

Electromagnetic Compatibility and Safety of the Medical Devices :

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

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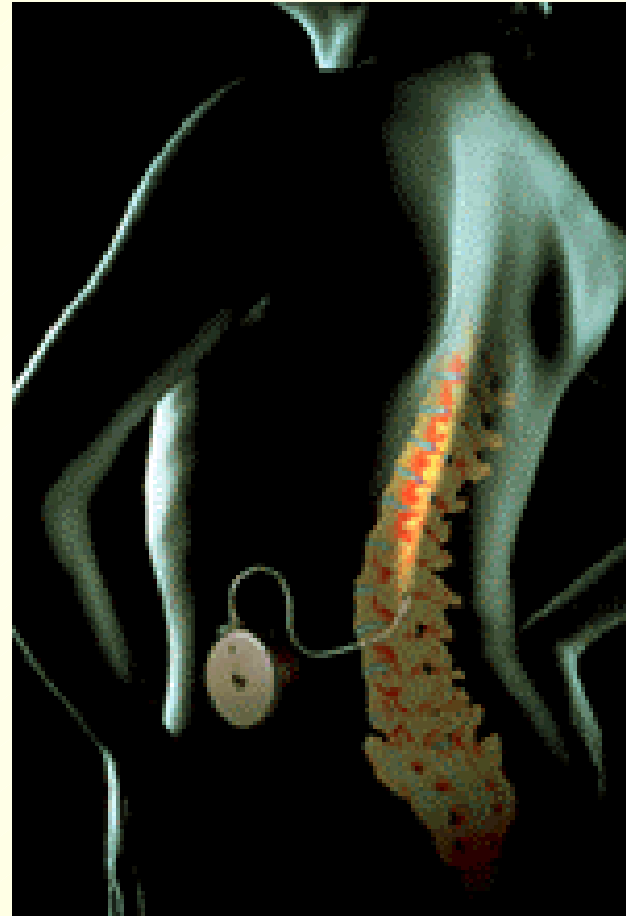


Suitability of the EMC standards for the Medical Devices as neurostimulators and infusion pumps in their environment.

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I. Active Implantable Medical Devices (AIMD)

Neurostimulator & Infusion pump / Spinal cord pain relief



AIMD examples: neurostimulator, infusion pump
(cardiac pacemaker, defibrillator)

Non active implantable Medical Devices for pain relief

Syringe, infusion pumps, diffusion pumps





II. Reported Safety & Regulatory Issues related to EMI in Therapeutic (TE) and Public Environments (PE)

AIMD devices (Active Implantable Medical devices):

- Neurostimulators (& Pacemakers)
 - TE: Burned patients during MR (RF), and CT (Xray) examination
 - TE: Failure of the device due a HF Surgery(bistoury) intervention
 - PE: Shock induced to the spinal cord due to EAS (Electrical Article Surveillance) systems.

MD devices (non active implantable):

- Infusion/syringe/diffusion/volumetric pumps
 - TE: Ambulatory Insulin infusion pump component failed due to MR exam (RF).
 - TE/PE: Diffusion Pump had its dose injection modified during the delivery work, onto the mother and the infant, due to a mobile phone.
 - TE/PE: Infusion pump stopped because of electrostatic discharges: insulin prescription was missing on a diabetic pathology.

☞ See «CDRH web site “<http://www.fda.gov/cdrh/>“ for further reported field issues.

III. EMC and Regulatory Standards for MD – UTE (“Union Technique de l’Electricité”) & organization of the standardization worldwide

- Standardization: Voluntary action based on consensus between the economic actors and all parties concerned, having common interests.



- UTE is the French Electrotechnical Committee, member of the International Electrotechnical Commission (IEC) and of the European Committee for Electrotechnical Standardisation (CENELEC).
- IEC/EN Standards are built with the contribution from UTE, governmental agencies, users, sanitary control agency (Afssaps), manufacturers.
- For example the EMC IEC/EN 60601-1-2 standard “Medical electrical equipment – Electromagnetic compatibility – Requirements and tests”, is developed thru UTE.

Neurostimulators & infusion pumps, are in the scope of two main European medical directives,

- **AIMD directive 90/385/EEC** includes active implantable MD, as pacemakers, defibrillators, neurostimulators, implantable infusion pumps.
 - EN/IEC60601-1, EN/ISO14971, EN45502-1, (& future EN/ISO14708-3, -4).
- **MDD directive 93/42/EEC** includes many non active implantable MD as ventilators, and external infusion pumps (ambulatory infusion pumps or not / life-support or non life-support).
 - EN/IEC60601-1, EN/ISO14971, EN/IEC60601-1-2, EN/IEC60601-2-24(pumps)



EMC and Regulatory Standards for Medical Devices

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

- **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,

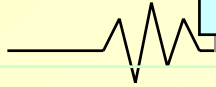
$$\text{RISK} = (\text{probability of occurrence of harm}) \times (\text{severity of that harm})$$

- . requires to determine if the risk is acceptable,
 - . allows to establish the immunity tests criterion for Safety versus EMI.
- **EMC** is presumed when the Medical Electrical Equipment (MEE) operates as intended (and without disturbing significantly its environment).

EMC implies Performance:

AIMD: EN45502-1, (& futures EN/ISO14708-3, -4).

MD: EN/IEC60601-1-2, EN/IEC60601-2-24(pumps).



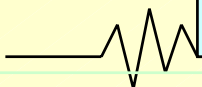
AIMD (implantable actifs):

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

Equivalent requirements are transposed to the future ISO/DIS 14708-4 standard addressing implantable infusion pumps.

MD (non implantable actif):

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. Standard evolution in the public environment / AIMD Neurostimulator (part1/2)

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 (ICNIRP 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 ISO/DIS 14708-3:2008 immunity requirements for the neurostimulators:

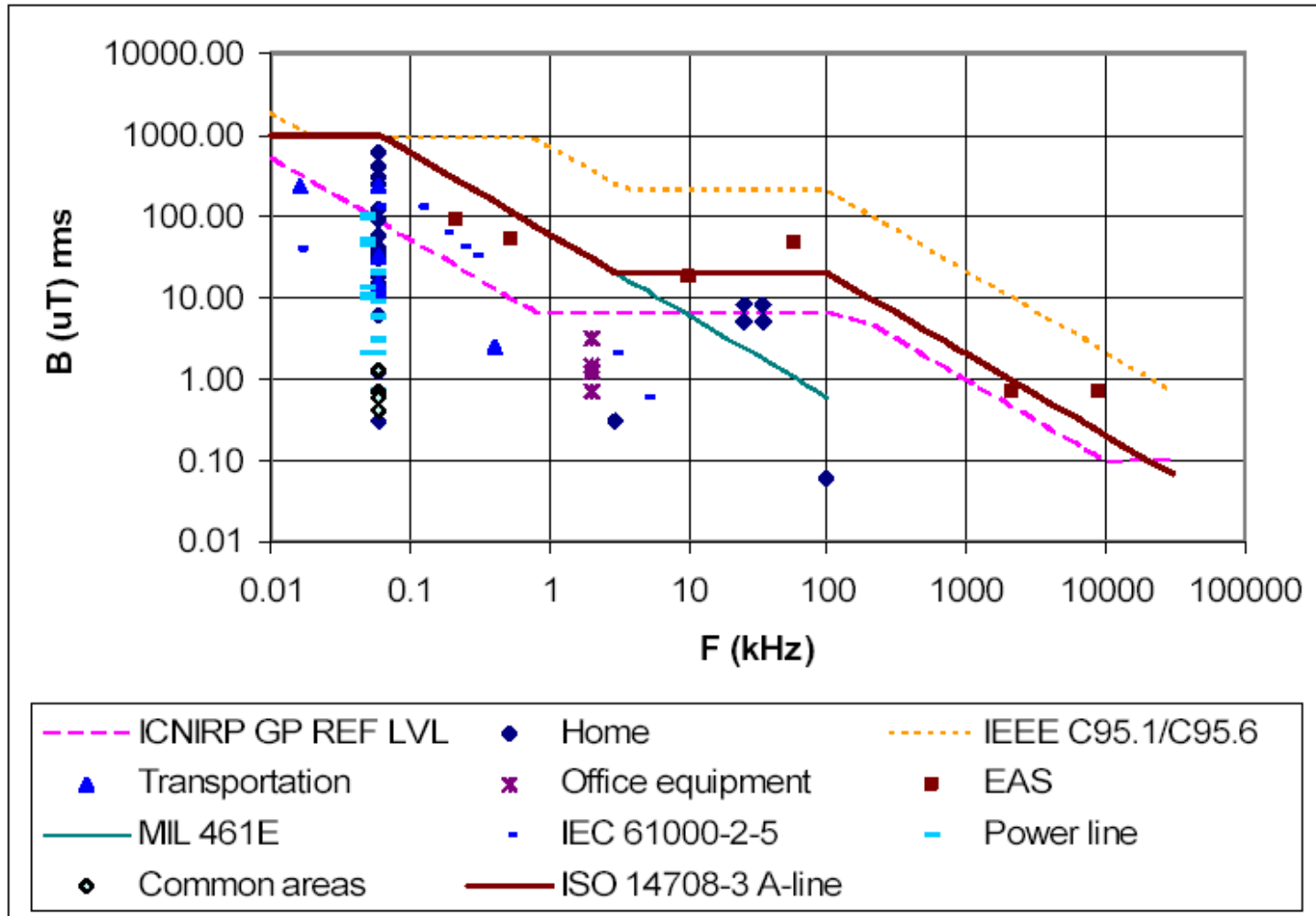
1/ DC magnetic field: 1mT and 50mT severity levels, compared to 40mT as per the public EMF recommendation.

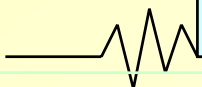
At 1mT level, the AIMD shall operate as intended during and after the stimulus (criterion A). But at 50mT level, a temporary degradation is acceptable, as far the AIMD operates as intended after the stimulus, and the patient is not exposed to an unacceptable risk (criterion B).

2/ 10Hz to 30MHz - Magnetic field immunity from (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).

Neurostimulator vs. magnetic field environment

- Immunity response: free from damage and from unacceptable risk.





Standard evolution in the public environment / AIMD Neurostimulator (part2/2)

3/ 30MHz to 450MHz - Electric field immunity as per IEC/EN 61000-4-3:

16V/m (criterion A) and 140V/m (criterion B). The corresponding public EMF level is established at 28V/m (450MHz).

4/ 450MHz to 3GHz - Electromagnetic field immunity as per ANSI/AAMI PC69:

40mW (criterion A); 2W and 8W levels are optional.

The 40mW specification covers usual handheld transmitters situations located at 15cm from the AIMD.

5/ > 3GHz: 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 a 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.

Standard evolution in the public environment / MD (non implantable)

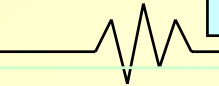
Medical Devices (MD) as non implantable infusion pumps (ambulatory or not) are covered by the particular IEC/EN 60601-2-24 standard, which refers to the collateral IEC/EN 60601-1-2 standard. Depending on the MD classification, as life or non-life supporting MEE, the specified severity level is set at 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), under the control of an operator, and using specific procedures.

The manufacturer has to evaluate if the overall electromagnetic risk is acceptable, and if the tested level should be greater than 3V/m or 10V/m, from the risk management (performed as per the EN/ISO14971 “Application of risk management to MD”).

He would decide to modify the immunity specifications and tests accordingly.

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.



V. Recommendations from government agencies for the therapeutic environment

Because of the therapeutic environment,
the induced effects may be 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.

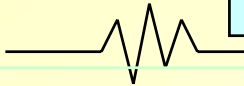
From AFSSAPS sanitary agency, the report “*Interactions between AIMD and medical devices*” recommends contraindications as per two categories about neurostimulators:

1/ Absolute contraindication.

2/ Relative contraindication, with required control measures.

MD interfering with AIMD (Neurostimulators)

Absolute contraindications examples



- **In the benefit/risk analysis the** Control/Mitigation measures allows that the overall risk remains acceptable (EN/ISO 14971)
- The risk is not acceptable compared to the benefit.

Source of disturbance	Risks	Benefit/Risk assessment.Control/Mitigation measures
Diathermy - electromagnetic (RF short waves & microwaves) promote healing	Short waves diathermy burns tissues around the electrodes and the neurostimulator. Neurostimulator failures risks, and patient death.	Absolute contraindicated therapy Death risk even if the Neurostimulator is turned off.
Electromagnetic stimulation (by current or magnetic field) for transcutaneous therapy, skin care, cosmetic	Induce high density currents on electrodes tips. Risk of neurostimulator deterioration, and stopping. May modify the programming. Lethal risk.	Absolute contraindicated therapy Death risk even if the Neurostimulator is turned off.

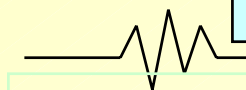
MD interfering with AIMD (Neurostimulators)

Relative contraindications examples

- **In the benefit/risk analysis the Control/Mitigation measures allows that the overall risk remains acceptable (EN/ISO 14971).**

Source of disturbance	Risks	Benefit/Risk assessment.Control/Mitigation measures
MR scanner	MR magnet and RF fields induce voltages on the neurostimulator, and its electrodes. They may modify the programming, induce spurious stimulations (stroke effect), or stop it. Warm up of the metal parts and electrodes. Burned tissues.	Relative contraindication, requires control measures. . Prefer conventional scanner. Limit magnet use to 1.5T. . Avoid and limit RF coil exposition from the entire body. . Examination depending of the stimulation implementation(encephalic, spinal cord, peripheral nerves). . Limit head SAR to 0.1W/kg.
HF surgery (electrical bistouri, electrocautery)	Induce HF currents(450KHz). Induced high density currents on electrodes tips. Burned tissues. Risk of deterioration and stopping the neurostimulator. May modify the programming.	Relative contraindication, requires control measures. Assess the benefit/risk. Shall replace the HF bistouri by laser, cryogenic, or ultrasound technique.

VI. Conclusion: summary and trends



By design, the manufacturer cannot solve all the EMI problems. Considering the benefit/risk ratio of the AIMD & MD, today the different actors from the standardization identify control measures, which minimize the safety risk versus EMI. Then, the labelling, accompanying documents, and mitigation procedures are communicated for implementation (education, relative contraindications...).

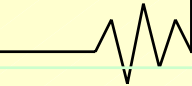
For example in the therapeutic environment, they would recommend, what MRI magnet field amplitude is compatible with such AIMD or such MD.

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 more specific 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 managing the EMI Risk as per the EN/ISO 14971 standard.



Special thanks to,

Medtronics: Veronica Ivans, Curt Sponberg.

If you have any questions....

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