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2017 EUROPE EMC GUIDE

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emc.live

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EDITORIAL

Hi, I hope you enjoy this issue of the 2017 Europe EMC Guide! Inside, you'll find several articles discussing recent regulations affecting the EU, as well as Andy Eadie's "Steps to CE Compliance" and an article on how current probes work and how to use them to help troubleshoot your products. We've also included a recap of important standards news, a Products & Services directory for each major country, as well as a reference section listing seminars, trade shows, standards working groups, and major EMC standards. We'll close out with Brexit.

Probably the two biggest changes in the European standards landscape are the implementation of the new Radio Equipment Directive (RED) and the latest EMC Directive. However, close at the heals of these new directives, is the New Legislative Framework, which requires CE compliance throughout the supply chain, and the update to EMC standard for medical products, IEC 60601-1-2 (edition 4). Let's take them in order:

Radio Equipment Directive - The Radio Equipment Directive, 2014/53/EU, becomes mandatory for new and existing products June 12, 2017. Charlie Blackham published an article on the updates and what it means to manufacturers earlier this year and we've included translations in this edition of the European EMC Guide. Because the RED now includes the requirements to meet the Low Voltage and EMC Directives, as well as providing a risk assessment due to EMI potential failures, it is going to cause many changes for manufacturers who think they can continue to comply with the LVD and/or EMC Directives. At the very least, it will require a rewrite of the Declarations of Conformity.

EMC Directive - The EMC Directive, 2014/30/EU, became mandatory for new and existing products April 20, 2016. For the most part, compliance with the new directive will not significantly impact conformity assessment. The essential requirements listed in Annex I of the directive remain the same as before and continue to be stated in very general terms. Some of the more significant changes in the recast directive relate to the operations of Notified Bodies and other practices that may not immediately impact manufacturers. Annex VII in the new Directive provides a helpful correlation table that relates requirements in 2004/108/EC to 2014/30/EC.

New Legislative Framework - One issue that seems to be overlooked is that the New Legislative Framework which now requires that essentially, everyone in a supply chain will carry full responsibility for all of the EU compliance issues of all products that pass through their hands. They'll have to be able to show that they had fully assessed a products compliance before accepting them in the first place. All products have to be permanently marked with their actual manufacturer and his actual address, plus the names and addresses of all the importers and distributors they have passed through, which could require some very large labels! Supply-chain issues might not sound very interesting, but they are when everyone in the chain has to bear responsibility for EMC compliance.

These new EU Directives are a huge issue for the entire supply-chain, something that has been overlooked completely by all the international test houses because, of course, their technical compliance/testing requirements haven't changed very much, and when they informed their customers about the changes they only focused on these issues. Test labs and test equipment suppliers would no doubt be interested to know about this new market for their services!

IEC 60601-1-2 - Finally, the update to IEC 60601-1-2 (Edition 4) for medical products was published February 2014 and becomes mandatory for all products December 31, 2018. The U.S. FDA has embraced the new edition and is urging manufacturers to incorporate it now for new products. The new edition will be a greater challenge for manufacturers, as they will now need to perform a detailed risk analysis, as well as quite a bit of additional documentation. There are also significant changes in immunity test levels. Author, Darryl Ray has contributed an article in this issue describing all the changes and it has been translated into several languages for your convenience.

Looking ahead, sometime during the next five years the three Medical Device EU Directives will be replaced with two Medical EU Regulations, which unlike Directives are directly imposed by Brussels, and which will make huge changes to how medical devices are supplied, regulated, and continuously monitored during their lifecycles in the EU.

Brexit - Finally, let's not forget the surprising Brexit vote. In June, Britain voted to leave the European Union, a monumental decision that's triggering some serious alarm bells throughout the country. As it stands, many UK laws and regulations are determined by EU legislation and it's not immediately clear what the EMC standards ramifications in Britain will be during the two year transition and in the future after that.

There's still a long road ahead, and many of the concerns expressed by the EMC standards community are likely to be addressed in the coming negotiations. Panic is obviously not the way to go, and to understand the issues with more clarity, John Woodgate and Keith Armstrong have provided some initial analysis. Both of these consultants are based in England, so have a unique perspective as events unfold. As the transition takes place, you can depend on Interference Technology to help inform and clarify the issues as the transition progresses. Read more here: https://interferencetechnology.com/britain-after-brexit-with-the-accent-on-emc/.

Be sure to check out the many excellent recorded presentations from EMC Live (April 2016) and EMC Live Test Bootcamp (November 2016). These web-based presentations include a number of interesting topics by top names in the industry.

Kenneth Wyatt
Sr. Technical Editor, Interference Technology


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2016-17 STANDARDS

EUROPEAN & INTERNATIONAL STANDARDS UPDATES

Compliance with standards can make or break any new product. This section recaps some of the major new and revised EMC standards in the last year from the European standards organizations: the European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC) and the European Telecommunications Standards Institute (ETSI). Standards are sorted by reference number. Standards information and updates are featured in our weekly Interference Technology eNews; and we also have a vast list of standards at interferencetechnology.com - just click on the Standards section.

LIST OF UPDATED IEC EMC STANDARDS

October 12, 2016

Recent updates to IEC EMC standards published by the IEC:

- **EC 62040-2:2016 PRV, Ed. 3.0** – (9/2/16) – Uninterruptible power systems (UPS) – Part 2: Electromagnetic compatibility (EMC) requirements
- **CISPR 25:2016 PRV, Ed. 4.0** – (9/2/16) – Vehicles, boats and internal combustion engines – Radio disturbance characteristics – Limits and methods of measurement for the protection of on-board receivers
- **CISPR 16-1-5/AMD1:2016 PRV** – (9/2/16) – Amendment 1 – Specification for radio disturbance and immunity measuring apparatus and methods – Part 1-5: Radio disturbance and immunity measuring apparatus – Antenna calibration sites and reference test sites for 5 MHz to 18 GHz
- **CISPR 16-2-3:2016, Ed. 2.0** – (9/15/16) – Specification for radio disturbance and immunity measuring apparatus and methods – Part 2-3: Methods of measurement of disturbances and immunity – Radiated disturbance measurements
- **CISPR 16-2-3:2016 RLV, Ed. 4.0** – (9/15/16) – Specification for radio disturbance and immunity measuring apparatus and methods – Part 2-3: Methods of measurement of disturbances and immunity – Radiated disturbance measurements
- **IEC 62228-2:2016 PRV, Ed. 1.0** – (9/23/16) – Integrated circuits – EMC evaluation of transceivers – Part 2: LIN transceivers

The Radio Equipment Directive (RED) 2014/53/EU becomes mandatory as of June 13, 2017. Products placed on the EU market as of that date must comply with the RED; the R&TTE Directive will no longer be valid.

For more standards:
http://www.iec.ch/

CISPR 35 PUBLISHED – MULTIMEDIA IMMUNITY

September 7, 2016 – Blog post by Ghery Pettit

Now that CISPR 35 is finally published, the questions that you want answered are:

What is the same as CISPR 24? What has changed? What is new?

To read the full blog post:
http://www.emc-zone.com/2016/08/cispr-35-published-multimedia-immunity.html

NEW CENELEC STANDARDS RECENTLY RELEASED

August 17, 2016

Rein Tech Laboratories recently listed several updates to standards in their July 2016 newsletter "MultiPoint". Among them are the following updates as published by CENELEC. There are additional standards updates listed for IEC and ETSI standards.

This is a shortened list of the CENELEC standards published or made available during the past month:

- EN 62610-5:2016 – 6/24/2016 – Mechanical structures for electrical and electronic equipment
- EN 60195:2016 – 7/15/2016 – Method of measurement of current noise generated in fixed resistors
- EN 55032:2015/AC:2016-07 – 7/22/2016 – Electromagnetic compatibility of multimedia equipment – Emission Requirements
- EN 60966-2-4:2016 – 7/22/2016 – Radio Frequency and coaxial cable assemblies – Part 2-4

For more information:
http://us4.campaign-archive1.com/?u=ea8729ded10d990820bca7414&id=d216be3e02&e=6066ceb8d3

BREXIT UPDATE

August 10, 2016

According to Bloomberg, "The U.K.'s departure from the European Union may turn out to be the most tortured divorce proceeding in history." This article provides more detail on the exact steps involved and the fact it could easily take years for the various negotiations.

Talks on Britain's departure can start as soon as the U.K. triggers Article 50. Legally, there must be separate sets of negotiations — one relating to the U.K. extricating itself from its current arrangements, the other dealing with the two sides' eventual future relationship — a process that will postpone Britain's clean break for years if the EU insists talks on the second can't start until the first is concluded.

In fact, there may need to be six sets of agreements: an EU divorce deal, a new U.K.-EU trade regime, an interim EU accord to cover the period between them, full membership in the World Trade Organization, new trade deals with other countries, and new foreign policy and defense arrangements.

For more information:
http://www.bloomberg.com/news/articles/2016-08-01/disentangling-43-years-of-rocky-marriage-how-brexit-happens

EMF DIRECTIVE – WORKPLACE HEALTH AND SAFETY IN ELECTROMAGNETIC FIELDS

August 10, 2016

As of July 1, 2016, all EU member states are required to have implemented Directive 2013/35/EU for the protection of persons from electromagnetic fields (EMF) in the workplace in national laws. As a consequence, companies throughout Europe must now ensure that their employees are not exposed to fields greater than the exposure limits, some of which have been newly defined. This requires monitoring and minimizing risk through preventive measures where necessary.

The underlying EMF Directive defines "Minimum health and safety requirements regarding the exposure of workers to the risks arising from the physical effects of electric, magnetic, and electromagnetic fields in the frequency range between 0 Hz and 300 GHz". Its limit values are primarily based on the recommendations of ICNIRP, the International Commission for Non-Ionizing Radiation Protection. They have been reworked in line with the latest scientific findings and refer exclusively to the proven direct short term effects on the human body.

The new feature of the EMF Directive is the requirement that employers must now assess the risk separately for each workplace. The responsibility of ensuring that the limit values for workers are not exceeded means that every risk has to be assessed first and then the actual exposure levels recorded in a way that complies with the Directive. The emission specifications of device manufacturers or computed values can be used for this, particularly in areas such as offices and laboratories where only low-current equipment is used.

For certainty, measurement is now required everywhere else where a higher local EMF exposure level is suspected, such as in metal industry production plant, welding or smelting equipment.
This new set of rules stipulates that specialist personnel should record the field values at regular intervals and then document these in traceable form for this purpose.

For more information:
https://www.narda-sts.com/en/company/press/

FDA FINALIZES GUIDANCE IN SUPPORTING CLAIMS OF EMC

July 20, 2016

The U.S. Food and Drug Administration (FDA) has issued final guidance in supporting claims of electromagnetic compatibility (EMC) of medical devices.

The document is recommended for use in conjunction with consensus standards, as well as other FDA guidance documents pertaining to specific devices.

Typically, the FDA reviews EMC information based on the risk of device malfunction and/or degradation if the device is exposed to electromagnetic interference by other devices near its intended electromagnetic environment. The proliferation of smartphones, wearables, home appliances, and other electronic devices poses a threat to safe performance of medical devices, and the FDA wants manufacturers to follow established standards and guidance documents to mitigate risks.

Manufacturers are recommended to follow device-specific guidance, such as one issued for Infusion Pumps Total Product Life Cycle, and cross-cutting guidances, such as Design Considerations for Devices Intended for Home Use.

In addition to following these FDA-recognized standards and guidance documents, and in order to support a claim of electromagnetic compatibility in premarket submissions, the FDA recommends in the final guidance that manufacturers include several items of information. The final guidance document applies to premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, premarket notification [510(k)] submissions, investigational device exemption (IDE) applications, and de novo requests.

To learn more:
http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm470201.pdf

FCC RELEASES UPDATED LED LIGHTING EMC GUIDANCE

July 14, 2016

(June 17, 2016) Effective June 17, 2016, all RF LED lighting devices, including those that have been considered to operate on frequencies below 1.705 MHz, are now required to have Radiated Emissions measurements performed at a minimum from 30 MHz to 1000 MHz.

Radio frequency (RF) light-emitting diode (LED) lighting products are subject to FCC rules to ensure that devices do not cause harmful interference to radio communications services. This KDB publication clarifies how the FCC rules apply to these products, and outlines manufacturers' responsibilities for controlling interference. This publication does not address older legacy lighting technologies such as incandescent, fluorescent, and high intensity discharge (HID)

lighting products.

For more information:
https://apps.fcc.gov/kdb/GetAttachment.html?id=K0pZdRE7biF3aqgO4XZ8cw%3D%3D&desc=640677%20D01%20RF%20LED%20LIGHTING%20v01&tracking_number=20518

ETSI RELEASES DRAFT STANDARD FOR LOW POWER MEDICAL IMPLANTS

July 14, 2016

(July 1, 2016) The present document together with ETSI EN 301 489-1 [1] covers the assessment of all radio transceivers associated with inductive Ultra Low Power Active Medical Implant (ULP-AMI) transmitters and receivers operating in the range from 9 kHz to 315 kHz and any associated external radio apparatus (ULP-AMI-Ps) transmitting in the frequency range of 9 kHz to 315 kHz including external programmers and patient related telecommunication devices in respect of ElectroMagnetic Compatibility (EMC).

Non-radio parts of the above equipment may be covered by other directives and/or standards when applicable.

To download the draft:
http://www.etsi.org/deliver/etsi_en%5C301400_301499%5C30148931%5C02.01.00_20%5Cen_30148931v020100a.pdf

IEC 60601-1-9 – ENVIRONMENTALLY CONSCIENCE DESIGN FOR MEDICAL EQUIPMENT

July 6, 2016

The standard for environmentally conscious design, IEC 60601-1-9, was published in 2007 (amended in 2013) as a collateral standard to IEC 60601, the widely accepted series of international standards for the basic safety and essential performance of medical electrical equipment. Compliance with the IEC 60601 series is required by regulatory bodies responsible for electrical medical equipment in many countries.

The requirements of IEC 60601-1-9 are based on practical experience made by reputable medical manufacturers which showed that the application of the standard may result in cost savings and marketing benefits.

Clients continue to increase pressure on manufacturers to develop medical devices with an environmentally conscious design, as it is seen as an aspect of an overall good design practice.

For more information:
http://www.intertek.com/medical/iec-60601-1-9/

LIST OF COMMON EMC STANDARDS

June 22, 2016

You shouldn't be surprised that Wikipedia has a comprehensive list of EMC standards. The list includes CISPR, IEC, ISO, European EN, FCC, and MIL-STD. There is also a link to the GR-1089-CORE EMC and product safety standards for network telecommunications equipment. A good link to bookmark.

For more information:
https://en.wikipedia.org/wiki/List_of_common_EMC_test_standards

COMPLYING WITH THE NEW EMC DIRECTIVE

May 26, 2016

Editor's Note: The following reply was received from Keith Armstrong, EMC consultant in the UK, to a news item regarding complying with the new EMC Directive.

Armstrong writes,

"I see lots of test labs publishing over-simplified guidance on complying with the new EMC Directive, including the one by [a test lab] in ITEM's latest Newsletter. They need to read it properly, and also widen their scope to look at the changes that will occur when the RED replaces R&TTE.

However, even people who have reviewed the RED in articles in ITEM and other trade mags have also missed an important issue: From 12 July 2017, if your product has an embedded radio function (bluetooth module) it will have to declare its compliance to the essential requirements of the EMCD, LVD, and RED using only RED-listed harmonised standards! Unless all the hundreds of current EMCD and LVD standards are quickly "dual-listed" in the OJEU under RED, this is going to cause huge problems.

Also there are new requirements for:

a) The Technical Documentation to include an adequate assessment of the risks of causing EMI or suffering from it;

b) Every "economic operator" in the supply chain to bear / share the responsibility for EU compliance

(This could mean sharing confidential information with importers, distributors, etc.)

c) Manufacturers name and address to be indelibly marked on the product (or that of his Authorised Rep.)

d) The names and addresses of all importers and distributors in the supply chain to be marked on the product

e) Perhaps the most important immediate change: the use of a specified format and wording in the DoC, and a single DoC covering all applicable Directives – effective from 20 April 2016. Products may well be being disallowed entry to the EU at this very moment simply because they don't use this specified DoC!"

MIL-STD-464C REVISION PROCESS UNDERWAY

May 26, 2016

US DoD has begun the process to revise MIL-STD-464C. Industry comments are welcome, and should be funneled through the two industry reps to the DoD Tri-Service Working Group:

ken.javor@emccompliance.com and briand.lessard@lmco.com.

Format for comment submission is very specific and must be adhered to rigorously. The comment should provide change from, change to, and rationale.

A suitable form is available from ken.javor@emccompliance.com.

ASSIST IS OFFICIAL ARCHIVE FOR MIL-STD DOCUMENTS

May 18, 2016

ASSIST is a web site used by standardization management to develop, coordinate, distribute, and manage defense and federal specifications and standards, military handbooks, commercial item descriptions, data item descriptions, and related technical documents prepared in accordance with the policies and procedures of the Defense Standardization Program (DSP).

Besides DoD-prepared documents, ASSIST also has selected international standardization agreements, such as NATO standards ratified by the United States and International Test Operating Procedures.

Since it always has the most current information, ASSIST is the official source for specifications and standards used by the Department of Defense.

Find all archived copies of MIL-STD-461:
http://quicksearch.dla.mil/qsDocDetails.aspx?ident_number=35789

TRANSITIONING TO NEW EMC DIRECTIVE 2014/30/EU

May 10, 2016

Now that the new EMC Directive 2014/30/EU is mandatory and in effect as of April 2016, what do manufacturers need to do to ensure continued compliance?

Elite Electronics Engineering has a five-step plan that explains the recommended steps involved. As a minimum, Elite recommends the following steps to ensure continuing compliance with European EMC requirements:

1. Check revision dates of the harmonized standards and update any technical reports
2. Review Annex IV and update the Declaration of Conformity (DoC) by updating the EMC Directive reference to 2014/30/EC, listing all current revisions of the harmonized standards applied, and clearly identifying the apparatus in the DoC to allow traceability.
3. For self-declared products, update technical documentation as specified in Annex II (3).
4. Review the CE label and confirm it's correctly applied.
5. Confirm the operator's information and technical instructions comply with Article 18.

For a copy of 2014/30/EU or questions concerning the new EMC Directive:
http://ec.europa.eu/growth/sectors

NEW EUROPEAN EMC DIRECTIVES PUBLISHED

May 4, 2016

Three new Directives for the electrical sector have been published: the EMC Directive (2014/30/EU), the Low Voltage Directive (2014/35/EU) and the Radio Equipment Directive (2014/53/EU). Two of these, the EMC Directive and Low Voltage Directive, are now in effect and are mandatory.

When comparing these directives to the previous version you will find that many changes were made, particularly to the Radio Equipment Directive and its applicability to certain product families.

WHAT'S NEW: IEC 61000-4-5 SECOND EDITION VS. THIRD EDITION

April 28, 2016

by Jeff Gray, Chief Technology Officer, Compliance West USA

Introduction

IEC 61000-4-5 is part of the IEC 61000 series, which describes surge immunity testing caused by over-voltages from switching and lightning transients. The second edition of IEC 61000-4-5 was released in 2005 and has been in use for many years. The third edition was released as an EN standard in 2014.

The general philosophy of the third edition is unchanged from the second edition. However there have been a number of refinements to the standard: additional explanation to clear up ambiguities, new descriptions that were not included in the second edition, and new (informative) Annexes that can be used to help in the application of the standard. The purpose of this article is to outline the changes and additions that are now part of IEC 61000-4-5 3rd edition.

Critical Transition Dates

Transition from the second edition to the third edition is already taking place within the EU according to the following dates:

- 19 Mar. 2015 – Date of Publication (dop): The third edition has to be implemented by publication of an identical national standard by CENELEC member countries.
- 19 June 2017 – Date of Withdrawal (dow): National standards that conflict with the third edition must be withdrawn (i.e. the second edition can no longer be used).

To read the full article:
https://interferencetechnology.com/whats-new-iec-61000-4-5-second-edition-vs-third-edition/

HOW TO SELECT THE RIGHT EMC STANDARD FOR YOUR PRODUCT

April 20, 2016

Many companies developing products find it difficult to determine the appropriate EMC standard to comply with. The IEC (International Electrotechnical Commission) has developed a web page that explains EMC and offers a tabbed selection method for determining the right standard that applies to your product family. You can then go to their web store and purchase downloadable standards applicable to your product.

For more information:
http://www.iec.ch/emc/emc_prod/prod_main.htm

HOW THE IEC IS ORGANIZED FOR EMC

April 20, 2016

International EMC standards can be confusing to the newcomer. The IEC has posted a chart as to how the various standards organizations are organized.

The first level of organization is the committees, such as TC77, CISPR, and various product committees. These committees have

liaisons with associated standards organizations, such as ISO, ITU, CENELEC, and many others. Many of these groups have working relationships with national, regional, and international organizations. In the U.S., for example, one of the primary standards organizations is ANSI.

For more information:
http://www.iec.ch/emc/iec_emc/

MIL-STD-461G: THE "COMPLEAT" REVIEW

April 15, 2016
Ken Javor, EMC Compliance January 2016
MIL-STD-461G was released on 11 December 2015 and will become contractually obligatory on programs initiated after that date.

This account is more than a simple laundry list arrived at by performing a side-by-side "F" vs. "G" comparison. Instead, it is an insider account into the issues with which the Tri-Service Working Group (TSWG) was grappling, and the thought processes behind the changes, as well as, of course, the changes themselves. It also lists some of the issues brought to the table that were not incorporated in MIL-STD-461G, and why. It will greatly assist the reader if a copy of MIL-STD-461G is available as this account unfolds.

To read the full article:
https://interferencetechnology.com/mil-std-461g-compleat-review/

WHY IS THERE AIR (IN MIL-STD-461G)?

April 14, 2016
Ken Javor, EMC Compliance January 2016
As noted in Javor's MIL-STD-461G review, SAE Aerospace Information Report (AIR), AIR 6236, In-House Verification of EMI Test Equipment was written specifically to support MIL-STD-461G.

Specifically, section 4.3.11 Calibration of measuring equipment has been reduced in scope to devices such as EMI receivers and spectrum analyzers, oscilloscopes and (RS103) electric field sensors. Section 4.3.11 now says, "After the initial calibration, passive devices such as measurement antennas, current probes, and LISNs, require no further formal calibration unless the device is repaired. The measurement system integrity check in the procedures is sufficient to determine acceptability of passive devices."

AIR 6236 was written to support the verification of proper operation of such devices in the EMI test facility using only test equipment commonly available in an EMI test facility. The idea behind the AIR was that if a measurement system integrity check was problematic, the AIR 6236 measurements would demonstrate whether or not there was a problem with a transducer. AIR 6236 was published in December 2015. Also, the procedures in the AIR can be used in-house to routinely self-check EMI test equipment, if desired.

This synopsis, by the AIR's author, discusses what's in it, and why, and includes a test procedure for one piece of equipment that was left out of the AIR.

The Introduction says that the AIR provides guidance on how to self-check the devices listed below, using equipment commonly found in EMI test facilities. The purpose is not to calibrate these devices, but to check that they have not varied significantly from manufacturer's specifications.

To read the full article:
https://interferencetechnology.com/air-mil-std-461g/

BLUE GUIDE FOR EU PRODUCT RULES AVAILABLE

April 12, 2016
The European Union's (EU) "Blue Guide" describes general rules for placing electronic products on the market within the EU.

It describes how the EU regulates the free movement of goods, when the harmonization rules apply, the product supply chain and their obligations, product requirements, conformity assessment, and accreditation.

The document goes on to describe how market surveillance works and includes several informative annexes.

To download the guide:
http://ec.europa.eu/DocsRoom/documents/18027

CISPR PROVIDES STANDARDS FOR SMARTGRID

April 5, 2016
CISPR's (International Special Committee on Radio Interference) primary role is standardization in the field of control of emissions above 9 kHz from devices, and as such has published various standards that cover or can be applied to SmartGrid system emission measurements and control.

To ensure protection of the radio frequency spectrum, emissions must be addressed effectively if the SmartGrid is to achieve its potential and provide benefits when deployed without interference complaints.

A significant additional requirement is that SmartGrid systems must be immune to sources of interference from a wide array of wanted RF signals and RF disturbances and other events which occur at SmartGrid component installations. Controlling emissions and ensuring an adequate level of immunity must both be taken on board.

CISPR has prepared a Guide to EMC in Smart Grid which gives further insight into issues which should be taken into consideration when designing and developing equipment for connection and inter-operation with the Smart Grid.

UK'S DECISION TO REGULATE INTERFERENCE FROM APPARATUS

March 30, 2016
In the UK, Ofcom has decided to issue new regulations for wireless telegraphy. Wireless Telegraphy (Control of Interference from Apparatus) Regulations 2016 is intended to tackle undue interference from electrical and electronic apparatus. In most cases, electrical and electronic apparatus are capable of emitting electromagnetic energy, but is minimal. However, in some cases the level of energy emitted from apparatus can cause undue interference to wireless communications.

"Ofcom has powers to take enforcement action in instances where some types of electrical or electronic apparatus causes undue interference to wireless communications (i.e. wireless telegraphy)." The regulations are intended to keep pace with technical developments and are expected to come into force on 18th April 2016.

To learn more:
https://stakeholders.ofcom.org.uk/consultations/undueinterference

NEW RADIO EQUIPMENT DIRECTIVE

March 30, 2016

As more products include wireless technology, designers need to specify wireless modules that meet the new Radio Equipment Directive (RED) 2014/53/EU, which was published on April 16, 2014. On June 13, 2016, the new Directive will become law and all products within its scope must meet the RED.

To learn more:
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014L0053

IEC REVISES COMMON TERMINOLOGY FOR INFORMATION SECURITY MANAGEMENT

March 16, 2016

All information held and processed by an organization is subject to the risks of attack, error and natural disaster, and other vulnerabilities inherent to its use. Information security is considered a valuable "asset" requiring appropriate protection, for example, against the loss of availability, confidentiality and integrity.

The recently revised ISO/IEC 27000:2016, Information technology – Security techniques – Information security management systems – Overview and vocabulary, gives a comprehensive view of information security management systems covered by the ISMS family of Standards, and defines related terms and definitions.

ISO/IEC 27000 gives a high-level overview of the ISMS family of Standards (ISO/IEC 27001), how they support the implementation of requirements contained in ISO/IEC 27001, Information technology – Security techniques – Information security management systems – Requirements, and how they relate to each other.

The Standard defines the key factors of a successful implementation and the numerous benefits of using the ISMS family of Standards. It provides an understanding of how the ISO/IEC 27001 family fits together through its multi-faceted approach, clarifying the Standards' scopes, roles, functions and relationship to each other. In addition, ISO/IEC 27000 gathers in one place all the essential terminology used in the ISO/IEC 27001 family.

For more information:
http://www.iec.ch/newslog/2016/nr0316.htm

THE WEARABLE FUTURE

March 8, 2016

The IEC has released a blog article, The Wearable Future, that explains the trend of smart wearable devices, the potential market, and how they are monitoring the technology and applying appropriate EMC and safety standards.
Several new interesting wearable devices are described that were announced at the recent Consumer Electronics Show (CES) in Las Vegas last January.

Author of the blog post, Antoinette, reports, "The IEC will continue to monitor this rapidly expanding industry and develop International Standards for the electronics used in wearables, which cover terminology, dependability and safety. This will allow manufacturers of components to be aligned when it comes to the technology.

Additionally, IEC Conformity Assessment Systems, based on IEC International Standards, provide independent testing and certification to ensure the safety, reliability and performance of products and the systems within which they work."

To read more of the blog post:
http://blog.iec.ch/2016/03/the-wearable-future/

HOW TO ACHIEVE FCC COMPLIANCE IN SIX STEPS

March 8, 2016

MET Labs explains how to achieve FCC compliance in six steps in their recent blog posting.

They first explain about the need for EMC compliance and the various routes to compliance in the U.S. – verification, declaration of conformity, and certification.

The six steps are outlined below:

- Step 1 – select radio frequency and design equipment
- Step 2 – test during development
- Step 3 – register with the FCC
- Step 4 – select a test lab
- Step 5 – perform compliance testing
- Step 6 – certification and filing

For more information:
http://www.metlabs.com/emc/6-steps-to-successful-fcc-testing-certification-of-electrical-products/

HAS THE EMC DIRECTIVE ACHIEVED WHAT IT SET OUT TO DO?

March 2, 2016

NewElectronics (UK) has written a white paper on the EMC Directive – its history, the new legislative framework and how it affected the Directive, how well it's being enforced, and market surveillance.

The EMC Directive is all about electrical interference – both emissions and immunity. As test house TUV puts it 'Do not disturb. Do not be disturbed'. When enacted in 1989, the Directive was regarded by many with horror and some degree of panic. Today, EMC is one of the constraints which designers deal with regularly and which results in better products.

The New Legislative Framework was a package of measures designed to improve market surveillance, boost the quality of conformity assessments, and clarify the use of CE Marking. As a result, the 2004 Directive will be replaced in April 2016 by Directive 2014/30/EU – and these changes are likely to have serious repercussions.

There were always concerns about how the EMC Directive would be policed and enforced. Being largely complaints driven, enforcement was expected to be self regulating, with competitors watching each other. "But this did not happen," observes Nick Wainwright, chief executive of York EMC Services. "Perhaps lack of confidence in their own efforts meant manufacturers kept their heads down."

As for market surveillance, for more than a decade, cross border EMC investigations have been undertaken by European authorities. They have tackled a range of products known to be sources of EMC problems, including 'energy saving lamps', power tools, consumer entertainment systems, LED lighting products and solar panel inverters.

In all cases, major shortfalls were found, both in terms of technical assessment (primarily emissions) and administration. Interestingly, the highest number of failures came from LED lighting.

To see more:
http://www.newelectronics.co.uk/electronics-technology/do-not-disturb-emc-directive-in-progress/114013/

EMC DIRECTIVE 2014/30/EU BECOMES MANDATORY APRIL 2016

February 23, 2016

Elite Electronic Engineering highlights some of the changes between the current EMC Directive 2004/30/EC and the new EMC Directive 2014/30/EU in a white paper published October 14, 2014.

It's time for manufacturers, importers, and distributors to adapt their CE Marking conformity assessment processes to the new directive by April 2016. The new directive will be required for all EMC compliance files, and declarations referencing 2004/108/EC will no longer be valid.

Elite reports, "For the most part, compliance with the new directive 2014/30/EC will not significantly impact conformity assessment. The essential requirements listed in Annex I of the directive remain the same as before and continue to be stated in very general terms. The requirements limit electromagnetic emissions to a level that will not affect telecommunications or other equipment and require products to have immunity to electromagnetic disturbances. For permanently fixed installations, Annex I still specifies applying good engineering practices to assess compliance."

The EN harmonized standards in the Official Journal don't change as a result of the recast directive, so the technical requirements used previously will remain the same going forward. However, all harmonized standards are regularly updated as they evolve to adapt to new technology.

Some of the more significant changes in the recast 2014/30/EU relate to the operations of Notified Bodies and other practices that may not immediately impact manufacturers. Annex VII in the new Directive provides a helpful correlation table that relates requirements in 2004/108/EC to 2014/30/EC.

For more information:
http://www.elitetest.com/blog/2014-10/transitioning-new-emc-directive-201430eu

CISPR PROVIDES "GUIDE TO EMC IN SMART GRID"

February 23, 2016

CISPR has prepared a "Guide to EMC in Smart Grid", which gives insight into issues which should be taken into consideration when designing and developing equipment for connection and interoperation with the Smart Grid.

SmartGrid systems must be immune to sources of interference from a wide array of wanted RF signals and RF disturbances and other events which occur at SmartGrid component installations.

Among the issues that must be addressed is EMC, which is the ability to withstand the electromagnetic (EM) environment (have sufficient immunity) without causing interference (disturbances) primarily to radio reception, but also to other digital/electronic devices.

Electromagnetic disturbances of various types, from a variety of sources, have been reported and have caused performance degradation, outages, shutdowns and even large scale system failure to the power grid. EMC is thus an important factor for consideration in standards relating to the IEC SmartGrid program.

The SmartGrid needs to function properly and have full interoperability, with other electrical and electronic systems. To ensure this these systems and their components must be designed with due consideration for conducted electromagnetic emissions injected into the grid and for immunity to various electromagnetic phenomena originating from the grid. This needs to include devices that will be mounted on the outside of buildings and homes as well as in newly designed "SmartGrid enabled" appliances.

For more information, and a copy of the grid:
http://www.iec.ch/emc/smartgrid/

A2LA AND ANSI RECOGNIZED BY NIST TO ACCREDIT NOTIFIED BODIES

February 16, 2016

A2LA and ANSI (American National Standards Institute) have been formally recognized by the National Institute of Standards and Technology (NIST) as an Accreditation Body offering Notified Body (NB) accreditation under ISO/IEC 17020:2012, ISO/IEC 17025:2005, and ISO/IEC 17065:2012.

Currently, A2LA is the only accreditation body recognized by NIST to offer accreditation to all three conformity assessment standards.

These standards form the basis for NB accreditation based on Section 4 of NIST's Requirements & Application for U.S. Conformity Assessment Bodies Seeking EU Radio Equipment Directive (RED) 2014/53/EU Notified Body Status and Requirements & Application of U.S. Conformity Assessment Bodies Seeking Electromagnetic Compatibility (EMC) Directive 2014/30/EU Notified Body Status, which both state that "The [organization] shall obtain formal accreditation for its Notified Body activities."

The newly published Directives become effective in a relatively short window of time, at which point the NB accreditation requirements come into place –April 20, 2016 for the EMC Directive, and June 13, 2016 for the RED.

For more information:
https://www.ansi.org/news_publications/news_story.aspx?menuid=7&articleid=5b8ca79c-a953-43b5-a1e5-009b28b9805f

ACMA RELEASES PRODUCT COMPLIANCE GUIDANCE FOR EMC

February 10, 2016

The electromagnetic compatibility (EMC) regulatory arrangements impose compliance labelling and record-keeping requirements for the supply of an extensive range of electrical and electronic products, vehicles and products with internal combustion engines.

The Australian Communications and Media Authority (ACMA) has detailed new requirements in the:

> Radiocommunications Labelling (Electromagnetic Compatibility) Notice 2008 (the EMC LN) made under section 182 of the Radiocommunications Act 1992.

The objective of the arrangements is to minimise the risk of unintentional electromagnetic interference from products which may affect the performance of other electrical products or disrupt radiocommunications services.

The EMC LN specifies, among other things, the form and placement of the compliance label, the compliance level, the applicable EMC testing and record-keeping requirements. The Radiocommunications (Electromagnetic Compatibility) Standard 2008 (the EMC Standard) specifies the technical standards that apply to a device.

The EMC regulatory arrangements require that, prior to supplying a product to the Australian market, a supplier must:

- Assess applicability – establish whether the product is subject to the EMC regulatory arrangement (refer to Part 2 in the EMC LN).
- Identify the applicable standards – identify the applicable EMC standard/s as listed on the ACMA website.
- Demonstrate compliance – ensure the product complies with the applicable standard/s at the specified compliance level (refer to section 4.3 of the EMC LN). Compliance can be demonstrated through testing and/or assessment of supporting documentation.
- Complete a Declaration of Conformity (DoC) and maintain compliance records – the DoC is a declaration made by, or on behalf of the supplier that all products comply with the applicable standard/s. A compliance record is a collection of documents (that may include the DoC and test reports) that support the supplier's claim the product complies with the standard/s (refer to section 4.3A and Part 5 of the EMC LN).
- Register on the national database – a supplier must register on the national database before affixing a compliance label to a compliant product (refer to sections 4.2 and 4.2A of the EMC LN).
- Apply a compliance label – a compliance label indicates the device complies with the applicable standards (refer to Part 3 of the EMC LN). The compliance label consists of the Regulatory Compliance Mark (RCM).

The EMC LN and its associated explanatory statement is available on the Federal Register of Legislative Instruments through the ComLaw website.

For more information:
http://www.acma.gov.au/Industry/Suppliers/Product-supply-and-compliance/Steps-to-compliance/emc-regulatory-arrangements

FCC TO CHANGE EMC APPROVALS PROCESS

February 1, 2016

Ghery Pettit Consulting reports a change in the FCC approvals process starting July 13, 2016.

Up until now, manufacturers have had the choice of using "FCC Listed" test labs or "FCC Recognized Accredited Test Laboratories." After that date, only the latter test labs – and ONLY those located in countries with mutual recognition agreements (MRAs) with the FCC may be used for the "Certification" approval process.

Countries with current MRAs include Australia, Canada, the EU, Hong Kong, Israel, Japan, South Korea, Singapore, and Taiwan. The country with the biggest impact will be those test labs in China, where an MRA does not yet exist.

These test labs (and others located in countries lacking an FCC MRA) will only be able to test products to the FCC's "Verification" process.

For more information:
http://pettitemcconsulting.com/what-has-changed-with-fcc-approvals/

GUIDE TO CISPR COMMITTEES

January 26, 2016

The International Special Committee on Radio Interference (CISPR) has several subcommittees working on various CISPR standards. The IEC offers a guide to these various subcommittees, along with their the scope of work.

In addition, there are useful downloadable guides for users of CISPR standards and standardization policy.

FUNCTIONAL SAFETY STANDARD IEC 61508

January 26, 2016

With more electronic systems controlling human-machinery interfaces, functional safety for EMC is becoming an important consideration.

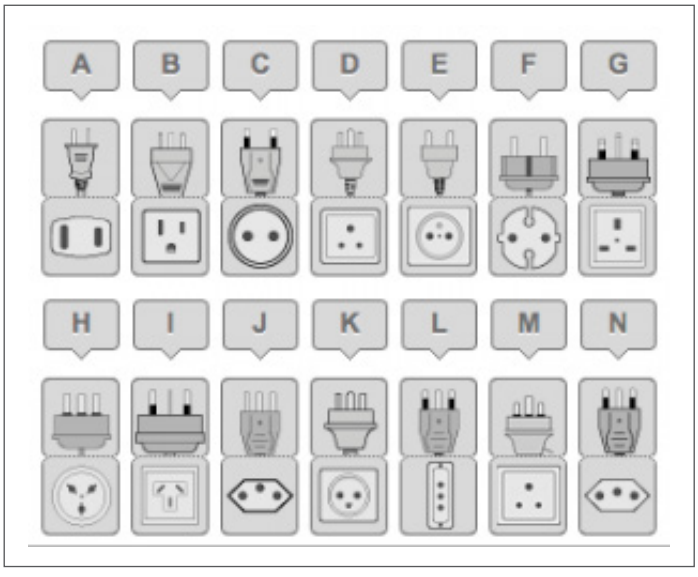
IEC 61508 addresses functional safety for industrial-process measurement, control and automation. This standard was developed by IEC SC 65A and you can read various comments and changes by leading experts.

For more information:
http://www.iec.ch/functionalsafety/?ref=extfooter

DIRECTORY OF WORLD POWER PLUGS FOR TRAVELERS

January 26, 2016

There are 14 commonly-used power line plugs used in over 200 countries. The IEC has made available a useful directory of power line plug styles used across the world. This handy guide for travelers is tabulated by country or by clicking on a world map.



WIRELESS BROADBAND ALLIANCE REPORT ON 5G

January 19, 2016

The Wireless Broadband Alliance (WBA) recently released an executive summary "From 2016 to 5G." The WBA is supported by more than 135 leading names in telecoms industry, including AT&T, BT, Cisco, Comcast, Google, Intel, Liberty Global, and Orange. This is a part of the WBA's "Vision 2020" to "harness the experience of creating seamlessly interconnected wireless services in new and emerging areas", such as IoT, "Big Data", and 5G.

"Looking ahead to 2020, the next wave of change is being considered, including the role Wi-Fi and the WBA will play in shaping 5G."

C63 COMMITTEE STANDARDS INCORPORATED BY FCC

January 11, 2016

IEEE, the world's largest professional organization dedicated to advancing technology for humanity, today announced that two Accredited Standards Committee on Electromagnetic Compatibility (ASC-C63®) standards have been 'incorporated by reference' into the updated U.S. Federal Communications Commission (FCC) rules by which telecommunications certification bodies (TCBs) authorize radio-frequency (RF) equipment.

The FCC's reference of the two ASC C63® standards impacts the work of wireless-device manufacturers, test laboratories, and trade associations globally.

The two ASC C63® standards referenced in FCC 14-208, 'Authorization of Radiofrequency Equipment', propose procedures for testing the compliance of a wide variety of wireless transmitters. ANSI C63.4-2014, American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz, defines measurement procedures for unintentional radiators such as computers and various digital electronic devices.

ANSI C63.10-2013, American National Standard of Procedures for Compliance Testing of Unlicensed Wireless Devices, for intentional radiators such as remote controls, cordless phones, hands-free microphones, some medical devices, security devices, and other unlicensed wireless devices.

'The rules we are adopting will facilitate the continued rapid introduction of new and innovative products to the market while ensuring that these products do not cause harmful interference to each other or to other communications devices and services,' as taken from FCC 14-208, which became effective 13 July 2015. Its rules in July 2016 will become mandatory for RF devices used in the United States.

For more information:
http://c63.org/news.htm

STANDARD FOR SPECTRUM CHARACTERIZATION AND OCCUPANCY SENSING

January 6, 2016

The IEEE has initiated a new standards working group, P802.22.3, whose purpose is to specify the operating characteristics of the components of a system to characterize and sense the occupancy of the radio spectrum.

To get involved:
https://standards.ieee.org/develop/project/802.22.3.html

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EMC EVENTS EUROPE

EUROPEAN EMC (AND RELATED) CONFERENCES

MICROWAVE AND RF EXPO
March 22-23, 2017
Paris, France
http://www.microwave-rf.com

EMV INTERNATIONAL EXHIBITION
March 28-30, 2017
Stuttgart, Germany
https://www.mesago.de/en/EMV/For_visitors/Welcome/index.htm

IEEE INTERNATIONAL SYMPOSIUM ON POWER LINE COMMUNICATIONS
April 3-5, 2017
Madrid, Spain
http://isplc2017.ieee-isplc.org/

EXPO ELECTRONICA
April 24-27, 2017
Moscow, Russia
http://www.expoelectronica.ru

CST - EUROPEAN USER CONFERENCE
April 26-28, 2017
Darmstadt, Germany
https://www.cst.com/EUC

AUTOMOTIVE TESTING EXPO (INCLUDES EMC)
June 20-22, 2017
Stuttgart, Germany
http://www.testing-expo.com/europe/english/

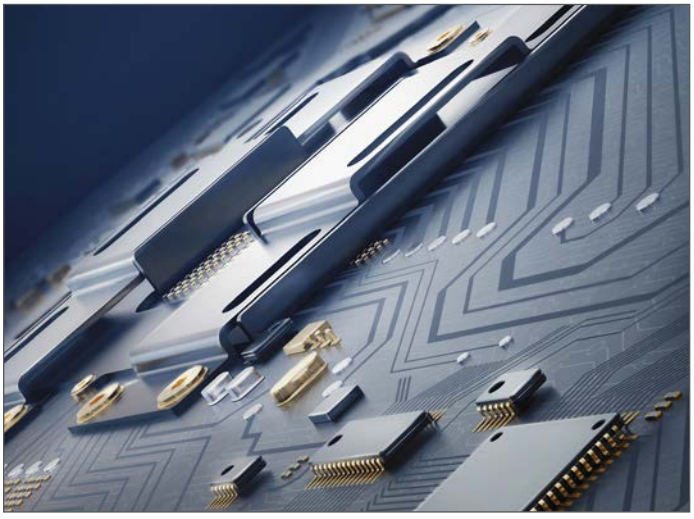
EMC COMPO - WORKSHOP ON THE ELECTROMAGNETIC COMPATIBILITY OF INTEGRATED CIRCUITS
July 4-8, 2017
St. Petersburg, Russia
http://www.emccompo2017.eltech.ru

EUROEM - EUROPEAN ELECTROMAGNETICS CONFERENCE
July 11-14, 2016
London, UK
http://conferences.theiet.org/euroem/

EMC EUROPE 2017
September 4-8, 2017
Angers, France
http://emceurope2017.org

EMC TURKIYE 2017, EMC TURKEY 2017, EMC TURKIYE KONFERANSI, EMC TURKEY SYMPOSIUM
September 24 - 27, 2017
Middle East Technical University (METU) Ankara
www.emcturkiye.org

EUROPEAN MICROWAVE CONFERENCE
October 8-13, 2017
Nuremberg, Germany
http://www.eumweek.com



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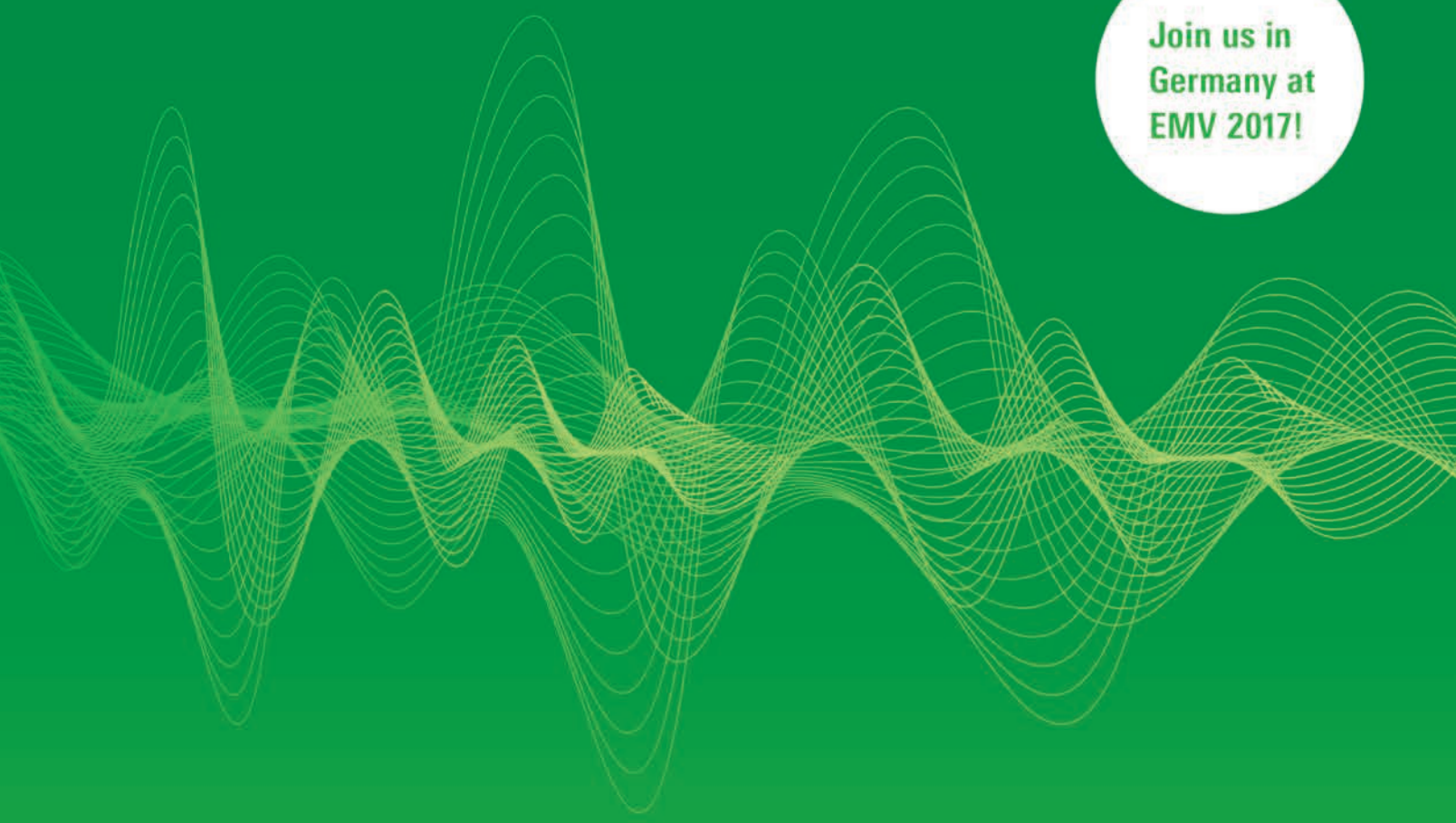

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IEEE EMC SOCIETY CHAPTERS IN EUROPE

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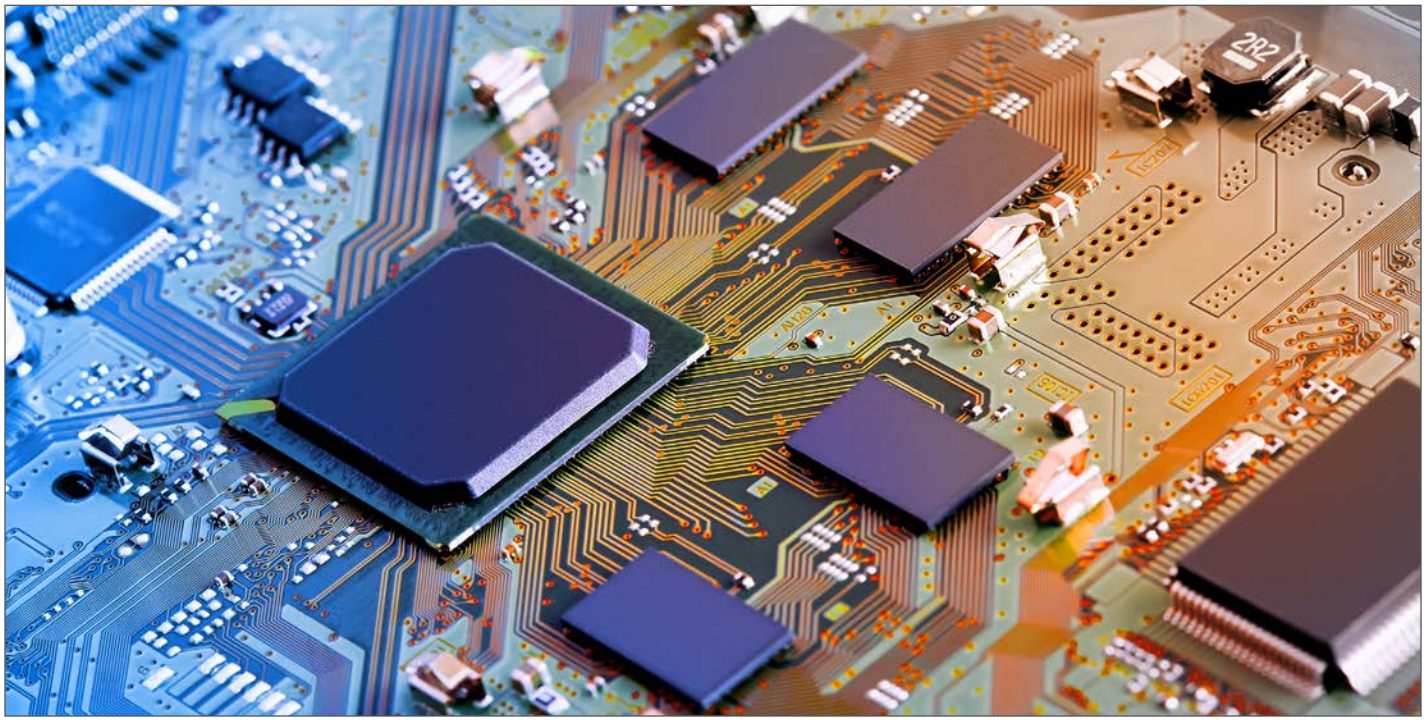

COMMON EMC STANDARDS

COMMERCIAL ELECTROMAGNETIC COMPATIBILITY (EMC) STANDARDS

Reference:
http://www.cvel.clemson.edu/emc/tutorials/commercial_emc_standards.html
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ANSI	
Document Number	Title
C63.4	Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz

IEC	
Document Number	Title
IEC 60050-161	International Electrotechnical Vocabulary. Chapter 161: Electromagnetic compatibility
IEC 60060-1	High-voltage test techniques. Part 1: General definitions and test requirements
IEC 60060-2	High-voltage test techniques - Part 2: Measuring systems
IEC 60060-3	High-voltage test techniques - Part 3: Definitions and requirements for on-site testing
IEC 60118-13	Electroacoustics - Hearing aids - Part 13: Electromagnetic compatibility (EMC)
IEC 60255-26	Measuring relays and protection equipment - Part 26: Electromagnetic compatibility requirements
IEC 60364-4-44	Low-voltage electrical installations - Part 4-44: Protection for safety - Protection against voltage disturbances and electromagnetic disturbance
IEC 60469	Transitions, pulses and related waveforms - Terms, definitions and algorithms
IEC 60533	Electrical and electronic installations in ships - Electromagnetic compatibility (EMC) - Ships with a metallic hull
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-2-2	Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
IEC 60601-4-2	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
IEC 60728-2	Cabled distribution systems for television and sound signals - Part 2: Electromagnetic compatibility for equipment
IEC 60728-12	Cabled distribution systems for television and sound signals - Part 12: Electromagnetic compatibility of systems

IEC (continued)	
Document Number	Title
IEC/TS 60816	Guide on methods of measurement of short duration transients on low-voltage power and signal lines
IEC 60870-2-1	Telecontrol equipment and systems - Part 2: Operating conditions - Section 1: Power supply and electromagnetic compatibility
IEC 60940	Guidance information on the application of capacitors, resistors, inductors and complete filter units for electromagnetic interference suppression
IEC 60974-10	Arc welding equipment - Part 10: Electromagnetic compatibility (EMC) requirements
IEC/TR 61000-1-1	Electromagnetic compatibility (EMC) - Part 1: General - Section 1: Application and interpretation of fundamental definitions and terms
IEC/TS 61000-1-2	Electromagnetic compatibility (EMC) - Part 1-2: General - Methodology for the achievement of the functional safety of electrical and electronic equipment with regard to electromagnetic phenomena
IEC/TR 61000-1-3	Electromagnetic compatibility (EMC) - Part 1-3: General - The effects of high-altitude EMP (HEMP) on civil equipment and systems
IEC/TR 61000-1-4	Electromagnetic compatibility (EMC) - Part 1-4: General - Historical rationale for the limitation of power-frequency conducted harmonic current emissions from equipment, in the frequency range up to 2 kHz
IEC/TR 61000-1-5	Electromagnetic compatibility (EMC) - Part 1-5: General - High power electromagnetic (HPEM) effects on civil systems
IEC/TR 61000-1-6	Electromagnetic compatibility (EMC) - Part 1-6: General - Guide to the assessment of measurement uncertainty
IEC/TR 61000-1-7	Electromagnetic compatibility (EMC) - Part 1-7: General - Power factor in single-phase systems under non-sinusoidal conditions
IEC/TR 61000-2-1	Electromagnetic compatibility (EMC) - Part 2: Environment - Section 1: Description of the environment - Electromagnetic environment for low-frequency conducted disturbances and signaling in public power supply systems
IEC 61000-2-2	Electromagnetic compatibility (EMC) - Part 2-2: Environment - Compatibility levels for low-frequency conducted disturbances and signaling in public low-voltage power supply systems
IEC/TR 61000-2-3	Electromagnetic compatibility (EMC) - Part 2: Environment - Section 3: Description of the environment - Radiated and non-network-frequency-related conducted phenomena

IEC (continued)	
Document Number	Title
IEC 61000-2-4	Electromagnetic compatibility (EMC) - Part 2-4: Environment - Compatibility levels in industrial plants for low-frequency conducted disturbances
IEC/TS 61000-2-5	Electromagnetic compatibility (EMC) - Part 2: Environment - Section 5: Classification of electromagnetic environments. Basic EMC publication
IEC/TR 61000-2-6	Electromagnetic compatibility (EMC) - Part 2: Environment - Section 6: Assessment of the emission levels in the power supply of industrial plants as regards low-frequency conducted disturbances
IEC/TR 61000-2-7	Electromagnetic compatibility (EMC) - Part 2: Environment - Section 7: Low frequency magnetic fields in various environments
IEC/TR 61000-2-8	Electromagnetic compatibility (EMC) - Part 2-8: Environment - Voltage dips and short interruptions on public electric power supply systems with statistical measurement results
IEC 61000-2-9	Electromagnetic compatibility (EMC) - Part 2: Environment - Section 9: Description of HEMP environment - Radiated disturbance. Basic EMC publication
IEC 61000-2-10	Electromagnetic compatibility (EMC) - Part 2-10: Environment - Description of HEMP environment - Conducted disturbance
IEC 61000-2-11	Electromagnetic compatibility (EMC) - Part 2-11: Environment - Classification of HEMP environments
IEC 61000-2-12	Electromagnetic compatibility (EMC) - Part 2-12: Environment - Compatibility levels for low-frequency conducted disturbances and signaling in public medium-voltage power supply systems
IEC 61000-2-13	Electromagnetic compatibility (EMC) - Part 2-13: Environment - High-power electromagnetic (HPEM) environments - Radiated and conducted
IEC/TR 61000-2-14	Electromagnetic compatibility (EMC) - Part 2-14: Environment - Overvoltages on public electricity distribution networks
IEC 61000-3-2	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
IEC 61000-3-3	Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
IEC/TS 61000-3-4	Electromagnetic compatibility (EMC) - Part 3-4: Limits - Limitation of emission of harmonic currents in low-voltage power supply systems for equipment with rated current greater than 16 A
IEC/TS 61000-3-5	Electromagnetic compatibility (EMC) - Part 3: Limits - Section 5: Limitation of voltage fluctuations and flicker in low-voltage power supply systems for equipment with rated current greater than 16 A
IEC/TR 61000-3-6	Electromagnetic compatibility (EMC) - Part 3: Limits - Section 6: Assessment of emission limits for distorting loads in MV and HV power systems - Basic EMC publication
IEC/TR 61000-3-7	Electromagnetic compatibility (EMC) - Part 3: Limits - Section 7: Assessment of emission limits for fluctuating loads in MV and HV power systems - Basic EMC publication
IEC 61000-3-8	Electromagnetic compatibility (EMC) - Part 3: Limits - Section 8: Signaling on low-voltage electrical installations - Emission levels, frequency bands and electromagnetic disturbance levels
IEC 61000-3-11	Electromagnetic compatibility (EMC) - Part 3-11: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems - Equipment with rated current <= 75 A and subject to conditional connection

IEC (continued)	
Document Number	Title
IEC 61000-3-12	Electromagnetic compatibility (EMC) - Part 3-12: Limits - Limits for harmonic currents produced by equipment connected to public low-voltage systems with input current >16 A and <=75 A per phase
IEC/TR 61000-3-13	Electromagnetic compatibility (EMC) - Part 3-13: Limits - Assessment of emission limits for the connection of unbalanced installations to MV, HV and EHV power systems
IEC/TR 61000-3-14	Electromagnetic compatibility (EMC) - Part 3-14: Assessment of emission limits for harmonics, interharmonics, voltage fluctuations and unbalance for the connection of disturbing installations to LV power systems
IEC/TR 61000-3-15	Electromagnetic compatibility (EMC) - Part 3-15: Limits - Assessment of low frequency electromagnetic immunity and emission requirements for dispersed generation systems in LV network
IEC TR 61000-4-1	Electromagnetic compatibility (EMC) - Part 4-1: Testing and measurement techniques - Overview of IEC 61000-4 series
IEC 61000-4-2	Electromagnetic compatibility (EMC)- Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test
IEC 61000-4-3	Electromagnetic compatibility (EMC) - Part 4-3 : Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test
IEC 61000-4-4	Electromagnetic compatibility (EMC) - Part 4-4 : Testing and measurement techniques – Electrical fast transient/burst immunity test
IEC 61000-4-5	Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test
IEC 61000-4-6	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields
IEC 61000-4-7	Electromagnetic compatibility (EMC) - Part 4-7: Testing and measurement techniques - General guide on harmonics and interharmonics measurements and instrumentation, for power supply systems and equipment connected thereto
IEC 61000-4-8	Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test
IEC 61000-4-9	Electromagnetic compatibility (EMC) - Part 4-9: Testing and measurement techniques - Impulse magnetic field immunity test
IEC 61000-4-10	Electromagnetic compatibility (EMC) - Part 4-10: Testing and measurement techniques - Damped oscillatory magnetic field immunity test
IEC 61000-4-11	Electromagnetic compatibility (EMC) - Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests
IEC 61000-4-12	Electromagnetic compatibility (EMC) - Part 4-12: Testing and measurement techniques - Ring wave immunity test
IEC 61000-4-13	Electromagnetic compatibility (EMC) - Part 4-13: Testing and measurement techniques - Harmonics and interharmonics including mains signaling at a.c. power port, low frequency immunity tests
IEC 61000-4-14	Electromagnetic compatibility (EMC) - Part 4-14: Testing and measurement techniques - Voltage fluctuation immunity test
IEC 61000-4-15	Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 15: Flickermeter - Functional and design specifications
IEC 61000-4-16	Electromagnetic compatibility (EMC) - Part 4-16: Testing and measurement techniques - Test for immunity to conducted, common mode disturbances in the frequency range 0 Hz to 150 kHz

IEC (continued)	
Document Number	Title
IEC 61000-4-17	Electromagnetic compatibility (EMC) - Part 4-17: Testing and measurement techniques - Ripple on d.c. input power port immunity test
IEC 61000-4-18	Electromagnetic compatibility (EMC) - Part 4-18: Testing and measurement techniques - Damped oscillatory wave immunity test
IEC 61000-4-19	Electromagnetic compatibility (EMC) - Part 4-19: Testing and measurement techniques - Test for immunity to conducted, differential mode disturbances and signalling in the frequency range 2 kHz to 150 kHz at a.c. power ports
IEC 61000-4-20	Electromagnetic compatibility (EMC) - Part 4-20: Testing and measurement techniques - Emission and immunity testing in transverse electromagnetic (TEM) waveguides
IEC 61000-4-21	Electromagnetic compatibility (EMC) - Part 4-21: Testing and measurement techniques - Reverberation chamber test methods
IEC 61000-4-22	Electromagnetic compatibility (EMC) - Part 4-22: Testing and measurement techniques - Radiated emissions and immunity measurements in fully anechoic rooms (FARs)
IEC 61000-4-23	Electromagnetic compatibility (EMC) - Part 4-23: Testing and measurement techniques - Test methods for protective devices for HEMP and other radiated disturbances
IEC 61000-4-24	Electromagnetic compatibility (EMC) - Part 4-24: Testing and measurement techniques - Test methods for protective devices for HEMP conducted disturbance
IEC 61000-4-25	Electromagnetic compatibility (EMC) - Part 4-25: Testing and measurement techniques - HEMP immunity test methods for equipment and systems
IEC 61000-4-27	Electromagnetic compatibility (EMC) - Part 4-27: Testing and measurement techniques - Unbalance, immunity test
IEC 61000-4-28	Electromagnetic compatibility (EMC) - Part 4-28: Testing and measurement techniques - Variation of power frequency, immunity test
IEC 61000-4-29	Electromagnetic compatibility (EMC) - Part 4-29: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations on d.c. input power port immunity tests
IEC 61000-4-30	Electromagnetic compatibility (EMC) – Part 4-30: Testing and measurement techniques – Power quality measurement methods
IEC 61000-4-31	Electromagnetic compatibility (EMC) - Part 4-31: Testing and measurement techniques - AC mains ports broadband conducted disturbance immunity test
IEC/TR 61000-4-32	Electromagnetic compatibility (EMC) - Part 4-32: Testing and measurement techniques - High-altitude electromagnetic pulse (HEMP) simulator compendium
IEC 61000-4-33	Electromagnetic compatibility (EMC) - Part 4-33: Testing and measurement techniques - Measurement methods for high-power transient parameters
IEC 61000-4-34	Electromagnetic compatibility (EMC) - Part 4-34: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current more than 16 A per phase
IEC TR 61000-4-35	Electromagnetic compatibility (EMC) - Part 4-35: Testing and measurement techniques - HPEM simulator compendium
IEC 61000-4-36	Electromagnetic compatibility (EMC) - Part 4-36: Testing and measurement techniques - IEMI immunity test methods for equipment and systems
IEC TR 61000-4-37	Electromagnetic compatibility (EMC) - Calibration and verification protocol for harmonic emission compliance test systems
IEC TR 61000-4-38	Electromagnetic compatibility (EMC) - Part 4-38: Testing and measurement techniques - Test, verification and calibration protocol for voltage fluctuation and flicker compliance test systems

IEC (continued)	
Document Number	Title
IEC/TR 61000-5-1	Electromagnetic compatibility (EMC) - Part 5: Installation and mitigation guidelines - Section 1: General considerations - Basic EMC publication
IEC/TR 61000-5-2	Electromagnetic compatibility (EMC) - Part 5: Installation and mitigation guidelines - Section 2: Earthing and cabling
IEC/TR 61000-5-3	Electromagnetic compatibility (EMC) - Part 5-3: Installation and mitigation guidelines - HEMP protection concepts
IEC/TS 61000-5-4	Electromagnetic compatibility (EMC) - Part 5: Installation and mitigation guidelines - Section 4: Immunity to HEMP - Specifications for protective devices against HEMP radiated disturbance. Basic EMC Publication
IEC 61000-5-5	Electromagnetic compatibility (EMC) - Part 5: Installation and mitigation guidelines - Section 5: Specification of protective devices for HEMP conducted disturbance. Basic EMC Publication
IEC/TR 61000-5-6	Electromagnetic compatibility (EMC) - Part 5-6: Installation and mitigation guidelines - Mitigation of external EM influences
IEC 61000-5-7	Electromagnetic compatibility (EMC) - Part 5-7: Installation and mitigation guidelines - Degrees of protection provided by enclosures against electromagnetic disturbances (EM code)
IEC 61000-5-8	Electromagnetic compatibility (EMC) - Part 5-8: Installation and mitigation guidelines - HEMP protection methods for the distributed infrastructure
IEC 61000-5-9	Electromagnetic compatibility (EMC) - Part 5-9: Installation and mitigation guidelines - System-level susceptibility assessments for HEMP and HPEM
IEC 61000-6-1	Electromagnetic compatibility (EMC) - Part 6-1: Generic standards - Immunity standard for residential, commercial and light-industrial environments
IEC 61000-6-2	Electromagnetic compatibility (EMC) - Part 6-2: Generic standards - Immunity standard for industrial environments
IEC 61000-6-3	Electromagnetic compatibility (EMC) - Part 6-3: Generic standards - Emission standard for residential, commercial and light-industrial environments
IEC 61000-6-4	Electromagnetic compatibility (EMC) - Part 6-4: Generic standards - Emission standard for industrial environments
IEC 61000-6-5	Electromagnetic compatibility (EMC) - Part 6-5: Generic standards - Immunity for power station and substation environments
IEC 61000-6-6	Electromagnetic compatibility (EMC) - Part 6-6: Generic standards - HEMP immunity for indoor equipment
IEC 61000-6-7	Electromagnetic compatibility (EMC) - Part 6-7: Generic standards - Immunity requirements for equipment intended to perform functions in a safety-related system (functional safety) in industrial locations
IEC 61326-1	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
IEC 61326-2-1	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-1: Particular requirements - Test configurations, operational conditions and performance criteria for sensitive test and measurement equipment for EMC unprotected applications
IEC 61326-2-2	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-2: Particular requirements - Test configurations, operational conditions and performance criteria for portable test, measuring and monitoring equipment used in low-voltage distribution systems

IEC (continued)	
Document Number	Title
IEC 61326-2-3	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-3: Particular requirements - Test configuration, operational conditions and performance criteria for transducers with integrated or remote signal conditioning
IEC 61326-2-4	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-4: Particular requirements - Test configurations, operational conditions and performance criteria for insulation monitoring devices according to IEC 61557-8 and for equipment for insulation fault location according to IEC 61557-9
IEC 61326-2-5	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-5: Particular requirements - Test configurations, operational conditions and performance criteria for field devices with field bus interfaces according to IEC 61784-1
IEC 61326-2-6	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
IEC 61326-3-1	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 3-1: Immunity requirements for safety-related systems and for equipment intended to perform safety-related functions (functional safety) - General industrial applications
IEC 61326-3-2	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 3-2: Immunity requirements for safety-related systems and for equipment intended to perform safety-related functions (functional safety) - Industrial applications with specified electromagnetic environment
IEC 61340-3-1	Electrostatics - Part 3-1: Methods for simulation of electrostatic effects - Human body model (HBM) electrostatic discharge test waveforms
IEC 61543	Residual current-operated protective devices (RCDs) for household and similar use - Electromagnetic compatibility
IEC 61800-3	Adjustable speed electrical power drive systems - Part 3: EMC requirements and specific test methods
IEC 61967-1	Integrated circuits - Measurement of electromagnetic emissions, 150 kHz to 1 GHz - Part 1: General conditions and definitions
IEC 62040-2	Uninterruptible power systems (UPS) - Part 2: Electromagnetic compatibility EMC) requirements
IEC 62041	Power transformers, power supply units, reactors and similar products - EMC requirements
IEC 62153-4-0	Metallic communication cable test methods - Part 4-0: Electromagnetic compatibility (EMC) - Relationship between surface transfer impedance and screening attenuation, recommended limits
IEC 62153-4-1	Metallic communication cable test methods - Part 4-1: Electromagnetic compatibility (EMC) - Introduction to electromagnetic screening measurements
IEC 62153-4-2	Metallic communication cable test methods - Part 4-2: Electromagnetic compatibility (EMC) - Screening and coupling attenuation - Injection clamp method
IEC 62153-4-3	Metallic communication cable test methods - Part 4-3: Electromagnetic compatibility (EMC) - Surface transfer impedance - Triaxial method
IEC 62153-4-4	Metallic communication cable test methods - Part 4-4: Electromagnetic compatibility (EMC) - Test method for measuring of the screening attenuation as up to and above 3 GHz, triaxial method
IEC 62153-4-5	Metallic communication cables test methods - Part 4-5: Electromagnetic compatibility (EMC) - Coupling or screening attenuation - Absorbing clamp method

IEC (continued)	
Document Number	Title
IEC 62153-4-6	Metallic communication cable test methods - Part 4-6: Electromagnetic compatibility (EMC) - Surface transfer impedance - Line injection method
IEC 62153-4-7	Metallic communication cable test methods - Part 4-7: Electromagnetic compatibility (EMC) - Test method for measuring of transfer impedance ZT and screening attenuation aS or coupling attenuation aC of connectors and assemblies up to and above 3 GHz - Triaxial tube in tube method
IEC 62153-4-8	Metallic communication cable test methods - Part 4-8: Electromagnetic compatibility (EMC) - Capacitive coupling admittance
IEC 62153-4-9	Metallic communication cable test methods - Part 4-9: Electromagnetic compatibility (EMC) - Coupling attenuation of screened balanced cables, triaxial method
IEC 62153-4-10	Metallic communication cable test methods - Part 4-10: Electromagnetic compatibility (EMC) - Transfer impedance and screening attenuation of feed-throughs and electromagnetic gaskets - Double coaxial test method
IEC 62153-4-11	Metallic communication cable test methods - Part 4-11: Electromagnetic compatibility (EMC) - Coupling attenuation or screening attenuation of patch cords, coaxial cable assemblies, pre-connectorized cables - Absorbing clamp method
IEC 62153-4-12	Metallic communication cable test methods - Part 4-12: Electromagnetic compatibility (EMC) - Coupling attenuation or screening attenuation of connecting hardware - Absorbing clamp method
IEC 62153-4-13	Metallic communication cable test methods - Part 4-13: Electromagnetic compatibility (EMC) - Coupling attenuation of links and channels (laboratory conditions) - Absorbing clamp method
IEC 62153-4-14	Metallic communication cable test methods - Part 4-14: Electromagnetic compatibility (EMC) - Coupling attenuation of cable assemblies (Field conditions) absorbing clamp method
IEC 62153-4-15	Metallic communication cable test methods - Part 4-15: Electromagnetic compatibility (EMC) - Test method for measuring transfer impedance and screening attenuation - or coupling attenuation with triaxial cell
IEC 62236-1	Railway applications - Electromagnetic compatibility - Part 1: General
IEC 62236-2	Railway applications - Electromagnetic compatibility - Part 2: Emission of the whole railway system to the outside world
IEC 62236-3-1	Railway applications - Electromagnetic compatibility - Part 3-1: Rolling stock - Train and complete vehicle
IEC 62236-3-2	Railway applications - Electromagnetic compatibility - Part 3-2: Rolling stock - Apparatus
IEC 62236-4	Railway applications - Electromagnetic compatibility - Part 4: Emission and immunity of the signalling and telecommunications apparatus
IEC 62236-5	Railway applications - Electromagnetic compatibility - Part 5: Emission and immunity of fixed power supply installations and apparatus
IEC 62305-1	Protection against lightning - Part 1: General principles
IEC 62305-2	Protection against lightning - Part 2: Risk management
IEC 62305-3	Protection against lightning - Part 3: Physical damage to structures and life hazard

IEC (continued)	
Document Number	Title
IEC 62305-4	Protection against lightning - Part 4: Electrical and electronic systems within structures
IEC 62310-2	Static transfer systems (STS) - Part 2: Electromagnetic compatibility (EMC) requirements
IEC/TR 62482	Electrical installations in ships - Electromagnetic compatibility - Optimising of cable installations on ships - Testing method of routing distance

CISPR	
Document Number	Title
CISPR 11	Industrial, scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement
CISPR 12	Vehicles, boats and internal combustion engines - Radio disturbance characteristics - Limits and methods of measurement for the protection of off-board receivers
CISPR 13	Sound and television broadcast receivers and associated equipment - Radio disturbance characteristics - Limits and methods of measurement
CISPR 14-1	Electromagnetic compatibility - Requirements for household appliances, electric tools and similar apparatus - Part 1: Emission
CISPR 14-2	Electromagnetic compatibility – Requirements for household appliances, electric tools and similar apparatus – Part 2: Immunity – Product family standard
CISPR 15	Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment
CISPR 16-1-1	Specification for radio disturbance and immunity measuring apparatus and methods - Part 1-1: Radio disturbance and immunity measuring apparatus - Measuring apparatus
CISPR 16-1-2	Specification for radio disturbance and immunity measuring apparatus and methods - Part 1-2: Radio disturbance and immunity measuring apparatus - Coupling devices for conducted disturbance measurements
CISPR 16-1-3	Specification for radio disturbance and immunity measuring apparatus and methods - Part 1-3: Radio disturbance and immunity measuring apparatus - Ancillary equipment - Disturbance power
CISPR 16-1-4	Specification for radio disturbance and immunity measuring apparatus and methods - Part 1-4: Radio disturbance and immunity measuring apparatus - Antennas and test sites for radiated disturbance measurements
CISPR 16-1-5	Specification for radio disturbance and immunity measuring apparatus and methods - Part 1-5: Radio disturbance and immunity measuring apparatus - Antenna calibration sites and reference test sites for 5 MHz to 18 GHz
CISPR 16-1-6	Specification for radio disturbance and immunity measuring apparatus and methods - Part 1-6: Radio disturbance and immunity measuring apparatus - EMC antenna calibration
CISPR 16-2-1	Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-1: Methods of measurement of disturbances and immunity - Conducted disturbance measurements
CISPR 16-2-2	Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-2: Methods of measurement of disturbances and immunity - Measurement of disturbance power
CISPR 16-2-3	Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-3: Methods of measurement of disturbances and immunity - Radiated disturbance measurements

CISPR (continued)	
Document Number	Title
CISPR 16-2-4	Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-4: Methods of measurement of disturbances and immunity - Immunity measurements
CISPR TR 16-2-5	Specification for radio disturbance and immunity measuring apparatus and methods - Part 2-5: In situ measurements for disturbing emissions produced by physically large equipment
CISPR TR 16-3	Specification for radio disturbance and immunity measuring apparatus and methods - Part 3: CISPR technical reports
CISPR TR 16-4-1	Specification for radio disturbance and immunity measuring apparatus and methods - Part 4-1: Uncertainties, statistics and limit modelling - Uncertainties in standardized EMC tests
CISPR TR 16-4-2	Specification for radio disturbance and immunity measuring apparatus and methods - Part 4-2: Uncertainties, statistics and limit modelling - Measurement instrumentation uncertainty
CISPR TR 16-4-3	Specification for radio disturbance and immunity measuring apparatus and methods - Part 4-3: Uncertainties, statistics and limit modelling - Statistical considerations in the determination of EMC compliance of mass-produced products
CISPR TR 16-4-4	Specification for radio disturbance and immunity measuring apparatus and methods - Part 4-4: Uncertainties, statistics and limit modelling - Statistics of complaints and a model for the calculation of limits for the protection of radio services
CISPR TR 16-4-5	Specification for radio disturbance and immunity measuring apparatus and methods - Part 4-5: Uncertainties, statistics and limit modelling - Conditions for the use of alternative test methods
CISPR 17	Methods of measurement of the suppression characteristics of passive EMC filtering devices
CISPR TR 18-1	Radio interference characteristics of overhead power lines and high-voltage equipment - Part 1: Description of phenomena
CISPR TR 18-2	Radio interference characteristics of overhead power lines and high-voltage equipment - Part 2: Methods of measurement and procedure for determining limits
CISPR TR 18-3	Radio interference characteristics of overhead power lines and high-voltage equipment - Part 3: Code of practice for minimizing the generation of radio noise
CISPR 20	Sound and television broadcast receivers and associated equipment - Immunity characteristics - Limits and methods of measurement
CISPR 22	Information technology equipment - Radio disturbance characteristics - Limits and methods of measurement
CISPR 24	Information technology equipment - Immunity characteristics - Limits and methods of measurement
CISPR 25	Vehicles, boats and internal combustion engines - Radio disturbance characteristics - Limits and methods of measurement for the protection of on-board receivers
CISPR 32	Electromagnetic compatibility of multimedia equipment – Emission requirements
CISPR 35	Electromagnetic compatibility of multimedia equipment - Immunity requirements

ISO	
Document Number	Title
ISO 13766:2006	Earth-moving machinery -- Electromagnetic compatibility

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- **Notification of Acceptance:** February 21, 2017
- **Final Paper Due:** May 3, 2017

Call for Experiments & Demonstrations

Experiments and demonstrations utilize hardware and software to demonstrate a principle or phenomena of EMI/EMC. The presentations are informal and non-commercial; they are usually conducted in specific areas within the Exhibit Hall.

To schedule, contact:
Bob Scully - **bob.scully@ieee.org**
Sam Connor - **sconnor@ieee.org**

Call for Abstract Reviewed Papers

Abstract Reviewed Papers provide opportunities to exchange experiences and ideas. Only an abstract is required for initial submission, papers are included in the conference proceedings; however, these papers are not published in the IEEE XPlore.

Proposals Accepted: November 1, 2016 - February 21, 2017
Acceptance Notification: March 27, 2017
Final Paper Due: May 3, 2017

Call for Special Sessions

Special Sessions focus on areas of interest not addressed in Technical Papers. Acceptance criteria are the same as for Technical Papers.

Proposals Accepted: November 1, 2016 - December 20, 2016
Notification of Acceptance: January 8, 2017
Preliminary Papers Due: March 6, 2017
Final Papers Due: May 3, 2017

Call for Workshops & Tutorials

Workshops and Tutorials are informal, interactive educational presentations, typically addressing the practical side of understanding and solving EMC issues. These sessions are held on Monday and Friday.

Proposals Accepted: November 1, 2016 - January 16, 2017
Notification of Acceptance: February 21, 2017
Final Presentations Due: May 3, 2017

Commercial Vendor Demonstrations

Please note: Commercial Demonstrations are presented by vendors and are not committee reviewed.

To schedule, contact:
Mark Maynard – **mmaynard@ieee.org**

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CISPR: INTERNATIONAL SPECIAL COMMITTEE ON RADIO INTERFERENCE

As its full name implies, CISPR's principal task is at the higher end of the frequency range, from 9 kHz upwards, preparing standards that offer protection of radio reception from interference sources such as electrical appliances of all types, the electricity supply system, industrial, scientific and electromedical RF, broadcasting receivers (sound and TV) and, increasingly, IT equipment (ITE).

SUBCOMMITTEES

As the scopes of the various subcommittees listed below indicate, **CISPR's** work involves equipment and methods for measuring interference, establishing limits and immunity requirements, and prescribing (in liaison with other IEC technical committees) methods of measuring immunity.

The committee also takes account of the impact of safety regulations on interference suppression of electrical equipment.

- **CIS/A** covers radio-interference measurements and statistical methods
- **CIS/B** handles interference relating to industrial, scientific and medical RF apparatus
- **CIS/D** deals with EM disturbances related to electric and electronic equipment on vehicles and devices powered by internal-combustion engines
- **CIS/F** covers interference relating to household appliances, tools, lighting and similar equipment
- **CIS/H** sets limits for the protection of radio services, and
- **CIS/I**, formed in 2001 from the former CIS/E and CIS/G, deals with EMC of information technology equipment (ITE), multimedia equipment and receivers.

In addition, CISPR has a steering committee known as SC S.

In some technical areas, there is the possibility of overlap in the standards adopted by CISPR and those of other IEC and ISO technical committees. Where this involves emission and immunity of devices other than receivers, CISPR considers the requirements jointly with the appropriate committee.

TECHNOLOGY CONVERGENCE

The convergence of certain newer technologies is making it difficult to decide whether some products should be designed to television or to computer EMC standards. This results in some manufacturers having to test their multimedia products to both, which is costly and time-consuming for industry.

CISPR SC I is working to produce new EMC standards, for example, CISPR 35, for multimedia products. Meanwhile, the existing product standards (CISPR 13, 20, 22 and 24) will continue to be fully maintained for the foreseeable future.

A GUIDANCE FOR USERS OF THE CISPR STANDARDS

- This guidance document is presented to you in order to guide you in the selection of appropriate CISPR EMC Standards applicable to your products, systems and installations. This document also gives an overview of the latest version of published CISPR Standards covering EMC aspects of products, systems and installations. **This may be downloaded here**: http://www.iec.ch/emc/pdf/cispr_guide_2015.pdf

THE CE MARK PROCESS FOR ELECTRONIC HARDWARE MANUFACTURERS

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Introduction

Navigating the CE Mark process can be a challenge for both startups and experienced manufacturers alike. This article is a guide for hardware manufacturers who want to do all the right things to legally get their product into Europe.

Here's what we're going to cover:

- *The typical CE Marking process for electronic equipment*
- *Outline of the most common directives*
- *How to find the standards that apply to your product*
- *Documentation requirements*

Disclaimer: There are many caveats and nuances to the CE Mark process. Do not rely solely on the contents of this article to navigate the process. Always contact an accredited test lab or notified body for advice specific to your product.

PREFACE

I just want to preface this article by stating that it's very possible to import products into Europe the illegal way or the legal way. An official report on market surveillance of electronic products in Europe undertaken in 2012 (based on a sample size of approximately 10,000 products) showed that approximately 2/3 of equipment was non-compliant with the rules. That included both technical and documentation issues.

There are clearly a high number of non-CE compliant devices entering Europe. So why bother? Really the two reasons are liability and liability. The first type of liability comes about if a competitor or a consumer lodges a compliant that your product is non-compliant in some way. You run the risk of fines, product recalls and shipments being blocked at the border.

The second type of liability is if your product is found to be unsafe in some way and actually causes damage or an accident. If you ever get dragged into court, having a safety test report on hand would probably come in handy to prove that you did some sort of due diligence around safety compliance.

But this article is really for the manufacturers who prefer to avoid liability, do things by the book and have a repeatable process in place for efficiently meeting conformity requirements.

WHAT IS THE CE MARK?

The CE Mark (or CE Marking is actually the correct way to say it) is a conformity scheme that allows for the free flow of products between countries in the European Economic Area (EEA). A manufacturer has the responsibility to prove compliance with whatever rules apply to their product in Europe and in theory, the CE Mark shows that the manufacturer has done their due diligence and the product is compliant.

GET THE CE MARK – TOP LEVEL STEP-BY-STEP PROCESS

This is the generic process that hardware manufacturers typically follow to undertake due diligence before applying the CE Mark to their products.

1. Identify the applicable directive(s) and harmonized standards
2. Verify product specific requirements
3. Identify whether an independent conformity assessment (by a notified body) is necessary
4. Test the product and check its conformity [Note that there are alternative routes to compliance that do not involve the use of 3rd party test labs, but those are outside the scope of this article. If you're interested in reading more on these alternative routes, check out this in-depth article on the subject by Keith Armstrong.]
5. Draw up and keep available the required technical documentation
6. Affix the CE mark and draw up the EU Declaration of Conformity

These six steps may differ by product as the conformity assessment procedure varies. Manufacturers must not affix CE marking to products that don't fall under the scope of one of the directives providing for its affixing. I'm going to go through these step by step below:

1. THE MOST COMMON APPLICABLE CE MARK DIRECTIVES

The directives are a series of legal acts. There are lots of them but you only need to comply with the ones that are applicable to your particular product.

It's important to note that the directives don't actually outline the test requirements that are required to prove conformance. Test requirements are contained within "harmonized standards", which we'll get into below.

If your product passes all of the tests outlined in the relevant harmonized standards, then your device is said to have a "presumption of conformity" with the directives.

Here are some of the most common directives that apply to electronic hardware products:

EMC Directive
The EMC directive applies to almost all non-wireless electronic equipment. It covers the radiated and conducted emissions performance of electronic products as well as the radiated and conducted immunity performance. You'll notice that Europe has the additional requirement of adequate 'immunity' performance compared to FCC requirements, which only specify emissions limits.

Safety (LVD – Low Voltage Directive)
The LVD, which is a safety directive, applies to almost all electrical equipment designed for use with a voltage rating of between 50 and 1000 V AC and between 75 and 1500 V DC. The lower voltage limits are removed for wireless devices, which essentially means every wireless device sold into Europe, even if it's a tiny 5V DC, 1 mW Bluetooth transmitter, needs to be tested for safety.

However, even if the LVD is not applicable to your product, the EU rules clearly state that a product must be still be 'safe'. Other directives such as the GPSD (General Product Safety Directive) may still apply.

Radio (RF Transmitters)
The "Radio Equipment Directive" (RED) superseded the older "Radio & Telecommunication Terminal Directive" and came into full effect in mid-2016. It applies to equipment, which intentionally transmits or receives radio waves for communications or radiodetermination, regardless of its primary function. It covers the radio characteristics and frequency allocation of wireless transmitters in Europe.

A point to note is that if your equipment falls under the RED, then the EMC Directive and Low Voltage Directive (safety) no longer apply. The essential requirements of those Directives are now covered by the essential requirements of the RED, with certain modifications. ETSI publishes separate EMC standards (available for free from ETSI.org) specifically for wireless devices.

RoHS
An often-overlooked aspect of CE compliance is the RoHS directive. This directive governs the maximum concentrations of hazardous substances contained within products.

Some examples of the concentration level limits, bases on weight within homogeneous materials are:

Lead:	0.1 %
Mercury:	0.1%
Cadmium:	0.01%

This has a real effect on electronics manufacturers for the components and technology you choose to use. Lead free solder is now widely available, but it can really suck to work with. If you want to be in compliance with the rules, make sure that your components and manufacturing processes comply with the RoHS requirements.

WEEE
The WEEE Directive (Waste from Electrical and Electronic Equipment Directive) is now applicable to most electronic and electrical equipment in Europe. It's aimed at redirecting waste electronic and electrical equipment from the landfill to a recycle depot instead.

As a manufacturer, you have some obligations under this directive, including:

- Marking your equipment with the WEEE logo
- Joining a PCS (producer compliance scheme) – this is to finance the collection and recycling scheme.
- Providing information to a PCS on items such as product sales

Even manufacturers who are based outside of the EU are required to join a PCS in every member state (country) that their product is sold into! Whether that is actually happening or not, is up for debate.

Other Directives
There are lots of other directives that could potentially apply to your product depending on the type and application of product. Some of the other directives include:

- The machinery directive
- Active implantable medical devices directive
- The medical device directive (MDD)
- REACH
- ECO design
- ATEX Directive (Equipment and protective systems for potentially explosive atmospheres)
- Toy safety directive

2. HOW TO FIND THE STANDARDS THAT APPLY TO YOUR PRODUCT

It's often a challenge to work out exactly which standards and directives apply to your product. Here are some ideas for tracking them down:

- Call a 3rd party test lab and request a test plan
- Check your competitor's documentation/datasheet using Google. If you're lucky, they have published their declaration of conformity
- Find them yourself (outside the scope of this article)

Having the latest standards in hand is very useful for working out what you actually have to comply with. Without them, you're running blind to a certain extent and run the risk of failing tests or requirements that you haven't prepared for.

Where to find and buy EMC/RF/Safety Standards
Standards can be very expensive. Before spending >€200 per standard, I recommend visiting the Estonian Centre for Standardization (https://www.evs.ee/shop) where many standards are available for under €30. Most radio standards are available for free from http://www.etsi.org.

3. VERIFY PRODUCT SPECIFIC REQUIREMENTS

Once you've identified all of the standards that apply to your product, you need to work out a few things:

- Which specific tests apply;
- What the test configurations are;
- What test levels apply (immunity);
- What emissions limits apply (radiated & conducted emissions);
- What pass criteria you need to meet;

This is all stuff that a test lab will need to collate when they create your 'test plan'.

4. IDENTIFY WHETHER AN INDEPENDENT CONFORMITY ASSESSMENT (BY A NOTIFIED BODY) IS NECESSARY

Depending on your product type, you may need to involve a notified body to conduct a conformity assessment. If you have a relatively risky product such as a medical device or non-standard radio transmitter for example, then you're more than likely going to need to go this route.

5. TEST THE PRODUCT AND CHECK ITS CONFORMITY

This is the part that everyone hates! It's usually the part where you send your product away to a 3rd party test lab for testing. It costs a fortune, it can take ages, and the failure rate is often over 50% (at least for EMC).

Assuming you're going the harmonized standards route to compliance rather than alternative routes, you'll need to modify your product and/or documentation until you pass the applicable tests. You can't sell your product until you do!

6. THE TECHNICAL FILE

Each of the directives that apply to your product have their own documentation requirements. Basically, the technical file needs to include all of the information and technical documents that a 3rd party would need to be able to successfully verify that your product is compliant with the requirements of the directive.

In general, the technical file needs to contain at least the following documents to satisfy each applicable directive:

- A general description of the apparatus such as conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc. As well as descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the electrical equipment
- An adequate analysis and assessment of the risk(s) involved
- Evidence of compliance with the harmonised standards, if any, applied in full or in part; including fixes required to conform with standards
- Results of design calculations made, examinations carried out, etc.,
- Test reports
- Statements from notified bodies (if applicable)

You as the manufacturer or your authorized representative located within Europe should keep copies of the technical documentation for a period of 10 years after the last product was placed on the market.For more on this, check out the European Commission's website and the "Red Book" guide.

7. CE MARK & DECLARATION OF CONFORMITY

The CE Mark DoC
Now that you've proven compliance with the rules, it's time to draw up a declaration of conformity. The Declaration of Conformity is a special document that the manufacturer signs to say that the product meets all of the requirements of the applicable directives. It must be issued by the manufacturer, and it states that the manufacturer is solely responsible for the conformity of the product.

The Declaration of Conformity must include (at least):

- a reference to the applicable Directive(s), standards and provisions complied with,
- an identification of the apparatus (name, type, model number and any relevant supplementary information),
- the manufacturer's details such as name and address,
- a dated reference of the specifications under which conformity is declared
- the date of the declaration,
- the identity and signature of the person empowered to bind the manufacturer or his authorised representative.
- the statement that the declaration is issued under the sole responsibility of the manufacturer and , if applicable, his authorised representative.
- Name of the notified body (if applicable)

In the new "Blue Book" guide to implementation of EU product rules, it states that, "A single declaration of conformity is required whenever a product is covered by several pieces of Union harmonisation legislation requiring an EU declaration of conformity."

The CE Mark "Sticker"

Once the necessary steps have been successfully completed, the CE marking must be affixed to the product and packaging. This isn't to be confused with the infamous "China Export" mark! The marking must be placed visibly and legibly on the product or, if not possible due to the size/nature of the product, be affixed to the packaging and the accompanying documentation. Good luck on your next product!

ABOUT THE AUTHOR

Andy Eadie is a senior hardware engineer, former EMC test lab owner and founder of EMC FastPass, an online resource for hardware manufacturers and engineers who want to learn how to speed up product compliance. He's the author of "Global Certifications for Makers & Hardware Startups", editor of "Getting EMC Design Right First Time" and instructor of several online courses on the subjects of EMC design for compliance, EMC testing and RF testing.

Visit www.emcfastpass.com for more information including lots of interesting guides and free webinars.

THE HF CURRENT PROBE: THEORY AND APPLICATION

Kenneth Wyatt
Wyatt Technical Services LLC

Introduction

This article describes one of the most valuable tools in the EMC engineer's "bag of tricks" – the high-frequency current probe. Current probes are invaluable for measuring high-frequency common-mode (or "antenna") currents flowing on wires or cables. Experience has proven that poorly terminated (bonded or filtered) cables are the no. 1 cause for radiated emissions failures at a test facility.

COMMON-MODE CURRENTS

By measuring the common-mode (CM) currents (sometimes referred to as "antenna" currents) on these cables it's possible to troubleshoot and apply fixes to a product right there in your development lab. You can also predict, to a good degree of accuracy, whether a given cable current will pass or fail in the measurement chamber. This will save you tons of time trying to apply fixes at the test facility while the clock is ticking away your test time. I'll also show you several ways to create do-it-yourself (DIY) probes that are quick to make and very useful in a pinch.

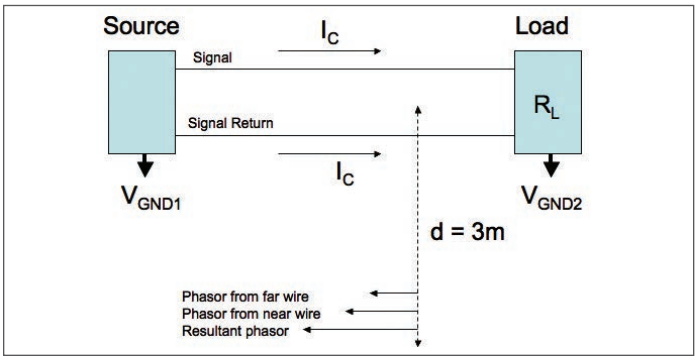

Figure 1. Common-mode currents in a circuit loop. The source is a digital signal (with harmonics) and we'll assume a resistive load. Because the phasor current in the far wire is in the same direction as the phasor current in the near wire, the resultant phasor is relatively large compared to that produced by differential-mode current phasors. In this case, lowering the harmonic content (by slowing the digital rise/fall-times) or diverting/blocking the CM current is very important in limiting radiated emissions.

CURRENT PROBES: THEORY OF OPERATION

The RF current probe is an "inserted-primary" type of radio frequency current transformer. When the probe is clamped over the conductor or cable in which current is to be measured, the conductor forms the primary winding. The clamp-on feature of this probe enables easy placement around any conductor or cable. This is essentially a broadband high-frequency transformer. High-frequency currents can be measured in cables without physically disturbing the circuit.

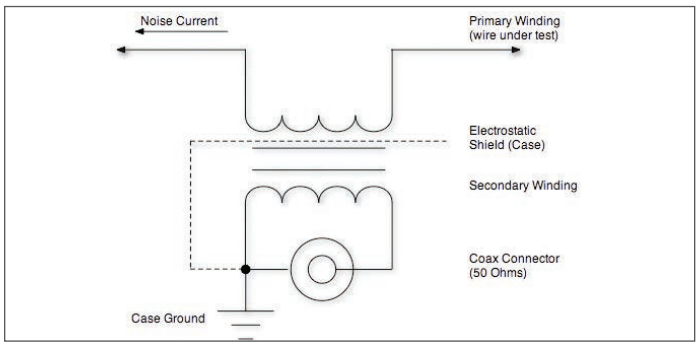

Figure 2. The basic current probe (high-frequency current transformer).

Since the current probe is intended for "clamp-on" operation, the primary shown in *Figure 2* is actually the electrical conductor in which CM currents are to be measured. This primary is considered as one turn since it is assumed that the CM currents flow through the conductor and return to the source via a return conductor such as a frame, common ground plane, or earth. On some current probe models the secondary output terminals are resistively loaded internally to provide substantially constant transfer impedance over a wider frequency range.

COMMERCIAL CURRENT PROBES

While commercial current probes are pricey, the advantage is that they can open up and snap around a cable, rather than having to be threaded onto the cable to be measured. See *Figure 3*. They are also a lot more rugged and can take a lot of abuse as compared to the "do-it-yourself" (DIY) versions below. Finally, they are also accurately characterized, allowing very precise measurements of cable currents.

DIY CURRENT PROBES

In a pinch, you can make your own current probe. Examples of several DIY probes are shown in *Figures 4* and *5*. I typically try to find a ferrite toroid or clamp-on core that offers good high-frequency characteristics in the 10 to 1000 MHz range. Winding a few (not too critical) turns and terminating with a coax connector is all you need. Keeping the turns as far apart as possible (as in *Figure*

4) will reduce inter-winding capacitance and yield better results at the higher frequencies. This is one of the largest drawbacks in performance of the clamp-on ferrites (as in *Figure 5*).

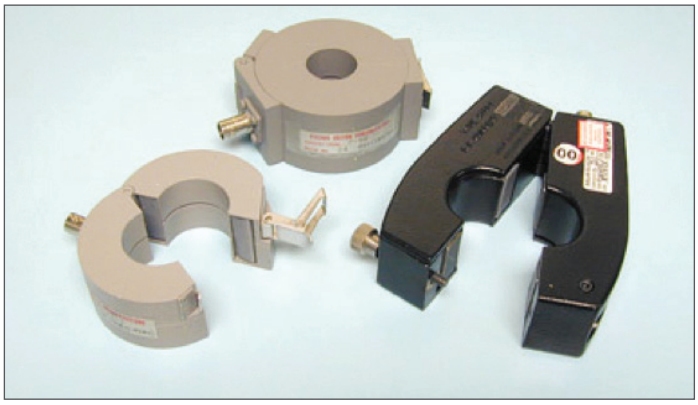

Figure 3. Examples of commercial current probes.

Figure 4. Examples of DIY current probes based on a large toroid core. These photos were taken prior to installing the E-field shield which consists of a layer of copper tape over the windings, leaving a small gap around the inside of the toroid. 14 turns of Teflon-insulated wire wound around a Würth Electronik #74270097 ferrite core (4W620 material) was used, which is useful from 10 to 1000 MHz.

TRANSFER IMPEDANCE

The CM current (Ic) in microamps in the conductor under test is determined from the reading of the current probe output (V) in microvolts divided by the current probe transfer impedance (ZT).

$$\mathbf{I = V/Z_T} \qquad \mathbf{(1)}$$

or, in dB

$$\mathbf{I(dBuA) = V(dBuV) - Z_T(dB\Omega)} \qquad \mathbf{(2)}$$

The typical transfer impedance of the current probe throughout the frequency range is determined by passing a known RF current (ic) through the primary test conductor and noting the voltage (V) developed across a 50-Ohm load. Then,

$$\mathbf{Z_T = V/Ic\ (in\ standard\ units)} \qquad \mathbf{(3)}$$

or

$$\mathbf{Z_T(dB\Omega) = V(dB\int V) - Ic(dB\int A)} \qquad \mathbf{(4)}$$

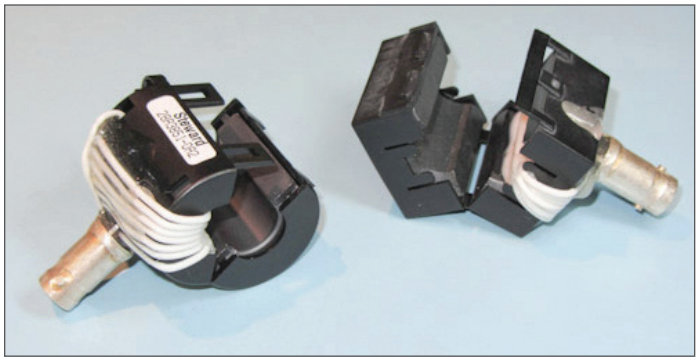

Figure 5. Examples of DIY current probes based on clamp-on ferrite chokes. I used a couple sample Steward (now a unit of Laird Technologies) chokes – a round one (model 28A3851-0A2) and a square one (model 28A2024-0A2). They each had 7 turns of Teflon-insulated wire wound around one-half and glued down on the inside to hold the windings. I later epoxied a PC board-style BNC connector to the outside, making sure there was enough epoxy to hold the outer turns together. Type 28 material was used, which is useful from 10 to 1000 MHz.

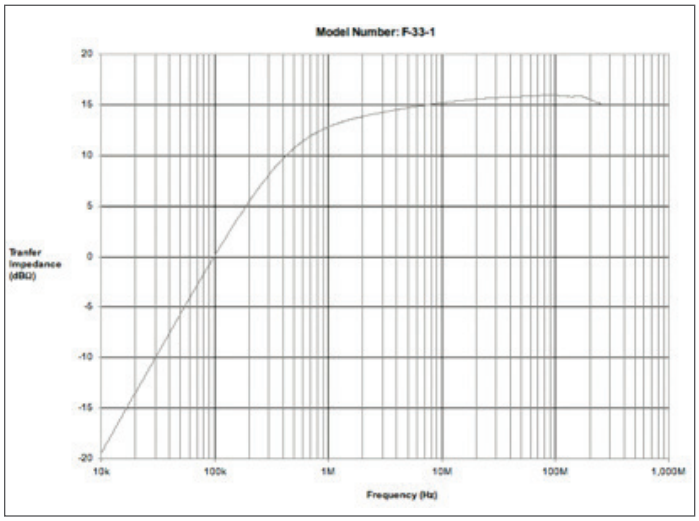

Figure 6. Transfer impedance (ZT) graph of an F-33-1 current probe (courtesy of Fischer Custom Communications). The x-axis is frequency, while the y-axis is dBΩ. Use this to calculate the value of IC (Equation 2), given the measured voltage at the probe terminals (VdBuV) and ZT.

The Fischer F-33-1 probe is a commonly used troubleshooting tool and has a flat frequency response from 2 to 250 MHz (*Figure 6*). The transfer impedance is about 5Ω (approximately +14 dBΩ on the graph), therefore, a 1 uA current will produce a 5 uV output voltage from the current probe.

PROBE CALIBRATION

The accurate calibration of RF current probes is a complex process. Characterization is a more correct term to use than calibration. The probe must be properly characterized to reflect how the user uses the probe. Probe manufacturers usually sell a calibration fixture that attempts to maintain a 50Ω impedance. A 50Ω load is connected to the output port and a calibrated RF generator (or network analyzer) is connected to the input port. The probe to be characterized is clamped around the fixture and the frequency is swept while measuring the probe output.

My test setup was a little more rudimentary (*Figure 7*), but for troubleshooting purposes, it's good enough. I used a short piece of stiff wire across the output port with a 50Ω resistive load in

series. I then adjusted the generator for zero dBm – a convenient amount. This is equivalent to an output voltage of 224 mV (or 73 dBuA of current) into 50Ω. The actual generator output doesn't matter, so long as the resulting probe voltage is large enough to be seen readily in the receiver or spectrum analyzer. I monitored the probe output with a Thurlby Thander TTi PSA2701T handheld spectrum analyzer.

Knowing the current through the wire in dBuA and the probe output in dBuV, the transfer impedance may be plotted graphically by subtracting: V(dBuV) – ic(dBuA) (expressed in dB). In this case, zt(dBΩ) = V(dBuV) – 73. While this may be useful for educational purposes, I wouldn't be too inclined to use the DIY probes to predict "pass/fail", as described further down. However, because they compare favorably to the commercial probes as far as output voltage, I believe (and have proven in practice) that they are completely suited for troubleshooting. You only need to know whether an EMC design fix made the cable current better or worse.

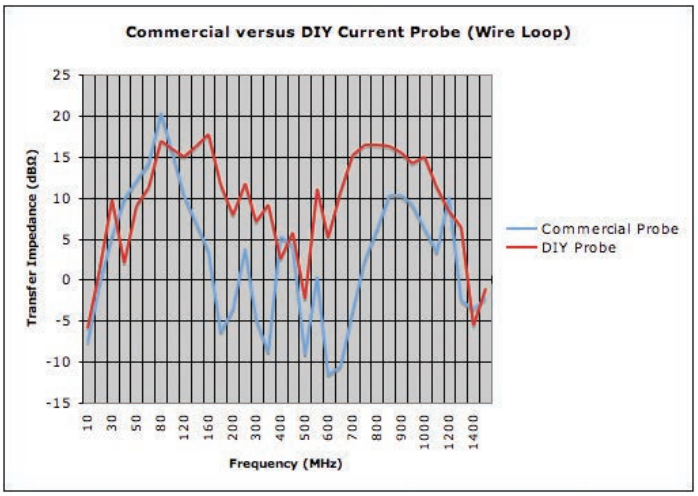

Figure 8. Transfer impedance (ZT) graph of a commercial current probe versus the DIY toroidal probe. The x-axis is frequency, while the y-axis is dBΩ. Note that the commercial probe is only designed and characterized to 250 MHz, so the data above that, while interesting, is probably not valid. The DIY probe, as well, performs poorly above 200 MHz and frankly, the wire loop used to introduce a "calibrated" current (while as short as possible) affects the measurement, as well.

PREDICTING PASS/FAIL

It is possible to predict whether a particular cable will pass or fail radiated emissions by measuring the CM current at the offending frequency, reading off the transfer impedance of the probe, Zt (dBΩ) in *Figure 6*, and solving for ic (using *Equation 2* above). Plugging ic(Amps) into *Equation 5* will calculate the E-field level in V/m. The length of the cable is L(m) and the offending harmonic frequency is f(Hz). Use a test distance, d, of either 3 or 10m to predict the outcome at those test distances.

$$|\hat{E}_{C,\max}| = 1.257 \times 10^{-6} \frac{|\hat{I}_C| f L}{d} \qquad (5)$$

Once you've determined a particular cable has CM currents that may cause a RE failure, you should to examine the connector where the cable is attached to the product enclosure. Very often, I find poor or non-existent bonding between the connector shield and enclosure shield. These points must be bonded well to permit the CM currents to flow back to their source within the product, avoiding associated cable radiation. Please refer to my previous articles on troubleshooting radiated emissions for more information (references below).

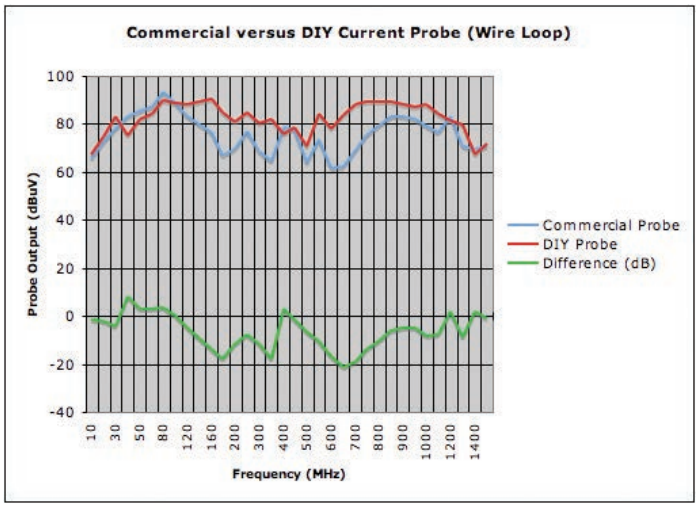

Figure 9. Probe output voltage (Vout) graph of a commercial current probe versus the DIY toroidal probe. The x-axis is frequency, while the y-axis is dBuV. This shows that the probes are very comparable in output voltage versus frequency. For troubleshooting purposes, absolute accuracy is not required – just consistency in measurements. All one really needs to know is, "did the fix I implemented make the CM current go up or down?" The DIY probe works well for this.

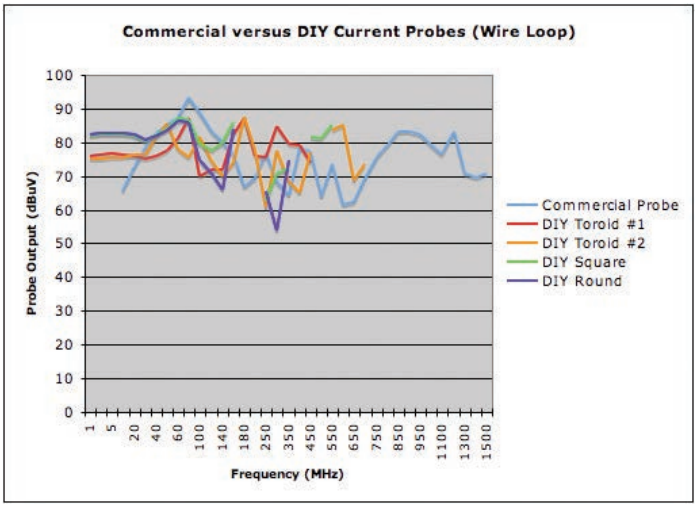

Figure 10. Probe output voltage (Vout) graph of a commercial current probe versus two DIY toroidal probes and two different clamp-on probes. The x-axis is frequency, while the y-axis is dBuV. This shows that all these probes are very comparable in output voltage versus frequency and therefore, useful for troubleshooting purposes. Just don't try using the DIY probes to determine "pass or fail" predictions. Commercial probes are better-suited for that.

Previously mentioned, one of the most common sources of radiated emissions is due to poorly bonded connectors mounted on shielded product enclosures. This occurs especially if the connectors are circuit board mounted and penetrate loosely through the shielded enclosure. Poorly bonded connectors allow internally generated CM currents to leak out and flow on the outside of I/O, mouse or keyboard cables. This will also allow ESD discharges inside the product – more bad news. If these currents are allowed out of the enclosure, the attached cables will act as

radiating antennas – often resonating around 300 MHz, due to their typical 1m length.

This was the case for a new digitizing oscilloscope prototype I worked on recently. The I/O connectors were all soldered onto the PC board and the board was fastened to the rear half of the enclosure. The connectors simply poked up through cutouts in the rear metal shield.

While using a current probe to measure the CM current flowing on the outside of the USB cable under test, I simply jammed the screwdriver blade of my Swiss Army knife between the connector bonding fingers and metal chassis enclosure and was able to drop the overall cable currents by 10 to 15 dB.

The solution was to fabricate a custom shim with spring-fingers that would slip over all the connectors creating a firm bond between the connector ground shell and inside of the shielded enclosure. More and more low-cost products are relying on PC board mounted I/O connectors as a cost-cutting measure. Any time you see this, be prepared to carefully examine the bonding between the connector ground shell and the shielded enclosure.

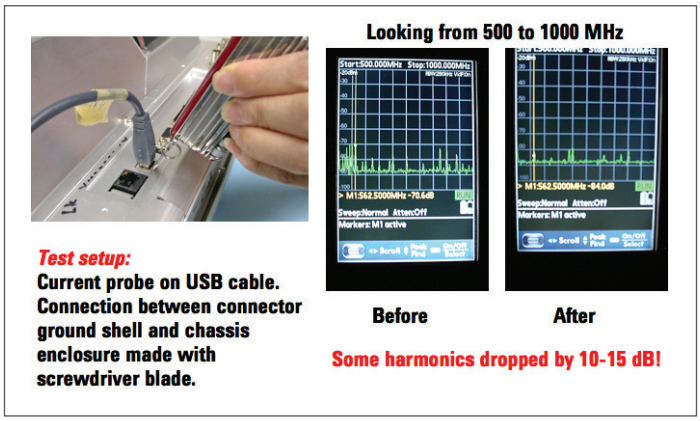

Figure 11. Cables should be tested individually. Here, I have a current probe clamped around the cable under test and am monitoring the harmonics with a simple hand-held spectrum analyzer. As I ground the connector shell to the chassis with the Swiss Army screwdriver blade, the harmonics were reduced 10-15 dB!

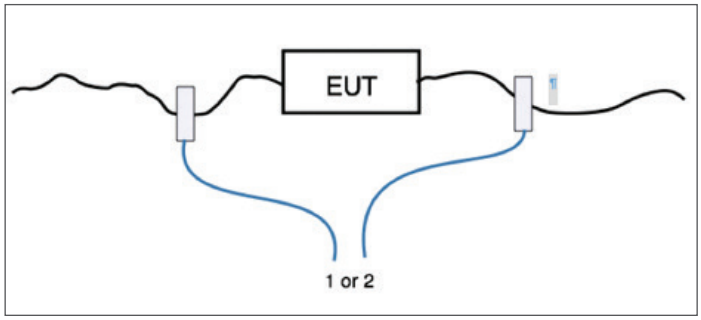

Figure 12. When measuring two cables from a system and the harmonic currents are approximately the same (point 1 is the same as point 2), the source is at the center (the EUT) and the two cables are acting as a dipole antenna. You may notice a peak in harmonic strength at the half-have length of the two cables combined. If the harmonic currents are larger in one side or the other, then you'll want to troubleshoot just that cable.

TROUBLESHOOTING TIPS USING CURRENT PROBES

Here are a few troubleshooting tips using current probes.

1. When evaluating the harmonics on a cable by using a current probe, if sliding the probe back and forth changes the harmonic levels, part of the coupling may be near-field, rather than conducted.

2. When using a pair of current probes; one on each of two cables, if the harmonics are the same in each, the source is in the middle. If one cable has stronger harmonics, then you'll want to work on that side first. See *Figure 12*.

3. Measuring the currents on two suspect legs of a dipole should read the same. Placing the two suspect legs through the same current probe should cause a big decrease due to current cancellation. See *Figure 12* below.

4. When measuring video cable currents and large cable movements cause big changes in amplitude, the coupling is likely inductive – otherwise, it's more likely conductive.

5. If you suspect inductive coupling, the phase at the victim will be 180-degrees from the source. This may be observed on an oscilloscope with H-field probes or current probes. Try syncing the scope trigger at the source using a scope probe.

My colleague, Doug Smith, has many more examples on how to use current probes for measuring cable and PC board resonances, injecting pulses for troubleshooting, interpreting the relative phase of common-mode currents and troubleshooting ESD issues. Refer to the references below.

SUMMARY

Use of a current probe is vital during the troubleshooting process. Poorly bonded cable connectors can be readily identified and fixed. The radiated E-field from a product I/O cable may be calculated by measuring the high-frequency common-mode currents flowing in the cable. All this may be performed right at the designer's workbench and without the expense of a third-party test facility or shielded chamber.

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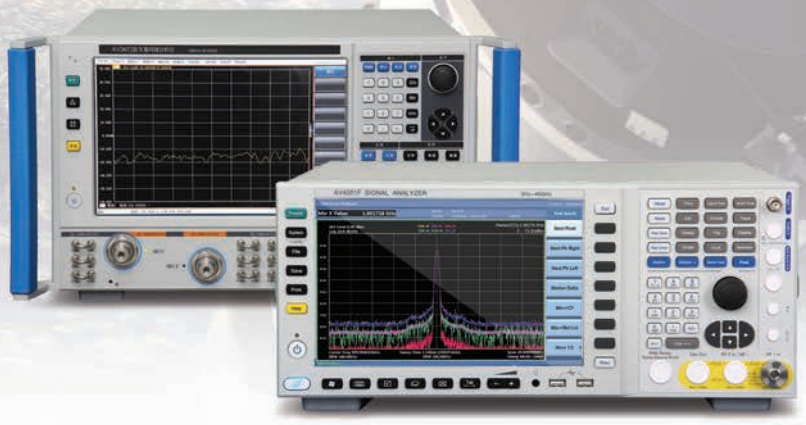

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UNITED KINGDOM

REVIEW OF IEC 60601-1-2: 2014 (4TH EDITION)

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Introduction

IEC 60601-1-2:2014 Edition 4 was published February 2014 and replaces IEC 60601-1-2 Edition 3 published on 2007. It pertains to EMC for medical electrical equipment and medical electrical systems. The European version (EN60601-1-2:2015) is identical to its IEC counterpart with exception of references to the EN versions of the 61000-4-x series and the addition of an Essential Requirements annex.

The motivation behind the 4th edition was to create a safety standard that pertains to electromagnetic disturbances in order to align with the general requirements of IEC 60601-1 Edition 3. The previous version of IEC 60601-1-2 did not adequately address the safety aspects as related to electromagnetic interference. In addition, the differences between edition 3 and 4 with respect to immunity are substantial.

GLOBAL IMPLEMENTATION

IEC 60601-1-2 Ed 4:2014 was published in February 2014. The FDA now recognizes the 4th edition and the mandatory compliance date for new submittals is December 31, 2018. That date was selected to harmonize with the requirements of the EU (EN 60601-1-2:2015). While not required until 2018, the FDA is currently accepting the 4th edition and prefers for products to be tested to that standard when submitting new applications, especially for devices to be used in the home healthcare environment.

The FDA does not require compliance to the 4th edition for legacy devices unless substantial changes are made to the product.

In the European Union, the Date of Withdrawal (DoW) of EN 60601-1-2:2007 is published as December 31, 2018. Therefore, all devices manufactured and imported into the EU after that date are required to comply with the 4th edition. There is no allowance for legacy devices as allowed by the FDA.

For other regions, the requirements vary significant by country. At least one major market does not currently accept the 4th edition.

SUMMARY OF CHANGES BETWEEN THE 3RD AND 4TH EDITION

The following significant changes were made for 4th edition.

- The classification of life support vs non-life support used in the third edition has been eliminated. It has been replaced with three intended use immunity categories. Professional Healthcare, Home Healthcare and Special Environment
- Modified emissions and immunity limits and levels as shown in *Tables 1* through *4* below
- The immunity pass/fail criteria is limited to maintaining the Essential Performance and Basic Safety
- The Potential Equalization Conductor Terminal is required connected to the local ground during testing. The third edition make no mention of the Potential Equalization Conductor Terminal
- The use of the Artificial Hand is clarified
- The test methodology for performing ESD testing on connectors is modified
- The standby mode for both emissions and immunity testing should be considered
- A new procedure has been added to establish a procedure if a device is damaged during immunity testing
- Non-medical equipment used as part of the medical electrical system shall meet its relevant EMC requirements. The system shall maintain Essential Performance and Basic Safety
- The AC input voltage and frequency requirements are streamlined. With the exception of the Voltage Dips and Interruptions tests, testing with just one voltage & frequency within the device rated rage is acceptable
- Testing of SIP/SOPS (signal input/output ports) not used during patent use is clarified
- The allowance for radio susceptibly during radiated immunity testing has been eliminated.
- Labeling requirements modified & partially streamlined. The EMC Declaration of Conformity Tables listed in the third edition have been eliminated.
- An EMC test plan is required and includes recommended content
- The minimum dwell time used for immunity testing is reduced
- An EMC test report is required and minimum content is defined

- Risk Management – numerous EMC considerations are required
- All standards referenced are dated references (3rd edition uses undated references)
- The warning statement required in the instructions for use for Class A devices differs from that found in CISPR 11
- Devices used in aircraft should consider meeting the immunity requirements listed in RTCA DO-160
- The use of the ESD warning symbol near sensitive connectors has been eliminated.

EMISSIONS REQUIREMENTS

In most cases, the emission limits in the 4th edition are the same as those in the third edition. Various clarifications were made in the 4th edition as shown in *Table 1* below.

Table 1 – Emission Requirements Comparison

Requirement	IEC 60601-1-2: 2007 (3rd Edition)	IEC 60601-1-2: 2014 (4th Edition)	Remarks
Conducted Emissions	CISPR 11	CISPR 11	
Radiated Emissions	CISPR 11	CISPR 11	
Harmonic Distortion	IEC 61000-3-2	IEC 61000-3-2	Class A limits apply
Voltage Fluctuations/Flicker	IEC 61000-3-3	IEC 61000-3-3	
Devices with Simple Components	May require compliance to CISPR 14	N/A	
Lighting Equipment	CISPR 15	N/A	
X-Ray Equipment	N/A	CISPR 11	20 dB relaxation applies for quasi-peak emissions
ITE Equipment	Must comply with CISPR 22	Must comply with CISPR 35	
Devices with Radio Subsystems	Intentional emissions exempt	Intentional emissions exempt	
Patient Cables - Conducted Emissions	N/A	Common Mode current limited to 24 dBµA (1-30 MHz)	Informative requirement
Devices with Motors or Switching Circuits	N/A	CISPR 14-1	

IMMUNITY REQUIREMENTS

Significant changes for the immunity levels were made in the 4th edition as shown in *Tables 2* through *4*. The levels were based on "reasonably foreseeable maximum".

IMMUNITY ACCEPTANCE CRITERIA

The pass/fail immunity requirements detailed in the 4th edition is based on the medical device maintaining basic safety and Essential Performance. The definitions of those concepts are detailed below" Basic Safety – As defined per IEC 60601-1:2012, Edition 3.1:

Basic Safety
freedom from unacceptable risk directly caused by physical hazards when ME equipment is used under normal condition and single fault condition[2]

Essential Performance
performance necessary to achieve freedom from unacceptable risk performance of a clinical function, other than that related to basic safety, where loss or degradation beyond the limits specified by the manufacture results in an unacceptable risk.

Note – Essential Performance is most easily understood by considering whether its absence or degradation would result in an unacceptable risk.

Table 2 – Immunity Level Comparison – Transient Phenomenon

Phenomenon	IEC 60601-1-2: 2007 (3rd Edition)	IEC 60601-1-2: 2014 (4th Edition)	
		Prof. Healthcare Environment	Home Healthcare Environment
ESD (test per IEC 61000-4-2)	8 kV Air Discharge (max.) 6 kV Contact Discharge	**15 kV** Air Discharge (max.) **8 kV** Contact Discharge	
EFT/Burst (test per IEC 61000-4-4)	2 kV - AC Mains 1 kV - I/O Ports 5 kHz or 100 kHz PRR	2 kV AC Mains 1 kV I/O Ports **100 kHz PRR**	
Surges - AC Mains (test per IEC 61000-4-5)	2 kV (max.) 0, 90, 270 degree phase angles	2 kV (max.) 0,90,180 & 270 degree phase angles	
Surges – 12 VDC Power (test per ISO 7637-2)	N/A	**600 V**	
Voltage Dips & Interrupts (test per IEC 61000-4-11)	• U_T < 5%, 0.5 periods • U_T = 40 %, 5 periods • U_T = 70%, 25 periods • U_T < 5%, 5 seconds	• **UT = 0%, 0.5 cycle (0, 45, 90, 135, 180, 225, 270 and 315°)** • **UT = 0 %; 1 cycle UT = 70%; 25/30 cycles (@ 0 degrees)** • **UT = 0%; 250/300 cycle**	

Bold = Changes from Edition 3

Table 3 – Immunity Level Comparison – Steady State Phenomenon

Phenomenon	IEC 60601-1-2: 2007 (3rd Edition)	IEC 60601-1-2: 2014 (4th Edition)	
		Prof. Healthcare Environment	Home Healthcare Environment
Conducted Immunit (test per IEC 61000-4-6)	3 V (0.15- 80 MHz) 10V ISM Bands - Life Support Equipment	3 V (0.15 - 80 MHz) **6 V (ISM bands)**	3 V (0.15 - 80 MHz) **6 V (ISM & Amateur)**
Magnetic Immunity (test per IEC 61000-4-8)	3 A/m 50 & 60 Hz	**30 A/m** 50 **or** 60 Hz	

Bold = Changes from Edition 3

Table 4 – Immunity Level Comparison – Steady State Electric Field Phenomenon

Phenomenon	IEC 60601-1-2: 2007 (3rd Edition)	IEC 60601-1-2: 2014 (4th Edition)	
		Prof. Healthcare Environment	Home Healthcare Environment
Radiated Immunit (test per IEC 61000-4-3)	3 V/m - Non Life Support 10 V/m - Life Support 80 MHz – 2.5 GHz 80%@2 Hz (or 1 kHz[1]) AM Modulation	**3 V/m** 80 MHz – **2.7 GHz** 80%@ **1 kHz** AM Modulation	**10 V/m** 80 MHz – **2.7 GHz** 80%@ **1 kHz** AM Modulation
Proximity Field from Wireless Transmit (test per IEC 61000-4-3)	N/A	**9 V/m to 28 V/m** 15 specific frequencies	

Bold = Changes from Edition 3

It is critically important for the manufacturer to understand and apply these above concepts for the medical device to be tested. In many cases, a device may be susceptible to electromagnetic disturbances, but if Basic Safety and Essential Performance are maintained, then the device may be judged as being compliant to the 4th edition.

ESD TESTING ON CONNECTORS

The third edition requires contact discharges be performed on individual connector pins that are accessible per the IEC guidelines of IEC 60601-1. There is no established test procedure to perform this test. The 4th edition refined this procedure per *Table 5* below:

Table 5 – ESD Connector Testing Requirements

Connector Shell	Discharge Requirements	Port Usage
Conductive	Contact Discharge to Shell Only	Intended and Normal Use[3]
Insulated	Air Discharge to Shell and Air Discharge to Pins (if reachable by the IEC Test Finger)	Intended Use

RISK MANAGEMENT

The concept of risk management for EMC is new. The 4th edition requires the following issues be addressed with respect to risk management. These items should be addressed and documented in the EMC test report and in the Risk Management file.

- The minimum separation distance with portable communication devices should be considered
- Annex F, Risk Management for Basic Safety and Essential Performance should be considered
- Operating modes used for testing should be based on Risk Analysis
- Testing of non-medical equipment (i.e. disturbances shall be taken into account in the risk management process)
- Effects observed of the EUT response during immunity testing should be addressed
- The Risk Management process shall be used to determine whether subsystem testing is allowed
- Reduced test levels, if used, must be justified
- Mitigations used to justify lower immunity test levels must be documented
- Alternative modulation frequencies can be used
- Current communications services shall be taken into account
- Must test to higher magnetic immunity levels if a device is closer than 15 cm to a power frequency magnetic source

Declaring compliance with the 4th edition requires five actions;

- A test plan be created prior to testing
- Compliance to relevant testing requirements
- A detailed test report with required minimum content specified
- The risk management requirements listed be addressed
- The device labeling be complaint per the requirements of clause 6.

Many test labs may be reluctant to assume the responsibility of reviewing the risk management and device labeling requirements. It is the responsibly of the manufacture to ensure all of the above items are adequately addressed.

Since publication, several errors and ambiguities have surfaced:

- There is discrepancy in the footnotes in *Tables 1* and *5*. Footnote c in Table 1 should be used.
- *Table 9* is sometimes misread to require testing be performed at a 0.3 m test distance. The test distance as specified in IEC 61000-4-3 applies.
- The FDA does not accept the allowance listed in *Table 8* Note b pertaining to cable length.

DATES FOR COMPLIANCE

The compliance dates to the 4th edition as well as many other standards can be a complex problem to solve. The dates are dependent of the type of device, the region it is sold into, and also may be driven by other higher level standards and regulations. *Table 6* summarizes the mandatory compliance dates based on the region.

Table 6 – Compliance Dates for IEC 60601-1-2:2014 (4th edition) by Region

United States	European Union	Other Regions
Legacy Devices: Never[4] New Submittals: January 1, 2019	All devices: January 1, 2019 (compliance to EN 60601-1-2: 2015)	Varies by: • Country Regulations[5] • IEC 80601-2-X Standards[6]

SUMMARY

This article has provided a comparison of IEC 60601-1-2 3rd and 4th editions. As shown in the above tables, the test levels in many cases are different and are often (but not always) more stringent. The 4th edition requires the basic safety and essential performance of the medical device by maintained in the presence of the various electromagnetic environments listed in the standard. Susceptibilities not related to Basic Safety and Essential Performance would usually not be considered a test failure. In addition, the 4th edition requires of number of aspects be considered with respect to risk management.

The two standards are significantly different with respect to test levels and the immunity pass/fail acceptance criteria, the modes of operation, and more. Given this, it would be incorrect to state compliance with the 4th edition would equate to compliance with the third edition.

REFERENCES

[1] 1 kHz modulation is used for medical devises that do not control, monitor or measure a physiological parameter.

[2] Although single fault condition is officially mentioned in this definition, many users of IEC 60601-1-2 would consider compliance during a single fault condition impractical to impossible to achieve and is therefore often ignored.

[3] Refer to IEC 60601-1 for the definition of intended and normal use.

[4] Per FDA substantial equivalence (predicate) scheme

[5] Some countries do not presently accept the 4th Edition

[6] The particular standards (IEC 60601/80601-2-X) are in process of converting to dated references to IEC 60601-1-2:2014. Until the conversion is completed, some of the part standards will reference IEC 60601-1-2:2014, some reference IEC 60601-1-2:2007 and others utilize an undated reference to IEC 60601-1-2.

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RADIO EQUIPMENT DIRECTIVE, 2014/53/EU

Charlie Blackman
Principal Consultant and Director of Sulis Consultants Ltd.

Editor's Note: *The Radio Equipment Directive (RED), 2014/53/EU, must be used for new products manufactured after June 13, 2016 and becomes mandatory for all products June 13, 2017.*

ABSTRACT

This article provides an update on changes occurring as a result of the new Radio Equipment Directive (RED) 2014/53/EU which can be used from June of 2016. It looks at the changes in the product and regulatory landscape and at what it means to equipment manufacturers.

More detail on the history of the RED can be found in the article, Radio Equipment Directive, in the Interference Technology 2015 EMC Directory and Design Guide.

SCOPE OF THE DIRECTIVE

The scope of the RED has been widened to include:

- "Radio determination" equipment, such as radars and RFID devices. These devices were considered to be within the scope of the R&TTE Directive, but the RED's scope is much clearer making it more obvious that they are included and must comply.
- "Sound and TV broadcast receivers" – these were excluded under R&TTE, so will now have additional requirements for radio spectrum performance.
- "Receiver performance" – whilst this was covered in a number of ETSI product standards, its importance in an increasingly congested radio spectrum has made it part of the Directive.
- "Devices operating below 9 kHz" – the lower frequency limit of R&TTE was 9 kHz, but that has been removed.
- In line with other directives there is a specific exclusion for "Custom-built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes."

TIMESCALES AND TRANSITION PERIODS

The European Commission has confirmed that there are four scenarios relating to the application of Directives 2014/53/EU, 2014/35/EU and 2014/30/EU [i]

It has been noted that following these dates could create a large administrative burden on manufacturers in updating documentation and Declarations of Conformity, particularly for devices that fall out of the R&TTE directive and into EMC and LVD as they cannot take advantage of the transition period written into the RED.

Guidance on content of Declarations of Conformity specifies minimum content, but does not generally specify maximum content and additional useful information is generally accepted. Based on this there is a couple of proposals currently under discussion within the commission to allow manufacturers to list both current and new directives on their Declarations of Conformity, e.g.

> *"The object of the declaration described above is in conformity with the relevant Union harmonisation legislation: Directive 1999/5/EC (until 12 June 2016), Directive 2014/30/EU (from 13 June 2016) and Directive 2014/35/EU (from 13 June 2016)."*

Please note: at the time of publication this proposal had **not been formally accepted.** It is expected to be accepted early in March and will be published in the EU Docs Room [ii]. We will bring you an update as soon as we have it.

Product Type	Compliance Requirements and Dates
Currently in scope of EMC and LVD and not in scope of R&TTE or RED	• Products placed on market before 20 April 2016: old LVD/EMCD • Products placed on market on or after 20 April 2016: new LVD/EMCD
Currently in scope of R&TTE and remain within scope of RED	• Products placed on market before 13 June 2016: R&TTED • Products placed on market between 13 June 2016 and 12 June 2017: R&TTED or RED • Products placed on market after 12 June 2017: RED
Currently outside scope of R&TTE but within scope of RED	• Products placed on market before 20 April 2016: old LVD/EMCD • Products placed on market between 20 April 2016 and 12 June 2016: new LVD/EMCD • Products placed on market between 13 June 2016 and 12 June 2017: RED or new LVD/EMCD • Products placed on market after 12 June 2017: RED
Currently in scope of R&TTE but falls outside scope of RED	• Products placed on market before 13 June 2016: R&TTED • Products placed on market after 12 June 2016: RED is not applicable; new LVD/EMCD, if applicable to the product in question

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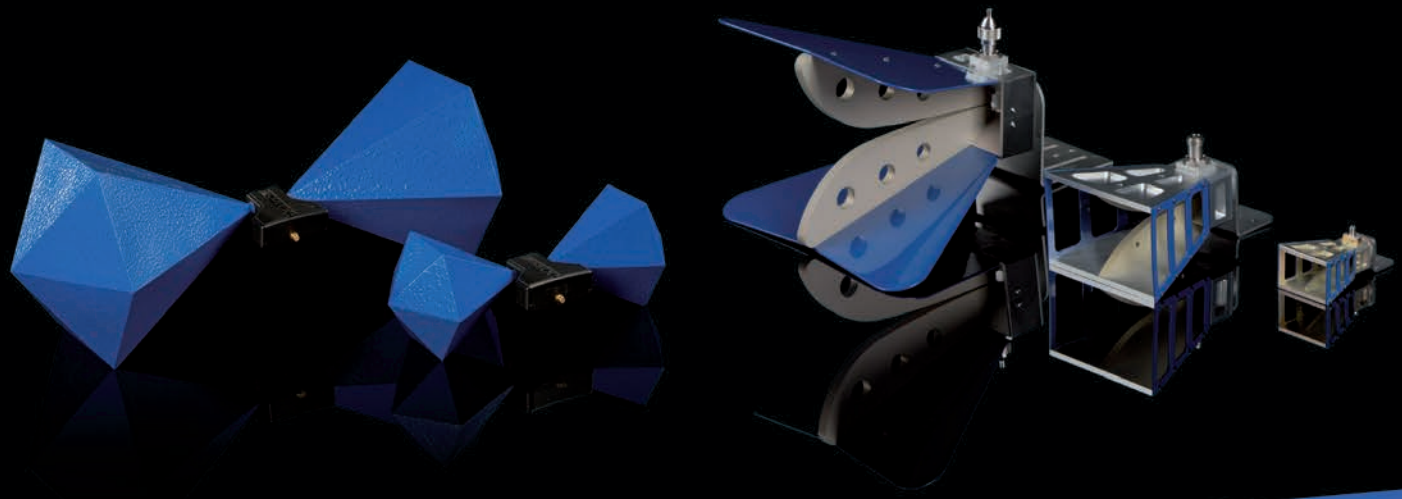

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MADE IN GERMANY

SOME KEY POINTS FOR MANUFACTURERS UNDER RED

- The CE marking must appear on the device and on the packaging – the RED no longer requires CE mark to be in the user manual
- The Notified Body number only goes on the product when the Full Quality Assurance route (R&TTE annex V / RED annex IV) and is not used where a NB has just reviewed the technical file.
- The list of permitted countries should still go on the packaging and the user manual but there is no requirement for the alert mark, , for class 2 equipment and country notifications are no longer required.
- The user manual must include frequency bands of operation and the maximum transmit power in each of those bands and this information must be in a language easily understood by the end user.
- Any product containing a piece of "radio equipment" as defined in RED Article 2, falls under the RED – so a washing machine with a Zigbee radio falls under RED and not EMC and LVD.

DEVELOPMENTS OF NEW STANDARDS FOR RED

EMC

The radio equipment does not allow application of the EMC Directive as was possible under the R&TTE, so all products containing radio equipment must be assessed against the Radio Equipment Directive.

- ETSI are developing guide EG 203 367 [iii], "Electromagnetic compatibility and Radio spectrum Matters (ERM); Guide to the application of harmonized standards covering Articles 3.1b and 3.2 of the Directive 2014/53/EU (RE-D) to multi-radio and combined radio and non-radio equipment" which provides guidance on the application of Harmonised Standards to multi-radio and combined equipment. The document is still in a draft

    * Examples of equipment to be covered by the document include, but are not limited to, combination of multiple radio products in one radio equipment, combination of radio and IT or electro-technical equipment, RLAN enabled domestic appliance, radio controlled heating system, radio controlled lighting system, etc.

Radio Spectrum

- ETSI are currently updating 156 article 3.2 radio spectrum standards for the RED, 34 of these are due for publication in the Official Journal during 2016 with the majority of the remainder following in 1st half of 2017.
- Following a review of compatibility between LTE operating in the 800 MHz band and UHF Short-Range Devices, ETSI has started work on the restructuring of EN 300 220. Work items have been adopted as follows:

    * EN 300 220-2: Harmonised Standard for non-specific radio equipment. Two versions are being developed: a version 3.1.1 with "category 3" receivers, intended to be replaced by v 3.2.1 with improved "category 2" receivers by December 2018.
    * EN 300 220-3-1: Social Alarms equipment operating in the designated frequency band (869.2 - 869.25 MHz)
    * EN 300 220-3-2: Wireless Alarms equipment operating in the designated frequency bands
    * EN 300 220-4: Metering radio equipment operating on designated frequency bands (169.4 - 169.4875 MHz)

- ETSI has already published draft standards for TV and Broadcast receivers that are moving into RED due to the change in scope of this directive:

    * Draft ETSI EN 303 340 V1.1.0v, Digital Terrestrial TV Broadcast Receivers; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU
    * Draft ETSI EN 303 345 V1.1.0vi, Radio Broadcast Receivers; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU

Transition periods

In common with normal practise, there will be a transition period during which time existing standards may continue to be used, but manufacturers should keep an eye on the ETSI work program iv and keep up to date with standards as they are published.

ABOUT

Sulis Consultants is an independent CE marking and Product Approvals consultancy based in Hampshire, England and specialising in helping manufacturers comply with the requirements of R&TTE, EMC, LV and RoHS Directives as well as radio certification for North America.

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REFERENCE LINKS

[i] http://ec.europa.eu/DocsRoom/documents/11983/attachments/1/translations/en/renditions/pdf

[ii] http://ec.europa.eu/DocsRoom/?locale=en

[iii] https://portal.etsi.org/webapp/WorkProgram/Report_WorkItem.asp?WKI_ID=47231

[iv] http://webapp.etsi.org/ena/cvp.asp?search=RADIO

[v] https://www.etsi.org/deliver/etsi_en/303300_303399/303340/01.01.00_20/en_303340v010100a.pdf

[vi] https://www.etsi.org/deliver/etsi_en/303300_303399/303345/01.01.00_20/en_303345v010100a.pdf

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BEWERTUNG DER IEC-NORM 60601-1-2: 2014

(4. AUFLAGE)

Darryl P. Ray
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Einleitung

Die IEC-Norm 60601-1-2:2014 in der 4. Auflage wurde im Februar 2014 veröffentlicht und ersetzt IEC 60601-1-2 3.Auflage, die 2007 veröffentlicht wurde. Die Norm bezieht sich auf medizinische elektrische Geräte und medizinische elektrische Systeme. Die europäische Version (EN60601-1-2:2015) ist mit Ausnahme der Referenzen zu den EN Versionen der Reihe 61000-4-x und einem Anhang mit grundlegenden Anforderungen mit der entsprechenden IEC-Norm identisch.

Motivation für die 4. Auflage war der Wunsch, einen Sicherheitsstandard in Bezug auf elektromagnetische Störungen zu schaffen, um die allgemeinen Anforderungen der 3. Auflage der IEC-Norm 60601-1 zu erfüllen- Die vorherige Version der IEC-Norm 60601-1-2 deckte Sicherheitsaspekte hinsichtlich elektromagnetischer Störungen nicht in angemessener Weise ab. Zudem sind die Unterschiede der Versionen 3 und 4 in Bezug auf Störfestigkeit gravierend.

WELTWEITE UMSETZUNG

Die IEC-Norm 60601-1-2 Auflage 4:2014 wurde im Februar 2014 veröffentlicht. Die FDA erkennt nun die 4. Auflage an und als verbindliches Datum für neue Einreichungen gilt der 31. Dezember 2018. Dieses Datum wurde gewählt, um EU-Anforderungen (EN 60601-1-2:2015) zu genügen. Obgleich bis 2018 nicht erforderlich, akzeptiert die FDA die 4. Auflage und bevorzugt beim Einreichen neuer Anträge, dass Produkte gemäß dieser Norm geprüft werden, insbesondere bei Geräten, die für die häusliche Gesundheitspflege eingesetzt werden.

Die FDA verlangt für Altgeräte nicht die Konformität mit der 4. Auflage, solange keine wesentlichen Änderungen am Gerät vorgenommen wurden.

In der Europäischen Union ist der 31. Dezember als Datum der Zurücknahme (Date of Withdrawal DoW) der Norm EN 60601-1-2:2007 festgelegt worden. Aus diesem Grund müssen alle Geräte, die nach diesem Datum hergestellt und in die EU importiert werden, der 4. Auflage entsprechen. Es gibt keine Zulassung für Altgeräte wie bei der FDA.

In anderen Regionen können die Anforderungen je nach Land signifikant unterschiedlich sein. Mindestens ein großer Markt akzeptiert derzeit die 4. Auflage nicht. Siehe Tabelle 6 (untenstehend) für weitere Einzelheiten. The FDA does not require compliance to the 4th edition for legacy devices unless substantial changes are made to the product.

ZUSAMMENFASSUNG DER UNTERSCHIEDE ZWISCHEN DER 3. UND 4. AUFLAGE

Die folgenden signifikanten Änderungen wurden in der 4. Auflage vorgenommen.

- Die Klassifizierung lebenserhaltend bzw. nicht lebenserhaltend aus der 3.Auflage wurde abgeschafft. Diese Klassifizierung wurde entsprechend der bestimmungsgemäßen Verwendung durch drei Störfestigkeitskategorien ersetzt. Gesundheitswesen, häusliche Gesundheitspflege und besondere Umgebungen
- Die geänderten Grenzwerte für Störausstrahlung und Störfestigkeit sind in den untenstehenden Tabellen 1 bis 4 gelistet.
- Die Störfestigkeitskriterien für bestanden/nicht bestanden sind auf die grundlegende Sicherheit und die wesentlichen Leistungsmerkmale beschränkt.
- Die Potentialausgleichsklemme muss während der Prüfung an die örtliche Erdung angeschlossen sein. In der 3. Auflage ist keine Potentialausgleichsklemme erwähnt.
- Der Gebrauch der Handnachbildung (Artificial Hand) wird erläutert.
- Das Prüfverfahren für ESD-Tests an Steckverbindern wurde geändert.
- Der Standby-Modus ist bei den Prüfungen zur Störausstrahlung und Störfestigkeit zu berücksichtigen.
- Eine neue Vorgehensweise wurde hinzugefügt, um festzulegen, wie vorzugehen ist, wenn ein Gerät bei der Störfestigkeitsprüfung beschädigt wird.
- Nicht-medizinische Geräte, die als Teil des elektrisch-medizinischen Geräts genutzt werden, müssen die entsprechenden

EMV-Anforderungen erfüllen. Das System muss die wesentlichen Leistungsmerkmale und die grundlegende Sicherheit gewährleisten.

- Die Anforderungen an Eingangswechselspannung und Frequenz wurden vereinheitlicht. Mit Ausnahme der Prüfungen zu Spannungseinbrüchen und Spannungsunterbrechungen, ist eine Prüfung mit nur einer Spannung und Frequenz innerhalb des Nennwertebereichs des Geräts akzeptabel.
- Die Prüfung der am Patienten nicht verwendeten Signal-Eingangs- und Ausgangsports (SIP/SOPS signal input/output ports) wird erläutert
- Die bisher berücksichtigte Störfestigkeit bei der Prüfung auf gestrahlte Störungen entfällt.
- Kennzeichnungsanforderungen wurden geändert und teilweise vereinheitlicht. Die in der 3. Auflage gelisteten EMV Konformitätserklärungstabellen entfallen.
- Ein EMV-Prüfplan ist erforderlich, der Inhalt wird empfohlen.
- Die minimale Verweilzeit bei Störfestigkeitsprüfungen wurde reduziert.
- Ein EMV-Testbericht ist erforderlich, ein Minimalinhalt ist definiert.
- Risikomanagement - verschiedene EMV-Betrachtungen sind erforderlich
- Alle Normen auf die Bezug genommen wird, sind datierte Referenzen (die 3. Auflage verwendete undatierte Referenzen)
- Der erforderliche Warnhinweis in den Gebrauchsanweisungen für Class A Gerät unterscheidet sich von dem der Norm CISPR 11.
- Bei in Luftfahrzeugen verwendeten Geräten sollte die Einhaltung der Störfestigkeitsanforderungen gemäß der Norm RTCA DO-160 in Betracht gezogen werden.
- Die Verwendung des ESD-Warnsymbols in der Nähe empfindlicher Stecker wurde abgeschafft.

EMISSIONSANFORDERUNGEN

In den meisten Fällen sind die Grenzwerte der 4. Auflage dieselben wie in der 3. Auflage. In der 4. Auflage finden sich zahlreiche Erläuterungen wie unten in Tabelle 1 dargestellt.

STÖRFESTIGKEITSANFORDERUNGEN

In der 4. Auflage gab es signifikante Änderungen bei den Störfestigkeitsgrenzen, wie in den Tabellen 2 bis gezeigt. Die Grenzwerte basieren auf einem "in vernünftigem Maße vorhersehbaren Maximum".

STÖRFESTIGKEITSKRITERIEN

Die Anforderungen der 4. Auflage für das Bestehen oder Nichtbestehen der Störfestigkeitskriterien basieren darauf, dass das medizinische Gerät die wesentlichen Leistungsmerkmale und die grundlegende Sicherheit gewährleisten muss. Die Definitionen dieser Prinzipien sind nachstehend erläutert:

Grundlegende Sicherheit – wie in IEC 60601-1:2012, Auflage 3.1 festgelegt

Grundlegende Sicherheit
bedeutet, dass das Gerät frei von nichtakzeptierbaren Risiken ist, die auf physikalische Einwirkung im Normalbetrieb und im Einzelfehlerfall zurückzuführen sind[2]

Tabelle 1 - Vergleich der Emissionsanforderungen

Anforderung	IEC 60601-1-2: 2007 (3. Auflage)	IEC 60601-1-2: 2014 (4. Auflage)	Anmerkungen
Leitungsgebundene Störausstrahlung	CISPR 11	CISPR 11	
Abgestrahlte Störungen	CISPR 11	CISPR 11	
Harmonische Verzerrung	IEC 61000-3-2	IEC 61000-3-2	Class A Grenzen werden verwendet
Spannungsschwankungen /Flicker	IEC 61000-3-3	IEC 61000-3-3	
Geräte mit einfachen Komponenten	muss evtl. CISPR 14 genügen	nicht zutreffend	
Beleuchtungsanlagen	CISPR 15	nicht zutreffend	
Röntgengeräte	nicht zutreffend	CISPR 11	Lockerung um 20 dB bei Quasi-Peak Emissionen
Informationstechnologiegeräte (ITE)	muss CISPR 22 entsprechen	muss CISPR 22 entsprechen	
Geräte mit Funkuntersystemen	Ausnahmeregelung bei gewollter Abstrahlung	Ausnahmere-gelung bei gewollter Abstrahlung	
Patientenkabel -Leitungsgebundene Störausstrahlung	nicht zutreffend	Gleichtaktstrom (Common Mode Current) begrenzt auf 24 dBµA (1-30 MHz)	Informative Anforderung
Geräte mit Motoren oder Schaltkreisen	nicht zutreffend	CISPR 14-1	

Fett = Änderungen gegenüber der 3. Auflage

Tabelle 2 - Vergleich von Störfestigkeitsgrenzwerten - Transienten

Test	IEC 60601-1-2: 2007 (3. Auflage)	IEC 60601-1-2: 2014 (4. Auflage)	
		Gesundheitswesen (Prof. Healthcare)	Häusliche Gesundheitspflege (Home Healthcare)
ESD (Prüfung gemäß IEC 61000-4-2)	8 kV Luftentladung (max.) 6 kV Kontaktentladung	15 kV Luftentladung (max.) 8 kV Kontaktentladung	
EFT/Burst (Prüfung gemäß IEC 61000-4-4)	2 kV - Wechselstromnetz 1 kV - I/O Ports 5 kHz oder 100 kHz Pulswiederholrate	2 kV - Wechselstromnetz 1 kV - I/O Ports **100 kHz Pulswiederholrate**	
Überspannung (surge) - Wechselstromnetz (Prüfung gemäß IEC 61000-4-5)	2 kV (max.) 0, 90, 270 Grad Phasenwinkel	2 kV (max.) 0,90,**180** & 270 Grad Phasenwinkel	
Überspannung (Surge) - 12 VDC Spannungsversorgung (Prüfung gemäß ISO 7637-2)	nicht zutreffend	**600 V**	
Spannungseinbrüche und -unterbrechungen (Prüfung gemäß IEC 61000-4-11)	• UT < 5%, 0,5 Perioden • UT < 40 %, 5 Perioden • UT < 70%, 25 Perioden • UT < 5%, 5 Sekunden	• **UT < 0%, 0,5 Zyklen (0, 45, 90, 135, 180, 225, 270 and 315°)** • **UT = 0 %; 1 Zyklus UT = 70%; 25/30 Zyklen (@ 0 Grad)** • **UT = 0%; 250/300 Zyklen**	

Fett = Änderungen gegenüber der 3. Auflage

Wesentliche Leistungsmerkmale

Wesentliche Leistungsmerkmale sind solche Leistungsmerkmale, die dafür sorgen, dass das Gerät bei klinischen Funktionen frei von nichtakzeptierbaren Risiken ist. Dies gilt für Funktionen, die nicht die grundlegende Sicherheit betreffen, wo eine Funktionsverschlechterung oder Funktionsverlust über die vom Hersteller festgelegten Grenzwerte hinaus ein nichtakzeptierbares Risiko darstellen würde.

Hinweis – Wesentliche Leistungsmerkmale erkennt man am einfachsten, indem man prüft , ob ihre Abwesenheit oder Funktionsverschlechterung ein nichtakzeptierbares Risiko darstellt.

Es ist von immenser Wichtigkeit für einen Hersteller, diese Prinzipien bei dem zu prüfenden Gerät zu verstehen und anzuwenden. In vielen Fällen kann ein Gerät anfällig für elektromagnetische Störungen sein, aber wenn die wesentlichen Leistungsmerkmale und die grundlegende Sicherheit gewährleistet sind, kann das Gerät dennoch als konform zu der 4. Auflage eingestuft werden.

Table 3 – Immunity Level Comparison – Steady State Phenomenon

Test	IEC 60601-1-2:2007 (3. Auflage)	IEC 60601-1-2: 2014 (4. Auflage)	
		Gesundheitswesen (Prof. Healthcare)	Häusliche Gesundheitspflege (Home Healthcare)
Leitungsgebundene Störfestigkeit (Prüfung gemäß IEC 61000-4-6)	3 V (0,15- 80 MHz) 10V ISM Band - Lebenserhaltende Geräte	3 V (0,15 - 80 MHz) **6 V (ISM Band)**	3 V (0,15 - 80 MHz) **6 V (ISM & Amateur)**
Magnetische Störfestigkeit (Prüfung gemäß IEC 61000-4-8)	3 A/m 50 & 60 Hz	**30 A/m** 50 **oder** 60 Hz	

Fett = Änderungen gegenüber der 3. Auflage

Tabelle 4 - Vergleich von Störfestigkeitsgrenzwerten - Normalbetrieb - elektrisches Feld

Test	IEC 60601-1-2:2007 (3. Auflage)	IEC 60601-1-2: 2014 (4. Auflage)	
		Gesundheitswesen (Prof. Healthcare)	Häusliche Gesundheitspflege (Home Healthcare)
Gestrahlte Störfestigkeit (Prüfung gemäß IEC 61000-4-3)	3 V/m - nicht lebenserhaltend 10 V/m - lebenserhaltend 80 MHz – 2.5 GHz 80%@2 Hz (oder 1 kHz1) AM Modulation	**3 V/m** 80 MHz – **2.7 GHz** 80%@ **1 kHz** AM Modulation	**10 V/m** 80 MHz – **2.7 GHz** 80%@ **1 kHz** AM Modulation
Nahfeld von Wireless-Funksendern (Prüfung gemäß IEC 61000-4-3)	nicht zutreffend	**9 V/m bis 28 V/m** 15 spezifische Frequenzen	

Fett = Änderungen gegenüber der 3. Auflage

ESD-PRÜFUNGEN BEI STECKVERBINDERN

Die 3. Auflage fordert Kontaktentladungsprüfungen an einzelnen zugänglichen Steckverbinderpins gemäß der IEC Richtlinie IEC 60601-1. Es gibt kein etabliertes Prüfverfahren für diesen Test. In der 4. Auflage ist das Prüfverfahren detailliert dargestellt, siehe Tabelle 5 unten.

Tabelle 5 - Anforderungen bei ESD-Prüfungen an Steckverbindern

Steckergehäuse	Entladungsanforderungen	Verwendung des Ports
Leitend	nur Kontaktentladung auf Gehäuse	bestimmungsgemäßer und normaler Gebrauch[3]
Isoliert	Luftentladung auf Gehäuse und Luftentladung auf Pins (sofern für den IEC Standardprüffinger zugänglich)	bestimmungsgemäßer Gebrauch

RISIKOMANAGEMENT

Das Prinzip des Risikomanagements ist für die EMV neu. Die 4. Auflage fordert, dass die Prüfung der folgenden Punkte hinsichtlich des Risikomanagements. Diese Punkte sind zu prüfen und im EMV-Bericht und den Risikomanagementunterlagen zu dokumentieren.

- Der Minimalabstand zu mobilen Kommunikationsgeräten ist zu berücksichtigen.
- Anhang F, Risikomanagement für grundlegende Sicherheit und wesentlichen Leistungsmerkmale ist zu berücksichtigen.
- Die Betriebsmodi, die bei der Prüfung verwendet werden, müssen durch die Risikoanalyse begründet werden.
- Prüfung von nichtmedizinischen Geräten (z.B. Störungen müssen in den Risikomanagementprozess aufgenommen werden)
- Beobachteten Auffälligkeiten beim zu prüfenden Gerät (EUT) bei der Störfestigkeitsprüfung sind nachzugehen.
- Der Risikomanementprozess wird dazu verwendet um zu entscheiden, ob eine Prüfung eines Untersystems zulässig ist.
- Wenn reduzierte Prüfschwellen verwendet wird, ist dies zu begründen.
- Minderungsmaßnahmen, die reduzierte Prüfschwellen rechtfertigen, sind zu dokumentieren.
- Es können alternative Modulationsfrequenzen verwendet werden.
- Aktuelle Kommunikationsdienste sind zu berücksichtigen.
- Eine Prüfung auf höhere magnetische Störfestigkeit ist erforderlich, wenn ein Gerät näher als 15cm an einer magnetischen Quelle mit Netzfrequenz ist.

Die Erklärung der Konformität mit der 4. Auflage erfordert fünf Maßnahmen:

- Ein Prüfplan vor Beginn der Prüfungen
- Konformität mit den relevanten Testanforderungen
- Einen detaillierten Prüfbericht mit spezifiziertem Minimalinhalt.
- Die gelisteten Risikomanagementanforderungen sind zu berücksichtigen.
- Die Gerätekennzeichnung muss den Anforderungen aus Satz 6 genügen.

Viele Prüflabore werden eher abgeneigt sein, die Verantwortung für die Prüfung des Risikomanagements und die Gerätekennzeichnung zu übernehmen. Es obliegt dem Hersteller sicherzustellen, dass alle obigen Punkte ordnungsgemäß berücksichtigt werden.

Seit der Veröffentlichung sind verschiedene Fehler und Zweideutigkeiten entdeckt worden:

- Die Fußnoten in Tabellen 1 und 5 sind widersprüchlich. Fußnote c in Tabelle 1 ist zu verwenden.
- Tabelle 9 wird manchmal so missverstanden, dass die Prüfung in einem Abstand von 0,3m durchzuführen sei. Es gilt der in IEC 61000-4-3 festgelegte Prüfabstand.
- Die FDA akzeptiert nicht die in Tabelle 8 Anmerkung b gelistete Erlaubnis hinsichttlich der Kabellänge.

FRISTEN FÜR DIE KONFORMITÄT

Die Fristen für die Konformität zu der 4. Auflage und die anderer

Normen ist ein sehr komplexes Thema. Die Fristen sind abhängig vom Gerätetyp, der Region, in der das Gerät verkauft wird, zudem können die Fristen auch durch andere Normen und Richtlinien bestimmt werden. In Tabelle 6 sind die vorgeschriebenen Konformitätsfristen für die einzelnen Regionen gelistet.

Tabelle 6 – Konformitätsfristen für IEC 60601-1-2:2014 (4. Auflage) nach Region

USA	EU	Andere Regionen
Altgeräte: Nie[4] Neueinreichungen: 1 Januar 2019	Alle Geräte 1 Januar 2019 (Konformität zu EN 60601-1-2: 2015)	hängt ab von • Richtlinien im jeweiligen Land[5] • IEC 80601-2-X Normen[6]

ZUSAMMENFASSUNG

Dieser Artikel bietet einen Vergleich der 3. und 4. Auflage der Norm IEC 60601-1-2 . Wie in obigen Tabellen gezeigt, sind die Prüfgrenzwerte in vielen Fällen unterschiedlich und oft (aber nicht immer) strenger.

Die 4. Auflage fordert, dass die grundlegende Sicherheit und wesentlichen Leistungsmerkmale des medizinischen Geräts in Gegenwart der verschiedenen elektromagnetischen Umgebungen, die in der Norm gelistet sind, gewährleistet sein müssen. Störempfindlichkeiten, die nicht die die grundlegende Sicherheit und wesentlichen Leistungsmerkmale beeinträchtigen, führen in der Regel nicht zu einem Nichtbestehen der Prüfung. Des Weiteren fordert die 4. Auflage, dass eine Reihe von Risikomanagementsaspekten zu berücksichtigen sind.

Beide Normen unterscheiden sich erheblich in Bezug auf die Prüfgrenzwerte und die Kriterien zum Bestehen/Nichtbestehen, die Betriebsmodi und in anderen Dingen. Unter diesen Gegebenheiten wäre es falsch zu behaupten, dass die Konformität mit der 4. Auflage automatisch auch die Konformität mit der 3. Auflage bedeutet.

REFERENCES

[1] Bei medizinischen Geräten, die einen physiologischen Parameter steuern, überwachen oder messen, wird eine 1 kHz Modulation verwendet.

[2] Obwohl der Einzelfehlerfall offiziell in dieser Definition verwendet wird, ist für Anwender der Norm IEC 60601-1-2 die Konformität im Einzelfehlerfall nur schwer bis unmöglich erreichbar und wird deswegen oft ignoriert.

[3] für bestimmungsgemäßen und normalen Gebrauchs siehe IEC 60601-1

[4] gemäß der Übersicht über wesentliche Gleichwertigkeit (Substantial Equivalence Scheme) der FDA

[5] Einige Länder akzeptieren derzeit die 4. Auflage nicht

[6] Diese besonderen Normen(IEC 60601/80601-2-X) werden gegenwärtig in datierte Referenzen der IEC 60601-1-2:2014 umgewandelt. Solange die Umwandlung noch läuft, werden einige der Teilnormen IEC 60601-1-2:2014 referenzieren, einige IEC 60601-1-2:2007 und andere werden undatierte Referenzen zur IEC 60601-1-2 verwenden.

FUNKANLAGENRICHTLINIE, 2014/53/EU

von Charlie Blackman
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Anmerkung der Redaktion: *Die Funkanlagenrichtlinie (Radio Equipment Directive - RED), 2014/53/EU gilt für neue Produkte, die nach dem 13. Juni 2016 hergestellt werden und wird zum 13. Juni 2017 verpflichtend für alle Produkte.*

ZUSAMMENFASSUNG

Dieser Artikel bietet ein Update über die Änderungen, die sich aufgrund der neuen Funkanlagenrichtlinie (Radio Equipment Directive - RED) 2014/53/EU seit Juni 2016 ergeben. Es werden Änderungen hinsichtlich Produktanforderungen und Regularien beleuchtet und was diese Änderungen für die Gerätehersteller bedeuten.

Weitere Einzelheiten zur Geschichte der Funkanlagenrichtlinie RED sind im Artikel "Radio Equipment Directive" im "Interference Technology 2015 EMC Directory and Design Guide" zu finden.

GELTUNGSBEREICH DER DIREKTIVE

Der Geltungsbereich der Funkanlagenrichtlinie RED wurde ausgeweitet und umfasst nun:

- Funkortungsanlagen (Radio Determination Equipment) wie etwa Radar oder RFID-Geräte. Diese Geräte wurden bislang in der Regel der Richtlinie über Funkanlagen und Telekommunikationsendeinrichtungen (RTTE) zugeordnet aber die Funkanlagenrichtlinie RED ist viel deutlicher und es ist nun offensichtlich, dass sie diese Geräte beinhaltet und diese konform sein müssen.
- "Ton- und Fernseh-Rundfunkempfänger" - diese fielen bislang nicht unter die RTTE, so dass jetzt zusätzliche Anforderungen bei den Empfangseigenschaften zu erfüllen sind.
- "Empfängerqualität" - war bislang durch einige ETSI-Produktnormen abgedeckt, da es aber wichtig ist, dass der Betrieb in einem immer "schmutzigeren" Funkspektrum gewährleistet ist, fällt dies nun unter diese Richtlinie.
- "Geräte die unter 9 kHz arbeiten" – die untere Frequenzgrenze , die bei RTTE bei 9 kHz lag, wurde aufgehoben.
- Genau wie bei anderen Richtlinien auch gibt es eine besondere Ausnahmeregelung für "Kundenspezifisch hergestellte Evaluation-Kits für Fachkräfte, die nur zum Zwecke von Forschung und Entwicklung in den entsprechenden F&E-Einrichtungen eingesetzt werden".

ZEITLICHER RAHMEN UND ÜBERGANGSREGELUNGEN

Die Europäische Kommission hat vier Szenarien zur Anwendung der Richtlinien 2014/53/EU, 2014/35/EU und 2014/30/EUi bestätigt.

Produkttyp	Konformitätsanforderungen und Fristen
Gegenwärtig in Geltungsbereich der EMV- und Niederspannungsrichtlinie und nicht im Geltungsbereich der RTTE- oder RED-Richtlinie.	• Produkte, dem 20 April 2016 am Markt eingeführt wurden: alte Niederspannungsrichtlinie/EMV-Richtlinie • Produkte, am oder nach dem 20 April 2016 am Markt eingeführt wurden: neue Niederspannungsrichtlinie/EMV-Richtlinie
Gegenwärtig in Geltungsbereich der RTTE-Richtlinie und verbleibend im Geltungsbereich der RED-Richtlinie.	• Produkte, die vor dem 13 Juni 2016 am Markt eingeführt wurden: RTTE-Richtlinie • Produkte, die zwischen dem 13 Juni 2016 und 12 Juni 2017 am Markt eingeführt wurden: RTTE- oder RED-Richtlinie • Produkte, die nach dem 12 Juni 2017 am Markt eingeführt wurden: RED
Gegenwärtig nicht im Geltungsbereich der RTTE-Richtlinie aber im Geltungsbereich der RED-Richtlinie.	• Produkte, dem 20 April 2016 am Markt eingeführt wurden: alte Niederspannungsrichtlinie/EMV-Richtlinie • Produkte, die zwischen dem 20 Juni 2016 und 12 Juni 2016 am Markt eingeführt wurden: neue Niederspannungsrichtlinie/EMV-Richtlinie • Produkte, die zwischen dem 13 Juni 2016 und 12 Juni 2017 am Markt eingeführt wurden: RED-Richtlinie oder neue Niederspannungsrichtlinie/EMV-Richtlinie • Produkte, die nach dem 12 Juni 2017 am Markt eingeführt wurden: RED
Gegenwärtig in Geltungsbereich der RTTE-Richtlinie aber außerhalb des Geltungsbereich der RED-Richtlinie.	• Produkte, die vor dem 13 Juni 2016 am Markt eingeführt wurden: RTTE-Richtlinie • Produkte, die nach dem 12 Juni 2016 am Markt eingeführt wurden: RED nicht zutreffend; neue Niederspannungsrichtlinie/EMV-Richtlinie, falls zutreffend beim betreffenden Produkt

Es ist festzustellen, dass die Beachtung dieser Fristen eine hohe administrative Belastung für die Hersteller hinsichtlich der Aktualisierung der Dokumentationen und Konformitätserklärungen bedeutet, insbesondere für Geräte, die aus der RTTE-Richtinie heraus- und in die Niederspannungsrichtlinie/EMV-Richtlinie hi-

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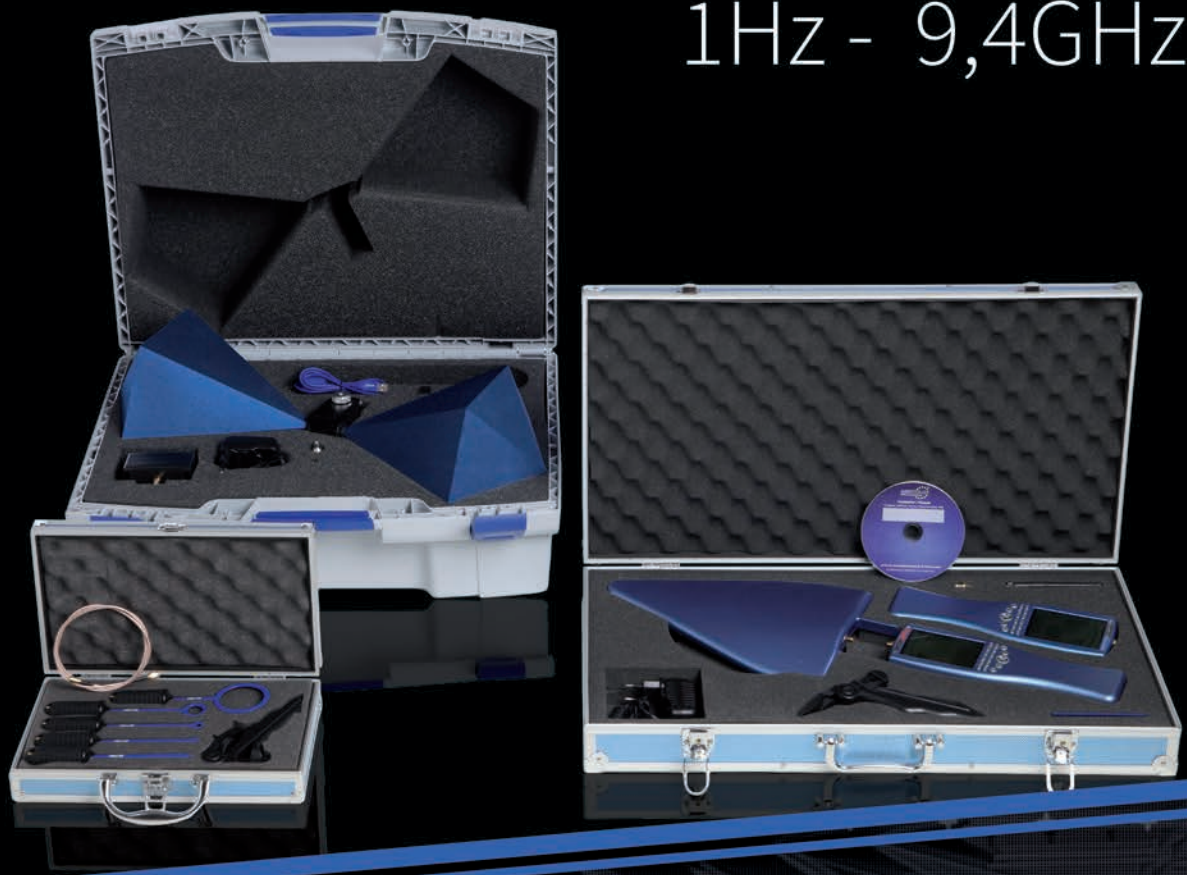

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neinfallen, da in diesem Fall die Übergangsfrist der RED-Direktive nicht genutzt werden kann.

Die Anleitung zum Inhalt der Konformitätserklärungen spezifiziert zwar den Minimalinhalt, aber es wird in der Regel kein Maximalinhalt spezifiziert und zusätzliche nützliche Informationen werden in der Regel akzeptiert. Darauf basierend gibt es einige Vorschläge, die innerhalb der Kommission diskutiert werden,

um Herstellern zu erlauben, sowohl aktuelle als auch neue Richtlinien auf ihren Konformitätserklärungen zu listen, z.B.

"Der Gegenstand der oben beschriebenen Erklärung ist konform mit den einschlägigen Harmonisierungsrechtsvorschriften der Union: mit der Richtlinie 1999/5/EC (bis 12 Juni 2016), mit der Richtlinie 2014/30/EU (vom 13 Juni 2016) und mit der Richtlinie 2014/35/EU (vom 13 Juni 2016)."

Hinweis: Zum Zeitpunkt der Veröffentlichung war dieser Vorschlag nicht formell akzeptiert. Es wird erwartet, dass der Vorschlag Anfang März akzeptiert und im EU Docs Room ii veröffentlicht wird. Wir werden Sie auf den aktuellen Stand bringen, sobald uns entsprechende Informationen vorliegen.

EINIGE ECKPUNKTE FÜR HERSTELLER HINSICHTLICH DER RED-RICHTLINIE:

- Das CE Zeichen muss auf dem Gerät und der Verpackung erscheinen - lt. RED muss das CE Zeichen nicht mehr in der Bedienungsanleitung erscheinen.
- Die Nummer der benannten Stelle kommt nur dann auf das Produkt, wenn der vollständige Qualitätssicherungsweg (RTTE Anhang V / RED Anhang IV) nicht beschritten wurde, falls eine benannte Stelle nur die technischen Unterlagen kontrolliert hat.
- Die Liste der zugelassenen Länder kommt weiterhin auf die Verpackung und in die Bedienungsanleitung aber es besteht keine Pflicht für das Alarmzeichen bei Class 2 Geräten und Ländernotifizierungen sind nicht mehr nötig.
- Die Bedienungsanleitung muss die Betriebsfrequenzbänder und die maximale Sendeleistung in jedem dieser Bänder enthalten und diese Information muss in einer Sprache verfasst sein, die einfach vom Endbenutzer zu verstehen ist.
- Alle Produkte, die eine Komponente einer "Funkanlage" wie in der RED-Richtlinie Artikel 2 beschrieben enthalten, fallen unter die RED-Richtlinie, d.h. eine Waschmaschine mit ZIGBEE-Sender fällt unter RED und nicht unter die Niederspannungsrichtlinie/EMV-Richtlinie .

ENTWICKLUNG NEUER NORMEN FÜR RED

EMV

Die Funkanlage erlaubt nicht die Anwendung der EMV-Direktive, wie dies unter RTTE möglich war, d.h. alle Produkte mit einer Funkanlage müssen entsprechend der RED geprüft werden.

- Das ETSI (Europäisches Institut für Telekommunikationsnormen) hat die Entwicklungsempfehlung EG 203 367 iii, "Electromagnetic compatibility and Radio spectrum Matters (ERM); Guide to the application of harmonized standards covering Articles 3.1b and 3.2 of the Directive 2014/53/EU (RE-D) to multi-radio and combined radio and non-radio equipment" herausgegeben, das Hilfestellung bei der Anwendung der harmonisierten Normen für Multi-Funk- und kombinierte Geräte bietet. Das Dokument ist immer noch ein Entwurf.

  * Beispiele für Geräte, die unter dieses Dokument fallen umfassen, sind aber nicht beschränkt auf eine Kombination mehrerer Funkprodukte in einer Funkanlage, eine Kombination von Funk und IT oder elektrotechnischen Geräten, Haushaltsgeräte mit RLAN , funkgesteuerte Heizanlagen, funkgesteuerte Beleuchtungsanlagen etc.

Frequenzband

- Das ETSI (Europäisches Institut für Telekommunikationsnormen) aktualisiert gegenwärtig 156 Artikel 2 3.2 Frequenzbänder für die Richtlinie RED, 34 davon sollen 2016 im Amtsblatt veröffentlicht werden, die meisten anderen sollen in der ersten Hälfte 2017 folgen.
- Nach einer Untersuchung zur Vereinbarkeit von LTE im 800 MHz Band und UHF Geräten kurzer Reichweite hat das ETSI begonnen, an der Restrukturierung von EN 300 220 zu arbeiten. Folgende Arbeitspunkte wurden aufgenommen:

  * 300220-2: Harmonisierte Norm für nicht-spezifische Funkanlagen. Zwei Versionen werden entwickelt: Eine Version 3.1.1. mit "Kategorie 3" Empfängern, welche im Dezember 2018 durch die Version 3.2.1 mit verbesserter "Kategorie 2" Empfänger ersetzt werden soll.
  * EN 300 220-3-1: Hilferufanlagen (Social Alarm), die in einem zugewiesenen Frequenzband (869,2 - 869,25 MHz) arbeiten
  * EN 300 220-3-2: Funkalarmanlagen, die in zugewiesenen Frequenzbändern arbeiten
  * EN 300 220-4: Funkmessgeräte), die in zugewiesenen Frequenzbändern (169,4 - 169,4875 MHz) arbeiten

- Die ETSI hat bereits Normentwürfe für TV- und Rundfunkempfänger veröffentlicht, die aufgrund des Gültigkeitsbereichs dieser Richtlinie unter RED fallen werden:

  * Draft ETSI EN 303 340 V1.1.0v, Digital Terrestrial TV Broadcast Receivers; Harmonisierte Norm, welche die wichtigsten Anforderungen von Artikel 3.2 der Richtlinie 2014/53/EU abdeckt
  * Draft ETSI EN 303 345 V1.1.0v, Digital Terrestrial TV Broadcast Receivers; Harmonisierte Norm, welche die wichtigsten Anforderungen von Artikel 3.2 der Richtlinie 2014/53/EU abdeckt

Übergangszeiten

Wie allgemein üblich gibt es eine Übergangsfrist in welcher bestehende Normen weiterverwendet werden können, aber Hersteller sollten das ETSI-Arbeitsprogramm iv im Auge behalten und sich an die aktuellen Normen halten, sobald diese veröffentlicht sind.

ÜBER DEN AUTOR

Sulis Consultants ist ein unabhängiges Beratungsunternehmen für CE Kennzeichnungen und Produktzulassungen in Hampshire, England und hat sich darauf spezialisiert, Hersteller bei der Einhaltung der RTTE-, EMV-, Niederspannungs- und RoHS-Richtlinen sowie

bei der Funkzertifizierung für Nordamerika zu unterstützen. Charlie Blackham ist staatlich geprüfter Ingenieur und hat über 20 Jahre im Bereich Produktzulassung und CE-Kennzeichnung gearbeitet. Nachdem er für verschiedene Hersteller als Zulassungsmanager tätig war, gründete Charlie im Jahr 2005 Sulis Consultants, um einem breiteren Kundenkreis Beratung und Support zu bieten.

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REFERENCE LINKS

i http://ec.europa.eu/DocsRoom/documents/11983/attachments/1/translations/en/renditions/pdf

ii http://ec.europa.eu/DocsRoom/?locale=en

iii https://portal.etsi.org/webapp/WorkProgram/Report_WorkItem.asp?WKI_ID=47231

iv http://webapp.etsi.org/ena/cvp.asp?search=RADIO

v https://www.etsi.org/deliver/etsi_en/303300_303399/303340/01.01.00_20/en_303340v010100a.pdf

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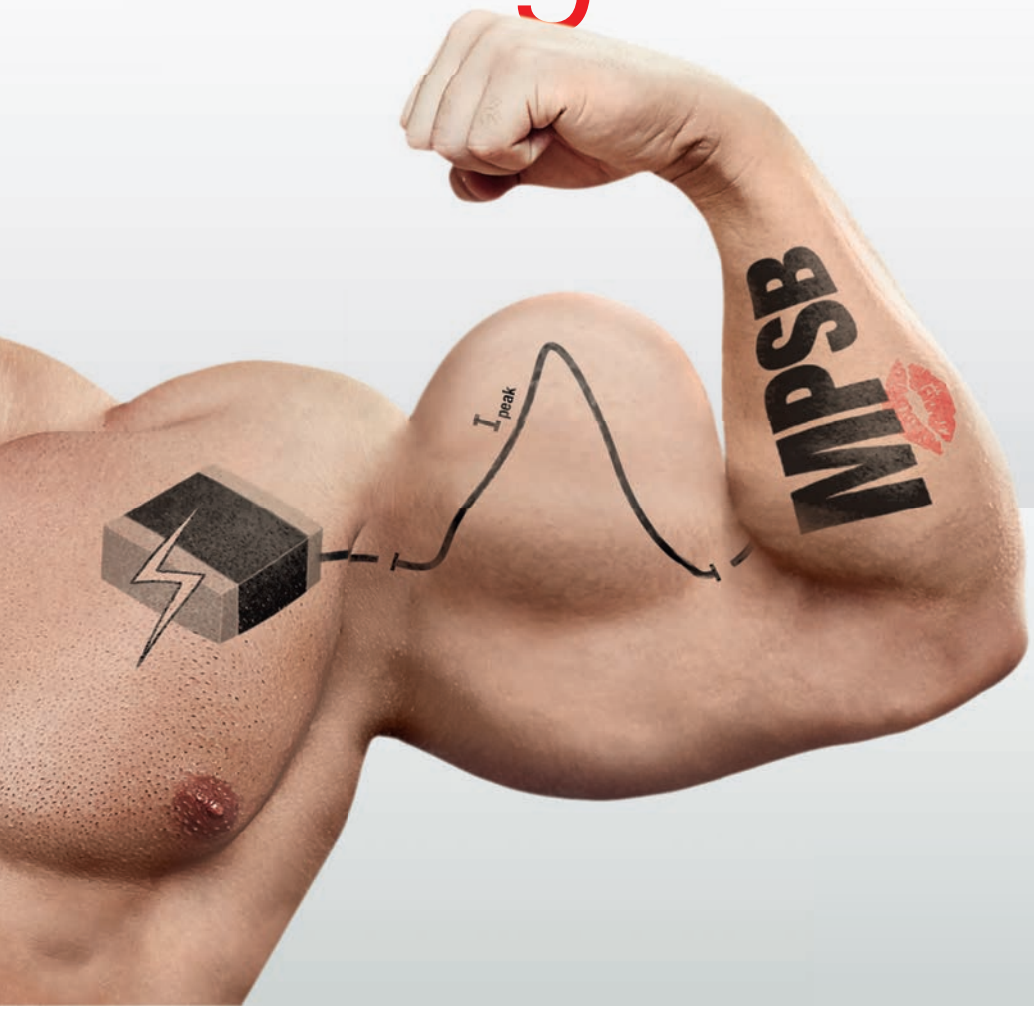

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REVUE DE LA NORME CEI 60601-1-2 : 2014 (4ÈME ÉDITION)

Darryl P. Ray
Darryl Ray EMC Consulting, LLC

Introduction

La norme CEI 60601-1-2:2014 édition 4 a été publiée en février 2014 et remplace la norme CEI 60601-1-2 édition 3, publiée en 2007. Elle se rapporte à la compatibilité électromagnétique (CEM) pour des appareils et des systèmes électromédicaux. La version européenne (EN60601-1-2:2015) est identique à son homologue CEI à l'exception des références aux versions anglaises (EN) de la série 61000-4-x et l'ajout d'une annexe des exigences essentielles.

La motivation derrière la 4ème édition a été de créer une norme de sécurité qui s'applique aux perturbations électromagnétiques afin de s'aligner sur les exigences générales de la norme CEI 60601-1 édition 3. La version précédente de la norme CEI 60601-1-2 ne traite pas de manière adéquate les aspects de sécurité liés à l'interférence électromagnétique. En outre, les différences entre l'édition 3 et 4 à l'égard de l'immunité sont substantielles.

MISE EN ŒUVRE À L'ÉCHELLE MONDIALE

CEI 60601-1-2 éd. 4:2014 a été publiée en février 2014. La FDA reconnaît maintenant la 4ème édition et la date de conformité obligatoire pour les nouvelles soumissions est le 31 décembre 2018. Cette date a été choisie pour s'harmoniser avec les exigences de l'UE (EN 60601-1-2:2015). Bien que non requise jusqu'en 2018, la FDA accepte actuellement la 4ème édition et la préfère pour des produits devant être testés à cette norme lors de la soumission de nouvelles applications, en particulier pour les appareils à utiliser dans l'environnement de soins de santé à domicile.

La FDA n'exige pas la conformité à la 4ème édition pour les appareils existants, à moins que des modifications substantielles ne soient apportées au produit.

Dans l'Union européenne, la date de retrait (« DoW ») d'EN 60601-1-2:2007 est publiée comme étant le 31 décembre 2018. Par conséquent, tous les appareils fabriqués et importés dans l'UE après cette date sont tenus de se conformer à la 4ème édition. Il n'y a pas de tolérance pour les périphériques existants comme autorisés par la FDA.

Pour les autres régions, les exigences varient beaucoup en fonction du pays. Au moins un grand marché n'accepte pas pour l'instant la 4ème édition. Voir le tableau 6 ci-dessous pour plus de détails.

SOMMAIRE DES MODIFICATIONS ENTRE LA 3ÈME ET LA 4ÈME ÉDITION

Les modifications importantes suivantes ont été faites pour la 4ème édition.

- La classification de maintien en vie vs le non-maintien en vie utilisée dans la troisième édition a été supprimée. Elle a été remplacée par trois catégories d'immunité d'utilisation prévue. Les professionnels de soins de santé, les soins de santé à domicile et l'environnement spécial
- Les limites et niveaux des émissions modifiées et d'immunité sont tels qu'indiqués dans les tableaux 1 à 4 ci-dessous
- Le critère de réussite ou d'échec de l'immunité est limité au maintien de la performance essentielle et de la sécurité de base
- Le terminal conducteur d'équilibrage des potentiels est requis être connecté à la terre locale pendant les tests. La troisième édition ne fait aucune mention du terminal conducteur d'équilibrage des potentiels
- L'utilisation de la main artificielle est clarifiée
- La méthodologie de test pour effectuer des tests de décharge électrostatique (DES) sur les connecteurs est modifiée
- Il convient de considérer le mode veille pour les tests d'émissions et les tests d'immunité
- Une nouvelle procédure a été ajoutée pour établir une procédure si un appareil est endommagé au cours des tests d'immunité
- Le matériel non médical utilisé dans le cadre du système électrique médical doit répondre à ses exigences applicables en matière de CEM. Le système doit maintenir la performance essentielle et la sécurité de base
- La tension d'entrée en courant alternatif (CA) et les exigences en matière de fréquence sont rationalisées. À l'exception des tests de creux de tension et de coupures, les tests avec une seule tension et une seule fréquence à l'intérieur de l'appareil sont acceptables
- Les tests de SIP/SOP (ports d'entrée/sortie de signaux) non

utilisés au cours de l'utilisation du brevet sont clarifiés
- La tolérance pour la susceptibilité à la radio pendant les tests d'immunité rayonnée a été éliminée.
- Les exigences en matière d'étiquetage modifiées et partiellement rationalisées. Les tableaux de déclaration de conformité de CEM énumérés dans la troisième édition ont été éliminés.
- Un plan de test de CEM est requis et comprend des contenus recommandés
- La durée de temporisation minimum utilisée pour les tests d'immunité est réduite
- Un rapport de test de CEM est requis et un contenu minimal est défini
- Gestion des risques - de nombreuses règles de CEM sont requises
- Toutes les normes référencées ont des références de dates (la 3ème édition utilise des références sans date)
- La déclaration d'avertissement exigée dans les instructions d'utilisation destinées aux appareils de classe A diffère de celle trouvée dans la norme CISPR 11
- Il convient de considérer les appareils utilisés dans les avions pour répondre aux exigences en matière d'immunité énumérées dans RTCA DO-160
- L'utilisation de symbole d'avertissement de DES proche de connecteurs sensibles a été éliminée.

Tableau 1- Comparaison des exigences en matière d'émission

Exigence	CEI 60601-1-2: 2007 (3ème édition)	CEI 60601-1-2: 2014 (4ème édition)	Commentaires
Émissions conduites	CISPR 11	CISPR 11	
Émissions rayonnées	CISPR 11	CISPR 11	
Distorsion harmonique	IEC 61000-3-2	IEC 61000-3-2	Les limites de classe A s'appliquent
Fluctuations/ papillotement de tension	IEC 61000-3-3	IEC 61000-3-3	
Appareils comportant des composants simples	Peuvent requérir la conformité à la norme CISPR 14	Sans objet	
Matériel d'éclairage	CISPR 15	Sans objet	
Appareils à rayons X	S.O.	CISPR 11	La relaxation de 20 dB s'applique pour les émissions quasi crêtes
Matériel informatique	Doit se conformer à la norme CISPR 22	Doit se conformer à la norme CISPR 35	
Appareils comportant des sous-systèmes radio	Émissions intentionnelles exemptes	Émissions intentionnelles exemptes	
Câbles du patient - Émissions conduites	Sans objet	Courant de mode commun limité à 24 dBµA (1-30 MHz)	Exigence en matière d'information
Appareils comportant des moteurs ou des circuits de commutation	Sans objet	CISPR 14-1	

Tableau 2 - Comparaison du niveau d'immunité - phénomène transitoire

Phénomène	CEI 60601-1-2: 2007 (3ème édition)	CEI 60601-1-2: 2014 (4ème édition)	
		Professionnels de soins de santé Environnement	Soins de santé à domicile Environnement
DES (test selon CEI 61000-4-2)	Décharge dans l'air 8 kV (max.) Décharge par contact 6 kV	Décharge dans l'air **15 kV** (max.) Décharge par contact **8 kV**	
Transitoire électrique rapide (EFT) / rafale (test selon CEI 61000-4-4)	2 kV - alimentation secteur alternatif 1 kV - ports d'E/S Récepteurs de reconnaissance de motifs (PRR) 5 kHz ou 100 kHz	2V - alimentation secteur alternatif 1 kV, - ports d'E/S **PRR 100 kHz**	
Surtensions - alimentation secteur alternatif (test selon CEI 61000-4-5)	2 kV (max.) Angles de phase de 0, 90, 270 degrés	2 kV (max.) Angles de phase de 0, 90, **180** et 270 degrés	
Surtensions - puissance de 12 V c.c. (test selon ISO 7637-2)	S.O.	**600 V**	
Les creux de tension et les interruptions (test selon CEI 61000-4-11)	• UT < 5 %, 0,5 période • UT = 40 %, 5 périodes • UT = 70%, 25 périodes • UT < 5 %, 5 secondes	• **UT = 0%, 0,5 cycle (0, 45, 90, 135, 180, 225, 270 et 315°)** • **UT = 0 % ; 1 cycle UT = 70 % ; (25/30 cycles @ 0 degré)** • **UT = 0%, 250/300 cycles**	

Gras = modifications à partir de l'édition 3

Tableau 3 - Comparaison du niveau d'immunité - phénomène en régime permanent

Phénomène	CEI 60601-1-2:2007 (3ème édition)	CEI 60601-1-2: 2014 (4ème édition)	
		Professionnels de soins de santé Environnement	Soins de santé à domicile Environnement
Immunité conduite (test selon CEI 61000-4-6)	3 V (0,15- 80 MHz) Bandes ISM (industrielles, scientifiques et médicales) 10 V - Matériel de maintien en vie	3 V (0,15- 80 MHz) **6 V (bandes ISM)**	3 V (0,15- 80 MHz) **6 V (ISM et amateur**
Immunité magnétique (test selon CEI 61000-4-8)	3 A/m 50 et 60 Hz	**30 A/m** 50 **ou** 60 Hz	

Gras = modifications à partir de l'édition 3

Tableau 4 - Comparaison du niveau d'immunité - phénomène en régime permanent

Phénomène	CEI 60601-1-2:2007 (3ème édition)	CEI 60601-1-2: 2014 (4ème édition)	
		Professionnels de soins de santé Environnement	Soins de santé à domicile Environnement
Immunité rayonnée (test selon CEI 61000-4-3)	3 V/m - non-maintien en vie 10 V/m - maintien en vie 80 MHz - 2,5 GHz 80 %@2 Hz (ou 1 kHz1) Modulation AM	**3 V/m 80** MHz – **2,7 GHz** 80 %@ **1 kHz** Modulation AM	**10 V/m** 80 MHz – **2,7 GHz** 80 %@ **1 kHz** Modulation AM
Champ de proximité de transmetteurs sans fil (test selon CEI 61000-4-3)	Sans objet	**9 V/m à 28 V/m** 15 fréquences spécifiques	

Gras = modifications à partir de l'édition 3

FRANCE

EXIGENCES EN MATIÈRE D'ÉMISSION

Dans la plupart des cas, les limites d'émission dans la 4ème édition sont les mêmes que celles de la 3ème édition. Diverses clarifications ont été apportées à la 4ème édition comme le montre le tableau 1 ci-dessous.

CRITÈRES D'ACCEPTATION DE L'IMMUNITÉ

L'exigence de réussite/d'échec en matière d'immunité dans la 4ème édition est basée sur l'appareil médical maintenant la sécurité de base et la performance essentielle. Les définitions de ces concepts sont détaillées ci-dessous :

Sécurité de base - telle que définie par la norme CEI 60601-1:2012, édition 3.1.

SÉCURITÉ DE BASE

Absence de risque inacceptable causée directement par les dangers physiques lorsque le matériel ME est utilisé dans des conditions normales d'état et condition de défaut unique2

PERFORMANCE ESSENTIELLE

La performance nécessaire pour achever la performance d'absence de risque inacceptable d'une fonction clinique, autre que celle liée à la sécurité de base, lorsque la perte ou la dégradation de l'environnement au-delà des limites spécifiées par l'usine entraîne un risque inacceptable.

Remarque - La performance essentielle est plus facilement comprise en considérant si son absence ou sa dégradation entraînerait un risque inacceptable.

Il est très important pour le fabricant de comprendre et d'appliquer ces concepts ci-dessus à l'appareil médical devant être testé. Dans de nombreux cas, un appareil peut être sensible aux perturbations électromagnétiques, mais si la sécurité de base et la performance essentielle sont maintenues, alors l'appareil peut être jugé comme étant conforme à la 4ème édition.

TESTS SUR LES CONNECTEURS DES

La troisième édition requiert que des décharges par contact soient mises en œuvre sur les broches du connecteur individuel qui sont accessibles selon les directives CEI de la norme CEI 60601-1. Il n'y a pas de procédure de test établie pour effectuer ce test. La 4ème édition ajuste cette procédure selon le tableau 5 ci-dessous:

Tableau 5 - Exigences en matière de tests DES de connecteur

Boîtier de connecteur	Exigences en matière de décharge	Utilisation des ports
Conducteur	Décharge par contact au boîtier seul	Utilisation prévue et normale[3]
Isolé	Décharge dans l'air au boîtier et décharge dans l'air aux broches (si accessible par le doigt d'épreuve de la norme CEI)	Utilisation prévue

GESTION DES RISQUES

Le concept de gestion des risques pour la CEM est nouveau. La 4ème édition exige que les questions suivantes soient abordées en ce qui concerne la gestion des risques. Il convient d'aborder et de documenter ces éléments dans le rapport de tests de CEM et dans le fichier de gestion des risques.

- Il convient de considérer la distance minimale de séparation avec les appareils de communication portables
- Il convient de considérer l'annexe F, gestion des risques pour la sécurité de base et la performance essentielle
- Il convient de baser les modes d'exploitation utilisés pour les tests sur l'analyse des risques
- Les tests du matériel non médical (c.-à-d. les perturbations doivent être prises en compte dans le processus de gestion des risques)
- Il convient de traiter les effets observés de la réponse de l'équipement sous test (EUT) lors des tests d'immunité
- Le processus de gestion des risques doit être utilisé pour déterminer si les tests des sous-systèmes sont admis
- Des niveaux de test réduits, si utilisés, doivent être justifiés
- Des mesures d'atténuation utilisées pour justifier des niveaux de test d'immunité inférieurs doivent être documentées
- Des fréquences de modulation alternatives peuvent être utilisées
- Les services de communications actuels doivent être pris en compte
- On doit tester les niveaux d'immunité magnétique plus élevés si un appareil est plus près de 15 cm d'une source magnétique à fréquence du réseau

Déclarer la conformité avec la 4ème édition nécessite cinq actions;

- Un plan de test doit être créé avant les tests
- Conformité aux exigences en matière de tests applicables
- Un rapport de test détaillé avec contenu spécifié minimum requis
- Les exigences en matière de gestion des risques énumérés doivent être traitées
- L'étiquetage de l'appareil doit être conforme selon les exigences de l'article 6.

De nombreux laboratoires de test peuvent ne pas être disposés à assumer la responsabilité de la revue de la gestion des risques et des exigences en matière d'étiquetage de l'appareil. Il est de la responsabilité de la fabrication de s'assurer que tous les éléments mentionnés ci-dessus sont traités de manière adéquate.

Depuis la publication, plusieurs erreurs et ambiguïtés sont apparues:

- Il y a une divergence dans les notes dans les tableaux 1 et 5. Il convient d'utiliser la note en bas de page c dans le tableau 1.
- Le tableau 9 est parfois mal lu pour exiger que des tests soient effectués à une distance de test de 0,3 m. La distance de test comme spécifiée dans la norme CEI 61000-4-3 s'applique.
- La FDA n'accepte pas la tolérance énumérée au tableau 8, note b relative à la longueur de câble.

DATES DE CONFORMITÉ

Les dates de conformité à la 4ème édition ainsi que de nombreuses autres normes peuvent être un problème complexe à résoudre. Les dates dépendent du type d'appareil, de la région il est vendu et peuvent également être commandées par d'autres normes et règlements de plus haut niveau. Le tableau 6 résume les dates de conformité obligatoire en fonction de la région.

Tableau 6 - dates de conformité CEI 60601-1-2:2014 (4ème édition) par région

États-Unis d'Amérique	Union européenne	Autres régions
Appareils existants Jamais[4] Nouvelles soumissions 1er janvier 2019	Tous les appareils : 1er janvier 2019 (conformité à la norme EN 60601-1-2 : 2015)	Varie en fonction de : • Réglementations du pays[5] • Normes CEI 80601-2-X[6]

SOMMAIRE

Cet article a fourni une comparaison des normes CEI 60601-1-2 3ème et 4ème éditions. Comme indiqué dans les tableaux ci-dessus, les niveaux de test sont différents dans de nombreux cas et sont souvent (mais pas toujours) plus sévères. La 4ème édition exige que la sécurité de base et la performance essentielle de l'appareil médical soient maintenues en présence des divers environnements électromagnétiques énumérés dans la norme.

Certaines susceptibilités non liées à la sécurité de base et à la performance essentielle ne seraient normalement pas considérées comme une défaillance du test. De plus, la 4ème édition exige que de nombreux aspects soient considérés en ce qui concerne la gestion des risques.

Les deux normes sont différentes de manière significative en ce qui concerne les niveaux de test et les critères d'acceptation de réussite ou d'échec de l'immunité, les modes de fonctionnement et plus encore. Compte tenu de ce fait, il serait incorrect d'affirmer que la conformité à la 4ème édition équivaudrait à la conformité avec la troisième édition.

REFERENCES

[1] La modulation 1 kHz est utilisée pour les appareils médicaux qui ne contrôlent pas, ne surveillent pas ou ne mesurent pas un paramètre physiologique.

[2] Bien que la condition de défaut unique soit officiellement mentionnée dans cette définition, de nombreux utilisateurs de la CEI 60601-1-2 voudraient considérer la conformité au cours d'une condition de défaut unique peu pratique voire impossible à réaliser, et elle est donc souvent ignorée.

[3] Se reporter à la norme CEI 60601-1 pour la définition de l'utilisation prévue et normale.

[4] Selon le schéma d'équivalence substantiel (prédicat) de la FDA

[5] Certains pays n'acceptent pas actuellement la 4ème édition

[6] Les normes (CEI 60601/80601-2-X) sont en cours de conversion aux références datées à CEI 60601-1-2:2014. Jusqu'à ce que la conversion soit terminée, certaines des normes partielles feront référence à CEI 60601-1-2:2014, certaines feront référence à CEI 60601-1-2:2007 et d'autres utiliseront une référence non datée à CEI 60601-1-2.

DIRECTIVE SUR LES ÉQUIPEMENTS RADIOÉLECTRIQUES, 2014/53/UE

Par Charlie Blackman
consultant principal et directeur de Sulis Consultants Ltd.

Note de l'éditeur: *La directive sur les équipements radioélectriques (RED), 2014/53/UE, doit être utilisée pour de nouveaux produits fabriqués après le 13 juin 2016 et devient obligatoire pour tous les produits le 13 juin 2017.*

RÉSUMÉ

Cet article fournit une mise à jour concernant les modifications survenues en conséquence de la nouvelle directive sur les équipements radioélectriques (RED) 2014/53/UE, qui peut être utilisée à partir de juin 2016. Il examine les modifications dans le produit et le paysage réglementaire et ce qu'elles signifient pour les fabricants d'équipement.

Plus de détails sur l'historique de la directive RED se trouvent dans l'article, Directive sur les équipements radioélectriques, dans le Répertoire et guide de conception de technologie d'interférence CEM 2015.

DOMAINE D'APPLICATION DE LA DIRECTIVE

Le domaine d'application de la directive RED a été élargi pour inclure:

- Équipements de détermination radioélectrique, comme les radars et des dispositifs RFID. Ces dispositifs ont été considérés comme faisant partie du domaine d'application de la directive R&TTE, (équipements hertziens et équipements terminaux de télécommunications), mais le domaine d'application de RED est beaucoup plus clair ce qui rend plus évident qu'ils soient inclus et doivent être conformes.
- Récepteurs de radiodiffusion de son et de télévision - ceux-ci étaient exclus selon R&TTE et devront donc avoir maintenant des exigences supplémentaires pour la performance du spectre radio.
- Performance du récepteur - alors que cela était couvert dans un certain nombre de normes de produits de l'institut européen des normes de télécommunication (ETSI), son importance dans un contexte de spectre radio de plus en plus encombré en a fait partie de la directive.
- Dispositifs fonctionnant en dessous de 9 kHz - la limite de fréquence inférieure de R&TTE était de 9 kHz, mais cela a été supprimé.
- En ligne avec d'autres directives, il existe une exclusion spécifique pour «les kits d'évaluation sur mesure destinés aux professionnels devant être utilisés uniquement dans les installations de recherche et développement pour de telles fins. »

CALENDRIER ET PÉRIODES DE TRANSITION

La Commission européenne a confirmé qu'il y a quatre scénarios liés à l'application des directives 2014/53/CE, 2014/35/CE et 2014/30/UE [i]

Type de produit	Exigences en matière de conformité et dates
Actuellement dans le domaine d'application de CEM et LVD (directive basse-tension) et non dans le champ d'application de R&TTE ou de RED	• Les produits mis sur le marché avant le 20 avril 2016 : anciennes directives LVD/EMCD • Les produits mis sur le marché à partir du 20 avril 2016 : nouvelles directives LVD/EMCD
Actuellement dans le domaine d'application de R&TTE et demeurent dans le domaine d'application de RED	• Les produits mis sur le marché avant le 13 juin 2016 : R&TTED • Les produits mis sur le marché entre le 13 juin 2016 et le 12 juin 2017 : R&TTED ou RED • Les produits mis sur le marché après le 12 juin 2017 : RED
Actuellement dans le domaine d'application de R&TTE, mais non le champ d'application de RED	• Les produits mis sur le marché avant le 20 avril 2016 : anciennes directives LVD/EMCD • Les produits mis sur le marché entre le 20 avril 2016 et le 12 juin 2016 : nouvelles directives LVD/EMCD • Les produits mis sur le marché entre le 13 juin 2016 et le 12 juin 2017 : RED ou nouvelles directives LVD/EMCD • Les produits mis sur le marché après le 12 juin 2017 : RED
Actuellement dans le domaine d'application de R&TTE, mais n'entrent pas dans le champ d'application de RED	• Les produits mis sur le marché avant le 13 juin 2016 : R&TTED • Les produits mis sur le marché après le 12 juin 2016 : RED n'est pas applicable ; nouvelles directives LVD/EMCD, si applicables au produit en question

Il a été noté que suivre ces dates pourrait créer un lourd fardeau administratif pour les fabricants dans la mise à jour de la documentation et des déclarations de conformité, en particulier pour les

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appareils qui relèvent de la directive R&TTE et dans CEM et LVD, car ils ne peuvent pas profiter de la période de transition prévue dans la directive RED.

Le guide de recommandations concernant le contenu des déclarations de conformité spécifie le contenu minimum, mais ne spécifie généralement pas le contenu maximum et des informations supplémentaires utiles sont généralement acceptées. En fonction de cela, il y a un petit groupe de propositions actuellement en discussion au sein de la commission pour autoriser les fabricants à énumérer les directives actuelles et nouvelles sur leurs déclarations de conformité, p. ex.

"L'objet de la déclaration décrite ci-dessus est en conformité avec les dispositions de la législation d'harmonisation applicable de l'Union européenne : directive 1999/5/CE (jusqu'au 12 juin 2016), directive 2014/30/UE (à partir du 13 juin 2016) et directive 2014/35/UE (à partir du 13 juin 2016)."

Veuillez noter: au moment de la publication, cette proposition n'avait **pas été formellement acceptée**. Elle est prévue d'être acceptée au début du mois de mars et sera publiée dans le dépôt de documents (Docs Room) de l'UE ii. Nous vous transmettrons une mise à jour dès que nous l'aurons.

Certains points clés pour les fabricants sous la directive RED:

- Le marquage CE doit figurer sur l'appareil et sur l'emballage - la directive RED n'exige plus le marquage CE dans le manuel de l'utilisateur
- Le numéro de l'organisme notifié figure seulement sur le produit lorsque la route d'assurance de la qualité est complète (annexe V R&TTE / annexe IV RED) et n'est pas utilisé lorsqu'un NB vient juste de revoir le dossier technique.
- Il convient de faire figurer la liste des pays autorisés sur l'emballage et dans le manuel de l'utilisateur, mais il n'y a aucune une exigence pour le marquage d'alerte, pour l'équipement de la classe 2 et les notifications de pays ne sont plus nécessaires.
- Le manuel de l'utilisateur doit inclure les bandes de fréquence de fonctionnements et la puissance de transmission maximale dans chacune de ces bandes, et ces informations doivent être dans une langue facilement comprise par l'utilisateur final.
- Tout produit contenant une pièce d'« équipement radioélectrique » telle que définie à l'article 2 de la directive RED, tombe sous la directive RED - de sorte qu'une machine à laver avec une radio Zigbee tombe sous la directive RED et non CEM et LVD.

DÉVELOPPEMENTS DE NOUVELLES NORMES POUR LA DIRECTIVE RED

CEM

L'équipement radioélectrique ne permet pas l'application de la directive CEM comme cela était possible sous R&TTE, ainsi tous les produits contenant un équipement radioélectrique doivent être évalués en fonction de la directive sur les équipements radioélectriques.

- ETSI développe un guide EG 203 367 iii, « Normes en matière de compatibilité électromagnétique et spectre radioélectrique (ERM) ; Guide pour l'application des normes harmonisées couvrant les articles 3.1b et 3.2 de la directive 2014/53/UE (RE-D) pour des équipements multiradio et combinés radio et non-radio » qui fournit un guide de recommandations concernant l'application des normes harmonisées aux équipements multiradio et combinés. Le document est toujours dans un état de projet

  * Des exemples d'équipement devant être couverts par le document comprennent, mais ne sont pas limités à, une combinaison de produits multiradios dans un équipement radioélectrique et une combinaison de radio et de technologie de l'information (IT) ou des équipements électrotechniques, des appareils domestiques activés par réseau local (RLAN), des systèmes de chauffage commandés par radio, des systèmes d'éclairage commandés par radio, etc.

Spectre radio

- L'ETSI met actuellement à jour 156 articles 3.2 des normes du spectre radio pour la directive RED, 34 d'entre eux sont dus pour publication au Journal officiel au cours de 2016 et la majorité restante suivra lors du 1er semestre 2017.
- À la suite d'une revue de la compatibilité entre LTE fonctionnant dans la bande 800 MHz et les dispositifs UHF à courte portée, l'ETSI a commencé à travailler sur la restructuration d'EN 300 220. Les éléments de travail ont été adoptés comme suit:

  * EN 300 220-2: Norme harmonisée pour les équipements radioélectriques non spécifiques. Deux versions sont en cours de développement : une version 3.1.1 avec les récepteurs de « catégorie 3 », destinée à être remplacée par v 3.2.1 avec les récepteurs de améliorés de « catégorie 2 » en décembre 2018.
  * EN 300 220-3-1: Les équipements d'alarmes sociales fonctionnant dans la bande de fréquence désignée (869,2 - 869,25 MHz)
  * EN 300 220-3-2: Les équipements d'alarmes sans fil fonctionnant dans les bandes de fréquences désignées
  * EN 300 220-4: Les équipements de mesure radio fonctionnant dans des bandes de fréquences désignées (169.4 - 169.4875 MHz)

- ETSI a déjà publié des projets de normes pour la télévision et les récepteurs de radiodiffusion qui se déplacent dans RED en raison de la modification du domaine d'application de la présente directive:

  * Projet de la norme ETSI EN 303 340 V1.1.0v, Récepteurs de diffusion de télévision numérique terrestre ; normes harmonisées couvrant les exigences essentielles de l'article 3.2 de la directive 2014/53/UE
  * Projet de la norme ETSI EN 303 345 V1.1.0vi, Récepteurs de radiodiffusion ; normes harmonisées couvrant les exigences essentielles de l'article 3.2 de la directive 2014/53/UE

Périodes de transition

En commun avec la pratique normale, il y aura une période de transition pendant laquelle les normes existantes peuvent continuer à être utilisées, mais il convient que les fabricants gardent un œil

sur le programme de travail de l'ETSI iv et restent à jour avec les normes telles qu'elles sont publiées.

À PROPOS DE

Sulis Consultants est un conseil indépendant en marquage CE et en agrément de produits basé à Hampshire, en Angleterre et spécialisé dans l'aide aux fabricants pour se conformer aux exigences de R&TTE, CEM, LV et RoHS ainsi que pour la certification radio pour l'Amérique du Nord.

Charlie Blackham est un ingénieur qui a travaillé dans le domaine du marquage CE et de l'agrément de produit depuis plus de 20 ans. Après avoir travaillé pour plusieurs fabricants en tant que responsable des approbations, Charlie a fondé Sulis Consultants en 2005 pour offrir conseils et assistance à un large éventail de clients. Un ancien expert technique d'organisme notifié, Charlie a aidé des clients au marquage CE d'une large gamme de produits fonctionnant à partir de 1 MHz jusqu'à 78 GHz et peut être contacté à l'adresse charlie@sulisconsultants.com ou par l'intermédiaire de www.sulisconsultants.com

REFERENCE LINKS

i http://ec.europa.eu/DocsRoom/documents/11983/attachments/1/translations/en/renditions/pdf

ii http://ec.europa.eu/DocsRoom/?locale=en

iii https://portal.etsi.org/webapp/WorkProgram/Report_WorkItem.asp?WKI_ID=47231

iv http://webapp.etsi.org/ena/cvp.asp?search=RADIO

v https://www.etsi.org/deliver/etsi_en/303300_303399/303340/01.01.00_20/en_303340v010100a.pdf

vi https://www.etsi.org/deliver/etsi_en/303300_303399/303345/01.01.00_20/en_303345v010100a.pdf

PRODUITS ET SERVICES

A

A.H. Systems Inc.
AR France, 7 Rue des Fosses Blanc Bat D1,
F-92230, Gennevilliers, France
+(0)11 33 1 47 91 75 30; Fax: +(0)11 33 1 47 91 75 35
contact@arfrance.eu; www.AHSystems.com
Produits et services: Antennes, Instrument de contrôle, Contrôles

AA Opto-Electronic
AA MCS, 18, rue Nicolas Appert, F-91898,
Orsay Cedex, France
+33 01 76 91 5012 Fax +33 01 76 91 5031
sales@aa-mcs.com;www.aa-mcs.com
Produits et services: Micro-ondes, amplificateurs de puissance, coupleurs à large bande, diviseurs, filtres

Aaronia AG
Kauthenbergstr. 14, Strickscheid,
DE-54597 Germany;
Fax:+49(0)6556-93034; +49(0)6556-93033;
Vanessa Bauer, VB@aaronia.de
Thorsten Chmielus, owner, TC@aaronia.de
Manuel Pinten, Materials contact, mp@aaronia.de
www.aaronia.de
Produits et services: Antennes, Protection, Instrument de contrôle

Apache Design Solutions
La Grande Arche, Paroi Nord, Paris La Defense,
92044, France
+33(0)1 43 25 92 45 Fax: +33(0)1 40 84 57 21 41;
Jose Gandlarz; jose@apache-da.com;
www.apache-da.com
Produits et Services: Miscellaneous

AR France
7 rue du Fosse Blanc, Bat D1, Gennevilliers,
France 92230
+33(0)1 47 91 75 30; Fax: +33(0)1 47 91 75 35
Bernard Bessot; contact@arfrance.eu; www.arfrance.eu
Produits et services: Amplificateurs, Antennes, Câbles et connexions, Espaces sous protection et clôtures,Hausse et éléments temporaires, Instrument de contrôle

Arrow Europe
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+33(0)1 4978 4949
www.arroweurope.com
Produits et services: Ferrites, câbles et connecteurs, applications de puissance

C

Carlisle Interconnect Technologies
United Kingdom
+44-7817-731-000
Andy Bowne, Andy.Bowne@carlisleit.com
www.CarlisleIT.com
Produits et services: Filtres

EMC Partner
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www.comtest.eu
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info@france.cst.com; www.cst.com
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E

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EM Test France, Le Trident - Parc de Collines
36, RuePaul Cezanne, 68200 Mulhouse, France
+33 389 31 23 50, Fax +33 389 31 235
info@emtest.fr, www.emtest.com
Products and Services: Hausse et éléments temporaires, Instrument de contrôle, Contrôles

EMC Partner France
Mr Pascal POIRET, 6 rue Clément VI
19300 Rosiers d'Egletons – France
+33 (0)5 55 74 31 68 ; Fax.: +33 (0)5 55 87 47 69
contact@emc-partner.fr; www.emc-partner.fr
Produits et services: Générateurs et solutions CEM & RF

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78180 Montigny le Bretonneux France
+33(0)1 30 57 55 55; Fax: +33(0)1 30 57 8640
Jean Luc Tisserand, jl.tisserand@emitech.fr
www.emitech.fr
Produits et services: Contrôles

Eurofarad
93, rue Oberkampf, F-75540 PARIS Cedex 11, France;
+33(0)1 49 23 10 00; Fax: +33(0)1 43 57 05 33
info@eurofarad.com; www.eurofarad.com
Produits et services: Filtres

EuroMC
12/24 Avenue de Stalingrad Stains, ZA St, Leger,
93240, France
+33 1 58 34 00 00; Fax. +33 1 58 34 07 07
EuroMC@wanadoo.fr; www.euromc.fr
Produits et services: Filtres, Protection, Espaces sous protection et clôtures

ETS-Lindgren
Z.A. Saint Léger - Batiment; 12-24 Avenue Stalingrad,
93240 Stains
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france@ets-lindgren.com; www.ets-lindgren.com
Produits et services: Antennes, ferrites, filtres, chambres blindées et boîtiers, Générateurs de signaux RFI / EMI, instrumentation de test, Divers

F

Fair-Rite Products
Schaffner EMC SAS, 112, Quai de Bezons B.P. 133
95103 Argenteuil France
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francesales@schaffner.com; www.fair-rite.com
Produits et services: Ferrite, Filtres, Espaces sous protection et clôtures, Protection

FCI Connectors
Immeuble Calypso, 18 Parc Ariane III, 3-5 rue Alfred Kastler, 78 280 Guyancourt, France
+33 1 72 67 35 00; Fax : +33 1 72 67 36 83
france@fci.com; www.fciconnect.com
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Federal-Mogul Corporation
69, rue Henri Laroche, 60800 Crépy-en-Valois
+33 3 44 39 06 06; Fax: +33 3 44 94 48 33
systems.protection@federalmogul.com
www.federalmogul.com/sp
Produits et services: Ensembles de câbles blindés & harnais conduits, tuyaux blindés blindé

G

GETELEC
375 rue Morane Saulnier, 78530 Buc- France
+33(0)1 39 20 42 42; Fax: +33(0)1 39 20 43 43
info@getelec.com; www.getelec.com
Produits et services: Matériaux conducteurs, Protection

Gowanda Electronics
ACAL BFI; ZI De La Petite Montagne Sud, 4 Allee Du Cantal, CE 1834 Lisses, Evry Cedex, France, 91018
+33 01 60 79 59 00; 33 01 60 79 89 01
info@bfioptilas.com; www.bfioptilas.com
Produits et services: Inducteurs

I

RF/Microwave Amplifiers

IFI-Instruments for Industry
AMETEK CTS Germany GmbH
Lünener Str. 211, 59174 Kamen, Deutschland
+49 2307 26070-0, Fax +49 2307 17050
sales.cts.de@ametek.com, www.ifi.com
Produits et services: Concepteurs et fabricants d' amplificateurs radiofréquences et hyperfréquences de haute puissance (Tetrode Tubes, Solid State and TWT)

K

Kemtron SARL
9, Avenue du Bois de l'Epine, Z.A. du bois de l'épine
91080 Courcouronnes, France
01.60.77.83.16; Fax : 09.72.38.81.33
Pascal Malblanc, info@kemtron.fr; www.kemtron.fr
Produits et services: Matériaux conducteurs, Protection CEM

L

Langer EMV-Technik GmbH
M2S SARL, 3 rue des Martins Pécheurs, F-66700
Argelès sur Mer France
04-68-81-49-52; Fax: 04-68-81-62-16
m2s@wanadoo.fr; www.langer-emv.de
Produits et services: Instrument de contrôle

M

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Produits et services: Concepteurs et fabricants d' amplificateurs radiofréquences et hyperfréquences de haute puissance

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Argeles Sur Mer, France; +04 68 81 49 52;
contact@m2s-argeles.fr; www.m2s-argeles.fr
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N

Nexio
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+33(0)5 61 44 02 47; Fax: +33(0)5 61 44 05 67
Frederic Amoros, President; frederic.amoros-routie@nexio.fr; www.nexio-online.com
Produits et services: Instrument de contrôle, Divers

P

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Z.I. La Marquisie, Avenue du 4 Juillet 1776,
Brive Cedex 19101 France
+33(0)5 55 86 49 33; Fax: +33(0)5 55 86 49 45
Dennis Dumont, ddumont@prana-rd.com
www.prana-rd.com
Produits et services: Amplificateurs

R

Rohde & Schwarz France
9 – 11, rue Jeanne Braconnier, 92366 Meudon-la-Forêt Cedex, France
+33 (0) 6 89 09 29 65; Fax: +33 (0) 1 41 36-1111
Vincent Lascoste, Vincent.Lascoste@rohde-schwarz.com; www.rohde-schwarz.fr
Produits et Services: EMC Test Equipment et Accessoires, amplificateurs à large bande, logiciel de mesure de CEM, clé en main de tester des solutions de système

S

Schlegel Electronic Materials
Yelloz Component - MILMEGA, 4 Rue de Mayotte
Z.I.de Courtaboeuf, FR- 91940 Les Ulis, France
+33(0)1 64 46 04 42; Fax: +33(0)1 64 46 92 70
Eric Stunault; estunault@yellozgroup.com
www.yellozgroup.com
Produits et services: Matériaux conducteurs, Protection

Schurter S.A.S.
Route de Châteauvillain, 52210 Arc en Barrios, France
+33 3 2502 5049
contact@schurter.fr; www.schurter.fr
Produits et services: Filtres, Protection

T

TDK Electronics France
41 rue Delizy, F-93500 Pantin, France
+33-(0)1-49466789
info@tdkrf.com; www.tdkrfsolutions.com
Produits et services: Antennes, filtres, logiciels, s ervices de test

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Yelloz Components
Za de Courtaboeuf, 4 Rue de Mayotte,
F-91940 Les Ulis, France
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yellozcomponents@yellowzgroup.com;
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W

Würth Elektronik France
1861 Avenue Henri Schneider CS 70029, 69881 Meyzieu CedexTel., France
+33 (0) 427 86 11 00; eiSos-france@we-online.com
Produits et services: Ferrites, câble et fiche

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aberthon@club-internet.fr

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aemc.lab@wanadoo.fr

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92260 Fontenay-aux-Roses, France
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asefa@lcie.fr

ASEFA - PLATE FORME F 03 - SCHNEIDER ELECTRIC INDUSTRIES
37 quai Paul Louis Merlin,
38050 Grenoble cedex 9, France
+33 4 76 39 85 51; Fax: +33 4 76 57 99 38
william.magnon@schneider-electric.com
www.schneider-electric.com

ASEFA - PLATE FORME P 01 - LEGRAND
128 avenue du Maréchal de Lattre de Tassigny, F87045
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didier.leblanc@legrand.fr

ASEFA - PLATE FORME V 01 - ALSTOM TRANSPORT
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Villeurbanne Cedex, France
+33 4 72 81 46 27
carlos-queiros-de-oliveira@transport.alstom.com
www.alstom.transport.com

CENTRE TECHNIQUE DES INDUSTRIES MECANIQUES
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+33 381 907590; Fax: +33 381 3236 28
s.afflard@eurocem.fr; commercial@eurocem.fr;
www.eurocem.fr

GYL TECHNOLOGIES
Parc d'activités de Lanserre 21 rue de la Fuye
F49610 Juigne sur Loire, Juigne sur loire, France
+33 241 575740; Fax: +33 2414525 77; gyl@gyl.fr

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toulouse@gerac.com

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33 avenue du Général Leclerc BP 8, F92266 Fontenay-aux-Roses cedex, France
+33 140 956060; Fax: +33 140 955407
contact@lcie.fr; www.lcie.fr

LABORATOIRE NATIONAL DE MÉTROLOGIE ET D'ESSAIS
1, rue Gaston Boissier, 75724 PARIS CEDEX 15, France
+33 140 433700; Fax: +33 140 433737
info@lne.fr; www.lne.fr

LABORATOIRE CENTRAL DES INDUSTRIES ELECTRIQUES - ETABLISSEMENT SUD-EST
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F38430 Moirans, France
+33 476 073636; Fax: +33 476 559088
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Autodrome de Linas-Montlhéry BP 20212
91311 Montlhéry Cedex, France
+33 169 801700; Fax: +33 169 801717
christian.pichon@utac.com; www.utac.com

OTHER

MINISTÉRE DE L'ECONOMIE, DES FINANCES ET DE L'INDUSTRIE DIGITIP/ SPIC/SQUALPI DIGITIP 5
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REVISIONE DELLO STANDARD IEC 60601-1-2: 2014 (QUARTA EDIZIONE)

Darryl P. Ray
Darryl Ray EMC Consulting, LLC

Introduzione

La quarta edizione dell'IEC 60601-1-2:2014 è stata pubblicata nel febbraio 2014 e sostituisce la terza edizione dell'IEC 60601-1-2 pubblicata nel 2007. Si riferisce alla compatibilità elettromagnetica delle apparecchiature e dei sistemi elettromedicali. La versione europea (EN60601-1-2:2015) è identica a quella della sua controparte IEC ad eccezione dei riferimenti alle versioni EN delle serie 61000-4-x e l'aggiunta di un allegato sui Requisiti Essenziali.

La motivazione sottostante alla quarta edizione è stata quella di creare uno standard di sicurezza che riguarda i disturbi elettromagnetici al fine di allinearli con i requisiti generali della terza edizione della norma IEC 60601-1. L'edizione precedente della norma IEC 60601-1-2 non affrontava in modo adeguato gli aspetti relativi alla sicurezza per quanto riguarda le interferenze elettromagnetiche. Inoltre, le differenze tra la terza e quarta edizione per quanto riguarda l'immunità sono sostanziali.

GLOBAL IMPLEMENTATION

La quarta edizione dell'IEC 60601-1-2 Ed 4: 2014 è stata pubblicata nel febbraio 2014. La FDA ora riconosce la quarta edizione e la data di conformità obbligatoria per le nuove richieste di approvazione è il 31 dicembre 2018. Tale data è stata scelta in linea con i requisiti dell'UE (EN 60601-1-2: 2015). Sebbene fino al 2018 non sia obbligatoria, la FDA ha recepito la quarta edizione e preferisce che al momento della presentazione di nuove richieste, i prodotti siano stati testati rispetto a questo standard, in modo particolare se si tratta di dispositivi da utilizzare nell'ambito dell'assistenza domiciliare.

La FDA non richiede la conformità alla quarta edizione per i dispositivi legacy a meno che non siano state apportate modifiche sostanziali al prodotto. Nell'Unione Europea, la Data di Cessazione (DoW) dell'applicabilità della EN 60601-1-2: 2007 è stata fissata al 31 dicembre 2018. Di conseguenza, tutti i dispositivi prodotti e importati nell'Unione Europea a decorrere da tale data sono tenuti a rispettare la quarta edizione. Non è prevista alcuna eccezione per i dispositivi legacy, come invece previsto dalla FDA.

Per le altre regioni, i requisiti variano significativamente da paese a paese. Attualmente almeno un mercato importante non accetta la quarta edizione. Per ulteriori dettagli, si faccia riferimento alla Tabella 6.

RIEPILOGO DELLE MODIFICHE TRA LA TERZA E QUARTA EDIZIONE.

Nella quarta edizione sono state apportate le seguenti modifiche significative:

- La distinzione tra apparecchiature di sostegno alla vita e apparecchiature non di sostegno alla vita utilizzata nella terza edizione è stata eliminata. È stata sostituita dall'uso di tre categorie di immunità a seconda dell'utilizzo: Assistenza a Domicilio Professionale, Assistenza a Domicilio e Ambienti Speciali.
- Le modifiche apportate alle emissioni e ai limiti di immunità sono riportate nelle tabelle da 1 a 4 di seguito.
- Il criterio per verificare se il test di immunità è stato passato o meno si limita a valutare la Prestazione Essenziale e la Sicurezza di Base
- È necessario che l'Impianto di Equalizzazione del Potenziale sia collegato alla messa a terra durante il test. La terza edizione non fa alcun riferimento all'Impianto di Equalizzazione del Potenziale
- Viene chiarito l'uso della mano artificiale
- È stata modificata la metodologia per l'esecuzione del test ESD di scarica elettrostatica sui connettori
- Deve essere prevista la modalità standby per le funzioni del test di emissione e del test di immunità
- È stato aggiunto un nuovo protocollo per stabilire una procedura nel caso in cui un dispositivo venga danneggiato durante un test di immunità
- Le apparecchiature non medicali utilizzate come parti di apparecchiature elettromedicali devono rispettare i relativi requisiti di Compatibilità Elettromagnetica. Il sistema deve garantire la Prestazione Essenziale e la Sicurezza di Base
- Sono stati semplificati i requisiti di tensione e di frequenza in ingresso della corrente AC. Ad eccezione dei testi su buchi e interruzioni di tensione, è accettabile che venga testato un solo livello di tensione e frequenza all'interno degli intervalli previsti per il dispositivo

- Sono stati forniti chiarimenti riguardo al test di SIP/SOPS (porte di ingresso/uscita del segnale) quando non utilizzato sul paziente
- È stata eliminata la tolleranza per l'immunità radio durante la fase di test dell'immunità irradiata
- I requisiti di etichettatura sono stati modificati e parzialmente semplificati. Le tabelle di Dichiarazione di Conformità di Compatibilità Elettromagnetica elencate nella terza edizione sono state eliminate
- È richiesto che venga elaborato un piano per il test di Compatibilità Elettromagnetica e ne viene specificato il contenuto raccomandato
- È stato ridotto il tempo minimo di pausa utilizzato per il test di immunità
- È richiesto che venga prodotto un rapporto del test di Compatibilità Elettromagnetica e ne viene specificato il contenuto minimo
- Gestione del Rischio – è richiesto che vengano considerati numerosi aspetti riguardo la Compatibilità Elettromagnetica
- Tutti gli standard fanno riferimento a una data specifica (nella terza edizione non venivano specificate date)
- Le avvertenze richieste nelle istruzioni per l'utilizzo di dispositivi di Classe A sono diverse da quelle che si trovano nel CISPR 11
- Per i dispositivi utilizzati sugli aeromobili si devono prendere in considerazione i requisiti di immunità elencati nel RTCA DO-160
- L'utilizzo del simbolo di avvertimento ESD vicino ai connettori sensibili è stato rimosso

REQUISITI DI EMISSIONE

Nella maggior parte dei casi, i limiti di emissione previsti dalla quarta edizione sono gli stessi previsti dalla terza. Nella quarta edizione sono stati forniti alcuni chiarimenti, come mostrato nella Tabella 1 di seguito.

Tabella 1 – Confronto dei requisiti di emissione

Requisiti	IEC 60601-1-2: 2007 (terza edizione)	IEC 60601-1-2: 2014 (quarta edizione)	Note
Emissioni condotte	CISPR 11	CISPR 11	
Emissioni radiate	CISPR 11	CISPR 11	
Distorsione armonica	IEC 61000-3-2	IEC 61000-3-2	Limiti previsti per Classe A
Fluttuazioni di tensione /Flicker	IEC 61000-3-3	IEC 61000-3-3	
Dispositivi con Monocomponenti	Potrebbe essere richiesta la conformità con il CISPR 14	Non applicabile	
Attrezzature per l'illuminazione	CISPR 15	Non applicabile	
Apparecchiature raggi X	Non applicabile	CISPR 11	È prevista una tolleranza di 20 dB sulle emissioni di quasi picco
Apparecchiature ITE	Deve essere conforme a CISPR 22	Deve essere conforme a CISPR 35	
Dispositivi con Sottosistemi Radio	Esenzione delle emissioni intenzionali	Esenzione delle emissioni intenzionali	
Cavi pazienti - Emissioni condotte	Non applicabile	La Modalità Comune è attualmente limitata a 24 dBµA (1-30 MHz)	Requisiti informativi
Dispositivi a Motore o con Circuiti di Commutazione	Non applicabile	CISPR 14-1	

REQUISITI DI IMMUNITÀ

Nella quarta edizione sono stati apportati cambiamenti importanti sui livelli di immunità, come mostrato di seguito nelle Tabelle da 2 a 4. I livelli sono basati sul "livello massimo ragionevolmente prevedibile".

CRITERI PER L'ACCETTAZIONE DELL'IMMUNITÀ

I requisiti per passare/ non passare il test di immunità dettagliati nella quarta edizione si basano sul fatto che il dispositivo medico mantenga la Sicurezza di Base e la Prestazione Essenziale. La definizione di questi concetti viene descritta di seguito:

Tabella 2- Confronto dei livelli di Immunità – Fenomeno transitorio

Fenomeno	IEC 60601-1-2: 2007 (terza edizione)	IEC 60601-1-2: 2014 (quarta edizione)	
		Contesto di cura professionale	Contesto di cura domiciliare
ESD (test per IEC 61000-4-2)	8 kV Scarica nell'Aria (max.) 6 kV Scarica a Contatto	**15 kV** Scarica nell'Aria (max.) **8 kV** Scarica a Contatto	
EFT/Scoppio (test per IEC 61000-4-4)	2 kV – Rete elettrica AC 1 kV – Porte I/O 5 kHz or 100 kHz PRR	2 kV Rete elettrica AC 1 kV Porte I/O **100 kHz PRR**	
Sovratensione – Rete elettrica AC (test per IEC 61000-4-5)	2 kV (max.) 0, 90, 270 gradi degli angoli di fase	2 kV (max.) 0,90,**180** & 270 gradi degli angoli di fase	
Sovratensione – potenza 12 VDC (test per ISO 7637-2)	N/A	**600 V**	
Buchi e interruzioni di tensione (test per IEC 61000-4-11)	• UT < 5%, 0.5 periodi • UT = 40 %, 5 periodi • UT = 70%, 25 periodi • UT < 5%, 5 secondi	• **U_T = 0%, 0.5 ciclo (0, 45, 90, 135, 180, 225, 270 e 315°)** • **U_T = 0 %; 1 ciclo UT = 70%; 25/30 cicli (@ 0 gradi)** • **U_T = 0%; 250/300 ciclo**	

In grassetto i cambiamenti rispetto alla terza edizione

Tabella 3 - Confronto dei livelli di Immunità – Fenomeno stato stazionario

Fenomeno	IEC 60601-1-2:2007 (terza edizione)	IEC 60601-1-2: 2014 (quarta edizione)	
		Contesto di cura professionale	Contesto di cura domiciliare
Immunità condotta (test per IEC 61000-4-6)	3 V (0.15- 80 MHz) 10V Bande ISM Apparecchiature di supporto alla vita	3 V (0.15 - 80 MHz) **6 V (bande ISM)**	3 V (0.15 - 80 MHz) **6 V (ISM & Amateur)**
Immunità magnetica (test per IEC 61000-4-8)	50 & 60 Hz	**30 A/m** 50 **o** 60 Hz	

In grassetto i cambiamenti rispetto alla terza edizione

Tabella 4 - Confronto dei livelli di Immunità – Fenomeno stato stazionario del campo elettrico

Fenomeno	IEC 60601-1-2:2007 (terza edizione)	IEC 60601-1-2: 2014 (quarta edizione))	
		Contesto di cura professionale	Contesto di cura domiciliare
Immunità radiata (test per IEC 61000-4-3)	3 V/m – Non salvavita 10 V/m –Salvavita 80 MHz – 2.5 GHz 80%@2 Hz (o 1 kHz1) Modulazione AM	**3 V/m** 80 MHz – **2.7 GHz** 80%@ **1 kHz** Modulazione AM	**10 V/m** 80 MHz – **2.7 GHz** 80%@ **1 kHz** Modulazione AM
Campo di vicinanza a trasmettitori Wireless (test per IEC 61000-4-3)	Non applicabile	**9 V/m to 28 V/m** 15 frequenze specifiche	

In grassetto i cambiamenti rispetto alla terza edizione

Sicurezza di Base – Come definita nell'IEC 60601-1:2012, edizione 3.1:

SICUREZZA DI BASE
Libertà dai rischi inaccettabili causati da pericoli fisici quando il dispositivo elettromedicale è utilizzato in condizioni normali e di guasto singolo2

PRESTAZIONE ESSENZIALE
Prestazione necessaria per ottenere libertà da rischi inaccettabili di una funzione clinica, oltre a quelli collegati con la sicurezza di base, dove la perdita o il danneggiamento oltre i limiti specificati dal fabbricante rappresenta un rischio inaccettabile.

NOTA – Per comprendere meglio il concetto d Prestazione Essenziale si valuti se la sua assenza o il suo danneggiamento potrebbero risultare in un rischio inaccettabile.

È di cruciale importanza che il fabbricante capisca e applichi i due concetti di cui sopra sui dispositivi medici da testare. In molti casi, un dispositivo potrebbe essere soggetto a disturbi elettromagnetici, ma se i concetti di Sicurezza di Base e Prestazione Essenziale sono rispettati, il dispositivo potrebbe essere considerato conforme alla quarta edizione.

TEST DELLE SCARICHE ELETTROSTATICHE (ESD) SUI CONNETTORI

La terza edizione richiede che test di scariche di contatto vengano effettuati individualmente su ciascuna spina dei connettori in base alle linee guida IEC 60601-1. Non esiste una procedura di test definita per effettuare questo test. La quarta edizione ha raffinato la procedura come specificato nella Tabella 5 di seguito:

Tabella 5 – Requisiti per il test ESD sui connettori

Corpo del connettore	Requisiti di Scarica	Utilizzo porta
Conduttivo	Scarica a contatto solo sul corpo	Destinazione d'uso e uso normale[3]
Isolato	Scarica nell'aria sul corpo e scarica nell'aria sulle spine (se raggiungibili dal IEC Test Finger)	Destinazione d'uso

GESTIONE DEL RISCHIO

Il concetto di gestione del rischio per la compatibilità elettromagnetica è nuovo. Con riferimento alla gestione del rischio, la quarta edizione richiede che vengano trattate alcune tematiche. Queste tematiche dovrebbero essere affrontate e documentate nel rapporto del test di Compatibilità Elettromagnetica e nel fascicolo di gestione del rischio.

- È necessario considerare la distanza minima di separazione da dispositivi di comunicazione portatili
- È necessario considerare l'allegato F, Gestione del Rischio per Sicurezza di Base e Prestazione Essenziale
- Le modalità di funzionamento dei test dovrebbero essere basate sull'Analisi del Rischio
- Test di apparecchiature non medicali (ad esempio, nel processo di gestione del rischio devono essere presi in considerazione i disturbi)
- È necessario analizzare gli effetti osservati riguardo alla risposta dell'EUT durante il test di immunità
- Il processo di Gestione del Rischio deve essere usato per determinare se è permesso testare il sottosistema
- Qualora fossero utilizzati livelli di test ridotti, è necessario dare spiegazioni
- È necessario dare spiegazioni riguardo fattori mitiganti utilizzati per giustificare livelli di test d'immunità più bassi
- È possibile utilizzare frequenze di modulazione alternative
- È necessario prendere in considerazione i servizi di comunicazione attuali
- Se un dispositivo dista meno di 15 cm da una sorgente di onde magnetiche è necessario eseguire il test a livelli di immunità magnetica più alti

La Dichiarazione di Conformità alla quarta edizione prevede cinque passi:

- Definizione di un piano di collaudo prima di iniziare i test
- Conformità ai requisiti di prova pertinenti
- Resoconto dettagliato del test con specifica del contenuto minimo richiesto
- Spiegazione dei criteri di gestione del rischio elencati
- Conformità dell'etichettatura ai requisiti di cui al punto 6.

DATE DI CONFORMITÀ

Le date per la conformità alla quarta edizione e a molti altri standard possono rappresentare un problema complicato da risolvere. Le date dipendono dal tipo di dispositivo, dalla regione nel quale è venduto e potrebbero essere influenzate da livelli di standard più elevati o altre normative. La Tabella 6 riassume le date di conformità obbligatorie in base alla regione.

Tabella 6 – Date di conformità al IEC 60601-1-2:2014 (quarta edizione) per Regione

Stati Uniti	Unione Europea	Altre regioni
Dispositivi Legacy: mai[4] Nuovi prodotti: 1 gennaio 2019	Tutti i prodotti: 1 gennaio 2019 (conformità con EN 60601-1-2: 2015)	Dipende da: • Normative Nazionali [5] • Standard IEC 80601-2-X[6]

SOMMARIO

Il presente articolo ha fornito un confronto tra la terza e la quarta edizione dell'IEC 60601-1-2. Come evidenziato nelle tabelle sopra riportate, i livelli di test in molti casi sono differenti e spesso (ma non sempre) più severi. La quarta edizione richiede che la Sicurezza di Base e la Prestazione Essenziale del dispositivo medico siano mantenute in presenza di vari ambienti elettromagnetici elencati nella norma.

Suscettibilità non legate alla Sicurezza di Base e alla Prestazione Essenziale non sarebbero normalmente considerate come un mancato superamento del test. Inoltre, la quarta edizione richiede che vengano considerati alcuni aspetti inerenti la gestione del rischio.

I due standard si differenziano significativamente con riferimento ai livelli di test e al criterio di superamento o mancato superamento del test di immunità, alle modalità di funzionamento e altro ancora. Ciò detto non è corretto affermare che essere conformi alla quarta edizione significhi essere conformi alla terza edizione.

REFERENCES

[1] Per i parametri che non controllano, monitorano o misurano un parametro fisiologico è utilizzata la modulazione 1 kHz.

[2] Sebbene il guasto singolo sia ufficialmente contemplato in questa definizione, molti utenti della IEC 60601-1-2 riterrebbero che la conformità sarebbe impraticabile e impossibile da raggiungere nel caso di singolo guasto e pertento spesso viene ignorata.

[3] Per la definizione di destinazione d'uso e uso normale si faccia riferimento a IEC 60601-1.

[4] In base allo schema di equivalenza sostanziale previsto dalla FDA

[5] Alcuni paesi al momento non hanno recepito la quarta edizione

[6] Per gli standard particolari (IEC 60601/80601-2-X) è in corso la conversione a referenze datate nel IEC 60601-1-2:2014. Finché la conversione non sarà completata, alcuni standard faranno riferimento all'IEC 60601-1-2:2014, altri all'IEC 60601-1-2:2007 e altri utilizzerannno una referenza non datata secondo l'IEC 60601-1-2.

DIRETTIVA 2014/53/UE SULLE APPARECCHIATURE RADIO

Di Charlie Blackman
Consulente e Direttore di Sulis Consultants Ltd.

Nota dell'editore: *la Direttiva sulle Apparecchiature Radio (RED), 2014/53/UE deve essere applicata ai nuovi prodotti a partire dal 13 giugno 2016 ed è obbligatoria per tutti i prodotti a partire dal 13 giugno 2017.*

SOMMARIO

Il presente articolo fornisce un aggiornamento sui cambiamenti apportati dalla nuova Direttiva sulle Apparecchiature Radio (Radio Equipment Directive, Direttiva RED) 2014/53/UE in vigore a partire dal giugno 2016. L'articolo esamina i cambiamenti per il prodotto e nel panorama normativo e ciò che la direttiva implica per i fabbricanti di apparecchiature.

Maggiori dettagli sulla storia della direttiva sono disponibili nell'articolo, Radio Equipment Directive, all'interno della guida Interference Technology 2015 EMC Directory and Design Guide.

AMBITO DI APPLICAZIONE DELLA DIRETTIVA

L'ambito di applicazione della Direttiva RED è stato ampliato per includere:

- Apparecchiature con "identificazione a radio frequenza", come ad esempio i radar e i dispositivi RFID. Questi dispositivi ricadevano nell'ambito di applicazione della Direttiva R&TT, tuttavia l'ambito di applicazione della Direttiva RED è molto più chiaro e pertanto è evidente che gli stessi sono inclusi e devono essere conformi.
- "Ricevitori per radio diffusione e trasmissione TV" – questi dispositivi non rientravano nell'ambito di applicazione della Direttiva R&TTE, pertanto ora le prestazioni dello spettro radio saranno soggette a ulteriori requisiti.
- "Prestazioni dei ricevitori" – sebbene questi prodotti fossero coperti in numerosi standard di prodotto ETSI, la loro importanza all'interno di uno spettro radio sempre più congestionato ha fatto sì che fossero disciplinati dalla Direttiva.
- "Apparecchi che operano sotto i 9 kHz" – il limite minimo di frequenza di 9 kHz previsto dalla Direttiva R&TTE è stato rimosso.
- In linea con quanto previsto da altre direttive, sono esplicitamente esclusi "i kit di valutazione personalizzati destinati a professionisti da utilizzare esclusivamente in strutture di ricerca e sviluppo per tali scopi."

Prodotti	Requisiti di conformità e date
Attualmente disciplinati dalle direttive EMC e LVD e non disciplinati dalle direttive R&TTE o RED	• Prodotti immessi sul mercato prima del 20 aprile 2016: vecchie direttive LVD/EMCD • Prodotti immessi sul mercato a partire dal 20 aprile 2016: nuove direttive LVD/EMCD
Attualmente disciplinati dalla direttiva R&TTE e che resteranno disciplinati dalla direttiva RED	• Prodotti immessi sul mercato prima del 13 giugno 2016: direttiva R&TTED • Prodotti immessi sul mercato tra il 13 giugno 2016 e il 12 giugno 2017: direttiva R&TTED o RED • Prodotti immessi sul mercato dopo il 12 giugno 2017: direttiva RED
Attualmente non disciplinati dalla direttiva R&TTE ma disciplinati dalla direttiva RED	• Prodotti immessi sul mercato prima del 20 aprile 2016: vecchie direttive LVD/EMCD • Prodotti immessi sul mercato tra il 20 aprile 2016 e il 12 giugno 2016: nuove direttive LVD/EMCD • Prodotti immessi sul mercato tra il 13 giugno 2016 e il 12 giugno 2017: direttiva RED oppure nuove direttive LVD/EMCD • Prodotti immessi sul mercato dopo il 12 giugno 2017: direttiva RED
Attualmente disciplinati dalla direttiva R&TTE ma al difuori dell'ambito di applicazione della direttiva RED	• Prodotti immessi sul mercato prima del 13 giugno 2016: direttiva R&TTED • Prodotti immessi sul mercato prima del dopo il 12 giugno 2016: la direttiva RED si applica; nuove direttive LVD/EMCD, se applicabili al prodotto in oggetto

TEMPISTICA E PERIODI DI TRANSIZIONE

La Commissione Europea ha confermato che ci sono quattro scenari per l'applicazione delle Direttive 2014/53/EU, 2014/35/UE e 2014/30/UE [i]

Si è preso nota del fatto che queste tempistiche potrebbero generare oneri amministrativi per i fabbricanti per l'aggiornamento della documentazione e le Dichiarazioni di Conformità, in particolare per le apparecchiature che non rientrano nell'ambito di applicazione della direttiva R&TTE ma rientrano in quello delle direttive EMC e LVD, in quanto non beneficiano del periodo di transizione previsto dalla direttiva RED.

La guida sui contenuti delle Dichiarazioni di Conformità specifica il contenuto minimo, ma generalmente non specifica un contenuto massimo e sono generalmente permesse informazioni aggiuntive utili. Su questa base, sono in discussione alcune proposte all'interno della commissione per consentire ai fabbricanti di citare nelle Dichiarazioni di Conformità sia la direttiva attuale sia quella nuova, per esempio:

"L'oggetto della dichiarazione di cui sopra è conforme alla pertinente normativa UE di armonizzazione: Direttiva 1999/5/CE (fino al 12 giugno 2016), Direttiva 2014/30/UE (dal 13 giugno 2016) e Direttiva 2014/35/UE (dal 13 giugno 2016)."

Si prega di notare che al momento della pubblicazione questa proposta **non è stata formalmente accettata**. La pubblicazione nella EU Docs Room ii è attesa per l'inizio di marzo. Ulteriori aggiornamenti saranno forniti non appena disponibili.

Alcuni punti importanti per i fabbricanti di prodotti disciplinati dalla Direttiva RED:

- La marcatura CE deve apparire sia sul dispositivo sia sull'imballaggio – secondo la Direttiva RED non è più necessaria la marcatura CE sul manuale dell'utente.
- Il numero di identificazione dell'Organismo Notificato va riportato sul prodotto solo in caso di Garanzia Totale di Qualità (Direttiva R&TTE allegato V / Direttiva RED allegato IV) e non deve essere utilizzato nel caso in cui la scheda tecnica sia appena stata rivista da un organismo notificato.
- L'elenco dei paesi consentiti dovrebbe essere ancora indicato sia sull'imballaggio sia sul manuale dell'utente ma non è più obbligatorio il simbolo di avviso per le apparecchiature di seconda classe.
- Il manuale utente deve contenere le bande di frequenza di funzionamento e la potenza massima di trasmissione per ciascuna delle bande: questa informazione deve essere fornita in un linguaggio facile da comprendere per l'utente finale
- Ogni prodotto che contiene parti di "apparecchiature radio" come definite nella Direttiva RED Articolo 2, rientra nell'ambito di competenza della Direttiva RED – pertanto una lavatrice dotata di un dispositivo radio Zigbee è disciplinata dalla Direttiva RED e dalle direttive EMC e LVD.

SVILUPPI DEI NUOVI STANDARD DELLA DIRETTIVA RED

EMC

Per le apparecchiature radio non è possibile applicare la Direttiva EMC come invece era possibile secondo la Direttiva R&TTE, pertanto tutti i prodotti che contengono apparecchiature radio rientrano nell'ambito della Direttiva RED (Direttiva sulle Apparecchiature Radio).

- L'ETSI sta sviluppando la guida EG 203 367 iii, "Electromagnetic compatibility and Radio spectrum Matters (ERM); Guide to the application of harmonized standards covering Articles 3.1b and 3.2 of the Directive 2014/53/EU (RE-D) to multi-radio and combined radio and non-radio equipment" che fornisce linee guida riguardo l'applicazione degli Standard Armonizzati ad apparecchiature, multi radio e combinate. Il documento è ancora in fase di completamento.

  * Esempi di apparecchiature coperte dal documento includono, tra gli altri, combinazione di diversi prodotti radio in un'apparecchiatura radio, combinazione di apparecchiature radio, IT o elettrotecniche, elettrodomestici abilitati a utilizzare la rete RLAN, sistemi di riscaldamento e sistemi di illuminazione radiocomandati, etc.

Spettro Radio

- L'ETSI sta aggiornando 156 standard dello spettro radio previsti dall'articolo 3.2 della Direttiva RED, 34 di questi saranno pubblicati sulla Gazzetta Ufficiale nel corso del 2016 e la maggior parte degli altri nella prima metà del 2017.
- A seguito di una revisione della compatibilità tra LTE funzionante nella banda di frequenza 800 MHz e apparati a corto raggio UHF, l'ETSI ha iniziato a lavorare sulla revisione della EN 300 220. L'oggetto dei lavori è descritto di seguito:

  * EN 300 220-2: Standard armonizzati per apparecchiature radio generiche. Sono in corso di sviluppo due versioni: la versione 3.1.1 con ricettori "categoria 3", che sarà sostituita entro dicembre 2018 con la versione 3.2.1 con ricettori di "categoria 2" migliorati.
  * EN 300 220-3-1: Dispositivi per allarmi sociali funzionanti in bande di frequenza predefinite (869.2 - 869.25 MHz)
  * EN 300 220-3-2: Dispositivi di allarme wireless funzionanti in bande di frequenza predefinite
  * EN 300 220-4: Dispositivi di misurazione radio funzion-

anti in bande di frequenza predefinite (169.4 - 169.4875 MHz)

- L'ETSI ha già pubblicato una bozza degli standard previsti per i ricevitori TV e broadcast che saranno disciplinati dalla direttiva RED per via del cambio del perimetro di questa direttiva:
  - Bozza ETSI EN 303 340 V1.1.0v, Digital Terrestrial TV Broadcast Receivers; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU
  - Bozza ETSI EN 303 345 V1.1.0vi, Radio Broadcast Receivers; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU

Periodi di transizione

In linea con la prassi, ci sarà un periodo di transizione durante il quale gli standard esistenti potrebbero continuare a essere usati: i fabbricanti tuttavia dovranno tenere d'occhio il programma dei lavori dell'ETSI [iv] e aggiornarsi in linea con i nuovi standard man mano che essi saranno pubblicati.

RIGUARDO A NOI

Sulis Consultants è una società di consulenza indipendente per la marcatura CE e Approvazione Prodotti con sede nell'Hampshire, Inghilterra e specializzata nell'aiutare i fabbricanti a rispettare gli standard previsti dalle direttive R&TTE, EMC, LV , RoHS e le certificazioni radio previste per l'America del Nord.

Charlie Blackham è un Ingegnere Qualificato che opera nel campo dell'approvazione dei prodotti e marcatura CE da oltre 20 anni. Dopo aver lavorato per numerosi fabbricanti come Responsabile dell'Approvazione, nel 2005 Charlie ha fondato Sulis Consultants per offrire consulenza e assistenza a un'ampia gamma di clienti. Charlie ha una notevole esperienza con gli Organismi Notificati e ha aiutato numerosi clienti a utilizzare la marcatura CE su un ampia gamma di prodotti radio funzionanti da 1 MHz a 78 GHz. Charlie può essere contattato al seguenti indirizzo email charlie@sulisconsultants.com o sul sito www.sulisconsultants.com

REFERENCE LINKS

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PRODOTTI E SERVIZI

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REVISIÓN DE IEC 60601-1-2: 2014 (4ª EDICIÓN)

Darryl P. Ray
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Introducción

IEC 60601-1-2:2014 4ª edición se publicó en febrero de 2014 y sustituye al documento IEC 60601-1-2 3ª edición, publicado en el año 2007. Pertenece a la Directiva de Compatibilidad Electromagnética (EMC) para equipos eléctricos médicos y sistemas eléctricos médicos. La versión europea (EN60601-1-2:2015) es idéntica a su homóloga de la IEC con excepción de las referencias a las versiones en inglés de las series 61000-4x y la adición del anexo de Requisitos imprescindibles.

Lo que ha motivado la publicación de una 4ª edición ha sido la creación de una norma de seguridad relacionada con las perturbaciones electromagnéticas de modo que se corresponda con los requisitos generales de IEC 60601-1, 3ª edición. La versión anterior del IEC 60601-1-2 no trataba correctamente los aspectos de seguridad relacionados con las interferencias electromagnéticas. Además, las diferencias entre la 3ª y la 4ª edición con respecto a la inmunidad son importantes.

APLICACIÓN GLOBAL

IEC 60601-1-2 Ed 4:2014 se publicó en febrero de 2014. La FDA reconoce la 4ª edición y la fecha de cumplimiento obligatoria para las nuevas presentaciones es el 31 de diciembre de 2018. La fecha se seleccionó para corresponderse con los requisitos de la UE (EN 60601-1-2:2015). Si bien no es obligatoria hasta 2018, la FDA ya acepta en la actualidad la 4ª edición y prefiere que los productos se prueben de conformidad con dicha normativa cuando se presentan nuevas solicitudes, especialmente en el caso de dispositivos destinados a atención doméstica.

La FDA no exige el cumplimiento de la 4ª edición para dispositivos anteriores salvo que se realicen cambios importantes en el producto.

En la Unión Europea, la fecha de retirada de EN 60601-1-2:2007 será el 31 de diciembre de 2018. Por lo tanto, todos los dispositivos fabricados e importados en la Unión Europea tras dicha fecha deberán cumplir con los requisitos establecidos en la 4ª edición. No se incluyen los dispositivos anteriores permitidos por la FDA.

Para otras regiones, los requisitos varían significativamente dependiendo del país. Al menos un mercado importante no acepta en la actualidad la 4ª edición. Consulte la Tabla 6 a continuación para obtener información adicional.

RESUMEN DE LOS CAMBIOS ENTRE LA 3ª Y LA 4ª EDICIÓN

Se han realizado los siguientes cambios importantes en la 4ª edición.

- Se ha eliminado la clasificación incluida en la tercera edición de soporte vital frente a soporte no vital. Se ha reemplazado por tres categorías de inmunidad de uso previsto. Asistencia profesional, asistencia doméstica y entorno especial
- Se han modificado las emisiones y los límites y niveles de inmunidad, tal y como se muestra en las Tablas 1 a 4 a continuación
- El criterio de apto/no apto de la inmunidad se limita a mantener el Rendimiento esencial y la Seguridad básica
- Se requiere un terminal conductor de ecualización potencial conectado a la toma de tierra local durante la realización de pruebas. La tercera edición no mencionaba el terminal conductor de ecualización potencial
- Se clarifica el uso de la Prótesis
- Se modifica la metodología de prueba para la realización de pruebas ESD en conectores
- Debe de tenerse en cuenta el modo de suspensión tanto para la prueba de inmunidad como para las emisiones
- Se ha añadido un nuevo proceso para establecer un procedimiento en caso de que un dispositivo resulte dañado durante una prueba de inmunidad
- Los equipos no médicos utilizados como parte del sistema eléctrico médico deberán cumplir los requisitos EMC básicos. El sistema debe mantener el Rendimiento esencial y la Seguridad básica
- Se racionalizan los requisitos de frecuencia y tensión de entrada de CA Con la excepción de las pruebas de Interrupción y Caída de voltaje, se acepta la realización de pruebas con el voltaje y la frecuencia dentro del margen de clasificación del dispositivo
- Se clarifica la prueba de los puertos de salida/entrada de señal

(SIP/SOPS) no utilizados durante el uso en patentes
- Se ha eliminado la previsión para susceptibilidad de radio durante la realización de pruebas de inmunidad radiadas.
- Se han modificado y se han simplificado parcialmente los requisitos de etiquetado. Se han eliminado las Tablas de declaración de conformidad de la EMC incluidas en la tercera edición.
- Se requiere un plan de prueba EMC y se incluye el contenido recomendado
- Se reduce el tiempo de exposición mínimo utilizado para las pruebas de inmunidad
- Se requiere un informe de prueba EMC y se define el contenido mínimo
- Gestión de riesgos: se establece el requisito de varias consideraciones de la EMC
- Todas las normativas llevan referencia de su fecha (la 3ª edición utiliza referencias sin fecha)
- La declaración de advertencia requerida en las instrucciones de uso para los dispositivos de la Clase A difiere a la encontrada en CISPR 11
- Los dispositivos utilizados en aviones deben satisfacer los requisitos de inmunidad enumerados en RTCA DO-160
- Se ha eliminado la necesidad de utilizar el símbolo de advertencia de descarga electrostática ESD cerca de los conectores sensibles.

REQUISITOS DE EMISIONES

En la mayoría de los casos, los límites de emisiones incluidos en la 4ª edición son los mismos que los que se establecían en la versión anterior. En la 4ª edición se indican varias clarificaciones, tal y como se muestra en la Tabla 1 a continuación.

Tabla 1 - Comparación de los requisitos de emisiones

Requisito	IEC 60601-1-2: 2007 (3ª edición)	IEC 60601-1-2: 2014 (4ª edición)	Observaciones
Emisiones conducidas	CISPR 11	CISPR 11	
Emisiones radiadas	CISPR 11	CISPR 11	
Distorsión armónica	IEC 61000-3-2	IEC 61000-3-2	Se aplican los límites de la Clase A
Fluctuaciones/ Oscilación de tensión	IEC 61000-3-3	IEC 61000-3-3	
Dispositivos con componentes sencillos	Puede que sea necesario el cumplimiento de CISPR 14	No aplicable	
Equipo de iluminación	CISPR 15	No aplicable	
Equipo de rayos X	No aplicable	CISPR 11	Se aplica una relajación de 20 dB para emisiones de cuasicresta
Equipo ITE	Debe ser conforme a CISPR 22	Debe ser conforme a CISPR 35	
Dispositivos con sistemas secundarios de radio	Exentos de emisiones intencionadas	Exentos de emisiones intencionadas	
Cables de paciente - Emisiones conducidas	No aplicable	Corriente de modo común limitada a 24 dBµA (1-30 MHz)	Requisitos informativos
Dispositivos con motores o circuitos de conmutación	No aplicable	CISPR 14-1	

REQUISITOS DE INMUNIDAD

Se realizaron cambios significativos en los niveles de inmunidad en esta 4ª edición, como se muestra en las Tablas 2 a 4. Los niveles se basaron en un «máximo razonablemente predecible».

Tabla 2 - Comparación del nivel de inmunidad, fenómeno transitorio

Fenómeno	IEC 60601-1-2: 2007 (3ª edición)	IEC 60601-1-2: 2014 (4ª edición)	
		Asistencia profesional Entorno	Asistencia doméstica Entorno
ESD (prueba conforme a IEC 61000-4-2)	Descarga de aire (máx) 8 kV Descarga de contacto 6 kV	Descarga de aire **15 kV** (máx) Descarga de contacto **8 kV**	
EFT/Ráfaga (prueba conforme a IEC 61000-4-4)	2 kV - Suministro CA 1 kV - Puertos E/S 5 kHz o 100 kHz PRR	2 kV CA suministro 1 kV Puertos E/S **100 kHz PRR**	
Sobrecargas, suministro de CA (prueba conforme a IEC 61000-4-5)	2 kV (máx.) Ángulos de fase de 0, 90, 270 grados	Ángulos de fase de 0, 90, 180 y 270 grados	
Sobrecargas, alimentación de 12 VCC (prueba conforme a Normativa ISO 7637-2)	N/A	**600 V**	
Caídas de tensión e interrupciones (prueba conforme a IEC 61000-4-11)	• U_T < 5%, 0.5 periodos • U_T = 40 %, 5 periodos • U_T = 70%, 25 periodos • U_T < 5%, 5 segundos	• **UT = 0%, 0.5 ciclo (0, 45, 90, 135, 180, 225, 270 and 315°)** • **UT = 0 %; 1 ciclo UT = 70%; 25/30 ciclo (@ 0 grados)** • **UT = 0%; 250/300 ciclos**	

Negrita = Cambios con respecto a la 3ª edición

Tabla 3 - Comparación de nivel de inmunidad, fenómeno estable

Fenómeno	IEC 60601-1-2:2007 (3ª edición)	IEC 60601-1-2: 2014 (4ª edición)	
		Asistencia profesional Entorno	Asistencia doméstica Entorno
Inmunidad conducida (prueba conforme a IEC 61000-4-6)	3 V (0,15 - 80 MHz) Bandas ISM de 10 V Equipo de asistencia vital	3 V (0,15 - 80 MHz) **6 V (bandas ISM)**	3 V (0,15 - 80 MHz) **6 V (ISM y Amateur)**
Inmunidad magnética (prueba conforme a IEC 61000-4-8)	3 A/m 50 y 60 Hz	**30 A/m** 50 o 60 Hz	

Negrita = Cambios con respecto a la 3ª edición

Tabla 4 - Comparación de nivel de inmunidad, fenómeno de campo eléctrico estable

Fenómeno	IEC 60601-1-2:2007 (3ª edición)	IEC 60601-1-2: 2014 (4ª edición)	
		Asistencia profesional Entorno	Asistencia doméstica Entorno
Inmunidad radiada (prueba conforme a IEC 61000-4-3)	3 V/m - Asistencia no vital 10 V/m - Asistencia vital 80 MHz – 2,5 GHz 80 % @2 Hz (o 1 kHz[1]) Modulación AM	**3 V/m** 80 MHz – **2,7 GHz** 80 %@ **1 kHz** Modulación AM	**10 V/m** 80 MHz – **2,7 GHz** 80 %@ **1 kHz** Modulación AM
Campo de proximidad desde transmisores inalámbricos (prueba conforme a IEC 61000-4-3)	No aplicable	**9 V/m a 28 V/m** 15 frecuencias específicas	

Negrita = Cambios con respecto a la 3ª edición

CRITERIOS DE ACEPTACIÓN DE INMUNIDAD

Los requisitos para que la inmunidad sea aceptable o no aceptable (apta/no apta) detallados en la 4ª edición se basan en el dispositivo médico manteniendo su seguridad básica y su rendimiento esencial. A continuación de detallan las definiciones de estos conceptos:

Seguridad básica, conforme a la definición establecida en IEC 60601-1:2002, Edición 3.1:

> **SEGURIDAD BÁSICA**
> ausencia de riesgos inaceptables causados directamente por peligros físicos cuando se utiliza un equipo ME bajo condiciones normales y en condición de error único2
>
> **RENDIMIENTO ESENCIAL**
> rendimiento necesario para conseguir que no existan riesgos no aceptables de a una función clínica, excepto los relacionados con la seguridad básica, donde la pérdida o degradación más allá de los límites especificados por el fabricante den como resultado un riesgo inaceptable.
>
> **NOTA**: el rendimiento esencial se entiende con mayor facilidad considerando si dicha ausencia o degradación resultaría en un riesgo inaceptable.

Es de vital importancia que el fabricante comprenda y aplique los anteriores conceptos al dispositivo a probar. En muchos casos, un dispositivo puede ser susceptible a interferencias electromagnéticas, pero si se mantiene la Seguridad básica y el Rendimiento esencial, entonces el dispositivo puede ser considerado como conforme con respecto a la 4ª edición.

PRUEBAS DE DESCARGA ELECTROMAGNÉTICA (ESD) EN CONECTORES

La tercera edición requiere que las descargas de contacto se realicen en clavijas de conectores individuales que sean accesibles según lo establecido en las directrices de IEC 60601-1. No existe ningún procedimiento de prueba establecido para llevar a cabo esta prueba. La 4ª edición ha mejorado este proceso tal y como se indica en la Tabla 5 a continuación:

Tabla 5 - Requisitos para la realización de la prueba ESD en conectores

Carcasa del conector	Requisitos de descarga	Uso del puerto
Conductivo	Descarga de contacto a la carcasa solamente	Uso normal y previsto[3]
Aislado	Descarga de aire a la carcasa y Descarga de aire a las clavijas (si se puede acceder mediante el dedo de ensayo del IEC)	Uso previsto

GESTIÓN DE RIESGOS

El concepto de gestión de riesgos para la Normativa de compatibilidad electromagnética es nuevo. La 4ª edición requiere que se traten los siguientes aspectos con respecto a la gestión de riesgos. Deben de tratarse dichos aspectos y documentarse en el informe de prueba de Compatibilidad electromagnética y en el archivo de Gestión de riesgos.

- Debe respetarse la distancia de separación mínima con dispositivos de comunicación portátiles.
- Es necesario respetar lo establecido en el Anexo F, Gestión de riesgos para la Seguridad básica y el Rendimiento esencial
- Los modos operativos utilizados para la realización de pruebas deben basarse en el Análisis de riesgos
- Pruebas de equipos no médicos (deben tenerse en cuenta las interferencias en el proceso de gestión de riesgos)
- Deben tratarse los efectos observados en la respuesta del equipo sometido a prueba durante la prueba de inmunidad
- Es necesario utilizar el proceso de Gestión de riesgos para determinar si se permite la prueba de los sistemas secundarios
- Si se utilizan niveles de prueba reducidos, deben justificarse
- Las mitigaciones utilizadas para justificar los niveles inferiores de prueba de inmunidad deben documentarse
- Se pueden utilizar frecuencias de modulación alternativas
- Deben tenerse en cuenta los servicios de comunicaciones actuales
- Deben realizarse pruebas a niveles superiores de inmunidad magnética en caso de que un dispositivo esté a una distancia inferior a 15 cm de una fuente magnética de frecuencia de red

La declaración de cumplimiento con la 4ª edición requiere que se tomen cinco acciones:

- Creación de un plan de prueba previo a la realización de la prueba
- Cumplimiento con los requisitos de prueba relevantes
- Un informe de prueba detallado con el contenido mínimo necesario especificado
- Deben abordarse los requisitos de gestión de riesgos enumerados
- El etiquetado del dispositivo debe ser conforme a los requisitos establecidos en la Cláusula 6.

Es posible que algunos laboratorios de prueba puedan ser reacios a asumir la responsabilidad de revisar los requisitos de gestión de riesgos y etiquetado del dispositivo. Es responsabilidad del fabricante el asegurarse de que se abordan todos los puntos arriba mencionados.

Tras la publicación, se han descubierto algunos errores y ambigüedades:

- Existe discrepancia en las notas de pie de página en las Tablas 1 y 5. Debe utilizarse la nota a pie de página de la Tabla 1.
- Es posible malinterpretar el contenido de la Tabla 9, interpretando que la prueba se debe realizar a una distancia de 0,3 m. La distancia de prueba aplicable es la especificada en IEC 61000-4-3.
- La FDA no acepta la asignación indicada en la Nota B de la Tabla 8 con respecto a la longitud del cable.

FECHAS PARA EL CUMPLIMIENTO

Las fechas de cumplimiento para la 4ª edición, así como de muchas otras normativas, pueden ser un problema de difícil solución. Las fechas dependen del tipo de dispositivo, de la región en la que se vende y también pueden verse afectadas por otras normativas y regulaciones de nivel superior. La Tabla 6 resume las fechas de cumplimiento obligatorias en base a la región.

Tabla 6 - Fechas de cumplimiento para IEC 60601-1-2:2014 (4ª edición) por región

Estados Unidos	Unión Europea	Otras regiones
Dispositivos anteriores: Nunca[4] Nuevas presentaciones: 1 de enero de 2019	Todos los dispositivos: 1 de enero de 2019 (de conformidad con EN 60601-1-2: 2015)	Varía en lo siguiente: • Regulaciones nacionales[5] • Normativas IEC 80601-2-X[6]

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Hand-held instruments and monitoring systems

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European Directive
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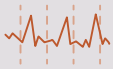
Broadband



LF Spectrum
analysis (FFT)

Weighted
Peak Exposure

EMC & RF

Test systems, equipment and components

RadiField Triple A
Revoluciona la inmunidad radiada con un nivel de integración único.

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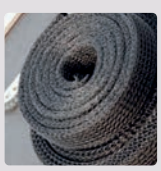
Amplificadores de potencia

Antenas de ensayo

Sondas de campo

Seguridad eléctrica



Apantalla-miento

Inductancias Ferritas, etc.

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RESUMEN

Este artículo ofrece una comparación entre las ediciones 3ª y 4ª de IEC 60601-1-2. Como se muestra en las tablas anteriores, los niveles de prueba son diferentes y en muchos casos (aunque no siempre) más estrictos. La 4ª edición establece el requisito de que se mantengan la seguridad básica y el rendimiento esencial del dispositivo médico en presencia de los diferentes entornos electromagnéticos establecidos en la norma. Las susceptibilidades no relacionadas con la Seguridad básica y el Rendimiento esencial no se considerarán por lo general como un fallo de la prueba. Además, la 4ª edición requiere que se tengan en cuenta varios aspectos con respecto a la gestión de riesgos.

Las dos normativas son diferentes en lo que respecta básicamente a los niveles de prueba y los criterios de aceptación como apta/no apta de la inmunidad, los modos de funcionamiento y otros aspectos. Teniendo en cuenta lo anteriormente mencionado, sería incorrecto declarar que el cumplimiento con la 4ª edición sería correspondiente al cumplimiento con la tercera edición.

REFERENCES

[1] Se utiliza una modulación de 1 kHz para dispositivos médicos que no controlan, vigilan o miden un parámetro fisiológico.

[2] Si bien la condición de error único se menciona de forma oficial en esta definición, muchos usuarios de IEC 60601-1-2 podrían considerar el cumplimiento durante una condición de error único impráctico o imposible de conseguir, y por lo tanto suele ser ignorada.

[3] Consulte el IEC 60601-1 para ver la definición de uso normal y previsto.

[4] Conforme al esquema (publicado) de equivalencia sustancial de la FDA

[5] Algunos países no aceptan en la actualidad la 4ª edición

[6] Las normativas concretas (IEC 60601/80601-2-X) están en proceso de conversión para ser mencionadas como referencias con fecha en el ICE 60601-1-2:2014. Hasta que se haya finalizado la conversión, parte de las normativas harán referencia a IEC 60601-1-2:2014, otras partes a IEC 60601-1-2:2007 y otras utilizan una referencia a IEC 60601-1-2 sin especificar la fecha.

DIRECTIVA SOBRE EQUIPOS RADIOELÉCTRICOS (RED), 2014/53/EU

Por Charlie Blackman
Asesor Principal y Director de Sulis Consultants Ltd.

Nota del editor: *Debe utilizarse la Directiva sobre equipos radioeléctricos (RED), 2014/53/EU, para productos fabricados después del 13 de junio de 2016, y será obligatoria para todos los productos a partir del 13 de junio de 2017.*

RESUMEN

Este artículo presenta una actualización sobre los cambios que se han producido como resultado de la nueva Directiva sobre equipos radioeléctricos (RED) 2014/53/EU, que se podrá utilizar a partir de junio del presente año. Examina los cambios en el producto y el entorno normativo, así como su significado para los fabricantes de equipos.

Podrá encontrar más información sobre la historia de la Directiva RED en el artículo Directiva sobre los equipos radioléctricos, en la Guía "Interference Technology 2015 EMC Directory and Design Guide."

ÁMBITO DE APLICACIÓN DE LA DIRECTIVA

Se ha ampliado el ámbito de aplicación de la Directiva RED para incluir:

- Equipos de «radiodeterminación», como radares y dispositivos RFID. Estos dispositivos se consideraban como pertenecientes al ámbito de aplicación de la Directiva RTTE, pero el ámbito de aplicación de la Directiva RED es mucho más claro, estableciendo claramente que se incluyen bajo dicha directiva y que, por lo tanto, deben ser conformes a la misma.
- "Receptores de transmisiones de sonido y televisión", estos estaban fuera del ámbito de la RTTE, de modo que ahora existen requisitos adicionales para el rendimiento del espectro radioeléctrico.
- "Rendimiento del receptor": si bien estaba cubierto en varias normativas de productos ETSI, su importancia en un espectro radioeléctro cada vez más congestionado ha dado como resultado su inclusión en la mencionada Directiva.
- "Dispositivos operando por debajo de 9 kHz": el límite de frecuencia inferior de la Normativa RTTE era de 9 kHz, pero se ha eliminado dicho límite.
- En línea con otras normativas, existe una exclusión específica para "Kits de evaluación personalizados diseñados para profesionales, con el único objetivo de ser utilizados con fines de investigación y en instalaciones de desarrollo habilitadas para dichos fines."

PLAZOS Y PERÍODOS DE TRANSICIÓN

La Comisión Europea ha confirmado la existencia de cuatro escenarios con respecto a la aplicación de las Directivas 2014/53/EU, 2014/35/EU y 2014/30/EU [i]

Tipo de producto	Requisitos y fechas de cumplimiento
Productos incluidos en la actualidad dentro del ámbito de EMC y LVD, y no incluidos en el ámbito de aplicación de RTTE o RED	• Productos comercializados con anterioridad al 20 de abril de 2016: LVD/EMCD anteriores • Productos comercializados en o tras el 20 de abril de 2016: LVD/EMCD nuevas
Productos incluidos en la actualidad dentro del ámbito de RTTE y que siguen estando dentro del ámbito de la RED	• Productos comercializados antes del 13 de junio de 2016: RTTED • Productos comercializados entre el 13 de junio de 2016 y el 12 de junio de 2017: RTTED o RED • Productos comercializados después del 12 de junio de 2017: RED
Productos que en la actualidad están fuera del ámbito de aplicación de RTTE pero dentro del ámbito de RED	• Productos comercializados con anterioridad al 20 de abril de 2016: LVD/EMCD anteriores • Productos comercializados entre el 20 de abril de 2016 y el 12 de junio de 2016: LVD/EMCD nuevas • Productos comercializados entre el 13 de junio de 2016 y el 12 de junio de 2017: RED o LVD/EMCD nuevas • Productos comercializados después del 12 de junio de 2017: RED
Productos que en la actualidad están dentro del ámbito de aplicación de la RTTE pero que están excluidos del ámbito de aplicación de la RED	• Productos comercializados antes del 13 de junio de 2016: RTTED • Productos comercializados después del 12 de junio de 2016: RED no es aplicable; LVD/EMCD nuevas, si es aplicable al producto en cuestión

Se ha observado que seguir estas fechas podría dar lugar a una gran carga administrativa para los fabricantes a la hora de actualizar la documentación y las Declaraciones de Conformidad, en concreto para dispositivos que estuviesen fuera del alcance de la directiva RTTE y dentro de EMC y LVD, debido a que no se podrían aprovechar del período de transición determinado en la Directiva RED.

Las directrices sobre las declaraciones de conformidad especifican el contenido mínimo, pero no especifican de modo general el contenido máximo y por lo general se acepta la inclusión de información adicional de utilidad. A este respecto, en la actualidad

se están debatiendo dos propuestas en la comisión para permitir a los fabricantes que incluyan ambas directivas (actual y nueva) en sus declaraciones de conformidad, por ejemplo:

"El objeto de la declaración descrita anteriormente es conforme a la legislación comunitaria de armonización correspondiente: Directiva 1999/5/EC (hasta el 12 de junio de 2016), Directiva 2014/30/EU (a partir del 13 de junio de 2016) y Directiva 2014/35/EU (a partir del 13 de junio de 2016)."

Tenga en cuenta que en el momento de publicación del presente documento esta propuesta **no se había aceptado formalmente**. Se espera que se acepte a principios de marzo y que se publique en la sección de documentos de la UE ii. Le proporcionaremos una actualización en cuanto la tengamos.

Puntos clave para los fabricantes bajo el ámbito de aplicación de la Directiva RED:

- El Marcado CE debe aparecer tanto en el dispositivo como en el embalaje: la directiva RED ya no exige la inclusión de la marca CE en el manual del usuario
- El número del organismo notificado solamente se indicará en el producto cuando se haya realizado un Aseguramiento total de calidad (RTTE anexo V y RED anexo IV) y no se utilizará en los casos en los que el organismo haya revisado solamente el archivo técnico.
- La lista de países permitidos debe estar incluida en el embalaje y en el manual del usuario, pero ya no será necesario incluir la marca de alerta para los equipos de la Clase 2, y ya no serán necesarias las notificaciones específicas del país.
- El manual del usuario debe incluir las bandas de frecuencia de funcionamiento y la potencia de transmisión máxima de cada una de esas bandas, y dicha información debe estar redactada en un lenguaje que pueda ser fácilmente comprensible para el usuario final.
- Cualquier producto que contenga una pieza de «equipo de radio» según la definición del Artículo 2 de la Directiva RED recaerá bajo el ámbito de aplicación de dicha Directiva RED, de modo que una lavadora con radio Zigbee estará incluida en el ámbito de RED y no de EMC y LVD.

DESARROLLOS DE NUEVAS NORMATIVAS PARA LA DIRECTIVA RED

Compatibilidad Electromagnética (EMC)

Los equipos radioeléctricos no admiten la aplicación de la Directiva EMC tal y como lo permitía la RTTE, de modo que todos los productos que contienen equipos radioeléctricos deben ser evaluados teniendo en cuenta la Directiva sobre equipos radioeléctricos.

- EL ETSI está desarrollando la guía EG 203 367 iii, «Electromagnetic compatibility and Radio spectrum Matters (ERM); Guide to the application of harmonized standards covering Articles 3.1b and 3.2 of the Directive 2014/53/EU (RE-D) to multi-radio and combined radio and non-radio equipment» que proporciona orientación sobre la aplicación de las normativas armonizadas para los equipos combinados y de múltiples sistemas de radio. El documento está todavía en proceso de desarrollo.
    - Como ejemplos de equipos que quedan cubiertos por dicho documento se incluyen, entre otros, la combinación de múltiples productos de radio en un equipo radioeléctrico, la combinación de radio y TI o equipos electrotécnicos, electrodomésticos habilitados para RLAN, sistemas de calefacción controlados por radio, sistemas de iluminación controlados por radio, etc.

Espectro radioeléctrico

- EL ETSI está actualizando el artículo 156 3.2 sobre los estándares del espectro de radio para RED. 34 de ellos se publicarán en el Diario Oficial durante el presente año y el resto en la primera mitad de 2017.
- Tras una revisión de la compatibilidad entre el LTE funcionando en la banda Mhz 800 y los dispositivos UHF de corto alcance, el ETSI ha comenzado a trabajar en la restructuración de EN 300 220. Se han adaptado los siguientes elementos de trabajo:
    - EN 300 220-2: Normativa armonizada para equipos radioeléctricos no específicos. Se están desarrollando dos versiones: una versión 3.1.1 con receptores de «categoría 3», que se reemplazará con la versión 3.2.1, con receptores mejorados de la «categoría 2» en diciembre de 2018.
    - EN 300 220-3-1: Equipo de Alarmas sociales operando en la banda de frecuencia designada (869,2 - 869,25 MHz)
    - EN 300 220-3-2: Equipo de Alarmas inalámbricas operando en las bandas de frecuencia designadas
    - EN 300 220-4: Equipos radioeléctricos de medición operando en las bandas de frecuencia designadas (169,4 - 169,4875 MHz)
-
- El ETSI ha publicado ya normativas en borrador para los receptores de emisiones y TV que pasan a RED debido al ámbito de aplicación de esta normativa:
    - Borrador ETSI EN 303 340 V1.1.0v, Digital Terrestrial TV Broadcast Receivers; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU
    - Borrador ETSI EN 303 345 V1.1.0vi, Radio Broadcast Receivers; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU

Períodos de transición

Tal y como lo establece la práctica habitual, habrá un período de transición durante el cual se pueden seguir utilizando las directrices existentes, no obstante, los fabricantes deben estar pendientes del programa de trabajo del ETSI iv para estar al tanto con las normativas en cuanto se publican.

QUIENES SOMOS

Sulis Consultants es una asesoría independiente sobre Marcado CE y Aprobaciones de producto con sede en Hampshire, Inglaterra, y estamos especializados en ayudar a los fabricantes a satisfacer los requisitos de las Directivas RTTE, EMC, LV y RoHS, así como con las certificaciones de radio para América del Norte.

Charlie Blackham es Doctor en ingeniería, y trabaja en el campo de aprobación de productos y Marcado CE desde hace más de 20

años. Tras haber trabajado para varios fabricantes como Gerente de aprobaciones, Charlie estableció Sulis Consultants en 2005 para ofrecer asesoramiento y asistencia a una amplia cartera de clientes. Anteriormente experto técnico de un Organismo notificado, Charlie ha ayudado a clientes a conseguir el Marcado CE en una amplia variedad de productos radioléctricos operando a frecuencias de 1MHa a 78 Ghz. Información de contacto: charlie@sulisconsultants.com o a través de www.sulisconsultants.com

REFERENCE LINKS

i http://ec.europa.eu/DocsRoom/documents/11983/attachments/1/translations/en/renditions/pdf

ii http://ec.europa.eu/DocsRoom/?locale=en

iii https://portal.etsi.org/webapp/WorkProgram/Report_WorkItem.asp?WKI_ID=47231

iv http://webapp.etsi.org/ena/cvp.asp?search=RADIO

v https://www.etsi.org/deliver/etsi_en/303300_303399/303340/01.01.00_20/en_303340v010100a.pdf

vi https://www.etsi.org/deliver/etsi_en/303300_303399/303345/01.01.00_20/en_303345v010100a.pdf

PRODUCTOS Y SERVICIOS

A

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www.AHSystems.com
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AFJ INSTRUMENTS SRL
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Raimon Gómez, raimon-gomez@wavecontrol.com
Productos y servicios: Receptores EMI, LISN, Analizadores de click, accesorios para CISPR 14 y 15, sondas de tensión, limitadores de pulsos, pinzas de absorción, etc.

APPLUS
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Spantech Microwave Technology S.A.
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Jordi Ferri, Shielding Division Manager
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Productos y servicios: Aislamiento

B

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C

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D

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Productos y servicios: Habitaciones y recintos aislados

E

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ESPAÑA

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Productos y servicios: generadores impulsionales, ensayos de inmunidad conducida, ESD (descargas electrostáticas), transitorios, ondas oscilatorias, ensayos de rayos para aplicaciones aeronáuticas y militares, ensayos de componentes

ETS Lindgren
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www.wavecontrol.es
Productos y servicios: Cámaras de Faraday y Anecoicas, antenas EMC, sondas de campo, instrumentación EMC.

F

Fair-Rite Products Corp.
Redislogar, Anabel Segura, 11 Centro de Negocios Albatros, Edificio B 28108 - Alcobendas Madrid, España;
+34 902 509 980; Fax: +34 916 591 436
redislogar@redislogar.es; www.fair-rite.com
Productos y servicios: Artículos con ferrita, Filtros, Habitaciones y recintos aislados, Aislamiento

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systems.protection@federalmogul.com
www.federalmogul.com/sp
Productos y servicios: Conjuntos de cables apantallados y blindados Arneses, Conductos, tuberías blindado

G

GCEM
UPC Campus Nord. Building C4,
c/ Jordi Girona 1-3., 08034, Barcelona, España
+34 934 011 021
info.gcem@upc.edu; www.upc.edu/web/gcem
Productos y servicios: Pruebas

Gowanda Electronics
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Productos y servicios: Inductores

I

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www.ite.es
Productos y servicios: Pruebas

K

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L

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www.labein.es
Productos y servicios: Pruebas

LACECAL
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emc@lacecal.es; www.lacecal.es
Productos y servicios: Pruebas

Langer EMV-Technik GmbH
Pallars, 65-71 E-08018 Barcelona, España
+34 933 208 055; Fax: +34 933 208 056
Raimon Gómez; raimon-gomez@wavecontrol.com;
Productos y servicios: sondas de campo cercano

LCOE
Laboratorio Central Oficial de Electrotecnia,
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+34 915 625 116; Fax: +34 915 618 818
www.ffii.es/lcoe/lcoe_portada.asp

Productos y servicios: Pruebas

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info@lifasa.com; www.lifasa.com
Productos y servicios: Filtros

M

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P

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R

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rses@rohde-schwarz.com; www.rohde-schwarz.es
Web Store: www.rohde-schwarz.es/surf-in
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S

Schlegel Electronic Materials
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Trespaderne, Edificio Barajas 1,
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salicru@salicru.com; www.salicru.com
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T

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+34 918 041 893
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TESEQ
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millan@adler-instrumentos.es
www.teseq.com
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W

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Y

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raimon-gomez@wavecontrol.com;
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Fax: +34 91 8041664; www.alter-spain.com

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INSTITUTO NACIONAL DE TECNICA AEROESPACIAL
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+34 91 5201396; Fax: +34 91 5202021
dejuancr@inta.es

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Calle José Gutíerrez Abascal, 2, 28006 Madrid, España;
+34 91 5625116; Fax: +34 91 5618818
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icem@itaca.upv.es; www.itaca.upv.es

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POLSKA

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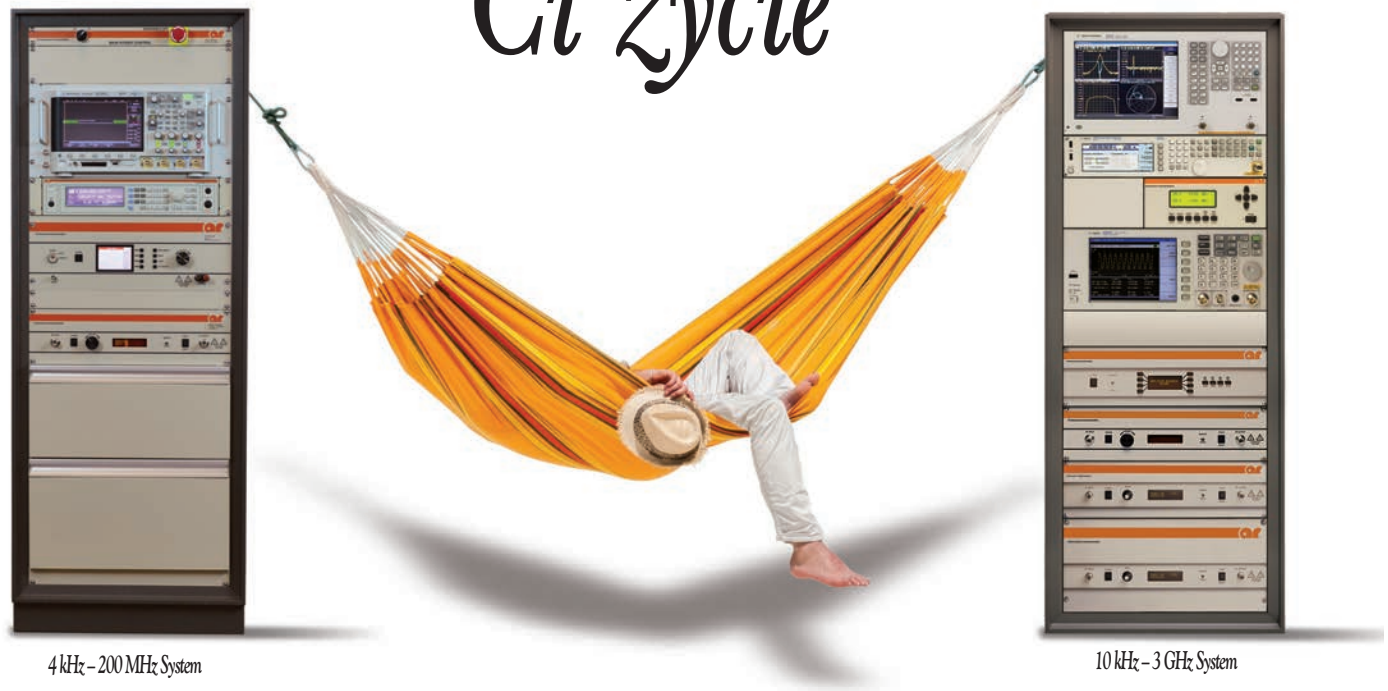

4 kHz – 200 MHz System

10 kHz – 3 GHz System

Systemy do testów odporności przewodzonej RF wg. standartów wojskowych, IEC i samochodowych

Jeśli jesteś zmęczony dopasowywaniem różnych komponentów, spróbuj użyć kompletną linię systemów AR do testów odporności przewodzonej RF. Oferujemy pięć w pełni skonfigurowanych, samodzielnych stanowisk do badań metodą CI od 4kHz do 3 GHz z mocą wyjściową zgodną z najnowszymi standardami komercyjnymi i wojskowymi oraz dopasowaną do życzeń klienta.

Każdy system CI posiada zainstalowane oprogramowanie umożliwiające indywidualne dostosowanie do potrzeb klienta wraz z predefiniowanymi standardami odporności przewodzonej, przyjazne użytkownikowi z możliwością generowania raportów bezpośrednio do Microsoft® Word lub Excel.

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PRZEGLĄD NORMY IEC 60601-1-2: 2014
(WYDANIE 4)

Darryl P. Ray
Darryl Ray EMC Consulting, LLC

Wprowadzenie
Norma IEC 60601-1-2:2014 Wydanie 4. została opublikowania w lutym 2014 r. i zastępuje normę IEC 60601-1-2 Wydanie 3. opublikowaną w 2007 r. Dotyczy kompatybilności elektromagnetycznej medycznych urządzeń elektrycznych i medycznych systemów elektrycznych. Wersja opublikowana w Europie (EN60601-1-2:2015) jest identyczna ze swoim odpowiednikiem IEC z wyjątkiem odniesień do wersji EN norm serii 61000-4-x i załącznika „Zasadnicze wymagania".

Motywem Wydania 4. było stworzenie normy bezpieczeństwa dotyczącej zaburzeń elektromagnetycznych w celu dostosowania do wymogów ogólnych normy IEC 60601-1 Wydanie 3. Poprzednia wersja normy IEC 60601-1-2 nie omawiała w wystarczającym stopniu aspektów bezpieczeństwa związanych z zakłóceniami elektromagnetycznymi. Poza tym między wydaniami 3. i 4. występują znaczne różnice w odniesieniu do odporności.

WPROWADZENIE NA ŚWIECIE

Norma IEC 60601-1-2 wyd. 4:2014 została opublikowana w lutym 2014 r. Obecnie agencja FDA uznaje Wydanie 4., a obowiązkowa data dostosowania dla nowych zgłoszeń to 31 grudnia 2018 r. Zdecydowano, że z tą datą nastąpi zharmonizowanie z wymogami Unii Europejskiej (EN 60601-1-2:2015). Chociaż do 2018 r. nie jest to wymagane, agencja FDA uznaje obecnie Wydanie 4. i preferuje, by w odniesieniu do nowych zgłoszeń, szczególnie dotyczących urządzeń używanych w domowej opiece medycznej, produkty były badane zgodnie z tą normą.

Agencja FDA nie wymaga zachowania zgodności z Wydaniem 4. normy w przypadku urządzeń dawnego typu, o ile nie zostały w nich wprowadzone istotne zmiany.

Opublikowana w Unii Europejskiej data wycofania (DoW) normy EN 60601-1-2:2007 to 31 grudnia 2018 r. Z tego powodu wszystkie urządzenia wyprodukowane i importowane do UE po tej dacie muszą spełniać wymogi Wydania 4. normy. Nie ma żadnych ulg dla urządzeń dawnego typu, jak dopuszczone przez agencję FDA.

Jeśli chodzi o inne regiony, wymagania w poszczególnych krajach są różne. Przynajmniej jeden główny rynek nie przyjmuje obecnie Wydania 4. normy. Dodatkowe informacje – patrz Tabela 6.

PODSUMOWANIE ZMIAN WPROWADZONYCH W WYDANIU 4. W STOSUNKU DO WYDANIA 3

W Wydaniu 4. wprowadzono następujące istotne zmiany.

- Wyeliminowano obecną w Wydaniu 3. klasyfikację na urządzenia podtrzymujące życie i niepodtrzymujące życia. Zastąpiono ją trzema kategoriami odporności odnoszącymi się do zamierzonego zastosowania: profesjonalna opieka medyczna, domowa opieka medyczna i środowisko specjalne
- Zmodyfikowane graniczne wartości emisji i odporności; patrz tabele 1–4 poniżej.
- Kryteria dopuszczenia/niedopuszczenia odporności ograniczone są do utrzymania zasadniczego działania i podstawowego bezpieczeństwa.
- Zacisk przewodnika wyrównania potencjałów musi być podczas badania podłączony do uziemienia lokalnego. W Wydaniu 3. nie ma wzmianki o zacisku przewodnika wyrównania potencjałów.
- Objaśniono użycie sztucznej dłoni.
- Zmodyfikowano metodologię wykonywania prób wyładowań elektrostatycznych (ESD) na złączach.
- Należy uwzględnić tryb gotowości zarówno podczas prób emisji, jak i odporności.
- Dodano nową procedurę ustalania, czy urządzenie jest uszkodzone, podczas badania odporności.
- Urządzenia niemedyczne używane jako część medycznego systemu elektrycznego muszą spełniać odpowiednie wymogi kompatybilności elektromagnetycznej. System musi zachowywać zasadnicze działanie i podstawowe bezpieczeństwo
- Ujednolicono wymogi dotyczące napięcia wejściowego i częstotliwości prądu przemiennego. Z wyjątkiem badania zapadu i zakłóceń napięcia dopuszczalne jest przeprowadzanie próby przy jednej wartości napięcia i częstotliwości, mieszczących się w zakresie znamionowym urządzenia
- Objaśniono niestosowanie badania portów sygnału wejściowego/wyjściowego w procedurze patentowej
- Wyeliminowano dopuszczenie wrażliwości na oddziaływanie fal radiowych podczas badania odporności na zakłócenia wypromieniowane.

- Zmodyfikowano i częściowo uproszczono wymogi dotyczące oznakowania. Wyeliminowano tabele deklaracji zgodności elektromagnetycznej wymienione w Wydaniu 3.
- Wymagany jest plan badania kompatybilności elektromagnetycznej; istnieją wymogi co do zawartych w nim informacji
- Skrócono minimalny czas oddziaływania podczas badania odporności.
- Wymagany jest raport z badania kompatybilności elektromagnetycznej; zdefiniowano minimalne informacje, jakie muszą być w nim zawarte.
- Zarządzanie ryzykiem — wymagane jest uwzględnienie licznych kwestii związanych z kompatybilnością elektromagnetyczną
- Odnośniki do wszystkich norm są datowane (w Wydaniu 3. stosowano odnośniki niedatowane)
- Treść ostrzeżenia, które należy umieścić w instrukcji urządzeń klasy A, jest inna niż w CISPR 11
- Urządzenia używane w samolotach powinny spełniać wymogi odporności podane w RTCA DO-160.
- Wyeliminowano konieczność stosowania symbolu ostrzegawczego o wyładowaniach elektrostatycznych (ESD) w pobliżu wrażliwych złączy.

WYMAGANIA DOTYCZĄCE EMISJI

W większości przypadków normy emisji podane w Wydaniu 4. są takie same, jak w Wydaniu 3. W Wydaniu 4. pojawiły się różnorodne objaśnienia. Podano je w tabeli 1 poniżej.

Tabela 1 – Porównanie wymagań dotyczących emisji

Wymaganie	IEC 60601-1-2: 2007 (Wydanie 3)	IEC 60601-1-2: 2014 (Wydanie 4)	Uwagi
Emisja przewodzona	CISPR 11	CISPR 11	
Emisje promieniowane	CISPR 11	CISPR 11	
Zniekształcenie harmoniczne	IEC 61000-3-2	IEC 61000-3-2	Stosuje się ograniczenia dla klasy A
Wahania napięcia/ migotanie	IEC 61000-3-3	IEC 61000-3-3	
Urządzenia z prostymi komponentami	Może być wymagane zachowanie zgodności z CISPR 14	Nie dotyczy	
Sprzęt oświetleniowy	CISPR 15	Nie dotyczy	
Urządzenia rentgenowskie	Nie dotyczy	CISPR 11	Relaksacja 20 dB ma zastosowanie do emisji quasi-szczytowych
Urządzenia ITE	Muszą spełniać wymogi CISPR 22	Muszą spełniać wymogi CISPR 35	
Urządzenia z podsystemami radiowymi	Zamierzone zwolnienie z wymogów dotyczących emisji	Zamierzone zwolnienie z wymogów dotyczących emisji	
Przewody pacjenta – Emisja przewodzona	Nie dotyczy	Prąd wspólny ograniczony do 24 dBµA (1-30 MHz)	Wymóg informacyjny
Urządzenia z silnikami lub obwodami przełączania	Nie dotyczy	CISPR 14-1	

WYMAGANIA DOTYCZĄCE ODPORNOŚCI

W Wydaniu 4. pojawiły się znaczące zmiany poziomów emisji. Wymieniono je w tabelach 2–4. Poziomy bazują na „możliwych do przewidzenia wartościach maksymalnych".

Tabela 2 – Porównanie poziomów odporności – zjawisko przelotne

Zjawisko	IEC 60601-1-2: 2007 (Wydanie 3)	IEC 60601-1-2: 2014 (Wydanie 4)	
		Profesjonalna opieka medyczna Otoczenie	Domowa opieka medyczna Otoczenie
Wyładowania elektrostatyczne (ESD) (badanie według normy IEC 61000-4-2)	Wyładowanie w powietrzu 8 kV (maks.) Wyładowanie kontaktowe 6 kV	Wyładowanie w powietrzu **15 kV** (maks.) Wyładowanie kontaktowe **8 kV**	
Szybkie elektryczne zakłócenia impulsowe (badanie według normy IEC 61000-4-4)	2 kV – sieć zasilająca prądem przemiennym 1 kV – porty wejścia/ wyjścia Częstotliwość powtarzania impulsów 5 kHz lub 100 kHz	2 kV – sieć zasilająca prądem przemiennym 1 kV – porty wejścia/ wyjścia **Częstotliwość powtarzania impulsów 100 kHz**	
Udary – sieć zasilająca prądem przemiennym (badanie według normy IEC 61000-4-5)	2 kV (maks.) Kąty fazowe 0, 90, 270 stopni	2 kV (maks.) Kąty fazowe 0, 90, **180** i 270 stopni	
Udary – zasilanie 12 V DC (badanie według normy ISO 7637-2)	Nie dotyczy	**600 V**	
Badania zapadu i zakłóceń napięcia (badanie według normy IEC 61000-4-11)	• UT < 5%, 0,5 okresu • UT = 40%, 5 okresów • UT = 70%, 25 okresów • UT < 5%, 5 sekund	• **UT = 0%, 0,5 cyklu (0, 45, 90, 135, 180, 225, 270 i 315°)** • **UT = 0%; 1 cykl UT = 70%; 25/30 cyklów (kąt 0 stopni)** • **UT = 0%; 250/300 cyklów**	

Pogrubioną czcionką oznaczono zmiany w stosunku do Wydania 3

Tabela 3 – Porównanie poziomów odporności – zjawisko stałe

Zjawisko	IEC 60601-1-2:2007 (Wydanie 3)	IEC 60601-1-2: 2014 (Wydanie 4)	
		Profesjonalna opieka medyczna Otoczenie	Domowa opieka medyczna Otoczenie
Odporność na zakłócenia przewodzone (badanie według normy IEC 61000-4-6)	3 V (0,15–80 MHz) Zakresy ISM 10 V – Urządzenia podtrzymujące życie	3 V (0,15–80 MHz) **6 V (zakresy ISM)**	3 V (0,15–80 MHz) **6 V (zakresy ISM i amatorskie)**
Odporność na zakłócenia magnetyczne (badanie według normy IEC 61000-4-8)	3 A/m 50 i 60 Hz	**30 A/m** 50 **lub** 60 Hz	

Pogrubioną czcionką oznaczono zmiany w stosunku do Wydania 3

KRYTERIA DOPUSZCZALNOŚCI ODPORNOŚCI

Podstawą wymogów dopuszczenia/niedopuszczenia określonych w Wydaniu 4. jest utrzymanie podstawowego bezpieczeństwa i zasadniczego działania urządzenia medycznego. Definicje tych koncepcji przedstawiono poniżej.

Podstawowe bezpieczeństwo – zgodnie z definicją przedstawioną w normie IEC 60601-1:2012, wydanie 3.1:

PODSTAWOWE BEZPIECZEŃSTWO
wolność od niedopuszczalnego ryzyka spowodowanego bezpośrednio przez zagrożenia fizyczne, kiedy urządzenia medyczne są używane w warunkach normalnych i w warunkach pojedynczej awarii2

ZASADNICZE DZIAŁANIE
Działanie konieczne do uzyskania wolności od stanowiącego niedopuszczalne ryzyko działania funkcji klinicznej, innej niż związana z podstawowym bezpieczeństwem, przy którym utrata lub degradacja działania przekraczająca wartości graniczne określone przez producenta powoduje niedopuszczalne ryzyko.

UWAGA — Zasadnicze działanie jest zwykle rozumiane jako rozważenie, czy jego nieobecność bądź degradacja spowodowałyby niedopuszczalne ryzyko.

Zrozumienie i stosowanie poniższych koncepcji do urządzenia medycznego, które ma być poddane badaniu, jest dla producenta kwestią o znaczeniu krytycznym. W wielu przypadkach urządzenie może być wrażliwe na zaburzenia elektromagnetyczne, jednak jeżeli utrzymane będą podstawowe bezpieczeństwo i zasadnicze działanie, urządzenie to może zostać uznane za zgodne z wymogami Wydania 4.

Tabela 4 – Porównanie poziomów odporności – zjawisko stałe w polu elektrycznym

Zjawisko	IEC 60601-1-2:2007 (Wydanie 3)	IEC 60601-1-2: 2014 (Wydanie 4)	
		Profesjonalna opieka medyczna Otoczenie	Domowa opieka medyczna Otoczenie
Odporność na zakłócenia promieniowane (badanie według normy IEC 61000-4-3)	3 V/m – niepodtrzymujące życia 10 V/m – podtrzymujące życie 80 MHz – 2,5 GHz 80% przy 2 Hz (lub 1 kHz1) Modulacja amplitudy	**3 V/m** 80 MHz – **2,7 GHz** 80% przy **1 kHz** Modulacja amplitudy	**10 V/m** 80 MHz – **2,7 GHz** 80% przy **1 kHz** Modulacja amplitudy
Pole bliskości nadajników bezprzewodowych (badanie według normy IEC 61000-4-3)	Nie dotyczy	9 V/m–28 V/m 15 konkretnych częstotliwości	

Pogrubioną czcionką oznaczono zmiany w stosunku do Wydania 3

BADANIE ZŁĄCZY POD KĄTEM WYŁADOWAŃ ELEKTROSTATYCZNYCH (ESD)

Wymogi Wydania 3. stanowią, by wyładowania kontaktowe były wykonywane na pojedynczych wtykach złącza dostępnych według wytycznych IEC 60601-1. Nie ma ustalonej procedury przeprowadzania tego badania. W Wydaniu 4. poprawiono tę procedurę; informacje podano w tabeli 5 poniżej:

Tabla 5 - Requisitos para la realización de la prueba ESD en conectores

Osłona złącza	Wymagania dotyczące wyładowań	Wykorzystanie portów
Przewodzące	Wyładowanie kontaktowe tylko do osłony złącza	Zamierzone i normalne zastosowanie[3]
Izolowane	Wyładowanie w powietrzu do osłony oraz Wyładowanie w powietrzu do wtyków (jeżeli dostępne dla palca probierczego IEC)	Zamierzone zastosowanie

ZARZĄDZANIE RYZYKIEM

Koncepcja zarządzania ryzykiem w odniesieniu do kompatybilności elektromagnetycznej jest nowa. W Wydaniu 4. wymaga się uwzględnienia następujących kwestii dotyczących zarządzania ryzykiem. Kwestie te należy uwzględnić i udokumentować w raporcie z badań kompatybilności elektromagnetycznej oraz w dokumencie dotyczącym zarządzania ryzykiem.

- Należy rozważyć kwestię minimalnego odstępu od przenośnych urządzeń komunikacyjnych.
- Należy uwzględnić zapisy załącznika F, Zarządzanie ryzykiem w celu zapewnienia podstawowego bezpieczeństwa i zasadniczego działania.
- Tryby pracy użyte do badań powinny bazować na analizie ryzyka.
- Badanie urządzeń niemedycznych (np. zakłócenia należy uwzględnić w procesie zarządzania ryzykiem)
- Należy zająć się skutkami reakcji badanych urządzeń zaobserwowanymi podczas prób odporności
- Do ustalenia, czy dozwolone jest badanie podsystemów, powinien być wykorzystany proces zarządzania ryzykiem.
- Należy uzasadnić obniżenie poziomów próby, jeżeli jest stosowane.
- Należy udokumentować powody złagodzenia wymogów uzasadniające zastosowanie niższych poziomów próby odporności.
- Można zastosować alternatywne częstotliwości modulacji.
- Należy uwzględnić obecne usługi komunikacji.
- W badaniu należy uwzględnić wyższe poziomy odporności magnetycznej, jeżeli urządzenie znajduje się w odległości mniejszej niż 15 cm od źródła oddziaływania magnetycznego o częstotliwości sieciowej.

Zadeklarowanie zgodności z wymogami Wydania 4. wymaga podjęcia pięciu działań:

- Przed badaniem należy stworzyć plan badania.
- Zgodność z odpowiednimi wymogami badań.
- Szczegółowy raport z badań zawierający wymagany minimalny zakres informacji.
- Należy uwzględnić wymienione wymogi dotyczące zarządzania ryzykiem.
- Oznakowanie urządzenia musi być zgodne z wymogami przedstawionymi w klauzuli 6.

Wiele laboratoriów probierczych może niechętnie brać na siebie odpowiedzialność za przegląd wymogów dotyczących zarządzania ryzykiem i oznakowania urządzenia. Producent jest odpowiedzialny za uwzględnienie wszystkich wymienionych powyżej kwestii.

Od czasu publikacji ujawniono kilka błędów i wieloznaczności:

- Istnieje rozbieżność w treści przypisów tabeli 1 i 5. Należy stosować przypis c tabeli 1.
- Informacje podane w tabeli 9 są czasami błędnie rozumiane jako wymóg przeprowadzenia badania w odległości probierczej 0,3 m. Zastosowanie ma odległość probiercza określona w normie IEC 61000-4-3.
- Agencja FDA nie przyjmuje dopuszczenia podanego w tabeli 8, uwaga b, dotyczącego długości kabla.

DATY DOSTOSOWANIA

Daty dostosowania do wymogów Wydania 4. oraz wielu innych norm mogą być skomplikowanym problemem. Są uzależnione od rodzaju urządzenia, regionu, do którego urządzenie trafia po sprzedaży. Mogą również zależeć od innych norm i przepisów wyższego poziomu. W tabeli 6 przedstawiono podsumowanie obowiązkowych dat dostosowania według regionów.

Tabela 6 – Daty dostosowania do wymogów normy IEC 60601-1-2:2014 (Wydanie 4) według regionów

Stany Zjednoczone	Unia Europejska	Inne regiony
Urządzenia dawnego typu Nigdy4 Nowe zgłoszenia: 1 stycznia 2019 r.	Wszystkie urządzenia: 1 stycznia 2019 r. (zgodność z normą EN 60601-1-2: 2015)	Różnie: • Przepisy krajowe[5] • Normy IEC 80601-2-X[6]

PODSUMOWANIE

W niniejszym artykule przedstawiono porównanie wydań 3. i 4. normy IEC 60601-1-2. Jak pokazano w powyższych tabelach, w wielu przypadkach poziomy próby są różne i często, choć nie zawsze, zaostrzone. W Wydaniu 4. wymaga się utrzymania podstawowego bezpieczeństwa i zasadniczego działania urządzenia medycznego w różnych wymienionych w normie środowiskach elektromagnetycznych. Podatności niezwiązane z podstawowym bezpieczeństwem i zasadniczym działaniem zwykle nie zostałyby uznane za niepowodzenie próby. Poza tym w Wydaniu 4. wymaga się uwzględnienia różnych kwestii odnoszących się do zarządzania ryzykiem.

Porównywane normy znacznie się od siebie różnią w odniesieniu do poziomów próby oraz kryteriów dopuszczenia/niedopuszczenia odporności, trybów pracy i innych kwestii. Biorąc to pod uwagę, nie można stwierdzić, że zgodność z wymogami Wydania 4. jest równoznaczna ze zgodnością z wymogami Wydania 3.

REFERENCES

[1] Stosuje się modulację 1 kHz dla urządzeń medycznych, które nie kontrolują, nie monitorują, ani nie mierzą parametru fizjologicznego.

[2] Chociaż warunki pojedynczej awarii są oficjalnie wspomniane w tej definicji, wielu użytkowników normy IEC 60601-1-2 uznałoby zachowanie zgodności w warunkach pojedynczej awarii za niepraktyczne lub niemożliwe do osiągnięcia, dlatego zapis ten jest często ignorowany.

[3] Definicje zwrotów „zamierzone zastosowanie" oraz „normalne zastosowanie" – patrz norma IEC 60601-1.

[4] Zgodnie z programem zasadniczej ekwiwalencji (predykatu) agencji FDA

[5] Niektóre kraje nie uznają obecnie Wydania 4

[6] Poszczególne normy (IEC 60601/80601-2-X) są w trakcie konwertowania na odnośniki datowane zgodne z IEC 60601-1-2:2014. Do czasu zakończenia konwersji niektóre normy częściowe odnoszą się do normy IEC 60601-1-2:2014, niektóre do IEC 60601-1-2:2007, a w innych stosuje się niedatowane odnośniki do normy IEC 60601-1-2.

DYREKTYWA W SPRAWIE URZĄDZEŃ RADIOWYCH, 2014/53/WE

Opracował Charlie Blackham
Główny Konsultant i Dyrektor Sulis Consultants Ltd.

Uwaga wydawcy: *Postanowienia dyrektywy w sprawie urządzeń radiowych (RED), 2014/53/UE, muszą być stosowane w odniesieniu do nowych produktów, wytworzonych po 13 czerwca 2016 r. i będą stanowić wymogi obowiązkowe dla wszystkich produktów od 13 czerwca 2017 r.*

ABSTRAKT

Niniejszy artykuł opisuje zmiany zachodzące w wyniku wprowadzenia nowej dyrektywy w sprawie urządzeń radiowych (RED) 2014/53/UE, która może być stosowana od czerwca 2016 r. Analizowane są w nim zmiany w produkcie i krajobrazie legislacyjnym oraz ich znaczenie dla producentów urządzeń.

Więcej szczegółów dotyczących historii dyrektywy RED znaleźć można w artykule Radio Equipment Directive, w „Interference Technology 2015 EMC Directory and Design Guide".

ZAKRES DYREKTYWY

Zakres dyrektywy został rozszerzony o:

- urządzenia „radiolokacji", takie jak radary i urządzenia RFID. Urządzenia te uznawano za wchodzące w zakres dyrektywy RTTE, jednak zakres dyrektywy RED jest bardziej klarowny; wynika z niego, że urządzenia te wchodzą w zakres dyrektywy RED i muszą być zgodne z jej wymogami.
- "odbiorniki radiofoniczne i telewizyjne" – urządzenia te były wyłączone zgodnie z dyrektywą RTTE, zatem obecnie pojawią się nowe wymogi dotyczące widma radiowego.
- "działanie odbiornika" – chociaż kwestia ta była omawiana w wielu normach produktowych ETSI, jej doniosłość w coraz bardziej przeciążonym widmie radiowym sprawiła, że uwzględniono ją w dyrektywie.
- "urządzenia działające z częstotliwością poniżej 9 kHz" – niższa wartość graniczna częstotliwości 9 kHz była uwzględniona w dyrektywie RTTE; zapis ten został usunięty.
- zgodnie z innymi dyrektywami istnieje specyficzne wyłączenie dla „zestawów kontrolnych zbudowane według indywidualnego projektu, przeznaczonych dla specjalistów i wykorzystywanych wyłącznie w ośrodkach badawczo-rozwojowych do odnośnych celów".

HARMONOGRAM I OKRESY PRZEJŚCIOWE

Komisja Europejska potwierdziła, że istnieją cztery scenariusze dotyczące stosowania dyrektyw 2014/53/UE, 2014/35/UE i 2014/30/UE i

Typ produktu	Zgodność z wymaganiami i daty
Obecnie w zakresie dyrektyw EMC i LVD, a nie w zakresie dyrektyw RTTE i RED	• Produkty wprowadzone do obrotu przed 20 kwietnia 2016 r.: stara dyrektywa LVD/EMCD • Produkty wprowadzone do obrotu w dniu 20 kwietnia 2016 r. lub później: nowa dyrektywa LVD/EMCD
Obecnie w zakresie dyrektywy RTTE i pozostanie w zakresie dyrektywy RED	• Produkty wprowadzone do obrotu przed 13 czerwca 2016 r.: dyrektywa RTTED • Produkty wprowadzone do obrotu między 13 czerwca 2016 r. a 12 czerwca 2017 r.: dyrektywa RTTED lub RED • Produkty wprowadzone do obrotu po 12 czerwca 2017 r.: dyrektywa RED
Obecnie poza zakresem dyrektywy RTTE, ale w zakresie dyrektywy RED	• Produkty wprowadzone do obrotu przed 20 kwietnia 2016 r.: stara dyrektywa LVD/EMCD • Produkty wprowadzone do obrotu między 20 kwietnia 2016 r. a 12 czerwca 2016 r.: nowa dyrektywa LVD/EMCD • Produkty wprowadzone do obrotu między 13 czerwca 2016 r. a 12 czerwca 2017 r.: dyrektywa RED lub nowa dyrektywa LVD/EMCD • Produkty wprowadzone do obrotu po 12 czerwca 2017 r.: dyrektywa RED
Obecnie w zakresie dyrektywy RTTE, ale poza zakresem dyrektywy RED	• Produkty wprowadzone do obrotu przed 13 czerwca 2016 r.: dyrektywa RTTED • Produkty wprowadzone do obrotu po 12 czerwca 2016 r.: dyrektywa RED nie ma zastosowania; w przypadku omawianych produktów ma zastosowanie dyrektywa LVD/EMCD

Zauważono, że przestrzeganie podanych terminów może przyczynić się do znacznego obciążenia administracyjnego producentów w związku z aktualizacją dokumentacji i deklaracji zgodności, w szczególności w przypadku urządzeń, które wychodzą poza zakres dyrektywy RTTE, a wchodzą w zakres dyrektyw EMC i LVD, ponieważ producenci ci nie mogą skorzystać z okresu przejściowego wpisanego w dyrektywie RED.

Wytyczne dotyczące zawartości deklaracji zgodności określają minimalny zakres informacji, ale zwykle nie podają maksymalnego zakresu informacji; zwykle akceptowane są dodatkowe przydatne informacje. W związku z tym pojawiło się kilka obecnie omawianych w komisji propozycji zezwolenia producentom na podawanie w deklaracjach zgodności zarówno obecnych, jak i nowych dyrektyw. Np.

"Opisany powyżej przedmiot niniejszej deklaracji jest zgodny z odnośnymi wymaganiami unijnego prawodawstwa harmonizacyj-

nego: dyrektywą 1999/5/WE (do 12 czerwca 2016 r.), dyrektywą 2014/30/UE (od 13 czerwca 2016 r.) oraz dyrektywą 2014/35/UE (od 13 czerwca 2016 r.)."

Uwaga: w momencie publikacji propozycja ta nie była formalnie zaakceptowana. Oczekuje się, że zostanie zaakceptowana na początku marca i opublikowana w DocsRoom ii. Poinformujemy o tym fakcie, jak tylko uzyskamy stosowne informacje.

Kilka kluczowych kwestii istotnych dla producentów, których produkty wchodzą w zakres dyrektywy RED:

- Oznakowanie CE musi być umieszczane na urządzeniu i na opakowaniu — dyrektywa RED nie wymaga, by oznakowanie CE było umieszczane w podręczniku użytkownika.
- Numer jednostki notyfikowanej jest umieszczany na produkcie, kiedy produkt przechodzi pełną procedurę zapewnienia jakości (dyrektywa RTTE, załącznik V/dyrektywa RED, załącznik IV); numer ten nie jest używany, gdy jednostka notyfikowana dokonała tylko przeglądu dokumentacji technicznej.
- Lista krajów, w których urządzenie jest dopuszczone do użytku powinna nadal być umieszczana na opakowaniu i w podręczniku użytkownika, jednak nie ma wymogu umieszczania znaku ostrzeżenia dla urządzeń klasy 2; nie jest też już wymagana notyfikacja państw.
- Podręcznik użytkownika musi zawierać informacje o pasmach częstotliwości, w których działa oraz maksymalnej mocy nadawania w każdym z tych pasm; informacja ta musi być podana w języku zrozumiałym dla użytkownika końcowego.
- Każdy produkt zawierający część „urządzenia radiowego" zgodnego z definicją podaną w dyrektywie RED, artykuł 2, wchodzi w zakres dyrektywy RED. Zatem pralka wyposażona w radio Zigbee podlega dyrektywie RED, a nie dyrektywie EMC i LVD.

OPRACOWYWANIE NOWYCH NORM DLA URZĄDZEŃ PODLEGAJĄCYCH DYREKTYWIE RED

Kompatybilność elektromagnetyczna

Dyrektywa w sprawie urządzeń radiowych nie pozwala na zastosowanie zapisów dyrektywy EMC, jak postępowano w odniesieniu do urządzeń objętych dyrektywą RTTE, zatem wszystkie urządzenia wyposażone w urządzenia radiowe muszą być oceniane zgodnie z dyrektywą w sprawie urządzeń radiowych.

- Europejski Instytut Normalizacyjny do Spraw Telekomunikacji (ETSI) opracowuje przewodnik EG 203 367 iii, „Kwestie kompatybilności elektromagnetycznej i widma radiowego (ERM); przewodnik stosowania norm zharmonizowanych obejmujących artykuły 3.1b i 3.2 dyrektywy 2014/53/UE (RE-D) do urządzeń wieloradiowych i łączonych urządzeń radiowych i nieradiowych", który zapewni wytyczne na temat stosowania norm zharmonizowanych do urządzeń wieloradiowych i urządzeń łączonych. Dokument ma nadal postać projektową.

* Przykłady urządzeń objętych dokumentem to, między innymi, połączenie wielu urządzeń radiowych w jednym produkcie, połączenie radia i sprzętu komputerowego lub elektrotechnicznego, urządzenie gospodarstwa domowego z możliwością połączenia RLAN, układ ogrzewania sterowany radiowo, system oświetlenia sterowany radiowo itp.

Widmo radiowe

- Europejski Instytut Normalizacyjny do Spraw Telekomunikacji (ETSI) aktualizuje 156 norm dotyczących widma radiowego związanych z artykułem 3.2 dyrektywy RED; publikacja 34 z nich w Dzienniku Urzędowym jest zaplanowana na rok 2016, a większości pozostałych — na pierwszą połowę 2017 r.
- Po przeglądzie kompatybilności między urządzeniami LTE działającymi w paśmie 800 MHz i urządzeniami bliskiego zasięgu UHF Europejski Instytut Normalizacyjny do Spraw Telekomunikacji (ETSI) rozpoczął prace nad restrukturyzacją normy EN 300 220. Założono opracowanie następujących pozycji:

  * EN 300 220-2: Norma zharmonizowana dla niespecyficznych urządzeń radiowych. Opracowywane są dwie wersje: wersja 3.1.1 z „kategorią 3" odbiorników, która ma zostać zastąpiona wersją 3.2.1 z udoskonaloną „kategorią 2" odbiorników do grudnia 2018 r.
  * EN 300 220-3-1: Alarmy osobiste działające w wyznaczonym paśmie częstotliwości (869,2–869,25 MHz)
  * EN 300 220-3-2: Alarmy bezprzewodowe działające w wyznaczonych pasmach częstotliwości
  * EN 300 220-4: Radiowe urządzenia pomiarowe działające w wyznaczonych pasmach częstotliwości (169,4–169,4875 MHz)

- Europejski Instytut Normalizacyjny do Spraw Telekomunikacji (ETSI) opublikował już projekty norm dotyczących odbiorników radiofonicznych i telewizyjnych, które zaczynają podlegać dyrektywie RED w związku ze zmianą jej zakresu:

  * Projekt normy ETSI EN 303 340 V1.1.0v, Cyfrowe naziemne odbiorniki telewizyjne; norma zharmonizowana obejmująca najważniejsze wymagania artykułu 3.2 dyrektywy 2014/53/UE
  * Projekt normy ETSI EN 303 345 V1.1.0vi, Odbiorniki radiofoniczne; norma zharmonizowana obejmująca najważniejsze wymagania artykułu 3.2 dyrektywy 2014/53/UE

Okresy przejściowe

Zgodnie ze zwykłą praktyką obowiązywał będzie okres przejściowy, w którym będzie można stosować istniejące normy, ale producenci będą musieli śledzić postępy prac ETSIiv i zapoznawać się na bieżąco z publikowanymi normami.

O NAS

Sulis Consultants to niezależna firma doradcza z siedzibą w Hampshire w Anglii, zajmująca się oznakowaniem CE i certyfikacją produktów. Specjalizuje się Pomaga producentom dostosować się do wymogów dyrektyw RTTE, EMC, LV i RoHS, jak również uzyskać certyfikację radiową w Ameryce Północnej.

Charlie Blackham to dyplomowany inżynier, który zajmuje się dziedziną certyfikacji produktów i oznakowaniem CE od ponad 20 lat. Pracował dla kilku producentów jako kierownik ds. certyfikacji, a w 2005 r. założył firmę Sulis Consultants oferującą pomoc i doradztwo szerokiej grupie klientów. Jako były ekspert ds. technicznych jednostki notyfikowanej pomagał klientom w uzyskaniu oznakowania CE dla dużego asortymentu produktów radiowych działających w zakresie od 1 MHz do 78 GHz. Można się z nim skontaktować pod adresem e-mail charlie@sulisconsultants.com lub przez stronę internetową www.sulisconsultants.com

REFERENCE LINKS

i http://ec.europa.eu/DocsRoom/documents/11983/attachments/1/translations/en/renditions/pdf

ii http://ec.europa.eu/DocsRoom/?locale=en

iii https://portal.etsi.org/webapp/WorkProgram/Report_WorkItem.asp?WKI_ID=47231

iv http://webapp.etsi.org/ena/cvp.asp?search=RADIO

v https://www.etsi.org/deliver/etsi_en/303300_303399/303340/01.01.00_20/en_303340v010100a.pdf

vi https://www.etsi.org/deliver/etsi_en/303300_303399/303345/01.01.00_20/en_303345v010100a.pdf

PRODUKTY I USŁUGI

A

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info@amt.pl; www.amt.pl; www.AHSystems.com
Produkty i usługi: Anteny, Przyrządy pomiarowe, Testowanie

ABC Elektronik Sp. z o.o.
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info@abcpol.pl; www.abcpol.pl
Produkty i usługi: Anteny, Filtry, Rdzenie ferrytowe, Ekranowanie

AR RF/Microwave Instrumentation
Urzadzenia Elektroniczne Import, ul. Kierbedzia 4 pok. 203, Warszawa, Polska 00-728
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Dr. inz Marek Synowiec, uei_war@uei.com.pl; arworld.us
Produkty i usługi: Wzmacniacze, Anteny, Kable i złącza, Ekranowane pomieszczenia i obudowy, Zabezpieczenia przepięciowe i przebiegu przejściowego, Przyrządy pomiarowe

ASTAT Sp. z o.o.
60-451 Poznań, ul. Dąbrowskiego 441, Polska;
Tel: +48 61 848 88 71; Fax:+48 61 848 82 76
emc@astat.com.pl; www.astat.com.pl
Produkty i usługi: Komory i systemy pomiarowe, Pomiary, Szkolenia, Elementy EMI

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Produkty i usługi: Ferryty, kable i złącza, Aplikacje zasilające

C

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E

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– Mr. Mike Violette, 2017 conference chair

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NEDERLAND

uniek [bn.; -er, -st]

1 waarvan geen tweede exemplaar bestaat, syn. *enig: een uniek exemplaar; een unieke gelegenheid,* zoals nooit meer terugkomt

2 (fig.) onvergelijkelijk (mooi, goed), syn. *heerlijk, kostelijk, enig*

Introductie van de Enige 4000 watt CW, 80-1000 MHz versterker in zijn soort

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EVALUATIE VAN IEC 60601-1-2: 2014

(4E EDITIE)

Darryl P. Ray
Darryl Ray EMC Consulting, LLC

Introductie

IEC 60601-1-2:2014 Editie 4 is uitgegeven in februari 2014 en vervangt IEC 60601-1-2 Editie 3 gepubliceerd in 2007. Het gaat over EMC voor medische elektrische apparatuur en medische elektrische systemen. De Europese versie (EN60601-1-2:2015) is identiek aan de IEC-tegenhanger, met uitzondering van referenties naar de EN-versies van de 61000-4-x serie en de toevoeging van een bijlage met Essentiële Voorwaarden.

De motivatie voor de 4e editie was om een veiligheidsnorm te creëren voor de elektromagnetische verstoringen om te kunnen voldoen aan de algemene voorwaarden van IEC 60601-1 Editie 3. De vorige versie van IEC 60601-1-2 heeft de veiligheidsaspecten met betrekking tot elektromagnetische interferentie niet goed afgehandeld. Daarnaast zijn er aanzienlijke verschillen tussen editie 3 en 4 wat betreft immuniteit.

GLOBALE IMPLEMENTATIE

NIEC 60601-1-2 Ed 4:2014 is gepubliceerd in februari 2014. De FDA erkent inmiddels de 4e editie en de verplichte nalevingsdatum voor nieuwe inzendingen is 31 december 2018. Die datum is geselecteerd om af te stemmen met de eisen van de EU (EN 60601-1-2:2015). Hoewel pas vereist in 2018, accepteert de FDA momenteel de 4e editie en geeft ze de voorkeur aan producten die volgens die norm zijn getest bij het inzenden van nieuwe aanmeldingen, vooral voor apparaten die in de thuiszorg worden gebruikt.

De FDA eist geen naleving van de 4e editie voor verouderde apparatuur tenzij er substantiële wijzigingen in het product hebben plaatsgevonden.

Binnen de Europese Unie is de Intrekkingsdatum (Date of WIthdrawal, DoW) van EN 60601-1-2:2007 gepubliceerd als 31 december 2018. Daarom dienen alle apparaten die in de EU worden gepubliceerd of geïmporteerd na die datum te voldoen aan de 4e editie. Verouderde apparatuur, toegestaan door de FDA, is niet toegestaan.

Voor overige regio's verschillen de eisen significant per land. Ten minste één grote markt accepteert de 4e editie momenteel nog niet. Zie Tabel 6 hieronder voor extra details.

SAMENVATTING VAN WIJZIGINGEN VAN DE 3E NAAR DE 4E EDITIE

De volgende significante wijzigingen zijn doorgevoerd in de 4e editie.

- De classificatie van levensondersteuning versus niet-levensondersteuning zoals in de derde editie gebruikt, is komen te vervallen. Ze is vervangen door drie immuniteitscategorieën beoogd gebruik. Professionele Gezondheidszorg, Thuiszorg en Speciale Omgeving
- Aangepaste stralings- en immuniteitslimieten en niveaus zoals getoond in Tabellen 1 tot en met 4 hieronder
- De criteria voor het halen/falen van immuniteit zijn beperkt tot het behouden van de Essentiële Prestatie en Basisveiligheid
- Het Geleiderstation voor Potentiaalvereffening is verplicht verbonden met de lokale aarde tijdens het testen. De derde editie vermeldt niets over het Geleiderstation voor Potentiaalvereffening
- Het gebruik van de Kunsthand wordt uitgelegd
- De testmethodologie voor het uitvoeren van ESD-tests op connectoren is gewijzigd
- De standby-modus voor testen van zowel straling als immuniteit moet worden overwogen
- Er is een nieuwe procedure toegevoegd om een procedure in te stellen wanneer een apparaat tijdens het testen van immuniteit is beschadigd
- Niet-medische apparatuur die wordt gebruikt als onderdeel van het medische elektrische systeem dient te voldoen aan de relevante EMC-voorwaarden. Het systeem dient de Essentiële Prestatie en Basisveiligheid te behouden
- De eisen voor AC invoervoltage en frequentie zijn gestroomlijnd. Met uitzondering van de tests voor Voltageverzwakkingen en Onderbrekingen, is het toegestaan te testen met slechts één voltage & frequentie in het apparaat
- Testen van SIP/SOP's (signaalinvoer/uitvoerpoorten) die niet worden gebruikt tijdens gepatenteerd gebruik wordt uitgelegd
- De toelating voor radiogevoeligheid tijdens testen van stralingsimmuniteit is verwijderd.

- De labelvereisten zijn aangepast & gedeeltelijk gestroomlijnd. De Tabellen EMC Conformiteitsverklaring die in de derde editie stonden vermeld, zijn verwijderd.
- Een EMC testplan is nodig en bevat aanbevolen inhoud
- De minimale verblijftijd gebruikt voor het testen van immuniteit is ingekort
- Er is een EMC testrapport vereist en de minimale inhoud is gedefinieerd
- Risicobeheersing - verschillende EMC-afwegingen zijn noodzakelijk
- Alle normen waarnaar wordt verwezen zijn gedateerde referenties (3e editie maakt gebruik van ongedateerde referenties)
- De waarschuwing vereist in de gebruiksinstructies voor Klasse A apparaten wijkt af van die gevonden in CISPR 11
- Apparaten gebruikt in luchtvaartuigen zouden mogelijk moeten voldoen aan de eisen voor immuniteit zoals in RTCA DO-160
- Het gebruik van het ESD-waarschuwingssymbool bij gevoelige connectoren is verwijderd.

STRALINGSVOORWAARDEN

In de meeste gevallen zijn de stralingslimieten in de 4e editie hetzelfde als die in de derde editie. Er zijn verschillende toelichtingen gegeven in de 4e editie zoals getoond in Tabel 1 hieronder.

Tabel – 1 Vergelijking Stralingsvoorwaarden

Voorwaarde	IEC 60601-1-2: 2007 (3e editie)	IEC 60601-1-2: 2014 (4e editie)	Opmerkingen
Uitstoot via geleiding	CISPR 11	CISPR 11	
Uitstoot via straling	CISPR 11	CISPR 11	
Harmonische verstoring	IEC 61000-3-2	IEC 61000-3-2	Limieten Klasse A zijn van toepassing
Voltagefluctuaties/ flikkeren	IEC 61000-3-3	IEC 61000-3-3	
Apparaten met kleine onderdelen	Naleving van CISPR 14 mogelijk vereist	Niet van toepassing	
Verlichtingsapparatuur	CISPR 15	Niet van toepassing	
Röntgenapparatuur	Niet van toepassing	CISPR 11	20 dB ontspanning is van toepassing op quasi piek uitstoten
ITE-apparatuur	Moet voldoen aan CISPR 22	Moet voldoen aan CISPR 35	
Apparaten met Radio Subsystemen	Opzettelijke uitstoot uitgesloten	Opzettelijke uitstoot uitgesloten	
Patiëntkabels Uitstoot via geleiding	Niet van toepassing	Stroom Gewone Modus beperkt tot 24 dBµA (1-30 MHz)	Informatieve voorwaarde
Apparaten met Motoren of Schakelcircuits	Niet van toepassing	CISPR 14-1	

IMMUNITEITSVOORWAARDEN

Er zijn significante wijzigingen doorgevoerd voor de immuniteitsniveaus in de 4e editie zoals getoond in Tabellen 2 tot 4 hieronder. De niveaus zijn gebaseerd op een "redelijkerwijs te verwachten maximum".

Tabel 2- Vergelijking Immuniteitsniveaus - vergankelijk fenomeen

Fenomeen	IEC 60601-1-2: 2007 (3e editie)	IEC 60601-1-2: 2014 (4e editie)	
		Prof. Gezondheidszorg Omgeving	Thuiszorg Omgeving
ESD (test volgens IEC 61000-4-2)	8 kV Luchtuitlaat (max.) 6 kV Contactuitlaat	**15 kV** Luchtuitlaat (max.) **8 kV** Contactuitlaat	
EFT/Burst (test volgens IEC 61000-4-4)	2 kV - netvoeding 1 kV - I/O-poorten 5 kHz of 100 kHz PRR	2 kV - netvoeding 1 kV - I/O-poorten **100 kHz PRR**	
Pieken - netvoeding (test volgens IEC 61000-4-5)	2 kV (max.) Fasehoeken 0,90, 270 graden	2 kV (max.) Fasehoeken 0, 90, **180** & 270 graden	
Pieken - 12 VDC Stroom (test volgens ISO 7637-2)	n.v.t.	**600 V**	
Voltageverzwakkingen & Onderbrekingen (test volgens IEC 61000-4-11)	• UT <5%, 0,5 perioden • UT = 40%, 5 perioden • UT = 70 %,25 perioden • UT <5%, 5 seconden	• **UT = 0%, 0,5 cyclus (0, 45, 90, 135, 180, 225, 270 en 315 °)** • **UT = 0 %; 1 cyclus UT = 70%; 25/30 cycli (@ 0 graden)** • **UT = 0%, 250/300 cycli**	

Vetgedrukt = Wijzigingen vanaf Editie 3

Tabel 3- Vergelijking Immuniteitsniveaus - stabiel fenomeen

Fenomeen	IEC 60601-1-2:2007 (3e editie)	IEC 60601-1-2: 2014 (4e editie)	
		Prof. Gezondheidszorg Omgeving	Thuiszorg Omgeving
Immuniteit bij geleiding (test volgens IEC 61000-4-6)	3 V (0,15- 80 MHz) 10V ISM-banden - Levensondersteunende apparatuur	3 V (0,15- 80 MHz) **6V (ISM-banden)**	3 V (0,15- 80 MHz) **6 V (ISM & Amateur)**
Magnetische immuniteit (test volgens IEC 61000-4-8)	3 A/m 50 & 60 Hz	**30 A/m** 50 **of** 60 Hz	

Vetgedrukt = Wijzigingen vanaf Editie 3

Tabel 4 - Vergelijking Immuniteitsniveaus - stabiel elektrisch veld fenomeen

Fenomeen	IEC 60601-1-2:2007 (3e editie)	IEC 60601-1-2: 2014 (4e editie)	
		Prof. Gezondheidszorg Omgeving	Thuiszorg Omgeving
Immuniteit bij straling (test volgens IEC 61000-4-3)	3 V/m - Niet-levensondersteuning 10 V/m - Levensondersteuning 80 MHz – 2,5 GHz 80%@2 Hz (of 1 kHz1) AM Modulatie	**3 V/m** 80 MHz – **2,7 GHz** 80%@ **1 kHz** AM Modulatie	**10 V/m** 80 MHz – **2,7 GHz** 80%@ **1 kHz** AM Modulatie
Nabijheidsveld van Draadloze Zenders (test volgens IEC 61000-4-3)	Niet van toepassing	**9 V/m tot 28 V/m** 15 specifieke frequenties	

Vetgedrukt = Wijzigingen vanaf Editie 3

NEDERLAND

ACCEPTATIECRITERIA IMMUNITEIT

De voorwaarden voor halen/falen van immuniteit zoals beschreven in editie 4 zijn gebaseerd op medische apparatuur die de basisveiligheid en Essentiële Prestaties behoudt. De definities van deze concepten staan hieronder vermeld
Basisveiligheid - zoals bepaald volgens IEC 60601-1:2012, Editie 3.1:

BASISVEILIGHEID
vrij van onacceptabel risico direct veroorzaakt door fysieke gevaren wanneer ME-apparatuur wordt gebruikt onder normale omstandigheden en enkelvoudige fouttoestand2

ESSENTIËLE PRESTATIES
prestaties die nodig zijn om vrij van onacceptabele risico's te functioneren voor medische functies, anders dan die gerelateerd aan basisveiligheid, waar verlies of verslechtering voorbij de grenzen zoals door de fabrikant bepaald resulteert in een onacceptabel risico.

OPMERKING - Essentiële Prestaties is het makkelijkst te begrijpen door u af te vragen of afwezigheid of verslechtering zou resulteren in een onacceptabel risico.

Het is van cruciaal belang voor de producent om bovenstaande concepten toe te passen op de te testen medische apparatuur. In veel gevallen kan een apparaat gevoelig zijn voor elektromagnetische verstoringen, maar wanneer de Basisveiligheid en Essentiële Prestaties worden behouden, dan kan het apparaat worden beoordeeld als in lijn met de 4e editie.

ESD-TESTS OP CONNECTOREN

De derde editie vereist dat contactontladingen worden uitgevoerd op individuele stekkers die toegankelijk zijn volgens de IEC-richtlijnen van IEC 60601-1. Er is geen standaard testprocedure om deze test uit te voeren. De 4e editie heeft deze procedure verfijnd volgens Tabel 5 hieronder:

Tabel 5 - ESD-eisen voor het testen van connectoren

Connectorhuls	Ontladingsvoorwaarden	Poortgebruik
Geleidend	Contactuitstoot alleen naar huls	Beoogd en normaal gebruik[3]
Geïsoleerd	Luchtuitstoot naar huls en Luchtuitstoot naar pennen (indien toegankelijk met de IEC Testvinger)	Beoogd gebruik

RISICOBEHEERSING

Het concept van risicobeheersing voor EMC is nieuw. De 4e editie vereist dat de volgende problemen worden aangepakt met het oog op risicobeheersing. Deze punten moeten worden aangepakt en gedocumenteerd in het EMC testrapport en het Risicobeheersingsbestand.

- De minimale tussenafstand tot draagbare communicatieapparatuur moet in overweging worden genomen
- Annex F, Risicobeheersing voor Basisveiligheid en Essentiële Prestaties moet in overweging worden genomen
- Gebruiksmodi voor testen moeten worden gebaseerd op de Risicoanalyse
- Testen van niet medische apparatuur (d.w.z. er moet rekening worden gehouden met verstoringen in het risicobeheersingsproces)
- Effecten die worden waargenomen bij de EUT-respons tijdens immuniteitstests moet worden aangepakt
- Het Risicobeheersingsproces wordt gebruikt om te bepalen of het is toegestaan subsystemen te testen
- Verlaagde testniveaus, indien gebruikt, moeten worden gerechtvaardigd
- Verzachtingen om lagere immuniteitsniveaus te corrigeren moeten worden gedocumenteerd
- Er kunnen alternatieve aanpassingsfrequenties worden gebruikt
- Er zal rekening worden gehouden met de huidige communicatiediensten
- Er moet worden getest op hogere magnetische immuniteitsniveaus wanneer een apparaat dichterbij is dan 15 cm bij een magnetische stroomfrequentiebron

Voor het verklaren van conformiteit met de 4e editie zijn vijf handelingen nodig;

- Er moet voor het testen een testplan worden gemaakt
- Er moet aan de relevante testvoorwaarden worden voldaan
- Er moet een gedetailleerd testrapport met vereiste minimale inhoud worden opgesteld
- De genoemde eisen voor risicobeheersing moeten worden nagelopen
- De apparaatlabels dienen te voldoen aan de voorwaarden van clausule 6.

Veel testlaboratoria nemen niet graag de verantwoordelijkheid voor het controleren van de eisen voor risicobeheersing en apparaatlabels. Het is de verantwoordelijkheid van de producent om te zorgen dat alle bovengenoemde zaken goed worden gecontroleerd.

Sinds de publicatie zijn verschillende fouten en ambiguïteiten naar voren gekomen:

- Er is een afwijking tussen de voetnoten in Tabellen 1 en 5. Voetnoot c in Tabel 1 dient te worden gebruikt.
- Tabel 9 wordt soms verkeerd gelezen alsof tests moeten worden uitgevoerd op een testafstand van 0,3 m. De testafstand zoals vermeld in IEC 61000-4-3 is van toepassing.
- De FDA accepteert de toelating niet die is genoemd in Tabel 8 Opmerking b over de kabellengte.

DATA VOOR CONFORMITEIT

De conformiteitsdata voor de 4e editie en vele andere normen kunnen een lastig probleem vormen om op te lossen. De data zijn afhankelijk van het type apparaat, de regio waar het wordt verkocht en soms worden ze beïnvloed door normen en regelgeving op hogere niveaus. Tabel 6 vat de verplichte conformiteitsdata samen op basis van de regio.

Tabel 6 - Conformiteitsdata voor IEC 60601-1-2:2014 (4e editie) per regio

Verenigde Staten	Europese Unie	Overige regio's
Verouderde apparaten: Nooit[4] Nieuwe inzendingen: 1 januari 2019	Alle apparaten: 1 januari 2019 (conform EN 60601-1-2: 2015)	Varieert per: • Landelijke regelgeving[5] • IEC 80601-2-X normen[6]

SAMENVATTING

Dit artikel biedt een vergelijking van IEC 60601/1/2 3de en 4e editie. Zoals getoond in bovenstaande tabellen, zijn de testniveaus in vele gevallen verschillend en ze zijn vaak) maar niet altijd' strenger. De 4e editie vereist dat de basisveiligheid en essentiële prestaties van de medische apparatuur worden gehandhaafd in aanwezigheid van verschillende elektromagnetische omgevingen zoals vermeld in de norm.

Gevoeligheden niet gerelateerd aan Basisveiligheid en Essentiële Prestaties tellen over het algemeen niet als het falen van een test. Daarnaast vereist de 4e editie dat een aantal problemen wordt aangepakt met het oog op risicobeheersing.

De twee normen zijn significant verschillend wat betreft testniveaus en de acceptatiecriteria voor het halen/falen van tests, de gebruiksmodi en meer. Daarom zou het onjuist zijn te stellen dat conformiteit met de 4e editie gelijk staat aan conformiteit met de derde editie.

REFERENCES

[1] 1 kHz aanpassing wordt gebruikt voor medische apparatuur die fysiologische parameters niet bestuurt, controleert of meet.

[2] Hoewel de enkelvoudige fouttoestand officieel in deze definitie wordt vermeld, zouden veel gebruikers van IEC 60601-1-2 de naleving tijdens een enkelvoudige fouttoestand onpraktisch tot onmogelijk vinden en deze wordt daarom vaak genegeerd.

[3] Raadpleeg IEC 60601-1 voor de definitie van beoogd en normaal gebruik.

[4] Volgens het FDA substantieel equivalent (predicaat) schema

[5] Sommige landen accepteren momenteel de 4e editie niet

[6] De specifieke normen (IEC 60601/80601-2-X) worden op dit moment gewijzigd naar gedateerde referenties naar IEC 60601-1-2:2014. Tot het herschrijven is voltooid, zullen sommige onderdeelnormen verwijzen naar IEC 60601-1-2:2014, sommigen verwijzen naar IEC 60601-1-2:2007 en anderen maken gebruik van ongedateerde verwijzingen naar IEC 60601-1-2.

RICHTLIJN RADIOAPPARATUUR, 2014/53/EU

Door Charlie Blackham,
Hoofdadviseur en Directeur van Sulis Consultants Ltd.

Opmerking van de redactie: *De Richtlijn radioapparatuur (Radio Equipment Directive, RED), 2014/53/EU, dient te worden gebruikt voor nieuwe producten die worden geproduceerd na 13 juni 2016 en wordt verplicht voor alle producten vanaf 13 juni 2017.*

SAMENVATTING

Dit artikel biedt informatie over de laatste wijzigingen die zich voordoen als resultaat van de nieuwe Richtlijn radioapparatuur (RED) 2014/53/EU die kan worden gebruikt vanaf juni 2016. Het beschouwt de wijzigingen in producten en regelgeving en wat dit betekent voor producenten van apparatuur.

Meer informatie over de geschiedenis van de RED is te vinden in het artikel, Radio Equipment Directive, in de gids Interference Technology 2015 EMC Directory and Design.

OMVANG VAN DE RICHTLIJN

De omvang van de RED is vergroot, zodat deze ook omvat:

- "Radiodeterminatie"-apparatuur, zoals radars en RFID-apparaten. Van deze apparaten is bepaald dat ze binnen de Richtlijn R&TTE vallen, maar de omvang van de RED is veel duidelijker zodat het logischer is dat ze erin zijn opgenomen en eraan moeten voldoen.
- "Geluid- en tv-uitzending ontvangers" – deze werden uitgesloten onder R&TTE, dus gelden hiervoor extra eisen voor radiospectrumfuncties.
- "Ontvangerfunctie" – hoewel dit werd omschreven in een aantal ETSI productnormen, zorgt het belang ervan in een steeds voller radiospectrum dat het onderdeel is van de Richtlijn.
- "Apparaten die werken onder 9 kHz" – de ondergrens frequentie van R&TTE was 9 kHz, maar die is verwijderd.
- In lijn met andere richtlijnen is er een specifieke uitsluiting voor "Op maat gemaakte onderzoeksapparatuur die is ontworpen voor professionals ten bate van onderzoek en ontwikkelingsfaciliteiten voor dergelijke doelen."

TIJDPADEN EN OVERGANGSPERIODES

De Europese Commissie heeft bevestigd dat er vier scenario's zijn met betrekking tot de toepassing van Richtlijnen 2014/53/EU, 2014/35/EU en 2014/30/EU [i]

Producttype	Conformiteitseisen en data
Momenteel binnen het bereik van EMC en LVD en niet binnen het bereik van R&TTE of RED	• Producten die op de markt zijn geplaatst voor 20 april 2016: oude LVD/EMCD • Producten die op de markt zijn geplaatst op of na 20 april 2016: nieuwe LVD/EMCD
Momenteel binnen het bereik van R&TTE en blijvend binnen het bereik van RED	• Producten die op de markt zijn geplaatst voor 13 juni 2016: R&TTED • Producten die op de markt zijn geplaatst tussen 13 juni 2016 en 12 juni 2017: R&TTED of RED • Producten die op de markt zijn geplaatst na 12 juni 2017: RED
Momenteel buiten het bereik van R&TTE maar binnen het bereik van RED	• Producten die op de markt zijn geplaatst voor 20 april 2016: oude LVD/EMCD • Producten die op de markt zijn geplaatst tussen 20 april 2016 en 12 juni 2016: nieuwe LVD/EMCD • Producten die op de markt zijn geplaatst tussen 13 juni 2016 en 12 juni 2017: RED of nieuwe LVD/EMCD • Producten die op de markt zijn geplaatst na 12 juni 2017: RED
Momenteel binnen het bereik van R&TTE maar buiten het bereik van RED	• Producten die op de markt zijn geplaatst voor 13 juni 2016: R&TTED • Producten die op de markt zijn geplaatst na 12 juni 2016: RED is niet van toepassing; nieuwe LVD/EMCD, indien van toepassing op het product in kwestie

Er is opgemerkt dat het opvolgen van deze data een grote administratieve druk zou kunnen leggen op producenten om documentatie en Conformiteitsverklaringen bij te werken, vooral voor apparaten die buiten de R&TTE richtlijn vallen en binnen de EMC en LVD omdat ze niet kunnen profiteren van de overgangsperiode die in de RED staat beschreven.

Richtlijnen voor de inhoud van Conformiteitsverklaringen specificeren minimale inhoud, maar geven doorgaans geen maximale inhoud en overige nuttige informatie wordt algemeen geaccepteerd. Op basis hiervan staan er momenteel een paar voorstellen ter discussie binnen de commissie om producenten de kans te geven

zowel huidige als nieuwe richtlijnen te noemen in hun Confrmiteitsverklaringen, bijv.

"Het object in de verklaring hierboven is conform de relevante harmonisatiewetgeving van de Europese Unie: Richtlijn 1999/5/EC (tot 12 juni 2016), Richtlijn 2014/30/EU (vanaf 13 juni 2016) en Richtlijn 2014/35/EU (vanaf 13 juni 2016)."

Merk op dat dit voorstel op het moment van publicatie **nog niet formeel is geaccepteerd**. Er wordt verwacht dat dit begin maart wordt geaccepteerd en wordt gepubliceerd in de EU Documentatiekameri. We zullen u op de hoogte brengen zodra wij erover beschikken.

Enkele hoofdpunten voor producenten onder RED:

- De CE-markering moet op het apparaat staan en op de verpakking - de RED vereist niet langer een CE-markering in de gebruikershandleiding
- Het nummer Geïnformeerde Instantie wordt alleen op het product geplaatst wanneer de Volledige Kwaliteitscontrole is doorlopen (R&TTE bijlage V / RED bijlage IV) en wordt niet gebruikt wanneer een GI net het technische bestand heeft ontvangen.
- De lijst met toegestane landen moet nog steeds worden vermeld op de verpakking en in de gebruikershandleiding, maar er is geen voorwaarde meer voor het let-op-teken, , voor klasse 2 apparatuur en landmeldingen zijn niet meer verplicht.
- De gebruikershandleiding moet gebruiksfrequentiebanden bevatten en de maximale zendkracht in elk van deze banden en deze informatie moet in een taal staan die door de eindgebruiker gemakkelijk wordt begrepen.
- Producten die "radioapparatuur" bevatten zoals beschreven in RED Artikel 2, vallen onder de RED - dus een wasmachine met een Zigbee-radio valt onder de RED en niet de EMC en LVD.

ONTWIKKELINGEN VAN NIEUWE NORMEN VOOR RED

EMC

De radioapparatuur staat geen toepassing van de EMC-richtlijn toe wat wel mogelijk was onder de R&TTE, dus alle producten die radioapparatuur bevatten moeten opnieuw worden gecontroleerd op de Richtlijn Radioapparatuur (Radio Equipment Directive).

- ETSI ontwikkelen de richtlijn EG 203 367 iii, "Elektromagnetische compatibiliteit en Radiospectrumzaken (ERM); Richtlijn voor toepassing van geharmoniseerde normen met Artikelen 3.1b en 3.2 van de Richtlijn 2014/53/EU (RE-D) voor multi-radio en gecombineerde radioapparatuur" die aanwijzingen geeft voor de toepassing van Geharmoniseerde Normen voor multi-radio en gecombineerde apparatuur. Het document is nog een conceptversie

  * Voorbeelden van apparatuur die door het document wordt gedekt, omvatten maar zijn niet beperkt tot, combinatie van multi-radio producten in één radioapparaat, combinatie van radio en IT of elektrotechnische apparatuur, huishoudelijk apparaat met RLAN-functie, op afstand bestuurbaar verwarmingssysteem, op afstand bestuurbare verlichting, etc.

NEDERLAND

Radiospectrum

- ETSI werkt op dit moment 156 normen van Artikel 3.2 Radiospectrum bij voor de RED, 34 daarvan worden gepubliceerd in het Officiëel Verslag in 2016 en het merendeel van de rest volgt in de 1ste helft van 2017.
- Na controle van de compatibiliteit tussen LTE die functioneren in de 800 MHz-band en UHF Korte Golf Apparaten, is ETSI begonnen aan het herstructureren van EN 300 220. De werkpunten zijn als volgt opgenomen:

    * EN 300 220-2: Geharmoniseerde Standaard voor niet-specifieke radioapparatuur. Er worden twee versies ontwikkeld: een versie 3.1.1 met "categorie 3" ontvangers, bedoeld om te worden vervangen door v 3.2.1 met verbeterde "categorie 2" ontvangers tegen december 2018.
    * EN 300 220-3-1: Sociale Alarmapparatuur die werkt in de toegewezen frequentieband (869,2 - 869,25 MHz)
    * EN 300 220-3-2: Draadloze Alarmapparatuur die werkt in de toegewezen frequentiebanden
    * EN 300 220-4: Radioapparatuur voor metingen die werkt in de toegewezen frequentieband (169,4 - 169,4875 MHz)

- ETSI heeft reeds conceptnormen gepubliceerd voor tv- en radio-ontvangers die onder de RED gaan vallen door de verandering van de omvang van deze richtlijn:

    * Concept ETSI EN 303 340 V1.1.0v, Digitale aardse tv-ontvangers; geharmoniseerde norm die de essentiële voorwaarden omvat van Artikel 3.2 van de Richtlijn 2014/53/EU
    * Concept ETSI EN 303 345 V1.1.0v, Digitale aardse radio-ontvangers; geharmoniseerde norm die de essentiële voorwaarden omvat van Artikel 3.2 van de Richtlijn 2014/53/EU

Overgangsperiodes

Net als in de normale praktijk, zal er een overgangsperiode zijn waarin bestaande normen nog kunnen worden gebruikt, maar waarbij producenten moeten letten op het ETSI werkprogramma iv en op de hoogte moeten blijven van normen die worden gepubliceerd.

OVER

Sulis Consultants is een onafhankelijk adviesbureau voor CE-keurmerken en Productkeuringen dat is gevestigd te Hampshire, Engeland en dat zich erin specialiseert producenten te helpen voldoen aan de eisen van de Richtlijnen R&TTE, EMC, LV en RoHS evenals radiocertificatie voor Noord Amerika.

Charlie Blackham is een Gecharterde Technicus die al meer dan 20 jaar actief is in het veld van productkeuringen en CE-keurmerken. Nadat hij voor verschillende producenten heeft gewerkt als Beheerder Goedkeuringen, heeft Charlie in 2005 Sulis Consultants opgericht om advies en hulp te bieden aan een breed scala van klanten. Als voormalig technisch expert bij een Geïnformeerde Instantie, heeft Charlie klanten geholpen een groot aantal radioproducten op de frequenties van 1 MHz tot 78 GHz voor CE te keuren en hij is bereikbaar via charlie@sulisconsultants.com of via www.sulisconsultants.com

REFERENCE LINKS

i http://ec.europa.eu/DocsRoom/documents/11983/attachments/1/translations/en/renditions/pdf

ii http://ec.europa.eu/DocsRoom/?locale=en

iii https://portal.etsi.org/webapp/WorkProgram/Report_WorkItem.asp?WKI_ID=47231

iv http://webapp.etsi.org/ena/cvp.asp?search=RADIO

v https://www.etsi.org/deliver/etsi_en/303300_303399/303340/01.01.00_20/en_303340v010100a.pdf

vi https://www.etsi.org/deliver/etsi_en/303300_303399/303345/01.01.00_20/en_303345v010100a.pdf

PRODUCTEN EN SERVICES

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info@eemc.nl; www.eemccoimex.nl;
www.AHSystems.com
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sales@acaltechnology.nl; www.acaltechnology.com
Producten en services: Ferrieten, Filters

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Stuart Mulhall, arbeneluxinfo@arworld.us;
www.arbenelux.com
Producten en services: Versterkers, Antennes,
Spanning en overgangen, Testinstrumenten

Arrow Europe
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B

Bal Seal Engineering Europe bv
Jollemanhof 16, 5th floor
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www.balseal.com
Products and Services: Shielding

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bicon@bicon.nl; www.bicon.nl
Producten en services: Consultants, Testen

C

Carlisle Interconnect Technologies
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Producten en services: Filtres

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Bas de Groot; BkdeGroot@dmas.eu; www.dmas.eu
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E

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F

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G

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I

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Producten en services: High Power Microwave and RF Amplifiers (Tetrode Tubes, Solid State and TWT) up to 40 GHz

M

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S

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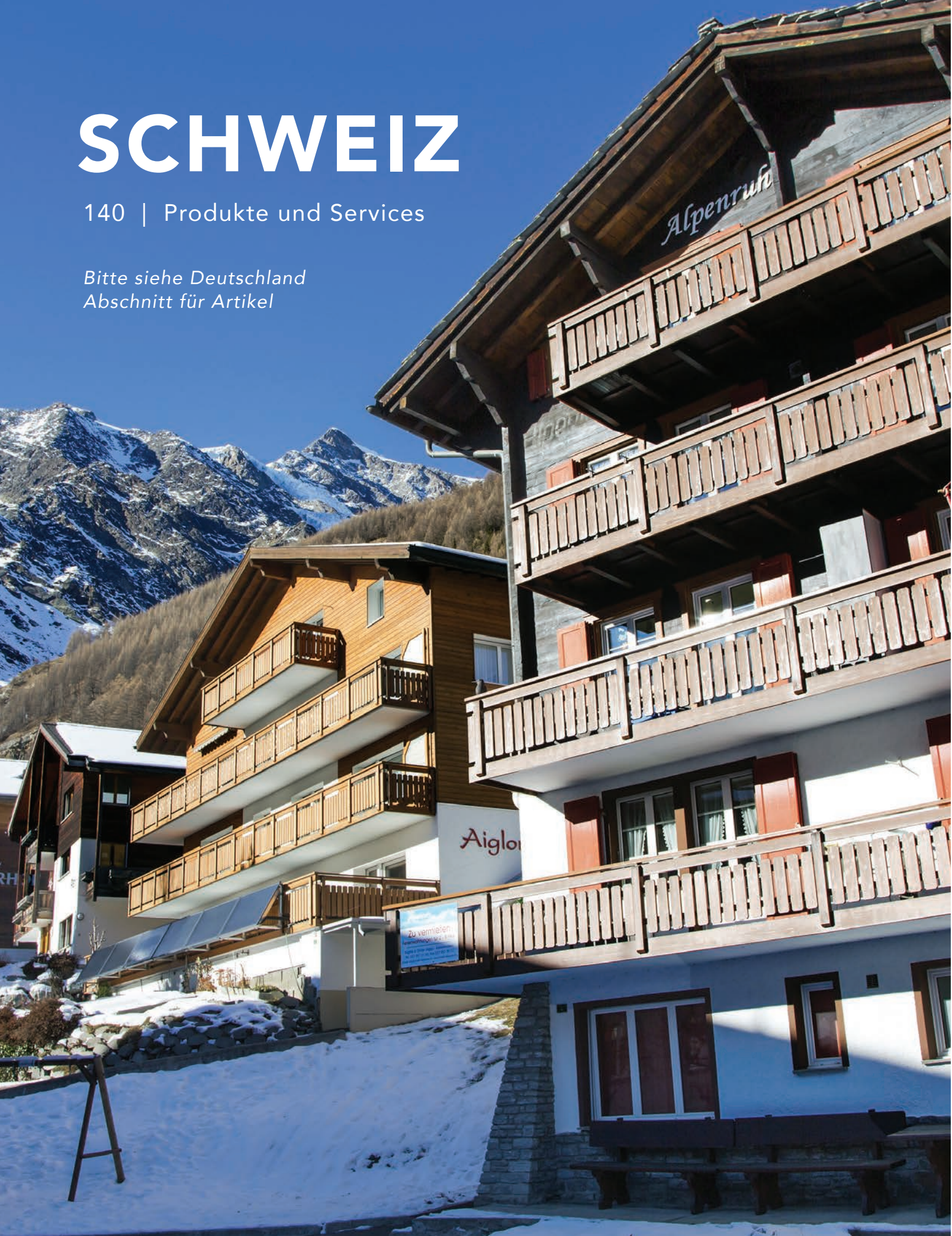

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Tijd is geld, verdien beide terug!

Zet onze Multistar Multi-Tone Tester in

Nauwkeurigheid is bij EMC testen van cruciaal belang. Maar als het te lang duurt om te testen kost het veel geld en staat dit ook een snelle marktintroductie in de weg. Met de snelheid van onze revolutionaire Multistar Multi-Tone tester, hoeft u geen tijd meer te verspillen aan tijdrovende EMC RF-immuniteitstesten.

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- IEC 61000-4-3 en IEC 61000-4-6
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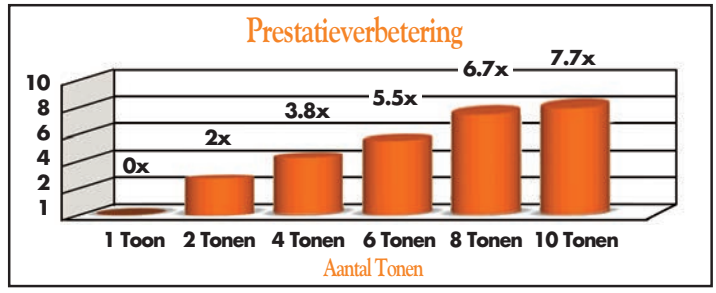

IEC 61000-4-3, stappen van 1%, rekening houdend met de dwell time

Dus, als u ook van mening bent dat tijd geld is, sta er dan niet te lang bij stil. Vraag naar onze Multistar Multi-Tone Tester. Verbazingwekkend snel, ongelofelijk nauwkeurig.

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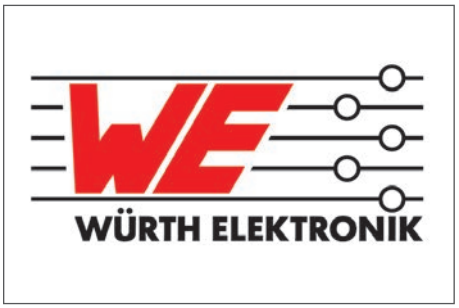

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