address. It is the manufacturers responsibility to ensure the risk management requirements of fourth edition are met.

For many active implantable devices the EMC requirements are contained in ISO 14708. That standard has multiple parts. ISO 14708-3 (implantable neurostimulators) was revised in 2017.

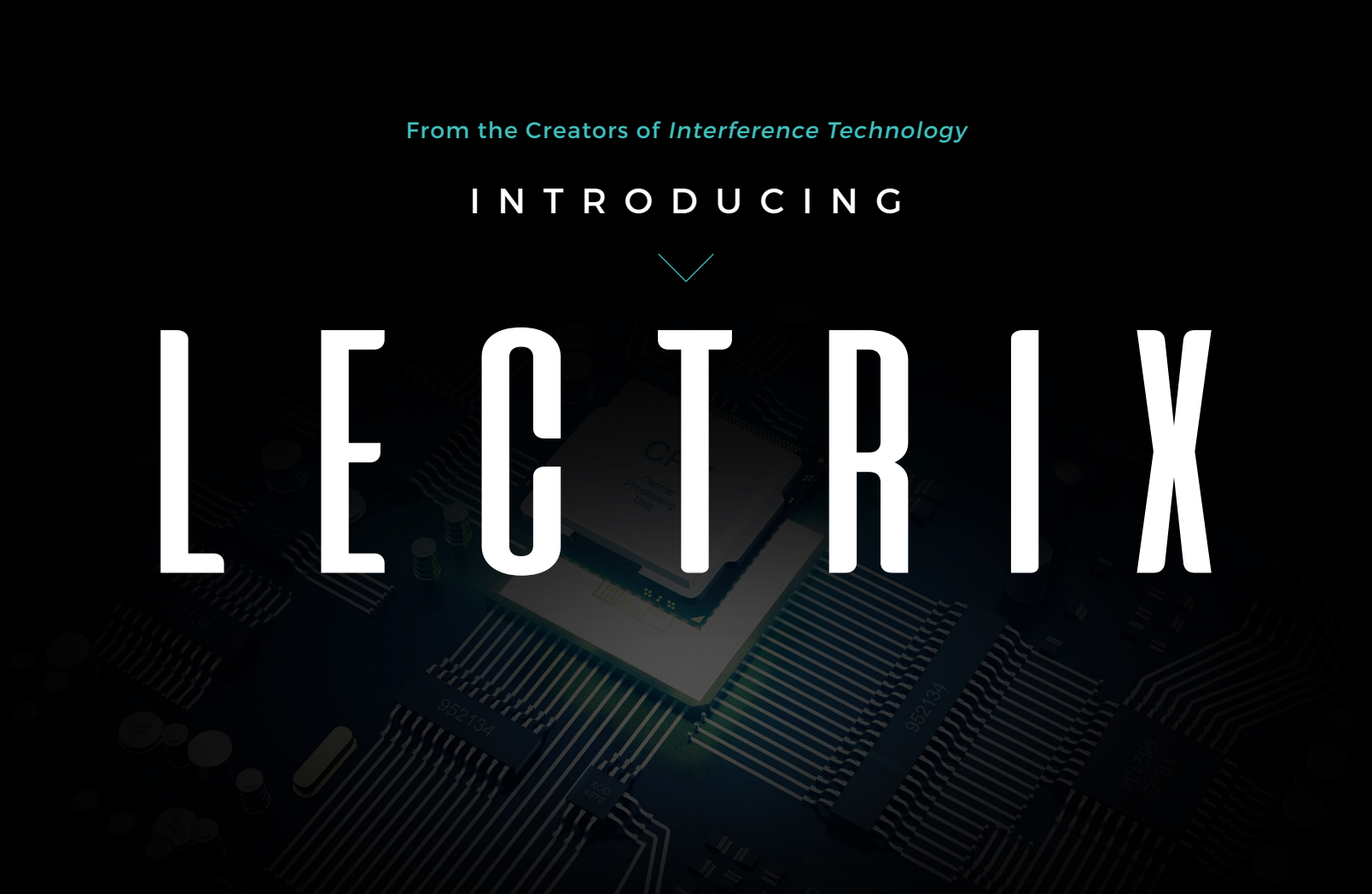
Many new medical devices can now operate wirelessly. Wireless issues with medical devices are getting increasingly complex. Some device regulators are expecting the manufacture to address “Wireless Coexistence” when they submit the application for device approval. The RED directive in Europe is likely to create new regulatory challenges as the directive mandates that if a medical devices include wireless functionality it therefore becomes radio equipment.

The next few years will be both interesting and challenging and as the medical device industry enters this brave new world. What was good enough in the past will likely not be the case in the future. The bar has been raised.

From the Creators of *Interference Technology*

INTRODUCING

LECTRIX



THERE'S ONLY ONE SPOTLIGHT

ARE YOU IN IT?

Positioning Ambitious B2B Electronics Companies
for Aggressive Growth

www.lectrixgroup.com

PHILADELPHIA, PA | HONG KONG

MEDICAL TEST EQUIPMENT & COMPONENT MANUFACTURERS

Ken Wyatt
Wyatt Technical Services LLC
ken@emc-seminars.com

Introduction

The next two charts are a quick reference guides of test equipment and medical-specific component manufacturers. The first chart includes everything you'll need from the bare minimum required for key evaluation testing and probing, and troubleshooting, to setting up a full in-house pre-compliance test lab. The list includes amplifiers, antennas, current probes, ESD simulators, LISNs, near field probes, RF signal generators, spectrum analyzers, EMI receivers, and TEM cells. Equipment rental companies are also listed. The products listed can help you evaluate radiated and conducted emissions, radiated and conducted immunity and a host of other immunity tests, such as ESD and EFT.

Several manufacturers make medical-specific components, such as connectors, EMI filters, and power supplies. Be sure the power supplies you select are designed and qualified to the latest medical EMC standard, IEC 60601-1-2 (edition 4). The second chart lists several possible manufacturers.

Medical Test Equipment Manufacturers		Type of Product/Service												
Manufacturer	Contact Information - URL	Antennas	Amplifiers	Near Field Probes	Current Probes	Spectrum Analyzers/EMI Receivers	ESD Simulators	LISNs	Radiated Immunity	Conducted Immunity	Pre-Compliance Test	TEM Cells	Rental Companies	RF Signal Generators
A.H. Systems	www.ahsystems.com	X	X		X						X			
Aaronia AG	www.aaronia.com	X	X			X					X			
Advanced Test Equipment Rentals	www.atecorp.com/category/emc-compliance-esd-rfi-emi.aspx	X	X			X	X	X	X	X	X		X	X
AR RF/Microwave Instrumentation	www.arworld.us	X	X			X		X	X	X	X			X
Anritsu	www.anritsu.com/en-us/					X					X			X
Electro Rent	www.electrorent.com		X			X	X	X	X	X	X		X	X
EM Test	www.emtest.com/home.php									X	X	X		
EMC Partner	www.emc-partner.com						X			X				
Empower RF Systems	www.empowerrf.com		X						X					
Emscan	www.emscan.com										X			
Fischer Custom Communications	www.fischercc.com			X	X			X	X		X	X		
Gauss Instruments	www.gauss-instruments.com/en/					X								
Haefely	www.haefely.com						X			X				
Instruments For Industry (IFI)	www.ifi.com		X						X	X				
Keysight Technologies	www.keysight.com/main/home.jspx?cc=US&lc=eng			X		X		X			X			X
Milmega	www.milmega.co.uk		X						X	X				
Narda/PMM	www.narda-sts.it/narda/default_en.asp	X	X			X		X	X	X	X			
Noiseken	www.noiseken.com						X			X	X			
Ophir RF	www.ophirrf.com		X							X				
Pearson Electronics	www.pearsonelectronics.com				X									
Rigol Technologies	www.rigolna.com			X	X	X					X			X
Rohde & Schwarz	www.rohde-schwarz.com/us/home_48230.html	X	X	X	X	X		X	X	X	X			X
Siglent Technologies	www.siglentamerica.com			X		X					X			X
Signal Hound	www.signalhound.com			X		X					X			X
Solar Electronics	www.solar-emc.com				X			X		X				
TekBox Technologies	www.tekbox.com		X	X				X			X	X		
Tektronix	www.tek.com			X		X					X			
Teseq	www.teseq.com/en/index.php		X		X		X		X	X	X	X		
Test Equity	www.testequity.com		X			X	X	X	X	X	X		X	X
Thermo Keytek	www.thermofisher.com/us/en/home.html						X			X				
Thurlby Thandar (AIM-TTi)	www.aimtti.us					X					X			X
Toyotech (Toyo)	www.toyotechus.com/emc-electromagnetic-compatibility/	X	X			X		X	X		X			
TRSRenTelCo	www.trs-rentelco.com/SubCategory/EMC_Test_Equipment.aspx	X	X			X		X	X	X	X		X	X

Medical Component Manufacturers		Type of Equipment		
Manufacturer	Contact Information - URL	Connectors	EMI Filters	Medical Power Supplies
Advanced Power Solutions	www.advpower.com			X
Americor	www.americor-usa.com/emirfi-line-filters.html		X	
Amphenol	www.amphenolalden.com	X		
Arch Electronics Corp.	www.archcorp.com.tw			X
Artesyn	www.artesyn.com/power/industries/healthcare			X
Astrodyne	www.astrodyne.com/power-supplies/medical		X	X
Binder USA	www.binder-usa.com/industries/medical	X		
Conversion Devices Inc.	www.cdipower.com			X
CUI Inc.	www.cui.com/medical			X
Delta	www.deltaww.com/Products/CategoryListT1.aspx?CID=17&hl=en-US		X	X
EFORE	www.efore.com/power-supplies/medical-grade-power-supplies			X
EMC Pioneer	www.cnemifilter.com/market/2413/		X	
Enerdoor	www.enerdoor.com/markets/medical-equipment		X	
ETA-USA	www.eta-usa.com			X
Fischer Connectors	www.fischerconnectors.com/global/en/applications/medical	X		
FSP Group	www.fspgroupusa.com/Medical.html			X
GlobeTek Inc.	www.en.globtek.com/power-supplies/			X
HAL	www.hal.com.tw		X	
Integrated Power Designs	www.ipdpower.com/medical-power-supplies/			X
ITG Electronics	www.ITG-Electronics.com		X	
ITT Cannon	www.ittcannon.com/markets/medical/	X		
Kemet	www.kemet.com/en/us/applications/medical.html		X	
LCR Inc.	www.lcr-inc.com/emi-filter-single-phase/		X	
Lemo	www.lemo.com/en/application/medical-connector	X		
Mean Well	www.meanwellusa.com/productSeries.aspx			X
MEV Elektronik	www.mev-elektronik.com/commercial-medical-emi-filters-en.html		X	
Molex	www.molex.com/molex/industry/industry?industry_key=medical&channel=Industries	X		
ODU	www.odu-usa.com/products-solutions/push-pull-circular-connectors/odu-medi-snap.html	X		
Onanon	www.onanon.com/disposable-medical-connectors	X		
Radius Power	www.radiuspower.com/emi-filters/medical-grade-emi-filters		X	
SAE Power	www.saepower.com/emirfi-filter-products/		X	
Schaffner	www.schaffner.com/products/emcemi/		X	
Schott	www.schott.com/epackaging/english/gtms/connectors/connectors-for-medical-applications.html	X		
Schurter	www.schurter.com/en/Landing-Page/Industry/Medical		X	
Sinpro Electronics Co. Ltd.	www.sinpro.com			X
Smiths Interconnect	www.smithsinterconnect.com	X		
Sunpower UK	www.sunpower-uk.com/ranges/Medical-Grade-Power-Supplies/11/default.htm			X
SynQor	www.synqor.com/medical/			X
TDK-Lambda	www.us.tdk-lambda.com/lp/products/medical.htm			X
Torven	www.torven.cn	X		
TRC Electronics	www.trcelectronics.com/medical-power-supply.shtml			X
TRUMPower	www.trumpower.com/Medical_Power.html			X
XP Power	www.xppower.com/Applications/medical-power-supplies			X

ESSENTIAL PERFORMANCE

Jim Conrad
Conrad EMC Consulting, LLC
jcemc@live.com

Introduction

Essential performance has been a mysterious term ever since its introduction in International Standard IEC 60601-1-2 in 2001. Essential performance is not unique to IEC 60601-1-2, but originates in the general standard, IEC 60601-1, and is used throughout all the collateral and Part 2 standards of the IEC 60601 family of standards for medical electric equipment, and medical electrical systems (medical devices).

ESSENTIAL PERFORMANCE

Introduction
Essential performance has been a mysterious term ever since its introduction in International Standard IEC 60601-1-2 in 2001. Essential performance is not unique to IEC 60601-1-2, but originates in the general standard, IEC 60601-1, and is used throughout all the collateral and Part 2 standards of the IEC 60601 family of standards for medical electric equipment, and medical electrical systems (medical devices).

Essential Performance
The essential performance of a medical device is determined by the following methods:

- The applicable IEC/ISO 60601-2-X standard for a device
- The general safety standard 60601-1
- The manufacturer as determined by risk analysis

Electromagnetic disturbances are only one phenomenon that could affect the device's essential performance, or basic safety. Immunity tests, such as electrostatic discharge (ESD) at 15kV or 2kV power line surges, could affect the safety barrier's dielectric characteristics, and must be considered as a safety risk. Dielectric and leakage currents should be evaluated after immunity testing to ensure it was not degraded by the EM testing.

The compliance criteria in IEC 60601-1-2 states that essential performance and basic safety must not be affected by electromagnetic disturbances. Basic safety is defined in IEC 60601-1 and Part 2 standards. One Part 2 standard identifies basic safety as unintentional or uncontrolled movement. It is important to include both essential performance and basic safety in the immunity compliance criteria.

Essential performance could be thought of as safety related performance, the lack of which results in an unsafe medical device. More specifically, it is that performance of a device that will produce an unacceptable risk to the patient or operator if the absence of performance or degradation results in misdiagnosis or unacceptable harm.

IEC 60601-1, Edition 3.1 subclause 4.3, states the manufacture shall identify which performance of a clinical function(s) of the intended use of the medical device are essential for safety. Note that essential performance is only related to safety of the medical device, and does not ensure that the device does what the manufacture specifies it will do. The medical device can stop functioning so long as it does not create unacceptable risk to the patient or operator. Not every function of the medical device is essential for safety of the device. When the risk from the loss or degradation of a clinical function is unacceptable, that performance is essential performance and must be evaluated during EM testing and documented in the risk management file.

Note that subclause 4.3 requires that essential performance must be maintained both during normal and single fault conditions. However, it is not practical to evaluate single fault conditions during electromagnetic immunity testing as stated in the third edition of 60601-1-2. This exclusion was inadvertently left out of the fourth edition and could be addressed in the risk management process. Another approach might be to generate an electromagnetic critical components list for emissions and immunity to ensure these components are evaluated from time to time. If not properly addressed, you will spend years doing single fault immunity testing!

Table 201.101 – Essential Performance Requirements	
Requirement	Subclause
Defibrillator Protection	201.8.5.5.1
Interruption of the Power Supply/Supply Mains to be Equipment	201.11.8
Protection Against Depletion of Battery	201.11.8.101
Essential Performance of ME Equipment	201.12.1.101
Electrosurgery Interference	202.6.2.103
Time to Alarm for Heart Rate Alarm Conditions	208.6.6.2.103
Technical Alarm Conditions Indicating Inoperable ME Equipment	208.6.6.2.104

Some examples of essential performance are listed below:

- The accuracy of a life-supporting function or correct administration of a drug, where incorrect administration would result in unacceptable risk to the patient;
- Correct operation of an alarm, where the failure to alarm would result in incorrect response by the medical personnel
- Correct acoustic output power level of a diagnostic ultrasound imaging system, where excessive acoustic output power would result in unacceptable risk to the patient
- Correct output of diagnostic information that is relied upon to determine treatment of the patient, where incorrect information would result in unacceptable risk to the patient
- Correct or precise movement of a robotic catheterization machine by the remote controls, where unintended or uncontrolled motion of the catheter tip would result in unacceptable risk to the patient

The risk management process is used exclusively in determining the essential performance of the medical device if there are no applicable particular standard for the product. Particular standards (IEC/ISO 60601-2-X) take precedence over the general safety standard (IEC 60601-1) and identify the essential performance for that

specific medical device.

The following is an example of Part 2 essential performance requirements for electrocardiographic monitoring equipment as specified in IEC 60601-2-27:

Note: All of the 60601 family of standards are being updated and this example may not represent the current standard and should not be used for the development of a product.

With the exception of defibrillator protection, the above essential performance parameters could be degraded by electromagnetic disturbances.

Probably the most interesting is 201.12.1.101, "Essential Performance of ME Equipment," which lists the following performance parameters as essential performance:

- Accuracy of signal reproduction
- Input dynamic range and differential offset voltage
- Input impedance
- Input noise
- Multichannel crosstalk
- Gain control and stability
- Sweep speed
- Frequency and impulse response
- Gain Indicator
- Common mode rejection
- Baseline reset
- Pacemaker pulse display capability
- Rejection of pacemaker pulses
- Synchronizing pulse for cardioversion
- Heart rate range, accuracy, and QRS detection range
- Channel height and aspect ratio
- Tall T-wave rejection capability

The above list of essential performance parameters is daunting. Imagine how long it would take to test and verify all these parameters to meet the requirements of the standard during the eight immunity tests required by IEC 60601-1-2. A test plan (required by IEC 60601-1-2:2014) is vital to determine and justify which parameters of a device need monitoring during immunity testing.

Performance

What is performance of a medical device? Is it essential performance? The answer is simpler than the confusion of essential performance. Device performance in the presence of electromagnetic disturbances is important because patients, operators, and regulators have an expectation that the medical device will not only remain safe, but will work as the manufacturer advertised in the environment it will be used in. For this article, we are only considering the electromagnetic environment.

Performance of a medical device is determined by the manufacturer's specifications and claims, and will include the device's essential performance as discussed below: Some examples of performance are:

- The ability to print an ultrasound image remotely
- The ability of a scale to accurately measure patient weight
- The accuracy of X-ray tube voltage in X-ray equipment, e.g. the error is less than 5%

Table 1: Comparison of Essential Performance to Performance for a Diagnostic Ultrasound System

Parameter	Essential Performance?	Performance?
Acoustic output power	Yes, if it increases to an unsafe level	Yes, if it affects image quality
Noise on waveform	Yes–any noise that may be attributed to a physiological effect and which may alter the diagnosis	Yes, if it affects waveform quality
Artifacts or distortion in an image	Yes–any artifacts or distortion that may be attributed to a physiological effect and which may alter the diagnosis	Yes, if it affects image quality
Displayed numerical value	Yes–errors in displayed numerical values associated with the diagnosis to be performed	Yes
Probe temperature	Yes, if the probe produces unintended or excessive surface temperatures	Yes–excessive probe temperature will be uncomfortable for the patient
Unintended or uncontrolled probe motion	Yes	Yes
Proper operation of a printer used to print reports or images	No	Yes–customer satisfaction
Unintended sound in the speakers	No	Yes
Unintended or uncontrolled joy stick control	No	Yes
Wireless interface	No	Yes
Short power interruption	No, provided the system remains safe, experiences no component failures, and is restorable to the pre-test state with operator intervention	Yes

The device's performance parameters must be monitored during immunity testing to ensure the effectiveness of the device per the manufactures specifications and claims.

The compliance criteria will be different for essential performance and performance. For essential performance, the device must remain safe as determined by the manufactures risk management process. For performance, the device must do what the manufacturer specifies and claims in the presence of electromagnetic disturbances.

Comparison of Essential Performance vs. Performance

Table 1 provides a comparison of essential performance vs. the performance parameters for a Diagnostic Ultrasound System.

Summary

The concept of Essential performance is often misunderstood. It is not the same as performance. Essential performance is best understood as safety related performance. A medical device's essential performance, basic safety, and device performance, are all very important to customer satisfaction, regulators, device safety, and the manufacture's quality system. All should be monitored before, during, and after IEC 60601-1-2 immunity testing. In addition, the requirements for the device's instructions for use play a very important role in the device's safe use and compliance with IEC 60601-1-2.

Call for Authors and Contributors!

Want to be a part of the next issue of Interference Technology? Have an article or blog post you'd like to write for InterferenceTechnology.com?

Please Contact Graham Kilshaw at
graham@lectrixgroup.com

INTERFERENCE TECHNOLOGY®

www.InterferenceTechnology.com

THE EMI RISK MANAGEMENT OF MEDICAL DEVICES

Keith Armstrong
Cherry Clough Consultants Ltd, U.K.
www.cherryclough.com

Introduction
The latest medical EMC standard (IEC 60601-1-2) now requires a safety risk analysis be performed as a part of the assessment and report. Typically, EMC test laboratories are not equipped or qualified to perform this assessment, so it is up to the manufacturer to perform this step. This article discusses risk management and an approach for assessing a product for safety risk due to EMI.

THE EMI RISK MANAGEMENT OF MEDICAL DEVICES

If only the medical world was entirely like *Figure 1*!

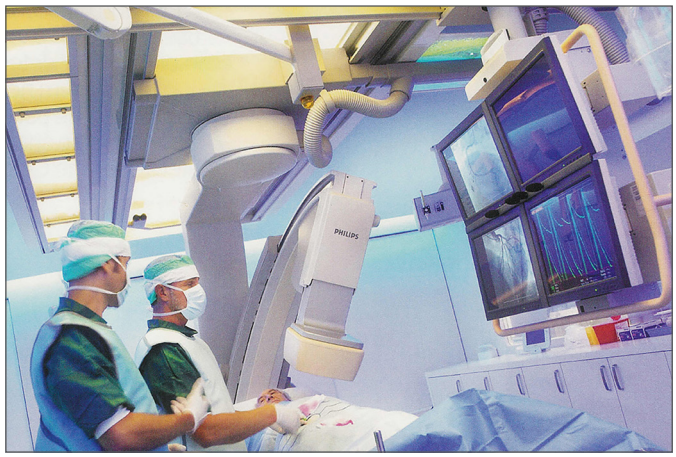


Figure 1: The dream of the medical electromagnetic environment (The Philips "Ambient Experience" catheterization lab, IET Engineering & Technology, April 2008)

Unfortunately, *Figure 2* is a more common sight in hospitals, and many medical devices are now expected to be taken home, and to work, by patients.

In real life, we are generally aiming for the equipment we design (and by 'equipment' I mean: module, device, product, machine, system, installation, etc...) to expose their users and anyone else to a risk of death of less than one in a million per year. Sometimes this is impossible, or at least impractical, and so we knowingly accept a higher risk of death because the function provided by our equipment is considered to be worth that risk. The riskiest occupations are estimated to create a risk of death of about one in a thousand per year, and it is widely agreed that no equipment should expose anyone to a higher risk of death than this.

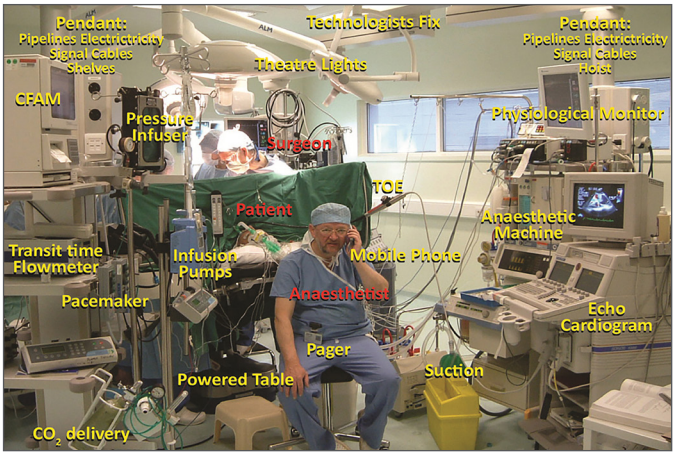


Figure 2: The reality of the medical electromagnetic environment (Operating theatre, Edinburgh, September 2010, © 2010 Dr. David Scott)

All this is very well, but how can we possibly test a medical equipment for EMC and have any clue at all whether errors, malfunctions or failures in its electronics caused by EMI would create a risk of death of between one in a million and one in a thousand per year? In real-life operation? *Figure 2* shows that real-life operation might bear no resemblance to the test set-ups required by IEC 60601-1-2.

Something else to understand: for several decades it has been impossible to fully test any microprocessor or its software, because they have become too complex. So, where errors, malfunctions or failures in a modern digital system could possibly result in an unacceptable safety risk, it is impossible–by testing alone–to prove that it should be safe enough throughout its 'Expected Service Life' (ESL).

And that was just for functional testing. It is even more true for EMC testing, because to prove EMI couldn't cause excessive safety risks we would have to a test digital system's functions by enough (which is impossible) for all reasonably foreseeable: combinations of cables, cable types, cable layouts, etc. (see *Figure 2*); close proximities to all other types of medical equipment (*Figure 2* again); electromagnetic disturbances; effects of physical and climatic stresses, aging, etc.; degradations/faults in filtering, shielding, surge suppression, and circuits; and angles of incidence and polarisation, modulation types/frequencies, transient waveshapes, and repetition rates, etc.

Not only that, but we must take into account combinations of any/all of the above (because they are all independent variables) that could possibly occur throughout its ESL, taking maintenance, repairs, upgrades, modifications, and refurbishments into account. The result is sometimes described as an 'exploding test plan', and I recently wrote an article in the IEEE EMC Society's Magazine, putting numbers to these issues [1]. Unfortunately, I don't have sufficient space in this article to repeat all this detail here.

This understanding that microprocessors and software can never be tested sufficiently to prove they are safe enough for the vast majority of safety-related applications gave rise to IEC 61508 [2], the IEC's basic standard on functional safety, first published in 2000, with Edition 2 published in 2010.

IEC 61508's solution to this problem is to require the use of well-proven techniques and measures (T&Ms) in system, hardware and software design, and in its verification and validation, to ensure that modern electronics does not cause excessive safety risks over its ESL.

All of the IEC's product-family functional safety standards have been developed from [2], except for its medical standards, which base their risk management requirements on ISO 14971 [3] instead. ISO 14971 has the same general, overall requirements as IEC 61508, but uses completely different terminology. Worse still, it does

not include any of 61508's well-proven T&Ms, leaving medical manufacturers and their regulatory assessors at a great disadvantage.

Long Story, Short

Both Edition 3:2007 and Edition 4:2014 of IEC 60601-1-2 (i.e. [4] and [5] respectively) require EMI to be risk assessed. Unfortunately, this is only an implied requirement in Edition 3 and many manufacturers and Medical Regulators are not aware of it, see [6] for details.

Guidance on risk managing EMI is provided by Annex F of Ed.4, strongly based on the IET's 2008 Guide [7] to IEC TS 61000-1-2:2008 [8]. The manufacturer documents what he has done about risk managing the EMI of his equipment over its ESL in a "Risk Management File". This is the same file that should also document all the other risk management activities that have been undertaken for compliance with IEC 60601-1 and any other 60601-x standards that apply. Compliance depends on the assessment of this file by the relevant safety assessor, such as an EU Notified Body [9], the FDA, etc., and not merely on EMC test results.

It is important to understand that these risk management activities cannot be performed by an EMC test laboratory. An EMC test lab can check that something has been written for each of the risk management requirements in the standard, but cannot perform the risk management on behalf of the manufacturer.

Unfortunately, after the work on Edition 4 had progressed to the point where significant changes to its text could not be made, we discovered that neither its Annex F, nor [7] nor [8], provided a practical method of complying. It all sounded very good, but was simply not practical for most manufacturers.

A Practical Way to Comply

My working group at the IET published the first practical guidance in 2013 [10]. It says either use rugged, high-specification electromagnetic mitigation (i.e., shielding, filtering, surge/transient suppression, galvanic isolation, etc.) that we are familiar with from military projects, see *Figure 3*, or else use 61508-type T&Ms that provide sufficient "EM Resilience."

But what is 'EM Resilience'?

It was determined which IEC 61508 T&Ms already had benefits for protecting against the effects of EMI, then developed, updated and added to them, to achieve the following (summarized in *Figure 4*):

- EM mitigation plus appropriate design ensure that devices, equipment and systems are mostly unaffected by most electromagnetic disturbances over the ESL (in other words, most electromagnetic disturbances will not cause EMI during the lifecycle)
- Any EMI that occurs is reliably-enough detected by appropriate T&Ms, whether it is caused by unforeseen levels of electromagnetic disturbances; multiple simultaneous electromagnetic disturbances; wear; aging; corrosion; faults; misuse, etc., combinations of any/all of these, or anything else
- When EMI is detected, other T&Ms ensure that appropriate actions are taken to maintain safety risks at acceptable levels–for example by switching the system into a "safe state"; or by correcting for the effects of the EMI and continuing to operate as usual

Figure 3: Some examples of rugged, high-specification electromagnetic mitigation

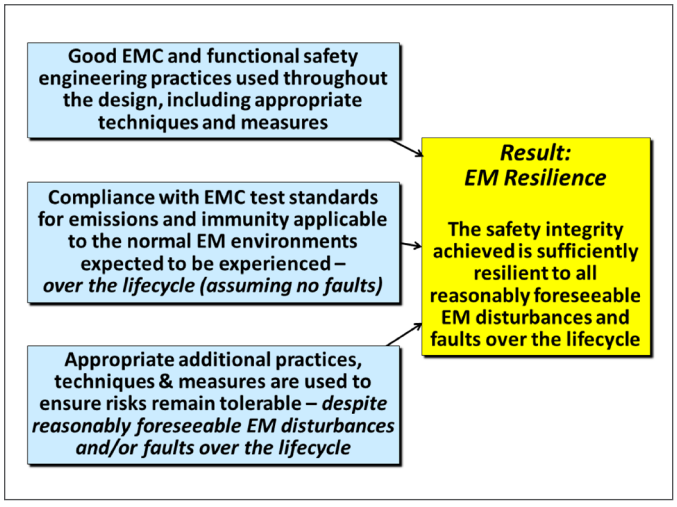


Figure 4: Overview of Electromagnetic (EM) Resilience

61508 industry functional safety designers and assessors are very experienced in the use of suitable T&Ms in design, verification, and validation to make systems, hardware and software more resilient to the effects of errors, malfunctions, faults, etc. [10] details which of these T&Ms are good for EM Resilience, and how to modify them to make them more effective for EMI, which will not require these designers and assessors to learn much more than they know already. Brief examples of good T&Ms for EM Resilience design follow.

EM Resilience T&Ms for system design, including: separating safety and non-safety functions in both hardware and software; specifying system requirements and design approaches (including for example: redundancy and diversity; error detection and error correction; static and dynamic self-testing); careful integration of subsystems, power supplies and communication links, and fault monitoring and recording.

EM Resilience T&Ms for redundancy and diversity, including: using multiple sensors to sense the same parameters; storing multiple copies of the same data; sending the same data over multiple communications links, and processing the same data in multiple processors. Each of these design techniques uses comparison (i.e. error detection) or voting (i.e. error correction) for example choosing any two that agree out of three outputs, any three that agree out of five, etc. All these can use a wide range of diverse technologies/techniques to improve their effectiveness against the common-cause failures typically caused by EMI.

EM Resilience T&Ms for error detection and correction, including: error detection coding (EDC) by adding redundant data designed to make errors detectable; and error correction coding (ECC) by adding enough redundant data that data corruption is not only detected, but also restored to sufficient accuracy.

EM Resilience T&Ms for self-testing, including: checking the safety functions' hardware and software before operation, preventing operation if necessary (called 'static testing'), and checking the correct operation of the safety functions during operation (called 'dynamic testing').

A number of good EM Resilience T&Ms will probably be designed-in for non-EMI reasons, and some of them may be modified to improve their EM Resilience (e.g. by using technological diversity). Additional T&Ms might need to be added to achieve sufficient EM Resilience overall.

Compliance with all of the normal EMC emissions/immunity test standards, both for the application and its EM environment(s) is still required. The EMC industry has great experience with doing exactly this, and the only new thing required by EM Resilience is that this compliance should be maintained throughout the ESL, and not simply achieved when the device, equipment or system is brand-new. This will not require designers or EMC experts to learn much more.

Using the IET's 2013 Guidance for Medical Devices, Equipment and Systems

The IET's 2013 guidance provides no guidance regarding how to choose which T&Ms to apply, but its abbreviated version published in Annex B of IEC 61000-1-2:2016 [11] does provide this.

So, Annex B of [11] can be used to comply with the requirements to risk manage electromagnetic disturbances for medical devices, equipment, and systems that are in IEC 60601-1-2 Ed.3:2007 and Ed.4:2014 ([4] and [5] respectively), with [10] providing additional details if required.

By the time you read this article, the IET will have published a Code of Practice on EM Resilience [12]. This is a paid-for publication, which updates and improves on [10], and also includes complete guidance on choosing which T&Ms to apply depending on the acceptable level of safety risk. The IEEE should also have published its new standard 1848 [13], which develops [12] into a full standard.

One difficulty is that [10] [11] [12] and [13] all use IEC 61508 terminology, the worldwide language of functional safety engineering used by every industry except medical. However, I don't believe this will present much of a problem once we translate IEC 61508's SILs (safety integrity levels) into ISO 14971's risk-graph approach. As a starting point, we might assume that SIL1 = Risk Level 1, SIL2 = Risk Level 2, SIL3 = Risk Level 3, and ignore SIL4 because it doesn't have any application in the medical industry.

Another difficulty, perhaps the larger one, is that most of the regulatory medical assessors worldwide do not appear to be at all familiar with the "well-proven T&Ms" approach used throughout the rest of the functional safety world. So, they will probably not be comfortable when manufacturers apply this practical approach in the context of ISO 14971 compliance.

However, most of the international safety assessment companies (UL, SGS, Intertek, the various TUVs, etc.) have departments dedicated to functional safety risk assessments, and regulatory medical assessors could sub-contract these experts to assess the EMI contents of a Medical Risk Management File based on [10] or [12].

The normative EMI risk management requirements in IEC 60601-1-2 Ed.4:2014 are in Clauses 4.1, 8.1, 8.9 and its tables 4 through 8, and 8.10. Clause 4.1 is simply a general requirement to apply ISO 14971-style risk management to EMI. Clauses 8.1, 8.9, and 8.10 require the assessment of the future electromagnetic environment(s), so that the immunity test methods and their levels are relevant. They also assess whether the medical equipment has any special electromagnetic susceptibilities, so that immunity tests can use the relevant modulations. Clause 8.9's risk management requirements also try to foresee the degradations in electromagnetic performance over the ESL, from faults, aging, wear, corrosion, etc. so that the risks that electromagnetic disturbances might cause EMI that causes a safety hazard can be kept low-enough by suitable design, testing, and maintenance.

Unfortunately, we now know that in most cases we can't do any of the above well-enough to, on their own, ensure

low-enough risks over the entire ESL. But by adopting the IET's EM Resilience approach we can comply with the requirements to risk-manage EMI risks to be low-enough, by:

- Assessing the existing and future electromagnetic environment, including the close proximity of mobile transmitters, etc., as best as we can, then testing accordingly to ensure no electromagnetic disturbances cause EMI in the medical device, equipment, or system most of the time throughout its ESL
- Using hardware, software, and system T&Ms to detect any/all occurrence of EMI in the medical device, equipment, or system, whatever its cause; and take appropriate actions to ensure that safety risks remain low-enough, thereby complying with the overall risk management requirements in Clause 4.1

Appropriate actions include, for example: switching the medical device, equipment, or system into one of its safe states; or correcting the effects of the EMI (e.g. by using diverse error-correcting T&Ms) so that its operation may continue with low-enough risks.

The remaining normative risk-management requirements (in Clauses 4.2, 4.3.1, 8.5, 8.7, and Table 3 of Ed.4:2014) have nothing specifically to do with EMI.

Conclusion

Risk management of EMI is now required by IEC 60601-1-2 Ed.3:2007, and by its Ed.4:2014. It can only be done by the manufacturer, not by an EMC test lab, and in this brief article I have outlined the practical guidance that exists and how to use it.

References

[1] "Why Do We Need an IEEE EMC Standard on Managing Risks?", Keith Armstrong, 2016 IEEE Electromagnetic Compatibility Magazine – Volume 5 – Quarter 1, pages 80-84, http://ieeexplore.ieee.org/stamp/stamp.jsp?arnumber=7477140.

[2] "Functional Safety of Electrical/Electronic/programmable Electronics Safety-Related Systems", IEC 61508 Parts 1-7, https://webstore.iec.ch.

[3] "Medical devices – Application of risk management to medical devices" ISO 14971, www.iso.org/iso/home/store.htm.

[4] "Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests", IEC 60601-1-2 Edition 3:2007, https://webstore.iec.ch.

[5] "Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests", IEC 60601-1-2 Edition 4:2014, https://webstore.iec.ch.

[6] "Why few (if any) medical devices comply with their EMC standard, and what can be done about it", Keith Armstrong, 2014 IEEE International EMC Symposium, Raleigh, NC, Aug 3-8, 2014, ISBN (CD-ROM): 978-1-4799-5543-5, available from www.ieeexplore.ieee.org.

[7] "IET 2008 Guide on EMC for Functional Safety", the IET, 2008.

[8] "Electromagnetic compatibility (EMC) – Part 1-2: General – Methodology for the achievement of functional safety of electrical and electronic systems including equipment with regard to electromagnetic phenomena", IEC TS 61000-1-2 Edition 2:2008, https://webstore.iec.ch.

[9] European Union Medical Device Directive Notified Bodies. A list is available from http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.main.

[10] "Overview of techniques and measures related to EMC for Functional Safety", The IET, London UK, August 2013.

[11] "Electromagnetic Compatibility (EMC) – Part 1-2: General – Methodology for the achievement of functional safety of electrical and electronic systems including equipment with regard to electromagnetic phenomena", IEC 61000-1-2 Edition 1:2016, https://webstore.iec.ch.

[12] "Code of Practice for Electromagnetic Resilience, supporting the functional safety of safety-related systems", The IET, London, UK, 2017, https://shop.theiet.org/code-of-practice-for-electromagnetic-resilience.

[13] IEEE Std 1848:2020, 'Techniques and Measures for Managing Functional Safety and Other Risks Due to Electromagnetic Disturbances', https://standards.ieee.org/standard/1848-2020.html

OVERVIEW OF IEC TR 60601-4-2: 2016

Darryl P. Ray
Darryl Ray EMC Consulting, LLC
Darryl.ray@Dray-emc.com

Introduction

IEC TR 60601-4-2 provides guidance on assessing the immunity performance of medical electrical systems and equipment. It is intended to be used in conjunction with IEC 60601-1-2. IEC 60601-1-2 limits it scope to safely related performance degradation (Essential performance and basic safety as defined in IEC 60601-1). IEC TR 60601-4-2 differs significantly from IEC 60601-1-2 in that it is not a safety related standard. A device may be susceptible but still may be safe. But a device claimed to be safe may not be effective. For example, if a device shuts off as a result of ESD discharges, it is usually considered to be safe. It would be difficult to argue however that the device is effective.

OVERVIEW OF IEC TR 60601-4-2: 2016

Introduction
For IEC TR 60601-4-2 the compliance is based on maintaining performance as per the manufactures specifications. Though the immunity levels are generally lower in IEC TR 60601-4-2, the acceptance criteria may be much more stringent as many non-safety related susceptibilities may impact the performance of the device.

Although IEC TR 60601-4-2 is a technical report and not explicitly referred to as a standard, it may be required by regulators in order to access the efficacy of a medical device submitted for regulatory approval. The FDA has recently included this document in their list of recognized standards. The document can also serve as internal guidance for immunity performance beyond simply accessing a product for its safety performance while exposed to the various EM environments specified in the standards. There is no plan in Europe to create an EN equivalent of IEC TR 60601-4-2. There are no emission requirements in this document. Emission requirements however are addressed in IEC 60601-1-2.

Examples of immunity performance that are not necessarily defined as basic safety or essential performance but that might be part of the device intended use and therefore performance include the following:

- the ability to print an ultrasound image remotely
- the ability of a scale to accurately measure patient weight
- accuracy of x-ray tube voltage in X-ray equipment, e.g. the error is less than 5%.

IEC 60601-1-2:2014 specifies the immunity test levels for basic safety and essential performance based on reasonably foreseeable maximum levels of EM disturbances. For IEC TR 60601-4-2:2016, immunity test levels for performance are based on typical levels of EM disturbances.

Performance Criteria
The performance criteria specified in IEC TR 60601-4-2:2016 is significantly different than the safety based criteria defined in IEC 60601-2:2014.

The following performance criteria are defined:

1. The medical equipment should continue to meet the performance criteria after the required tests. Operator intervention is not allowed.
2. The medical equipment should continue to meet the performance criteria after the required tests. The manufacturer should specify in the instructions for use the maximum recovery time. Operator intervention is not allowed.
3. The medical equipment should continue to meet the performance criteria after the required tests. Operator intervention is allowed.

Summary of Changes Between IEC TR 60601-4-2:2016 and IEC 60601-1-2:2014

- The Pass/Fail criteria is based on “performance”
- Essential performance and basic safety is not relevant in IEC TR 60601-4-2
- ESD test procedure on connectors is modified
- The ESD warning symbol Is allowed
- Concurrent testing with safety testing of IEC 60601-1-2 is possible if:
  - Same test setup is used
  - Same modes of operation are used
    Note: ESD testing methods on connector shells and pins may be different

Table 1: Performance criteria listed by the required EMC tests

Test	Performance Criteria
ESD	B
Radiated Immunity	A
EFT/Burst	B
Surge	B
Conducted Immunity	A
Magnetic Immunity	A
Voltage Dips	B/C
Voltage Inturrupts	C
Vehicle Power Supply Transients	B
Close Field Proximity	A
Surge – 12VDC Powered	B

Comparison between IEC 60601-1-2:2014 and IEC 60601-4-2:2016.
Tables 2 through *6* provided a detailed comparison of the various requirements of the two documents.

As mentioned above, a medical device can show severe susceptibility during EMC testing but if the device remains safe, that is considered a passing condition per IEC 60601-1-2:2014. That’s not the case per the criteria listed in IEC TR 60601-4-2:2016. Refer to *Table 2* below for several examples.

Table 2: Comparison of Susceptibility Test Results

EUT Response	IEC 60601-1-2 4th Edition*	IEC TR 60601-4-2 1st Edition**
Shuts Off / Latch Up	Pass	Fail
False Alarms	Pass	Fail
Performance Anomalies	Depends on the Essential Performance	Fail

*Assumes essential performance is maintained
**Assumes performance degradation beyond manufactures specifications

Table 3: RF Proximity Test Level Comparison		
Test Frequency (MHz)	Test Level (Volts/meter)	
	IEC TR 60601-4-2:2016	IEC 60601-1-2:2014
385	6	27
450	9	28
710, 745, 780	3	9
810, 870, 930	9	28
1720, 1845, 1970	9	28
2450	9	28
5240, 5500, 5785	6	9

Table 4: Steady State Immunity Test Level Comparison			
Phenomenon	IEC TR 60601-4-2:2016	IEC 60601-1-2: 2014	
		Professional Healthcare Environment	Home Healthcare Environment
Magnetic Immunity (50/60 Hz)	3 A/M Criteria B	30 A/M	
Conducted Immunity	3 V (0.15 - 80 MHz) Criteria A	3 V (0.15 - 80 MHz) 6 V (ISM Bands)	3 V (0.15 - 80 MHz) 6 V (ISM + Amateur)
Radiated Immunity	3 V/m 80 MHz – 2.7 GHz 80%AM @ 1 kHz Criteria A	3 V/m 80 MHz – 2.7 GHz 80%AM @ 1 kHz	10 V/m 80 MHz – 2.7 GHz 80%AM @ 1 kHz

Table 5: Comparison of Transient Immunity Test Levels			
Phenomenon	IEC TR 60601-4-2:2014	IEC 60601-1-2: 2016	
		Professional Healthcare Environment	Home Healthcare Environment
ESD	6 kV Air Discharge (max.) 4 kV Contact Discharge Criteria B	15 kV Air Discharge (max.) 8 kV Contact Discharge	
EFT/Burst	1 kV - AC Mains 500V - I/O Ports 5 kHz or 100 kHz PRR Criteria B	2 kV AC Mains 1 kV I/O Ports 100 kHz PRR	
Surges (AC Mains)	2 kV Criteria B	2 kV (max.)	
Voltage Dips & Inturrupts	• UT = 0%, 0.5 cycle (0 & 180°) • UT = 0 %; 1 cycle UT = 70%; 25/30 cycles @ 0 degrees • UT = 0%; 250/300 cycle • Criteria B/C	• UT = 0%, 0.5 cycle, every 45° • UT = 0 %; 1 cycle UT = 70%; 25/30 cycles @ 0 degrees • UT = 0%; 250/300 cycle	

ESD Testing on Connectors

When performing ESD testing on connectors, there are numerous factors to take into consideration. Note, the test requirements as outlined below differ from those defined in IEC 60601-1-2:2014. In some cases, ESD testing on connector pins is required. Refer to *Table 6* below to determine the applicable test conditions.

Table 6: ESD test matrix based on the connector shell and cover material			
Connector Shell material	Connector Cover Material	Perform Air Discharge Testing to:	Perform Contact Discharge Testing to:
Conductive	None	N/A	Shell
Conductive	Non-conductive	Cover	Shell if accessible
Conductive	Conductive	N/A	Shell and cover
Non-conductive	None	Shell and pins	N/A
Non-conductive	Non-conductive	Cover	N/A
Non-conductive	Conductive	N/A	Cover

Summary

IEC 60601-1-2:2014 defines the EMC testing requirements pertaining to safety of medical devices. It does not address the device effectiveness (or performance) while exposed to various electromagnetic environments. IEC TR 60601-4-2:2016 is intended to address the medical device full performance when subjected to electromagnetic disturbances.

The two documents are similar but quite different with respect to the acceptance criteria. Compliance to IEC TR 60601-4-2:2016 may prove to be more challenging than meeting IEC 60601-1-2 as the device performance may be easily degraded from electromagnetic disturbances but still remains safe.

With careful planning many devices may be able to perform one set of tests to demonstrate compliance to both document. ESD testing on connectors may require separate testing however.

THE DICHOTOMY OF RED AND THE MDD FOR WIRELESS MEDICAL DEVICES

Steve Hayes
General Manager, ESQ – Element Materials Technology

Executive Summary
A medical device is one of the most heavily regulated product types available on the market today and rightly so–any type of product failure can result in a patient not seeing the therapeutic benefit of the device through to a fatality in the worst extreme. When the medical device is merged with a wireless functionality, the regulatory framework becomes even more complex and is subject to a greater depth of knowledge in the regulatory aspects to ensure that the overall product is safe, fit for purpose, and is compliant with the various regulations. Many medical device manufacturers rightly focus on the clinical aspects of their product and don't always understand the impact of adding a wireless functionality and what that does for the overall compliance of the product. This paper seeks to highlight the issues and provide guidance of what to do.

THE DICHOTOMY OF RED AND THE MDD FOR WIRELESS MEDICAL DEVICES

EMC for Non-Radio Medical Devices

Firstly it is important to understand that in the medical world, the term 'EMC' is not sufficient enough to categorise the assessment of electromagnetic disturbances as required by the various regulations throughout the world. For medical products, it is the basic safety that the product provides as well as the essential performance that need to be assessed to ensure that the product delivers the expected benefits and protection that it is designed to provide. The requirements can be considered as being similar to functional safety for the assessment of the EM disturbances in other areas of industry.

EM testing is not, and cannot be, the sole responsibility of the EMC test engineer or community to define the EM requirements for a medical device, since the clinical evaluation and risk management are essential to achieving both electromagnetic compatibility and electromagnetic safety. The actual EM testing is a relatively small part of medical device approval and takes into account the environment as well as EM risk identification, analysis, and controls to mitigate the threats posed by other electrical equipment.

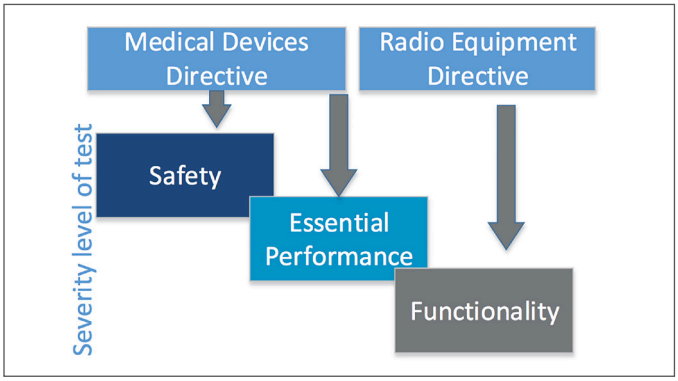
As any medical device manufacturer will be aware the IEC updated the medical EMC standard, IEC 60601-1-2 in 2014 and now stands at Edition 4. There is a fundamental difference between the current and early versions of the standard in so far that it is now a safety standard (as opposed to EMC). However on the face of it, an EMC engineer may review the standard and conclude that many of the same tests are included in both versions and hence the differences are minor.

This summary however would be to overlook the whole emphasis from a standard based on functionality to one based on safety. IEC has issued a new document IEC TR 60601-4-2:2016, which defines the medical device performance requirements while exposed to electromagnetic disturbance.

The performance when exposed to electromagnetic phenomena is what a most traditional EMC experts understand as EMC whilst the EM safety is clearly an aim to focus on the safety aspects of the product.

Approval of Medical Devices with Wireless Functionality

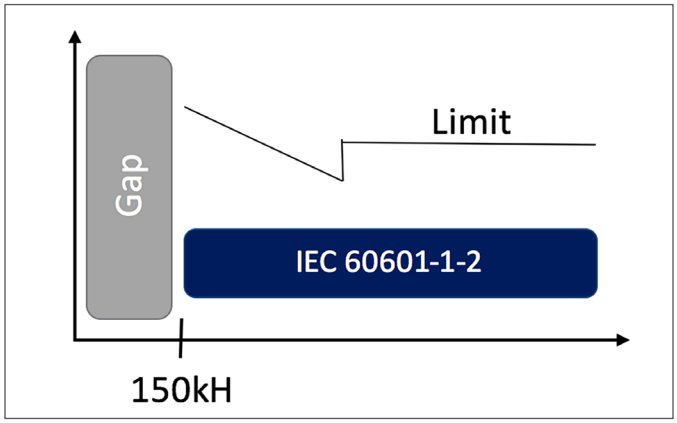
The new Radio Equipment Directive (RED) in Europe mandates that any product which is or integrates a wireless functionality becomes a radio equipment. This includes medical devices. In the case of medical devices both the Medical Devices Directive (MDD) and the Radio Equipment Directive (2014/53/EU) become mandatory requirements in the CE Marking process (there may be additional CE Marking directives applicable, for example the Restriction of Hazardous Substances–RoHS). Both of these directives require the EM disturbances to be measured and an assessment of the product's EM performance made. The difference between the two directives, however, is that the MDD focuses on the safety and essential performance, whilst the RED focuses only on the performance (functionality).



It is important to understand the range of assessments required for each of the criteria defined above as this will yield a different set of modes of operation and acceptable assessment criteria when performing the tests.

The assessment of the immunity for the RED will focus on maintaining a radio link, ensuring that the transmitter does not operate when not requested and any relevant functional aspects of the product. By contrast, the MDD requires that an assessment of both the essential performance and basic safety are undertaken. This can however only be performed after the manufacturer has completed their risk analysis and included this in their risk management file (as per ISO 14971) since this process may identify additional test and assessment requirements not included within the standard. A point of note however; given that some medical products provide functional safety, it does not necessarily mean that simply increasing the immunity level will provide the assurance that is desired. This is where the risk assessment of all the hazards and management of these aspects in both the design, manufacture, and through life assessment form an integral part. The risks are mitigated through these actions, which complement the tests.

As an example, imagine a 125 kHz RFID system used in a hospital for patient or asset tracking. There is a network of transceivers used throughout the hospital installed in a variety of locations and are not considered as medical devices. However an ECG machine is a medical device and without knowledge of the clinical EM environment, a manufacturer of an ECG machine may simply test to the IEC 60601-1-2 standard not realizing that RFID systems are in use. There are no mandatory test requirements below 150 kHz in most of the traditional EMC standards and hence no assessment on the basic safety or essential performance of the ECG machine, leaving it to luck that it continues to provide the functions that it was designed for.



Integrating a Wireless Function Into a Medical Device
Many manufacturers of an existing medical devices are now integrating a wireless functionality into their product to provide remote monitoring, elimination of wires, or a human/machine to machine interface.

The impact of doing this from a regulatory perspective, however, is quite profound and one that the medical industry isn't fully aware of. In addition to the Medical Device approval (based on clinical performance) an additional set of regulatory requirements is now applicable–the Radio Equipment Directive in Europe is perhaps the most onerous and explained below of what changes when a radio product is integrated into the medical device.

There are essentially two ways of providing a wireless function to a product:

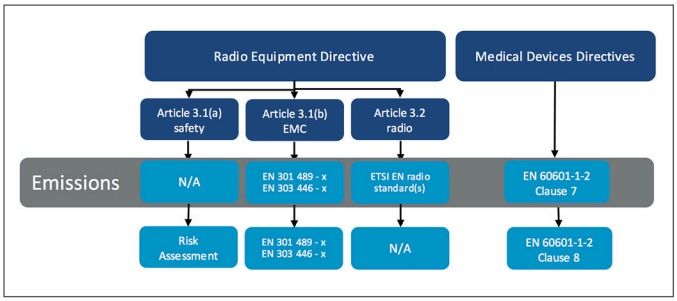
1. Use an off the shelf radio module
2. Integrate a radio chipset into the product

There are benefits of either of the above however the decision of which to use will be largely decided based on manufacturing volume, knowledge of RF design, and the current state of design of product.

If a radio module is selected it may be purchased as 'approved'. This however will be a limited approval since the module manufacturer will very rarely know the intended EM environment for the end product or how the module will be used. However, the approved radio module will have the advantage that the radio parameters will largely be taken care of, saving the integrator this expense. Most radio modules are designed to meet the requirements for household, commercial, or light industrial environments–the medical environment is often very different and can lead to significant delays in getting to market if not considered early in the design process since the module may simply not be designed for the environment in which it will be used.

A radio chipset will be cheaper to purchase but requires the integrator to know how to design for RF and will require all the radio characteristics to be assessed against the regulations in addition to EMC and safety.

If multiple radio devices are used in the same product, additional radio characteristic assessments are required in the form of intermodulation and radiated spurious emissions.



As the above table illustrates, the requirements in the directives overlap in certain areas and will also require the medical device manufacturer to perform additional assessments when multiple radios are used in the same equipment (co-located). It is tempting and/easy to overlook the RED requirements if purely focused on the medical device directive requirements and yet this will be a critical aspect to ensure that the product fulfils the objectives of both directives.

Not only does the manufacturer need to understand these requirements but all the stakeholders in the regulatory process as well. New requirements are imposed on medical device Notified Bodies to ensure that they have the expertise to assess the technology of the product that they are assessing or at least have access to it. It should be made clear that any approval that has involved a Notified Body for one directive does not exclude it from other relevant directives.

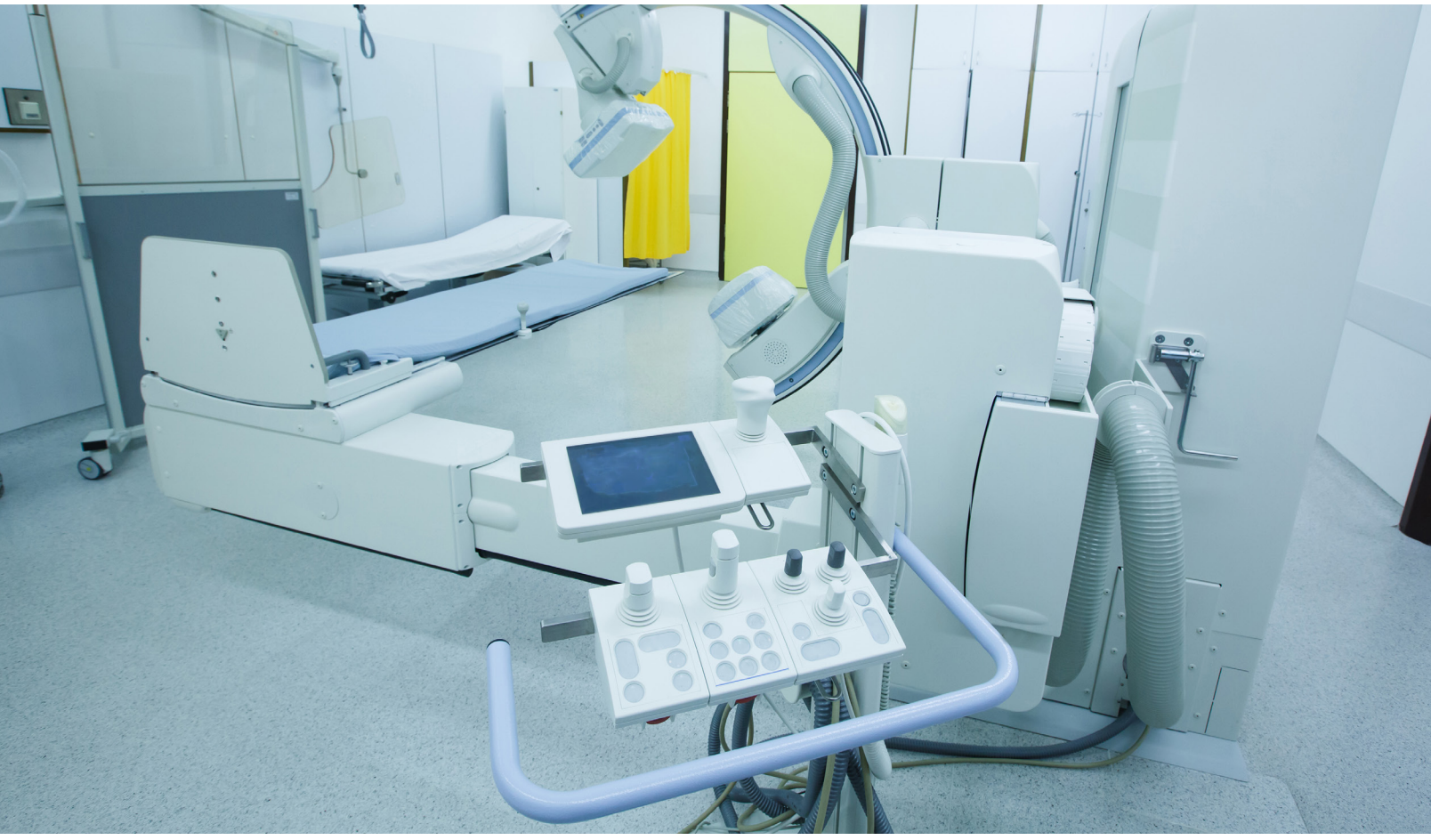
The regulatory framework for radio products is rapidly changing, not least as a result of the new Radio Equipment Directive. Manufacturers of medical equipment are advised to regularly review the requirements for the radio (including EMC and radio performance aspects) as well as the MDD to ensure that the 'approved' product continues to comply with the requirements of these directives.

SOME OF THE MANY STORIES OF MEDICAL EMI

Keith Armstrong
Cherry Clough Consultants Ltd, Stafford, ST17 0TF, UK
www.cherryclough.com

Introduction

I have been collecting stories about EMI for a long time, publishing many of them in the 'Banana Skins' column of The EMC Journal, www.theemcjournal.com. Some come from official reports, some from anonymous whistleblowers, some are amusing, and some concern deaths and injuries. At the present time, I have published 855 of them, all indexed by application and by type of EMI, all downloadable from www.emcstandards.co.uk where I will soon start posting some more. I recently collected together all the stories of medical EMI, and got 41 pages' worth–here are a few of them, with their original numbering preserved.



SOME OF THE MANY STORIES OF MEDICAL EMI

3) RF Interference in Ambulance Causes Death
Medical technicians taking a heart attack victim to the hospital in 1992 attached her to a monitor/defibrillator. Unfortunately, the heart machine shut down every time the technicians turned on their radio transmitter to ask for advice, and as a result the woman died. Analysis showed that the monitor unit had been exposed to exceptionally high fields because the ambulance roof had been changed from metal to fiberglass and fitted with a long-range radio antenna. The reduced shielding from the vehicle combined with the strong radiated signal proved to be too much for the equipment.

(An article in the Wall Street Journal reported in Compliance Engineering Magazine's European edition September/October 1994.)

16) More Medical Incidents:
The magnetic field caused by ground currents in a water pipe system made it impossible to use sensitive electronic instruments in part of a hospital.

A patient-coupled infusion pump was damaged by an electrostatic discharge, but thankfully the alarm system was not affected and a nurse was alerted.

An operation using a plastic welding machine caused interference with a patient monitoring and control system, causing failure to detect that the circulation had stopped in a patient's arm, which later had to be amputated.

(Taken from Compliance Engineering European Edition March/April 1998.)

20) Licensed TV Transmissions Interfere With Intensive Care, Kills Babies
While taking classes in the early 80's, my professor got involved with a terrible incident down in New Jersey. Seems a hospital had a high incidence of infant deaths in the intensive care section of the maternity ward. Late at night, the alarms on the babies' monitors would go off for no apparent reason. Annoyed, the nurses would turn them off and do the rounds on foot.

After some preliminary investigations, my professor found out that a nearby TV transmitter was allowed by their FCC license to increase their output wattage by some enormous amount after say midnight, but had to reduce it prior to 6am, or some such arrangement. The cable interconnecting the nurse's station to the various baby monitors sang like a lark with these frequencies and set off alarms with the induced voltages.

Not sure now of all the specifics except what I have related above, nor the name of the hospital, but they lost something like six kids before fixing it.

(From Doug Mckean, via emc-pstc@ieee.org, 29th July 1998)

38) Cell Phones Can Interfere With Pacemakers
The Therapeutic Goods Administration of Australia (TGA) continues to review findings of clinical and laboratory research indicating a potential for temporary interaction or interference between mobile phones and the operation of pacemakers and implantable defibrillators. The findings have indicated that interference may be caused by holding the phone within about 150 mm of the implanted device, or in direct contact between the phone antenna and the user's skin. Interference can occur with the phone in standby mode, as well as in use. Some phones incorporate magnets, at least in their loudspeakers, and while held close to the implanted device these can cause them to go into their "magnet" mode, which for a pacemaker is a fixed pace.

Based on the most recent testing, simply moving the phone away from the implanted devices will return it to its correct state of operation. Recommendations for users of implanted pacemakers or defibrillators include: not keeping the phone in a pocket over the site of an implant; using the ear that is furthest away from the site of the implant when using the phone; and not allowing the phone antenna to touch any part of the body.

(From Compliance Engineering's European edition Jan/Feb 1998.)

55) New Kidney Dialysis Machines Very Susceptible to Power Quality Issues
Power quality is especially critical in hospitals, where life-sustaining processes demand clean reliable electrical supplies. This was recently highlighted at Glan Clwyd Hospital in North Wales where a problem became apparent on the renal dialysis unit during the testing of emergency generators. The switch from mains power to generator power was causing the newer, computer-controlled dialysis machines to close down and generate an alarm. This caused distress to patients and problems for staff who needed to reset several machines quickly before their blood began to coagulate.

Resets were generally successful, though occasionally a unit would not respond so a patient would need to be moved onto a spare machine. The problem was solved with uninterruptible power supplies to provide continuity of operation at the hospital during generator testing. Ten 2.5 kVA UPSs are now used in the dialysis unit and one on a treadmill in the cardiovascular unit to safeguard patients from injury should power failure cause the treadmill to stop suddenly.

(Extracted from page 121 of IEE Review, May 1999,

www.theiet.org. Take care: not all UPSs appear to be as reliable as we might wish!)

72) Trams Fitted With Inverter Drives Interfere With Hospital Equipment Along Their Route
The Helsinki City Transport (HKL) rolling stock is ageing fast. In each tram there were six ventilation fans with DC motors cooling the passenger compartment, brake resistor, and traction motor. The thinking was that one big inverter supplying six AC motors was going to be cheaper than several smaller inverters supplying one motor each, so a 15 kW unit was mounted in the main electrical panel of one of the trams. The existing cabling was retained because of cost considerations and this connected the various motors in parallel. EMC problems very quickly surfaced. Not only was the vehicle's own radio system badly affected, but crucially–third party electrical equipment also suffered interference, including that of a hospital on the tram's route. The problem was solved in the end by siting individual inverters close to the motors they controlled.

(From an article by Les Hunt in dpa Magazine, March 99, Drives Supplement page 29, www.dpaonthenet.net.)

80) Anti-Theft Devices Interfere With Pacemakers
Retail shops use anti-pilferage devices (the hoops that are to either side of their doors), which operate in the USA between 510-1,705 kHz. The goods to be protected have a small label stuck on them that resonates at the appropriate frequency and disturbs the field produced by the hoops, allowing detection. It was found that heart pacemakers were susceptible to the anti-pilferage fields, so pacemaker manufacturers had to improve their designs to make them less susceptible.

(From comments by Art Wall (Associate Chief of the Policy and Rules Division of the USA's Federal Communications Commission) during an EMCTLA seminar on FCC requirements on the 18th May 2000, www.emctla.co.uk.)

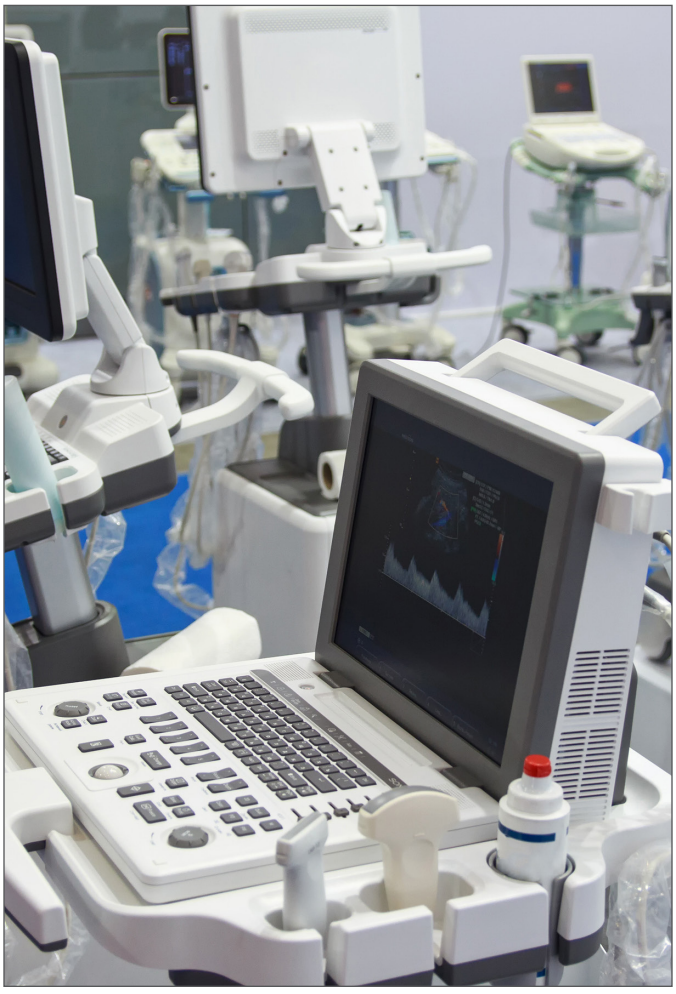
577) RFID Interferes With Critical-Care Medical Equipment
In 123 EMI tests (three per medical device), RFID induced 34 EMI incidents: 22 were classified as hazardous, two as significant, and 10 as light. The passive 868-MHz RFID signal induced a higher number of incidents (26 incidents in 41 EMI tests) 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.

(From: "Electromagnetic Interference from Radio Frequency Identification Inducing Potentially Hazardous Incidents in Critical Care Medical Equipment", van der Togt, R., E. J. van Lieshout, et al, JAMA 299(24): 2884-90, 2008, Jeff Silberberg (US FDA) to the 20th Annual AAMI/FDA International Conference on Medical Device Standards and Regulation, March 9, 2010.)

578) EMC of Pacemakers and ICDs Exposed to RFID Readers 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%).

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 eight of the 76 possible tests (11%).

(From: "Electromagnetic Compatibility of Pacemakers and Implantable Cardiac Defibrillators Exposed to RFID Readers", Seidman S, Ruggera P, Brockman R, Lewis B, Shein M., International Journal of Radio Frequency Identification Technology and Applications, Vol. 1, No. 3, 2007:237-246, , Jeff Silberberg (US FDA) to the 20th Annual AAMI/FDA International Conference on Medical Device Standards and Regulation, March 9, 2010.)



MEDICAL ELECTRICAL EQUIPMENT AND SYSTEMS STANDARDS

Darryl P. Ray
Darryl Ray EMC Consulting, LLC
Darryl.ray@Dray-emc.com

Tables 1 and 2 below list the collateral (vertical) and particular (product specific) standards within the IEC/ISO 60601 family[1]. Requirements in the particular standards take precedence over those in the General Safety standard (IEC 60601-1) or the Collateral standards (IEC 60601-1-X). Table 3 lists several other relevant standards. Refer to the standard for the exact title.

Table 1: Collateral Standards	
Document	Description
IEC 60601-1-1	Medical electrical systems
IEC 60601-1-2	Electromagnetic disturbances - requirements and tests
IEC 60601-1-3	Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6	Usability
IEC 60601-1-8	Alarm systems
IEC 60601-1-9	Requirements for environmentally conscious design
IEC 60601-1-10	Physiologic closed-loop controllers
IEC 60601-1-11	Medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 60601-1-12	Medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

Table 2: Particular Standards	
Document	Description
IEC 60601-2-1	Electron accelerators in the range 1 MeV to 50 MeV
IEC 60601-2-2	High frequency surgical equipment and high frequency surgical accessories
IEC 60601-2-3	Short-wave therapy equipment
IEC 60601-2-4	Cardiac defibrillators
IEC 60601-2-5	Ultrasonic physiotherapy equipment
IEC 60601-2-6	Microwave therapy equipment
IEC 60601-2-7	High-voltage generators of diagnostic X-ray generators
IEC 60601-2-8	(replaced by IEC 60601-2-63 and IEC 60601-2-65)
IEC 60601-2-9	Therapeutic X-ray equipment operating in the range 10 kV to 1 MV
IEC 60601-2-10	Patient contact dosemeters used in radiotherapy
IEC 60601-2-11	Nerve and muscle stimulators
ISO 80601-2-12	Gamma beam therapy equipment
ISO 80601-2-13	Critical care ventilators
IEC 60601-2-14	Anaesthetic workstations

Table 2: Particular Standards (continued)	
Document	Description
IEC 60601-2-15	Capacitor discharge X-ray generators (withdrawn)
IEC 60601-2-16	Haemodialysis, haemodiafiltration and haemofiltration equipment
IEC 60601-2-17	Automatically-controlled brachytherapy afterloading equipment
IEC 60601-2-18	Endoscopic equipment
IEC 60601-2-19	Infant incubators
IEC 60601-2-20	Infant transport incubators
IEC 60601-2-21	Infant radiant warmers
IEC 60601-2-22	Surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60601-2-23	Transcutaneous partial pressure monitoring equipment
IEC 60601-2-24	Infusion pumps and controllers
IEC 60601-2-25	Electrocardiographs
IEC 60601-2-26	Electroencephalographs
IEC 60601-2-27	Electrocardiographic monitoring equipment
IEC 60601-2-28	X-ray tube assemblies for medical diagnosis
IEC 60601-2-29	Radiotherapy simulators
IEC 80601-2-30	Automated non-invasive sphygmomanometers
IEC 60601-2-31	External cardiac pacemakers with internal power source
IEC 60601-2-32	Associated equipment of X-ray equipment (withdrawn)
IEC 60601-2-33	Magnetic resonance equipment for medical diagnosis
IEC 60601-2-34	Invasive blood pressure monitoring equipment
IEC 80601-2-35	Heating devices using blankets, pads or mattresses
IEC 60601-2-36	Equipment for extracorporeally induced lithotripsy
IEC 60601-2-37	Ultrasonic medical diagnostic and monitoring equipment
IEC 60601-2-38	Electrically operated hospital beds
IEC 60601-2-39	Eritoneal dialysis equipment (withdrawn)
IEC 60601-2-40	Electromyographs and evoked response equipment

MEDICAL ELECTRICAL EQUIPMENT AND SYSTEMS STANDARDS
CONTINUED

Table 2: Particular Standards (continued)	
Document	Description
IEC 60601-2-41	Surgical luminaires and luminaires for diagnosis
IEC 60601-2-42	N/A
IEC 60601-2-43	X-ray equipment for interventional procedures
IEC 60601-2-44	X-ray equipment for computed tomography
IEC 60601-2-45	Mammographic X-ray equipment and mammographic stereotactic devices
IEC 60601-2-46	Operating tables
IEC 60601-2-47	Ambulatory electrocardiographic systems
IEC 60601-2-48	N/A
IEC 60601-2-49	Multifunction patient monitoring equipment
IEC 60601-2-50	Infant phototherapy equipment
IEC 60601-2-51	Recording and analysing single channel and multichannel electrocardiographs (withdrawn)
IEC 60601-2-52	Medical beds
IEC 60601-2-53	N/A
IEC 60601-2-54	X-ray equipment for radiography and radioscopy
ISO 80601-2-55	Respiratory gas monitors
ISO 80601-2-56	Clinical thermometers for body temperature measurement
IEC 60601-2-57	Non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
IEC 80601-2-58	Lens removal devices and vitrectomy devices for ophthalmic surgery and associated accessories
IEC 80601-2-59	Screening thermographs for human febrile temperature screening
IEC 80601-2-60	Dental equipment
ISO 80601-2-61	Pulse oximeter equipment
IEC 60601-2-62	High intensity therapeutic ultrasound (HITU) equipment
IEC 60601-2-63	Dental extra-oral X-ray equipment
IEC 60601-2-64	Light ion beam medical electrical equipment
IEC 60601-2-65	Dental intra-oral X-ray equipment
IEC 60601-2-66	Hearing instruments and hearing instrument systems
ISO 80601-2-67	Oxygen-conserving equipment
IEC 60601-2-68	X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment

Table 2: Particular Standards (continued)	
Document	Description
ISO 80601-2-69	Oxygen concentrator equipment
ISO 80601-2-70	Sleep apnoea breathing therapy equipment
IEC 80601-2-71	Functional near-infrared spectroscopy (NIRS) equipment
ISO 80601-2-72	Home healthcare environment ventilators for ventilator-dependent patients

Table 3: Other Relevant Standards	
Document	Description
CISPR 11	Emissions requirements for ISM equipment
IEC 60601-1	General Safety Standard
IEC TR 60601-4-2	Electromagnetic immunity performance
IEC TR 60601-4-3	Considerations of unaddressed safety aspects in the third edition of IEC 60601-1
ISO 14708	Active implantable medical devices
ISO 14117	EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices

[1] Some of the Part 2 standards are listed within the IEC or ISO 80601 family.

IEC 60601-1-2:2014 COMPLIANCE CHECKLISTS

Darryl P. Ray
Darryl Ray EMC Consulting, LLC
Darryl.ray@Dray-emc.com

Compliance to IEC 60601-1-2:2014 is more than simply dropping off the product to a lab and having the tests performed. Table 1 below provides an overview of the required elements of the standard. Table 2 and 3 list the risk management and labeling requirements.

Table 1: IEC 60601-1-2:2014 Checklist		
Item	**Clause**	**Remarks**
Test Plan	6.2	• The requirement to create a test plan prior to test is normative (mandatory) • The suggested contents of the test are listed in Annex G • It is vital to understand and apply the intended use environment and the essential performance criteria as part of the immunity acceptance criteria
Testing – General Conditions	4	• Clause 4 specifies general test setup conditions • Ensure the Potential Equalization Conductor Terminal (if applicable) is connected to the local ground during all EMC tests
Testing – Use of the Artificial Hand	4.3.2 7.1.9 – 11 8.2 8.4 Table 7	The use of the artificial hand is sometimes overlooked during testing. As the artificial hand impacts the coupling of RF energy, its use can significant impact the test results
Emissions Testing	7	• Make sure the AC mains Cord is bundled per CISPR 11 for both conducted and radiated emissions. Most EMC product standards require the AC mains cords be bundled for conducted emissions testing only • Check both the standby and active modes of operation
Emissions Testing on Patient Coupled Cables	Annex G	• This test is informative (not mandatory) but is recommended • See Annex G for the test setup and emissions limits
Immunity Testing	8	• Ensure the applicable clauses are met • Check both the standby and active modes of operation • Note the FDA does not accept footnote c in Table 6 pertaining to testing to cables less than 0.4m in length • For EFT testing ensure that the Pulse Repetition Rate (PRR) is set to 100kHz (not 5kHz) as used by most other EMC test standards. The 100kHz PRR may prove to be more challenging to comply with than 5 kHz • Use 1000kHz modulations for Conducted and Radiated Immunity testing
Test Report	9	The required minimum content for the test report is listed in clause 9. There are up to 37 items that may apply

Table 2: Risk Management Check List	
Clause	**Requirement**
4.1	Verify that risk management entries are present in the Risk Management File (RMF)
4.2	Non ME equipment used with Medical Electrical Systems
4.3.1	Verify test configuration
8.1	Effects observed during immunity testing shall be analyzed
8.1	Pass/Fail criteria and method of monitoring shall be listed in the RMF
8.1	Assess the EM environment and add additional EMC tests as necessary

IEC 60601-1-2:2014 COMPLIANCE CHECKLISTS
CONTINUED

Table 2: Risk Management Check List (continued)	
Clause	Requirement
8.1 & Table 8	Take into consideration current communication services
8.5	Assessment of subsystem testing
8.7	Selection of operating modes
8.8	Use of non-ME equipment
8.9	Modified immunity test levels and modulations
Table 3	Equipment that is damaged during immunity testing
Table 4	Modified Immunity levels may be used
Table 9	Consider reduced distance to mobile communication devices

Table 3: IEC 60601-1-2:2014 Labelling Requirements	
Clause	Requirement
5.1	Equipment used in a shielded location. Marking required on the outside of the equipment
5.2.1.1. a)	Statement of the suitable environments of use
5.2.1.1. b)	Magnetic resonance system warning
5.2.1.1 c)	A description of the performance of the equipment that could degrade and the possible consequences
5.2.1.1 d)	Warning of use of equipment adjacent to or stacked with other equipment
5.2.1.1 e)	List of cables, and other accessories that are likely to affect the device compliance
5.2.1.1 f)	Warning statement about use of accessories, cables, etc. other than those specified or provided by the manufacturer
5.2.1.1 g)	Warning of separation from RF communication equipment
5.2.1.2	CISPR 11 class A warning statement. Note this differs from that in CISPR 11, Edition 5.1
5.2.2.1	Description of precautions to be taken to prevent adverse events to the patient and operator due to electromagnetic disturbances
5.2.2.1 a)	Compliance information for each emissions and immunity standard or test specified
5.2.2.1.b)	Deviations from IEC 60601-1-2:2014 and any allowances used
5.2.2.1.c)	The performance equipment that was determined to be essential performance and a description of what the operator can expect if the essential performance is compromised
5.2.2.1 .d)	Instructions for maintaining basic safety and essential performance with regard to the electromagnetic disturbances
5.2.2.2. a)	Warning for equipment specified for use only in a shielded location
5.2.2.2. b)	Shielded location specifications for equipment to be used in a shielded location
5.2.2.2. c)	Recommendation for equipment specified for use only in a shielded location: test methods for measurement of RF shielding effectiveness and RF filter attenuation
5.2.2.2. d)	Specification of the emissions characteristics of other equipment allowed inside the shielded location
5.2.2.3. a)	Frequency band of reception for equipment that intentionally receives RF electromagnetic energy
5.2.2.3. b)	Warning of possible interference caused by other equipment that intentionally receives RF electromagnetic energy
5.2.2.4	Frequency or frequency band of transmission for equipment an RF transmitter
5.2.2.5. a)	A statement that an exemption has been used permanently installed large equipment
5.2.2.5. b)	A warning that testing for radiated RF immunity was done only at selected frequencies for permanently installed large equipment
5.2.2.5. c)	A list of the frequencies and modulations used for immunity testing permanently installed large equipment
5.2.2.6	Statement of hf surgical equipment compatibility and the conditions of intended use during hf surgery, if applicable

USEFUL MEDICAL EMC REFERENCES
(JOURNALS, WEBSITES, LINKEDIN, ASSOCIATIONS, & ORGANIZATIONS)

TRADE JOURNALS & WEBSITES

Medical Device and Diagnostic Industry
www.mddionline.com

QMED
www.qmed.com

U.S. National Library of Medicine
www.nlm.nih.gov

LINKEDIN

- IEC 60601-1, Third Edition
- IEC 60601-1 Edition 3.1 Compliance Help
- IEC 60601 Series - Medical Electrical Equipment
- IEC 60601-1-2 Collateral standard Electromagnetic compatibility
- IEC 62366 and 60601-1-6-Usability for Medical Devices

INDUSTRY ASSOCIATIONS

Advamed
www.advamed.org

Medical Device Manufacturers Association
www.medicaldevices.org

STANDARDS ORGANIZATIONS

- **AAMI** – www.aami.org
- **ANSI** – www.ansi.org
- **CENELEC** – www.cenelec.eu
- **ETSI** – www.etsi.org
- **IEC** – www.iec.ch
- **IEC TC62** – www.iec.ch/tc62
- **ISO** – www.iso.org

REGULATORY BODIES

Country	Agency	URL
Australia	Department of Health Therapeutic Goods Administration	tga.gov.au
Brazil	National Health Surveillance Agency (ANVISA)	portal.anvisa.gov.br
Canada	Health Canada	hc-sc.gc.ca
China	State Food and Drug Administration (SFDA)	www.sfda.com
European Union	Consumers, Health, Agriculture and Food Executive Agency (CHAFEA)	ec.europa.eu
Japan	Ministry of Health Labour and Welfare	mhlw.go.jp
Korea	Korea Food and Drug Administration (KFDA)	eng.kfda.go.kr
United States	Food and Drug Administration (FDA)	www.fda.gov

INDEX OF ADVERTISERS

Schaffner EMC Inc.
52 Mayfield Avenue
Edison NJ, 08837

t: (800) 367-5566
e: usasales@schaffner.com
w: www.schaffnerusa.com
page: 3

LECTRIX
1000 Germantown Pike,
Plymouth Meeting, PA 19462

t: (484) 688-0300
e: info@lectrixgroup.com
w: www.lectrixgroup.com
page: 5