EMI filters for cardiac pacemakers and implantable defibrillators

The use of ceramic feed-through capacitors, as well as specific filter designs and installation techniques, can make cardiac pacemakers immune to EMI.

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Under the coordination of Wireless Technology Research, L.L.C. (WTR), the interaction between cellular phones and cardiac pacemakers has been widely investigated in the last 2½ years. In September of 1996, WTR released their final report entitled "*Evaluation of Interference Between Hand-Held Wireless Phones and Implanted Cardiac Pacemakers.*"[1] In this investigation, WTR drew upon previously published reports and coordinated the new work of U.S. researchers performing *in vivo* and *in vitro* testing using various model cellular phones and various model cardiac pacemakers. These researchers included: The Center for the Study of Wireless Electromagnetic Compatibility at the University of Oklahoma,[2] Dr. R. Carrillo of the Mount Sinai Medical Center,[3,4] Dr. D. L. Hayes, et al.,[5] and P. S. Ruggera, D. M. Witters and H. I. Bassen of the Food and Drug Administration (FDA)–Center for Devices and Radiological Health.[6]

The researchers documented many cases of undesirable electromagnetic interaction between cellular phones and cardiac pacemakers up to distances of approximately 23 cm.[6] It was found that certain model pacemakers (those without a broadband ceramic feed-through filter) exhibited the bulk of the responses to EMI from certain model digital cellular phones (such as TDMA 11 Hz, TDMA 50 Hz, and European GSM). Pacemaker inhibition and/or asynchronous pacing were commonly observed; however, there were no cases of permanent damage or reprogramming of the pacemaker. Analog phones were not found to cause a significant problem.

Dr. Carrillo and his colleagues were among the first researchers to report that certain model pacemakers were designed with an EMI filter that made them immune to the effects from hand-held communication devices.[3,4] Dr. Carrillo's team also verified that when this "EMI filter" was removed, the pacemakers once again became sensitive to EMI from digital cellular phones. Further investigation revealed that, in general, pacemakers that exhibited a very high level of immunity incorporated a ceramic feed-through capacitor EMI filter as described herein.

Figure 1 shows a cardiac pacemaker with four platinum lead wires which egress through a titanium housing (can) via a gold-brazed alumina hermetic terminal. The titanium can is seam-welded to act both as an electromagnetic shield and a

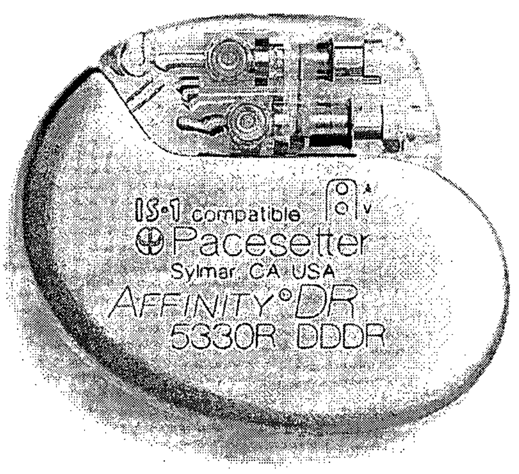

Figure 1. Typical cardiac pacemaker with lead wires.

hermetic barrier to protect the internal components from body fluids. These lead wires, which normally carry the pacing pulses and sense cardiac activity, can also act as an antenna and conduct undesirable RF carrier signals (such as EMI induced by cellular phones) to sensitive internal electronic circuits. The EMI filter design described effectively decouples and shields such signals over a broad frequency range before they can enter into the titanium can and disrupt normal pacemaker or ICD functions.

It has been demonstrated that maximum susceptibility of pacemakers to digitally modulated cellular phones occurs when the phone antenna (at the location of maximum H field) is placed in close (near-field) proximity to the pacemaker header (where the leads enter the titanium can).[3,4] This, in turn, induces relatively short wavelength electric fields (cellular phones typically operate from 950 MHz to 1.8 GHz) which readily couple to the inside of the titanium can through the device hermetic seal and leads. Once the EMI carrier signal is inside the can, it can conduct and/or re-radiate to pacemaker sensing circuitry. Pacemaker nonlinear circuit elements (such as semiconductor devices) can then demodulate this RF carrier. Internal amplifier circuits and related digital signal processing circuitry within the implanted device can inadvertently confuse this demodulated EMI signal as if it were a normal electrical signal from the heart.

Cellular phones which utilize extremely low frequency digital modulation such as that produced by TDMA 11 Hz (now obsolete), TDMA 50 Hz, or European GSM 2- to 4-Hz phones are of concern because these frequencies are relatively close to the frequency of a normal heartbeat (1 to 2 Hz). Particularly problematic is digital modulation with a 15- to 25-millisecond pulse width which falls directly within the passband of typical pacemaker sensing and bandpass filter circuitry.

WHY SOME FILTERS AND CHIPS FAIL

Cardiac pacemakers often incorporate EMI lowpass filters and bandpass filters which are designed with surface-mounted components mounted on an internal substrate, circuit board or flex cable. Unfortunately, these components are generally not effective at cellular phone frequencies. For example, a 1000-pF surface-mounted rectangular ceramic "chip" capacitor exhibits undesirable series resonance at approximately 192 MHz. (At this frequency and above, the chip capacitor becomes increasingly inductive and less effective as a bypass element).[7] These parasitic resonances of the various surface-mounted components cause poles and zeros in the network transfer function which result in many undesirable peaks and valleys in the filter attenuation curve.[7] In addition to component resonance, the internal lead wires and circuit traces of the pacemaker have substantial stray capacitance and inductance. Accordingly, they become effective coupling devices at the short wavelengths of wireless communication devices. This means that, at high frequencies (950 MHz for example), EMI can re-radiate or couple across a pacemaker substrate-mounted EMI filter to sensitive amplifier circuits. Figure 2 illustrates this effect and shows the proper EMI filter location bonded directly to the hermetic terminal; the EMI must be removed before it enters the can.

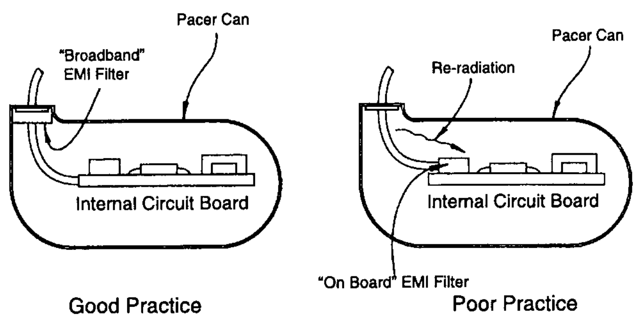

Figure 2. Proper EMI filter installation practice.

BROADBAND EMI FILTER DESIGN

The monolithic ceramic EMI feed-through capacitor is a coaxial device designed to decouple and/or shield the undesirable RF carrier (EMI) over a broad range of frequencies before it can reach the interior of the titanium can and couple or radiate to sensitive internal circuitry. With this approach, the type and frequency of digital modulation is not of concern since it is removed along with the RF carrier before it can be detected and confused with a normal heartbeat.

Figure 3 illustrates a unipolar monolithic ceramic feedthrough capacitor EMI filter. This is a single-element lowpass filter which allows desirable (pacing or sensing) frequencies to pass. Because it is a coaxial device, it provides effective attenuation to undesired signals (EMI) over a very broad frequency range (30 MHz to 10 GHz).[7] When designed and installed properly, feedthrough capacitors are very low inductance devices

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which are relatively free of the parasitic behavior exhibited by surface-mounted or leaded components. Typical feed-through capacitance values for human implant applications vary from 680 to 4500 pF. For example, the self-resonant frequency for a 2200-pF unipolar ceramic feed-through capacitor (0.140" diameter) is approximately 1.5 GHz.[8] Unlike the rectangular chip capacitor, at frequencies above resonance the ceramic feed-through capacitor will continue to provide effective attenuation (40 to 70 dB from 950 MHz to 10 GHz).[7,8]

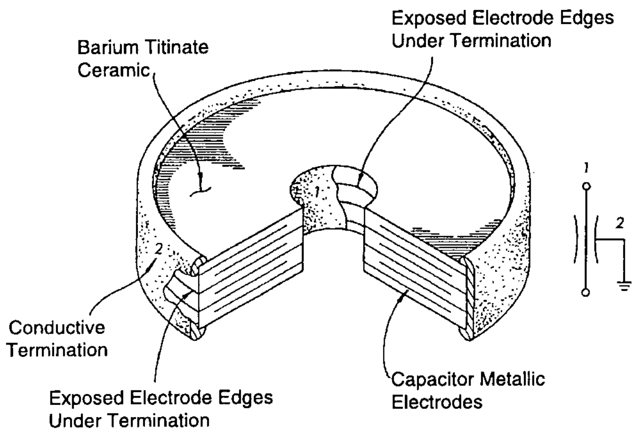

Figure 3. Unipolar ceramic feed-through capacitor (discoidal feed-through).

Implantable devices usually have many lead wires connected to the heart (pacing leads, sensing leads, high voltage cardioversion leads, etc.). All leads must be filtered as EMI can cross-couple to sensitive circuits if it gets inside of the pacemaker housing. Standard ceramic feed-through capacitors include bipolar (2), tripolar (3), quadpolar (4), pentapolar (5), and hexpolar (6) lead configurations. Figure 4 illustrates a typical quadpolar ceramic feed-through capacitor. Figure 5 shows the internal electrode plate lay up patterns for both unipolar and quadpolar designs.

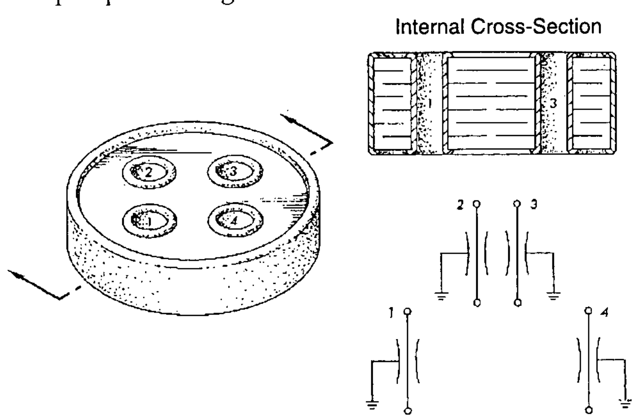

Figure 4. Quadpolar feed-through capacitor.

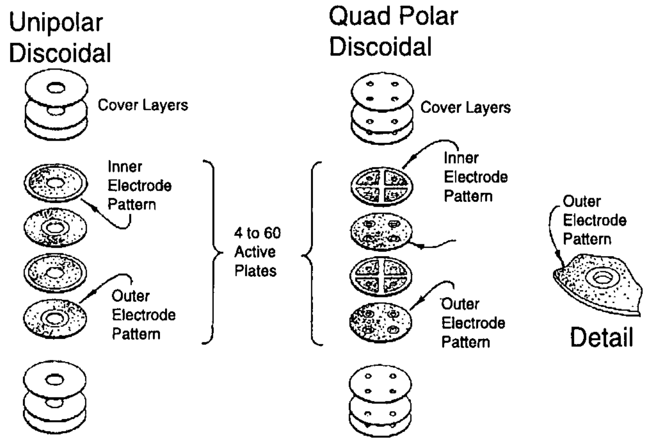

Figure 5. Internal electrode lay-up patterns.

An equally important feature of the ceramic feed-through capacitor is that it acts electrically as a continuous part of the electromagnetic shield (titanium can) which houses the pacemaker circuitry. Figure 6 illustrates the design of a ceramic feed-through capacitor which is surface-mounted onto the hermetic terminal of a pacemaker or ICD (U.S. Patent Number 5,333,095).[9] An alternate (but less volumetrically efficient) configuration based on internal coaxial cavity mounting is described by U.S. Patent Number 4,424,551.[10]

FILTER DESIGN RECOMMENDATIONS

- The ceramic feed-through capacitor must be installed such that it becomes a continuous part of the electromagnetic shield (titanium can) which houses the medical implant device. Accordingly, the ceramic feed-through capacitor should be physically and electrically bonded directly to the hermetic terminal (or point of lead penetration) in order to shunt, reflect and absorb EMI (plug the RF hole) before it can enter the housing and couple and/or re-radiate.
- Mounting of the ceramic feed-through capacitor should be on the inside of the terminal/housing to protect the capacitor from body fluids.
- The ceramic feed-through capacitor must be installed

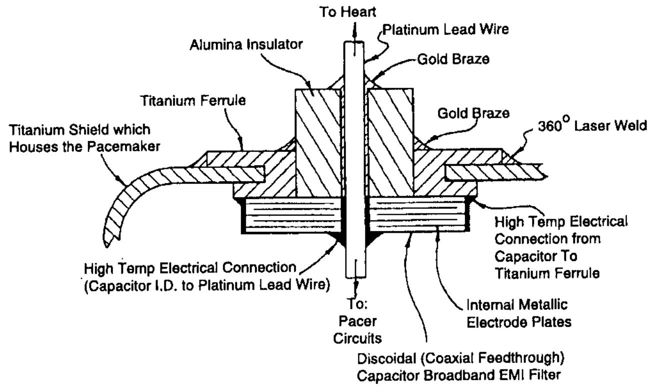

Figure 6. Ceramic feed-through capacitor EMI filter surface-mounted to hermetic cardiac pacemaker terminal.

with high temperature conductive materials that are capable of withstanding the welding temperatures and thermal coefficient of expansion (TCE) stresses during hermetic terminal installation into the titanium housing.

- The ceramic feed-through capacitor EMI filter should be installed such that it cannot form an adjunct hermetic seal. (The polymer material used to bond the capacitor to the hermetic terminal may form a false or temporary seal). By "standing off" the feed-through capacitor by a small space (1- to 2-mil gap), a leaking hermetic terminal will still show up in fine leak testing as defective.

EMI FILTER COMPARISON TEST

An implantable cardioverter defibrillator (ICD) was instrumented with miniature SMB-type RF connectors. These connectors were installed in the ICD electromagnetic shield housing (titanium can) directly over and connected to the inputs of various ICD/pacemaker internal sensing amplifiers. The electrical connections to the SMB connectors were between the on-board type EMI or bandpass filters and the sensing amplifier inputs. In this way, the efficacy of the traditional onboard chip capacitor EMI filter could also be evaluated.

Swept RF signals (130 MHz to 3 GHz) from a Hewlett Packard Model 4720 network analyzer were alternatively injected by direct coupling into each of the ICD lead wires at the hermetic terminal to simulate EMI picked up from the ICD lead wires. The network analyzer detector/receiver was connected alternatively to each of the SMB connectors and a hard copy plot of RF signal level, in dB, verses frequency was recorded. A 3880-pF ceramic feed-through capacitor was then installed and the above test was repeated. All measurements were performed in a balanced 50-ohm system.

Figures 7, 8 and 9 represent a summary of the network analyzer test results. Figures 7 and 8 are sweeps of an ICD without a ceramic feed-through capacitor installed (the 0-dB reference line is at the top of the sweeps). Figure 7 is with RF signal injection and detection on the same cardiac rhythm sensing circuit (circuit A). Figure 8 is with RF signal injection on one cardiac rhythm sensing circuit (circuit A) and detection on a separate sensing circuit (circuit B). This is an indication of crosstalk within the ICD circuitry at cellular phone frequencies.

Before the ceramic feed-through capacitor was installed, the level of RF signal detected at the ICD sensing amplifier inputs was relatively high (in the worst case only 27 dB down in the cellular phone frequency range). The parasitic behavior characterized by many peaks and valleys is believed to be caused by stray inductance and capacitance within the ICD as well as the self-resonance of ICD substrate-mounted chip capacitors. In addition, the degree of internal stray coupling is

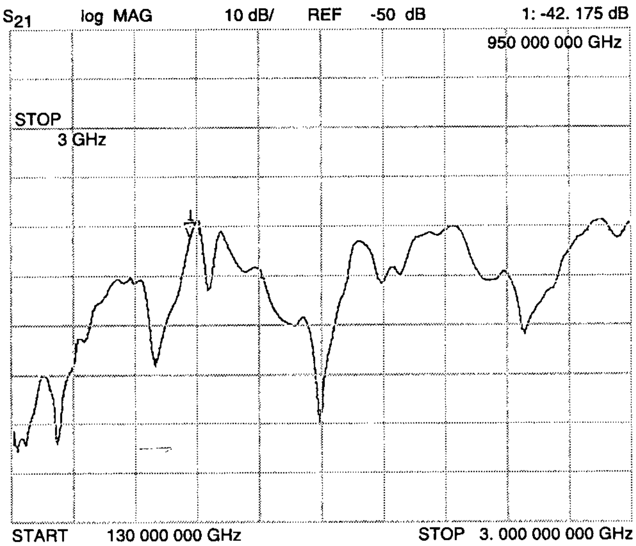

Figure 7. ICD network analyzer plot from 130 MHz to 3 GHz without ceramic feed-through capacitor (0 dB at top, 10-dB increments going down y axis). Injection and detection on sensing circuit "A." Marker 1 is at 950 MHz.

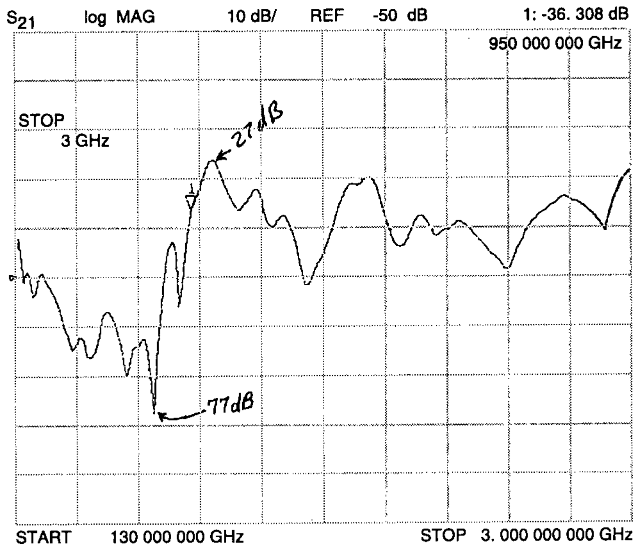

Figure 8. ICD network analyzer plot from 130 MHz to 3 GHz without ceramic feed-through capacitor. Injection on circuit A, with detection on circuit B. Marker 1 is at 950 MHz.

severe, as shown in Figure 8 (injection on one sense lead and detection on a completely different sense circuit).

Figure 9 is typical of all of the ICD sensing circuits measured after the 3880-pF ceramic feed-through capacitor was installed. The actual attenuation exceeds

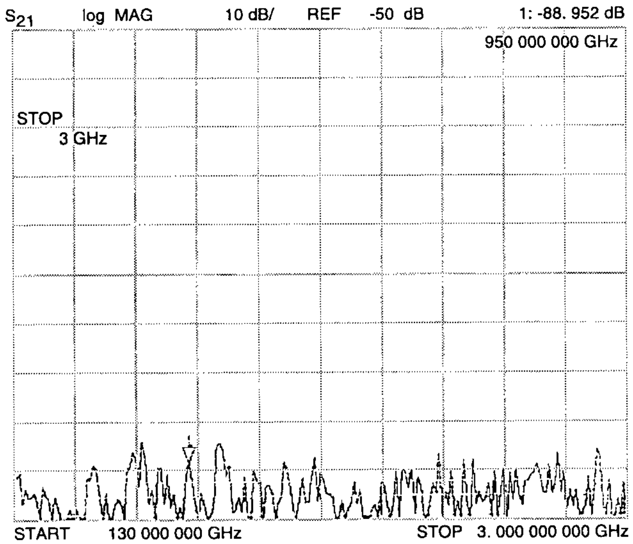

Figure 9. ICD network analyzer plot from 130 MHz to 3 GHz with 3880-pF ceramic feed-through capacitor installed. Marker 1 is at 950 MHz.

the amount shown because the bottom of the plot represents network analyzer internal noise (the dynamic range limit of the network analyzer was reached). The ceramic feed-through capacitor EMI filter provided approximately 50-dB of attenuation at the 950-MHz cellular phone frequency.

SUMMARY AND CONCLUSIONS

In vivo and in vitro research has demonstrated that, when designed with a ceramic feed-through capacitor EMI filter, cardiac pacemakers are resistant to EMI from cellular phones operating in the 950 MHz through 1.8 GHz wireless communication device band.[3]

It is not practical to characterize the frequency, modulation, pulse repetition rates or power levels of all existing and future emitters to which cardiac pacemakers and ICDs may be exposed. Therefore, a broadband EMI filter is required which offers significant (> 40 dB) and continuous (free of drastic peaks and valleys) attenuation of the incident RF carrier over wide frequency ranges.

Accordingly, cardiac pacemakers and ICDs should have their lead interfaces protected by ceramic feed-through capacitor EMI filters. Feed-through capacitors effectively attenuate, absorb, and reflect EMI from 30 MHz to 10 GHz before it can enter the inside of the pacemaker or ICD housing and couple to sensitive internal circuits. Feed-through capacitors are far superior when compared to chip or substrate-mounted capacitors because they do not exhibit undesirable parasitic resonances at high frequencies.

The feed-through capacitor should be backed up by internal chip capacitors to provide effective low frequency filtering, particularly below 30 MHz (frequency overlap is desirable). It is usually not practical to put sufficient capacitance in the feed-through capacitor to perform both the low and high frequency filtering functions.

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