Volume 11, No 2

PRODUCT SAFETY ENGINEERING NEWSLETTER

What's Inside

President's Message

I hope many of you were able to attend the symposium this year! I was there and it was a great event as usual with many good technical presentations and papers, a great turnout of exhibitors and ample opportunity for networking. The call for papers for our 2016 Symposium has already been published (see page 6) and I hope to see many of you next year in Orange County California.

As I mentioned at the symposium, the Board of Directors has been busy. For current members of the board, please see us at http://www.ieee-pses.org/bod.html. As usual, we had a face-to-face board meeting the day before the Symposium (see picture on page 34 of this newsletter) and were able to continue our management of the Society with exciting new activities. We will start including highlights of our meetings in the newsletter moving forward and I encourage you to get involved as a board member or on one of our many committees.

As with most organizations, we have developed a strategic plan that we have recently adopted and will use to focus our resources. Some of the results of that plan have already been demonstrated in our new website and membership materials that you may have seen at the symposium.

There are some additional developments that you will see in the coming months/years as well. These will include additional conference type events. Our symposium in May will continue to be our flagship event. Additionally, we will be introducing other, smaller, regional workshop type events in other locations within the US and internationally to provide more access to all our members. We don't expect this to take away from our flagship symposium, but instead allow for more members and potential members to get involved with the PSES. Stefan Mozar will be taking the lead on these activities with a Conference Committee he is forming – please contact Stefan if you are interested.

We will also be developing our publications activities more as well. You will see some changes in the newsletter and additional technical articles from the PSES in the CE Society Magazine (that all PSES Members receive as an added benefit). Additionally we will begin efforts to develop formal PSES Transactions that will be published in Xplore – this is a longer process that requires approval within the IEEE, but we are beginning the process. To facilitate these advances in our publications, we will be establishing an Editorial Committee to develop and ensure a steady flow of content. Please contact Stefan Mozar if you are interested in joining the Editorial Committee.

We have a new Chapters Coordinator as well and one of the first priorities will be to set up our Virtual Chapter we have been discussing – watch out for an upcoming announcement.

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

The Product Safety Engineering Newsletter is published quarterly during the last month of each calendar quarter. Closing dates for articles, news items, and advertising:

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

Long Island

Long Island PSC Hosts Two Technical Meetings

The Long Island CAS recently hosted two enlightening technical meetings.

In April Frank O'Brien from OBCM presented Risk Acceptability. Medical device manufacturers are required to conduct risk management in accordance with ISO 14971 and IEC 60601. After a brief review of the overall risk management process, this presentation focuses on risk evaluation. FDA and EU guidance speak to the need that risk be reduced as low as possible, consistent with generally acknowledged state-of-the-art and international standards, which take into account economic and technological constraints. The future evolution of risk acceptability as technology advances, is also discussed.

In May Shane Filer from Neal Systems presented Electrical Instruments in Hazardous Locations. The four primary electrical protection methods are explosion proof, intrinsic safety, purging, and non-incendive. Guidelines for the use of each of these protection methods are reviewed in addition to typical applications found in hazardous locations. Factors driving solutions and optimizing solutions for a given applications are outlined. Finally, the strengths and weaknesses to be considered when designing, installing, or maintaining each system type are summarized.

For more information about these lectures and the Long Island PSE Chapter visit http://www.ieee.li/safety/index.htm.

James Colotti, PSE Chair, IEEE Long Island Section

Northern NJ Section Chapter Kickoff

The joint PSES/EMCS chapter has formed in northern New Jersey. The first meeting was a technical presentation by Professor David Larrabee from East Stroudsburg University. He presented work his students have done in the construction and operation of a reverberation chamber at ESU. He has involved undergraduates in this work and they really enjoy the metal bending and machining; it seems to make the theory go down a little easier. Professor Larrabee teaches in the physics department.

http://sites.ieee.org/northjersey/chapter/emc-pses/
Dan Roman, PSES/EMCS Chair, NNJ Section
dan.roman@ieee.org

India

The India PSES chapter in the Madras Section is reforming after a period of inactivity. V. Jayaprakasan, Professor/ECE in Ganaidpathy Tulsi's Jain Engineering College, Vellore, Tamilnadu, India is the new Chapter Chair.

He has a plan to organize IEEE Student Branch Counselors and try to encourage those counselors to initiate a PSES chapter in their respective institutions.

Please contact Mr. Jayaprakasan at jprakasan@gmail.com if interested.

CHAPTERS - WE NEED YOUR NEWS!

Telecom Safety TAC

The group has been discussing draft IEC Standards and activity from the TC108 Meeting in Northbrook, IL. IEC 60950-22 CDV – Batteries, DC surge voltage of 1.5 kV. Edition 2 has passed. It has ventilation requirements in it, particularly the use of tubes, and addresses mechanical dampers in the worst position. IEC standard says if have VRLA or NiCd batteries, then assume you have boost charge, unless you can show otherwise. Boost charge phase requires 8 times the ventilation as non-boost charge. Not much mentioned about the DC surge voltage.

The group is also discussing the RFT standard –IEC 62368-3.

For any powering external circuit. For USB or POE, should comply with ES1 or ES2. Issue: A note was added underneath the definition saying communications on RFT don't need to be present. We've identified 18 issues where there's a problem. A proposal has been made to allow lines with power but no signal. That was accepted. The standards that cover RFT-V are used primarily in North America. Asked to bring the D3 deviations into the standard, which was accepted in principal. If no one complains, those will stay in the standard.

Further discussion around adding POE and RFT to the Scope is ongoing.

Al Martin is leading a discussion on the protection of DC feeds to radio equipment at the top of towers. This is an issue that has a lot of interest with outdoor wireless installations. Topics being discussed include:

a. What protection is typically installed on equipment that will be located at the top of towers, and is any consideration given to the height of the tower?

b. What lightning waveshape is considered when designing protection for equipment to be located at tower tops?

c. Is there any information about the failure of installed protection to protect equipment located at tower tops?

Mick Maytum updated the group on K.50 Updates to Voltage environment Classifications. At a recent ITU-T SG5 WP1 , Mick presented a comparison of IEC 60950-1 and IEC 62368-1 terms as ITU-T Recommendation K.50 needs to bridge the past and future equipment standards. K.50 is based on IEC60950-1. The group is discussing the need to provide a bridge to IEC62368.

Paul Ng reported on SC22E United States technical committee on stabilized power supplies. ANSI and UL have agreed to reinstate the SC22E United States technical committee on stabilized power supplies. Kevin Ravo is the committee secretary. This is relevant to the telecom audience since telecom centralized dc mains power distribution requirements from UL1801 (QPQY)/ IEC61204-7 1st Edition have been ported over to the IEC61204-7 2nd Edition. Bulk power – UL60950 going away is causing all kinds of problems. The industry doesn't want to use UL62368 - use UL62477 instead. UL DEMCO added an annex for bulk power. The TAG for this is for SC22e, not TC108. Voting on changes is in September.

The group is also discussing summation of touch currents requirements that have made their way from UL 1459 for PBXs to generically defined equipment in IEC 62368. Some background has been discussed and how to properly deal with the issue in IEC 62368 will be discussed in future meetings.

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!

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.

IEEE

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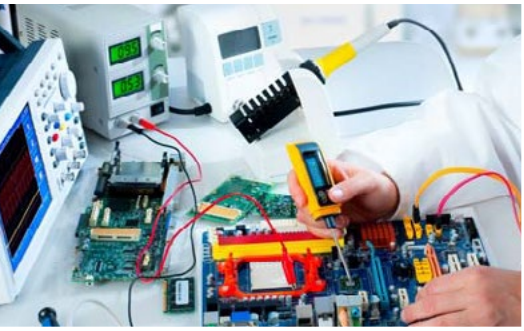

Annual Symposium

Meet the World Experts!

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- How-To Workshops
- Technical Committee meetings
- Publish & present ideas
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News and Notes

Compliance News Shorts

News To Know

RoHS News - Four phthalates have been added to the restricted substances listed in RoHS Annex II

On 4-Jun-2015 the European Directive (EU) 2015/863 was published and adds four phthalates to the EU RoHS Directive 2011/65/EU. The new substances are Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP). All four are also listed as substances of very high concern (SVHC) under REACH.

The amendment also makes clear that the restriction of DEHP, BBP and DBP does not apply to toys, which are already subject to the restriction of DEHP, BBP and DBP through entry 51 of Annex XVII to Regulation (EC) No.1907/2006.

These four substances can have a negative impact on recycling, the environment, and on human health during waste management and recycling operations. Phthalates are primarily used as plasticizers in plastics. Soft PVC is a common use for phthalates and can be found in wires and cables and also some electronic components or plastic parts.

The new full list of restricted substances under RoHS and their concentration limits at the homogeneous level are 0.1 % weight by weight for Lead (Pb), Mercury (Hg), Hexavalent chromium (Cr VI), Polybrominated biphenyls (PBB), Polybrominated diphenyl ethers (PBDE), Bis (2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), and Diisobutyl phthalate (DIBP) and 0.01% weight by weight for Cadmium (Cd).

The new restrictions for phthalates take effect on 22-Jul-2019 for all electronic and electric equipment covered by RoHS except for medical devices and monitoring and control instruments. These category 8 and 9 products have an additional 2 years to comply (until 22-Jul-2021).

Full text is available at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.137.01.0010.01.ENG.

Recently Published Standards

EN 50500:2008/A1:2015 - (3/6/2015) - Measurement procedures of magnetic field levels generated by electronic and electrical apparatus in the railway environment with respect to human exposure

EN 60730-2-5:2015 - (2/27/2015) - Automatic electrical controls - Part 2-5: Particular requirements for automatic electrical burner control systems

EN 61010-2-081:2015 - (3/20/2015) - Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

EN 62320-1:2015 - (2/27/2015) - Maritime navigation and radiocommunication equipment and systems - Automatic identification system (AIS) - Part 1: AIS Base Stations - Minimum operational and performance requirements, methods of testing and required test results

EN 62813:2015 - (2/20/2015) - Lithium ion capacitors for use in electric and electronic equipment - Test methods for electrical characteristics

IEC 60050-161:1990/AMD5:2015, Ed. 1.0 - (2/25/2015) - Amendment 5 - International Electrotechnical Vocabulary - Chapter 161: Electromagnetic compatibility

IEC 61010-2-051:2015, Ed. 3.0 - (3/10/2015) - Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-051: Particular requirements for laboratory equipment for mixing and stirring

IEC 62368-1:2014/COR1:2015, Ed. 2.0 - (2/24/2015) - Corrigendum 1 - Audio/video, information and communication technology equipment - Part

1: Safety requirements

IEC 62493:2015, Ed. 2.0 - (3/10/2015) - Assessment of lighting equipment related to human exposure to electromagnetic fields

ISO 80601-2-13:2011/AMD1:2015, Ed. 1.0 - (3/6/2015) - Amendment 1 - Medical electrical equipment -- Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

ISO/IEC 29197:2015, Ed. 1.0 - (3/17/2015) - Information technology -- Evaluation methodology for environmental influence in biometric system performance

EN 50121-1:2015 - (3/27/2015) - Railway applications - Electromagnetic compatibility - Part 1: General

EN 50121-3-1:2015 - (3/27/2015) - Railway applications - Electromagnetic compatibility - Part 3-1: Rolling stock - Train and complete vehicle

EN 50121-4:2015 - (3/27/2015) - Railway applications - Electromagnetic compatibility - Part 4: Emission and immunity of the signalling and telecommunications apparatus

EN 60079-10-2:2015 - (3/6/2015) - Explosive atmospheres - Part 10-2: Classification of areas - Explosive dust atmospheres

EN 60598-2-22:2014/AC:2015 - (3/5/2015) - Luminaires - Part 2-22: Particular requirements - Luminaires for emergency lighting

EN 60839-11-1:2013/AC:2015 - (2/27/2015) - Alarm and electronic security systems - Part 11-1: Electronic access control systems - System and components requirements

EN 62368-1:2014/AC:2015 - (2/24/2015) - Audio/video, information and communication technology equipment - Part 1: Safety requirements (IEC 62368-1:2014, modified)

IEC 60079-29-2:2015, Ed. 2.0 - (3/16/2015) - Explosive atmospheres - Part 29-2: Gas detectors - Selection, installation, use and maintenance of detectors for flammable gases and oxygen

IEC 60079-32-2:2015, Ed. 1.0 - (2/25/2015) - Explosive atmospheres - Part 32-2: Electrostatics hazards - Tests

IEC 60335-2-103:2015 Household and similar electrical appliances - Safety - Part 2-103: Particular requirements for drives for gates, doors and windows

IEC 60335-2-27:2009/AMD2:2015 Amendment 2 - Household and similar electrical appliances - Safety - Part 2-27: Particular requirements for appliances for skin exposure to optical radiation

IEC 60335-2-58:2002/AMD2:2015 Amendment 2 - Household and similar electrical appliances - Safety - Part 2-58: Particular requirements for commercial electric dishwashing machines

IEC 60335-2-81:2015, Ed. 3.0 - (4/9/2015) - Household and similar electrical appliances - Safety - Part 2-81: Particular requirements for foot warmers and heating mats

IEC 60519-1:2015, Ed. 5.0 - (3/10/2015) - Safety in installations for electroheating and electromagnetic processing - Part 1: General requirements

IEC 60601-2-52 ed1.1 (2015-03) Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds

IEC 60601-2-52-am1 ed1.0 (2015-03) Amendment 1 - Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds

IEC 60601-2-54:2009/AMD1:2015 Amendment 1 - Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy Safety

IEC 60669-2-1 ed4.2 (2015-03) Switches for household and similar fixed electrical installations - Part 2-1: Particular requirements - Electronic switches

IEC 60669-2-1-am2 ed4.0 (2015-03) Amendment 2 - Switches for household and similar fixed electrical installations - Part 2-1: Particular requirements - Electronic switches

IEC 60695-11-20:2015 Fire hazard testing - Part 11-20: Test flames - 500 W flame test method

IEC 60730-2-12:2015 Automatic electrical controls - Part 2-12: Particular requirements for electrically operated door locks

IEC 60730-2-6:2015 Automatic electrical controls - Part 2-6: Particular requirements for automatic electrical pressure sensing controls including mechanical requirements

IEC 61010-2-061:2015, Ed. 3.0 - (3/10/2015) - Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-061: Particular requirements for laboratory atomic spectrometers with thermal atomization and ionization

IEC 61496-1:2012/COR1:2015 Corrigendum 1 Safety of machinery - Electro-sensitive protective equipment - Part 1: General requirements and tests

IEC 62485-1:2015 Safety requirements for secondary batteries and battery installations - Part 1: General safety information

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

IEC TR 60601-4-3:2015, Ed. 1.0 - (4/13/2015) - Medical electrical equipment - Part 4-3: Guidance and interpretation - Considerations of unaddressed safety aspects in the third edition of IEC 60601-1 and proposals for new requirements

IEC TR 62921:2015, Ed. 1.0 - (2/24/2015) - Quantification methodology for greenhouse gas emissions for computers and monitor

IEC/TRF 60335-2-11 ed10.0 (2015-03) This Test Report applies to: IEC 60335-2-11: 2008 (Seventh Edition) + A1:2012 used in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IEC/TRF 60335-2-9,15 ed1.0 (2015-03) This Test Report applies to: IEC 60335-2-9:2008 (Sixth edition) + A1:2012 and IEC 60335-2-15:2012 (Sixth Edition) in conjunction with IEC 60335-1:2010 (Fifth Edition)

IECEE TRF 60335-2-6:2015 This Test Report applies to: IEC 60335-2-6:2014 (Sixth edition) in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60335-2-8:2015 This Test Report applies to: IEC 60335-2-8:2012 (Sixth Edition) in conjunction with IEC 60335-1:2010 (Fifth Edition) incl. Corr. 1:2010 and Corr. 2:2011 + A1:2013

IECEE TRF 60601-1-3:2015 This Test Report applies to: IEC 60601-1-3:2008 (Second Edition) + A1:2013 for use in conjunction with IEC 60601-1:2005 (Third Edition) + A1:2012

2015 ISPCE

ISPCE 2015 was a great success!! We had over 200 attendees, 32 exhibitors, and 62 presentations and papers. I received so many complements on the symposium in general and about the technical program. Compliance 101 was a hit with people new to compliance and the Panels were very well attended and real world issues and questions got answered by the best in the business!!

We also listened to the feedback from last year and many of the new features were greatly received.

- We now have Professional Development Hours (PDHs) for each presentation.
- We added a Compliance 101 track to help those new to compliance understand the basics
- We included transition time between presentations
- Many of the presentations and papers are transferring knowledge on compliance requirements for some of the latest technologies.
- We continue to have presentations updating us on Global Regulations
- We were able to get a draft program together before the early registration to make it easier for you to show your management the value of attending
- We extended the Symposium to 3 full days

The following Awards were presented:

Best Paper Winners: Tobias Lueddemann, Jonas Schiebl, Daniel Roppenecker, Franziska Klein, and Tim C. Lueth, all from Technical University of Munich for their paper, **"Towards a Logic-Based Extension of a Relational Software Tool for Coherent Technical Documentation of Medical Devices."**

IEEE PSES Appreciation Awards: Dan Roman, Doug Nix, Thomas Ha, Ivan van de Wege, Jan Swart, Juha Junkkarinen, Mike Nicholls, Paul Wang, Kevin Ravo, Charlie Bayhi, and Paul Herrick received.

IEEE PSES Recognition Awards: Art Henderson, Julia Ivanov, Khanh Luu, Conference Catalysts, and HP.

Chapter of the Year went to The Orange County Chapter.

Congrats to all! Be sure to get your nominations in to our Awards Committee (murlinm@ieee.org) for the 2016 awards!

I would like to thank everyone for attending with a special thanks to the committee for volunteering their time and making it a success and to Richard Georgerian our photographer. And a big thank you to all our exhibitors and sponsors – without you we don't have a symposium.

2016 ISPCE is already on its way with the first monthly meeting commencing June 23rd. Bansi Patel is the Chair and has a lot of exciting things coming. The call for Submissions is out and all information can be found in this newsletter on page 6 and on the website - http://2016.psessymposium.org/.

John Allen
2015 ISPCE Chairman


Fitness Wearable Devices


Surface Pro


PSES
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If you're not a part of the solution, there's good money to be made in prolonging the problem
IEEE


COMPLIANCE
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Legal Column

Dr. Boris Handorn

ECJ confirms liability for a mere potential defect in medical devices

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 a recent judgment by the European Court of Justice concerning the EU Product Liability Directive 85/374/EEC.

Can the mere suspicion of a product defect already be a defect for which the manufacturer is liable? The ECJ in a recent judgment concerning the EU Product Liability Directive has affirmed this as far as the costs for an operation to replace the defective product after a recall of the implants (judgment of 5 March 2015 – C-503/13 and C-504/13) are concerned. The ECJ therefore, under certain circumstances explained in more detail below, introduces no-fault liability for complete series of models and products. This leading decision will have considerable effects on the exposure of medical devices manufacturers and their EU importers to liability.

Background

The judgment of the ECJ is based on two requests of the German Federal Court of Justice (BGH) for preliminary rulings. Statutory health insurers had claimed against a distribution company of a US manufacturer of pacemakers and implantable cardioverter defibrillators (ICDs) for the costs of replacement operations.

The manufacturer had previously issued a warning. Internal quality controls had shown that possibly defective components in pacemakers and ICDs could – compared to similar production series – have a higher probability of failure. In the case of the pacemakers, the manufacturer recommended that replacement of the devices be considered. For the ICDs, in which a magnetic switch might remain stuck in the closed position, the manufacturer recommended that the magnetic switch be deactivated *in situ*. Following this information, patients, after consulting their doctors, decided on replacing the devices. The statutory health insurers thereupon demanded reimbursement for the costs of the replacement operation. The BGH took two of the many claims in Germany as the occasion for its decision to refer specific questions of interpretation regarding the European Product Liability Directive 85/374/EEC to the European Court of Justice (ECJ).

Legal background and questions referred by the BGH

The proceedings before the German courts concerned claims by the health insurers for reimbursement of the costs of fitting and removal according to Sec. 1 ss. 1 Product Liability Act (1990) which reads as follows:

"If due to a defect in a product, a person dies, is injured or his health is impaired or there is damage to an item of property, the producer of the product shall compensate the injured person for the damage which arises as a result thereof".

This Section of the German Product Liability Act implements the corresponding provision in the European Product Liability Directive 85/374/EEC into German law. The plaintiff bears the full burden of proof for the defect, the damage and the causal connection in each particular case according to Sec. 1 ss. 4 Product Liability Act (1990). In none of the proceedings had it been possible to prove the potential defect of the specific devices that, as is often the case in practice, were disposed of after the replacement operation and were no longer available for technical investigation. The health insurers therefore had no evidence of the *actual* product defect. This was the stringent judgment of the OLG Munich (judgment of 21 July 2009 – 18 U 1549/09), dismissing the claim in a case in which a possible manufacturing defect in a small number of pacemakers led to the recall of a product series of 26,000 devices. The OLG Hamm (judgment of 26 October 2010 – I-21 U 163/08) on the other hand found that a mere abstract probability of failure related to the entire product series was an adequate basis to assume a defect in each of the devices causing liability without evidently distinguishing between manufacturing and

design defects. Consequently, it would not be necessary to examine the device that actually has been implanted.

Since the Product Liability Act (1990) in Germany implements the European Product Liability Directive 85/374/EEC, the ECJ had jurisdiction for the interpretation of the Directive.

The judgment of the ECJ

The ECJ accepted the wider opinion of an *abstract concept of defect*. A medical device belonging to a group or production series of medical devices such as pacemakers and ICDs in which a potential defect has been ascertained, can itself be classified as defective. The defect does not need to be established in the product actually affected. If these products are replaced following a warning of the manufacturer (issued precisely because of a possible increased probability of failure), the manufacturer is liable for the costs of the necessary replacement operations since, according to the ECJ, the necessary operation constitutes damage in the meaning of the EU Product Liability Directive. Whether replacement operations were necessary in any particular case or whether the risk could have been otherwise averted, e.g. by the recommended deactivation of the magnetic function in the case of the ICDs, must now be decided by the national courts in each individual case.

In order to determine the level of safety which a person is entitled to expect from a product, the purpose, the objective characteristics and properties of the product in question must be taken into account as well as the special characteristics of the group of users for which it is intended. With regard to "medical devices" such as pacemakers and ICDs, the safety standards which the patients are entitled to expect due to their function and the particularly vulnerable situation of patients are particularly high.

The benchmark for these reasonable safety expectations therefore are the patients, not, for example, medical experts. This is not, however, compelling because precisely in case of implants, the communication of the manufacturer to users about e.g. purpose, symptoms and contra-indications, weighing of benefit and risk of therapy, is addressed to medical professionals. However, the BGH relied in the preliminary ruling application on patients who are entitled to expect "in principle a defect rate close to zero" (however unrealistic practical absolute safety from a technical point of view may be).

Outlook

Genuine or alleged scandals (PIP breast implants, MoM hip joints) receive considerable media attention. The Advocate General at the ECJ took these cases also as the occasion in his final submission to openly demand more intensive liability precisely for medical devices.

The grounds of the ECJ are rather apodictic *("the potential lack of safety"* of the products stems *"from the abnormal potential for damage which these products might cause to the person concerned!"*). It remains to be seen what the national courts make of that. The discussion about the consequences of the judgment is only beginning. Some indications for practice can already be identified, however:

The grounds of the ECJ for a possible equation of a potential defect with an actual product defect are not restricted to medical implants. The ECJ refers more generally to *medical devices such as the pacemakers and ICDs in question*. The ECJ also links the particularly high safety expectation for *such devices* to their function and the situation of special vulnerability of the patients, i.e. the "abnormal potential" of personal injury which could be caused by such devices.

It is a cause for concern that the ECJ's relies one-sidedly on an "abnormally" high risk of damage associated with the therapy. The criterion of "abnormal potential" of personal injury is hardly helpful (what may on the contrary be "normal potential for damage" of medical devices?). Secondly, the benefits of innovative therapy balanced against the risks is obviously excluded.

It is still unclear whether the liability for mere probable failure of an entire product series is applicable to manufacturing defects. In the case of increased probability of failure due to design, it can be understood that each product of a series, when being placed on the market, is in fact subject to a defect (which may potentially become reality in each individual product). The situation of a manufacturing defect which may be limited only to a few products or batches appears to be unclear. Can such deviants in a series of products sold without any problems for years, i.e. products which have long been on the market, retrospectively create a defect? Since a product defect must be present at the time when the individual product is placed on the market (Sec. 1 ss. 2 No. 2 Product Liability Act) the answer is likely to be "No!". The distinction is not made obsolete by the ECJ judgment either because the basic situation related in each case to design defects.

Finally, it is hard to see how a causal link between a mere potential defect and the actual damage can be proven apart from specific constellations of operation costs due

to recall of an implant. In the present case, the personal injury was in any event based on the recommendation of a medically indicated review which the manufacturer had called for due to the increased probability of failure of its devices. In contrast, a patient who alleges a health damage caused by a malfunction of the device cannot simply refer to the mere potential defect allegedly becoming real. The apportionment of the statutory burden of proof in Sec. 1 ss. 4 Product Liability Act cannot, however, be circumvented. The damaged party must prove the product defect and the causal link precisely between the defect and the health damage (and that the damage was not caused by a defect in medical treatment, false use of the product or simply the fateful course of the illness). The reference to a mere potential defect cannot replace the proof of causality in any particular case.

However, a necessary differentiated consideration will not change the fact that medical technology companies will in future be increasingly claimed against with simple reference to a judgment on allegedly clear potential suspicion. The challenges to the industry both for recall communication and defense against liability in litigation are increasing.

DR. BORIS HANDORN

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Noerr LLP is a European law firm founded in Germany with offices in Brussels, Alicante and various CEE-capitols. 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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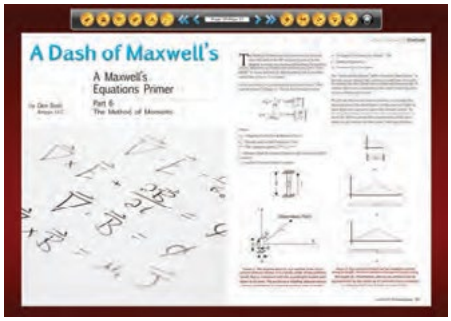

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OUCH! Hot Laptop

Peter E. Perkins

What's the problem?

In the January 2003 *Test & Measurement World*, Brad Thompson related a Reuters story from London entitled "Scientist burns penis with hot laptop." This story was widely circulated on CNN under the heading "Ouch". Summarizing the details, the man spent about an hour working on his laptop wearing a pair of pants, noting a burning sensation. Later the area blistered and became infected. The article noted that the user's manual warned against operating the laptop against the open skin.

Later, in the May 2004 *IEEE Spectrum*, in an article "Beat the Heat" by Philip E Ross which discusses the issues of heat rise in integrated circuits a similar example was discussed. He related that a Swedish scientist was blistered and burned in a very sensitive place after an evening writing a report on his laptop, periodically shifting position to avoid heat from the machine, according to a report in *The Lancet*, the British medical journal.

We will examine the current requirements for case temperatures on these products as well as what is known about burning the skin along with some data collected in an effort to look at making appropriate measurements along these lines.

This seminal work led to the inclusion of these requirements in IEC 62368 and the development of IEC Guide 117, "Temperature of touchable hot surfaces," which has reduced the temperature of touchable parts accessible to the user in all products.

Reviewing the extant, historic product technical standards requirements in the early 21st century:

A) IEC 60950, *Information technology equipment – Safety – Part 1: General requirements*

Parts in operator access areas	**Maximum**	**Temperature**	**(Tmax) °C**
	Metal	**Glass, porcelain and vitreous material**	**Plastic and rubber**
Handles, knobs, grips, etc., held or touched for short periods only	60	70	85
Handles, knobs, grips, etc., continuously held in normal use	55	65	75
External surfaces of equipment which may be touched	**70**	**80**	**95**
Parts inside the equipment which may be touched	70	80	95

Figure 1: from IEC 60950 Table 4B, accessible parts temperature limits

The Table from IEC 60950 is shown in Figure 1; the associated requirement and notes from the standard are below:

For equipment intended for installation in a restricted access location, the temperature rise limits in table 4B, parts 1 and 2, apply, except that for external metal parts which are evidently designed as heat sinks or which have a visible warning, a temperature rise of 90 °C is permitted.

1) If the temperature rise of a winding is determined by thermocouples, these figures values are reduced by 10 °C, except in the case of
   - a motor, or
   - a winding with embedded thermocouples.
2) The classification of insulating materials (Classes A, E, B, F and H) is in accordance with IEC 60085.
3) For each material, account shall be taken of the data for that material to determine the appropriate maximum temperature.
4) Due to their wide variety, it is not possible to specify maximum permitted temperature temperatures rises for thermoplastic materials. These shall pass the tests specified in 4.5.2.
5) For areas on the external surface of equipment and having no dimension exceeding 50 mm, and which are not likely to be touched in normal use, temperatures up to 100 °C are permitted.
6) For each material, account shall be taken of the data for that material to determine the appropriate maximum temperature rise.
7) Temperature rises exceeding the limits are permitted provided that the following conditions are met:
   - unintentional contact with such a part is unlikely;
   - the part has a marking indicating that this part is hot. It is permitted to use the symbol (60417-1-IEC-5041) to provide this information.

B) IEC 60065, *Audio, Video and Similar Electronic Apparatus – Safety Requirements*

Table 3 DC DE DU – Permissible temperature rise[a] of parts of the apparatus

Parts of the apparatus	Normal operating conditions K	Fault conditions K
a) ACCESSIBLE parts		
Knobs, handles, etc. if		
– metallic	30	65
– non-metallic[c]	50	65
Enclosures if		
– metallic[a] [b]	40	65
– non-metallic [b] + [c]	60	65
b) Parts providing electrical insulation [d]		
Supply cords and wiring insulation with		
– polyvinyl chloride or synthetic rubber		
– not under mechanical stress	60	100
– under mechanical stress	45	100

Figure 2: from IEC 60065 accessible parts temperature limits

Figure 2 from IEC 60065, consumer electronic equipment, describes the accessible temperature limits.

Figure 3 lays out the conditions under which the temperature limits apply to accessible parts for consumer electronic products.

Table 3 DC DE DU – Permissible temperature rise[a] of parts of the apparatus Continued

Parts of the apparatus	Normal operating conditions K	Fault conditions K
[b] For parts not likely to be touched during intended use, temperature rises up to 65 K are allowed under normal operating conditions. The wooden test box of 4.1.4 shall not be used when evaluating access to parts likely to be touched. The following parts are considered not likely to be touched: – rear and bottom panels, except those incorporating switches or controls handled during normal use, – external heatsinks and metallic parts directly covering external heatsinks, except those on surfaces incorporating switches or controls handled during normal use, – parts of the top surface which are more than 30 mm below the general plane of the top surface. For outside parts of metal which are covered with plastic material, the thickness of which is at least 0,3 mm, a temperature rise which corresponds to the permissible temperature rise of the insulating material is allowed. [c] If these temperature rises are higher than those allowed by the class of the relevant insulating material, the nature of the material is the governing factor. [d] For the purpose of this standard, the permissible temperature rises are based on service experience in relation to the thermal stability of the materials. The materials quoted are examples. For materials for which higher temperature limits are claimed, and for materials other than those listed, the maximum temperatures shall not exceed those which have been proved to be satisfactory, for example in accordance with ~~IEC 60085~~ UL 1446. [e] Natural rubber and synthetic rubbers are not considered as being thermoplastic materials. [f] Due to their wide variety, it is not possible to specify a generic permissible temperature rise for thermoplastic materials. In order to determine the softening temperature of a specific thermoplastic material, the softening temperature as determined by the test B50 of ISO 306 shall be used. If the material is not known or if the actual temperature of the parts exceeds the softening temperature, the test described under 1) shall be used. 1) the softening temperature of the material is determined on a separate specimen, under the conditions specified in ISO 306 with a heating rate of 50 °C/h and modified as follows: – the depth of penetration is 0,1 mm; – the total thrust of 10 N is applied before the dial gauge is set to zero or its initial reading noted. 2) the temperature limits to be considered for determining the temperature rises are: – under normal operating conditions, a temperature of 10 K below the softening temperature; – under fault conditions, the softening temperature itself. If the required softening temperature exceeds 120 °C, condition [c] shall be taken into account. [g] For switch mode transformers temperature rises may be measured with a thermocouple placed as close as practicable to the winding. The permitted temperature rise shall be 10 K less than that given in table 3.		

Figure 3: from IEC 60065 accessible parts temperature limits conditions

C) IEC 60601-1, ***Medical electrical equipment - Part 1: General requirements for basic safety and essential performance***

The folks who should have the most experience with this—medical products—have this requirement: **max 50 °C for brief patient contact under normal use.**

D) IEC 62368, ***Audio/video, information and communication technology equipment – Part 1: Safety requirements***

Finally, this work directly resulted in the introduction of surface temperature limits in Clause 9, Thermal Burn Injury, which contains touch temperature limits for accessible parts plus safeguard requirements.

Looking at the physiological issues:

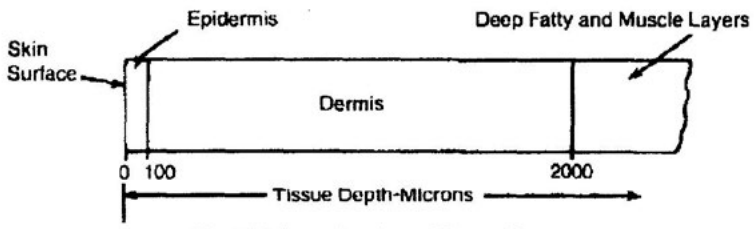

FIG. X1.1 Cross Section of Human Tissue

Figure 4: Typical skin cross-section

To get an idea of the dimensions of the skin as shown in Figure 4, recall that 25 microns equal one mil (1/1000 in.), and 40 mils equal one mm. So the Epidermis is 100 microns = 0.1 mm = 4 mils = 0.004 inches, which is the thickness of a piece of film or paper. And the dermis is 2000 microns = 2 mm = 80 mils = 0.080 inches. This is the thickness of a substantial plastic part.

This work is not new; the basic studies were done in the late 1940s, with applications mid - 70s to early 80s and broad application to IEC product standards in the 21st century.

How are burns classified?

There are different systems in Europe and North America.

European EN designations:

– Superficial partial thickness: follicles and glands survive.

– Deep partial thickness: substantial dermis and glands mostly destroyed.

– Whole thickness: full skin destroyed, no surviving glands.

US ASTM designations:

– First degree: incomplete necrosis of epidermal layer (redness).

– Second degree: complete necrosis of epidermis (blistering)

– Third degree: 75 percent destruction of dermis, scarred upon healing.

Sensation and tissue effects from ASTM 1055 table Fig x1.2 are related in Figure 5.

Sensation	Skin color	Tissue	Temperature	Process	Injury
		deg C	deg F	Protein	
Numbness	White	**72**	**162**	Coagulation	Irreversible
		68			Possible
	Mottled	**64**		Thermal	Reversible
	Red & White	**60**	**140**	Inactivation	
Max Pain		**56**		of Tissue	
Severe Pain	Bright Red	**52**		Contents	Reversible
Threshold Pain	Light Red	**48**			
Hot		**44**	**111**		
	Flushed	**40**		Normal	None
Warm		**36**	**97**	Metabolism	
		32			

Figure 5: Sensations & tissue effects

Sensation, technical temperature data and injury descriptions

ASTM C 1055 (R2014): Standard Guide for Heated System Surface Conditions That Product Contact Burn Injuries

1.1 This guide establishes a process for the determination of acceptable surface operating conditions for heated systems. The human burn hazard is defied, and methods are presented for use in the design or evaluation of heated systems to prevent serious injury from contact with the exposed surfaces.

1.3 The maximum acceptable temperature for a particular surface is derived from an estimate of the possible or probable contact time, the surface system configuration, and the level of injury deemed acceptable for a particular situation.

1.4 For design purposes, the probable contact time for industrial situations has been established at 5 s. For consumer protection a longer (60 s) contact time has been proposed…to reflect the slower reaction times for children, the elderly, or the infirm.

1.5 The maximum level of injury recommended here is that causing first degree burns on the average subject.

The basic work of Moritz & Henriques is foundational to all of the information presented in this article. The burn threshold values specified in EN ISO 13732-1 (nee EN 563) were based upon their scientific research.

In the late 1940s, Moritz and Henriques carried out experiments with the skin of pigs, which is very similar to human skin. They investigated the temperature values of the skin surface, which lead to a burning of the skin. The occurrence of a skin injury depends on the skin's surface temperature and on the time during which the skin surface

is exposed to this temperature. As a result of the investigations, Moritz and Henriques distinguished for each period of high temperature exposure two temperature boundaries for the skin's surface. The lower indicates the boundary between non-injury and the onset of a reversible cutaneous injury. The upper one indicates the boundary between the occurrence of a reversible injury and the occurrence of an irreversible cutaneous injury which cannot heal and results in compete destruction of the skin (whole thickness burn).

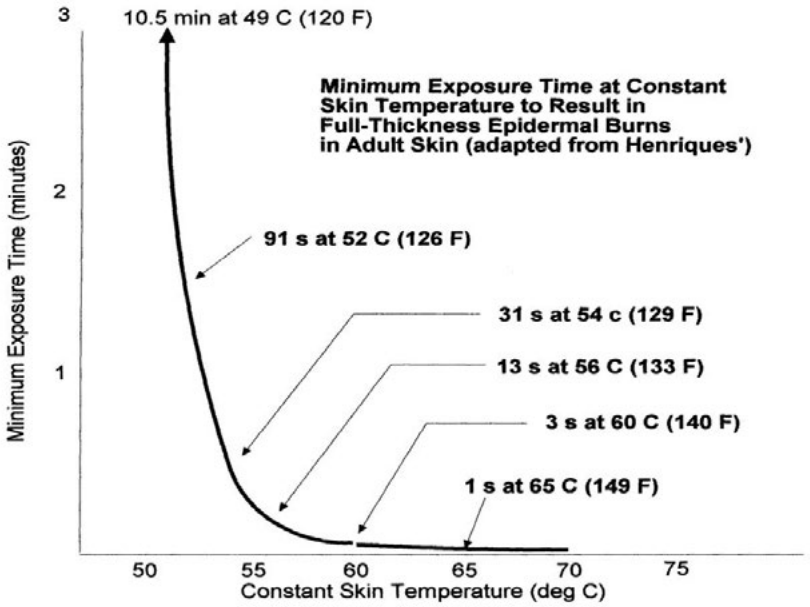

Figure 6: Adult skin burn curve

Figure 7 shows the variability across materials with regard to temperature due to heat transferred by various materials at a fixed short time and a longer time. The material surface temperature varies from material to material for the same injury. Figure 6 does not take that into account.

Material	Surface temperature °C	
	Casual contact (1 s)	Continuous contact (5 s)
Aluminium	60	50
Copper	61	50
Steel	63	51
Hercuvit	74	57
Polyester-Alkyd-glass	76	58
Glass	80	60
Phenolic-mica filled	81	60
ABS	89	64
Phenolic-unfilled	94	67
Teflon	95	67
Nylon- Unfilled	98	68
Polypropylene	105	72
Masonite	108	73
Polycarbonate-unfilled	108	73
Polycarbonate-glass filled	100	70
Polystyrene	117	78
Polystyrene glass filled	100	70

Figure 7: Measured surface temperature at threshold of pain

The EU has issued standards covering this issue:

EN ISO 13732-1, *Ergonomics of the thermal environment – Methods for the assessment of human responses to contact with surfaces – Part 1: Hot surfaces*

This standard combines the requirements of two earlier standards which were used in the initial development of product requirements covering hot surfaces.

EN 563, *Safety of machinery – Temperatures of touchable surfaces – Ergonomics data to establish temperature limit values for hot surfaces*

EN 13202, *Ergonomics of the thermal environment – Temperatures of touchable hot surfaces – guidance for establishing surface temperature limit values in production standards with the aid of EN 563.*

Here is a summary of the organization of key factors and application.

Ergonomic data on Hot surface temperatures

- Key factors
  - Surface temperature
  - Surface material
  - Contact period with skin
- Applicable to
  - Relative high thermal capacity compare skin
  - < 10 percent skin surface contact; not head, airway
  - Adults
  - No pain protection provided

From historical data:

Figure 8 is the relationship between the burn threshold and the contact period when a hot surface is touched by the skin (from the historical data).

This is the basic data summarizing burn thresholds. As can be seen, the burn threshold is time dependant.

For short times the curves are drawn as spreads. This takes into account the uncertainties surrounding the onset of burning. The burn threshold depends upon several factors which include: skin thickness, moisture (sweating), contamination (e.g. grease), touching force, differential conductivities across combined groups above, uncertainties in determining burn threshold. All are small compared to the conductivity across material groups above.

For long times, these differences disappear.

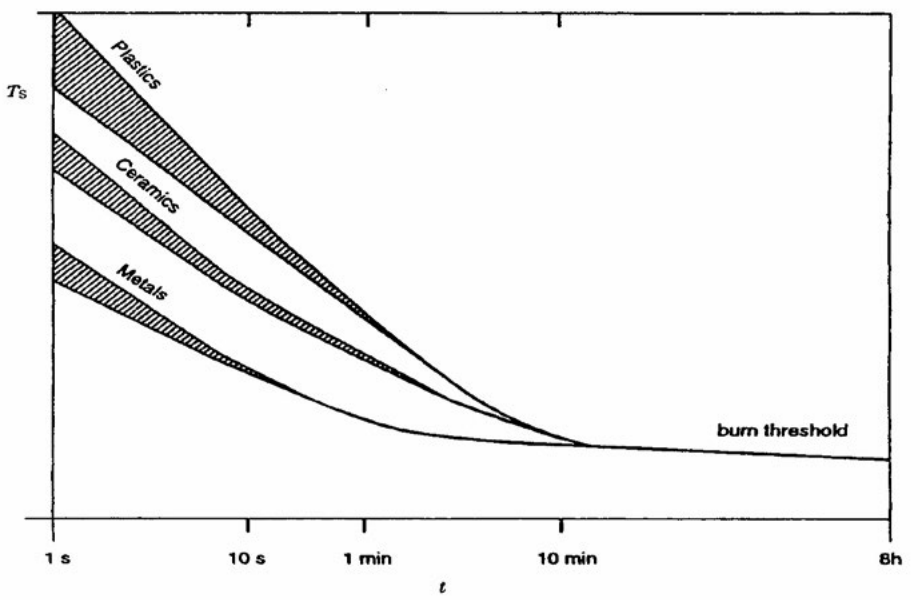

Figure 8: Burn threshold vs. contact period when touched by the skin

Examples of contact periods taken from Figure 9 from historical data

For the estimation of the contact period of the skin with a hot surface these values apply. This clearly shows that a hot surface of a product must not provide a burn when touched for a few seconds by the general public.

Contact period up to:	Examples for touching – unintentional	Examples for touching - intentional
0.5 sec	Fastest withdrawal from pain - healthy adults	
1 sec	Quick withdrawal from pain	
4 sec	Extended reaction - min children & elderly reaction	Activate switch, press button
10 sec	Accidental contact without recovery	Prolonged contact with switch or handwheel
1 min	Accidental contact without recovery	Turning handwheel, valve, etc.
10 min	Accidental contact without recovery	Control elements, handles, etc.
8 hr	contact without recovery	Continuous use of controls, handles, etc.

Figure 9: Example of contact periods

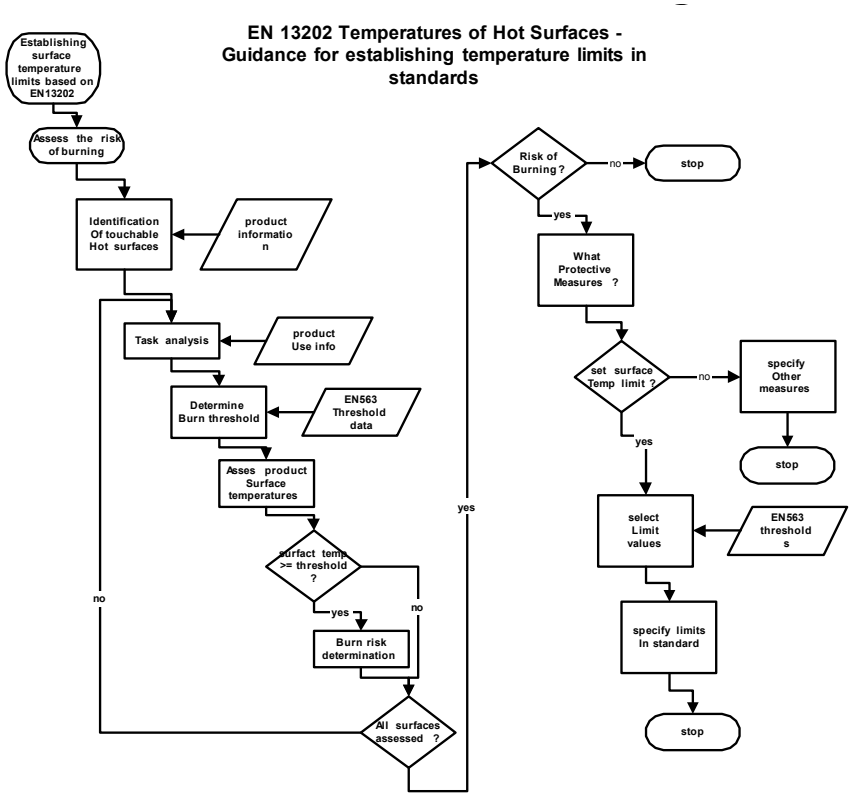

Figure 10: from EN ISO 13732-1 (nee EN 13062) Temperatures of hot surfaces; methods of establishing limits

EN ISO 17732-1 (nee EN 13062) provides the method for assessing the risk of burning which is carefully laid out in Figure 10 from the historical document

Identify touchable hot surfaces – use product info

Task analysis – product use info

Determine burn threshold – historical threshold info

Measure temperature of product surface

Exceed burn threshold?

Determine risk of burning

What appropriate protective measures?

Surface temp limit needed? – other protective measures?

Select limit values – historical thresholds

Incorporate limits in product standard

The method is outlined in Figure 10, from the historical standard.

Material and Conditions	Burn Thresholds contact periods:
Material:	**1 min 10 min 8 hr+**
Uncoated metal	51 C 48 C 43 C
Coated metal	51 C 48 C 43 C
Ceramics, glass, etc.	56 C 48 C 43 C
Plastics	60 C 48 C 43 C
Wood	60 C 48 C 43 C

Figure 11: Historical Burn thresholds, 1 minute or longer

Figure 11 provides these values for longer times.

This provides the needed information for comparison with equipment that is routinely handled such as cell phones, laptops and handheld meters or control units. The expansion into wearable electronics will require that the temperatures be kept at the lowest limits.

Looking at some data

The author took some data on his personal laptop; this data shown in Figure 12 is for the equipment operating in free air.

Figure 12: Laptop bottom temperatures

This data was presented to the technical committee as shown in Figure 13 to initialize the technical discussion of the issue within the Technical Committee.

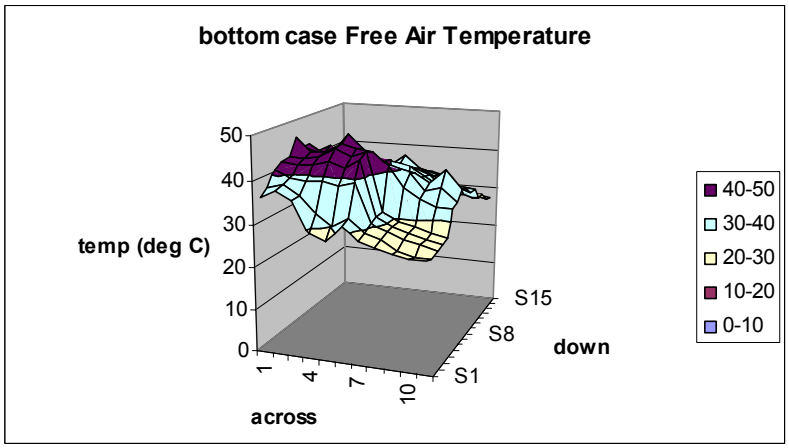

Figure 13: Laptop bottom temperature profile

Typical lap temperature curve with thermocouple placed on the bottom hotspot. The unit was initially laid flat on the table surface in preparation to placing it on my lap. Note that Figure 14 shows that the temperature at the thermocouple location is rising from that noted in free air.

Then, as seen in Figure 14, when the unit is placed on the lap the body acts as a heat sink carrying away enough to hold the temperature as shown. This rise in temp when constrained on the test table brings the use of the direct Free Air Temperature into question as the basis for compliance.

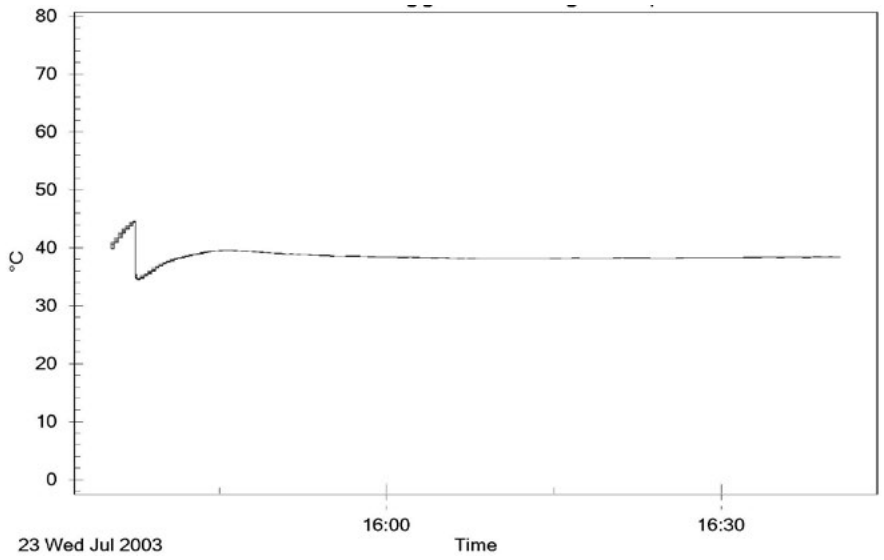

Figure 14: Laptop/skin interface temperature

Typical lap temperature curve shown in Figure 14 with a thermocouple placed on the bottom hotspot. The unit was initially laid flat on the table surface in preparation to placing it on the lap. Note that the temperature at the thermocouple location is rising above that measured in free air.

When the unit was placed on the body, the temperature dropped; the body acts as a heat sink carrying away enough to hold the temperature as shown. This rise in temperature when constrained on the test table bring the use of the direct Free Air Temperature into question as the basis for compliance.

The table in Figure 15 summarizes the data collected on a small sample of laptops. Note that the hotspot temperature does not always rise when constrained by the test table.

Ambient temp	Laptop	Power	Max free air temp	FAT at 25C	Table constrained temp	Stable lap temp	Stable temp at 25C	Lap results
24.4	C1	24.63W 53.63VA	47.2	**47.8**		38.4	39.0	Noticible redness of skin; dozen dime sized spots an hour later
22	D2	39.63W 59.14VA	42.8	**45.8**		37.6	40.6	No significant redness
23.6	H1	101.4W 170.5VA	41.9	**43.3**	27.3	36.4	37.8	Warm, no noticeable redness
21.4	D1	60.13W 87.56VA	38.3	**41.9**		39.1	42.7	Not uncomfortable, no significant redness on skin
23.0	T1	28.78W 43.01VA	37.7	**39.7**	46.7	39.6	41.6	Not uncomfortable, no significant redness

Figure 15: Laptop data summary table

Manufacturers and Test Labs can opt for an alternative data collection method such as the use of thermal cameras to get temperature data on equipment; see Figure 16 examples. This example shows the range of temperature exhibited by one laptop along with the color calibration scale that would give the measurement information needed.

This corresponds more to the Free Air Temperature and does not give any skin temperature information.

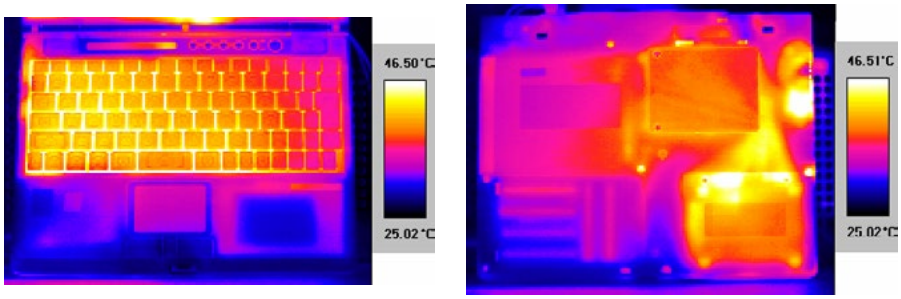

Figure 16: Alternative data collection results

A quick fix

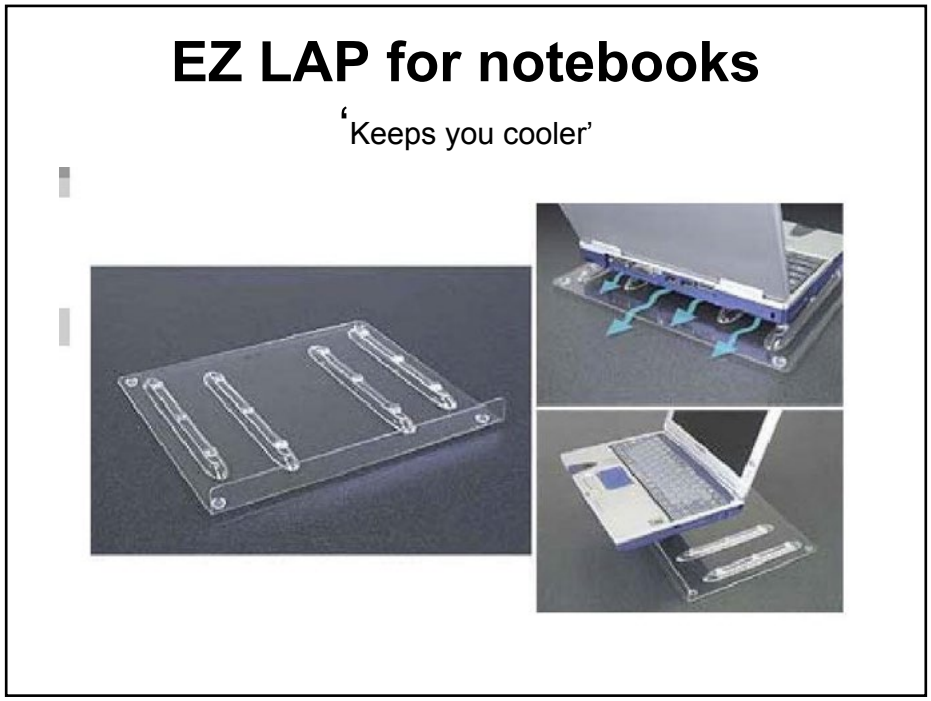

Figure 17: simple commercial problem fix

The "EZ LAP FOR NOTEBOOKS" quickly appeared to resolve the issue.

This is one of those simple ideas that make you say, "Why didn't I think of that?" the EZlap raises your computer up about ¾" (≈2 cm) and provides just enough space for air to circulate underneath, keeping it and you cooler as shown in Figure 17. It is lightweight with non-slip/non-scratch pads on top and bottom. Now you can actually use your laptop on your lap, without that uncomfortable hot feeling.

- Provides a stable, non-slip platform fro all laptops
- Prevents overheating by improving air circulation
- Made from clear acrylic with non-slip/non-scratch feet
- Dimensions: 12 in. x 10.25 in. with a 1 in. lip on bottom.

Other commercial products using USB driven fans have also been available.

It should be noted that manufacturers quickly changed the name of their products from laptop to notebook to avoid any association with the injuries that brought this discussion about.

Data collection issues

The initial measurements were made to facilitate a discussion at the IEC product standards level.

Measurement issues

The measurement exercise pointed out difficulties:

- Max loading in the same way was difficult as the machines didn't contain the same
  - hardware features nor
  - software to exercise the equipment uniformly.
- Insufficient experience to correlate the proper measured surface temperature to the skin condition so that limits can be set.

Testing details

An attempt was made to maximize power usage during the testing. The battery was fully discharged so that the

maximum charging current would be applied. The processor was fully exercised, playing a DVD was the preferred method (but not all products tested had a DVD player) this also exercised the screen driver. Where a DVD could not be played, a CD was played or the hard disk compressed during the thermal evaluation.

Path forward

- Develop a uniform assessment method
- Collect more data to understand the breadth of the problem
- Ascertain applicability to other portable appliances
- Correlate product temperature data to skin temp results
- Specify skin contact temperature limits in safety standards
- Educate product designers as to the hazard and mitigation techniques.
- There is a standard measurement tool available, but it is complex.

Standard Practice for Determination of Skin contact Temperature from Heated Surfaces Using a Mathematical Model and Thermesthesiometer – ASTM C1057-12

- Procedures for evaluating the skin contact temperature for heated surfaces:
  - A purely mathematical approximation that can be used during design or for worst case evaluation, or
  - Using the thermesthesiometer, an instrument that mimics the human sensory mechanism to be used on operating equipment.

ASTM C1057 provides the option to do an analytical assessment of the burn hazard which is attractive in the design stage.

The method outlined here could easily be adapted to an analysis program such as Matlab, MathCAD or the like or be used in conjunction with thermal analysis programs that are in common use today. The usual modeling develops temperatures for surfaces and this analysis would easily provide a further extension to evaluate the potential for burning the skin of someone in contact with the surface.

The thermesthesiometer would be a useful substitute for the skin in getting accurate, comparative measurements.

IEC Guide 117 Temperatures of touchable hot surfaces

The issues raised in the news and the work reported here sparked a more general interest in hot surfaces which resulted in the IEC issuing Guide 117, *Temperatures of touchable surfaces*. This Guide provides "... guidance for assessment of the risk, to any person, of a burn from contact with hot touchable surfaces of electrotechnical equipment. This Guide establishes surface temperature limits, where such limits are required, and describes the maximum contact periods with a hot surface that any person may be subjected to without being exposed to a risk of burn. Curves of maximum temperatures versus contact times are described for different types of material with different types of surfaces."

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.

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今天就成为会员！







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年会

会晤世界级的专家

- 全世界安规专家的演讲
- 实际操作指导讲座
- 专业分会会议
- 专业出版及新理念分享
- 每年在不同城市召开年会：
  获得新知识的同时参观新城市

会员专属网页

扩充专业知识

- 安规知识中央信息库
- 网络研讨会；学术研讨会及文献分享
- 产品安规出版物档案
- 安规学会动态
- 世界安规动态
- 为会员提供折扣的安规公司名单

产品安规分会

加入最先进的专业团队

- 世界各国安规专家的演讲
- 与当地在共同领域的工程师会商
- 分布在各主要城市的分会
- 会员共享网络专业分会

产品安规通讯

获得最新的业界讯息

- 技术文献
- 实际操作研讨
- 各技术分会的专业报告
- 学会分会活动报告

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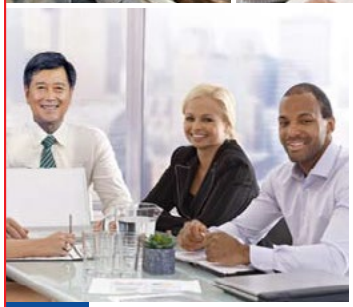
IEEE PSES

Sociedad de Ingeniería de Seguridad de Productos






Obtén tu membresía hoy mismo!

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Intégrate a una gran sociedad a la vanguardia en la innovación de la seguridad de producto!

Simposio Anual

Conoce expertos de todo el mundo!

- Presentaciones de expertos en conformidad de producto reconocidos mundialmente
- Talleres
- Reuniones de comités técnicos
- Publica ideas innovadoras y artículos
- Diferentes ubicaciones cada año, visita lugares nuevos mientras aprendes

Página web para Miembros

Aumenta tu conocimiento!

- Acceso a un banco de datos en temas de conformidad de producto
- Seminarios, seminarios web, artículos
- Ediciones anteriores de Boletines de Seguridad de Producto
- Información de actividades de la sociedad
- Noticias de conformidad mundial
- Descuentos para miembros de diferentes organismos de conformidad de producto

Obtén tu membresía hoy mismo!

Capítulos de Seguridad de Producto

Únete a un equipo excepcional!

- Discusiones con expertos internacionales en el tema
- Conoce ingenieros cerca de ti, que comparten tus intereses
- Capítulos en muchas de las grandes ciudades del mundo
- Capítulo web accesible para todos los miembros

Boletines informativos de Seguridad de Producto

Mantente actualizado con los cambios en la industria!

- Artículos técnicos
- Discusiones con información práctica
- Informes de los comités técnico
- Reporte de las actividades de los capítulos

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New PSES Members from 11 March 2015 through 15 June 2015

Our new members are located in the following countries: Bulgaria, Canada, India, Oman, United Kingdom, and USA .

Adhev Pankhania
Alexander Grey Krause
Ayida Al Shabibi
Daniel Hebert
David Behner
David Creagen
David G Bascom
Fabio Furlan
Frederick Porter
Graham Boechler
Hussam Tarazi
Hyera An
Johanna Goforth
John S Niklewicz
Keith Byron Herrin
Lisa Chan
Mustafa Al Hadhrami
Nikolay Dimitrov Georgiev
Rajesh Karki
Thomas Leslie Killam
Todd Heriford
Vimal Nandhan Ramasamy Krishnamoor

2015 PSES Board of Directors

Board of Directors meeting, May 17, 2015, Chicago, IL Hilton/Rosemont hotel. During PSES2105 Symposium.

Front row, left to right -
Steli Loznen, Mark Maynard, Dan Arnold, Bansi Patel, Mariel Acosta-Geraldino

Second row, left to right -
Thomas Lanzisero, Luiz Araujo, Rich Nute, Kevin Ravo, Daniece Carpenter

Back row, left to right-
Elya Joffe, Grant Schmidbauer, Stefan Mozar, Mike Nicholls

Photographer- Richard Georgerian

Volunteer Positions Available

PSES members wanted to volunteer for small but important roles within the PSES organization. No in-person meetings required. E-mail and conference calls only. All it takes is a couple of hours a month to help improve and grow our organization.

- PSES Global Outreach Rep: Help establish the PSES Country Reps - the country reps will serve as a leader within each foreign country that currently has PSES members (make contact with our foreign membership). Work with the Chapter Coordinator to help the Country Reps start local chapters.
- PSES Strategic Partner Rep: Make contact with other societies and organizations that have Product Safety interest. Work to help integrate our safety content into their societies and organizations (i.e. PSES has partnered with the Consumer Electronics Society).
- PSES PR Rep: Prepare and issue press releases regarding our Symposium and other special events and activities. Invite news organizations and other interested parties to cover our events.
- PSES Marketing Team: Team members participate in plan review and refinement, and each member leads 1 item within the plan (work at your pace - pick an area that interests you - no marketing experience or background needed - many tasks are technically oriented that serve marketing purposes).

For more details, please contact Bill Bisenius at +1-919-469-9434.

WANTED: Editor - For the Product Safety Engineering Newsletter. Word-smithing, content soliciting, and author hand holding required. Interested? Contact Mike Nicolls VP-Communications, mnicholls@a-m-c.com.

E-Mail List: http://www.ieee-pses.org/emc-pstc.html
Virtual Community: http://product-compliance.oc.ieee.org/
Symposium: http://psessymposium.org/

Membership: The society ID for renewal or application is "043-0431".

Advantages of Membership in the IEEE PSES

Makes you part of a community where you will:

- Network with technical experts at local events and industry conferences.
- Receive discounts on Society conferences and symposiums registration fees.
- Participate in education and career development.
- Address product safety engineering as an applied science.
- Have access to a virtual community forum for safety engineers and technical professionals.
- Promotion and coordination of Product Safety Engineering activities with multiple IEEE Societies.
- Provide outreach to interested engineers, students and professionals.
- Have access to Society Publications.

OFFICERS OF THE IEEE PSES

President
Kevin Ravo (14-15)

Immediate Past-President
Elya Joffe (14-15)

President-Elect
Mark Maynard (15)

Secretary
Daniece Carpenter (NA)

Treasurer
Dan Arnold (NA)

Vice President - Communications
Mike Nicholls (15-17)

Vice President - Member Services
Homi Ahmadi (15-17)

Vice President - Technical Activities
Luiz Araujo (15-17)

Vice President - Conferences
Stefan Mozar (15-17)

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Term Expires 12/15
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Grant Schmidbauer
Kevin Ravo
Rich Nute

Term Expires 12/16
Silvia Diaz Monnier
Stefan Mozar
Mark Maynard
Jack Burns

Term Expires 12/17
Mariel Acosta-Geraldino
Thomas Lanzisero
Steli Loznen
Bansi Patel

Ex Officio (without vote)
Young Professionals Member (formerly GOLD)
Chapter Chairs
Standing Committee Chairs
IEEE HQ
IEEE TAB Division VI Director

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