BIOMEDICAL TECHNOLOGY TRANSFER

Applications of NASA Science and Technology

FINAL REPORT
July 1, 1971 - September 30, 1972

Submitted by
STANFORD UNIVERSITY SCHOOL OF MEDICINE
CARDIOLOGY DIVISION

Prepared for
National Aeronautics and Space Administration
Technology Utilization Division
Washington, D.C. 20546

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INTRODUCTION

This report summarizes the activity of the Cardiology Division, Stanford University School of Medicine under contract NASw-2216 to the National Aeronautics and Space Administration, Technology Utilization Division during the period of June 15, 1971 to September 31, 1972.

Under the NASA Technology Utilization Program, the purpose of this contract was application of aerospace technology developed by NASA to problems of medicine and biology where significant technological needs exist.

Primary emphasis has been directed towards the identification, acquisition and solution of research and clinical problems in cardiovascular medicine. At the present time, cardiovascular disease is by far the leading cause of death and disability in the United States. Secondarily, efforts have been made to promote problem solution in other medical specialities unrelated to cardiovascular disorders.

This contract has been under the direction of Donald C. Harrison, M.D., Chief of the Cardiology Division and Mr. Harry A. Miller, Administrative Officer, Cardiology Division.

Activities of this program have been reported on a monthly basis to Mr. James T. Richards, Jr., Chief, Technology Applications Division, NASA Headquarters, Washington, D.C. who has served as contract monitor and advisor.

Grateful appreciation is acknowledged for the cooperative assistance of all NASA field centers, Southwest Research Institute, Research Triangle Institute, George Washington University, Stanford Research Institute and particularly to Mr. James T. Richards, Jr. and the Office of Technology Utilization.

Donald C. Harrison

D.C. Harrison, ~~M.D.~~, Director

H. A. Miller

Harry A. Miller, Deputy Director

PROGRAM SUMMARY

SUMMARY

Contract Establishment

In July, 1970 members of the Cardiology Division, Stanford University School of Medicine, met with the National Aeronautics and Space Administration's Technology Utilization Office to discuss innovative methods in which NASA aerospace technology could be applied more effectively to the Medical (health) sector.

The Stanford University team suggested exploring specific specialized areas of medicine having substantive problems amenable to high technology. A contract proposal was submitted to NASA Technology Utilization Division (TUD) on October, 1970 for consideration and received approval for initiation in June, 1971. A no-cost time extension to the contract was executed by NASA extending the original contract through September, 1972 and was mutually agreed upon by Stanford and NASA to permit evaluation of the initial twelve-month effort and to assist in the redirection of efforts for the second year. Essential elements of the proposal consisted of applying high-level medical and engineering expertise to problems within cardiology and concentrating efforts geographically to the West Coast.

Team Formation

A Biomedical Technology Transfer (BTT) team was established by the Cardiology Division to act as the instrument in the technology transfer process. By nature of the medical subspeciality (cardiovascular) in which concentration was to be focused, a team was formulated comprising three essential areas of professional expertise (medicine, engineering and administration).

The major corps of medical team members consisted of five cardiologists-internists from the Cardiology Division listed as follows with respective individual areas of expertise:

D. C. Harrison, M. D., pharmacology, critical care
Edwin Alderman, M. D., cardiovascular hemodynamics
William Barry, M. D., physiology-instrumentation
David Cannom, M. D., electrophysiology
Richard Crow, M. D., vectorcardiography-computers
Alan Rider, M. D., biochemistry

Five retired NASA engineers, all of whom held high positions in diverse areas of specialization, were organized to represent the physical science and engineering component of the transfer team. They are:

Mr. Andre G. Buck, electrical/mechanical engineering
Mr. J. S. W. Davidsen, mechanical engineering
Mr. Manley Hood, general aerospace
Mr. Paul Purser, manned space flight
Mr. James White, instrumentation

These engineers are intimately familiar with the capabilities, policy and practices of NASA and have an aggregate experience in excess of 160 man years with NASA.

Technical and fiscal management of this program, which is reflected in the daily involvement and contact with problem originators, physicians, engineers and NASA personnel is performed by Mr. Harry Miller, Cardiology Division Manager and Mrs. Donna Hall, Program Secretary.

In addition to the immediate team members, individuals or groups within the Stanford School of Medicine and University at large have been available as consultants, thereby providing incomparable depth to the Stanford Cardiology Biomedical Technology Transfer team.

From the staff complement described above, medical-engineering teams of two or three members are selected on the basis of the nature of the problems and individual expertise required to achieve problem resolution. This team provides liaison between the problem originator and NASA; it functions as a catalyst.

Objectives and Medical Field

Since cardiovascular disorders are by far the leading single cause of death in the United States, frequently causing death and/or disability in men during the most productive years of their careers and since the Cardiology Division is a nationally recognized authority in this field, primary emphasis has been directed to solving urgent problems in this area. Related or peripheral medical problem areas are included into the scope of this program since problems related to cardiology share numerous disciplines. As examples, problems concerning respiratory medicine and intracranial disturbances are under consideration by this team since they involve the vascular system and employ basic disciplines of pressure, flow and resistance, which are central to cardiovascular medicine.

Less obvious problem areas have been approached as part of this program. One major technological need relevant in many areas of medicine is the development of improved electrodes. Over the past 15 years, there has been little improvement in generally available bioelectrodes. In addition to the critical need for better electrodes in coronary care units, intensive care units and operating rooms, identical problems occur in electromyographic, prosthetic and sensory aids field, and physical-rehabilitation medicine. In these instances, commonalities of materials and techniques are involved to resolve the difficult task of transducing complex biologic signals. The Stanford team has considered electrode technology a problem of major medical importance and has accepted several problems which clearly lie outside cardiovascular medicine, fully realizing the potential application to cardiology if resolved.

To avoid the dilemma of spreading limited resources too thinly, the major priority has been assigned to cardiology or directly related specialty problems. However, consideration has been given to several problems that were known to have a readily available NASA "quick fix" solution. The rationale in such instances consists of being able to provide solutions as a direct result of personal knowledge of team members, bring together problem originators and knowledgeable scientists from NASA field centers, or transmit knowledge of commercially available solutions. Such service is included in view of the fact that this team does represent NASA and situations of this nature, although not always of high impact, do provide a needed service without undue expenditure of time or funds.

Team objectives are to seek out problem areas, contact individuals, observe and communicate the nature of the problem and expedite the technology transfer process according to the approach established by the Stanford Cardiology team.

Geographical Area

In the solicitation of problems from the medical community, the activities of Stanford University have been restricted to the West Coast. In this vast area, there are in excess of 50 major medical institutions providing advanced medical care or research related to cardiology and countless agencies, hospitals and clinics involved in health care. Although there are numerous other institutions nationally which could well be incorporated into the Stanford-NASA Biomedical Applications Team concept, the time, man-power and magnitude of the Stanford contract is compatible with sustaining the West Coast exclusively. Information and applied technology as a result of one BA Team is readily available to other institutions serviced by the two other national BA Teams through the communications project of George Washington University, Washington, D. C.

Within this geographical area there exist three levels associated with cardiovascular medicine, i. e., major medical centers, private or community hospitals and the private physician. Considering the time and resources available, this team endeavored to establish a relationship first with teaching/research hospitals and major medical institutions. These units generally are faced with critical problem areas affecting a relatively large and critically ill population base. Therefore, the criteria of high impact problems is met when such major centers are involved. Community hospitals collectively provide care to the largest patient population base and ultimately are the functional units which will most benefit from technological breakthrough. In addition, few hospitals have the resources of bioengineering, medical instrumentation specialists or sophisticated purchasing departments to provide high technology services necessary to solve most problems. The private practicing physician is the third-level entity with whom the Stanford program interacts. It is obvious that dealing with the problems of individual cardiologists is imprudent and not cost-effective. However, experience has shown that a few of the innovative approaches to the solution of medical problems, as well as the successful medical application to patients, occur with physicians or nurses. A serious limitation of this association, of which the Stanford team is aware, is that time and funds of the problem originator are relatively limited. This is a constraint which one must consider but should not be the determining factor for acceptance of a worthwhile problem.

Assistance has been received from various NASA Field Centers, NASA Headquarters and other national Biomedical Application Teams. The following diagram indicates groups and locations involved.

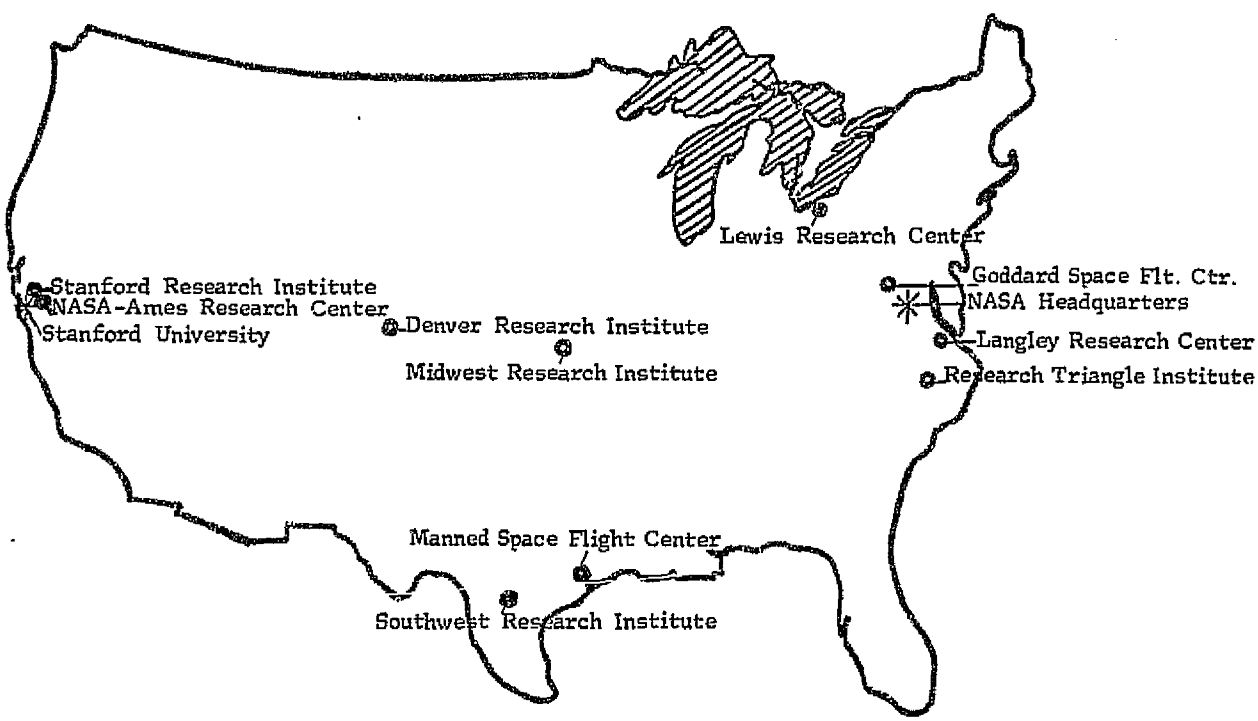


FIGURE I Location of NASA Field Centers and Application Teams

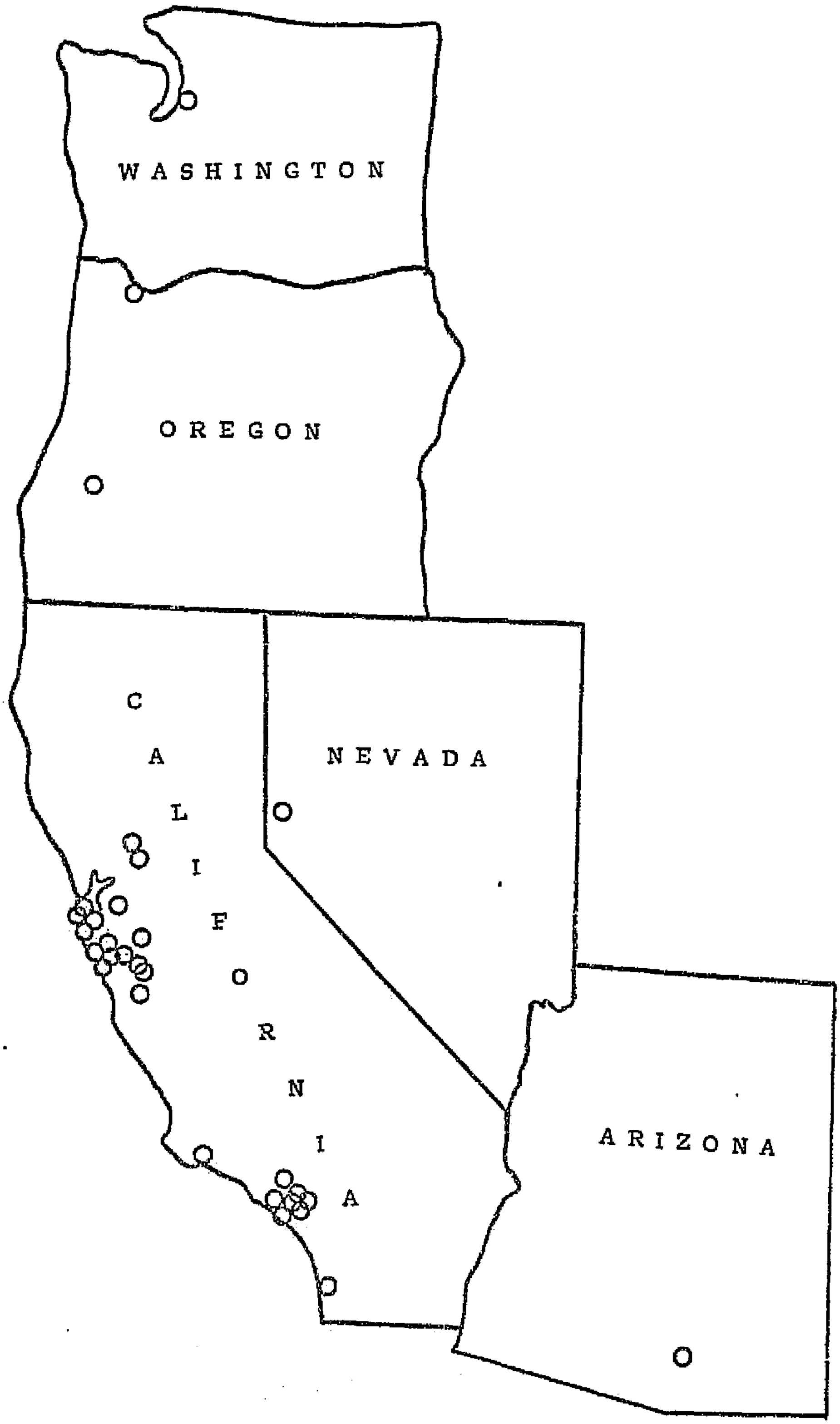


FIGURE 2 Locations of medical institutions either contacted or participating in the Biomedical Applications Program through Stanford University

Program Introduction

The NASA-TUD Biomedical Applications Program, in the reapplication of aerospace technology is, unfortunately, neither well publicized nor well understood by the physicians, scientists or academicians who could well benefit therefrom. Other governmental programs well known to the medical sector are so completely at variance with the NASA program that a differential understanding must be achieved at the onset.

Since the establishment of a Biomedical Technology Transfer team is a new concept to the West Coast, an initial extensive effort has been made to rapidly apprise a large group of potential recipients. Consequently, Dr. Harrison, Stanford University program director, initiated letters and personal calls during the first month to colleagues and directors of cardiology departments at the following institutions:

HOSPITALS:

CEDARS OF LEBANON-SINAI HOSPITAL
4833 Fountain Avenue, Los Angeles, California 90029
William Parmley, M.D., Associate Director, Cardiology Division
H.J.C. Swan, M.D., Cardiology Division

CITY OF HOPE HOSPITAL CENTER
Duarte, California
Simon Rodbard, M.D., Cardiology Division

EL CAMINO HOSPITAL
Mountain View, California 94040
Mr. Edward Hawkins, Director

EUGENE HOSPITAL AND CLINIC
Eugene, Oregon
Thomas Roe, M.D., Cardiology Department

HARBOR GENERAL
1000 West Carson Street, Torrance, California 90509
Michael Criley, M.D., Chief, Cardiology Division

HOSPITALS (continued)

KAISER HOSPITAL
Santa Clara, California
Robert Franklin, M.D.

KAISER-PERMANENTE MEDICAL GROUP
Santa Clara, California
J. Hicks Williams, M.D.

KAISER FOUNDATION HOSPITAL
1697 Ala Moana Boulevard, Honolulu, Hawaii 96815
T. K. Lin, M.D., Chief of Cardiology

OAKLAND CHILDREN'S HOSPITAL
Oakland, California
Samuel Abraham, Ph.D.

PACIFIC MEDICAL CENTER
Clay and Webster, San Francisco, California 94115
Keith Cohn, M.D., Cardiology
John Osborn, M.D., Cardiology

RANCHO LOS AMIGOS HOSPITAL
Downey, California
Claire Stiles, M.D.

SAN FRANCISCO GENERAL HOSPITAL
San Francisco, California
Elliot Rapaport, M.D., Professor of Medicine, Director of Cardiology

SANTA BARBARA HEART AND LUNG INSTITUTE
Santa Barbara, California
John H.K. Vogel, M.D.

STANFORD CHILDREN'S HOSPITAL
Palo Alto, California
Harry M. Jennison, M.D., Director

VETERANS ADMINISTRATION HOSPITAL
San Francisco, California 94121
Milton Hollenberg, M.D., Chief, Cardiology Division

SCHOOLS OF MEDICINE

LOMA LINDA UNIVERSITY
Loma Linda, California 94354
Varner J. Johns, Jr., M.D., Department of Medicine
Alan Boyer, M.D., Cardiology Division, Assoc. Prof. of Med.

UNIVERSITY OF ARIZONA COLLEGE OF MEDICINE
Tuscon, Arizona 85721
Frank I. Marcus, M.D., Chief, Department of Cardiology

UNIVERSITY OF CALIFORNIA AT DAVIS
Davis, California 95616
Dean Mason, M.D., Chief, Department of Cardiology
Robert Zelis, M.D.

UNIVERSITY OF HAWAII
3675 Kilauea Avenue, Honolulu, Hawaii 96816
Richard Blaisdell, M.D., Chief, Department of Medicine
Kenneth D. Gardner, M.D.

UNIVERSITY OF CALIFORNIA AT LOS ANGELES
Los Angeles, California 90024
Albert L. Kattus, M.D., Chief, Department of Cardiology
Glenn A. Langer, M.D., Professor of Physiology and Medicine

UNIVERSITY OF NEVADA
Reno, Nevada 89507
George Smith, M.D., Dean

UNIVERSITY OF OREGON
1381 S.W. Sam Jackson Park, Portland, Oregon 97201
Herbert E. Griswold, M.D., Chief, Department of Cardiology

UNIVERSITY OF CALIFORNIA AT SAN DIEGO
La Jolla, California 92037
John Ross, Jr., M.D., Chief, Department of Cardiology
James Covelle, M.D., Associate Professor of Medicine

UNIVERSITY OF SAN FRANCISCO
Third & Parnassus, San Francisco, California 94122
Maurice Sokolow, M.D., Chief, Department of Cardiology

UNIVERSITY OF SOUTHERN CALIFORNIA
2025 Zonal Avenue, Los Angeles, California 90033
David H. Blankenhorn, M.D., Chief, Department of Cardiology
Julian Haywood, M.D., Director, Coronary Care Unit

SCHOOLS OF MEDICINE (continued)

UNIVERSITY OF WASHINGTON
Seattle, Washington 98105
Robert A. Bruce, M.D., Chief, Department of Cardiology
Harold Dodge, Director, Cardiovascular Research Center

STANFORD UNIVERSITY
300 Pasteur Drive, Stanford, California 94305
Alfred Spivack, M.D., Director, Coronary Care Unit

RESEARCH FOUNDATIONS

PALO ALTO MEDICAL RESEARCH FOUNDATION
860 Bryant Street, Palo Alto, California
Alvin Sacks, Ph.D., Senior Research Associate, Bioengineering
Marcus Krupp, M.D., Director of Research

Following the personal explanation of the program, visits have been made by a team of at least two members (one cardiologist and one engineer) to the institutions listed below.

University of Oregon, Portland, Oregon

Eugene Hospital and Sacred Heart Hospital, Eugene, Oregon

Oakland Children's Hospital, Oakland, California

University of California at San Francisco, California

University of California at San Diego, California

Valley Medical Center, San Jose, California

Cedars of Lebanon Hospital, Los Angeles, California

City of Hope Medical Center, Duarte, California

Rancho Los Amigos Hospital, Los Angeles, California

Good Samaritan Hospital, Los Angeles, California

University of Nevada, School of Medicine, Reno, Nevada

Stanford University Children's Convalescent Hospital

San Francisco County General Hospital, San Francisco, California

University of Arizona, Tucson, Arizona

University of California at Davis

University of California at Davis, Sacramento Medical Center

University of Washington, Seattle, Washington

University of Southern California Children's Hospital

Pacific Medical Center, San Francisco, California

El Camino Hospital, Mountain View, California

Stanford Research Institute, Menlo Park, California

Palo Alto Medical Research Foundation, Palo Alto, California

Stanford University Hospital, Palo Alto, California

Repeat visits have been made as required to the following institutions:

El Camino Hospital

Palo Alto Medical Clinic

University of California at San Francisco

University of California at Davis

Stanford Children's Hospital

Oakland Children's Hospital

Formal letters of introduction and intent were sent to the following NASA Field Center Directors from Dr. D.C. Harrison:

Dr. Hans M. Mark

Ames Research Center
Moffett Field, California

Mr. Paul F. Bikle, Director
Mr. DeElroy Beeler, Deputy Director

Flight Research Center
Edwards, California

Dr. John F. Clark, Director

Goddard Space Flight Center
Greenbelt, Md.

Dr. William H. Pickering, Director

Jet Propulsion Laboratory
Pasadena, California

Dr. Kurt H. Debus, Director

John F. Kennedy Space Center
Kennedy Space Center, Florida

Mr. Edgar M. Cortright, Director

Langley Research Center
Hampton, VA.

Mr. Bruce T. Lundin, Director

Lewis Research Center
Cleveland, Ohio

Dr. Robert R. Gilruth, Director

Manned Spacecraft Center
Houston, Texas

Dr. Eberhard Rees, Director

George C. Marshall Space Flight Center
Marshall S. F. C., Alabama

Mr. Milton Klein, Manager

AEC-NASA Space Nuclear Systems Office
Washington, D.C.

Mr. Robert W. Schroeder, Chief
Space Nuclear Systems Office
Lewis Research Center
Cleveland, Ohio

Mr. Robert L. Kreiger, Director

Wallops Station
Wallops Island, VA.

Due to a lack of information by the West Coast institutions concerning the NASA-TUD program, approximately half of the entire contract effort has been concerned with program presentation and establishing credibility of the transfer concept. With the exception of those departments previously contacted by Southwest Research Institute in a few institutions on the West Coast, essentially all groups contacted by Stanford had no prior knowledge of the NASA program. Recognizing the need to disseminate information to the various medical groups, Stanford, Research Triangle Institute (RTI), and Southwest Research Institute (SwRI) have successfully publicized the program in national medical and engineering journals. Stanford prepared and published an article directed at the cardiologist in the American Journal of Cardiology. This journal has a monthly circulation of 18,000. The article is reprinted on the next page.

Problem Solution Approach

The medical solution procedure adopted by the Stanford BTT team and proven so highly effective, is described in detail and represented schematically as follows:

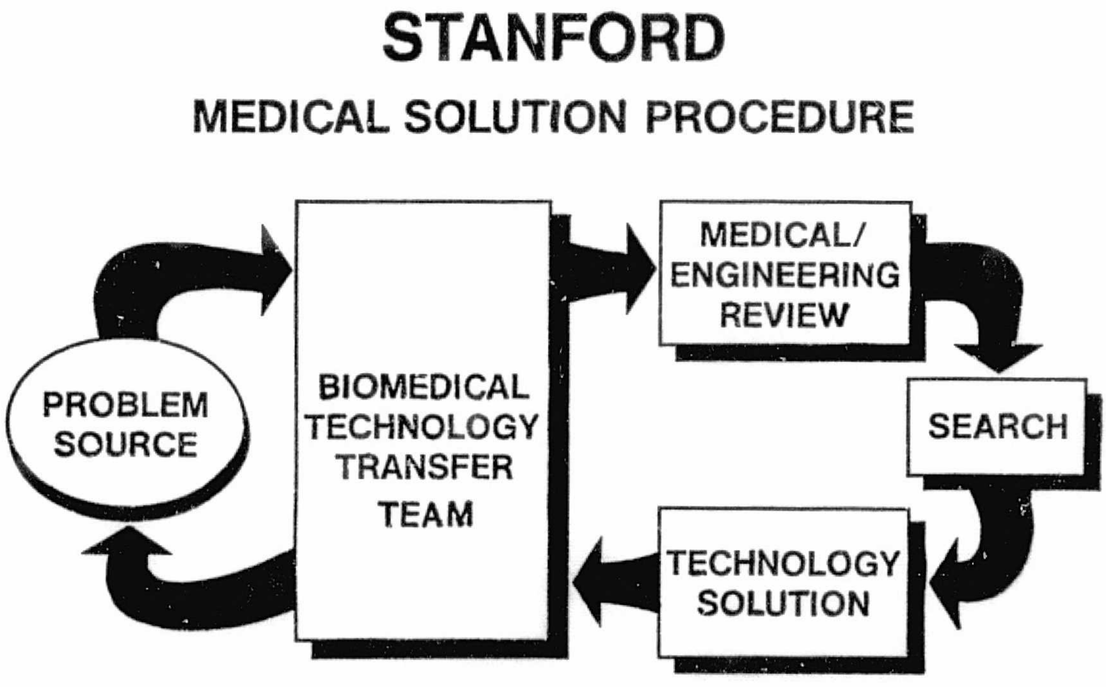


FIGURE 3

Cardiovascular Medicine: A New Program

a new attack on heart attacks

The Cardiology Division of the Stanford University School of Medicine is participating in a new program with NASA to apply aerospace technology for the solution of significant problems related to Cardiovascular Medicine.

The program is designed to assist physicians and those involved in clinical research by making advanced technology and expertise available. Specific physicians and aerospace engineers working as a team constitute the Biomedical Technology Transfer Program at Stanford University and act as the interface between the problem originators and sources of NASA Technology. Following visitation and consultation these medical engineering teams systematically search NASA data banks and the NASA field centers for relevant technology. Emphasis of these teams is directed toward implementing the transfer of identifiable space technology.

These services are available at no charge. Selection of problems is based on significance to broad base needs and to potentially shared contributions in related fields of Cardiovascular Medicine.

The key points of this program are to:
(a) make advanced technology and new knowledge generated by NASA available to the private and public health sector.
(b) reduce the time span between development of new technology and its broad and effective utilization.
(c) provide valid and novel problem solutions in both the clinical and research sciences which are directed to health care delivery and overall advancement of the quality of medicine.

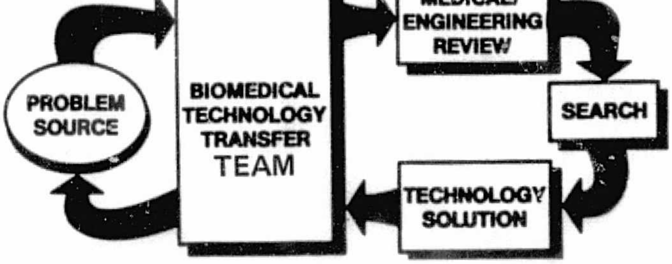
The medical community is encouraged to submit problems for consideration in this program to any one of the three Biomedical Technology Transfer teams:

☐ **Stanford University School of Medicine**
Division of Cardiology
701 Welch Road, Suite 3303
Palo Alto, California 94304

☐ **Research Triangle Institute**
P.O. Box 12194
Research Triangle Park, North Carolina 27709

☐ **Southwest Research Institute**
8500 Culebra Road
San Antonio, Texas 78228

TECHNOLOGY TRANSFER PROCESS

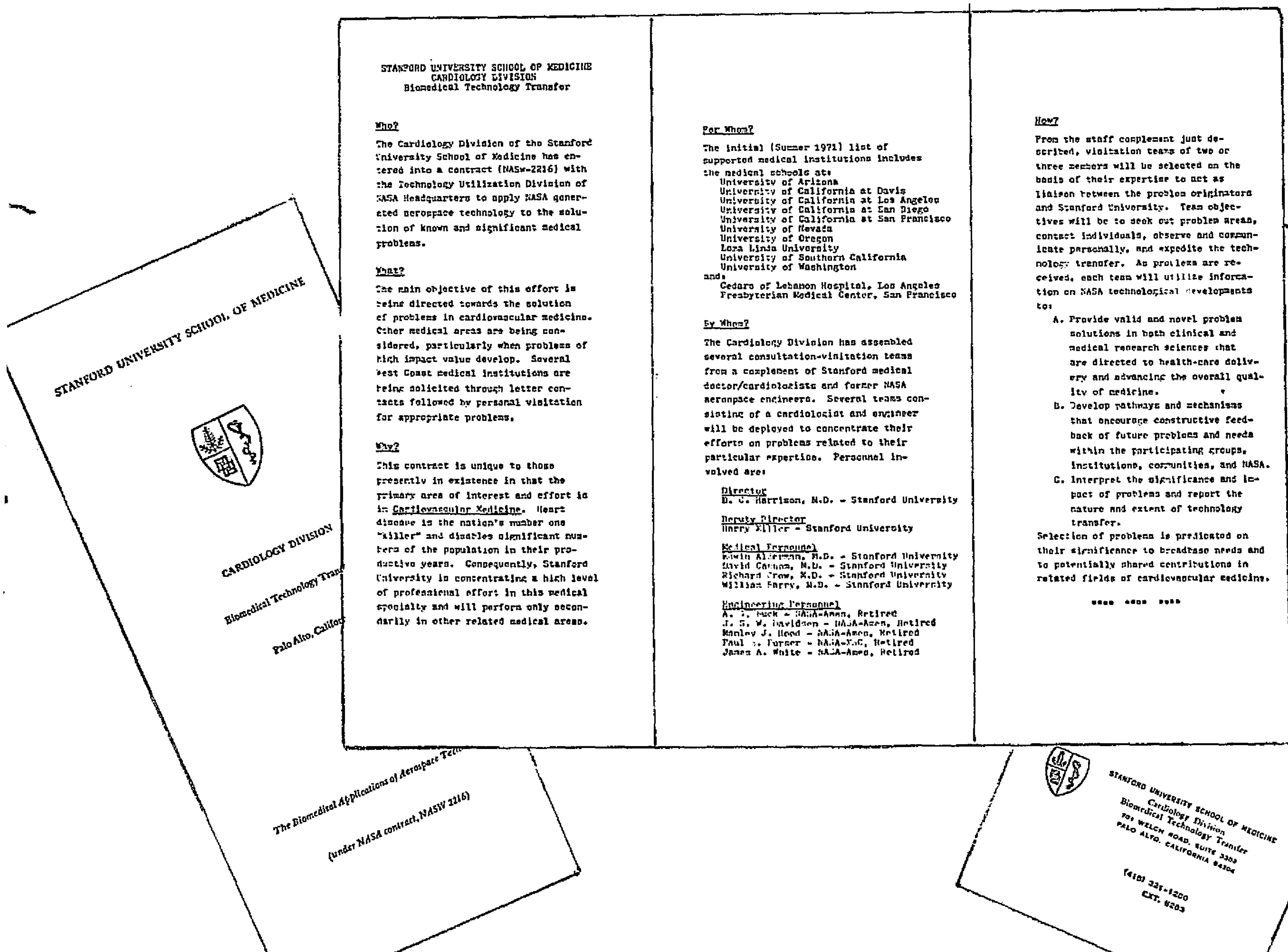


Visitation to Institutions. Following introduction and initial contact of key individuals in selected institutions by the Stanford Program Director, an in-depth personal visit is then performed by members of the Stanford Biomedical Technology Transfer team. The usual practice has been to have a cardiologist and an engineer travel as a team to the site (laboratory, hospital ward, critical care unit) and review the NASA-TUD program, analyze and tentatively accept problems. The obvious advantage of this approach is that physicians are communicating with physicians, the engineer can analyze and assess potential solutions and the team has an opportunity to observe the resources and constraints of the problem originator and his environment. At the outset, problems undergo initial medical-engineering review for acceptance and potential solution. Direct visitation in this manner has been successful. All problems within the Stanford program, with the exception of one, have been derived this way.

To help explain the Biomedical Application Team concept, a brochure describing the program has been prepared. In addition to this brochure, problem statement forms, relevant NASA Tech Briefs and current articles describing NASA technology applications reports are distributed to potential users. Examples of the Stanford BTT program brochure and problem statement form are included in Figures 4 and 5.

Team Review. After a problem statement is received, an extensive medical-engineering review is performed. At biweekly team meetings, problems undergo critical analysis by all members of the team representing a broad spectrum of experience in medicine and engineering. Problems are accepted when it is determined that they meet valid medical criteria and have potential of NASA solution.

A cardiologist and engineer selected on the basis of required expertise (e.g., an electrophysiologist and an electronic systems engineer) are then assigned to the problem. This team works closely with the problem originator and NASA from inception to completion. At biweekly meetings



STANFORD UNIVERSITY SCHOOL OF MEDICINE
CARDIOLOGY DIVISION
Biomedical Technology Transfer

Who?

The Cardiology Division of the Stanford University School of Medicine has entered into a contract (NASw-2216) with the Technology Utilization Division of NASA Headquarters to apply NASA generated aerospace technology to the solution of known and significant medical problems.

What?

The main objective of this effort is being directed towards the solution of problems in cardiovascular medicine. Other medical areas are being considered, particularly when problems of high impact value develop. Several West Coast medical institutions are being solicited through letter contacts followed by personal visitation for appropriate problems.

Why?

This contract is unique to those presently in existence in that the primary area of interest and effort is in Cardiovascular Medicine. Heart disease is the nation's number one "killer" and disables significant numbers of the population in their productive years. Consequently, Stanford University is concentrating a high level of professional effort in this medical specialty and will perform only secondarily in other related medical areas.

For Whom?

The initial (Summer 1971) list of supported medical institutions includes the medical schools at:

University of Arizona
University of California at Davis
University of California at Los Angeles
University of California at San Diego
University of California at San Francisco
University of Nevada
University of Oregon
Loma Linda University
University of Southern California
University of Washington

and:

Cedars of Lebanon Hospital, Los Angeles
Presbyterian Medical Center, San Francisco

By Whom?

The Cardiology Division has assembled several consultation-visitation teams from a complement of Stanford medical doctor/cardiologists and former NASA aerospace engineers. Several teams consisting of a cardiologist and engineer will be deployed to concentrate their efforts on problems related to their particular expertise. Personnel involved are:

Director
D. C. Harrison, M.D. - Stanford University

Deputy Director
Harry Miller - Stanford University

Medical Personnel
Edwin Alderman, M.D. - Stanford University
David Cannom, M.D. - Stanford University
Richard Crow, M.D. - Stanford University
William Parry, M.D. - Stanford University

Engineering Personnel
A. [illegible]. Buck - NASA-Ames, Retired
J. S. W. Davidsen - NASA-Ames, Retired
Manley J. Hood - NASA-Ames, Retired
Paul [illegible]. Turner - NASA-MSC, Retired
James A. White - NASA-Ames, Retired

How?

From the staff complement just described, visitation teams of two or three members will be selected on the basis of their expertise to act as liaison between the problem originators and Stanford University. Team objectives will be to seek out problem areas, contact individuals, observe and communicate personally, and expedite the technology transfer. As problems are received, each team will utilize information on NASA technological developments to:

A. Provide valid and novel problem solutions in both clinical and medical research sciences that are directed to health-care delivery and advancing the overall quality of medicine.
B. Develop pathways and mechanisms that encourage constructive feedback of future problems and needs within the participating groups, institutions, communities, and NASA.
C. Interpret the significance and impact of problems and report the nature and extent of technology transfer.

Selection of problems is predicated on their significance to broadbase needs and to potentially shared contributions in related fields of cardiovascular medicine.

FIGURE 4 Stanford Cardiology BTT Program Brochure

STANFORD UNIVERSITY SCHOOL OF MEDICINE

701 Welch Road, Suite 3303, Palo Alto, California 94304 • (415) 321-1200, Ext. 6283

CARDIOLOGY DIVISION
Biomedical Technology Transfer

PROBLEM STATEMENT

1. DEFINE THE PROBLEM IN DETAIL:

2. IN WHAT SPECIALTY OF MEDICINE IS THIS APPLICABLE?

3. THE PROBLEM IS PRIMARILY IN (check appropriate box):

Medicine ☐ Engineering ☐ Both ☐

4. DO YOU INTERPRET THIS PROBLEM AS (check appropriate box):

New ☐ Recurrent ☐ New Application ☐

5. HOW HAS THE PROBLEM BEEN MET IN THE PAST AND WHAT AVENUES HAVE BEEN EXPLORED?

(CONTINUED)

The Biomedical Applications of Aerospace Technology (under NASA contract, NASW 2216)

6. SHOULD A SOLUTION RESULT, WHAT WOULD BE THE BROAD-BASED MEDICAL SIGNIFICANCE?

7. WHAT SPECIFIC RESOURCES ARE AVAILABLE TO YOU FOR IMPLEMENTING ANY SOLUTIONS THAT MAY BE OFFERED:

FUNDING:	STAFF:	FACILITIES:
☐ Existing	☐ Committed & Adequate	☐ Committed & Adequate
☐ Applied For	☐ Available; to be Scheduled	☐ Available; to be Scheduled
☐ None	☐ Must be Acquired	☐ Must be Acquired

8. LIST REFERENCES YOU SUGGEST AS PERTINENT TO THIS PROBLEM:

a.)

b.)

c.)

d.)

e.)

SIGNATURE: ______________________ DATE: __________

TITLE: ______________________

ORGANIZATION: ______________________

(*do not fill in*)

Project:

Consultant:

(front) (back)

FIGURE 5 Originator Problem Statement Form of all Stanford members, problem status reports and discussions are handled by respective team members. The man-to-man relationship of physician-engineer with the problem originator is not only effective and efficient, but clearly establishes the credibility and professional status of the NASA program as being unique

NASA Technology Search. Immediately upon problem acceptance, a search of NASA technology and NASA expertise is initiated. Where appropriate, a complete documentary search of the NASA data base is requested through Western Research Application Center (WESRAC), one of the six NASA national regional dissemination centers, in Los Angeles, California. In most cases, NASA data files are searched retrospectively for the previous five years. On two occasions, retrospective searches have been performed on Index Medicus and Nuclear Medicine Abstracts.

Seven documentary searches have been undertaken under this program to date. In each case the cost was justifiable. Six of the searches have proved to be most useful to the investigators; one search indicated that NASA simply had not undertaken pertinent work in this field of concern. One search lead directly to a problem solution (UCD-1) involving vectorcardiogram computer analysis.

Concurrent with documentary searches, personal contact is performed with NASA field centers. Individual expertise and resources within field centers are explored through knowledge of the team's engineers and under the Technology Utilization Officers. It is recognized that a time lag exists between work being performed at field centers and the availability of published information in Technical Briefs and for incorporation into data banks. Furthermore, experience has indicated that many of NASA's accomplishments responsible for solution of technological problems are never reported in documents. The unique expertise and experiences within NASA have been found to be more valuable when dealing with sophisticated and "state-of-the-art" problems than dated information from documentary files. Fifteen problems have received assistance by this direct field center approach.

Technology Solution. Without qualification, NASA has been able to provide expert assistance, and in many instances, prototype or surplus hardware to resolve many problems. Interestingly, technology identification and resolution of most problems occur as direct results of contact with NASA staff in its widespread field centers. With current reductions in manpower at NASA field centers, this resource is clearly shrinking. A second but no less important benefit has been the solution of a variety of medically oriented problems requiring exotic, unique, or cost-prohibitive equipment. Our experiences have been that whenever and wherever NASA has had available hardware or could obtain such, it has been loaned without charge to the problem originator. Under the Stanford contract, loan of twelve pieces of hardware has been effected.

Acknowledgement for the loan of equipment is made to Ames Research Center, Goddard Space Flight Center, Lewis Research Center, Langley Research Center and the Manned Spacecraft Center.

As with many custom fabricated instruments, modification and re-engineering is required to render the device useable in the medical environment. These modifications generally require funds and the knowledge or time of NASA personnel. Therefore, in subsequent programs, provisions are recommended for implementing engineering applications. Under the present contract, approximately five percent of the allocated funds have been expended in time and materials to accomplish necessary and rapid re-engineering. Provisions were not included in the initial contract budget for this contingency, but were performed within budget.

Problems Received and Accepted

The following tabulation summarizes the types of problems covered by the Stanford BTT team from June, 1971 through September, 1972. All problems received under this contract are included in this tabulation, irrespective of the status or disposition. A detailed description of every problem is included in Section III.

Problem Number	Title	Status
CCH-1	Electrodes for Hemiplegia Research	Completed
COH-1	Unsteady Flow Through Heart Valves	Completed
ELC-1	Apnea Monitor for Wide Range of Patients	Completed
ELC-2	Tissue Transilluminating Surgical Light	Completed
MFG-1	60 Hertz Interference Removal from ECG Signals	Completed
PAM-1	Miniature ECG Telemetry Unit for Ambulatory Patients	Completed
PAM-2	Temperature Telemeter for GI Tract Diagnosis	Completed
SSM-1	Detection of Turbidity, Birefringence and Fluorescence Changes in Cardiac Muscle	Completed
SSM-2	Electrode Applications to Myoelectric Control Systems	Completed
SSM-3	Nerve Conduction Velocity Electrodes	Completed
UCD-1	Vectorcardiogram Computer Analysis for Exercised Patients	Completed
UCD-2	Digital Transmission of Medical Data	Completed
UCD-3	QRS Detection and Heart Rate Determination in Exercising Patients	Completed
VSF-1	Respiration and Phonation Electrodes	Completed

Problem Number	Title	Status
AMC-1	A Miniature Portable Patient Arrhythmia Detector	Active
CED-1	ECG Monitoring During Emotional Stress	Active
CED-2	Transducer Referencing Technics in Echocardiography	Active
CED-3	Esophageal Balloon Bipolar Pacemaker	Active
PMD-1	Noninvasive Intracranial Pressure Monitor	Active
UOO-1	Catheter System for Measuring Intravascular Radiation	Active
UOO-2	Catheter System for Measuring Transluminal Radiation	Active
VMC-1	Radiotelemetry of Intracranial Pressure	Active
CHO-1	Innovative Pediatric Tracheostomy Tube	Rejected
CHS-1	Electronic-symbolic Communications System for Nonverbal Children	Rejected
CHS-2	Derotating Heel Device for Orthopedic Children	Rejected
NEV-1	Portable Biofeedback Control of Cardiac Activity in Ambulatory Patients	Rejected
NEV-2	Audiotransform of the Electrocardiographic Signal	Rejected

Detailed Description and Status of Problems

Twenty-two problems accepted into the Stanford program during the contract period are described in detail on subsequent pages. Whenever possible, information concerning the nature, history, constraints, solution and significance of each problem are included. Problems are categorized into: a) Completed, b) Active.

DESCRIPTION OF TECHNOLOGICAL PROBLEMS

A. COMPLETED

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PROBLEM NO. CCH-1

ELECTRODES FOR HEMIPLEGIA RESEARCH

Acquisition Date: November 4, 1971 Transfer Completed: June, 1972
Institution: Contra Costa County Hospital
Department: Physical Medicine
Investigator: Katharine B. Robertson

PROBLEM OBJECTIVE

To develop flexible securely attached electrodes to measure abdominal muscle flexing and bending in patients with hemiplegia and other balance disorders.

BACKGROUND

Current kinesiologic research is limited by the present state of commercially available electrodes which tend to be rigid in configuration, slip, produce artifact and become detached. Tissue irritation is also prevalent. Improved electrodes will permit the establishment of data on normal and well subjects leading to controlled exercise patterns in patients undergoing therapy and retraining of involved muscles.

RESOLUTION

Mr. Salvador A. Rositano of NASA-Ames Research Center supplied samples of ultraflexible electrode discs 1 cm. in diameter with hard-wire lead attachments. These electrodes were in a variation of the ultraflexible biomedical electrodes and wires described in Tech Brief 70-10420. The hard wire lead was terminated with a connector to adapt it to an electromyographic laboratory recorder (model #TE4 Teca Electromyograph).

Electrodes were attached to the external oblique muscles bilaterally and held in place with micropore tape (see Figure 6). Recordings were performed according to the research design developed for testing stability in hemiplegic patients. This type of electrode was found to be extremely suitable for this type of investigation. Patients could bend laterally and pull against a dynamometer at maximal strength levels without displacing the electrodes and without exhibiting motion artifact. No untoward patient response was observed due to their application. Clinical application of these electrodes in the study of hemiplegia patients with trunk instability is presently under investigation with good success.

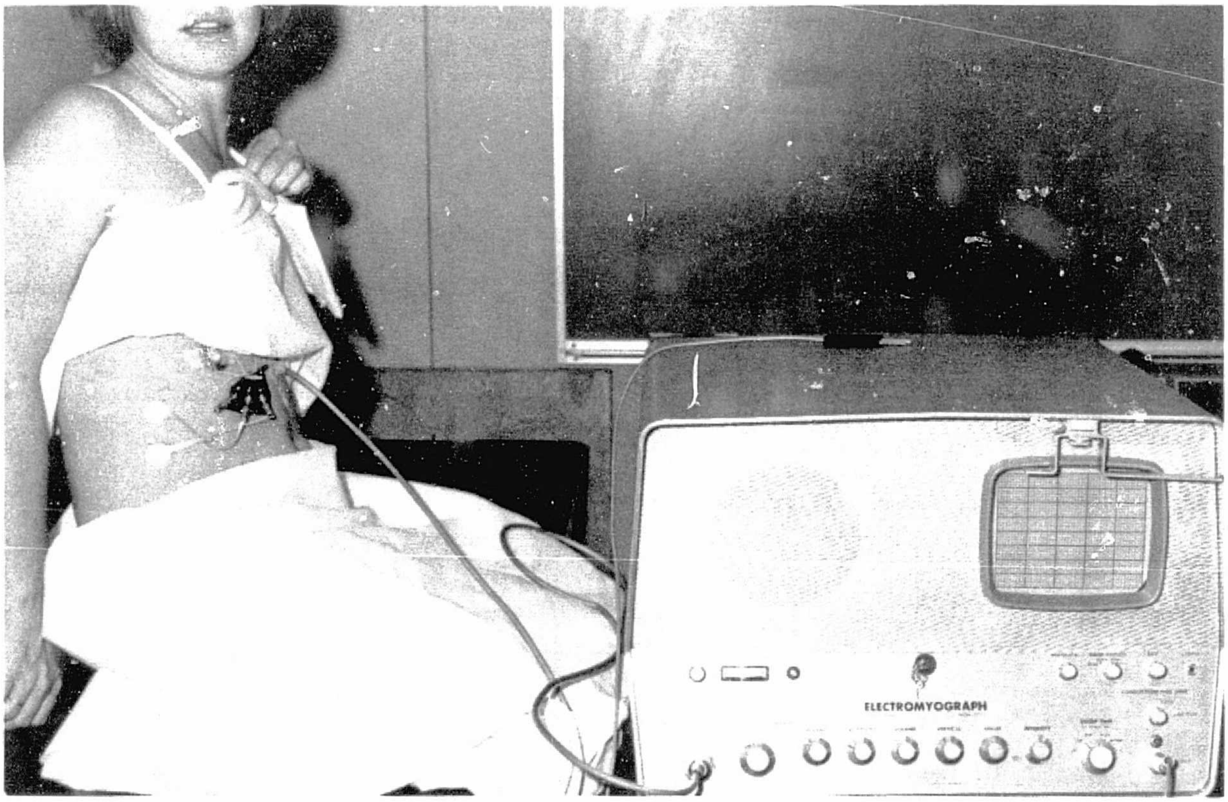


FIGURE 6 Ultraflexible biomedical electrodes attached to the patient's abdomen and recorded on a commercially available electromyograph

OTHER CONTRIBUTORS

Dr. Leon Lewis, Medical Director of the Rehabilitation Services, and Dr. Gerald G. Hirschberg, Director of Physical Medicine Services, Contra Costa County Hospital.

TECHNOLOGY IDENTIFICATION

The basic technology used in resolving this problem resulted from NASA Tech Brief 70-10420 and is a variation of electrode type A70-1095C.

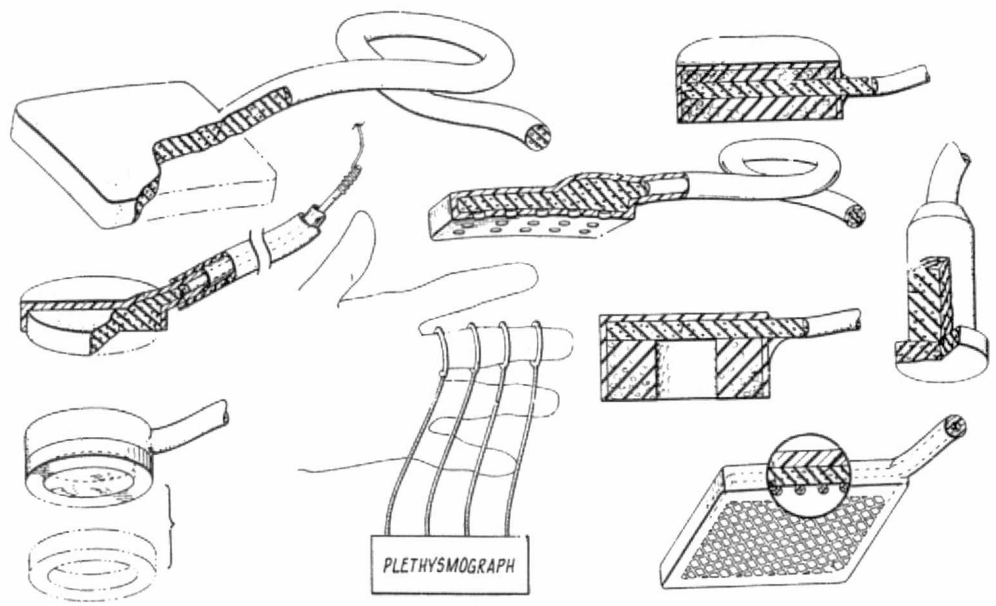
IMPACT

Electrodes of the type described above were presented in conjunction with a short course given for the American Physical Therapy Association Convention in Las Vegas, June 10 and 11, 1972 in which the use of this particular type of flexible electrode was reported in conjunction with kinesiological studies. Considerable interest in this type of electrode has been expressed by therapists engaged in kinesiological studies. Use of this electrode has enabled this research team to rapidly record data accurately and with ease under difficult and complicated test situations.

NASA TECH BRIEF

NASA Tech Briefs announce new technology derived from the U.S. space program. They are issued to encourage commercial application. Tech Briefs are available on a subscription basis from the Clearinghouse for Federal Scientific and Technical Information, Springfield, Virginia 22151. Requests for individual copies or questions relating to the Tech Brief program may be directed to the Technology Utilization Division, NASA, Code UT, Washington, D.C. 20546.

Ultra-Flexible Biomedical Electrodes and Wires



The problem:

To develop a very flexible, uniformly conductive, comfortable, and easily applied biomedical electrode that conforms to the body contour during body motion.

The solution:

A soft, flexible electrode fabricated from an elastomer impregnated with a conductive powder which can be configured into any required shape, including a wire shape to connect the electrode directly to an electrical instrument or to a conventional metallic wire.

How it's done:

As shown in the figure, the device consists of the electrode and a conductor, both formed of silicone rubber as the elastomer and loaded with silver-plated particles as the conductive material. The electrode can be molded or cut to fit over any irregular body contours and to accommodate body location and type of measurement. A wide variety of electrode configurations can be fabricated using accessory materials such as silicone rubber sponge, silicone rubber adhesives, or adhesive bandages. Electrodes and "wires" made of the impregnated elastomeric material are suitable for implantation and connection to implanted telemetry equipment. The impregnated elastomeric wire is not only flexible but stretchable, in some cases up to 40% of its length, while maintaining excellent conductivity. This is a significant improvement over the normal metallic lead wires, which always present the danger of breaking at the junction

(continued overleaf)

with the electrode. Where external electrodes are used, improved contact with the skin can be obtained with sodium chloride electrolyte paste or jelly. In this case, the electrode can be designed with wells in which the electrolyte is placed. It is not always necessary to use an electrolyte paste, since the electrode moves with the skin. Long-term monitoring of relatively motionless bed-ridden patients can be accomplished with the electrode alone. Use of the electrode without the wet electrolyte avoids the problem of periodic replenishment and the discomfort of a continuously damp interface with the skin. The dry electrode does result in a higher impedance, but this is readily handled with a high input-impedance amplifier. Previous studies with electrodes have shown that silver-silver chloride provides the lowest galvanic potential when used with a sodium chloride jelly. The chloride ions provide the mechanism by which the biopotentials are sensed. A layer of silver-silver chloride can be plated on the elastomeric electrode surface by conventional electroplating using a 10% HCl solution with silver wire as a cathode and a 6-V power source. Plating on the electrode does not alter its flexibility. Insulation can be provided on any part of the electrode by spraying, dipping or brushing with nonconductive silicone rubber.

Note:

Requests for further information may be directed to:

Technology Utilization Officer
Ames Research Center
Moffett Field, California 94035
Reference: TSP70-10420

Patent status:

Inquiries about obtaining rights for the commercial use of this invention may be made to NASA, Code GP, Washington, D.C. 20546.

Source: S. A. Rositano
Ames Research Center
(ARC-10268)

INVENTION ABSTRACT

NASA Case No. ARC-10268-1

ULTRA-FLEXIBLE BIOMEDICAL ELECTRODES AND WIRES

The present invention relates to a flexible, stretchable biomedical electrode and connector which is designed for use by physicians, medical technicians and researchers to connect an electric instrument to the body.

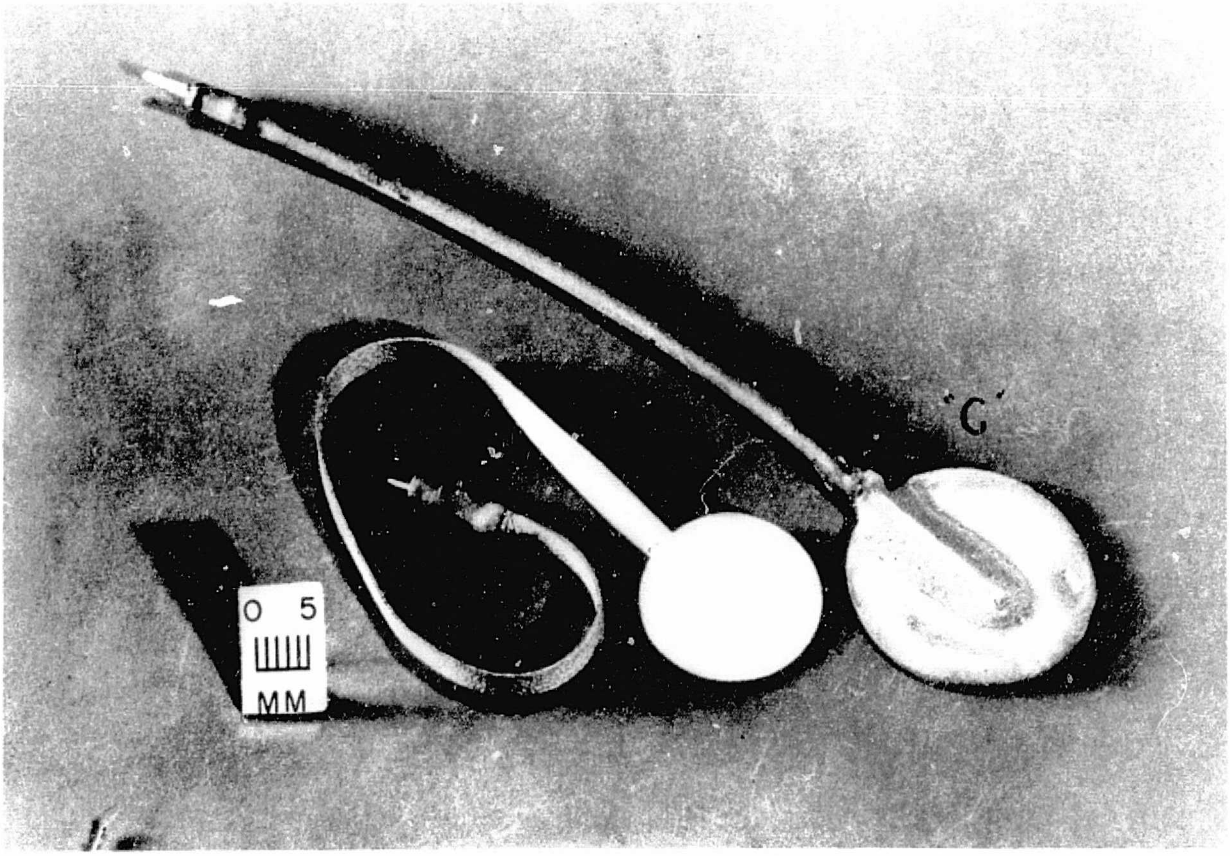
In the past, body electrodes have ordinarily consisted of a solid member coupled to the skin by a conductive paste. Such electrodes have been relatively inflexible so that they could not be used over a considerable portion of the body and were often uncomfortable even when applied to small areas of the body. Normally metallic lead wires are used with such electrodes and, even if the electrode itself is satisfactory, there is always the danger of the wire breaking at its junction with the electrode.

In accordance with the present invention, a soft, flexible electrode is provided by using an elastomer which has been loaded with a conductive powder with a connecting "wire" formed as part of the electrode of the same material.

The basic form of the invention is shown in Figure 1 of the drawings and consists merely of the electrode 14 and its conductor 16, both formed of an elastomer which is loaded with metal particles to render it conductive. A number of variations of this basic structure are possible. One is the employment of an insulating layer over the back of the electrode which can form a continuation of an insulating layer of the connecting wire. Further, an insulating layer can be formed over the face of the electrode with one or more apertures therein which may be filled with one of the usual conducting jellies for connecting the electrode to a body.

Thus the present invention provides a soft, flexible conductive electrode for biopotential measurements or stimulation which has a low contact potential and which has an electrical cable which will conform to the body contour during body motion. The "wire" itself is not only flexible but stretchable.

Inventor: Salvadore A. Rositano
Employer: NASA - Ames Research Center
Initial Evaluator: Ralph K. Hallett, Jr.



A70-1095:- The application here was for a dry-type electrode without the insulating washer shown in the previous photographs. One can get the same electrical characteristics as the standard clinical plate-type electrode with the additional advantage of the extreme flexibility, very soft, body-conforming-style material. The electrode shown on the left was formed with Emerson and Cuming type SV-R, .020 inch thick. The entire electrode and wire were cut from one piece providing a very strong and yet completely flexible electrode. The wire in this case could be stretched up to 40% of its length, while maintaining excellent conductivity. The tip plug, shown on the end, was affixed to the wire with Emerson and Cumings Type RVS adhesive. The electrode on the right was formed with Chomerics .020 inch thick Type 1224. The wire is again a stretchable conductor made with Chomerics Type 1215 rod-shaped material, 1/16 inch in diameter and covered with heat-shrinkable, silicone-rubber tubing. The elastomeric wire was attached to the electrode with Chomerics Type 1022 conductive adhesive. The entire electrode back surface and a short length of the wire was then covered with Dow 3140 clear-adhesive coating. The tip connector was fixed to the end of the rod-shaped material with Chomerics Type 1025 adhesive. The baking process here for curing the 1022 on the electrode surface, the 1025 on the tip, and shrinking the silicone-tubing over the conductive wire, was performed in an oven at 350°F. for 5 minutes.

PROBLEM NO. COH-1

UNSTEADY FLOW THROUGH HEART VALVES

Acquisition Date: March 20, 1972 Transfer Completed: June, 1972
Institution: City of Hope Medical Center, Duarte, California
Department: Cardiology
Investigator: Simon Rodbard, M.D.

PROBLEM OBJECTIVE

To develop equations of unsteady flow through heart valves and soft-walled vessels so that such flows can be studied through simulation in computers.

BACKGROUND

Understanding the causes of and the interpretation of cardiovascular murmurs could be expedited if the phenomena could be simulated in computers. Only experimental techniques have been available for research on these unsteady flows.

Dr. Rodbard is a cardiologist who has been interested, for some time, in the physical principles which affect the flow of blood through soft-walled vessels. His research is pertinent to the flow through arteries and veins and, in addition, to flow through cardiac valves. He has been able to show that in a physical model system, which he constructed, flow of air through flexible valve leaflets generates a flutter phenomenon at certain critical velocities of flow. Dr. Rodbard feels that a similar phenomenon may occur in the human heart during blood flow through cardiac valves. This analysis has considerable hemodynamic importance because of the fact that when flutter develops, there are considerable energy losses due to increased turbulence of flow and to the actual flutter motion of the valves, which reduces the mechanical efficiency of the heart.

Dr. Rodbard's problem was submitted in anticipation that the science of fluid-mechanics might provide information relative to this problem. Specifically, he was interested in possible mathematical equations describing the flutter phenomenon, which he might be able to computer simulate. This will enable him to study flutter from a more theoretical standpoint as opposed to the practical modeling approach used in the past. Successful computer simulation of unsteady blood flow could be of large practical importance, not only in understanding pathological processes affecting cardiac valves, but also in the design and characteristics of artificial heart valves. When this problem was reviewed by the Stanford BTT team, it was considered to be a difficult but medically worthwhile and important area for further effort. Dr. Robert T. Jones, a NASA scientist who is a recognized expert in theoretical fluid mechanics and has done some basic work on artificial hearts and circulation aids, was then consulted.

RESOLUTION

Consultation with Robert T. Jones of NASA-Ames Research Center confirmed the opinion of the BTT consultants that the science of fluid dynamics is not yet capable of expressing such unsteady flows in useful mathematical form. The investigator has been advised of this conclusion and has been encouraged to continue with his experimental approach. He was supplied with copies of Dr. Jones' publications relative to blood flow and with a list of texts on fluid dynamics which delineate the physical requirements for simulation in fluid dynamic experiments.

TECHNOLOGY IDENTIFICATION

Expertise of NASA personnel in the general field of fluid dynamics has offered major contributions to the identification of pertinent technology. Particularly notable was the consultation of Dr. Robert T. Jones of NASA-Ames Research Center.

IMPACT

Dr. Rodbard was provided with information on the state-of-the-science of fluid dynamics relevant to his problem. That information has aided him in directing his future research on a vital aspect of hemodynamics.

STANFORD UNIVERSITY SCHOOL OF MEDICINE

701 Welch Road, Suite 3303, Palo Alto, California 94304 • (415) 321-1200, Ext. 6283

CARDIOLOGY DIVISION
Biomedical Technology Transfer

June 9, 1972

Simon Rodbard, M.D.
City of Hope Hospital
1500 E. Duarte Road
Duarte, California

Dear Doctor Rodbard:

We have carefully considered the feasibility, as proposed by you, of computer simulation of flow-induced flutter of heart valves and soft-walled vessels.

Most importantly, we have discussed your problem with Dr. Robert T. Jones of NASA's Ames Research Center. Dr. Jones has spent most of his career in basic research or fluid dynamics. In this science, he has made a number of important contributions which have won him wide recognition and respect. For several years Dr. Jones took leave from his aeronautical studies while he applied his expertise in fluid dynamics to heart-assist pumps at the Avco Research Laboratory. In that work he was associated with Adrian Kantrowitz, M.D. Reference 1 through 4 in the enclosed list describes some results of that effort. A copy of each is enclosed for your convenience. We give this background to establish Dr. Jones' credentials in relation to your problem.

Before your problem can be investigated by computer it must, of course, be formulated or "modeled" in mathematical terms. Probably your problem, like a host of other problems in fluid mechanics, could be expressed in the form of the Navier-Stokes equations. These equations can be found in text books of fluid mechanics, for example references 5 through 7. Unfortunately, no general solutions to the Navier-Stokes equations are known. Thus, we come to an impass, even though fluid mechanics has been a favorite hunting ground of mathematicians for a number of decades.

Simon Rodbard, M.D.
June 9, 1972
Page 2

It is for just such reasons that aerodynamics and other aspects of fluid dynamics resort so extensively to experiments using wind tunnels and such devices to simulate the situations under study. They do this even when the experiments are expensive and time-consuming. Under the present state of the science, we conclude that your problem too is best attacked by formulating experimental models to study the phenomenon of flow-induced flutter. This, of course, has been your approach in the past.

The enclosed papers by Dr. Jones, and the texts cited discuss Reynolds number and some of the other parameters that must duplicate or approximate real-life values if experiments such as yours are to simulate actual hemodynamic situations accurately.

We regret that we are unable to suggest a practical way to computer simulate the important problems which you propose to study. Such computer simulation seems to be beyond the present state of the science. In aeronautical research, active efforts to solve flow problems by computer simulation continue. We will advise you if we learn of any important advances. We hope that our remarks will help you to carry your experiments to fruitful conclusions.

Please let us know if we can be of any further service in relation to this or other problems.

Sincerely,

Wm Barry MD.
William Barry, M.D.
Medical Consultant

Manley J. Hood
Manley J. Hood
Engineering Consultant

WB/MH:dh
Enclosures: List of Refs.
Copies of Refs.

ROBERT T. JONES

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CITY OF HOPE NATIONAL MEDICAL CENTER
1500 EAST DUARTE ROAD • DUARTE, CALIFORNIA 91010 • (213) 359 8111

DEPARTMENT OF CARDIOLOGY
Simon Rodbard, M.D., Director

June 21, 1972

Dr. William Barry
Mr. Manley J. Hood
Stanford University
School of Medicine
Cardiology Division
Biomedical Technology Transfer
Palo Alto, California 94304

Dear Dr. Barry and Mr. Hood:

Thank you for your letter of June 9, 1972, and for the xeroxes of the papers on fluid dynamics. I appreciate your interest in the question that I raised. I regret that it will be necessary to go through the difficult task of establishing model experiments for the purpose of clarifying flow-induced flutter.

With appreciation for your efforts,

Sincerely yours,

Simon Rodbard

Simon Rodbard, M.D.
Director
Department of Cardiology

SR:bl

PROBLEM NO. ELC-1

APNEA MONITOR FOR WIDE RANGE OF PATIENTS AND APPLICATIONS

Acquisition Date: October 20, 1971 Transfer Completed: February, 1972
Institution: El Camino Hospital, Mountain View, California
Department: Anesthesiology
Investigator: David V. Thomas, M. D.

PROBLEM OBJECTIVE

To provide a simple, inexpensive apnea (cessation of breathing) monitor suitable for patients ranging from tiny infants to adults and for application to nostril breathing, respirator lines and oxygen masks.

BACKGROUND

Breathing difficulties, including temporary cessation of breathing are a common problem in a variety of patients. Dr. Thomas described the need for a simple, reliable device to alert nurses to apnea in patients who are unable to summon help.

In the past, breathing of such patients has been observed continuously by nurses or monitored electronically from chest movements or with sonic measuring devices. There was a need for a better way to monitor patients while alleviating the need and expense for nurses to be present at the bedside. A simple, reliable, inexpensive device was needed. The device should be suitable for all types of patients, including premature infants, comatose patients of all ages, and paralyzed patients. The device should function with normal nostril breathing, tracheostomy tubes, respirators and oxygen masks or tubes.

In 1968, NASA - Ames Research Center, in cooperation with the Children's Medical Center, Oakland, California had developed a device which proved successful in meeting some of these needs. That device activates an audible or visual alarm seconds after a patient with a tracheostomy tube ceases breathing. Using a thermistor and special electronic circuits, the device senses the cyclical temperature differences between inhaled and exhaled air. Interruption of the cyclic changes causes actuation of an alarm after the selected time lapse. In that application, a temperature-sensing thermistor was mounted in the tracheostomy tube and the signal was transmitted by FM radio to the nursing station. This technology for tracheostomy application is described in NASA Tech Brief 68-10365, October, 1968.

Since extensive usage of the equipment is patient-dependent, Dr. Thomas has invited Dr. Alvin Hackel, of the Children's Hospital at Stanford University to share use of the equipment.

RESOLUTION

NASA-Ames Research Center extended the aerospace technology applications described in the NASA Tech Brief 68-10365, cited above, to serve the broader range of needs described by Dr. Thomas.

To permit the desired broader range of uses, several new sensor arrangements were devised and provided to Dr. Thomas for evaluation by the Stanford BTT team. All of these depended on cyclic temperature changes sensed by thermistors, but new types were provided for use in respirator lines, insertion in nostrils of premature infants, use in oxygen lines and two types for taping on to the upper lip in addition to the tracheostomy type. Breathing rates from 12 to 180 per minute must be accommodated and volumes/breath from 4-2000 cc.

Since the present devices are intended for confined patients, radiotelemetry described in NASA Tech Brief 68-10365 was omitted and wired circuits have been substituted in the interests of simplicity and economy (See Fig. 7). Radiotelemetry can be employed whenever deemed advantageous.

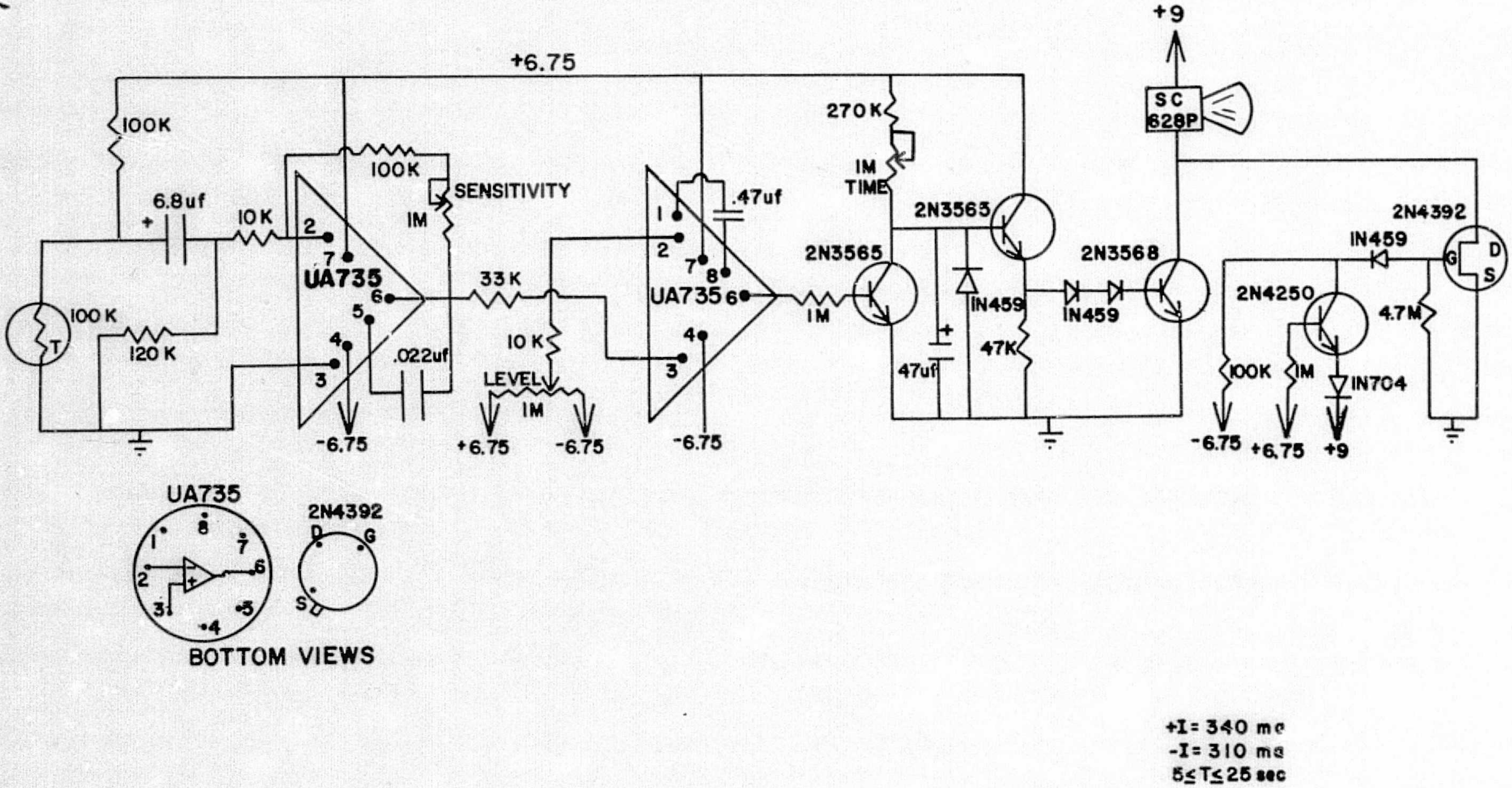


FIGURE 7 Respirator Failure Alarm Circuit

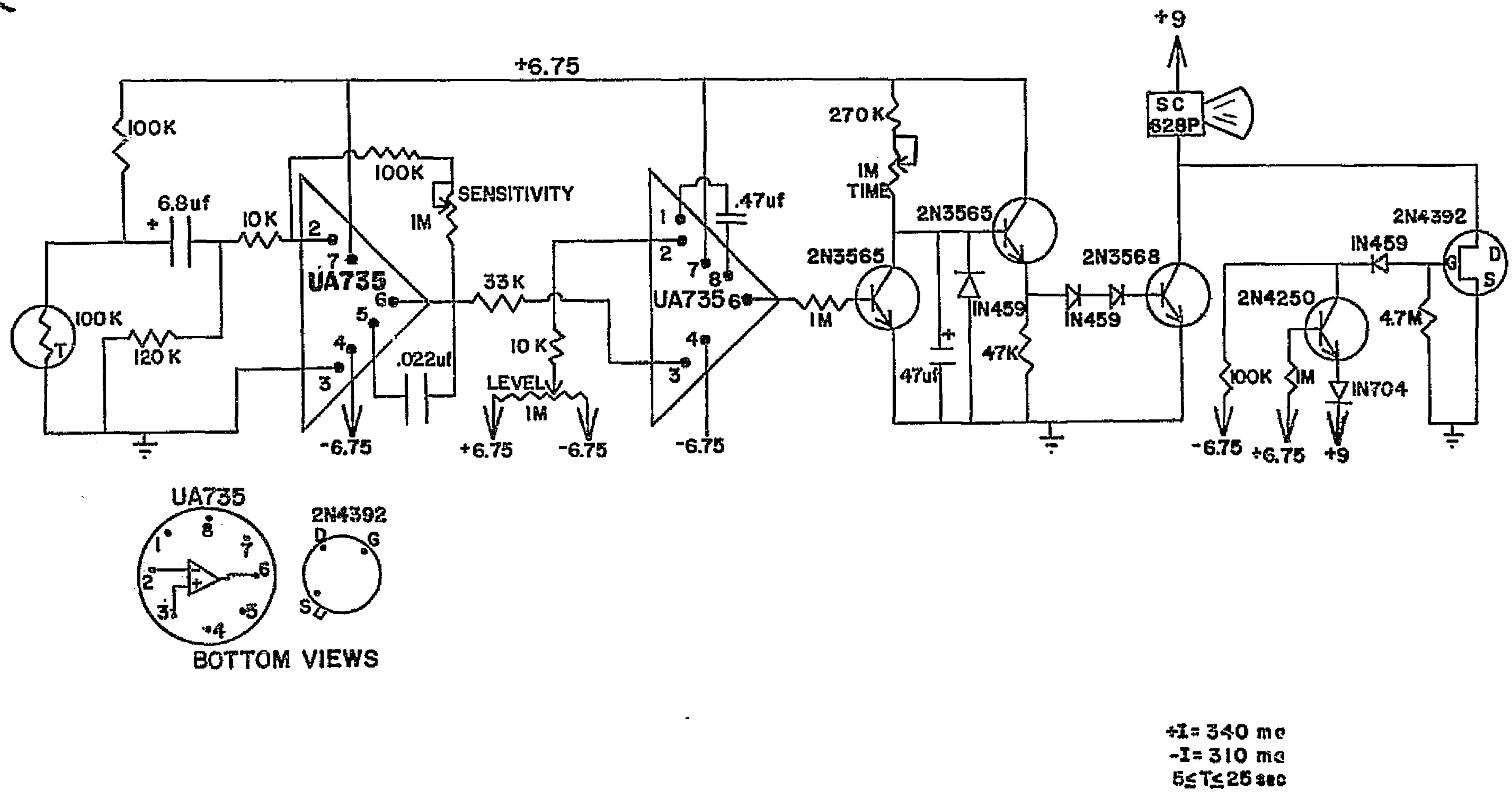


FIGURE 7   Respirator Failure Alarm Circuit

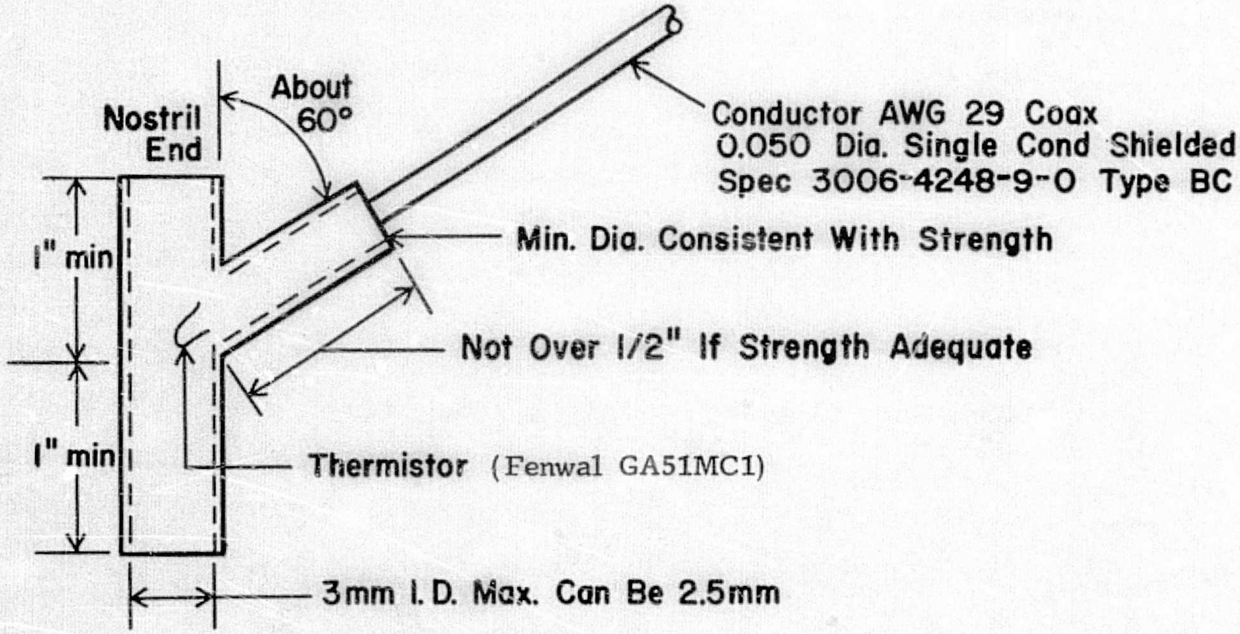


FIGURE 8 Thermistor and silastic housing for nostril insertion application to small infants. Tape is applied to secure the silastic housing to the upper lip.

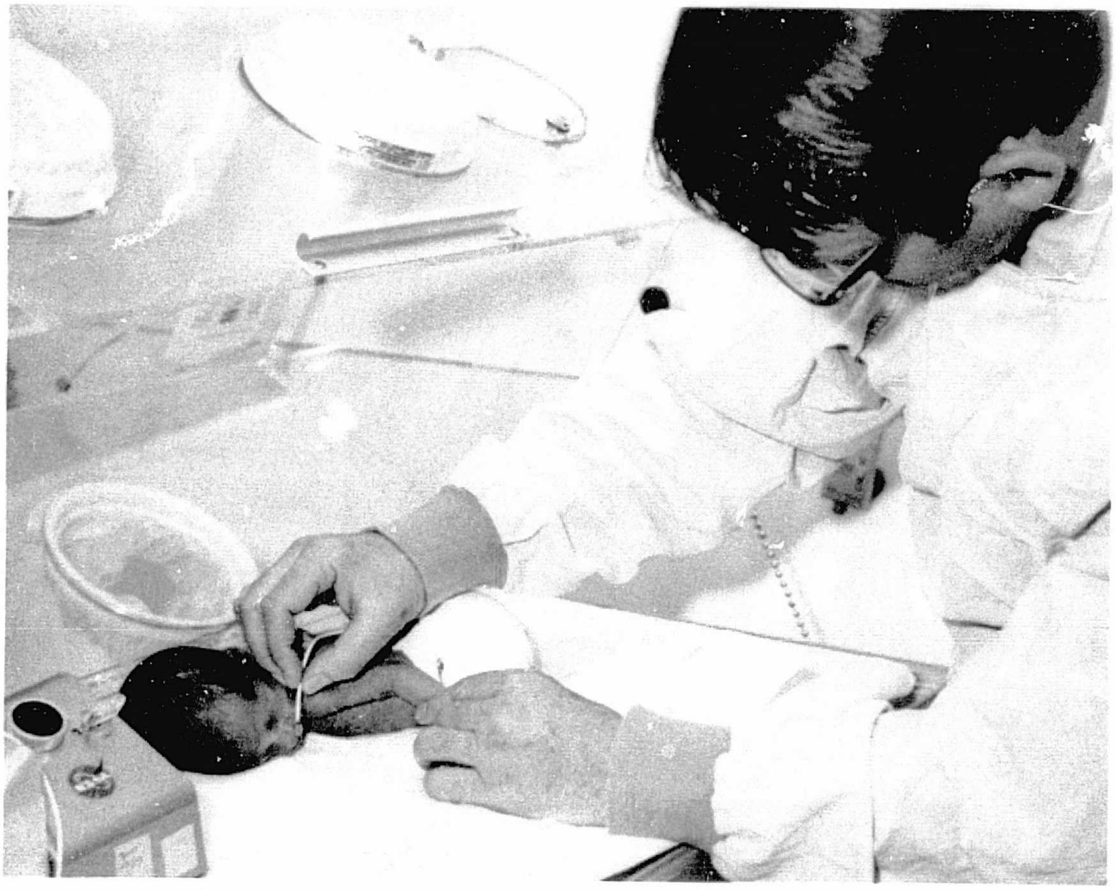


FIGURE 9 NASA Apnea Monitor used to monitor respiration patterns of a premature infant

FIGURE 10 NASA Apnea Thermistor being applied under the nose of a four pound infant

In each new thermistor application listed above, Stanford utilized fast response, 100K ohm thermistors, such as Fenwall Electronics No. GA 51MC1. Nostril-insertion tubing is very soft and flexible silastic, for patient comfort. All sensors and wiring are of hospital quality and are all capable of cold sterilization.

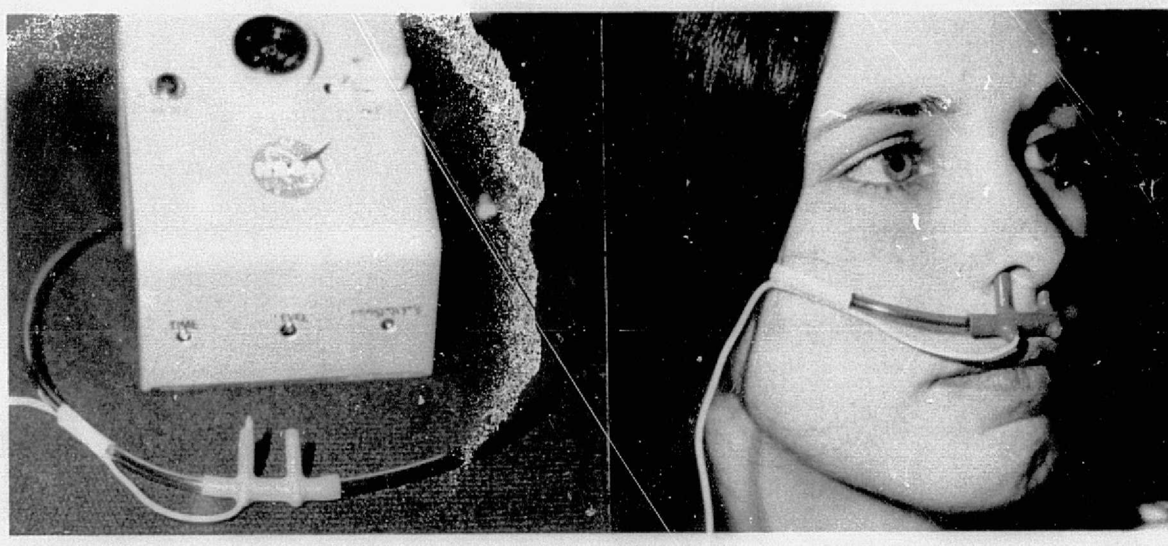


FIGURE 11 Nostril-insertion design used with nasal methods of oxygen administration

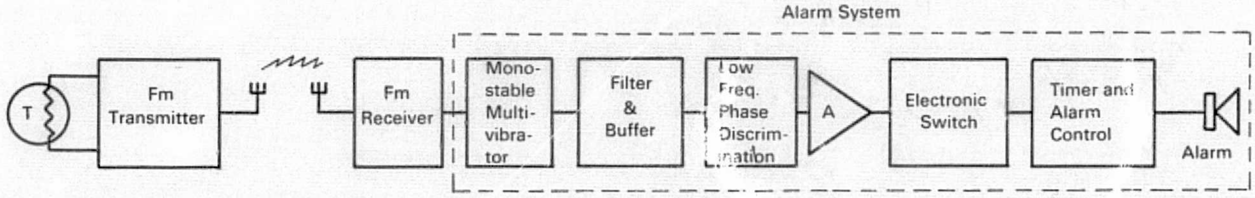
TECHNOLOGY IDENTIFICATION

The basic NASA technology applied to this problem is described in NASA Tech Brief 68-10365. The expertise applied to solution of the problem by Messrs. John M. Pope, Richard M. Westbrook, Thomas Hamon and John Dimeff of NASA-Ames Research Center, was derived from their experience in developing instrumentation for measuring airflow in aerospace research.

No literature search was necessary because the work described in the cited NASA Tech Brief was well known to engineering consultants of the BTT team.

NASA TECH BRIEF

Automatic Patient Respiration Failure Detection System with Wireless Transmission



The problem:

Infants or comatose children and adult patients sometimes require a tracheostomy tube which is surgically implanted in the patient's windpipe to ease breathing difficulties. Because of the ever present danger of the tube becoming clogged and suffocation resulting, a continuous visual watch by a nurse is required to detect respiration failure and to take immediate corrective action. This is not only expensive, but even with continuous surveillance, there is always the possibility that the nurse might be distracted for the short interval (2–4 minutes) necessary for brain damage or death to result from lack of sufficient oxygen.

The solution:

An automatic Respiration Failure Detection System which immediately recognizes respiration failure or partial failure and ten seconds later, actuates an audible and/or visual alarm. The system incorporates a miniature radio transmitter so that the patient is unencumbered by wires yet can be monitored from a remote location such as a nurse's station or a room other than the patient's room at home.

How it's done:

The temperature sensor–FM transmitter is attached directly to the tracheostomy tube, thereby allowing the inspired and expired air to flow directly over a thermistor temperature sensor. This sensor responds to differences in the temperature of the airflow through changes in its resistance. The FM transmitter has a nominal subcarrier pulse frequency which increases as the thermistor resistance decreases with increasing temperature. An FM receiver is used to receive the respiration signal. The pulsed receiver output is used to trigger the alarm system. The first stage in the alarm system is a monostable multivibrator which provides amplitude discrimination against changes in the level of the receiver output signal. This output is filtered, buffered by an emitter follower and coupled to a low frequency phase discriminator which serves as a frequency-to-voltage converter. The voltage changes caused by respiration are amplified with an adjustable gain of approximately 2 to 23 and are used to actuate an electronic switch which provides a reset pulse for each respiratory cycle considered to be of sufficient length (as determined by the setting of the amplifier gain control). The reset pulse is used to discharge a capacitor that serves as the timing element of the alarm control. If the capacitor does not receive a reset pulse for a preselected time (arbitrarily chosen to be 10 seconds), the alarm control actuates an audible and/or visual alarm. A "Reset-Normal" switch is provided that turns off the alarm when placed in the "Reset" position and allows 1½ minutes to clear any obstruction in the tracheostomy tube. At the end of this time interval, the alarm will sound

(continued overleaf)

again and will continue to operate until the "Reset-Normal" switch is again placed in the "Normal" position and a proper respiratory signal is received.

Notes:

1. The system could be used to monitor normal nose-mouth breathing by the use of an air-directing mask which directs the flow of respiratory air across the thermistor temperature sensing element.
2. Since the lead length of the thermistor is "non-critical" to circuit operation, the thermistor need not be located near the transmitter. Any cyclic point temperature could be monitored for gross variations and could be used to trigger the alarm system if arbitrary limits are exceeded.
3. A prototype system has been assembled largely from components developed for space research purposes. First trials of this equipment to monitor the respiration of human patients have been conducted at Children's Hospital Medical Center, Oakland, California after initial experiments on a young dog. The patients, all children, had tracheostomy tubes implanted and ranged in age from 6 weeks to 4 years. These trials, conducted under continuous monitoring by a doctor or a nurse, are continuing with excellent results. An indication of the sensitivity of the apparatus is provided by the fact that it was successfully used to monitor the respiration of a six-week old child that was housed in an isolette where the temperature is maintained at 85°F.
4. Inquiries concerning this invention may be directed to:

   Technology Utilization Officer
   Ames Research Center
   Moffett Field, California 94035
   Reference: B68-10365

Patent status:

Inquiries about obtaining rights for the commercial use of this invention may be made to NASA, Code GP, Washington, D.C. 20546.

Source: Jack M. Pope and John Dimeff
(ARC-10174)

OTHER CONTRIBUTORS:

Samuel Abraham, Ph. D., of the Bruce Lyon Memorial Laboratory Oakland, California first called attention to tracheostomy apnea monitoring problems and later offered valuable suggestions concerning the broader applications described herein (See Figures 12, 13, 14).

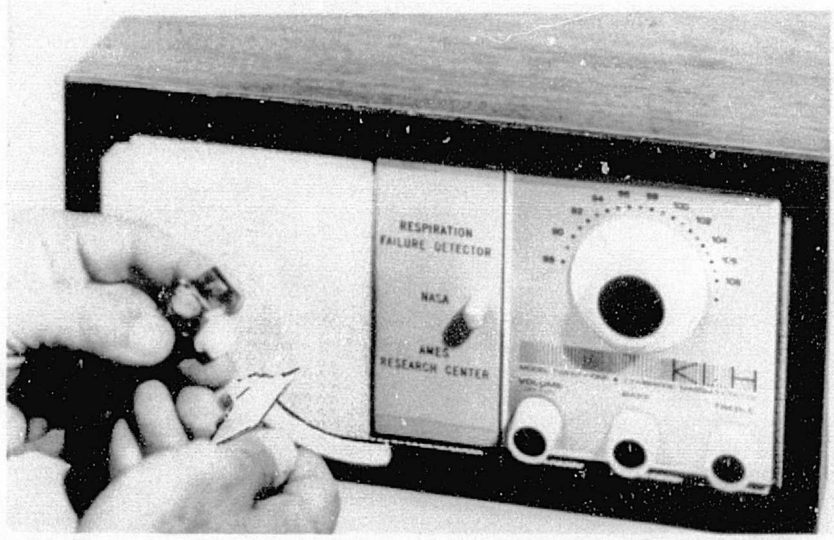


FIGURE 12 Transmitter being attached to endotracheal tube and KLH receiver

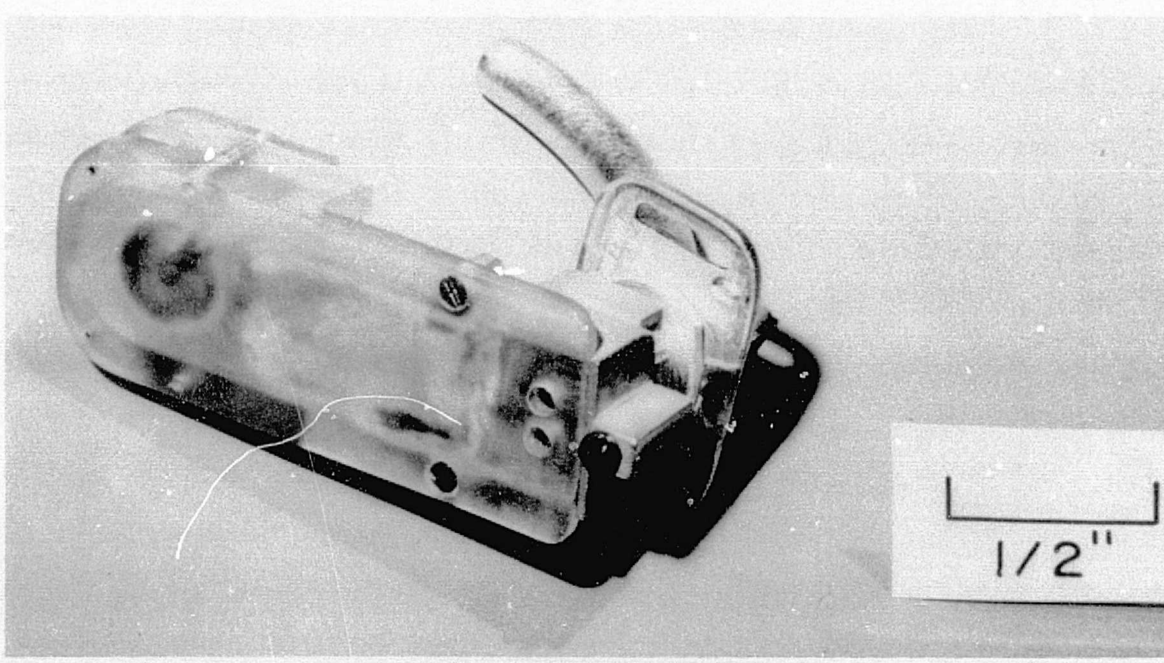


FIGURE 13 Endotracheal tube with attached transmitter

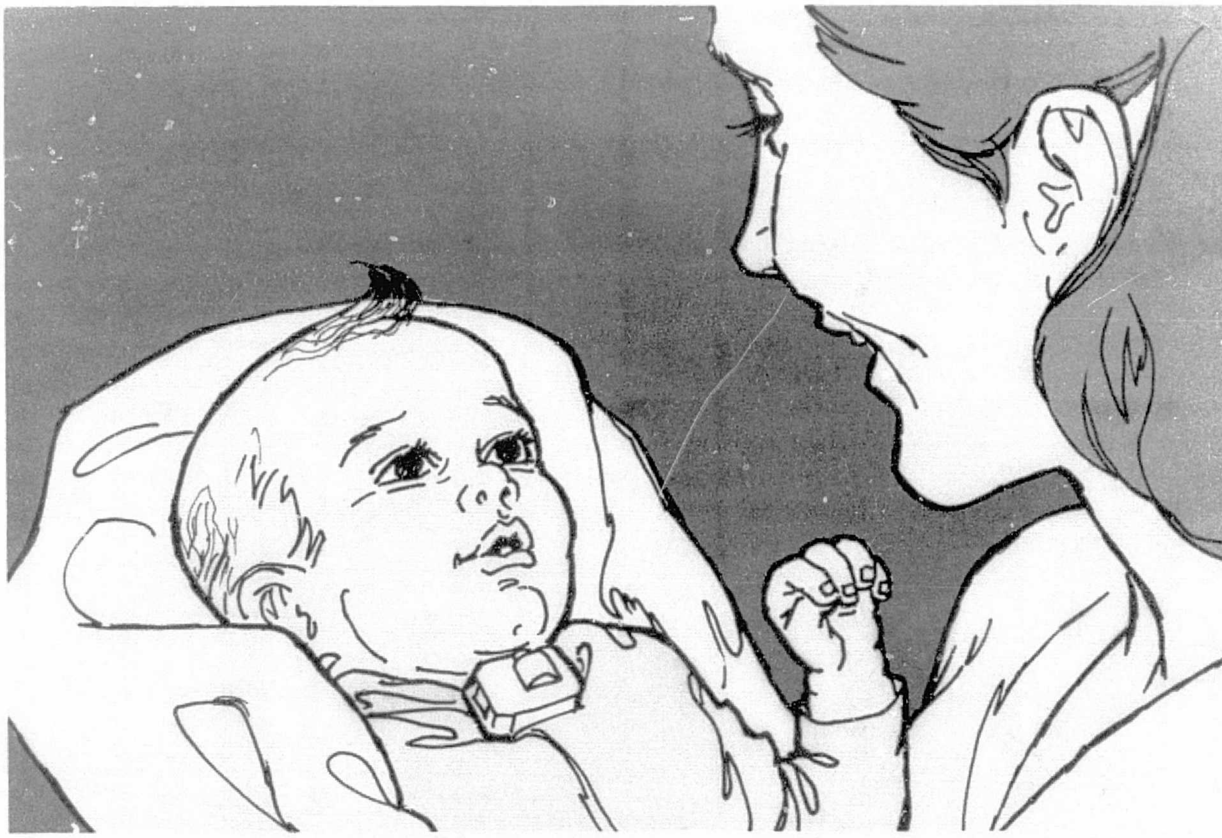


FIGURE 14 Application of endotracheal tube and transmitter to monitor respiration in infants

IMPACT

NASA Technology has been adopted to the development of devices which can automatically monitor patients threatened with apnea. These devices can protect lives while relieving nurses from continuous bedside vigilance and provide improved surveillance. Inexpensive and simplified respiration monitoring can now permit observation of the patient outside of the hospital environments (home, convalescent units)

PROBLEM NO. ELC-2

SMALL, INTENSE LIGHTS FOR SURGICAL TRANSILLUMINATION

Acquisition Date: February 29, 1972 Transfer Completed: July, 1972
Institution: El Camino Hospital, Mountain View, California
Department: Surgery
Investigator: Donald F. Phillips, M.D.

PROBLEM OBJECTIVE

To provide small, cool, intense and sterilizable lights for transillumination of tissue during surgery. The lights must be electrically safe and sterilizable for use in surgical fields.

BACKGROUND

In addition to the usual overhead lights in surgical theaters, backlighting and transillumination of internal organs and tissues would be highly effective in revealing lines of demarcation, blood vessels and lesions.

For such uses, lights of two shapes are desired by Dr. Phillips. The first should be a disc, approximately 2.5-inches in diameter by 0.25 inch thick with light emanating only from one flat side. This light would be placed behind intestines, mesentery tissue, blood vessels, etc. during abdominal surgery. The second light source should be of bullet shape, 0.75 inch diameter by 0.75 to 1.0 inch long. It should have a cylindrical handle, of the same diameter, about four inches long. This bullet-shaped light would be inserted in the rectum or vagina for transillumination (See Figure 15).

Lights of both shapes should be as bright as possible, consistent with the required coolness and electrical safety, but they should provide not less than 100 foot-candles intensity.

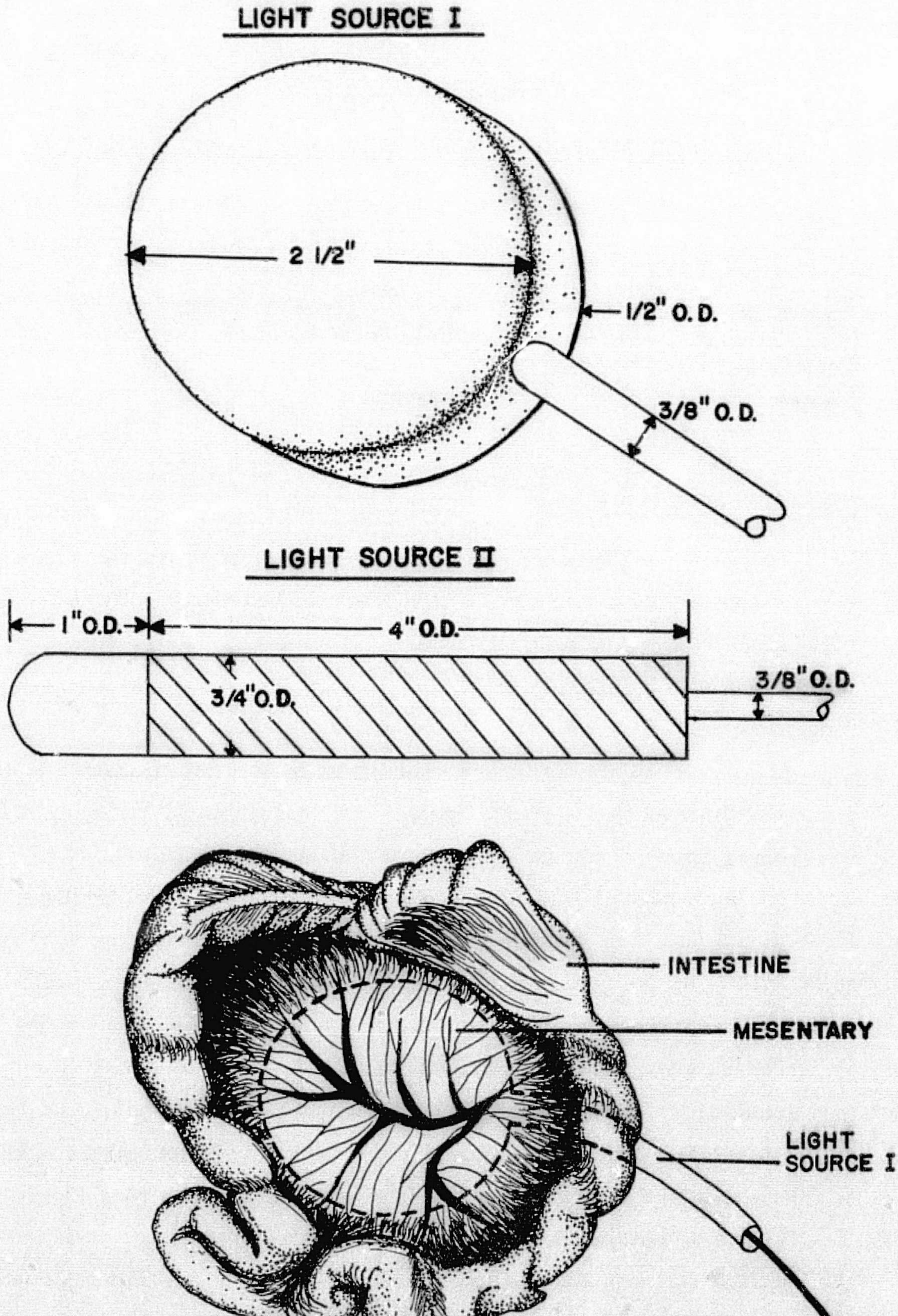


FIGURE 15 Dimensional description of two fiber optic light sources; light source type I is depicted during abdominal surgery

RESOLUTION

Work of NASA-Ames Research Center with fibre optics, a promising technique for this problem, with animals was known to the BTT consultants. Consultation with Ames scientists, George R. Grant and Ralph W. Donaldson, Jr. established the Ames expertise, but no directly applicable solution. Mr. Grant provided information on line losses, acheivable light outputs and suggested specifications. He also recommended commercial sources which could make such lights to order. A concurrent literature search by WESRAC revealed no useful published information

Dr. Phillips expects to procure lights made to his specifications by a commercial source recommended by Ames. For economy, he plans to initially use existing light sources, though their output could be increased 40 percent at an additional cost. El Camino Hospital has existing medical fibre optic light sources ranging from 100-200 watts. For maximum illumination, a 500 watt source was recommended. Calculations based on Ames expertise indicate that, with the hospital required six foot length and the existing light source, the fibre optics cable must be 3/8 inch in diameter to provide the required 100 foot-candles with the 2.5-inch disc (a smaller disc would give a higher intensity). With the bullet-shaped light, a smaller cable can be used with an expected 300 foot-candle intensity.

TECHNOLOGY IDENTIFICATION

No published information was found to offer a solution to this problem. However, from their knowledge, scientists at NASA-Ames Research Center readily identified applicable state-of-the-art technology which could meet the requirements and suggested commercial firms capable of fabricating lights to Dr. Phillips' specifications. The firms contacted were: American Optical, American Cystocope, Bausch & Lomb, Circon, Dupont, Edmunds Scientific, Fibre Photics, Flexioptics and Optics Technology. Flexioptics was capable of meeting all the specifications at a reasonable cost.

IMPACT

Through identification of state-of-the-art technology and a capable fabricator, it appears that new types of lights for safe transillumination of tissue during surgery will become available. Dr. Phillips expects the lights to be quite helpful in facilitating identification of lines of demarcation in tissues, blood vessels and lesions.

PROBLEM NO. MFG-1

60 HERTZ INTERFERENCE REMOVAL FROM ECG SIGNALS

Acquisition Date: May 4, 1972 Transfer Completed: July, 1972
Institution: Humetrics Corporation, Los Angeles, California
Department: Engineering
Investigator: Lee R. Baessler, Director of Engineering

PROBLEM OBJECTIVE

To provide a method of removing or attenuating strong 60 Hertz interference from amplified ECG signals without significant distortion of the ECG waveform.

BACKGROUND

60-Hertz interference in ECG recording and transmission has been a common and recurrent problem, since 60-Hertz is so universal and falls within the informative ECG frequency domain.

ECG recordings and health surveys are frequently performed in the field near schools, industrial parks and urban environments containing intense induced interference from transmission lines, substations and heavy building-feeder circuits.

Notch filtering and improved common-mode rejection input amplifiers have been largely used in the past to alleviate this interference problem, with a good measure of success. When strong 60-Hz is present, even these measures are frequently unsuccessful.

The problem originator is highly skilled in the field of biopotential recording and conventional filtering technics. Most published methods have been explored and found to be unsuccessful. A novel and highly sophisticated approach is needed.

RESOLUTION

Stanford BTT consultants had personal knowledge that NASA-Ames Research Center had done a great deal of significant research into noise rejection. A conference was arranged with Mr. Gordon DeBoo of the Electronic Instrument Development section. Mr. DeBoo confirmed that while Ames had performed extensive design in frequency filtering in the past, present commercial suppliers of quality instrumentation were available to achieve a probable solution of the problem in question. Ames has discontinued instrumentation research effort in this area.

Mr. DeBoo furnished technical literature published by NASA and commercial suppliers together with a list of recommended vendors to the problem originator.

Simultaneously, with this personalized contact with the NASA Field Center, a search (WESRAC) of NASA data banks was performed and sent to the problem originator for review.

Following Mr. DeBoo's recommendations, Mr. Baessler selected a commercial firm for the design and manufacture of a specialized notch-filter, with notch suppression ± 0.75 Hz at 60 Hz, specifically designed to match the Humetrics equipment. Although the filter worked extremely well, it did require extraordinary precision in manufacture, delicate field handling, and was expensive; it was abandoned accordingly. Proceeding further, Mr. Baessler designed a unique Bessel roll-off filter, which has been successful and has none of the disadvantages of the notch-filter. While the high frequency response of the Bessel filter system is modestly impaired, the important low and mid-frequencies are completely unimpaired. The Bessel filter has been incorporated into the Humetrics ECG equipment and Humetrics has notified their several hundred previous purchasers that a retrofit is available at a modest cost.

STANFORD UNIVERSITY SCHOOL OF MEDICINE

701 Welch Road, Suite 3303, Palo Alto, California 94304 • (415) 321-1200, Ext. 6283

CARDIOLOGY DIVISION
Biomedical Technology Transfer

May 5, 1972

Mr. Lee Baessler
Director of Engineering
Humetrics, Incorporated
6374 Arizona Circle
Los Angeles, California 90045

Dear Mr. Baessler:

In confirmation of our telephone conversation of this morning, there are enclosed:

1. A 60-Hz. notch filter (developed in 1964) which has been used with success at the Ames Research Center of NASA in ECG recording,
2. One commercial device which has been used with success,
3. Three papers on notch filter design which may be of interest to you, should you have not already seen them.

Mr. Gordon DeBoo, the designer of the 1964 filter, of the NASA Ames Research Facilities and Instrumentation Division, was also the supplier of the reprints of the papers on filter design and the commercial reference.

Realizing that the information above may only be preliminary in the attempt to assist you with your interference problem, your critique of this first step will be most appreciated. As suggested, should you be in this area, I am sure that conferences can be arranged with both Ames and with the Cardiology Division at Stanford.

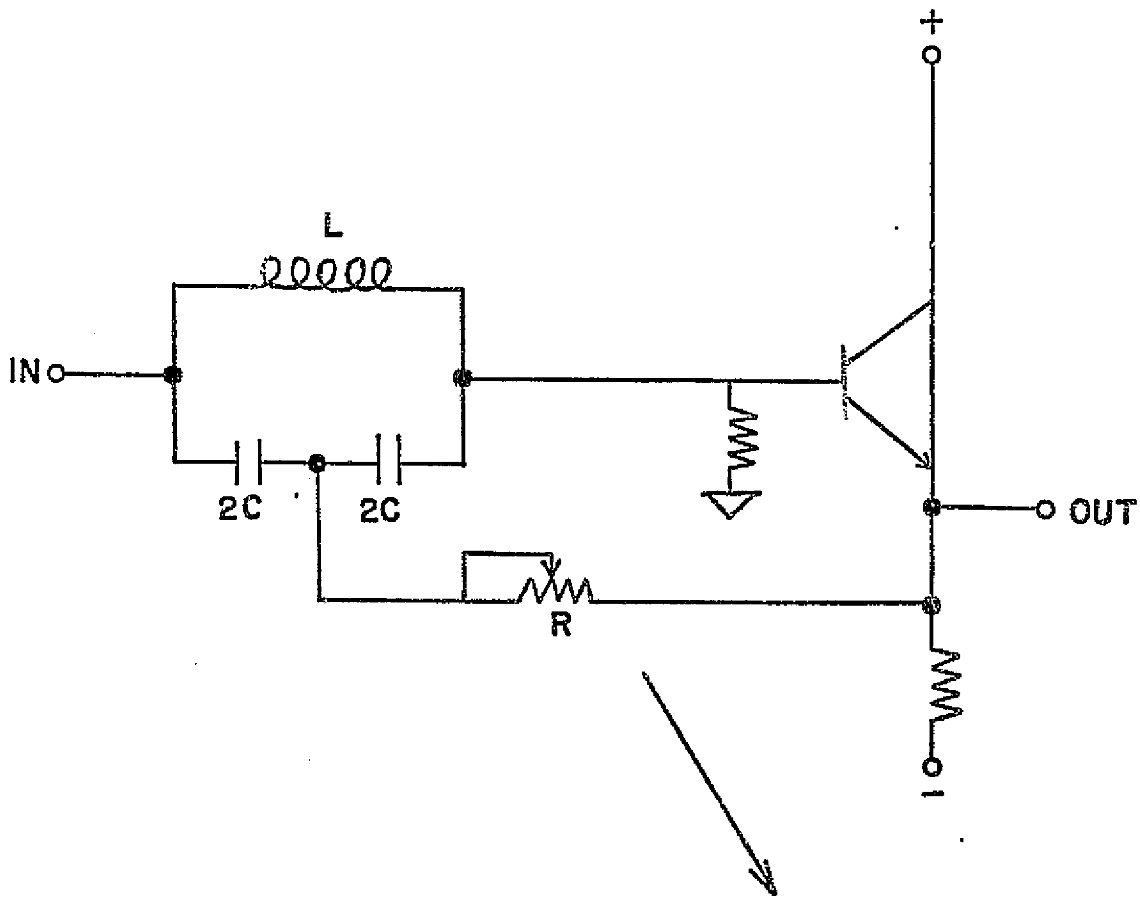
Very sincerely,

A. G. Buck
Engineering Consultant

AGB:dh
Enclosures

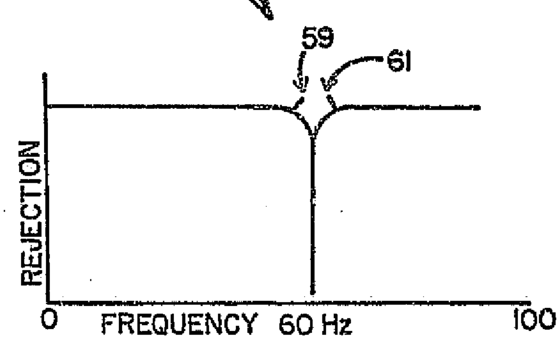
COPY

Gordon Deboo
NASA-Ames Research Center
1964



$$F = \frac{1}{2\pi\sqrt{LC}} = 60 \text{ Hz}$$

SET Q WITH R



60 Hz NOTCH FILTER

6374 Arizona Circle
Los Angeles, California 90045
213 / 641-7555

Thiokol / HUMETRICS CORPORATION

August 7, 1972

Mr. Geoffrey Buck
Cardiology Division
School of Medicine
Stanford University
701 Welch Road
Palo Alto, California 94304

Dear Mr. Buck:

Thank you for the help you have given Humetrics in resolving the line voltage interference problems we were experiencing with one of our units. Although our solution to the problem did not utilize a notch filter, the references you supplied concerning this type of filter made our decision much easier.

I hope to take advantage of your offer to visit your facility on my next trip North and express my thanks personally.

Sincerely,

HUMETRICS CORPORATION

Lee R. Baessler

Lee R. Baessler
Director of Engineering

LRB:knh

PROBLEM NO. PAM-1

MINIATURE TELEMETRY UNIT FOR AMBULATORY PATIENTS

Acquisition Date:	July 5, 1971 Transfer Completed: February, 1972
Institution:	Palo Alto Medical Clinic and Research Foundation Palo Alto, California
Department:	Nuclear Medicine, Internal Medicine
Investigator:	John F Scholer, M.D., Director, Nuclear Medicine Lab.

PROBLEM OBJECTIVE

To provide a practical means for obtaining diagnostic electrocardiograms (ECG) of exercising subjects unencumbered by wires or bulky, heavy devices.

BACKGROUND

Numerous patients suffer chest pain symptomatic of heart disease during exercise or other forms of stress but may show no symptoms or ECG abnormalities during examination either at rest or during stress tests. A device which would allow the patient to engage freely in normal activities and strenuous sports while having his ECG monitored would have major medical significance. Specific stressful situations (both emotional and physical) could thus be evaluated as to their relationship to electrocardiographic abnormalities. The primary application of such a unit would be in the investigation of subjects with cardiac arrhythmias or in which ischemic heart disease is suspected but not demonstrated with conventional ECG recording techniques.

Typical of such patients is an avid tennis player who suffers severe chest pain at the onset of play, but with decreasing and changing discomfort as strenuous exercise continued. Monitoring the electrocardiogram during stressful symptom-producing activities without encumbrance or restraint would greatly facilitate diagnosis.

RESOLUTION

NASA-Ames Research Center has been telemetering ECG's and electroencephalograms of pilots and astronauts to ground stations as part of a human performance stress research project since 1964. Considerable research with free-ranging animals has also been accomplished. Simple modifications adapted existing NASA techniques and equipment to use on exercising subjects for diagnosis of the electrocardiographic problems. A modified NASA ECG transmitter, FM receiver and a special signal demodulator have been loaned to Dr. Scholer for trial. Effective range of the transmitter is 30-40 feet and is adequate for present requirements. It has a continuous battery life of 72 hours. Further NASA developments may extend the useful range to about 300 feet. The transmitted signal is FM/FM at approximately 90 M Hz.

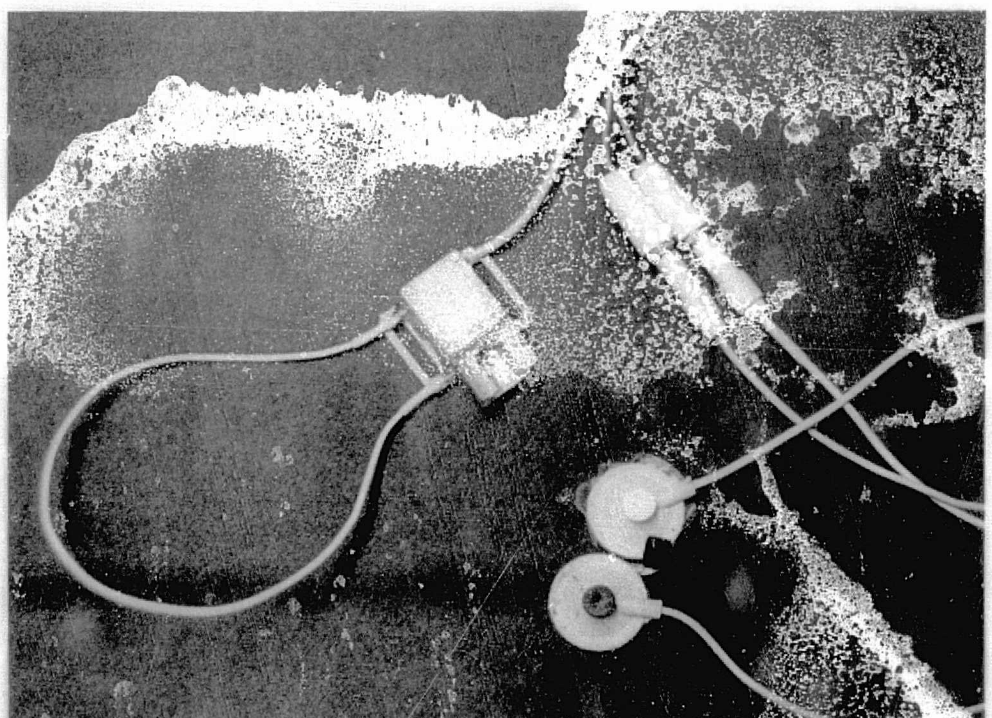


FIGURE 16 NASA FM transmitter, loop antenna and ECG electrodes

FIGURE 17 NASA transmitter applied to an ambulatory patient

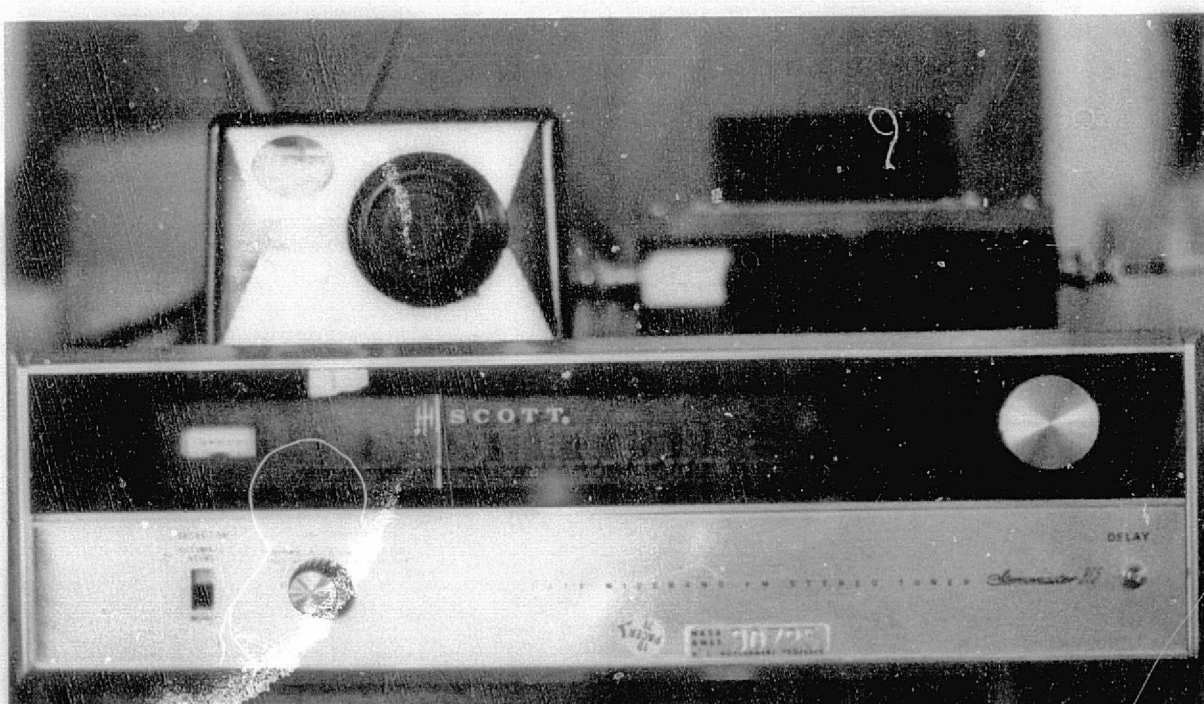


FIGURE 18 FM receiver and signal demodulator

TECHNOLOGY IDENTIFICATION

The basic biotelemetry technology applied to this problem is described in NASA Tech Brief, 64-10171, October, 1964, which is reprinted on the following page.

Messrs. John M. Pope, Thomas B. Fryer and Richard M. Westbrook of NASA-Ames Research Center, contributed the necessary specialized expertise developed through their experience in aerospace research. The loan of suitable equipment to Dr. Scholer was arranged through NASA-Ames Research Center.

No literature search was necessary. Readily applicable NASA technology was known to engineering consultants of the BTT team and modification was not required.

OTHER CONTRIBUTORS

Mr. Charles Laenger of Southwest Research Institute had assisted by calling attention to a "wrist-watch" radio transmitter of ECG signals and to a portable cassette ECG recorder. Both devices were developed by Southwest Research Institute and they may be useful in cardiac diagnoses under some circumstances.

IMPACT

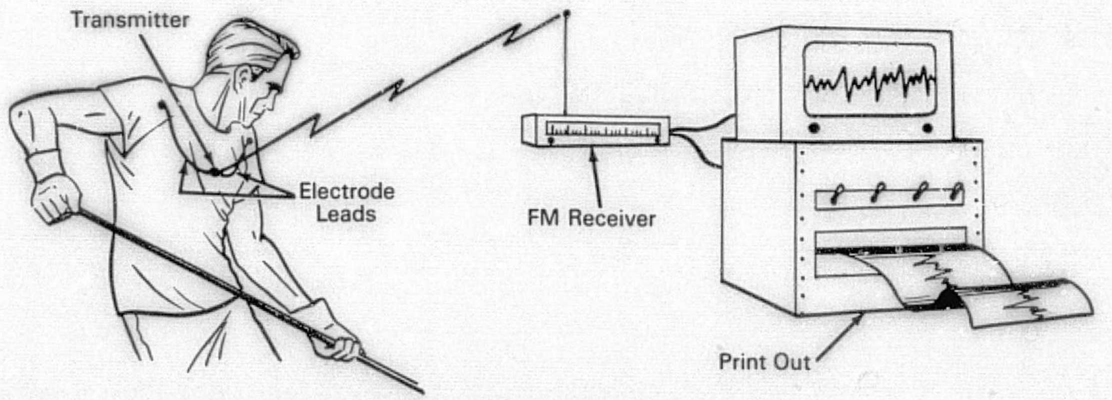
NASA technology developed for monitoring pilots and astronauts under stress has been adapted to develop a system for obtaining electrocardiograms of patients during vigorous exercise or other stressful activities without encumberance of wires or bulky devices.

October 1964 Brief 64-10171

NASA TECH BRIEF

This NASA Tech Brief is issued by the Technology Utilization Division to acquaint industry with the technical content of an innovation derived from the space program.

Subminiature Biotelemetry Unit Permits Remote Physiological Investigations



The problem: The measurement of biopotential response in humans or animals to controlled environmental stimuli has traditionally been impaired by encumbering electrical leads or bulky amplifying and transmitting equipment.

The solution: A subminiature, high-performance, biopotential telemetry transmitter operating in the standard 88- to 108-megacycle FM band.

How it's done: The transmitter was designed using standard, inexpensive, commercially available components and assembly techniques which permit easy and repeatable assembly with no sacrifice of performance or reliability. The transmitter is 0.74 inch in diameter by 0.20-inch thick and weighs two grams. A mercury cell provides power for operation in two modes, selected by the interchange of three components in the basic circuit. In one mode the transmitter has a two-day operating life with a 100-foot range; in the other, the transmitter has a 48-day operating life with a 10-foot range. Conventional biomedical electrodes are used to connect the transmitter to the subject.

Notes:

1. In tests, humans have worn the unit for four or five days without discomfort and have generated useful data while engaged in normal activities.
2. Further information concerning this innovation is described in NASA-TM-X-54068, "A Miniature Biopotential Telemetry System" by Gordon J. Deboo and Thomas B. Fryer, May 1964.
3. A related innovation is described in NASA Tech Brief 64-10025, May 1964.
4. Inquiries may also be directed to:

   Technology Utilization Officer
   Ames Research Center
   Moffett Field, California, 94035
   Reference: B64-10171

Patent status: NASA encourages commercial use of this innovation. No patent action is contemplated.

Source: Ames Research Center (ARC-39)

PROBLEM NO. PAM-2

TEMPERATURE TELEMETER FOR GI TRACT DIAGNOSIS

Acquisition Date: July 8, 1971 Transfer Completed: April, 1972
Institution: Palo Alto Medical Clinic and Research Foundation
Palo Alto, California
Department: Nuclear Medicine, Internal Medicine
Investigator: John F. Scholer, M.D., Director, Nuclear Medicine Lab

PROBLEM OBJECTIVE

To measure local temperatures in the gastrointestinal tract during transit of a swallowable temperature-telemeter capsule.

BACKGROUND

Diagnosis of gastrointestinal ulceration, polyps and carcinoma by conventional means is often difficult and expensive. Local elevated temperatures are thought to be associated with these maladies, hence a reliable method of detecting temperature variation throughout the gastrointestinal tract could offer a valuable new diagnostic approach. A swallowable temperature radiosonde could detect and telemeter these local temperatures as it passes through the tract. Anatomic location could be determined at any time.

RESOLUTION:

It was known to the BTT consultants that the NASA-Ames Research Center was developing a temperature radiosonde for use in long-term weightlessness studies in connection with the Skylab program. Conferences with Messrs. John Dimeff, Thomas Fryer, Richard Westbrook and Jack Pope confirmed the above. An order was placed for a radiosonde; NASA-Ames supplied the radio receiving gear and demodulators. Dr. Scholer has tested the equipment on well subjects and is currently planning its use on ill patients.

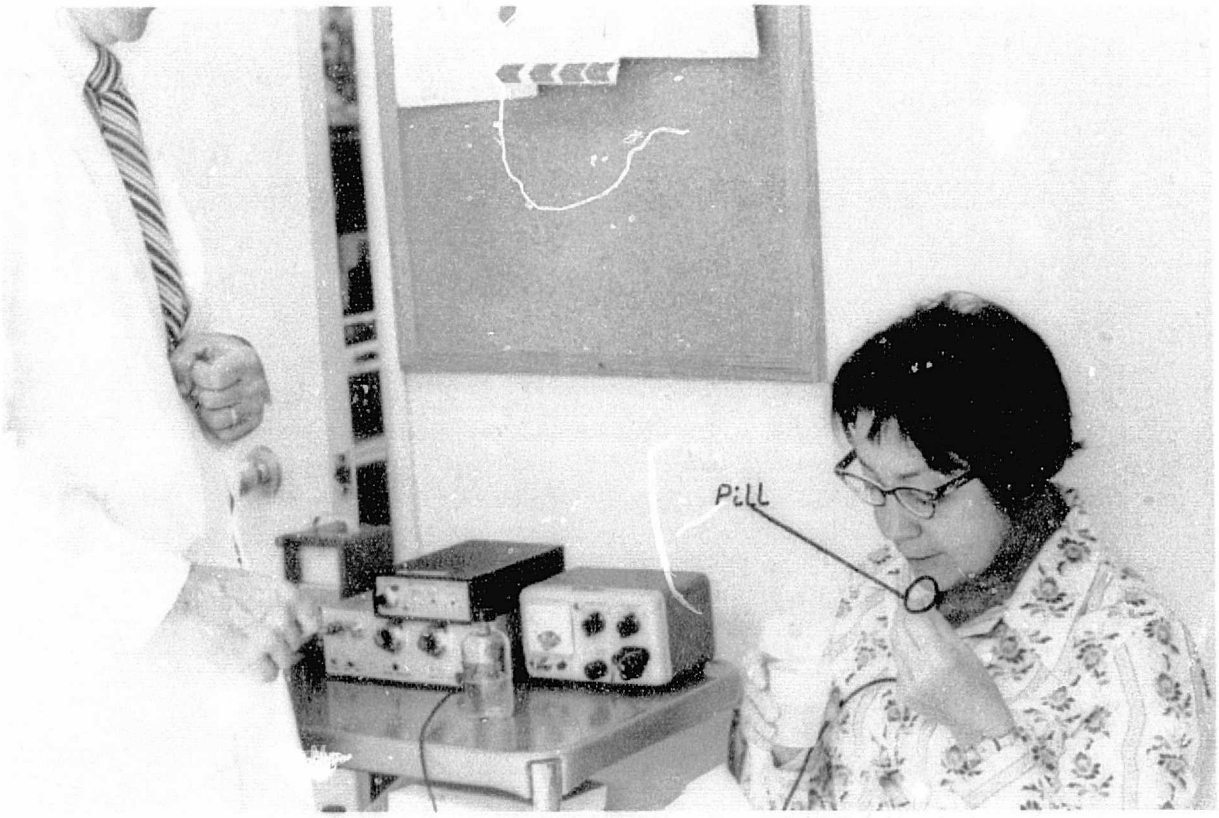


FIGURE 19 Patient is preparing to swallow temperature pill

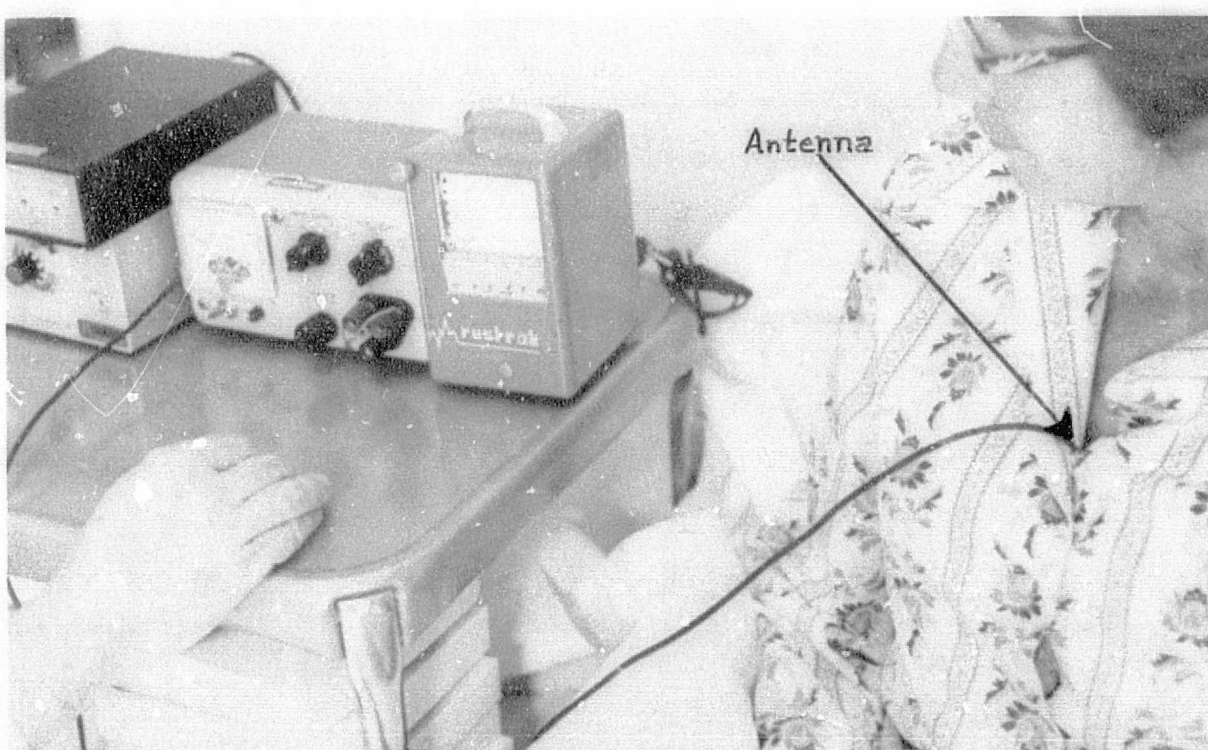


FIGURE 20 GI temperature is detected by loop antenna and recorded in the physician's office

The system is pulsed code modulated FM, operating at approximately 91.4 M Hz. and has a range of three to five feet. Both transmitter and receiver are specially designed NASA units, fabricated commercially under contract. The loop antenna of the receiver can be adjusted in diameter, as the experimenter wishes, to have either broad-body coverage with the large diameter or to have pin-point location of the "pill" within two inches by using a small diameter loop. Under continuous usage, battery life is approximately 160 hours.

TECHNOLOGY IDENTIFICATION

The technology used in the resolution of this problem was reported in NASA-ARC 10583, at the November 1971 ACEMB meeting in a paper entitled "Ingestible Temperature Transmitter" by Messrs. Pope, Fryer and Dr. Sandler, and in Tech Brief 72-10275.

IMPACT

Dr. Scholer has at his disposal new and novel equipment which appears to be suitable for his research. Should his effort meet with success, medicine will have a new diagnostic tool for the noninvasive detection and location of ulcerations, polyps, carcinomas, etc. Applications can be extremely broad with significant impact.

An Ingestible Temperature Transmitter

35.14

JACK M. POPE, THOMAS B. FRYER, and HAROLD SANDLER

Ames Research Center
Mail Stop 213-4
Moffett Field, California 94035

Telemetry
A.M., Thursday
4 November

A pill sized temperature transmitter suitable for swallowing has been developed to obtain deep body temperature. Deep body temperature is an important parameter in circadian rhythm studies and also in determing general health. Hard wired thermistor ear probes custom fitted to the subject's ear have been used in the past in bed rest studies,[1] but this method of obtaining temperature has several disadvantages. The probe must be in intimate contact with the ear drum to obtain reliable temperature data; prolonged insertion of the ear probe produces discomfort to the subject; and being hard-wired, the probe is subject to breakage.

Ingestible transmitters that have been reported in the past[2,3] have been primarily blocking oscillator type telemeters using a single transistor as the active element. These initial temperature telemeters were simple but had relatively poor long term stability and limited transmission distance. More complicated, stable, and highly accurate transmitters were later developed for long term implant studies in animals,[4] but because of increased size, cost, and circuit complexity, these units were not well suited as swallowable telemeters. A compromise between accuracy, circuit complexity, size, and transmission range has been achieved in the circuit shown in Fig. 1. A typical plot of pulse period versus transmitter temperature is also shown in Fig. 1.

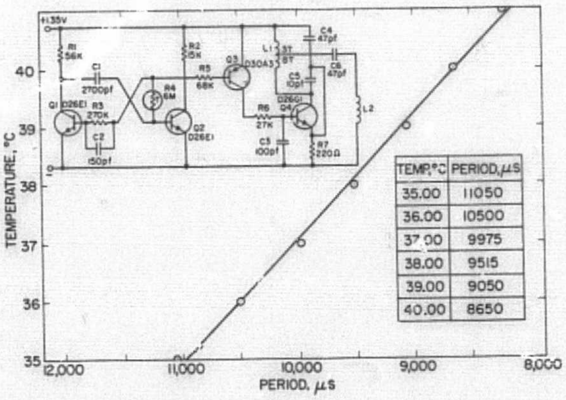


Fig. 1. Temperature Transmitter Circuit with Typical Calibration Data.

Figure 2 shows a photograph of the pill transmitter, the battery, the gelatin capsule and the completed unit. The discrete component transmitter with an attached RM212 battery is placed in a size 0 gelatin capsule, coated with a liquid vinyl and two coats of silicone rubber. The completed unit has been tested for 35 hours in a HCl solution with pH 1 at 45°C to insure that the coatings prevent the gelatin capsule from dissolving.

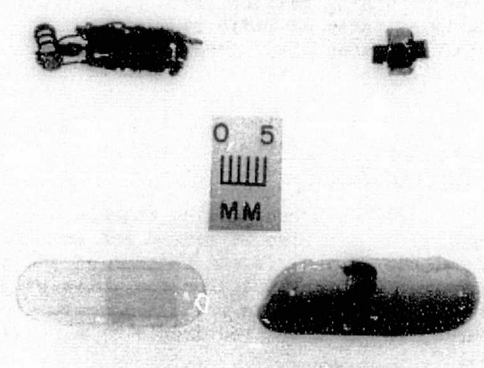


Fig. 2 Temperature Transmitter Electronics Before and After Encapsulation.

Nominal current drain from the battery at body temperature is 100 microamps. This provides an operating life of approximately 160 hours using a RM212 battery. After battery attachment and sealing, the current drain can be reduced to about 25 ua by storage at 5°C thereby extending the useful storage time. The advantage of this transmitter is that it is simple in construction, does not require critical tolerance parts and provides a readout with a ±0.1C accuracy.

1. P. B. Mack, "Evaluation of Flight Foods Under Hypokinetic Conditions", Final Report, Contract NAS9-9755, Texas Women's Univ., Denton, Texas.
2. R. S. Mackay, "Endoradiosonde", Nature 179, 1957, 1239-40.
3. R. H. Fox, R. Goldsmith, H. S. Wolff, "The Use of a Radio Pill to Measure Deep Body Temperature", J. Physiology 160, 1961, 22P-23P.
4. T. Fryer, "Micropower Transmitter for Temperature Measurements", Proc. 8th Annual Conf. on Engrg. in Med. & Biology, Vol. 7, 1965.

NASA TECH BRIEF
Ames Research Center

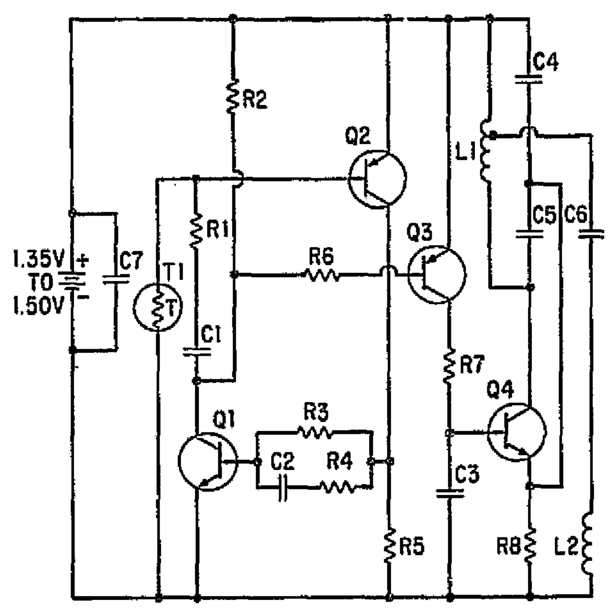
An Ingestible Temperature-Transmitter

Deep body-temperature is an important parameter in studies of circadian rhythm as well as an indicator of general health. In the past, deep body-temperature has been measured by hard-wired thermistor ear-probes that must be fitted to the subject's ear and be in intimate contact with the ear drum; naturally, the subject is in constant discomfort.

Small, ingestible temperature-transmitters cause no discomfort. The ingestible transmitters that were first developed were primarily blocking-oscillator telemetry devices using a single transistor as the active element; these devices are simple, but their long-term stability is rather poor and their transmission distances are quite limited. More complicated, stable, and highly accurate transmitters were later developed for long-term implant; however, these units have not been considered suitable for use because they are expensive and too large and complex. A pill-sized ingestible temperature-transmitter has now been developed that is a compromise between accuracy, circuit complexity, size, and transmission range.

The circuit of the pill transmitter consists of a complementary astable multivibrator comprised of Q1 and Q2; the on-off cycle of each transistor is controlled by a fixed resistor and a thermistor. A buffer transistor, Q3, decreases the amount of frequency modulation of the radiofrequency transistor, Q4. The tuned section of the transmitter consists of L1, C4, and C5; inductor L1 is tapped to provide appropriate impedance-matching for the RF-radiation element, L2, driven through DC-decoupling capacitor, C6. The transmitter operates in the 88- and 108-MHz band in order to take advantage of readily available commercial FM receivers.

The complete miniature unit, consisting of an RM-212 battery and a transmitter circuit, is placed in a size 0 gelatin capsule and then sealed with vinyl acetate–beeswax mixture and two coats of silicone



rubber. Completed units are tested by immersion for 35 hours in a hydrochloric acid solution of pH 1 at 45°C to insure the integrity of the coatings which prevent the gelatin capsule from dissolving.

Nominal current drain from the battery at body temperature is 25 microamperes, and the operating life of the encapsulated device is approximately 600 hours. A unique feature of the device is that power consumption can be reduced to a negligible value by storage at approximately 0°C, thereby extending the

(continued overleaf)

storage time indefinitely. The transmitter does not require critical-tolerance parts and after calibration it provides temperature measurements well within ±0.1°C from 35° to 41°C.

Note:

Requests for additional information may be directed to:

Technology Utilization Officer
Ames Research Center
Moffett Field, California 94035
Reference: TSP 72-10275

Patent status:

Inquiries about obtaining rights for the commercial use of this invention may be made to:

Patent Counsel
Mail Code 200-11A
Ames Research Center
Moffett Field, California 94035

Source: Jack M. Pope, Thomas B. Fryer, and Harold Sandler
Ames Research Center
(ARC-10583)

PROBLEM NO. SSM-1

DETECTION OF TURBIDITY, BIREFRINGENCE AND FLUORESCENCE CHANGES IN CARDIAC MUSCLE

Acquisition Date: September 13, 1971 Transfer Completed: March, 1972
Institution: Stanford University School of Medicine
Department: Medicine, Cardiology
Investigator: William H. Barry, M.D.

PROBLEM OBJECTIVE

To develop an optical system for determining changes in turbidity and birefringence of muscle segments in vitro during isolated cardiac contraction.

BACKGROUND

Changes in optical properties of nerve tissue and skeletal muscle have been detected during excitation and contraction by using a battery-powered quartz-iodine light source. A ten-stage photomultiplier and a computer of average transients were used to detect reflected light. However, the tissues used in these studies were much larger than the cardiac muscle segments presently employed. A coherent light beam no larger than 0.5 mm in diameter is needed. The light intensity must not damage muscle tissue and the wave length should be preferably within the visible range. The detecting system must resolve changes of the order of 10^{-3} to 10^{-4} of the resting light intensity.

RESOLUTION

The BTT consultants suggested that a laser light source with fiber-optics could provide the needed coherent light in a small working area. A conference was held with Dr. Leonard P. Zill, Chief of the NASA-Ames Exobiology Division and Mr. Benjamin H. Beam, Assistant Chief of the NASA-Ames Research Facilities. A laser-chopper system, such as was used previously by Mr. Beam in a hydrocarbon detector, was adopted. The chopper system was modified to fit this specialized application. The necessary equipment has been loaned by Ames to the problem originator for use in his research.

TECHNOLOGY IDENTIFICATION

The basic technology responsible for resolution of this problem is found in NASA Tech Brief No. 70-10631 and in ARC-10156, "Laser Beam Hydrocarbon Detector," Benjamin H. Beam, Dean N. Jaynes, and Clifford N. Burrous. The helium-neon gas laser is of commercial manufacture. The chopper is of NASA-Ames Research Center design and fabrication.

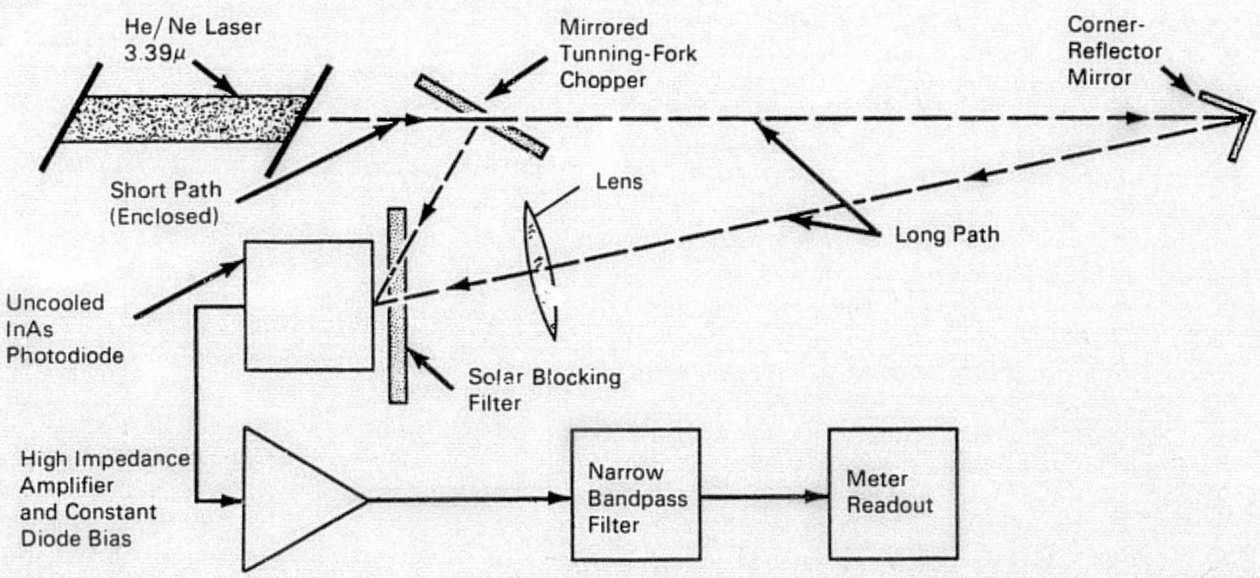
IMPACT

Optical studies of cardiac muscle will provide new information about excitation-contraction coupling. This information will provide a far better understanding of the contraction process in muscle. It will aid in the definition of the mechanism of action of numerous drugs which affect the strength of contraction of the heart and which are used to treat heart failure.

The ability to selectively apply pharmaceuticals effectively to certain sections of the heart, unmasked by the entire heart, should be of great value to cardiologists in patient treatment and applicable to large numbers of patients.

NASA TECH BRIEF

Laser Beam Hydrocarbon Detector



The problem:

To detect low-level concentrations of hydrocarbon vapors which may constitute a toxic, combustible, or explosive hazard.

The solution:

A portable instrument which passes light from a helium-neon laser at a wavelength of 3.39 microns through the atmosphere being monitored and measures the attenuation of the laser beam. The attenuation of the original beam is due almost exclusively to absorption of radiation by hydrocarbons; therefore a quantitative measure of their concentration is available.

How it's done:

As shown in the figure, a helium-neon laser beam at 3.39 microns is intercepted by a mirrored tuning fork chopper which alternately reflects the light directly to the detector or allows it to traverse a longer path to a corner reflector which returns it to the detector. The longer path is about two meters overall, while the short path (enclosed in a protective box) is only a few centimeters. The detector is an uncooled indium-arsenide photodiode which is reasonably efficient at 3.39 microns. A solar blocking filter prevents spurious signals from sunlight when the instrument is used outdoors.

The instrument is adjusted so that the light intensity received via the long path is exactly equivalent to that from the short path when no hydrocarbons are present. The presence of an absorbing gas in the long path results in a difference of signal strength from the long and the short path; the ac component of this

(continued overleaf)

signal is subsequently filtered, amplified, and indicated on a meter.

The design of the detector circuit is straightforward; the indium-arsenide photodiode is held at near-zero voltage bias by the operational amplifier since operation in this mode produces less dark current, distortion, and bias shift. The amplifier output voltage is proportional to the product of photodiode current and feedback resistance, and is linear with incident irradiance for several decades. This signal is fed to a bandpass filter in order to increase the S/N ratio and to enhance nulling capability.

Since the stability of the system is critically dependent on the stability of the light beam chopper, it is operated at constant amplitude and further stabilized by a feedback loop in which the mechanical structure of the chopper is incorporated in the tuned circuit of the feedback oscillator. In this arrangement, voltage induced in a sensing coil by the motion of the chopper is proportional to the velocity of the chopper blade; this voltage is amplified and applied to a bridge containing two back-to-back zener diodes; the unbalanced signal from the bridge is amplified and supplied to the chopper drive coil. At low amplitude, the zener diodes have a high resistance and act as linear circuit elements; hence, when the chopper drive is first turned on, positive feedback is applied to the drive coil and the chopper begins to oscillate. At high amplitudes, the impedance of the zener diodes drops, reducing the unbalanced signal until it is just sufficient to keep the amplitude from rising further. This simple circuit is quite effective in producing stable operation in a variety of adverse environments.

The prototype instrument was arranged to be handcarried and was tested in the field, operating from a lead-acid battery and converter carried in an automobile. The sensitivity was limited by mechanical instabilities in maintaining optical alignment in field conditions, but was sufficient for detecting natural gas at concentrations of about one part per million. This concentration is well below the health hazard level and considerably below explosive concentration.

Reference:

Jaynes, D. N.; and Beam, B. H.: Hydrocarbon Gas Absorption by a HeNe Laser Beam at a 3.39-Micron Wavelength, Applied Optics, vol. 8, August 1969, page 174

Notes:

1. Disadvantages of the prototype instrument are: (1) the potential hazard of the high-voltage supply in an explosive environment; (2) the presence of dust in the long path gives spurious indications of hydrocarbons; (3) hydrocarbons cannot be identified.
2. Requests for further information may be directed to

   Technology Utilization Officer
   Ames Research Center
   Mail Stop N-240-2
   Moffett Field, California 94035
   Reference: TSP70-10631

Patent status:

No patent action is contemplated by NASA.

Source: B. H. Beam, D. N. Jaynes, and C. N. Burrous
Ames Research Center
(ARC-10156)

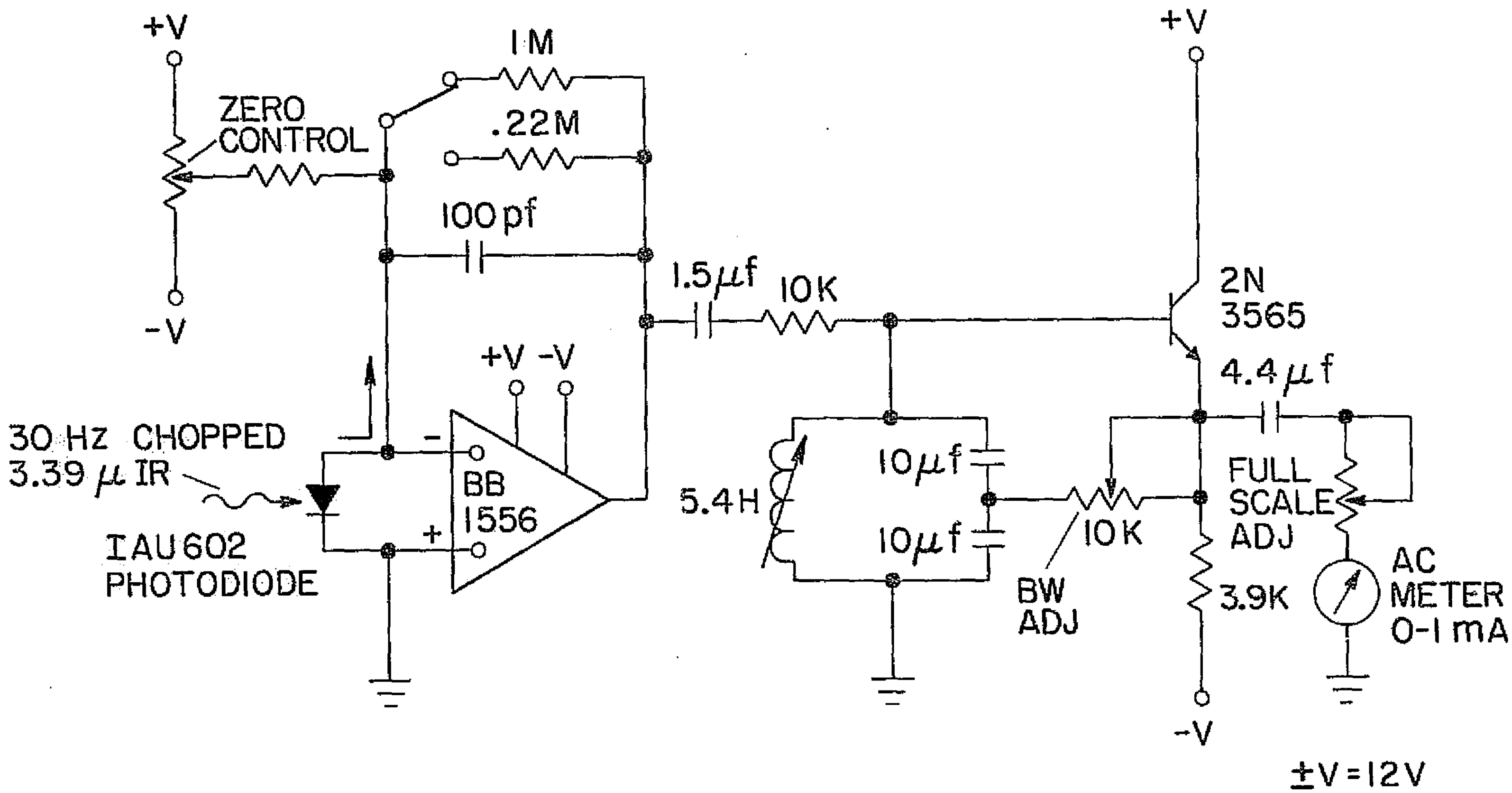


FIGURE 21 Detector electronics.

ARC-10156

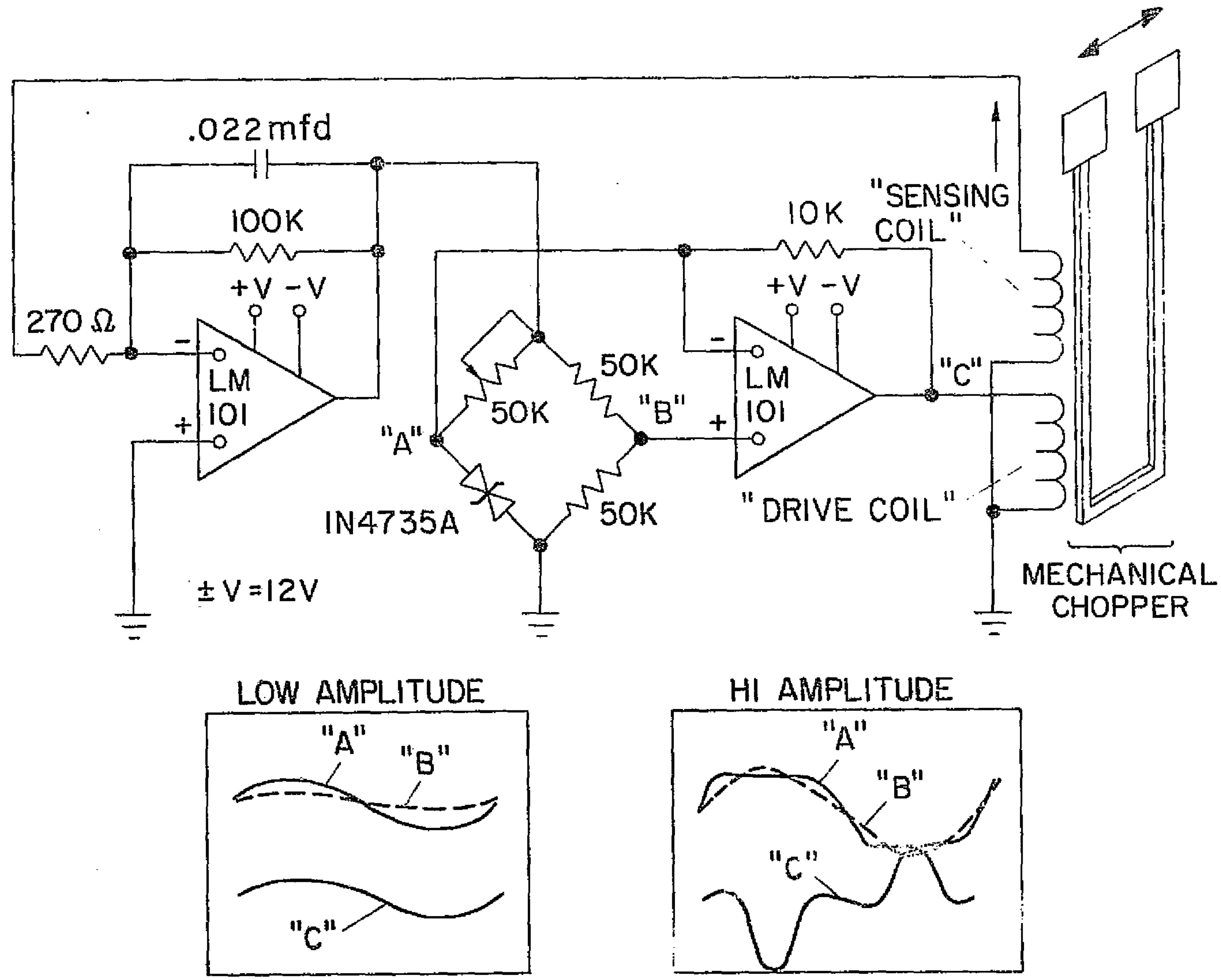


FIGURE 22 Chopper st bilizing circuit.

-72-

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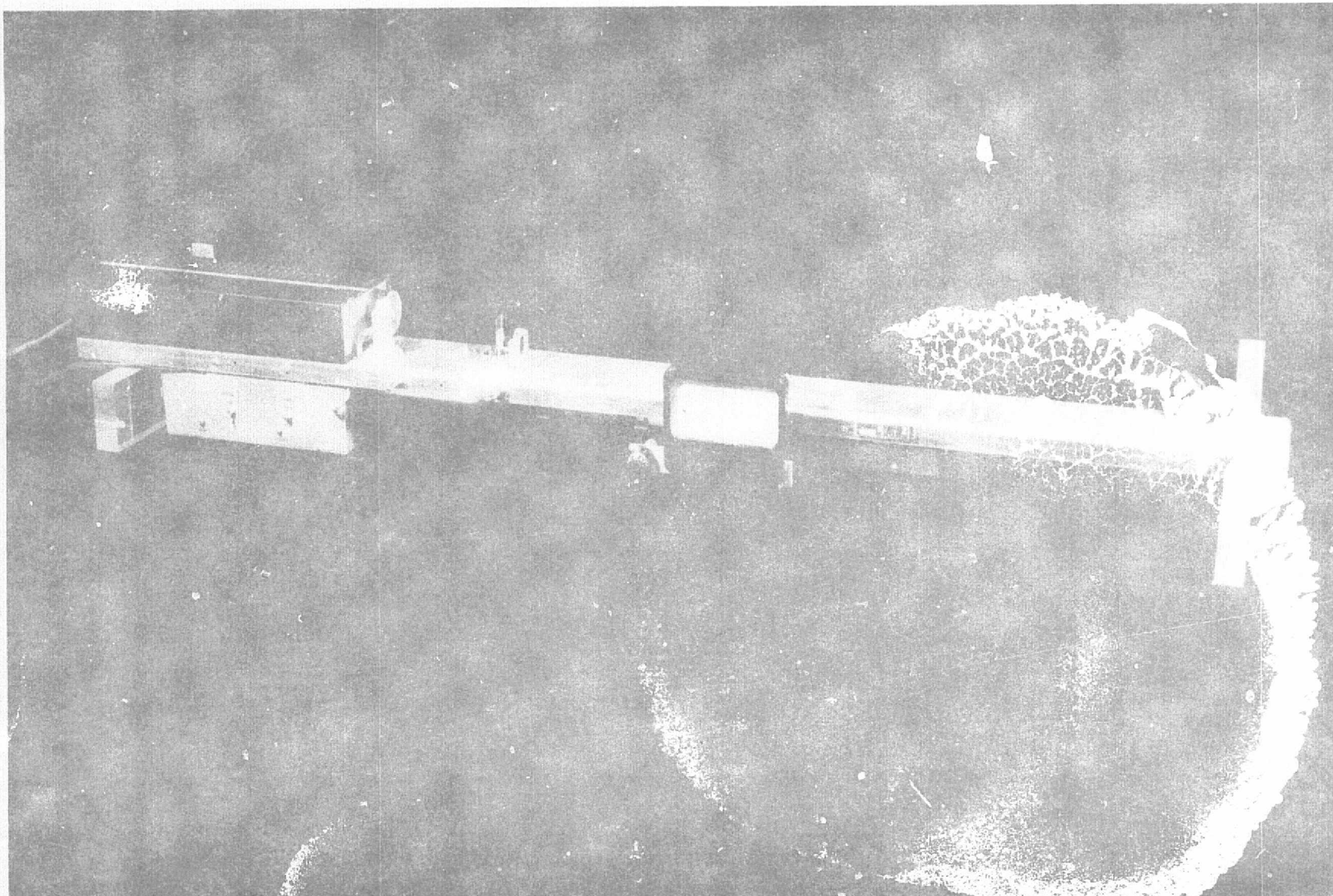


FIGURE 23 Hydrocarbon gas detector.

PROBLEM NO. SSM-2

ELECTRODE APPLICATIONS TO MYOELECTRIC CONTROL SYSTEMS

Acquisition Date: September 24, 1971 Transfer Completed: June, 1972
Institution: Stanford University School of Medicine
Department: Physical Therapy
Investigator: Katharine B. Robertson

PROBLEM OBJECTIVE

To develop flexible electrodes suitable for application to amputee patients fitted with prosthesis and myoelectric control systems.

BACKGROUND

Conventional stainless steel and other metallic electrodes previously used with amputee patients fitted with prosthesis and myoelectric control devices are difficult to apply and maintain in position. The use of very flexible electrodes appears to offer improved muscle-nerve interface for application of prosthetic control systems.

RESOLUTION

Mr. Salvador Rositano, NASA-Ames Research Center, worked with Katharine Robertson, investigator and Earl Lewis of the Veterans Administration, Prosthetics and Sensory Aids Service, Department of Medicine and Surgery in Washington, D.C., in developing various electrodes for trial in relation to myoelectric control systems. Approximately one dozen electrodes were fabricated at NASA-Ames. These electrodes were given to the V.A. for testing in their New York laboratory. It has been determined that electrodes of this type are suitable for sensing myoelectric signals in the amplitude range required for controlling motors in the prosthesis. Techniques for attaching flexible electrodes to the socket of the amputated limb are under consideration. Consideration is being given to placing the electrodes on the appropriate motor sites to operate a myoelectric control device during the phase immediately following amputation. In this way, a person can regain consciousness following a traumatic accident and have a functioning prosthesis powered voluntarily. Present electrodes have not been placed under cast material due to anticipation of skin reaction from the silver/silver chloride conducting material.

OTHER CONTRIBUTORS

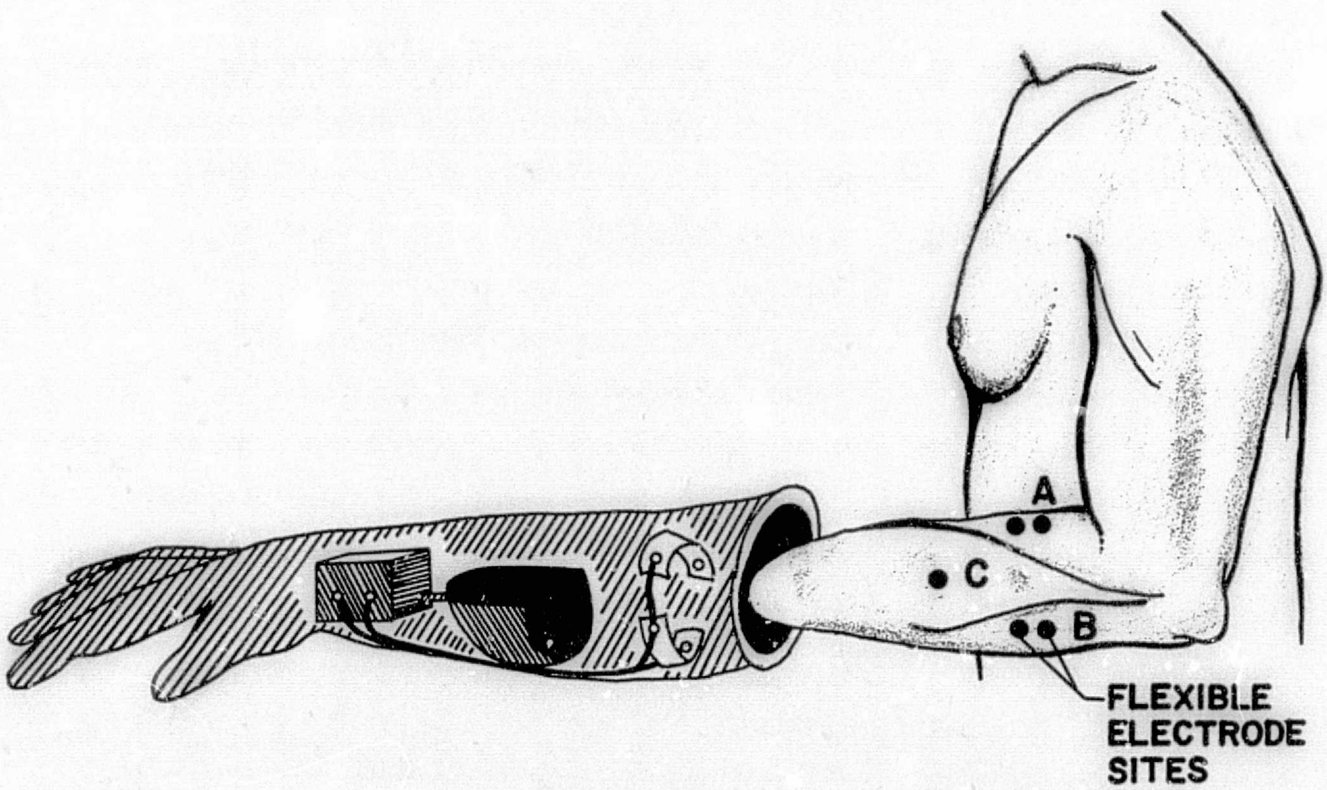
Mr. Dudley Childress of the Prosthetic Center at Northwestern University and the research section of the Prosthetic and Sensory Aids Service at the Veterans Administration in New York also contributed to the research of this problem.

TECHNOLOGY IDENTIFICATION

The basic technology used in the resolution of the problem was reported in NASA-ARC 70-1095 and 70-10420. Configurations and geometric designs were catered to individual patient requirements.

IMPACT

The need for a flexible, soft, dry electrode in myoelectric control systems is unquestionable. While conventional, rigid, stainless steel electrodes perform adequately for many amputees, there are many patients with irregular configurations who could never be fitted with this type of device. Further development of these electrodes will permit more patients the use of prostheses presently being developed.



APPLICATION TO AMPUTATED LIMB
(IMMEDIATE POST-OP FITTING)

A - ELECTRODES ON FINGER FLEXOR MUSCLES

B - ELECTRODES ON FINGER EXTENSOR MUSCLES

C - GROUND ELECTRODES

FIGURE 24 Flexible electrodes are attached to prosthesis which correspond to appropriate sites on amputated limb. Once prosthesis is fitted and electrodes in place, nerve muscle impulses transduce to the power box which moves hand.

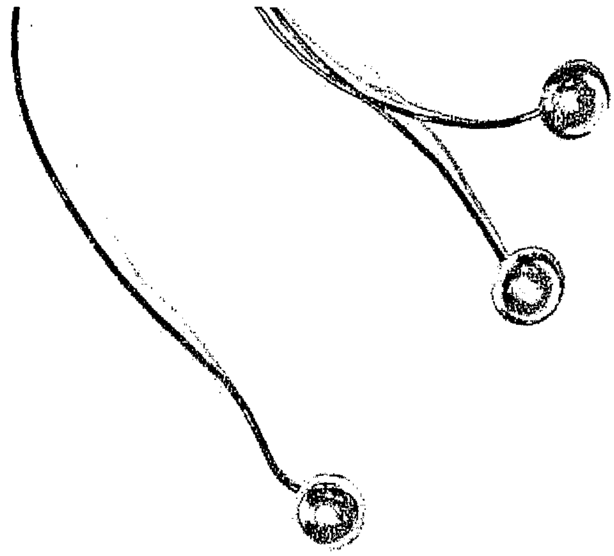


FIGURE 25 Conventional 1/4" rivet stainless steel electrodes in widespread use

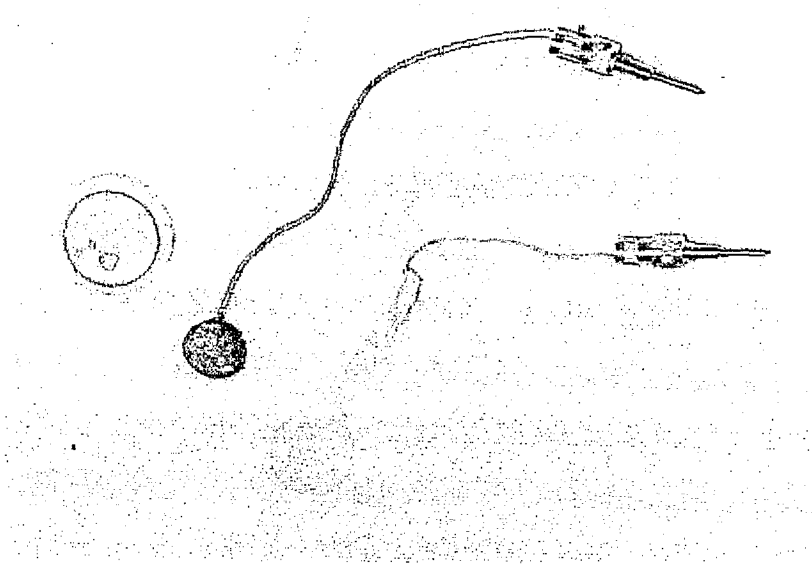
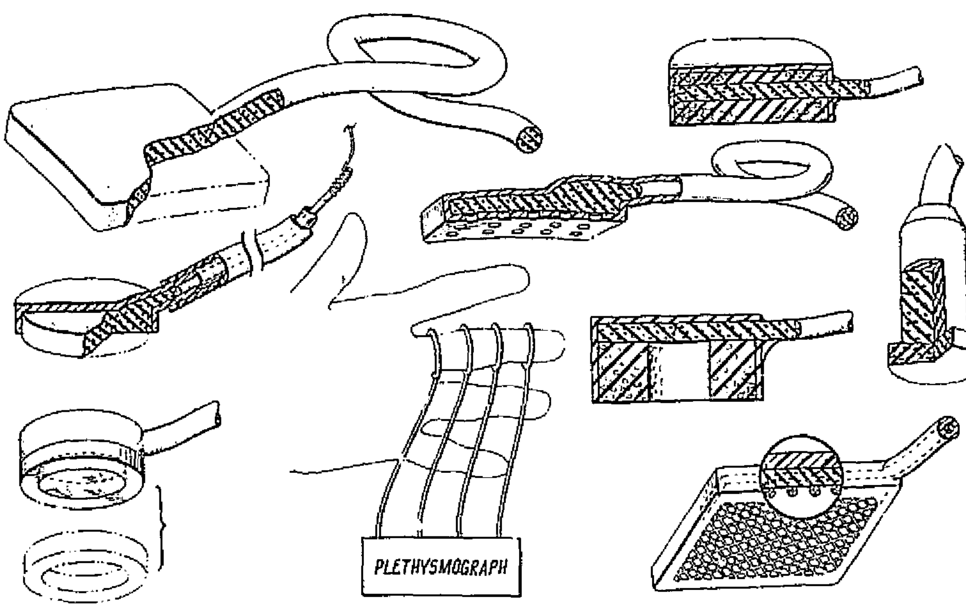


FIGURE 26 New NASA elastomeric electrodes presently undergoing clinical trial

NASA TECH BRIEF

Ultra-Flexible Biomedical Electrodes and Wires



The problem:

To develop a very flexible, uniformly conductive, comfortable, and easily applied biomedical electrode that conforms to the body contour during body motion.

The solution:

A soft, flexible electrode fabricated from an elastomer impregnated with a conductive powder which can be configured into any required shape, including a wire shape to connect the electrode directly to an electrical instrument or to a conventional metallic wire.

How it's done:

As shown in the figure, the device consists of the electrode and a conductor, both formed of silicone rubber as the elastomer and loaded with silver-plated particles as the conductive material. The electrode can be molded or cut to fit over any irregular body contours and to accommodate body location and type of measurement. A wide variety of electrode configurations can be fabricated using accessory materials such as silicone rubber sponge, silicone rubber adhesives, or adhesive bandages. Electrodes and "wires" made of the impregnated elastomeric material are suitable for implantation and connection to implanted telemetry equipment. The impregnated elastomeric wire is not only flexible but stretchable, in some cases up to 40% of its length, while maintaining excellent conductivity. This is a significant improvement over the normal metallic lead wires, which always present the danger of breaking at the junction

(continued overleaf)

with the electrode. Where external electrodes are used, improved contact with the skin can be obtained with sodium chloride electrolyte paste or jelly. In this case, the electrode can be designed with wells in which the electrolyte is placed. It is not always necessary to use an electrolyte paste, since the electrode moves with the skin. Long-term monitoring of relatively motionless bed-ridden patients can be accomplished with the electrode alone. Use of the electrode without the wet electrolyte avoids the problem of periodic replenishment and the discomfort of a continuously damp interface with the skin. The dry electrode does result in a higher impedance, but this is readily handled with a high input-impedance amplifier. Previous studies with electrodes have shown that silver-silver chloride provides the lowest galvanic potential when used with a sodium chloride jelly. The chloride ions provide the mechanism by which the biopotentials are sensed. A layer of silver-silver chloride can be plated on the elastomeric electrode surface by conventional electroplating using a 10% HCl solution with silver wire as a cathode and a 6-V power source. Plating on the electrode does not alter its flexibility. Insulation can be provided on any part of the electrode by spraying, dipping or brushing with nonconductive silicone rubber.

Note:

Requests for further information may be directed to:

Technology Utilization Officer
Ames Research Center
Moffett Field, California 94035
Reference: TSP70-10420

Patent status:

Inquiries about obtaining rights for the commercial use of this invention may be made to NASA, Code GP, Washington, D.C. 20546.

Source: S. A. Rositano
Ames Research Center
(ARC-10268)

INVENTION ABSTRACT

NASA Case No. ARC-10268-1

ULTRA-FLEXIBLE BIOMEDICAL ELECTRODES AND WIRES

The present invention relates to a flexible, stretchable biomedical electrode and connector which is designed for use by physicians, medical technicians and researchers to connect an electric instrument to the body.

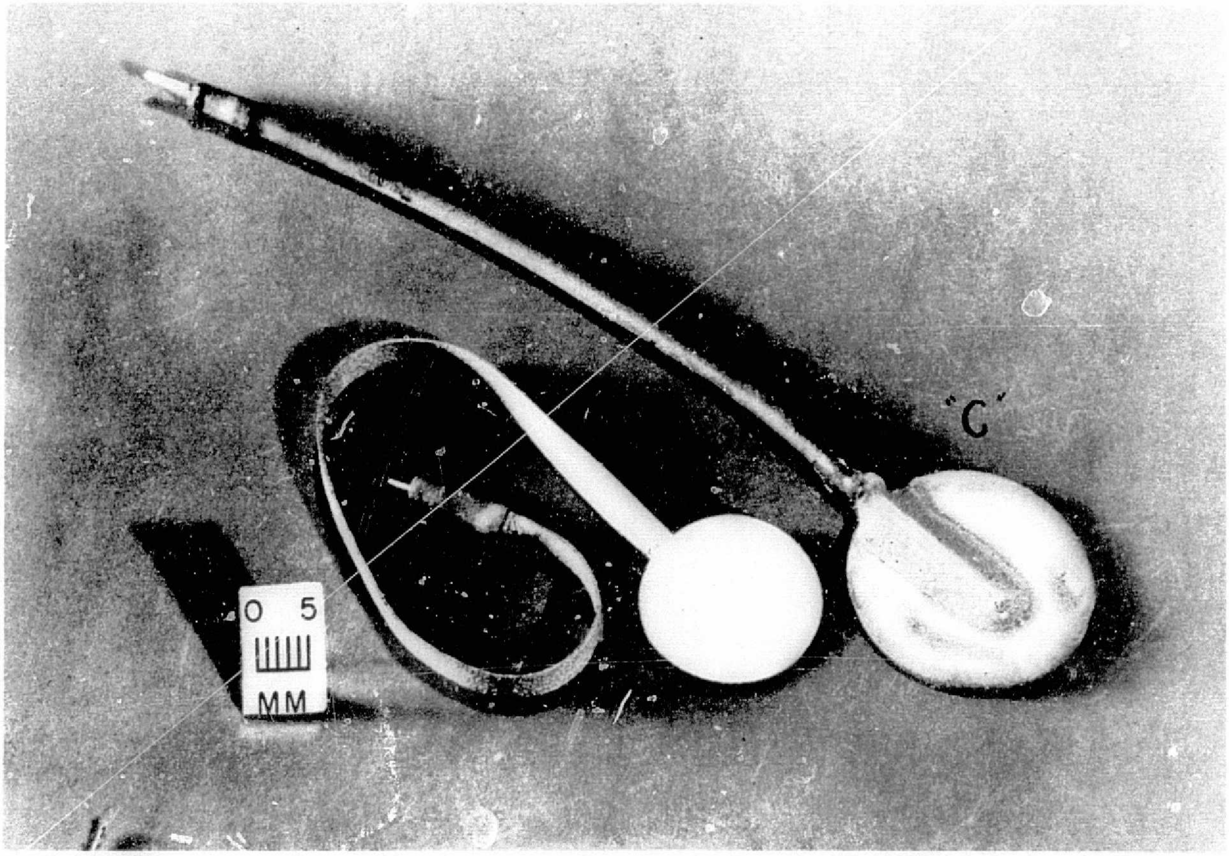
In the past, body electrodes have ordinarily consisted of a solid member coupled to the skin by a conductive paste. Such electrodes have been relatively inflexible so that they could not be used over a considerable portion of the body and were often uncomfortable even when applied to small areas of the body. Normally metallic lead wires are used with such electrodes and, even if the electrode itself is satisfactory, there is always the danger of the wire breaking at its junction with the electrode.

In accordance with the present invention, a soft, flexible electrode is provided by using an elastomer which has been loaded with a conductive powder with a connecting "wire" formed as part of the electrode of the same material.

The basic form of the invention is shown in Figure 1 of the drawings and consists merely of the electrode 14 and its conductor 16, both formed of an elastomer which is loaded with metal particles to render it conductive. A number of variations of this basic structure are possible. One is the employment of an insulating layer over the back of the electrode which can form a continuation of an insulating layer of the connecting wire. Further, an insulating layer can be formed over the face of the electrode with one or more apertures therein which may be filled with one of the usual conducting jellies for connecting the electrode to a body.

Thus the present invention provides a soft, flexible conductive electrode for biopotential measurements or stimulation which has a low contact potential and which has an electrical cable which will conform to the body contour during body motion. The "wire" itself is not only flexible but stretchable.

Inventor: Salvadore A. Rositano
Employer: NASA - Ames Research Center
Initial Evaluator: Ralph K. Hallett, Jr.



A70-1095:- The application here was for a dry-type electrode without the insulating washer shown in the previous photographs. One can get the same electrical characteristics as the standard clinical plate-type electrode with the additional advantage of the extreme flexibility, very soft, body-conforming-style material. The electrode shown on the left was formed with Emerson and Cuming type SV-R, .020 inch thick. The entire electrode and wire were cut from one piece providing a very strong and yet completely flexible electrode. The wire in this case could be stretched up to 40% of its length, while maintaining excellent conductivity. The tip plug, shown on the end, was affixed to the wire with Emerson and Cumings Type RVS adhesive. The electrode on the right was formed with Chomerics .020 inch thick Type 1224. The wire is again a stretchable conductor made with Chomerics Type 1215 rod-shaped material, 1/16 inch in diameter and covered with heat-shrinkable, silicone-rubber tubing. The elastomeric wire was attached to the electrode with Chomerics Type 1022 conductive adhesive. The entire electrode back surface and a short length of the wire was then covered with Dow 3140 clear-adhesive coating. The tip connector was fixed to the end of the rod-shaped material with Chomerics Type 1025 adhesive. The baking process here for curing the 1022 on the electrode surface, the 1025 on the tip, and shrinking the silicone-tubing over the conductive wire, was performed in an oven at 350°F for 5 minutes.

PROBLEM NO. SSM-3

NERVE CONDUCTION VELOCITY ELECTRODES

Acquisition Date: November 8, 1972 Transfer Completed: March, 1972
Institution: Stanford University School of Medicine
Department: Physical Therapy
Investigator: Helen Blood, Director

PROBLEM OBJECTIVE

To record nerve conduction velocities at multiple points on the upper extremity.

BACKGROUND

Medical progress in this field has been constrained by limitations of commercially available attachable electrodes. In some instances, hand-held rigid electrodes have been used. A soft, flexible electrode, securely attached, will materially improve and expedite the techniques used in electro-diagnosis. While the electrodes required vary somewhat from those known to have been employed by NASA, it was hoped that the NASA reported technology and expertise would permit the solution of this problem.

RESOLUTION

Mr. Salvador Rositano of NASA-Ames Research Center was approached concerning this problem and developed a miniature electrode for recording nerve conduction velocity from motor areas on the body. This electrode is approximately 4 mm in diameter and is attached to the skin surface of the arm or hand with micropore tape. The extreme flexibility and body conforming characteristics of this electrode have made it ideal for recording evoked potentials. At present, studies have been initiated to develop other technics for attaching dry electrodes with promising preliminary results.

TECHNOLOGY IDENTIFICATION

The basic technology used in the resolution of this problem was a variation of the NASA electrode material described in NASA ARC A70-1095 with hard wire lead attachments.

IMPACT

It is expected that with continued application of this type of electrode, nerve conduction velocity studies will occur to more accurately establish and assess variations from normal motor-nerve function.

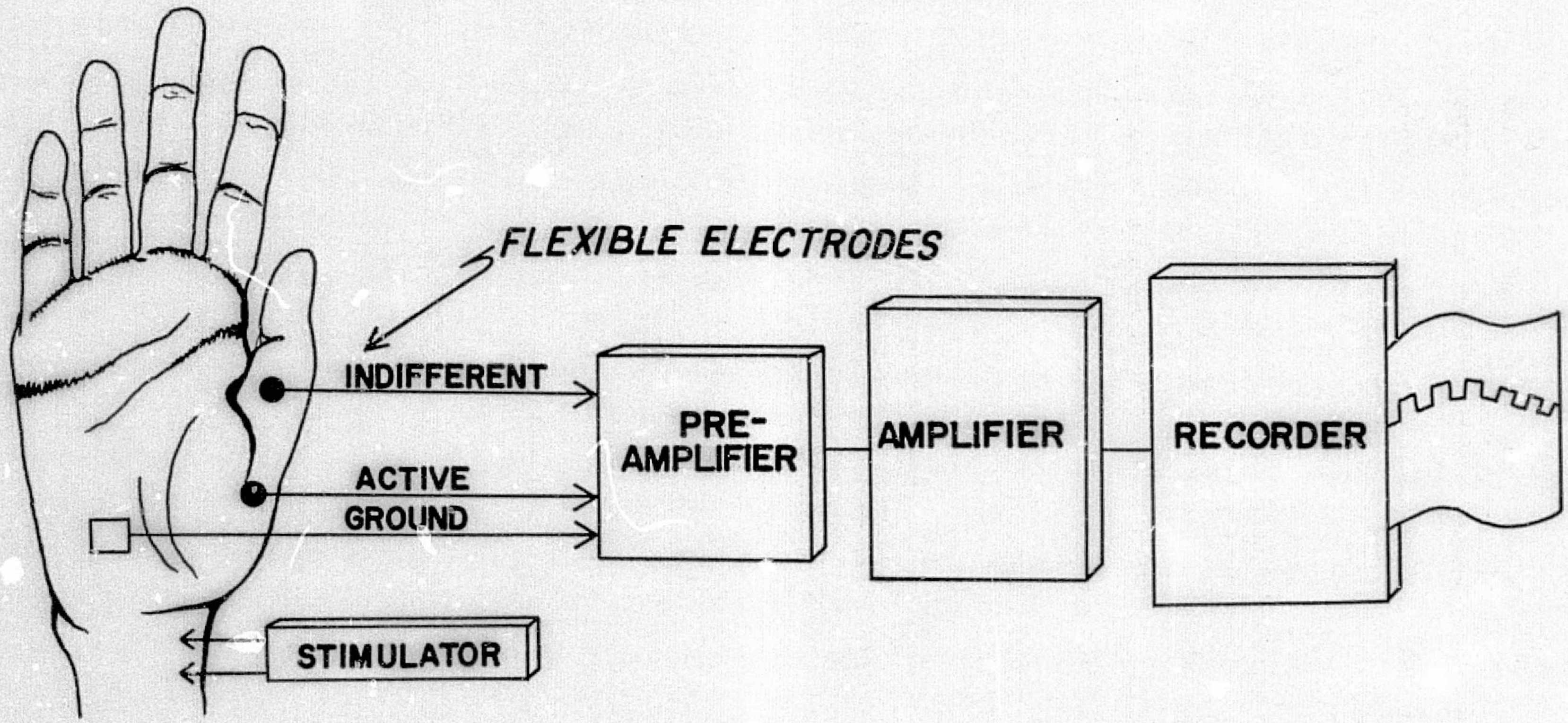
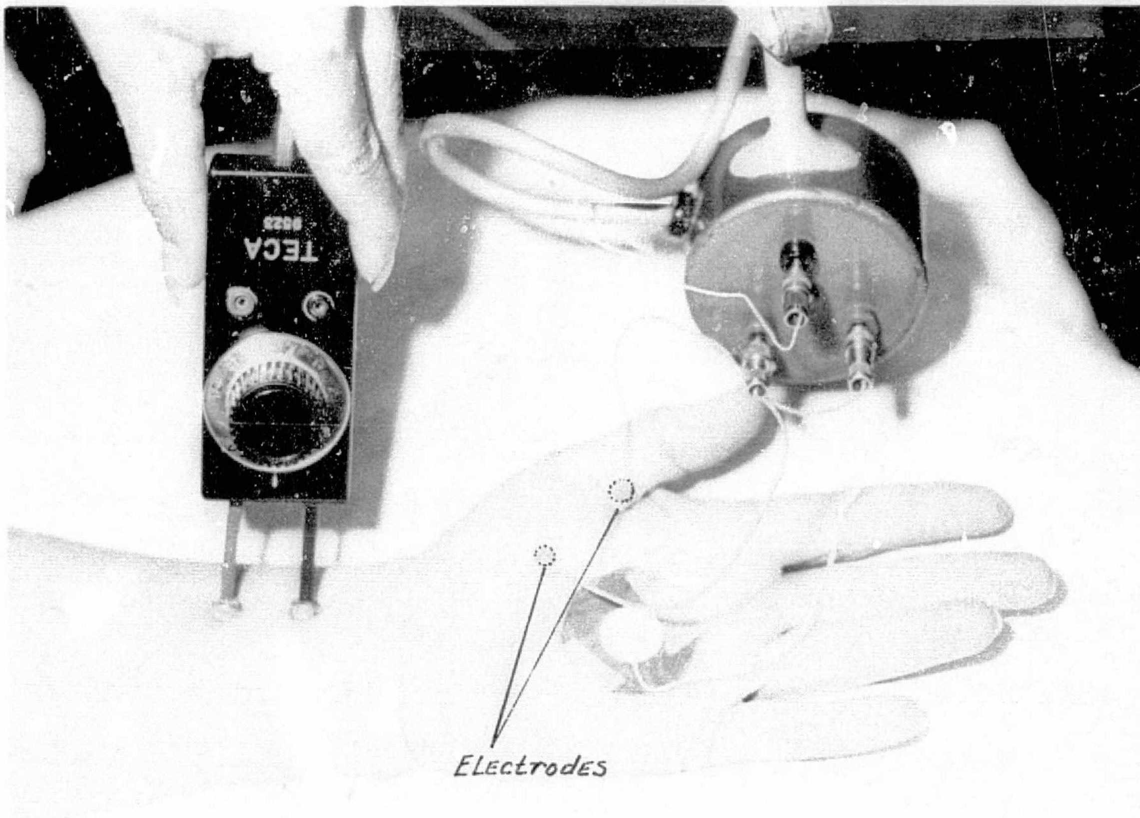


FIGURE 27 Investigative scheme for recording evoked responses from the hand



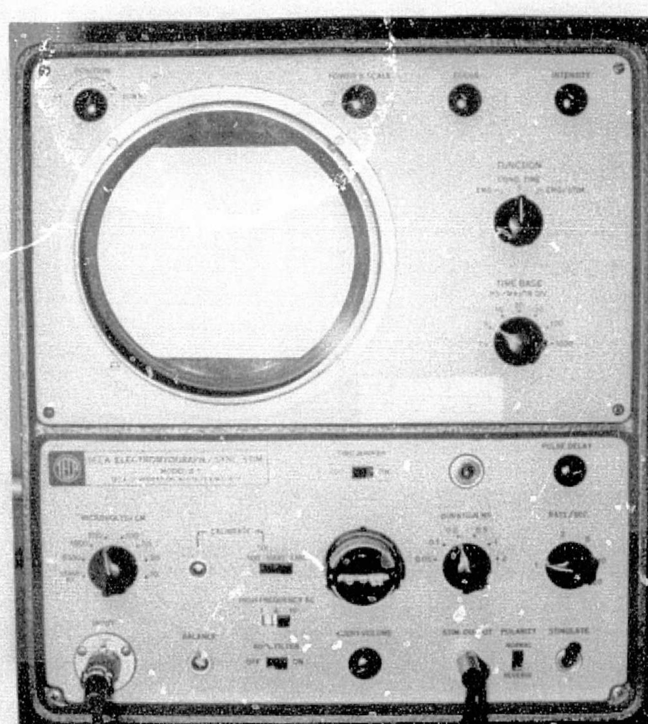
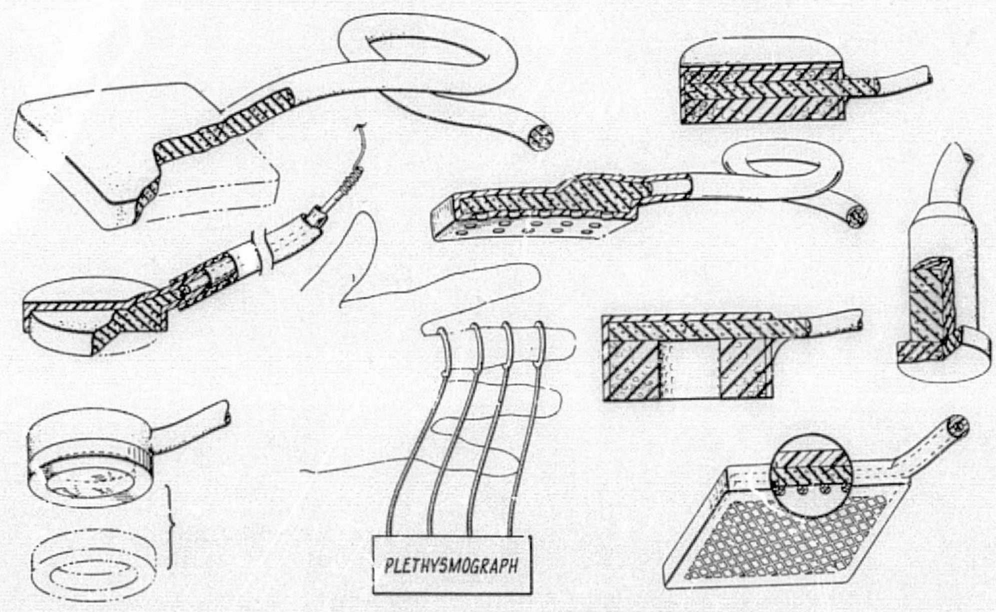


FIGURE 28 Application of elastomeric electrodes with commercially available nerve stimulating and recording equipment

NASA TECH BRIEF

Ultra-Flexible Biomedical Electrodes and Wires



The problem:

To develop a very flexible, uniformly conductive, comfortable, and easily applied biomedical electrode that conforms to the body contour during body motion.

The solution:

A soft, flexible electrode fabricated from an elastomer impregnated with a conductive powder which can be configured into any required shape, including a wire shape to connect the electrode directly to an electrical instrument or to a conventional metallic wire.

How it's done:

As shown in the figure, the device consists of the electrode and a conductor, both formed of silicone rubber as the elastomer and loaded with silver-plated particles as the conductive material. The electrode can be molded or cut to fit over any irregular body contours and to accommodate body location and type of measurement. A wide variety of electrode configurations can be fabricated using accessory materials such as silicone rubber sponge, silicone rubber adhesives, or adhesive bandages. Electrodes and "wires" made of the impregnated elastomeric material are suitable for implantation and connection to implanted telemetry equipment. The impregnated elastomeric wire is not only flexible but stretchable, in some cases up to 40% of its length, while maintaining excellent conductivity. This is a significant improvement over the normal metallic lead wires, which always present the danger of breaking at the junction

(continued overleaf)

with the electrode. Where external electrodes are used, improved contact with the skin can be obtained with sodium chloride electrolyte paste or jelly. In this case, the electrode can be designed with wells in which the electrolyte is placed. It is not always necessary to use an electrolyte paste, since the electrode moves with the skin. Long-term monitoring of relatively motionless bed-ridden patients can be accomplished with the electrode alone. Use of the electrode without the wet electrolyte avoids the problem of periodic replenishment and the discomfort of a continuously damp interface with the skin. The dry electrode does result in a higher impedance, but this is readily handled with a high input-impedance amplifier. Previous studies with electrodes have shown that silver-silver chloride provides the lowest galvanic potential when used with a sodium chloride jelly. The chloride ions provide the mechanism by which the biopotentials are sensed. A layer of silver-silver chloride can be plated on the elastomeric electrode surface by conventional electroplating using a 10% HCl solution with silver wire as a cathode and a 6-V power source. Plating on the electrode does not alter its flexibility. Insulation can be provided on any part of the electrode by spraying, dipping or brushing with nonconductive silicone rubber.

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Source: S. A. Rositano
Ames Research Center
(ARC-10268)

INVENTION ABSTRACT

NASA Case No. ARC-10268-1

ULTRA-FLEXIBLE BIOMEDICAL ELECTRODES AND WIRES

The present invention relates to a flexible, stretchable biomedical electrode and connector which is designed for use by physicians, medical technicians and researchers to connect an electric instrument to the body.

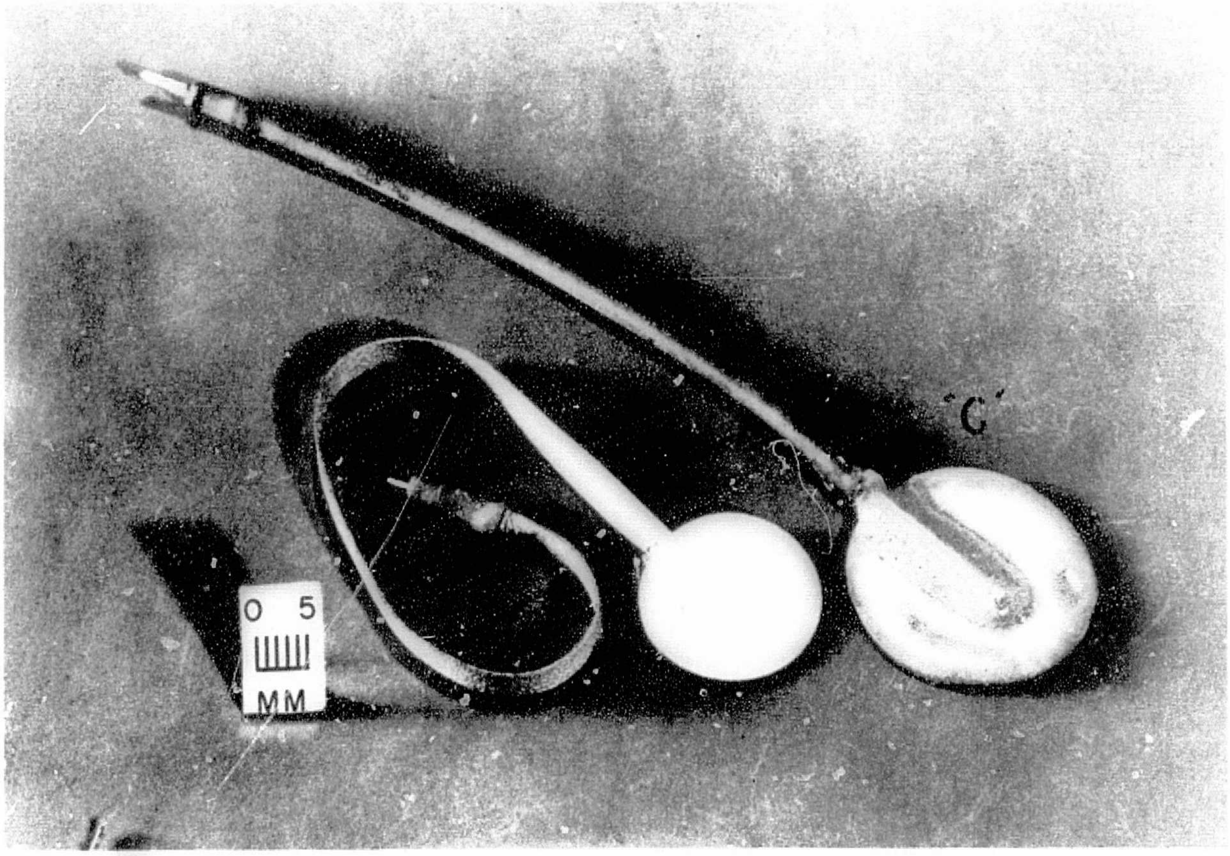
In the past, body electrodes have ordinarily consisted of a solid member coupled to the skin by a conductive paste. Such electrodes have been relatively inflexible so that they could not be used over a considerable portion of the body and were often uncomfortable even when applied to small areas of the body. Normally metallic lead wires are used with such electrodes and, even if the electrode itself is satisfactory, there is always the danger of the wire breaking at its junction with the electrode.

In accordance with the present invention, a soft, flexible electrode is provided by using an elastomer which has been loaded with a conductive powder with a connecting "wire" formed as part of the electrode of the same material.

The basic form of the invention is shown in Figure 1 of the drawings and consists merely of the electrode 14 and its conductor 16, both formed of an elastomer which is loaded with metal particles to render it conductive. A number of variations of this basic structure are possible. One is the employment of an insulating layer over the back of the electrode which can form a continuation of an insulating layer of the connecting wire. Further, an insulating layer can be formed over the face of the electrode with one or more apertures therein which may be filled with one of the usual conducting jellies for connecting the electrode to a body.

Thus the present invention provides a soft, flexible conductive electrode for biopotential measurements or stimulation which has a low contact potential and which has an electrical cable which will conform to the body contour during body motion. The "wire" itself is not only flexible but stretchable.

Inventor: Salvadore A. Rositano
Employer: NASA - Ames Research Center
Initial Evaluator: Ralph K. Hallett, Jr.



A70-1095:- The application here was for a dry-type electrode without the insulating washer shown in the previous photographs. One can get the same electrical characteristics as the standard clinical plate-type electrode with the additional advantage of the extreme flexibility, very soft, body-conforming-style material. The electrode shown on the left was formed with Emerson and Cuming type SV-R, .020 inch thick. The entire electrode and wire were cut from one piece providing a very strong and yet completely flexible electrode. The wire in this case could be stretched up to 40% of its length, while maintaining excellent conductivity. The tip plug, shown on the end, was affixed to the wire with Emerson and Cumings Type RVS adhesive. The electrode on the right was formed with Chomerics .020 inch thick Type 1224. The wire is again a stretchable conductor made with Chomerics Type 1215 rod-shaped material, 1/16 inch in diameter and covered with heat-shrinkable, silicone-rubber tubing. The elastomeric wire was attached to the electrode with Chomerics Type 1022 conductive adhesive. The entire electrode back surface and a short length of the wire was then covered with Dow 3140 clear-adhesive coating. The tip connector was fixed to the end of the rod-shaped material with Chomerics Type 1025 adhesive. The baking process here for curing the 1022 on the electrode surface, the 1025 on the tip, and shrinking the silicone-tubing over the conductive wire, was performed in an oven at 350°F. for 5 minutes.

PROBLEM NO. UCD-1

VECTORCARDIOGRAM COMPUTER ANALYSIS FOR EXERCISED SUBJECTS

Acquisition Date: October 11, 1971 Transfer Completed: April, 1972
Institution: University of California at Davis, School of Medicine
Department: Cardiovascular Medicine
Investigator: Richard F. Walters, Ph. D.

PROBLEM OBJECTIVE

To determine the suitability of 12-lead or vectorcardiogram computer-analysis programs for screening exercised subjects and to predict human performance ranges clinically.

BACKGROUND

The screening of subjects having potential cardiovascular problems, and monitoring the progress of patients recovering from myocardial infarctions or surgical coronary bypass procedures could be improved and expedited by a suitable computer analysis of electrocardiac potentials. To fulfill these needs, a computer system could monitor ECG's to: a) determine heart rate continuously in real-time and, b) to respond immediately to the occurrence of any arrhythmias or specific wave-form (S-T segment) changes. With such information, the speed and inclination of exercising treadmills could be adjusted immediately and automatically to suit the needs of the patient study.

Numerous computer programs for ECG analysis are in use. Each program has different medical applications and possesses different constraints.

Among these are NASA developed programs for monitoring the well-being and work-load responses of astronauts, both in research programs and in flight associated with Mercury, Gemini and Apollo projects.

RESOLUTION

After detailed discussion of the problem with Dr. Walters to define the requirements, the BTT team surveyed available computer programs. A literature search was performed by WESRAC. Information and personal experience was obtained on relevant programs from NASA-Manned Spacecraft Center.

Relevant available programs and techniques were explained to the problem originator on subsequent visits. Total system approaches, including data acquisition, data processing, pattern recognition, preprocessing (signal averaging), ECG analysis programs, quality control and system testing, were discussed in detail. The problem has been adequately solved and clinical application studies are being initiated to apply technology.

OTHER CONTRIBUTORS

Reports of the United States Public Health Service on ECG computer programs were quite useful.

TECHNOLOGY IDENTIFICATION

A very useful list of relevant ECG computer programs was furnished by Dr. David Golden of NASA-Manned Spacecraft Center. Reports on data acquisition and analysis prepared by M.D. Anderson Hospital and Tumor Institute under NASA contract (NAS-9-7153) were of value. A report on data-compression techniques by TRW Corporation under NASA contract (NAS-9-10876) with the Manned Spacecraft Center was also very useful. NASA report SP5078, outlining the work of Dr. C. Caceres was directly applicable. Five significant and useful references were located through the WESRAC literature search of recent NASA technology.

IMPACT

With the help of this transfer of NASA technology, screening tests may be developed to make practical the early detection and preventive treatment of incipient cardiovascular deficiencies. Also, recovery of patients from heart illness may be aided by frequent, accurate monitoring during recovery periods. Both the early detection and quality of care during convalescence are very significant, considering that in excess of one million cases of heart disease occur in the United States each year.

PROBLEM NO. UCD-2

DIGITAL TRANSMISSION OF MEDICAL DATA

Acquisition Date:	November 18, 1971 Transfer Completed: August, 1972
Institution:	University of California at Davis, School of Medicine
Department:	Cardiovascular Medicine
Investigator:	Richard F. Walters, Ph.D.

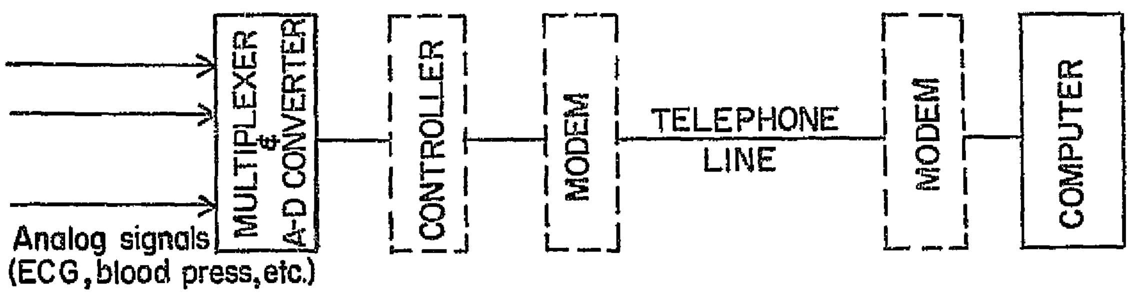
PROBLEM OBJECTIVE

It is desired to transmit biomedical data (ECG, blood pressure, temperatures, oxygen, etc.) over telephone lines to a Raytheon 703 computer at the University of California at Davis. In the long run, it is thought that digital transmission will be preferable, but analog transmission using standard IRIG telemetry equipment (such as is commonly used in rocket and missile work) is a possibility for immediate use. The technology is available for both approaches. The question is: a) In the digital mode, is there already-designed equipment available which will do this particular job economically without the expense and time of engineering a suitable system? and b) For the analog mode, is there surplus equipment available within NASA or other government agencies, which can be made available on loan to the problem originator.

BACKGROUND

A group at the School of Medicine, University of California at Davis, is using a Raytheon Model 703 computer to analyze signals measuring heart rate, thermal changes, and other physiological functions in research on human performance. The research is aimed at developing a more secure knowledge of human physical performance in both normal and diseased states so that information can be used n planning work loads and therapeutic exercise. They need to extend their capabilities so as to receive data from a distant laboratory (up to several hundred miles) using telephone lines. They are, in general, familiar with the state of the art but sought NASA's help relative to knowledge of specific equipment designs that might be directly applicable to their situation or in helping to provide equipment which might be surplus property to the government.

A block diagram for the desired digital data transmission system would be about as follows:



The dashed boxes are components which are needed. The main concern is in respect to the box marked "Controller." This unit would control the flow of data and provide whatever adaptation is required to make the entire system compatible from analog data source to computer.

The main function of the boxes marked "Modem" is to adapt between the usual two-voltage-level digital signals and the transmission requirements of the telephone line. One common method, for example, is to convert the two-voltage-level digital signals into levels of frequency modulation of a carrier signal. The frequency of the carrier signal would be chosen to be in the range of efficient transmission for a telephone line.

The controller unit must either be especially designed to handle a particular situation or it may be a more general-purpose product which was designed with a high degree of flexibility in order to be applicable to a variety of individual situations. A specifically designed system may result in a minimum cost of hardware, but design costs would be high.

C-2

In presenting his problem, the investigator hoped that NASA might have had experience with a similar situation so as to eliminate design work and equipment could be duplicated at a moderate cost.

RESOLUTION

Nothing was found within NASA that would solve the investigator's "Controller" problem; nor was any lead found on such commercially available equipment. The general concurrence was that the most practical course would be to use a minicomputer, of which several are on the market in the \$5,000-\$7,000 range and can be programmed as a flexible controller.

We did, however, find that NASA's Goddard Space Flight Center had a pair of suitable Modems (Bell Systems Model No. 205B) which were being surplused and could be made available. These were delivered to the investigator at the University of California at Davis in May, 1972 and will save him a major item of expense.

As an interim system while the longer-range digital system is being procured, the investigator can use conventional analog telemetry equipment such as has been developed for use in rockets, etc., and which has been standardized by the International Range Instrumentation Group (IRIG). IRIG standard channels, nos. 1-8, operate within the frequency range directly suitable for transmission over telephone lines. IRIG telemetry equipment was very successfully used in connection with the Bio-Satellite program at Ames for transmitting biomedical data over long-distance telephone lines for Dr. Adey's experiment. A former Ames employee, Pierre Hahn, who worked on that system at Ames, is currently continuing such work with Dr. Adey at UCLA. A block diagram of such a system is shown on the following page.

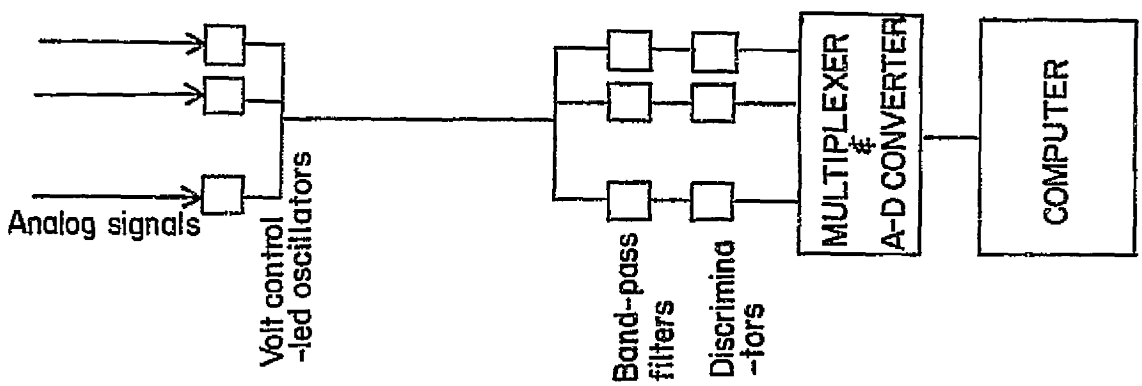
In presenting his problem, the investigator hoped that NASA might have coped with a situation essentially like his so that the design work was already done and he could duplicate the equipment at moderate cost.

RESOLUTION

Nothing was found within NASA that would solve the investigator's "Controller" problem; nor was any lead found on such commercially available equipment. The general concurrence was that the most practical course would be to use a minicomputer, of which a number of makes are on the market in the $5,000-$7,000 range, as a flexible Controller which can be programmed to do this job.

We did, however, find that NASA's Goddard Space Flight Center had a pair of suitable Modems (Bell Systems Model No. 205B) which were becoming surplus and could be made available. These were delivered to the investigator at the University of California at Davis in May, 1972 and will save him a major item of expense.

As an interim system while the longer-range digital system is being procured, the investigator can use to advantage conventional analog telemetry equipment such as has been developed for use in rockets, etc., and which has been standardized by the International Range Instrumentation Group (IRIG). IRIG standard channels nos. 1-8 operate within the frequency range directly suitable for transmission over telephone lines. IRIG telemetry equipment was very successfully used in connection with the Bio-Satellite program at Ames for transmitting biomedical data over long-distance telephone lines for Dr. Adey's experiment. A former Ames employee, Pierre Hahn, who worked on that system at Ames, is currently continuing such work with Dr. Adey at UCLA. A block diagram of such a system is shown on the following page.



Surplus IRIG telemetry equipment was located at NASA-Manned Spacecraft Center. A set of voltage-controlled oscillators, band-pass filters, and discriminators for the seven channels, Nos. 2-8 inclusive, were made available to the University of California at Davis and were delivered in August, 1972.

As soon as the investigator completes his preparations and successful performance of the equipment is demonstrated, this project should be complete.

TECHNOLOGY IDENTIFICATION

The equipment involved in this problem is largely the result of the advancements of aero and space technology even though they were in the form of commercially available products. It is as a result of their application in space research and surplus availability that NASA is able to make a direct contribution in this case. IRIG telemetry equipment, in particular, was a direct product of NASA and military research and development involving rocketry. NASA and military activities, either directly or sponsored by contract are still the principal users of such equipment.

OTHER CONTRIBUTORS

In addition to the Stanford BTT consultants, the following persons at MSC were instrumental in locating equipment and following through on arrangements:

Mr. Richard S. Johnston
Mr. James M. Satterfield
Ms. Sally Parker
Mr. H. James Wood, Jr.
Mr. Calvin F. Herman
Mr. Charles L. Ritterhouse
Dr. J. M. Lewallen
Mr. Parker Carroll
Mr. J.J. Weiland

IMPACT

With the full 4800 baud capacity, the NASA loaned equipment will permit Dr. Walters to carry on his research immediately. Should this research be as successful as Dr. Walters expects, the logical extension of of technics will be to bring to those isolated areas where specialized medical services are unavailable the medical force available at the University of California at Davis, under medically controlled supervision.

The critical shortage of medical specialists, especially to isolated areas, could be greatly alleviated by the technics envisioned herein. Obviously, the patient areas covered by the University of California at Davis could be expanded nation-wide by other institutions.

PROBLEM NO. UCD-3

QRS DETECTION AND HEART RATE DETERMINATION IN EXERCISING PATIENTS

Acquisition Date: July 3, 1972   Transfer Completed: September, 1972
Institution: University of California at Davis, School of Medicine
Department: Cardiovascular Medicine
Investigator: Richard F. Walters, Ph.D.

PROBLEM OBJECTIVE

To detect the occurrence of electrocardiographic "QRS" accurately in the presence of extreme noise and muscle artifact during human physiologic stress tests.

BACKGROUND

The Human Performance Laboratory at U.C. Davis is investigating the effects of stress on several physiological parameters (ECG, respired gases maximum O_2 uptake, respiratory quotients, respiratory rate and temperature). These variables are recorded from individuals undergoing graded stress on a motorized treadmill and are then input into a small digital computer which performs on-line, real-time measurements during the test period for display on a cathode-ray tube or teletype.

A major problem has been accurate measurement of heart rate and ST segmental changes in exercising subjects because of gross noise artifact superimposed on the electrocardiographic signal. The need for a "QRS" detecting device is of paramount importance in this computer system.

This device must be able to a) recognize the "QRS" in high noise environment, b) trigger at the same point (fiducial marker) on similar cycles, and c) interrupt the computer for each cardiac cycle. The Stanford Biomedical Technology Transfer team had been asked to investigate the various NASA resources for such a device and obtain a loan for the clinical testing as soon as possible.

RESOLUTION

A portable "R" wave detector unit developed by Mr. Vernon Gebben at NASA-Lewis Research Center has been obtained. The "R" wave detector is capable of detecting the cardiac electrical cycle in exercising patients and can supply compatible input to digital computers. The "R" wave detector unit with monor modification has been interfaced with a Raytheon computer at the Human Performance Laboratory and is presently being evaluated on exercised subjects.

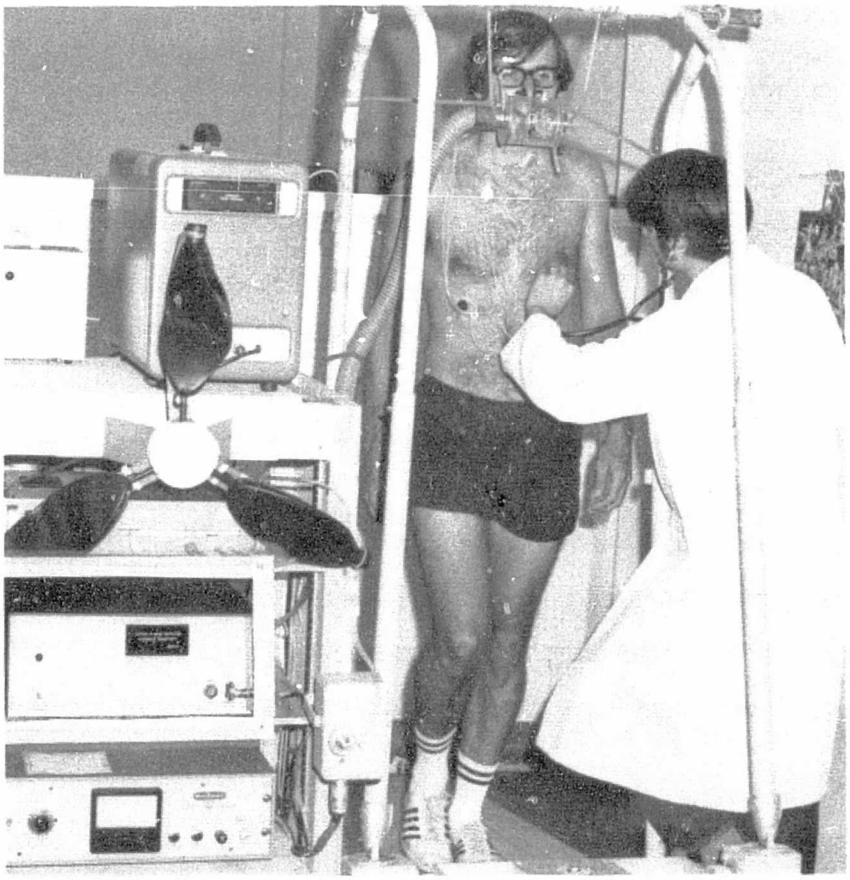


FIGURE 29 "R" wave detector in use with exercising subject to assess human performance

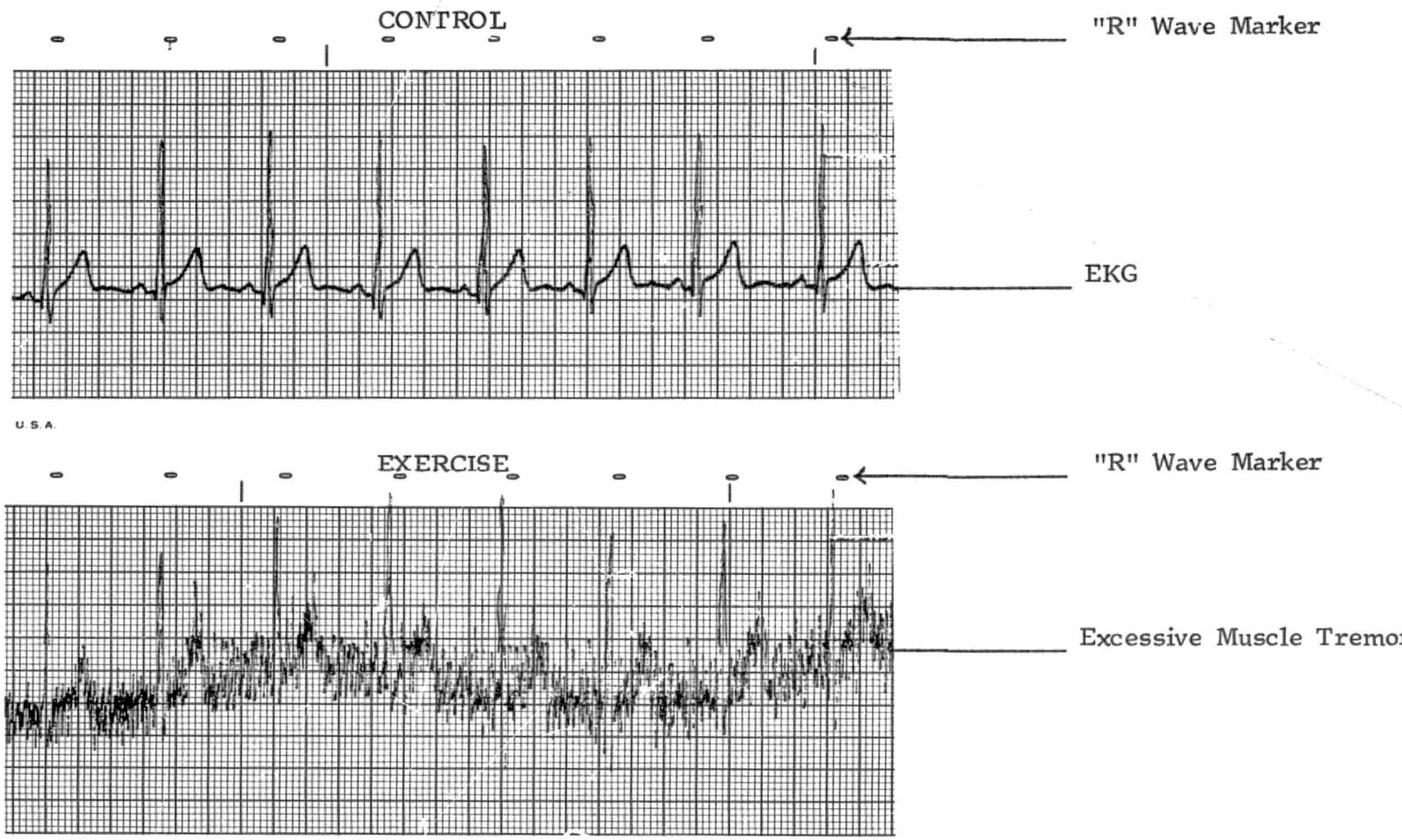


FIGURE 30 Sample of electrocardiogram and "R" Wave Detector recordings before and during exercise study

NASA
C-72-622

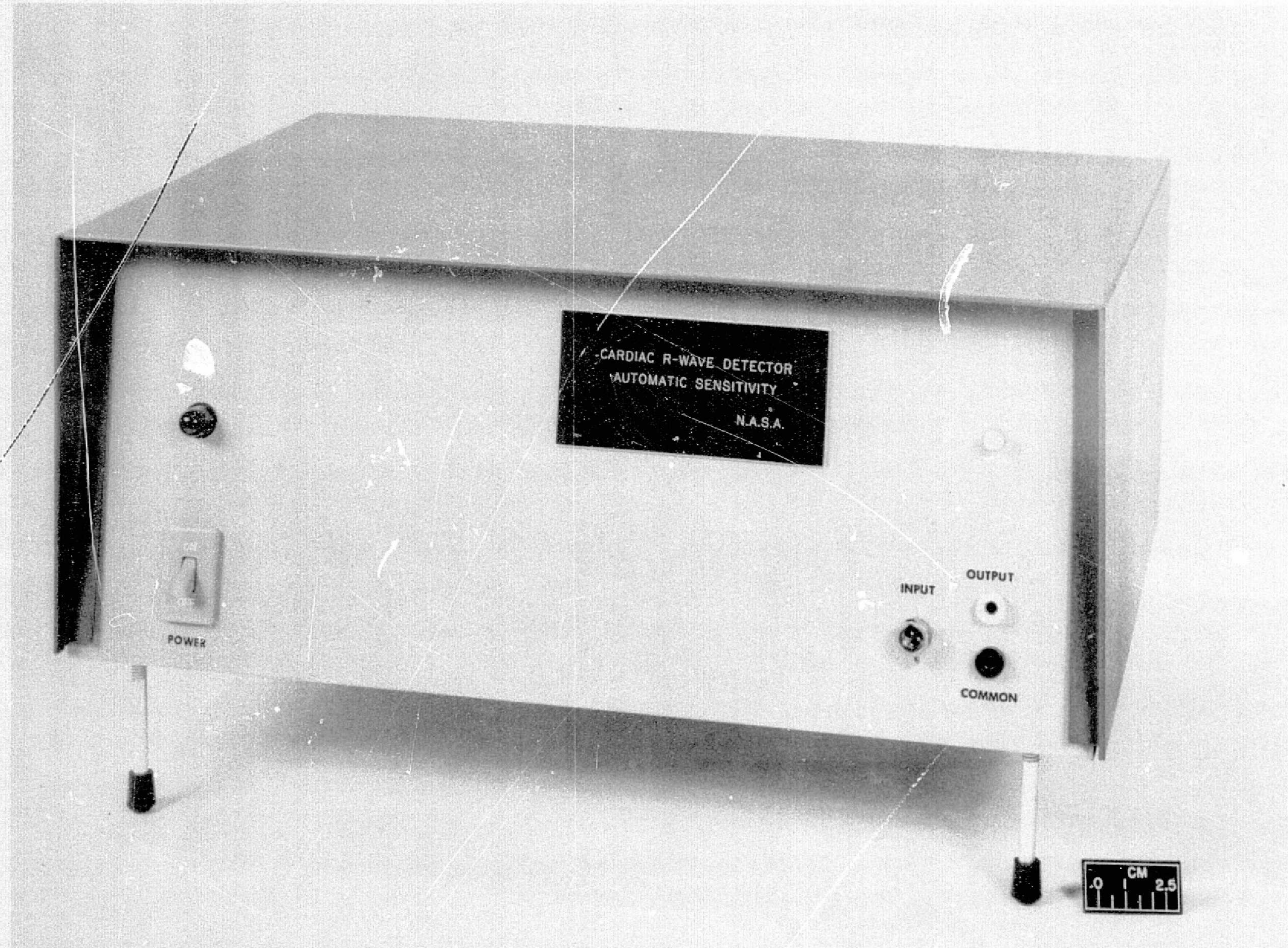


FIGURE 31 NASA Lewis Cardiac "R" Wave Detector (front panel view)

NASA
C-71-4336

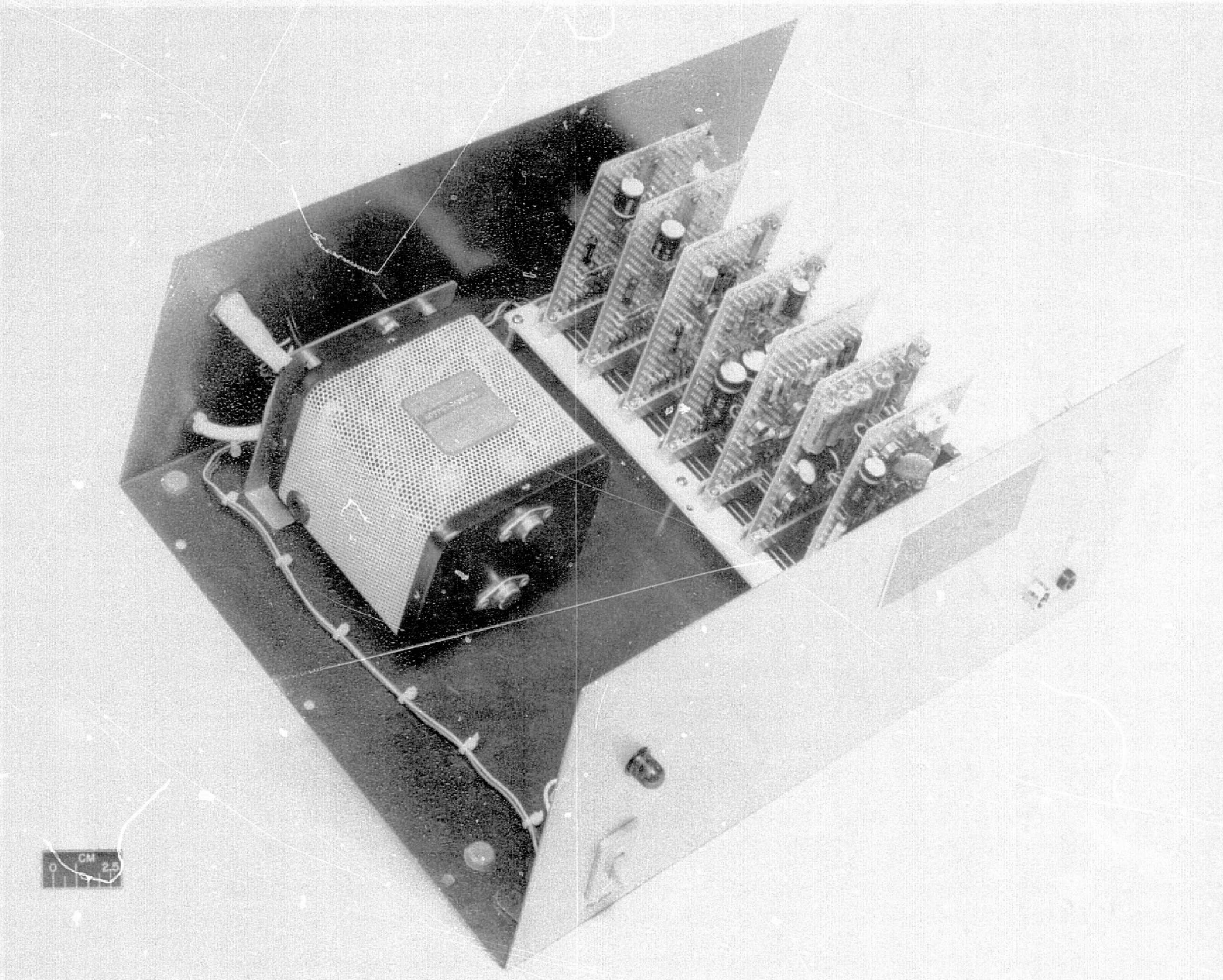


FIGURE 32 NASA Cardiac "R" Wave Detector electronics

TECHNOLOGY IDENTIFICATION

NASA Tech Brief 68-10144, which describes the nature of the device employed is provided on the following page.

IMPACT

If the applied technology is successful, several research protocols involving on-line physiologic detection and computer processing will be undertaken and significantly expedited.

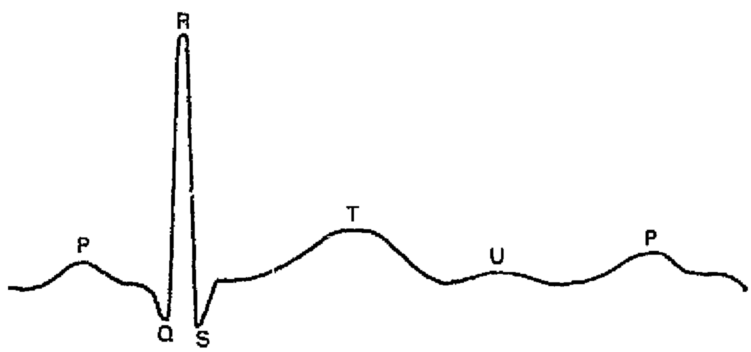
1. Analysis of the physical fitness of a large group of normal and well trained athletes is planned. Approximately 300 exercise tests are anticipated to be performed within a six week period.

2. The U.C. Davis and the U.S. Air Force academy are conducting an extensive study into the effect of altitude on human performance. Subjects will receive training regimens and undergo testing at sea level and moderate altitude.

3. The police and fire departments of Sacramento, California are undertaking an evaluation of stress testing on high-risk employees. Forty asymtomatic male subjects who are considered at high risk from coronary artery disease will be tested. Studies are planned for interval follow-up periods to elucidate the symptomatology and identification of high-risk patients.

NASA TECH BRIEF

Cardiac R-Wave Detector



EKG Input Waveform

The problem:

To obtain a reliable signal from a natural heart's systolic contraction in order to coordinate the action of a heart-assist device with the action of the failing natural heart.

The solution:

A cardiac R-wave detector (designed from aerospace controls systems technology) that processes the natural heart's electrocardiac signal in a sequence of operations which essentially eliminates all components from the input signal except the R-wave.

How it's done:

At the beginning of the heart's pumping cycle, the isometric contraction of the ventricular muscle mass generates a pronounced electrical signal known as the QRS wave complex of the electrocardiogram (EKG). The R-wave portion of the QRS complex can be detected and used as the reference signal for a heart-assist pump cycle. The cardiac R-wave detector obtains an input signal from surface electrodes attached to the patient's right arm and left leg and produces an electrical output pulse used to actuate a heart-assist device. It does not require the use of blood pressure or pump pressure waves.

The cardiac R-wave detector processes the input signal in a sequence of operations which detects the R-wave in the presence of high electrical interference. All false signals except those generated by vigorous motion or extreme muscle tensions are rejected. In succession, the detector's electronic circuit rejects signals that occur equally from the two surface electrodes attached to the patient's body, attenuates low- and high-frequency components, rejects low amplitude signals, rejects short duration signals, and rejects signals during the pumping time of the heart assist pump.

Notes:

1. Advantages of this detector, compared to conventional detectors, appear to include: better discrimination between the R and T waves, generally better noise filtering characteristics, and flexibility in the polarity of the trigger pulse.
2. Details of design and operation are described in NASA Technical Memorandum X-1489, "Cardiac R-Wave Detector," by Vernon D. Gebben.

(continued overleaf)

3. Inquiries concerning this innovation may be directed to:
   Technology Utilization Officer
   Lewis Research Center
   21000 Brookpark Road
   Cleveland, Ohio 44135
   Reference: B68-10144

Patent status:

No patent action is contemplated by NASA.

Source: Vernon D. Gebben
(LEW-10394)

PROBLEM NO. VSF-1

RESPIRATION AND PHONATION ELECTRODES

Acquisition Date: November 4, 1971 Transfer Completed: June, 1972
Institution: Veterans Administration Hospital, San Francisco
Department: Speech Research Section
Investigator: Thomas Shipp, Ph. D., Chief

PROBLEM OBJECTIVE

To record action potentials from abdominal muscles during forced respiration and phonation.

BACKGROUND

Currently available commercial electrodes, which are rigid in nature, frequently become displaced during forced trunk motions, resulting in loss of signal, artifact appearance and skin irritation. Securely attached flexible electrodes will permit more vigorous activities of speech, respiration and coughing during normal and diseased conditions.

RESOLUTION

Mr. Sal Rositano of NASA-Ames Research Center supplied several experimental electrodes to the problem originator for recording from abdominal muscles of patients having problems in phonation. Electrodes recommended were of type A70-1095C with a hard wire lead attachment. For the initial studies, electrodes were hard wire connected without consideration of impedance matching. Initial records showed a certain amount of artifact and low level signals. In an attempt to eliminate these problems, better care was taken in preparation of the electrode site before applying the dry electrode and a different interconnecting wire with lower impedance characteristics was used. With these modifications, markedly improved recordings are being performed. Reports of this application will be available shortly.

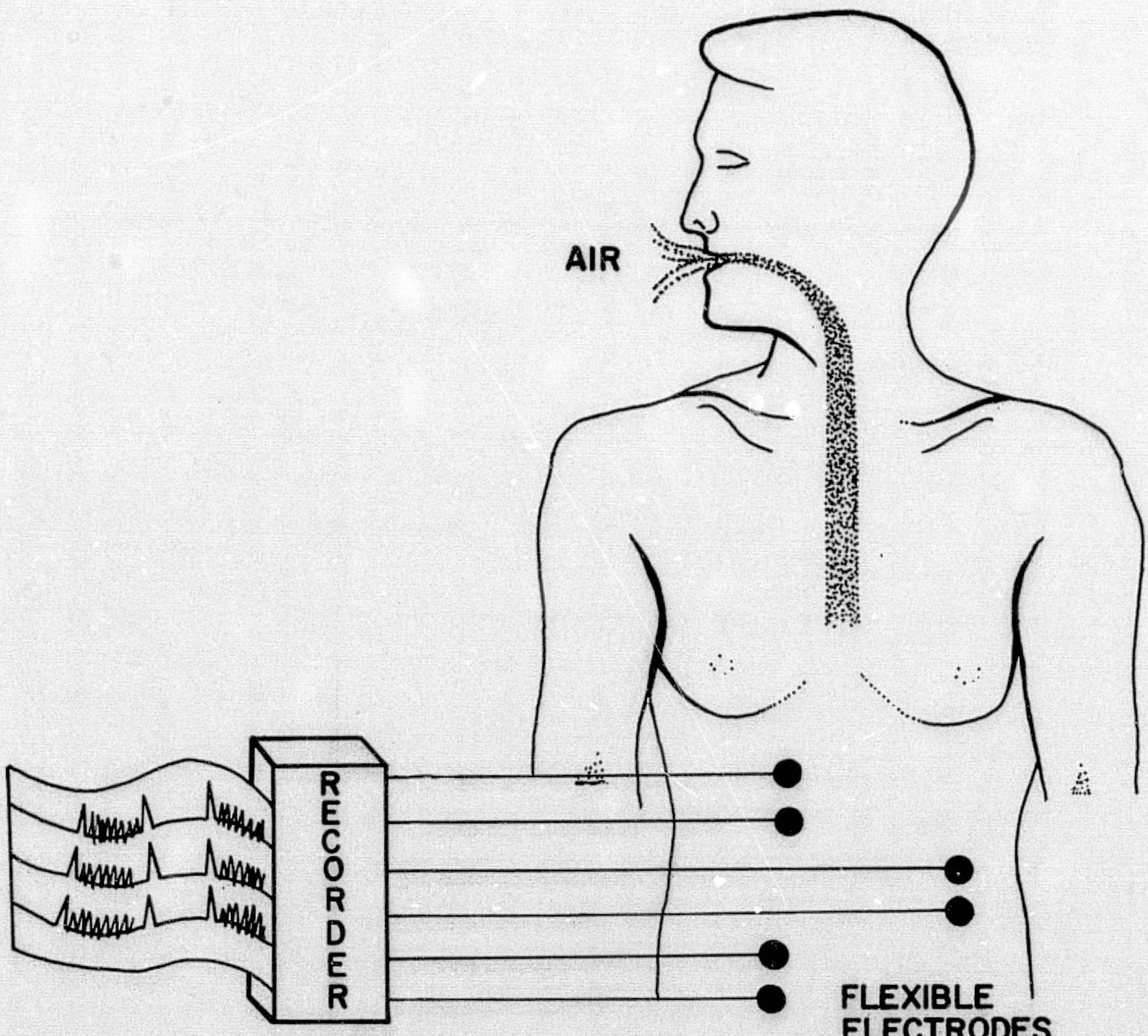


FIGURE 33 Application of dry electrodes to various abdominal muscles for recording of action potentials during phonation

TECHNOLOGY IDENTIFICATION

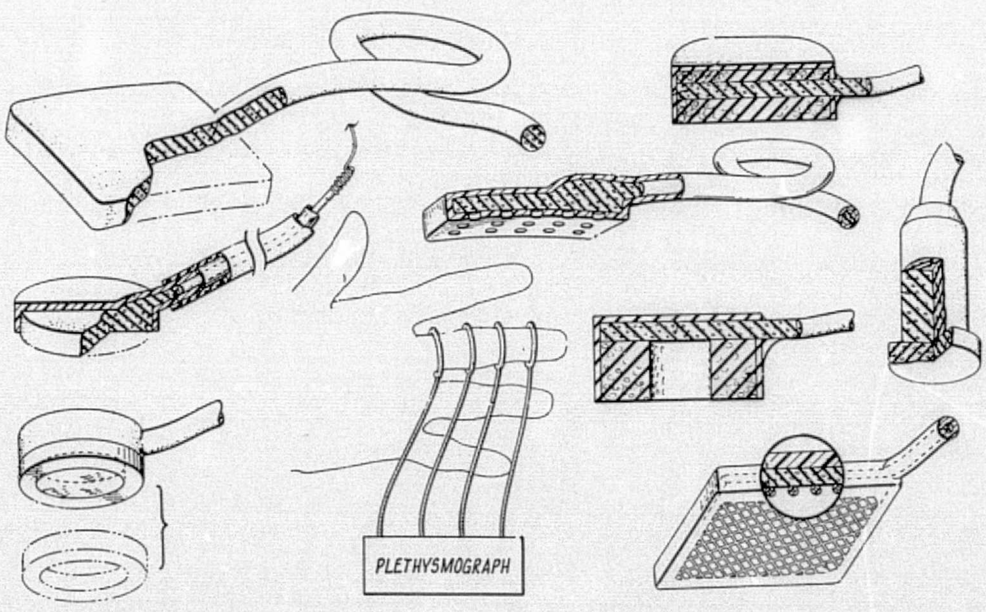
Technology leading to the resolution of this biomedical problem is described in NASA-Ames Tech Brief A70-1095. The specific technology was a modified electrode type A70-1095C with hard wire low impedance cable attachment.

IMPACT

Advanced NASA technology in exotic materials has allowed the recording of action potentials from surface muscles in normal subjects and patients with speech pathology problems with ultraflexible biomedical electrodes. This material has permitted the study of patients during more strenuous maneuvers and maximal phonation efforts than previously possible. Routinely available electrodes do not permit recording of action potentials under these difficult diagnostic maneuvers.

NASA TECH BRIEF

Ultra-Flexible Biomedical Electrodes and Wires



The problem:

To develop a very flexible, uniformly conductive, comfortable, and easily applied biomedical electrode that conforms to the body contour during body motion.

The solution:

A soft, flexible electrode fabricated from an elastomer impregnated with a conductive powder which can be configured into any required shape, including a wire shape to connect the electrode directly to an electrical instrument or to a conventional metallic wire.

How it's done:

As shown in the figure, the device consists of the electrode and a conductor, both formed of silicone rubber as the elastomer and loaded with silver-plated particles as the conductive material. The electrode can be molded or cut to fit over any irregular body contours and to accommodate body location and type of measurement. A wide variety of electrode configurations can be fabricated using accessory materials such as silicone rubber sponge, silicone rubber adhesives, or adhesive bandages. Electrodes and "wires" made of the impregnated elastomeric material are suitable for implantation and connection to implanted telemetry equipment. The impregnated elastomeric wire is not only flexible but stretchable, in some cases up to 40% of its length, while maintaining excellent conductivity. This is a significant improvement over the normal metallic lead wires, which always present the danger of breaking at the junction

(continued overleaf)

with the electrode. Where external electrodes are used, improved contact with the skin can be obtained with sodium chloride electrolyte paste or jelly. In this case, the electrode can be designed with wells in which the electrolyte is placed. It is not always necessary to use an electrolyte paste, since the electrode moves with the skin. Long-term monitoring of relatively motionless bed-ridden patients can be accomplished with the electrode alone. Use of the electrode without the wet electrolyte avoids the problem of periodic replenishment and the discomfort of a continuously damp interface with the skin. The dry electrode does result in a higher impedance, but this is readily handled with a high input-impedance amplifier. Previous studies with electrodes have shown that silver–silver chloride provides the lowest galvanic potential when used with a sodium chloride jelly. The chloride ions provide the mechanism by which the biopotentials are sensed. A layer of silver–silver chloride can be plated on the elastomeric electrode surface by conventional electroplating using a 10% HCl solution with silver wire as a cathode and a 6-V power source. Plating on the electrode does not alter its flexibility. Insulation can be provided on any part of the electrode by spraying, dipping or brushing with nonconductive silicone rubber.

Note:

Requests for further information may be directed to:

Technology Utilization Officer
Ames Research Center
Moffett Field, California 94035
Reference: TSP70-10420

Patent status:

Inquiries about obtaining rights for the commercial use of this invention may be made to NASA, Code GP, Washington, D.C. 20546.

Source: S. A. Rositano
Ames Research Center
(ARC-10268)

INVENTION ABSTRACT

NASA Case No. ARC-10268-1

ULTRA-FLEXIBLE BIOMEDICAL ELECTRODES AND WIRES

The present invention relates to a flexible, stretchable biomedical electrode and connector which is designed for use by physicians, medical technicians and researchers to connect an electric instrument to the body.

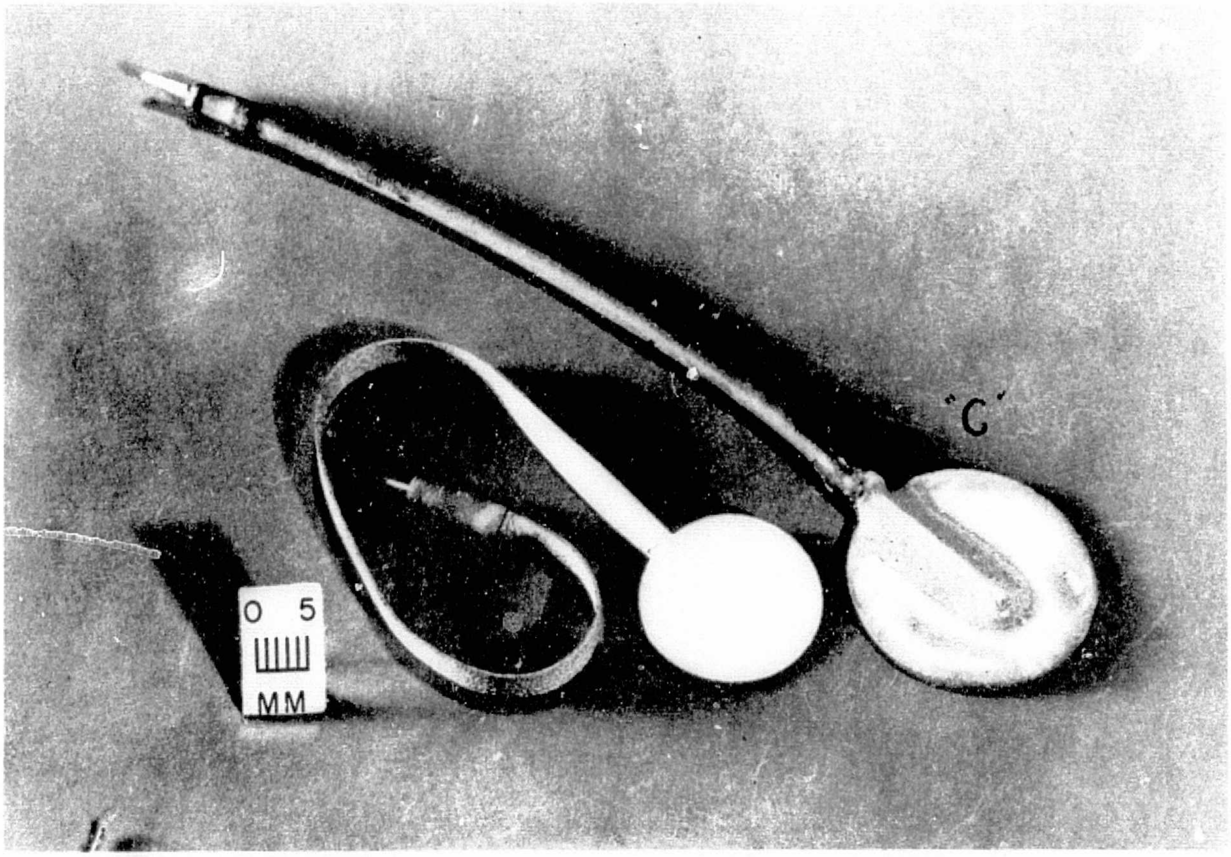
In the past, body electrodes have ordinarily consisted of a solid member coupled to the skin by a conductive paste. Such electrodes have been relatively inflexible so that they could not be used over a considerable portion of the body and were often uncomfortable even when applied to small areas of the body. Normally metallic lead wires are used with such electrodes and, even if the electrode itself is satisfactory, there is always the danger of the wire breaking at its junction with the electrode.

In accordance with the present invention, a soft, flexible electrode is provided by using an elastomer which has been loaded with a conductive powder with a connecting "wire" formed as part of the electrode of the same material.

The basic form of the invention is shown in Figure 1 of the drawings and consists merely of the electrode 14 and its conductor 16, both formed of an elastomer which is loaded with metal particles to render it conductive. A number of variations of this basic structure are possible. One is the employment of an insulating layer over the back of the electrode which can form a continuation of an insulating layer of the connecting wire. Further, an insulating layer can be formed over the face of the electrode with one or more apertures therein which may be filled with one of the usual conducting jellies for connecting the electrode to a body.

Thus the present invention provides a soft, flexible conductive electrode for biopotential measurements or stimulation which has a low contact potential and which has an electrical cable which will conform to the body contour during body motion. The "wire" itself is not only flexible but stretchable.

Inventor: Salvadore A. Rositano
Employer: NASA - Ames Research Center
Initial Evaluator: Ralph K. Hallett, Jr.



A70-1095:- The application here was for a dry-type electrode without the insulating washer shown in the previous photographs. One can get the same electrical characteristics as the standard clinical plate-type electrode with the additional advantage of the extreme flexibility, very soft, body-conforming-style material. The electrode shown on the left was formed with Emerson and Cuming type SV-R, .020 inch thick. The entire electrode and wire were cut from one piece providing a very strong and yet completely flexible electrode. The wire in this case could be stretched up to 40% of its length, while maintaining excellent conductivity. The tip plug, shown on the end, was affixed to the wire with Emerson and Cumings Type RVS adhesive. The electrode on the right was formed with Chomerics .020 inch thick Type 1224. The wire is again a stretchable conductor made with Chomerics Type 1215 rod-shaped material, 1/16 inch in diameter and covered with heat-shrinkable, silicone-rubber tubing. The elastomeric wire was attached to the electrode with Chomerics Type 1022 conductive adhesive. The entire electrode back surface and a short length of the wire was then covered with Dow 3140 clear-adhesive coating. The tip connector was fixed to the end of the rod-shaped material with Chomerics Type 1025 adhesive. The baking process here for curing the 1022 on the electrode surface, the 1025 on the tip, and shrinking the silicone-tubing over the conductive wire, was performed in an oven at 350°F. for 5 minutes.

DESCRIPTION OF TECHNOLOGICAL PROBLEMS

B. ACTIVE

PROBLEM NO. AMC-1

A MINIATURE PORTABLE PATIENT ARRHYTHMIA DETECTOR

Acquisition Date:	September 15, 1971
Institution:	Arizona Medical Center
Department:	Cardiology
Investigator:	Frank I. Marcus, M.D.

PROBLEM OBJECTIVE

To develop a light-weight, portable EKG pattern recognition system capable of detecting and storing ventricular premature beats (potentially serious cardiac arrhythmias).

BACKGROUND

The occurrence of ventricular arrhythmias (abnormal heart beats) and their relation to sudden death is an important area requiring medical investigation. Ventricular premature beats (VPBs) are classified as one of the dangerous rhythm disorders and frequently precursors to sudden death. Early detection of these arrhythmias in certain high-risk individuals may provide the opportunity to treat these disturbances and possibly prevent sudden death.

The problem originator desires to carry out a study utilizing the proposed technology to determine the frequency of ventricular premature beats and association with sudden death. The investigator has existing funding, adequate staff and facilities to perform both engineering and clinical validation of the device.

The desired technology is required to be small, portable, self-contained system for application to ambulatory subjects and should:

a) receive a single bipolar EKG signal as the input source

b) be capable of detecting and storing the subject's normal EKG wave shape (Figure 34)

c) compare all subsequent beats to the stored normal for a minimum time of 24 hours

d) detect abnormality by some type of comparator technics noting characteristic signs of: (Figure 35)

   1) absence of a "P" wave in front of the QRS
   2) distortion and prolongation of the primary waveshape (ARS)
   3) existence of a long pause between PVC and next normal beat
   4) T wave usually being inverted in polarity

e) register the count (total number) of occurrence of abnormal beats for rapid physician review.

TECHNOLOGY IDENTIFICATION

A rapid search of the NASA data bank by WESRAC and Field Centers was performed with no suitable applicable technology to be found. A survey of commercially available devices revealed that some instruments are provided for similar purposes. One device (Holter Monitor) consists of a relatively bulky portable tape recorder which is worn by the patient and records and stores all electrocardiographic signals continuously for a duration of 4-10 hours. Tracings are reviewed at a later date through an expensive scanning device. Abnormal complexes are identified by a physician or skilled technician. Another device has been found which records a one minute strip of an abnormal segment (multiple normal-abnormal beats); however, it will not record a single isolated abnormal beat. Suitable technology was not found available from commercial sources. Knowledge by the Stanford team of a new device (ventricular impulse detector alarm) presently undergoing research and development was called to the attention of the investigator. The VIDA was not found to be suitable; although it could detect and recognize PVBs, no provision was made for counting or storing of the frequency of abnormal beats.

IMPACT

In the study of heart disease, early detection and documentation of life-threatening EKG disturbances in high-risk patients is mandatory to offer treatment and possibly prevent sudden death. With the proposed technology, epidemiological studies can be efficiently undertaken with consequential medical significance.

PRESENT STATUS

After three months of attempting to obtain applicable NASA technology, the problem originator was informed by Stanford of the NASA-MSC request for proposal to submit significant medical problems amenable by NASA aerospace technology. These proposals offered potential source of grant funds by which technological solutions might be developed to worthwhile medical problems. A proposal was submitted on December 15, 1971 by the problem originator to engineer and clinically evaluate the subject technology.

During the review period of the originators proposal to NASA, very little effort was invested on the problem by Stanford. A reply was received in late June, 1972 notifying "proposal is not able to be granted due to lack of available funds." At the present time, the Stanford team is preparing a detailed problem statement to disseminate to all NASA Field Centers before inactivating the problem.

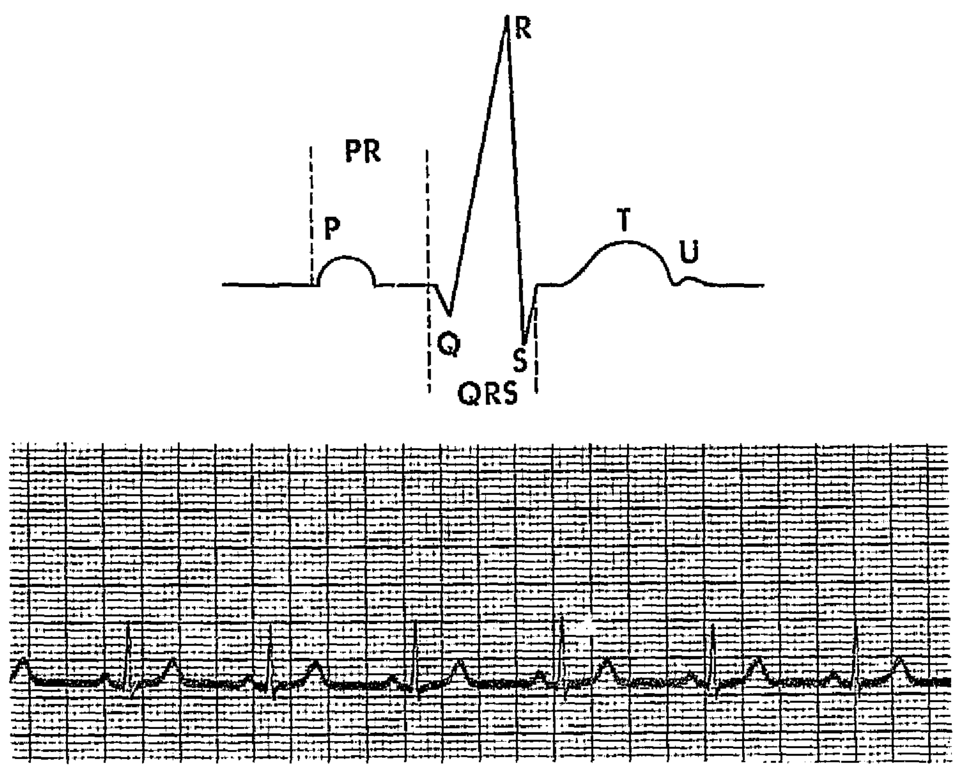


FIGURE 34 Schematic of a normal electrocardiogram wave shape with nomenclature and typical analog strip chart recording

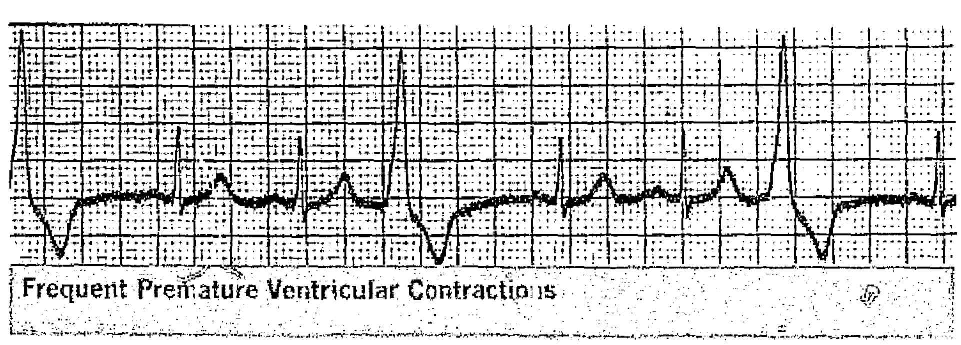


FIGURE 35 Analog record of the electrocardiogram illustrating intermittent abnormal wave shapes (PVB's)

PROBLEM NO. CED-1

ECG MONITORING DURING EMOTIONAL STRESS

Acquisition Date: March 18, 1972
Institution: Cedars of Lebanon Hospital, Los Angeles, California
Department: Cardiology
Investigator: James Forrester, M.D.

PROBLEM OBJECTIVE

To measure the ECG reaction during emotional stress involving professional, scientific and executive personnel.

BACKGROUND

Serious arrhythmias and sudden death frequently occur during the everyday stress encountered by some occupational groups. How such stress affects the cardiovascular system is poorly understood.

There is a need for data on the cardiovascular effects of emotional stresses frequently experienced by members of certain occupational groups; e.g., surgeons, executives, scientists. Examples of such stress are numerous. What is the effect upon a cardiac surgeon while he is performing major surgery upon a patient? How does a civic leader respond to the stress of civic sessions on critical matters? How does a scientist react during a presentation of an important paper?

The determination of ECG stress relationships may provide a basis for training such individuals in what situations to avoid. Unless some commonality of pattern develops, it is expected that each subject will be treated individually and prescribed attention to methods of alleviation of stress levels will be developed. It is quite conceivable that routine screening methods may result as well.

RESOLUTION

The work of NASA-Ames Research Center in the telemetry of ECG is well known to the BTT consultants. Conferences with Thomas B. Fryer and Richard M. Westbrook of the Electronic Instrument Development Branch revealed that Ames was developing new and advanced ECG telemetry equipment for the Skylab program.

Further conferences with Messrs. Fryer, Evans and Emerson resulted in the manufacture of an additional unit above that which is required by Ames. This unit will be clinically tested by the Stanford Cardiology Division and then loaned to Dr. Forrester for research application.

The new Ames telemetry equipment retains the desirable diagnostic-quality features of the previous Ames' telemetry equipment, however it varies in a number of respects. Both transmitter and receiver are crystal controlled, permitting "push button" operation, with no frequency drift. The range (effective line of sight) has been increased to 300 feet. Pulse-code modulation is employed, modulating a very narrow band FM carrier operable in the 88-108 MC band with complete conformance to FCC requirements. Radiated power is 5 mW. The very narrow band feature is designed to eliminate local FM station interference.

TECHNOLOGY IDENTIFICATION

Report ARC 970-23-30-02-00-21, by Messrs. Fryer and Westbrook was presented to the 1972 International Telemetering Conference in October, 1972 in Los Angeles.

Illustrations of NASA bioinstrumentation and circuit diagrams are provided in figures 36,37 and 38.

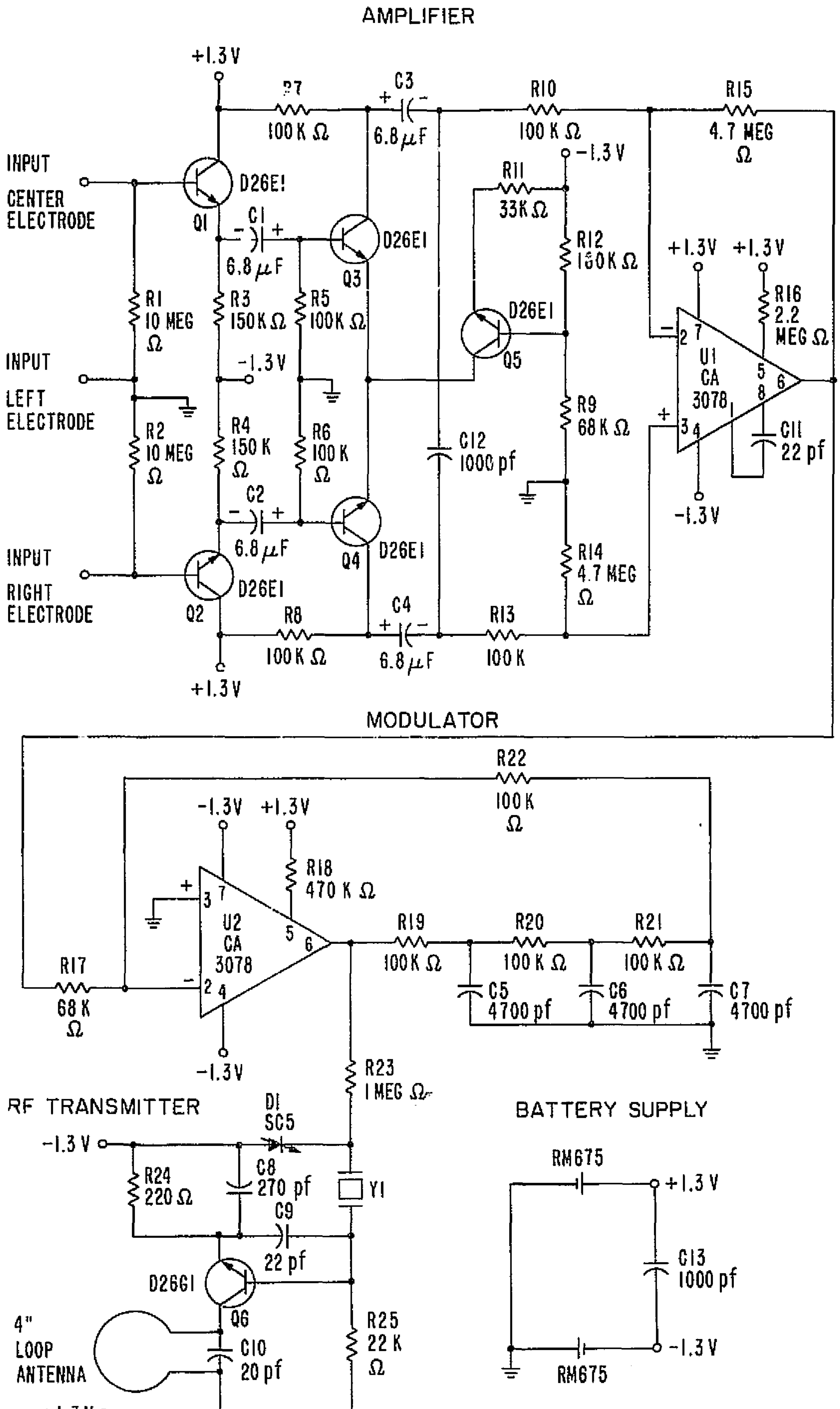


FIGURE 36 Circuit diagram of NASA-Ames ECG Transmitter

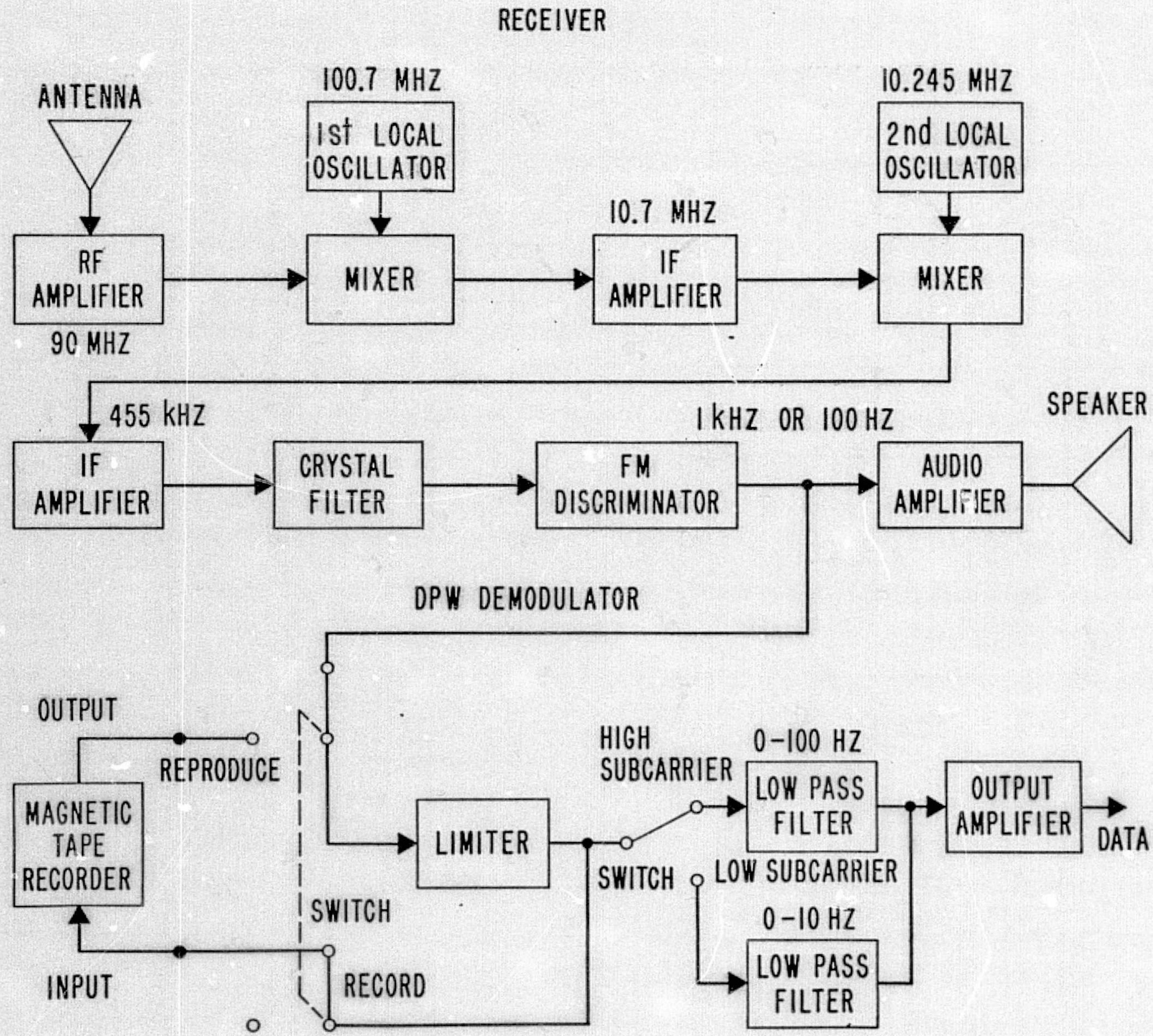


FIGURE 37 Circuit diagram of NASA-Ames ECG receiver

IMPACT

Since the Ames ECG telemetry equipment was designed for this specific purpose and since the problem solution is achieved by this alone, this is a direct application of NASA hardware to the solution of a medical problem different from those required of NASA. It is quite likely that the results of Dr. Forrester's research will prove of interest to NASA in connection with psychological and physiological stresses suffered by aircraft pilots and astronauts. In this regard, NASA may realize a direct return resulting from their equipment loan.

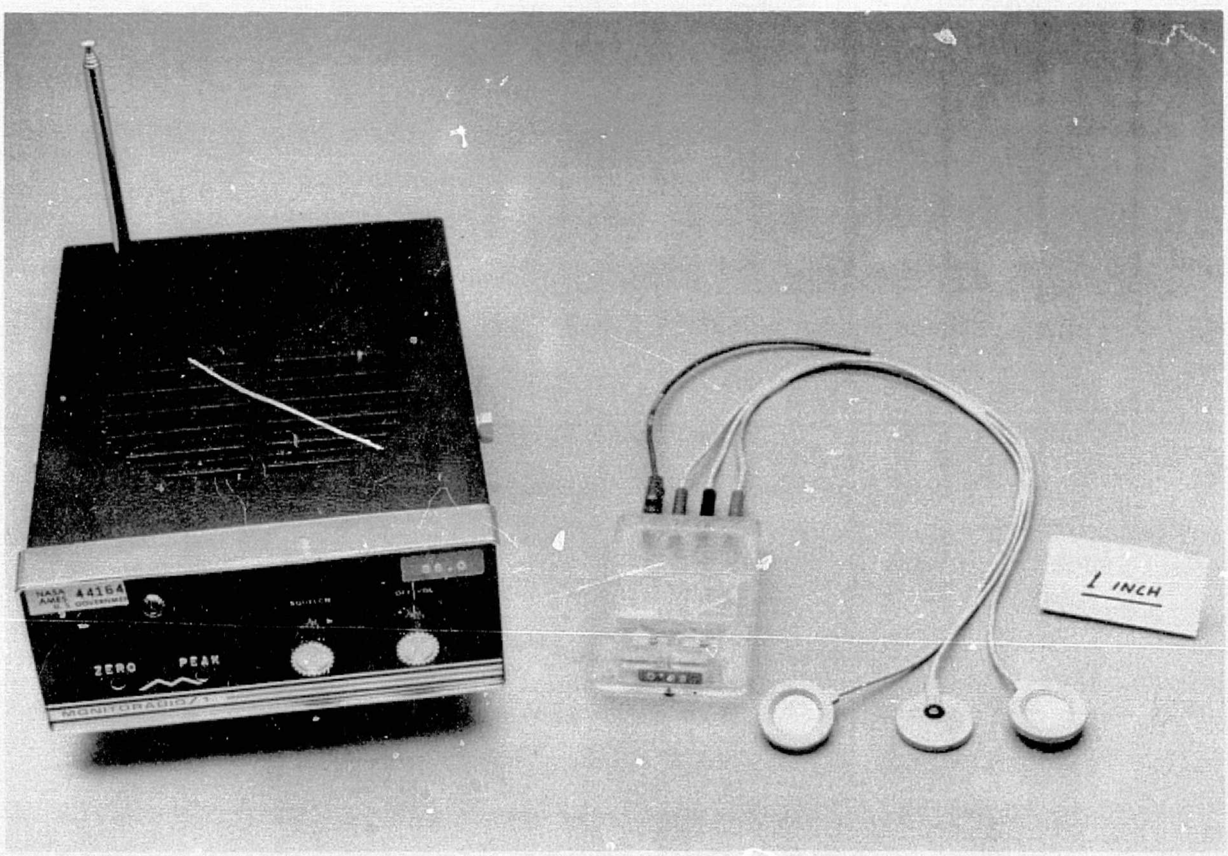


FIGURE 38 New NASA-Ames transmitter-receiver system

PROBLEM NO. CED-2

TRANSDUCER REFERENCING TECHNICS IN ECHOCARDIOGRAPHY

Acquisition Date: April 4, 1972
Institution: Cedars Sinai Medical Center, Los Angeles, California
Department: Cardiology
Investigator: J.A. Don Michael, M.D.

PROBLEM OBJECTIVE

To provide an improved method of referencing ultrasound transmitting/receiving transducers with respect to the cardiac anatomy.

BACKGROUND

The present technics of cardiac ultrasound are the sole non-traumatic means of measuring cardiac end diastolic volume and stroke volume. These are critical measurements in the myocardial infarction research unit, both to follow the time course of compliance changes and to determine blood ejection fraction. These measurements are also routinely obtained at follow-up. At present, these measurements are unreliable, principally because the transmitting-sensing transducer applied to the chest does not define a reproducible relationship to the dimensions being measured. Anatomical landmarks for localizing the transducer and orienting the observer are not presently incorporated into the recording instrumentation.

Attempts have been made to obtain echocardiograms from certain regions of the left ventricle and to avoid structures such as the chordae (valve ligaments). Optimal echocardiograms with good motion of the septum and posterior wall are selected, based upon the skill of the recording physician.

Suggested alternative solutions may consist of: A) fabricating a transducer with a collimated beam placed at the back of the chest and used as a reference point behind. B) fabrication of an esophageal dual or triple head transducer to localize the echo in a longitudinal way (head-foot) with respect to the heart. This would also enable recordings to be obtained in patients in whom echocardiograms cannot be obtained because of dressings or other technical reasons (about 15% of cases).

PRESENT STATUS

NASA-Ames Research Center is presently being consulted regarding the optimum approach. This problem is a new and substantive one. Prior experience by NASA is limited, however, ARC has been working on ultrasonography during the past several years and recommendations for a suitable approach look promising.

The letter on the following page indicates the most recent developments.

STANFORD UNIVERSITY SCHOOL OF MEDICINE

701 Welch Road, Suite 3303, Palo Alto, California 94304 • (415) 321-1200, Ext. 6283

CARDIOLOGY DIVISION
Biomedical Technology Transfer

October 26, 1972

J.A. Don Michael, M.D.
2973 Meyerloa Lane
Pasadena, California 91107

SUBJECT: Problem No. CED-2, "Transducer Referencing Technics in Echocardiography"

Dear Doctor Michael:

We have made an effort to find NASA technology which might lead to an improved method of locating ultrasound transducers relative to the heart for echocardiography. This effort was in response to the problem you submitted in April, 1972.

In our search, we discussed your problem with Richard L. Popp, M.D. of the Cardiology Division at Stanford University School of Medicine and with Mr. Robert D. Lee of NASA-Ames Research Center. Dr. Popp and Mr. Lee are actively cooperating under NASA sponsorship to develop improved instruments and techniques for echocardiography. Some potential improvements are being evaluated, but Dr. Popp and Mr. Lee are still faced with the same problem of location reference as described by you. These two researchers are so thoroughly familiar with NASA ultrasonic technology that we believe further search is not likely to be fruitful at this time. However, their work is continuing and we will inform you of any promising developments.

We regret that we have not been able to offer any immediate help in the solution of your problem. We hope, Dr. Michael, that you will submit additional problems which NASA technology might help to solve and that we will be able to provide more immediate assistance in locating applicable technology.

Sincerely,

Manley J. Hood
Engineering Consultant

MH:dh
Enclosures

cc: Richard L. Popp, M.D.
Mr. Robert Lee

PROBLEM NO. CED-3

ESOPHAGEAL BALLOON BIPOLAR PACEMAKER

Acquisition Date: April 4, 1972
Institution: Cedars Sinai Medical Center
Department: Cardiology
Investigator: J. A. Don Michael, M. D.

PROBLEM OBJECTIVE

To provide a pacemaker electrode that can be inserted via the esophagus to record the internal electrocardiogram and permit artificial pacemaking in temporary or emergency situations.

BACKGROUND

Transvenous cardiac pacemakers and electrodes have come into widespread use for sudden cardiac arrest, A-V conduction abnormalities, recording intracardiac electrograms and for pacing the heart at rapid rates as a screening test for angina. The transvenous approach requires a minor surgical procedure, generally fluoroscopic observation and therefore is of limited use for emergency and non-hospital situations.

Esophageal pacing has been attempted in the past, but utilized relatively high energy (20-30v) principally due to poor or intermittent contact of the electrodes and tissue adjacent to the heart. The problem originator has designed an esophageal tube with a balloon tip as described in Lancet, December 21, 1968, pg. 1329. This device has been used as both a mouth to lung airway and mouth to esophagus probe in emergency situations. The balloon can be inflated to assume a horsehoe shape. With the balloon inflated, the anterior surface can be made flush with the posterior surface of the heart.

at the level of either the left atrium or left ventricle.

Electrodes are proposed to be placed on the anterior surface of the balloon. Upon balloon inflation, the probe is held in stable anatomical position and in electrical contact with conductive tissue in close proximity to the heart.

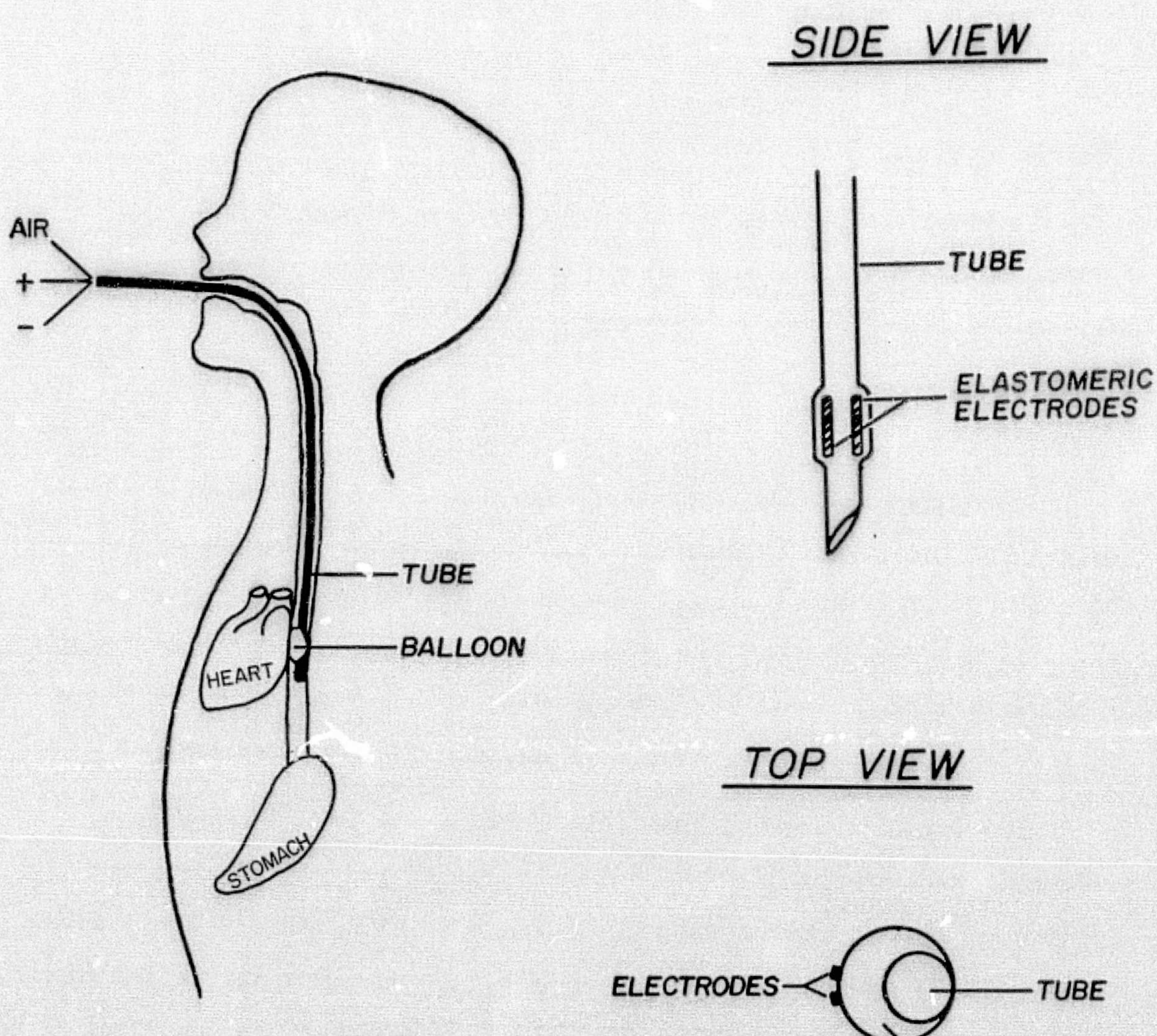


FIGURE 39 Configuration and anatomic location of balloon pacemaker

RESOLUTION

New materials are required that will accommodate extreme dimensional changes and maintain relatively constant conductive properties. Metallic impregnated elastomeric materials under investigation at NASA-Ames Research Center (Tech Brief 70-1020) show promise in offering a solution.

Two elastomeric electrode segments would be attached to the non-conductive balloon. Either rigid metallic wires or insulated elastomeric material would be employed to transmit signals from electrodes on the balloon to external instrumentation.

The electrode system must have relatively low resistance and capable of carrying currents of 2-5 milliamps. The material must undergo dimensional changes of 50% normal and maintain good conductivity. The material must be biocompatible.

Upon receipt of the esophageal tube from the problem originator (it is now undergoing manufacture), the prototype tube will be given to Mr. Salvador Rositano of NASA-Ames Research Center for development and incorporation of conductive elastomere.

IMPACT

Fabrication of a suitable esophageal balloon electrode will permit emergency ECG recording and cardiac pacing by noninvasive technics. This new method has the advantage of being safer and more rapid.

It does not invade the circulatory system and can be applied outside the hospital environment. In addition, this approach would lend itself to noninvasive electrical pacing in the diagnostic studies of angina pectoris (chest pain).

PROBLEM NO. PMD-1

NONINVASIVE INTRACRANIAL PRESSURE MONITOR

Acquisition Date: August 13, 1971
Institution: Private Medical Practice
Department: Neurosurgery
Investigator: Paul J. Pitlyk, M.D.

PROBLEM OBJECTIVE

To determine a means for noninvasively monitoring intracranial pressure or, alternatively, sensing the build-up of cerebral edema, which results in an increase of intracranial pressure.

BACKGROUND

Head injuries may cause the formation of edema in the brain with resultant increase in the intracranial pressure (ICP). If not promptly recognized and corrected, this pressure can cause brain injury or death. Short of invasive techniques, such as drilling through the skull, physicians now rely on indirect clinical signs to detect ensuing problems.

A noninvasive technique is needed which can be used in the intensive care unit to monitor continuously the intracranial pressure or presence of cerebral edema. The method should be sufficiently specefic so as not to require the presence of an attending physician.

RESOLUTION

Review of NASA Tech Briefs has revealed nothing applicable to this problem. Unfortunately, it does not appear possible to measure the pressure phenomenon directly. That is, there is no point at which the brain or the cerebral spinal fluid is accessible for direct pressure measurement by noninvasive means. Strain gage measurements on the skull (restraining member) are possible, but with the overlying layer of soft scalp and tissue, this appears impracticable.

Discussions with Drs. Winter and Ogden of the Life Sciences Directorate at NASA-Ames Research Center; a literature search by the NASA-sponsored Western Research Application Center; and the initial thoughts of the problem originator suggest several phenomena which are affected by intracranial pressure or the presence of edema. These warrant consideration as possible means of sensing the increase in intracranial pressure and are briefly listed:

a) Edema is known to contain a higher concentration of sodium ions than does blood or normal tissue. This offers a possibility of sensing a change in electrical resistance or a concentration of a radioactive sodium isotope tracer.

b) Rheoencephalography

c) Ultrasonic phenomena

  1) midline shift as sensed by ultrasonic echo
  2) pulsations of echos at pulse frequency

d) Acoustical impedance of the middle ear

e) Cushings reflex (blood pressure goes up while pulse rate goes down in the presence of elevated intracranial pressure)

Each approach has advantages and disadvantages. To our knowledge, no one has explored the sensing techniques involving sodium ion differential suggested in item "a". All other approaches, in general, share the criticism that they are indirect indications of elevated intracranial pressure. The same indication may appear for other reasons and the response to intracranial pressure may not always appear. Hence, extensive physiological research would be required in order to determine whether any of items "b" through "e" would be sufficiently reliable indications of intracranial pressure.

For example, McHenry, investigating changes in the rheoencephalograph (REG) with increased intracranial pressure, notes a definite change in the wave form with increased intracranial pressure. Such differences are not so apparent in some other work. Lugaresi, et al, point out that changes in wave shape (similar to those observed by McHenry) occur due to aging and due to cerebral arteriosclerosis. It appears that the REG is largely related to blood circulation. Since increased intracranial pressure is only one of many factors which affect cerebral blood flow, it might be expected that the REG would not be a very specific indicator of high intracranial pressure.

Item "d" (acoustical impedance of the inner ear) is rather interesting. According to two references, there is a specific relation between the sound level reflected from the ear drum and the fluid pressure in the inner ear. The fluid pressure in the inner ear, in turn, is essentially equal to the intracranial pressure. However, the effect does not occur in cases where there is fixation of the ossicular chain. Since some degree of fixation of the ossicular chain is a common affliction, especially with older persons, this approach would not be a reliable ICP indicator.

A combined conference was held on December 21, 1971 at Stanford to consider reasonable solution approaches and to design a pilot research project. The meeting was attended by Dr. Pitlyk (problem originator), Dr. Winter (Deputy Director, NASA-Ames Life Sciences Directorate), Dr. Scholer (internist specializing in nuclear medicine at the Palo Alto Medical Clinic) and Dr. Barry, Messrs Buck, White and Miller of the Stanford BTT team. It was concluded that a radioisotope method for sensing the concentration of sodium ions in edema would have the greatest probability of success and could be evaluated with a reasonable amount of effort. As a consequence of this meeting, a pilot research program was implemented by a consortium of Drs. Pitlyk and Scholer, NASA-Ames and Stanford.

An initial pilot study of the radioisotope method was undertaken with the injection of a small amount of Na^{22} in a well person to demonstrate the sensitivity of measurements and determine isotope dose levels. Comparative measurements in the region of the heart and the region of the brain showed greater radiation from the heart (approximately 4:1), indicative of the greater amount of tissue and less blood in the brain. At the same time, an attempt was made to obtain a radiograph of the brain region, although it was realized that the available collimator was not optimum for the weak energy levels of the sodium isotope. Na^{22} has a half-life of about 2 1/2 hears. Much higher concentrations will be possible in the future by using Na^{24} with a half-life of only 12 days.

A second study was initiated with edema artificially induced in the brain of an anesthetized dog, using a sodium isotope and also chromium-labeled red cells. With two tracers, whose radiations can be separately identified, the labeled red cells would monitor blood concentration while the the sodium tracer would display edema concentration. This experiment was unsuccessful because the duration of study was too short relative to the time required for edema formation (see Figure 40).

Following the successful outcome of a third feasibility study, the problem investigators will be seeking $4,000 in funds to purchase isotope monitoring equipment and $3,000 for operating expenses to provide a working model for clinical evaluation. Formal request for assistance is being made to the Stanford BTT team for referral to NASA Headquarters.

TECHNOLOGY IDENTIFICATION

A WESRAC computer search, No. 145-955, cited a number of references on items "b" through "d", listed under "Resolution" in this report, as well as the first leads on items "c-2" (pulsed echo technics) and "d" (acoustical impedance of the middle ear). Discussions with Dr. David L. Winter and the late Dr. Eric Ogden of the Life Sciences Directorate at

NASA-Ames Research Center helped lead to the selection of the sodium isotope approach.

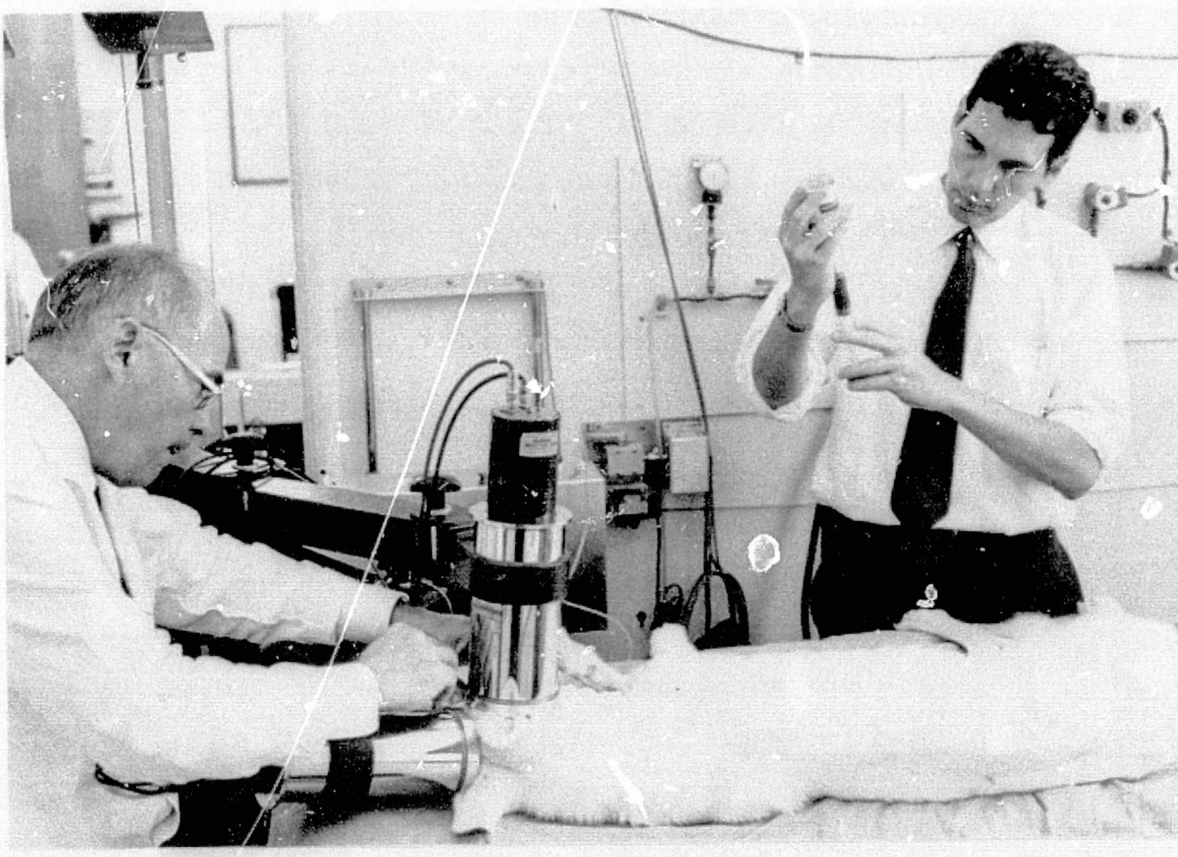


FIGURE 40 Research investigators evaluating the dual radioisotope monitoring technic in an animal model with induced cerebral edema

OTHER CONTRIBUTORS

Dr. John F. Scholer, a radiologist with the Palo Alto Medical Clinic and Research Foundation became enthusiastic about the promise of the radioisotope approach for disclosing the presence and location of edema. He very generously offered to conduct some experiments for a preliminary evaluation of this technique and is now a collaborator.

PROBLEM NO. UOO-1

CATHETER SYSTEM FOR MEASURING INTRAVASCULAR RADIATION

Acquisition Date: May 15, 1972
Institution: University of Oregon Medical School
Department: Diagnostic Radiology
Investigator: Charles T. Dotter, M.D.

PROBLEM OBJECTIVE

To provide a catheter system for the measurement of radiation levels within the circulatory system.

BACKGROUND

Suitable technology is being sought to enable the measurement of either beta or gamma emission at sites within the circulatory system. The severity of thrombi and atheromas are presently demonstrated angiographically by the injection of x-ray contrast material, serial filming and subsequent visual inspection. This technic is suitable for gross observations only and incapable of showing early thrombo-atherogenic activity.

RESOLUTION

The problem originator proposes to administer fibrinogen into the vascular system tagged with I^{125} or some other isotope emitting either beta or gamma radiation. At suitable time intervals, radiation levels are monitored at various suspect intravascular sites by means of an intraluminal detector (Figure 41). Increasing levels of ratiation would indicate accumulation of fibrinogen and yield useful information on the location, history and size of blood clots. This principle can be applied to atherogensis within the arterial system.

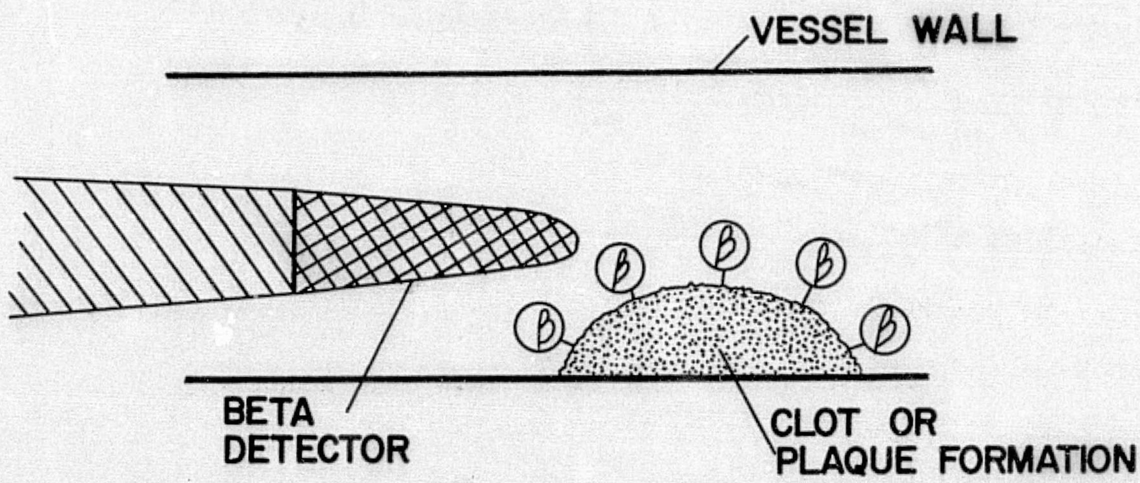


FIGURE 41 Catheter detector for measuring radiation emitted from clots or plaques attached to vessel walls

Needed: a catheter system permitting quantitative determinations of beta (gamma) radiation from within the vascular system. A particle counting ratemeter-detector mounted on the tip of a catheter, 125 cm. long and approximately 1.7 mm. in diameter is the essential element. Associated excitation, preamplification and signal display can be connected distal to the catheter.

TECHNOLOGY IDENTIFICATION

A search of the NASA data bank from the period of January, 1962 to June, 1972 produced several abstracts relevant to the subject of ratemeter tipped catheters. Approximately 10 abstracts contained some information concerning either catheters or probes employing radiation detecting devices for application internal or external to the body. Almost all devices mentioned employ semi-conductor ratemeters and a few deal with possible fiber optic application. None of the abstracts described a detector configuration meeting the desired specifications.

An extensive search of Nuclear Science Abstracts (NSA) substantiated the validity of employing radioactive tagged fibrinogen and other bio-substances of interest, but was uneventful in enumerating suitable technology for detection in this specific application.

Subsequent manual search of current NASA field center and Biomedical Application Team technology lead to the awareness of a catheter tip radiation sensor used for radio Krypton blood flow studies by Laenger, Wilbur and McGraw of Southwest Research Institute. The original NASA development was performed at Langley Research Center. Communications with Messrs. Wilbur and Laenger of the SwRI BAT team resulted in detailed information and a brief loan of prototype catheter to discuss with the problem originator (see Figures 42 and 43).

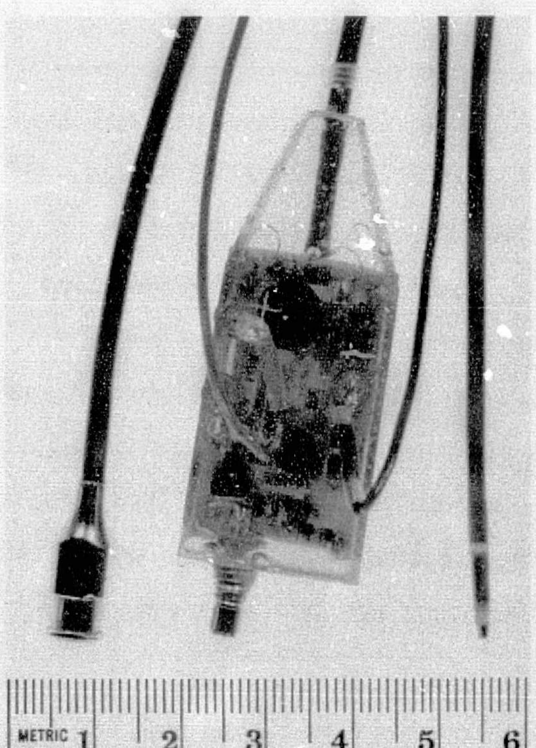


FIGURE 42 Essential elements of the catheter consist of (left to right) a lumen for flushing and obtaining blood samples, signal processing electronics, and the catheter tip detector

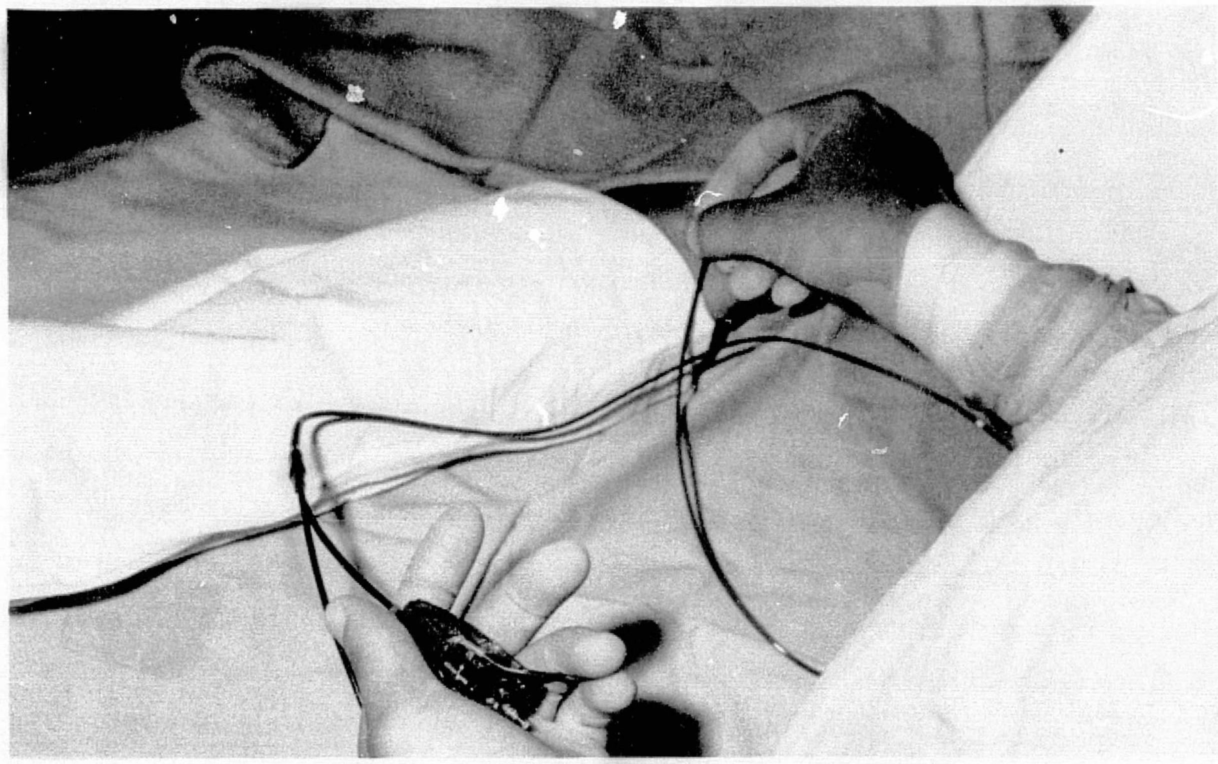


FIGURE 43 Technic for introduction of catheter detector into the circulation

The NASA technology potentially suitable in this situation consists of a miniature semi-conductor radiation detector (sensitive to both Gamma and Beta emission) and a preamplifier mounted on the tip of a conventional 125 cm cardiac catheter. Solid State Radiation, Inc. developed the detector while under contract to NASA. SwRI has added the matching circuitry and refined the technic into a useable package for medical applications. Matching circuitry as well as input and output connections are provided in an encapsulated module at the distal end of the catheter. Signal processing and output display are simplified by using a inexpensive commercially available radiation ratemeter (counter). Figures 44 and 45 a commercial display unit (Packard ratemeter) suitable as a readout device.

PRESENT STATUS

Although suitable NASA technology has been identified, and most desired by the problem originator, attempts by Stanford have been unsuccessful in transferring working hardware because of the following constraints:

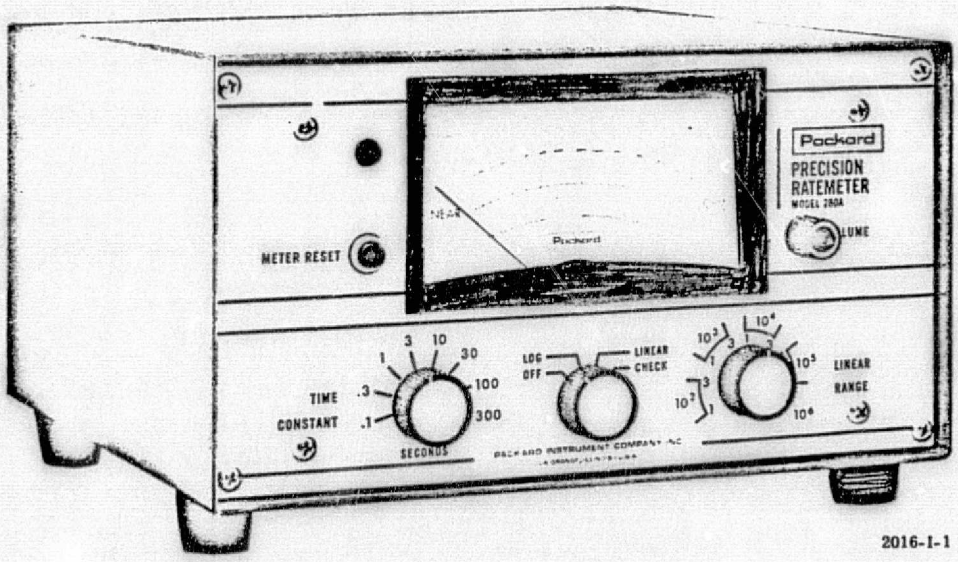
a) At the present time the device has not been man-rated for clinical application.

b) An operable prototype is not presently available.

c) The problem originator has no available funds with which to purchase or have the technology fabricated. He is requesting that NASA subsidize the hardware and in return he will provide clinical evaluation.

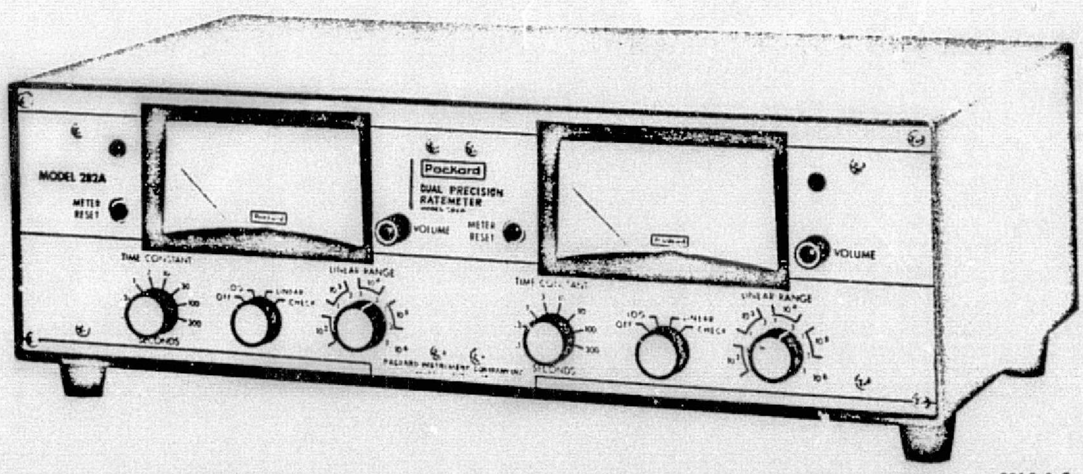
IMPACT

Successful application of the proposed catheter would add to the basic understanding of atherogensis, thrombogenesis and fibrinolysis (major pathologic and metabolic processes in man). Substantial progress could be expected in the clinical monitoring and management of coronary and other forms of atherosclerosis.



2016-I-1

FIGURE 44 *Model 280A Precision Ratemeter*



2016-I-2

FIGURE 45 *Model 282A Dual Precision Ratemeter*

PROBLEM NO. UOO-2

CATHETER SYSTEM FOR MEASURING TRANSLUMINAL RADIATION

Acquisition Date: May 15, 1972
Institution: University of Oregon Medical School
Department: Diagnostic Radiology
Investigator: Charles T. Dotter, M.D.

PROBLEM OBJECTIVE

To provide a catheter system for the detection and quantitation of radiation across the blood vessel wall in man.

BACKGROUND

Research investigators in the specialties of Nuclear Medicine and Diagnostic-therapeutic Radiology seek to exploit a new technic for the detection and measurement at points across the lumen of blood vessels of various types of ionizing radiation. Sources of radiation may be either external or internal. A catheter system capable of measuring radiation intensities at selected points within the body after administration of suitable isotope-labeled carriers would be useful in studying cancer localization, metabolic disturbances or activities at selected sites and specificicity. Such a system could also be used to determine dose levels during the treatment of cancer by externally or internally administered ionizing radiation.

TECHNOLOGY IDENTIFICATION

The technology thought to be suitable for potential solution of this medical problem has been traced to the NASA "Beta Radiation Detector" described by Laenger, Wilbur and McGraw of the Southwest Research Institute, Biomedical Applications Team. This catheter is primarily sensitive to Beta radiation, but under certain circumstances it can be employed to detect Gamma emission. With suitable modifications dependent upon the type of emission particle employed and dose levels used, this technology appears to be amenable to this application.

The technology and present status is similar to that of problem UOO-1 and is described in detail on pages of this report.

IMPACT

Transluminal radiation measurement would permit new means of medical diagnosis and management of a variety of disorders, and in addition, would allow:

a) determining depth dosages from external radiation sources,

b) monitoring of regional metabolic activities,

c) the study of the characteristics of various radioisotopes.

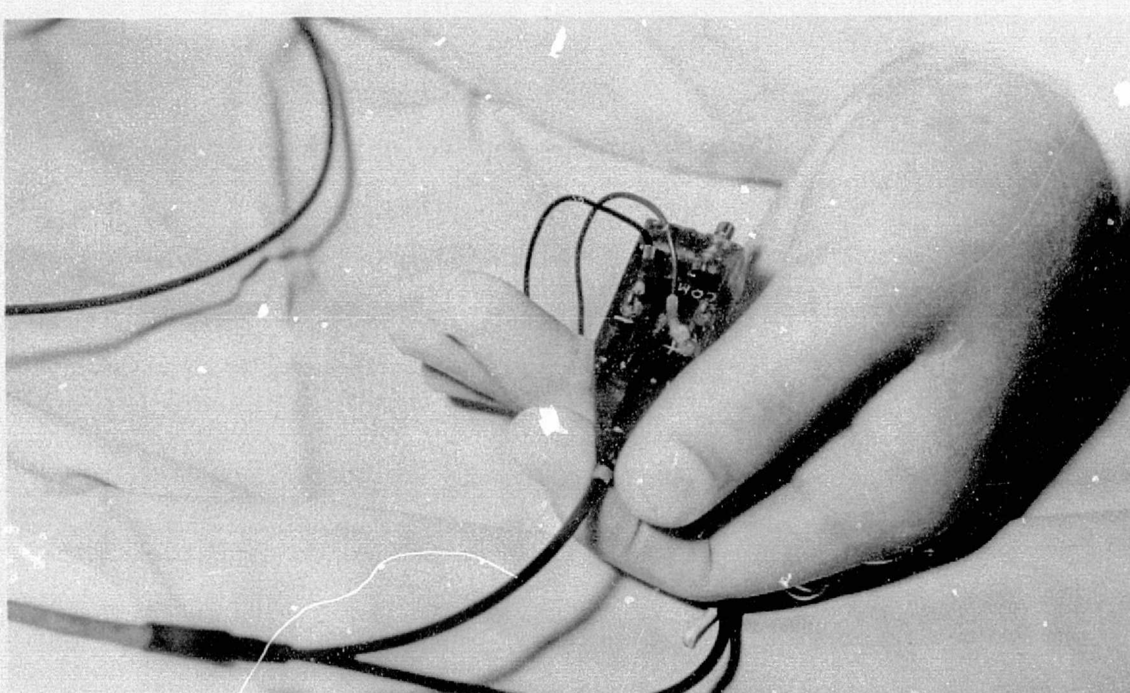


FIGURE 46 Catheter detector in clinical use during a cardiac catheterization procedure

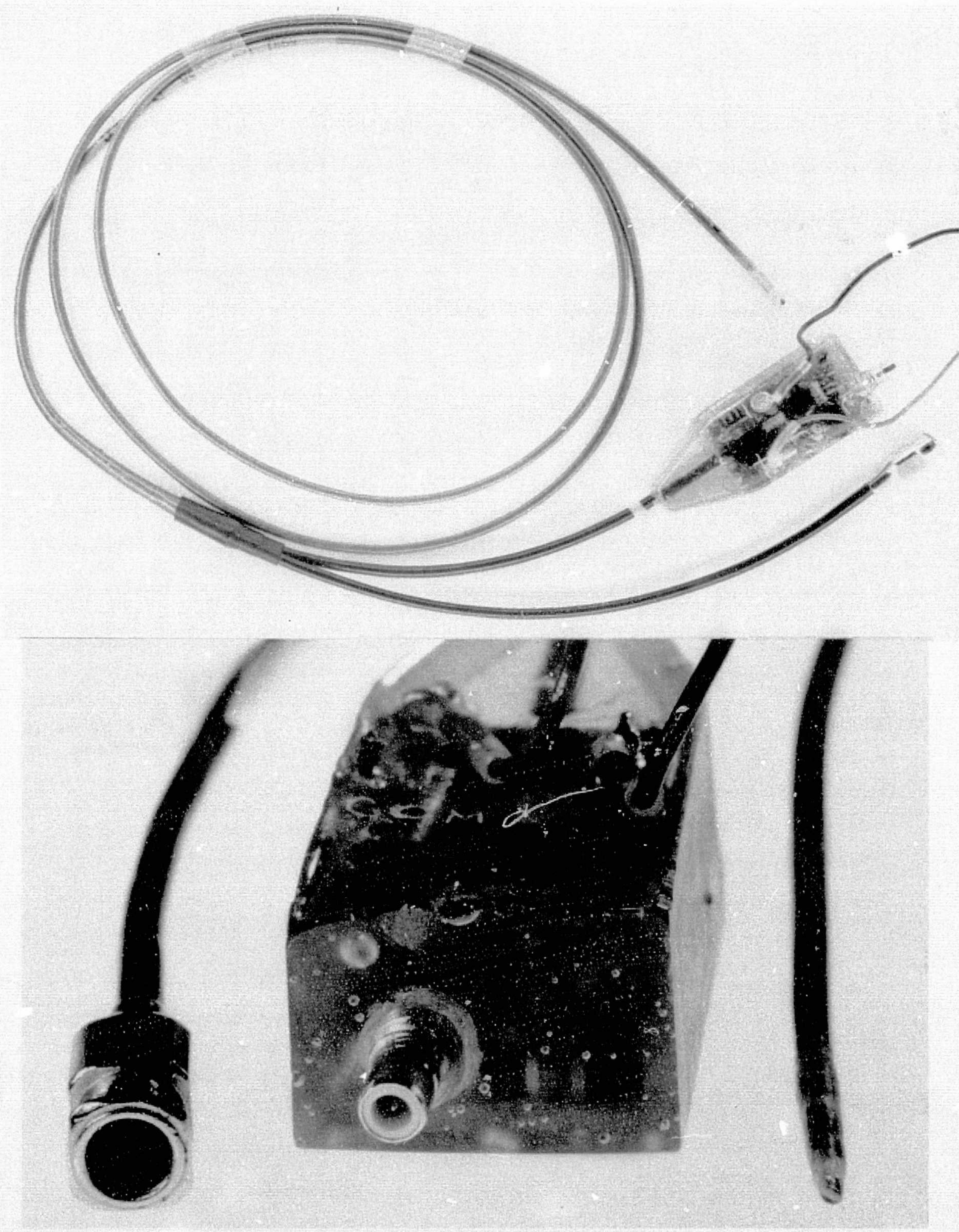


FIGURE 47 Beta radiation detector configured as a catheter with the detector located at the tip and preamplifier housing and lumen for flushing located at the other end

STANFORD UNIVERSITY SCHOOL OF MEDICINE

701 Welch Road, Suite 3303, Palo Alto, California 94304 • (415) 321-1200, Ext. 6283

CARDIOLOGY DIVISION
Biomedical Technology Transfer

October 2, 1972

Charles Dotter, M.D.
University of Oregon, School of Medicine
3181 S.W. Sam Jackson Pike Road
P rtland, Oregon

Dear Doctor Dotter:

We have discussed the purchase of a beta radiation catheter for you among ourselves and NASA Headquarters and there does not appear to be ample funds to provide the catheter at this time. We have also consulted the NASA-Ames Research Center and they pointed out that the catheter has not been man-rated.

Consequently, it is our recommendation that a possible solution may be for you to contact SwRI and attempt to acquire the catheter from them. If, through your experiments, it could achieve man-rating this could be of benefit to both you and NASA. The contact at SwRI is:

David F. Culclasure, Ph.D.
Biomedical Applications Program
NASA Biomedical Applications Team
Southwest Research Institute
8500 Culebra Road
P.O. Drawer 28510
San Antonio, Texas 78284
Telephone: 512/684-5111, extension 2695

I regret that due to a shortage of funds and internal policy changes Stanford cannot fund the catheter directly. As your areas of interest are of high impact, I am hopeful you will still be able to acquire the necessary technology.

I surely have enjoyed my visits with you and your colleagues.

Sincerely,

David S Cannom, MD

David S. Cannom, M.D.
Consultant

DSC:dh
cc: David F. Culclasure, Ph.D.

PROBLEM NO. VMC-1

RADIOTELEMETRY OF INTRACRANIAL PRESSURE

Acquisition Date:	March 8, 1972
Institution:	Santa Clara Valley Medical Center, San Jose, Calif.
Department:	Neurosurgery
Investigators:	G. Silverberg, M.D.; R.D. Hamilton, M.D.

PROBLEM OBJECTIVE

To provide a non-encumbering system for measuring intracranial pressure over periods of several days. The technic must not penetrate the dura.

BACKGROUND

The development of intracranial pressure (ICP) following head injury may take several days. Present clinical technics often indicate serious situations only after irreparable damage has occurred. Precise knowledge of increased pressure before such damage has been done should permit for superior medical management of the patient.

It is desirable to be able to monitor intracranial pressure by completely noninvasive means. However, no reliable noninvasive means is yet available. Lacking such, the investigating surgeons have decided to accept penetrating the skull for measurement, but the risks of infection or brain damage are greatly reduced if the dura remains intact. Thus, a pressure sensor is required to be mounted so as to sense the pressure across the dura lining the brain tissue. Zero stability of the system is of prime importance because the pressure levels of concern are quite low. Abnormal levels of intracranial pressure approximate 25 cm of water or more.

The investigators also have in mind using the system for research in situations where it is important that no encumbering wires or harness be employed. Hence, the use of a small telemeter transmitter is indicated. The telemeter should be sufficiently small to be implanted under the scalp, thus further reducing the risk of infection.

PROGRESS TO DATE:

Scientists at Ames have developed very small implantable telemeter transmitters, including a pressure telemeter with characteristics suited to this application. The unit, exclusive of transducer and battery, measures 3 x 2 x 1 cm (see photograph) The pressure transducer and battery are separately packaged so that best advantage can be taken of available spaces for implantation. With an RM 675 mercury cell measuring 1.15 cm in diameter x 0.5 cm high, the system has an operating life of 160 hours. This telemeter unit is judged suitable for this application though an even smaller unit would be desirable and is feasible for development. Ames Research Center has provided one telemeter unit for this project.

The preferred pressure transducer for use with the telemeter having low-zero-drift, is the Konigsberg Instruments, Inc. Model P-22HD with 5000 ohm semiconductor strain gauge bridge elements.

In order to mount the transducer in proper contact with the dura, a housing has been fabricated similar in design to that reported by H. Rudenberg, et al, "Improved Method for Measuring Intracranial Pressure," proceedings of the 24th ACEMB, Las Vegas, Nevada, 1971 (Rudenberg's application differed in that he penetrated the dura). The Stanford housing design is shown in Figure 1. . The threaded outer housing self-taps into a hole in the skull and can be screwed down until the desired degree of contact with the dura is obtained. The housing must be long enough to accommodate a range of skull thicknesses. Housings in two or more different lengths will alleviate the problem of wide variations in skull thickness. The housings have been constructed by a retired NASA-ARC instrument maker, Mr. James W. Fitzgerald.

Improved Method for Measuring Intracranial Pressure

23.6

HERMANN RUDENBERG, H.H. PEEL, H. O. WENDENBURG,
C. P. MCGRAW and G. T. TINDALL

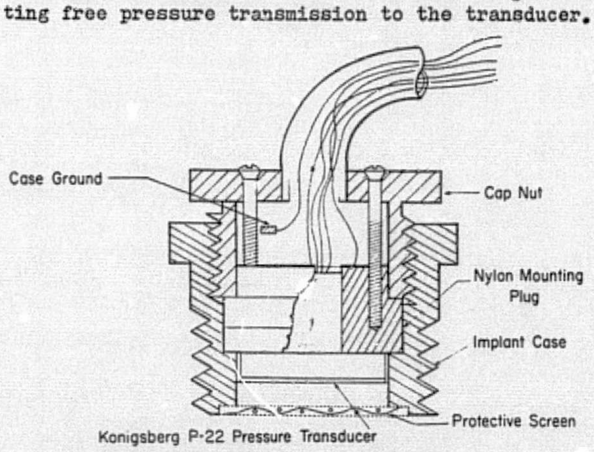
University of Texas Medical Branch
Department of Physiology
Galveston, Texas 77550

Biological Systems: Neurophysiology
A.M., Wednesday
3 November

It is important to obtain accurate indications of the extent of cerebral edema for predicting when therapeutic measures are needed to decrease the intracranial pressure (ICP). Improved methods are being developed for determining ICP with precision and reliability. The method described here represents an advance over previous techniques (1).

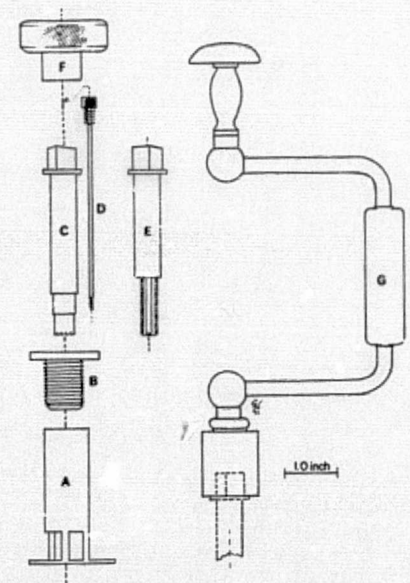
A Konigsberg Instruments P-22 Pressure transducer is used because it shows a significantly improved stability. Its excitation voltage, 12V DC, is obtained from the polygraph used for concurrent recordings of patient vital signs.

A stainless steel housing has been designed to hold and protect the pressure transducer while preventing direct contact between brain tissue and the transducer diaphragm. The housing is 1.2 cm long, 1.2 cm in diameter, and is threaded. One end is covered with a nylon screen to reduce the potential for herniation of brain tissue while permitting free pressure transmission to the transducer.



A flange on the housing is hexagonal to fit a wrench. Each transducer assembly is statically calibrated at 37° C against a manometer in the range 0-100 mm Hg. Transducers are used only after "drift" is less than 15 mm H_2O per month and instability of sensitivity is half this. Additional calibration occurs both before and after use.

In order for the housing to seal against the skull a threaded trephine opening is made with specially designed instruments. A cylindrical stand (A) is screwed to the skull temporarily. This stabilizes and guides first a hole saw (C) and then a matching tap (E). Windows around the base permit observation of the cutting process and removal of debris. The hole saw has a spring-loaded bone plug extractor (D). An adjustable collar (B) limits the depth of movement of the tap to that of the bone plug. After the stand is removed the dura mater is opened. Then the transducer assembly



(sterilized previously with ethylene-oxide at room temperature and pressure) is filled with sterile saline and screwed into the opening. The electrical cable is sutured to the scalp for a strain relief and most of the 50 cm long cable is coiled within the surgical dressing. An extension cable connects to the recorder.

Transducers have been implanted in 20 patients for 1 to 20 days (average 7) for 3280 hours of recording. Whenever the clinical care of a patient requires countermeasures against a sustained ICP in excess of 300 mm H_2O, patients received an intravenous infusion of 20% mannitol. This was given usually at the rate of 2 gm/kg body weight over a 2 hour period and promptly reduced the ICP with a minimum of pressure rebound. The need, sometimes, for repeated infusions became readily apparent from the continuous ICP recording and permitted titrating the ICP in these patients.

The use of reliable, continuous determinations of ICP has made it possible to obtain indications for necessary preventive therapy much earlier than may be obtained from standard clinical signs (2).

(1) Coe, Nelson, Rudenberg & Garza, J. Neurosurg. 27:370-375, 1967. Jacobson & Rothballer, J. Neurosurgery 26:603-608, 1967; ISA Biomedical Sciences Instrumentation 4:179-184, 1968. Hulme & Cooper, J. Neurol. Neurosurg. Psychiat. 29:154-156, 1966. de Rougemont, Barge & Benabid Genie Biologique et Medical 1:82-86, 1970.

(2) Support: USPHS grant DHEW-5-PO-1NS07377-04.

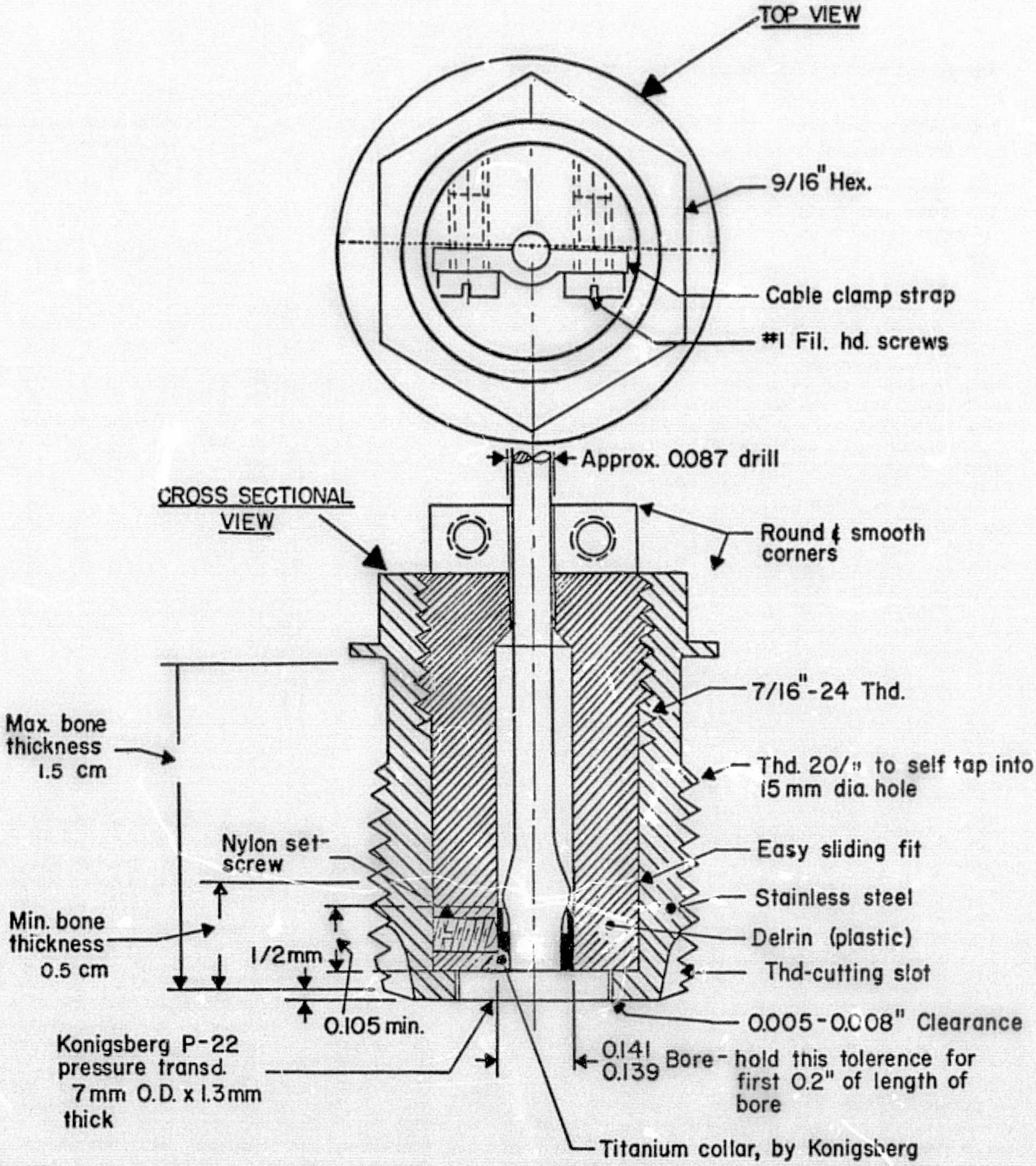
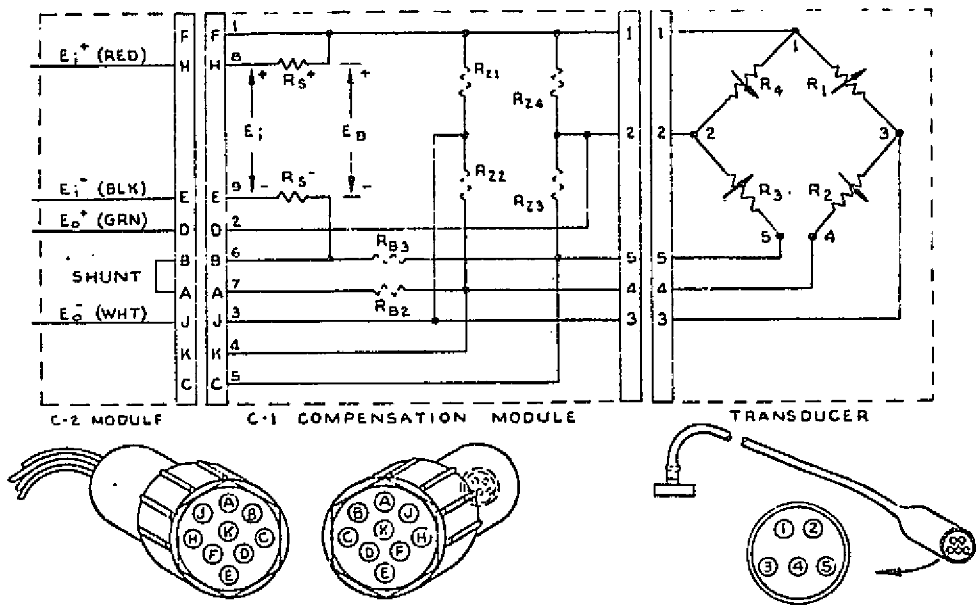


FIGURE 48 PRESSURE TRANSDUCER HOUSING
SCALE: 4 x FULL SCALE

JAMES A. WHITE 8/18/72



1. Strain gages R_1 & R_3 increase and R_2 & R_4 decrease resistance with applied pressure.
2. R_z1,2,3,4 are temperature zero shift compensation resistors. Customarily either R_z3 or R_z4 is used.
3. Either R_{b2} or R_{b3} is used for zero balance; R_{s+} and R_{s-} are used for voltage dropping resistors.
4. E_i is input voltage; E_b is bridge voltage; E_o is output voltage.

FIGURE 49 Schematic of the transducer and external control unit employed as part of recording system for intracranial pressure monitoring

In the first experiments, the transducer and housing will be hard wired to a recorder to establish transducer stability characteristics (Figure 51). Thereafter, the NASA-Ames telemeter will be used to excite and transmit the transducer output to a remote receiver in the clinical setting (Figure 52). The telemeter will not be implanted at first, but rather, will be taped to the head. Thus, it will be accessible for trouble-shooting or battery changing and, in case of telemetry difficulties, a hard-wire read-out can be substituted. As experience and confidence are gained, later installations can be implanted.

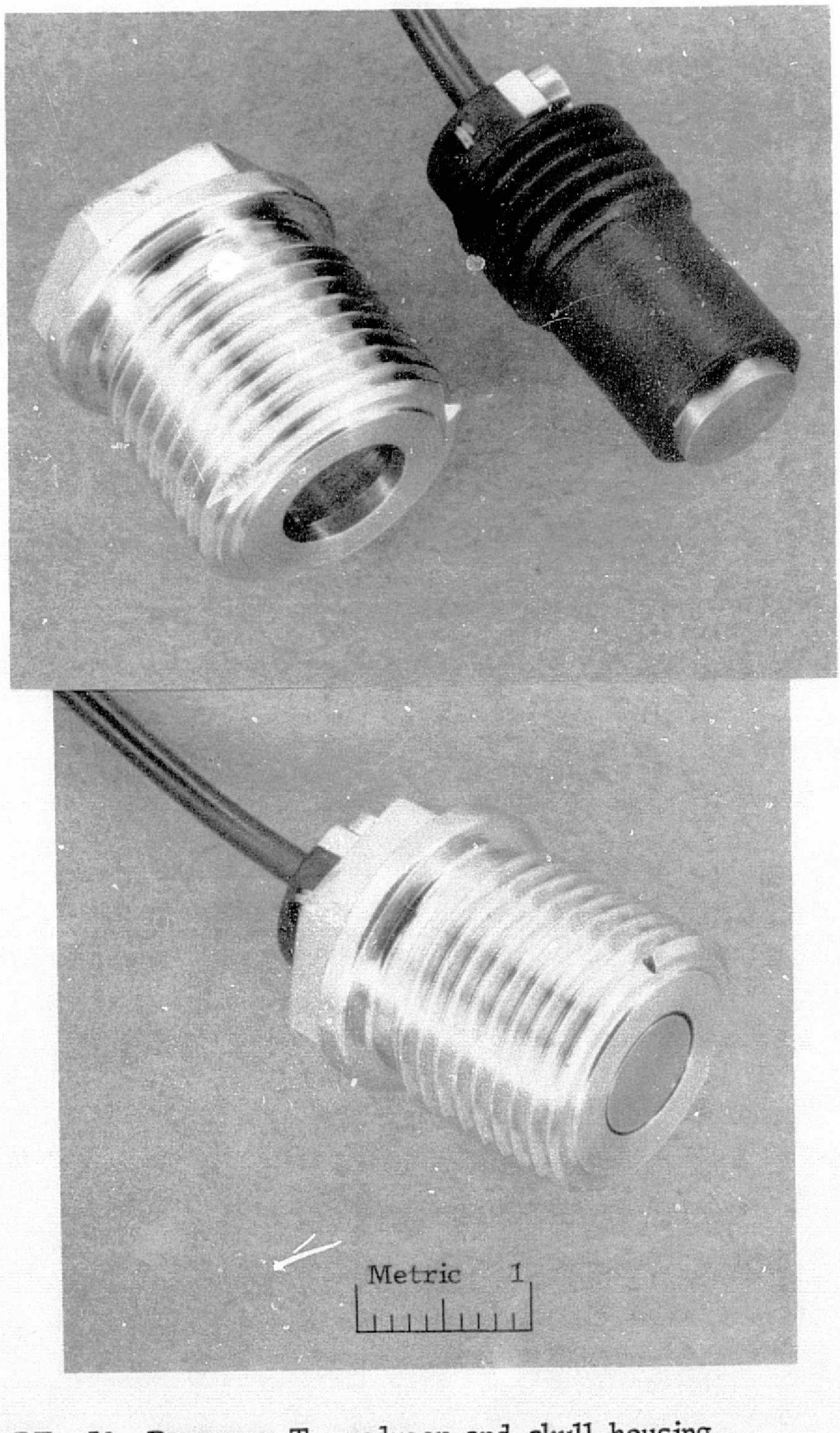


FIGURE 50 Pressure Transducer and skull housing

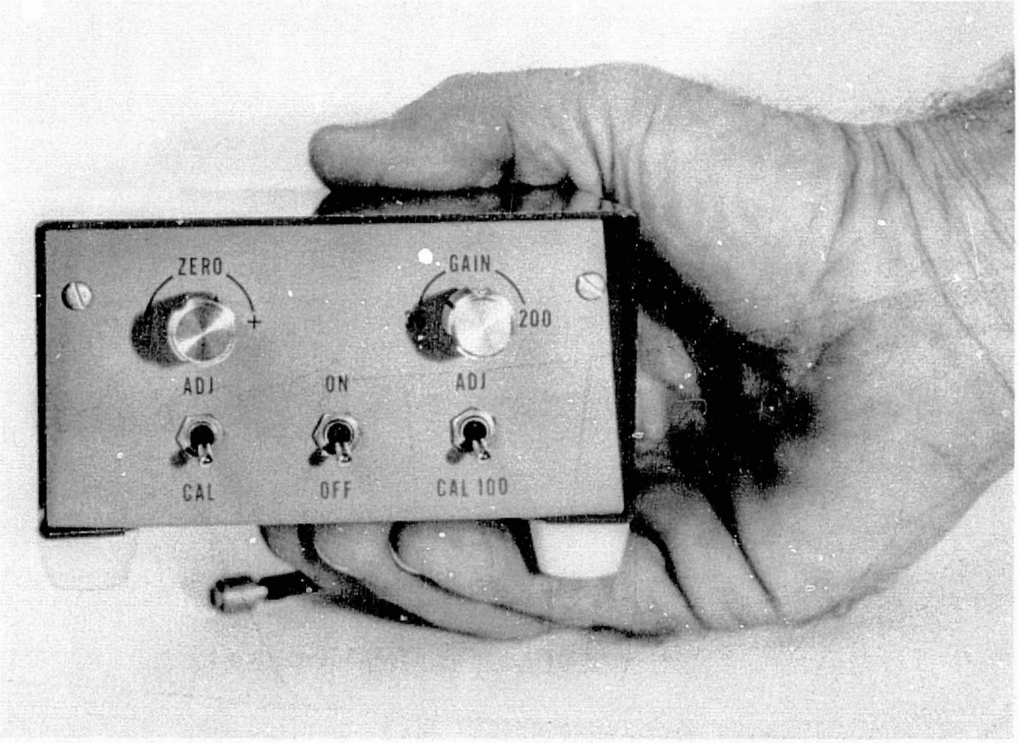


FIGURE 51 Pressure transducer electronic (hardware) control unit

TECHNOLOGY IDENTIFICATION:

The telemetry for this application is directly drawn from developments at ARC and is fully described in NASA Technology Utilization Report, SP-5094 entitled, "Implantable Biotelemetry Systems" by Thomas B. Fryer. A telemetry unit for the first experiment is being made available by Ames.

The scientific assistance of Messrs. Fryer, Rositano (ARC) and J. W. Fitzgerald (ARC, retired) is gratefully acknowledged.

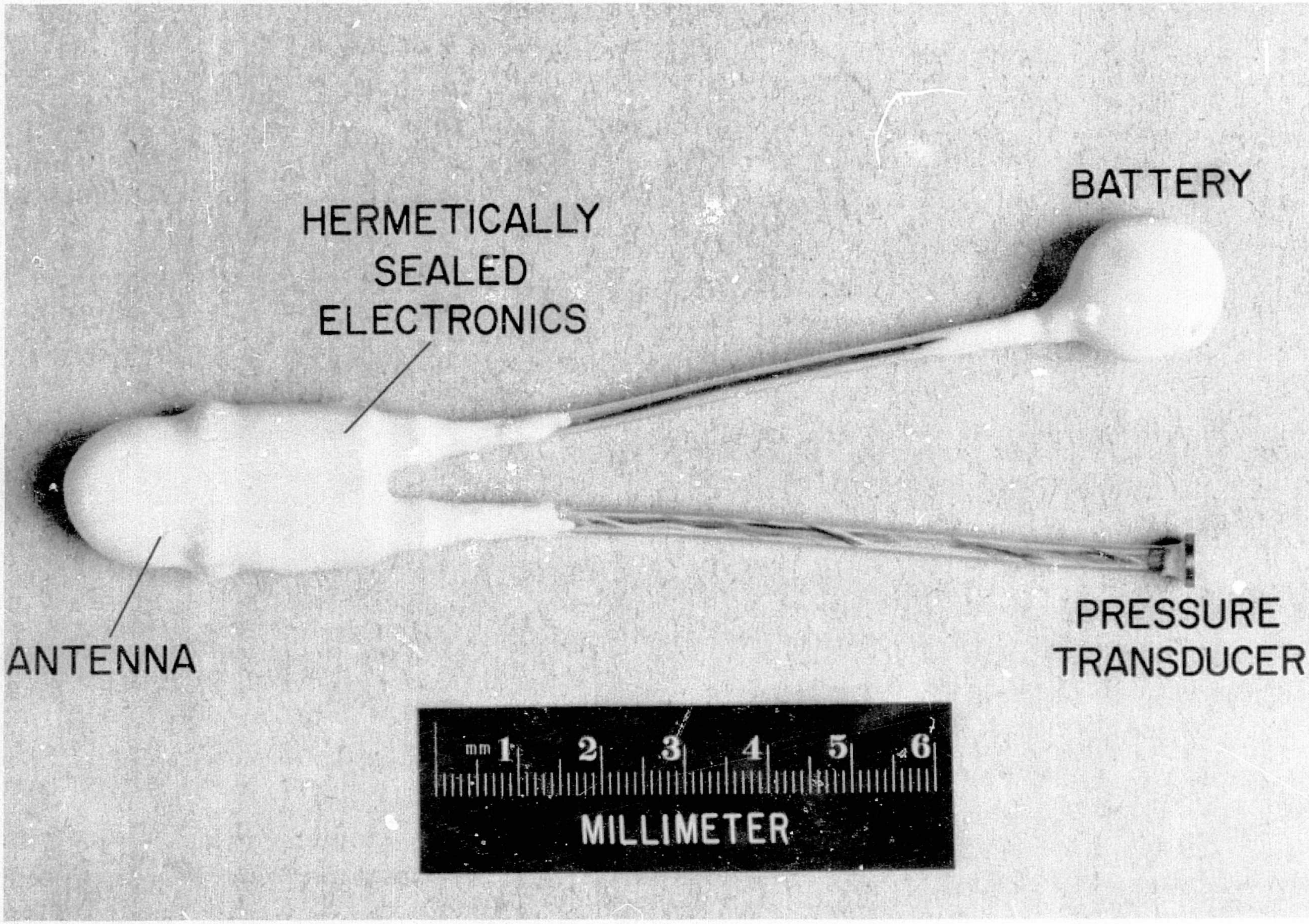


FIGURE 52 Photograph of implantable telemetry system used with the cranial housing. Transmitter system is implanted subcutaneously for cosmetic and sterility purposes.

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
AMES RESEARCH CENTER, MOFFETT FIELD, CALIFORNIA

ADDITIONAL ACTIVITIES

ADDITIONAL ACTIVITIES

NASA-Ames Research Center Symposium

Members of the Stanford Biomedical Technology Transfer team attended a scientific symposium entitled, "Technology and the Neurologically Handicapped" on October 9, 1971. This meeting was co-sponsored by NASA and the United Cerebral Palsy Research Foundation and convened at NASA-Ames Research Center.

"Exploring Aerospace Technology for Solution of Community Problems"

Members of the Stanford BTT participated in the above entitled conference on October 28, 1971. This conference served to inform potential manufacturers, entrepreneurs, and users of the existence of aerospace technology which could be applied to community problems and how such technology can be readily identified. Sponsors were NASA-Ames Research Center and seven local planning groups from public and private sectors. Dr. Harrison, Stanford Program Director, was an invited speaker, representing the Stanford University Biomedical Technology team. In addition, six representatives from Stanford provided information to attendees at an information exhibit.

Annual Meeting of NASA Regional Dissemination Center Directors

Mr. Harry Miller, Stanford Deputy Director, was a speaker at the NASA-Ames Research Center on January 17, 1972 to address an annual program review of NASA with directors of the six Regional Dissemination Centers. Topic of the presentation involved Stanford's program, types of problems and assistance required from documentary searches.

Medical World News Conference

Dr. Donald C. Harrison, Stanford BTT Director, participated in a panel discussion on March 27, 1972 at the Fourth National Conference on Electronics in Medicine held in Chicago, Illinois. This panel was organized by Mr. James T. Richards, Jr. on request of the Medical World News publication group. Other panel members were Drs. Wooten and Culclasure representing other NASA Biomedical Application Teams. The program concerned experiences in transferring aerospace technology to the health sector.

Stanford-NASA Ames Conference on the Biomedical Technology Transfer Process

On May 11, 1972, medical research investigators from the Cardiovascular Research Institute at the University of California School of Medicine attended a tour and programmatic sessions regarding NASA technology applied to the Life Sciences. A morning tour and review of six major investigative areas was provided by NASA-Ames Research Center and hosted by Mr. Melvin Sadoff of the Life Sciences Directorate. Messrs. Buck, Miller and Dr. Rider arranged the conference, discussed the Stanford Program and provided a tour of the clinical facilities at Stanford in the afternoon.

Second Urban Technology Conference

Mr. Manley J. Hood, engineering consultant of the Stanford Biomedical Technology Transfer team was an invited member of the working group on Health and Medical Care Delivery Systems; part of a scientific session of the Second Urban Technology Conference and Exhibit. This conference was held in San Francisco on July 24 through 26, 1972. The working group focused on problems of expediting emergency care to the critically ill. Two-thousand eight-hundred municipal, county, federal and private business representatives were in attendance.

Meeting with San Diego Chamber of Commerce

Health care is the second largest single "industry" in San Diego, California and is being promoted by the city through the aegis of the Health Sciences Council of San Diego.

Mr. Harry Miller, Deputy Director, met with members of the San Diego Chamber of Commerce on August 28, 1972 to discuss NASA Application Team Programs (biomedical and industrial). This conference explored the various programs within NASA that might benefit the San Diego metropolitan community. Representatives were in attendance from the Chamber of Commerce, Health Sciences Council, local chapter of the American College of Surgeons, and the San Diego Biomedical Symposium.

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PROGRAM ANALYSIS

PROGRAM ANALYSIS

Review of Initial Year's Experience

The participation of Stanford University Cardiology Division in the NASA Technology Utilization Program as a Biomedical Applications Team is presently concluding the first 15-month contract period. During the initial phase, Stanford established a professional team consisting of five physicians, five NASA-affiliated engineers and a management staff. The group was designated the Cardiology Biomedical Technology Transfer Team and has directed major emphasis on applying aerospace technology to the solution of problems in cardiovascular medicine.

The Stanford BTT team has corresponded with 28 and visited 22 major West Coast medical institutions to confer with them about participation in the NASA Technology Utilization Program. It was apparent from these visitations that virtually none of the medical centers were aware of a NASA Technology Utilization Program nor the availability of NASA developments to the medical community through the transfer process. As a result of visits, informational mailings and professional efforts, 22 investigators' problem statements have been received over the past 15 months. Identification of pertinent aerospace research literature (documents), assistance from NASA field center personnel and indefinite loan of prototype hardware developed by NASA have substantially aided many investigators. To date 14 problems have been completely resolved (transferred) and with additional effort, several others will shortly achieve resolution.

Analysis of the Program

During the initial contract period, several inherent shortcomings have been noted which deserve comment. Although contacts were established with investigators in a variety of medical centers and community hospitals, these contacts remained quite superficial primarily because only information exchanged hands. Information is derived from medical-engineering consultation, computer search or expertise from various NASA field centers. In most cases, application of technological information and, in fact, hardware loan is achieved only with engineering assistance. It is customary for the average investigator to query the program for engineering assistance in order to apply published NASA research results or developed hardware properly. Clearly in medicine, new equipment, methods and innovative concepts sought from the technology transfer process necessitate engineering assistance. Adequate mechanisms to provide this assistance have not been delineated during the period of this contract.

From the point of view of the investigator, little investment of his time or effort was required with a resultant lack of serious interest for pursuing aggressively a specific project to completion. Moreover, there is no selection in this process for accommodating sophisticated investigators who have the expertise and facilities to properly document a new application as opposed to individual practitioners who, although badly needing assistance from this program, have little time or resources available.

During a substantial portion of this contract period, which is understandably in a development phase, a great deal of time of the Stanford team had been spent in program orientation and presentation, travel and informational handling. Even by limiting the medical specialty primarily selected to numbers of cardiovascular problems, it is evident that the program approach resulted in spreading resources too thinly and an inability to focus intensively on several specific and more meaningful projects.

Major instances in which substantive transfer of technology into biomedicine have occurred when there has been direct participation of NASA Field Center personnel. Such was the case with the Stanford contract and cooperative efforts of NASA-Ames Research Center. It is clear that the most effective and desirable form of transfer takes place when field center personnel can bring their scientific expertise and resources to bear on a particular problem.

APPENDICES

APPENDIX A

TABULATION OF FIGURES

Appendix A (continued)

APPENDIX B

TABULATION OF PROBLEMS