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MEASURED EFFECTS OF 450-, 350-, AND 250-MHZ PULSED AND 26-MHZ C--ETC(U)
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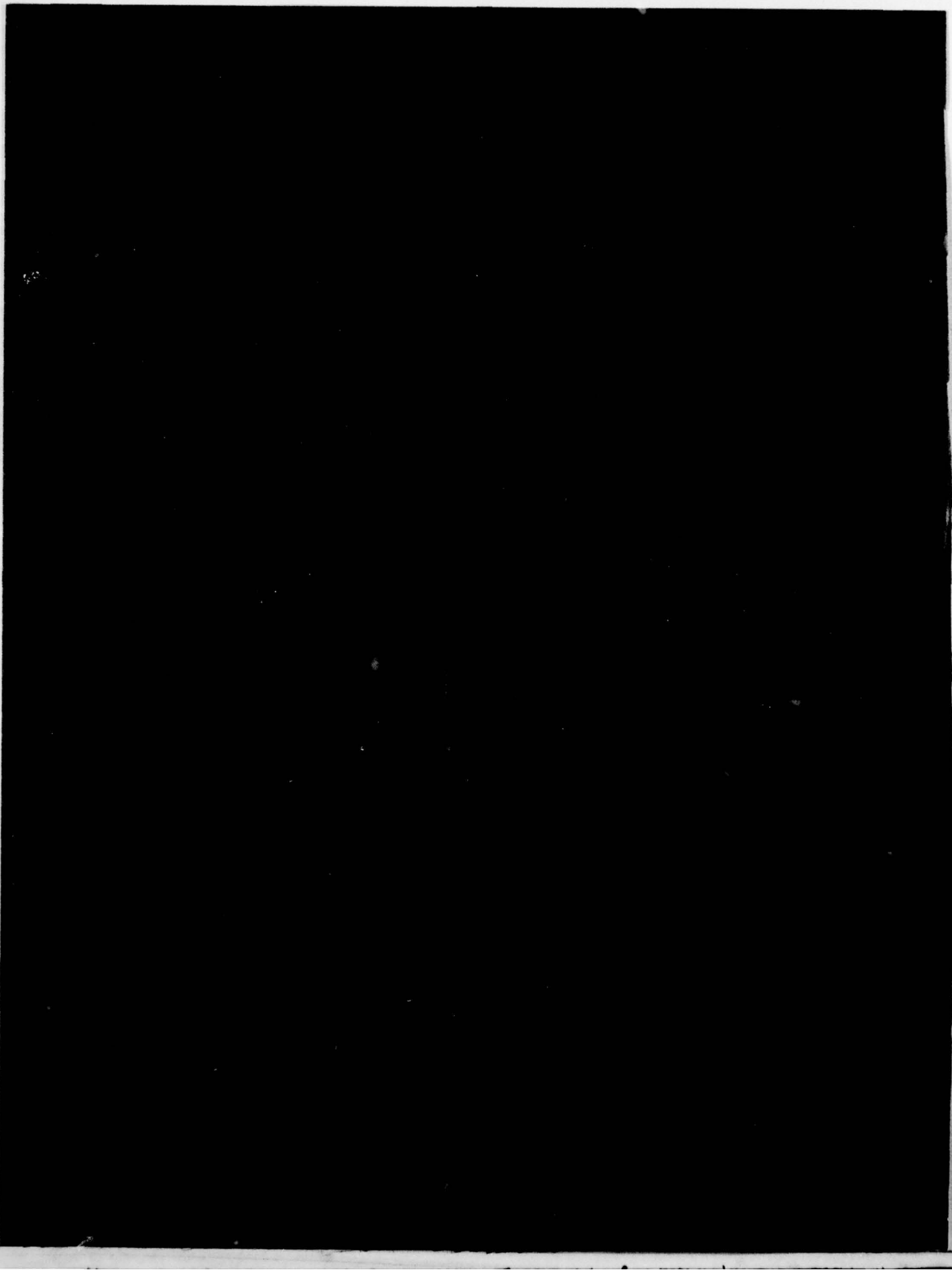

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Tests were performed to measure the effects of 450-, 350-, and 250-MHz pulsed and 26-MHz CW radiofrequency radiation on cardiac pacemakers. Thirty-three pacemaker models from fourteen different manufacturers were tested both in a free field and simulated implant configuration. The test results presented indicated that the majority of the manufacturers represented had succeeded in producing EMI-resistant pacemakers.

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MEASURED EFFECTS OF 450-, 350-, AND 250-MHz PULSED AND 26-MHz CW RADIOFREQUENCY FIELDS ON CARDIAC PACEMAKERS

INTRODUCTION

Electromagnetic interference (EMI) of medical prosthetic devices such as the cardiac pacemaker is a unique biological effect of nonionizing radiofrequency radiation. The potential hazard of such interactions was well established soon after the development of the demand-type pacemaker, which makes up the majority of currently implanted pacemakers. Demand pacemakers sense the depolarizations of the heart muscle activity and produce their own depolarization signals (electrical stimulus) only if the normal heart depolarizations are not present. Energy pulses induced externally via the pacemaker leads or circuitry can erroneously cause the pacemaker to inhibit its needed output. In addition, in some pacemakers, depending on the electronic circuitry, EMI can induce changes in pacemaker pulse rate of sufficient magnitude to be considered hazardous without actually inhibiting pacemaker output.

Since 1972 the USAF School of Aerospace Medicine (USAFSAM) has been conducting tests on the EMI characteristics of cardiac pacemakers, both in the USAFSAM radiofrequency radiation (RFR) laboratory and in close proximity to a variety of Air Force RF emitters (1-5). During this period of time, the manufacturers have continuously improved the EMI characteristics of their product and have significantly reduced the potential hazard. The following report provides the results of tests conducted at USAFSAM in 1976-1978 on some of the more recently available pacemakers and serves as an addendum to the previous reports.

TEST PROCEDURES

Implant Simulation

Realistic assessment of the effects of radiofrequency electromagnetic radiation (EMR) on cardiac pacemakers requires actual implant conditions or accurate simulation of implantation. At USAFSAM a pacemaker test chamber is used to simulate implant conditions. The chamber is designed to specifications set forth in a protocol for cardiac pacemaker testing drafted by the Association for the Advancement of Medical Instrumentation (AAMI). The chamber consists of an 80 x 40 x 20 cm container made of 5-cm-thick low dielectric plastic foam (density of 0.035 g/cm^2). This container is filled with 0.03 molar saline solution. The pacemaker is placed in the solution on a plastic frame such that

approximately 1 cm of solution lies between the pacemaker and its leads and the anterior (source) side of the container. The pacemaker lead is stretched out horizontally, and the pacemaker response is picked up via 2 x 2 cm copper mesh electrodes placed in the solution at both ends of the container. The signal is fed out via lossy line leads to an electrocardiogram amplifier. The amplified signal in turn is relayed to a strip-chart recorder and Hewlett-Packard Model 5360A computing counter. The computing counter is used to give a direct readout of pacemaker pulse rate. A more complete description of this system can be found in a previous report (4).

Tests were also conducted under "free field" conditions as per the AAMI recommendation. In this mode the pacemakers were exposed in the pacemaker container without the saline solution. An LED fiber optics monitoring system was used to feed the pacemaker output to the computing counter and strip-chart recorder. A complete description of this system can be found elsewhere (6). Only the simulated implant data is presented herein.

Both sides of the pacemaker were tested in accordance with the AAMI protocol; that is, first one, and then the other, side of the pacemaker was exposed to the RF source. In some instances a difference was observed in EMI sensitivity from one side to the other. In this situation the lowest EMI threshold value is presented in this report.

Instrumentation

Four radiation frequencies were used: 26, 250, 350, and 450 MHz. The 26-MHz exposures were conducted under continuous wave (CW) conditions in a copper-screen TEM exposure chamber. The radiation source was provided by a Federal Telephone & Radio Corp. AN/FRT-6B transmitter. The maximum E-field obtained was 850 V/m.

The 250-, 350-, and 450-MHz tests were performed in the USAFSAM RFR anechoic chamber. The radiation source was a Microwave Cavity Laboratory (MCL) Model 15022 power generator, amplifed by an MCL Model 10110 power amplifier (up to 1000 W) and fed via an air dielectric "Heliax" transmission line to an EMCO Model 3101 conical longspiral antenna. The maximum E-fields obtained were 270, 300, and 330 V/m, respectively.

The RF fields at the test location were measured with a National Bureau of Standards (NBS) 5-cm dipole antenna field intensity probe. The voltage output of the dipole probe is fed via lossy line to a Kiethly Model 600B electrometer. The E-field was measured as a function of transmitter power output at each test frequency. In the 26-MHz exposures the power output was monitored with a Bird Thruline Model 3122 wattmeter. A Bird Thruline Model 43 wattmeter was used to monitor the power output at 250, 350, and 450 MHz.

The RF field as a function of output power was measured in the empty pacemaker chamber at the pacemaker position. In addition, the field was

mapped across the length of the pacemaker chamber with the power output constant. The E-field distribution across the chamber was found to be approximately "Gaussian." The E-field value listed with the data is the average value across the length of the chamber. The maximum E-field at the center of the chamber was approximately 10% higher than the average value.

Free-field tests were then conducted in the test chamber. The pacemaker performance was monitored as a function of gradually increasing RF output power. Those power levels at which the pacemaker performance was affected were noted on the strip chart recorded along with the measured pacemaker pulse rate as given by the computing counter. When the free-field tests were completed, the chamber was filled with saline solution, and the tests were repeated in the simulated-implant mode. The pacemakers were tested on both sides in both modes.

TEST RESULTS

A total of 33 pacemaker models from 14 different manufacturers were evaluated to establish their relative electromagnetic interference susceptibilities as a function of the radiation frequency, pulse width, and E-field intensity.

Twenty were current production models or test models planned for production at the time of the initiation of the study provided by the manufacturers for evaluation. The remainder were different models, chosen from the USAFSAM pacemaker inventory, that had been tested previously for EMI susceptibility at 450 MHz under simulated-implant conditions (3, 4). Their inclusion served (1) to check the validity of current EMI test procedures, and (2) to confirm prior EMI test results under more accurately controlled laboratory conditions.

The test results are summarized in Table 1. A survey of the manufacturers at the time of the writing of this report indicates that eighteen of the models tested were no longer in production. Of these obsolete models, thirteen (72%) exhibited definite EMI susceptibility below 200 V/m, the required E-field limit recommended in the AAMI protocol. Of the fifteen models still in current production or planned for production, ten (67%) exhibited no EMI susceptibility below 200 V/m, thereby showing a marked improvement in the EMI reliability of current pacemaker models.

Of the thirteen models with previous EMI test data, agreement with prior test results was achieved with regard to susceptibility or non-susceptibility for eleven cases. The two exceptions were the CPI Models 301UD and 401BD, which exhibited EMI susceptibility in the present study, but did not do so previously (4). The former was found to be quite a bit more sensitive on the back (nonlabel) side, which was not looked at in the previous study at 450 MHz. In the case of the 401BD, both sides were equally susceptible at 450 MHz to EMI in the present study.

Two of the manufacturers, American Optical and General Electric, were found to be no longer manufacturing pacemakers. Of the twelve still producing pacemakers, nine had models with EMI thresholds greater than 200 V/m, thus demonstrating that the majority of manufacturers represented had succeeded in developing high-quality EMI-resistant pacemakers.

DISCUSSION

The data in Table 1 illustrates the extent to which pacemaker EMI depends on the emission characteristics of the radiation source. For example, none of the pacemaker models tested exhibited any EMI below 200 V/m for the continuous-wave fields at 26 MHz, whereas 18 pacemaker models exhibited EMI below 200 V/m in the pulsed radiation modes. Of the 15 pacemaker models which exhibited no EMI below 200 V/m in the pulsed radiation modes, the majority were the newer production models or the test models, indicating that most of the manufacturers have succeeded in developing pacemakers that are compatible with the electromagnetic environment.

In general, those pacemakers found to be affected in the "free field" mode of exposure were also found to be affected in the simulated-implant mode, with the EMI thresholds somewhat higher in the latter case, illustrating the effect of shielding as a protective factor. In addition, testing of the pacemakers on both sides in some cases revealed differences in EMI threshold, thus illustrating the added effect of pacemaker orientation.

CONCLUSION

Cardiac pacemaker EMI is strongly dependent on frequency, pulse width, E-field level, and pulse repetition rate of the incident radiation signal. Also important are shielding and pacemaker orientation. These test results (Table 1) provide substantial evidence of continued overall improvement in the EMI characteristics of currently marketed cardiac pacemakers. These findings demonstrate the technical feasibility of manufacturing high-quality EMI-resistant pacemakers, thus resolving a problem that existed with devices marketed in the early 1970s.

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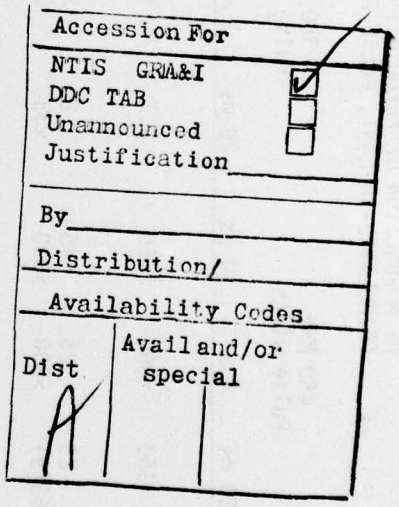

TABLE 1. CARDIAC PACEMAKER EMI THRESHOLDS IN VOLTS/METER AS A FUNCTION OF FREQUENCY AND PULSE WIDTH (SIMULATED-IMPLANT, PULSE REPETITION RATE, 10 PPS)

Pacemaker	450 MHz Pulse width			350 MHz Pulse width			250 MHz Pulse width			26 MHz
	20 ms	1 ms	10 μs	20 ms	1 ms	10 μs	20 ms	1 ms	10 μs	CW
American										
1613	>360	>360	>360	N.T.	N.T.	N.T.	N.T.	N.T.	N.T.	N.T.
American Optical										
281003 N.L.I.P.	25	25	45	20	20	72	20	20	32	670
281143[a] N.L.I.P.	265(5)	>330	>330	>330	>300	>300	>270	>270	>270	>850
Biotronik										
IDP-44	110(5)	125(5)	>330	60(5)	60(5)	>300	20	20	145	>850
IDP-54	165(5)	40(5)	290	70	70(5)	>300	45(5)	45	>270	390
Cardiac Pacemakers, Inc.										
301UD N.L.I.P.	85(5)	145(5)	>330	55	120	>300	30(5)	50	>270	550
401BD N.L.I.P.	30(5)	75(5)	>330	110	185	>300	20(5)	30(5)	>270	620
501UD	>330	>330	>330	>300	>300	>300	>270	>270	>270	230
Coratomic										
L-500	>360	>360	>360	N.T.	N.T.	N.T.	N.T.	N.T.	N.T.	N.T.
Cordis										
Stanicor K "DX"[b]	>330	>330	>330	>300	>300	>300	>270	>270	>270	>850
Stanicor K "D"[b]	>330	>330	>330	>300	>300	>300	>270	>270	>270	>850
Omni Stanicor 162C N.L.I.P.	20	20	80(5)	20(5)	20	230	20	20	30	>850
General Electric										
A2075A[b] N.L.I.P.	165(5)	260	235	90(5)	30(5)	105	20	20	>270	660
Medcor										
"C" (Equiv 3-70C)	>330	>330	>330	>300	>300	>300	>270	>270	>270	720
3-70A N.L.I.P.	20(5)	25(5)	70(5)	20(5)	20(5)	110	20(5)	20(5)	75(5)	>850
3-70B N.L.I.P.	20(5)	30(5)	90(5)	20(5)	25	35(5)	20(5)	20	230(5)	>850

[a] 3 pacers tested
[b] Test model

TABLE 1 (continued)

Pacemaker		450 MHz Pulse width 20 ms	450 MHz Pulse width 1 ms	450 MHz Pulse width 10 μs	350 MHz Pulse width 20 ms	350 MHz Pulse width 1 ms	350 MHz Pulse width 10 μs	250 MHz Pulse width 20 ms	250 MHz Pulse width 1 ms	250 MHz Pulse width 10 μs	26 MHz CW
Medtronic											
5842	N.L.I.P.	25	25	40	20	20	25	20	20	27	>850
5942	N.L.I.P.	30	30(5)	195	N.T.	N.T.	N.T.	20	20	230	>850
5944	N.L.I.P.	55	85	>330	70	140	>300	185(5)	>270	>270	N.T.
5950	N.L.I.P.	>330	>330	>330	>300	>300	>300	>270	>270	>270	>850
5972		>330	>330	>330	>300	>300	>300	>270	>270	>270	>850
5973		>330	>330	>330	>300	>300	>300	>270	>270	>270	>850
9000		25	25	190	20	25	>300	>270	>270	>270	>230
Pacesetter Systems Inc.											
BD-101	N.L.I.P.	>330	>330	>330	>300	>300	>300	>270	>270	>270	760
Starr-Edwards											
8114	N.L.I.P.	30(5)	30(5)	50	20	30	85	20	20	35	620
8116	N.L.I.P.	>330	>330	>330	>300	>300	>300	>270	>270	>270	>850
Edwards Laboratories											
8116S	N.L.I.P.	>330	>330	>330	>300	>300	>300	>270	>270	>270	>850
20S		>330	>330	>330	>300	>300	>300	>270	>270	>270	>850
21S		>330	>330	>330	>300	>300	>300	>270	>270	>270	>850
Stimtech											
3821	N.L.I.P.	30	105	>330	20	45	>300	35	110(5)	>270	560
Vitatron Medical											
MIP-40RT	N.L.I.P.	25(5)	50	310	20(5)	20	300	20(5)	20	40	850
MIP-42RT1.0		25	35(5)	110	20	50(5)	300	20	20	270	350
MIP-42RT0.5		30(5)	90(5)	200(5)	20	55(5)	300	20	20	105(5)	590

NOTE: The maximum E-fields available were 360, 300, 270, and 850 V/m for the 450-, 350-, 250-, and 26-MHz frequencies, respectively.

(5) These EMI thresholds were observed at 5 pps.

N.T. Not tested.

N.L.I.P. No longer in production.

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