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FINAL ADMINISTRATIVE AND TECHNICAL REPORT ON THE SUMMER INSTITUTE FOR BIOMEDICAL RESEARCH IN TECHNOLOGY UTILIZATION

JUNE 22 — AUGUST 28, 1970

JANUARY 1971

GSFC — GODDARD SPACE FLIGHT CENTER
GREENBELT, MARYLAND

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Wayne T. Chen

January 1971

GODDARD SPACE FLIGHT CENTER
Greenbelt, Maryland

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PART I

PROGRAM ADMINISTRATION

SUMMER INSTITUTE FOR BIOMEDICAL RESEARCH IN TECHNOLOGY UTILIZATION

- 1970 -

INTRODUCTION

The health care facilities of this country are being severely overtaxed and are in need of technologies to help mitigate, if not entirely eliminate this critical problem. Automated diagnostic equipment and the development of efficient mass screening techniques offer a partial solution. This approach would allow maximum utilization of existing facilities while others may be constructed. Both the clinician and the patient would benefit since high quality care could be administered more expeditiously.

The professionals to identify and apply the relevant technologies toward the solution of this problem, must come from both the medical and engineering disciplines. The emerging profession of biomedical engineering is the source for a third contributor possessed of the facility to communicate with both specialties. Unfortunately, the opportunities and means to work cooperatively and constructively are too few.

The Technology Utilization Office at the Goddard Space Flight Center was desirous of establishing a means by which secondary applications of NASA technology to societal problems could be encouraged. It was believed by this office that this objective could be accomplished in the context of a summer workshop which would provide an environment in which these professions could interact, actively pursue their ideas, and as a result, provide the medical community with needed diagnostic tools. Thus, the Summer Institute for Biomedical Research in Technology Utilization was established in 1969 for this purpose. The effort during the summer of this year represented a continuation of this program and demonstrated the feasibility for more ambitious approaches in the future.

This report was written to formally present the technical results and the administrative procedures of the program so that others might benefit from these efforts.

SEARCH FOR A CONTRACTOR

Since support from the engineering and medical professions would be necessary, the responsibilities for conducting the summer program were divided equally among organizations from these two disciplines. The Technology Utilization (TU) Office, Goddard Space Flight Center, provided the technical/administrative support and established the criteria for the organization to provide the medical/administrative support. Selection of this organization was predicated upon its involvement with the medical community in the following manner: (1) that it actively participated in administering clinical health services to the public; (2) that it was exposed to and understood the technical problems of health care units; and (3) that it had an affiliation with an educational institution. Also, as a matter of practicality, the location of this organization had to be within a reasonable driving radius of Goddard since the students and the staff from the medical facility would be required to commute between both. This factor automatically eliminated several possible candidates qualified to support the program.

However, three organizations were considered for the contract. They were the Department of Electrical Engineering, University of Maryland, College Park, Maryland; the Medical College of Johns Hopkins University, Baltimore, Maryland; and the Department of Clinical Engineering, George Washington University, Washington, D. C. All contacts with these institutions were made during the early weeks of March of this year.

The University of Maryland – At the College Park campus of the University of Maryland, a small group of professors within the Department of Electrical Engineering were aspiring to establish a school of biomedical engineering which would include the disciplines of other departments and cooperate with the university's medical college in Baltimore. After discussions with their spokesman, it was decided that their curriculum, staffing, and structuring were presently inadequate to properly support the Summer Institute. These overriding factors precluded this group from further consideration. The College Park location, however, would have been ideal because of its proximity to Goddard.

Johns Hopkins University – Although quite distant from Goddard, the medical college of Johns Hopkins University was still considered because of their involvement with another medically related project at the Center and their prestigious position within the medical community. The emphasis of their research, however, was in areas other than our interests for the program. Whereas, our projected involvement should be in diagnostic monitoring instrumentation and automated health care, which would best utilize our resources; our respective facilities could not immediately complement each other. Since the Summer Institute would be working under a severe time constraint, this factor would

tend to reduce the program's overall effectiveness. As with the University of Maryland, further discussions were precluded through mutual agreement.

George Washington University – The third and final attempt at identifying an organization to support the program, was fruitful. The Department of Clinical Engineering (DCE), George Washington University, was selected based not only on their capability to provide the necessary medical support but equally on their attitudes and experiences with utilizing emerging technologies for medical applications. In addition to standard medical instrumentation, they were in possession of computer facilities capable of processing the voluminous amounts of data gathered during patient examinations. They were staffed with the required technical personnel to operate the equipment and utilized biomedical engineers to provide the proper medical/engineering interface within their clinic. Also, the department is strategically located within two city blocks of the University's hospital. This availability was highly desirable and would later prove to be invaluable to the program.

Since DCE's objectives were in concert with the Summer Institute's, serious negotiations followed preliminary contacts. The contract was consummated shortly thereafter.

THE CONTRACT AND PROGRAM FUNDING

After preliminary agreements had been made, the Technology Utilization Office issued a request for a formal written proposal from the Department of Clinical Engineering, George Washington University.

Based on experiences with the other colleges and our criteria, the Department of Clinical Engineering was able to submit their proposal on a noncompetitive/sole source justification basis. Since time was of the essence, an emergency procurement request was issued so that the contract could be consummated as expeditiously as possible. The total cost for the Summer Institute was $28,000.

Included in the contract was the New Technology Clause to ensure proper reporting and documentation of the results at the conclusion of the program.

Prior to the formal submission of the Department of Clinical Engineering's proposal, the question of funding the program was resolved during a joint meeting of representatives from Goddard's Technology Utilization Office, DCE, and Mr. Ronald J. Philips, Director, Technology Utilization Division, NASA Headquarters. It was decided to utilize monies available within the TU Division at

NASA Headquarters rather than from Goddard's budget. The funds were transferred to GSFC shortly thereafter.

PROGRAM RESPONSIBILITIES

Technology Utilization Office, GSFC – The responsibilities of the Technology Utilization Office were to: (1) provide technical/administrative support; (2) arrange housing facilities for the students and to furnish them with continuous and detailed program information prior to their arrival (including security and automobile passes); (3) provide technical advisors for each project team, laboratory work space, equipment; (4) library privileges, and relevant TU publications; (5) fabricate design components; and (6) arrange for daily transportation between Goddard and the Department of Clinical Engineering. The Goddard personnel that supported and participated in the Summer Institute are listed in Appendix A.

1. Technical/Administrative Support – Mr. Wayne T. Chen, of Goddard's Technology Utilization Office, coordinated all contractual and administrative activities between the TU Office and DCE prior to the commencement of the program (as enumerated (2) through (6)); and those related to the functioning of the program at the Center.

Although the students were employed by the Department of Clinical Engineering, they were under the direct jurisdiction of Mr. Chen while working at Goddard. Any activities involving Goddard in which the students participated (such as obtaining information or establishing contacts with governmental or industrial representatives) had to be cleared through the TU Office. In most cases, however, Mr. Chen merely requested from the students that he be kept informed as to the nature of these contacts rather than actively screening them for content. This control was specifically enacted to prevent any misunderstandings or misrepresentation, legal or otherwise, that would adversely affect Goddard, the students, and others concerned.

Mr. Chen was also responsible for establishing and maintaining a line of communications between all the participants of the program. They included the students, their advisors and assistants, Goddard management, visitors, and the staff from DCE. This served to simplify the procedures and minimized the time required for obtaining program guidance, information, and assistance.

2. Housing and Program Information – Because of proximity, economy, and practicality, housing arrangements for the students were made with the Phi Delta Theta Fraternity house at the University of Maryland, College Park, Maryland. Each student was charged a nominal amount of $10 predicated and renewable on

a weekly basis. The students, therefore, were under no obligation to remain at the fraternity house for periods longer than a week if they did not wish to do so. Those that did not wish to live at the fraternity chose to reside with relatives living in the Washington area.

After becoming more familiar with the area, several students decided to take advantage of this option by moving into a furnished apartment and sharing expenses in that manner. This flexibility was much appreciated by all involved.

Also, project descriptions, area maps, program information, security regulations, and selected NASA publications were packaged and sent to each student prior to the start of the program. It was specifically designed to familiarize him with both his working and social environment for the summer. These steps greatly facilitated their arrival to the area and positively affected their attitudes at the commencement of the program.

3. Advisors Equipment and Laboratory Space – For each project, a scientist or engineer in a related field was selected to advise each team (two students per team) in the performance of its task. The advisor's role was to guide and suggest alternative approaches to the team in their work but not to directly supervise or oversee its activities. He was also to be the team's source for technical information and to provide equipment and laboratory space for the students to do their work.

These advisors acted on a voluntary basis and were in no way obligated to perform this function. It is gratifying to note their positive responses to the program after they were asked, on a general basis, whether or not they would again be interested in providing this kind of support in the future. Their responses were overwhelmingly positive. Those that were not selected either made periodic inquiries about the program or assisted those selected whenever possible. It is interesting to note that three of the five advisors selected, acted in this capacity in the previous year's program.

4. The Library and TU Publications – The students were also extended Goddard Library privileges and given access to Technology Utilization publications to supplement their research efforts. They were also introduced to a new information system called RECON; a name formed from the first syllables of two words that describe its chief distinguishing feature: REmote CONsole. The system enables rapid identification and access to technical documents relating to numerous research topics at locations remote from the central storage facility. RECON is located with the library and was used quite extensively by the students. The TU publications were readily available through the Technology Utilization Office. These publications discuss in detail the latest advances in

such fields as integrated circuits, microminiaturization techniques, computer software, and portable electrical power sources. Again, these were of great value to the investigators.

5. Fabrication – To transform their concepts into testable hardware, the students had the cooperation of Goddard's Experimental Fabrication and Engineering Division and the supply depot. Establishing special work and job order numbers and having the support of the people in those areas, helped to minimize the time for their construction. Also, money was specifically allocated in the contract to provide for these services and the purchase of needed components.

6. Transportation – The students were required to commute between Goddard and the Department of Clinical Engineering on Tuesdays and Thursdays for the first five weeks of the program. They were to have used government vehicles supplied by Goddard's transportation division but due to the contractual arrangements, the students could not be considered as government employees privileged to use government transportation. Rather, they were considered as contractors working at a government facility which was under no obligation to supply them with transportation. This problem was identified early enough so that provisions could be made in the contract to reimburse the students for this travel using their own vehicles at a rate of $.10 per mile. This provision was stated under a line item separate from other student expenditures such as books and stipends.

The Department of Clinical Engineering, GWU – The Department of Clinical Engineering (DCE) was responsible for: (1) providing the medical/administrative support; (2) university notification of the program; (3) establishing the admittance criteria and selecting the students; (4) defining the projects and setting their goals; (5) structuring the lecture series on biomedical engineering; (6) administration of finances and procurement requests; and (7) providing clinical staff support.

1. Medical/Administrative Support – For matters pertaining to DCE, the administration of the program was under the direction of William R. Ayers, M.D., Associate Professor, Department of Clinical Engineering, GWU. In this capacity, responsibilities enumerated (2) through (7) were under his direct jurisdiction. Like Mr. Chen, his counterpart at Goddard, Dr. Ayers had authority over the students while they were at the clinic.

Although Dr. Ayers' and Mr. Chen's authority and responsibilities were clearly delineated, occassional problems of mutual concern and jurisdiction arose. They were quickly resolved through cooperation which served to maintain a close coordination of effort for the program.

2. University Notification – It was decided jointly by the TU Office and DCE to publicize the program in all major colleges east of the Mississippi River; that is, within the eastern half of the United States. Territories such as Puerto Rico and the Virgin Islands were not included.

3. Program Criteria and Student Selection – Essential for qualifying for the program was that the applicant be an undergraduate engineering or science (mathematics, physics, biology, etc.) student either entering or having just completed his senior year. Desired but not mandatory for acceptance were three additional requirements. They were weighted differently and are listed in descending order of importance: (a) a 3.0 cumulative index out of a possible 4.0; (b) strong recommendations from professors and/or employers; and (c) prior work experience in medical institutions (as hospital or staff orderlys, etc.). These were sought to obtain a clearer representation of both the applicant's academic and practical abilities; and to prevent any one of these requirements from having an overriding influence during selection. Although, for example, the grade point average was weighted more heavily than the others, it was not sufficient; and conversely an applicant slightly deficient in this requirement but strong in the others, was taken into consideration.

Balance was sought in the professional makeup of the student so that he could derive maximum benefit from the program and vice versa. The ten students that were selected, are listed in Appendix B. Their personal and academic histories are not included since they were submitted in confidence.

4. Project Descriptions and Goals – A list abstracting several problems in medical diagnostic monitoring instrumentation was constructed by the staff of DCE. The list not only reflected DCE's professional interests and the needs of the medical community but also the technical restraints imposed by Goddard. This was to ensure against inclusion of a project which Goddard could not support. The students backgrounds and the ten week time constraint also placed limitations on the scope and complexity of the projects.

To work within these constraints, some compromises had to be made. The projects selected, did not represent unique or totally unresolved problems in diagnostic techniques. Rather they represented ideas, concepts, or existing instrumentation requiring further attention; that is, they needed design and engineering improvements that have been neglected for lack of funds or proper technologies.

Before presenting the list to the students, a preliminary literature search was conducted for each project and the material was included with the descriptions. The purpose was to guide them to other relevant literature and to make them aware of current investigations in those areas.

For an appraisal of the projects and their relevance to health care units on a national scale, the final list was submitted to Mr. Herbert Cantor for his review. Mr. Cantor is the Director of the Biological Sciences Communications Project, GWU, which is an organization contracted by the Technology Utilization Division of NASA to provide administrative assistance and guidance to the various Biomedical Applications Teams supported by the TU Program.

Mr. Cantor deemed the projects to be of great relevance to other health care units and encouraged their completion. This endorsement ensured DCE against any possible accusations of self interest, and Goddard for naively and unproductively expending its resources.

The projects are described in Appendix C.

5. The Lecture Series – The lecture series was designed and administered by DCE to provide the students with a broad, comprehensive, view of the biomedical engineering profession. They were conducted twice a week at the clinic for the first five weeks of the program. To maintain maximum flexibility in content and scheduling, no academic credit was offered for the series. A listing of the lectures presented and their speakers are presented in Appendix D.

6. Financing and Purchase Orders – The allocation of funds and purchasing of needed items were under the jurisdiction of Mr. Peter Goodman, Associate Administrator, DCE. Payment to the students was made on a biweekly basis under the laws governing student stipends for educational grants. The specified rate of pay, therefore, was $100.00 per week, nontaxable.

Special procedures were established to expedite the purchase of materials. If the student needed a particular component or something fabricated, he was required first to check with his advisor as to its technical specifications and desirability. If approved, a verbal request to Mr. Chen or Mr. James Landoll, Patient Monitoring Project, DCE and their verbal approval was all that was necessary to have Mr. Goodman prepare and process the paper work for the allocation of funds.

However, the students were first required to make a thorough check of their respective resources, for such items, before submitting their requests. Thus, all requests, reviews, and authorizations were, for the most part, to be verbal. The only formal documentation needed were the actual purchase forms. Valuable time was saved since the entire procedure could be accomplished in less than a day.

7. Staffing and the Clinic – Like Goddard, DCE made whichever facilities needed, available to the students. The proper interfacing of man, medicine, and machines was enhanced by the constant assistance and vigilence of DCE's medical staff (doctors, biomedical engineers, and technicians). They also made daily visits to Goddard to meet with the students and to answer any questions that may have arisen. Thus, the mutual exchange of knowledge was encouraged at both Goddard and DCE. The students, therefore, did not have to wait until they were scheduled to be at the clinic to see the staff. Rather, the staff made themselves readily available to both the students and their advisors for consultation.

The clinic itself is a unique example of a systems engineering approach to medical care, providing for a methodical interface of technology with man.

In particular, their Multi-Test Screening Facility is the culmination of this interface. It consists of various subsystems in automated diagnostic equipment. Since involvement was the philosophy behind the Summer Institute, the students were required to actively participate in a physical examination utilizing the Multi-Test Screening Facility. This was to familiarize them with existing techniques and their associated problems from first hand experience. Thus, the examination was conducted during the first week of the program. Their results were discussed in confidence with the doctors of DCE providing the students with a greater insight into their own physiological conditions.

A listing of the participating staff of the Department of Clinical Engineering and a description of the clinic and its operational philosophy are included in Appendix E.

The Students – The students' responsibilities were simple and direct. They were to: (1) select their partners and pair off into five teams with one project per team; (2) select their projects and work diligently toward the stated goals; (3) clearly document their activities in laboratory notebooks; and (4) present their results before a professional audience for comment and review.

1. Selection of Partners – Since they would be working closely with each other for ten weeks, the students were permitted to select their own partners. This obviously mitigated the possibilities of personality clashes as would might have been the case had they been assigned to work with each other. As a result, harmonious relationships were established early which lasted well beyond the conclusion of the program.

2. Project Selection – As the teams formed, they were to select their own projects for the same reasons that they were permitted to choose their partners. It was made abundantly clear that more than conceptual studies were expected;

that construction of testable prototypes from their concepts was to be the major emphasis of each teams efforts. All of the teams executed their assignments admirably well to the satisfaction of all the participants involved.

3. Laboratory Notebooks – As in all research activities, work notebooks for each project were also expected to be maintained and kept up to date. Although reviewed occasionally by the staff of DCE, the students were responsible for their technical integrity and clarity. Since these notebooks were to serve as the basis for the final technical reports on each project, their content would also reflect each team's competence and professionalism.

4. Presentation – Two seminars were scheduled and held at Goddard during the ninth week of the program in which the students presented the status of their projects. They were attended by Goddard engineers, the staff from DCE, and representatives from the Atomic Energy Commission, Applied Physics Laboratory of Johns Hopkins University, and the National Academy of Engineers. Another purpose for holding these seminars was to provide the students with a forum to present both themselves and their efforts before a professional audience and to gain further recognition for the program. They were successful in accomplishing both.

The students were not required to maintain rigid schedules nor were they restricted from any areas of the Center while at Goddard. They were free to establish contacts with professionals outside the Center in regard to their projects and to work with these people if necessary. In essence, the students were being treated as professionals rather than summer employees with limited responsibilities. In turn, they were expected to utilize these priviledges in a responsible manner.

These priviledges were utilized to the advantage of both the students and the program. Outside contacts were made with other NASA installations and several commercial enterprises. At the same time, the students understood that in no way were they to commit or compromise Goddard's resources in the course of these interactions. It is gratifying to note that cooperation from these organizations was abundant and much appreciated by the students.

In summation, all these elements were designed not only to utilize the student's education but also to provide them with a maturing experience in an environment of their chosen professions.

It should be noted that one of the students could not remain for the entire program. Unfortunately, Mr. André Hebert had to leave the program during its fourth week for personal reasons. Although his partner, Mr. J. Lauris Christensen,

was required to work alone for the remainder of the program, he received additional assistance from his advisor and the other students, and should be complimented for his fine work under these adverse circumstances.

EXTENSION OF THE PROGRAM

At the request of the students, the Summer Institute was extended for an additional week. To do this the funds for the program had to be reallocated to properly support the additional period. Because of class scheduling and other unexpected committments; however, only three of the remaining nine students were able to stay the additional week. They remained productive and used the time to refine and improve their projects. The three that remained were Messrs. J. Lauris Christensen, Mohammad Ali Hooshmand, and Robert Martino.

At the conclusion of the eleventh week, the Summer Institute officially ended. Mr. Martino at that time wished to remain with DCE for an additional twelve weeks to continue work on his project. Because of a cooperative work-study arrangement with his university, he had this additional time to utilize.

He was again funded under the program's contract for an additional three weeks. This again required a slight modification of the contract and a further reallocation of funds. However, the TU Office was more than happy to accommodate him in this effort. His remaining nine weeks were supported by DCE. This was a great opportunity for Mr. Martino to gain additional professional experience and to contribute further to the success and utilization of his project.

PROGRAM RECOGNITION

Other organizations not connected to the program, have shown serious interest in the projects and their results. This is exemplified by the coordinators of the Joint Symposium for Bioengineering and Instrumentation sponsored by the Ames Research Center and the National Institutes of Health. They have included on their agenda, each project for discussion before the attendees.

Further, the National Heart Association and the Rippley Foundation had expressed interest in financially supporting further development of these projects. Since post program activities are under the direction of DCE, all future developments in these projects will reflect their efforts.

THE PROJECTS

Reporting – In accordance with the New Technology Clause in the contract, a technical report for each project was submitted to Goddard's Patent Office for review and possible patent action. Also, the Technology Utilization Office is presently evaluating these reports for future publications. If they are selected, there are two types of publications in which the projects may appear: (1) Tech Briefs or (2) TU Compilations. Each has a distribution of several thousand copies to government, industry, and private citizens. This determination will have been made by January 1, 1971.

Further, the dissemination of these reports within the medical community will be handled by DCE. Their affiliations with other medical facilities and their participation in related conferences provide many opportunities for their exposure.

In essence, both the TU Office and DCE will utilize all means available to them to communicate the results of the Summer Institute to as wide and varied an audience as possible. In so doing, they hope to minimize the time between discovery and utilization of this technology.

The Technical Results – The following technical reports presented in Part II represent the results of a ten or eleven week effort by the investigators. Developments did not cease; however, at the conclusion of the program. The Department of Clinical Engineering is seriously interested in bringing these efforts to fruition by continuing these projects with their own biomedical engineering staff. DCE plans to report these additional results, utilizing the methods previously stated.

THE FOLLOW-ON EFFORT

Actual use and further development of much of the prototype equipment produced during this Institute is underway and being conducted by DCE.

The ECG electrode chest harness development will be continued for implementation in the cardiovascular data acquisition module being separately developed for use in the George Washington University Multitest Clinic.

Further refinement of the miniaturized microphone and preprocessing system (Tasks II and III) and the actual joining of the two pieces of hardware, has been accomplished. This subsystem of transducer and preprocessor does complement our previously developed physiologic data acquisition units now employed as state-of-the-art equipment in automated medical signal processing systems. The digital device for setting pulmonary test screening parameters will be

interfaced with a spirometer specially designed to incorporate motivational techniques into the data acquisition phase of this effort-dependent test. The combined unit, (digital device, motivational device and spirometer) will be used to test patients' pulmonary function in the George Washington University Multitest Clinic.

The Intensive Care Alarm System principles will be extended to control message relay not only to intensive care unit nurses but also to medical technician-hostesses. In the latter application, a physiologic repeat back system for quality control of data acquisition in the Multitest Unit will be the focus rather than alarm indication, which is the focus of application in intensive care units.

The 1970 Summer Institute emphasized the transducer and data acquisition subsystems of medical signal processing. Subsequent institutes might well be directed toward other subsystems within medical systems and toward other body systems rather than the cardiopulmonary system. This recommendation will be the subject of a new proposal for the 1971 Summer Institute which is expected to again be held at the George Washington University, Department of Clinical Engineering.

COMMENT AND CONCLUSION

The intent of the Summer Institute was to provide ten undergraduate engineering and science students with the opportunity to apply their talents toward the solutions of specified problems in biomedical engineering; and to encourage secondary applications of NASA technology to societal problems.

The Summer Institute again demonstrated the ability of multidisciplined professionals to interact, catalyzed by the probing minds of the students. For its intended purposes, the program was an unqualified success. The actual contributions to medical engineering and patient care; the rapid professional growth demonstrated by the students; and the intellectual exchanges between the disciplines, encourages this office to establish more ambitious goals for such programs in the future.

Through this program, the TU Office and DCE was able to maintain and expand their roles as active participants in utilizing NASA's technology for advancing the present capabilities of medical diagnostic monitoring instrumentation. We hope that this effort will have a lasting effect on both the participants and the medical community. Further, Goddard Space Flight Center has served not only the community in which it resides but also those across the country

from which these students came. It is clearly evident that these benefits impact more than those directly involved in the program and justify further explorations and commitments under the guidance of the Technology Utilization Program.

PART II

THE TECHNICAL REPORTS

TASK I

ELECTROCARDIOGRAPHIC ELECTRODES FOR RAPID APPLICATION

Mitchell Weisberg
Rolfe D. White

Warner H. Miller
Technical Advisor

INTRODUCTION

The title of our project and its goal is the development of an electrode for rapid application and a method of rapidly applying the new electrode.

The need for the apparatus to be developed is apparent in both Multitest Screening facilities and Emergency Situations where a 12-lead scalar electrocardiogram would be desired and time is the governing parameter for application. In the multitest screening unit, minutes saved add up in terms of elimination of a possible backlog at the ECG station and an increased number of patients covered per hour. In an emergency situation where a patient may be suffering from a myocardial infarction, it is of the utmost importance to have as complete an assessment of his condition to submit to the doctor so that he may direct proper treatment on the way to the hospital in an attempt to save some of the 60 percent of the heart attack victims that die before getting to the hospital or on arrival because proper treatment could not be given, due to a lack of an adquate diagnosis.

The first part of any research project involves a literature search to find out who has done similar research. In this phase of the project we employed the National Library of Medicine's Computerized Search System, Medlar, and the National Aeronautics and Space Administration's Computerized Search System, Recon.

After the search, at the risk of spreading ourselves too thin, we decided to retain both aspects of our project; i.e., the electrodes and the application. It was at this stage that we fully realized the handicap we would be under with only 10 weeks to complete our full project. Various designs for the electrodes and the harness were discussed, however, only a few of those chosen could be constructed and tested. We tried to carry as many of the ideas as we could to the testing stage, however, at this date we have not yet completed our evaluation.

The goals of the electrode phase of our project is to increase the quality of ECG recordings to the required accuracy for complete analysis. Much research was done to find a method of applying dielectric material to the surface of the electrode. We had to be careful in choosing the dielectric material; a dielectric constant too low – not enough capacitance for electrode to work while a dielectric constant too high – distortion due to aid bubbles or surface discontinuities beneath the electrode. Silver plate copper dishes were used for high conductivity.

In addition to anoidized Tantalum Electrodes we contacted Mr. David Robertson, of Surface Technology, Incorporated in Mountain View, California to tap his resource of knowledge in the area of thin film dielectrics. After much coaxing he agreed to squeeze a few samples of sputtered Quartz (silicon dioxide), and

Tantalum oxide (Ta_2O_5) on a stainless steel substrate for us. As of last night, work had not yet been completed on these samples.

We were able to have silver plated copper disks coated with a 500 Angstrom layer of Silicon Monoxide. This procedure, done in the optical plating laboratory, consists of placing the electrodes substrates in a vacuum chamber and vaporizing silicon monoxide in the same chamber by electrically heating it. The vapors then condense on all available surfaces. The thickness of the coating is time dependent. Also being tested are silver plate electrodes with a silicon monoxide film 1000 Angstroms, the result of the SiO electrode is viewgraph number 8.

From the original viewgraph number 7 standpoint of trying to simply mount an operational amplifier on a standard commercial electrode or on a die cut metal disk we have come a long way.

With our stepping into the area of a capicative coupling with the body we encountered a whole slew of electrical problems. The output impedance of the electrode plate was now quite formidable. On theoretically the order of 10^{10} olms, it was felt that the operational amplifiers that were available could not reduce this value enough to be acceptable for low resistance transmission.

A Field Effect transistor (FET) was used in a voltage follower configuration to cope with the impedance. In this arrangement (viewgraph) the voltage seen from the source follows that observed at the gate of the FET. The output impedance of the FET is on the order of 4 k olms which is acceptable to present electrocardiograph machines. This design utilized state-of-the-art circuiting.

Although we are not really ready to present a finished, tested and approved final electrode, we do have one prototype silver/SiO_2 electrode complete with circuitry, potteed in a stainless steel cup. The actual final size of the electrode, complete with circuitry, will be much smaller – we plan to eventually use a small integrated circuit chip simply mounted to the electrode disk. It was the time element alone that prevented us from reaching fruition of this phase of the project.

Springs with a constant coefficient of expansion were also considered, but rejected because of their unavailability. Commercially available elastic bandage seemed to be the material best suited for this harness attempt.

July 7, 1970

The purpose of our project, as we see it to date, is (1) to reduce noise, i.e. extraneous signals on EKG recordings and (2) to develop a method for rapid application of the pre-cordial EKG leads. We are attacking the project from four angles: the electrodes, the electrode-skin interface, uses of amplifiers and cables from the electrodes to the machine. At present we have no plans to modify existing EKG machines.

A restriction on the project is that our outputs must be of the same style as present EKG outputs. The low noise level is required since an eventual goal is the digitalization in computer analysis and diagnosis of EKG recordings.

In the area of electrodes we are studying existing models with respect to materials of which they are constructed. We are weighing advantages of those with high conductivity with disadvantages of corrosion and/or polarization in order to find an optimum.

We are planning to carry out a comparison of large electrode surfaces which imply high capacitance and lower impedance to small electrodes which are producing more accurate recordings, but must be positioned more accurately. We also hope to determine whether the shape of the electrode has any effect reference point on the Xiphisternal point and/or on the anterior axial line. These devices must be able to compensate for the chest expansion due to breathing.

The final product of our research should be an integrated system composed of electrodes, amplifiers, cables and an EKG machine with the noise level of the recordings reduced to within the desirable limits.

Studies in the area of electrode-skin interface deals mostly with the impedance seen by the electrode. Possibly, these can be removed through signal amplification. Perspiration, which increases skin conductivity, also presents a difficult problem since this impedance may be changing during the time of our recordings.

A point of present confusion is whether the body can be represented as a resistor or a capacitor, or some combination of these devices, but with two leads of the EKG.

By direct contact electrodes, the impedance has wide variability, not only between patients, but between electrode sites of the same patient. Patient studies also show that the skin-to-electrode implies variability with frequency. One study shows that at a frequency of ten hertz (average frequency for the

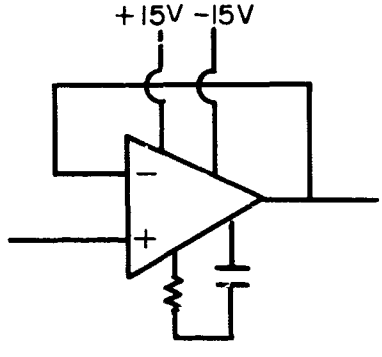
majority of QRS complexes) impedance variability from zero (±500 ohms) to over 200 K ohms. This variability is at present a large source of error in EKG recordings.

The uses of operational amplifiers to improve the quality of readings is being attempted. A buffer amplifier characterized by a high input impedance and a low output impedance, is to be placed on the actual electrode with the purpose of reducing the impedance in the long-cord (six foot) reading between the electrode and the EKG machine. Thus, lowering the amount of noise picked up in this lead in response to Ohm's Law.

$$V_{noise} = I_{noise} R_{cable}$$

A method must also be found to reduce artifacts due to muscle movement.

We are also going to attempt the elimination of the right-leg-driven ground, possibly by grounding the amplifier to the forward point supply. This would eliminate the two microVolts to 50 microVolts from this electrode. At present we are testing an operational amplifier of the following circuit design:



Operational Amplifier Circuit Diagram from
EKG Electrode Design Number One

We are using a Burr Brown IC operational amplifier model 3050/01, chosen arbitrarily. We plan to study the operating range of this amplifier reducing the bandwidth to 200 cycles, to determine the offset voltages for up to 500 miliVolts from this electrode. We are also considering the use of other designs employing fet's or mosfet's.

July 20, 1970

ANODIZATION

EXPERIMENT I

TANTALUM SHEET ANODIZATION

DATA:	Voltage:	170 Volts DC
	Solution:	9.8g H_2SO_4/litre H_2O
	Current:	Off Scale (low)
	Anode:	Tantalum Foil Samples #1 and #2
	Cathode:	Tantalum Alloy

The anodization of tantalum was done in the electroplating lab with the help of Mr. Charles Whitfield. This is a relatively simple process (inexpensive) which will be explained more later.

It was decided at this point not to attempt construction of a multipoint electrode because: (1) the corneal epithelium is of differing thicknesses, (2) application would be uncomfortable.

We talked to Clifford Link today. He is with the Division of Materials and Fabrication.

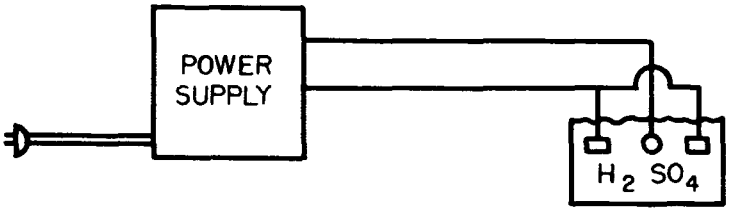
Dr. William Brenner of the National Bureau of Standards is going to supply us with tantalum 15 mils thick. It will be punched out by Mr. Cliff Owen of Materials and Fabrication.

More tantalum squares and eventually discs of .015 inch tantalum 7/8 inch in diameter were anodized.

The final anodizing procedure was set up:

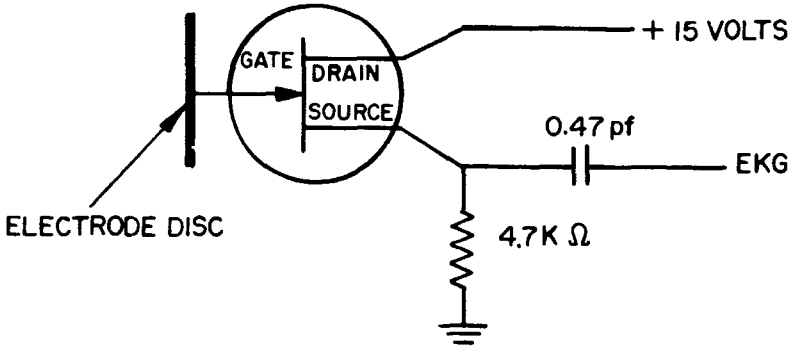
Current:	1 milli amp per cm^2
Voltage:	160 volts
Time:	1 hour after reaching voltage

PROCEDURE: Disc to be anodized is placed in .1 molar H_2SO_4, as the anode of the circuit. The cathode is made of the same material as the anode (in this case – both are made of tantalum). An ammeter is placed in the circuit and a power supply capable of supplying 160 volts completes the set up. The voltage is slowly supplied so that the current never exceeds 1 milliamp per square centimeter. When the voltage reaches 160 volts, the circuit is left for an hour. After an hour the power is shut off and the discs are removed and dried.



A Field Effect Transistor (FET) circuit was designed in a standard voltage follower configuration and mounted on the back of the new electrode discs for the purpose of lowering the transmission line impedance and making a low enough output impedance to be acceptable to standard EKG machines.

The circuit is:



On several evenings we rode on the "Heartmobile," a cardiac emergency vehicle sponsored by the Montgomery County Heart Fund. The purpose of these excursions was to explore the applicability of our harness to an emergency situation.

Our conclusion is that our harness can be used in such a situation.

We contacted a Mrs. Mary Beth Lagoey to ride in the heartmobile (Montgomery County Heart Association).

We questioned the necessity of a 12-lead ECG enroute and decided that the present belt of Landoll's would not be suitable, due to the weight of it. A person having a heart attack would not want the weight on his chest. Another system is necessary for a close electrode skin contact.

Several days were spent testing and trouble shooting our electrodes and circuits. We are also attempting impedance measurements.

Harness:

A Mechanical arm system was considered to be run either manually or by motor. However, time limits caused us to reject this idea.

We tried spraying inflatable bladders out of silicon rubber RTV and Magicvvlc rubber, but both of these attempts led to failures. We sprayed the rubber onto an aluminum mold and removed them after they were dry.

All the bladders exploded upon inflation.

The silicon rubber RTV did not have the desired stretch for our use.

Impedance Circuit

It was found necessary to test impedance somehow at the electrode site for a comparable basis.

The first circuit tried (see Index) was unsuccessful because we were forced to use DC equipment – what was available – Spach's Test, and there is, according to one advisor, an AC capacitance present at the skin.

However, we did manage to use another test: with a Hewlett-Packard Vector Impedance Meter. See Index.

This proved to be very efficient. The only readings we were able to take prior to our presentation are as follows:

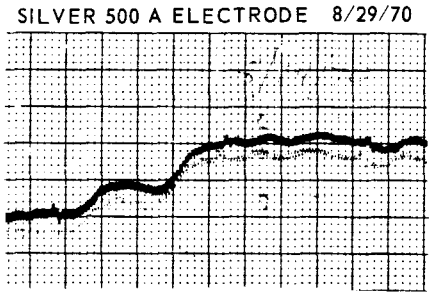
	Capacitance @ 3"	Impedance @ 100 Hz
Silver/Silver Chloride Electrodes	.025 uf	2.3 kilohms
Silicon Dioxide Electrodes	.005 uf	1.5 kilohms

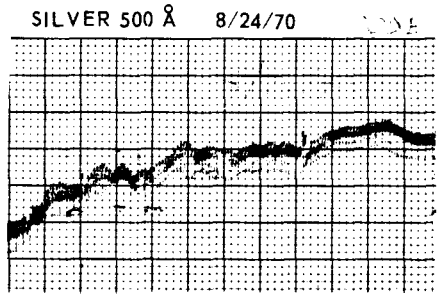
This set up was discovered the day of the presentation.

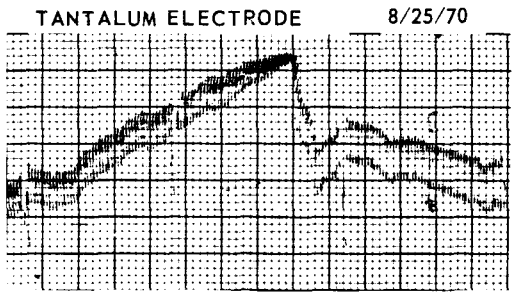
Further research will be made particularly in comparing impedances on some ohmic electrodes (platinum, silver/silver chloride, silver over stainless steel, etc.) with FET circuits on the back of them.

One particularly interesting side light is that we took a GE electrode-disposable (Daisy) and mounted a circuit on the back of this. This electrode was obtained from Miss Siebelt. It retails for $.70 a piece A FET can be purchased individually at $.56 a piece. The cost of our capacitor and resistor are negligible. It is extremely possible to have very soon available commercially, a disposable dry electrode. We are just beginning to test these as well as the others.

The tantalum electrodes and silver electrodes (SiO) are described in the index. The vacuum plating of the SiO, is described here also. The dielectric was 500Å on the SiO_2. Below are comparable readouts of our different EKG electrodes.





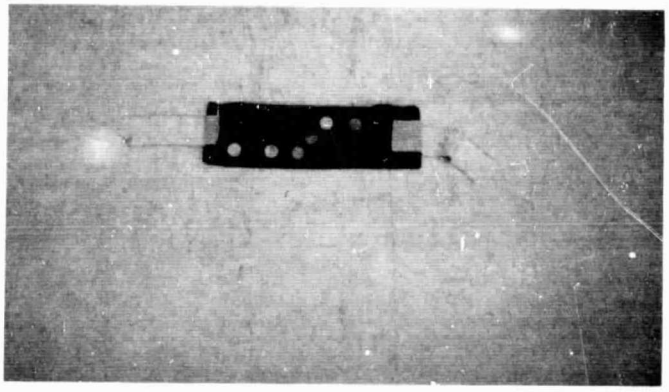


HARNESSES

(See Index for Harness pictures)

The above is a model employing the elastic cloth idea of Landoll's (and approximately his proportional distances). The plexi-glass is just a support mechanism. The ends are fastened with velcro.

This is the copper (berillium spring clamped to the chest. Hopefully, we hope to employ an inflatable bladder with imbedded electrodes in it (V_1 and V_2 would be built up). See Index for schematics.



This is an idea that we had for an ambulance situation rapid application belt. It employs elastic cloth and disposable elastic adhesive strips. Its disadvantage is that it needs skin for application. (The patient's clothes must be removed completely in the chest area.)

We have also done research on construction of small, inflatable bladders (latex), but have yet to come up with one strong enough to fit in a harness (cross section) as pictured in the index.

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TASK I
ELECTROCARDIOGRAPHIC ELECTRODES FOR RAPID APPLICATION

COMMENTS

METHODOLOGY

Report written for this project took the form of a narrative in the laboratory notebook. It was not structured to a formal report style, but did have reasonable continuity. The project was identified and the scope of work stated in the introductory section. The results of the NASA literature search were included in the report, but not the actual literature. Goals were stated along with methods of achieving the goals. The experts in the field of medical electrodes were sought out. Their work was reviewed and used to a large extent in the breadboarding of developments in the latest techniques in electrodes. Students were very resourceful in acquiring source material, either through manufacturers, medical facilities and governmental agencies (NBS). The scope of the project was accepted as one input by the students. It was then modified by other inputs during the course of study. Thus, a genuine contribution was made to the task.

RESULTS

This project allowed several solutions in the area of electrodes and electrode application. Several ideas were tried. Although students were not electrical engineers, buffer amplifiers and electrodes were constructed and breadboarded based on guidance of NASA mentor (an instrumentation engineer experienced in amplifier design). Procedures for fabrication of electrodes were noted, including an anodizing procedure of tantalum. They were able to place themselves in an environment of ECG's under various conditions; for example, first-hand experience in the heartmobile, a cardiac emergency vehicle sponsored by the Montgomery County Heart Fund. Interaction between students and NASA was evident. (Measurements for harness were taken on several NASA personnel.) The students' enthusiasm is exhibited by the number of persons contacted and the number of prototype circuits and harnesses fabricated.

CONCLUSION

No formal conclusions were stated. Areas of future work were stated; for example, other belt arrangements, impedance investigation and so on.

Basic concepts of instrumentation and ECG amplifiers were not grasped (not instrumentation engineers). For example, is it necessary to quantify impedance, especially based on the work of others. What are the principles of shielding and grounding and reason for right leg driven ground. Is it necessary to ground the subject. These point out areas which should be emphasized in the formal lectures.

FUTURE APPLICATION/EXPANSION

The technology of dry electrodes and techniques of ECG instrumentation seem to be available. The problem is one of implementing a workable system of instrumentation at a reasonable cost. The Multitest Facility of the Department of Clinical Engineering does provide a 12-lead scaler ECG on one of the test procedures. The instrumentation for this testing station can be improved. Tangled leads, messy electrode paste and sixty cycle noise are the common problems that have existed for many years in electrocardiographic acquisition. Although no harness or electrode was developed, the contribution of the state-of-the-art review will provide the input for the further economical development of dry electrodes with appropriate instrumentation and perhaps a technique for application.

TASK II

MICROPHONE MINIATURIZATION AND IMPROVEMENT

Alan Lipschultz
Paul Turer

Harry E. Wannemacher, Jr.
Technical Advisor

INDEX

MICROPHONE MINIATURIZATION AND IMPROVEMENT

We have decided that the purpose of this project is to take an existing microphone and reduce it in mechanical size and to work on a method of measuring the response of the microphone. This was done after reviewing the different types of microphones available.

July 9, 1970

An ideal heart sound microphone should encompass some of the following characteristics:

1. Flat frequency response from 20-2000 Hz
2. Sensitivity must be sufficient to pick up heart sounds while at the same time be insensitive to environmental noise
3. In light of #2, a contact-type microphone is recommended
4. The response of the device should be linear
5. A constant probe pressure must be maintained which is independent of the applicator pressure of the device against the chest wall
6. Light weight and small size required for easy application to chest wall
7. Durable for day to day clinical use

Keeping the above criteria in mind the following types of microphones were considered:

1. Carbon microphone – high inherent noise
2. Condenser 11 – requires large D. C. voltage which may be dangerous to patient
3. Foil-Electret Condenser Mic. – Direct pressure application not possible
4. Moving Coil –
5. Ribbon Microphone – not good for direct pressure applications

6. Crystal (Piezoelectric)

7. Piezoelectric transistor (Pitran) – too delicate for clinical use as present stage of development.

Piezoelectric or moving coil-type microphones appear to be best suited for heart sound pickup.

Some of the characteristics of an existing heart sound microphone, as described in the article, "Heart-Sound Transducer" by Coleman are:

A. Polyurethane foam spring holds transducer against chest – minimizing pressure variation between microphone and chest wall which might alter the microphone's response.

   Pressure does not vary by more than 50 gm. over the functional range of movement.

B. Heart-Sound Transducer

   Ceramic crystal acts as the sensing element.
   Disc probe used to transmit chest wall vibrations.

C. Microphore Specifications

   Maico contact heartbeat pickup with dic probe
   Contact microphones are needed to avoid room noise
   Transducer had a high impedance of 270K
      Any direct cable from transducer would tend to pick up noise
      Preamplifier is incorporated into microphone housing to reduce noise problem.
   Polyurethane foam spring is used as a switch to turn off the amplifier when probe is not in contact with chest wall. This eliminates the monitoring of extraneous noises and reduces battery drain.

A check of the frequency response of the existing preamplifier was made and found to be linear, approximately between 30 Hz and 1000 Hz. Nevertheless, we plan on eliminating this amplifier and replacing it with a smaller-integrated circuit.

The results of this check can be seen on pages and

July 15, 1970

Unholtz-Dickie Calibration Shaker Table #106

Double-backed tape was applied between disc probe and shaker head.

at 700 Hz, 1 g 40 u inches

20 Hz, 1 g .5000 u inches

OUTPUT

-700Hz,

Check shows support bracket was vibrating with shaker head.

8 ISMS=T

Very little coupling between support and shaker at 2000 Hz

Connecting 500r load across output – because output was not referenced to ground and load must be added for this reason.

Experiment was declared a failure, probably because of the inability of this machine to produce a small enough signal.

July 22, 1970

CALIBRATION

Since the Unholtz-Dickie machine was not sensitive for our measurements, we decided to look elsewhere. To try something to make sure the microphone worked properly, we hooked a signal generator to a 7 1/2" Jenson loudspeaker.

A crude setup was used, just holding the microphone to the anchored speaker. A very good sinusoidal output was obtained down to 15 cycles per second.

We were satisfied the microphone worked and so borrowed a MB electronics Model FA 1250 shaker from GWU. Upon experimentation, however, we found that below approximately 80 Hertz we could not obtain a sinusoidal output. Either the signal was a clipped sine wave or just noise. We concluded that this shaker was also too large and not sensitive enough.

Then we borrowed from the Goddard Space Flight Center a one pound shaker, Model LT-100, made by Gutton Industries, Metuchen, New Jersey. After initial failure in obtaining a sine wave output, success was obtained by feeding in a signal directly from a Hewlett-Packard test oscillator on the order of .1 volt rms at low frequencies down to 18 Hz. The signal output was very unstable and appeared to turn into noise without warning.

We decided to both search for a flesh-like material to act as a buffer between the shaker head and the microphone tip to simulate more closely the microphone in contact with the chest wall.

July 27, 1970

Design of Microphone Housing

We decided that the main objective of this project would be the reduction in size of the microphone housing to the smallest dimensions possible without replacing the existing microphone element. The complete microphone will be small enough to be strapped to the chest. We would have preferred to work on the utilization of a new transducer element, but felt, since we only have 10 weeks to work, that if nothing else, we should reduce the complete microphone to manageable proportions. The overall response of the streamlined microphone will be compared with that of the original microphone. Although the microphone element will be the same in both cases, the size reduction in the new design will result in new mechanical resonance frequencies, so this must be investigated. While work on the microphone housing is proceeding we made contact with: Shegoto Industries, Ltd., Empire State Building, 350 Fifth Avenue, New York, New York (Telephone 212-695-0200), a manufacturer of contact-type microphones. We spoke to their sales manager, Irwin Weinstein, and he agreed to submit a proposal covering a microphone with a flat response from 20 to 2 KH_2 which will be small enough to be strapped to the chest. Mr. Weinstein's letter was dated July 15, 1970 and he said we would hear from him in seven to ten days. So far we have not heard from him and plan to call tomorrow if nothing arrives today.

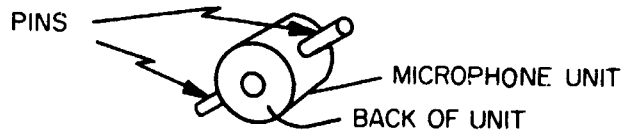
New technology will be utilized in replacing the existing transistor amplifier with a Motorola MC1303 L 11 Dual Stereo Preamplifier Integrated Circuit," a printed circuit board will also be used to simplify wiring.

In our new design we decided to eliminate the bearing rod which was present in the original design. We viewed this rod as unnecessary and space consuming. The elimination of this rod presented us with two new problems:

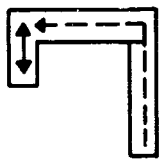
1. How to keep the microphone unit from falling out when the microphone was held in a vertical position and
2. How to limit the distance that the microphone unit would be allowed to slide back into the teflon sleeve.

We first thought of placing an "O" ring near the outer edge of the teflon sleeve. However, this would not permit the contact disk to extend out (beyond the white rubber cover ring) far enough, so this idea was deemed unfeasible.

We then came upon the idea of using a bayonet-type groove mechanism as a solution to our problem. Two pins would be placed on opposite sides of the microphone unit. This is indicated below.



A side view of the channel to be cut into the teflon sleeve is indicated on the next page.



The pin would be guided by the long channel and then the microphone unit would be twisted around so it would slide to and fro in the smaller channel (marked by double-headed arrow). This type of arrangement would prevent the microphone unit from falling out by accident and would also act as a stop mechanism to prevent the microphone unit from being pushed back too far into the

housing. Several possibilities came to mind after it was decided to use the bayonet groove:

1. Using the channel-pin setup as a means of activating and turning off the microphone. This would be done by lining part of the smaller groove with a thin metal strip, so that when the pin slides across the strip, electrical contact is made. We decided against this method because we questioned the reliability of the method. Dust and age may affect the electrical contact.
2. Small spring may be placed inside the groove to maintain the constant pressure feature of the microphone. If time permits, this method will be tried if we can't find a suitable substitute.

Since we are having much difficulty in calibrating the microphone, we decided to at least put down some of our efforts. This first one is using a Jensen loudspeaker with the microphone attached to a metal table, but mechanically insulated from the table by foam rubber. A constant input of .33 volts RMS was fed into the speaker. The output was taken from the integrated circuit preamp and monitored for uniform output on a scope and simultaneously measured on a VTVM with a decibel scale. Following are some of the output values.

FREQ	20	30	40	50	80	100	110	117	125	140
DB	-17	-14	-7	-6	+1	+75	+13	+14.4	+13	+8

FREQ	160	180	200	250	325	350	435	470	625	800
DB	+4	+1	-.5	-3	-1.2	-10.8	-2.7	-15.6	-9	-13

FREQ	940	1040	1.25K	1.5K	1.8K	2.0K
DB	-20	-14	-16	-8	-6	-8

0 db = 1 VRMS

This measurement was taken using a buffer of foam rubber between the microphone tip and the speaker. A sinusoidal output was only obtained down to 35 cycles. Below that the signal was distorted.

Next I tied the microphone directly coupled to the Gulton one-pound shaker. Again 0 db = 1 VRMS. The input was .13 volts RMS

FREQ	20	35	39	50	100	150	250	400	500	600	750
DB	-24	-26	-3db	-6db	-5db	-2db	+2.4	+8	+13.6	+12.4	+10.3

FREQ	900	1000	1.1K	1.2K	1.33K	2K	1.6K
DB	+4	-2	+7	+11.6	+5	-5.3	0

As a check I measured the response of the integrated circuit amplifier alone and found it to have a perfectly flat response from 40 to 2000 Hertz and dropped of .4db between 20 and 40 db, quite adequate for our purposes.

With the shaker we still would not get good sinusoidal output below 35Hz.

July 28, 1970

Next I tried the shaker table with a piece of silicone rubber as a buffer. Input = .3 V RMS

FREQ	20	30	35	40	50	75	100	125	150	175	200	250	350
DB	-21	-20	-15	-7	-7	-4	0	4.6	+11	+15	+10	+4	-.5

FREQ	400	500	750	1000	1250	1500	1750	2000
DB	-1.5	-12.6	-18	-20	-20	-25	-23	-21

Again, I could not obtain a sinusoidal output below 35 Hz.

Because I was getting an irregular response, I obtained a calibrated accelerometer, an ENDEVCO Model 2221D and an ENDEVCO Charge Amplifier Model 2620 associated with the accelerometer.

The accelerometer is very small and light. I placed it between the shaker head and the silicone rubber of the previous test with the microphone loading the rubber. I was trying to duplicate the above test only looking at the output from the shaker.

I could not get even a near sinusoid below 50 cycles, so I'm going to go on the assumption that it is not the microphone's fault, rather the shaker's. The results follow

Input is 2.6 volts RMS

FREQ	50	60	70	80	90	100	110	130	150	200	300	400
DB	-14	-10	-4.5	+1	+7.5	+10	+8	+4	+1.5	-1	-2.5	-3.2

0db = 1 volt RMS

FREQ	500	750	1000	1250	1500	2000
DB	-3.5	-4	-3.4	-3.5	-3	-4

The accelerometer was calibrated so that 0db = 2g and -10 db = 1g. It appears as though the loaded shaker is putting out a fairly consistent and uniform output above about 300 cps.

July 30, 1970

The following is the work done on the first prototype of the new design microphone. We have decided to use the set up of the Gulton vibrator, the Endevco accelerometer attached to the shaker head, a piece of silicone rubber on top of the accelerometer and the microphone tip depressed on top of the silicone rubber. The microphone is held in place by a table overhanging the whole setup with a hole in the center. The microphone is in the center of the hole, mechanically isolated by a piece of foam rubber.

First I took measurements on the microphone output. The constant input is .4 volts RMS. Below 25 cycles the output was not a perfect sine wave, but is a close approximation.

August 13, 1970

Using the described integrated circuit we fabricated a printed circuit. We bought the cable into the microphone using several layers of shrinkable tubing. This was done because space was very limited and we wanted to have some sort of strain relief.

Once that was completed I went back to calibration. This time we ran into many problems from 60 cycle hum. After much experimentation we found that grounding the table, even though it was electrically isolated from the circuit, considerably reduced the hum.

We used the same setup as previously described with the accelerometer sandwiched between the accelerometer and microphone.

A set of points was obtained for the output of the microphone and another set from the accelerometer. I subtracted the two to eliminate any variations caused by the shaker. The composite curve follows.

August 14, 1970

Since our microphone is a displacement device, an ideal curve for it would have a slope of -2, as indicated by the dotted line or since we have a db scale a slope of -20 db per decade.

The graphs from the above tests are in the lab book on pages 32 and 33. Both graphs are from the same microphone and yet widely vary in the low frequency region.

I am concluding that the obtained data in the graphs is essentially meaningless, for some of the following reasons. When in use the microphone outer rubber ring is in contact with the medium, the chest, something we did not have here. The mechanical impedance of the chest and coupling of the microphone to the skin was not even closely approximated here by the simple piece of rubber. The rubber itself has a resonance frequency that would not be picked up and subtracted by the accelerometer. If the microphone was not perfectly vertical our curves would be different. The accelerometer noise level was so high below 50 Hz so as to render virtually meaningless the obtained results.

August 24, 1970

FABRICATION PROBLEMS

On the preceding pages are the mechanical drawings of the microphone unit. On the actual fabrication of the microphone unit, the shop cut four grooves instead of two. The microswitch was not clicking off each time so we elevated the switch with a piece of cardboard, which did the job. The spring wafer should be made to have maybe another 1/8" trovel so that the spring is always in compression.

One problem we had not allowed for was the cable between the transducer and the input of the amplifier. We wanted to be able to remove the transducer from the rest of the case for servicing, if necessary. Shielded cable was used to reduce noise pickup. The method used of putting a long wire in is adequate, but not completely satisfactory since in order to reinsert the transducer, the back must be removed also.

One other adequate, but not entirely satisfactory arrangement, is the tip itself. With normal use it will begin to unscrew and become loose. However, it is not worth spending that much time on it. A better method would be to use a different transducer, where the copper plate attached to the crystal, can be

directly applied to the skin. This has several other advantages. There is not the problem of someone applying pressure to the tip at an improper angle and exerting a torque on the crystal. It also reduces the mass of the sound-receiving area. Since sound is a pressure variation, and P = F/A = MA/A, reducing the mass with the same pressure would increase the acceleration and therefore the displacement on the crystal. Eliminating the tip would increase the area receiving the sound, also giving a bigger displacement.

All of the preceding are problems with the existing design, however, if we had more time, we would not use the existing transducer. The next step for someone who has more time is to either design or purchase a better transducer – one in which, as I spoke about before, the whole face of the transducer is available for contact to the chest.

Another possible step is to coat the outer aluminum case with some soft sound-absorbing material. This will reduce contact noise in holding the case.

For calibration, a possibility might be using the forearm to simulate the impedance of the human chest, as described in the article later in this book.

EVALUATION OF MICROPHONE SAMPLES FROM SHIGOTO INDUSTRIES

Two moving coil-type microphone samples received from Shigoto were connected to a commercial operational amplifier. The diaphragm of the microphone was placed against the chest wall. Despite changing the gain on the amplifier, no heartbeat of any kind was recorded on an oscilloscope. This is probably due to the fact that the diaphragm of the microphone is not sensitive enough to detect the vibrations of the chest wall. A special contact-type probe, similar to the one used on the crystal microphone, may help. This was not tried due to lack of time.

Maico Electronics, Inc.	
21 N. Third Street	maker of original
Minneapolis, Minn.	crystal microphone
612-941-3900	

TASK II

MICROPHONE MINIATURIZATION AND IMPROVEMENT

COMMENTS

METHODOLOGY

Methodology for this project was good. The documentation consisted of daily entries in the laboratory notebook. A formal report was not generated for this project. The initial entries revealed the effort of the literature search in the area of microphones and previous works. Methodology was quite thorough in that the characteristics of types of microphones were reviewed and a plan was followed, although not written. This team was also very resourceful. Generous use was made of outside resources such as manufacturers, various experts and other NASA installations.

RESULTS

The present existing microphone was then reviewed and method of miniaturization was developed. Standard electronic testing was done to monitor the work such as data on frequency response. In this manner resonant frequencies could be dealt with. This project required interface with fabrication shops at NASA. They experienced the technique of the fabrication and machining of parts through sketches and not formal drawings. There were problems in fabrication, but they were able to be worked out in conjunction with NASA personnel. The students were made aware of some of the seemingly complicated procedures that can be accomplished in a research (electronic) laboratory such as the ease by which a printed circuit board can be fabricated. A prototype miniature microphone was constructed, tested and demonstrated.

CONCLUSIONS

The documentation showed no formal section on conclusions of the work. The student's conclusions were stated as follows. A special contact-type probe similar to the one used in the crystal microphone may help. Thus, this project succeeded in miniaturizing a crystal-type microphone for use with the cardiogram. The miniaturization of this microphone is crucial to the acceptance of patient testing. The microphone is extremely useful in the recording of phonocardiograms when used with envelope detector developed by another task for patient screening.

FUTURE APPLICATIONS/EXPANSION

The prototype miniature microphone has been delivered to the Department of Clinical Engineering where a project to evaluate the envelope of the phonocardiogram is being conducted. The work is being conducted by one of the former Summer Institute students on a part-time basis. The microphone is being interfaced to the envelope detector. The plan is to record preliminary data of phonocardiograms and evaluate the merit of the envelope detector in disease detection.

TASK III

PHONOCARDIOGRAPHIC PREPROCESSOR

Mohammad Ali Hooshmand
Robert Martino

William Olden
Technical Advisor

June 29, 1970

Proposed Project

After reviewing the previous work, either design a new circuit to produce heart sound envelopes, or improve the existing one. Design requirements are to provide frequency information to some extent, calibrate the signal for true intensity and produce a portable prototype, preferably of very small size. The circuit which meets these requirements should thereby make it feasible to identify either by physician or computer the interpretations listed on page 2 of this notebook.

Routine clinical evaluation of the phonocardiographic amplitude/time signal is subject to interpretation of the complex waveform which carries a full continuum of frequency information. The true intensity and frequency relations are very difficult to perceive in this situation. A circuit which would produce an intensity (power) signal from the amplitude (voltage) signal would provide information better related to what the physician heard, i.e., loudness of sounds and their temporal relations. Frequency related information, analogous to pitch of audible heart sounds would need to be retained to some extent, but not to the equivalent of spectral analysis methods.

Discussion with Dave Winer from George Washington University on the sound envelope project. Topic: Preprocessor for Health Sounds Output of preprocessor: instantaneous value of intensity with respect to time.

The output of the preprocessor must have the following characteristics:

1. Gives the physician a picture of what he hears
2. Gives the computer a waveform that can easily be stored and analyzed.

The output of the preprocessor can be shifted in time from the real sounds – although it is desirable not to have a time shift.

In the final design the preprocessor should be small enough to connect to the microphone or to a recording unit.

July 1, 1970

Notes from: Winer, Et al; Heart Sound Analysis: A Three Dimensional Approach; The American Journal of Cardiology, Vol. 16, October, 1965.

"It is difficult to relate audible intensity of complex sounds to instantaneous values of amplitude as portrayed in the oscillographic form."

"Visible fluctuation in amplitude may not in many instances correspond to audible sensations because the ear responds to root-mean-square pressure, which means that sound must persist for some duration in order to be perceptible. Some transients visible on the oscillograph, therefore, may be of insufficient duration for audible recognition."

Notes from: Winer, David; Notebook: Phonocardiogram Project. December 1, 1964.

"A simplified waveform can be obtained which will include the same information which is presently used and needed. But it should have these advantages:

1. easier to program
2. easier to interpret visually
3. slower sampling rate
   a. compressed feed time to computer
   b. data phone transmission"

Method:

"Before the PCG signal is digitized it can be full wave rectified. The next stage in the circuit would be introduction of a suitable time constant to prevent return to baseline (this constant can be adjusted for the desired resolution for timing of split sounds, etc.) This is esentially the technique described by:" Rushmer, et al; "Sonvelographic Recording of Murmurs During Acute Myocarditis;" American Heart Journal, 48:835, 1954.

"The result is still an amplitude curve, which does not divulge intensity. If one wished for an intensity/time curve, this could be accomplished by a circuit similar to that in a vacuum tube voltmeter which has output calibrated in decibels. This output signal could be put on tape at the data acquisition system or could be generated at the computer center immediately prior to digitizing."

Note added: (February 19, 1965)

"Speech data are carried largely by the varying shape of the power density spectrum and not – as many wrongly believe – in the sound pressure vs. time plot seen on an oscilloscope."

S. E. Gerber and E. J. Strausman ("speech scientists," Communication Division Hughes A/C Co., 5440 W. Century, Los Angeles, California) in Digital coding for wire communication, Space/Aeronautics v. 40, No. 5, October, 1963, pp. 95-96.

(February 25, 1965) "A baseline was determined by finding the MODE of all values of amplitude. (The mode is that value which appears most frequently.) We have found that this makes an excellent baseline – Don Sherman's contribution.

(July 29, 1966) "If an analog network were designed to create this type of output (visual records of the way heart-sounds sound to the ear) from the microphone amplitude signal, it could be handled much the same as other low-frequency signals, such as ECG, PTG, EEG, etc. We could expect to find the following benefits:

- 500 digitizing rate vs 3000
- FM channel recording
- Easy computer pattern recognition program
- Telemetry over standard circuits
- Lower pulse code modulation rate if NASA would like to send heart-sounds from space
- Less computer care"

(November 31, 1968) Referring to Mark Wilber's circuit:

"This technique can be used to 'preprocess' heart sounds before recording, allowing all data acquisition, telemetry, preprocessing and processing the computer using the standard MSDL ECG hardware."

(December 4, 1968) Comment about computer analysis:

"Note that this is a digital computer approach to the intensity curves of pp. 6, 7, and 8 of this book. The analog preprocessor saves MUCH computer time."

Perry, et al.; Computer Analysis of the Phonocardiogram; reprinted from Engineering in the Practice of Medicine; The Williams and Wilkins Company, 1967.

"Rectification and smoothing techniques may aid in more precise identification of the heart sounds in the presence of artifacts or murmurs."

Siebert; from notes given in course titled "Signals and Systems" given at MIT in Spring, 1969. Notes were written in 1967.

Square-law and other non-linear-resistive devices

An ideal square-law devide is described by the formula

$$Y(+) = A\, x^2\,(+) \qquad (2)$$

(where A is a constant) and is often used to represent approximately the input-output characteristics of full-wave rectifier circuits such as shown in Figure 1.

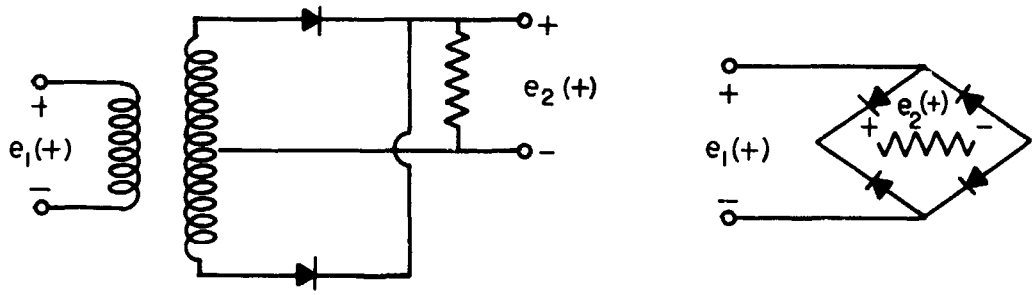


Figure 1. Two Examples of Full-Wave Rectifier Circuits

Other common devices which might be represented by (2) are the temperature of the heater element in a thermocouple-type ammeter as a function of the current, and the output of photomultiplier illuminated by a laser. The actual input-output characteristics of such devices might more accurately be described as in Figure 2. The extent to which such a graph will be adequately represented by (2) depends, of course, on the particular diodes employed, on the amplitude of the signals and on the precision required in the representation.

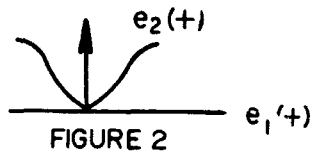
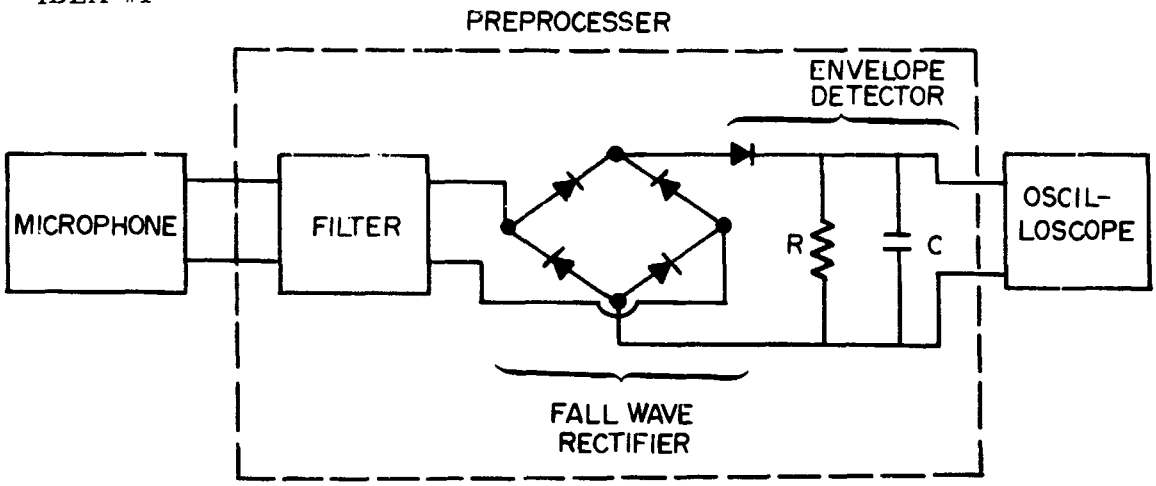


FIGURE 2

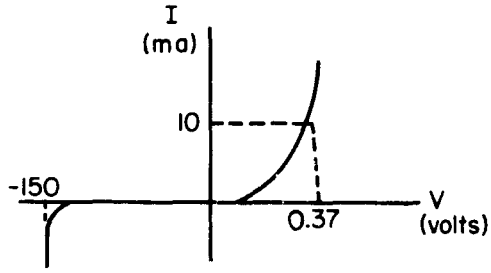
IDEA #1



TIME CONSTANT OF ENVELOPE DETECTOR = RC

The voltage across the capacitor may have an undesired ripple frequency which may be filtered out by a low-pass filter.

Diodes used for full wave rectifier



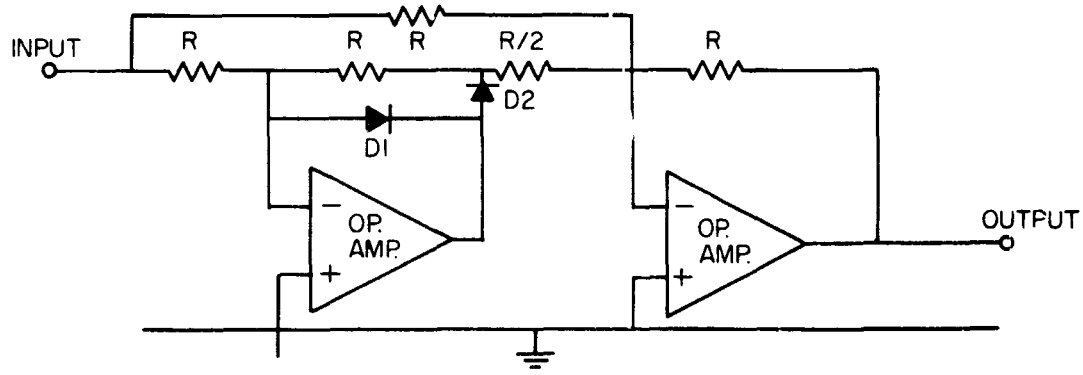
rectifier diodes and D1 : DR435 diodes
C = 20 ufd., electrolytic capacitor
R = ranges from 0 to 5 M ohms

changing the value of R the time constant varies from 0 to 20 sec.

problem with the four diode full wave rectifier:

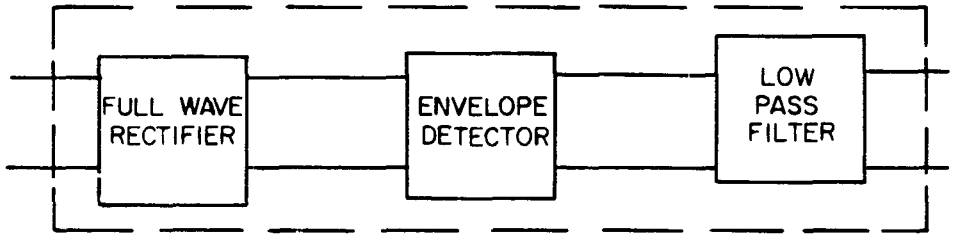
It is desirable to have both sides of diode D2 above grounded. With both sides of this diode grounded there will not be full wave rectification making it necessary to find another full wave rectifier.

Full Wave Rectifier Found in Burr-Brown Application Notes



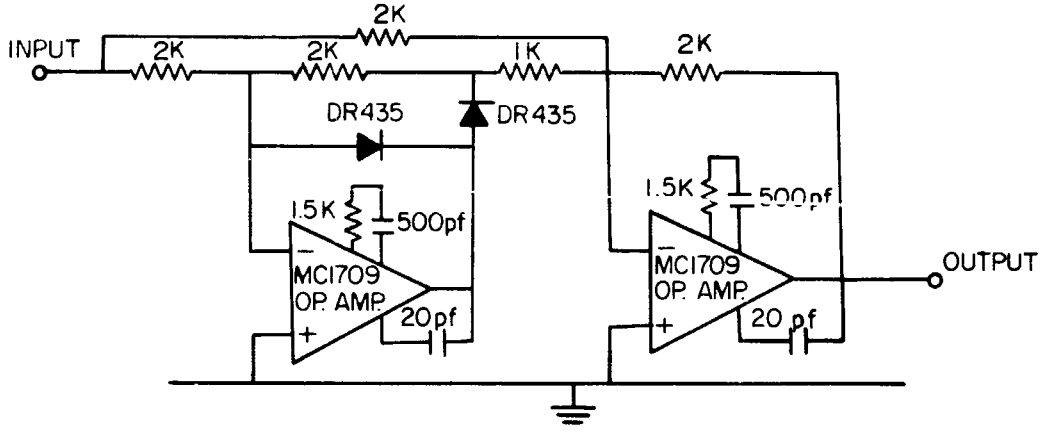
August 27, 1970

PREPROCESSOR



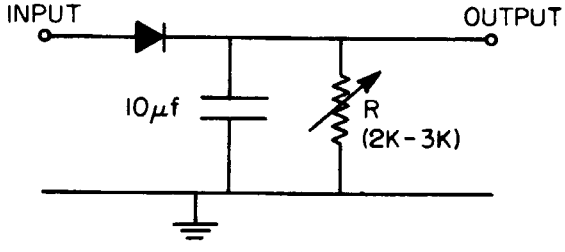
This full wave rectifier is good at all of the frequencies that are needed to rectify heart sounds. It has a low output impedance and there is no grounding problem which makes it a good match for the next stage of the preprocessor.

Full Wave Rectifier Used:



August 28, 1970

Envelope Detector:



This envelope detector simply smooths out the rectified signal. It does not filter out any part of the signal that is needed retaining the information from all the frequencies contained in a heart sound.

An RC time constant is chosen so that the necessary diagnostic information is retained while at the same time the waveform is smoothed. Time constant used = RC = .02 to .03 seconds.

On the positive cycle of the input signal, the capacitor C (10 uf) charges up to the peak voltage of the input signal. As the input signal falls below the peak value, the diode is cut off because the capacitor voltage (which is very nearly the peak voltage) is greater than the input signal voltage, thus causing the diode to open. The capacitor then discharges through the resistor R. During the next

positive cycle, near the peak of the input signal, the input signal becomes greater than the capacitor voltage and the diode conducts. The capacitor again charges to the peak value of this new cycle. During the cutoff period the capacitor will discharge completely with no new input.

Low Pass Filter

"Frequency selective networks for use in the frequency range below 100 KHz have always been a problem. In this area of operation the inductors and capacitors required are large, both in value and physical size. Also, at these frequencies inductors and capacitors become quite lossy and the circuit Q's begin to suffer.

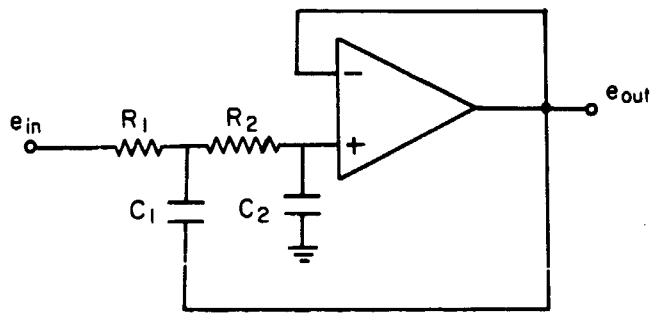
"The answer to this problem is to exchange the large inductor and capacitor for a large block of gain and use well known feedback principles to achieve selectivity with R-C active filters. Previously, to achieve a high degree of accuracy and circuit stability, a large number of active components was required in a fairly sophisticated circuit. Consequently, the design time and number of active components required made the use of active filters quite expensive.

"The solution to this problem came with the advent of integrated circuits which allowed transistors to be "less expensive" than resistors. Now, excellent gain blocks can be fabricated at fairly reasonable costs. And as technology improves, the performance will continue to improve and the costs will continue to decline, making the use of active filters very economical."

_____from Motorola Application Notes

After rectifying the heart sounds and putting the rectified wave into the envelope detector, we put the output of the envelope detector into a Rockland filter to determine what cutoff frequency was needed for a smooth envelope. This filter is filtering the envelope, not the heart sounds. Desired cutoff frequency = 35 cycles/sec.

Second Order Low Pass Active Filter



Configuration from:

OPAMP LABS
172 S. Alta Vista Blvd.
Los Angeles, Calif. 90003
(213) 934-3566
Application notes for Model 4009 Medium Voltage D. C. Operational Amplifier

$$\frac{e_0}{e_i} = \frac{1}{\left(\frac{S}{Wn}\right)^2 + d\left(\frac{S}{Wn}\right) + 1} \qquad \text{where } d = \frac{2 + R_1C_2}{12}$$

$$Wn^2 = \frac{1}{2\ 2} \qquad 1 = R_1C_1 \qquad 2 = R_2C_2$$

$$\text{want } n = 35\ \frac{\text{cycles}}{\text{sec.}} \text{ so } Wn = 2 = \frac{\text{rad.}}{\text{sec.}}$$

pick $R_1 = 120$ K and $C_1 = .05$

$$1 = R_1C_1 = (1.2 \times 10^5)\ (.05 \times 10^{-6}) = 6 \times 10^{-3} \text{ sec.}$$

$$Wn^2 = \frac{1}{1\ 2} = \frac{1}{(6 \times 10^{-3})_{\ 2}} = 4.84 \left(\frac{\text{rad.}}{\text{sec.}}\right)^2 \times 10^4$$

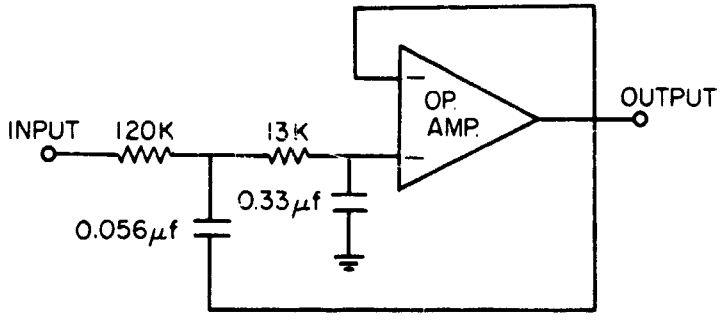
$$2 = \frac{1}{(6 \times 10^{-3})\quad (4.84 \times 10^4)} = 3.4 \times 10^{-3} \text{ sec.}$$

pick $R_2 = 13$ K

$$r_2 = R_2C_2$$

$$C_2 = \frac{2}{R_2} = \frac{3.4 \times 10^{-3}}{1.3 \times 10^{4}} = .26$$

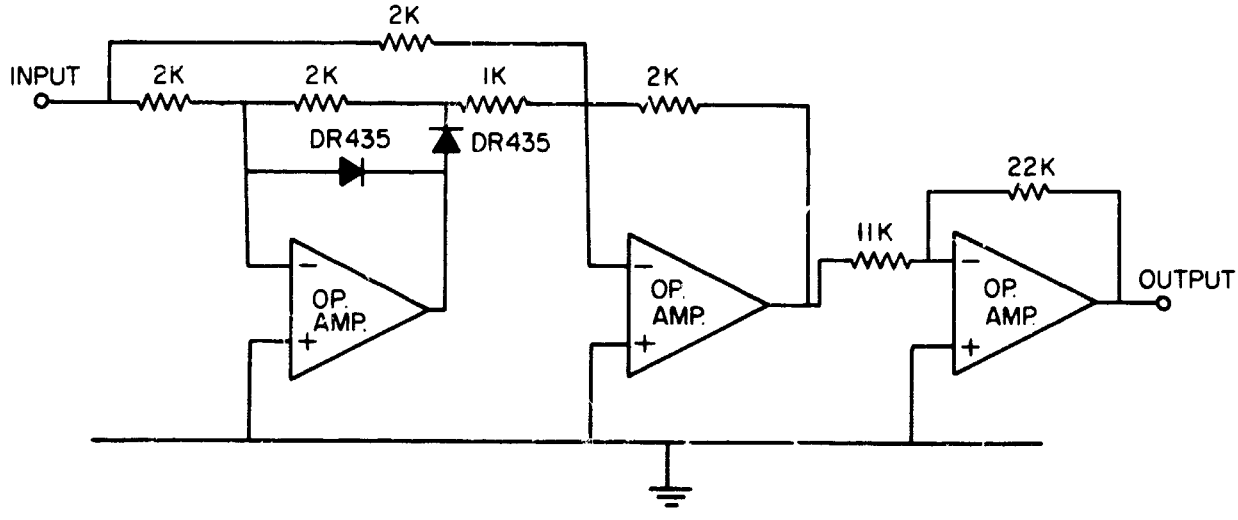
Low pass active filter used for preprocessor
(from calculations on previous page)



Operational amplifiers use: Model 4009 Medium Voltage D. C. Operation Amplifier from:
OPAMP LABS
172 S. Alta Vista Blvd.
Los Angeles, Calif. 90036
(213) 934-3566

Cutoff frequency determined in the lab = 33 cycles/sec.

Latest full-wave rectifier used:



Operational amplifiers used: Burr Brown

August 20, 1970

Note from Innocent Murmurs

Murmurs –

The intensity of the murmur is related to the velocity of blood flow and according to one theory intensity varies as the fourth power of velocity of flow.

Velocity is dependent on factors like volume of shunt, cardiac output, etc. So, if a small shunt and low velocity of blood exists the murmur will be of low intensity.

August 28, 1970

AM Approach for "Demodulation" of Heart Sounds

From the meetings I had with Mr. Mark Wilbur the following points became clear about this method and the way it had been used.

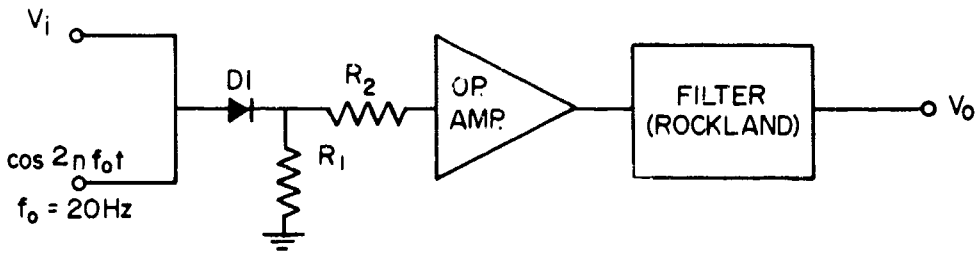
1. Assume heart sound is an amplitude modulated signal and try to demodulate it.
2. Pick a suitable carrier frequency to do the demodulation
3. Pick a suitable filter (cutoff frequency and voll. off) for blocking redundant information
4. Devise a method to multiply the carrier into the AM signal.

The carrier frequency was picket at 20 Hz in order to demodulate the signal by sending the lowest end of the audible range of the spectrum. Any frequency lower than 20 Hz cannot be heard, therefore, we do not (it was assumed) need that part of the frequencies of the signal in the envelope.

The filter was picked as low pass filter with the cut off point at 17 Hz with a roll off of 24 db/octave. This choice was made by looking at the output of the filter and changing the cutoff frequency and the roll off until a reasonable envelope was achieved.

The device to multiply the signal with the carrier signal was chosen to be a diode.

The simplified circuit which was used to get the result was the following.



The assumption was that the diode in the above circuit could behave as a multiplier. Current in the forward direction of the diode If = $V + V^2/2! + V^3/3! \ldots$ using the exponential characteristic of a diode where V is the voltage across it.

$$I_f = (V_i + \cos 2\pi f_0 t) + \frac{(V_i + \cos 2\pi f_0 t)^2}{2!} + \frac{(V_i + \cos 2\pi f_0 t)^3}{3!} + \ldots$$

$$I_f \cong V_i + \cos 2\pi f_0 t + \frac{V_i^2}{2} + \frac{\cos^2 2\pi f_0 t}{2} + \cos 2\pi f_0 t \, v_i$$

$$I_f \cong V_i + \cos 2\pi f_0 t + \frac{V_i^2}{2} + \frac{1 + \cos 4\pi f_0 t}{4} + V_i \cos 2\pi f_0 t$$

This current goes through R_1 and converts itself to a voltage value to go into the high impedance Op Amp to eventually go through the filter. The filter having a cutoff frequency at 17 Hz blocks the Cos $(2\pi f_0 t)$ obviously, blocks Cos $(4\pi f_0 t)/4$ term blocks most part of $Vi^2/2$ (because $Vi^2/2$ is formed of higher frequencies because of the fact that most of Vi spectrum is above 20 Hz, so most of $Vi^2/2$ will be above 20 Hz). Most of the vi term will be blocked too, so we will end up with the Vi.

The results which were obtained from this method were OK because the output of the filter looked like the envelope of the incoping signal with approximation.

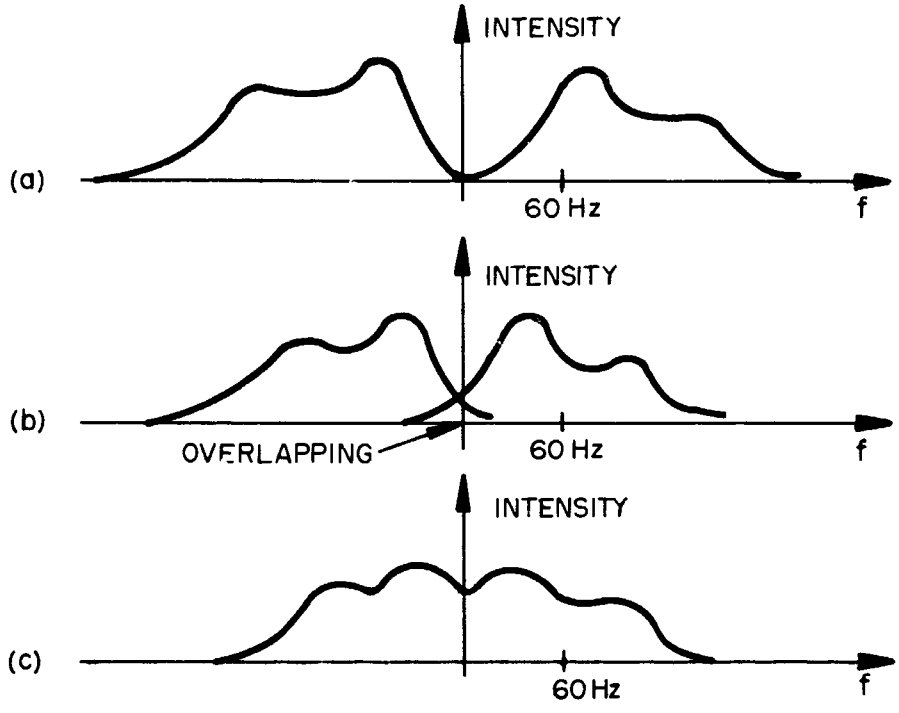
The high frequency murmurs were not being detected and the low intensity portion of the signal was not detected well. The important point was that the patient's murmurs were usually of higher frequencies and sometimes of low intensity. So, the diagnostic value of the envelope was almost very small, if any.

In order to get better results from this method we replaced the diode with a real multiplier. The multiplier was a Fast Quarter-Square Multiplier/Divider. It was a definite improvement over a diode. The diode was picked on the assumption that we could ignore the higher terms in the Taylor Series of the Exponential curve of the diode. This is usually not a valid assumption with the kind of signal we have here. The voltage goes high and low and we know when V is not very small. The assumption of ignoring the higher terms is invalid. Furthermore, in order to get better results we decided to improve the choice of carrier frequency and also filtering.

The Rockland Filter was used as a frequency analyzer to determine a spectrum knowledge (intensity vs. time) of the heart sound. The bandwidth of 20 Hz was picked and the intensity of the sound was measured in this bandwidth as it was swept across all frequencies involved (0-1000 Hz). Many curves were obtained for different heart sounds. The conclusion was most of the spectrums were very different from each other, but the fact was that most of them had high intensity components (usually belonging to first and second sounds) between 40 Hz and 100 Hz. This knowledge determined the choice of carrier frequency for us. It was picked to be 40 hz. This would shift the "important" part of the spectrum down to D.C. and around it. The filter cutoff was at 25 Hz with a roll off of 24 db/octave. The result was a signal similar to the envelope of the sound, but again very approximate and poor with respect to higher frequency murmurs.

One important mistake with the previous circuit is that because of the diode half of the sound signal is completely ignored. In any case, the second attempt with the AM approach failed too. This was because the spectrum of the sounds we achieved showed that no <u>one</u> frequency can be picked to demodulate the signal with, for the simple reasons that the complex signal received from the heart is <u>not</u> even close to something of that kind. The spectrums were very much distributed and there were no definite peaks to suggest choice of several carrier frequencies for "demodulation." This idea to pick different parts of the spectrum, shift them to DC and low frequencies and then add them to each other, fails to be a good one for several reasons. As mentioned above there is difficulty with choice of carrier frequencies. Then there is the problem of the negative frequency components of the Fourier Transform of the signal which gets shifted to DC and low frequencies each time.

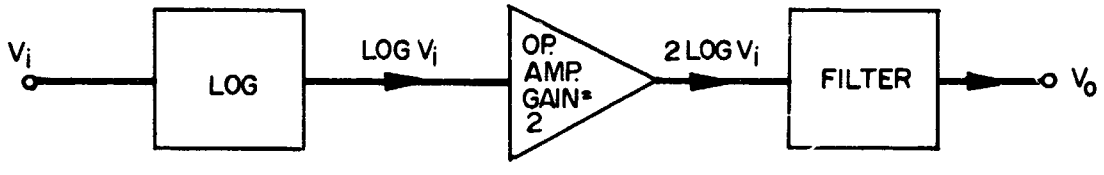
We multiply the signal with cosine of some frequency of time.



In (a) we have spectrum of a typical heart sound which is shifted down in (b) and the resultant spectrum is shown in (c). The overlapping of the negative frequency components introduces distortion of the results. This error could be very much amplified when several carrier frequencies are used for demodulating adding and getting the result. This important point of the addition of errors, the fact that the spectrum does not have well-defined peaks and it is disbributed fairly smoothly makes it unwise to use the method of demodulating and adding the signals to get a good envelope.

The Log Approach for Detection of Envelope of Heart Sounds

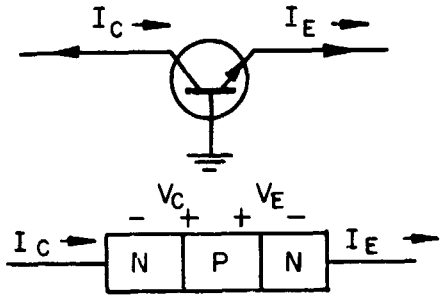
Ear is sensitive to log of intensity of the sounds, therefore, in order to get an envelope that looks like what the sound sounds like, we can initiate this biological process by electronics.



vi is the rectified (full wave) of the heart sound signal. The Op Amp puts out 2 log Vi which is log Vi^2 which is log of intensity (proportional to it) and the filter smooths the output signal. A time constant or delay could be introduced at the output to simulate the refractory periods of audio sensations of the ear.

The circuit to get the log of the full wave rectified signal is based upon the property of exponential character of current voltage relationship in a transistor.

(a)

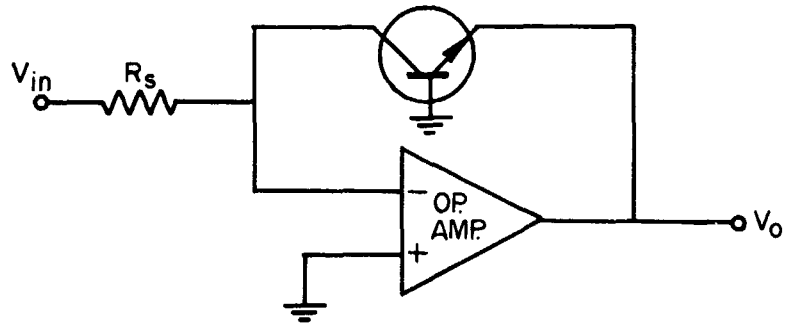


$$I_c = \alpha_n I_{es} [e^{qV_E/kt}]$$

I_{es} is the reverse saturation current of the emitter.

The basic circuit used is shown in Figure (b).

(b)



$$I_c = \alpha_n I_{es} [e^{qV_E/kt}] \qquad (a)$$

$$I_c = \frac{E_{in}}{R_s} \qquad (b)$$

Combining equations (a) and (b) we get

$$\frac{E_{in}}{R_s} = \alpha_n I_{es} [e^{qV_E/kt}] \quad V_0 = \frac{kt}{q} \ln \frac{E_{in}}{R_s \alpha_n I_{es}}$$

Converting from $\log_e$ to $\log_{10}$ gives:

$$V_0 = 2.3 \frac{K^T}{q} \log_e \frac{E_{in}}{R_s \alpha_n I_{es}}$$

$$V_0 = 2.3 \frac{K^T}{q} \log_{10} E_{in} + 2.3 \frac{K^T}{q} \log_{10} \frac{1}{R_s \alpha_n I_{es}}$$

$$\text{at } T = 27^\circ C \; \frac{K^T}{q} = 0.026 \text{ V} \quad V_0 = .06 \log_{10} E_{in} + K$$

Empirically it was found that V_0 and E_i have the following relationship:

$$V_0 = 0.062 \log_{10} (E_{in}) + 0.450$$

V_0 and E_i are in volts.

We tried this method, but did not succeed to have a meaningful output. This was probably because we should have had extra circuits for frequency compensation of the operational amplifier.

The correct circuit and information is given in Application Note AN-261 of Motorola Semiconductor Products, Inc.

TASK III

PHONOCARDIOGRAPHIC PREPROCESSOR

COMMENTS

METHODOLOGY

No formal outline was set up for the project. However, the material is well ordered in narrative form in the laboratory notebook. Previous work was reviewed and discussion was frequent with the Department of Clinical Engineering personnel. The various methods of intensity detection, such as square law detection by diodes, temperature devices and frequency shifting, were reviewed and discussed in the laboratory notebook.

Electronic circuits were breadboarded in NASA laboratories and parts were supplied by NASA. Various parameters of the circuit were measured and the data evaluated.

RESULTS

A breadboard circuit consisting of a full wave rectifier with simple resistance capacity filtering was demonstrated. This circuit did produce an envelope of the phonocardiogram. The envelope, however, seems to have excessive time constant and was lacking in defining many of the characteristics of the phonocardiogram. Actual phonocardiographic recording on 1/4" magnetic tape was used to develop the circuit. It was interesting to note on this project, that the solution tended to be a sophisticated engineering approach, while the users (Clinical Engineering) saw a simplified empiric solution. This is a common theme in the area of medical instrumentation. This does not mean that instrumentation should not be technically sound, but rather that simplified solutions of less accuracy are many times acceptable.

CONCLUSION

The conclusion of the project, although not specifically stated, was that full wave rectification with an appropriate time constant circuit is feasible for the detection of phonocardiograms.

FUTURE APPLICATION/EXPANSION

Work has continued on this project at the Department of Clinical Engineering. A circuit called a "box-car detector" was added to the original breadboard circuit of the full wave rectifier. This seems to have less of a "time-constant" problem. The signal still needs the appropriate filtering. The filter characteristics will be developed using a computer program on sampled data input to simulate the response with the results reviewed by physicians and engineers until an acceptable envelope is presented for the appropriate disease categories.

TASK IV

INTENSIVE CARE ALARM INDICATOR SYSTEM

J. Larry Christensen
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INTENSIVE CARE ALARM INDICATOR SYSTEM

TASK V – SCOPE OF WORK

June 26, 1970

A further clarification of the Task IV Scope of Work was prepared. A carbon copy of the memo to Wayne Chen is included below.

June 26, 1970

Wayne Chen
Technology Utilization Branch

André L. Hebert
Biomed Summer Institute

Revisions to the Task IV Scope of Work

This week Larry and I have made slight revisions to the Task IV Scope of Work. We are submitting these to you for your approval and for the approval of those involved at George Washington University Department of Clinical Engineering. The revised Scope of Work is as follows:

> Develop a device to be work by the Intensive Care Unit (ICU) staff (within the immediate area or room) which will indicate when alarms on the monitoring equipment have been activated. The alarm indicator must be noted by the personnel who are wearing the device. Minimum recognition by the patients in the ICU area will be kept in mind.
>
> The input to this device will be a (transmitted) signal (pulse burst) from the monitoring equipment presently available in the ICU. In development of the prototype attempts will be made to use available transmitters and receivers to communicate the signal. The emphasis on the task will be on the development of the alarm devide.

Any comments from you or from those at GW will be greatly appreciated.

Andre L. Hebert
Biomed Summer Institute

cc: Mr. Nace
Mr. Ayers
Mr. Landoll
Mr. Lee

CONSTRAINTS ON TASK IV, INTENSIVE CARE ALARM INDICATOR SYSTEM

June 26, 1970

In a meeting on Wednesday, June 24, 1970 certain constraints were tentatively established on the alarm indicator system. This meeting took place on the first floor of Building 22 at Goddard Space Flight Center, Greenbelt, Maryland. Those in attendance were as follows:

Wayne Chen, NASA, T.U., 982-6242
James Landoll, G. W., 331-6836
David Lee, G. W., 331-6871
Larry Christensen, NASA-G.W., 982-5982
Andre Hebert, NASA-G.W., 982-5982

A listing of the constraints established were as follows:

1. Cost $100
2. Range of signal required; 8 beds maximum
3. Reliability; 95%
4. Number of nurses on duty; 3 during the day, 2 at night
5. Acknowledgement of receipt of alarm by nurse; via reset button at bedside
6. Batteries; rechargeable
7. Function of hardware; reception of alarm only*
8. Size; pack of king size cigarettes
9. Fake alarms; not to be considered

*Isolated input interface which takes relay closure to ground and stays on until reset by console or at bedside.

Those questions not answered are as follows:

1. The nurses activities and daily routine?
2. Output from the ICU console?
3. Type of existing equipment?
4. Interfacing required?
5. Preferable type of signal?
6. Major problems and gripes with existing equipment?
7. When lessons available on how the system operates, what is the system supposed to do, etc.?
8. When alarm goes off, how important for patients never to hear or see alarm?
9. How frequently do the alarms go off?
10. Communications and medicine specifications for use in hospitals?

June 26, 1970

PROBLEM OUTLINE

I. Find out generally about the intensive care units and the nursing procedure followed in the ICU to determine the best size and location of the alarm device.

II. Determine which device would provide minimum stress to patients, but would effectively call the nurse.

III. Determine what information would be most helpful to the nurse.

IV. Research various possible alarm systems. Determine the advantages and disadvantages of audible, visual and sensory devices.

Assumption – any alarm system using smell or taste senses will not be effected because of the time involved and because of the limited amount of information that can be received. Also, hearing aid type is out because of nurses' dislike.

V. Proceed in developing various devices.

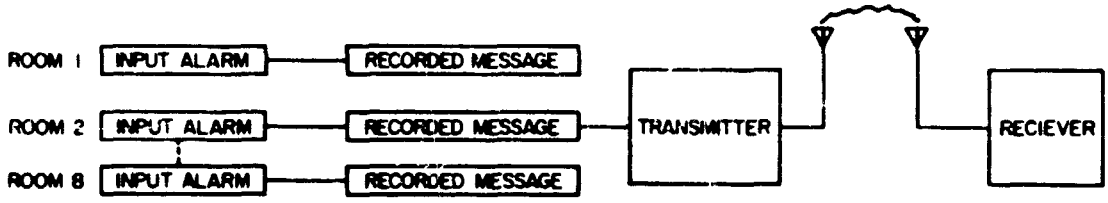
Yesterday, June 25 Dr. Ayers told me that the alarm device should not restrict the movement of the nurses and that it does not have to be waterproof. The signal emitted by the machine is a simple pulse signal. Suggested either a pin to the lapel or something on the wrist.

Information most needed by the nurse (D. Lee, June 25) would be the indication that the alarm went off and which patient needs care. Assumption – it will not be necessary to inform the nurse of pulse EKG information, temperature and heart rate because all of this information is given at the patient's bedside and there are no special procedures followed when just the information above is known (at console) without visiting patient's bedside.

Idea – Use a small radio receiver to accept a vocal command from the console. The vocal command could be given by some tape recording device. The message would be something like "Nurse, patient in room 5 needs care." There are two possible devices which could possibly be used directly: B58 warning device and telephone answering device.

Assumption – It would be less stressful for patient to know or at least think they understand what the signal means. With a vocal message as given above, the patient would know (1) who needs the help (which room) and (2) would not have to believe that it is an emergency, maybe just a patient calling for help of another kind.

Scheme of Device



June 30, 1970 – J. Landoll – not necessary to broadcast which patient needs the assistance.

INFORMATION ON INTENSIVE CARE UNITS

June 26, 1970

The Organization of Intensive Care Units

Report on Prepetory Meeting (Copenhagen, February 3-6, 1969)
Regional Office for Europe – World Health Organization

Number, Location and Optimum Size of CCU

- 8 to 10 beds (one unit) for every 250,000 people
- it is important to ensure that the specific requirements of patients with acute myocardial infarction are respected, particularly with regard to protection by partitions or walls from distressing and dramatic events occurring in adjacent beds
- for economic reasons, optimum size is 6 to 10 beds

Standards of Design and Equipment

- patients should be accommodated in separate, sound proof and opaque from each others rooms
- optimum size room is 15 to 20 meters^2
- each window should be provided with a window permitting inspection of the patients from the nursing area
- because it is impossible to directly survey any more than 5 patients there should be a control surveillance area
- displays – ECG's of all patients and slow heart rate warning system for each patient in control area
- following equipment at bedside

  1. oscilloscope to display ECG
  2. blood pressure apparatus
  3. oxygen and vacuum supply
  4. solid board for external cardiac massage

- following items should be available in the CCU

  1. at least one mobile multi-lead ECG
  2. one or two DC defibrillators
  3. portable oscilloscopes
  4. non-implantable pacemaker for transvenous internal pacing (one for every 3 patients)
  5. a mobile x-ray unit
  6. equipment for sustained artificial respiration
  7. an inter-communication system between the several areas
  8. adequate laboratory services

Standards for Staffing

- an electronics technician should be available to insure proper functioning of equipment

Participant at this meeting – Dr. S. M. Fox, Chief, Heart Disease and Stroke Control Program, Department of Health, Education and Welfare, Public Health Service, Arlington, Virginia.

A Study of Noise and Its Relationship to Patient Discomfort In a Recovery Room

Nursing Resrarch pp 247-250, Minchly, 1968.

- the sense of hearing is of prime importance to postoperative recovery room patients
- neither smell, touch or taste can provide sensory cues for patients reorientation as readily as hearing
- hearing may be distorted by drugs so that unwanted sounds may be subjectively interpreted by the patients as noxious stimuli, adding to their discomfort
- Melzack (Perception of Pain, Sci. Amer. 204 pp 41-49, February, 1961) has defined pain as the complex experience rather than single sensations produced by specific stimuli. The modifiability of events in the central nervous system and the interpretation placed on it by the individual poses problems in the alleviation of pain
- Gardner (Suppression of Pain by Sound Science, 132, pp 32-33, July 1, 1960) has shown that noise can be used to reduce sensations of pain

June 30, 1970

- Gardner's hypothesis – the postoperative patient, already suffering from surgical pain, is made more uncomfortable as the noise over which he has no control in his immediate area increases.
- sources of noise

inanimate – from initially areas at both ends of rooms, e.g. water taps running, telephone ring, clatter of utensils
animate – talking

- sound ranges -- 40-50 decibels (low), 50-60 decibels (medium), 60-70 decibels (high). Each increase of ten decibels in the intensity of sound stimuli doubles the subjective sensation of loudness.
- the experimenter found sounds of 60-70 decibels produced a decidedly noisy environment
- noted that more drugs are requested as the noise level increases
- a patient is sickened by the sound of vomiting; pained by the cries of others and most disturbed by the laughter of working personnel
- lack of response by the patient to the sound of the telephone or a patient's snoring may indicate that such sounds do not connote human distress or that they do not evoke the same response that would occur if the telephone were the patient's own telephone

Environment of ICU – Nursing Forum 6:262-272

- they may not have seen what was happening, but they heard a great deal and imagined much more
- noticed a general sense of urgency in the ICU
- people talked about them without including them in the conversation
- patients receive an over stimulation and emotional deprivation
- use could be made by sound devices by which patients can be heard by the staff, but do not themselves hear sound from other areas

July 1, 1970

Hackett, T. P. et al. The Coronary Care Unit: An Appraisal of Its Phychological Hazards, New England Journal of Medicine 1365-1370, December 19, 1968

Modern Hospital, Special Section on Intensive Patient Care, Vol. 100, Number 1, January, 1963.

- pacemakers – start up the stopped heart
- electronic defibrillator – to convert a fibrillating (random beating) heart to a stopped heart so that the pacemaker may be used
- these methods must be employed within a few minutes of when the unpredictable hazard strikes the heart

Pilot Oxygen Mask With Tactile Transducer Providing Warning Signals From Wireless Communication A65-11394

Some Neglected Possibilities of Communication. Science 131:1583-1588 May 27, 1960 Frank Bildard (Xerox copy)

- chest region – amplitude of 50 and 400 microns
  duration 0.1 to 2.0 seconds
  frequency 70 cps

Potential Answers to Communications Problems. Glenn R. Hawkes, Ph.D. Aerospace Medicine, Vol. 33, No. 6, June, 1962, p 657

- In situations where subjects respond to the presence of infrequently presented electrical cutaneous, mechanical or auditory signals of weak intensity levels, response latency and signal detection relative to that with auditory stimuli were poorer for vibratory systems
- when moderate stimulation was employed, the efficiency of cutaneous signal detection relative to auditory was well maintained

July 6, 1970

TELEPHONE CORRESPONDENCE AND INFORMATION COLLECTION

Listed below, in no particular order, are some of the more important telephone calls placed by André L. Hebert during the period from June 25, 1970 to July 2, 1970 for the intensive care alarm indicator system. Names of firms and individuals, together with telephone numbers and cities, if available, are included for later reference. More elaboration and/or content of the call(s) will be included following the list as deemed necessary.

1. NASA Tech. Brief 68-10365
   T. U. (Technology Utilization)
   Ames Research Center
   Moffett Field, California 94035
   Mr. Emerson
   415-961-2631
   Sending additional information 6/26/70 and has mini-transmitter

2. John Dirneoff
   Instrumentation Division
   Ames Research Center
   Moffett Field, California 94035
   415-961-2186

3. Jack Pope
   Ames Research Center
   Moffett Field, California 94035
   415-961-2951

4. Alexian Brothers Hospital
   225 North Jackson Avenue
   East San Jose, California 95216
   408-259-5000

   John Roden, Director of Engineering at Alexian
   Details of how use Motorola
   Pocket Beepers, $200-$300/unit
   3 years old

5. Motorola Hospital Division
   301-647-8900
   Benedict Allison
   Set up meeting at 9:30 a.m., Wednesday, July 1, 1970
   to discuss the Automatic Mark II Motorola System. Features
   Allison mentioned on phone:
   (a) can split ICU for nurse responsibility
   (b) can set priorities and override
   (c) Size 11/16" × 2-1/2" × 4-7/16"
   (d) 6-1/2 oz. Mercury battery
   (e) Worn in pocket or on belt
   (f) $202/payer + $5 installation

6. NASA Tech. Brief 69-10725
   Pocket-sized tone-modulated
   FM Transistor and patrol car receiver
   Transmitter-tape recorder-player combination
   T. V. "Squer"
   NASA Pasadena Office
   212-354-2240

7. NASA Tech. Brief 67-10369
   Alarm Monitoring
   Wheeler, Manned Spacecraft Center
   T. U. Houston, Texas 77058
   713-483-3809

8. NASA Tech. Brief 68-10131
   Patient Monitoring System
   David Winslow
   T. U., Marshall Space Flight Center
   Huntsville, Alabama 35812
   205-453-2224

9. Joseph L. Seminara
   Bioastronautics Organization
   Lockheed Missiles and Space Co.
   Sunnyvale, California
   408-742-4321
   Re to: Warning – Systems Design, in Machine Design, Vol. 37,
   September 30, 1965, pp 106-116

10. Bell Labs
    Murray Hill, New Jersey
    201-582-3000
    Jim Kaiser Ext. 2058

11. Johns Hopkins University
    301-955-3131
    Morse Goldstein (in Jerusalem 7/1/70 - 7/1/71)
    Spoke with Andrews (physics graduate and in biomedical engineering
    field 6 years)
    a. Pocket on nurse 3/4 size of man's pocket
    b. Bothered by audio sound
    c. If worn in upper pocket can use muscle frequency and not
       audio and not visual
    d. Known receivers belt size and for a large range (1 building, etc.)

12. Amperex
    North American Philips Co.
    Slatersville, Rhode Island 02876
    Providence Pike
    401-762-9000
    and Walter Bosse – Integrated Circuits, 401-737-3200
    and Roger White – Speakers, 516-234-7000

13. Arlington Electronics
    Amperex (a) TAA 300 and (b) TAD 100 in stock at (a) $3.37 and (b) $3.99

14. Telex Lapel Paging Speaker LS99
    1-1/2" × 1-3/4" × 5/8", .78 oz., $12.50 each
    David H. Brothers
    Brothers and Conneen Associates
    6302 Lincoln Avenue
    Baltimore, Maryland 21209
    301-764-7189

15. Dr. Charles Vunss
    Louisiana State University
    Electrical Engineering Department
    504-388-5241
    (a) Integrated circuits and small video amplifiers broad band FM and use tuner and amplifier watch which would beat diaphram on back
    (b) Buzzer take a lot of current
    (c) Medium shock little current and easy on batteries Tingling sensation if electrodes close to each other
    (d) Super regenerative detector, coils wound, transistor (chip type) and vibrator, shocking and battery
    (e) watch out for FCC regulations

16. Jack Pope
    415-961-2925
    To develop receiver for specific job is very expensive ($500) and black magic
    Ames Research Center
    Moffett Field, California

17. Dr. Irene Hsu
    G. W. Hospital, Head of Intensive Care
    331-6170 or 331-6646

July 8, 1970

Meetings July 1, 1970 and July 7, 1970 About Motorola Pocket Beepers

On Wednesday, July 1, 1970, Benedict Allison from Motorola Hospital Communications visited Goddard. General information was presented by Allison to

Hebert, Christensen and Landoll. The apparatus thought to be applicable by Allison for the given problem was the Automatic Mark II Automatic Nurse Call System.

Further information was presented to Hebert and Christensen on Tuesday, July 7, 1970, on the Automatic Mark II System. At this time it was decided that the above system was not applicable to this problem. Allison then recommended the installation of a Motorola Bay Station ($2,500) with "pocket beepers" to be able to be used in the event the Motorola System came under more serious consideration.

Methods of Signaling

The types of signals considered for indication of the alarm to the nurse are generally as follows:

1. Music
2. Small lights
3. Broadcasting names of nurse and/or verbal message
4. Beeps, buzzes
5. Sensory touch stimulation

Two experimental setups have been tried in the lab, the first with Nase and Hebert and the second with Nase, Christensen and Hebert.

The first was to attach a 1-1/2" diameter speaker to the wave generator. Some questions were still unanswered in that with this speaker both the nurse and the patients could hear the alarm from the 1-1/2" speaker.

The second one, performed today, was using a 50 ft., 4-wire inductive loop. The input to the loop was by the wave generator and a 10-watt amplifier. A Radioear Model 990 Microphone-Telephone (Inductive loop systems receiver as the telephone end). Hearing aid was used as a receiver. Satisfactory results were obtained to substantiate the promise that, to a certain extent, the nurse only could be warned without, or with a minimum, recognition by the patients in the intensive care unit.

Further investigations will probably be directed to try to reduce the cost of the $300 Model 990 hearing aid and incorporated this new receiver into an inductive loop system.

Meeting on Inductive Loop Systems at the Kendall School
On the Gallaudet College Campus, July 6, 1970

On July 6, 1970 Christensen and Hebert visited Dr. Behrens and Art Keiser at Gallaudet College. Demonstrations were performed on many of their hearing and signaling devices including their inductive loop systems in the classrooms and on bone conductor receivers.

A Radioear Model 830 hearing aid with both telephone and microphone capabilities was loaned to Hebert and Christensen.

Art Keiser gave further explanation on inductive loop systems and their installation at Kendall School.

Art Keiser	–	386-5009
Dr. Behrens	–	386-5571
Kendall School	–	386-5009

Also, at Gallaudet College Speech and Hearing Center can contact Bill Mullen or Dr. Cox at 386-6531. Supposedly, (from Dan Drake at Telex Hearing Center – RE 7-1977, 601 13th Street, N. W., Washington, D. C.) another inductive loop system and knowledge thereof can be seen and discussed by contacting Mullen and/or Cox.

Radioear Hearing Aid Inductive Loop Receiver Meeting, July 7, 1970

Mr. Fred Steward at Radioear, 916 19th Street, N. W., Washington, D. C. 541-4557 (Home phone 654-6908) on July 7, 1970 gave Christensen and Hebert a demonstration on bone conductor receivers and miniature hearing aids.

A Model 990 Radioear Hearing Aid-Telephone inductor coil receiver was loaned to Hebert for 10 days. This was the receiver used in the second experiment on page 14.

The inductive loop system used was a modification of the one included in a report entitled "Recommendations for Radioear Phonomaster Installation in the Translux Theater, 14th and H Streets, N. W., Washington, D. C." for McKee and McCormick, 711 14th Street, N. W., Washington, D. C., by Radioear Corporation, 306 Beverly Road, Pittsburgh, Pennsylvania, dated March 3, 1952.

The above report and a report by Charles Diaz, E. E., 121 Oak Street, S. W., Vienna, Virginia, entitled "General Description of Operation of an Induct-A-Loop in Conjunction with a 'T' Pad," were both given to Hebert and Christensen by Stewart.

July 8, 1970

Information on miniature batteries was requested on July 6, 1970 from Power Information Center, 3401 Market, Philadelphia, Penn., 215-EV2-8683, Mr. John Peirson (also can contact Col. Paul Balas).

Additional information was requested from Mr. Tirk of Gould-National Batteries, Inc., 2630 University Avenue, S. E., Minneapolis, Minnesota, about Ni-Cad Button size batteries. Also, Mr. Bill Kuhl, 654-6712, Silver Springs, can be contacted locally about these batteries. A catalog is supposed to be on the way.

July 9, 1970

Tactile Device Literature Search

Some Defected Possibilities of Communication. Frank Gildard, Science 131:1583-1588, May 27, 1960.

- signal applied to chest region can be felt at following conditions:

  amplitude – 50 to 400 microns

  duration – 0.1 to 2.0 secs.

  frequency – 70 cps

- this is for a vibrator system

Oxygen Mask with Tactile Communication Devices. F. Zawestowski, Aerospace Medicine, November, 1964, p. 1040.

- the tactile transducer is composed of five components:

  1. vibration generator
  2. head
  3. transmitting
  4. casing
  5. connective cable

Potential Answers to Communications Problems Glen Hawkes, p. 657, June, 1962, vol. 33, No. 6, Aerospace Medicine.

- when moderate stimulation was employed . . . efficiency of cutaneous signal detection relative to that with auditory stimuli was well maintained.

Information on piezoelectric material as possible vibrator was received from:

Piezoelectric Division Clevite Corporation, Bedford, Ohio
Telephone 216-232-8699

July 9, 1970

From the Clevite Corporation we got material concerning their Biomorphs as motor transducers. It would appear possible to obtain the necessary amplitudes for cutaneous stimulation from these Biomorphs.

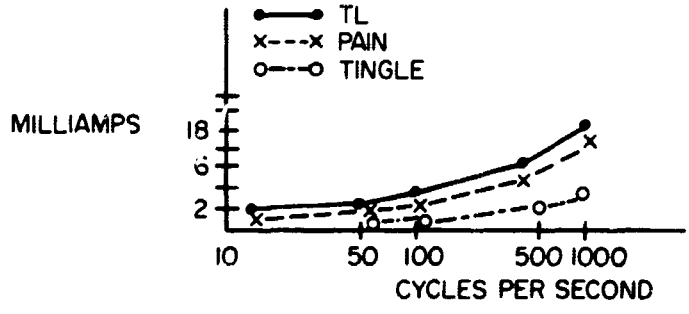
The Sensory Range of Electrical Stimulation of the Skin

G. W. Hawkes (U. S. Army Research Laboratory). American Journal of Psychology, Vol. 73 #3, September, 1960.

- application of alternating current to the skin under appropriate conditions will elicit sensations of pain, pressure, tingle, warmth, cold. Of these only pain and tingle can be routinely elicited.

- RL – absolute threshold of tingle and pain

  TL – tolerance limit of tingle and pain



- Qualitative reports

  tingle - weak sensation localized in a small area

  pain - localized sensation similar to a needle penetration

  TL - burning and muscle contractions

- It should be noted that the energy ranges determined by such a procedure are still considerably less than comparable ranges for vision, audition, or mechanical vibration of the skin.

Modifications to Radioear Model 1000 as Per Telephone Conversation with Lybarger

July 9, 1970

On July 9, 1970, Hebert called S. F. Lybarger at Radioear headquarters, 412-941-9000, 375 Valley Brook Road, Cannonsberg, Pennsylvania 15317. Lybarger was receptive to the idea of using the inductive loop features of the Radioear hearing aids as a small receiver for the I.C.U. nurse alarm system.

He recommended the use of a Model 1000 Radioear hearing aid rather than the more powerful Model 990 on loan from Fred Stewart, Radioear, Washington, D. C. He intends to modify the existing Model 1000 by removing the microphone and adding an inductive loop.

July 10, 1970

On July 10, 1970, Hebert placed a follow-up call to Lybarger to indicate the possible interest in his modified Model 1000 unit. Lybarger was ill but Hebert left a message indicating the interest he had found during his and Christensen's morning visits, described on the following pages.

Comments from Meeting at Veterans Administration Hospital, Washington, D. C., with Miss M. Geraghty, R.N., et al, July 10, 1970.

On July 10, 1970, Hebert and Christensen visited Miss M. Geraghty, R.N., at the Veterans Administration Hospital Medical Intensive Care Unit in Washington, D. C., 483-6666, 4-B East.

General comments from the meeting this morning are as follows:

1. When in the ICU, Bed #4 alarm on console went off twice in less than 5 minutes;
2. Prefer using existing buzzer tone as the transmitted signal;
3. Not want voice communication – sometimes it becomes garbled;
4. Very important to have receiver worn by nurse, especially at night with skeleton shifts;
5. Would be advantageous to cut down existing buzzer blaring through the whole ICU;
6. Like to have nurse reset alarm only when go to bedside;
7. Prefers receiver – speaker in pin form rather than behind the ear;
8. Not really needed to broadcast room (or bed) number, but only that there is an alarm;
9. Like to add Code Blue alarms to ICU warning alarms as a later feature;
10. No interference picked up with Model 990 Radioear when walked in V. A. Hospital, ICU.
11. Alarm thone should be obnoxious enough to be sure she hurries to turn it off and take care of patient.

Comments from Meeting at Sibley Hospital, Washington, D. C. with Miss Bright, R. N., July 10, 1970.

On July 10, 1970 Hebert and Christensen visited Miss Bright, EM 3-9600, ext. 558, at Sibley Hospital in Washington, D.C.

General comments from the meeting this morning are as follows:

1. Cannot hear alarm when in patient's room with door closed (i.e. while bathing, using bed pan, etc.) – small receiver worn by nurse badly needed;
2. Not needed to tell which room – can tell room number when in corridor from number of clicks on EKG machine;
3. Pin-on type receiver preferred;
4. No interference picked up when using Model 990 Radioear in ICU at Sibley;

5. Buzzer OK – Music would be nice, voice messages not necessary;
6. Buzzer not alarming to patients due to large number of false alarms.

Pro's and Con's of Inductive Loop System

Why Inductive Loop?

1. very small chance of outside disturbances
2. no operator required
3. used by Motorola in some of their pocket beeper systems
4. low cost – 4 lead copper wire and simple amplifier
5. inductive loop is good for small areas such as intensive care units
6. used at Kendall School
7. no permit from FCC required

Why Audible Signal?

1. not necessary to completely isolate patient from signal – just reduce intensity of signal
2. attracts attention of the nurse no matter what position her head is in – as opposed to lights
3. most common form of alarm
4. much work has been done in this area – as opposed to tactile
5. request of nurses at Sibley and V. A. Hospitals
6. easily interfaced with existing equipment which uses same type of buzzer and/or clicks

Why Hearing Aid Type of Receiver?

1. very small
2. very reliable
3. developed to work on induction coil type systems
4. can be made relatively cheap, although actual hearing aids are not

Why Not Such A System?

1. possible notification of patients
2. adds another buzz and/or beep in intensive care unit

July 13, 1970

Telephone Call – S. F. Lybarger

During a telephone call with Hebert this morning, Lybarger recommended not to have the output in the 500 hertz range, but rather in the 1500-4000 hertz range.

In addition, if the nurses object to wearing the small receiver behind the ear, Lybarger suggests either

1. Hair barrette with receiver cemented on, or
2. Small pin on plate with receiver cemented on.

When and if his receiver modifications are successful, more information will be available.

When Hebert spoke with Lybarger this afternoon, Lybarger had successfully packaged an inductive loop into a Model 1000 hearing aid casing. Final weight of this modified Model 1000 with battery, was 0.2 oz. Checks for feedback still had to be completed. Packaging was probably going to be in the form of a pin and/or behind the ear.

July 17, 1970

Must determine whether the inductive loop will interfere with other equipment found in the intensive care unit.

Preliminary List of Equipment Found in Intensive Care Unit

EKG

Pacemakers

Defibrillators

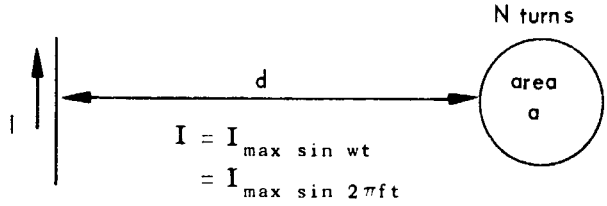
Mobile x-ray

Artificial respirator

Intercom-telephone

Lab equipment

Calculation of Magnetic Field Generated (D. Nace)



for an infinately long conductor

$$B = \frac{\mu_{air} I}{2\pi d}$$

$$\epsilon = -N \frac{d\phi}{dt}$$

$$\phi = AB = \frac{a \mu I_{max \sin wt}}{2\pi d}$$

$$\epsilon = -N \frac{d}{dt}\left(\frac{a\mu}{2\pi d} I_{max \sin wt}\right)$$

$$= -N \frac{a \mu I_{max}}{2\pi d} w \cos wt$$

$$\epsilon_{rms} = -\frac{N a \mu w I_{rms}}{2\pi d}$$

$$\boxed{\epsilon_{rms} = -\frac{N a \mu f}{d} I_{rms}}$$

estimate

$d = 10$ meters

$a = 5 \times 10^{-4}$ m^a

$I = 2.75$ amps

$$\epsilon_{rms} = \frac{4\pi \times 10^{-7} (5.0 \times 10^{-4}) 10^3 (2.75)}{10}$$

$$\epsilon_{rms} = .17 \times 10^{-6} \frac{volts}{turn}$$

$$= .17 \frac{microvolts}{turn}$$

Today Hebert spoke with Jim O'Brien, Applications Engineer and Marketing with American Optical Company, the main office in Bedford, Massachusetts. His telephone number was 8-0-617-275-0500, ext. 336. He seemed enthusiastic and referred Hebert to:

Mr. Phil Brooks, Research Division, Farmington, Mass.
Telephone 8-0-617-527-2785
879-1880

Brooks felt that the device using the inductive loop would not interfere with any of the existing equipment for the following reasons: most equipment is in a metal cabinet, temp and thermometer run direct current beyond the frequency of EKG 100 cycles, pacemakers – no, telemetry is in RF region

July 20, 1970

Hebert came in touch with American Optical Co. local representative Dick Williams, telephone 946-5012 (answering service) or 273-5341 (home). Williams suggests getting together on July 23, 1970.

Some articles that were read concerning the equipment in an ICU:

1. G. Church: Low Cost Coronary Care Unit Equipment, Journal of the American Medical Association 206:2523-2524, 1968.

Equipment was provided by Sanborn Division of Hewlett Packard Co.

- oscilloscope
- heart rate meter with light alarm
- synchronized direct current defibrillator
- an internal-external pacemaker
- electrocardiograph machine
- battery operated fixed rate pacemaker, a catheter and a few items for transvenous pacing
- non-synchronized defibrillator

2. Good reference is needed - D. G. Julian. Disturbances of Rate Rhythm and Conduction in Acute Myocardial Infarction. American Journal of Medicine 37:915-927, 1964

3. Medical Electronic Equipment, 1969-1970, ed. by G. W. A. Dummel and J. M. Robertson, Pergamon Electronics Data Sines

Cardiac Arrest Systems

* Beam-Matic Hospital Supply, Inc. Sorensen Division 25-11 49th Street Long Island City, New York 11103	Model 5000 Cardiac Arrest System 273-7010

Pacemakers

American Optical Instrument Company Cosby Drive Bedford, Massachusetts 01730	Model 10950
Electrodyne Division of Becton, Dickenson and Company 15 Southwest Park Westwood, Mass. 02090	portable transistor Pacemaker Model TR-3
* General Electric Co. X-Ray Department 4855 Electric Avenue 8-0-414-383-3211	Implantable Cardiac Pacemaker Generators Interim Cardiac Pacemaker Dual or single pass electrodes For abdominal and myocardial implant

July 20, 1970

Defibrillators

American Optical
Medical Division - Cat No. 10645

* The Birtcher Corporation – Model 415 Depolarizer
Medical International Division
4731 Valley Boulevard
Los Angeles, California 90032
8-0-213-222-9101

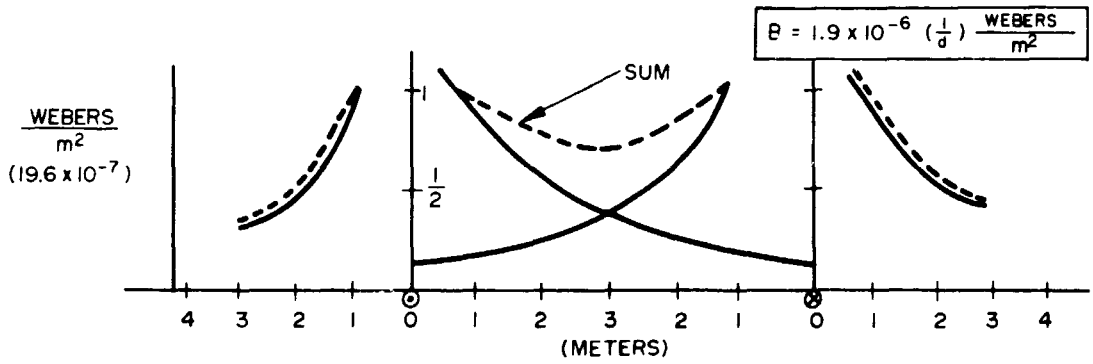
July 21, 1970

Graph of Distribution of Magnetic Field (two parallel wires)

We know that $B = N(\mu_{air} I / 2\pi d)$ for an infinitely long wire. Assuming an amplifier of 60 watts is used and the coil has a resistance of 10 ohms, then B becomes

$$B = N \frac{4\pi \times 10^{-7} (2.45)}{2\pi d} = \left(\frac{4}{d}\right) 4.9 \times 10^{-7} \frac{\text{webers}}{\text{m}2}$$

Assume hall corridor is 3 meters across



July 21, 1970

More telephone calls.

Referred by Bam-Matic to Cardiac Electronics, Mr. George Tatoian, 8-0-716-759-6167

Load rejection system. Operated on 100 cps bandwidth

Dr. Peter L. Frommer, Myocardial Infarction Branch, National Heart Institute, Bethesda, Maryland 496-1081.

July 23, 1970

Christensen called Lybarger today concerning the receiver end of the alarm system. Mr. Lybarger related that the model 100 radioear has an output of 121 db when an ear model is used. The model 990 can be made to release more power than the model 100 because (1) it has a larger gain and (2) the space occupied by the microphone can be also filled with a larger inductance coil.

Concerning the inductance coil, Lybarger said that best results would be obtained if the coil completely surrounded the intensive care unit along the outside walls. The magnetic field drops very quickly when one is outside of the loop.

July 24, 1970

Called Dr. P. L. Frommer to find out if he knows of any electrical standards that have been developed for Intensive Care Units. He said that more have been developed as of now. Dr. Frommer suggested fluorescent lights and portable x-ray equipment as possible interference sources.

Idea: Add a mechanical horn to audioear.

INTENSIVE CARE UNIT NURSE ALERTING SYSTEM

A Report for

GEORGE WASHINGTON UNIVERSITY
DEPARTMENT OF CLINICAL ENGINEERING

AND

NASA GODDARD SPACE FLIGHT CENTER
SUMMER BIOMEDICAL TECHNOLOGY UTILIZATION INSTITUTE

by

Andre L. Hebert
and
J. Larry Christensen

on

July 14, 1970

INTENSIVE CARE UNIT NURSE ALERTING SYSTEM

ABSTRACT

In the Intensive Care Unit (ICU) of 3 hospitals in the Washington, D. C. area (George Washington,[1] Veterans Administration,[2] and Sibley[3]), it has been noted that improvements could be made in the nurse alerting system used with the physiological monitoring equipment. A possible solution using an inductive loop system with an audible signal is presented below.

DEFINITION OF ICU

Generally, a medical ICU is an area of the hospital used for those patients requiring more attention than is usually available in the normal hospital environment, hence the name of Intensive Care Unit. This condition of the patient might be necessitated by many factors, such as a severe heart condition.

BACKGROUND

Physiological monitoring units, such as an electrocardiographic (EKG) unit, keep a constant surveillance on the patient. If and when the HIGH-LOW limits set by the physician are exceeded on the existing equipment, a buzzer alarm is sounded from and together with a light being activated on the centrally-located console of the ICU equipment. As an example, this alarm was sounded twice in less than 5 minutes when observed during the actual use.[1,2]

Whether these are actual or erroneous alarms from the existing monitoring equipment, still they are broadcast up and down the corridors and into any of the patients' rooms with the doors open.

SCOPE OF WORK

Therefore, it was decided to "Develop a device to be worn by the staff responsible for care (usually within the immediate area of room) which will indicate when alarms on monitoring equipment have been activated."[4]

INDUCTIVE LOOP SYSTEM WITH AUDIBLE SIGNAL

Several alternatives were investigated as solutions for this problem, but an inductive loop system, using an audible signal was selected. Reasons for this selection include the following:

1. low cost 4-lead copper wire and commercially available amplifier and receiver;
2. no permit from FCC required;
3. small chance of outside disturbances;
4. low ambient noise level;
5. no operator required; and
6. inductive loop system is good for small areas such as classrooms [5] and Intensive Care Units.[6]

A sketch of the prototype system as could be used in an ICU is presented in Figures 1 and 2. The floorplan, type of interface, amplifier output, and packaging of the receiver are some of the variables which must be established prior to final installation at each location.

Three major types of signals, (a) audible, (b) visual, and (c) tactile, were investigated for use in this alerting system. An audible signal was selected for many reasons including those listed below:

1. attracts attention of the nurse no matter what the position of her head;
2. a common and usually recognized form of alerting signal;
3. easily interfaced with existing equipment which uses some type of buzzer and/or clicks; and [2,3]
4. request of nurses in ICU.

PROTOTYPE EQUIPMENT

Loop System

The loop system used in the prototype is a modification of the loop system described by Lybarger.[7] A diagram of the prototype loop system, as applied to an ICU, is indicated in Figures 1 and 2.

The output of the Hewlett Packard Model 3310A Function Generator was fed into a Harman Kardon Model C-100 amplifier. As a safety feature, a Hewlett Packard Model 3400A RMS Voltmeter was used to insure a low (7 volts) voltage level.

From the amplifier the signal was carried to the 5-140 strip and then through the loop. The loop wire, 4 strands of 50 foot insulated copper wire connected in series, was wrapped in masking tape for ease in handling and then taped onto the walls in the lab.

The system while in operation was tested with the Model 990 Radioear receiver[8] described below.

Receiver

The small (1.79 inches by 0.63 inches by 0.45 inches, 0.3 ounce) Model 990 Radioear receiver, which was on loan,[8] but which can be modified for use exclusively with an inductive loop system, was selected for the following reasons:

1. small size;
2. readily available;
3. reliable;
4. repair service when needed; and
5. ease in change of batteries.

During the hospital investigations in the actual ICU's,[2,3] the Model 990 was operated to check the interference from the existing hospital equipment. The results were negative.

CONCLUSION

In conclusion, it is advised to use an inductive loop system, such as the one described above, for a Medical Intensive Care Unit Nurse Alerting System.

In the prototype, attempts to use existing equipment were successful. At the same time, the equipment was relatively inexpensive and, in the case of the receiver, already in a miniaturized form.

FOOTNOTES

1. NASA-GW Summer Biomedical Technology Utilization Institute Visit, June 23, 1970, Washington, D. C.

2. Veterans Administration Hospital Investigation and Visit by Hebert and Christensen, July 10, 1970, Washington, D. C.

3. Sibley Hospital Investigation and Visit by Hebert and Christensen, July 10, 1970, Washington, D. C.

4. NASA-GW Summer Biomedical Technology Utilization Institute Problem Outlines, June 22, 1970.

5. Kendall School of Galludet College Speech and Hearing Center Visit by Hebert and Christensen, July 6, 1970, Washington, D. C.

6. Motorola Hospital Communications Division Visit to Goddard, July 1, 1970.

7. Lybarger, S. F., "Recommendations for Radioear Phonemaster Installation in the Translux Theatre, 14th and H Streets, N. W., Washington, D. C.," March 3, 1952.

8. Model 990 Radioear receiver, V9069, 2F2134, and Radioear Engineering Bulletin Model 990, EB-22 7/1/MCL, Radioear Corporation, 375 Valley Brock Road, Cannonsburg, Pa. 15317.

TASK IV

INTENSIVE CARE UNIT NURSE ALARM SYSTEM

COMMENTS

METHODOLOGY

Methodology for this task was extremely good. One of the students was heavily oriented in system analysis; therefore, he developed a very detailed plan to approaching the problem. Considerable time was spent in problem definition. Preliminary data were gathered from various sources, both medical and non-medical, such as intensive care units in three hospitals in the Washington, D. C. area; various vendors of telemetry equipment; nurse call systems; radio links and other related equipments. Several alternative solutions were investigated, such as several methods of interfacing the alarm signals to the personnel responsible for patient care. This could be a buzzer, a light, tactile device or other. Good organization of material and thought are evident throughout and a fairly formal report was included in the laboratory notebook. The report was well ordered, included a table of contents and contained basic elements of an acceptable engineering technical report, listing scope of work, methodology and conclusions.

RESULTS

The work revealed a commercially available nurse call system which met most of the requirements, but was very expensive to implement. Further work included a design of an inexpensive inductive loop transmitter and modified hearing aid. This system was breadboarded to the extent that actual tones were transmitted and received by an "ear" receiver. The laboratory notebook reflects an in depth search into many of the aspects of this task. The personal contact with intensive care unit areas was invaluable to the students and contributed significantly to the task.

CONCLUSIONS

The students' conclusion of this task was to recommend the use of an inductive loop system. The prototype that was constructed indicated that such a system is relatively inexpensive and in the case of the receiver in miniaturized form.

FUTURE APPLICATION/EXPANSION

Mr. Christensen extended his work period for two weeks and analyzed the requirements of the Multitest Facility at the George Washington University. A plan was worked out for placement of the inductive loop in the Facility. Equipment was specified as to power requirements and cost. A decision can now be made to use the Multitest Facility as a prototype testing environment before implementation of the more stressful area such as an intensive care unit.

TASK V

DIGITAL REALIZATION OF PULMONARY SCREENING AND MOTIVATING DEVICE

Israel F. Charo
Donald Gorelick

H. Moffette Tharpe, Jr.
Technical Advisor

June 29, 1970

DIGITAL DEVICE

Statement of the Problem

The purpose of this effort is to improve the motivation and screening spirometer, by converting its analog output to digital form for computer analysis. At present it is necessary to manually adjust the reference voltage level of the comparators, through the use of prepared charts. We are to design a device with thumb switch inputs (age, sex, height), which will calculate using Kory's Regression Equations, the normal levels of Forced Expiratory Volume (FEV1); Peak Flow Rate (FR); and Forced Vital Capacity (FVC) for a given individual.

July 1, 1970

New Statement of Problem

We met with Mark Wilbur at G. W. yesterday and discussed, to some length our problem. He has already designed and built an analog computer with thumbwheel switch input to evaluate Kory's Regression equations. Our mission, should we decide to accept it, is to construct a digital equivalent to his device. The digital computer is necessary because of its higher accuracy, greater reliability, and greater repairability. The comparator circuitry can be either analog or digital. Mr. Wilbur has none of the hardware of his device available, so we may also construct the comparator, light driver and lighting circuitry.

July 24, 1970

We have been doing the computer logic design for the last two weeks. Many different ideas were thrown around and when we arrived at our "final" logic diagram we designed a timer circuit to perform operations in their correct order. Phone calls were made locating parts and information. We received some free samples from our Fairchild representative to serve as our parallel adder. We rounded up all the parts we will need, except switches. We got two Augat boards on which to build our breadboard model. We practiced the wirewrap technique which we are going t use to construct our breadboard model.

The steps used in our computer (MIMI) to calculate FVC and FEV1 are:

1. Multiply .0176 × A
2. Add 2.88 to it

3. Store result
4. Multiply .1064 × H
5. Take 2's complement of (3)
6. Add (4) + (5) ignoring last carry
7. Store result in comparator flip flops
8. Clear registers
9. Follow same steps for FEV1
10. Store in other comparator flip flops

Kory's Equations

MALE FVC = .1065 × H - .0176 × A - 2.88 Liters

FEV1 = .0752 × H - .0224 × A - 1.272 Liters

FEMALES FVC = .0833 × H - .0144 × H - 2.1512

FEV1 = .0569 × H - .0168 × A - .6936

H = height in inches A = age in years

PROBLEM : How to implement Kory's equations in binary form.

ANSWER : We have decided to multiply each equation by 1000. We therefore can multiply and subtract in the integer mode. The corresponding division by a 1000 will be done by adjusting the gain of the D/A or comparator circuit.

PROBLEM : How many bits should we use to get the accuracy required.

ANSWER : We decided to use G bits, which will give us an accuracy of about 1.5% which is "plenty good" considering the inherent inaccuracies of the test and other equipment. One estimate is that the test is 15% accurate.

PROBLEM : Using six bits to represent large numbers like 75.0.

SOLUTION : Drop off least significant bit since it is less than 2% accurate anyway.

August 6, 1970

We have completed most of the wiring and mounted our 2 circuit boards as shown below.

We have constructed the panel of switches shown, which we use in conjunction with the light set to check our multiplier and subtractor. We have successfully made "MIMI" multiply! It must be remembered that the 6 least significant digits are now shown on the panel. We have noticed that when all switches in the top now are in the "1" position, the answer is larger than can be shown on the panel and does not remain constant. This has been our only problem with the multiplication thus far. We have not been able to include the schematic diagrams for the timing and logic circuits as they cannot fit on a sheet this size. Reproduction of this diagram has thus far also not been possible. Detailed entries are not possible now, as we are still wiring our calculator, and can only report the problems we encounter.

August 24, 1970

We have completed the major portion of work on the computer. It can now correctly evaluate Kory's equation, which is what we set out to do. We have already given our presentation of the project, and have successfully demonstrated it. Our major effort now will be directed towards documenting our work.

We discovered an effective way of checking to see what values are in our registers and adder, at a particular instant. We do this by setting the scope on EXTERNAL triggering, and using the timing pulse which clocks in our observed operation as the triggering pulse as well. In this manner, the scope will not show any signal, except when triggered by this one unique pulse. However, since the times we are dealing with are in 10-9 seconds, we get a continual trace. The method is superior to our previous one, of gating out the clock pulses following the one we are observing. This has the disadvantage of not having a free running clock, rather we are producing a static system. We cannot look at other clock pulses without a free running clock, so our trouble-shooting ability was somewhat limited. Many times our erroneous answers were due to a failure in the timing circuit to generate the correct pulses at the proper time.

Note on the adder – We have used a 6 bit adder. This was constructed using three (3) Fairchild 9304 chips. Each chip is a 2 bit full adder.

We recommend that future versions of this computer be made at least 8 bits. This is due to our method of shifting in the multiplication cycle, and carrying

through only the 6 most significant digits. We have also made this problem more serious by multiplying all of our coefficients by 1000 (10^3) before using them in the equations. This was done to avoid binary representation of decimal numbers. We therefore are actually dropping off bits that are significant and our machine should be an eight (8) bit device. This change should be made only after the 6 bit machine has been made operational and successfully integrated with the existing spirometry hardware.

We are having a problem with time. We find that we won't have time to complete wiring of the FEV 1 equation, the six switch and make some changes which we feel will help the accuracy of our device. We feel it is necessary to document all the wiring we have done. The diagram is too large for the book so we are doing a large working drawing which may be blueprinted.

The switches for inputs of age and height must change a base 10 number from 0-99 to a binary number. We have thumbwheel switches which could be connected to a diode matrix to give us the correct binary representation. However, we don't have time to design the matrix. A switch which incorporates the matrix into its design can be bought from:

Digitran Company
855 S. Arroyo Parkway
Pasadena, California 91105
Phone: 213-449-3110 ATTENTION: Bob Nichols

Dual Binary Thumbwheel Switch - 3-D-173 Price $95.00

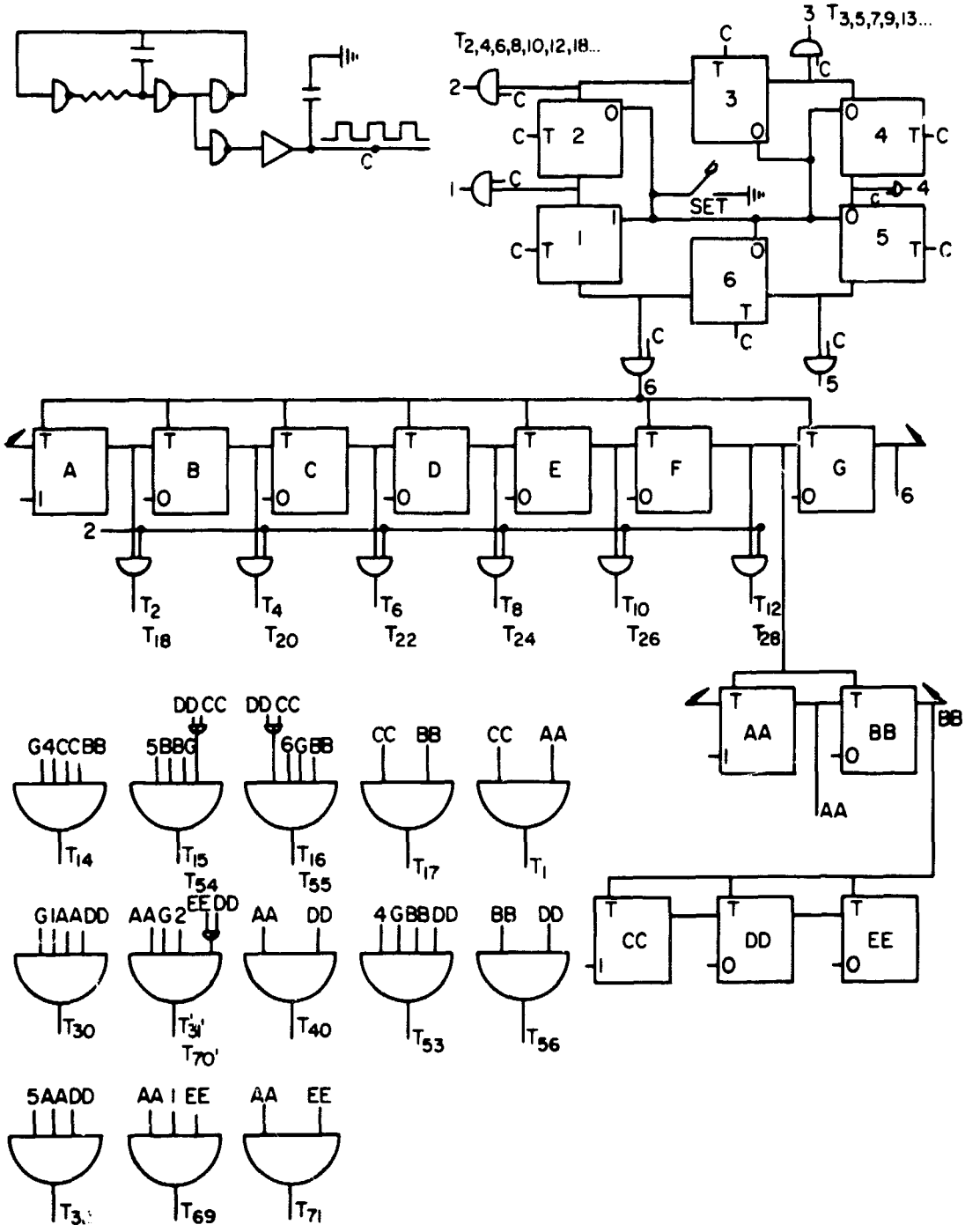
August 25, 1970

SUMMARY

I will attempt to summarize our project to this point. We have made the computer correctly evaluate Kory's equation. The Kory Regression Module is now digitalized, which has the following advantages:

1. As accurate as desired (adding bits)
2. Not dependent on line voltage
3. Greater reliability
4. Easy to repair

It now must be integrated with the existing spirometry electronics, which should not be difficult. All other items are commercially available.


T2,4,6,8,10,12,18...
3 T3,5,7,9,13...
SET
A
B
C
D
E
F
G
AA
BB
CC
DD
EE
T2
T18
T4
T20
T6
T22
T8
T24
T10
T26
T12
T28
T14
T15
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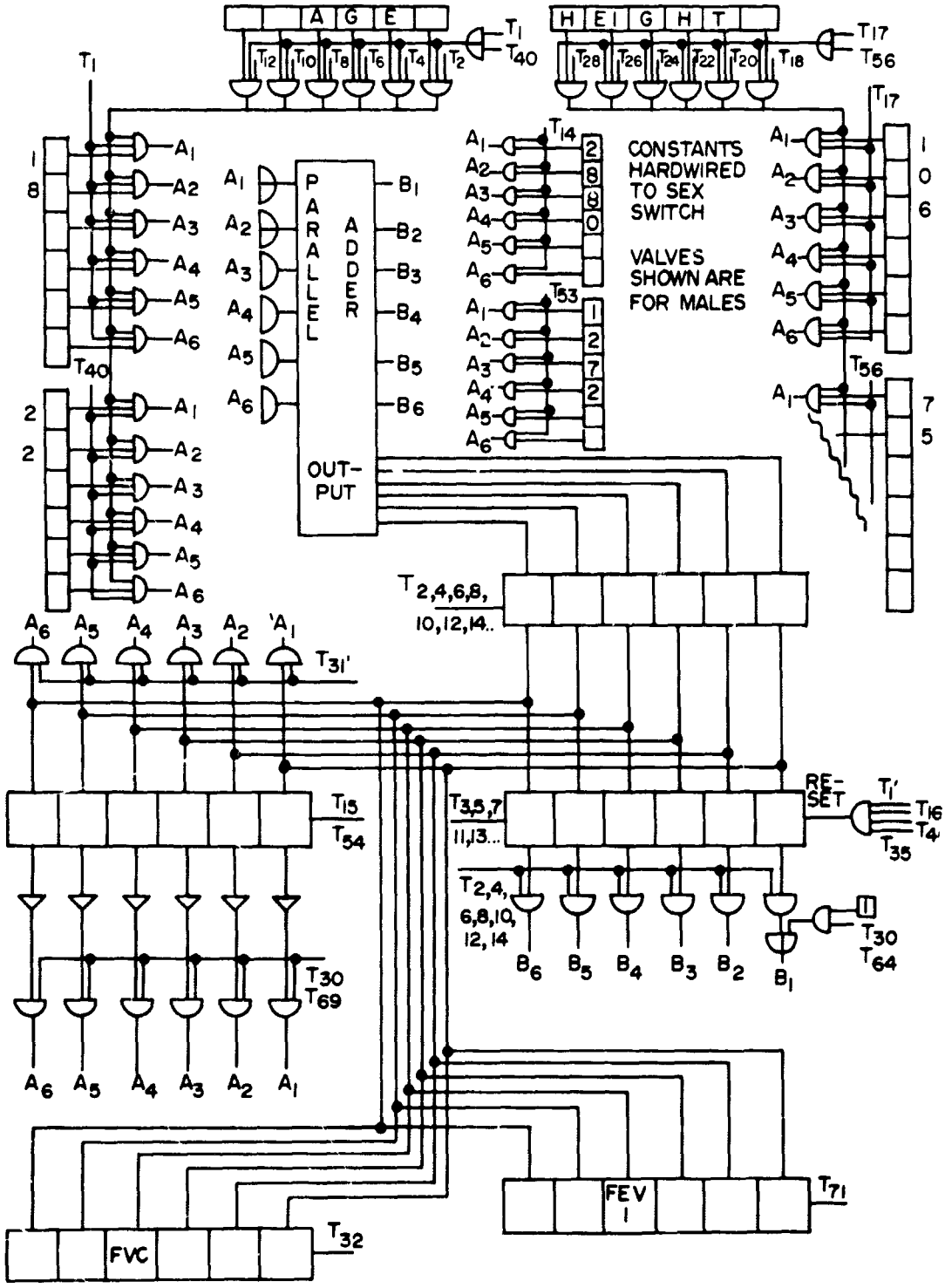
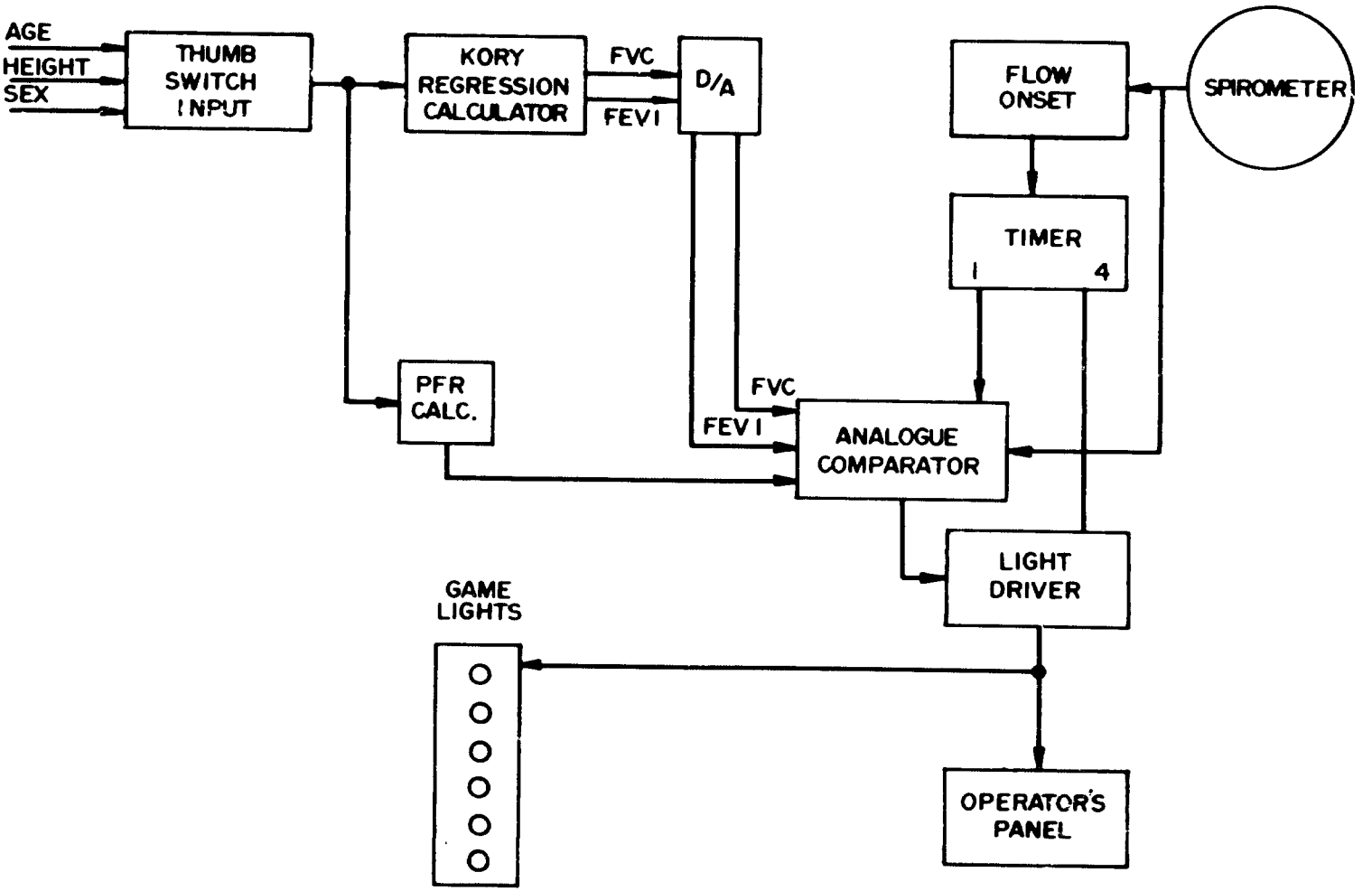
T55
T30
T31'
T70'
T40
T53
T56
T3
T69
T71


A G E
H E I G H T
T1
T40
T17
T56
CONSTANTS HARDWIRED TO SEX SWITCH
VALVES SHOWN ARE FOR MALES
PARALLEL ADDER
OUT-PUT
T2,4,6,8, 10,12,14..
T31'
T15
T54
T3,5,7 11,13...
RE-SET
T16
T4'
T35
T2,4, 6,8,10, 12,14
T30
T64
T30
T69
T71
FEV 1
FVC
T32


AGE
HEIGHT
SEX
THUMB SWITCH INPUT
KORY REGRESSION CALCULATOR
FVC
FEV1
D/A
FLOW ONSET
SPIROMETER
TIMER
1
4
PFR CALC.
FVC
FEV1
ANALOGUE COMPARATOR
LIGHT DRIVER
GAME LIGHTS
OPERATOR'S PANEL

TASK V

DIGITAL REALIZATION OF PULMONARY SCREENING AND MOTIVATING DEVICE

COMMENTS

METHODOLOGY

No formal report was written for this project. Documentation of this task consisted of daily progress notes in a laboratory notebook. The flow of work, although not outlined on paper, is quite reasonable. As problems were encountered they were documented, along with appropriate discussion and conclusions. For example, how many bits (6 bit vs 10 bit circuits) should the calculations be resolved to get the required accuracy. This requirement was determined by the engineers' (students') reviewing the medical use and the range of values considered to be clinically significant in spirometric testing as contrasted to cost.

RESULTS

The result of the project was a working breadboard model of digital logic design duplicating the concept of the motivation and screening spirometer. The broadboard model was constructed of digital logic components supplied by NASA and "debugged" in NASA's laboratories. "Flight line" components were used for the breadboard, but commercial grade logic circuits are available so that the cost would be considerably reduced.

CONCLUSION

It is interesting to note that after the actual prototype was built that some initial decisions should be changed. The students' remarks are as follows: "We recommend that future versions of this computer be made at least 8 bits. This is due to our method of shifting in the multiplication cycle, and carrying through only the 6 most significant digits. We have also made this problem more serious by multiplying all of our coefficients by 1000 (10^3) before using them in the equations. This was done to avoid binary representation of decimal numbers. We therefore are actually dropping off bits that are significant – and our machine should be an eight (8) bit device. This change should be made only after the 6 bit machine has been made operation(al) and successfully integrated with the existing spirometry hardware."

The students have done a formidable job in digital logic design, noting that neither student had experience in digital design. They have gained experience in the expansion of computers required by digital logic over analog devices, but have also noted the advantages of digital logic design:

"1. as accurate as desired (adding bits)

2. not dependent on line voltage

3. greater reliability

4. easy to repair"

Although the above are not succinctly stated they do alude to some of the inherent advantages of a digital design.

FUTURE APPLICATION/EXPANSION

Future application or expansion of the task is the application of the recent economic breakthrough of digital logic devices. This tends to make a small digital processing and motivation device for spirometry very reasonable to use in screening applications. The motivation portion should be implemented in the Multitest Facility of the George Washington University. However, present commitments and budget restricts immediate implementation.

APPENDICES

APPENDIX A

Goddard Space Flight Center
Participating Personnel

Special Programs Office, Code 207

Charles P. Boyle, Chief
Wayne T. Chen, TU, 1970 Summer Institute
Helen T. Attick, TU Assistant
Karyn D. Wions, TU Staff

Advisors

William Olden, Advanced Development Division, Code 521
Warner H. Miller, Information Processing Division, Code 562
H. Moffette Tharpe, Jr., Information Processing Division, Code 562
Harry E. Wannemacher, Jr., Spacecraft Technology Division, Code 716
David A. Nace, Systems Division, Code 733

Experimental Fabrication & Engineering Division, Code 280

Maurice Levinsohn, Chief
Leon L. Fontaine, Head, Main Shop

APPENDIX B

Participating Students
1970 Summer Institute

Israel F. Charo, Engineering Science
State University of New York at Stonybrook

J. Lauris Christensen, Engineering Science
Notre Dame University

Donald Gorelick, Electrical Engineering
University of Maryland

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Louisiana State University

Mohammad Ali Hooshmand, Electrical Engineering
Massachusetts Institute of Technology

Alan Lipschultz, Electrical Engineering
University of Maryland

Robert Martino, Electrical Engineering
Northeastern University

Paul E. Turer, Electrical Engineering
Rutgers University

Mitchell Weisberg, Engineering Science
Cornell University

Rolfe D. White, Engineering Science
Virginia Military Institute

APPENDIX C

Task Descriptions

TASK I

TITLE: Electrocardiographic Electrodes for Rapid Application

STATEMENT OF PROBLEM

In screening procedures (12-lead electrocardiogram), a suitable electrode that can be applied rapidly and provide good short-term (less than five minutes) performance is needed for both the precordial and limb sites.

SCOPE OF WORK

Investigate the commercially available electrodes such as those consisting of buffer amplifiers, right leg drive ground and other "dry" type electrodes and develop a suitable amplifier system (electrode, cable and input stages) for use with presently available electrocardiographic machines. The electrodes should be applied simultaneously or as rapidly as possible to the precordial and limb positions with a suitable skin electrode interface. For the precordial electrodes, the device or technique must be usable on a variety of individuals. This device could be incorporated in a special examining table.

PROBLEM

In the attempt to automate ECG data acquisition, machines have been designed and built which will automatically sequence through the various electrode sites. However, for the 12-lead scalar ECG, the electrodes are still clumsy and awkward to apply, particularly the six suction type electrodes which are applied to the chest. Therefore, to make maximum use of the new automated acquisition devices, a new technique and electrode must be designed to reduce the awkwardness and improve the efficiency of electrode placement. The technique or placement of the electrode with a harness or strap is related to the design of the electrode itself. That is, the electrode must not require prior preparation, must give good results and must be able to be placed easily and lend itself to good sanitary practices.

The task will draw upon determining a suitable method for the placement of electrodes on a variety of subjects and the selection of suitable electrodes (cable and amplifier system) for use with the device.

REFERENCE MATERIAL

Enclosed are selected materials to indicate previous work and present status in this area:

1. Electrode System for Automatic Recording of Electrocardiograms.
2. Mennen-Greatbatch, Physiological Skin Electrodes Model 407.
3. Hewlett Packard brochure of Automatic Cardiograph ECG/Phono System Models 1513A, 1514A.
4. NASA TECH BRIEF – Six briefs on related NASA sponsored research.
5. A Note on the Proper Technique of Precordial Electrocardiography.
6. The Polarization Impedance of Stainless Steel Recording and Stimulating Electrodes in Saline.
7. Skin Electrode Impedance and Its Effect on Recording Cardiac Potentials.

TASK II

PROPOSED PROJECT: Microphone Miniaturization and Improvement

Background Information

Microphones for detection of heart sounds are readily available from many manufacturers. Perhaps it is sufficient to say that such microphones are inadequate for many clinical purposes. Typical problems associated with their use are:

- non-linear response
- non-existing or improper acoustical evaluations
- massive
- bulky
- unsatisfactory signal to noise ratio
- lack of environmental noise insulatipn
- response is a function of application pressure

An improvement in the design of heart sound microphones is clearly worthwhile, and, with modern circuits, materials and engineering techniques, this appears eminently feasible.

Clinicians need more than a sophisticated design. In order to make a worthwhile contribution the designers should include in the list of constraints the requirement for mass production at reasonable cost.

Proposed Project

As a starting point in the study phase of the project, an existing design[1] is suggested for analysis. This design has been produced in limited quantity and has proved to offer exceptional improvements in noise rejection and stable response at varying application pressure. However, this prototype is heavy and bulky and probably is not better than most in terms of frequency response. Circuit diagrams, mechanical drawings and a prototype are available for analysis.

[1]Coleman, et al, "Heart Sound Transducer," Proceedings of the 5th International Conference on Medical Electronics, July, 1963.

Areas of new technology which might prove useful in the project are miniaturized circuitry and power supplies, during and acoustically superior materials, telemetry and computer evaluation of response signals.

The project should include mechanical drawings, circuit diagrams, prototype construction (of the mass-producible design), evaluation and test.

TASK III

PROPOSED PROJECT: Sound Envelope Circuit

Background Information

The art of auscultation is well advanced. Physicians, with practice, learn to distinguish sounds and identity cardiac symptoms extremely well. But, the method has some drawbacks, primarily because interpretation is so subjective, fraught with observer variation, and difficult to teach. As a result, visual recordings of heart sounds, in the form of amplitude/time tracings, have achieved wide acceptance as a complimentary method of diagnosing acoustical manifestations. Unfortunately the phonocardiogram (PCG), as this tracing is called, also has drawbacks which are distinguished by the fact that they are largely unrecognized in the medical community.

The PCG looks simple. From a microphone the signal is an electrical analog of the pressure variations with time produced by heart vibrations. But, the simplicity is deceptive since the sounds actually comprise a continuum of frequency and intensity as a function of time. Figure 1 illustrates this relation. A typical PCG tracing is shown below a spectrally analyzed version of the same sounds.[1] The upper picture demonstrates the true three-dimensional characteristics of heart sounds. Although the information content of the upper picture is carried by the PCG signal, it is obviously not amenable to interpretation from visual study of the PCG itself. This is also illustrated by Figure 2, the caption of which is self explanatory.[2]

Physicians do attempt to relate the baseline crossing rate of the PCG to "pitch," and the amplitude of the PCG to "loudness." Indeed they are often essentially correct in doing so, but a difficulty arises because they cannot really know when they are misled.

We are suggesting a further simplification of the signal which retains essential diagnostic information, but which avoids the pitfalls of the complex acoustical waveform. The approach is to create a true sound intensity signal from the amplitude signal. If accomplished properly, this would take the form of sound envelopes which would appear proportional in amplitude and time to the loudness of sounds detected by ear. A first approximation can be seen in Figure 3. Here a portion of the PCG of Figure 1 was digitized, manipulated in a computer (rectification and smoothing), and plotted on paper.[3] (The artifact furnishes a common fiducial point for comparison of the various tracings of Figures 1 and 3.)

A more refined attempt to produce sound envelopes is shown in Figure 4. Here an electronic circuit was devised to create the envelope equivalent (upper tracing) of a PCG (lower tracing). The envelope method has the following potential advantages: (1) It is simpler to relate to audible sounds, (2) It is easier to program for computer analysis, (3) It requires far less computer core space to store since it can be digitized at a lower rate while retaining full resolution, (4) It can be transmitted by standard FM techniques widely available for almost all other medical signals.

The circuit used to create Figure 4 is a laboratory prototype. It should be be improved in several respects before it is acceptable for clinical trials: (1) The energy in all frequency domains is integrated so that the physician cannot ascertain any conception of his familiar and important notion of "pitch." (2) It is not truly calibrated for intensity of sound so that an objective description can be made. (3) The prototype is in breadboard form and cannot be transported for clinical trials.

Proposed Project

After reviewing the previous work, either design a new circuit to produce heart sound envelopes, or improve the existing one. Design requirements are to provide frequency information to some extent, calibrate the signal for true intensity and produce a portable prototype, preferably of very small size. The circuit which meets these requirements should thereby make it feasible to identify either by physician or computer the interpretations listed in Table 1.

References

1. Winer, et al, "Heart Sound Analysis; A Three Dimensional Approach," American Journal of Cardiology, October, 1965.

2. Ibid.

3. Perry, et al, "Computer Analysis of the Phonocardiogram," Engineering in the Practice of Medicine, Chapter 19, Williams and Wilkins, Co., 1967.

TASK IV

TITLE: Digital Realization of Pulmonary Screening and Motivating Device.

STATEMENT OF PROBLEM

Screening procedures involving spirometry, a test in which a subject, upon full inspiration, expires into a device from which flow rates and lung volumes are determined, has two major difficulties. The first difficulty stems from the test dependency on patient motivation and the second involves the procedure to rapidly separate normals from abnormals. A device was built employing analog computation and gates that have apparently alleviated these difficulties in spirometric screening. The problem is to build a digital equivalent to this device.

SCOPE OF PROBLEM

As in any design situation, the designer must shoot for a case of maximum reliability and minimum cost. Of course, this is not always obtainable, but analysis of different configurations often lead to a best case. New design considerations that should be incorporated in the digital device are:

1. Modular Regression Module. The section of the device that calculates the normals for subjects of a specified height, age and sex must be removable and standard enough so that other regression equations may be substituted.

2. Digital Output of Test Results. Provisions have to be made so that the test results can be outputed to such things as digital tape, computer input, punched cards, etc., dependent on the user's demands.

3. Recording of Spirometer Analog Signal. In certain conditions the output of the spirometer must be recorded on either analog or digital tape, for further analysis. Recording capability must be "plug in" compatible with the screening device.

Inclusion of all the aforementioned design criteria, with heavy emphasis on system reliability, should produce a screening device capable of a wide variety of useful applications.

BACKGROUND PROBLEMS

The Forced Expiratory Spirogram exhalation is an effort dependent maneuver. A valid test demands maximum subject cooperation and voluntary participation.

Anything less result in recordings that have no diagnostic value and are often misleading if accepted as valid.

There are various factors that contribute to a restrained expiratory effort during the performance of the FES. In the event that this test is being conducted to evaluate claims for disability or other financial gain, willful malingering sometimes presents a problem. The majority of cases in this category are represented by elderly, discouraged individuals applying for disability. A captive population, such as school children taking part in a health survey, frequently withholds a maximal effort despite the best efforts of the technician administering the test. This is usually due to disinterest, or takes the form of "showing off" to classmates. Some other causes of severely depressed performance without ventilatory impairment are fear of pain on exertion, or the precipitation of a coughing spasm.

Those being evaluated for disability or known respiratory disease are usually tested in a hospital cardio-pulmonary laboratory. Here, time is available to work with the subject to overcome any anxieties present and acquaint the subject with the test procedure. Under these circumstances, a fairly reliable analysis of lung status is usually obtained.

In screening situation the circumstances are quite different. One screening test is used. This is not a diagnostic test requiring a medical history, signs, symptoms, or clinical impressions. The purpose of this test is to separate from a large population of normal persons, those who have a high probability of respiratory impairment.

Probably the most common cause of poor test data is due to failure of the subject to comprehend the test instructions. Screening surveys[1,2] frequently draw their populations from various ethnic and socio-economic groups,[5] therefore, problems of language, low intelligence and poor education combine to frustrate meaningful data collection. Quite often, examinees from these areas are taking medical test for the first time. This can be an uncomfortable experience and often results in an unacceptable test despite the best efforts of the technician. To others, the test instructions have little meaning because they cannot relate the required maneuver to anything familiar.

Respiratory function testing is one of the few tests that not only requires maximum subject participation, but also an astute technician. Current practice dictates that verbal encouragement be given to the subject to stimulate a maximal effort. An experienced technician is a combination of psychologist, bully, and cheerleader, as he strives to elicit a maximal response from the subject. It is the technician who explains the test, demonstrates from the subject. It is

the technician who explains the test, demonstrates the procedure, and evaluates the degree of cooperation obtained. He is the one who cheers on or goads the subject into putting forth his best effort. Finally, it is the technician who judges whether or not a test is acceptable. He has a cardinal role in the gathering of valid data. Not all technicians have the same abilities to do all of these tasks well.[3] Some work well only under supersivion, and if this is variable, so is technician performance. Even experienced technicians frequently vary in performance for a variety of reasons. Day-to-day testing can be extremely boring, and test subjects can be frustratingly uncooperative; therefore, stamina to maintain the same level of expertise during a lengthy screening operation is variable.[4]

METHOD

In an effort to control some of the described problems, a device known as a motivation and screening spirometer (MASS) has been devised.[6] MASS works in much the same way that carnival games of skill and strength challenge the participant. The individual taking the test is confronted by a column of seven unlit lights. Each subject is then challenged to light all the lights after a maximal inspiration by exhaling into the spirometer as rapidly and completely as possible. The underlying concept of this approach is based on information feedback. Motivation is maintained by a feedback loop consisting of subject reward (lights) which in turn reinforces motivation from moment to moment during the expiratory effort. This method simplifies the test instruction. The subject readily relates to the test and participates in the game without further verbal exhortation from the technician. In addition, this approach permits all attending technicians to present the test instruction in a uniform manner. Six of the lights represent a specific portion of the predicted vital capacity. The seventh light is an end-of-test light that comes on if the test has been performed correctly. The lights are mounted in a vertical column on the face of the spirometer. The first light at the bottom of the column is switched on if the subject blows 1/6 of 80% of his predicted vital capacity, the second light after 1/3 has been reached, the third at 1/2, the fourth at 2/3, the fifth at 5/6, and the sixth light when 80% of the predicted vital capacity is reached. The seventh light at the top of the column comes on 4 seconds after the onset of flow providing the subject is still maintaining his expiratory effort.

Six of the seven lights located on the face of the spirometer reflecting the various levels of the FVC are controlled by the programming module located on the technician control panel. Three switches on the module permit the technician to enter the age, sex and height of each examinee prior to the test. This information goes into an electronic analog of the Kory regression equation.[7] Eighty percent of the predicted vital capacity is computed electronically, and the value

used to set up the triggering levels of the lights. There are also four pilot lights located on the programming panel. Three of these lights represent screening values. These measurements are the PFR, FEV1, and FVC and they light up when critical values have been reached during the test. Circuitry similar to that used to compute the FVC, is also used to determine the predicted Forced Expiratory Volume at one second (FEV1)[7] and the Peak Flow Rate (PFR). Since the relationship between PFR and any set of parameters is not well defined compared with the volume equations, the best approximate linear relationship between PFR age and sex was used. The regression equation is as follows:

$$\text{MALES} = -.0794\ \text{Age} + 10 = \text{L/SEC}$$
$$\text{FEMALES} = -.0518\ \text{Age} + 7.5 = \text{L/SEC}$$

Triggering levels for both the motivation lights and the screening lights are set for each individual by the encoding module. All screening level lights trigger when 80% of predicted values have been reached.[8] The fourth pilot light is an end of test light similar to the EOT light on the motivation panel. Failure to light this light would indicate an unsatisfactory test.

The MASS, when coupled with a simple test instruction, permits semi-skilled personnel to administer the Forced Expiratory Spirogram Screening Test and obtain superior data. Questionable trials are immediately apparent from the screening lights so the test may be immediately repeated, or the subject referred for follow-up studies.

The challenge of the game acts to motivate the disinterested to perform maximally. The examinee is immediately rewarded for his effort by the presence of the lights going on. This represents tangible feedback of his effort. Also, the presenting of a uniform stimulus that is unchanging from trial to trial and not subject to the variabilities of technician influence, coupled with a simple but uniform test instruction, serve to eliminate most of the variability due to those factors.

REFERENCES

1. Bebol, B. J.: The Mid-Maximum Flow Rate, A Re-Examination. American; Review of Respiratory Diseases, 92:914, 1965.

2. Rosner, S. W., Abraham, S., and Caceres, C.: Spirometry in Medical Clinic. Journal of the American Medical Association, 194:239, 1965.

3. Discher, D. P., Massery, F. J., and Hallet, W. Y.: Quality Evaluation and Control Methods in Computer Assisted Screening. Presented to the Joint Program of the American College of Preventive Medicine, Section of the American Medical Association, American Medical Assoc. Conv., San Francisco, Calif., June 1968.

4. Rosner, S. W., Palmer, A., Ward, S. A., Abraham, S., and Caceres, C.: Clinical Spirometry Using Computer Techniques, Precision and Accuracy. American Review of Respiratory Diseases, 94:181, 1966.

5. Hyatt, R. E., Schilder, D. P., and Fry, D. L.: Relationship Between Maximum Expiratory Flow and Degree of Lung Inflation. Journal of Applied Physiology, 13:331, 1958.

6. Palmer, A., and Wilbur, M., The Forced Expiratory Spirogram: Uniform Stimulus and Rapid Screening. IEEE Journal of Biomedical Engineering, 42:112, July 1969.

7. Boren, H. G., Kory, R. C., and Syner, J. C.: The Veterans Administration-Army Cooperative Study of Pulmonary Function II, The Lung Volume and Its Subdivisions in Normal Men, American Journal of Medicine, A1:96, 1966.

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TASK V

TITLE: Intensive Care Alarm Indicator System

STATEMENT OF PROBLEM

Present alarm systems in intensive care situation add to the stressfulness in the intensive care unit by activating a multiplicity of lights or tone alarms. In general, these alarms are often ignored and are stressful to the patient and attending staff.

SCOPE OF WORK

Develop a device to be worn by the staff responsible for care (usually within the immediate area or room) which will indicate when alarms on monitoring equipment have been activated. The alarm indicator must be noted only by the personnel who are wearing the device. The input to this device will be a (transmitted) signal (pulse burst) from the monitoring equipment presently available in the intensive care units. The device to send (transmit) the signal to the alarm indicator worn by the staff must also be developed and designed.

PROBLEM

The intensive care or coronary care units are areas of high stress. The goal is to minimize the stressfulness that has been created by the multiplicity of alarms that take place in a monitored special care unit. Usually equipment is monitoring a patient for heart rate, premature contractions or other pertinent signals. When these parameters deviate from predetermined limits, alarms in consoles at the nurses' station are activated. It is these alarms that should be transmitted to a personal alarm indicator on the special care personnel. It is to be unobtrusive to others within a room (maximum size 50' × 70'). Environmental conditions are such as encountered in a monitoring system described by NASA Tech. Brief 68-10131.

APPENDIX D

The Lecture Series

1970 LECTURE/SEMINAR SCHEDULE
NASA – SUMMER INSTITUTE – CLINICAL ENGINEERING

PLACE: Department of Clinical Engineering, 2300 K Street, N.W., Washington, D. C. – Auditorium – 1st Floor.

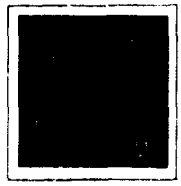
TIME: 9:30 a.m. on Tuesday, June 23
1:30 p.m. on all other days

DATE	SUBJECT	LECTURER
Tuesday, June 23	Introduction, Project Description Participation in Multitest Facility	W. R. Ayers, M.D. and J. R. Landoll
Thursday, June 25	Systems Analysis of Medical Measurement Systems – Medical Overview	C. A. Caceres, M.D.
Tuesday, June 30	The Human Machine – Physiologic Subsystems	C. W. Shilling, M.D.
Thursday, July 2	The Human Signal Emitter – Altered Physiologic Subsystems	W. R. Ayers, M.D.
Tuesday, July 7	Instrumentation for Medical Signal Analysis	M. Marro
Thursday, July 9	Data Acquisition Systems for Medicine	J. R. Landoll
Tuesday, July 14	Medical Information Systems	A. Pratt, M.D.
Thursday, July 16	Hospital Information Systems	J. Lang
Tuesday, July 21	The Clinical Laboratory	W. Lawrinson, M.D.
Thursday, July 23	Cardiopulmonary Monitoring and Analysis of Sound for Clinical Use	F. Siegel, M.D. and W. R. Ayers, M.D. D. E. Winer

DATE	SUBJECT	LECTURER
Tuesday, July 28	Diagnostic Radioisotopes	K. Williams
Thursday, Aug. 20	Seminar – Project Report (time and place to be announced)	Groups A, B, C
Tuesday, Aug. 25	Seminar – Project Report (time and place to be announced)	Groups D, E
Thursday, Aug. 27	Discussion of Exam Results and Submission of Student Critiques	C. A. Caceres, M.D. and staff

APPENDIX E

PARTICIPATING PERSONNEL AND FACILITIES
GEORGE WASHINGTON UNIVERSITY
DEPARTMENT OF CLINICAL ENGINEERING



MEDICAL CENTER

Department of Clinical Engineering

August 15, 1970

MEMORANDUM TO : Department Chairmen

FROM : C.A. Caceres, M.D.
Professor and Chairman
Department of Clinical Engineering

SUBJECT : Department of Clinical Engineering at Medical Center

The charge from the Medical Center to the Department of Clinical Engineering can be summarized by three points. These are to:

1. Organize a Medical Center-wide resource.

2. Make it self sustaining.

3. Do it with seed monies as available and existing Medical Center resources.

Organization was begun August 1, 1969. Key man staffing was effected January 1, 1970. Housing suitable to begin concentrated work became available April 1, 1970.

The Department will be pleased to: (1) collaborate with departments that so desire on joint efforts. That is, efforts in which the Clinical or Basic Science Department has an input more or less equal to that of The Department of Clinical Engineering. (2) provide ad hoc academic consulting services to other departments. (3) provide continuing consultive services for any department's grant, contract, or project, if funding allows. (4) provide any technical service that it has available to itself at hourly rates sufficient to cover costs.

The Department as "trustee" (with an administrative and operational staff) for various computers obtained by the Medical Center for specific projects can provide computer time on these to all Departments as project directors allow the Department to dispose of unused time. A PDP-8, a CDC 150-A and 8090, and a CDC 3300 are available. The Department of Clinical Engineering charges operational costs to the user.

Our background and proposed initial mode of operation are herewith attached for your review, comment or approval.

BACKGROUND

New areas of technology are rapidly growing in importance to medicine. The next decade will bring decisive changes. In the past, components of George Washington University Medical Center have pioneered in engineering and computer technology in health services, specifically computer electrocardiography. The Center had the advantage of the cooperation of the Medical Systems Development Laboratory of the U.S. Public Health Service. Outstanding contributions to the field have been made in research and development, telemetry and clinical evaluation. Teaching of medical engineering to medical and engineering students has been one by-product.

To preserve and broaden its leadership role in education, the Center has decided to move beyond automated electrocardiography as a model to wider aspects of engineering in the delivery of health services by expanding its own medical faculty and establishing a new department.

In combination with the available talents of other groups in the University, and by recruiting or relating to outside people, the new department will develop plans suitable to fulfill its community responsibility. Communication lines will be sought with governmental planning and development groups, foundations, and commercial organizations, to determine areas of joint effort and appropriate overlap.

OBJECTIVES

To describe the area of interest, the term "clinical engineering" has been selected. The field encompasses: 1) education in advances to comprehensive health care made possible by electronics, computers, and health systems analysis, 2) patient-oriented services such as a) multiphasic health screening for physicians and community health-care centers, b) automated monitoring for interpretation of status change in surgery, obstetrics, medicine, and other areas of intensive care, particularly to aid nurses and staff, c) hospital and health center safety implementation in regards to all phases of equipment, 3) development of systems such as integrated medical records and hospital information systems with appropriate interface with the community, 4) analysis of community medical services supplied through hospitals to determine interfacing mechanisms with other disciplines to use combined talents for medicine--e.g. statistical techniques of diagnostic and prognostic simulation, 5) research in technology to produce less expensive and more effective management of patients and better use of medical manpower, instrumentation and systems.

PERSONNEL

In the light of current experience, the future of a medical center will be closely tied to its expertise in computers and newer technology based on first-hand daily experience. The faculty to work in Clinical Engineering will encompass physicists, statisticians, analysts, programmers, as well as physicians and engineers.

In general, the Faculty will be comprised of persons trained and experienced in clinical systems work to effect the general purposes of clinical engineering by: 1) design, adaptation and application of new technology and methods to achieve modern health care at determined quality and cost objectives, 2) promotion of acceptance and routine use of quality control, 3) assistance to the Center to meet community responsibilities in care and health services research, and 4) evaluation of old as well as new methodologies and techniques, 5) supervision of the facilities required in these efforts, 6) consultative services to serve national, regional, local and other institutional groups.

FUNDING

Projects in clinical engineering will be initiated only as resources and available staff experience permit.

Funding is expected to come from several possible sources: a) the Medical Center, reflecting the amount that each department might benefit, b) grants from foundations to cover cost of initiation of projects, c) commercial concerns to cover equipment to recompense for trials and reports of tests and evaluations, d) health or other agency contracts and/or grants for research, development or establishment of evaluatory and test groups and trials, e) patient charges to cover service costs.

OPERATIONS OF THE DEPARTMENT

Education

The growth of health services has increased the demand on the people capable of delivering services. Thus, the cost has risen. The quality will tend to decrease unless we can educate health workers to focus appropriately upon the community's most urgent and solvable health problems. This implies study of the methods of delivery and manpower and better tools, and establishment of formal means of assuring a continued supply of both.

The educational role of the Department of Clinical Engineering will be effected by stimulation of the development of practical medical service systems. To make these possible, the Department will provide the academic and practical training needed by professionals in this field. This will be done initially through development of educational courses and material. By providing service projects students will best be able to acquire creditable experience. Faculty will be comprised of professionals experienced in health care delivery using technology.

It is proposed to develop courses utilizing symposia techniques. Our own texts will be developed. Faculty will be directed to acquaint those in the health field with the differing points of view of the researcher, the community, the consumer, the industrial concern, and the "middlemen" or overviewer group that coexist in the field. The concept of hospitals as institutions in flux and not as monuments, must be understood. Mobility, flexibility and responsiveness to needs could be a foremost consideration, as well as the provision of medicine via satellite groups for all community areas. The international role of U.S. hospitals as training media for underdeveloped nations should not be forgotten. The Clinical Engineering Faculty will constantly study the results of its teaching sessions as the input for material which would be up to date, relevant to community needs, and could provide a protocol for regional or national action.

Patient-Oriented Service

The basic facility of provision of care is the Medical Center. It is there that the mechanisms for delivery of health services must be studied and perfected. The utilization of a medical center structure as a nucleus with numerous satellites is the key to delivery of health services appropriate for the current decade.

The Department will look at the interrelations of the Center, its satellites, and the community. In each, systems analysis, automation and use of paramedical personnel usage will be applied and evaluated. Two basic model projects will be undertaken. One refers to diagnostic testing and the other to monitoring.

a) Multitest Facility

An active group needs a model project on which to test and evaluate its ideas and to build its methodology. This theme will be emphasized in all model projects. The Multitest Facility will expand on current testing methods. The immediate goal will be to utilize the group of physical parameters that can be measured with today's technology, provide needed clinical output, and require a minimum of skilled personnel to operate. Special efforts will go to stimulating industrial interest in mass-producing the mechanical and electronic components of practical systems.

A special goal will be to produce reports, based on discussion and experience, that various agencies, health administrators and industrial developers can use in guidelines in planning and equipping health care facilities. Our models will consider patient volume, selection of tests, techniques, and instruments, automation and electronic data processing procedures, and paramedical staffing patterns. Modes of education of the medical staff, to assure acceptance, and utilization, will be studied. The Facility itself will be a major teaching vehicle for students.

Studies will be conducted on: a) how a system can reduce costs by decreasing the time and manpower required, b) increasing service by decreasing hospital space needs, c) serving a greater load of patients at lower unit costs, d) augmenting quality of data generally made available to practitioners, e) standardization of data to ease record room problems, f) improved teaching methods by clearer definition of interface problems, g) increasing professional time to better establish and sustain patient-doctor relationships.

The Multitest Facility is in effect a research study being undertaken by George Washington University Medical Center to determine means by which it can facilitate community physician efforts to improve health-care delivery. The Multitest Facility is for physician use. An educational program, including seminars and mailings of scientific journal reprints, has been established to carry on continuing professional education in this area. Results of this continuing research project in health services delivery will be made available to community physicians.

Patients will be admitted to the Multitest Facility on the request of physicians. Results and records of the batteries of tests performed will be sent to the referring physician for his use. The initially used tests will include, among others, automated electrocardiography, spirography, audiometry, tonometry, vision tests, cervical smear analysis, urine tests, blood analysis, blood chemistry battery, chest x-ray film, and an automated historical review. Multitest Facility services will be charged to the patient, or as directed by the referring physician. Because of volume and facility and personnel concentration, savings should be possible in many instances.

b) Monitoring Facility

The Department will apply technological expertise to the care of acutely ill patients through this Facility. The systems are intended to provide for on-line, real-time monitoring of basic physiological parameters.

Evaluation of interactive real-time patient monitoring systems will be conducted. In addition to developing clinical application programs for use by the various specialities of the hospital, projects to allow for development of remote terminals, interfaces and data communications equipment and techniques will be undertaken.

Research studies will be conducted on the large data bases available to begin to use statistics as an active tool in daily patient care.

c) Hospital and Health Care Safety

Studies will be done to evaluate needs, a teaching and acceptance program. This area is being initially covered by research and development type efforts described below.

Research and Development

Research and development activities will be carried out partly as self-sufficient in-house activities, partly by combined cooperative work with other university or clinical groups, and partly with interested institutions from which funding can be obtained. Evaluation and Operations Analysis areas will be prominent.

The Department will focus on the potentials of medical electronics, data processing, telemetering, modeling and simulation, laboratory technology, and mass-testing techniques. An intimate contact with all Hospital, Medical Center and University departments will be indispensable. The impact and stimulating effect of the group should be felt in all areas of the Medical Center. The group will also be in a position to make and maintain outside contact for appropriate interfacing to, and in, hospital or medical center groups.

WORKING WITH THE DEPARTMENT OF CLINICAL ENGINEERING

This memorandum is to clarify the basis for the Department of Clinical Engineering's (1) collaboration between departments, (2) cooperation in setting up a basic research system for an investigator in another department, and (3) service areas.

It should be understood that the intent of these pages, based on recent experiences are to obtain a draft for submission to the Medical Center for discussion and hence, direction. In order for the Department of Clinical Engineering to best meet current Medical Center needs, further suggestions for correction, etc. would be appreciated. It is noted that the Department was organized to supply G. W. needs from the efficient and economic centralized source. It is considered that by this means the small user will benefit almost as much as the large user.

In collaborative projects, the Department of Clinical Engineering will either supply members of the Department or recruit for the effort. The Department will supervise and certify the academic caliber of analysts, programmers, engineers, mathematicians, statisticians, researchers, physicians in Clinical Engineering and supporting technical personnel for such efforts.

(1) Collaboration Between Two Departments

It appears best to effect active collaboration through a Project Director from the Department with major interest and budget status in the grant or contract. A transfer of funds, people or other resources must be made to the Department of Clinical Engineering to enable it to perform.

The Project Director is responsible for formulation of the project's scope of work, in conjunction with his departmental authority and with involvement of both departments.

The scope of work, as accepted by the Department of Clinical Engineering, is in effect, a contract of what the Department of Clinical Engineering is expected to achieve. Once accepted, changes in scope of work, direction, and mode of operation would be effected by the Project Director after consultation with the Department of Clinical Engineering and with the concurrence of the Project Director's Department.

A possible mean to effect the collaboration is to consider the Department of Clinical Engineering as a "subcontractor" as shown in the following outline.

1) Principal Investigator (Project Director)
   - Defines objectives
   - Estimates budget
   - Establishes personnel requirements
   - Itemizes spaces and equipment
   - and clears with:

2) Division Director who
   Sets priorities
   and clears with:

3) Department Chairman who
   Sets priorities and
   Presents a "subcontract" request to:

4) Chairman of Department of Clinical Engineering:
   Based on budget and objectives of its "subcontract"
   Allocates personnel space and equipment for its portion of work
   Assures quality control, performance effort and time schedule fulfillment for its efforts

The Clinical Department should assume authority and responsibility for patient care activities, actual usage of equipment in care, and personnel involved in care and insures quality control for its area of responsibility.

In general, it should be noted that cost effectiveness consideration of large and costly computer or engineering systems involved should tend to limit activity in major grants or contracts to applied and directed research or development and not to basic research problems subject to change on a daily basis. (Thanks are due Drs. Kelser, Kaufman and Rudman in the preparation of this section.)

(2) Cooperation on Basic Research System Implementation

Basic research systems for investigators in Clinical or Basic Science departments are a requirement in any educational institution. Maturity and expertise in an investigator is fundamental for him to obtain a best mix of guidance, consultation and independent activity. It is his Department Chairman that must make judgment regarding best mix. Once made, the Department of Clinical Engineering can provide guidance, consultation or resources for independent activity as required by the investigator's Department.

The Department of Clinical Engineering will cooperate by obtaining specialized personnel for research projects when possible and will assume responsibility for their work when guided or supervised by the Department. This may not be possible or prudent in some research projects.

(3) Service Areas

In addition to the above and to conventional consultation, the Department can also supply contractual, hourly, engineering, technical services, computing or programming to Departments as required, based on a standard charge.

Department of Clinical Engineering
Chairman: C. A. Caceres, M. D.

Facilities* and Directors

1.	Health Care Evaluation Facility	W. Ayers, M. D., Director
2.	Instrumentation Facility	J. Landoll, Director
3.	Computer Facility	D. Winer, Director
4.	Multitest Facility	C. A. Caceres, M. D., Director
5.	Operations Research	Director, Under Appointment

* Facilities effect the objectives of the Department principally by offering required services to Project Directors.

Projects** and Directors

1.	Automated Patient Monitoring Project	P. Russell, M. D. (Dept. of Anesthesia)
2.	Coronary Care Project	G. Kelser, M. D. (Dept. of Medicine)
3.	Electrocardiographic Translation	A. L. Weihrer
4.	Engineering Foundation Study	G. Devey
5.	Multitest and Community Health	W. Ayers, M. D.
6.	Multitest Establishment	B. Bellman
7.	Patient Examination Module	J. Landoll
8.	Summer Institute	W. Ayers, M. D.

** Projects are time limited efforts based on a specified scope of work. Directors "negotiate and buy" required services from the Facility Directors.

Project Coordinators***

1.	Automated Patient Monitoring Project	J. Landoll
2.	Coronary Care Project	J. R. Whiteman, M. D.**** (National Center for Health Services Research and Development)

*** These individuals assume the responsibility of project performance within the Department of Clinical Engineering with full authority vested in them by the Project Director. Generally, these are required when a project has a component within the Hospital and one within Warwick.

**** Project Officer

ADMINISTRATIVE LINES

The administrative lines for the Department of Clinical Engineering are helpful in orienting Department members to their area of authority and responsibility.

The Department is divided into three groups that will do the bulk of research, development and teaching, along with a fourth, to be established in September. The existing groups are the: Evaluation, Computer Facility, Instrumentation Facilities and the fourth is to be the Operations Research Group. There is a service group for patient care--the Multitest Facility; another is planned for a Monitoring Facility.

Lines of command in any organization require that an individual report to a single individual and not to two or three simultaneously. This means that Project Directors, who need not be Departmental Faculty, must communicate (once their projects have been approved in terms of scope of work, funding, etc.) with Facility Directors to establish the details of the scope of work.

Project Directors are not members of a Facility but obtain services as required to meet their needs through the Facility Director who is responsible for quality as well as accounting for time and expenditures in the particular task. The Facility Director does not approve time or expenditures. This is done by the Project Director. The Facility Director may, when necessary, assign an individual to work with the Project Director on day to day details for as long as might be required. It is understood that each individual in each Facility is acting for the Facility at the direction of the Director of the Facility, who is complying with needs of a project approved of by the Faculty of the Department. In this way Project Directors can be assured that the Department will supply all of the needs for their specific projects.

Members of each Facility will operate according to the detailed methodology developed by the Facility Director. These are now in the formative stages and for the most part, currently, experimental.

It is a fact that this is the first time that a University has given Departmental status to this long overdue type of endeavor. George Washington is pioneering and it is therefore not expected that we will find a smooth and well-worn pathway for direction.

DIFFERENTIATION OF RESPONSIBILITIES FOR MEDICAL CENTER DATA PROCESSING AND DEPARTMENT OF CLINICAL ENGINEERING

In attempting to establish some guidelines as to which applications areas should be assigned to each department, discussions have been held with the Medical Center Data Processing group under Mr. H. Dorsey. The points of agreement are herein summarized. The Department of Clinical Engineering would be responsible for taking source data and performing all computational work needed to develop the final output information, and Data Processing would be responsible for maintaining the central data bank and writing programs to perform file maintenance and report generation.

The focus of Clinical Engineering would be at the clinical level--input from teh patients and output to doctors. Data Processing would generate management reports and become involved in data input only from areas such as the Billing Office, Admission clerks and management data in ancillary areas such as Housekeeping, Pharmacy, etc.

Data Processing should be responsible for management information rather than all patient information. For example, Data Processing would schedule the patient prior to admission, assign available beds, maintain management control of the patient insofar as billing, delivery of food, central supplies and pharmaceuticals, retrieve medical records, produce Disease and Operation Index, schedule housekeeping employees, maintain inventories in Dietary, CSR and Purchasing and be involved in other management-oriented applications.

Clinical Engineering would work at the patient and doctor level. For example, in a laboratory application, Clinical Engineering would add test result data to the biographic file maintained by Data Processing. Data Processing would be responsible for producing the physician's report of results, but Clinical Engineering would designate format, content, etc.