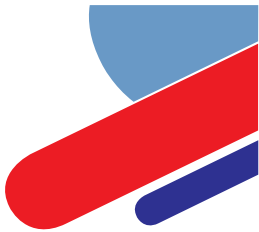




Grup de Compatibilitat Electromagnètica
UNIVERSITAT POLITÈCNICA DE CATALUNYA



Mireya Fernández Chimeno
Ferran Silva Martínez
GCEM-UPC

BIOSTEC 2021
14TH INTERNATIONAL JOINT CONFERENCE ON BIOMEDICAL
ENGINEERING SYSTEMS AND TECHNOLOGIES



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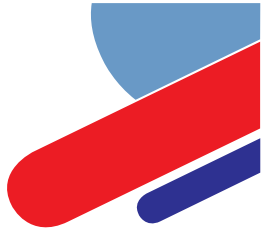
ETERNITY

European Training Network on Electromagnetic Risks in Medical Technology



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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

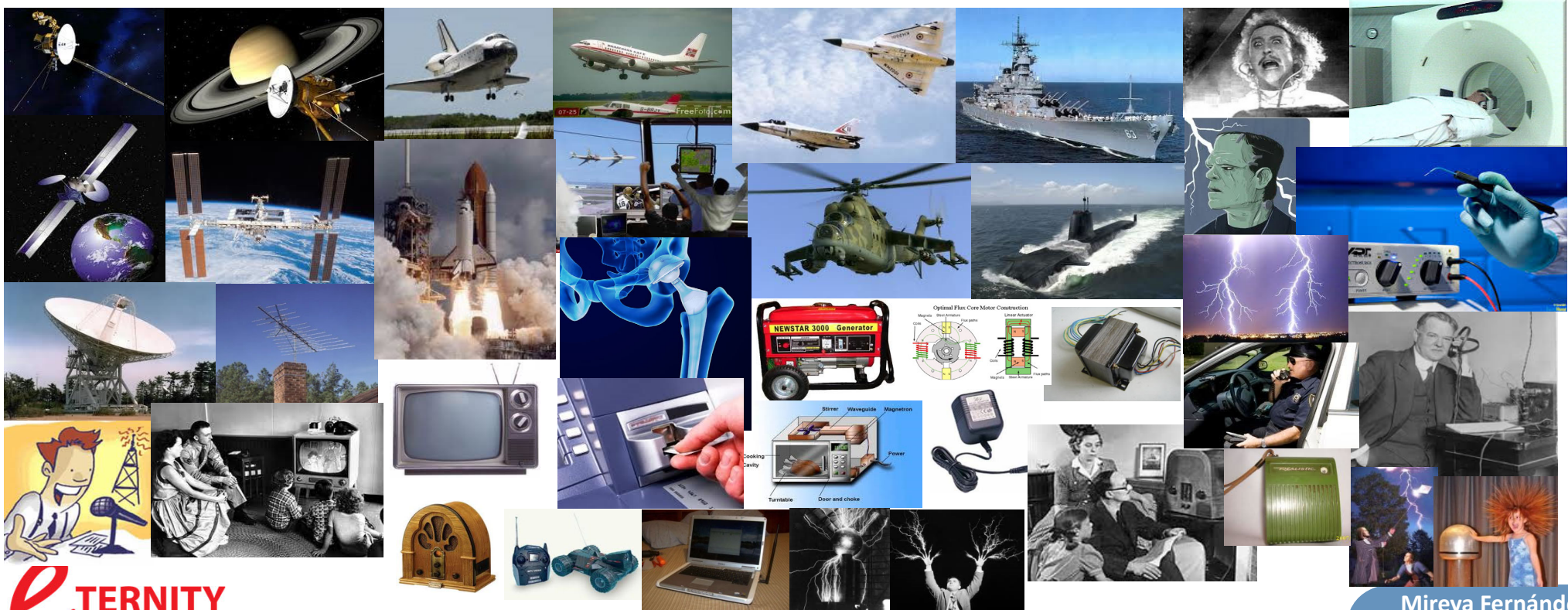


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Introduction

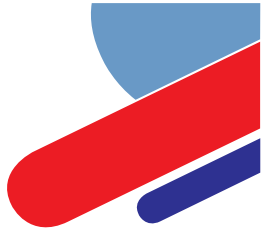
Electromagnetic Risks in Medical Technology → electromagnetic energy





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Introduction



Electromagnetic interferences (EMI)

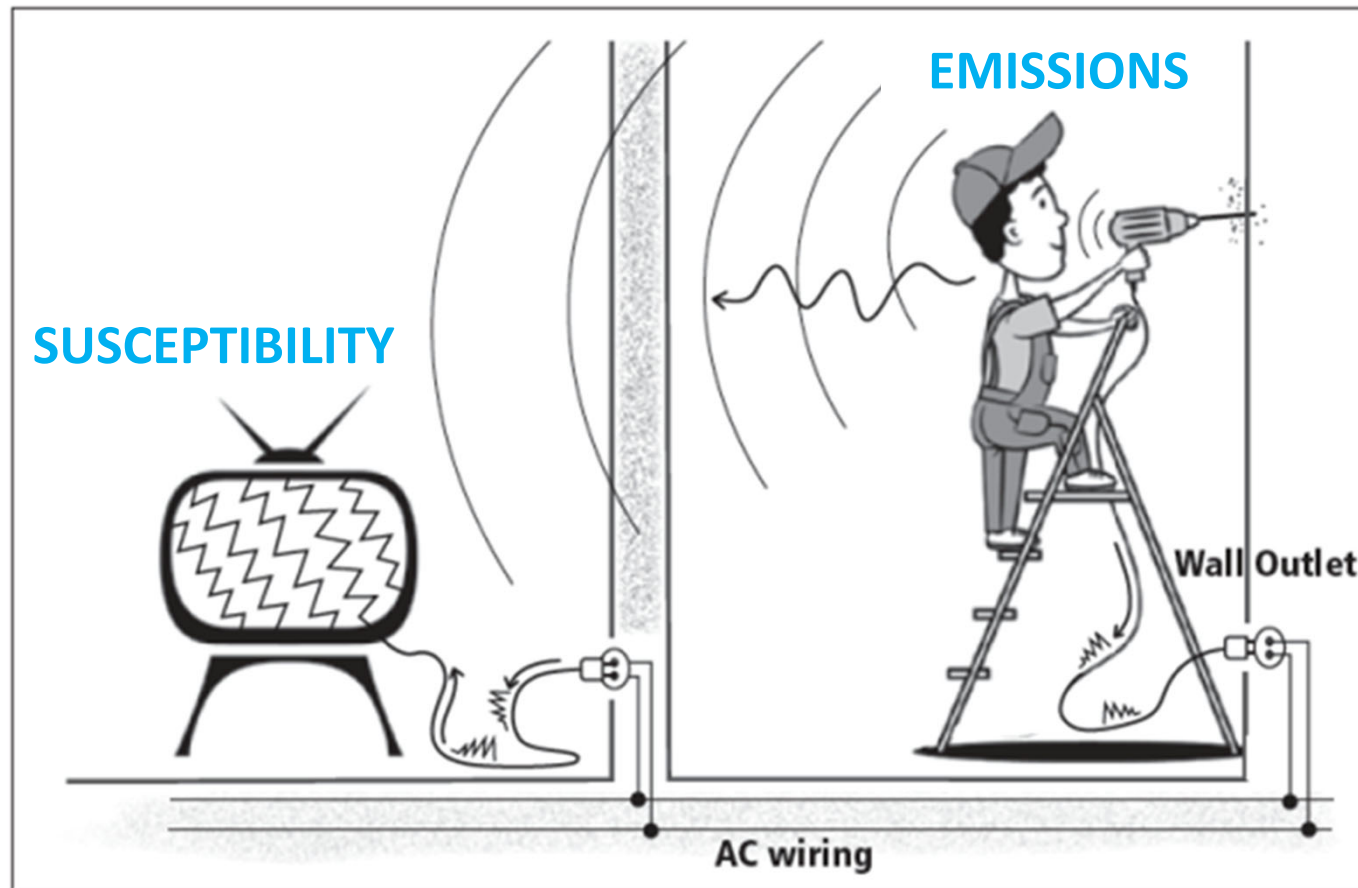
- Any electromagnetic disturbance that interrupts, obstructs, or otherwise degrades or limits the effective performance of electronics and electrical equipment.
- The IEC/IEV defines electromagnetic interference (EMI) as “degradation of the performance of a device, equipment or system by an electromagnetic disturbance”



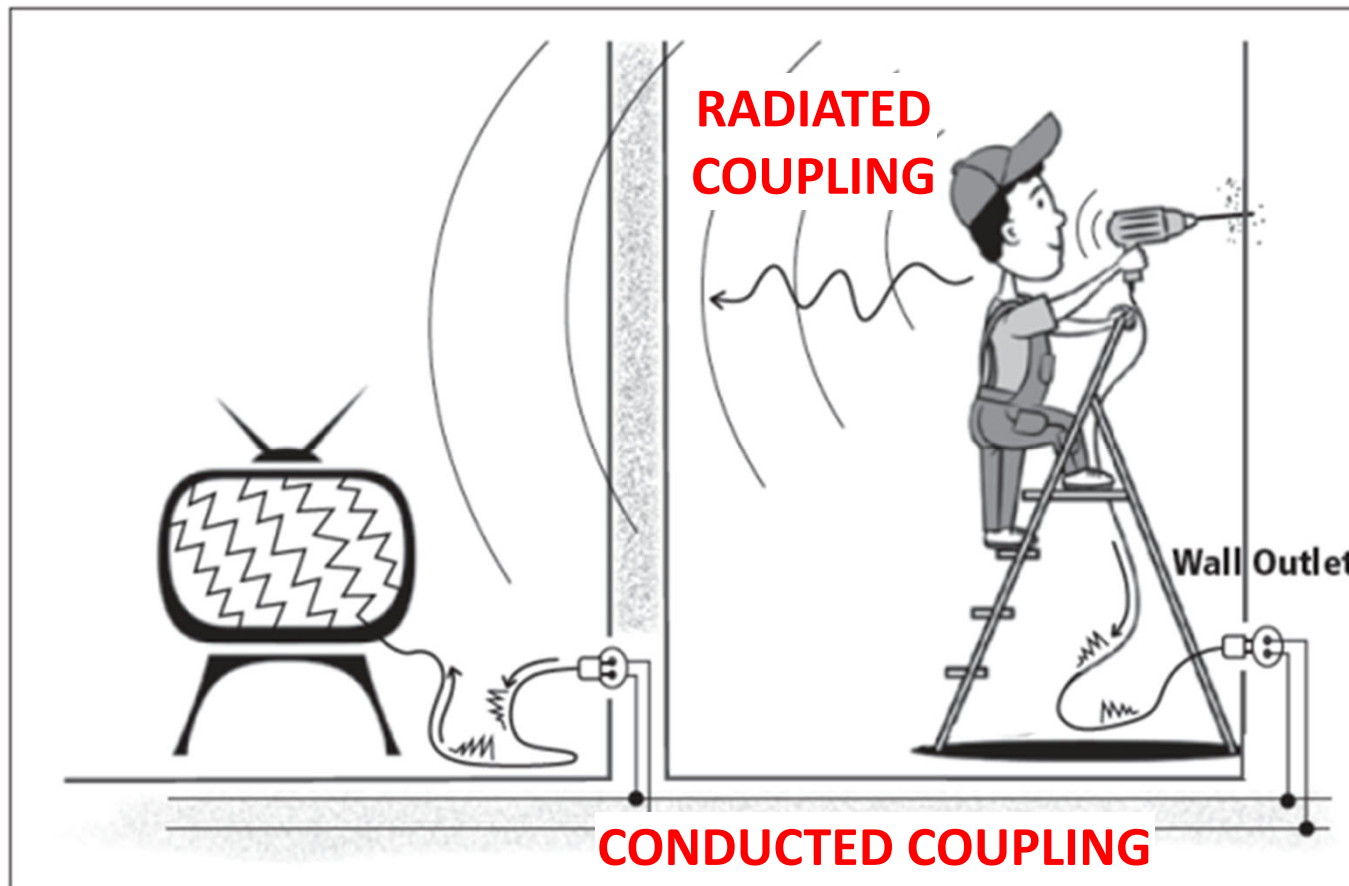
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What is an EMI?

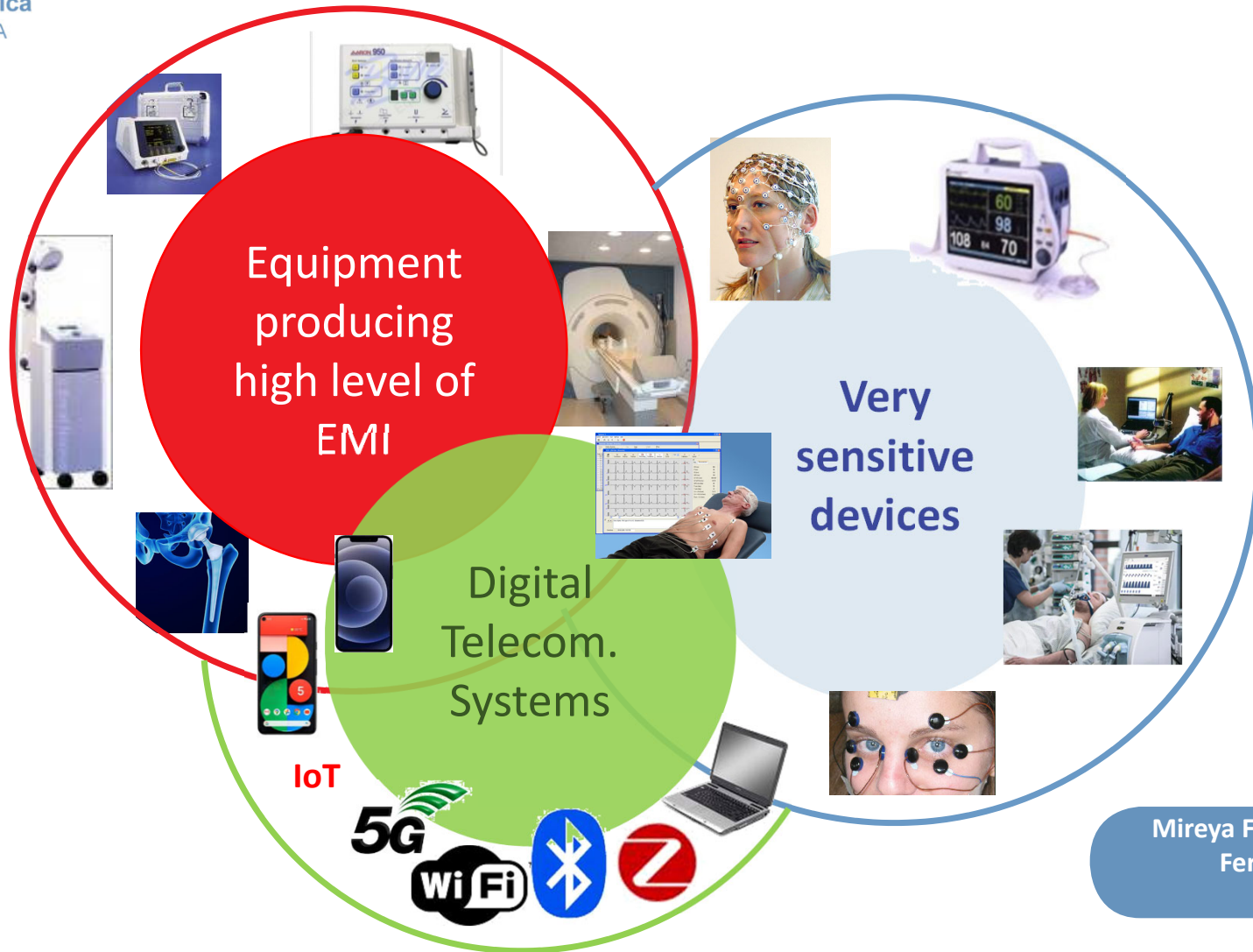
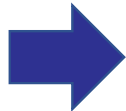


What is an EMI?



medical devices environment: Hospital

Hospital





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medical devices environment: at home


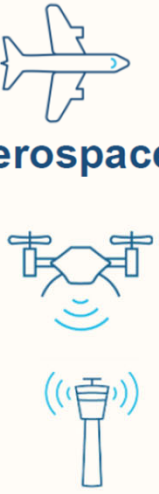



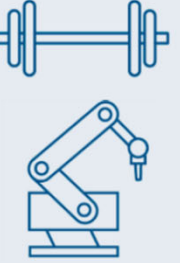


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medical devices environment: at home

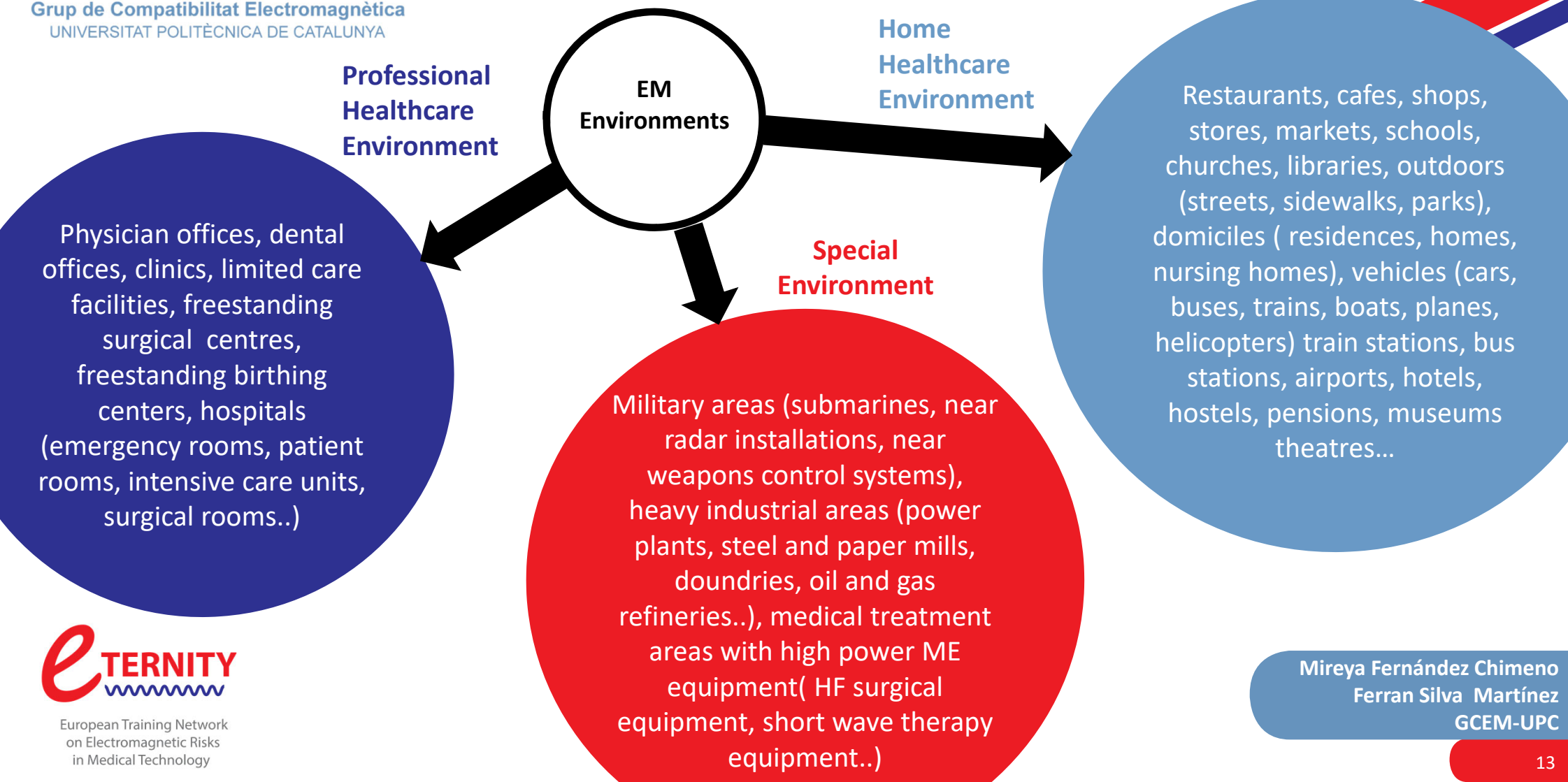
CONNECTED IoT PRODUCTS

Smart Home	Aerospace	Smart City	Transportation	Medical	Others
					
<ul style="list-style-type: none"> • Home Appliances • Smart Lighting • Home Automation • Smart Door Lock • Smart Meter 	<ul style="list-style-type: none"> • Drone • ATC • Aeroplane • Satellite FSS • Navigation 	<ul style="list-style-type: none"> • Smart Parking • Street Lighting • Trashcan • Public Hotspot • Payment Device 	<ul style="list-style-type: none"> • Fleet management • V2I • Customer Hotspot • Payment Device 	<ul style="list-style-type: none"> • Remote Surgery • Wireless Medical Implants • External Control device 	<ul style="list-style-type: none"> • Factory • Smart Fitness & health



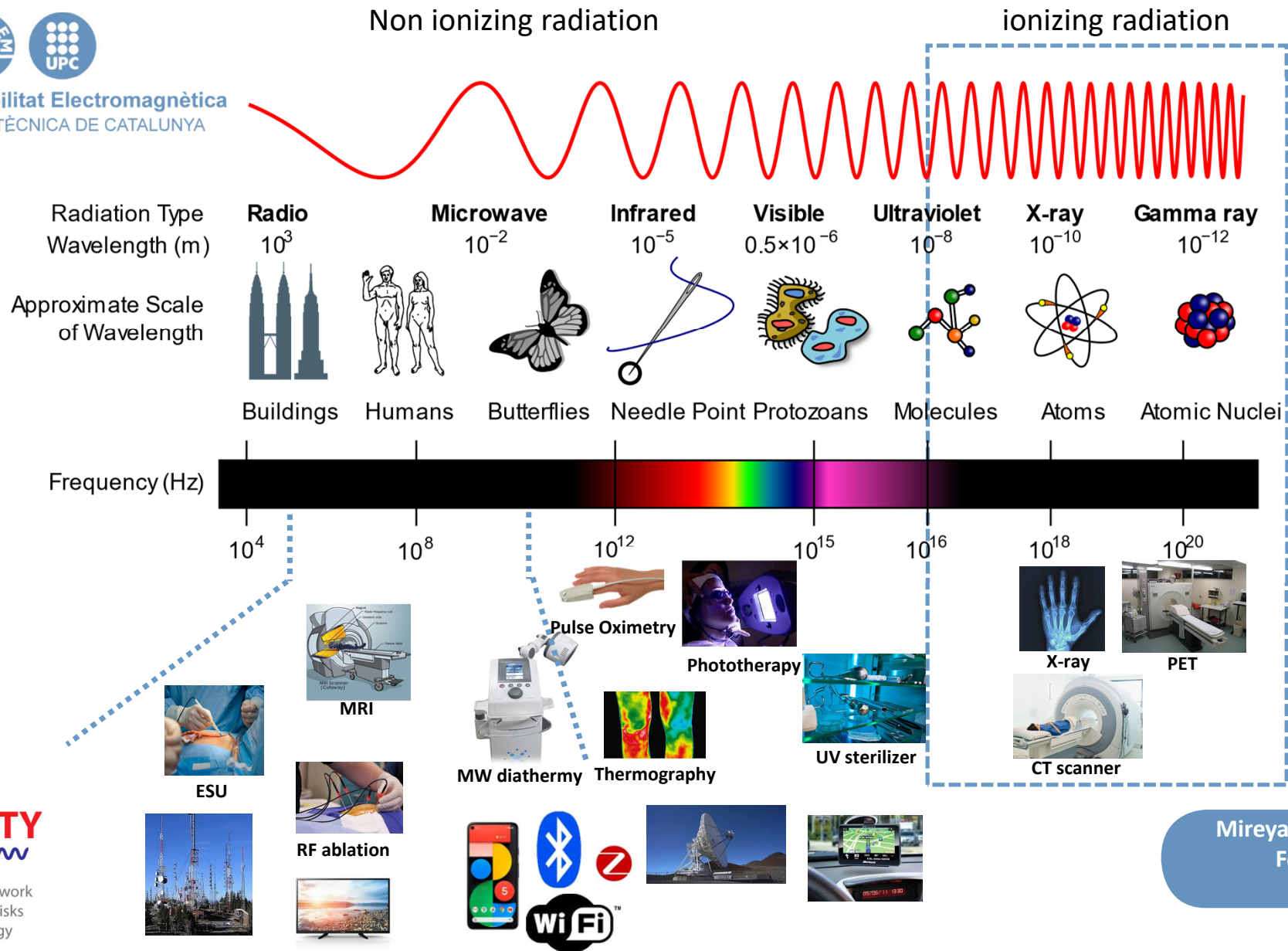
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medical devices electromagnetic environment



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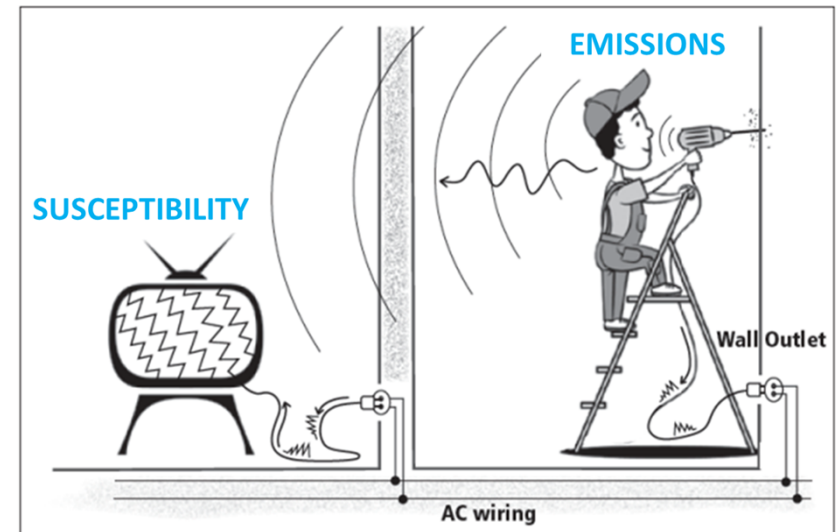
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What is EMC?

The European EMC Directive says:

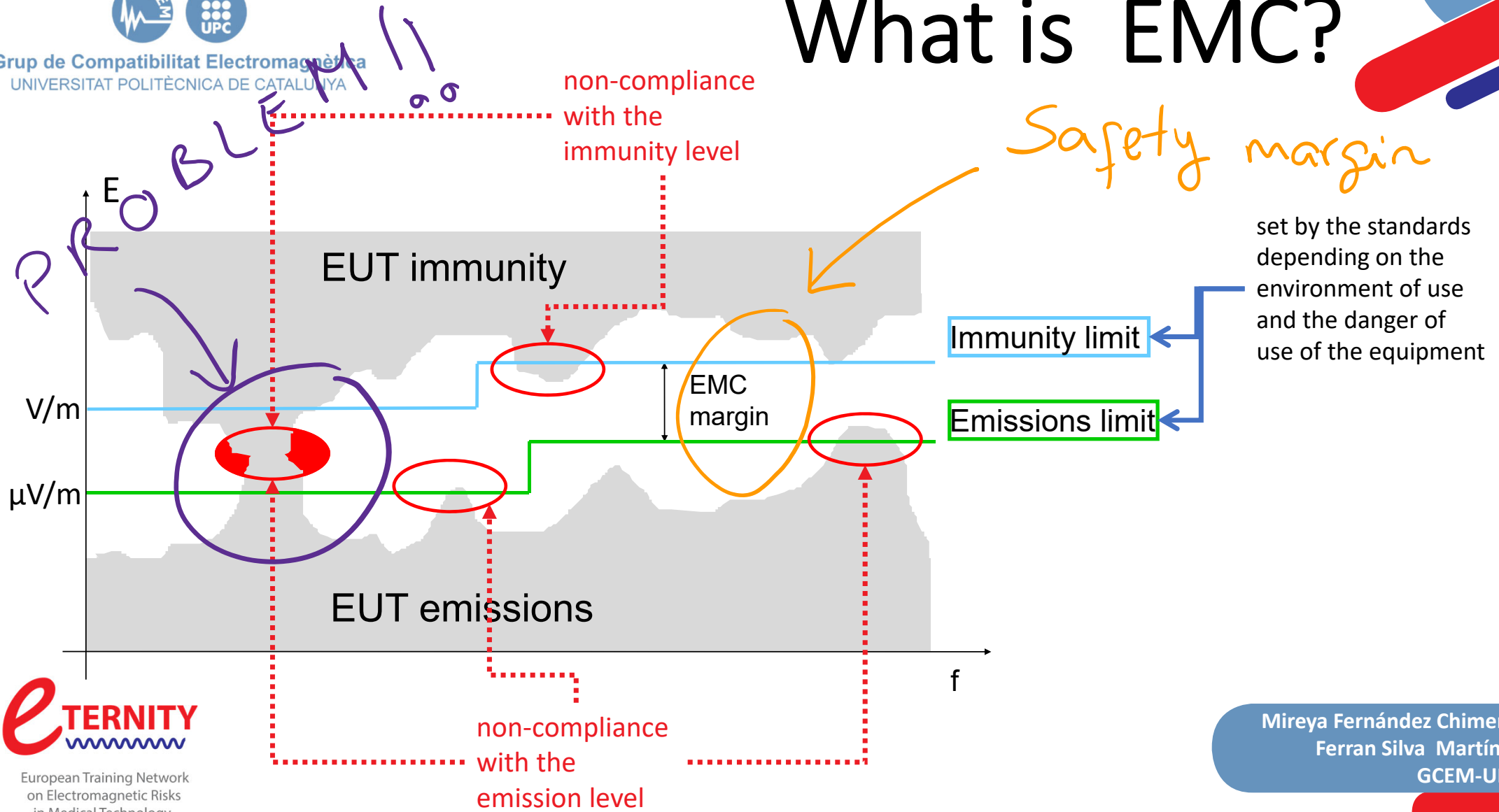
- “Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:
 - (a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;
 - (b) it has a level 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)

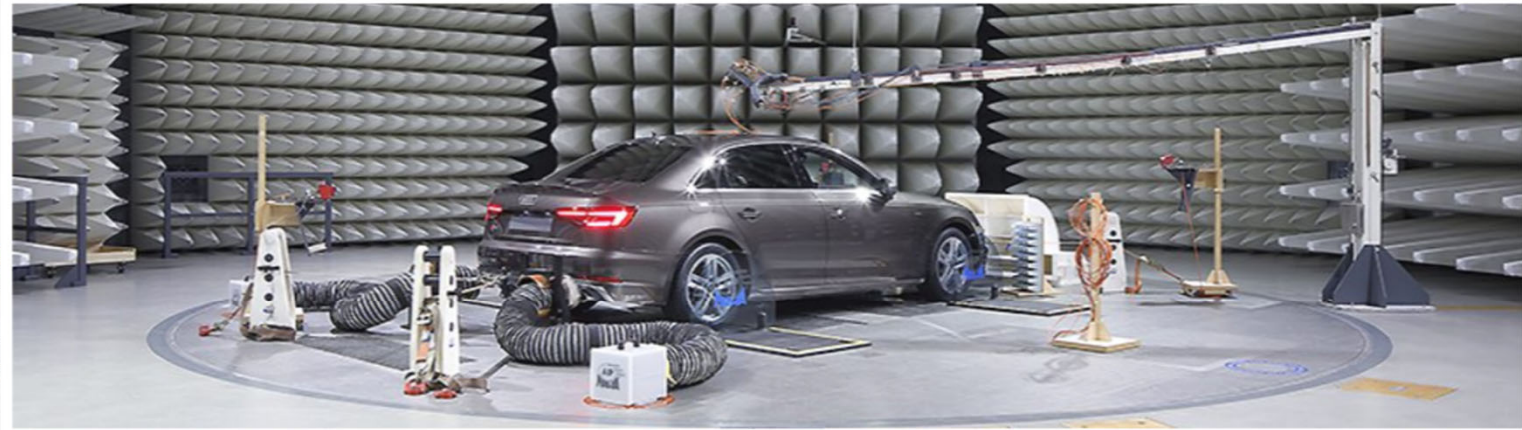
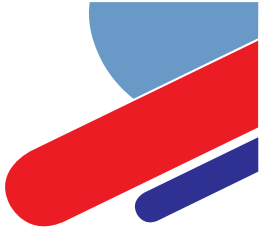
What is EMC?





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What is EMC?



TESTING



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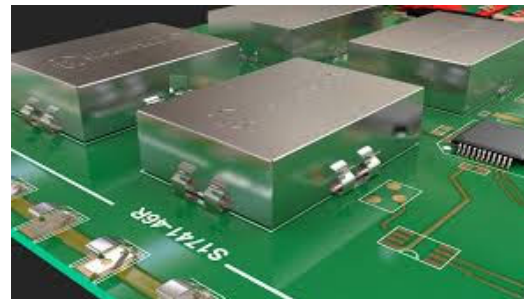
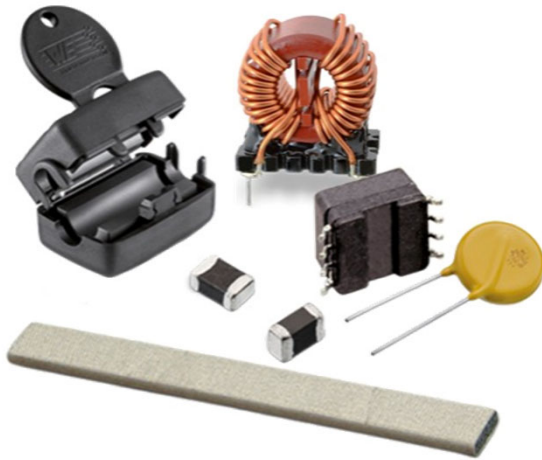
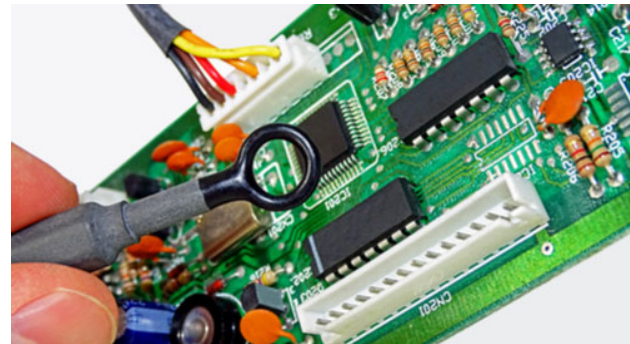
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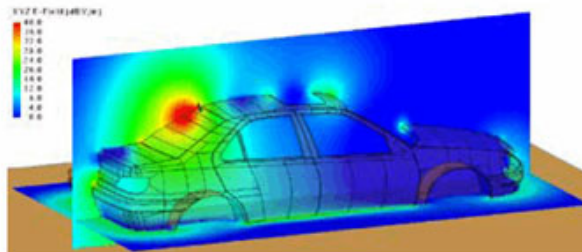
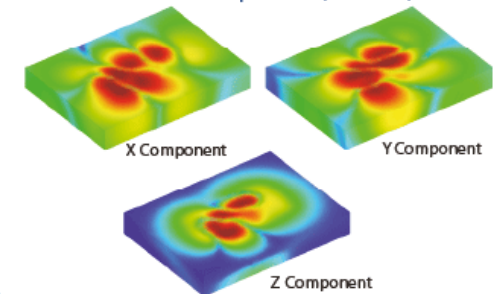
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What is EMC?

ELECTRONIC DESIGN FOR EMC



Electric Field Components (500 MHz)



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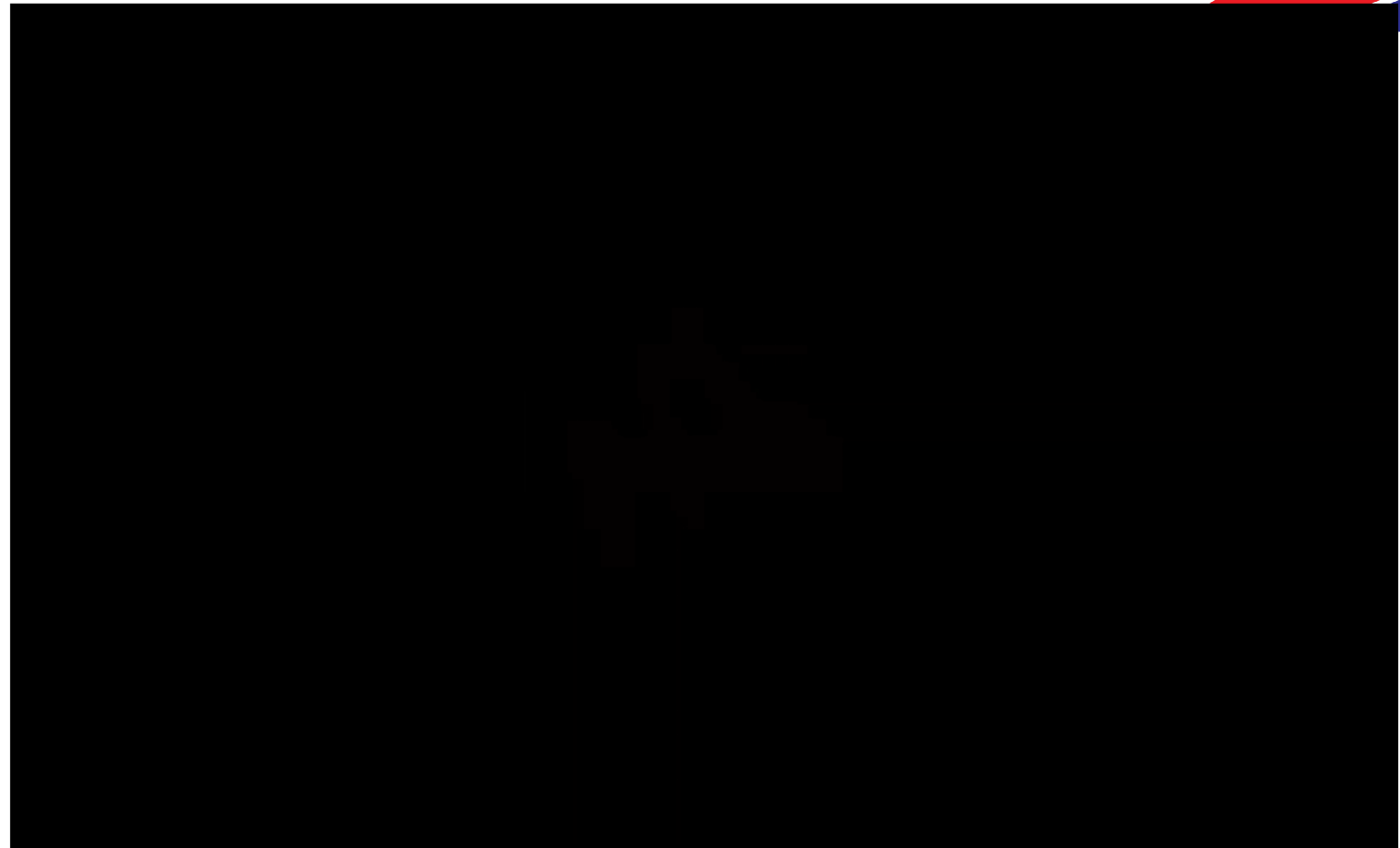


Rowan Sebastian Atkinson was born on January 6, 1955, in Newcastle upon Tyne, England. Atkinson studied at Newcastle University and Oxford University and earned a **master's degree in electrical engineering**.



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What is EMC?



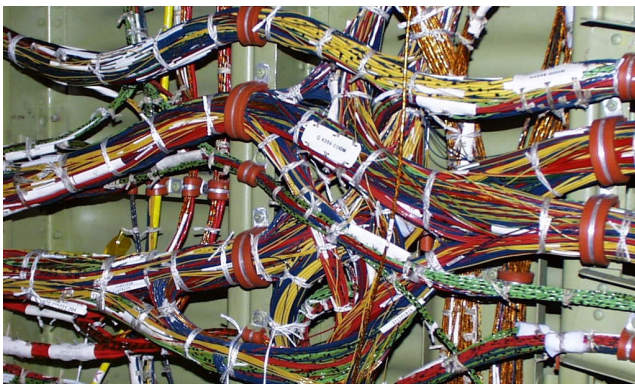
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What is EMC?

but real life is much more complex



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Is this the
real life?



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What is EMC?

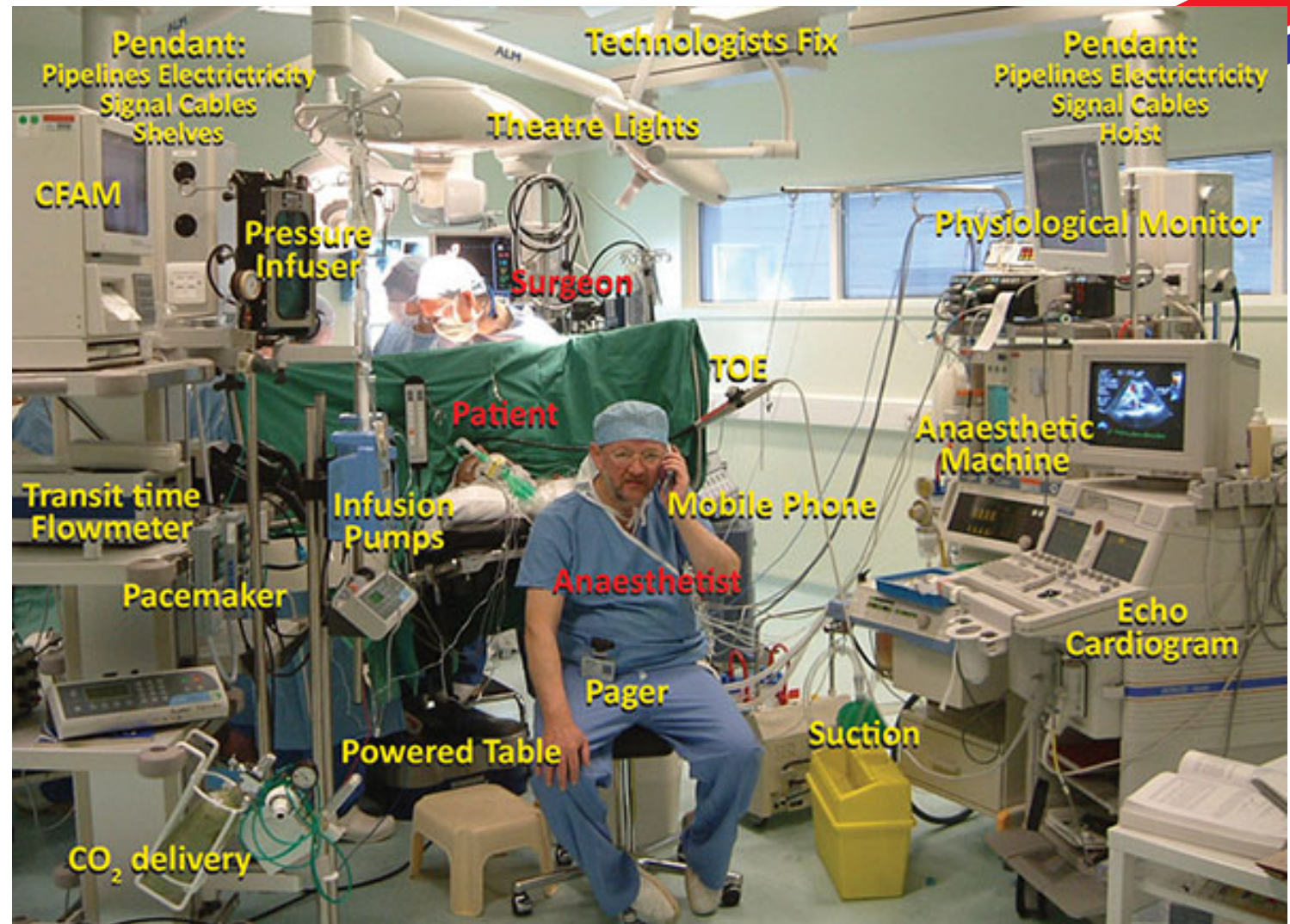


Photo courtesy of Dr. David H T Scott, Department of Anesthetics, The Royal Infirmary of Edinburgh, United Kingdom

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.

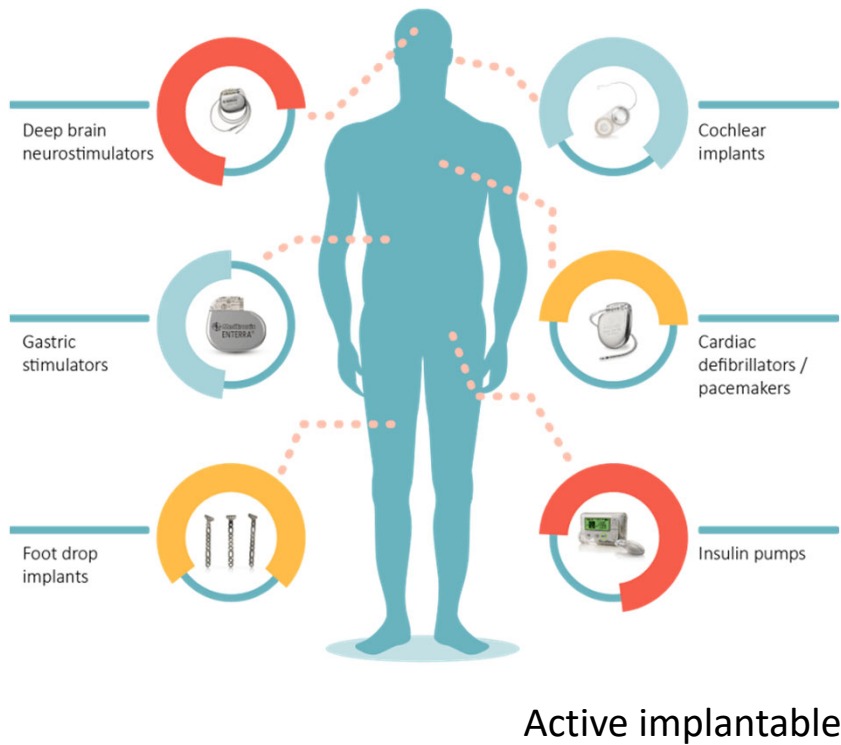
The following products shall also be deemed to be medical devices:

- 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



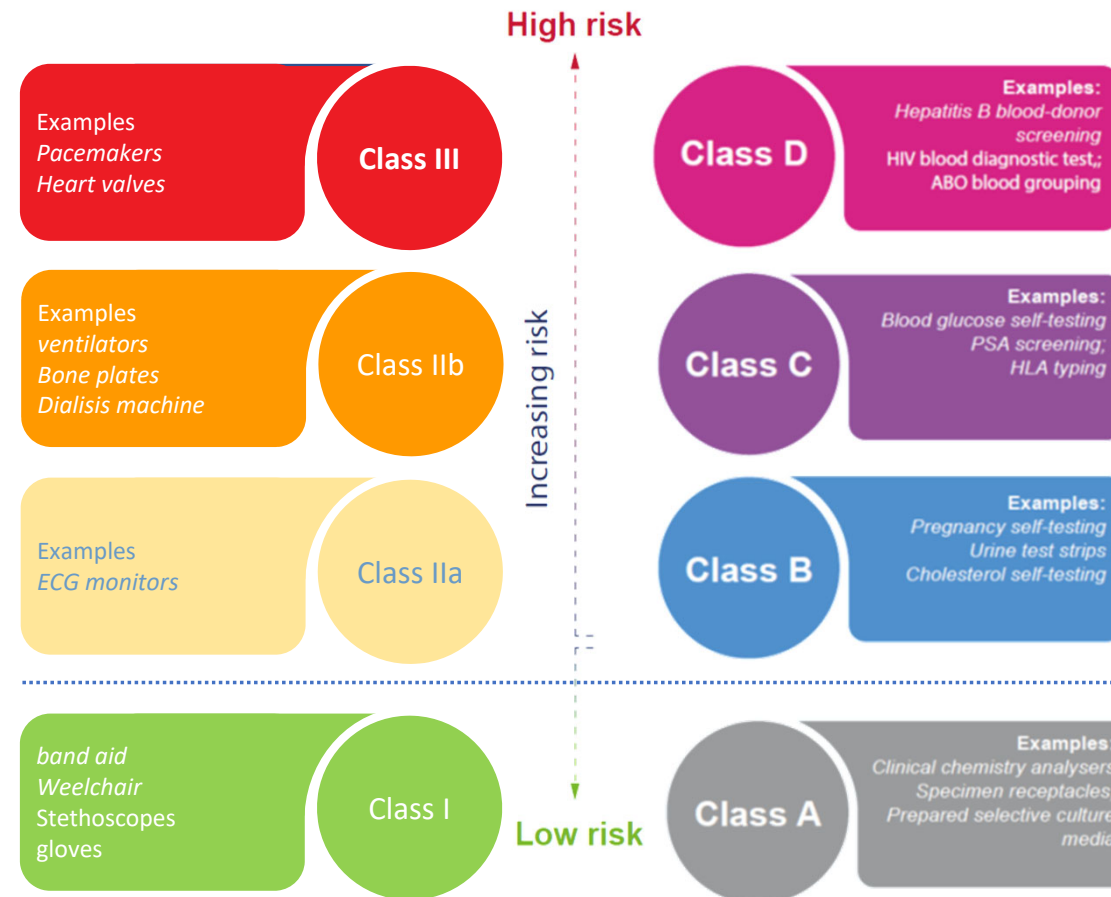
in vitro diagnosis

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

Medical devices

Notified Body
approval required

Self-assessment

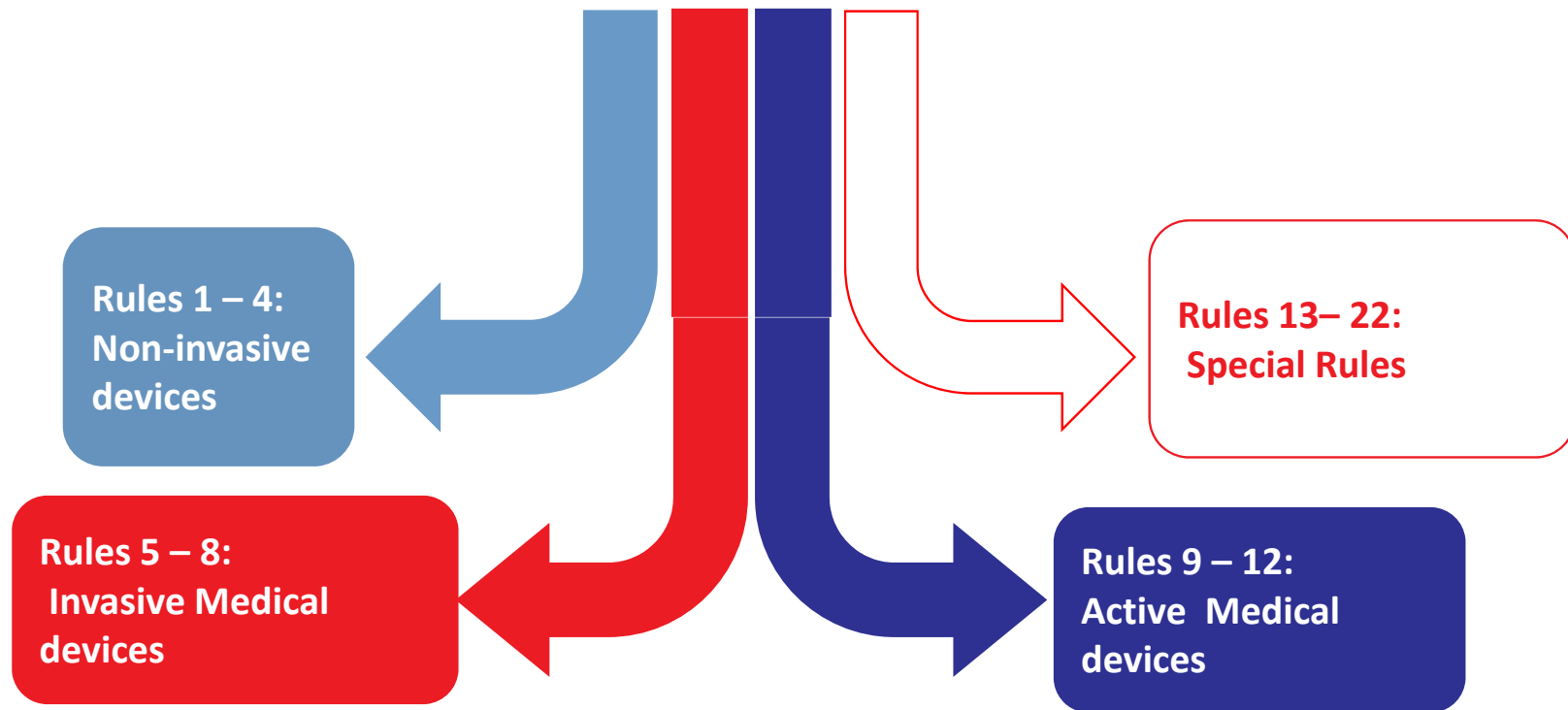


In Vitro Diagnosis

Classification is based on risk

Medical devices classification

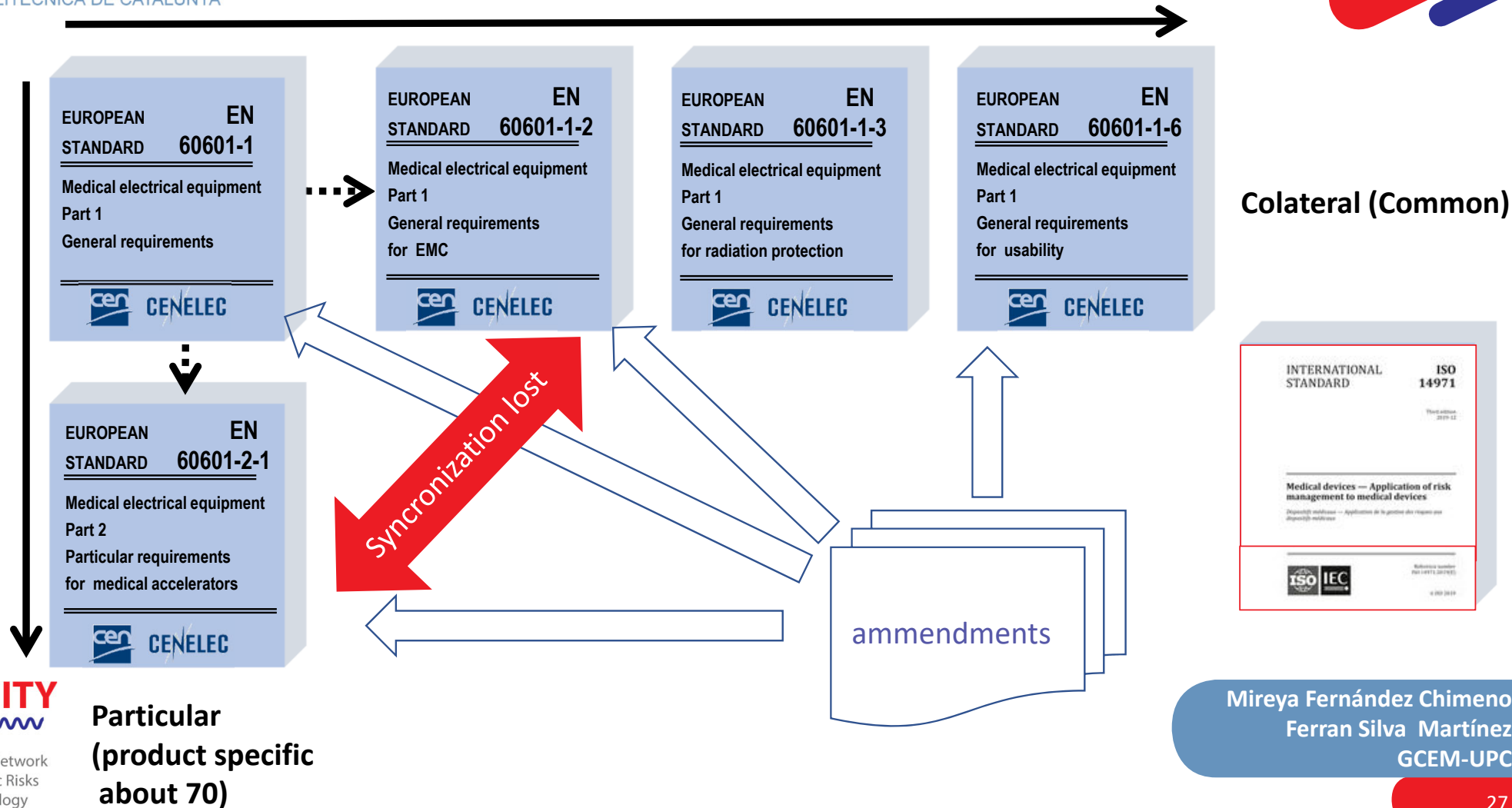
The 22 Classification Rules





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European medical devices standards: the EN-60601 Family



Medical devices risk management

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.





Medical devices risk management



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

Medical devices risk management

Common terms	Possible description
Significant	Death or loss of function or structure
Moderate	Reversible or minor injury
Negligible	No injury or slight injury

Example of three qualitative **severity** levels

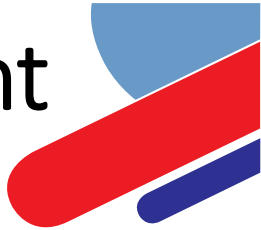
		Qualitative severity levels		
		Negligible	Moderate	Significant
Qualitative probability levels	High	R1	R2	
	Medium		R4	R5,R6
	Low		R3	

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

Example of three qualitative **probability** levels

Medical devices risk management

severity



Common terms	Possible description
Catastrophic / Fatal	Results in death
Critical	Results in permanent impairment or irreversible injury
Serious / Major	Results in injury or impairment requiring medical intervention
Minor	Results in temporary injury or impairment not requiring medical intervention
Negligible	Results in inconvenience or temporary discomfort

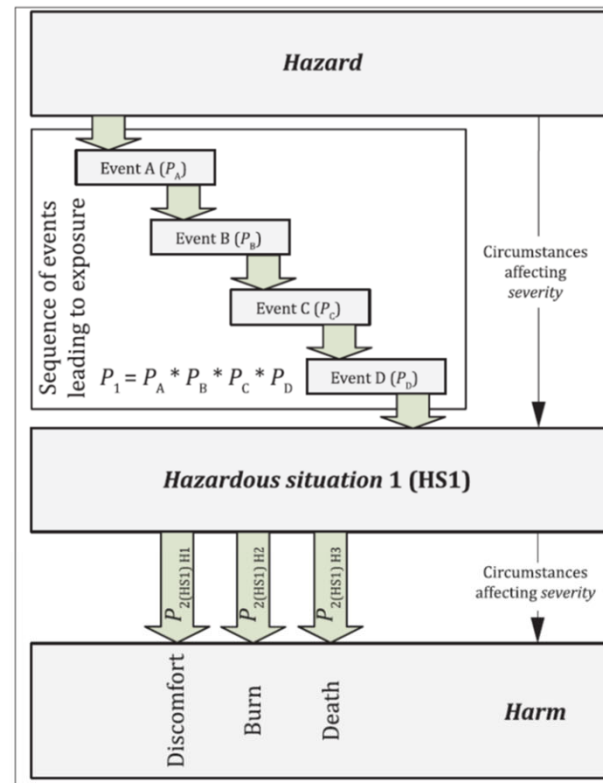
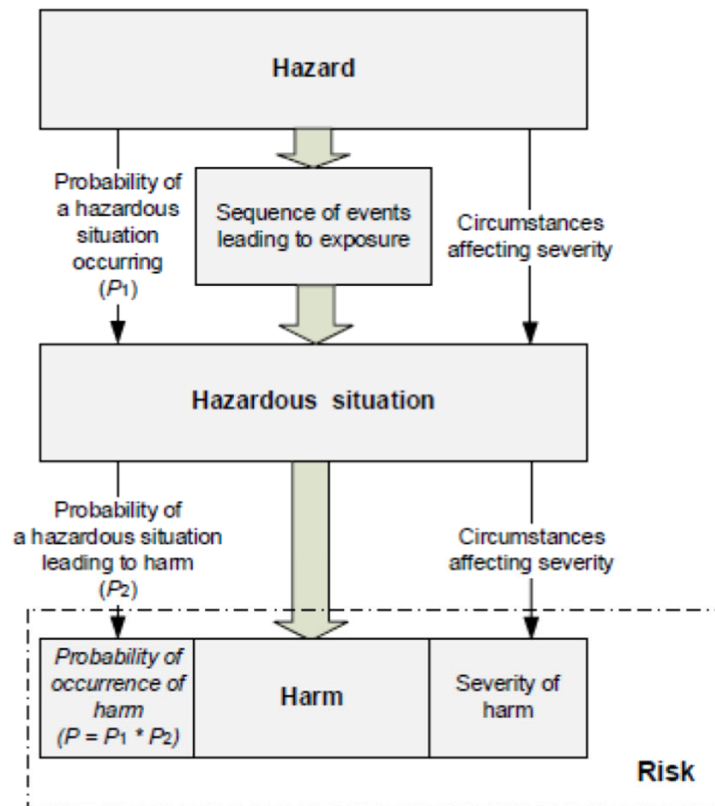
Example of five qualitative **severity** levels and of five semi- qualitative **probability** levels

Common terms	Ex. of probability range
Frequent	$\geq 10^{-3}$
Probable	$< 10^{-3}$ and $\geq 10^{-4}$
Occasional	$< 10^{-4}$ and $\geq 10^{-5}$
Remote	$< 10^{-5}$ and $\geq 10^{-6}$
Improbable	$< 10^{-6}$

probability

		Qualitative severity levels				
		Fatal	Critical	Major	Minor	Negligible
Semi-Qualitative probability levels	Frequent	R1	R2		R3	
	Probable					
	Occasional					
	Remote		R4	R6		
	Improbable					R5

Medical devices risk management



Hazard: electricity

Situation: line voltage (220 V) of an insulated wire beneath a cover of the medical device

Events:

- A. Insulation material is damaged by cracks ($P_A = 0,01$)
- B. Insulation material falls off the wire ($P_B = 0,10$)
- C. User connects and turns on the device ($P_C = 0,10$)
- D. User removes cover ($P_D = 0,10$)

*Hazardous situation: user is exposed to line voltage ($P_1 = P_A * P_B * P_C * P_D = 1 \times 10^{-5}$)*

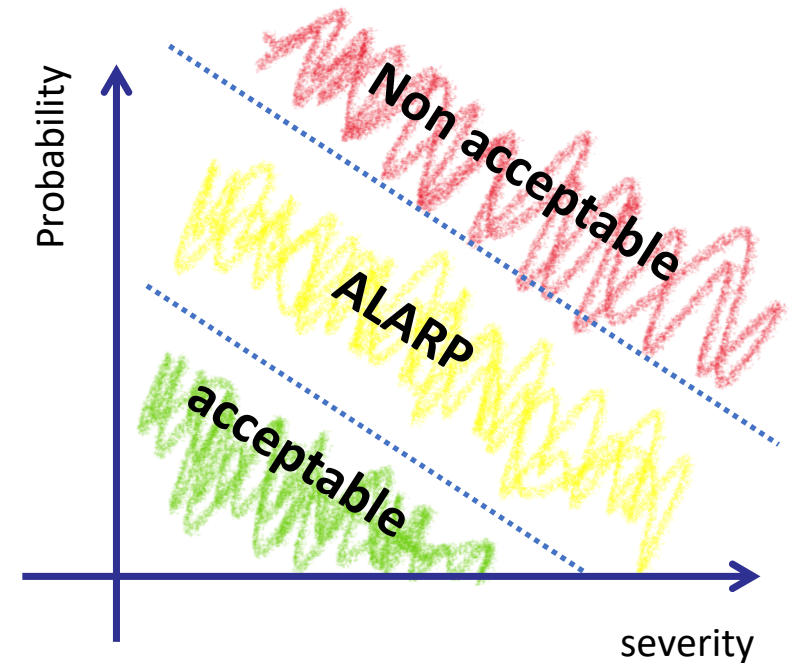
Probability that the user touches the wire and experiences:

- discomfort ($P_2 = 0,10$)
- burn ($P_2 = 0,01$)
- death ($P_2 = 0,001$)

Medical devices risk management

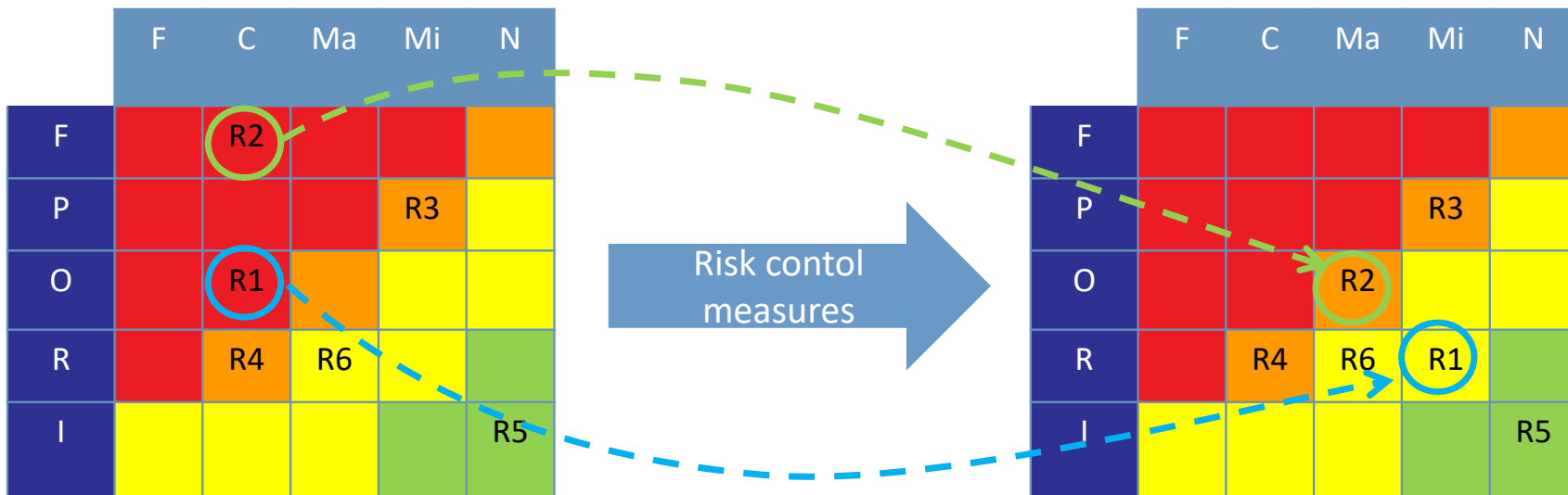
severity levels

Probability levels	severity levels				
	Fatal	Critical	Major	Minor	Negligible
	Frequent	R2			
	Probable			R3	
	Occasional	R1			
	Remote	R4	R6		
	Improbable				R5



You should stay in the green or yellow area

Medical devices risk management



Medical devices risk management

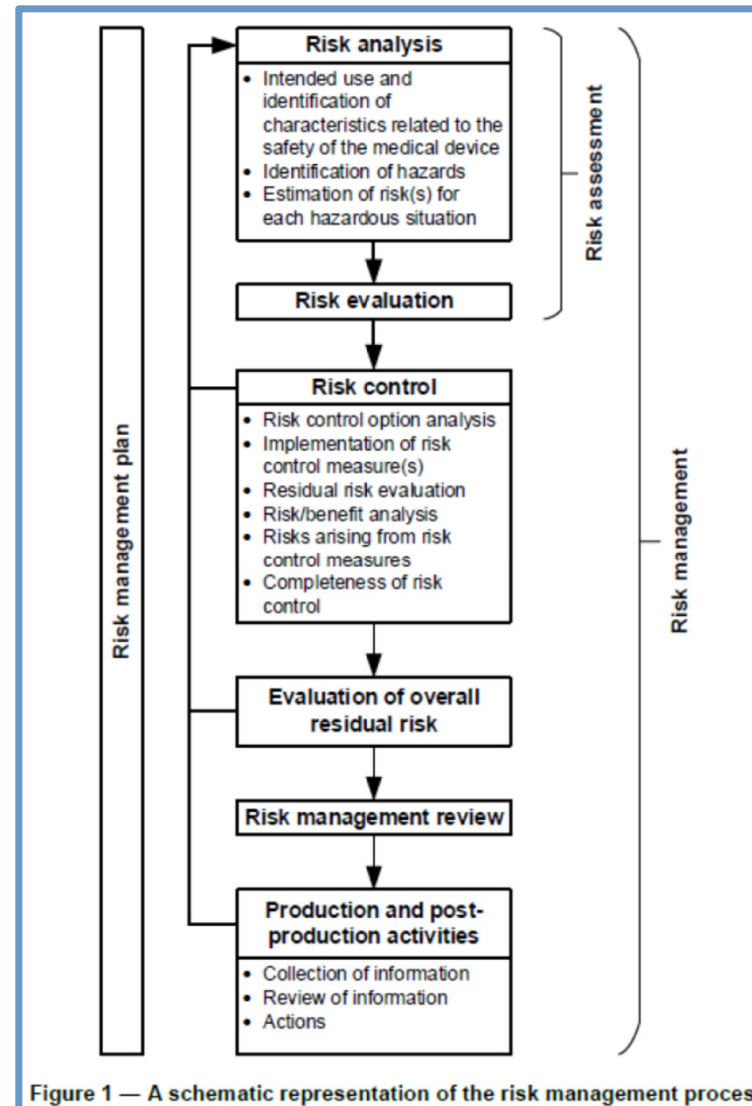
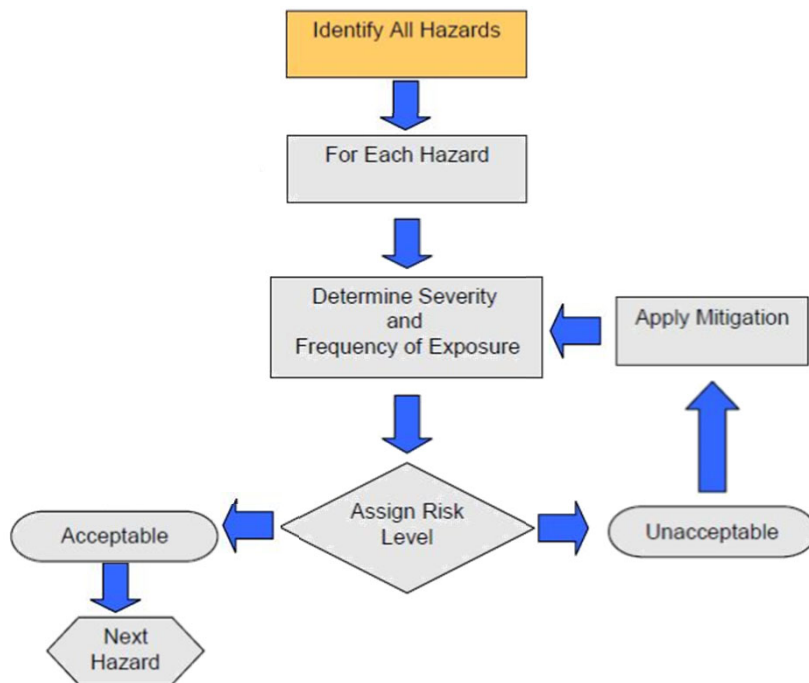
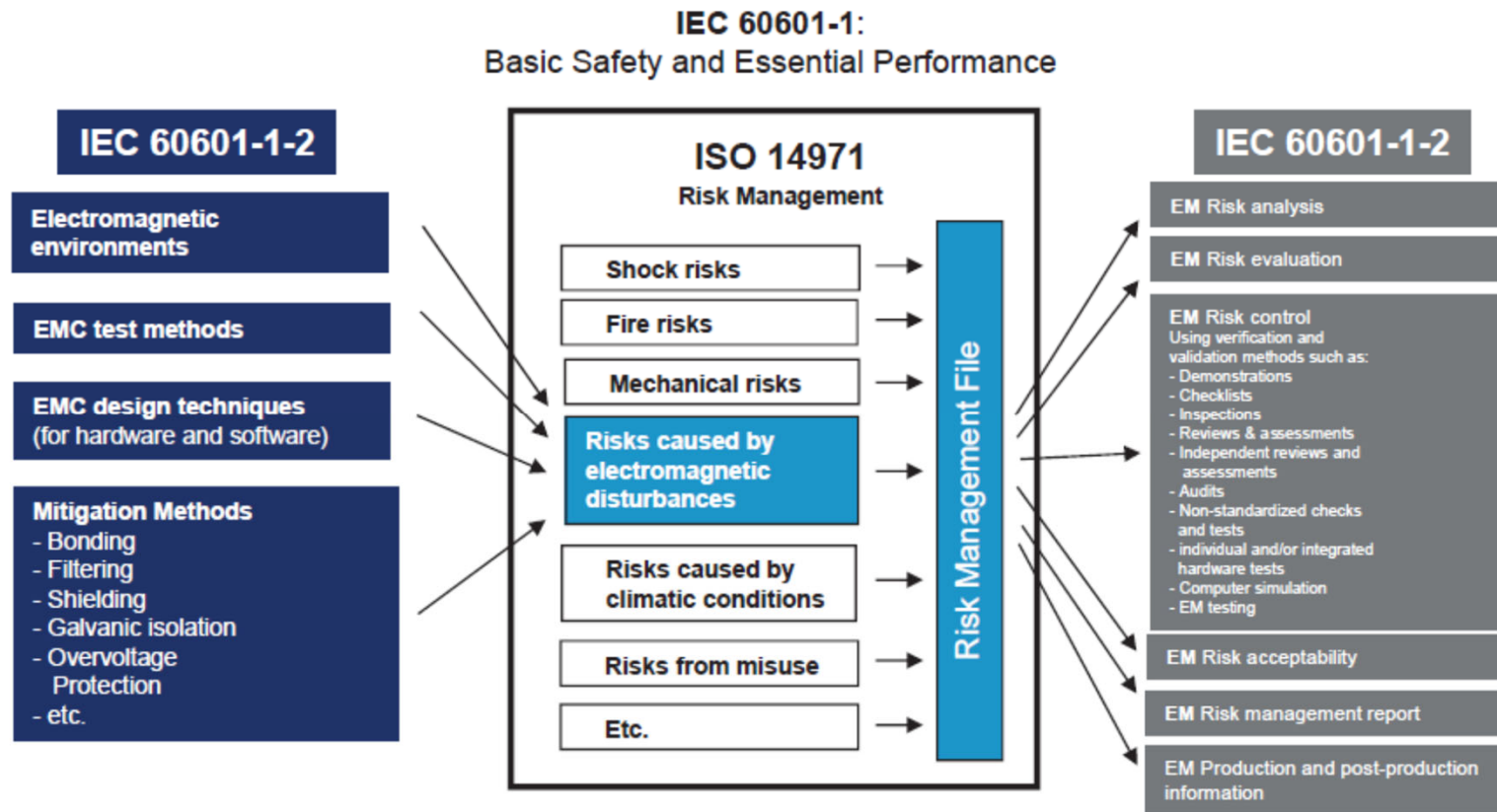


Figure 1 — A schematic representation of the risk management process

Risk Management Tools

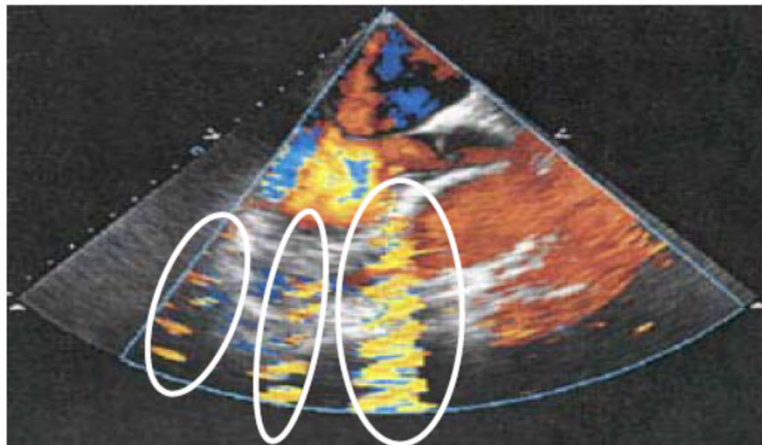
- FMEA
- FRA
- HACCP
- HAZOP
- ETA
- Others

EMI risk management in medical devices

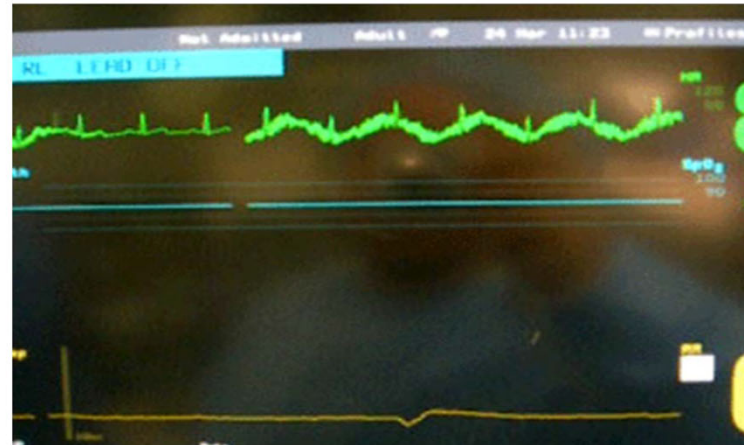


EMI examples in medical devices

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.

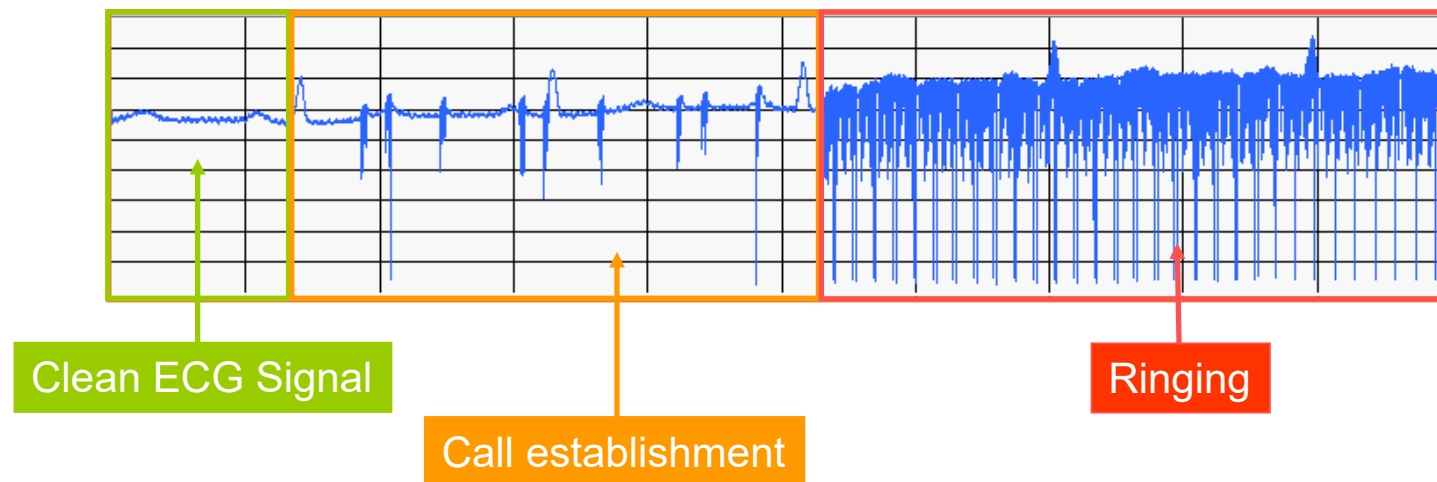
Relieved, **you decide to call you brother**, to tell him that everything looks fine. But at the first ring of your phone, the situation changes completely... The monitors in the examination room go blank – what is happening? You notice the worried faces of the doctors, who are urgently pressing buttons, 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:

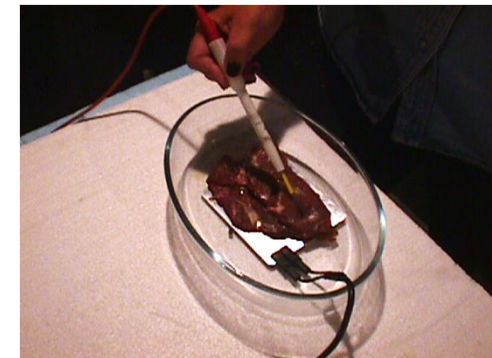
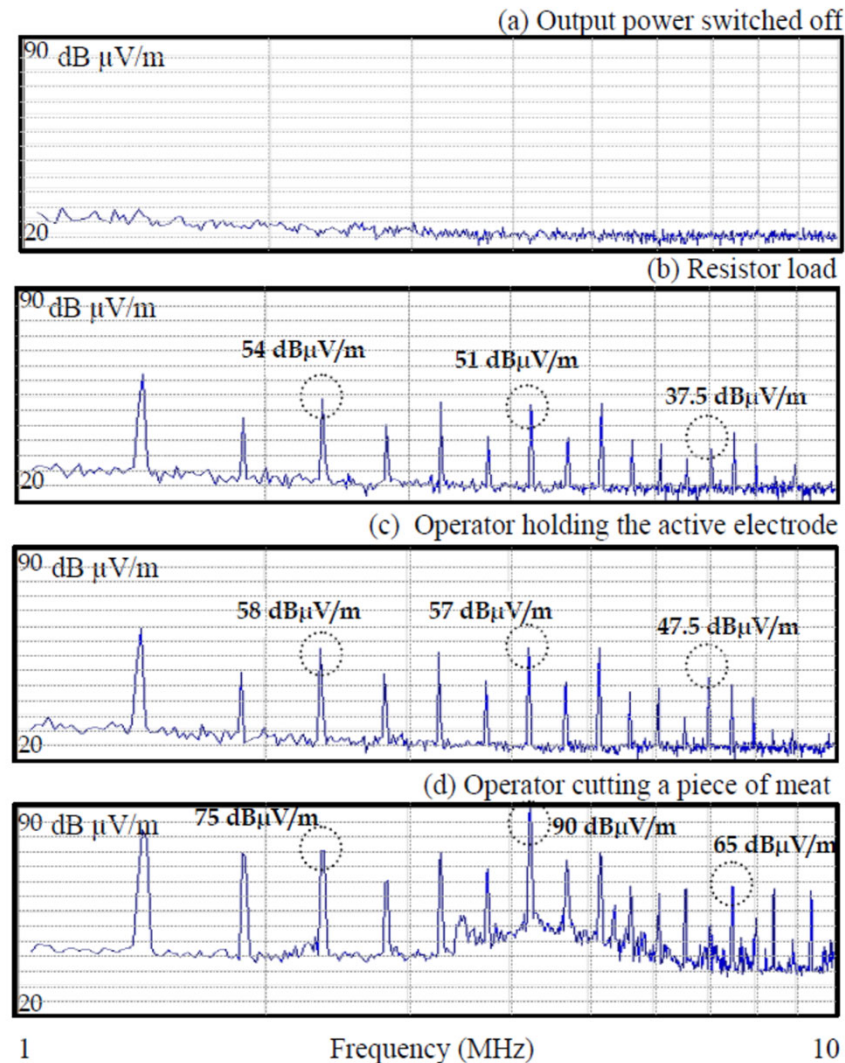
Could a short duration interference (a mobile phone signal during the call establishment), affect the performance of a low frequency medical device (an ECG recorder)?



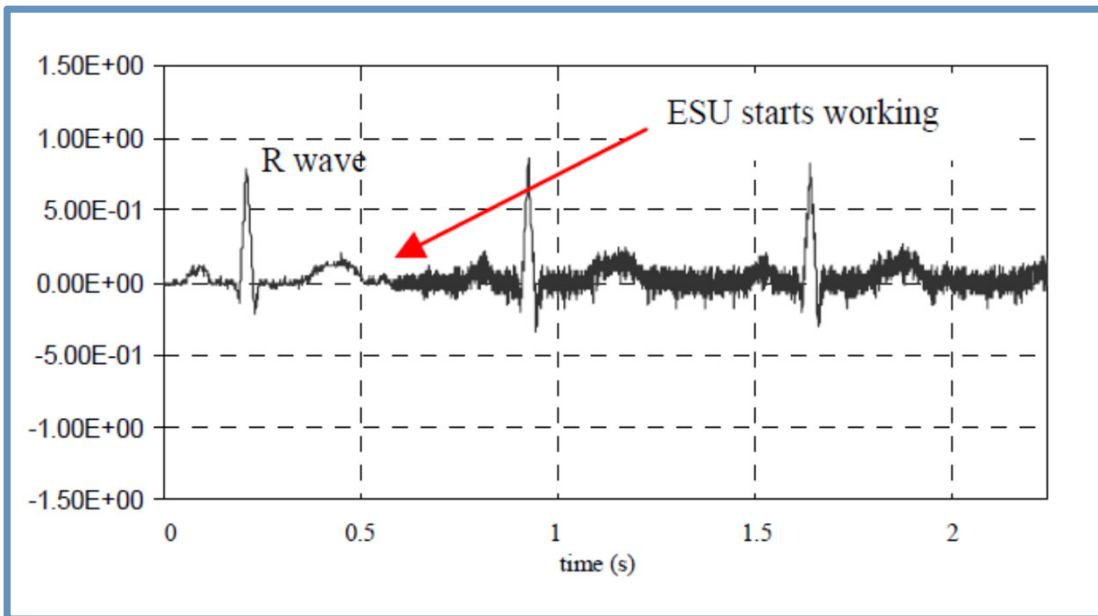
Electromagnetic risk management in medical devices

Electromagnetic radiated spectrum from an Electrosurgical Unit (ESU):

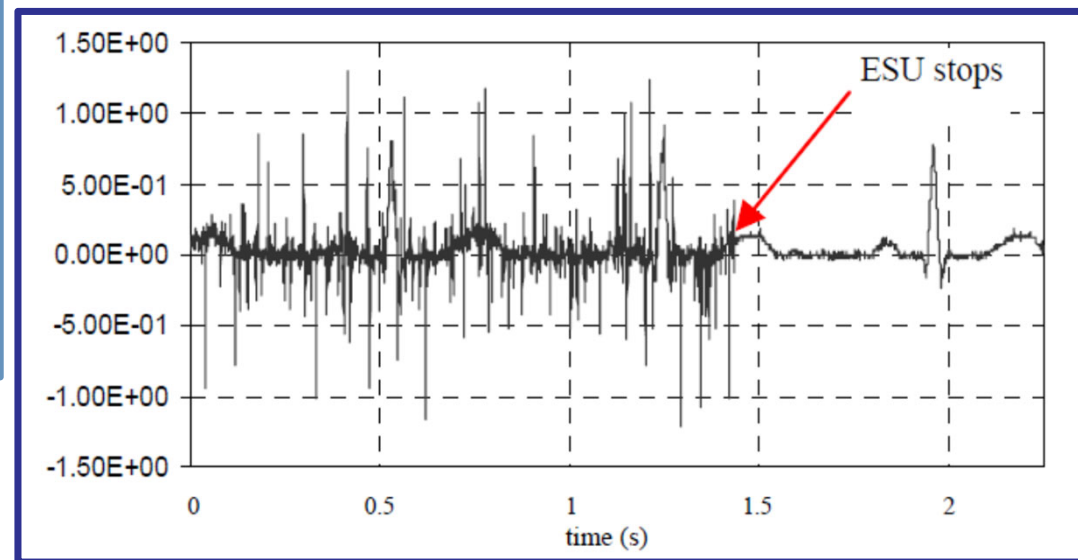
- (a) in standby (as described in the standard)
- (b) with a resistor as a load (to allow current flowing in the electrode wires),
- (c) with a volunteer holding the ESU active electrode and with a resistor as a load (allowing the current flow in the electrode wires and considering the presence of a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



Electromagnetic risk management in medical devices



Effect of ESU interference in an ECG signal



Electromagnetic risk management in medical devices

The number of reported incidents in hospitals relating to EMI is clearly increasing.



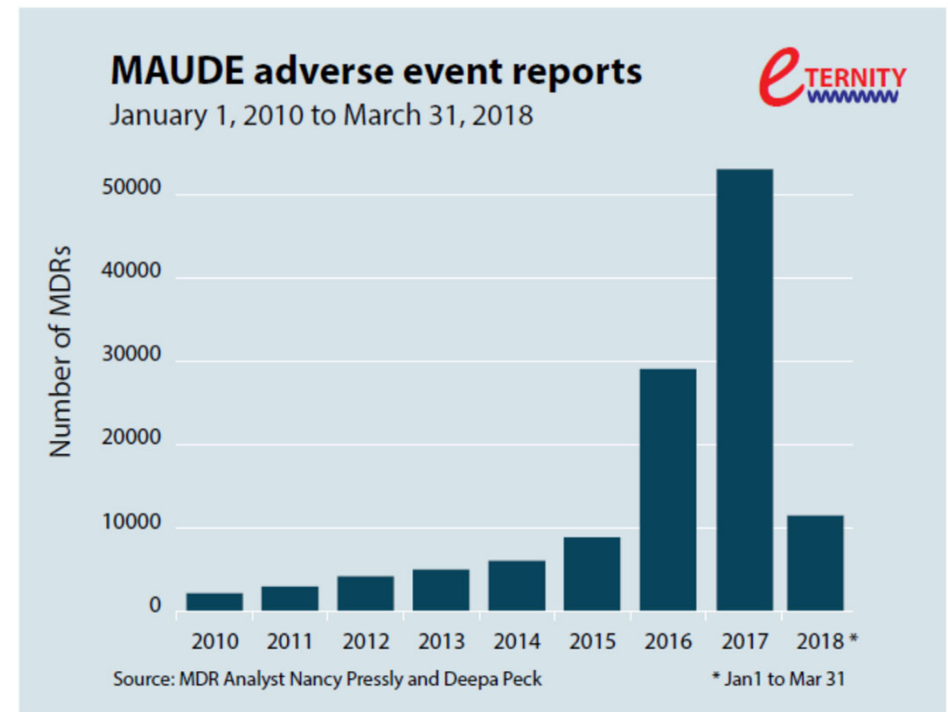
Managing EMI in complex scenarios becomes priority because people's lives are being put at risk.

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.



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.





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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.



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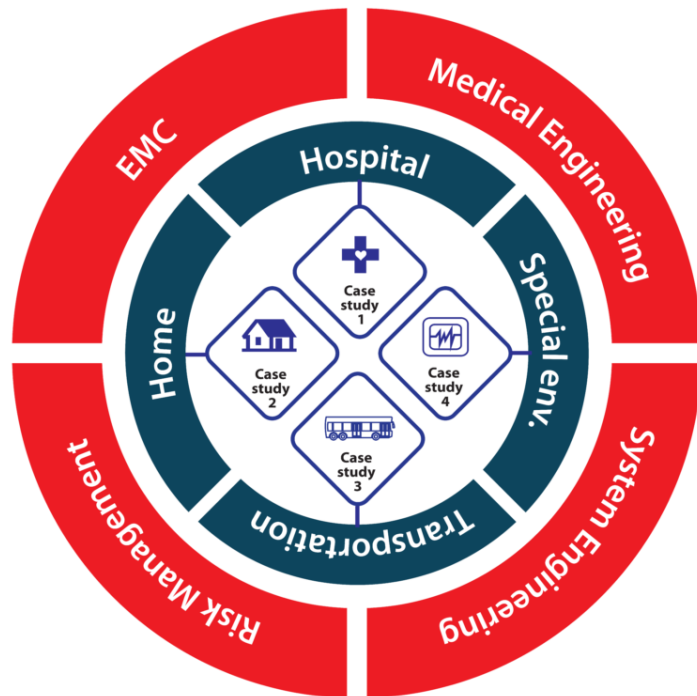
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Eternity



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.*

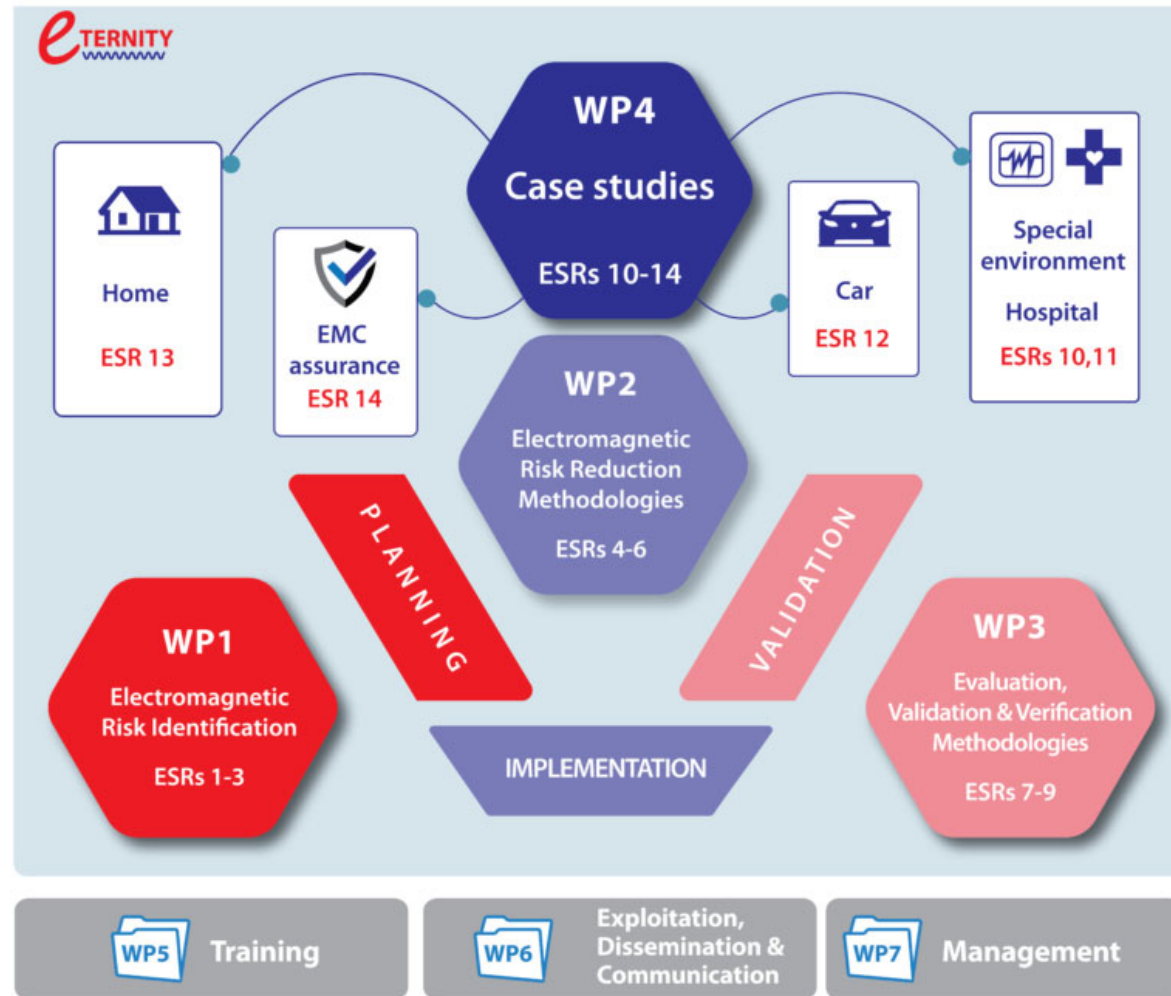
From the regulatory perspective, ETERNITY covers all 4 key medical environments: hospital, homecare, transportation and the special environment of medical imaging and treatment systems.



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ETERNITY Work Packages

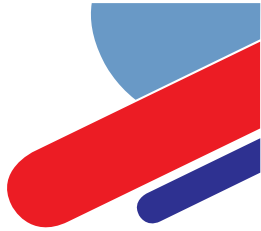




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- EMI footprint characterization of medical devices (ESR1)
- Characterization of medical electromagnetic environments for the use of new digital communication systems (DCS) (ESR2)
- Risk-Based EMI-Aware Design of Complex Systems (ESR4)
- Optimal Digital 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)



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in Medical Technology

<https://eternity-project.eu/esr-projects/>

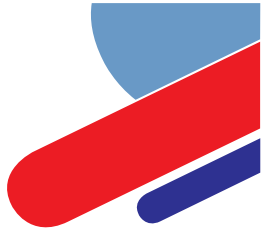
Mireya Fernández Chimeno
Ferran Silva Martínez
GCEM-UPC



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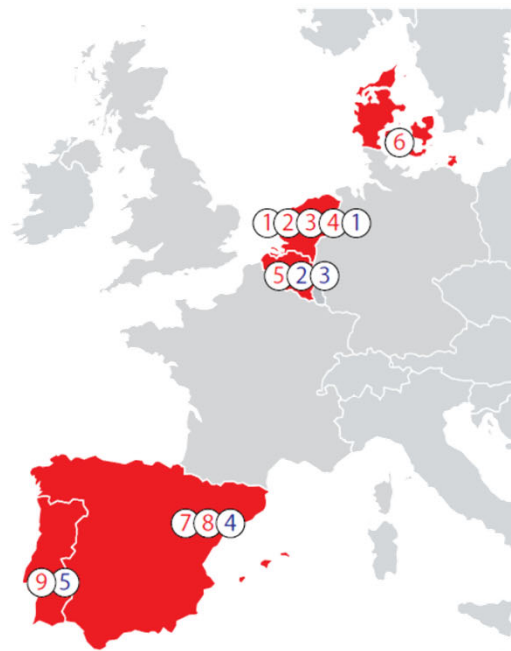
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Beneficiaires

TU/e EINDHOVEN UNIVERSITY OF TECHNOLOGY [TU/e]	①
UNIVERSITY OF TWENTE. [UWente]	②
PHILIPS [PHC]	③ ④
KU LEUVEN [KU Leuven]	⑤
FORCE TECHNOLOGY [Force]	⑥
UNIVERSITAT POLITÈCNICA DE CATALUNYA BARCELONA [UPC]	⑦
Ficosa Adas SLU [FIC]	⑧
plux [PLUX]	⑨



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Partner Organisations

① Plasmacure [PMC]	
② UMC Utrecht [UMCU]	
③ eurofins [EUF]	
④ Sanitas Hospital CIMA [CIMA]	
⑤ FCT FACULDADE DE CIÊNCIAS E TECNOLOGIA UNIVERSIDADE NOVA DE LISBOA [FCT]	

Network-wide events

Eindhoven M7
Bruges M16
Lisbon M25
Barcelona M34
Eindhoven M42

①-⑨ Beneficiaries

①-⑤ Partner Organisations

Academic Participants

Non-academic participants

Hospital

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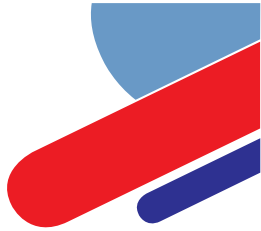
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Thanks!

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