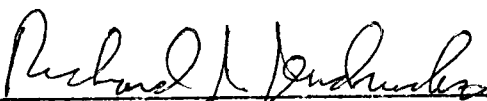
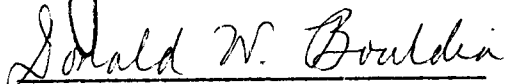


To the Graduate Council:

I am submitting herewith a thesis written by Wm. Patrick Moore entitled "Development and Evaluation of a Portable Automatic Test System for Clinical Use." I have examined the final copy of this thesis for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Master of Science, with a major in Engineering Science.


Richard J. Jendrucko, Major Professor

We have read this thesis
and recommend its acceptance:

Accepted for the Council:


The Graduate School

3

DEVELOPMENT AND EVALUATION OF A PORTABLE
AUTOMATIC TEST SYSTEM FOR
CLINICAL USE

A Thesis
Presented for the
Master of Science
Degree
The University of Tennessee, Knoxville

Wm. Patrick Moore

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ABSTRACT

The intensifying development of biomedical instrumentation is having a major impact on the delivery of health care. All of the diagnostic, monitoring and therapeutic equipment within a hospital must be inspected on a regular basis to insure proper operation and patient safety. In this project an automatic test system was configured to accomplish automatic performance testing of selected medical equipment. Much work by others has been done to automate the scheduling of inspections, the generation of inspection forms and the storing of test results. The emphasis here is to automate the actual test process. The test system eliminates the necessity for the reading of test procedures, logging of test results, manual calculations and the checking of test values obtained against published tolerances. The system was required to be portable, economical, easy to operate and reconfigurable for testing a variety of clinical equipment.

The developed system consisted of a Hewlett-Packard Model 41C programmable calculator with printer and mass storage device on a digital interface loop. A general purpose multimeter and special interface device were also connected to the loop. Dedicated test interface devices and complete software programs were developed for testing a Travenol Model BW-5 blood warmer and a IMED Model 960 infusion pump. In addition, general formats and routines were developed which would facilitate producing test programs for other devices.

Four biomedical equipment technicians and the author performed

eighteen final test trials using the system. Several major conclusions were drawn from the system development. First, the \$3,000 hardware cost is negligible compared to engineering time required for program development. Secondly, the increase in reliability and thoroughness in performance inspections is offset by a corresponding increase in test time. Thirdly, portability and modularity in the system was achieved but at the expense of operational ease. Finally, the major advantage associated with the use of the automatic system is the required rigorous application of specifications and procedures while testing clinical equipment.

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CHAPTER I

INTRODUCTION

Medical equipment has become inseparable from patient care in modern hospitals. It is used in routine diagnosis, for physiological systems monitoring and in delivery of treatment of underlying pathologies. For example, a complete annual physical requires the use of a thermometer, sphygmomanometer, electrocardiograph, X-Ray unit, various light sources and guides and a host of automatic laboratory equipment for the analysis of bodily fluids and tissues. A routine surgical procedure usually requires all of the above and in addition, an anesthesia machine, electrosurgery machine, cardiac, carbon dioxide, oxygen and temperature monitors, suction equipment, infusion pumps and additional laboratory equipment. Patients requiring intensive care may be instrumented with computerized cardiac and respiratory monitors, automatic thermal control units, artificial respirators, special radiographic or ultrasonic diagnostic equipment, multi-channel recorders and plotters, as well as, hourly analysis of blood gases, electrolytes and metabolites from the clinical laboratory.

The use of this equipment may not always help the patient. Every device has the potential of harming the patient directly by such events as catching fire, falling on him or shocking him. Patient harm may also be due to incorrect system operation resulting in such problems as, over inflating the lungs, overcooling the body, or infusing drugs at a dangerous rate. Diagnostic and analytic equipment may

provide the physician with inaccurate or incorrect information. Emergency resuscitation equipment may be inoperative, possibly resulting in the patient's death. The significant probability of these failure modes indicates the necessity of rigorous periodic checks of the performance of all medical equipment.

Early medical equipment such as sphygmomanometers and suction apparatus was often inspected and repaired by the user, sometimes with the aid of general maintenance personnel. By 1950, more complex electronic devices such as defibrillators, electrosurgical units, colorimeters and spectrophotometers had become commonplace. Detection and correction of problems in these devices became more difficult with increasing complexity. Repair work was left to manufacturer's representatives or persons experienced in industrial equipment repair who received necessary instructions about failures from the operator of the medical equipment. This symbiosis of a general repairman working with a medical equipment operator worked well as long as the correct operation of the equipment was relatively obvious.

Other areas of need had become apparent by the late 1960's. Subtle equipment shortcomings frequently could be detected only by trained personnel using specialized test equipment. Although the muscle contractions of a person undergoing defibrillation was used as an indication of defibrillator power output, it was certainly not a quantitative measure. The rate of paper feed in an electrocardiograph could be checked quantitatively against a simultaneous check of the patient's heart rate. However, the high frequency response of that same machine could at best be guessed by the operator. Leakage currents below the

threshold of perception of technicians were determined to cause ventricular fibrillation when applied directly to a patient's heart. These situations illustrated the need for routine specialized performance checks of the equipment. Clinical laboratories recognized this fact and, regularly, used control solutions of known characteristics to routinely test their technique and equipment. Hospitals slowly instituted programs of periodic testing of all medical equipment. Testing was performed by manufacturer's service personnel, contracted service organizations or by newly organized in-house biomedical departments.

By the early 1970's the biomedical equipment technician (BMET) and later the clinical engineer (CE) were to be found in most large hospitals. The Joint Commission on Accreditation of Hospitals began requiring documentation of periodic testing. Other organizations had begun formulating specifications and test procedures. Titles for biomedical personnel, organizational charts and span of control varied widely from facility to facility. However, the BMET was normally responsible for periodically inspecting special items of medical equipment to insure current and continued correct operation. The BMET was trained, or self-trained, in the operation of medical equipment, as well as, the operation of electronic and mechanical test equipment. His test equipment typically consisted of an oscilloscope, digital multimeter meter, power supplies, signal generator, fluid flow and pressure measuring instruments and an accurate stopwatch. This common test equipment was augmented by dedicated medical test devices, such as an electrocardiac simulator, defibrillator and electrosurgery simulated loads and test meters, and an always available leakage current meter.

Technical advances have produced an accelerated growth in the use of medical equipment in the last decade. It is now common practice to continuously monitor ECG, temperature and blood pressure of every surgical and intensive care patient. Simple mechanical devices such as thermometers, sphygmomanometers, fluid administration clamps and tourniquets have been replaced with complex electro-mechanical equivalents. Increases in numbers and complexity of equipment has reduced the time available for performance of inspections and, at the same time, a climate of heavy regulations, product liability and malpractice suits are demanding greater documentation and more complete checks. With a stopwatch, burette and an hour without interruptions, a BMET can completely and accurately check an infusion pump. Having to check as many as sixty of them while typically being frequently interrupted to perform other tasks necessitates introduction of automated methods. Additionally, beginning in the late 1970's more instruments became computerized or designed with microprocessors. Many of these systems now do, or in the near future, will require automatic testing due to their operational speed and complexity.

Fortunately, a similar accelerated growth in other areas of the electronics industry has made available the technology and produced the need for advanced automatic test equipment (ATE). Traditional improvements in accuracy, speed, reliability and flexibility of ATE has occurred. At the same time the price of what was formerly the most expensive component, the controller or computer, has dropped radically. Small systems built around personal computers and fast analog/digital conversion packages have become commonplace. They are flexible, "user

friendly," powerful and available at a reasonable cost. All of these events seem to indicate the timeliness for introducing automatic test systems into the hospital setting. Traditional advantages associated with automatic testing are: increased speed, more reliable and accurate test results, improved repeatability and better documentation using less skilled and costly technicians.

In November of 1981 Hewlett Packard introduced a portable interface network for its then current Series 40 handheld programmable calculators. This system was called the Hewlett Packard Interface Loop (HP-IL). It has many of the characteristics of an interface bus introduced ten years earlier which formed the bases of the IEEE-488 interface presently used on many large automatic test systems. The portability of the HP-IL system, the availability of key peripheral instruments, its relatively low initial cost and Hewlett Packard's reputation for reliability made it seem an ideal candidate for use in an automatic equipment testing program in a clinical engineering department.

CHAPTER II

LITERATURE SURVEY

1. THE USE OF CLINICAL EQUIPMENT IN PATIENT CARE FACILITIES

An understanding of the scope of the problem of routine testing of medical equipment can be gained by first considering the number and size distribution of hospitals in the United States and the types and quantities of equipment present in a single institution. Hospital statistics compiled for 1982 listed 2,655 United States community hospitals having fewer than 100 beds, 2,541 facilities between 100 and 400 beds, and 605 hospitals having 400 or more beds [1]. There are another 1,114 non-community hospitals associated with larger institutions such as the Veterans Administration and universities whose varying characteristics make categorization difficult. Government statistics indicate that seven billion dollars were spent on X-ray, electro-medical and surgical equipment in 1982 [2]. The cost of inspection and maintenance of medical equipment has been estimated as averaging five or ten percent of its purchase price per year [3]. Taking five years as the average life of a medical instrument, one arrives at an estimated annual inspection and maintenance cost range of \$1,400 to \$4,300 per hospital bed.

A recent survey reported an even greater cost range of \$216 to \$4,286 per bed [4]. Such a wide range may be indicative of the responding hospitals' lack of knowledge of their total maintenance cost. The costs of maintenance of plant, communication, and office equipment, as

well as laboratory, anesthesia, radiology and nuclear instrumentation are included to differing degrees with other medical maintenance costs. Even the dollar worth of medical instrumentation within hospitals and the average annual increase in its worth are difficult to determine. Although annual capital expenditures are well documented, engineering studies, new medical equipment and plant improvements are often grouped into the same capital equipment account as hardware. Furthermore, much of the medical equipment in use today is obtained through leasing or through contracts in which the price of the equipment is incorporated in the cost of disposable supplies. Maintenance costs are, consequently, hidden in hospital overhead, equipment repair contracts, rentals, and supply prices.

The author of this thesis undertook a study of the property control records and the annual budgets of a single 525 bed general care community hospital in 1983 [5]. The aim of the study was to determine the number of instruments maintained by the in-house clinical engineering personnel, the rate of addition to and deletion from the equipment inventory, and what portion of it could benefit by the use of automatic test equipment [ATE]. For the cited study, it was concluded that clinical equipment under direct control of the clinical engineer in January 1983 had a total purchase price of two and a half million dollars. Clinical equipment is here defined as monitoring, therapeutic, diagnostic and analytic equipment used for direct patient care. Ancillary equipment, such as electric beds, television sets or nurse call equipment is excluded. Direct control implies that primary responsibility of inspection and maintenance of the equipment had been given

to the in-house personnel. For this large hospital new equipment added to the clinical engineering program was \$320,598 in 1981, \$421,436 in 1982 and \$861,000 projected for 1983. The indicated accelerated growth of purchases of high technology equipment and the accompanying increase cost of hospital care is presently a topic of national concern [6]. A "Health Program" was formed in 1975 as part of the United States Office of Technology Assessment in order to study the effects and implications of medical technology.

Since maintenance costs of medical equipment is certainly substantial, the author felt that automating portions of preventive maintenance could be cost effective. At the same time certain other improvements traditional with automatic testing might be realized. As a first step, a classification of the equipment in the above mentioned clinical engineering program was performed in order to determine its suitability for automatic testing. It must be recognized that the nomenclature of medical equipment varies with manufacturers, localities, institutions, and even departments within an institution. There are some 6,000 generic categories of clinical instruments [7]. The Food and Drug Administration has discovered as many as ten commonly used names for some of these. Nevertheless, the clinical equipment possessed by the studied hospital was categorized into fewer than 100 types then into three groups. The first group contains these devices generally uncomplicated in nature which could be checked by a competent operator using a minimum of test devices, typically including only a calibration gage and a leakage current meter. In contrast, the second group includes equipment which is relatively large or complex and

which requires very extensive testing. Evaluation of such systems frequently requires the subjective judgement and experience of a trained operator. The final group contains those items which might be amendable to automatic testing. Each meets one or more of the requirements for which automatic testing will be shown to be practical.

Generally recognized criteria for the effectiveness and efficiency of automatic testing were used to group the various medical instruments. Table 1 lists those items in the first group. Inspection

TABLE 1
TYPES AND QUANTITIES OF HOSPITAL EQUIPMENT WHICH WERE
CLASSIFIED AS RELATIVELY SIMPLE TO INSPECT

Common Name	Quantity	Inspection Time in Hours
Electronic Thermometer	67	0.5
Sphygmomanometer	80	0.25
Heated water pumps	35	0.5
Pulsatile Air Pumps	12	0.5
Mechanical Percussors	4	0.25
Traction Units	5	0.5
Phototherapy Lamps	7	0.25
Portable Suction Machines	42	0.25
Wall Suction Unit	45	0.25
Infant Warmer, Manual	15	0.5
Nebulizer	28	0.5
Gas Flowmeters	27	0.5
Oxygen Blender	15	0.5

times are roughly those suggested by procedures developed by the American Society of Hospital Engineering [8]. For these relatively uncomplicated devices the additional setup time, equipment cost and operator

training required for automatic testing would be considerably more than that for simple conventional test devices. This added cost would outweigh possible advantages that might be achieved in measurement accuracy and recording reliability. The very complex medical instruments of the second group are listed in Table 2. The requirement that the

TABLE 2

TYPES AND QUANTITIES OF HOSPITAL EQUIPMENT WHICH WERE CLASSIFIED
AS TOO COMPLEX TO BE TESTED WITH SMALL ATE

Common Name	Quantity	Inspection time in hours
Central Monitor Station	7	2.0
Capnometer	4	1.0
Echocardiograph	2	1.0
Fetal Ultrasound	1	1.0
Stress Test Computer	1	1.5
Pulse Volume Recorder	1	1.5
Vector Cardiograph	1	1.5
Electromyograph	1	0.8
Evoked Response System	1	1.5
Electroencephalograph	2	1.5
Holter Recorders & Scanner	1	1.5
Operating Video System	5	0.5
External Pacemakers	5	0.5
Pacing Analysers	2	1.5
Operating Laser	1	1.5
Cardiac Output Computer	4	1.0
Drug Computer	1	0.5
Dialysis Machine	3	6.0
Cryosurgical Unit	1	1.0
Electric Drill System	1	0.5
Eye Surgical Equipment	3	1.0
Dye Injector	2	1.0
Diathermy	2	0.5
Surgical Microscope	4	1.5
Pulmonary Laboratory system	1	2.0
Catherization Monitor	1	2.0
Ocularplethmograph	1	1.5
Special Monitors	5	1.5

clinical ATE be inexpensive was the major factor in assigning equipment to this table. Test of such systems requires that the test technician also be an experienced operator, capable of interpreting information on various displays. Automation of those tests would require extensive hardware and a great deal of programming. Small portions of the inspection of these systems might benefit by automatic testing, but as a class this group will be avoided during this introduction of ATE.

There are two physical characteristics which make a device very unsuitable for automatic testing. First, the presence of numerous control knobs and switches that must be manipulated frequently requires complex special purpose interface devices. The construction of such test fixtures would be cost effective only for exceedingly high test volumes [9]. Programmable instrumentation with digital calibration, on the other hand, is the simplest to control and test automatically [10]. Secondly, complex displays, digital readouts, audible and visual alarms, and paper recording present major automation problems [11]. Automation requiring video detection and pattern recognition is beyond the scope of small test systems.

Table 3 contains those items of equipment for which automatic testing appears to offer some definite advantages. The relatively large numbers of some items indicate that a small time savings during each test could produce a significant total savings. Other items are not numerous in a typical hospital but have a relatively long manual test time while requiring few actual control manipulations. Equipment requiring a specified operation time or warm-up period is easily monitored by ATE [12]. Automatic test equipment also excels at being

TABLE 3

TYPES AND QUANTITIES OF HOSPITAL EQUIPMENT CLASSIFIED AS
SUITABLE FOR TESTING WITH PORTABLE ATE

Common Name	Quantity	Inspection time in hours
Bedside Cardiac Monitor	63	1.0
Fetal Monitor	8	1.2
Vital Sign Monitor	35	0.5
Oxygen Monitor	11	0.5
Electrocardiograph	7	0.8
Defibrillator	19	1.1
Volume Ventilator	28	1.0
Intermittent Positive Pressure Breathing Apparatus	19	1.0
Anesthesia Assistor	15	0.7
Anesthesia Gas Machine	23	1.2
Infusion Pump	65	0.8
Electrosurgical Unit	35	0.5
Operating Light Supply	32	0.5
Blood Warmer	8	0.6
K-Thermia Unit	6	1.5
Infant Warmer (Servo)	4	0.5
Physical Therapy Stimulator	23	0.5
Infant Care Center	9	1.0
Doppler	13	0.5
Modular Analyzer	28	0.5
Insufflator	4	0.5
Automatic Tourniquet	8	0.7

constantly vigilant while waiting for some particular condition, such as a pump's delivery of the prescribed volume, to occur [13]. For equipment of this type the ATE can continuously monitor the output while the technician is free to accomplish other work. Another reason for designating a device suitable for automatic testing is a requirement for uncompromised test quality. Some devices are particularly apt to harm a patient in case of a malfunction [14]. For these, the automatic test may not be a time saver but may result in more reliable

and repeatable inspections. A reduction in the frequency of patient injury could then be expected.

An automatic test system must be designed with the specific benefits one hopes to obtain from it in mind. Simple tests are sometimes automated in order to allow the use of unskilled workers. Tests of complex systems are often automated because the numerous measurements must be made at high speed operational rates that cannot be performed manually. These cases are not applicable to the ATE considered for routine clinical use. A relatively skilled BMET is assumed to be operating the test system. A reasonable limit on total test equipment cost of under \$5,000 restricts the complexity of devices which can be tested. Benefits that are expected from a small automatic test system are:

1. increased measurement and timing accuracy;
2. rigid adherence to test procedure;
3. greater repeatability of test results;
4. automatic calculations and conversions of data into
recognized quantities and units;
5. automatic test of specifications and tolerances;
6. less capability and attention demanded of the
operator;
7. more accurate and uniform documentation;
8. shorter test time.

There is an additional class of equipment, not specifically included in the three groups discussed above, which already uses automatic testing. Many new computerized systems in critical care

areas have considerable processing power and memory capacity for controlling many separate inputs and outputs. Computerized equipment is subject to "state dependent" or "pattern sensitive" failure modes, which are apparent only with specific combinations of inputs and outputs [15,16]. All possible situations likely to occur cannot be routinely checked manually in the time that is practical to remove these systems from patient use for testing. Consequently, items in this group of equipment must presently be tested automatically. One solution to this problem is to design into the equipment several layers of self testing programs. Such self tests are initiated automatically when the equipment is first energized and at regular intervals thereafter. Other tests are designed to be utilized when operational problems are suspected [17]. These programs are collectively referred to as Built-in-Tests (BIT). Alternately, manufacturers have designed separate diagnostic programs or test modules which can be used by a technician when a malfunction is suspected [18,19]. All of these test algorithms and devices are applicable to only specific models of equipment. They are not general purpose automatic test equipment.

2. REQUIREMENT FOR ROUTINE PERFORMANCE TESTING OF EQUIPMENT

Periodic testing of performance and calibration of medical equipment did not become commonplace in hospitals until the early 1970's. Reports were published in the late 1960's detailing dangers of minute electrical leakage currents from electrical equipment during cardiac catheterization [20,21]. Problems with electrosurgical equipment

and diathermy units had led to the publishing of the National Fire Protection Association (NFPA) manual 76CM in 1970. A survey of cardiac electronic equipment in the Detroit area was taken in 1970 wherein 149 "insufficiencies" were noted [22]. The published result was:

Tentatively it is suggested that examination of all external controls, connectors and power cords and internal inspection for failing components be done every three months. Output testing of pacemakers and defibrillators and frequency response calibration of monitors and electrocardiographs should be carried out at least once a year.

In 1971 the NFPA began to develop guidelines for the safe use of electricity in patient care facilities [23].

The wave of consumerism that was apparent in the late 1960's and early 1970's demanded a solution to these published problems. Congress inacted the Williams-Steiger Occupational Safety and Health Act of 1970 which mandated the periodic testing of all equipment in the work environment [24]. In 1972 the president signed into law the Consumer Product Safety Act which was designed to protect the public against unreasonable injury associated with consumer products [25]. Ralph Nader, the well-known consumer advocate, pronounced to the public that 1,200 people were being killed annually by faulty hospital equipment [26]. Product liability judgements in excess of one million dollars which became common in the late 1970's indicated that that the public was no longer willing to accept accidents caused by faulty equipment. The Association for the Advancement of Medical Instrumentation (AAMI) published its Safety Standard for Electromedical Apparatus in 1971 which detailed the prescribed safe current limits and methods of testing for

current leakage [27]. Various regulatory agencies and licensing bureaus referenced compliance with these standards as prescribed conditions. One such agency was the Joint Commission of Accreditation of Hospitals which included in it's Accreditation Manual for Hospitals the standard:

Written policies and procedures shall be established for, but not be limited to, the following:

.....
Methods and frequency of testing, and verification of performance-specifications and use-specifications, for all electrical and electronic patient care equipment, based upon established safety requirements, performance criteria, and manufacturers' claims. Such testing and verification shall apply to both fixed and mobile equipment, with particular emphasis on life-support equipment such as respirators, defibrillators, physiologic monitoring systems, infant incubators and warmers, as well as devices with a high hazard potential such as electrosurgical equipment. All new equipment shall be so evaluated prior to its use. The testing interval for each device or category of equipment shall be consistent with the manufacturer's recommendations, standards promulgated by recognized technical organizations, and frequency of use. In no case shall the testing interval exceed six months. [28]

The Joint Commission continues to inspect hospitals at one to three year intervals. Failure to be accredited can result in the loss of substantial Federal funding such as Medicare/Medicaid [29].

Other organizations and groups produced standards and procedures directly applicable to the medical equipment industry. Table 4 lists the most notable of these prominent organizations and the areas in which they promulgated regulations and standards. In general, large organizations publish general safety guidelines, whereas detailed performance standards usually originate with smaller organizations having specific expertise in a particular field. These small

TABLE 4

A SELECTION OF ORGANIZATIONS PRODUCING STANDARDS AND REGULATIONS
FOR MEDICAL EQUIPMENT

Organization	Area of Interest
Joint Commission on Accreditation of Hospitals (JCAH)	Establishes standards for all phases of operation of hospitals and health related facilities.
National Fire Protection Association, Inc. (NFPA)	Develops standards to prevent fires, explosions, burns or serious injuries due to equipment or facility design.
Bureau of Medical Devices, Division of the Food and Drug Administration (FDA)	Safeguard the public by controlling design, production, labeling and sale of medical instrumentation.
Occupational Safety & Health Administration (OSHA)	Safety requirement for equipment to protect the hospital employee.
American National Standards Institute (ANSI)	An organization which coordinates and reviews standards produced by other organizations.
Underwriters Laboratories, Inc. (U.L.)	A nonprofit organization which evaluates all types of equipment by use by the general public.
National Committee for Clinical Laboratory Standards (NCCLS)	Establishes standards for equipment and practices in clinical pathology laboratories.
National Electrical Manufacturers Association (NEMA)	Establishes volunteer standards to be followed by manufacturers of equipment.
International Electro-technical Commission (IEC)	Develops standards to aid international exchange and sales of equipment.
Association for the Advancement of Medical Instrumentation (AAMI)	Produces standards for specific areas of equipment and practices.
Emergency Care Research Institute (ECRI)	Nonprofit company which evaluates and compares existing medical equipment.
American Dental Association (ADA)	Typical of many special organizations which produce standards in areas for which they have special expertise.

organizations have no authority to require mandatory compliance with their standards. In past years performance standards have become law only when they were referenced by an organization having specific jurisdiction over hospitals or the medical industry. Federal reimbursement tied to JCAH accreditation is an example of such control. Once established, these requirements concatenate. The Joint Commission requires compliance with NFPA 56A which in turn requires products approved by Underwriters Laboratories.

Table 5 gives a representative sample of standards governing biomedical equipment. A publication "The Guide to Biomedical Standards" is a current 91 page summary index listing general safety standards and specific performance standards [30]. The Food and Drug Administration has been given the power to regulate the manufacture and marketing of all medical devices. In the past the FDA has relied upon manufacturers' compliance with voluntary standards. However, the Medical Device Amendment of 1976 requires that the FDA promulgate mandatory standards for the 1200 types of medical equipment it has identified as needing regulatory standards [31]. Although FDA requirements will be aimed at manufacturers and marketers of medical equipment, JCAH requires that the hospital inspect for all safety and performance criteria specified by the manufacturer.

The Food and Drug Administration has established three categories of medical devices. Class I contains those devices which are relatively simple and for which good manufacturing practices and general guidelines are sufficient to insure their safety. Class II contains those instruments which, if improperly designed or manufactured

TABLE 5

SELECTED STANDARDS GOVERNING MEDICAL EQUIPMENT

Standard	Contents
1. JCAH Accreditation Manual for Hospitals	Standards for overall operation of every area of the hospital.
2. NFPA 76B	Rules for safe use of electricity in patient care areas of hospitals.
3. NFPA 76C	Rules for safe operation of high-frequency medical equipment.
4. NFPA 56A	Standards governing the use of inhalation anesthetics.
5. NFPA 56C	Standard for safe operation of clinical laboratories.
6. NFPA 56K	Criteria for medical and surgical vacuum systems within a hospital.
7. NFPA 75	Standards for special safeguards to be followed for computer and data processing equipment.
8. NFPA 70	National Electric Code.
9. Federal Register	All regulations and notices issued by the FDA and other government agencies.
10. UL 73	Standard for the design of motor operated appliances.
11. UL 544	Standard for general safe design of medical and dental equipment.
12. UL 943	Criteria for ground-fault interrupters.
13. UL 1244	Safe design for electrical and electronic measuring equipment.
14. ANSI Z79.8	Performance and safety requirements for continuous flow anesthetic machines.
15. ANSI Z79.10	Requirements for oxygen monitors for direct patient use.
16. ANSI Z136.1	Rules for safe use lasers.
17. NCCLS I1-A	Guidelines for installation, operation and repair of laboratory equipment.
18. NCCLS I6-T	Guidelines for service of clinical laboratory equipment.
19. NEMA XR-8	Test methods for diagnostic radiographic equipment.
20. NEMA UL-1	Safety standard for clinical diagnostic ultrasound equipment.
21. IEC 601	General safety standards on clinical electrical equipment.
22. AAMI SCL-12/78	Limits and test methods for leakage currents in medical equipment.
23. AAMI DF2	Criteria for Cardiac Defibrillators.
24. ADA 44	Standard for dental electrosurgical equipment.
25. NFPA 99A	Replaces several of the above standards in order to combine all medically related documents.

could be of significant risk to a patient. Class III contains devices which are so new or complex that standards can not yet be written to govern their production. Instruments in this class must undergo an extensive pre-market approval process before they can be sold for routine use. There also exists an investigational device category that temporarily exempts that instrument from further FDA regulations. The manpower to produce mandatory standards for the 1200 items in Class II is not presently available to the FDA. However, if these standards are eventually written, a burden will be placed on the hospital to insure that its equipment remains in compliance after it leaves the manufacturer. There is a danger that a requirement for additional tests will burden small BMET shops as just as it is certain to burden small manufacturers.

Realistically, every test required to ensure compliance with every standard cannot be performed for each medical device in a busy hospital setting. Practical time constraints on equipment testing make it essential that the most important tests be performed regularly, with tests of secondary importance being performed as time permits [33]. "Important" tests are those which cover areas most likely to fail or most likely to cause serious harm if they do fail. Each specific situation must be evaluated independently. A particular model of equipment within a manufacturer's line may have a characteristic failure mode. Of course, the nature of the daily use and abuse received by a device will also influence its failure rate.

The theories concerning instrument reliability must be considered in order to develop test protocols. Devices subjected to the

natural enemies of electronics, including: heat, vibration, and voltage spikes must be checked more thoroughly [33]. Equipment failures can be classed into premature failures, random failures, and wear-out failures [34]. These failure modes must be considered when developing equipment inspection protocols. New equipment must be checked relatively more often and more thoroughly in order to detect early failures [35]. As a device ages, routine inspections will detect changing values in output possibly signifying impending failures. For most of a device's useful life malfunctions should be rare and limited to random component failures. During this period an effective inspection schedule will result in identification of problems on 2-5% of the inspections [36]. Insuring that the equipment is built using fault tolerant design and high quality components is the primary safeguard against these types of random failures. Good design should be checked during equipment pre-purchase evaluations and rechecked during an in-depth acceptance test.

The particular application of a device must also be considered in its testing. Control settings most often used should be the settings most often checked. Ultimately, the selection of which tests are to be performed remains the responsibility of the individual hospital. Nevertheless, several organizations have produced standard test procedures for a variety of equipment.

The Emergency Care Research Institute (ECRI) has published 32 inspection and preventive maintenance procedures [37]. Of these, 15 relate to equipment listed in Table 3 (page 12), 14 relate to equipment listed in Table 1 (page 9), and the remainder are for the equipment in

Table 2 (page 10). These forms were extensively used by many hospitals in the late 1970's before an increase in the variety of models available in every category of equipment made a detailed general purpose test procedure less practical. In 1979 the usefulness of such procedures and forms were re-evaluated and interest in developing new forms seems to have wained [38]. The Veterans Administration produced a more extensive set of procedures which included various levels of inspection and estimated times for each instrument type [39]. These guidelines suggest that a thorough inspection and detailed adjustments be undertaken only once a year, and less rigorous inspections be performed quarterly. Another set of procedures and check sheets are published by the American Society for Hospitals Engineering of the American Hospital Association [40]. These same check sheets form the basis of a computerized clinical engineering management program marketed by American Medical Resources [41]. The College of American Pathologists have published detailed procedures for testing clinical laboratory equipment [42]. Similarly, AAMI has published specific check procedures with their standards, notably the procedure in "Safe Current Limits for Electromedical Apparatus" [43]. AAMI has also published a draft standard "Guideline for Establishing and Administering Medical Instrumentation Programs," but it does not contain specific procedures for tests [44].

Certain groups of tests are common in all the procedures mentioned. For electrical equipment a complete leakage current check of chassis and patient leads is always included. An inspection of all cables for broken insulation or exposed conductors is essential. A

visual inspection of the entire instrument for signs of wear or physical damage is also required. Cleanliness is checked and appropriate lubrication is performed. Often a check that controls are in designated positions and that required accessories are present is included in the inspection. Finally, the focus of the performance check is summarized well by the words contained in many of the Veterans Administration procedures: assure that "appropriate specific responses will occur when placing controls in specific positions as specified by the manufacturer's operating manual." In years past one could perform a complete test of an instrument simply by measuring and recording the response from each possible control position.

The era in which a BMET could understand typical hospital equipment by studying its front panel controls and their indicated ranges is totally past. Modern keyboard inputs, "menu displays" and "soft" keys make testing of equipment less simple. Many of the possible functions of instruments are concealed or used only during alarm conditions in order to simplify normal operation. These special case automatic functions improve the operation of the instrument but can be faulty and easily overlooked during routine inspections of the device. Furthermore, means and procedures to check such hidden safeguards can only be provided by the manufacturer and will be applicable only to that one machine. This condition is also limiting the usefulness of the generic inspection forms designed to be applicable to every manufacturer's equipment.

Generalized check sheets will continue to be needed whenever specific test instructions are not available for an instrument. Some

manufacturers, especially those of equipment that has been in use for years, do not provide recommended check procedures. For example, Gomoco Thermotic Thoracic pumps have been widely used since the late 1950's, yet it is difficult to find any written standard for the time limit that should be allowed for development of a bounded degree of suction in the device. The standard NFPA 76B requires the "operation and repair manual" for each item include "comprehensive preventive and corrective maintenance and repair procedures" [45]. Unfortunately, medical equipment makers are not legally required to comply with this standard.

Although many manufacturers do publish test procedures and check sheets, often the procedures are not updated to agree with the current model of equipment or is impractical to perform. For example, the performance check for the IMED 960 infusion pump mentions disassembly of the machine for each inspection [46]. Such disassembly is impractical during every inspection. Sometimes the test procedure references a detailed calibration procedure that is too lengthy to be practical for routine checks. The 38 page calibration procedure for the Vitatek 400-Series cardiac monitor is an example of such a lengthy procedure [47]. Clinical engineers prefer that test procedures be included with all new equipment but these procedures must be realistic. There is widespread belief that some manufacturers are using suggested operational checks as a means to limit their own liability [48]. There is certainly less possibility of harming a patient if the operator is required to test every function of a machine at short intervals. However, such exhaustive check procedure often discourage the performance on any test when

the operator has little available time. From the standpoint of practical resource limitations, the healthcare industry might be better served if future emphasis was placed on relatively short procedures which check the few elements most likely to fail or those most potentially harmful to the patient [49].

3. HISTORY OF AUTOMATIC TEST EQUIPMENT

Automatic test equipment for use on military weapons systems had its introduction slightly prior to the rapid introduction of electronics into medical care [50]. Radiographic techniques, electrosurgery and kidney dialysis were in use in the 1940's. The Cambridge operating room cardioscope and the DeWall heart-lung machine were not introduced until ten years later [51]. By this time, automatic test equipment as used on military weapons systems was into its first generation [52]. First generation ATE was costly, characterized by dedicated hardware designed and packaged to test a particular product. Early test programs were written in a machine dedicated language, stored on a simple medium, such as punched paper tape and stepped the test generators and measurement devices through a sequentially defined test protocol.

The basic components of all ATE are illustrated as a block diagram in Figure 1. These individual components were not always well defined or separate devices in first generation systems. The controller, as the name implies controls all phases of the automatic test. It may be a computer or it may access a computer for calculations and

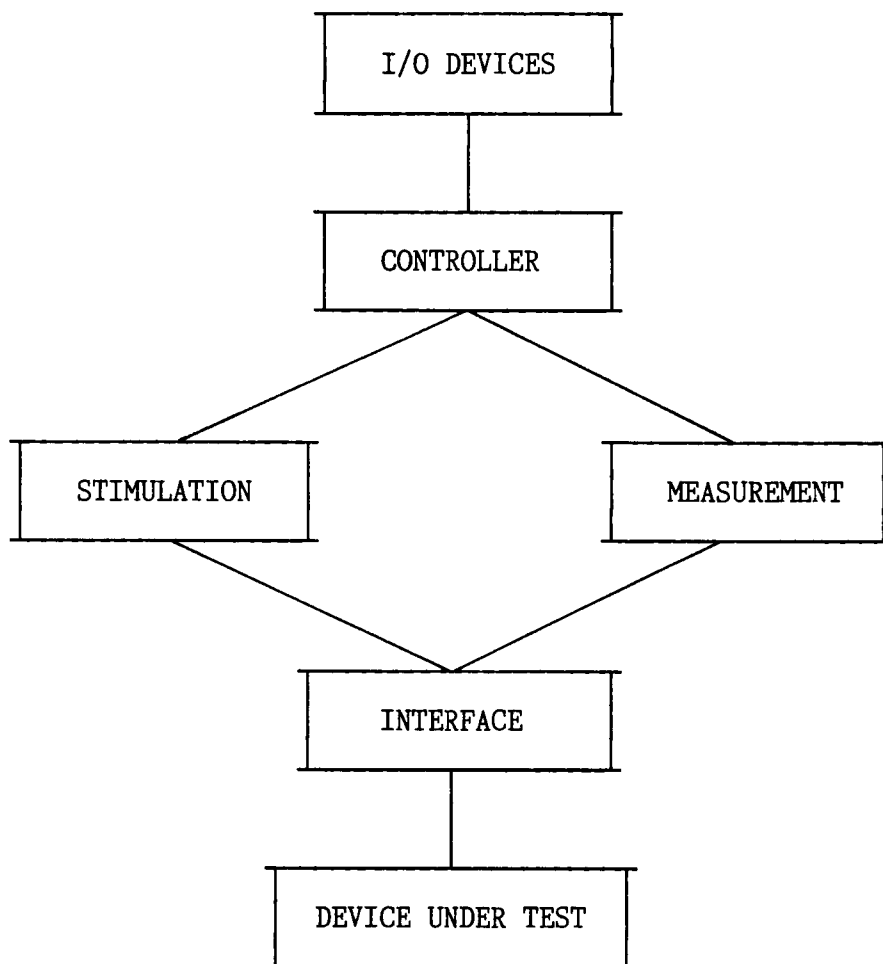


Figure 1. Fundamental sections present in all automatic test systems.

data manipulating. The Input/Output devices normally includes mass storage mediums for the test program and test data. A visual display unit and keyboard normally are present to direct the test technician and allow data input. A printer is usually included for permanent documentation. The stimulation section normally consists of power

supplies, signal generators and digital pattern generators. These may be traditional programmable instruments or simply fast digital to analog converters directed by the test program. Stimulation is required to simulate normal inputs to the device under test (DUT). The measurement section includes equipment for determining the response of the DUT to the test stimulus. This section is also referred to as the data logger or scanner. It may consist of general purpose programmable test equipment for measuring traditional analog electrical parameters such as time, voltage, current, impedance, frequency response, signal-to-noise ratio, standing-wave ratio, and total harmonic distortion [53]. It may consist of one or more fast analog to digital converters relaying outputs of analog sensors into the controller. For digital test systems there may be nothing but a buffer between the DUT and the automatic test equipment.

The final section of the ATE is the DUT-ATE interface device. In this section is found all the special equipment necessary to connect the ATE to a particular device to be tested. This includes mechanical "Knob turners", switch matrixes, and test point fixtures often referred to as a "Bed-of-nails". The interface also includes transducers to convert mechanical responses, such as linear displacement, flow and pressure to electrical signals [54]. A Test Program Set (TPS) is usually available for each device to be tested. The TPS contains:

1. the test program in machine readable form;
2. operation and service manuals for TPS;
3. interface sensors, connectors, and adaptors [55].

Second generation systems were characterized by well defined

separate instruments making up each of the above basic components integrated into a complete system. The use of a general purpose computer with peripherals, standardized test languages, and commercially available signal generation and measurement equipment created flexible test systems [56]. Each type of measurement was performed by a dedicated test instrument that was timed and sequenced by a central controller. Little actual processing capability was needed in this controller. It simply directed some equipment to stimulate the DUT, while auxiliary equipment measured the response and presented this information to the operator.

The evolution of second generation equipment coincided with, and was made possible by, the development of interface standards. Some notable standards in use by the late 1960's were:

1. Computer Automated Measurement and Control (CAMAC) for connecting test "boxes" in a large system [57];
2. American National Standard code for Information Exchange (ASCII) for assigning specific bit streams to numeric and alphabet characters [58];
3. Abbreviated Test Language for All Systems (ATLAS) for specifying the test and measurements to be performed by a system [59].

The introduction of the parallel interface bus standard IEEE-488 greatly simplified the development of an automatic test system. This standard specified the connectors and interface protocol which allowed manufacturers of electronic test equipment to build programmable components that could be immediately connected with equipment produced by

other manufacturers [60]. At the time of this writing (1984) there are an estimated 180 manufacturers marketing over 2000 types of programmable test instruments with the IEEE-488 style interface [61]. Such a wide base of support and ease of use insures that second generation ATE will continue to be produced for years.

The necessity for testing large numbers of components and circuit boards manufactured in the 1970's made automatic testing essential. Much emphasis was placed on testing at the circuit board level [62]. Three types of tests became prominent [63]. "In-circuit" tests stimulated each component and measured its response. If each component tested good, the circuit was assumed to be good. "Functional" tests consisted of supplying a signal to an energized circuit and measuring its output. A circuit board passed inspection if its output was within specifications. This was referred to as a "Go/No Go" test. A "Go" implied that the board was useable but there was no guaranty that individual components were all within specification. "Diagnostic" tests were performed to locate the cause of a malfunction found in the circuit board during one of the other types of tests. Diagnostic testing was, and remains, the most difficult type of test to program and perform. The effects of every possible component failure has to be analyzed before an effective test program can be written.

During the 1970's there developed a heavy emphasis on the testing of strictly digital components. With the emergence of Large Scale Integration (LSI) and later Very Large Scale Integration (VLSI), many separate logic gates needed to be checked. Tested parameters in digital circuits are commonly separated into three types: Direct Current,

Alternating Current, and Logic Integrity Tests [63]. Alternating Current tests measure setup, hold, and propagation delay times, pulse width, and rise and fall times. Direct Current tests measure output drive and input sense capabilities, and power requirements. Logic Integrity Tests check a circuit's output based upon its input states and its logical equivalent circuit.

After the 1971 introduction of Intel's first integrated microcomputer, the MCS-4 system, the cost of computing hardware dropped radically [64]. Digital signal processing techniques had improved to such an extent that what had been strictly analog signal processing could be duplicated within a digital computer. Concurrently, Digital to Analog (D/A) and Analog to Digital (A/D) converter circuits developed rapidly. These three technologies were combined to form third generation automatic test systems. In the third generation ATE, separate signal generation and measurement equipment was replaced by a digital computer accepting signals from sensors through A/D converters and generating stimulus signal waveforms with D/A converters [65]. A computer with considerable computational speed and power performed measurements and analysis on these digital signals.

With increased use of microprocessors, and the incorporation of LSI and VLSI in many instruments, automatic testing of those products became essential. Thousands of gates are present in these integrated circuits that must be checked at their normal high operational speed [66,67]. Microprocessor testing provides totally new challenges. For example, exhaustive tests of all possible functions cannot be performed on circuits which can, themselves, alter their response depending on

the input. Efficient programs designed in terms of the "probability" of detecting hard and soft failures had to be developed.

Automatic test equipment is now in its fourth generation, characterised by the use of small personal computers and single rapidly scanning A/D and D/A circuits [68]. In the 1980's the distinction between generations is blurred. A single present day "smart" measurement instrument connected by a parallel bus forming a second generation automatic test system may itself have all the characteristics of fourth generation ATE.

In 1983 a total of 600 million dollars was spent on ATE in the United States. Most of the test systems are currently utilized for testing unassembled parts of equipment: 49% for testing semiconductors and other components, 42% for testing circuit boards, the remainder for interconnect testing [69]. The capital spent on automatic system-level test equipment is not as readily available because these systems are most often constructed by or directly for the end user. Such users are typically manufacturers of machinery, instrumentation, vehicles, aircraft, and weapons systems. There is an increasing number of small special and general purpose automatic testers being developed for field-service use [70,71]. Such "suitcase" testers may provide a solution to hospital equipment inspection problems in the future.

Much of the present and past work on automatic testing has been supported directly by the military for checking weapons systems, avionics, and vehicles, as mentioned previously. This activity is of interest because it has been a major financial resource making possible advancement of the field of automatic testing [72]. Some recently

published works warrant attention here for their special applicability to automatic testing of medical equipment. The military term for clinical type testing of equipment is organizational or "0" level testing [73]. Organizational level testing attempts to determine the operational readiness of a weapon system in the field. This is "Go/No Go" type test to determine if the weapon should or should not be used. This type of test is essentially the same as that required by JCAH for medical instrumentation.

The results reported for a particular general purpose vehicle automatic test set are particularly relevant [74]. The test system criteria are, first, that the memory of the unit should be very large, on the order of megabytes, so that no accompanying manual is necessary. Second, the unit should be field reprogrammable. Updating of the device for new models of equipment or improved procedures consists of replacing a removable bubble memory. Third, the ATE to DUT interface had to be field changeable.

Two other areas receiving special attention by the military are improved standardization between test systems and manufacturers and improved testability built into the weapons systems. The Air Force has published its Modular Automatic Test Equipment (MATE) protocol which defines in great detail the requirements for standardization of test systems [75]. It requires the use of the IEEE-488 bus and the ATLAS test language. Modularity is used to describe a system which is reconfigurable and expandable. Testability is simply defined as the requirement that each subassembly has adequate controllability and observability [76]. Testability must be built into a system during the

design phase. Feedback loops that tie all sections of a system together must be decoupled in order to test individual sections. External connectors to the system's data bus and control lines must be provided. These requirements are as applicable to medical instrumentation systems as they are to military hardware.

The military is also interested in automatic test program generation [77,78]. This interest recognizes the fact that development of a Test Program Set is as costly as the test hardware. The components of a TPS have already been mentioned. A number of questions must be answered before the set can be developed:

1. What parts of the system is one to test?
2. What are the acceptable measurement ranges?
3. What program language is best for the test equipment being used and the tests being performed?
4. What devices, sensors and controllers are needed to interface the ATE and DUT?

These same questions must be answered each time a medical test system is to be used for testing any clinical instrument. The complexity of TPS generation would quickly make the use of an automatic test system cost prohibitive unless the same interface components and test routines could be adapted easily to many medical instruments. Additioanlly, the same programs need to be useable with few modifications by many different institutions.

4. AUTOMATIC TEST EQUIPMENT PRESENTLY USED IN HOSPITALS

There seems to be little general purpose ATE in use in hospitals at the time of this writing. Most clinical engineering shops have standard electronic, mechanical and pneumatic test equipment such as digital multimeters (DMM), oscilloscopes, calibrators, power supplies, signal generators, scales, pressure gages, timers and flow meters. Portable packages containing combinations of these instruments are also popular. The most common such device is the leakage current meter which combines a voltmeter, ohmmeter, AAMI leakage current load, and manual power switching in a small portable instrument. Some of these leakage current units include automatic ranging, digital displays, EKG lead leakage switching, and isolation power panel checking capabilities [79,80]. Special devices for checking defibrillators, electrosurgical units, and pneumatic ventillators, and for generation of simulated patient signals are commercially available and in common use [81,82]. Typically, these devices are not automated and have no program for sequencing through a series of tests.

A notable example of test equipment that consists of several test functions packaged together to facilitate the testing of a particular class of equipment is the Timeter RT-100 [83]. This instrument can be used to check most functions of respiratory ventillators, including breath and flow rates, tital volume, pressure, vacuum, leakage current, voltage, and ground cord resistance. It may also be connected to a printer to automatically record test results. The test technician must decide which tests are to be performed and manually

control the tester functions. There are typically significant limitations in the use of such equipment. For example, the RT-100 will not properly test a Puritan-Bennett model 7200 volume ventilator, due to the fact that the later detects the tester as a problem in the patient circuit. Such a problem reflects on limitations in both the test device as well as the testability of the ventillator.

Two "automatic" safety analysers are currently available. The Dempsey System 1 checks line voltage and polarity, measures line cord resistance, chassis leakage, and patient lead leakage, and produces several waveforms suitable for checking cardiac monitors. This system includes a printer, IEEE 488 interface, and an optional RS 232 interface for storage of data on cassette tape [84]. The Bio-design Model SMG-500 measures receptacle voltage and polarity, chassis and lead leakage, isolated power trip points, and line cord resistance [85]. It can step the operator through a defibrillator check after an external load is applied. It generates ECG, pressure, and repiration input waveforms. Its output is directed to a small printer or cassette recorder. No general purpose interface is provided for computer control of the unit.

Two noncommercial general purpose automatic safety analysers have been constructed and used at the U.S. National Institute of Health. One unit built in 1973 can automatically step through a series of electrical tests for chassis leakage [86]. No automatic recording of the measured values was made. In 1976 a small instrument constructed at Auckland Hospital in New Zealand performed several leakage current tests automatically and recorded the output on a numeric printer [87].

A larger unit constructed in 1982 included automatic cassette recording of test results [88]. Printed reports were then generated by a large IBM computer programmed to read the cassette tape. The unit also included a bar code reader to automatically store the identification number of a DUT on which is attached a readable bar code label. A third automatic test system has been in use at Northwestern Memorial Hospital in Chicago since 1981 [89]. It consist of a cart-mounted HP-85 desk top computer, PEI 2000 digital safety analyzer and a HP-6942A Multiprogrammer. Programs written in BASIC step a technician through the manual operation of the PEI 2000 and manipulation of the controls of the DUT. The combination of a HP-85 computer and a fully loaded HP-6942A is a powerful test system at cost of over \$10,000 in 1984.

Automatic devices are also available for testing individual items of equipment. Infusion pumps can be checked automatically by devices maufactured by two companies, Dynatech Nevada and IVPT. The Dynatech model 404A times the delivery of either 3.5 ml or 35 ml of fluid into a column fitted with infared level detectors. However, automatic test sequencing or output recording are not provided in this test system [90]. The IVPT test device consists of two calculators. One calculator provides timing and the other counts indivitual drops for drop-counting infusion pumps [91]. Volume delivered by volumetric pumps must be visually measured in a calibrated column but is automatically timed. The method of drop counting devices is interesting because it duplicates the function of some infusion pumps. Therefore, it will detect a good or bad pump independently of the documented error in volumes delivered based on drop counting.

Some automatic testing has been introduced into the hospital setting directly by medical instrument manufacturers. Many microprocessor based instruments incorporate built in tests (BIT). In its simplest form BIT consists of a power-on self test. When power is first applied to the instrument an initialization routine pulls a test program from read only memory (ROM). Typically, this program will exercise the instrument's microprocessor, random access memory (RAM), input/output ports, alarm circuits and display devices. If start-up test criteria are met, the instrument will indicate to the user readiness for operation. As an example the Aspen Model 1000 automatic tourniquet checks itself, illuminates all displays and tests the audible alarms upon start-up [92].

A second type of BIT checks an instrument continually during its normal operation. Parity checking in computers is an example of such "back-ground testing." Additionally, an instrument may continually check the outputs of critical circuits and produce an error message if values fall out of a predetermined range. The Hewlett-Packard Model 78508 patient information center continually monitors data buses and other parameters. It will display error messages and revert to backup operational modes if certain errors are detected [94]. Such operation is sometimes referred to as a "soft failure." Soft failures allow the continued use of an instrument but in a limited capacity.

Extended self tests (EST) and diagnostic routines are BITs that require assistance from the instrument user before completion. The Puritan-Bennett Model 7200 volume ventilator requests that the operator perform an EST whenever a background or start-up BIT detects certain

errors [94]. The EST steps the operator through a five minute system check involving connecting and removing hoses, adjusting controls and entering data. The ventilator makes measurements between parallel systems, checks tolerances and, depending on the results, resumes normal operation or requests another test. Some equipment manufacturers sell diagnostic programs and test devices for users who want to perform in-house maintenance on certain devices [95]. Purittan-Bennett is presently evaluating a System Performance Self Tester (SPST) to be used by a hospital's technician for complete inspection of the Model 7200 ventilator [96].

5. SUMMARY OF CURRENT NEEDS AND PROJECT OBJECTIVES

The more important needs to improve the testing of clinical equipment in the medical community may be readily identified. First, there needs to be greater standardization among manufacturers, medical centers, and testing technicians as to what must be included in a routine test for each equipment type. This includes specification of both the procedure used as well as the test equipment required. Second, the uncontrolled increase in the amount of time required to adequately check the increasingly numerous and complex equipment within a hospital must be controlled. Third, an order of magnitude improvement in the record keeping associated with these test must occur. The number of check sheets presently required, the time it takes to complete them, the number of transcription failures, the number of items that must be manually entered into an equipment historical record and

the number of variations in their completion must all be decreased. Fourth, requirements for training time and experience of test technicians must be decrease while maintaining or improving their effectiveness. Finally, there must be a limit set on the requirement for additional special-purpose test equipment. The latter need can be realized by increasing its useful life by improving flexibility and adaptibility. Its capability of taking more different types of measurements faster and more reliably must also be added. If the above needs are met, one should see a net decrease in the costs of equipment testing while producing an increase in the quality of patient care.

Having a need to accurately and reliably check a large number of various types of medical instruments and having recognized the availability of diverse automatic test equipment, the present author investigated the feasibility of introducing ATE into the hospital for routine performance checks of equipment. The advantages which might be expected are listed above on page 13. The additional special requirements of the hospital environment include the following:

1. general purpose ATE suitable for many types of DUTs;
2. portabilty for testing medical equipment at it's site of actual use;
3. relatively inexpensive, so that each BMET could have one;
4. accuracy suitable for "Go/No Go" testing;
5. common language and components to aid the exchange of programs between hospitals and manufacturers;
6. friendly operation which simplifies the tasks which remain for the operator.

The requirement that the system be "friendly" implies the following characteristics:

1. step by step directions provided;
2. easy and extensive error recovery;
3. automatic identification of DUT and Procedure;
4. automatic hard copy of test results;
5. automatic input of results into a computerized equipment database and scheduling system.

Certain other advantages often associated with automatic testing were not considered important. First, it was felt that the automated test need not provide absolute checkout of a machine. On rare occasions such as during initial inspection of a new device, during some calibrations, or after extensive repair, the automated test would be supplemented with detailed manual tests. Secondly, the system need not be useful for diagnostic testing after a failure has been detected. This would definitely be a useful eventual feature but the complexity of such programs make them unsuitable for inclusion in initial system development. It is hoped that eventually automatic diagnostic test programs will be generated during computer aided design and manufacturing of medical instruments and passed to the hospital for use in its ATE program. Finally, the ATE is to aid the BMET and not to replace him. It should relieve him of the monotonous chores and provide him with greater freedom to observe and interact with a device under test.

The small cost and portability requirements immediately narrowed the choice to one of the following types of systems:

1. a complete system built around a single board computer,

standard bus and packaged signal processing modules [97];

2. a "suitcase" type testers mentioned previously;

3. a desk-top computer and data acquisition module with suitable software [98];

4. a system based on a handheld or notebook size computer [99].

Each of these alternatives had definite advantages in certain areas. Choice 1 was discarded because specially built devices cannot provide the widespread use desired for this test system. Choice 2 may be the best solution in a few years but at present these tester are expensive and still not generally developed. Choice 3 initially appeared very workable but was finally discarded due to size and cost limitations. Choice 4 was finally selected because of the system's small size and the author's judgement that a handheld system provides the maximum convenience, minimum cost and sufficient power and capabilities.

With the above needs and objectives in mind the author undertook the development of a portable automatic test system for use within the medical center at which he is employed. The objective was to assemble a system based on the fewest number of components in order introduce automatic testing. This objective required the construction of interface equipment, the designing of two illustrative programs for testing two commonly used medical devices, the evaluation of the developed system and the investigation of its future applications.

CHAPTER III

SYSTEM HARDWARE DESIGN

1. AVAILABLE HANDHELD COMPUTERS

Having decided that the functional requirements of the automatic test system could best be met using a handheld size computer, the first step in the design of the system was the selection of the type of computer to be used. In the first months of 1982 such computers or programmable calculators were being manufactured by Casio, Panasonic, Sharp, Hewlett Packard and Texas Instruments. Three systems seemed to have sufficient power and peripherals to form the base for ATE. The relative merits and characteristics of systems that were available are summarized in Table 6. The capabilities of each were expanding daily.

No single computer clearly had all of the functions necessary for an optimal automatic test system. With this fact in mind it remained to select the model with the most complete functional capabilities. A standard QWERTY keyboard was considered desirable to facilitate the writing and exchanging of programs. A non-standard keyboard layout like the Hewlett-Packard calculator would be satisfactory but would require some additional operator and programmer training time. The programming language needed to be a common language especially suitable for real-time control applications such as Pascal, Modula 1 or "C" [100]. BASIC language is relatively universal but not especially suitable for real-time control because of its interpretive nature.

TABLE 6

HAND HELD COMPUTERS COMMERCIALY AVAILABLE IN 1982

Manufacturer	Panasonic	Sharp	Hewlett-Packard
Model	RLH-1000 HHC	PC-1500 PC-2	41CV
Language	SNAP/BASIC	BASIC	Special/RPN
Printer	B ^a	A (Color)	B
ROM	16 K	32 K	48 K
RAM	4 K	7.5 K	6.4 K
Display	26 Characters	26 Characters	12 Characters
Clock/Calendar	A	A	B
Interface	RS-232 44 pin bus	RS-232	HP-IL
Clock speed	1 Mhz	1.3 MHz	1 Mhz
Modem	B	B	B
Bar-code wand	B	D	B
Keyboard	QWERTY	QWERTY	NON-STANDARD
Calculator functions	NO	YES	NO
TV Adapter	B	C	C
Voltmeter	D	D	A
Bus converter	C	C	B
Existing software	B	B	A

^aThe letter code where used is intended to reflect the relative quality of each manufacturers peripheral:

"A" function immediately available & very satisfactory;

"B" function supplied by peripheral satisfactorily;

"C" function probably obtainable from another source;

"D" function missing or not mentioned in the literature.

A dedicated language such as that in the HP-41C might prove advantageous if it were fast enough.

Selection of the computer having the best memory involves much more than counting the number of bytes. In general, the size of the Random Access Memory (RAM) limits the size of the program which can be stored and executed. However, the many functions stored in Read Only

Memory (ROM) in handheld computers allow them to better utilize their relatively small RAM space. The availability of many built-in functions and programs was desirable. Even if all functions were not to be used immediately, they imply greater future capability and longer life before the system becomes obsolete.

A decisive factor was that only the Hewlett-Packard machine directly supported electronic test instrument peripherals. A digital multimeter (DMM) was available immediately, other instruments with the HP-IL interface appeared to be forthcoming, and the HP-IL Converter was available to connect with any user designed instrument. The HP-IL interface was felt to be superior to the RS-232 interface for several reasons. First, it was battery powered; secondly, it could communicate with several devices attached to it simultaneously; and finally, because it had many of the characteristics of the IEEE-488 bus discussed earlier. Considering all of these capabilities the HP-41C seemed the most promising as an ATE controller. As an extra incentive the author was familiar with the programming language of the HP-41C and knew it to be a reliable device.

Having selected a controller, it was necessary to decide what peripherals to purchase or fabricate. The test system developed had to be useful for inspecting a large variety of medical instrumentation. Consequently, the components of the system were selected without regard to the particular medical devices chosen for system evaluation. Only general criteria were considered in system requirements. Table 7 lists these criteria and some realistic expected values to be achieved.

TABLE 7
CRITERIA FOR A GOOD AUTOMATIC TEST SYSTEM

-
- A. Speed:
Test program set development time...less than 40 hours.
Setup and disassembly time...less than 5 minutes.
Test performance time...less than 125% of manual time.
- B. Accuracy and Reliability:
Documented accuracy traceable to the standards of the
National Bureau of Standards (NBS)...within 5%.
Durability in maintaining accuracy and repeatability...
only an annual calibration necessary.
Means of confirming accuracy...self test on start-up.
Method of recalibrating on a periodic basis...calibration
programs for ATE and PTS.
- C. Maximal Utilization:
Down time for maintenance and quality control...less than 2%.
Time for operator training...less than three walk-throughs.
Useful lifetime...5 years minimum.
- E. Low Total Cost per Test Performed:
ATE Hardware cost...less than \$5,000.
TPS generation cost...
less than \$500 for program and documentation.
less than 5% of DUT cost for interface adaptors and sensors.
Operator skill level...
program prompts can be followed by an unskilled person.
documentation suitable for trained BMET or CE.
Life cycle cost...low due to long life, rapid test,
minimum technician training.
- F. Safety:
Contains operator and DUT protection...input isolation.
Meet requirments for use in patient vicinity...UL-544.
-

2. DESCRIPTION OF COMPONENTS IN THE TEST SYSTEM

The hardware that was finally assembled is shown in block diagram form in Figure 2. The combination of all equipment is referred to

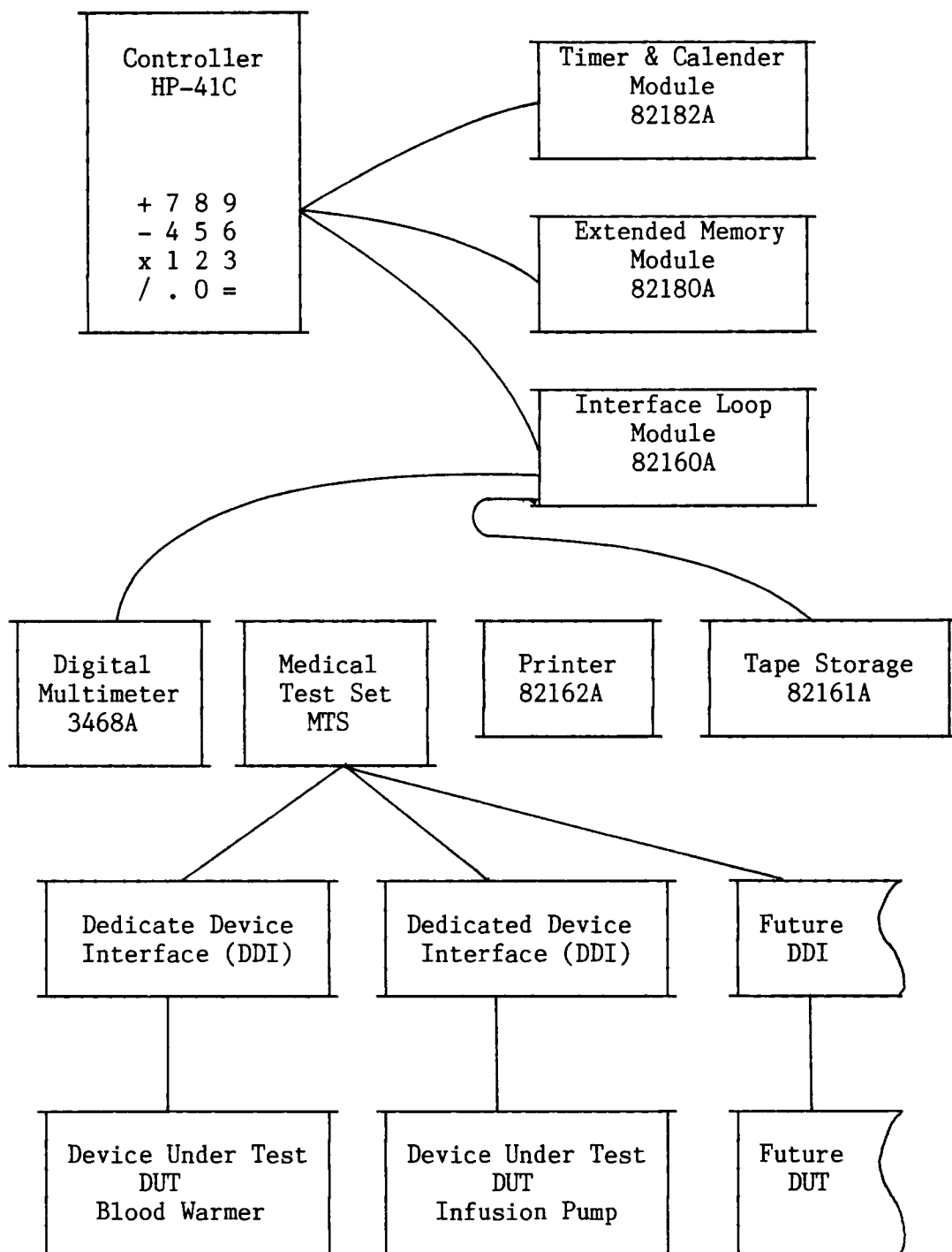


Figure 2. The portable medical automatic test system shown in a block diagram.

as a Portable Medical Automatic Test System (PMATS). Instruments could be added to the system indefinitely. However, for this evaluation the test set was limited to those components shown. It can be seen that this system has all the basic components of the ATE as shown in the block diagram of figure 1 (page 26). A detailed description indicating the purpose and capability of each component follows.

The controller for the system is the model HP-41CV handheld calculator. It is a programmable device with a 12 character alphanumeric display. The language used is dedicated to this particular device and consists of 130 basic keyboard type functions. A list of these functions and an explanation of each is provided in Appendix A (page 115). Programming is similar to assembly language programming in that there are no variable names. Variables are, instead, assigned to numbered registers and their location must be remembered by the programmer. A stack consisting of four registers referred to as X, Y, Z and T are also available. Calculations are normally performed using the contents of these stacks as arguments. This method of performing operations is referred to as Reversed Polish Notation by Hewlett-Packard. All keys are redefinable to execute other functions or complete programs. Memory consists of 319 storage registers which can accomodate about 2,000 program steps.

The computer is enhanced with three plug-in modules containing additional software in ROM. An Extended Functions/Memory module provides additional file handling capabilities and another 127 memory registers. A Timer module provides a real time clock and calendar functions along with stopwatch capabilities. An HP-IL module provides

access to and control of an interface loop which can link as many as 30 separate instruments. It includes commands for printing and file handling. It also provides commands for locating and addressing specific instruments on the loop, passing data to and from them, and for turning them on or off.

The second instrument on the interface loop is a Thermal Printer/Plotter having a 24-character line. It includes a 101 character print buffer, provides 127 standard characters and the capability of generating special characters and plots. The next instrument is a Digital Cassette Drive providing 131,000 bytes of mass storage on each tape. The following instrument is the HP 3468A multimeter (DMM) which functions as the heart of the measurement system. It is a battery powered, programmable, 5 1/2 digit, autoranging, five function meter with a one microvolt sensitivity. It measures AC and DC voltages, AC and DC current, as well as, two or four wire resistances. The last instrument on the interface loop is called the Medical Test Set (MTS). Built into the MTS is a Hewlett-Packard Model 82166 Converter. This is a device designed to allow a user-constructed instrument to communicate with the other instruments on the loop. The MTS and the Dedicated Device Interfaces (DDI) were constructed by the author and will be explained in detail below.

The major components of the PMATS are shown in the photograph in Figure 3. The Medical Test Set, shown with its cover removed, is basically a programmable-switch containing some additional circuitry peculiar to medical testing. A complete wiring schematic is provided in Appendix B (page 113). It consists of six parts: a Converter, a

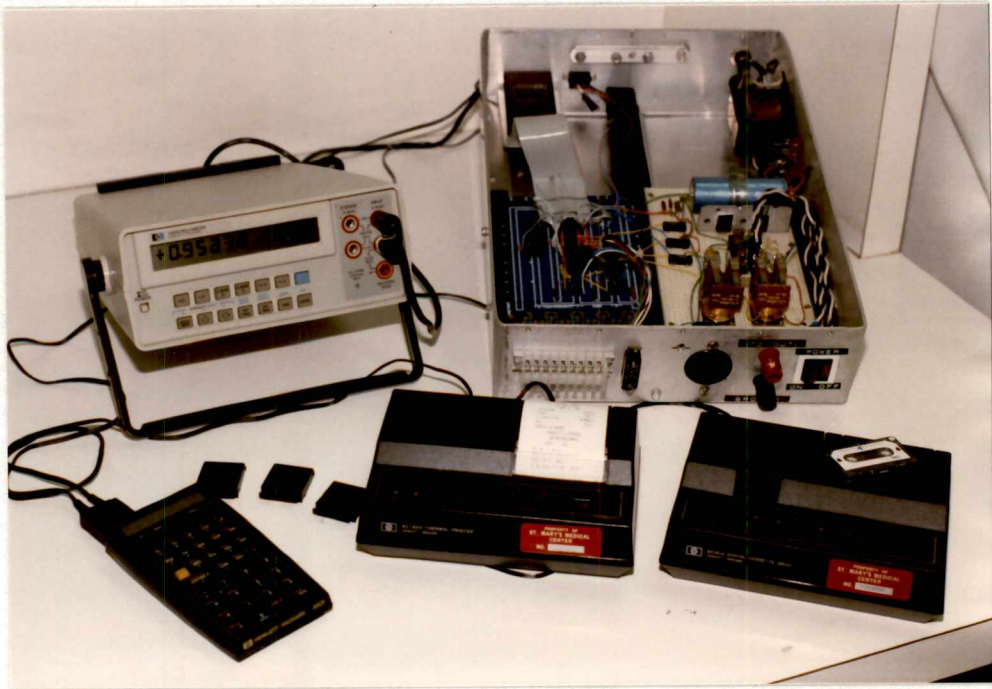


Figure 3. Photograph of the basic components of the portable automatic test system.

power supply, a filter recommended by AAMI for measuring leakage currents, a power relay, small signal relays and logic circuitry.

The DC power supply includes a 5 volt and a 12 volt output regulated by two three-terminal integrated circuits. The 5 volt supply is used to power the logic circuitry and signal relays while the 12 volt supply is used by the power relay. Additional capacity was built into both supplies in order to power external circuits on the DDI or DUT. Integrated circuits 3, 4, 5 and 6 are used to latch the eight bit word passed by the Converter. An ASCII character passed by the test program is stored in binary form. A "0" in any bit location causes the corresponding relay to be activated. Integrated circuits 7 and 8 are

buffer drivers capable of energizing the small relays. An additional driver stage was required to activate the single power relay RL1. This relay performs a function peculiar to medical safety testing. It reverses the Hot and Neutral conductors supplying power to the DUT. Chassis leakage current measured in this condition gives an indication of the danger that would be presented if the medical device were connected into an incorrectly polarized electrical outlet.

Leakage current is the amount of current passing through the third wire ground of an instrument. If relay RL2 is opened, the leakage current from the DUT is routed through the filter recommended by AAMI. Using this filter allows a millivolts reading obtained with the DMM to be substituted for a leakage current microamperes measurement. The characteristics of the filter gives maximum emphasis to low frequency leakage currents which tend to produce fibrillation within the heart while de-emphasizing high frequency components which are relatively less harmful. Relays RL2 and RL3 connect the voltmeter across this filter. Relays RL5, RL6 and RL7 are general purpose two pole signal relays. They are used to route the DMM to specific parts of the device under test (DUT).

3. DEDICATED DEVICE INTERFACES

The test instrumentation thus far discussed was used during all evaluation tests. Additionally, a dedicated device interface (DDI) had to be constructed for each particular medical instrument tested. Any number of medical devices could have been selected as a trial DUT for the developed automatic test system. The characteristics considered

essential in the first devices to be tested were:

1. classification in the group likely to benefit from automatic testing;
2. demonstrative of specific capabilities of the ATE;
3. accompanied by a good operators' and service manual with factory recommended performance inspection procedures;
4. provided with a check procedure and average test times in the America Hospital Association maintenance manual;
5. testable using a relatively uncomplicated test program.

Test program sets were begun for several devices having the above qualities before a blood warmer, shown under test in Figure 4, and an infusion pump were selected as the final trial DUTs.

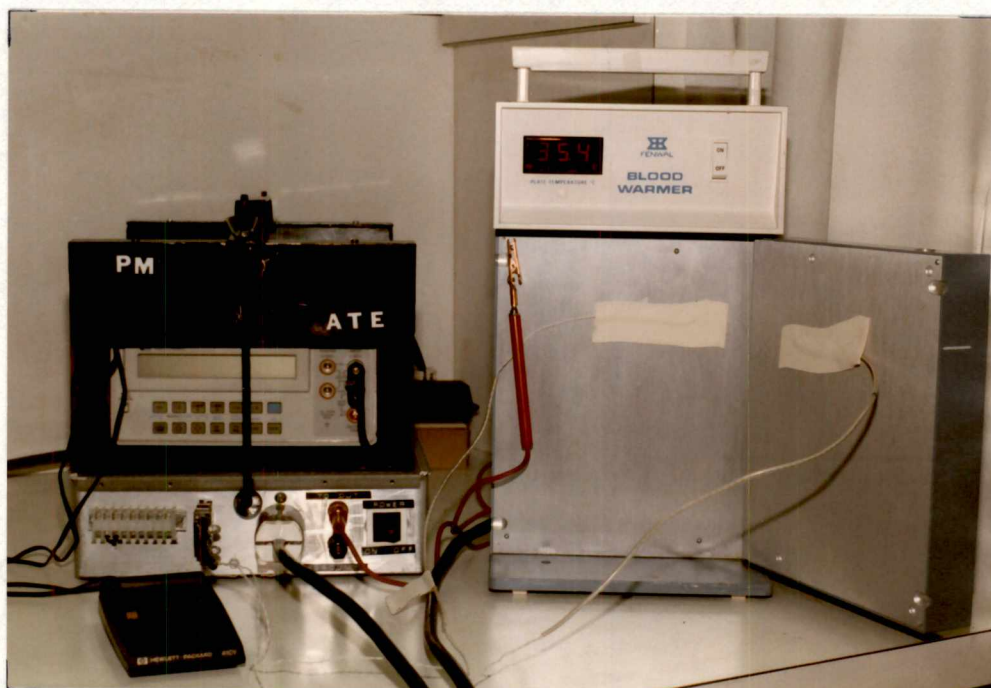


Figure 4. Photograph of the PMATS configured to test a blood warmer.

The first device selected was a Travenol Model 4R4305 blood warmer, referred to as a BW-5. The BW-5 is an inline device using dry heat to warm human blood to between 32 °C and 37 °C as it is being administered to a patient. The blood is warmed while flowing within a plastic bag between two warming plates. Specific reasons for choosing this blood warmer for the first device under test were:

1. It typified a modern trend of replacing simple mechanical devices with complex electronics and layers of safeguards.
2. It illustrated the use of inexpensive thermistor sensors for converting resistance measurements to temperature readings.
3. It demonstrated PMATS's ability to monitor slowly changing conditions.
4. A short test program was possible, leaving sufficient memory to demonstrate the use of a menu type display.

There is irreversible damage sustained by blood if it is heated above about 40 °C. Consequently, the manufacturer recommends "periodically" performing the tests indicated in Figure 5. The test consisting of running chilled water through the unit at a prescribed rate while monitoring its warming was not incorporated into the performance inspection. That test is more suitably performed at rare intervals on a workbench rather than in the operating room, where the warmers are most often tested.

A schematic representation of the Blood Warmer Dedicated Device Interface (DDI) is shown in Figure 6. It consists simply of two Yellow Spings Instruments 400-Series type of patient thermometers. These were

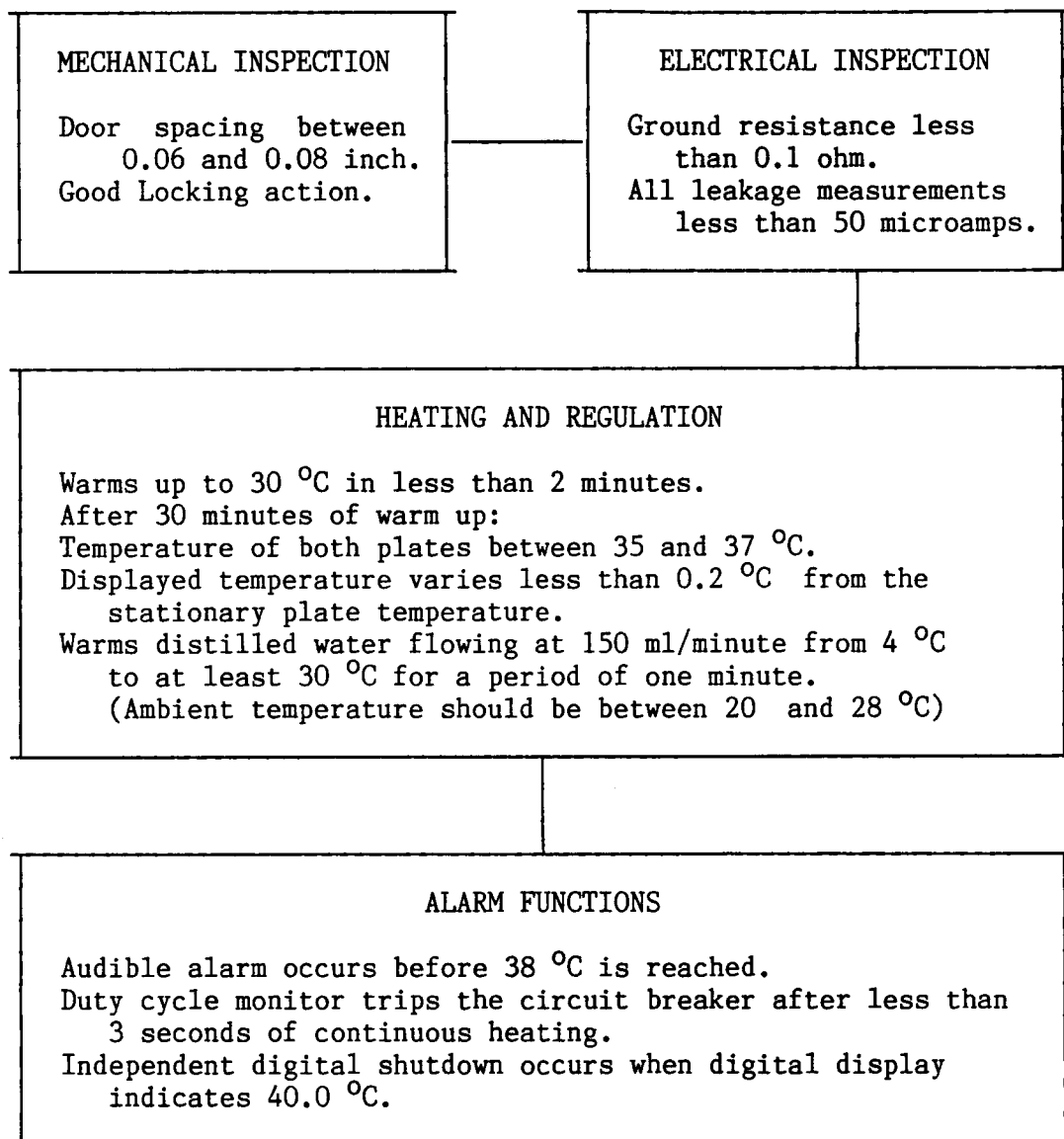
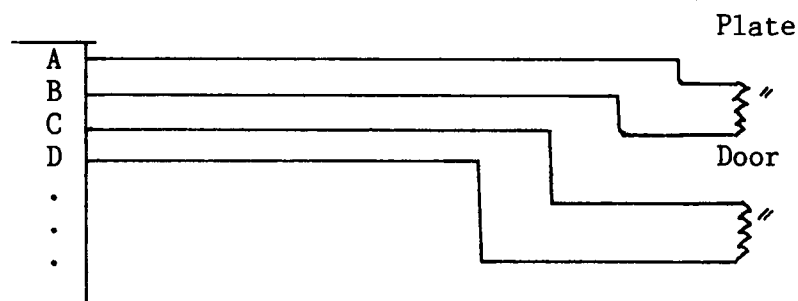


Figure 5. Required tests and allowable tolerances for a Model BW-5 blood Warmer.

Connector to MTS:

Thermistors:



Temperature/Resistance
Conversion Chart

Relay Activation Codes

Temperature °C	Resistance (Ohms)
+20	2814
25	2252
30	1815
35	1471
40	1200
45	984

	Plate	Door
ASCHI	0	-
Binary	1101111	1011111
Realy	5	6

Figure 6. Dedicated device interface for the blood warmer.

selected because they met the small size constraint, are accurate in the range required of the warmer, and because they are readily available in the hospital environment. The manufacturer provides a table of temperatures and corresponding resistances for the thermistors. The DMM was activated at prescribed times in order to obtain resistance readings from one of the two thermistors. Measurements were not made continuously in order to prevent self heating of the thermistors. The conversion table between resistances and temperature was not stored directly in the computer because of memory limitations and because a better method was available. The Steinhart and Hart equation was used.

The Steinhart and Hart equation provides a method of calculating temperature using three coefficients A, B and C. The BW-5 test program uses this equation:

$$1/T = A + B \log R + C (\log R)^3$$

where T = Degrees Kelvin
R = Resistance in ohms

The BASIC program, listed in Appendix C (page 116), was provided by the thermistor manufacturer. It was used to calculate the three coefficients based upon resistance measurements at three known temperatures. The resistance values for 20, 32 and 45 °C were used to obtain the following coefficients which were then used in the BW-5 test program: A=0.001465, B=0.000239, C=0.000000098. A test run of the program allowed the reproduction of the manufacturer's resistance/temperature table exactly.

The IMED Model 960 volumetric infusion pump was the second device selected for testing. Figure 7 shows this volumetric infusion pump connected to the automatic test system. The Model 960 is designed to deliver clear and opaque fluids through an intravenous delivery set to a patient at a rate between 1 and 999 milliliters per hour. The pump fills and empties a piston assembly in a disposable cassette at a controlled rate. The Model 960 was chosen as a trial device specifically because of the following characteristics:

1. it typifies microprocessor based instruments having complex displays and error messages;
2. Its precision challenged the measurement capability of the test system;
4. It demonstrated the need for development of inexpensive interface sensors.

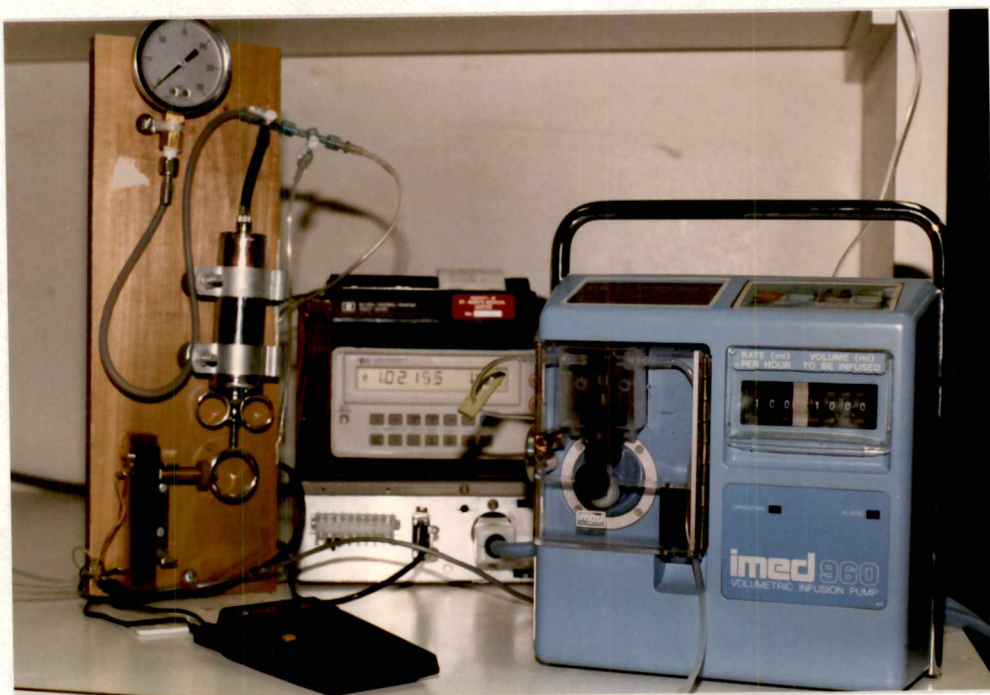


Figure 7. Photograph of the PMATS configured to test an infusion pump.

The IMED infusion pump is complex and required an elaborate interface device. Because of the obvious dangers in an incorrect drug delivery rate the manufacturer of the IMED 960 infusion pump has provided a test procedure to be performed routinely. The flow diagram of Figure 8 summarizes the tests required.

A dedicated interface was constructed to connect the infusion pump to the medical test set (MTS). Its schematic is shown in Figure 9. Two cables are necessary: one connects to the MTS and the other is inserted into the "Nurse call" receptacle of the infusion pump. This receptacle provides a normally open set of contacts which closes automatically to signal a nurse upon completion of a set volume to be infused. Connected in parallel to these contacts is a linear

VISUAL INSPECTION Liquid crystal display has all elements operational. Rate and Volume rotary controls function properly. Audible alarm and malfunction indicators operate correctly.																	
PRESSURE CHECKS Occlusion of tubing on cassette's input side prevents the pump from cycling. Operate occlusion pressure between 10 psig and 25 psig for three cycles. Purge occlusion pressure at least 10 psig for three cycles.																	
DELIVERY TESTS With rate dial set to 033 and volume to be infused dial at 0007: Delivery time between 12 min. 41.6 sec. and 12 min. 45.6 sec. Volume delivered between 6.8 ml. and 7.2 ml. <table> <tr> <td>Rate Setting:</td><td>Volume to be Infused Setting:</td><td>Allowable Range:</td></tr> <tr> <td>144 ml/hr.</td><td>0007 ml.</td><td>6.8 - 7.2 ml.</td></tr> <tr> <td>288 ml/hr.</td><td>0048 ml.</td><td>46.6 - 49.4 ml.</td></tr> <tr> <td>799 ml/hr.</td><td>0048 ml.</td><td>46.6 - 49.4 ml.</td></tr> <tr> <td>999 ml/hr.</td><td>0048 ml.</td><td>46.6 - 49.4 ml.</td></tr> </table>			Rate Setting:	Volume to be Infused Setting:	Allowable Range:	144 ml/hr.	0007 ml.	6.8 - 7.2 ml.	288 ml/hr.	0048 ml.	46.6 - 49.4 ml.	799 ml/hr.	0048 ml.	46.6 - 49.4 ml.	999 ml/hr.	0048 ml.	46.6 - 49.4 ml.
Rate Setting:	Volume to be Infused Setting:	Allowable Range:															
144 ml/hr.	0007 ml.	6.8 - 7.2 ml.															
288 ml/hr.	0048 ml.	46.6 - 49.4 ml.															
799 ml/hr.	0048 ml.	46.6 - 49.4 ml.															
999 ml/hr.	0048 ml.	46.6 - 49.4 ml.															

Figure 8. Required tests and allowable tolerances for a Model 960 infusion pump.

Connector to MTS

Connector to
Alarm Switch

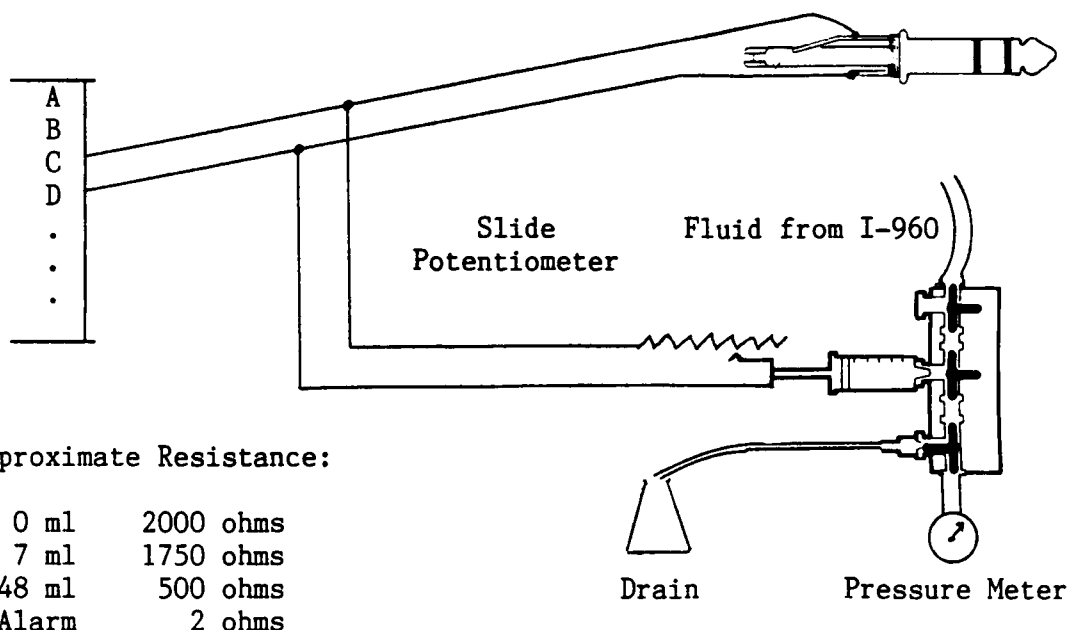


Figure 9. Schematic of the dedicated device interface used to test the Model 960 infusion pump.

slide potentiometer. The plunger of a 50cc syringe is mechanically connected to the slide potentiometer. A manifold is provided for routing of the pumped fluid into the syringe or to a pressure gage and eventually to a waste receptacle.

The operation of the device interface is simple. The syringe is emptied by pressing the plunger. A resistance reading is taken by the DMM and is recorded as the zero volume point. The computer prompts the operator to set a volume to be infused and a rate of infusion. The start button on the pump is pressed simultaneously with the run button on the controller and timing begins. The pump forces the fluid into

the syringe and provides an infusion complete signal after it has pumped the set amount. The accompanying closure of the "Nurse call" contacts is detected by the DMM and stops the program timer. The pump is turned off and the DMM takes another resistance reading from the slide potentiometer. The "empty" resistance reading minus the "full" reading can be converted directly into a volume measurement by the program. The resistance to volume ratio was calibrated with a laboratory burette to be 38.37 ohms/ml. This factor provides the means of recalibrating the interface device for individual characteristics of the syringe chosen.

CHAPTER IV

SOFTWARE DESIGN

As part of the development of the first test program, guidelines for the structure of future programs were established. A fully implemented automatic test system would include hundreds of programs. The source of these programs would be various manufacturers, service organizations and clinical engineers. Although originating at different locations, these programs would be easily useable by all test personnel if a uniform format was followed in their design. Consequently, guidelines for programming style, content and written documentation were essential to aid both programmers and users. In the following pages the software design philosophy and formats that were followed in the presently described effort are outlined and a brief summary of four programs used as test cases is presented.

The design of a test program should be tailored to the characteristics of the test personnel as well as to the device to be tested. A relatively inexperienced and untrained operator needs step-by-step and detailed instructions. To minimize his confusion the novice operator should be presented with little measurement data except the final printout indicating a passed or failed test. He needs no knowledge of the program itself and he should have no control over it for modification of tests performed or values obtained. On the other hand, an experienced user may require all of this information. He may desire to repair the DUT as the test proceeds. In this case, he will want

displays of measurements and test results as they are generated. He may need to back up within the program to repeat a portion of the test after a problem in the DUT has been identified and corrected. He may desire to change slightly the control settings of the DUT or vary the acceptable test limits. Finally, he may desire to modify the test program for DUTs somewhat different from the model for which the program was designed.

The design philosophy used in the developed programs is a working compromise between these extremes. Complete program documentation is provided for the experienced user. However an inexperienced user is not required to refer to the complete program description while routinely using the tester. After two or three practice runs any person should be able to complete a test relying solely on prompts presented by the system. Furthermore, standardization of local labels gives the operator some knowledge of all programs and allows control of the test procedure without having to refer to the detailed program listing. Pushing the "A" key provides a menu of the tests initiated by the remaining keys, "B" through "J". If all prompts are followed, these routines are accomplished in alphabetical order. However, the subroutines are self-contained and may be performed in any order. For example, pressing "C" at any time initiates the leakage current program. Likewise, Pressing "I" at any time gives a printout of the last test results. This printout can be attached to a work order for historical records. The system could easily be configured so that a push of the "J" key could transmit the data to a centrally located computerized record system, thereby reducing the necessary paperwork.

Once a test is performed and another similar DUT is to be tested a short restart method is provided. If the next DUT is the same as the last one tested, pushing "B" begins the testing without having to re-initialize the calculator. To test a different type of device the new program must be read from the tape drive. A complete start-up procedure is provided in Appendix D (page 118). This procedure must be followed only for a new calculator or one from which batteries have been removed for an extended period.

The test technician is provided with a standard documentation package for each test program. The first page of each program documentation package is a condensed user's guide. The first section of the guide indicates all special control settings necessary for each instrument in the PMATS. Most programs use the first 50 data registers of the HP-41C for storage of test results. The remaining registers contain the program itself. The Data Register section of the user's guide lists the test parameter stored in each location. Using this guide a technician can view test results in each register without having to wait for the final printout. Similarly, measurements stored in these registers can be manually changed if recorded incorrectly during a test procedure.

Throughout the program, flags are set to indicate to the operator the status of certain tests. The Error Flags section of the user's guide provides the meaning of the appearance of a numerical flag during the course of a test run. The Key Assignment section indicates the subprogram which is initiated when that label key is pushed. The comments section contains additional information that has proven useful

during operational runs of the test program. The condensed operator's guide also assists the programmer in remembering which registers and functions have been used.

The body of the program documentation is arranged in columns as follows:

1. The center of the page contains a complete program listing.
2. At the left of the page are instructions to be followed by the test operator.
3. The right column contains programmer's comments explaining in some detail what the program actually does.

An actual printed output from each program is included on the last page of the program documentation.

Complete documentation for four developed and tested programs are contained in the Appendices. Appendix E (page 120) contains the first program, called PRTEM, which is an acronym for "Printer Program in Extended Memory." It is written to be used by larger test programs. When executed it produces a printout heading followed by the date and time of the printing. It then uses data stored in designated registers to print the department which owns the DUT, control number of the device, technician's name, length of the test in hours, ground wire resistance, and leakage current values in a standard format.

The next program, in appendix F (page 125), is also written to reside in extended memory and to be called upon by other test programs. It is called LEAKEM for "Leakage Current Program in Extended Memory." The first 30 instructions are explained in detail in Table 8. A study of this section will provide the reader with an understanding of the

TABLE 8
DETAILED EXAMPLE OF PROGRAMMING LANGUAGE

Statement	Explanation
01 LBL "LEAKEM"	A label provides the means for calling and executing a subroutine or program.
02 .01101	A loop control constant 0.01101 is stored in register 10.
03 STO 10	Beginning of a loop which will clear flags 0-10.
04 LBL "CLFG"	Clear flag specified by the integer part of the number in register 10.
05 CF IND 10	Controls the loop by using the constant xx.yyyzz in register 10. Specifically, increment the number xx by zz and skip the next statement if the new xx is greater than yyy.
06 ISG 10	Go to label "CLFG" and reiterate the loop.
07 GTO "CLFG"	
.	Similar loop clears all data registers.
.	
15 LBL "GR"	Beginning of routine which checks the resistance of the DUT ground wire.
16 "CONNECT GRD"	Store this message in the Alpha register.
17 AVIEW	Display the Alpha register.
18 PSE	Pause to allow operator to read the Alpha register.
19 "DUT OFF=R/S"	Enter message in Alpha register.
20 BEEP	Produce an audible tone.
21 PROMPT	Stop and display the Alpha register until R/S is pushed.
22 XEQ "SELCON"	Execute a program written to select the converter in the MTS in order to pass data to it.
23 115	Put the constant in the X register.
24 Trigger	Send a trigger command over the interface loop to the selected device. The MTS uses it as a reset.
25 ACCHR	Send the ASCII character numbered 115 to the MTS. This is an "s" corresponding to binary 001110011 which energizes relays 3 and 4.
26 XEQ "OHM"	Execute a program that takes a resistance measurement with the DDM.
27 STO 11	Store the resistance reading in register 11.
28 2	Store the number "2" in register X.
29 X<=Y?	Execute the next statement if the value in X is less than or equal to the value in Y.
30 GTO "GR"	Loop back if the ground wire fails the test.

HP-41C language and of the passing of information around the interface loop. This annotated excerpt represents approximately 5% of the test program. The difficulty of understanding a program written in this calculator language is also illustrated.

Specifically the 30 lines of code in Table 8 tests that the green wire in the DUT's power cord is intact. Standard leakage current measurements are made next. Millivolts of alternating current (MV AC) are measured across the AAMI filter with the DUT grounded and with the polarity of the power cord correct. This reading is converted into microamperes and stored in register 12. The ground wire is opened and another reading is taken and stored. The hot and neutral lines are reversed and a third reading is taken and stored. The operator is prompted to turn the device on and the three tests are performed again. The maximum allowable value of each of these readings are contained in the program. The AAMI standard suggests 100 microamps as the upper limit for this test. However, for the particular devices tested, a normal reading is much lower. Therefore 25 microamperes is chosen for an upper limit in program step 57. A DC leakage current is an unusual condition. A value greater than five microamperes seemed appropriate to flag the operator of a possible fault. A very low leakage current indicates that a faulty building power ground may be present. To warn the operator of this condition, flag 03 is set if a normally high reading is less than 5 microamperes.

The LEAKEM program is not completely self-contained. In order to conserve memory, the subroutines SELCON, MVAC, OHM and MVDC are normally included as part of a main program. A typical example of

these routines in a calling program is included in the program documentation on page 133.

Appendix F (page 125) contains the complete program document for the model BW-5 blood warmer test program. The program follows the performance test flow-chart provided earlier in Figure 5, page 53. In the HP-41 programming language "Labels" are used to designate subsections or subroutines. An explanation of each of these labels follows. Subroutine "A" provides a handhed computer's version of a "MENU" found on larger user-friendly computers. When key "A" is pressed a listing of the test steps initiated by each of the remaining keys, "B" through "I", is displayed. Label "B" begins the test program after asking for the DUT's control number. The operator is prompted to perform visual and mechanical inspections of the blood warmer. The mechanical check requires that the operator enter the measurement of the door gap using a test gage. Tolerances are checked by the controller. This subroutine also performs some necessary initialization steps.

Label "C" checks the warm-up rate of the blood warmer. The prompt "DUT ON=R/S" signals the operator to start the controller when the DUT is energized. After two minutes a temperature reading is taken at the warming plate. An error flag is set if this temperature is less than 30 °C. Label "D" executes the LEAKEM program which was described earlier.

The subroutine "RDTMP" is not directly initiated by any function key. It is called in any step requiring a temperature determination. The controller routes the thermistor leads to the DMM, makes a resistance measurement, then converts that reading into degrees using the

Steinhar and Hart equation. The temperature control capability of the warmer is checked in routine "E". The DUT is allowed to stabilize for 30 minutes. A series of three sets of three readings from the door warmer, the plate warmer and the digital display are recorded. Allowable variations in these readings, provided by the manufacturer, are tested within subroutine "E".

The next two subroutines, "F" and "G", tests safety features of the blood warmer. Holding the alarm switch and pressing R/S initiates a process of timing the DUT until an over-temperature alarm sounds. The plate temperature is then measured. An audible alarm signals the operator to press the breaker test switch. The R/S key is pushed when the breaker is heard to trip, and a time interval measurement is completed. The breaker should activate in three seconds reaching a maximum temperature of 40 °C. This completes the test and the operator is instructed to push the "I" key to obtain the printout. The last part of the printout contains an error list. The flags are reviewed and an error message is printed if appropriate.

Appendix H (page 142) contains the documentation for the program which tests the model 960 IMED infusion pump. The first sections of the program are similar to the blood warmer test program. Subroutine "A" initializes the test equipment and clears the storage registers. Subroutine "B" executes LEAKEM after the control number for the DUT is entered. Subroutine "C" prompts the operator to perform a series of visual operational checks. These prompts are a duplicate of those contained in an inspection sheet provided by the manufacturer. If any test fails, the operator is instructed to press the sequence "STO 10".

This action eventually results in an error code for that section being printed in the failure list of the final output.

Subsections "D" and "E" insure that the infusion pressure for the operation and purge modes are within specified ranges. The purge function is used to clear the pump of any air in the tubing. The test technician is required to operate manifold valves in order to route the pumped solution to a mechanical pressure gage. He then enters the resulting measurements into the calculator. Flag 00 is set if the operating pressure does not fall between 10 and 25 psig or the purge pressure is less than 10 psig.

Measurement of the flow rate and total volume infused are accomplished in subroutine "H". There are five flow rates and volumes recommended by the manufacturer for testing. In each case the operator is prompted to dial in these settings and initiate pumping at the same time the controller is started. Subroutine "N2" accomplishes the measurement by first storing the start time and the resistance value of the slide pot for an empty syringe. Resistance values are read at a rapid rate until a reading of less than 50 ohms occurs. Such a low reading indicates that the infusion complete signal has been activated. A time interval and a net change in resistance provides means to calculate a volume infused and a rate. A calibration factor of 38.78 ohms/ml of volume in the syringe was obtained from calibration runs. Storage register 4 was designated for the error tolerance in order to allow an easy adjustment of this factor.

After all five rate tests are performed, the operator is instructed to start a printout. The PRTEM routine is called to provide

a standard heading and leakage current values. Tables of operating and purge pressures, flow rates and infused volumes are then printed. Error messages are provided based upon flags that have been set through-out the program. A few additional times and resistance measurements are printed during the program. These were primarily used during test runs of the program to detect operator errors.

CHAPTER V

SYSTEM AND SOFTWARE EVALUATION

1. EARLY TESTING AND CALIBRATION

Subsections of each program were first tested independently. Next they were combined and tested in real-time using an actual DUT. Each real-time run with no errors was found to consume approximately one hour. Most of the runs required to locate and correct programming errors were completed by the author. However, early in the design stage, two hospital BMETs were asked to run the programs and report their assessment.

Several conclusions suggested by these early runs influenced the final design of the programs and of subsequent test runs. The first conclusion was that the many manual interventions required of an operator throughout the test cycle made periodic erroneous control settings or data entry a virtual certainty. The number of such interventions was subsequently reduced to a minimum. Additionally, since size, complexity and expense of "knob turners" and automatic actuators prohibited the incorporation of such devices into the PMATS, extensive error recovery procedures were added to the programs.

The second conclusion was that test cycle times would vary by 50% even when no problems or errors occurred during the program run. The speed of operator performance often increased significantly after the first or second run. This variation resulted because the required

actions were fresh in the operator's mind and he prepared to do them prior to the appearance of a prompt. This normal variation was found to be lost if several days elapsed between test runs of a particular program.

Abnormal occurrences during test runs produced even greater time variations. Often an operator performed a step incorrectly and totally disrupted the normal program sequence. Such early runs were terminated and not used as final data. Some portions of the performance checks were much more quickly performed by the person familiar with the test protocol and setup. To discount the effect of this variation several of the operator intensive steps were excluded from the final test runs. These steps included the initial setup of cables and tubing, the final removal of the test equipment, the mechanical check of the blood warmer and the drop sensor check of the infusion pump.

Another early discovery was that once a program has been finalized, changes should be made only if absolutely necessary. Small problems of procedure or calibration were better left unchanged for a time. Testing should proceed until a significant number of problems are detected. Several changes should then be made simultaneously and a new program designation should be provided on printouts. Such a procedure provided more meaningful comparisons between early and final test data and resulted in less operator confusion.

Calibration of all devices and interface equipment was accomplished prior to the final test runs. The leakage current program LEAKEM, which was used as a part of several tests, was used for the first calibration checks. The program's performance and the accuracy

of the DMM switched through the MTS was evaluated using a test adaptor having a known leakage current in each of the six modes of operation. Table 9 contains the data from this test.

TABLE 9
TEST RESULTS USING ADAPTORS HAVING KNOWN VALUES

Configuration	Actual Value	-----Measured-----			
		1	2	3	4
Ground resistance (Ohms)	0.2	1.1	1.1	1.1	1.1
DUT Off (Microamperes)					
Normal Grounded	0.0	0.8	0.7	0.7	0.8
Normal Ungrounded	100.0	98.8	98.8	98.7	98.3
Reverse Ungrounded	12.0	13.8	13.8	13.8	13.8
DUT On (Microamperes)					
Normal Grounded	0.0	0.6	0.6	0.6	0.6
Normal Ungrounded	40.0	42.4	42.5	42.8	42.7
Reverse Ungrounded	350.0	352.9	352.9	352.0	351.9

As can be seen from the above data, the consistency of the measured values is good. The error is less than 1% at 350 microamperes, but increases to 15% at 12 microamperes. Similarly, 0.9 ohms is added to all resistance measurements. The difficulty of obtaining accurate low values is probably due to errors introduced in the MTS. Both the DMM routing relays and the ground breaking relay adds resistance to the ground cable measurement. The proximity of the power reversal relay to the signal path inside the MTS probably adds 0.5

microamperes to all readings. With additional calibration these errors could be better estimated and subtracted from the final printed values.

Tests of the calibration of the temperature probes used during the check of the blood warmer were performed next. The two test thermistors, a Fluke Model 80T-150 temperature probe, and a Brooklen calibration thermometer were placed together in a circulating water bath and a series of readings were taken. Table 10 contains the temperature measurement obtained from this test. The Brooklen thermometer reading

TABLE 10
COMPARISON OF VALUES OBTAINED FROM FOUR TEMPERATURE INDICATORS

Probe	----- Temperature °C -----					
Brooklen Thermometer	30.2	30.9	32.1	34.1	36.5	37.5
Fluke 80T-150	30.0	30.6	32.1	33.9	36.3	37.4
PMATS Probe #1	30.4	31.1	32.5	34.3	36.7	37.8
PMATS Probe #2	30.3	31.0	32.5	34.2	36.6	37.7

was accepted as the correct reference temperature. The first thermistor probe read an average of 0.25 °C high. The second thermistor probe read an average of 0.17 °C high. The Fluke probe, which is used for manual blood warmer tests, read an average of 0.17 °C low. Because of the difficulty in obtaining reliable temperature readings without a constantly-mixed and well-regulated bath, the coefficients used in the

Steinhart and Hart equation given on page 55 were not changed based on these error readings.

Two factors were involved in the calibration of the DDI for measuring fluid volume and flow rate from the infusion pump. Accuracy of the clock in the HP-41C was determined using long-term time checks against Universal Coordinate Time in Bolder, Colorado accessed by telephone. The timer module originally lost 28 seconds a month. This error was reduced by using the calculator's "CORRECT" function. However, this time inaccuracy was considered to be nonexistent since it was very much smaller than errors from program execution times. Calibration of the volume measurement syringe, which was accomplished during design of the infusion pump interface, has been explained on page 59.

2. TEST SETTING AND PERFORMANCE CRITERIA

The PMATS was designed specifically for testing equipment within patient areas of a hospital. Currently such testing is accomplished by equipment users, hospital BMETs, service organizations and manufacturing representatives. A complete evaluation of the test system would include use by persons from each of these groups. Of course the criterion for success or failure of the system would be somewhat different in each case. Each of these test groups has relatively well defined requirements for the test equipment which they must use.

The criterion for evaluating the performance of the test system is its fulfillment of the attributes of a good test system as listed in Table 7 (page 45). The factors as discussed previously are speed, accuracy, reliability, utilization, cost per test and safety. An

important question is what relative weight to assign to each of these factors. Hospital administration might prefer a system having high utilization, requiring untrained operators and having a rapid throughput. On the other hand, a nursing unit might suggest accuracy and convenience as the most important criteria. The data reported here provides the reader with a comparison between results from the manual test method and the automatic test system for each attribute and notes, where applicable, the relative merits of each attribute. This merit is based upon indications from various sources which the author has received over several years of inspecting equipment and direct conversations with other service and hospital personnel. Table 11 summarizes the general system requirements as expressed by members from each of these groups.

An appropriate test of an automatic system would have been to provide the programs and hardware to persons in each of these groups and ask for their evaluation. Various lengths of training on the test system could have been provided prior to use by each of these groups. It is recognized that such outside evaluations would be essential to fully determine the system's usefulness and practicality.

Due to the reasonable time constraints the author chose to keep the system and test it completely within the hospital in which he was employed. This was done to extend the learning process into the problems of system evaluation and to permit immediate program changes if problems occurred. The final test protocol included the following test of each program:

1. two standardization test using conventional equipment;

TABLE 11
IMPORTANCE ATTACHED TO TEST SYSTEM QUALITIES
BY VARIOUS PERSONNEL

Characteristic of the System	-----Group-----				
	B ^a	N	I	M	A
Accuracy Traceable to NBS	2 ^b	3	1	1	1
Small Enough to Hand Carry	3	5	1	1	5
Constructed to Sustain Drops During Transportation	3	5	1	1	5
Short Assembly and Setup Time and Disassembly Time	1	5	1	1	2
Reconfigurable to all Types and Manufacturers' Equipment	1	5	1	5	1
No User Technical Knowledge Required	5	1	3	3	1
Total Test Time a Minimum	1	1	1	1	1
Test Program Generation Time Minimal	1	5	1	5	2

^aAn answer of "1" indicates a primary requirement. An answer of "5" indicates a reluctance to accept additional cost for the indicated capability. Other answers are intermediate variations.

^bGroup "B" includes BMETs working within one facility; Group "N" includes nurses or medical technicians; Group "I" includes independent organizations performing operational tests on equipment from various manufacturers; Group "M" includes service representatives working on a limited number of models of equipment; Group "A" includes administrative personnel.

2. three tests of PMATS on an actual DUT performed by the author;
3. three test performed by a BMET familiar with the DUT;
4. three test performed by a BMET unfamiliar with the DUT.

None of the participating BMETs had extensive knowledge of the test program or of the test language used by the controller. Manufacturer's test protocols and PMATS documentation were reviewed during the introduction time. Each BMET was initially given a demonstration of the performance test using the PMATS. He was then asked to run the test on his own with the author observing. Difficulties arising during the test and all pertinent BMET comments were noted on evaluation sheets and are summarized in the next section.

Subjective feelings about the design and usefulness of the test system were also solicited from the BMETs and recorded. Each technician was asked the following questions:

1. Is the automatic test system useful?
2. In what ways could it be beneficial?
3. What are its disadvantages?
4. Is it enjoyable to operate?
5. Would he like to use it for equipment inspections?

Since the goal of this evaluation was the testing of PMATS rather than the testing of a DUT, the same DUT was tested in each of the final runs reported. Actual DUT performance values were taken as the average measurement obtain with that DUT during two manual standardization runs. Error analysis for the PMATS were based upon these standard values rather than on the control setting of the DUT.

3. FINAL TRIAL DATA

Table 12 contains the time measurements obtained during the nine final test runs of the BW-5 test program. The initials of the operator are used in the test name. The two minute warm up values are included since the blood warmer was warm from previous test runs. Similarly, all times are from a test which substituted a two minute warm-up period for the normal 30 minute wait. The average error in both temperature and leakage current is less than 5%. The time increase for the automatic test is 12%.

TABLE 12
REPRESENTATIVE MEASUREMENTS FROM THE BLOOD WARMER TEST PROGRAM

Test Name:	Length: Minutes	Average Temperature °C:			Leakage uA:	
		Plate	Door	Display	Off/NUG	On/NUG
Standard	8.61	36.2	35.3	36.6	16.8	25.0
Manual #1	8.57	36.2	35.2	36.6	16.5	24.0
Manual #2	8.65	36.1	35.4	36.6	17.1	25.0
WPM #1	9.58	36.4	35.9	36.6	17.8	24.3
WPM #2	9.08	36.6	35.4	36.7	18.1	25.5
WPM #3	9.27	37.0	37.5	36.3	17.8	24.2
DEO #1	10.42	37.1	37.7	36.7	19.9	31.4
DEO #2	9.83	37.0	37.0	36.7	16.7	23.8
DEO #3	10.77	36.9	36.7	36.7	17.1	24.5
SCM #1	10.33	37.0	36.8	36.8	17.8	25.4
SCM #2	8.87	37.0	36.7	36.8	17.7	25.3
SCM #3	8.85	36.9	36.4	36.8	17.8	25.3

Table 13 lists the time required for completion of the individual sections of the infusion pump final test runs. There is approximately a 6% increase in test time using the automatic test system. With the average automatic test time of 52.8 minutes there is a standard deviation of 5.6 minutes. The standard deviation for the two manual test times is 8.78 for an average of 50.5 minutes.

TABLE 13

TIME MEASUREMENTS IN MINUTES FOR PORTIONS OF FINAL TEST RUNS OF
THE INFUSION PUMP PROGRAM

Test Name	Setup/Leakage	Pressure	Delivery	Total
Standard	6.28	5.98	38.26	50.51
DAC Manual	4.23	4.77	35.30	44.30
ELB Manual	8.32	7.18	41.22	56.72
WPM #1	13.22	6.00	35.00	50.00
WPM #2	5.17	5.00	43.33	56.30
WPM #3	6.58	4.50	35.50	45.00
DAC #1	10.17	5.75	33.08	51.20
DAC #2	9.62	4.35	39.02	53.20
DAC #3	5.12	5.77	35.17	45.68
ELB #1	10.03	6.87	39.50	60.90
ELB #2	8.50	7.27	37.13	53.33
ELB #3	10.51	6.52	42.50	60.00

Table 14 lists the time and infused volumes measured during each of the eleven final test runs of the infusion pump program. The average error in time measurements was less than 1%. Volume measurements were consistently 3% low. For a mean volume of 45.3 ml the standard deviation was 0.64 ml.

Table 15 contains abbreviated responses of the test technicians to the subjective questions asked during the tests. The overall feeling was that the system would be beneficial but requires simplification and an increase in speed.

TABLE 14
LISTING OF CYCLE TIME AND INFUSED VOLUME FOR EACH FLOW
SETTING DURING THE FINAL INFUSION PUMP TESTS

Test Name		Flow Rate Setting				
		33	144	288	799	999
	minutes	ml	ml	ml	ml	ml
STANDARD	12.72	6.9	6.9	46.7	46.7	46.8
DAC MANUAL	12.72	7.0	6.9	46.5	46.7	46.7
ELB MANUAL	12.72	6.8	6.8	46.8	46.6	46.8
WPM #1	11.97	6.3	6.6	43.9	43.6	46.0
WPM #2	12.67	6.9	6.4	45.4	44.5	44.8
WPM #3	12.73	6.3	6.5	45.7	45.2	44.8
DAC #1	12.60	6.8	6.4	46.0	45.9	45.6
DAC #2	12.75	6.8	6.4	46.1	46.1	45.5
DAC #3	12.63	6.8	6.4	44.4	45.1	46.2
ELB #1	12.80	7.4	6.6	46.1	44.4	44.2
ELB #2	12.65	6.3	6.7	43.3	45.6	44.9
ELB #3	-	-	6.6	44.4	45.1	45.5

TABLE 15

TECHNICIAN RESPONSES TO SUBJECTIVE QUESTIONS ABOUT THE TEST SYSTEM

Question: Is the test system useful?

- Answers:
1. Not likely, because of additional time required to perform test.
 2. Possibly.
 3. In special cases.
 4. For some tests.

Question: In what way is the system beneficial?

- Answers:
1. It requires less attention once it is operational.
 2. For performing tests requiring much data processing.
 3. Reduces the necessity to read inspection procedures.
 4. Fewer operator actions are required and no inspection sheets have to be written.

Question: What are its disadvantages?

1. Extends the time necessary to complete the tests.
2. Abbreviated instructions are hard to follow.
3. Difficult to move to test site.
4. Easy to make minor errors that produces erroneous results and significantly increases the test time.

Question: Would you like to use it routinely?

1. Only if it were less complex, with a single on-off switch.
2. No, because it significantly increases test times.
3. Yes, whenever there were tests required on a number of items of the same type.
4. Sometimes, if the tests were self explanatory without the necessity of reading instructions.

Question: Is it enjoyable to use?

1. No, because there is already a shortage of test time.
 2. Yes, because it is reminiscent of use of larger automatic test system.
 3. Yes, because of a personal interest in programing and computers.
 4. Yes, at least for a short time, because having only to push buttons rather than writing and switching equipment is a novel experience.
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CHAPTER VI

DISCUSSION OF RESULTS

1. APPRAISAL OF SYSTEM HARDWARE

The calculator, peripherals and DVM purchased from Hewlett-Packard functioned well and in accordance with all factory specifications. There were no unexplained failures in the PMTS caused by incorrect operation of the calculator, interface loop or peripherals. The timer module with calendar and stopwatch was also exceptionally useful as a system component. The DMM functioned accurately and reliably and was often used as a stand-alone device without the test system. The DMM's maximum measurement rate was limited to approximately once per second due to the combined time to locate and set the relays in the MTS and configure the DMM. This sample rate is much too slow for analysis of any waveform with a frequency greater than about two hertz. However, this limitation was evident prior to equipment selection and was deemed relatively unimportant. Such a dual slope integrating DMM is generally used for its high accuracy rather than measurement speed.

The system's modularity requirement was well satisfied. As explained on page 32, modularity applies to a system which is both expandable and reconfigurable. Each component included in the PMATS has uses not related to its application in this system. The modules selected to be used with the HP-41C have proved so popular that they are a part of the new Model HP-41CX calculator. Other portable instru-

ments are now available for use directly on the interface loop. These include a disk drive, printer, signature analyser and three models of computers.

The Hewlett-Packard equipment did have some unexpected shortcomings. The HP-41 calculator was incapable of fully utilizing all capabilities of the interface loop, such as changing the control parameters. The bar code wand would only read a special format of bar code and, in particular, would not read standard Universal Product Code (UPC) which had been considered as a control number to be placed on each medical instrument.

The digital multimeter seemed physically larger than desirable for a portable system. The DMM would operate on battery power only for a few hours and it could not respond to the "sleep command" which allowed all other devices on the interface loop to conserve battery power. Batteries in general seemed to be a source of failure. The rechargeable batteries in the cassette drive would not hold a charge and had to be replaced. Sustained battery operation was seldom needed, however, since the DUT and the MTS require external power. Line power adaptors were used with the printer, cassette drive and DVM.

The use of the line power adapters added to the numerous connecting cables. There were five power cables, four HP-IL interconnect cables, a DMM input cable, chassis ground, and dedicated device connections. These cables and the numerous separated instruments made movement of the system difficult. Part of this problem was overcome after the wooden case with a metal bracket and handle, shown in figure 4 (page 51), was constructed to keep all the instruments together.

The limitations of the 12 character calculator display became evident immediately. The tape drive had the capacity to store detailed operating instructions. This capability was of little use because of the time required to scroll sentences across the calculator display. An operator would quickly tire of these instructions after having read them once.

The devices fabricated by the author also operated satisfactorily. The MTS functioned reliably throughout the test. It was in constant use because all instruments connected into the interface loop had to be powered up in order to use any peripheral device. A short reset program called TRG was used to initialize all relays to their inactive state to prevent them from being energized for long periods. The main fuse in the MTS blew one time due to the heavy current draw of the blood warmer during its first few minutes of warming. This problem never occurred subsequently.

The interface device constructed for testing blood warmers was simple effective and efficient. It demonstrated well the ability of the test system to use its combined measuring and calculating power to achieve accurate measurement of temperature with the use of very inexpensive probes. The DDI used for testing infusion pumps was also simple and effective. The linear potentiometer and mechanical linkage allowed the measurement of flow rate for any volume and were not sensitive to an incompletely emptied syringe. The fluid manifold proved to be a troublesome component, as it tended to leak and its operation was difficult to learn by the test technicians.

2. APPRAISAL OF SYSTEM SOFTWARE

Each test program functioned satisfactorily. The programming characteristics that proved most beneficial were:

1. program structured with self-contained subsections;
2. built-in error recovery procedures;
3. immediate displays of test measurements and flags.

Self-contained subsections were easy to relocate, modify, and reuse in case of operator error. Simple operator errors occurred in most test runs. Automatic procedures for recovering from these mistakes were essential for operator acceptance of the test system. Displays of measurements served to keep the operator informed and interested in the test being performed.

The arrangement used to document all programs was convenient for program generation, modification and execution. Modifications were penciled into the explanation column and new program listings were conveniently taped over the older listing. An inexperienced operator had only to look at the left hand side of the page for operating instructions. Those operators who wished to know more about the program referred to the explanations given on the right column of the page. The program listing in the center of the page provided needed detail for modification of the program operation.

3. APPRAISAL OF THE PRINTING PROGRAM

The printing program PRTEM was always used in conjunction with another program. It produced a precisely formatted print-out that was

used as the basis of the final output of several programs. The automatic printing of the time and date of the test is extremely valuable for permanent reports. The standard format for equipment number, measured values, department and test technician's name made references to the performance inspection straightforward. The small size of the printer paper made it convenient for attaching to larger test sheets. One notable shortcoming associated with the use of thermal sensitive paper was found to be a significant degradation in print quality after extended storage.

4. APPRAISAL OF THE LEAKAGE CURRENT PROGRAM

The combination of two programs, LEAKEM and PRTEM, produced an effective package for automatically testing any instrument's leakage current. Consequently, the LEAKEM program was tested with many different types of medical equipment. Using the PMATS for testing of leakage current requires no additional test equipment and requires about one minute for performance. A trained technician with a leakage meter can obtain and record the measurements in about the same time. There is a small possibility that the operator may read the meter incorrectly or transcribe an incorrect value. Neither occurrence is likely while using the automatic test system. The automatic system removes the possibility of transcription errors. The measurement of very small leakage values is somewhat less accurate than those obtained by conventional means. However, the automatically obtained values were found to be more repeatable, since they were taken at exactly the same time and under the same conditions during all test runs. Variations which occur

due to insulation degradation are expected to be more apparent under such conditions.

Using a human observer to take a leakage current reading has an additional benefit. Some equipment has a surge of leakage upon initial power-on or varying leakage during different operational cycles. These changes are obvious to an observer obtaining a measurement. An operator who sees a variation normally writes down a range of values for future reference. The LEAKEM program, on the other hand, records only a single value taken at one instant in time. To correct this situation the PMATS could be programed to take two or more readings for each test. The resulting values would be significant for some instruments under test but would also lengthen the test time for all instruments.

The excessive ground wire resistance, mentioned in the calibration section, is also observed in the data. This error could have been removed using the four wire resistance measuring capability of the DMM but the results did not seem to justify the additional cabling and relays required for a four-wire test. The power relay and wiring of the MTS introduces a small amount of leakage to the total for the device tested. This error could have been subtracted from the reading since it is expected to remain relatively constant over the life of the test equipment.

5. APPRAISAL OF THE BLOOD WARMER TEST

The BW-5 program proved quite effective in use. Its completion time is approximately a minute longer than the manual method. This slight difference in time is largely outweighed by the 30 minutes of

warm-up waiting time that normally is required. Although attaching the thermistors to the warming surfaces is time consuming the delays of having to wait for a manually held probe to reach new temperatures are removed. Several advantages were found to result from using the PMATS. The operator can not easily take short cuts in the testing procedure, there is relatively no chance of logging an incorrect reading and prescribed tolerances are automatically checked. No special equipment was purchased for this test other than two disposable temperature probes.

A leakage error message always occurs with the program printout. The maximum limit was set at 25 microamperes, which was unintentionally low. It was left that way to demonstrate a potential problem in medical equipment checks. The AAMI standard is a maximum of 100 microamperes leakage for this instrument, the manufacturers tolerance is 50 microamperes and its actual maximum was found to be 40 microamperes. An engineer might set a error message to occur at a reading above 40 microamperes in order to detect a small change. If this limit were exceeded an error message would be printed even though the device met all published standards. If a patient was subsequently harmed by the device, even from an unrelated problem, a case could be presented that the unit should have been removed from service. Tolerance set on any such system would have to be very well considered for possible liability implications.

The blood warmer program is significant in that steps were take to keep the operator informed as to the stage of program testing. A menu is displayed early, each operator prompt is printed as well as

displayed, and the operator must initiate each section by pushing the appropriate subroutine label key. These actions tended to slow the routine execution of the program somewhat but error recovery is easier if the operator knows at which point he is in the program. The infusion pump program, which will be discussed next, is more streamlined without these prompts.

6. APPRAISAL OF THE INFUSION PUMP TEST

The automatic infusion pump test outcome was very similar to a conscientiously done manual test. Both methods require approximately 50 minutes to complete. The automatic test equipment is somewhat less bulky than the burette that must be used during a manual test. The burette is an extremely accurate device if care is used in obtaining and recording fluid levels from it. However, in practice the operator tends to read close values in favor of the accuracy which he believes the pump to have. The automatic recording of values removes this operator bias.

These tests provided a meaningful study in accuracy of performance tests. The 960 pump is an expensive device, well designed to deliver accurate volumes. The pump carefully controls the movement of the piston contained in a disposable cassette which are not always manufactured under close tolerances. As a result the time taken to deliver a set volume may be a better indicator of correct pump operation than actual volume delivered. This may explain why the test data shows less error in delivery times than in delivered volumes or flow rates. Also, like the pump itself, the timing accuracy of PMATS has

fewer sources of error than its volume measurement system. Error in volume measurement can occur from:

1. non-linearity of the slide potentiometer...2%;
2. manufacturer's tolerance in ohms reading...2%;
3. stretching of connecting tubing under infusion pressure...5%;
4. leakage of connections and stopcocks...1%;
5. program delay in taken of ohms reading...1%.

Error percentages in items 1 and 2 are from the manufacturer's literature. Percentages in items 3 and 4 are from estimations of the volumes of fluid considered with respect to the syringe size. The percentage of item 5 is from an estimated one second of extra flow over a total period of three minutes. The characteristic accuracy of PMATS is very acceptable for a Go/No Go tester. Measurements are not used to calibrate the pump, rather, simply to detect a considerable deviation from normal.

The major shortcoming of the PMATS which the infusion pump test demonstrates is the limitation of a 12 character calculator display. In the pump's operational evaluation, the BMET is instructed to perform certain tests and insure that the pump's display indicates correctly. The display has several lines and is best checked by comparison with a picture that graphically shows which segments must be operating. No single line character display could adequately do this. During the trials the operator familiar with the pump performed this step from memory, while the inexperienced operator referred to the manufacturer's written test procedure.

7. GENERAL DISCUSSION

Within the hospital where the author is employed performance inspections of similar equipment are scheduled as a group. The reasoning is that this decreases the test time in several ways:

1. It decreases test equipment set-up and disassembly time.
2. It decreases travel time since equipment of the same type is often in the same location.
3. It takes advantage of the BMET's ability to temporarily remember a test procedure.

These effects are noted for both conventional and automatic testing of equipment. The third factor decreases conventional testing time considerably because a BMET normally refers to the written test procedure only during the first test. Thereafter he relies on memory and a short inspection sheet to insure that he does not miss a particular test. This short term memory allows the BMET to perform subsequent tests increasingly faster.

The automatic test programs provided here do not allow such a savings in time. The BMET must still read each prompt and perform the required action. These actions can not be optimized extensively because the test program does not know where the BMET is standing or what he has in his hands at that time. On the contrary, if the BMET already knows what the next prompt will be and performs it ahead of time the test program may fail or be lengthened.

Another disadvantage of the PMATS is its inability to perform tests on multiple instruments simultaneously. On one occasion the

hospital received 30 small pumps which were designed to circulate warm water through special blankets for warming patients. The device had a single control for regulating the water temperature. A quick program was written using subroutines LEAKEM, RDTMPS and PRTEM which would test the device at various settings over a one hour period. The program functioned well and required little operator intervention but could test only eight pumps a day because of the necessity of following the pump's warmup while testing temperature regulation. The process was accurate and thorough but unacceptably slow. To finish the tests several pumps were operated simultaneously. Leakage current readings were taken manually at each pump while the others were warming. At 15 minute intervals a temperature probe was dipped into each tank and the readings were recorded. All the pumps were given a one hour check in about the time required to check a single pump automatically. In this case testing several pumps is easier than testing a single pump. Remembering to test water temperatures of a single pump at 15 minutes intervals is relatively difficult. It was easier in this case since the interim time was spent testing the temperatures of other pumps.

Although in this instance PMATS was not beneficial for conducting multiple test, it did prove beneficial for testing single pumps at a latter date. The test BMET had forgotten the details of the multiple test routine, the exact warmup rates and temperature regulating measurements. However, the PMATS test program provided a test routine whose measurement compared exactly with those performed earlier.

Automating the test process results in a relatively consistent performance time. This simplifies manpower allocation but requires

management to consider the benefit to cost ratio of each test performed. Such a rigorous indication of test time required would certainly be a welcomed figure if presented in equipment specification lists. Management could weigh necessary testing time in the decision to purchase a certain brand of equipment. This would allow for future man power allocations. It would also encourage manufacturers to provide convenient testability and not to suggest excessive periodic testing when a competitor might specify a lower test time requirement.

Evaluation and comparisons of test systems are difficult when the test systems do not produce comparable outputs. Minimum necessary outputs and accomplishments must be decided upon and then comparisons made between the relative effectiveness with which each system produces those outputs. As an example, a calculator-based test system can easily convert measurements of output currents into equivalent power based upon known load resistances. Power output is the general measurement specification of an electrosurgical unit. However a tester which simply records current is sufficient if specification sheets are rewritten in terms of current outputs. Similarly, a very neatly recorded output is of limited value over a quickly written measurement result if the output is seldom reviewed after recording.

CHAPTER VII

MAJOR CONCLUSIONS

Automatic medical equipment testing has already been introduced into hospitals in diverse ways. A small flexible test system of the type developed in this thesis has the capability to automate general performance testing. The author's evaluation of the PMATS is in agreement with the conclusions drawn from military operational level testing as presented on page 32. Certain additional general conclusions were presented on page 70 as drawn from the early trials of this portable test system. Pertinate specific achievements and deficiencies relating to the two devices tested are provided in the discussion of those particular tests.

Significant general conclusions drawn from this development and evaluation of a portable medical test system are as follows:

1. The size and cost constraints of such a system mandates that it be limited to the relatively inaccurate Go/No Go type testing. Device calibration and fault diagnostics are not easily handled by such a small system.
2. Greater thoroughness and reliability of test data were obtained. However, this benefit must be paid for directly by increased operator test time.
3. The cost of introduction of a small system of this type is minor for hardware but is major in engineering time needed for development of the test program sets.

4. In general, those qualities which contribute to the modularity of the system also contribute significantly to operator confusion and training time.
5. The major advantage that results from the introduction of such a system is the rigorous application of specifications and procedures to equipment performance inspections.
6. The major disadvantage results directly from the advantage listed in conclusion 5. Rigorous specifications and test protocols must be developed and additional time provided for test accomplishment.
7. Questions of medical liability must be considered when designing criteria which may result in a "failed" test of a needed medical device.

CHAPTER VIII

FUTURE DEVELOPMENTS

Several immediate changes could be made to the portable test system to improve it based on the evaluation runs reported here. The MTS was constructed larger than necessary to facilitate incorporating additional future capabilities. This space should be used to incorporate AC outlets for peripherals and to add a relay capable of switching heavy loads. Several valuable modifications to improve specific test programs were suggested by the BMETs while evaluating the system. One such modification to the programs would be to set the DMM to display automatic resistance readings after detecting high ground cable resistance. This would allow the operator to repair a defective power cable and to check its resistance prior to reinitiating the test sequence.

One additional modification should be made in the medical test set. It is not recommended that reverse polarity leakage current be checked on each inspection cycle and certainly not in the vicinity of a patient. This test is better reserved for the single acceptance test of a new device arriving at the hospital. Removal of the power relay, which was needed for the reverse polarity leakage measurement, would remove a source of error during the remaining leakage current tests.

Several instruments have recently become available which would provide needed improvements to the PMATS while keeping the same general system characteristics. Hewlett-Packard now produces a data logger which combines a DMM with configurable switching capabilities which, in

turn, would have been desirable for use in this application, replacing both the DMM and the MTS. An improved circuit for performing safety checks could then be developed. In general the switching of AC power to a device is an electronically noisy process and should not be accomplished using relays alone. One additional improvement would be to use the HP-75C or HP-110 portable computer as a controller. These machines, which were not available at the initiation of this project, use BASIC programming language, have larger memory and provide more complete control of the interface loop than the HP-41. It would not be desirable to spend a considerable amount of time learning the HP-41's language in order to write test programs in the future. This language is not transferrable to any larger system and has a limited useful future. Work with transportable languages such as Pascal, Ada, or Basic would better justify future expenditures of time for system improvements.

Future work is needed towards the development of basic sensors to be included in the test system. Important among these, are those to measure fluid flows and pressures suitable for use in checking a volume ventilator's operation. A Radio Frequency to Direct Current converter would allow the checking of electrosurgical units. Both of these medical devices are particularly capable of harming a patient and are complex enough to benefit from automatic testing.

Many new technological developments are now available which should be considered as replacements or additions to the PMATS as herein described. Several companies have introduced powerful computing systems in smaller packages. Good combinations of printers, mass

storage capability, large display and standard interface systems will allow the design of a system that a technician can carry with him routinely. Such a system could interface directly with an equipment data base. For example, the reading of a bar coded control number attached to a device could automatically draw up that equipment's test procedure and last inspection results. After the automatic test, significant changes could be flagged and new values could be automatically entered into the equipment data base.

Recent administrative changes have taken place in the health care delivery system which will impact upon future performance testing within hospitals. Third party prospective payment systems based upon diagnostic related groups has created a critical need to reduce the cost of hospital care. New changes in the Joint Commission's plant technology and safety management standards has given each hospital greater flexibility in developing its own equipment inspection guidelines. Such guidelines will have to be documented and followed in detail. These requirements, reduction in cost and an improvement in procedure, are exactly the aim of automatic testing.

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APPENDIXES

APPENDIX A

COMMANDS AND FUNCTIONS AVAILABLE FOR THE HP-41C

HP-41 FUNCTIONS LIST

■—Shift key.
 +—Addition operator.
 -—Subtraction operator.
 *—Multiplication operator.
 /—Division operator.
 1/X—Reciprocal.
 10^xX—Common antilogarithm.
 ABS—Absolute value.
 ACOS—Arc (inverse) cosine.
 ADV—Advance paper.
 AOFF—Alpha mode off.
 AON—Alpha mode on.
 APPEND—Append characters (+).
 ARCL—Alpha recall.
 ASHF—Alpha shift left.
 ASIN—Arc (inverse) sine.
 ASN—Assign.
 ASTO—Store Alpha data in register.
 ATAN—Arc (inverse) tangent.
 AVIEW—Alpha view.
 BEEP—Beeper.
 CAT—Catalog.
 CF—Clear flag.
 CHS—Change sign.
 CLA—Clear Alpha register.
 CLD—Clear display.
 CLP—Clear program.
 CLRG—Clear register.
 CLΣ—Clear statistics registers.
 CLST—Clear stack registers.
 CLX—Clear X-register.
 COPY—Copy program from module or peripheral into program memory.
 COS—Cosine.
 D—R—Degrees to radians conversion.
 DEC—Octal to decimal conversion.
 DEG—Degrees mode.
 DEL—Delete program memory lines.
 DSE—Decrement, skip if equal.
 EEX—Enter exponent.
 END—End program.
 ENG—Engineering notation.
 ENTER—Enter number in X-register into Y-register.
 E¹X—Natural antilogarithm.
 E¹X - 1—Natural antilogarithm for arguments close to zero.
 FACT—Factorial.
 FC?—"Flag clear" test.
 FC?C—"Flag clear" test and clear.
 FIX—Fixed point display.
 FRC—Fractional portion of number.
 FS?—"Flag set" test.
 FS?C—"Flag set" test and clear.
 GRAD—Grads mode.
 GTO—Go to label.
 HMS—Decimal hours to hours, minutes, seconds conversion.
 HMS +—Hours, minutes, seconds addition.
 HMS -—Hours, minutes, seconds subtraction.
 HR—Hours, minutes, seconds to decimal hours conversion.

INT—Integer portion of number.
 ISG—Increment, skip if greater.
 LASTX—Recalls LAST X register contents to X-register.
 LBL—Program label.
 LN—Natural logarithm.
 LN1 + X—Natural logarithm for arguments close to one.
 LOG—Common logarithm.
 MEAN—Mean.
 MOD—Modulo (remainder).
 OCT—Decimal to octal conversion.
 OFF—Power off.
 ON—Power on (continuous) function.
 P—R—Polar to rectangular conversion.
 PACK—Pack program memory.
 %—Percent.
 %CH—Percent of change.
 PI—Pi (3.141592654).
 PROMPT—Prompt.
 PSE—Pause.
 R[↑]—Roll up stack.
 R—D—Radians to degrees conversion.
 R—P—Rectangular to polar conversion.
 R/S—Run or stop a program.
 RAD—Radians mode.
 RCL—Recall data from register into X-register.
 RDN—Roll down stack.
 RND—Round.
 RTN—Return.
 SCI—Scientific notation.
 SDEV—Standard deviation.
 SF—Set flag.
 Σ +—Accumulations for statistics.
 Σ -—Accumulation correction.
 ΣREG—Statistical register block specification.
 SIGN—Sign of x.
 SIN—Sine.
 SIZE—Size of data storage register allocation.
 SQRT—Square root.
 ST +—Storage register addition.
 ST -—Storage register subtraction.
 ST*—Storage register multiplication.
 ST/—Storage register division.
 STO—Store numeric data in register.
 STOP—Stops program execution.
 TAN—Tangent.
 TONE—Tone.
 VIEW—View register contents.
 X = 0?—"X = 0?" conditional test.
 X ≠ 0?—"X ≠ 0?" conditional test.
 X < 0?—"X < 0?" conditional test.
 X ≤ 0?—"X ≤ 0?" conditional test.
 X > 0?—"X > 0?" conditional test.
 X = Y?—"X = Y?" conditional test.
 X ≠ Y?—"X ≠ Y?" conditional test.
 X < Y?—"X < Y?" conditional test.
 X ≤ Y?—"X ≤ Y?" conditional test.
 X > Y?—"X > Y?" conditional test.
 X < >—Exchange X- and any register.
 X < > Y—Exchange X- and Y- registers.
 XEQ—Execute.
 X²—Square.
 Y^xX—Exponential.

HP 82160A HP-IL Interface Module (cont.)

MASS STORAGE OPERATIONS

CREATE—Create new file with zero values.
DIR—Display or print a directory of stored files.
NEWM—Initialize medium.
PURGE—Remove file from medium.
READA—Read "write-all" file.
READK—Read key-assignment file and reassign keys.
READP—Copy program file, replacing last program in memory.
READR—Copy data file into HP-41 registers.
READRX—Copy part of data file according to X-register.
READS—Read status file and set calculator status.
READSUB—Copy program file after last program in memory.
RENAME—Rename stored file.
SEC—Secure a stored file.
SEEKR—Position medium to specified file data register.
UNSEC—Unsecure a stored file.
VERIFY—Verify that a stored file can be read.
WRTA—Store "write-all" file onto medium.
WRTK—Store key assignments onto medium.
WRTP—Store program onto medium.
WRTPV—Store program onto medium and make file private.
WRTR—Copy all storage registers into data file.
WRTRX—Copy some storage registers according to X-register.
WRTS—Store calculator status onto medium.
ZERO—Fill data file with zero values.

INTERFACE CONTROL OPERATIONS

AUTOIO—Set interface to Auto mode.
FINDID—Find address of selected device.
INA—Input ALPHA string from selected device.
IND—Input decimal number from selected device.
INSTAT—Input status information from selected device.
LISTEN—Set device as a listener, or remove all listeners.
LOCAL—Set selected device to local mode.
MANIO—Set interface to Manual mode.
OUTA—Output ALPHA string to selected device.
PWRDN—Set all devices to low power state.
PWRUP—Set all devices to operating power state.
REMOTE—Set selected device to remote mode.
SELECT—Select device as primary device.
STOPIO—Stop I/O communication in loop.
TRIGGER—Trigger all devices set to respond.

HP82401A HP-IL Interface Functions List (Cont.)

SECURE—Prevents a file from being altered or purged.
UNSECURE—Cancels security for a file.

GENERAL I/O OPERATIONS – DATA TRANSFER

ENTER—Reads data from HP-IL into numerical and string variables.
OUTPUT—Sends data from numeric and string expressions to HP-IL.

GENERAL I/O OPERATIONS – HP-IL INTERACTION

CLEAR—Clears an individual HP-IL device or all HP-IL devices.
DEVADDR—Returns the address of a device.
DEVAID—Returns the accessory ID of a device.
DEVID\$—Returns a string containing the device ID of a device.
ENABLE INTR—Specifies the events that can cause an HP-IL interrupt.
LOCAL—Sets an individual HP-IL device or all HP-IL devices to Local mode.
LOCAL LOCKOUT—Sets all HP-IL devices to Local Lockout condition.
OFF INTR—Cancels HP-IL interrupt branching.
ON INTR—Defines how a program branches when an enabled HP-IL interrupt event occurs.
READDDC—Returns the number of the last HP-IL device-dependent command message received.
READINTR—Returns the value of the interrupt-cause byte.
REMOTE—Enables all HP-IL devices to change to Remote mode and can also set an individual HP-IL device to Remote mode.
REQUEST—Defines the HP-71 status byte that is sent when serially polled by an HP-IL controller.
SEND—Sends individual HP-IL messages on the loop.
SPOLL—Returns a value that represents one or more status bytes from an HP-IL device.
STANDBY—Sets the HP-IL timeout period and verify interval.
STATUS—Returns the HP-IL interface status.
TRIGGER—Triggers an event at an HP-IL device.

GENERAL I/O OPERATIONS – PASSING CONTROL

CONTROL OFF-ON—Sets the controller status of the HP-71.
PASS CONTROL—Gives control of the HP-IL system to another device.

BINARY FUNCTIONS

BINAND—Returns the value of the binary AND operation.
BINCMP—Returns the value of the binary complement.

Time Module Functions List

REAL TIME AND DATE

ADATE—Append number to ALPHA register as a date.
ATIME—Append number to ALPHA register as a time.
ATIME24—Append number to ALPHA register in a 24-hour time format.
CLK12—Switch to 12-hour time display format.
CLK24—Switch to 24-hour time display format.
CLKTD—Switch clock to time and date display.
CLOCK—Display the clock.
CORRECT—Set time and adjust accuracy factor.
DATE—Place number for current date in X-register.
DMY—Switch date format to Day-Month-Year.
MDY—Switch date format to Month-Day-Year.
RCLAF—Recall clock accuracy factor.
SETAF—Set clock accuracy factor.
SETDATE—Set clock date.
SETTIME—Set clock time.
TIME—Place current time number in X-register.
T - X—Adjust clock time by specified factor.
■ON—Display the clock.

CALENDAR FUNCTIONS

DATE - —Calculate new date from date and number of days.
DDAYS—Calculate days difference between two dates.
DOW—Replace a date number with a Day-of-Week number.

STOPWATCH

RCLSW—Place stopwatch time in X-register.
RUNSW—Run stopwatch.
SETSW—Set stopwatch to specified starting time.
STOPSW—Stop running stopwatch.
SW—Set the calculator to Stopwatch mode.

ALARMS

XYZALM—Set alarm.
ALMCAT—Provide listing of alarms.
ALMNOW—Activate past due label alarms.

Extended Functions/Memory Module Functions List

PROGRAMMABLE FUNCTIONS

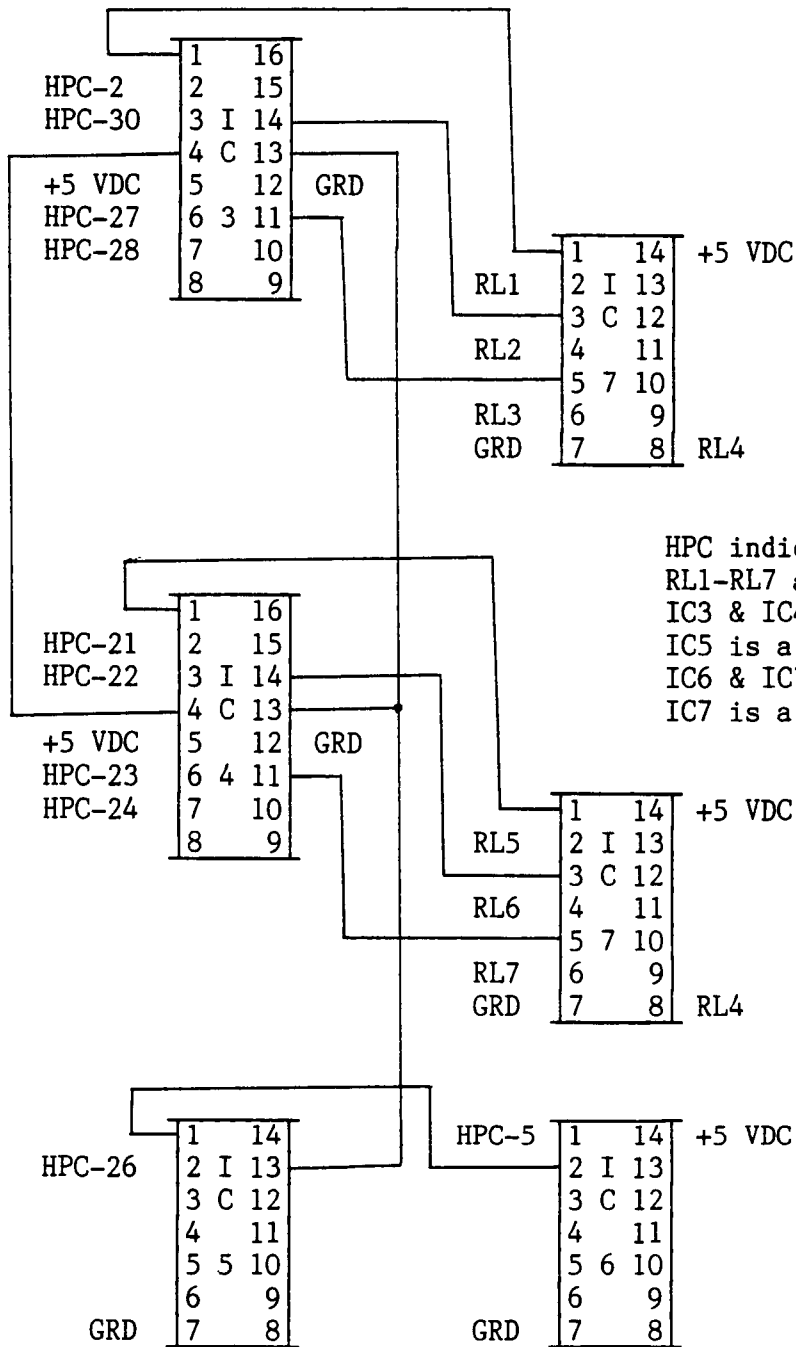
PASN—Programmable ASN function.
CLKEYS—Clear all key assignments.
PCLPS—Delete named program and all following it from main memory.
PSIZE—Programmable SIZE function.
SIZE?—Return number of data storage registers to X-register.
GETKEY—Return keycode for pressed key.
REGMOVE—Copy contents of a block of registers.
REGSWAP—Swap contents of two blocks of registers.

RCLFLAG—Recall flag-status data to the X-register.
STOFLAG—Restore flag status.
X<>F—X-register exchange with flag 00-07 status.
ATOX—Convert left-most ALPHA character to numeric character code.
XTOA—Convert X-register to its equivalent character and append to ALPHA register.
ALENG—Return number of characters in ALPHA register.
ANUM—Value of an ALPHA-formatted number.
POSA—Position of ALPHA character.
AROT—Rotate contents of ALPHA register.
APPCHR—Append contents of ALPHA register at the end of current register.
APPREC—Append contents of ALPHA register as a new record at the end of current file.
ARCLREC—Append record from current file to main memory.
CRFLAS—Create text (ASCII) file.
CRFLD—Create data file.
DELCHR—Delete characters in file.
DELREC—Delete record in current file.
EMDIR—Directory of extended memory files.
FLSIZE—Return number of registers in file.
GETAS—Copy text (ASCII) file from mass storage.
GETP—Replace last program in main memory.
GETR—Copy data file to main memory registers.
GETREC—Copy record from current file to main memory.
GETRX—Copy current data-file registers to X-register.
GETSUB—Copy program into main memory.
GETX—Copy current register in current file to X-register.
INSCHR—Insert contents of ALPHA register into text (ASCII) file.
INSREC—Insert contents of ALPHA register as a new record.
PURFL—Purge file.
RCLPT—Recall pointer value of current file.
RCLPTA—Recall pointer value of named file.
SAVEAS—Copy text (ASCII) file to mass storage.

APPENDIX B

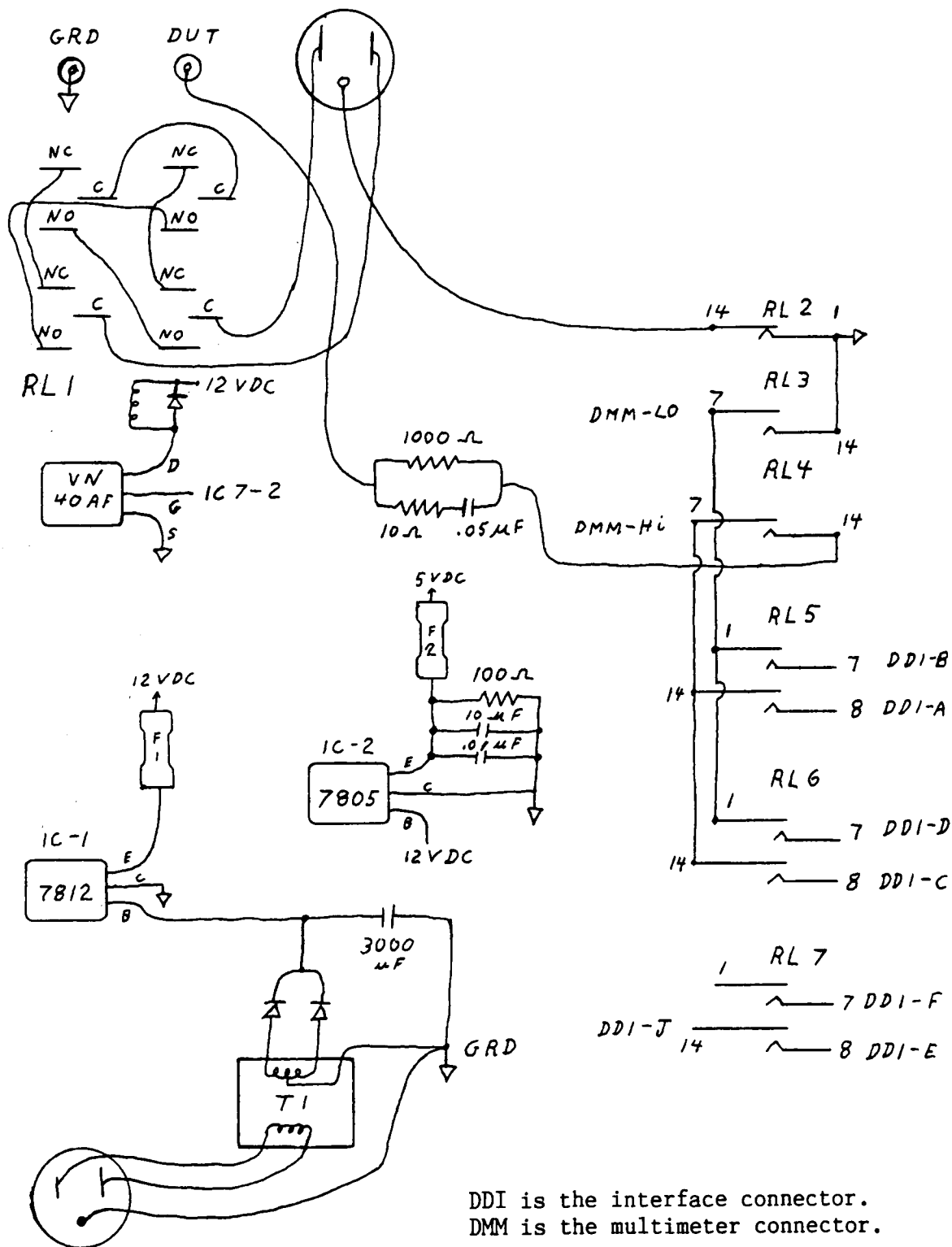
SCHEMATICS FOR THE MEDICAL TEST SET

MEDICAL TEST SET (MTS): LOGIC CIRCUITS



HPC indicates HP82166A.
 RL1-RL7 are relay coils.
 IC3 & IC4 are SN7475s.
 IC5 is a SN7473.
 IC6 & IC7 are SN7404s.
 IC7 is a SN7406.

MEDICAL TEST SET (MTS): RELAYS AND POWER SUPPLY



DDI is the interface connector.
DMM is the multimeter connector.

APPENDIX C

BASIC PROGRAM FOR DETERMINING THE COEFFICIENTS OF THE
STEINHART AND HART EQUATION

```

100 READ R1,T1,R2,T2,R3,T3
101 LET T1=T1+273.15
102 LET T2=T2+273.15
103 LET T3=T3+273.15
110 LET X1=LOG(R1)
111 LET X2=LOG(R2)
112 LET X3=LOG(R3)
120 LET S=X1-X2
125 LET U=X1-X3
130 LET V=1/T1-1/T2
135 LET W=1/T1-1/T3
200 LET C=(V-S*W/U)/((X1**3-X2**3)-S*(X1**3-X3**3)/U)
250 LET B=(V-C*(X1**3-X2**3))/S
300 LET A=1/T1-C*X1**3-B*X1
350 PRINT "A=";A,B=";B,"C=";C

```

APPENDIX D

PROCEDURE FOR INITIALIZATION OF A NEW CALCULATOR

STEPS NECESSARY FOR FIRST INITIALIZATION

1. Connect the HP-IL cables to all instruments.
2. Turn on all devices except the HP-41.
3. Turn on the HP41:
 - a. Set its time, date, and calibration factor according to its operation manual.
 - b. Set register "size" according to documentation for program to be run (usually 50).
 - c. Clear all unnecessary programs using "CLP."
4. Insert program tape in tape drive.
5. Read Leakem & Prtem using "READP."
6. Put Leakem & Prtem into extended memory using "SAVEP"
7. Read in triggering program "TRG"
8. Read in the actual test program, say, "BW5A"
9. Install dummy program by going to the program mode.
10. Set all controls in accordance with the first page of the program documentation.
11. Run the test program using "XEQ" command.

RECOVERY PROCEDURE FOR CALCULATOR TIME-OUT DURING A TEST RUN

1. The calculator turns itself off after approximately 15 minutes of idle time.
2. Programmed alarms "wake" the calculator automatically.
3. If the operator leaves the PMATS the calculator will complete the test in progress and turn itself off.
To begin the test again follow these steps:
 - a. Turn the calculator on.
 - b. Turn it to the Alpha mode and read the last prompt.
 - c. Perform the indicated action.
 - d. Push R/S.

APPENDIX E

USER'S DOCUMENTATION FOR PRINTING PROGRAM

PROGRAM NAME: PRTEM

CONDENSED OPERATOR'S GUIDE

CONTROL SETTINGS:

User mode: ON
Printer: MANUAL
Memory Size: 50

DATA REGISTERS:

1.	26.
2.	27.
3.	28.
4.	29.
5.	30.
6.	31.
7.	32.
8.	33.
9.	34.
10.	35.
11. Grd Wire ohm	36.
12. NG OFF	37.
13. NUG OFF	38.
14. RUG OFF	39.
15. NG ON	40.
16. NUG ON	41.
17. RUG ON	42.
18. DUT Number	43.
19. Technician	44.
20. Location	45.
21. Start time	46.
22.	47.
23.	48.
24.	49.
25.	50.

ERROR FLAGS:

00.	
01.	
02.	Leakage High
03.	Leakage Low
04.	Leakage DC
05.	
06.	
07.	
08.	
09.	
10.	

KEY ASSIGNMENT:

A.
B.
C.
D.
E.
F.
G.
H.
I.

NOTES:

1. With "PRTEM" in the alpha register execute SAVEP to put the program in extended memory.
2. With "PRTEM" in the alpha register execute GETP to replace the last program in main memory with PRTEM.
3. A dummy program is required after the main test program.
4. Requires 28 empty registers in extended memory.

PROGRAM NAME: PRTEM

OPERATOR INSTRUCTION		PROGRAM LISTING		EXPLANATION
PRTEM or Printer	I	01+LBL "PRTEM"	I	
program in extended	I	02 "BIOMED. DEPT."	I	Center heading in
memory is a self	I	03 ACR	I	printer buffer and
contained program	I	04 FMT	I	print it.
which prints a	I	05 ADV	I	
standard heading	I	06 FIX 6	I	
and leakage current	I	07 DATE	I	Obtain date and
readings.	I	08 CLA	I	convert it to a
	I	09 ADATE	I	format suitable for
	I	10 ACR	I	printing.
	I	11 FMT	I	
Normally used to	I	12 ADV	I	
form the first part	I	13 TIME	I	Obtain current time.
of a printout.	I	14 FIX 4	I	
	I	15 CLA	I	Center and print.
	I	16 ATIME	I	
DUT model and	I	17 ACR	I	
measurement data	I	18 FMT	I	
will be contained	I	19 ADV	I	
in the calling	I	20 HR	I	Recall test start
test program.	I	21 RCL 21	I	time and subtract
	I	22 HR	I	from current time.
	I	23 -	I	
	I	24 CLA	I	
	I	25 ACX	I	
	I	26 ACR	I	
	I	27 FMT	I	
	I	28 "HOURS"	I	
	I	29 ACR	I	Print total time
	I	30 ADV	I	required for the
	I	31 CLA	I	test in hours.
	I	32 ARCL 20	I	
	I	33 ACR	I	
	I	34 FMT	I	
	I	35 "DEPT"	I	
	I	36 ACR	I	Obtain and print
	I	37 ADV	I	department which
	I	38 CLA	I	owns the DUT.
	I	39 FIX 0	I	
	I	40 ARCL 10	I	
	I	41 ACR	I	Obtain and print
	I	42 FMT	I	control number for
	I	43 "NUMBER"	I	the DUT.
	I	44 ACR	I	
	I	45 ADV	I	

PROGRAM NAME: PRTEM

OPERATOR INSTRUCTION	PROGRAM LISTING	EXPLANATION
	I 46 CLA	I
	I 47 ARCL 19	I Obtain and print
	I 48 ACR	I technician's name.
	I 49 FMT	I
	I 50 "TECH"	I
	I 51 ACR	I
	I 52 ADV	I
	I 53 FIX 1	I Obtain and print
	I 54 "GRD="	I power cord green
	I 55 ARCL 11	I wire resistance.
Subroutine calling	I 56 "F OHMS"	I
PRTEM is usually	I 57 PRA	I
assigned to key "I."	I 58 "CHASIS LEAKAGE"	I
	I 59 FMT	I
	I 60 ACR	I
	I 61 ADV	I
	I 62 "IN MICROAMPS"	I
Leakage values are	I 63 FMT	I Obtain and print
assumed to have been	I 64 ACR	I 6 leakage current
put in appropriate	I 65 ADV	I measurements in
registers by calling	I 66 " OFF ON"	I standard format.
program.	I 67 PRA	I
	I 68 "NG "	I
	I 69 ARCL 12	I
	I 70 "H "	I
	I 71 ARCL 15	I
	I 72 PRA	I
	I 73 "NUG "	I
	I 74 ARCL 13	I
	I 75 "H "	I
	I 76 ARCL 16	I
	I 77 PRA	I
	I 78 "RUG "	I
	I 79 ARCL 14	I
	I 80 "H "	I
	I 81 ARCL 17	I
	I 82 PRA	I
	I 83 SF 12	I If flag 02 is set
	I 84 "LEAKAGE HI"	I print "LEAKAGE HIGH."
	I 85 FS? 02	I
	I 86 PRA	I If flag 03 is set
	I 87 "LEAKAGE LO"	I print "LEAKAGE LOW."
	I 88 FS? 03	I
	I 89 PRA	I If flag 04 is set
	I 90 "LEAKAGE DC"	I print "Leakage DC."

PROGRAM NAME: PRTEM

[illegible]

APPENDIX F

USER'S DOCUMENTATION FOR LEAKAGE CURRENT MEASUREMENT PROGRAM

PROGRAM NAME: LEAKEM

CONDENSED OPERATOR'S GUIDE

CONTROL SETTINGS:

User mode: ON
Printer: MANUAL
Memory Size: 50

DATA REGISTERS:

1.	26.
2.	27.
3.	28.
4.	29.
5.	30.
6.	31.
7.	32.
8.	33.
9.	34.
10.	35.
11. Grd Wire ohm	36.
12. NG OFF	37.
13. NUG OFF	38.
14. RUG OFF	39.
15. NG ON	40.
16. NUG ON	41.
17. RUG ON	42.
18.	43.
19.	44.
20.	45.
21.	46.
22.	47.
23.	48.
24.	49.
25.	50.

FLAGS:

00.	
01.	
02.	Leakage High
03.	Leakage Low
04.	Leakage DC
05.	
06.	
07.	
08.	
09.	
10.	

KEY ASSIGNMENT:

A.
B.
C.
D.
E.
F.
G.
H.
I.

NOTES:

1. With "LEAKEM" in the alpha register execute SAVEP to put the program in extended memory.
2. With "LEAKEM" in the alpha register execute GETP to replace the last program in main memory with PRTEM.
3. A dummy program is required after the main test program.
4. The program requires 30 empty registers in extended memory.

PROGRAM NAME: LEAKEM

OPERATOR INSTRUCTION	PROGRAM LISTING	EXPLANATION
"Leakage subroutine in extended memory" is called automatically as label "C" in most main programs.	I 01*LBL "LEAKEM" I 02 .01101 I 03 STO 10 I 04*LBL "CLFG" I 05 CF IND 10 I 06 ISG 10 I 07 GTO "CLFG"	I I Clear flags I 1-10 I I I Clear Regs I 11-17
At prompt connect MTS ground to DUT chassis.	I 08 11.017 I 09 STO 10 I 10 0 I 11*LBL "CLRG"	I I I Characters sent to MTS will select I relays for switch-
Press R/S when DUT is off.	I 12 STO IND 10 I 13 ISG 10 I 14 GTO "CLRG"	I ing power and for I taking measurements.
Will again prompt "connect grd" if resistance >2 ohms.	I 15*LBL "GR" I 16 "CONNECT GRD" I 17 AVIEW I 18 PSE I 19 "DUT OFF=R/S" I 20 BEEP I 21 PROMPT I 22 XEQ "SELCON"	I I Operator prompt. I I I I I Set MTS relays to I measure ground I wire resistance.
Wait while the PMATS switches power and measures leakage.	I 23 115 I 24 TRIGGER I 25 ACCHR I 26 XEQ "OHM"	I I I I
Flag 02 is set for:	I 27 STO 11 I 28 2	I SELCON selects the I converter in MTS
Normal grounded leakage greater than 2 microamperes;	I 29 X<=Y? I 30 GTO "GR" I 31 XEQ "MYAC" I 32 1000 I 33 * I 34 STO 12 I 35 2 I 36 X<=Y? I 37 SF 02 I 38 XEQ "SELCON"	I to receive data. I Loop for high I resistance. I I Acceptable limits I are 2 ohms and I 2 microamperes
Leakage test lasts approximately 1 min.	I 39 113 I 40 TRIGGER I 41 ACCHR I 42 XEQ "MYAC" I 43 1000 I 44 * I 45 STO 13	I I I I I I

PROGRAM NAME: LEAKEM

OPERATOR INSTRUCTION	PROGRAM LISTING	EXPLANATION
	I 46 25	I
	I 47 X<=Y?	I
	I 48 SF 02	I
	I 49 XEQ "SELCON"	I
	I 50 112	I
	I 51 TRIGGER	I
	I 52 ACCHR	I Microamps
	I 53 XEQ "MVAC"	I Reverse
	I 54 1000	I Ungrounded
Flag 2 implies	I 55 *	I
RUG > 25 uA	I 56 STO 14	I
	I 57 25	I Make "ON"
	I 58 X<=Y?	I measurements
Turn DUT "ON"	I 59 SF 02	I
at prompt	I 60 "DUT ON=R/S"	I
	I 61 PROMPT	I
	I 62 XEQ "MVAC"	I Microamps
	I 63 1000	I Reverse
	I 64 *	I Ungrounded
	I 65 STO 17	I
	I 66 25	I
Flag 2 implies	I 67 X<=Y?	I
RUG > 25 uA	I 68 SF 02	I
	I 69 XEQ "MVDC"	I
	I 70 5	I
	I 71 X<=Y?	I
Flag 4 implies	I 72 SF 04	I Special DC
NUG > 5 uA DC	I 73 XEQ "SELCON"	I measurement
	I 74 113	I
Back to all AC	I 75 TRIGGER	I
	I 76 ACCHR	I
	I 77 XEQ "MVAC"	I
	I 78 1000	I Microamps
	I 79 *	I Normal
	I 80 STO 16	I Ungrounded
	I 81 25	I
Flag 2 implies	I 82 X<=Y?	I
NUG > 25 uA	I 83 SF 02	I
	I 84 RCL 16	I
	I 85 5	I
	I 86 X>Y?	I
Flag 3 implies	I 87 SF 03	I
leakage is	I 88 XEQ "SELCON"	I
unusually low.	I 89 115	I
Check wall ground.	I 90 TRIGGER	I

PROGRAM NAME: LEAKEM

[illegible]

APPENDIX G

USER'S DOCUMENTATION FOR THE BLOOD WARMER PROGRAM

PROGRAM NAME: BW5A

CONDENSED OPERATOR'S GUIDE

CONTROL SETTINGS:

Size to 50
User mode ON
Printer to MANUAL
Put LEAKEM and PRTEM in extended memory
Read BW5A from Tape
Install an END after BW5A
XEQ BW5A

DATA REGISTERS:

1.	26. Shutoff Temp.
2.	27.
3.	28.
4. ISG for Temp.	29.
5. Scratch reg.	30. Indirect Temp.
6. Scratch reg.	31. Plate Temp.
7. Scratch reg.	32. Door Temp.
8.	33. Display Temp.
9.	34. Plate Temp.
10.	35. Door Temp.
11. Grd Wire ohm	36. Display Temp.
12. NG OFF	37. Plate Temp.
13. NUG OFF	38. Door Temp.
14. RUG OFF	39. Display Temp.
15. NG ON	40. MTS Relay Code
16. NUG ON	41.
17. RUG ON	42.
18. DUT Number	43.
19. Technician	44.
20. Location	45.
21. Start time	46.
22. Door Gap	47.
23. 2 Min Temp.	48.
24.	49.
25. Room Temp.	50.

ERROR FLAGS:

00. Alarm Temp.
01. 2 min. Warm
02. AC leak. Hi
03. AC leak. low
04. DC leak. Hi
05. Door Gap
06. Ckt. Brkr.
07. Regulation
08.
09.
10.

KEY ASSIGNMENT:

A. MENU
B. Visual checks
C. 2 min warm-up
D. Leakage
E. Regulation
F. Back up thermostat
G. Circuit breaker
H.
I. Printout

NOTES:

1. Flags 00, 01, 02, 05, 06, 07 cleared in "B"

PROGRAM NAME: BW5A

OPERATOR INSTRUCTION		PROGRAM LISTING		EXPLANATION
Executing BW5A begins test for blood warmer.	I	01*LBL "BW5A"	I	
	I	02 AUTO10	I	
	I	03*LBL A	I	
	I	04 "B=INITIALIZE"	I	Print MENU,
	I	05 AVIEW	I	Operations
	I	06 PSE	I	performed by
	I	07 "C=WARMUP"	I	labeled key.
	I	08 AVIEW	I	
	I	09 PSE	I	
	I	10 "D=LEAKAGE"	I	
	I	11 AVIEW	I	
	I	12 PSE	I	
	I	13 "E=REGULATION"	I	Keys may be
	I	14 AVIEW	I	pushed in any
	I	15 PSE	I	sequence.
	I	16 "F=ALM TEST"	I	
	I	17 AVIEW	I	
	I	18 PSE	I	
	I	19 "G=BRKR TEST"	I	
	I	20 AVIEW	I	
	I	21 PSE	I	
	I	22 "H=OVER TEMP"	I	
	I	23 AVIEW	I	
	I	24 PSE	I	
	I	25 "I=PRINTOUT"	I	
	I	26 AVIEW	I	
	I	27 PSE	I	
Type name of dept. owning DUT then press R/S.	I	28 "LOCATION ?"	I	Prompts for
	I	29 AON	I	data to be stored
	I	30 PROMPT	I	in registers.
	I	31 ASTO 20	I	
	I	32 "TECHNICIAN ?"	I	
Type name of test technician then R/S.	I	33 AON	I	
	I	34 PROMPT	I	
	I	35 AOFF	I	
	I	36 ASTO 19	I	
	I	37 TIME	I	
Push "B" for next BW5 test to avoid reentering data.	I	38 STO 21	I	
	I	39*LBL B	I	
	I	40 "CNTRL NO. ?"	I	Automatically
	I	41 AVIEW	I	stores start time
	I	42 STOP	I	when "B" is pressed
Perform visual inspection of DUT.	I	43 STO 18	I	for additional runs
	I	44 "VISUAL CHECK"	I	
	I	45 AVIEW	I	

PROGRAM NAME: BW5A

OPERATOR INSTRUCTION	PROGRAM LISTING	EXPLANATION
	I 46 PSE	I
	I 47 CF 00	I Clear flags that
	I 48 CF 01	I may have been set
	I 49 CF 02	I during last run.
	I 50 CF 05	I
	I 51 CF 06	I
	I 52 CF 07	I
	I 53 "MECH. CHECK"	I
Insert .07" gage.	I 54 RVIEW	I Operator
Enter ".07 R/S"	I 55 PSE	I prompts.
if fit is good.	I 56 "DOOR GAP ?"	I
	I 57 RVIEW	I
Test and enter other	I 58 STOP	I
value if necessary.	I 59 STO 22	I Store door gap
	I 60 .060	I that was entered.
	I 61 X<>Y	I
	I 62 X<=Y?	I Test against
	I 63 SF 05	I stored tolerances.
	I 64 .080	I
	I 65 X<>Y	I
	I 66 X>Y?	I
	I 67 SF 05	I
	I 68*LBL "INI68"	I
	I 69 AUTO10	I
	I 70 CF 17	I Subroutine to
	I 71 "HP3468A"	I DMM and set
	I 72 FINDID	I controls.
	I 73 SELECT	I
	I 74 REMOTE	I
	I 75 GTO 01	I
	I 76*LBL "SELDM"	I
	I 77 AUTO10	I Subroutine to
	I 78 CF 17	I select the DMM to
	I 79 "HP3468A"	I exchange data.
	I 80 FINDID	I
	I 81 X=0?	I
	I 82 STOP	I
	I 83 SELECT	I
	I 84 REMOTE	I
	I 85 RTN	I
	I 86*LBL "SELCON"	I
	I 87 AUTO10	I Subroutine which
	I 88 CF 17	I finds then selects
	I 89 "HP82166"	I MTS for data
	I 90 FINDID	I transmission.
	I	I

PROGRAM NAME: BW5A

OPERATOR INSTRUCTION	PROGRAM LISTING	EXPLANATION
	I 91 X=0?	I The following
	I 92 STOP	I routines initiate
	I 93 SELECT	I measurements with
	I 94 MANIO	I the DVM and pass
	I 95 RTN	I values back to
	I 96*LBL "OHM"	I the calculator.
	I 97 XEQ "SELDVM"	I
	I 98 "F3"	I Ohms
	I 99 GTO 00	I
	I 100*LBL "MVAC"	I Millivolts AC
	I 101 XEQ "SELDVM"	I
	I 102 "F2"	I
	I 103 GTO 00	I
	I 104*LBL "MVDC"	I
	I 105 XEQ "SELDVM"	I Millivolts DC
	I 106 "F1"	I
	I 107 GTO 00	I
	I 108*LBL 00	I
	I 109 "PRZIN4T2"	I
	I 110 OUTA	I Sets range of DMM.
	I 111 IND	I
	I 112 RTN	I
	I 113*LBL 01	I Inputs a decimal
	I 114*LBL C	I from the DMM.
Install thermistors.	I 115 "THERMISTORS"	I
	I 116 AVIEW	I
6" in from edge	I 117 PSE	I
2.5" down on plate	I 118 "DUT ON=R/S"	I Operator prompts.
3" down on door	I 119 AVIEW	I
	I 120 STOP	I
	I 121 "↑↑HTR"	I
	I 122 0	I
Push R/S when the	I 123 ENTER↑	I Set clock alarm to
DUT is turned on.	I 124 ENTER↑	I activate routine
	I 125 ENTER↑	I HTR after two
	I 126 TIME	I minutes.
	I 127 HR	I
	I 128 .033333	I Preset register
Room temp. is	I 129 +	I 30 to give an
stored in reg. 25.	I 130 HMS	I indirect location
	I 131 XYZALM	I to store temps
	I 132 25	I measured.
	I 133 STO 30	I
	I 134 XEQ "RDTMP"	I
	I 135 XEQ "MVAC"	I

PROGRAM NAME: BW5A

OPERATOR INSTRUCTION	PROGRAM LISTING	EXPLANATION
Wait 2 minutes for warm-up rate test.	I 136 23	I
	I 137 STO 30	I
	I 138 "WAIT 2 MIN"	I
	I 139 RVIEW	I
	I 140 STOP	I
	I 141+LBL "HTR"	I
	I 142 111	I Code 111 sets
	I 143 STO 40	I the appropriate
	I 144 XEQ "RDTMP"	I relays for
	I 145 30	I obtaining
	I 146 PCL 23	I plate temperature.
	I 147 X<>Y	I
	I 148 X>Y?	I Take temperature
	I 149 SF 01	I after 2 minutes.
	I 150 BEEP	I
	I 151 "LEAKEM"	I Get the program
Flag 01 indicates warm-up was less than 30 °C after 2 minutes.	I 152 GETP	I for leakage
	I 153 "PUSH D"	I measurements.
	I 154 RVIEW	I
	I 155 RTN	I
	I 156+LBL "RDTMP"	I
	I 157 XEQ "SELCON"	I
	I 158 RCL 40	I Subroutine RDTMP
	I 159 TRIGGER	I measures thermistor
	I 160 ACCHR	I ohms then converts
	I 161 XEQ "OHM"	I the reading to
	I 162 LN	I degrees Centigrade.
	I 163 STO 01	I
	I 164 3	I
	I 165 Y+X	I
	I 166 .000000098	I
	I 167 *	I
	I 168 RCL 01	I Coeficients
	I 169 .00023962	I for the
	I 170 *	I Steinhart
	I 171 +	I and Hart
	I 172 .001465004	I equation.
	I 173 +	I
	I 174 1/X	I
	I 175 273.15	I
	I 176 -	I
	I 177 STO IND 30	I
	I 178 XEQ "SELCON"	I
	I 179 TRIGGER	I
	I 180 AUTOIO	I

PROGRAM NAME: BW5A

OPERATOR INSTRUCTION		PROGRAM LISTING	EXPLANATION
Follow prompts	I	181 RTN	I Execute
of leakage current	I	182*LBL D	I leakage current
program and connect	I	183 XEQ "LEAKEM"	I subroutine.
ground wire to	I	184 "PUSH E"	I
hanger pin on plate.	I	185 AVIEW	I
	I	186 RTN	I
Push "E" to begin	I	187*LBL E	I
regulation test.	I	188 "↑↑RDTS"	I
	I	189 0	I
	I	190 ENTER↑	I Set clock
	I	191 ENTER↑	I for 0.5 hours.
	I	192 ENTER↑	I
Double check	I	193 TIME	I
thermistors and	I	194 HR	I
open door.	I	195 .033333	I
	I	196 +	I
	I	197 HMS	I
	I	198 XYZALM	I
	I	199 30	I
	I	200 STO 30	I
	I	201 .02010	I
	I	202 STO 04	I
	I	203 "THERMIS ?"	I Preset loop
	I	204 PROMPT	I for three
	I	205 "OPEN DOOR"	I temperature
	I	206 PROMPT	I cycles.
	I	207 "WAIT 30 MINS"	I
Calculator signals	I	208 AVIEW	I
after 0.5 hours.	I	209 STOP	I
	I	210*LBL "RDTS"	I
	I	211 1	I
	I	212 ST+ 30	I
	I	213 111	I
	I	214 STO 40	I
	I	215 XEQ "RDTMP"	I Read plate
	I	216 37	I thermistor and
	I	217 RCL IND 30	I store results in
	I	218 STO 05	I register 31.
Flag 07 indicates	I	219 X>Y?	I
reading outside	I	220 SF 07	I
35-37 range.	I	221 RCL 05	I
	I	222 35	I
	I	223 X>Y?	I
	I	224 SF 07	I
	I	225 1	I

PROGRAM NAME: BW5A

OPERATOR INSTRUCTION	PROGRAM LISTING	EXPLANATION
	I 226 ST+ 30	I
	I 227 95	I
	I 228 STO 40	I
	I 229 XEQ "RDTMP"	I
	I 230 37	I Read door
	I 231 RCL IND 30	I temperature then
Flag 07 indicates	I 232 STO 06	I test limits.
temp outside the	I 233 X>Y?	I
range 35-37.	I 234 SF 07	I
	I 235 RCL 06	I
	I 236 35	I
	I 237 X>Y?	I
	I 238 SF 07	I
	I 239 1	I
Enter temperature	I 240 ST+ 30	I
shown on digital	I 241 "DISP TEMP ?"	I
display then press	I 242 RVIEW	I
R/S.	I 243 STOP	I
	I 244 STO IND 30	I
	I 245 STO 07	I Store display
	I 246 RCL 06	I temperature.
Flag 07 indicates	I 247 -	I
plate temperature	I 248 ABS	I Test variance.
and display differ	I 249 .2	I
more than 0.2 °C.	I 250 X<>Y	I
	I 251 X>Y?	I ISG command will
	I 252 SF 07	I cycle back three
	I 253 RCL 07	I times.
	I 254 RCL 05	I
	I 255 -	I
Hold alarm switch.	I 256 ABS	I
(First button using	I 257 .2	I Subroutine F tests
left hand).	I 258 X<>Y	I for audible alarm
	I 259 X>Y?	I before temperature
	I 260 SF 07	I reaches 37.5 °C.
	I 261 ISG 04	I
Push R/S when alarm	I 262 GTO "RDTM"	I Set flag 00 in
sounds.	I 263+LBL F	I incorrect.
	I 264 "HOLD ALM SW"	I
Do not turn DUT off.	I 265 RVIEW	I Resetting DMM
	I 266 PSE	I prevents heating
	I 267 24	I of the termistor.
	I 268 STO 30	I
	I 269 "R/S AT ALM"	I
	I 270 RVIEW	I

PROGRAM NAME: BW5A

OPERATOR INSTRUCTION		PROGRAM LISTING		EXPLANATION
	I	271 STOP	I	
Have left hand near	I	272 111	I	
second button.	I	273 STO 40	I	
	I	274 XEQ "RDTMP"	I	
Push breaker switch	I	275 37.5	I	Subroutine G
when tone sounds.	I	276 X<Y	I	test that the
	I	277 X>Y?	I	breaker trips in
	I	278 SF 00	I	less than three
	I	279 LBL G	I	seconds.
	I	280 "BKR SW/TONE"	I	
	I	281 AVIEW	I	
	I	282 PSE	I	
	I	283 PSE	I	
	I	284 PSE	I	
	I	285 TONE 2	I	
	I	286 TIME	I	
	I	287 HR	I	
Press R/S when	I	288 STO 05	I	
breaker trips.	I	289 "R/S AT TRIP"	I	
	I	290 AVIEW	I	
Flag 6 set indicates	I	291 STOP	I	
the duty cycle limit	I	292 TIME	I	
is not correct.	I	293 HR	I	
	I	294 RCL 05	I	
	I	295 -	I	
	I	296 .0028	I	Set an alarm to
	I	297 X>Y?	I	execute BKR after
	I	298 SF 06	I	seven minutes.
	I	299 X<Y?	I	
Wait seven minutes	I	300 SF 06	I	0.1167 = 1/2 hour
then hold breaker	I	301 26	I	0.0028 = 2 min.
switch and turn DUT	I	302 STO 30	I	
on. Press R/S.	I	303 111	I	Prompt the operator
	I	304 STO 40	I	for the digital
	I	305 XEQ "RDTMP"	I	temperature limit
	I	306 40	I	test.
	I	307 X<Y	I	
Press R/S when	I	308 X>Y?	I	Set register 30
breaker trips.	I	309 SF 06	I	for data storage.
	I	310 XEQ "MVAC"	I	
	I	311 "PRTEM"	I	
	I	312 GETP	I	
	I	313 "PUSH I"	I	
	I	314 AVIEW	I	
	I	315 RTN	I	

PROGRAM NAME: BW5A

OPERATOR INSTRUCTION		PROGRAM LISTING		EXPLANATION
	I	316+LBL 1	I	
Breaker should trip	I	317 ADV	I	Record temperature
at 40.0 on display.	I	318 SF 12	I	at digital high
	I	319 "BW-5 TEST"	I	temperature shut
Flag 06 indicates	I	320 ACA	I	off.
high temperature.	I	321 FMT	I	
	I	322 ADV	I	Load PRTEM program
	I	323 CF 12	I	to be used for
	I	324 XEQ "PRTEM"	I	printout.
	I	325 FIX 1	I	
	I	326 "AMBIENT DEG C= "	I	
Push I when ready	I	327 ARCL 25	I	
to obtain printout.	I	328 PRA	I	
	I	329 "2 MIN TMP= "	I	
	I	330 ARCL 23	I	
	I	331 PRA	I	
	I	332 FIX 3	I	
	I	333 "DOOR GAP= "	I	
	I	334 ARCL 22	I	Print heading for
	I	335 "ALRM TMP= "	I	BW5A program then
	I	336 ARCL 24	I	print standard
	I	337 PRA	I	information.
Test is complete	I	338 "MAX TMP= "	I	
printout follows.	I	339 ARCL 26	I	
	I	340 PRA	I	Print additional
	I	341 FIX 1	I	data recorded
	I	342 ADV	I	during test.
	I	343 "TEMP IN DEG C"	I	
	I	344 PRA	I	
	I	345 "PLT DOOR DISP"	I	
	I	346 PRA	I	
	I	347 30	I	
	I	348 STO 30	I	
	I	349 .02010	I	
	I	350 STO 06	I	
	I	351+LBL "TOP"	I	
	I	352 1	I	
	I	353 ST+ 30	I	
	I	354 CLA	I	Format and print
	I	355 ARCL IND 30	I	three sets of
	I	356 1	I	temperature
	I	357 ST+ 30	I	measurements.
	I	358 "F "	I	
	I	359 ARCL IND 30	I	
	I	360 1	I	

[illegible]

[illegible]

APPENDIX H

USER'S DOCUMENTATION FOR THE INFUSION PUMP PROGRAM

PROGRAM NAME: I960B

CONDENSED OPERATOR'S GUIDE

CONTROL SETTINGS:

Size to 50
User mode ON
Printer to MANUAL
Put LEAKEM and PRTEM in extended memory
Read I960B from Tape
Install an END after I960B
XEQ I960B

DATA REGISTERS:

1.	26. Purge press 2
2. ISG press,	27. Purge press 3
3.	28.
4. 5% error	29.
5.	30. IND press
6. Rate set	31. Rate start time
7. Rate cal factor	32.
8. Volume set	33.
9.	34.
10. Error code	35.
11. Grd Wire ohm	36. Rate for 33
12. NG OFF	37. 144
13. NUG OFF	38. 288
14. RUG OFF	39. 799
15. NG ON	40. 999
16. NUG ON	41. V.I. for 33
17. RUG ON	42. 144
18. DUT Number	43. 288
19. Technician	44. 799
20. Location	45. 999
21. Start time	46. Final ohms
22. Op Press 1	47. Final time
23. Op Press 2	48. start ohms
24. Op Press 3	49. start time
25. Purge press 1	50.

ERROR FLAGS:

00. Pressure
01. Inf Rate
02. AC leak. Hi
03. AC leak. low
04. DC leak. Hi
05.
06.
07. Inf Vol
08.
09.
10.

KEY ASSIGNMENT:

A. Initialization
B. Restart & Leakage
C. Display check
D. Operate Pressure
E. Purge Pressure
F.
G.
H. Rate
I. Printout
a. 33 7
b. 144 7
c. 288 48
d. 799 48
e. 999 48

NOTES:

1. Flags 00, 01, 02, 05, 06, 07 cleared in "B"

PROGRAM NAME: I960B

OPERATOR INSTRUCTION		PROGRAM LISTING	EXPLANATION
	I	01*LBL "I960B"	I
Execute I960B and	I	02*LBL A	I Prompts for data
begin test for the	I	03 .05	I to be stored in
infusion pump.	I	04 STO 04	I registers.
	I	05 "DEPT. ?"	I
	I	06 AON	I
	I	07 PROMPT	I
Connect pump's	I	08 AOFF	I
power cable to MTS.	I	09 ASTO 20	I
	I	10 "TECHNICIAN ?"	I
	I	11 AON	I
	I	12 PROMPT	I
Insert DDI plug	I	13 AOFF	I
into Nurse Call	I	14 ASTO 19	I
jack.	I	15 GTO "SKIP"	I
	I	16*LBL "SELDM"	I
	I	17 AUTOIO	I Subroutine which
Insert infusion	I	18 CF 17	I locates voltmeter
cassette into pump	I	19 "HP3468A"	I for passing data.
and connect tubing	I	20 FINDID	I
to DDI manifold.	I	21 X=0?	I
	I	22 STOP	I
	I	23 SELECT	I
	I	24 REMOTE	I
Empty syringe into	I	25 RTN	I
drain and using	I	26*LBL "SELCON"	I
stopcock route pump	I	27 AUTOIO	I Subroutine which
to syringe.	I	28 CF 17	I locates MTS for
	I	29 "HP82166"	I selecting relays.
	I	30 FINDID	I
	I	31 X=0?	I
	I	32 STOP	I
	I	33 SELECT	I
	I	34 MANIO	I
	I	35 RTN	I
	I	36*LBL "OHM"	I
	I	37 XEQ "SELDM"	I Commands programming
	I	38*LBL "OOHM"	I the voltmeter for
	I	39 "F3"	I various types of
	I	40 GTO 00	I measurements.
	I	41*LBL "MVAC"	I
	I	42 XEQ "SELDM"	I
	I	43 "F2"	I
	I	44 GTO 00	I
	I	45*LBL "MVDC"	I
	I		I

PROGRAM NAME: I960B

OPERATOR INSTRUCTION	PROGRAM LISTING	EXPLANATION
	I 46 XEQ "SELDVM"	I
	I 47 "F1"	I
	I 48 STO 00	I
	I 49+LBL 00	I
	I 50 "FRAZIN4T2"	I Control settings for
	I 51 OUTA	I DMM.
	I 52 IND	I
	I 53 RTN	I
	I 54+LBL "SKIP"	I
Press "B" for all	I 55+LBL B	I
test of additional	I 56 TIME	I
pumps.	I 57 STO 21	I Prompt operator to
Test timing begins	I 58 "CNTL NO. ?"	I enter data.
now.	I 59 PROMPT	I
	I 60 STO 18	I
	I 61 "LEAKEM"	I
	I 62 GETP	I Leakage current
	I 63 XEQ "LEAKEM"	I test performed by
Follow prompts for	I 64+LBL "TEST"	I "LEAKEM" program.
leakage current	I 65+LBL C	I
measurements.	I 66 "INSERT TUBE"	I
	I 67 PROMPT	I
	I 68 "R/S IF OK"	I
	I 69 AVIEW	I
Place clear tubing	I 70 PSE	I Operational test
in air-in-line	I 71 "STO 10 UNOK"	I section.
detector.	I 72 AVIEW	I
	I 73 PSE	I Register "X" will
	I 74 0	I contain test number
	I 75 STO 10	I to be stored if a
	I 76 1	I step is failed.
If any operational	I 77 ENTER↑	I
check fails press	I 78 ENTER↑	I
"STO 10". This will	I 79 ENTER↑	I
record an error for	I 80 "ON LCD ?"	I
that test in the	I 81 +	I Prompt operator
final printout.	I 82 PROMPT	I to perform next
	I 83 "45 S ALM"	I appropriate test.
	I 84 +	I
	I 85 PROMPT	I
	I 86 "RATE INHIB ?"	I 1
	I 87 +	I
	I 88 PROMPT	I
Review infusion pump	I 89 "VOL INHIB ?"	I 2
operation manual for	I 90 +	I
procedure to follow.	I	I 3

PROGRAM NAME: I960B

OPERATOR INSTRUCTION		PROGRAM LISTING		EXPLANATION
	I	91 PROMPT	I	Test number
Peform the test	I	92 "PURG INHIB ?"	I	
indicated by the	I	93 +	I	4
prompt.	I	94 PROMPT	I	
	I	95 "RESET INHB ?"	I	
	I	96 +	I	5
Press "STO 10"	I	97 PROMPT	I	
if DUT fails the	I	98 "SET 100 0005"	I	6
test.	I	99 PROMPT	I	
	I	100 "OP TEST ?"	I	
	I	101 +	I	7
	I	102 PROMPT	I	
	I	103 "DOOR ALM ?"	I	
	I	104 +	I	8
	I	105 PROMPT	I	
	I	106 "AIR ALM CLR"	I	9
	I	107 +	I	
	I	108 PROMPT	I	
	I	109 "AIR ALM OPAQ"	I	10
	I	110 +	I	
	I	111 PROMPT	I	
	I	112 "BATT CHARG"	I	11
	I	113 +	I	
	I	114 PROMPT	I	12
	I	115 "INF COMP ?"	I	
	I	116 +	I	
	I	117 PROMPT	I	13
	I	118 "AUDIO ALM ?"	I	
	I	119 +	I	
	I	120 PROMPT	I	
	I	121 "OFF MEM"	I	14
	I	122 +	I	
	I	123 PROMPT	I	
	I	124 "MALENC 11 ?"	I	15
	I	125 +	I	
	I	126 PROMPT	I	
	I	127 "INLET OCLU ?"	I	
	I	128 PROMPT	I	16
	I	129*LBL D	I	
Subroutine "D" is	I	130 22	I	
used to record max-	I	131 STO 30	I	Program loop for
imum pressures.	I	132 .02010	I	recording 3 operate
Set stopcock and	I	133 STO 02	I	pressure.
obtain pressures.	I	134*LBL "PO"	I	
Then press "R/S"	I	135 "OP PRES ?"	I	

PROGRAM NAME: I960B

OPERATOR INSTRUCTION	PROGRAM LISTING	EXPLANATION
	I 136 PROMPT	I
	I 137 STO IND 30	I Set flag 00 if
Three infusion and	I 138 10	I pressure is >25
purge pressures are	I 139 X>Y?	I or <10 psi.
required.	I 140 SF 00	I
	I 141 25	I
	I 142 X<>Y	I
	I 143 X>Y?	I
	I 144 SF 00	I
	I 145 1	I
	I 146 ST+ 30	I Register 02 is
	I 147 ISG 02	I incremented until
	I 148 GTO "PO"	I 3 readings are
	I 149+LBL E	I entered.
	I 150 25	I
	I 151 STO 30	I
	I 152 .02010	I
	I 153 STO 02	I
Subroutine "E" is	I 154+LBL "PP"	I Program loop for
used to record and	I 155 "PURG PRES ?"	I recording 3 purge
check maximum purge	I 156 PROMPT	I pressures.
pressures as	I 157 STO IND 30	I
indicated on gage.	I 158 10	I Set flag 00 if
	I 159 X>Y?	I pressure is <10.
Enter a pressure	I 160 SF 00	I
measurement then	I 161 1	I
push "R/S".	I 162 ST+ 30	I
	I 163 ISG 02	I
	I 164 GTO "PP"	I
	I 165+LBL H	I
	I 166 TIME	I
	I 167 FIX 4	I
	I 168 CLA	I
Subroutine "H"	I 169 ATIME	I
measures rate and	I 170 PRA	I
volume infused for	I 171 0	I
5 pump settings.	I 172 STO 36	I Zero all data
	I 173 STO 37	I registers.
	I 174 STO 38	I
	I 175 STO 39	I
	I 176 STO 40	I
	I 177 STO 41	I Locate MTS and
	I 178 STO 42	I enter the relay
	I 179 STO 43	I code "11011111"
	I 180 STO 44	I

PROGRAM NAME: I960B

OPERATOR INSTRUCTION	PROGRAM LISTING	EXPLANATION
	I 181 STO 45	I
	I 182 XEQ "SELCON"	I Set DMM to measure
	I 183 95	I resistance.
	I 184 TRIGGER	I
	I 185 ACCHR	I
	I 186 AUTOIO	I
	I 187 XEQ "SELDVM"	I
Set controls:	I 188 "F3R2ZIN4T1"	I Store start time.
Volume to be infused	I 189 OUTA	I
7 ml.	I 190*LBL a	I Store volume set.
Rate 33 ml/hr.	I 191 "STR 033 0007"	I
	I 192 PROMPT	I
	I 193 TIME	I Input decimal
Press DUT "START"	I 194 STO 31	I resistance value
and controller "R/S"	I 195 33	I for empty syringe.
simultaneously.	I 196 STO 06	I
	I 197 IND	I Store acceptable
	I 198 STO 07	I limits for rate
	I 199 7	I and volume.
	I 200 STO 08	I
Labels a,b,c,d,e	I 201 41	I "N2" is the
may be repeated at	I 202 STO 30	I measurement sub-
any time if mistakes	I 203 XEQ "N2"	I routine.
occur during the	I 204*LBL b	I
infusion process.	I 205 "STR 144 0007"	I
	I 206 PROMPT	I Repeat for the next
At infusion complete	I 207 TIME	I volume and rate
signal, turn the DUT	I 208 STO 31	I values.
off then push R/S.	I 209 144	I
Final resistance	I 210 STO 06	I
reading is automa-	I 211 IND	I
tically taken.	I 212 STO 07	I
	I 213 42	I
	I 214 STO 30	I
	I 215 XEQ "N2"	I
Empty syringe into	I 216*LBL c	I Repeat for the next
drain and set the	I 217 "STR 288 0048"	I values.
next prompted values	I 218 PROMPT	I
	I 219 TIME	I
	I 220 STO 31	I
	I 221 288	I
	I 222 STO 06	I
48 ml.	I 223 IND	I
288 ml/hr.	I 224 STO 07	I
	I 225 48	I

PROGRAM NAME: I960B

OPERATOR INSTRUCTION	PROGRAM LISTING	EXPLANATION
	I 226 STO 08	I
	I 227 43	I
	I 228 STO 30	I
48 ml.	I 229 XEQ "N2"	I Repeat the test
799 ml/hr.	I 230 LBL d	I for three volumes
	I 231 "STR 799 0048"	I and flow settings.
	I 232 PROMPT	I
	I 233 TIME	I
	I 234 STO 31	I
	I 235 799	I
	I 236 STO 06	I
	I 237 IND	I
	I 238 STO 07	I
	I 239 44	I
	I 240 STO 30	I
48 ml.	I 241 XEQ "N2"	I
999 ml/hr.	I 242 LBL e	I
	I 243 "STR 999 0048"	I
	I 244 PROMPT	I
	I 245 TIME	I
	I 246 STO 31	I
	I 247 999	I
	I 248 STO 06	I
	I 249 IND	I
	I 250 STO 07	I
	I 251 45	I
	I 252 STO 30	I
Operator portion of	I 253 XEQ "N2"	I Subroutine "N2"
the test is com-	I 254 "PUSH I"	I measures infusion
plete. Push "I" to	I 255 PROMPT	I time and calculates
obtain a printout.	I 256 LBL "N2"	I flow rates.
	I 257 IND	I
	I 258 STO 46	I Loop back to
	I 259 TIME	I measure resistance
	I 260 STO 47	I until nurse-call
	I 261 RDN	I switch activates.
	I 262 50	I
	I 263 X<=Y?	I
	I 264 GTO "N2"	I Take a final
	I 265 "TURN DUT OFF"	I resistance reading
	I 266 PROMPT	I after the DUT is
	I 267 IND	I turned off.
	I 268 STO 46	I
	I 269 PRX	I
	I 270 RCL 07	I

PROGRAM NAME: I960B

OPERATOR INSTRUCTION	PROGRAM LISTING	EXPLANATION
	I 271 RCL 46	I
	I 272 -	I Syringe calibration
	I 273 38.78	I is 38.78 ohm/ml.
	I 274 /	I
	I 275 STO IND 30	I Store calculated
	I 276 RCL 47	I volume.
	I 277 HR	I
	I 278 RCL 31	I
	I 279 HR	I
	I 280 -	I
	I 281 /	I Store calculated
	I 282 5	I flow rate.
	I 283 ST- 30	I
	I 284 RDN	I
	I 285 STO IND 30	I
	I 286 ST- 30	I
	I 287 RTN	I
	I 288 LBL 1	I
	I 289 SF 21	I
	I 290 "PRTEM"	I
	I 291 GETP	I
	I 292 XEQ "PRTEM"	I
Subroutine PRTEM is called to produce the first part of the heading.	I 293 "OP PRES PSI"	I
	I 294 PRA	I
	I 295 FIX 0	I
	I 296 CLA	I
	I 297 ARCL 22	I
	I 298 "t "	I
	I 299 ARCL 23	I Format to print
	I 300 "t "	I table of operate
	I 301 ARCL 24	I pressure.
	I 302 PRA	I
	I 303 "PURG PRES PSI"	I
	I 304 PRA	I
	I 305 CLA	I
	I 306 ARCL 25	I
	I 307 "t "	I
	I 308 ARCL 26	I Format to print
	I 309 "t "	I table of purge
	I 310 ARCL 27	I pressure.
	I 311 PRA	I
	I 312 ADV	I
	I 313 "SET RATE VOL"	I
	I 314 PRA	I
	I 315 FIX 1	I

PROGRAM NAME: I960B

OPERATOR INSTRUCTION	PROGRAM LISTING	EXPLANATION
I	316 "33 ="	I
I	317 ARCL 36	I
I	318 "F "	I
I	319 ARCL 41	I
I	320 PRA	I
I	321 "144 ="	I Format to print
I	322 ARCL 37	I settings, infusion
I	323 "F "	I rates, and volumes.
I	324 ARCL 42	I
I	325 PRA	I
I	326 "288 ="	I
I	327 ARCL 38	I
I	328 "F "	I
I	329 ARCL 43	I
I	330 PRA	I
I	331 "799 ="	I
I	332 ARCL 39	I
I	333 "F "	I
I	334 ARCL 44	I Check each error
I	335 PRA	I flag. If it is
I	336 "999 ="	I set, print an
I	337 ARCL 40	I appropriate
I	338 "F "	I message.
I	339 ARCL 45	I
I	340 PRA	I
I	341 "FAILURE LIST"	I
I	342 PRA	I
I	343 SF 12	I
I	344 "PRESSURE"	I
I	345 FS? 00	I
I	346 XEQ "PRA"	I
I	347 "INF RATE"	I
I	348 FS? 01	I
I	349 PRA	I
I	350 "OP ERR="	I
I	351 ARCL 10	I
I	352 PRA	I
I	353 CF 12	I
I	354 "END I-960 TEST"	I
I	355 PRA	I
I	356 ADV	I
I	357 .END.	I
I		I
I		I
I		I

PROGRAM NAME: I960B

OPERATOR INSTRUCTION	PROGRAM LISTING	EXPLANATION
	I CONNECT GRD	I
	I R/S IF OK	I
Typical Printout:	I STO 10 UNOK	I
	I 10:41:06 AM	I Time of infusion
	I 2,002.0000 ***	I test beginning and
First section is	I 1,747.5000 ***	I last measured re-
is printed during	I 519.8000 ***	I sistence value is
the test.	I 523.6000 ***	I printed during
	I 524.6000 ***	I test in order to
	I BIOMED. DEPT.	I aid in the detec-
Only the portion	I 10/18/1984	I tion of oerator
following	I 11:16:49 AM	I errors.
BIOMED. DEPT.	I 0.7502 HOURS	I
is printed when the	I CSS DEPT	I
"I" is pushed.	I 1,166,255. NUMBER	I
	I PM TECH	I
	I GRD=1.1 OHMS	I
	I CHASIS LEAKAGE	I
	I IN MICROAMPS	I
	I OFF ON	I
	I NG 0.8 0.7	I
	I NUG 6.2 6.2	I
	I RUG 8.2 8.1	I
	I	I
	I OP PRES PSI	I
	I 10. 11. 12.	I
	I PURG PRES PSI	I
	I 14. 14. 15.	I
Error message would	I	I
occur if any value	I SET RATE VOL	I
is out of tolerance	I 33 =29.7 6.3	I
or an operational	I 144 =135.4 6.5	I
test failed.	I 288 =275.0 45.7	I
	I 799 =759.0 45.2	I
	I 999 =942.0 44.8	I
	I FAILURE LIST	I
	I OP ERR=0.0	I
	I END I-960 TEST	I
	I	I
	I	I
	I	I
	I	I
	I	I
	I	I
	I	I

VITA

The author, Wm. Patrick Moore, was born in Nashville, Tennessee on December 16, 1946. He attended elementary schools in that city and graduated from Father Ryan High School in 1964. He went into the United States Air Force immediately thereafter. After one year of technical training in electronic repair, he spent the remaining three years of his enlistment installing and repairing electronic cryptographic equipment.

Following his honorable discharge in 1968 he attended the University of Michigan for three years. He returned to Tennessee in 1972 to work at St. Mary's Medical Center in Knoxville and attend college on a part time bases. He graduated from The University of Tennessee, Knoxville, in 1975 with a Bachelor of Science degree in Engineering Science and in 1984 with a Master of Science in that same field.

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