RF SUSCEPTIBILITY OF CARDIAC PACEMAKERS

Interference Effects[1]

Dysfunctioning (malfunctioning) in pacemaker performance, as a result of exposure to electromagnetic fields, can be manifested as any one of a number of different effects. For example, it can be in the form of an irregular rate of stimulation pulses within a given time period. Other forms of dysfunctioning include an excessive number of stimulation pulses (more than 150 pulses per minute) or an insufficient number of stimulation pulses (less than 50 pulses per minute).* A final form of dysfunctioning is pulse inhibition, i.e., no pulse output from the pacemaker.

Of four types of pacemakers, the demand type is, in general, the most susceptible to electromagnetic interference and thus poses a more hazardous threat to the patient. The circuitry of this type of pacemaker is inherently susceptible to those fields which mimic the frequency characteristics and periodicity of the heart's normal activity. Under these conditions, the interference may cause the unit to shut off completely.

In addition to the above types of dysfunctioning, demand pacemakers may suffer "reversion." Reversion is a "designed-in" operational mode in which the pacemaker, in the presence of interference or "noise," essentially switches its sensing circuitry off and begins to function in an asynchronous mode to gain a considerable degree of RF immunity. Since reversion is a design capability, it usually is not considered to be a form of dysfunction. However, in the reversion mode, the pacemaker stimulation pulse may compete with the heart's normal electrical pulse to alter its rate, an undesirable effect.

Historical Trends

Over the 5-year history (ending 1976) of a testing program, at the Engineering Experiment Station, Georgia Institute of Technology, there has been a noticeable improvement in the susceptibility threshold levels as the manufacturers have paid more attention to shielding, filtering, and circuit-design techniques for interference reduction. Such improvement is evidenced, at 450 MHz, by the susceptibility levels of pacemakers increasing from an average of 35 V/m in 1973 to an average of 144 V/m in 1976 (Figure 1).

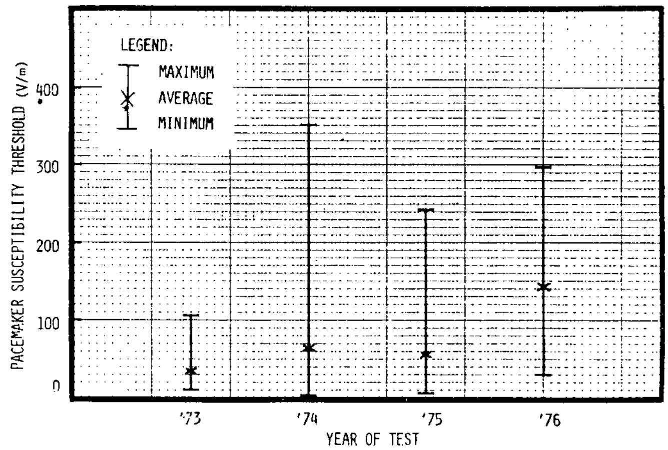

Figure 1. Historical behavior of susceptibility threshold data.

Subsequent discussion with J.C. Toler, one of the co-authors of this paraphrased material, indicated that current (1981) pacemakers are even less susceptible than those represented by the above data.

Measured Data

Since over 90% of pacemaker wearers can be expected to have demand-type pacemakers,[2] the data for this type are of greatest interest. Pacemaker data have been obtained in-vivo (canines), in saline solution (an approximation to in-vivo), and in air.

*As defined by the Association for Advancement of Medical Instrumentation (AAMI) Standard for EMC Performance for Implantable Cardiac Pulse Generators, June 18, 1975.

Field Strength

Figures 2 and 3 show the variation in percent failure with field strength for 244 demand pacemakers exposed to 450-MHz fields. Note that the curves do not extend to 100% failure because some units did not fail under the strongest (300 V/m) field available. It is evident from Figure 2. that the demand pacemakers are much more susceptible to the lower PRR's (2 and 10 pps) than to those higher (20 to 40 pps).

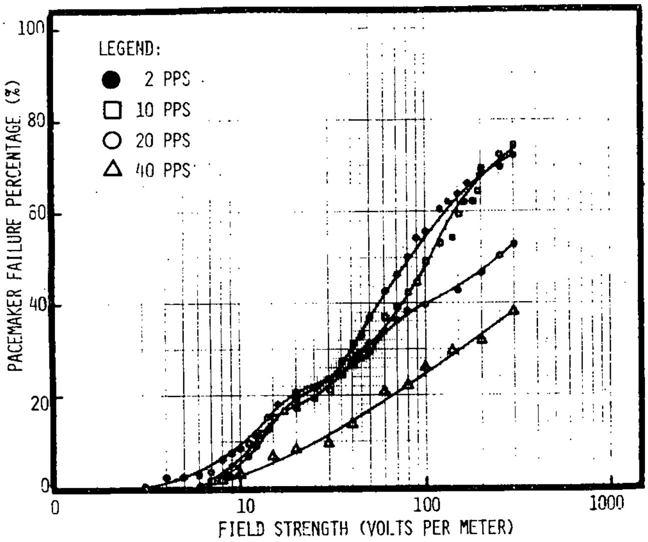

Figure 2. Demand pacemaker failure rate in percentage versus field-strength level; saline.

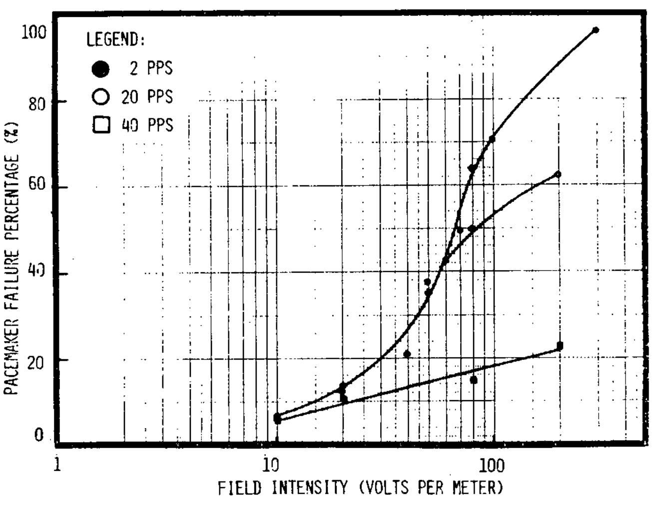

Figure 3. Demand pacemaker rate in percentage versus 450-MHz field-strength level; in-vivo.

Pulse Width

The averaged susceptibility threshold of 11 pacemakers at each pulse width are shown in Figures 4 and 5. The figures show that, as the pulse width increases, the peak-pulse power density necessary to cause interference decreases. This behavior suggests that a measure of demand pacemaker susceptibility might be the product of pulse amplitude times pulse width, i.e., the energy of the pulse. Also shown in Figures 4 and 5 is this "pulse energy density" factor.

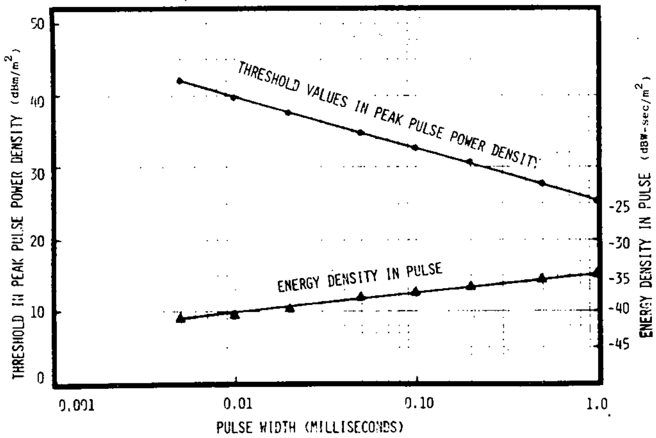

Figure 4. Susceptibility threshold versus pulse width at 2 pps.

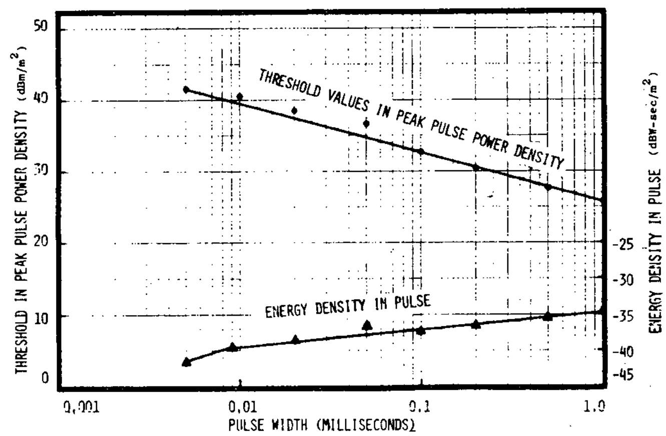

Fig. 5. Susceptibility threshold versus pulse width at 50 pps.

Pulse Repetition Rate

To further test the possibility of developing generalized threshold parameters for pacemakers, additional tests were run on the 11 pacemakers to determine their susceptibility thresholds as a function of pulse repetition rate at a constant pulse width. Again, the measured susceptibility thresholds of the 11 pacemakers were averaged and are shown in Figure 6. Also included in the figure are the calculated values of the "pulse energy density" for the various peak-pulse power density/PRR conditions. As is evident from the figure, neither the peak-pulse power density level nor the "pulse energy density" level at susceptibility thresholds change as the pulse repetition rate is varied. These data again suggest that, at least for demand pacemakers, the susceptibility threshold at a given frequency is strongly related to the energy in the pulse.

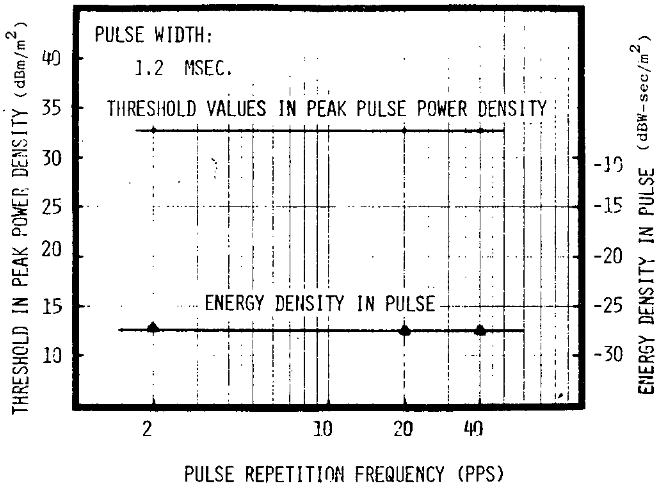

Figure 6. Susceptibility threshold versus pulse repetition rate.

Power-Frequency Effects[3]

For pacemakers exposed to a 60-Hz magnetic field, the relative number of failures in percentage of units is shown in Figure 7 as a function of field strength. The range of magnetic exposure field over which pacemakers failed varied from 1.1 to 4.0 Gauss. If a unit did not fail at field strengths up to 4.0 Gauss, failure did not occur as the field strength was further increased to a maximum level of 20 Gauss.

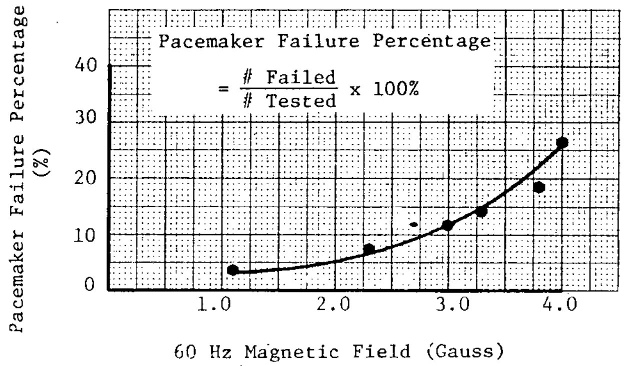

Figure 7. Demand pacemaker failure in percentage versus magnetic-induction field strength.

Remarks

1. The continuing improvement in immunity of cardiac pacemakers to electromagnetic fields is substantially reducing the risk of malfunction. Even so, precautions would still be required to circumvent malfunction of older installed units.
2. For pulsed fields, a significant susceptibility parameter for demand pacemakers appears to be the threshold energy density per pulse, which is constant over a wide range of pulse repetition rates for a fixed carrier frequency.
3. This constant pulse-energy-density threshold is approximately -27 dBWs/m² *for a 450-MHz carrier only.* Experiments show greater immunity to 3-GHz signals. Frequency dependence is due not only to variation in the pacemaker pickup capability, but also to variation in the effective electromagnetic shielding properties of the body in which the pacemaker is implanted.

References

1. H.W. Denny, B.M. Jenkins and J.C. Toler, "Behavior of Cardiac Pacemakers in Pulsed EM Fields", Record of 1977 IEEE International Symposium on Electromagnetic Compatibility, pp. 272-277, August 1977.
2. O.Z. Roy, *CRC Critical Reviews in Bioengineering*, Vol. II, Issue 3, p. 287, June 1975.
3. B.M. Jenkins and J.A. Woody, "Cardiac Pacemaker Responses to Power Frequency Signals", Record of 1978 IEEE International Symposium on Electromagnetic Compatibility, pp. 273-277, June 1978.

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