NASA Contractor Report 159106

NASA-CR-159106
19820007896

APPLICATIONS OF AEROSPACE TECHNOLOGY IN BIOLOGY AND MEDICINE

H. C. Beall, R. L. Beadles, J. N. Brown, Jr.,
W. H. Clingman, M. W. Courtney, D. J. Rouse,
and R. W. Scearce, Jr.

RESEARCH TRIANGLE INSTITUTE
Research Triangle Park, North Carolina 27709

Contract NAS1-14708
July 1979

National Aeronautics and
Space Administration

Langley Research Center
Hampton, Virginia 23665

RTI/1411/00-05F

NASA BIOMEDICAL APPLICATIONS TEAM PROGRAM

Applications of Aerospace Technology in Biology and Medicine

by

Dr. H. C. Beall
Mr. R. L. Beadles
Dr. J. N. Brown, Jr.
Dr. W. H. Clingman
Ms. M. W. Courtney
Ms. D. J. Rouse
Dr. R. W. Scearce, Jr.

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

January 1979

NASA Contract No. NAS1-14708

Technical Monitor

Mr. John Samos
Ms. Sheila Ann T. Long (Alternate)

Technology Utilization and Applications
Programs Office
Langley Research Center
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
Hampton, Virginia 23665

PREFACE

This report covers the activities of the Research Triangle Institute's Biomedical Applications Team program for the period 1 January 1978 through 31 December 1978. The work was performed in the Center for Technology Applications under the technical direction of Dr. J. N. Brown, Jr., Director. Dr. Brown was also the Biomedical Applications Team Director. Assistance in development of marketing strategy was provided by Dr. W. H. Clingman of William H. Clingman and Company, Inc., a marketing and management consulting firm. Other participants in the program were Dr. H. C. Beall, Ms. D. J. Rouse, Dr. R. W. Scearce, Mr. R. L. Beadles, Mr. P. N. Kizakevich, and Ms. M. W. Courtney.

The work reported herein was supported by the National Aeronautics and Space Administration--Contract No. NASL-14708. Mr. John Samos, Head, Technology Utilization and Applications Programs Office, Langley Research Center, was the Technical Monitor. Ms. Sheila Ann T. Long, Technology Utilization Engineer--Biomedical Programs, was the alternate Technical Monitor.

The authors gratefully acknowledge the contributions of many individuals to the success of the RTI Biomedical Applications Team program. The time and effort contributed by managers, engineers, and scientists throughout the National Aeronautics and Space Administration and that of medical researchers and clinicians were absolutely essential to program success. Industry managers and technical staff have always been cooperative and open in their participation. Dr. W. H. Clingman has continued to increase the team's understanding of medical manufacturing and marketing practices and how these practices impact medical technology transfer. The continued contribution to the team's efforts by Dr. F. Thomas Wooten, Executive Assistant to the President at RTI, is appreciated. Finally, Mr. John Samos and Ms. Sheila Long have contributed significantly to the success of the program, and, as technical monitors, they have always been supportive.

TABLE OF CONTENTS

TABLE OF CONTENTS (Con.)

INDEX OF PROBLEMS

INDEX OF PROBLEMS (Con.)

ABSTRACT

The objective of the Research Triangle Institute (RTI) Biomedical Applications Team is to achieve widespread utilization of National Aeronautics and Space Administration (NASA) technology in medicine. This objective is best approached by stimulating the introduction of new or improved commercially available medical products incorporating aerospace technology.

A bipolar donor-recipient model of medical technology transfer is presented to provide a basis for the team's methodology. That methodology is designed to: (1) identify medical problems and NASA technology that, in combination, constitute opportunities for successful medical products, (2) obtain the early participation of industry in the transfer process, and (3) obtain acceptance by the medical community of new medical products based on NASA technology.

One commercial technology transfer and six institutional technology transfers were completed in 1978. A low-cost TV display device developed by NASA was transferred during the reporting period to a manufacturer of medical electronics.

During 1978 the RTI team performed an informal study of the NASA Tech Brief publications to evaluate the potential of Tech Briefs as a source of ideas for marketable products. In addition, the team conducted a market survey on the NASA Black Bag to determine the most acceptable configuration as well as the potential market.

The team has identified 17 new medical problems or needs during the reporting period. There are currently 27 active transfer cases.

For the convenience of the reader, the names and addresses of the sources of certain commercial products are included in this report. This listing does not constitute an endorsement by either the National Aeronautics and Space Administration or the Research Triangle Institute.

1.0 INTRODUCTION

The preamble to the Space Act of 1958, which created the National Aeronautics and Space Administration, says: "It is the policy of the United States that activities in space should be devoted to peaceful purposes for the benefit of all mankind."[1] Further, this Act of Congress charged NASA with providing "for the widest practical and appropriate dissemination of information concerning its activity and the results thereof." The NASA Technology Utilization Program was initiated in 1962 to assist in satisfying this Congressional obligation.

Since 1962, NASA has been a leader and an innovator in the establishment, operation, and evaluation of technology transfer programs. Through its Tech Brief, Special Publications, Technology Survey, and Industrial Applications Center programs, NASA has successfully transferred the results of aerospace research to the non-space-related sectors of society.[2]

In 1966, NASA introduced a new approach to technology transfer that involved the activities of multidisciplinary "applications teams." The objective of these applications teams--called Biomedical Applications Teams--was to effect the transfer of NASA technology to applications in medical research and clinical medicine. The general approach of the Biomedical Applications Teams was: (1) to identify medical problems through direct interactions with clinicians and medical researchers, (2) to identify potentially applicable NASA technology by a variety of mechanisms, and (3) to take necessary and appropriate action to effect actual utilization of NASA technology in solving technology-related medical problems.

Since the establishment of the applications team program in 1966, NASA has applied the applications team concept in the transfer of technology to applications in: (1) environmental science, (2) housing construction, (3) transportation, and (4) manufacturing processes.

At present, Biomedical Applications Teams are sponsored by NASA at the following institutions:

Research Triangle Institute
Post Office Box 12194
Research Triangle Park, North Carolina 27709

Stanford University School of Medicine
701 Welch Road
Palo Alto, California 94304

University of Wisconsin
1500 Johnson Drive
Madison, Wisconsin 54706

This report presents the activities and accomplishments of the Biomedical Applications Team located at the Research Triangle Institute for the period 1 January 1978 through 31 December 1978.

1.1 Biomedical Applications Team Objectives

The primary objective of the RTI Biomedical Applications Team is to assist NASA in achieving widespread utilization of aerospace technology in the medical field. Widespread utilization implies that, by the application of NASA technology in medicine, a significant sector of the medical field and of those seeking medical services realize some benefit. Implicit in this program objective is that widespread utilization be realized in a relatively rapid manner.

The successful transfer of NASA technology to applications in the medical field via the Biomedical Applications Team program has been demonstrated.[2-5] NASA technology has been successfully applied to applications both in clinical medicine and in medical research. These applications have resulted in advances in medical research, improved clinical diagnosis and treatment, and the introduction of beneficial new or improved medical products.

While advances in medical research ultimately have widespread positive impact on the delivery of health care in the United States, medical research is a slow, complex, and expensive process. On the other hand, much can be accomplished in a relatively short time by solving technology-related problems in clinical medicine. Applications of technology in clinical medicine usually involve the introduction of a new or improved commercially available medical product.

Thus, the approach of the NASA Biomedical Applications Teams in obtaining widespread utilization of NASA technology is to direct its

efforts primarily to solving problems that involve the introduction of a new or improved medical product. The teams take every opportunity to apply NASA technology in medical research.

This emphasis on achieving widespread utilization by commercializing NASA technology is reflected in the activities and methodology of the Biomedical Applications Team program. The team methodology is built around the following four activities: (1) identification of medical problems and needs and potentially applicable NASA technologies that together constitute a new or improved medical product, (2) screening of opportunities to find those that represent potentially successful commercial products, (3) development of commercialization strategies that take into account any necessary adaptation of NASA technology, evaluations and clinical trials, FDA regulations, manufacturer's marketing systems, and required funding, and (4) implementation and monitoring of commercialization strategies. These tasks are discussed in more detail in section 2.0, Technical Approach.

1.2 Biomedical Applications Team

The RTI Biomedical Applications Team is a multidisciplinary team of engineers and scientists. Their educational backgrounds are physiology, biophysics, engineering, biochemistry, and biomedical engineering; their experience includes basic and applied research, development, and marketing. The individuals who participated in the Biomedical Applications Team program during the reporting period are:

Name	Professional Background	Responsibility
Dr. J. N. Brown, Jr.	Electrical Engineer	Biomedical Applications Team Director
Mr. R. L. Beadles	Electrical Engineer	Internal Technical Consultant
Dr. H. C. Beall	Biophysics, Physiology	Solution Specialist
Dr. W. H. Clingman*	Chemical Engineer	Marketing Consultant
Ms. M. W. Courtney	Resource Specialist	Solution Assistant
Mr. P. N. Kizakevich	Biomedical Engineer	Internal Technical Consultant
Ms. D. J. Rouse	Biochemist, Physiology	Solution Specialist
Dr. R. W. Scearce,Jr.	Biomedical Engineer	Solution Specialist

*Dr. Clingman is a marketing and management consultant to RTI.

1.3 Participating Institutions

The Biomedical Applications Team may be viewed as one component in a technology transfer network that involves individuals at NASA headquarters; NASA field centers; medical institutions; manufacturing and marketing firms; and other individuals, groups, and organizations concerned with medical technology transfer.

At present, medical researchers and clinicians from 27 medical institutions participate in the RTI Biomedical Applications Team program. Medical researchers and clinicians participate in the program by: (1) identifying medical problems and needs appropriate for investigation by the Biomedical Applications Team, (2) serving as a knowledge base on medical problems and needs, markets, and potential applications of NASA technology, and (3) receiving NASA technology to be applied in their medical research programs or to be evaluated within their clinical practice. Figure 1 presents the geographical locations of participating medical institutions and NASA field centers. Participating institutions are listed in table 1.

1.4 Conference Attendance

Biomedical Applications Team members attend and participate in conferences and workshops in order to be familiar with the state of the art of medical technology and to discuss new product opportunities with medical industry representatives. Conference attendance, presentations, and publications are listed in Appendix C.

1.5 Report Summary

The Biomedical Applications Team's technical approach to technology transfer in medicine is described in section 2.0. Emphasis on commercialization of NASA technology is evident in the overall structure of the team's methodology. That is, the team's activities are segmented into four major phases leading logically from the identification of opportunities for commercialization to the implementation and monitoring of commercialization strategy. Within each of these four phases, program flexibility allows for technology transfer activities related to medical research and leading to institutional technology transfer.

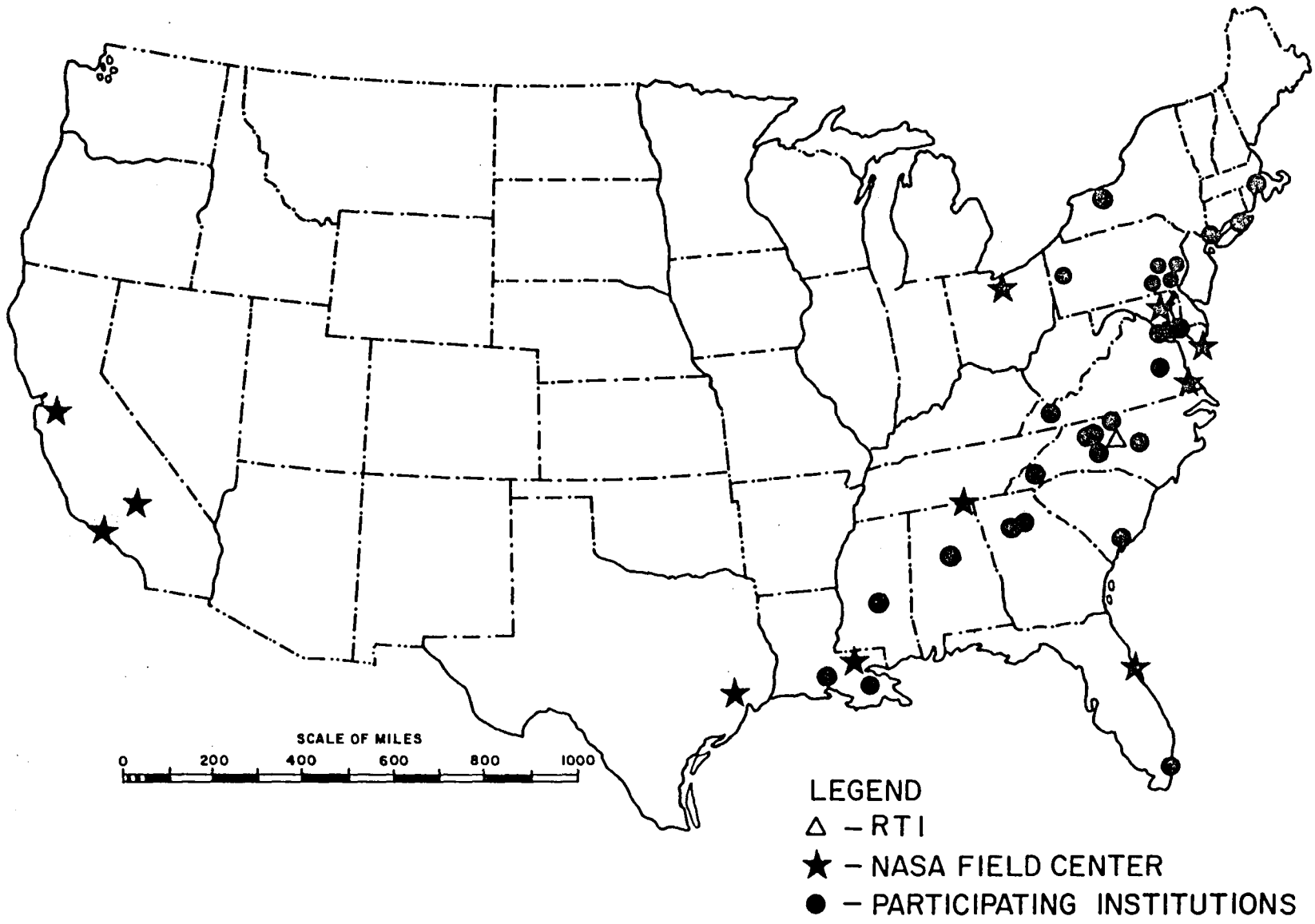


Figure 1. Biomedical Technology Transfer Network

TABLE 1. PARTICIPATING MEDICAL INSTITUTIONS

Bowman Gray School of Medicine, Wake Forest University, Winston-Salem, NC

Carnegie-Mellon Institute of Research, Pittsburgh, PA

Dorothea Dix Hospital, Raleigh, NC

Duke University Medical Center(including VA Hospital), Durham, NC

Eye Research Institute of Retina Foundation, Boston, MA

Guilford County Communications Center for the Deaf, Greensboro, NC

Jefferson Medical College, Philadelpha, PA

Johns Hopkins University Medical School, Baltimore, MD

Louisiana State University School of Dentistry, Baton Rouge, LA

Medical College of Virginia, Richmond, VA

Medical University of South Carolina, Charleston, SC

National Cancer Institute, Bethesda, MD

National Heart, Lung, and Blood Institute, Bethesda, MD

National Institute of Dental Research, Bethesda, MD

National Institute of Neurological, Communicative Disease and Stroke, Bethesda, MD

National Institute on Aging, Bethesda, MD

Rochester General Hospital, Rochester, NY

The Children's Hospital Medical Center, Boston, MA

The University of Alabama Department of Rehabilitation, Birmingham, AL

Tulane University School of Medicine, New Orleans, LA

University of Miami School of Medicine (including VA Hospital) Miami, FL

University of Mississippi Medical Center, Jackson, MS

University of North Carolina School of Medicine, Chapel Hill, NC

University of North Carolina Dental School and Research Center, Chapel Hill, NC

Veterans Administration Hospital, Atlanta, GA

Veterans Administration Hospital, Oteen, NC

Woodrow Wilson Rehabilitation Center, Fishersville, VA

Technology transfers brought to fruition during the reporting period are documented in sections 3.1 and 4.0. One commercial technology transfer and six institutional technology transfers are discussed. This documentation describes the technology transferred, the situational context to which the technology was transferred, and the role of the Biomedical Applications Team as a transfer agent.

The team's problem solving and transfer activities in twenty-six active transfer cases are summarized in section 5.0. Projects inactivated during the reporting period are discussed in section 6.0. Two special projects included in the report are The NASA Black Bag: An Analysis of the Commercialization Potential in section 3.2 and The Tech Brief Study in section 7.0. Problem statements describing medical problems and needs identified by the team during the reporting period are presented in Appendix B.

Section 8.0 is a statement of conclusions and recommendations. Emphasis in this statement is on what has been learned concerning medical technology transfer and how these lessons may be applied in increasing the productivity of the NASA Biomedical Applications Team program.

1.6 Definition of Terms

Biomedical Applications Team -- A multidisciplinary group of engineers and scientists engaged in assisting NASA in achieving widespread utilization of aerospace technology in the medical field.

Commercial opportunity -- The combination of a significant medical need or problem and appropriate, relevant NASA technology that constitutes the basis for a potentially successful new or improved commercial medical product.

Commercial technology transfer -- The successful development and marketing of a new or improved medical product that incorporates NASA technology.

Computer information search -- A computerized search of NASA's aerospace information bank at one of six Industrial Applications Centers (IAC's). This information bank consists of more than 1 million documents that have been indexed and abstracted in the Scientific and Technical Aerospace Reports (STAR's) and the International Aerospace Abstracts (IAA's).

Donor -- Organization or individual that originally developed technology that is transferred. Within the context of the Biomedical Applications Team, NASA is the donor.

Institutional technology transfer -- The application of NASA technology to solve a significant medical problem that does not result in a new or improved medical product.

Medical problem (or need) -- A specific and definable technology-related medical problem or need that cannot be satisfied by commercially available equipment or by the information available to the problem originator through routine information channels.

Participating institution -- A medically oriented educational institution, hospital, medical center, or government agency that works with the Biomedical Applications Team in identifying medical problems and needs and in evaluating NASA technology that represents solutions to those problems and needs.

Potential transfer -- The identification of technology that has the possibility of solving a particular medical problem or meets a need and the identification of strategy for achieving commercialization or implementation.

Problem originator - A clinician or medical researcher actively involved in reaching a specific medical objective and faced with a specific technology-related problem or need.

Problem statement -- A concise written description of a medical problem or need that contains sufficient details to allow a computer search to be performed and sufficient information to enable NASA engineers and scientists to consider possible solutions.

Recipient -- The clinical medical sector or medical researcher that uses or applies the technology transferred.

RTOP (Research and Technology Objectives and Plans) -- A proposal submitted by a NASA field center to NASA headquarters for funding of research and development projects and specifically for funding to adapt NASA technology for application in medicine.

Technology -- All of the skills, techniques, and understanding that constitute a specific technology. Technology includes, but is not limited to, hardware.

Technology transfer -- Instances in which a specific technology moves from one situational context--the one for which it was developed--to another. As a result, changes are seen in either the technology or the situation to which it is moved or both.

Transfer agent (or linker) -- The individual or organization that plans, stimulates, and facilitates technology. Within this context, the transfer agent or linker is the Biomedical Applications Team.

2.0 TECHNICAL APPROACH

The objectives, operations, and methodology of the RTI Biomedical Applications Team are presented in this section. The conceptual framework for medical technology transfer described in section 2.1 facilitates the description of and supplies a rationale for the Biomedical Applications Team methodology.

2.1 Conceptual Framework for Medical Technology Transfer

A conceptual framework for medical technology transfer is presented diagrammatically in figure 2.[6] The framework is basically a bipolar donor-recipient model. The role of the donor, in this case NASA, is to reveal, disseminate, and promote technology. The role of the recipient, the medical community, is to seek out, evaluate, and utilize technology.

As explained in the introduction, the primary thrust of the Biomedical Applications Team program is to transfer technology by the introduction of new and improved medical products. Thus, a manufacturer of those products is included in figure 2. Medical technology transfer normally involves the identification of a medical problem or need within the medical community. In response, the National Aeronautics and Space Administration recognizes the relevance of specific aerospace technology and makes that technology available. The manufacturer designs, develops, evaluates, and markets a new or improved medical product that incorporates aerospace technology and represents a solution to the medical problem or need.

The purpose of the transfer agent* in this framework is to plan, stimulate, and facilitate such technology transfer. This is the role of the Biomedical Applications Team.

Research into the process of medical technology transfer at the Syracuse University Research Center has concluded that the donor, recipient, and manufacturer are frequently at cross purposes.[7] The recipient is primarily concerned with solving a problem. The manufacturer by necessity is concerned with introducing a commercially viable product. The donor obtains satisfaction as reward for involvement in the transfer

---

*The term "linker" is frequently used in this context.

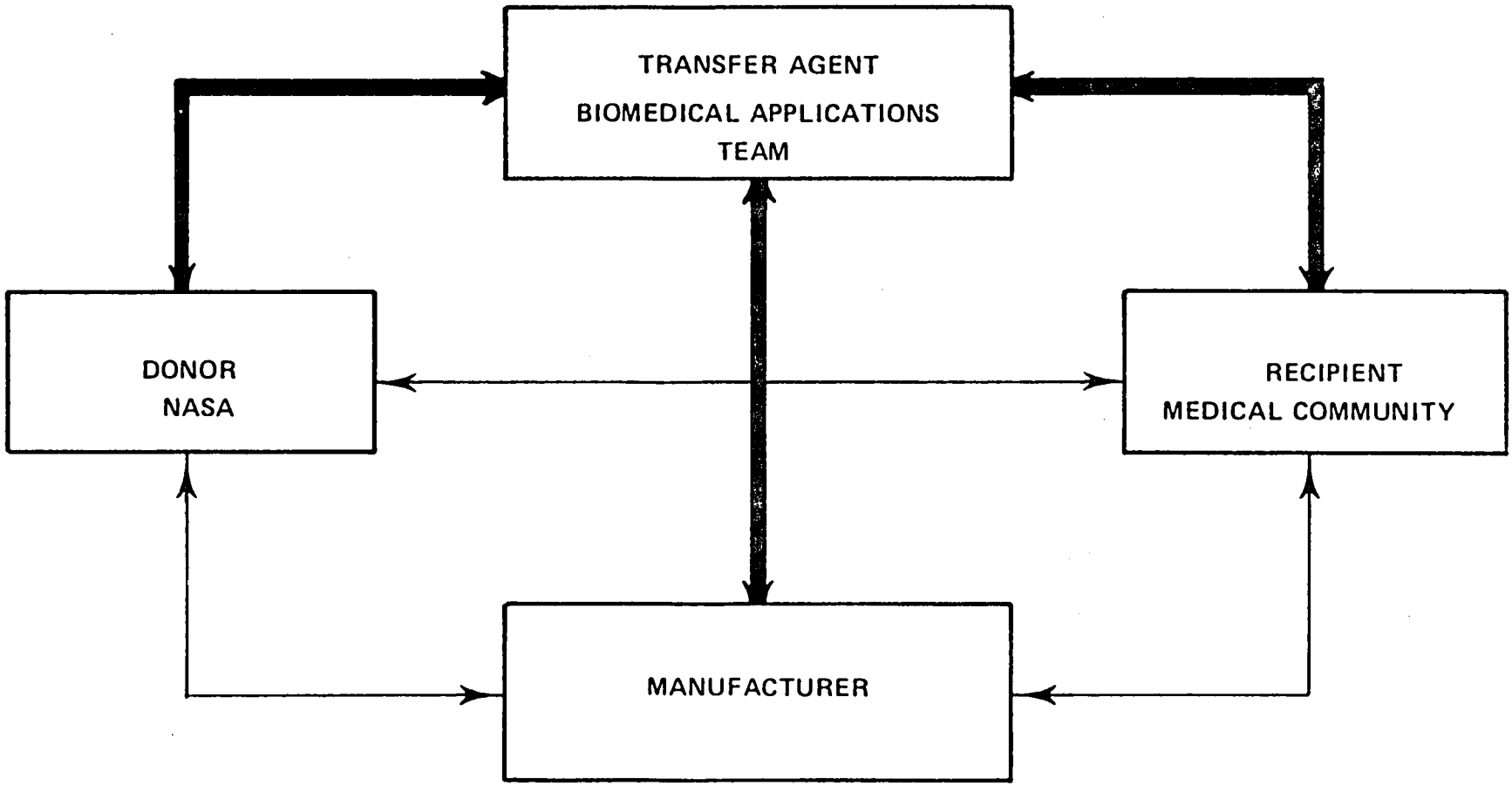


Figure 2. Conceptual Framework for Medical Technology Transfer

process. It is the task of the transfer agent to bring the donor, recipient, and manufacturer together in such a way that each views successful technology transfer as the primary objective. Completeness of the transfer effort must be a major goal for all parties involved.

The specific role of the Biomedical Applications Team, the transfer agent, depends upon the motivation, competence, and organization of the donor, recipient, and manufacturer. NASA is highly motivated to transfer aerospace technology to applications in non-space-related fields. Further, its organization is structured to facilitate the development of sophisticated and advanced technology. NASA's understanding of the medical industry and clinical medicine, on the other hand, is not great. The technological competence of the recipient is varied. Many medical researchers in large medical centers and teaching hospitals are technologically competent; the physicians in clinical practice, in general, are not technologically competent. The manufacturer of medical products may have a long and successful history of developing and marketing medical products or may be a small aggressive company exhibiting innovative behavior but lacking relevant experience.

The relative importance and role of each participant depends on the technological gap between that participant and the technology being transferred. It is the role of the Biomedical Applications Team to recognize the strengths and weaknesses of each participant and to supply the motivation, competence, and institutional linkages to ensure success. The methodology of the Biomedical Applications Team as presented in section 2.2 addresses these factors.

Technology will be interpreted throughout this report as including all of the skills, techniques, and understanding as well as the materials, devices, and hardware that make up a specific technology.[8] Technology transfer as used here will refer specifically to horizontal technology transfer. That is, the transfer of technology from one situational context--the one for which the technology was originally developed--to another situational context.[9] This transfer will normally result in

some modification of either the technology or to the situational context to which it is transferred.

Ruttan and Hayami have defined three levels at which technology transfer can occur. These levels are:[10]

Level 1: Material Technology Transfer. This involves the transfer of hardware from one situational context to another.

Level 2: Design Technology Transfer. In this case both hardware and software may be transferred for the purpose of imitating the original technology with some modifications for a new application.

Level 3: Capacity Technology Transfer. This level involves the transfer of knowledge and ability so that the recipient can generate his own technology.

In medical technology transfer, there are few instances in which a level 1 transfer can occur. The transfer of physiological electrodes developed for use in space vehicles to use in clinical medicine represents a level 1 transfer. Most medical technology transfers are levels 2 and 3. Redesigning an aerospace component or system for application in medicine constitutes a level 2 transfer. The utilization of NASA-generated knowledge, techniques, and procedures in the development and design of a new medical product constitutes a level 3 transfer.

2.2 Biomedical Applications Team Methodology

As noted in the introduction, and indicated in figure 3, the activities of the Biomedical Applications Team can be separated into four phases. Within each of these phases of the program, the specific actions and responsibilities of the team are, to a certain extent, fixed. However, team methodology incorporates flexibility, which allows it to respond appropriately to the specific characteristics of particular technology transfer cases.

2.2.1 Identification of Opportunities

The identification of technology transfer opportunities involves the identification of (1) a medical problem or need and (2) relevant aerospace technology that potentially can solve the medical problem or satisfy the medical need.

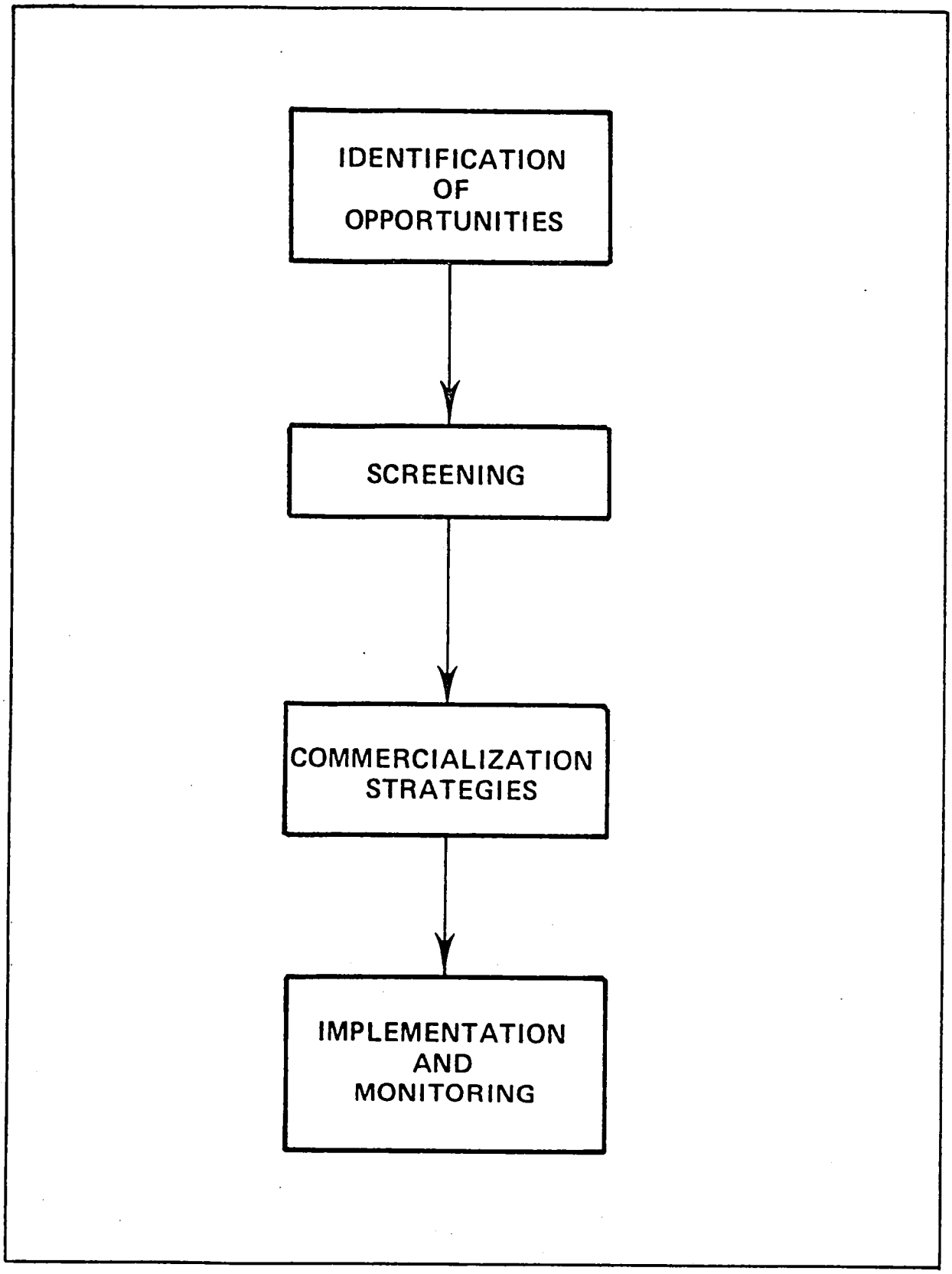


Figure 3. Phases of RTI Biomedical Applications Team Activity

The identification of medical problems occurs through the direct interaction between a team member and a researcher or physician within a medical institution. At present, the RTI team interacts directly with medical staff at 27 medical institutions throughout the eastern United States. These institutions are listed in table 1.

A study of medical technology transfer by the National Academy of Engineering and funded by NASA has concluded that the recipient must take the lead in defining medical problems.[11] This is consistent with the experience of the RTI team. As a result, the Biomedical Applications Team emphasizes obtaining complete and extensive descriptions of medical problems and needs from the problem originator or recipient.

Certain medical institutions and medical professionals are more innovative than others.[12] Research has shown that the first hospitals to adopt innovation are generally large medical centers or teaching hospitals geographically close to the place where the technology was developed. Further, those hospitals with highly trained medical staff tend to be more innovative. The "innovative elite" in medicine generally act to improve the quality of health care rather than to achieve maximum economic efficiency. Finally, once a hospital has adopted an innovation, the widespread use of that innovation is enhanced if the innovating hospital interacts frequently with other medical institutions. The Biomedical Applications Team, in its problem identification activities, considers these factors.

Because of the innovative physician's emphasis on quality, medical technology introduced in the past 10 to 20 years has tended to increase the sophistication of medical diagnosis and treatment, but has not contributed to a reduction in the cost of health care nor to increasing the quality of health care for the population as a whole.[13] This indicates that there is an opportunity for introducing aerospace technology in a manner to reduce the cost of health care or at least to assist in containing health care costs. The efforts of the Biomedical Applications Team are directed toward identifying opportunities that potentially reduce or contain medical costs.

Technology relevant to medical problems and needs is identified by a variety of techniques. Once a medical problem or need is specified, a computerized information search of the aerospace literature is performed by one of the six Industrial Applications Centers (IAC's). The RTI team utilizes the services of the North Carolina Science and Technology Research Center located in Research Triangle Park, North Carolina. Computerized information searches can identify information on potentially relevant technologies.

An additional approach to identifying aerospace technology is the circulation of problem statements to NASA field centers. Individual medical problems are concisely described in problem statements. Each problem statement is sent to NASA engineers and scientists working in areas related to the technological aspects of the medical problem. Responses to problem statements from these engineers and scientists can lead to the identification of technological solutions.

Finally, the Biomedical Applications Team frequently contacts NASA scientists and engineers known to have a strong interest in transferring technology to medicine. This is the most direct, efficient, and rapid approach to locating technology. The next phase of the program is the investigation of factors that determine which opportunities are most likely to be successful.

2.2.2 Screening

Effective screening enables the RTI Biomedical Applications Team to focus on those opportunities with the most promise for successful medical solutions and commercial products. In order to continue work on a particular opportunity, the team must determine that most of the following requirements are satisfied:

- The solution improves medical treatment or diagnosis or reduces the cost of health care,
- The solution is recognized by a medical mission agency and the medical community as a contribution to improved health care,
- The solution incorporates NASA technology or expertise,

- The market for the new or improved medical product justifies the required capital investment and production cost to the manufacturer,
- A manufacturer can be offered protection either by exclusive license or by lead time to allow sudden entry of the product into the medical market,
- The solution represents a discrete, well-defined transfer of technology involving limited research and development effort, and
- Candidate manufacturers with the required marketing and production capabilities have expressed an interest in commercialization.

These factors are evaluated by review of the biomedical literature, market surveys, interviews with industry representatives, and discussions with appropriate medical staff. Much of the data collected in this process is used in the development of commercialization strategies as described in the next section.

2.2.3 Commercialization Strategies

The development of strategy for successful technology transfer must consider product development and marketing, clinical trials, FDA approval when appropriate, acceptance by the medical profession, and identification of funding sources for the various tasks involved. Because of the emphasis on obtaining commercialization of NASA technology, strategies must involve obtaining industry participation.

The previously mentioned National Academy of Engineering study of medical technology transfer reached some important conclusions concerning strategy for technology transfer.[11] Successful technology transfer requires intimate and significant involvement of the donor and recipient throughout the transfer process. Further, the involvement of industry throughout the transfer process is essential. The manner in which new technology is introduced to the medical field is a critical factor in its success; the new or improved product must be accepted by and applied by the medical community.

The experience of the RTI Biomedical Applications Team has confirmed and expanded upon these conclusions. Industry must be involved throughout the transfer process and must be included as early as possible. Further,

the involvement of industry will generally require some means for giving a specific manufacturer a proprietary position. This may involve either an exclusive license or lead time to allow sudden entry of the new product into the medical market. Industry will view new product opportunities from the outside as being in competition with its own internally generated product ideas. This means that opportunities for technology transfer generated through the Biomedical Applications Team Program will have to compete for industry capital and management attention.

The acceptance of a new product by the medical community involves a fairly specific sequence of events. The product must be subjected to clinical trials, and the results published by a recognized medical expert. Generally, the product must be exhibited at medical meetings. This sequence normally leads to physician acceptance.

Medical marketing and distribution frequently are not an integral function of medical product manufacturing firms. Thus, in addition to obtaining the participation of a medical product manufacturer, the team must also identify and involve an organization capable of marketing and distributing those products.

Each specific opportunity for medical technology transfer will offer a new set of barriers and strategic options. Thus, the formation of strategy is not a specific activity. It is in itself a problem-solving effort. The most important common feature of strategy formation is thoroughness; all contingencies must be anticipated.

2.2.4 Implementation and Monitoring

Experience in the implementation of strategy has shown that the chance for successful technology transfer is increased by active involvement of the Biomedical Applications Team throughout the transfer process. By monitoring and coordinating the activities of the participants, minor problems can be prevented from becoming major obstacles.

Reports and documentation are an integral part of the team methodology; they are involved throughout the technology transfer process. Implementation of strategy is no exception; periodic status reports are

issued informally to keep all participants informed. Upon completion of the transfer process, the team prepares a technology transfer report documenting all important aspects of the transfer process. Sections 3.1, 4.0, and 5.0 of this report present documentation on completed technology transfers and status reports on active technology transfer cases.

Page 21 is missing from original

Page 22 is missing from original

Their design is based directly on the NASA design. The retail cost of the TV display modules is approximately $800.

As part of the RTI team's commercialization activities, Dr. Clingman performed a clinical market study of the digital display device. The total market and possible segmentation deriving from three distinct applications were examined.

Applications

The dealer representative suggests three possible applications of the digital TV display module, and would segment the market accordingly.

- Use of the device as test apparatus in hospital biomedical laboratories. It is estimated that all hospitals with 100 or more beds would normally have such a facility, and that each laboratory could employ one unit in repairing other equipment.
- Use of the device in cardiac stress laboratories. The device would be used by physicians for real time monitoring of patients during testing. Digital capability would enable the monitoring of more EKG channels and the memory storage of desired sections of each trace for referencing. Further study and selection of EKG traces before making hard copies would be possible. All 300 bed or larger facilities are estimated to have such a stress laboratory.
- Integration of the module into monitoring systems where it is desirable to digitize patient information for computer input and diagnosis. An existing trend in this direction is projected to continue and accelerate in hospitals with 500 or more beds. Monitoring systems would require multiple unit installation of the device.

Market Segment Evaluation

For the development of broad marketing strategy the dealer representative made these evaluations.

- Biomedical laboratory usage of the device essentially as a test instrument is not likely to develop substantial customer interest. As such, this segment would not support the investment necessary to support the primary sales effort.
- Cardiac stress laboratories are generally capable of the budget outlay necessary for the module. Additionally, the testing

capabilities of the device in this area would be income producing for the customer. This is viewed as the primary target for sales, with opportunity for immediate return. Possibilities in this market segment are the principal motivator for involvement of the dealer firm.

- Integration of the module into patient monitoring systems is viewed as an emerging, yet future marketing opportunity involving different sales techniques and support, as well as additional interface capability.

Table 2. Digital TV Display Market Analysis, National Market

Market Segment	Number of Beds	Number of Hospitals	Display Units per Hospital	Total Units
#1	100-299	2370	1	2370
#2	300-499	745	2	1490
#3	500 or more	608	2	1216
Total Units		3723	1.36	5076

Table 3. Digital TV Display Market Analysis, Louisiana Market

Market Segment	Number of Beds	Number of Hospitals	Display Units per Hospital	Total Units
#1	100-299	50	1	50
#2	300-499	12	2	24
#3	500 or more	8	2	16
Total Units		70	1.29	90

These clinical applications of the display device appear promising. Before this second marketing area can be entered, however, two tasks remain: (1) to redesign the display unit for clinical use and (2) to establish an agreement between the electronics manufacturer and the medical device distributor for the production and marketing of the clinical unit.

3.2 The NASA Black Bag: An Analysis of the Commercialization Potential

Objective and Methodology

The objective of this study was to evaluate the commercialization potential for the physicians' black bag that has been developed by the NASA Johnson Space Flight Center. The study was done through interviews of potential users in a number of key areas. The potential for commercialization depends both on the number of units that could be put into use as well as the desired configuration of those units by each user group. Thus, our objective was different from measuring the market size for a specific NASA product. Our objective was to develop a product description within general constraints that would have a sufficiently large market to achieve commercialization.

The general product description that was used in this study is given below. The product is essentially a physician's black bag containing a number of optional electronic and nonelectronic modules. These are primarily for use in emergency situations. One of our objectives was to determined the optimum modules to include to achieve commercialization.

NASA Johnson Space Flight Center has built a prototype of the bag. The contractor was Telecare in Houston. They were interviewed in this study and were interested in commercializing the black bag, provided a sufficient market could be identified.

The potential market could be divided into four sectors. These were emergency medical services, physicians, institutions, and government. The development of the product description within each sector was carried out through interviewing potential end users. For the most part, these were people who would make the purchase decision in each sector. Within the general constraints described below, there was a free discussion of what the product should be. Within each sector conclusions were then drawn as to what product specifications should be. Published statistics were then used to estimate the market for that product.

The four market sectors are discussed below, and the overall conclusions are given in the final section of the report.

Product Description

The black bag was presented as a suitcase that contains optional modules which are electronic and nonelectronic (Figure 5). The modules are listed in Figure 6. Not all of these would be present in every black bag. These packages are intended to provide the instruments, expendibles, and drugs that would be required in an emergency situation.

The electronic modules can be divided into three general categories. First is the monitoring of vital signs such as heart rate, blood pressure, etc. Second is a defibrillator, and third is commercialization equipment. Illustrations of the product were obtained from Dr. LaPinta at Johnson Space Flight Center and were used in the interviews.

In the interviews, it was emphasized that the particular modules shown were only meant to be examples. The interviewer explained that the primary NASA contribution was miniaturization of the modules, thereby achieving potential weight and cost savings. The total weight and cost of the package, however, would depend on the number of modules included. The more functions that could be performed, the higher the weight and cost. The interview discussions focused on the specific attributes that would be needed for that end user to purchase the product.

Market Sectors

Dr. LaPinta at Johnson Space Flight Center and Raymond Whitten at NASA Headquarters had explored several potential application areas prior to this study. Presentations had been made to various government groups, such as the U.S. Navy, and the prototype had been exhibited at AMA meetings. Based on the response obtained, four market sectors were selected. These were emergency medical services (EMS), physicians, institutions, and government. In covering each of these sectors applications were limited to emergency use of the black bag. The sectors differ primarily in who would purchase the product.

In the EMS sector the purchaser would usually be a local government agency that is operating the ambulance service. It may be the fire or police department; it may be a volunteer group; it may be a local hospital. In these cases the person making the purchasing decision would

Figure 5

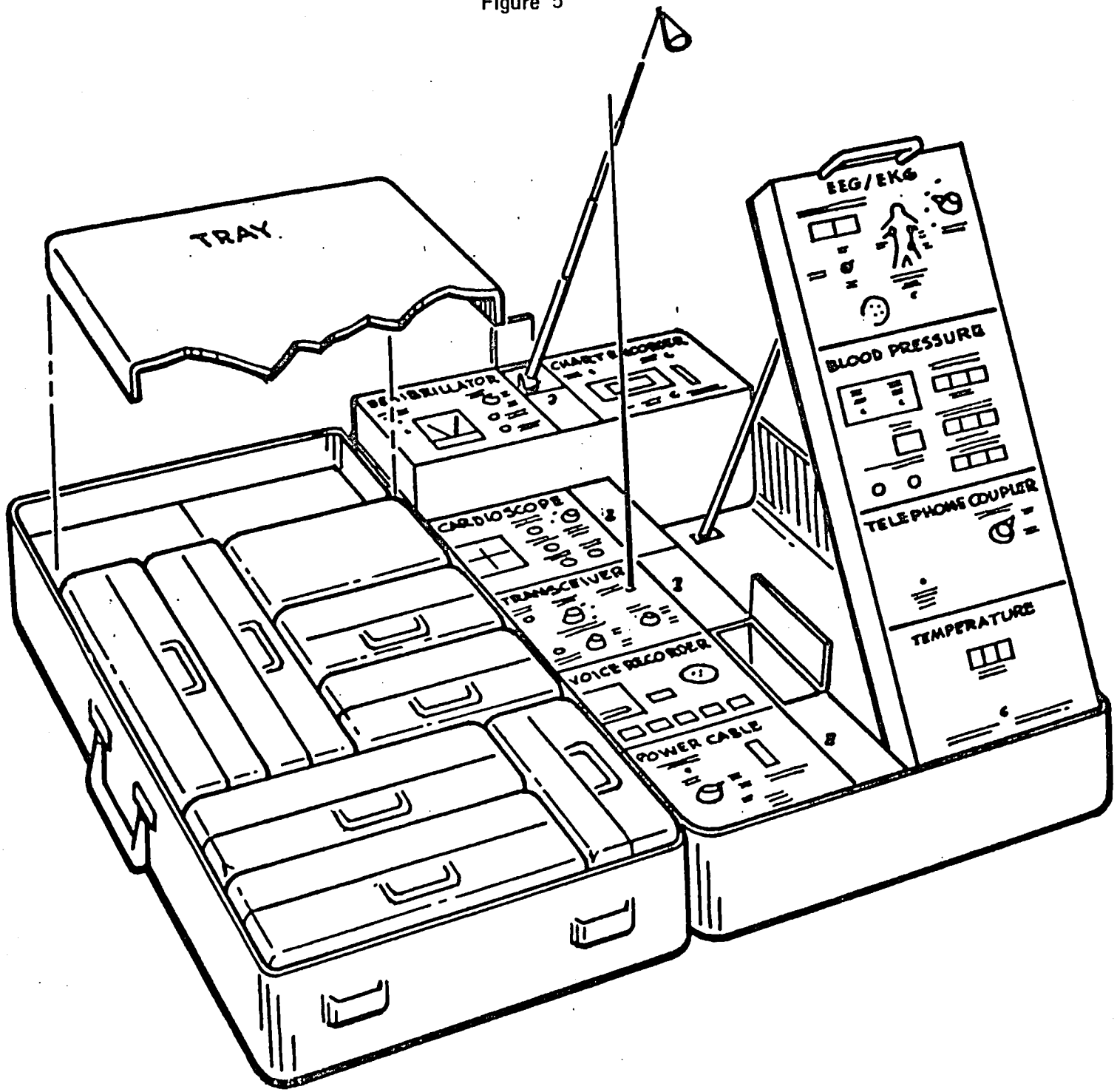

TRAY
EEG/EKG
BLOOD PRESSURE
TELEPHONE COUPLER
TEMPERATURE
DEFIBRILLATOR
CHART RECORDER
CARDIOSCOPE
TRANSCEIVER
VOICE RECORDER
POWER CABLE

FIGURE 6. PROPOSED PMS/TS CONFIGURATION

ELECTRONIC DIAGNOSTIC AND TREATMENT COMPONENTS

BASELINED

- EKG
- HEART RATE
- RESPIRATION RATE
- TEMPERATURE
- BLOOD PRESSURE

OPTIONAL

- EEG
- DEFIBRILLATOR

RECORDING AND COMMUNICATIONS COMPONENTS

BASELINED

- STRIP CHART RECORDER
- AUDIO CASSETTE RECORDER
- PHONE COUPLER

OPTIONAL

- CRT

FIGURE 6. PROPOSED PMS/TS CONFIGURATION (CONTD)

MEDICAL KITS - INSTRUMENTS, DRUGS AND SUPPLIES

BASELINED KITS

- ORAL MEDICATIONS
- DIAGNOSTIC
- EMERGENCY
- MINOR MEDICATIONS
- BURN
- BANDAGE
- INJECTABLES
- TOPICALS

OPTIONAL - SPECIALTY KITS

- MINOR SURGERY
- OB/GYN
- ORTHOPEDICS
- PEDIATRICS
- DENTAL
- EENT
- CARDIAC

be the administrator of the agency operating the emergency medical services. If advanced EMT's were employed, then it was found that they would also make a significant contribution to the selection of equipment.

In the physician sector the purchase would be made by a physician in private practice. Those with urban and rural practices were interviewed. In the institution sector the potential customers would be industrial clinics, hospital emergency rooms, etc. Finally, the government sector would comprise those units purchased by the U.S. Government. In this case, interviews were conducted within the military, FAA, and the Peace Corps.

Conclusions

In each market sector the desired product would contain a defibrillator, and in most cases there would be little interest in the nonelectronic modules. The largest single market area would be the military. They will be purchasing the equivalent of several thousand black bags over the next 2 to 3 years. There is also a firm market in the EMS sector of about 300 units a year. These sales would be associated with the upgrading of ambulances from EMT to advanced EMT capability. In both the EMS and military markets, there is a need to compete with other equipment by achieving lighter weight or lower cost. There is only a small fraction of physicians that would purchase the black bag. Less certainty can be attached to the estimate because of the small number of interviews carried out. It is probably of the order of a few hundred units per year. These would be sold to rural physicians making house calls in sparsely populated sections of the United States.

Institutional Market

The conclusions drawn from the interviews was that this market sector was very small. No institution was found that would buy any modification of the NASA black bag for institutional use. The only purchase by an institution such as a hospital would be for use on a vehicle.

In a hospital emergency room or clinic they would have a "crash cart" that already has stored on it the components needed for emergencies. This serves the same function as the black bag. From the viewpoint of the

hospital administrator the crash cart has advantages. Most important is that he can control the unit ratio of components purchased. In a multi-cart environment he is not artificially constrained to obtaining some components which he does not need in order to obtain others that he does need. Another perceived advantage of the crash cart is that he can optimize the selection of each individual component and not be confined to just one supplier. This is also an advantage from the viewpoint of the physician performing emergency services. The physicians interviewed were concerned over the reliability of the NASA black bag because of the miniaturization of the electronic modules. Without an overriding advantage to them in the black bag, they would tend to purchase equipment that has been on the market for some time and with which they were familiar.

Government Market

There is a significant military market for the purchase of either the NASA black bag or an equivalent set of components. The Navy is now purchasing the separate modules that could go into a black bag. This includes a defibrillator, monitor, and nonelectronic kits. The NASA black bag prototype has been shown to the Navy on at least two occasions. The most recent was in August when Roy Gage, Dr. LaPinta, and Dr. Clingman visited Dr. Mantel in the Navy Bureau of Medicine and Surgery. Roy Gage is President of Telecare, a manufacturer of EMS equipment and the NASA contractor who built the prototype black bag. Dr. LaPinta is with the NASA Johnson Space Flight Center and participated in the development of the bag. Dr. Mantel is responsible for selection of all medical equipment that will be purchased by the Navy. He likes the NASA black bag concept and would purchase it today except for two factors. He needs a defibrillator in the unit but this was not included in the prototype. He also needs a finished product that is available for purchase.

Dr. Mantel is now buying a Life-Pac 5 defibrillator and monitor. He is combining these with other modules to form the equivalent of the NASA black bag. He is assembling these units at the rate of 300-700 per year. These are for shipboard applications in emergency situations. After the first

2 years they may purchase another 1,000-2,000 units for additional applications. There is an interagency committee that covers this equipment. Dr. Mantel said that his colleagues in the Army and Air Force are waiting to follow their lead in the Navy. Thus the total military market over the next 5 years could be several thousand units.

Dr. Clingman also interviewed by telephone both the Peace Corps and FAA, where prior interest had been expressed in the NASA black bag. At the Peace Corps, he talked with Dr. Alvin Alio who said that, as a matter of policy, they provide no diagnostic or emergency medical services in the host country. Their only requirement for a black bag is in the treatment of their own volunteers. There would be a maximum of about 50 units required. Dr. Alio first suggested that the manufacturer contact each of the physicians in charge of a field section and sell the black bag directly to him. In discussing this point further he did say that it might be possible to sell a group of bags to a central purchasing facility of the Public Health Service.

The FAA interview was with Dr. Stan Mohler. He had seen the black bag, and in his opinion there should be one on every commercial aircraft. He said that there normally would be a physician on board who could use the equipment. He also said that there were a number of heart attacks each year on commercial flights. According to Dr. Mohler, the problem is that the airlines would resist purchase of the equipment. It would have to be done through regulation, and the political environment would prevent this for some time to come. FAA management feels that there are many other areas of higher priority requiring new regulations.

Thus the principal government market is in the military, and this is the largest of the market sectors evaluated. At this point in time the market is a few thousand units. The market is decreasing with time, and in 2 to 3 years the prospect would be many fewer units. Thus, a rapid entry into this market with a NASA device would be significant.

Emergency Medical Services

Some general conclusions could be drawn from the interviews. First of all, for the NASA black bag to be used on an emergency vehicle, there would need to be advanced EMT's assigned to the vehicle. The market would

be associated with those vehicles being upgraded with equipment for advanced EMT's. Such equipment would include a defibrillator, for example. Once the vehicle was upgraded, then no interest was found in replacing existing equipment with the NASA black bag. Thus, the annual market would be limited to those vehicles that are upgraded during the next year.

A second conclusion was that, in upgrading a vehicle, a necessary component was a defibrillator. The primary advantage of the NASA black bag as seen by those interviewed was a lower weight or lower cost through miniaturization and a combination of functions. The defibrillator-monitor combination is where the primary interest is for weight reduction. Little interest was found in purchase of the vital signs monitors alone from the black bag. There also was no interest in the nonelectronic modules. Drugs carried on the vehicle have to be sealed, checked out of the hospital, and separately controlled. The bandages, instruments, and other nonelectronic items are already available in kits selling at $700-800. Many of the paramedics interviewed put together their own kits and would want to maintain control over the selection of the contents.

If an electronic package could be provided that contained a defibrillator and offered a weight and/or cost advantage, then keen interest would be found. The potential annual market would be all ambulances upgraded or added with equipment for advanced EMT's. An estimate of the number of such units was made using statistics obtained from the congressional hearings on Emergency Medical Services and Burn Facilities, House Subcommittee on Health and the Environment, January 27, 28, and 29, 1976.

The following statistics are for the year 1976 and indicate the rate at which Federal money will be spent in upgrading ambulance service. This is the key to determining the available market for black bags. In 1976 there were 27,500 ambulances in operation. This was considered to be about the proper number needed by DOT. Only about 20 percent of these met DOT-GSA specifications. About 80 percent of the ambulances would be replaced by 1981. There were 14,300 ambulance services. Of these, 20 percent will be converted to advanced EMT status over a 5-year period. Of those services being upgraded they will have on the average four ambulances, two hospitals, and one repeating station. There were

also plans to upgrade about 20 percent of the EMT's to advanced EMT status over the same 5-year period.

One conclusions from the interviews was that purchase of the NASA black bag would be no different in rural or urban areas. Thus, from the above statistics it follows that about 2300 vehicles would be upgraded per year. This would be the available market for the black bag. It would seem that, because of competition, an aggressive manufacturer might gain 20 percent of this market or about 460 units per year.

Physicians

In all of the face-to-face interviews no physicians were found who said that they would purchase a NASA black bag. Those contacted were in family practice, some in a rural and some in an urban setting. Those in the urban practice feel that in an emergency their first concern would be to move the patient as rapidly as possible to a hosptial. They would be reluctant to use a defibrillator themselves without trained technicians present. They felt that use of the vital signs monitors would just delay transfer of the patient to the hospital. No urban physicians were found who make house calls or know anyone who makes house calls.

The doctors in rural practice who were interviewed had the same comments. They had the further disadvantage of patients who could not afford the use of special equipment. Even though the travel time to a hospital emergency room might be 30 minutes, the desire was still to move the patient to the hospital as soon as possible. Some rural physicians were interviewed who previously had made house calls in their careers. They said at that time they could have used the NASA black bag.

Telephone interviews were carried out by Earl Herron of nine physicians in rural practice. These are listed in Table 4 along with an indication of the result. When the physician was in a sparsely populated area, there was interest. Thus, it is assumed that some fraction of these physicians could be sold the black bag.

There is some statistical information on the number of house calls being made. House calls in rural areas for a number of years are shown in Table 5. If doctors were making these house calls, then this would average 1000

Table 4

Telephone Interviews of Rural Physicians
Conducted by Earl Herron

Location	County Population	County Area	Response
Prentiss, Mississippi	12,936	414 sq. mi.	Negative
The physician's policy is to send emergency cases directly to the hospital			
Brattleboro, Vt.	33,476	784 sq. mi.	Negative
The physician was worried about malpractice suits arising from use of the black bag			
Havre, Montana	17,358	2,700 sq. mi.	Negative
The unit including the defibrillator is too expensive ($6,000—$7,000)			
Glendive, Montana	11,269	2,370 sq. mi.	Negative
The physician might have purchased the black bag five years ago but now his policy is that patients go directly to the hospital.			
Bend, Oregon	30,442	3,031 sq. mi.	Positive
They would purchase one without the defibrillator ($1,500) for hospital emergency use			
Rawlins, Wyoming	13,354	7,905 sq. mi.	Negative
The sheriff goes directly to the hospital with the ambulance			
Thermopolis, Wyoming	4,952	2,022	Positive
The physician makes house calls and was interested but he thought it was expensive			
Flagstaff, Arizona	48,326	18,540 sq. mi.	Positive
The physician was interested and sometimes goes to the scene of an accident			
Madison, West Virginia	25,118	501 sq. mi.	Negative
There are two small hospitals close to the physician and he always has the patient transferred directly to the closest.			

Table 5

Number of Physician Visits Outside of SMSA
('000)

	Place of Visit					
Year	Office	Home	Hospital	Company	Telephone	Other
1966-1967	205,774	6,610	22,563	(1)	(1)	33,487
1971	237,733	4,696	26,964	1,632	36,519	13,267
1973-1974	210,749	(1)	26,748	(1)	29,504	19,485

each or 2-3 a day. Thus 4,700 units is considered a lower limit on the potential market size. Actual sales would be some fraction of this significant market, but the market is not expected to be a large sector.

Conclusions

The total available market for the NASA black bag over the next 5 years is several thousand units. These units would need to contain a defibrillator. The largest sector of this market was the military, but it will probably become saturated over the 5-year period. The second largest sector was emergy medical services. Aggressive marketing could generate sales of about 400-500 units per year. Time is important in pursuing both of these market sectors.

4.0 INSTITUTIONAL TECHNOLOGY TRANSFERS

During the reporting period, six institutional technology transfers were completed: EMG Spectral Analysis, Enhancement of X-Ray Diffraction Images, Lung Sound Modeling, Optical Profilometer, SCA Receiver for the Handicapped, and Multi-Level Care Management. While these transfers have not resulted in new medical products, they represent significant contributions to health care management and research. One transfer, the SCA Receiver for the Handicapped, has potential for future commercialization.

These six transfers are documented in the following pages. The medical applications, NASA technologies, the transfer process, and major participants are identified.

EMG Spectral Analysis

BATeam Personnel: Dr. Richard Scearce

The rapid expansion of marine resource development has stimulated man's interest in deepsea diving. The rush to exploit offshore oil deposits is one example. A well cannot produce until a diver on the ocean's floor has attached the pumps and valving. Thus, offshore drilling requires scuba divers to live and work at depths of 700 to 1000 feet of water. Drilling companies lower habitats to the ocean floor where several divers live for weeks. Unfortunately, research has discovered that man develops tremors at depths of 1000 feet of water, and at 1500 feet, man experiences microsleep--momentary lapses into deep sleep. Either phenomenon could cause an accident, which at those depths would be fatal. Unfortunately, these phenomena are not understood.

The problem originator, Dr. Michael Ackerman, is studying the physiological effects of deepsea diving. In his research, he instruments animals and places them into pressure chambers to simulate deep dives.

One measurement of particular interest is the electromyogram (EMG). Dr. Ackerman plans to do a spectral analysis of the EMG data to detect the subtle changes in frequency content that are the first signs of the onset of tremor. The researcher asked the team whether NASA had developed computer software for this purpose that he could use in his diving studies.

In 1976, a NASA contractor at Johnson Space Center (JSC) published a special report titled A Computer Program for Time and Frequency Domain Reduction of Electromyographic Data. A team member contacted the author and

discussed the program. It was evident the program was exactly what the problem originator wanted. Computer language was no problem, since the JSC computer system was identical to Dr. Ackerman's computer system. In December 1978, the author recorded the program onto a magnetic tape for Dr. Ackerman.

This direct application of NASA software has significantly reduced the time and the cost of completing an important research project on the physiology of deepsea diving. Thus, aerospace technology has contributed to the understanding of man's response in yet another environment in preparation for the safe harvesting of marine resources.

Enhancement of X-Ray Diffraction Images

BATeam Personnel: Dr. Clark Beall

NASA technology for the recovery of grossly underexposed photographic images has been applied by the RTI team to improve the quality of X-ray diffraction images. The NASA technique also enables a researcher to reduce drastically the experiment time required for the recording of a satisfactory X-ray diffraction image. Researchers at Duke University Medical Center have accepted the concept of the NASA autoradiography technique and are purchasing the equipment necessary for producing the autoradiographs. Ms. Barbara Askins, of Marshall Space Flight Center, has provided them with comprehensive documentation of the technique. The researcher plans to evaluate the NASA technique in several research applications.

Lung Sound Modeling

BATeam Personnel: Ms. Doris Rouse

Disabling pulmonary illnesses may result from a variety of causes including environmental factors, pulmonary vascular pathology, asthma, and cystic fibrosis. Researchers have examined the structure and function of the normal lung as well as the mechanisms by which alterations in a respiratory function may lead to disease. In many pulmonary diseases, especially lung cancer, early detection and accurate diagnosis can enhance the success of the treatment.

In 1971, Dr. F. T. Wooten of the RTI team worked with Dr. W. W. Waring at Tulane School of Medicine on a project to improve diagnosis of

respiratory disease by lung sound detection. The team introduced the problem originator at MCV, Dr. John Patterson, to Dr. Waring. As a result, a useful exhange of techniques and research results took place.

Dr. Jay Hardin, of the Acoustics Division at Langley Research Center, is working with the problem originator to employ sound analysis techniques, lung airflow parameters, and a lung model to determine the location and nature of the alterations in lung structure responsible for compromised lung function. Dr. Hardin and Dr. Patterson presented a paper entitled "Theory of Sound Generation in the Human Lung" at the Mid-Atlantic Conference on Bio-Fluid Mechanics in August 1978.

The team will continue to provide Dr. Patterson and Dr. Hardin any assistance they may require in this continuing project.

Optical Profilometer

BATeam Personnel: Dr. Richard Scearce

Cleft lip or palate occurs in 1 of every 600-700 births. Surgical closure of the cleft is required. Orthodontists must carefully schedule this surgical fusion of the bone segments so that normal growth and development are possible. The proper time for the surgery is determined by a careful examination of the palate size, shape, and growth patterns. To obtain these data, the orthodontist forms permanent casts from impressions of the palate taken periodically from infancy. The orthodontist's treatment plan is based on his analysis of the casts using calipers and measuring tapes. The inability of these measuring techniques to describe the complex three-dimensional surface of the palate casts means that subtle changes in shape, size, and volume of the palate go undetected. Thus, a system capable of quantitatively surveying the complex cast's surface would enable orthodontists to improve their understanding of the morphology of the cleft palate and their treatment plans for this facial deformity.

The problem originator, Dr. Samuel Berkowitz, developed a stereo photography system and utilized standard mapping techniques to quantitate the complex surfaces of the palatal vault cast more precisely. The results of his analysis of many casts demonstrated the utility of this additional information in the treatment of cleft palate. This stereo

photography technique, however, was too costly to compete with conventional analysis methods.

In response to an RTI team problem statement, engineers at Langley Research Center suggested that NASA's automatic focus control system for a facsimile camera be modified to measure the cast surface. This focus control system, used on the Viking Lander, automatically compensates for changes in the distance to the photographed object. A modification of the Viking system has resulted in a relatively simple and inexpensive optical profilometer.

The optical profilometer provides the digital data necessary to characterize the small, complex three-dimensional surfaces present in palatal casts. To obtain this information, the optical system correlates the change in energy distribution of reflected light with surface depth at the point of reflection. Variations in surface slope, surface reflectance and lamp intensity cause unwanted changes in the output signal. These errors are significantly reduced by normalizing the sample photodetector output to a reference photodetector output.

In December 1978 the completed profilometer was shipped to Dr. Berkowitz. He is collaborating with the ten leading cleft lip and cleft palate centers to develop a research record system for craniofacial anomalies. The optical profilometer will be utilized as the primary data collection device. Thousands of palatal vault casts will be analyzed. The resulting numerical data will be accumulated in a data file to be used both as a research and a clinical tool. By studying the data, researchers will learn more about the subtle surface changes that take place. By comparing casts of new patients with data from previous patients, the orthodontist will be able to recommend the optimal treatment. Thus, this application of NASA-developed technology will provide a vastly improved quantitative evaluation of morphological subtleties which will enable medical personnel to improve the treatment of this facial deformity.

SCA Receiver for the Handicapped

BATeam Personnel: Dr. Clark Beall

In 1975 the Federal Communications Commission granted permission for the use of audio machine code programming on the SCA (Subsidary Communication Authority) subcarrier of commercial FM radio stations. Organizations

for the deaf are interested in utilizing the SCA subcarrier for the transmission of Radio Teletype (RTTY) programs in large urban areas. The audio tones that comprise the RTTY transmissions are exactly the same tones that are generated and decoded by the phone couplers that are already widely used by the deaf for telephone communication by Teletype. All that is needed for these homes to be able to receive the RTTY broadcasts is the addition of an SCA subcarrier receiver at each site. The SCA subcarrier receivers (designed for commercial SCA systems) are too costly for large scale purchases by the deaf.

Utilizing phase-locked-loop technology, engineers at the Goddard Space Flight Center have designed and built a circuit board that enables a low cost, commercially available FM radio to receive the SCA RTTY broadcasts. In November 1977 a team member visited Goddard Space Flight Center, picked up this radio and took it to the Philadelphia area for a field test. The FM station of Temple University, in downtown Philadelphia, broadcasts SCA RTTY twice daily from programming material provided by the Pennsylvania School for the Deaf. This RTTY system is the first, and at the present time, the only RTTY system for the deaf in the United States. These RTTY broadcasts are received by more than 30 deaf families in the Greater Delaware Valley area. More than 300 families will eventually be equipped with SCA receivers in this area. In the Philadelphia test of the NASA SCA receiver, the reception was satisfactory with the set at a distance of 10 miles from the transmitter site, even though the set was equipped only with a whip antenna. This range should be more than doubled when the receiver is attached to a properly oriented, directional TV or FM antenna.

In order for commercialization of the SCA receiver to proceed, more demand must be generated by the development of more RTTY systems in the larger urban areas. There are several reasons why more of the RTTY systems for the deaf do not exist in the United States. First, most of the local organizations of the deaf are not aware of the possibility for initiating a local RTTY system. Second, if the local organization does not have technical personnel readily available, they are intimidated by the technical aspects of the project. Third, the cost of purchasing a large number of commercial SCA receivers is too great. Finally, a cooperative local FM station is not always available for transmitting the RTTY.

Multi-Level Care Management

BATeam Personnel: Dr. Richard Scearce

Dr. John D. Chase, former medical director of the Veterans Administration, described the Multi-Level Care (MLC) Program as the "most significant project VA has launched in the last half dozen years." Faced with increasing costs and growing demands for health care services, the VA designed the MLC program to: (1) improve the quality of health care by organizing the resources of the VA's medical districts and health care facilities so as to focus on the health care needs of the individual patient, (2) improve the financial management system by modifying existing budgetary, resource allocation, and cost-control mechanisms at VA central office, district, and facility levels, and (3) provide an improved billing and reimbursement system. To accomplish this the MLC Program is divided into 15 levels of care. Each level of care is defined by the type, number, and intensity of physician, nursing, and support staff, space, beds, and equipment organized to meet a defined range of patients' needs. Cost accounting is also divided along these same levels. Thus, under this system (see Figure 7) a physician places each new patient at a level of care according to preestablished criteria. As an example, if the patient required in-hospital medical and surgical services, the physician would assign the patient to one of five levels of care: intensive, acute I, acute II, extended hospital, or minimal. As the patient's needs change, the staff would shift the patient to the appropriate level. Since cost accounting is also divided by level of care, the bill would reflect the number of days at each level.

Dr. Karl Eurenius, director of the MLC Program, plans two trial implementations. Each trial will involve two VA medical districts. If these trials are successful, the MLC Program will be implemented in the remaining 24 VA medical districts by 1982.

Dr. Eurenius contacted NASA headquarters to ask if any of NASA's project managers could assist his staff. He felt that managing this program might be very similar to managing one of NASA's large multidiscipline projects.

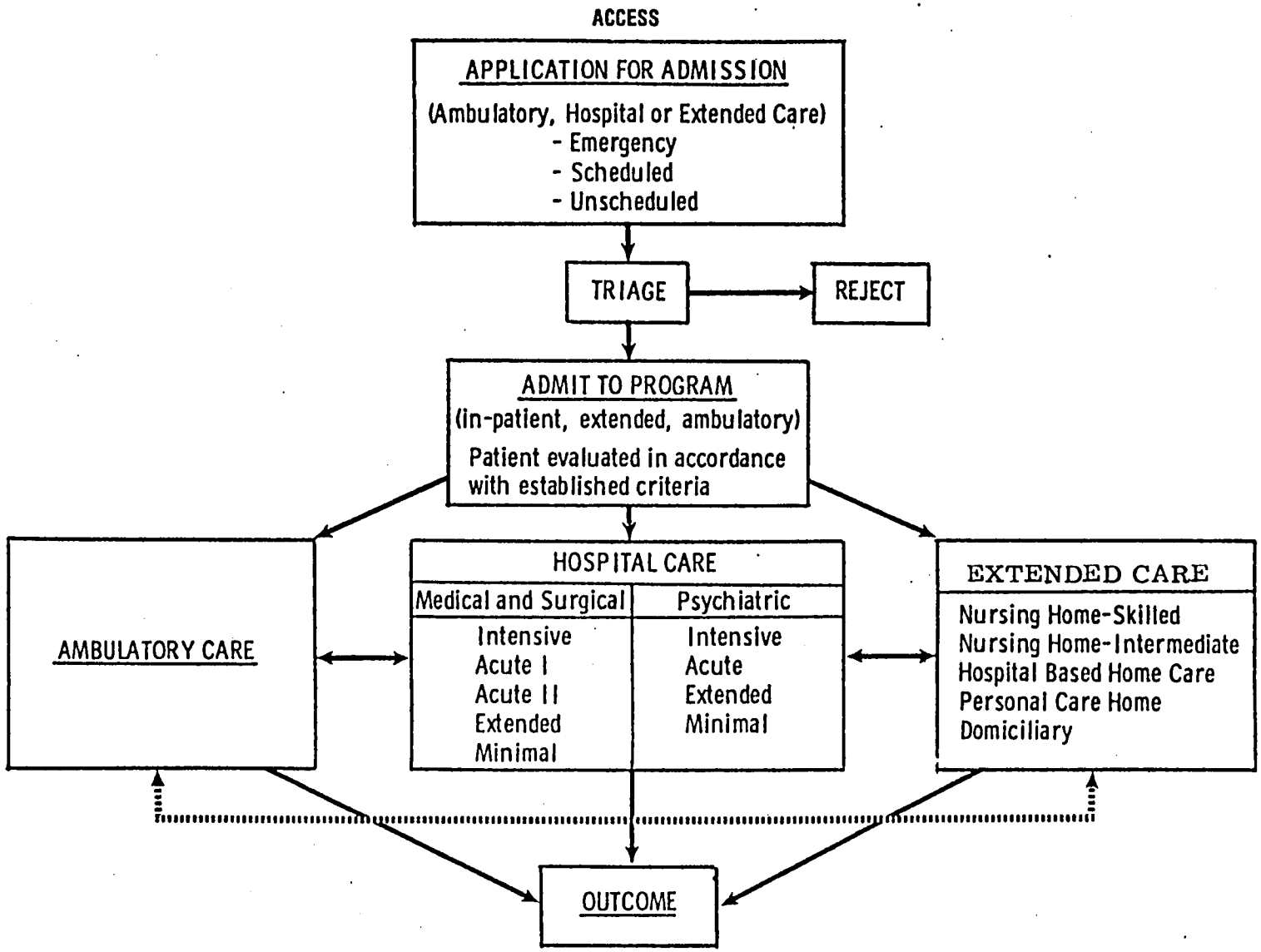


Figure 7. Patient Flow in a Multi-Level Care System

Some years before, the team had worked with Colonel Lee B. James. Colonel James, who is retired, had held numerous NASA management positions. These included deputy director of the Apollo Program, direction of program management at Marshall Space Flight Center, director of the Saturn Program, program manager of the Saturn 5 Program and program manager of the Saturn 1 and 1B programs. He had also been a professor of cybernetics at the University of Tennessee, where he wrote a book entitled Management of NASA's Major Projects.

In April 1978, the team contacted Colonel James, described the MLC program to him, and explained that Dr. Eurenius had requested management assistance. Colonel James agreed to investigate the situation. Thus the team arranged for Colonel James to attend an MLC program conference held in Cincinnati, Ohio, on April 10-12, 1978. The conference initiated the first trial implementation of the MLC Program. Attending were the hospital administrators and chiefs of staff from 10 VA hospitals. On the final day of the conference, Colonel James was asked to present his observations. He spoke for approximately 30 minutes, and demonstrated an amazing grasp of the program and the obstacles to its implementation.

Immediately after the conference, Dr. Eurenius hired Colonel James as a management consultant. Subsequently, he has helped plan and execute an evaluation of the early MLC trials. Colonel James is presently assisting Dr. Eurenius and his staff in the program's long-range planning.

Both Dr. Eurenius and his deputy have personally thanked the team for introducing them to Colonel James. Because of his experience in directing NASA's large multidiscipline projects, he has been able to quickly identify problem areas and help the VA team avoid unnecessary delays.

5.0 STATUS OF ACTIVE TRANSFER PROJECTS

The Biomedical Applications Team is investigating 27 transfer projects at the present. These projects include 12 medical problems identified during the reporting period and 15 identified prior to 1 January 1978.

Of the 27 active transfer projects, all but one have the potential for becoming commercialization technology transfers. This is a direct result of the emphasis by the RTI team on the potential for commercialization in the team's identification of opportunities and screening activities as described in section 2.0. The approach of the team in obtaining widespread utilization of NASA technology is to direct its efforts primarily to solving problems that involve the introduction of a new or improved medical product. It should be noted that the team does not exclude opportunities for applying NASA technology in medical research.

Seventeen new problems were identified during the reporting period. Problem statements describing these new problems are presented in Appendix B. Reports on those new projects that are still active are included in this section.

Four of the active transfer projects reported here have been reported as institutional technology transfers in previous final reports. In these instances, the team has recognized opportunities for commercialization transfers, and is taking appropriate action. Problems in this category are:

Neuropathic Tester
Weight Alleviation Device
Controlled Rate of Freezing a Liquid
Pressure Transducer Calibrator.

Breast Cancer Screening Technique

BATeam Personnel: Dr. Richard Scearce

In 1975, Dr. John N. Wolfe of Detroit described a technique for predicting women likely to develop breast cancer. Based on the breasts' radiographic appearance, Dr. Wolfe can classify women into risk categories. Other medical groups have verified the technique. Unfortunately, the method requires a highly trained radiologist to study each mammogram. Thus it would be impractical to use this technique to screen the 100 million women in this country. Such a task requires an automated method.

Robert Butterfield of Kennedy Space Center developed image processing methods for analyzing radiographic and ultrasound images of the breast. He designed his processing methods to automatically perform Dr. Wolfe's predictive technique. Mr. Butterfield requested the team's assistance in developing a strategy to evaluate and commercialize his image-processing methods.

Interviews with medical researchers and a review of the literature verified the importance of Dr. Wolfe's work, the need to automate the technique, and the need for this analysis system to be applicable to both ultrasound and X-ray mammograms. In May 1978 a team member and Mr. Butterfield visited the problem originator, who is director of the Division of Diagnostic Ultrasound at Thomas Jefferson University Hospital. During the vist they arranged for an evaluation of the ultrasound image-processing methods. The problem originator or his assistant will visit Kennedy Space Center in February 1979 to initiate this evaluation.

The team also contacted personnel at Duke University's Breast Cancer Screening Center, where researchers had verified Dr. Wolfe's predictive technique. In a controlled study of 171 X-ray mammograms, their results agreed with Dr. Wolfe's findings. The team is completing arrangements with the Duke medical group for the evaluation of Mr. Butterfield's X-ray mammography image-processing methods. An initial test set of mammograms will be forwarded to Kennedy Space Center in January 1979.

Composite Material Applications

BATeam Personnel: Dr. Richard Scearce

Although NASA has demonstrated the feasibility of utilizing composite materials in orthotics, to achieve widespread utilization of this technology two tasks remain: (1) the identification of additional appropriate applications of composites, and (2) the development of manufacturing techniques suitable for use in the orthotic shop. Mississippi Methodist Rehabilitation Center has received a contract from Langley Research Center to meet these objectives.

At the request of the director of engineering at the rehabilitation center, Dr. Scearce met with Robert M. Baucom and Sheila T. Long of Langley Research Center to discuss an evaluation of the quality of the composites produced in the Mississippi Methodist Rehabilitation Center Shop. Mr. Baucom has agreed to validate the quality of samples from the rehabilitation center.

Progress has been made thus far in the identification of new applications and development of manufacturing techniques. The team is working closely with Langley Research Center and the rehabilitation center in assessing the commercial potential of these applications.

Controlled Rate of Freezing a Liquid

BATeam Personnel: Dr. Richard Scearce

The treatment of several forms of cancer and certain other diseases requires the infusion of large quantities of stem cells or other blood components (e.g., red cells, white cells). To obtain the necessary quantities, the cells are collected, frozen, and stored for later use. Unfortunately, many of the cells are damaged by the traditional freezing process. Some authorities suggest that the nonlinear rate of freezing causes the damage.

Jet Propulsion Laboratory (JPL) personnel have suggested a technique that would detect the onset of freezing and would increase the heat transfer rate during the release of latent heat so that a nearly constant rate of freezing would be maintained from room temperature to -50°C.

Goddard Space Flight Center personnel have developed the JPL suggestion into hardware using computer analysis techniques developed for such applications as ensuring the thermal balance in spacecraft. The completed freezing system has been tested at the National Cancer Institute and at the Johns Hopkins University Medical Center in Baltimore. The successful test results have been documented in three journal publications.

A manufacturer has shown interest in commercializing the freezing unit, but the unit requires some redesign to make it more reliable and convenient to use. He has submitted a proposal to redesign and to market the system. Dr. Scearce and Dr. Clingman are working with Don Friedman, Technology Utilization Officer of Goddard Space Flight Center, to evaluate this opportunity.

In a separate commercialization project, JPL has entered into a contract with a large commercial organization to develop a commercial system for preserving red cells. JPL has completed and tested a sophisticated freezing system. JPL's progress pleased the corporation, but its new product development funds were depleted. Thus JPL terminated its development and testing program. When additional development funds are available, the commercial organization will reconsider this project. The team will: (1) continue to monitor this situation, (2) provide assistance as appropriate, and (3) insure that no conflict exists between Goddard and JPL commercialization projects.

Female Incontinence

BATeam Personnel: Ms. Doris Rouse

One of the techniques for the management of urinary incontinence in males involves the use of an external roll-on rubber cuff and a collection bag attached to the leg. This closed collection system overcomes many social and health problems resulting from exposure of the urine to the air and the skin. A successful closed collection system for females is not available. Urine incontinence in females, therefore, must be managed by diapers and pads or by catheterization.

The RTI team is working with Johnson Space Center in the development and evaluation of a female urine incontinence collection apparatus (FEMUICA). The objective of the program is to develop an external urine collection device that is leakproof, comfortable, and simple to apply, remove, and keep clean. The following modifications have been made to the original design: (1) the positioning pessary has been eliminated and replaced with a flexible vaginal seal, and (2) a panty support system has been added to maintain the device in position.

An initial configuration, fit, and function demonstration has been completed on a healthy volunteer subject. The subject was able to wear the device for 12 hours as specified by the protocol with no discomfort. A management advisory panel consisting of urologists as well as NASA physicians and engineers will meet in January to review these initial test results and to design the protocol for the next evaluation. The RTI team will participate in this session.

The FEMUICA has a promising commercialization potential. Two major manufacturers of devices for management of incontinence have expressed an interest in marketing the FEMUICA. A representative from one company visited Johnson Space Center in August 1978. Dr. W. H. Clingman has arranged for representatives from the other manufacturer to discuss the project at JSC in late January.

Gait Analysis Data Bank

BATeam Personnel: Dr. Richard Scearce

Technology advances have made gait analysis a more useful analytical tool for rehabilitation. Computers rapidly analyze large quantities of data that have been gathered using electromyographic electrodes, force plates, and motion picture cameras. Graphic displays present the integrated data in a format that allows detailed study and analysis of the patient's gait. Although these techniques are available, physicians and therapists seldom use them because much more data are available than can be assimilated in a reasonable time period. Thus researchers must devise means to extract, from the voluminous data, parameters that correlate well with specific diagnoses.

The problem originator, Dr. Sheldon Simon, has an extremely advanced gait analysis laboratory which he uses as a clinical tool. Records from each gait analysis performed in this laboratory are compiled into a gait analysis data bank. From this growing volume of data, the clinician must identify the parameters that correlate with disease states. Dr. Simon has asked whether NASA has technology, in the form of data processing, analysis, and storage techniques, applicable to his research.

The team has enlisted the talents of Dr. C. Frank Starmer, of Duke University, to assist Dr. Simon with his computerized data bank management. During a summer fellowship at Jet Propulsion Laboratory, Dr. Starmer mastered many of NASA's image-processing techniques and used them to develop the Duke Cardiovascular Data Bank. Dr. Starmer and Dr. Simon discussed the gait analysis data management problem and agreed that NASA technology appeared applicable.

Dr. Simon visited Dr. Starmer in November and inspected the Duke Cardiovascular Data Bank. He found the computer hardware and software compatible with his computer system, but he also found that the software would require some rewriting to be directly applicable to his needs. Fortunately, another university currently is rewriting much of this software as part of an effort to install the Duke Cardiovascular Data Bank in its hospital. The rewrite will be completed in 6 months. Dr. Starmer plans to give Dr. Simon a copy of the new software to adapt to his needs. The problem originator estimates this software package will save him years of development effort.

High-Speed DC Log Amplifier

BATeam Personnel: Dr. Clark Beall

Logarithmic processing of transducer signals is a unique data compression technique that greatly amplifies the smaller amplitude signals while attenuating larger ones. At the present time, several types of electronic function modules are available commercially, which convert AC analog signals to voltage levels proportional to the logarithm

of the input voltage level. However, the logarithmic conversion of DC signals is a more difficult problem because the frequency response of the logarithmic converter falls off as an inverse function of the DC signal amplitude.

A medical researcher has requested NASA assistance in identifying a logarithmic circuit that could process high-frequency low-current signals, such as those detected in experiments with artificial membranes.

A search of NASA literature has located a contractor report (vol. 1, contract NAS5-22577) which contains a description of a DC log amplifier that seems to fulfill the requirements of the original problem statement. This patented circuit will be evaluated in the near future and should find acceptance in the marketplace because log amplifiers are utilized in many areas of the chemical and physical sciences, research, and industry.

Horizontal Shower

BATeam Personnel: Dr. Clark Beall

The National Institute of Aging has funded a project for Research Triangle Institute and Dorothea Dix Hospital to identify means of improving health care for elderly bedridden patients. The NASA horizontal shower has been identified as an item of technology that has promise for safer and more convenient bathing of these patients.

Two models of the horizontal shower are ready for shipment from the NASA Ames Research Center. These showers were built from original NASA blueprints in response to a request from the RTI team to the Ames Technology Utilization Office.

As soon as bailment papers can be prepared, the shower units will be shipped to Dorothea Dix Hospital. There they will be evaluated for efficacy by a protocol examination of a variety of parameters.

Hydrocephalus Shunt

BATeam Personnel: Dr. Richard Scearce

Hydrocephalus is a condition of abnormal enlargement of the cerebral ventricles resulting from a rise in pressure of the cerebrospinal fluid. To relieve this pressure, surgeons implant a shunt to drain the excess cerebrospinal fluid into other cavities of the body. These shunts frequently fail because of inlet blockage of the device's ventricular catheter. The inlet is blocked by an ingrowth of choroid plexus, or the accumulation of cellular or fibrin debris. Mr. Bruce A. Banks of Lewis Research Center has proposed a catheter inlet design to minimize this blockage. He proposes a multiended inlet catheter, with hundreds of tiny inlets formed by ion-etching techniques. This design has these advantages: (1) the hole's small diameter inhibits tissue ingrowth, and (2) the multiplicity of holes limits the possibility of blockage.

The team worked closely with Mr. Banks and Sandy F. Felder of Lewis Research Center to evaluate the proposal, review the medical literature, and visit the problem originator. As a result of the team's discussions concerning the project with individuals within the National Institutes of Health, Dr. Ayub K. Ommaya of the National Institute of Neurological Communicative Disorders and Stroke will forward a written statement of his support of the design to Ray Whitten of NASA headquarters. Currently, the team is assisting Mr. Banks in arranging a pre-engineering design meeting between the potential manufacturer, several neurosurgeons (including the problem originator) and NASA-Lewis personnel to discuss the proposed design. A written summary statement from each attendee will be submitted to Mr. Whitten for his consideration in evaluating the project.

Improved Optics for Vitrectomy Surgery

BATeam Personnel: Ms. Doris Rouse

Visualization of the retina is an important diagnostic procedure in ophthalmology. Reflections from the eye lens or a clouded vitreous,

especially in older patients, can seriously impair the resolution of the image seen by the physician.

In response to the RTI team description of this problem, Don Buchele at Lewis Research Center has constructed an optical scanning system that minimizes the effects of light scattering and improves resolution. Dr. Oleg Pomerantzeff, the problem originator, visited Lewis Research Center with Ms. Rouse in July 1978 for a demonstation and was enthusiastic about Mr. Buchele's system.

Ms. Rouse visited Lewis Research Center in October with a representative from an ophthalmology instrumentation manufacturer to discuss the scanning system. This company is currently evaluating the efficacy and market potential of the device. Mr. Buchele has prepared a patent disclosure and journal manuscript.

Investment Casting of Chromium Alloys

BATeam Personnel: Dr. Clark Beall

Chromium alloys seem to be attractive alternatives to gold in the fabrication of dental fixtures. These alloys are 50 to 70 percent chromium, with the remainder either nickel or cobalt.

During fabrication, the molten chromium alloy is cast in a ceramic mold that has been made from an impression model of the patient's mouth. The problem encountered in this "investment casting" process is that the molten metal interacts with the ceramic surface of the mold to produce defective surfaces on the castings.

A comprehensive search of NASA literature on investment casting techniques has been concluded. The researcher has requested copies of many documents listed in the search abstract.

Bill Waters, of the Lewis Technology Utilization Office, has responded to the original problem statement. Mr. Waters has an extensive background in metallurgy and metal fabrication and has volunteered to assist the dental researcher in the application of NASA investment casting technology.

Microliter Fluid Delivery System

BATeam Personnel: Dr. Clark Beall

Several types of fluid pump systems have been identified during recent searches of NASA literature. One type of pump seems useful for delivery of fluid in the microliter range. Another type of pump is capable of delivery of fluid in the fractional milliliter volume up to 10 milliliters per minute.

An engineer at NASA Lewis Research Center has proposed a gas-driven pump which uses an electrochemical means to generate known volumes of gas which, in turn, moves the volume of fluid. Dr. Clingman, commercialization consultant to the RTI team, is evaluating the commercial potential of this pump.

Another type of gas-driven pump has been identified in Tech Brief MSC-14905. This pump uses CO_2 gas from a cartridge to power a small bellows system. The bellows produces a constant force which expresses fluid from a bladder at a constant preadjustable rate. The performance data for this pump are presented in the support package for the Tech Brief. Usable flow rates vary from 6 ml/minute to 100 ml/minute. About $\pm$ 5 percent accuracy is maintained. Improvement of low flow-rate performance of the pump by the incorporation of a feedback control is being investigated. This type of pump would be useful as a bedside infusion pump which could maintain long-term accuracy of flow.

Microwave Thermography

BATeam Personnel: Dr. Clark Beall

Microwave thermography theoretically can measure temperature gradients in the human body to 0.1 K. Therefore, the technique has application potential in several areas of medical research. A proposal for a biomedical evaluation of NASA microwave thermography has been prepared by Duke University Neurology Department researchers at the request of the Technology Utilization Office of Goddard Space Flight Center.

An essential item of instrumentation for this research is an expensive device known as a microwave radiometer. The research project

was unable to proceed at first because all the NASA radiometers at Goddard were in use. However, the medical researchers located another source for acquiring a radiometer on loan.

The project plan is to conduct a brief survey study to determine the potential for microwave thermography in neurological applications. Once several specific applications have been identified, requests for National Institutes of Health funding will be prepared.

To facilitate this survey study, the Goddard Technology Utilization Office has funded a grant of $5,000 to the researchers. These funds will be used for the immediate purchase of required laboratory materials.

Neonate Thermal Control Garment

BATeam Personnel: Ms. Doris Rouse

A newborn child's inability to compensate for body heat loss in the operating room can lead to serious metabolic and respiratory difficulties. As a result, surgery is especially hazardous in the first 4 weeks of life. Efforts to solve this problem include the use of heated operating tables, elevated room temperature and infrared radiation sources. Each method has an undesirable side effect such as hot spots on the infant, unacceptable working conditions for the surgical team, or uneven heating of the infant. A modification of the astronaut liquid-cooled space suit design has been applied to this problem.

NASA's Ames Research Center built an infant thermal control suit incorporating a series of parallel, closely spaced flow channels that are supplied with water from an external water bath and pump. A wrap-around, form-fitting modular design with Velcro fasteners is used to provide easy surgical access to various body areas of the infant.

Dr. J. N. Brown participated in a thermal control system commercialization meeting at Ames Research Center on March 14, 1978. Other participants included representatives of NASA, a medical devices manufacturing and distributing company, and the Stanford Bateam. The participants discussed the broad spectrum of medical applications of NASA technology and the present state of the art of that technology. Ongoing demonstration programs involving the thermal control systems were described.

The manufacturer's representative indicated a specific interest in possible commercialization of a neonate thermal control system that would be applicable during neonate surgery and in neonate temperature control in general. Three company representatives visited RTI and North Carolina Memorial Hospital in May 1978 to discuss the market potential for the neonate garment. A firm commitment to develop a product from this NASA technology, however, was deferred pending documentation of the garment's efficacy in surgery by Dr. Ernest Kraybill, the problem originator. Efforts to repair a defective water-bath and pumping unit have delayed this clinical evaluation for several months. Following an extensive evaluation of the unit by the RTI Electrical Safety Laboratory, Ames Research Center will send Dr. Kraybill a new unit for use in his surgical evaluations.

Neuroelectric Control

BATeam Personnel: Dr. Richard Scearce

Powered prostheses usually use myoelectric signals to control movements of the artificial limb. Since the available myoelectric signals often are not related to the desired movement, this control technique is not entirely satisfactory. The amputee usually must focus his entire attention to supervise movement of the prosthesis.

The problem originator, Dr. Carlo DeLuca, has proposed an alternate approach consisting of a neuroelectric control system. He proposes to detect, within the amputee's stump, the electrical signals being transmitted along several pertinent nerves and to use these signals to control an upper limb prosthesis. Special electrodes would detect the neuroelectric signal. A miniaturized implanted telemetry device would amplify the signal and transmit it to the prosthesis. The implanted system could be externally powered via an RF inductance coupling.

Dr. DeLuca and his colleagues developed a successful recording electrode, which was implanted in rabbits. The electrode successfully detected the motor control signals throughout long periods of implantation. Autopsy indicated that the nerves tolerated the electrode. Dr. DeLuca's group now must develop the implantable electronics to

process and transmit the control signal. He asked if NASA has technology or experience in the development of reliable miniaturized electronics that could be applied to this problem.

The team discussed the need with Dr. Doug O'Handley of Jet Propulsion Laboratory (JPL). They agreed that JPL has the capability and experience, especially in the areas of miniaturized implantable, biocompatible telemetry systems. The team forwarded copies of Dr. DeLuca's publication which described the neuroelectric control, with the design specifications of the proposed electronics to Dr. O'Handley. Dr. John W. Wojnaroski of JPL contacted Dr. DeLuca and discussed establishment of a collaborative effort. Dr. Wojnaroski plans to visit Dr. DeLuca in January 1979.

Neuropathic Tester

BATeam Personnel: Dr. Richard Scearce

The problem originator described the need for an improved method of diagnosing and evaluating the therapy for several disorders, including Parkinson's disease. In response to these needs, Langley Research Center engineering personnel developed the neuropathic tester. The problem originator evaluated the device and was pleased with its performance.

The team identified a manufacturer interested in marketing the neuropathic tester. The commercial version initially would be sold as a research tool, but its eventual market would be primarily as a diagnostic device. Before commercialization, however, two major problems must be solved: (1) how to pay for the clinical trials, and (2) how to redesign the device so it could be marketed at an acceptable price.

The solution to the first problem was quickly found. In March and June 1978, a team member visited Dr. Donald B. Calne of the National Institute of Neurological Communicative Disease and Stroke. Dr. Calne agreed to perform the clinical evaluation at no cost to NASA, if he was provided a commercial version of the tester. This arrangement was acceptable to the manufacturer.

The second problem has proved more difficult. The team has shipped the neuropathic tester to the manufacturer, where the engineering staff

is attempting to redesign it. The team also contacted an independent engineering firm, which agreed to study the device and submit a proposal to Langley Research Center for the redesign task.

New Method for Cleaning Teeth

BATeam Personnel: Dr. Richard Scearce

Dr. Joseph Heyman of Langley Research Center proposed a new method for cleaning teeth that would couple very low-level ultrasound into a water jet. An abrasive material such as diatomaceous earth would be suspended in the water. Powered by ultrasound energy, the suspended abrasive material would clean the teeth.

In August 1978, Dr. Heyman submitted a patent application for this device. In a meeting with an RTI team member, individuals from the National Institute of Dental Research verified the need for an improved cleaning technique, but indicated that they could not become involved until the feasibility of the concept had been demonstrated. Thus the team is working with Dr. Heyman and John Samos, the Technology Utilization Officer of Langley Research Center, to develop a functional prototype. In January 1979, Dr. Heyman will begin fabrication of the prototype.

Portable Cooling System for Quadriplegics

BATeam Personnel: Ms. Doris Rouse

One consequence of the quadriplegia caused by cervical spinal lesions is vulnerability to heat stress resulting from the inability to perspire below the level of injury. This condition is due to the interruption of autonomic neural pathways that mediate thermoregulatory sweating and vasomotion. Quadriplegics exposed to even moderately high temperatures risk hyperventilation, increased heart rate, and heat stroke. A portable cooling garment would eliminate this risk, thus opening new employment and daily living opportunities for individuals previously confined to a temperature-controlled environment.

Ames Research Center responded immediately to the RTI team's problem statement. A contract for fabrication of a prototype cooling vest has been

awarded. Engineers at Ames are designing a small, lightweight water cooling and pumping system for the unit. Design parameters for the vest and the pumping unit were derived from conversations with quadriplegics who will participate in the early evaluation of the system. This study is scheduled to begin in March 1979.

Powered Rim Control Wheelchair

BATeam Personnel: Dr. Richard Scearce

A two-axis joystick is the mechanism commonly used to control powered wheelchairs. However, elderly persons and persons with muscular deficiencies often lack the necessary skill and reaction time to operate this control safely. They may be capable of operating nonpowered wheelchairs with the hand-rim control, but they tire quickly. Thus these individuals are confined to their homes. With a powered wheelchair that uses a modified hand-rim control system, they would regain much of their lost mobility and independence.

The Applied Physics Laboratory of Johns Hopkins University designed and built a demonstration wheelchair with a powered rim control. The test results have been encouraging, but more engineering development is needed. The APL engineers plan to utilize NASA technology in the redesign effort.

Dr. Jules Taylor of Goddard Space Flight Center requested assistance from the team in planning a joint project on this wheelchair involving NASA, the National Institute on Aging, and Johns Hopkins University. The team is currently working with these organizations to coordinate the cooperative effort.

Pressure Transducer Calibrator

BATeam Personnel: Dr. Richard Scearce

The device was evaluated by a cardiologist, a major manufacturer of pressure transducers, and Dr. William H. Clingman. Their initial tests indicated that the device had to be modified to accept the manufacturer's transducers and to permit the introduction of a sterile

catheter into the pressure chamber. These modifications have been made. Testing will resume in January 1979.

Proper Technology for Cold Forming Titanium Alloys

BATeam Personnel: Dr. Clark Beall

Titanium alloys have been recently introduced into dentistry for the manufacture of prostheses of the human jaw. A final fit of the prosthesis to the patient involves the surgeon's adjusting and bending the metal with various types of pliers. This "cold forming" seems to introduce hairline fractures in the metal, resulting in the failure of a significant number of these titanium prostheses. A broken prosthesis must be replaced by another surgical operation.

Dental researchers have requested NASA assistance in solving the problems introduced by cold forming titanium metal. A comprehensive literature search has been concluded, and the researcher has requested copies of many documents listed in the survey abstract.

Bill Waters, of the Lewis Technology Utilization Office, has volunteered to assist the dental researcher with NASA metallurgical technology. Mr. Waters has extensive experience in metallurgy and metal fabrication.

Prosthetic Urinary Sphincter

BATeam Personnel: Ms. Doris Rouse

Urinary incontinence may result from congenital, traumatic, post-surgical, or neurogenic disorders. A malfunctioning urethral sphincter is often responsible for this inability to control voiding. In these cases, continence can be restored by an implanted device that occludes the urethra and allows voluntary voiding by the manual release of the occluding pressure. While results with currently available devices are encouraging from the standpoint of restoring urinary continence, two factors prevent widespread acceptance of these sphincter systems by the medical community: (1) surgical complexity of the implantation procedure, and (2) the high rate of device malfunction, often a result

of valve failure. The availability of a simpler, more reliable system, therefore, would represent a significant advance in the management of urinary incontinence.

In response to a problem statement by the team, Ray Helms and Harold Smyly of Marshall Space Flight Center designed a prosthetic sphincter system. The two primary advantages of this design are minimum surgery for implantation and improved miniaturized valves for maximum reliability. The valve incorporates design characteristics developed by NASA to obtain "zero"-leakage high-reliability valves for rocket systems.

Medical device manufacturers were asked to submit proposals to Marshall Space Flight Center for the fabrication and testing of a prosthetic urinary sphincter incorporating the NASA valve system. Three proposals were received from organizations experienced in the design and assembly of prosthetic devices. The proposals were reviewed by a panel consisting of the team, Marshall Space Flight Center and NASA Headquarters personnel and urologists, and a representative from the National Institute on Aging. The contract was awarded to Rochester General Hospital in July 1978. Valves for the prototype systems are currently being fabricated. Animal implant studies are scheduled to begin in July 1979. Commencement of clinical trials is planned for July 1980. Several medical device manufacturers have already expressed an interest in marketing the NASA sphincter system.

Simple Presettable Torque Brake System

BATeam Personnel: Dr. Clark Beall

The RTI team has responded to an inquiry from a manufacturer of low-cost exercise machines for a torque brake that would be easy to set to various torques yet could be reset exactly to any given torque value. With such a presettable torque brake, many people could use the exercise machine within a day by simply setting the torque brake to the level prescribed for them by their physicians.

A proposed solution to this problem is in the hands of the manufacturer. The manufacturer has fabricated several exercise machines

incorporating the proposed torque brake. These models are being evaluated in several medical centers by the manufacturer. Preliminary feedback to the RTI team is favorable. The RTI team is awaiting the manufacturer's decision to begin large-scale production of the exercise machine.

Teletype Test Set

BATeam Personnel: Dr. Clark Beall

The teletype (TTY) test set was designed to perform field maintenance and repair the typical home teletype installation used by the deaf for phone communications. Prototype models of the teletype test set have proved to be useful devices in field tests by teletype repairmen. Engineers at Gallaudet College have evaluated the device and plan to make several units for their own use in the maintenance of teletype sets on campus.

The present RTI team efforts concentrate on identifying a suitable manufacturer for the TTY test set. A team member's visit to the office of Eugene Rosen, of the NASA Small Business Advisor Office, resulted in the identification of several minority businesses capable of manufacturing the teletype test set. Contacts with these manufacturers have been initiated.

Tissue Viability

BATeam Personnel: Dr. Clark Beall

This problem has emphasized devising a means of sensing and measuring the viability of human body tissue by some remote means. The optical measurement of infrared absorbence changes in cellular cytochromes is a promising technique that would assay the intrinsic oxygenation of biological tissues. The difficulty lies in developing an instrumental protocol for this optical test.

Engineers at Marshall Space Flight Center have decided that reflectance spectroscopy is not sensitive enough to serve as the analysis technique and have suggested internal reflection spectroscopy be used. This technology is being investigated.

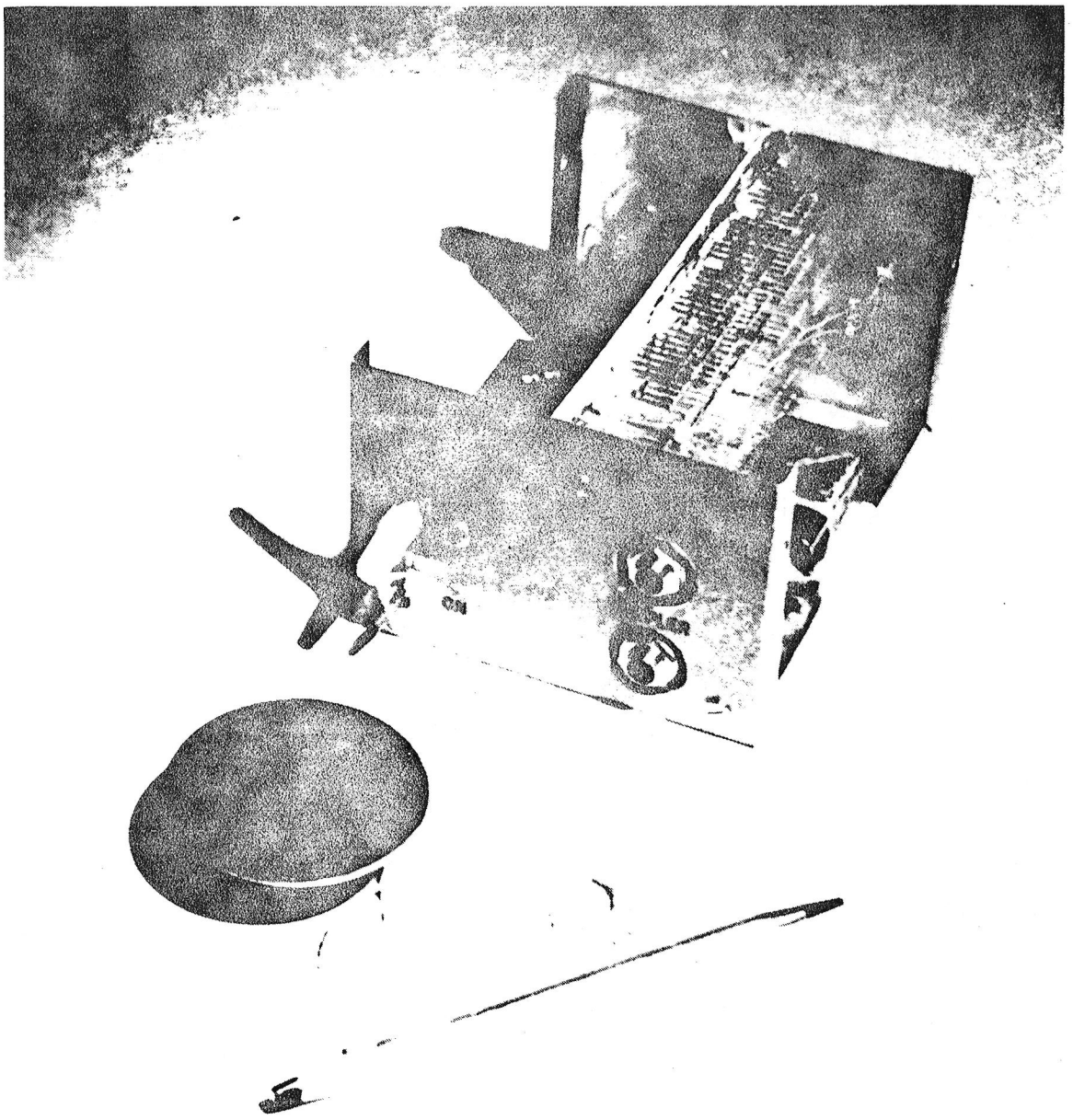


Figure 8. Teletype Machine Test Unit Prototype.

TTY Keyboard Tester

BATeam Personnel: Dr. Clark Beall

The TTY keyboard tester is a companion device to the TTY test set. Both devices are intended for use by repairmen who must service Baudot Teletypes in the homes of the deaf who use the teletypes for telephone communication. Preliminary designs have been formulated for the TTY keyboard tester by the NASA engineer at Langley Research Center who developed the TTY test set. The actual prototype development of the keyboard tester awaits the successful commercialization of the TTY test set.

Weight Alleviation Device

BATeam Personnel: Dr. Richard Scearce

An evaluation of the weight alleviation device at the Mississippi Methodist Rehabilitation Center demonstrated that this NASA-developed system could significantly reduce the time required for training the severely handicapped to transfer into and out of a wheelchair. This training, called transfer training, normally must be delayed until the patient has regained his strength. With this device, transfer training and strength-building therapy may be done concurrently, thus reducing the hospital stay as much as 3 weeks.

The weight alleviation device was redesigned to meet the marketing requirements for a less expensive device. In December 1978 this lower cost version was delivered to the Mississippi Methodist Rehabilitation Center for a 1-month evaluation. With favorable test results, a manufacturer has agreed to fabricate a commercial model. Clinical trials then will be initiated at other rehabilitation centers.

6.0 INACTIVATED PROJECTS

During the reporting period, 10 projects were removed from the team's active list. A successful NASA technology transfer was not anticipated in these projects as a result of inadequate mission agency support, or absence of a unique NASA solution, or the identification of a satisfactory non-NASA solution. These projects and the rationale for their inactivation are presented below.

Advanced Rugged Hearing Aid for Children
BATeam Personnel: Mr. Robert Beadles

In 1977 the Bureau of Education for the Handicapped approached NASA Headquarters concerning the need for a child's hearing aid capable of withstanding substantial vibration, shock, and occasional immersion in water. Currently available hearing aids, especially the devices designed for children, have unacceptable failure rates. The team prepared a problem statement for NASA Headquarters to distribute to the field centers. Several promising proposals were received. At this time, however, other committments forced the Bureau of Education for the Handicapped to withdraw co-funding support from the project. Further action has been delayed, therefore, pending the identification of another supportive mission agency.

A Tool for Rapidly Fusing Surgical Suture Knots
BATeam Personnel: Dr. Clark Beall

Ultrasonic melting devices are used in the plastics fabrication industry for forming spotwelds and seams in plastic sheeting. A small-scale device of this type would probably be a good solution to the problem of fusing surgical suture knots. A more promising NASA technology was not identified.

Electromagnetic Flowmeter Calibrator

BATeam Personnel: Dr. Richard Scearce

The team investigated several suggested solutions, but none of the ideas were suitable. No other solutions were identified and, therefore, the team closed this problem in February 1978.

Inert Material for Insertion into Cranial Burr Hole

BATeam Personnel: Dr. Clark Beall

The search for a machinable, durable, X-ray permeable material (for use as a tap for cranial burr holes) has concluded in a non-NASA solution. The material that shows the most promise is the Corning machinable ceramic. This material is commercially available and is being evaluated for this application by the medical researcher.

Infrared Two-Dimensional Imaging

BATeam Personnel: Dr. Clark Beall

The original problem statement described an application that has since proven untenable due to the very low light intensity available for imaging. The concept of an infrared light probe of living tissue is a viable concept, however. This concept is being considered as part of the solution to the RTI team problem entitled "Tissue Viability."

Sealing of Amputation Stump Neuromas to Prevent Pain

BATeam Personnel: Ms. Doris Rouse

The end of a severed nerve often develops a bulb or swelling called a neuroma which is hypersensitive to pressure or traction. A neuroma represents a distorted portion of the injured nerve in which regenerating axons have escaped the normal perineurial barrier to grow in a disorderly fashion. Neuromas which form in amputation stumps are particularly painful because they occupy an unprotected position at the new extremity where they are subject to repeated blows, pressure and

irritation. The amputee is often incapacitated by severe pain, and, in these cases, the constant need for painkilling drugs can lead to drug addiction.

A thorough search of the medical literature revealed that the numerous techniques employed to relieve the neuroma pain had all been unsuccessful. The possibility of sealing the severed nerve to prevent neuroma formation, however, appeared to be the most promising solution. Attempts to cap the nerve with silastic were unsuccessful due to the inability of preformed caps to form an effective seal of the nerve. An adhesive material, rather than a preformed cap, was needed to form a sufficient seal. Neither the material nor the method of application should injure the nerve.

Response to the problem statement from the NASA field centers indicated that no unique NASA technology was applicable to the solution of the problem. Names of individuals to contact in the polymer industry, however, were provided by chemists at Langley Research Center.

In a review of the medical literature, a paper in a conference entitled "Kunstoffe in der Chirurgie" was found. The paper discussed the use of cyano-acrylates in peripheral nerve repair. The adhesives found unsuitable for nerve repair due to their inhibition of nerve growth may be quite useful in preventing neuroma formation at a severed nerve ending. The paper was translated from German by Doris Rouse and forwarded to the problem originator who is currently testing these compounds with animals.

The problem and the results of the literature search were presented to the Surgical Products Division of an adhesive manufacturing corporation. They were very positive in their response and are currently working with the problem originator.

Although a NASA solution for this medical need was not available, the activities of the team did provide the basis for an industry/clinician research effort that may result in a new surgical treatment of wide impact.

Upgrading of Performance of the Tracheal Stethoscope for Reliable Respiration and Heart Rate Monitoring During Surgery

BATeam Personnel: Dr. Clark Beall

Several companies are now marketing esophageal monitoring probes for the measurement of either electrocardiogram, or heart and lung sounds, or core body temperature. No unique NASA technology was ever identified for combining several of these medical parameters into a single probe.

UV Dosimeter/Sunburn Monitor

BATeam Personnel: Dr. Clark Beall

This problem failed to receive RTOP funding due to the lack of cofunding. Cofunding for research and development is not anticipated in the next year.

Vaginal Mucosal Blood Flow

BATeam Personnel: Dr. Richard Scearce

The problem originator has developed his own solution to this problem. Since the solution is adequate and NASA technology is not needed, this problem is closed.

V-Slotted Head Screws

BATeam Personnel: Dr. Richard Scearce

The objective of this project was to evaluate the use of V-slotted head screws in prostheses and orthoses. The team obtained the screws and special screwdrivers necessary for the problem originator to fabricate several braces. Faulty screwdrivers, however, invalidated the initial evaluation. Before another test could be arranged by the team, the problem originator died. The project was closed pending the identification of another innovative, aggressive investigator.

7.0 TECH BRIEF STUDY

During 1978 the RTI team conducted an informal study of the NASA Tech Brief publications to evaluate the potential of the Tech Briefs as a source of ideas for marketable biomedical products. The study was based upon the hypothesis that marketable products may be derived more easily from those items of NASA technology that generated the most inquiries for Tech Brief Technical Support Packages.

Procedure

Two individuals who were familiar with the NASA technology transfer procedure surveyed a representative sample of NASA Tech Briefs published during 1970-1975 and selected those titles that seemed likely candidates for biomedical applications. The titles then were matched against a listing of the "most popular" Tech Briefs of this period. Douglas Johnson, of Denver Research Institute, supplied the RTI team with a list of the "10 most popular" Tech Briefs in each of the nine categories into which Tech Briefs were segregated during the period 1970-1975. The Denver Research Institute's computer also provided a listing of approximately 40 randomly selected Tech Briefs in each of the nine categories. Copies were made of all 502 Tech Briefs, and the copies were stacked by NASA serial number designation. These Tech Briefs were evaluated by Dr. Clark Beall, of the RTI NASA BATeam, and Dr. Theo Pilkington, chairman of the Duke University Biomedical Engineering Department. The purpose of the evaluation was to select those Tech Briefs that seemed to have potential utility in biomedical product development. A short paragraph was requested to describe the more obscure application ideas.

Results

Table 6 is the breakdown of the Tech Briefs selected in the evaluation. Note that the "random" listing from the Denver Research Institute contained 14 Tech Briefs that had already been listed on the "10 most popular" list.

Table 6. Breakdown of Tech Briefs Selected for Evaluation

Tech Classification	Random Listing		"Most Popular" Listing	Duplicates (both lists)		Total Tech Briefs in Study
1	61	+	11	2	=	70
2	56	+	11	1	=	66
3	69	+	10	1	=	78
4	66	+	11	1	=	76
5	27	+	10	1	=	36
6	42	+	10	5	=	47
7	37	+	9	1	=	45
8	23	+	9	2	=	30
9	44	+	10	0	=	54
	425		91	14		502

Table 7 gives the raw data from the evaluation of the Tech Brief selection. Note that about one-third of the selected titles were from the Life Sciences category, so the applications potential of these was obvious. Those selections not from the Life Sciences category were set aside for further study.

Table 7 shows that Drs. Beall and Pilkington selected about one each of the "10 most popular" Tech Briefs in each of the nine Tech Brief categories. The table also shows the relative numbers of all NASA Tech Briefs falling within the nine categories during the period 1970-1975.

Of all the titles that were selected by the evaluation as showing promise for biomedical applications, only six titles were selected by both persons. Table 8 lists the titles of these Tech Briefs. Three of these six titles were from the "10 most popular" listing of Tech Briefs. These three items deserve special attention:

1. One describes a device that is now commercially available (70-10282),

2. One describes a device very similar to the subject of a current RTI BATeam problem statement (70-10508), and

3. One is a computer program from Marshall Space Flight Center (72-10614) and can be obtained through the COSMIC facility.

Table 7. Tech Brief Selection

Tech Brief Category	Theo Pilkington		Clark Beall	
	Random List	"Most Popular" List	Random List	"Most Popular" List
1. Electronics	7	2	9	1
2. Electric Systems	8	2	7	1
3. Physical Science	7	1	7	1
4. Materials Chemistry	3	1	2	1
5. Life Sciences	19	1	7	3
6. Mechanics	0	1	2	1
7. Machinery, Tools, etc.	1	0	1	0
8. Fabrication Technology	0	1	0	0
9. Computer Programs	3	1	2	1
	48	10	37	9

Table 8. Titles of Tech Briefs Chosen in Common

Number	Titles
70-10096	Signal Condition for Photomultiplier Tube
70-10282*	High Speed TV Camera System Processes Photo Data
70-10508*	Log Amplifier for Biological Signals
70-10528	Technique for Analyzing Human Respiratory Process
72-10614*	Spectral Analysis of Multiple Time Series
75-10170	Continuous Detection of Viable Microorganisms

*Also listed in "10 most popular" Tech Briefs.

Conclusion

If both individuals had selected titles at random without reading the Tech Briefs for content, the probability for selection of a "most popular" Tech Brief would have been 92/503, or 0.183. The study showed that both persons who participated in the evaluation displayed about the same probability (0.172 and 0.200) for selecting one of the "most popular" Tech Briefs. But these values were not significantly different from the random selection value. Thus, it seems that, even a person familiar with the NASA Technology Utilization program cannot select a significant percentage of Tech Briefs that have proven popular to the nationwide scientific and technical readers of Tech Briefs.

The conclusion stated above affirms the operating procedure utilized by the RTI BATeam for the transfer of technology. The team has always advocated the advantages of "pulling" technology from the NASA source, in contrast to the philosophy of "pushing" technology from the NASA source. The concept of "pushing" technology involves the selection of an item of NASA technology as being useful in a particular application, and attempting to promote consumer utilization. Note that the selection step, involved in "pushing" technology, closely resembles the attempt in this study to select technology items with wide public acceptance and interest.

An economy of effort is obtained with the technique of "pulling" technology, as practiced by the RTI Biomedical Applications Team. In this process, the need is first carefully identified within the biomedical field. Then the field of NASA technology is searched for the item of technology that satisfies this need. With this method, widespread consumer acceptance is seldom a problem. The method also seems to have more potential for identifying second applications of technology, in which a technology item is used in a way distinctly different from the original NASA use.

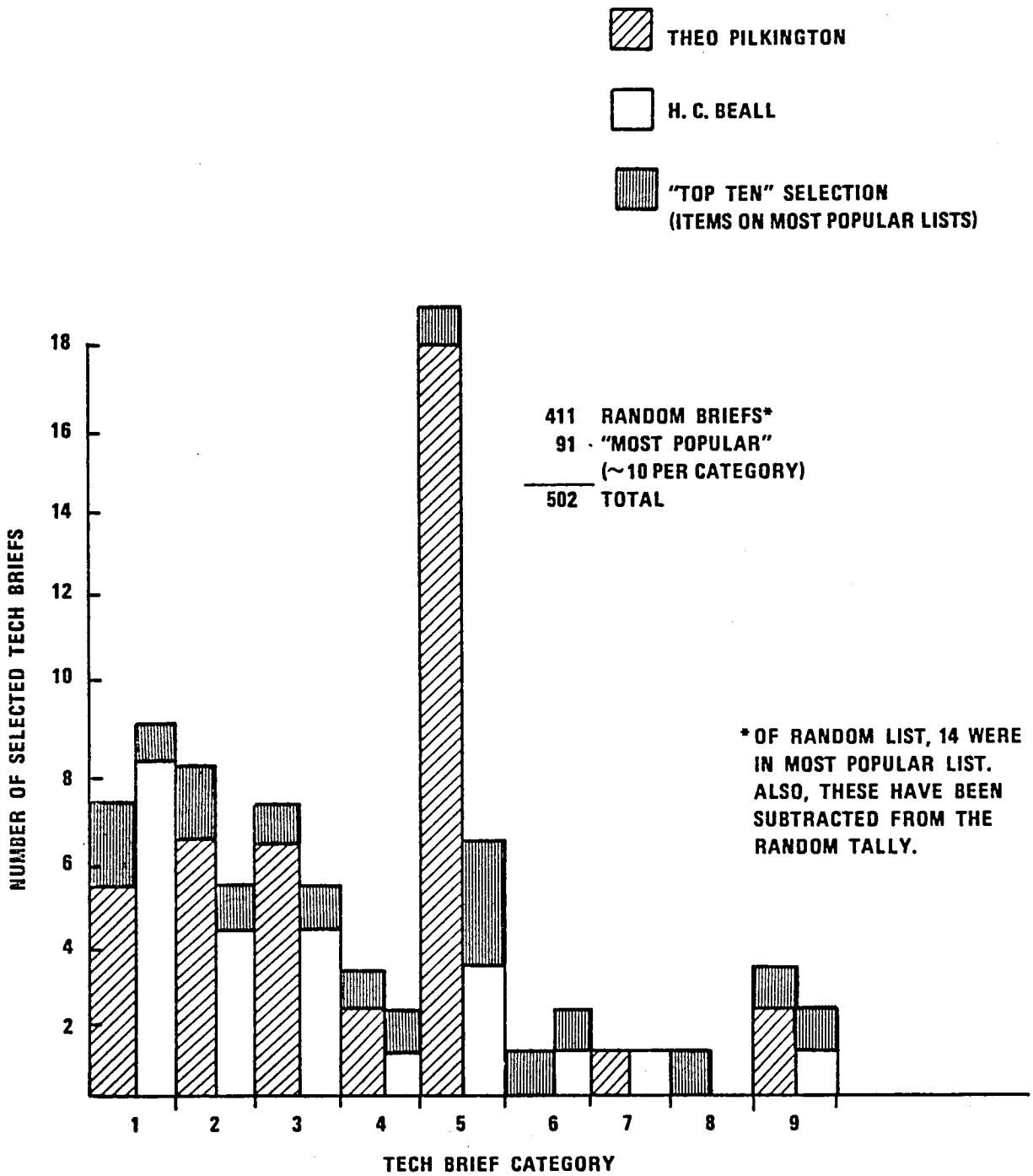


Figure 9. Summary of Tech Brief Study Results

8.0 CONCLUSIONS

During the reporting period, one commercial technology transfer and six institutional technology transfers were completed. Twenty-six of 27 currently active transfer cases have the potential for introducing new or improved commercial medical products incorporating NASA technology. These numbers reflect the emphasis in the RTI Biomedical Applications Team program on transferring technology by the introduction of commercially available medical products. It is through this commercialization of NASA technological solutions that widespread utilization is achieved. To better accomplish this goal, the team has studied in depth the technology transfer process within the context of the medical field.

The insights gained from this study and from the team's experience have resulted in the team's present methodology. By adapting its methodology to the requirements for commercialization, the team is increasing its effectiveness and efficiency in converting medical problems and needs into commercial solutions based on aerospace technology. The team concentrates on medical problems that are perceived as problems by a significant fraction of the medical community and on obtaining the participation of the medical manufacturing industry throughout the technology transfer process. Frequent discussions by each team member with industry representatives responsible for new product development have led to a keen understanding of the potential difficulties in the transfer of technology into the medical devices industry. The team has also stressed a more thorough survey of the potential user population to determine the desired configuration and specifications for the medical devices under consideration.

Problem solving activities during the reporting period have involved all NASA Field Centers. This broad interaction between the team and NASA scientists and engineers engaged in a broad spectrum of activities has been an essential part of the identification of technologies relevant to medical problems. By the combined use of NASA computer information searches and direct contacts with field center staff, the team has been able to identify the most appropriate aerospace technology for solving specific medical problems.

Team experience has demonstrated that interaction with medical mission agencies is important to the Biomedical Applications Team program. The expertise and experience of the medical and engineering staffs of these agencies in specific medical areas can assist the team in validating the importance of specific medical needs. In addition, the support by these agencies of the objectives in particular transfer cases can be of assistance in the commercialization process. The RTI team has worked extensively with mission agencies by participating in a number of workshops and by consulting with individuals on specific transfer cases. In addition, the RTI team has been an active participant in the establishment of interagency agreements between NASA and mission agencies.

Perhaps the most important lesson that can be derived from the team's experience in working with medical manufacturers is that technology transfer in medicine is extremely complex. The barriers to technology transfer are numerous and include the characteristics of medical device manufacturers, medical marketing distribution practices, acceptance of a new product by the medical community, and all the well-known barriers to technology transfer in general and not peculiar to the medical field. The team's better understanding of medical manufacturing, marketing, and distribution has enhanced its ability to form successful commercialization strategies. However, there is still much to be learned concerning this aspect of medical technology transfer and the team will continue and expand its interactions with the medical industry in order to gain this understanding. Of most importance in this area are ways of effectively handling patents and licensing agreements. More generally, all aspects of government-industry interfaces must be understood and facilitated.

REFERENCES

1. Public Law No. 85-568, National Aeronautics and Space Act of 1958.

2. Haggerty, J. J., Spinoff 1977--An Annual Report, National Aeronautics and Space Administration, January 1977.

3. Brown, J.N., Applications of Aerospace Technology in Biology and Medicine, Research Triangle Institute, Research Triangle Park, North Carolina, December 1977.

4. University of Wisconsin, UW Biomedical Applications Team, University of Wisconsin-Madison, Madison, Wisconsin, December 1977.

4. Stanford University, Biomedical Technology Transfer, Stanford University School of Medicine, Palo Alto, California, December 1977.

6. Brown, J.N., W.A. Fisher, and F.T. Wooten, "Medical Technology Transfer," Proceedings of the Fifteenth Space Congress, Cocoa Beach, Florida, April 26-28, 1978.

7. Teich, A., et al., Federal Laboratories and Technology Transfer: Institutions, Linkages, and Processes, Syracuse University Research Corporation, Syracuse, New York 13210, March 1974.

8. Kohler, B.M., et al., "A Behaviorial Study of International Technology Transfer Between the United States and West Germany," Research Policy, Vol. 2, 1973, pp. 160-184.

9. Braahs, H., "National Science Policy and Technology Transfer," in NSF 67-5, Technology Transfer and Innovation, National Science Foundation, 1967.

10. Ruttan, V.W. and Y. Hayami, "Technology Transfer and Agricultural Development," Technology and Culture, Vol. 14, No. 2, Part I, 1973, pp. 119-151.

11. Committee on the Interplay of Engineering with Biology and Medicine, National Academy of Engineering, Study of Aerospace Technology Utilization in the Civilian Medical Field, Final Report to National Aeronautics and Space Administration.

12. Tannol, C.P. and E.M. Rogers, "Diffusion Research Research Methodology: Focus on Health Care Organizations," in G. Gordan and G.L. Fischer (eds.), The Diffusion of Medical Technology, Ballinger Publishing Co., Cambridge, Mass., 1975, pp. 66-69.

13. Wilson, V.E., "The Structure of the Health Industry and its Import for Managing Technology," in W.J. Abernathy, A. Sheldon, and C.K. Prahalad (eds.), The Management of Health Care, Ballinger Publishing Co., Cambridge, Mass., 1974.

APPENDIX A

PROJECT ACTIVITY SUMMARY

APPENDIX A-1

SUMMARY OF BIOMEDICAL APPLICATIONS TEAM ACTIVITIES

Activity	Number
Commercial Technology Transfers	1
Institutional Technology Transfers	6
New Problems	17
IAC Information Searches	6
Medical Literature Information Searches	21
Problem Statements Circulated	7
Responses to Problem Statements	25
Projects Inactivated	10
Active Project Investigations	27
Field Centers Team Worked with in 1978	10
Professional Papers Published or Presented at Professional Meetings	8

APPENDIX A-2
TECHNOLOGY TRANSFERS

Commercial Technology Transfers

Digital TV Display Device

Institutional Technology Transfers

EMG Spectral Analysis
Enhancement of X-Ray Diffraction Images
Lung Sound Modeling
Multi-Level Care Management
Optical Profilometer
SCA Receiver for the Handicapped

APPENDIX A-3
NEW PROBLEMS

Problem Title

Breast Cancer Screening Techniques
EMG Spectral Analysis
Enhancement of X-Ray Diffraction Images
Gait Analysis Data Bank
High Speed DC-Log Amplifier
Hydrocephalus Shunt
Infrared Two-Dimensional Imaging
Investment Casting of Chromium Alloys
Meter for Very Slow Fluid Flow
Microliter Fluid Delivery System
Microwave Thermography
Multi-Level Care Management
Neuroelectric Control
Portable Cooling System for Quadriplegics
Powered Rim Control Wheelchair
Proper Technology for Cold Forming Titanium Alloys
UV Dosimeter/Sunburn Monitor

APPENDIX A-4

INACTIVATED PROJECTS

Problem Title

Advanced Rugged Hearing Aid for Children

A Tool for Rapidly Fusing Surgical Suture Knots

Electromagnetic Flowmeter Calibrator

Inert Material for Insertion into Cranial Burr Hole

Infrared Two-Dimensional Imaging

Sealing of Amputation Stump Neuromas to Prevent Pain

Upgrading of Performance of the Tracheal Stethoscope

UV Dosimeter/Sunburn Monitor

Vaginal Mucosal Blood Flow

V-Slotted Head Screws

APPENDIX A-5

ACTIVE PROJECTS AS OF DECEMBER 31, 1978

Problem Title

Breast Cancer Screening Technique
Composite Material Applications
Controlled Rate of Freezing a Liquid
Female Incontinence
Gait Analysis Data Bank
High Speed DC-Log Amplifier
Horizontal Shower
Hydrocephalus Shunt
Improved Optics for Vitrectomy Surgery
Investment Casting of Chromium Alloys
Meter for Very Slow Fluid Flow
Microliter Fluid Delivery System
Microwave Thermography
Neonate Thermal Control Garment
Neuroelectric Control
Neuropathic Tester
New Method for Cleaning Teeth
Portable Cooling System for Quadriplegics
Powered Rim Control Wheelchair
Pressure Transducer Calibrator
Proper Technology for Cold Forming Titanium Alloys
Prosthetic Urinary Sphincter
Simple Presettable Torque Brake System
Teletype Test Set
Tissue Viability
TTY Keyboard Tester
Weight Alleviation Device

BREAST CANCER SCREENING TECHNIQUE

BATeam Personnel: Dr. Richard Scearce

Problem Statement

A mass screening technique that can reliably predict which women are likely to develop breast cancer is needed.

Breast cancer is the leading cause of cancer deaths in American women. At the present time, the only hope of modifying the picture is the detection and removal of the lesion prior to its metastasis. This requires a cancer detection technique capable of identifying: (1) most malignancies in their subclinical stage (tumors less than 5 mm in diameter), and (2) the fast growing cancers in their premalignant stage. Although much progress has been made in developing diagnostic techniques, none of the available screening techniques fully meet the requirements.

Diagnostic Techniques

Mammography: Dr. Gerald A. Dodd (ref. 1) recently reviewed the status of the four clinical techniques used to detect breast cancer: (1) X-ray mammography, (2) thermography, (3) physical examination, and (4) ultrasound. He found X-ray mammography produces the best results. In correctly diagnosing breast cancer, it has an overall true-positive rate of 87%. This includes the diagnosis of subclinical cancers. Dr. John N. Wolfe (refs. 2, 3) suggests mammography can also be combined with other techniques to predict which women are likely to develop breast cancer. Based on the breasts' radiographic appearance, Dr. Wolfe can classify women into four cancer-risk categories. His technique is promising, but the technique is still under evaluation by the National Cancer Institute (NCI). If verified, the technique will enhance X-ray mammography's potential as a screening tool. However, X-ray mammography has two major limitations: (1) its decreased effectiveness in firm, young breast tissue, and (2) its use of low level ionizing radiation which could be carcinogenic. Thus, physicians are not routinely using X-ray mammography to screen women under fifty-one years of age. Some better or complementary screening technique is needed.

Thermography and Physical Examination: Neither thermography nor physical examination, according to Dodd (ref. 1), should be used as the sole modality in a breast cancer screening program, as both systems fail to reliably detect subclinical cancers. Their greatest use is as an adjunct to X-ray mammography.

Together, these three methodologies significantly increase the accuracy of screening for preclinical cancer (ref. 1), but this screening system is ineffective against fast growing cancers.

Ultrasound: The spatial resolution presently obtainable in ultrasonograms is inadequate for the detection of subclinical cancer (ref. 1). However, in the last five years research in water bath instruments has shown that ultrasound has a role in the examination of the breast, particularly in screening the breasts of young women (ref. 4). Two new scanners were recently made commercially available, while several other breast scanning devices are under development. All have improved spatial resolution, but it is questionable if they are adequate to reliably detect subclinical cancers. NCI has contracted with the problem originator to evaluate ultrasound as a screening technique using two of the latest scanning devices.

Screening Concept

Screening results indicate ultrasound and X-ray mammography are complementary (ref. 4), ultrasound working better in the young breast while mammography works better in the older breast. If Dr. Wolfe's techniques (refs. 2, 3) could be adapted to work with ultrasound, the physician could identify the young women who are high risk for developing breast cancer, without exposing these women to ionizing radiation. Unfortunately, skilled and experienced personnel are required to analyze the images produced by ultrasound and mammography. This would make a mass screening program very expensive. If these images would be analyzed on a digital computer and simple algorithms were used, it would be possible to develop a microprocessor system to perform the analysis. Since the new ultrasound scanners and X-ray mammography units digitally process the image, the analysis system could be integrated into the scanner. The scanner would then automatically provide the mammogram and the risk category.

The constraints and specifications for a breast cancer screening technique are as follows:

(1) Algorithms must automatically analyze the images and quantitate the risk level.

(2) Processing algorithms must be digital and it must be possible to put these algorithms in microprocessors.

(3) Scanning technique must not use ionizing radiation.

References

1. Dodd, Gerald D., "Present Status of Thermography, Ultrasound, and Mammography in Breast Cancer Detection," Cancer, June Supplement 1977, Vol. 39, pp. 2796-2805.

2. Wolfe, John N., "Risk for Breast Cancer Development Determined by Mammographic Parenchymal Pattern," Cancer, May 1976, Vol. 37, No. 5, pp. 2486-92.

3. Wolfe, John N., "Breast Patterns as an Index of Risk for Developing Breast Cancer," Amer. J. of Roentgen., Rad. Ther. and N. Med., June 1976, Vol. 126, No. 6, pp. 1130-1139.

4. Kossoff, G., "Diagnostic Ultrasound--The View from Down Under," J. of Clin. Ultrasound, June 1978, Vol. 6, No. 3, pp. 144-149.

INVESTMENT CASTING OF CHROMIUM ALLOYS

BATeam Personnel: Dr. Clark Beall

Problem Statement

There is a move away from using gold in the construction of dental fixtures, and chromium alloys seem to be attractive alternatives. These alloys are fifty to seventy percent chromium, with the remainder being either nickel or cobalt.

The metal dental fixture is actually made in a mold, part of which is formed from the impression model of the patient's mouth, and the remainder being sculptured by the dental technician. The mold is a ceramic which can withstand the chromium based molten alloys. This process is referred to as "investment casting." The problem that has been encountered with the chromium alloys is that the molten metal and the ceramic mold material interact so as to produce defective surfaces for the castings.

The dental researcher has requested a NASA technical information search and advice from NASA personnel for determining the ideal conditions, parameters, and techniques for performing perfect investment casting of chromium alloys.

PROPER TECHNOLOGY FOR COLD FORMING TITANIUM ALLOYS

BATeam Personnel: Dr. Clark Beall

Problem Statement

Titanium alloys have recently been introduced into dentistry for the manufacture of prostheses of the jaw. These prostheses replace major sections of the upper and/or lower jaw that have been surgically removed because of cancer. Castings of the metal alloy are "cold formed" at room temperature, by the surgeon with various types of pliers, in order to achieve a final fit to the patient. A significant number of these prostheses have failed after installation due to chipping, cracking, or major fracture. A broken prostheses must be replaced by yet another surgical operation.

The dental experts suspect that the failure of these titanium alloy prostheses is due to fatigue susceptibility. They believe that the fatigue is probably induced as a result of the cold forming that is done during the implant surgery. It may be that minute surface cracks are caused by the cold forming of the alloy. Human body fluids perhaps invade the metal alloy via these surface cracks, thus causing the cracks to propagate into large structural defects.

Two types of titanium metal alloys have been used for these prostheses: "commercial purity" titanium, and "aircraft alloy" (titanium-6-Aluminum-4-Vanadium).

The dental researchers have asked for NASA technical and metallurgical advice in any of the following areas:

(1) Comprehensive details about the process of fatigue susceptibility of the two above types of titanium alloy,

(2) The proper procedure for cold forming titanium alloys,

(3) Possible surface treatments, such as etching procedures, that can be used to eliminate the microscopic surface cracks that are caused by cold forming of these titanium alloys.

POWERED RIM CONTROL WHEEL CHAIR

BATeam Personnel: Dr. Richard Scearce

Problem Statement

Although many companies market powered wheelchairs, the mechanism used throughout the wheelchair industry to guide and control powered wheelchairs is some form of a two axis joy stick. This mode of control is practical for many wheelchair users, but some elderly persons and persons with muscular deficiencies lack the necessary skill and time response to operate the wheelchair--especially in confined quarters. They may be capable of operating nonpowered wheelchairs with hand-rim control, but they quickly become fatigued and cannot maintain their mobility. Since they are unable to master the joy stick control, they cannot use available powered chairs. Thus, these individuals are isolated to the confines of their homes. If they had a powered wheelchair that used a control system similar to the hand rim control, they would regain much of their lost mobility.

Applied Physics Laboratory of Johns Hopkins University has proposed a powered rim control technique for wheelchairs. They decoupled the hand rim of a conventional manually powered wheelchair from the wheel and used a transducer to measure the hand rim's velocity. The transducer output controls the power drive to each wheel. The concept is similar to power steering.

The Applied Physics Laboratory fabricated and tested a demonstration model. The results were very encouraging, but more engineering development is needed before a practical wheelchair is available. The problem originator believes NASA technology can significantly aid in this redesign effort. He sees NASA technology as applicable to at least three of the wheelchair's subsystems: high efficiency power drive, integrated electronic control circuitry, and battery technology. A project for developing NASA's battery technology is already planned, but the power drive and circuitry needs are unmet.

The power drive must be lightweight and reliable. It must be capable of providing all the power needed to drive a wheelchair. In some designs, the power drive should be able to share the total load requirements with the wheelchair user. (The maximum force a user can exert against the rim is 5 pounds).

Circuit technology for 1/2 horsepower motor pulse width modulated power drives and optical tachometer circuits are needed. Monolithic hybrid solid-state is preferred for a major portion of these systems because they are small, lightweight, reliable, and have low power consumption.

NEUROELECTRIC CONTROL

BATeam Personnel: Dr. Richard Scearce

Problem Statement

The effective neuromuscular control of the position of a human limb resembles what is known to engineers as a closed-loop control system. Various sensory signals travel toward the brain through major nerves to form the "feedback" path. Motor signals travel from the central nervous system through adjacent nerve bundles and form the "forward" path. Ideally, a prosthesis should utilize whatever muscles and nerves remain at the injury site to form an artificial control system that functions much like the original closed-loop system of the missing limb. In the case of virtually all of the presently available powered prostheses, vision provides the primary feedback. The prosthesis control system and the neuromuscular control system can be united to form the forward control path. The actual interface between the two components of the forward control path is a myoelectrode. This electrode is mounted on the skin above a selected muscle. The electrode detects the electrical signal generated by the contracting muscle. A control system using this arrangement is called a myoelectric control system.

Myoelectric control is not entirely satisfactory. This is particularly true when the available myoelectric signals do not originate from muscles that were directly related to the human limb's motion that now is to be replicated by the artificial limb. Myogenic control is also not satisfactory when the control electrode is situated on a muscle that exerts nonporportional control over the motion of a body limb. In such cases, the amputee must concentrate to supervise the movement of the prosthesis. This "unnatural" control is one of the limiting factors in patient acceptance of powered prostheses. Variations in electrode placement and electrode interface characteristics make the control even more "unnatural."

In prosthetics, the term "degree-of-freedom" refers to a pair of antagonistic motions of a limb or prosthesis (for example, flexion and extension of the elbow). The electrode interface and its impedance become major concerns in the control of multiple degrees-of-freedom prostheses. Such prostheses require several electrode pairs. The impedance of each differential pair must be maintained reasonably stable with respect to each other. This stability is

difficult to achieve when the patient perspires. These electrode pairs must also be consistently positioned each time the prosthesis is fitted to the amputee. Currently, this positioning problem is unresolved. Thus, it is apparent that myoelectric control has serious deficiencies.

The problem originator has proposed an alternate approach consisting of a neuroelectric control system. Figure 1 is an artist's conception of the system. He proposes to detect within the amputee's stump the electrical signals being transmitted along several pertinent nerves and to use these signals to control an upper limb prosthesis. Special electrodes detect the neuroelectric signal. The miniaturized implanted telemetry device amplifies the signal and transmits the signal to the prosethesis. The implanted system is to be externally powered via an RF inductance coupling. Figure 2 is a block diagram of the system. The design specifications of the implanted system are described in the following lists:

A. Amplifier Differential

Input impedance	>10 MΩ (resistance between each input and ground)
Shorted input noise	≥ 5 mV
Voltage input range	± 5 μV to ± 800 μV p-p
Bandwidth	flat response with 3 dB points at 100 Hz and 6 kHz
Gain	to be chosen
Gain stability	+ 5% with power supply variations caused by movement of induction coils
Common Mode Rejection Ratio	≥ 80 dB
Temperature Stability	< 0.1 μV/Δ 1¼C referred to input voltage

B. Transmitter

FM modulated	
Center Frequency	Three different values to be chosen so that the three channels of information can be transmitted simultaneously
Modulation Sensitivity	To be chosen
Transmitting Distance	2 meters (7 cm through body tissue)

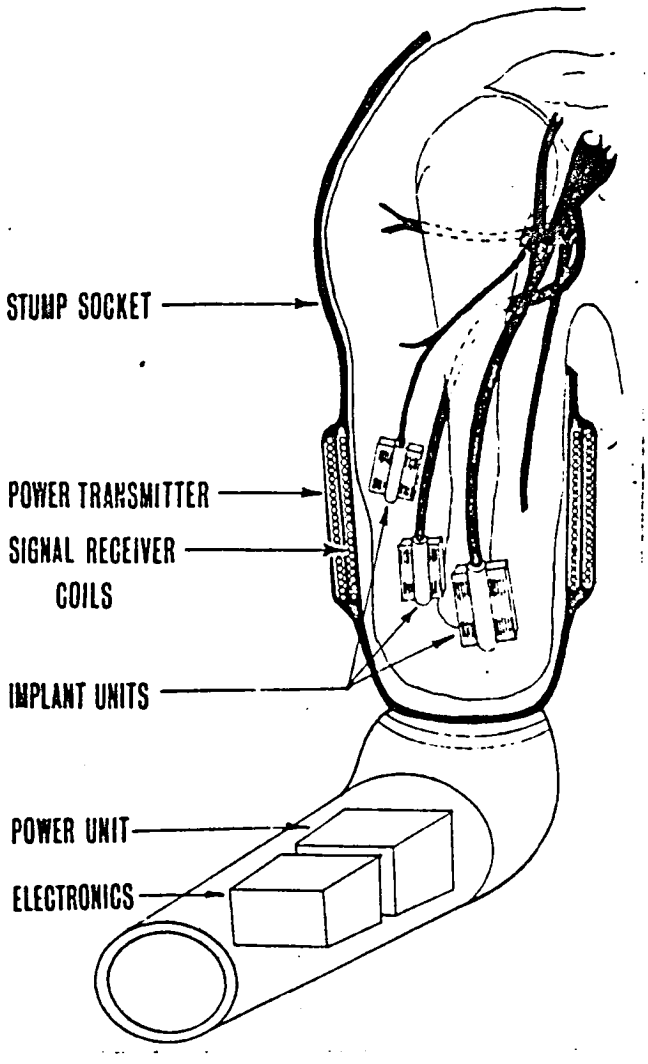


FIGURE 1. PROPOSED NEUROELECTRIC CONTROLLED UPPER LIMB PROSTHESIS

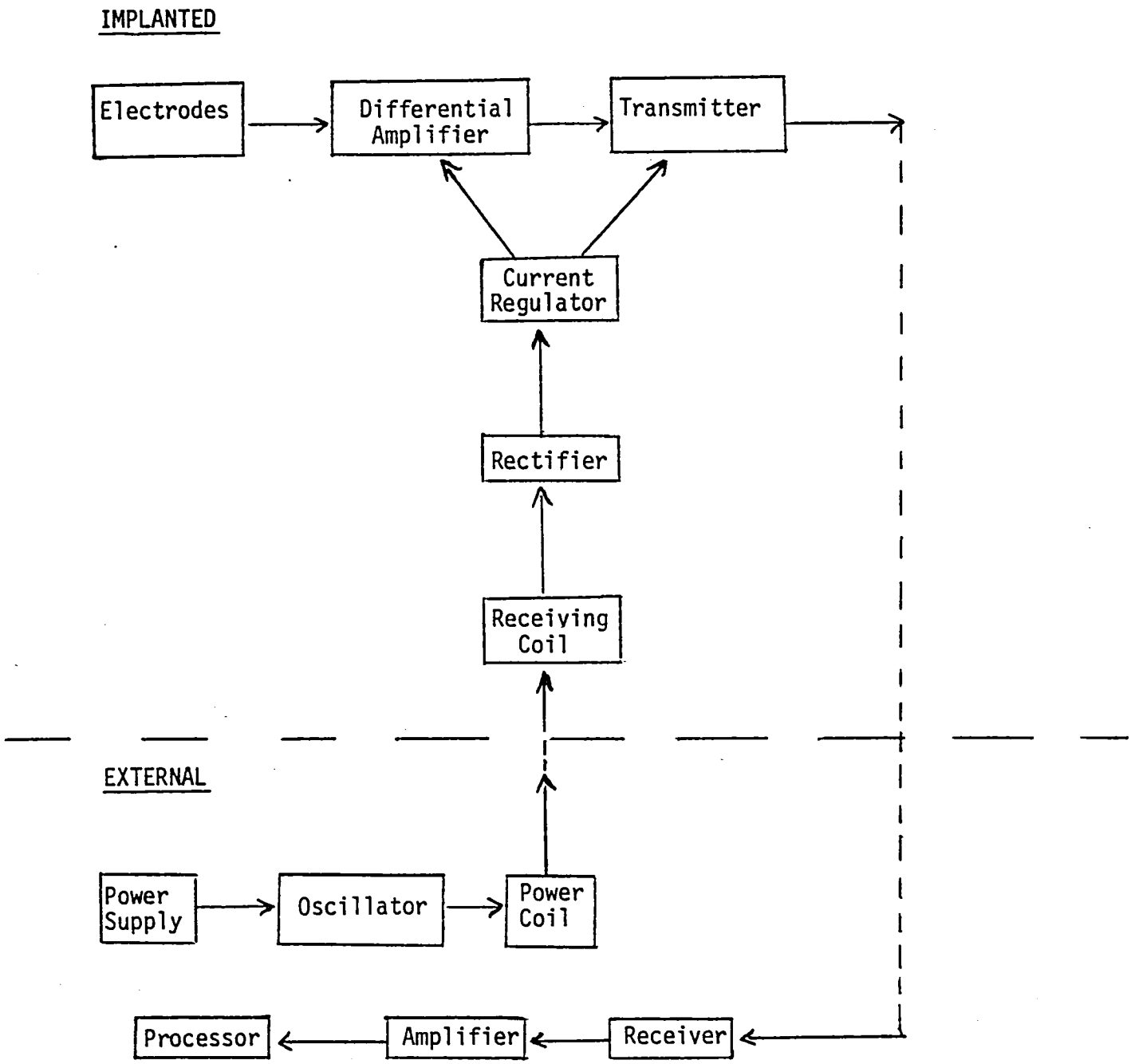


Figure 2. Block diagram of proposed neuroelectric control system telemetry.

C. Total Power Requirements

RF inducation coupled from outside the limb	
Total quiescent power drain	As low as possible (preferably < mw)
Outside voltage source	12 V

D. Materials

Electrode metal	90% platinum-10% iridium or 100% platinum
Encapsulation	Epoxy encapsulation enclosed in dense alumina ceramic

The neuroelectric control would have several advantages over myoelectric control. First, the amputation often badly damages, or removes, the muscles of interest while the nerves are left intact. Second, the electrode interface changes caused by perspiration (and tissue changes) would be eliminated. Third, the overnight removal and replacement of the prosthesis would not change the electrode position. Fourth, the extraction of the control signal directly from the nerve would provide the amputee a more "natural" control of the prosthesis.

The concept of neuroelectric control, however, introduces its own set of problems. The first, and most obvious, is the development of an implantable recording electrode that may be attached to the nerve without inducing nerve degeneration, while remaining capable of detecting neuroelectric signals. The second problem is that the placement of the recording electrode requires surgery. Third, a desirable method of transmitting the neuroelectric signals outside the body would be by radio signal. This requires the development of small, lightweight, durable electronic devices that can be implanted near the nerve.

The problem originator, in order to demonstrate the feasibility of the concept, solved the first problem. He and his colleagues developed a successful recording electrode and implanted it in rabbits. The electrode successfully detected the motor control signals throughout long periods of implantation. Autopsy indicated that the nerves tolerated the electrode. Currently, he has several rabbits with functioning implanted electrodes, and he is initiating a program to test the electrodes in baboons.

The other two problems remain. Surgery, however, is acceptable if the neuroelectric system significantly improves the amputee's control of powered prostheses. Surgery requires that the device be small and relatively easy to implant. Thus, a miniaturized, durable electronic device is the major need which must be satisfied. Although the problem originator has proposed a conceptual system, he does not have access to the capability to solve this problem. If a group, within NASA, with the needed capability could be identified, engineers on the problem originator's staff could assist in the development and implantation of the device. The problem originator has asked if NASA has technology or experience in the development of reliable miniaturized electronics that could be applied to this problem.

Reference

1. DeLuca, C. J., "Control of Upper-Limb Prostheses: A Case for Neuroelectric Control," J of Medical Engineering and Technology, Vol. 2, No. 2, March 1978, pp. 57-61.

PORTABLE COOLING SYSTEM FOR QUADRIPLEGICS

BATeam Personnel: Ms. Doris Rouse

Problem Statement

A portable cooling garment is needed for quadriplegics. These individuals are unable to tolerate heat stress as a consequence of their inability to perspire below the level of injury. This garment, therefore, would open new employment and daily living opportunities for individuals previously confined to a temperature controlled environment.

One dangerous sequela of the quadriplegia caused by cervical spinal lesions is a vulnerability to thermal stress. This condition is due to the interruption of automatic pathways mediating thermoregulatory sweating and vasomotion as well as interruption of motor pathways controlling shivering. In a recent study, six quadriplegic men were exposed to a 38°C environment for two hours while several physiological parameters were monitored (ref. 5). The results, as shown in Figure 1, illustrate the danger of heat stress in individuals with impaired sweating response. During heat exposure, the quadriplegics developed hyperthermia and hyperventilation, as well as significantly increased oxygen consumption and heart rate. The potential for heat stroke on continued exposure is obvious.

In addition to spinal cord injuries, several other pathological conditions result in impaired sweating and, therefore, vulnerability to heat stress. Ectodermal dysplasia is a congenital disorder with decreased sweating as a result of a reduced number of sweat glands. The effect of a heat stress on an ectodermal dysplasic is shown in Figure 2. The drastic increases in heart rate, oxygen consumption, and pulmonary volume resemble those seen with the quadriplegics.

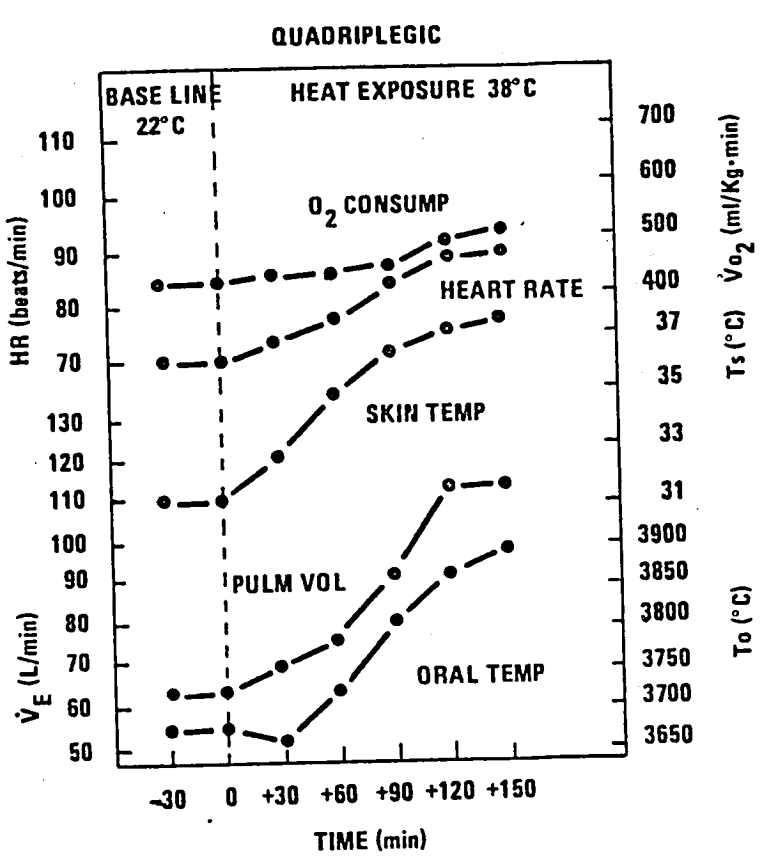
In another disease, multiple sclerosis, the demyelination often causes lesions in the autonomic system that lead to impaired thermoregulation.

The constraints and specifications are as follows:

(1) Cooling garment should be as lightweight and unobtrusive as possible. Ideally, a cooling vest to be worn under everyday clothes would be sufficient. A cooling cap should be avoided if possible.

(2) Cooling unit should weigh no more than 12 pounds and should be easily mounted on a wheelchair.

(3) Garment should be easy to put on and remove. If Velcro fasteners or zippers are used, large loops should be put on the outside for easy removal by individuals unable to grip a smaller tab.



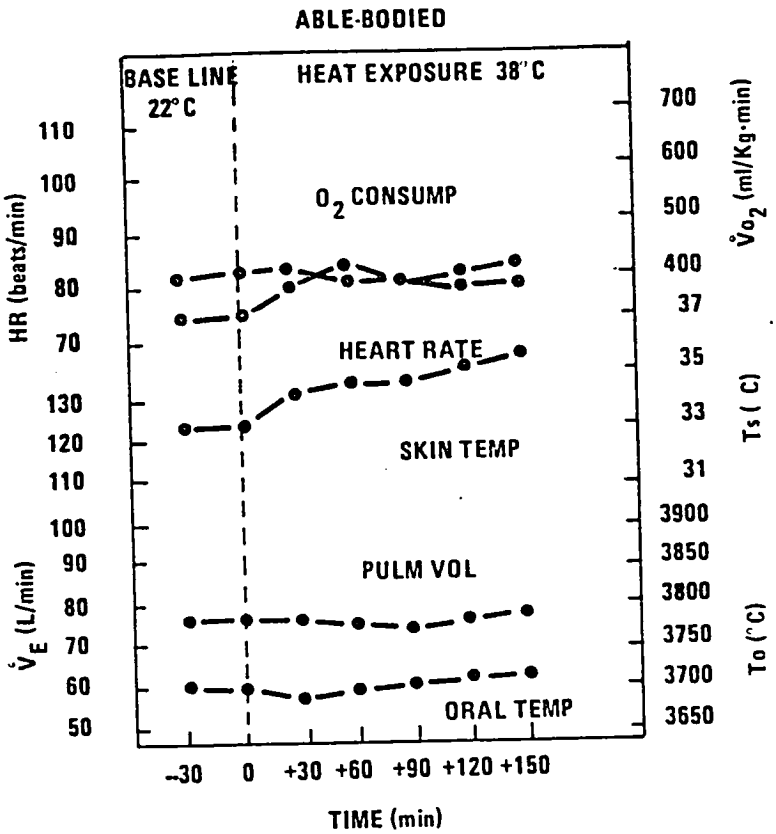
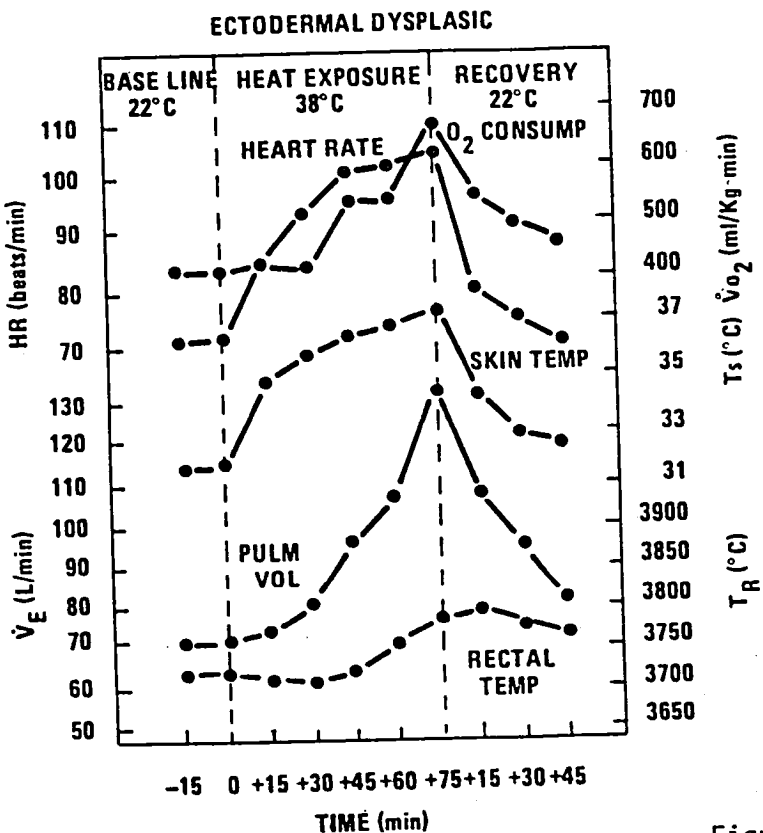


Figure 1



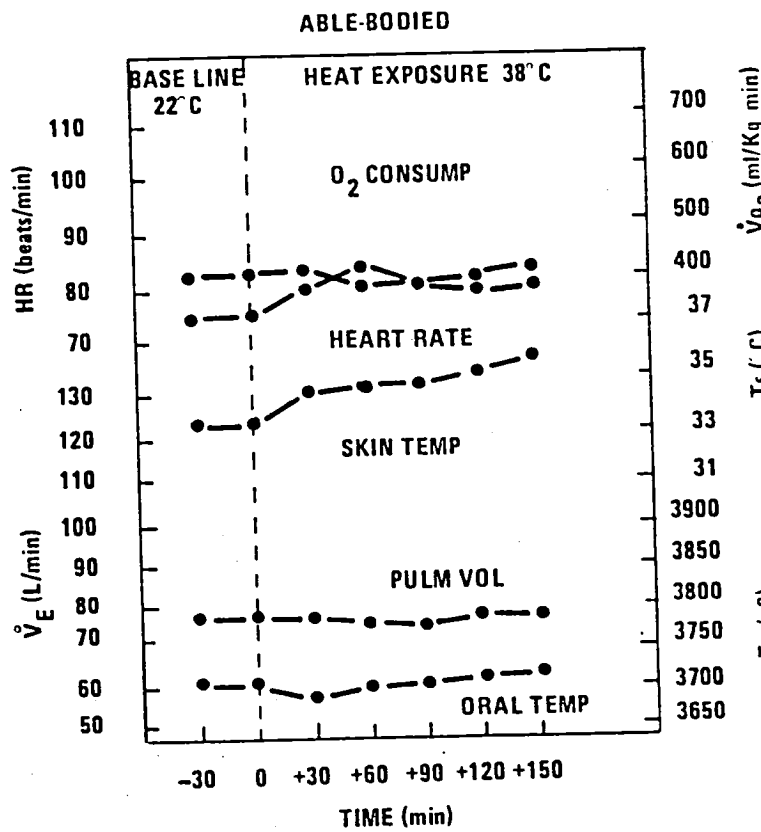


Figure 2

(4) Cooling unit should be battery powered and rechargeable.

(5) Cooling unit should have capability of cooling for four to eight hours, depending on the environmental conditions.

(6) A user regulated temperature control on the cooling unit would be convenient. Feedback from the patient's skin to the control unit is not required.

The RTI Bateam is investigating the use of NASA's liquid perfused garment technology as a solution.

References

1. Downey, J. A., C. E. Huckaba, P. S. Kelley, H. S. Tam, R. C. Darling, and H. Y. Cheh, "Sweating responses to central and peripheral heating in spinal man," J. of Applied Physiology, 40, No. 5, May 1976, pp. 701-706.
2. Downey, J. A., J. M. Miller, and R. C. Darling. "Thermoregulatory responses to deep and superficial cooling in a spinal man," J. Applied Physiology, 27, 1969, pp. 209-212.
3. Guttman, L., J. Silver, and C. H. Wyndham, "Thermoregulation in spinal man," J. Applied Physiology, 142, 1958, pp. 406-419.
4. Johnson, R. H., "Disorders of the Autonomic Nervous System--Body Temperature Regulation--Sweating and Disturbances of Body Temperature," Contemp. Neurol. Series, (11), 1974, pp. 136-195.
5. Totel, G. L., "Physiological responses to heat of resting man with impaired sweating capacity," J. Applied Physiology, 37, No. 3, 1974, pp. 346-52.

HYDROCEPHALUS SHUNT

BATeam Personnel: Dr. Richard Scearce

Problem Statement

Hydrocephalus is a condition of abnormal enlargement of the cerebral ventricles caused by a rise in pressure of the cerebrospinal fluid. Although the condition may arise as a result of tumors, infection, or trauma, it is normally a congenital condition associated with malformations at the base of the brain. The occurrence of hydrocephalus is surprisingly common (4-12 per 1000 births). Medical treatment has been of little use, and surgical treatment has increased the one-year infant survival rate to only 15 to 20 percent. Current hydrocephalus shunts fail frequently due to inlet blockage of the ventricular catheter. The single tube catheter is blocked by either an in-growth of choroid plexus or hemorrhage cellular and fibrin debris. During the first several years after birth, hydrocephalic children typically require two revisions (surgical replacement or correction operations) per year to maintain proper functioning of the shunt.

Many design modifications of the ventricular catheter of the hydrocephalus shunt have been used, unfortunately resulting in little or no improvement in long-term success rate. A design modification of the ventricular shunt's inlet is needed. This modification should minimize tissue ingrowth and debris blockage of the inlet.

The team is investigating Lewis Research Center's suggestion to develop an inlet using ion etching techniques.

MICROWAVE THERMOGRAPHY

BATeam Personnel: Dr. Clark Beall

Problem Statement

This evaluation of passive microwave thermography originated from a request of the NASA Goddard Space Flight Center's Office of Technology Utilization. Many personnel of this NASA center have expertise in microwave technology, and it was felt that this technology could be successfully applied to many specific areas of medical practice.

The overall objective of this study is to evaluate microwave thermography in laboratory animals under normal and abnormal conditions in order to test its use for the measurement of tissue temperatures at the surface of the body and in deep tissues. The long-term goal would be to discover possible medical applications for this technique in clinical medicine. The principal emphasis of this study will be directed at the subcutaneous structures of the body, such as brain, spinal cord, peripheral nerve, muscle, bone, and blood vessel.

The potential importance of the ability to measure temperature gradients deep within the body tissue may be unlimited in clinical medicine and research. The proposed research will initially be concentrated on the potential neurological uses. The possible clinical applications are as follows:

(1) Detection of core temperatures in the brain and spinal cord following various types of trauma to localize hemotomas or brain edema,

(2) The identification of brain abscesses deep within the substance of the brain,

(3) The identification of spontaneous blood clots in the brain, and

(4) The use of temperature gradients in the evaluation of certain diseases which result in temperature changes in the body, such as autonomic and vascular dysfunction.

The facilities of Duke University Medical School are available for this study. Specifically, the Division of Neurological Surgery is equipped to carry out detailed neurophysiologic, neurovascular studies using up-to-date monitoring and electronic equipment. For the purposes of long-term animal studies, the university maintains a vivarium under the guidelines of the National Institutes of Health.

INFRARED TWO-DIMENSIONAL IMAGING

BATeam Personnel: Dr. Clark Beall

Problem Statement

A professor of physiology at Duke University Medical Center, Franz Jobsis, Ph.D., has proposed a scheme for noninvasively assessing the oxygenation of human tissue. Medical specialities ranging from surgery to clinical diagnosis routinely require some type of information about tissue oxygenation. Several fields of medicine, therefore, would benefit from the development of such a technique. In particular, the brain is perhaps the most difficult organ in which to measure oxygen delivery to the tissue. Present medical techniques are invasive; a burr hole is drilled through the skull for the insertion of the appropriate sensors. The promise of a noninvasive technique for the measurement of actual brain tissue oxygenation is, therefore, welcome news indeed.

The proposed noninvasive technique relies on a physiological phenomenon that occurs in virtually all soft tissues of the body. The observed phenomenon is the in vivo reversible light absorption changes in a selected species of cytochrome when the cytochrome changes from its oxygenated state to its reduced state. When the cytochrome exists in its oxidized state, a weak light-absorption peak can be observed in the 780 to 870 nanometer region of the near infrared (IR) of the spectrum. This absorption peak disappears when the enzyme is reduced. The proposed monitoring technique relies upon the spectral change of this cytochrome. Dr. Jobsis has published a paper (ref. 1) describing the system that he now uses. Essentially, it is a one-dimensional system whereby a light pipe directs monochromatic infrared light onto one side of the skull while a light pipe on the opposing side of the skull conducts the emerging IR light to a detector. The results from these studies look so encouraging that Dr. Jobsis wants to expand the technique into a two-dimensional viewing system.

If the IR light emerging from the skull could be recorded as a two-dimensional image, one would essentially have a "picture" of the skull contents. The picture's various levels of shadow would correspond to areas of variation in the oxygenation of the cytochrome. Areas of dead cells would appear in contrast to surrounding areas of living cells. Blood vessel clots would be expected to appear in suitable contrast to surrounding areas of

living cells. Additional effects could be observed by having the test subject hold his breath or hyperventilate in order to change the oxygen content of the blood.

Dr. Jobsis has requested the team's assistance in obtaining an imaging system for IR in the wavelength region of 700 to 1,000 nanometers. The detection system must be very sensitive to the IR light because the light emerging from the tissue is of very low intensity. The IR light that serves as the test beam is generated from solid state IR lasers that are multiplexed into a mixed fiber optical bundle. The multiplex pattern of pulsed IR light will be used to advantage in recovering the absorption information.

There are at least four NASA field centers that have state-of-the-art technology in IR detection and imaging. Interviews will be conducted at all four centers to determine the most appropriate technology for this application.

Reference

1. Jobsis, F. F., "Noninvasive, infrared monitoring of cerebral and myocardial oxygen sufficiency and circulatory parameters," Science 198: 1264-66 (23DEC77).

HIGH SPEED DC LOG AMPLIFIER

BATeam Personnel: Dr. Clark Beall

Problem Statement

The wide variety of transducers used in medical research produce analog signals which can vary in amplitude over several orders of magnitude. Often, it is desirable to observe or record the time course of such an analog signal on a single plot or record. In order to accomplish this without range-switching of the instrumentation, one can utilize logarithmic processing. Logarithmic processing is a unique data compression technique which greatly amplifies the smaller amplitude signals while, at the same time, attenuates the larger signals. At the present time, there are available commercially several types of electronic function modules that convert alternating current (a.c.) analog signals to voltage levels proportional to the logarithm of the input voltage level. These devices are often used to process radar return signals which are a.c. signals that can vary over several orders of magnitude in voltage amplitude. In the biomedical sciences, however, the logarithmic conversion of direct current (d.c.) signals is more important.

The logarithmic conversion of d.c. signals is a more difficult problem because the frequency response of the logarithmic converter falls off as a function of the d.c. signal amplitude. Some types of logarithmic d.c. conversion modules are commercially available. Unfortunately, the performance of all of these modules is unsatisfactory when they are used to measure extremely low current (10^{-6} to 10^{-11} ampere) at high frequency (50 kHz to 1MHz). This type of analog signal is typical of the analog output signal of various types of transducers found in applications such as ion detectors, current relaxation experiments, and recordings of biological membrane current.

There is a need for an electronic circuit that can respond to d.c. analog signals in the frequency range from 10Hz to 1MHz and in the current range of 10^{-11} to 10^{-6} ampere. Logarithmic converters are utilized outside the biomedical field in many areas of the chemical and physical sciences, in research and in industry. Therefore, it is anticpated that a new type of logarithmic converter, capable of the above specified performance, would find a wide acceptance in the marketplace.

References

1. "Designers guide to: logarithmic amplifiers," EDN 18:42-51 (5AUG73).

2. "Accurate 9-decade temperature compensated log amp," Rev. Sci. Instr. 39: 1068-9 (JUL68).
3. "Fast and stable log converter employing resistance match," Nucl. Instr. and Meth. 116(1):74-5 (1974).

UV DOSIMETER/SUNBURN MONITOR

BATeam Personnel: Dr. Clark Beall

Problem Statement

Outdoor work and recreational activities cause many people to be exposed to extended periods of solar radiation. For those with normal skin, the adverse effects of solar radiation are caused by the ultraviolet (UV) portion of the solar spectrum. For convenience, the UV can be subdivided into three bands: UVA (320 to 400 nanometers), UVB (290 to 320 nanometers), and UVC (less than 290 nanometers). Fortunately, the ozone layer of the stratosphere absorbs virtually all of the UVC band. This particular band of radiation can cause skin cancer. Sunburn is due to the radiation of the UVB band. A much greater dosage of UVA is needed to produce reddening of the skin or actual sunburn.

Although many seek solar exposure to develop a "healthy tan," UV initiates the tanning, and the suntan is actually the manifestation of the body's mechanism of shielding itself from further UV injury. Unfortunately, the repeated exposure regimen that is necessary for the stimulation of a suntan also brings with it an increased risk of skin cancer.

Commercial suntanning oils and creams are properly referred to as sunscreens in medical literature because these aids actually filter out the UVB radiation and thereby prevent the suntanning radiation from being absorbed by the skin. Thus, they are actually effective in preventing initial overexposure due to extended periods of time in the sun.

Sunburning is caused by a combination of three factors: solar intensity, period of exposure, and condition of the skin's tan at the beginning of exposure. The first factor is particularly difficult to assess, due to such variables as changing cloud cover, haze, and time of day. The second factor can result from a lack of attention to the passage of time during recreational or work activities. A device that can sum over time or integrate the amount of UVB radiation to which an individual is exposed is needed. When a predetermined dosage has been received, the device should sound an alarm.

References

1. Blum, H. F., "Ultraviolet radiation and skin cancer: in mice and men," Photochemistry and Photobiology 24:249-54 (1976).

2. Sprount, W. L., "Skin cancers and the environment," Del. Med. Jrl. 48 (12): 685-89 (1976).

3. Wurtman, R. J., et al., "The effects of light on man," Birth Defects: Original Article Series, Vol XII, No. 2 (1976).

ENHANCEMENT OF X-RAY DIFFRACTION IMAGES

BATeam Personnel: Dr. Clark Beall

Problem Statement

X-ray diffraction is a valuable medical research technique for the analysis of the size, orientation, and packing of an array of biomolecules. Although electronic detectors are now being used by a few researchers, most X-ray diffraction patterns are still being recorded on photographic film plates. An acceptable film plate record of a diffraction pattern consists of a very faint image of concentric arcs and circles that are typically spaced only fractions of a millimeter apart. The exact spacings can be read visually through a jeweler's loupe, or the film can be read by an optical densitometer.

Experimental considerations impose upper limits both on the X-ray intensity that can be used and the time duration that an X-ray tube can be run continuously without deterioration. A means of producing acceptable X-ray diffraction images with a minimum of X-ray intensity and time of exposure is needed.

Barbara Askins of the NASA Marshall Space Flight Center has published several scientific papers describing research conducted at the center for the enhancement of photographic images on films. NASA Tech Brief MFS-23461 outlines the method. This technology is being tested for its applicability to the enhancement of the photographic images of the X-ray diffraction patterns.

The problem originator has begun acquisition of the laboratory equipment that is needed for the process.

METER FOR VERY SLOW FLUID FLOW

BATeam Personnel: Dr. Clark Beall

Problem Statement

The flow of fluid becomes rather difficult to measure when the flow rate drops below 0.5 ml/min. However, heparin and other drugs are often dispensed at even lower flow rates. Thus, a need exists for meter systems capable of precision measurement of fluid flow at rates below 0.5 ml/min. The meter should generate an electronic signal that can be used as a feedback signal for the control of fluid pumps and valves. Also, the electronic signal could be routed to a plotter, or other display device, for recording the time course of the rate of drug delivery.

NASA Tech Brief MSC-18112 describes an electronic meter for the precision measurement of very slow flow rates. The system can detect flow rates up to 0.5 ml/min with a sensitivity of 0.01 ml/min. The technical support package for this Tech Brief describes the construction of the flow sensor and includes the schematic of the electronic circuit.

One problem with this device is that the sensor must be inserted in series with the fluid delivery line. Thus, the sensor must be sterile. This need not be a complicating factor if the sensor can be manufactured as an expendable item for one-time use. However, if the sensor is so expensive that it must be reused, it must be able to withstand the rigors of sterilization.

MULTILEVEL CARE MANAGEMENT

BATeam Personnel: Dr. Richard Scearce

Problem Statement

The Veterans Administration (VA) developed the Multilevel Care Program to reduce the cost of operating their 200-hospital health care complex. In this fiscal and facilities management program, they divide the health care into five levels--from intensive care to outpatient care. They also divide the hospital facilities usage management and the cost accounting into five levels. This division cuts across established hospital organization lines (e.g., Dept. of Surgery, Dept. of Medicine, etc.), thus creating a matrix management problem that complicates the program implementation.

The distinctive characteristics of a VA hospital further complicate program implementation. Each VA hospital is autonomous. Although many similarities exists, each hospital is significantly different. Size, staff capability, and medical emphasis all vary. Implementation of the multilevel care program must consider these differences. The program must assimilate these different organizational structures and be able to reduce operating costs without reducing health care delivery.

The problem originator requested NASA technology specifically related to program management and to program and policy analysis. He wishes to utilize these technologies to aid in the organization and management of the multilevel care program implementation.

GAIT ANALYSIS DATA BANK

BATeam Personnel: Dr. Richard Scearce

Problem Statement

Advances in technology have resulted in the improvement of gait analysis as an analytical tool for rehabilitation. For example, new techniques of electromyography can be used to simultaneously monitor the contraction patterns of 16 muscles. Also, force plates are now available which can sense the dynamic pressure distribution on the bottom of the human foot. This enables the medical researcher to determine when, and in what manner, the foot of the subject contacts and leaves the ground during a test session. New optical tracking techniques can sense the path through space that is taken by preselected points on the surface of the body of the human subject during test sessions. Computers are available which can rapidly analyze the data that is generated by the various electronic sensor systems. Finally, graphic displays can present the integrated data from the computer to the rehabilitation researcher in a manner that allows detailed study and analysis of the subject's gait. Once the defects of the subject's gait have been documented, the causes of these defects can be identified and corrected through therapy.

Even though this wide selection of instrumentation is presently available, it is seldom used by physicians and therapists because there are much more data available to the researcher than he can handle. The rehabilitation researchers have yet to devise means to extract from the voluminous data the pertinent parameters that correlate well with specific diagnoses.

The problem originator has one of the most advanced gait analysis laboratories in the world which he uses as a clinical tool. Records from each gait analysis performed in this laboratory are compiled into an ever expanding gait analysis data bank. Currently, this data bank contains the gait records of 415 patients, with each record containing the following types of information:

Electromyographic Data

8 channels of data, 3 seconds of data per channel, digitized at the rate of 1 sample each 2 milliseconds;

Spatial Location of Body Points

24 body points, 3 seconds of x, y, z 3-dimensional spatial data per selected body point, with all data digitized at the rate of 1 sample per 20 milliseconds;

Force-Plate Data

16 channels of data that have been reduced to 3 types of information (vertical force, fore and aft force, and mediolateral force), accumulated as 3 sections of data on these 3 types, sampled once every 2 milliseconds.

From this growing volume of data, the problem originator must identify parameters that correlate with disease states, hereditary defects, and then plan treatments. He has asked whether NASA has technology, in the form of data processing, analysis, and storage techniques, that is applicable to his research.

MICROLITER FLUID DELIVERY SYSTEM

BATeam Personnel: Dr. Clark Beall

Problem Statement

A need has been defined for a fluid delivery system capable of delivery, upon demand, of microliter quantities of sterile fluid into an open air fluid reservoir. The accuracy of fluid delivery must be ± 2 percent. The range of fluid delivery lies within the range of 10 microliters to 150 microliters. It is desirable that the measured volume of fluid be delivered in less than 15 seconds. It is also desirable to control the delivery system by electronic command signals. This would permit programming the system to operate in synchrony with other units, allowing delivery of several fluids into a chemical reaction chamber in a predetermined sequence.

NASA Tech Brief B72-10708 described a concept for an infusion pump that utilized gas to drive from a separate reservoir at very low delivery rates. However, no control system was outlined either for constant flow or for discrete volume delivery.

MSC-14905 is a Tech Brief that describes a gas-driven system for delivery of fluid at a constant rate from a bladder reservoir. However, there is no provision for controlling the delivery of discrete quantities of fluid upon demand.

An ideal solution would seem to be one that utilizes electrochemistry to generate a known quantity of gas which would, in turn, force a known quantity of fluid from a small fluid reservoir. Such a solution was touched upon by an engineer at Lewis Research Center in his response to a previous RTI problem statement (CM-1) dealing with a bedside constant rate infusion pump. Perhaps such a concept could be considered for the solution to the need for delivery of discrete volumes of fluid in the microliter range.

EMG SPECTRAL ANALYSIS

BATeam Personnel: Dr. Richard Scearce

Problem Statement

The rapid expansion of marine resource development has stimulated man's interest in deep-sea diving. This interest is evident in the rush to exploit offshore oil deposits. A well cannot produce unless a diver has attached the pumps and valving on the ocean floor. Thus, offshore drilling requires scuba divers to dive and work at depths of 700 to 1,000 feet of water. However, man develops tremors at depths of 1,000 feet and experiences momentary lapses into deep sleep at 1,500 feet. Either phenomenon could cause an accident, which at those depths would be fatal. These phenomena are not understood.

Dr. Ackerman is studying the physiological effects of deep-sea diving. In his research, he instruments animals and places them into pressure chambers simulating deep-sea dives.

One measurement of particular interest is the electromyogram (EMG). Dr. Ackerman plans to do a spectral analysis of the EMC data to detect the subtle changes in frequency content that are the first signs of the onset of tremor. The researcher asked the team whether NASA had developed computer software for this purpose that he could use in his diving studies.

APPENDIX C

CONFERENCES ATTENDED, PRESENTATIONS, AND PUBLICATIONS BY BATEAM MEMBERS

CONFERENCES

1. The Conference on the Biomedical Applications of Engineering Skills to the Problems of the Elderly, was held January 26, 1978, at the Jewish Institute for Geriatic Care in Long Island, N.Y. Dr. R. W. Scearce and Ms. D. J. Rouse attended the conference, which was sponsored by the National Aeronautics and Space Administration and the National Institute on Aging.

2. The 22nd Annual Biophysical Society Meeting held on March 26-29, 1978, in Washington, D.C., was attended by Dr. H. C. Beall.

3. Ms. Doris Rouse and Dr. R. W. Scearce attended the 13th Annual Conference of the Association for the Advancement of Medical Instrumentation held on March 28-April 1, 1978, in Washington, D.C.

4. Dr. H. C. Beall attended the two-day "Workshop on Monitoring the the Acutely Brain-Injured Patient," sponsored by the National Institute of Neurological, Communicative Diseases and Stroke of National Institute of Health, held in Winston-Salem, N.C. on 5-6 June 1978. The workshop was hosted by the Department of Neurology, Bowman Gray School of Medicine of Wake Forest University. NASA telemedicine technology was described by a film presented by Mr. Norman Belasco of the Johnson Space Flight Center.

5. One June 7-9, 1978, Dr. James Brown and Dr. R. W. Scearce took part in the National Aeronautics and Space Administration and the Bureau of the Education of the Handicapped jointly sponsored workshop. Representatives from both organizations identified opportunities for applying technology to special education needs.

6. Dr. Brown and Ms. Rouse participated in the July 25 and 26, 1978 Biomedical RTOP review at the NASA Scientific and Technical Information Facility in Baltimore, Maryland.

7. On August 10 and 11, 1978, Dr. R. W. Scearce attended the International Disabled Expo in Chicago, Illinois. The Paralyzed Veterans of America sponsor this annual meeting to provide a forum for interaction between manufacturers, professionals, and the disabled.

8. Ms. Rouse participated in a program review for the FEMUICA/FEMURA project at Johnson Space Center on August 15 and 16, 1978.

9. Ms. Rouse and Dr. Scearce attended the Interagency Conference on Rehabilitation Engineering in Washington on September 4-8, 1978.

10. On October 16, 1978, in Washington, D.C. Dr. James Brown and Dr. Richard Scearce met with representatives from 10 government agencies. This was the second in a series of meetings in which the development of a rehabilitation facility is being considered. Participants unanimously agreed that NASA should manage the project, and the feasibility study should be initiated immediately.

CONFERENCES (continued)

11. On October 27, 1978, Dr. Scearce attended a seminar at the Applied Physics Laboratory in Baltimore on the development of an implantable infusion pump. Dr. William Spencer of Sandia Laboratories was the main speaker.

12. In response to a request by Mr. Ray Whitten, Dr. Richard Scearce participated in a workshop held November 20, 1978, at the University of Florida Medical School. Representatives from the fields of rehabilitation, prosthetics, orthopedics, neurosurgery, and engineering discussed the hip disarticulation prosthesis and how it might be improved.

13. On December 11, 1978, Dr. Beall attended a colloquium on "Non-Destructive Testing" at Langley Research Center.

PRESENTATIONS

1. On March 14, 1978, Dr. R. W. Scearce gave a presentation on the Biomedical Applications Team program to a class on Technology Assessment at the Duke University Department of Mechanical Engineering and Material Science, in Durham, North Carolina.

2. Dr. James Brown presented a paper entitled "Medical Technology Transfer" at Langley Research Center on May 3, 1978.

3. On June 8, Dr. Brown presented a paper entitled "NASA's Biomedical Applications Team Program" at a workshop held in Baltimore on innovative approaches to the design of teaching facilities for severely retarded students. The conference was jointly sponsored by NASA, the National Association for Retarded Citizens, and the Bureau of Education for the Handicapped.

4. Ms. Rouse presented a paper entitled "Mechanical Methods of Incontinence Management" at the Interagency Conference on Rehabilitation Engineering in Washington, D.C., on September 7, 1978.

PUBLICATIONS

1. J. N. Brown, W. A. Fisher, and F. T. Wooten, "Medical Technology Transfer," Proceedings of the Fifteenth Space Congress, Cocoa Beach, Florida, April 26-28, 1978.

2. B. S. Wilson and S. M. Scott, "Hemodynamic Design Considerations for an Improved Artery Shunt Prosthesis," in Bio-Fluid Mechanics, D. J. Schenck (Ed.), VPI Press, Blacksburg, Va., 1978, pp. 93-98.

3. F. T. Wooten, W. W. Waring, M. J. Wegmann, W. F. Anderson, and J. D. Conley, "Methods for Respiratory Sound Analysis," Medical Instrumentation 12(4) (1978) pp. 254-257.

4. James N. Brown, Leader of the Health Technology Working Group, "Health Technology", Aerospace Technology Transfer to the Public Sector, An AIAA Workshop Conference, Crystal City, Virginia, November 9-11, 1977, Sponsored by NASA, edited by Jerry Grey and Martin Newman, June 15, 1978, pp. 35-44.