Electromagnetic fields and implantable medical cardiac apparatus

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The sources of electromagnetic interference that can affect the operation of implantable pacemakers and cardioverter defibrillators (ICD) are more and more numerous, and cover the whole range of frequencies from 0 to 300 GHz, including very low (ELF) and radio frequencies (RF). For a patient with this apparatus, the possible consequences range from a lowering of the person’s well being, with no clinical repercussions, to a dangerous situation.

Now, the recommended limit values [1] for human exposure, are much higher than the threshold of immunity required by the standard of electromagnetic compatibility of this apparatus [2]. Moreover, the European Recommendation excludes cardiac pacemakers and ICD patients from its scope [3].

From the 1980s onwards, experimental studies with cardiac pacemakers on a laboratory table revealed dysfunction risks. This has led manufacturers to offer innovative technological solutions, using filters positioned on the input of the electronic circuits, and software solutions, with the introduction of so-called “reversion mode” emergency programmes, should an interference be detected.

This article intends to report the chief conclusions of the studies on the possible interference between electromagnetic fields and implantable medical cardiac apparatus, following upon the scientific conference, “Electromagnetic fields, cardiac pacemakers and defibrillators”, organised by the Non Ionising Radiation Section of the Societe Francaise de Radioprotection and the Cardiac Stimulation Group of the Societe Francaise de Cardiologie held on 25 October 2002 in Paris.

What is a cardiac pacemaker?

A pacemaker is made up of a case including a battery and a computer controlled electronic circuit. This circuit allows the detection of the electric pulses emitted by the auricles and/or the ventricles and the consequential action. The case is implanted in the upper thorax, most frequently to the left. It is connected to the heart by one or more probes. It is designed to detect cardiac activity and automatically stimulate the heart. It enables bradycardia (very slow heart beat) to be treated. It analyses the signals received within a range of 10 to 100 Hz.

The sensitivity of the pacemaker to electromagnetic interference depends on several factors, the most important of which are the setting of the probe: single-pole detection (between an electrode and the case), or two-pole detection (between two electrodes located on the probe at the heart), and the adjusting of the detection sensitivity: the higher the sensitivity, the more receptive the apparatus is to interference. Other factors also have an influence such as the frequency of the field or its orientation.

An interference arises when the circuit thinks it detects cardiac activity when there is none. This can be an outside source, or due to muscular activity i.e. from the greater pectoral muscle, above all with single-pole detection.

Approximately 50 000 cardiac pacemakers are implanted in France each year.

What is an implantable cardioverter defibrillator (ICD)?

An ICD is made up of the same components as a pacemaker, but with a larger battery, to give electric shocks in answer to the disturbance detected in the cardiac rate.

They are designed to detect and automatically treat episodes of troubled heart rate, i.e. tachycardia, and ventricular fibrillation, but they can also have a stimulation function. Detection is necessarily two-pole, which greatly reduces the risk of perceiving interference. However, ICD are naturally more sensitive than pacemakers, since they have to detect lower signals.

Approximately 2000 ICD are implanted annually in France, a figure that is constantly rising. The first operation dates back to the beginning of the 1980s. There are far fewer studies for this kind of apparatus that is of a more recent technology.

Today, pacemakers and ICD are capable of stimulating or giving a shock, storing diagnostic information in its memory, and providing graphs with electrograms that enable the fine adjustment of settings, the adjustment of treatment and the spotting of interference. The consequences of interference range from an acceleration of the heart rate to cardiac arrest, an inappropriate shock, or even a deprogramming. Generally speaking, the consequences are reversed when the patient is no longer exposed. With ICD, interference cannot go unfelt, since it generates an inappropriate shock, while the stopping of a pacemaker for a few seconds only causes a slight turn or may not even be felt.

In the literature we can find three types of study:

- In vitro tests: with the apparatus on a laboratory table. These tests fail to reproduce all the constraints that apply to implanted apparatus. At present, they are often carried out with phantoms, as in the example of Pr. Nadi’s work at the Laboratoire d’Instrumentation Electronique de Nancy (UEN). Therefore, these studies are more credible.
- In vivo tests: on voluntary patients during or after implantation, with a standard programme or with a specific programme reproducing the most unfavourable case (single-pole detection, maximum sensitivity).
- Clinical cases: reported in literature.

Power frequency electric and magnetic fields (ELF)

The case of pacemakers

In the 1980s, studies of interference with 50 Hz chiefly concerned the effects of induced current in the human body. In 1983, Butrous [4] showed that the interference threshold varied with the model, and the size and position of the...
The induced current modifying the operation of the pacemaker varies between 20 and 337 µA, which corresponds to fields of 2 kV to 24 kV/m. The interference described takes the form of permanent or intermittent reversals in an asynchronous mode (the emergency programme written by the manufacturer), slowing down or irregularity of the heart rate. The asynchronous mode can be unpleasant for patients.

In 1988, Kaye [5] directly applied a 50 Hz current to patients which simulates the exposure to a high voltage electric field. He found a great variation in the threshold current which triggered an interference, 27 to 246 µA, and the role of the position of the patient. He showed that by gradually increasing the intensity of the current, it moves from normal operation to failure of detection and then intermittent inhibition.

Astridge [6] widened this study to dual chamber pacemakers, and, in 1993, showed the importance of the polarity, the single pole mode being more sensitive (10 to 40 µA) than the two pole mode (80 to 170 µA) for the highest sensitivity settings. This corresponds to electric fields respectively of 1.5 kV/m and 13 kV/m for the most sensitive apparatus.

Toivonen [7] is the only person who, besides electric fields, took an interest in magnetic fields in an in vivo study. The latter was carried out in an electric substation, by varying the polarity and the sensitivity of pacemakers and measuring the electric and magnetic fields in different places, with continuous monitoring via telemetry. He again found a relative lack of sensitivity in the two pole mode compared with the single pole mode, and the harmful effect of programming with a maximum sensitivity, in the single pole mode, that causes disturbances starting at 1.7 kV/m, whilst the two pole mode is exceptionally disturbed by intense fields of 7 to 8 kV/m. He found no anomaly for magnetic fields of between 48 and 90 µT with normal sensitivity, whilst the same fields disturb the operation of a pacemaker when the settings are single pole with a high sensitivity.

In 1990, in an in vitro study in old single chamber models, Salmi [8] showed that the lowest magnetic field that changed the functioning of the pacemaker was 40 µT for frequencies of 40 Hz to 70 Hz. However, it is difficult to draw conclusions for present day apparatus, whose technology is based on microprocessors. In this study, it was purely a question of the switching to an interferential mode, without interrupting stimulation, or any other anomaly.

More recently, Silny [9] studied 100 pacemakers in vitro. He showed that a 50 Hz vertical electric field of over 6 kV/m could lead to an interference in the most unfavourable case. In the case of a magnetic field, the interference threshold is between 552 µT at 10 Hz and 20 µT at 250 Hz (a frequency found in some electronic article surveillance gates: EAS gates).

The French study by Frank [10] concerns 60 volunteers representing the 9 manufacturers of pacemakers implanted in France. They were exposed to a magnetic field of 50 µT at 50 Hz and 60 Hz with two apparatus settings. With the basic setting, no disturbance was revealed. With the most unfavourable setting (maximum sensitivity, single pole detection), 6 cases of transient reversions and 3 cases of transient acceleration were detected. However, no deprogramming, or inhibition was observed. There was no interference below 40 µT.

The case of ICD

We have found no study published for this frequency range regarding ICD. An in vitro study is underway at the Laboratoire d’Instrumentation Electronique de Nancy (Pr. Nadi).

Induction heating (kHz range)

The only study published is that of Frank quoted above [10] which concerns cardiac pacemakers. The volunteers were invited to use a normal induction hob (3rd generation), with different methods. This hob operates with fields of between 20 and 50 kHz. No disturbance was detected, neither with the basic setting, nor with the most unfavourable setting, whether the hob was used on a low or high power setting, or with a sequential mode.

Metal detectors

For 20 years, all cardiac pacemaker patients have been warned of the dangers of gates used in airports, banks of prisons to detect weapons. Starting in 1988, the Coppenman [11] study regarding single-pole pacemakers proved that these detectors had no influence even with apparatus programmed for the maximum sensitivity. In 2003, Kolb [12] tested 200 volunteers with an implanted pacemaker and 148 with an ICD. No interference or deprogramming was observed with this recent apparatus. The main risk remains the triggering of the detector alarm by the pacemaker or ICD case which is made of metal!

Mobile telephones (RF)

The case of cardiac pacemakers

These potential EMC problems have been the subject of numerous publications. The first were alarming: Barbaro [13], Hayes [14] or Nuegell [15] described inhibitions or accelerations in the heart rate, mainly with 8 W analogue telephones placed at less than 10 cm from the case, set at the maximum sensitivity and with a single-pole detection (the most unfavourable setting).
In 1997, Hayes [16], in a multecentric in vivo study, found 20% interference with digital telephones, 7% of which being symptomatic, and only 2.5% interference with analogue telephones.

Recently, Trigano [17, 18] carried out in vivo studies on 255 patients, representing 82 pacemaker models, of the 9 manufacturers represented in France, with the most unfavourable setting conditions (maximum sensitivity of the pacemaker, contact with an analogue telephone with a maximum power of 2 W). The results show that the pacemaker model is a deciding factor. They also highlight the importance of the distance between the telephone and the window of the connector of the "sealed feedthrough" (the part of the pacemaker linking the connector to the metal case). The interference found is above all inhibitions or salvos of fast ventricular stimulation. In 4% of the cases, the inhibitions was sustained and potentially symptomatic. At the same time, Jacquemart [19] showed that the design of the "sealed feedthrough" seems to play a major role in sensitivity with regard to mobile telephones. For a few years now, these works have led manufacturers to modify this sealed feed through by adding filters (RF are easy to filter because they are not within the range of the cardiac frequency).

The case of ICD

Irnich [20] and then Occhetta [21] studied the interference between telephones and ICD and drew the same conclusions. In Occhetta's in vivo study, analogue and digital telephones were brought into contact with 5 ICD for 5 min when a defibrillator was being implanted. No inappropriate shock, nor a fault in the detection of an induced ventricular fibrillation were observed. Hence, there is no reason to forbid the use of mobile telephones for ICD patients.

Conclusion on mobile telephones

It is recommended to hold a safety distance between the case of the pacemaker or the ICD and the telephone, ranging from 15 to 20 cm for a telephone with a maximum power of 2 W to 40 cm for a maximum power of 8 W. A piece of advice that is common sense is not to put a telephone in a chest pocket on the side where the case of the pacemaker or ICD is implanted.

Electronic article surveillance gates (EAS)

The case of cardiac pacemakers

With EAS gates, the problem is more complex because it is a question of apparatus whose frequencies are multiple and cover the whole range. Each one has its own signature.

Beaugarde [22] in an in vitro study, as early as 1992, insisted on the danger of EAS gates in shops. The following year, Dodinot [23] confirmed the high potential sensitivity of cardiac pacemakers with regard to EAS gates, in his in vitro study. However, in his in vivo study, asking patients to walk through a 300 kHz EAS gate, he observed a ventricular pause with one single type of pacemaker (already out-of-date in 1993) that had no safety ventricular stimulation (reversion mode). The pause was transient and spontaneously reversible. There was no deprogramming.

As for Lucas [24], he observed reassuring in vitro results, only bringing to light minor dysfunctions with the maximum sensitivity and single-pole detection. For Fetter [25] and Mc Ivor [26], the main interference was asynchronous stimulations (switching to emergency mode). They observed no deprogramming.

Wilke [27] published an in vivo study of 53 patients with different pacemaker models which confirmed Lucas' results. For Trigano [28], the dangerous systems are magneto-acoustic gates emitting a pulsed field (58 kHz). The other risk factors are above all the movement in the field and the exposure duration.

ICD cases

Only clinical cases have been published, describing inappropriate shocks received by patients remaining within EAS [29, 30].

Conclusion for electronic article surveillance gates

It is recommended to not remain unnecessarily inside the gate, in particular for ICD patients. This of course means that the EAS must be visible! "Don't lean, don't stop, just go".

Interference in the work place

These different ranges of frequency can also be found in the industrial sector. For static fields, it is recommended not to exceed 0.5 mT but the compatibility standard is 10 mT, a level that is practically never exceeded in the professional environment.

For the other frequency ranges (ELF, induction, RF) the interference risks are negligible but there is no guarantee of an absence of risk [31]. There is no exhaustive study that has researched into disturbances according to a particular type of exposure for all existing apparatus. Usually a pacemaker or ICD patient would be said to be inapt or require a job change, in the case of exposure to electric or magnetic fields. In fact, conflict is rare and the psychosocial problems raised by this attitude are much higher than the interference risk.

The procedure is rather to wear a holter at the work station or to interrogate the apparatus if it has sufficient memory, after setting it to the maximum sensitivity with a single-pole detection, whilst working with a cardiologist. If no anomaly is detected, it is preferable not to change the work conditions, with the pretext of a potential, but not real risk.
In the case of ICD there is however, a strict contra-indication, i.e. arc welding.

**Conclusion**

Interference with cardiac stimulation is quite well apprehended and the consequences are generally low. The same fails to apply to defibrillation, where interference can be the source of an inappropriate operation of the apparatus, the first consequence being for the patient to receive an unjustifiable shock.

In the case of cardiac stimulation, the interference problem often remains anecdotal, without major practical consequences. Regarding ICD, data from publications incite us to be more careful, in particular regarding EAS gates. However, for ICD, there is one formal contra-indication, i.e. arc welding.

Cardiac pacemakers and automatic implantable cardioverter defibrillators (ICD) are frequently well protected from outside interference. A little common sense, advice and elementary precautions are often sufficient to reduce risks, e.g. do not put a drill against a pacemaker or ICD case; put a mobile telephone on the opposite side to the case; do not lean inside an EAS gate; etc.

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**References**


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