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On the mechanisms of interference between mobile phones and pacemakers: parasitic demodulation of GSM signal by the sensing amplifier

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Abstract

The aim of this study was to investigate the mechanisms by which the radiated radiofrequency (RF) GSM (global system for mobile communication) signal may affect pacemaker (PM) function. We measured the signal at the output of the sensing amplifier of PMs with various configurations of low-pass filters. We used three versions of the same PM model: one with a block capacitor which short circuits high-frequency signals; one with a ceramic feedthrough capacitor, a hermetically sealed mechanism connecting the internal electronics to the external connection block, and one with both. The PMs had been modified to have an electrical shielded connection to the output of the sensing amplifier. For each PM, the output of the sensing amplifier was monitored under exposure to modulated and non-modulated RF signals, and to GSM signals (900 and 1800 MHz). Non-modulated RF signals did not alter the response of the PM sensing amplifier. Modulated RF signals showed that the block capacitor did not succeed in short circuiting the RF signal, which is somehow demodulated by the PM internal non-linear circuit elements. Such a demodulation phenomenon poses a critical problem because digital cellular phones use extremely low-frequency modulation (as low as 2 Hz), which can be mistaken for normal heartbeat.

1. Introduction

The topic of electromagnetic interference (EMI) between mobile phones and pacemakers (PMs) has raised much interest among physicists since 1994, when several sets of research data were reported on the adverse effects of electromagnetic fields radiated from mobile phones on implantable PMs (Barbaro *et al* 1995, 1996, Hayes 1996, Carillo *et al* 1995, Irnich *et al* 1996, Nowak *et al* 1996, Sparks *et al* 1996).

The majority of these studies systematically evaluated the PM models in the market, described the adverse effects observed and suggested a safe separation distance. The great variability of the outcomes in the existing literature reflects the complexity of the study designed to assess mobile phone interaction with PMs. This complexity is attributable to a number of factors such as the rapid evolution of both PMs and mobile phone technologies, the characteristics of the phone antenna, PM implantation and programming, electrode configuration, distance between the PM and the radiation source, etc. The results obtained so far have shown interference to occur when the phone is very close (less than 5 cm) to the PM connection to the cardiac leads (i.e. the PM 'header'). The EMI phenomena observed include pulse inhibition, noise reversion, false triggering, over-sensing and under-sensing, while no cases of permanent damage or reprogramming were found (Barbaro *et al* 1995, 1996, Irnich *et al* 1996, Wilke *et al* 1996).

Few studies have investigated the mechanisms through which electromagnetic fields interact with PMs. PMs have a titanium case acting both as an electromagnetic shield and as a barrier against body fluids. Platinum lead wires come out of the case through hermetic terminals and connect with the heart. It is largely believed that the physical interaction between mobile phones and PMs is due to the electric coupling with the lead conductors inside the silicon head of the PM, which can act as an antenna and conduct undesirable radiofrequency (RF) carrier signals to the electronic circuits inside the PM (Stevenson 1997). Most implantable PMs employ EMI low-pass filters designed with chip or substrate mounted capacitors which should decouple and shield these signals. Such a solution turned out to be inadequate to guarantee a high level of immunity to high-frequency sources such as GSM mobile phones (Ruggera *et al* 1997). The introduction of the feedthrough assembly has significantly improved PM immunity (Carillo *et al* 1996), giving *a posteriori* evidence that the physical interaction occurs at the lead conductors.

The aim of our study was to investigate the mechanisms through which the GSM signal affects the PM function, by measuring the signal at the output of the sensing amplifier of PMs with various configurations of low-pass filters and exposed to modulated and non-modulated RF signals. The PMs have been modified so as to have an electronic connection with the output of the sensing amplifier, just before the comparator circuit that detects any spontaneous activity of the heart.

2. Methodology

2.1. Modified pacemakers

We used three versions of the PM MINIOR 100 (Sorin Biomedica, Italy): one uses a block capacitor which short circuits high-frequency signals (33 nF, resonance frequency at about 20–30 MHz); another uses a ceramic feedthrough capacitor (4.99 nF, resonance frequency at about 2 GHz), consisting of a hermetically sealed mechanism that connects the electronics inside the PM to the connection block outside (Stevenson 1997) and the third uses both (see block diagram in figure 1).

A feedthrough capacitor is a coaxial device designed to filter out the undesirable RF signal before it reaches the interior of the titanium PM housing. It is generally mounted onto the hermetic terminal of the PM and thus acts electrically as a continuous part of the electromagnetic titanium shield (PM housing). This device prevents the RF signals from

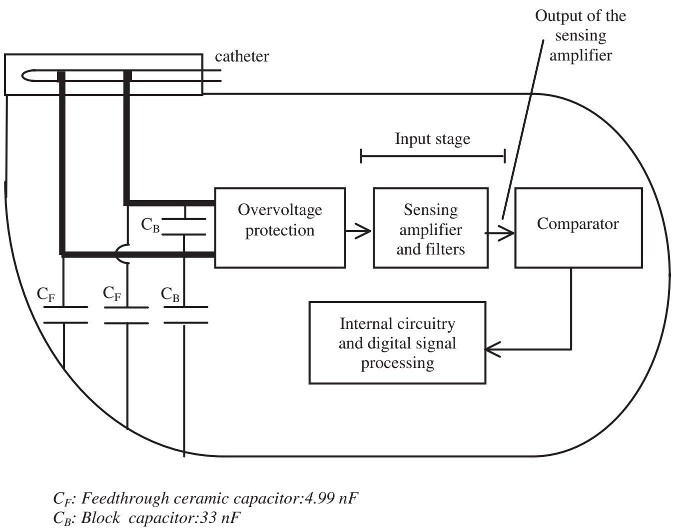

Figure 1. Block diagram of a PM. Only the blocks of the input stage are shown.

Figure 2. Picture of a modified PM.

accessing the PM enclosure, thus attenuating EMI signals over a broad range of frequencies (Stevenson 1997).

The three PMs have been modified in order to have an electrical connection to the output of the sensing amplifier (see figure 1). Figure 2 shows a picture of a modified PM. All PMs were programmed with the same parameters, shown in table 1.

To avoid any spurious interference from the extra electrical connection, the PMs were placed inside an aluminium box along with an instrumentation amplifier (INA114AP, Burr-Brown, USA) to buffer the output signal. The output of the amplifier was connected to a digital acquisition board (DAQCard 1200, National Instrument) through BNC connectors and shielded cables. In this way only the silicon connection head and the lead connectors were exposed to RF radiation. A standard catheter was connected to the PM and the catheter was

Table 1. Parameter value set for the three PMs.

PM MINIOR 100–Sorin Biomedica	
Parameter	Value
Stimulation mode	SSI
Heart rate	30 bpm
Stimulation polarity	Bipolar
Amplitude	5.0 V
Duration	0.50 ms
Sensing polarity	Bipolar
Sensitivity	0.6 mV
Refractory period	324 ms

immersed in a 0.9% saline solution in a Plexiglas box (Barbaro *et al* 1996). All the connections were shielded with aluminium foil.

This shielded PM configuration was tested at the Center for Devices and Radiological Health ((CDRH), Food and Drug Administration, USA) by measuring the electric fields within the aluminium box with a miniature electric field probe (Schmid & Partner Engineering AG (SPEAG), Zurich, Switzerland, Model ET3DV6R) (Pokovic 1999) and CDRH designed robotic probe positioning system. The fields measured within the aluminium block, at the position where the PMs were placed during exposure, were at least 24 dB lower than the exposure fields, thus the PM header was the predominant entry point for the EMI into the PM.

2.2. Data acquisition and power spectral estimation

The output of the PM amplifier was acquired by a DAQCard 1200 (National Instruments, USA) at 20 kHz with 12 bit resolution fitted into a laptop PC (figure 3).

The noise level was computed online by estimating the power spectral density of the signal at the output of the sensing amplifier. The spectral estimation was obtained by averaged periodogram on 8192 sample segments without windowing or zero-padding. Fifty spectra of PM signal tracks between two consecutive PM spikes were averaged. In order to have the largest possible number of samples between two consecutive spikes, the PM frequency stimulation was set to the lowest value (30 bpm).

2.3. Experimental protocol

For each PM, the output of the sensing amplifier was monitored under four conditions: (1) no signal was delivered to the catheter and no electromagnetic field was applied (baseline noise); (2) white noise signal was delivered to the catheter, in the presence and absence of non-modulated RF signals (at 900 and 1800 MHz); (3) no signal was delivered to the catheter with exposure to modulated RF signals (at 900 and 1800 MHz) and (4) no signal was delivered to the catheter with exposure to GSM signals (at 900 and 1800 MHz). The experiments were conducted at the Biomedical Engineering Laboratory of the Italian National Institute of Health.

2.3.1. Exposure to non-modulated RF signals. In order to evaluate whether the characteristics of the PM input stage were affected by exposure to RF signals, a white noise signal (bandwidth 0–400 Hz, Stanford Research Systems, model DS 360) was delivered to the catheter through the saline solution with chloride-silver square plates, avoiding any ohmic contact with the catheter tip (Barbaro *et al* 1996). The complete experimental set-up is shown in the upper

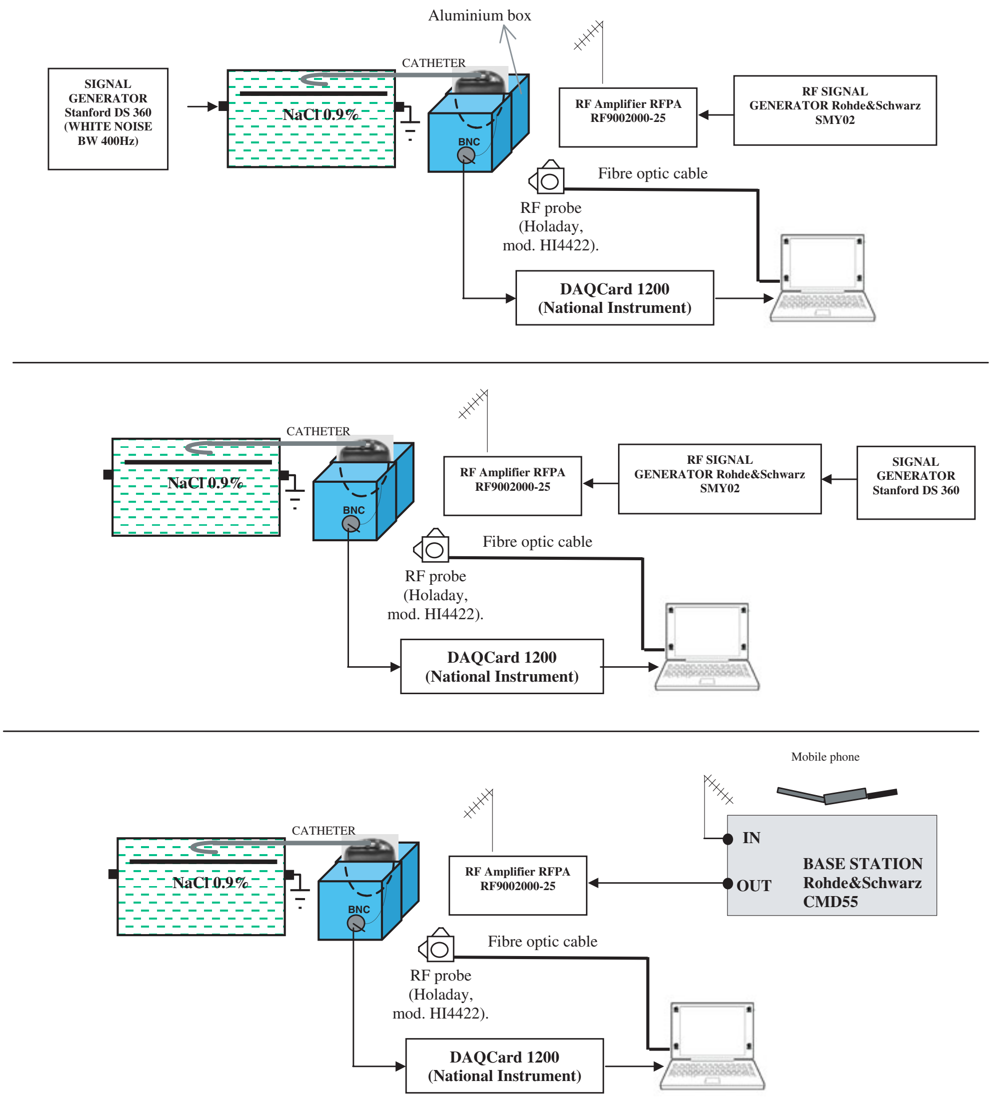

Figure 3. Upper panel: experimental set-up for the exposure to the non-modulated RF signal; middle panel: experimental set-up for the exposure to the modulated RF signal and lower panel: experimental set-up for the exposure to the GSM signal.

panel of figure 3. The signal applied to the chloride-silver plates was set to have a root mean square of 10 mV at the PM catheter. This input makes the PM work in its linear region, over the band of physiological signals. The white noise was applied both when the PM was exposed to RF signals and when it was not. 900 MHz and 1800 MHz carrier signals were radiated from a dipole antenna, using a signal generator (Rohde & Schwarz, model SMY02) connected to a radiofrequency amplifier (RFPA, model RF 9002000-25, amplification 43 dB), which yielded an electromagnetic field of about 20 V m^{-1} at the PM head. This field level is the new Italian immunity level for the population in the 3–3000 MHz range. The radiated field was continuously measured by an RF meter (Holaday, model HI4422).

Table 2. Root mean square in mV (mean ± standard deviation) of the output of the sensing amplifier of each PM, excited with 10 mV (rms) white noise. The output values are shown for the three PMs in the absence of RF radiation and when the PMs were exposed to non-modulated 900 MHz and 1800 MHz.

	Root mean square (mV)		
	Block capacitor	Feedthrough capacitor	Block and feedthrough capacitors
No radiation	84.64 ± 1.68	125.16 ± 2.47	68.61 ± 1.39
Radiation at 900 MHz	85.50 ± 1.71	125.38 ± 2.49	69.75 ± 1.40
Radiation at 1800 MHz	86.05 ± 1.70	126.23 ± 2.51	69.14 ± 1.38

2.3.2. Exposure to modulated RF signals. This experiment aimed to detect demodulation products which may appear at the comparator stage of the PM (figure 3, middle). 900 MHz and 1800 MHz amplitude-modulated signals were radiated from a dipole antenna, using a signal generator (Rohde & Schwarz, model SMY02) connected to an RF amplifier (RFPA, model RF 9002000-25, amplification 43 dB) in order to produce an electromagnetic field of about 20 V m^{-1} at the PM site. The radiated field was continuously measured by an RF meter (Holaday, model HI4422). Amplitude modulation (100%) of 900 and 1800 MHz carriers was obtained connecting the RF generator to a low-frequency signal generator (Stanford Research Systems, model DS 360). Modulation signals consisted of pure sine waves (2 Vpp) at the following frequencies: 8, 16, 32, 64, 128, 256 and 512 Hz. The PM catheter was immersed in saline solution, with no signal applied to it.

2.3.3. Exposure to the GSM signal. GSM modulation was obtained connecting the power amplifier to a base station simulator (Rohde & Schwarz, model CMD 55). The complete experimental set-up is shown in the lower panel of figure 3. A commercial mobile phone was used. The output of the sensing amplifier was analysed during ringing and talking (1 min each). The discontinuous transmission protocol was on. In all the tests we used 900 MHz GSM and 1800 MHz GSM, with the mobile power class set to the maximum of the European standards (2 W for 900 MHz, 1 W for 1800 MHz). Again, the PM catheter was immersed in saline, but no signal was applied.

3. Results

The root mean square of the baseline noise (no signal delivered to the catheter and no electromagnetic field applied) at the output of the PM sensing amplifier was 3.99 mV for the PM with the block capacitor only, 4.04 mV for the pacemaker with the ceramic feedthrough capacitor and 3.45 mV for the PM having both capacitors.

3.1. Characteristic of the PM input stage

The radiated RF fields (non-modulated, 900 MHz and 1800 MHz) did not alter the root mean square of the output of the sensing amplifier of any of the PMs when a white noise was applied to the chloride-silver square plates of the Plexiglas box that hosted the catheter. Table 2 shows the root mean square of the output of the sensing amplifier (in mV, mean ± standard deviation), in the absence of RF radiation and when the PM was exposed to 900 MHz and 1800 MHz, for the three PMs.

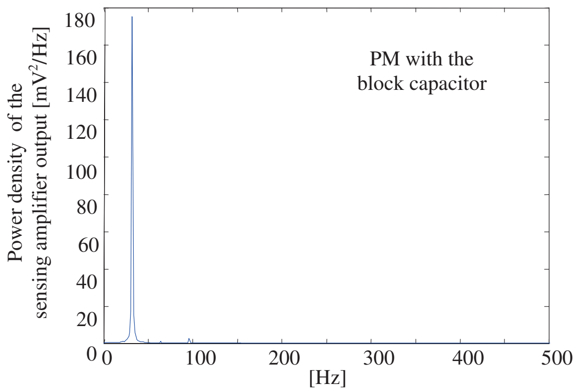

Figure 4. Spectral density of the output of the sensing amplifier in the PM equipped with the block capacitor only, exposed to 32 Hz amplitude modulated radiation (900 MHz).

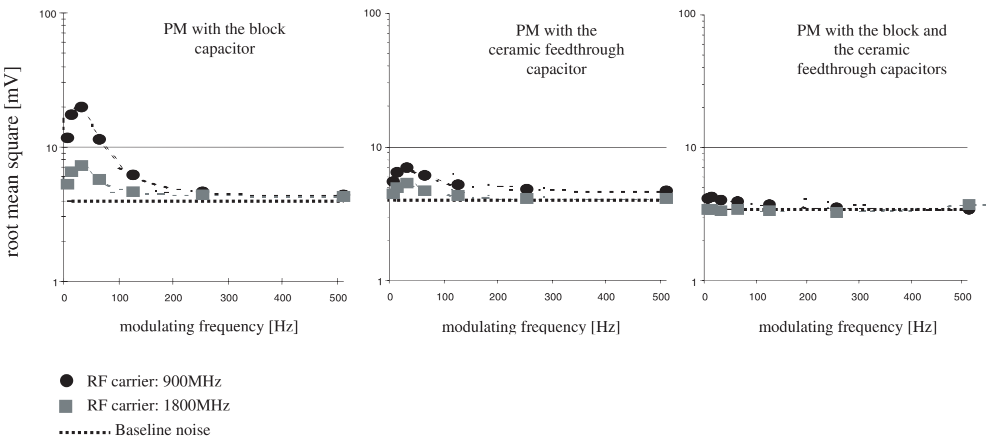

Figure 5. Root mean squares at the output of the sensing amplifier, for all the modulating signals at 900 MHz (black circles) and 1800 MHz (grey squares), for the three PMs. The root mean square of the baseline noise is also reported (dashed line).

3.2. Exposure to modulated RF signals

Figure 4 shows the spectral density of the output of the sensing amplifier for the PM equipped with the block capacitor only when exposed to a 32 Hz amplitude-modulated radiation (900 MHz). The occurrence of a significant harmonic component at 32 Hz indicates an underlying demodulation effect.

In order to compare the results of the three PMs at the various modulation frequencies and carriers, we computed the total power from the raw spectral data. Figure 5 shows the root mean square at the output of the sensing amplifier in mV for the three PMs for exposure to all the modulating signals at 900 and 1800 MHz. The total spectral power of the baseline noise (no RF applied) is also reported. Note that the PM equipped with the block capacitor and the ceramic feedthrough showed no effect at 1800 MHz and minimal demodulation phenomena at 900 MHz. Table 3 shows the root mean square at the output of the sensing amplifier for the three PMs for exposures to all the modulating signals at 900 and 1800 MHz, expressed as mean $\pm$ standard deviation.

Table 3. Root mean square in mV of the output of the sensing amplifier, at all modulating frequencies, for the three PMs and for both RF carriers. Values are expressed as mean ± standard deviation.

	Root mean square (mV)		
Modulation frequency (Hz)	Block capacitor	Feedthrough capacitor	Block and feedthrough capacitors
	Carrier: 900 MHz		
8	11.77 ± 0.23	5.42 ± 0.11	4.15 ± 0.08
16	17.64 ± 0.34	6.47 ± 0.13	4.22 ± 0.08
32	19.80 ± 0.38	6.94 ± 0.13	3.99 ± 0.08
64	11.37 ± 0.22	6.15 ± 0.12	3.93 ± 0.08
128	6.22 ± 0.12	5.18 ± 0.10	3.72 ± 0.07
256	4.69 ± 0.09	4.80 ± 0.09	3.54 ± 0.07
512	4.45 ± 0.09	4.73 ± 0.09	3.39 ± 0.07
	Carrier: 1800 MHz		
8	5.32 ± 0.10	4.42 ± 0.09	3.43 ± 0.07
16	6.51 ± 0.13	4.93 ± 0.10	3.40 ± 0.07
32	7.25 ± 0.14	5.30 ± 0.10	3.38 ± 0.07
64	5.69 ± 0.11	4.67 ± 0.09	3.41 ± 0.07
128	4.63 ± 0.09	4.27 ± 0.08	3.36 ± 0.07
256	4.44 ± 0.09	4.13 ± 0.08	3.21 ± 0.06
512	4.28 ± 0.08	4.10 ± 0.08	3.73 ± 0.07

3.3. Exposure to GSM signal

Figure 6 shows the power spectral density of the output of the sensing amplifier for the three PMs when exposed to the 900 MHz GSM signal. A 217 Hz harmonic component characterizes the noise of the PMs without the feedthrough assembly. Similar results were obtained for the GSM signal at 1800 MHz.

4. Discussion

Although there have been improvements in technology and design, PMs remain to some extent susceptible to interference from external sources of electromagnetic energy. In particular, concerns have been raised about the interference produced by mobile devices such as analogue/digital phones and hand-held radios. PMs are designed to work with band-limited signals up to few hundred hertz; nevertheless, several authors have shown adverse effects from devices working at 900 MHz (Barbaro *et al* 1995, Hayes 1996, Carillo *et al* 1995, Irnich *et al* 1996, Barbaro *et al* 1996, Nowak *et al* 1996, Sparks *et al* 1996, Wilke *et al* 1996). Scarce attention has been paid to the mechanisms behind these interferences.

We exposed various configurations of PMs to modulated and non-modulated RF signals and measured the output of the sensing amplifier that the PM actually uses to determine if therapy should be provided to the patient. We conducted experiments aimed to (1) detect changes in the gain or in the frequency response of the PM input stage and (2) investigate the generation of low-frequency demodulation products.

Most of the evidence collected so far, using PMs completely immersed in liquid, indicated the cell phone transmissions likely couple into the PM via the area of the PM where the leads

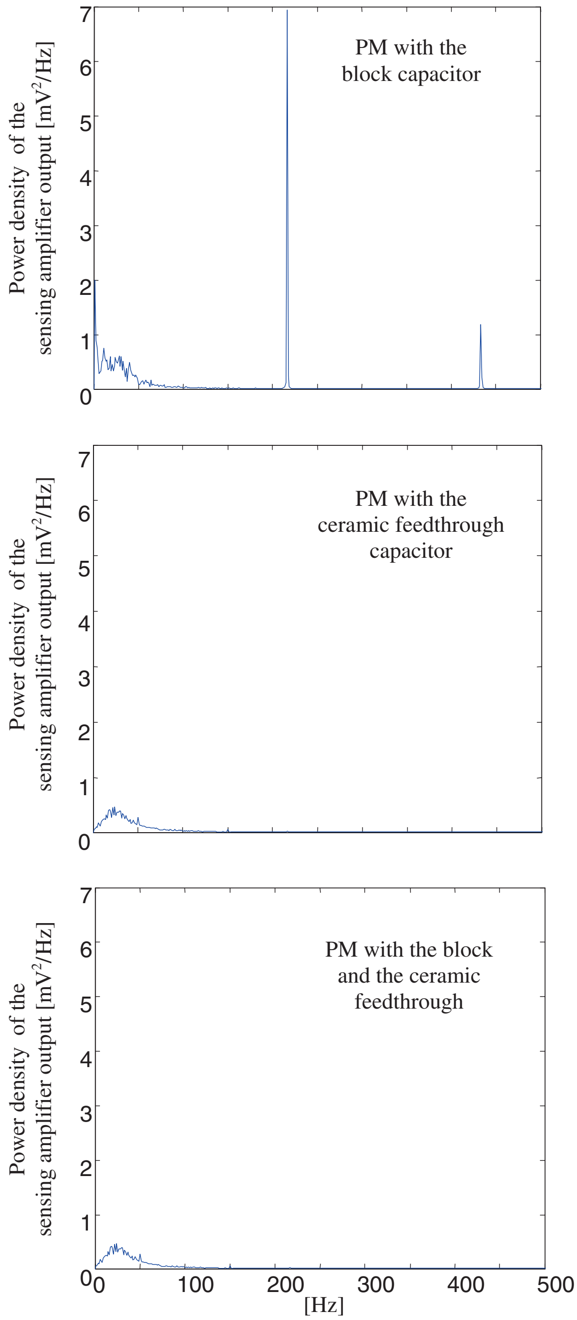

Figure 6. Spectral density of the output of the sensing amplifier for the three PMs exposed to the GSM signal at 900 MHz.

connect into the sealed PM generator (also know as the 'header') suggesting that most of the lead length plays a minor role. Ruggera *et al* (1997) also suggested the PM header area as the likely site where the external transmissions couple in the PM. In our experiments we investigated the coupling of modulated and non-modulated EM fields to the PM header via air, while the PM lead was immersed in saline solution. *In vivo*, the PM is usually located just under the skin and surrounded by a certain amount of normal body fluid very much like the saline solution.

We found that the exposure to RF signals does not alter the response of the PM sensing amplifier. The output of the sensing amplifier to a band-limited white noise applied via the PM catheter was not affected by a 20 V m^{-1} non-modulated RF signal at 900 and 1800 MHz, in any of the PMs tested. The hypothesis that the saturation and/or non-linear operation of the PM sensing amplifier could be responsible for EMI phenomena does not appear to be consistent with our findings.

When we exposed the PM equipped only with the block capacitor to modulated RF signals, demodulation products were present at the output of the sensing amplifier. The total spectral powers of such products were significantly higher than the baseline noise at all modulating frequencies. This finding corroborates the hypothesis that the PM functioning can be affected by an RF signal through its modulating components, which may fall within the PM passband and reach the input of the comparator. It has already been shown that relatively short wavelength electric fields, such as 900 and 1800 MHz GSM bands, can couple with the PM through its hermetic seal and leads (Stevenson 1997). Once the RF signal is inside the PM case chip or substrate mounted block capacitors do not succeed in short circuiting such a signal and it is somehow demodulated by PM internal non-linear circuit elements. In other words, the EMI filter for the radiated RF carrier designed with the block capacitor only does not have significant and continuous attenuation over a wide RF frequency range (up to GHz).

The PM equipped with the ceramic feedthrough capacitor only showed demodulation products slightly higher than the baseline noise. When both capacitors are installed, the total spectral powers of the output of the sensing amplifier exposed to modulated RF signals are as low as the baseline noise. Thus, the combination of both filters provides an effective attenuation of RF signals, and prevents demodulation phenomena.

We used various modulation frequencies of the radiated RF exposure fields in order to obtain a sort of 'demodulation transfer function'. The demodulation transfer function obtained had a shape similar to the typical linear PM transfer function. We speculate that the demodulation phenomenon occurs before the filter stage of the sensing amplifier, perhaps at the diodes that provide the overvoltage protection of the input stage.

Demodulation effects were more evident at 900 MHz than at 1800 MHz. Several geometric and electric factors, such as the stray capacitance and inductance of internal wires and traces, may explain this finding. Thus, in our opinion, no extrapolation for higher frequencies can be undertaken.

The GSM signal utilizes low-frequency RF digital modulation. The digital modulation of the European GSM contains a 217 Hz component. When exposed to a base-station GSM signal, a 217 Hz component appeared at the output of the input stage of the PM equipped with only the block capacitor. We observed demodulation products also at lower frequencies (below 10 Hz), although no specific harmonic components appeared. PMs equipped with the feedthrough capacitor did not show demodulation products. These findings demonstrate that RF carriers with digital modulations may originate low-frequency demodulation products in the PM if these carriers are not adequately attenuated by the PM RF filters. Such low-frequency components fall within the typical PM passband; they can be erroneously detected as heart electrical activity and may interfere with the normal PM functions. This finding is consistent with, and can explain, the higher sensitivity of PM to EMI from digital phones than from analogue ones, as reported by our and other research groups.

5. Conclusions

In this study we investigated the mechanisms by which the GSM signal affects PM functioning. If modulated 900 MHz or 1800 MHz carriers do access the PM enclosure, non-linear circuit elements demodulate the GSM signal and produce low-frequency components at the output of the PM sensing amplifier. Internal PM amplifiers and signal processing circuits could mistake this demodulated EMI signal for heart electrical activity. The feedthrough assembly improves the EMI immunity of PMs to GSM signals by preventing the RF signal from entering the PM housing. No changes in characteristics of the PM sensing amplifier were observed.

Acknowledgments

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