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SÉNAT

Electromagnetic compatibility between mobile telephony and electronic medical equipment

Public hearing of Wednesday 5 July organised by

Mr Jean Dionis du Séjour, Deputy, Lot-et-Garonne,
Mr Daniel Raoul, Senator, Maine-et-Loire

Given the concerns expressed over the risks related to 'electromagnetic pollution' generated by mobile phones and run by persons fitted with implantable medical devices, such as pacemakers, the Parliamentary Office for Science and Technology Assessment (L'Office parlementaire d'évaluation des choix scientifiques et technologiques) organised, on 5 July 2006, a public hearing on this subject, chaired by Mr Jean Dionis du Séjour, deputy, and Mr Daniel Raoul, senator, members of the OPECST.

Overview

Already, in 2002, the context was marked by growing concern over the possible effects on human health of mobile phones, and more specifically of relay antennae. A study on the *'possible incidence of mobile telephony on health'* was brought before the OPECST and it adopted a report (Rapport no. 346 -National Assembly-, no. 52 -Senate-, by Messrs. Jean-Louis Lorrain and Daniel Raoul, Senators).

The debate, without being exhausted, is tending today to shift from the direct impact of electromagnetic waves on health to 'electromagnetic pollution', which is accused of disturbing the operation of vital equipment for human health, such as pacemakers.

The public hearing did not allow the scientific debate to be settled once and for all, but it highlighted issues that are rarely mentioned, such as the difficulty of passing on to the public authorities information on incidents whose causes have been identified and ascribed to electromagnetic disturbances.

Apart from this finding, the public hearing revealed the complexity of the issue at hand. This complexity undeniably hinders the organisation of objective information accessible to the general public.

Another decisive fact resides in the focussing of those heard on the degree of electromagnetic immunity or sensitivity of medical equipment itself, rather than on the disturbances caused by mobile phones. Also, those heard mentioned more often than the disturbances that may be caused by security scanning stations, or by domestic appliances or other medical equipment, that generated by mobile phones.

An understanding of the phenomena under study is based on ***three essential notions.***

Electromagnetic compatibility is the aptitude of equipment to operate satisfactorily, without disturbing other equipment.

All marketed equipment must guarantee a ***level of immunity***, in other words a threshold below which an electromagnetic disturbance does not hinder correct operation of the equipment.

If this is not the case, we are in the presence of ***electromagnetic sensitivity***, i.e. the incapacity of a given piece of equipment to operate in the presence of a signal, without a decline in quality.

Electromagnetic sensitivity exists but is difficult to quantify and modelise

Electromagnetic sensitivity has given rise to the drafting of approximately 150 harmonised European standards.

The public hearing highlighted the difficulty that could arise in quantifying, analysing and preventing electromagnetic disturbances.

Involuntary remote sources of interferences can be produced by :

- the electric field (electric circuits, overhead electric lines, transformers),
- the B magnetic field produced by electric engines and other types of applications,
- and, lastly, by a component of both the electric and magnetic fields that can be encountered in the presence of welding equipment, high frequency presses, or close to microwave ovens or radars.

Interferences are rare in the daily environment; they are more frequent in the professional environment, where the most intense sources of electromagnetic fields are to be found.

Measuring the phenomenon is difficult. Many research studies measuring interferences, at the frequencies most currently met in the professional and public environment, have shown that immunity is generally far higher than what is required by electromagnetic compatibility standards.

But, in electromagnetic compatibility, it is difficult to conduct an exhaustive analysis of complex systems. For instance, according to standards, a heart defibrillator is 'immunised' with regard to the disturbances that a drill can cause, but provided the drill itself complies with the requirements to which it is subject. The compatibility principle applies between several elements, and each of them must meet its own requirements. A given element, especially a heart defibrillator, must not therefore be necessarily accused. The problem is perhaps caused by the tool used, because it does not conform with standards or no longer conforms with them because it is damaged.

As it is impossible to simulate all situations that can be met by a piece of equipment, the matter of electromagnetic compatibility is examined through a series of hypotheses which, of course, do not cover the whole issue.

The connection must also be taken into account. The fact that a set of cables are laid out according to a given configuration will lead to a given coupling between equipment; a change in this configuration will cause a coupling at another frequency, with perhaps different polarisations. The issue is then different than that related to equipment. This matter does not however arise with implanted devices which, normally, are not inter-connected. It does arise, on the contrary, for other medical equipment at hospitals, or even in the setting of home care. This is because equipment, even with individual EC marking, may not have the same degree of immunity once connected.

Turning to modelisation, the ongoing work must be intensified, in order to allow reasoning applied to a whole set of equipment and not limited to each piece of equipment. The fact that individual pieces of equipment comply with standards does not in effect guarantee that the whole set is free from electromagnetic disturbances.

It is practically impossible to predict, for a given frequency, what intensity of the electric field or magnetic field will cause a difference in potential that leads to disturbances. This fact can be tested and verified in the laboratory, at manufacturers, but experimentation does not reproduce real operation conditions. The difficulty cannot be summarised as an issue of the field level, but resides in a matter of the coupling between systems.

Its impact in the medical field appears limited however.

First finding: implantable devices are better immunised than external medical devices.

Some associations have taken a particular interest in the issue of the impact of electromagnetic devices on human health via the disturbances that can affect active implants, especially pacemakers, which were introduced into France in 1959.

The Direction générale de la santé (General Health Directorate), in a note on this subject, admits *'the regulatory weakness in Europe and also in France and the impossibility of being certain of the total absence of risk.*

However the resistance to electromagnetic interferences of modern, active, implantable, medical devices has been considerably improved, to meet in particular the development of the use of mobile phones.

In addition, pacemakers are subject to standards, especially the standard NF EN 45502-2-1 of May 2004.

As a rule, these devices are fitted with a bandpass filter allowing them to be insensitive to mobile telephony equipment. In addition, the higher the frequency, the better pacemakers are protected.

A weakness of non-implantable medical devices resides in the wiring for, in this case, electromagnetic immunity is more difficult to guarantee. The same hospital ward can, moreover, house various pieces of equipment.

Second finding: no serious health problem has been identified.

Potential risks arise in the industrial environment and in the medical environment. But no accidents were reported that would incite the health authorities to act.

However, the absence of serious accidents must not be interpreted as the absence of incidents resulting from interferences.

In ten or fifteen years very few incidents have been documented by the health authorities. Nevertheless, manufacturers and cardiologists consider there are no insignificant incidents and that all have consequences.

If we take the example of heart defibrillators, incidents occur in three manners:

- In the best case, the defibrillator simply records a disturbance.
- The second case is slightly more troublesome, entailing the erasure of the memories.
- The third case is the reception of an inappropriate shock.

The reported cases have generally shown shortcomings in the equipment used and not in the defibrillator itself.

However it became apparent during the hearing that identifying the cause of an incident is not always easy. In many cases incidents are not declared to the health authorities owing to their lack of seriousness for the patient's health and because the isolated clinician is generally faced with a single case.

An important lesson was therefore learnt from the debates: ***the insufficient passing on of information to the health agencies*** when no problem is seen as a serious danger. In our view, thought should be paid to the mechanisms to be implemented to better supervise the operation of medical equipment that is not the subject of a marketing authorisation procedure.

The bodies centralising incidents, such as the AFSSAPS (Agence française de sécurité sanitaire des produits de santé - French health products safety agency) or the AFSSE (Agence française de sécurité sanitaire de l'environnement - French environmental health safety agency), do not have watch units allowing citizens to signal the problems met, whatever their seriousness.

If, *a priori*, no serious accident has been reported, either in France, England or the United States, it cannot therefore be guaranteed that no risk exists.

Are the standards sufficient ?

Standards are instruments made available to manufacturers to meet the essential requirements of the directives on electromagnetic compatibility.

These standards result from international consensus. They are established by players specialised in their field, in the framework of technical commissions meeting internationally or at the European or national level. If we take the example of electro-medical equipment, the commission is composed of experts from the medical profession, producers of medical products, laboratories, associations and representatives of the authorities.

Each of these commissions participates in elaborating a standard accepted internationally by all the countries participating in the Electromagnetic Compatibility Standardisation Committee. These international standards are then taken up at the European level by the European Committee for Electrotechnical Standardization (CENELEC). This body adopts and adapts them in keeping with the requirements of the applicable directives, in other words the directive on electromagnetic compatibility (89-

336) or the two directives on electro-medical equipment.

This 'set of standards', in the electro-medical field in particular, will serve as a basis ensuring a presumption of conformity of a given piece of equipment with the essential requirements of the directives concerned.

The basic standards are based on ***three principles***:

- They require first of all a level of immunity of medical devices, such as artificial respiration systems, mammographs, echographs, and syringes in a typical environment of 3 V/m, modulated in amplitude for medical devices that do not present a high risk, and of 10 V/m for so-called life-assisting medical devices such as anesthesia reanimation equipment. This is the minimum level for which it can be demonstrated that the product is immunised, which does not mean that beyond this point the product will be subject to a dysfunction.
- The second principle consists in imposing use requirements for these items of equipment in order to guarantee their correct use in a typical environment. A very simple recommendation, contained in user manuals, is not to stack items of equipment on top of each other, as stacking can lead to exceeding the levels of 3 or 10 V/m. Protection distances from emitters are also imposed: it will be laid down not to install a medical device at less than a given minimum distance from an emitter located in the environment. This emitter can be a mobile phone, a base station or any other type of radio emitters. The use of a medical device therefore supposes that the manual be read and its specifications respected by the user.
- The third principle is based on an analysis of the risk by the manufacturer: if he feels that the use of his medical device does not allow the defined basic guarantees to be respected, it is his responsibility to check the immunity of his product at higher levels. His risk analysis will concern what can occur in the event of a failure of his equipment, to ensure that the risk is minimised for the patient. Should an artificial respirator fail, for instance, the regulation of oxygenation will stop but will not be cut off: the valves open completely and trigger the alarms to alert all the medical personnel to intervene immediately. The aim pursued is therefore to find situations where the risk is mastered.

These three principles underlie the basic standards and must be used by the manufacturer to meet essential safety requirements.

But an important criticism has been expressed by users themselves: manufacturers set forth very strict use stipulations allowing them to avoid incurring liability. This sometimes pointlessly disturbs users of devices.

At the end of this hearing, several remarks can be made.

➥ ***In the present state of the documented incidents, electromagnetic compatibility matters must not be considered as a serious public health problem.***

➥ ***However, important research work must be conducted to better analyse the disturbances of equipment related to wiring and their environment.***

➥ ***The passing on of information, from users to health agencies, is not satisfactory and must be improved.***

➥ ***The use recommendations for devices should not be excessively restrictive.***

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