Biological Effects of Radiofrequency Fields

Indirect Effects: Interference With Medical Devices

Electromagnetic compatibility (EMC), *i.e.*, the use of RF spectrum separation and adoption of techniques and measures to avoid interference of an RF-emitting device function, that is potentially susceptible to RF, has been a major preoccupation of the telecommunication industry. This is called electromagnetic interference (EMI).

The possibility that medical devices could be adversely affected by RF emitted by the antennas of base stations and portable wireless devices in their proximity has prompted, in the 1990s, many engineering and clinical tests around the world.

Although initially deemed a rare event (very few cases were actually observed or reported), the potential impact on the well-being and lives of patients hooked up to these medical devices justified a cautious approach. The low frequency of such EMI events attests to its rare occurrence since only 5 reports in the MAUDE FDA database of adverse effects of EMI on medical devices have been reported since 1993 (http://www.fda.gov/cdrh/maude.html), none of which could be traced to the proximity of a telecommunications device. The most common EMI being caused by exposure to an electrocautery device, which use high power outputs. Indeed, an early experimental study with more powerful handheld phones (Irnich *et al*., 1996) indicated that only 1 in 100,000 pacemaker patients were expected to suffer a clinically relevant interference event in their lifetimes.

The interest in EMI was justified because this might be one of the few documented, albeit indirect detrimental effects of low level RF fields on the health of exposed people. This is especially the case for patients using implanted cardiac pacemakers or defibrillators, or hooked up to life support devices, such as mechanical ventilators, which are vital for their continued survival. Since its invention, these devices were known to be susceptible to external EMF, such as those used for metal detection in airports and for shop security against theft; and a number of warnings and protection measures were implemented since then (see ICNIRP, 2000, for a review).

Initial studies soon documented that these adverse effects of EMI were indeed possible, at least for the handsets in close proximity to medical devices and that there was almost no in-built protection from RF interference in current (i.e., 1980's generation) medical devices. The ongoing explosive growth in the use of mobile phones both inside and outside healthcare facilities was also a major motivation of such studies, because it could increase the incidence of heretofore-rare events of EMI. Due to the extremely low level of signals from base stations, however, most of experimental studies focused on EMI for handsets.

- Medical devices that might, in theory, be susceptible to RF emitted by communication equipment in its proximity, are legion. For example:

- Implantable: cardiac pacemakers, defibrillators, chronic neural and gastric stimulator packs, artificial cochleas, etc.

- Wearable: hearing aids, Holter and MAPA monitoring devices, TENS (transdermal electronic neural stimulator), etc.

- External: bedside signal monitoring equipment, anesthesia machines, renal dialysis and heart-lung pump machines, infusion pumps, external cardioverters and pacemakers, mechanical ventilators, signal recording equipment (EKG, EEG, etc.), imaging terminals, computers with telecommunication capabilities, telemetry equipment and several others.

Two kinds of research studies been performed: *in vivo*, with implanted or wearable devices used by patients, and *in vitro*, with detached or external devices. In both situations, mild to extremely deleterious interference events were observed during tests under laboratory and clinical conditions, such as the sudden malfunction of pacemakers, arbitrary and unexpected change of parameters and resetting of devices, triggering of false alarms, sensor artifacts, alteration of readings and tracings; many of which could cause serious harm or even death in case a real patient would be plugged to any of these devices.

But what was the prevalence of such events?

In 1995, the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) conducted a large survey of provocation studies in 18 locations, including hospitals, based on data for 178 different models of medical devices, subjected to interference attempts by a wide variety of radio handsets. The startling result was that in 23% of tests medical devices suffered some kind of EMI from handsets, and that overall 43% of these interference incidents would have had a direct impact on patient care, and were rated as serious. Emergency and security communication two-way radios were the most deleterious, reaching 41% and 35%, respectively of EMI events at less that 1 m distance, with 49% of the events considered serious.

Thus, real concern increased in the mid-1990s, and reports started to leak to the mass communication media. This influenced heavily the perception of the public towards cell phones, when, in fact, they were much less effective in this respect, since in the MHRA study, only 4% of handsets caused interference at less than 1 m distance, with a negligible 0,1% being regarded as serious. At the time, most of the handsets tested were analogical, and thus had a higher power output than current CDMA, TDMA and GSM digital models.

Thus, it was discovered, not surprisingly, that distance between devices was the major factor for EMI, since, due to the law of inverse squares, mobile phones typically produce RF of up to 42 V/m at 0.1 m, dropping to below 7 V/m at 1 m. The US FDA established in 1979 a voluntary standard of a maximum 7 V/m for medical devices to become immune to EMI from wireless devices (FDA, 1979), but several studies (e.g., Clifford *et al,* 1994) had determined that analogue cell phones and two-way radios easily exceeded this limit at 1 m distance or so.

The first extensive experimental studies of EMI on pacemakers came out in 1995 and 1996. The first large scale *in vivo* study was published by Barbaro *et al.l* (1995), in which the authors evaluated 42 different models of cardiac pacemakers implanted in 101 patients. The results were worrisome, since among pacemeaker patients with a GSM cell

phones activated in contact over the pacemaker pocket, 26% suffered an EMI event, a very large proportion. Clinically relevant anomalies were mostly ventricular trigging (20%), pulse inhibition (10%) and asynchronous pacing (8%), but pacemaker malfunction and physiopathological events were entirely temporary, reverting to normal after the cell phone was removed or disconnected. Fortunately, the authors determined that the maximum distance to achieve EMI was 10 cm only.

Similar results were confirmed by the large multicentric, prospective study by Hayes *et al.* (1997), who tested 980 patients implanted with 6 different models of pacemakers and four different types of cell phones. They observed an overall incidence per test of 20%, an incidence of symptoms of 7.2% and an incidence of clinically significant interference of 6.6%. These were not present when the telephone was placed in the normal position over the ear. They were composed by 14.2% of atrial interferences, 7.3% of asynchronous pacings and 6.3% of ventricular inhibitions. The authors were the first to classify EMI interference clinical consequences into three levels: the level I included consequences that included symptoms, such as vertigo, dyspnea or cardiac syncope. Level II included interference of limited clinical importance, such as heart palpitation. Level III grouped all other consequences with improbable clinical importance. Of these, 1.7% were Class I, 4.9% Class II and 13.4% Class III interference. Therefore, interference that was definitely clinically significant occurred in only 1.7% of tests, and only when the telephone was held over the pacemaker.

In 1996, Irnich *et al.* published a large and influential *in vitro* experimental study where 231 different models of cardiac pacemakers of 20 manufacturers were tested with respect to interference by three signals: a 900 MHz analogue cell phone signal (C-Net), a 900 MHz digital pulsed signal (D-Net) and a 1,800 MHz digital pulsed signal (E-Net). The result was that 30.7% of the pacemaker models tested were sensitive to interference from the analogue signal, 34.2% from the digital 900 MHz signal and 0% from the 1,800 MHz signal. This sounded serious, but an essential discovery was that the maximum distance that caused EMI effects was less than 20 cm. This led to the recommendation that pacemaker-implanted patients should use the cell phone to the contralateral side of the head in relation to the side of the implant, since this assures the required safe distance.

Between 1995 and 1997, seven other well-designed experiments were published, all of them reporting between 18% and 37% overall EMI, both in relation to devices/patients or to tests (see Censi *et al,* 2007 for a comparative review on cardiac pacemakers).

As a consequence, a number of national and international regulatory agencies began to examine closely the issue of EMI of wireless communication systems upon medical devices, and, recognizing the potential risks of adverse effects, started to publish around 1997 several technical reports, guidelines and recommendations to professionals and the general public on the subject. These early reports set an alarming tone and made a large number of restrictive and precautionary recommendations, which later proved to be unnecessary, as we will see, mostly due to the evolution of technologies and adoption of filtering and protection measures by medical equipment manufacturers.

For example, the MHRA published two device bulletins, one in 1997, and another in 1999. They were later supplemented by a document on new mobile communications technologies, such as Bluetooth, WiFi, etc., in 2004. Other authorities, such as the International Standards Organization (ISO, 2005), the American National Standards Institute (ANSI), the Association for the Advancement of Medical Instrumentation (AAMI)

and the United States' Food and Drug Administration (FDA) also issued a number of studies and recommendations. Following the initial wave of alarm, AAMI published a detailed technical report to its members (AAMI, 1997). In the same year, ANSI published its report on recommended practices for estimating EMI immunity of medical devices (ANSI, 1997).

Among these early recommendations, officials responsible for safety in healthcare facilities were urged to implement a serious and costly effort to curb the apparently mounting menace of RF "on the loose" in their institutions. For example, AAMI recommend that RF transmitters in use in the facility should have the lowest possible output power rating that could be used to accomplish the intended purpose, that electrically-powered medical devices should meet EMC standards, that electronic medical devices used in intense electromagnetic environments, such as near ambulance radios or in electrosurgery, should have EMC specifications suitable for these environments; that a system be implemented for tracking problem service calls by the location, date, and time of the reported malfunction, and that EMI problems should be reported to the manufacturer and to regulatory authorities.

Furthermore, AAMI recommended that "clinical and biomedical engineers should be the focal point for EMC, EMI mitigation, and EMC/EMI education/training within the health care organization (as well as the) purchase, installation, service, and management of all equipment (medical, communications, building systems, and information technology) used in the facility." AAMI emphasized that the Safety Committee of healthcare organizations should take permanent responsibility for EMC/EMI, and coordinate educational and information to the public, and have a say on site selection, design, construction and layout of facilities. AAMI felt, at the time, that there should be an intention and effort to "designate areas of the facility where the use of common hand-held RF transmitters (e.g., cellular and PCS telephones, two-way radios) by staff, visitors, and/or patients was to be managed or restricted". With this next to impossible task (how do you detect an active cell phone inside the pockets of visitors?), the recommendation actually resulted in the total ban of cell phones and base stations in the entire building by many health care facilities, and the passing of local legislation to enforce it. The air travel industry went through the same dilemmas, when suspicion was aroused that cell phones could interfere with electronic flight equipment, and the ban is still enforced today, although, most passengers still do not respect it, in the best of hypotheses.

Particularly costly and difficult to implement was AAMI's recommendation that "*ad hoc* radiated RF immunity testing should be considered when EMI was suspected, when RF transmitters are likely to operate in proximity to critical care medical devices, in pre-purchase evaluation of new types of RF transmitters to determine their effect on existing medical devices, in pre-purchase evaluation of new electronic medical devices, and when checking for age-related changes in medical device RF immunity".

It was predicted that all these harsh measures would cause a high organizational and financial impact on healthcare organizations should they be moved to comply rigorously with such recommendations. The fact that the great majority of extant, potentially vulnerable medical equipment in most hospitals were relatively old, and designed without consideration to protection against RF interference coming from novel mobile communication devices, made a rapid response to AAMI's recommendations a virtually impossible affair.

As new engineering tests were carried out, and as the industry moved fast to incorporate filters and other RF protection circuits into medical devices, the situation changed considerably in the succeeding years. The initial alarm was relieved by the discovery that adverse events would occur only when RF emitting devices would be put in very close proximity to medical devices (less than 20 to 30 cm), and that beyond distances of 100 cm, no effects could be observed, at least with devices of medium wattage and greater prevalence, such as mobile phones. Newer models of implantable devices were rendered immune to RF interference within the RF spectrum, and the technical evolution of portable digital communication devices, which emit at very low output power, have now practically eliminated or reduced considerably the risk of severe interference. In fact, micro- and nanocells, and the widely prevalent use of mobile phones and wireless communication networks within hospitals around the world, has become exceedingly common, without any reported incidents.

According to the most recent FDA/CDRH report on EMC (FDA, 2008), a different stance has been adopted, which leans more towards social engineering, education and prevention, than towards prohibition and banning. The main CDR/CDRH recommendation for healthcare facilities are to inform and educate all professionals involved, as well as patients and visitors; to assess the RF environment of the facility, particularly with a higher concentration of vulnerable medical equipment, such as in emergency rooms, intensive care units, surgical theaters, etc., to manage such environment with the goal of reducing interference risks to a reasonable extent, including a policy to select, acquire and substitute older equipment; and to establish and implement written policies and procedures, and the systematic reporting of adverse effects related to RF interference with medical devices, implanted or not.

Many authorities, such as FDA, MHRA, ICNIRP, WHO and others have recognized recently that a total ban on mobile communication devices inside hospitals, even in critical care areas, would be very difficult to enforce and that it is not reasonable, or even necessary. One of the reasons is that it is increasingly difficult to pinpoint accurately which of the user's equipment has wireless communication capabilities (for example, PDAs with cell phone features, laptops with embedded WiFi interfaces, etc.). Another is the enormous growth of such devices in possession of visitors, patients and professionals working in the healthcare institutions and their reluctance to cease operation within its confines. Still another is that healthcare professionals consider that pagers and cell phones are very important for timely communication and have a significant impact on quality of care in all areas of a hospital, so that their use should not be restricted.

Soto *et al.* (2006) did a survey in 2003 members of the American Society of Anesthesiologists and reported that cellular telephone use by anesthesiologists was associated with a reduction in the risk of medical error or injury resulting from communication delay (relative risk = 0.78; 95% confidence interval, 0.6234-0.9649). A review by Ruskin *et al.* (2006) on the use of wireless technologies by anesthesiologists has ascertained that the very low risk of EMI events in operating rooms is offset by a significant reduction in medical errors that results from more efficient communication.

Thus, in a 2005 technical report by ISO on the use of mobile wireless communication in healthcare facilities (ISO, 2005), it was recognized that

> "*misinformation regarding mobile wireless systems, electromagnetic interference and management procedures has led to a broad range of inconsistent policies*

among healthcare organizations (and that) a balanced approach is necessary to ensure that all the benefits of mobile wireless technology can be made available to them. Overly restrictive policies may act as obstacles to beneficial technology and may not address the growing need for personal communication of patients, visitors and the workforce. At the other extreme, unmanaged use of mobile communications can place patients at risk (…). It may not be feasible for healthcare organizations to manage every mobile wireless handset that is randomly brought into their facility without certain restrictive limits."

More realistically, the 2004 MHRA recommendations classified risks of interference according to more recent knowledge, into three levels: high, medium and low. Analogue emergency service radios and private business radios (two way communication radios, such as those used by porters, maintenance and security staff), were classified as being at a high risk of interference with many medical devices, and MHRA recommended its use in hospitals only outside clinical areas, only in an emergency and never for routine communication. An experimental analysis of walkie-talkie radios by Stroud *et al* (2006) determined that these devices usually emit at a higher power output, typically 4 W or more, and that they interfere much more with medical equipment than cell phones, to the point that hardware component failure may occur. Thus MHRA recommended that these walkie-talkie radios should be changed to lower risk technologies, with a power below 2 W, such as mobile phones. These, together with TETRA (Terrestrial Trunked Radio Systems), laptop computers, palmtops and gaming devices equipped with higher power wireless communication devices, such as GPRS, 3G and HYPERLAN, were classified as having a medium risk of interference. MHRA recommended to use them only in designated areas and to switch them off near critical care or life support equipment. Finally, cordless phones (DECT) and low power wireless networks, such as RLAN and Bluetooth have been classified as low risk of interference with medical devices, and require no action in relation to their use in the health care environment. These recommendations were supported by several studies, such as one carried out with several kinds of ventilators used in intensive care (Jones & Conway, 2005).

Many countries and regional governments now have adhered by revising their guidelines to this less restricted view of cell phones in healthcare facilities. As an example, we cite a guideline circular by the New South Wales government (NSW Health Dept, 2005) in Australian, whereby it is recommended that a general 2 m distance be observed at all times between RF emitting mobile equipment and sensitive medical equipment in certain areas, such as ICUs, ERs, OTs, etc., and a 0.5 m distance in wards and general areas, and that two-way emergency and security radios should not be turned off, but used only in required situations.

Another interesting recommendation by the ISO technical report (ISO, 2005) is to "*issue particular mobile wireless equipment to doctors and staff for healthcare-specific communication and health information access. This would allow the full benefit of wireless technology operating compatibly throughout the healthcare facility, even in sensitive areas in proximity of life-critical medical devices*". This recommendation has probably been superseded by the new digital cell phones, which emit very low power at frequencies to which most medical devices are considered now immune, and which have largely substituted alphanumeric pagers used by medical personnel. Use of VoIP (voice over Internet Protocol) handset devices using very low power nanocell WiFi data communication networks are now being deployed, which will probably put the issue to rest.

Indeed, the evolution of wireless communication technology on the one hand, and of radiation protection of medical devices on the other, has greatly changed the situation. For example, in contrast to the HRMA and Irnich studies in the 1990s, Lawrentschuck & Bolton could demonstrate almost a decade later (2004) that the EMI risks were significantly reduced. They carried out a systematic review of 7 published research studies between 1996 and 2004 on EMI of cell phones on 28 different types of external medical devices. The authors found that clinically relevant EMI potentially endangering patients occurred in 45 of 479 (9.3 %) devices tested at 900 MHz and 14 of 457 (3 %) devices tested at 1800 MHz, mostly occurring when mobile phones were used within 1 m of medical equipment. Overall, the prevalence was low, but the authors observed that all studies still recommend some type of restriction of mobile phone use in hospitals, with use greater than 1 m from equipment and restrictions in clinical areas being the most common.

The trend continued, as demonstrated by an experimental study carried out by van Lieshout *et al* (2007), on a total of 61 medical devices in 17 categories and 27 different manufacturers. They studied novel digital transmission technologies, such as GPRS-1 and UMTS signals used by third generation (3G) cell phones. The distance to achieve an interference effect was reduced to 3 cm (i.e., with the handset practically in close contact with the medical device), with only one hazardous incident occurring beyond 100 cm.

More recent experiments with modern implantable stimulators, for instance, have demonstrated no effects of GSM cell phone transmissions nearby (Kainz, 2003, Tandogan, 2005; Calcagnini, 2006). Mechanical invasive and non-invasive ventilators have not suffered any malfunction from GSM cell phones, and a few effects with two-way communication radios at less than 1 m distance (Dang *et al* 2007). In Sweden, Wallin *et al* (2005) tested the interference of GPRS, UMTS, WCDMA and IEEE 802.11b (WLAN) signals on 76 medical devices, including during 11 surgical operations with a total duration of 100 h. They concluded that UMTS and WLAN signals caused little interference and that “devices using these technologies can be used safely in critical care areas and during operations, but direct contact between medical devices and wireless communication devices ought to be avoided. GPRS can be used safely at a distance of 1 m. Terminals/cellular phones using these technologies should be allowed without restriction in public areas because the risk of interference is minimal.”. The particularly large *in vivo* study by Tandogan *et al* (2005), which tested 679 implanted pacemakers, arrived at an overall 5.5% figure of incidence of EMI per patient.

Although Tri *et al* (2005) demonstrated that current cell phone technologies in use, such as GSM, CDMA, TDMA and IDEN are still able to cause malfunctions on external medical equipment over short distances, clinically relevant EMI occurred only 1.2% of the tests made. Only four years before that, the same authors (Tri *et al*, 2001) had detected a 7.4% incidence of clinically relevant EMI events in cardiopulmonary monitors. Finally, in 2007, the same authors again, working at the Mayo Clinic (Tri *et al*, 2007) determined, in more than 300 tests involving a total of 192 medical devices, that the incidence of clinically important interference was 0% (95% confidence interval, 0%-4.8%). Thus, they concluded that “although cellular telephone use in general has been prohibited in hospitals because of concerns that these telephones would interfere with medical devices, this study revealed that when cellular telephones are used in a normal way no noticeable interference or interactions occurred with the medical devices.”

A review by Francis & Niehaus (2006) of 14 published research papers on the effect of cell phones on implantable cardiac rhythm devices, arrived at the conclusion that “no

dangerous malfunction was found in any of the analyzed studies, but most of the studies noted interference with device function when the phone was operated very close to the device. Interference was minimally in those devices with built in feed-through filters for eliminating electromagnetic interference. Device programming and interrogation were the most susceptible phases of operation."

Other reviews of the literature by Boyle (2006) and by Lapinsky & Easty (2006) concluded that "*wireless technologies are deemed suitable for use throughout hospital areas including intensive care units and operating rooms, given that recommended separation distances from medical equipment are observed.*" And that "*medical device malfunction is extremely rare if the distance from the transmitting device is greater than 1 m*".

Censi *et al* (2007) observed that older pacemaker models seemed to be more sensitive to EMI from cell phones, due to a lack of feedthrough filters. Feedthrough filters are broadband filters using ceramic capacitors that reduce significantly the influence of radio frequency sources on pacemakers. They discovered that modulated RF signals are demodulated by the pacemaker's internal non-linear circuit elements, if no feedthrough filtering assembly is incorporated to its circuitry. The problem is that digital cellular phones use extremely low-frequency modulation (as low as 2 Hz) can be mistaken for normal heartbeat. Therefore, healthcare institutions are urged to advise patients who still have implanted pacemakers dating before the year 2000, particularly in countries where analogue cell phones are still in use, that they incur unreasonable risks of EMI and adverse events. The use of two-way long range HT communication radios, used in entertainment, security and staff emergency communications is also dangerous, even for more recent pacemakers.

Finally, this review concludes with a note regarding the almost continuous state of technical evolution of both medical devices and wireless communication devices. Technologies that use very high frequency EMF, in the THz range, security imaging devices using RF fields, electrical power transmitted via wireless connections, and others, may pose risks for EMI on medical devices, both implanted and external, not yet foreseen. Thus, Gladman & Lapinsky (2007) conclude that "*increased use of cellular phones and ever changing communication technologies require ongoing vigilance by healthcare device manufacturers, hospitals and device users, to prevent potentially hazardous events due to EMI*". Restrictive policies are also better facilitated when easily accessible areas are designated where mobile phone use is encouraged (Morrissey, 2004), obviating the problems and difficulties of following up all imaginable wireless technologies that will arrive in the future.

Review of Research in Latin America

This review regards that there are particular circumstances in Latin America that have caused a disproportionally large number of experimental and review papers on the subject of electromagnetic interference on medical devices:

Hospitals in the region have a higher proportion of old medical equipment which has not yet been technically screened against the RF fields used by modern wireless technologies, such as GSM, 3G and WiFi; therefore, the situation favors a higher number of EMI incidents. Analogue phones are still in use in many regions of Latin America, and most of digital mobile phones using CDMA and TDMA technologies automatically shift to analogue mode when roaming outside their home areas, without the user being aware of this. The

overall result is that the situation is partially similar to what happened in the 1990s, in other countries, and thus a higher number of EMI events can be expected.

Furthermore, the ignorance of medical and technical staff about medical devices susceptibility to EMI is also higher in the region, and the absence of hospital security committees with organized plans of RF protection is very common.

On the other hand, the experimental and exact nature of testing for EMI, at least in laboratory conditions, and the fact that “technology poses problems that can be solved by technology itself”, make this field of study an easy one to tackle, as well as free of polemical issues. Guidelines for minimal distance and restriction policies can be easily established and applied.

Thus in a literature survey using MEDLINE and LILACS (Latin American Literature on Health Sciences, available at http://www.bireme.br) we were able to locate nine published papers by Latin American authors between 1970 and 2008. Six of these papers were related exclusively to implanted pacemakers and defibrillators (Ferreira *et al*, 1988; Mateos *et al*., 1996; Gauch *et al*., 1997; Muratore *et al*., 1998. Santomauro *et al*., 2002 and Fernández Banizi *et al*., 2004). Most of these papers were reviews of the literature and guidelines. The two other published papers were related to EMI on electromedical devices (Cabral & Mühlen, 2002) and equipment used in surgical rooms (Hermini, 1996).

One of the earliest and few *in vitro* experimental studies published by Latin American researchers was carried out by Cabral & Mühlen (2001), from the State University of Campinas’ Center of Biomedical Engineering, Brazil. The effect of a single RF source at 900 MHz (an analogue cell phone) was investigated using 31 medical devices of 14 different manufacturers: infusion pumps, pulse oxymeters, non-invasive blood pressure device, multiparametric vital signal monitors and cardiac monitors. The authors were careful to note the year of manufacturing of the devices, the majority being before 2000. A proportion of 55% of equipments manifested any form of EMI in distances up to 0.5 m in this study. This dropped to 11% up to 1.3 m of distance.

Another, more recent experimental study by Calvo *et al* (2008) was carried out in Colombia. They examined EMI generated by four models of GSM cell phones and one Motorola radio communicator, on 16 types of medical equipment (ventilators, infusion pumps, defibrillators, incubator, lighting chamber, pulse oxymeter, EEG recorder, multiparametric vital signal monitors). The authors observed that 87% of all equipments tested presented some form of interference with their function. Of these, 19% regained normal function after interruption of the EMI disturbance, 25% required the intervention of a clinical operator to return to normal function, 12% required specialized technical intervention, and 31% of the equipments presented data display interferences. However, these effects were obtained in general at very short distances between source and medical equipment, usually below 10 cm, and in several cases in close contact only. Worrisome to the authors, 11% of the equipments presented interference with distances around 100 cm from the source, 14% of the equipments presented interference below a field gradient of 5 V/cm, *i.e.,* below the international EMC standards, and 75% of the failures were clinically significant and might have caused death or injury to patients.

Conclusions and Recommendations

1. Wireless communication technologies with enough output power and very close

proximity to medical devices of several kinds, including implanted devices, has the possibility of causing electromagnetic interference with potential hazardous effects on the well being and critical life support of patients;

2. The low power technologies and frequency spectrum used by present-day digital wireless communication devices, such as mobile phones, laptop and palmtop computers, base stations and access points, and electronic filters installed on modern medical devices have reduced to practically zero the chance of occurrence of such hazards, when they are used normally;

3. Large mobile telephony base stations outside the healthcare institution, or smaller micro- or nanocell base stations and wireless data communication network access points inside the institution have presently too low power density microwave electromagnetic fields to cause any significant interference with all kinds of medical devices;

4. Clinically relevant electromagnetic interference with medical devices is very unlikely to occur, particularly when a minimum distance of 0.3 m for implanted devices, and 0.5 m for external medical equipment is respected;

5. Therefore, scientifically and technically there is presently no restriction regarding the use of medium risk mobile phones and wireless data communication devices in any area of healthcare institutions, and no general ban policy is necessary, or legislation to this effect. Higher powered communication radios and data communication modems, which may pose a higher risk of interference, should be used sparingly and in emergency situations, only, very near to medical devices, implanted or not;

6. Patients implanted with pacemakers and similar devices should be oriented to always talk on cell phones at the contralateral side of the implant, and user the newer low power digital models;

7. Healthcare institutions should be encouraged to carry out a survey and maintain records of high EMI risk areas and equipments, and issue and enforce policies of monitoring and restriction of use

8. Healthcare institutions should be encouraged to set apart and signalize areas for the free use of mobile wireless telecommunications by professionals and visitors;

9. Further mitigation of potential EMI effects on medical devices can be achieved by installing special low-risk wireless communication systems inside healthcare institutions which are issued for routine use by its workers;

10. Safety norms at national, regional and local levels should take into account the current knowledge base about EMI on medical devices, and educate the healthcare professionals accordingly;

11. In Latin American institutions where a large part of medical equipment manufactured without filters for preventing RF EMI interference are still in use should be encouraged to gradually phase out and substitute these equipments in order to avoid potential hazardous events;

12. As wireless telecommunication technologies continue to evolve, scientists and technicians should keep vigilance and test them for potential EMI hazards on medical devices of all types;

13. National organizations in charge of establishing standards for electromagnetic compatibility should be urged to take into consideration the issue of EMI on medical devices;

14. Correct risk perception and acceptance by the general population in respect to EMI of wireless devices on medical equipment, pacemakers, etc., should be addressed.