emc STANDARDS

Another EMC resource
from EMC Standards

EMC requirements in IEC60601-1-2 Taster

Helping you solve your EMC problems

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The medical EMC requirements in IEC 60601-1-2's 2007 and 2014 editions

Eur Ing Keith Armstrong CEng, FIET, Senior MIEEE, ACGI
phone & fax: +44 (0)1785 660 247
keith.armstrong@cherryclough.com
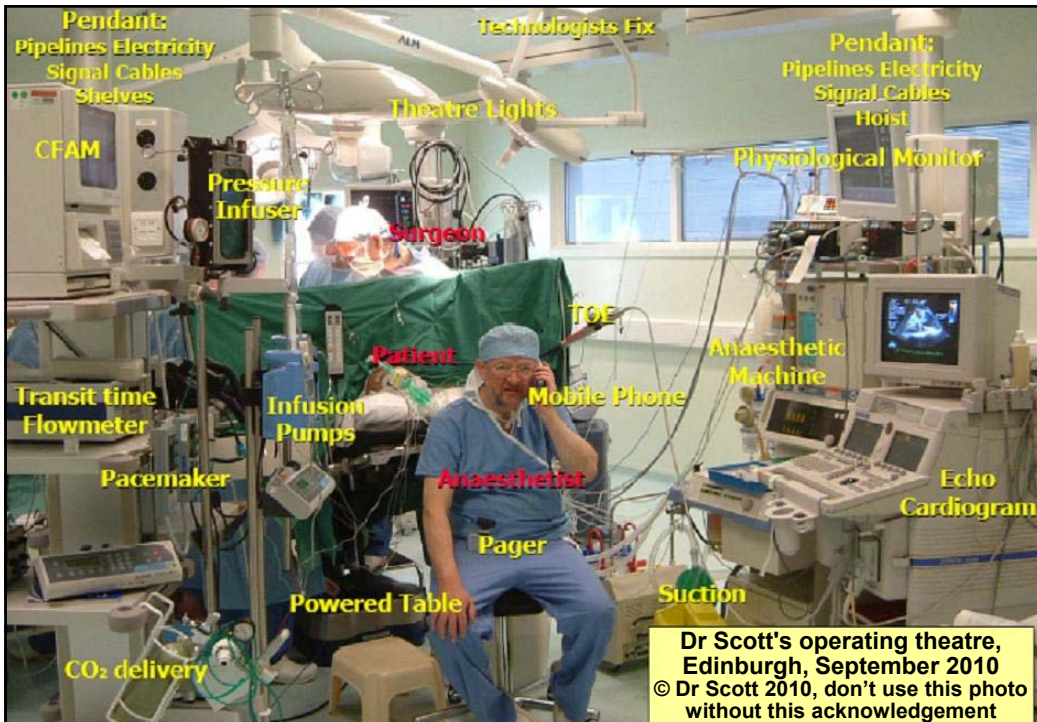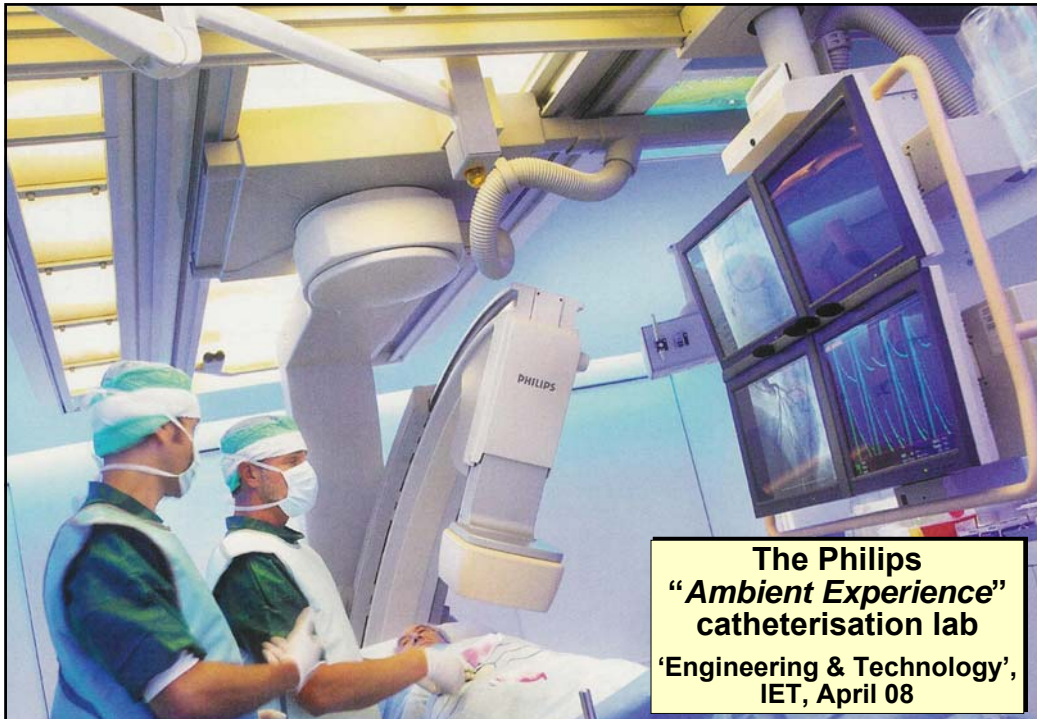**www.cherryclough.com**

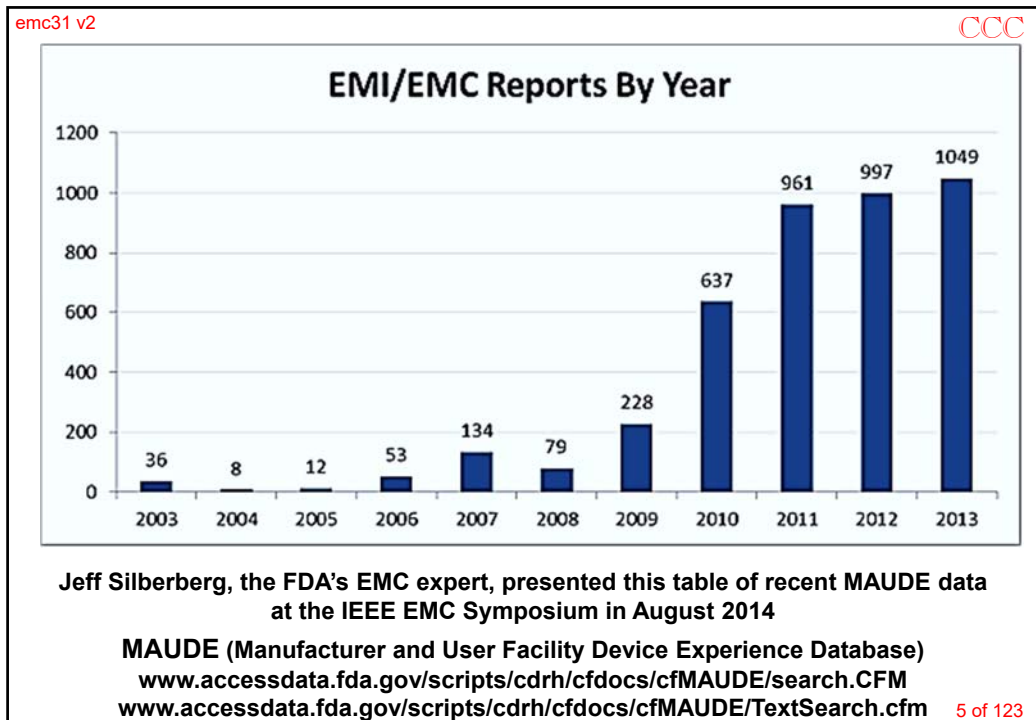1 of 123

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Contents

- **IEC 60601-1-2:2007 (Edition 3)**
    - now required for legal compliance in EU and USA
    - its test requirements for emissions and immunity
    - its EMC Risk Management Requirements

- **IEC 60601-1-2:2014 (Edition 4)**
    - only covers EMC safety, not performance
    - its test requirements for emissions and immunity
    - its EMC Risk Management requirements

- **A practical way to comply with the EMC Risk Management requirements of both**

- **Appendix 1: An effective near-field immunity test method**

- **Appendix 2: Some useful references**

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Keith Armstrong

The Philips
"*Ambient Experience*"
catheterisation lab
'Engineering & Technology',
IET, April 08

Dr Scott's operating theatre,
Edinburgh, September 2010
© Dr Scott 2010, don't use this photo
without this acknowledgement

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EMI/EMC Reports By Year

Jeff Silberberg, the FDA's EMC expert, presented this table of recent MAUDE data
at the IEEE EMC Symposium in August 2014

MAUDE (Manufacturer and User Facility Device Experience Database)
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm   5 of 123

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Terminology

■ **IEC 60601-1-2 applies to**
medical electrical equipment and medical electrical
systems...

– **which it calls ME EQUIPMENT and ME SYSTEMS**
respectively...

◆ **using SMALL CAPITAL LETTERS**
which makes reading it a trial

– **so the remainder of this course will just use**
***equipment/systems* to mean the same thing**

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IEC 60601-1-2:2007
(Edition 3)

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Eur Ing Keith Armstrong CEng, FIET, Senior MIEEE, ACGI
phone & fax: +44 (0)1785 660 247
keith.armstrong@cherryclough.com
www.cherryclough.com

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EU compliance requires
IEC 60601-1-2 Ed.3 from June 2012

Cenelec	EN 60601-1-2:2007 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests IEC 60601-1-2:2007 (Modified)	27/11/2008	EN 60601-1-2:2001 and its amendment Note 2.1	01/06/2012
	EN 60601-1-2:2007/AC:2010	18/01/2011		

Copied from http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/medical-devices/index_en.htm, on 14 March 2012

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