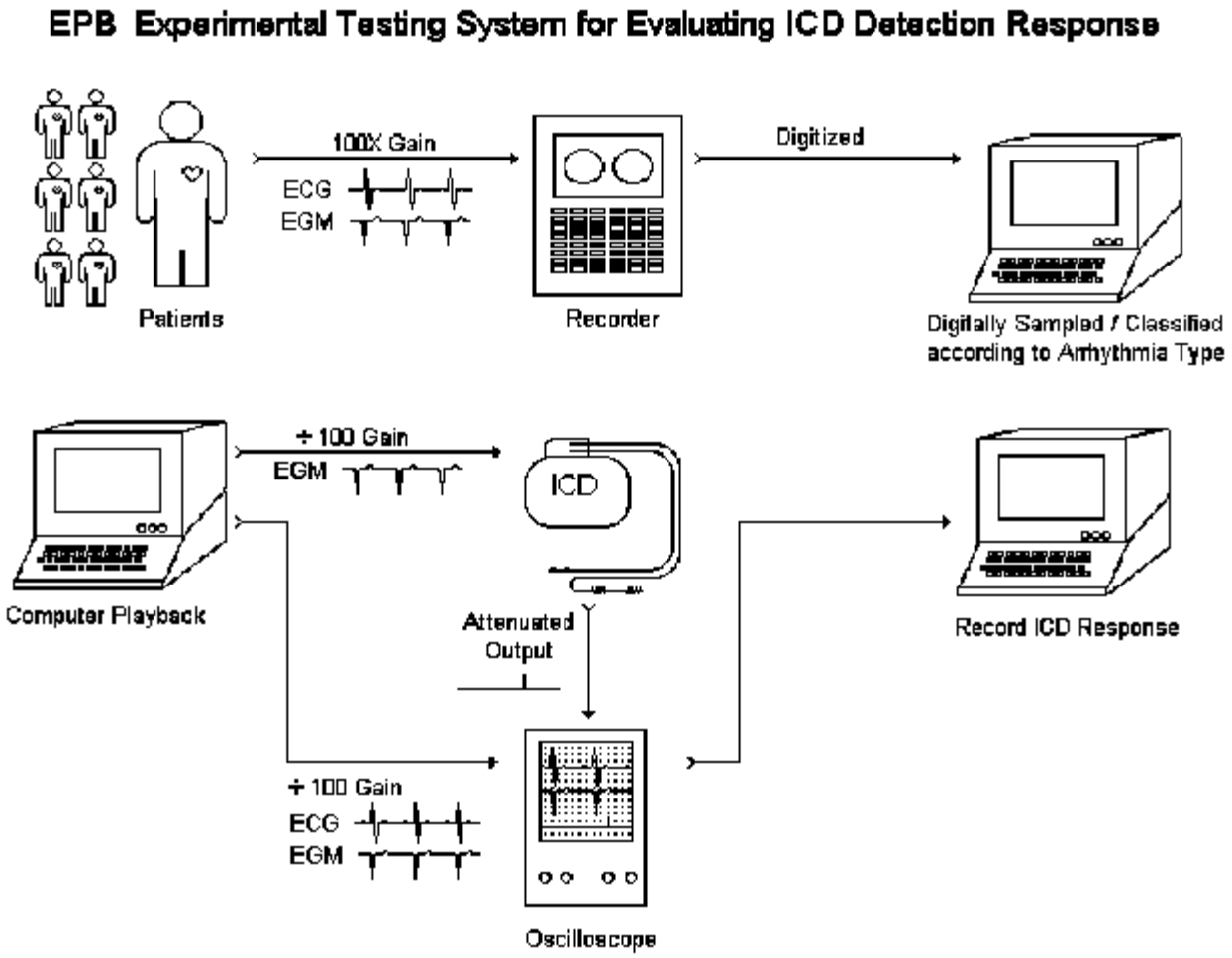

In a feasibility study, recorded data from the actual implanted transvenous leads of over 20 patients undergoing ICD implantation were collected. These data were stored in a digital computer database. The purpose of the tests was to determine if the defibrillator could provide the appropriate therapy when a recorded electrogram of ventricular fibrillation was presented to its sensing leads. In addition, the testing insured that no inappropriate firing occurred when a wide range of non-fibrillation electrograms was presented to the sensing leads. Preliminary tests of the ICD test system indicated that it can indeed perform its intended functions.

Exhaustive computerized lab testing with the OST electrogram database can improve the device review process. It may also reduce the number of FDA-approved ICDs that fail to deliver the appropriate therapy to patients in a postmarket approval setting. During the next fiscal year, a large (< 50) number of recorded electrograms representing many normal and abnormal electrograms, including artifacts, will be tested with samples of ICDs that have been approved by FDA. These lab test results will be compared with clinical results presented in the PMAs for each device, as well as with postmarket records from several clinical centers. If results are positive, premarket lab testing may be recommended using a broad array of arrhythmias and artifacts in the OST database. [PreME]

Return to the Table of Contents.

Radiofrequency Cardiac Ablation

Key words: cardiac, ablation

Radiofrequency (RF) cardiac ablation is becoming a commonly used procedure for the treatment of cardiac arrhythmias. It is a procedure in which high frequency energy is delivered to the myocardium via an electrode catheter

to create thermal lesions, thereby, eliminating arrhythmia pathways. One reason for its popularity is that, unlike other treatments for cardiac arrhythmias, cardiac ablation provides a cure for the patient instead of simply treating the patient's symptoms. From 1989 to 1993, the number of cardiac ablation procedures in the U.S. went from approximately 450 to 14,975. Although this procedure is widely used, only recently have there been approved devices, and there are still some unanswered questions regarding safety and efficacy.

One of the efficacy concerns for cardiac ablation is the optimal temperature for lesion formation. Several of the FDA-approved ablation devices automatically adjust their power output to maintain a constant temperature at the target site. This move toward temperature monitoring being an important aspect of ablation is also heralded in the literature. Previous research has shown that steady state temperature is a better predictor of lesion size than power, current, voltage, or energy delivered. The range of useful temperatures has also been established. The lower limit begins at approximately 48° C, where irreversible myocardial injury occurs. The upper limit is defined at the temperature where coagulum formation occurs with its associated large impedance rise at temperatures of 100° C or more. However, neither the previous research nor the industry has established the optimum temperature for cardiac ablation. Furthermore, ODE recognized the need for the optimal choice of target temperature to be objectively studied following a recent Circulatory Systems Device Panel meeting. Therefore in FY 95, OST performed laboratory studies of the relationship between the steady state tip temperature and the duration of treatment on lesion size.

The in vitro experimental setup consisted of an RF signal source, power meters, and an ablation catheter with a thermocouple sensor in its tip. Also, a thermocouple meter, a water bath, and plastic container (tank) were used. A butchered beef heart was the test material. To control for variables that can affect the lesion size, such as tissue contact force, fluid flow, and electrode catheter size, each of these variables was held constant.

Two experimental protocols were run: one in which the duration of the experiment was held constant at 60 seconds and the steady state tip temperature was varied, and the second protocol called for the steady state temperature to be held constant and the duration was varied. During both protocols, the power of the RF signal was varied to hold the steady state tip temperature constant. After lesion formation, the tissue was stained using a tetrazolium solution, which stains normal tissue red, giving a good contrast to the lesion and surrounding tissue. Finally, the lesion size was measured using calipers.

The temperature and power were recorded over time for each ablation. It took, on average, 3 to 4 seconds for the temperature to reach its steady state temperature. As the duration increased, the amount of power needed to maintain the steady state temperature decreased. The power needed to reach and maintain a steady state temperature of 60° C was, on average, 12.6 Watts. To maintain 70° C was an average of 20.7 Watts. To maintain 90° C, it took an average of 40.3 Watts, respectively.

The first protocol, in which duration was held constant at 60 seconds, found a linear relationship between lesion size and the steady state tip temperature. The steady state temperature was varied from 50° C to 90° C in steps of five degrees. Lesion depth was directly proportional to the temperature and varied from 1 mm at 50° C to 7.5 mm at 90° C. Lesion widths varied from 3.5 mm at 50° C to 9 mm at 90° C. For the second protocol, temperature was held constant and the time duration was varied. For each steady state temperature, an exponential curve was fitted to the data. A plateau in lesion depth was reached after 120 - 180 seconds seconds for both lesion depth and width.

The use of temperature-sensing catheters and temperature control increases the safety of cardiac ablation, because it prevents the tip temperature from reaching 100° C where coagulum is formed on the tip. Temperature sensing can also increase the efficacy of cardiac ablation because it is a good predictor of lesion size. Finally, steady state tip temperature and lesion size have a linear relationship, which supports the industry's move toward temperature-controlled ablation generators. [PreME]

Return to the Table of Contents.

Studies of Safety of Cardiac Defibrillation