



## Suitability of the EMC standards for the Medical Devices as neurostimulators and infusion pumps in their environment.

**Author : Jean-Claude Labourie**

General Electric Healthcare, 283, Rue de Minière, 78530 Buc (France)  
Member of UTE SC62 and IEC MT23 standard committees. [jeanclaude.labourie@med.ge.com](mailto:jeanclaude.labourie@med.ge.com)

**Summary** Through the continuous electrical technology innovations, electromagnetic interferences (EMI) on medical devices (MD), and consequences on the patient are still relevant.

In order to prevent the patient from injury, the standards evolution is an important mission for the UTE French standard organization, which develops standards for MD.

First considering the public environment, by design the patient deals with minimum critical situations. Then in the therapeutic environment, some high power MD interfere with active implantable MD (AIMD) and non-implantable MD, inducing significant patient risks. Control measures allow establishing the benefit/risk to an acceptable level. Considering neurostimulators, and infusion pumps, the radiated field immunity is the main EMC specification and testing requirement.

### I. INTRODUCTION

In the therapeutic environment as hospitals, interferences and safety issues between therapeutic MD, and Active Implantable Medical Devices (AIMD) or non-implantable MD were identified several years ago. EMI alerts and complaints are reported to different regulatory agencies, as the Afssaps (“Agence Française de sécurité sanitaire des produits de santé”), the FDA (Food and Drug Administration), or the Health Canada.

This document mainly focuses on critical MD as the AIMD neurostimulators, and the infusion pumps. The associated analysis involves the recent standards works about these devices (ISO 14708-3:2008, and ongoing ISO14708-4, IEC/EN 60601-2-24, IEC/EN 60601-1-2 standards).

The following reported EMI situations have a significant impact on the patient safety, and on the performance of the AIMD and MD. The patient injury severity varies, depending on the environment (therapeutic, public), and as per the technology of the disturbed MD.

### II. EMI REPORTED SAFETY ISSUES ON MD

Here is enclosed several reported safety issues and alerts, involving mainly safety critical MD as neurostimulators AIMD, and ambulatory MD.

- Serious injury reports, including coma and permanent neurological impairment, in patients with implanted neurological stimulators who underwent magnetic resonance imaging (MRI) procedures. The mechanism for these adverse events is likely to involve heating of the electrodes at the end of the lead wires, resulting in injury to the surrounding tissue. Although these reports involved deep brain stimulators, similar injuries could be caused by any type of implanted neurological stimulator, such as spinal cord stimulators [1].
- Burned patient tissues along the AIMD metallic parts during the diathermy therapy (2 reported deaths) [2], or during computerized tomography (CT) examination [3].
- A patient received an epinephrine dose (adrenaline) through an infusion pump when a visitor received a call on his cell phone [4].
- Three cases where a direct exposure to Magnetic Resonance Imaging system (MRI) has resulted in damage of ambulatory infusion pumps (and hypoglycemia created from the insulin syringe) [5].
- Electronic Article Surveillance Systems (EAS), based on pulsed-magnetic principle affected pacemakers at up to 18 cm, and would produce premature failures [6].

### III. EMC AND REGULATORY STANDARDS FOR MEDICAL DEVICES

#### III.1 Medical Devices in the European regulatory field

The medical devices (MD), as per the European regulation, are in the scope of two main directives involving implantable neurostimulators, and infusion pumps:

- AIMD directive 90/385/EEC including implantable pacemakers, defibrillators, neurostimulators, implantable infusion pumps.
- MDD directive 93/42/EEC including many MD as ventilators, and external infusion pumps (ambulatory infusion pumps or not).

### III.2 UTE Standard organization in France

The standardization is a voluntary action based on consensus between the economic actors and all parties concerned. UTE is the French Electrotechnical Committee, member of the International Electrotechnical Commission (IEC) and of the European Committee for Electrotechnical Standardization (CENELEC).

ITU	ISO	IEC	International Level
ETSI	CEN	CENELEC	European Level
CG TeC	AFNOR	UTE	French Level

Besides standardization (French, European and international standards) UTE writes, publishes and circulates technical documents. UTE helps the Civil Service Administration in setting out French regulations (UTE helps the Civil Service Administration in working out French and European regulations and the uses covered by the World Trade Organization). Standards are built with the contribution from governmental and sanitary control agency (as the AFSSAPS in France, the FDA-CDRH in USA), users (as hospital physicians, biomedical specialists), representatives from testing laboratories, and manufacturers.

For example the EMC IEC/EN 60601-1-2 standard “Medical electrical equipment – Electromagnetic compatibility – Requirements and tests”, is developed and implemented through the IEC/CENELEC/UTE organizations.

### III.3. EMC related standards for AIMD and MD

Several standards are used, in order to manage the EMC and the safety versus EMI.

There is EMC when the MD operates as intended (and without disturbing significantly its environment). The safety versus EMI is achieved when the patient (and the operator) doesn't experience any unacceptable risk. The EN/ISO 14971:2007 “Application of risk management to MD” standard allows to manage the risk, identifying if the risk is acceptable, and writing the immunity tests criterion [9].

The EN 45502/ISO14708 standards family address the requirements for AIMD, which the neurostimulators EMC requirements are covered by the ISO 14708-3:2008.

The same level of requirements will be transposed to the future ISO 14708-4 standard addressing implantable infusion pumps. [7],[8],[10].

The non-implantable infusion pumps, for ambulatory use or not, are covered by the IEC/EN 60601-2-24 particular standard. Its latest version (Ed2 2007 draft) refers to the collateral IEC 60601-1-2:2007 (Ed3) standard for the EMC and safety versus EMI.

## IV. STANDARDS EVOLUTION FOR THE PUBLIC ENVIRONMENT

### IV.1 AIMD in the public environment

Out of the therapeutic environment, it is assumed the patients would move around mainly in the public environment, where the electrical devices would emit at an amplitude below the Public EMF recommendation 1999/519/EC, and ICNRP levels. Therefore the AIMD standards requires immunity severity levels, such as the design specifications of this MD intend to ensure the safety of the patient versus EMI, in most of the public situations including some margin.

Here is a summary of the ISO14708-3:2008 immunity requirements for the neurostimulators.

1/ DC magnetic field: 1mT and 50mT severity levels. At 1mT level, the AIMD shall operate as intended during and after the stimulus (criterion A). But at 50mT level, a temporary degradation is acceptable, as far the AIMD operates as intended after the stimulus, and the patient is not exposed to an unacceptable risk (criterion B).

2/ Magnetic field immunity from 10Hz to 30MHz (see Fig.1): at 100KHz, the test specifies 16A/m (criterion A) and 160A/m (criterion B), compared to 5A/m as per the public EMF recommendation (ICNIRP level).

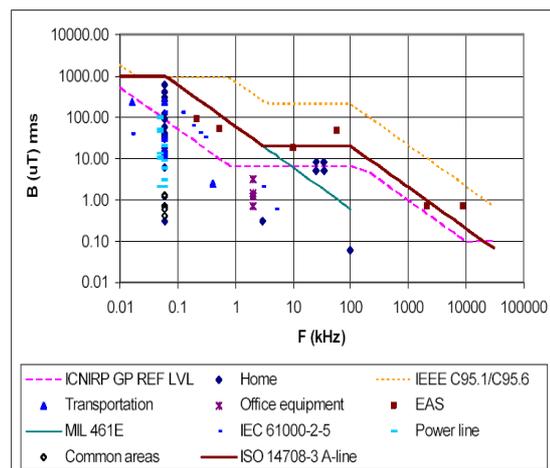


Fig.1 – Neurostimulator magnetic field immunity

3/ Electric field immunity as per IEC/EN 61000-4-3, from 30MHz to 450MHz: 16V/m (criterion A) and 140V/m (criterion B). The corresponding public EMF level is established at 28V/m (450MHz).

4/ Electromagnetic field immunity as per ANSI/AAMI PC69 from 450MHz to 3GHz: 40mW (criterion A). 2W and 8W levels are optional. The 40mW specification covers usual handheld transmitters situations located at 15cm from the AIMD.

5/ Due to the tissue attenuation versus frequency, it is established the radiated field immunity is not required above 3GHz.

In the public environment, the patient education is important, in order to identify and manage risky situations as crossing a retail or airport EAS system, or being located closed to cell phone with amplification and gain antenna (booster kit) able to provide more than 20W.

The usual recommendation from manufacturers is to minimize the radiated field exposure period versus identified intentional emitters. The patient shall cross quickly the EAS system, and keeping a minimum separation distance with cell phones, but function of its maximum power [10].

#### IV.2 MD in the public environment

Medical Devices (MD) as non implantable infusion pumps (ambulatory or not) are covered by the particular IEC/EN 60601-2-24, which refers to the collateral IEC/EN 60601-1-2 standard. Depending on the MD classification, as life or non-life supporting MEE, the specified severity level is set at 3V/m for non-life, and 10V/m for life supporting MEE. The radiated field immunity test from 80MHz to 2.5GHz is performed as per the IEC/EN 61000-4-3 standard. Therefore there is an immunity severity level difference between the AIMD and the life-supporting MEE equipment. For example a neurostimulator passes 140V/m at 450MHz, compared to 10V/m for life-supporting infusion pump. Meanwhile, it is assumed the life-supporting MEE remains in a controlled environment (as an hospital emergency room) and under the control of an operator. Today the manufacturer has to evaluate by himself if the tested level should be greater than 3V/m or 10V/m, and if the overall electromagnetic risk is acceptable. From the risk management (performed as per the EN/ISO14971 “Application of risk management to MD”), he could decide to modify and add immunity tests and levels.

Usually, the EMI encountered on MD depends first on the amplitude and frequency of the disturbance, but the modulation characteristics, the exposure duration, and the coupling path might be critical too [6],[10].

### V. RECOMMENDATIONS FROM GOUVERNMENT AGENCIES FOR THE THERAPEUTIC ENVIRONMENT

In the therapeutic environment, the physicians, the biomedical specialists, the manufacturers, and the safety agencies have identified the main EMI sources and effects on the AIMD and MD.

Compared to the public environment, when the medical device is located in the therapeutic environment (usually hospitals, and clinics), the potential severity of the harm increases.

Because of the emission amplitude is above the immunity level of the MD, the benefit/risk ratio shall be assessed, and control (or mitigations) measures are necessary. Special procedures are established and used, from different alert reports, manufacturer documents, and safety agencies recommendations. From AFSSAPS sanitary agency, the report [2]

“Interactions between AIMD and medical devices” recommends contraindications as per two categories:

1/ Absolute contraindication.

2/ / Relative contraindication, with required control measures.

#### V.1 Absolute contraindication with AIMD

There is a significant lethal risk even if the AIMD (Neurostimulator) is turned off, about diathermy and the electromagnetic stimulation.

Table 1 - Diathermy – electromagnetic (RF short waves and microwaves)

Risks	Benefit/Risk assessment.
Short waves diathermy burns tissues around the electrodes and the neurostimulator casing. Components failure.	Significant death risk even if the Neurostimulator is turned off.

Table 2 - Electromagnetic stimulation (transcutaneous therapy or for skin cosmetic)

Risks	Benefit/Risk assessment.
Induced high density currents on electrodes tips. Burned tissues. Stimulator programming or component failure.	Significant death risk even if the Neurostimulator is turned off.

#### V.2 Relative contraindications with AIMD

The benefit/risk ratio shall be assessed, and the recommended control (or mitigation) measures should be applied, in order to avoid the lethal risk, and unacceptable overall risks, on MRI scanners, HF surgery, external defibrillator, radiotherapy systems (non exhaustive list).

Table 3 – Radiotherapy (RT)

Risks	Benefit/Risk assessment. Control/Mitigation measures
Risk of immediate deterioration, stopping the neurostimulator	. Limit the maximum Rx dose to 5Gy onto the stimulator. . May need to modify the stimulator layout. . Verify the stimulator performance after the exposure, and several months after.

Table 4 – MRI scanner

Risks	Benefit/Risk assessment. Control/Mitigation measures
MR magnet and RF fields induced voltages on the stimulator, and on electrodes. They may modify the programming, induce spurious stimulations (stroke effect), or stop it. Burn tissues risk along the metal parts and electrodes.	<ul style="list-style-type: none"> <li>. Prefer conventional scanner</li> <li>. Limit magnet use to 1.5T</li> <li>. Avoid and limit RF coil exposition from the entire body depending of the stimulation implementation (encephalic, spinal cord, peripheral nerves,...),</li> <li>. Limit head SAR to 0.1W/kg.</li> <li>. Keep opportunity for quickly downloading the software.</li> </ul>

Table 5 – HF surgery (bistoury)

Risks	Benefit/Risk assessment. Control/Mitigation measures
Induce HF currents. Induced high density currents on electrodes tips Risk of deterioration and stopping the MD. May modify its programming.	Assess the benefit/risk. Shall replace the HF bistoury by laser, cryogenic, or ultrasound technique.

Table 6 – External Defibrillator

Risks	Benefit/Risk assessment. Control/Mitigation measures
Risk of heating the stimulator, the electrodes, and burn the nearby tissues. May raise the stimulation frequency. Risk of deterioration and stopping the neurostimulator. May modify the programming, and induce erroneous stimulations.	Use minimum power, maximum distance from stimulator. Deactivate the programmation before the shock, and verify stimulator after defibrillation.

## V. Conclusion

By design, the manufacturer cannot solve all EMI issues: labelling and customer education are required. Considering the benefit/risk ratio of the AIMD and MD, and in order to prevent the patient from safety hazards, today the different actors of the standardization identify control measures, which minimize the safety risk versus EMI. Then, the labelling, accompanying documents, and mitigation

procedures are communicated. For example in the therapeutic environment, they would recommend, what MRI magnet field amplitude is compatible with such AIMD or such MD. For the public environment, the manufacturer would list recommendations front of specific pulsed-magnetic emitters as EAS systems, as well as what cell phone, power or separation distance, is recommended.

The ongoing IEC/CENELEC/UTE (IEC MT23) work about the future IEC/EN 60601-1-2 Edition 4 standard, forecasts to cover different environments. It would address MD, as non-implantable infusion pumps. Depending of the targeted environment, as the hospital (non therapeutic area), residential, ambulance transportation, etc... several environment categories would be defined. Then, corresponding severity levels would be specified.

Therefore updated requirements and guidance would be available for assessing the EMI risk as per the EN/ISO 14971 standard.

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