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BIOMEDICAL ELECTRODE TECHNOLOGY

THEORY AND PRACTICE

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BIOMEDICAL ELECTRODE TECHNOLOGY

THEORY AND PRACTICE

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INTRODUCTION

With cardiac disease being by far the most common cause of disability and death in the United States, the vital importance of reliable monitoring systems is quite clear. Unfortunately, failures of cardiac monitoring systems are all too common. Haslam and Bruner report that half the monitoring system failures in a typical hospital were a result of difficulties with leads and electrodes.[1] That conclusion emphasizes how improvements in electrode technology could confidently be expected to contribute to improved care and survival of cardiac patients. Rapid advances in the understanding and diagnostic use of biopotentials related to the heart and other human functions further emphasize the urgent need for better biomedical electrode systems.

In an effort to promote advances in electrode technology, more than 200 concerned specialists in various disciplines, representing academia, government, industry, and medicine, participated in a Conference at Stanford University on September 13 and 14, 1973. It is intended that the papers presented and discussions, as published in this book, comprise an organized and comprehensive view of present biomedical electrode technology, clarify needs and deficiencies in present technology, suggest routes for improvements, and stimulate further research to advance the state of electrode technology. The end product, it is hoped, will be better, more effective care for the increasing num-

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[1]Haslam, Kenneth D., M.D., and Bruner, John M. R., M.D.: The epidemiology of failure in cardiac monitoring systems. Medical Instrumentation, Vol. 7, No. 5, November-December 1973, pp. 393-396.

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bers of unfortunate victims of cardiac disease and other disabilities.

In addition to the presented papers and summaries of the open discussions, this book includes several worthwhile papers which could not be accommodated into the two days of formal presentations. The publication cannot adequately reflect the extensive, constructive interchange of expertise among the many participants which was essential to the Conference. The open discussions, which followed the presentation of papers in each session, are summarized through paraphrased excerpts.

The session chairmen and speakers were indispensable to the effectiveness of the Conference. As a special discussion panel, the four chairmen presented an excellent overall summary. Their summations delineate what they concluded to be the most urgently needed advances in electrode systems and suggested avenues of research for achieving these advances.

Special thanks are due the National Aeronautics and Space Administration for financial support of the Conference.

The hope of all concerned is that the Conference and this book will help to advance the reliability and usefulness of biomedical electrodes in their various applications and thereby improve health care.

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SESSION I

MATERIALS SCIENCES

Chairman

ALAN PINKERSON, M.D.

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MATERIALS SCIENCES

CHAIRMAN'S OVERVIEW

Alan Pinkerson, M.D.

As in many scientific and technical endeavors, there are marked influences of material types, fabrication processes, product configuration, and user acceptance in the success of any technology. The subject of materials science plays a major role in biosensing, and thus forms a logical starting point for the Conference.

In the past, electrodes have generally been of rigid metal construction in the form of a needle, wire, plate or cup. However, recent research endeavors have provided information concerning ultraflexible, disposable, long-term microminiature implantable and insulated electrode types. Problems concerning material types, structural behavior, and tissue compatibility are basic to improving the state-of-the-art.

Each of the papers in this session demonstrates increased awareness of the prime importance of materials properties and fabrication to the effective measurement of all biopotentials. A great deal of effort and innovation has been applied to the development of new electrode types for a variety of applications.

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INSULATED ECG ELECTRODES

W. M. Portnoy *
R. M. David **
L. A. Akers *

INTRODUCTION

Electrocardiographic data are usually obtained by employing some type of a metal-electrolyte system. Conventional conductive electrodes have several features in common: polarization effects are minimized; the electrode-skin interface impedance is low, and the electrolyte is almost physiologically inert. However, the effectiveness of such electrodes is limited, under conditions where long measuring times are involved, or when the subject is in motion. The electrolyte, unless changed, will dry out, and the interface impedance become great enough to cause degradation of the ECG signal (15). After extended periods, the region of the skin in contact with the electrolyte may become irritated or infected (8,15). Motion artifacts will often interfere with the waveform during subject exercise or activity.

The work described here was undertaken to determine if an insulated electrode system, in which the subject is capacitively coupled to the measuring system, might be superior to a conductive electrode. A priori, an insulated electrode appears to possess two advantages; it can be applied directly to the unprepared skin, and

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it blocks DC drift directly at the electrode-skin interface. Non-stimulating capacitive electrodes have been constructed and tested with some success. Dielectric materials which have been used have been anodized aluminum oxide (6,10,11,12), anodized tantalum oxide (5), silicon monoxide and quartz (11,13,16), organic compounds (4,9,11) and barium titanate ceramic (7). The aluminum, tantalum and silicon (with two exceptions) oxides were formed using procedures which required the participation of the substrate; only a limited number of dielectric films can be obtained by anodization and thermal oxidation. (The exceptions were sputtered (11); this method is discussed below.) The restriction respecting substrates did not apply to the organic dielectric films and to the ceramic, but the formation and thickness of organic films is difficult to control, and the thickness of the ceramic button required a very high permittivity material, barium titanate, for the dielectric.

In order to permit a relatively extensive evaluation of insulated electrodes, a variety of dielectric permittivities and thicknesses was required, and since the previous work revealed deficiencies in the various procedures which were used to obtain the films, a systematic examination of the available techniques was undertaken to determine if the reported limitations could be circumvented. There are a number of procedures which have been developed for the formation of dielectrics on various substrates. These fall basically into two categories: chemical and mechanical. The chemical technique contains procedures such as anodic oxidation, thermal oxidation and pyrolytic decomposition, that is, formation from the vapor phase. The mechanical technique involves evaporation in a vacuum or sputtering from a dielectric target. Anodic oxidation and pyrolytic decomposition are the least successful procedures. Good anodic oxides are difficult to obtain. Since the anodization takes place in an aqueous electrolyte, ionic species are incorporated into the oxide during its formation; furthermore, anodic oxides are not dense and are susceptible to the forma-

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tion of pinholes. It is to be expected that dielectrics grown by anodic oxidation are leaky and tend to drift. Also, since the substrate must participate in the formation of the oxide, the types of dielectrics available are limited by the number of suitable substrates. Dielectric thin films which have been deposited by pyrolytic decomposition of chemical vapors can be used to construct capacitively coupled electrodes, but they exhibit defects similar to those exhibited by anodically obtained dielectrics, particularly with respect to their densities and structural integrity. Their densities can be increased by subsequent thermal treatment, but at the elevated temperatures required for such work, the substrates are thermally damaged. Furthermore, only a limited number of reactions are available. The best chemical process appears to be thermal oxidation. Thermally grown oxides are dense and have much better mechanical properties than anodically or pyrolytically formed films. Thermal oxidation, however, has at least one serious drawback: thermal oxide growth requires substrates which can withstand high temperatures.

The mechanical processes offer one common advantage over the chemical processes: film deposition does not require the participation of the substrate. For example, consider the formation of a film of titanium oxide. Chemical formation requires a titanium substrate, whereas an oxide can be mechanically deposited on silicon, aluminum, copper, silver or any suitably prepared material. The choice of substrate material allowed by a mechanical deposition process has obvious advantages. Evaporation can be performed either by Joule heating or by electron beam bombardment. In Joule heating, a material is volatilized in a vacuum from a filament or boat heated by passing an electric current through it until melting and evaporation of a charge takes place. In electron beam evaporation, the material is bombarded in a vacuum by a high energy electron beam. The high kinetic energy contained in the electron beam is absorbed by the target, resulting in a large increase in target temperature, causing

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evaporation of the target material. Although these techniques may be employed in the deposition of dielectric thin films, they are used to a much greater advantage when depositing conductive thin films. The procedure which has been found to be the best for depositing thin films of dielectrics is radio frequency sputtering. A dielectric material is used as a target for bombardment, but instead of a high energy electron beam, ions bombard the surface. These ions are produced in a gas discharge, usually of some inert gas, which has been excited in the presence of RF energy. As the ions bombard the surface, they dislodge target atoms which deposit on the substrate. A great advantage of the RF sputtering method is the availability of a large number of dielectric targets.

After considering these factors, it was concluded that the best technique for the fabrication of the insulated electrodes was RF sputtering, and the design and construction of the electrodes began. The electrode structure and test results are described below. (Some of the following material has been partially reported (1,2.)

ELECTRODE SYSTEM DESIGN

The design of the electrode system may be divided into two parts: the selection of the dielectric and the substrate, and the impedance transforming circuit.

Dielectric Film and Substrate

Although many dielectric targets are available, the selection of the dielectric materials is limited by the compatibility of the materials with the skin; that is, they must exhibit no skin toxicity. The toxicity of a number of materials was examined (14) and five dielectrics were chosen which not only provided a wide range in permittivities, but which were also inert with respect to human tissue. These were barium titanate, titanium dioxide, tantalum pentoxide, aluminum dioxide and silicon dioxide, with respective nominal permittivities of 1500, 100, 25, 12 and 4. The substrate material initially chosen was high purity

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aluminum, 0.03 cm thick, cut into disks 1.6 cm in diameter; this diameter was chosen for compatibility with the geometry of the electrode housing. The disks were polished to a mirror finish with 0.5 micrometer alumina granules and rinsed thoroughly before use. It was found, however, that during the deposition of the dielectric, the disks became hot enough to deform. Although adhesion of the film to the aluminum was good, after the deposition was complete and the disks had cooled, stress cracks developed in the dielectric film. When these disks were tested as electrodes, skin electrolytes filled the cracks, and shorting paths developed between the skin and the conductive aluminum substrate. Since some heating was to be expected during the deposition, it was concluded that film cracking would generally take place when a thin metal was used, and another type of substrate was required. It was not convenient to use thicker metals, and silicon was finally chosen because of its rigidity and good dielectric adhesion. Squares, approximately 1 cm^2 in area, were scribed out of Blanchard ground slices, highly polished and very flat; the starting slices were n-type, around 1 ohm-cm and 0.25 mm thick. They were degreased for fifteen minutes in boiling methanol/xylene (1:1) solution, rinsed in deionized water, immersed in hot concentrated sulfuric acid for fifteen minutes, water rinsed, placed in hot nitric acid for fifteen minutes, and water rinsed. After a final rinse in trichloroethylene, they were air dried and placed in the sputtering chamber of the system (R. D. Mathis Model SP 310A RF sputtering module and generator).

Impedance Transforming Circuit

The insulated electrode consists of a thin dielectric film on a conducting substrate chip, arranged so that skin contact is made directly to the dielectric thin film layer. The skin acts as one plate of a simple capacitor while the substrate acts as the other. Because of the nature of capacitive coupling and the requirement of the best possible electrode voltage transfer characteristics, an impedance trans-

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former is required as a buffer between the capacitor and the monitoring device. This system is designed as a replacement for the conductive type electrode. It should therefore possess as many of the electrical and physical properties of the conductive electrode as possible, and it should be usable with any standard monitoring and recording system. Over the short term, conductive electrodes yield good quality ECG signals, but this is an obvious requirement for any ECG electrode. The conductive electrode can be made quite small, which not only makes it easier to use, but also approaches the ideal point contact desired for best ECG analysis. Because of the direct coupling of the conductive electrode, it provides no DC offset voltage at its output. Perhaps the most important characteristic of the conductive electrode is that two such devices of identical design will have closely matched voltage transfer functions. In order to understand the significance of this parameter, consider the system of figure 1.

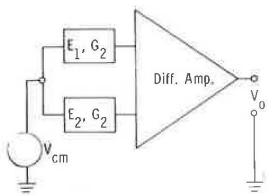


Fig. 1. Equivalent circuit for an ECG system with a common mode input.

This represents the equivalent circuit for an ECG monitoring system with some common mode input signal. For simplicity, it is assumed that the unity gain differential amplifier has an infinite common mode rejection ratio so that no common mode signal appears at the output. Now, suppose that electrode E_1 has a voltage transfer function of $G_1 = 1$, while the second electrode has a voltage transfer function of $G_2 = 0.99$. Under these conditions a one-volt common mode input signal could result in a 0.01-volt differential signal at the output. The system would thus, even with a perfect differential amplifier, correspond to a sys-

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tem with the poor common mode rejection ratio of -40 dB. It is easy to see that even a very small (1%) difference in transfer functions of the electrodes can cause a large degradation of the common mode rejection vital to a good ECG monitoring system. The frequency response characteristics of the insulated electrode also must be comparable with those of a conductive electrode. For the purposes of this work, upper and lower -3 dB points were chosen to be 0.05 Hz and 1000 Hz, respectively.

The insulated electrode, therefore, must have a transfer function which is the same for all electrodes, provide minimum DC offset, satisfy the required frequency characteristics and have a very high input impedance. The latter constraint may be understood using the circuit of figure 2. The capacitor C repre-

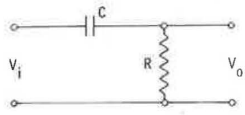


Fig. 2. Equivalent circuit for dielectric thin film and impedance transformer input impedance.

sents the capacitance of the dielectric thin film and R represents the input impedance of the impedance transformer. In the frequency domain, the transfer function of this circuit is given by

$$G(j\omega) = \frac{j\omega}{j\omega + \omega_o}$$

where

$$\omega_o = 1/RC.$$

Imposing the requirement that the low end cutoff frequency is 0.05 Hz, the requirements on R and C can be determined by the following calculation. Since

$$f_o = 0.05 \text{ Hz} = \omega_o/2\pi,$$
$$RC = 1/2\pi f_o = 3.18 \text{ seconds.}$$

Considering the electrode area (around 1 cm^2), and the

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expected thicknesses (5000 to 50000 Angstroms) of the dielectric films, a value of C in the neighborhood of 1×10^{-8} farads is a reasonable assumption. The last equality then implies that R must be at least 318 megohms; conventional ECG monitoring devices often have input impedances of only a few hundred kilohms, so that the necessity of the impedance transformer becomes obvious. The transformer circuit must also be reproducible; that is, when combined with the capacitor, any two electrodes must exhibit identical or as close to identical as possible transfer functions. At midband frequencies, this condition will be determined by the transfer function of the impedance transformer.

Finally, the output impedance of the transformer must be low. The output impedance has an effect on both the noise susceptibility and the voltage transfer qualities of the electrode. Suppose that the output impedance and voltage of the transformer are R_1 and V_1, respectively, and the input impedance of the monitoring unit is R_2. The voltage transferred to the monitoring unit will be given by

$$V_2 = V_1 \frac{R_2}{R_1 + R_2}$$

It is obvious that if R_1 is anywhere near the value of R_2, an appreciable loss of the input signal can result. Notice also that if R_1 differs between electrodes, different outputs can occur for common mode inputs. Another reason for making R_1 very low is that of noise. Figure 3 represents an equivalent circuit whereby extraneous outside electromagnetic noise (e.g., noise from 60 cycle power lines, etc.) can be coupled into the system. C represents the capacitance between the electrode and the noise source. The output will be a summation of desired information and noise. The amount of noise coupled into the system is a function of the impedance transformer output impedance. The modulus of the noise transfer function is

$$|G_{noise}(j\omega)| = \left|\frac{j\omega}{j\omega + \omega_o}\right|$$

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$$= \frac{\omega/\omega_o}{(1 + \omega^2/\omega_o{}^2)^{1/2}} ,$$

where

$$\omega_o = 1/RC, \text{ and}$$

$$R = \frac{R_1 R_2}{R_1 + R_2} ,$$

with R_1 and R_2 as defined above. It is seen that in order to reduce the noise transfer, ω_o must be large, implying that R must be small.

A succession of possible networks for the impedance transformer was considered before arriving at the final choice, which was the non-inverting operational amplifier configuration of figure 4.

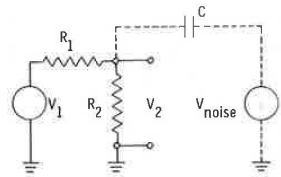
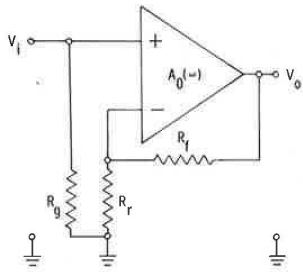


Fig. 3. Equivalent circuit for noise coupling into an ECG system. →



←*Fig. 4. Operational amplifier impedance transforming circuit.*

The voltage gain in this configuration at midband is given by

$$G_v = 1 + R_v/R_r ,$$

assuming that the open loop gain of the operational

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amplifier is very large and that the intrinsic input impedance of the operational amplifier is also very large, which are realistic assumptions for solid-state operational amplifiers. The resulting gain equation is not dependent on the actual value of the gain of the operational amplifier, but only upon the ratio R_f/R_r. The input impedance of this configuration is given by

$$R_{in} = \frac{R_g A_o(\omega) R_{ii}}{R_g(1+R_f/R_r) + A_o(\omega) R_{ii}}$$

where

R_{ii} = intrinsic input impedance of the operational amplifier and

$A_o(\omega)$ = open loop gain.

It can be seen that for the condition in which the quantity $A_o(\omega)R_{ii}$ is much greater than the quantity $R_g(1+R_f/R_r)$, which is often the case, the input impedance merely becomes R_g. The output impedance is

$$R_{out} = \frac{R_{io}(1 + R_f/R_r)}{A_o(\omega)}$$

where

R_{io} = intrinsic output impedance of the operational amplifier.

In order to determine the relative magnitude of the output impedance which might be expected, consider a typical operational amplifier. The intrinsic output impedance is seldom greater than 100 ohms, while $A_o(\omega)$ is seldom less than 1000. If the quantity $(1 + R_f/R_r)$ is 10, as it would be if the gain of the transformer were chosen to be 10, then the output impedance is only one ohm.

The best transformer would have zero output impedance and a voltage transfer function which is not dependent upon circuit parameters. By examining the ex-

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pressions for G_v and R_{out}, it is seen that these conditions may be satisfied by setting R_f equal to zero. Then G_v becomes unity and the output impedance is minimized. For obvious reasons this circuit is called the unity gain configuration. The DC offset of this configuration can easily be nulled to zero.

FABRICATION OF THE ELECTRODE

The fabrication of the electrode consisted of the deposition of the dielectric thin film and the formation of the contact plate itself, the choice of components for the impedance transformer, and the assembly of the complete electrode system.

Deposition of the Dielectric

The sputtering work chamber consisted of a pyrex bell, a water-cooled copper target electrode (cathode), a water-cooled copper substrate (receiving electrode) adjustable in height, and an accessory base ring containing water, gas and electrical feedthroughs. It was found that, when the output power was increased beyond around 60 percent of its maximum, spurious discharge modes developed, and the glow discharge spread out of the electrode region, filling the entire work chamber and creeping into the vacuum system. A grounded copper screen skirt around the receiving electrode eliminated the undesirable modes. In order to obtain sputtering from the entire dielectric target surface, and provide adequate heat dissipation, the targets were bonded to aluminum plates with Eccobond 59C moldable conductive epoxy adhesive. The plates were then fastened to the copper cathode by means of screws on their backs which fitted a threaded hole in the cathode. Although the uniformity of sputtering was improved by increasing the effective sputtering area, sputtering rates for a given input power level were reduced, increasing sputtering times and the probability of contamination and pinholes. Sputtering of the barium titanate, titanium dioxide and tantalum pentoxide took place in an argon-oxygen gas mixture, to prevent reduction of the oxide, at a pres-

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sure of around 25 microns. The silicon dioxide and aluminum oxide depositions were performed in argon alone, at the same pressure. Pilot slices were used to obtain the deposition thicknesses, which were measured with a Hacker Model 7000016 interference microscope, at a wavelength of 5896 Angstroms. Successful depositions, between 5000 and 50000 Angstroms thick, were obtained for all the materials except the aluminum oxide. A flaky white material was formed during the formation of the aluminum oxide film, and it was not possible to circumvent its formation. Capacitance values were not consistent between samples in a given run, but the differences could be attributed to differences in film thickness, since deposition was not completely uniform across the receiving electrode. It was also found that measured capacitance was between one-fifth and one-tenth as large as the calculated capacitance for the barium titanate films, and around twice as large as the calculated capacitance for the tantalum pentoxide films. These differences are not too surprising, since the calculated values were based on bulk permittivities, and the deposited films were probably not stoichiometric.

Impedance Transformer

The circuit for this work is shown in figure 5. The compactness of the unity gain configuration is desirable when space is limited. In addition to the operational amplifier requirements of very large input impedance, very large open-loop gain and low output impedance, certain other constraints exist. If the operational amplifier requires external frequency compensation, as many do, the simplicity of the unity gain configuration is lost in a maze of lead and lag circuits. It was therefore required that the operational amplifier be internally compensated, so that no external circuitry was required. Since the electrode was to be small in size, the operational amplifier packaging must be compatible with simple miniaturization. The dual-in-line package is consequently eliminated from consideration. One additional character-

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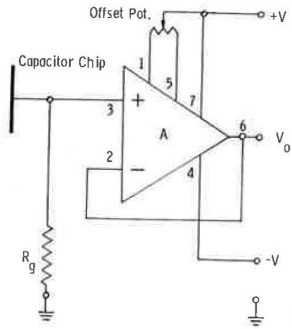
istic is perhaps the most important in determining the choice of amplifiers. Consider the effect of input bias current, which is present to some degree in all direct coupled operational amplifiers. This current must flow through the grounding resistor R_g. Because of the nature of the RC coupling of the insulated ECG electrode, R_g must be quite large. If R_g is chosen to be 100 megohms and the input bias current is 10 nanoamperes, then an input voltage of 1 volt is obtained and seen as a DC offset voltage at the output. While most operational amplifiers are designed so that an output offset can be nulled, they are not designed for compensation of such magnitudes. It is therefore necessary to specify that the operational amplifier have a low input bias current in order to maintain a high value of R_{in}.

The Fairchild μA 740 operational amplifier meets all these requirements. It is a high performance FET input operational amplifier constructed by the planar-epitaxial process. Its intrinsic input impedance is typically 10^{12} ohms. Its open loop gain is typically in the neighborhood of 5×10^5 or 114 dB, while the intrinsic output impedance is nominally 75 ohms. In addition to these characteristics, it is internally frequency compensated and comes in a TO-99 package which is quite suitable in size. Finally, the input bias current is typically 100 picoamperes. In order to be certain that the amplifier did in fact behave according to prediction, two measurements were performed on several configured circuits, after they had been wired into the electrode housings (R_g was between 100 and 200 megohms). The circuits of figure 6 were used in these measurements. In figure 6a, the input impedance of the system is

$$R_{in} = R_s \frac{V_o}{V_i - V_o}$$

A step voltage was applied as the input in figure 6b, and the output voltage was observed to be a decaying exponential of time constant τ; R_{in} was found to be

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← *Fig. 5. Circuit diagram for insulated ECG electrode.*

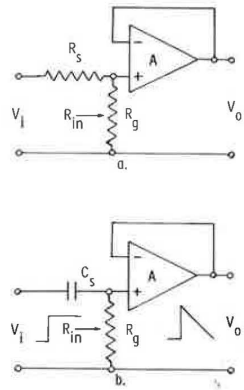


Fig. 6. Impedance measuring circuits. →

$R_{in} = \tau/C_s$. The value of the input impedance was equal to R_g in both measurements. The impedance transformer gain and bandwidth were measured for the same amplifiers (R_g = 100 to 200 megohms) by varying the frequency of the input signals at constant voltage and measuring the magnitude and phase of the output voltage. The circuits were found to have a voltage gain of unity from DC up to 20 KHz. No -3 dB point could be found between DC and 600 KHz.

The output impedance was not specifically measured, but an upper bound was obtained by applying a DC voltage to the input and measuring the open circuit output voltage. Without changing the input, a load resistance of 510 ohms was attached and the output voltage was determined again. No difference was measured in the output levels of any of the amplifiers tested. Since the accuracy of the measurement was within 1%, it was inferred that the upper bound on the output impedance was 5 ohms. It was not considered desirable to permit the amplifier to drive a smaller

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load than 510 ohms, since some damage could result to the impedance transformer. The input bias current was not directly measured, but output offset voltages of only a few millivolts were observed and easily nulled. It was also observed that circuit operation was satisfactory over a supply voltage range between $\pm$ 3 volts and $\pm$ 22 volts, which provided an extensive choice in power supply design. At the supply voltage chosen, $\pm$ 5 volts, a supply drain of 7 milliamperes was measured.

Insulated Electrode Assembly

The chip electrode, grounding resistor R_g, and operational amplifier were all incorporated into a Project Mercury electrode housing (3), which easily accommodated the electronics, resistor, and wiring, as well as providing a compact arrangement. A hole was drilled into the back of the housing to allow the snug insertion of the TO-99 case. To assure adhesion, 3M Scotchcast electrical resin was spread across the case-housing interface. Following the insertion of the operational amplifier, Teflon insulated number 29 AWG single strand wires were inserted into the housing through a small hole in its side, wrapped around the appropriate pins of the amplifier and soldered in place. Since it was desirable to have the grounding resistor inside the housing, it was covered by irradiated polyolefin shrink tubing, and soldered into place. The pins were then bent back into the housing cavity so that no protrusion past the front surface occurred. A top view of the electronics is shown to the left of the five cent piece in figure 7; the five cent piece is shown for relative size. Since the primary objective of the work was the evaluation of the dielectric squares and not the electrode electronics, and to conserve on cost, it was desirable to change dielectric squares without disturbing the electronics or housing, and the following scheme was adopted. A disk of clear plastic, 3.2 mm thick and 27 mm in diameter (approximately the outside diameter of the housing) was cut with a hole saw, which also drilled

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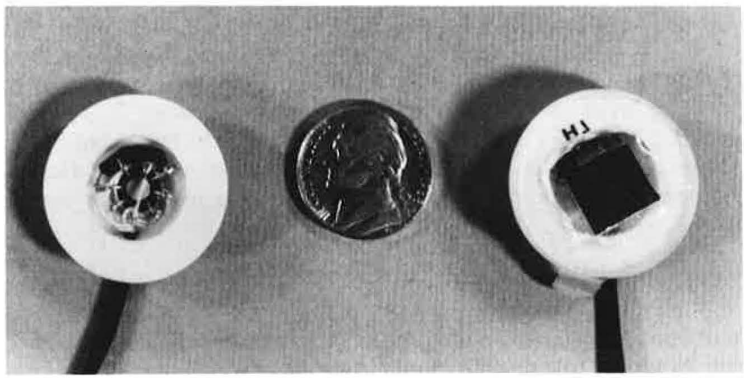


Fig. 7. Insulated electrode. Electronics are shown at the left, and the assembled electrode at the right.

a small hole in the center of the disk. A single wire (29 AWG, Teflon insulated) was bonded to the back side of the dielectric square using the same conductive epoxy that was employed in the sputtering target fabrication. The chip was then fastened to the plastic disk with insulating electrical resin, the wire passing through the center hole. Sufficient resin was used not only to assure a secure bond but also to cover the edges of the dielectric square. This eliminated any possible contact between the skin and the substrate, avoiding skin-to-substrate shorts. Connecting the capacitor disks to the impedance transformer now merely required soldering the protruding wire to the input pin of the operational amplifier. The plastic disk was held firmly to the face of the electrode housing with double-sided adhesive tape. Changing the electrode capacitor disks was simply a matter of detaching the disk from its tape connection and unsoldering the single wire. This procedure was performed in excess of 100 times on one electrode without damage to the operational amplifier or to any capacitor disk used. The assembled housing is shown at the right side of figure 7. External DC offset potentiometers

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were used to provide a zero offset voltage at the recorder input (although the offset voltage was very low). These could have been eliminated by using biasing resistors inside the housing, however potentiometers were used for convenience.

EVALUATION OF THE ELECTRODES

The evaluation of the capacitive electrodes was separated into two parts: the capacitance of the electrode chip and the electrode frequency response, and their performance in electrocardiographic applications.

Electrical Characteristics

Since the deposition of a counterelectrode for the measurement of the chip capacitance would have required the destruction of the chip, it was decided that the capacitance measurement should be made with the electrode in place on a subject. This procedure has the advantage also of providing information respecting the electrode capacitance when the chip is in actual contact with the skin. Figure 8 illustrates the measurement, in which the body volume conductor acts as a voltage divider. This measurement is similar to that used to obtain the input impedance of the impedance transformer. Since R_{in} had already been obtained for the electronics, and since the exponential time constant could easily be measured, the

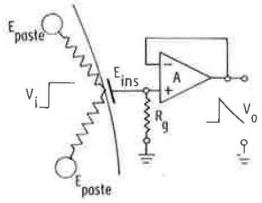


Fig. 8. Measurement of the frequency response of the electrode-subject system.

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effective capacitance could be calculated from $C = \tau/R_{in}$. This measurement also allows a simple specification of the lower frequency -3 dB point of the frequency response of the system. Since $\omega_o = 1/\tau$ corresponds to the first pole of the electrode transfer function specifying the lower cutoff frequency, this point is easily calculated from $f_o = 1/2\pi\tau$. Standard paste electrodes were used as contacts to which a step input voltage was applied. The output response was plotted on a direct writing recorder, the Offner Dynagraph type 504B, 3806 Preamplifier, which was also used to obtain the ECG data discussed later. A typical system response is shown in figure 9. The dielectric thin film on the capacitor disk is tantalum pentoxide, around 6000 Angstroms thick, but the response

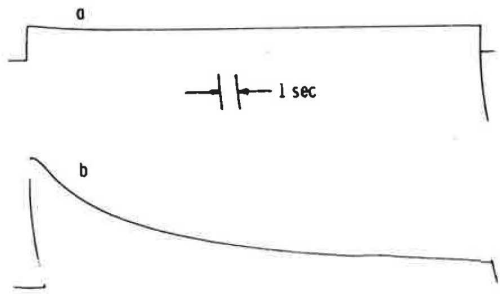


Fig. 9. Response (b) of insulated electrode (tantalum pentoxide, 6000 A) to step input (a).

is typical of that obtained with other thicknesses and dielectrics. It is clear from the nature of charging characteristics that the insulated ECG electrode is capacitively coupled; however, it is not apparent from the curve whether the response is a simple exponential or if it is more complex in nature. In order to be certain that the response was exponential, the data were replotted semilogarithmically. For most electrodes with medium to fast decay times, the plot

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indicated that the decay was that of a single exponential. Upon plotting the data associated with longer decay times, a second long time constant was discovered. The second time constant (approximately 15 seconds in duration) was attributed to an unknown decay of either mechanical or electrical nature in the recorder, which appeared despite direct coupling. The long decay can be noted in the upper curve of figure 9, which corresponds to the step voltage input applied to the paste electrodes. The second time constant was of sufficient length so that it did not interfere significantly with the acquisition of the decay data for the electrode system. It was assumed that the RC charging time corresponded to the time constant of the measured data so that the electrode capacitance and lower cutoff frequency for each electrode was obtained from the previous expressions. Average values obtained from the measurements are listed in table 1. Measured capacitance values are compared with values calculated from the bulk permittivities.

Electrode Performance

This portion of the evaluation consisted of two parts, the comparison of the insulated electrodes with conventional conductive electrodes, and the degree to which the electrodes--that is, the dielectric films--withstood skin exudates.

Comparison Studies. Simultaneous Lead II measurements, using NASA Project Mercury silver-silver chloride electrodes and electrolyte paste (3) and the insulated electrodes, were made. The two types of electrodes were placed close to each other in modified Lead II positions (figure 10), and both used a silver-silver chloride paste ground electrode on the right leg of the subject. Figures 11 and 12 are typical results. The upper curves in both illustrations are the reference electrocardiograms. In figure 11, the lower curve was obtained with a titanium dioxide electrode 6000 Angstroms thick, with a cutoff frequency of around 0.01 Hz; a silicon dioxide electrode, around

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Table 1. Average Capacitances and Cut-Off Frequencies for Insulated Electrodes with Various Dielectric Films

Film Thickness (Angstroms)	f_o (Hertz)	Specific Capacitance (μF per cm^2)	
		Measured	Calculated
	Barium Titanate (1500)		
47000	.027	.053	.28
24000	.029	.051	.55
17000	.014	.098	.78
	Titanium Dioxide (100)		
14500	.017	.086	.061
8800	.013	.11	.10
5900	.012	.16	.15
	Tantalum Pentoxide (25)		
47000	.13	.012	.0047
32000	.10	.017	.0069
17000	.073	.022	.013
	Silicon Dioxide (4)		
32000	1.1	.0014	.0011
20000	.70	.0018	.0018
4000	.16	.0094	.0089

30000 Angstroms thick, with a cut-off frequency of around 1 Hz, was used in obtaining the lower curve of figure 12. The apparent suppression of the S-wave and elevation of the T-wave are typical of the overshoot which takes place with reduced low frequency response.

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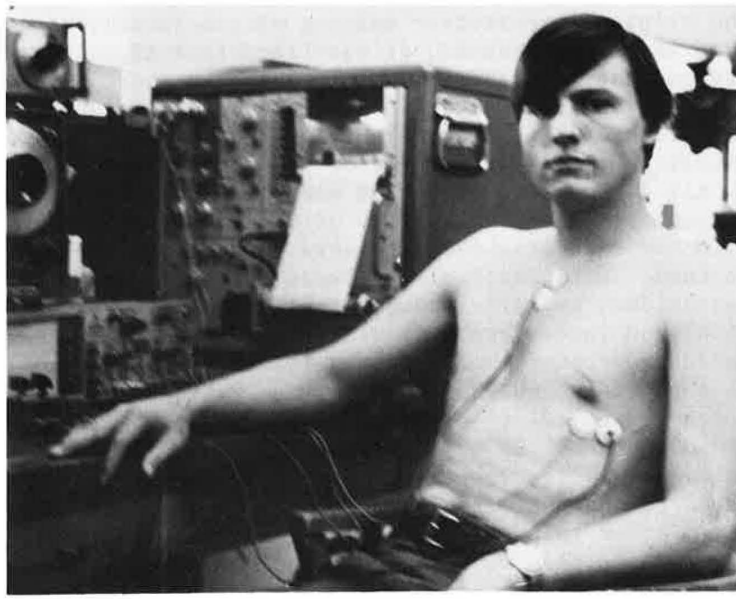


Fig. 10. Positioning of electrodes on a subject.

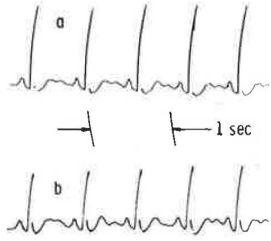


Fig. 11. ECG (modified Lead II) obtained with (a) reference and (b) titanium dioxide (6000 A) electrodes.

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When the insulated electrode measurements were begun, the skin was prepared by washing with methanol; however as work proceeded, it was found that signal quality was not degraded by leaving the skin unprepared. This represents a significant improvement over paste electrodes, which require not only degreasing, but usually abrasion or removal of the stratum corneum.

All the measurements were made in a very noisy environment. The high quality of the signals obtained with the insulated electrodes was attributed to three factors: uniformity of electrode transfer functions, operational amplifier power supply line noise rejection, and the extremely low output impedance of the impedance transformer. The μA 740 is specified to have a power supply noise rejection ratio of 70 microvolts per volt, or -83 dB; noise from the power supply or noise picked up by the supply lines was effectively eliminated. The low output impedance effectively isolated the output line from noise.

In order to establish the extent to which the insulated electrodes were free from noise and other artifacts, two sets of exercise measurements were undertaken. In the first set of measurements, four healthy college age subjects, three men and one woman, participated, and a bicycle ergometer was used to estab-

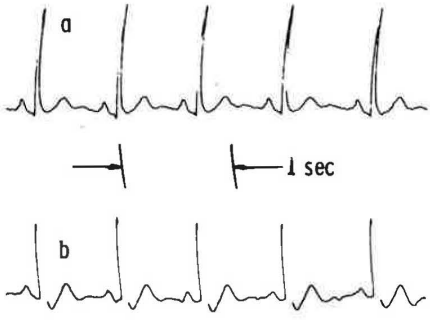


Fig. 12. ECG (modified Lead II) obtained with (a) reference and (b) silicon dioxide (32000 A) electrodes.

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lish the exercise protocol. A subject was seated on the bicycle ergometer and the insulated electrodes (tantalum pentoxide films, 17000 Angstroms thick) were placed in a modified Lead I configuration, just below the clavicle approximately halfway between the nipples and the axilla. The electrodes were positioned just above the breasts, in line with the nipples, on the female subject. Standard paste electrodes were placed adjacent to the insulated electrodes as references. A paste electrode was used as ground. An ECG was obtained with the subject at rest. The subject then pedalled against a resistance of 2.5 kilopounds at 20 kilometers per hour for thirty seconds, during which time another ECG measurement was made. Following the exercise period, ECG measurements were continued until the subject had recovered. Figure 13 is an ECG of a healthy 22-year-old male subject at rest. Figure 14

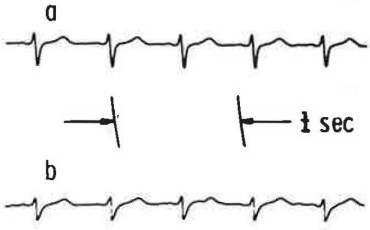
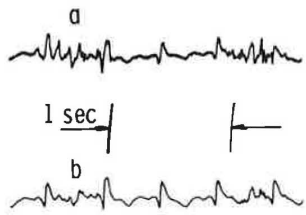


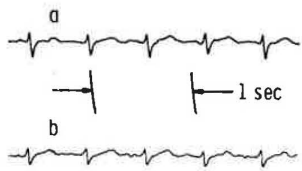
Fig. 13. Rest ECG (modified Lead I) obtained with (a) reference and (b) tantalum pentoxide (17000 A) electrodes.

Fig. 14. First protocol exercise ECG (modified Lead I) obtained with (a) reference and (b) tantalum pentoxide (17000 A) electrodes. (Signal polarities are inverted.)



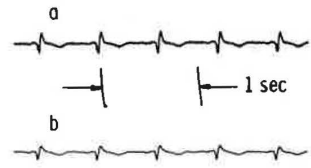
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is a representative portion of the ECG of the same subject during exercise; the insulated electrodes appear to exhibit fewer motion artifacts than the paste electrodes. During the measurements, erratic baseline shifts and saturation effects were observed, but these occurred with the subject at rest as well as during exercise, and it is believed that the erratic behavior was the result of electronic equipment malfunction, and was not related to the electrodes. In the second set, another protocol was established. In the new protocol, the subject stood relaxed for 30 seconds, ran in place for 30 seconds at a rate of approximately 120 steps per minute (high steps were required to avoid entanglement in the electrode wires) and stood at rest until his ECG had recovered. Measurements were made in the modified Lead I configuration, with a paste electrode ground on the left calf. Reference paste electrodes were placed adjacent to the insulated electrodes (tantalum pentoxide films approximately 17000 Angstroms thick). Figure 15 is the ECG during exercise. The data again indicate that the insulated electrodes are relatively artifact free. Figures 16



← *Fig.15. Second protocol exercise ECG (modified Lead I) obtained with (a) reference and (b) tantalum pentoxide (17000 A) electrodes.*

Fig.16. Rest ECG (V_3) obtained with (a) reference and (b) tantalum pentoxide (17000 A) electrodes. (inverted signal polarities). →



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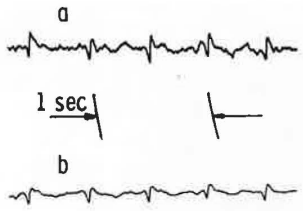


Fig. 17. Exercise ECG (V_3) obtained with (a) reference and (b) tantalum pentoxide (17000 A) electrodes. (Inverted signal polarities.)

and 17 are V_3 ECG measurements, with an insulated electrode in the V_3 position and a reference paste electrode placed adjacent to it. Figure 16 was obtained with the previous subject at rest and figure 17 with the subject exercising. The performance of the insulated electrode is considerably better than that of the standard.

The characteristics of the insulated electrodes which were determined by the previous measurements indicated that they could be used for screening purposes, where rapid attachment and removal of the electrode from the subject is required. Twenty-four college men and women (twelve each, of various physical and skin types) were used as subjects in a measurement in which electrodes were attached in a modified Lead I position (for rapidity). Tantalum pentoxide dielectric films, around 17000 Angstroms thick, were used, and a paste-type electrode was attached as ground to the right arm of the subjects. The subjects were seated at rest, and requested to unbutton the upper several buttons of their shirts, and the electrodes were placed in position with double-sided tape. There was no skin preparation, including degreasing. Readings were obtained immediately after the electrodes were attached, except for the first subject; some time was required for the electrode capacitance to charge up. It was found that a considerable time was required to affix the electrodes with the tape, and a number of the measurements were made with the subjects holding the electrodes in place during the measurement. Figure 18 shows a subject holding the electrodes; figure 19 is an ECG obtained with the elec-

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Fig. 18. Subject holding insulated electrodes in modified Lead I position.



Fig. 19. ECG (modified Lead I) obtained with insulated electrodes (tantalum pentoxide 17000 A) taped in place.

trodes taped in place and figure 20 is one obtained (from another subject) with the electrodes held in place. The quality of the ECGs which were obtained is fairly good, with the exception of those obtained from an exceptionally hairy subject, which were noisy. The effect of body hair on the measurement has not yet been studied. Several subjects performed the Valsalva

Fig. 20. ECG (modified Lead I) obtained with insulated electrodes (tantalum pentoxide, 17000 A) taped in place.



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maneuver (with and without the adhesive tape), and although some noise was present, the waveform was not badly obscured, and the typical rate response was observed.

The screening measurements were performed over a period of approximately one and one-half hours without apparent degradation of the electrodes. Similar demonstration measurements had also been performed over a seven hour period without a loss of signal quality. In order to test more explicitly the effects of skin exudates on the dielectric film, the following experiment was performed. Two plastic electrode disks, without housings or electronics were affixed to each of eighteen subjects, with double-sided adhesive tape, so that the dielectric films on the silicon chips were in intimate contact with the skin of the subjects. The disks were placed approximately level with the navel, laterally displaced around twelve inches to either side. Each disk was then completely covered with nonallergenic adhesive tape, except for a small slit through which the pigtail connection to the back of the silicon chip protruded. The dielectric films barium titanate, titanium dioxide and tantalum pentoxide were used in this experiment. It had been previously concluded that, for equal thicknesses, the silicon dioxide films were inferior to these others, and they were not tested in this measurement. The quality of the dielectric films was determined by charging the electrode capacitance through the pigtail and a paste electrode serving as ground, and observing the behavior of the voltage across the capacitor to ground with time as the capacitor charged in parallel to the leakage resistance of the dielectric film (figure 21). The capacitance and parasitic resistance of the films, determined from the voltage-time characteristics, were measured for all the electrodes after they had been affixed initially, and for specified electrodes after two, eight and twenty-four hours had elapsed. The three groupings of electrodes involved were: two hours (barium titanate: 17000 [2 each], 24000 and 47000 Angstroms; titanium dioxide:

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5900 [2 each] 8800 and 14500 Angstroms; tantalum pentoxide: 6000, 17000 and 32000 [2 each] Angstroms), eight hours (barium titanate: 17000, 24000 [2 each] and 47000 Angstroms; titanium dioxide: 5900, 8800 [2 each] and 14500 Angstroms; tantalum pentoxide: 6000, 18000 and 22000 [2 each] Angstroms), and twenty-four hours (barium titanate: 17000 [2 each], 47000 [2 each]; titanium dioxide: 5900, 8800 and 14500 [2 each] Angstroms; tantalum pentoxide: 18000, 32000 [2 each] and 48000 Angstroms). Two subjects continued to wear their electrodes for forty-eight hours (tantalum pentoxide: 18000 Angstroms and 48000 Angstroms). Since body bulk and film substrate resistances remained constant, any changes in the charging characteristics could be attributed to changes in the film quality. At the conclusion of the measurement, the results of

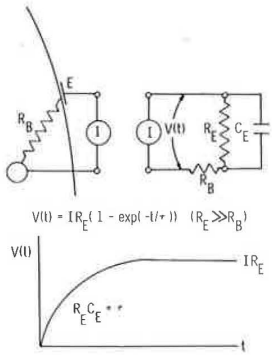


Fig. 21. Measurement of electrode capacitance and leakage resistance.

table 2 had been obtained. Certain general observations can be made. A number of films were poor at the outset, having leakage resistances as low as one megohm, although several films had values between 100 and 225 megohms. The thinner films of all the dielectrics appeared to have the highest leakage. Resistance values tended to remain constant at low values, or degraded with time, initial-to-final resistance ratios being as high as 90 to 1, although the average decrease for the films of moderately high initial resis-

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Table 2. Capacitance and Leakage Resistance of Thin Film Dielectric Layers. The Values of Resistance Are Lower Bounds.

Film Thickness (Angstroms)	Initial Values R (MΩ)	Initial Values C (μF)	Final Values R (MΩ)	Final Values C (μF)
	Barium Titanate Two Hours			
47000	16	.15	2.5	.24
24000	82	.012	3.1	.19
17000	94	.11	3.1	.19
17000	26	.096	8.8	.32
	Eight Hours			
47000	127	.083	1.4	.49
24000	31	.071	2.1	.96
24000	59	.051	2.5	.060
17000	6.2	.48	.71	.98
	Twenty-four Hours			
47000	12	.20	10	.18
47000	26	.17	3.1	.32
17000	58	.12	8.3	.22
17000	2.1	1.9	1.7	.25
	Titanium Dioxide Two Hours			
14500	88	.068	20	.12
8800	30	.66	7.5	.27
5900	27	.092	6.4	.22
5900	22	.29	2.0	.62
	Eight Hours			
14500	154	.075	9.2	.25
8800	58	.086	8.3	.24
8800	22	.21	2.1	.72
5900	48	.12	2.5	.80

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Film Thickness (Angstroms)	Initial Values R (MΩ)	C (μF)	Final Values R (MΩ)	C (μF)
	Twenty-four Hours			
14500	225	.057	2.7	.45
14500	bad data	bad data	15.4	.13
8800	3.2	1.4	3.3	.24
5900	1.0	.14	.32	3.1
	Tantalum Pentoxide Two Hours			
32000	100	.06	39	.076
32000	88	.057	15.6	.096
17000	82	.021	9.0	.10
6000	6.0	.16	6.0	.20
	Eight Hours			
22000	31	.064	14	.070
22000	33	.036	17	.12
18000	154	.020	46	.032
6000	54	.092	12	.17
	Twenty-four Hours			
48000	225	.004	133	.016
32000	65.5	.030	15	.10
32000	60	.025	5	.12
18000	27	.032	54	.037
	Forty-eight Hours			
48000	225	.004	63.5	.016
18000	154	.020	53.7	.037

tance (around 50 megohms) was perhaps between 5 to 1 and 10 to 1. Barium titanate exhibited the worst degradation of film quality with time. Capacitance values tended to increase in all cases. It is likely that pinholes existed in the films, and penetration of skin electrolytes into the pinholes increased the leakage and the film capacitance. It is interesting to note that tantalum pentoxide exhibited the best char-

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acteristics, generally beginning with the highest leakage resistance and degrading the least with time. At the end of forty-eight hours, two tantalum pentoxide films (18000 Angstroms and 48000 Angstroms) were still in good condition.

It might be pointed out that no significant skin irritation was found under the films and chips, although the skin in adjacent areas, under the adhesive tape, was frequently puckered and red.

SUMMARY

Electrocardiographic electrodes have been obtained by RF sputtering various dielectric films on silicon substrates and by suitable impedance transformation. The fabrication technique is general enough so that it may be used for any dielectric film, provided that no skin toxicity is present. Electrode performance is equal, and, with respect to noise, superior to conventional paste electrodes. (The latter characteristic has been observed with low level signals, in obtaining electroencephalograms (7).) Of the films examined, tantalum pentoxide appears to provide the best results.

At the present time, work is being performed to attempt to improve the film integrity. The sputtering system has been modified to improve the quality of the starting vacuum and a new gas purification system has been designed. A better pre-deposition substrate cleaning procedure, particularly respecting particulate material, has been developed. The cost of the operational amplifier is relatively high, and lower cost devices are being examined. Longer term testing of the electrodes is also planned.

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RECORDING ELECTRODES FOR CHRONIC INTRACEREBRAL IMPLANTATION IN MAN

A. M. Dymond*

INTRODUCTION

The use of electrodes placed intracerebrally in man has increased steadily in recent years. Many types of electrodes are being implanted today for a wide variety of clinical purposes, and the prospect is for even wider usage in the future (59). This increasing utilization of implanted electrodes requires an understanding of the many factors involved in their design and use. Whether the electrodes are being used to monitor potentials or to pass currents, their properties influence the interaction between the equipment used and the physiological system being confronted. Both the effectiveness of the procedure and the safety of the patient depend upon our understanding of the properties of the electrodes. Even in the case of passive recording of biopotentials, error and injury are possible. All electrodes can potentially irritate the surrounding tissue by mechanical means or by release of toxic substances, and they present interfaces with physiochemical properties capable of catalyzing unexpected biochemical reactions. Over time, these factors can result in perturbations of the normal physiological behavior of the surrounding tissue, or produce changes in the physical properties of the electrodes, further complicating the problem of recording through the complex impedance of the elec-

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trode-tissue interface.

The majority of chronic depth brain implantations in man so far has utilized electrodes comprised of clusters of wires cemented together. These electrodes have been used most frequently for recording the electroencephalogram (EEG) and for electrical stimulation. The regions in the brain where they could be placed have been somewhat limited, and the duration of implantation has usually not exceeded a few months. Today, techniques are being applied to record many other parameters with implanted electrodes in addition to the EEG. There is also an increasing need to place electrodes chronically into regions of the brain where they have not been used frequently before. As well, there is a tendency now to place larger numbers of electrodes, and to leave them implanted for longer periods of time. In applications such as seizure control, relief of chronic pain, and sensory and motor prosthesis, varying numbers of electrodes would be permanently implanted. To deal with these increasing requirements, it is necessary to make advances in the design and fabrication of implanted electrode systems. New materials and techniques, often first developed for aerospace applications, are finding their way into the operating room (71). The design of these systems must take into account many factors, such as electrical performance when recording, tissue toxicity in the brain, and mechanical performance of materials.

TISSUE TRAUMA AND MATERIAL TOXICITY

Any material which will be in contact with tissue for an extended period must not produce any irritation (43,48,72). Not only would this be an obviously unacceptable insult to the patient, but it is also likely to invalidate any recordings made, since they will be taken from tissue disturbed from its normal physiological state (19).

Recordings from disturbed tissue is a problem encountered to some extent in all measurements with implanted electrodes, since the introduction of an

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electrode is unavoidably associated with tissue trauma. For nontoxic materials placed in the brain, the end result of healing is encapsulation of the material in a cicatrix formed of fibrous and glial cells. This process follows a number of steps involving invasion of the damaged tissue by glial and vascular elements, edema, and demyelenization, and occurs more slowly in the brain than in most other tissues (3,16). Even after a month, when most of the debris has been removed and encapsulation of the electrode has begun, there is still a marked reaction in the surrounding tissue. The final stages of encapsulation may not be completed until six months after implantation.

Biochemical and electrical changes accompanying healing have been demonstrated (2). Tissue impedance measurements show a marked rise at around seven to ten days after implantation (64). EEG changes also occur during this first week after implantation, and recordings which require a stable baseline are usually postponed until after this period. Other measurements are also unstable shortly after implantation. For example, the rhythmic fluctuations in oxygen availability are not seen immediately after implantation, but develop slowly, reaching their full amplitude after several weeks (14). In practice, recordings from implanted electrodes are usually considered stable after one to two weeks have passed. However, this is the case only for implantation of nontoxic materials. When toxic materials are implanted, a stable recording condition may not ever be reached due to continuing insult to the surrounding tissue, and there is even a possibility of a deterioration in the patient's general condition (19).

Implanted materials might irritate the surrounding tissue for a variety of reasons. Mechanical irritation may arise from brain movement relative to an electrode rigidly attached to the skull, since the brain undergoes limited rotational and gliding movements within the skull (40,61,62,65). Motion is limited in areas where there are dural or bony restric-

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tions, and appears greatest in the parietal and occipital lobes.

This motion of the brain around a rigid electrode is a possible explanation of the expanded and cone-shaped gliosis sometimes seen in the cortex where an electrode has entered the brain (16). However, histological examination of human brain tissue after electrode implantation has shown minimal damage (26, 30), and severe vibration tests on monkeys with implanted electrodes have shown no histological differences from controls (1). Although these instances did not demonstrate any gross adverse effects of electrode movement, small-scale movements have been seen in acute microelectrode studies in man using conventional metal microelectrodes. In this case, very slight movements of the head cause displacement of the electrode tip from a neuron being recorded. This can be eliminated by using very fine, flexible electrodes, and chronic single unit recordings have been obtained from patients with those electrodes for periods of months (3).

Materials can exert toxic effects for several reasons. Much of the toxic effects of metals arises from the release of ions into the adjacent tissues. The magnitude of this effect depends on the specific toxicity of the individual ion, and the numbers of ions released. The exact mechanisms whereby these ions affect cells are generally not known. Silver ions may exert their toxic effects by complexing with protein acid and sulfhydryl groups (51). Besides local tissue reaction, ions can cause long-term stimulation of brain tissue, as has been demonstrated for ferric ions (31).

The release of some metallic ions into an electrolyte is a normal thermodynamic process as a metal comes to equilibrium with its environment. The quantity of ions released is determined by a number of factors, including the metal's position in the galvanic series. When measured relative to a calomel reference electrode, most metals suitable for brain implantation show a positive potential greater than

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300 mV (56). However, many other factors must be determined before a metal can be deemed suitable for implantation (50,81). For example, metal corrosion can occur on a single piece of metal whenever there are adjacent dissimilar surface regions, just as it occurs between two dissimilar metals in contact in an electrolyte. Dissimilar regions occur at a microscopic level on any piece of metal, and the magnitude of this effect is dependent on the prior processing of the metal (13,55). Prior processing can also affect the nature of any films or oxide layers on the surface which partially shield the metal from contact with the electrolyte.

Implantation of various metals in the brain has provided a number of candidates for chronic electrodes (8,24,27,34,42,50,70). In general, metals such as gold, platinum and many platinum alloys, some stainless steels, tantalum, zinconium, rhenium, titanium, and tungsten appear to be sufficiently nontoxic for chronic implantation in the brain. Other alloys such as gold-nickel-chromium and nickel-chromium-molybdenum (Vittalium) also may be satisfactory. Silver and silver chloride are definitely toxic and should not be placed in the body for any extended interval.

Plastics and other dielectrics are also being used more extensively for implanted devices and must also satisfy a number of criteria in regard to toxicity. Many of these materials are complex compounds, and the possibility exists for incomplete reactions to occur during fabrication, allowing toxic substances to diffuse out of the material after implantation (48, 72). For this reason, assurance of nontoxic behavior in an implanted electrode must depend upon fabrication techniques as well as material selection.

INFLUENCE OF THE METAL-TISSUE INTERFACE ON RECORDING

The metal-tissue interface of an implanted electrode is the junction between the recording equipment and the tissue under study. All signals must pass through this interface, and its properties can influence the characteristics of the signal recorded (37).

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Our present model of the metal-tissue interface shows a complex interplay of phenomena (9,17,49). After coming to equilibrium, the metal generally has some potential relative to the bulk electrolyte, resulting from chemical reactions between them. The reaction most frequently cited involves the release of metal ions into the electrolyte. However, other simultaneous reactions may be occurring, such as redox reactions with organic species from the tissues. These parallel reactions can produce a "mixed potential" across the electrode interface, which may fluctuate with changes of reacting species concentrations in the electrolyte (23). Net forward and reverse currents, called exchange currents, pass through the interface due to these chemical reactions, and are equal when the electrode is at equilibrium.

The detailed structure of the metal surface also influences the electrode's behavior. At a microscopic level, the electrode surface usually appears heterogeneous and polycrystalline. This can be dependent on the pretreatment of the electrode, and will vary due to factors such as heating and mechanical processing. These different regions can have different physical and chemical properties, and potentials can exist between them (7). These potentials between different surface regions on the same electrode can cause corrosion currents to flow in the same way they would between two dissimilar metals. The surface of the electrode may also be covered by films, oxide layers, and precipitates, all of which may be in a state of flux, and may be associated with changing corrosion currents as regions of metal are exposed and covered (47,83). Organic species are also absorbed and removed in the interface, and undergo changes in orientation with changing potential (41). The potential between the metal and electrolyte causes ions from the electrolyte to be attracted toward the electrode, which becomes surrounded by ions in an inner compact layer and an outer diffuse layer (63).

When the metal-tissue interface impedance is measured with sine waves, it is found to vary with both

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the frequency and voltage (39,45,52,73,79,80). Fortunately for recording purposes, the impedance is fairly stable until the potential across the interface reaches one volt. However, the impedance changes with frequency are large throughout the frequency range of biological signals. These effects are shown in figure 1 for a selection of different metals having possible applications in chronic recording electrodes. The impedances were measured in

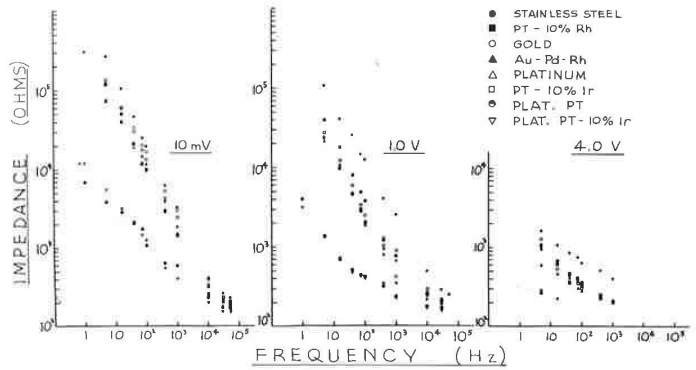


Fig. 1. Impedance versus frequency curves for eight different metal electrodes with apparent surface areas of 10^{-2} cm^2, measured in saline at three different voltages.

saline, relative to a large reference electrode whose impedance was always much less than the electrode under study. In all cases, the impedances decrease with frequency until they reach the impedance level of the electrolyte solution with which they were in series. At a potential of one volt, the impedances show a slight drop, with the effect being least for stainless steel. At four volts the decreases in impedance are marked. At these two higher voltages, it is possible to separate the metals into three groups based on their impedances, with the stainless steel having the highest impedance, the two platinized electrodes in

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the lowest group, and the remainder of the metals showing similar intermediate values.

The slight impedance differences between the three groups may be due to general surface properties. For example, the platinized metals have the lowest impedance because of a larger effective surface area due to the porosity of the platinized layer. Except for this difference, the overall AC impedances of the different metals are similar, suggesting similar mechanisms underlying the impedance changes. Many mechanisms could potentially play a role in determining the AC impedance. One of the most important is diffusional factors in the surrounding electrolyte, which would ideally show an impedance decrease proportional to one over the square root of the frequency. Another possible factor is the varying relaxation times of molecules absorbed onto the metal surface of the electrode (8). A further possible explanation of the impedance variation with frequency is due to the heterogeneous polycrystalline microstructure of the metal surface (35,66). Each region of this surface may have a different effective resistance and capacity between it and the bulk electrolyte surrounding the electrode, resulting in many parallel RC pathways to the metal surface. Each pathway would have a different relaxation time, and the total impedance would show frequency dispersion.

The physical properties of electrodes can affect recording characteristics. Variations in recording properties between different metals used in recording applications such as polarography are well known. One of the most common polarographic applications of chronically implanted electrodes is recording oxygen availability or pressure (22). For this use, the electrode has a negative potential in the range of 0.6 volts applied to it, relative to a low impedance reference electrode. This applied potential causes a current to flow, and the magnitude of the voltage causes the major chemical reaction mechanism to be consumption of molecular oxygen in the vicinity of the electrode. The current flow through the electrode, on

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the order of a few microamperes or less, depending on the size of the electrode, is dependent on the amount of oxygen available to react at the tip of the electrode.

The most commonly used metals for polarography are gold and platinum. The current-voltages curves and the best operating voltage are different for the two metals. The responses in complex biological media also differ, as do the effects of aging of the electrode during use (12,58). Investigators must choose one metal over the other after considering the details of their application.

There are also numerous possible sources of error when making passive recordings with metal electrodes. One of the most practical problems comes from the interrelationships between the source of the electrode and the input impedance of the recording amplifier. Accurate recordings of bioelectric phenomena can be made only if the input impedance of the amplifiers is much larger than the source impedance being recorded from. If the source impedance becomes comparable to the amplifier input impedance, the original potential appears divided between those two impedances, and the signal actually being amplified is reduced correspondingly. This is illustrated in figure 2, which shows autospectrums of EEGs recorded with and without sufficiently high amplifier input impedance.

These figures point out a further complication encountered when dealing with the metal-tissue interface, resulting from the impedance variation with frequency. The higher electrode impedance at low frequency can cause attenuation of the low frequency portion of the biological signal, while the high frequency components are being recorded satisfactorily. This effect is seen in the second autospectrum in figure 2, and can result in waveform distortions (29,36).

Noise and spontaneous artifacts provide another source of error in recording with depth electrodes (57,60). These artifacts are somewhat dependent on the surface condition of the metal and have been shown to be different for different types of metals (46).

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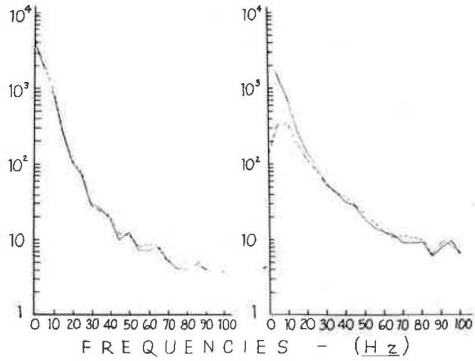


Fig. 2. Autospectrums of monopolar EEGs recorded simultaneously from adjacent stainless steel electrodes placed acutely beneath the visual cortex in a cat. The autospectrum on the left was obtained from recordings made when both amplifiers had high input impedance. On the right, the input impedance of one amplifier (dashed line) was reduced by shunting it with a resistor, causing attenuation of the lower frequency components recorded from this lead.

Spontaneous artifacts are often due to corrosion currents which can arise from formation and disruption of films and oxide layers (47). Fluctuating potentials can also arise from interaction of the electrode with material in the electrolyte (10,33). This has been demonstrated for several metals placed in tissue being subjected to X-ray irradiation (11,32). The irradiation caused a voltage drop in some platinum metals, but did not affect gold. There were no changes in pH or oxygen availability observed during irradiation, and the effect was explained in terms of aborption on the platform surface by radiolytically generated hydrogen and hydrogen peroxide.

In practice, chemical interaction producing spurious potentials could come from fluctuations of chemical species from the electrode itself, and from biochemically generated species capable of redox reac-

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tions with the electrode. Unknown chemical products formed during electrical stimulation may also exert an effect when the same electrode is immediately used to record (50,74).

Another problem when recording could come from spontaneous polarography (15,44). This form of polarography obtains the voltage applied to run the reactions by forming an electrochemical cell from the contact of dissimilar metals. This behavior could occur accidentally on a large scale during recording if several electrodes were tied directly together at some point, or even perhaps if they were tied together through amplifiers with low input impedance. If such a current is allowed to flow, it will be polarographic and the current magnitude will fluctuate in response to whatever chemical species was controlling the polarographic reaction mechanism. These current fluctuations would be accompanied by voltage fluctuation at the input of the amplifier which would be superimposed on the bioelectric potentials.

In an effort to evaluate the recording properties of different metals (stainless steel, gold, platinum, gold-platinum-rhodium alloy, platinum-10% iridium, platinum-10% rhodium, platinized platinum, and platinized platinum-10% iridium) when used to obtain the EEG, electrode bundles with closely spaced tips were made of different metals and chronically implanted intracerebrally in cats (29). Simultaneous recordings were made through these electrodes, and autospectrums of the EEGs were compared. In this study, for frequencies in the range of 0.3 Hz to 100 Hz, no significant differences in recording properties could be demonstrated. It is probably valid to extrapolate this finding to recordings in higher frequency ranges, such as neuronal discharges which have large components around one kiloHertz. However, it is unlikely recordings from different metals below a few tenths of a Hertz are comparable since the unstable DC potential of the metal is superimposed on the biologically generated potentials.

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PRESENT AND FUTURE IMPLANTABLE ELECTRODE SYSTEMS

Most electrode implantation in man uses a stereotaxic system to permit accurate electrode placement into specified targets in the brain (78). Unlike the stereotaxic systems for animals such as cats and monkeys in which external bony landmarks of the skull can be used as positional references for anatomical sites inside the brain, accurate human depth implantation must rely on internal landmarks. These are obtained from recognizable structures within the ventricular system, which are visualized during surgery on X-ray radiographs made after filling the ventricular system with an X-ray contrast medium.

The Trent-Wells stereotaxic apparatus is representative of the hardware systems in use today for human depth implantation. Figure 3 shows this device in the operating room with a patient's head mounted in place. Four posts secure the head to the framework, and adjustments in three directions allow positioning within the instrument. After filling the ventricles with air or a suitable liquid contrast medium, lateral and anterior-posterior radiographs are made which show the internal structure of the brain superimposed on reference marks on the stereotaxic. After alignment, coordinates for specific targets in the brain can be calculated from the radiographs and a stereotaxic atlas of the brain.

In the technique used by Crandall for chronic implantation of patients with uncontrolled focal epilepsies, a twist drill mounted in a stereotaxic-held guide aimed at the desired target is used to make a small burr hole in the skull (20,21). A small opening is then made in the dura by electrocautery. The drill is replaced in the guide by a special screwdriver which is used to place a hollow guide screw in the skull. An electrode with an appropriate length to reach the target is then inserted through the guide screw into the brain and fixed in place on the screw with polymethyl methacrylate. Electrode tip position is confirmed by radiograph.

After all of the electrodes have been implanted,

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the head is wrapped in a turban bandage and the lead wires from the electrodes are bundled together and brought out. The patient wears this head dressing for the duration of his stay in the hospital.

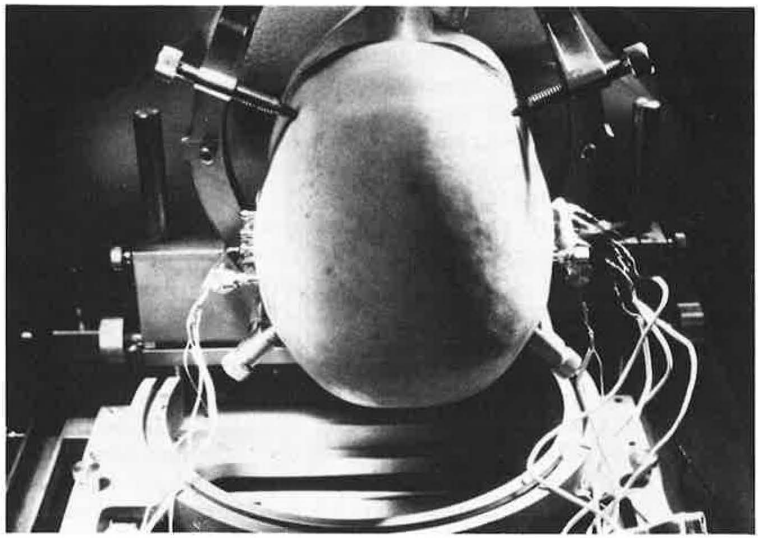


Fig. 3. Top view of a patient's head in place in the Trent-Wells stereotaxic device in the operating room. Hollow guide screws have been placed bilaterally in the temporal regions, and electrodes have been inserted through some of them.

In the past, the electrodes implanted have been either bipolar or coaxial, with diameters on the order of 0.025 inches. These were made of medical grade stainless steel wires and tubing, held together by epoxylite, and were either made by hand in the laboratory or obtained commercially. The electrodes were used to record the EEG over a period of several months, and for brief sessions of electrical stimulation. Electrodes of this general type are often used for implantation in man today, and are satisfactory for lim-

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ited applications.

Implanted electrodes are capable of recording much more than the EEG alone. For example, single neuronal discharges have now been recorded on a chronic basis from patients (3). Oxygen availability and temperature have also been measured, and hydrogen clearance can be obtained as an estimate of regional cerebral blood flow (6,18). Impedance has also been measured with implanted electrodes, and the permeability of the blood brain barrier can be studied with compounds detectable by polarography (64,67-69). Cannulae included in electrodes can be used to inject and sample compounds in the brain (25).

An example of this type of "combination" electrode is shown in figure 4. This electrode is presently being implanted at UCLA, and is able simultaneously to measure EEG, oxygen availability, temperature, and single neuron discharge. The electrode is still built by hand, and is centered around a platinum tube. The tip of this tube and the tip of a platinum wire attached to its side are used for bipolar EEG recording and limited electrical stimulation. Oxygen availability is obtained from a gold wire attached to the side of the tube, and temperature is monitored by a miniature bead thermistor mounted near the electrode tip. Neuronal discharges are recorded by fine wires inserted through the lumen of the tube, and allowed to project out a few millimeters into the tissue. The tube serves as a guide for the fine wires which are not stiff enough to be inserted by themselves. Once placed in the tissue, these fine wires are sufficiently flexible to be able to follow movements in the brain without damaging the surrounding cells.

Electrodes must have sufficient rigidity for accurate placement in the brain. This can be obtained by using a stiff cannula or supporting rod to carry a flexible electrode into position, after which the support may be removed, or, more frequently, the electrode itself is made sufficiently rigid for insertion. With either a flexible or rigid electrode, the electrode is usually fixed firmly to the point of entry. This fix-

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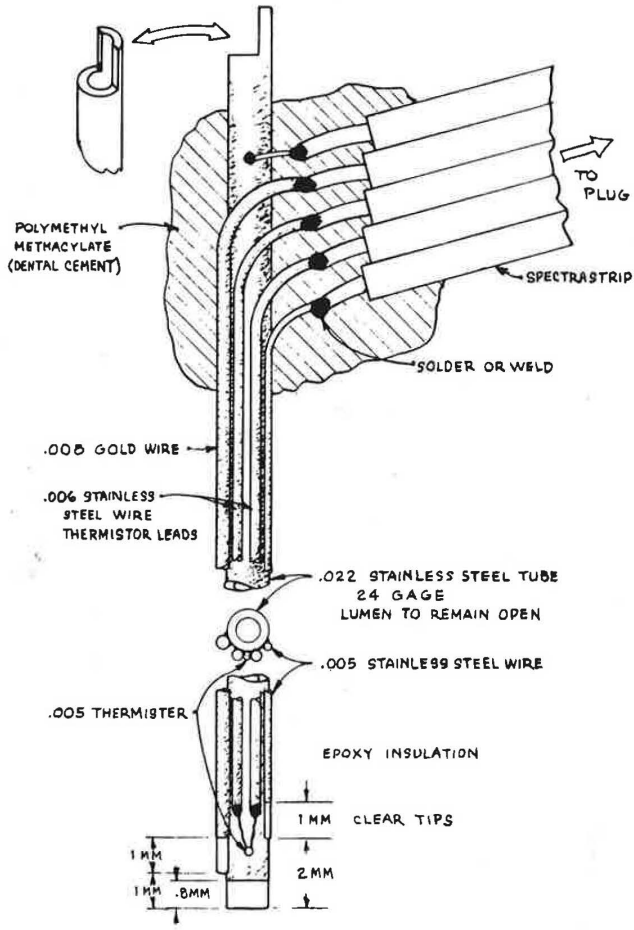


Fig. 4. "Combination" electrode implanted for diagnostic purposes in patients with uncontrolled focal epilepsy. This design permits electrical stimulation of the brain and simultaneous measurement of the EEG, O_2 availability, temperature and single neuronal discharges.

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ation may result in protruding guides fastened to the skull, and in some procedures requires the maintenance of a sterile field under the head dressing for the duration of the implant (5,20,53,69,75).

Major technical problems would have to be overcome to enable accurate insertion of electrodes into the brain by means other than the conventional approach of pushing a probe to the target. A very flexible electrode is desirable, particularly for long term implantation, since it would minimize trauma around the electrode resulting from relative movement between the brain and the electrode which is rigidly attached to the skull. Possible trauma along the electrode track due to motion of the brain is a serious consideration which has discouraged many investigators from implanting regions such as the brain stem which may be more subject to this motion than other regions. However, if the electrode is too flexible, it is necessary to guide it through or attach it to some type of more rigid support for implantation. This increases the trauma produced along the electrode track during insertion, and allows possible dislocation of the electrode tip during removal of the guide.

The problem of trauma could be minimized by finding the finest electrode which could be accurately inserted by itself into the brain. In addition to factors of electrical behavior and toxicity, fabrication of a long fine electrode must also consider material properties influencing mechanical stiffness and failure mode. The stiffness of an electrode is dependent on the physical dimensions and the modulus of elasticity (Young's modulus) of the material. For a round electrode, the resistance to buckling caused by axial loads varies as the fourth power of the diameter, and linearity with the modulus of elasticity. The strength behavior of interest in an electrode concerns the failure mode. Depending on the material and the fabrication technique used to make an electrode, a sufficiently large load will cause it either to bend or break (38). An electrode would have to be strong enough to avoid bending during normal handling and insertion.

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Brittle fracture would be unacceptable in an electrode used for depth implantation, as would breaking or chipping of materials from the side of the electrode.

Preliminary studies to estimate minimum electrode size for accurate insertion have been conducted using tungsten-boron filaments (28). These had an inner tungsten core of 0.0005 inches surrounded by boron, and were chosen because of their high elastic modulus. After insertion of symmetrical composite filaments 6 cm long and 0.0005 inches in diameter through fresh steer brain, the mean tip dispersion was found to be 0.7 mm. This is safely within the dispersion tolerance limits for human implantation. The 0.0005 inch diameter tungsten-boron electrode is satisfactory in terms of reaching a target in the brain, and it will stand up to normal handling without damage. Several such electrodes were implanted and used successfully in animals. Unfortunately, this electrode cannot be visualized using standard operating room X-ray technique, and when it is deformed sufficiently, it fails by brittle fracture.

Both of these problems can be eliminated by increasing the relative amount of metal in the electrode. Also, it might be possible to add another layer of metal and dielectric to form a coaxial electrode. Fabrication of this type of electrode has to make use of advanced technology. Materials chosen must satisfy requirements for toxicity, electrical recording and stimulation, mechanical stiffness and strength, and compatibility with an applicable fabrication technique. Possible fabrication methods include sputtering, thermal deposition, and evaporative and chemical vapor deposition. Of this group, the last two techniques offer good versatility. Materials which could be used to make a satisfactory composite coaxial electrode include titanium and titanium dioxide dielectric, and tungsten and a mixed aluminum oxide-silicon dioxide dielectric (54). Efforts to fabricate these types of electrodes are under way. This electrode would represent the lower diameter limit of an electrode which could be implanted using conventional human stereo-

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taxic apparatus. Modifications of the equipment and procedure will incorporate electrode guidance from the guide block of the stereotaxic itself, rather than by using the intermediate step of inserting guide screws into the skull. A cap at the top of the electrode could press fit into the burr hole in the skull, and the lead wires would be tunneled subcutaneously to a central connector plug, as is illustrated in figure 5. This would permit subcutaneous placement of all components except the connector, and would eliminate the dangers of infection around the electrode entry points, and of mechanical forces on the electrode protruding above the scalp (5,53). This basic fine electrode would also be suitable for further modifications, such as the additions of extra conductors, dielectrics or thermocouples, by the integration techniques used for

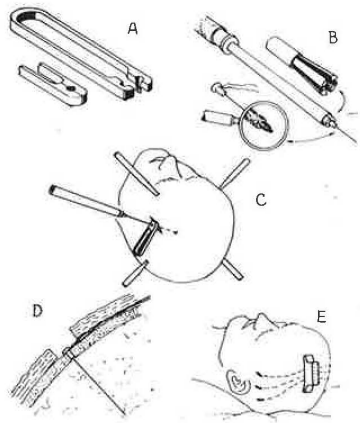


Fig. 5. A new electrode and implantation technique under development for use in man. A small composite electrode would receive guidance during insertion from an electrode holder traveling in the stereotaxic guide. The precast electrode cap would press fit into a twist drill hole in the skull, and the lead wires would be tunneled subcutaneously to a central connector plug. (From (28): by permission.)

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electronics (76,77,82). Further modifications could include encapsulation of miniaturized preamplifiers into the plug at the top of the electrode, and completely subcutaneous implantation of the system by the use of multichannel telemetry.

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TECHNICAL & DESIGN CONSIDERATIONS OF DISPOSABLE ELECTRODES

Joseph H. Johnson*
Tracy Floren*

The most widely used ECG monitoring electrodes are the disposable type. Disposable electrodes can be divided into two classes: pre-gel and dry (non-gel) electrodes. Pre-gel electrodes are the most popular, as they are immediately ready for use. Dry electrodes require the addition of electrolyte prior to use. This is time consuming and necessitates the additional purchase of gel for use with the electrodes. Because the gel is already in contact with the electrode in the pre-gel type, any reaction between the gel and the electrode has already taken place during storage, thus immediate stability when the electrode is first applied.

Design considerations of a disposable electrode include:

1. Function. The electrode should work well with all brands of monitors, including telemetry units.
2. Patient comfort. As the electrode may be worn as long as five days it should be comfortable and non-irritating.
3. Cost. Cost is particularly important in disposable products as they are viewed as recurring expenses by the customer. Also the product must be competitively priced.
4. Mass production capabilities. The electrode must be designed to facilitate volume production for cost and delivery reasons.
5. Usage. Ease of use by hospital personnel, such

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as packaging and application time.

6. Governmental requirements. The electrode and packaging should meet all state and federal regulations.

Material selection and component design satisfies the requirements of the foregoing. Further explanation of these considerations can be made by a close look at a pre-gel and dry electrode.

PRE-GEL ELECTRODE (Figure 1)

A disposable electrode should adhere to the body for three to five days. The longer it remains on the patient, the less its true cost and the more convenient from a personal standpoint. Allowing the electrode to remain attached beyond five days is not advised as the patient may develop a skin irritation beneath the pad. Removal of the electrode, inspection of the skin, and reapplication of a new electrode in a different location, is the generally accepted procedure. Adhesive area and tack determine how long an electrode will stay attached. The strength of the adhesion must be

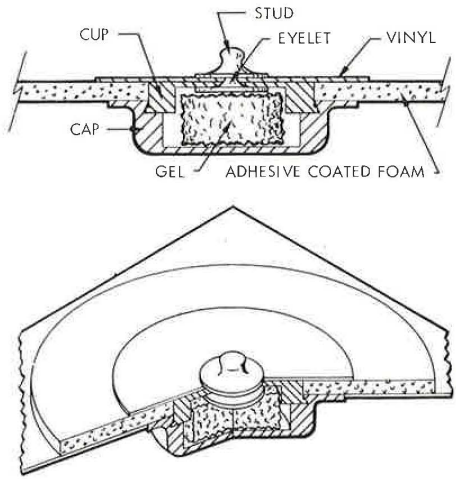


Fig. 1. Pre-gel electrode.

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moderate as extreme tack may cause damage to the patient's skin upon removal. Thus an electrode which has more area and a little less tack is more desirable than a smaller area electrode with more tack. For electrodes made from 3M brand Micropore tape, an effective balance between tack and area was found to be about 6.59 in square inches (total area less gel area). Hayes foam electrode, using 3M brand medical adhesive has an effective adhesive area of 4.12 square inches. The adhesive used should be selected for its tack, non-allergenic features, and ease of use in manufacturing.

Adhesive Carriers

The two basic adhesive carriers in common use today are Micropore tape and thin flexible closed cell foams. 3M brand Micropore tape is a combination adhesive, carrier and backing, which is ready for use when received from the factory. This tape was specifically designed for attachment to the skin in various medical applications and is therefore well adapted to use in electrode construction. When considering foam, application requirements dictate that it should be light and flexible for patient comfort yet strong enough to prevent tearing when removed from the body. Before selection, tests must be conducted to assure that the foam and adhesive are compatible.

Cup

The cup serves several purposes. Its prime function is to hold the gel, keeping it in place until use. After the electrode is applied to the body the cup forms a seal with the skin, preventing the gel from spreading or drying. The floor of the cup (through which the metal snap is inserted) gives stability to the snap, thus reducing movement of the snap and artifacts. The cup is made of a soft rubber-like material for patient comfort. Materials with a Shore A hardness range of 50-60 allow the cup to conform to the contours of the body; yet the cup is rigid enough to retain its shape and function in conjunction with the cap.

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Cap

The cap protects the gel during handling and shipment and forms an airtight seal with the cup, preventing the gel from drying. Though the friction fit between cap and cup is airtight, the softness of the two materials allows easy removal of the cap for electrode use.

Vinyl Disc

A hole through the adhesive-coated foam makes movement of the cup somewhat independent of the foam pad, helping to reduce artifacts. The vinyl disc secures the cup to the body of the electrode. A soft vinyl should be used and the disc diameter kept to a minimum so that the flexibility of the foam is not impaired.

Metal Contact

It has been well documented that silver/silver chloride contacts make the best electrodes. The principal reasons are electrical stability of individual units and the consistency of offset voltage (as measured against a standard) in mass production units. Furthermore, in a pre-gel electrode a contact must be used that is not corroded by the electrolyte. In that aspect, silver/silver chloride and stainless steel are acceptable materials. Since most disposable electrodes available today use the clothing type snap as a contact, availability of materials from their manufacturers must be considered. Clothing snaps used in the electrode consist of a stud and eyelet and are often referred to as a snap or metal contact. Table I shows a comparison of voltage offsets exhibited by electrodes utilizing metals in current production. Data in this table were prepared by placing two electrodes back to back (pre-gel surface to pre-gel surface) and measuring the voltage potential between them for five days. The first reading (day one) was taken immediately after the electrodes were placed together without allowing them to stabilize, therefore these readings may be more erratic than if they had been taken 10-15 minutes later. This table was prepared to com-

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pare the available materials, and not to establish absolute electrode values. Silver/silver chloride is clearly the most stable and reproducible of the materials. Though table I shows silver/silver chloride electrodes to be the most reliable, this does not mean that the other materials are not acceptable. In fact, most dry electrodes use nickel snaps. A potential problem exists: that a monitoring instrument may not function due to the offset potential or voltage fluctuations between two electrodes. In these cases the silver/silver chloride electrodes must be used.

Though silver plating will work in the manufacture of a silver/silver chloride electrode, chlorided solid silver works the best. Plating techniques and machines used in the electrode manufacture do not produce a product reliable enough for this market. If for any reason the silver plate cracks, exposing base metal, the offset potential can become excessive and corrosion causing discolorization may result. If extreme caution is taken, silver plating may be used and the plated part chlorided with the same method as solid silver. Best results are obtained by using the base metal brass, plating the brass with nickel to form a less porous surface, then adding about .002 inch silver plating.

Chloriding. Chloriding for mass production is best accomplished by electrolysis. One good method of depositing a silver chloride layer on solid silver is to make the silver parts positive to a saline solution (1-5% concentration), at a current of 0.1 to 10 ma/cm^2 of surface area for several minutes. The parts are then rinsed and dried. Care must be taken with the purity of the silver, purity of the saline solution, the amount of current and length of time the current is applied or a purplish color will result. Actually, the purplish electrode is a good quality silver chloride, but looks dirty and may cause customer complaints.

Electrolyte

The electrolyte or gel is important as it must be

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TABLE I

POTENTIAL BETWEEN TWO ELECTRODES BACK-TO-BACK

Day	1			2			3			4			5		
	Avg.	Hi	Lo	Avg.	Hi	Lo	Avg.	Hi	Lo	Avg.	Hi	Lo	Avg.	Hi	Lo
Silver/Silver Chloride	2.57	7.50	0.53	0.79	2.80	0.05	0.42	1.26	0.07	0.32	0.90	0.02	0.4	1.51	0.2
Brass	8.65	28.9	0.23	10.6	34.8	1.01	35.3	80.3	2.35	29.5	71.0	5.65	21.3	58.8	1.00
Nickel	11.8	31.7	0.37	15.9	46.1	0.93	17.0	49.6	.01	21.9	56.0	.05	28.5	57.0	2.0
Stainless Steel	51.7	192	0.25	75.0	196	0.21	24.4	74.7	0.15	14.9	96.0	0.13	0.13	0.24	0.02

compatible with the metal contact and skin. Utilization of silver/silver chloride offers a great deal of flexibility since its reaction with a chloride solution is minimal. Potassium or sodium chloride offers the best conductivity of the salts. Other media such as citric acid may be used, but are inferior to the chlorides. A gel viscosity of 10,000-15,000 centopoise and a ph range from 5.5 to 7.0 is recommended. The gel should not be buffered, allowing the ph of the gel to float and match the ph of the skin. Another consideration is the evaporation rate of the gel in conjunction with the packaging. The Hayes electrode utilizes a friction seal between the cup and cap to prevent the gel from drying and the gel is formulated to be compatible. For use in the electrode a small open cell foam pad saturated with gel is placed in the cup. This foam pad supports the gel and maintains a continuous column of electrolyte between the contact and skin.

DRY ELECTRODE (Figure 2)

Many of the same criteria such as adhesive area, adhesive quality, and relia-

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bility apply to the non-gel as well as the pre-gel electrode. As gel is applied to the electrode just prior to use, the number of parts are reduced and other contact materials may be used. Nickel is the most commonly used snap. Though its electrical stability is not as good as silver/silver chloride, it is considerably cheaper and will function well in combination with most electrolytes for short periods of time. The snap is covered with an open cell foam or other suitable material to prevent metal contact with the body and hold the gel in place. This electrode should also last 3-5 days.

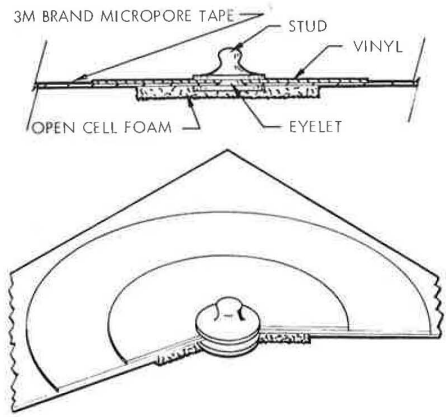


Fig. 2. Dry electrode.

Figure 3 shows a dry electrode that incorporates a cup instead of a foam pad over the contact. This offers all the advantages of the cup described in the pre-gel electrode but is less expensive, as nickel snaps may be used and other pre-gel features are removed.

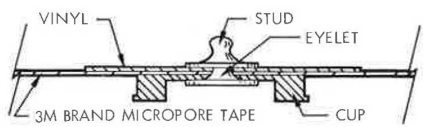


Fig. 3. Dry electrode.

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A little used, but effective electrode is the one shown in figure 4. This dry electrode is constructed with an open cell foam about 0.080 thick, similar to the foam pre-gel electrode. The cup is left out and the metal contact snap is covered with an open cell foam as the dry electrode in figure 2. The adhesive-coated foam's thickness serves as a cup, helping to retain the gel in its place, and the simple construction reduces cost.

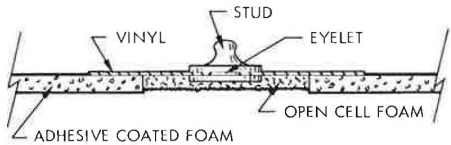


Fig. 4. Dry electrode.

CABLE CONNECTION

Most disposable electrodes connect to the cable at the electrode via the stud shown in figures 1, 2, 3 and 4. Typical cable connectors are shown in figure 5. A connector with the top portion covered with an electrical insulator (figure 5a, 5b) is the best.

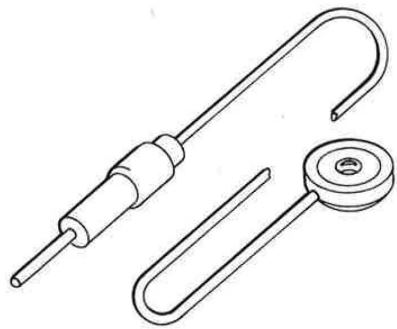


Fig. 5a. Cable connector.

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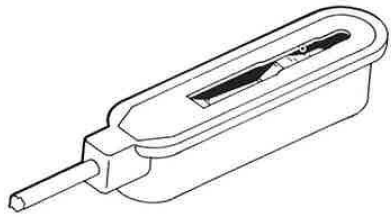


Fig. 5b. Cable connector.

Exposed connectors such as 5c often introduce noise when touched by hands, bed clothing, etc. The connector should fit the stud tightly yet be easily removed.

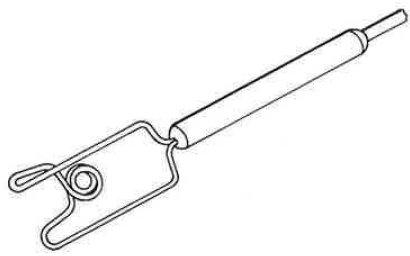


Fig. 5c. Cable connector.

The electrode in figure 6 utilizes a permanently attached wire, with the cable connection being made through the small connector at the wire's end. The wire is usually 18"-24" long and the entire unit is disposable. This approach offers a thin flexible wire and good cable connection; however, some of the newer cable connections attaching directly to the stud are solid enough to eliminate artifact caused by loose connections. A cable that connects directly to the stud may also be shielded the entire length. An electrode with a permanently attached lead wire is more complicated to manufacture and more costly from a material standpoint. For these reasons electrodes with a stud type connector are the most widely used. When-

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ever possible the metal part of the cable or lead wire connecting to the electrode stud should be gold plated. Gold is a good conductor of electricity and resists corrosion from gel and body chemicals.

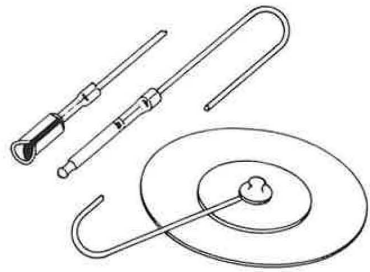


Fig. 6. Electrode with wire attached.

SUMMARY

Now that the individual parts of an electrode have been explained we can again look at the original design considerations.

Function

All parts are designed and selected for a reason, but from a functional standpoint the adhesive, contact material and gel are the most important. An adhesive must hold the electrode firmly in place and without irritating the skin. The contact and gel must be compatible and provide a low resistance path between patient and monitoring equipment. Contact materials are limited and were previously discussed. There are many good gels on the market with each manufacturer having his own formulation. Gels are usually of a water base with a thickening agent like carboxyvinalpolymer added to increase the viscosity and a salt such as sodium chloride added to provide electrical conductivity. The amount of salt used can be somewhat flexible (2-10%) but should not exceed the minimum amount necessary to make the electrode function, as salt is a potential skin irritant. Keep in mind that a pre-gel electrode should function with all types of monitors and the gel

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(in combination with its packaging) should have a shelf life of at least six months. Gel for use with dry electrodes should allow the electrode to function with all monitors and in doing so must be compatible with various contact materials. A good antibacterial agent like parachlorometaxylenol should be used to preserve the gel. Other chemicals are usually added to mask odors or allow the above chemicals to function. Choice of these additives depends on selection of the basic chemicals with detailed information available from their manufacturer.

Patient Comfort

A soft adhesive carrier such as foam or Micropore tape offers ample flexibility to move with the patient's skin. The adhesive and gel should be non-irritating and thoroughly tested. Profile of the electrode and connecting cable combination should be as low as possible. This can be achieved by keeping cup depth and thickness of cable connectors to a minimum.

Cost

Design and materials must result in a product that the user can afford, and be competitively priced. When you consider time saved and not having to stock gel, the pre-gel electrode is in some cases as inexpensive as the dry electrode. Parts selected should either be commercially available or designed to be mass produced by either stamping or injunction molding techniques. Improved plating techniques may some day result in a savings in silver parts used in pre-gel electrodes. Plating of plastics can eliminate many problems associated with plating of brass and may be practical in the near future.

Mass Production

Automatic production equipment and labor are closely tied to cost. Therefore an electrode design should lend itself to mass production. Furthermore, the electrode must be deliverable on short notice, reemphasizing mass production capabilities.

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Usage

The electrode should be available for use with a minimum of preparation. Unit packaging is preferable, as the electrode may be attached to the monitor's cable long before use. Though electrodes packaged in foil packs have good protection from drying, the package must be opened prior to use, and all the electrodes used. A precut hole in the liner paper of the dry electrodes in figures 2, 3, and 4 allows the gel to be applied to the electrode before separation from the liner, facilitating handling just prior to use.

Governmental Regulations

This is a good time to mention the Food and Drug Administration. At this time the F.D.A. classifies the pre-gel electrode as a "device." When introducing a product of this nature to the market it is a good idea to work closely with the F.D.A. and, whenever possible, use materials that already meet with their approval. Even though the individual components are made of approved materials, the entire product should be tested by an independent laboratory. An abstract of a report prepared by Food, Chemical and Research Laboratories, Inc., Seattle, Washington is shown in Appendix A. This report covered two types of gel manufactured by Hayes Products, Inc.

There are many good pre-gel and dry electrodes on the market today. Each is different in construction, demonstrating that the basic technical and design criteria can be met using a variety of materials and manufacturing techniques. Theoretically it should be possible to design an electrode with a few calculations based on available materials, current marketing information, and a little horse sense. In reality this rarely is the case. After prototypes and even production models enter the field, problems not even remotely anticipated come to light, requiring alterations of the basic design and/or material selection. Many months of testing, correction of problems and feedback from customers results in a successful product. Business competition, new designs in monitoring equipment

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and customer needs continually encourage the electrode manufacturer to improve his design and reduce the costs. With these improvements always in progress, new and better electrodes are sure to come.

APPENDIX A

ABSTRACT OF LAB REPORT FROM FOOD, CHEMICAL & RESEARCH LABORATORIES, INC.

SUBJECT

Determination of dermal toxicity and secondary sensitization of two gels ("P-Gel" and "New Aromatic Gel" manufactured by Hayes Products, 7440 Perimeter Road, Seattle, Washington) when used with an adhesive coated foam electrode.

METHOD

The fur of 12 male albino rabbits (2-3 kilo weight) was clipped by means of a small animal clipper to a length of less than 1/16 of an inch over an area approximately 4 square inches in the region between and just below the shoulders. The animals were housed in separate cages to eliminate possible injury by clawing from other animals.

The skin of 3 of the rabbits in each group was scarified with a metal instrument to abrade the skin. The electrodes were attached with the appropriate electrolyte solution and anchored in place with gauze to maintain contact for a period of seven days.

After a 10-day waiting period the rabbits were reclipped and the skin abraded again in 3 animals in each group. The test gels were reapplied and the rabbits were observed for an additional 7 days for irritation and/or sensitization reactions.

During both tests the animals were observed daily for signs of skin irritation, such as redness, erythema and/or formation.

The method is that described by Draize, J. H., "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics," Association of Food and Drug Officials of the United States, Austin, Texas, 1959, pages 46-59.

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RESULTS

"P-Gel"

Rabbit No.	Primary Irritation	Sensitization
1	0	0
2	0	0
3	0	0
4 abraded skin	0	0
5 abraded skin	0	0
6 abraded skin	0	0
"New Aromatic Gel"		
7	0	0
8	0	0
9	0	0
10 abraded skin	0	0
11 abraded skin	0	0
12 abraded skin	0	0

Animals scored 0-4. 0 indicates no erythema or edema.

The sensitization reaction was scored in a similar manner.

CONCLUSION

Neither the "P-Gel" nor "New Aromatic Gel" used as electrode pastes with the respective electrodes produced any evidence of primary irritation or secondary sensitization.

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FLEXIBLE ELECTRODES - FOR THE PATIENT'S SAKE

S. A. Rositano*

BACKGROUND

Biosensors for long-term use on active subjects have special requirements. Rigid sensors composed of solid metallic electrodes in plastic housings are satisfactory for short-term measurements on resting subjects; however, patient comfort is not always achieved. Monitoring experience with intensive care and coronary care patients and long-term recordings from ambulatory/active subjects has demonstrated a need for new electrode styles which are cosmetically, mechanically, and electrically compatible.

Advanced electrode development has also been stimulated by needs for electromyographic sensors for prosthesis control, physical therapy and stimulation for muscle control which require special attention be given to sensor shape, texture and flexibility since they are to be used over irregular body contours. Conventional clinical electrodes tend to irritate skin when used in these long-term applications because no skin motion is permitted.

Monitoring bioelectric signals for infants and small children requires sensors that are physically small to minimize the immobilized skin area. Reduced electrode surface area can result in poorer signal quality due to increased electrode-skin impedance (lower current density). An ideal electrode would not impair skin motion while being of sufficient size to permit high fidelity sensing.

Electrodes have ordinarily consisted of a solid or

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powdered metal contact coupled to the skin by direct contact or indirectly by a conductive paste. One of the most popular types consists of a flat plastic cup housing a silver/silver chloride pellet (1,2,3). Relatively flexible electrodes have been produced using a metallic screen in place of the silver pellet (4). Another has used a saturated cellulose sponge to improve flexibility (5). Spray-on dry electrodes have been used successfully for short-term ECG recordings during flight condition (6). Evaporated gold on latex has also been reported (7). Recently, several disposable types have been introduced commercially (Hayes Products) which achieve excellent electrical results while providing improved patient comfort through use of a saturable open cell foam covering over the rigid metal surface.

Requirements to study cardiovascular function during space flight or simulated weightlessness (bed rest) have led to the development of several bioelectrodes which may be helpful to the solution to the several problems just stated. These developments have been initiated by monitoring needs lasting several weeks to several months (6,8, 9,10). Several new conductive materials developed within the last five years for use as RF shielding form the basis of the conductors used in the electrode system to be described.

ELASTOMERIC ELECTRODE MATERIALS

Several elastomeric materials have been tested and evaluated to replace the conventional metal electrode used in biopotential recording. These materials have included carbon-filled rubber, wire-particle-filled rubber and vinyls, silver-filled silicone rubber and vinyl, and silver-plated particle-filled elastomers. Primary use of the materials prior to these applications has been in gaskets for microwave applications and high frequency RF work. Tests of the elastomers demonstrated that materials made with pure silver in a silicone rubber matrix offered the lowest resistivity (< .001 Ωcm) and greatest flexibility (100%) and softness (durometer 25). A wide variety of electrode configurations were made using pure silver-filled sil-

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icone rubber (Chomerics 1224, Emerson & Cuming SU-R, Tech Wire Conmax). Construction techniques and evaluation of these elastomeric electrodes have been previously published (10). The material may be molded to any shape to fit irregular body contours and is available in sheet, rod and bulk form. Wires capable of elongation may be formed of the same material to provide increased flexibility. Cost in small quantities ranges from $40 to $150 per pound for silver-filled materials. Principal difficulty with these materials includes long-term degradation of metal/elastomer joints at the lead wire junction. This has been remedied by one manufacturer of electro-stimulation electrodes by providing a housing containing a cylindrical socket for a pin plug on the electrode cable.

METALLIC CLOTH

One of the lowest cost and most flexible materials is a silver-coated nylon knit fabric (Technical Wire Products). Similar to support hosiery in texture and appearance, the material costs about 1¢/square inch and exhibits stable resistivity of 1 Ω/square over a 100% elongation. It permits construction of large surface area electrodes without restriction of skin motion (figure 1). Lead wire bonding is achieved by riveting or use conductive epoxy. Low electrode-skin interface impedance is accomplished with a gel-impregnated porous paper (GEL PAD 3M Co.). GEL PADS eliminate the need for electrode paste. Prior tests using paste and flexible electrodes showed early electrode degradation due to escape of electrolyte from the flexible housing. The GEL PAD electrode configuration has been used for continuous (24 hours per day) ECG monitoring for six days in ten subjects and for eight and one-half days in two additional subjects. Excellent quality recordings were obtained from all subjects. Closed cell 1/16" thick polyurethane foam was used to keep the electrode in place. No subject complained of irritation while ambulatory or in bed and all showered daily and maintained normal routines of work, play and exercise. In another test, the

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electrodes composed of a 1/8" foam back and gel-electrolyte were placed under an elastic bandage encircling the thorax during bicycle ergometry. Except for EMG activity, no electrode-induced artifact was noted up to the subject's maximal effort of 150 watts at 150 RPM. Because of the low mass and relatively large electrode area, these electrodes seem particularly adaptable to active subjects.

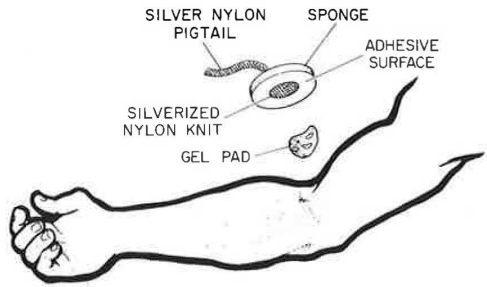


Fig. 1. Semi-dry soft electrode for surface use.

"DRY" ELECTRODES

Several dry electrodes have been fabricated using a built-in field-effect source follower. A 2N2277 micro "T" pak FET is encapsulated along with a 220K 1/10 watt resistor in series with the electrode and gate to form an impedance transformer. Both elastomers and metallic cloths have been used as electrode materials. Although no moisture is theoretically needed, short-term stability has not been good because a small amount of moisture builds up and a stabilization period of several minutes is required for stabilization of the skin-metal interface. A quick water wipe prior to electrode placement reduces the stabilization period to no more than 30 seconds. No other skin preparation is necessary; in fact, results are better without removing residual salinity from the skin. Elastomeric or fabric electrode materials permit relatively large size elec-

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trode contact which reduces initial impedance in areas where large rigid electrodes are not permissible. Construction cost is high for these electrodes and the FET is susceptible to damage from any high voltage field such as the use of a defibrillator and X-ray exposure.

The active dry electrode is currently being evaluated in a configuration which allows quick application and removal. These units are being used for routine monitoring and for rapid vector ECG measurements. Dry electrodes are also being evaluated for incorporation into normal clothing and wearing apparel such as underwear.

APPLICATIONS

Muscle Control

Several applications of conductive knit fabric electrodes have been made for muscle control and stimulation. The drop-foot phenomenon in post-stroke patients has been treated by peroneal nerve stimulation using a bipolar electrode placed behind the knee. A switch in the heel of the subject's shoe activates a pulse train which stimulates the peroneal nerve and results in lifting the dragging foot at the correct point of leg travel. Primary requirement for electrode design, in addition to proper electrical function (low skin-electrode impedance), is patient comfort and ease of placement and attachment by the patient. Electrodes are being fabricated from a supple 1/16" foam (supplied by Hayes Products) and adhesive transfer tape coupled with 2 cm^2 of metallic knit cloth and a conductive pad for low-interface impedance. An athletic knee support bandage with the electrodes sewn in place is also being investigated. Both techniques allow the electrode to bend and stretch with the knee. The large surface area has the additional advantage of lowering the current density and minimizing "shock" sensation of the constant current pulse train.

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Physical Therapy

The knit fabric electrode is being evaluated by physical therapists in a bio-feedback mode for rehabilitating inactive muscle groups. An elastic band housing the electrode is centered over the desired muscle group. The EMG indicates to the patient when the desired muscle is activated. Exercise usually accompanies the therapy and conventional rigid electrodes would present discomfort or artifact. Low mass flexible electrodes permit unencumbered motion.

Prosthesis Control

Placement of EMG electrodes for prosthesis control presents a comfort problem for many patients. Although motion is not usually present, long-term comfort from electrodes placed within the prosthesis housing is difficult. By matching the electrode softness to that of the skin, significant increase in comfort is realized. Dow Corning subdermal implant silicone foam and a conductive fabric combine to form a satisfactory electrode.

Pediatric Electrodes

Soft ultra-flexible electrodes described above have significant potential as infant biosensors. In one approach, the nylon knit may be used as previously described with a soft, stretchable adhesive pad covering. Large physical size can be realized for good signal-to-noise ratios without discomfort. In another approach, a small adhesive bandage is used to attach the electrodes to the skin. An elastomeric or cloth electrode, 1/2"x1/2", is inserted between the gauze pad of the bandage and the adhesive strip. Saline is used to saturate the gauze to form an electrolyte bridge. Cost of the semi-disposable type can be as low as 1¢ per application.

Nerve Stimulator

An implantable nerve stimulating electrode suitable for use on the carotid sinus nerve was developed using a platinum-filled silicone rubber. Previous nerve stimulators used a rigid electrode cuff with 180° elec-

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trical contact (11). The present technique provides 360° electrical contact as well as flexibility approaching that of the nerve.

SUMMARY

Routine ECG measurements for short-term applications are adequately obtained by conventional surface electrodes. Long-term monitoring or signal acquisition from irregular skin surface contours with comfort to the patient imposes requirements in which a new approach appears to have potential value. This method uses conductive elastomers and cloths in place of rigid metal electrodes. Large electrode surface area and improved patient comfort have been demonstrated in several applications including long-term ECG, physical therapy, prosthesis control and pediatrics. Conductive elastomers offer a wide variety of shapes and can be molded to any desired shape, whereas silverized nylon cloth provides the lowest cost, most distendable and softest electrode material. Evaluation of dry and semi-dry electrodes using this new technique is continuing.

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DISCUSSION

KATER: Regardless of the type of electrode employed, one has to use some kind of adhesive to attach the electrode to the skin. I understand that very little research has been done in formulating an adhesive that is absolutely compatible with the skin. Adhesives manufactured by the Minnesota Mining and Manufacturing Company (3M) are widely used. Would you comment on this?

ROSITANO: We use Dow Corning, Type B, spray silicone rubber adhesive with the Dow silicone foam-backed electrode and find it to be very satisfactory, though removing it takes extensive rubbing. We obtained removable material from Dow, but did not have as good luck with it. However, our experience with these adhesives has been only for periods of eight days or less.

DAY: Many adhesive tapes and materials are provided by Remco in North Hollywood, California. They use type 15/22 3M tape, a very good adhesive. However, it is die cut and develops a concavity with extremely sharp edges which can cut or irritate the skin if attention is not given to application.

SMYTH: My question is clinically related. Which type of electrode paste or gel is better for rejecting 60 Hz interference and possesses lasting qualities by resisting drying?

FLOREN: I am not sure that the problem of 60 Hz interference is related to paste at all. The problem is more in shielding cables and assuring that all electrical connections are secure. However, paste drying is certainly a matter of formulation. Our electrode cannot dry out until it is opened and put on the patient. After it is on the patient there has to be the correct formulation of the gel with a low evaporation

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rate.

SMYTH: On many occasions we have found that applying extra paste to electrodes on patients will cut down interference even though all other connections are secure. This leads me to believe that there is some association between the interference and paste. Are there some pastes that overcome the patients' skin resistance better than others? This is a major clinical problem which we find to recur very frequently.

PORTNOY: It appears that you have problems with the actual interface resistance at the electrode. Insufficient paste will yield high electrical impedances. Electrodes will then couple with ambient electrical noise.

ROSITANO: 60 Hz interference is related to the size of the electrode and contact with the skin, and is not dependent upon the type of paste used.

KATZ: If the skin is well cleaned with an alcohol pad to remove the protective oil layer, we obtain much better signals with a large reduction in 60 Hz interference.

BOTHWELL: Very little is really known at the biological level about how tape adhesives affect skin in a variety of medical applications. The concern that I have is the skin-adhesive interface and what happens to skin when tapes are placed upon it. For one-time application and removal, one can tolerate a little skin damage. However, if there is repeated redressing of an area, one must apply entirely different principles to the development and formulation of the adhesive. There are specific adhesive blends that can solve many of the problems that have been discussed at this Conference. However, research organizations have not delineated these specific problems to guide manufacturers in producing specific products. This is an area in which research organizations and the industrial community can work cooperatively to solve obvious medical concerns.

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(unidentified): Mr. Rositano, why would you prefer to use elastomeric or metallic cloth electrodes that you described here for long-term recording from active subjects, rather than the conductive spray-on electrodes?

ROSITANO: The spray-on electrode that was originally developed by Dr. Roman was a silver powder in Duco cement. Duco cement is not flexible after some period of time. For our purposes, spray-on electrodes do not adhere for a sufficiently long period of time. For Dr. Roman's needs, rapid application and a short-term (one or two hours) use, it was satisfactory. Emerson and Cummings have a conductive silicone rubber paste that can be dabbed on and will remain intact for three to four days, depending on the viscosity at which it is applied. Initially, the impedance may approximate 0.5 megohms, but decreases to 5 or 10 thousand ohms as the solvent evaporates. My experience has been with a square centimeter application over a period of 24 hours. Silver paint-on electrodes are now commercially available. I have been using them with satisfactory results for up to three days. They are quite flexible and use perspiration as the basic electrolyte. Over a period of time as perspiration builds up, impedance decreases, resulting in an improved signal. Many users find this initial stabilization period to be unacceptable. However, if one must make a rapid, instantaneous measurement, as in a hazard situation, the dry electrode can be applied by licking the patient's skin or applying some small amount of moisture.

MANSOUR: I am concerned about the variation in resistivity from one electrode to another. In recording vectorcardiograms, as with the Frank lead system, how does the individual electrode variation affect the weighting resistance in networks?

GEDDES: The effect of electrode impedance on the weighting networks used in the chest (V) leads and for the Frank lead system to obtain vector electrocardiograms is a terribly important aspect. It is clear that electrode impedance adds to the weighting resistor

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network. The suggestion that is prevalent at the moment is to use a buffer amplifier between each electrode and the electrode-averaging network.

PORTNOY: We too were faced with precisely that problem in using the insulated electrode. I feel that if one does use a source or voltage follower of some type, so that the output impedance of the electrode can be controlled, then one has essentially a voltage source. An ideal voltage source has no impedance. The obvious problem with this situation is the cost and additional power requirements to provide biased voltages of constant current. However, with an active system, the output impedance of electrodes can be controlled and therefore control the common-mode rejection of the amplifier. It is entirely possible with sufficiently high common-mode rejection and low enough output impedance that one does not need a ground electrode. The differential mechanism of the amplifier will then be sufficient to eliminate any noise coupled into the system.

MANSOUR: I don't know whether Frank had in mind weighting the voltages as they developed on the torso surface as buffered by an active network; or, as apparently his experiments showed, whether he was trying to add a perturbation to a resistive network already existent in the body in order to minimize the wandering of the vectorcardiogram. With active networks, we may get other kinds of averages than the ones he had in mind.

DYMOND: I may be incorrect, but I think what is being done is averaging the biopotentials as they appear at different parts of the body, and that we are obtaining an average of the voltages rather than of the impedances. In this case, a source follower would improve the averaging. It would put control of the averaging process into the resistances in the instrument rather than depending on the resistances between the electrodes and the body.

ROSITANO: I tend to agree that use of some type of

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buffer as a means of controlling the signal source would be the method of choice, so that one starts out with a stable voltage source.

CARR: We have to recognize that with dry electrodes there will be higher impedances between the body and the electrode, resulting in 60 Hz interference and elevating common-mode potential. Recorders and monitors connected to these electrodes must be able to withstand a higher common-mode rejection than was required for low impedance, wet electrodes.

ROSITANO: The advent of instrumentation-quality amplifiers on integrated circuit chips, at low cost (under $10), with high common-mode rejection, is pointing to the future for surface electrodes. I think that within the next two years we will see an economically feasible, low-power, high-input impedance amplifier built into the connector of the electrode cable.

KATER: I would like to submit an interesting finding published in a paper by Lewis from England in 1961, concerning electrode gels. Lewis had gone to a food market and bought K-Y jelly, hollandaise sauce, mayonnaise and tomato paste and found, much to his surprise, they all worked as well on the skin as an electrode paste. He had shown that it was the skin preparation and I believe, more so, the input impedance of the instrument which is important in obtaining 60 Hz free signals.

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SESSION II

PHYSICS & ENGINEERING

Chairman

LESLIE A. GEDDES, Ph.D.

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