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APPLICATIONS OF AEROSPACE TECHNOLOGY IN BIOLOGY AND MEDICINE

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NASA BIOMEDICAL APPLICATIONS TEAM PROGRAM

Applications of Aerospace Technology in Biology and Medicine

by

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PREFACE

This report covers the activities of the Research Triangle Institute's Biomedical Applications Team program for the period 1 January, 1977 through 31 December 1977. The work was performed in the Center for Technology Applications under the technical direction of Dr. J. N. Brown, Jr., Director. Dr. R. W. Scearce was the Biomedical Applications Team Director. Assistance with the development of marketing strategy was provided by Dr. W. H. Clingman of W. 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, and Mr. J. C. Ruddle.

The work reported herein was supported by the National Aeronautics and Space Administration--Contract No. NAS1-14708. 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 increased the team's understanding of medical manufacturing and marketing practices and how these practices impact medical technology transfer. Dr. William A. Fischer, Assistant Professor, School of Business Administration, University of North Carolina at Chapel Hill, has contributed much to the team's understanding of and approach to technology transfer. The continued interest in, support of, and contribution to the team's efforts by Dr. F. Thomas Wooten, Executive Assistant to the President, RTI, are considerable and are 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 and understanding.

II, III, IV

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, commercially available, medical products incorporating aerospace technology.

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

Two commercial technology transfers and five institutional technology transfers were completed in 1977. A new, commercially available teaching manikin system uses NASA-developed concepts and techniques for effective visual presentation of information and data. Drugs shipped by the National Cancer Institute to locations throughout the world are maintained at low temperatures in shipping containers that incorporate recommendations made by NASA. A clinical information system that enhances medical and surgical treatment of ischemic heart disease patients at Duke University Medical Center incorporates NASA image processing technology.

The team's emphasis on commercial technology transfers is reflected in the character of transfer cases active in December 1977: twenty-six of twenty-eight active cases have potential for becoming commercial transfers.

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.

TABLE OF CONTENTS

INDEX OF PROBLEMS

INDEX OF PROBLEMS (Continued

1.0 INTRODUCTION

The preamble to the Space Act of 1958 creating the National Aeronautics and Space Administration (NASA) expressed clearly: "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 to "provide 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 whatever action was necessary and appropriate to effect actual utilization of NASA technology involving 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 1977 through 31 December 1977.

1.1 Biomedical Applications Team Objectives

The primary objective of the Research Triangle Institute (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 in both 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 U.S., medical research is a slow, complex, and expensive process. On the other hand, there is potentially much that 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. It should be noted that the teams do not ignore opportunities for applying 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) the 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 identify those that represent potentially successful commercial products; (3) the 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	Educational Background	Responsibility
Dr. J. N. Brown, Jr.	Electrical Engineer	Laboratory Supervisor
Dr. R. W. Scearce, Jr.	Biomedical Engineer	Team Director
Dr. W. H. Clingman*	Chemical Engineer	Marketing Consultant
Dr. H. C. Beall	Biophysics, Physiology	Solution Specialist
Mr. J. C. Ruddle	Biomedical Engineer	Solution Specialist
Ms. D. J. Rouse	Biochemist, Physiology	Solution Specialist

*Dr. Clingman, William H. Clingman and Company, Inc., is a marketing and management consultant to Research Triangle Institute.

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.

1.3 Participating Institutions

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

1.4 Conference Attendance

Biomedical Applications Team members attend and participate in conferences and workshops to remain thouroughly familiar with the state-of-the-art of medical technology and to discuss new product opportunities with medical industry representatives. Conference attendance and presentations 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 the four major phases of team activity, program flexibility allows for technology transfer activities related to medical research and leading to institutional technology transfer.

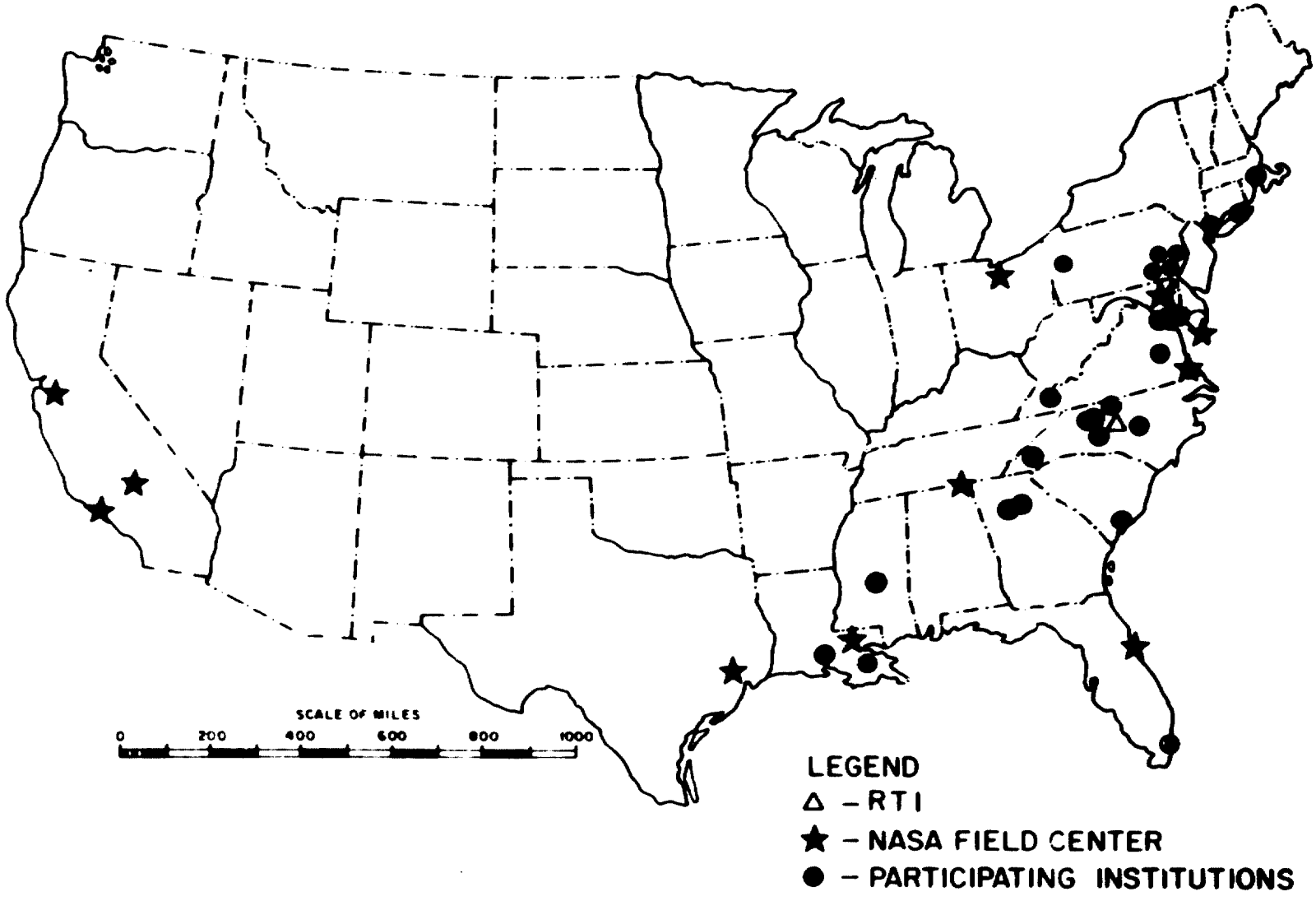

Figure 1. Biomedical Technology Transfer Network.

TABLE 1.

PARTICIPATING MEDICAL INSTITUTIONS

Bowman Gray School of Medicine, Wake Forest University, Winston-Salem, North Carolina (WF)*

Carnegie-Mellon Institute of Research, Pittsburgh, Pennsylvania (CM)

Dorothea Dix Hospital, Raleigh, North Carolina (DIX)

Duke University Medical Center, Durham, North Carolina (including Veterans Administration Hospital, Durham, North Carolina) (DU)

Emory University School of Medicine, Atlanta, Georgia (EU)

Eye Research Institute of Retina Foundation, Boston, Massachusetts (ERI)

Guilford County Communications Center for the Deaf, Greensboro, North Carolina (GCCC)

Hahnemann Medical College, Philadelphia, Pennsylvania (HMC)

Institute for Cancer Research, Philadelphia, Pennsylvania (ICR)

Jefferson Medical College, Philadelphia, Pennsylvania (JEF)

Johns Hopkins University Medical School, Baltimore, Maryland (JHU)

Louisiana State University School of Dentistry, Baton Rouge, Louisiana (LSD)

Medical College of Virginia, Richmond, Virginia (MCV)

Medical University of South Carolina; Charleston, South Carolina (MUSC)

Mount Sinai Medical Center, New York, New York (MS)

National Cancer Institute, Bethesda, Maryland (NCI)

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*Letters in parentheses are used in identifying problems investigated by the Biomedical Applications Team; e.g., WF-1 is identification code for problem number 1 originated at Bowman Gray School of Medicine, Wake Forest University.

TABLE 1. (CONTINUED)

National Heart, Lung, and Blood Institute, Bethesda, Maryland (NHLI)

Temple University School of Medicine, Philadelphia, Pennsylvania (TE)

Tulane University School of Medicine, New Orleans, Louisiana (TU)

United Cerebral Palsy Association of Nassau County, New York (UCP)

University of Georgia College of Veterinary Medicine, Athens Georgia (UGA)

University of Miami School of Medicine, Miami, Florida, (including Veterans Administration Hospital, Miami, Florida) (VAM)

University of Mississippi Medical Center, Jackson, Mississippi (UMISS)

University of North Carolina School of Medicine, Chapel Hill, North Carolina (UNC)

University of North Carolina Dental School and Research Center, Chapel Hill, North Carolina (UNCD)

Veterans Administration Hospital, Oteen, North Carolina (VAO)

Woodrow Wilson Rehabilitation Center, Fishersville, Virginia (WWRC)

Technology transfers brought to fruition during the reporting period are documented in section 3.0. Two commercial technology transfers and five institutional technology transfers are documented. This documentation describes the technology transfer, the situational context to which the technology was transferred, and the role of the Biomedical Applications Team as a transfer agent.

The technology transfer activities of the Biomedical Applications Team are summarized in section 4.0. Medical problems and needs identified during the reporting period are documented. The status of the team's investigation of these problems is documented. The status of 13 potential technology transfers is described and progress in strategy development and implementation is documented.

Section 5.0 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 in general.

1.6 Definition of Terms

Biomedical Applications Team (team) -- A multidisciplinary team 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 together constitute 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). This information bank consists of more than one million documents that have been indexed and abstracted in the Scientific and Technical Aerospace Reports (STAR) and the International Aerospace Abstracts (IAA).

Donor -- Organization or individual that originally developed technology that is transferred. Within the context of the Biomedical Applications Team, the donor is the National Aeronautics and Space Administration.

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 application of information that is available to the problem originator through routinely used information channels.

Participating institution -- A medically-oriented educational institution, hospital, medical center, or government agency that participates 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 potentially solves 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 statement of a medical problem or need that contains: (1) sufficient details to allow a computer search to be performed, and, (2) sufficient information to enable NASA engineers and scientists to consider possible solutions.

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

RTOP (Research and Technology Objectives and Plans) -- A proposal submitted by a NASA Field Center to NASA Headquarters for funding of R & D projects in general and, in particular, for funding to adapt NASA technology for application in medicine.

Technology -- All of the skills, techniques, and understanding that constitute a specific technology. While technology includes hardware it is by no means limited to hardware.

Technology transfer -- ("Horizontal transfer" is implicit throughout this report.) Instances in which a specific technology moves from one situational context -- the one for which it was developed -- to another resulting in changes in the technology or the context to which it is moved or both.

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

Technology -- All of the skills, techniques, and understanding that constitute a specific technology. While technology includes hardware it is by no means limited to hardware.

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2.0 TECHNICAL APPROACH

The conceptual framework for medical technology transfer presented 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 the aerospace technology and that 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 and appropriately concerned only with solving a problem. The manufacturer by necessity is concerned with introducing a commercially

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

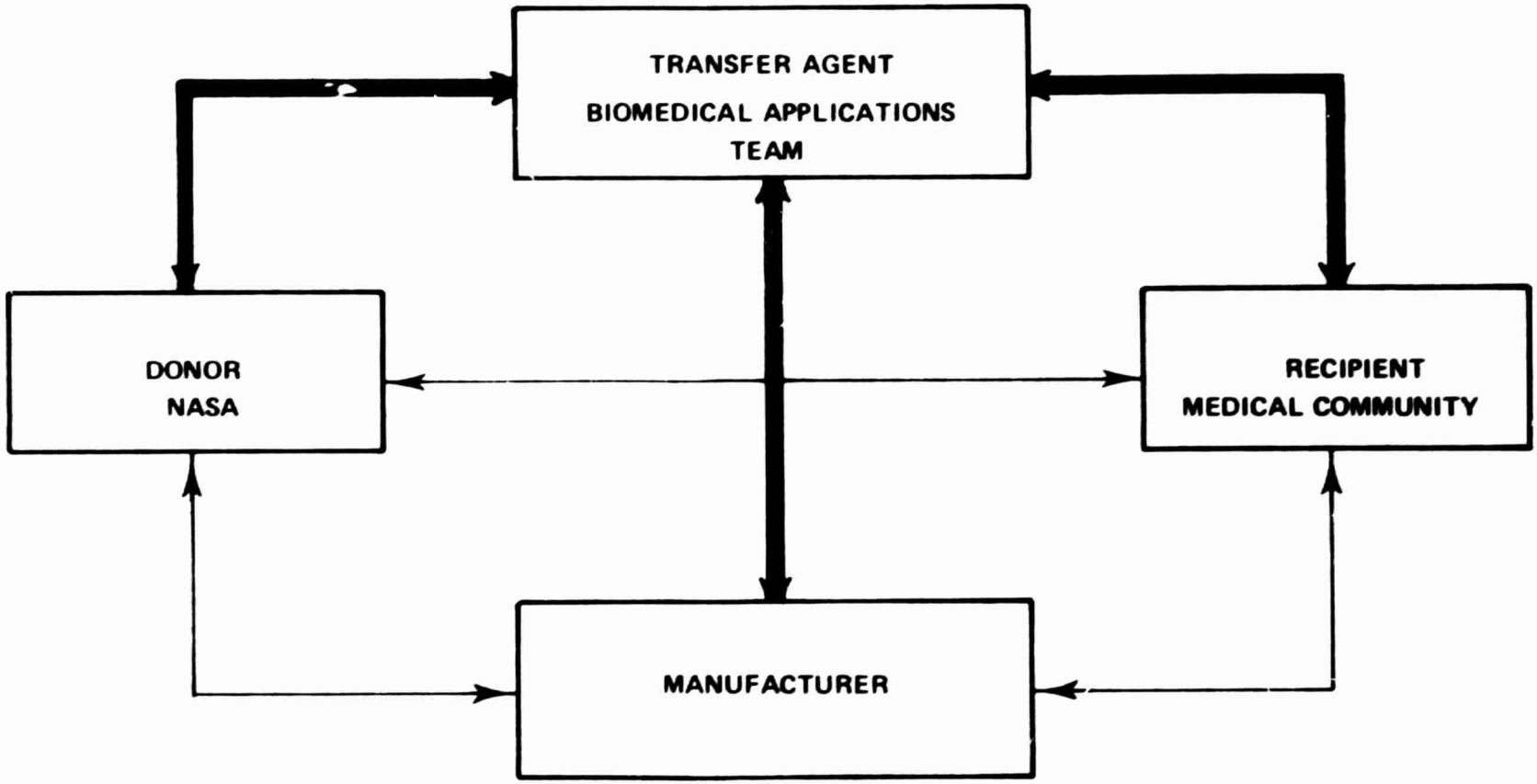


Figure 2. Conceptual Framework for Medical Technology Transfer.

viable product. And, the donor obtains only satisfaction as reward for involvement in the 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 significantly 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, are not great. The technological competence of the recipient is highly variable. Many medical researchers in large medical centers and teaching hospitals are technologically competent; the physician in clinical practice, in general, will not be 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 agressive company exhibiting innovative behavior but lacking relevant experience.

The relative importance of and role played by each participant is dependent, in any specific case, 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 throughout this report 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 material transfer will 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 level 2 and level 3 transfers. The redesign of 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 that allows it to respond appropriately to the specific characteristics of particular technology transfer cases.

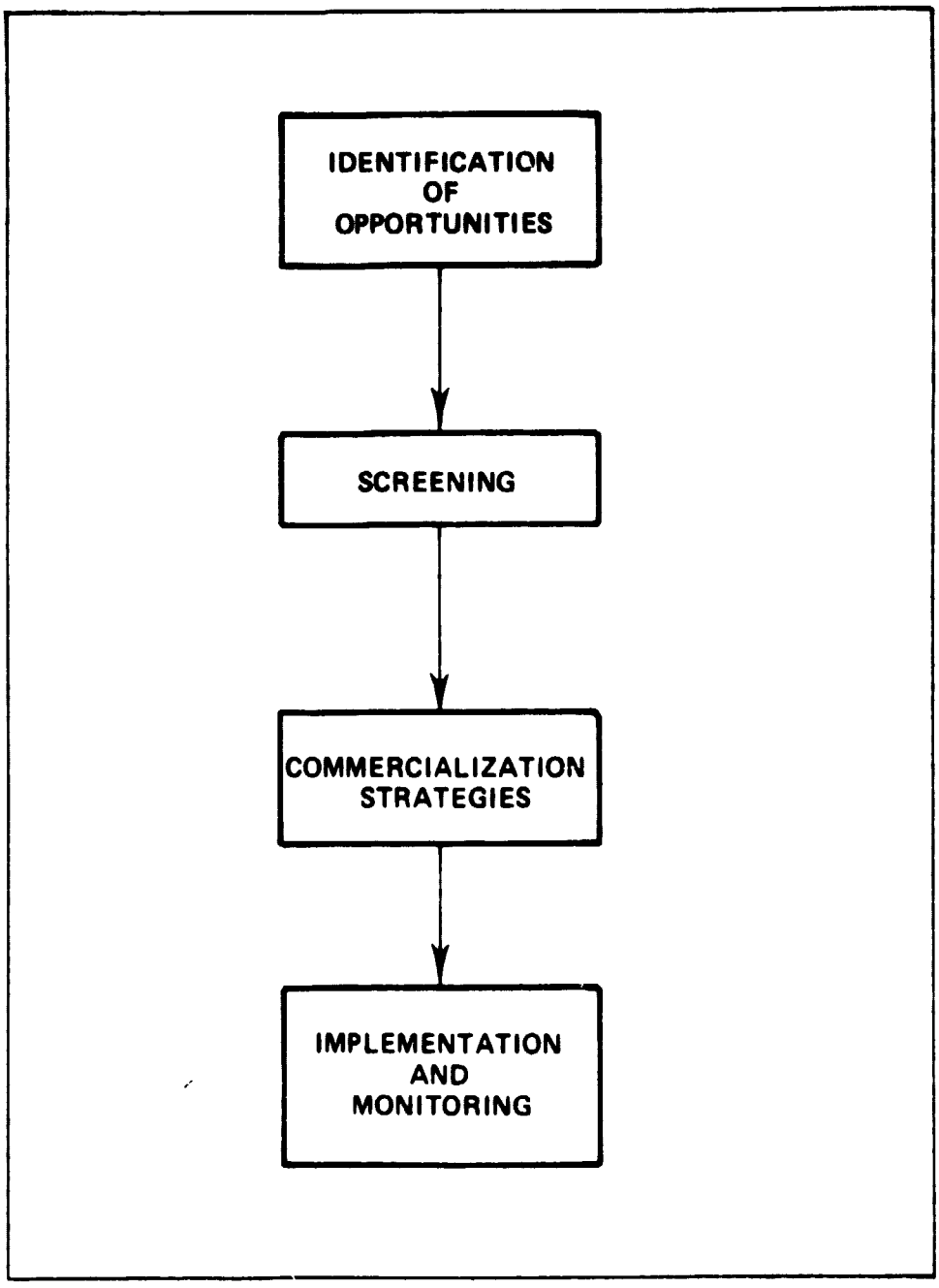


Figure 3. Phases of RTI Biomedical Applications Team Activity.

2.2.1 Identification of Opportunities

The identification of technology transfer opportunities involves: (1) the identification of a medical problem or need; and, (2) the identification of relevant aerospace technology that solves the medical problem or satisfies the medical need.

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 insitutions 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 medical researcher or clinician who is referred to as 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 takes into account these factors concerning innovative behavior of the medical community in its problem identification activities.

As noted above, innovative physicians emphasize quality of health care to a greater extent than achieving maximum economic efficiency. There is ample indication that medical technology introduced in the past 10 to 20 years often 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 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 (IACs). The RTI team utilizes the services of the IAC located in Research Triangle Park, North Carolina -- the North Carolina Science and Technology Research Center. These 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 medical problem. Responses to Problem Statements from these engineers and scientists can lead to the identification of technological solutions.

Finally, the Biomedical Applications Team frequency contacts NASA scientists and engineers known by the team to have a strong interest in transferring technology to medicine. This is the most direct, efficient, and rapid approach to locating technology.

A medical problem in combination with a potentially relevant aerospace technology constitutes an opportunity for technology transfer. 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 of opportunities 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 product justifies the required capital investment and production cost to the manufacturer;
- A manufacturer can be offered protection either by exclusive license or 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 Development of Strategies

The development of strategy for successful technology transfer must take into account product development and marketing, clinical trials, acceptance by the medical profession, and identification of funding sources for the various tasks involved. With 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 both the donor and recipient throughout the transfer process. Further, the involvement of industry throughout the transfer process is essential. Finally, 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 these conclusions and expanded upon them. Industry must be involved throughout the transfer process and must be brought into that process as early as is 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 sudden entry of the new or improved 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. Following development of the product it must be subjected, in general, to clinical trials. This must be followed

by publication of the results by a recognized medical expert. Generally, the product must be exhibited at medical meetings. This sequence of events normally leads to physician acceptance.

Medical marketing and distribution frequently are not an integral function of medical product manufacturing firms. Thus, in addition to selecting and obtaining the participation of a medical product manufacturer, the team must also identify and bring into the transfer process an organization having the capability to market and distribute 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 repeatable and 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 3.0 and 4.0 of this report present documentation on completed technology transfers and status reports on all active technology transfer cases.

3.0 TECHNOLOGY TRANSFERS

During the reporting period, seven technology transfers were completed. Two of the seven transfers involved the incorporation of NASA technology in commercially available medical products: VAM-32, a Cardiology Teaching Manikin, and NCI-14, Containers for Maintaining Drugs at Low Temperature during Shipment. The remaining five are institutional technology transfers. Two of the institutional transfers (CP-3, Clinical Information System, and UNC-89, Protein Separation) have long term potential for commercialization.

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

PROBLEM VAM-32: Cardiology Information Presentation Techniques

Education of medical students in cardiology requires access to patients having a variety of specific forms of heart disease. Bringing together the student, instructor, and patient is an expensive, time consuming process that does not benefit the patient. An alternate approach is for the student to observe and work with a lifelike manikin that simulates heart disease.

Dr. Michael S. Gordon of the University of Miami Medical School started developing a manikin that simulated a single disease state over ten years ago. He began work on a multiple disease state manikin in 1969. As the number of disease states being simulated increased, the quantity of visual information and data that must be presented to the student increased significantly. This information, which must be presented visually, includes patient histories, electrocardiograms, X-rays, hemodynamic data, and responses to medical and surgical treatments. Gordon was concerned with the quality of the visual presentation of this supplemental information. The visual presentation techniques used in conjunction with the manikin should allow effective and efficient transfer of information to the student.

The Biomedical Applications Team determined that NASA studies of techniques for effective visual presentation of data were directly applicable to the presentation of information to medical students. In its early investigation of this medical requirement, the team determined that Gordon's manikin was far superior to other commercially available medical manikins. It simulated a larger number of disease states with greater realism. Also, it was easier to use and was highly reliable. Finally, team interviews with cardiologists at other medical schools indicated that Gordon's manikin met their requirements.

The Biomedical Applications Team, in searching the NASA technical literature, identified studies of visual information presentation techniques performed at NASA's Kennedy Space Center (KSC). Mr. S. A. DeMars who had been involved in this NASA study met with the chief engineer of the manikin project, Mr. D. Patterson, and the Director of Instructional Resources for the University of Miami, Mr. John Fisk. Samples of 35 mm color slides to be used with the manikin system were studied and discussed. Mr. Demars noted that the NASA studies were relevant to the manikin information presentation system and that the manikin presentation could be improved considerably. Working relationships were established between KSC, the University of Miami, and the manikin project staff. KSC staff made many recommendations regarding color and format and recommendations concerning information content of slides to be used with the manikin. Incorporation of NASA-developed concepts into the slide presentation was initiated by KSC staff and completed by the medical communications staff of the University of Miami.

The now commercially available cardiology teaching manikin illustrated in figure 4, which simulates 40 disease states incorporates NASA visual presentation concepts throughout the information presentation program. This system, manufactured by Messmore and Damon in New York, was recently judged the best medical exhibit at the Annual Meeting of the American College of Cardiology.

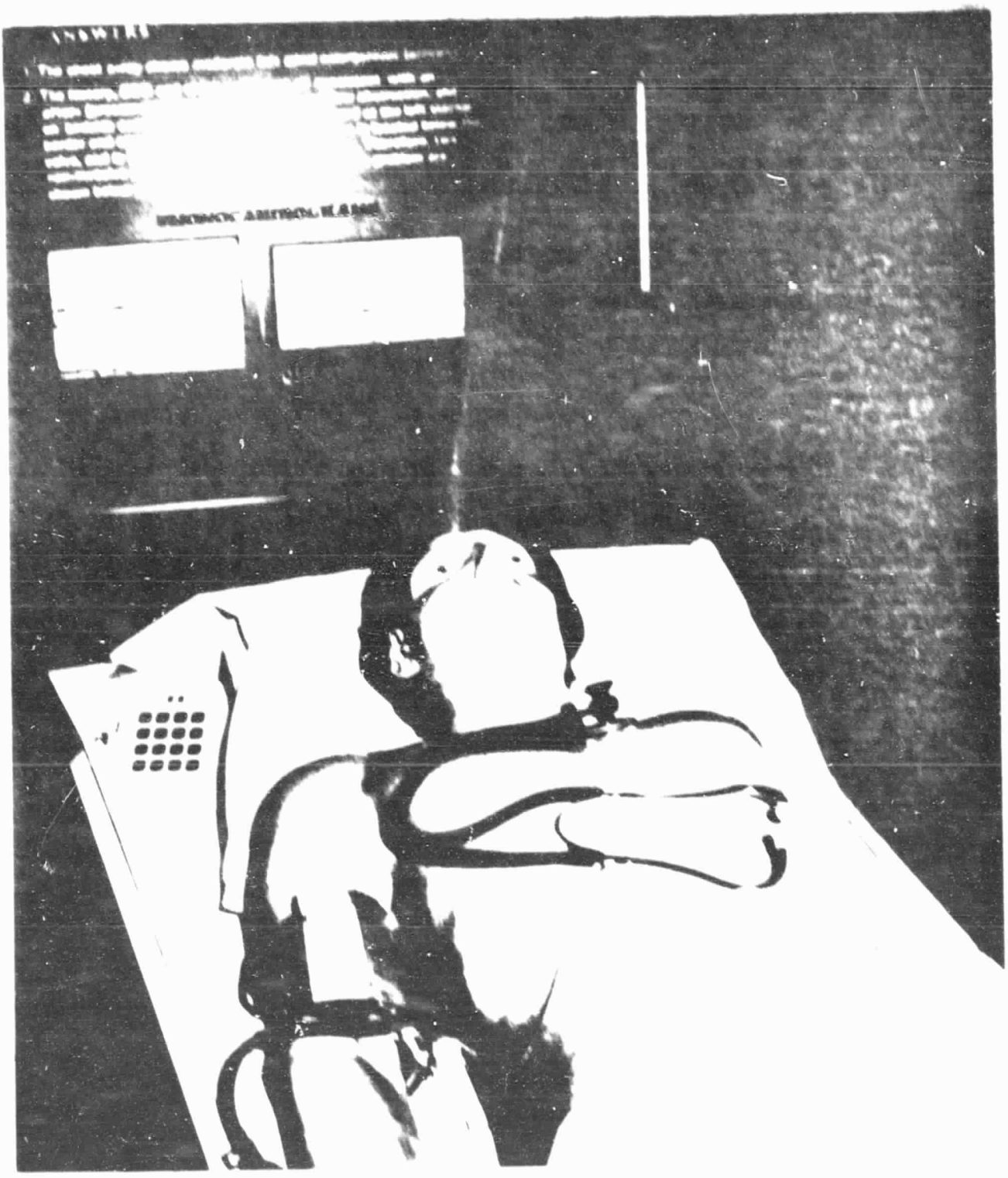


Figure 4. Caregiver Teaching Infant

PROBLEM NCI-14: Thermal Protection for Drug Shipments

The National Cancer Institute (NCI) makes about 250 shipments per month of heat-labile drugs to locations in the U.S. and about 50 shipments per month to foreign countries. Most of the drugs shipped are in powder form and packaged in sealed sterilized glass injection vials. Each shipment typically contains from 25 to 150 vials.

The temperature of these drugs must be maintained at or below 55°F during shipment and delivery, i.e., a period up to 74 hours. The required period of time, the low heat capacity of the materials comprising a drug shipment, and size and weight limitations imposed by air shipment make this a difficult problem.

The Biomedical Applications Team identified this problem through discussions with the NCI chief pharmacist who is reponsible for proper packaging of drug shipments to locations throughout the world. The NCI requirements and sample shipping containers were submitted to NASA's Langley Research Center (LRC) engineers for study and recommendations concerning adequate packaging concepts for heat-labile drugs. LRC tests indicated that NCI drug containers used at that time did not allow adequate thermal protection of drugs. They made a number of recommendations related to an improved container: (1) The dry ice used previously by NCI has insufficient thermal capacity and should be replaced by water ice. (2) The ice should be frozen in flat plastic bags placed around the outer surface of the package as opposed to being placed in the center of the drug container. (3) At least two inches of molded polystyrene or urethane foam insulation should be placed on all six sides of the shipment container. (4) Use as many airtight vapor seals as possible in the packaging configuration. The NASA-developed quilted aluminized mylar sheets would be appropriate for these seals.

While LRC was investigating this problem, NCI requested Harry Diamond Laboratories to test their old method of drug packaging. Results of tests at and recommendations made by Harry Diamond Laboratories were consistent with test results and recommendations from NASA. The results of

both NASA's study and that at Harry Diamond Laboratories were incorporated into the specification of a new packaging container for the delivery of heat-labile drugs. Within the last year, NCI has contracted with a company in the Silver Springs, MD area for containers for shipment of drugs from the NCI pharmacy.

PROBLEM CP-3: Automated Measurement from Coronary Angiograms

The utilization of NASA technology has aided Dr. C. F. Starmer and his colleagues at the Duke University Medical Center in developing the Duke Cardiovascular Data Bank. This data bank documents their clinical experience with more than 4,000 patients with suspected and confirmed ischemic heart disease; it is used to augment their ability to diagnose and treat such patients. All data are stored in a computerized information system that allows the physician to recall historical data and related information on patients with medical profiles similar to that of a new patient. Prognostic information based on similar experience is available for each new patient both in video and printed laboratory report from. This data bank is proving to be an effective clinical tool for providing medical care.

Numerous problems had to be solved to develop this clinical information system. Two of the more difficult problems required that Dr. Starmer and his group develop: (1) an input mechanism for graphic data that was easy to use and would aid in grouping patient data according to patient characteristics; and (2) a data storage system that would facilitate the use of accumulated data to develop meaningful prognoses. Solutions to these problems were aided significantly by the utilization of computerized image processing techniques developed by the Jet Propulsion Laboratory (JPL).

The existence of this NASA technology was brought to Dr. Starmer's attention in 1969 by a member of the RTI Biomedical Applications Team. Through his continued interaction with the team, Dr. Starmer received a summer fellowship at JPL in 1970. During that training period, he mastered many of NASA's image processing techniques. These techniques have become a vital part of the data system.

Although we have classified this application of NASA technology as an institutional transfer, it does have commercial potential. The magnitude of this potential will become clear as more clinical experience is gained. A second data bank system is currently being installed in the Harvard School of Public Health; it is expected to provide some of this clinical experience. The team will continue to monitor this effort.

PROBLEM DU-97: A Compact, Highly Sensitive Light Detection System

X-ray diffraction is a powerful biomedical research technique for determining the orientation and spacing of macromolecular subunits of biological tissues. The diffraction pattern is usually recorded on a photographic emulsion that has a glass plate as its backing. The optical density data of the diffraction pattern are read from the plate by an optical densitometer. A microscope objective lens focuses on the emulsion side of the back-lighted plate as the plate is mechanically moved back and forth. The light beam that passes through the emulsion is less than 100 microns in diameter. However, when the diffraction pattern is very faint, the densitometer scanning unit cannot produce satisfactory results due to low contrast between exposed and unexposed emulsion.

An alternative optical scanning technique can be used to read weak diffraction patterns. This method uses a stationary, slit of light about 100 microns wide and one centimeter long. The plate is moved mechanically so that the slit sweeps out a repetitive raster pattern. The light passing through the plate is collected and refocused to a point by an elliptical front-surface mirror. At the focal point, the light modulates a photodetector. The output of the detector is sampled by an analog-to-digital converter and input to a minicomputer. The computer is programmed to process the data into a format consisting of a matrix of optical density values.

The researcher constructed a mechanical scanning device and optical system but found that the allotted space for the photodetector was very

limited. He requested help in designing a photodetector that would perform satisfactorily and fit into the system.

Because of the very restricted space available for the detection system, a photomultiplier detector could not be used. Instead, a phototransistor or photodiode appeared more appropriate. The NASA literature was surveyed and a phototransistor, the photo-FET, was identified as a solution. This device is as sensitive as a photomultiplier tube, when rated by output microamperes of current per microwatt of input light.

The team worked with the researcher in designing an operational amplifier circuit to interface with the photo-FET. Both the sensor and the amplifier circuitry were fitted into the case that holds the objective lens of the microscope. This system was placed in operation and has performed satisfactorily.

PROBLEM MISC-47: Miniaturized Tension Measuring System

The problem originator contacted Mr. John Samos at Langley Research Center (LRC) regarding a technical problem being encountered in a cardiovascular physiology research project. Mr. Samos and a team member visited the problem originator and received a thorough explanation of the problem and research into the response of vascular smooth muscle to various stimuli.

Smooth muscle is one of the several types of muscle tissue found in the body. It is usually found in the walls of hollow organs and in the walls of blood vessels. It is known that vascular smooth muscle responds with contraction or relaxation under various stimuli. To study these response patterns and other mechanical characteristics, a techniques has been developed which uses small lengths of isolated blood vessels. These lengths of vessel are formed into loops and hooked over two prongs on a holder. The distance between the prongs is increased incrementally and with each incrememental increase, the tension developed by the muscle is measured. In some experimental preparations, the loop is suspended in a solution and muscle tension is measured.

A preliminary problem statement was prepared by the team. Mr. Samos and a team member discussed the problem statement with an LRC engineer,

Mr. John D. Thompson, who has extensive experience in the development of miniaturized electromechanical instrumentation for NASA applications. The problem originator visited LRC and met with Mr. Thompson to discuss a proposed solution. Mr. Thompson fabricated the miniaturized holder and tension measuring device. Upon completion of the device, Mr. Thompson visited the problem originator's laboratory and installed the holder and measuring system; the device has functioned satisfactorily.

This successful application of NASA technology has advanced progress in this cardiovascular research project by at least 6 months. A savings in both time and money has resulted.

PROBLEM UNC-89: Protein Separation

It has been hypothesized that growth hormone from the anterior pituitary gland causes bone growth by stimulating the production of the protein somatomedin which then serves as the active growth agent. The isolation and identification of somatomedin has been hindered by three factors: (1) no reservoir organ is known from which relatively large quantities of the protein may be extracted; (2) somatomedin, therefore, must be isolated from blood, where it is present in very small quantities; and (3) identification of the amino acid sequence of the protein requires a highly purified extract.

The problem originator, Dr. Judson Van Wyk of the University of North Carolina at Chapel Hill, had successfully isolated a few hundred milligrams of the purified protein through a lengthy and costly procedure requiring several tons of blood. An improvement in the efficiency of the isolation process was needed to obtain a sufficient quantity of pure somatomedin to determine its amino acid composition and sequence.

Personnel in the Marshall Space Flight Center (MSFC) Technology Utilization Office reviewed the problem statement. They suggested that the team contact Dr. Bier of the University of Arizona. Dr. Bier has worked closely with MSFC in the development of new electrophoresis techniques that utilize the low-gravity environment of Skylab. Dr. Bier, Dr. Van Wyk, and a team member discussed the project in detail and agreed to undertake a collaborative effort to define a technique for isolating pure somatomedin more efficiently.

Dr. Van Wyk forwarded to Dr. Bier carefully prepared samples. Dr. Bier used NASA-developed techniques and instrumentation to accurately identify key isoelectric potentials. With this information, Dr. Van Wyk was able to improve the separation process. Their success thus far has made possible the sequencing of many of the 66 amino acids comprising the protein, resulting in significant savings in time on this research project.

PROBLEM VAM-27: Contour Mapping of Head

Surgical techniques to repair severe congenital facial abnormalities have been developed. They involve sectioning of the skull and relocating and reshaping various facial features (e.g., nose, mouth, eye sockets). Patients who previously were disfigured hopelessly now have hope for a reasonably normal life.

Contour maps of the front, rear, side and top views of the human head are used to determine the best surgical procedure and to monitor the recovery process. These maps are obtained using standard stereophotographic techniques. Stereophotographic pairs are made of each view and analyzed using a stereo plotter. Through analysis of these data, critical volumes and surface areas are computed and primary landmarks are located in three-dimensional space. Unfortunately, stereophotogrammetry, especially using the stereo plotter, is slow and expensive. Better techniques to produce and analyze the data are needed.

Dr. Yoram Yakimovsky reported that a system for extracting three dimensional measurements from a pair of stereo images had been developed at the Jet Propulsion Laboratory (JPL) and that this system could be modified to meet the problem originator's requirements. Yakimovsky discussed with the problem originator the feasibility of adapting the JPL to accurately locating key anatomical points in three dimensional space. The problem originator agreed to supply stereo pairs in the form of glass plate negatives that had been previously analyzed using stereophotogrammetry to Yakimovsky for analysis.

Yakimovsky performed the analyses and documented the results in: Three Dimensional Measurement and Display System for Assisting Diagnoses of Craniofacial Abnormality. Results of Yakimovsky's analysis compared favorably with the results obtained using stereophotogrammetry.

This transfer of NASA technology makes possible the development of a more effective tool for the study and treatment of craniofacial abnormalities. The resulting system can simplify the process of obtaining three dimensional descriptions of objects such as the head. In addition, the NASA-developed interactive analytical system can give the physician more flexibility in analyzing patients.

4.0 STATUS OF ACTIVE TRANSFER CASES

The Biomedical Applications Team is investigating 28 transfer cases at present. These 28 cases include 13 medical problems identified prior to 1 January 1977 and 15 new problems identified during the reporting period.

Of the 28 active transfer cases, all but two have the potential for becoming commercialization technology transfers. This represents a significant change in the character of the problems investigated by the RTI team when compared to problems investigated in previous years. The change is a direct result of emphasis on the potential for commercialization in the team's identification of opportunities and screening activities as described in section 2.0.

As noted in the preceding, 15 new problems were identified during the reporting period. Problem statements describing these new problems are presented in Appendix B. The team has identified potential solutions for 11 of these problems. The status of those new problems for which potential solutions have been identified is reported in this section.

Four of the transfer cases categorized as active problems have been reported as institutional technology transfers either in this report or in previous final reports.[3] In these instances, the team has recognized opportunities for commercialization transfers, and is taking appropriate action. Problems in this category are:

DU-74	Testing of Neuropathic Patients
MISC-37	Weight Alleviation Device
NCI-4*	Controlled Rate of Freezing a Liquid
WF-56	Pressure Transducer Calibrator

*Jet Propulsion Laboratory staff are entirely responsible for the progress made in moving this case toward commercialization.

PROBLEM DU-74: Testing of Neuropathic Patients

The neuropathic patient testing system has been reported previously as an institutional transfer[3]. The team has evaluated the potential market for the system for testing neuropathic patients. It has been determined that the potential market has two major sectors: institutional and noninstitutional. The private practitioner composes the noninstitutional sector. From interviews with physicians, research personnel, and manufacturers, it was determined that the private practitioner would not purchase a testing device similar to the neurological tester, because both doctor and patient are concerned only with gross changes in behavior which can easily be observed. In addition, less concern exists over an incorrect diagnosis here than in the hospital environment.

The institutional sector of the market was found to have two parts. The first is a group of about 50 to 100 physicians doing research on Parkinson's Disease and related neurological disorders. This market, however, is not large enough to cover product development and marketing costs. The second part of the institutional market involves use of the device as a diagnostic tool. Every hospital with a neurology department is a potential customer. The utility of the device in this application, however, has not been established. As a result of discussions with physicians in the field, a one year project to establish this utility has been specified. Patients in several different disease groups and control groups would be tested. One disease group would include those with Parkinson's and other related diseases. Another would include psychotic patients that are being treated with drugs that induce Parkinsonian behavior. The experiments would be designed on a sound statistical basis and would involve well over a hundred patients. To accomplish this study, the design of the neuropathic tester would have to be upgraded and a new unit fabricated.

A manufacturer has been identified who is interest in collaborating in this market-development project. The manufacturer met with his board

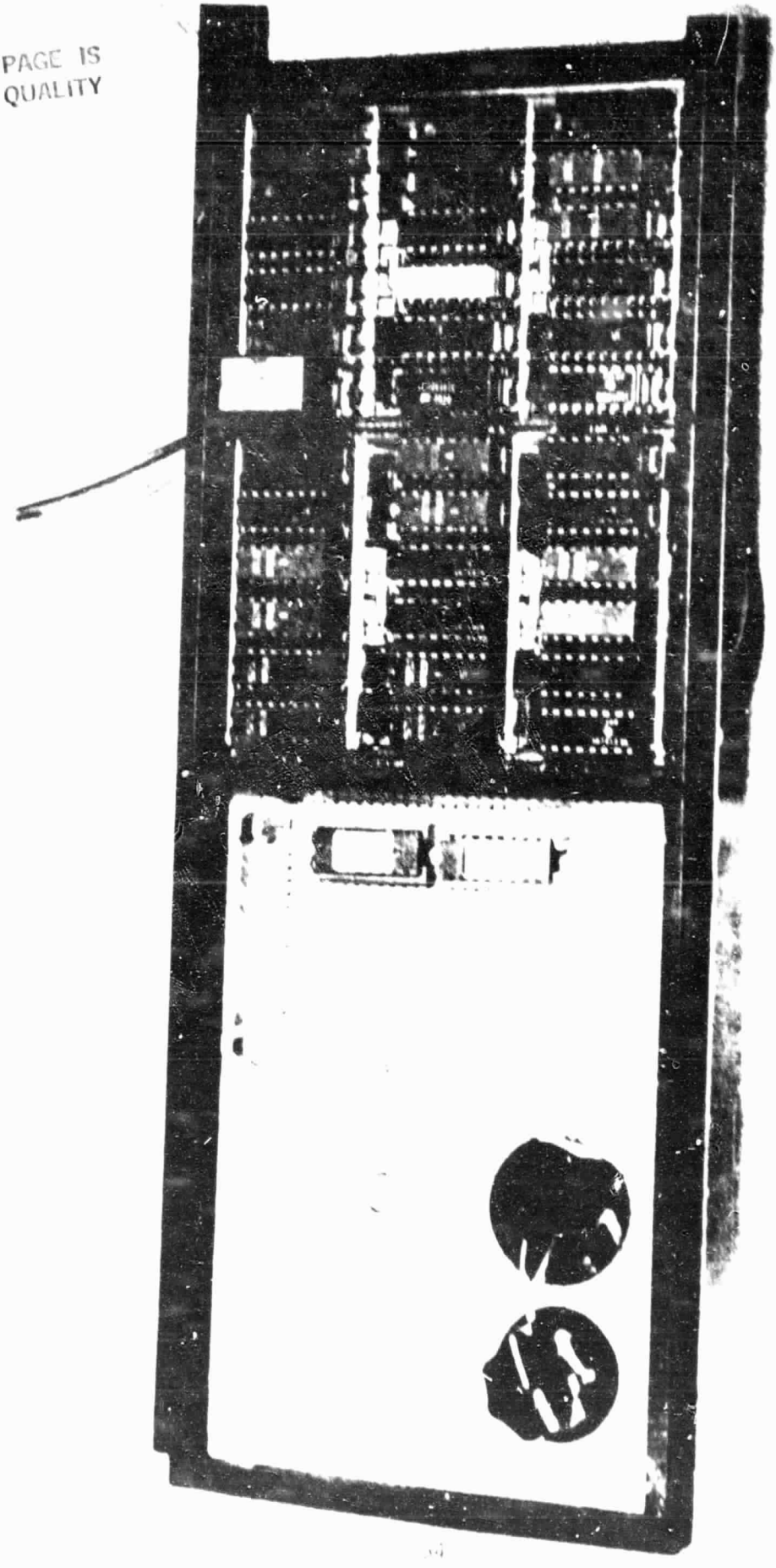
of directors and obtained their approval of participating in this project. The board also authorized the expenditure of the necessary manhours and development funds, confirmed by a letter to this effect from the manufacturer to the RTI team. According to the agreement, an engineer from the company will work closely with NASA and team personnel to finalize the design and ensure that it can be manufactured. Once a design is agreed upon, the manufacturer will repackage the device and make it available to the research market. His entrance into the diagnostic market will depend upon verification that the device meets the medical need for diagnosis.

PROBLEM DU-98: Digital TV Display Device

A ubiquitous instrument in basic medical research laboratories is the cathode ray oscilloscope. However, the basic oscilloscope cannot display effectively waveforms that change very slowly or that are due to single, transient events. No basic oscilloscopes can produce a permanent record of the displayed waveform, and such a record (paper copy) often is needed for the laboratory notebook. Frequently, the instrumentation funds are not adequate to support the purchase of specialized oscilloscopes that can do one or more of the above special tasks. The RTI team defined the specific needs for oscilloscopes and searched the NASA literature for applicable instrumentation or expertise.

The digital instrumentation group at the NASA Langley Research Center proposed several items of technology for the solution to the need for an adaptable, low cost, oscilloscope. The "digital TV display device" is an instrument utilizing a unique combination of digital data manipulation technology and analog television display technology. The TV display device has been constructed as a wire-wrap prototype (fig. 5) and its capabilities have been demonstrated.

Several prospective manufacturers have been sent information describing the TV display device. One company responded with such enthusiasm that the team loaned the prototype to them for quick verification of the



potential of the device. Because this company already manufactures and sells analog and digital instrumentation, the TV display device would seem to be a logical extension of the product line. At the present time there is no known impediment to the acceptance of the TV display device by this prospective manufacturer. The team will work closely with the manufacturer to develop and implement the marketing strategy. Because of the manufacturer's established market position, this device might become commercially available in 1978.

PROBLEM DU-99: V-slotted Head Screws

The problem originator described the difficulty of adjusting orthotic braces when they are held together with screws. When loosening these screws to make brace adjustments, the screwdriver often cams out of the screw head and destroys it. The manufacturer must drill out the screw, retap the brace, and then make the necessary adjustment. What should have been a 3- or 4-minute job turns into a 30- or 40-minute job. V-slotted-head screws have been designed specifically to eliminate this problem.

The team obtained several samples of different sized V-slotted-head screws and delivered them to the problem originator. He agreed to evaluate these screws in the actual manufacturing environment. Depending on his results, other prostnetic and orthotic shops may be included in an expanded study from which publications can result. This will conclude the first major step in a market development program for the screws.

PROBLEM ERI-1: Improved Optics for Vitrectomy Surgery

During vitrectomy eye surgery, the surgeon's visualization of the vitreous humor near the retina requires placement of a contact lens or lens/mirror system on the cornea and the use of an operating microscope. Unfortunately, available lens systems do not provide a satisfactory view of the vitreous humor. They are either too bulky or too limited in their field of view. The problem originator is interested in improving these optical systems for vitrectomy surgery.

Suggested solutions to this problem are being evaluated. A manufacturer who currently markets a surgical kit for vitrectomy surgery has been identified for contact in the event a NASA contribution to this important problem is found.

PROBLEM GCCC-1: A Teletype Machine Test Unit

A profoundly deaf person needs to be able to use the telephone system, but cannot unless special equipment is available. Most important is the need to summon emergency services (fire, police, and rescue). To alleviate this problem, the Sertoma Club (a civic club) has instituted a program in North Carolina (and elsewhere) to equip emergency services communications centers in each city with Teletype (TTY) machines and to equip the homes of all the deaf of the city with a TTY set. Each TTY is interfaced to the phone system by an acoustic coupler. A state-wide telephone directory lists the phone numbers of all holders of such TTY equipment. Such a directory enables the deaf to use the TTY for nonemergency purposes, such as communicating informally with other deaf individuals. Nationwide, there are more than 12,000 such installations in homes of the deaf and their hearing friends.

Virtually all of the TTY machines in the program in North Carolina are model 15 machines that were obtained when the news wire services changed to new and faster TTY printers. These TTY machines are unreliable, require frequent maintenance, and are not particularly desirable because they use the old 5-bit Baudot TTY code instead of the modern ASCII code. While in many communities the deaf have a local serviceman to maintain these machines, upkeep is a major problem. As a result, a request was made to the team for a device that could be used by the field repairman to facilitate troubleshooting and adjusting the TTY machines.

A digital communications engineer at the Langley Research Center, who has design experience with CMOS digital integrated circuitry, suggested an integrated circuit signal generator as a means of solving the TTY repairman's need. Following this suggestion a wire-wrap prototype device was constructed. This test set (figure 6) generates the TTY machine code for

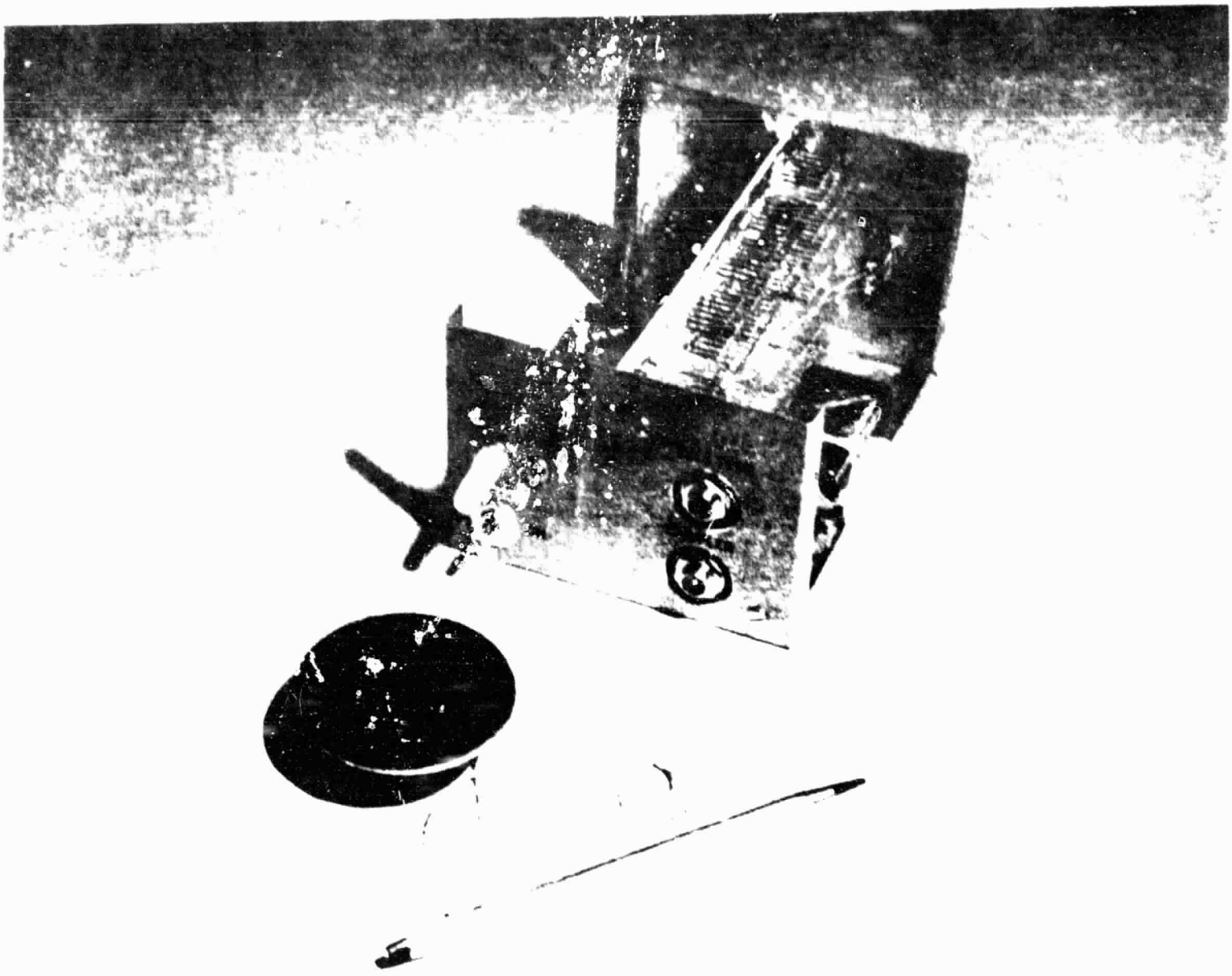


Figure 6. Teletype Machine Test Unit Prototype.

the test character pair "RY" in sufficient repetitions to fill a full line of TTY text, followed by the carriage-return and line-feed characters. These machine code patterns are available as contact closures of a reed relay or as audio tones. The audio tones are used to test the acoustic phone coupler while the relay contacts may be connected in series with the local loop of the TTY selector magnets or keyboard mechanism.

The TTY signal generator shows promise as a commercial device. The device has been demonstrated to a West Coast electronics company in the last two months and the blueprint of the device has been submitted to another West Coast company to determine their interest in manufacturing it.

Currently the prototype is being evaluated by a field TTY repairman. This field test will be concluded at the end of January 1978. The report of the evaluation will be included in the descriptive literature that is being prepared by the team as part of the commercialization procedure.

PROBLEM GCCC-2: SCA Receiver for the Handicapped

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 now available 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. On November 8, a team member visited Goddard and 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.

There are several reasons why more RTTY systems for the deaf do not exist in the United States. One is that the equipping of many homes of the deaf with SCA subcarrier receivers has been rather expensive. The NASA-developed SCA subcarrier receiver can perhaps demonstrate a method whereby the cost of such receivers can be reduced. The team is identifying a manufacturer for the circuit boards and an electronics firm to install the boards, on a contract basis, for organizations of the deaf who are interested in initiating SCA RTTY transmission systems in other communities.

PROBLEM LSD-1: New Method for Cleaning Teeth

A new method for cleaning teeth has been proposed by NASA personnel. This method consists of coupling ultrasonic energy into a water jet. Dr. Joseph Heyman at Langley Research Center, an expert in clinical ultrasound, expressed interest in working on this problem. However, he was concerned that the energy levels necessary to remove plaque would damage both the gums and the teeth. Believing that a very effective teeth cleaning system could be developed using ultrasound, he proposed a system requiring very low energy levels. During the past year the team identified a manufacturer that was very interested in pursuing development of this system. This manufacturer is one of the world's largest producers of toothbrushes, and such a device

would meet an immediate new product need. Currently the team is attempting to have a NASA patent application initiated, which must be done if this commercial opportunity is to be pursued.

PROBLEM MCV-3: Determination of Deltopectoral Flap Viability

Wounds too extensive to heal by suturing may be closed by skin grafts or skin flaps. A skin flap consists of skin and subcutaneous tissue that is moved from one part of the body to another with an attachment to the body being maintained for nourishment. Often, with cancer in the throat region, large areas must be dissected. A flap from the shoulder and upper chest (deltopectoral flap) is commonly used to cover the head and neck defects after surgery. The clinical problem with this flap is that its survival is unpredictable (5% to 20% sustain necrosis). A method to determine accurately the viability of a flap could direct treatments to enhance flap survival.

The Jet Propulsion Laboratory (JPL) has proposed a solution for prediction of flap survival using computerized image processing of photographs in the visible and infrared portions of the spectrum. Dr. Victor Anselmo of JPL has suggested visiting the problem originator at Medical College of Virginia to take photographs of flaps for analysis at JPL. This application is being evaluated by the RTI team for clinical feasibility and commercial potential.

PROBLEM MCV-4: Sealing of Amputation Stump Neuroma to Prevent Pain

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 perineural 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 use of pain killing drugs can lead to drug addiction. Attempts to prevent neuroma formation fail if they injure the perineural seal which functions normally to present an effective barrier to diffuse axon growth. A successful remedy must provide an effective, permanent seal of the severed nerve without injury to the perineurium.

An important potential solution to this problem was found when the RTI team translated papers from the 1969 Innsbruch Conference on Kunstoffe in der Chirurgie (Plastics in Surgery). Kotter reported that in his nerve repair work, he discovered inadvertently that certain cyanoacrylates effectively prevent nerve regeneration. The problem originator is anxious to test this tissue adhesive in the prevention of neuromas. The RTI team is working with the problem originator, industry, and chemists at Langley to identify the specific cyanoacrylate best suited for this application.

PROBLEM MCV-5: Lung Sound Modeling

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.

Dr. J. 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.

PROBLEM MISC-37: Weight Alleviation Device

The weight alleviation device has been evaluated at the Mississippi Rehabilitation Center. Evaluation results demonstrated that this NASA-developed system solved a significant medical need. Although the evaluation indicated that the device required extensive modifications, it also demonstrated that a definite market exists for the device.

The device was returned to Langley Research Center (LRC). Dr. Clingman and a team member visited LRC during mid-July and met with the problem originator and the engineering staff there. This group discussed the desired modifications including modifications required by a potential manufacturer. A complete redesign was required, but the NASA-developed concept of the weight support mechanism would be retained. Complying with suggested design criteria, the engineering staff at LRC developed several novel designs. They were reviewed by the problem originator and the potential manufacturer. While the problem originator suggested only minor changes, the manufacturer saw major manufacturing cost difficulties with the designs. In effect, a production engineering effort was required that was beyond the experience of either the manufacturer or the NASA engineering group. The team is exploring several possible avenues to obtaining this production engineering effort. When the effort is completed, the team can finalize the commercialization strategy that has already been partially completed.

Dr. Clingman has arranged for the manufacturer to take the redesigned weight support mechanism developed at LRC, mount it in a frame, and add all required harnesses. At that point the system will be made available for evaluation in a therapeutic environment. This evaluation must be a structured program, the results of which must be published by a physical therapist. More than one evaluation is highly desirable. This type of evaluation is necessary because the market for this device does not exist and must be developed.

PROBLEM MISC-48: A Simple, Presettable Torque, Brake System

Exercise machines are typically used by more than one person. It is desirable that the braking system of such a machine allow a desired work load to be set by each person who uses the machine. Also, because exercise regimens are often prescribed by a physician, the braking device of the exercise machine must be calibrated in units of braking torque. Unfortunately, currently available methods for meeting these requirements are costly.

A manufacturer of an exercise machine described to Dr. W. H. Clingman of W. H. Clingman and Co., the need for a low cost, presettable brake. Dr. Clingman, who was visiting the manufacturer in conjunction with the development of commercialization strategy for another team project, relayed the requirement to the team. In response, the team conducted a NASA literature search and discussed the problem with a NASA contract engineer. It was concluded that the classic "prony brake" system had many of the features of the desired brake system. The prony brake is a rather simple capstan device in which braking torque is delivered to a rotating drum surface. With such a brake, the torque can be preset rather accurately by measuring the tension exerted on the entrance and exit wraps of the brake's belt. Both tensions can be adjusted so that the desired braking torque is applied to the rotating drum.

With this information, the team was able to rapidly respond to the request. A report describing the solution and a suggested design was prepared and forwarded to the manufacturer. At the present time, the company is in the process of fabricating several prototypes of an exercise machine that incorporates a prony brake. They will be placed in hospitals and rehabilitation centers for clinical evaluation.

PROBLEM MISC-49: Microwave Thermography

Conventional thermography at infrared frequencies (>>10GHz), a tool in the detection of breast cancer for many years, can detect thermal profiles at the skin's surface only. A method for precise measurement of

subsurface temperatures is required for the safe, effective application of hyperthermia to cancer treatment. A number of studies have shown that hyperthermia in the range of 42°C to 43°C is synergistic with radiation therapy in the induction of tumor regressions. To prevent destruction of normal tissue, however, the subsurface increase in temperature must be carefully monitored.

Microwave thermography is a low frequency analog of infrared thermography. A shift to lower frequencies permits the detection of thermal profiles at depths of up to several cm below the body's surface. Langley Research Center (LRC) is working with Eastern Virginia Medical School and the Medical College of Virginia in a project to study the use of microwave focusing to induce local subsurface hyperthermia and to measure the resulting temperature changes. The RTI team will attend a hyperthermia conference to be held at LRC in January, 1978.

PROBLEM MISC-50: Advanced Rugged Hearing Aid for Children

There are 200,000 or more children in the United States who have a sufficient hearing loss to interfere with normal acquisition of speech and language. Fortunately, most of these children do have some useful hearing remaining; for such children the hearing aid remains the primary device for compensating the hearing loss. Since a hearing loss of even a moderate level, if uncompensated, seriously interferes with the normal acquisition of speech and language and therefore has profound educational implications, the early fitting and consistent use of a proper hearing aid is one of the most essential elements if the child is to succeed in the hearing world.

So far as level of physical activity is concerned, a child who wears a hearing aid is no different from any other healthy child. Specifically, a hearing aid worn by a child will be subjected to substantial shock, vibration, and occasionally immersion in water. That hearing aids presently available for children are inadequate to withstand these environmental

stresses is well demonstrated by studies of hearing impaired children which show that typically one-third to one-half the hearing aids that these children wear are not working properly at any one time. A major redesign of the hearing aid for children with emphasis on making the aid as child proof as practicable is clearly in order.

The Bureau of Education of the Handicapped approached NASA Headquarters concerning this need. In response, the team prepared a problem statement in July 1977 for NASA Headquarters to distribute to the Field Centers. Several responses were received. The team will work with Headquarters in the evaluation of the proposals.

PROBLEM NCI-4: Controlled Rate of Freezing a Liquid

The treatment of several forms of cancer and certain other diseases involves 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 have suggested that a nonlinear rate of freezing is the damage mechanism.

Jet Propulsion Laboratory (JPL) personnel suggested a technique which would detect the onset of freezing and then 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 (GSFC) personnel developed the JPL suggestion into hardware using computer analysis techniques developed for such space applications as ensuring the thermal balance in spacecraft. The completed freezing system was tested at the National Cancer Institute with excellent results.

JPL entered into a contract with a large commercial organization to develop the new freezing technique into a commercial system for preserving red cells. Work on the contract began in the spring of 1977, and the commercial organization is very pleased with progress. The team will continue to monitor the development of this commercial product and provide assistance to the JPL effort as appropriate.

PROBLEM UMISS-5: Leg Brace Weight Problem

While NASA has demonstrated the feasibility of the use of composite materials in orthotics, more appropriate applications must be identified, and manufacturing techniques that are practical for use in the orthotic shop must be developed. A plan to accomplish this was submitted to NASA in October 1975, and an RTOP based on this proposal was submitted by Langley Research Center (LRC) in March 1976 and subsequently was approved. A major rehabilitation center has received a contract from LRC to demonstrate applications in rehabilitation. The problem originator, a materials expert who is familiar with composites, is the director of engineering at the rehabilitation center. He visited LRC in July 1977 for one week of training in the use of composite materials. During that visit, the team met with the problem originator and Mr. John Samos, the Technology Utilization Officer, and discussed the objectives and strategy of the contract. Several possible applications of composites were also explored at this meeting.

The problem originator has procured the necessary equipment and materials and has installed and tested the equipment. He and his colleagues have identified a simple but promising application and are developing the appropriate manufacturing technique. The resulting item could be produced in quantity and commercially distributed to other prosthetics and orthotics shops. Dr. Clingman is exploring several possible marketing strategies and has met with potential distributors. One distributor is interested in working with the team to move composites into the rehabilitation market.

PROBLEM UNC-83: Neonate Thermal Control for Use in Surgery

The need for a neonate thermal control system was presented to the RTI team by Dr. E. N. Kraybill of the Neonatology Department of the North Carolina Memorial Hospital. Neonates (infants up to 4 weeks of age) often experience a marked fall in body temperature during anesthesia and surgery.

This hypothermia causes respiratory depression and may result in cardiac and circulatory failure. Heat loss by an infant during X-ray and catheterization procedures presents the same hazards as anesthesia and surgery; regulation of body temperature is especially difficult for the premature infant. Further, heart and neural tube defects, which account for one-third of all major congenital defects, often require cardiac surgery during the neonate period. The prognosis for neonate cardiac surgery is enhanced by a carefully monitored and controlled cooling of the infant.

A need exists, therefore, for a method both to warm and to cool the neonate during surgical, X-ray and catheterization procedures. Current efforts to meet this need include heated operating tables, elevated room temperature and radiant heating. These techniques suffer the disadvantages of nonuniform heating, uncomfortable conditions for the surgical team, and lack of capability to cool as well as heat the neonate.

Dr. Bill Williams of Ames Research Center responded to the RTI problem statement with the suggestion that the liquid-cooled garments designed for astronaut thermal protection could be modified for this application. Incorporating design features to obtain optimal surgical access, flexibility and heat exchange characteristics, a neonate prototype is now ready for surgical testing. The RTI team will continue working closely with Dr. Kraybill in this initial evaluation stage.

The commercialization strategy for the neonate suit was developed during the team's verification of the need for a neonate thermal control system. Through interviews with anesthesiologists and neonatologists at NIH and medical centers, it became apparent that designing a liquid-circulating neonate garment to be compatible with existing hospital hypo-hyperthermia pumping units would have the following advantages:

(a) Greater willingness of physicians to use the garment as a result of the low initial equipment investment. Surgeons could use the pumping units already available in their departments for initial trials. Investment

in a unit dedicated to neonate surgery would be necessary only after demonstration of the technique's efficacy.

(b) Greater confidence of physicians in the technique as a result of using familiar, trusted equipment. An important factor in this confidence is the physician's knowledge that the hospital electronics personnel have shown themselves capable of repairing the existing pumping units.

Information packages including selected articles from the medical literature and a description of the NASA-neonate suit were sent to the three major manufacturers of hypo-hyperthermia pumping units. The enthusiastic response to this package led to plans by RTI team and Mr. Herb Holley of the Ames Technology Utilization Office for a commercialization meeting to be held at Ames in March 1978. At this meeting, all of the liquid-circulating garment applications will be reviewed for the potential manufacturers.

PROBLEM UNC-90: Electromagnetic Flowmeter Calibrator

Studies show that variations in the shape of the blood flow pulses are good indicators of the condition of the cardiovascular system. In order to measure the pertinent variations, a flowmeter must have a frequency response curve that is flat from 0 to nearly 100 Hz. Electromagnetic flowmeters, which are the most widely used instrument to measure blood flow, generally meet these requirements, but an effective method for dynamically calibrating them does not exist.

A problem statement was prepared and distributed in 1976. No solution was found. Recently the team received a new inquiry for such a device. This reflects a growing interest in the clinical importance of the dynamic characteristics of blood flow. As a result the team is reconsidering this problem, but, if a brief solution search is unproductive, the problem will be inactivated.

PROBLEM UNC-91: Prosthetic Urinary Sphincter

An estimated 4 million people in the United States suffer urinary incontinence from a variety of etiologies, including multiple sclerosis, spinal cord injuries, cerebrovascular disease, birth defects, diabetes mellitus, and as a surgical complication resulting from prostatectomy. Efforts to restore continence have included electrical stimulation, operative urinary diversion, external collection, and implantation of prosthetic devices. These attempts have thus far yielded unsatisfactory results for one or more of the following reasons: (1) decrement of muscle response over time; (2) surgical complexity and attendant risk; (3) unsuitability for use by both males and females; and (4) lack of patient control. One very promising solution to this problem is a prosthetic sphincter designed by Drs. Scott, Bradley, and Timm (see figure 7). This prosthetic sphincter, which is commercially available, is a fluid system with a reservoir located in the abdomen and two operator bulbs to control the flow. When the fluid is transferred from the reservoir to the cuff around the urethra at the neck of the bladder, urine flow is prevented by the urethral occlusion. During voiding, the fluid is transferred back to the reservoir, thus deflating the cuff and allowing urine flow through the open urethra. This system has the advantages of (1) providing voluntary external control of bladder function and (2) eliminating the urinary tract infection problem that results from a continually open urethra with constant urine dripping. Success with this technique has been limited as a result of:

(1) leakage from tubing, reservoir, or cuff;

(2) pump malfunction;

(3) overpressurizing the cuff with resulting urethral tissue necrosis; and

(4) complexity of the implantation surgery.

The problem originator, Dr. Peter Stevens of the North Carolina Memorial Hospital Urology Department, suggested that a simplified, more reliable prosthetic sphincter would be of great benefit in the management of urinary incontinence. A review of the medical literature confirmed

Figure 7. Scott-Bradley-Timm Prosthetic Urinary Sphincter.

Dr. Stevens' description of the problem. A problem statement was written by the RTI BATeam and distributed to every NASA field center.

Mr. Ray Helms and Mr. Harold Smyly of Marshall Space Flight Center, who have been involved in the development of miniaturized valves, responded to the RTI problem statement with several designs for a prosthetic sphincter. All of the suggested systems eliminate the abdominal reservoir and reduce the number of operator bulbs to one (see figure 8). In addition, the valve employed in the new sphincter design is based on a NASA-developed miniaturized ball valve in which NASA introduced the use of a sapphire ball instead of a stainless steel ball. Sapphire can be polished to a finer finish than stainless steel and, therefore, is better suited for use in "zero" leakage, high reliability valves than is stainless steel. Thus, the major advantages of these new prosthetic sphincter designs are: (1) minimum surgery for implantation; and (2) simplicity and improved miniaturized valves for maximum reliability.

The Helms/Smyly designs were reviewed by the following individuals:

(1) Dr. L. Keith Lloyd
Department of Urology
Spain Rehabilitation Center
University of Alabama
Birmingham, AL

(2) Mr. Joseph Traub
Director of Rehabilitation Engineering
Rehabilitation Services Administration
Washington, DC

(3) Dr. Anton J. Beuschen
Director, Division of Urology
University Medical Center
Birmingham, AL

(4) Dr. Peter Stevens
Director of Pediatric Urology
School of Medicine
University of North Carolina
Chapel Hill, NC

(5) Dr. Gerald Timm
Vice President
American Medical Systems, Inc.
Minneapolis, MN

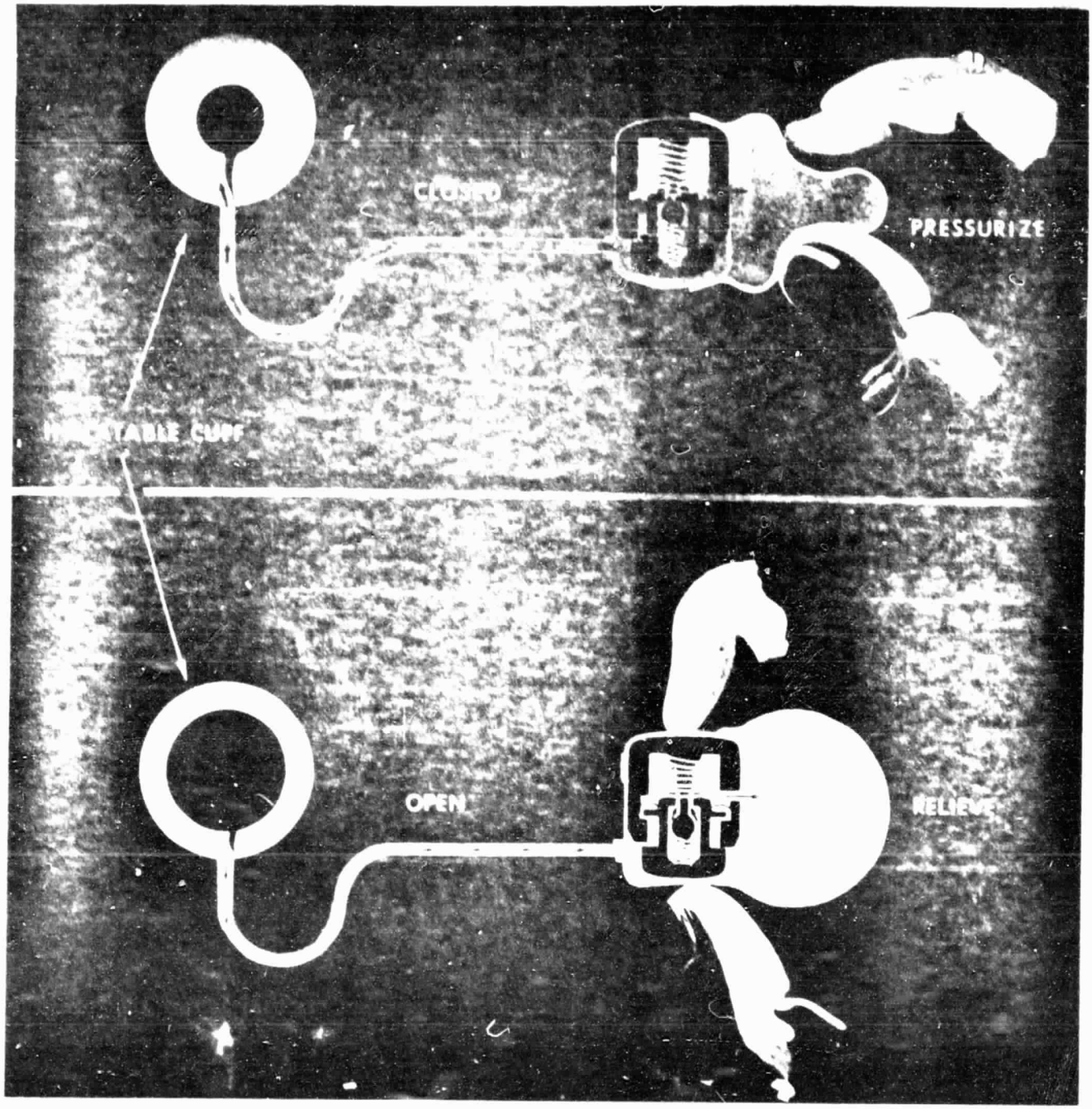


Figure 3. MSFC Press/Relieve Bulb Concept of Prosthetic Urinary Sphincter.

(6) Dr. Russel Fine
Director of Research
Rehabilitation and Training Center
University Medical Center
Birmingham, AL

Each of the reviewers concluded that the NASA sphincter designs showed enough potential for success to warrant further design and prototype development work by NASA.

Medical device manufacturers were asked to submit proposals for a joint NASA-industry effort to fabricate and test these sphincter designs. This early involvement by industry is important to the successful solution of the incontinence problem. Review by the manufacturer's engineering and medical personnel will provide additional information on the viability of the proposed NASA solution. Early involvement by the manufacturer can ensure adequate support for the required animal and clinical trials. The capability of the manufacturer to build and market the resulting product will ensure commercial availability of the sphincter for all patients in need of this device. It is planned that a team of NASA personnel, urologists, and the RTI team will evaluate the proposal in February 1978.

PROBLEM VAM-17: Optical Profilometer

A machine tool company identified by Dr. Clingman is interested in developing the optical profilometer for use in quality control of a machining process. The company is waiting for the team to determine the capability of the device.

The team used the device to measure several known surfaces. In November 1977, the resulting 3-dimensional information was forwarded to the problem originator for analysis. Unfortunately, the results from this analysis suggest that the device is not applicable to the machining problem, but the analyses results are compatible with the application planned by the problem originator. In this application, the device will be the data collection instrument for an international consortium that is dedicated to the treatment and study of cleft palate. Modifications of the device

will be required. The depth, range, and speed of operation must be increased, and a simple method for identifying specific surface areas must be developed. The team is working closely with engineering personnel at Langley Research Center and the University of Miami to determine if these modifications can be made within established cost constraints.

PROBLEM WF-56: Pressure Transducer Calibrator

Personnel from the Fabrication Division at Langley Research Center repaired the pressure transducer calibrator. Dr. Clingman delivered the repaired device to a major manufacturer of pressure transducers for their evaluation. In his discussions with officers of that company, he learned that users of pressure transducers are becoming more sophisticated in checking and calibrating their transducers including catheter transducer assemblies. Although the potential market for this device as a calibrator remains very small, a related clinical application appears to have a much broader market. Dr. Clingman has arranged with this manufacturer and several hospitals to explore the clinical application. First, the manufacturer will run a technical evaluation. Based on the positive results from this evaluation, Dr. Clingman will arrange the clinical evaluations. These evaluations are the initial steps in the commercialization strategy for this device.

PROBLEM WF-123: Tool for Fusing Surgical Suture Knots

Artificial monofilament fibers, such as polypropylene, are currently in wide use as surgical suture material for suturing the skin of humans. These fibers are very difficult to tie into secure, non-slip knots. The problem has been described in various medical journals. The common solution seems to be the practice of tying five and six repetitive knots on top of each other. Because this is a time consuming process that extends the duration of surgery, a need exists for a method of more rapidly securing the surgical filaments emanating from the first basic knot tied by the surgeon.

The team has contacted engineers at both the Langley Field Center and the Marshall Space Flight Center (MSFC). In particular, the inquiry at MSFC was directed to engineers who had reported in the NASA literature a technique of ultrasonic welding of thin plastic material to metals. However, it appears that the technology is not applicable to the suture problem.

During these conversations, several alternative techniques were suggested. One envisioned the possible use of a tool, similar to a wire-wrap tool, to wrap the loose ends of the suture thread about a tiny plastic bobbin having protrusions similar to Velcro fasteners. These suggestions are being pursued.

PROBLEM WF-124: Upgrading of Performance of the Tracheal Stethoscope for Reliable Respiration and Heart Rate Monitoring During Surgery

The tracheal stethoscope is a device that can be used by an anesthesiologist during surgery to monitor vital signs of the surgical patient. By listening to the sounds conducted through the stethoscope, the anesthesiologist can determine the heart rate and breathing rate of the patient. Although, using the stethoscope for several hours is an arduous task for the anesthesiologist, the stethoscope remains a simple, reliable, and useful instrument. The suggestion has been made that the acoustic signals detected by the tracheal stethoscope could be routed to an electronic signal processing device. The device could be programmed to automatically display both the heart rate and the breathing rate of the surgical patient.

To determine whether such an automatic analysis is feasible, the acoustic processing laboratory at Langley Research Center, which has every modern device for acoustic signal processing, is being utilized. Personnel at this lab are being provided with tape recordings originating from the tracheal stethoscope during surgery. They are attempting to identify several acoustic frequency bands that can be used as distinctive signals of the heart rate or the respiration rate. If such unique frequency bands can be identified, the electronic processing circuitry can be designed to

segregate the sounds from the tracheal stethoscope, process these acoustic signals, and display the heart and respiration rates. At the present time, the acoustic processing of the tape recordings is still in progress.

PROBLEM WWRC-18: Female Incontinence

Urinary incontinence is a frequent disorder that can result from spinal injuries, neurogenic bladder disease, multiple sclerosis, cerebral palsy, prostrate surgery, stroke, and nonspecific etiologies, especially in the elderly. The current method for managing a large number of incontinent males involves the use of an external roll-on rubber cuff and a collection bag attached to the leg. This closed collection system solves 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. Incontinent females, therefore, are managed by diaper and pads or by catheterization.

The RTI team is currently collaborating with Mr. Roger Michaud at Johnson Space Center (JSC) to evaluate the female urine collection system developed at JSC. Sizing parameters are being determined for prototype fabrication in early 1978. Involvement by medical device manufacturers awaits a feasibility study and patent clarification.

5.0 CONCLUSIONS

During the reporting period, two commercial technology transfers and five institutional technology transfers were completed. Twenty-six of 28 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 to 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. The addition of a management and marketing consultant to the RTI team has significantly enhanced the team's understanding of the medical manufacturing industry and how to interact with that industry.

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 interactions 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.

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.

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APPENDICES

APPENDIX A

PROJECT ACTIVITY SUMMARY

APPENDIX A-1 SUMMARY OF BIOMEDICAL APPLICATIONS TEAM ACTIVITIES

APPENDIX A-2 TECHNOLOGY TRANSFERS

APPENDIX A-3 NEW PROBLEMS

APPENDIX A-4 PROBLEMS INACTIVATED

APPENDIX A-5 ACTIVE PROBLEMS AS OF DECEMBER 31, 1977

APPENDIX A-1
SUMMARY OF BIOMEDICAL APPLICATIONS TEAM ACTIVITIES

Commercial Technology Transfers	2
Institutional Technology Transfers	5
New Problems	15
IAC Information Searches	10
Medical Literature Searches	8
Problem Statements Circulated	6
Responses to Problem Statements	19
Problems Inactivated	30
Active Problem Investigations	28

APPENDIX A-2
TECHNOLOGY TRANSFERS

Commercial Technology Transfers

NCI-14 *Packing Design for Thermal Control of Drug Shipments*

VAM-32 *Cardiology Information Presentation Techniques*

Institutional Technology Transfers

CP-3 *Automated Measurements from Coronary Angiograms*

DU-97 *A Compact, Highly Sensitive Light Detection System*

MISC-47 *Miniaturized Tension Measuring System*

UNC-89 *Protein Separation*

VAM-27 *Contour Mapping of Head*

APPENDIX A-3
NEW PROBLEMS

PROBLEM NUMBER	PROBLEM TITLE
CM-1	*A Miniaturized Constant Rate Infusion Pump*
DIX-1	*Horizontal Shower*
DU-99	*V-Slotted Head Screws*
DU-100	*Vaginal Micosal Blood Flow*
ERI-1	*Improved Optics for Vitrectomy Surgery*
GCCC-1	*Teletype Tester*
GCCC-2	*SCA Receiver for the Handicapped*
GCCC-3	*TTY Keyboard Test Device*
MISC-48	*Simple Presettable Torque Brake System*
MISC-49	*Microwave Thermography*
MISC-50	*Advanced, Rugged Hearing Aid for Children*
MISC-51	*Instrumentation for Acoustic Fetal Assessment*
TU-43	*Long-Term Monitor of ICP and Oxygen*
UGA-1	*Aerosol Vaccination System*
WF-126	*Intracranial Fluid Pressure Measurement*

APPENDIX A-4
PROBLEMS INACTIVATED

PROBLEM NUMBER	PROBLEM TITLE
DU-94	*X-Ray Screens*
DU-96	*Source of 7600°A Monochromatic Light*
DU-97	*A Compact, Highly Sensitive Light Detection System*
EU-23	*Miniature Telemetry Unity for Monitoring EMG*
EU-24	*Miniature Telemetry Unit for use as a Therapeutic Tool to Control Spasticity*
JEF-2	*Electronic Instrumentation for Detecting and Quantifying Motion in Closed Circuit TV Pictures*
JEF-3	*Development of a Miniature, Portable, Multi-Channel Biofeedback Apparatus*
MISC-47	*Miniaturized Tension Measuring System*
MISC-51	*Instrumentation for Acoustic Fetal Assessment*
NCI-14	*Packing Design for Thermal Control for Drug Shipments*
TE-1	*An Improved Method for Applying Phosphor Coating on Glass in UV Radiation Detectors*
TU-43	*Long-Term Monitor of ICP and Oxygen*
UCP-1	*Nonverbal Communications System*
UGA-1	*Aerosol Vaccination System*
UMISS-6	*TV Gait Analysis*
UNC-71	*Hand Therapy Assist Device*
UNC-73	*Image Intensifier for Microscopes*
UNC-82	*Method for Measuring Villi Motion*

APPENDIX A-4
PROBLEMS INACTIVATED (CONTINUED)

PROBLEM NUMBER	PROBLEM TITLE
UNC-87	*Quadrupole Mass Spectrometer*
UNC-88	*Improved Cooling Technique*
UNC-89	*Protein Separation*
UNC-92	*Method for Analyzing Video Tape Record*
VAM-24	*Processing of Rapid Microfluorimetry Data*
VAM-25	*Mechanical-Energy Storage Device for Hip Disarticulation*
VAM-27	*Contour Mapping of Head*
VAM-33	*Breast Cancer Screening Technique*
VAM-34	*Neonate Eye Tracker*
WF-121	*Accurate Measurement of Input and Output from Ultrasonic Probes*
WF-125	*Evaluation of Ferromagnetic Fluids*
WF-126	*Intracranial Fluid Pressure Measurement*

APPENDIX A-5
ACTIVE PROBLEMS AS OF DECEMBER 31, 1977

PROBLEM NUMBER	PROBLEM TITLE
CM-1	*A Miniaturized Constant Rate Infusion Pump*
DIX-1	*Horizontal Shower*
DU-74	*Testing of Neuropathic Patients*
DU-98	*Digital TV-Display Device*
DU-99	*V-Slotted Head Screws*
DU-100	*Vaginal Mucosal Blood Flow*
ERI-1	*Improved Optics for Vitrectomy Surgery*
GCCC-1	*Teletype Tester*
GCCC-2	*SCA Receiver for the Handicapped*
GCCC-3	*TTY Keyboard Test Device*
LSD-1	*New Method for Cleaning Teeth*
MCV-3	*Determination of Deltopectoral Flap Viability*
MCV-4	*Sealing of Amputation Stump Neuromas to Prevent Pain*
MCV-5	*Lung Sound Modeling*
MISC-37	*Weight Alleviation Device*
MISC-48	*Simple Presettable Torque Brake System*
MISC-49	*Microwave Thermography*
MISC-50	*Advanced Rugged Hearing Aid for Children*
NCI-4	*Controlled Rate of Freezing [illegible]*
UMISS-5	*Leg Brace Weight Problem*
UNC-83	*Neonatal Thermal Control for Use in Surgery*
UNC-90	*Electromagnetic Flowmeter*
UNC-91	*Prosthetic Urinary Sphincter*

APPENDIX A-5
ACTIVE PROBLEMS AS OF DECEMBER 31, 1977 (CONTINUED)

PROBLEM NUMBER	PROBLEM TITLE
VAM-17	*Optical Profilometer*
WF-56	*Pressure Transducer Calibrator*
WF-123	*A tool for Rapidly Fusing Surgical Suture Knots*
WF-124	*Upgrading of Performance of the Tracheal Stethoscope for Reliable Respiration and Heart Rate Monitoring During Surgery*
WWRC-18	*Female Incontinence*

APPENDIX B

PROBLEM STATEMENTS

PROBLEM DDH-1

HORIZONTAL SHOWER

DATE OF PREPARATION: December 21, 1977
INSTITUTION: Dorothea Dix Hospital
Raleigh, N.C.
PROBLEM ORIGINATOR: Dr. Harold Glascock, Jr.
BATEAM PERSONNEL: Ms. Doris Rouse

WHAT IS NEEDED: An effective, pleasant and safe bathing system for bedfast patients.

BACKGROUND: A large number of institutionalized patients are unable to bathe themselves. This population includes spinal cord injury victims, cerebral palsy patients, multiple sclerosis, spina bifida, epileptic, and spastic patients. The two methods most widely used to bathe these patients are as follows: (a) sponge bath; and (b) tub bath by lowering patient on a gurney transport system. The advantages and disadvantages of these techniques are discussed below.

The major disadvantages of the sponge bath are the time factor and the level of cleanliness. Hospitals estimate the administration of a sponge bath to require fifteen to twenty minutes of staff time and to involve the risk of staff injuries while turning the patient. Sponge baths do not ensure adequate patient cleanliness for chronic use in the long term care facility. This is especially true in the large number of bedridden patients who are incontinent of urine and feces and who have decubitus ulcers. The primary advantage of a sponge bath is that no special equipment is required.

The major disadvantages of the tub bath involve the current methods of transport and immersion, the cleanliness of incontinent patients, and the staff injuries resulting from patient lifting and lowering. One common patient transport method is the Hoyer hoist with a sling seat. This seat provides no head or neck support for the patient in the bath and does not allow thorough cleaning of the buttocks. The possibility of self contamination with microorganisms is a serious disadvantage in the use of a tub bath with incontinent patients. Nursing staff injuries related to patient bathing are a serious problem. An investigation by the Swedish Planning and Rationalisation Institute of Hospital and Health Care showed 25 days in a single year lost for four people due to backache in a hospital's central bath department.[1] A primary advantage of the tub bath is the psychological benefit derived from immersion in warm water.

According to the Aberdeen Formula, a method of determining nursing staff requirements used in Scotland, an acceptable standard of basic nursing care for all helpless bedfast patients consists of bathing once daily.[2] Inadequate staffing and inefficient, awkward bathing facilities result in patients receiving only two baths per week in most long term care facilities. A more efficient, convenient bathing technique may increase bathing frequency, and, thus, improve patient cleanliness and health. A recently developed showering system by Arjo of Sweden is the most advanced system available today. This

system consists of a trolley/stretcher that is wheeled to the patient's bedside where it is raised to the bed height by a hydraulic foot control. The patient is then transferred to the trolley and wheeled to the bathroom. The stretcher carrying the patient is then rolled onto a table which is slowly lowered into a bath. Approximately twenty of these units are currently in use in this country. The disadvantages of this system are as follows:

(a) Bathing, not showering system. As a result, patients that are incontinent of feces must bathe in water contaminated by their own fecal matter.

(b) No access to the buttocks or perineal area. Adequate washing in these areas is essential for patients that are incontinent and have decubitus ulcers. Adequate and frequent washing in these areas may decrease the incidence of urinary tract infections.

(c) Lack of patient privacy while bathing.

Proposed Technology

The technology presently being considered for improving the bathing system is a modified version of the horizontal shower developed by NASA to determine the effects of prolonged bed rest. A description of this system before modification for hospital use is found in the attached NASA Tech Brief B73-10272 from Ames Research Center. Advantages of the NASA horizontal shower are as follows:

(a) Employs a trolley/stretcher that both transports the patient and serves as a bed in this shower. This minimizes lifting of the patient by the nursing staff.

(b) Shower heads provide thorough washing without exposing the patient to his/her own waste water.

(c) Shower heads have inner rotating vanes which spin the water into tiny droplets and produce a soft, dense full coverage spray that massages the body.

(d) Water temperature is regulated to prevent patient scalding.

(e) The gurney on which the patient is transported and showered is made of a nylon web. This allows easy washing of the buttocks and perineal area by a shower head located below the gurney.

(f) The shower is enclosed, thus maintaining patient dignity and privacy during bathing.

Current Status:

A manufacturer of patient transport devices is currently evaluating NASA's proposed modified shower for market potential.

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PROBLEM GCCC-3

TTY KEYBOARD TEST DEVICE

DATE OF PREPARATION: December 19, 1977
INSTITUTION: Guilford County Communication Center for the Deaf, Greensboro, NC
PROBLEM ORIGINATOR: Ms. Marzi Maury, Director
BATEAM PERSONNEL: H. Clark Beall

WHAT IS NEEDED: A small portable test device to display TTY character bit patterns in order to facilitate field repair.

BACKGROUND: Many of the deaf in the United States utilize a Teletype machine (TTY) and acoustic coupler to communicate over the telephone. The TTY that are typically used in these installations are the older 60 wpm Baudot models.

Field servicemen have observed that the most frequent malfunction in the Baudot machine is in the keyboard sending mechanism. Because this mechanism is a rather complex device, consisting of mechanical levels, springs, and electrical contacts, the proper adjustment is seldom achieved by a field repairman. Usually, TTY keyboard adjustments are made by the repairman until correct printing is achieved on the TTY machine. At this point, the keyboard may be only marginally operational. However, this may be discovered only later after frustrating attempts to communicate reliably with other TTY installations.

What is needed for the field repairman is a battery operated, portable, test device that can certify the operation of the keyboard sending mechanism. What is envisioned is a device that can monitor the local loop current that flows through the keyboard sending mechanism. As the sending mechanism operates, the test device could monitor the direct current pulses flowing in the line.

Because the seven-bit TTY machine code pattern for a single character is completed in less than one fifth of a second, the test device should be able to both record this transient signal and then display the serial pattern of current pulses so that the repairman can observe the sequence and dwell time of each individual bit of the pattern. It has been suggested that the commercially available 5 x 7 LED matrix be utilized as a low cost display, with each of the seven horizontal rows of the matrix representing the 22-millisecond dwell time intervals of the seven bits of the Baudot TTY code.

The utility of the proposed test device would not be limited to the testing of only the TTY keyboard. If the interface were properly designed, the test device could be used to measure signal distortion at virtually any site within the send and receive local loop circuits.

PROBLEM RTI/CM-1

A MINIATURIZED CONSTANT RATE INFUSION PUMP

DATE OF PREPARATION: September 19, 1977
INSTITUTION: Carnegie-Mellon Institute of Research
Pittsburgh, PA
PROBLEM ORIGINATOR: Mr. R. K. Olson
BATEAM PERSONNEL: Doris J. Rouse

WHAT IS NEEDED: A small, constant rate infusion pump to deliver approximately 6 ml. of a drug per twelve hour period. Pump must be small enough to be worn by ambulatory adults and children.

BACKGROUND: The conventional unit dosage drug delivery techniques (i.e., one tablet every 6 hours or an injection twice per day) are often inefficient and undesirable as a result of side effects. These pulsed delivery systems can result in an oscillation between toxic and subtherapeutic levels (Figs. 9 and 10). A constant infusion of a drug, however, would result in a zero-order delivery and a steady therapeutic level. Side effects, therefore, are minimized.

This factor becomes extremely important in disease states such as diabetes which require daily injections of a drug for the lifetime of the patient. Thalassemia (Cooley's anemia) is an inherited disorder in which there is a deficient synthesis of globin chains of normal hemoglobin. Most children with this disease need chronic blood transfusions to maintain an active life. Accumulation of excess amounts of iron from these transfusions and by increased intestinal absorption is a major problem in these children. The excess iron may be partially responsible for organ damage, particularly to the heart, leading to complications of the disease and death from cardiac failure.[1,2] Deferoxamine is a drug that combines with the excess iron and prevents its accumulation and harmful effects to some degree.[3] Poor absorption of this drug in the stomach necessitates daily injections for the lifetime of the thalassemia patient. As in the case of insulin, a constant infusion device would provide a more efficient and safer method for drug delivery of deferoxamine.

Current Drug Delivery Devices

Diffusion Devices: Several methods for the delivery of a drug from a resevoir at a predetermined rate have been designed. Examples of some of these systems are as follows:

(1) Capsules of polymeric material filled with a solid or liquid drug or with a suspension or solution of a drug in a fluid, in which the release of agent is controlled by Fickian diffusion through the capsule walls.

(2) A heterogeneous dispersion of particles of drug in a solid polymeric matrix, which can be either biodegradable or non-biodegradable, and which controls the release of drug by diffusion through the matrix, by erosion of the matrix, or by a combination of a diffusion and erosion.[4]

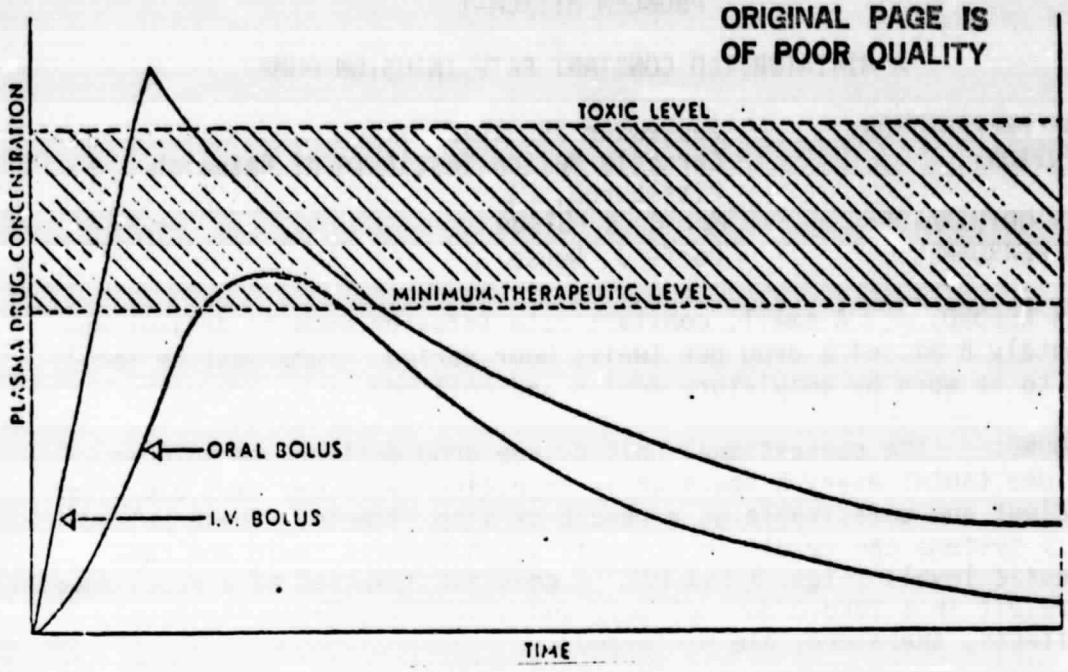

Figure 9.

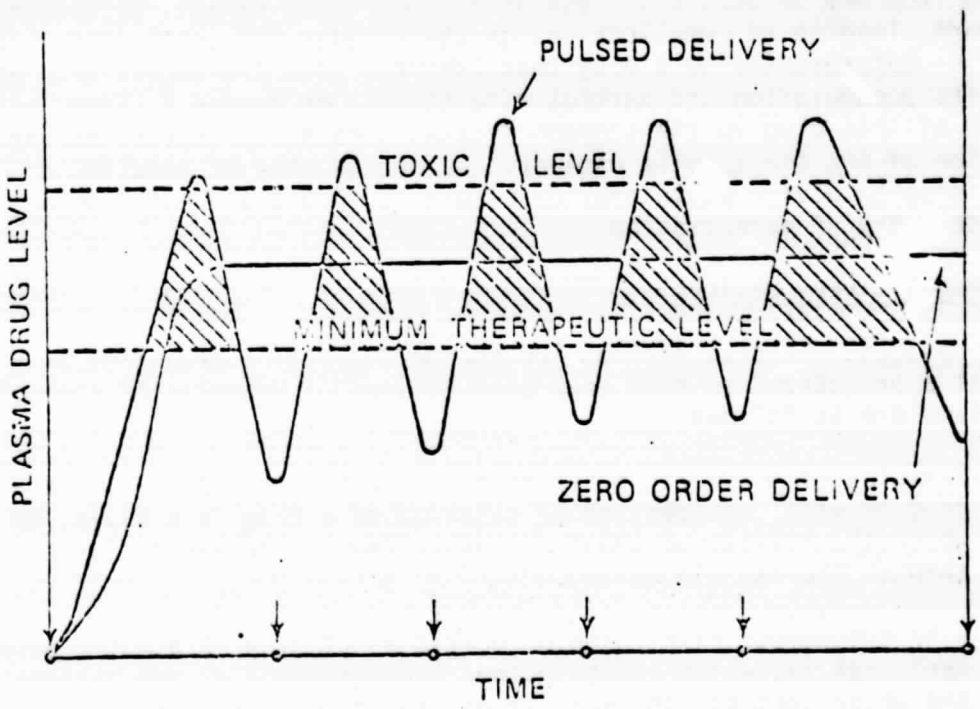

Figure 10.

Most systems currently being explored control the release of the drug by diffusion through a polymeric membrane. Alza Corporation has pioneered this research and is currently demonstrating in clinical trials that intrauterine devices that release progesterone at low constant rates can provide effective contraception for a year using the equivalent dosage of three oral pills, thus minimizing side effects. Although these diffusion systems are useful in long term delivery of low levels of drugs, they are not practical for the delivery of 12 ml. per day as is required in the use of deferoxamine to treat thalassemia.

A continuous long-term injector was developed by Rose and Nelson.[5] The motive force of the injector depends on the osmotic pressure developed by a saturated solution of Congo red against water. This solution is contained in a partially collapsed rubber compartment and is separated from a second water compartment by a semipermeable cellophone membrane. By osmosis, water moves into the Congo red solution and expands the rubber compartment. It is this expansion which provides the mechanical force to eject the drug out of the apparatus.

Syringe Infusion Pumps: Syringe infusion pumps worn externally are commonly used to deliver larger volumes at a constant rate. These have always been too large and cumbersome for convenient, life-long use by ambulatory patients.[6,7] Researchers at the National Institute for Medical Research in London have recently developed a portable and reliable miniature syringe pump called the Mill Hill infuser for continuous administration of drugs and hormones.[8] This system is driven by a lead-screw and arm. A mercury battery, with an operating life of at least twenty syringe loads, supplies a quartz-crystal-controlled oscillator and integrated circuit divider, providing gating pulses every few seconds to energize a motor with integral gearbox. After each activation the gate circuit is reset by a pulse derived from the output shaft. The overall dimensions are 30x70x130mm. and weighs 300g. A 2 ml. disposable plastic syringe is positively locked to the drive mechanism, but can be replaced quickly. Two models are designed for a 2 ml. per 8 hours or 2 ml. per twenty-four hour delivery rate.

Although the Mill Hill infuser represents a significant advance over previous models, a smaller pump that can operate with larger reservoir volumes is needed for use with ambulatory patients, including children stricken with Thalassemia. A pumping device with no moving parts that approaches the size of a cardiac pacemaker would significantly enhance the practicality of using constant rate infusion devices. An energy source with a longer lifetime that meets the size constraints would also improve the acceptance of the device by the medical community and the patient population.

Constraints and Specifications

(1) Flow Rate of 6 ml./12 hrs. Rate constant ± 20% maximum.

(2) Small size. Reservoir of 6 ml. Pump size approximately that of a cardiac pacemaker. The device is required throughout the patient's life and will be worn by infants.

(3) A miniaturized, long term energy source for the pump.

(4) Flow Resistance. The pressure head required is that associated with subcutaneous infusion and will probably consist predominately of the resistance of the tubing and needle connecting the patient to the drug supply. (Up to 50 p.s.i.)

(5) Operation. Simple for patient or non-medically trained assistant to load and actuate. Must operate independent of patient's position (horizontal, vertical).

(6) Durability. Rugged enough to permit relatively normal activity by user.

(7) Tamper proof for use on infants.

Characteristics of Relevant Technology: NASA techniques and expertise in the sensitive delivery of fluids would be applicable to the solution of this problem. The NASA technology in miniaturized, high reliability energy sources may also transfer to this application.

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PROBLEM DU-100

VAGINAL MUCOSAL BLOOD FLOW

DATE OF PREPARATION: September 6, 1977
INSTITUTION: Duke University Medical Center
Durham, N.C.
PROBLEM ORIGINATOR: John F. Steege, M.D.
BATEAM PERSONNEL: Richard W. Scearce

WHAT IS NEEDED: A device is needed that is capable of remotely measuring vaginal blood flow in the resting state in an office setting.

BACKGROUND: It is a common presumption that most sexual difficulties arise from "psychological" causes, which in the experience of a sex therapist often means that contributory physical or psychophysiologic components are either overlooked or misunderstood. Meager knowledge of sexual psychophysiology is often an obstacle in dealing with these problems.

Vaginal mucosal blood flow, observed qualitatively by Masters and Johnson[1] to be a major parameter in sexual response, has attracted considerable attention during the past few years. Although some intriguing data have been generated, methodologic and technical difficulties have prevented reliable quantitative measurement.

A device is needed that is capable of remotely measuring vaginal blood flow. It would prove invaluable in investigating physiologic vaginal changes in response to "normal" events such as phases of the menstrual cycle, variations in menstrual cycle length, use of contraceptive hormones, variations in sleep patterns, etc. Vaginal blood flow measurements might also prove useful in measuring the pharmacologic side effects of widely used psychotropic and antihypertensive drugs, topically and systemically administrated antibiotics, chemotherapeutic agents, local and external beam irradiation, etc. The vigor of the vaginal mucosa could also be evaluated before and after vaginal or abdominal surgery on the female reproductive tract and bladder. Consistent data from studies of this kind would help gynecologists and family physicians greatly in evaluating the psychophysiological components of sexual complaints. In this circumstance there would be an obvious need for devices capable of measuring vaginal blood flow in the resting state in an office setting.

Previous Work

Several investigations have used photoplethysmographic devices to measure vaginal blood flow.[2-4] Unfortunately, it has not been possible to eliminate several important variables that most likely affect results with this technique, such as: (movement of the measuring device along the longitudinal axis of the vagina; (2) variation in the extinction coefficient of hemoglobin proportional to the pO_2 of the blood,[5] with the wavelength used. 6900A, (cf. Hoon, et al.[6]); (3) varying distance between the vaginal mucosa surface and the photoplethysmograph; and (4) varying angle between the mucosa and the light beam emitted by the device.

Preliminary work has been done with hard-wired thermistors in a laboratory setting,[7] but similar location problems have limited the value of the data.

Technical Requirements

In order to generate more useful physiologic data for evaluation of sex response, a device designed to measure vaginal blood flow must:

(1) be small enough to fit comfortably in the vagina without pressing against the mucosa firmly enough to alter blood flow (e.g., a contraceptive diaphragm is usually not felt by the wearer once it is in place),

(2) be capable of remaining in a relatively fixed position relative to a given area of the vaginal mucosa as the vagina expands during sex response,

(3) be largely unaffected by total body movement artifact,

(4) be capable of being calibrated quantitatively so as to give reproducible results in the same subject, and comparable results among many subjects, and

(5) be capable of coupling with a radiotelemetric device to transmit data signals to a nearby receiver for recording.

The last requirement listed above would permit subjects to generate data in privacy, thus minimizing whatever artifacts are introduced by the laboratory setting as well as making data collection acceptable to a much larger subject population.

As an initial approach, the problem originator suggests considering a device that would either (1) fit inside the perimeter of a vaginal diaphragm (most commonly 60 to 80 mm in diameter) or (2) adhere directly to the vaginal mucosa with a non-toxic adhesive. The latter device would probably have the more stringent size requirements, i.e., maximally about 2.5 x 2.5 cm.

If the radiotelemetric and device-positioning requirements described can be met, this approach could possibly be adopted to the measurement of other parameters of interest to the vaginal physiologist, such as the mucosal pO_2, pCO_2, and pH.[8] Again, the capacity for data collection in a private nonlaboratory setting would greatly facilitate the expansion of our knowledge of vaginal physiology.

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PROBLEM MISC-50

ADVANCED, RUGGED HEARING AID FOR CHILDREN

DATE OF PREPARATION: July 1977
INSTITUTIONS: Bureau of Education of the Handicapped, and NASA Headquarters
PROBLEM ORIGINATOR: Dr. Frank Withrow (BEH)
BATEAM PERSONNEL: R. L. Beadles (RTI); E. Engstrom (WISC)

WHAT IS NEEDED: A hearing aid of substantially improved design, which incorporates superior technical features and is specifically designed to withstand much greater physical abuse without damage than are currently available hearing aids.

BACKGROUND: There are 200,000 or more children in the United States who have a sufficient hearing loss to interfere with normal acquisition of speech and language. Fortunately, most of these children do have some useful hearing remaining; for such children the hearing aid remains the primary device for compensating the hearing loss. Since a hearing loss of even a moderate level, if uncompensated, seriously interferes with the normal acquisition of speech and language and therefore has profound educational implications, the early fitting and consistent use of a proper hearing aid is one of the most essential elements if the child is to succeed in the hearing world.

SPECIFICATIONS:

I. Physical and environmental requirements

So far as level of physical activity is concerned, a child who wears a hearing aid is no different from any other healthy child. Specifically, a hearing aid worn by a child will be subjected to substantial shock, vibration, and occasionally immersion in water. That hearing aids presently available for children are inadequate to withstand these environmental stresses is well demonstrated by studies of hearing impaired children which show that typically one-third to one-half the hearing aids that these children wear are not working properly at any one time. A major redesign of the hearing aid for children with emphasis on making the aid as child proof as practicable is clearly in order. Specifically,

A. Aids must be packaged for children in a rugged format which allows for functional operation within a wide range of humidity and temperature conditions. The aid should be able to withstand considerable shock and vibration as well as be waterproof (or have a failsafe feature such as moisture-activated shutdown).

B. The aid should be designed with easily operated rugged control settings. However, an override lock should be available so that children can be prevented from playing with the controls.

C. Cords for body aids of CROS headworn aids should be designed so that they are virtually indestructible if they are used at all.

II. Technical and performance requirements

In addition to the need for making a hearing aid for children which is essentially child proof, there are a number of important technical features each of which has the potential for providing significant added benefit over present designs. In particular, the following three factors must be addressed:

1. The normal external ear and ear canal provide substantial shaping of the speech frequency range through acoustic resonances.[1] Specifically, in the 3,000 to 4,000 Hz range, these resonances provide at least a 15 dB boost relative to the response at 1 KHz. The frequency response of the advanced, rugged hearing aid for children should be capable of being set to match that provided by these normal resonances (to a tolerance of + 2dB).

2. A major functional limitation of present hearing aids is the serious degradation of speech intelligibility in noise relative to performance in quiet.[2] Methods for increasing the signal to noise ratio at the wearer's ear must be incorporated; one example of such a method is a highly directional microphone.

3. Although a person with a 90 dB hearing loss may have significant useful hearing, the problem of acoustic feedback limits the maximum useable gain of a headworn hearing aid to no more than approximately 50 dB and that of a body aid to no more than approximately 60 dB even when a tight fitting, unvented earmold is used. Particularly for young children, achieving this useable gain requires that earmolds be frequently replaced as the child grows; replacing of earmolds at 3 month intervals is not uncommon for young children if they are to obtain these levels of gain without feedback.

The several advantages of headworn hearing aids over bodyworn aids have not been fully utilized because of the useful gain advantage of the bodyworn aid over the headworn aid because of the acoustic feedback problem. There are a number of technical approaches to solving the problem of acoustic feedback.[3,4] The advanced, rugged hearing aid for children must incorporate features which enable the gain before feedback to be increased by at least 10 dB.

In addition to the above factors, the following general performance requirements, largely representative of present hearing aids, must be met:

A. Frequency response should be adjustable so that the aid can be tailored to meet the needs of individual children. True flexibility in the shaping of frequency gain characteristics should be developed. minimum acceptable frequency response range should be 200 to 6000 Hz (HAIC).

B. The minimum acoustic gain at the maximum volume control setting shall be 60 dB at 1000 Hz.

C. Maximum Power Output control shall be independent of the gain control (± 3 dB).

D. Maximum Power Output shall be adjustable, but should not exceed 135 dB (-3, +0 dB).

E. Distortion such as intermodulation at different frequencies, transient responses, and peaks in responses should be eliminated.

F. Performance shall remain within specification with a change of 10% in battery voltage.

G. The electronic signal to noise ratio shall be at least 40 dB.

H. Consideration shall be given to the inclusion of a cost effective malfunction detection unit.

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PROBLEM MISC-51

INSTRUMENTATION FOR ACOUSTIC FETAL ASSESSMENT

DATE OF PREPARATION; September 19, 1977
INSTITUTION: Sinai Hospital
Baltimore, Maryland
PROBLEM ORIGINATOR: Phillip J. Goldstein, M.D.
BATEAM PERSONNEL H. Clark Beall

WHAT IS NEEDED: Electronic circuitry is needed which converts instrumentation output from scales of millimeters of mercury to decibels.

BACKGROUND: In problem pregnancy cases, the well being of the fetus can be assessed at intervals during the last trimester of pregnancy by means of the oxytocin hormone challenge test. The response of the fetus is monitored during the cycles of mild contractions of the womb that are caused by the injection of a small quantity of the hormone into the mother's bloodstream. The challenge test is widely used, although sometimes it causes the premature onset of birth. For this, and other reasons, efforts are under way to develop different types of fetal assessment tests.

Of the fetal sensory organs, the auditory sense is most mature during the last trimester. It is logical to investigate whether a fetal assessment test can be developed that utilizes auditory stimulation. The problem originator believes that he has the proper facilities and personnel to develop such a test.

The RTI team has responded to the originator's enquiry for technical help in the experimental design of the auditory fetal assessment test. After discussing the technical and experimental aspects of the test with the problem originator, it appears that the RTI team can contribute technical expertise in the specification and design of some of the instrumentation. In particular, the capability of one instrument would be enhanced by converting it into an audiometer with an output scale reading directly in decibels. This would eliminate the manual conversion of data that is now required.

PROBLEM STATUS: The RTI team has provided a quantity of technical literature that should enable the investigator to modify the electronics of their instrument so as to achieve the proper output scale for his data. No further assistance to the investigator is anticipated.

PROBLEM ERI-1

IMPROVED OPTICS FOR VITRECTOMY SURGERY

DATE OF PREPARATION: June 20, 1977
INSTITUTION: The Eye Research Institute of Retina Foundation
PROBLEM ORIGINATOR: Dr. Oleg Pomerantzeff
BATEAM PERSONNEL: Doris Rouse

WHAT IS NEEDED: An optical device for visualization of the peripheral vitreous during surgery.

BACKGROUND: The vitreous humour is the transparent jelly that fills the posterior 80 percent of the globe of the eye. Intravitreous opacities resulting from hemorrhage or inflammation often result in a permanent profound loss of vision. Vitreous hemorrhages occur as a complication of a variety of diseases, including diabetes mellitus, sickle cell disease, hypertension, arteriosclerosis, and Eales' disease, as well as trauma to the head and directly to the eye. If there is no substantial clearing of the hemorrhage within six months, a vitrectomy surgery is performed in an attempt to restore vision. In this surgery, an instrument called the vitreous nibbler is introduced into the eye to dissect the opaque vitreous, aspirate the tissue, and infuse fluid to maintain proper intraocular pressure. (See Fig. 11.)

Visualization of the vitreous near the retina requires placement of a contact lens on the cornea and the use of an operating microscope (See Fig. 12.) The purpose of the lens is to neutralize the refractive power of the cornea so that areas in the posterior vitreous cavity are brought to a focus in the anterior vitreous cavity. Thus, the image comes within the focusing range of the operating microscope and appears erect and clear. (See Fig. 13.) However, this lens permits only a narrow field of view and does not allow visualization of the peripheral vitreous. Thus, removal of opacities in these areas is not possible.

One technique currently employed to obtain visualization of the entire fundus and vitreous cavity is the Goldmann three-mirror contact lens. (See Fig. 14.) A flat contact lens with a single adjustable mirror has also been developed. These lenses, however, are 15 mm high and, thus, too bulky for convenient use in surgery.

CONSTRAINTS AND SPECIFICATIONS: Functional requirements for an optical device for visualization of the vitreous peripheral to the equatorial region are as follows:

1) Small size, preferably no larger than the 2.3 mm x 10 mm contact lens used currently for direct visualization of the posterior vitreous;

2) The capability of sharp chromatic and spatial resolution; and

3) Suitability for use with an operating microscope.

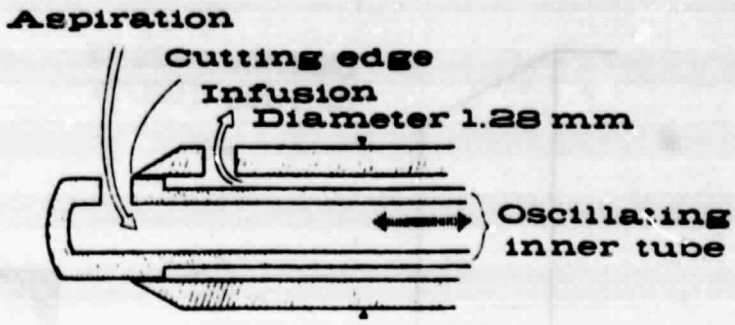

Figure 11. Oscillating vitreous cutter (vitreous stripper) developed by Klöti. (From Klöti, R.:Vitrektomie. II. Chirurgische Technik mit dem Vitreous Stripper. Albrecht v. Graefes Arch. Klin. Exp. Ophthal. 189: 125-136, 1974.)

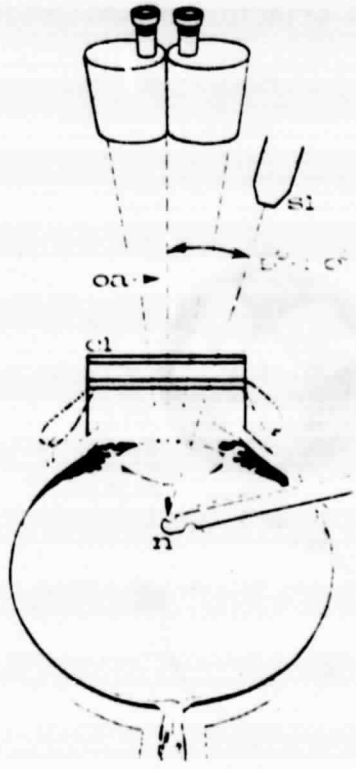

Figure 12. When operating room slit lamp is used during closed vitrectomy, slit illumination (s1) is positioned 5 to 20 degrees from the observation axis (oa). Contact lens (c1); on the cornea; nibbler (n) in the vitreous.

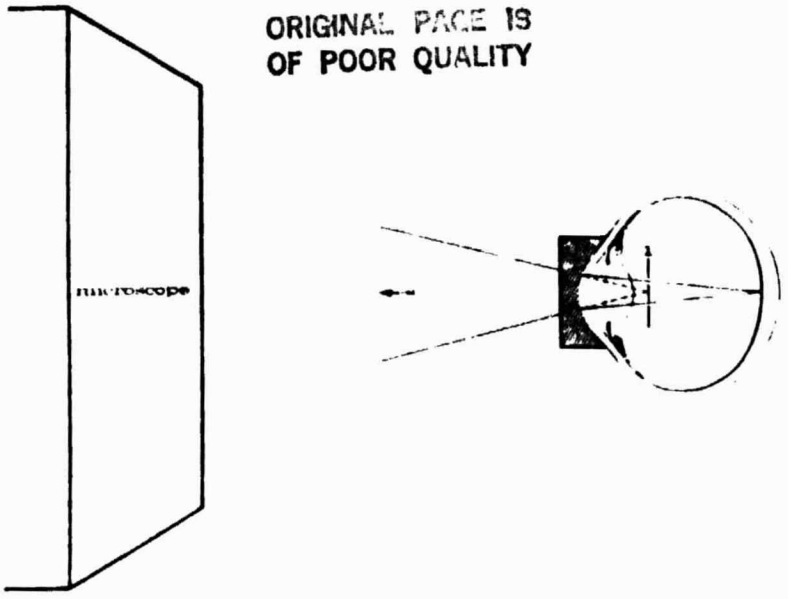

Figure 13. Optical principle of posterior fundus contact lens.

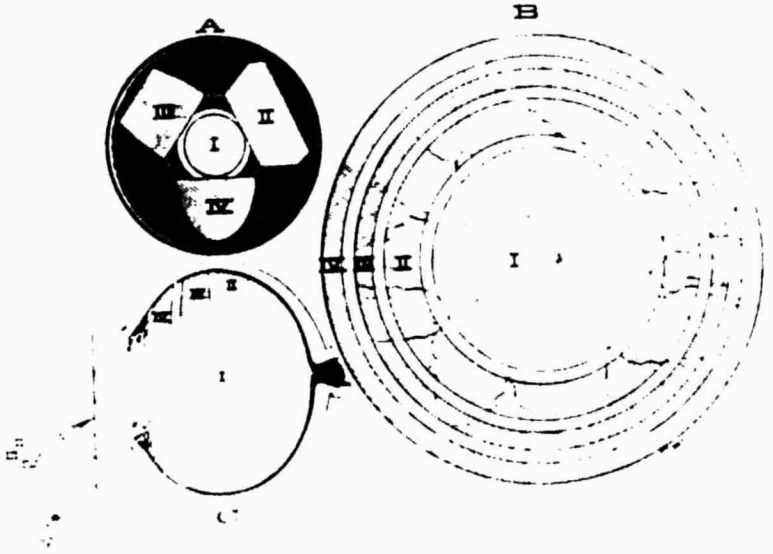

Figure 14. Optical principle of Goldmann three-mirror contact lens. A. Composite picture of three-mirror contact lens. B. Sketch of fundus. C. Section of vitreous cavity. Areas of vitreous cavity and fundus viewed with different parts of three-mirror lens are illustrated. Central part of mirror (I): equatorial mirror (II): peripheral mirror (III): gonioscopic mirror (IV). Angle of inclination of each mirror is shown in C.

PROBLEM STATUS: Fresnel lenses are currently being used in the treatment of diplopia (double vision) to shift the image in one eye so that it is focused on the same area of the retina as in the other eye. The problem originator has experimented with the use of these Fresnel lenses to visualize the peripheral vitreous with some success. Problems of chromatic and spatial resolution may be overcome by developing a lens designed for use with a microscope.

The RTI BATeam is investigating NASA's capabilities in the design and fabrication of Fresnel lenses.

PROBLEM GCCC-2

SCA RECEIVER FOR THE HANDICAPPED

DATE OF PREPARATION: May 5, 1977
INSTITUTION: Guilford County Communications Center for the Deaf, Greensboro, N.C.
PROBLEM ORIGINATOR: Ms. Peggy Bull Nelson, Director
BATEAM PERSONNEL: H. Clark Beall

WHAT IS NEEDED: A low cost Subsidiary Communications Authorization receiver and decoder for reception of SCA subcarrier broadcasts for the handicapped.

BACKGROUND: The Greensboro, North Carolina, area is perhaps the most active region in the United States, per capita, in providing a means of telephone communication for the deaf. Emphasis has been placed on equipping all of the homes of the deaf with Teletype (TTY) machines and acoustic couplers. To date, more than 320 such installations have been completed in North Carolina, with more than 150 units being within a 40-mile radius of Greensboro.

Although the system was originally conceived as an emergency communications means for a deaf person, a widely appreciated secondary utilization has developed. The deaf now use the TTY to talk informally with one another via phone. The Guilford County Communications Center for the Deaf (GCCCD) compiles daily information of special interest to the deaf, such as announcements of education opportunities, social events, job openings, and local news. A paper tape TTY transmission, of about ten minutes in duration, is available to the TTY stations of those individuals who phone the GCCCD daily and request the newsletter. However, because of the large number of TTY stations in the Greensboro area, queueing problems develop when more than one TTY station attempts to obtain a transmission during the same time period that a transmission is in progress to another station. The situation is especially severe in the evenings. Also, due to the rural environment, most of the TTY stations must make a toll phone call.

GCCCD has requested that the RTI team investigate what is available as a radio broadcast means whereby several daily broadcasts of TTY machine code from GCCCD could reach virtually all of the TTY stations of the Greensboro area.

The RTI team has investigated this problem and has determined that radio transmission is indeed feasible not only for the Greensboro area, but for any other geographical area which would desire to establish a limited audience broadcast capability to reach a handicapped audience. In fact, the FCC has recently revised its rules to permit both "aural" and "visual" transmission modes on the Subsidiary Communications Authorization (SCA) subcarriers available to FM stations of the FM broadcast band. The "visual" mode refers to the transmission of audio-encoded information that the receiving station decodes back into a visual format. Examples of "visual" modes that are permitted include slow-scan TV, facsimile, and TTY

C-2-

There are several commerical sources of equipment for SCA transmission and reception. This equipment is sold to FM stations that desire to establish "Storecast" music on the SCA subcarrier as a commercial subscription service. Representatives of the FM station install and maintain the SCA decoder units at each subscriber's site. The price of the reception decoders is too high to be considered appropriate for a broadcast service for the handicapped. The RTI team activity will focus on making available a low cost SCA decoder device for the handicapped market at a much lower price than the currently available units.

It is of interest that the blind have utilized the SCA for the last ten years as a basis of their radio reading service for the blind. At the present time, the blind must purchase their SCA receivers from commerical sources. As a result of the high cost of the decoders, the audience for the radio reading service has not grown as expected. Thus, the device that the RTI team proposed to bring to the marketplace for the handicapped should be flexible enough to be used by both the blind (who already utilize the SCA in half a dozen states) and the deaf (who can perhaps share programming time on the SCA stations being utilized by the blind). The national organizations for the deaf and for the blind already have the capability to serve as marketing and distribution centers for specialized devices such as the SCA decoder.

In summary, the Greensboro, N.C., area can serve as a model system for the development of services and devices for the deaf. The development of SCA broadcast capability in the Greensboro area can serve as a prototype system which can be duplicated in many other sites having larger geographical areas and higher population densities.

PROBLEM MISC-48

SIMPLE, PRESETTABLE TORQUE, BRAKE SYSTEM

DATE OF PREPARATION: May 15, 1977
BATEAM PERSONNEL: H. Clark Beall

WHAT IS NEEDED: A means of easily and reliably presetting braking torque on an exercise machine.

BACKGROUND: A national distributor of physical-therapy devices requested Team assistance in suggesting a means of presetting the braking torque on the rotary handle mechanism of an exercise machine. As presently configured, the braking torque is delivered by a shoe brake mechanism that presses against the outer polished circumference of an axial brake drum. This type of brake is very difficult to reset to a given value of braking torque.

CONSTRAINTS AND SPECIFICATION: The problem restrictions are that the solution be easy to implement, low in cost, and involve no major change in configuration of the exercise machine.

PROBLEM STATUS: A solution has been found and is being evaluated by the problem originator.

PROBLEM MISC-49

MICROWAVE THERMOGRAPHY

DATE OF PREPARATION: May 30, 1977
INSTITUTION: East Virginia Medical School
PROBLEM ORIGINATOR: Mr. Ken Carr
BATEAM PERSONNEL: Doris J. Rouse

WHAT IS NEEDED: Microwave instrumentation for the detection of subsurface temperature anomalies typical of cancerous growth with high spatial resolution.

BACKGROUND: Conventional thermography at infrared frequencies (>>10 GHz), a tool in the detection of breast cancer for many years, can detect thermal profiles at the skin's surface only. Subsurface thermal anomalies, such as those produced by certain cancerous growths, are indirectly measured to the extent that these sources of heat affect the thermal profile at the surface by the processes of thermal conduction and convection. The inability to measure directly the subsurface thermal profile is a significant deficit of infrared thermography because (1) there is no way to discriminate surface and subsurface contributions to the measured thermal profile at the surface, and (2) thermal dispersion seriously degrades the spatial resolution for detection of heat sources buried beneath the surface.

Microwave thermography can be thought of as a low-frequency analog of infrared thermography. A shift to lower frequencies permits the detection of thermal profiles at depths of up to several cm below the body's surface. This phenomenon is illustrated, in the graph (see Fig. 1) of microwave penetration depths in different biological tissues at different frequencies.

The selection of microwave frequency for optimal detection of breast cancer is an extremely complex matter. It is difficult to select such a single frequency because detailed knowledge of the internal thermal fields of the human body is sparse. The specification of thermal field disturbances produced by cancerous growths of different sizes, locations, and stages of growths within the breast is, if not impossible, nearly impossible. At first glance, the microwave penetration data shown in Figure 15 would argue for the use of low frequencies for the detection of deep-lying cancers. It is noteworthy, however, that spatial resolution decreases as wavelength increases (frequency is inversely proportional to wavelength). The utility of noninvasive means for the detection of breast cancer is often gauged by the system's ability to detect a tumor sphere 1 cm in diameter. Tumors of this size can be effectively treated by surgery, chemotherapy, X-radiation, or a combination of these treatment modalities. The average size of cancers found by physical examination is 3.5 cm in diameter. In approximately 65 percent of such cases, the cancers have metastasized, sharply reducing survival expectancy. The spatial resolution of a microwave thermography system is controlled by the selection of microwave frequency and the design of the antenna, which couples microwave energy from the body to the detector.

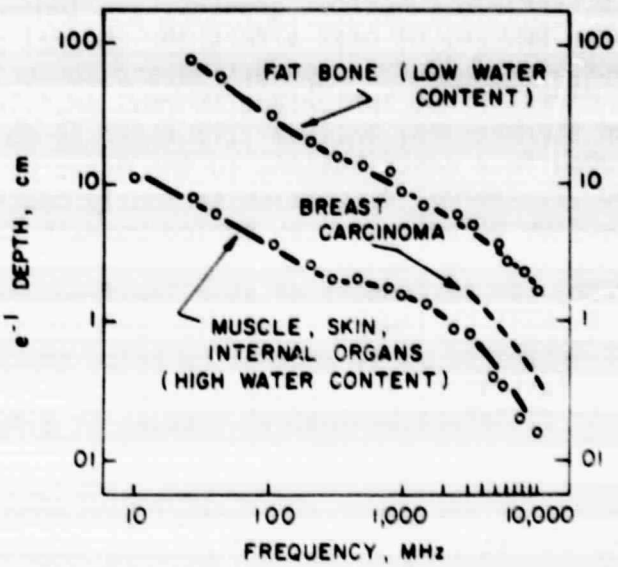

Figure 15. Microwave penetration depth in human tissue, based on dielectric properties reviewed by Johnson and Guy [1972].

Microwave thermography has been explored by Barrett and Myers[1,2] and by Bigu del Blanco and Romero-Sierra[3,4] as a possible means to measure directly the subsurface thermal profiles in animal tissue. Most of the work of Barrett and Myers has been with a 3.3 GHz radiometer coupled to the body with an open-ended, dielectric filled, X-band waveguide. Barrett and Myers have also conducted preliminary investigations at 10, 5, and 1.3 GHz. Bigu del Blanco and Romero-Sierra have measured microwave emission from the body at 9.2 GHz with a refined version of a Dicke radiometer operating on a self-nulling principle coupled to an airfilled antenna placed some distance from the body. The optimal frequency for the best depth penetration versus spatial resolution, however, has not yet been determined.

CONSTRAINTS AND SPECIFICATIONS:

1. To determine the optical operating parameters for a spatial resolution of approximately 0.3 cm with an effective depth of penetration in the breast tissue of 2 cm. (This compares favorably with the 1 cm x 2.3 cm resolution obtained by Barrett and Meyers at 3.3 GHz.)

2. To sample an array of subsurface temperatures simultaneously for enhanced clinical applicability.

PROBLEM STATUS: A commercial organization in the field of microwaves is interested in applying NASA technology in this area to the problem of cancer detection. A vice president from this company has visited Langley Research Center to explore possible interaction with their efforts to develop clinical instrumentation for microwave heating of tumors. Dr. Jim Beebe of NASA Scientific and Technical Information Facility is working with the RTI BATeam on the development and commercialization of this promising diagnostic technique.

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PROBLEM UGA-1

AEROSOL VACCINATION SYSTEM

DATE OF PREPARATION: May 31, 1977
INSTITUTION: University of GA, Veterinary Medicine Department
PROBLEM ORIGINATOR: Dr. S. H. Kleven
BATEAM PERSONNEL: Dr. R. W. Scearce

WHAT IS NEEDED: An aerosol generation system which controls the particle size distribution and determines the effective exposure dosage.

BACKGROUND: Poultry production and processing is a major industry in Georgia (#2 in U.S. broiler production) and represents a significant element in that state's agricultural economy. It is still a highly labor intensive industry with extremely small per unit profit margins and dependent upon large volume production for financial success. Flocks of 20,000 to 30,000 birds are common. These large flocks are vulnerable to contagious diseases. Marek's disease and Newcastle disease are two of the most deadly. In the past, outbreaks of either of these have nearly destroyed the poultry industry in large sections of the country. Fortunately, today vaccines are available to protect against both of these diseases, but innoculation of large flocks of birds poses several problems. One possible solution is to administer the vaccine by spraying.

The technique of applying vaccines in aerosol form has seen very limited use because the details of this technique have not yet been adequately defined. Its effectiveness appears to be a function of several factors, including type of vaccine, droplet size, and depth of penetration in the airway. The Disease Research Center in Athens, Georgia, is very interested in studying the dynamics of this technique in order to develop an effective innoculation system. The availability of such a system would be of considerable benefit to the poultry industry. Unfortunately, the Disease Research Center has neither the expertise in aerosol generation and dynamics nor the necessary equipment to conduct this study.

PROBLEM STATUS: JPL is working closely with the Department of Avian Medicine to apply aerosol expertise and equipment developed in support of the Viking Project. Vaccine producers and aerosol generating equipment manufacturers are being identified to collaborate in this project.

PROBLEM DU-99

V-SLOTTED HEAD SCREWS

DATE OF PREPARATION: June 30, 1977
INSTITUTION: Duke Medical Center, Rehabilitation Center
PROBLEM ORIGINATOR: Mr. Burt Titus
BATEAM PERSONNEL: Dr. R. W. Scearce

WHAT IS NEEDED: A fastner is needed which will resist screw driver cam out and requires a special tool to adjust.

BACKGROUND: The manufacturers of prosthetic and orthotic devices are faced with rapidly increasing costs. Key materials, which are used extensively, are involved in international pricing wars. This, added to increasing wages, has put these manufacturers in a very difficult position. Since medical insurance pays for most of the devices, the maximum for which a device can be sold is limited. This makes the situation even worse. Thus, unnecessary manufacturing costs cannot be tolerated.

Often it is necessary to make minor adjustments to braces and various prostheses. These adjustments involve loosening screws. All too often the screws cam out and must be replaced. Replacement requires drilling out the remains of the screw. What should have been a five-minute job becomes a thirty-minute job. If some type of fastener which would reduce or eliminate this problem were available, it would make a significant contribution towards controlling manufacturing costs. If such a fastener required a special tool to loosen it, it would also help limit the unofficial brace adjustments made by the patient, his family, and friends.

CONSTRAINTS AND SPECIFICATIONS: A low cost fastener which resists cam out is needed. It is also desired that a special tool be required to loosen this fastener.

PROBLEM STATUS: Arrangements have been made to obtain samples of V-slotted head screws to evaluate.

PROBLEM GCCC-1

A TELETYPE MACHINE TEST UNIT

DATE OF PREPARATION: March 15, 1977
INSTITUTION: Guilford County Communications Center for the Deaf, Greensboro, N.C.
PROBLEM ORIGINATOR: Ms. Peggy Bull Nelson
BATEAM PERSONNEL: Dr. H. Clark Beall

WHAT IS NEEDED: A portable, low cost electronic signal generator for testing Teletype machine operation in the home of the deaf.

BACKGROUND: A profoundly deaf person has need to use the telephone system, but such utilization is limited by the very nature of his handicap. Especially is this true when the deaf person attempts to summon emergency services (fire, police, and rescue) to his home. In attempting to address this problem, the Sertoma Club (a civic club) has instituted a program in North Carolina (and elsewhere) to equip emergency services communications centers with Teletype (TTY) machines. After installation of a TTY at a communications center, an effort is made to equip the homes of all the deaf of the city with a TTY set. Each of these machine installations is interfaced to the phone system by an acoustic coupler. A state-wide telephone directory lists all the phone numbers of the holders of such TTY equipment. Such a directory enables the deaf to use the TTY for nonemergency purposes, such as communicating informally with other dead individuals. Nationwide, there are more than 5,000 installations in homes of the deaf.

At the present time, the TTY system does provide emergency communications for some of the deaf population. However, there are serious problems in attempting to provide such equipment to all of the deaf population. The RTI Team has established an interest in solving these problem.

The central theme of any project in this area must be that of cost reduction. Obviously, if each deaf person had unlimited resources, he could simply purchase a new TTY system for his private use. But this is usually not the case. Therefore, the purpose of the Team effort will be to reduce the cost of establishing, maintaining, and operating a reliable TTY system to an absolute minimum so that any deaf person who desires one can afford it.

Virtually all of the TTY machines in the program are aged model 15 machines that were obtained when the news wire services changed to new and faster TTY printers. Everyone in the program agrees that the TTY machines are not too dependable, require regular maintenance, and are not too desirable because they use the old 5-bit Baudot TTY code instead of the modern ASCII code. However, for the immediate future, the machines are serving a useful purpose. For this reason, several problems unique to TTY machines will be investigated first. Later, specific means of replacing the TTY machines by electronic display devices will be investigated.

CONSTRAINTS AND SPECIFICATIONS: The job of maintaining a large number of TTY machines in working order is a technical task that has been assumed by several of the deaf in the Greensboro, N.C., area. There is definite need for a

portable device which can be used by these technicians to test the operation of the TTY machine in the home of the deaf. Often, an adjustment of the machine's mechanism can be made in the home. Without such a test device, the TTY must be removed from the home and returned to the central service center for testing and adjustment.

It is desired that the TTY test unit be compact and portable. Preferably, it should be battery operated. The unit must originate on/off current pulses by reed-relay contact closures. The machine character code that is generated must be 60 wpm Baudot TTY code.

The cost of the test unit must be held to an absolute minimum.

PROBLEM TU-43

CRANIAL BLOOD FLOW MONITORING

DATE OF PREPARATION: March 15, 1977
INSTITUTION: Tulane Medical School, Neurosurgery
PROBLEM ORIGINATOR: Dr. R. F. Llewellyn, Chairman
BATEAM PERSONNEL: Dr. H. Clark Beall

WHAT IS NEEDED: A means for long-term monitoring of cerebral blood flow and/or cerebral tissue oxygen tension.

BACKGROUND: Following acute cerebral insult, there is scientific evidence to support the theory that most of the resulting brain damage is due to severe reduction in blood supply to the brain. Oxygen and glucose must be continually provided to the brain by the blood because the brain tissue does not contain any stores of these substances. When the cerebral blood flow (CBF) is reduced to a critical level of 40 percent of normal, the brain vascular system cannot further adapt and the tissue metabolism changes from aerobic metabolism to anaerobic metabolism as the oxygen supply continues to fall. Low oxygen tension causes reduced mitochondrial phosphorylation and neuronal activity diminishes. The patient can then lose consciousness and develop serious clinical problems.

The normal CBF in awake man is approximately 50 ml/100 g/min and the cerebral metabolic rate of oxygen utilization ($CMRO_2$) is approximately 3.5 ml/100 g/min. If the metabolism remains normal as CBF falls, low blood flow oxygen starvation of the brain occurs when CBF declines to about 20 ml/100 g/min. But, if the metabolic rate decreases, the oxygen demand also declines (as in the case of hypothermia). Therefore, measurements of $CMRO_2$ (and CMR glucose) are as important as measurements of CBF in the treatment of brain insults.[1]

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PROBLEM WF-126

A LONG-TERM INTRACRANIAL FLUID PRESSURE MONITOR

DATE OF PREPARATION: March 15, 1977
INSTITUTION: Bowman Gray School of Medicine
Wake Forest University
PROBLEM ORIGINATOR: Dr. C. P. McGraw
BATEAM PERSONNEL: Dr. H. Clark Beall

WHAT IS NEEDED: A fluid pressure monitor that can be installed for long-term monitoring of intracranial fluid pressure.

BACKGROUND: The clinical value of continuous intracranial pressure (ICP) monitoring in the management of patients with head injury is well established in the medical literature. Investigations have shown that clinical signs, particularly vital signs, are unreliable in indicating the rise in ICP that often follows severe head injury. For this reason, a method of directly monitoring ICP has obvious advantages as clinical management can be more securely based if ICP is directly and continuously measured.[1]

At the present time, when a decision is made to install an ICP monitor device, a burr hole is made in the skull into which the device can be seated and sealed. Typically, the burr hole is 15 mm or less in diameter.

The ICP elevation above atmospheric can be expected to be 20 mm Hg in the most severe cases. However, atmospheric pressure itself typically can change by as much as 50 mm Hg over the period of a month, due to the passage of storm fronts and other such atmospheric disturbances. Therefore, if one expects to utilize an absolute pressure transducer (in which the reference pressure is zero mm Hg), the value of clinical significance, ICP, represents a variation of 20 mm Hg and must be measured with 1 percent accuracy in the face of atmospheric pressure which is some thirty-eight-fold larger (760 mm Hg $\pm$ 25).

In the past 15 years, numerous techniques have been utilized for continuously measuring ICP. Search for an optimal device and technique continues. There are several requirements a potential device must address:

(1) The recording must be from the intracranial space. Subarachnoid lumbar pressure no longer is considered to accurately reflect ICP.

(2) The device used to measure ICP should not produce brain damage.

(3) There should be little or no risk of infection. Any method that requires a continuous column of fluid from a cerebro-spinal fluid space (CSF) to an external transducer carries with it a risk of infection that is greater than a technique that does not violate the intradural space.

(4) Any technique that does not record pressure directly from a CSF space must be demonstrated to be as accurate and reliable as one that does record from the ventricle or subarachnoid space.

(5) The frequency response of a transducer must be satisfactory and the temperature sensitivity of the instrument must be minimal.

(6) The transducer must be drift-free, or correctable for drift.

(7) The operative procedures for inserting the transducer should be simple.

The ideal method for continuously recording ICP in man should eliminate all external connections. The device should be chronically implanted within the extradural space so as to reduce the risk of infection and injury of the brain adjacent to the device.[2]

One possible method is the use of a chronically implanted capacitance probe such as is being developed by Mr. Tom Fryer of Ames Research Center and the Stanford Biomedical Applications Team. However, the objective of problem statement WF-126 is to explore other possible solutions to this important medical need.

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2. T. W. Langfitt, "Clinical methods for monitoring intracranial pressure and measuring cerebral blood flow," Clinical Neurosurgery 22:302-20 (1975).

APPENDIX C

CONFERENCES ATTENDED BY AND PRESENTATIONS MADE BY BIOMEDICAL APPLICATIONS TEAM MEMBERS

CONFERENCES ATTENDED BY AND PRESENTATIONS MADE BY BIOMEDICAL APPLICATIONS TEAM MEMBERS

1. On February 8-9, 1977, Dr. R. W. Scearce attended the World Trade Show in Chicago, Illinois. He assisted NASA in showing the space technology exhibit.

2. The Rehabilitation Services Administration Workshop on Internal Joint Replacement, held on March 3-5, 1977, at the Rehabilitation Institute of Chicago, Chicago, Illinois, was attended by Dr. R. W. Scearce. Dr. Scearce made a presentation on the RTI Biomedical Applications Team program at the workshop, and participated on the panel on Functional Evaluation and Mechanics of Joints.

3. On March 14-16, 1977, Dr. F. T. Wooten and Mr. J. C. Ruddle of RTI attended the 12th Annual Conference of the Association for the Advancement of Medical Instrumentation in San Francisco, California. Dr. Wooten and Mr. Robert Zimmerman chaired the session on National Aeronautics and Space Administration Development.

4. The NASA Technology Utilization Meeting, held on March 30 and 31, at the Illinois Institute of Technology Research Institute in Chicago, Illinois, was attended by Dr. J. N. Brown. Dr. Brown made a presentation at the meeting on the RTI Biomedical Applications Team program.

5. On April 1-3, 1977, Dr. R. W. Scearce attended the Rehabilitation Services Administration Workshop on Prosthetics and Orthotics, in Miami, Florida. Dr. Scearce participated as a panel member on the panel on Upper Limb Prosthetics.

6. The Convention of the Georgia Association of the Deaf, held on August 11-12, 1977, in Atlanta Georgia, was attended by Dr. H. C. Beall. Dr. Beall made a presentation on the Teletype program for the deaf, and demonstrated the teletype test device.

7. On September 21 and 22, 1977, Dr. R. W. Scearce attended the Veteran's Administration/National Aeronautics and Space Administration Conference on Habitability in Extended Care Environments, held in Minneapolis, Minnesota. Dr. Scearce participated on the panel to define immediate technology needs.

8. On November 9-11, 1977, Drs. J. N. Brown and R. W. Scearce attended the meeting on Aerospace Technology Transfer to the Public Sector. Dr. Brown chaired the panel on Health Care at this meeting which was jointly sponsored by the American Institute of Aeronautics and Astronautics, and the National Aeronautics and Space Administration..

CONFERENCES ATTENDED BY AND PRESENTATIONS MADE BY BIOMEDICAL APPLICATIONS TEAM MEMBERS (CONTINUED)

9. The Conference on the Application of Technology to the Needs of the Elderly, was held December 8, 1977, in Baltimore, Maryland. 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 for the Aging.

10. On March 8, 1977, Dr. R. W. Scearce presented a program on the National Aeronautics and Space Administration and Technology Transfer, at the Crestwood Hospital, in Huntsville, Alabama.

11. On March 15, 1977, 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.

12. On March 29, 1977, Dr. R. W. Scearce gave a presentation on the Biomedical Applications Team program to the local chapter of IEEE at the Virginia State University, Department of Electrical Engineering, in Blacksburg, Virginia.

13. The 22nd North Carolina Symposium for Electrical and Electronic Engineers, held November 3-4, 1977 in Greensboro, North Carolina, was attended by Dr. R. W. Scearce. Dr. Scearce gave a presentation on Medical Uses of National Aeronautics and Space Administration Technology.