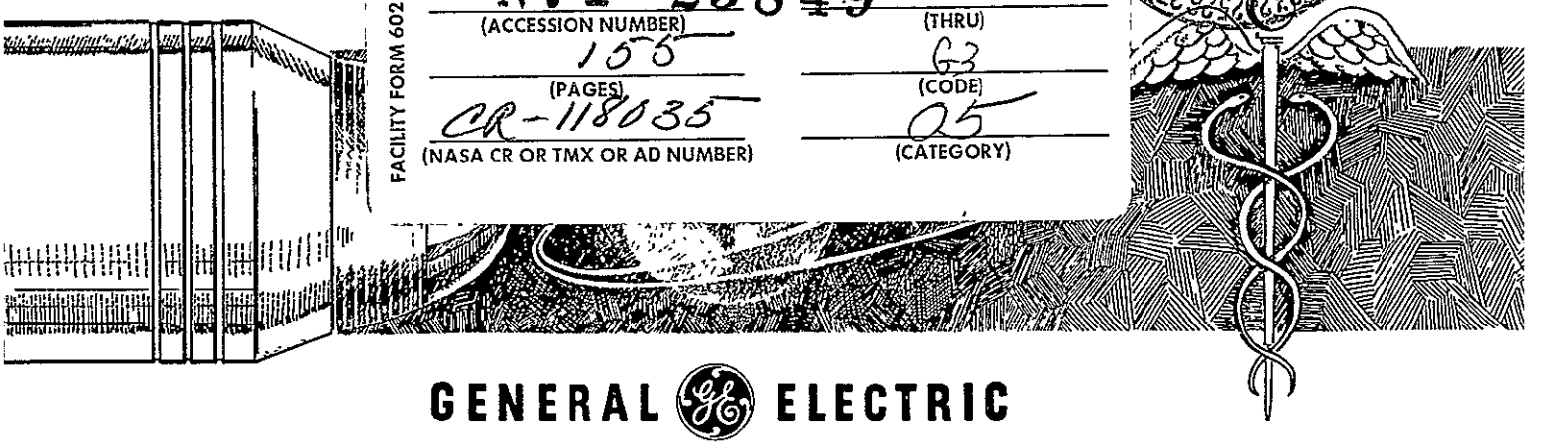
STUDY OF APPLICATIONS OF BIO-SPACE TECHNOLOGY TO PATIENT MONITORING SYSTEMS

CONTRACT NO. NASW-2073

FINAL REPORT SUPPLEMENT

17 FEBRUARY 1971



GENERAL ELECTRIC
Re-entry & Environmental Systems Division
3198 Chestnut St., Philadelphia, Pa. 19101

STUDY OF APPLICATIONS OF BIO·SPACE TECHNOLOGY TO PATIENT MONITORING SYSTEMS

CONTRACT NO. NASW-2073

FINAL REPORT SUPPLEMENT PROGRAM PLANS & BUDGETARY COST ESTIMATES

17 FEBRUARY 1971

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SECTION I

A. CONTRACT SUMMARY

I. INTRODUCTION

I A. CONTRACT SUMMARY

The Study of Applications of Bio-Space Technology to Patient Monitoring Systems was conducted for NASA by the Re-entry and Environmental Systems Division of the General Electric Company under Contract NASW-2073 during the last half of 1970. The primary program objective was to establish the potential for application of NASA developed technology to cardiovascular and pulmonary patient monitoring to achieve improved availability, reliability and utility of data for medical use. Salient activities included:

- Survey and evaluation of existing patient monitoring systems within selected medical centers
- Preparation of a preliminary system requirements specification for a cardiopulmonary patient monitoring system
- Definition and rationale for a preliminary preferred system configuration - including estimated cost and schedule for prototype development
- Identification of critical areas of patient monitory techniques requiring further research and development - including estimated cost and schedule

The groundwork for these detail tasks, including survey of medical centers, hardware vendors and medical professionals, has been documented in periodic progress reports issued 18 August 1970 and 8/9 October 1970. The second report was supplemented by a volume titled "Summary of Biosatellite Technologies", providing a comprehensive guide to potential medical applications of Bioscience/Aerospace experience, capabilities and hardware developments. A third progress report dated 8/9 December 1970 presents initial data for those tasks noted above, namely:

- The preliminary patient monitoring system specification
- The configuration trade-off study and selection of preliminary configuration with tentative implementation schedule
- The definition of 15 technical areas for further research and development with tentative milestone schedules

A Summary of the Program Effort

A detailed report of the program effort is presented in the basic volume of the final report. This Final Report Supplement delineates the Preliminary Program Plan, Management Plan, and the budgetary cost and schedule data associated with the implementation of a patient monitoring system prototype and performance of recommended R&D tasks.

SECTION I

B. RECOMMENDED PATIENT MONITORING SYSTEM DEVELOPMENT

I B. RECOMMENDED PATIENT MONITORING SYSTEM DEVELOPMENT

The Patient Monitoring System recommended as a result of this study has the following characteristics:

(1) Modular concept allowing for scheduled growth, selection of options, and improved maintainability.

(2) Four basic physiologic monitoring modules:

- I Cardiac
- II Cardiovascular
- III Pulmonary
- IV Body Chemistry

(3) Each modular configuration includes computional capability which is provided by a mini computer.

(4) Module II - Cardiovascular must interface via its local processor with a full scale computer either on site or remotely accessed; remaining modules may interface with a larger computer for achieving extended capabilities.

(5) A modular Nurses Station capable of growth by add-on; basic station handles four patients.

(6) Displays at bedside and/or nurses station include patient vital signs, ECG trace (with recording on alarm), physiologic alarm, equipment alarm, and any stored, entered or monitored data selected for display via alpha-numeric-graphic (A/N/G) CRT with keyboard.

(7) Remote monitors consisting of A/N/G CRT and keyboard.

(8) Peripheral equipment for program loading, debugging, system maintenance, etc.

Development of a prototype patient monitoring system for clinical demonstration is recommended. Preliminary work statement, schedules, potential demonstration configurations and budgetary cost estimates are delineated in Section II B.

It is recommended that the patient monitoring system concept resulting from this study, which is in the form of a preliminary system specification, be further developed through a design specification and then implemented as a prototype for clinical evaluation.

The interest expressed by the Steering Committee at the 3rd Progress Report Meeting along with subsequent evaluation by the study team indicates that either Module II (Cardiovascular) or Module III (Pulmonary) would be logical candidates for further development and clinical evaluation.

Module I, Cardiac Surveillance, was not considered by the study team on the basis of its cost and present lack of computer programs for the detection and classification of arrhythmia. This basic cardiac surveillance capability can be achieved by incorporating this in the Cardiovascular Module II. Module I was intended as an initial and basic step that a hospital could take in evolving a computerized patient monitoring capability: First by the addition of a minicomputer to interface with its existing cardiac monitoring equipment, and then expanding into the pulmonary and/or cardiovascular capabilities.

SECTION I

C. RECOMMENDED RESEARCH AND DEVELOPMENT TASKS

I C. RECOMMENDED RESEARCH AND DEVELOPMENT TASKS

Seventeen technical tasks associated with patient monitoring which may benefit from application of Bio-Space skills, approaches and developments were identified during contract performance. Several tasks, as will be shown later, have a direct relationship to achievement of an optimized patient monitoring system.

A detail description and proposed time duration for each task is given in Section II A - 5.0; Budgetary Cost Estimates are provided in Section II B - 6.0.

SECTION II

PROPOSED APPROACH

SECTION II

A. PROGRAM PLAN (PRELIMINARY)

1.0 SCOPE

1.0 SCOPE

The Program Plan delineates the major task elements, subtasks, documentation and schedule leading to implementation of a prototype Patient Monitoring System for clinical demonstration and evaluation.

Similarly, detailed descriptions and performance time sheets are provided for each of seventeen recommended R&D tasks, including two tasks added since Progress Report Number Three (Tasks 1 and 2).

This Program Plan is preliminary. Upon contractural agreement to perform one or more of the tasks delineated herein, a detailed Program Plan and associated documents, structured on the plan delineated in the following pages, will be prepared.

2.0 OBJECTIVES

2.0 OBJECTIVES

Primary objectives of the Program Plan include:

1. Describe the approach to be taken in the overall implementation of the system, and the integration of appropriate R&D tasks.

2. Identify all program tasks required to implement the specified patient monitoring system.

3. Delineate the recommended R&D tasks which will include stated objective, requirements, subtasks, and intended results.

4. Provide scheduling estimates required to support both the system implementation and performance of the tasks.

3.0 APPROACH

3.0 APPROACH

Design of PMS

The work performed on the study contract has resulted in the evolution of a conceptual design for a patient monitoring system. The concept utilizes a modular approach, and marries advanced state-of-the-art medical techniques to available low-cost, high-performance minicomputers. The result is a system which will have wide applicability to a variety of hospitals by fulfilling a multiplicity of needs with the same basic equipment.

It is recommended that the conceptual design be further developed and refined to evolve a system configuration which is oriented towards specific hardware and software. This detailed design work is further delineated by the tasks noted in the Section titled "System Implementation".

Research and Development Tasks

The research and development tasks defined herein address technologic activities in which GE-RESD has developed expertise from similar tasks encountered in Aerospace and related programs. Application of this capability to the tasks defined will provide a cost effective means of providing a coordinated resolution of those salient problems identified.

A number of the tasks directly relate to optimization of elements of the Patient Monitoring System delineated above. These items are shown in a preliminary recommended sequence in the integrated performance schedule, Section II B - 6.0. Detail work elements for each recommended R&D task are also documented in paragraph 5.0 of this section. Technical tasks teams of personnel specifically oriented towards the technology involved will be assigned to those tasks selected for further effort.

It is recommended that the integrated schedule be reviewed by appropriate medical professionals and a task priority list be established for future effort.

4.0 PATIENT MONITOR

SYSTEM IMPLEMENTATION

4.0 PATIENT MONITOR SYSTEM IMPLEMENTATION

The Preliminary Patient Monitoring System (PMS) defined in the progress reports in conceptual only. Initial steps leading to the potential implementation of PMS hardware and software must therefore include the basic design tasks noted below.

Task Descriptions

1. Review conceptual design and iterate requirements. Factor in results of consultations with the study contract advisory board, and the reactions of hospitals who would be potential users of the system. Finalize measurement parameters and modular breakdowns. Issue the preliminary system requirements specification.

2. Perform detailed trade-offs in significant areas, including computation, data transmission, display techniques, sampling rates, blood and urine analysis techniques. Select approaches for system implementation considering overall cost, efficiency, patient usage, medical acceptance.

3. Select hardware approaches and software programs and algorithms to implement the functions required. Factor in the results of current or planned R&D activities to ensure the current and future timeliness of the system, including growth potential.

4. Perform breadboard and computer simulation tests as necessary to validate the selection of hardware and software techniques. Iterate the design based on the results of these tests.

5. Generate system documentation including the final system requirements specification, equipment specifications, software specifications, interconnection diagrams, block diagrams, timing and logic diagrams where appropriate, manufacturing and test plans.

6. Generate a firm estimate of costs to build, install and test the system based on quotations from vendors and internal estimates.

7. After review and integration with the customer, including incorporation of design review changes, initiate procurement activity. This task includes order of long lead items, supplier evaluations, bidder review and purchase order release.

8. Initiate the manufacturing cycle for prototype hardware. Fabricate and assemble detail parts and subsystems.

9. Where practical, initiate the test and validation cycle in parallel with manufacturing activity. Terminate the in-house test effort upon completion of successful demonstration of the supplied hardware as a system.

10. Initiate a clinical demonstration of the PMS in the assigned medical center. The supplied system will be validated followed by integration and validation of interfaces with equipment supplied by the medical center. An on-line clinical evaluation of the PMS system will be accomplished for approximately four months.

4.1 PROPOSED SCHEDULE

A proposed schedule (elapsed time) for implementation of the prototype Patient Monitoring System is given in Figure IIA-1. The implementation of a prototype system has three phases, all dependent upon initial customer authorization to proceed and the generation of firm cost estimates (see Figure IIA-2). The first phase following initial go-ahead involves generation of firm costs for Tasks 1-6 (design, evaluation and hardware costing). The second phase is accomplishment of Tasks 1-6 including design, breadboard evaluation, documentation and generation costs for producing, testing and demonstrating a prototype Patient Monitor System. Based upon Phase I and II results, Phase III is the manufacture of the prototype system, in-house test/validation, followed by the clinical demonstration.

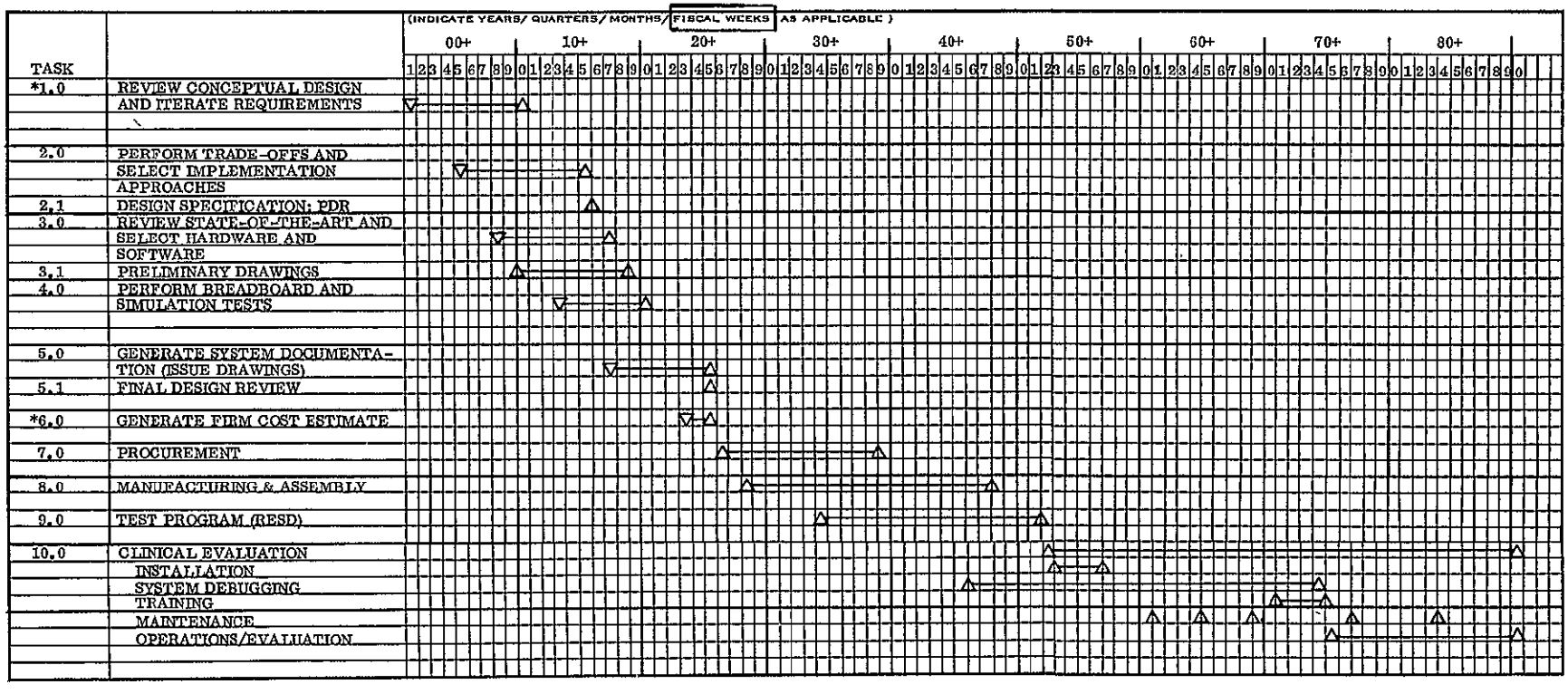


Figure IIA-1. Patient Monitoring Preliminary Design of PMS

STUDY PHASE (NASW-2073)	PMS PROTOTYPE IMPLEMENTATION			PMS SYSTEM IMPLEMENTATION
	PHASE I	PHASE II	PHASE III	
PRELIMINARY DEFINITION	PROVIDE FIRM COSTS FOR SYSTEM DESIGN AND DOCUMENTATION	ACCOMPLISH SYSTEM DESIGN AND DOCUMENTATION; PROVIDE FIRM COST FOR PROTOTYPE FABRICATION TEST AND DEMONSTRATION	ACCOMPLISH PROTOTYPE FABRICATION, IN-HOUSE TEST AND VALIDATION FOLLOWED BY FOUR MONTH CLINICAL EVALUATION	POTENTIAL EXPANSION OF PROTOTYPE SYSTEM, PRODUCTION OF ADDITIONAL SYSTEMS
		BUDGETARY ESTIMATE PROVIDED FOR PHASES I THRU III, SECTION IIB-6.0		

Figure IIA-2. PMS Implementation Phases

4.2 REQUIREMENTS

It will be necessary to determine the detail requirements of the specific application for which the system will be implemented. The assessment of the specific requirements will be coupled with the preliminary systems specification and will ultimately result in the generation of a design specification which will be the basis for design and procurement efforts.

The requirements task of Phase II will consist of the following:

1. Perform detailed systems requirements analysis of specific user's requirements which result in an applicable system requirements specification factoring in:
    a. immediate needs and specific application (CCU, ICU, O/R, etc.)
    b. growth requirements
    c. use of existing equipment/software
    d. facility requirements
    e. special design requirements (hardware and software)
    f. personnel requirements
2. Perform trade-off evaluations relative to user's specific requirements and hardware/software requirements and capabilities.
3. Generate system documentation including a system design specification.

4.3 DESIGN

Specifications

The formal source for the system engineering direction for the design effort will be the Design Specification.

Design Tasks

Systems Engineering shall maintain control of the technical integration of design efforts to assure the timely completion of design tasks and technical design compatibility. The basic tasks in the design area are as follows:

1. Perform system design
2. Design of subsystems
    - sensors
    - signal conditioning

- data processing
- display
- control
- software
- data transmission
- special support subsystems, e.g., urine collection

3. Generate subsystem and system interface specifications as required

4. Conduct preliminary and final design reviews

5. Generate drawings and procurement documentation

6. Generate a Facility Specification if required

4.4 MANUFACTURING

The manufacturing effort will consist of fabrication of the selected "make" items and subsequent assembly of the make and buy items. The major manufacturing tasks are outlined as follows:

1. Establish a Make or Buy list which will include potential vendors

2. Generate a Build Plan which encompasses both procured and make items and will include a fabrication and assembly flow chart

3. Generate the necessary material request forms (purchase orders)

4. Implement production and control plan

4.5 QUALITY ASSURANCE

Quality Assurance will be applied on a limited basis for the prototype development, and shall follow good commercial practice. Specific tasks include implementation of quality assurance provisions for:

- vendor qualification and selection
- incoming inspection of purchased material
- in-process inspection of manufactured material
- final inspection prior to shipment for clinical evaluation

4.6 INTEGRATED TEST PLAN

The Integrated Test Plan will be a composite delineation of all tests to be performed during the implementation of the prototype patient monitoring system. It will provide a systematic approach to the various levels of testing required to verify the design and fabrication/assembly of the system and subsystems. This approach is intended to provide the minimum number of tests in the most effective manner to assure validation of design integrity with respect to functional performance, safety and reliability. The plan will have a direct applicability to future developments.

This plan also required each major vendor, e.g., computer subsystem, to submit for approval a test plan for the subsystem being supplied. The Integrated Test Plan will include the following:

1. test schedules
2. test flow plans
3. development test descriptions
4. component/subsystem test descriptions
5. vendor test descriptions
6. system validation test description

4.7 OPERATIONS PLAN

The Operations Plan will contain detailed task descriptions and schedules concerning the following operational aspects:

1. installation
    - facility preparation
    - installation
    - verification
    - schedule
2. training of user personnel
    - implementation of training plan
    - schedule

3. maintenance plan

- general preventative maintenance
- malfunction maintenance and repair
- spares provisioning

5.0 R&D TASK DESCRIPTIONS

AND SCHEDULES

5.0 R&D TASK DESCRIPTIONS AND SCHEDULES

During the course of contract performance, certain areas became apparent that could be enhanced by the systematic application of scientific, engineering, and operational research and development skills.

The development of the recommendations for supplemental task effort occurred in three phases. The first phase involved the categorical listing and brief over-view of each of the Biosatellite products and technologies. Against each category was recorded a "shopping list" of possible applications of the Biosatellite products and technologies to the medical field-more specifically that of patient monitoring. In defining these potential applications, informal discussions related to several potential task categories were held with members of the advisory committee. A formal presentation and discussion of the completely developed list was then conducted at the second progress report session in Philadelphia. The next phase involved the incorporation of the advisory committee's recommendations which resulted in a modified task list. Additional refinement of the list was made by eliminating those areas which did not have unique attributes and/or were not already commercially available. For each item of the modified list, a detailed explanation was developed along with estimates of schedule requirements (elapsed time). The majority of these R&D tasks were included for review by the advisory committee in the third progress report.

After the Third Progress report was published and reviewed the third phase of development of the R&D tasks was begun. The tasks were changed as recommended by the advisory committee. Estimated schedules and costs were developed for the tasks as defined.

Seventeen areas are identified for the application of bio-science, Bio-satellite, and/or aerospace technologies to patient monitoring. These are summarized as follows:

	Biosatellite and Other Aerospace Technology	Application
5.1	Complex systems integration; detailed computer planning, programming and operations	Combined PM Systems.
5.2	Extensive systems designs, measurement requirements definition; hi reliability parts program.	Evaluation of significant parameters of existing medical equipment.
5.3	Telemetry of physiological parameters.	Patient monitoring using telemetry techniques.
5.4	Aerospace experience in computer analysis of complex waveforms.	Computer analysis techniques for ECG wave shape analysis, arrhythmia detection and classification, etc.

	Biosatellite and Other Aerospace Technology	Application
5.5	Same as 5 - Plus GMA (provisioning of Habitable Atmosphere).	Respiratory analysis that does not interfere with the patient.
5.6	Same as 9	Amplifier and signal conditioner standard requirements specification.
5.7	Same as 8 plus extensive development and test techniques.	Narrow band video systems for remote patient monitoring, consulation and diagnosis.
5.8	Aerospace experience in techniques for non-destructive testing.	Non-invasive techniques for patient monitoring.
5.9	Systems engineering. High reliability parts, parts and materials standards.	Sensor connector standardization.
5.10	Primate heparin system technology in Biosatellite, pneumatic and fluid systems.	Positive control of IV fluid dispensing.
5.11	Production of systems requirements in Biosatellite.	Sensor materials and attachment requirements study.
5.12	Systems engineering in aerospace data handling and measurement systems.	Standard measurements lists; standard derivations, terminology, etc. for patient monitoring.
5.13	Biosatellite urine-analyzer.	Evaluation and development of automated urinalysis techniques.
5.14	Phenol analysis of Biosatellite water supply.	Analysis of phenolic compounds (natural products, drugs, drug metabolites) of clinical interest.
5.15	Day/night photographic surveillance of primates.	Day/night monitoring of patients requireing real-time or near-real-time unobtrusive surveillance.
5.16	Primate feces collection and storage unit with gas management assembly.	Odor controlled waste collection system for colostomy and ileostomy patients requiring surgical appliances.
5.17	Biosatellite urine transport system.	Urine collection and measurement. (Ref. CCN to Contract AASW 2073 - Proposal F32012).

The following paragraphs explain in more detail what the recommendations involve, how they could be useful, and the schedules for their implementation. The cost estimates are included in Paragraph IIB-6.0 of this Final Report Supplement.

5.1 COMBINED PATIENT MONITORING SYSTEMS

1. Introduction

During the survey of the hospitals participating in this study, three computer program systems for handling patient monitoring applications were studied. These programs were developed under federal grants. It was found that each program system was well advanced in the specific areas for which it was designed, however the design goals were not identical. The differences were medically compatible with each other but of variant application; that is, one contained pulmonary measurements, another contained screening routines, and still another contained infusion techniques, etc. Also, the programs were written on two different types of computers, (the CDC 3200/3300 and the IBM 1800) and were written in different languages (FORTRAN and Assembly).

2. Unique Advanced Technology

A uniquely powerful patient monitoring program system could be created from these existing programs. This could be done by combining the three programs into one. The specialized, highly developed functions unique to each program would be lifted out and integrated into one overall system. System optimization would be engineered. Redundant, overlapping functions would be eliminated. Routines that perform essentially the same function would be evaluated and only the most efficient of these routines would be used. Also, routines which are of specialized use to research institutes but not of general application to clinics and hospitals would not be included. Complete documentation of the three systems would be produced plus the documentation describing the combined system.

The hospital functional areas serviced by such a combined system would include:

screening
catheterization labs
x-ray labs
operating rooms
intensive care units
cardiac care units
exercise labs
rehabilitiation facilities

The overall physiological measurement areas for monitoring would include:

cardiovascular
pulmonary
temperature
blood chemistry
urine and post operative thoracic fluid drainage
fluid infusions

The combined measured and derived parameters that could be obtained from this system might include those parameters listed in Table IIB-1. In developing such a system, a number of steps would be required beginning with an initial evaluation of the three systems. This involves:

a. Studying the current technical documentation describing the programs. (NOTE: It is understood from conversations with the hospitals using these programs that this type documentation is essentially non-existent.)

b. Studying and documenting the programs under the advice of consultants from the host hospitals. This includes gaining an understanding of and the documentation of the overall structure of the program system, the individual functions of the program, the algorithms making up the functions, the program coding in many instances, and the functional timing interfaces between the various parts of the programs.

Once this basic overall and detailed understanding had been gained and documentation of the three systems has been reviewed, the next step would entail the selection of those patient monitoring functions generally applicable to non-research hospitals and clinics. This could be done in conjunction with the host hospital's consultation with the contractor team.

After the functions had been selected that would make up the combined patient monitoring system, then the overall program design would be made. This design would integrate existing functional blocks of coding into a total program system.

Once this basic system had been assembled, integrated and coded, it would have to be debugged and checked out on a computer. Once all this work was complete the system would be clinically evaluated by a team consisting of a host hospital and the contractor.

Thus, produced at this time would be a uniquely powerful patient monitoring system that was engineered for efficiency and applicability to hospitals and clinics (not necessarily of a research orientation). This system would have been derived from the best possible combinations of functions of three thoroughly proven, eminent, and successful existing systems.

A follow-through phase, which is not part of this R&D task, would involve the conversion, checkout, system augmentation/interfacing, and operator training for a host hospital or clinic desirous of adopting this newly combined system for their use.

TABLE IIA-1. COMBINED MEASURED/DERIVED PARAMETERS (Continued)

2. PULMONARY

- respiration amplitude
- respiratory rate
- forced vital capacity
- max. expiratory flow rate
- one second expiratory volume
- maximum instantaneous respiratory pressure
- respiratory minute volume
- tidal volume
- respiratory work, inspiration
- respiratory work, expiration
- lung compliance
- oxygen uptake
- respiratory quotient
- respiratory resistance

3. TEMPERATURE

- central and extremity temperature

4. BLOOD CHEMISTRY

- arterial blood bicarbonate
- venous blood bicarbonate
- blood analysis
- blood oxygen concentration

5. URINE

- urine output volume and rate

6. OTHER

- measurement of empty blood unit
- chest drainage fluid volume and rate

TABLE IIA-1. COMBINED MEASURED/DERIVED PARAMETERS

1. CARDIO-VASCULAR

heart rate
stroke volume
cardiac output
duration of systole ejection
peripheral resistance
systolic pressure
diastolic pressure
mean venous pressure
electrocardiogram signals
vector cardiogram signals
mitral insufficiency index
appearance time
buildup time
mean circulation time
central blood volume
cardiac index
average arterial pressure
pulse deficit
premature beat rate
arterial pressure first derivative
premature ventricular contraction
arrhythmia (premature & widened beat)
left atrial pressure
densitometer calibration
superior vena cava % saturation
mid right atrium % saturation
pulmonary artery trunk % saturation
pulmonary artery wedge % saturation
radial artery % saturation

SCHEDULE PLANNING SHEET

PROGRAM NAME	
COMBINED P.M. SYSTEM	

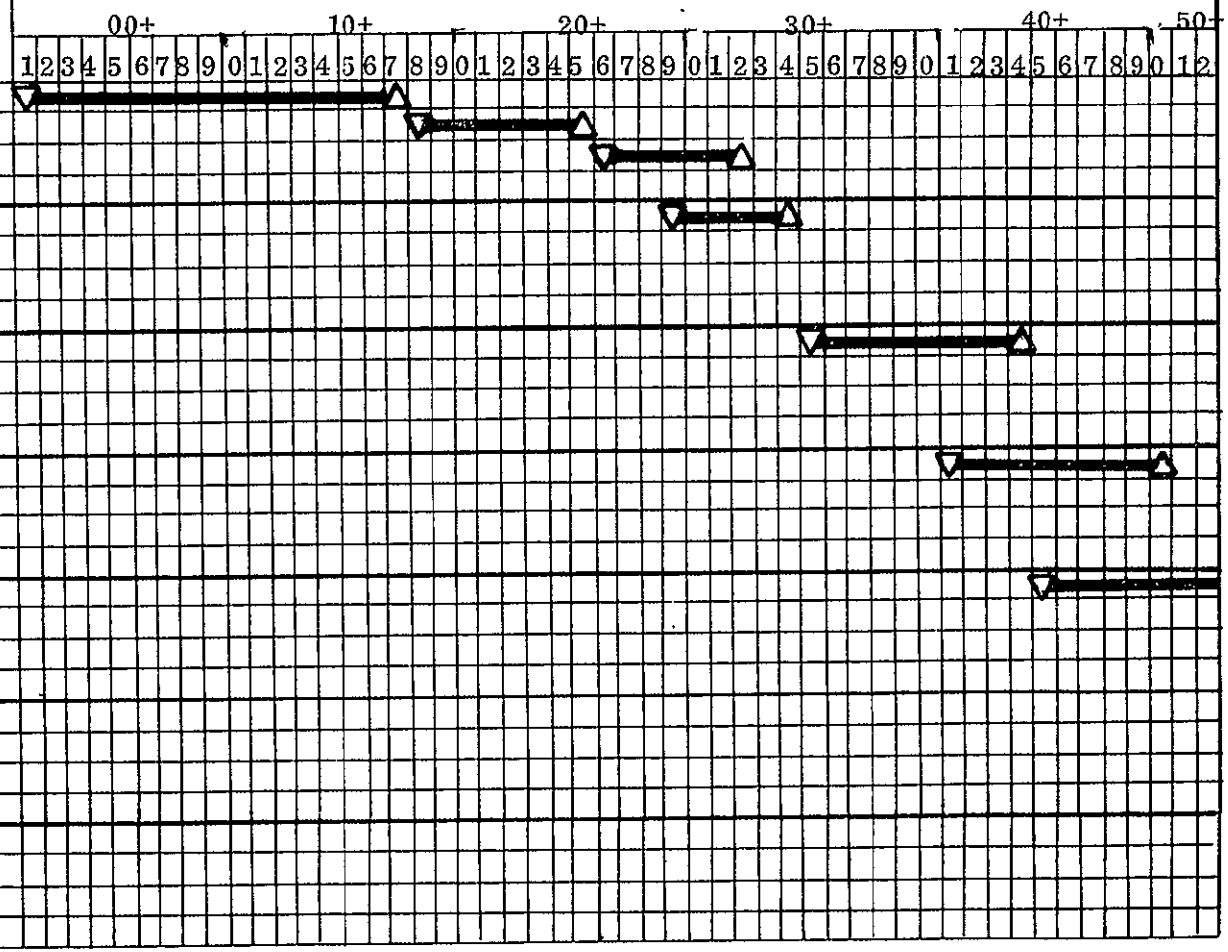
RESP. ORGAN	PROG	WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	TITLE OF SEGMENT OF WORK

PURPOSE FOR ESTIMATE	APPROVALS	REFERENCES – P.P.I.NO.	REV.	OTHER

ITEM NO.	DESCRIPTION OF WORK ITEM
1.	EVAL. & DOCUMENTATION PROGRAM #1
	#2
	#3
2.	SELECTION OF P.M. FUNCTIONS
3.	SYSTEM DESIGN
4.	CODING
5.	CHECKOUT & CLINICAL EVALUATION

ELAPSED TIME SCHEDULE

(INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL WEEKS AS APPLICABLE)



△=MILESTONES – DISCRETE, AUDITABLE EVENTS
E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲=COMPLETED MILESTONES

◇=PROJECTED MILESTONE SLIP

◆=SLIPPED MILESTONE

———=TIME PERIOD OF WORK

STATUS AS OF 2/11/71

PAGE 1 OF 2

FORM RS 1702 B REV (1-67) – SCHEDULE PLANNING SHEET

FIGURE IIA-3

SCHEDULE PLANNING SHEET

PROGRAM NAME
COMBINED P.M. SYSTEM

RESP. ORGAN	PROG WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	TITLE OF SEGMENT OF WORK

PURPOSE FOR ESTIMATE	APPROVALS	REFERENCES – P.P.I.NO.	REV.	OTHER

ITEM NO.	DESCRIPTION OF WORK ITEM	ELAPSED TIME SCHEDULE (INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL WEEKS AS APPLICABLE)
		62
5.	CHECKOUT & CLINICAL EVALUATION	

△=MILESTONES – DISCRETE, AUDITABLE EVENTS
E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲=COMPLETED MILESTONES

◇=PROJECTED MILESTONE SLIP

———=TIME PERIOD OF WORK

◆=SLIPPED MILESTONE

STATUS AS OF
2/11/71
PAGE 2 OF 2

FORM RS 1702 B REV (1–67) – SCHEDULE PLANNING SHEET

FIGURE IIA-3 (CONTINUED)

5.2 EVALUATION OF SIGNIFICANT PARAMETERS OF EXISTING MEDICAL EQUIPMENT

1. Explanation of the Technology

The evaluation of significant parameters relates to product effectiveness technology whith provides an overall measure of the degree to which a product or system achieves a specified value criterion. This technology considers not only performance, but also reliability, safety, maintainability, and availability. The application of this technology permits an objective trade-off of these parameters versus relative cost. As applied in the health care environment, this technology would permit the hospital or other health care facility to predetermine the relative merits of competing products or systems. These evaluations then form the basis for health care management decisions relative to product and/or system procurement.

2. Uniqueness of the Technology

Many management techniques exist which provide a basis for cost trade-off against single value criterion elements. Thus, evaluations of performance versus cost, reliability versus cost, safety versus cost, etc. are relatively common. The effectiveness technology was developed in the aerospace industry to combine the various value criteria elements into a single index for systems-efforts. At GE-RESD the effectiveness technology development has recognized that the value criterion can be partitioned into elements other than or in addition to the more conventional elements. Hence, the technology as applied possesses a high degree of flexibility to enable adaptation to virtually any situation.

3. End Products

There will be two end products resultant from the research and development task described herein. The first end product will be a technology utilization manual which will enable health care system management to apply to effectiveness technology as a tool for making management decisions for the acquisition of products and/or systems. The second end product will be a separate appendix to the technology utilization manual which will compare the specific products and systems selected for the technology demonstration in the study. The latter manual can serve as an immediate guide to hospital management in the selection of currently available products and systems.

4. Recommended Program

The recommended program would be accomplished in six interrelated steps:

a. Select at least three products (for example arrhythmia detector, electric bed and X-ray) and one system (for example, a typical four or eight patient monitoring system); and develop the specific value criteria elements.

b. Develop the effectiveness models for the products and system(s) selected.

c. Develop data sources to be utilized in exercising the models.

d. Exercise the effectiveness models and develop the figures of merit.

e. Prepare the technology utilization manual appendix which compares specific products and systems.

f. Prepare the technology utilization manual which will permit the application of the effectiveness technology by health care systems management.

SCHEDULE PLANNING SHEET

RESP. ORGAN	PROG WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	PROGRAM NAME: EVALUATION OF SIGNIFICANT PARAMETERS
							TITLE OF SEGMENT OF WORK: OF EXISTING MEDICAL EQUIPMENT
PURPOSE FOR ESTIMATE			APPROVALS	REFERENCES – P.P.I. NO.		REV.	OTHER

ITEM NO.	DESCRIPTION OF WORK ITEM	ELAPSED TIME SCHEDULE (INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL WEEKS AS APPLICABLE)
		0 00+ 10+ 20+ 30+ 4-+ 50+
a.	PRODUCT IDENTIFICATION FOR EVALUATION; DEFINITION OF EVALUATION CRITERIA	
b.	DEVELOP EFFECTIVENESS MODELS	
c.	DEVELOP DATA SOURCES	
d.	DEVELOP RELATIVE FIGURES OF MERIT	
e.	PREPARE MANUAL APPENDIX	
f.	PREPARE BASIC MANUAL	

△ = MILESTONES – DISCRETE, AUDITABLE EVENTS
E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲ = COMPLETED MILESTONES

◇ = PROJECTED MILESTONE SLIP

——— = TIME PERIOD OF WORK

◆ = SLIPPED MILESTONE

STATUS AS OF

PAGE OF

FORM RS 1702 B REV (1–67) – SCHEDULE PLANNING SHEET

FIGURE IIA-.4

5.3 PATIENT MONITORING USING TELEMETRY TECHNIQUES

1. Explanation of the Technology

Small, light transducer-transmitter units are needed to monitor physiological parameters during unrestricted normal activity or during rehabilitating exercise. They free the patient from lead connections, ensure safety from dangerous electrical currents and enhance comfort for the ambulatory patient. The use of telemetry in monitoring physiological data has widespread application and opens up new and lifesaving possibilities in modern health and emergency services. Some of the applications are:

A. In Hospitals

1. For ambulatory patients
2. In surgery (NASA SP-5023, p. 11)
3. In intensive care units (NASA SP-5023, p. 5)
4. In the rehabilitation unit

B. For Out Patients

1. For patients during recovery from disease
2. For patients having diseases in a dormant state, but who need advanced warning of acute attacks (cardiac problems, epilepsy, diabetes)
3. For patients under diagnostic observation

C. Emergency Cases

1. At the place of the event
2. During transit in the ambulance

Small, light transducers and transmitters are desirable. These items would measure physiological parameters, transmitting the data to data receivers, processors and/or display units which may be located at distances ranging from a few feet to a few miles from the patient. The transmission mode would not involve physical linkage between the patient and the data center.

A microminiature transmitter-temperature sensor unit was developed during the biosatellite program. The temperature sensor and transmitter unit is .6 inches in diameter, .2 inches thick and weighs 4 g. It is powered by a mercury cell. NASA personnel (AMES Research Center) have carried this development further by microminiaturizing signal conditioning and processing circuitry.

These devices provide a basis for the development of similar devices which will measure other parameters. Some important parameters for observation and transmission listed below:

1. Temperature

2. Blood Pressure

3. EEG

4. Diabetic Shock Monitoring

5. Arrhythmia Detector Based on EKG

6. Others - See R. S. Mackay, Bio-Medical Telemetry, for an exhaustive list of uses for transducer-telemetry systems.

Besides the selection design, and microminiaturization of the appropriate circuitry compatible with selected transducers such problems as artifacts through patient mobility, uniform radiation coupling to local receiver, elimination of RF interference, etc. must be overcome.

2. Uniqueness of the Technology

Virtually all of the parameters mentioned above are routinely monitored for hospital patients having severe problems. Relatively small transmitter units for physiological telemetry are commercially available, for some applications. The uniqueness of the suggested technology is the proposed development of an assembly of transducers, transmitters and some degree of signal conditioning and preprocessing into a microminiature device which can be attached to the patient with the least amount of discomfort. In addition, the monitoring and/or recording period may be controlled by an event sensor, which if so desired, can act as an information valve limiting the information flow to periods selected by events of predetermined interest. Thus, monitoring may be extended to ambulatory patients, both in and out of hospitals. However, certain of these technological advances, largely developed on NASA programs have been employed on a limited basis by numbers of medical investigators who have assimilated these techniques into their own areas for the past several years. Implementation for the purposes mentioned below appears relatively straightforward.

3. End Products

The end products involve two separate aspects leading to broad application in patient monitoring:

1. Microminiature sensor-transmitter signal conditioning packages which can be implanted or strapped to patients. Here, the blood pressure sensor and improved EKG sensor are problably most important from the monitoring point of view.

2. The design of automated data handling techniques which will sift the data gathered for important signs (abnormalities) and then send warnings, etc. This insures that the data center is not bogged down in gathering, storing and displaying masses of essentially ordinary data. Most physiological parameters are not significant unless they exceed certain bounds.

4. Recommended Program

An initial program is recommended to define candidate systems which are to be developed for the monitoring of physiological parameters within and outside of the hospital environment by telemetry techniques.

Following an extensive requirements and applications survey, candidate systems for monitoring individual or a multiplicity of physiological parameters, will be breadboarded and evaluated with animals as a separate task. Ultimate selection of systems for prototype development and human trials will be based upon this study.

SCHEDULE PLANNING SHEET

PROGRAM NAME: PATIENT MONITORING USING TELEMETRY TECHNIQUES

RESP. ORGAN	PROG WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	TITLE OF SEGMENT OF WORK

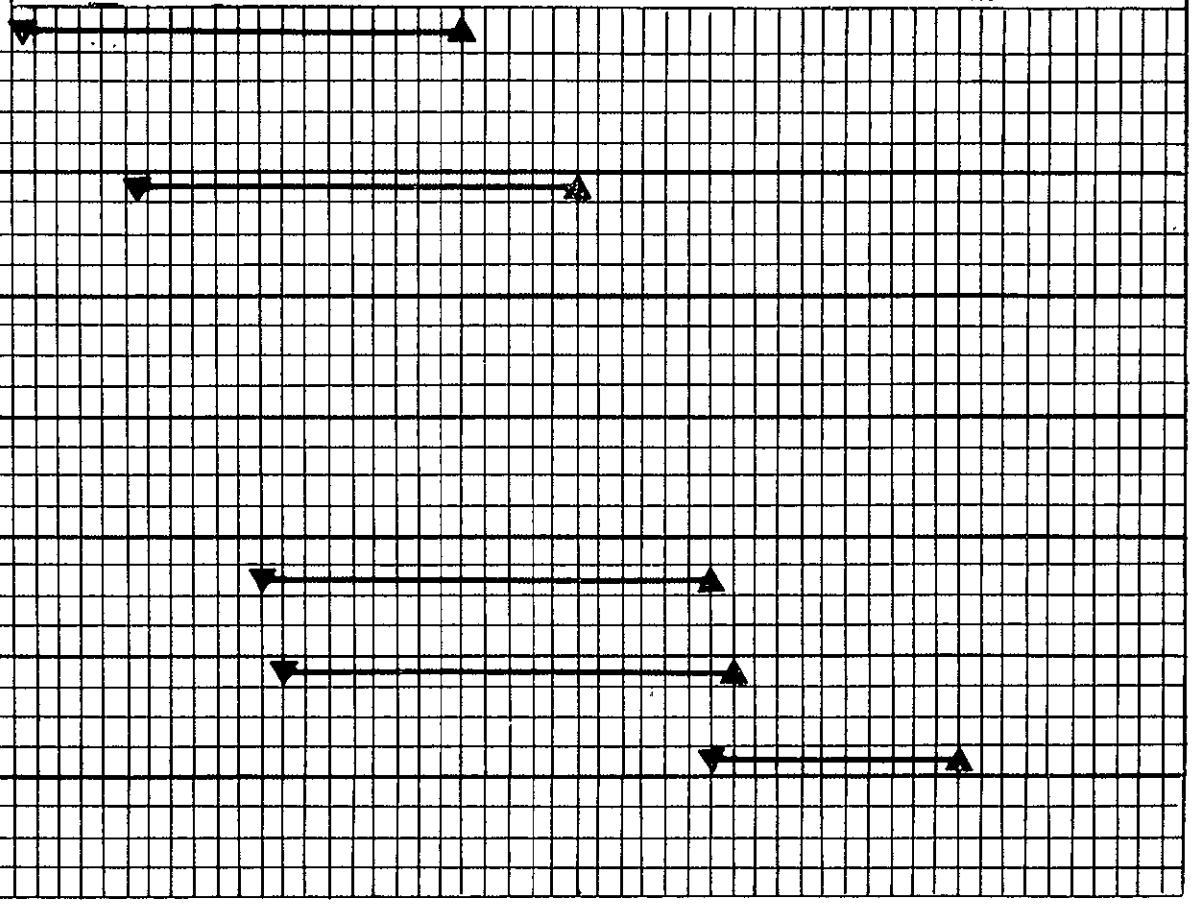
PURPOSE FOR ESTIMATE	APPROVALS	REFERENCES – P.P.I.NO.	REV.	OTHER

ITEM NO.	DESCRIPTION OF WORK ITEM
1.0	Establish Criteria
	1.0 Applications
	2.0 Patient/Physician Acceptance
	3.0 Circuit Design Requirements
2.0	Existing Product Survey
	2.1 Specifications/Design
	2.2 Physician Acceptance
	2.3 Patient Acceptance
	2.4 Data Acquisition and Processing
	2.5 Range
	2.6 Patient Signatures
	2.7 Rapid Identification Patient Location
	2.8 Monitoring Eqpt. Available
	2.8.1 USA
	2.8.2 Europe
	2.8.3 Japan
3.0	Physician Surveys
	3.1 Mail
	3.2 Personal
4.0	Hospital Surveys
	4.1 Mail
	4.2 Personal
5.0	Final Report – Recommendations for Systems to be Breadboarded and Evaluated

ELAPSED TIME SCHEDULE

(INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL WEEKS AS APPLICABLE)

MONTH



△ = MILESTONES – DISCRETE, AUDITABLE EVENTS
E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲ = COMPLETED MILESTONES

◇ = PROJECTED MILESTONE SLIP

——— = TIME PERIOD OF WORK

◆ = SLIPPED MILESTONE

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FIGURE IIA-5

5.4 ANALYSIS TECHNIQUES FOR ECG, ARRHYTHMIA DETECTION AND CLASSIFICATION

EXPLANATION OF THE TECHNOLOGY

Several computer codes are available which permit, to some degree, automated analysis of ECG and the detection and classification of arrhythmia. However, the various signal leads show considerable variation between different patients which makes the application of automatic methods extremely difficult. Variations in lead configuration, analytical programs and monitor hardware exist. To make automated computer analysis of cardiac patients extensively available and similar (if not identical), combinations of program functions and techniques, VCG processing and other physical phenomena should be explored. An optimized program, incorporating techniques of the various ECG programs may be developed, in parallel with development of other technique. Optical data analysis may prove to be advantageously employed for the characterization of the ECG/VCG complexes of interest. For example optical Fourier Analysis can be carried out in nearly real time without the use of an expensive large scale computer.

UNIQUENESS OF THE TECHNOLOGY

The suggested technology is unique in that it involves the combined use of ECG signals and other physical measurements such as the reflection or absorption of pulsed electromagnetic energy which may depend on the polarization or depolarization process of the heart muscle. In addition optical methods for data processing are relatively new and so far, to the knowledge of the author, have not been explored for their potential use in ECG evaluation or arrhythmia detection or classification. Additionally, a systematic approach to analysis and integration of the many independantly developed, not fully disseminated programs will assist in channelling activities in a common direction.

END PRODUCT

The end product will be a universally applicable ECG monitor and analysis program, definition of recommendations for an improved method to detect the depolarization and polarization phenomena throughout the heart wall, and analysis of optical analyzer to characterize the polarization and depolarization signals through their Fourier spectrum.

RECOMMENDED PROGRAM

It is recommended that a survey and analysis be carried out of all existing schemes which are presently being used to analyze ECG/VCG or to detect and classify arrhythmias. Requirements will be defined from the analysis of information obtained from selected medical centers and institutes and from analysis of existing software techniques. Recommendations for meeting these requirements will be made by outlining one or several approaches using advanced technology. Subsequent activity will include development of an integrated software program and application of new hardware techniques.

SCHEDULE PLANNING SHEET

RESP. ORGAN	PROG WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	PROGRAM NAME / TITLE OF SEGMENT OF WORK
							PMS STUDY FOLLOW-ON / PMS APPLICATION OF VCG/ECG

PURPOSE FOR ESTIMATE	APPROVALS	REFERENCES – P.P.I.NO.	REV.	OTHER

ITEM NO.	DESCRIPTION OF WORK ITEM
1	Equipment Surveys
2	Center/Institute Surveys
3	Requirements/Analysis & Definition
4	(Sample data Collection and Correlation) Analysis of Existing Methodology)
5	Program Matrices & Flow Diagrams for PMS Application
6	Program Devel. & Debug
7	Program Validation
8	PM Handbook, VCG/ECG
9	VCG Additions to PMS Spec.
10	Task Review & Discussion
11	Periodic Reports (Letters)
12	Final Report

ELAPSED TIME SCHEDULE

(INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL WEEKS AS APPLICABLE)

WEEKS FROM INITIATION

00+ 10+ 20+ 30+ 40+ 50+

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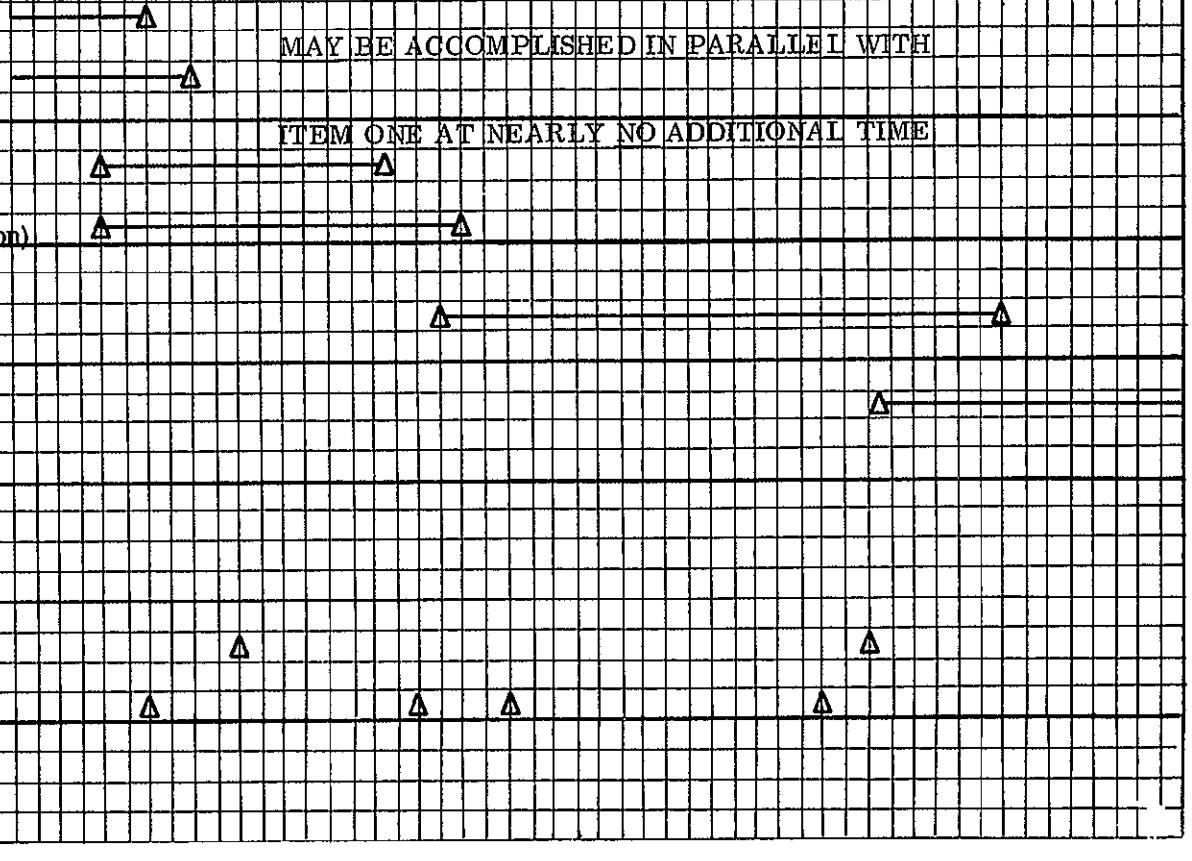

△=MILESTONES – DISCRETE, AUDITABLE EVENTS
E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲=COMPLETED MILESTONES

◇=PROJECTED MILESTONE SLIP

———=TIME PERIOD OF WORK

◆=SLIPPED MILESTONE

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FIGURE IIA-6

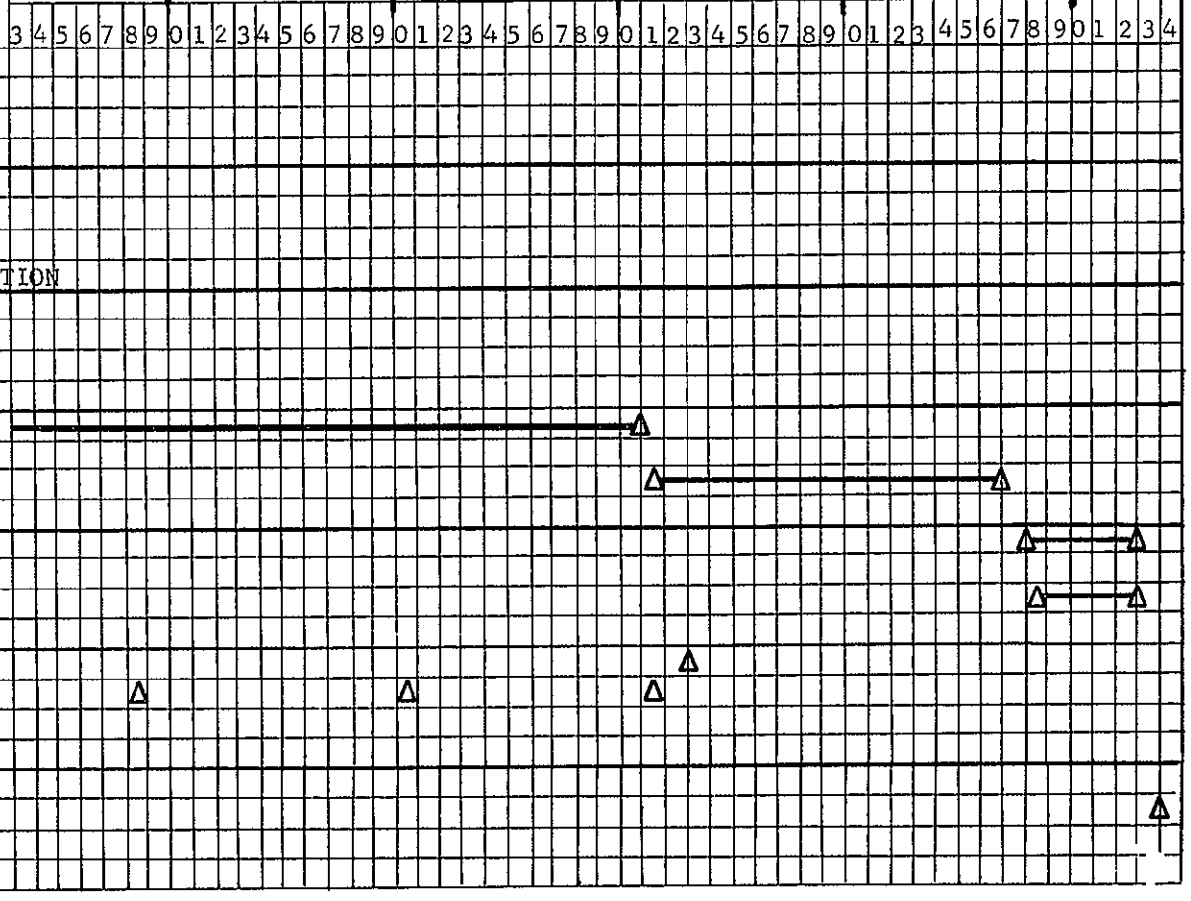
SCHEDULE PLANNING SHEET

PROGRAM NAME	
PMS STUDY FOLLOW-ON	

RESP. ORGAN	PROG WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	TITLE OF SEGMENT OF WORK
							PMS APPLICATION OF VCG/ECG

PURPOSE FOR ESTIMATE	APPROVALS	REFERENCES – P.P.I.NO.	REV.	OTHER

ITEM NO.	DESCRIPTION OF WORK ITEM	ELAPSED TIME SCHEDULE (INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL WEEKS AS APPLICABLE)
(1)	EQUIPMENT SURVEYS	
(2)	CENTER/INSTITUTE SURVEYS	
(3)	REQUIREMENTS/ANALYSIS & DEFINITION	
(4)	SAMPLE DATA COLLECTION AND CORRELATION ANALYSIS OF EXISTING METHODOLOGY	
(5)	PROGRAM MATRICES & FLOW DIAGRAMS FOR PMS APPLICATION	
(6)	PROGRAM DEVEL. & DEBUG	
(7)	PROGRAM VALIDATION	
(8)	PM HANDBOOK, VCG/ECG	
(9)	VCG ADDITIONS TO PMS SPEC.	
(10)	TASK REVIEW & DISCUSSION	
(11)	PERIODIC REPORTS (LETTERS)	
(12)	FINAL REPORT	



△=MILESTONES – DISCRETE, AUDITABLE EVENTS
E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲=COMPLETED MILESTONES

◇=PROJECTED MILESTONE SLIP

———=TIME PERIOD OF WORK

◆=SLIPPED MILESTONE

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FIGURE IIA-6 (CONTINUED)

5.5 RESPIRATORY ANALYSIS

EXPLANATION OF TECHNOLOGY

The pulmonary system is presently the subject of intense interest. Among the reasons for this are:

A. The expoloration of hostile environments such as the oceans and space, in which artificial atmospheres having abnormal gas composition and pressures are utilized;

B. The increasing incidence of primary pulmonary diseases such as emphysema, asthma, cystic fibrosis, and lung cancer, as well as pulmonary complications due to cardiovascular diseases.

New approaches are needed for the rapid screening of the population for evidence of pulmonary disease, the diagnosis of specific diseases, and the monitoring of pulmonary patients.

The pulmonary system is concerned with the transfer of certain gases between the external atmosphere and the blood. As such, pulmonary abnormalities may involve:

A. Inadequate movement of air into the lungs (i.e., abnormal ventilation, due to changes in the mechanical properties of the lung or its supporting muscles.

B. Destructive changes in the membrane which separates the air and blood sides of the lung and thus decreases gas diffusion.

C. Inadequate flow of blood through the lungs (i.e., abnormal perfusion).

The assessment of these three types of abnormalities involves different types of measurements. Tests of ventilatory function generally involve measurements of mechanical factors such as total volumes of gas breathed per breath or per unit time; pressure-volume flow rate - time correlations; and velocity-time correlations. In such measurements, the patient breathes in a specified manner and the data is recorded either in the vicinity of the nose or mouth, or from each lung separately (bronchospirometry).

The functioning of the membrane and pulmonary circulation generally measured by chemical analysis of the gas breathed, or by chemical analysis of the blood. That is, compositions of gas inhaled and exhaled, and O_2 and CO_2 saturations and pH in the blood are needed.

UNIQUE TECHNOLOGY

Recent technology makes possible the advancement of present pulmonary measurement techniques. Examples of possible improvements are:

A. Improved data analysis of present instruments such as the spirometer.

B. New instruments which, for example, "drive" the lungs with forced breathing at various frequencies, thus enabling information regarding the location of abnormalities to be gathered. The frequency response of the lungs is markedly effected by the physical state of the lung tissues, thus enabling various diseased conditions to be uncovered and diagnosed. Furthermore, the reflection of pulses sent into the lungs gives clues as to the location and extent of ventilatory abnormalities.

C. Improvements in gas analysis which will allow more accurate and rapid measurements to be taken. Particularly important is a unit which is small enough to become part of a body transducer system.

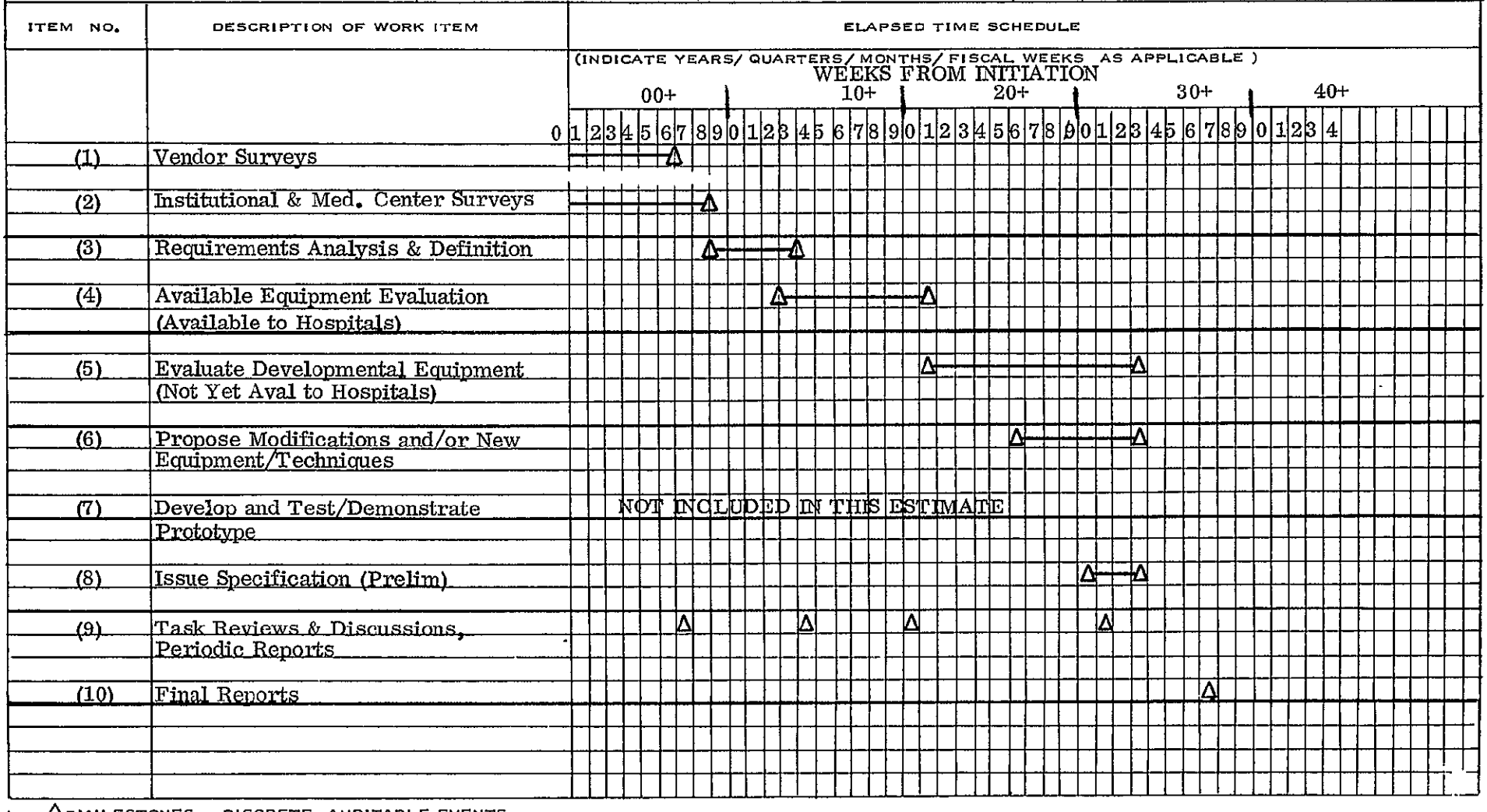
NASA has developed a small mass spectrometer for the dynamic analysis of alveolar samples. Mass spectrometers using radio-frequency quadrupole fields can be miniaturized so that they become suitable for continuous patient monitoring. An R and D program is required to meet clinical requirements and safety standards. GE's R and D center has developed a three-dimensional quadrupole mass spectrometer of unusual simplicity which could be used as a point of departure.

END PRODUCT

A report of the state-of-the-art of respiratory monitor equipment and techniques including evaluation of existing (in-use or developmental) approaches and recommendation for design and/or modification of an optimized system resulting from requirements defined during this effort.

SCHEDULE PLANNING SHEET

RESP. ORGAN	PROG WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	PROGRAM NAME
							TITLE OF SEGMENT OF WORK: ACCURATE RESPIRATORY MEAS.
PURPOSE FOR ESTIMATE: ROM		APPROVALS	REFERENCES — P.P.I.NO.		REV.	OTHER: TECHNIQUES	



△ = MILESTONES — DISCRETE, AUDITABLE EVENTS
E.G. — REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲ = COMPLETED MILESTONES

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FIGURE IIA-7

5.6 AMPLIFIER AND SIGNAL CONDITIONER STANDARD REQUIREMENTS SPECIFICATION

Investigate availability and capabilities of standard amplifiers - signal conditioners, i.e., modules with selectable input/output impedance, gain change, etc., such that they are adaptable and interchangeable as well as cost effective. Generate requirements for desirable units.

The work tasks for completing this project involves the surveying of equipment in use as well as evaluating that equipment. The manufacturers of the equipment must be contacted and determine the equipment that is either in design or is already available. A preliminary specification will have to be generated to define the requirements. All this effort should then be reviewed and discussed at this point. The results from this review will be used to update the specification and would then be issued to industry for comment. Applicable comments from industry would then be screened and used to update the specification. An equipment listing and a vendor listing would be then generated. Periodic and a final report should also be issued.

The following Schedule Planning Sheet outlines the estimated schedule.

SCHEDULE PLANNING SHEET

RESP. ORGAN	PROG WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED

PROGRAM NAME: STANDARD AMPLIFIERS AND SIGNAL CONDITIONERS REQUIREMENTS SPECIFICATION

PURPOSE FOR ESTIMATE	APPROVALS	REFERENCES – P.P.I.NO.	REV.

ITEM NO.	DESCRIPTION OF WORK ITEM	ELAPSED TIME SCHEDULE (INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL WEEKS AS APPLICABLE)
		WEEKS: 00+ 10+ 20+ 30+ — 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0
(1)	Survey Equipment in Use	
(2)	Evaluate Equip. In Use	
(3)	Con tact Manufacturers Determine Equipment Designed and/or available	
(4)	Define Requirements (Preliminary Specifications)	
(5)	Review and Discussion	
(6)	Update and Issue to Industry	
(7)	Review and/or Incorporate Applicable Comment from Industry	
(8)	Provide Equipment/Vendor Listing	
(9)	Periodic Reports	
(10)	Final Report	

△ = MILESTONES – DISCRETE, AUDITABLE EVENTS
E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲ = COMPLETED MILESTONES

◇ = PROJECTED MILESTONE SLIP

——— = TIME PERIOD OF WORK

◆ = SLIPPED MILESTONE

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FIGURE IIA-8

5.7 NARROW BAND VIDEO SYSTEMS FOR REMOTE PATIENT MONITORING, CONSULTATION, AND DIAGNOSIS

1. INTRODUCTION

It has been generally accepted that video systems can play a basic part in the health field for both remote observation of patients and for access to diagnostic measurements, tables and files of symptomology when consultation and personal presence is not available. Examples of such instances include remote clinic operations in rural and ghetto areas, disaster area and shipboard emergencies, first aid, and anywhere where medical assistance is limited.

The systems should be adaptable so that consultants in one field can consult with specialists in allied fields, or in the same field to give support to their diagnoses.

With the widespread use of such video systems in conjunction with physiological data systems, it can be foreseen that not only will the physicians and patients benefit, but monitoring physicians can continue their association and education with their procedures transmitted and discussed. Recordings of the transmissions including both video and related data will form a bank of medical information for future review by students and practitioners. The technique may be used in some cases to accelerate the student's exposure to a large cross section of cases, and thus to broaden his education.

However, normal video signals require a wideband transmission media of the order of 4-8 MHz bandwidth, such as a coaxial cable or microwave circuit. These media are costly, and require special semi-permanent installation. It should therefore be a design objective that the video be transmitted over inexpensive telephone circuits and provide a close man-machine relationship between patients, paramedics, physicians and consultants; this objective, moreover, must be realized taking into account the requirements of resolution, must be realized taking into account the requirements of resolution, grey scale or color quality, and commercial error rates, over all available communications media including cable, microwave and satellite.

2. RECOMMENDED DESIGN STUDY APPROACH

For the purpose of explanation, bandwidth can be expressed by the relation:

$$\text{Bandwidth} \propto \left(\begin{matrix}\text{No. of picture} \\ \text{elements}\end{matrix}\right) \times \left(\begin{matrix}\text{No. of grey or} \\ \text{color levels}\end{matrix}\right) \times \left(\begin{matrix}\text{Frame} \\ \text{Rate}\end{matrix}\right)$$

The number of picture elements and the number of grey or color levels required for medical purposes shall be a subset of this study; however, it may be assumed that the minimum requirements are comparable with commercial television standards. Accordingly, for bandwidth reduction it is considered that the frame rate is the prime candidate for achieving the design goals.

Techniques are available for implementing reduced frame rate video including:

a. At the transmitting end: -

Slowspeed scan cameras
Storage tube converters with standard cameras
Sampling scan converters with standard cameras

b. At the receiving end: -

Storage monitor CRT's each with one standard monitor.
Storage tube scan converters with standard monitors.
Magnetic disc scan converters with standard monitors.

According to available information, "snap-shot" representation with a new frame displayed instantaneously on the order of once every 10 seconds may be an acceptable design approach for medical video systems.

3. RECOMMENDED TASK

It is recommended that a technical and clinical evaluation be held to identify a practical cost-effective, narrow band video system for the health field within the current state-of-the-art, and to establish subjective signal-to-noise and resolution standards for such a system.

Selected equipment will enable a comparison to be made between the performance of:

1. Slow scan camera versus storage tube transmission, and
2. Storage tube versus magnetic disc scan conversion.

The evaluation should not however by limited to the compatability above described; any other equipment identified as being applicable would be evaluated by mutual agreement.

An Implementation Plan for the proposed evaluation is shown in the attached schedule planning sheet.

TABLE IIA-2

TYPICAL TRANSMISSION & RECEPTION EQUIPMENT

(A) Transmission Equipment

Based upon a 1 in 10 frame rate, the following transmission equipment is available for use, either in development or production state:

1. Slow Scan TV Cameras

Most vidicon cameras can be used for slow scan transmission, however with modifications to the deflection system.

For special high resolution the General Electric 1" (Z7872, Z7873 and Z7894) and 1 1/2" (Z7921 and Z7940) FPS Vidicons are available with magnetic, electrostatic or hybrid deflection and focusing designed for military and space cameras. These tubes have been used for up to 1600 lines resolution in the focus projection and scanning mode.

The RCA 1" (RCA-7735) Vidicons are specified for resolutions up to 900 lines.

A review will be made to determine applicability of these tubes with the necessary modifications for their use in commercial cameras.

2. Storage Tube Converters

(a) Marconi 3V21 camera capable of 800 lines resolution at the center and 650 lines at the corners of the picture, and standard sweeps of 525 and 800 lines, modified with a Westinghouse Permachron Tube WX-5123

(b) Standard Vidicon camera GE-TE33; and Princeton Electronic Products PEP400 storage terminal using a Lithicon storage tube. The tube has a resolution of 800 or 1200 lines.

3. Magnetic Disc Converters

Standard Vidicon Camera GE-TE33; and
Colorado Video Magnetic Disc 220B to convert 525 line video to slow scan video with selectable bandwidth of 8, 4, 2, 1 or 0.5 KHz

4. Sampling Scan Converters

Standard Vidicon Camera GE-TE33; and
Colorado Video Converter/transmitter VC201B which compresses the video bandwidth to the audio range of 8, 4, 2, 1 or 0.5 KHz as desired. Time taken to reproduce a single frame will vary from 7 seconds to 2 minutes according to the bandwidth selected.

(B) Reception Equipment

Video processing equipment to receive the slow scan video and convert it to 30 frames/sec. 525 line or 800 line video for display on standard video monitors.

1. Princeton Electronics Storage Tube Scan Converter PEP 400, using a Lithicon storage tube (See 3.2 above) for storage of the incoming video at slow rate and simultaneous playback at conventional rates. A separate converter is required for each video channel.

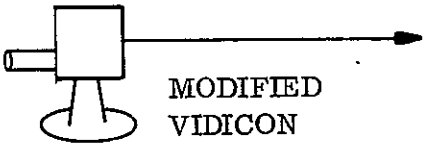
2. Colorado Video Magnetic Disc Scan Converter 220B, using a rotating video memory disc to store the sampled picture with a frame rate of between 4 seconds and 2 minutes. The converter is available in one, two, three and four channel versions.

3. Data Disc Video Disc Files capable of storing up to 600 images from the disc's 600 separate tracks. Is designed specifically for pulsed and time-lapsed fluoroscopy including instant history, image subtraction and animation.

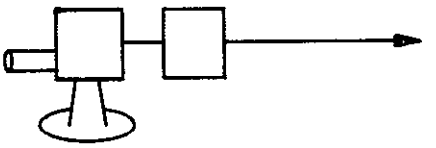
TRANSMITTING END:

RECEIVING END:

1. SLOW SCAN



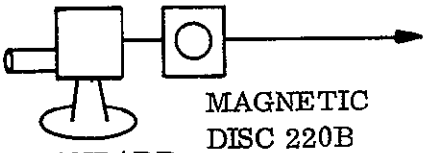
2. STORAGE TUBE CONVEPTERS



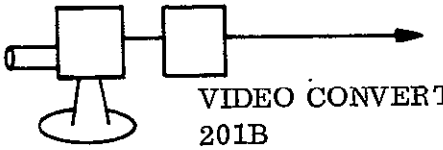
A. STANDARD VIDICON WITH LITHOCON STORAGE TUBE OR

B. MODIFIED CAMERA WITH PERMACHRON STORAGE TUBE

3. MAGNETIC DISC CONVERTERS



4. SAMPLE SCAN CONVERTERS



1. STORAGE TUBE SCAN CONVERTERS

2. STORAGE DISC SCAN CONVERTERS

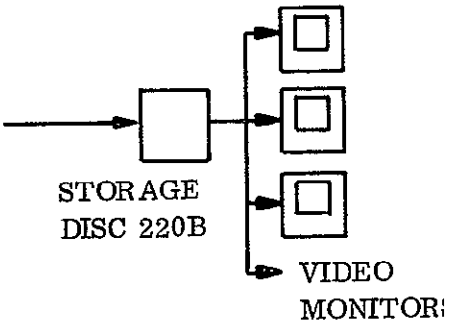


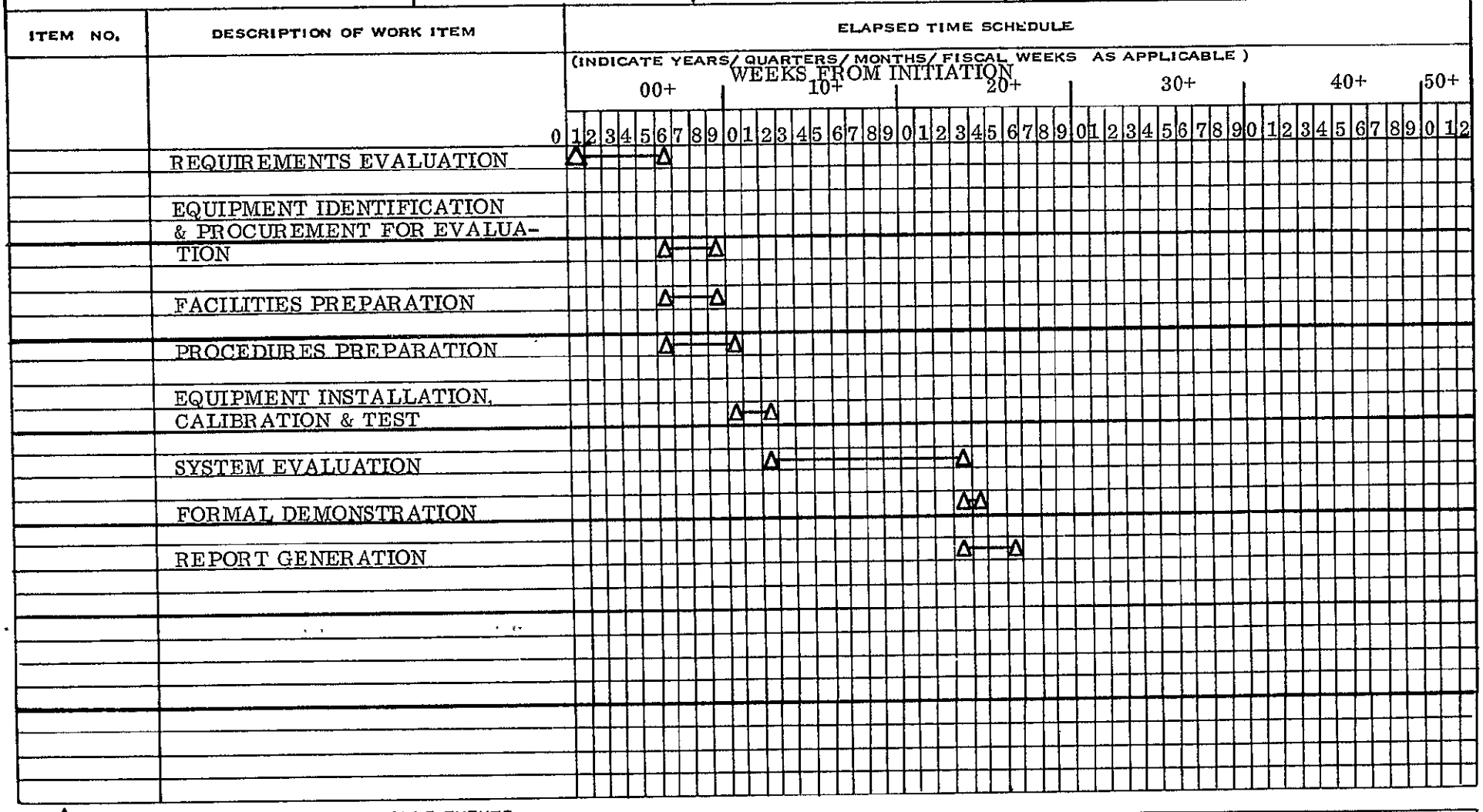
Figure IIA-9. Transmitting and Receiving Equipment

SCHEDULE PLANNING SHEET

PROGRAM NAME: NARROW BAND VIDEO EVALUATION

RESP. ORGAN	PROG WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	TITLE OF SEGMENT OF WORK

PURPOSE FOR ESTIMATE	APPROVALS	REFERENCES – P.P.I.NO.	REV.	OTHER



△=MILESTONES – DISCRETE, AUDITABLE EVENTS
E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲=COMPLETED MILESTONES

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———=TIME PERIOD OF WORK

◆=SLIPPED MILESTONE

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FIGURE IIA-10

5.8 NON-INVASIVE TECHNIQUES FOR PATIENT MONITORING

EXPLANATION OF THE TECHNOLOGY

There is a great need for non-invasive techniques to measure such physiological parameters as central and peripheral blood flow velocity, volume rate, stroke volume, ventricular chamber volume, blood distribution, ventricular, arterial and venous pressure, arterial and ventricular compliance, myocardial contractility and so forth. Present techniques to obtain a direct measurement or indirect physiological parameters from which the parameter of interest can be derived frequently require catherization, arterial cut down and other invasive procedures. These measurements, therefore, require high skills and produce discomfort to the patient who frequently must be immobilized. Additionally, problems of blood clotting, interface leakages and infection are encountered.

There are a number of physical methods which are basically non-invasive and do not require catherization or the injection of contrast materials, such methods are

1. Ultrasonic measurements
2. Recording of passive sounds and vibrations
3. Measurements of thermal gradients
4. Impedance measurements
5. Plethysmographic methods
6. Colorimetric measurements and so forth.

The use of these methods to measure some of the mentioned physiological parameters is complicated by the difficulty of controlling artifacts which are introduced by the remoteness of the measurement and the external environment. In addition, remoteness permits physiological noise to be collected which must be dealt with so that the wanted signal can be interpreted.

UNIQUENESS OF THE TECHNOLOGY

NASA developments contributed heavily to the advancement of non-invasive techniques (for example, NASA SP-5041, NASA SP-5054, NASA SP-5023). Presently many bio-engineering organizations are engaged in just such programs. The need for stepping back and looking at the basic ommon problems which are associated with all these techniques is now in order. From such an evaluation reflected against our present technological background, one may expect the definition of the major problems and recommendation for their solutions.

END PRODUCT

The product of this program will be an exhaustive discussion of non-invasive techniques presently under consideration or in use in hospitals or medical centers, with recommendation and suggestions or how to solve some of the inherent difficulties associated with these methods. Follow-on activity would include design, breadboard and test of candidate systems leading to demonstration prototypes for clinical evaluation.

RECOMMENDED PROGRAM

Institute medical center contact and survey. Establish requirements and determine the efficacy and problems associated with equipment in use.

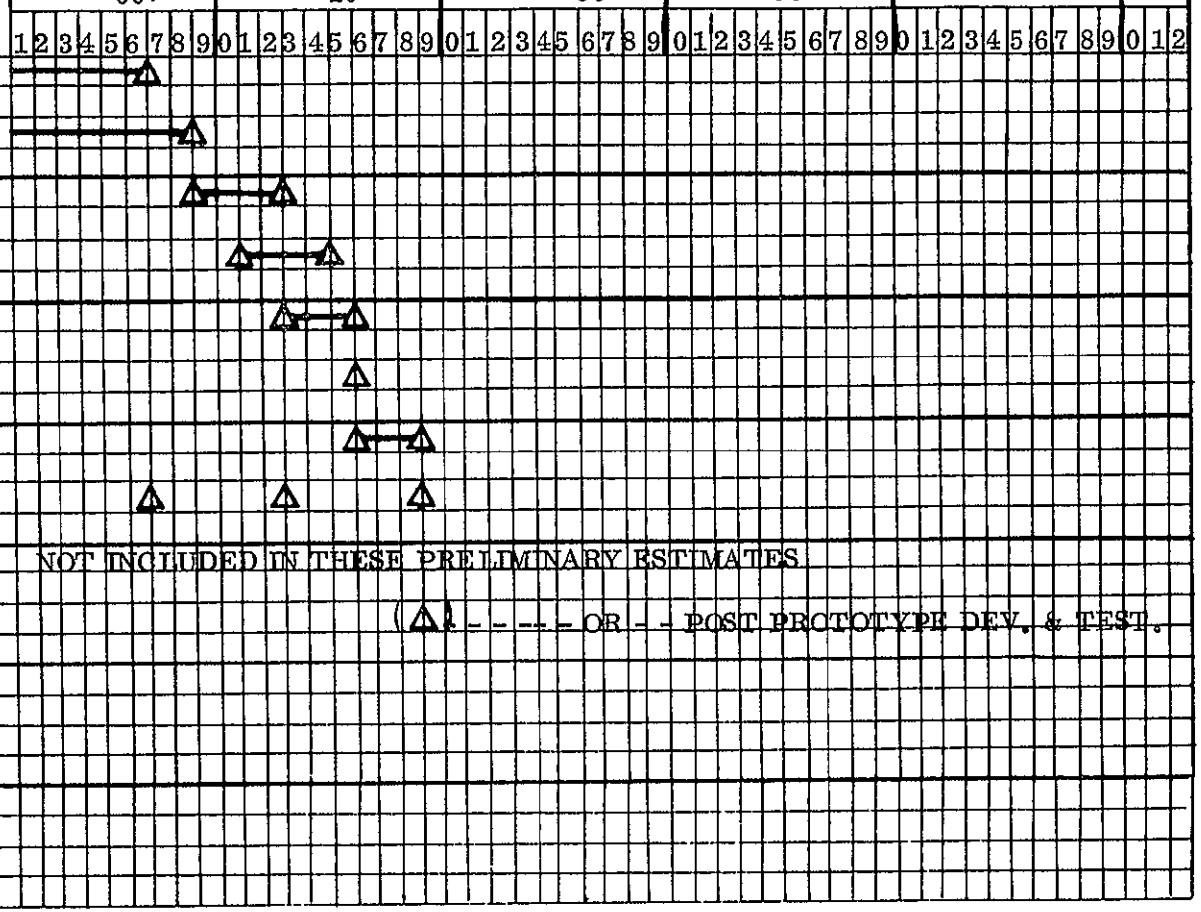
Analyze the commonality of problems associated with existing equipment and other ideas presently under consideration.

Prepare suggestions and recommendations for their solution. Proceed with hardware development of selected devices and techniques as a follow-on phase to this task.

SCHEDULE PLANNING SHEET

RESP. ORGAN	PROG WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	PROGRAM NAME
							TITLE OF SEGMENT OF WORK: SURVEY, NON-INVASIVE TECHNIQUES
PURPOSE FOR ESTIMATE			APPROVALS	REFERENCES – P.P.I.NO.		REV.	OTHER

ITEM NO.	DESCRIPTION OF WORK ITEM	ELAPSED TIME SCHEDULE (INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL WEEKS AS APPLICABLE) IN WEEKS FROM CONTRACT INITIATION
(1)	Prepare Evaluation and Applications Questions	
(2)	Institute/Med. Center Contacts	
(3)	Requirements Definition	
(4)	Efficacy Analysis	
(5)	Design/Fab Recommendations	
(6)	Prototype Discussions	
(7)	Specifications Issue (Preliminary)	
(8)	Periodic Reports (Letters)	
(9)	Prototype Development & Test	NOT INCLUDED IN THESE PRELIMINARY ESTIMATES
(10)	Final Report	(△)- - - - - OR - - POST PROTOTYPE DEV. & TEST.



△=MILESTONES – DISCRETE, AUDITABLE EVENTS
E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲=COMPLETED MILESTONES

◇=PROJECTED MILESTONE SLIP

———=TIME PERIOD OF WORK

◆=SLIPPED MILESTONE

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FIGURE IIA-11

5.9 SENSOR CONNECTOR STANDARDIZATION

EXPLANATION OF TECHNOLOGY

There are a multitude of physiologic sensor connectors marketed today of various types and configurations. The dissimilarity of connectors presents difficulties in application of various sensor leads and monitoring equipment. Physicians have preferences for sensors, cables and monitor equipment which often are incompatible from the connector aspect. Additionally, equipment available at the medical center (existing or newly purchased) often must be modified to enable interconnection in a desired configuration.

UNIQUENESS OF TECHNOLOGY

Application of a single source systems engineering approach to optimizing connector design both from a fit and functional standpoint, and the issue of a specification to which these connectors may be produced will be unique in the medical hardware area and hopefully would initiate action to create similar standards for other equipment and interfaces.

END PRODUCTS

The end product of this effort would include a Medical Systems Connector Standard, optimized connector designs and a recommended source tabulation including connector description, application and qualified vendors.

RECOMMENDED PROGRAM

Initiate those tasks delineated in the schedule planning sheet attached, leading to the issue of a standards document to industry. As a result of this task, additional effort may be undertaken to evaluate industry response, test responsive products and issue approved source lists.

SCHEDULE PLANNING SHEET

RESP. ORGAN	PROG	WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	PROGRAM NAME
								TITLE OF SEGMENT OF WORK: CONNECTOR
PURPOSE FOR ESTIMATE				APPROVALS	REFERENCES – P.P.I.NO.		REV.	STANDARD

ITEM NO.	DESCRIPTION OF WORK ITEM	ELAPSED TIME SCHEDULE (INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL WEEKS AS APPLICABLE)
		WEEKS FROM INITIATION: 00+ 10+ 20+ 30+ 40+
(1)	Establish Standards Format	
(2)	Survey Current Usage/Rqmts. (Med. Inst., Centers, etc.)	
(3)	Survey Market (Connector Manufacturers)	
(4)	Define Detail Requirements (Preliminary Standards)	
(5)	Task Review & Discussion	
(6)	Update and Submit Spec for Industry Review (HEW Document?)	
(7)	Review, evaluate and/or Integrate Industry Comments	
(8)	Test Designs, provide "Approved Part List, Vendor List	NOT DEFINABLE UNTIL QUANTITY & DESCRIPTIONS AVAIL. – NOT INCLUDED –
(9)	Periodic Reports	
(10)	Final Report	

△=MILESTONES – DISCRETE, AUDITABLE EVENTS
E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲=COMPLETED MILESTONES

◇=PROJECTED MILESTONE SLIP

———=TIME PERIOD OF WORK

◆=SLIPPED MILESTONE

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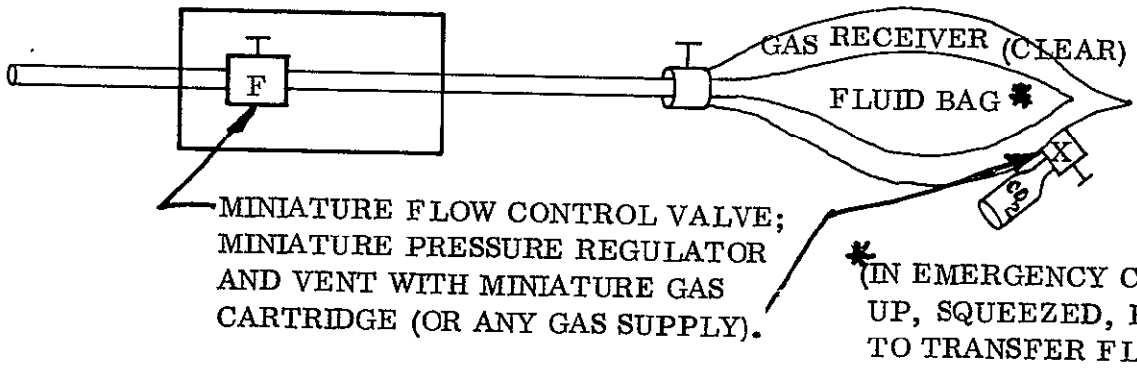
FIGURE IIA-12

5.10 POSITIVE CONTROL OF IV FLUID DISPENSING

Investigate and demonstrate non-gravity techniques of IV fluid dispensing - to avoid holding or hanging of bottles and bags, etc. and develop a better means for controlled infusion. One system recently developed by a southern university in response to needs of medical profession uses plastic bags compressed by negator springs. An interesting alternate is a double bag with a gas cartridge. See the diagram below.



The work items involved in order to accomplish the program for investigating non-gravity techniques of IV fluid dispensing involves the evaluation of existing alternate means. This would be followed by evaluating the need vs approximate costs and the accompanying trade-off. The requirements would have to be defined followed by the fabrication and testing of a prototype. The system should be then reviewed and critiqued. A detailed specification would then be issued which contains the findings above, plus the building of a demonstration unit.

SCHEDULE PLANNING SHEET

RESP. ORGAN	PROG	WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	PROGRAM NAME
								TITLE OF SEGMENT OF WORK: NON-GRAVITY TECHNIQUES OF FLUID INFUSION
PURPOSE FOR ESTIMATE			APPROVALS	REFERENCES – P.P.I.NO.		REV.		

ITEM NO.	DESCRIPTION OF WORK ITEM	ELAPSED TIME SCHEDULE (INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL WEEKS AS APPLICABLE)
		WEEKS: 00+ 10+ 20+ 30+ — 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0
(1)	Evaluate Existing Alternate Means	
(2)	Evaluate the Need/vs Approx. Cost	
(3)	Define Requirements	
(4)	Fabricate & Test Prototypes	
(5)	System Review & Discussion	
(6)	Issue Detail Specification	
(7)	Fabricate Demonstration Units	
(8)	Periodic Reports	
(9)	Final Report	

△=MILESTONES – DISCRETE, AUDITABLE EVENTS
E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲=COMPLETED MILESTONES

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FIGURE IIA-13

5.11 SENSOR MATERIALS AND ATTACHMENT REQUIREMENTS STUDY

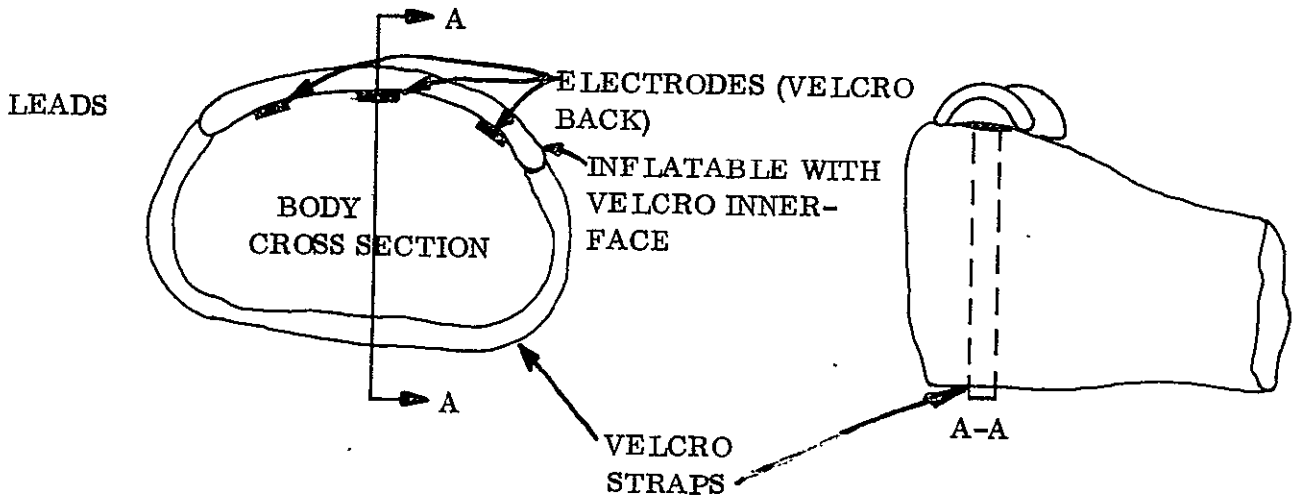
Investigate, develop and document requirements for sensor materials and attachment (sensor - patient, interface) techniques with intent of promulgating standardization and providing producibility effort to expedite availability of "production" items.

Determine optimum size, shape and materials for various sensors (evaluate multitude now available and proposed items).

Define, develop and document attachment requirements and existing techniques for long term, short term, disabled, ambulatory and exercise type applications.

EXAMPLE:

EEG sensor fastened by Velcro to a shaped inflatable belt that provides both placement and pressure; consider effect of pressure on respiration and subsequent interpretation of data.



The work tasks involved in executing the above will involve a number of tasks stated in the following. Surveys of utilization and manufacturer should be made. The definition of requirements should be developed with an accompanying task review and discussion. From this the requirements document would be updated. A test prototype system should then be fabricated. This system should be tested and documented.

SCHEDULE PLANNING SHEET

PROGRAM NAME					
RESP. ORGAN PROG WORK IDEN CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	TITLE OF SEGMENT OF WORK SENSOR MATERIALS & ATTACHMENT TECH.
PURPOSE FOR ESTIMATE	APPROVALS	REFERENCES – P.P.I.NO.	REV.	OTHER	

ITEM NO.	DESCRIPTION OF WORK ITEM	ELAPSED TIME SCHEDULE (INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL WEEKS AS APPLICABLE)
		00+ 10+ 20+ 30+ 40+ 50+
		0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2
(1)	Requirements Study	
(2)	Utilization Surveys & Manufacturer Surveys/Reports	
(3)	Requirements Definition	
(4)	Task Review & Discussion	
(5)	Issue Updated Requirements Document	
(6)	Fabricate & Test Prototype Systems or Test and Document Results of Submitted Systems	
(7)	Review Industry Comments, etc. – Update Specification	
(8)	Periodic Reports	
(9)	Final Report	

△ = MILESTONES – DISCRETE, AUDITABLE EVENTS
E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲ = COMPLETED MILESTONES

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FIGURE IIA-14

5.12 STANDARD MEASUREMENTS LISTS, STANDARD DERIVATIONS, TERMINOLOGY, ETC., FOR PATIENT MONITORING

Accomplish the documentation (and/or development) of measurement lists, standard derivations, terminology, etc., including dimensions and "conditions" under which they are valid for application to patient monitoring data processing and handling.

For example there are about nine formulas for determining body volume from weight and height (body volume is used for example in determination of cardiac index) - the hardware and software designers need be told which formula is required to be used for each particular calculation.

The work tasks for executing the project are as follows:

- review data derivations (via tests, advisory committee, consulting doctors)
- expand patient monitoring system measurement list definition for derivations
- delineate measurement methology - computational methodologies and variations
- detail evaluation of sample rates, accuracies, etc., for each patient monitoring system application
- update measurement list for specifications per (4)
- provide initial data processing and handling specification criteria
- periodic reports
- final report

The following Schedule Planning Sheet outlines the estimated schedule.

SCHEDULE PLANNING SHEET

RESP. ORGAN	PROG WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	PROGRAM NAME
							TITLE OF SEGMENT OF WORK: IDENTIFICATION OF MEASUREMENTS, FORMULAS, MANIPULATION
PURPOSE FOR ESTIMATE			APPROVALS	REFERENCES – P.P.I. NO.		REV.	RQMT'S FOR PM SYSTEM

ITEM NO.	DESCRIPTION OF WORK ITEM	ELAPSED TIME SCHEDULE (INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL WEEKS AS APPLICABLE)
		00+ 10+ 20+ 30+
		0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9
(1)	Review Data Derivations (via tests, Advisory Committee, Consulting MD's)	
(2)	Expand PMS Measurement List Definition for Derivations	
(3)	Delineate Measurement Methodology – Computational Methodologies and Variations	
(4)	Detail Evaluation of Sample Rates, Accuracies, etc. for each PMS Application	
(5)	Update Measurement List for Specs Per (4)	
(6)	Provide Initial Data Processing and Handling Spec. Criteria	
(7)	Periodic Reports	
(8)	Final Report	

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FIGURE IIA-15

5.13 A STUDY TASK LEADING TO EVALUATION OF THE PACE/RHO AUTOMATIC URINE ANALYSIS EQUIPMENT FOR CLINICAL APPLICATION

1.0 INTRODUCTION

The Pace/Rho system was designed to provide real time analysis of urinary calcium, creatine and creatinine during the 30 day Mission of the Biosatellite.

2.0 UNIQUE TECHNOLOGY

This system (11.75 long x 5.5" high x 6.0" deep) contained a fluid handling block; calcium analyzer; creatinine-creatine analyzer; reagent reservoirs, reagents; calibration fluid reservoirs; optical read out unit; metering pumps; pressure regulator; timers; and associated electronic equipment (Figure XIV-1).

Two milliliter alliquots of urine were sequentially analyzed according to a pre-determined schedule or on command from a ground station. Data transmitted included the concentrations and temperature of calcium, creatine and creatinine, the number of samples and dilutions, and engineering status (power, lamps, internal temperature and pressure). In addition, provisions was made for flushes between samples and automatic calibration with pre-loaded calibration fluids.

Based on the compactness of this unit and its flight proven reliability, it would be of interest to investigate application of the automated Pace/Rho urine analysis techniques to analyses of clinical interest. This would include those normally accomplished on a "routine" basis in clinical chemistry laboratories as well as specialized analyses required for research activities. Initial emphasis would be placed on urine analysis but may later be extended to include blood serum analysis.

3.0 PRELIMINARY STUDIES AND GOALS

An initial program would include survey and evaluation of requirements for manual and automatic urine analysis. Emphasis would be placed on comparing specifications of available manual instrumentation and evaluation of adopting and integrating that methodology, identifying specific tests and techniques which appear amendable to the automated Pace/Rho approach. Application of membrane technology, toxicity studies, electrode separation techniques and related methods will be evaluated in conjunction with the automated colorimetric techniques employed in the Biosatellite system for application to a urinalysis system for patient monitoring. Blood serum analysis capabilities will also be evaluated.

Breadboarding of the Pace/Rho equipment, for analysis of other than that for which it was originally intended (calcium; creatinine/creatine), cannot be justified in advance of conducting surveys to identify analytical procedures amicable to this type instrumentation and modifications. In addition, it will be necessary to concurrently identify the most significant parameters that clinicians consider obligatory to monitor in certain patient types

on a near real time basis. This combination of information will make it possible to recommend a logical plan for breadboarding and testing advanced concepts of the Pace/Rho urine analysis equipment suitable for patient monitoring.

The Pace/Rho equipment, as designed for the Bio-satellite program, contains a logic system suitable for delivering specific volumes of reagents (picric acid, sodium hydroxide, sulfuric acid, hydrochloric acid, calcium reagent) on a programmed schedule. Other tests for example, uric acid, urea nitrogen, choride, sodium, potassium, steroid hormones, lactic acid, catecholamines, PSP excretion, etc., require different reagents, sample dilution incubation for varying periods of time, and an optimal readout system required for a specific test. In this instance the spectoal response characteristic of the photo diode suitable for the analysis of creatinine/creatine, in all probability, would not be suitable for a number of the tests above. Certainly, if we were monitoring urine on a near real time basis for catecholamines as five-hydroxytryptamine, florescence would be the readout system of choice. If other analysis were being done concurrently; ultraviolet, visable, or infra red spectro-photometric readout systems might be required.

Advanced surveys, as recommended, would also investigate possible applications of the Pace/Rho instrumentation, with appropriate modifications, for the analysis of serum samples. Serum analyses, however, frequently are a problem unto themselves, and a breadboard suitable for urine chemistry would probably require further modifications for serum.

In summary, thorough surveys of clinical laboratories (mail, surveys, and personal interviews) plus a comprehensive literature search, are deemed requisite to planning breadboard studies for patient monitoring applications of the Pace/Rho urine analysis equipment.

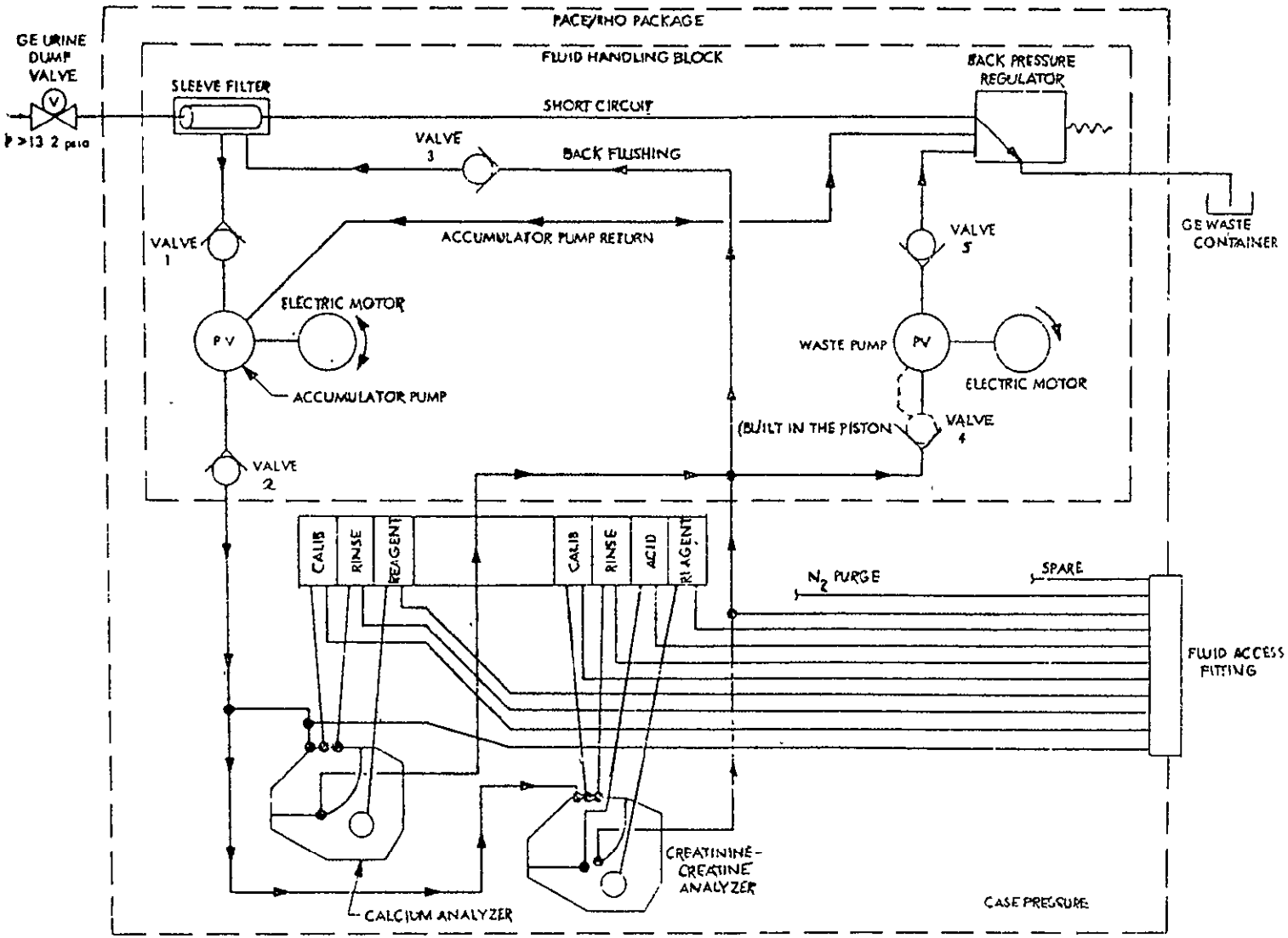


Figure IIA-16

SCHEDULE PLANNING SHEET

PROGRAM NAME CLINICAL APPLICATIONS PACE/RHO

RESP. ORGAN	PROG WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	TITLE OF SEGMENT OF WORK

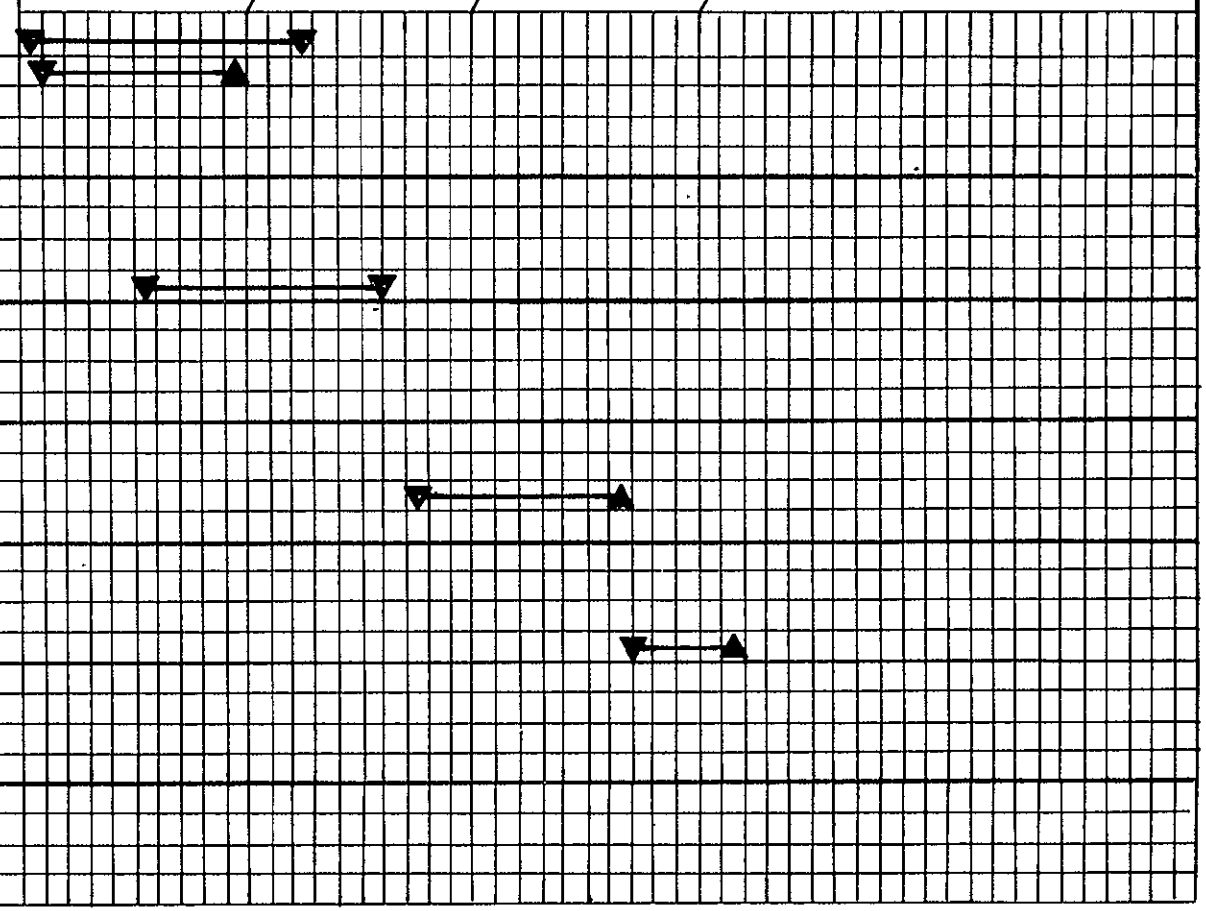
PURPOSE FOR ESTIMATE	APPROVALS	REFERENCES – P.P.I.NO.	REV.	OTHER

ITEM NO.	DESCRIPTION OF WORK ITEM
1.0	REQUIREMENTS DEFINITION
	1.1 URINE ANALYSIS
	1.11 MANUAL TECHNIQUES
	1.12 MANUAL VARIATIONS
	1.13 AUTOMATIC TECHNIQUES
	1.14 AUTOMATIC EQUIPMENT
2.0	SERUM ANALYSIS
	2.1 MANUAL TECHNIQUES
	2.11 MANUAL VARIATIONS
	2.12 AUTOMATIC TECHNIQUES
	2.13 AUTOMATIC EQUIPMENT
3.0	COMPARATIVE ANALYSIS OF TECHNIQUES & EQUIPMENT
4.0	FINAL REPORT

ELAPSED TIME SCHEDULE

(INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL WEEKS AS APPLICABLE)

#1 #2 #3



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E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

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FIGURE IIA-17

5.14 ANALYSIS OF PHENOLIC COMPOUNDS OF CLINICAL INTEREST

INTRODUCTION

NASA specifications for fuel cell derived potable water in the Biosatellite Program called for the total phenol concentration not to exceed one (1.0) part per billion (ppb). Methods of analysis available, including the Standard Methods[1] procedure, lacked accuracy and precision, or were too time consuming to insure a completed analysis within 30 minutes of launch.

For this reason it was considered essential to develop methodology which would permit analysis with a high degree of confidence at the 1.0 ppb level within the allotted time limit.

UNIQUE TECHNOLOGY

The method of choice resulting from this effort is based upon continuous liquid-liquid extraction of aqueous samples with diethyl ether and the elimination of interfering substances by the selective partitioning of phenols into the ether phase[2].

These are separated from the ether as lithium phenolates with lithium hydroxide and re-converted to phenols with hydrochloric acid in a volume of deionized water equivalent to the original volume of the sample (100 ml). Analysis is achieved by treating the aqueous mixture of phenols with a modification of the 4-aminoantipyrine/potassium ferricyanide reagents and comparing a chloroform extract of the 4-aminoantipyrine dye complex with an appropriate standard in a spectrophotometer at 458 nanometers.

Reduction of the concentration of 4-aminoantipyrine from 60 μ moles to 40 μ moles per test significantly reduced reagent blank color and enhanced sensitivity. This was further augmented by optimization of the reaction pH and final adjustment of the dye complex with tartaric acid buffer to pH 4.0 immediately prior to extraction with chloroform.

Many phenolic compounds, including phenol per se and those capable of influencing the taste and odor of the Biosatellite water supply, e.g., 2-chlorophenol; 2,4-dichlorophenol, 2,6-dichlorophenol, can be detected in concentrations of 1.0 ppb or less in approximately 20 minutes.

(1) Standard Methods for the Examination of Water & Wastewater. APHA, AWWA, & WPCF, 514-523, 12th ed (1965).

(2) STARKEY, R.J. & ORR, E.D. Rapid Total Phenols Analysis by Liquid-Liquid Extraction with Diethyl Ether. Presented at 160th ACS Meeting, September 14, 1970.

For the most part phenolic compounds analyzed have been limited exclusively to contaminants of potable water and have not included derivatives frequently found in biological materials.

The proposed study will consider application of the Biosatellite method of phenol analysis or modifications thereof, to the analysis of phenolic compounds found in body fluids as urine, feces, sputum, blood serum and gastric washings.

New or improved methods of analysis would be of interest to clinical biochemists, physiologists, pharmacologists, pathologists, toxicologists and others concerned with the fate and distribution of phenolic compounds in biological materials.

END PRODUCTS

A report delineating phenolic compounds including those found in natural products, drugs and drug metabollies for which analytical methodology may be significantly improved, and recommendations of advanced techniques applicable to these analyses.

RECOMMENDED PROGRAM

An extensive evaluation is required to identify phenolic compounds of clinical interest for which suitable analytical methodology is not available. Based upon the results of this study recommendations will be made to develop analytical techniques for the analysis of specific naturally occurring phenols; phenolic pharmaceuticals and their metabolites. Task outline is indicated on the accompanying schedule.

PRELIMINARY STUDIES AND GOALS

An extensive evaluation is required to identify phenolic compounds of clinical interest for which suitable analytical methodology is not available. Based upon the results of this study recommendations will be made to develop analytical techniques for the analysis of specific naturally occurring phenols; phenolic pharmaceuticals and their metabolites.

1.0 SURVEY OF STATE OF THE ART TECHNIQUES USED FOR THE ANALYSIS OF PHENOLIC COMPOUNDS IN BIOLOGICAL MATERIALS

1.1 Literature survey of analytical procedures for compounds outlined in Tables IIA-3 and IIA-4.

1.1.1 Wet chemistry/UV spectroscopy

1.1.2 Fluorescence spectroscopy

1.1.3 Infrared spectroscopy

1.1.4 Thin layer chromatography

1.1.5 Gas-liquid chromatography

1.2 Compile the following information:

1.2.1 Limits of sensitivity

1.2.2 Normal and pathological limits in body fluids

1.2.3 Significance and frequency of analysis in the clinical pathology laboratory

1.2.4 Problems associated with interfering substances

1.2.5 Time constraints

1.2.6 Reagents required

1.2.7 Glassware required

1.2.8 Special equipment required

1.2.9 Economics of analysis

2.0 CHOICE OF CANDIDATE COMPOUNDS

2.1 Choice of compounds for which advanced analytical methodology will be developed is dependent upon the data derived from item 1.1 and 2.2

2.2 Answers to the following questions will be documented.

2.2.1 Are there requirements for advanced analytical techniques for the analysis of specific phenolic compounds for which methodology is either not satisfactory or available?

2.2.1.1 Natural products

2.2.1.2 Drugs (conventional therapeutic agents)

2.2.1.3 Drug metabolites

2.2.2 What other phenolic type compounds should be considered for the development of analytical methodology, e.g., experimental pharmacological agents and their metabolites?

TABLE IIA-3. PHENOLIC PHARMACEUTICAL PRODUCTS

	NANOMETERS	
Terramycin	390	520
Achromycin	390	515
Isoreserpine	390	510
Dehydroreserpine Perchlorate	390	510
Harmaline Hydrochloride	390	490
Aureomycin	355	445
Chlorpromazine	350	480
Norharmane	350	380
Tetradehydroreserpine Chloride	340	440
Menadione	335	480
Chloroquin	335	400
Chlorpromazine Sulforide	335	400
Oxychloroquin	335	380
LSD	325	465
Pentothal	315	530
Cinchonine	320	420
Brom LSD	315	460
Cinchonidine	315	445
Surital	310	530
Rescinnamine N-oxide	310	440
Rescinnamine	310	440
Salicylic Acid	310	435

TABLE IIA-3. PHENOLIC PHARMACEUTICAL PRODUCTS (Continued)

	NANOMETERS	
Rescinnamine	310	400
Plasmoquin	300,370	530
N-ethylharmine	300,365	450
p-Aminosalicylic Acid	300	405
Harmine	300,365	400
Trimethoxycinnamic Acid	300	400
Reserpine	300	375
Methyl Reserpate	300	360
Syrosingopine	300	360
Reserpine	300	360
Eserine	300	360
Methyl 0-(3,5-dimethoxy 4 hydroxybensoyl reserpate	300	360
Adrenalin	295	335
Norepinephrine	295	335
Epinephrine	295	335
Syrosingopine N-oxide	290	350
Piperoxan	290	325
Quinacrine	285,420	500
Norharmane	285	380
Allylmorphine	285	355
Azaguanine	285	405

TABLE IIA-3. PHENOLIC PHARMACEUTICAL PRODUCTS (Continued)

	NANOMETERS	
Aminopterin	280,370	460
Thiophenobarbital	280	470
Methotreaxate	280,375	460
Descrpidine	280	360
Renoxidine (reserpine N-oxide)	280	360
Reserpine	280	360
Trimethoxybenzoic Acid	280	360
Indole	280	340
Podophyllotoxin	280	325
Mc Niel	280	320
Flexin	280	320
Neocinchophen	275,345	455
Tolserol	280	315
Procaine	275	345
Dromoran	275	320
Paredrin	275	300
Neosynephrin	270	305
Yohimbine	270	360
Synephrin	270	310
Phenobarbital	265	440
Pentobarital	265	440
Amytal	265	410

TABLE IIA-3. PHENOLIC PHARMACEUTICAL PRODUCTS (Continued)

	NANOMETERS	
Acetylcolchinol	265	380
Thymol	265	300
Quinine	250,350	450

Note: Measurements in mu

TABLE IIA-4. NATURALLY OCCURRING PHENOLIC COMPOUNDS FOUND IN BIOLOGICAL MATERIALS

	NANOMETERS	
5-Hydroxykynurenine	375	460
Kynurenine	370	490
Folinic Acid	370	460
Thiochrome	370	445
3-Hydroxykynurenine	365	460
Pteroic Acid	365	450
Folic Acid	365	450
p-Hydroxycinnamic Acid	350	440
DPNH	340	435
5-Hydroxyanthranilic Acid	340	430
Pyridoxine	340	400
Pyridoxamine	335	400
Pyridoxal	330	385
Vitamin A	325	470
Kynurenic Acid	325	440
Kynurenic Acid	325	405
Uric Acid	325	370
3-Hydroxyanthranilic Acid	320	415
Xanthine	315	435
Anthranilic Acid	300	405
p-Hydroxymandelic Acid	300	380

TABLE IIA-4. NATURALLY OCCURRING PHENOLIC COMPOUNDS FOUND IN BIOLOGICAL MATERIALS (Continued)

	NANOMETERS	
5-Hydroxyindolenetic Acid	300	355
Serotonin	295	540
p-Aminobenzoic Acid	295	345
Serotonin	295	340
Tocopherol	295	330
Tryptamine	290	360
5-Hydroxyindole	290	355
Equilih	290	345, 420
p-Hydroxyphenylpyruvic Acid	290	345
Homogentisic Acid	290	340
p-Hydroxyphenylserine	290	320
ATP	285	395
Adenylic Acid	285	395
Adenosine	285	395
Tryptophan	285	365
Guanine	285	365
Estradiol	285	330
3,4-Dihydroxyphenylalanine	285	325
Estrone	285	325
3,4-Dihydroxyphenethylamine	285	325
Adrenalin	285	325

TABLE IIA-4. NATURALLY OCCURRING PHENOLIC COMPOUNDS FOUND IN BIOLOGICAL MATERIALS (Continued)

	NANOMETERS	
Noradrenalin	285	325
p-Hydroxyphenethylamine	285	325
Adenine	280	375
Indole	280	355
3,4-Dihydroxyphenylacetic Acid	280	330
3,4-Dihydroxyphenylserine	280	320
p-Hydroxyphenylacetic Acid	280	310
Tyramine	275	310
Tyrosine	275	310
Vitamin B12	275	305
Riboflavin	270,370,445	520
Homovanillic Acid	270	315
Equilenin	250,290,340	370

Note: Measurements in m_{μ} (millimicrons or nanometers)

TABLE IIA-4. NATURALLY OCCURRING PHENOLIC COMPOUNDS FOUND IN BIOLOGICAL MATERIALS (Continued)

	NANOMETERS	
Th-1-amino-4 hydroxyanthraquinone	550-580	660
Be-1-4-dihydroxy anthraquinone	530-570	630
Be-1-amino-4 hydroxyanthraquinone	530-560	620
Al-PBBR	470,580	630
Al-AAGR	470	590
Re-morin	470	555-585
Al-morin	430	500
Zr-flavonol	400	465
A-Creatinine	390	495
B-Dimethyl-guanidine	390	495
C-Guanido Acetic Acid	390	495
D-Methy guandine	390	495
E-Aginine	390	495
F-Guandine	390	495
Li-oxine	370	580
B-benzoin	370	480
7-Hydroxyquinolines	370	490
Hydroxyquinolines	365	460
7-Hydroxycoumanins	365	460
Hydroxycoumanins	320	480

TABLE IIA-4. NATURALLY OCCURRING PHENOLIC COMPOUNDS FOUND IN BIOLOGICAL MATERIALS (Continued)

	NANOMETERS	
0-Hydroxycinnamic (cis) (coumarinic acid)	365	510
0-Hydroxycinnamic (trans) (coumaric acid)	365	500
4-Pyridioxic Acid lactone	360	440-445
8-Naphthol	350	460
p-Hydroxycinnamic	350	440
3-Hydroxyquinolines	350	450 420-430
2:6-di (Y-resorcylic)	340	455
3-(10 ug./ml.) hydroxycoumanins	340	480
a-Naphthol	330	480
2-Hydroxyquniolines	325	380
2:5-di-(gentisic)	325	455
o-Hydroxydiphenyl	320	420
Warfairn in methanol	320	385
Potasan (in methanol)	320	385
3-Salicylic Acid	315	425
2,3-Dihydroxy indole	315	400
3,4,Dibenzpyrene 8,9	310,335,390,410	480,510
p-Hydroxydiphenyl	310	410
Hydroxycoumanins	310	390-400
4-(5 ug./ml.) hydroxycoumanins	310	360-380
Indoxyl	310	395
2:3-di-(catechuic)	305	440

TABLE IIA-4. NATURALLY OCCURRING PHENOLIC COMPOUNDS FOUND IN BIOLOGICAL MATERIALS (Continued)

	NANOMETERS	
1,12 Benzperyiene	305,375,395	430
3:4-di-(protocatechuic)	300	370
Oxindole	300	345
p-Hydroxymandelic	300	380
8,9 Benzfluoranthrene	295,330,385, 405	480,515
2-(salicylic acid)	295	420
2:4-di-(B-resorcylic)	295	400
3-Salicylic Acid	295	350
Naphthacene	290,310	480,515
1,2 Benzpyrene in cyclohexane	290,330	410
Skatole	290	370
Methylaniline	290	360
p-Hydroxyphenylpyruvic	290	340-350
2:5-Dihydroxy (homogentisic)	290	340
Indoxyl acetate	285	375
Indole acetic acid in methanol	285	345
Quinol (1:4)	285	340
p-Cresol	285	315
2:4-Xylenol	285	310
Naphthacenene	280,390,415, 445	480
8-Methyl Fluorene	280,290,365	460-480
1-2 Benzanthrene	280,340	390,410

TABLE IIA-4. NATURALLY OCCURRING PHENOLIC COMPOUNDS FOUND IN BIOLOGICAL MATERIALS (Continued)

	NANOMETERS	
2-Methyl indole	280	355
Indole	280	350
Aniline	280	340
Aniline	280	340
3:4-Dihydroxy (homoprotocatechuic)	280	330
3:4-Dimethoxy	280	325
1-Arternol Bitartrate	280	320
1-Epinephrine Bitartrate	280	320
3:4-Xylenol	280	310
m-Cresol	280	305
4-Hydroxy	275	315
o-Cresol	275	305
2:6-Xylenol	275	305
3:4-trimethoxy-benzoic acid 5-	270	375
Catechol (1:2)	270	325
3-Hydroxy-4-methoxy (homovanillic)	270	315
Phenol	270	310
2-Hydroxy	270	310
Phenol	270	310
Anisole	270	300
Resorcinol (1:3)	265	315
3:4-Dibenzpyrene 9,10	255,290,300 395,415,445	455,485

TABLE IIA-4. NATURALLY OCCURRING PHENOLIC COMPOUNDS FOUND IN BIOLOGICAL MATERIALS (Continued)

	NANOMETERS	
Dimethylaniline	255	370
Guthione	250, 312	380
Chrysene	250, 300, 310	360, 380
n-Propylisome	248, 292	326
Piperonyl butoxide in methanol	248, 292	320
Benzanthrene	245, 325, 340	385, 400
1, 2, Dibenzpyrene 3, 4	230, 285, 305 325, 340, 375	440, 470
Naphthalene acetamide in methanol	230, 286	327
Naphthalene acetic acid	230, 282	325

Note: Measurements in $m\mu$ (millimicrons or nanometers)

SCHEDULE PLANNING SHEET

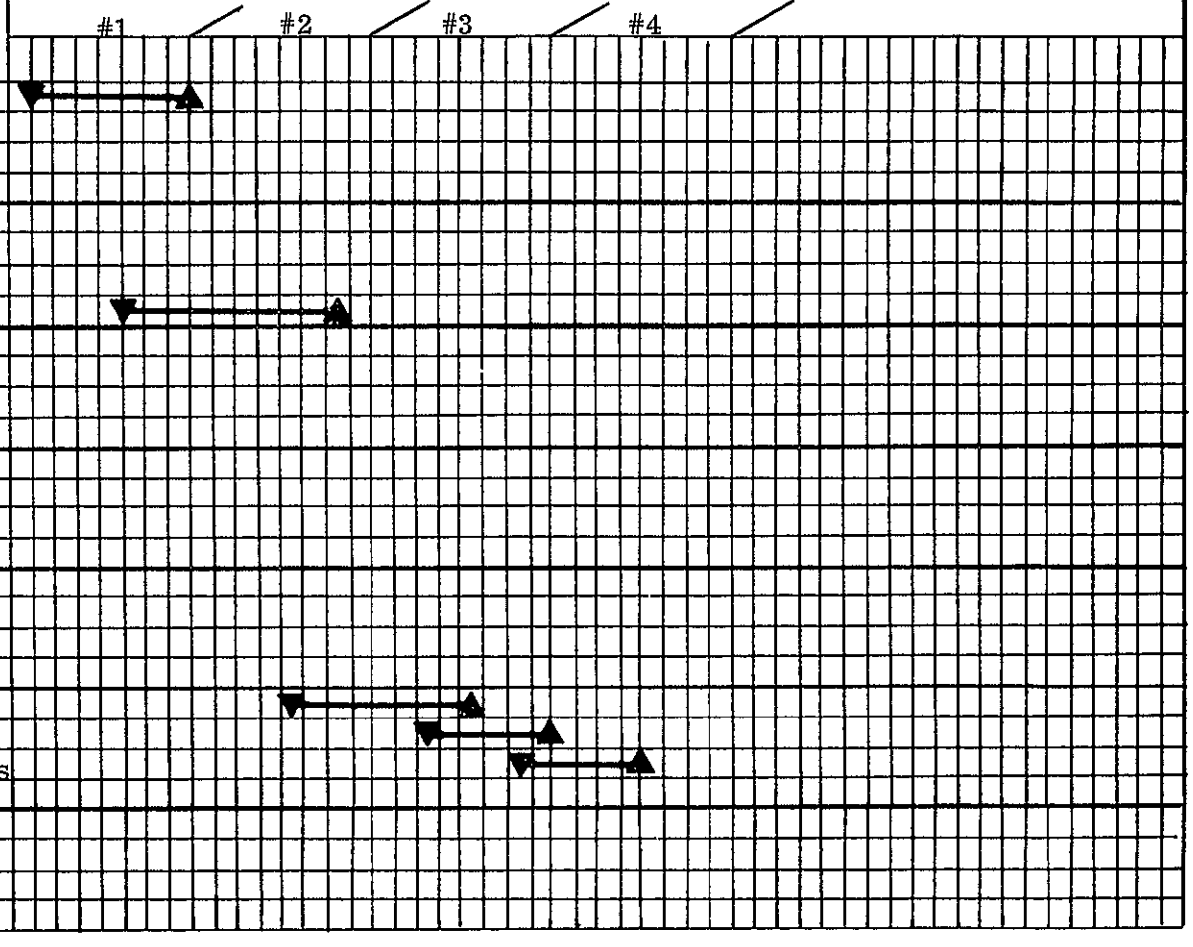
RESP. ORGAN	PROG	WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	PROGRAM NAME / TITLE OF SEGMENT OF WORK
								Adv. Phenol Methods / Survey

PURPOSE FOR ESTIMATE	APPROVALS	REFERENCES – P.P.I.NO.	REV.	OTHER

ITEM NO.	DESCRIPTION OF WORK ITEM
	ANALYTICAL METHODS AND REQUIREMENTS EVALUATION
1.0	Compounds in Tables 1 and 2 attached
1.1	Wet Chemistry
1.2	UV/Visible Spectroscopy
1.3	IR Spectroscopy
1.4	Fluorescence Spectroscopy
1.5	TLC
1.6	GLC
2.0	Compare
2.1	Limits of Sensitivity
2.2	Normal and pathological limits
2.3	Significance and frequency of analysis in clinical path lab.
2.4	Problems with interfering substances
2.5	Problems associated with different body fluids
2.6	Time Constraints
2.7	Reagents required
2.8	Glassware required
2.9	Special equipment required
2.10	Economics of analysis
3.0	Survey of Clinical Labs/ Pharmaceutical Companies
4.0	Report and Program Recommendations

ELAPSED TIME SCHEDULE

(INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL WEEKS AS APPLICABLE)



△=MILESTONES – DISCRETE, AUDITABLE EVENTS
E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲=COMPLETED MILESTONES

◇=PROJECTED MILESTONE SLIP

———=TIME PERIOD OF WORK

◆=SLIPPED MILESTONE

STATUS AS OF 1-31-71

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FIGURE IIA-18

5.15 DAY-NIGHT PHOTOGRAPHY

EXPLANATION OF TECHNOLOGY

Behavioral studies of the Primate Mission required black and white still and cine mode photography of the animal subject during both day and night periods while maintaining the day to night lighting intensity ratio at greater than 30:1 in the visible spectrum to maintain circadian response.

Plus X Pan-film was employed which has a dynamic range of only 8:1 with incadescent lighting, and therefore required two different exposure settings to obtain both day and night photographs if unfiltered incandescent lighting were employed. Because variable exposure represented major modification to the camera and to the electronic control components, a means was sought to provide high resolution day and night photography without such changes.

The system developed took advantage of the difference in spectral response of the film and the primates' eye. Because about one third of the film's response is in the visible range and two-thirds in the near infrared, the night light was filtered with a Wratten 70 (deep red) filter while the day light remained unfiltered. The resu;ting night light had a visible energy content 1/30 to 1/125 of that of the day light while maintaining a film-responsive energy content 1/2 to 1/8 that of the day light, or within the latitude of the film. Consequently, a single camera setting could then accommodate both day and night lighting conditions.

The influence of the white/red day/night lighting system on circadian response was tested at the Ames Research Center, using both chickens and primates. Normal circadian rhythms were reported.

UNIQUENESS

Although state-of-the-art technology was used in this method of black and white day-night photography, its application to medicine may provide costs savings where it is desired to provide unattended photography for recording visual observations of patients. Where the normal method involves changing exposure for different lighting conditions, less expensive equipment without automated exposure setting may be employed with the photography/ lighting method described. A unique feature of the approach will be the use of a simple logic circuit and sensors to automatically control the camera so as to take pictures only when patient condition warrants. This will limit and mimimize the number of photographs to those of potential clinical interim.

END PRODUCTS

A report shall be supplied detailing the requirements and application of an automated camera-lighting system for medical use. Also, the report shall include conceptual designs on economical lighting and photography systems for automated time-lapse monitoring of intensive care patients, psychiatric patients, or significant subjects in operating rooms.

RECOMMENDED PROGRAM

Investigate the potential usefulness of day-night photographic techniques for monitoring different types of patients, e.g., psychiatric, pediatric etc., who require continuous or intermittent surveillence. This would include application of state of the art time-lapse or continuous cinema-photography with closed circuit (CCTV) options. Analyze and define camera control techniques based on physiologic parameter status.

An initial program would call for an applications evaluation to determine the requirements of the medical profession for such a system. Based upon the outcome of this study, recommendations would be made to design and fabricate a prototype system which would be evaluated clinically.

SCHEDULE PLANNING SHEET

RESP. ORGAN	PROG WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	PROGRAM NAME
							DAY-NIGHT PHOTOGRAPHY
PURPOSE FOR ESTIMATE			APPROVALS	REFERENCES – P.P.I.NO.		REV.	TITLE OF SEGMENT OF WORK: LITERATURE SEARCH & SURVEY
							OTHER

ITEM NO.	DESCRIPTION OF WORK ITEM	ELAPSED TIME SCHEDULE (INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL WEEKS AS APPLICABLE)
		#1 2 3 4 5 6 7
1.0	Prepare/Update Survey Criteria	
2.0	Hospital Survey (Mail & Interview)	
	2.1 Pediatric	
	2.2 Psychiatric	
	2.3 Geriatric	
3.0	Physicians Survey (Mail & Pers Inter)	
	3.1 Private Practice	
	3.2 Hospital Only	
°	3.1 Psychiatrists	
	3.2 Pediatricians	
	3.3 Others Requiring Patient Surveillance	
4.0	Hospital Audio-Visual Survey	
5.0	Analysis and definition of camera control by physiologic monitors	
6.0	Final Report with Recommendations for Advanced Program	

△=MILESTONES – DISCRETE, AUDITABLE EVENTS
E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲=COMPLETED MILESTONES

◇=PROJECTED MILESTONE SLIP

———=TIME PERIOD OF WORK

◆=SLIPPED MILESTONE

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FIGURE IIA-19

5.16 ODOR CONTROLLED WASTE COLLECTION SYSTEM FOR COLOSTOMY AND ILEOSTOMY PATIENTS REQUIRING SURGICAL APPLIANCES (FECES COLLECTION)

INTRODUCTION

A Primate Feces Collection and Storage Assembly was developed for the Biosatellite Program to provide retention of primate feces (liquid and solid) for periods in excess of 30 days.

Liquids and solids accumulating during this period were retained by a filter in the container wall while permitting gasses to flow through a bacterial filter into a Gas Management Assembly system equipped with a charcoal scrubber. Recirculation of air in this system provided continuous removal of primate flatus and odors eminating from waste materials.

It would be of considerable interest to apply this technology, or modifications thereof, to the development of an advanced odor controlled waste collection system suitable for colostomy and ileostomy patients.

STATE OF THE ART TECHNOLOGY

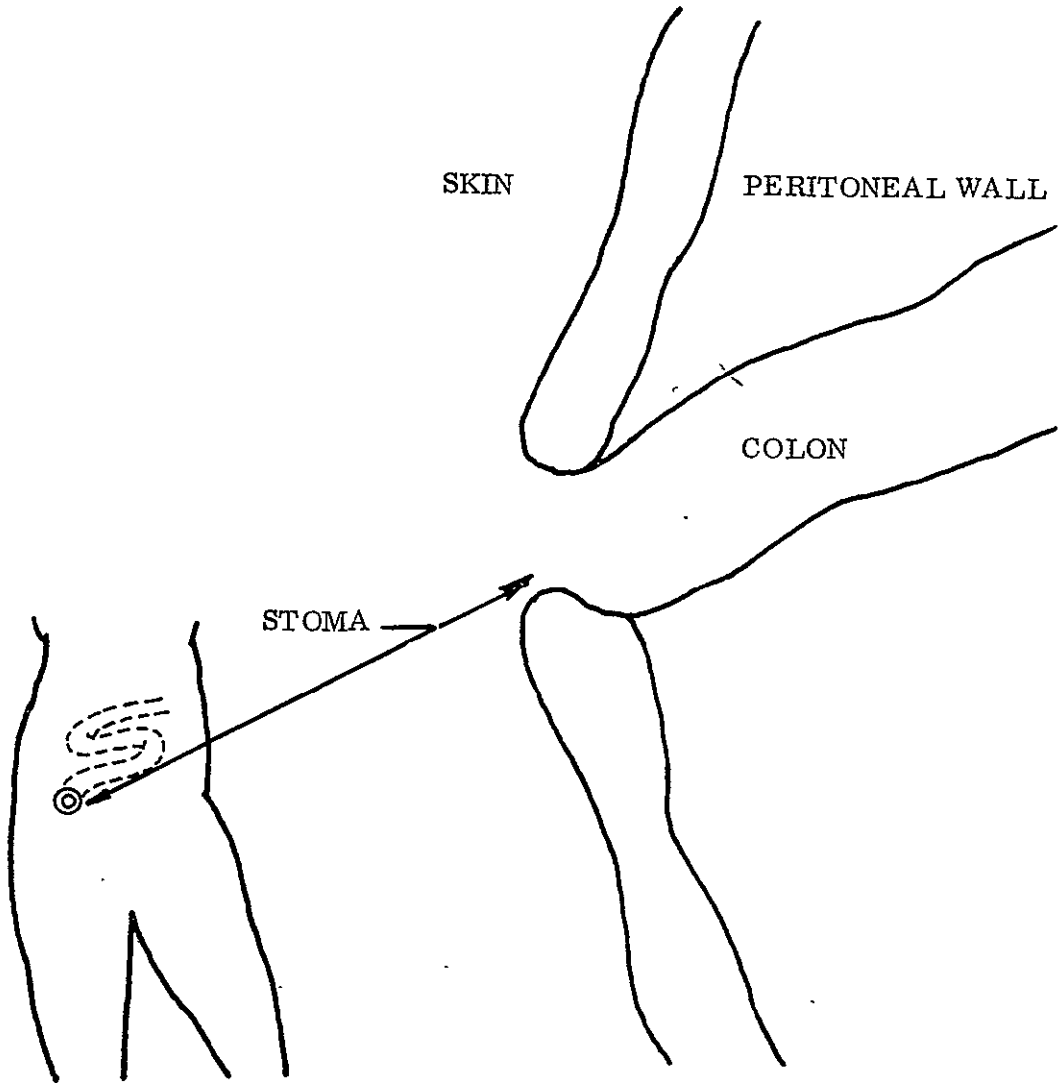
Radical surgery of the intestinal tract in adults and children frequently requires the terminal end of the colon or ileum to be exteriorized in the abdominal wall. Waste products are collected in a plastic or rubber container frequently referred to as "-ostomy or surgical appliances".

The appliance is attached to the "stoma" with a non-irritating gasket and held in place with a belt fastened around the patient's waist. Although the gasket is primarily intended to minimize friction between the stoma and collection system, it likewise acts as a seal to prevent leakage of intestinal secretions capable of irritating the skin and staining clothing.

Filling of the waste collection system is partially dependent on intra-intestinal flow produced by successive peristaltic waves, and gravity displacement of air in the appliance. Offensive odors, e.g., H_2S, eminating from the feces may leak out at the seal site or diffuse through the appliance wall.

Gas production and the volume of waste products collected daily varies with the physiological status of the individual, age, eating habits, as well as miscellaneous contributory factors. For this reason, some patient types may have severe odor problems and require frequent emptying and/or replacement of the appliances. Bed ridden geriatric patients, conversely, may only require appliance replacement every 7-10 days, but will still have annoying moderate to severe odor associated problems. Chemical masking agents have been variously used, but unfortunately only provide a temporary relief. In many instances, these may be highly perfumed and not aesthetically acceptable to the patient or his associates.

To date waste collection systems are not available that provide effective control of odor producing gases and/or constituents of feces.



A. Locus of stoma in colostomy patient.

B. Cross section of abdominal wall, colon, and stoma.

Figure IIA-20. Exteriorized Colon with Exposed Stoma in Colostomy Patient

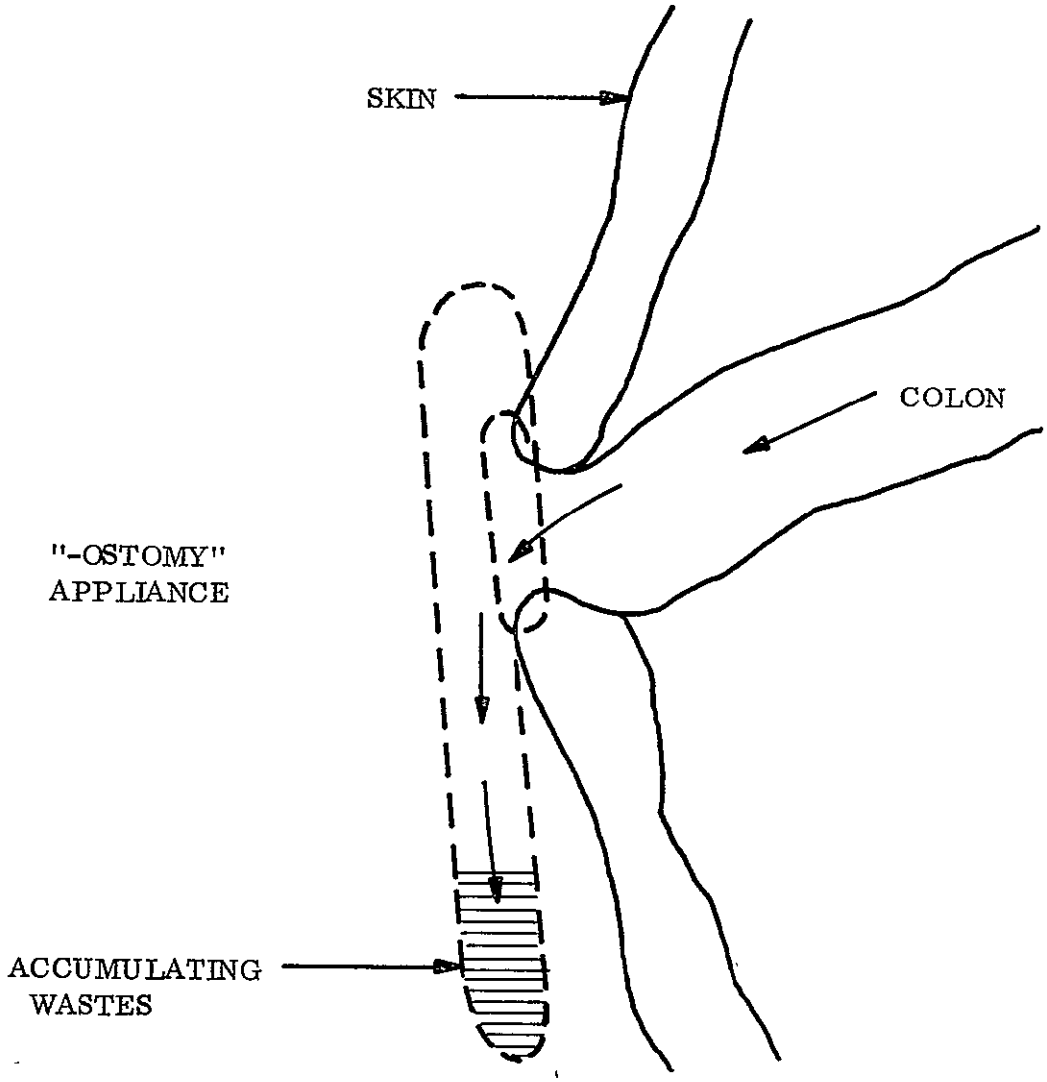
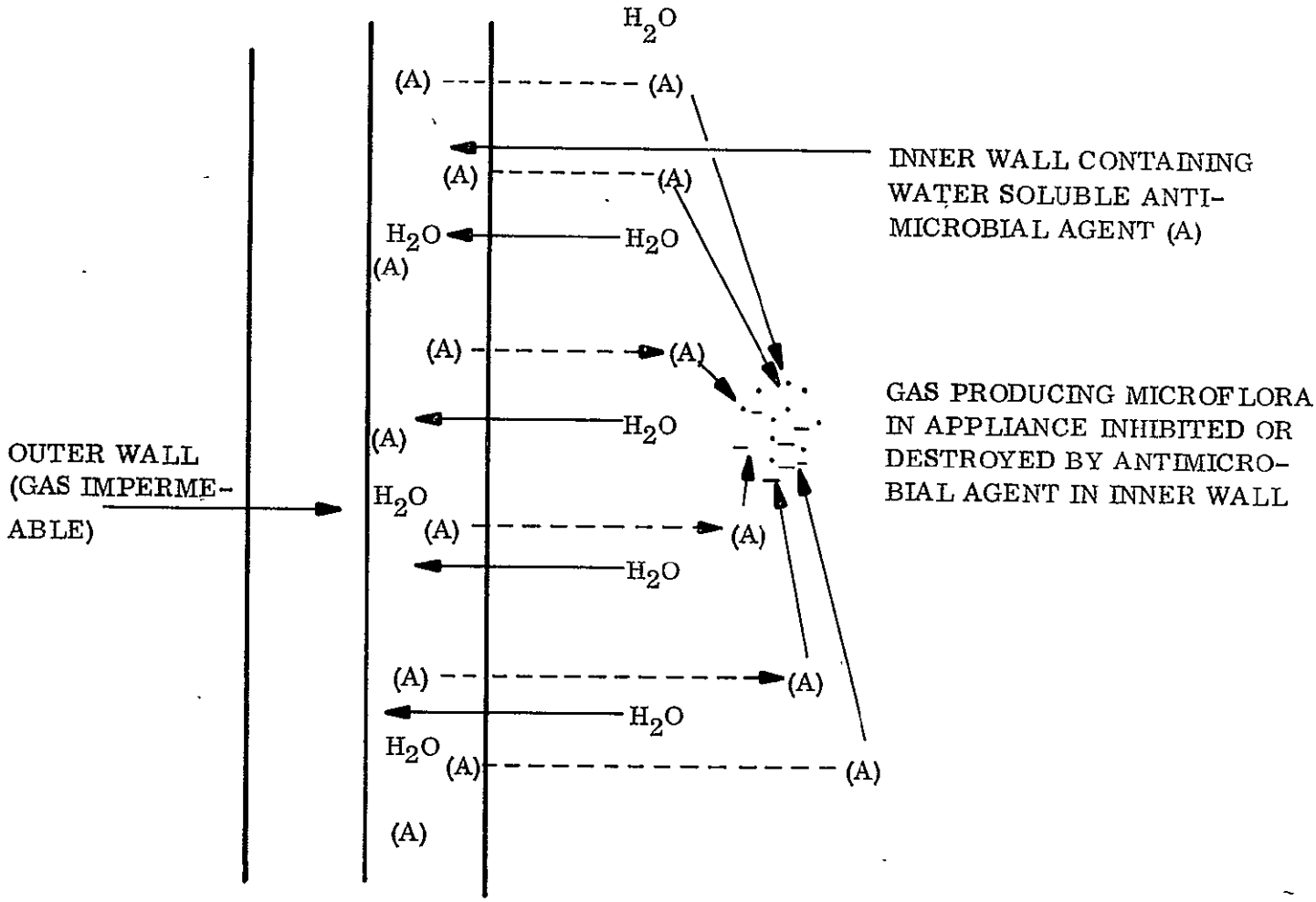


Figure IIA-21. Conventional "-Ostomy Appliance" Attached to Stoma of Colostomy Patient. Gas and Odors Escape from Appliance at Site of Attachment (Stoma) to Body

CROSS SECTION OF
HYPOTHETICAL LAMINATED
APPLIANCE MATERIAL



(1) Water (H_2O) in feces leaches antimicrobial agent, e.g., sodium dibutyldithiocarbamate (A), from inner wall of appliance and kills and/or inhibits the growth of gas (odor) producing microflora.

(2) This is intended to minimize or eliminate "back pressure" of gases and their subsequent escape into the surrounding environment.

Figure IIA-22. Leaching of Water Soluble Antimicrobial Agent from Internal Wall of Appliance and Destrubtion of Gas Producing Microflora

UNIQUE ADVANCED TECHNOLOGY

An advanced waste collection system for colostomy and ileostomy patients would provide the following features:

1) Disposable appliances

   a) adult sizes

   b) children sizes

2) Gas scrubber options

   a) Self contained scrubber

   b) Reuseable cartridge type

   c) Gas management assembly (self contained scrubber): line or battery operated

3) Appliance materials

   a) Laminated plastic (gas impermeable) exterior

   b) Antimicrobial containing lining

   c) gas permeable lining

4) Silastic seal

5) Non-toxic

6) Adjustable belt

The proposed system would use a new concept in odor control for this type of product: (a) scrubbing of odor producing flatus and gases by means of (1) a self-contained activated carbon scrubber, (2) replaceable, cartridge-type scrubber, (3) isolated gas management assembly (GMA) suitable for operation from a nickle-cadmium battery. (b) retard growth of gas producing microflora in the feces by incorporating a water soluble antimicrobial agent in the lining of the gas-permeable lining.

In addition, the appliance would be equipped with a non-toxic, non-irritating silastic seal based upon the size of the patient's stoma; an adjustable belt to hold the appliance securely to the body; and a polyethylene bag and tie for disposal purposes.

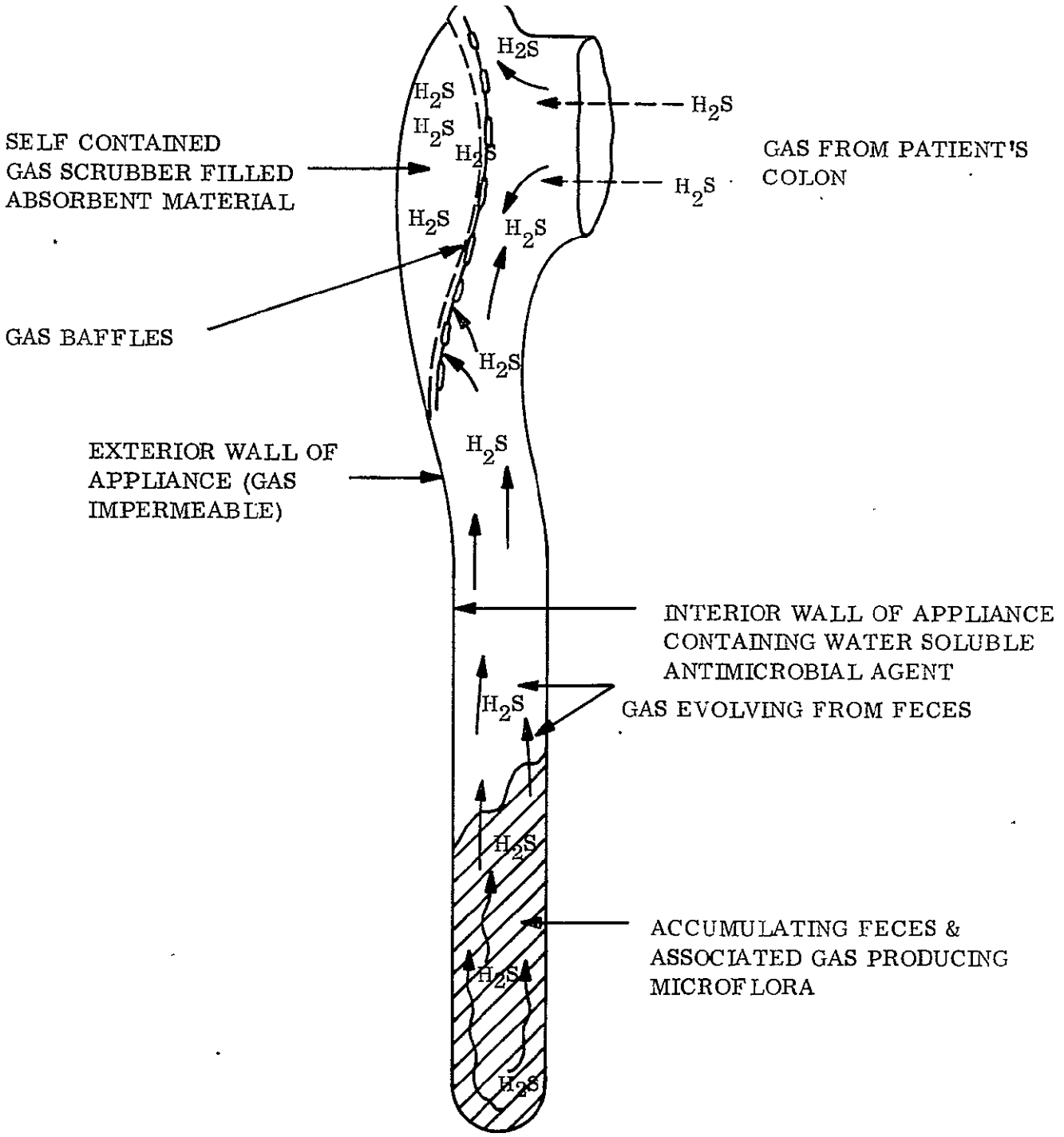


Figure IIA-23. Conceptual Design of a Odor Control System for a Disposable "Ostomy" Appliance. Cross Section to Show Gas Scrubber in Operation

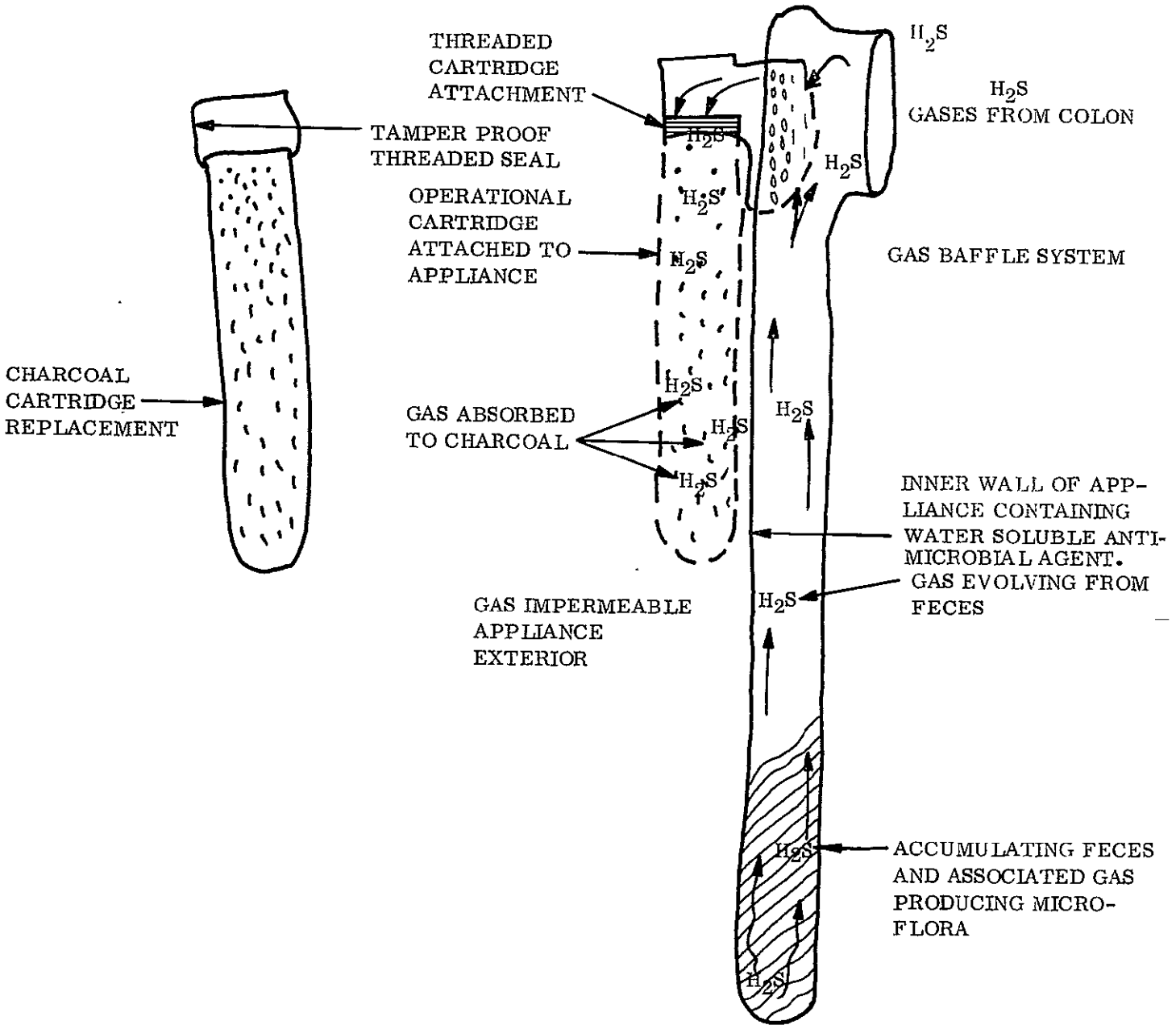


Figure IIA-24. Cenceptual Design of a Odor Control System for a Reuseable "-Ostomy" Appliance. Cross Section to Show Gas Scrubber in Operation and Replaceable Charcoal Cartridge

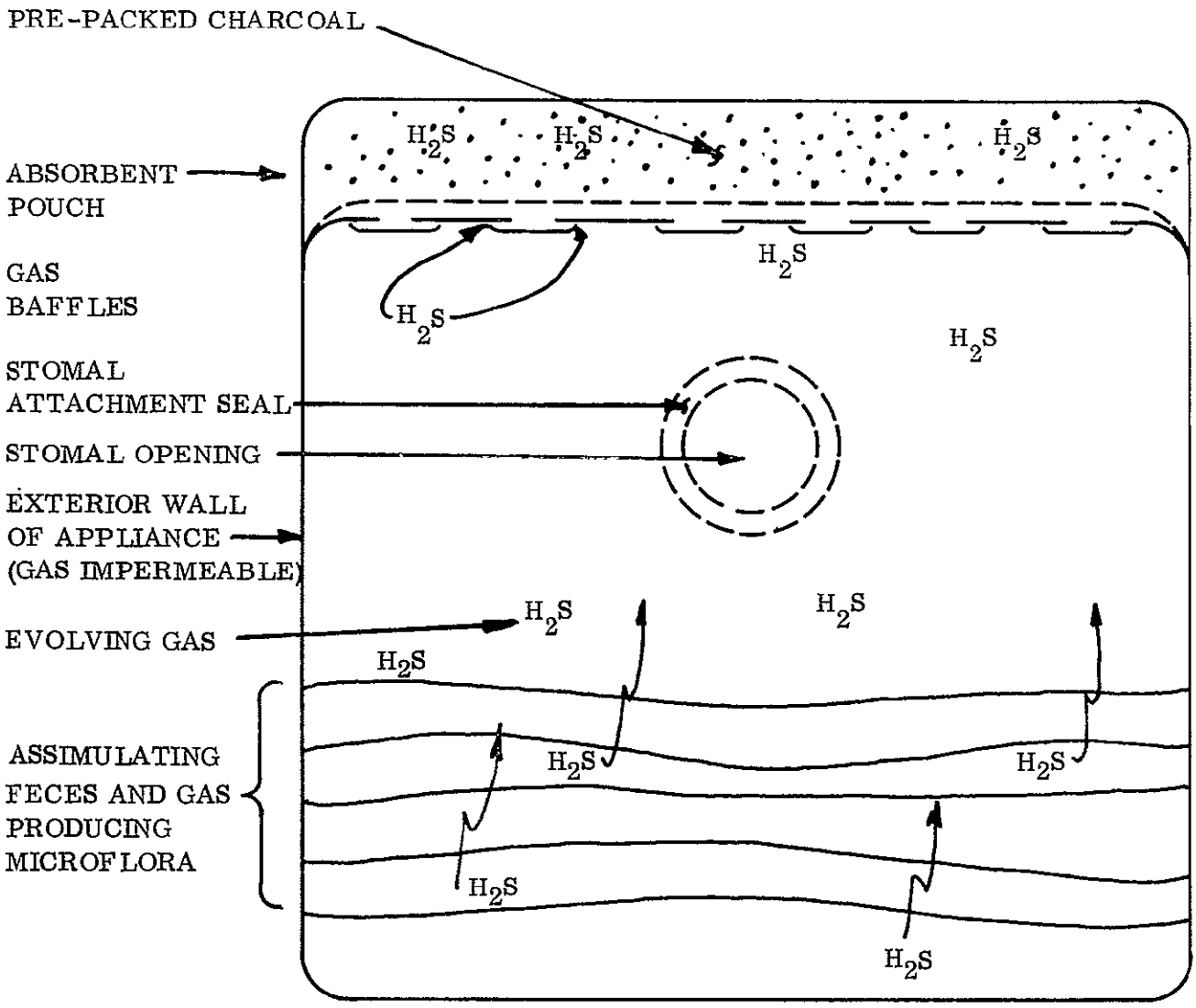


Figure IIA-25. Conceptual Design of a Odor Control System for a Disposable "-Ostomy" Appliance. Front View to Show Simple Charcoal Unit with Gas Baffles. Charcoal is Sealed in pouch at top of unit; Baffle prevents openings in scrubber from being Obstructed by Particulate Matter and/or Moisture.

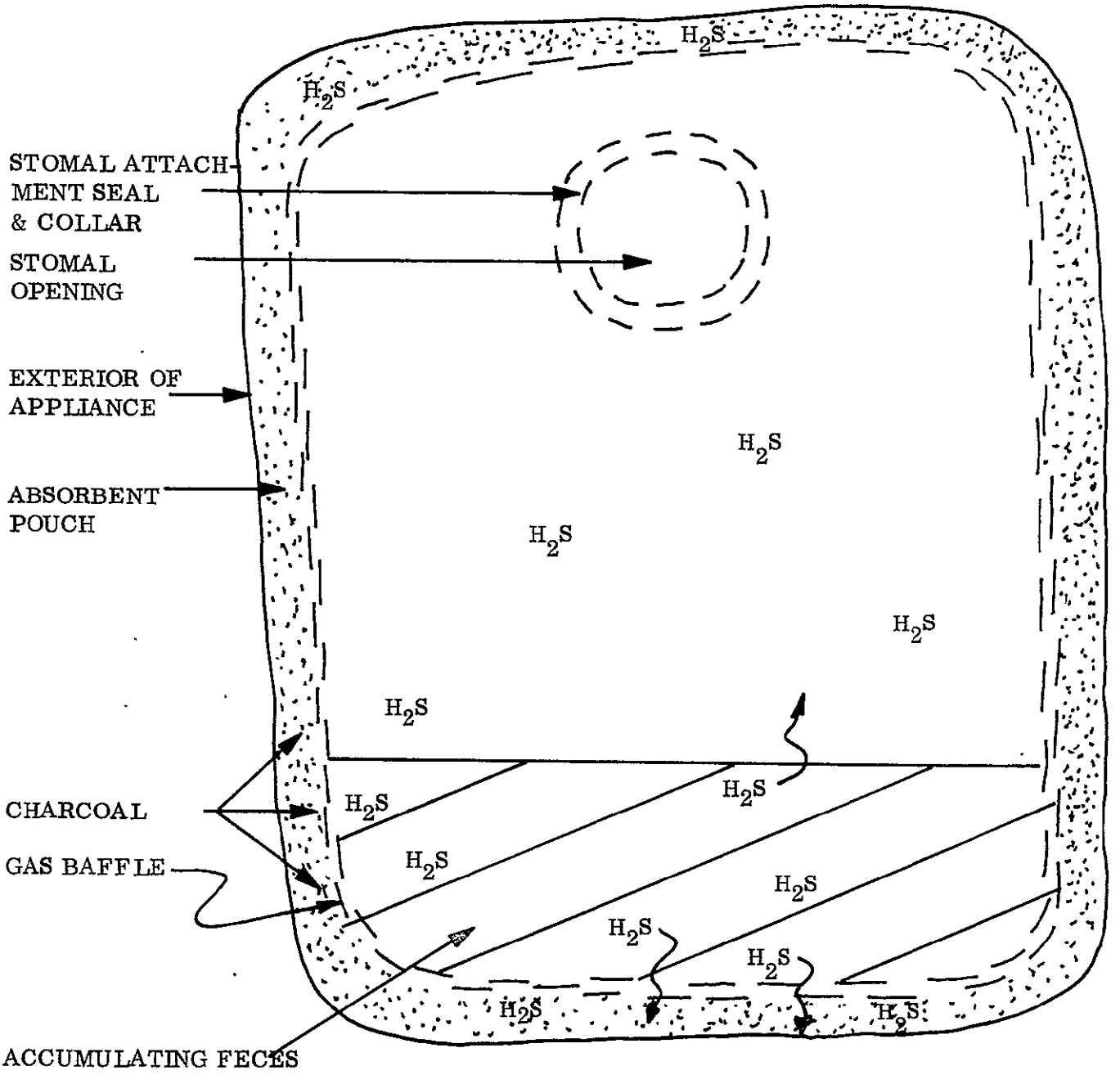
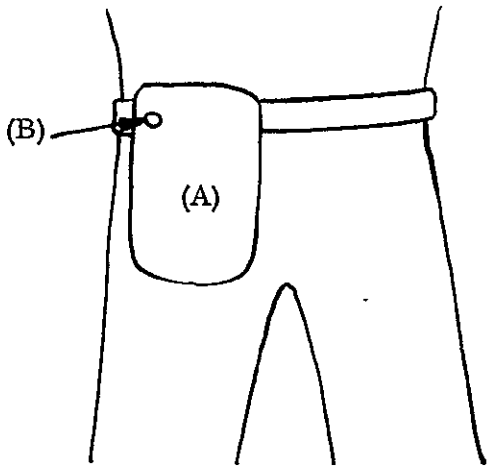
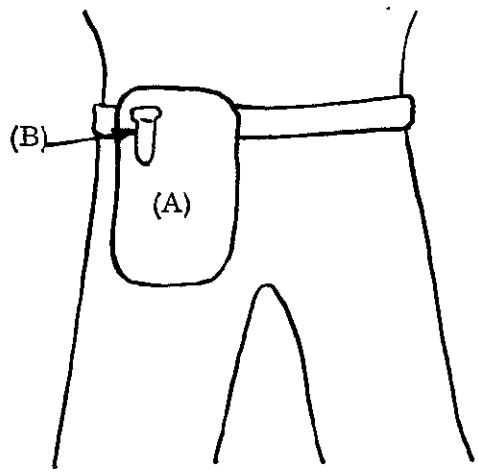


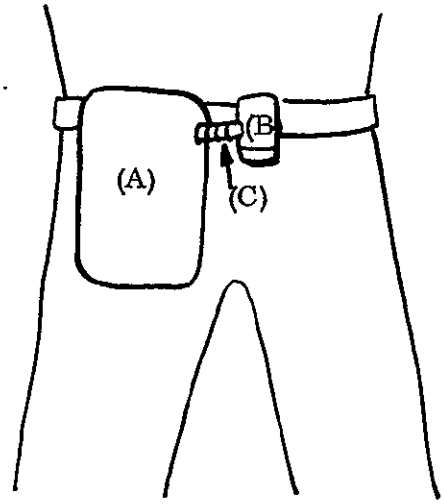
Figure IIA-26. Conceptual Design of a Odor Control System for a Disposable "-Ostomy" Appliance. In Comparison to Design Illustrated in Figure 6 Pouch for Absorbent is Continuous and Not Limited to the Top of the Unit.



Concept #1. Disposable waste collection system (A) with self contained odor control sub-system, See Figs. 4,6,7, equipped with a bacterial filter vent (B).



Concept #2. Re-useable waste collection system (A) with disposable (cartridge-type) charcoal scrubber (B).



Concept #3. Disposable waste collection system in sita (A) connected with flexible tubing (C) to battery operated Gas Management Assembly (B).

Figure IIA-27. Odor Controlled Waste Collection System: Conceptual Design of Gas Management Assembly

SUGGESTIONS FOR PRODUCING AN END PRODUCT

1) Optimize design of gas scrubbing sub-systems and breadboard

2) Optimize materials for appliance fabrication

3) Optimize appliance and seal design

4) Breadboard system and test

5) Prototype fabrication

6) 6-9 month clinical trials

SCHEDULE PLANNING SHEET

PROGRAM NAME ODOR CONTROLLED HUMAN WASTE COLLECTION

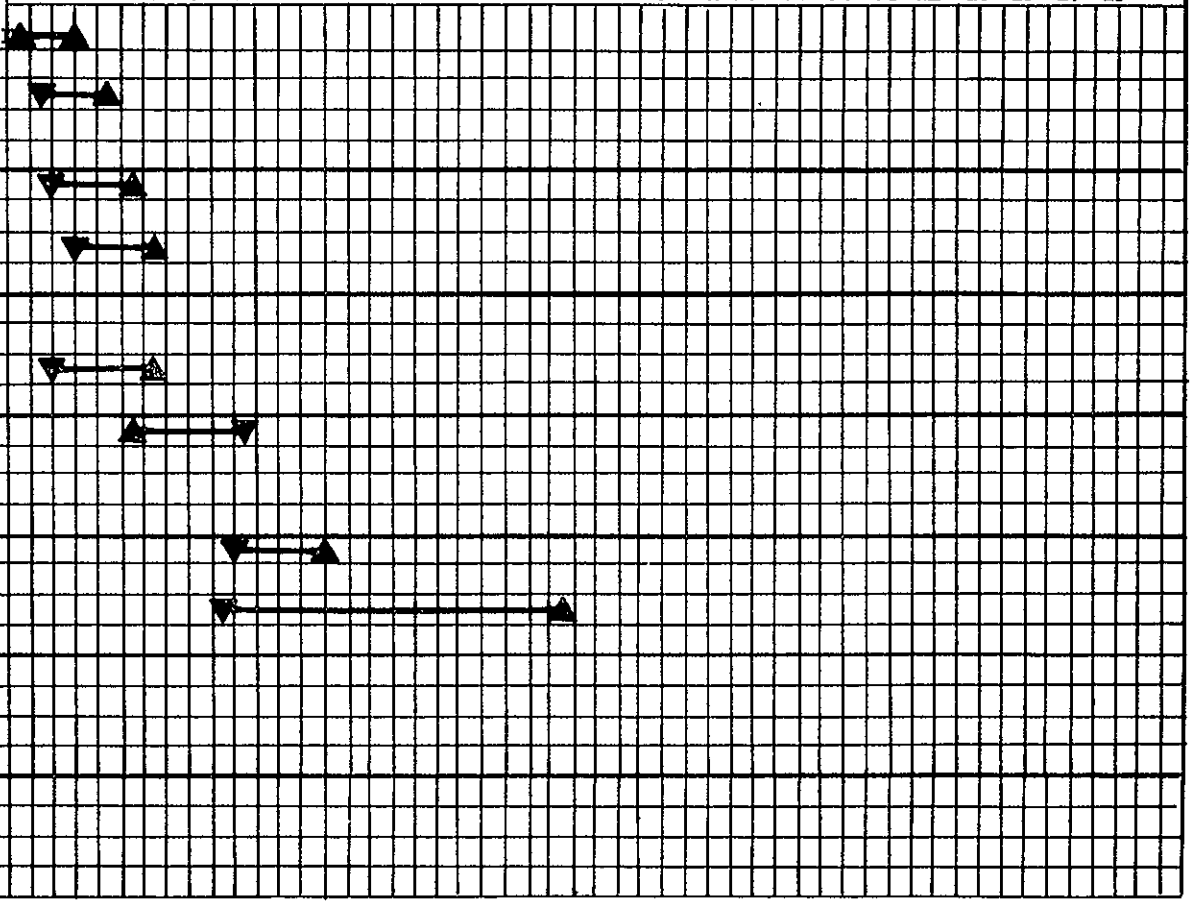
RESP. ORGAN	PROG WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	TITLE OF SEGMENT OF WORK

PURPOSE FOR ESTIMATE	APPROVALS	REFERENCES – P.P.I.NO.	REV.	OTHER

ELAPSED TIME SCHEDULE

(INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL WEEKS AS APPLICABLE)

ITEM NO.	DESCRIPTION OF WORK ITEM
1	Preliminary Field Survey (Med. Center)
2	Optimize design of gas scrubbing sub-system
3	Breadboard gas scrubbing system
4	Test breadboard gas scrubber
5	Optimize appliance materials
6	Test appliance materials
7	Breadboard total system
8	Advanced Field Survey
9	Prototype fabrication
10	Clinical trials



△=MILESTONES – DISCRETE, AUDITABLE EVENTS
E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲=COMPLETED MILESTONES

◇=PROJECTED MILESTONE SLIP

———=TIME PERIOD OF WORK

◆=SLIPPED MILESTONE

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FIGURE IIA-28

5.17 DEVELOPMENT OF AN AUTOMATED URINE COLLECTION AND MEASUREMENT SYSTEM

1.0 TECHNOLOGY DESCRIPTION

Urine collection and measurement was accomplished on the Biosatellite Primate Mission to provide urine for analysis (See XIV) and to maintain the cabin habitable for the primate. This task was accomplished with a 100 milliliter capacity collector, a peristaltic pump and a metering valve (10 cc), see Biosatellite Technology Summary. It is proposed that a prototype system, based on this technology, be developed and clinically demonstrated.

2.0 RECOMMENDED PROGRAM

Early verification of the applicability of the biosatellite type system may be demonstrated utilizing available biosatellite hardware. Conversion of the equipment design to satisfy clinical application and remove aerospace constraints would be followed by fabrication, installation and checkout of a prototype operational unit in a receptive hospital (approximately four months after contractual authority to proceed). Technical liaison, data evaluation and reporting in support of the hospital staff would be accomplished over a three month period.

Further technical, scheduling, and costing details are in the CCN to Contract AASW 2073-Proposal F32012.

SCHEDULE PLANNING SHEET

RESP. ORGAN	PROG WORK IDEN	CUST TASK NO.	PREPARED BY	RM.	EXT.	DATE ISSUED	PROGRAM NAME: DEVELOPMENT AND DEMONSTRATION OF AN AUTOMATED URINE COLLECTION AND MEASUREMENT SYSTEM
PURPOSE FOR ESTIMATE			APPROVALS	REFERENCES – P.P.I.NO.		REV.	OTHER

ITEM NO.	DESCRIPTION OF WORK ITEM	ELAPSED TIME SCHEDULE (INDICATE YEARS/ QUARTERS/ MONTHS/ FISCAL (WEEKS) AS APPLICABLE)
		00+ 10+ 20+ 30+ 40+ 50+
		0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2 3 4 5 6 7 8 9 0 1 2
(1)	DEMONSTRATE BIOSATELLITE URINE C&M ASSY AND LIFE SUPPORT CONTROLLER.	△
(2)	EVALUATE CLINICAL REQUIREMENTS	△——△
(3)	ACCOMPLISH PRELIMINARY DESIGN CHANGES	△——△
(4)	PRODUCE AND EVALUATE PROTOTYPE SYSTEM; FUNCTIONAL PROCEDURES	△——△——△——△
(5)	DELIVER, INSTALL AND TEST PROTOTYPE	▲
(6)	SUPPORT CLINICAL EVALUATION	△——△
(7)	PERIODIC PROGRESS REPORTS	
(8)	FINAL REPORT	△——△

△ = MILESTONES – DISCRETE, AUDITABLE EVENTS
E.G. – REPORT, HARDWARE DELIVERY, FLIGHT TEST, ETC.

▲ = COMPLETED MILESTONES

◇ = PROJECTED MILESTONE SLIP

——— = TIME PERIOD OF WORK

◆ = SLIPPED MILESTONE

STATUS AS OF 1-31-71

PAGE 1 OF 1

FORM RS 1702 B REV (1-67) – SCHEDULE PLANNING SHEET

FIGURE IIA-29

SECTION II

B. PRELIMINARY MANAGEMENT PLAN

1.0 ORGANIZATION

1.0 ORGANIZATION

1.1 CORPORATE ORGANIZATION

The General Electric Company is organized into eleven product groups reporting to the Corporate Executive Officers. Each group is composed of a number of divisions which are charged with the responsibility of fulfilling their respective business objectives and obligations. The Patient Monitor System Prototype Implementation and selected R&D Tasks will be performed within the Re-entry and Environment Systems Division (RESD) of the Aerospace Group (see Figure IIB-1). Mr. Mark Morton, is the Aerospace Group Executive and a GE Vice President. The Re-entry and Environmental Systems Division is under the leadership of Mr. Otto Klima, Jr., Vice President and General Manager.

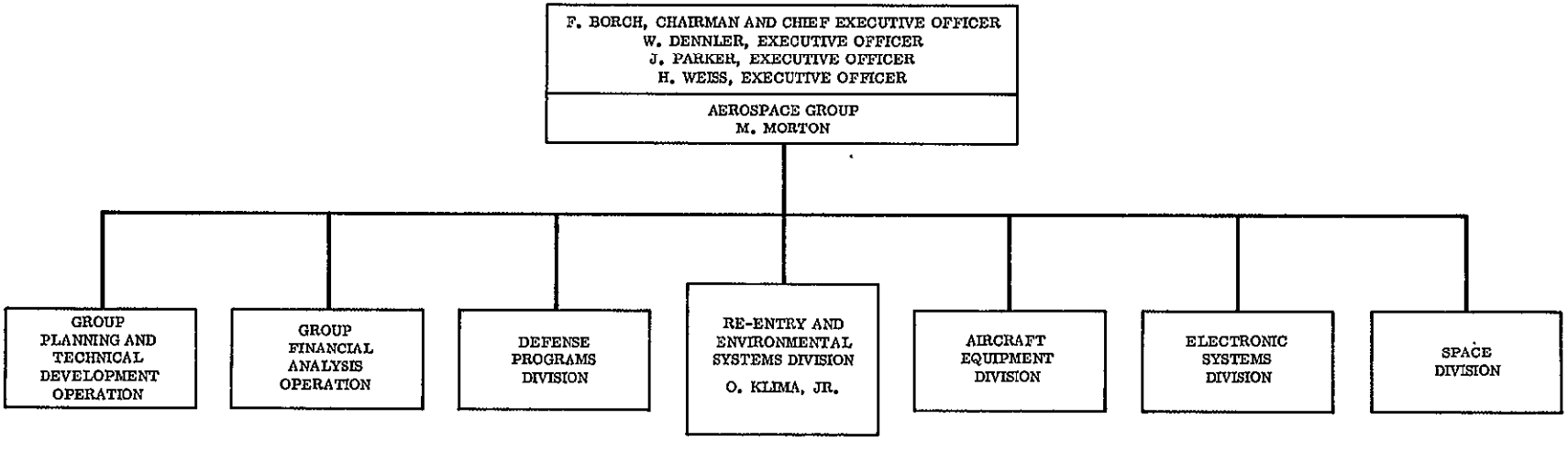

Figure IIB-1. General Electric Corporate Organization

1.2 DIVISION ORGANIZATION

In the program management/functional organization structure of GE-RESD, as illustrated in Figure IIB-2, a number of program management sections have been established: Space Re-entry Systems, Strategic Systems, Ocean Systems, Urban Systems, and Operational Systems. These sections are supported by the functional organizations of Research and Engineering, and Operations and Evaluation (which includes Systems Test and Operations, Manufacturing, Quality Assurance, Materiel and Facilities), as well as the service organizations such as Finance, Legal, and Contracts.

Space re-entry systems programs, including Bioscience Programs, are performed under the management of Mr. Walter D. Smith, General Manager, Space Re-entry Systems Programs. Mr. R.F. Welsch, Manager of Bioscience Programs has cognizance of all Bio-Space and Medical activities for the Division.

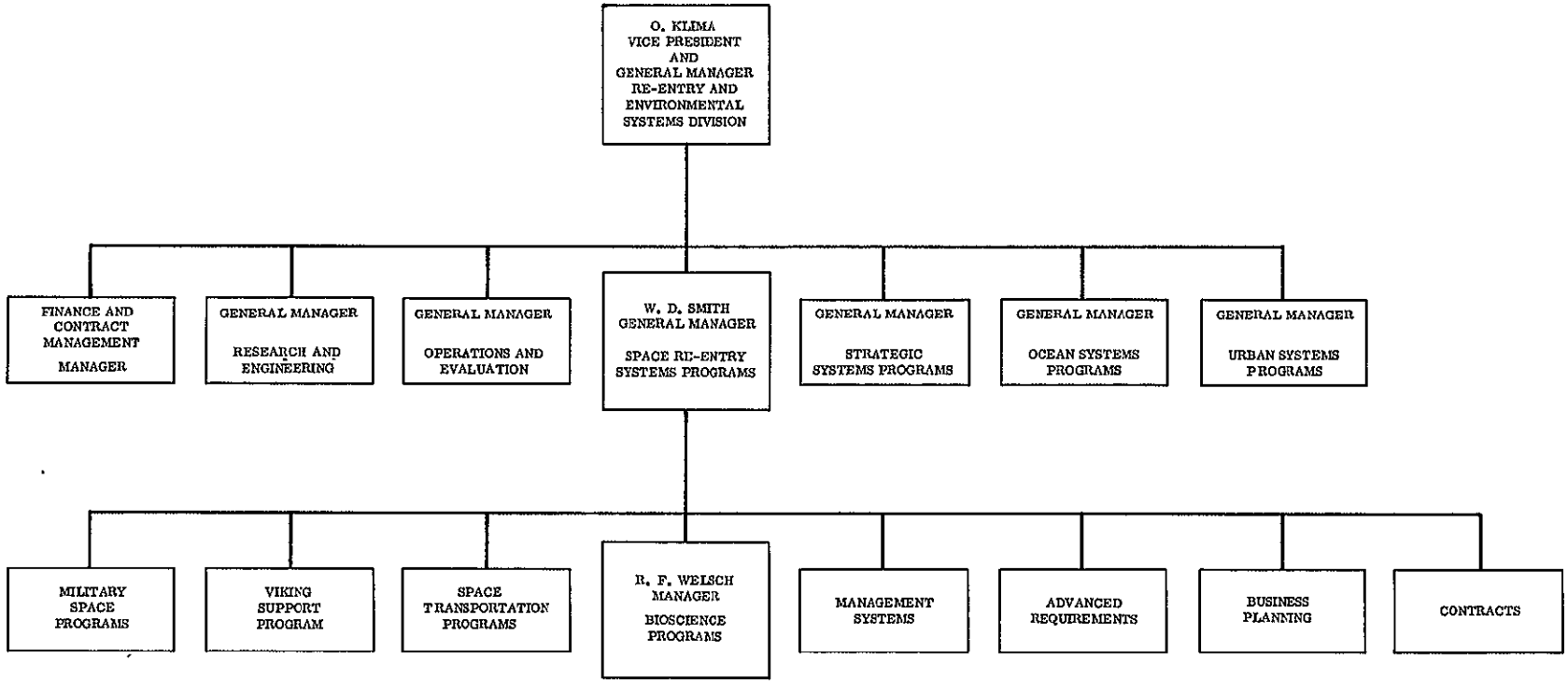

Figure IIB-2. General Electric Re-entry and Environmental Systems Division Organizations

2.0 MANAGEMENT

2.0 MANAGEMENT

The proposed tasks will be under the direction of Mr. Welsch with support of the contributors to the PMS study contract effort. Mr. W.A. Buck, as Project Manager will focus all tasks associated with this effort.

The PMS task will be organized to provide single point control of three key functional activities:

- Hardware Design
- Software Design
- Manufacture, Assembly and Test

The R&D tasks will be lead by individuals with proven technical skill and experience related directly to the specified task as well as managerial capability. R&D task support teams will be assigned on the basis of capabilities and experience in the disciplines and technological skills.

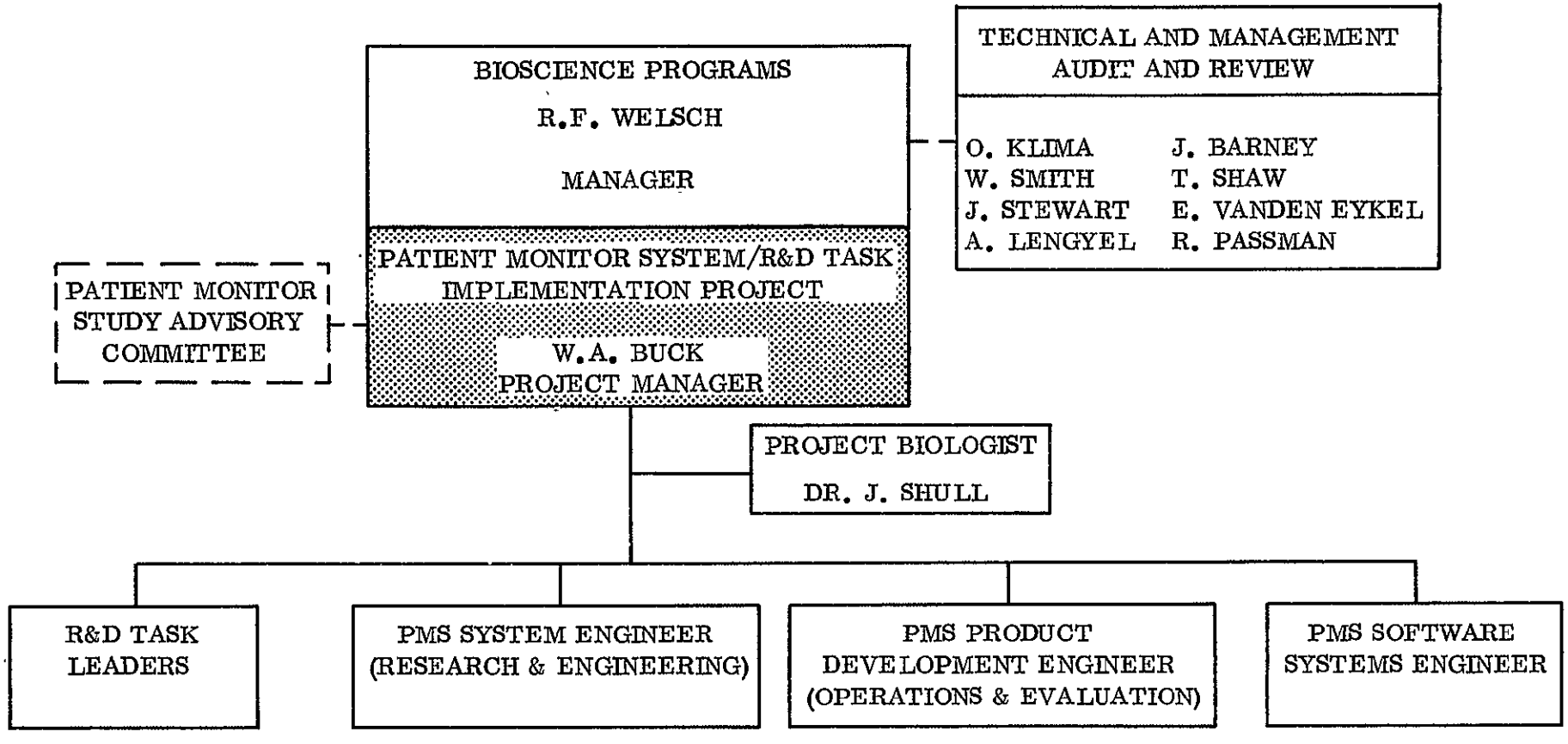

Figure IIB-3. Project Team Organization

3.0 KEY PERSONNEL

TABLE IIB-1. KEY PROGRAM PERSONNEL

Name and Function	Education and Related Experience	Percent of Time	Years Experience	
			Total	GE
R.F. WELSCH Bioscience Programs Manager	BSME - University of Wisconsin. • Program Manager, MK-3C Program - An airborne radar map-matching system using terminal guidance equipment in re-entry vehicles. • Program Manager, Terminal Radiation Program - An optical tracking system for re-entry measurements. • Program Manager, Maneuvering Ballistic Re-entry Vehicle Program (MBRV). • Program Manager - Overall responsibility for management of NASA's Biosatellite series of orbital-recoverable spacecraft.	-	22	20
W.A. BUCK Project Manager	BSME, University of Rochester • Supervising Engineer - Apollo Program - digital data systems design for automatic spacecraft acceptance checkout equipment (ACE). Operations Engineering of the ACE system and related spacecraft checkout systems. • Manager - Central Ground Station - established and developed centralized computer controlled data acquisition system for support of systems test. • Manager - Minuteman III R/S and P/A systems test, performance of systems development, flight proof qualification and acceptance tests of R/S and P/A systems.	80	11	7

TABLE IIB-1. KEY PROGRAM PERSONNEL (Continued)

Name and Function	Education and Related Experience	Percent of Time	Years Experience	
			Total	GE
DR. J.J. SHULL Biologic Consultant	BS, MS, and PhD - Pennsylvania State Univeristy • Manager, Biological, and Medical Services Laboratory - Responsible for studies of preservation and analysis of biological materials, cardiovascular research, and development of life support techniques for spacecraft. • Contributed substantially in the area of sterilization and microbial control research and development and water and waste water treatment and monitoring. • Experiments Consultant for Biosatellite - Responsible for interface between experimenters and spacecraft design personnel.	25	19	5
DR. D. EKBERG R&D Tasks	BS - University of Illinois (Chemistry) MS - University of Chicago (Physiology) PhD - University of Illinois (Physiology) • Senior Aeromedical Engineer, Martin Company - Aviation Physiology. • Postdoctoral Fellow, U.S. Public Health Service - Research in Temperature adaptation. • Physiologist, General Electric Co. - Manned Space Vehicle Studies, BIOS I, research involving the biological effects of very low magnetic fields, biorhythms, temperature adaptation, atmosphere selection; amoeba experimenter on Biosatellite I. • Adjunct Professor, Environmental Engineering, Drexel University. • Manager, Biosciences Operation; Space Systems.	25	13	11

TABLE IIB-1. KEY PROGRAM PERSONNEL (Continued)

Name and Function	Education and Related Experience	Percent of Time	Years Experience	
			Total	GE
DR. N. KUCHAR R&D Tasks - Bio Fluid Mechanics Manager	BS, MS, and PhD - Case Institute of Technology • Group Leader, Bio Fluid Mechanics - Concerned with research in the area of mathematical modeling of fluid dynamics, solid mechanics and transport phenomena in biological systems. Areas of research include modeling of the pulmonary circulation, an investigation of flow and mass transfer in blood oxygenators, a study of the onset of turbulence in blood flowing in artificial pumping devices, and investigation of the effects of weightlessness and high acceleration on the distribution of blood in the human body.	25	3	3
B.C. BURGESS PMS Software Systems	BSEE, University of Southern California ME Administration, Syracuse University • Urban System Engineering - data systems management, programming and data processing. • Systems engineering of electronic and digital systems for air weapon control and spacecraft/launch vehicle pre-flight checkout. • Manager - Data Processing, Apollo/Saturn Space Programs.	90	15	10
S.G. KRITZSTEIN PMS System Engineer	BSEE, MSEE, University of Pennsylvania • System Design Consultant to Telemed Program, University of Missouri. • System Design Consultant for Arizona Heart Institute Facility. • Primary system design for manned simulator on the Manned Orbital Lab Program.	90	11	11

TABLE IIB-1. KEY PROGRAM PERSONNEL (Continued)

Name and Function	Education and Related Experience	Percent of Time	Years Experience	
			Total	GE
M.A. MALO PMS Product Development Engineer	BSEE, University of Miami • Product Development Engineer, Multiphase Medical Data Acquisition Unit. • Product Development Engineer, Ocean Programs. • Project Test Engineer, Biosatellite. • Group Leader, Thor/Delta Space Vehicle Test and Launch, Douglas Aircraft Co.	80	12	5
J.A. GANNON PMS Project Test Engineer	BEE, Catholic University of America MS Electrical Engineering, University of Connecticut • Biosatellite Project - primate mission - primate/spacecraft interface engineer covering life support, behavioral testing and physiological monitoring system. • Project Engineer on Lankenau Hospital Electrocardiogram Program. • Design/development and test of electronic and electromechanical analog computer systems.	75	13	4
R.B. LANDIS Project Integration	Aero Engineer, Pennsylvania State University, and Oklahoma A&M • Chief Project Engineer - Prewitt Aircraft Corp., Clifton Heights, Pa. Design/development of bonded metal rotor blades. • Development Engineer - Skybolt Project, GE-RESD. Subsystem requirements, design and integration. • Program Requirements - Biosatellite Project - GE-RESD. Technical requirements, interface control, documentation, technical integration.	50	27	8

TABLE IIB-1. KEY PROGRAM PERSONNEL (Continued)

Name and Function	Education and Related Experience	Percent of Time	Years Experience	
			Total	GE
M.K. WOLFSON Project Control	BSE (ME & AeE), University of Michigan. Registered Professional Engineer - Massachusetts • 206 Program: Project Engineering Manager in program office responsible for system and subsystem integration and planning, and control of all in-house activities in support of vehicle delivery. • MBRV: Project Manager responsible for planning, scheduling, and control of total program with special assignments as Vehicle Manager to assure on-time delivery. • Biosatellite: Program Manager responsible for planning, scheduling, and control of detailed program activities, customer interfaces for scheduling, financial and business matters, and proposals.	25	24	24
T.P. FROST Computer System Engineer	BS Electrical Engineering - (cum laude) Princeton University • Information systems and digital computer applications engineer. • Biosatellite Project - design/development of computer systems used in systems testing of spacecraft. • Automated real-time systems testing for dynamic environment tests of all types of aerospace equipment.	75	20	16

TABLE IIB-1. KEY PROGRAM PERSONNEL (Continued)

Name and Function	Education and Related Experience	Percent of Time	Years Experience	
			Total	GE
DR. KARL SITTEL Consultant, Biomedical Technology Projects	Physics, Physical Chemistry, Biophysics University and Max Planck Institute for Biophysics, Frankfurt am Main, German, PhD 1940 • Staff Consultant with GE/ESL - Physiological systems modeling: cardiovascular system and myocardium biomedical technology. • RCA - System physics, staff member and group leader. • Franklin Institute - Senior Staff Physicist; bio-acoustics, viscoelasticity, instrumentation. • Jefferson Medical College - Consultant in Bio-acoustics. • US Navy - Aeromedical Equipment Laboratory, Leader of Bioinstrumentation Laboratory, electrical impedance of biological materials, bioacoustics. • German Marine Observatory - Director of Aerological Instrumentation Laboratory	75	31	4
DR. W. EDWIN SAUER Biochemical Engineer	BS Chemistry, Ursinus College, 1957 MS Physics, University of Pennsylvania, 1964 PhD Materials Engineering, Drexel Institute of Technology, 1969 • Biochemical Engineer - GE Environmental Sciences Laboratory. • Materials Engineering Department, Drexel Institute of Technology - Research Associate, transition metal solutes and the electronic and magnetic structure of iron-base alloys. • Space Sciences Laboratory, GE - Materials Physicist, thin film processes, sputtering process for metallizing fivers, laser evaporation process for congruent alloy deposition.	50	13	7

TABLE IIB-1. KEY PROGRAM PERSONNEL (Continued)

Name and Function	Education and Related Experience	Percent of Time	Years Experience	
			Total	GE
DR. W. EDWIN SAUER (Continued)	• Semiconductor Division, Philco-Ford Corp. - Chemist, electro-chemical processes for transistor fabrication; Department Supervisor, directed electrical testing of transistors.			
DR. MARCEL MARTIN Cardiac Programs Development	PhD (Physics) - Institute of Optics, Paris, France, 1934 • Research and Design - Microscopes & Microscopy, American Optic Co. • Digital Computer Design, Jacob Instruments • Digital Computer Design and Applications, Burroughs • Manager, Scientific Data Processing and Handling • Consulting Physicist - Cardiac Program Development	50	36	14
DR. E. LANGBERG Manager, Cardiac Monitoring Systems RESD	BSEE, University of Pennsylvania, 1953 PhD Electrical Engineering - (Physics) 1956, Princeton University • Industrial, Scientific and Medical Instrumentation • Research Staff, New York Medical College • Consultant, MIT Lincoln Lab. • Consulting Engineer, Bio-science Program RESD	50	14	1
A. BRYCE Bio-Chemical Systems Engineer	BA (Biology) - Temple University • Pharmaceutical screening, BMR measurements, Bioassay procedures - Smith, Kline & French • Research and development of closed cycle ecological systems and waste recycling. • Biological and biochemical methods development for clinical testing and bioassay procedures.	30	14	10

TABLE IIB-1. KEY PROGRAM PERSONNEL (Continued)

Name and Function	Education and Related Experience	Percent of Time	Years Experience	
			Total	GE
DR. V. KLEMAS Manager Optical Physics	BS, Electrical Engineering, M.I.T. MS, Electrical Engineering & Physics, M.I.T. PhD, Optical Physics, Technical University Braunschweig • Manager of Optical Physics and Pollution Sensing Projects at GE's Environmental Sciences Laboratory; remote sensing of environment and detection of man-made targets, water and air pollution monitors, remote sensing, multispectral imaging, photoimaging studies, new optical modulation techniques. • Dr. Klemas is currently a lecturer on Laser Theory and Applications, Pollution Sensing and Remote Sensing of Environment at the Penn State Graduate Center.	30	10	10

4.0 TASK STATEMENTS

4.0 TASK STATEMENTS

The following tasks statements broadly define the proposed activity for Patient Monitor System implementation and R&D Task Performance.

4.1 PATIENT MONITOR SYSTEM IMPLEMENTATION

- Provide design and development costs (up to *)
- Develop and issue program and management plans (including detail work statements)
- Finalize the PMS system specification
- Analyze and trade off design solutions; issue design specification
- Accomplish prototype hardware and software design and development; issue prototype drawings
- * Provide a manufacturing plan and schedule, an integrated test plan and schedule, and estimated costs
- Procure material and hardware; initiate fabrication cycle
- Issue prototype test and evaluation procedures
- Complete fabrication and initiate factory test and development tasks
- Issue operations plan, operational procedures, evaluation criteria and maintenance notes
- Box, pack and ship
- Install and verify equipment operability
- Integrate hospital supplied equipment, procedures and personnel; provide operational training
- Support clinical evaluation of system
- Provide routine maintenance and repair
- Provide periodic task reviews and reports
- Provide a final report and recommendations

4.2 R&D TASKS

- Provide expanded descriptions of task elements as delineated in the task summary sheets, Section II A-5.0
- Provide task costs (excluding hardware costs since hardware is not yet defined)
- Proceed with authorized tasks as delineated
- Where applicable provide hardware recommendations, conceptual designs and estimated hardware costs
- Provide periodic task review and letter reports
- Provide final report and recommendations

5.0 PROJECTED INTEGRATED SCHEDULE OF R&D TASKS WITH PATIENT MONITORING SYSTEM IMPLEMENTATION

5.0 PROJECTED INTEGRATED SCHEDULE OF R&D TASKS WITH PATIENT MONITORING SYSTEM IMPLEMENTATION

A recommended integrated schedule of tasks is given in Figure IIB-4. This schedule coordinates R&D task activities that are interactive with PM System Implementation phases and with other R&D tasks. Although each task may be accomplished and effective independently, significantly increased value or application of value will be realized by phasing and coordinating the results of the tasks as shown.

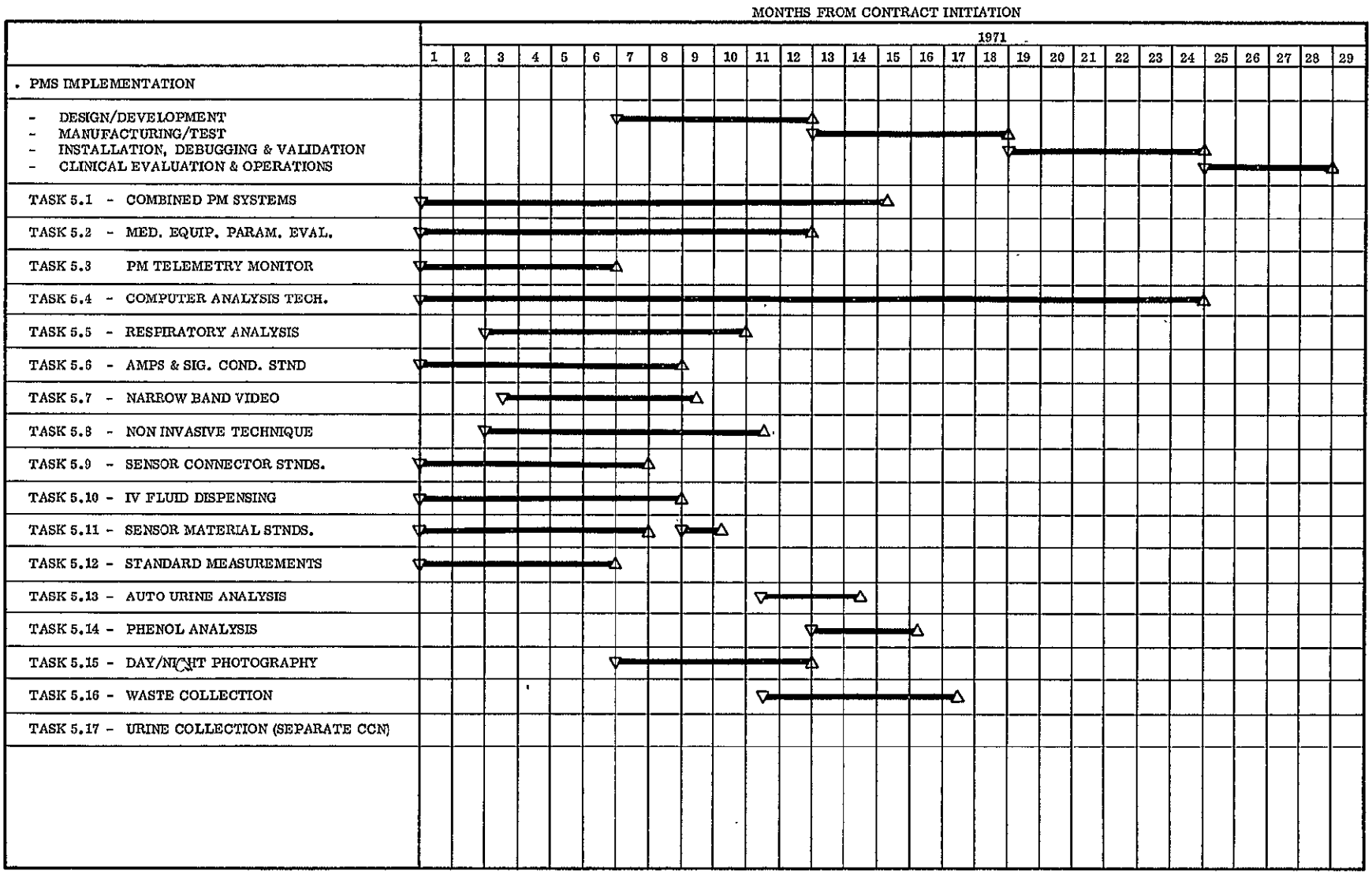

Figure IIB-4. Recommended Integrated Schedule

6.0 BUDGETARY COST ESTIMATES

6.0 BUDGETARY COST ESTIMATES

6.1 INTRODUCTION

Budgetary cost estimates were developed for implementation of the patient monitoring system and are delineated in paragraph 6.2. Order of magnitude cost data are provided for a total prototype systems and for portions thereof.

Additionally, in paragraph 6.3, preliminary cost data are provided for each of the research and development tasks proposed in Section IIA, paragraph 5.0.

6.2 PATIENT MONITOR SYSTEM

6.2.1 Assumptions

Certain assumptions have been made in costing the patient monitoring system. These assumptions were made to reflect the availability of already developed medical, aerospace, and commercial technology, equipment, and facilities. As found from the survey of the four host hospitals, from the literature searches, from endeavors by the team members in other medical areas, and from aerospace experience it is possible to assemble advantages that can save time, money, and strengthen the communications between the medical and engineering personnel who will perform this work.

In configuring the systems for the purposes of program planning, scheduling, and budgetary cost estimates; the following assumptions were made:

a. The same basic computer would be used for Modules I, II, III and IV. As requirements (unique to the applications of each module) change, the basic computer configuration would change in such things as core size, peripherals, etc.

b. The larger "host" computer of Module II, used to augment the basic minicomputer, is not included in the costing. The relatively small amount of time required of the more powerful machine was considered to be made available by the hospital.

c. The "OPTIONAL" equipment as listed in the Final Report in the Section VI matrix DATA PROCESSING SUB-SYSTEM are not included in the costing.

d. Equipment usually supplied by the hospital that would be employed by the Patient Monitoring System was not costed. These include such items as EKG machines, blood and urine analyzer, catheters, sensors, etc.

e. Consultant/services, as required, would be supplied through the contracting agency.

f. In acceptance of the computer it was assumed that that function would be performed in the manufacturer's facility.

g. The patient monitoring program in the form of a card deck copy, printout listing, and/or a magnetic tape copy in machine level language and/or assembly language would be available on request to the contractor. These programs would not have descriptive documentation.

h. Each of the modules described will handle four (4) patients each. The full system will handle four (4) patients per module or potentially sixteen (16) patients total.

i. In defining and costing the systems the following types of equipment configurations were included:

Modules I, II, III, IV, and Full System*

Signal Conditioner (4)

Multiplexer - Analog to Digital Converters

Analog to Digital Interface

Time Code Generators

Time Code Interface

Data Entry and Logical Controls

Minicomputer

Paper Tape Reader/Punch

Remote Input/Output Interface

Nurse's Station Input/Output

Cables

Equipment Cabinet

Power Supplies

Nurse's Station

Data Entry

Alarm System

Analog Recorders

Digital Display

* NOTE: The "Full System" includes the functions performed by Modules I, II, III, and IV but it does not include a Nurse's Station.

Alpha-numeric/Graphic CRT Device

Command and Control Logic

Switching Interface

Hardcopy Printer

Analog CRT

Console Enclosure

Analog Amplifier Assembly

System Switching and Data Bus

j. The prototype system's minicomputer will have customer furnished peripheral equipment to be used in the development and checkout stages of the systems. This would include magnetic tape, disc, card reader/punch, typewriter, printer equipment, and adequately large core memory appropriate for developmental activities.

k. Development or demonstration of the Patient Monitoring System's capability for remote sites is not in scope.

6.2.2 Cost and Pricing Information

Classification of Direct Labor

The direct labor effort to perform each task/subtask of this proposal has been estimated in units of manhours by engineering, manufacturing, quality control, and project personnel. These manhour estimates have been evaluated based upon past experience to assure their reasonableness; e.g., the engineering direct labor hours for this program were developed by the engineering section planning personnel through analysis of the work statement requirements.

The labor rates used in this estimate come from the latest table of Labor Estimating Rates. These approved rates include a factor representing a share of each employee's vacation and holiday time, as well as an increment factor for salary increases.

Direct Material

The following is a brief description of the types of direct materials used in the costing of this estimate, and the basis for arriving at the estimated costs for these materials.

Material prices are determined in one of three ways:

(a) They are priced from vendor quotations

(b) They are priced from recent purchases of similar items.

(c) They are priced from engineering estimates for unique or specially designed items for which we are unable to obtain vendors' quotes because of design uncertainties.

Purchase Orders

Where the functional operations determined that the required items are identical or similar to items previously purchased the latest purchase prices for these items were used.

Other GE Departments

Work orders and intra-company purchase orders placed with other GE Departments are treated as direct material for cost computation purposes.

Catalog Items

Prices are based on vendor catalog prices.

Travel and Living

Travel and living expenses are charged to burden accounts and are liquidated through the application of negotiated burden rates.

Reports

This amount represents the estimated cost of publishing reports, exclusive of the research, development, and technical writing; it includes editing, illustrating, and typing effort.

Burden Rates

Engineering Overhead Expense (EOE)

Engineering overhead expense includes operating costs that are not considered direct contract charges. Examples are salaries of supervisory and clerical personnel, depreciation, travel and living expenses, maintenance, and indirect materials. The estimated EOE rate included in the proposal is based upon historical data plus projected future expenses. Allocation of EOE is based on the applied labor costs charged to contracts.

General and Administrative Expense (G&A)

This represents the cost of overall administration of the department for the functions of Contract Administration, Finance, Legal, and Employee Relations. Total G&A expenses are allocated to contracts on the basis of total cost, excluding G&A. The estimated G&A rates used in the proposal are based upon historical data plus projected future expenses.

6.2.3 Patient Monitoring System Budgetary Cost Estimates

1. The costs in the table below are related to only one of many different combinations and permutations of the four patient monitoring modules. This data represents a progression from one basic four patient module, through additions of other modular functions to that basic module. That is, Module II would be constructed first. Then, to that basic Module II, would be added the required elements of Module I, Module III, and/or Module IV. The initial development costs include non-recurring costs associated with the first system only. The costs associated with provisioning subsequent identical modules are estimated to be less than 40 percent of the initial costs.

Patient Monitoring System ROM Costs

Modules	Initial Modules		
	labor	material	total
II	$498.7K	$112.9K	$591.6K
add I	117.6K	56.8K	174.4K
add III	306.6K	64.3K	370.9K
add IV	336.9K	64.3K	401.2K

2. Another method of producing the four modules is described below. These figures represent that which would be required to build modules I, II, III, and IV all at once. Again, additional systems would cost on the order of 60 percent less than the initial prototype system.

Modules I, II, III, and IV ROM Costs

Initial System		
labor	material	total
$847.1K	$232.8K	$1,079.9K

3. The modules described in 1 and 2 above do not include a nurse's station. The cost for producing the first nurse's station is as follows:

Nurse's Station ROM Costs

Initial Station		
labor	material	total
$145.7K	$130.9K	$276.6K

Nurse's stations are estimated to cost approximately 30 percent less for production versions of the developed prototype.

6.3 RESEARCH AND DEVELOPMENT TASKS

6.3.1 Assumptions

Budgetary costing has been developed for purposes of assessing the magnitude of each proposed R&D task. In assembling these cost estimates, the following assumptions were made:

a. Consultant services required would be supplied through and funded by the Customer. These services include those of the advisory committee and those individuals responsible for cardiac computer programs.

b. All hardware required for evaluation and/or modification of "existing methods" shall be supplied at no cost to GE-RESD.

c. All software required for analysis, evaluation and/or modification shall be supplied by the Customer.

d. No production costing is included since hardware definition is dependent upon early task effort defined herein.

e. All hardware received on loan from or through the Customer shall have configuration documentation maintained. No irreversible modifications shall be made.

f. All "on loan" hardware shall be returned to the Customer within 30 days of task completion.

6.3.2 Cost and Pricing Information

Refer to paragraph 6.2.2 for cost and pricing information.

6.3.3 Budgetary Cost Estimates

Budgetary cost estimates for each recommended R&D task are tabulated in the table on the following page.

TABLE IIB-2. R&D TASK BUDGETARY COST ESTIMATES

Task No.	Task Title	Labor Costs	Material Costs	Total Costs	Relative Time Span
5.1	Combined PM Systems Software	$203.5K	-	$203.5K	14.5 Mo.
5.2	Existing Medical Equipment Evaluation	52.0K	-	52.0K	12.0 Mo.
5.3	PM Via Telemetry	46.2K	$ 3.6K	49.8K	9.5 Mo.
5.4	Computer Analysis Techniques	288.4K	-	288.4K	24.0 Mo.
5.5	Respiratory Analysis	66.0K	5.7K	71.7K	8.0 Mo.
5.6	Amplifier & Signal Conditioner Spec.	46.2K	-	46.2K	6.0 Mo.
5.7	Narrow Band Video Systems	44.0K	-	44.0K	6.0 Mo.
5.8	Non-Invasive Techniques	46.8K	5.3K	52.1K	8.5 Mo.
5.9	Sensor Connectors	90.0K	1.2K	91.2K	7.0 Mo. To Hardware Evaluation, 10.0 Mo. Total
5.10	IV Fluid Dispensing	36.7K	2.3K	39.0K	8.0 Mo.
5.11	Sensor Materials	45.9K	0.8K	46.7K	8.0 Mo.
5.12	Standard Measurement Spec.	40.0K	7.3K	47.3K	6.0 Mo.
5.13	Automated Urine Analysis	19.6K	5.4K	22.0K	3.0 Mo.
5.14	Advanced Phenol Analysis	20.4K	3.6K	24.0K	3.5 Mo.
5.15	Day/Night Photography Applications	22.7K	2.4K	25.1K	6.0 Mo.
5.16	Human Waste Collection	128.2K	31.5K	159.7K	6.0 Mo.
5.17	Urine Collection & Measurement	(Submitted via Separate CCN)			

7.0 PLACE OF PERFORMANCE

7.0 PLACE OF PERFORMANCE

The tasks previously defined will be accomplished at Division Headquarters of GE-Re-entry and Environmental Systems Division located at 3198 Chestnut Street, Philadelphia, Pennsylvania except as noted herein.

Exceptions include specialized elements of research and development tasks which are more suitably accomplished in specific technology oriented laboratories at nearby suburban facilities of the Division. These facilities are located in the Space Technology Center at Valley Forge and the Cabot, Cabot and Forbes Industrial Park in King of Prussia.

Additionally, the installation, validation and operational evaluation of PMS equipment provided by GE-RESD will be accomplished at a medical center designated by the customer.

SECTION III
RELATED EXPERIENCE

SECTION III

A. CORPORATE

III. RELATED EXPERIENCE

III A. CORPORATE

The General Electric Company makes and sells products that are:

- used in construction of medical facilities
- used in hospitals for non-medical purposes
- components supplied to producers of medical equipment (including internal GE elements)
- health products sold directly to the general public
- software and services for the medical profession; including computer time sharing
- plastics and other materials used in prosthetics
- communications products
- medical x-ray and related products

Current medical product areas include equipment supplied to professional medical specialists; specifically, radiologists, thoracic surgeons and cardiologists.

This equipment includes:

- an extensive array of medical monitoring instruments produced by the Medical Systems Division at Milwaukee
- operating room monitors produced by Canadian GE
- intravenous flow regulators developed by the Heavy Military Electronics Division
- Nuclear Eye Monitor, a radioisotope scanner marketed by Space Technology Products
- Cardio-Alert monitors - an ECG telemetry system for emergency vehicles marketed by the GE Mobile Radio Department and Canberra Industries

In summary, diverse capability, experience and beneficial products have been and are being developed within the GE Corporate complex. Direct and supporting activities extend from the broadly applied Research and Development Center and the Electronics Laboratory to the product oriented divisions and departments including the Re-entry and Environmental Systems Division in Philadelphia.

SECTION III

B. DIVISION

1.0 RE-ENTRY AND ENVIRONMENTAL SYSTEMS DIVISION, GENERAL ELECTRIC COMPANY

1.0 RE-ENTRY AND ENVIRONMENTAL SYSTEMS DIVISION, GENERAL ELECTRIC COMPANY

The Re-entry and Environmental Systems Division of the General Electric Company has been actively engaged in research, development and product oriented activities in the bioscience area for nearly a decade. Bioscience related skills and experience were extensively increased during performance of the internationally significant Biosatellite space exploration program. As a result of this program and related activity, additional research, development and application of Bioscience techniques have been, and are now, being accomplished on salient Biomedical problems that have been identified. A brief description of pertinent tasks, in process or completed, is given in the accompanying paragraphs.

1.1 BIOSATELLITE PROGRAM

During the last several years, GE-RESD has been engaged in a number of programs with NASA and the medical community in the biological and medical fields. In the NASA Biosatellite Program, GE-RESD designed and built a number of space laboratories to study the effects of relatively long-duration flights on a wide variety of plant and animal specimens in controlled environments that could not be duplicated on earth. For details, see the supplement to Report No. 2 titled: "A Summary of Biosatellite Technologies". Flights were made in December 1966 and September 1967 to study the effects of weightlessness and radiation on several simple organisms. Thirteen experiments were carried on these flights, seven of the experiment's organisms being exposed to gamma radiation from an on-board Strontium source. A third flight was made during June and July 1969 to study the effects of prolonged weightlessness on a primate, specifically its brain functions and performance, cardiovascular functions, metabolic functions and the bone density changes in various sites of the skeletal anatomy.

The third Biosatellite Spacecraft demonstrated significant advances in the state-of-the-art of unmanned satellites. Since the Biosatellites carried no high-level intelligent life aboard, all data gathering and command functions were controlled either automatically or by remote control from the ground.

1.2 MEDICAL DATA ACQUISITION UNIT (MDAU)

Under contract to the Metropolitan Life Insurance Company, GE-RESD has developed a portable unit for use by non-medical personnel for obtaining medical data on a prospective client as to their insurability. The data acquired includes: ECG, blood pressure, weight, overall height, waist to head length, and waist measurements. Evaluation of a prototype unit is currently under way and ten additional units are to be fabricated. The circuit designs, system concepts and experience developed on this system are directly applicable to the tasks proposed herein.

1.3 EXERCISE ELECTROCARDIOGRAM PROGRAM

During the last several years, GE-RESD has been engaged with the Lankenau Hospital of Philadelphia, Pa., in conducting a long term Exercise Electrocardiogram (EECG) research program. The co-project directors and principal investigators of this program are Dr. J.W. Daly and Dr. G.J. Haupt.

The long-term purpose of this project is to establish the electrocardiogram obtained during examination, as opposed to that obtained at rest or after exercise, as a fundamental clinical tool to:

- Detect early cardiac conditions in asymptomatic subjects.
- Determine safe activity levels for all types of cardiac patients.
- Assist in training cardiac patients to accept, safely, increased activity levels.

Among the benefits accuring to the field of vocational rehabilitation would be:

- Preventive rehabilitation by detection of incipient heart disease.
- Determination of employability.
- Correlation of safe work levels with job requirements.
- Repeated evaluation of work capability to provide guidelines for continuous job adjustment.

The primary and secondary objectives of the current effort on this program are to establish an extensive EECG data base and to validate the data processing system respectively.

The EECG data acquisition system is installed at Lankenau Hospital and the data processing system developed at GE-RESD is employed to obtain the data base. All data is processed at the GE-RESD data processing center.

A bicycle ergometer is employed for exercise stress. The EECG signal is obtained via small disposable electrodes, continuously displayed on an oscilloscope for instantaneous observation by the attending physician, and permanently recorded on a strip chart recorder for permanent samples. Along with patient identification information, the EECG is recorded on magnetic tape on the hospital premises.

At the data processing center, the EECG data is digitized as required for presentation to the digital computer for parameter extraction. A simplified block diagram of the EECG System is shown in Figure IIIB-1.

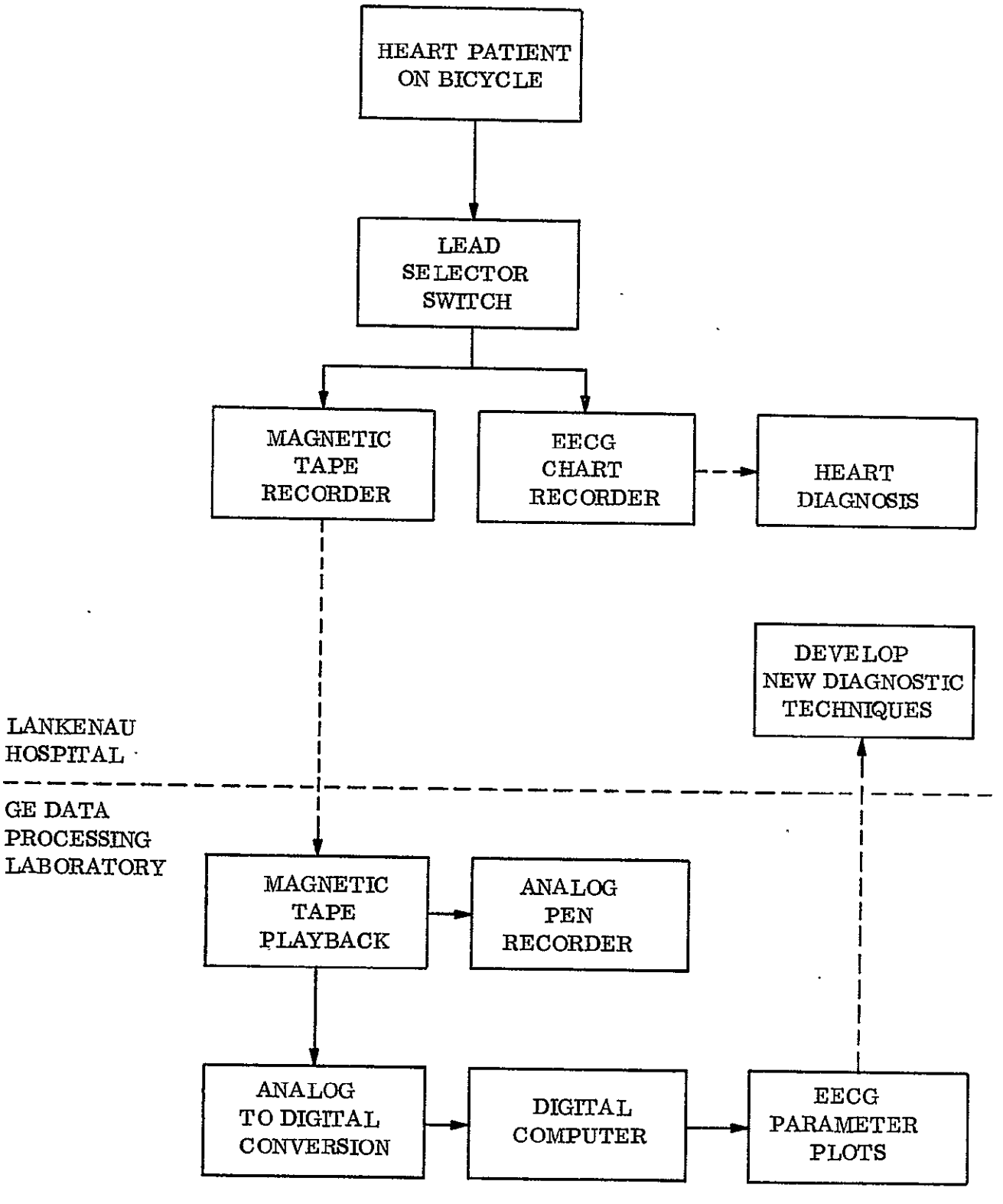

Figure IIIB-1. Exercise Electrocardiogram System

The data base that is being established consists of EECG data for each patient in three different formats. The raw data is stored on analog magnetic tapes recorded at the hospital and on digital magnetic tapes generated from the analog tapes at the GE-RESD data processing center. The third format is microfilm tabulations and plots of EECG parameters obtained from the parameter extraction computer program.

The computer program measures 29 parameters (amplitudes of/widths of/intervals between waves) in the EECG complex. Quality of the measured data is indicated by code words in the tabulated output.

Noise, which is often a problem in cardiography, is removed by a specially designed low-low pass digital filter which does not alter D.C. components and very nearly eliminates 60 Hz components. Only the data between QRS complexes are so filtered, resulting in a "selectively smoothed" wave, partly filtered and partly raw data. This digital filter has proved to be a very powerful tool for identifying the dominant wave (R or S), estimating noise level, and identifying T and P waves.

Special techniques are used to detect and eliminate spikes.

GE-RESD has developed a data acquisition system which made it possible to acquire raw data with very low noise content over a nominal intelligence frequency range of 0.05 Hz to 220 Hz. Based on the experience to date, the quality of the raw data will provide an excellent base for future EECG research.

Some operational advantages of the data acquisition system are as follows:

- Patient and procedural identification is by automatic digital encoding instead of by voice.
- Procedural control is almost completely automatic rather than manual.

1.4 RELATED BIOSCIENCE STUDIES

In addition to the aforementioned programs, GE-RESD has had many years of applicable experience and background in the field of bioscience. Salient research and development programs in this area include the following:

	PROGRAM IDENTIFICATION	CONTRACTING AGENCY
1.	Bone Demineralization Study	USAF School of Aerospace Medicine Brooks AFB
2.	Studies of Pulmonary Circulation	NASA Headquarters (OART)
3.	Mass Transport & Hemolysis in Capillary Blood Oxygenator Equipment	US Army M&RDC

	PROGRAM IDENTIFICATION	CONTRACTING AGENCY
4.	Coronary Research Analytic Support	Peter Bent Brigham Hospital, Boston, Mass.
5.	Theoretical/Experimental Study of the Myocardium	Albert Einstein Medical Center Philadelphia
6.	Physiological Systems Modeling (Cardiovascular & Body Fluids)	NASA Manned Space - Houston, Tex.
7.	Asceptic Maintenance by Pressurization (AMP #3) - Penetration of Bacteria Through Small Holes	NASA Langley Research Center Hampton, Va.
8.	Studies of Blood Flow in Artificial Blood Pumps	NIH - Wash., D.C.
9.	Mass Transfer in Artificial Oxygenators	U.S. Army

1.5 RESEARCH AND DEVELOPMENT ACTIVITY

The funding allocated to RESD and the GE Space Division at Valley Forge, Penna., for the CY-1970 Independent Research and Development (IR&D) Program was approximately seven million dollars. The proximity of, and the close working relationship between, the two GE Divisions allows continuous cross-correlation of results on individual programs/tasks regardless of organizational auspices for the specific tasks. The 1970 IR&D tasks shown in Table IIIB-1 are appropriate to the implementation of the PMS system and the R&D tasks defined herein. Results of the tabulated tasks will augment the activities proposed in this submittal.

TABLE IIIB-1. IR&D PROGRAM TASKS APPLICABLE TO IMPLEMENTATION OF PROTOTYPE PMS AND R&D TASKS

1. HEALTH AND LIFE SCIENCE SYSTEMS

- Bio-Isolation and Sterilization Techniques
- Non-invasive Medical Measurements
- Improved Phenol Analysis Techniques
- EECG Multi-Lead Data Acquisition
- Improved Portable Volume Control Respirator
- Computer-Assisted Diagnostics
- Improved PO_2 Sensor
- Diagnostic and Predictive Bio-Medical Systems Development
- Electric Fields in Blood Clotting
- Multi-Measurement Body Plethysmograph
- Permselective Membranes
- Body Waste Treatment Systems

2. INFORMATION AND DATA SYSTEMS

- Data Search Systems
- Two-Dimensional Optical Fourier Transforms by Varying Area Techniques
- Advanced Discrete Data Techniques
- Universal Development and Demonstration Console
- Flexible Data Retrieval Subsystem
- Image Processing and Analysis
- Multi-Processing Techniques

TABLE IIIB-1. IR&D PROGRAM TASKS APPLICABLE TO IMPLEMENTATION OF PROTOTYPE PMS AND R&D TASKS (Continued)

2. CONTINUED

- Information Management System Test Bed and Workshop Simulation
- Data Bus Technology
- Distributed Processor/Interface Module Development

N71-23849 (NASA-CR-118035) STUDY OF APPLICATIONS OF BIOSPACE TECHNOLOGY TO PATIENT MONITORING SYSTEMS: PROGRAM PLANS AND BUDGETARY COST ESTIMATES. Final report supplement. (General Electric Co. . . pp. 155

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