

AD-757 930

Cardiac Pacemaker Electromagnetic Interference (3050) MHz

School of Aerospace Medicine

DECEMBER 1972

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AD-757930

**CARDIAC PACEMAKER
ELECTROMAGNETIC INTERFERENCE (3050 MHz)**

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FOREWORD

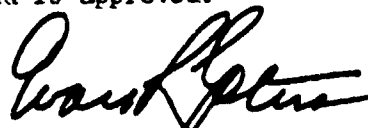
This research was performed in the Radiobiology Division, under task No. 775701-24, from November 1971 to March 1972. The resulting report was submitted for initial review on 3 November 1972, and for final editing on 30 November 1972.

The animals involved in this study were maintained in accordance with the "Guide for Laboratory Animal Facilities and Care" as published by the National Academy of Sciences--National Research Council.

The author gratefully acknowledges assistance from the following sources at the USAF School of Aerospace Medicine (SAM): for their participation and professional support, Mr. J. C. Mitchell, Dr. J. W. Frazer, Major C. H. Bonney, Captain G. E. Ford, and Airman P. L. Rustan; for their surgical aid and animal care during these experiments, the members of the USAFSAM Veterinary Sciences Division--and, in particular, Captain C. A. Rawlings, Major W. H. Pryor, Jr., and Captain D. K. Obeck.

Appreciation is also expressed to: Mr. Mark Grove, for his professional and technical support in the experiments performed at the microwave exposure facilities of the Walter Reed Army Institute of Research; and to Messrs. E. E. Donaldson, J. C. Toler, and B. M. Jenkins, for their technical support during experiments at the Georgia Institute of Technology Experiment Station.

This report has been reviewed and is approved.



EVAN R. GOLTRA, Colonel, USAF, MC
Commander

Unclassified

Security Classification

DOCUMENT CONTROL DATA - R & D

(Security classification of title, body of abstract and indexing annotation must be entered when the overall report is classified)

1. ORIGINATING ACTIVITY (Corporate author) USAF School of Aerospace Medicine Aerospace Medical Division (AFSC) Brooks Air Force Base, Texas 78235		2a. REPORT SECURITY CLASSIFICATION Unclassified	
		2b. GROUP	
3. REPORT TITLE CARDIAC PACEMAKER ELECTROMAGNETIC INTERFERENCE (3050 MHz)			
4. DESCRIPTIVE NOTES (Type of report and inclusive dates) Nov 1971 - Mar 1972			
5. AUTHOR(S) (First name, middle initial, last name) William D. Hurt			
6. REPORT DATE December 1972		7a. TOTAL NO OF PAGES 20	7b. NO OF REFS None
8a. CONTRACT OR GRANT NO		8b. ORIGINATOR'S REPORT NUMBER(S) SAM-TR-72-36	
b. PROJECT NO 7757			
c. Task No. -01		9b. OTHER REPORT NO(S) (Any other numbers that may be assigned this report)	
d. Work Unit No. -24			
10. DISTRIBUTION STATEMENT Approved for public release; distribution unlimited.			
11. SUPPLEMENTARY NOTES		12. SPONSORING MILITARY ACTIVITY USAF School of Aerospace Medicine Aerospace Medical Division (AFSC) Brooks Air Force Base, Texas 78235	
13. ABSTRACT Tests were performed to determine the effect of 3050 MHz radio-frequency radiation on cardiac pacemakers. Five pacemaker models were implanted in large dogs and tested in each of two laboratories. The electrocardiographs of each animal were continuously monitored for various exposure conditions. Most of the pacemakers exhibited some electromagnetic radiation interference (EMI) under certain conditions of these tests. The most sensitive unit, of those tested, cut off at ~100 V./m. at pulse repetition frequencies less than ~35 pps--while one pacemaker exhibited no effects from EMI throughout these tests.			

Unclassified

Security Classification

14. KEY WORDS	LINK A		LINK B		LINK C	
	ROLE	WT	ROLE	WT	ROLE	WT
Cardiac pacemakers Electromagnetic interference Microwave radiation						

11-6

Unclassified

Security Classification

ABBREVIATIONS

bpm	beats per minute
cm.	centimeter(s)
CW	continuous wave
ECG	electrocardiograph
E-field	electric field (V./m.)
EMI	electromagnetic radiation interference
FM	frequency modulation
GIT	Georgia Institute of Technology
Hz	Hertz
kg.	kilogram(s)
kHz	kilohertz
MHz	megahertz
μ sec.	microsecond(s)
msec.	millisecond(s)
mW.	milliwatt(s)
nps	pulse(s) per second
prf	pulse repetition frequency (rate)
V./m.	volts per meter
WRAIR	Walter Reed Army Institute of Research

CARDIAC PACEMAKER ELECTROMAGNETIC INTERFERENCE (3050 MHz)

I. INTRODUCTION

To assess the effects of radio-frequency electromagnetic radiation on cardiac pacemakers, a series of tests are being performed at the USAF School of Aerospace Medicine (SAM). This report describes results obtained at two different test sites: the U.S. Army Walter Reed Army Institute of Research (WRAIR) Microwave Laboratory, Silver Springs, Maryland; and the Georgia Institute of Technology (GIT) Engineering Experiment Station, Atlanta, Georgia.

For tests conducted at the 3050 MHz frequency, each of five pacemakers was implanted in anesthetized dogs weighing 18 - 20 kg., respectively. As part of the surgical implant procedure, an amount of 10% buffered formalin solution adequate to produce a total atrioventricular block was injected in the bundle of His. No tests were conducted during the 2 weeks after surgery.

For the tests performed at GIT, the 3050 MHz microwave radiation signal was square-wave modulated with a 125 μ sec. pulse width. The pulse repetition frequency (prf) was continuously variable from 13 - 400 pulses per second (pps), and the maximum field strength obtained was 365 volts per meter (V./m.) The exposures were conducted in an anechoic chamber energized by a circularly polarized log spiral antenna.

At WRAIR, the exposure characteristics included continuous wave (CW), sine wave half-wave rectified, and square-wave modulated signals. The only prf used for the half-wave rectification mode was 120 Hz. However, many different pulse width and repetition rate combinations were investigated in the study of the square-wave modulation effects. These exposures were conducted in an anechoic chamber energized by a pyramidal horn, and the maximum field strength obtained was 400 V./m.

II. TEST PROCEDURE

Immediately before the tests, 10 mg. promazine were administered I.M. to the respective animal and, 15 min. later, 100 mg. sodium pentobarbital I.V. Then electrocardiographic (ECG) silver disk electrodes were attached with paste to the thorax, and the animal was placed on a styrofoam pedestal in the far-field region of the chamber and on the center line of the radiating device. Acquisition of the ECG signal from each dog was accomplished with a frequency modulated (FM) telemetry system designed and fabricated by the Test and Evaluation Section, Medical Systems Division, USAFSAM. The ECG signal was obtained by using the classic chest lead II, and was amplified in the telemetry transmitter package by an electrocardiographic amplifier (Mennen-Greatbatch model 621). The amplifier output was used to modulate the frequency of a field effect transistor radio-frequency oscillator operating at 4115 MHz.

The oscillator output was inductively coupled to a quarter-wave rod antenna. To minimize degradation of the ECG signal by the microwave field, the input, amplifier, and RF oscillator sections of the transmitter were isolated by using electrostatic shields; and all interconnecting wires were passed through shields in bypass capacitors or EMI filters. The bandpass of the ECG modulating signal was approximately 0.1 - 90 Hz.

A type 901A receiver (Communications Electronics, Inc.), which was used to receive the FM signal, tunes from 30 - 300 MHz with a bandwidth of 300 kHz. The video output section was modified to provide a low frequency ECG signal. The receiver video output was fed to a spectrum analog filter (type LH-420), which was set up as a low pass filter with a high frequency cutoff of about 100 Hz. The filter output was carried to a Brush strip-chart recorder.

III. TEST RESULTS

In the test results (tables I-XII)* are indicated the following effects on the pacemakers at the indicated power densities and electric field (E-field) strengths, and for the parameters specified:

- No apparent change in rate
- Intermittent rhythm and rate changes
- Fixed rate
- Steady rate between 50 and 120 beats per min. (bpm)
- Rate more than 120 bpm
- Rate less than 50 bpm
- Cutoff (inhibition)

The general findings for the respective pacemakers at test frequency 3050 MHz are summarized in the following paragraphs.

Medtronic 5842

This unit was not affected by 3050 MHz CW fields up to 360 V./m. It was, however, generally affected by the square-wave modulated signal at field strengths of approximately 100 V./m. for transmitter prf values from 400 - 18 nps. The unit reverted from a baseline rate of 68 bpm to a fixed rate of 54 bpm for prf values greater than approximately 25 - 35 nps, and was cut off for the repetition rates which were lower. Little if any change occurred in EMI sensitivity as the pulse width was varied over the range 3 μ sec. - 5 msec.

General Electric A2072D

This pacemaker was unaffected by the exposure conditions used in these tests.

*Editor's Note: All tables are grouped at the close of this report.

American Optical 281013 (Non-polar)

This unit was not affected in the GIT exposures; but, during tests at WRAIP, the pacer exhibited a gradual decrease in rate from 54 bpm (baseline rate) to 42 bpm for the C4 exposure. For a prf of 120 nps and a pulse width of 5 msec., the baseline rate of 54 bpm gradually increased to a maximum of 72 bpm as the E-field was increased. As the pulse width was decreased from 5 msec. to 3 μ sec. at a prf of 120 nps and a field strength of 360 V./m., the pacer rate gradually decreased from 72 bpm to its preexposure rate of 54 bpm.

Cordis Stanicor

The operation of this pacemaker was not affected by C4 exposure for fields up to 350 V./m. For the pulsed mode, however, the unit generally reverted to its fixed rate for field strength values of approximately 200 V./m.

Cordis Atricor

As the transmitter prf was decreased from 400 - 18 nps while 360 V./m. was maintained, this pacer gradually changed from its normal rate of 60 bpm up to 100 bpm. This change was noted both at GIT for a pulse width of 125 μ sec. and at WRAIR for a 1.5 msec. pulse width. The unit also gradually increased in rate from 60 to 100 bpm as the pulse width was decreased from 5 msec. to 3 μ sec. while maintaining the prf at 120 nps and field strength at 360 V./m. For repetition rates of 35 and 18 nps at GIT, the pacer reverted to the higher rate of 100 bpm for field strengths greater than 300 V./m.

IV. CONCLUSIONS

Although these empirical results are based on single test samples, they demonstrate the importance of prf in assessing the CMI of cardiac pacemakers operating in the demand mode. The pacemakers (which are commercially available) in the tests were chosen from those most commonly used in 1971. In general, after an E-field threshold level of susceptibility has been established, the effect (i.e., either reversion to fixed rate or complete cutoff) appears primarily dependent on the transmitter or EMI prf. At pulse rates greater than ~35 nps, those pacemakers affected generally reverted to their fixed rate. If the pulse rate was less than ~35 nps, the pacemaker generally cut off.

TABLE I

Effects on pacemakers tested at 3050 MHz, 400 pps, and 120 μ sec. pulse width (Georgia Institute of Technology)

Pacemaker	Effects	mw./cm. ² (V./m.)
Medtronic 5842	No apparent change in rate Cutoff (inhibition)	0 - 0.11 (95) 0.11 (95) - 17 (365)
General Electric A2072D	No apparent change in rate	0 - 17 (365)
American Optical 281013		
Cordis Stanicor	No apparent change in rate Cutoff (inhibition) Fixed rate	0 - 0.49 (197) 0.49 (197) - 0.50 (198) 0.50 (198) - 17 (365)
Cordis Atricor	No apparent change in rate	0 - 17 (365)

TABLE II

Effects on pacemakers tested at 3050 MHz, 365 V./m., and 125 μ sec. pulse width (Georgia Institute of Technology)*

Pacemaker	Effects	prf (in pps)
Medtronic 5842	Fixed rate Cutoff (inhibition)	400 - 27 27 - 18 (95 V./m.)
General Electric A2072D	No apparent change in rate	400 - 18
American Optical 281013	No apparent change in rate	
Cordis Stanicor	Fixed rate	
Cordis Atricor	Steady rate between 50 and 120 bpm†	

* Transmitter prf was gradually decreased from 400 - 18 pps while E-field was maintained at a high level (365 V./m.) through this test.

† Pacemaker rate gradually increased from 60 - 96 bpm.

TABLE III

Effects on pacemakers tested at 3050 MHz, 18 pps, and 125 μ sec. pulse width (Georgia Institute of Technology)

Pacemaker	Effects	mw./cm. ² (V./m.)
Medtronic 5842	No apparent change in rate Cutoff (inhibition)	0 - 0.0054 (95) 0.0054 (95) - 0.79 (365)
American Optical 281013	No apparent change in rate	0 - 0.79 (365)
Cordis Stanicor	No apparent change in rate Fixed rate	0 - 0.017 (170) 0.017 (170) - 0.79 (365)
Cordis Atricor	No apparent change in rate Steady rate between 50 and 120 bpm	0 - 0.54 (300) 0.54 (300) - 0.79 (365)

TABLE IV

Effects on pacemakers tested at 3050 MHz, 35 pps, and 125 μ sec. pulse width (Georgia Institute of Technology)

Pacemaker	Effects	mw./cm. ² (V./m.)
Medtronic 5842	No apparent change in rate Fixed rate	0 - 0.0082 (84) 0.0082 (84) - 1.5 (365)
General Electric A2072D	No apparent change in rate	0 - 1.5 (365)
American Optical 281013		
Cordis Stanicor	No apparent change in rate Cutoff (inhibition) Fixed rate	0 - 0.031 (164) 0.031 (164) - 0.032 (166) 0.032 (166) - 1.5 (365)
Cordis Atricor	No apparent change in rate Steady rate between 50 and 120 bpm	0 - 0.91 (280) 0.91 (280) - 1.5 (365)

TABLE V

Effects on pacemakers tested at 3050 MHz, CW
(Walter Reed Army Institute of Research)

Pacemaker	Effects	mw./cm. ² (V./m.)
Medtronic 5842	No apparent change in rate	0 - 35 (360)
General Electric A2072D		
American Optical 281013	Rate less than 50 bpm*	0 - 32 (350)
Cordis Stanicor	No apparent change in rate	0 - 32 (350)
Cordis Atricor		

* Pacemaker rate gradually decreased from 54 - 42 bpm.

TABLE VI

Effects on pacemakers tested at 3050 MHz and 120 Hz sine wave, half-wave rectification (Walter Reed Army Institute of Research)

pacemaker	Effects	mw./cm. ² (V./m.)
Cordis Stanicor	Steady rate between 50 and 120 bpm*	0 - 11 (360)
Cordis Atricor	No apparent change in rate	0 - 8 (310)

* Pacemaker rate gradually increased from 68 - 75 bpm.

TABLE VII

Effects on pacemakers tested at 3050 MHz and 120 pps, square wave
(Walter Reed Army Institute of Research)

Pacemaker	Effects	mw./cm.² (V./m.)
Medtronic 5842	No apparent change in rate Fixed rate	0 - 1.7 (110) 1.7 (110) - 16 (350)
Medtronic 5842	No apparent change in rate Cutoff (inhibition) Fixed rate	0 - 1 (90) 1 (90) - 5 (190) 5 (190) - 16 (350)
General Electric A207CD	No apparent change in rate	0 - 19 (380)
American Optical 281013	Steady rate between 50 and 120 bpm*	0 - 16 (350)
Cordis Stanicor	Steady rate between 50 and 120 bpm†	0 - 15 (340)
Cordis Atricor	No apparent change in rate	0 - 16 (350)

* Pacemaker rate gradually increased from 54 - 72 bpm.

† Pacemaker rate gradually increased from 68 - 75 bpm.

TABLE VIII

Effects on pacemakers tested at 3050 MHz, 360 pps, and 3 μ sec. pulse width
(Walter Reed Army Institute of Research)

Pacemaker	Effects	mw./cm. ² (V./m.)
Medtronic 5842	No apparent change in rate	0 - 0.03 (320)
American Optical 281013		0 - 0.01 (180)
Cordis Stanicor		0 - 0.03 (320)
Cordis Atracor		0 - 0.05 (410)

TABLE IX

Effects on pacemakers tested at 3050 MHz, 360 pps, and 1.5 msec. pulse width (Walter Reed Army Institute of Research)

Pacemaker	Effects	mw./cm.² (V./m.)
Medtronic 5842	No apparent change in rate Fixed rate	0 - 1.7 (110) >1.7 (110)
Medtronic 5842	No apparent change in rate Cutoff (inhibition)	0 - 2.0 (120) 2.0 (120) - 12.0 (290)
General Electric A2072D	No apparent change in rate	0 - 18.0 (350)
American Optical 281013	No apparent change in rate Fixed rate	0 - 8.0 (240) 8.0 (240) - 17.0 (340)
Cordis Atracor	No apparent change in rate	0 - 18.0 (250)

TABLE X

Effects on pacemakers tested at 3050 MHz, ~360 V./m., and 1.5 msec. pulse width (Walter Reed Army Institute of Research)*

Pacemaker	Effects	prf (in pps)
Medtronic 5842	Fixed rate	360 - 36
	Cutoff (inhibition)	36 - 20
Medtronic 5842	No apparent change in rate	360 - 40
	Cutoff (inhibition)	40 - 20 (290 V./m.)
General Electric A2072D	No apparent change in rate	360 - 20
American Optical 231013	No apparent change in rate	360 - 35
	Cutoff (inhibition)	35 - 20 (370 V./m.)
Cordis Stanicor	No apparent change in rate	360 - 20
Cordis Atracor	Steady rate between 50 and 120 bpm†	360 - 20

* Transmitter prf was gradually decreased from 360 - 20 pps while E-field was maintained at a high level (~360 V./m.) throughout this test.

† Pacemaker rate gradually increased from 60 - 100 bpm.

TABLE XI

Effects on pacemakers tested at 3050 MHz, 120 pps, and 5 msec. pulse width
(Walter Reed Army Institute of Research)

Pacemaker	Effects	mw./cm ² (V./m.)
Medtronic 5842	No apparent change in rate Fixed rate	0 - 0.1 (25) 0.1 (25) - 20 (350)
General Electric A2072D	No apparent change in rate	0 - 16 (320)
American Optical 281013	Steady rate between 50 and 120 bpm*	0 - 20 (350)
Cordis Stanicor	Steady rate between 50 and 120 bpm†	0 - 19 (340)
Cordis Atricor	No apparent change in rate	0 - 19 (340)

* Pacemaker rate gradually increased from 54 - 72 bpm.

† Pacemaker rate gradually increased from 68 - 75 bpm.

TABLE XII

Effects on pacemakers tested at 3050 MHz, 120 pps, and ≈ 360 V./m.
(Walter Reed Army Institute of Research)*

Pacemaker	Effects	Pulse width
Medtronic 5842	Fixed rate	5 msec. - 3 μ sec.
General Electric A2072D	No apparent change in rate	
American Optical 281013	Steady rate between 50 and 120 bpm [†]	
Cordis Stanicor	Steady rate between 50 and 120 bpm [‡]	
Cordis Atracor	Steady rate between 50 and 120 bpm [§]	

* Transmitter pulse width was gradually decreased from 5 msec. to 3 μ sec.

while maintaining a large E-field (≈ 360 V./m.) throughout this test.

[†] Pacemaker rate gradually decreased from 72 - 54 bpm.

[‡] Pacemaker rate gradually decreased from 75 - 68 bpm.

[§] Pacemaker rate gradually increased from 60 - 100 bpm.