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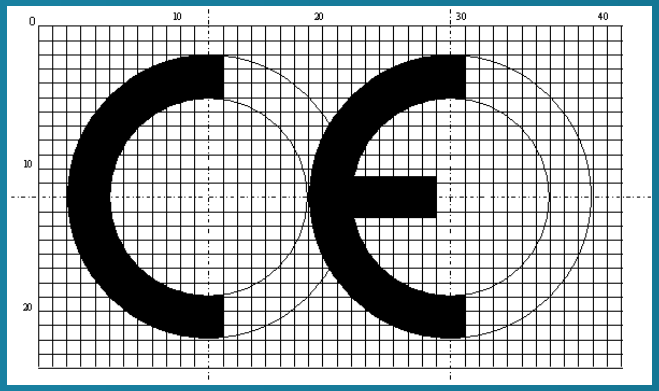
ELECTRONICS & AUTOMATION
2/3/4 JUNI 2015 JAARBEURS UTRECHT

From CE-Marking to Practical Testing for Wearable Electronics

Davy Pissoort, KU Leuven
Jun 2, 2015



CE-Marking of Wearable Electronics?

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Example DoC Wearable Electronics

ASUS ZENWATCH

EC Declaration of Conformity

ASUS IN SEARCH OF INCREDIBLE

We, the undersigned,

Manufacturer:	ASUSTeK COMPUTER INC.
Address:	4F, No. 150, LI-TE Rd., PEITOU, TAIPEI 112, TAIWAN
Authorized representative in Europe:	ASUS COMPUTER GmbH
Address, City:	HARKORT STR. 21-23, 40880 RATINGEN
Country:	GERMANY

declare the following apparatus:

Product name :	ASUS ZenWatch
Model name :	WI500Q

conform with the essential requirements of the following directives:

☒2004/108/EC-EMC Directive

☒ EN 55022:2010+AC:2011	☒ EN 55024:2010
☒ EN 61000-3-2:2006+A2:2009	☒ EN 61000-3-3:2013
☐ EN 55013:2001+A1:2003+A2:2006	☐ EN 55020:2007+A11:2011

☒1999/5/EC-R&TTE Directive

☒ EN 300 328 V1.8.1(2012-06)	☒ EN 301 489-1 V1.9.2(2011-09)
☐ EN 300 440-1 V1.6.1(2010-08)	☐ EN 301 489-3 V1.4.1(2002-08)
☐ EN 300 440-2 V1.4.1(2010-08)	☐ EN 301 489-4 V1.4.1(2009-05)
☐ EN 301 511 V9.0.2(2003-03)	☐ EN 301 489-7 V1.3.1(2005-11)
☐ EN 301 908-1 V5.2.1(2011-05)	☐ EN 301 489-9 V1.4.1(2007-11)
☐ EN 301 908-2 V5.2.1(2011-07)	☒ EN 301 489-17 V2.2.1(2012-09)
☐ EN 301 893 V1.6.1(2011-11)	☐ EN 301 489-24 V1.5.1(2010-09)
☐ EN 302 544-2 V1.1.1(2009-01)	☐ EN 302 326-2 V1.2.2(2007-06)
☐ EN 302 623 V1.1.1(2009-01)	☐ EN 302 326-3 V1.3.1(2007-09)
☐ EN 50360:2001	☐ EN 301 357-2 V1.4.1(2008-11)
☐ EN 62479:2010	☐ EN 302 291-1 V1.1.1(2005-07)
☐ EN 50385:2002	☐ EN 302 291-2 V1.1.1(2005-07)
☐ EN 62311:2008	

☒2006/95/EC-LVD Directive

☒ EN 60950-1 / A12:2011	☐ EN 60065:2002 / A12:2011

☒2009/125/EC-ErP Directive

☐ Regulation (EC) No. 1275/2008	☒ Regulation (EC) No. 278/2009
☐ Regulation (EC) No. 642/2009	☐ Regulation (EC) No. 617/2013

☒2011/65/EU-RoHS Directive

Ver. 140331

☒CE marking

CE (EC conformity marking)

Position : CEO

Name : Jerry Shen

Declaration Date: 29/08/2014

Year to begin affixing CE marking: 2014

Signature : _____

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DoC: Content?

EC Declaration of Conformity

ASUS IN SEARCH OF INCREDIBLE

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Model name :	**WI500Q**

Description of the product & “manufacturer”

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DoC: Content?

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☐ Regulation (EC) No. 642/2009	☐ Regulation (EC) No. 617/2013

☒2011/65/EU-RoHS Directive Ver. 140331

☒CE marking

CE (EC conformity marking)

To what is conformity claimed?

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DoC: Content?

CE (EC conformity marking)

Position : **CEO**
Name : **Jerry Shen**

Declaration Date: 29/08/2014
Year to begin affixing CE marking: 2014

Signature : _____

Signature of “authorized” person

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Directives, Standards, Conformity Assesment?

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Directive vs Standard?

European "rules" comprise directives and standards

- **What is a directive ?**
  - Has the legal status of a law at European level because it is approved by the European Parlament
  - Must be "*transposed*" in National law
  - They describe the essential requirements to comply with

    e.g. EMC: limited EM emissions / immune to EM environment
  - How to show proof of evidence about compliance ?
    - Applying harmonised standards which give presumption of compliance
    - Another method, well documented

Examples of Directives

- 90/385/EEC Active implantable medical devices
- 2004/108/EC Electromagnetic compatability

  → **2014/30/EU from April 16, 2016**
- 2006/95/EC Low Voltage Equipment
- 2006/42/EC Machinery safety
- 93/42/EEC Medical devices
- 1999/5/EC Radio & Telecommunications Terminal Equipment

  → **2014/53/EU Radio Equipment Directive from April 16, 2016**
- 88/378/EEC Toys safety
- 2011/65/EU Restriction of the use of certain hazardous substances (RoHS)

Directive vs Standard

- **What is a standard?**
  - Describes limits and/or test/measurement methods
- **What is a harmonised standard ?**
  - They have the technical requirements to comply with the essential requirements of the directive
  - Should be issued by CEN / CENELEC or ETSI
  - Published in the OJEU
  - To be transposed into National set of standards
  - Give **presumption of compliance**
  - *Note: not all standards starting with EN are harmonised standards*

Global and New Approach

- What is new and global approach in Europe?
  - “New”: full responsibility by the manufacturer or legal representative
  - “Global”: recognised by all countries from EEA (European Economic Area)

- How to prove conformity with European “rules”:
  - Self-declaration
    - Technical documentation (incl. manual)
    - Declaration of Conformity (DoC)
    - CE marking
  - EC type-examination by notified body

Practical Example: EMC Directive

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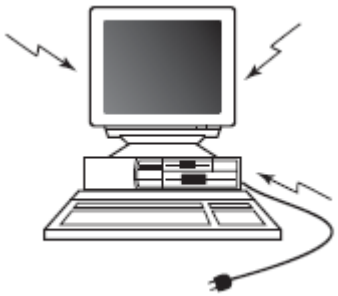
ElectroMagnetic Compatibility?

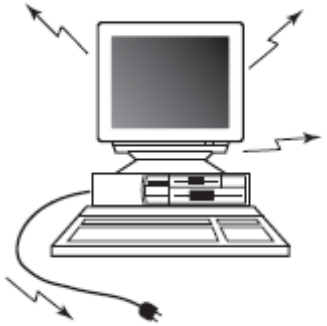
The definition of EMC, as it appears in the International Electrotechnical Vocabulary [152], is:

> The ability of a device, equipment or system to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbance to anything in that environment.

1. Immunity



2. Emission



Essential requirements

1. **Protection requirements**

Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:

(a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;

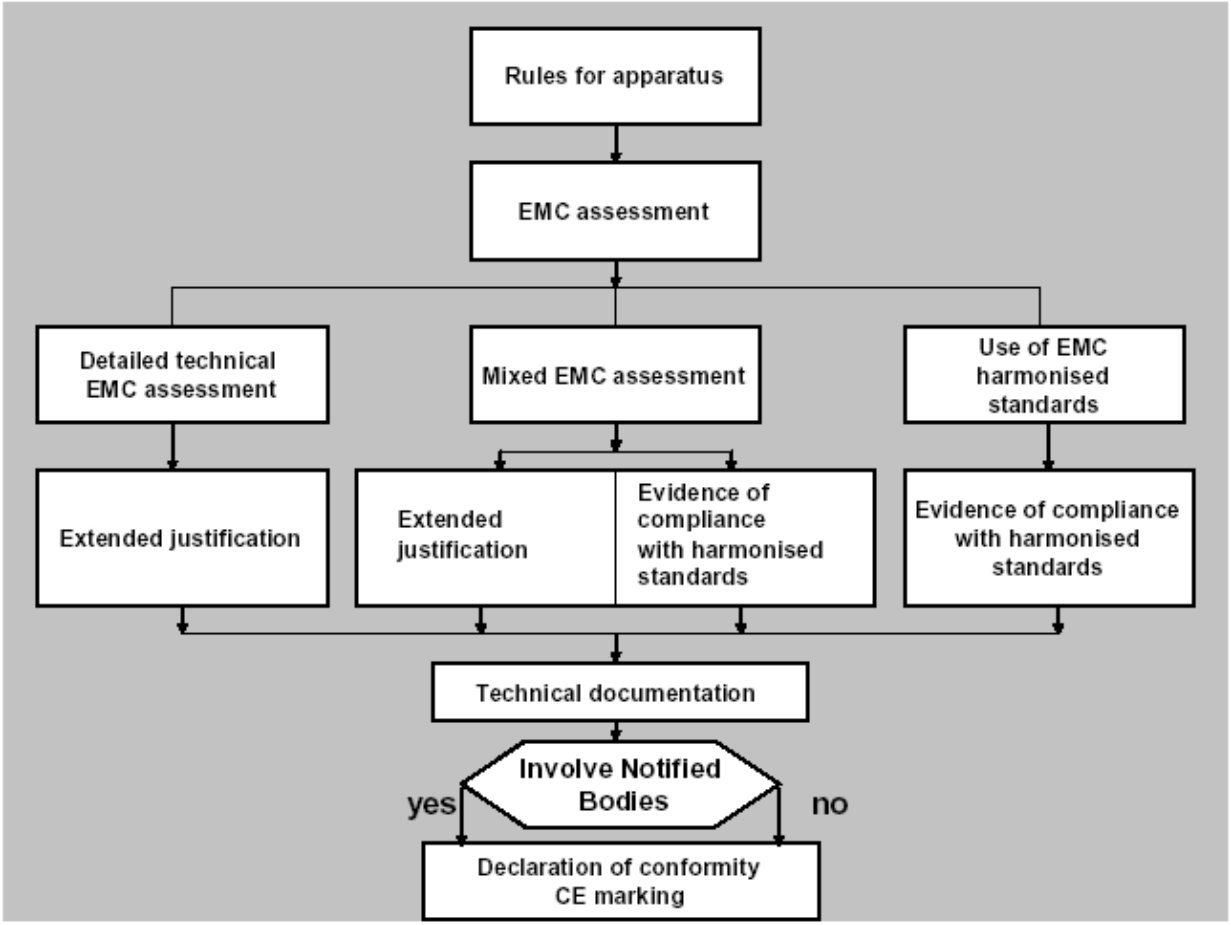
→Emission

(b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

→Immunity

!! No test methods, levels or limits in the EMC Directive!!

Conformity Assessment Procedure



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Technical documentation

Technical documentation

- General description of the electrical equipment
- Design and manufacture drawings (diagrams of components, subassemblies, circuits etc...)
- Explanations to understand above drawings and operation of the equipment
- A list of standards used and when not used the solutions to meet the safety aspects of the LVD
- The results of design calculations, checks
- Traceability of all components following article 9.1 of EMC directive

This documentation to be kept in Community

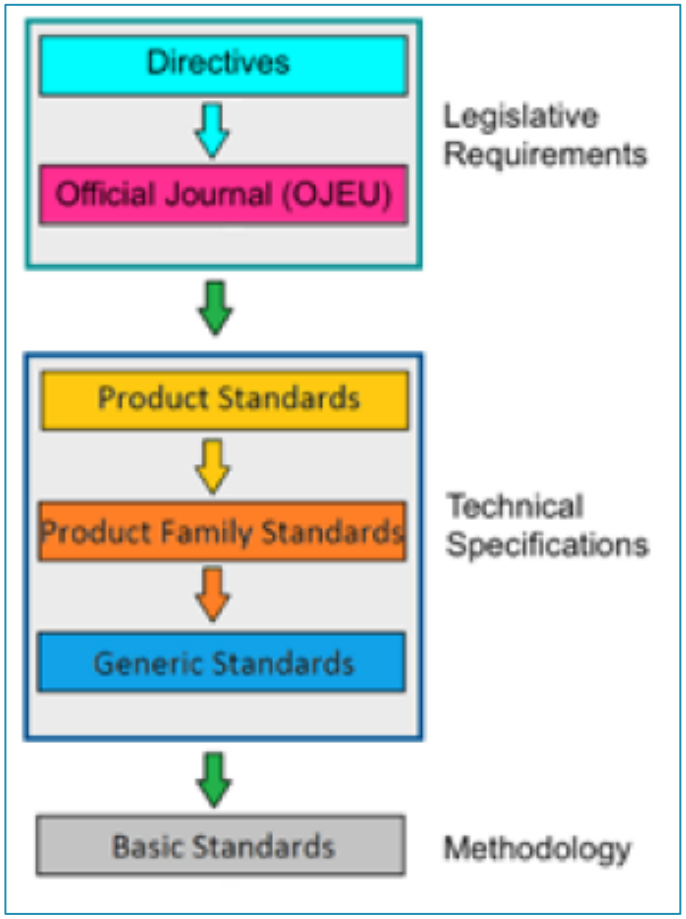
Declaration of Conformity

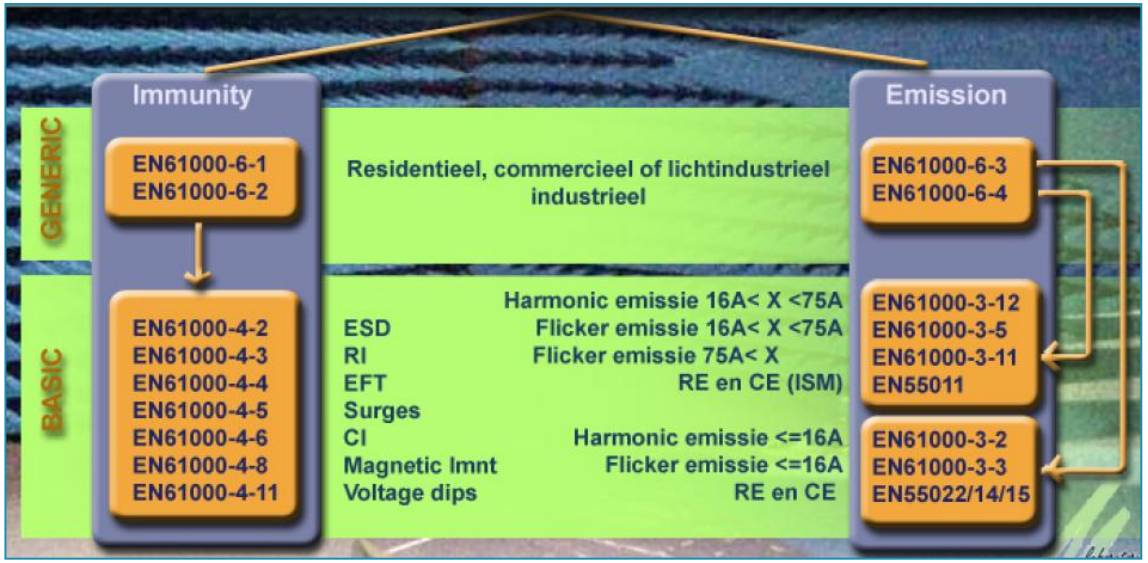
EC Declaration of Conformity

- Name and address of manufacturer or authorized representative established within the Community
- Description of the electrical equipment
- Reference to the harmonized standards or other specifications when harmonised standards are not followed
- Identification of the empowered signatory
- In one of official languages of the Community

This document to be kept in Community

Hierarchy in Standards





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EMC Testing?

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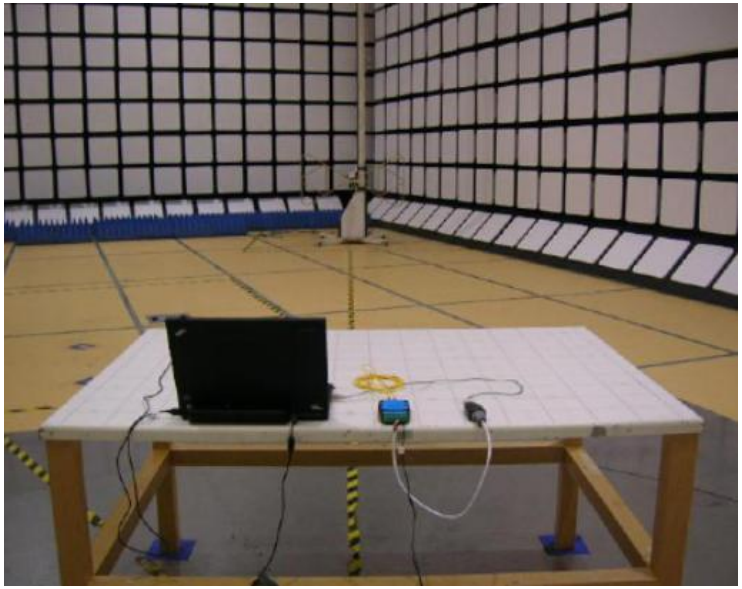
Radiated Emissions

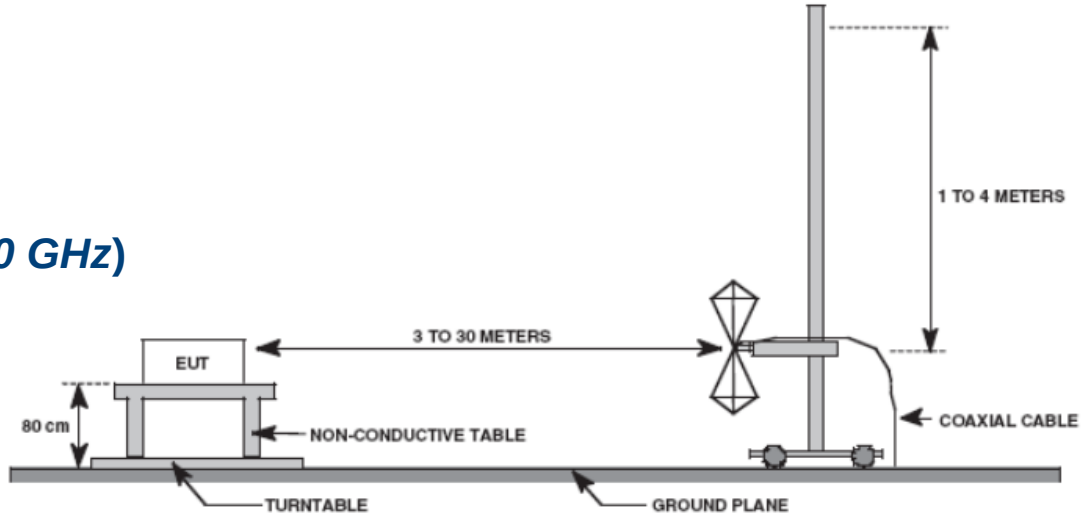
1. **What are radiated Emissions?**

   EM disturbances radiated out of equipment through openings, non conductive materials, or via its interconnectng cables which act as antennas.

2. **Test Equipment (internal)**
   - **(Semi)-Anechoic Chamber**
   - **Antenna**
   - **EMI receiver**
   - **Software**

3. **Frequency: 30 MHz – 6 GHz (*40 GHz*)**





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Radiated Immunity

1. **What is Radiated Immunity?**

   EM disturbances entering equipment through openings, non conductive materials, or via its interconnectng cables which act as antennas.

2. **Test Equipment**
   - **(Semi)-Anechoic Chamber**
   - **RF Generator / amplifier**
   - **E-field meter**
   - **Antenna**
   - **Software**

3. **Test Levels**

AM modulation of 80% at 1 KHz
3 V/m on carrier wave from **80 MHz to 1GHz**
Medical equipment:
3 V/m on carrier wave from **80 MHz to 3 GHz**
Industrial equipment:
10 V/m on carrier wave from **80 MHz to 2 GHz**

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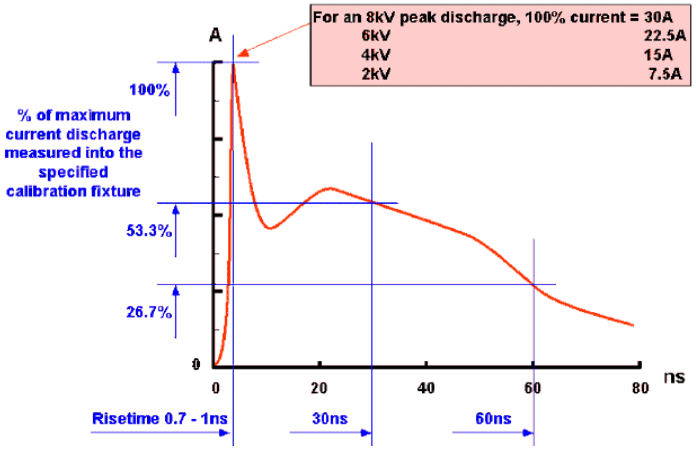
ESD

1. What is ESD?

Is an electrostatic discharge between person/object and product which creates

- *Impulse i(t) and v(t)*
- *E and H-fields*

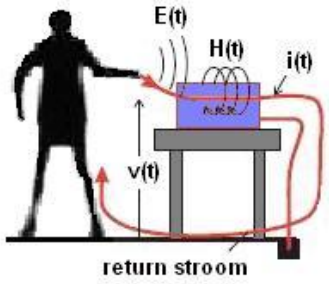


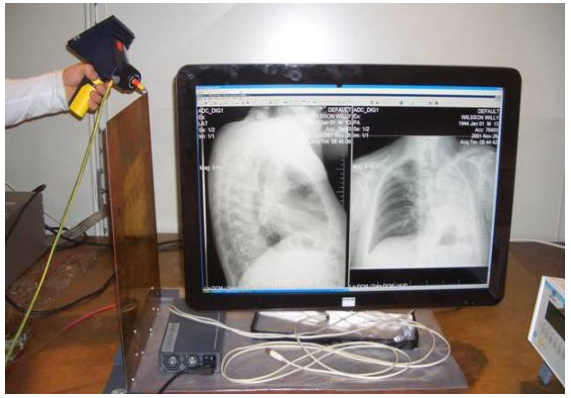
3. Test Equipment

- **ESD generator**
- **Horizontal & vertical coupling planes**
- **Insulation sheet**

4. Test Levels

	Contact discharge	Air discharge
• Level 1	2kV	2kV
• Level 2	4kV	4kV
• Level 3	6kV	8kV
• Level 4	8kV	15kV





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EMC & Medical Wearable Devices?

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IEC 60601-1-2 4th Edition:2014

IEC 60601-1-2

Edition 4.0 2014-02

INTERNATIONAL STANDARD

Published February, 2014

NORME INTERNATIONALE

colour inside

Medical electrical equipment –
Part 1-2: General requirements for basic safety and essential performance –
Collateral Standard: Electromagnetic disturbances – Requirements and tests

Appareils électromédicaux –
Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques – Exigences et essais

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE CODE PRIX XD

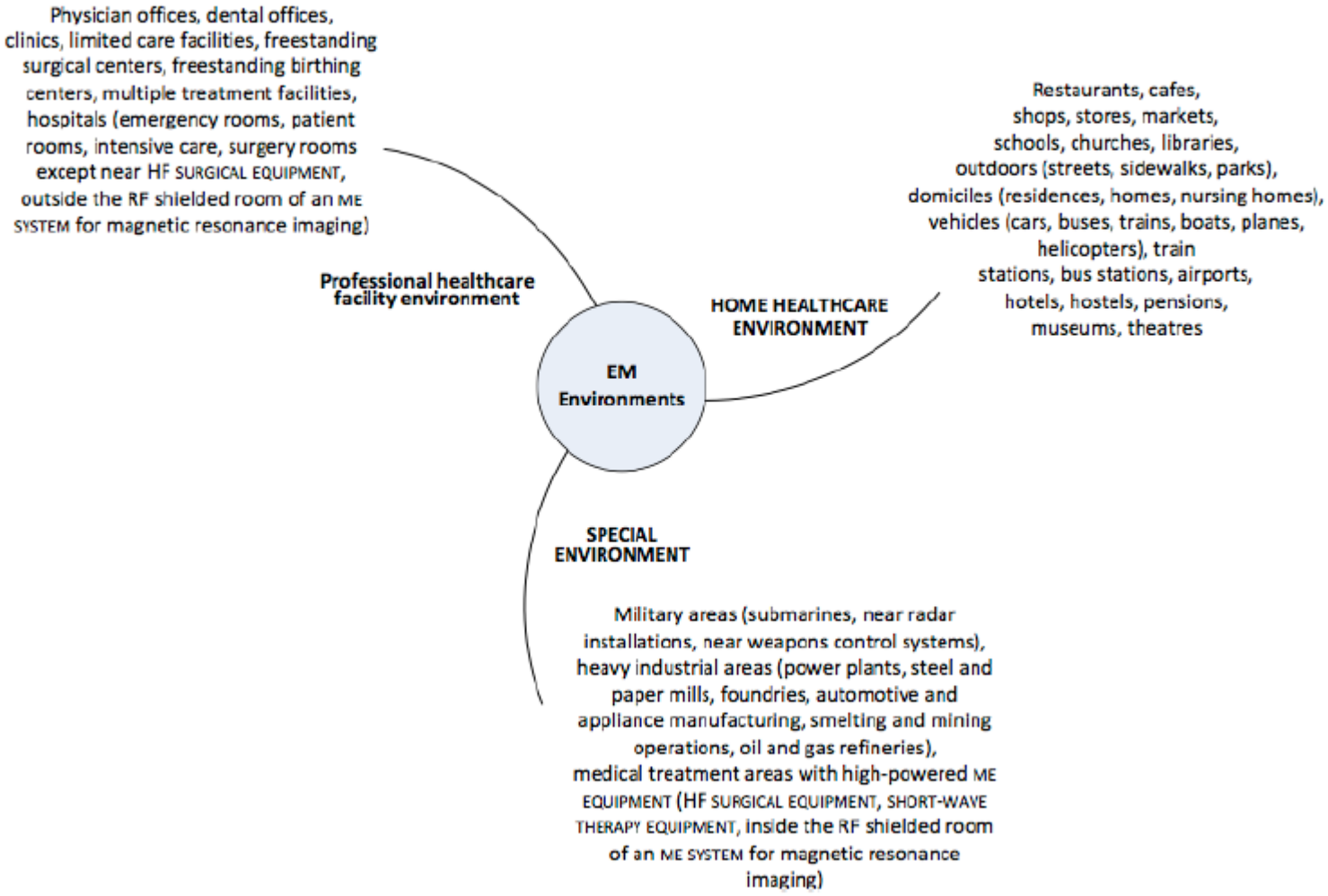
IEC 60601-1-2 4th Edition:2014

- Create safety standard w/ respect to EM disturbances
- Drawbacks with the 3rd edition
  - Basic Safety and Essential Performance aspects – not adequately addressed
  - Test levels in the current standard are 13+ years old *(new EM environments unaccounted for, e.g. cell phones)*
  - Mobile device usage restrictions are now generally ignored
  - Devices in the same intended use location meet different immunity levels

4th Edition Philosophy

- Requirements based on the intended use environment *(not the device type)*
- Immunity levels based on the *reasonably foreseeable maximum*
- Susceptibility from mobile transmitters must be addressed

Intended Use Environment



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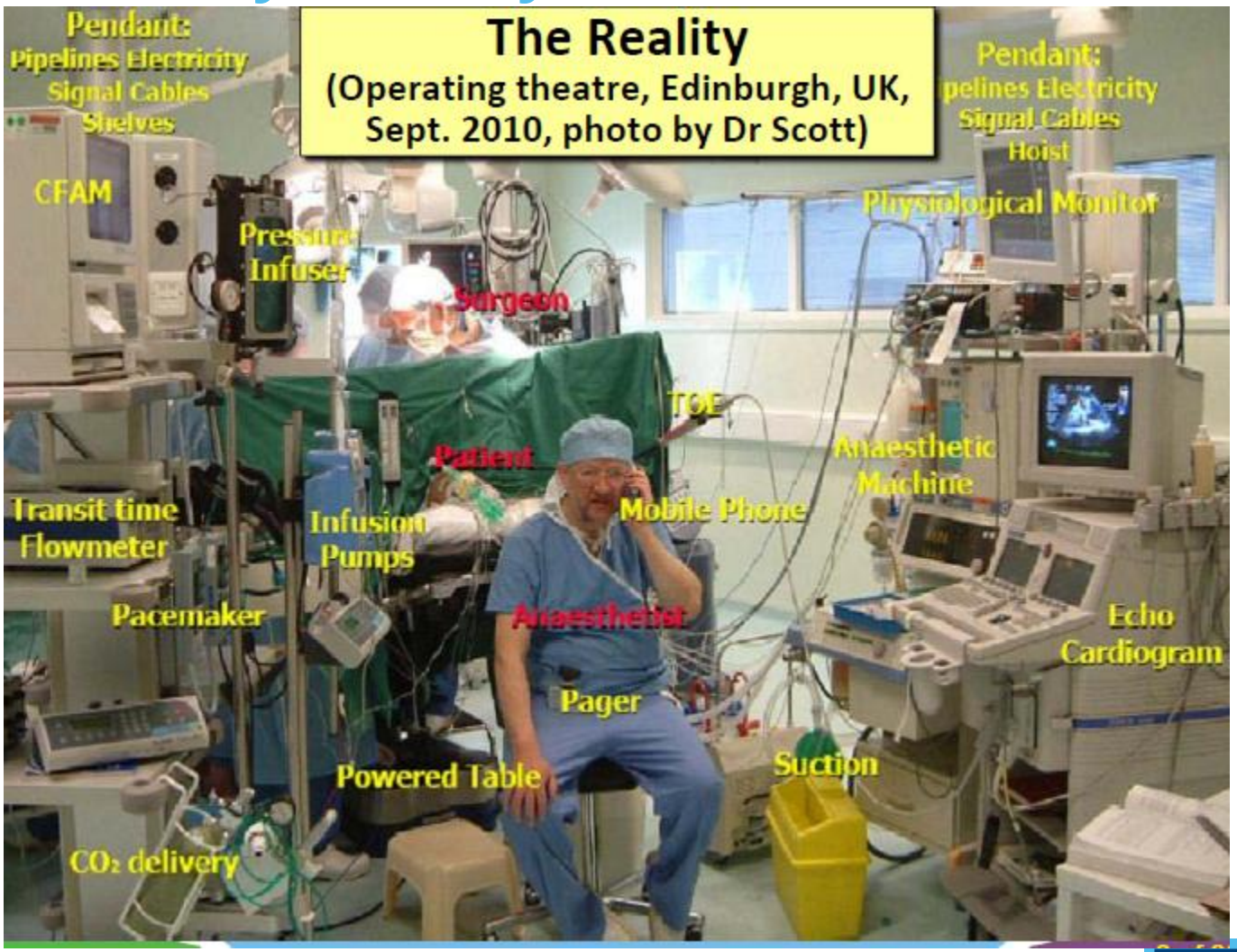
Immunity Test Levels: Example

Phenomenon	IEC 60601-1-2: 3rd Edition	IEC 60601-1-2: 4th Edition	
		Prof. Healthcare Environment	Home Healthcare Environment
Radiated Immunity	3 V/m - Not Life Support 10 V/m - Life Support 80 MHz – 2.5 GHz 80%@2 Hz (or 1 kHz) AM Modulation	**3 V/m** 80 MHz – **2.7 GHz** 80%@ **1 kHz** AM Modulation	**10 V/m** 80 MHz – **2.7 GHz** 80%@ **1 kHz** AM Modulation
Proximity Field from Wireless Transmitters **(New Test)**	N/A	**9 V/m to 28 V/m** 15 specific frequencies	
Bold = Changes From the 3rd edition			

Is Immunity Really Tested Sufficiently?



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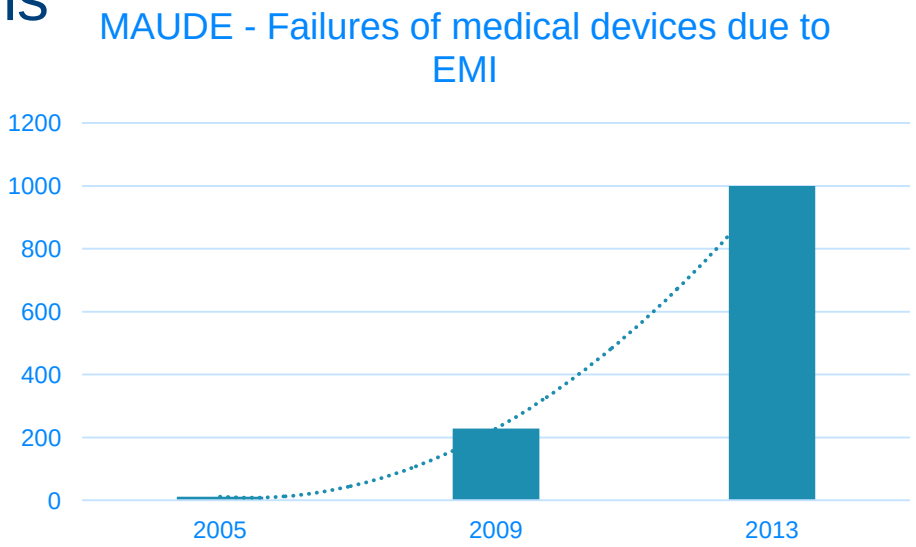
Failures due to EMI

- Manufacturer and User Facility Device Experience (MAUDE)
- Only medical device reports
- Submitted to the FDA (U.S. Food and Drug Administration)
- Suspected device-associated deaths, serious injuries and malfunctions



Within 2 years?
Within 10 years?

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Why Immunity Testing is Not Sufficient

- Just as for microprocessors and software, no practicable test plan could prove risks caused by EMI were acceptably low, because it would need to cover all reasonably foreseeable…
  - maximum EM disturbances over the entire lifecycle (normal tests aim for 80-90% of typical)…
  - physical and climatic stresses, aging, etc.…
  - degradations/faults in EM mitigation and circuits, simulated individually, and foreseeable combinations…
  - angles of incidence, polarisations, modulation types/frequencies, transient waveshapes and rates, etc.
  - combinations of any/all of the above!

Cost-Effective EMI Risk Management (1)

- New IET Guideline on EMI Risk Management released in 2013.
- The IET's WG determined which "Functional Safety-inspired" Techniques & Measures (T&Ms) have benefits for EMC, and developed them to be capable of providing EMI resilience…
  - hardware / software that reliably detects the effects of EM, i.e. EM disturbances that exceed the protection provided by the EM mitigation…
  - and take appropriate actions (described in the Safety Case) to maintain risks at acceptable levels…
  - for example by switching the system to a 'safe state'…
  - or correcting for effects of the EMI (e.g. by switching control to a backup using different technology)

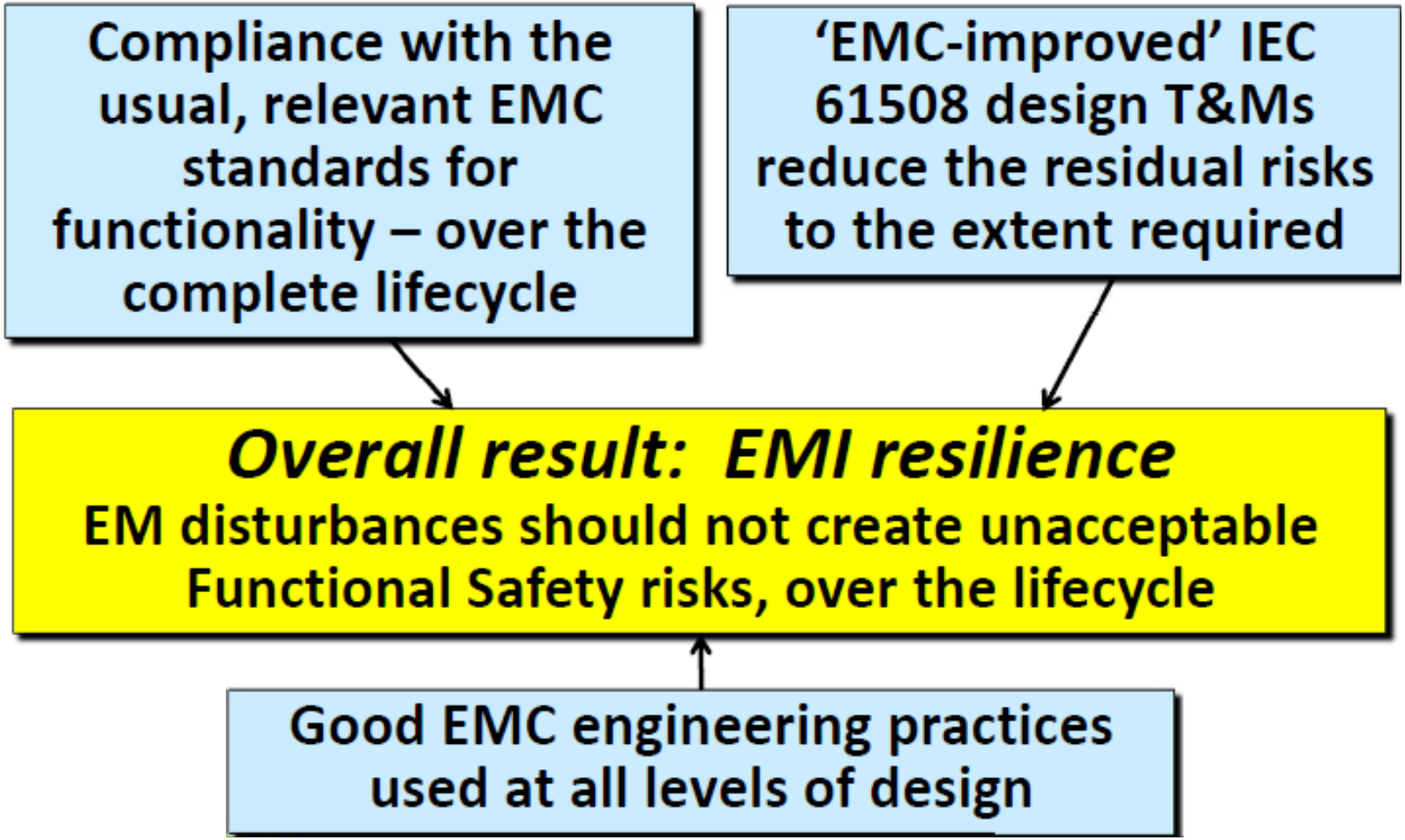
Cost-Effective EMI Risk Management (3)

- It is possible to rely solely on such T&Ms to create functionally safe systems…
  - but they can suffer too much downtime,
  - i.e. have unacceptably low availability
- Such systems can be expected to be modified by users or owners to improve availability…
  - any subsequent dangerous failures would be the manufacturer's fault…
  - because such misuse is reasonably foreseeable

Cost-Effective EMI Risk Management (4)

- Adequate availability simply needs compliance with the normal EMC emissions/immunity test standards…for the application and its EM environment(s)…
  - the EMC community has (of course) great experience with doing exactly this…
  - the new thing in the IET's new guide, is that this compliance should be maintained throughout the whole lifecycle…

Cost-Effective EMI Risk Management



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Questions?

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