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DEVELOPMENT OF A PACEMAKER MONITOR WITH CARDIAC SIMULATOR [for testing in RF fields]

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USAF SCHOOL OF AEROSPACE MEDICINE
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NOTICES

This final report was submitted by personnel of the Radiation Physics Branch, Radiobiology Division, USAF School of Aerospace Medicine, Aerospace Medical Division, AFSC, Brooks Air Force Base, Texas, under job order 7757-01-46.

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A cardiac pacemaker monitoring system was developed for use in testing cardiac pacemakers in RF fields. The system provided for both continuous monitoring of the pacemaker output and simulating normal cardiac activity at the pacemaker leads. Fiber optics techniques were used to provide the necessary electrical isolation of the pacemaker. Tests have shown that the monitoring system does not significantly affect pacemaker response to RF fields.

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pacemaker. Fortunately, a portion of this energy can be attenuated by the load resistance, with the amount of attenuation depending to a degree on the value of the load resistance.

The telemetry system must also have a minimum number of electrically conducting components connected to the pacemaker leads because they can act as miniature receiving antennas and induce RF energy into the pacemaker being tested.

Since this system would be used at remote RF sites, it was desirable that the system be small and battery powered. The monitoring point should be 10 to 20 ft from the pacemaker under test to introduce as little field perturbation as possible at the test location.

Additionally, the system must be capable of monitoring pacemaker output pulses of approximately 5-V amplitude with a pulse width of 1 msec. The input sensitivity for both R-wave and P-wave pacemakers is 1-2 mV with an approximately 50-msec pulse width. A signal with these characteristics will simulate normal heart activity.

Development of the USAFSAM Monitoring System

A monitoring system designed and built at the Georgia Institute of Technology Experiment Station satisfied some of the above requirements and employed a light-emitting diode in parallel with a 500-ohm resistive pacemaker load, a photoresistive voltage divider, and a light pipe coupled to the LED and photoresistor. The simplicity of this system prompted the development of a similar system at the USAF School of Aerospace Medicine (USAFSAM).

The system was built to present a resistive load near the upper limit encountered with implanted pacemakers. For this reason, a higher impedance load than normal was used, approximately 1000 ohms. This value was chosen for the convenience it allows in the testing process when the circuit shown in Figure 1 is used. Such a circuit will limit the possible range of load resistance from 350-1000 ohms as the resistance across the jack varies from 0 to infinity.

Thus, the firing of the LED will not radically change the load when the pacemaker pulses (as would occur if the LED were connected in either series or parallel with the load). If the LED were connected in series with the load resistance, the load would be over 100 kilohms until the pacemaker pulsed; if the LED were connected in parallel, the load

DEVELOPMENT OF A PACEMAKER MONITOR WITH CARDIAC SIMULATOR

INTRODUCTION

A requirement to test cardiac pacemakers in the vicinity of radio-frequency (RF) emitters was the impetus for developing a fiber optics telemetry system to monitor pacemaker output and response. It was necessary that the system be immune to the high RF fields encountered in such tests and that it present to the pacemaker a load and signal simulating those encountered in an actual implant situation so that the results obtained would apply to a human implant.

Several models of pacemakers have interference rates identical to their demand rates, so it is often difficult to determine susceptibility thresholds for pulse repetition rates above approximately 10 Hz. Thus, a method to simulate normal heart activity at the pacemaker leads was required so that an R-wave inhibited pacemaker would be inhibited by this simulated activity and would not produce a pulse until it detected interference and reverted to its interference mode. An additional requirement was imposed for a P-wave synchronous pacemaker to track the simulated activity up to the E-field threshold. A system of this type has been developed and incorporates a light-emitting diode (LED) monitoring system.

DESIGN AND DEVELOPMENT

Design Considerations

The telemetry systems which can be used effectively to test pacemakers in RF fields are limited to those which are transparent, or nearly so, to such fields. That is, the system must be immune to radio-frequency interference (RFI), and it must affect the pacemaker in the same manner as does the implantation environment. To achieve this, the system must present a resistive load to the pacemaker similar to that encountered by an implanted pacemaker, ranging from 100 to 1000 ohms with 600 ohms the nominal value. The value of the loading resistance is important to RFI effects since some RF energy can be picked up by the pacemaker leads and the load resistance, and be sensed by the

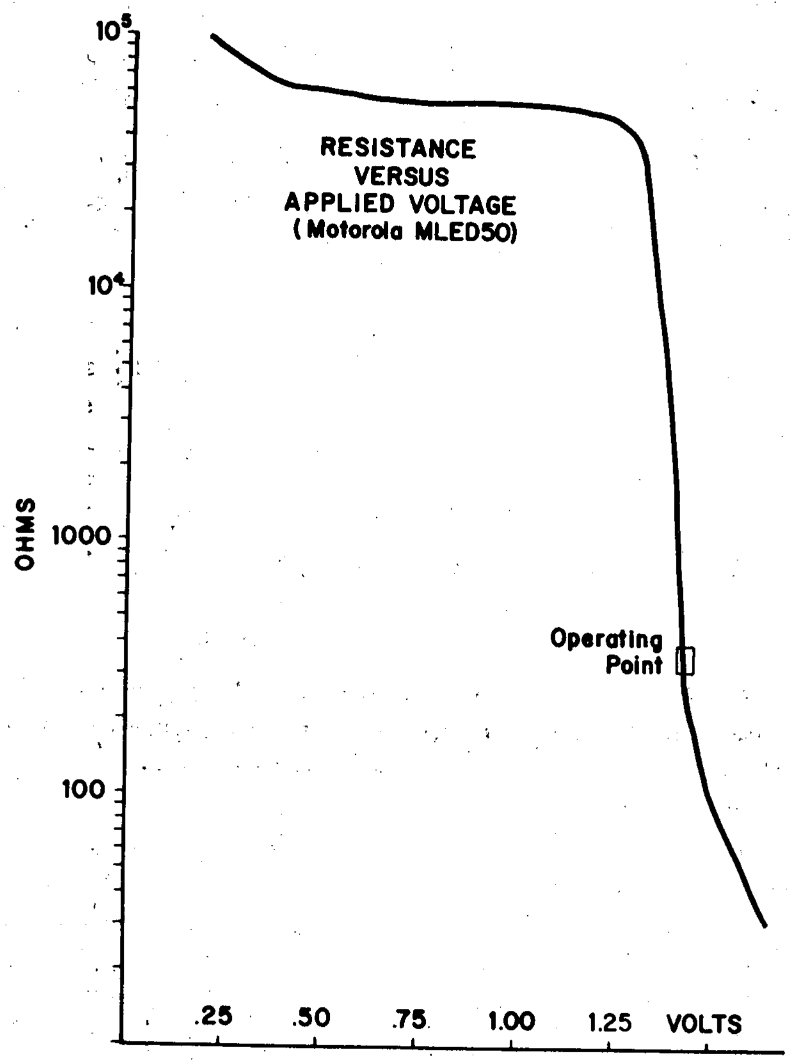


Figure 2. Operating resistance of an LED.

In the first design, the photoresistor was used as one leg in a bridge circuit to take advantage of d.c. coupling. However, changes in the ambient light level affected the system to such an extent that it was not possible to keep the bridge balanced, thus necessitating the use of a.c. coupling and a voltage divider as shown in Figure 1. The value of the resistor in series is equal to the dark resistance of the photoresistor (with the photoresistor used, the value was 5 megohms), and the voltage is supplied by a 9-V battery. The output of the divider is coupled to the external circuitry through a .01-μF capacitor and a BNC connector. All of the circuitry is contained within a metal box for RF and light shielding.

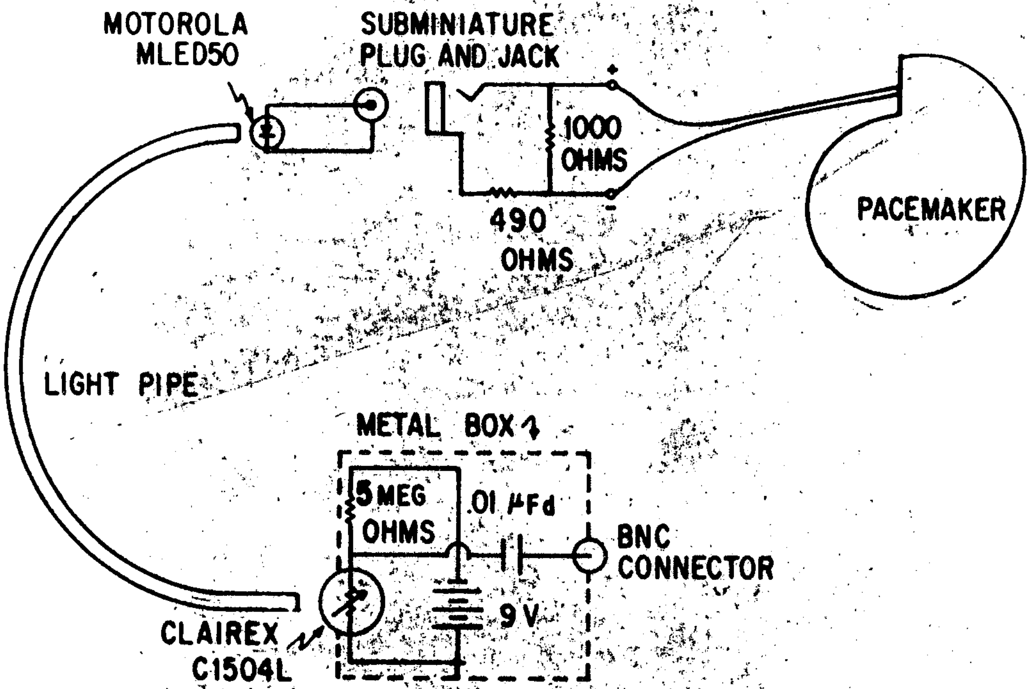


Figure 1. LED pacemaker monitor.

would drop to under 100 ohms when the pacemaker pulsed. Our design also enables a magnetic earphone to be plugged into the jack to be used as an audio monitor to ensure that the pacemaker is properly connected to the load. The 1000-ohm resistor in parallel with the pacemaker (Fig. 1) is the load the pacemaker sees except when emitting a pulse, in which case the LED has a fairly low impedance (since it conducts during the pulse). When the LED fires, the load on the pacemaker is approximately 500 ohms, depending on the output voltage of the pacemaker (Fig. 2).

The LED was mounted in a subminiature audio plug. The light pipes are sheathed, contain approximately 36 plastic fibers, and are of two different lengths--10 and 25 ft. The end of the light pipe is held in contact with the LED by a friction fit between heat-shrink tubing over the plug and over the jacket of the light pipe. This enables the light pipe to be removed and exchanged for a longer or shorter length. A similar technique is used at the photoresistor to couple the light pipe. The length of light pipe which can be used effectively is limited because it has a loss of approximately 10% per 1 ft, 65% per 10 ft, and 93% per 25 ft.

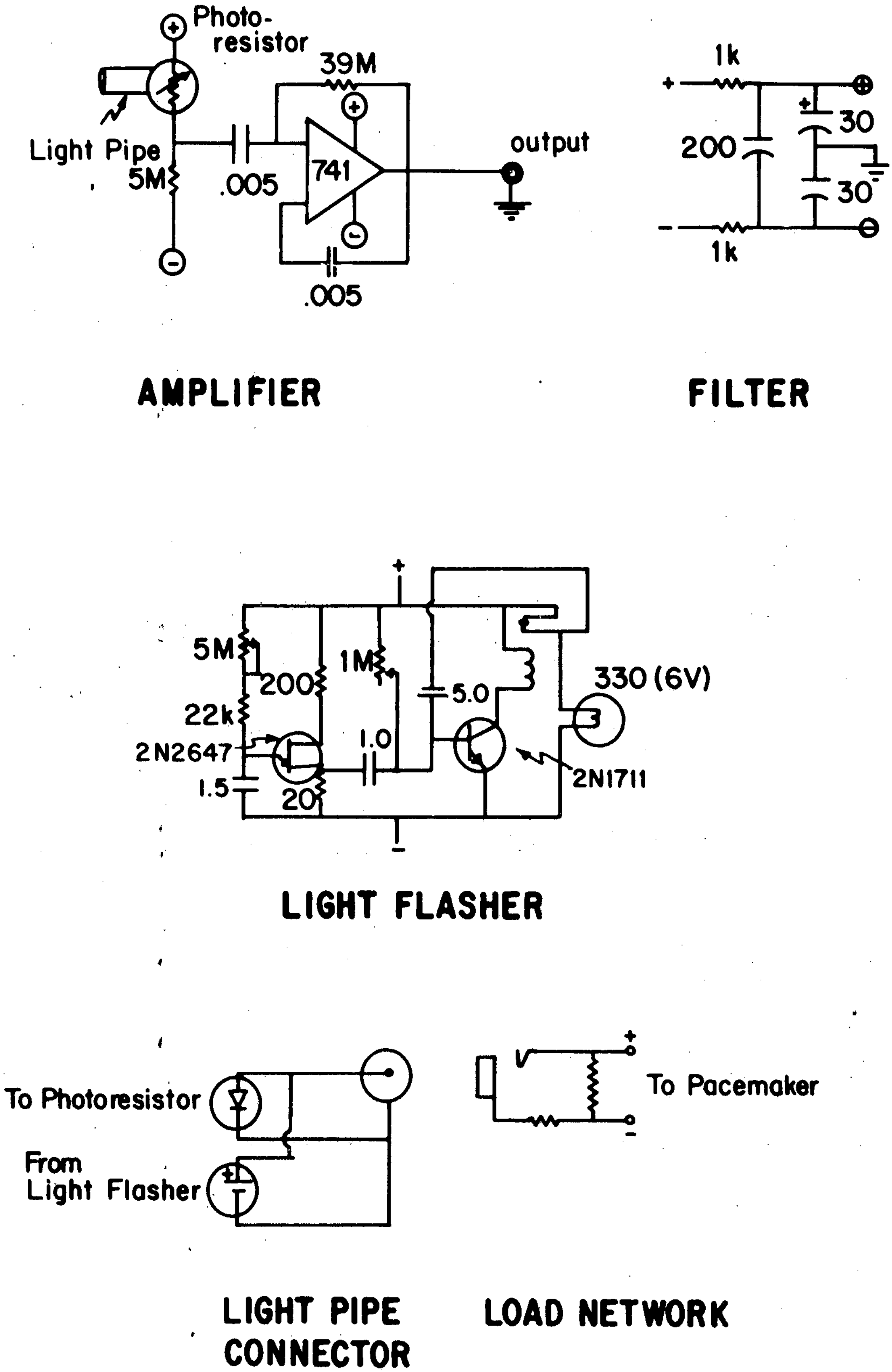


Figure 3. Schematic for LED pacemaker monitor with simulator. (Resistances are in ohms; capacitances are in μF.)

The output of the divider is between 10 and 100 mV under normal circumstances and is sufficient to drive a high-input impedance recorder, oscilloscope, or amplifier. When required to drive a device with a low-input impedance, it is necessary to amplify the signal from the divider with a high-input impedance amplifier. An electrocardiograph amplifier (Mennen-Greatbatch model 621) is used because of its suitability for handling such signals. The gain of the amplifier is adjusted to develop an output of approximately 1 V, a level sufficient to drive most devices.

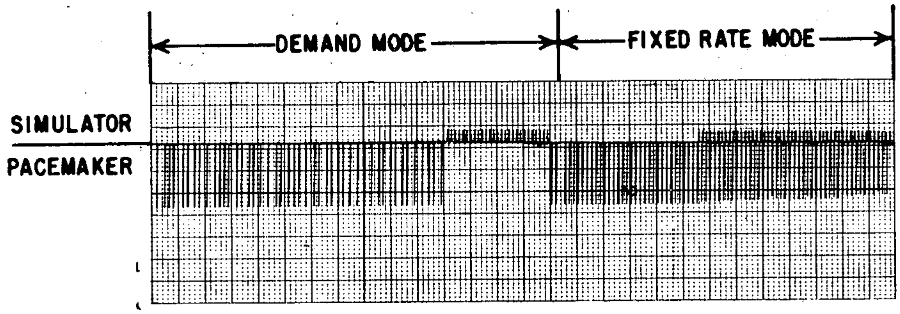
Development of the Heart Simulator

With a device added to simulate cardiac output, the pacemaker testing system is a satisfactory simulation of the environment experienced by an implanted pacemaker. The need to provide artificial cardiac activity became apparent during a recent series of tests incorporating several new models of pacemakers which revert to rates close to their demand rate in the presence of electromagnetic interference (EMI). Determining the EMI threshold for these can be difficult with the pacemaker free running (running at its demand rate into a load). For this reason, a device to simulate cardiac activity at the pacemaker without deteriorating the RF transparency of the monitor was developed.

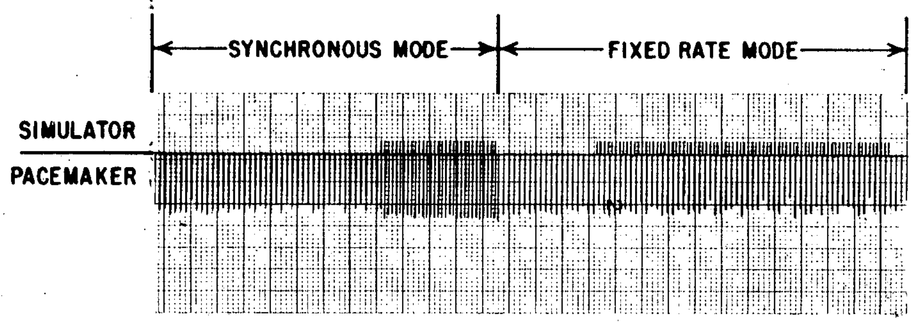
Two different designs were considered for the simulator. The first was a high-impedance lossy line to feed an electrical pulse from the monitoring point to the pacemaker. A prototype was built using two leads of 8 kilohms/ft lossy line between a cardiac simulator and the pacemaker. This was tested for its effect on pacemaker thresholds at 26.6 MHz in the USAFSAM RF test facility. It was found that a significant increase in pacemaker sensitivity ($\sim$3 dB) was caused by the lossy line coupling a signal into the pacemaker. A higher impedance lossy line would have reduced the effect, but would probably have still been unacceptable.

The final design uses an additional fiber optics light pipe to transmit a pulse of light from the monitoring point to a photovoltaic cell connected to the pacemaker leads (see Fig. 3). The cell used is a small chip, approximately 1/4" x 1/4", from a large photovoltaic cell and is mounted inside the connecting plug so that it does not significantly affect the pacemaker by inducing RF into the leads. The pulse of light is generated by a small lamp driven by a variable frequency oscillator.

The lamp pulsing circuit is shown in Figure 3 (light flasher). The timer is a classic unijunction transistor circuit with a variable timing resistor to vary the simulated heart rate. The output from the unijunction



(a) R-WAVE INHIBITED PACEMAKER



(b) P-WAVE SYNCHRONOUS PACEMAKER

Figure 4. Pacemaker responses to the simulator.

and a P-wave synchronous pacemaker in both synchronous and asynchronous modes. These recordings show how easy it is to determine if the pacemaker is in an EMI mode.

One of the most important considerations for a telemetry system to be used in RF fields is its immunity to those fields. Any spurious or suppressed signals caused by interference with the telemetry system could lead to an incorrect conclusion about the device under test. The simple monitor part of this system has been tested without failure under a wide variety of field conditions; e.g., in electromagnetic pulse field levels up to 6000 V/m at a pulse repetition rate of up to 60 pps. The entire system has been successfully tested at 26.6 MHz in the USAFSAM RF facility, and in the vicinity of several RF emitters covering the frequency range 200-3000 MHz; the addition of the simulator did not affect the pacemaker threshold.

is used as the input to a relay driver transistor with the relay switching power to the lamp. The capacitors and biasing resistor are used to stretch the very short pulse from the unijunction into the ~50-msec pulse needed to trigger the pacemakers. The 6-V lamp is used at a low duty factor, so its life is not particularly short on the 18-V supply.

For simplicity of use, both the simulator lamp driver and the pacemaker-output monitoring circuitry were built into a single 2 1/4" x 2 1/4" x 5" metal box with a built-in high-gain amplifier for the photoresistor. The amplifier (Fig. 3) consists of a 741 operational amplifier a.c. coupled to the voltage divider photoresistor. The .005-μF positive feed-back capacitor increases the output voltage swing on an input pulse. The 39-megohm resistor provides a small amount of negative feedback for stability. Because of space limitations, the lamp driver and the photoresistor and amplifier are operated from the same bipolar power supply of two 9.6-V nickel-cadmium rechargeable batteries. A filter (Fig. 3) and other techniques were used to minimize the effect of the voltage drop due to the periodic drain of the lamp. To provide an indication at the recorder output when the lamp is lit, the lamp was arranged so that it produces a positive spike in the output, and the photoresistor produces a negative spike, thus allowing comparison of the pacemaker output rate with the simulator rate.

The connector at the pacemaker end of the two light pipes contains both the LED, as in the simple monitor, and the photovoltaic cell chip. The polarity of the photovoltaic cell is the same as the pacemaker pulse which fires the LED. The load network on the jack which connects to the pacemaker leads is the same as used in the simple monitor. The impedance of the photo cell does not affect the load significantly because it has a high resistance (~10 kilohms) compared to the load circuit.

A P-wave synchronous pacemaker, with an atrial-sensing lead, is attached to the load circuit so that the atrial and ventricular leads are connected to the same clip on the load. If desired, it would be feasible to provide a third clip for connection of the atrial lead to the photovoltaic cell; however, connecting the atrial lead to the ventricular lead does not affect significantly the EMI threshold.

EVALUATION

Figure 4 is a recording of two pacemakers' responses to the simulator: an R-wave inhibited pacemaker in both demand and fixed rate, The only disadvantage that has been noted with this system is that it is polarity sensitive. The pacemaker leads must be connected so that the pulse from the pacemaker forward biases the LED. The polarity of the photo cell is not particularly important because most pacemakers will detect either a positive or negative cardiac-simulating pulse. The polarity need not be a problem because the pacemaker leads are normally arranged in a fixed pattern so that the polarity is obvious.

We believe that a system of this type is ideally suited to testing cardiac pacemakers for interference at all types of RF fields.

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