

CLINICAL BIOTELEMETRY

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Summary Telemetry and telemetric techniques are of increasing significance in clinical medicine. Diagnostic data is acquired in this way for both manual and automated interpretation or processing. It has become practical to assemble clinical monitoring systems from non-custom equipment. Clinical biotelemetry is reviewed briefly, and a recent composite system is described in some detail.

Background The first devices of technical sophistication were those intended for animal implant. These systems permitted acquisition of data related to nearly every physiological function. It was even practical to close the loop; to provide feedback stimulus. The term “telestimulus” was coined. These systems were not applied to humans due to the inherent risk of implant surgery. Later, these implant techniques, developed for telemetry, were responsible for the clinical success of cardiac pacemaker implants in humans.

Human biotelemetry owes much of its development to man’s ventures into hostile environments. Of particular significance have been the “man-in-space” program and “man-in-the-sea” program. It has been essential to determine the physiological changes that occur with prolonged exposure to weightlessness and high pressures. The physiological parameter telemetered most often in these programs has been electrocardiographic data. Among the many technical advancements has been reliable long-term cutaneous electrodes.¹

Perhaps the first clinical application of biotelemetry was in monitoring cardiac patients during their normal every-day activities, Among the equipment developed were small, pocket tape recorders. They use such basic telemetric techniques as FM subcarriers. Both long and short range FM/FM radio telemetry are now in common use for monitoring ambulatory coronary patients. Such radio telemetry is also utilized for monitoring malignant tumor activity, thus determining efficacy of various therapeutic procedures and agents.² Endoradiosonde techniques show great promise for full-scale diagnostic use in the near future.³

Hard-wire biotelemetry has been in fairly continuous use since the early sixties. In recent years the demands of the data-processing industry have decreased the cost and greatly increased the feasibility of this technique. Figures 1 through 5 illustrate the major variations in biotelemetry.

Biotelemetry has contributed importantly to medical and biological research. There has been increasing clinical application, first in various areas of clinical research and, more recently, in the everyday delivery of health care. Characteristic of the new technical maturity is the increasing off-the-shelf availability of sub-systems and systems for clinical, as well as research, purposes. Recently, there has been some attempt to apply I.R.I.G.⁴ and other standards of interfacing and sub-carrier frequencies. If this trend continues, practical clinical systems will be more numerous.

An Expansible Coronary Care Monitoring System This system combining RF and hard-wire telemetry, provides an excellent overview of current clinical biotelemetry. Component sub-systems are, almost without exception, off-the-shelf items. This monitoring system is complementary to protecting the “electrically-susceptible patient” from microshock, as well as macroshock and ignition hazards.

It is important that coronary patients be continuously monitored by specially-trained medical personnel. This can be accomplished with great flexibility by combining hard-wire monitoring within the coronary care unit with telephonic and RF telemetry outside of the Coronary Care Unit. Should it be necessary, it is practical to extend the monitoring to incoming ambulance vehicles. Since the technology of clinical biotelemetry is quite mature at this time, we will concentrate on the systems engineering of such an expanded coronary care unit monitoring system rather than on details of subsystems.

The patient load of a coronary care unit is never completely predictable. The bed capacity within the unit is severely limited by economic factors. Transient overloading is quite common. The system under discussion permits continuous monitoring at the Unit Console, of patients located anywhere. These patients may either be in the Unit, in general-care beds, or ambulatory, permitting monitoring of both seriously-ill over-flow patients and patients that are recovering. Figure 6 illustrates the system flexibility.

For the most part, coronary care patients are in the category of “electrically-susceptible patients.” Protection from shock hazards must be provided in the Unit by special power systems and “equipotential grounding”. Remote patients are protected by the electrical isolation of air coupling to the telephone system and temporary procedures at bedside. When RF telemetry is utilized, no protective measures are necessary.

Modern technology is, today, applied throughout the entire health care complex, but is nowhere more concentrated than in areas organized to provide coronary care. The design

of an effective, safe Unit is, like all design, primarily an engineering responsibility. The task is to meet the present and future medical needs within the technical and economic constraints. Biomedical Engineering is characterized by multidiscipline systems engineering. A systems approach is necessary to integrate the modern medical environment of specialists, instrumentation, computers, and communications into effective systems.

Throughout the design of the Coronary Care Unit, electrical safety must be a primary consideration. A subsystem interacts with other subsystems and the personnel. This interaction determines electrical safety as well as the efficiency of the Unit.

The acute care facility consists of all permanent portions of power, signal, and lighting sub-systems. Initial design decisions relate to the protection of the "electrically-susceptible patient" as well as the performance, and interaction of these sub-systems. The power sub-system influences decisions in all other areas. For example, telemetry may be used to monitor bedside-acquired signals at the nursing station in order to prevent violation of an isolated power sub-system at bedside.

Regardless of the protection method, the electric design must include two factors: a "local grounding system" of proven integrity, encompassing the patient's immediate and personal environment, and isolation from the building's power distribution system. In the design and construction of the facility and ancillary equipment we can greatly reduce the electrical hazards. We can never completely eliminate the consequences of human failure in either utilization or in maintenance. Consequently, personnel and their training become an important part of the systems engineering responsibility.

Three general categories of patients are continuously monitored by specially trained medical personnel at the Coronary Care Unit Console: 1) those in beds within the Unit, 2) those in beds elsewhere in the hospital (anywhere with telephone service), and 3) those recovering ambulatory patients not confined to bed. Referring to Figure 6, it is clear that all these acute and intermediate patients may be monitored at the Unit Console.

Within the Unit, conventional bedside monitors are utilized. The derived electrocardiographic signal (.05 to 150 cps) however, is not applied directly to a signal cable for monitoring remotely. Rather this signal frequency modulates an audio sub-carrier oscillator. The sub-carrier tone is applied to the signal cable passing through a special audio isolation transformer at the Unit Console. The frequency modulated sub-carrier is demodulated and the recovered electrocardiographic signal is utilized in the usual display, recording, and rate monitoring sub-systems. By adherence to I. R. I. G. Standards, "remote patients" are monitored at the Unit Console with identical sub-carrier demodulators.

The remote patient, confined to bed, is provided with an electrocardiographic preamplifier, an FM modulator similar to those used in the Unit and an air coupler to provide access to the hospital telephone network. The patient is protected against microshock hazards by the use of battery power and the electrical isolation provided by air coupling with regard to monitoring. When additional appliances or instruments are required in this patient's immediate environment, redundant grounding, portable isolated power centers, and other precautionary measures must be utilized.

The ambulatory patient is monitored with conventional R. F. telemetry usually of short range. The pocket transmitter provides an FM/FM signal that is acquired by the telemetry receiver, usually located at the nurses' station. Although the recovered electrocardiographic signal is available at this receiver for monitoring, the specially-trained medical personnel are usually not available. For telemetry over the telephone network to the Coronary Care Unit (where these personnel are continuously available), we require an audio tone modulated with the electrocardiographic information. You will note in Figure 6 that the RF receiver has the modulated sub-carrier available for air coupling to the telephone instrument. Thus a sub-carrier demodulation and remodulation, with some signal degradation, is avoided. Since this sub-carrier is also I.R.I.G. compatible, the demodulator at the Unit Console is identical to the demodulators used in monitoring within the Unit and remotely at bedside.

In Conclusion We have outlined the trend toward utilizing biotelemetry in clinical, as well as research medicine. A recently designed clinical monitoring system has been described as an example of this trend. Biotelemetric techniques have permitted, 1) improvements of flexibility, 2) greater patient capacity, 3) reduction of electrical hazards, and 4) economies in the monitoring and power systems.

The Coronary Care Unit system design work, the example of modern clinical biotelemetry was supported by the Pennsylvania Hospital of Philadelphia. Although we are indebted to many members of the Hospital's medical and administrative staffs, the technical contributions of Dr. Peter F. Binnion, physician in charge of the Coronary Care Unit, and Mr. Joseph Daniel, Director of Building Services, have been of primary importance.

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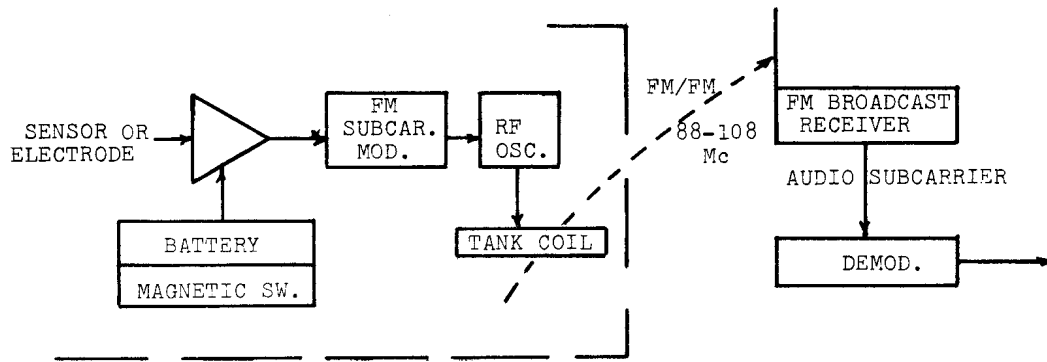


Figure 1. TYPICAL IMPLANTABLE BIOTELEMETRY

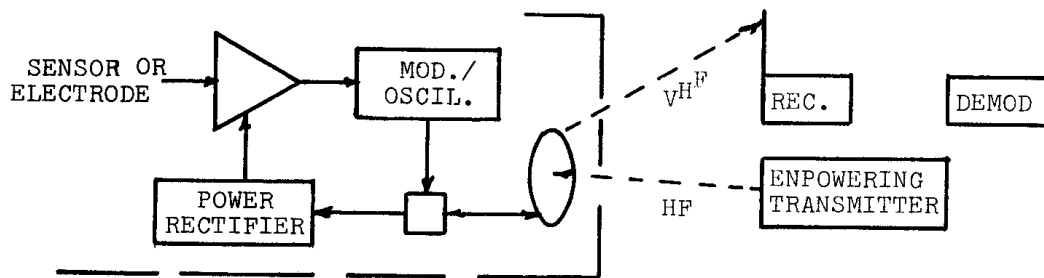


Figure 2. QUASI PASSIVE IMPLANTABLE BIOTELEMETRY

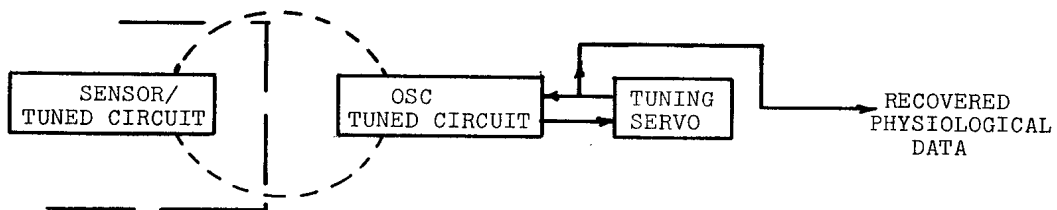


Figure 3. PASSIVE IMPLANTABLE BIOTELEMETRY (RADIOSONDE)

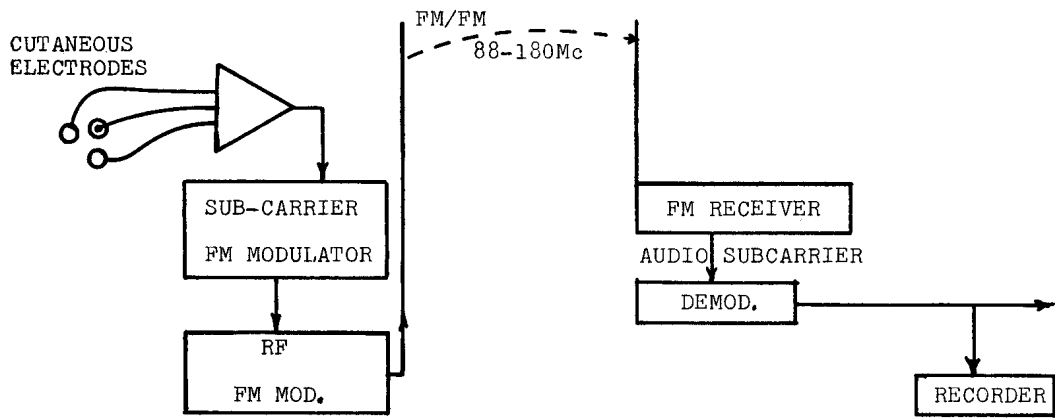


Figure 4. TYPICAL CLINICAL TELEMETRY

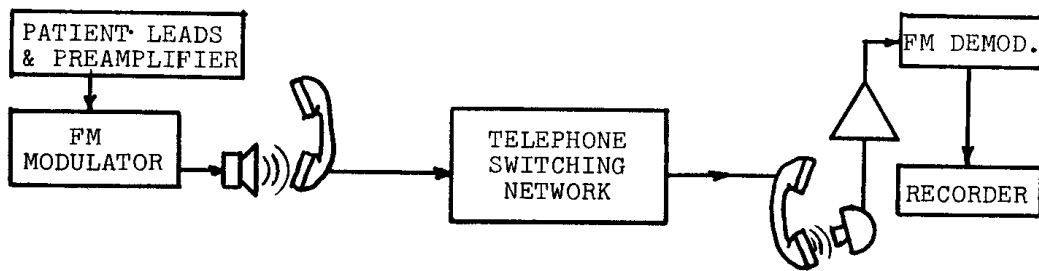


Figure 5. TELEPHONIC OR "HARD WIRE" TELEMETRY

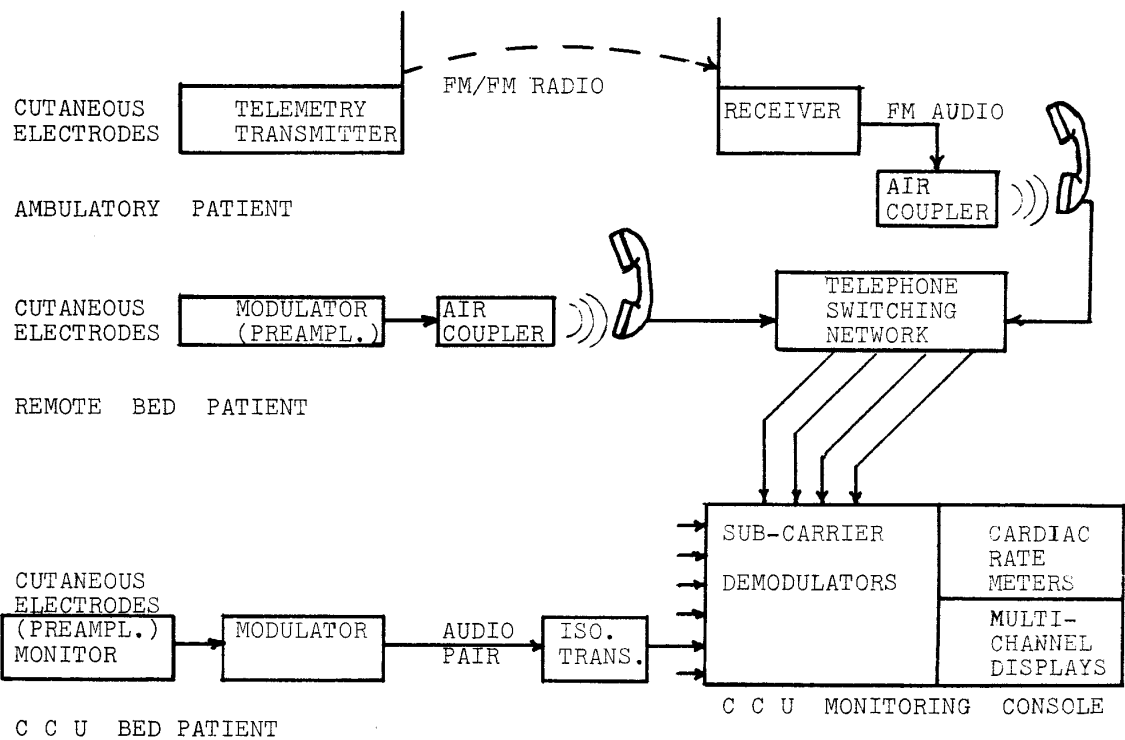


Figure 6. AN EXPANSIBLE CORONARY CARE MONITORING SYSTEM