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# MEASURED EFFECTS OF SQUARE-WAVE MODULATED RF FIELDS (450 AND 3100 MHz) ON CARDIAC PACEMAKERS

SCHOOL OF AEROSPACE MEDICINE

DECEMBER 1974

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Tests were performed to measure the effect of pulsed 450 and 3100 MHz RF radiation on cardiac pacemakers. All models were tested in both a free-field and a simulated-implant configuration and were continuously monitored during testing. Most of the models exhibited some type of electromagnetic interference under some conditions of the tests, although five recent, different models were unaffected under all conditions of these tests.

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## NOTICES

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This technical report has been reviewed and is approved for publication.

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## Figures and Tables

MEASURED EFFECTS OF SQUARE-WAVE MODULATED RF FIELDS (450 AND 3100 MHz) ON CARDIAC PACEMAKERS

## INTRODUCTION

The potential hazard from the interaction of radiofrequency (RF) electromagnetic radiation and cardiac pacemakers has been identified through tests conducted by personnel at the USAF School of Aerospace Medicine (USAFSAM) during the past three years. Such tests defined the type and extent of interference possible, and established the relative electromagnetic radiation interference (EMI) sensitivities among the pacemakers marketed or available at each point in time (5, 6, 11, 12, 13, 14, 17, 21).

In spite of the fact that many of the earlier model pacemakers and some currently marketed devices still have adverse effect thresholds below 10 volts per meter (V/m), it has been apparent from the beginning of the pacemaker testing program that designing a demand type pacemaker with good EMI characteristics--without sacrifice of other functional aspects--was technically feasible. Hence, in May 1973, USAFSAM personnel prepared and presented to the Food and Drug Administration a recommendation that manufacturers design and qualify their pacemakers to function properly at an E-field level of 200 V/m (rms), in the frequency range 200 - 500 MHz, using a square-wave pulse at a pulse repetition rate (PRR) of 5 pulses per second (pps) with a 1 - 10 millisecond (msec) pulse width. It is recognized that 200 V/m is the maximum E-field level associated with a 10 $mW/cm^2$ continuous wave (CW) emission, and that pulsed fields could be much higher than 200 V/m while staying below 10 $mW/cm^2$ (average power density). However, if all marketed pacemakers would function properly in a pulsed 200 V/m field, the potential EMI problem areas would be essentially eliminated.

By early 1974, an overall improvement became apparent in the EMI characteristics of pacemakers being marketed, and a new test program was initiated at USAFSAM to evaluate the significance of this trend.

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<u>EDITOR'S NOTE</u>: The principal abbreviations and acronyms in this report are listed and briefly defined on p. 35.



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This program was to include laboratory tests at radiofrequencies of 27 MHz, 450 MHz, and 3100 MHz as well as field tests around numerous high-power RF emitters.

## TEST PROCEDURES

The first of these tests was conducted by USAFSAM personnel at the Georgia Institute of Technology (GIT) Engineering Experiment Station (Atlanta, Georgia), 18 - 29 March 1974. Here, 72 pacemakers representing 10 manufacturers and 24 different designs (Fig. 1 and Table 1) were tested in an anechoic chamber in square-wave modulated 450 MHz and 3100 MHz RF radiation fields. The 450 MHz fields were circularly polarized with electric field (E-field) levels up to 292 V/m. The ranges of pulse width and repetition rate used were 1 microsecond (μsec) to 1 msec and 2 - 50 pps, respectively. The 3100 MHz fields were vertically polarized with levels up to 320 V/m (rms) for a pulse-width range of 10 - 120 μsec at 7 - 400 pps.

Both free-field and simulated-implant configurations were investigated for the purpose of determining the shielding factor afforded by implantation. The effect of pulse-width and repetition rate on pacemaker response was studied. A cursory study of the effect of different pacemakers leads on interference thresholds was also accomplished.

When tested, the pacemakers were positioned in the far-field region of the anechoic chamber on the center line of the radiation device. For the free-field configuration: the pacemakers and leads were mounted on a Plexiglas stand (Fig. 2). For the simulated-implant configuration: the Plexiglas stand was so placed in the phantom (20 x 30 x 30 cm with 0.15-cm wall thickness), filled with 0.03 molar saline solution, that the pacemaker was 1 cm from the phantom wall facing the incident radiation.

The pacemaker response was recorded via a telemetry system which was designed to present the pacemaker with a load comparable to that produced by the heart and to provide as much isolation of the pacemaker as possible. The load network was mounted on a subminiature audio jack to which the pacemaker leads were attached with "flea clips." A light-emitting diode (LED) was mounted in a mating plug;

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<u>EDITOR'S NOTE</u>: All tables are grouped at the close of this report.

and when the pacemaker fired, approximately one-half of the pacer output current passed through the LED, causing it to flash during the pulse. The LED was optically coupled to a 20-ft light pipe which was terminated by a photoresistor in a voltage divider circuit. The output of the voltage divider was ac coupled into an ECG amplifier (Mennen Greatbatch Model 621), the output of which was fed to one channel of a two-channel strip-chart recorder for a permanent record and to a computing counter (Hewlett-Packard, model #5360A) which constituted a real-time pacemaker rate monitor (Fig. 3). The E-field was monitored by an antenna positioned above and behind the pacemaker test point, and was recorded on the second channel of the strip-chart recorder.

The E-field was controlled by means of a set of attenuators in-line between the transmitter output and radiating device. The calibration was insured by maintaining a constant transmitter output power.

The E-field levels to which the pacemakers were exposed were measured independently by GIT personnel and by personnel from the AF Communication Service (1839 EIGp, Keesler AFB, Biloxi, Miss.). In conjunction with a standard gain dipole for the 450 MHz field and a pyramidal horn for the 3100 MHz field measurements, a power meter (Hewlett-Packard, model 432A) was used. All field measurements were within 0.6 decibel (dB). At 3100 MHz, a cavity-back spiral antenna (Transco, model 9C15100) was used for measuring the attenuation as a function of depth in 0.03 molar saline solution as well as the attenuation of different proposed phantom materials.

## TEST RESULTS

Among cardiac pacemakers (of the fixed rate type and the synchronous or R-wave inhibited types), the latter are most likely to be affected by pulsed EM radiation because these use a sensing circuit to control the pacing mode (either demand, synchronous, or fixed-rate) and/or rate. The Cordis models 133C6, 133C7, and 164A were the only synchronous pacemakers tested. The 133C6 and 133C7 have a limiting circuit designed to prevent the pacemaker rate from exceeding a predetermined rate of ~140 beats per minute (bpm). The 164A also has a circuit design, which limits the pacemaker synchronous rate, as well as a noise-sensing circuit which causes the pacemaker to revert to a fixed rate when EMI is detected. The Cordis omni models (162C and 164A) were tested at 70 bpm. For R-wave inhibited demand pacemakers, the sensing circuit reverts the pacemaker to a fixed rate when R-wave mocking EMI pulses come in at a rate greater than that for which the manufacturer's design provided. If the EMI rate is less than the designed rate, the pacemaker will interpret it as signals from the normally functioning heart, and will inhibit.


Figure 1. Sample pacemaker test population.

Top row: Stimtech 3821; G.E. A2075A; Medcor 3-70A
Middle row: Amer. Opt. 281003, and 281143;
Biotronik IDP-44
Bottom row: Medtronic 5842, and 5942

(Continued on facing page---)


(Cont'd. from facing page--Figure 1. Sample pacemaker test population.)

Top row: Starr-Edwards 8116, and 8114; Pacesetter BD-101
Middle row: Cordis 162C, and 164A; Vitatron MIP-40-RT
Bottom row: Medtronic 5944, and 9000.

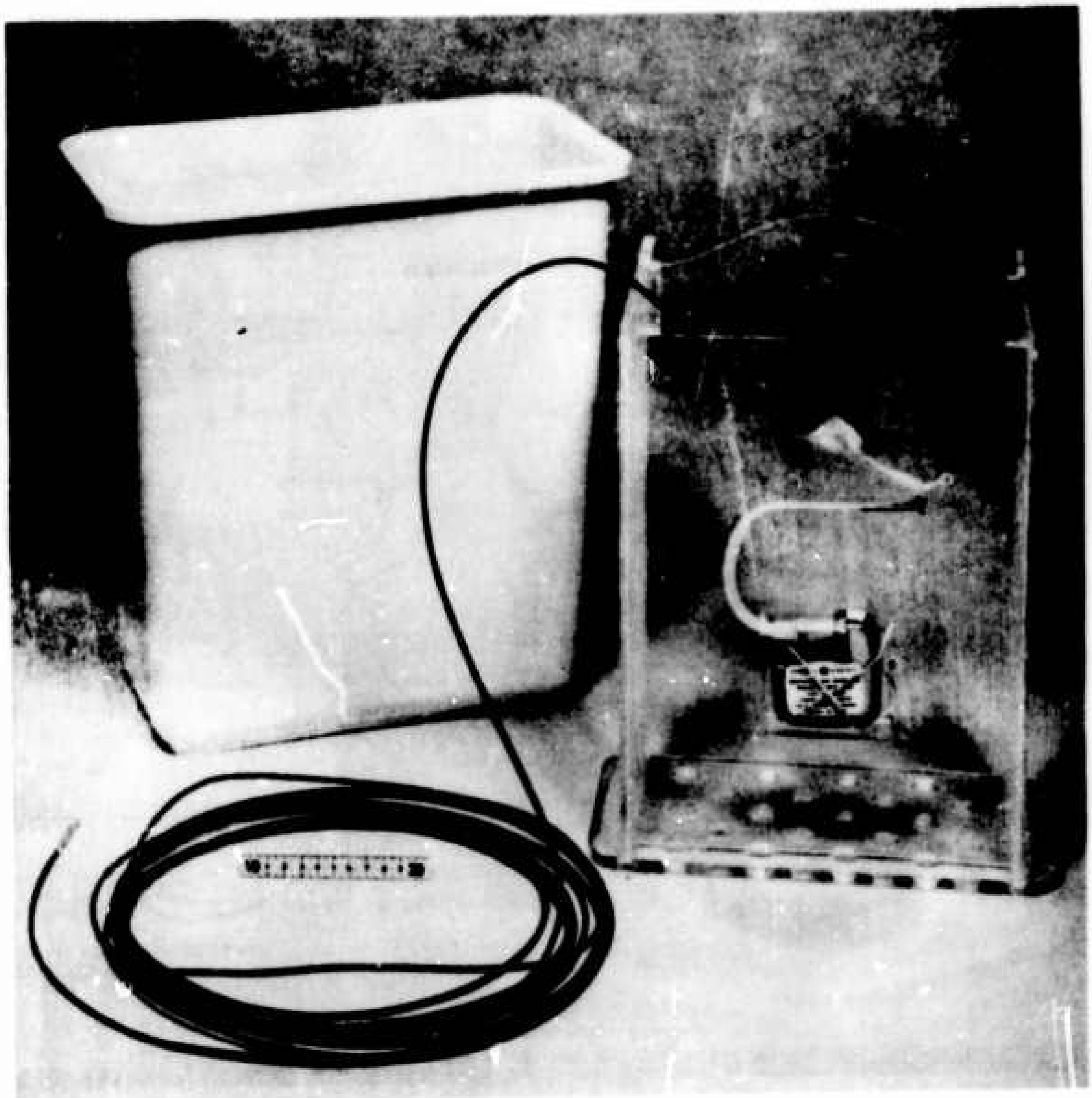

Figure 2. Plexiglas, pacemaker test stand and saline phantom.

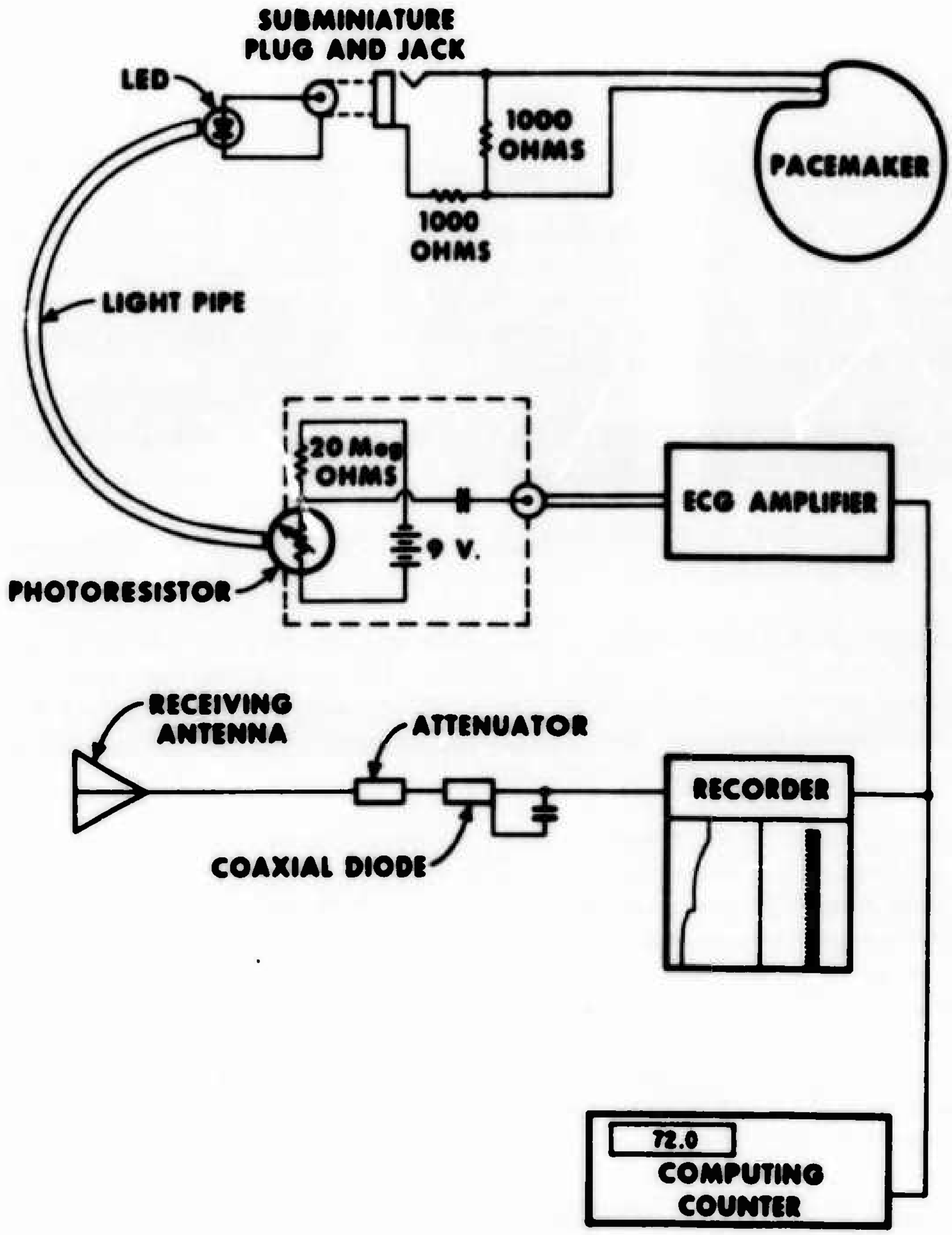


Figure 3. Test equipment for pacemaker response (block diagram).

The following pages of this report present a model-by-model description of the responses of the pacemakers to both 450 and 3100 MHz radiation. The response to PRR is the same at both frequencies, except for thresholds (as noted) and other indicated differences. The thresholds noted are generally those of the most sensitive pacemaker (out of the so-called 'identical' devices tested).

American Optical Model 281003--This model pacemaker reverted to a fixed rate between 65 and 80 bpm for a PRR ≥40 pps, and cut off at 20 pps and below when the threshold was reached. The thresholds at 450 MHz were 7 V/m in the free-field configuration and 13 V/m in the simulated-implant configuration. At 3100 MHz, the thresholds were 77 V/m for the free-field configuration and greater than 320 V/m for the simulated-implant configuration.

American Optical Model 281013--This model was affected in a manner similar to the 281003.

American Optical Model 281143 (Predicta)--No effects were observed under all conditions tested.

Biotronik Model IDP-44--This model pacemaker cut off at 2 and 4 pps, and reverted to fixed rate for PRRs ≥10 pps at the threshold. The free-field threshold at 450 MHz was 40 V/m, while the simulated-implant threshold was 141 V/m. One pacemaker was not affected at 450 MHz, while none were affected at 3100 MHz.

Cordis Model 133C6 and 133C7 (Atricor)--Since this model pacemaker is atrial synchronous, it has no fixed rate as such, but is designed to maintain a rate below 140 bpm. After the EMI threshold was reached, the pacemaker rate increased with increasing E-field. The pacemaker rate can exceed 120 bpm for some PRR values and/or some E-fields. The EMI threshold at 450 MHz was 17 V/m in the free-field configuration and 85 V/m in the simulated-implant configuration. The maximum rate was 172 bpm at 40 pps. At 3100 MHz, the EMI threshold was 43 V/m in the free-field configuration and 141 V/m in the simulated-implant configuration.

Cordis Model 143E7 (Stanicor)--This model pacemaker reverted to fixed-rate mode (70-85 bpm) for PRRs of 20 pps and greater when the E-field threshold was reached. The pacemaker cut off at 10 pps at the threshold. The threshold at 450 MHz was 10 V/m in the free-field configuration and 15 V/m in the simulated-implant configuration. At 3100 MHz, the threshold was 36 V/m for the free-field configuration and 141 V/m for the simulated-implant configuration.

Cordis Model 162C (Omni-Stanicor)--This model pacemaker reverted to a fixed-rate mode (equal to the demand rate) at PRRs above 20 pps at the threshold, and cut off at 10 pps and below. At 450 MHz, the threshold was 6 V/m for the free-field configuration, and 8 V/m for the simulated-implant configuration. At 3100 MHz, the threshold was 229 V/m for the free-field configuration, and 302 V/m in the simulated-implant configuration.

Cordis Model 164A (Omni-Atricor)--This pacemaker is an atrial synchronous pacemaker which, unlike models 133C6 and 133C7, reverts to a fixed rate (equal to the demand rate) when interference becomes severe. The threshold level was somewhat dependent on PRR (decreasing with decreasing PRR) at 3100 MHz. The threshold at 450 MHz was 4 V/m for free-field configuration and 13 V/m for the simulated-implant configuration. At 3100 MHz, the threshold was 116 V/m for the free-field configuration and 320 V/m in the simulated-implant configuration for PRRs below 100 pps--while the pacemaker was not affected between 100 pps and 400 pps.

General Electric Model A2072D--This model pacemaker exhibited a rate increase with increasing E-field. After the E-field was increased above the threshold level, the pacemaker would cut off at 2 pps and revert to its fixed rate mode at 10 pps and above. The RF interference apparently affected the timing circuitry, causing both the demand and fixed rates to increase. The threshold at 450 MHz was 8 V/m in the free-field configuration and 29 V/m in the simulated-implant configuration. The thresholds at 3100 MHz were 77 V/m in the free-field configuration and >320 V/m in the simulated-implant configuration.

General Electric Model A2075A (Sentry)--At 450 MHz, the pacemaker cut off at the threshold at 2 pps, and increased in rate at the threshold at 10 pps and above. The threshold was 10 V/m free-field and 23 V/m in the simulated-implant configuration. This model was not seriously affected in the free-field configuration at 3100 MHz (demand rate increased to 86 bpm at 302 V/m), and was unaffected for simulated-implant configuration at this frequency.

Medcor Model 3-70A--At 450 MHz, this pacemaker cut off at 2 pps at the threshold. At 10 pps and above, it reverted to fixed rate, then cut off at a high E-field. The free-field threshold was 13 V/m, and the simulated-implant was 29 V/m with a high level cutoff at 141 V/m. At 3100 MHz, this model exhibited an increasing fixed rate with increasing E-field above the threshold (60-102 V/m). At 320 V/m, the rates were generally above 146 bpm. In the phantom, the rate did not exceed 72 bpm.

Medtronic Model 5842--At the threshold, this model reverted to a fixed rate of operation (45-55 bpm) at 100 pps and above, and cut off at 20 pps and below. At 40 pps, pacemakers of this type either cut off or went into fixed rate at the threshold. At 450 MHz, the pacemakers generally tracked the PRR at a high E-field level (114 V/m shielded). The thresholds at 450 MHz were 2 - 5 V/m for the free-field configuration, and 12 V/m for the simulated-implant configuration. At 3100 MHz, the free-field thresholds ranged from 40 - 100 V/m, and the simulated-implant threshold was >320 V/m.

Medtronic Model 5942--This model reacted in a manner similar to model 5842, except that no tracking was observed. The 450 MHz thresholds were 2 V/m free-field and 12 V/m for the simulated-implant configuration. The thresholds at 3100 MHz were 88 - >320 V/m for the free-field configuration, and greater than 320 V/m for the simulated-implant configuration.

Medtronic Model 5943--This pacemaker cut off for PRRs of 20 pps and below, and went into fixed rate (45 - 66 bpm) at PRRs of 40 pps and above for E-fields above the threshold. At 450 MHz, the pacemaker tracked the PRR at 114 V/m in the free-field configuration. The free-field threshold at 450 MHz was 6 V/m; and 19 V/m, in simulated-implant configuration. At 3100 MHz, the free-field threshold was 77 V/m; and >320 V/m, in simulated-implant.

Medtronic Model 5944--This model reverted to a fixed rate mode (44 - 52 bpm) at PRRs of 20 pps and above, and cut off for 10 pps and below. At 450 MHz, the free-field threshold was 6 V/m and the simulated-implant threshold was 19 V/m. At 3100 MHz, the free-field threshold ranged from 129 to 302 V/m and the simulated-implant threshold was greater than 320 V/m.

Medtronic Model 5950--No effects were observed under conditions tested. [Note: This model was a preproduction prototype pacemaker design.]

Medtronic Model 5951--No effects were observed under conditions tested. [Note: This model was a preproduction prototype pacemaker design.]

Medtronic Model 9000 (Nuclear)--This model pacemaker cut off at the threshold at 20, 10, and 2 pps. At 40 pps and above, it reverted to fixed rate at the threshold. The free-field threshold at 450 MHz was 1 V/m, and the simulated-implant threshold was 7 V/m. At 3100 MHz, the free-field threshold was 52 V/m for one pacemaker (the other two were unaffected up to 320 V/m). The pacemaker was not affected in the simulated-implant configuration up to 320 V/m at 3100 MHz.

Pacesetter Model BD-101 (Rechargeable)--No effects were observed under conditions tested.

Starr-Edwards Model 8114--This model pacemaker cut off at the threshold below 10 pps. At PRRs of 20 pps and above, the pacemaker reverted to fixed rate at the threshold. The E-field threshold at 450 MHz was 33 V/m free-field, and 23 V/m in the simulated-implant configuration. This relationship between free-field and simulated-implant thresholds was not reasonable and was, therefore, thought to be due to variability in the pacemaker EMI response. At 3100 MHz, the free-field threshold was 60 V/m, and the simulated-implant threshold was 204 V/m.

Starr-Edwards Model 8116--No effects were observed under conditions tested.

Stimtech Model 3821--This model showed a great deal of variability in response from pacemaker to pacemaker. At 450 MHz, this model pacemaker cut off at the threshold at 2 pps. At 10 pps, the pacemaker would either cut off or revert to a fixed-rate mode at the threshold. At 20 pps, the pacemaker would revert to fixed rate at the threshold. One pacemaker of this model was unaffected at this frequency. The thresholds were 46 V/m in the free-field configuration and 107 V/m in the simulated-implant configuration. At 3100 MHz, one pacemaker was not affected to the limits of the tests. Another was unaffected from 400 to 100 pps, but cut off at 320 V/m at PRRs from 10 to 40 pps. A third cut off at PRRs of 40 pps and below at 302 V/m, but went to fixed rate at 100 pps and above. The oldest pacemaker of this model reverted to fixed rate at a threshold of 158 V/m in the free-field configuration for PRRs between 400 pps and 100 pps. From 40 to 10 pps, this pacemaker cut off at the threshold. This model was not affected in the simulated-implant configuration at 3100 MHz.

Vitatron Model MIP-40-RT--At 450 MHz, this model cut off at the threshold at 2 pps and 10 pps. At 20 pps and 40 pps, this model reverted to fixed rate at the threshold, but had a cut-off threshold at 243 V/m in the simulated-implant configuration. The free-field configuration threshold was 40 V/m, and the simulated-implant configuration threshold was 93 V/m. At 3100 MHz, as the E-field was increased above the threshold, the pacing rate (for all PRRs) increased to between 270 bpm and approximately 2000 bpm. The threshold was 178 V/m in the free-field configuration, and the rate exceeded 120 bpm near 229 V/m. This model was unaffected in the simulated-implant configuration at 3100 MHz.

The pacemaker free-field and simulated-implant threshold data for 450 MHz and 3100 MHz are presented in Tables 2 - 4. The double entries indicate the insignificant and significant interference thresholds for those pacers which demonstrated both for the same PRR. A significant effect is defined as a pacemaker rate which falls below 50 bpm or exceeds 120 bpm as a direct result of RF radiation interference.

Measured with a cavity-back spiral antenna at 3100 MHz was the attenuation of: two different thicknesses of Plexiglas (1/8 in. and 1/4 in.); 1.5 in. of ethafoam coated on the inside with epoxy waterproofing; and 1.5 mm of polyethylene. These materials were considered for use as phantoms. The ethafoam and polyethylene contributed no measurable attenuation. The attenuation due to 1/8 in. and 1/4 in. of Plexiglas was 0 dB and 0.2 dB, respectively.

The attenuation for several depths of 0.03 molar saline solution was also investigated with the cavity-back spiral antenna at 3100 MHz. The results are presented in Figure 4. Table 5 contains attenuation factors derived from the free-field and simulated-implant pacemaker threshold data for 450 MHz and 3100 MHz. The variability is not believed to be indicative of anything except a seemingly inherent spread in EMI thresholds. Reproducibility of threshold data on any one pacer can vary by 6 dB. To eliminate as many variables as possible, however, the pacemakers used for the attenuation study remained on the Plexiglas plate and, as much as possible, undisturbed after the free-field test while being transferred to the phantom for the simulated-implant test. The only PRRs used in the acquisition of these data were 2 pps at 450 MHz, and 7 pps at 3100 MHz. Based on these data and the antenna measurements, the attenuation afforded by implantation at 3100 MHz is expected to be approximately 5 (14 dB). The average of the 450 MHz attenuation data gives an estimated implantation shielding factor of approximately 3 (10 dB).

The effect of pulse width and repetition rate on the pacemaker EMI threshold was investigated. At 450 MHz, thresholds were measured for pulse widths between 1 μsec and 1 msec at 2 pps and 50 pps (Fig. 5). The curves are parabolic least square fits to the data normalized to the 1 msec points. Each curve generally represents data from more than one pacemaker, i.e., the data from the G.E. model A2075A and Medcor model 3-70A are represented by one curve, as are: the A.O. models 281003 and 281013; the Stimtech model 3821 and Vitatron model MIP-40-RT;

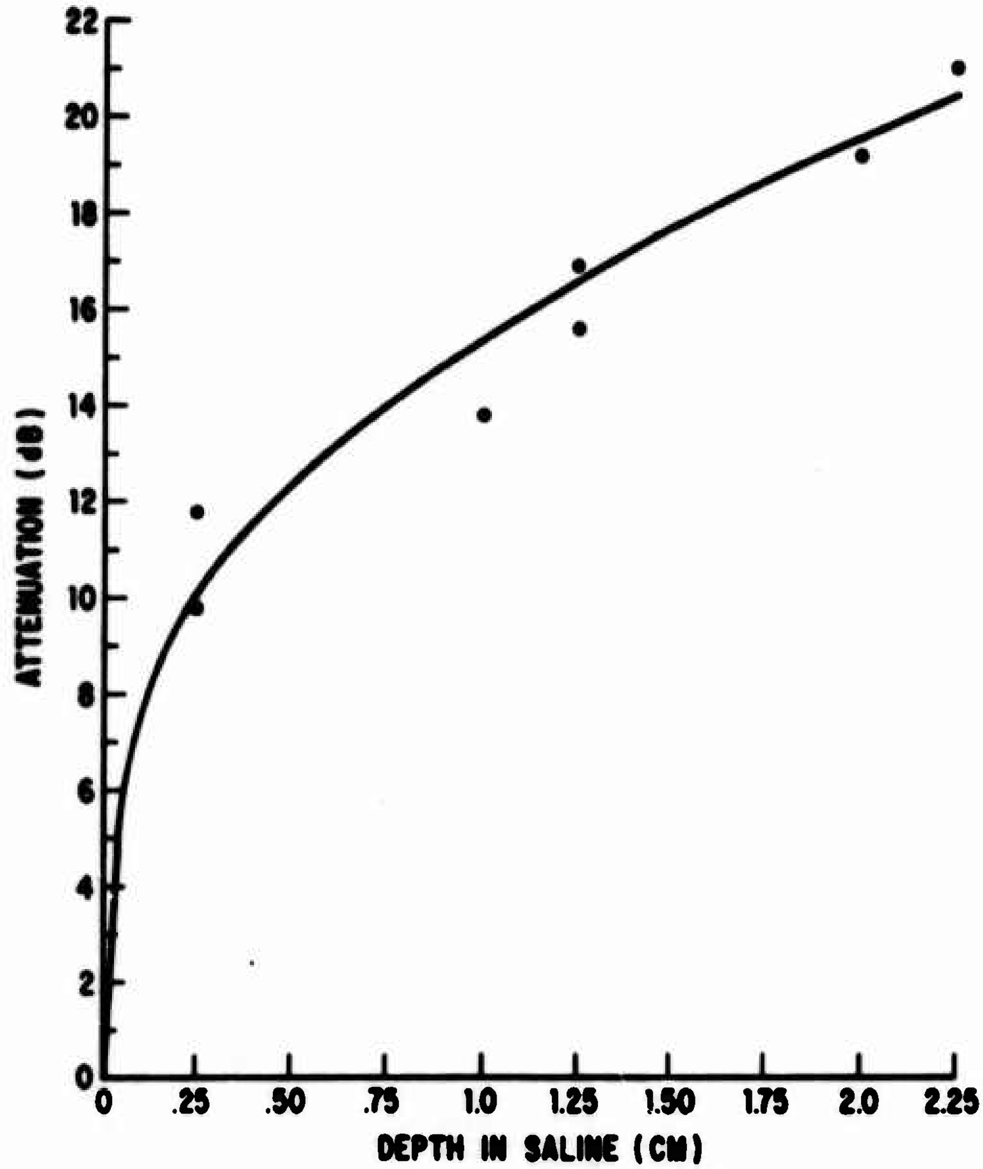


Figure 4. Attenuation of 3100 MHz EMR by saline solution as measured by a cavity-back spiral antenna.

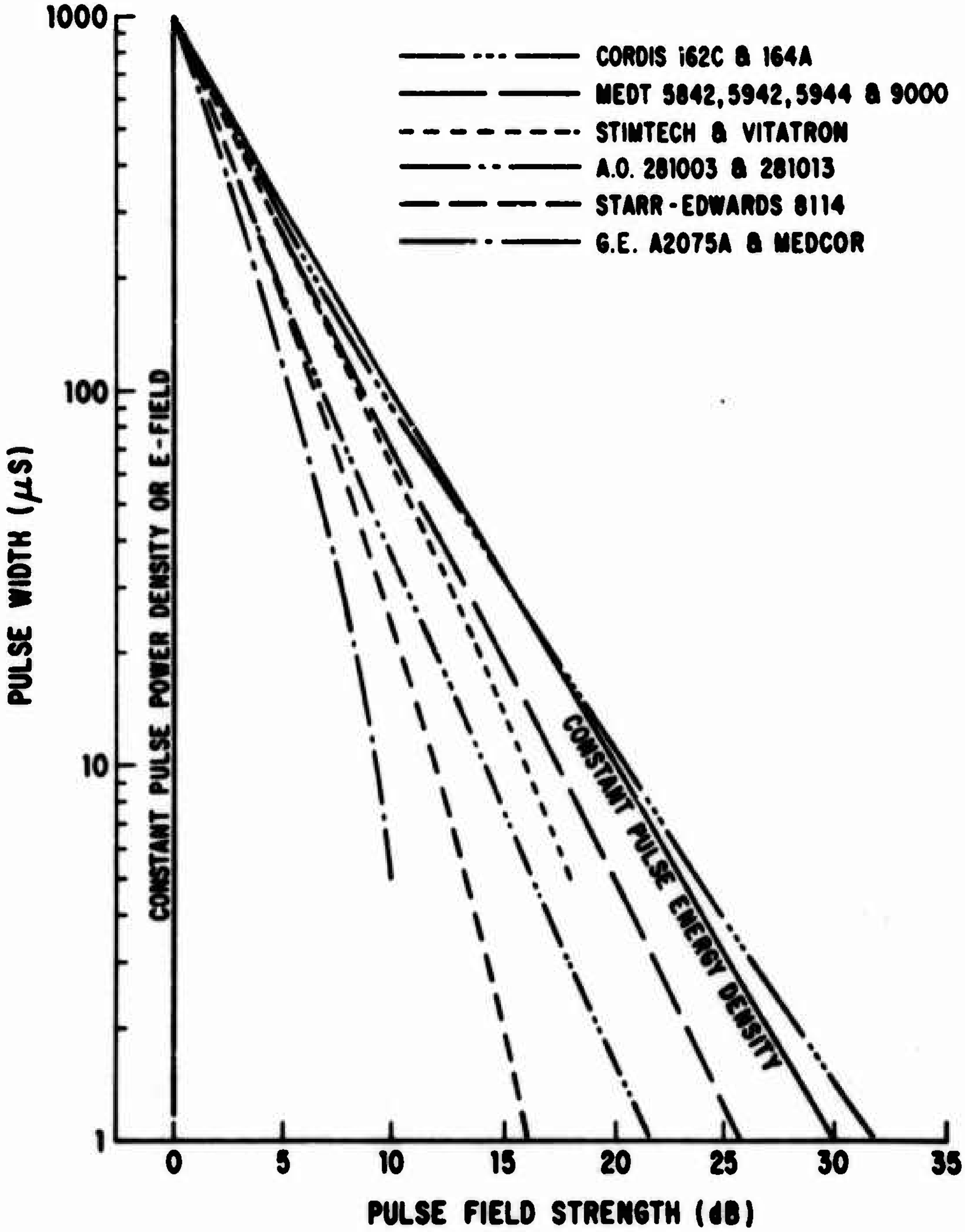


Figure 5. Relative 450 MHz EMI thresholds vs. pulse width for various pacemakers.

Medtronic models 5842, 5942, 5944, and 9000; and Cordis models 162C and 164A. One curve is based only on Starr-Edwards model 8114 data. There was no significant difference between the 2 pps and 50 pps data. The constant pulse energy density curve shows the relation between pulse width and the product of power density during the pulse and pulse width (energy density). These data demonstrate that the E-field threshold is inversely proportional to pulse width.

For 3100 MHz, a pulse-width range of 10 - 120 μsec for 7 pps and 400 pps was investigated (Fig. 6). The data were normalized to the 120 μsec points. Data from the Cordis models 133C7 and 164A are represented by one curve; from the A.O. model 281003, by another curve; from the Medtronic models 5842, 5942, 5944, and 9000 and the G.E. model A2072D (7 pps), by a third curve; and from the G.E. model A2072D (400 pps), by another curve. The G.E. model A2072D was the only pacemaker which demonstrated a significant difference in relationship between threshold and pulse width for different PRRs. The 3100 MHz data also demonstrated that the E-field threshold is inversely proportional to pulse width.

A cursory evaluation of the effect of leads was also made. For instance, the data presented for the Medtronic and A.O. pacemakers were taken using the Medtronic model 6914 epicardial leads. Switching to the model 5818 endocardial leads appears to raise the E-field thresholds somewhat for the Medtronic pacemakers, while the A.O. pacemakers thresholds remained the same for both leads.

## CONCLUSIONS

These tests indicate an improvement in EMI characteristics of the more recent models of cardiac pacemakers (A.O. model 281143, Cordis models 162C and 164A, G.E. model A2075A, Medtronic model 5944, Pacesetter model BD-101, and Starr-Edwards model 8116) over their predecessors. This improvement reflects the abilities of manufacturers to solve the potential interference problems.

The data show that shielding factors of approximately 3 (10 dB) at 450 MHz and approximately 5 (14 dB) at 3100 MHz can be expected for EMI thresholds from the free-field to the implanted situation. These tests also showed that the EMI thresholds are inversely proportional to pulse width.

The comparison of the Medtronic leads, models 5818 and 6914, indicated that at 450 MHz the model 5818 might afford a slight reduction

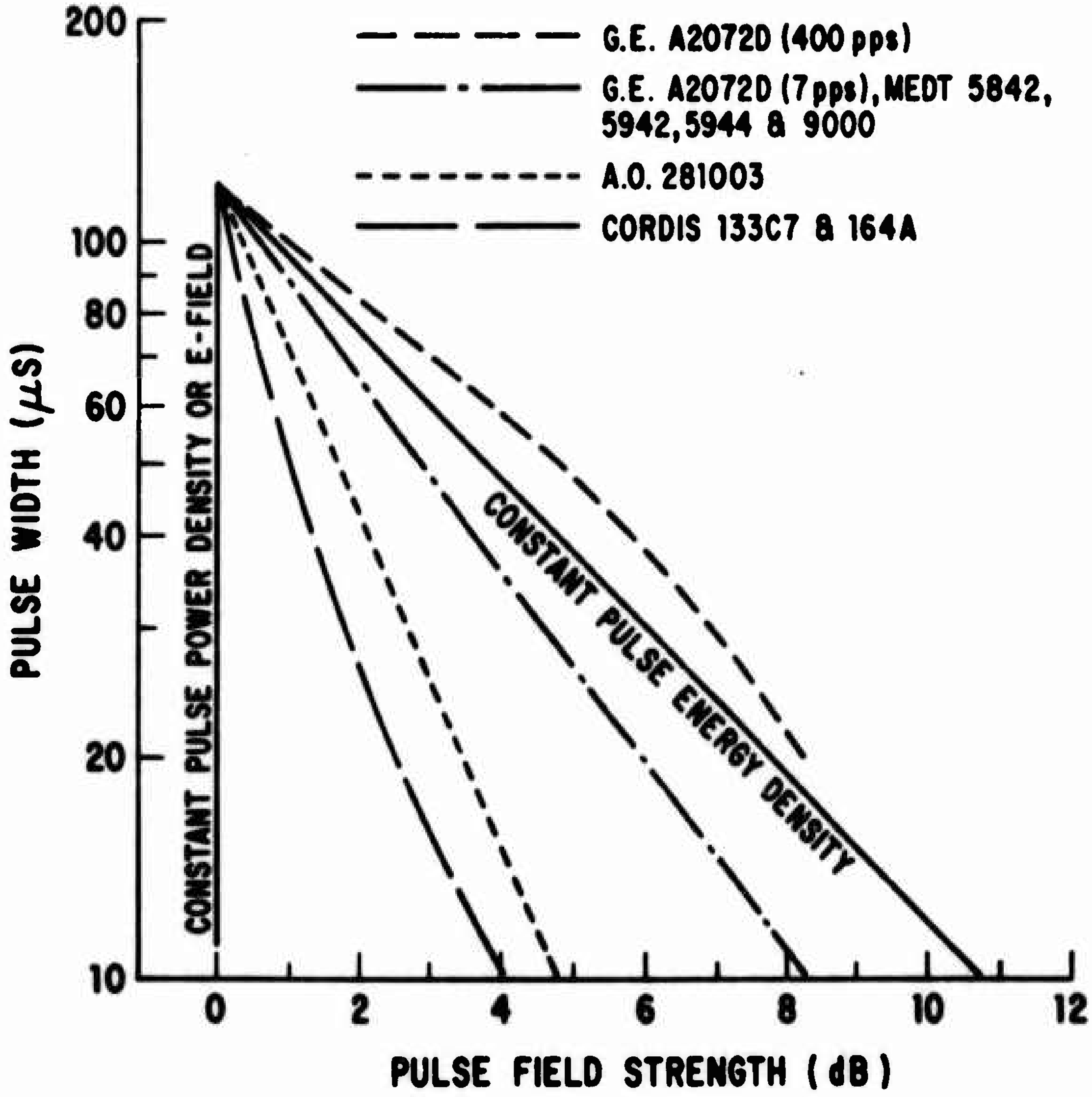


Figure 6. Relative 3100 MHz EMI thresholds vs. pulse width for various pacemakers.

in EMI sensitivity over the model 6914 (∿5 dB). However, no difference was noted at 3100 MHz.

At 450 MHz, three models (the A.O. model 281143, Pacesetter model BD-101 and Starr-Edwards model 8116) were not affected at 200 V/m in the simulated-implant tests. Three other models (the Biotronik model IDP-44, Cordis model 133C7, and G.E. model A2072D) demonstrated no serious effects at 200 V/m for PRRs greater than 10 pps. All other pacemakers tested were significantly affected at E-field values below 200 V/m and PRRs greater than 10 pps. At the 3100 MHz frequency using 120 μsec pulse width, none of the pacemakers tested under simulated-implant conditions were seriously affected at an E-field level of 200 V/m.

Subsequent tests to higher E-field levels would probably serve to establish the relative EMI thresholds for those pacemakers not affected at the limit of these tests.

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TABLE 1. CARDIAC PACEMAKER NOMENCLATURE AND NUMBER OF UNITS TESTED

| Manufacturer | Model No. | No. of units tested | Nomenclature |
|---|---|---|---|
| American Optical | 281003 | 3 | Bipolar Cardio-Care Demand Pacemaker (R-wave Inhibited) |
| | 281013 | 2 | Monopolar Cardio-Care Demand Pacemaker (R-wave Inhibited) |
| | 281143 | 3 | Bipolar Predicta Demand Pacemaker (R-wave Inhibited) |
| Biotronik | IDP-44 | 4 | R-wave Inhibited Unipolar Demand Pacemaker |
| Cordis | 133C6 | 1 | P-wave Synchronous Cardiac Pacemaker |
| | 133C7 | 2 | P-wave Synchronous Cardiac Pacemaker |
| | 143E7 | 1 | R-wave Inhibited Standby Cardiac Pacemaker |
| | 162C | 3 | Programmable R-wave Inhibited Standby Cardiac Pacemaker |
| | 164A | 3 | Programmable P-wave Synchronous Cardiac Pacemaker |
| General Electric | A2072D | ? | Standby (Ventricular Inhibited) Pulse Generator |
| | A2075A | 3 | Sentry Ventricular Inhibited Pulse Generator |
| Medcor | 3-70A | 3 | Demand (R-inhibited) Pacemaker |
| Medtronic | 5842 | 10 | Ventricular Inhibited Bipolar Pulse Generator |
| | 5942 | 9 | Ventricular Inhibited Bipolar Pulse Generator |
| | 5943 | 1 | Ventricular Inhibited Unipolar Pulse Generator |

TABLE 1 (Cont'd.)

| Manufacturer | Model No. | No. of units tested | Nomenclature |
|---|---|---|---|
| Medtronic | 5944 | 3 | Ventricular Inhibited Bipolar Pulse Generator |
| | 5950[a] | 1 | Ventricular Inhibited Bipolar Pulse Generator |
| | 5951[a] | 1 | Ventricular Inhibited Unipolar Pulse Generator |
| | 9000 | 3 | Ventricular Inhibited Bipolar Pulse Generator |
| Pacesetter | BD-101 | 3 | Rechargeable Demand Pacemaker |
| Starr-Edwards | 8114 | 1 | Ventricular Tracking Standby Pulse Generator |
| | 8116 | 3 | Ventrac Ventricular Tracking Standby Pulse Generator |
| Stimtech | 3821 | 4 | R-wave Inhibited Demand Pacemaker |
| Vitatron | MIP-40-RT | 3 | On Demand Unipolar R-wave Blocked Pacemaker |

[a] Pre-production prototype pacemaker designs.

TABLE 2. PACEMAKER EMI THRESHOLDS

| Manufacturer | Model No. | Serial No. | Threshold values, 450 MHz Pulse repetition rate (pps) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | Free-field | | Simulated-implant | | | | |
| | | | 2 V/m(bpm) | 50 V/m(bpm) | 2 V/m(bpm) | 10 V/m(bpm) | 20 V/m(bpm) | 40 V/m(bpm) | 50 V/m(bpm) |
| American Optical | 281003 | 11591 | 7(0) | | 13(0) | | 15(0) | 15(71)[a]<br>243(0)[a] | |
| | 281013 | A2545 | 6(0) | 6(71) | 26(0) | | 26(0) | 26(71) | |
| | 281143 | 27322 | >292[b] | | >292 | | | >292 | |
| | | 27560 | | | >292 | | | >292 | |
| | | 27312 | | | >292 | | | >292 | |
| Biotronik | IDP-44 | 61034 | 40(0) | | 141(0) | 141(82) | 141(82) | | |
| | | 61035 | | | 178(0) | 178(82) | | | |
| | | 61443 | | | >292 | >292 | | | |
| Cordis | 133C7 | 2352 | 17(122) | | 85(122) | | | 85(75)<br>141(172) | |
| | 143E7 | 11575 | 10(0) | | 15(0) | 15(0) | 15(76)<br>243(0) | 15(74) | |
| | 162C | 342 | 8(0) | 6(69) | 8(0) | 9(0) | 9(68) | | |
| | | 4246 | 10(0) | | 15(0) | | 15(69) | 15(69) | |
| | | 5296 | | | | 12(0) | 12(67) | 12(67) | |
| | 164A | 118 | 4(83) | 4(69) | 21(126) | 17(69) | | 17(69) | |
| | | 284 | | | 13(107) | 13(69) | | | |
| | | 286 | | | 85(124) | 85(69) | | | |

[a] Throughout Table 2, double entries indicate the existence of both insignificant and significant thresholds.

[b] Such entries indicate that pacemaker not affected to limit of test.

TABLE 2 (Cont'd)

| Manufacturer | Model No. | Serial No. | Threshold values, 450 MHz Pulse repetition rate (pps) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | Free-field | | Simulated-implant | | | | |
| | | | 2 V/m(bpm) | 50 V/m(bpm) | 2 V/m(bpm) | 10 V/m(bpm) | 20 V/m(bpm) | 40 V/m(bpm) | 50 V/m(bpm) |
| General Electric | A2072D | 891930 | 8(0) | | 29(0) | 29(71)<br>207(122) | | | |
| | A2075A | 937015 | 10(0) | 15(78) | 51(0) | 51(78)<br>141(125) | | | |
| | | 937147 | | | 23(0) | 33(69)<br>141(125) | | | |
| | | 937164 | | | 36(0) | 36(67) | | | |
| Medcor | 3-70A | 2015 | 13(0) | 17(69) | 29(0) | 33(69)<br>141(0) | 33(71)<br>141(0) | 33(69)<br>141(0) | |
| | | 3753 | | | 33(0) | 33(68)<br>141(0) | | | |
| | | 3754 | | | 58(0) | 58(71)<br>141(0) | | | |
| Medtronic | 5842 | 3M00123 | 5(0) | 3(0) | 15(0) | | 15(0) | 15(0) | 15(46)<br>85(0) |
| | | 3M00154 | | | | | | 13(0) | 13(46)<br>85(0) |
| | | 3M00158 | | | 13(0) | | 12(0) | 13(30)<br>51(0) | 13(53) |
| | 5942 | 3K04597 | 3(0) | 2(51) | 12(0) | | | 12(0) | 12(51) |
| | | 3K20660 | | | | | | 26(0) | 26(36) |
| | | 3K29624 | | | | | 51(0) | 51(35) | 51(46) |

TABLE 2 (Cont'd)

| Manufacturer | Model No. | Serial No. | Threshold values, 450 MHz — Pulse repetition rate (pps) — Free-field: 2 V/m(bpm) | Free-field: 50 V/m(bpm) | Simulated-implant: 2 V/m(bpm) | Simulated-implant: 10 V/m(bpm) | Simulated-implant: 20 V/m(bpm) | Simulated-implant: 40 V/m(bpm) | Simulated-implant: 50 V/m(bpm) |
|---|---|---|---|---|---|---|---|---|---|
| Medtronic | 5943 | 1L1282N | 6(0) | | 23(0) | | 19(0) | 19(47) | |
| | 5944 | 3G20824 | 6(0) | 5(43) | 26(0) | 19(0) | 19(43) | 19(43) | |
| | | 3G20877 | | | | 26(0) | 26(42) | | |
| | | 3G20881 | | | | 33(0) | 33(42) | | |
| | 5950 | 3XX2022[c] | >292 | | >292 | | | >292 | |
| | 5951 | 3XX2025[c] | >292 | | >292 | | | >292 | |
| | 9000 | 3R00001 | 1(0) | .7(41) | 21(0) | | 17(0) | 21(45) | |
| | | 3R00003 | | | | 10(0) | 10(0) | 10(37) | |
| | | 3R00004 | | | | 10(0) | 7(0) | 7(48) | |
| Pacesetter | BD-101 | 1196KC | >292 | | >292 | | | >292 | |
| | | 1395JD | | | >292 | | | >292 | |
| | | 1404ND | | | >292 | | | >292 | |
| Starr-Edwards | 8114 | 4399 | 33(0) | 33(65) | 23(0) | 26(65) | 26(65) | | |
| | 8116 | ELX15514 | >292 | | >292 | | | >292 | |
| | | ELX15518 | | | >292 | | | >292 | |
| | | ELX15520 | | | >292 | | | >292 | |

[c] Pre-production prototype pacemaker designs.

TABLE 2 (Cont'd)

| Manufacturer | Model No. | Serial No. | Threshold values, 450 MHz Pulse repetition rate (pps) Free-field 2 V/m(bpm) | 50 V/m(bpm) | Simulated-implant 2 V/m(bpm) | 10 V/m(bpm) | 20 V/m(bpm) | 40 V/m(bpm) | 50 V/m(bpm) |
|---|---|---|---|---|---|---|---|---|---|
| Stimtech | 3821 | H38030 | 46(0) | 46(107) | 107(0) | 114(0) | 114(107) | | |
| | | J38015 | | | >292 | | >292 | | |
| | | J38016 | | | 114(0) | 114(67) | | | |
| Vitatron | MIP-40-RT | 0505 | 40(0) | 141(72) | 141(0) | 141(74)<br>243(0) | 207(81)<br>243(0) | 141(72)<br>243(0) | |
| | | 0507 | | | 93(0) | 92(70)<br>243(0) | 85(69) | 114(70)<br>243(0) | |
| | | 5146 | | | 93(0) | 107(0) | 114(72)<br>243(0) | | |

TABLE 3. FREE-FIELD PACEMAKER EMI THRESHOLDS

| Manufacturer | Model No. | Serial No. | Threshold values, 3100 MHz Pulse repetition rate (pps) 7 V/m(bpm) | 10 V/m(bpm) | 20 V/m(bpm) | 40 V/m(bpm) | 100 V/m(bpm) | 200 V/m(bpm) | 400 V/m(bpm) |
|---|---|---|---|---|---|---|---|---|---|
| American Optical | 281003 | 11591 | 159(0) | 141(0) | 141(0) | 88(70) | 129(75) | 129(75) | 141(72) |
| | | A6124 | | 71(0) | 71(0) | 88(69) | 77(75) | 71(77) | 77(75) |
| | | A6995 | | 229(0) | 129(71)[a] | 129(70) | 141(72) | 141(73) | 141(74) |
| | | | | | 229(0)[a] | | | | |
| | 281013 | A2202 | | 77(0) | 71(0) | 33(71) | 57(72) | 57(74) | 52(72) |
| | | A2545 | 77(0) | 52(0) | 57(0) | 64(70) | 29(75) | 43(77) | 52(76) |
| | | | | | | 282(0) | | | |
| | 281143 | 27322 | | >320[b] | >320 | | >320 | | >320 |
| | | 27560 | | >320 | >320 | | >320 | | >320 |
| | | 27312 | | >320 | >320 | | >320 | | >320 |
| Biotronik | IDP-44 | 55038 | | >320 | >320 | >320 | >320 | >320 | >320 |
| | | 61034 | | >320 | >320 | >320 | >320 | >320 | >320 |
| | | 61035 | | >320 | >320 | >320 | >320 | >320 | >320 |
| | | 61443 | | >320 | >320 | >320 | >320 | >320 | >320 |
| Cordis | 133C6 | 2210 | | 204(86) | 116(62) | 116(64) | 102(64) | 64(64) | 88(63) |
| | 133C7 | 2352 | 36(105) | 43(118) | 43(117) | 43(104) | 43(83) | 43(73) | 102(87) |
| | | | | | | | 248(177) | 204(126) | |
| | | 2958 | | 71(117) | 71(101) | 71(103) | 71(80) | 71(75) | 71(75) |
| | | | | 266(123) | 229(148) | 248(159) | 223(124) | 204(124) | 229(124) |
| | 143E7 | 11575 | | 40(0) | 40(76) | 40(76) | 36(76) | 40(76) | 43(76) |

[a] Throughout Table 3, double entries indicate the existence of both insignificant and significant thresholds.

[b] Such entries indicate that pacemaker not affected to limit of test.

TABLE 3 (Cont'd)

| Manufacturer | Model No. | Serial No. | Threshold values, 3100 MHz Pulse repetition rate (pps) 7 V/m(bpm) | 10 V/m(bpm) | 20 V/m(bpm) | 40 V/m(bpm) | 100 V/m(bpm) | 200 V/m(bpm) | 400 V/m(bpm) |
|---|---|---|---|---|---|---|---|---|---|
| Cordis | 162C | 342 | | 302(0) | 302(69) | 302(69) | 320(69) | >320 | >320 |
| | | 4246 | | >320 | >320 | >320 | >320 | >320 | >320 |
| | | 5290 | | 229(14) | 248(54) | 248(67) | 266(67) | 302(67) | >320 |
| | 164A | 118 | | 159(69) | 159(69) | 159(69) | 178(69) | 178(69) | 204(69) |
| | | 284 | | 141(70) | 141(70) | 141(70) | 141(70) | 141(70) | 178(70) |
| | | 286 | 102(105) | 116(70) | 116(70) | 129(70) | 129(70) | 129(70) | 141(70) |
| General Electric | A2072D | 888012 | | 204(88) | 229(93) | 266(105) | 266(104) | 248(100) | 255(100) |
| | | 891930 | 77(71) | 102(71) | 102(72) | 116(72) | 159(76) | 159(77) | 141(75) |
| | | | | 248(201) | 248(205) | 248(217) | 266(240) | 248(158) | 266(150) |
| | A2075A | 937015 | | >320 | >320 | >320 | >320 | >320 | >320 |
| | | 937147 | | >320 | >320 | >320 | >320 | >320 | >320 |
| | | 937164 | | 302(86) | >320 | 320(76) | >320 | >320 | >320 |
| Medcor | 3-70A | 2015 | | 77(70) | 77(70) | 77(71) | 77(72) | 77(73) | 77(74) |
| | | | | | 266(120) | 248(121) | 266(126) | 266(121) | 266(126) |
| | | 3753 | | 60(71) | 60(71) | 60(71) | 60(68) | 60(72) | 60(72) |
| | | | | 302(147) | 266(133) | 266(132) | 266(130) | 266(129) | 266(120) |
| | | 3754 | | 102(71) | 102(71) | 102(71) | 102(71) | 102(72) | 102(72) |
| | | | | 266(150) | 266(151) | 266(142) | 266(138) | 266(128) | 282(150) |
| Medtronic | 5842 | 03851KK | | 47(0) | 43(0) | 43(52) | 43(53) | 43(54) | 43(54) |
| | | | | | | 204(0) | 178(0) | 159(0) | 159(0) |
| | | 16669KK | | 102(0) | 102(0) | 102(53) | 102(54) | 102(54) | 88(52) |
| | | | | | | 229(0) | 229(0) | 229(0) | 204(0) |

TABLE 3 (Cont'd)

| Manufacturer | Model No. | Serial No. | Threshold values, 3100 MHz Pulse repetition rate (pps) 7 V/m(bpm) | 10 V/m(bpm) | 20 V/m(bpm) | 40 V/m(bpm) | 100 V/m(bpm) | 200 V/m(bpm) | 400 V/m(bpm) |
|---|---|---|---|---|---|---|---|---|---|
| Medtronic | 5842 | 2M00520 | | 40(0) | 40(0) | 40(47) | 40(49) | 40(53) | 40(52) |
| | | 2M00522 | | 57(0) | 52(0) | 52(45) | 52(47) | 52(49) | 52(49) |
| | | | | | | 204(0) | | | |
| | | 2M00815 | | 47(0) | 43(0) | 43(48) | 43(48) | 43(49) | 43(50) |
| | | | | | | 302(0) | 266(0) | 248(0) | 248(0) |
| | | 2M00981 | | 71(0) | 71(0) | 71(44) | 71(47) | 71(49) | 77(52) |
| | | | | | | 229(0) | | | |
| | | 2M02202 | | 36(0) | 36(0) | 36(0) | 36(53) | 40(59) | 36(55) |
| | | 3M00123 | 71(0) | 52(0) | 52(0) | 52(0) | 52(50) | 52(51) | 52(50) |
| | | 3M00154 | | 52(0) | 52(0) | 52(0) | 52(51) | 52(54) | 52(53) |
| | | 3M00158 | 33(0) | 33(0) | 33(0) | 33(32) | 33(54) | 33(54) | 33(54) |
| | | | | | | 129(0) | | | |
| | 5942 | 1K19384 | | 229(0) | 229(0) | 229(55) | 229(55) | 229(55) | 204(55) |
| | | 1K33732 | | 141(0) | 141(0) | 141(55) | 141(55) | 159(55) | 159(55) |
| | | 1K39359 | | 302(0) | 302(0) | 282(47) | 282(47) | 302(50) | 320(58) |
| | | 2K18159 | | 159(0) | 159(0) | 159(0) | 159(52) | 159(52) | 159(52) |
| | | 3K04222 | | >320 | >320 | >320 | >320 | >320 | >320 |
| | | 3K04597 | 159(0) | 88(0) | 88(0) | 88(0) | 88(49) | 88(49) | 88(49) |
| | | 3K18607 | | >320 | >320 | >320 | >320 | >320 | >320 |
| | | 3K20660 | 159(0) | 159(0) | 159(0) | 159(0) | 141(48) | 141(48) | 141(48) |
| | | 3K29624 | | 282(0) | 282(0) | 302(0) | 302(49) | 282(49) | 242(49) |
| | 5943 | 1L1282N | 77(0) | 102(0) | 88(0) | 88(47) | 88(47) | 88(47) | 60(48) |

TABLE 3 (Cont'd)

| Manufacturer | Model No. | Serial No. | Threshold values, 3100 MHz Pulse repetition rate (pps) 7 V/m(bpm) | 10 V/m(bpm) | 20 V/m(bpm) | 40 V/m(bpm) | 100 V/m(bpm) | 200 V/m(bpm) | 400 V/m(bpm) |
|---|---|---|---|---|---|---|---|---|---|
| Medtronic | 5944 | 3G20824 | 248(0) | 266(0) | 266(48) | 266(48) | 266(48) | 266(48) | 266(48) |
| | | 3G20877 | 129(0) | 178(0) | 178(50) | 178(50) | 178(50) | 178(50) | 178(50) |
| | | 3G20881 | | 302(0) | 302(46) | 302(46) | 302(46) | 302(46) | 282(47) |
| | 5950 | 3XX2022[c] | | >320 | >320 | >320 | >320 | >320 | >320 |
| | 5951 | 3XX2025[c] | | >320 | >320 | >320 | >320 | >320 | >320 |
| | 9000 | 3R00001 | 71(0) | 57(0) | 57(0) | 52(44) | 57(50) | 57(50) | 60(51) |
| | | 3R00003 | >320 | >320 | >320 | >320 | >320 | >320 | >320 |
| | | 3R00004 | | >320 | >320 | >320 | >320 | >320 | >320 |
| Pacesetter | BD-101 | 1196KC | | >320 | >320 | >320 | >320 | >320 | >320 |
| | | 1395ND | | >320 | >320 | >320 | >320 | >320 | >320 |
| | | 1404ND | | >320 | >320 | >320 | >320 | >320 | >320 |
| Starr-Edwards | 8114 | 4399 | 88(0) | 60(0) | 60(65) | 60(65) | 60(65) | 60(65) | 60(65) |
| | 8116 | ELX15514 | | >320 | >320 | >320 | >320 | >320 | >320 |
| | | ELX15518 | | >320 | >320 | >320 | >320 | >320 | >320 |
| | | ELX15520 | | >320 | >320 | >320 | >320 | >320 | >320 |
| Stimtech | 3821 | CA-88 | | 178(0) | 178(0) | 178(0) | 159(107) | 159(107) | 178(107) |
| | | H38030 | | >320 | >320 | >320 | >320 | >320 | >320 |
| | | J38015 | | 302(0) | 302(0) | 302(0) | 302(107) | 302(107) | 320(107) |
| | | J38016 | | 320(0) | 320(0) | 320(0) | >320 | >320 | >320 |
| Vitatron | MIP-40-RT | 0505 | | 204(85) | 204(36) | 204(84) | 204(84) | 204(86) | 204(77) |
| | | | | | | 229(124) | 248(162) | 229(124) | 266(148) |
| | | 0507 | | 302(375) | | | | | 320(117) |
| | | 5146 | | 178(75) | 178(75) | 178(76) | 178(75) | 178(75) | 102(68) |
| | | | | 229(150) | 229(149) | 229(161) | 229(156) | 229(156) | 320(118) |

[c] Pre-production prototype pacemaker designs.

TABLE 4. SIMULATED-IMPLANT PACEMAKER EMI THRESHOLDS

| Manufacturer | Model No. | Serial No. | Threshold values, 3100 MHz<br>Pulse repetition rate (pps)<br>7<br>V/m(bpm) | 20<br>V/m(bpm) | 40<br>V/m(bpm) | 100<br>V/m(bpm) | 400<br>V/m(bpm) |
|---|---|---|---|---|---|---|---|
| American Optical | 281003 | 11591 | | >320[a] | | >320 | >320 |
| | 281013 | A2545 | >320 | 320(0) | >320 | >320 | >320 |
| | 281143 | 27560 | >320 | >320 | | >320 | >320 |
| Biotronik | IDP-44 | 61035 | >320 | >320 | | >320 | >320 |
| Cordis | 133C7 | 2352 | 141(105) | 141(110) | | >320 | >320 |
| | 143E7 | 11575 | 282(0) | 302(76 | | 141(73) | 141(72) |
| | 162C | 5296 | 302(0) | 320(67) | | >320 | >320 |
| | 164A | 286 | 320(104) | 320(72) | | >320 | >320 |
| General Electric | A2072D | 891930 | >320 | >320 | | >320 | >320 |
| | A2075A | 937147 | >320 | >320 | | >320 | >320 |
| Medcor | 3-70A | 3753 | 116(71) | 116(71) | | 129(71) | 129(71) |
| Medtronic | 5842 | 3M00123 | >320 | | >320 | | |
| | | 3M00158 | >320 | >320 | | >320 | >320 |

[a] Such entries indicate that pacemaker not affected to limit of test.

TABLE 4 (Cont'd)

| Manufacturer | Model No. | Serial No. | Threshold values, 3100 MHz Pulse repetition rate (pps) 7 V/m(bpm) | 20 V/m(bpm) | 40 V/m(bpm) | 100 V/m(bpm) | 400 V/m(bpm) |
|---|---|---|---|---|---|---|---|
| Medtronic | 5942 | 3K04597 | >320 | >320 | | >320 | >320 |
| | | 3K20660 | >320 | | >320 | | |
| | 5943 | 1L12821 | >320 | >320 | | >320 | >320 |
| | 5944 | 3G20824 | >320 | | >320 | | |
| | | 3G20877 | | >320 | | >320 | >320 |
| | 5950 | 3XX2022[b] | >320 | >320 | | >320 | >320 |
| | 5951 | 3XX2025[b] | >320 | >320 | | >320 | >320 |
| | 9000 | 3R00001 | >320 | >320 | >320 | >320 | >320 |
| Pacesetter | BD-101 | 1395ND | >320 | >320 | | >320 | >320 |
| Starr-Edwards | 8114 | 4399 | 204(0) | 204(65) | | 229(65) | 248(65) |
| | 8116 | ELX15518 | >320 | >320 | | >320 | >320 |
| Stimtech | 3821 | J38015 | >320 | >320 | | >320 | >320 |
| Vitatron | MIP-40-RT | 5146 | >320 | >320 | | >320 | >320 |

[b] Pre-production prototype pacemaker designs.

TABLE 5. PACEMAKER EMI ATTENUATION IN SALINE SOLUTION

| Manufacturer | Model No. | Attenuation (dB) 450 MHz | Attenuation (dB) 3100 MHz |
|---|---|---|---|
| American Optical | 281003 | 5.1 | |
| | 281013 | 13.1 | >12.3 |
| Biotronik | IDP-44 | 11.0 | |
| Cordis | 133C7 | 14.2 | 11.9 |
| | 143E7 | 3.2 | |
| | 162C | 3.2 | |
| | 164A | 15.3 | 9.9 |
| General Electric | A2072D | 10.8 | 12.3 |
| | A2075A | 13.9 | |
| Medcor | 3-70A | 6.9 | |
| Medtronic | 5842 | 8.9 | >19.8 |
| | 5942 | 11.0 | > 6.1 |
| | 5943 | 11.1 | >12.3 |
| | 5944 | 12.3 | > 2.2 |
| | 9000 | 25.3 | >13.1 |
| Starr-Edwards | 8114 | -3.2 | 11.2 |
| Stimtech | 3821 | 7.3 | |
| Vitatron | MIP-40-RT | 11.0 | |

## ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| ac | alternating current |
| bpm | beats per minute |
| cm | centimeter(s) |
| CW | continuous wave |
| dB | decibel(s) |
| ECG | electrocardiographic |
| E-field | electric field strength (V/m) |
| EMI | electromagnetic radiation interference |
| EMR | electromagnetic radiation |
| GIT | Georgia Institute of Technology |
| kHz | kilohertz |
| LED | light-emitting diode |
| MHz | megahertz |
| min | minute(s) |
| µsec | microsecond(s) |
| msec | millisecond(s) |
| mW | milliwatt(s) |
| pps | pulse(s) per second |
| PRR | pulse repetition rate |
| RF | radiofrequency |
| rms | root mean square |
| sec | second(s) |
| V/m | volt(s) per meter |