Preview of Abstracts

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Frontiers of Engineering and Computing in Health Care consists of technical sessions, workshops, and tutorials, with both contributed and invited presentations. Emphasis is on up-to-date technical advances that influence the design, safety, evaluation, and management of medical data devices and systems. The goal of the conference is to fulfull the professional needs of EMBS members. Presentations given in the technical sessions are supplemented by papers written by the participants. The full text of the papers will be published in the *Conference Proceedings* (volume 5), which will be available at the time of the Conference. Additional information about the Conference is available from Glen C. Gerhard, Ph.D., Program Chairman, Department of Electrical and Computer Engineering, University of Arizona, Tucson, AZ 85721; telephone (602) 621-5986/2434.

Abstracts of papers as prepared by the authors follow.

Session 1—Functional Assessment of The Handicapped I

Co-Chairmen: G. V. Kondvaske, Ph.D.
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Perspectives on Approaches to the Measurement of Function

(*Invited Paper*)

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The phenomenon and issues associated with the development and clinical utilization of coded scoring sheets (ordinal scale ratings) and instrumented devices to measure the functional level of patients with sensory or motor disorders cut across many scientific disciplines and professions. Basic investigative studies and clinical trials are found in such fields as biomedical engineering, biostatistics, gerontology, industrial and human factors engineering, neurology, personnel management, pharmacology, psychiatry, psychology, psychotherapy, rehabilitation, surgery, and toxicology. Recognizing the importance, pharmaceutical and medical device companies, and health-related regulatory and funding agencies (such as the Food and Drug Administration and the National Institutes for Handicapped Research) are increasingly requiring sensitive, objective, and comprehensive analyses to document changes in function over time. In addition to clinical studies, experimental evaluation studies of test systems are oftentimes carried out to verify such factors as reliability, validity, effects of learning from test repetition, motivation, and the relation of age and gender on normal and abnormal function. The advent of low-cost mini- and microcomputers have already been commercially applied to quantify evoked potentials, EEG, nerve conduction velocity, and EMG, and may soon be used to comprehensively assess such functions as vision, hearing, memory, strength, reactions, steadiness, sensations, speed and coordination movement, stance, gait, range of motion, and activities of daily living. In the process, measurement techniques may become more standardized and widely applied to the mutual benefit of clinicians and investigators in numerous scientific disciplines.

This presentation includes a broad review of coded and instrumented tests of function and their applications, an assessment of current status, and a prospectus for future developments.

ACKNOWLEDGMENT

This work was supported by the National Institutes for Handicapped Research, and by the VA Research and Development Service.

Functional Assessment of the Handicapped for Assistive Aids

(Invited Paper)

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The role of rehabilitation engineering is to enhance handicapped persons' communication, environmental control, mobility, seating, and postural support through the use of technology. An individual's needs and functional capabilities must be carefully assessed in order to provide an effective assistive device or system. The "rehabilitation team" (nurse, occupational therapist, orthotist/prosthetist, physical therapist, physician, rehabilitation engineer, speech pathologist) uses its combined expertise and available evaluation tools to assess the patient's functional capabilities. A few commercial aids and systems currently available have "evaluation systems" which can be used to determine feasibility for an individual and optimal system configuration. A thorough knowledge of commercial devices and techniques for their modification, as well as the ability to develop custom devices, are used to match a handicapped person's needs and functional capabilities with an appropriate aid. It is the obligation of the rehabilitation team to take cost, durability, and serviceability into consideration in choosing a technological aid. Examples of patient evaluations are presented, and the need for generalized assessment systems is discussed.

Activity-Oriented Functional Assessment of the Handicapped

(Invited Paper)

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The more severe the physical handicap, the greater the need for detailed, quantitative information on the individual. The Louisiana Tech Rehabilitation Engineering Research, Development and Training Center has performed research directed at the development of a series of activity-oriented functional assessments to assist the moderate-to-severely physically handicapped person. These computer-aided assessments are directed at three major areas (work, independent living, driving) and complement existing assessment and evaluation services available to this population. An interdisciplinary team approach (including engineers, physicians, therapists, rehabilitation counselors, and driving specialists) was utilized. Since the Center houses a resident dormitory for the moderate-to-severely handicapped, the user population had the opportunity to actively participate in their development. This presentation will discuss these activity-oriented functional assessment procedures and will emphasize their development, implementation, and application.

ACKNOWLEDGMENT

This work was supported by the Division of Vocational Rehabilitation, State of Louisiana.

Event-Related Potentials and Functional Assessments

(Invited Paper)

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Electrical potentials can be recorded from the scalp that are temporally locked to the occurrence of a sensory event. These sensory evoked potentials are sensitive indicators of the functional integrity of structures along the primary sensory pathways of the input channel from receptor to primary cortical processing areas. Another class of brain electrical potentials has been described whose occurrence and characteristics are relatively independent of the physical properties of the eliciting stimulus or event. Such event-related potentials are associated with a patient's subjective interpretation of the information conveyed by the event and have been termed "endogenous." They are thought to index cerebral activity underlying hypothesized constructs such as expectancy, motivation, decision-making, context updating, memory, and others. Results of initial clinical applications suggest their special sensitivity to disorders of higher cognitive functions such as in dementia, schizophrenia, aphasia, and others. When coupled with sensory evoked potentials and more traditional behavioral assessments, the endogenous event-related potentials may offer measures for the objective evaluation of the speed, strength, and possibly spatial localization of neural processes underlying cognition. This paper reviews the various types of event-related potentials and their potential clinical applications.

Controlling Multiple Degree-of-Freedom Powered Prostheses

(Invited Paper)

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Over the past ten years, the technologic development of powered prosthetic arms has proceeded at a rapid pace. Unfortunately, relatively little attention or resources have been directed at developing methods to train individuals fitted with these devices. As a result, acceptance of multiple degree-of-freedom devices by amputees has been disappointingly low. At the present time, few clinics will fit high level or bilateral amputees with devices designed to (theoretically) provide a wide range of motion. A study was undertaken with a high level, bilateral amputee who had received two myoelectrically controlled prosthetic arms to identify methods of training him to control a total of five degrees-of-freedom. These five degrees-of-freedom are controlled

by eight different electromyographic recording sites and one mechanical switch.

The subject was first trained to isolate individual muscles using visually displayed EMG signals. Using goniometry at each powered joint, the subject next learned to track visually displayed waveforms with each joint. Finally, multiple joint movements were learned in which all joints moved simultaneously. These training methods were developed specifically to 1) produce natural looking motion, 2) with a minimum of visual attention to the arm itself, and 3) with hardware which could be used in an "in-home" setting.

Real-Time Microprocessor System for EMG/Foot Force Analysis

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The clinical assessment of the weight bearing foot during locomotion is normally based on subjective evaluation rather than on objective measurement. We have previously described an instrumentation system which measures both the magnitude and the distribution of the time dependent vertical forces acting on the foot during gait and which displays this clinical data in real time.

The original system consists of a force plate made from 16 Plexiglas beams mounted on load cells. The total force on each beam and the location of the center of force on each beam is displayed interactively with a video image of the plantar surface of the foot and with a lateral view of the subject. A video casette recorder stores this information so that a frame by frame analysis of the data and a complete loading history can be presented to a clinician.

Experience with the system has shown the need for correlation of EMG with the force and visual data. An upgraded system based on an Intel 8088 microprocessor includes

1) Four channels of EMG information as on/off markers.
2) On screen alpha-numerics.
3) Real-time graphic loading histories following each walking cycle.
4) Automatic system calibration.
5) Direct interface with the gait lab minicomputer.

The upgraded segmented force plate system is now a primary clinical aid in the Gait Laboratory at the University Hospital, Stony Brook.

ACKNOWLEDGMENT

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Assessment of Spinal Cord Function Via Epidural Electrodes

(Invited Paper)

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The technique of electrical stimulation of the spinal cord with epidurally placed electrodes is used for modification of pain and abnormal motor control. This relatively noninvasive percutaneous placement technique enables the recording of potentials from the cord as well as stimulation. A system for epidural spinal cord evaluation (SESCE) is described which enables both stimulation and recording. The SESCE system is capable of being introduced in the spinal canal and positioned at various sites along the cord. Since the electrodes are in close proximity to spinal cord structures, focal stimulation and recording can be accomplished. Subjective sensation, somatosensory evoked potentials, long loop reflexes, and segmental and distant muscle twitches can be elicited with epidural stimulation. Spinal cord potentials resulting from peripheral nerve stimulation or supra-segmental epidural stimulation can be recorded with a signal-to-noise ratio and bandwidth that are not possible to achieve with surface techniques. With this method, more precise definition of spinal cord function above and below the lesion level in spinal cord injured patients as well as in patients with progressive disorders can be accomplished. Furthermore, it is possible that use of spinal cord evaluation by means of an epidurally placed system can be used to study subclinical manifestations of progressive diseases of the nervous system.

Frequency Spectral Measures of the Myoelectric Signal

(Invited Paper)

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Human muscle function and fatigue during exercise can be quantified using measures of the frequency power spectrum of the myoelectric signal. By computing the mean and median power frequencies (MPF and MDPF, respectively) and total signal power (rms voltage) of the myoelectric signal spectrum using digital signal processing techniques, correlations between these variables and muscle force, endurance time, and fatigue can be evaluated. Myoelectric signals obtained from erector spinae and rectus abdominis muscles during isometric exercise were digitized and stored on a DEC LSI-11/23 minicomputer. A 512 point fast Fourier transform was used to obtain an averaged periodogram, from which MPF, MDPF, and total signal power for the frequency band of 12-512 Hz were obtained. Fatigue time constants derived from MPF changes over time showed positive correlations with endurance time ($r = 0.88$) and positive test-retest reproducibility ($r = 0.79$).

ACKNOWLEDGMENT

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Interpretation of Myoelectric Signals in Gait

(Invited Paper)

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Traditional analyses of myoelectric signals during gait have focused on active muscles as generators of the torques which result in joint motions. In fact, this role is generally unnecessary, except at the initiation of swing, forcing a reappraisal of the standard view. Most muscle activity acts to tune the locomotor suspension and to maintain postural stability. In light of this approach, pathological gaits in central neurological diseases may be considered to arise from muscles acting abnormally as generators of inappropriate torques, modifying the normal patterns and interfering with the coincident postural stabilizations.

This paper will outline the interpretation of myoelectric activity within this alternative framework. Normal gait will be described briefly, followed by the commonest gaits in adult stroke patients, and in children with cerebral palsy. Guidelines for applying the methodology to gaits in other diseases, as well as some implications for lower limb prosthesis design, will be outlined.

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A Syntactic Method for Evaluation of Abnormalities in Human Gait

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This paper describes a syntactic pattern recognition method for the evaluation of abnormalities in human gait. One essential prerequisite for detecting abnormalities is the existence of a description of the normal characteristics of gait. The system constructed in this research contains a normative database which includes conventional descriptive terms such as swing, stance, degree of flexion, etc., and information derived from the electromyogram (EMG), foot-contact patterns, and kinematics.

Data acquired by the analysis system are on-off EMG patterns; bilateral foot-contact patterns indicating the heel, ball, and toe contact sequences of both feet; and the angular motions of the major joints. The foot-contact patterns demarcate the gait periods, and EMG and kinematic data are reduced to lists of descriptive labels (EMG) and lists of flexions by joint for each of the seven time periods in the gait cycle. These lists are compared to the lists of normative data with the objective of determining deviations from normality. Syntactic rules are then used to amalgamate all lists produced across channels to secure a distilled report pinpointing the specific abnormalities. This report is to be ultimately used as input to an artifical intelligence-based expert system which will provide diagnostic and therapeutic recommendations.

ACKNOWLEDGMENT

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Session 2—Medical Imaging I: Medical Tomographic Imaging

Chairman: Ernest M. Stokely, Ph.D.
University of Texas Health Science Center at Dallas, TX

Single Photon ECT—Is It Here to Stay?

(Invited Paper)

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Single photon emission computed tomography (ECT) is able to noninvasively measure *in vivo* biochemical and hemodynamic function by using single photon radiopharmaceuticals which depict the spatial and temporal distribution of biological processes in healthy and diseased tissue. The physics of single photon ECT presents a challenge to improving image quality and quantitative capability. Characteristically single photon ECT has poor sensitivity ($\approx 10^{-4}$) because of the small detectable solid angle and poor resolution ($\approx$ 1–2 cm) which is limited by the collimator. In addition, there is the problem of attenuation which gives a perceived reduction in perfusion and potential volume deformation, and scatter which compromises low contrast detectability. However, the technology has developed to the extent that single photon ECT has become a useful clinical tool. The availability of inexpensive radiopharmaceuticals and the mechanical simplicity of a rotating gamma camera make single photon ECT an attractive imaging modality. Single photon ECT is used routinely in liver imaging with ^{99m}Tc sulfur colloid, heart imaging with ^{201}Tl, and various types of brain imaging, as for example, imaging the temporomandibular joint with ^{99m}Tc pyrophosphate. Some of the exciting potential applications include the use of iodoamphetamine to image brain blood flow, and the use of antibodies to image neoplastic lesions.

Tomography by Linear-Aperture Nuclear-Image Data Inversion

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Previous work on a two-dimensional coded-aperture nuclear imaging system has shown that tomographic reconstruction by matrix inversion is a feasible technique for small objects. The matrix inversion method substantially reduces inter-plane feedthrough, thus improving axial resolution. The primary objective of this work is the application of this technique to a multiple-pinhole coded-aperture image of the human heart. This requires the design of an imaging system whose resultant point source response (PSR) matrix is sufficiently well-conditioned to tolerate the noise level inherent in nuclear imaging. For a two-dimensional aperture, matrix dimension increases and conditioning rapidly deteriorates as object size increases. This paper investigates a one-dimensional aperture as a potential solution. For L object planes, each of dimension $M \times N$, the use of a linear aperture converts the overall $L \times M \times N$ system PSR matrix to M independent $L \times N$ matrices. Computer simulations with one-dimensional apertures for various object shapes in adjacent planes gave excellent results. Planar radioactive objects in adjacent planes were also imaged and reconstructed, with good planar separation. Based on these encouraging results, work continues on efficient aperture design and testing with three-dimensional objects approaching heart size.

ACKNOWLEDGMENT

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Ultrasonic Imaging Instrumentation

(Invited Paper)

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There is a variety of instrumentation available for ultrasonic imaging in the clinic today and also a substantial research effort to develop new instrumentation for the characterization of tissue from its acoustic properties. Commercially available cross-sectional imaging instruments employ either manually, mechanically, or electronically scanned transducers to create images of echo amplitude shown as a shade of gray. Rapid, repeated scanning in some instruments produces a sequence of images which demonstrates the coordinated movement of structures within the scanning plane. Mechanical scanning is typically accomplished by rocking a single element back and forth or by rotating a few elements continuously in a circular path and using each element only as it moves through a specified arc. Electronic scanning is realized by linear arrays in which elements are active in groups or by electronically phasing elements so that the beam is steered. Annular arrays are used in some systems to narrow beamwidth uniformly in all directions normal to the beam axis. Instrumentation also exists to extract information about blood flow from the Doppler shifts of ultrasonic signals. Current research is directed at improved utilization of echo amplitude characteristics and the extraction of other information besides position and amplitude to characterize tissue. Among the various promising analyses are those which extract frequency-dependent attenuation from backscattered signals and determine reflector spacing from measurements of the angular dependence of scattering. Results are expected to extend the clinical utility of ultrasonic imaging as a noninvasive diagnostic tool.

Microwave Thermoelastic Tissue Imaging—System Design

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Microwave-induced thermoelastic pressure waves appear to possess some unique features that may allow them to become as useful as other imaging methods and permit noninvasive imaging of tissue characteristics which are not identifiable by other techniques. In this paper, we present a system design of microwave-induced thermoelastic tissue imaging along with an example which demonstrates the feasibility of the design approach. A brief burst of microwave pulses generates either deep or superficial, wide-area acoustic illumination according to a selected microwave absorption pattern. An array of 20 × 20 hydrophone transducers are used to detect the thermoelastic pressure waves. The received signal is amplified, bandlimited, filtered, and digitally processed to produce thermoelastic images of the irradiated body region. A theoretical signal-to-noise ratio calculation is included. Different design approaches for data acquisition are discussed. A parallel design is the most efficient, but it is also the most expensive one. A serial design is limited by present technology. A hybrid parallel/serial design of dividing the 20 × 20 array into segments and collecting data from each segment sequentially is suggested. This design gives good picture quality with reasonable cost, provided the object is quasistationary.

The Instrumentation of Nuclear Magnetic Resonance Imaging

(Invited Paper)

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First, for the purpose of establishing a common level, a brief introduction will be provided to the basic concepts involved in nuclear magnetic resonance (NMR) imaging. Aspects to be reviewed will include the quantum mechanical foundations of NMR, magnetization in a rotating frame, the macroscopic equations of motion (Bloch equations), relaxation parameters (T_1, T_2), and the principle of magnetic field gradient imaging.

A functional description of the basic NMR spectrometer will be provided including aspects of pulse programmer protocols, quadrature detection, Fourier transform techniques, and microcomputer control and processing of NMR signals. Aspects of the design and technology of whole body magnet systems options, radio frequency coils, and gradient coils for NMR imaging systems will be presented.

Amplitude Modulated Selective Pulses in NMR Imaging

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In NMR imaging, a radio frequency (RF) pulse in the presence of static magnetic field gradients is used to select the region from which the NMR signal is obtained. The design of selective pulses is important as it controls the resolution of the NMR imaging.

In this paper, we evaluate the effect of amplitude modulation of the RF pulse on the spatial distribution of the spin magnetization [$M(x)$]. The Bloch equations which describe the behavior of $M(x)$ in the presence of the RF pulse have time-varying coefficients, and closed form solutions cannot be obtained. We have used numerical integration of Bloch equations to study the relationship between the shape of the pulse, its frequency spectrum, and $M(x)$. The rectangular, triangle, Hanning, and Gaussian pulse shapes have been compared.

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Session 3—Body Surface Potential Mapping-Imaging The Electrical Activity of the Heart

(Sponsored by the EMBS Bioelectric Phenomena Committee)

Chairman: Yorim Rudy, Ph.D.
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ECG-BSPM-Partial RBBB Versus RVH with Terminal Right Conduction Delay

(Invited Paper)

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Methodology for developing electrocardiographic (ECG) body surface potential maps (BSPM) with color display, utilizing 180 active electrodes enclosed in a vest, has been developed and previously reported. Analysis of normal children's *QRS* and *T* including various quantifications of specific events in the cardiac cycle has also been reported. Among the events was invariable evidence for right ventricular (RV) epicardial breakthrough (avg 25 ms) with no evidence for left ventricular (LV) breakthrough. A series of 40 children with right bundle branch block (RBBB) will be presented demonstrating the spectrum from very advanced to partial. In no type of RBBB was RV breakthrough found. Of 20 children operated upon for Tetralogy of Fallot, who developed advanced RBBB, LV breakthrough was always present. With less extensive surgery and less advanced RBBB, LV breakthrough was sometimes not found. In RBBB, especially when advanced, evidence for activation of the right ventricle appeared very late and took longer to activate, often 100 ms, than the entire *QRS* duration prior to surgery, indicating that the Purkinje system was being utilized very inefficiently. Ten additional children with RVH and terminal right conduction delay, due to atrial septal defect, indistinguishable from partial RBBB utilizing standard ECG methods, showed definite RV breakthrough and no LV breakthrough. Preliminary data will also be presented to demonstrate the unique BSPM approach to the ECG interpretation of ventricular hypertrophy.

Surface Potential Mapping: A Problem in Statistical Imaging

(Invited Paper)

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The classical inverse problem in electrocardiography is to determine the electrical cardiac sources from the body surface potential distributions which they generate. Ultimately, the solution might exist in terms of the intracellular and extracellular current distributions from which localized assessment of tissue normalcy could be obtained. The complexity of the problem, both in terms of the underlying physics and physiology and the known lack of a unique solution for the unconstrained case, have greatly impeded progress in obtaining a useful inverse solution. Now that sufficiently large libraries of body surface potential map data are becoming available, a different approach to the inverse problem should be considered. Specifically, maps from patients with similar diagnostic classifications will presumably have common characteristics. Moreover, multivariate distributions of quantitative descriptors should provide the necessary information to identify those features which best discriminate between classes of maps as well as to suggest the significant temporal and spatial features of maps which point to the underlying physiological differences between the classes.

In this paper, we present evidence that significant map feature differences provide a "statistical image" of classes of compared cardiac states and have physiologically plausible interpretations. Comparisons between normal subjects (over 1000), and patients with left ventricular hypertrophy (23), hypertrophic cardiomyopathy (70), and those with previous inferior wall myocardial infarction (80) will be discussed.

ACKNOWLEDGMENT

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Error Analysis in Forward Electrocardiographic Problems

(Invited Paper)

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This paper examines the magnitude of numerical and aliasing errors encountered in the formulations and discretized computer simulations of forward electrocardiographic problems which relate epicardial and torso potentials. Single layer, double layer, and Green's Theorem formulations which relate epicardial and torso potentials are considered. The errors inherent in these simulations are very sensitive to the multipolar content of the epicardial potentials, and the errors encountered using the Green's Theorem formulation can be considerable for certain quadrupole terms, e.g., greater than 100 percent for the b_{21} term. The errors using the single layer and the double layer approach are considerably less for the b_{21} component. However, the three formulations yield comparable errors for the other four quadrupole terms and for the three dipole terms. It is concluded that for epicardial distributions which can be represented with dipolar and quadrupolar sources and for formulations which utilize a few hundred epicardial and torso segments that one should expect numerical and aliasing errors of approximately 30–60 percent for the calculated torso potentials using any of the three formulations. These errors can be reduced by multipolar filtering, but this requires either an *a priori* specification or careful estimation of the multipolar content of the epicardial potentials.

Inverse Solutions from Human Body Surface ECG Maps

(Invited Paper)

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A 23 dipole model incorporating a realistically shaped homogeneous torso was used to explore inverse solutions. Surface electrocardiograms studied included patient data and simulated data. 144 electrode sites were used; only *QRS* was considered. Inverse solutions were obtained on a least-squared error basis.

Even when dipole orientations were constrained, individual dipoles often gave highly inaccurate pictures of cardiac depolarization. A single resultant dipole (vectocardiogram) derived from the multiple inverse dipoles was accurate. Another model used two moving dipoles taken to be the resultant of the inverse dipoles in the left ventricle, and right ventricle plus septum, respectively. Paradoxically, while the time courses of the two dipoles seemed to be reasonably consistent with excitation patterns, the two dipole model gave a higher error in terms of reconstructing the surface ECG than did the single dipole.

Constraining dipole orientations reduced the best fit to human surface potentials, obtained near the peak of *QRS*, from about 95 percent to about 80–85 percent. The fit was as low as 30 percent at the onset and end of *QRS*. Simulation studies showed that a comparable error could result from variations in assumed dipole orientations. In-

troduction of time-varying dipole orientations did not result in significant improvement.

Dipole areas did not prove to be useful in quantifying the infarcted region for the patient data. A simulation experiment indicated a significant shift in dipole area away from the infarcted region.

ACKNOWLEDGMENT

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Recovery of Two Dipoles Using a Realistic Human Torso Model

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We investigated the accuracy of a mathematical technique for the inverse determination of two independent dipole sources from surface potentials generated on a computer torso model. Potential distributions produced by two dipoles located inside the cardiac region of the model were sampled at 120 uniformly distributed points and contaminated with noise. The terms of a multipolar expansion were computed from these potentials with a least-squares error (LSE) method. The parameters describing the two dipoles were evaluated with a nonlinear LSE Marquardt-type algorithm using the Brody multipolar shift equations. The rms error between the estimated dipole parameters and those of the original dipole sources were computed for 253 different dipole pairs of unit amplitude and random orientation. For a signal-to-noise ratio (SNR) of 50 dB, the location, magnitude, and orientation errors were 2.5 mm, 11 percent, and 1.1°, respectively; for a lower SNR of 30 dB, the errors were 8.6 mm, 20 percent, and 5.7°, respectively. When regions of lower conductivity describing the lungs were added to the torso model with a 50 dB SNR, the errors were 3.9 mm, 14 percent, and 5.5°, respectively. In conclusion, this simulation study demonstrates that two dipoles can be accurately recovered in a realistic torso model and suggests the feasibility of representing complex cardiac activity such as two simultaneous wavefronts by a two moving dipole model.

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Application of the Single Moving Dipole Technique in Man

(Invited Paper)

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We evaluated the capability of a single moving dipole (SMD) to accurately represent the propagation of ectopic beats in man. The electrical and geometrical measurements were performed on patients with implanted pacemakers. The SMD parameters were computed from the multipole components which best reproduced, on the surface of various computer torso models, the body surface potentials recorded with 63 leads. The SMD location at *QRS* onset was compared to the position of the pacing electrodes determined from chest X-rays. The results repeatedly showed that the SMD started its trajectory in the vicinity of the pacing electrode and then traversed the cardiac silhouette. The trajectory computed according to different modelization hypotheses showed some differences. For example, the addition of multipole components in a least-squares error (LSE) fit for a fixed-geometry homogeneous torso model made the trajectories more eccentric with respect to the center of the heart. The best results with the LSE method were obtained with 15 multipoles and were similar to trajectories obtained by surface integration for models with a torso geometry adapted to the individual patients. The inclusion of regions of lower electrical conductivity representing the lungs in the torso model for the LSE method produced a small (1 cm) rightward and forward shift of the trajectories. In conclusion, the SMD localized the origin of an ectopic beat within about an inch and provided an adequate representation of the movement of the ectopic depolarization wavefront.

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Current Flow Patterns in Two-Dimensional Anisotropic Bisyncytia

(Invited Paper)

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Cardiac tissue has been shown to function as an electrical syncytium in both intracellular and extracellular (interstitial) domains. Available experimental evidence and qualitative intuition about the complex anatomical structure support the viewpoint that different (average) conductivities are characteristic of the direction along the fiber axis as compared to the cross fiber direction, in intracellular as well as extracellular space. This paper analyzes two-dimensional cardiac tissue properly characterized as anistropic and achieves integral equations for finding intracellular and extracellular potentials, longitudinal currents, and membrane currents directly from a (given) description of the transmembrane voltage. These mathematical results are used as a basis for a numerical model of realistic (although idealized) two-dimensional cardiac tissue. A computer simulation based on the numerical model was executed for conductivity patterns including nominally normal ventricular muscle conductivities and a pattern having the intra/extra conductivity ratio along x (the reciprocal of that along y). The computed results are based on assuming a simple spatial distribution for V_m, usually a circular isochrone, to isolate the effects on currents and potentials of variations in conductivities without confounding propagation differences. The results are in contrast to the many reports that explicitly or implicity assume isotropic conductivity or equal conductivity ratios along x and y.

Development of a Modifiable Computer Body Model

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We have developed a three-dimensional human body computer model based on the finite element numerical technique. It solves Poisson's and Laplace's equations with boundary conditions for the potential distribution inside inhomogeneous and anisotropic domains with complex and irregular surface boundaries and internal interfaces. We have applied this model in three areas. In the dispersive-electrode study, we compare the temperature-rise distributions from simulation with experimental results from human subjects. In the impedance-imaging study, we reconstruct impedance images of one cross section of the model noninvasively, while in the electrocardiographic study, we make surface potential maps and calculate the transfer and lead coefficient matrices. We show that with minor modifications, we can use the same model in many diverse studies governed by either Laplace's or Poisson's equation. We will also discuss other bioengineering areas where this model may be useful, and refinement efforts being made to improve this model.

Session 4—Cardiovascular Control

Chairman: Francis A. Spelman, Ph.D.
Primate Center, University of Washington
Seattle, WA

Simulation of Overall Cardiovascular Control

(Invited Paper)

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Highly effective control processes seem to be an important part of biological phenomena, including the regulation of cardiovascular function. This contention is supported by the observation that arterial pressure is relatively invariant over extended periods while cardiac output appears to be adjusted continually to match metabolic needs. According to current understanding, this control is complex; a wide variety of time constants are involved. Many very interesting cardiovascular phenomena are characterized by longer-term time constants including the generation of new blood vessels, myocardial hypertrophy and the chronic diseases of hypertension and heart failure. Appropriately configured mathematical models might help to analyze and demonstrate cardiovascular complexity.

One such model is called "HUMAN." It consists of a family of nonlinear integral and algebraic equations that describe cardiovascular function and cardiovascular interaction with other organ systems. In addition to the circulatory system, the organ systems and processes that are included in the model are respiratory control and gas exchange, renal function, acid-base balance, some aspects of neural function, thermoregulation, and elementary endocrine function. This model has been used to demonstrate the details of such complex phenomena as the cardiorespiratory and thermal responses to exercise; hemodynamic, neural, and endocrine interactions during the development of hypertension; acclimatization to high altitude; and hemodynamic, renal, and endocrine responses to heart failure.

Transmitter-Specific CNS Control of Cardiovascular Function

(Invited Paper)

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If we are to eventually understand the CNS mechanisms affecting normal and pathological cardiovascular function, it will be requisite to rigorously identify and characterize relevant neural pathways. This will of necessity include detailed investigations of the spinal and supraspinal afferentation to thoracolumbar sympathetic preganglionic cells (SPN's). Recent results from several laboratories, including our own, suggest that substantial progress on this problem is being made. First, some of the cells of origin for the norepinephrine and epinephrine inputs to SPN's have been definitively localized in brain stem. Studies on the putative neurotransmitter actions of these catecholamines suggest that their synaptic release inhibits SPN discharge. This effect appears to be mediated by an α_2 adrenergic receptor. The presence of α_2 receptors in the SPN cell column has been verified using both autoradiographic receptor and radioligand binding techniques. Second, it has been established that a subpopulation of neurons within the medial medullary "depressor" area projects directly to the SPN's. The cells are localized within the raphe complex and may release the neurotransmitter serotonin. Finally, of the several neuropeptides found in the SPN cell column, evidence is accumulating that substance *P* may be an excitatory neurotransmitter and that many of the cells of origin are in the spinal grey. (HL24103 to JBC.)

The Excitation Mechanism of Carotid Baroreceptors

(Invited Paper)

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A new model for the excitation mechanism of carotid baroreceptors is developed by combining the receptor model of Zerbst and Dittberner and the carotid sinus wall model of von Maltzahn. It incorporates receptor properties such as adaptation, proportional-differential behavior, and accommodation as well as arterial wall properties such as physical and geometrical nonlinearity, two layers, incompressibility, and axial symmetry. In the carotid sinus the baroreceptive nerve endings cluster around the border between the two arterial layers, media and adventitia, and high tangential and longitudinal stress gradients occur there. Since these stress gradients directly cause the deformation of the strain sensitive baroreceptors, they are chosen to be the linking parameters between the two models that make up the new model. With this new model the effect of various wall properties and geometric dimensions on the firing activity of the sinus nerve has been studied. In diseases like hypertension, arteriosclerosis, and atherosclerosis it is known that wall properties and geometric dimensions are altered. The results from these calculations are interpreted in terms of their importance on the blood pressure regulation system.

Hand Blood Flow in Hypertensive and Normal Subjects

(Invited Paper)

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The present study is concerned with whether hypertensive subjects show evidence of structural vascular changes, whether such changes can be detected in early stages of hypertension, and whether they are reversible with treatment. Hypertensive and normal subjects were studied under conditions of maximum vasodilatation wherein flow at a given driving pressure and identical transmural pressure was considered to give an index of structural changes in resistance vessels. A noninvasive method was developed which permits comparisons of hypertensive and normotensive patients at equivalent transmural pressures. 32 subjects were divided into four groups: eight sustained hypertensives (SH), eight intermittent hypertensives (IH), eight hypertensives maintained at average systolic pressures below 125 mm Hg by drugs for five years (TH), and eight normals (N). Flow was measured by venous occlusion plethysmography after 10 min of ischemia, using a water filled plethysmograph at 43°C. Arterial pressure was measured by the arm cuff method. Transmural pressure (TP), calculated as mean arterial minus external pressure, was varied by imposing varying external hydrostatic pressures. Flow at a TP of 85 mm Hg was calculated for each subject from the least-mean squares plot of TP and flow. Mean flow for N was 41 ml/100 ml/min and differed significantly from that for SH (30), TH (33), IH (32), ($P < 0.05$). There was no overlap between SH and N but half of TH were normal. Intermittent as well as sustained hypertensives showed evidence of pronounced arterial changes. Prolonged therapy appeared to reverse changes in some patients. This noninvasive method permits comparisons of hypertensives and normotensives at equivalent transmural pressures.

Coupling Between LV Ejection and Relaxation

(Invited Paper)

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Left ventricle (LV) pump properties were studied in anesthetized open-chest dogs. Measurements were made of LV outflow (*LVQ*), LV pressure (*LVP*), and ECG. Sudden total and graded partial occlusions of the aorta were imposed using a pneumatic ECG-triggered device with moveable jaws. The occlusions were administered only when a stable reference pumping state was obtained, so that multiple single-beat responses to occlusion could be compared. The response to total aortic occlusion was defined to be isovolumic pressure (Piso). Partial occlusions generated graded levels of LVP. The difference between Piso and *LVP* of an ejecting beat was considered to be the driving force (*Pd*) for *LVQ*. The results were: 1) progressive elevation of *LVP* with graded occlusions resulted in reduced magnitude of *LVQ*, but prolongation of ejection period; 2) *Pd* demonstrated a biphasic behavior under all ejection conditions with a second hump in the waveform occurring during very late systole and the relaxation period; 3) progressive elevation of *LVP* resulted in progressive delay of the onset of the second phase of *Pd*; 4) at *LVP* close to Piso, *Pd* approached zero value just prior to the onset of the second phase of *Pd*. These observations indicate that ejection events determine the onset and rate of relaxation. An elastance-resistance LV pump model did not represent ejection relaxation coupling. However, such a model with a nonlinear shunting element added around the time-varying elastance did reproduce the four observed phenomena. Coupling between ejection and relaxation suggests that events that take place during ejection have an influence on cardiac events over the entire cardiac cycle.

Some Aspects of the Rheology of the Large Arteries

(Invited Paper)

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The arterial tissue can be characterized as an incompressible, curvilinearly orthotropic, nonlinearly viscoelastic material capable of undergoing large deformations. Mathematical as well as experimental characterizations of its elastic and viscoelastic behavior, and mathematical characterization of its thermoviscoelastic behavior have been described before. However, these characterizations are too formal and detailed for everyday use and, whereas they enhance our understanding of the general tissue behavior, they are not easy for a nonspecialist to follow. This communication will, therefore, outline some aspects of the rheology of the arterial tissue from a somewhat simpler point of view, and discuss the role that arterial properties play in the control of circulation. Specifically discussed will be the significance of Laplace's law, nonlinearity of response, incremental response, wall stress distribution, and the possible phenomenological mechanism by which the control of blood pressure is effected.

Session 5—Electrodes

Chairman: Clifford D. Ferris, Ph.D.
University of Wyoming
Laramie, WY

Practical Considerations in the Use of Skin-Surface Recording Electrodes

(Invited Paper)

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This presentation will be a minitutorial paper treating some of the practical aspects associated with the use of metallic electrodes for biopotential recording from the skin surface. Topics to be examined include: electrode polarization, offset potentials between electrodes, Ag-AgCl electrodes versus pure metallic electrodes, electrolyte interface, electrode surface preparation, skin preparation, static problems, and measurement of impedance between electrodes.

Input circuits for amplifiers used with skin-surface recording electrodes will also be discussed.

Origin of Stretch-Caused Motion Artifacts Under Electrodes

(Invited Paper)

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The outside of the skin is typically 30 mV more negative than the inside. Stretching the skin causes a reduction in the magnitude of this skin potential V, which we observe as motion artifact ΔV. We seek to determine the origin of this motion artifact by successively stripping 25 layers of the skin using scotch tape. Between each stripping we measure artifact ΔV, 10 Hz impedance Z, and change in impedance ΔZ. On the volar surface of the forearm, Z decreases with the number of strippings. ΔZ first has a small decrease, then a larger (10 percent) decrease, then a small decrease. ΔV decreases with Z and ΔZ. ΔZ increases with stretch weight up to a saturation limit for a stretch weight of about 500 g. ΔV shows little change up to a stretch weight of 400 g and thereafter increases rapidly until a saturation of about 1 kg. We have expanded the model of Thakor and Webster to best fit the waveforms of ΔZ and ΔV caused by stretch.

The Effect of Metal Electrodes on Stimulation Thresholds

(Invited Paper)

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In typical bioelectric stimulation with metal electrodes, voltage threshold levels do not agree with theoretical predictions from a study of the field strength distributions around the stimulating tip and the interface polarization impedance values. The complexity in the interpretation of these levels stems partly from the difficulty in analyzing the polarization phenomena at the electrode interface carrying large amplitude currents. The question is not merely of academic interest since it involves stimulation effectiveness with implanted sources. Also, nonlinear polarization is associated with irreversible electrochemical processes raising the issue of stimulation safety. The situation worsens as the dimension of the electrode tip is reduced down to microscopic scales as in neural and neuromuscular applications.

In an attempt to study the contribution of the electrode interface to voltage thresholds, we have simulated the electrical transfer characteristic of the interface by a nonlinear model solely based on the knowledge of the small signal impedance and the specific steady-state current-voltage polarization curve of the interface. We have used the Advanced Continuous Systems Language (ACSL) to mimic experimental results obtained *in vitro* from a Pt electrode in physiological saline, thus verifying the validity of the proposed model.

Practical implications of the study are considered and are extended to chronic stimulation when appropriate.

Low Threshold Cardiac Pacing Electrodes

(Invited Paper)

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It has long been a goal to reliably reduce chronic cardiac pacing thresholds. It was discovered in previous studies that dexamethasone phosphoric acid (DPA) delivered directly to the electrode-tissue interface reduces chronic threshold rise without systemic side effects. But devices with a DPA monolithic controlled release device (MCRD) in the center of a ring electrode, in direct tissue contact, had design-related problems such as MCRD volume change, too fast an elution rate, etc. A new design encapsulates the sodium salt of DPA in an MCRD within a porous surface electrode. Canine performance ($N = 5$ and 12) has been superior to any previously known ventricular electrode. Thresholds remained essentially stable over the 12-week experiment (0.45 $\pm$ 0.20 V chronic at 0.5 ms), a three-fold improvement over ring tip standard, model 6971 (1.5 $\pm$ 0.75 V chronic at 0.5 ms). In humans ($N = 20$), pulse width thresholds have remained low and constant through six weeks at 0.075 $\pm$ 0.025 ms at 1.35 V. In different studies, model 6971 had 0.32 $\pm$ 0.20 ms peak and 0.17 $\pm$ 0.06 ms chronic threshold at 2.7 V ($N = 81$). Three patients with previous histories of repeated exit block have had no recurrence of threshold rise with the new lead. *In vitro* tests on rabbit atrial preparations show no effect of sodium DPA on action potential, threshold, absolute refractory, or cycle length. Thus, we tentatively conclude that the threshold lowering effect is due to the drug's anti-inflammatory action.

Design Techniques for Chronic Active Electrodes

(Invited Paper)

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Chronic sensing of human EMG, neural, and other bioelectric signals outside the laboratory is often hampered by interference, signal crosstalk, and noise. The primary cause of these recording problems is the high impedance of many electrodes. An implantable active unity gain buffer located at the electrode site can virtually eliminate most common recording problems.

A stable, low-noise, bioelectric interface could enhance the capabilities of many protheses and motor-link systems by providing numerous independent control sites. The lack of crosstalk and interference possible with an on-site buffer would permit several control signals to be recorded in close physical proximity.

Using a dual monolithic J-FET follower, a sensor of this type has been constructed and tested. Although intended for implanted EMG use, with minimal alteration it can be adapted to a variety of electrodes. Silicone resins and elastomers have been used to protect the electronic device and provide biocompatibility. The 1 mm diameter of this bipolar sensor has not formerly been achieved for a chronic device. This size reduction has been achieved through the use of nonstandard hybrid techniques in conjunction with novel applications of state-of-the-art encapsulants.

A Parametric Study of the Ion-Sensitive Diode

(Invited Paper)

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The purpose of this work is to gain a greater understanding of the gate-controlled diode for use as an ionic concentration sensor. This is accomplished by a parametric study of the pn junction capacitance versus gate voltage characteristic through which ionic concentration in solution is measured.

The parameters varied in this study are substrate doping concentration, gate oxide thickness, surface layout, and frequency. A quasidistributed lumped element computer model is used to simulate the capacitance characteristic as these parameters are changed. A first-order model is extracted from the more complex computer model to aid in forming a fundamental understanding of the capacitance characteristic. Devices are fabricated on n-type substrates using standard IC MOS processing and the pn junction capacitance as a function of gate voltage is measured. The measured and calculated results are then compared.

The computer calculated capacitance characteristic was found, in general, to agree well with the measured results. The effects of the parameters on the capacitance characteristic were revealed and physical mechanisms for them suggested. A design strategy based on the computer model and measurements for a gate-controlled diode suitable as an ionic concentration sensor is given.

1983 marks the twenty-fifth anniversary of the first implant of a cardiac pacemaker in an experimental animal. Pacemaker development can be traced along three parallel paths: one for the pulse generator, one for the power source, and one for the electrode and lead. The first successful human implant used a two-transistor, fixed-rate, blocking oscillator and amplifier. It was powered by a zinc-mercury battery and used a Hunter-Roth electrode structure consisting of two stainless steel pins in a silicone rubber patch. All three structures eventually proved inadequate. Anodic corrosion of the positive electrode pin resulted in early electrode failure and Chardack introduced a spring-coil structure of platinum, 10 percent iridium, soon to be followed by a transvenous, endocardial catheter. The mid 1960's saw the introduction of demand pacing and synchronous or "*P* wave" pacing. By 1970, the zinc-mercury battery was limiting pacemaker longevity to an average of two years. This led to a number of new power sources. Rechargeable batteries, nuclear batteries, and biological batteries all had their proponents, but the lithium iodine battery soon dominated the field, as it still does today. In the 1980's, pacemaker usage is approaching one per thousand population in the northeast USA. Pulse generators are now minicomputer chips with thousands of transistors. New high-current liquid-electrolyte battery systems permit telemetry, anti-arrythmic pulse therapy, programmability, and will soon permit autoclavable implants. The field continues to advance at a breathtaking pace.

Computer Aided Design of Implantable VLSI Systems

(Invited Paper)

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Implantable electronic systems have been traditionally designed with compact construction, ultra-low power battery-based operation, and high reliability as primary objectives. First discrete and then hybrid integrated circuits were used. Very large scale integrated (VLSI) circuit technology is now likely to revolutionize this field. Potential for putting hundreds of thousands of transistors on a chip now exists. Further computer aided design (CAD) tools will make this task quite feasible. This paper describes the functions and applications of various CAD tools. With the aid of circuit layout aids, circuit simulation, and functional simulators, we have designed a fully programmable pacemaker. For modest costs and rapid turnaround, we have implemented this design using gate arrays. VLSI technology should similarly have impact on the design of implantable defibrillators, insulin pumps, sensory prosthetics, and stimulators.

Session 6—Pacemaker Technology and Other Implanted Devices

Chairman: Nitish V. Thakor, Ph.D.
Northwestern University
Evanston, IL

Design and Developmental Changes in Pacemakers

(Invited Paper)

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Reduced Mortality After Automatic Defibrillator Implantation

(Invited Paper)

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Fifty-two survivors of multiple arrhythmic cardiac arrests unresponsive to therapy underwent implantation of automatic defibrillators along with coronary bypass grafting in 14 and endocardial resection in 12 patients. The longest follow-up has been three years, the average 14.4 months. In the hospital, the implanted device correctly identified and reverted 66 episodes of spontaneous and 64 induced malignant ventricular arrhythmias. Following discharge from the hospital, 62 episodes of automatic out-of-hospital resuscitation were observed in 17 of the patients. Twelve deaths have occurred in this series. Four patients died in end-stage heart failure, two patients with recent endocardial resection and bypass grafting died from cardiogenic shock, eight and ten days, respectively, following device implantation. One patient died from cerebral hemorrhage and another of pancreatic carcinoma. Four deaths were unwitnessed and presumably sudden and arrhythmic. Kaplan-Meier life tables were constructed suggesting a one-year expected mortality of 48 percent compared to the observed mortality of 22.9 percent. This represents a 63 percent reduction in anticipated deaths with the portion of sudden deaths virtually eliminated at 8.5 percent. We conclude that the automatic implantable defibrillator is capable of identifying and correcting potentially lethal ventricular tachyarrhythmias, leading to a substantial increase in one-year survival in properly selected high-risk patients.

Computer Aided Telephone Monitoring of Cardiac Pacemakers

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Telephone monitoring has become an important part of the overall treatment of the pacemaker patient. The purpose of telephone monitoring is to determine capture, proper sensing, and the presence or absence of pacer rhythm and arrhythmia. A basic telephone monitoring system consists of an EKG transmitter and a telephone receiver which usually includes a chart recorder. This paper presents a microcomputer controlled EKG receiver which detects and demodulates the transmitted EKG signal. The EKG waveform is then sampled, converted to digital data in an 8 bit A/D converter, and stored in the system RAM. These data are displayed on the monitor in a real-time mode and may also be recalled and displayed at any time. The advantage of this system is that the EKG waveform is in a digital format which can be stored on floppy disk or transmitted to another location by means of a MODEM. The pacemaker's rate, pulse duration(s), and AV delay are also calculated and stored. From these data and a real-time clock, a rate versus time graph is generated to aid in pacemaker end of life calculations.

The components of this system are an Apple II microcomputer, monitor, disk drive, demodulation circuit, and EKG signal processing circuit. All of the circuitry is contained on a single board which plugs into an Apple 1/0 slot. An isolation amplifier is also included on this board so that the system can be used without the telephone link.

Radiographic Studies of Occluder Dynamics

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Medical Incorporated

Tissue interference frequently precludes full opening of prosthetic heart valves, especially oversized mitral implants. Partial opening, even on a transient basis, of a pivoting-occluder type aortic or mitral prostheses may introduce substantial risk to the patient. Reliable noninvasive methods are needed to determine the maximum degree of occluder opening under various levels of exercise.

The initial phase of the study was to develop a sound theoretical basis for measuring the *rate* and *extent* of heart-valve occluder movement using a three-dimensional radiopaque marker and typical fluoroscopy techniques. Analytic work was concentrated on definition of image contrast and sharpness limits for successive cine fames produced from electronic image intensifiers at framing rates in the range 60/s.

The second phase of the study was a measurement of occluder velocity changes throughout the opening and closing process (frame-to-frame). This was done on fluoroscopy film of a double-valve patient with no occluder interference. As expected from theory, the opening process is extremely rapid in the early stages (12–30°) and slows significantly as the lift torque decreases toward the full open angle (~79°). The peak angular velocity of occluder opening (aortic implant, 25 mm TAD) was found to be extremely high (~ 1000°/s, 70 bpm/resting). The mitral prostheses (29 mm TAD) showed lower peak opening velocities (~ 500–800°/s).

Towards Quantitative Guidelines for Assessment of Valvular Pathology, Stenotic Aortic Valves and Malfunctioning Prosthetic Valves

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This paper reports on our comprehensive cardiac engineering approach to quantitative i) inferences of valvular pathology from analysis of appropriate heart sounds, ii) indication for stenotic aortic valve replacement, by computing pressure drops across stenotic aortic valves from echocardiographic monitoring of the aortic outflow tract dimensions, along with assessment of index of left ventricular hypertrophic compensation to the resulting left ventricular pressure load, and iii) estimation of pressure drops across malfunctioning prosthetic aortic valves from continuous wave Doppler monitoring of the aortic velocity.

Aortic and mitral valve pathology are related to spectral characteristics of second and first heart sounds, respectively, by mathematical modeling of the vibrations of aortic and mitral valves.

Computation of the pressure drop across stenotic aortic valves provides an indication of the pumping load on the left ventricle. We have invoked Bernoulli theorem to compute the pressure drop in terms of the dimensions of the aortic outflow tract and the cardiac output. The associated myocardial hypertrophic compensation to the increased left ventricular pressure loading is quantified in terms of the noninvasive index of the "ratio of local radius of curvature to wall thickness," to provide an indication for valve replacement.

Indications of prosthetic valves becoming thrombogenic are provided in terms of the high pressure drops across them, due to occlusion of their blood flow tracts. By means of continuous wave Dopper, we have determined the aortic velocity and, therefrom, the pressure drops by invoking Bernoulli equation.

Session 7—Functional Assessment of the Handicapped, II

Co-Chairmen: G. V. Kondraske, Ph.D.
A. R. Potvin, Ph.D.
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An Upper Extremity Electo-Ergometer

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A new ergometer has been designed to meet the needs of evaluating and exercising paraplegics and lower extremity amputee subjects. This device is more versatile than earlier ergometers as it can be used as a traditional exercise bicycle or as a means of studying the work tolerance of an individual using upper extremity power. The device permits the evaluator to select a power output requirement within the range of a few watts to 500 W for the subject. Once the power requirement is set and the exercise speed is set, the ergometer will maintain a constant power sink regardless of variation of ±20 percent in the speed of exercise. The device internally compensates for friction in the mechanical system so that the power readout on the machine is accurate to ±2.5 W.

ACKNOWLEDGMENT

This work was supported in part by a grant from the Veterans Administration and the REC Grant to Baylor College of Medicine from the National Institute for Handicapped Research, Department of Education, 23P-57888/6.

Human Motion Analysis During Cart Pushing and Pulling

(Invited Paper)

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A specialized laboratory with gait analysis capabilities and a cart push/pull simulator has been developed to validate a biodynamic model of the human body during push/pull tasks. Although the experiments to date have been with young, healthy, and functionally normal subjects, the potential exists for functional assessment of dynamic push/pull capabilities. Maximum hand forces exerted on the cart handles, maximum speed of progression against a pre-set cart resistance, gait patterns, and integrated EMG's of the trunk muscles (erector spinae and rectus abdominus) can be measured for different handle heights and cart resistances; thus, actual job requirements can be simulated in the laboratory. Coupled with our biodynamic model, which predicts the risk of slipping and of lower back injury, these studies are applicable to job placement and task redesign.

ACKNOWLEDGMENT

This work was supported by NIOSH Contract 210-81-3104.

Quantitative Analysis of Position and Motion Sense

(Invited Paper)

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A brief overview of the physiology of joint and other receptors possibly responsible for position and motion sensation is presented. Some of the historical and present controversies are discussed in terms of the critical elements of the system and its central organization. The properties of various receptor types in system terms set the stage for understanding quantitative aspects of position and motion sensation that might be mediated by these receptors. Receptor properties such as hysteresis, displacement, velocity, and acceleration transduction are related to subjective sensations of position, motion, and vibration sensation. Specific frequency limits on the primary ranges of these sensations are suggested. Some research results in a clinical neurological setting involving a population of normal young subjects and a population of normal aged subjects are discussed in terms of the previous considerations.

ACKNOWLEDGMENT

This work was supported by USPHS Grant NS08470.

Functional Assessment of Upper Extremity Joints

(Invited Paper)

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Instrumentation and methodologies have been developed in the past several years for the functional evaluation of patients' upper extremities. These include goniometric measurement of elbow and wrist joint motion; biplanar radiographic analysis of finger and thumb joint deformity; biplanar video analysis of shoulder motion; isometric strength of hand, forearm, and elbow functions; isokinetic strength of shoulder muscles; and hand dexterity assessment. A normal database in these evaluation areas has been established from measurement of a sizable population. In addition, patients with various pathologies have been evaluated and their function documented. These patients include those with artificial joint replacement, peripheral neuropathies, scleroderma, and ruptured and surgically repaired tendon and muscle.

In this presentation, the design and implementation of the assessment techniques will be reviewed. The application of these methods for documenting functional loss with various pathologies and improvement with various therapeutic and surgical treatments will be discussed.

ACKNOWLEDGMENT

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Objective Analysis of the Lower Extremity: Its Clinical Use

(Invited Paper)

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The Mayo Gait Lab is currently undergoing an evolution from a research facility to a combined research and clinical facility as increased clinical applications are developed.

Our functional evaluation process relies on an automated method of gait analysis developed by this laboratory, which uses three-dimensional electrogoniometric measurement of lower extremity joint motion, force plate analysis, foot pressure distribution, isometric and isokinetic muscle torque measurement, and various techniques for the measurement of time/distance gait factors. In addition to the development of a sizable normal database in the above areas, patients with various pathologies have been evaluated and their function documented. The subject matter for this presentation involves some of the larger patient groups consisting of preoperative and postoperative conventional total joint replacement patients, postoperative custom joint replacement patients, amputees, and foot patients who suffer from painful heel syndrome or plantar fasciitis. Clinicians have found this objective documentation of function helpful in evaluating patients and in monitoring their response to treatment.

Computer Automated Evaluation in Patients with Motor Disorders

(Invited Paper)

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The existence of numerous therapies for treatment of neuromotor disorders makes it increasingly important to devise objective tests to evaluate motor functions. Since many motor diseases present transitory symptoms, the test battery should be easily and rapidly administered and should provide rapid access to test results. We have developed a test battery using PDP-11 computers for test administration, data recording, and data evaluation. This battery measures gait, movement time, reaction time, postural sway, and involuntary movements. Gait is evaluated by monitoring movement along a mat fitted with a linear array of switches. Arm movements directed between targeted touch pads or electronic plates assessed self-paced and cued movement and reaction times. A triaxial accelerometer provided information about involuntary movements. Postural abilities were examined in the standing patient with a force plate and in the forearm with torque motors.

In one-half hour or less, an examiner can collect a broad range of indicators, record the data on media, and have a printed copy of the results. The brevity of the evaluation procedures allows it to be an adjunct to clinical ratings. We will present data from parkinsonian, deafferented, and cerebellar patients and age-matched controls. In addition, we will demonstrate clinical applications of the tests.

ACKNOWLEDGMENT

We thank the technical support of the Research Services Branch, National Institute of Mental Health.

Neurofunction Laboratory for Movement Disorder Evaluation

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A laboratory was developed specifically for patients with movement disorders who require easily learned tests which demand a minimum degree of skill and understanding. The tests developed gage reaction time, speed and accuracy of voluntary movement, dexterity, static strength, and coordination. Instruments were developed and modified to quantify the patient's neurological function. A 20 bit microcomputer (Nicolet Pathfinder II) was used to digitize, store, and display real-time data. A diffused flash stimulus was used to gage reaction time in conjunction with a short-travel pushbutton capable of activation by finger, hand, or wrist. A school desk fit with a dual-axis, spring-loaded, self-centering joystick for both anteroposterior and mediolateral movement allowed tracking using specific muscle groups. Single degree of freedom modes were used to eliminate complexity in the tracking task. Pursuit tracking data were averaged to eliminate artificial movement and to enhance the patient's consistent, characteristic effort. Reaction time (ms), hand velocity (rad/s), and absolute integrated error (rad · s) were calculated. Static strength was measured with a hand dynamometer using both multiple-maximum and sustained-maximum protocols. Digital storage and subsequent analysis yielded maximum static strength (kg), maximum effort (kg), grip velocity (kg/s), release velocity (kg/s), sustained maximum (kg · s/s), and fatigue (kg/s). Testing was completed in less than 1.5 h, a reasonable nonexhausting clinical timeframe.

ACKNOWLEDGMENT

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A System to Assess Sensory and Motor Function in the Clinic

(Invited Paper)

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A computerized system has been developed that makes routine quantitative assessment of a broad range of sensory and motor functions clinically practical. An arrangement of special stimulators, transducers, and sensors is integrated into a system that is programmed to execute various tests upon command from a trained technician. Software is used for timing, stimulus generation, control of data acquisition, and signal processing to minimize hardware requirements, automate test execution, and facilitate modification and expansion. A unique monitor system allows flexible selection of tests and entry of associated parameters, while overseeing the storage of test results in automatically named

floppy disk files. An analysis program processes test session results and provides a formatted printout within minutes of session completion. No manual data handling is required. Tests of mental state, sensation (visual, auditory, touch, vibration, two-point discrimination, and thermal), speed, coordination, body balance, tremor, and multichoice reaction time, resistance to passive motion (for spasticity, rigidity, etc.), and strength are currently available. Expansion is in progress to include automated assessment of gait, proprioception, and range of motion as well as evaluations of strength and resistance to passive motion at additional body sites.

An overview of this computer automated system, its use for two years in a neurology clinic, and current expansion will be presented.

ACKNOWLEDGMENT

This work was supported by the National Institute of Handicapped Research.

An Automated Biomechanics Laboratory Applied to Rehabilitation

(Invited Paper)

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An automated biomechanics laboratory system is being developed for the Department of Rehabilitation Medicine (DRM) of the Clinical Center at the National Institutes of Health. The system will be used to automatically acquire anatomical and physiological information from the patients, perform the required calculations on the data obtained, display the necessary results to the medical staff, and store information in a patient database for later retrieval. The configuration and use of the laboratory in the DRM is presented as well as future development plans. The instrumentation required to perform the automated measurements include an Oxford Medilog, Inc. VICON system containing five cameras that are used to acquire the spatial coordinates of anatomical points on the patient's body with reflective markers, two Advanced Mechanical Technology, Inc. force platforms that measure patient ground reaction forces, and electromyogram acquisition equipment that is used to measure patient muscle activity. This instrumentation is connected to a Digital Equipment Corporation VAX-11/750 computer system that performs the necessary data acquisition, calibration, processing, display, and storage functions. The laboratory will be used with arthritic, orthopedic, and neurological patients and with amputees in order to evaluate drug therapy, orthotic and prosthetic devices, and medical interventions.

ACKNOWLEDGMENT

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Session 8a—Medical Imaging II: 3D Graphics in Medicine

Chairman: Ernest M. Stokely, Ph.D.
University of Texas Health Science Center at Dallas,
Dallas, TX

Computer Graphics as an Adjunct to Medical Imaging

(Invited Paper)

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Medical imaging devices produce voluminous amounts of data that can be difficult to organize and interpret. Using computer graphics to present the data may assist qualitative interpretation and suggest fruitful approaches to quantitation. Graphics tools, which require large memories and powerful processing capabilities, are becoming less expensive and more widely available. Already the raster displays and image memories used for CT, NMR, digital radiography, ultrasound, and nuclear medicine systems permit limited graphics as well as image processing. Simple image interpretation aids are provided by use of pseudocolor, gray-scale windowing, and cinematic displays of multiframe data. Three-dimensional structures may be depicted on two-dimensional graphics displays as wire-frame or shaded-surface pictures, with shading and hidden lines/surfaces to strengthen the impression of three dimensions. Special purpose vibrating mirror systems may be used to produce a "true" three-dimensional sensation. Three-dimensional displays are especially useful to show complex structure data obtainable from CT, NMR, and ultrasound. However, such pictures require definition of the three-dimensional objects of interest, and the display calculations require sophisticated software. Current research efforts are directed at improving the ease and speed with which useful graphics can be generated and manipulated.

Molded 3-D Representations from Sequential CT Sections

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The concept of making a molded surface and 3-D views of body parts from sequential CT sections originated almost from the inception of whole-body CT scanning. Recently we have prepared a computer program which gives a detailed view in either molded surface form and/or 3-D views using a number of enhancements to previously developed algorithms. The results will be shown in the form of a complete vertebral column constructed from 250 CT scans of a body. We believe that such representation of body parts will have great value in both clinical and research application.

A Computerized System for Planning Reconstructive Surgery

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Surgical reconstruction of post-traumatic and congenital skeletal deformity presents the surgeon with significant challenges in:

1) the preoperative definition of the deformity,
2) the planning of surgery, and
3) the generation of the implant or onlay.

We have developed a system for surgical planning and reconstruction based on a 32 bit microcomputer, an intelligent color display system, and a numerically controlled milling machine.

CT images, 1.5 mm apart, are taken using a GE8800 CT scanner. An interactive, menu-based graphics system is used to extract automatically the bony-soft tissue interface. The resulting data of the bone surface are presented on the color display as a shaded solid, viewable from many angles, for use in planning surgery. Appropriately formatted data can also be output to a numerically controlled milling machine to generate a model of the bones of interest, thus providing the surgeon with an alternative method for visualization and planning.

A three-dimensional graphics editing capability permits the surgeon to interact with the displayed data to plan osteotomies and repositioning of bony segments. Onlays and implants can be designed, and milled versions can be made.

Session 8b—Medical Imaging III: Image Enhancement, Restoration, and Classification

Chairman: Ernest M. Stokely, Ph.D.
University of Texas Health Science Center at Dallas
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Mammographic Feature Enhancement

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Starting from digitization with extended dynamic range to cover the wide range of gray levels in a mammogram, we present digital processing techniques for contrast and feature enhancement, and simulation of xeromammography.

Mammographic image acquisition is begun with digitization of the film mammogram. In order to overcome the limited gray level dynamic range of the video digitizing system, we acquire two images of the mammogram at low and high illumination and combine them digitally to generate a composite digital image with a dynamic range wider than those of its components. A calibrated gray scale is used to compute the true gray levels in the image.

Using the composite image, a digital xeromammogram is next computed incorporating contrast enhancement and gray level reversal. In one method, we measure contrast at each pixel using the standard 8-neighborhood, increase the contrast according to a specified function, and compute a new pixel value using the new contrast value and the average neighborhood value. In a more elaborate method, we estimate the best "adaptive neighborhood" for each pixel based upon a contrast measure to obtain the optimum "center" and "surround" for each pixel location, and proceed as before to achieve feature and object enhancement, rather than general contrast enhancement. Results of application of these techniques to mammograms and cardiac angiograms will be presented.

ACKNOWLEDGMENT

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Motion Correction for Digital Subtraction Angiography

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Digital subtraction angiography is based on computing the difference between two X-ray images made before and during injection of contrast media. Small amounts of patient motion can misregister the images enough to seriously degrade the subtracted image quality. We have developed automated techniques for reregistration of misaligned images which correct for both translational and rotational motion. Two-dimensional cross-correlation is used to detect translational shift between the two images. Shift values are interpolated to subpixel resolution using an efficient hierarchial search strategy. Rotational correction is achieved by maximizing the rotational cross correlation between either the power spectra or autocorrelation functions of the original images. This determines the amount of rotation independently from any translation correction since these functions are translation invariant. Both the translational and rotational cross-correlation maxima are made more precise by using edge enhanced versions of the original images. We are also studying registration measures other than cross correlation which may be more appropriate for matching contrast and noncontrast image pairs. Finally, automated local (elastic) image registration by matching smaller image subregions is being investigated, since it can correct for more general forms of image misalignment and provides for optimization within regions of interest.

A Parallel Classification Scheme for Muscle Tissue Images

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We report on the development and implementation of a parallel classification scheme for muscle tissue images. A sample image con-

sists largely of fibers of three gray level values—black, gray, and white. Global structure as well as local structure of the three different types of fibers were stressed as features in the classification scheme. We adopt a base-2 pyramid data structure by which the image is partitioned into $2^p \times 2^p$ windows, $p = 0, \cdots, n$. At each level p, different information about the distribution of fibers can be obtained. Local processing is carried out concurrently in each window at the lowest level $p = n$. The number of black and white fibers is counted in each window at level $p = n$. Information at higher levels are expressed in terms of statistics at the lowest level $p = n$. Five features were extracted and the estimated joint probability of the feature vector was used for classification. Sample data were classified into three classes—normal, intermediate, and pathological with a correct classification rate of 88 percent. The classification scheme obtained better performance than prior works, both in terms of speed and accuracy.

ACKNOWLEDGMENT

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Session 9—Analysis and Control of the Neuromuscular System

Chairman: Moshe Solomonow, Ph.D.
Tulane School of Medicine
New Orleans, LA

Motor Control and Spring Like Muscles, Some Problems

(Invited Paper)

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The fact that muscle shows a spring like exchange between force and length is again being emphasized in motor control theories. Small force errors trade for a length change instead of producing sustained acceleration error, and nerve signals can control either force or position. For static positions, these muscle properties are like feedback without loop delay. Feedback actions of synergists and antagonists are all additive. Excitation adjusts combined muscle "stiffness" and unloaded lengths. Also, position balance depends on load. However, the lag in neural control of "elastic" properties probably makes complete resetting impossible within the time of a fast movement. Due to history dependence of muscle properties and position dependent loads, the relationship between excitation and stable position is subject to appreciable short term variability. Unlike a loaded spring, shortening muscle delivers power from chemical processes while oscillation is damped by energy absorbed in breaking chemical bonds. For orthotic or prosthetic design, it is important to recall that in addition to the lagging adjustment and viscoelastic actions in physiologic control, there is also continual trimming to current operating conditions. Apparently, high quality normal control represents muscle effects in a crude global controller momentarily fitted to a local problem.

Decomposition of the Myoelectric Signal: An Engineering Problem with Biomedical Applications

(Invited Paper)

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A system has been developed for acquiring, processing, and decomposing the myoelectric signal for the purpose of identifying the shapes and interpulse intervals for as many motor unit action potential trains as possible. The system has been designed to satisfy the requirements of both the clinician and the researcher. It consists of four main sections: a) methodologies for acquiring three simultaneous channels of EMG signals via a quadripolar needle electrode and a computer automated signal-quality verification system to monitor the detected signals; b) methodologies for signal sampling and conditioning so as to reduce data storage and emphasize distinctions between motor unit action potential shapes; c) signal decomposition computer algorithms which employ a continuously updated template matching routine and firing statistics to identify motor unit action potentials within the myoelectric signal, even when they superimpose or undergo slow-varying modifications in appearance; d) a variety of graphics arrangement for displaying the motor unit action potential shapes and firing statistics.

To date, myoelectric signals containing up to nine motor unit action potential trains, and signal records as long as 144 s in time duration have been decomposed successfully. The most important aspect of the system is that its accuracy and reliability can be tested, and it has been shown that decompositions of 100 percent accuracy can be obtained.

Numerous and varied applications are foreseen. To date, this system has been used to investigate: a) the behavior of motor unit recruitment and firing rate in functionally distinct muscles; b) the interaction among the firing rates of concurrently active motor units; c) the interaction between the firing rates of motor units and the fluctuations of the muscle force output; d) the interaction between recruited motor units and previously active motor units, and e) interaction between the discharge statistics of motor units in different muscles.

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A Monitor of Surface EMG Median Frequency

(Invited Paper)

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The median frequency of the surface EMG power spectrum appears to be an optimal parameter for monitoring spectral compression during muscle fatigue and some pathological situations. A device for on-line tracking of such parameter without computers and complex FFT algorithms has been developed using the INTEL 2920 microprocessor which handles analog inputs and outputs, performs A/D and D/A conversions, and digital signal processing.

A unity amplitude sine wave carrier having frequency *fc* is multiplied by the EMG voltage. The resulting modulated signal is applied to a sharp high-pass digital filter whose output power is compared with one-eighth of the total EMG input power. A closed loop feedback system automatically adjusts *fc* to drive such power difference to zero. It can be shown that, when this condition is verified, the difference between *ff* (filter cutoff frequency) and *fc* equals *fm*.

All functions, except an active input pick-up, an antialiasing filter, and part of a 10 to 1 A.G.C. feature, are implemented on the INTEL chip. The system tracks the median frequency with a slew rate ranging from 3 to 25 Hz/s according to the integration interval selected for the power calculation (which ranges from 0.12 to 0.96 s). Due to the unequally spaced discrete values of *fm* obtained with the algorithm used, the measurement error ranges from ±10 percent near 80 Hz to ±3 percent above 180 Hz, but it could be reduced by 30 percent using the faster 2921 version of the chip. With respect to previously available devices, this instrument has a simpler hardware, better dynamic response, shorter initial transient, lower cost, and it is more suitable for clinical applications and industrial production.

Development of a Reference EMG Signal Acquisition System

(Invited Paper)

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Clinical interpretation of recorded EMG signals implicity assumes that the data collection system faithfully reproduces the biological signal characteristics. The extent to which acquisition and processing equipment alters the nature of the original signal was evaluated by: 1) determining the physical and physiological parameter influence on electrode impedance, 2) design, fabrication, and evaluation of an idealized amplifier, and 3) evaluation of the effects of changes in electrode and amplifier parameters on the spectral density characteristics of the acquired signal.

The electrode model which represented the experimentally derived data was found to be

$$Y = \left(Yo \begin{matrix} +\Delta Y_1 \\ -\Delta Y_2 \end{matrix}\right) f^{\nu} d^{\delta} s^{\xi} A^{\alpha} l^{\lambda}$$

where: *Yo* is the intercept of the regression equation, ΔY is the estimated 95 percent C.I., *f* is the frequency in Hz, *d* is the surface electrode diameter, *S* is the interelectrode spacing, *A* and *l* are the exposed area and length of the wire electrodes.

Intramuscular electrodes were found to be more sensitive to effort than surface electrodes by a factor of seven. Ninety-five percent of the power from surface electrodes is below 300 Hz while 95 percent of the wire electrode power is below 650 Hz. The recommended EMG amplifier characteristics are: gain = 1000; input impedance, 300 MΩ common mode; frequency response = 20 Hz–1 kHz, and a CMMR of greater than 100 dB @ Hz with an unbalanced input.

ACKNOWLEDGMENT

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Respiratory Muscle Recruitment During Diaphragm Paralysis

(Invited Paper)

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The effects of bilateral diaphragm paralysis on both inspiratory and expiratory muscle activity and ventilation were determined in four anesthetized dogs. All dogs breathe both room air and 7–8 percent CO_2 in O_2. Changes in ventilation were obtained from measurements of tidal volume and respiratory rate. Respiratory muscle activity was assessed from the moving time averages of the electrical activity of the external intercostal and external oblique muscles. Resting minute ventilation was not dramatically affected by diaphragm paralysis. At end tidal PCO_2 levels of 50 and 60 torr, however, minute ventilation was significantly decreased in all animals. The reduction in ventilation was due to a reduction in tidal volume, and not respiratory rate. Following diaphragm paralysis, both the peak and average rate of rise (moving time average) of the external intercostal muscles increased with increasing CO_2 levels, but at a significantly reduced rate in three of four dogs. The other dog demonstrated greater levels of intercostal activity after paralysis. External oblique activity, both peak and rate of rise, were also significantly less following paralysis. In the anesthetized dog with a total absence of diaphragm function, the nonparalyzed respiratory muscles and their associated reflex mechanisms appear incapable of maintaining ventilation during moderate chemical challenge.

ACKNOWLEDGMENT

This work was supported in part by HL 21743.

Electrical Stimulation of Paralyzed Under Feedback Computer Control

(Invited Paper)

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Ever since the time of Luigi Galvani in 1791, it has been known that electrical stimulation can be used to make paralyzed muscles move. However, obtaining smooth, coordinated movement in the body requires extensive feedback from sensors located throughout the periphery. A system has been modeled using electronic sensors involving microprocessor-controlled electrical stimulation of muscle. This system has been extensively tested on male and female paraplegic and quadriplegic subjects. This system allows automatic control of balance and rudimentary walking under voluntary control. The link to the thought process is achieved through pattern recognition of movement of shoulders. Electrical stimulation has been applied to the appropriate muscles in the abdominal area and legs to allow the initiation of walking movements. Sensors in the hips, knee, ankle, and feet provide sensory feedback to the computer to show the progress of the program. The current system has lead to the initiation of the development of the multiprocessor system for portable use.

Frequency Response of Isometric Muscle Force During Recruitment

(Invited Paper)

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A recruitment model of the soleus muscle was obtained. Recruitment was accomplished by an electrode placed distally on the sciatic nerve with stimulus characteristics of rectangular pulses of 100 μs at 600 pps and sinusoidally varying amplitude. Background fused contraction resulted from a supramaximal stimulus delivered via a proximally placed electrode at 35 pps.

Simultaneous recordings of muscle isometric force and sinusoidal amplitude variations of the distal stimulus in the range of 0.1 Hz–6 Hz were obtained. Frequency response analysis indicated similar response in three different cats. The force response was constant at low frequencies. Force deterioration and increasing phase lag were evident above 2 Hz.

Body plots of the data indicated a fourth-order system with double poles at $W_{1,2}$ = 20 r/s and $W_{3,4}$ = 25 r/s. A high-frequency zero at W_5 = 31.4 r/s was also indicated.

Curve fitting of the experimental data and the developed model indicated satisfactory agreement.

Analysis of the frequency response at 20 percent, 40 percent, 60 percent, and 80 percent force perturbation demonstrated the linearity of the model with respect to perturbation level.

Time Response of Isometric Muscle Force During Recruitment

(Invited Paper)

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The time response of isometric muscle force during recruitment was studied. Recruitment was induced by a stimulus of sinusoidally varying amplitude with 100 μs pulse duration at 600 pps delivered distally on the sciatic nerve. Background fused contraction was obtained by a supramaximal stimulus at 35 pps applied proximally on the nerve.

Simultaneous recordings of muscle force and stimulus amplitude for the frequency range of 0.1–2 Hz were obtained and analyzed. Traces of muscle force during nonsinusoidal stimulation at 600 pps during background stimulation and without it were also obtained.

Analysis of the data show instantaneous sinusoidal force response to the recruitment stimulus with 5 percent reduction in amplitude during the first four seconds. The amplitude gradually recovered to its original level within the following 15 seconds.

The transient response was present for all recruitment stimulus frequencies in the range of 0.1 Hz–2 Hz and was equivalent in peak undershoot level as well as settling time.

Analysis of data where only recruitment stimulus was applied as well as data with recruitment stimulus applied on background fused contraction demonstrated similar behavior. The peak undershoot however indicated 15 percent reduction in blocking efficiency.

It is concluded that force time response of muscle is dependent only on the modulation frequency of the recruitment stimulus (600 pps) and its probably the result of rapid depletion of Ach at the endplate with subsequent peak partial recovery within four seconds and stabilization of Ach reuptake rate within 20 seconds.

Bioelectric Control of Powered Prostheses for Amputees

(Invited Paper)

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Forty upper extremity human amputees have been fitted with powered electric prostheses in an ongoing program at the University of Alberta. Different methods of controlling these prostheses are compared and evaluated. The most common method processes EMG signals obtained from skin surface electrodes over the remaining muscles. Processing may include different degrees of filtering, one or more levels of threshold switching, or various types of proportional control. For amputees at shoulder level for whom satisfactory muscle control sites are not available, different methods must be used. Skin conductivity touch control may be used to replace bulky and unreliable mechanical switches. Recent developments in chronic nerve recording using permanently-implantable nerve cuffs are discussed, together with the development of an FM-telemetry system which may avoid the risks otherwise associated with passing signal leads through the skin on a long-term basis. These developments, used in combination, offer a promise of fitting the high-level or bilateral amputee with the benefits of cosmetic appearance, functional range, comfort, and self-sufficiency that modern electric hands, wrist rotators, and powered elbows can provide.

ACKNOWLEDGMENT

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Periodic and Random Evoked Potentials in Frog Sciatic Nerve

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Evoked potentials (EP) have over the last few years developed into a meaningful clinical diagnostic tool. The usual approach is to elicit the potentials through periodic stimulation of the afferent nervous system. As the nervous system is by nature nonlinear, it is debatable whether a periodic stimulation is appropriate.

Randomly elicited EP's may be used to compute the first-order Wiener–Volterra kernels. The latter model shows the linearity of the system under test. EP's produced by periodic stimulation do not duplicate first-order kernels. Because of nonlinearities, the responses to periodic stimuli are affected by both linearities and nonlinearities of the systems, and they contain harmonics beyond those in the stimuli. Comparisons of EP's obtained from random and periodic stimuli, therefore, yield qualitative information about the nonlinearities of a system. Furthermore, the random stimulus approach can be exploited to extract information about specific orders of nonlinearities by computing Wiener–Volterra kernels of second and higher order.

In this contribution, we present results of a comparison of frog sciatic nerve evoked potentials obtained with periodic and random (Poissonian) stimuli. The random stimuli are obtained from a digitized magnetic tape record of radioactive decay data. Several different mean rates were tried, the first order Wiener–Volterra kernels were computed, and comparisons with "periodic" evoked potentials were made.

Session 10—Cardiac Dynamics and Assessment I

Chairman: Robert Peura, Ph.D.
Worcester Institute of Technology
Worcester, MA

A Microprocessor Based Rate-Pressure Product Computer

(Invited Paper)

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Open-heart surgery requires precise and continuous physiological monitoring of a patient throughout the operation and during recovery. One important parameter used to assess the status of the patient's heart is the myocardial oxygen consumption. An approximation of the myocardial oxygen consumption can be made by determining the product of the heart rate and the systolic pressure. This parameter is referred to as the rate-pressure product (RPP).

This paper describes a method for measuring the systolic and diastolic pressure, heart-rate, and RPP. A microprocessor device was designed, constructed, and tested to obtain presettable averaged values of these vital signs. An Intel 8085 microprocessor and a compatable system were chosen for both speed and accuracy.

The instrument utilizes the arterial blood pressure waveform obtained from a standard pressure monitor. The systolic and diastolic values are found by sliding "slope bars" along the waveform. Optimum values for these "slope bars" were found from an analysis of over 100 patient arterial blood pressure waveforms. It was found that, by using systolic and diastolic "slope bars" with their corresponding time durations and slopes, noise or waveform abnormalities did not trigger the system. The computer was used in over 400 open-heart cases and it was found that the RPP is a valuable asset for the anesthesiologist in the open-heart operating room.

Single Thermistor System for Continuous Cardiac Output

(Invited Paper)

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This paper describes a technique for continuous measurement of cardiac output by means of a single thermistor. At present, there is no convenient and reliable way to measure cardiac output continuously in the intensive-care unit and operating room. This method is based on the use of a catheter-tip, self-heated thermistor which acts as a blood flow velocity sensor. A thermodilution catheter with its integral thermistor is introduced into the pulmonary artery. Using an instrumentation feedback control system, the thermistor is held at a constant temperature, typically 5°C above the ambient blood temperature. Since the power dissipation of the thermistor is a function of blood flow rate in the self-heated mode, the velocity of blood flowing over the thermistor surface can be determined.

The cardiac output can be measured provided the vessel area is known. However, a viable alternative method is to calibrate the self-heated thermistor instrumentation by conventional thermal dilution techniques. After the initial cardiac output calibration, the single thermistor system will track cardiac output continuously. This method assumes that the pulmonary artery diameter does not change by more than a few percent, and that the velocity profile is nearly flat. The feasibility of this approach has been shown to be promising in bench studies.

Microprocessor Techniques for Postoperative Cardiac Care

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Postoperative management after cardiac surgery requires the assessment of dynamic cardiac function. Intraoperative placement of ultrasonic dimension transducers to measure left ventricular (LV) dimensions and micromanometers to measure LV and pleural pressure provides more precise data during the immediate postoperative period. However, microprocessor techniques are necessary for the derivation of clinical parameters. The analog data are digitized on-line and displayed as time plots, or in an X–Y mode. Accurate definition of the phases of the cardiac cycle is achieved in real time by analysis of the first time derivative of LV pressure. The end-diastolic diameter quantifies LV filling, while the diameter change during ejection models stroke volume for each beat. Pressure-dimension data provide an estimate of LV work and an assessment of compliance, a sensitive indicator of myocardial status and the major determinant of ventricular filling. Thus, with an appropriate microprocessor based data acquisition system, clinicians can observe direct digital readouts of end-diastolic pressure and diameter, LV work and compliance, and stroke volume and cardiac output. Using these data, changes in the patient status and the results of therapeutic interventions are immediately evident. Thus, the management of these critically ill patients is improved.

Didactic Microcomputer Simulation in Cardiac Dynamics

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This paper describes network models of a ventricle implemented on a microcomputer for teaching purposes. These models are: a dynamic compliance (to study the basis of Starling's law and the interaction with pre- and afterload); the preceding model plus an internal resistance (to analyze flow at large ejection fractions); a cylindrical chamber driven by an analog muscle model (study of Laplace law, interaction of muscle and geometry and length-dependent deactivation); the preceding model plus a discretized sliding filament model of muscle (to establish the physiological basis of the dynamic compliance and resistance and to study the interaction with excitation-contraction); a dynamic compliance in a whole cardiovascular loop (analysis of steady state equilibrium).

These models allow study of cardiac dynamics at various levels (from contractile proteins to venous return). Parameters and visualization may be changed interactively. The study of each model proceeds in three steps: computer assisted teaching of the relevant facts and theories, preprogrammed simulation demonstrating the salient features of behavior, free simulation to solve some problem of interest. In this phase, the simulation program combines discrete and continuous simulation to permit the design of complex experiments (e.g., intraaortic balloon, parameter identification).

Simulation of Activation Sequence Effects in Heart Tissue

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Open chest canine experiments have demonstrated that changes in the activation sequence can alter the measured refractory period. The objective of this study is to utilize a one-dimensional propagation model to investigate the cell-to-cell interactions during different activation sequences. The model incorporates the McAllistar, Nobel, and Tsien Purkinje fiber membrane model with membrane sections interconnected using the cable equation model. Improvements have been made in the model which allow automatic time step determination, error control, and refractory period calculations. The transmembrane voltage as well as the various ionic and cell-to-cell current flows are monitored during control, initiation, and fusion drive sequences. Computer simulations using this model successfully demonstrate the experimental finding of a lengthening in the measured test site refractory period as the stimulus site is moved closer to the test site. The phenomenon demonstrates that activation sequence can change the regional differences in tissue refractory periods and could play an important role in modifying the vulnerability to reentrant arrhythmias.

ACKNOWLEDGMENT

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A Practical Approach to Epicardial Mapping During Open-Heart Surgery

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Successful surgical resection of the electrophysiological substrate for ventricular tachycardia depends on precise localization of the arrhythmogenic areas. Mapping techniques have been developed to locate these areas by finding sites of earliest electrical activity. Epicardial mapping techniques currently employed at various centers range from the use of single roving probe electrodes to multielectrode arrays coupled to computerized isochrone generators. This report describes a multielectrode recording system which offers speed, precision, and is relatively simple to implement.

The electrode array consists of stainless steel ventricular pacing wires imbedded in a silicon elastomer (Sylgard). The elastomer is poured into a wax mold containing the shaped electrodes and when cured, becomes a tough, flexible material. The dimensions of our array are 9 by 11 by 0.5 cm, and it contains three columns with five bipolars each. The electrodes are coupled through a manual multiplexor to a standard multichannel recorder.

Four patients undergoing surgery for ventricular tachycardia were mapped with the electrode array. The array was placed on the heart in the anterior, lateral, and posterior positions, sequentially producing 45 individual recordings from the epicardial surface within 3-5 min. Anatomic landmarks were used to position the array reproducibly.

Permanent recordings made of ventricular tachycardia were analyzed immediately during surgery, and this information was used to aid localization of the diseased area. Later, isochrone maps were constructed. An automated version of this system is now being assembled.

Atrial Activation as Seen from the Esophagus—A Solid Angle Analysis

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The solid angle theory has long been applied to the interpretation of the electrocardiogram, however, quantitative evaluation of its applicability has been minimal. We have applied solid angle method quantitatively to the interpretation of esophageal electrocardiograms. A computer atrial model based on atrial electrical activity has been developed and the solid angle subtended by the boundary of distributed dipole layer at a point p in esophagus calculated at successive time intervals. The potential at the esophagus has been analytically determined and experimentally recorded. Information recorded by the esophageal lead promises to add arrhythmia diagnostic capabilities not possible in present systems. Knowledge of the pattern and spread of activation should aid the interpretation of the esophageal electrocardiogram. The possibility of precise recognition of retrograde and ectopic atrial activation is based on a careful determination of the underlying theoretical principles.

Cardiac Action Potential Processing

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Microelectrode recording is often used to investigate the electrophysiological properties of isolated cardiac fibres. During routine experimental drug testing, normal or pathological environmental conditions are set up and short sequences of action potentials (AP's) are recorded, both before and at different times after drug perfusion. For each of these recordings, a total of 16 feature parameters consisting of slope, amplitude, and duration measurements are usually estimated from a series of consecutive AP cycles.

To improve the quality and speed of signal analysis and parameter estimation, a general purpose graphic calculator based system was configured to undertake sequential processing of cardiac AP's. Successive sequences of prerecorded *in vitro* AP waveforms are played back for signal digitization and analysis. The hardware used includes a customized signal conditioning unit, a programmable acquisition processor (HP/6942A), a graphic calculator (TEK/4051), and a hard copy unit (TEK/4631).

Different types of spontaneous or stimulated AP morphologies can be interactively processed by this system. Sino-atrial signals are sampled at fixed rate (1 kHz typical), whereas with Purkinje fibres, different sampling rates are respectively used for the rapid depolarization phase (25 kHz) and the slow repolarization phase (250 Hz). In this case, two separate sampling clocks are synchronized by the signal conditioning unit. For each sequence, feature parameters are located by curve analysis, and the computed values are averaged over five cycles. The system is presently used for the evaluation of the cellular electrophysiological effects of antiarrhythmic drugs as a complement of conventional electrocardiographical *in vivo* studies. Preliminary results show that most parameters are correctly estimated (within 2 percent) with somewhat greater variability (5-15 percent) for parameters such as the plateau or the pacemaker potential slopes, presumably because of their characteristic low relative values. In these situations, a modification of the corresponding detection criteria may be carried out to improve reproducibility between cycles.

Session 11—The EEG and Evoked Potentials

Chairman: Arthur M. Sherwood, Ph.D.
T.I.R.R.
Houston, TX

Classification of Event-Related Brain Potentials

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Quadratic Bayes classifiers were designed to discriminate by stimulus and condition single event-related potentials to two equiprobable task-relevant stimuli (0.0 and 1.0 presented on a CRT). The experiment was designed to test the sensitivity of P300 (a late, positive component of the event-related potential) to stimulus incentive value. Incentive value was established by rewarding or fining subjects one dollar for correct or incorrect responses to the 1.0 stimulus in accuracy/incentive and speed-accuracy/incentive conditions.

Event-related potentials were recorded from EEG electrodes on the scalp at Fz, Cz, Pz, Oz, P3, and P4. The data were amplified, filtered to 60 Hz, and sampled at 7 ms intervals. Data from electrode Pz were chosen for processing. Five features were selected for classification using a modified forward sequential feature selection algorithm. Upper and lower bounds on the classification accuracy were determined by the resubstitution and leave-one-out methods. Classification accuracies bounded between 75 and 90 percent were typical. Analysis of the results shows that a feature in the P300 range is best for classifying stimuli with different incentive values under both accuracy and speed-accuracy conditions.

ACKNOWLEDGMENT

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A System for Off-Line Analysis and Storage of the Electroretinogram and Visual Evoked Response

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A flexible data acquisition and processing system has been developed for the human electroretinogram (ERG) and visual evoked response (VER). It is based on an earlier version which incorporates data acquisition from FM-tape, analog-to-digital conversion, and signal averaging of selected responses. The earlier system also included the option of digital filtering and produced a plot of the averaged ERG and VER. The new system incorporates all these features and also provides storage and retrieval of the averaged ERG/VER, as well as relevant information, both on the patient or subject and on the test conditions, in a format that is suitable for both clinical and research purposes. Attention has been devoted to the user interface. Any suitable remote terminal can be used for data retrieval as well as performance of operations such as filtering of data. The system has been developed for the HP-1000 computer running under RTE-IVB and comprises a collection of Fortran coded programs arranged in a hierarchical fashion.

Multiprocessor Electroencephalogram (EEG) Analyzer

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EGG analysis requires the simultaneous inspection of different activities in as many as 16 derivations. The clinician looks for the succession of temporal patterns as well as for spatial asymmetries and/or inter-channel coincidences. To pursue this analysis automatically a distributed processing system was developed where each peripheral processor may access, though DMA, the main processor's memory. Each peripheral acts as a preprocessor performing a single type of analysis over one EEG channel and converting each event into a set of characteristic features then fed to an assigned area in the main's memory; the main processor acts as an information concentrator and pattern analyzer, both along time and across channels.

The algorithms already installed in the preprocessors detect and quantify epileptiform spikes, petit-mal paroxyms, and basic EEG rhythms (alpha, beta, etc.). The main processor tasks concern epileptic foci detection and sleep staging (according to the Rechtschaffen and Kales sleep scoring) along with statistical description of the features and event occurrence, printouts, displays, and mass storage.

The single-channel, single-object analysis allows a simple and modular hardware configuration with identical preprocessors. Furthermore, the data reduction achieved enables the use of a microcomputer-based system as the main processor.

A New Data-Reduction Technique for EEG and EMG Signals

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We have investigated the compression of clinical electroencephalographic (EEG) and electromyographic (EMG) data using delta modulation.

The quantitative analysis based on digital signal processing of EEG and EMG signals is widely used in applications ranging from routine clinical tests to basic research. The major drawback common to these applications is the vast size of the database. This presents difficulties not only in storing the records for off-line playback or analysis, but especially in real-time applications. The compression method presented here remedies these problems by eliminating the retention and the transmission of the redundant data.

Delta modulation (DM) is a tracking method of quantization which retains a single bit corresponding to a new sample. It is widely used in communications, particularly in speech processing and telemetry.

We have compressed sampled clinical EEG and EMG data using simulated linear (LDM) and adaptive delta modulators (ADM). With ADM, we have achieved typical signal-to-noise ratios (SNR) between the original and reconstructed EEG signals in the range of 15 dB (i.e., rms difference of 3 percent) corresponding to a data compression of the order of 80 percent (5 : 1) with room for further improvement through

the optimization of the design parameters. Similar results were obtained for the compression of EMG signals.

The practical implementation of the method in the form of a specialized tracking analog/digital–digital/analog converter is also considered.

Objective Response Detection for Sensory Evoked Potentials

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Sensory evoked potentials offer a method to obtain data from comatose patients on function in the central nervous system. However, background noise, due, for example, to posturing by the patient, is often high, making a decision as to whether or not a response is present difficult. We recently studied a group of comatose patients in an intensive care unit using brainstem and cortical auditory evoked potentials. To facilitate a decision as to whether a response was present, our averaging system delivered a stimulus in the middle of the data window. In addition, two averages were formed simultaneously to test for reproducibility. The period before the stimulus provided a control region from which we could estimate the residual noise level after averaging. To obtain a quantitative indicator of the presence of a response, we calculated the ratios of the squared amplitude of the two control regions and of the response region to the control region. The former ratio indicated consistency of the responses, while the latter indicated whether a response was present. The quantitative indicators were generally consistent with visual detection of the responses, although differences occurred.

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Intraoperative Cortical and Spinal SEP Monitoring

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The effectiveness of monitoring intraoperative cortical and spinal somatosensory evoked potentials (SEP's) in preventing spinal cord injury during corrective surgery for scoliosis was investigated. SEP's of 22 patients were monitored using posterior nerve stimulation at 4.9 Hz. A 20 bit microprocessor-based averaging system (Nicolet Pathfinder II) used a dual timebase to record SEP's. Cortical electrode sites were C'_3–F_{pz}, C'_4–F_{pz}, C_z–A_1, and C_z–C_{III}. A safe and simple method of obtaining spinal SER's was developed using bipolar recording between adjacent wires passing through the epidural space used to secure the Luque rods at each spinal segment. Intraoperative wakeup was performed in all patients immediately after securing the Luque rods for maximal correction or if the SER's decreased significantly in amplitude. The effects of various anesthetic regimens were studied with respect to changes in the waveform configuration and amplitudes of the component waves recorded. Halogenated inhalational anesthetics in concentrations higher than 1.0 percent resulted in significant amplitude reduction and loss of waveform morphology. A nitrous oxide-narcotic anesthetic regimen permitted the most reliable cortical recordings. Of 22 cases monitored, there was one false-positive reduction in amplitude with complete recovery of the waveform immediately following wakeup. There have been no instances of spinal cord damage in this series and, thus, no false-negative SER's.

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Auditory Discharges as Simulated by Pseudorandom Sequences

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We understand fairly well the response of a typical auditory hair-cell neuron. If it is unstimulated, the spontaneous discharge obeys a Poisson point process. This becomes modified in various ways as a function of stimulus amplitude and frequency. In general, the discharge can be represented by an interval histogram.

By applying pseudorandom square-wave (PRSW) sequences, it is possible to realistically transform the interval histogram into a typical action-potential train of pulses. A PRSW sequence has special properties that account for the realistic outcome. Because a PRSW sequence is easily synthesized, it is applied to a single experiment which yielded a train of over five million action potentials. Four other cases are also examined: 1) a relatively low-frequency, small-amplitude auditory stimulus; 2) the same frequency but with a very large amplitude; 3) a relatively high-frequency, small-amplitude auditory stimulus; and 4) the same frequency but with a very large amplitude. In each case the generator potential, interval histogram, and simulated action-potential train are presented.

The simulation supports the conjecture that the central processor is tonotopically organized, and that each local group of neurons is "tuned" to integer multiples of the fundamental interval.

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Coherence Study on the Brain 40 Hz Rhythm

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Pronounced 40 Hz rhythms show in many regions of the brain. Initially the 40 Hz rhythm was described in the rhinencephalic brain in animals from fish to man. There is variance in the component frequencies of the rhythms in different species and spatially in different brain regions. The 40 Hz activity is found in most regions of the cerebral cortex and subcortical nuclei. In these studies cortical and limbic subcortical nuclei are studied in the cat. Analog data are recorded on an FM tape recorder and a polygraph system. The data are analog-to-digital converted and processed on a Varian V-72 minicomputer. Coherence

and partial coherence estimates are used to study the spatial distribution and interaction of 40 Hz between cortical and subcortical areas. Recent data in man have shown 40 Hz activity to increase markedly during problem solving. This increase is absent in some learning processes in mentally disabled children.

Session 12—High Resolution Electrocardiography

(Sponsored by the EMBS Bioelectric Phenomena Committee)

Co-Chairmen: Edward J. Berbari, Ph.D.
Michael Simson, M.D.
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High Resolution Electrocardiography

(Invited Paper)

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Computer analysis of the ECG has traditionally focused on the *P*, *QRS*, and *T* waves. High resolution electrocardiography (HI-RES ECG) uses other signal processing techniques to quantify cardiac electrical events which are not seen with the standard methods. For example, His-Purkinje system (HPS) potentials and post-*QRS* potentials are in the microvolt range and can be recorded on the body surface using signal averaging or nonlinear analog electronics. Included in this definition of HI-RES ECG are measurements in the frequency domain and fetal ECG's.

Noninvasive measurement of HPS potentials and late ventricular activity (LVA) provide new ways to study heart block and arrhythmogenesis. Studies now show that an HPS waveform can be recorded in the PR segment which reflects the state of health of the conduction system, but further work is needed to develop a useful clinical tool. LVA recorded directly from the heart in man and dogs has been correlated with reentrant ventricular arrhythmias. HI-RES ECG is used to record LVA from the body surface. The significance of these potentials and their response to heart rate and drugs and their link to reentrant ventricular arrhythmias is currently being studied.

HI-RES ECG differs from previous methods in that new indexes directly related to the diseased myocardium are being developed as opposed to the measurement and quantification of the traditional ECG waveforms.

A Signal Averaging System for High Resolution Electrocardiography

(Invited Paper)

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The elucidation of high-frequency, low-amplitude components of the electrocardiogram has been simplified by adding averaging software to a microcomputer based electrocardiograph.

Signals from three electrodes are bandpassed from dc to 300 Hz, and sampled at 2000 Hz. The 12 bit A/D converter has a resolution of 2.5 μV. A dithering signal and 25 bit arithmetic permit increased resolution in the averaged signal.

Beats are aligned using a 20 ms period near *QRS* onset. Automatic and manual controls determine the *QRS* morphology to be averaged and maximum noise level permitted. Averaging occurs over a selectable 640 ms window, and is done on the full bandwidth available.

Ouput includes three bipolar leads between the three electrodes, and three augmented leads. 12 levels of gain are provided between 2.5 and 8000 mm/mV. The output may be digitally high-pass filtered at 50, 100, and 200 Hz. A first difference filtering scheme is used to limit the duration of filter effects.

Previous studies have demonstrated the clinical accuracy of the system by comparison of surface signals from the His bundle with those measured directly from a proximal catheter. Methodology of direct measurement of the accuracy of signal averaging systems is discussed.

Late Potential—A Noninvasive Marker for Ventricular Tachycardia

(Invited Paper)

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Recently, several groups have used a signal averaged ECG to detect low-amplitude late potentials following the *QRS* complex in patients with ventricular tachycardia (VT). In our system, bipolar *X*, *Y*, *Z* leads are signal averaged and high-pass filtered (>25 Hz) with a bidirectional filter which does not ring after the *QRS* ends. A late potential is defined as <25 μV in the last 40 ms of the vector magnitude of the filtered *QRS* complex. In initial studies, 58 patients with sustained VT after myocardial infarcation (MI) were compared with 28 control patients who had no complex ventricular ectopy on prolonged ECG monitoring. 90 percent of the VT patients had late potentials; in contrast, only 6 percent of control patients had late potentials ($p < 0.001$). In another study, the findings on the signal averaged ECG, Holter monitoring, and cardiac catheterization were compared in 76 control patients without VT after MI and 98 patients with inducible VT after MI. Multivariant logistic regression showed that the late potential is independent of findings on Holter monitoring or cardiac catheterization and was the most powerful descriptor of patients with VT. The late potential recorded by the signal averaged ECG is a reliable and independent marker for VT in patients after MI.

Electromyographic Noise Reduction for High Resolution Electrocardiography

(Invited Paper)

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In order to record low-level (1–10 μV) electrocardiographic potentials such as delayed ventricular depolarizations and His bundle potentials from the body surface on a beat-to-beat basis, it is essential that tech-

niques be employed to reduce noise. A significant source of noise in such recordings is the electromyographic (EMG) potentials. We have investigated the role of two techniques for reducing EMG noise. 1) Spatial averaging. The reduction in EMG noise during spatial averaging depends primarily on the spacing between electrode pairs and their position. Electrode pairs were placed at various interelectrode distances and positions on the chest surface and EMG potentials were recorded during the TP segment. The coherence function of such potentials was calculated and, based on the data, an optimum interelectrode distance and position was determined. 2) Use of volume conductor (VC) electrodes. The VC is an indirect electrode with a large conductive sponge between the skin and the recording electrode. With such electrodes placed on the chest during normal respiration and on the thenar muscle during controlled stimulation of the median nerve, significant improvement in ECG signal/EMG noise was observed. The results of these two techniques which can reduce EMG noise during high-resolution electrocardiography will be presented.

High Frequency Information in Electrocardiography

(Invited Paper)

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The field of electrocardiography is almost eight decades old, and a vast amount of effort is being invested in developing its diagnostic reliability and capabilities. The conventional ECG is mainly based upon the low-frequency electrocardiographic records and has limited diagnostic reliability and capabilities.

In this proposed paper, we present some experimental and clinical investigations in which we make use of the high-frequency information contents in the electrocardiac signals. These high-frequency information signals arise from the isochemic and other abnormal regions in the heart, and appear in the form of random modulation on the low-frequency ECG. Statistical information processing techniques are used in order to detect the presence of these random information components.

Experiments on dogs under various induced cardiac abnormalities, viz., coronary ligation and ischemia, have given a clear indication of the presence of these high-frequency disturbances (information) arising from the abnormal cardiac cells. Clinical studies have yielded some encouraging results; in these studies extensive use of other conventional diagnostic tools have also been made.

There is a clear indication of high-frequency information contents in electrocardiac signals from an abnormal heart, and the detection and further experimental and clinical work is underway.

Session 13—Medical Instrumentation

Chairman: Kenneth C. Mylrea, Ph.D.
University of Arizona
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48 Channel Multiplexer for Recording EEG on FM Tape

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A multiplexer-demultiplexer was developed to record 48 channels of EEG on seven-track FM tape, for use during cortical evoked response studies in awake patients undergoing craniotomy for intractable focal epilepsy, and patients with implanted cortical strip electrodes.

The multiplexer incorporates ROM selected sampling rates for maximum bandwidth at all tape speeds from 1¾ to 60 ips. PLL techniques produce a one-of-eight master sync pulse for recording on one tape track, avoiding sync rate/bandwidth limitations. On playback, the demultiplexer employs PLL circuitry to eliminate problems with tape jitter, noise, etc. In case of lost sync, the master sync system will relock the demultiplexer address code on the next recorded pulse, minimizing data loss to one sample per channel. Due to the one-time-only nature of these recordings, on-line monitoring of the demultiplexed playback is essential. A ROM-controlled sequential sweep of all 48 channels allows monitoring all data channels with one oscilloscope channel. Any one data channel may be selected and locked.

A series of cases using this device indicate it as a solution to the problem of accurately recording multiple channel EEG on a limited number of FM tape tracks, with maximum bandwidth utilization.

Comparison of Blood Pressure with Two Noninvasive Monitors

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New techniques for blood pressure (BP) measurement require a definition of stability for valid comparisons. This study examines limits and compares two different principles used in automatic BP monitoring: oscillometry and infrasonics. There were ten runs, each with ten pairs of measurements over 30 min, alternating arms and instruments. Data for systolic, diastolic, and mean pressures were analyzed by a linear multiple regression ANOVA. Five factors included as sources of variance were 1) run number, 2) time point, 3) right/left arm, 4) oscillometry/infrasonic, and 5) two units of each type. Oscillometry and infrasonics gave the same results for mean and diastolic. Systolic averaged 8.3 mmHg higher by oscillometry and 4.3 mmHg higher on the right arm. Diastolic was the same on both arms. There were relatively large variations among and within runs, but time point was not significant. Coefficients of variation were between 4 and 6 percent; R^2 was 0.55 for systolic, 0.378 for diastolic, and 0.284 for mean. This study shows sources of variance for consideration in comparing BP measurements taken with different instruments, at different sites and times. Higher systolic pressure by oscillometry may be due to different signal or processing algorithms. Similarities in coefficients of variation indicate neither instrument was more stable, nor was BP in either arm. R^2's being relatively low shows the variance factors considered did not account for all variation present, underlying physiological factors making a major contribution.

Instrumentation for Prosthetic Heart Valve Sound Analysis

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Phonocardiography is a recognized technique for the follow-up of patients with prosthetic heart valves. The technique is noninvasive, atraumatic, and has the potential for detecting minute changes in valve performance due to wear or deterioration of any of its components. To achieve this objective, state-of-the-art instrumentation and computer processing are required to improve the quality of the sounds recorded from the body surface and the power of the methods of analysis. A microcomputer-based system designed for the acquisition of heart sounds produced by the majority of currently available prosthetic valves will be described. To accommodate the wide dynamic range and frequency bandwidth of the variety of these prostheses, a special data acquisition module has been designed for the acquisition of heart sounds and integrated to the system. The versatility of this instrument makes its use envisageable in other medical fields such as phonoangiography, phonopneumography, and hemodynamics.

A Computer-Based Tomoflow System

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A flowmapping system is proposed to display an intracardiac blood flow profile on a cardiac image. The blood flow information and the cardiac image are detected by an ultrasonic pulsed Doppler flowmeter. A multichannel data acquisition system based on a microcomputer was developed to capture the spatial Doppler signals and cardiac image signals backscattered from 100 depth channels along the beam axis. As the beam direction was controlled by the microcomputer, the two-dimensional map of the blood flow and the cardiac structure was detected by scanning the beam at every cardiac cycle. The image parameters, the mean Doppler frequency and frequency distribution, are calculated from the Doppler spectrum, and the cardiac image is also estimated from a signal amplitude. These information were reconstructed by microcomputer and were displayed on a color graphic device. The results show that this system may be used to characterize the intracardiac blood flow dynamics.

Nonlinear Filtering of Thermographic Images

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Quantitative thermographic imaging is an attractive temperature measurement method for many biological studies since it provides a nearly instantaneous determination of two-dimensional temperature distributions. Its application in sensitive studies, such as tumor hyperthermia studies, is hampered by the inherent noise of the photodetector. In transient temperature measurement applications, frame integration is impractical and some smoothing process must be applied. Linear smoothing operators all have the undesirable side effect of smearing the few edges and other details in the image. Nonlinear Kth ranked order operators, such as median filters, offer the potential of filtering detector noise while preserving edges and other details. Since the effects of these filters are not conveniently expressible in mathematical terms, their effect on the accuracy of calibrated images must be determined quasi-empirically. For example, detector noise processes (such as impulse noise) which have asymmetrical density functions have differing mean and median values.

Median filters have been applied to digitally calibrated thermal images and the results are striking. Subtle thermal details which were totally obscured by detector noise become readily identifiable, simply connected regions in the filtered image. Experiments are under way to determine the effect on minimum resolvable temperature difference and calibration accuracy.

Cortical Hearing Instrument

J. CODOMO AND C. R. SCHAFER

Electro-Physical Research, Inc.

The Schafer Cortical Hearing Instrument is designed to enable profoundly deaf (more than 90 dB hearing loss or no measurable hearing) patients to discriminate speech and enjoy music. The encoded audio signal is introduced directly into the auditory cortex in either temporal lobe of the brain. No electroacoustic transducers or implanted electrodes are used; only a small metal disk lightly held against the appropriate spot on the head.

Of 78 such patients tested, 59 (76 percent) could discriminate speech and were taught small vocabularies of from 4 to 12 words within an hour's time. The frequency range of the Schafer Cortical Hearing Instrument is from 125 Hz to 10 kHz, and the majority of patients could hear any tone within this range.

Two significant facts were discovered: 1) the signal intensity versus perceived response relationship is linear rather than logarithmic; and 2) the auditory cortex does not resolve phase shifts the way the normal auditory channel does.

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Stereo Reconstruction of Eardrum Surfaces

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We have developed a system for three-dimensional (3D) reconstruction of eardrum surfaces from stereo photomicrographs, to assist in the diagnosis of certain middle ear pathologies. The system is implemented on a PDP-11 minicomputer and requires no special photographic equipment. Ink spots sprayed onto the eardrum from an airbrush provide a

dense set of landmarks for matching corresponding points in the stereo views. Automated local cross correlation of gray levels produces a 64 × 64 grid of matched points. Permanent calibration of the 3D object space is achieved by photographing a stack of microscope reticles and thereafter using reference points on the film for image registration. This results in a linear transformation matrix that relates each stereo view to the calibrated 3D space. Overlapping stereo fields are needed to cover the entire human eardrum. Reconstructed 3D coordinates in the overlap areas are used to map the individual sections into a common coordinate system with an affine transformation. Reconstructed cat and human eardrums range up to 3 mm in depth. Currently the resolution of the method is 0.007 mm in the image plane and 0.08 mm in depth. Known objects such as flat and tilted reticles and ball bearings have been reconstructed with an accuracy of 0.06 mm.

Efficacy of Four Noninvasive Infant Respiration Sensors

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Accurate monitoring of respiration is crucial for detecting apneic episodes in infants. Apnea monitors often fail to alarm when the infant stops breathing. Such failures may result in severe hypoxia or death. This study compares the reliability of a nasal thermistor, abdominal strain gauge, transthoracic electrical impedance, and a piezoelectric motion sensor for breath detection.

Preliminary data on eight full-term neonates show significant differences in these signals. The thermistor was least affected, providing a readable respiration signal during 67.3 percent of all movement. The strain gauge and impedance signals showed 36.5 percent and 31.5 percent respective readability while the piezoelectric signal was readable in only 5.3 percent of all movement. All methods were unreliable during extreme body movement and crying.

Cardiac artifact was found to be significant during quiet periods in all the piezoelectric signals and about half of the impedance signals. Using the thermistor signal as a standard, the strain gauge detected 95.9 percent of all breaths while the impedance and piezoelectric sensors detected 86.6 percent and 58.9 percent, respectively.

These preliminary results show the thermistor providing the best signal, followed by the strain gauge, impedance, and piezoelectric signals.

ACKNOWLEDGMENT

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A New Audio and Video Biofeedback Technique

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Biofeedback represents an attempt to utilize the engineering principle of feedback control on human organisms. However, whereas machines have a hard wired algorithm ("drive") to reduce the error signal, humans require a "voluntary" motivation drive to develop the algorithm that achieves the goal of physiological control. Hitherto used error signal means of presenting information have not been intrinsically motivating (i.e., nobody likes or dislikes a meter needle). Since development of those algorithms in humans (learning) requires error signal detection (stimulus discrimination) as well as optimum drive level (motivation), it would be more efficient to manipulate both variables through the same feedback device. The description of such a device is the subject of this presentation.

The new biofeedback device permits simultaneous visual and auditory presentation of any intrinsically motivating stimuli, together with continuous information pertaining to the physiological parameter to be controlled. Essentially, it varies the signal-to-noise ratio (S/N) of an audio or video signal as a function of any physiological parameter. That is, intrinsically motivating stimuli, visual and auditory, are presented through a color TV set; image and sound are initially masked by white noise, set to a level just below perception (minimum signal and maximum noise). As the experimental subject changes a certain physiological parameter, image and sound become clearer if the change occurs in the desired direction. The video signal remains synchronized at any noise level. The final S/N ratio has been utilized as an index of motivation in an experiment to evaluate the efficiency of the new technique.

Performance Testing Respiratory Gas Exchange Measurement Systems

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Increasing use of respiratory gas exchange measurement systems (RGEMS) for clinical and research applications has prompted the need for a simple and predictable testing method. Damask *et al.* (1982) introduced a system utilizing a 13.5 ℓ glass jar with a one-liter rebreathing bag attached. One port on the jar was used to attach a ventilator, while another was used to introduce precise flows of N_2 or CO_2 with calibrated Matheson flow meters. This was used to simulate either O_2 consumption or CO_2 production. Equations predicting the steady-state fractions of O_2 and CO_2 in the jar were utilized. In the present study, a mathematical model was derived to apply the Damask system as a general method for testing RGEMS during both steady and transient states. A differential equation was derived to describe the concentration of a particular gas (G) in the test system as a function of time. This equation has a first-order solution with the time constant

$$T = \frac{V_S((\dot{V}_G + \dot{V}_I F_I)/(\dot{V}_G + \dot{V}_I) - F_0)}{\dot{V}_G + \dot{V}_I F_I - (\dot{V}_G + \dot{V}_I) F_0}. \quad (1)$$

T = time constant; V_S = test system volume; V_G = minute flow of gas G introduced into the system; V_I = minute volume provided by ventilator; F_I = fraction of gas G delivered by the ventilator; F_0 = initial fraction of gas G in the system.

Equation (1) was validated by measuring the concentration of O_2 expired from the system at 15 s intervals with a Beckman MMC Horizon System. A Siemans-Elema 900 B Servo Ventilator was used to provide a precise minute volume. Precise fractions of inspired gas were provided by a calibrated Siemans-Elema O_2–Air Mixer. Ten independent trials using V_I, V_G, and F_I as independent variables were recorded by the Horizon System. In each case, T was calculated from the system parameters using (1). The largest difference between the calculated and measured values for T was 0.20 min with T ranging from 1.25 to 2.80 min. The major limiting factor was an accurate measurement of V_I.

Ergonomic Design in Perinatal Monitoring

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Medical staff often find difficulty in accepting the products of recent advances in bioengineering because communication with the apparatus and/or its designer must be carried out in an unfamiliar technical language. In this paper we shall refer particularly to the field of perinatal monitoring and diagnosis, in which the results of the automatic analysis of fetal heart rate and uterine pressure signals are sometimes presented to the doctor in a form that prevents his contributing effectively to the design process by indicating desirable modifications.

Ergonomics is now understood as including the presentation of information in a form that is comfortable for the person who must use it, and in this sense we have designed a number of ergonomic perinatal diagnostic aids. These include the use of intrinsic dimensionality algorithms to produce two- or three-dimensional visual displays showing clusters on whose position the obstetrician can comment intelligently; a multilevel artificial language designed specifically for fetal state analysis and prediction of the time of birth; and a fast, interactive two-dimensional visual display of what we have called the "fetal topogram."

Session 14—Medical Instrumentation II

Chairman: W. Thomas Miller, Ph.D.
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Durham, NH

Microcomputer-Based Noninvasive Tissue Blood Flow Monitor

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The objective of this research is to develop a noninvasive thermal probe capable of accurately measuring tissue blood flow at the surface. The noninvasive probes are constructed by placing a spherical thermistor bead at the surface of an insulating barrier. Electrical energy is dissipated in the thermistor at a rate sufficient to maintain the volume average temperature of the bead at some predetermined fixed increment above the initial equilibrium temperature of the bead and the surrounding tissue. The insulation isolates the tissue temperature field from the surrounding air. A microcomputer-based instrument has been constructed which implements this noninvasive measurement technique. The Zilog Z80 based system has the following features: Intel 8231 A floating point arithmetic unit, 4K PROM, 52K RAM, an analog instrumentation bus, magnetic tape secondary storage, 14 bit A/D converter, analog feedback circuitry to control the thermistors, and a precision real-time clock. The stack-oriented interactive compiler (STOIC) instrumentation operating system was used to translate the problem statement into a prototype instrumentation system. STOIC has a number of features uniquely well suited for microcomputer-based instruments. The sequential control structure of most instrumentation problems has been captured in the organization of the STOIC language. The prototype system has an interpreter which greatly simplifies debugging and evaluation. The final solution can be compiled so memory efficiency and processor speed can be achieved. STOIC has features of a high-level language: floating point, data structures, and program structures as well as features of assembly language: assembly language programming, ROM, and interrupts.

Stimulating and Monitoring of Ambulatory Patients Via Telemetry

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A wireless stimulating and monitoring telemetry system has been designed for use with freely roaming patients. The system consists of an EEG crystal-controlled transmitter, FM receiver, analyzing unit, stimulus controller, and wireless remote-controlled portable stimulator. The stimulus current and frequency are controlled by the stimulus controller.

The system can be operated in two different modes: a) an evoked potential mode which is synchronized by a stimulus and during which the evoked potential is analyzed; and b) a mode in which the EEG signal is continuously monitored and analyzed, and upon detection of a specific pattern, a stimulus is delivered to the patient.

Advantages of the system are: a) it enables complete freedom of the patient; b) battery operation eliminates the need for safety procedures; c) crystal-controlled transmitters increase stability and reliability; and d) the units are lightweight and small in size.

Pattern Discrimination Helps Specify Risks of Disease

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For clinically healthy young adult women living on a standardized routine, the risk of developing a high rhythm-adjusted mean of blood pressure (RHBP) is negatively correlated with the circannual amplitude of plasma aldosterone—a finding which, however, is not promptly exploitable in practice (requiring sampling at least for a year). Pattern discrimination by dimensionality reduction and classification (with functions of distance) suggests which hormone(s) for the assessment of RHBP, as well as of the risks of developing breast cancer, emotional disease, alcoholism, and drug addiction, can be cost-effectively tested at no more than two clock hours, specified for each season. Aldosterone, with other hormones, is a consistent classifier for RHBP, yet the relation between aldosterone concentration and RHBP is an inverse

one in summer, fall, and winter and a direct one in spring. The inverse relation of the circannual aldosterone amplitude to RHBP may contribute to this seasonal change in the sign of a relation which seems to be part of a cost-effective predictor of RHBP.

Quadratic Field Induced Effects in Macromolecular Solution

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When a continuous ac electric field E is applied to a solution of macromolecules, a field-induced effect (e.g., induced anisotropy, induced nonlinear impedance) may exist in the solution. This effect may not follow the applied field instantaneously because of the large friction of the molecules. However, if the intensity of this induced interaction is proportional to the square of E, then there will be a net, time-averaged, dc effect existing in the medium, because the time average of the square of an ac periodical function in time, in general, is not zero. This dc effect or dc force will accumulatively drive the molecules to move or to stretch until a saturation level is reached. Consequently, large displacements of molecules under small but continuous ac fields result. This paper reports a large dc anisotropy effect of a macromolecular solution stressed under a medium strength (300 V/cm) homogeneous ac field. The degree of anisotropy is measured by the induced birefringence as detected by the Kerr scheme. Comparison to other related work is discussed and a possible application leading to a novel concept in E-field-biomedium interaction is proposed.

Session 15—Clinical Engineering Management

Chairman: G. I. Johnston, P.E., C.C.E.
Oregon Health Sciences University
Portland, OR

Clinical Engineering—A Natural for the Systems Approach

(Invited Paper)

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Research of the clinical engineering literature from the period 1973 to the present shows the growing role of clinical engineering in the health care setting. Initially, the perceived need was for someone to maintain the increasing numbers of complex equipment. "Trained" clinical engineers did not exist but many biomedical engineers were able to convert and fill the role. Strategies of in-house and shared service versus outside maintenance were constantly touted and debated. By the mid 1970's the demand for clinical engineers and biomedical equipment technicians had resulted in a growth of education programs and the beginning of certification for both. As the true complexity of the total equipment (technology) problem became understood, the role of the clinical engineer became much wider in scope. Concurrently, those engineers and technicians entering the profession proceeded to examine their career ladder and future roles. The literature of the late 1970's and to date refects the awareness of the clinical engineers management role, the complexity and multiplicity of interaction involving that role and the department's role, and the career concerns of both engineers and technicians. It is also this complexity which makes the systems approach an appropriate tool for modeling and analyzing the clinical engineering function in a health care setting. In this session some theoretical models from the systems viewpoint will be presented, followed by a number of real-world models which, in the discussion period, can be compared as to their differences from theory and each other.

The Integrated Health Care Engineering Department

(Invited Speaker)

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There are over 6000 hospitals in the United States. There are probably less than 1000 qualified clinical engineers available to staff the engineering functions in these hospitals and a much smaller number of engineering professionals capable of a leadership role in the advancement of health care engineering as a profession. The result is an over reliance on manufacturers' technicians for local maintenance at a cost that is typically on the order of $100 000 per man-year. This is only the direct cost, as the systems that result from this dearth of skilled professionals are frequently not suited to coordination of maintenance, and all too frequently initial costs are high, maintenance is too poor, allowing for excess down time, and initial costs are excessive. The integrated hospital engineering department is a reasonable solution to this problem, as a team is developed with appropriate overlapping skills so that there is an in-house knowledge of the technical aspects of the total health care system.

Clinical Engineering Support for an Academic Medical Center

(Invited Speaker)

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The Biomedical Engineering Division provides clinical engineering support for the University Hospital. We also provide engineering and maintenance for the College of Medicine and other University components. The Division employs seven engineers, eleven technicians, four secretaries, and several students.

The Division provides a variety of services which have been defined by the engineering staff and by the clients. Maintenance and some consulting services are provided in quantity and type largely defined by

clients and JCAH standards. Equipment training and planning may be initiated by client or engineering staff. New tools for equipment and resource management, however, have largely been defined by the engineering staff. At the heart of this is a team concept which has forged close ties between the Division and its clients.

Examination of communications channels, team efforts in problem solving, and the types of service offered reveals that success in this academic hospital environment is largely due to placing equal emphasis on engineering and maintenance support. The integration of personnel and goals within the Division and within the medical center are described in detail.

ACKNOWLEDGMENT

The authors wish to acknowledge the support of the staff and administrators who have made this program successful.

One Hospital's Clinical Engineering System

(Invited Speaker)

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Our Clinical Engineering Services are organizationally located under the Professional Support Division. This is one of five operational divisions of the institution. As the Department (BMP) was formed over 20 years ago, the present operations and management are dependent on the historical evolution of technology within the Hospital.

The Department performs the engineering, metrology, repair, and clinical specialty needs for a 500+-bed hospital of the same approximate size. However, BMP is a direct patient billing area generating in excess of two million dollars income each year. BMP crosses departmental and divisional lines to achieve maximum efficiency and utilization of available resources.

Many of the clinical engineering issues that have been raised over the years can be addressed by internal departmental management principles that in turn relate to external management needs. One such item is the acceptance by Administration and the Hospital's Medical Staff of Clinical Engineering acting as the single source for rapid technical response concerning operating and service problems when standardization of procedures/equipment is involved. This presentation will explain the management tools we have found effective and some of the "systems" inputs and outputs that can be utilized to achieve a more functional Clinical Engineering Department.

Another Hospital Clinical Engineering System

(Invited Paper)

S. S. MACK

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The Johns Hopkins Hospital is a decentralized institution consisting of 17 clinical and 11 support functional units. Clinical Engineering Services (CES) is organizationally located under Corporate Services, which includes Plant Operations, Housekeeping, Nutrition, Communications, and Material Management.

Clinical Engineering Services' charge is to provide each functional unit with the engineering services required to assure the safety and performance of clinical equipment (currently 6000 pieces), and to provide central management with the engineering expertise to establish and implement sound policy in the area of patient-related systems and equipment.

There are five (5) main problem areas that Clinical Engineering Services must overcome in order to execute their charge:

1) enforcing policies concerning safety and performance of clinical equipment;

2) competition between CES and revenue-producing units for space allocations;

3) insufficient manpower to meet demand for our services;

4) services performed for a functional unit appear as an expense on the user's budget, resulting in hesitation in utilization of our services;

5) professional recognition is a concern when clinical personnel view CES staff as only a "Mr. Fix-It."

This presentation will explain our efforts to overcome these problems and how we make Clinical Engineering a viable profession at Johns Hopkins Hospital.

Role of Codes and Standards in Clinical Engineering

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Codes and standards serve two roles for the clinical engineer.

First, they provide a great body of knowledge and experience which can be of great help in evaluating and testing in a manner that has usually been well tested itself. Without these, each of us would need to do a great deal of research or trial and error work to collect the equivalent information.

Second, they represent a set of requirements against which our work will be evaluated and failure to comply with them may bring some serious consequences.

The clinical engineer also has a role with codes and standards. His or her experience and knowledge can be of great assistance in revising codes and standards so that they can be improved. The potential for collecting data for substantiating recommended changes is substantial.

Codes and standards produced by the National Fire Protection Association, the Joint Commission on Accreditation of Hospitals, the Association for the Advancement of Medical Instrumentation, and the Department of Health and Human Services will be discussed in terms of the above three areas impacting on the clinical engineer.

Session 16—Drug Delivery Systems

Chairman: Peter G. Katona, Ph.D.
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Clinical Use of a Totally Implantable Drug Delivery Device

(Invited Paper)

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In 1969, my colleagues and I developed a totally implantable drug delivery system, now known as the Infusaid™ implantable infusion pump. After approximately five years of bench testing and animal trials, clinical trials of this device in human patients got underway in 1975. Since then, it has been implanted in more than 3000 patients worldwide for a variety of diseases, with some patients having functioning pumps in place for longer than five years. Currently, the device is approved by the FDA for intraarterial infusion of certain anticancer drugs, intravenous heparin infusion for refractory clotting problems, and intrathecal morphine infusion for intractable pain of malignant origin. Other experimental trials now underway include insulin infusion in the treatment of patients with diabetes, chemotherapeutic agent infusion for certain head and neck and CNS tumors, and trials of numerous substances in various animal models of human disease.

During this experience, we have recognized many problems of drug-device incompatibility that were not obvious from the outset. For example, many commercially available drugs are too dilute to be of practical use in a totally implantable device of limited infusate volume. Some drugs were incompatible with device components; others lost potency at physiological temperatures; still others formed insoluble precipitates.

As the science of new drug delivery systems evolves, it will clearly become necessary to develop a parallel branch of clinical pharmacology specifically designed to deal with these problems.

A Design Concept for an Implantable Drug Delivery System

(Invited Paper)

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Sandia National Laboratories, in conjunction with the University of New Mexico School of Medicine, has developed an implantable drug delivery system using a peristaltic pump driven by a rotary solenoid. The system has been implanted in diabetic dogs and three diabetic humans.

Reliability and safety are primary considerations in the development of an implantable drug delivery system. Hardware and programming flexibility must be maintained as the drug delivery requirements are optimized, yet provide safety limits to minimize the effects of operator error and errors due to hardware faults.

The peristaltic concept provides occlusion of the delivery tubing and eliminates the need for valving systems. The flow path is entirely of silicone tubing so there are no discontinuities or joints of dissimilar materials. The rotary solenoid pump driver is runaway resistant in that a failure of the driving electronics in a dc "on" state will not cause a runaway as it would with a dc motor driven pump. A separate reservoir allows the system to be tailored to a specific drug.

The design concepts utilized in the electronics include a wire jumper configuration which is set up at final assembly to determine the personality of each system. This concept allows a relatively narrow programmable delivery range to limit the dose range. Additional flexibility and safety are provided by the external controller program limits.

ACKNOWLEDGMENT

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A Multipurpose Implantable Drug Administration System

(Invited Paper)

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A multipurpose implantable drug administration device and noninvasive control system have been developed. This drug administration system consists of four basic components: 1) an implantable device housed in a laser welded titanium can containing a 20 cc titanium reservoir, peristaltic pump and motor, a lithium power source, and a sophisticated microprocessor-based electronic hybrid; 2) catheters which direct the medicants to selected sites; 3) a hand-held programmer with digital display and controls to actuate the implantable device; and 4) a computer-based physician's programmer containing a keyboard, CRT, programming head, and optional printer.

The infusion device is totally programmable while implanted and capable of delivering medicants at a multitude of rates of infusion from continuous to piecewise volume delivery in a variety of complex infusion patterns. This administration capability is necessary for obtaining glycemic control in the insulin-dependent diabetic patient.

Nonclinical verification studies in various animal models have included analgesic, cancer chemotherapy, anticoagulation, insulin, and saline infusions by several modes of administration. Cumulative experience with this system for these applications is in excess of eleven (11) animal device years. Over three (3) animal device years, experience administering insulin has demonstrated success in maintaining glucose control in diabetic dogs.

The Medtronic implantable drug administration system is presently under study in clinical trials. The first implant for the delivery of morphine in a patient suffering intractable pain occurred in March 1982. Since that time a number of devices delivering chemotherapeutic drugs as well as additional devices delivering analgesics have been implanted. Programmability of the system has allowed adjustments of prescriptions to aid in patient management during the course of treatment. Clinical results suggest that the programmable system is a useful tool in the management of pain and for the infusion of chemotherapeutic agents.

Three Generations of Insulin Infusers

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Microprocessor-controlled infusers for three separate phases of open loop insulin infuser research have been developed since 1979. The first device, using a 2650 microprocessor, was developed to assist hospital clinical staff to accurately infuse small doses of insulin. It was a syringe

infuser, programmed directly with the dosage required (in units per hour). Patient acceptance was disappointing so a miniature controller, 4 in × 2 in × 1 in, using an 80C35, and an associated syringe driver, 6 in × 1.75 in × 1 in, were subsequently developed in order to allow the patient greater mobility. Data were entered via a subminiature keyboard and three-digit LCD display. A dc motor-gearbox drove the syringe with dosage regulated by pulses from a Hall effect sensor. The syringe driver was strapped near the infusion site (usually a limb) with a flexible wire connecting to the controller.

In order to maximize clinical effectiveness, a larger preprogrammed infuser using an MC146805 to infuse step profiled meal boli in addition to multiple basal rates was developed. The programming is performed by connecting an HP41CV calculator (used for numerical processing and data storage). Meal cycles are activated by individual keys for meal type and size. Miniature LED's show the currently activated cycle. Preliminary clinical data show excellent glycemic normalization with this protocol.

ACKNOWLEDGMENT

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The Programmable Implantable Medication System (PIMS) Design and Applications

(Invited Paper)

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and

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The programmable implantable medication system (PIMS) consists of an implantable programmable infusion pump (IPIP) and the necessary support equipment. The IPIP is the implanted device which can provide controlled release of medication. Basal delivery of medication is programmed by the physician; additional programming for self-medication can be performed (at the physician's option) by the patient himself. The patient's programming unit (PPU) is a hand-held device used by the patient to communicate with the IPIP for self-medication. The physician uses a medication programming system (MPS) which consists of a "smart" terminal called a medication programming unit (MPU) used for basal programming of the IPIP, and a paper printer which provides a permanent record of the IPIP programming. Communication between the IPIP and the MPS can also take place via telephone transceivers. A medication injection unit (MIU) is used to refill the IPIP through the skin by means of a special hypodermic needle.

The IPIP utilizes a unique fluid handling system developed by the Biomedical Products Group of the Parker Hannifin Corporation. A 10 ml reservoir stores 3 months of concentrated insulin for treatment of the diabetic. A pulsatile pump delivers 2 μl fluid pulses utilizing a daily average of less than 12 μW of power. An antechamber with an inlet valve opened by the hypodermic needle provides a safe refilling method using the MIU.

Test results in several laboratory dogs over an 18-month period provide evidence that PIMS will be suitable for the treatment of a variety of medication conditions.

Macromolecular and Magnetic Controlled Drug Delivery Systems

(Invited Paper)

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and

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Over the past two decades, increasing attention has been paid to the development of polymeric systems capable of delivering drugs for long time periods at controlled rates. Such controlled release systems have been developed for treatment of eye diseases, birth control, and motion sickness. However, relatively little attention has been given to developing systems for the controlled release of large molecules (mol. wt.>1000) such as polypeptide hormones (e.g., insulin), polysaccharides (e.g., heparin), antigens, antibodies, enzymes, and others (e.g., interferon). In early studies, we demonstrated that small ethylene-vinyl acetate copolymer pellets could release many different macromolecules in bioactive form for over 100 days *in vitro* and *in vivo*. In order to achieve constant release rates, a hemispheric device laminated with an impermeable coating, except for a small cavity in the center face, was developed. Constant release was achieved for over 60 days. In order to provide increased release rates on demand, a polymer-drug system containing small magnetic beads was designed. Release rates were controlled by an oscillating external bar magnet. When exposed to the magnetic field, polymer matrices released up to 30 times more drug. This system has been shown to be able to lower blood glucose levels in diabetic rats for over a two month period from a single implant.

Low-Potential Voltammetry of Glucose in Human Dialysate

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The low-potential approach to electrochemical glucose sensing has previously shown to be successful in Krebs–Ringer phosphate buffer solution (KRPB). The estimation of glucose concentration in human serum dialysate was studied using a low-potential electrochemical technique. A standard human serum (Sera Chem®) was dialyzed against an equal volume of KRPB. The dialysate was submitted for SMAC analysis prior to electrochemical studies. Glucose concentration ranged about 40 mg/dl. The method was tested in an electrochemical cell consisting of a smooth Pt sensing electrode of our manufacture, a Pt counter-electrode, and a Ag/AgCl reference. The cyclic voltammetric scan range was −0.80 to +0.80 V versus Ag/AgCl at 30 mV/s. Serial additions of glucose provided dialysate glucose concentrations of 100–200 mg/dl. While all other glucose current peaks that we had observed in KRPB, and particularly the peak at +0.70 V, were completely inhibited by dialyzable substances from serum, the peak at −0.65 V (hydrogen oxidation region) remained very pronounced. The uninhibited

peak was used to plot the current versus glucose concentration. A linear relationship clearly exists for the clinically important monitoring range.

Implantable Glucose Measurement System

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and

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As part of an implantable artificial pancreas, a glucose sensor has been developed in combination with a custom integrated circuit for continuous monitoring of the glucose level and data/energy transfer between the implant and an external programmer. The latter portable base transmits energy towards the implant through an RF coupler. It also transmits the drive voltage for the polarographic measurement of the glucose level. The current from the sensor is encoded and transmitted back to the external programmer, where the information is stored for further processing.

Most circuitry is implemented in a custom CMOS integrated circuit, which is added in a hybrid circuit containing the coils, the rectifier, etc. Total power consumption is about 2 mW.

This measurement system can be applied for the measurement of any other implantable sensor output or biomedical parameter, for which power has to be drawn from a portable box through an RF coupler and for which continuous and programmable monitoring is required. The leading application, however, is an artificial pancreas.

ACKNOWLEDGMENT

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A State-Space Analysis of Phasic Insulin Secretion

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The secretion of insulin from the endocrine pancreas exhibits multiphasic patterns following an increase or decrease in the concentration of specific chemicals ("secretagogues"). We describe a technique for analyzing the multiphasic response to a continuous, time-varying stimulus in terms of a mathematical model.

A two-component model of insulin secretion serves to illustrate the technique. The input to the system consists of a succession of ramp functions, separated by constant functions. We demonstrate how to partition the state space into regions of states having the same number of phases (relative maxima or minima) in the insulin-secretory rate. Successive ramp functions are interpreted in terms of displacement vectors in the state space.

Our technique for analyzing the state space extends previous results obtained for discontinuous input functions. Application of this method to a hypothetical model under consideration allows one to decide on its feasibility. In addition, constraints on parameters of the model can be inferred from the state space analysis, aiding in the assignment of values to these parameters.

Uremic Dog Dialysate Urea Removal by Direct Electrolysis

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Urea has been removed from physiologic electrolyte solution by direct electrolysis. The sole products were N_2, CO_2, and water. Dialysate from a uremic dog model (ureteral ligation; BUN > 80 mg/dl, creatinine > 12 mg/dl) was tested to detect the possibility of interference or electrode poisoning by small or middle molecular particles. A hollow fiber dialyzer was attached to a chronic carotid/jugular shunt. The dialysis (Eri-lyte®, Erika, Inc.) proceeded for 6 h with hourly 50 percent exchanges with fresh fluid. The final hour's spent dialysis fluid was analyzed and contained urea-nitrogen 103 mg/dl, creatinine 6.1 mg/dl, and glucose 149 mg/dl. In electrolysis, the urea removal rate was 0.3 $g/hr \cdot m^2$. Standard electrolysis tests indicate that the Pt-black electrodes are not poisoned by any substances present in the dog dialysate. This work demonstrates both that the electrochemical system functions when exposed to actual fresh dialysate, and the feasibility of direct electrolysis for urea removal in the hemodialysate of uremic dogs, the next step being actual continuous dialysate regeneration with electrolysis.

ACKNOWLEDGMENT

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Session 17—Cardiac Dynamics and Assessment II

Chairman: Robert Peura, Ph.D.
Worcester Institute of Technology
Worcester, MA

Simulation of First-Transit Cardiac Radionuclide Curves

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A discrete-time, lumped parameter mathematical model of the human cardiopulmonary circulation as it appears during a first-transit radionuclide study has been developed. The model consists of 11 chambers, four delays, and 26 transfer paths including forward and reverse flow through the heart valves, backflow from the atria into the veins, and five types of shunts. A method of modeling continuously variable de-

lay segments with discrete time sample points was devised to allow more versatility in specifying delays. Simulated curves representing several heart defects will be presented. Using optimal fitting techniques, this model has been matched to curves obtained from patient first-transit studies to provide an estimate of the patient's heart parameters. An input function for the model is derived from the patient study. Separate regions of interest are selected for end-systolic and end-diastolic data and corrected curves are generated for these regions and interleaved to provide an entire time sequence representing each chamber selected for analysis. A method of scaling the data from the various chambers to account for variable radiation attenuation in the body was devised. This analysis provides a method of estimating many parameters of heart function using a single, simple, rapid procedure.

Resuscitation by Intrathoracic Pressure Variations

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Most cardiopulmonary resuscitation (CPR) methods involve some degree of direct heart compression. It has recently been postulated that intrathoracic pressure (ITP) variations rather than heart compression cause blood flow in CPR. In order to isolate the effect of pressure variations, a system for rapid intrathoracic and intra-abdominal pressure wave generation was developed for the detailed study of the relation between the intrathoracic pressure and blood flow. Pressure of 90.3 ± 13.6 mmHg and 105.2 ± 19.2 mmHg were measured in the aorta and right ventricle during high ITP phase (systole) and pressures of 20.7 ± 7.2 and 13.3 ± 5.8 mmHg during low ITP phase (diastole). The negative pressure gradient during systole between the aorta and right ventricle is assumed responsible for a positive systolic blood flow through the lungs and heart. The positive pressure gradient during diastole is responsible for the systemic blood flow. The carotid flow is characterized by a positive wave of flow throughout systole and a transient negative flow during the beginning of diastole. The average flow index (the ratio between the average flow during CPR to the average flow in the normal state) was 0.23 ± 0.11. It was found that the flow to the carotid artery was considerably affected by two factors: 1) increase of the pulse rate from 60 to 100 cpm and 2) initiation of the intra-abdominal pressure wave 50–100 ms before the start of intrathoracic pressure. The results obtained in the clinical experiments were in fair agreement with the results of a mathematical model presented elsewhere under similar conditions.

ACKNOWLEDGMENT

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Cardiopulmonary Resuscitation Mechanisms–Computer Model

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Cardiopulmonary resuscitation (CPR) during cardiac arrest is currently done by external chest compression causing systemic blood flow. The classic explanation for the mechanism of blood flow or direct compression of the heart between the sternum and spine has been opposed by a new concept of intrathoracic pressure (ITP) variations in CPR. Based on the new theory, intrathoracic and abdominal pressure variations were simulated by a lumped parameter computer model of the cardiovascular system (CVS). The computer model was based on representation of the CVS by resistive capacitive and inertial elements, the existence of unidirectional valves between central and peripheral veins, and the heart valve system. It was found that blood flow during CPR depends mainly on the existence of an effective valving system in the veins, which prevents retrograde blood flow during the high pressure phase (artificial systole). The venous return of blood from the periphery takes place during artificial diastole. A peripheral arteriovenous gradient generated by intrathoracic pressure variation is responsible for the systemic blood flow which is 10–20 percent of its normal value. The maximum flow under a forcing pressure of 50/0 mmHg was 663 ml/min and was achieved by a pulse rate of 115 cpm and duty cycle (ratio of artificial systole to cycle duration) of 58 percent. The coronary blood flow takes place only during the artifical diastole phase while the systemic blood flow continues throughout the cycle.

ACKNOWLEDGMENT

This work was supported by the Israel/American Binational Grant.

A Nonlinear Model for Estimating Right Atrium Contractility

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In this paper we apply the proposed nonlinear compartmental model to the right atrium cavity with a tricuspid valve at its output. The problem is formulated in terms of producing the right ventricular (RV) blood pressure as an output to the relevant actual input pressure of right atrium. A procedure for estimating an index for right atrium contractility and the pressure gradient across the tricuspid valve is depicted. An experiment of 20 patients with tricuspid stenosis was set up to validate the model output with normal and pathological conditions. A comparative study among RA angiocardiogram, echocardiogram, and myocardial index of contractility (force–velocity loop) is given.

A New Model for the Reconstruction of the Left Ventricle

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A new computerized model for tridimensional reconstruction of the left ventricle from a single plane silhouette has been developed. The ventricular contour, from images in RAO projection, is sampled on the xy plane into a 100 × 100 array. For all possible pairs of contour points (P_i, P_j) the central point (P_c) of the $\overline{P_iP_j}$ segment is calculated. Then the estimate (Z_c) of the Z value in P_c is obtained, based on the least distance of P_c from the ventricular boundary. In the orthogonal plane including P_i and P_j the cross section is approximated by a function, defined as a weighted average of an ellipse and a Bernstein-Bezier spline, which satisfies the following conditions:

$$Z(P_i) = Z(P_j) = 0, \quad Z'(P_i) = -Z'(P_j) = +\infty, \quad Z''(P_i) = Z''(P_j) = -\infty,$$
$$Z(P_c) = Z_c, \quad Z'(P_c) = 0, \quad Z''(P_c) = -1/\overline{P_iP_c}.$$

The surface resulting from the envelope of all the cross sections is iteratively smoothed by cubic splines until it becomes stable. The model has been tested on 41 plastic casts simulating the left ventricle. The least squares method and the paired t-test on the hypothesis of equality applied between the calculated and the real volumes gave: slope = 1.007, $r = 0.9904$, SEE = 6.9, $t = 0.23$, $p > 0.8$. The method allows a good reconstruction of the left ventricular shape.

Signal Processing of Heart Sounds—A New Statistical Approach

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A new method for heart sound processing based on statistical characteristics of heart sounds was developed and tested on patients. Heart sounds can be roughly divided into deterministic repetitive sounds (S_1, S_2, S_3, S_4) and nondeterministic sounds (murmurs). The repetitive sounds show some variation in timing relative to the ECG R waves (jitter), while the murmurs are random in nature. The method includes dividing the phonosignal into a set of repetitive signals according to the R wave trigger of the ECG. The average and the variance functions are calculated for consecutive beats. The deterministic sounds preserve their pattern with attenuation which is dependent upon the jitter and the frequency. Murmurs tend to disappear after averaging, resulting in a clean sound signal. The variance function show maxima in the highest derivative point of the deterministic sounds and a characteristic pattern for certain murmurs. The jitter of heart sounds was calculated from the average and variance functions and showed a value of 5.5 ± 2.6 ms for S_1 and 8.2 ± 3.3 ms for S_2. This new approach provides us with a) a better discriminatory power in cases of strong murmurs; b) "jitter"—an objective parameter in the trigger response linkage, and c) characteristic patterns of the variance function which can be used for diagnosis.

Fourier Descriptors for ECG Data Compression

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Data storage and transmission requirements of a large number of electrocardiograms call for efficient data compression methods. Several methods are available with varying degrees of success. In this paper a method based on the Fourier descriptors (FD's) of vectorcardiograms (VCG's) is presented for data compression of ECG signals. The ECG record is segmented into *QRS* complexes and the following *S-Q* intervals using the planar velocity of two leads of the Frank orthogonal system. The FD's of these component VCG loops are obtained by computing the Fourier transform of the sequence representing the contour of the loops as a complex function $X(t) + i\,Y(t)$. In this representation, it is not necessary to sample the contour uniformly along its length and, thus, there is no loss of temporal information. While compression ratios of 10:1 are feasible for the *S-Q* interval, the clinically significant information in the *QRS* complex limits this ratio to 3:1 for acceptable range of errors. Thus, average compression ratios better than the existing methods, such as orthogonal transforms and heuristic techniques, have been obtained. The compressed data from 15 abnormal and 20 normal subjects using the present technique show promising results.

Besides data compression, the method simultaneously provides rhythm and contour information required for ECG analysis. The present method can be extended to any other ECG lead system and can be implemented in real time.

Session 18—Medical Microprocessor Techniques

Chairman: William G. Crozier, Ph.D.
Technology, Inc.
Houston, TX

Electronic Fetal Monitoring and Interpretation by Computer

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A microcomputer system for the continual display and interpretation of fetal monitoring information is operational at Sinai Hospital in Detroit. This system includes a programmed Apple II personal computer. The microcomputer converts signals from four bedside fetal monitors simultaneously. Monitor tracings, similar in quality to those at bedside, are displayed at the central unit and at remote locations throughout labor and delivery. Another aspect of the program is the interpretation of abnormal conditions. Mathematical analysis determines baseline activity, variance from a smoothed heart rate display, and timing of heart rate decelerations. Based on numeric analysis, warnings are displayed on the screen and verbally using an electronic speech synthesizer. These are updated every two minutes. Other functions include printouts of monitor displays and labor information, and the transmission of this information to physicians' homes. Benefits include rapid dissemination of information to physicians and staff, improved medical record storage through graphic production of monitor tracings, and educational support to nursing and medical staff through computer interpretation of abnormal fetal heart rate conditions.

Noninvasive Monitoring of Respiration by Microcomputer

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Respiratory inductance plethysmography (RIP), a noninvasive method of studying respiration, uses transducers placed around the ribcage (RC) and abdomen (ABD). Recommended calibration requires manually reduced data from two postures. A problem with this approach is that positional changes may not be possible and it seems preferable to calibrate in the position of monitoring. We developed software to calibrate, acquire, and analyze RIP signals in a single position, over a prolonged period of time. The calibration procedure consists of having the subject breathe spontaneously for one minute, as a computer samples (at 20 Hz) volume (digitally integrated pneumotachograph flow), and RC and ABD signals. Multiple linear regression (volume versus RC and ABD excursions) yields a prediction (calibration) equation: volume = intercept + b_1RC + b_2ABD. Calibration stability was assessed in eight normal adults, by applying the initial equation to data collected at 20 min intervals over 1 h. Mean slope, the relationship between observed and predicted volume, for the initial and subsequent trials was 0.995 ± 0.074 (SEM); mean intercept was 0.012 ± 0.018. Once calibrated, a continuous respiratory waveform can be produced using RC and ABD data. The timing and volume components of each breath are summarized by descriptive statistics, frequency histograms, regression, and trend plots.

Speech Synthesis for ICU Alarms

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The patient alarm system in most intensive care units (ICU) consists of several tone encoded signals informing the nurse of a particular problem occurring within the unit. Before the nurse can determine which bed is generating the alarm, she or he must walk to the central console.

To assist the nurse in meeting patient needs more quickly, the Department of Biomedical Engineering has developed a microprocessor-based alarm enunciator. The enunciator enhances the existing alarm mechanism by verbally announcing the module number of the troubled bed.

Designed around the Motorola 6802 microprocessor and the National Semiconductor Digitalker Speech Processor chip, the circuit is simple yet provides a high-quality speech output.

A Microcomputer Application: Neurotoxic Assessment

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A microcomputer program calculates the interaction of a subject's life stress load, errors and rate of information processing under different task loads, rate of visuo-spatial scanning, auditory short-term memory, ability to solve problems of inductive reasoning, levels of anxiety and depression, and involvement of the autonomic and central nervous systems.

Estimating equations, calculated for the several parameters, make it possible to predict retest from baseline performance. The equations have been used in serial studies to determine the reversibility of pathophysiological and/or psychopathological changes associated with certain toxic agents.

Performance data are generated by direct interaction of the subject with the computer terminal. Data acquisition requires about 1 h; report processing requires 1 min. If desired, reports may be transmitted by phone modem.

The program is in Tandy Basic, and requires 48K RAM and one disk drive. Protected disks acquire performance data, process those data, and generate hard copy reports.

A Portable μ-Computer Digital Recorder

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A 35 lb microcomputer system from Scientific Micro Systems, Inc., is being used as a digital recorder to store various physiological signals in several experiments at the NASA/Johnson Space Center in Houston, TX. This system, the MDX-01172, is an LSI-11/23 Q-bus based system. The MDX was ordered with a 10.6 Mbyte Winchester, RX02 compatible floppy drive, 128 kbytes memory, and a four-port serial interface, and operates under DEC RT-11. An eight channel analog-to-digital converter and a clock board were added to duplicate several larger, heavier LSI-11 systems in various NASA laboratories. Currently, two channels of physiological data are being sampled 120 times per second and three at 8 samples per second. The -5 V to +5 V signals are digitized and stored on the Winchester and up to 30 min of data can be stored continuously. A LEXICON LEX-21 5 lb microterminal completes the system allowing a fully operational LSI-11/23 equivalent system to be carried to the experiment site. Programs already written for a Nystagmus analysis can be used with the MDX system to display the data on a Tektronix 4014 graphics monitor.

A Microcomputer-Controlled Linear Accelerator System

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A linear accelerator sled system has been developed for use in the NASA/JSC Neuroscience Research Laboratory. This system is used for vestibular experiments involving responses to linear sinusoidal accelerations. In particular, Hoffman reflex studies have been conducted with the system in order to investigate the use of this vestibular-modulated reflex in learning more about changes in the human vestibular system following space flight.

The hardware for the system consists of a commercially available LSI-11 microcomputer with standard interface boards, and a custom-designed dc motor driven sled and control panel. In normal use the computer controls all functions of the sled, including calibration and velocity control during a test run. In addition, the custom software collects analog information from several channels during each test and stores it on flexible disks for later interactive analysis. Independent hardware continuously monitors several parameters for faults and rapidly stops the sled through a separate braking system if abnormalities occur.

The system has been used in a number of trials and has undergone two major revisions in software and hardware. Current plans call for its use before and after certain flights on the Space Shuttle crewmembers.

Microcomputer Analysis of Signal Characteristic of EMG

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The study of EMG signals of muscles and biological feedback is attractive because the artificial retrieval of lost functions should be aimed at the complementation of those functions at the most physiological possible level; the upper limb prosthesis design is within this lineament.

The present paper describes a system design based on a microcomputer which operates with signals of two antagonistic muscles. It aims to facilitate the problems presented by the generation of a system that performs the recognition of myoelectrical signals.

Microcomputer for Diagnosis of Neurological Disorders

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The design of a microcomputer-based data acquisition system for electrooculography is described. The system measures the absolute voltage excursion corresponding to a horizontal eye movement of a specific amplitude. Several parameters of eye motion are measured including saccadic velocity, eye movement latency, and accuracy of fixation. Calibration, light stimulus, data acquisition, and processing are performed automatically. Individual tests are displayed in real time and can be aborted to inhibit acquisition of bad data. The system is currently being used in early diagnosis of some neurological disorders such as myasthema gravis, multiple sclerosis, and Huntington's chorea.

The system incorporates a Z80-based microcomputer with graphics terminal, dual double-density floppy disk drives, and printer. Data acquisition hardware is separated and modularized in a standard 19 in subrack assembly. The system is inexpensive and portable and can easily be adapted for other medical applications.

ACKNOWLEDGMENT

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Microprocessor-Based System for Self-Measurement Applications

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We describe a prototype portable microprocessor-based device, called the autochronor, which is intended for the self-measurement and recording, as a function of time, of physiologic and pertinent environmental variables, with an ensuing inferential statistical estimation of temporal parameters. This instrument offers 1) multivariate data acquisition, from a keyboard with numerical feedback on a liquid crystal display; 2) a sampling sequence automatically programmed from a local time routine that can be used a) to program the sampling sequence with sampling rates defined along the scales of the day or week, b) to call the subject accordingly, to prompt the start of the self-measurement routine, c) as a general register that is addressed and records any time a measurement is done, d) for the counting of time intervals or event recording, and e) easy but reliable assessment of certain variables of interest, such as the time elapsed in eye-hand coordination, random number addition, short-term memory, and other problem-solving tests; and 3) flexibility in input-output operation, in terms of human-autochronor intervention, i.e., feasibility of the implementation by added hardware and/or software of any idea of interest, with particular reference to autorhythmometry of blood pressure and other psychophysiologic variables.

ACKNOWLEDGMENT

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Session 19a—Frontiers in Electrophysiology I: Cellular Electrophysiology and Neurology

Sponsored by the EMBS Committee on Bioelectric Phenomena

Chairman: John W. Clark, Jr., Ph.D.
Rice University
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Electrophysiological Studies of Compound Action Potentials

(Invited Paper)

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The development and application of computer-based models for the neural compound action potential (CAP) has occurred within the last decade. The "forward" models have attempted to map extracellular myelinated fiber waveforms to CAP waveforms recorded with monopolar or bipolar electrodes on the nerve or skin surface. The distributions of myelinated fiber diameters or conduction velocities have been the basis for the forward models. The "backward" or inverse models have attempted to predict fiber diameter or conduction velocity distributions from recorded CAP waveforms.

The background and basis for the forward and reverse methods will be reviewed in the context of several basic assumptions associated with models developed to date. Several anatomical foundations for the fiber diameter histogram will be examined. The classical "relationship" between fiber diameter and conduction velocity will be questioned on the basis of conduction velocity distributions obtained from hundreds of single myelinated fiber recordings. The effect of temperature on CAP waveforms and conduction velocity histograms will be described.

The material presented here should provide important background

for the papers that follow. The treatment of the questions raised by our anatomical and electrophysiological results will be important in the validation of CAP and single myelinated fiber models.

Modeling and Analysis in Electroneurography

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The analysis of the electrical activity of human peripheral nerves is commonly restricted to the determination of the latency and amplitude of the evoked compound action potential (CAP). Since the CAP results from the activity of a large population of individual nerve fibers with different characteristics, only partial information concerning the nerve's function is obtained in this manner. In recent years several studies have concentrated on the extraction of more basic electrophysiological properties of the fiber population by making a more detailed analysis of the CAP waveshape. One approach has been the forward modeling of CAP's based on volume conduction theory and electrophysiological and morphological data on the single fiber level. Alternatively, inverse models have been developed concentrating on the estimation of the distribution of conduction velocities in the larger diameter fibers, employing surface recorded CAP's.

Results obtained thus far indicate that clinically relevant information about the smaller fiber diameter group can only be obtained if near-nerve recording techniques are used, in which case many of the simplifying assumptions employed in existing inverse models do not hold. It appears possible, however, to establish an accurate forward CAP model, in which the assumption of an anisotropic, inhomogeneous volume conductor and finite sample properties of the underlying fiber diameter distribution form essential parts.

Current work concentrates on procedures for the inversion of this model and its evaluation on the basis of *in situ* electrophysiological measurements and subsequent sural nerve biopsy findings in humans.

Electrophysiologic Characterization of Focal Peripheral Nerve Injuries

(Invited Paper)

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The electrophysiologic properties of nerves provide the basis for most quantitative analyses of axon function in health and disease. In many cases, the analysis of peripheral nerves entails the measurement of compound action potentials (CAP's) recorded from a population of axons comprising a nerve bundle. Over the last 10 years, several methods have been developed which attempt to infer the fiber diameter distribution of axons giving rise to the CAP, typically by estimating the distribution of conduction velocities (DCV) of the nerve bundle. Parameterization of the conduction properties of axons using such velocity measures implicitly assumes a constant or piecewise constant propagation rate along the axons. However, such models of the CAP do not apply when there is significant focal (localized) slowing, since affected axons will have their action potentials "displaced" in time from their appropriate conduction delays.

We are currently evaluating nerve function in populations of regenerating axons with focal slowing. Our approach is to obtain a "distribution of added delays" (DAD), which provides an estimate of the total fraction of axons crossing a focal lesion or repair site and a histogram of the fractions conducting at various added delays. A procedure for estimating the DAD using an extended model of the CAP was developed and tested using computer simulations. The method was also applied to the evaluation of nerve repair procedures in primate peripheral nerve. It is felt that this method for evaluating focal nerve abnormalities can be used as a quantitative measure of nerve regeneration following nerve repair, and as an objective tool for use in clinical and intraoperative decision making following peripheral nerve injury.

ACKNOWLEDGMENT

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Simulation of Conduction in Myelinated and Demyelinated Axons

(Invited Paper)

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Simulation of nerve conduction phenomena can augment physiological studies in several respects. Using an appropriate model, simulations allow control and observation of individual parameters which are often not possible in a laboratory environment. Parameters may be tested over a wider range and with finer resolution than might be possible given cost and time constraints of actual experiments. Discrepancies encountered when comparing simulation results to physiological findings can lead to improvements in the model, a better understanding of the phenomena under observation, and possibly an indication of what new experimental direction might be valuable. Generally, the simulation results will give qualitative understanding rather than precise quantitative predictions. A model is presented which has been used by several investigators for a variety of simulation studies. Specific studies of refractory effects on the conduction of trains of impulses, bidirectional refractory effects in collision neurography, and the effects of ionic conductance variation on the invasion of demyelinated axon segments are reviewed. Experimental findings related to these simulation studies are discussed.

ACKNOWLEDGMENT

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Cellular Magnetism: Theory, Experiments, and Applications

(Invited Paper)

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We have demonstrated theoretically that the magnetic field associated with a propagating nerve action potential is determined primarily by the axial intracellular action currents. This magnetic field can be readily measured by surrounding the nerve with a small room-temperature toroidal pickup coil which can be thought of as the secondary of a transformer that has the nerve as a one-turn primary. The currents induced in the coil by the neuromagnetic field are sensed by a low-noise solid-state amplifier. The fundamental difference between magnetic techniques for measuring cellular action currents and more conventional electric ones lies in the fact that the proportionality between magnetic field and current is determined by the physical constants in Ampere's law, whereas the relation between electric potential and current is determined by membrane and tissue impedances, which may vary with time, direction, position, or voltage. We have also shown that extracellular magnetic measurements of intracellular action currents can be used to obtain the transmembrane action potential without penetrating the nerve membrane. Magnetic measurements offer the practical advantage of being made with the nerve immersed in saline, whereas electric measurements are most readily made with the nerve suspended in air. While this measurement technique is quite new, the ease with which we can measure the magnetic field from isolated nerves and the potential advantages offered by direct magnetic measurement of intracellular currents suggest that our technique may have several important practical applications to both basic research and clinical medicine.

ACKNOWLEDGMENT

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Session 19b—Frontiers in Electrophysiology II: Electromyography

(Sponsored by the EMBS Committee on Bioelectric Phenomena)

Chairman: John W. Clark, Jr., Ph.D.
Rice University
Houston, TX

Myoelectric Manifestation of Localized Muscular Fatigue in Humans

(Invited Paper)

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It is well known that during sustained muscle contractions, the power density spectrum of the myoelectric signal detected with surface electrodes displays a frequency shift towards the low-frequency end. The high-frequency components decrease and the low-frequency components increase in amplitude. During the past two decades, various studies have attempted to investigate if the cause of the frequency shift originated from "physical properties" of muscle fibers, such as conduction velocity, or from "control properties," such as firing statistics. This question was investigated by deriving mathematical expressions for the power density spectrum of the myoelectric signal which contained separate functions expressing the individual effect of the firing statistics and the shape of the motor unit action potentials. Experiments and detailed data analysis were performed to obtain the power spectrum of the motor unit interpulse intervals throughout sustained muscle contractions. The results strongly indicate that the effect of the firing statistics of the motor units on the power density spectrum of the myoelectric signal is minimal, and cannot account for the frequency shift observed during sustained contractions.

A detailed review of the literature, as well as our own work, has indicated that the frequency shift may be monitored by tracking the median or the mean frequency. Through mathematical analyses and empirical results (reported in the literature), it is possible to provide a logical explanation involving a series of biochemical events, muscle architecture, physiological properties, and signal propagation properties that explain the occurrence of the frequency shift during sustained contractions. Furthermore, the explanation supports the use of the frequency shift as an objective measure of localized muscle fatigue in the human.

Characterizing the Interference EMG

(Invited Paper)

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When high levels of muscle contraction are studied, the electromyographic signal observed via surface or needle electrodes is the noise-like "interference EMG." This paper starts with a brief consideration of the processes contributing to this signal and of methods proposed to characterize it for diagnostic and scientific purposes. Ideas based on spectral analysis are seen to have a special attraction in this work, but have also been shown to suffer from significant limitations due to complex interactions of effects arising from changes in, for example, conduction velocity, firing time statistics, action potential shape, and synchronization.

Consideration is given to related methods of data reduction which are now in the research stage. In particular the spectral analysis of one or more point processes derived from the EMG is shown to be promising as a method of abstracting information on action potential shape and synchronization. Results indicate that the spectral shape is to a significant extent characterized by the number of phases in the action potentials, and classification of spectra related to various disease states may therefore be possible by such methods as principle component analysis.

Processing of the EMG Signal

(Invited Paper)

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Electromyographic signals (EMG's) have been utilized as a control signal for electrically powered prostheses. Processing of the EMG has evolved to a high degree of sophistication over the last decade. For the case of multistate myoelectric control systems, use of optimum communication and pattern recognition principles has resulted in systems that theoretically are able to control up to eight functions with acceptable error performance. Practically error rates have been considerably greater than predicted by theoretical analysis. Signal models for the stationery EMG signal are well established, and thus this discrepancy is postulated to be due to operator error.

This paper discusses EMG processing that takes into account operator error. The EMG signal produced is modeled as a composite hypothesis problem. Based on this model, several algorithms of varying complexity are developed and are discussed. Since analytical results for error performance are difficult to obtain, experimental results via computer simulation are presented. The robustness of these algorithms in terms of operator error is discussed and compared to Bayesian and sequential algorithms.

Automatic Decomposition of the Electromyogram

(Invited Paper)

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We present a new, automatic signal processing method for identifying and measuring the individual motor-unit action potentials (MUAP's) comprising the electromyographic interference pattern (IP). The sampled IP signal is first digitally filtered to accentuate the rapidly rising spike components of the MUAP's. These spike "signatures" are then sorted by template matching, and the MUAP waveforms are averaged from the IP using the identified spikes as triggers. New algorithms are used for aligning and comparing the spikes, resolving superimpositions, and simultaneously averaging the overlapping MUAP's; these algorithms efficiently achieve high temporal resolution from slowly sampled (Nyquist rate) data by working with the Fourier series expansion of the continuous interpolating waveform. In a typical clinical application, 5 s of IP are recorded with a needle electrode from the biceps brachii muscle during a 2-3 kg isometric contraction; from these data the method identifies 8-14 distinct MUAP's, detects 30-80 percent of their firings, and measures their amplitudes, durations, rise times, and firing rates. The analysis is automatic and takes 90 s on a PDP-11/34 computer. For motor control studies, the method can also be used to track all firings of multiple MUAP's simultaneously, at the expense of longer (but not prohibitive) computation time.

Session 20—Cardiac Assist Devices

Chairman: Dov Jaron, Ph.D.
Drexel University
Philadelphia, PA

Velocity Control of Motor Driven Ventricular Assist Device

(Invited Paper)

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It is necessary to control the velocity of the LVAD brushless dc motor in order to minimize inertial rocking during reciprocation. A digital velocity feedback control system was developed with the aid of a mathematical model of the motor plus circulatory load. The desired velocity profile is calculated from a constant acceleration model with three input parameters: beat rate, stroke length, and the ratio of systolic to diastolic duration. The linear velocity of the motor pusher plate is obtained by taking a backward difference of the sensed plate position.

A digital compensator incorporating two integrators and two lead networks was designed and tested. The average voltage applied to the motor is changed through pulse width modulation in response to the velocity error, i.e., difference between actual and desired velocity. The control system was implemented using a 6502 microprocessor-based dedicated system. The system is interfaced to an Apple computer so that system parameters can be monitored and the desired velocity profile can be easily changed.

Mock circulatory system testing indicates that the desired velocity profile is closely followed at low beat rates and full stroke lengths. However, as the beat rate is increased, motor limitations cause tracking errors. These errors can be reduced by departing from the ideal velocity profile.

ACKNOWLEDGMENT

This work was supported by the National Heart Lung and Blood Institute under Grants Rol-HL-20536 and Rol-HL13426.

In Vivo Experience Using a Motor Driven Heart Assist Pump with Implanted Compliance Chamber

(Invited Paper)

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Electric motor-driven left heart assist pumps have been implanted in six calves. An implanted compliance chamber (CC) has been employed in the last three animals. The average period of pumping for the six animals is 85 days.

The CC is an intrathoracic rectangular velour covered Biomer sac. The dimensions are 19.7 × 15.2 × 1 cm. Typical power requirements for the entire system including all losses were 12.5 W to pump 7 l/min with a mean outlet pressure of 100 mmHg with a mean inlet pressure of 15 mmHg. At these pumping conditions, the motor surface temperature is <42°C. Of the six implant experiments performed, the first two (123, 73 days) were terminated due to bearing failures. The next two (19, 84 days) were terminated due to corrosion caused by moisture in the system and an electrical leak creating an electrochemical reaction. The last two experiments employed the same motor; it was removed from the first animal at 103 days when the animal died of infection. The motor was cleaned on the outside (no relubrication), resterilized, and used in the next animal. This last animal survived for 105 days and was terminated due to sac calcification and rupture. Upon removal the motor drive showed no measurable (<0.0005 in) wear.

Trace amounts of liquid H_2O (<5 ml) increased pCO_2 and decreased pO_2 were measured in the CC. Excellent compliance was retained for the entire study.

The use of a CC and implanted pump eliminates the need for an air vent and represents another step toward clinical acceptability of a long-term assist pump.

A Magnetic Energy Converter for Left Ventricular Assist Devices

(Invited Paper)

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A magnetically actuated left ventricular assist device (MALVAD) presently is being developed which offers two distinct advantages over current LVAD development: 1) no moving parts and increased reliability, and 2) direct, single stage energy conversion. The elctromagnet actuator is flux-coupled with a like-polarity, rare-earth, permanent magnet (REPM) pusher plate/pump diaphragm assembly. Dynamic flux enhancement provided by the use of passive bias magnets critically located in the ferro-magnetic structure presently enables a 30 percent reduction in electromagnet field/current requirements from conventional design methods.

Adaptive Control Strategies for Artificial Hearts and Assist Devices

(Invited Paper)

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This paper investigates the extent to which adaptive control strategies can be expected to be beneficial in computer-based automatic control of artificial hearts and assist devices. The paper considers the selection of output and control variables and the instrumentation and hardware required to make the system effective. The emphasis of the paper is on the design of systems which control the physiological state of the recipient of the artificial device, that is, the control of blood pressures and cardiac output.

Hemodynamic Models of a Pneumatic Artificial Ventricle

(Invited Paper)

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An artifical ventricle can either pump a fixed volume or a variable volume, dependent on its filling pressure. The latter mode allows the ventricle to operate in a Starling-like manner and therefore requires no external automatic control system. This is the mode of pumping of a Jarvik 7 (J-7) artifical ventricle.

We are describing the hemodynamics of a J-7 ventricle as two three-dimensional surface models, one for systole and one for diastole. The axes for diastole are filling (atrial) pressure, filling time (diastolic period), and the subsequently filled volume. The systolic axes are the volume to be pumped (relating diastole to systole), the pumping time (systolic period), and the pressure transfer function of the system (arterial pressure/driving pressure). The surfaces will indicate the proper driver settings to take advantage of the Starling mechanism (i.e., allow variable volume pumping throughout the entire range of fill pressures). Deviations from the surfaces will indicate certain pathologic conditions.

The data are being collected on a microprocessor-based data acquisition system (described elsewhere) and a noninvasive cardiac output algorithm developed here and at the University of Utah. The algorithm computes the filled volume via the air being expelled from the drivelines during diastole. Pressure transducers in the drivelines yield indexes of ventricular emptying.

A Simple Closed Loop Model for Intraaortic Balloon Pumping

(Invited Paper)

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The objective of cardiac assistance by intraaortic balloon pumping is to improve the balance between cardiac supply and demand. This can be achieved by increasing ventricular output, reducing cardiac load, and by lowering oxygen consumption. Optimization of assistance entails controlling the balance between such desired outcomes. Last year we described a simple, lumped, first-order model of the aorta-balloon system. The impetus for developing such a simulation was to enable the formulation of closed-form equations which could be solved to predict optimal pumping strategies. Such simulation also provides an insight into the direct relationships between the physiologic and the assist systems. This model did not include the effects of assistance on oxygen consumption. It also assumed a fixed pressure source representation for the heart.

We have now added two new features to the simulation: a lumped model of the venous system and a time-varying representation of the left ventricle which allow the estimation of oxygen consumption and provide for the effects of venous return. The new, closed loop model still permits the formulation of closed-form equations. The results of our new simulation suggest that parameters and weighting factors comprising a performance index used to determine optimal balloon inflation time may differ from those comprising a performance index used to determine optimal balloon deflation time. Consequently, for maximum hemodynamic benefits, two different indexes may be needed for determining time of inflation and time of deflation. Our results should help quantify the choice of parameters and of the weighting factors to be used in an automatic control system for cardiac assist pumps.

ACKNOWLEDGMENT

This work was supported by the National Science Foundation under Grant ECS-7924354.

Pulsatile Versus Nonpulsatile Flow in the Development of a Total Artificial Heart (TAH)

(Invited Paper)

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The specifics of this paper flow from the long-range objective to develop a completely implantable TAH system. The current work addresses two questions. First, what is the best control algorithm for a TAH configured out of existing energy converters and the CCF biolized pusher plate pump? Second, is it possible to broaden the scope of this

configuration by demonstrating that mammalian physiology can remain viable with nonpulsatile (NP) flow?

To accomplish these goals, two sets (TAH and NP) of calves (90 kg range) were implanted with devices and followed up with identical postoperative protocols. This protocol included hemodynamic, blood chemistry, and stress (exercise) testing measurements. The drive system for each TAH calf had five different control modes, which were then compared. Left flow in the NP calves was adjusted manually once a day for maximum and the right pump more frequently to maintain normal left atrial pressures (LAP's). Frequent NP pump changes (every 20 days) were necessary due to deposition at the shaft-seal interface.

TAH results, based on three calves surviving from 45 to 108 days have shown that any future control system must be able to accommodate a variable left-right flow differential. The five approaches have been essentially graded, and now in depth work is proceeding to optimize the three best methods. NP studies have shown, as a result of five calves living from 34 to 99 days, that chronic NP flow is indeed acceptable (although relatively insensitive to transient demand), as long as overall perfusion rates are kept above 90 ml/min/kg. The bulkiness of the pulsatile devices and the poor controllability of the NP pumps suggest a hybrid combination may result in the best overall TAH configuration.

Optimization Aspects of Cardiovascular Control Systems

(Invited Paper)

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Applications of classical control theories to the studies of neural-mechanical interaction of the cardiovascular system are numerous. The optimal control aspects, however, have not been extensive. This paper provides an overview of modern control theories applicable to these situations, and selected to examine parametric alterations in the natural and the assisted circulation.

The heart-arterial system is represented by a simple electric analog. Pulsations generated by the heart are optimized with respect to minimal external left ventricular work. These pulses propagate through the arterial system, characterized by structural-functional features that facilitate one-way transmission. The pulses arrive at vital organ vascular beds which present minimal peripheral resistance to the ejection pulses.

In a failing cardiovascular system, these pulses and features are no longer optimal. Consequently, a different set of constraints is necessary to describe the altered system characteristics. Whether the optimal features are restored via cardiac assistance are analyzed via modern control theories.

Session 21—Invasive and Minimally Invasive Ultrasound

Chairman: Roy W. Martin, Ph.D.
University of Washington
Seattle, WA

Intraoperative Ultrasound During Heart Surgery

(Invited Paper)

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This paper will review our efforts at providing methods for intraoperative scanning during heart surgery. For valve imaging in reconstructive surgery and for the evaluation of congenital heart surgery, we have used gas sterilized phased array probes or a miniaturized phased array probe at 3.5 MHz which was about the size of a Maalox tablet. The miniaturized probes have unique maneuverability and allow one to get posterior and subcostal equivalent views during intraoperative echocardiography. We have studied the following utilities in these settings: assessment of right ventricular outflow tract resections for tetralogy and other forms of pulmonic stenosis, assessment of Mustard baffles for transposition, and assessment of AV valve chordal attachments in complex VSD's and AV canals. In adult patients we have studied reconstructive valvular surgery for mitral and tricuspid insufficiency using Carpentier ring and chordal shortening procedures. We have studied commissurotomies for aortic and mitral stenosis and assessed valve function by 2-D echo, saline echo contrast injection, and Doppler interrogation intraoperatively.

The second type of ultrasound imaging technique which we have developed and which we have utilized at the University of Arizona is very high frequency waterpath standoff scanning at 12–13 MHz for evaluation of coronary atherosclerotic lesions. Our experience with these techniques suggest that very high resolution images can be derived to allow the surgeon to map the coronary bed, to localize lesions seen angiographically, to fill in information which is not adequately supplied by the angiogram, for instance, in totally obstructed arteries (information about the area downstream), and also to assess the position and insertion of proximal and distal graft anastomoses.

The results provided by ultrasound methods for heart surgeons using dedicated instruments designed for surgical application, the miniaturized phased array probe or the waterpath scanner, suggest that the surgeon will indeed become an ultrasonographer and that his surgical skills will be improved by using ultrasound to aid in his decision-making processes.

Recent Improvements in Pulse Transit Sonomicrometry

(Invited Paper)

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Pulse transit sonomicrometry has been used to measure cardiac dimensions for 30 years. However, limitations in signal amplitude caused by transducer directionality and circuit design have posed significant problems in certain applications, such as measurement of large dimensions. Recent technical advancements have reduced these problems and greatly expanded the utility of this method. Hemispheric piezoelectric transducers allow 90° deviations with minimal signal reduction, simplifying placement and increasing reliability. System electronic developments improve sensitivity both by optimizing the driving pulse waveform to couple more energy to the sending transducer and by increasing

the signal-to-noise ratio of the receiver circuit. Wide-band operational amplifiers allow frequency and phase characteristics to be tailored for the maximal extraction of received signal features and a four-quadrant multiplier provides accurate gain control and phase reversal. Improved controls and a wide-range calibrator increase flexibility and simplify setup. In addition to basic research in cardiac physiology, this system allows routine monitoring of ventricular dimensions after cardiac surgical procedures. With pressure data from micromanometers and using digital processing techniques, estimates of ventricular volume, stroke volume, stroke work, myocardial compliance, and inotropic state are displayed continuously, providing a simple and more precise method for assessing myocardial function.

Endoscopic Applications of Ultrasound

(Invited Paper)

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Fiber-optic endoscopes are now used routinely in clinical medicine to examine the mucosal surface of the esophagus, stomach, duodenum, and colon. New ultrasound endoscope systems both with and without fiber-optic endoscopy enable the endoscopist to look through the intestinal wall to study organs beneath the mucosal surface. This combination of endoscopy and ultrasound is providing real-time, high-resolution information about patients which cannot be obtained through any other methodology. New systems include 1) a high-frequency (8 MHz) linear array positioned on the tip of a fiber-optic endoscope which provides excellent images of the gastrointestinal wall in the anterior field, 2) a mechanical sector scanner (8 or 10 MHz) which provides a 360° view of the structures surrounding the endoscope, and 3) a phase array at 3.5 MHz which provides imaging of the heart through the esophageal wall. By being in close contact to the target tissue and/or organs, these systems use high frequencies and achieve excellent resolution. This new methodology may provide new approaches to the diagnosis of a variety of diseases such as carcinoma of the pancreas and esophagus and a variety of cardiac conditions in the near future.

An Ultrasound Imaging System for Invasive Applications

(Invited Paper)

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An ultrasound imaging system whose main intended use is in invasive and minimally invasive applications has been developed. The system employs a high frequency (up to 12 MHz) linear array to obtain high-resolution real-time images during endoscopy and surgery. It is capable of focusing the ultrasound beam at multiple depths and storing only a focused region into the image memory. Thus, at the end of multi-focal point scanning, high resolution images are constructed at approximately 15 frames/s.

The linear array is miniaturized (40 × 6.5 × 3 mm) and is housed in a sterilizable and hermetically shielded case or in an endoscope. In order to minimize patient risk against electrical hazard, the system is doubly isolated to the extent that the probe can be placed directly on the heart. The system is also capable of handling lower frequencies down to 3 MHz for general abdominal use.

An Endoscopic Doppler Probe for Intestinal Vascular Studies

(Invited Paper)

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Direct observation of the intestinal lining is now performed routinely with fiber-optic endoscopes. Channels within endoscopes make it possible to pass small devices through them for performing diagnostic and therapeutic procedures under visual guidance; however, it has not been possible to endoscopically evaluate intestinal vasculature. To address this problem we have developed a miniature ultrasonic catheter which can be passed via the endoscope channel. The associated Doppler electronic system and the 1.8 mm diameter are optimized for evaluating vascular structures in close proximity to the catheter tip. Features include: high-frequency ultrasound (8 MHz), range gating to limit depth of interrogation (1-11 mm) and avoid artifacts, air-backing to prevent internal catheter resonance, a cylindrical transducer configuration to provide for operation of the device irrespective of how it is applied to the mucosa, and electrical isolation for patient safety.

Tests have been conducted in the duodenum and bile duct of 10 anesthetized dogs to assess the probe's ability to detect blood flow safety. Arterial and venous blood flow were detected in all dogs and no evidence of tissue damage was found in histological and blood serum analysis. Clincal investigation of the method is underway.

Joint Transform Correlator for Echostructure Recognition

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We used a joint transform correlator (JTC) for optical pattern recognition in order to compare different ultrasonic parenchymal textures, based on the hypothesis that every texture and its Fourier transform are linked by a biunivocal correspondence.

The two textures to be correlated, illuminated by coherent light, are located in the input plane (at any foreplane) of a convergent lens.

On the back focal plane is formed the joint Fourier transform of the two images. The intensity of this transform is registered and once more transformed. In the back focal plane of the lens, a pair of correlation terms can be separated from the output pattern.

This method allows comparison of an unknown texture to one or more comparison textures, subsequently or in the same time.

The JTC is very insensitive to positioning imprecisions and does not require a vibration-isolation table. The joint transform can be obtained directly on a TV camera tube and reconstructed by a computer.

The most useful feature of this optical digital correlator is that it operates in quasi-real time.

The preliminary results demonstrate the effectiveness of the method for the recognition of diffuse liver diseases.

Adaptive Processing for Ultrasound Signals

(Invited Paper)

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This paper describes a new technique which, in the context of existing technology, is designed to enhance the capability of diagnostic ultrasound by improving image resolution and simultaneously providing a physiological characterization of tissue state. A new approach to this problem is achieved by modeling the overall acoustic system as a time-varying linear dynamic system whose output and input represent, respectively, the observed reflected ultrasound signal and the locations and strengths of reflecting boundaries within the tissue. The impulse response of the time-varying system model is specified to within a constant but unknown parameter which contains information on the physiological state of the tissue. The resolution enhancement and tissue characterization problem is shown to be equivalent to one of combined input estimation and system identification and is solved through application of Kalman filtering and parallel processing techniques. A statistical error characterization of the input and system parameter estimates, including probability of error bounds, is also provided. Results using both simulated and real (Lucite block) data are presented and demonstrate the viability of this scheme for application to diagnostic ultrasound.

Can Ultrasonic Backscatter Be Used for Quantitative Imaging?

(Invited Paper)

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Conventional ultrasonic imaging systems generate qualitative images, where the pixel brightness is not directly related to an intrinsic property of the tissue. In this talk we will discuss the generation of quantitative images based on estimates of the backscatter coefficient. To carry out these studies a *B*-scan imaging system was adapted to permit recording of both *B*-scan data and pertinent signal processing parameters, such as the TGC curve. Using correction algorithms designed to minimize propagation errors, quantitative backscatter images were generated in addition to the conventional *B*-scan.

To test the diagnostic utility of quantitative backscatter imaging, three groups of subjects were investigated. The first group of subjects consisted of 13 healthy volunteers. The second group consisted of six subjects with cirrhosis of the liver, while the third group consisted of six subjects with adenocarcinoma metastasis of the liver. The average backscatter of normal liver obtained from the backscatter images was consistent with the results of *in vitro* studies. Moreover, the average backscatter was significantly higher than normal ($p < 0.01$) in the cirrhotic livers, whereas the average backscatter was significantly lower than normal ($p < 0.01$) in regions of metastatic adenocarcinoma.

Computation and Imaging of Ultrasonic Tissue Features

(Invited Paper)

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Studies are being conducted to investigate useful means of characterizing diseases of the eye and, also, of abdominal organs by applying digital processing to stored ultrasonic RF echo signals. Signals from 100 adjacent scan lines are captured during a conventional clinical examination. A series of computer programs then generates *B*-scan images and derives calibrated spectral and cepstral features from selected areas. While one set of features works well in ocular diagnosis, a different feature set must be used in abdominal organs.

Tissue features that are useful in diagnosis are derived from linear regression analysis of calibrated power spectra. In ocular examinations, these features include the amplitude, slope, and residual uncertainty of the straight-line fit. In abdominal examinations, these features include spectral amplitude, slope dispersion, and attenuation estimates.

A means of depicting features related to the above in *B*-scan formats has been implemented. Using this technique, it is possible to "stain" objects whose characteristics are consistent with such ocular tumors as malignant melanoma or metastatic carcinoma.

ACKNOWLEDGMENT

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Session 22—Clinical Engineering Practices

Chairman: William B. Jarzembski, P.E., Ph.D., C.C.E.
Texas Tech University School of Medicine
Lubbock, TX

Equipment Life Cycle Strategy in the Biomedical Department

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and

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Equipment maintenance and management in health care is a challenging and complex task. This is even more true today because of

technological advance, high equipment and labor costs, governmental regulations, and society pressures for improved care at a lower cost. A Biomedical Instrumentation Department can provide for a range of services to an institution, from just repair work (reactive management) to full consultation, maintenance, and management of all clinical and diagnostic equipment (proactive management). Depending upon types of services desired, a Biomedical Department can be run cost effectively by utilizing a proactive management approach.

This paper deals with a "total service" concept in promoting proactive management of a Biomedical Department. The "equipment life cycle strategy" design is discussed to identify the various phases through which the equipment moves in a hospital and the respective role of the Biomedical Engineering Department for each of the phases. The various phases of life cycle beginning with equipment conceivement (or needs analysis) to equipment retirement are discussed for ensuring maximum utilization of personnel, talents, equipment, and facility dollars.

An institution, irrespective of its size, can utilize the equipment life cycle strategy in part or full to suit its needs and identify services desired from a Biomedical Engineering Department. The paper also highlights some helpful examples for selection of in-house versus outside services for an institution to optimize their dollar returns.

Analysis of Engineering Purchasing

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Too many hospital administrators view purchasing as the exclusive domain of the hospital purchasing department for routine supplies purchased and the medical staff for specialized medical equipment. This view has resulted in a proliferation of various devices in many hospitals that are unsafe, difficult to service, and unduly expensive. The engineering aspects of purchasing fall into several distinct categories: as a systems trained person, the engineer should be able to assist in the selection of data processing equipment and software to decrease the costs of purchasing while improving availability; as a professionally trained engineer, he should be able to assist the entire staff in understanding the need for compatibility within the hospital environment; he should be able to write purchasing specifications to ensure compliance with the actual needs at reasonable costs while maintaining technical integrity of the purchased product; and he should be able to provide an economic analysis for eventual replacement.

Energy Management for Conservation

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Most clinical engineers have enough background in thermodynamics, fluid flow, electric power, etc., to readily grasp the principles of building energy management for conservation. One can start with a short course and/or one of several manuals available on hospital energy management. This may be followed by an ongoing program of study in principles of heating, ventilating, and air conditioning (HVAC), using commonly available design manuals. Vendor workshops on HVAC controls and on treatment of boiler and cooling water are recommended. Energy management starts with a baseline derived from utility bills of the past year. An audit of building energy systems using standard checklists will identify an initial set of inexpensive conservation measures and be a good introduction to your systems. As you grow in your understanding of HVAC system and control theory, more opportunities will become obvious. Some precautions are in order. Worker efficiency will suffer if task lighting is reduced to inadequate levels or comfort conditions are significantly compromised. (Labor is more expensive than energy!) When proposing changes in fan speeds or cycling of fans, be sure the new condition does not violate ventilation and pressure relationships required for infection control.

Analysis of In-House Costs

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Hospital administrators and clinical engineers are both interested in obtaining equipment maintenance at the lowest possible cost. In-house service groups are generally perceived as not only cost effective in providing this maintenance, but also able to provide rapid response and in-service training for users.

In a 1982 survey of 82 Oregon hospitals, I asked each hospital for the effective rate per hour of their in-house service group and whether that rate was documented or "best guess." I obtained numbers ranging from $9/hour to $32/hour–which would seem to indicate that the outside vendors are doing something wrong!

Telephone follow-up of four (4) respondents verified my suspicions concerning how they determined their effective rate per hour. For instance:

1) One said that was the rate at which he paid his technician plus the taxes and fringe benefits.

2) Another failed to allow for vacation or other leave of his technicians, much less consider nonproductive hours.

3) A third said that rate was determined by the hospital account office and he had no idea how it was determined.

4) Only one person, after considerable dialogue, was willing to recognize the appropriateness of including space, heat, light, etc., *and was able* to recompute his effective rate, which turned out to be competitive with the low end of outside service rates.

In this presentation I propose an approach for clinical engineers to assess a rate which can be properly compared between themselves as well as against outside vendors.

Session 23—Frontiers in Electrophysiology III: Cardiac Electrophysiology/ Electrocardiography

(Sponsored by the EMBS Committee on Bioelectric Phenomena)

Chairman: John W. Clark, Jr., Ph.D.
Rice University
Houston, TX

Modeling of Electrical Propagation in Cardiac Muscle

(*Invited Paper*)

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Until recently, the results of many experiments on cardiac muscle were considered consistent with the theory of continuous structures (cable theory). Differences in propagation from area to area or variations of conduction velocity with time were assumed to be due either to a change in the cytoplasmic resistance or to a modification of the membrane ionic conductances. But recent observations on the inhomogeneous and anisotropic distribution of the connections between cells have shown the existence of discontinuities of effective axial resistivity which give rise to discontinuous propagation. One of the major tasks now is to account for the functional role of the structural complexities of cardiac muscle. Appropriate models need to be devised for that purpose. Such models are also necessary to establish how the membrane ionic currents and the complexities of cell and tissue structure interact to determine propagation in both normal and abnormal cardiac muscle.

ACKNOWLEDGMENT

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A Model of Propagation in Idealized Two-Dimensional Anisotropic Tissue

(Invited Paper)

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Achieving an understanding of propagation in two-dimensional tissue is difficult both for electrophysiological and computational reasons. Electrophysiologically, the conducting media in both intracellular and interstitial volumes are significantly anisotropic, but in different ratios. The complex current flow patterns that result create a computationally complex problem because of the resulting variability in space as well as time. The purpose of the model reported here was to evaluate, by a computer simulation, propagation in idealized two-dimensional tissue of infinite extent, following a stimulus to a central site. The Hodgkin-Huxley equations were used to describe local membrane behavior. Mathematical results from a related project were used to find the membrane current density at each site. The computational procedure used a strategy that involved dynamically following the active region of the tissue so as to avoid becoming overwhelmed by the number of calculations required. For extreme anisotropy ratios, isochrones resulting from a stimulus to a single site were markedly different from those predicted by the Muler-Markin theory for steady-state propagation, or from those resulting from "equivalent" one-dimensional propagation problems.

Assessment of Ventricular Repolarization by Potential Mapping

(Invited Paper)

R. L. LUX AND C. K. MILLAR

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The significance of ventricular repolarization properties in contributing to arrhythmiogenesis is well accepted, but the exact roles which the distribution of these properties plays in enhancing or diminishing the probability of arrhythmias is not well defined. Classical methods of measuring recovery, such as the extra stimulus method of refractory period measurement, have yielded important information concerning relatively "static" states including the normal distribution of recovery properties. Since this measurement requires time for evaluation at each site, however, it is not satisfactory for determining recovery at many sites during rapidly changing cardiac states which most probably exist both preceding and during arrhythmias.

In this paper, we present two methods of recovery property assessment currently under development in our laboratory. Each utilizes measurements on unipolar recordings and yields recovery information on a beat-to-beat basis. In the first, repolarization is treated as a classical propagating phenomenon and times of recovery and activation are extracted from the first derivative of the unipolar electrograms. In the second, *QRST* areas are determined from the electrograms. Distributions of both of these measurements provide information concerning the underlying distribution of recovery properties, are sensitive to local alterations of recovery, and are not appreciably altered by activation sequence.

ACKNOWLEDGMENT

This work was supported by the National Heart Lung and Blood Institute under Program Project Grant HL 13480 and by grants from the Nora Eccles Treadwell Foundation and the Richard A. and Nora Eccles Harrison Fund for Electrocardiographic Research.

Comparisons of Theoretical and Experimental ECG's in Frog Heart Strips

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It has been reasonably established that *QRS* and *T* waveforms may be qualitatively reproduced by assuming, on the membrane surface, time-varying bipolar charge densities proportional to recorded action potentials. The purpose of this investigation was to verify that recorded electrograms can be theoretically and quantitatively reproduced by comparing the theoretical predictions from action potential measurements with electrograms measured *in vitro*.

Experimental procedure consisted of stimulating excised frog heart atrial strips suspended near the surface of a hemispherical bowl with Ringers solution of ionic concentration similar to that found in frogs' plasma. Recordings on tape were made of intracellular and extracellular waveforms. Waveforms were then digitized to perform theoretical calculations. Intracellular and extracellular measurements showed normal action potentials and ECG's at 22°C. Experimental and theoretical results revealed striking similarities in absolute magnitudes and waveforms. Near the strips' point of stimulation, *QRS* complexes were negative and quickly time varying (0.1 s between zero crossings), with the *T*-waves being positive and slowly time varying (0.7 s between zero crossings). At the strips' center, *QRS* complexes were bipolar (a positive deflection followed by a negative deflection) and 0.2 s in duration. *T*-waves were also bipolar (a negative deflection followed by a positive deflection) and 0.8 s in duration. At the furthest end of the strip, ECG's were of opposite polarity and of the same duration as those seen near the strips' point of stimulation. From these reproducible results, we conclude that hypothesized time-varying bipolar surface charge densities, proportional to action potentials recorded in biological systems, may be utilized with field-theoretical concepts to accurately compute the electrogram. These results provide considerable support to theoretical studies of the electrocardiogram presently being pursued in many laboratories.

Session 24—Medical Data Acquisition and Analysis
(A COMPMED Session)

Chairman: W. Thomas Miller, Ph.D.
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Integrated Real-Time Data Acquisition and Control System

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Often during medical research, such as cardiopulmonary resuscitation, it is necessary to control several interrelated devices, to collect and store many channels of information, and to make real-time control decisions based on this information. Chart recording of raw data optimally shows dynamic changes in the experimental preparation and is often the required documentation for archival purposes; however, real-time decision making requires quantitation of parameters. We have constructed a system which includes an oscillographic recorder, a microcomputer-based data acquisition and analysis system, and a microprocessor-based four-channel peripheral controller. Transducer signals are routed to the A/D converter through specially designed buffers installed in the individual recorder amplifiers, thereby eliminating level dependency on recorder settings. The microcomputer processes data at a rate of up to 800 channels/s. The processed data, such as mean flow, pressure, etc., are displayed on a CRT, and stored on disk. Event numbers are recorded on disk, and corresponding numbers are marked in BCD code on the chart. Data can be further analyzed locally or on a mainframe. A peripheral controller is menu driven from the same CRT. Thus, the data acquisition and control requirements are met by this relatively inexpensive (under $5000) system incorporating available equipment.

A Visual Function Data Manipulation System, VF_DMS

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Earlier work resulted in FM_DMS, a data manipulation system for analyzing results of the Farnsworth-Munsell 100-hue test, used in color vision assessment. Since the test results are sequences each comprising an 85 element vector, there existed from the outset the prospect of evolution to a more powerful VF_DMS that would handle digitized signals, such as electroretinograms or visual evoked responses, that are routinely captured in the visual function laboratory. As a consequence of adopting this computerized method, patient records are now, for the first time, being stored in computer files. So that researchers may now proceed and use these to obtain answers to medical questions, we have specified the following enhancements necessary to synthesize VF_DMS: 1) improved accessibility of subject data, 2) "signal processing" and statistical algorithms, and 3) improved graphics. To realize these enhancements, VF_DMS includes an interface with three existing software packages, IDA™, an interactive data management tool for research involving small or medium-size databases, NEXUS™, an interpreter for physiological system and signal analysis, and BMD-P™. In addition to efficiently accessing data fields, IDA provides VF_DMS with an interactive query language to interrogate the database. Thus, the user may now perform database query operations on vectors, in this case time domain sequences corresponding to the physiological signals captured. The signal analysis algorithms of NEXUS, the statistical algorithms of BMD-P, and the graphics algorithms of both complement the processing power of VF_DMS. VF_DMS is intended to support diagnosis with quantitative substantiation. Eventually it may be used to refine the classification of diseases that afflict human vision.

Remote Physiological Data Acquisition in Dogs and Primates

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Physiological changes that occur in dogs and primates are an important aspect of the toxicological profile of a new pharmaceutical compound. A laboratory system has been developed to monitor physiological parameters during toxicology studies in these animals with minimal human intervention. The laboratory facilities include a central instrumentation room flanked on both sides by an animal housing room. Instrumented animals can be viewed from the central laboratory through one-way glass. 16 dogs or primates can be monitored for changes in ECG via telemetry, and for changes in blood pressure via cannulation of the femoral artery in conjunction with a tethering system. Automated data acquisition, processing, and reporting are controlled by a DEC PDP 11/24 minicomputer. The data acquisition system is flexible and data can be viewed on monitors, recorded on analog tape, stored on disk, or recorded on strip-chart recorders. Another feature of the system is the ability to preview stored data on a graphics CRT before generating hard copy final reports on a graphics plotter. Software routines calculate heart rate from ECG data, and diastolic, systolic, and mean pressure from blood pressure data. The system has proven to be an accurate and efficient method of assessing physiological changes during dog and primate toxicology studies.

Computer Analysis and Recognition of Respiratory Patterns

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The determination of pathological degrees of respiratory rhythm disorders requires detection of such phenomena as depth of respiration, apneic episodes, and respiratory rhythms. It was a purpose of this work to develop a computer system for automatic respiration analysis, which operates in either real-time (monitoring) or off-line (rapid scanning) modes. The development of the system has aimed at reliable apnea detection in the presence of noise, accurate recognition of respiratory patterns, and simplicity of operation. This has been realized through the implementation of an adaptive algorithm for noise rejection and recognition of respiratory waveforms based on statistical feature extraction. Respiratory pattern classification was accomplished by means of cluster analysis. The system proved to be successful in the

recognition of apneic episodes, variety of respiratory patterns, and rhythms not detected by other automated systems. The portion of detection errors to short apneic events in the presence of noise and motion artifacts is typically about 0.5 percent.

Numerical Method for the Analysis of the Phonopneumogram

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Efforts to extract objective information on lung condition from respiratory sounds have led to the development of phonopneumography. In this technique, the lung sounds are recorded and subsequently analyzed by simple analog or digital methods. However, due to the complexity of these acoustic signals and to their low intensity, the phonopneumograms (PPG's), heavily colored by heart sounds and body noises, have failed to yield valuable clinical data. It is the purpose of this paper to present results obtained with a more refined analysis of the PPG, by numerical methods, involving synchronized FFT analysis for spectral estimation, Karhunen-Loeve transform for classification of spectra, and linear predictive coding (LPC) for data compression. The pulmonary sounds are first recorded, along with a respiration signal indicating the duration of each of the components of the respiratory cycle, on high-quality magnetic medium. Both signals are then digitized and the PPG's spectral estimate is computed. Inspiratory or expiratory spectra are then transformed by means of the Karhunen-Loeve matrix. This representation has the property of differentiating between spectra of normal and abnormal lung sounds. For data compression and record keeping, LPC coefficients are computed and an LPC estimate fitted on the spectra. All these techniques are implanted on a microcomputer-based system. Their use may lead to the development of a noninvasive pulmonary evaluation based on the PPG.

Automatic Determination of Glottal Volume-Velocity

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The glottal volume-velocity (v-v) is an important indicator of laryngeal function, but cannot be measured directly because of the influence of the filtering of the vocal tract. Current methods to determine the glottal v-v include analog inverse filtering of recorded speech or measurement of the glottal area by high-speed cinematography, both of which are difficult to implement.

We have developed a method to determine the glottal v-v waveform by digital inverse filtering of voiced speech signals. The method addresses three critical areas associated with the inverse filtering of speech.

1) The attenuation of low frequencies by the microphone is compensated for by a digital filter.

2) A reliable identification of the vocal tract configuration is found by singular value decomposition of the backwards covariance matrix of the closed phase speech signal.

3) The period of the closed glottis is determined by analysis of an electroglottographic signal.

The method has been shown to be effective in the determination of the glottal v-v waveform from real speech.

Fourier Processed Images of Dynamic Lung Function

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Time- and volume-correlated amplitude and phase images are computed from nuclear medical ventilation studies and for dynamic transmission scans of the lungs. This is made possible by a hardware interface and data acquisition system, developed in-house, allowing camera events and multiple ancillary physiological signals (lung volume) to be acquired simultaneously in list mode. Kr-81m and Xe-127 functional images of ventilation and lung volume are obtained with two opposing LFOV cameras. The transmission studies are carried out with the patient interposed between a Tc-99m point source and one uncollimated camera.

The first harmonic amplitude and phase images are constructed on an event-by-event basis. These are computed for equal time as well as equal lung volume increments. Results show that quite different respiratory functions are measured by these separate techniques, which are being evaluated in a pilot study on healthy normals and patients with nonembolic pulmonary diseases. The concept of time- and volume-correlated Fourier images for ventilation studies has shown details and functional structures not usually seen in conventional imaging techniques. Relating the change in density of the lungs, obtained by transmission scanning to time and lung volume has resulted in new clinical information, whose correlation to ventilation is being investigated.

ACKNOWLEDGMENT

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Computer Image Analysis of Nerve Cell Particles

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The mechanism of nerve cell transport, the process by which substances made in a nerve cell body are moved long distances along a nerve cell process or axon, remains a major unsolved problem in biomedicine. Using a light microscope with the recently developed video enhanced contrast method with interference contrast optics, it is possible to detect small subcellular structures down to 25 nm in size, and organelle traffic within axons can be visualized. Up until now, relatively few direct measurements on the transport of these structures have been made.

The TEXAC whole-picture image analysis computer [2] has been used to develop an automatic neural particle tracking system. The automatic analysis of neural particle movement involves several steps: 1) recording of serial microscopic images on a high-speed Winchester disk, 2) image enhancement using whole-picture subtraction, thresholding, and noise removal, 3) identification of the particle of interest using characteristics such as size, gray level, and location, and 4) calculation

and display of important variables such as distance travelled and velocity for large numbers of particles.

This automated computer image processing and tracking method can be used to analyze the motions of directly observed intraaxonal organelles. Quantitative analysis of this phenomenon with high spatial and temporal resolution may yield clues to the molecular transport mechanism. It may also yield further insight into several lethal human neurologic disorders such as amyotrophic lateral sclerosis and Alzheimer's disease, enigmatic disorders in which a nerve cell transport abnormality has been implicated.

Computer Graphics Study of Two-Dimensional Eye Movements

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The study of two-dimensional eye movements is of relevance in the clinical evaluation of certain forms of oculomotor dysfunction (e.g., rotary nystagmus). As part of our CENOG (computerized electro neuro ophthalmograph) device for testing oculomotor function, we have developed a software system for the two-dimensional plotting of such eye movements, in a near-real-time dynamic playback mode. Eye movement data are acquired in digital form and stored on floppy disk, and the graphical playback is done on a video monitor driven by 512 × 512 refresh memory; this equipment is part of our standard CENOG system. Horizontal and vertical axes on the video monitor label the absolute eye deflection, and the instantaneous eye position is denoted by a single spot. By dynamically "playing back" the data at various speeds (e.g., very slowly, or close to real time), better insight into the dynamics of the disorder can be obtained. In addition, in another playback mode the spot leaves a "trail," and in this fashion, the overall two-dimensional pattern is plotted and played back on the video monitor. There is also the option to digitally filter the data in various ways. Once the data have been observed and a qualitative feel obtained, further analytical studies can be more easily carried out. Other preliminary tests have been performed in which the subject is instructed to follow a light spot stimulus traveling in various two-dimensional patterns. The path followed by the light is under computer control, and the eye movement data are acquired as above. By dynamically "playing back" the data and superimposing both the two-dimensional path followed by the eye and the target position path, an interesting test of oculomotor (and, in particular, extraocular muscle) function can be obtained.

Session 25—Modeling of Physiological Systems

Chairman: A. J. Koivo, Ph.D.
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A Nonlinear System Approach for Analyzing Drug Absorption

(Invited Paper)

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The model independent pharmacokinetic methods for evaluating drug absorption are based on linear pharmacokinetic assumptions and, therefore, cannot be applied to drugs with nonlinear disposition kinetics. A method is presented which enables the percentage of drug absorbed to be calculated as a function of time, without modeling the kinetic processes involved. The method assumes that, following an IV bolus administration, the derivatives of the drug concentration–time profile at arbitrary drug levels are independent of the dose given. Such a kinetic behavior is found for any nonlinear pharmacokinetic system when the rate of change of the drug level following IV bolus dosing only depends on the drug level, i.e., $dc/dt = -q(c)$, where q stands for any function dependent on c and constant kinetic parameters. The method is based on a transformation of the absorption response profile, using IV bolus data to define the transformation function. A testing was done on the basis of 36 data sets containing simulated data with 0, 5, and 10 percent normally distributed errors and published phenytoin data from six human subjects each receiving a single oral and an IV bolus administration of phenytoin. The method appears to be a valuable tool for the evaluation of drug input and bioavailability.

Identification in an Intracranial Pressure Model and Closed-Loop Feedback Control Using Mannitol

(Invited Paper)

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A nonlinear, discrete-time mathematical model is derived in order to examine intracranial pressure under the influence of a drug input. Derivation of the drug input term is approached by examining the pharmacological action of mannitol at the intracranial compartment. Estimation of parameters is accomplished by an on-line least squares algorithm that accounts for any bias correction due to measurement noise. Parameter updating can then be utilized to examine the relationship between the shape of the intracranial pressure-volume curve and the absorption resistance. A closed-loop feedback control system is then examined to determine the optimal drug input needed at each sampling interval to maintain a desired intracranial pressure level. Simulations of the identification and control aspects of the model are presented.

Biomembrane Transient Response Modeling

(Invited Paper)

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This paper presents a new approach for modeling biomembrane transient response with RC equivalent circuits, which have long been used in biophysics to model the electrochemical response of living cell membranes to small perturbations from equilibrium. Identification of such RC circuit models should be useful for determination of appropriate characteristics (pulse height, width, and repetition rate) of a class of signals which, coupled through pulsed electromagnetically induced fields, are being used to modulate cell function as well as to effect

human bone fracture repair *in vivo*. A time-domain analysis (TDA) technique which is based on projection of the input (current) and output (voltage) on an orthonormal set of exponential functions is described. Algorithms for interactive data acquisition and TDA have been implemented on an HP 1000 minicomputer on-line with a Nicolet 1090A digital storage oscilloscope. Results using TDA with third-order RC circuits and with human red blood cells are presented, and indicate the superiority of this technique over classical frequency-domain analysis. Further application of this TDA technique to biomembranes should lead to a better understanding of cell kinetics and their underlying mechanisms.

Control Strategies Used by Humans in Maximum Vertical Jumps

(Invited Paper)

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This study considers the effects of varying initial conditions and trunk loading on humans performing maximal height jumping tasks. Using force plate data and state-estimation algorithms, it was possible to estimate joint torques and compare them to recorded electromyograms from selected leg muscles as well as strength measurements from the same subjects. Of particular interest was the sensitivity of performance index (how high the subject jumped) and controller strategy (as reflected by muscle activation patterns and joint torques) to the different tasks.

EMG-Controlled Electrical Stimulation of Paraplegics

(Invited Paper)

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The paper presents some results on EMG-controlled electrical stimulation of paraplegics for the purpose of providing certain paraplegics with walking functions, between parallel bars or with a conventional walker. The method is applicable only to traumatic paraplegics, with injury levels from T-5 to T-11. Control is provided via identifying the time series parameters of EMG signals taken from above the level of the lesion, and using a compact microcomputer system. The EMG signals are produced by the patient at will, through contracting certain back or chest muscles in a manner closely related to natural such contractions, when the patient would have intended to stand up or walk had he not been a paraplegic. Following identifications, the computer decides which limb functions the patient intended to activate. It then controls electrical stimulation of peripheral leg nerves accordingly.

The Range of Motion of a Computer-Simulated Wrist

(Invited Paper)

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A computer simulation of the human wrist has been developed to assist surgeons with tendon transfer operations. The simulation uses a model which includes a representation of the geometry of the wrist joint, and changes in muscle tension due to changes in length and neural activation. In order to evaluate the normative model, the wrist simulator was used to compute the equilibrium wrist position for many different neural conditions. From one to five muscles at a time were activated from zero to maximum and the resultant wrist positions computed, yielding a range of motion. In addition, the torque developed by the simulated wrist in discrete positions with varying neural activation was computed. Comparison of the range of motion of the simulated wrist with the measured range of motion of the wrists of several subjects showed discrepancies. Possible sources of error in the model are inaccuracies in the muscle tension versus length characteristics, and the absence of any motion constraints (such as bones and skin) other than the muscles themselves.

A Heuristic Model for Tonic Accommodation

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The normal eye has a competently designed lens control system. The existence of optical dead band, or depth-of-field, causes a fundamental nonlinearity in the operation of an automatically focused camera. The lens support muscles generate a "noise" signal which produces a back-and-forth motion in the lens across the optical dead band. To better understand the functioning of this device, we have designed an analog computer which predicts the eye's focal status as a function of depth-of-focus, noise in the muscles, and the diopter value of the eye's environment.

The focal status of the lens is controlled by blur, as long as the retina can sense blur. When the eye is in darkness, the lens is driven to a "standby," or tonic accommodation position. Experimental evidence has been presented which demonstrates that the eye's focal status will show a servo response to a long-term change in the visual environment. It is probable that tonic accommodation will exhibit a similar response. This heuristic model yields focal status predictions for tonic accommodation as a function of time, and the individual's long-term environment.

Software for Block-Bond-Graph Simulation in Physiology

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The last decade saw the minicomputer progressively replacing the analog computer in simulation experiments in physiology. However, very often, the input language of the simulation program, having procedural characteristics (as in some equation oriented simulation programs), has a logical structure different from the physiological system under study. This requires an extra effort in the modeling phase. This paper describes the main characteristics of a software, including a nonprocedural language, accepted by the simulation program SIBLO (simulation with blocks) and its postprocessor. It is derived from THTSIM, and so it includes, in the primitive operations set, bond-graphs elements and the usual functions performed by an analog computer. SIBLO can be run in interactive or batch modes, allowing either a conversational modeling phase or long simulation experiments. The results are then treated by a postprocessor. It has been used in our laboratory intensively in cardiovascular system simulation. To illustrate the use of the software, a simulation study of the relation between pulsatile and nonpulsatile models is presented. Using this experience, the advantages of a block-bond-graph input language, in physiological simulation, are emphasized.

Session 26—Quantification of Neuronal Activity

Chairman: Joseph D. Bronzino, Ph.D.
Trinity College/Hartford Graduate Center
Hartford, CT

Electrophysiological Signal Techniques—General Concepts to Quantify Alterations in the EEG

(Invited Paper)

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Clinical evaluation of electroencephalographic (EEG) tracings today is still based primarily on complex subjective processes of data reduction and feature extraction. Quantitative approaches in EEG analysis, especially those based upon spectral analysis and amplitude histograph techniques and their applications, are reviewed. The purpose of this paper is to discuss the use of modern analysis techniques in studying alterations in the EEG and to describe a variety of systems that have been designed and developed for the collection, manipulation, and presentation of these EEG data.

EEG Ontogeny in Malnutrition

(Invited Paper)

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Bipolar stainless steel electrodes were chronically implanted into the main olfactory bulb (MOB) of normally nourished (25 percent casein) and protein malnourished (8 percent casein) rats (prenatal and postnatal malnutrition). Electrodes were implanted in rats at 4, 8, 10, 12, 14, 16, 18, 30, and 90 days of age. MOB electrical activity was recorded from freely moving rats. Specific olfactory stimuli were soiled nest material and an anesthetized lactating dam.

The electrical signal was recorded on a polygraph and FM tape recorder for computer analysis. The EEG signal was analyzed for frequency content using the fast Fourier transform. Various 8 s epochs were digitized at 256 Hz yielding power spectral values with 0.125 Hz resolution over a frequency range of 0–128 Hz.

In normally nourished rats, two major frequency components were present within the MOB electrical signal, and both components increased during development. Two frequency components were present in the MOB signal of malnourished rats, and these also increased during development. However, while the lower frequency components did not differ between groups, there was a delayed development of higher frequency components in malnourished rats. These results parallel the morphological development of the MOB in normal and protein malnourished rats.

Frequency Analysis of Olfactory Bulb EEG in the Rat

(Invited Paper)

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In the present study, patterns of sniffing, measured with an indwelling nasal thermocouple, and main olfactory bulb EEG, analyzed using power spectral procedures, were evaluated during a variety of behavioral states in freely moving rats. The EEG consistently was found to contain five major frequency components with center frequencies as follows. I: 1–10 Hz (at the frequency of sniffing); II: 15–22 Hz; III: 43–53 Hz; IV: 70–90 Hz; and V: 140–175 Hz. Components II and III tended to covary in frequency and amplitude. Based upon analysis of state-dependent variations in sniffing patterns and spectral characteristics of the EEG, it was felt that the amplitude and frequency of components II and III were primarily dependent on the magnitude of the sensory volley which accompanied each sniff. Component IV did not exhibit state-dependent variations in frequency but increased in amplitude slightly during resting, when the animal seemed inattentive to sensory input. The frequency of component V varied directly, although somewhat loosely, with the frequency of sniffing. Components III and IV correspond with Adrian's "induced" and "intrinsic" waves, respectively, while components II and V have not been well documented previously.

ACKNOWLEDGMENT

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Analysis of Sleep-Waking Profiles and Spectral Characteristics of Cortical and Hippocampal EEG During Development

(Invited Paper)

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Electrographic indexes of brain development, such as EEG activity, serve as key indicators of neuronal organization, differentiation, and level of functional maturity. Since various electrographic measures undergo definite sequences during normal development, they can serve as baseline indicators against which to compare these same measures fol-

lowing various insults to the brain. Therefore, it is of interest to recognize and quantify normal ontogenetic development of the EEG and sleep-waking behavior. Consequently, we utilized power spectral analysis techniques, to study the normal, postnatal development vigilance states in the rat. Particular attention was paid to the areas of the frontal cortex and hippocampus at 14, 18, 22, 30, and 45 days of age.

Analysis of the power spectral data obtained from the frontal cortex of rats during this developmental period (14-45 days) indicated increases in the power in the 0.5-3.5 Hz frequency band primarily during slow-wave sleep. While power spectral data obtained from the hippocampal EEG during REM sleep revealed that the frequency at which the peak power occurs in the theta band (4-11 Hz) was found to increase from 4.4 to 6.6 Hz. In addition, power in the 4-7 Hz band also increased during this preweaning period. Finally, analysis of vigilance profiles showed that rats normally progress from 14 days of age when REM sleep dominates their vigilance profile, to 45 days of age when they spend significantly more time in slow-wave sleep.

Assessment of Brain Damage in Malnourished Infants

(Invited Paper)

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Fourier analysis of transient evoked potentials (EP's) has frequently been used to assess the power in different frequency bands, but the phase is generally ignored in the analysis of transient EP's. We report here that there are significant differences between the phase and amplitude of auditory and visual EP's recorded from severely malnourished infants and those of age-matched controls. Cortical auditory evoked potentials (AEP's) were recorded to clicks at C_z, and visual evoked potentials (VEP's) to flash were recorded at O_z from 23 infants hospitalized in Mexico City for severe malnutrition, and from 24 age-matched controls. The AEP's of the malnourished infants had significantly less power in the range 12-26 Hz than the controls ($t = 3.12$, $df = 46$, $p < 0.01$). The VEP's of the malnourished infants had significantly smaller values of the group delay $(1/2\pi)(d\phi/df)$, where ϕ is phase, in the range 1-12 Hz ($t = 2.35$, $df = 46$, $p < 0.025$). A discriminant analysis using both AEP spectral amplitudes and VEP phase values discriminated significantly between the two groups. This method, using both phase and amplitude values obtained from the Fourier transform of the EP's, appears to be capable of quantifying changes in brain function due to malnutrition in infancy.

Brainstem Modulation of Hippocampal EEG Activity

(Invited Paper)

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In previous reports, we recorded single cell activity from the freely moving rat during states of sleep and waking and identified a distinct type of cell within the pontine reticular formation whose discharge was highly correlated with the theta rhythm of the hippocampus. This type of cell not only discharged maximally during the identical states in which theta is present in the hippocampus (general movements of waking and REM sleep) but also showed discharge properties remarkably parallel to hippocampal theta. These results suggested that these pontine reticular cells may be involved in hippocampal theta generation. In order to evaluate this possibility, we systematically mapped the brainstem with stimulation to determine its effect on hippocampal EEG activity. We found that stimulation of the reticular nucleus, pontis oralis (RPO), was very effective in driving hippocampal theta and, in a follow-up report, we identified three synchronizing (theta) pathways that ascended from RPO to the diencephalon. In mapping the brainstem for its synchronizing effects, we also found that stimulation of the median raphe nucleus (MR) profoundly desynchronized hippocampal EEG activity and that a sole desynchronizing system could be followed forward from MR to the diencephalon. At present we are electrophysiologically and anatomically examining the routes by which RPO and MR fibers reach the medial septum/diagonal band–the known pacemaker nuclei for hippocampal EEG activity.

Application of Square Transforms to Quantify Changes in EEG

(Invited Paper)

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The value of bioelectrical investigations conducted in clinical as well as research laboratory settings depends on the ability of the numerical tools available to perform an unequivocal and rapid reduction of data. As it applies to the EEG, the family of square transforms has repeatedly proven to have reached this degree of maturity. The most attractive attributes stem from a computer-compatible binary form combined with frequency interval partitions which match surprisingly well with the characteristic energy bands found in the spectral form of the EEG. Research and diagnostic applications which can take advantage of this computational format are abundant. So are the questions related to its trueness of representation, phase sensitivity, and stability. Several practical conclusions will be presented based on observations involving the comparison of Walsh and Harr transforms of the cortical and hippocampal EEG obtained during different vigilance states at various states of development.

Structural Analysis of Human EEG's

(Invited Paper)

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An electroencephalogram (EEG) can be considered as being composed of short (1 s) elementary patterns. When properly chosen, EEG signals could be reproduced from consecutive combinations of these patterns. Earlier studies have indicated that the number of elementary patterns is limited [1]. Hence, the EEG can be modeled using a first-order Markov chain model with a finite number of states, where each state represents an elementary pattern. A finite first-order Markov chain with m states is completely described by its $m \times m$ transition probability matrix. The elements of the transition matrix are the probabilities that a one-step transition will occur from state i to state j, where $i,j = 1,2,\cdots,m$. Subtle changes in an EEG, not easily quantifiable otherwise, may be detected by studying the changes in the tran-

sition probabilities. These probabilities are estimated from consecutive EEG intervals.

The value and limitations of this type of analysis, termed "structural EEG analysis," are currently being investigated using a wide variety of EEG's. Preliminary results regarding the "optimal" duration of an EEG interval in order to obtain a reliable estimate of the Markov chain transition matrix, and the feasibility of relating changes in this matrix to variations in the psychophysiological conditions of the subjects under consideration, will be presented.

ACKNOWLEDGMENT

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Session 27—Devices for the Handicapped

Chairman: Sally L. Wood, Ph.D.
Cornell University
Ithaca, NY

Portable Printer for Severely Handicapped Children

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We have been developing a small-format portable printer, a "typewriter" for severely handicapped children. It uses row and column scanning of a character display matrix to access numbers and letters of the alphabet. Each word is displayed on an LCD array and printed upon command. A small printer using 2½ in roll paper provides hard copy. As the display matrix is scanned, a speech synthesis subassembly provides audible naming of the symbols. The printer is therefore suitable for children with multiple handicaps such as impaired vision and motor disability. It is intended to aid in the learning of the alphabet as well as providing a means of communicating in writing. The device is portable and has rechargeable batteries. A chin movement switch or other switch closure activates the character scan.

The unit uses two 8748 microprocessors in a master–slave configuration and commercially available dot-matrix printer and LCD display. Smaller than a portable typewriter, it is easily used in the school or home. It is suitable for educational use with handicapped children and for other people with severe motor disabilities.

A Computer Terminal for the Visually Impaired

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The system is specially designed to be used by visually impaired individuals in a wide variety of educational and employment activities that require access to information stored in a computer without the need to know braille.

The hardware configuration consists of a standard CRT terminal, a speech synthesizer box, and a 6802 microprocessor system board. The terminal is equipped with an RS232C interface. The speech synthesizer box itself is able to prounounce over 96 percent of the 1000 most commonly used words in English. However, because English is not a phonetically spelled language and has so many exceptions to the rules, the box will mispronounce many words. This problem can be overcome by misspelling the word or breaking it up into segments separated by spaces.

Collecting most of the words commonly used in the computer environment that will be mispronounced, we misspell them to get correct pronunciations and store that list of data in ROM's of the microprocessor board. Other than storing the misspelled words, we include RAM buffers for the computer and the screen in the microprocessor board.

The system allows the visually impaired to listen to anything he types and any information displayed on the screen word by word or letter by letter, to change the volume/pitch of the sound, and to know the position of the cursor.

ACKNOWLEDGMENT

The authors with to thank K. Strube for his helpful suggestions in designing both hardware and software. This work was done at St. Mary Medical Center, Long Beach, CA.

End-Point Prosthetic Control Via Binary Coded EMG Signal

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A new approach for interface strategy communication between a disabled person and a prosthetic/orthotic arm has been developed. This method gives the disabled person the ability to control a prosthetic arm (or another electromechanical device, e.g., a wheelchair) via one anatomically chosen site where surface electrodes measure an EMG signal.

The control system is organized into three hierarchical levels. Any decision that the operator (decision-oriented level) makes is translated into an appropriate command through an EMG signal to a computer (algorithmic level) which activates the prosthetic (dynamic level). The format of the command is analogous to a binary word where each muscle contraction is assigned the binary value 0 or 1.

In this control system, the operator's task is to adequately determine the entire algorithm rather than controlling piecemeal all of the separate parts of the motion. The algorithm, stored in the computer, is based on what is called resolved motion rate control.

Man-interactive computer simulation was successfully used in our study of this method. The operator drove a three-link model of an upper extremity (stimulated on a minicomputer) from any initial position to any destination by means of an EMG signal coming from a single site of surface electrodes.

Optimal Site Selection for Prosthetic Control

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A microcomputer-based algorithm for the selection of optimum surface electrode sites for the Liberty Mutual Boston Elbow has been

developed. The objective was to identify the most differentiable electrode pair for flexion and extension control of the prosthesis. While the existing patient evaluation system for the Boston Elbow has been proven successful, it is based on a tedious and inexact process requiring the repeated positioning and evaluation of a single pair of electrodes. By employing two stationary electrode arrays to monitor flexion and extension activity over two broad spatial areas and statistically analyzing the activity at these sites, a more efficient and reliable evaluation process is possible. Briefly, the process includes the acquisition and analysis of data from four flexion and four extension electrodes. This results in 16 possible control site pairs. Muscle force levels at each electrode are computed via the standard deviation of the respective signals [Hogan, 1976]. Data are obtained through nonfatigue isometric contractions of the tricep and bicep muscle groups. The results of successive trials are averaged and interelectrode magnitude comparisons are performed. The relative utility of all electrode pairs is then displayed to the prosthetist. Although this method provides an efficient and reliable evaluation of possible control sites for the Boston Elbow, we envision that it could be easily adapted to other prosthetic devices requiring differentiable motion control.

ACKNOWLEDGMENT

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Plasticity in Electrotactile Frequency Discrimination

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The capability of human subjects to detect frequency variations during exposure to prolonged electrotactile stimulation was studied. Stimulus was applied via small concentric electrodes of 6.55 mm outside diameter and consisted of 100 s duration rectangular pulses set at an amplitude resulting in the subject's most comfortable sensation. Pulse frequency variations in the range of 0–100 pps were conducted daily over 14 consecutive days while subjects indicated the associated frequency JND's.

It was shown that the frequency increment $-\Delta f$ necessary to elicit a JND is a linear function of the stimulation frequency $-f$. The ratio $\Delta f/f$ is constant for the tested frequency range, but improves during the first three days and deteriorates thereafter to stabilize at the first day's level by the 11th day.

The average number of detected frequency JND's increases from 15 to 18 during the first three days, but stabilizes at 13 by the tenth day.

It was also evident that the nervous system is better capable to discriminate ascending frequency changes as compared to descending changes. Perception of ascending frequency changes was also more reliable.

The discrimination capacity for electrotactile frequency coding was calculated to provide 3.7 bits/channel.

Towards Quantification of Scoliosis Correction

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Towards quantification of scoliosis correction, we have been developing a comprehensive system of characterizing scoliosis deformity, before and after surgery, of determining spinal stiffness, and of prescribing orders of magnitude of correction obtainable by safe values of corrective forces applicable by means of "distraction" and "distraction plus segmental transverse force" applicatory instrumentations.

Our system of scoliosis deformity characterization entails determination and depiction of the distributions of both spinal curvature and rotation. These results are depicted for the two above-mentioned instrumentation systems, and enable assessment of relative efficacies of these two techniques in rectifying these two deformities.

Then, in order to be able to prescribe custom-tailored corrective forces, we need to know the spinal stiffness. For determining scoliotic spinal stiffness, we have developed a harness for applying distraction forces of incremental levels and radiographically imaging the scoliosis deformity at these levels.

Then by means of a finite element model of the spine, we develop the values of the distribution of nonlinear spinal stiffness. The paper presents the results of this procedure on patients about to undergo surgery. The above custom-tailored finite-element model is then employed to prescribe the optimal levels of safe corrective forces by which optimal correction can be gained.

Repair of Spinal Nonunions with a Pulsed dc Stimulator

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Spinal fusion is a commonly performed procedure for segmental spinal instability. It unfortunately has a high failure rate. A literature search reveals that an average 20 percent of spine fusions fail to unite. On reoperation the failure rate is even higher.

Electrical stimulation of bone has been practiced clinically for several years and the initial results are promising. Over the last year the author has used a totally implantable pulsed dc unit in repairing spinal nonunions. An intertransverse fusion is carried out and the cathode is laid only on one side amid the bone graft. Ten cases have been performed.

At three months no difference between the two sides is noted, as the bone graft is still revascularizing. At six months the stimulated side appears better formed in all cases. At one year, when the fusion is solid, no difference is again noted. All have united.

It is concluded that this is a very useful adjunct to spine fusion and should probably be carried out in all cases.

Paraplegics Should Learn to Walk with Fingers

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In 1977 a research program entitled "Learn to Walk with Fingers" was founded. The basic idea is to control a very complex implanted multichannel-nerve-stimulation unit by simulating gait processes with two fingers. More than 100 *in vitro* and *in vivo* experiments on rats and sheep were done the last six years. For clinical use, an implantable 16-channel stimulation unit (thinfilm hybrid technology) with an external control device and transcutaneous transmission (27 MHz) was developed. Worldwide, the first application was done in October 1982 on two paraplegic patients. The aim of this first application is to make these patients stand up by stimulation of the quadriceps and gluteus

muscles via nerves. In this first clinic application, we could achieve a smooth but strong stretching of knee joints with ½ of normal force, although one patient had been completely paralyzed for 21 years. The hip joint movement functions with less effectivity due to muscle atrophy. Improvements are expected during the following training. This first clinic result leads us to hope that paraplegic people in the near future will be able to stand up and walk with the help of functional electric stimulation.

Session 28—Microprocessor-Based Instrumentation: Hardware and Software

Chairman: Willis J. Tompkins, Ph.D.
University of Wisconsin
Madison, WI

Video Image Analyzer Using a High Resolution Touch Screen

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An inexpensive microcomputer video image analyzer is developed to facilitate the processing of biological images which utilizes an interactive high resolution touch screen peripheral. The analyzer is developed from an existing system which featured an available high resolution light pen. The touch screen peripheral is controlled by the host microcomputer (Apple II+) and the new configuration, without the traditional light pen, provides increased speed, resolability, and operator convenience. A hardware controller for the commercially available touch screen was designed and constructed. The device resides on the (Apple) peripheral expansion bus and provides control voltages and measurement signals to the screen. The touch screen is used to initiate and edit edge and boundary detection algorithms for cellular morphometry and planimetric measurements of lung tissue.

Rapid Assessment of Hemodynamic Cardiorespiratory Functions for the Critically Ill with a Personal Computer

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The importance of prompt assessment of hemodynamic cardiorespiratory function in critically ill medical and surgical patients has already been established. In 1977 M. Shabot *et al.* presented a system for rapidly computing these variables in real time in the ICU at a very low cost, involving the use of a hand-held programmable calculator. This paper shows, with recent advances in microcomputing, a new system which was developed with a personal computer which results in a tremendous improvement in the overall performance during analysis of the data, without incurring a financial problem in the operating room procedures. The new system allows you to enter information into a matrix spread sheet structure, that is, a series of 63 labeled columns and 254 rows which display at all times: the time at which the observations were made, the values read from the monitors, and the ones computed by the system. Each of the cells in the matrix has been preprogrammed with the appropriate formulation, so that as the raw data are entered, the derived variables can be computed. Currently the system is composed of 17 raw data variables and 28 derived variables.

Microcomputer-Based Data System for Medical Research

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To allow flexible formatting, storage, and retrieval of research data we have developed a random access data system (RADS) that manages up to 32 760 records per file on CP/M compatible microcomputer systems. An individual RADS data record can be up to 512 characters, with both double precision numerics and string fields allowed. Up to three separate databases can be linked via record numbers, resulting in three separate "pages" of data for each record entered. RADS has been linked with a commercially available sort program for disk-based sorting of data, up to 32 levels of criteria deep, with numeric ranges allowed. Special user formatted reports and printouts are generated by scanning records, in a previously constructed report file, or scanning a presorted database subset for report criteria. Linked databases can be processed for reports independent of one another. Data from RADS can also be linked to word processing and electronic spread sheet programs. Thus far we have constructed databases to provide operating room log data, follow up a large diabetic patient population, and store objective data regarding balloon catheter dilatation procedures. The system has proved flexible enough to accommodate any number of medical applications.

A Report Writer Language

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A report writer language (RWL) has been implemented on the DEC PDP 11/44 using the RSXM-11 operating system. The RWL consists of a series of software modules written in Compiled Basic Plus 2 that allows the user to generate medical or clinical reports from a database. The RWL has the characteristics of simplified Basic and includes new language verbs to allow cursor control, to search for records, to open databases, and to read records from a working file. A user writes programs in the RWL language using the EDT editor and then compiles them with the RWL modules. The RWL allows the user to read records from any user UIC number and device, thus permitting access to any database on any mounted disk, tape, etc. Reports can be generated for display on a VT-100 terminal with cursor control, a TTY type terminal, or a high-speed printer. Indirect record addressing is included in the RWL and allows a field in one record to point to a field

in another record in another database. This feature permits information which is common to two or more different databases to be placed in a separate database to reduce redundancy.

The Use of a Personal Computer for Patient-Condition-Treatment in a CCU/ICU Environment

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The CCU/ICU environment requires a very fast response, from the staff point of view, in order to treat a patient effectively. Not only is time a critical factor, but the amount of information regarding treatment, medications; e.g., amount of drugs, choice of drugs, complications or side effects, etc., and other elements are extensive and tend to grow as ongoing research comes with new information in all related areas. The last consideration is a financial one. Most sophisticated computer systems have been nonaffordable for the small hospital, and those who could afford such a system would raise the price of health care delivery. With these ideas in mind, an application was developed to have a simple system which would allow us to retrieve critical information at a low cost. To implement the idea of a patient-condition-treatment program, J. Alpert's manual of coronary care was used as information entry for the databased system. A menu free-type hierarchical structure was used to allow user friendliness. This structure was based on three levels of depth. The first two are made of all conditions and subconditions in the CCU; i.e., arrhythmias and sinus bradycardia, respectively. For each of these conditions, the third level provides a suggested treatment to be followed by the staff.

Designing Digital Filters for Microcomputers

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Digital filters boast several advantages over analog filters. But designing digital filters for microcomputers requires special care. A limited precision of the data represented and a lack of floating point arithmetic must be kept in mind. We present digital filter designs that use only integer coefficients, and that do not need floating point arithmetic or multiplications. For further simplicity, the quantization of the filter coefficients may be restricted. We find that this restricts the exact possible locations of the poles and zeros. Still, a large number of filter designs are possible with some very attractive properties. Some of these are: easily specified center and corner frequencies, linear phase response, very narrow pass/reject bands, and limits on computations—additions, subtractions, and shifts—performed by the microcomputer. We present some examples of ECG filter designs for microcomputers.

A Synchronous Bus Structured Microcomputer

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A synchronous bus for multiprocessor systems is introduced. It can interconnect two Intel 8080A microprocessors with a shared memory and peripherals, with a minimal set of control lines and circuits.

The synchronization scheme is based on producing a phase shift between the clocks of the two microprocessors so that simultaneous bus requests can be avoided and no contention can occur. The synchronous bus has a centralized clock which synchronizes the clocks of the microprocessors with the multiplexing operation of their buses over the synchronous bus.

This synchronization achieves assigning a proper and a sufficient bus cycle slot to each microprocessor.

The two microprocessors will exchange data through the shared memory.

Session 29—Frontiers in Electrophysiology IV: Electroretinography and Electroenchlography

(Sponsored by the EMBS Committee on Bioelectric Phenomena)

Chairman: P. Ktonas, Ph.D.
University of Houston
Houston, TX

A Model of the ERG and the Effect of Vitreous Hemorrhage

(Invited Paper)

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The spatial distribution of the electroretinogram (ERG) was modeled, and the effects of the volume conductor inhomogeneities were investigated. The bioelectric source in the retina was depicted as a spatially uniform dipole layer of arbitrary magnitude and specified frequency representing the ERG at any instant of time (e.g., the peak of the *b*-wave). The passive volume conductor was represented in the model by discrete homogeneous regions possessing shapes and relative dimensions corresponding to structures in and outside of the eye. Laplace's equation was solved numerically within the volume conductor utilizing a finite-difference overrelaxation technique and the axially symmetric, spherical geometry of the eye. Good agreement was demonstrated when the potentials computed with the model were compared with data from physiological experiments conducted by others.

The model was used to provide more insight into the question of whether the presence of blood in the vitreous could alter its electrical conductivity enough to attenuate what would have been a normal ERG. According to the model, blood in the vitreous has no significant effect on the magnitude of the ERG recorded at the cornea or on the *b* to *a* wave ratio, when the frequency content was considered. A reduced ERG would be due to another cause(s) and might preclude vitrectomy.

ACKNOWLEDGMENT

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Recording Evoked Potentials from Spinal Cord and Brain

(Invited Paper)

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Repetitive electrical stimulation of peripheral nerves of arms and legs can be used to generate somatosensory evoke potentials recordable over the peripheral nerves, from the skin over the spinal cord, and from the scalp. Recording at the various levels gives information regarding the localization of lesions in the nervous system. Careful attention to the placement of stimulating and recording electrodes, patient cooperation, and stimulus parameters can result in technically adequate representation of the potentials. A comparison of surface recordings in various pathological conditions with recordings from electrodes in the epidural space provides additional insight into the generators of the potentials, and to their diagnostic relevance. Potentials from the lumbosacral portion of the spine have features of both conducted and segmentally generated waves, both from epidural and surface recordings. Cervical responses from the skin surface are primarily from segmental generators, although epidural recordings can emphasize conduction wave components as well.

ACKNOWLEDGMENT

This work was supported by the Vivian L. Smith Foundation for Restorative Neurology, Houston, and by the Rehabilitation Services Administration under Grants 16-P-56813-6 and 13-P-59275-6.

Digital Signal Processing of Evoked Potentials

(Invited Paper)

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Interest in the digital signal processing of evoked brain potentials has increased recently as a result of the availability of inexpensive microcomputers.

The relatively simple operations of ensemble averaging which required dedicated averagers such as the CAT (computer of average transients) can now be done rapidly and inexpensively in general purpose microcomputers such as the Apple or the IBM PC.

Ensemble averaging remains one of the most used and, at the same time, abused tools in evoked potentials research. It conveys only one facet of the information, and perhaps others need to be considered as well. Averaging does not convey information as to the spread or variance of the numbers that are being averaged, and consequently it is often useful to consider alternate techniques of signal enhancement. Cross-correlation averaging was developed by Woody in the late 1960's as a way of removing time variations from a signal embedded in noise. One difficulty of working with this technique seems to be its predilection for locking to signal components that may bear no relation whatsoever to the evoked potential one is trying ultimately to extract.

The technique of latency corrected averaging was introduced as a procedure that makes no assumptions concerning the determinism of the signal and assumes that components of the signal need not be time-locked to each other, and, in fact, treats them as if they were independent. The end result of this analysis is a latency compensated representation of the single evoked potential. In addition, the technique reports on latency and amplitude variations of the individual peaks that make up the complex waveform.

The classification of single event-related potentials has recently been undertaken with a high degree of success. The results obtained utilizing both linear and quadratic statistical classification techniques indicate that it is highly possible to achieve on-line classification of single event-related potentials with classification accuracies exceeding 90 percent. Both endogenous and exogenous types of event-related potentials have been examined and studied in detail. Typical classification accuracies are in the order of 85 percent for endogenous event-related potentials and in the order of 93 percent for exogenous event-related potentials.

Clinical Application of DLM

(Invited Paper)

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The dipole localization method (DLM) is a technique for finding an equivalent source (a current dipole) for scalp potentials evoked by sensory stimuli. Since evoked potentials provide a noninvasive way to test the integrity of sensory pathways, we have applied DLM to data obtained from a patient population in an effort to characterize normal responses and distinguish abnormal ones by looking at the dipole equivalent sources.

An example of our results—one component of the response to light flash has an equivalent source that in normal volunteers has a locus near the occiput and is oriented from nasion toward inion. The latency of this component is quite stable across subjects and stimulus conditions. In a patient population, however, this component is absent (dementias) or has an abnormal latency and orientation (focal disorders). Many of these abnormal cases exhibit normal CT scans and normals EEG's.

In addition to scientific results, we shall discuss the acquisition and DLM analysis of evoked potential data in clinical practice.

ACKNOWLEDGMENT

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The Neurophysics of EEG

(Invited Paper)

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Three major EEG topics of interest to bioengineers and biophysicists are signal processing, volume conduction, and models of neural interaction. The interrelationship of these subfields is emphasized.

A theoretical basis for scalp EEG is proposed. The scalp electrode records neural activity averaged over large cortical regions containing millions of neurons. Thus, it is postulated that the numbers of synaptic and action potentials in columns of cortex can be followed, while ignoring the small-scale interactions characteristic of local circuit models. With the inclusion of a finite velocity of propagation of the action potential in association fibers, this approach leads naturally to the prediction of standing waves in the cortex. The frequency of the fundamental mode is roughly 5–13 cps when a threshold parameter is small. When this parameter is increased (easier for cortical neurons to fire), EEG amplitude increases and frequency abruptly drops in a man-

ner suggestive of the transition from the awake to sleeping state. Connections between the wave theory, EEG experiments, and the mind-brain identity problem are discussed.

Relation of EEG Characteristics to Cerebral Blood Flow

(Invited Paper)

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The EEG frequency content is known to be closely related to the mean cerebral blood flow. Since the energy needed for the generation of the EEG is supplied through the cerebral blood flow, it is conceivable that several features of the EEG might be related to the cerebral blood flow. Some of the features under investigation in this study are the Gaussianity, asymmetry, and modulation of the EEG.

Right-handed volunteers, neurologically normal and without any risk factor for stroke, were selected. The cerebral blood flow was measured using the ^{133}Xe inhalation method while the subjects were lying in the supine position with eyes closed but awake. Using the International 10-20 System's electrode placement sites of F3-A2, F4-A2, C3-A1, C4-A2, 01-A1, and 02-A2, six channels of EEG were recorded simultaneously with the blood flow measurement.

It was found that there was no significant correlation between the degree of Gaussianity of the EEG and the blood flow for both homologous areas of the frontal and central regions of the brain. Using EEG asymmetry measures developed for this work, the EEG asymmetry was found not to be linearly related with the blood flow.

Both the amplitude and the frequency modulation indexes of the left occipital EEG showed a linear correlation with the blood flow through the grey matter in that region. The amplitude modulation had a correlation coefficient of 0.81, and for the frequency modulation that value was 0.91. These correlation coefficients are higher than the previously reported value of 0.76 for the mean frequency content of the EEG and the blood flow. No correlation was found between the modulation parameters of the EEG and the blood flow at the right occipital lobe.

Rule-Based Methods for Electroencephalogram Evaluation

(Invited Paper)

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This paper describes 1) fundamental concepts of rule-based systems technology and 2) practical methods for applying these concepts to electroencephalogram (EEG) interpretation and other allied problems. First, the use of rules in syntactic pattern recognition for data-driven assessment of pattern characteristics is described, including several examples. Methods for identification of fundamental signal characteristics and parsing strategies for waveform evaluation are outlined as well as a summary of the perceived utility of these techniques for EEG assessment. Next, rule systems for encoding semantic knowledge are examined and an example of a backward chaining goal-driven system for multichannel EEG evaluation is reported. The design of an "expert system" for simulation of clinical knowledge, including EEG knowledge, is presented. A critical review of problems in the design of such systems is given next. Design issues concerned with control strategies, knowledge acquisition, representation, and compilation are examined. The advantages of advanced system features such as explanation modules and natural language user interfaces are discussed. Programming methods for implementation of rule-based expert systems are explored including observations about appropriate programming languages and development tools. Finally, a prospectus for research using rule-based systems technology is presented. Current problems in the field are highlighted and suggestions for fruitful research directions given.

ACKNOWLEDGMENT

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Session 30—Arrhythmia Monitoring

Chairman: W. Buck Locke
Hewlett-Packard
Waltham, MA

Computer Detection of Cardiac Arrhythmias—Historic Review

(Invited Paper)

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and

CardioData Corporation

Realizing the need for accurate detection of ventricular ectopic activity in patients recently hospitalized with acute myocardial infarction and the opportunity presented by the then emerging computer technology, several groups in the mid-1960's commenced the development of algorithms and systems suitable for the detection of ventricular premature beats (VPB's) in the continuously monitored electrocardiogram. In the nearly 20 years since then, two algorithms—the WPI correlation and Washington University ARGUS—have achieved widespread use. Declining computer prices have led to extensive use of computerized arrhythmia detection systems for both hospitalized and ambulatory patients. Accuracy and acceptance of these systems have improved continously, and methods and databases have been developed for their evaluation. Despite these impressive gains, the goal of totally automated arrhythmia monitoring remains elusive. The enormous variability inherent in the abnormal human electrocardiogram and the frequent occurrence of artifact limit the sensitivity of unsupervised systems for VPB detection to about 95 percent and produce false positive rates of one to five per patient hour, limiting quantitative usefulness of the data and leading to operator mistrust. At present, Holter systems with efficient use of operator interaction make the most effective use of automated arrhythmia detection.

A Digital Format for Recording Physiological Data

(Invited Paper)

S. D. WILSON, M. ADAMS, A. HALPERN, AND J. BEAZELL

Spacelabs, Inc.
Chatsworth, CA 91311

It is increasingly common to record physiological data such as ECG and pressure waveforms in digital form for subsequent analysis and for use in developing and testing signal processing algorithms. The publi-

cation of the AHA and MIT/Beth Israel ECG tapes has established incomplete *de facto* standards for digital ECG recording formats. These formats are restricted to two-channel ECG data having fixed sample rates, data representations, and annotation codes. Clinical information is not included in the digital data record. We have extended the M.I.T. format to give it the generality required to accommodate varying numbers of data channels, sample rates, data wordlengths, and types of physiologic parameters. All information required to utilize the data, including recording parameters (number of channels, sample rate, channel ID's, etc.), clinical data, and annotation conventions, are incorporated into the digital record. The recording format is compatible with a wide range of media including floppy and rigid disks as well as magnetic tape. When used with nine-track magnetic tape, the format is independent of the computer hardware, programming language, and operating system. FORTRAN programs to manipulate data recorded in this format have been published and are in the public domain.

An Automated System for On-Line Analysis, Storage, Recall, and Editing of Arrhythmia Activity

(Invited Paper)

H. COMERCHERO, P. FISCHER, E. SALANT, T. LEISING, L. ANDREWS, C. BOCK, AND K. ROBINSON

Mennen Medical, Inc.
Clarence, NY 14031

The Mennen ECG Storage/Recall/Edit System (SRE) is a stand-alone microcomputer-based system providing on-line ECG waveform analysis, waveform storage and retrieval, and beat-label editing of the arrhythmia activity of up to 16 patients. The system is implemented on an LSI-11/23 with 256K words of MOS memory utilizing a 7.5 Mbyte Winchester drive and a 640 × 480 resolution alphanumeric graphic terminal. The SRE system can be used in conjunction with any arrhythmia detection system for verification of system performance, or stand-alone in support of research or drug therapy programs.

Up to 16 simultaneous ECG waveforms are analyzed simultaneously utilizing a real-time feature extraction algorithm to derive such parameters as current heart rate, PVC's per minute, VTACH, and bigeminal rate. These parameters are continuously trended over a 72 h period at one-minute resolution and can be graphically displayed on the SRE terminal. Upon parameters exceeding user specified thresholds, the system will automatically store 12 s ECG waveform segments with beat-by-beat annotations.

By means of a keyboard-entered cursor index, the user may recall and display any previously stored 12 s waveform. Upon review of the waveform, the user can edit any or all of the beat labels, delete the waveform from storage, or request a permanent annotated record of the event upon a dedicated chart recorder. When not in interactive mode, the SRE terminal presents a continuously updated status display of all monitored patients and their derived arrhythmia data.

Multitasking in a Microcomputer-Based Arrhythmia Monitor

L. SENGUPTA AND J. M. JENKINS

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Real-time diagnosis of cardiac arrhythmia in a two-channel ECG bedside monitoring unit is done on a single-board computer with multitasking capability. The arrhythmia monitor employs an esophageal lead for *P*-wave detection and can diagnose many significant arrhythmias of supraventricular as well as ventricular origin as well as nonconducted beats. The multitasking operating system provides means for concurrent execution of the following tasks: digital data acquisition of the electrocardiographic signal at 500 Hz on each channel, waveform analysis of the *QRS* complex, single beat analysis, and contextual diagnosis of the underlying cardiac rhythm. The system executes on a 16-bit processor (Intel 8086) with 32 Kbytes of random access memory and iRMX86 real-time multitasking executive. The executive permits flexible and minimal hardware and is well suited for systems which monitor or control events occurring asynchronously in real time. The microcomputer monitoring system can provide complex rhythm classification and is designed to be interfaced to a coronary care monitoring unit.

A Manufacturer's Perspective on Arrhythmia Monitoring

(Invited Paper)

W. B. LOCKE AND S. BOTZKO

Hewlett-Packard
Waltham, MA 02254

To remain on the frontiers of health care requires a continuous investment in product development. We will cover the genesis and evolution of the Hewlett-Packard Arrhythmia Monitoring Systems. This began as a joint development with Stanford University Medical Center leading to introduction at the American Heart Association Convention in 1974. From an initial product that had as its major feature the detection and classification of VPB's in graded alarm categories, the original system has evolved into a range of Arrhythmia Information Management Systems.

Many possible product sets could be (and have been) derived from the available technology and the health care practices in the CCU. The choices that were made have reflected a specific product strategy. This strategy has been to expand the product set capabilities (and scope) in an attempt to increase the product's perceived value in the CCU. Other possible strategies could have aggressively lowered the product price (by reducing capability), or leveraged into new markets (such as Holter monitoring), using the original technology as a base. This paper discusses the feature set of the product family, and how that feature set has been influenced by the product strategy.

Reasoning from Multiple Information Sources in Arrhythmia Management

(Invited Paper)

W. J. LONG*, T. A. RUSS*, AND W. LOCKE**

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Effective ventricular arrhythmia management depends on knowing the cause of the arrhythmia, interpreting the arrhythmia itself, and selecting and controlling the therapeutic interventions. Current technology for assisting the physician in this endeavor has focused on isolated aspects of the process—arrhythmia monitoring to interpret the beats and pharmacokinetic programs to aid in achieving desired drug levels. The result is an increasing volume of information for the physician to assimilate, most of which is not relevant in the context of a given patient.

We are designing a computer program to accept information from various sources, assess it in the context of the patient, and provide a concise summary of the state of the patient. In addition to the electrocardiographic data, the cause of the arrhythmia, the therapy, and changes to the therapy are considered in the patient assessment. Thus, the program will have the appropriate perspective to focus on the ar-

rhythmic events that are significant clues to managing the patient, providing a filter for the information coming from the monitor. The program will also assist in determining the appropriate therapy by using pharmacokinetic models and the pateint's response to previous therapy to determine any needed changes. The methodology for program development has two parts: using formal algorithms where they exist, and emulating the reasoning methods employed by an expert cardiologist for interpreting and integrating the data. As case data are collected, the algorithms are refined to match the performance of an experienced cardiologist.

We have implemented a preliminary version of the program for testing algorithms. The current arrhythmia assessment algorithm is based on the Lown arrhythmia classification system modified to make greater use of the changes in the frequency of abnormal beats. We are currently designing a more comprehensive version of the program.

ACKNOWLEDGMENT

This work was supported in part by the National Institutes of Health under Grant 1P01 LM 03374-03 from the National Library of Medicine and in part by the Whitaker Health Sciences Fund.

Efficient Measurement of Long-Term *ST* Segment Trends

(Invited Paper)

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and

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An algorithm structure for testing long-term *ST* segment measurement strategies was implemented. The development and evaluation of these strategies was carried out using a newly created database of 48 digitized ECG intervals ranging from 13 to 65 min in length. The ECG data came predominantly from exercise stress tests and offered diverse *QRS-ST* morphologies under varying noise conditions. One algorithm strategy incorporated the traditional approach of baseline compensation, beat rejection, and beat averaging as a means of noise reduction. When used to measure the *ST* segment level 110 ms beyond the peak of the *QRS*, this algorithm produced *ST* level measurements which differed from human-measured values by a mean of 0.07 mm with a standard deviation of 0.37 mm. The need for a robust but more computationally efficient algorithm motivated the investigation of alternate averaging strategies, including the less commonly used technique of incremental averaging. It was found that a simple incremental average implemented without the benefit of any noise reduction techniques yielded the same performance (mean = 0.07 mm, st. dev. = 0.33 mm) at a fraction of the computational cost. This result has significant implications for resource allocation in algorithms for long-term ECG analysis.

Session 31—Impacting the Profession Through Professional Activities

Chairman: Larry Feingkoh, P.E., C.C.E.
St. Lukes Hospital
Milwaukee, WI

Professionalism in Medical Engineering

(Invited Paper)

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In any interdisciplinary undertaking, one discipline or the other often assumes a superior status. Engineering discipline teaches its students to follow, in a supporting team. Medical discipline teaches its students from an early age to lead paraprofessional followers (nurses, technicians, etc.). Thus, the engineer enters the undertaking at a disadvantage. However, the engineer is needed on the team as a full contributing partner. To achieve this status, he must prove himself to be a true professional in three ways: through his credentials, his credibility, and his proven performance.

I highly recommend that every medical engineer be accredited, either by his state, as a licensed professional engineer, or through some accrediting society such as AAMI. He should also actively participate, and aggressively seek the highest level to which he is entitled, in the society of his specialty. (Both ASME and IEEE have a large number of Fellows who are biomedical engineers.)

Physicians must often rely completely on a biomedical engineer's opinion, sometimes in very critical situations. It is incumbent on the engineer to accurately and knowledgeably state the case whenever such an opinion is required. You must be precise and you must be right. Otherwise, keep your mouth shut!

Lastly, the bioengineer will be judged by his contributions to the literature. *Before* going into an undertaking, he should insist on coauthorship on all his work and *senior* authorship in engineering journals. This is the least measure of full partnership.

IEEE—More than a Technical Society

(Invited Paper)

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In this paper the author discusses IEEE's involvement during the past decade in those professional activities not strictly technical in nature, but rather concerned with fulfilling the career needs of its members and influencing national policy on social-technical issues. Beginning with the seven basic needs of an engineering professional, the author shows that no other American organization is as uniquely qualified to satisfy these needs as IEEE. This role for the Institute is as true today as it was in the early 1970's, when our members voted overwhelmingly to modify the IEEE's constitutional purpose to include the full gamut of professional activities, nontechnical as well as technical.

A short historical review of IEEE's U.S. professional activities over the past decade is given, including a description of the board entrusted with carrying out that involvement, the United States Activities Board (USAB). The organizational structure of USAB is explained and the principal task forces under each of its four councils outlined. The relationship of USAB to the members through the National Professional Activities Committees for Engineers (PACE), with its three major purposes of member services, public awareness, and government action, is described. Current USAB/PACE activities of special interest to EMBS members are then summarized.

The author concludes with a plea for increased support of the Insti-

tute's professional activities by our U.S. membership. Only with this support can the IEEE be as effective in participating in the political process as the medical and legal professions. With our cooperative efforts the Institute can become a more creative force and positive contributor to the enhancement of our engineering careers, to the process of U.S. technical policy development, and to the well-being of American society.

The 1983 IEEE Salary Survey

(Invited Paper)

H. N. BOWES

Lockheed Engineering and Management Services Company, Inc.
Houston, TX

The 1983 salary survey results show that engineering salaries have continued to increase. The impact on entry level personnel and the more experienced engineers will be examined. A comparison of the regional trends with the national average will be presented. A significant portion of the survey dealt with fringe benefits and the support services industry. The background of this thrust and the results of the survey will be presented.

IEEE Health Care Technology Policy

(Invited Paper)

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The EMBS is a technical society within the IEEE with a membership made up primarily of those with a deep interest in the application of engineering skills to the life sciences and health care. There are others within the many IEEE technical societies who are not members of EMBS but who also have an interest in this important field. For this reason, the IEEE Board of Directors has established the Health Care Technology Policy Committee to represent the entire IEEE at the federal government level with respect to IEEE policy with regard to any matters that relate to the interface of engineering and health care. This committee functions to gather information in this area, develop positions that reflect the IEEE membership, and communicate these positions to the federal government. The committee is currently increasing its activities and seeks input from all IEEE members.

Session 32—Restoration of Extremity Function by Electrical Activation of Paralyzed Muscle

(Sponsored by the EMBS Bioelectric Phenomena Committee)

Chairman: J. T. Mortimer, Ph.D.
Case Western Reserve University
Cleveland, OH

Input-Output Properties of Electrically Activated Muscle

(Invited Paper)

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Muscle is a neurally controlled mechanical actuator. During electrical stimulation, the neural input is achieved by exciting the nerve axons innervating the muscle. This input does not control length or force uniquely; rather, it controls the relationship between length and force. The muscle interaction with the load determines movement and force production. The muscle properties are modulated by two mechanisms: recruitment, which is variation of the number of muscle fibers excited by a given stimulus pulse, and temporal summation, which is variation of the frequency of the stimuli. Recruitment is characterized by a nonlinear, length-dependent relationship, and temporal summation is characterized by a linear dependence on the stimulus period (the inverse of stimulus rate) that also varies with muscle length. Although an adequate control model of muscle for predicting behavior under a wide range of loading conditions has not been developed, a second-order low-pass filter model is adequate for some conditions. The stimulator is best modeled as a sampler, and for the design of controllers the whole system can be treated as a discrete-time, sampled-data system. Parameters for the muscle model have been identified using discrete time techniques that allow changes in the model parameters to be tracked as a function of time.

ACKNOWLEDGMENT

This work was supported by the NIH-NINCDS Neural Prosthesis Program under Contract N01-NS-02330.

Controllers for Electrically Activated Muscle

(Invited Paper)

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The development of neuroprostheses utilizing functional electrical activation of paralyzed muscles to restore extremity function requires the design and testing of controllers for "good" regulation of muscle force, length, and/or stiffness so as to control the positions, angles, torques, and forces at upper or lower extremity joints. These controllers must be *robust,* in the sense that they perform well despite changing muscle properties, loads, operating environments, and modeling errors, or the controllers must adapt (i.e., adjust themselves) in response to their performance quality. This tutorial will describe and evaluate several controller designs for single-muscle regulation. Issues and requirements for the coordinated control of multiple-muscle systems in upper and lower extremity neuroprostheses will be described in terms of controller design and interconnection.

ACKNOWLEDGMENT

This work was supported by the NIH-NINCDS Neural Prosthesis

Program under Contracts N01-NS-02330 and by the National Institute of Handicapped Research (U.S. Department of Education).

Open Loop Control in Restoration of Upper Extremity Function

(Invited Paper)

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Electrical stimulation of paralyzed muscle can restore functional movement in the hand of the high-level quadriplegic. Clinical realization of this technique requires that the patient need to generate, on simple command, signals for regulation of the position of hand opening or the grasp force. A single degree of freedom proportional command signal is used to simultaneously regulate and coordinate the activity of each of up to eight muscles involved in grasp–release. Because of the inherent nonlinear properties of electrically stimulated muscle, piecewise linear modulation control of the input pulse width is required to provide a more linear relationship between the input command and the output force or position.

Clinical systems have been developed and are in outpatient usage by C5 and C6 level quadriplegics. These systems generally employ shoulder position as the command signal source, and utilize chronically indwelling percutaneous electrodes for stimulation of the muscles. The stimulation hardware consists of a small, low-power, microprocessor-based device to process the command generated by the patient and to output the stimuli to the muscles. Ten subjects currently are evaluating these systems.

The next generation systems will employ implantable technology, eliminating the need for percutaneous lead wires. The development of these systems and their incorporation into clinical usage will be discussed.

ACKNOWLEDGMENT

This work was supported in part by Paralyzed Veterans of America (NTO-319).

Electrical Activation of Muscles for Open-Loop Walking

(Invited Paper)

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and

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In 1972 we evaluated an external and later an internal footdrop control device. Patients generally rejected the external due to donning problems; the internal was too expensive and complicated relative to the defect corrected. Next we implanted electrodes in the hip and knee muscles of three previously rehabilitated, partially paralyzed nonwalking subjects with upper motor neuron deficit. Control was through footswitches and timers. All walked with supervision. Four complete paraplegic patients (T4–T12) were instrumented giving selective knee and hip control using a 15-channel microprocessor-controlled stimulator. The gait cycle stopped at double support unless reactivated by the patient. One patient walked with a walker, another in parallel bars, and another stood at the time of this communication. We conclude that functional electrical stimulation can increase the lower extremity function of the upper motor neuron patient in heretofore unachievable ways.

ACKNOWLEDGMENT

This work was supported by the Prosthetics Research Service of the Veterans Administration.

Electrical Stimulation for Standing in Paraplegia

(Invited Paper)

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Great expectations exist for utilizing functional electrical stimulation (FES) to allow paraplegics to walk. These expectations are predicated on a number of assumptions, the most important of which is that stable standing postures can be reliably and repeatedly obtained. Conventional bracing technology relies on mechanical braces to lock the knee and ankle joints, while the hips are locked in hyperextension. Bilateral quadriceps stimulation is the minimum configuration for standing in paraplegia. Our present two-channel stimulator incorporates adjustable time delays between activation and delivery of stimulation, user feedback regarding onset of stimulation, and adjustable ramp up/down of contraction. The hips are locked as with braces and the ankles are essentially unstable, which necessitates use of balance aids. Six subjects have been able to stand in our laboratory, and two of them will soon attempt to stand at home daily.

Electrostimulation and Paralyzed Muscles

(Invited Paper)

J. S. PETROFSKY

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National Center for Rehabilitation Engineering
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Historically, electrical stimulation has been used in physical therapy as a means of potentially reducing muscle spasticity and atrophy of muscle associated with muscular paralysis. In our own lab we have developed a closed loop stimulation system to allow weight training (isokinetics) and dynamic exercise (bicycling) in paraplegic and quadriplegic individuals. The results of these experiments show a dramatic increase in strength, endurance, and muscle size with minimal workouts on these devices. For the quadriplegic whose blood pressure can be extremely unstable, electrically enduced bicycling causes an increase of 11 mmHg in resting blood pressure and a reduction of 30 mmHg in exercising blood pressure with an increase in blood pressure stability during the exercise. The overall result from these devices is the achievement of sufficient return of body function to allow safe ambulation.

Using the same closed loop principles, a microprocessor-controlled walking system was developed. This system was based on previous studies of closed loop control and ambulation on the cat (Petrofsky *et al.*, 1976, 1978, 1979, 1980, 1981, 1982). This system of stimulation uses all 12 muscle groups with sensing of the result of that stimulation on muscle movement by position sensors at the ankle, knee, and hips and contact sensors on the shoes. Furthermore, a series of gyros (solid-state level sensors) placed around the body show gravity vector to allow balance in paraplegics and, to a limited extent, quadriplegic subjects. The system has been tested in laboratory conditions and allows standing and walking in both paraplegic and quadriplegic subjects. The system is currently undergoing miniaturization to allow surgical implantation in portable use.

Workshop Abstracts

Workshop W-1

Manufacturing and Marketing of Devices for Functional Assessment of the Handicapped

Co-Chairmen: A. R. Potvin and G. V. Kondraske
The University of Texas at Arlington

There are presently no standardized methods, few commercial devices, and fewer broad-based test batteries available to facilitate and promote routine clinical use of sensitive objective methods to assess function of handicapped individuals. If promising research devices could be modified for manufacture and delivery to service providers, the evaluation of drugs and assist devices could be substantially improved over the current general practice of relying on the clinician's and the patient's subjective impressions, and the occasional, but generally inadequate, objectively obtained data. This workshop brings together industry leaders and research investigators to address key issues associated with taking functional assessment devices from the research laboratory to the marketplace. After each industrial leader delivers a short incisive presentation of currently available products and future trends, a panel discussion with audience input will follow.

Panel: D. Bayer, R. J. Branconnier, P. Bussman, V. Davidson, D. Devilt, L. Kun, and S. McFarland

Workshop W-2

Biomedical Engineering Program Directors Meeting

Chairman: Blair A. Rowley, Ph.D., P.E., C.C.E.

An informal round-table discussion for directors of biomedical engineering educational programs will be held. One major topic is the gradual erosion of programs which appears to be coupled with the lack of U.S. graduate students in engineering across the country. As a result, it seems that our educational base is departing for industry. If this trend continues, our country may be seriously harmed in its ability to advance health care. Also, coupled with this is the reduction in funds available to support research and, therefore, graduate students. These and other problems are open for discussion.

Workshop W-3

Simulation: Animals and Animal Research

Chairman: Francis A. Spelman, Ph.D.
University of Washington, Seattle, WA

Simulation Versus Experimentation in Cardiovascular Research

T. G. COLEMAN

Department of Physiology and Biophysics
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The overall usefulness of mathematical modeling and simulation in cardiovascular research remains unclear. Certainly, the current proliferation of digital computers and computer networks allows an evaluation that was heretofore not practical. Traditional laboratory methods have provided large volumes of experimental data in cardiovascular medicine and many other areas and these data are being used with emerging computer technology to create and solve mathematical models focused on relevant cardiovascular problems. One might anticipate that these models will rapidly become a useful adjunct to traditional laboratory research or might even replace such research. This is an attractive idea because many important cardiovascular phenomena are complex and ideally suited to mathematical analysis. Further, cardiovascular anatomy is well understood and anatomy is likely to be the cornerstone of any comprehensive cardiovascular model. However, analyses may not reach their full potential in the near future because in many instances the essential quantitative and even qualitative data are not available. For instance, the mechanisms underlying some common clinical observations such as the connection between renal disease (or obesity) and high blood pressure or the mechanism of fluid retention in heart failure remain speculative. These considerations suggest that simulation and critical experimentation must be carefully coordinated if orderly scientific advances are to be achieved.

The Role of Modeling in Biomedical Experimental Design

D. M. FOSTER

Center for Bioengineering
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Seattle, WA 98195

Mathematical modeling as a research tool in the biomedical sciences has gained considerable credibility in recent years, yet its full power is poorly understood by most experimentalists. This comes not only from confusion over the definition of a model, but what one can expect from modeling. Moreover, the persistence of old analytical methodologies even after they have been shown to be incorrect underlines the failure of communication between the experimental and theoretical biologist.

This talk will describe one investigator's approach to using mathematical modeling as an integral part of a total experimental design. It will

show how the traditional barriers and difficulties between experimental and theoretical biologists have been overcome by describing 1) what to expect from a model, 2) uniqueness and validity of a model, 3) incomplete models and data, and 4) simulation of experiments. An example from lipid metabolism will be discussed to illustrate these points.

Humanizing Animal Research

F. A. SPELMAN, Ph.D.

Regional Primate Research Center
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and

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Seattle, WA 98195

It is essential to use animals as subjects in biological research that tests basic hypotheses, treatments, or surgical procedures. This essential use of animals has been attacked as unnecessary and inhumane; thus it is necessary for bioengineers and other biological scientists to seek those techniques that will ensure the efficient and humane use of animals as research subjects.

Animal research provides benefits to both humans and animals. The total number of animals that is used in research can be reduced with the judicious use of technology. Computerized animal records systems provide scientists with detailed information on the animals in their colonies. Armed with those data, scientists can select the animals which have suitable backgrounds for their research, using animals multiply and reducing the total number of animals used.

When animals are used experimentally, it is necessary to reduce or eliminate restraint. Bioengineers have provided precise and reliable biotelemetry systems that permit the measurement of multiple physiological variables from free-ranging animals. Some studies require that animals be infused with fluids or that specific biomaterials be examined daily. Those studies can employ tethering systems which permit free movement within a comfortably-sized cage. When animals are tested in specific test chambers, they can be housed in specially-designed, spacious cages and trained to attend to specific tasks when their cages are moved into the test chambers.

Workshop W-4

Flow Transduction and Transducers

Chairman: **Christopher Druzgalski, Ph.D., California State University, Long Beach**

The objective of this workshop is to discuss and assess traditional and novel techniques of flow transduction and the design of transducers used in clinical practice and research applications. These presentations will emphasize, although will not be limited to, blood flow and velocity measurements and will address industrial as well as academic research accomplishments and trends. It will be followed by an open informal discussion among workshop participants.

Panel: J. Battocletti, Ph.D., C. Hartley, Ph.D., F. Ingle, Ph.D., and J. L. McGuire

Workshop W-5

(Tutorial)

Practical Digital Filters for Real-Time Signal Processing with Microprocessors

Chairman: **Willis J. Tompkins, Ph.D.**

Analog filters have traditionally been used to process biomedical signals. As microprocessors have made their way into medical instrumentation, digital filtering algorithms have been included to replace the tasks previously done by the analog filters. In fact, filtering techniques are being developed that cannot even be implemented with analog filters. Using the ECG as an example biomedical signal, this tutorial will cover simple filtering techniques for 1) smoothing and low-pass filtering, 2) bandpass filtering, 3) dc elimination, 4) 60-Hz rejection using a novel adaptive or "learning" filter that continuously tracks and eliminates 60 Hz noise, and 5) *QRS* detection using filtering techniques. To fully understand the material, the attendee should have a knowledge of basic z-transform theory and the fundamentals of assembly language programming. All the algorithms to be presented are suitable for real-time use on an 8 bit or 16 bit microprocessor and can be implemented using integer arithmetic.

Workshop W-6

(Tutorial)

Modern Techniques of Computer Analysis of ECG

Chairman: **N. V. Thakor, Ph.D., Department of Electrical Engineering and Computer Science, Northwestern University Evanston, IL**

ECG interpretation has long been practiced in a form somewhere between a hard science and a practical art. Computer programs that attempt to match the performance of cardiologists have been a challenge. I will review conventional ECG interpretation techniques such as feature extraction, and correlation analysis. But new and potentially more powerful techniques based on the advances in the fields of pattern recognition and artificial intelligence are on the horizon. Further presentation will include related topics of digital filtering, annotated database, and performance evaluation.

Workshop W-7

Advances in Pacemaker Technology

Chairman: **N. V. Thakor, Ph.D., Northwestern University**

This year marks the 25th anniversary of the implanted pacemaker. We will trace the history of the pacemaker development. Presentations will include physiologic and clinical basis of pacing, development of power supply, and instrumentation. This workshop will include some presentations from the panel members, followed by open discussions.

Panel: W. Greatbach, B. V. Berkovits, P. C. Gillette, R. G. Houser, and M. M. Mower

Workshop W-8

(Tutorial)

Teaching Robotics to Biomedical Engineers—The Easy Way

Chairman: Willis J. Tompkins, Ph.D.

As the field of rehabilitation engineering continues to evolve, it is becoming necessary to teach biomedical engineers about design of electronic and electromechanical devices to aid the handicapped. A new robot available in the marketplace includes a number of devices that demonstrate the principles of rehabilitation aids. For example, the robot includes an arm that can be programmed to move with several degrees of freedom—a model that can be used to study the control of an electromechanical prosthetic arm. Also included with the robot is an ultrasound ranging system—a model device that can be used to study the ultrasonic aids for the mobility of the blind. This workshop/tutorial will review the session chairman's experience with using this robot as a teaching tool for a biomedical engineering course and will encourage an exchange of ideas among members of the audience.

Workshop W-9

Technology Transfer to the Third World

Chairman: Richard Aston, Department of Engineering Wilkes College

Technology transfer occurs whenever techniques originally intended for one environment are adopted in another, as for example, the transfer from the aerospace industry into the hospital; or from one of the technically advanced countries to a developing third world country.

In this workshop, a panel of people who have participated in such technology transfer will discuss the procedures, beginning with familiarization of the existing technique currently used in the industry or the country where change is contemplated. The special problems associated with biomedical equipment transfer, technical retraining, biomedical technician education, and university engineering education in third world countries will be addressed.

The issues raised by technology transfer to a foreign country are often cultural, social, historical, and economic as well as technical. There are differences in the availability of public services, hospital maintenance facilities, in attitudes toward the work ethic, and the use of advanced hardware in general.

The importance of having the new technique actually adopted in the new environment, after those who transfer it leave, is stressed. One method is to train counterparts as catalysts of the process and to stress education.

Panel: H. R. Weed, S. Aronow, J. Nobel, R. Morris, E. Murphy, E. Charle, and U. Nejib

Tutorial Course TC-1

Hospital Energy Conservation Concepts

(Fee Charged)

W. B. JARZEMBSKI, P.E., Ph.D., C.C.E.

Department of Biomedical Engineering and Computer Medicine
Texas Tech University Health Sciences Center School of Medicine
Lubbock, TX 79430

This course will consider the basic concepts of energy use and conservation in a modern health care center. Included will be a study of basic energy concepts followed by discussion of HVAC, lighting, electrical systems, and mechanical systems. Discussions will include design of new construction as well as modifications to old buildings.

Tutorial Course TC-2

Specification Writing

(Fee Charged)

W. B. JARZEMBSKI, P.E., Ph.D., C.C.E.

Department of Biomedical Engineering and Computer Medicine
Texas Tech University Health Sciences Center School of Medicine
Lubbock, TX 79430

This course will cover fundamentals of specification writing with reasons for and benefits of well written spec's. Qualifications of spec writers will be included as will description of content. Examples will be used.

Tutorial Course TC-3

Personnel Documents

(Fee Charged)

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This course will cover the rationale for and design of two very important documents that are too frequently overlooked: the position description and the position evaluation. Each of these documents has a valid function and each is quite valuable to the health care engineer.