

PRODUCT SAFETY ENGINEERING NEWSLETTER



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President's Message

Hello Fellow PSES Members!

Well, it doesn't seem like two years already since I stepped in as President of the PSES. The time has sure gone by quickly. During that time, I have tried to encourage the Board to try some new things with our Symposium and otherwise to try and bring more value to our members and increase our membership overall.

We have had a few good years now financially and are in pretty good shape, which provides to us the opportunity to try some more new activities and products as well. As I mentioned in my last article, in addition to the changes with the Symposium and additional Conferences, we will be looking at adding some new publications as well – this will get more content published and available for members as well as help us generate additional income to provide more value to our members. We also have some great new members on the Board with fresh ideas and we are looking to implement more of those as we move forward as well.

I recommend that you look visit our new Website often – information there is updated regularly and the amount of content and changes will continue to increase. Be sure to bookmark it - <http://www.ieee-pses.org/>.

The 2016 Symposium is off to a good start – again, check the website <http://2016.psessymposium.org/>! It will be in Anaheim in 2016 and the call for papers is already out – please consider submitting a presentation or paper and sharing with your colleagues. Please also share the call for papers with others you know and who may not have seen it since they are not members of the Society.

As I close out my term I would like to thank all the Board members and other PSES Members I have worked with who have worked very hard to help us grow the Society and again bring more value to all of our members. I also encourage you all to consider getting involved in any small way to help continue our efforts – it doesn't have to be a large commitment even – again check the Website or contact any one of the Board members at any time for information or opportunities.

I will now continue on as Immediate Past President for the next couple of years. During that time I will be helping with our Succession planning for BOD Members and Officers as well as organizing related elections. I will also be working with the IEEE to update our Bylaws, Constitution and formally incorporate our Strategic Plan that we are now implementing.

Finally at this time of the year we have the election results for new Board members and as such, I would like to welcome the new Board of Director members at large: John Allen, Harry Jones, Ken Kapur, and Grant Schmidbauer (returning). I would also like to welcome Mark Maynard as he begins his two year term as President – I look forward to some of the new ideas Mark will be trying to implement to keep the Society growing – you will be hearing more from Mark in future issues of the Newsletter.

Stay tuned for more developments as we endeavor to increase value to members and grow the Society. As always, if you have any ideas or feedback, do not hesitate to let me know!

Sincerely,
Kevin Ravo




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1Q issue: February 15
2Q issue: May 15
3Q issue: August 15
4Q issue: November 15

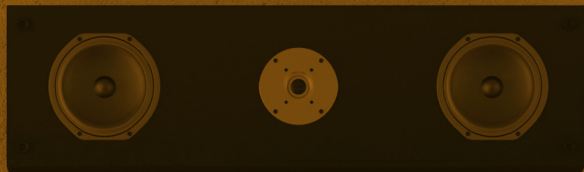
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Chapter and TAC Safety Probes

News about Chapters and Technical Activity Committees

To see current chapter information and people looking to start chapters please go to the Chapter page at: <http://www.ieee-pses.org/Chapters/index.html>

Technical Activity Committee information can be found at: <http://www.ieee-pses.org/technical.html>

San Diego

The IEEE PSES (Product Safety Engineering Society) San Diego Chapter held a meeting on Sep. 8 at 6:00pm, with a guest speaker, Leszek Langiewicz Regulatory Program Manager at Hewlett-Packard Company.

The meeting details were as follows.

Agenda:

- Start @ 6:00pm
- 30 min Social Dinner & Networking
- 10 min Intro & housekeeping
- 60-90 min feature presentation/topic
- 5 min wrap-up

Location:

Hewlett-Packard Company

16399 West Bernardo Dr., San Diego, CA 92127

Meeting Room: Pacific (Conference Center)

Topic: "2015 ISPCE recap"

Abstract:

This informal talk shared what 2015 ISPCE (IEEE Symposium on Product Compliance Engineering) was offering and why this event becomes a one stop shopping for information on Product Compliance.

To receive more information, please contact Gabe Alcala gcalcala@atecorp.com or 858-558-6500 x390.

For details on past present and future events, please visit our page [Product Safety Engineering \(PSES\)](#) San Diego Section of the IEEE.

Telecom Safety TAC

The group is continuing discussion on the RFT standard –IEC 62368-3 and the summation of touch current requirements. Because of questions raised with regard to the handling of telecom circuits in the new standard the group has taken a deep dive comparing telecom related requirements in UL 1459, IEC 60950, and IEC 62368.

The discussion on the protection of DC feeds to the top of radio towers is also continuing.

For information about the TSTC contact Don Gies at Don.Gies@ALCATEL-LUCENT.COM. Meetings are generally held on the last Wednesday of the month.

TACS - WE NEED YOUR NEWS!

CHAPTERS - WE NEED YOUR NEWS!



ISPCE 2016 Orange County, CA, USA May 16-18, 2016

IEEE Symposium on Product Compliance Engineering **CALL FOR SUBMISSIONS** { <http://psessymposium.org>

The IEEE Product Safety Engineering Society seeks original and unpublished formal papers, presentations (without formal papers), workshops, & tutorials on all aspects of product safety and compliance engineering including, but not limited to:

- EMC Compliance
- Energy Storage & Batteries
- Forensics
- Hazard-based Safety Engineering & Safety Science
- Innovation
- Wearable Technology
- Environmental
- Standards
- Compliance 101
- Leadership
- Medical Devices
- Risk Analysis, Assessment & Management
- Anti-counterfeiting
- Components
- 3D Printers
- Functional & software safety

Please go to the Submission page on the ISPCE website for details & comprehensive submission instructions, including separate formal paper and presentation templates: www.psessymposium.org. Formal papers & presentations not submitted per submission instructions by the initial deadline may need to be held over until next year depending on the number of submissions.

Submission Schedule (preliminary)

Indicated deadlines require that the associated documents be loaded into the submission portal, EDAS, (<http://edas.info>) by the due date:

December 6, 2015

Formal Paper/Reviewable Presentation Submission

February 1, 2016

Acceptance Notification

April 1, 2016

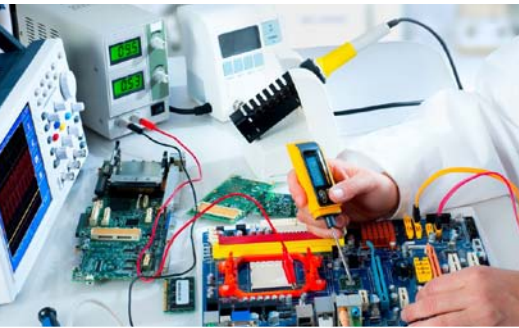
Final Camera-ready Paper/Presentation Submission

Please note, when serving as an educational presenter during ISPCE 2016, speakers are permitted to introduce themselves and make reference to the company they represent, or their company activities, as is necessary for context within the course of their presentation. Company sales or other promotional activities should be reserved for other times.



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Product Safety Engineering Society

Be part of a Great Society at the Forefront of Product Safety Innovation!



Annual Symposium

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- Presentations by Compliance Professionals from around the world
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- Technical Committee meetings
- Publish & present ideas
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News and Notes

Compliance News Shorts



News To Know

REACH News - According to a press release dated 10 September 2015, the EU Court of Justice has ruled that articles incorporated as components of a complex product must be notified to the European Chemicals Agency when they contain a substance of very high concern in a concentration above 0.1%.

The REACH Regulation provides that, where a chemical substance 'of very high concern' for health or the environment because, in particular, of its carcinogenic, mutagenic or toxic properties is present in a concentration above 0.1% of the mass of an article, the producer or importer must, in principle, notify the European Chemicals Agency (ECHA). Similarly, the supplier must inform the recipient thereof and, on request, the consumer of the article.

In 2011, a note sent by the Commission to the Member States and a guide published by ECHA specified how the regulation is to be applied as regards substances of very high concern included in articles. In essence, with regard to articles incorporated in goods, those documents provide that the duties to notify and provide information laid down in the regulation apply only if the substance of very high concern exceeds 0.1% in the entire article.

That interpretation was not shared by five Member States or Norway.

Not being convinced that the instructions in those documents ensure a high level of protection of human health and the environment, the French authorities issued an opinion on the manner in which they intended to apply the relevant provisions of the regulation. They are of the view that the concept of 'article' covers all objects meeting the definition of an article within the meaning of the regulation.

By its judgment, the Court recalls, firstly, that the regulation defines the concept of 'article' as 'an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition'. However, it does not contain any provisions specifically governing the situation of a complex product containing several articles. Consequently, there is no need to draw a distinction between the situation of articles incorporated as a component of a complex product and that of articles present in an isolated manner.

In those circumstances, the Court rules that each of the articles incorporated as a component of a complex product is covered by the relevant duties to notify and provide information when they contain a substance of very high concern in a concentration above 0.1% of their mass.

The Court finds that the producer's duty to notify covers only those articles which the producer itself has made or assembled. That duty is therefore not applicable to an article which, although used by that producer as input, was made by a third party. None the less, that third party is also subject to the duty to notify in respect of the article which it makes or assembles.

Similarly, the importer of a product the composition of which comprises one or more of the objects coming within the definition of the term 'article' must also be considered to be the importer of that article or those articles. In that regard, the Court points out that the fact that it can be difficult for importers to obtain the required information from their suppliers established in non-EU countries does not alter their duty to notify.

The Court finds that the duty to provide information with regard to the recipients and consumers of the product is not restricted to the producers and importers but applies to all operators along the supply chain when that person supplies an article to a third party. It is therefore for the person supplying a product one or more constituent articles of which contain(s) a substance of very high concern in a concentration above 0.1% to fulfil his duty to provide information and provide the recipient and the consumer of the product, as a minimum, with the name of the substance in question.

Full text is available at <http://curia.europa.eu/jcms/upload/docs/application/pdf/2015-09/cp150100en.pdf>.

Recently Published Standards

CISPR 11:2015 Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement

EN 50416:2005/A1:2015 - (9/18/2015) - Household and similar electrical appliances - Safety - Particular requirements for commercial electric conveyor dishwashing machines

EN 55024:2010/A1:2015 - 6/5/2015 - Information technology equipment - Immunity characteristics - Limits and methods of measurement

EN 55032:2015 - 7/3/2015 - Electromagnetic compatibility of multimedia equipment - Emission Requirements

EN 60320-1:2015 - (9/18/2015) - Appliance couplers for household and similar general purposes - Part 1: General requirements

EN 60601-1-2:2015 - (9/18/2015) - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

EN 60601-2-37:2008/A1:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

EN 61000-4-6:2014/AC:2015 - 6/12/2015 - Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields

EN 61010-031:2015 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 031: Safety requirements for hand-held probe assemblies for electrical measurement and test

EN 61010-2-040:2015 - (9/11/2015) - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040 Particular requirements for sterilizers and washer-disinfectors used to treat medical materials

EN 61851-24:2014/AC:2015 - 6/17/2015 - Electric vehicle conductive charging system - Part 24: Digital communication between a d.c. EV charging station and an electric vehicle for control of d.c. charging

EN 62061:2005/A2:2015 - (8/28/2015) - Safety of machinery - Functional safety of safety-related electrical, Electronic and programmable electronic control systems

EN 62841-1:2015 Electric motor-operated hand-held tools, transportable tools and lawn and garden machinery - Safety - Part 1: General requirements

IEC 60086-1:2015, Ed. 12.0 Primary batteries - Part 1: General

IEC 60320-1:2015 Appliance couplers for household and similar general purposes - Part 1: General requirements

IEC 60335-2-17:2012/AMD1:2015 Amendment 1 - Household and similar electrical appliances - Safety - Part 2-17: Particular requirements for blankets, pads, clothing and similar flexible heating appliances

IEC 60335-2-27:2009+AMD1:2012+AMD2:2015 CSV/COR1:2015 Corrigendum 1 - Household and similar electrical appliances Safety Part 2-27: Particular requirements for appliances for skin exposure to optical radiation

IEC 60335-2-3:2012/AMD1:2015, Ed. 6.0 Amendment 1 - Household and similar electrical appliances - Safety - Part 2-3: Particular requirements for electric irons

IEC 60335-2-34:2012/AMD1:2015/COR1:2015 Corrigendum 1 - Amendment 1 - Household and similar electrical appliances - Safety - Part 2-34: Particular requirements for motor-compressors

IEC 60335-2-54:2008/AMD1:2015 Amendment 1 - Household and similar electrical appliances - Safety - Part 2-54: Particular requirements for surface-cleaning appliances for household use employing liquids or steam

IEC 60335-2-90:2015 Household and similar electrical appliances - Safety - Part 2-90: Particular requirements for commercial microwave ovens

IEC 60364-4-44:2007/AMD1:2015 Amendment 1 - Low-voltage electrical installations - Part 4-44: Protection for safety - Protection against voltage disturbances and electromagnetic disturbances

IEC 60601-2-33:2010/AMD2:2015 Amendment 2 - Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and

essential performance of magnetic resonance equipment for medical diagnosis

IEC 60601-2-37:2007/AMD1:2015 Amendment 1 - Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

IEC 60601-2-45:2011/AMD1:2015 Amendment 1 - Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices

IEC 60601-2-66:2015 Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems

IEC 61000-4-6:2013/COR1:2015 Corrigendum 1 - Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields

IEC 61643-22:2015 Low-voltage surge protective devices - Part 22: Surge protective devices connected to telecommunications and signalling networks - Selection and application principles

IEC 62061:2005/AMD2:2015 Amendment 2 - Safety of machinery - Functional safety of safety-related electrical, electronic and programmable electronic control systems

IEC 62304:2006/AMD1:2015 Amendment 1 - Medical device software - Software life cycle processes

IEC 62321-6:2015 Determination of certain substances in electrotechnical products - Part 6: Polybrominated biphenyls and polybrominated diphenyl ethers in polymers by gas chromatography-mass spectrometry (GC-MS)

IEC 62321-7-1:2015 Determination of certain substances in electrotechnical products - Part 7-1: Hexavalent chromium - Presence of hexavalent chromium (Cr(VI)) in colourless and coloured corrosion-protected coatings on metals by the colorimetric method

IEC 62471-5:2015 Photobiological safety of lamps and lamp systems - Part 5: Image projectors

IEC 62560:2011/AMD1:2015/COR1:2015 Corrigendum 1 - Amendment 1 - Self-ballasted LED-lamps for general lighting services by voltages >50 V - Safety specifications

IEC 62841-2-14:2015 Electric motor-operated hand-held tools, transportable tools and lawn and garden machinery - Safety - Part 2-14: Particular requirements for hand-held planers

IEC 80601-2-71:2015 Medical electrical equipment - Part 2-71: Particular requirements for the basic safety and essential performance of functional near-infrared spectroscopy (NIRS) equipment

IECEE TRF 32:2015 This Test Report applies to: IEC CISPR32: 2015 (Second Edition)

IECEE TRF 60335-1:2015 This Test Report applies to: IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-10:2015 This Test Report applies to: IEC 60335 2 10:2002 (Fifth edition) + A1:2008 in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-101:2015 This Test Report applies to: IEC 60335-2-101:2002 (First Edition) + A1: 2008 + A2:2014 in conjunction with IEC 60335-1 2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-13,15:2015 This Test Report applies to: IEC 60335 2-13:2009 (Sixth Edition) & IEC 60335-2-15:2012 (Sixth Edition) in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-13:2015 This Test Report applies to: IEC 60335 2-13:2009 (Sixth Edition) in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-14,15:2015 This Test Report applies to: IEC 60335-2-14:2006 (Fifth Edition) + A1:2008 + A2:2012 and IEC 60335 2 15:2012 (Sixth Edition) in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-14:2015 This Test Report applies to: IEC 60335-2-14:2006 (Fifth Edition) + A1:2008 + A2:2012 used in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-16:2015 This Test Report applies to: IEC 60335-2-16 (Fifth Edition) + A1: 2008 + A2 :2011 in conjunction with IEC 60335-1 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-17:2015 This Test Report applies to: IEC 60335-2-17:2002 (Second Edition) + A1:2006 + A2:2008 used in conjunction with IEC 60335-1:2010 (Fifth Edition) + A1:2013

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IECEE TRF 60335-2-2,54:2015 This Test Report applies to: IEC 60335-2-2: 2009 (Sixth Edition) + A1:2012 ; IEC 60335-2-54:2008 (Fourth Edition) in conjunction with IEC 60335-1:2010 (Fifth Edition) (incl. Corrigendum 1:2010) + A1:2013

IECEE TRF 60335-2-23:2015 This Test Report applies to: IEC 60335-2-23:2003 (Fifth Edition) incl. Corr.2:2008 + A1:2008 + A2:2012 in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-25:2015 This Test Report applies to: IEC 60335-2-25: 2012 (Sixth edition) with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-27:2015 This Test Report applies to: IEC 60335-2-27:2009 (Fifth Edition) + A1:2012 in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-29:2015 This Test Report applies to: IEC 60335-2-29:2002 (Fourth Edition) +A1:2004 +A2:2009 for use in conjunction with IEC 60335-1:2010 (Fifth Edition) +A1:2013

IECEE TRF 60335-2-3,54:2015 This Test Report applies to: IEC 60335-2-3:2002 (Fifth Edition) + A1:2004 +A2:2008 and IEC 60335 2 85:2002 (Second edition) + A1:2008 in conjunction with IEC 60335-1:2010 (Fifth Edition) + A1:2013

IECEE TRF 60335-2-3,85:2015 This Test Report applies to: IEC 60335-2-3:2002 (Fifth Edition) + A1:2004 +A2:2008 and IEC 60335 2 85:2002 (Second edition) + A1:2008 in conjunction with IEC 60335-1:2010 (Fifth Edition) + A1:2013

IECEE TRF 60335-2-30,80:2015 This Test Report applies to: Safety of household and similar electrical appliances Safety -Part 2-30: Particular requirements for room heaters Part 2-80: Particular requirements for fans

IECEE TRF 60335-2-32:2015 This Test Report applies to: IEC 60335-2-32:2002 (Fourth edition) + A1:2008 + A2:2013 used in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-34:2015 This Test Report applies to: IEC 60335-2-34:2012 (Fifth Edition) + A1:2015 in conjunction with IEC 60335-1:2010 (Fifth Edition) + A1:2013

IECEE TRF 60335-2-35:2015 This Test Report applies to: IEC 60335-2-35:2012 (Fifth Edition) in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-36:2015 This Test Report applies to: IEC 60335-2-36:2002 (Fifth Edition) + A1:2004 + A2:2008 in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013 incl. Corr. 1:2014

IECEE TRF 60335-2-37:2015 This Test Report applies to: IEC 60335-2-37: 2002 (Fifth Edition)) + A1:2008 + A2:2011 in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013 incl. Corr. 1:2014

IECEE TRF 60335-2-38:2015 This Test Report applies to: IEC 60335-2-38:2002 (Fifth Edition) + A1:2008 in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013 incl. Corr. 1:2014

IECEE TRF 60335-2-39:2015 This Test Report applies to: IEC 60335-2-39 (Fifth Edition): 2002 + A1:2004 + A2:2008 in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013 incl. Corr. 1:2014

IECEE TRF 60335-2-4,7:2015 This Test Report applies to: IEC 60335-2-4:2008 (Sixth Edition) +A1:2012 and IEC 60335-2-7:2008 (Seventh Edition) + A1 :2011 in conjunction with IEC 60335-1:2010 (Fifth Edition)) incl. Corrigendum 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-4:2015 This Test Report applies to: IEC 60335-2-4:2008 (Sixth Edition) + A1:2012 used in conjunction with: IEC 60335-1:2010 (Fifth Edition) + A1:2013

IECEE TRF 60335-2-41:2015 This Test Report applies to: IEC 60335-2-41:2012 (Fourth Edition) in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-42:2015 This Test Report applies to: IEC 60335 2 42:2002 (Fifth Edition) + A1:2008 in conjunction with IEC 60335 1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-43:2015 This Test Report applies to: IEC 60335-2-43:2002 (Third edition) + A1:2006 + A2:2008 used in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-45:2015 This Test Report applies to: IEC 60335-2-45:2002 (Third edition) + A1:2008 + A2: 2011 used in conjunction with IEC 60335-1:2010 (Fifth Edition) including Corr. 1:2010 and Corr. 2:2011 + A1:2013

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Legal Column

Dr. Susanne Wende

RAPEX System - What is it about?

With Decision 2010/15/EU, the European Commission launched the “Guidelines for the Management of the Community Rapid Information System RAPEX.” The RAPEX system is supposed to enable the market surveillance authorities of the member states to swiftly exchange information in regard to unsafe consumer products and actions to be taken to reduce the risk. Manufacturers, importers and dealers sometimes wonder what this RAPEX-system is all about – specifically because also non-serious risks and b2b-products have recently been published in the weekly RAPEX Reports.

A. RAPEX as information system

As the name states, RAPEX was intended mainly as a rapid information system. It still has this function today: Market surveillance authorities of the single EU Member states electronically exchange information on (potential) product risks with each other and with the European Commission. Member States are obliged to use this system if they are aware of a serious product risk or if they take measures which restrict placing consumer products onto the market (Art. 11, 12 General Product Safety Directive 2001/95/EC).

By now, the evolving system of European product compliance law prescribes additional information duties of market surveillance authorities to-wards each other and towards the European Commission. It can be seen that the RAPEX-System is used for these purposes as well. This is of relevance for economic operators because information shared within the RAPEX-System might lead to a publication in the weekly RAPEX Report.

B. Weekly RAPEX Reports

The second important aspect of RAPEX is the weekly RAPEX Report (accessible under <http://ec.europa.eu/consumers/safety/rapex/alerts/main/index.cfm?event=main.listNotifications>). Every consumer and consumer associations can see the consumer products published in the weekly RAPEX Reports issued by the European Commission. The full name, the brand, the safety problem and, in most cases, a picture of the product in question are visible.

According to Art. 12 General Product Safety Directive 2001/95/EC, only “serious risks” of consumer products

PSEN includes a regular column on product compliance from the European perspective. The column is provided by Noerr LLP’s Product Compliance Team. This column discusses the RAPEX system used in the European Union for market surveillance with regard to unsafe consumer products.

were to be published in these Reports. With the so called New Legislative framework, however, the responsibility of market surveillance authorities and of the European Commission to publish product risks has been expanded. According to Art. 22 et seqq. Regulation (EC) No. 765/2008, the exchange of information is not limited to serious risks and consumer products anymore. As a consequence, non-serious risks of b2c- and b2b-products are actually published in the weekly RAPEX Reports. As legal remedies against an existing publication are very difficult and tedious, economic operators should try to prevent a RAPEX notification in the first place. This is a challenge subject to legal argumentation.

C. RAPEX Risk assessment

As stated above, the classification of a product risk has an impact on information and publication activities of EU Member States and the European Commission. The classification of a product risk also affects the corrective action to be taken by the manufacturer to reduce such risk. According to Art. 20 of Regulation (EC) No. 765/2008, a serious risk generally calls for recall or withdrawal of the product from the market – i.e. from the consumer. The decision of the market surveillance authority whether or not a product presents a serious risk shall be based on an appropriate risk assessment. Part IV.5 of Decision 2010/15/EC (hereinafter referred to as “Guidelines”) defines a very detailed and quite complex method for the assessment of product risks. It is enormously important for economic operators (mainly manufacturers but also importers and dealers) to be familiar with the method of risk assessment provided in these guidelines. Using the risk assessment

method as described in the Guidelines makes it possible to provide an internal risk assessment to the market surveillance authorities, which has a good chance of being accepted as correct and reasonable. The guidelines explain the method of risk assessment in No. 2.2. Following this explanation, the risk assessor sets up one or several injury scenarios, determines the probability of the happening of the injury scenario and thus finds the risk level.

I. Setup of Injury Scenarios

The starting point of such risk assessment is the set-up of injury scenarios. An injury scenario describes the individual steps that are necessary for the product risk to result in a personal injury. The guidelines explicitly point out the ways to set up different injury scenarios and advise that different in-jury scenarios be set up (if possible) to be able to take into account different aspects influencing the risk assessment.

II. Different Users

The risk level found to be appropriate for a specific product may, according to the guidelines, significantly be affected by the behavior and the abilities of the consumer using the product. Table 1 of the guidelines shows different categories of consumers - "very vulnerable consumers" (e.g. children up to 36 months), "vulnerable consumers" (e.g. children younger than 14 years or persons with reduced physical, sensory or mental capabilities) and "other consumers" (all other consumers).

The risk assessor also has to take into account consumers who might not use the product themselves but might be exposed to a product risk as innocent bystanders. The guidelines, however, also narrow the huge scope of persons to be considered in regard to some aspects.

III. Typical Injury Scenarios

The guidelines also provide a framework for setting up injury scenarios, which may be used as a solid basis. This basis can be used to fit the special-ties of every product into the risk assessment:

No. 3.4 of the guidelines gives an example for a typical injury scenario consisting of three main steps. The first step is the defect of the product or the fact that a product might lead to a hazardous situation during its lifetime. As a second step, an accident occurs (caused by the defective product or the hazardous situation). The third step describes how the accident would result in an injury.

These three steps can be subdivided into further steps. The more steps an in-jury scenario has, the lower will the overall probability of the injury scenario be because the probabilities of each of the steps are multiplied by each other in order to find the overall probability of the injury

scenario.

The guidelines provide in Table 2 examples of typical injury scenarios for different hazard groups.

IV. Probability of the Injury Scenario

The probability of the injury scenario is found by multiplying the probabilities of the individual steps. Determining a probability for every single step might be difficult if statistical data is not available. The risk assessor might find some guidance in facts and figures collected in regard to the specific or a comparable product (especially in the course of the internal product monitoring).

According to No. 2.1 of the guidelines, the proper use of the product has to be taken into account. This will generally reduce the probability of an injury. Additionally, the foreseeable lifetime of the product has to be taken into account, though it is often difficult to determine the lifetime of a product and its (possibly changing) behavior during this time.

An important aspect in this regard is the failure of an old product due to worn-out parts. The phenomenon of aging products involves many uncertain aspects. The risk assessor must, therefore, often revert to realistic estimation. The plausibility of such estimation might be reassessed in the sensitivity analysis according to No. 6.3 of the guidelines.

The purpose of the sensitivity analysis is to establish how much the risk level varies when the estimated factors vary. The sensitivity analysis works as follows: The risk assessment for a certain scenario is repeated but with a different probability for one or more steps (which are particularly uncertain).

V. Determination of the Risk Level

According to Table 4 of the guidelines, the risk level is found by a combination of the probability of an injury during the foreseeable lifetime of the product and the severity of the possible injury. The guidelines provide four risk levels: "Low", "Medium", "High" and "Serious". As stated before, the category "Serious Risk" has specific relevance because it obliges the market surveillance authorities of EU Member States to order a product recall – which can be avoided by taking these measures voluntarily.

D. Evaluation

The RAPEX-System is a major tool of market surveillance in Europe as it is used for intra-authority communication as well as for publication activities. The publicly available weekly RAPEX Reports also contain non-serious risks and b2b-products even though originally only created for serious risks of b2c-products. The prevention of an unjustified RAPEX

publication is a legal challenge. It is, however, of essential importance because the publication in the weekly RAPEX Report shifts the control over risk assessment and potential corrective action from the manufacturer towards market surveillance authorities across the European Economic Area and – even worse – to views expressed via press and social media.

The third aspect of the RAPEX-System, the only method of risk assessment explicitly acknowledged by European product safety law, is an essential tool for economic operators to keep this control. The method of risk assessment allows very specific reaction to a product safety risk and its specific circumstances. Specifically, the assessment of different injury scenarios with their individual steps makes it possible to give a realistic, distinctive picture of the product and its behavior in the market. The European Commission provides

an online tool for the creation of a risk assessment. Inserting data into this tool does not, however, replace the good thinking through of the product risk and possible injury scenarios. As the tool is based on an online form, it does not give room for text explaining specific characteristics of the product and its use. It, therefore, does not replace a detailed risk assessment describing the product, its specific characteristics and giving reasons for the probabilities determined as necessary, especially in regard to technically complex product risks. If carefully drawn, the injury scenario shows very clearly if a product risk might result from the product itself or if different (mostly random) circumstances have to come together to make a personal injury possible. This will also be seen in the overall probability of the injury scenario.

DR. SUSANNE WENDE, LL.M.

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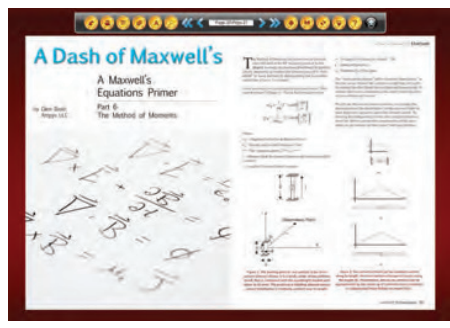
Noerr LLP is a European law firm founded in Germany with offices in Brussels, Alicante and various CEE-capitals. Noerr's Product Compliance Team advises its clients on all questions related to placing products onto the European market, defends them against complaints from European market surveillance authorities, and conducts product recalls.



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Physical body parameter calculations based upon electrical measurement

Peter E. Perkins

A common demonstration that is done to illustrate the effects of Touch Current on the body provides a line voltage, current limited supply that volunteers touch usually with a contact area on the order of 10 cm² or slightly more. The low current is limited to a maximum value of 0.5mA (a historical equipment limit called startle-reaction limit) or a high current value of 3.5mA (a common fault current limit approaching the let-go immobilization limit used in such standards as IEC 60950 or IEC 61010). Either of these currents is safe to touch, although the higher current is quite unpleasant to many people. Figure 1 shows the range of current experienced by a group of participants, comparing the low current value to the high current value. From this plot we can see the range of current applied to the group of persons and we then understand that the body resistance is variable from person to person, by almost a factor of two.

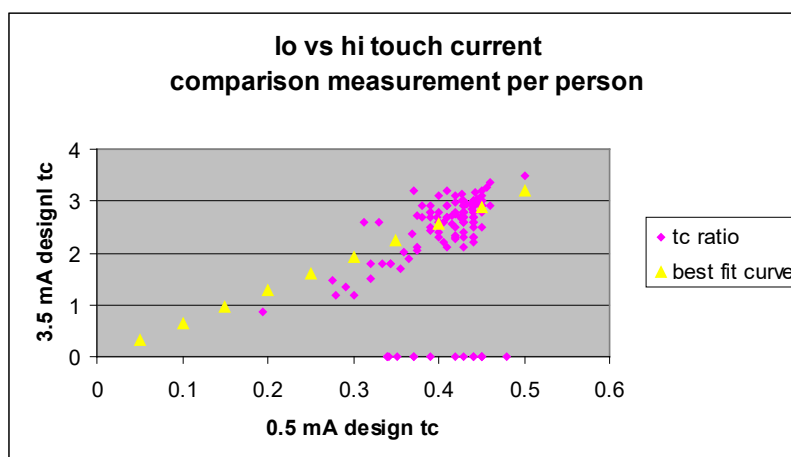


Figure 1: Current limited TC data

Human body model:

The IEC human body model used for electric shock testing is shown in Figure 2. This model combines the incoming and outgoing skin RCs into one element of 1500 ohms and 0.22uF with the internal body resistance of 500 ohms. This model, which is based upon the worst-case large area contact from left hand to both feet, has been used for more than 50 years by IEC safety standards and is accepted worldwide as the appropriate body model for electric shock evaluation; it is used in many IEC standards for determining adequacy of protection from electric shock in equipment. SPICE output shown in Figure 3.

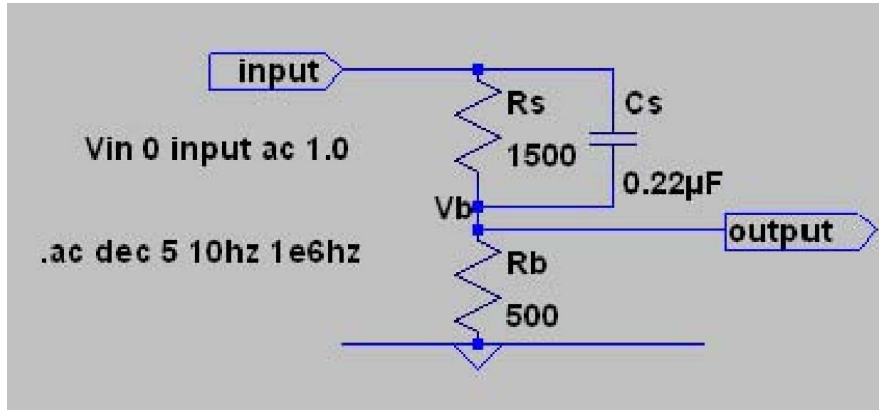


Figure 2: IEC 60479 human body model schematic
With SPICE input parameters shown

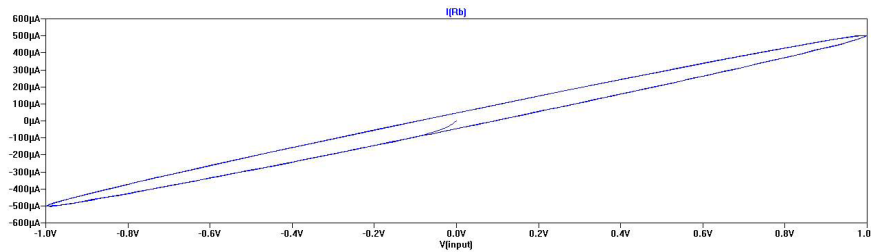


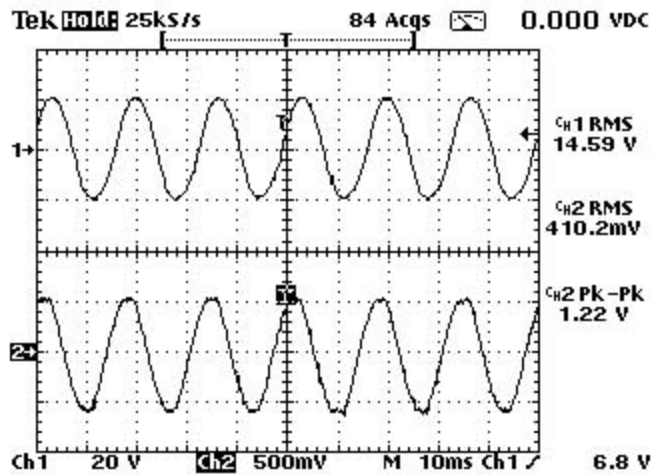
Figure 3: Body current, R_b , as a function of applied voltage
SPICE plot from the IEC 60479 body model analysis

Note the open oval due to the capacitance

From observation as to the reaction of the participants, it is surprising that any individual's reaction is not due to any specific level of current. Some folks seem to have a low pain tolerance and complain whether or not they draw a high TC (lower body impedance).

For the general constant current measurements discussed here the open circuit voltage is nominal 120Vac line voltage and the voltage will be reduced during the measurement to the value needed to drive the desired current in the circuit. For 3 specific subjects discussed here for the 0.5mA mode and about 10cm² contact area the voltage/current settled to 14.6Vrms/0.41mArms, 23.9Vrms/0.39mArms and 33.1Vrms/0.36mArms in the last case.

One example is shown in the discussion that follows.



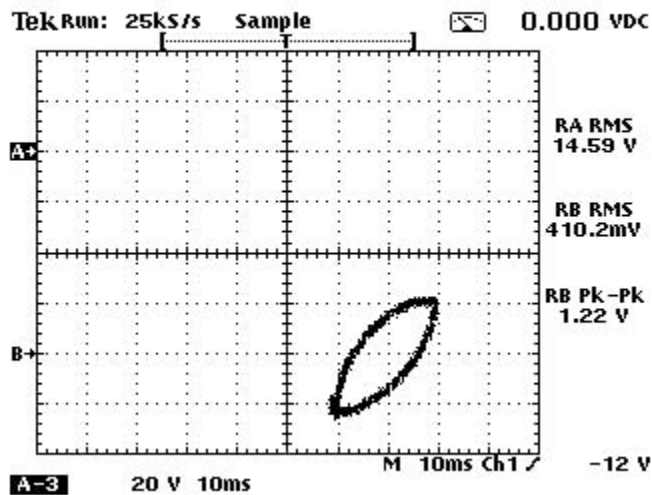
WaveStar - tc4amph : NotesSheet (1) P:

Figure 4: Typical TC YT waveforms

When these measurements are made the voltage and current curves are sinusoidal (or near sinusoidal) waveforms as shown in Figure 4 where the upper waveform CH 1 is the applied voltage and the lower waveform CH 2 is the voltage across the measurement resistor.

To see the phase relationship between the voltage and the current waveform an XY plot of the same data gives an oval describing this (Figure 5); note that the same digital V measurements show that this is the same data. This plot more distinctly provides the relationship between these waveforms.

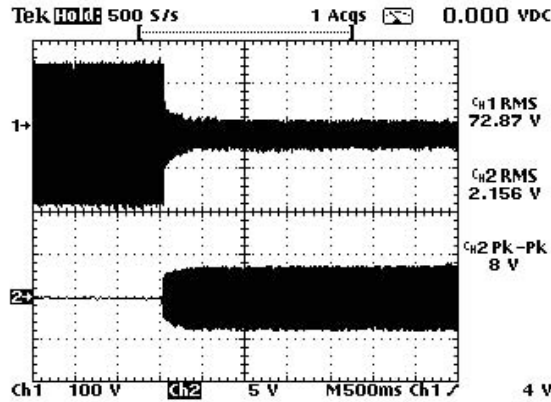
These XY or V-I plots have been seen before; they describe the actions of an RC circuit under applied AC voltage.



WaveStar - tc4amph : NotesSheet (2) P:

Figure 5: Typical TC XY waveform

Initial contact startup charging current:



WaveStar - t04apep3h-startup : NotesSheet(1)

Figure 6: Typical start-up charging current
This example for the 3.5mA mode

The current to the body takes a measurable time to settle down to the final value under these conditions. Figure 6 shows almost a half second to the stable value.

This settling-in time was not a principal measurement for the experimental work but was incidentally noted and captured during the measurements. When touch voltage is suddenly applied, the skin resistance takes some time to be adjusted to the final skin voltage. In IEC 61201 a time constant of 50 ms is expected for the charging of the skin resistance depending on the skin voltage which further depends on the touch voltage. This measurement seems to show a longer time for this to settle down.

V-I curves, historical review:

In the 1981 paper of Bridges low-voltage electric shocks were used to develop V-I curves which showed the body response as a function of voltage in the range of North American line voltage.

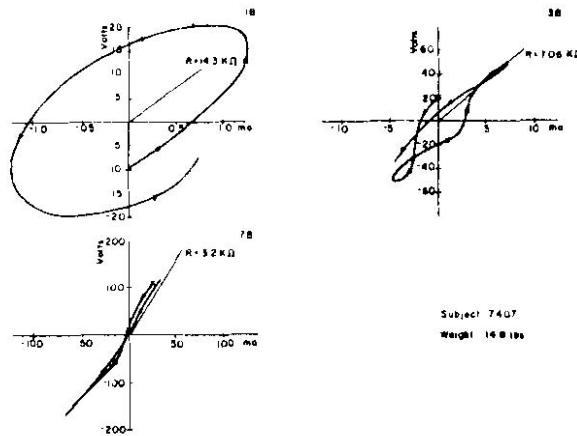


Figure 7 V-I CURVE, SHORT DURATION SHOCK TEST, DRY CYLINDER CLANPED IN HAND, SIMULTANEOUS ELECTRODE IN FOOT

Figure 7: V-I curves from Bridges;
(Bridges Figure 7. V-I curve, short duration electric shock test, normal saline wetted cylinder clasped in hand, subcutaneous foot electrode)

He also noted the observance of an initial charging spike during these tests; this spike was unexpected and not carefully measured but was discussed in some detail noting that this could affect the level of electric shock of the

subject.

The open oval shown in Figure 7 is due to body capacitance that collapses at higher voltage to form a resistance line. In the 1983 paper of Nute some discussion is given to determining parallel resistance and capacitance from a V-I display of electrical shock data, Figure 8.

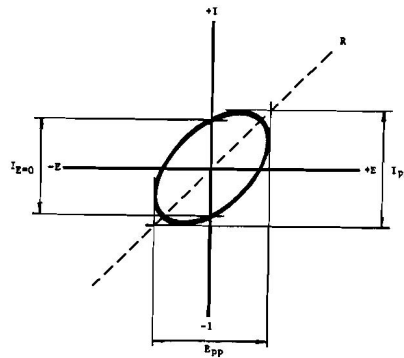


Fig. 1. Parameters of the X-Y display.

Figure 8: V-I analysis parameters from Nute

From these analyses it is clear that it should be possible to determine the parameters of the body model from direct measurements. This would be especially useful if this could be done in a way that provided specific R and C values for the body model that is normally considered.

Basic analysis:

Phasor analysis of the standard IEC 60479 body model was carried out. This involves calculating the complex values for the voltage and current in each element remembering that $Z = R + jX$ in each case; the RC elements then combine this with the body impedance, Z_b , to get an overall analytical model for the body circuit. This analysis determines the current carried by each element of the model under the specified input condition. The analysis was done in MathCad which handles the algebra nicely and provides numerical results of voltage and current for each component to as many significant digits as needed. See Appendix starting on page 32.

Proof of concept:

With all of this in hand it seems possible to take measured V & I information and work backward to the body model parameters. To check this out a SPICE analysis of the 479 body model using conditions defined as 33v@60Hz was run (which models the voltage from the measured constant current test setup for one case, Figure 9) then the data was analyzed as described above and the calculation of the skin R_s and C_s was done.

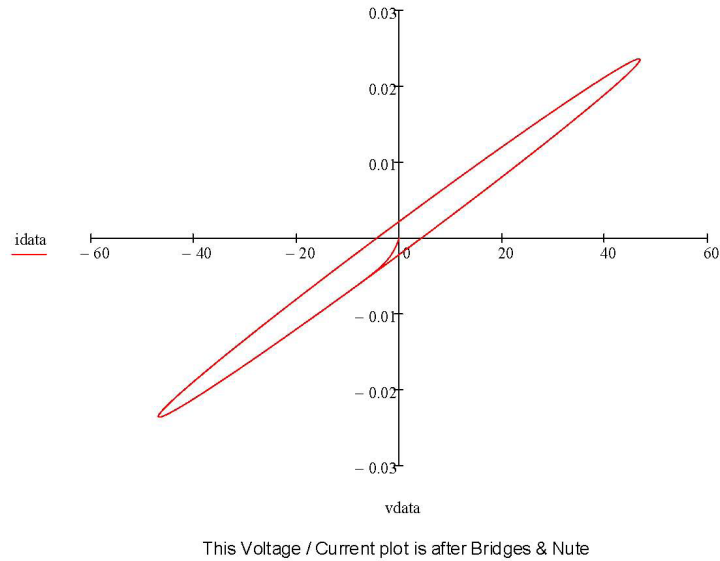


Figure 9: V-I curve for body model analysis

The oval shape is due to the skin capacitance in the model

The internal body resistance, R_b , was assumed to be 500 ohms. The skin resistance, R_s , was calculated to be 1477 ohms compared to the 1500 ohms in the model. The skin capacitance, C_s , was calculated to be 0.223 μF compared to 0.22 μF in the model. This method seems adequate for this analysis.

Body data analysis summarized:

Finally, real human data body data can analyzed in the same way to determine the body circuit parameters. Data taken under constant current conditions give the Figure 10. The measured body current under these conditions 0.35mA. The internal R_b is still assumed to be 500 ohms; the skin R_s is 77k ohms (51x the value in the standard model) and the skin C_s is calculated to be 0.024 μF (10% of the value in the standard model).

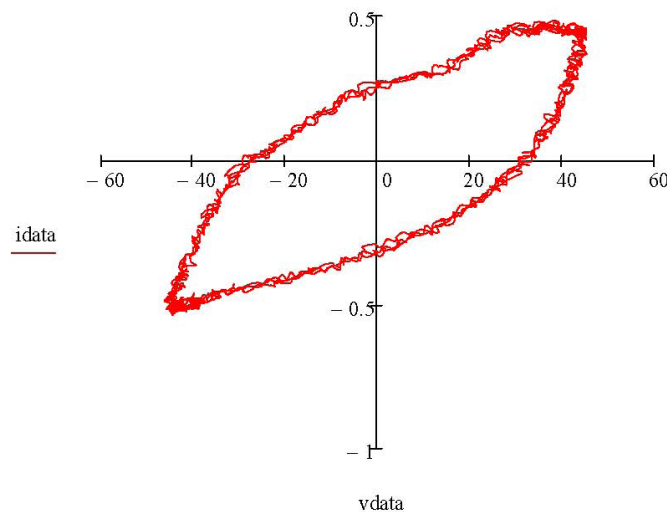


Figure 10: V-I curve from test data

The internal resistance needs to be specifically considered as an input to the analysis. It is clear from Bridges and from Prieto that the initial/internal resistance is lower than the steady state value. Bridges believes that it might be on the order of 200 ohms; Prieto shows values below 150 ohms for small areas - but either value, or the standard value of 500 ohms, is small compared to the 77k ohms calculated (and not significant, it appears, in the outcome based upon varying the Rb value along these lines).

Other waveform results.

An initial look at using this analysis under other conditions has been looked at cursorily.

The method seems to work adequately with sin wave input into the standard startle-reaction circuit of IEC 60990 Figure 4 ($R_s=1485$ ohms; $C_s=0.222$ uF).

The method seems to work adequately for triangular wave input (50Hz rep rate – $R_s=1400$ ohms; $C_s=0.229$ uF) but gives more anomalous results as the frequency is increased to 500 Hz (R_s decreases as expected; C_s goes to a minimum then increases again).

The direct measurement and the calculated results for the total body resistance gives the same result for a number of cases studied. Figure 11 compares the Rbt value calculated from the RMS input data to the analytical value, Rbody_calc, of body resistance calculated as discussed earlier. This shows a nice, linear relationship between the two sets of values. The same overall value is obtained by either measurement and confirms the validity of this analysis.

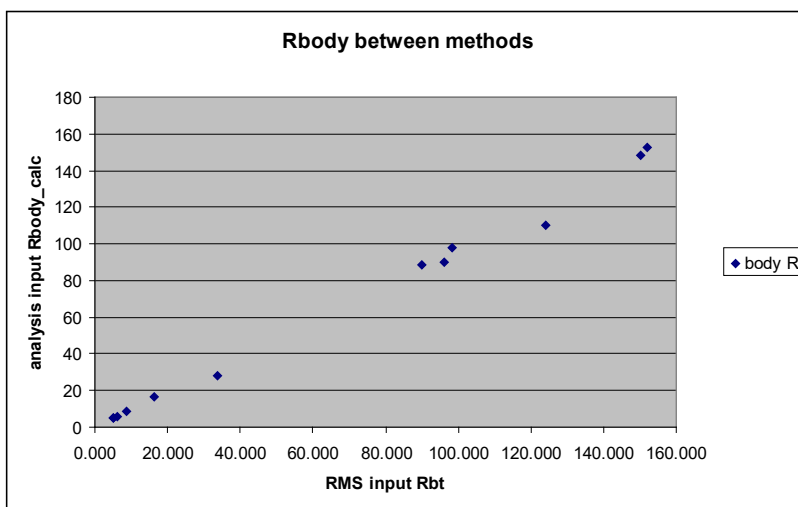


Figure 11: Body resistance, measurement vs calculated

Data taken under the usual constant current conditions shows the range of body parameters for separate persons. There is, as we noted in the beginning, person-to-person variation in impedance. Figure 12 shows this variation under conditions of contact area variation – forearm contact as well as finger-to-finger contact – a factor of more than 2x for the larger contact area and a factor of more than 3x for the smaller contact area.

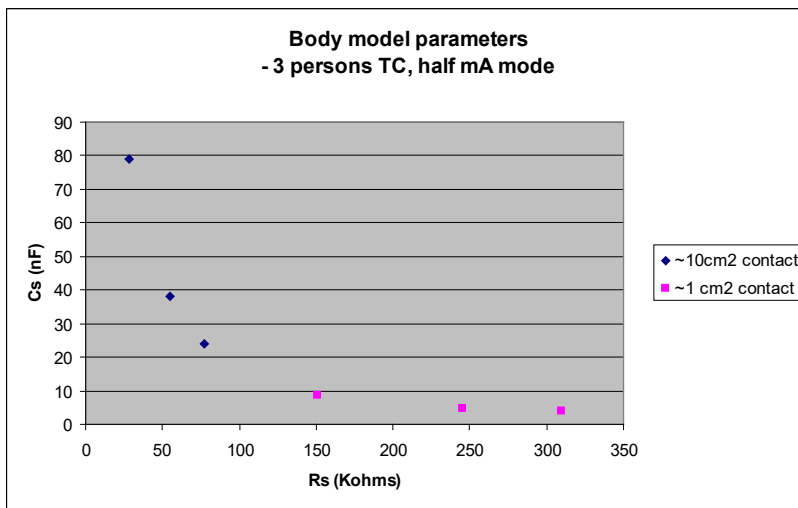


Figure 12: Variation between persons constant current TC measurement

For data taken on the constant current setup under variable voltage conditions, the body parameters as a function of voltage for each of the two levels is shown in Figure 13. This is data for one subject and is all over the map.

For data taken on the constant current setup under variable voltage conditions, the body parameters as a function of current for two levels is shown in Figure 14. This is for one subject. The skin parameters, Rs & Cs values, show an inverse relationship to one another.

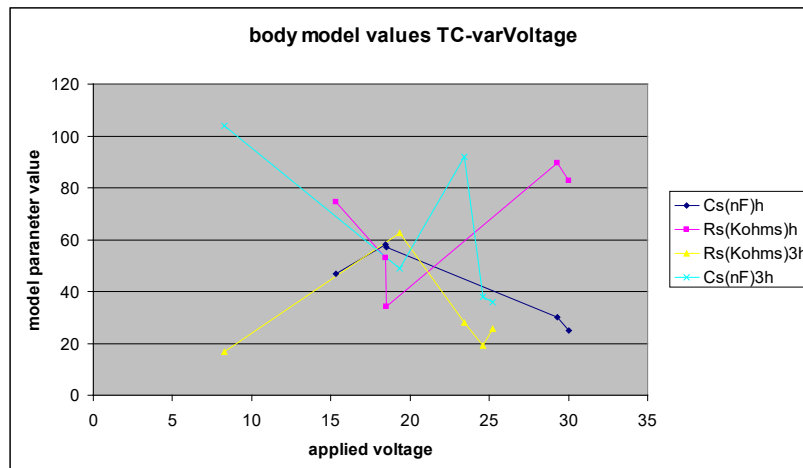


Figure 13: Body parameters as a function of voltage

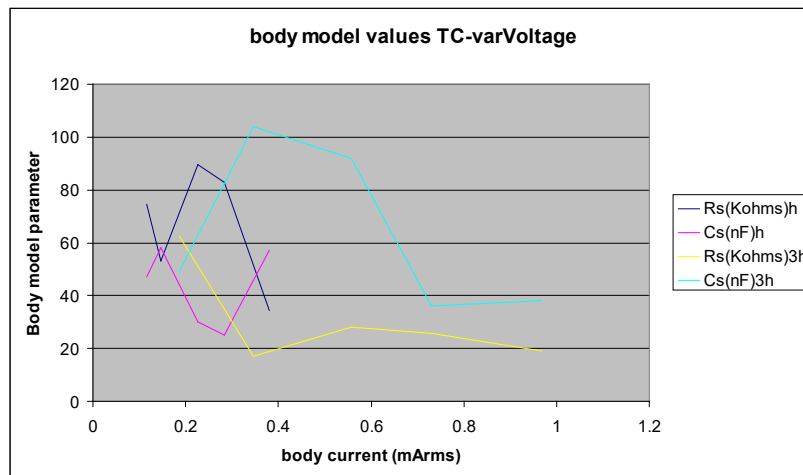


Figure 14: Body parameters as a function of current

When the data is taken under constant voltage conditions we see in Figure 14 the range of body parameters as both a variation between two subjects as well as a function of the applied voltage.

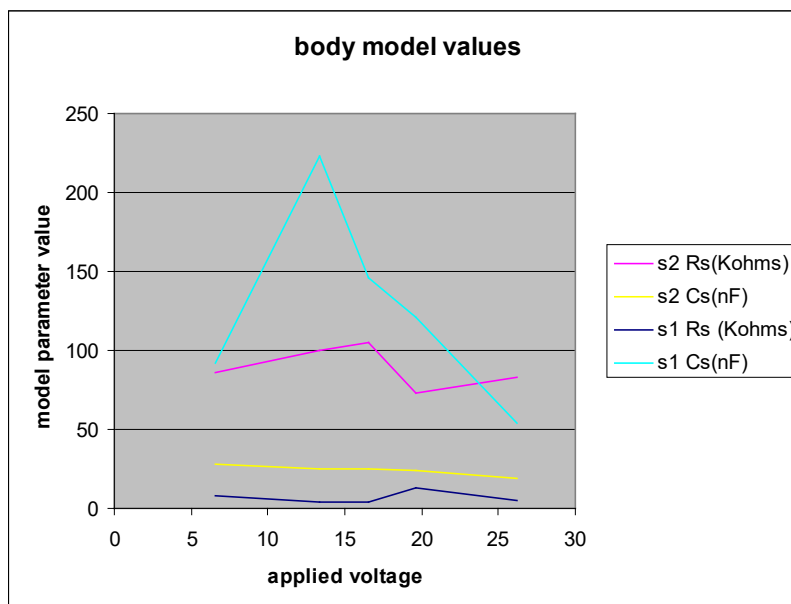


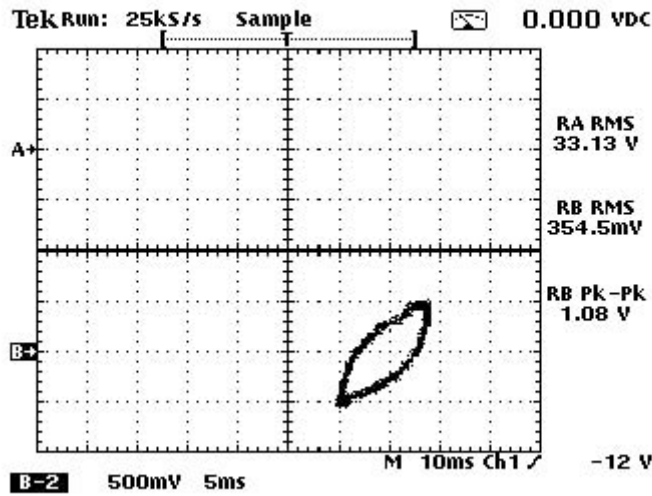
Figure 15: Body parameters as a function of applied voltage

Analysis of results; TC measurements

The earlier work had pointed to the significance of the VI plot in showing the influence of the skin capacitance. We have determined how to calculate the capacitance from the plots.

These plots were from a constant current source (open circuit voltage of 120V and short circuit current of 0.5mA max or 3.5mA max depending upon the case being run).

The plot of Figure 16 is a measurement at half mA TC and gives the usual oval plot. From this we can calculate the skin R_s of 77k ohms and the skin capacitance, C_s , as 0.024 μF . The applied voltage is 33V during this test, after settling down.



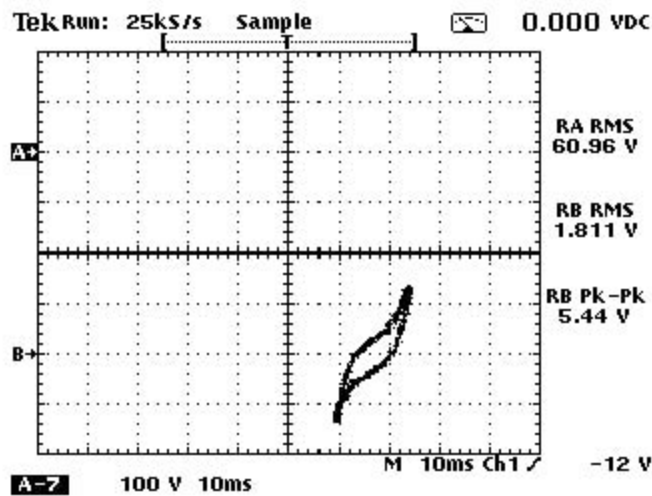
WavesStar - tchapeph : NotesSheet (2) Page

Figure 16: Touch Current V-I plot, half mA mode

The plot of Figure 17 is under the 3.5 mA conditions. The electrical interpretation is that the capacitance is collapsing and the plot will eventually become a straight resistance line. The applied voltage is 61V after settling down. From this we can calculate the skin R_s of 49.3K ohms and the skin capacitance, C_s , as 0.088uF.

The half mA calculation seems ok – it follows the pattern expected. These results can be explained and values given for the body model parameters – including a range from several subjects.

The 3.5mA data is more problematic. The ACrms resistance calculation is: $60.96V / 1.811mA = 33.67Kohms$; about half the value of the lower voltage / current calculation.



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Figure 17: Touch Current V-I plot, 3 1/2 mA

There is the further issue as to the interpretation of the data from a physiological point of view.

With this data, taken on the forearm, small red spots will develop as a result of the test. It is usually assumed that these conductive spots are related to natural breaks in the skin which would reduce its insulation properties – where hair follicles or sweat glands interrupt the skin.

Unfortunately, the data taken finger-to-finger shows the same collapse to resistance tendency – at a higher voltage even tho the finger does not have hair or sweat glands.

Summarizing all results:

This paper has demonstrated that the analysis method easily provides body parameter values according to the model analyzed.

Looking at all the test cases together, we see the results plotted in Figure 18.

Although there is quite a bit of variation across all the data, within the data it falls into smaller groups.

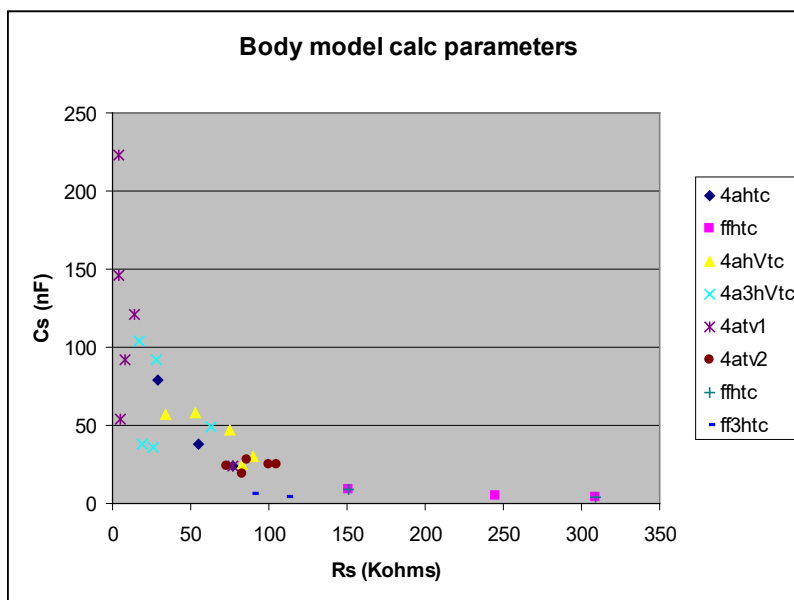


Figure 18: Summary of calculated Rs & Cs all cases

The standard body model uses a 2K ohm total body resistance. From these measurements we see that for a body contact area on the order of 10cm² this value is on the order of several 10's of Kohms and for a contact area on the order of 1cm² the body resistance is on the order of a couple of hundred Kohms.

The general conclusion that can be drawn is that the method will provide body model parameters directly by calculation from data taken on subjects under specific conditions of voltage, frequency, etc.

A much larger sample would give statistical detail to these results.

The explanation of the results relating to specific physiological body aspects will depend upon a more detailed analysis as to the electrical function of the body on a much smaller, or macroscopic, scale.

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See also IEC Human Body model Phasor analysis of ES body circuit, Appendix to Physical body parameter calculations starting on page 32 of this issue.

PETER E PERKINS

Peter E Perkins is convener of IEC TC108/WG5, which is responsible for IEC 60990, Measurement of touch current and protective conductor current, an IEC Basic Safety Publication. He is a Life, Senior member of IEEE, BS & MSEE and Principal in PE Perkins, PE. He has more than 50 years experience in the electronics industry, specializing in product safety and regulatory affairs for most of that time. He can be reached at p.perkins@ieee.org.



$$Z_{RCs} := \frac{1}{Y_{RCs}} \rightarrow 1499.99998387800138409226 \text{ } 0.1555088346812859491290i$$

$$Z_{RCs} = 1.5 \times 10^3 - 155.509j \times 10^{-3} \quad \text{ohms}$$

$$Z_{Rb} := 500 + j \cdot 0$$

$$Z_{body} := Z_{RCs} + Z_{Rb} \rightarrow 1999.99998387800138409226 \text{ } 0.1555088346812859491290i$$

$$Z_{body} = 2 \times 10^3 - 155.509j \times 10^{-3}$$

$$I_{body} := \frac{V_{input}}{Z_{body}} \rightarrow 0.00050000000100762492364871943.88772090620579314629162e$$

$$I_{body} = 500 \times 10^{-6} + 38.877j \times 10^{-9} \quad \text{Amps; } 0.5\text{mA}$$

$$\text{mag}I_{body} := \sqrt{\text{Re}(I_{body})^2 + \text{Im}(I_{body})^2} \rightarrow 0.00050000000251906230277331184i$$

$$\text{mag}I_{body} = 500 \times 10^{-6} \quad \text{amps, or } 3.5\text{mA}$$

The phasor angle for I_{body} is:

$$\Theta I_{body} := \text{atan}\left(\frac{\text{Im}(I_{body})}{\text{Re}(I_{body})}\right) \rightarrow 0.000077754417810726706360248679i$$

$$\Theta I_{body} = 77.754 \times 10^{-6} \quad \text{radians}$$

$$\Theta I_{body} = 4.455 \times 10^{-3} \cdot \text{deg}$$

The voltage drops are:

for the body resistor:

$$V_{Rb} := I_{body} \cdot Z_{Rb} \rightarrow 0.2500000005038124618243597 \text{ } 0.00001943860453102896573145i$$

$$V_{Rb} = 250 \times 10^{-3} + 19.439j \times 10^{-6} \quad \text{volts.}$$

$$\text{mag}V_{Rb} := \sqrt{\text{Re}(V_{Rb})^2 + \text{Im}(V_{Rb})^2} \rightarrow 0.25000000125953115138665592i$$

$$\text{mag}V_{Rb} = 250 \times 10^{-3} \quad \text{volts}$$

The phasor angle for V_{Rb} is:

$$\Theta V_{Rb} := \text{atan}\left(\frac{\text{Im}(V_{Rb})}{\text{Re}(V_{Rb})}\right) \rightarrow 0.000077754417810726706360248679i$$

$$\Theta V_{Rb} = 77.754 \times 10^{-6} \quad \text{radians}$$

$$\Theta V_{Rb} = 4.455 \times 10^{-3} \cdot \text{deg}$$

for the skin impedance:

$$V_{RCs} := I_{body} \cdot Z_{RCs} \rightarrow 0.749999999496187538175640313170.000019438604531028965731458099$$

$$V_{RCs} = 750 \times 10^{-3} - 19.439j \times 10^{-6} \quad \text{volts}$$

The current for the skin elements;

$$I_{Rs} := V_{RCs} \cdot Y_{Rs} \rightarrow 0.0004999999996641250254504268754466671.295906968735264382097206654e$$

$$I_{Rs} = 500 \times 10^{-6} - 12.959j \times 10^{-9} \quad \text{amps.}$$

$$I_{Cs} := V_{RCs} \cdot Y_{Cs} \rightarrow 1.34349989819579318559308335157413e-125.18362787494105752839532728435369j$$

$$I_{Cs} = 1.343 \times 10^{-12} + 51.836j \times 10^{-9}$$

The current is carried by the resistors in the circuit at line frequency.

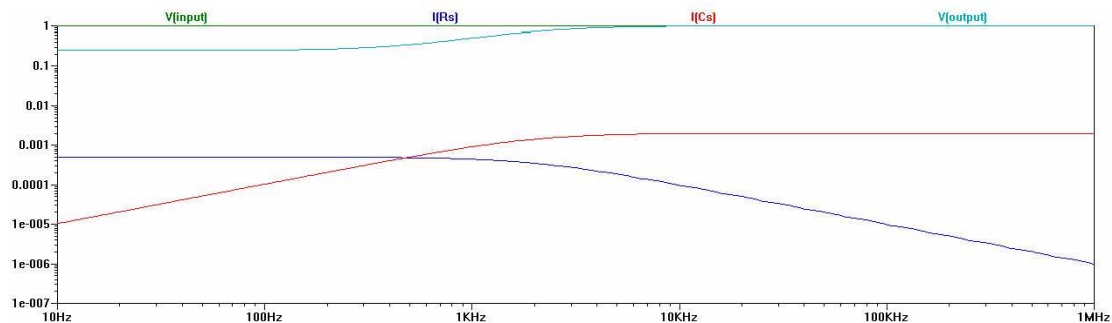


Figure 2: Skin resistance current and skin capacitance current as a function of frequency
a SPICE plot from the circuit shown in Figure 1



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