OCTOBER 2014

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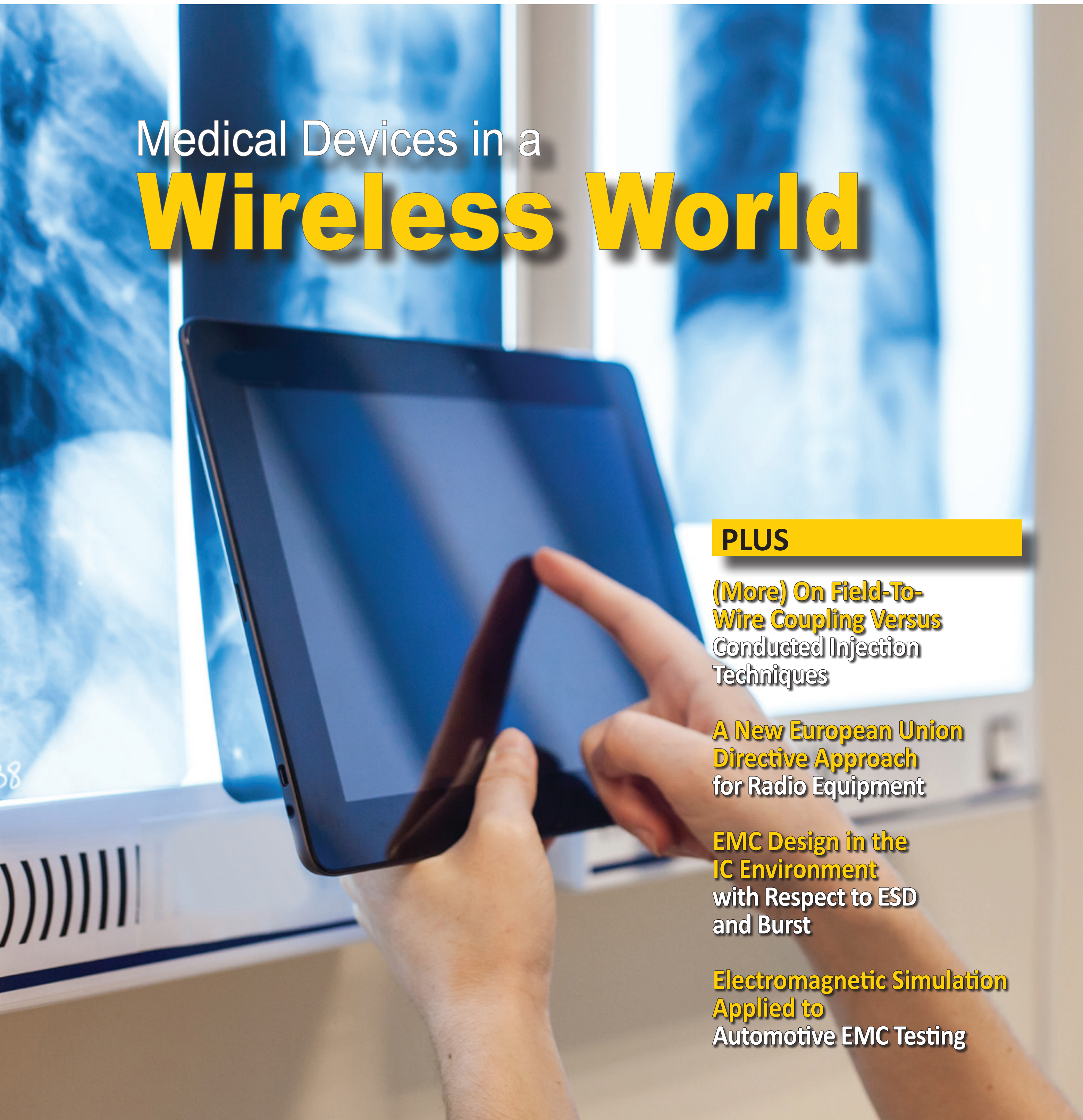

Medical Devices in a Wireless World

PLUS

(More) On Field-To-Wire Coupling Versus Conducted Injection Techniques

A New European Union Directive Approach for Radio Equipment

EMC Design in the IC Environment with Respect to ESD and Burst

Electromagnetic Simulation Applied to Automotive EMC Testing

IN COMPLIANCE

In Compliance Magazine
ISSN 1948-8254 (print)
ISSN 1948-8262 (online)
is published by

Same Page Publishing Inc.
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Littleton, MA 01460-1279
tel: (978) 486-4684
fax: (978) 486-4691

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October 2014

Volume 4 ● Number 10

DEPARTMENTS

FEATURES

News in Compliance

FCC News

$100k Fine for Oklahoma Carrier for Failure to Route 911 Calls

The U.S. Federal Communications Commission (FCC) has proposed a financial forfeiture of $100,000 against an Oklahoma local telephone exchange carrier for failing to properly route 911 emergency calls.

According to a Notice of Apparent Liability for Forfeiture issued in August 2014, Hinton Telephone Company routed 911 calls originating from Caddo County, Oklahoma to an automated AT&T operator message for several months during 2013. That message instructed callers to "hang up and dial 911" in the event of an emergency. The FCC says that the company continued to allow emergency calls to be routed to the automated message, even after discovering the problem, for a period of three months. The problem was only addressed when the company was contacted by FCC investigators.

The FCC has cited Hinton for apparent willful and repeated violations of FCC rules that required carriers to use reasonable judgment when routing emergency calls to an automated operator message.

The complete text of the Notice of Apparent Liability is available at incompliancemag.com/news/1410_1.

FCC Implements New Rules to Spread Text-to-911 Availability

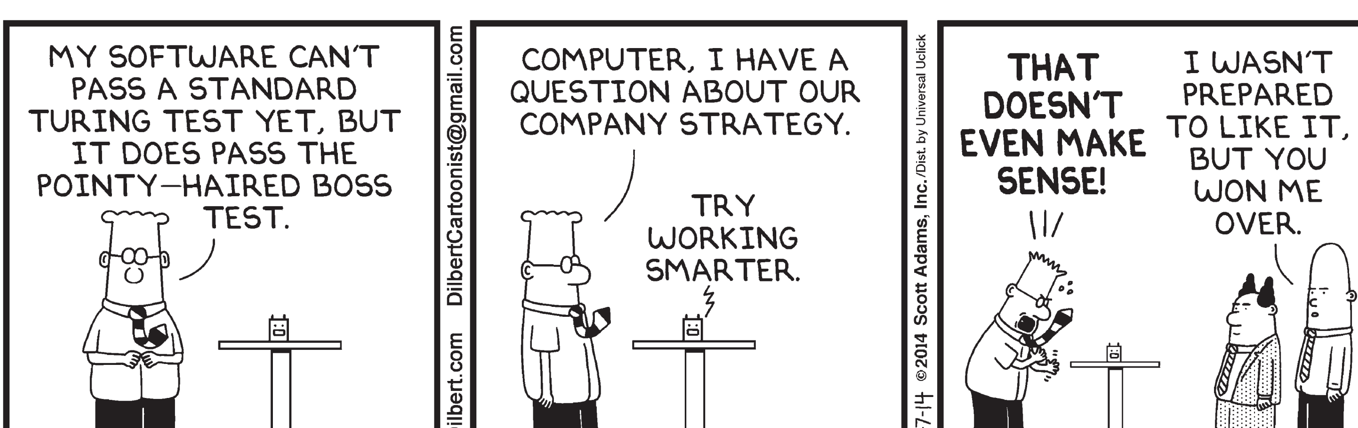
The U.S. Federal Communications Commission (FCC) has adopted new rules that will help to make text-to-911 services universally available to Americans by the end of 2014.

In a Second Report and Order and Third Further Notice of Proposed Rulemaking issued in August 2014, the Commission set a 12/31/2014 deadline for all wireless carriers and "interconnected" text messaging providers to provide text-to-911 services to their subscribers.
The nation's four largest wireless carriers already provide text-to-911 services to those call centers that are technically capable of receiving text messages.

In addition, under the new FCC rules, providers will have six months to deploy text-to-911 service in any area upon receipt of a request from a 911 call center.

According to Commission data, 91 percent of American adults own a cellphone, and 81 percent of cellphone owners use text messaging, making text-to-911 services essential for both public safety authorities and citizens. In addition, text-to-911 helps to bridge the emergency communication gap for the more than 50 million Americans with speech disabilities or who are deaf or hard of hearing.

The complete text of the FCC's latest Order regarding Text-to-911 is available at incompliancemag.com/news/1410_2.



FCC News

FCC Modifies Rules for Medical Body Area Networks

Furthering its efforts to foster the development and deployment of advance wireless medical, the U.S. Federal Communications Commission (FCC) has modified its rules for medical body area networks (MBANs).

MBANs are low-powered networks that transmit a range of patient data from multiple body-worn sensors to a control device. MBANs can be used to monitor patient vital health signs in real time, thereby providing advanced notice of potential problems. And, because they are wireless, MBANs make it easier to move patients to different areas of a healthcare facility for specialized treatment.

The FCC originally allocated 40 MHz of spectrum in the 2360-2400 MHz band for MBAN use on a secondary basis in 2012. The Commission also modified the provisions of its rules governing medical device radio communications so that users do not have to apply for individual operating licenses.

In an Order on Reconsideration and Second Report and Order issued in August 2014, the Commission has modified its rules to facilitate the coordination, deployment and use of MBAN systems, as well as to facilitate the development and implementation of technical standards applicable to MBAN devices. The Commission has also defined the process for selecting a MBAN Coordinator, who will be responsible for facilitating the use of MBAN frequencies.

Read the complete text of the FCC's latest Order regarding MBANs at incompliancemag.com/news/1410_3.

News in Compliance

European Union News

EU Commission Publishes Standards for Energy Design and Labeling of Vacuum Cleaners

The Commission of the European Union (EU) has published a list of standards that can be used to demonstrate compliance with its regulations related to the energy design and labeling of vacuum cleaners.

The list of standards, which was published in August 2014 in the *Official Journal of the European Union*, includes six new EN standards addressing various aspects of vacuum cleaner operation.

The EU Commission originally set eco-design and energy efficiency requirements for vacuum cleaners in its Regulation No 666/2013, with the requirements slated to take effect in September 2014. Energy labelling requirements for vacuum cleaners are prescribed in EU Regulation No 665/2013.

The list of newly published standards is available at incompliancemag.com/news/1410_4.

EU Commission Expands REACH Test Methods

The Commission of the European Union (EU) has authorized additional test methods that can be used to assess the properties of materials under its regulations related to the registration, evaluation, authorization and restriction of chemicals (REACH).

Published in the *Official Journal of the European Union* in August 2014, Commission Regulation No. 900/2014 authorizes the use of six new and updated alternative test methods for demonstrating compliance with various requirements of the REACH regulation. The Regulation provides extensive details on each of the new and updated alternative test methods, updating and expanding the Annex to Regulation 440/2008, which originally defined the test methods that could be used under the REACH Regulation.

The new and updated alternative test methods published in Regulation 900/2014 can be used for the termination of toxicity and other health effects, and were adopted in order to reduce the number of animals used for testing and experimental purposes.

The complete text of Commission Regulation 900/2014 is available at incompliancemag.com/news/1410_5.

FDA News

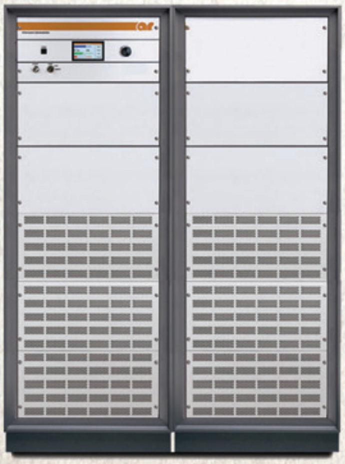
Recalled Medical Product Lacked FDA 510(k) Approval

In conjunction with the U.S. Food and Drug Administration (FDA), ConvaTec, Inc. has initiated a recall of its Flexi-Seal CONTROL-brand fecal management systems. Fecal management systems are temporary containment devices used with incontinent patients.

According to a press release issued by the FDA, the voluntary recall was initiated following a determination that the device should have received independent 510(k) clearance from the FDA, instead of a “note to file” based on an existing Flexi-Seal 510(k) clearance.

In addition, ConvaTec has reportedly received reports from U.S. healthcare facilities of 13 adverse events in connection with patients using the recalled device, including 12 serious injuries and one death, during the period from February 2013 to March 2014. Concern has focused on an auto-valve feature in the device that may not have performed consistently during normal operations.

The FDA press release regarding this medical device recall is available at incompliancemag.com/news/1410_6.



u • nique [yōō-nēk']
adjective
being the only one of its kind; unlike anything else:

[predic] (unique to) belonging or connected to (one particular person, group, place or thing)

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News in Compliance

CPSC News

Recalled Smoke Detectors Fail to Alert

Two separate operating units of the United Technologies Corporation of Hartford, CT have recalled a combined total of over 140,000 smoke detectors manufactured in China.

According to a press release issued by the U.S. Consumer Product Safety Commission (CPSC), radio frequency interference (RFI) can cause the smoke detectors to fail to alert consumers of a fire. There has been no reports of incidents or injuries related to the smoke detectors, but the company has issued the product recall to prevent the risk of future incidents.

The recall involves Edwards-branded and Interlogix branded units that have been hardwired into security systems. They were sold through alarm system, security system and electrical equipment contractors, dealers and installers for use in fire alarm systems installed in commercial buildings, hotels, apartments, dormitories and homes from March 2013 through February 2014. The estimated price of individual detectors, which were typically sold as part of complete security system installation, ranges between $30 and $50.

For more information about this recall, go to incompliancemag.com/news/1410_7.

Electric Space Heaters Recalled

Vornado Air, LLC, of Andover, KS has issued a recall for nearly 80,000 of its whole room vortex space heaters manufactured in China.

According to the company, the space heater can overheat, causing the unit to melt, catch fire and ignite nearby items. This condition can pose a fire and burn hazard to consumers. Vornado says that it has received 29 separate reports of the space heaters overheating and melting, along with seven report of space heater catching fire, resulting in one report of property damage and one case of smoke inhalation.

The recalled space heaters were sold at major home supply and retail stores nationwide, including Bed, Bath and Beyond, Home Depot, Menards and Target, from June 2013 through May 2014 for about $60.

Additional information about this recall is available at incompliancemag.com/news/1410_8.

"Shocking" Aquarium Heaters Recalled

PetSmart of Phoenix, AZ has recalled about 33,000 aquarium heaters manufactured in China and imported for sale in PetSmart retail stores.

According to the company, the aquarium heaters are not sufficiently grounded, posing a risk of electrical shock to consumers. PetSmart says that is has not received any reports of incidents or injuries related to the recalled heaters, but has initiated the recall to prevent consumer injuries.

The recalled aquarium heaters were sold at PetSmart stores nationwide during March and April 2014 for between $27 and $37.

Additional details about this recall are available at incompliancemag.com/news/1410_9.

You Can't Make This Stuff Up

Jet Fuel from Tobacco

Reuters reports that U.S. aircraft manufacturer Boeing has partnered with South African Airways in a project to develop jet fuel from a tobacco plant.

The nicotine-free tobacco plant, known as Solaris, is being developed by SkyNRG, an alternative jet fuel maker. It is hoped that the tobacco-based biofuel can be blended with diesel and other petroleum products to reduce the use of traditional fuels in airplanes. South African Airways has set October 2015 as a target date for its initial use of tobacco biofuel in its operations.

South Africa is not only a major hub for the global biofuels industry, but a leading producer of tobacco products, making the country a logical home for this interesting experiment.

Erratum

In our September issue, we ran the news story "Fines for Amateur Radio Operators" reporting that the FCC had proposed a $22,000 fine for a Detroit area operator. The amateur radio operator, Michael Guernsey, is located in Parchment, MI (in the southwestern part of MI near Kalamazoo) not in the Detroit area as originally reported.

Thank you to the keen eye of reader, Wes Plouff, for bringing this to our attention.

News in Compliance

UL Standards Update

Underwriters Laboratories has announced the availability of these standards and revisions. For additional information, please visit their website at www.ul.com.

STANDARDS

UL 1449: Standard for Surge Protective Devices
New Edition dated August 20, 2014

UL 2789: Environmental Claim Validation Procedure for Calculation of Estimated Recyclability Rate
New Edition dated September 12, 2014

UL 6703: Standard for Connectors for Use in Photovoltaic Systems
New Edition dated August 28, 2014

REVISIONS

UL 5B : Standard for Strut-Type Channel Raceways and Fittings
Revision dated August 1, 2014

UL 94: Standard for Tests for Flammability of Plastic Materials for Parts in Devices and Appliances
Revision dated September 10, 2014

UL 96A : Standard for Installation Requirements for Lightning Protection Systems
Revision dated August 12, 2014

UL 142: Standard for Steel Aboveground Tanks for Flammable and Combustible Liquids
Revision dated August 26, 2014

UL 231: Standard for Power Outlets
Revision dated September 11, 2014

UL 242: Standard for Nonmetallic Containers for Waste Paper
Revision dated August 18, 2014

UL 305 : Standard for Panic Hardware
Revision dated August 8, 2014

UL 360 : Standard for Liquid-Tight Flexible Metal Conduit
Revision dated August 14, 2014

UL 474: Standard for Dehumidifiers
Revision dated August 22, 2014

UL 558: Standard for Industrial Trucks, Internal Combustion Engine-Powered
Revision dated September 2, 2014

UL 574 : Standard for Electric Oil Heaters
Revision dated August 13, 2014

UL 710B : Standard for Recirculating Systems
Revision dated August 14, 2014

UL 758: Standard for Appliance Wiring Material
Revision dated September 2, 2014

UL 810: Standard for Capacitors
Revision dated August 18, 2014

UL 842 : Standard for Valves for Flammable Fluids
Revision dated August 14, 2014

UL 916 : Standard for Energy Management Equipment
Revision dated August 11, 2014

UL 935 : Standard for Fluorescent-Lamp Ballasts
Revision dated August 7, 2014

UL 1042: Standard for Electric Baseboard Heating Equipment
Revision dated September 9, 2014

UL 1247 : Standard for Diesel Engines for Driving Stationary Fire Pumps
Revision dated August 5, 2014

UL 1331: Standard for Station Inlets and Outlets
Revision dated August 25, 2014

UL 2200: Standard for Stationary Engine Generator Assemblies
Revision dated August 26, 2014

UL 2586: Standard for Hose Nozzle Valves
Revision dated August 22, 2014

UL 60730-2-2: Standard for Automatic Electrical Controls for Household and Similar Use; Part 2: Particular Requirements for Thermal Motor Protectors
Revision dated September 4, 2014

UL 60730-2-5 : Automatic Electrical Controls for Household and Similar Use, Part 2-5: Particular Requirements for Automatic Electrical Burner Control Systems
Revision dated August 5, 2014

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This course is intended for working engineers who are interested in using the latest state-of-the-art tools to help meet project cost and schedule requirements. It will also be of value to managers and engineers who are interested in obtaining a better understanding of electromagnetic computational modeling so they can better evaluate which commercially available software tool would best suit their needs.

Meet Dr. Bruce

Dr. Bruce Archambeault is an IEEE Fellow, an IBM Distinguished Engineer Emeritus and an Adjunct Professor at Missouri University of Science and Technology. He received his B.S.E.E degree from the University of New Hampshire in 1977 and his M.S.E.E degree from Northeastern University in 1981. He received his Ph. D. from the University of New Hampshire in 1997. His doctoral research was in the area of computational electromagnetics applied to real-world EMC problems. He has taught numerous seminars on EMC and Signal Integrity across the USA and the world, including the past 12 years at Oxford University.

Course Topics

EMC Fundamentals

- Common Mode Noise from High Speed Differential Signals
- High speed board-to-board connector analysis
- Electromagnetic Band Gap Filters
- PCB power decoupling myths busted

Signal Integrity

- Using lossy materials to mitigate EMI at GHz frequencies
- Survey of EMC/SI simulation techniques and tools and their strengths/weaknesses

Decision Making Tools

- Breaking real-world complex problems into realistic simulation models
- Validation of modeling/simulations
- Possible pitfalls with specific vendor modeling tools

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REALITY Engineering

Off In Space

A Visit to NASA Glenn and Plum Brook Test Facilities

BY MIKE VIOLETTE

The next couple of installments of Reality Engineering will carry a spacey theme, in recognition of the ongoing efforts of rocket scientists and engineers in our community. Testing and verification of space-borne systems are critically important, You don't get "do-overs" in space shots (we found that out in an earlier post "The Ringing Rocket" (October 2013 www.incompliancemag.com/article/the-ringing-rocket). Here we visit some NASA facilities that proved out Apollo-era designs and are being maintained for the next phase of space engineering.

When I was a chubby lad back in the 1960s, one of my favorite things to spend my allowance on was something called *Space Food Sticks*®: "Good nutrition and lasting energy in a chewy tasty snack." You see, these exotic neo-candy bars were allegedly developed for the astronauts. They must have had some kind of magic if they were the ambrosia of space pioneers and we Air Force brats coveted them wildly. (You can find out information about the *Space Food Sticks Preservation Society* at www.spacefoodsticks.com, by the way). The other fond food memory of the space age was *Tang*®, which was apparently used on Gemini flights to mask the foul taste of some of the drinking water that was consumed on-board. Both of these nutritious items can still found on Earth, but it's been a while since I've sought them out.

The allure of space travel: the Apollo program, heroes in space helmets, artificial food products–all captured my boyhood imagination. All the aging nerds of my vintage know the LEM from the Command Module and marveled at the Earth-shaking thrust of the Saturn V launch vehicle. Audacious! So it is against the backdrop of these fine memories we toured the Glenn Research Center facilities a bit ago, not far from Cleveland ("The Forest City").

NASA spending during the 1960s peaked in 1966 and during the expansion of the space program (Apollo spending was north of 60% of the budget). All that funding fueled the expansion of several laboratories in our industry as well as the construction of almost bigger than life facilities under the aegis of the US Government, featured in this month's Reality Engineering. If one takes the long view that the human race might be around for another few millennia, it's worth keeping the pressure and funding for the noble objectives of advancing our understanding of Earth and our place in the universe. And it can all be done with less than 10% of a round of a tottering bank's bailout.

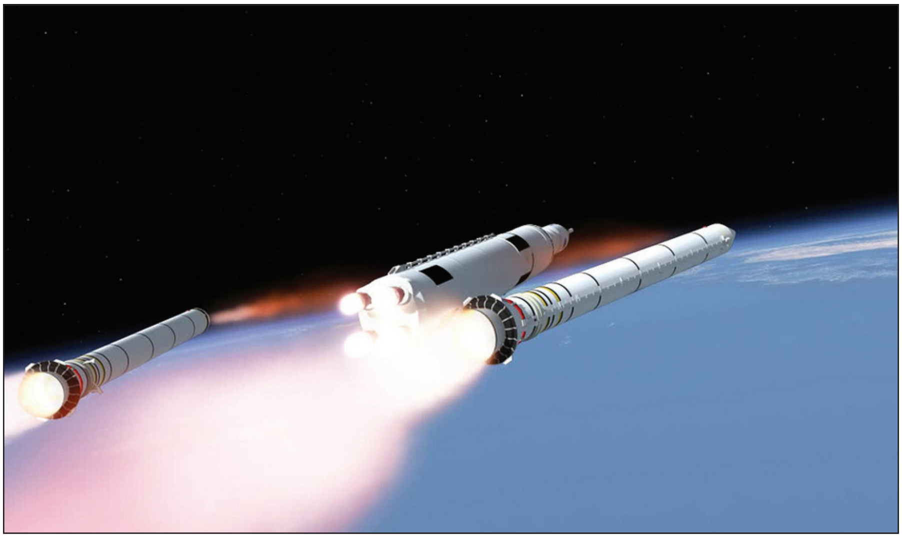
TV Astronaut enjoying Space Food Sticks Is it Captain Nelson? Where's Jeannie?

THE SPACE LAUNCH SYSTEM

The moon hasn't gotten any closer since our last visit in 1972 and at a quarter of a million miles away, it will require a new heavy lift vehicle to bring cargo and astronauts to the surface, and back.

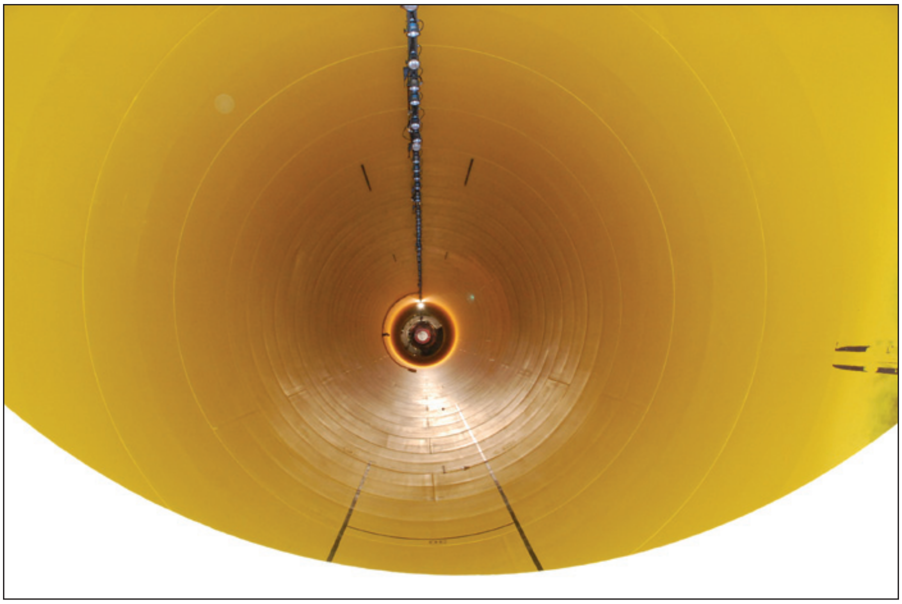
The Space Shuttle, sadly mothballed/museum'd, has left the field to a few commercial competitors, but we really need something that will do some *heavy lifting* and achieve **"ΔV,"** the escape velocity necessary to kiss off Earth's grip. What, hence, is serving as our ride to the exo-atmosphere? *Russian Soyuz Rockets*! Hmm. While it's nice that we are cozy enough to ask our "friends" (a relationship that is pretty shaky at the moment) for a ride now and then, it's a little bit like putting your eggs AND your hen in one basket. Hence, we need new kind of launch vehicle.

Enter the **Space Launch System** or **SLS**, a mighty beast scheduled for first flight in 2018. (SLS has superseded another



SLS Booster Separation

REALITY Engineering



Drop Tube: Don't let your glasses fall!

We not long ago paid a visit to the NASA Glenn Research Center and Plum Brook Test Facility and got the cook's tour of the Apollo-era facilities. Impressive is such an under-powered word to use to describe the mechanical and electrical achievements at these two locations.

GEEZ...ZERO

First stop was a 500+' deep hole used to perform experiments in the "Zero G Facility." It is about as deep as the Washington Monument is high.

The facility drops specialized pods with science experiments down the hole. The entire apparatus is in free-fall in a vacuum and, as a result, simulates near-zero gravity.

design, called Ares, since cancelled.) SLS will be the largest launch vehicle ever put into space and built using many of the shuttle concepts and components, including Solid Rocket Boosters for launch and first-stage ignition and the mighty RS-25 rocket engines. The 384 foot tall (eighty feet taller than the Statue of Liberty on her pedestal) launch vehicle will weigh 6.5 million pounds and carry a max payload of almost 300,000 pounds. The primary payload for the SLS will be the Orion Multi-Purpose Crew Vehicle (MPCV).

There are a couple of drivers for SLS, not solely the jones to plant our feet on the dusty lunar surface (and Mars), but includes advancing the goals to support the National Space Policy Directive, namely, to replace the Space Shuttle and to complete the International Space Station.
Also needed: advancing the state-of-the-art. As with many of my fellow boomers, the Apollo and other programs inspired an interest in technology and science. The aims of STEM programs (Science, Technology, Engineering and Math) are very much the same. What better way to get some kid's attention than with a Richter-registering 9 million pounds of thrust?

And, with the changes afoot in the world order—China's successes in space for example and the uncertainty in the underbelly of Russia—there is no small need to keep our edge keen.

For a free falling five seconds, the experiment records the effects of the microgravity. Various phenomena have been observed and the result has been to modify the mechanics of spacecraft systems engineering, particularly when it comes to fluids behavior in microgravity. This is critical to understand because (non-solid)

Crane Inside Chamber

propellants are composed of liquids that need to mix nicely in order to burn and provide thrust. Seems that, in zero Gs, propellants tend to separate into their component parts and gloop together in the propellant tank. If the fluids aren't mixed and available at the nozzle in the right proportion, then the engine won't start, may quit or will burn poorly. Given that there is not a way to get back down to Earth to re-fuel, the efficient and proper operation of the rockets is paramount. These effects were observed in the micro-gravity chamber when it was built in the 60s and, as a result, there are several designs that now are utilized to mitigate this (baffles and such).

Door Hardware: Now that's a lock!

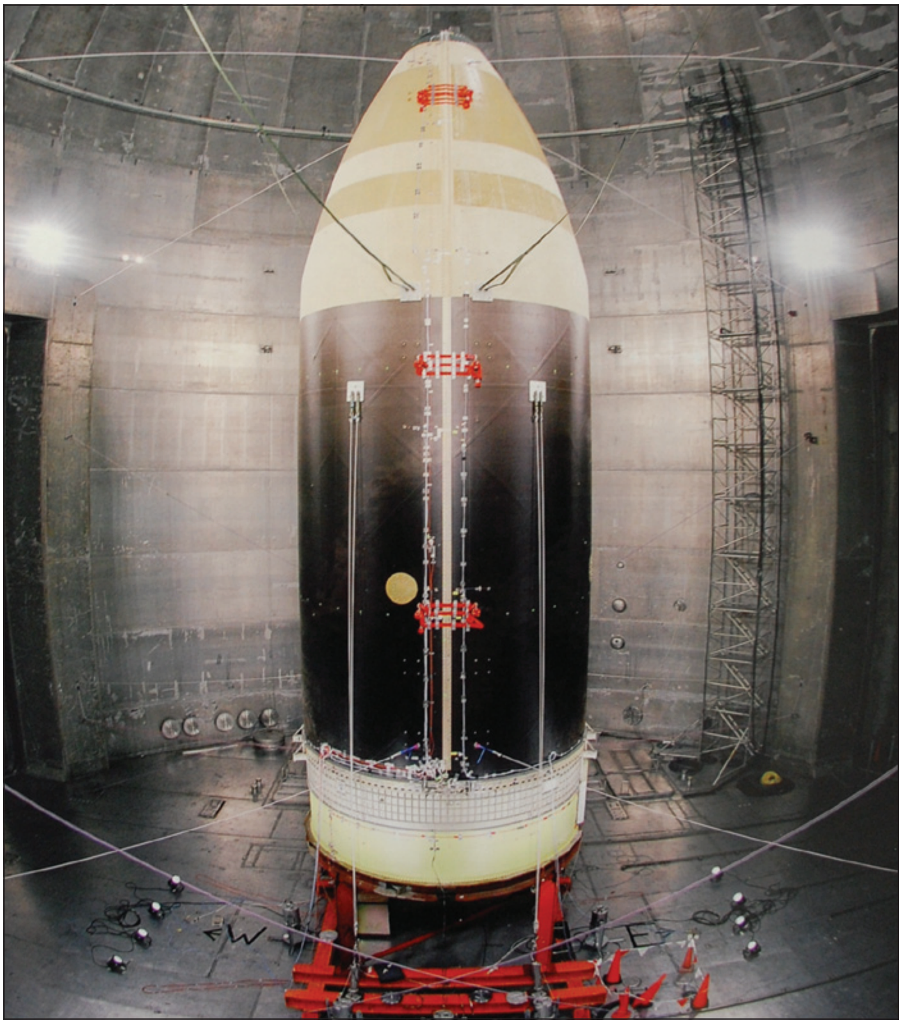
SPACE POWER FACILITY

Next on the tour was the truly awesome Space Power Facility at Plum Brook Station, an hour down the road from Cleveland. Personnel from the facility provided a walking, driving and talking narrative of the Plum Brook facility, originally built as a TNT development and test facility during WWII.

It is no exaggeration to say that there is nothing like the Space Power Facility in the world. The 125' tall chamber simulates deeeeeep space by evacuating all the air, heating and cooling the area to simulate the 'dark side' of the Moon and high noon on orbit. The thermal vacuum chamber is sealed by a large "pocket door." In the photo on page 16, the white structure in the middle is the door that slides shut and latches for an airtight fit. The door weighs 5 million pounds, about the same as 11.2 million Big Macs.

The upper stage of the rocket will be set in the chamber and subjected to not only environmental extremes, but will also be tested for EMC and radio frequency characteristics. The chamber is constructed of a double-walled

REALITY Engineering



Delta IV Shroud Test

Concrete pour

configuration with an inner aluminum shell and an outer concrete shell. The space is evacuated by sets of enormous pumps that can hold negative pressure (near-vacuum) for the duration of the testing.

The picture to the left shows a test of a Delta IV shroud (basically the upper stage of the rocket).

The final piece of our tour was a massive project to upgrade a vibration test stand that has a concrete pour (inertial mass—think huge anchor) the size of a couple of tennis courts. The shaker arrangement will subject the launch vehicle to the stresses encountered during liftoff and ascent. The concrete will keep it from shaking loose.

After viewing the marvels of the 60s we are humbled by the great efforts of the space pioneers. It truly was a time of soaring aspirations and the inventive spirit. We are also encouraged that some real attention is being paid to keeping the R&D testing capability alive and in service, ready for the next generation of space dreamers. IN

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Budgets

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(the author)

MIKE VIOLETTE
is President of Washington Labs and Director of American Certification Body. The next installment of RE stays with the space theme, but leaps forward, sort-of, by returning back to the 1960s. He can be reached at mikev@wll.com.

MR. Static

Surface Voltage and Field Strength Part I: Insulators

By definition, insulators do not have a voltage.

BY NIELS JONASSEN, sponsored by the ESD Association

This article, the first of a two-part series on measuring voltage and field strength, examines the controversial topic of an insulator's surface voltage and field strength. The discussion will include both theory and actual measurements, and will begin with a review of the most important features for a charged conductor and how these features differ for a charged insulator.

INTRODUCTION

Associate Professor Neils Jonassen authored a bi-monthly static column that appeared in *Compliance Engineering Magazine*. The series explored charging, ionization, explosions, and other ESD related topics. The ESD Association, working with *In Compliance Magazine* is re-publishing this series as the articles offer timeless insight into the field of electrostatics.

Professor Jonassen was a member of the ESD Association from 1983-2006. He received the ESD Association *Outstanding Contribution Award* in 1989 and authored technical papers, books and technical reports. He is remembered for his contributions to the understanding of Electrostatic control, and in his memory we reprise "Mr. Static".

~ The ESD Association

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Mr. Static Column

CHARGED CONDUCTORS

Figure 1 shows an insulated conductor A with a charge *q*. The charge will automatically distribute itself on the surface of the conductor in such a way that the field in the interior of the conductor will be zero, the field will be perpendicular to the surface, and the integral of the field strength *E* from any point P in or on the conductor to a ground point G is constant and given by

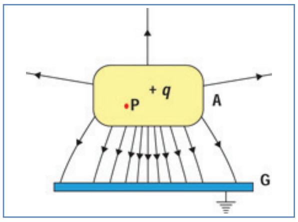

Figure 1: Charged conductor

$$V = \int_P^G E \cdot da \qquad (1)$$

where *V* is the voltage or potential of the conductor.

The voltage *V* and the charge *q* are proportional, and *q* is usually written as

$$q = C \cdot V \qquad (2)$$

where *C* is the capacitance of the insulated conductor and is determined by the conductor's size and shape, and its placement relative to other conductors and ground. The charged system stores an electrostatic energy of

$$W = \frac{1}{2} C \cdot V^2 \qquad (3)$$

which can be dissipated in a single discharge or current pulse.

CHARGED INSULATORS

Figure 2 shows a charged insulator. The field conditions here are very different from those at a charged conductor: The polarity of the charge may be different from point to point, the field in the interior may be different from zero, the field is not necessarily perpendicular to the surface, and the integral of the field strength from a point on or in the insulator to ground is usually different from point to point.

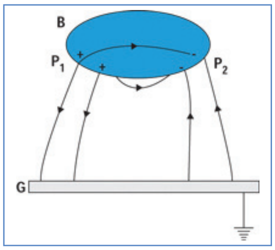

Figure 2: Charged insulator

In Figure 2, the integrals of the field strength for P_1 and P_2 are

$$V_{P_1} = \int_{P_1}^G E \cdot da > 0 \text{ and } V_{P_2} = \int_{P_2}^G E \cdot da < 0$$

respectively. V_{P1} and V_{P2} are the surface voltages (or surface potentials) of the two points. In general, the surface voltage of an insulator will vary from point to point, as will the voltage of

any point in the interior. It is therefore not possible to characterize a charged insulator with a single voltage figure. In other words, an insulator does not have a voltage.

Many people do not like to accept this simple fact, so specifics need to be discussed. There are cases in which the surface of an insulator has a constant surface voltage. But apart from such instances, there is only one situation in which all points in and on an insulator can be ascribed a well-defined (but unmeasurable) voltage. If a spherical insulator with radius *R* and uniform charge *q* (see Figure 3) is placed infinitely far (a distance much greater than *R*) from any conductors, the sphere would have a voltage of

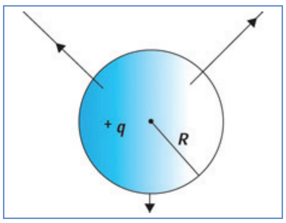

Figure 3: Uniformly surface-charged, spherical insulator

$$V_{sphere} = \frac{q}{4\pi\varepsilon_o R} \qquad (4)$$

However, this very theoretical situation is the only case in which it makes sense to talk about the voltage of an insulator.

Similarly, the concept of an insulator's capacitance is meaningless. Although it is possible to get a discharge from a charged insulator, the discharge will always be partial, and the energy dissipated can neither be related to the total charge nor be related to any kind of voltage. In other words, voltage and capacitance are quantities of a conductor, not an insulator.

So a natural question arises: what measurements can be taken from a charged insulator? The simple answer is that the effect of the field from the charge, and sometimes the total charge, can be measured. This article will concentrate on the direct effect of the field. As with conductors, the instruments used for measurement are field meters and noncontacting voltmeters. Both types of instruments will distort the fields to be measured unless properly screened. Uniformly charged free insulative sheets and uniformly charged insulative sheets backed by a grounded conductor are the only two cases in which it is possible to make quantitatively reliable measurements of charged insulators.

UNIFORMLY CHARGED SHEETS

Figure 4 shows a uniformly charged insulative sheet. If the field strength indicated on the meter is *E*, the charge density s on the part of the insulator in front of the meter should be

$$\sigma = \varepsilon_o E. \qquad (5)$$

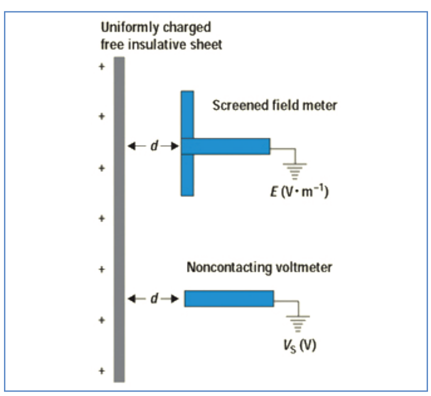

Figure 4: Static measurement on free charged sheet

If a noncontacting voltmeter is placed at a distance *d* from the sheet, then the surface voltage V_s indicated on the meter would be given by

$$V_s = E \cdot d = \frac{\sigma}{\varepsilon_o} \cdot d \qquad (6)$$

Figure 5 shows the field strength *E* from a free plastic sheet with a total charge *q* @ $0.5 \cdot 10^{-7}$ C. The area of the sheet is 21 x 29 cm^2, which gives an average charge density of

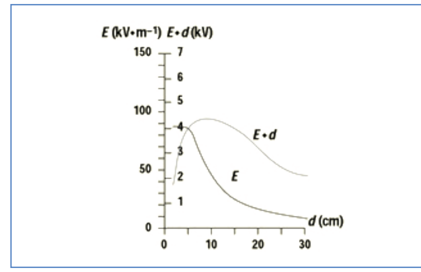

Figure 5: Field strength from and surface voltage of free plastic sheet

$$\sigma_{avg} = \frac{0.5 \cdot 10^{-7}}{21 \cdot 29 \cdot 10^{-4}} = 0.82 \cdot 10^{-6}\ \mathrm{C \cdot m^{-2}}$$

The figure shows that the field strength *E* is relatively constant at about 88 kV·m^{-1} to a distance of approximately 5–6 cm. According to Equation 5, this corresponds to a charge density of s = $8.85 \cdot 10^{-12} \cdot 88 \cdot 10^3 = 0.78 \cdot 10^{-6}$ C·m^{-2}. Considering the uncertainty of the measurements of the total charge and of the field strength, the agreement between the calculated and measured values of the charge density ($s_{avg} = 0.82 \cdot 10^{-6}$ C·m^{-2} versus s = $0.78 \cdot 10^{-6}$ C·m^{-2}) seems satisfactory.

It therefore appears that measurement of the field strength near a free charged sheet leads to information about the charge density and charge distribution on the surface. In the region where the field is homogeneous, the surface voltage of the sheet is proportional to the distance from the sheet and is measured, using Equation 6, by a noncontacting voltmeter. This measurement then leads to the surface charge density, given that the measuring distance can be estimated with reasonable accuracy. However, it should be stressed that a measurement of the surface voltage does not provide any more or better information about the charged state of the insulative sheet than a measurement of the near-surface field strength does.

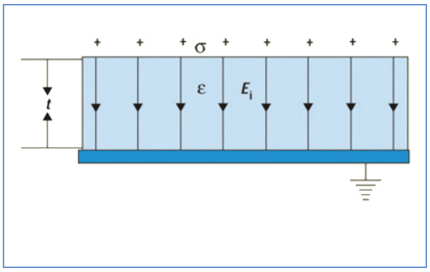

Figure 6: Uniformly charged insulator disk, backed by grounded conductor.

INSULATOR DISK

Figure 6 shows an insulator disk with permittivity e and thickness *t*. The disk is resting on a grounded plane and has a positive charge with density s ($C \cdot m^{-2}$). If the disk is far from other conductors, the field inside the material will be given by $E_1 = {}^s/_e$, and each point on the surface will then have a voltage of

$$V_s = E_i \cdot t = \frac{\sigma}{\varepsilon} \cdot t \qquad (7)$$

It should be stressed that V_s is not the voltage of the insulator disk, but only of the surface. Any point inside the insulator has a different, unmeasurable voltage.

The situation shown in Figure 6, with the disk far from conductors other than the grounded base, is of little practical interest because it excludes the presence of meters. A more common situation is shown in Figure 7, in which a grounded electrode A is parallel to the charged

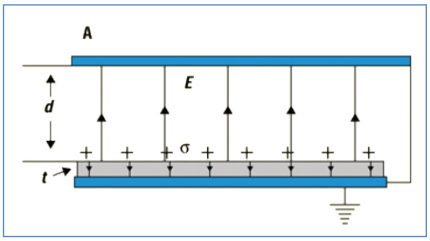

Figure 7: Uniformly charged insulator disk between grounded backing electrode and free grounded electrode.

disk at a distance *d*. The field strength in the space between the charged disk and A would be given by

$$E = \frac{\sigma \cdot t}{\varepsilon \cdot d + \varepsilon_o \cdot t} \qquad (8)$$

The grounded plane A might typically be the place where a field meter or noncontacting voltmeter is placed, with distance *d* being much greater than thickness *t*. The charged disk can be, for instance, an electret or a web. With these conditions, Equation 9 can be written as

$$E = \frac{\sigma}{\varepsilon} \cdot \frac{t}{d} \qquad (9)$$

The surface voltage, which is almost equal to the undisturbed value, can be written as

$$V_s = \frac{\sigma}{\varepsilon} \cdot t \qquad (10)$$

It appears that, under these conditions, it is possible to estimate the charge density by measuring either the field strength or the surface voltage from the charged disk, assuming the permittivity and thickness of the disk are known.

SHEET WITH GROUNDED CONDUCTOR

Figure 8 (page 24) shows an experimental set-up corresponding to the conditions described in Figure 7. This could, for example, be a charged web or an electret. The charged insulator is a 1-mm plate with dimensions of 0.21 x 0.29 m^2. The relative permittivity (dielectric

MR. Static

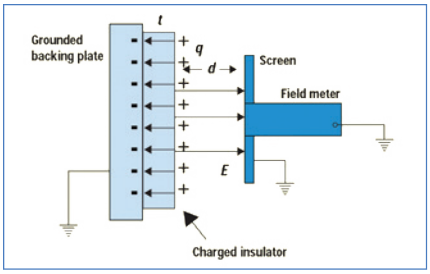

Figure 8: Uniformly charged insulator backed by a grounded conductor.

constant) of the material is e_r » 2 (e = 1.77 · 10^{-11} F·m^{-1}). The total charge on the free surface of the insulator is *q* » 2.7 · 10^{-7} C, leading to an average surface charge density of s » 4.4 · 10^{-6} C·m^{-2}.

In the absence of a field meter (and other grounded objects, not including the backing plate), the surface potential of each point on the surface can be calculated using Equation 7 as

$$V_s = \frac{4.4 \cdot 10^{-6}}{1.77 \cdot 10^{-11}} \cdot 10^{-3} \approx 250\ \mathrm{V}$$

When the field meter is placed in front of a charged plate, the electric flux from the charge is shared between the field meter and the backing plate. Consequently, the internal field and the surface voltage will be reduced slightly, depending on how far away the meter is placed. There will also be a field E_d in the space between the charged plate and the field meter. This field is the only quantity of the charged plate that can possibly be measured.

Figure 9 shows the field strength from and surface voltage of the disk shown in Figure 8. At 5 cm, the field strength and surface potential are measured to be E_5 » 4.6 kV·m^{-1} and V_s » 235 V, respectively. According to Equation 9, this corresponds to a charge density of

$$\sigma = \frac{\varepsilon \cdot D \cdot E}{t} = \frac{1.77 \cdot 10^{-11} \cdot 5 \cdot 10^{-2} \cdot 4.6 \cdot 10^{3}}{10^{-3}} \approx 4.1 \cdot 10^{-6}\ \mathrm{C \cdot m^{-2}}$$

Comparing this with the calculated value of s = 4.4 · 10^{-6} C·m^{-2} and considering the uncertainties in the quantities involved, especially in the uniformity of the initial surface charging and the effective distance to the meter, the agreement between the calculated and measured values is surprisingly good: 4.4 · 10^{-6} C·m^{-2} and 4.1 · 10^{-6} C·m^{-2}, respectively.

As shown in Figure 9, the surface voltage, *E·d*, is relatively independent of the distance to the meter, and this feature will be even more pronounced in the cases of thinner insulators such as real electrets and webs, which have thicknesses on the order of 50–100 µm.

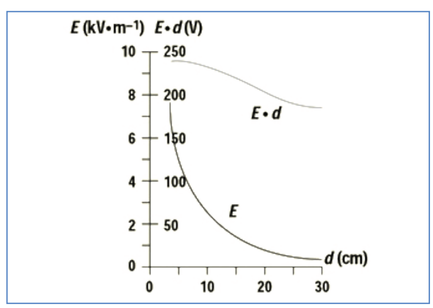

Figure 9: Field strength from and surface voltage of a uniformly charged plastic sheet backed by a grounded conductor.

GENERAL COMMENTS

Free insulative sheets and insulative sheets backed by a grounded conductor are the only cases in which it is possible to extract reliable information from a noncontacting measurement of the charged state of an insulator. In both cases, the electric field from the charge is the deciding factor. With a free sheet (or just a relatively planar insulator), the electric field measured at a short distance (a few centimeters) will provide all the possible information—that is, the charge density. If a noncontacting voltmeter is used, the distance will have to be measured in order to convert the surface voltage to surface charge density. Surface voltage in itself does not provide extra information.

In the case of a sheet backed by a conductor, the surface voltage is relatively constant. If the thickness and permittivity of the material are known, then the surface voltage could be used to calculate the surface charge density. If a field meter is used, then the distance would also have to be measured. Field strength depends on the surface parameters (thickness and permittivity) in the same way surface voltage does.

Even in the well-defined situations of a free charged sheet and a backed charged sheet, a noncontacting measurement will, at best, only provide information about the charge density. Sometimes a field measurement (free charged sheet) is the most relevant, whereas at other times a direct surface-voltage measurement (backed charged sheet) is the most relevant. However, either measurement will only lead to the charge density.

But what happens if the charged insulator is not one of the well-defined objects previously described, and the meter is just pointed toward an ordinary object? The answer can be found in Figure 10, which shows a plastic container. A screened field meter very close to the container identifies a field strength *E* = +100,000 V·m^{-1}. A noncontacting voltmeter at a distance of 2 cm (as well as the distance can be measured) identifies a surface voltage V_s = +2 kV. What can be concluded from these

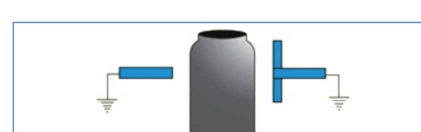

Figure 10: Static measurement of the field strength and surface voltage on a plastic container.

measurements? A prudent and safe answer is that the container is positively charged.

If the situation in Figure 10 is approximated with that of Figure 4, using Equations 5 and 6, both readings would suggest that the surface charge density in front of the meters is positive and on the order of 1 $\mu C \cdot m^{-2}$. This result, however, is very uncertain, especially when using a noncontacting voltmeter, because the reading is approximately inversely proportional to the measuring distance. If the measuring distance of 2 cm can be read with an accuracy of ±2 mm, then there is already an uncertainty of 10%, regardless of meter sensitivity. If the distance is increased, then charges other than those on the surface immediately facing the meter will influence the reading and make the interpretation even more uncertain.

STATIC LOCATORS

Probably the most common way to do a fast static survey is to point a handheld meter at the suspicious item and pronounce a voltage. Often this is the only "measurement" done, and very often this is not enough.

The meters so used are known as *static locators*. And that is exactly what they are: instruments used to locate a static-electric field. As long as that is the only thing they are used for, everything should work fine. Static locators are scaled in volts and have a stipulated measuring range. However, the meter is not a voltmeter, meaning it doesn't react to voltage, but rather to an electric field.

If a static locator is a real field meter (e.g., a field mill) and has a scale in $V \cdot m^{-1}$ (or kV/in.), it may be used close to charged insulators to estimate the surface charge density, as explained above. If the scale is in volts, the reading may approximate the surface voltage and can, using Equation 6, lead to the surface charge density.

With both types of measurements, the results may have a high uncertainty and even errors, especially if the meters are not screened. Even if the meters are screened, there is also the influence of charges other than the ones immediately facing the meters—for instance, the charges on the other side of the insulator. The second part of this series on voltage and field strength will discuss static locators in more detail.

CONCLUSION

It is easy to determine whether an insulator is charged. Just point a suitable meter at the insulator and take a reading. If the measurement is done carefully, then the reading may provide information about how much charge is located on a unit area of the facing surface (i.e., the surface charge density, $C \cdot m^{-2}$), as well as the polarity of the charge.

However, the problem is that no meters are calibrated for this unit of measurement. The meters with the closest unit are field meters with scales in volts per meter, $V \cdot m^{-1}$. Fortunately, the volts-per-meter measurement can be multiplied by e_o ($8.85 \cdot 10^{-12}$ $F \cdot m^{-1}$) to arrive at the charge density.

The bad news, however, is that most meters have scales in volts. In all cases, these meters have been calibrated relative to conductors, where the concept of voltage makes sense. Used in connection with insulators, the reading may at best be an approximation of the surface voltage, which characterizes only a part of the insulator's surface, not the insulator. In this case, the reading in volts, when multiplied by e_o and divided by the measuring distance, can also lead to the surface charge density. It should be stressed that the voltage of an insulator has no meaning. All that can be found by any noncontacting measurement on a charged insulator is the polarity of the charge and, if the measurement is done carefully, the surface charge density. IN

(the author)

NIELS JONASSEN, MSC, DSC, worked for 40 years at the Technical University of Denmark, where he conducted classes in electromagnetism, static and atmospheric electricity, airborne radioactivity, and indoor climate. After retiring, he divided his time among the laboratory, his home, and Thailand, writing on static electricity topics and pursuing cooking classes. Mr. Jonassen passed away in 2006.

Designing Effective Product Safety Labels: How to Convey Risk Severity Levels

BY GEOFFREY PECKHAM

Designing product safety labels that help to prevent injuries and save lives is a multi-faceted task. This month, we'll focus on another key element: communicating risk using signal words.

In this year's series of *On Your Mark* columns, I've explored fundamental topics related to effective product safety labeling, including overall best practices, symbols and content. This brings us to our final topic: risk severity levels. If you're making a product that has one or more risks associated with it at any point in its lifecycle, you need to either eliminate those risks, guard them or communicate them so people can effectively avoid them. Visually communicating degrees of risk on your product safety labels can be a complex task. But here, once again, it's standards to the rescue!

Figure 1: ANSI Z535 signal word panels for hazard alerting labels

SIGNAL WORDS – ACCORDING TO ANSI AND ISO

When it comes to hazard alerting labels – labels that communicate potential personal injury hazards and how to avoid them – the color-coded signal words "DANGER," "WARNING" and "CAUTION" are used identically by the ANSI Z535.4 and ISO 3864-2 product safety label standards to indicate varying degrees or levels of risk severity (see Figure 1).

Both of these standards carefully define the use of these signal words as follows:

- **DANGER** is used to indicate a hazardous situation which, if not avoided, **will** result in **death or serious injury**. This signal word is to be limited to the most extreme situations.
- **WARNING** is used to indicate a hazardous situation which, if not avoided, **could** result in **death or serious injury**.
- **CAUTION** is used to indicate a hazardous situation which, if not avoided, **could** result in **minor or moderate injury**.

There are two additional signal words in the ANSI Z535 standards. One is "NOTICE." It's used to address safety-related practices not related to physical injury (for example, maintenance information that, if not followed, might result in equipment damage). The second is "SAFETY INSTRUCTIONS." This signal word can actually be changed; you can substitute a more specific name for an instructional message, like "SAFE BOILER SHUT-DOWN PROCEDURE." This category of signal word is used to communicate a set of detailed safety-related instructions or procedures. The main idea behind the relatively new "SAFETY INSTRUCTIONS" signal word (2011 ANSI Z535 edition) is that separating out safety instruction information will help keep your "DANGER," "WARNING" and "CAUTION" labels' messages short and concise so they can be more easily read.

As you can see by the definitions, each of the three hazard alerting signal words communicates a different level of risk – with risk being defined as a combination of **severity** of injury and **probability** of the accident or injury occurring if the sign's message is ignored. The ANSI Z535 and ISO 3864-2 system of using "DANGER," "WARNING" and "CAUTION" signal words to convey various levels of risk matches today's best practice methodologies for risk assessment and risk reduction.

YOUR FOUNDATION: RISK ASSESSMENT

In order to choose the right signal word, your first step – your foundation – is to perform a risk assessment. At its most basic level, risk assessment involves considering the probability and severity of outcomes that can result from a hazardous situation, and then considering various strategies to either eliminate or reduce the risk.

The risk assessment scoring matrix shown in Figure 2 is one way to rank a risk's severity as either high, medium or low. Defining the **terms** of the grid – defining the likelihood of the accident happening and the severity of harm or physical injury – is not always a straightforward task. You must ask: What is the probability of a person being injured or killed by this hazard? What is the worst credible injury that will or could result if an accident occurs? What, in your opinion, distinguishes a serious injury from a minor or moderate injury? These are questions and decisions that your company needs to discuss and define.

As you go through the risk assessment process, I highly suggest that you make use of the recent ANSI and ISO standards written on this topic, as they can be immensely helpful. ANSI Z10, ISO 31000 and ISO 31010 have annexes or appendixes that can serve as important guides for your company when it comes to defining the "likelihood" and "severity" terms related to your products' potential risks. I also suggest that you meet with your insurance carrier and legal counsel to utilize their expertise and industry experience related to risk reduction, from both a safety and liability perspective.

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Risk Assessment Scoring Matrix

Location:	Date:	Description:

(Circle One)

Severity of Injury or Illness Consequence

Likelihood of OCCURRENCE or EXPOSURE for a selected unit of time or activity	**Negligible**	**Marginal**	**Critical**	**Catastrophic**	**Notes**
Frequent →	Medium	Serious	High	High	
Probable →	Medium	Serious	High	High	
Occasional →	Low	Medium	Serious	High	
Remote →	Low	Medium	Medium	Serious	
Improbable →	Low	Medium	Medium	Medium	

Source: MILSTD 882

Figure 2: Risk assessment grid

ON Your Mark

CHOOSING YOUR SIGNAL WORD

Once the risk presented by your product's potentially hazardous situation has been determined and you have chosen to use a safety label as a means to lessen the risk, then the task becomes one of choosing the right signal word to convey the severity of risk involved. When you use a risk assessment that defines the likelihood and severity of injury related to each one of your product's potential hazards, you will find it's a relatively easy task to choose the right ANSI Z535/ISO 3864-2 signal word.

Annex E in the ANSI Z535.4 *Standard for Product Safety Signs and Labels* clearly lays out the decision tree for choosing the right signal word based on your risk assessment's decisions concerning a particular hazard's likelihood and degree of potential injury. See the illustration in Figure 3.

It should be noted that the level of content (meaning the amount of information that needs to be conveyed on a product safety label, including the decision to use signal words) can vary depending on many factors. There is no single right way to do things. Many factors must be considered when designing product safety labels, including the characteristics of your intended audience and the markets where your products are sold. Added to these two overarching considerations are the specific details related to the complexity of your industry, the complexity of your product and the hazards associated with its entire lifecycle – from installation, use and maintenance to disassembly and disposal. Combine all of these factors and you have the ingredients needed to design effective product safety labels. The use of signal words to communicate risk is one safety label component that can be used to accomplish the job of better protecting people from harm.

I hope this series of articles on symbols, content and risk severity levels – the core elements of today's best practices for product safety labels – has been helpful. I look forward to continuing these columns in the coming year by honing in on additional topics related to safety labeling to give you the guidance you need to achieve the goal: effective hazard communication that helps prevent accidents and save lives from tragedy.

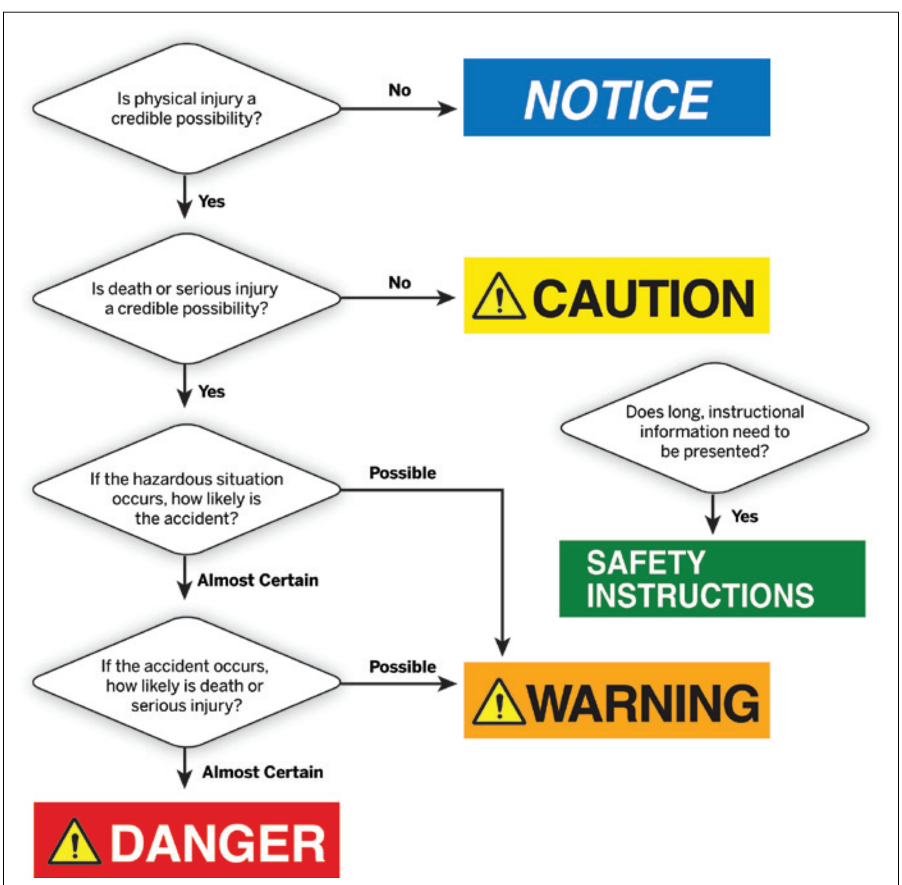


Figure 3: ANSI Z535.4 Annex E signal word selection process illustration

For more information on the product risk assessment process and communicating risk through warnings, watch a short, educational video produced by Clarion Safety Systems.

(the author)

GEOFFREY PECKHAM
Geoffrey Peckham, CEO of Clarion Safety Systems, is chair of both the ANSI Z535 Committee for Safety Signs and Colors and the U.S. Technical Advisory Group to ISO Technical Committee 145 - Graphical Symbols, and member of the U.S. Technical Advisory Group to ISO Project Committee 283 - Occupational Health and Safety Management Systems. Over the past two decades, he has played a pivotal role in the harmonization of U.S. and international standards dealing with safety signs, colors, formats and symbols. This article is courtesy of Clarion Safety Systems

Medical Devices in a Wireless World

What You Need to Know About Medical Device Manufacturing, Wireless Technologies and Compliance

BY IVAYLO TANKOV

While wireless technology is now an integral component of a wide variety of manufactured products, factors unique to the medical device market have kept wireless from making inroads there. However, the tide is turning to the point where manufacturers can now offer wireless benefits to North American practitioners, patients and payers, as long as the medical device manufacturers can meet the standards established by different and unrelated regulatory bodies.

This article will define the regulatory bodies involved, the criteria important to each of them, and the steps a medical device manufacturer needs to take to sell wireless medical devices in North America.

THE POWERS THAT BE

There are basically two regulatory bodies that impact compliance for wireless medical devices in the United States: the Food & Drug Administration (FDA) and the Federal Communications Commission (FCC).

All medical device manufacturers are familiar with the FDA regulations for placing a medical device on the US market. Although the agency was not known by its present name until 1930, its roots go back to 1848, and its modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act.

The FCC is no stranger to those of us who live here in the world of compliance. Since its formation by the Communications Act of 1934 "…for the purpose of promoting safety of life and property through the use of wire and radio communications" among other things, the FCC has established a broad base of rules and standards that have impacted virtually every American in one way or another.

Every medical device using wireless technology must comply with both the FDA and FCC requirements. As the primary function of the device is medical, the FDA requirements are considered primary with the FCC requirements considered supplementary. Both, however, are mandatory. The FDA expects a wireless product to comply with FCC requirements before its compliance with the FDA regulations is demonstrated.

Further, the FDA just recently updated its recommendations for medical devices using/integrating wireless technologies. While full compliance with the new regulations is not yet mandated, the agency has made it quite clear that it expects to see its recommendations addressed.

FCC RULES OF COMMUNICATION

As most *In Compliance* readers already know, typically a wireless medical device must follow the FCC rules particular to the type of wireless technology it employs. The rules consider various frequencies, power and other radio features. The FCC's main requirements for this product type are presented in Title 47 of the Code of Federal Regulations, which contains more than 100 parts; each part regulating a specific technology or combination of technologies using the same radio spectrum.

The type and scope of testing will also depend on the type of radio used in a given device. Manufacturers can use the FCC pre-certified radio modules, which still require limited testing on the system level to show compliance of the finished device. Using them saves time and money. Alternatively, companies can design and manufacture their own radios to incorporate into a product, which will require a full scope of wireless testing to certify the radio and the product.

THE FDA'S EXPECTATIONS

Every medical device is considered unique in its functionality and as such, needs to be evaluated individually to determine the best regulatory approach to take it to market. The FDA's generic requirements apply to all devices, but the manufacturer and testing laboratory need to choose the most applicable technical standards to which the product will be tested. Each technology performs differently, and the choice of technology automatically impacts a product's performance and also has bearing on the device's security and susceptibility to interference from other electronic devices. Generally, the FDA mandates that a medical device be tested to satisfy the FDA's and international minimal requirements for safety and electromagnetic compatibility (EMC).

"Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff" is the main document governing the use of wireless technology in medical devices. The document was originally published in 2007, and the most recent revision, published in August 2013, outlined several new recommendations for medical device manufacturers to follow. While at this point the recommendations are only suggestions, the FDA is on file as having urged manufacturers to demonstrate that they have considered the recommendations in their application for approvals. The specific recommendations suggest the medical device manufacturer:

1. Explain clearly why and how it selected a specific wireless technology.

2. Prove that the quality of the wireless service has been considered.

3. Show that its product can co-exist with other radio equipment in the vicinity without generating any problems; the intent being to minimize the possibility of a technology error where decisions about people's well-being are made in an environment full of wireless cell phones, tablets and laptops.

4. Illustrate how the security of wireless signals and data has been addressed to protect confidential patient information.

5. Demonstrate how other electronic devices might interfere with the radio portion of the medical device; i.e. EMC performance of the wireless technology.

6. Provide clear operations instructions in the user documentation for both the medical staff and patients.

7. Offer detailed maintenance and care instructions for the medical device.

The FDA also wants medical device manufacturers to perform risk management as part of their quality system under Title 21 CFR Part 820. When preparing pre-market submissions for the FDA, manufacturers should know that in the risk-based approach to verification and validation section, the agency will expect to be given information about:

1. Quality of wireless service: With wireless technology, a medical device might experience a delay in administering or terminating therapy. This depends on how fast data is transferred back and forth between a medical device in question and other medical or IT infrastructure equipment.

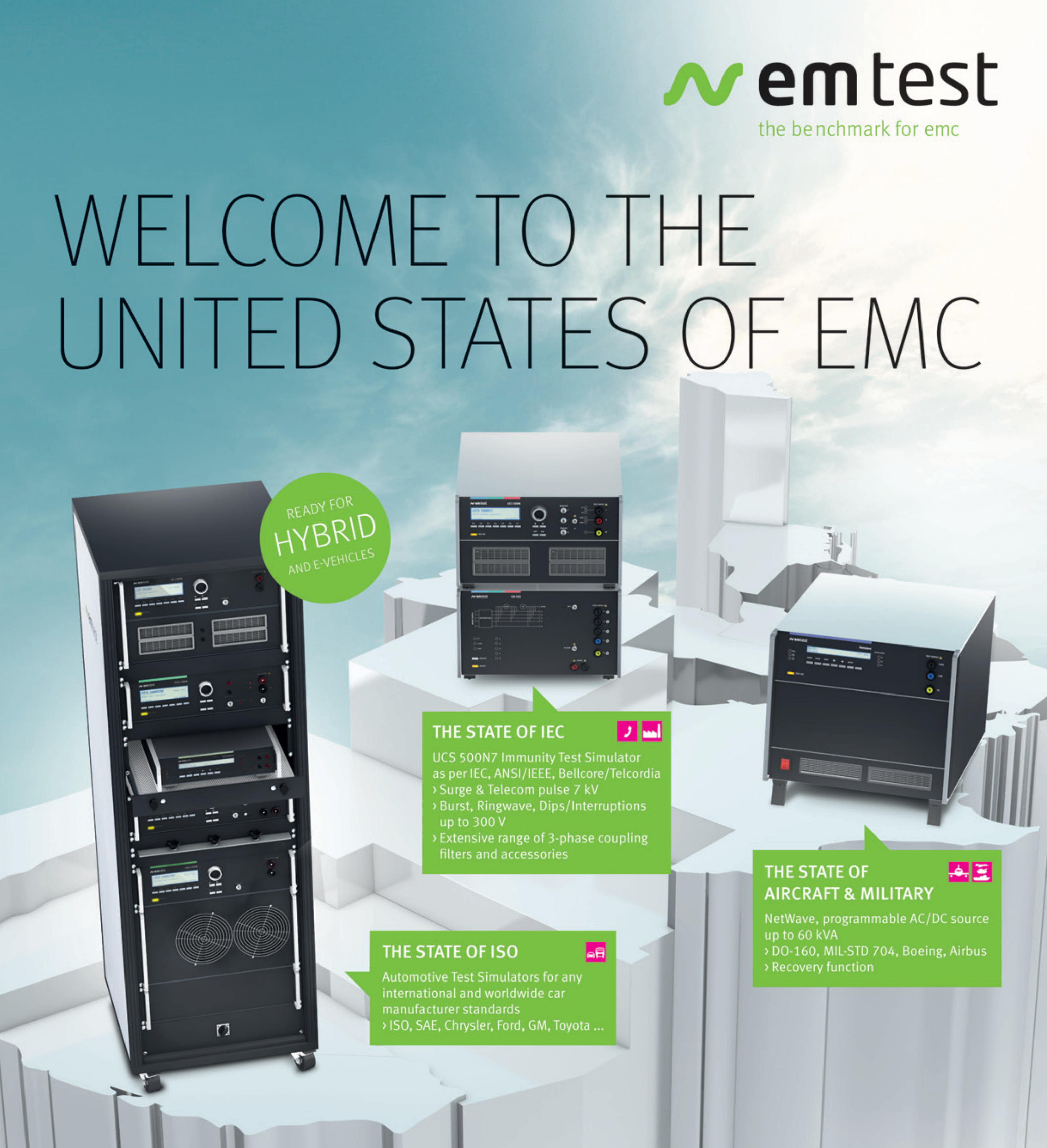
2. Wireless coexistence: A device's radio channel might interfere with other wireless devices nearby. Multiple devices in a hospital use various wireless technologies and might interfere with each other on the radio portion of the spectrum.

3. Security of wireless signals and data: When patient information is transferred over the air and is not properly encrypted, it can be intercepted. Unauthorized access or harmful interference (such as maliciously altering data) will compromise patient's private records and might impact healthcare delivery.

4. EMC of the wireless technology: Yet another consideration is how susceptible a medical device's interface is to the electromagnetic interference (EMI) from nearby devices that do not use radio transmission, such as computers. For example, a pacemaker worn by a patient might be affected by a PC of the nurse who is checking him in.

INTERNATIONAL COMPLIANCE

From an international perspective, medical devices are covered by the International Electrotechnical Commission's (IEC) 60601 standard. IEC 60601-1 addresses basic safety and essential performance (BS&EP)



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THE STATE OF IEC
UCS 500N7 Immunity Test Simulator as per IEC, ANSI/IEEE, Bellcore/Telcordia
› Surge & Telecom pulse 7 kV
› Burst, Ringwave, Dips/Interruptions up to 300 V
› Extensive range of 3-phase coupling filters and accessories
THE STATE OF AIRCRAFT & MILITARY
NetWave, programmable AC/DC source up to 60 kVA
› DO-160, MIL-STD 704, Boeing, Airbus
› Recovery function
THE STATE OF ISO
Automotive Test Simulators for any international and worldwide car manufacturer standards
› ISO, SAE, Chrysler, Ford, GM, Toyota ...

criteria. The BS&EP criteria describe the product's intended use and operation and any of its features or functions that might cause harm or injury to the users, patients and surroundings. Degradation of features and functions is allowed, provided it does not affect essential performance and safety of the product.

In order to demonstrate compliance, the medical device manufacturer must develop a list of the product's key functions and associated risks, and this list would be used to determine if the product is in a pass or fail status during and after the test. From this, the manufacturer will develop an essential performance document. During immunity testing, degradation of performance that affects essential performance would not be acceptable. Some examples of these situations include:

- Changes in programmable parameters,
- Distortion of image/data,
- Change/interruption of intended operating mode,
- Unintended operation/movement,
- Component failures, and
- False alarms.

EMC TESTING ACCORDING TO IEC 60601-1-2

EMC testing according to IEC 6060-1-2 can be broken into two parts: emissions and immunity. The emissions test evaluates the RF energy the product emits, while immunity testing determines product performance according to its EP & BS criteria under the electromagnetic effects. All operational modes should be considered for testing in full or partially to determine compliance for the overall system. The summary of the EMC tests to be performed is listed below:

EMISSIONS (Class AB, Group 1/2)

- Conducted
- Radiated
- Harmonics
- Flicker

IMMUNITY (EP & BS, Life-Supporting/Non-Life Supporting)

- ESD
- Radiated Immunity
- Conducted Immunity
- Surge
- EFT/Burst
- Voltage Dips/Interrupts
- Magnetic Fields

Group 1: All equipment that does not fall into Group 2.

Group 2: All equipment that intentionally generates and uses, or only uses, radio-frequency energy in the range of 9 kHz to 400 GHz in the form of electromagnetic radiation, inductive and/or capacitive coupling, for the treatment of material or inspection /analysis purposes.

Class A: Equipment suitable for use in all establishments except domestic and establishments directly connected to a low voltage power network supplying residential buildings.

Class B: Equipment suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which services residential buildings.

Life Supporting or Non-Life Supporting: Based on this classification, some immunity test strengths would be higher for Life-Supporting equipment due to the inherent risks associated with the use of this equipment.

Determining the correct product class and group is essential in that the limits for various classes and groups are defined differently in the standard. For example, conducted emissions limit (the main terminal disturbance voltage limit) between 5-30 MHz for Class A, Group 1 product is 73 dB(μV)- Quasi Peak & 60 dB(μV)-Average. If the product is a Class B, Group 1 type, the limit between 5-30 MHz is 60 dB(μV)-Quasi Peak and 50 dB(μV)-Average, regardless of the rated input power. The summary matrix of tests mandated by the IEC60601-1-2 standard is featured in Figure 1.

<table>
<tr><th>60601-1-2</th><th>Magnetic Immunity</th><th>Radiated Immunity</th><th>ESD</th><th>Conducted Immunity</th><th>SURGE</th><th>EFT/B</th><th>DIPS & INT</th><th>Radiated Emissions</th><th>Conducted Emissions</th></tr>
<tr><td>Non Life Supporting</td><td>3 A/m</td><td>3 V/m</td><td rowspan="3">6/8 kV</td><td>3V</td><td rowspan="3">1 kV/2 kV
DM, CM</td><td rowspan="3">1 kV/2 kV
I/O, AC</td><td rowspan="3">0%V
0.5 cycle
& 5 sec

40%V
5 cycle

70%V
25 cycle</td><td rowspan="3">Class A/B,
Group 1/2</td><td rowspan="3">Class A/B,
Group 1/2</td></tr>
<tr><td rowspan="2">Life Supporting</td><td></td><td></td><td></td></tr>
<tr><td>3 A/m
50 & 60 Hz</td><td>10 V/m</td><td>3V 10V for ISM</td></tr>
</table>

Figure 1

WHAT ELSE IS INVOLVED IN THE STANDARD?

The medical device manufacturer's responsibility for EMC is not limited to testing. Per 60601-1-2, the product-related risks and warnings are to be clearly indicated and explained to the user, patient and others so they can take necessary actions to limit any interruption. Some warnings must be placed in an obvious location on the product itself and in related files and documentation. A summary is listed below:

Warnings & Markings:

- Non-ionizing radiation use for diagnosis or treatment
- ESD sensitive port
- Interference warning
- Minimum amplitude of the patient's physiological signals and consequence of use below specified standard limits
- If tested in-situ, the list of frequencies tested and a warning that some frequencies specified by the standard were omitted due to the specifics of the in-situ testing

Environment Use:

- Shielded location,
- Domestic, hospital, etc. use,
- Potential electromagnetic site survey at the installation location, and
- An EMC site survey might be needed for EMC sensitive products; if EMC noise level is too high, preventive actions need to be taken.

Limitation of Use:

- Use by healthcare professionals only
- Interaction with adjacent equipment
- Distance to RF communication equipment (tables)
- Floor specification
- Mains power quality
- UPS use for respiratory devices

Safety Instructions for Accessories:

- Cable types and lengths
- Specifications for replacement parts of the manufacturer-provided cables, accessories and components

Justification for Lower Immunity Levels:

- Due to physical, technological or physiological limits of the device; for example, Radiated Immunity tested at 1V/m between 150-160MHz.

OTHER GLOBAL ACCESS CONSIDERATIONS

Above and beyond the above-mentioned considerations, medical devices also face the same hurdles as most every other product intended for sale in foreign markets. For example, the product will need to be designed to meet all mandatory base certifications and safety deviations peculiar to each individual country, which may be different from those in the US, Canada and EU. In addition, certain countries require the applicant to be a legal entity in that country, while some require the actual testing to be done in-country, meaning manufacturers need to assure samples are available in sufficient quantities and timeliness. Translation of user documentation can also pose problems.

Further, some countries have specific EMC regulations that may have more stringent limits than the US, Canada or the EU, while other countries may not allow the use of certain radio frequencies.

The bottom line is that garnering international approvals can be difficult enough for any type of product; getting approvals for a medical device is only more difficult. However, choosing the right testing partner can help a medical device manufacturer lower its level of difficulty. The right testing laboratory will help a medical device manufacturer identify legal requirements and harmonized standards, make sure properly configured product samples are available, coordinate shipping, assure appropriate documentation and language, and execute pre-tests to assure compliance.

BRAVING THE NEW WIRELESS WORLD

While wireless technologies have opened up a seemingly unlimited world of potential, many medical device manufacturers face a delayed introduction for their products utilizing wireless technologies due to the additional compliance requirements. Unfortunately for those manufacturers, a delayed product launch in a hotly contested market such as that for medical devices can have severe downstream ramifications in terms of market adoption and acceptance, resulting in lower share-of-market opportunities and lost revenues.

The easiest way for medical device manufacturers to mitigate the likelihood of compliance-caused launch delays is to involve the testing laboratory as early in the product development cycle as possible. While the product is still in the concept stage a testing laboratory can advise the manufacturer about the general regulatory requirements and suggest wireless technology options suitable from the point of view of technical certification. When the manufacturer has a clear idea of what the product looks like, the test lab can determine exact requirements based on technical specifications. This approach introduces a significant degree of confidence into the regulatory compliance process, increasing the odds that the product passes the tests and gets to market on time and on budget. IN

(the author)

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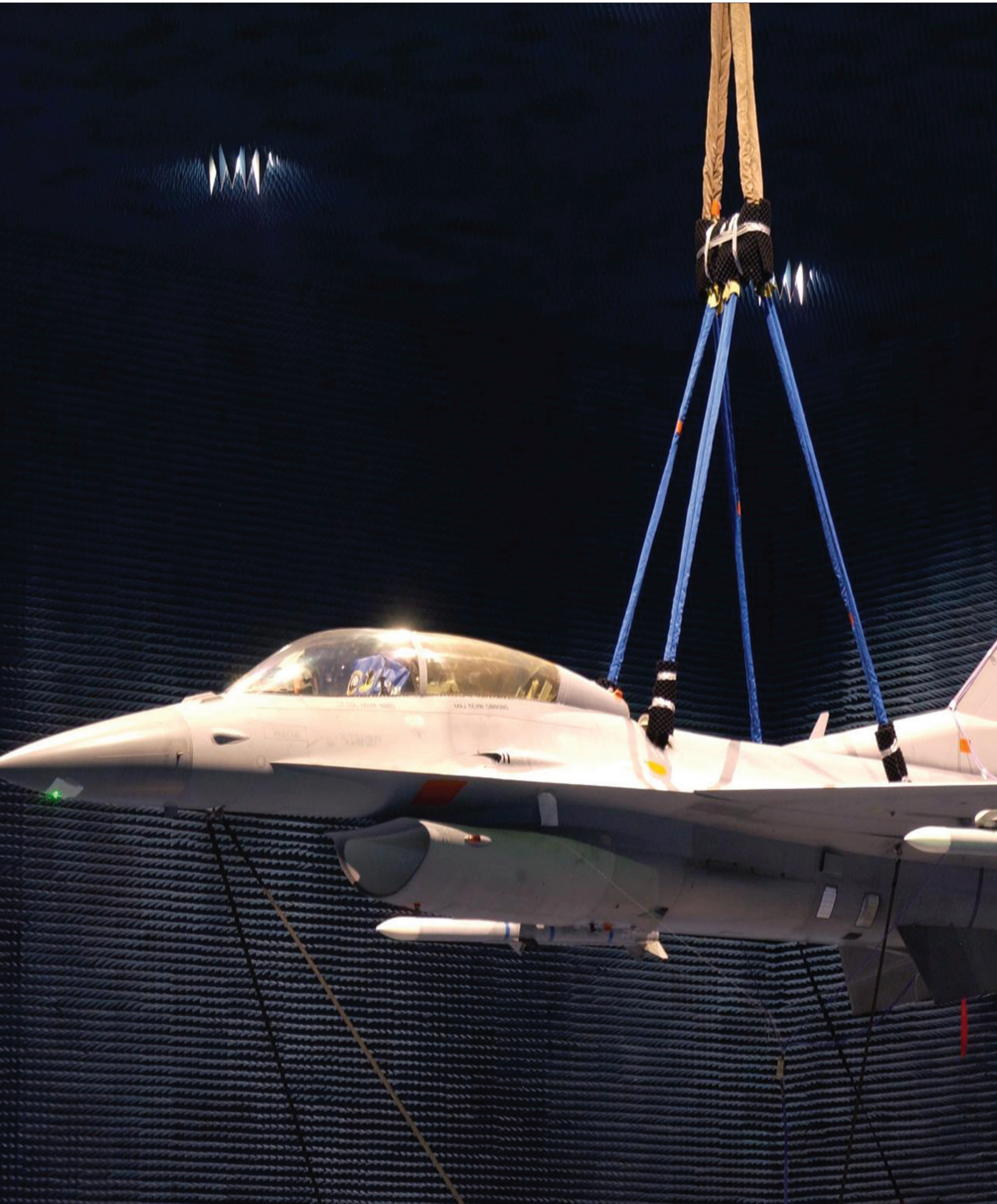

(More) On Field-To-Wire Coupling Versus Conducted Injection Techniques

Investigating a Significant Discrepancy in Modern Bulk Cable Injection Test Methods

BY KEN JAVOR

In the 1990s, bulk cable injection (BCI) techniques were still relatively new and controversial. BCI in support of high intensity radiated field (HIRF) certification had been incorporated in RTCA/DO-160C section 20 in 1989. In 1993, MIL-STD-461D added (for the first time) BCI type CS114, CS115, and CS116 requirements. Long after adoption in these standards and others, controversy raged in some quarters over their legitimacy. Figure 1 shows representative BCI-type limits.

In this charged atmosphere, (Javor 1997) entitled, "On Field-To-Wire Coupling Versus Conducted Injection Techniques"

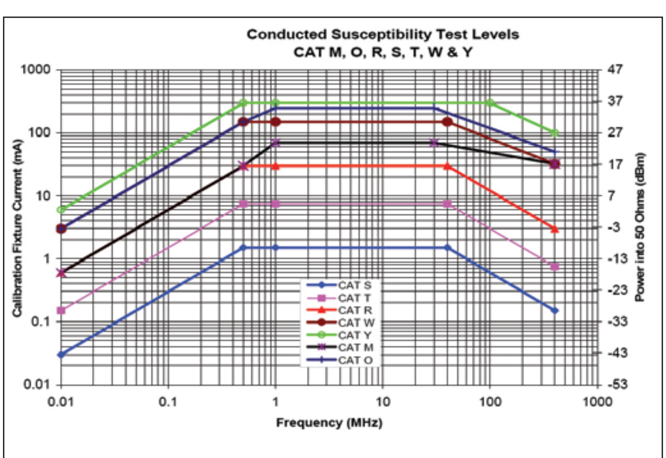

Figure 1a: RTCA/DO-160G Section 20 Rf Conducted Susceptibility Limits

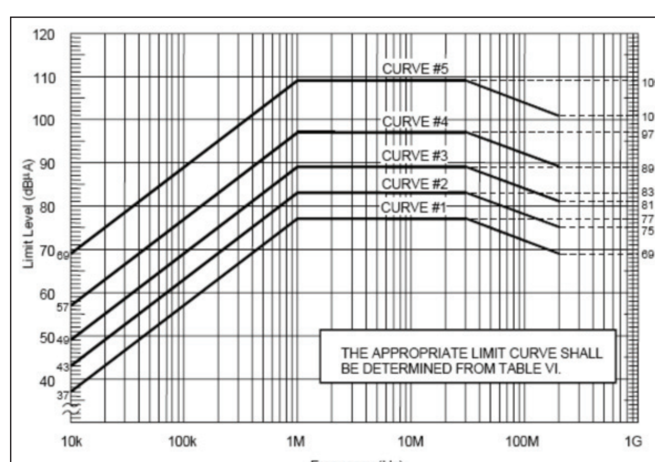

Figure 1b: MIL-STD-461F CS114 Limits

was presented and published, then publicly debated in front of audiences. It provided the canonical basis for bulk cable injection (BCI) requirements.[1] In addition to the physical analysis basis, various practical objections were listed and discussed.

But one item escaped perusal by both pro and con factions. Hence the present effort and title. MIL-STD-461 CS114 and CS116 test methods did something different than the BCI test methods in RTCA/DO-160C/D. All BCI test methods require the same pre-calibration of forward power in a calibration fixture, but RTCA/DO-160C/D, SAE ARP-1972 and DEF STAN 59-41 all use that recorded forward power to inject on the cable-under-test (CUT), subject only to an over-current limit that is a set value (roughly 10 dB in RTCA/DO-160) above the maximum level in the appropriate curve. So for instance, in Figure 1a, the over-current limit for the green curve according to RTCA/DO-160C/D is 1 Amp, at any frequency from 10 kHz to 400 MHz. For the blue curve, the over-current limit would be 5 mA, over the same frequency range. But MIL-STD-462D (1993), the test procedures for MIL-STD-461D, made the over-current limit 6 dB above the appropriate curve in Figure 1b, *at the frequency of interest*. RTCA/DO-160E (2004) partially followed along with that for some categories, but retained the 10 dB over-current limit for others. RTCA/DO-160F went the MIL-STD-461 route completely in 2007 and that was retained in RTCA/DO-160G.

The purpose of this investigation is to compare and contrast the original and modern methods – the differences are stark. Relative to the original technique, and to how electromagnetic fields actually couple to wires, the modern technique can under-test shielded cables at low frequencies by up to 40 dB.

(Javor 1997) explains the physics of electromagnetic field-to-wire (FTW) coupling and presents experimental test results validating the analytical treatment (Figure 2). Faraday's Law is sufficient to explain the Figure 1 limits. The low-frequency limit flattens above the frequency at which the cable's physical length becomes 1/2 wavelength electrical length, the boundary condition for maximum coupling.

Both CS114 and Section 20 (-160F/G) present a family of limits (expressed as induced currents vs. frequency) that are initially calibrated in a standardized fixture. The power required into the injection clamp to induce those current levels is recorded. Then the injection clamp is placed around the cable-under-test (CUT), along with a current probe to monitor injected current. Probe power is increased until either the desired current level from the standard limit (plus 6 dB) is induced, or the power limit is reached, whichever comes first.

ELECTROMAGNETIC FIELD-TO-WIRE COUPLING – RESULTS DEPEND ON WIRE LOAD IMPEDANCE

But that isn't how the technique was developed – it was much simpler to begin with, and the point of this investigation is to show the original technique provided a better simulation of electromagnetic FTW coupling.

Originally, once the power required to drive current in the calibration fixture had been recorded, that power was used to drive the clamp placed on the CUT, irrespective of the actual current induced on the CUT. A current probe was used to monitor and record the induced current, but it was for information only, not part of the control/leveling loop during the test (except for the really stringent frequency-independent over-current limit cited in the introduction). Anyone familiar with these tests can see the workload is much lower, and in fact commensurate with manual operation, whereas the modern test procedure practically demands automation, and was in many cases one of the first susceptibility tests to be automated, due to the workload.

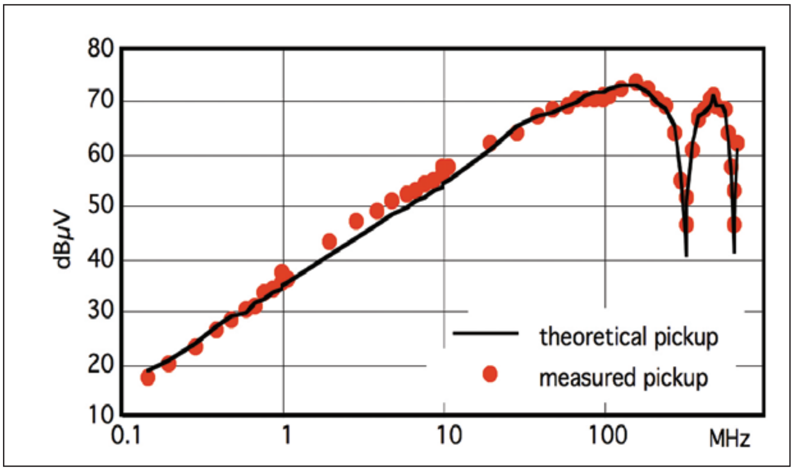

Figure 2: Theoretical and experimental prediction of field-to-wire coupling [Figure 7 in (Javor 1997)]

The discrepancy between the two test methods is most noticeable on a low impedance cable at low frequencies, i.e., a shielded cable with good terminations to continuous metallic structure at both ends, and at frequencies where the cable is electrically short. Under these conditions, the impedance presented by the CUT is at greatest variance from that of the calibration fixture, which provides a 100 Ohm loop. One might expect more current in the lower impedance loop, but the physics is more complex than that. (Javor 1997) uses Faraday's Law to compute FTW coupling, and demonstrates that the coupling will increase monotonically with increasing frequency when the cable is electrically short, and then flatten out

when the cable approaches and exceeds a half-wavelength in length, which is the characteristic of the limits shown in Figure 1. But, and here is the crux of the problem discussed herein, Faraday Law's calculates the coupled potential, and these limits control coupled current. The relationship between coupled current and potential is only constant when the circuit has resistive terminations whose value dominates the cable impedance. That is not true when a cable is shielded, and the shield is well-terminated, as is the case for safety-critical flight and engine controls. Under such conditions the cable impedance is inductive from the low end of the requirement frequency range (10 kHz) until the cable is at least a tenth wavelength long. Over that frequency range, the impedance of the cable increases monotonically with increasing frequency, just as does the Faraday Law coupled potential. Therefore the coupled current, expressed as the ratio of coupled potential to cable impedance, should be constant as a function of frequency. This is hardly a new observation; it was presented by A.A. Smith in 1977 in his seminal book on the topic of "Coupling of External Electromagnetic Fields to Transmission Lines," (Smith 1977). Figure 2-4 on page 25 of the second edition, reproduced here as Figure 3, displays the results of a numerical analysis showing the significant difference between the flat current vs. frequency profile for a low impedance cable vs. the increasing current on a resistively loaded high impedance cable.

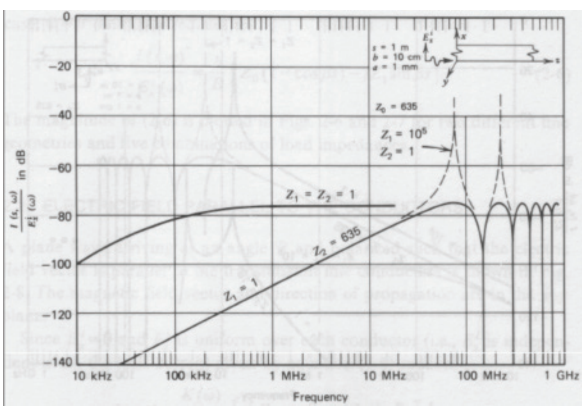

Figure 3: Figure 2-4 from (Smith 1977), by permission from Interference Control Technologies

Upwards of 40 dB difference is evident between the high and low impedance cases.

This report presents measurements of electromagnetic field coupling to high and low impedance electrically short transmission lines, and the correspondence to the two different BCI test methods.

For the FTW coupling measurements, the same parallel plate was used as in (Javor 1997). The plate, shown in Figure 4a, is 12" wide, and 6" tall (one-tenth wavelength at 200 MHz), yielding a 90 Ohm characteristic impedance, with 50 to 90 Ohm and 90 to 50 Ohm matching networks used at each end to match to 50 Ohm test equipment. Plate performance as shown in Figure 4b over test frequency range (up to 30 MHz) is lossless. The transmission line exposed beneath it was one meter long, suspended five centimeters above ground. As such, it was one half-wavelength long at 150 MHz, and a tenth wavelength long at 30 MHz. Over the investigation range of 10 kHz to 30 MHz, the cable is very short and thus coupling is inefficient. There was no attempt to make it a matched transmission line; the wire was terminated in 50 Ohms at each end, to aid in direct comparison to BCI testing in the

Figure 4a: Parallel plate used to illuminate cable (the observation that red Solo© cups are easy to stack is not original, although stacking them to provide precise plate height adjustment might be)

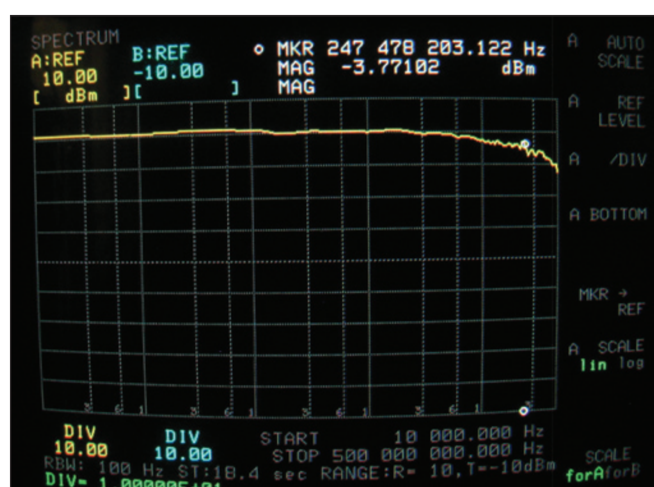

Figure 4b: Load end plate potential when driven by 15 dBm with nominal 15 dB loss impedance matching adapters: plate is lossless below 30 MHz

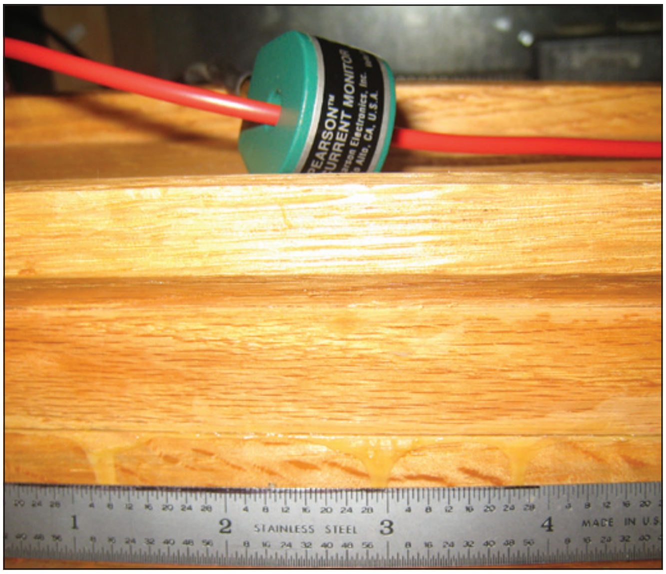

Figure 5a: Model 2877 current probe installed on wire under plate

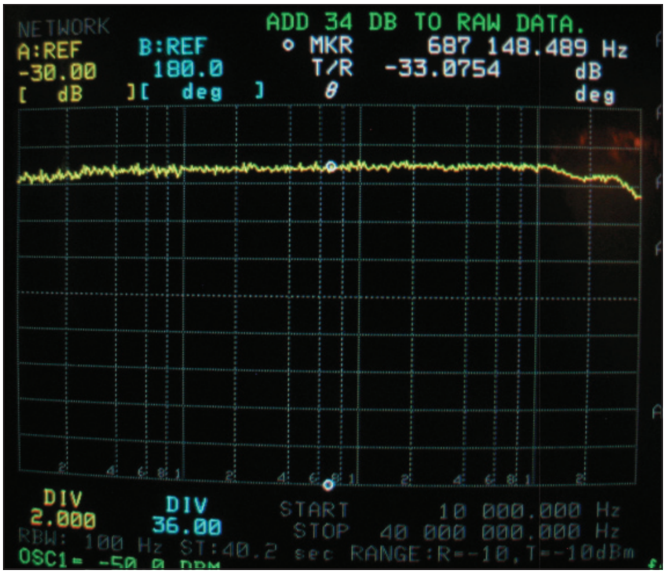

Figure 5b: Model 2877 transfer impedance loaded by Stoddart 95010-1 rod antenna base. Units are dB above 1 Ohm. Trace is noisy because fixture current is 20 dBuA. Using an active impedance-matching device with the current monitor requires assessment of noise contribution.

second half of the investigation. At a tenth wavelength and smaller, the resultant mismatch causes no measurement inaccuracy.

Figure 5 portrays a 1 Volt/Amp Pearson Electronics Model 2877 current monitor used for these measurements. The high and flat transfer impedance (1 Ohm, 1 kHz to >100 MHz) of this small monitor (0.25” window diameter) was necessary to measure extremely small currents when exposed to a 4.6 V/m field intensity. Ordinary-sized hinged current probes did not provide sufficient rejection of the electric field. Since the probe is designed to have a 50 Ohm output impedance, and the 1 V/A transducer factor only applies into a high impedance, a Stoddart 95010-1 rod antenna base was used as a matching network. It was specifically designed for this very purpose: the amplifier has 0 dB (voltage) gain from 10 kHz to 40 MHz. The dBuV legends on the plots in Figures 6, 7b and 9 are dBuA rather than dBuV as shown, when the 1 V/A transfer impedance or other pertinent conversion factors are applied to the raw data.

An HP 4195A network/spectrum analyzer was configured as a spectrum analyzer, using its maximum source output of 15 dBm to drive the plate. This results in 4.6 V/m field intensity, due to losses in the matching network and the 15 cm plate height. This can be computed looking at Figure 4b and from a knowledge of the matching networks, which provide a 75 Ohm shunt resistor facing the 50 Ohm side, and a 60 Ohm series resistor facing the 90 Ohm side. The loss on the load end is 9.5 dB, so the 107.25 dBuV reading is adjusted upwards 9.5 dB and then further adjusted for the 15 cm height to reach a field intensity of

107.25 dBuV + 9.5 dB – 20 log (0.15) dB meter = 133.25 dBuV/m = 4.6 V/m

Figures 6a and b show coupled current from this 4.6 V/m field to the previously described transmission line beneath it from 10 kHz to 30 MHz (where the cable is one-tenth wavelength long). Figure 6a is coupled current to the line terminated in 50 Ohms. Figure 6b is the same as 6a, but the line has both ends shorted to ground.

Analysis based on (Javor 1997) computes the induced potential on an electrically short line as

$V_i = 2\pi lh\, E_O/\lambda$

Using the one-meter length, wire height of 5 cm, 4.6 V/m illumination and the stop frequency of 30 MHz (10 meter wavelength), the coupled potential is 0.145 Volt. That will induce 57 dBuA into a transmission line terminated in 50 Ohms at both ends (100 Ohms terminations in addition to ~180 Ohms loop inductance). The measured value in Figure 6a is 57 dBuA.

Also note that while the coupling has begun to flatten out near 20 MHz, the slope from 100 kHz to 10 MHz is 20 dB/decade as predicted by theory – below 100 kHz the data is noise floor limited. The flattening at the high frequency end is due to the selection of 50 Ohm loads on the ~300 Ohm transmission line; line inductive reactance is a significant fraction of the termination resistance on this mismatched line.

The same analysis computes a coupled current of 58 dBuA in a shorted line at 30 MHz, based on an inductive reactance of 1 uH/m for one meter, at 30 MHz. The measured value is 59 dBuA. The important property to be noted is the flat current vs. frequency profile all the way down to almost 10 kHz, as compared to the current vs. frequency profile in the matched transmission line. At 10 kHz, there is 50 dB difference between the current in the two lines, and that is dynamic range-limited: Figure 6a is showing noise floor below 100 kHz.

What this means is if we limit BCI current on a shielded cable to that induced in a 100 Ohm calibration jig circuit, or even 6 dB above that, we are vastly under-testing relative to what is induced by electromagnetic field illumination, which is checked when an aircraft is HIRF-qualified. During a low-level swept cw (LLSCW) illumination of an aircraft undergoing HIRF certification, we expect to measure more current on an aircraft-installed shielded cable at low frequencies than to what it was subjected during Section 20 rf conducted susceptibility testing, assuming the illumination and curve categories line up. In turn, this would force requalification of the installed system to the value predicted by the LLSCW scan.

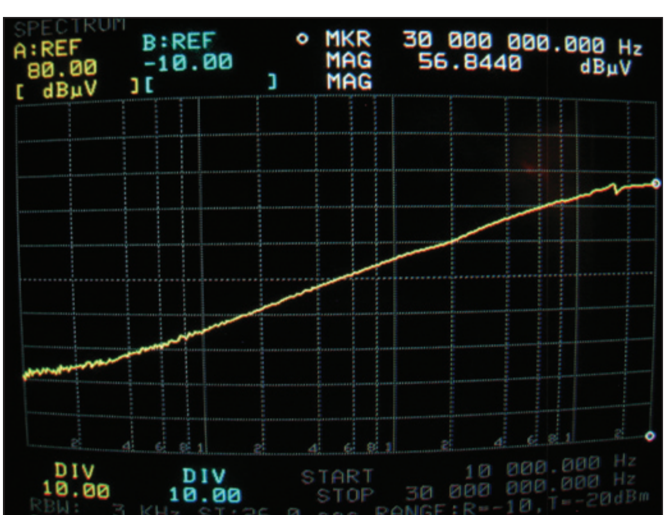

Figure 6a: Current coupled to XMSN line terminated in 50 Ohms from 10 kHz to 30 MHz. 4.6 V/m illumination. (white line is 20 dB/decade)

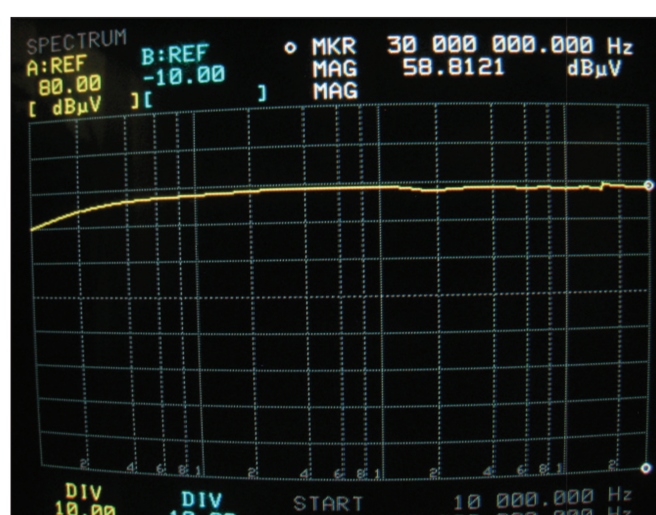

Figure 6b: Current coupled to short-circuited transmission line 10 kHz to 30 MHz. 4.6 V/m illumination.

BULK CABLE INJECTION TEST RESULTS

Figure 7a shows the set-up for pre-calibrating the forward power required to inject Figure 6a currents in the standard 100 Ohm calibration fixture per aircraft, automotive, and defense BCI test procedures. Figure 7b shows very close agreement between the electromagnetic field-to-wire coupling in Figure 6a and the current in the calibration fixture when the Tegam Model 95242-1 clamp is driven by -13 dBm from 10 kHz to 30 MHz. The Model 95242-1 has a nominal frequency range of 2 – 400 MHz, but note that for a cable of this length, its 20 dB/decade insertion loss roll-off at lower frequencies works very well to model FTW coupling.

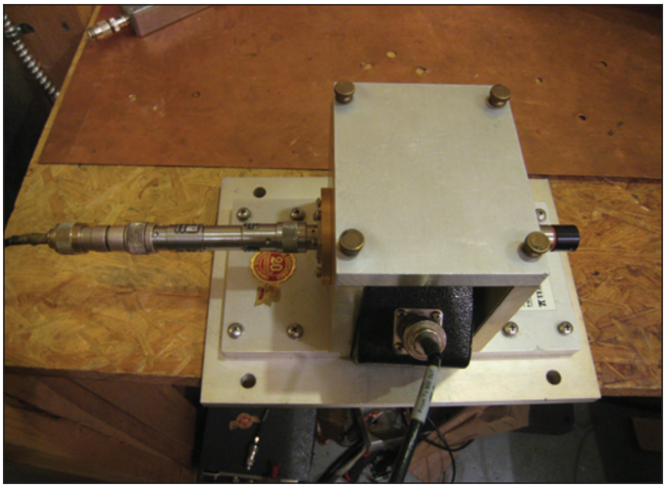

Figure 7a: BCI Pre-calibration set-up. To the left is 34 dB attenuation, so that the spectrum analyzer reads current directly.

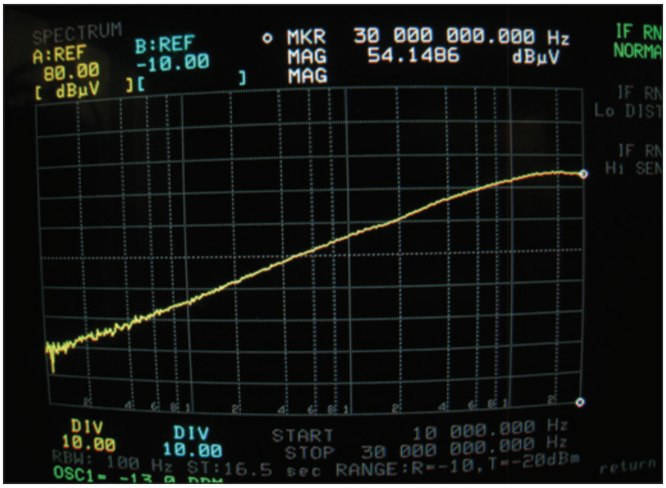

Figure 7b: Current in 100 Ohm calibration fixture – compare to Figure 6a.

Figure 8a: BCI on wire terminated in 50 Ohms at each end.

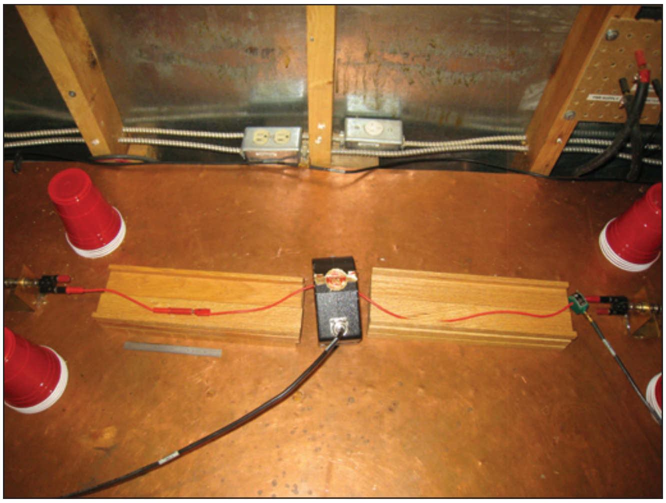

Figure 8b: BCI on wire terminated in short-circuit at each end.

Figures 8a and b show the set-up for injecting current in the same transmission line that was formerly under the parallel plate shown in Figure 4a. The wire has not been disturbed, only the top plate has been removed. Figure 8a shows injection on the wire terminated in 50 Ohms at each end, while Figure 8b shows the injection on the same wire terminated in a short to ground. The only change is which banana jack is selected.

Figures 9a and b show current coupled to the 50 Ohm and short-circuited wire, respectively. Not surprisingly, Figure 9a is identical to Figure 7b, because the only difference between the calibration fixture and the cable is conductor length, and both are electrically short in this investigation.

Comparing Figure 9b to Figure 6b is the payoff. Although the BCI calibration was performed in a 100 Ohm fixture, using the pre-calibrated drive value in the short-circuited wire yields the same current as when the short-circuited wire was exposed to an electromagnetic field. The roll-off at the high end of Figure 9b is due to the insertion loss of the 95242-1 flattening out in a manner not compensated for by the simple single-value pre-calibration performed in Figures 7. Had a true frequency-by-frequency pre-calibration been performed, curves 6b and 9b would have been identical. Also note that the short-circuit BCI results are due to the high insertion loss of the clamp at the lower frequencies, which is carefully controlled by identical Bode plot limits in both MIL-STD-461 CS114 and RTCA/DO-160 section 20. Insertion loss at lower

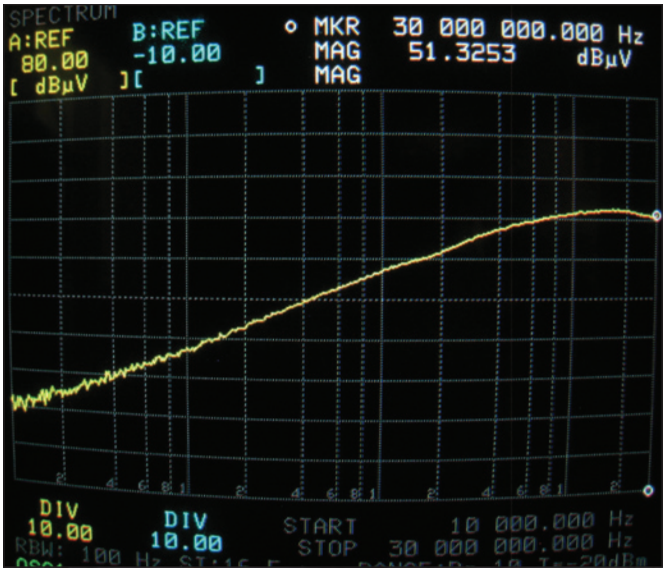

Figure 9a: Current coupled to 50 Ohm wire due to BCI driven at the Figure 7b -13 dBm level. Compare to Figure 7b.

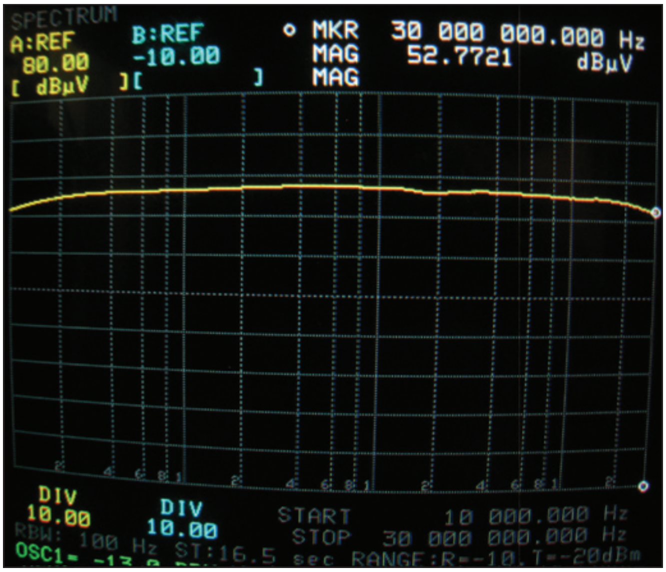

Figure 9b: Current coupled to short-circuited wire due to BCI driven at the Figure 7b -13 dBm level. Compare to Figure 6b.

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  - PDN optimization
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  - 3-D IC, TSV, and Multi-Chip Modules
- Tools and methodologies
  - Jitter/Noise/Crosstalk/BER;
  - De-embedding methodologies
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  - Embedded test
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  - Simulation and measurement correlation
  - Advanced simulation tools/algorithms
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  - SI/PI for chip/package/board/connector / cable co-design
  - SI/PI co-analysis
  - System-level SI/PI/EMI co-design

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- Unmanned Aircraft Systems EMC
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- Legal Issues

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- Standards and Regulations

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- Atmospheric & Man-Made Noise

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Low Frequency EMC (TC7)
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frequencies is due to magnetizing inductance, which is a low impedance in shunt with the 50 Ohms driving the clamp. If it weren't for the magnetizing inductance, the clamp would act as a near ideal transformer with either 1:1, or 2:1 step-down ratio, depending on model, which in turn would insert either a 50 Ohm or 12.5 Ohm impedance in series with the CUT, severely limiting short-circuit current. These insertion loss limits are archaic relics in the present versions of these standards, since it is injected current that is controlled, with a power limit protecting against too much *potential* in a *high* impedance circuit. But with a change back to injecting a pre-calibrated power, these insertion loss controls become critical to achieving correct low impedance cable current.

RAMIFICATIONS

It is clear that the original, simple method of injecting a pre-calibrated power level and "letting the chips fall where they may" does a better job of simulating electromagnetic field-to-wire coupling at frequencies where the cable is electrically short. Which is precisely the frequency range where the BCI-type requirement and test method is needed; BCI requirements allow proper stressing of such a cable when it is impossible to electromagnetically illuminate the actual length.

However, just blindly using the limits shown in Figure 1 on platforms smaller than battleships will result in a massive over-test instead of the present under-testing. This is because the 500 kHz/1 MHz breakpoints in the Figure 1 limits correspond to platforms respectively 300 meters and 150 meters long. While MIL-STD-461 contains instructions to tailor the limit for platform size, in the author's experience this is rarely done. While RTCA/DO-160 is not tailored, the application to HIRF certification recognizes that the low frequency breakpoint shifts upwards for smaller aircraft (FAA 2014). Applying the original BCI test technique on a shielded cable using these untailored limits applies the flat portion of the limit all the way down to 10 kHz. If a platform is instead 15 meters in length, the breakpoint frequency for the limit would be 10 MHz, which means that the pre-calibrated drive levels below 1 MHz would be 20 dB lower than for the untailored limit.[2] See Figure 10.

From the above discussion, we can make the following inferences and draw some conclusions.
Assume the tailored green curve of Figure 10 is correct and the proper baseline for a fifteen-meter platform.

The drive level relative to the untailored limit is 20 dB lower below 1 MHz, so the short-circuit current will be 20 dB lower than for the untailored limit. Figure 11 shows actual (scaled) test results using a Tegam 95236-1 injection clamp.[3] Figure 11 data was taken at specific frequencies along the continuous curves of Figure 10. The dashed lines are there to make trends clear, not to represent actual data.

Green data points are current in a low impedance cable when subjected to the MIL-STD-461F Curve 5 limit tailored for a 15 meter long platform as shown by the green curve in Figure 10. The forward power drive level into the 95236-1 was recorded when the green curve of Figure 10 was induced in the 100 Ohm calibration fixture.

Black data points in Figure 11 are the currents on a low impedance cable tested to MIL-STD-461F Curve 5. The levels are 6 dB above those shown in the black curve of Figure 10 because MIL-STD-461F CS114 requires testing to 6 dB over the limit if the precalibrated power limit is not exceeded before achieving the +6 dB level.

The red data points are the currents in a low impedance cable if the MIL-STD-461F CS114 limit is not tailored and the

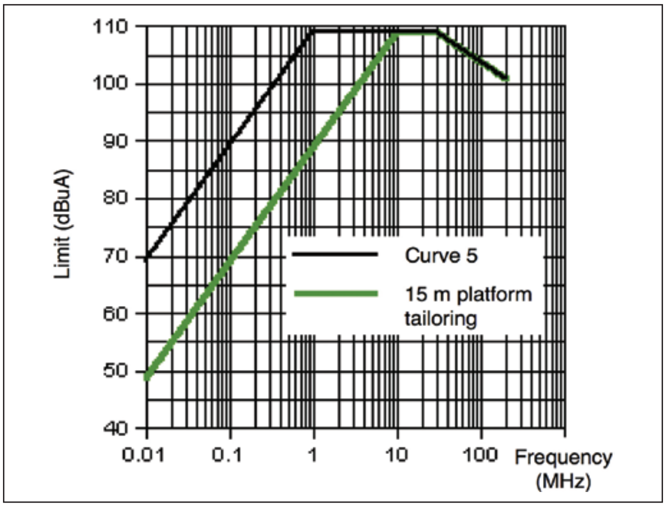

Figure 10: MIL-STD-461F CS114 Curve 5 (200 V/m equivalent) limit original, and tailored for a 15 meter platform

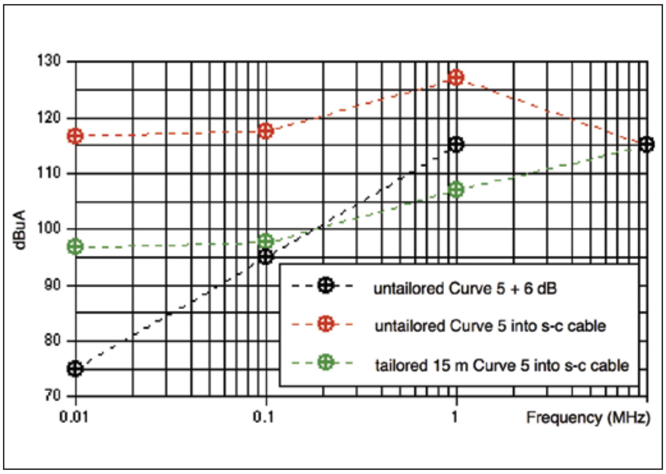

Figure 11: Comparison of modern and traditional injection protocols, based on MIL-STD-461F CS114 Curve 5, including tailoring of that limit for a 15-meter platform

precalibrated forward power is applied without the modern limit as for the black data points.

Using the green data points as a baseline best approximation to the reality of electromagnetic field-to-low impedance wire coupling, it is clear that the presently used method of MIL-STD-461F (and similarly, RTCA/DO-160E/F/G) results in under-testing up to 20 dB at 10 kHz. At the same time, applying the original testing approach without tailoring the limit for a fifteen-meter platform results in over-testing for the smaller platform by up to 20 dB.

CONCLUSION

It is important to note that if the original test method were re-adopted but the present limits not tailored, the increase in injected current would be up to 40 dB at 10 kHz. For field-to-wire coupling, this would only be appropriate on a very large platform, and, on the basis of field-to-wire coupling alone, would result in massive over-testing for the majority of platforms that are fifteen meters in extent, or smaller. But airborne and ground vehicles tend to use structure for primary power return, and such large currents are in fact present on structures for that reason, and cables with shields terminated to structure at both ends will have such currents induced, and possibly causing ground plane interference (GPI) to poorly designed circuits. This is one more reason for adopting the original BCI test technique.

ACKNOWLEDGEMENTS

The author wishes to thank Mr. Mark Nave of Mark Nave Consultants and Mr. David Brumbaugh (Boeing) for thorough and thoughtful reviews. Any errors are the sole responsibility of the author.

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ENDNOTES

1. Canonical meaning rule-based: induced current of 1.5 mA per Volt per meter when cable is at least one-half wavelength long; 20 dB per decade roll-off when cable is shorter than that. As opposed to the heuristic approach, where cable currents are measured on a variety of aircraft in various locations and some sort of statistical average is used as a limit. The reader should be aware that this article presents a canonical school of thought on this matter, and there are those who disagree, and feel that BCI limits should be solely based on heuristics – DEF STAN 59-41 and 59-411 use heuristically-based limits. In effect, the commercial aircraft HIRF certification process described herein is a heuristic process, but the BCI limits in MIL-STD-461 and RTCA/DO-160 are canonical. The heuristic school-of-thought considers such limits a convenient simplification. If currents measured on various platform cables are the sole basis for limits, as in DEF STAN 59-411, then the present method of leveling on injected current with a power limit for high impedance cables does suffice.
2. Fifteen meters (~50 feet) was arbitrarily chosen to cover the vast majority of vehicles, air and ground. Clearly ships and large transport aircraft are a different story.
3. The (Eaton) 95236-1 and the 95242-1 are the original clamps around which the test method centered back in the 1980s when it was first developed. The 95236-1 is well-suited to the low frequency portion of both the MIL-STD-461 and RTCA/DO-160 limits. The 95242-1 used when tailoring the limit for the short wire used in this investigation was developed for use at higher frequencies, and is generally used above 10 MHz, where it is more efficient than the 95236-1, which is more efficient below 10 MHz.

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KEN JAVOR

has worked in the EMC industry over thirty years. He is a consultant to government and industry, runs a pre-compliance EMI test facility, and curates the Museum of EMC Antiquities, a collection of radios and instruments that were important in the development of the discipline, as well as a library of important documentation. Mr. Javor is an industry representative to the Tri-Service Working Groups that write MIL-STD-464 and MIL-STD-461 (the "G" effort presently underway). He has published numerous papers and is the author of a handbook on EMI requirements and test methods. Mr. Javor can be contacted at ken.javor@emccompliance.com.

Current Probe Electric Field Rejection Challenges

Figure 1: Results of illuminating a conventional hinged current probe in a 4.6 V/m field. There is a 30 dBuV low-frequency plateau, which is well above the actual current coupled to a wire by the illuminating field (see article).

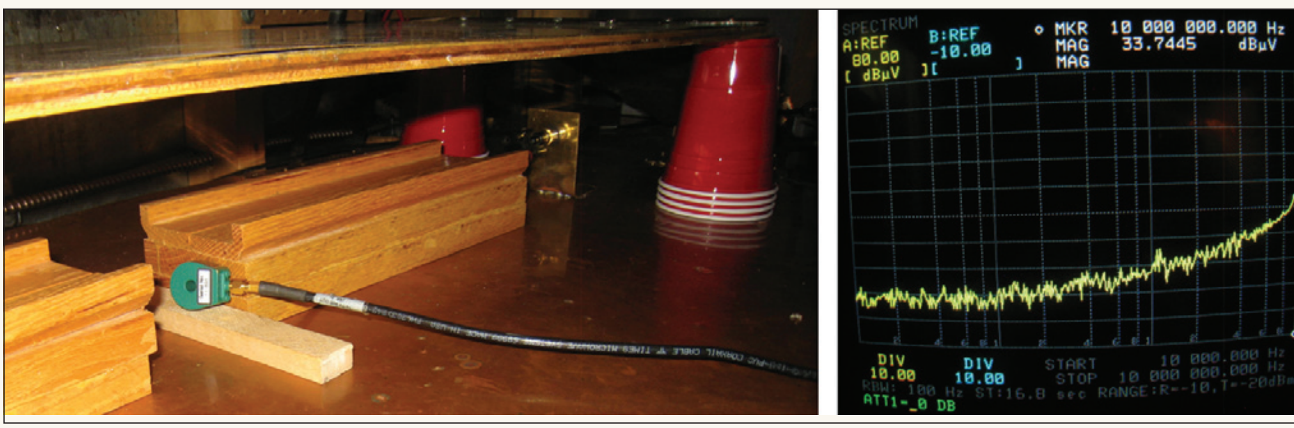

Figure 2: Results of illuminating a physically small current monitor in a 4.6 V/m field. The noise floor is below 10 dBuV and compared to the coupling data in the article, does not pollute the test results.

Measuring minute low-frequency currents in the presence of a strong external electric field proved challenging. The actual coupling to the 50 Ohm terminated line at 10 kHz was noise floor at lower than 10 dBuA. Even with a high transfer impedance such as 1 Ohm, that means any electric field coupling must be less than 10 dBuV. Given the 4.6 V/m incident field, that means the current probe's "antenna factor" had to be larger than 123 dB/m. Ordinary hinged current probes used in EMI testing proved unequal to the task. See Figure 1 for typical results from a 1 Ohm transfer impedance probe.

A current monitor works according to the same principle as a current probe, but lacks the ability to be opened and closed. This makes it less appealing as test equipment, but when maximum rejection of electric field is a necessity, Figure 2 shows that the current monitor provides the necessary performance.

Prior to resorting to the use of a small current monitor, an attempt was made to seal up all the possible leaks in a conventional probe. The results were fruitless, even though Figure 3 shows comprehensive extra shielding.

Figure 3: Conventional probe all taped up – leakage wasn't affected. Leakage through the inner seam circumferential around the probe's window (must be left open to avoid eddy currents on the enclosure) dominates.

A New European Union Directive Approach for Radio Equipment

The New European Union Radio Equipment Directive and the New Legislative Framework

BY MARK MAYNARD

"Progress is impossible without change, and those who cannot change their minds cannot change anything." - George Bernard Shaw

The current European Union (EU) Directive for Radio and Telecommunications Terminal Equipment (R&TTE), was originally adopted by the European Commission (EC) in 1995, almost two decades ago. As I am sure you have noticed, there have been a multitude of engineering advances in radio and telecom devices in that time, and the industry stakeholders have been clamoring more and more for a major overhaul of these requirements, to ensure that compliant products utilizing the latest technologies are safe for consumers, and are efficiently and quickly brought to the EU market countries, without undue or unnecessary regulatory hurdles.

A different EC regulatory effort, started by the EU member states about fifteen years ago, was driven by a desire to institute a better way to make laws, by identifying all of the parties that were involved in the entire lifecycle of products placed into the EU marketplace, so specific roles and tasks could clearly be assigned to each. Other drivers included the need to clarify the definition for placing products on the market, the need for more robust market surveillance methods and activities, and clarification on the responsibilities of the national regulatory compliance authorities.

These two forces resulted in the release of a new Radio Equipment Directive (RED) this year, which will be replacing the R&TTE Directive over the next few years, so it is important for manufacturers, product developers, and all other interested parties to start preparing for this change. We'll first look at the changes that have been made to the EU law-making processes and guidance, then look at the new RED, and how all the different groups will need to transition and adapt to the new regulatory landscape.

A NEW FRAMEWORK FOR EU LEGISLATION

Right around the millennium, the EC was able to obtain agreement from all of the EU member states for an initiative to perform a thorough review and extensive update of the regulations that were in place. The results of these efforts came in 2008, with the adoption of Regulation 765/2008/EC, which set the requirements for accreditation and market surveillance related to marketing of products in the EU, consolidated the meaning of CE marking, and at the same time

An additional key change is the legislative emphasis for EU market access. What is currently defined as "placing on the market" has changed in the New Legislative Framework to the first "making available on the market" of a product in the EU.

repealed and replaced the previous Regulation 339/93/EEC, and Decision 768/2008/EC, which established a common framework for the marketing of products in the EU by harmonizing and consolidating the various directives with common definitions, conformity assessment procedures, conformity assessment bodies notification criteria, economic operator responsibilities, and rules for CE marking, and at the same time repealing and replacing the previous regulation Decision 93/465/EEC. Together, these two pieces of legislation established the "New Legislative Framework" (NLF), which provided all of the necessary elements for a robust and comprehensive regulatory framework.

One of the main pillars of the NLF is to ensure that the definitions and obligations of all of the "economic operators" are clarified; *economic operators* is the term used in the NLF for commercial business stakeholders such as manufacturers, authorized representatives, distributors, and importers. An emphasis is placed on the roles and responsibilities of the manufacturers and importers, as they are seen as the two groups that are the most accountable for any issues resulting from the placement of products into the EU.

A second NLF pillar can be seen in the comprehensive measures incorporated to trace the product supply chain, identifying all of the economic operators in the whole process, and their relation to the product and to each other. One key change is that the manufacturers and importers must provide more information to aid in their identification and contact by customers and other stakeholders.

Another NLF focus can be seen in the consideration given to the entire product life cycle, "from cradle to grave," to enhance the market surveillance activities. This is being done to help prohibit non-compliant or risky products being placed in the EU. To support this, the responsibilities for all of the national authorities are clarified and defined, recognizing the variety of activities of the different groups, including regulatory authorities, notification authorities, national accreditation entities, market surveillance bodies, and importation agencies.

An additional key change is the legislative emphasis for EU market access. What is currently defined as "placing on the market" has changed in the NLF to the first "making available on the market" of a product in the EU. "Placed on the market" was defined as when it is made available for the first time on the EU market, so this created some ambiguity with those that thought this implied when it was first placed for sale, and some manufacturers would send product samples to customers for free, before it had been tested for conformity, since it wasn't yet placed on the market for sale. The NLF removes this ambiguity with the phrase "made available on the market," which is defined as when it enters the EU, whether it is supplied for distribution, consumption, or use on the EU market in a commercial activity, whether it is sold or is given away for free no longer matters; if you bring it into an EU member state, it must be in conformity with a full technical construction file and CE Declaration of Conformity to the applicable EU Directives.

Market surveillance policy has been revised, to make it more comprehensive, and to place equal emphasis on both setting product requirements and market surveillance enforcement criteria. The market surveillance authorities are now not only required to check the conformity of a product according to its intended purpose, as defined by the manufacturer, but also under the conditions of use, which can be "reasonably foreseen," meaning when such use could result from predictable human behavior, but with the assumption that the product will be used in accordance with the applicable laws. A very helpful EC publication covering these topics is the "Blue Guide on the Implementation of EU Product Rules" that is also available for free download from the EC website referenced at the end of this article.

Directive	Entered into Force	Repeal Date	Notes
R&TTE 1999/5/EC	April 7, 1999	June 13, 2016	Products placed on the market prior to June 13, 2016 can continue under R&TTE until June 13, 2017
RED 2014/53/EU	June 11, 2014	TBD	Products placed on the market on June 13, 2016 or later must utilize RED

Table 1: R&TTE Directive and Radio Equipment Directive Transition

BECOMING RED

Now we will take a look at the transition from the R&TTE Directive 1999/5/EC to the new Radio Equipment Directive 2014/53/EU, and some of the specific changes this will bring. One of the first questions is *When do we have to change?* There is a transitional grandfathering period given in RED, which addresses this concern. Any products that are placed on the EU market in R&TTE conformity prior to June 13, 2016, can continue to be placed on the market under R&TTE until June 13, 2017. However, any products placed on the market on June 13, 2016 or later must be in conformity to RED, and all grandfathered products must conform to RED by June 13, 2017.

Development of RED started in 2007, and the EC sent the first proposals to the European Parliament in 2011. Following the normal process of requesting feedback from stakeholders, and using the provided input to revise the requirements, a compromise on the final text was achieved in January 2014. As mentioned, this is a New Legislative Framework directive, and it was published on May 22, 2014 in the Official Journal of the European Union. It entered into force on June 11, 2014, and all EU member states must amend their national regulations before June 13, 2016 to align with the RED criteria.

One of the first things you may notice about RED is that "Telecommunications Terminal" has been dropped from the title of the previous R&TTE Directive. This is because telecommunications terminal equipment, such as wired telephones and fax machines, has been removed from the scope of RED, and has been transferred to the scopes of the EMC Directive 2014/30/EU and Low Voltage Directive 2014/35/EU. RED will only apply to wireless and radio devices and equipment.

There is specific definition given for radio equipment in RED, which is "an electrical or electronic product, which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radio determination, or an electrical or electronic product which must be completed with an accessory, such as an antenna, so as to intentionally emit and/or receive radio waves for the purpose of radio communication and/or radio determination."
This definition is important in understanding the extent of the types of radio equipment to be covered under the scope of this directive.

The scope of RED will cover radio transmission, including both radio communication and radio determination. The term *Radio Determination* is used to make clear that equipment such as RADAR, RFID, movement detection, and velocity measurement are within the scope of RED. Equipment which is not for radio communication or determination is not in the scope, such as equipment classified for Industrial, Scientific, & Medical (ISM), EN 55011, and CISPR 11.

Also in the scope will be radio reception equipment, including receive-only radio devices. One key change to the scope is the inclusion of broadcast receivers in RED, which were specifically excluded in R&TTE. Broadcast receivers had been in the scope of the EMC and Low Voltage Directives, but this will no longer be the case. Some items specifically excluded from the RED scope include aeronautical radio equipment, and custom evaluation kits intended for professional Research & Development, which are used in actual R&D facilities.

The frequency range of RED is expanded, up to 3 THz (3000 GHz), with no lower limit, meaning that zero Hertz to 9 kHz is now included in the scope. So any radio technologies that operate below 9 kHz now fall under this directive, and other standards bodies such as ETSI and ECO will have to catch up to this change in a standard update.

Another big change is that radio equipment assessed must be able to operate in at least one EU country; if

Under RED, the Class 2 Alert symbol has been removed from the requirements.

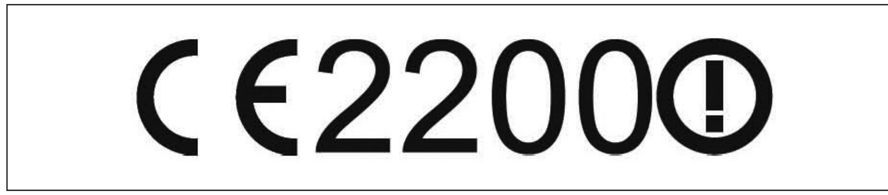

Figure 1: CE Mark for Non-Harmonized Class 2 Equipment with Alert Symbol

not, it cannot obtain CE Mark. While under the R&TTE Directive, products could obtain Notified Body opinions and CE Marking for non-European markets, without being authorized for use in any EU country or CE-marking country, but this is not allowed under RED.

The requirements for animal safety have been clarified in RED. Although the R&TTE Directive did include safety considerations for animals, it wasn't clear. RED specifies and clarifies the requirements for the protection of the health and safety of persons, domesticated animals, and property, including the objectives with respect to safety requirements set out in Directive 2006/95/EC (Low Voltage Directive), but with no voltage limit.

One of the main changes was to clearly identify and define all of the economic operators involved in the process of placing products onto the EU market, so clear roles, obligations, and responsibilities could be assigned, and the market surveillance agencies would be able to assign accountability when issues are found. The four key economic operators are identified as manufacturers, authorized representatives of the manufacturers, distributors, and importers. The manufacturers and importers have been called out as being the two operators that will be held the most accountable for any conformity issues found in the EU, and their expanded roles spelled out in RED reflect this. The chapter 2 definitions in the directive should be closely studied by all of the identified groups, as there will be much more scrutiny and market surveillance activities associated with the different parties, and it will be vital to clearly understand what is required for each operator.

Another new requirement is RED is the mandate to provide more contact information for the economic operators. EU Member States will require the economic operators to include both website addresses and physical location postal addresses, in order to facilitate better communications between the member states, market surveillance authorities, economic operators, and consumers. The equipment must show the product identification numbers and contact information for the responsible parties. A contact name and details must be supplied with each device, and also placed on the device, or in documentation if it is a small device. Importers must show similar information on the equipment or on the packaging; the supply chain must accept the legal responsibility for providing valid contact information.

The conformity of equipment is covered in chapter 3 of RED, with two types of procedures. Internal production controls are covered in detail in Annex II, and the EU-type examination procedures are specified in Annex III. Information that concerns the continued conformity of the equipment will be reviewed, checking that specific precautions that must be taken when the device is assembled, installed, maintained, or used are included and valid. Any equipment that does not meet the requirements for residential areas must be accompanied by a clear indication in the user instructions on the restriction of use to non-residential areas only, and where appropriate it must also be on the packaging.

The requirements and procedures for the notification of Conformity Assessment Bodies (CAB) is found in chapter 4. This includes the requirements and obligations of notifying authorities and notified bodies, including information on applications, changes, operations, appeals, coordination, and notification procedures. Also included is information on challenging the competence of notified bodies, and how to make an appeal against a decision made by a notified body.

Chapter 5 covers market surveillance, which is an area that will be subject to much more activity under the NLF scheme. The national market surveillance authority will act on any product that presents a risk at the national level, and under the referenced procedure they will notify all member states and the EC. The specific definition of risk, however, is left open, so this presents some ambiguity on when the authority might act.

For any formal non-compliance, such as an incorrect CE mark, or a product that is missing manufacturer or importer details, the EU member states will require the relevant economic operator to correct the non-compliance. If the issue is not corrected, the member state must take all appropriate measures to restrict or prohibit the product being made available on the market, or they should ensure that it is recalled or withdrawn from the market. The member states have the authority to set the rules on penalties that are applicable to any national law violations by the economic operators, and they can take all necessary measures to ensure enforcement, including criminal penalties for serious infractions.

The updated requirements for the CE Declaration of Conformity (DOC) are found in Annex IV. The product model name and identification numbers are required as before, but it must also include all of the expanded contact information, to support the traceability requirements. A photograph of the equipment can be included in the DOC, but it must be in color, and of high enough resolution to clearly identify the product. One new benefit is that all of the applicable directives and standards can be listed on one DOC for the product, although it may need to include multiple pages for all of the required listings for the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared. When it is applicable, the notified body that performed the type examination and issued the certificate should also be identified and listed. Also, the DOC must be translated into the language or languages required by the member states for which the apparatus is placed or made available on the market.

Universal charger requirements have been codified under RED. Presently, common or universal chargers are optional under industry memorandums of understanding, but it will be a requirement in RED for universal chargers for certain products, such as mobile phones, tablets, cameras, and music players. The intent is to reduce the environmental impacts of a multitude of chargers, and the inconvenience they present for consumers.

RED allows electronic labelling for certain appropriate types of equipment, such as devices with a built-in display screen. Other information may also be permitted electronically, such as the model and contact points. Devices requiring an initial charge could have a removable label for shipping.

Under RED there won't be a requirement for EU member state notifications for non-harmonized Class 2 equipment, although this was required under the R&TTE Directive. In addition, the Class 2 Alert symbol (the circle with the exclamation mark) has also been removed from the requirements.

The CE Mark will no longer be required to be printed in the user manual. The R&TTE Directive had required the CE Mark in user manual, but RED removed this.

WHERE TO GO FROM HERE?

We've covered a lot of ground, but I've only provided a broad overview of the upcoming changes. You should start now to understand the impacts this will have for your organization, and start making your own transition plans and alerting your management of these upcoming requirements. The good news is you have at least a couple of years to get this all completed.

There is a wealth of information that can be found on the official European Commission website (ec.europa.eu), including EU compliance publications, such as free downloads of the EU Directives in PDF and HTML file formats, and Official Journal of the European Union documents. A very helpful EC publication is "Blue Guide on the Implementation of EU Product Rules" that is also available for free download. Two other official EU websites that are useful are the Official Journal of the EU website (www.eur-lex.europa.eu), and the official European Union website (www.europa.eu). IN

INTERNET RESOURCES

The European Commission website
ec.europa.eu

The EU New Legislative Framework (NLF), European Commission webpage
ec.europa.eu/enterprise/policies/single-market-goods/documents/internal-market-for-products/new-legislative-framework/index_en.htm

The EU New Radio Equipment Directive (RED), European Commission webpage
ec.europa.eu/enterprise/sectors/rtte/radio-equipment-directive/index_en.htm

EU Eur-Lex, the Official Journal of the EU, website
www.eur-lex.europa.eu

EUROPA, the Official EU website
www.europa.eu

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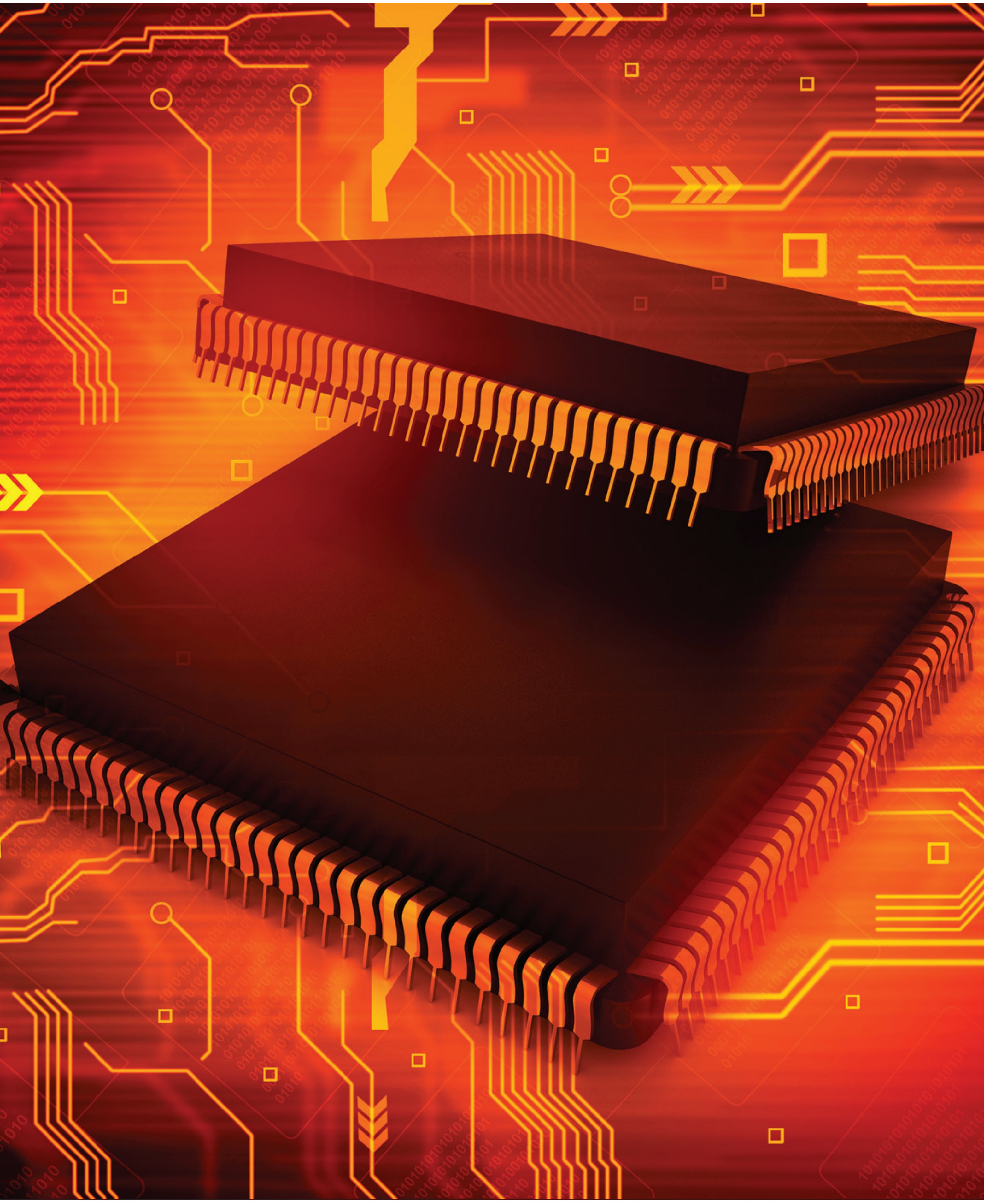


EMC Design in the IC Environment with Respect to ESD and Burst

BY GUNTER LANGER

Today's integrated circuits (IC) are very sensitive to disturbances. Fast pulses which were not perceived by slower ICs in the past may now lead to serious disturbances or even total failure. The characteristics of ICs can no longer be ignored if one wishes to ensure a high immunity to electromagnetic disturbances of electronic devices.

Burst and ESD disturbances enter electronic devices from outside and reach the pins of ICs via conductors. Disturbances enter the ICs both through their pins and also directly via magnetic and electrical fields. Their effects on its function may vary considerably, from brief tolerable faults such as short-time toggling of a port's output, for example, through to the IC's total failure, i.e. a permanent loss of function.

This article deals with conducted interference via IC pins. In these cases disturbances enter the IC via the electronic board's line networks. Electric and magnetic burst and ESD fields originating from the electronic board's environment are responsible for these conducted disturbances.

How do ESD and burst generate electromagnetic disturbances in an electronic system?

Disturbances that are injected in an electronic device during an EMC test produce magnetic and electric disturbance fields. These fields penetrate the electronic board (Figure 1, page 60).

Inductive coupling (B/H-field)

The lines of the electronic board form loops relative to the ground plane. If a magnetic field now enters these loops, a voltage to ground is induced in them. If the conductor loop is connected to an IC pin, the induced voltage to ground is present on this pin (Figure 2, page 60). The induced voltage may interfere with the useful signals on the signal line and drive a disturbance current into the IC.

Inductive coupling has a low source impedance and drives high-intensity currents into the IC. The current values are in the range up to 30 A. The line must be connected to ground outside the IC at a low resistance (capacitors) for the low source impedance to be effective.

Capacitive coupling (E-field)

Lines on the electronic board form coupling electrodes for the electric field of the disturbance (Figure 3, page 61). The electric field couples a disturbance current to the lines (coupling electrodes). The disturbance current flows to ground via a pull-up, pull-down or driver and generates a disturbance voltage drop across them (Figure 4). The induced disturbance voltage is present at the IC input and can modify useful signals or drive a disturbance current into the IC. Capacitive coupling has a high source impedance and drives low-intensity currents into the IC. The current intensity is in the range up to 1 A. The line must be connected to ground outside the IC via a pull-up, pull-down at a high resistance (resistor R) for the high source impedance to be effective.

IC PINS WITH THEIR EMC CHARACTERISTICS FOR CONDUCTED DISTURBANCES

Conducted disturbances enter the IC via its pins due to capacitive or inductive coupling mechanisms.

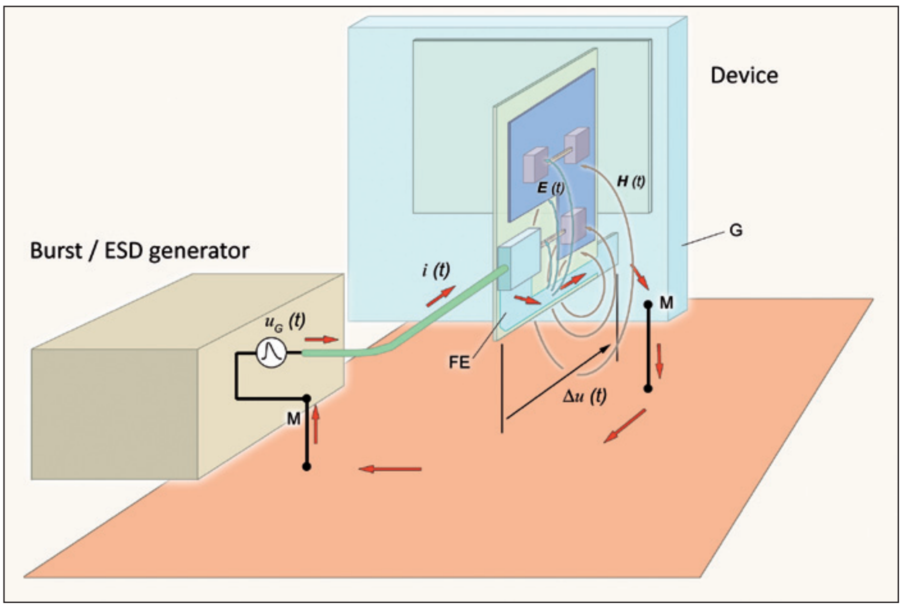


Figure 1: Effect of a burst or ESD disturbance on an electronic board.

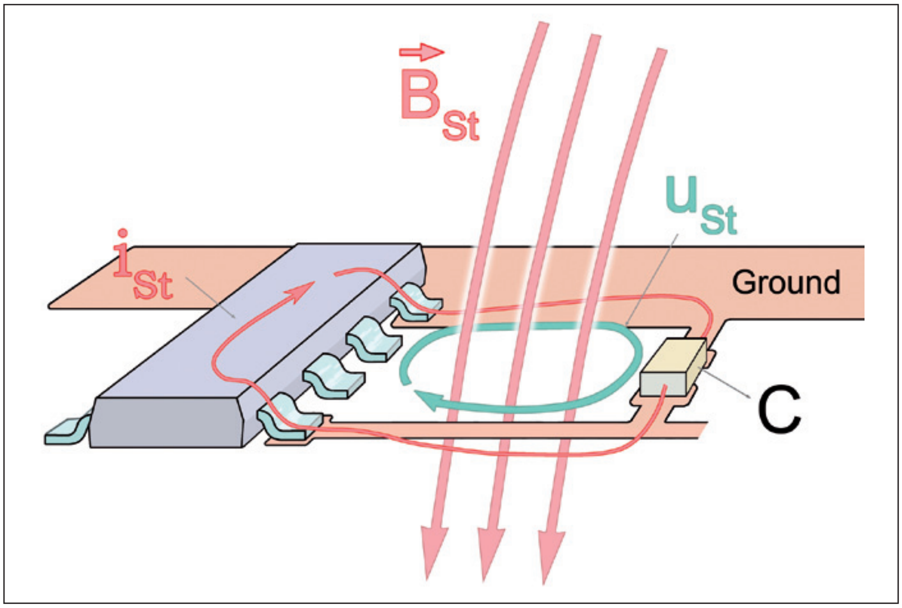


Figure 2: Interference with a line network on the electronic board via a magnetic field.

The characteristics of the coupling mechanisms together with the respective characteristics of the IC electronics connected to the IC pins are responsible for certain cause-and-effect relationships. IC pins can be classified in several pin groups depending on the EMC characteristics of the connected IC electronics.

The most significant groups of signal pins are:

1. Port pins
2. Test pins
3. Interfaces (USB, UART, etc.)
4. Bus pins
5. Crystal oscillator connection pins
6. Reset pins

Supply pins

7. Vdd and Vss pins

SIGNAL PINS

Reaction of the IC to disturbances due to electric-field coupling

First possible reaction:

A disturbance voltage is superimposed over the useful signal as a result of capacitive coupling to the signal lines of the electronic board. The disturbance voltage changes the logic states of the useful signal. When the useful signal is read by the microcontroller, the following reactions are possible:

1. The useful signal is checked for a possible disturbance by multiple scanning in the microcontroller. Spurious pulses can be filtered out based on this principle.
2. If the test pin is not properly locked, a spurious signal switches the microcontroller over to the test mode, which in turn will result in the microcontroller's total failure.
3. Interfaces have error detection and correction mechanisms that can detect and correct changes in the logic states of the useful signal.

4. If the useful signal is a bus signal there is usually no protection against spurious pulses. The erroneous data, address or control signal is read and may lead to a microcontroller crash.
5. Disturbances that are coupled to crystal oscillator connection pins may result in the failure of the crystal oscillator and the PLL circuit. [1].
6. If the useful signal is a reset signal, filters are arranged in the microcontroller to eliminate disturbances. The disturbance will be able to pass through the filters if these are not dimensioned adequately.

Second possible reaction:

The disturbance voltage that is coupled in rises up to the limit voltage of the protection diodes and opens them. A disturbance current thus flows into the IC's Vdd and Vss networks via the protective diodes. The disturbance current reverses the internal capacitances between Vdd and Vss. If a current flows in the negative direction, the internal capacitances will discharge and result in a supply voltage dip. This is not visible from outside. The microcontroller loses its logic register states and crashes. In addition, the disturbance current generates disturbance voltages across the series inductance of the Vdd, Vss system. These disturbance voltages cause interferences between different logic areas of the IC (chore, memory, PLL) and the resulting voltage differences interfere with the signal exchange between the logic areas.

The ESD protection diodes integrated in Vdd and Vss may also respond to this disturbance (power clamps) and short-circuit the IC if the circuitry layout is unfavourable. This may result in an IC failure or even its destruction.

Reaction of the IC to disturbances due to magnetic-field coupling

A disturbance voltage is superimposed over the useful signal as a result of inductive coupling to the signal lines of the electronic board. Coupling is only effective if the signal lines on the electronic board are connected to ground at a low resistance. The best way to ensure this is to connect the signal lines to ground via a filter capacitor.

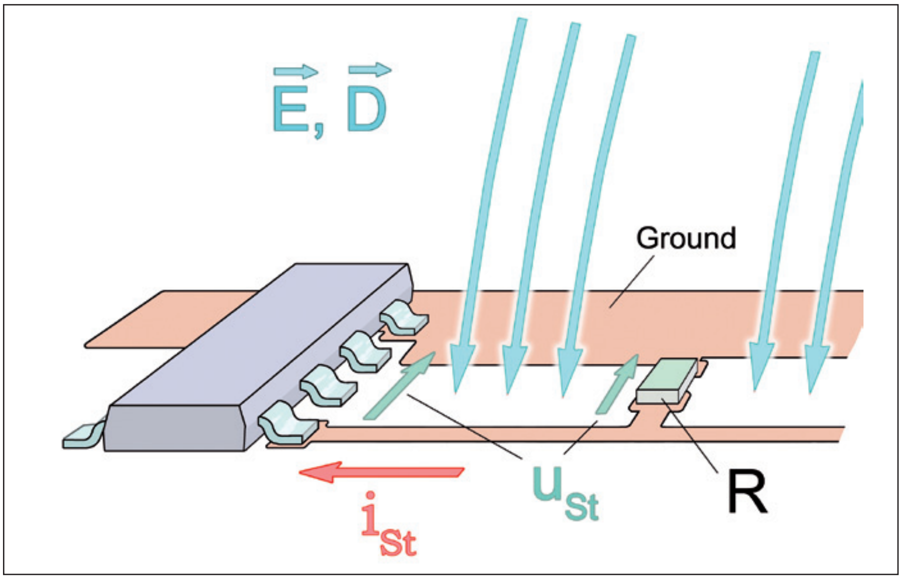


Figure 3: Interference with a line network on the electronic board via an electric field.

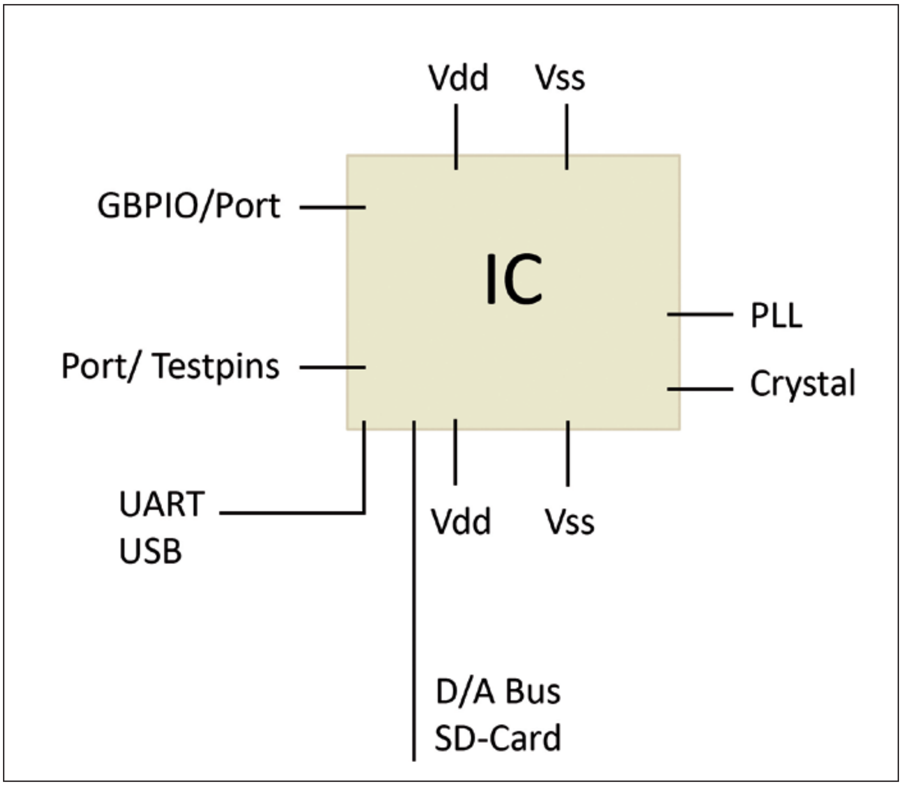


Figure 4: IC pins with their respective EMC characteristics.

[1] *Boards & Solutions*, ICC Media, 2014 September Issue, Gunter Langer

The drivers' resistance is generally low enough to cause disturbances due to a magnetic field. These prerequisites allow the magnetic field to drive disturbance currents of a much higher intensity into the IC than the electric field. The effects are especially strong for power clamps. Depending on the inner impedance relations in the IC, the effect of the magnetic field can be weaker or stronger than that of the electric field. The two reactions described above for electric fields may also occur under the influence of magnetic fields.

SUPPLY PINS

Disturbances can usually only enter supply pins if a magnetic field couples to the supply networks of the electronic board.

The magnetic field drives a disturbance current into the Vdd / Vss loop of the IC. The disturbance current reverses the internal capacitances between Vdd and Vss. If a current flows in the negative direction, the internal capacitances will discharge and result in a supply voltage dip. This is not visible from outside. The microcontroller loses its logic register states and crashes. In addition, the disturbance current generates disturbance voltages across the series inductance of the Vdd, Vss system. These disturbance voltages cause interferences between different logic areas of the IC (chore, memory, PLL) and the resulting voltage differences interfere with the signal exchange between the logic areas. The disturbance effect is more intense compared to that of disturbance current entering the IC via the protection diodes due to an electric field. The disturbance current generated by the magnetic field can be up to 10-times higher than the current flowing via the protection diodes.

The disturbance current coupled to the Vdd/ Vss loop by the magnetic field can also cause the integrated ESD protection diodes to respond (power clamps). The IC may be short-circuited if the power clamp circuit has an unfavourable design. This may result in an IC failure or even its destruction.

Design rules for the IC environment – electric/ magnetic-field coupling

The following design rules have proven successful to solve the aforementioned problems in practice.

Electric field

The effect of the electric field (ESD, burst) is attenuated or is prevented completely if the line networks of the electronic board to neighbouring ground areas are kept very short or are totally embedded in the ground plane. This means that the lines should be laid between two ground layers.

The IC pin's sensitivity determines the degree to which the line networks have to be shielded by ground. The IC pin

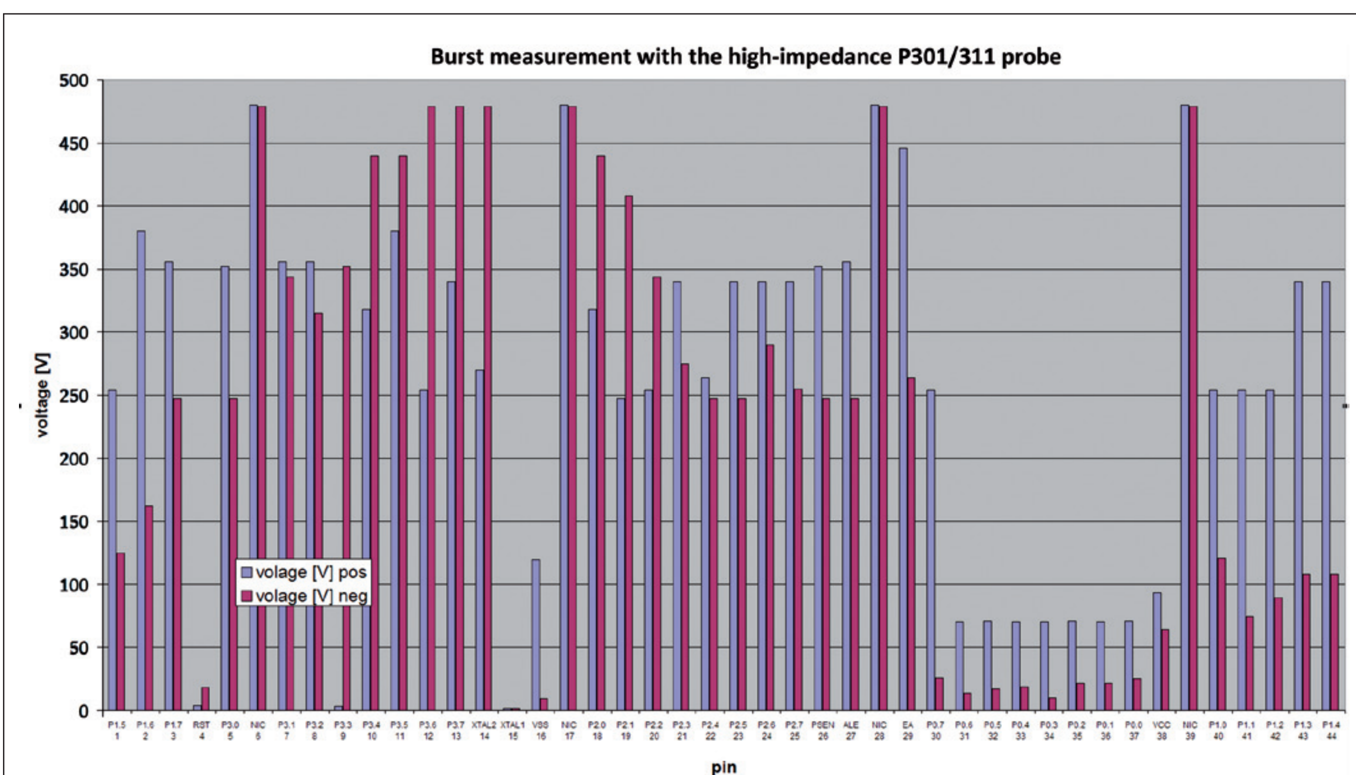


Figure 5: Conducted sensitivity of microcontroller pins to disturbances that affect the line networks of the electronic board.

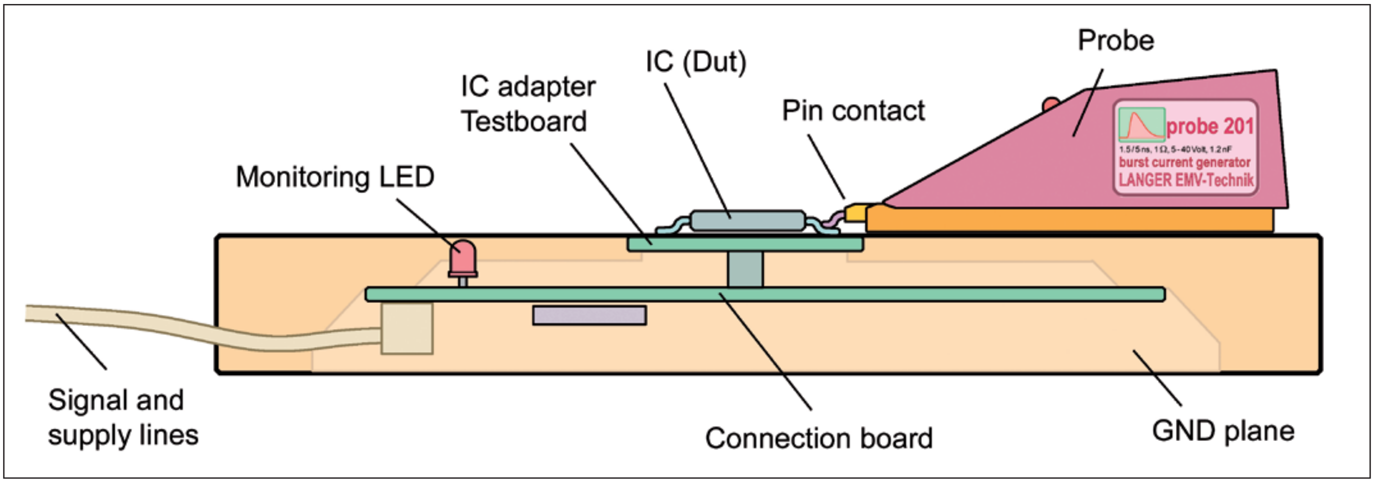


Figure 6: Measurement set-up to determine the sensitivity of pins to conducted disturbances caused by electric fields on the electronic board.

sensitivity is a value that can be defined and thus also measured for each individual pin (Figure 5).

Figure 5 shows that the IC pin sensitivity varies considerably. If the pins are insensitive, line networks may lay at the surface of the electronic board unprotected by the ground plane without any disturbance due to an electric field (level of > 400 Volt in Figure 5). If the pins are sensitive, even complete shielding of the line networks by the ground plane may still be inadequate. The surface of a test point or the surface of the IC pin that is connected to the line network may be sufficient to absorb disturbance current from the electric field. The surface area of the line network (only a few square millimetres) is large enough to cause IC disturbances due to an electric field. The crystal oscillator connections of microcontrollers may have such a high sensitivity, for example (level of approx. 1-2 Volt)

Figure 6 shows the measurement set-up to determine the sensitivity to conducted disturbances. The IC pins can be contacted separately with a special probe and a test pulse applied. This test pulse corresponds to the effect of the electric field (burst, ESD) on the line networks of the electronic board.

Magnetic field

The sensitivity of the IC pins to disturbance current pulses (burst, ESD magnetic field) can be shown in a diagram similar to Figure 5. The currents relevant for disturbances are in the range between 0.5 and 35 Ampere. If the pins are sensitive, induction loops of a few square millimetres are enough to cause inductive coupling. These loops may be formed by short line pieces with a layer distance of 0.5 mm to the ground plane. Blocking capacitors may also form critical loops, especially if arranged at the edge of the electronic board. The highest magnetic field intensity can usually be found there and this results in the highest voltage induction.

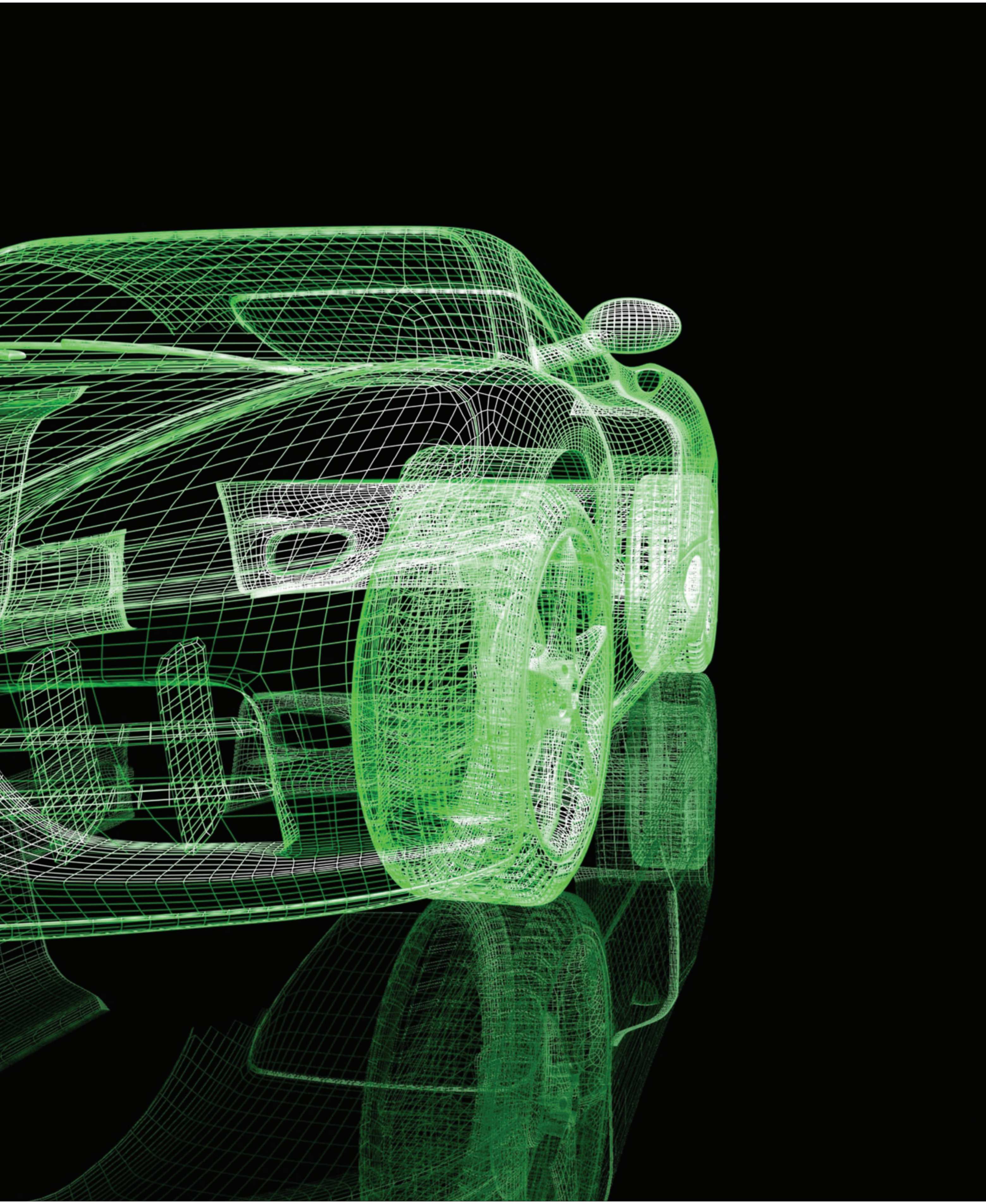
If the electronic board has a ground system with slots (separated ground), magnetic fields may enter and induce voltages in crossing line networks. This often happens if the analogue and digital ground planes are separated. The problem can only be solved if the ground planes are not separated and are continuously connected. The supply pins of crystal oscillator and PLL circuits are the most sensitive pins in practice. The IC's signal connections such as reset, crystal oscillator or test pins can also be very sensitive.

It is beneficial to match the layout design and mechanical structure to the IC pin sensitivity at an early stage of electronic board development. This increases the EMC immunity of the electronic board. Today, the conducted sensitivity of IC pins is already measured by the IC manufacturers. IN

(the author)

GUNTER LANGER

Dipl. Ing. Gunter Langer (*1950) focuses on research, development, and production in the field of electromagnetic compatibility (EMC) since 1980. He founded the Gunter Langer engineering office in 1992 and Langer EMV-Technik GmbH. in 1998. His interference emission and interference immunity EMC measurement technology as well as the IC test system are used mainly in the development stage and are in worldwide demand.



Electromagnetic Simulation Applied to Automotive EMC Testing

The process of designing and testing vehicles for EMC compliance can be long and expensive. Electromagnetic simulation allows potential compliance issues to be identified early in the development process, before the construction of prototypes. However, it is desirable that the simulation is able to model the test setup accurately. In this article we look at the set-up of a virtual EMC test chamber using a commercially available software and compare the simulated results to measurements from a General Motors automotive EMC test.

BY MICHEL GAVIÃO, MARCELO B. PEROTONI, ALVARO B. DIETRICH

Nearly every product that has some sort of electronic circuitry must be subjected to EMC testing prior to its commercialization. In the automotive industry, the large number of electronic modules, sensors, and cable harnesses, many in safety-critical systems, in modern vehicles demands strict standards for reliability and security under challenging conditions. Vehicles must comply with standards such as CISPR-25 and ISO 11451, and individual regulations from the automakers which, very often, are even more stringent.

The contemporary mass consumption market means that the development of a new vehicle must be finished quickly to remain competitive. This means that all the steps, from the initial drafts and sketches to the final prototype tests must be performed quickly and efficiently. Vehicular EMC tests in particular are critical, but can be daunting for project management, since the costs associated with the laboratory measurement are high. A one day measurement in a typical semi-anechoic chamber that can accommodate vehicles can cost tens of thousands of dollars. Adding together the costs of logistics and overall prototype construction, a single vehicle EMC evaluation test can reach hundreds of thousands of dollars. By comparison, the costs associated with electromagnetic simulation software licenses and hardware are much less expensive. The use of electromagnetic simulation to address EMC problems, when possible, can be highly attractive from an economic viewpoint.

Though the complete substitution of real world EMC tests with simulations may be still years ahead, the intensive use of virtual evaluations in a smart way can help engineers understand causes and effects that would otherwise be impossible to address with pencil and paper and very costly to investigate with measurements. Especially in the initial development phases, the correct identification of EMC problems can be very cost effective, by avoiding scenarios where e.g. a harness has to be moved somehow after the complete car is already in production. Figure 1 shows the trade-off between cost of modifications and the stage where eventual modifications take place. The earlier problems are identified, the better. Recalls, the ultimate late-stage modifications, are nightmares that not only dent the company public image but also bleed its budget since a large scale replacement has to be publicized and provided.

EMC evaluation is not only the realm of auto makers. Suppliers must also provide evidence that their products comply with the existing regulations. The use of electromagnetic simulation software by automakers and their suppliers enables an easy interchange of information, where data from the supplier can be correctly integrated in a complete vehicle model. This can be in form of an SPICE or IBIS model, for electronic circuits and modules (the latter IBIS format preserving the intellectual property since it is a behavioral description not reaching the circuit description level); near field measurements of the component or even the complete electromagnetic model.

This article aims to describe the correlation between the laboratory tests of a real General Motors car in a semi-anechoic chamber and the respective virtual testing by simulations. It is part of a large program that aims to lessen the costs in the design phase and gain further confidence and familiarity with the electromagnetic simulation[2].

MEASUREMENT SITE

The Instituto Nacional de Pesquisas Espaciais (INPE) institution in Brazil has a semi anechoic chamber, shown in Figure 2, where vehicular tests can be performed. Its dimensions are 24 x 11 x 10 meters and conducted and radiated tests can be performed up to 40 GHz. A shielded box blocks signals from the outside, and the walls and ceiling are covered with electromagnetic absorbers whereas the floor is metallic. The car is placed on a turntable, which allows the vehicle to be rotated. An antenna excites and/or receives the field, depending on the type of the test.

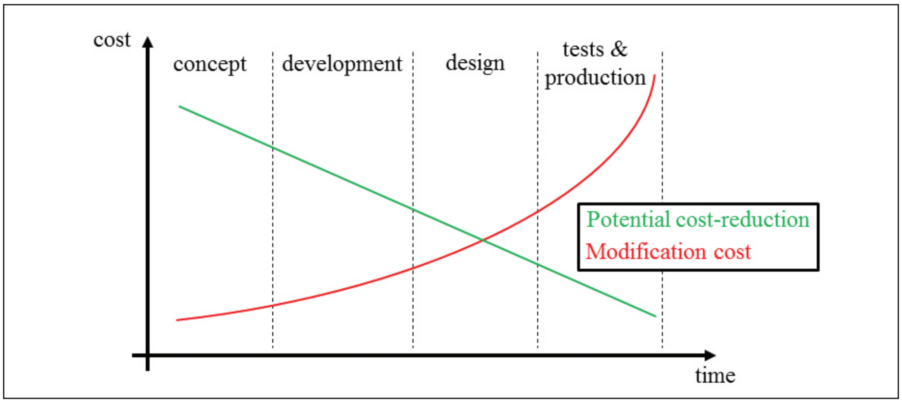


Figure 1: Curves describing the impact of eventual modifications in a generic industrial project on its cost. Adapted from [1].

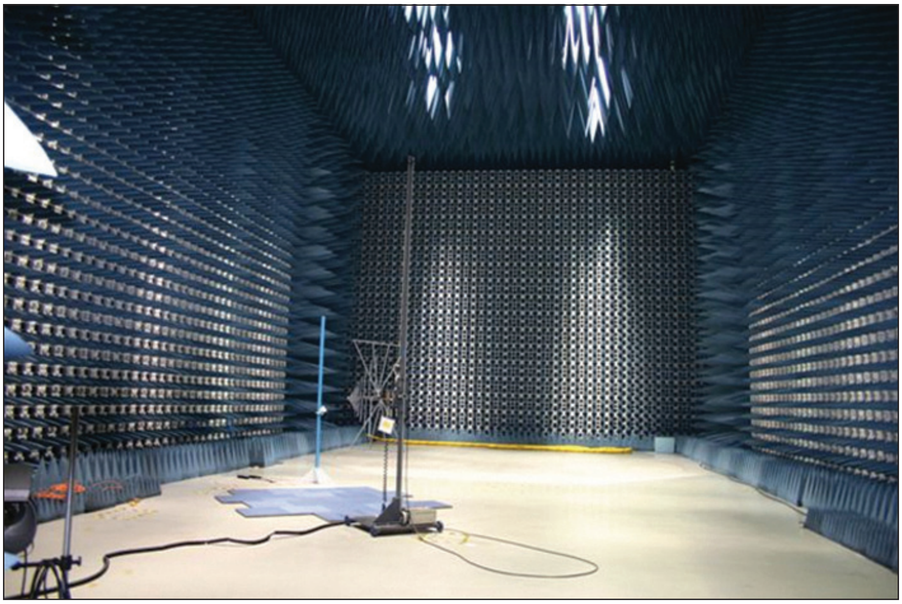


Figure 2: INPE semi-anechoic chamber[3]

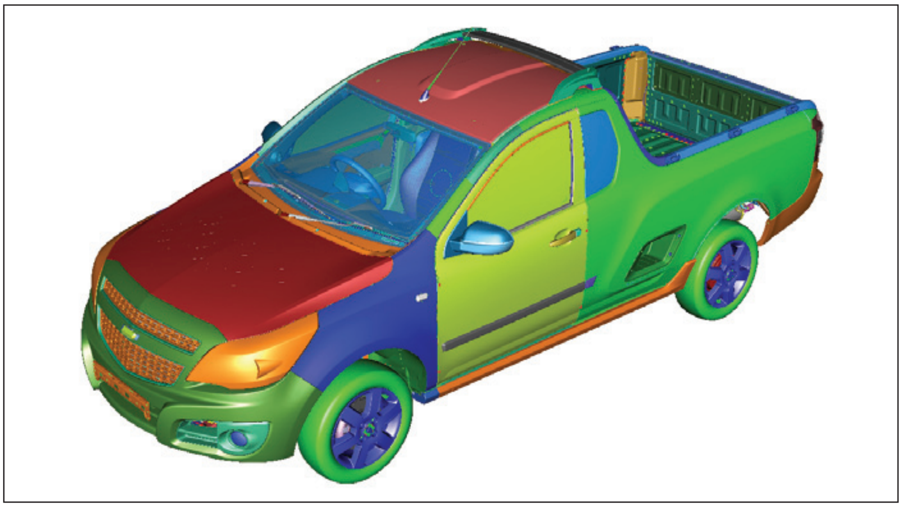


Figure 3: Mechanical CAD model. The colors represent different sub-projects that are later integrated to compose the entire product.

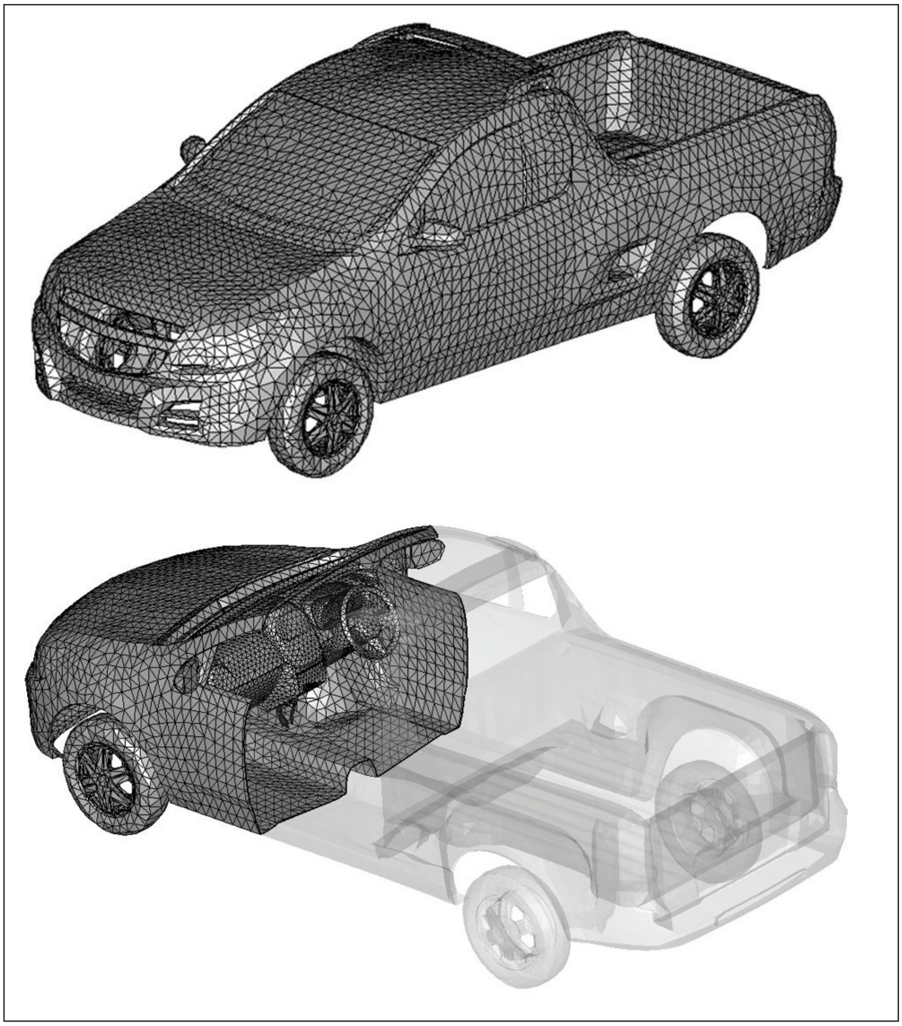


Figure 4: Views of the CST electromagnetic model

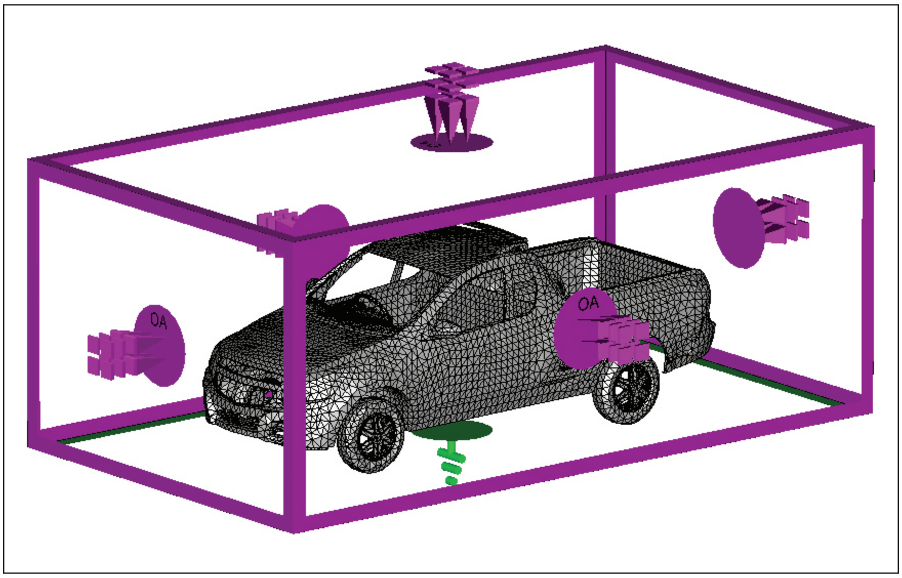


Figure 5: CST model with boundary conditions. The purple color represents absorbing condition and the green the metallic floor.

MECHANICAL AND ELECTROMAGNETIC MODEL

The automobile model was first processed from the original mechanical CAD file (Figure 3), so that unnecessary details could be removed to reduce the complexity of the mesh. The mechanical CAD comes from Siemens Unigraphics NX[4] and the processing tool that helps remove details is the CAE software Altair Hypermesh[5]. This simplification is very important since it turns an otherwise intractable situation (from the viewpoint of electromagnetic simulation) into a feasible problem. Small details and parts that are not made of electrically relevant materials are removed, such as upholstery and cloth.

The final electromagnetic model can be seen in Figure 4. Three materials were considered, all with lossless characteristics: metal, glass (relative permittivity of 4.82) and plastic (relative permittivity of 3.40). Tires, bumpers and structural details were all assigned to plastic, for the sake of simplicity.

The imported model has its chassis made out of a metal sheet, with zero thickness. It is a perfect electric conductor, which is consistent with the real world model as long as the frequencies are above the HF range. Assuming real thicknesses for the metallic chassis parts would make the simulation time much longer without any gain in terms of accuracy. The correct balance between simplification and accuracy is one of the main considerations when setting up the numerical evaluation in order to extract the best results in minimum time and least computational resources. In other words, frequently less is more when an EMC problem is tackled by simulation.

The boundary conditions were modeled as a ground plane on the floor and the rest of the enclosing walls were set to emulate the effect of a perfect semi-anechoic chamber, as shown in Figure 5.

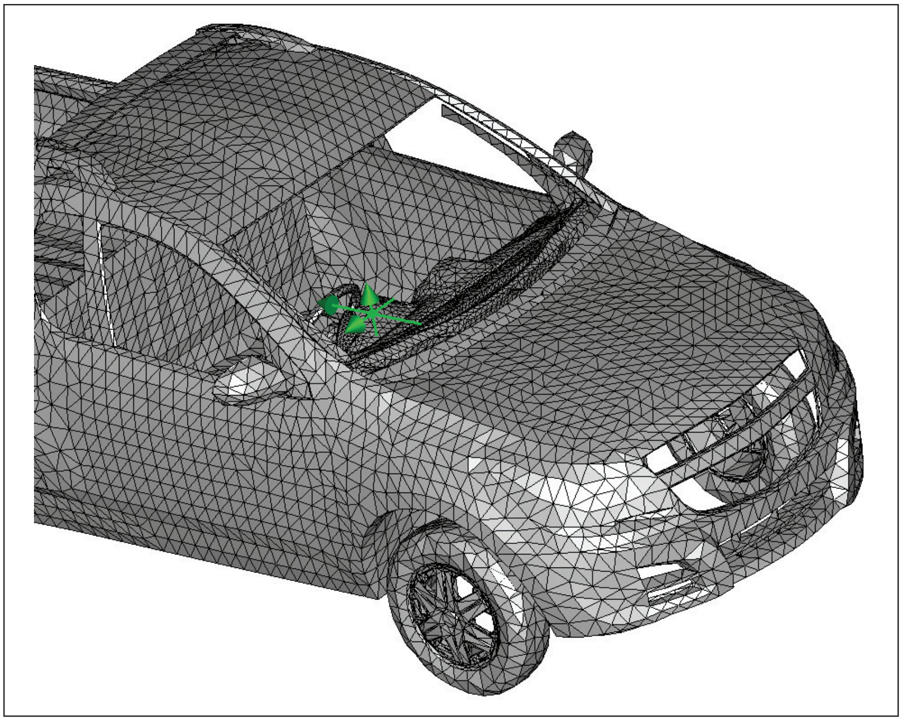


Figure 6: The green arrows show the point where the fields are recorded, at the same location as the physical probe in the semi-anechoic chamber measurement site.

Frequency band	Antenna
1.5 MHz to 30 MHz	Stripline
30 MHz to 100 MHz	Biconical
100 MHz to 1 GHz	Broadband Horn
1 GHz to 2 GHz	Horn

Table 1: Frequency bands and associated antennas

Finally, to emulate the laboratory measurement, a probe (the element that records the fields in both frequency and time domains) was placed above the dashboard, as shown in Figure 6. The measurements had the car remaining stationary; therefore the turntable was not used.

The simulations were performed using CST STUDIO SUITE [2] on a desktop computer HP Z400, with 12 GB RAM memory, a 3.06 GHz Intel Xeon W3550 processor and the Windows 7 operating system. All evaluations used a transient solver with varied mesh configurations (to check the convergence). When possible, the global mesh settings were progressively refined until the results did not show any significant variation. The transient solver is well-suited to this sort of electrically large broadband simulation.

RESULTS

The simulations and measurements were divided into different frequency bands. Each one had an associated antenna, as shown in Table 1.

It is important to note that these antennas were roughly modeled (due to the commercial unavailability of their construction details) with an antenna

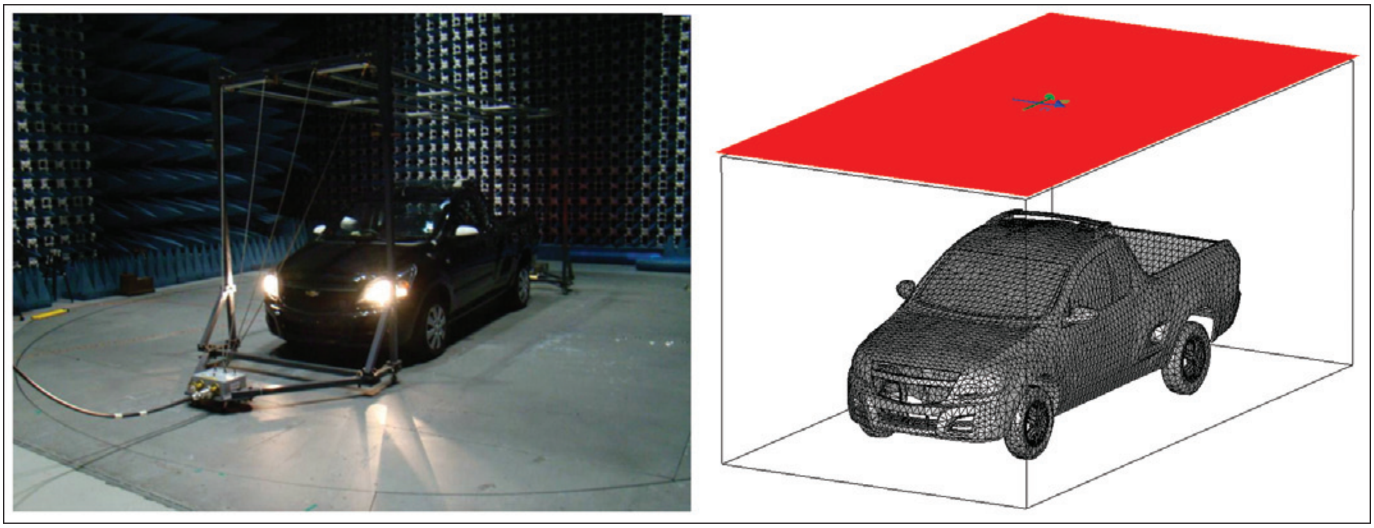


Figure 7: (Left) Vehicle in the semi anechoic chamber excited by a stripline antenna and (right) its electromagnetic modeling.

The simulations and measurements were divided into different frequency bands. It is important to note that these antennas were roughly modeled (due to the commercial unavailability of their construction details) with an antenna design software capable of simulating similar designs.

design software[6] capable of simulating similar designs. All presented results have the field measured by an electric probe placed as in Figure 6, and different antennas illuminating the vehicle.

Each band is addressed in the following sections.

1.5 MHz to 30 MHz

The stripline antenna and the vehicle in measurement can be seen in Figure 7. Without access to the stripline antenna model, it was decided that a plane wave excitation, shown in Figure 7, would be used. The plane wave emulates a source placed far away, so that a TEM wave illuminates the vehicle, as in the stripline antenna case.

The comparison between the measured and simulated results is shown in Figure 8. It can be seen that there is a good agreement across the entire band, stressing the fact that the comparison uses a linear, not logarithm scale.

30 MHz to 100 MHz

This frequency range used a biconical antenna, depicted in Figure 9. Because the dimensions of the biconical antenna were unavailable, it was not possible to carry out an accurate simulation of this stage of the testing process. Attempting to simulate the test using a different antenna model did not produce satisfactory results.

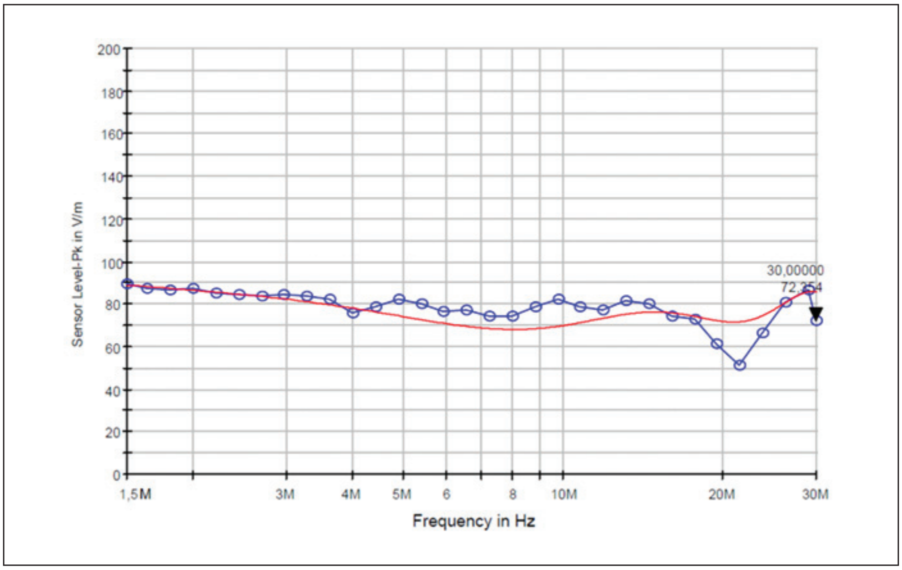


Figure 8: Comparison between the simulated and measurement results, frequency 1.5 MHz to 30 MHz. Blue measurements; red simulation.

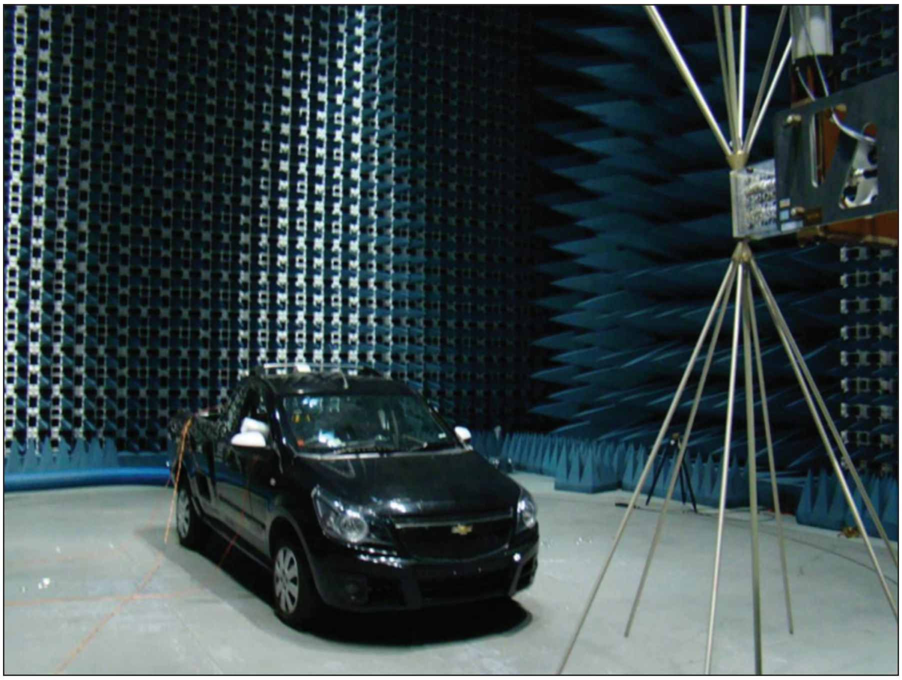


Figure 9: Laboratory evaluation

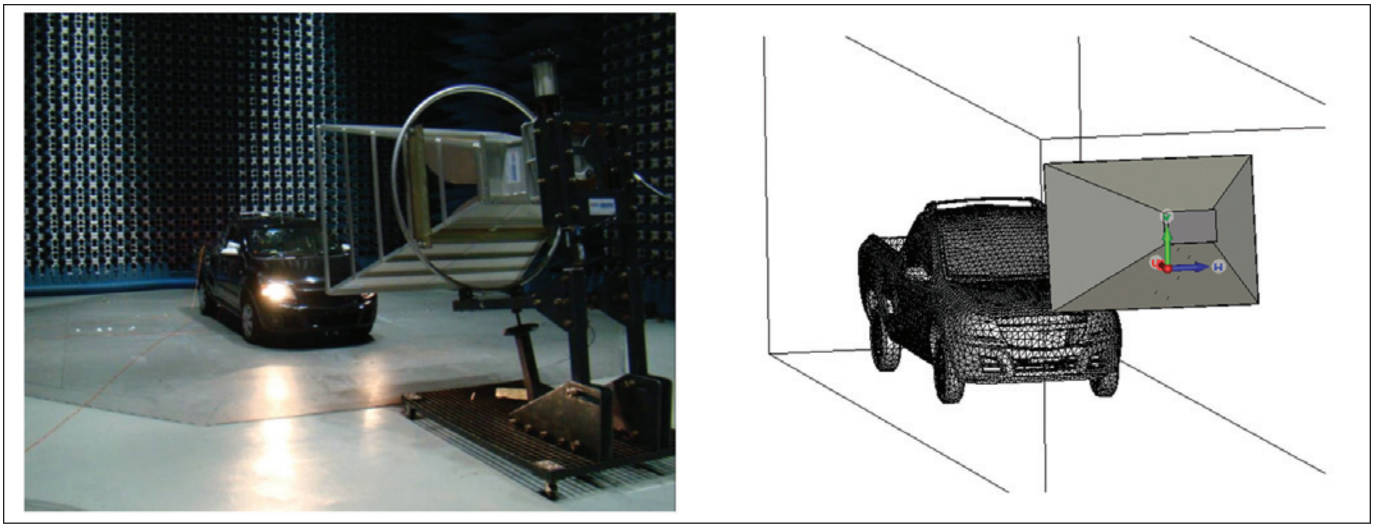


Figure 10: (Left) Laboratory evaluation and (right) electromagnetic modeling.

100 MHz to 1 GHz

This frequency range used a broadband horn antenna, as Figure 10 shows in the simulation and in the measurement site. It can be seen that again the antennas are not alike; the software's model had solid walls whereas the measurement site antenna did not. In addition, the antenna design software synthesizes broadband horns with minimum frequency of 300 MHz, higher than the necessary 100 MHz, so the synthesis was done with this 300 MHz minimum frequency. Since the model provided by it is fully parameterized, the whole antenna was scaled up in dimensions as to shift down the frequency back to 100 MHz.

Figure 11 shows the comparison between the measurements and simulation. It can be seen that there is a reasonable agreement between both scenarios.

1 GHz to 2 GHz

This frequency range used another type of horn antenna, shown in Figure 12 in measurement site and the simulation environment. Since the antennas were operating with a smaller wavelength (1 GHz equals to 30 cm) the fields generated by the antenna were considered to be a plane wave in the vehicle region. Therefore the excitation was again made with a plane wave.

The results are shown in Figure 13. The comparison shows good agreement, in spite of the use of a plane wave instead of the antenna in the simulation setup.

CONCLUSIONS

This study proved the feasibility of a large scale set of semi-anechoic chamber vehicular measurements prognostication. Using an average equipped computer it was possible to see and forecast measurement results that are very costly in terms of budget and logistics. The process could be made more efficient in the following ways:

- Easier workflow for transforming the complex and detailed mechanical CAD file into a suitable electromagnetic model;
- More accurate antenna modeling, perhaps by using the real world nearfield or farfield patterns as

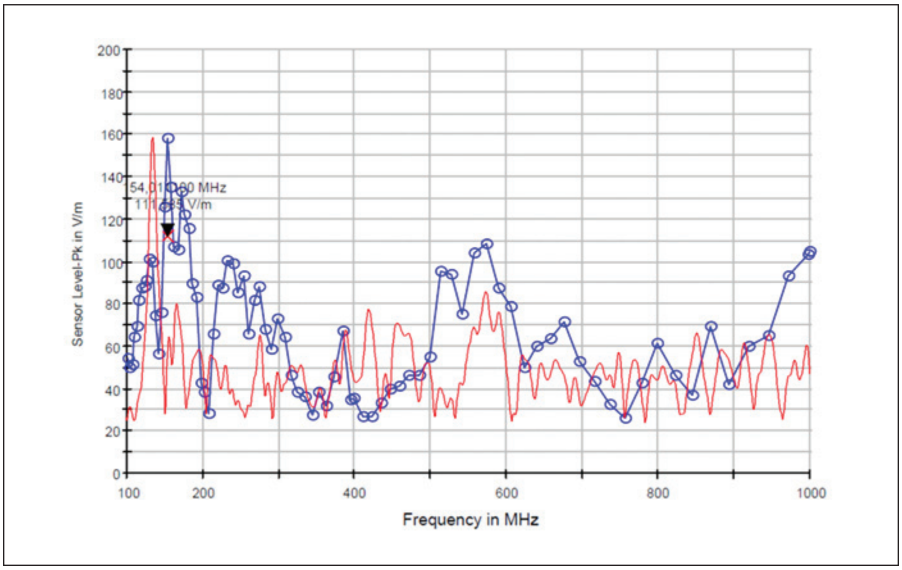


Figure 11: Comparison between the simulated and measurement results, frequency 100 MHz to 1 GHz. Blue measurements; red simulation.

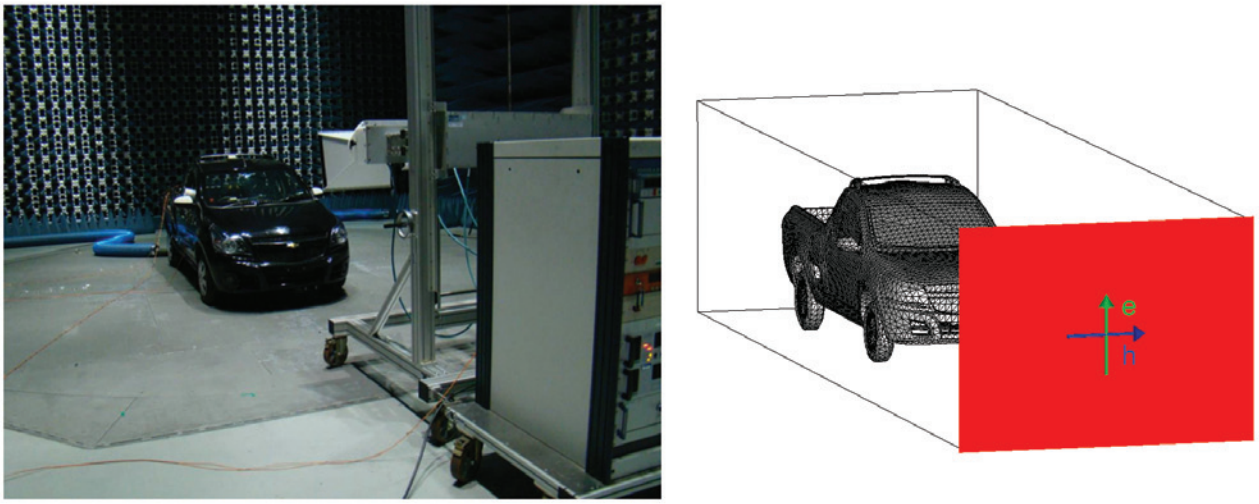


Figure 12: (Left) Laboratory evaluation and (right) electromagnetic modeling.

nearfield/farfield sources. This makes realistic simulation possible while protecting the manufacturer's intellectual property.

- High performance computing, using GPU cards to accelerate lengthy simulations.

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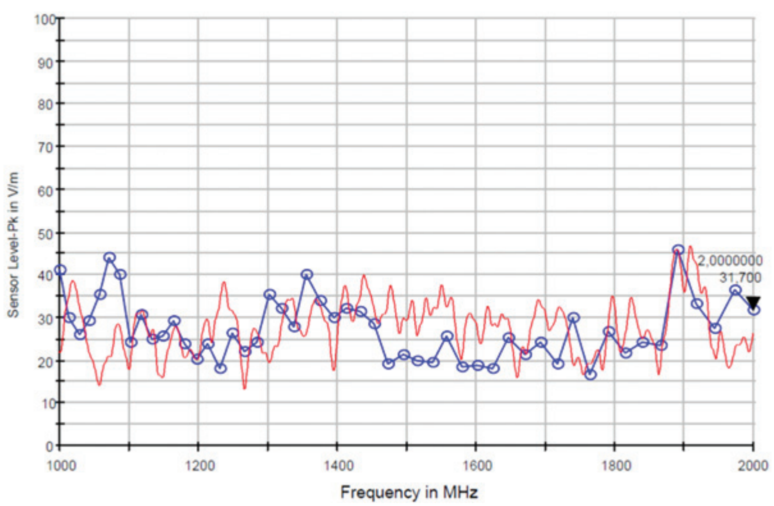

Figure 13: Comparison between the simulated and measurement results, frequency 100 MHz to 1 GHz. Blue measurements; red simulation.

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was born in Poços de Caldas, south of Minas Gerais, Brazil, on April 19 in 1978. He graduated in Control and Automation Engineering at Federal University of Itajubá, and concluded the MSc in Electrical Engineering at Federal University of ABC.His professional experiences includes the AFL and Leoni (automotive suppliers), and also Peugeot Citroen, Volkswagen and General Motors. His special fields of interest include electromagnetic modeling and simulation, EMC testing and automotive electrical development.

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ALVARO B. DIETRICH

is a professor at UFABC, Brazil.

BUSINESS News

Fairview Microwave Debuts Comprehensive Lines of IP67 RF Adapters

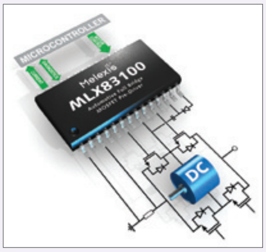
Fairview Microwave Inc. has introduced a comprehensive line of IP67 RF adapters commonly employed in the DAS, cellular, aviation and military industries due to their ingress protection from water and dust. Fairview Microwave's new RF adapters are IP67 rated, meaning they use advanced ingress protection to make them virtually impenetrable to contaminants like dust, sand, and water. Offered in this release are in-series adapters including 7/16 DIN, 4.1/9.5 mini-DIN, Type-N and TNC. Fairview Microwave's IP67 adapters are in-stock and available now. You can view these new products by visiting www.fairviewmicrowave.com.

Keysight Technologies Announces Best-in-Class Femto/Picoammeters and Electrometers

Keysight Technologies, Inc. introduced the B2980A Series of femto/picoammeters and electrometers, the world's first graphical picoammeters and electrometers to confidently measure down to 0.01 fA which is 0.01 x 10-15 A, and up to 10 petaohms (PΩ) which is 10 x 10^{15} ohms. The B2980A Series meters offers best-in-class performance, with a 2 pA to 20 mA operating range and an internal 1000 V source, as well as a host of innovative capabilities designed to optimize measurement confidence. More information on the B2980A Series is available at www.keysight.com.

Low Pin Count N-FET Pre-Driver from Melexis Targets Automotive High Current DC Motor Applications

To complement its successful brushless direct current (BLDC) pre-driver portfolio and address conventional DC motor applications, Melexis introduces the MLX83100 N-FET pre-driver IC. Offered in a compact 28-pin package, with four digital inputs, this pre-driver IC provides a very flexible, inexpensive and space-saving solution for high current N-FET DC motors. The MLX83100 has the capability to simultaneously drive four 500nC-rated N-FETs at up to 28V operating voltage with minimal self-heating. For more information, visit www.melexis.com.



Leroy Merlin Chooses MetricStream for Quality and EU Product Safety Compliance Management

Leroy Merlin, one of the world's largest Do-It-Yourself (DIY) home improvement retailers headquartered in France, has selected MetricStream to provide a comprehensive solution for quality and product safety compliance management. MetricStream's solution will help Leroy Merlin streamline, automate, and integrate a range of quality assurance and product safety compliance processes, including quality audits, inspections, product compliance risk assessments, product testing, preventive actions, and curative actions such as the treatment of non-compliance, product blocking, and recall management. Visit www.metricsystem.com.for more information.

TÜV Rheinland Urges Wireless Device Manufacturers to Account for Upcoming ETSI Standard Changes

The European Telecommunications Standards Institute (ETSI) issued the updated versions of the EN 300 328 and EN 301 893 standards, introducing changes to testing procedures of applicable wireless equipment. TÜV Rheinland strongly encourages manufacturers of wireless devices to comply with the updated testing and certification requirements in order to ensure they can sell in the European Union and other countries following the standard after the January 1, 2015 deadline. The EN 300 328 standard regulates wireless transmitters in the 2.4 GHz band and affects multiple wireless technologies, including Wi-Fi®, Bluetooth® and ZigBee®. The EN 301 893 standard applies to 5 GHz RLAN equipment used in wireless local area networks and intended to operate at 5150 MHz – 5350 MHz and 5470 MHz – 5725 MHz frequency ranges. For more information, visit www.tuv.com/us.

Low Noise Desktop Preamplifier for EMC with Built-in Battery

US Microwave Laboratories has released the USMC0125, its latest low noise broadband preamplifier that covers 1 MHz to 2500 MHz, providing outstanding flatness, 30 dB of gain, very low noise figure, and an optional built-in battery and smart charger for more than 20 hours of field operation. The unit is IP65 compliant and it is ideal for Electromagnetic Compatibility (EMC) testing and certification. For more information, visit www.usmicrolabs.com.

PRODUCT Showcase

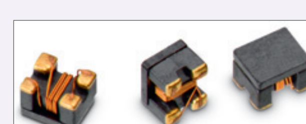
Business News

Vishay MC AT Professional Automotive Resistors AEC-Q200-Qualified Over Entire Resistance Range

To meet the growing demand for AEC-Q200-qualified parts, Vishay Intertechnology, Inc. announced that its MC AT professional series of automotive thin film chip resistors is now AEC-Q200-qualified over its entire resistance range from 1 Ω to 1 MΩ. Designed to deliver stability under harsh environmental conditions in automotive and industrial applications, the Vishay Beyschlag devices offer high-temperature performance to +175 °C for 1,000 hours. Offered in standard case sizes from 0402 to 1206, MC AT professional resistors feature tolerances down to ± 0.5 % and TCR down to ± 25 ppm/K. For more information, visit www.vishay.com.

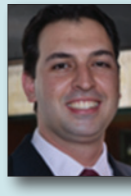
Wurth Electronics Adds Smart, Current Compensated, Common Mode Choke to its Product Portfolio

Wurth Electronics is adding a current compensated common mode choke in package size 0504 to its WE-CNSW HF family portfolio. Its design allows the use of a fine bifilar winding technology. Combined with a NiZn core, this enables a broadband attenuation response that operates into the GHz frequency range.



A special winding technology results in higher current carrying capability, twice the current of the 0805 design. Visit www.we-online.com for more information.

(Authors)



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graduated in Control and Automation Engineering at Federal University of Itajubá, and concluded the MSc in Electrical Engineering at Federal University of ABC. For more information, visit page 71.

KEN JAVOR
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NIELS JONASSEN, MSC, DSC,
worked for 40 years at the Technical University of Denmark, where he conducted classes in electromagnetism, static and atmospheric electricity, airborne radioactivity, and indoor climate. For more information, visit page 25.

GUNTER LANGER
focuses on research, development, and production in the field of electromagnetic compatibility (EMC) since 1980. He founded the Gunter Langer engineering office in 1992 and Langer EMV-Technik GmbH. in 1998. For more information, visit page 63.

MARK MAYNARD
is the Director for Business Development and Marketing at SIEMIC, a global compliance testing and certification services firm with locations in the US, China, Taiwan, and South Korea. For more information, visit page 57.

GEOFFREY PECKHAM
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MIKE VIOLETTE
is President of Washington Labs and Director of American Certification Body. The next installment of RE stays with the space theme, but leaps forward, sort-of, by returning back to the 1960s. For more information, visit page 18.

We wish to thank our community of knowledgeable authors, indeed, experts in their field - who come together to bring you each issue of *In Compliance*. Their contributions of informative articles continue to move technology forward.

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