

IEC60601-1-2 Edition4 (2014-02) EMD Standard requirements depending from the EM Disturbance environment



IEC 60601-1-2

Edition 4.0 2014-02

**INTERNATIONAL
STANDARD**

**NORME
INTERNATIONALE**

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



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IEC62A/MT23 TC - IEC60601-1-2 EMD Standard.
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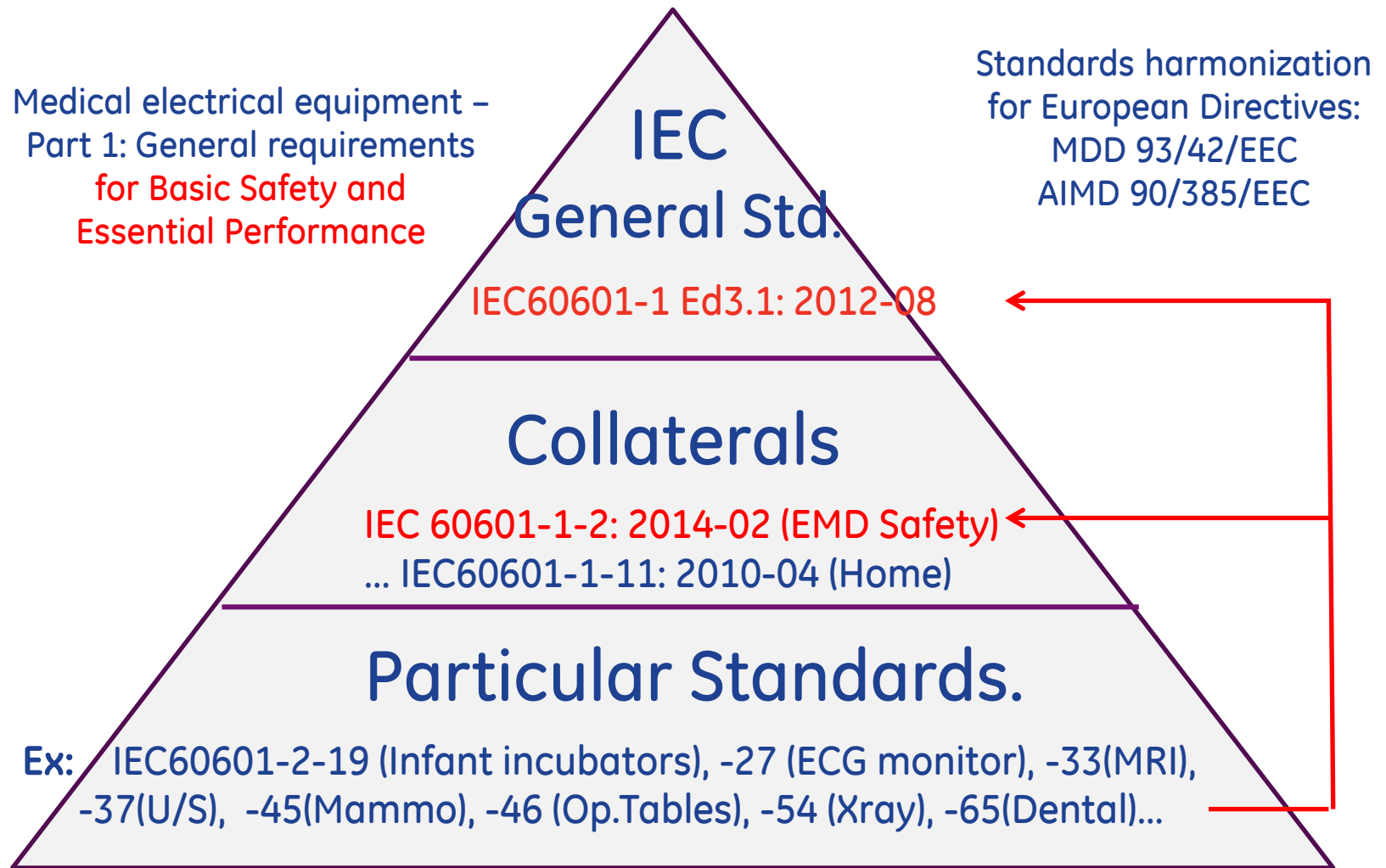
imagination at work

EC60601-1-2 Ed4:2014 EMD Standard requirements

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Introduction – Links between IEC standards for MEE



A Particular Standard uses to call IEC60601-1 Ed3.1:2012-08, IEC 60601-1-2: 2014-02,...

IEC60601-1-2 Ed4

reshapes the EMD Environments

IEC60601-1-2 Ed4:2014 reshapes the EMD Environments

since the Typical Healthcare Environment as per Edition 3:2007

Physician offices, dental offices, clinics, limited care facilities, freestanding surgical centers, freestanding birthing centers, multiple treatment facilities, hospitals (emergency rooms, patient rooms, intensive care, surgery rooms except near HF SURGICAL EQUIPMENT, outside the RF shielded room of an ME SYSTEM for magnetic resonance imaging)

Professional healthcare facility environment



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

SPECIAL ENVIRONMENT

Military areas (submarines, near radar installations, near weapons control systems), heavy industrial areas (power plants, steel and paper mills, foundries, automotive and appliance manufacturing, smelting and mining operations, oil and gas refineries), medical treatment areas with high-powered ME EQUIPMENT (HF SURGICAL EQUIPMENT, SHORT-WAVE THERAPY EQUIPMENT, inside the RF shielded room of an ME SYSTEM for magnetic resonance imaging)

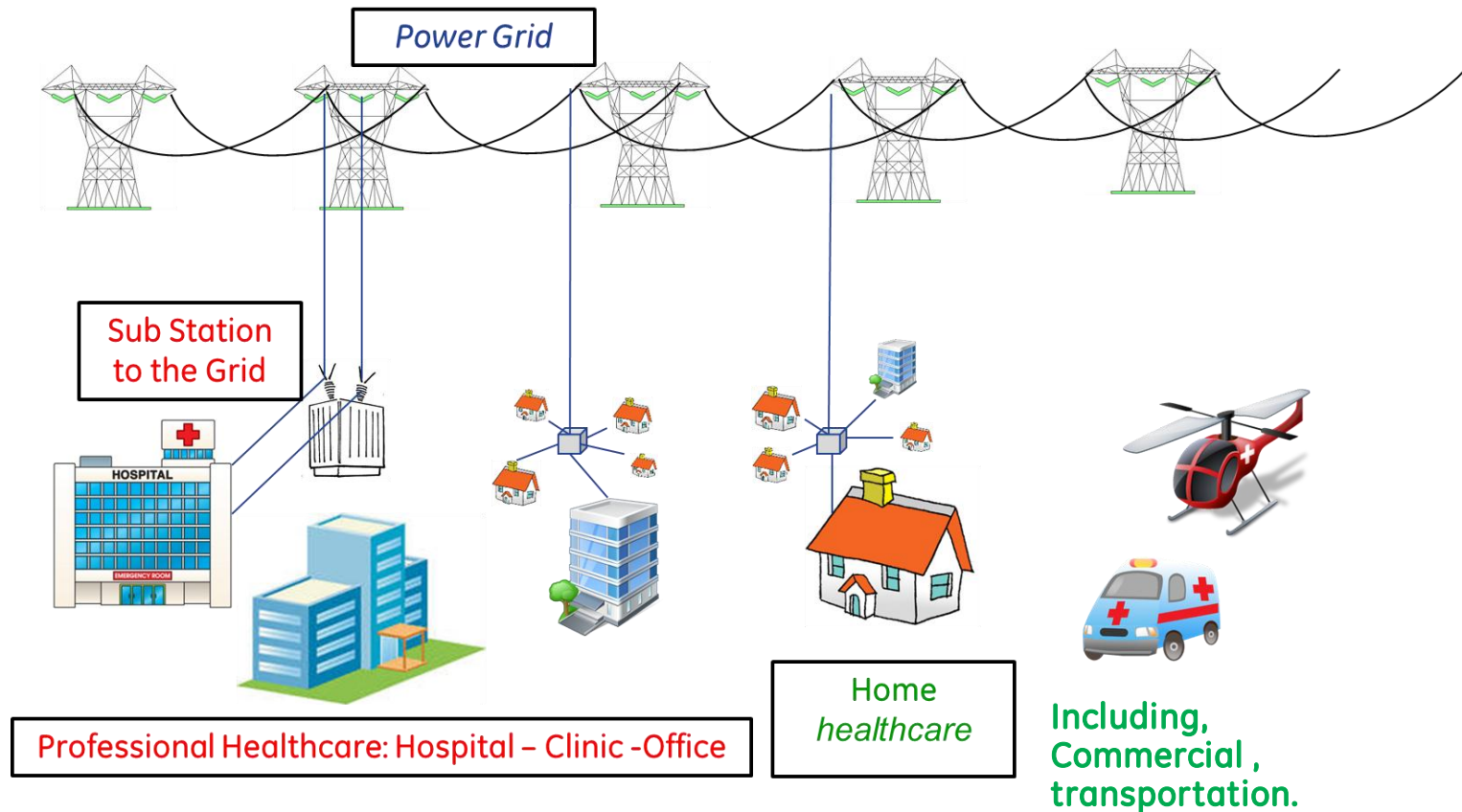
Upon ISO 14971 Std. Risk Management & Analysis,

- *additional Disturbances from the Special Environment may be added as,*
- the HF Surgical Equipment located in the MEE vicinity*
- *IEC60601-2-2 additional EMD requirement Testing.*

IEC 60601-1-2 Ed4 standard differentiates EMD environments

The Edition 3:2007 addresses the Typical Healthcare - disturbance environment.

The Edition 4:2014 addresses mainly 2 different - disturbance environments.



IEC 60601-1-2 Ed4 presents

Similar Emission Testing Requirements

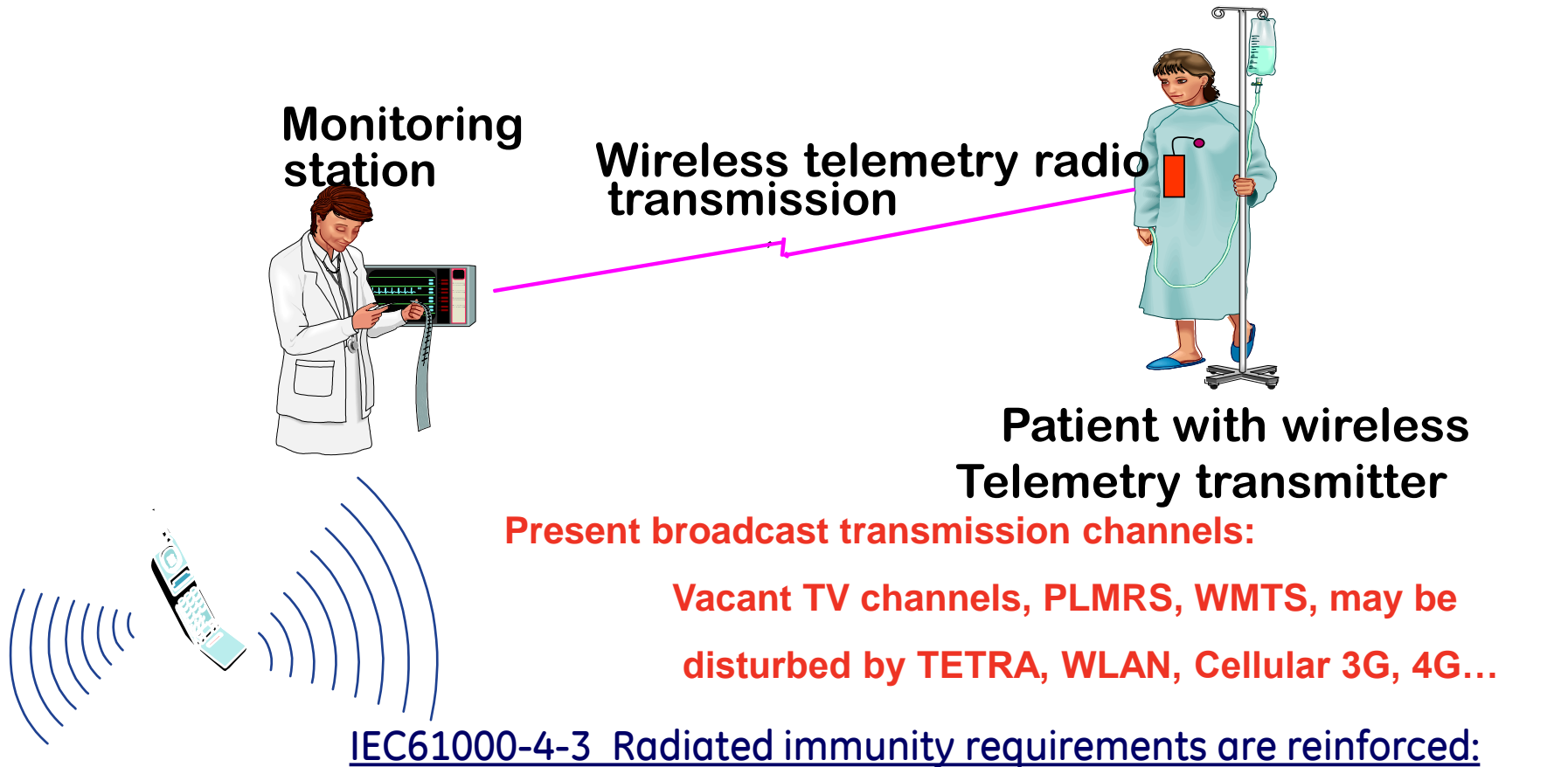
IEC 60601-1-2 Ed4 Emission Testing Requirements

EMISSION: *Cispr 11 class A, or class B limits are driven by the Power Grid.*

IEC 60601-1-2 EMISSION Tests	EMD Edition 3:2007 Requirements	EMD Edition 4:2014 Requirements <ul style="list-style-type: none"> Professional Healthcare Home Healthcare
CISPR 11 Radiated Emissions	Class A (Industrial): / separated power lines : Large Hospital. Class B (Residential): / Non separated power lines: as offices.	Class A (Industrial): / separated power lines : Large Hospital. Class B (Residential): / Non separated power lines: as offices and Home Healthcare.
CISPR 11 Conducted Emissions	Class A (Industrial): / separated power lines : Large Hospital. Class B (Residential): / Non separated power lines: as offices.	Class A (Industrial): / separated power lines : Large Hospital. Class B (Residential): / Non separated power lines: as Home Healthcare.
IEC 61000-3-2 Harmonics emissions	Tested at 50 or 60Hz	Tested at 50 or 60Hz
IEC 61000-3-3 Flicker and Fluctuations	Tested at 50Hz	Tested at 50Hz

IEC 60601-1-2 Ed4 focuses on New Immunity Test Requirements

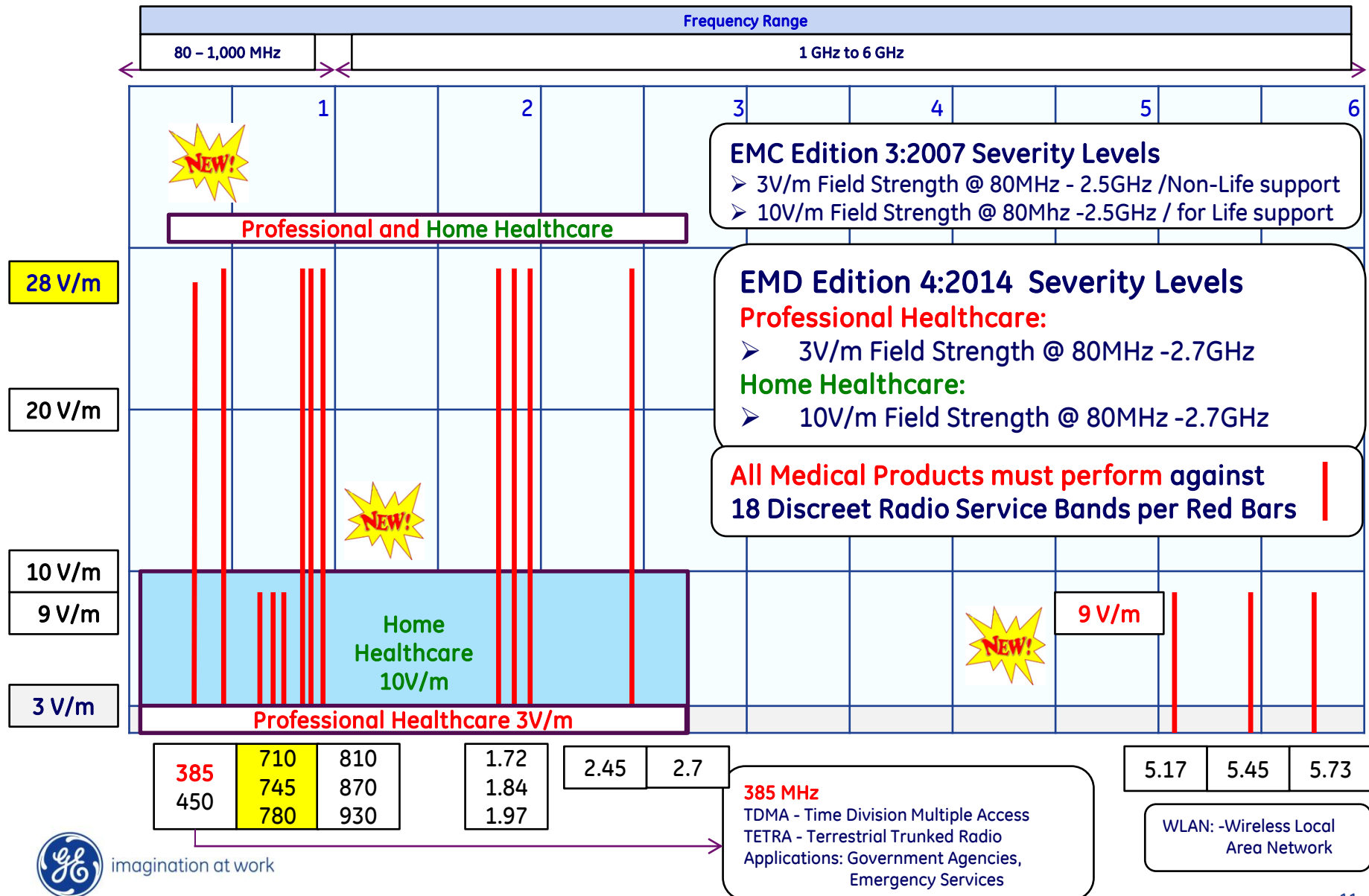
EMD environment evolution unveils a broad deployment, and recurrent proximity fields, from the RF Wireless technology



imagination at work

=> New testing frequencies and severity levels, and No exclusion band.

IEC 61000-4-3 Radiated RF Immunity update



Focus on IEC 60601-1-2 Ed4 Immunity Test Requirements

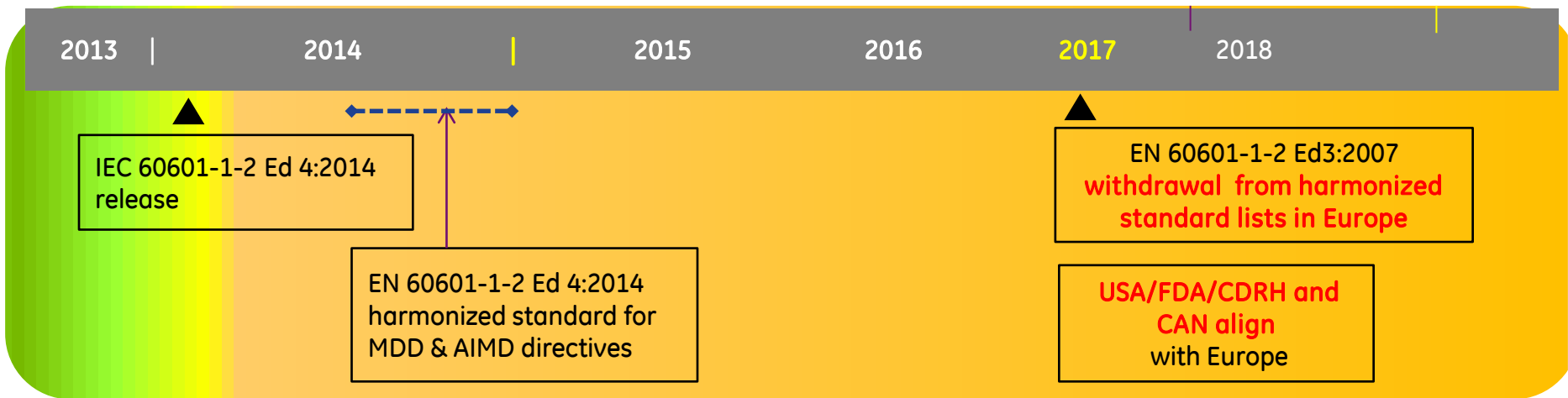
IMMUNITY: *Severity Levels defined upon the reasonable foreseeable maximum EM disturbance level, and upon the IEC/TR 61000-2-5:2011 EMC std*

IEC 60601-1-2 IMMUNITY Tests	Edition 3;2007 Requirements	EMD Edition 4:2014 Requirements <ul style="list-style-type: none"> Professional Healthcare Home Healthcare
IEC 61000-4-2 Electrostatic Discharges	6 kV Contact Discharge 8 kV Air Discharge	8 kV Contact Discharge 15 kV Air Discharge
IEC61000-4-3 Radiated fields and proximity fields	3 V/m at 80 - 2,500MHz, AM Modulation 10V/m for Life-Support:	3 V/m (10V/m Home Healthcare) at 80 - 2,700MHz , AM Modulation. And 9-28V/m at 385-6000MHz, Pulse Mode and other Modulation (upon Risk Analysis).
IEC 61000-4-4 Electrical Fast Transients / Burst	2 kV Power Lines, 1 kV Interconnect Lines at 5kHz rate	2 kV Power Lines, 1 kV Interconnect Lines at 100kHz rate
IEC 61000-4-5 Power Surge	2kV Power Lines	2kV Power Lines
IEC 61000-4-6 Conducted Radio Frequency Immunity	3V at 0.15 – 80MHz Additionally for Life-Support: 10V at ISM Frequencies.	3V at 0.15 – 80MHz & 6V at ISM Frequ. Home Healthcare: 3V at 0.15 – 80MHz, and 6V at ISM & Radio Amateur Frequ.
IEC 61000-4-8 Magnetic Field	3 A/m, 50/60Hz	30 A/m , 50/60Hz
IEC 61000-4-11 Voltage Dips and Interruptions	<5 % Ut for 0.5 cycle; 70% Ut on 25 cycles ; 40% Ut on 5 cycles	0% Ut for 0.5 at 8 Φ angles; 0% 1 cycle; 70% Ut for 25 cycles; 0% for 5 sec.

IEC 60601-1-2 Ed4

Requirements Summary and Implementation Roadmap

EMD Edition 4 - Current Voter Timeline and expected Transition



- 2014-01: FDIS (Final Draft) was voted and accepted by most of the National Committees.
- 2014-02: IEC 60601-1-2 Ed4 standard release.
- 2014/2015: EN Ed4 European standard harmonized (EN Annex ZZ ?) and such Ed3 DOCOPOCOSS > 2017-01.
- After 2017-02: Adoption by EEC MDD & AIMD, USA, CAN... after a 3 years transition period (estimate).

IEC60601-1-2 Ed4:2014 EMD Standard requirements: Summary

- Main changes involve the Immunity requirements:
 - The manufacturer shall state the suitable environment(s) for use, and design the MEE for emission and immunity accordingly.
 - Some Ed4 testing Severity Levels are higher than Ed3 SL: they match the reasonably foreseeable maximum level found in the environment.
 - There is no distinction between Life-Support and Non-Life Support MEE; all MEE shall ensure its Safety (Basic Safety + Essential Performance).
 - Immunity criteria focus on the Basic Safety and the Essential Performance verification (not the EMC standard Class A,B,C responses).
 - Mitigations as “Sensitive connector to ESD” are not allowed.
The risk associated with ESD disturbances should be mitigated by design (as adding a cover on the connector).

Thank you for your attention

