ETERNITY
European Training Network on Electromagnetic Risks in Medical Technology
Outline

• Introduction
• What is EMI?
• The medical devices environment
• What is EMC?
• What is a medical device?
• Medical devices classification
• European medical devices standards: the EN-60601 Family
• Medical devices risk management
• Electromagnetic risk management in medical devices
• ETERNITY
Introduction

Electromagnetic Risks in Medical Technology → electromagnetic energy
Introduction

Electromagnetic interferences (EMI)

• Any electromagnetic disturbance that interrupts, obstructs, or otherwise degrades or limits the effective performance of electronics and electrical equipment.

• The IEC/IEV defines electromagnetic interference (EMI) as “degradation of the performance of a device, equipment or system by an electromagnetic disturbance”
What is an EMI?
What is an EMI?
Equipment producing high level of EMI

Very sensitive devices

Digital Telecom. Systems

IoT
medical devices environment: at home
medical devices environment: at home

CONNECTED IoT PRODUCTS

**Smart Home**
- Home Appliances
- Smart Lighting
- Home Automation
- Smart Door Lock
- Smart Meter

**Aerospace**
- Drone
- ATC
- Aeroplane
- Satellite FSS
- Navigation

**Smart City**
- Smart Parking
- Street Lighting
- Trashcan
- Public Hotspot
- Payment Device

**Transportation**
- Fleet management
- V2I
- Customer Hotspot
- Payment Device

**Medical**
- Remote Surgery
- Wireless Medical Implants
- External Control device

**Others**
- Factory
- Smart Fitness & health

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Rohde & Schwarz

* Living with the IoT Neighbors: Demonstrating Wireless Coexistence Testing

Naseef Mahmud
medical devices electromagnetic environment

Professional Healthcare Environment

Physician offices, dental offices, clinics, limited care facilities, freestanding surgical centres, freestanding birthing centers, hospitals (emergency rooms, patient rooms, intensive care units, surgical rooms..)

Special Environment

Military areas (submarines, near radar installations, near weapons control systems), heavy industrial areas (power plants, steel and paper mills, doundries, oil and gas refineries..), medical treatment areas with high power ME equipment( HF surgical equipment, short wave therapy equipment..)

Home Healthcare Environment

Restaurants, cafes, shops, stores, markets, schools, churches, libraries, outdoors (streets, sidewalks, parks), domiciles (residences, homes, nursing homes), vehicles (cars, buses, trains, boats, planes, helicopters) train stations, bus stations, airports, hotels, hostels, pensions, museums theatres...

Mireya Fernández Chimeno Ferran Silva Martínez GCEM-UPC
Non ionizing radiation

ionizing radiation

Radiation Type

Wavelength (m)

Radio

$10^9$

Microwave

$10^{-2}$

Infrared

$10^{-5}$

Visible

$0.5 \times 10^{-6}$

Ultraviolet

$10^{-8}$

X-ray

$10^{-10}$

Gamma ray

$10^{-12}$

Approximate Scale of Wavelength

Buildings

Humans

Butterflies

Needle Point Protozoans

Molecules

Atoms

Atomic Nuclei

Frequency (Hz)

$10^4$

$10^8$

$10^{12}$

$10^{15}$

$10^{16}$

$10^{18}$

$10^{20}$

ESU

MRI

MW diathermy

Thermography

UV sterilizer

CT scanner

Radiation Types and their Frequencies

- **Radio** ($10^9$ m)
- **Microwave** ($10^{-2}$ m)
- **Infrared** ($10^{-5}$ m)
- **Visible** ($0.5 \times 10^{-6}$ m)
- **Ultraviolet** ($10^{-8}$ m)
- **X-ray** ($10^{-10}$ m)
- **Gamma ray** ($10^{-12}$ m)

Non-ionizing Radiation:

- Pulse Oximetry
- Phototherapy
- UV sterilizer

Ionizing Radiation:

- ESU
- MRI
- MW diathermy
- Thermography
- X-ray
- PET
- CT scanner

European Training Network on Electromagnetic Risks in Medical Technology

Grup de Compatibilitat Electromagnètica
UNIVERSITAT POLITÈCNICA DE CATALUNYA
What is EMC?

The European EMC Directive says:

• “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;

  • (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.”

STANDARDS (with TESTS) ensures LOW EMISSIONS and LARGE IMMUNITY (low susceptibility)

This is ELECTROMAGNETIC COMPATIBILITY (EMC)
What is EMC?

- Immunity limit
- Emissions limit

**Problem**

- EUT immunity
- EUT emissions

EMC margin

- Non-compliance with the immunity level
- Non-compliance with the emission level

Immunity limit

Emissions limit

Safety margin

Set by the standards depending on the environment of use and the danger of use of the equipment.
What is EMC?
What is EMC?

ELECTRONIC DESIGN FOR EMC
Rowan Sebastian Atkinson was born on January 6, 1955, in Newcastle upon Tyne, England. Atkinson studied at Newcastle University and Oxford University and earned a master's degree in electrical engineering.
but real life is much more complex
What is EMC?

Is this the real life?

Photo courtesy of Dr. David H T Scott, Department of Anesthetics, The Royal Infirmary of Edinburgh, United Kingdom
What is a medical device

REGULATION (EU) 2017/745 on medical devices establishes that

“medical device” means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

• diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
• diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
• investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

• devices for the control or support of conception;
• products specifically intended for the cleaning, disinfection or sterilization of devices.
What is a medical device
What is a medical device

Active implantable

in vitro diagnosis

Borderline products: Medicated surgical dressings, head lice products
Aesthetic Products: Non-corrective contact lenses, Equipment for liposuction
Medical devices classification

Classification is based on risk

Medical devices

Class I
- band aid
- Wheelchair
- Stethoscopes
- Gloves

Class IIa
- ECG monitors

Class IIb
- Ventilators
- Bone plates
- Dialysis machine

Class III
- Pacemakers
- Heart valves

Class A
- Clinical chemistry analysers
- Specimen receptacles
- Prepared selective culture media

Class B
- Pregnancy self-testing
- Urine test strips
- Cholesterol self-testing

Class C
- Blood glucose self-testing
- PSA screening
- HLA typing

Class D
- Hepatitis B blood donor screening
- HIV blood diagnostic test
- ABO blood grouping

High risk

Notified Body approval required

Self-assessment

In Vitro Diagnosis
Medical devices classification

The 22 Classification Rules

Rules 1 – 4: Non-invasive devices

Rules 5 – 8: Invasive Medical devices

Rules 9 – 12: Active Medical devices

Rules 13– 22: Special Rules
European medical devices standards: the EN-60601 Family

- EU EUROPEAN STANDARD 60601-1
  Medical electrical equipment
  Part 1
  General requirements

- EU EUROPEAN STANDARD 60601-1-2
  Medical electrical equipment
  Part 1
  General requirements for EMC

- EU EUROPEAN STANDARD 60601-1-3
  Medical electrical equipment
  Part 1
  General requirements for radiation protection

- EU EUROPEAN STANDARD 60601-1-6
  Medical electrical equipment
  Part 1
  General requirements for usability

Colateral (Common)

Particular (product specific about 70)

Synchronization lost
ISO 14971 specifies a process for risk management of medical devices, including software as a medical device and in vitro diagnostic medical devices. The process intends to assist manufacturers of medical devices to identify the hazards associated with the medical device, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.
Risks can be related to injury, not only to the patient, but also to the user and other persons. **Risks can also be related to damage to property** (for example objects, data, other equipment) **or the environment**.

*Risk management* is a complex subject because each stakeholder can place a different value on the acceptability of *risks* in relation to the anticipated *benefits*. The concepts of *risk management* are particularly important in relation to *medical devices* because of the variety of stakeholders, including *medical practitioners*, the organizations providing *health care*, *governments*, *industry*, *patients* and *members of the public*.

The concept of *risk* has two key components:

— the probability of occurrence of *harm*; and
— the consequences of that *harm*, that is, how severe it might be.

The acceptability of a *risk* is influenced by the stakeholder’s perception of the *risk* and the *benefit*. 
Medical devices risk management

Examples of hazards in ISO14971:2019

**Energy hazards**
- Acoustic
- Electric
- Mechanical
- Radiation
- Thermal

**Biological and chemical hazards**
- Biological agents
- Chemical agents
- Immunological agents

**Hazards related with performance**
- Data
- Delivery
- Diagnostic information
- Functionality

Electromagnetic radiation
## Medical devices risk management

### Qualitative severity levels

<table>
<thead>
<tr>
<th>Common terms</th>
<th>Possible description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant</td>
<td>Death or loss of function or structure</td>
</tr>
<tr>
<td>Moderate</td>
<td>Reversible or minor injury</td>
</tr>
<tr>
<td>Negligible</td>
<td>No injury or slight injury</td>
</tr>
</tbody>
</table>

Example of three qualitative **severity** levels

### Qualitative probability levels

<table>
<thead>
<tr>
<th>Qualitative probability levels</th>
<th>Negligible</th>
<th>Moderate</th>
<th>Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>R1</td>
<td>R2</td>
<td></td>
</tr>
<tr>
<td>Medium</td>
<td>R4</td>
<td>R5, R6</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>R3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Example of three qualitative **probability** levels

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**Example of three qualitative severity levels**

**Example of three qualitative probability levels**

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**Common terms**

**Possible description**

- **High**
  - Likely to happen, often, frequently, always
  - Likely to happen several times during the lifetime of the medical device

- **Medium**
  - Can happen, but not frequently
  - Likely to occur a few times during the lifetime of the medical device

- **Low**
  - Unlikely to happen, rare, remote
  - Not likely to occur during the lifetime of the medical device
Medical devices risk management

<table>
<thead>
<tr>
<th>Common terms</th>
<th>Possible description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catastrophic / Fatal</td>
<td>Results in death</td>
</tr>
<tr>
<td>Critical</td>
<td>Results in permanent impairment or irreversible injury</td>
</tr>
<tr>
<td>Serious / Major</td>
<td>Results in injury or impairment requiring medical intervention</td>
</tr>
<tr>
<td>Minor</td>
<td>Results in temporary injury or impairment not requiring medical intervention</td>
</tr>
<tr>
<td>Negligible</td>
<td>Results in inconvenience or temporary discomfort</td>
</tr>
</tbody>
</table>

Example of five qualitative severity levels and of five semi-qualitative probability levels

### Probability

<table>
<thead>
<tr>
<th>Common terms</th>
<th>Ex. of probability range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
<td>$\geq 10^{-3}$</td>
</tr>
<tr>
<td>Probable</td>
<td>$&lt;10^{-3}$ and $\geq 10^{-4}$</td>
</tr>
<tr>
<td>Occasional</td>
<td>$&lt;10^{-4}$ and $\geq 10^{-5}$</td>
</tr>
<tr>
<td>Remote</td>
<td>$&lt;10^{-5}$ and $\geq 10^{-6}$</td>
</tr>
<tr>
<td>Improbable</td>
<td>$&lt;10^{-6}$</td>
</tr>
</tbody>
</table>

### Severity

<table>
<thead>
<tr>
<th>Qualitative severity levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatal</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>Frequent</td>
</tr>
<tr>
<td>Probable</td>
</tr>
<tr>
<td>Occasional</td>
</tr>
<tr>
<td>Remote</td>
</tr>
<tr>
<td>Improbable</td>
</tr>
</tbody>
</table>
Medical devices risk management
### Medical devices risk management

#### Severity levels

<table>
<thead>
<tr>
<th>Probability levels</th>
<th>Fatal</th>
<th>Critical</th>
<th>Major</th>
<th>Minor</th>
<th>Negligible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent</td>
<td>R2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Probable</td>
<td></td>
<td>R3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occasional</td>
<td>R1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remote</td>
<td>R4</td>
<td>R6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improbable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>R5</td>
</tr>
</tbody>
</table>

#### Probability

- Frequent: R2
- Probable: R3
- Occasional: R1
- Remote: R4
- Improbable: R5

You should stay in the green or yellow area.

---

*Non-acceptable* | *ALARP* | *Acceptable*
### Medical devices risk management

<table>
<thead>
<tr>
<th></th>
<th>F</th>
<th>C</th>
<th>Ma</th>
<th>Mi</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>F</td>
<td></td>
<td>R2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P</td>
<td></td>
<td>R3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>O</td>
<td>R1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R</td>
<td>R4</td>
<td>R6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td></td>
<td></td>
<td>R5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Risk control measures:

- F: Risk factor
- C: Control
- Ma: Major
- Mi: Moderate
- N: None

- F: Risk factor
- C: Control
- Ma: Major
- Mi: Moderate
- N: None
Medical devices risk management

Figure 1 — A schematic representation of the risk management process

Risk Management Tools
- FMEA
- FRA
- HACCP
- HAZOP
- ETA
- Others
EMI risk management in medical devices

IEC 60601-1-2

Electromagnetic environments
EMC test methods
EMC design techniques (for hardware and software)
Mitigation Methods
- Bonding
- Filtering
- Shielding
- Galvanic isolation
- Overvoltage Protection
- etc.

ISO 14971
Risk Management

Risks caused by electromagnetic disturbances

IEC 60601-1-2

EM Risk analysis
EM Risk evaluation
EM Risk control
Using verification and validation methods such as:
- Demonstrations
- Checklists
- Inspections
- Reviews & assessments
- Independent reviews and assessments
- Audits
- Non-standardized checks and tests
- Individual and/or integrated hardware tests
- Computer simulation
- EM testing

EM Risk acceptability

EM Risk management report
EM Production and post-production information
Electromagnetic risk management in medical devices

EMI examples in medical devices

Artifacts in an Image  
Noise in an ECG Trace

An FDA perspective on EMC on Medical Devices. Jeffrey L. Silberberg. FDA. EMC+SIPI 2017
Electromagnetic risk management in medical devices

The call you wish you’d never made

Imagine yourself at a family gathering. Everyone seems to be enjoying themselves. All of a sudden you notice your father. One side of his face is drooping. His speech is slurred. This is serious; maybe it’s a stroke. You call an ambulance, and it arrives within 15 minutes. As soon as your father gets to the hospital he is taken to the catheterization lab. A thoughtful nurse takes you to the control room, where you are allowed to watch the medical procedure. Your father is in good hands. For the medical staff this is routine. A doctor comes to tell you that you did exactly the right thing, that your father was lucky to reach the hospital in a short time after the event, and there is a good chance that his brain will suffer no long-term damage.

Relieved, you decide to call you brother, to tell him that everything looks fine. But at the first ring of your phone, the situation changes completely... The monitors in the examination room go blank – what is happening? You notice the worried faces of the doctors, who are urgently pressing buttons, trying to get the system back up again. Nurses are rushing in and out of the room. The machines connected to your father are no longer illuminated. This is serious. Then you remember the warnings at the entrance. Did your mobile-phone call just bring the whole system crashing down?
Problem to analyze:

Could a short duration interference (a mobile phone signal during the call establishment), affect the performance of a low frequency medical device (an ECG recorder)?
Electromagnetic risk management in medical devices

Electromagnetic radiated spectrum from an Electrosurgical Unit (ESU):

(a) in standby (as described in the standard)
(b) with a resistor as a load (to allow current flowing in the electrode wires),
(c) with a volunteer holding the ESU active electrode and with a resistor as a load (allowing the current flow in the electrode wires and considering the presence of a surgeon)
(d) cutting a piece of meat
Effect of ESU interference in an ECG signal

Electromagnetic risk management in medical devices
There is a gradual shift towards prevention and care taking place **away from the hospital environment**.

Wearables, the Internet of Things (IoT) and 5G technologies are playing an increasing role in the remote delivery of care.

Managing EMI in complex scenarios becomes priority because people’s lives are being put at risk.

Many new, high-tech, electronic medical devices need to be able to operate safely when surrounded by everyday electronic equipment that produces a lot of EMI.
Electromagnetic risk management in medical devices

But...

• The traditional rule-based approach (application of a set of mitigation techniques as filtering, shielding, cable routing, etc.) clearly do not satisfy the EMC requirements of complex electromagnetic medical environments.
• A “risk-based approach” will offer much higher levels of safety as medical equipment becomes more complex and we become increasingly dependent on its reliability.
• The law demands a risk-based approach. The recent EU Blue Guide (regarding the implementation of EU product rules) made an EMI risk-based approach mandatory for any new piece of equipment. The specific regulations for medical equipment (MDR3), which also refer to a risk-based approach, are mandatory since May 2020.
• Many hospitals and industries report that there is no clearly prescribed risk assessment methodology in place.
• Small and medium-sized enterprises (SMEs), which are often not in a position to cope with such a major shift in approach, make up almost 95% of the medical technology industry.

This new, risk-based methodology will require not only a formalization, but also trained specialists to address the complexity of the systems and all the individuals and institutions involved.
ETERNITY is about including the risk management of EMI in the design of innovative, electronic medical equipment.

The safer use of medical equipment based on assessing EMI risks requires bringing together expertise from 4 key areas – electromagnetic compatibility (EMC), medical engineering, system safety engineering and risk management.

From the regulatory perspective, ETERNITY covers all 4 key medical environments: hospital, homecare, transportation and the special environment of medical imaging and treatment systems.
ETERNITY Work Packages
ETERNITY ESR

- EMI footprint characterization of medical devices (ESR1)
- Characterization of medical electromagnetic environments for the use of new digital communication systems (DCS) (ESR2)
- Risk-Based EMI-Aware Design of Complex Systems (ESR4)
- Optimal Digital Communication Systems in electromagnetically noisy medical environments (ESR 5)
- EMI- Resilient Sensor and Communication Networks for complex medical systems-of-systems (ESR 6)
- Behavioural EMI Risk-based testing of medical devices (ESR7)
- Improvement of digital communication systems immunity tests to include complex electromagnetic disturbances (ESR8)

https://eternity-project.eu/esr-projects/
ETERNITY CONSORTIUM

Eternity

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Thanks!

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