Bra UNCLAS SECURITY CLASSIFICATION OF THIS PAGE (When Date Entered) **READ INSTRUCTIONS REPORT DOCUMENTATION PAGE** BEFORE COMPLETING FORM REPORT NUMBER 2. GOVT ACCESSION NO. 3. RECIPIENT'S CATALOG NUMBER THE XIL SAM-TR- 73-304 5. TYPE OF REPORT & PERIOD COVERED TITLE (and Subtitle) 6 Technical Paper Empirical Studies of Cardiac Pacemaker Aug 72 - Apr 73, Interference. 2 ENFORMING ORG. REPORT NUMBER 9 AUTHOR(A) CONTRACT OR GRANT NUMBER(#) John C. Mitchell, William D. Hurt, 16 William H./Walters III and James K./Miller AF-175 ADA011 PERFORMING ORGANIZATION NAME AND ADDRESS GRAM ELEMENT, PROJECT USAF School of Aerospace Medicine (RAP) Aerospace Medical Division (AFSC) 77570146 Brooks AFB TX 78235 11. CONTROLLING OFFICE NAME AND ADDRESS USAF School of Aerospace Medicine (RAP) 12. REPORT DATE Feb 1974 Aerospace Medical Division (AFSC) 13. NUMBER OF PAGES Brooks AFB TX 78235 14. MONITORING AGENCY NAME & ADDRESS(If different from Controlling Office) 15. SECURITY CLASS. (of this report) 1973 UNCLASSIFIED 15a. DECLASSIFICATION/DOWNGRADING SCHEDULE 16. DISTRIBUTION STATEMENT (of this Report) Approved for public release; distribution unlimited 17. DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report) 18. SUPPLEMENTARY NOTES 19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Cardiac pacemakers Electromagnetic interference Radiofrequency radiation effects on pacemakers Radar effects on pacemakers 20. BSTRACT (Continue on reverse side if necessary and identify by block number) To evaluate the relative susceptibility of cardiac pacemakers to electromagnetic radiation interference, tests were conducted at several representative radar sites in the United States. The 21 pacemakers, of different types and manufacture, were evaluated in a "free-field" configuration as well as in a saline solution phantom (implantation simulation). Test results are pre-sented for five frequency bands between 200 and 6,000 MHz. Many pacemakers skipped one or two beats when the main beam of the radars scanned past the DD 1 JAN 73 1473 EDITION OF 1 NOV 65 IS OBSOLETE UNCLAS SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

UNCLAS SECURITY CLASSIFICATION OF THIS PAGE(When Data Entered) point of closest approach. This effect, observed regularly for some pacemakers at distances out to a mile or more from 'he radar, might result in a pacemaker patient losing a normal heartbeat every 10-12 sec (about 5-6 beats per minute). Although this interference is not considered a threat to life, the effect can become more serious for a patient closer to the radar-depending on the particular pacemaker in use, the state of the patient's health, and the activity in which he is involved. THE CONSTRUCTION OF A DAMAGE will avoit / in colf. w - School newspace Links -"l'ensels ississit entres. GEC L STAT MAA L IMMAR Band ment the state of a second 이상님께는 노동 방법에 위해 이상해. Established all the second as a life, and inclusion The second second will be a second building and ad to see a second contract of the second -ulasantitu (mangalas and producto and solar and the rest of the conversion of the second second to and the second an and the second se see the least plan have control from the second and a second she UNCLAS SECURITY CLASSIFICATION OF THIS PAGE(When Data Entered)

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Clinical Aviation and Aerospace Medicine

Empirical Studies of Cardiac Pacemaker Interference

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To evaluate the relative susceptibility of cardiac pacemakers to electromagnetic radiation interference, tests were conducted at several representative radar sites in the United States. The 21 pacemakers, of different types and manufacture, were evaluated in a "free-field" configuration as well as in a saline solution phantom (implantation simulation). Test results are presented for five frequency bands between 200 and 6,000 MHz. Many pacemakers skipped one or two beats when the main beam of the radars scanned past the point of closest approach. This effect, observed regularly for some pacemakers at distances out to a mile or more from the radar, might result in a pacemaker patient losing a normal heartbeat every 10-12 sec (about 5-6 beats per minute). Although this interference is not considered a threat to life, the effect can become more serious for a patient closer to the radar-depending on the particular pacemaker in use, the state of the patient's health, and the activity in which he is involved.

I N 1971 THE USAF School of Aerospace Medicine (USAFSAM) initiated a study to assess the effects of a specific HF band (3-30 MHz) pulsed radar on cardiac pacemakers. Subsequently, the program was expanded to include other frequencies (30 kHz-6000 Mhz) of interest to the Air Force as well as the microwave-oven frequencies (915 MHz and 2450 MHz) of specific interest to the U.S. Public Health Service. Laboratory tests were conducted at USAFSAM, the Walter F.ed Army Institute of Research, and the Georgia Institute of Technology. Responses were recorded for pacemakers in a "free-field" configuration, in saline liquid phantoms, and while implanted in large dogs. The extent of electromagnetic interference (EMI) on 10 different types of pacemakers representing seven manufacturers was determined as a function of E-field intensity and pulse repetition rate for 11 discrete frequencies (6,8).

After these laboratory tests, a scries of field tests was conducted near various electromagnetic radiation sources common in today's environment. The sources included outboard motors for small pleasure boats, metal-casting induction heaters, radiation therapy accelerators, microwave ovens, and representative radar systems. Each of these sources—and many others—can disrupt normal operation of the more sensitive pacemakers (1-8). For most of these sources of interference, the pacemaker user must be within a few feet of the device to be in jeopardy; but, for larger and more powerful emitters (such as television and radar transmitting antennas) the effect can extend out to 1,000 feet or more from the source.

MATERIALS AND METHODS

The present tests were conducted in proximity to six different radiofrequency (RF) emitters having nominal operating frequencies of 220, 450, 1300, 2800, and 5600 MHz. These systems were representative of many search, height finder, and air route surveillance radar in population centers throughout the world. The systems operated with transmitter peak powers between 1 and 5 megawatts, pulse repetition frequencies (PRF) from 100-400 pulses per second (pps), and pulse widths between 2-25 μ sec. All of the search and surveillance systems scanned a 360° sector at 5 rpm. The height finder systems scanned a -2° to $+32^{\circ}$ elevation sector in a 3-sec sweep at any azimuth setting.

Listed and described in Table I are the 21 pacemakers evaluated in these tests. The instrumentation system (Fig. 1) recorded simultaneously, on a dual channel strip-chart recorder: (a) the pacemaker response, and (b) the peak electric field (E-field) level to which the pacemaker was exposed. The pacemakers were evaluated in a free-field configuration and also when placed in a nominal $30 \times 30 \times 20$ cm liquid phantom which puts 1 cm of 0.03 molar saline solution between the pacemaker and the incident radiation and about 15-20 cm of solution on all other sides. The only exception to this

The research reported in this paper was conducted by personnel of the Radiobiology and Clinical Sciences Divisions, USAF School of Aerospace Medicine, Aerospace Medical Division, AFSC, United States Air Force, Brooks AFB, TX; and by personnel of the 1839th Electronic Installation Group, AFCS, United States Air Force, Keesler AFB, MS. Further reproduction is authorized to satisfy the needs of the U.S. Government.

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Manufacturer	Model No. (and No. of Units Tested)	Nomenclature
Medtronic	5842 (6)	Implantable Demand Pulse Generator
	5942 (3)	Implantable Demand Pulse Generator
General Electric	A2072D (2)	Standby Pacemaker (Ventricular Inhibited)
American Optical	281003 (2)	Cardio-Care Implantable Demand Pacer
	281013 (1)	Cardio-Care Implantable Demand Pacer
Cordis	133C6 Atricor (1)	Synchronous (P-wave) Implantable Pacer
	133C7 Atricor, Jr (2)	Synchronous (P-wave) Implantable Pacer
	143E7 Stanicor (1)	Blocking Standby (Demand) Pacer
Devices Implants	3821 (1)	Demand Pacemaker
Biotronik	IDP-44 (1)	Schrittmacher
Medcor	3-70A (1)	Cardiac Pacer Demand (R-Inhibited)

TABLE I. CARDIAC PACEMAKER TEST SAMPLE

procedure occurred during the carly stages of these tests where the liquid phantom was not used for the 220 and 450 MHz studies. Previous laboratory tests at USAFSAM had shown that less protection was provided by body shielding at these frequencies than at all others tested. A small FM telemetry system was used to transmit the pacemaker response to an FM receiver located 5-20 ft from the pacemaker. The pacemaker leads, terminated with a nominal 500 ohm resistor, were connected to a Mennen-Greatbatch Model 621 electrocardiograph amplifier. The amplifier output was used to modulate a field



Fig. 1. Instrumentation system for cardiac pacemaker EMI field tests. 2

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Fig. 2. E-field level 2000 ft from source D (Table II) for both the 1305 and 1340 MHz frequencies. (Typical recording for the real-time E-field levels measured around such radar systems.)

effect transistor (FET) RF oscillator operating at a frequency of about 115 MHz. The oscillator output was inductively coupled to a short rod antenna. To minimize degradation of the pacemaker signal by the electromagnetic field, the input, amplifier, and RF oscillator sections of the transmitter were isolated by using electrostatic shields; and all interconnecting wires were passed through the shields using bypass capacitors or EMI filters. The bandpass of the modulating signal was approximately 0.1-90 Hz. The FM receiver, used to receive the pacemaker response signal, tunes from 30-300 MHz, and has a bandwidth of 300 kHz. The output of the receiver was fed into the strip-chart recorder.

The specific test equipment used to measure E-field exposure levels varied, depending on the electromagnetic frequency which was being measured. In general, this equipment consisted of a field intensity meter (FIM), associated calibrated antennas, and a strip-chart recorder. The FIM is an internally calibrated receiver capable of measuring amplitudes of electromagnetic energy at the FIM input. Applying known calibration factors for the respective antenna enables an operator to measure the field intensity at the antenna. The field intensity in this study is referred to as the E-field level (Fig. 2). An oscilloscope was intermittently used to observe the pulse rate and width of radar signals.

To assure maximum accuracy, pulse and signal generators were used, before each field test, to calibrate the field measurement equipment—and, after each field test, to validate the proper functioning of the field measurement equipment. For such calibration tests, known amplitudes of electromagnetic energy were inserted into the input of the FIM. This signal substitution was at the operating frequency, pulse rate, and pulse width of the radiation source being tested. All test equipment was certified and was within the normal calibration cycle.

RESULTS AND DISCUSSIONS

Test record samples of observed pacemaker inter-



Fig. 3. Example of class II interference effect in which pacemaker regularly misses a beat with each 360° antenna scan. Pacemaker rate: 64 bpm.



Fig. 4. Example of class III interference effect in which the pacer maintains a fairly constant rate between 50 and 120 bpm. Pacemaker rate: 60 bpm (normal rate was 70 bpm).

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ference are presented in Figs. 3-7. The five classes of general effects are:

- I = No apparent change in rate.
- II = Intermittent change in rate; e.g., missing one or two beats per radar scan (Fig. 3).
- III = Steady rate between 50 beats per minute (bpm) and 120 bpm (Fig. 4).
- IV = Rate is less than 50 bpm (Fig. 5).
- V = Cut off: misses ≥5 consecutive beats per radar scan (Figs. 6 and 7).

In Table II, summarizing the significant empirical observations on these field tests, the classifications I-V are used to designate the pacemaker effects. At some radar sites (such as source A, Table II), where measurements could not be made at all distances due to lack of access roads into the areas, no data were obtained between the 600 ft distance (where significant pacemaker interference was observed) and the 3,000 ft distance (where effects were minimal).

All test results were based on a limited number of pacemakers obtained through normal medical procurement channels. No attempt was made to interpret observed variabilities in the responses of apparently identical pacemakers. We observed such variabilities throughout many hours of testing under both laboratory and field-test situations at a number of different test sites. Notwithstanding, these empirical data (Table II) are useful in assessing the effects of relatively large pulsed RF emitters on cardiac pacemakers.



Fig. 6. Example of class V interference effect. Pacemaker rate: ~ 10 bpm.



Fig. 5. Example of class IV interference effect in which the pacemaker rate is less than 50 bpm. Pacemaker rate: 24 bpm.

Fig. 7. Another example of class V interference effect (also showing benefit of 30 cm body shielding). Pacemaker rate: 0 bpm.

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SOUDCE	DISTANCE			PACER	FREE-F	IELD R	ESPONSE	SHIF	LDED R	ESPONSE
(& frequency)	(feet)	E ₁ (v/m)	$E_2(v/m)$	NO.	E ¹	E.2	(bpm)	E	E2	(bpm)
A(220 MHz)	600	80	35	5842	v	IV	35	and the second second second		
			~	5942	H H		65			
				281013	v	V	13			
	*		~	A2072D	л і	, i	55			
	-		**	133C7	1	i i	70			
	3000	148	15	5842	п	I	66			
	~	*	*	281003	11	1	64			
B(450 MHz)	1300	216	14	5842	V	IV	24			
	2000	151	11	5842	v	v v	32			
		N 199	"	5942	īv	iv	23			
	*	*	*	A2072D	11	1	68			
		"	**	281003	11	П	59			
	4000	46	1	5842	11	1	67			
	7500	108	2	5842			67			
	-	~	ũ,	281003	11	I I	68 68			
C(1300 MU-)	100	\$0	17	5847	V	V	12	v	V	20
	300	<i>30</i>	52 **	5942	v	ň	24	ů.	. i	64
	**	**	**	A2072D	п	i	64	1	i	72
	**	*	*	133C7	111	Ш	104			
	"	**	*	143E7	п	11	62	1	I.	72
	~	~		281003	I	1	72			
	"			281013	11	I	68			
	~			1DP44 2821			68			
	1000	63	16	5847	v V	v	16	п	1	64
	1000	"	"	5942	й	Ĭ	64	ü	i	66
	*	"	"	133C7	ш	ш	85	1	i	70
	*	"	"	143E7	11	11	66	н	11	68
	**	**	~	281003	п	1	65	11	1	66
		~		281013	1	1	68	1		68
			-	IDP-44 2921	11		66			68
				3821	1	1	60	ł	L	09
D(1305,	150	165	100	5842	п	v	21	v	п	24
1340 1112)	"			5942	ü	v	28	i	ï	69
	"	**	*	A2072D	П	п	60	1	I	72
	*	"	**	133C7	111	Ш	92	I.	111	92
	*	**	*	143E7	П	IV	48	1	1	69
	*		<i>μ</i>	281003	II	1	65	I	ļ	69
	<u>.</u>			281013	v		32		1	68
		"	*	3821	í	i	68	1	i	69
		"		3-70A	m	i	82	n i	i	68
	300	50	70	5842	V	v	0	ii	11	36
	*	**	"	5942	v	v	10	1	I	67
	*	"	~	A2072	П	П	64	1	1	71
	*	**		133C7	ш	ш	94	111	111	91
				143E7			45	1	ļ	69
	"			201003	11	11	47	1	1	64
	"		*	IDP44	ï	1	69	1	i	68
	"	*	**	3821	i	i	69	i	i	69
	*	"	"	3-70A	111	I	72	n	1	60
	1400	112	17	5842	v	IV	35	u	1	62
				5942	11	1	64	I	1	68
	*	~	"	A2072D	ш	1	68			
	"			13307	1		70			
				281003	11		60			
				281013	11		63			(6)

TABLE IL EMPIRICAL RESULTS OF PACEMAKER INTERFERENCE TESTS.

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Web All and their supporting supporting		and an and a second	And a state	PACER	FREE-F	IELD R	ESPONSE	SHIELD	ED RES	PONSE
SOURCE (& frequency)	DISTANCE (feet)	$E_1(v/m)$	$E_2(v/m)$	MODEL NO.	E,	E2	PacerRtae (bpm)	E	E ₂	PacerRate (bpm)
D(1305,	- and pages	En explice came			9					
1340 MHz)	1400	112	17	IDP44	1	1	69			
	*	"	*	3821	11	1	65			
	**	*	*	3-70A	IV	1	45	111	1	73
	1700	112	16	5842	IV	v	8	11	1	62
	*	*	"	5942	11	I	66	T	1	70
	"	"	"	3-70A	IV	1	54	11	1	70
E(2800 MHz)	1400	1500		5842	11		60	11		60
	*	*		5942	IV		44	H		64
	"	"		A2072D	11		62	11		64
	*			133C7	11		60	111		74
	"			143E7	11		62	11		68
	*			281003	11		66	П		68
	*	~		281013	11		62	п		68
	*	*		IDP44	11		62	1		68
				3821	11		62	11		68
F(5600 MHz)	100	70	40	5842	11	I	55	I	I	68
	~	*	*	5942	1	I	68			
	*	*		133C7	III	I	88	111	I	80
	*		*	143E7	11	1	57	11	I	68
			*	A2072D	11	1	68	I	I	70
		-		281003	11	I	59	1	1	66
				281013	11	1	60	i	Ī	68

TABLE II. EMPIRICAL RESULTS OF PACEMAKER INTERFERENCE TESTS. (Cont.)

Pacemaker EMI effects designated by classifications I - V explained in text.

Our experimental results were obtained at and near various relatively large and high-powered radar sites. Typical of such radar systems is the Air Route Surveillance Radar (ARSR), operated at about 100 different sites throughout the U.S. to control the flight paths of commercial aircraft. Typically, the ARSR system operates at about 1250-1350 MHz (sometimes propagating two frequencies simultaneously). It operates at a peak power of ~2.5 megawatts, and has PRF of 360 pps and a pulse width of 2-6 μ s; it rotates at 5-6 rpm, and operates 24 hours a day. Although these systems are usually located on five- to six-story structures, they create E-field levels (Fig. 2) which are clearly of sufficient strength at ground level to disrupt some cardiac pacemakers at distances of 1000 ft or more from the base of structure.

Pacemakers can be affected: by the relatively intense E-field at ground level (peak E-field level designated E_1) associated with passage overhead of the main beam; by the other lobes of the antenna pattern (secondary peak E-field level greater than 30° past main beam center, designated E_2); and by the variation in the E-field level, due to antenna lobe pattern structure which effectively produces a ~1-10 Hz pulse repetition rate (PRR) throughout most of the total scan for most of the systems used in these tests. In fact, this resultant PRR affects pacemakers in much the same manner as the 1-10 Hz PRR produced by the mode stirrer in a microwave oven (4,6,7).

Many of the pacemakers tested at distances of a mile or more from the ARSR routinely missed one beat per radar scan (as the main beam passed overhead), resulting in the loss of 5-6 bpm. At positions closer to the radar, where the average E-field intensity remains above the pacemaker interference threshold for longer periods of time, the pacemaker might be expected to revert to its fixed interference rejection rate when the PRF of the radar propagation is ~360 Hz. However, with the added 1-10 Hz effective PRR, some devices missed enough beats to be seriously disrupted. This finding is consistent with previous USAFSAM laboratory findings that pacemakers would either revert to their fixed rate or cut off at the same E-field level, depending on the PRR of the incident radiation. For PRR values greater than about 40 Hz, pacemakers would generally revert to their fixed rate at the critical E-field level, Holding the same Efield level and reducing the PRR would then cause the pacemaker to cut off.

CONCLUSIONS

Most cardiac pacemakers now in use in the United States will register some type of electrical interference in proximity to large pulsed RF sources. For continuous scanning systems (such as the ARSR), many of the pacemakers will skip one beat as the main beam of the radar passes. This effect has been consistently observed at distances of a mile or more. Such an effect can cause a pacemaker patient to lose a normal heartbeat every 12 seconds (about 5 bpm). Although this loss is not considered a threat to life, the effects can become more serious (Table II) at closer distances—depending on the particular pacemaker in use, the state of health of the individual, the activity in which the user is involved, and the extent of pacemaker shielding provided by orientation of the person with respect to the incident radiation and any other type of shielding between him and the source.

No clear-cut basis yet exists on which to generalize the significance or seriousness of pacemaker interference. However, most patients can apparently tolerate a few missed beats, spread over a minute for sustained periods, and perhaps as many as 20-25 bpm in a l-min period (provided that the missed beats are not consecutive). Sustained rates of fewer than 40-50 bpm can, however, represent a serious threat to the health of certain patients. Using this criterion, a person dependent on one of the more senstive pacemakers located within 1,000-2,000 ft of a high-powered 200-500 MHz pulsed radar would be seriously jeopardized.

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