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CONTRACTING ORGANIZATION: Konigsberg Instruments, Inc.
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Equipment for ambulatory monitoring of troops in the field, measuring deep body temperature, skin and/or internal suit temperature, heart rate (ECG derived), and activity has been developed. The equipment includes an ingestible temperature pill RF transmitter, body mounted electronics (Man-Pack) to acquire, process and/or store sensor-obtained data, and to transmit such information to Relay and/or Base Stations up to one mile away. Relay and/or Base Stations are software-reconfigured versions of Man-Pack modules, with additional battery, antenna, keyboard-control and display capabilities. The system design permits up to fifty individuals within a one-square mile area of uneven terrain to be monitored by one Base Station with appropriately placed Relay Stations. System design is modular, so various configurations of Man-Packs, Relay Stations, or Base Stations are possible. The system, in various Man-Pack configurations built from furnished Phase III modules, has worked well in field exercises.

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NA In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

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Introduction

The purpose of this contract was to define, develop, validate, and produce a health monitoring system which would facilitate the study of soldiers in simulated battlefield conditions where Chemical Defense (CD) garments were used. The contract was separated into three phases:

I. Systems Analysis

II. Design, Development and Validation

III. Manufacture and Delivery of Systems

1.0 Phase I - Systems Analysis

This phase defined which physiological parameters needed to be monitored, how the data would be acquired, how the data would be processed for transmission to medical monitors, and the algorithms to be employed in defining "alarm" conditions.

1.1 Parameters Monitored: The parameters to be monitored, and the devices used to acquire these signals were:

Deep Body Temperature: An ingestible temperature sensor and radio transmitter, plus a body-worn radio receiver and demodulator to acquire and process the pill's Radio Frequency (RF) signal was proposed. The proposed pill was to be disposable, a single-use swallowed device, simple to use and "culturally" acceptable.

The design of the pill was envisioned as a semi-custom integrated circuit (IC) which would encode two types of information: core temperature, and an identification code which would permit the decoding of several pills transmitting on the same frequency, enabling the monitoring of temperature in several parts of the digestive tract at the same time.

The pill would be designed to operate from a 1.5 Volt silver oxide "watch battery". Shelf-life considerations dictated low power design in both encoding electronics and the amount of power which the pill could radiate. A transmit range of one meter was proposed as being adequate. A receiver would be required in the Man-Pack to acquire and decode the temperature information from the pill for subsequent signal processing and relay to the remote Base Station.

Heart Rate: Lead II ECG signals plus electronic circuits to amplify the signals, and further circuits to extract heart rate from the QRS intervals.

Skin Temperature: A skin surface-mounted temperature sensor plus circuitry to produce and amplify the proportional electrical signal.

Activity: A one-channel, *non-directional* accelerometer (an off-balance mass mounted on a single, strain-gaged, cantilever beam) sensitive to motion in any direction. Added to this device was to be circuitry to produce and amplify the resultant electrical signal.

Other: A seven-data-channel system was proposed, one channel for RF pill-derived temperature, one channel each for heart rate, skin temperature, and activity. The remaining three channels could be assigned for additional data of these types, or similar ones, such as EMG.

1.2 System Hardware Requirements: The Chemical Defense User Safety System (CDUSS) required three principal packaging modes: a *Man-Pack*, i.e. a body-mounted electronics package, a *Relay Station*, which could relay information from up to fifty Man-Packs, operating simultaneously, to a Base Station, and a *Base Station*, which could receive information from either Man-Packs or one or more Relay Stations.

Man-Pack The Man-Pack had to perform five functions:

1) Receive RF Signals from one or more ingested temperature pills.

2) Power and/or amplify signals from other sensors.

3) Reduce data from sensors so that data could be stored "on board" and/or transmitted in "packet" form (see below).

4) Store data as required.

5) Transmit data to Relay and/or Base Stations.

Size and weight requirements for the Man Pack were one liter and one kilogram respectively.

The Man-Pack would be designed with a six-channel instrumentation amplifier with differential voltage inputs capable of processing both static (or slowly varying) signals from sources such as the activity sensor and surface temperature electrodes, as well as AC-coupled biopotential signals such as ECG or EMG. Heart rate was to be derived from detection of an ECG QRS complex. The general-purpose nature of the instrumentation amplifiers would permit monitoring of a wide variety of input signals. It was proposed that a semi-custom IC be designed to implement the amplifier function so as to reduce component count and save power and space.

Two modes of data acquisition were proposed: the primary technique would be on-Man-Pack data reduction by an embedded microcontroller (μC) which would store average core temperature, heart rate, and activity rate in the on-board memory. In this mode, packets of reduced data would be relayed to a remote Base Station every few minutes on pseudo-random intervals. The relay of these six reduced-data channels to a Base Station was to be accomplished using serial pulse encoding techniques.

The advantage of pseudo-random packet transmission was that it simplified Base Station requirements. All individual Man-Packs could theoretically transmit on the same frequency, since the time required to transmit a packet of data was very short. The low duty cycle required for packet transmission (RF time ON to OFF) guaranteed that few, if any, packets would be lost due to interference from transmissions from another Man-Pack. Redundant transmission of packets would guard against data being lost. The alternative, continuous transmission (real-time encoding) by each Man-Pack, would tie-up one Base Station for each such Pack, either preventing the monitoring of other Man-Packs by that Base Station, or requiring uneconomic multiple Base Stations.

Data would be stored in two locations: the Man Pack itself would have the ability to store several days worth of reduced data, and the Base Station IBM-type Personal Computer (PC) would be programmed to store all data relayed from all test subjects in the field. It was also proposed that the Man-Pack be provided with an output which could be connected to an auxiliary tape recorder.

Since the pill battery had to be small, yet required an adequate shelf life, RF transmission used a "burst mode", low duty cycle, Amplitude Modulated (AM) transmitter. This dictated that the Man-Pack receiver be capable of processing low power AM signals, hence a logarithmic RF detector output was recommended.

Relay Stations: The Relay Stations had to perform two functions:

1) Receive and process RF signals from one or more Man-Packs.

2) Relay signals to the Base Stations.

Size and weight limitations of the Man-Pack did not apply, although portability was important, as was the ability to withstand adverse weather conditions. In essence, Relay Stations were software-reconfigured Man-Packs, without sensors, and with larger RF antennas and more robust power supplies.

Software reconfiguration was implemented as follows:

The embedded μC was designed with a built-in Electrically Erasable Programmable Read Only Memory (EEPROM). The EEPROM would be loaded with a System Executive Routine which operated the Man-Pack and performed the on-body data reduction of biodata. During setup, various System Executive Routine programs could be entered to configure the unit either as a Man-Pack, Relay Station, or Base Station, as well as to load different instructions for making data reduction decisions.

Base Stations: The Base Station had to perform two functions:

1) Receive and process RF signals from one or more Man-Packs or Relay Stations.

2) Display information on the screen of a PC.

Size and weight limitations of neither Man-Packs nor Relay Stations applied, although portability and ability to withstand adverse weather conditions were important. In essence, Base Stations were software-reconfigured Man-Packs, with Relay Station type RF antennae and power supplies, plus keyboard control and display screen additions.

1.3 System Data Processing and Software Requirements

General: Since it was necessary to monitor up to fifty Man-Packs simultaneously, a "packet" transmission technique was chosen. Each Man-Pack would periodically assemble the reduced physiological data acquired into a "packet" -- data from up to seven sensor channels, plus man-pack I.D. and time of data summary acquisition -- and release a burst of RF energy containing the above information. These bursts would be emitted at pseudo-random intervals. Since the bursts were short and the "on-the-air" duty cycle low, the probability of data crashes (interfering pulses from various other Man-Packs and/or Relay Stations) was small.

Alarm Algorithms: Several alarm algorithms were devised. Excessively high body temperature, excessively high rate of increase of body temperature, and excessively high heart rate were among the criteria considered. (See further, below, for validation procedures.) These algorithms were so devised that the "presets" could be changed as medical considerations, field experience, and individual subject physiological variations required.

1.4 Preliminary Systems Design Proposals and Tests

Several preliminary studies were undertaken in Phase I, using a combination of Army personnel and consultant physiological expertise, and available commercial hardware in production at Konigsberg Instruments (KI). These preliminary steps included:

Initial: A conference at the University of Oklahoma at which WRAIR personnel, other exercise and heat stress experts, and KI project members considered and recommended methods of data collection, and physiological warning algorithms.

Canine Experiments: A number of prototype (no I.D. channel) temperature pills were fabricated, then fed to dogs. Two passages through a dog's GI tract were considered equivalent to one human passage. Failure mode incidents were analyzed by dissection and visual microscopic inspection and evaluation of failed pills, then appropriate redesign was undertaken. One-hundred percent survival of the redesigned pills in multiple such tests in canines were deemed indicative of pill integrity and human safety. All animal experiment protocols were approved by the WRAIR Contracting Officer's Technical Representative (COTR) and the University of Oklahoma's Institutional Review Board (IRB).

Human Experiments: Prior to design of Phase II equipment, tests were designed to test pill RF propagation through both the human body and CD protective garments, body antenna design, and the relative efficacy of various heat stress alarm algorithms. To do this, additional redesigned prototype pills were constructed, and standard KI telemetry transmitters and receivers were produced and shipped to the University of Oklahoma for such tests. Tests were run with CD-suited human volunteers on exercise treadmills. All test protocols were approved by the WRAIR COTR and the University of Oklahoma's IRB.

Summation: General agreement on the hardware and software techniques to be employed, and the successful experimental tests, resulted in approval of KI's Phase I work, and a go-ahead for Phase II.

The KI Phase I report is appended. A separate report on the results of the University of Oklahoma tests is also appended.

2.0 Phase II Design and Development

This Phase was originally projected to develop prototype and breadboard systems which, after approval by the WRAIR COTR, were to proceed to Phase III, the shipment of fifty such systems. However WRAIR program needs changed the original scenario, as follows:

2.1 Phase IIA WRAIR deemed it desireable to have a Beta test, in which a simplified version of the final CDUSS Man-Pack was used to evaluate pill performance. Such a unit, the "TR6A", was built, and consisted of an early version of the final TR6B RF Receiver, plus a decoder, plus electronics to display pill-transmitted body temperature on the TR6A built-in LCD screen. The complete unit, measuring 3 x 5 x 1 inches, plus antenna connector, was built, and ten such units plus prototype pills were shipped to WRAIR. Results were satisfactory, and were a factor in approval of KI's transition from Phase II to Phase III.

2.2 Pill Validation: Not as a part of the KI contract, but associated with it were tests at Johns Hopkins University, Applied Physics Laboratory (APL) in which a series of KI pills were calibrated against high-grade laboratory standards to determine their accuracy. Results demonstrated accuracy to approximately 0.05 °C, well within the 0.1 °C accuracy desired. A summary of APL findings are contained within the KI FDA 510K application (see below).

2.3 Rectal Temperature Correlation Also not part of the KI contract but associated with it were additional series of tests conducted both by WRAIR and by the University of Oklahoma Physiology Testing Laboratory, to correlate pill-derived deep body temperature with thermistor-based rectal temperature monitoring.

The tests showed good correlation in most circumstances with, as expected, slightly higher deep body temperatures than rectal. These tests, too, were a factor in approval of KI's program transition from Phase II to Phase III.

2.4 Software Control As KI software development progressed, it became apparent that the Base Station display and test subject pill tracking were highly application specific. In addition, KI was not charged with developing the facilities and training or acquiring personnel necessary for conducting human subject tests. Accordingly, once the initial software programs were deemed functional by the WRAIR COTR, further software development and control was taken over by WRAIR.

2.5 Breadboard Demonstration The final portion of Phase II was a breadboard demonstration of the individual elements: pill, AM receiver, FM transmitter and receiver, telemetry packet encoding and decoding, Man-Pack recorder, microcontroller operation of receiver and demodulator, and software. Demonstration of functionality was performed at the KI facility, witnessed by the WRAIR COTR. Upon the COTR approval, project transition to Phase III was approved. This demonstration took the place of a Phase II report.

Discussion of the individual elements comprising the CDUSS system is set forth in the Phase III section of this report, below.

3.0 Phase III: Manufacturing & Delivery of Systems

In Phase III, KI was tasked with the production of five hundred ingestible temperature transmitters and fifty Man-Pack electronics modules. This phase required a significant effort in the design and fabrication of special tooling and test fixtures to aid in the manufacture of the various elements of the system. KI also designed and tooled custom castings for the case of the Man-Pack and a semi-custom IC which was used in both the ingestible pill and in the Man-Pack.

3.1 T2D Ingestible Temperature Transmitter

The T2D Ingestible Temperature Transmitter was designed as a more complex, yet lower cost version of the temperature pill manufactured in limited quantities for the Phase II validation program. The Phase III pill used a KI designed semi-custom IC named the "TO", and was intended for use in both the temperature pill and on the amplifier board of the Man-Pack. The T2D pill included an extra pulse code format in its transmission which allowed the Man-Pack to identify which pill it was decoding, so that up to eight pills could be identified and received at any one time.

TO Custom IC The TO IC was conceived as a general purpose functional block whose primary function would be to optimize space utilization in both the ingestible pill and in other more conventional amplifier applications.

KI personnel designed, breadboarded and tested the TO circuit with a "Designer's Kit" from Ferranti Interdesign. Ferranti Interdesign manufactured a line of "mask programmable" ICs, which had a variety of predesigned functional circuit blocks These blocks could be connected together at the last wafer manufacturing step by a custom-designed metal mask. In this way each customer could characterize the IC to perform an application specific function, so as to reduce parts count on a conventional circuit card assembly.

Once the breadboard was complete, KI personnel designed the metal mask layer which Ferranti Interdesign would deposit on the IC as a part of their manufacturing process. Ferranti engineers reviewed the KI design, after which about one thousand TO IC "dice" were produced and delivered. The parts were delivered in die form rather than as parts in conventional packages with mounting leads, so that the dies could be installed by KI in a variety of different packages and used in different applications.

Capsule and Coatings The outer coatings of the pill assembly performed two primary functions: to provide biocompatibility and ease of ingestion, and to protect the internal electronics from the environment of the digestive tract.

The electronics module was placed with in a "000" size gelatin capsule, routinely used in the manufacture of herbal and medicine preparations. The capsule was made in two interlocking halves, which after electronics insertion, was assembled and sealed with purified beeswax. The capsule assembly was then doubly sealed by dipping it in a photo-cure dental acrylic, also bio-compatible, specially formulated for this purpose for KI by Lee Pharmaceuticals. The dental acrylic was used in order to further protect the internal electronic assembly from the environment of the digestive tract. After the dental acrylic coating was shaped by hand filing and sanding, an additional coating of urethane was applied both to seal the outer surface of the acrylic and as a primer for the final coating. The final coating, a Silastic elastomer, was a time-tested material with proven biocompatibility. The pills were coated with this material to ease ingestion (Silastic is slippery when wet) and to ensure that the presence of the pill would not cause any reaction in the digestive tract.

Encoder Subassembly The purpose of the encoder subassembly was to generate a temperature code and an identification code which would be specific to each pill. The temperature information was encoded by varying the repetition rate or frequency of a set of pulses from the encoder board. A typical pill would send out these pulses at a nominal repetition rate of 500 per second (500 Hz rate) with a 20 Hz change from the nominal repetition rate per degree Celsius change. Pill identification code information was added to the temperature code by generating a second pulse between the temperature pulses. The width of the ID pulse and the delay in time between the temperature pulse and ID pulse could be varied to achieve 8 different ID codes.

The heart of the encoder subassembly was the TO IC. For this application the TO was packaged by KI in a ceramic flatpack. The packaged IC was then sealed and electrically tested in a special-built test fixture prior to assembly onto the encoder subassembly circuit board.

In addition to the TO IC, the circuit card supported about 20 other miniature components which programmed the function of the TO IC. A thermistor was used to provide temperature information to the TO IC for coding.

Transmit Antenna Subassembly The antenna subassembly consisted of a ring-shaped bobbin made from a glass-epoxy material and several turns of copper magnet wire. The wire was bonded to the bobbin with epoxy.

Transmitter Subassembly The purpose of the transmitter subassembly was to convert the temperature and identification pulse codes from the encoder subassembly to RF energy pulses, so that the information could be sent through the body to an outside receiver. Transmitters could be tuned anywhere between 87 and 108 MHz.

The transmitter design used in the T2D pill was adapted from circuits which had been used for years by KI in both ingestible and implantable electronics. It consisted of a single transistor gated oscillator mounted on a small circuit card assembly. The antenna subassembly was integral to the oscillator circuit, and also coupled the RF energy from the pill to the surrounding tissue.

Final Assembly The T2D pills were manufactured on a make-to-order basis with customer-specified identification codes and were tuned to specific frequency(ies) requested by WRAIR. The T2D final assembly was made up of a 1.5 Volt Silver Oxide Battery, the transmit antenna assembly, transmitter circuit board assembly, encoder circuit board assembly, and a gelatin capsule with a series of biocompatible coatings.

3.2 TR6B Man-Pack/Radio Relay System

The TR6B Man-Pack was conceived as a general purpose transceiver and mobile data acquisition system. It could perform the following functions and was capable of the following features:

a. MicroTransmitter Receiver/Decoder
b. Six Channel Instrumentation Amplifier
c. Stand-Alone Data Analysis/Relay System Encoding
d. Programmable to a Radio Relay Station Configuration
e. Programmable to a Base Station Configuration

In order to perform these functions the TR6B was configured as a dual co-processor computer system. Two Motorola embedded μC were used to accomplish this. One μC was used in the transceiver part of the TR6B, with the second μC used in the analog Data Acquisition System (DAS) part of the system. The transceiver μC assembly was called the microRadioControl (μRCtl) and the DAS μC assembly was called the microDataControl (μDCtl).

Each μC could be loaded with a different program, which was changed depending on the function which was to be performed (a, b, c, d, and/or e above).

Man-Pack In the Man-Pack mode the TR6B μRCtl IC was programmed to monitor one or more ingested T2D ingestible temperature pills (microTransmitters). The μRCtl memory was programmed with frequency, temperature calibration, and ID code information prior to sending the soldier into the field for maneuvers. In operation, the μRCtl would scan a preset RF band looking for the pill's frequency and ID code. When the appropriate conditions were met, the μRCtl would lock onto the RF signal from the pill and then decode the core temperature data from the pill. The temperature data, as well as other bio-information from the μCtl portion of the TR6B, would then be transmitted via the μRCtl transceiver either to a remote radio relay station or base station for further processing.

The bio-data from the TR6B was transmitted in "packets" of reduced data on a pseudo-random, intermittent basis. This technique was used to simplify operation and in order to allow all the transceivers to send data on the same carrier frequency. This technique ensured that the system would function even in a crowded RF spectrum.

In the Man-Pack mode the TR6B μCtl side was also programmed to monitor up to six channels of analog data from non-ingested, body- or suit-mounted sensors. The μCtl assembly included a six channel instrument amplifier circuit board assembly which used the same TO integrated circuit as in the T2D temperature transmitter. This amplifier board was called the Data Acquisition System (DAS) circuit assembly. In this application the TO was assembled in a "Quad" ceramic package in order to "pin-out" more of the functions designed into the TO IC. Information such as heart rate, activity, EMG information, etc, could be conditioned, reduced to numbers, and stored in a logging memory in the μCtl assembly. This information could then be routed to the μCtl for relay back to the remote medical base station.

Radio Relay In the radio relay mode, the μRCtl side was programmed to receive data from up to fifty different Man-Pack transmitters and to retransmit the data packets to a remote Base Station. In this way the transmit range of the Man-Pack transmitters of each soldier could be extended to cover a wider area.

Base Station In the Base Station mode, the μRCtl IC was programmed to receive data from up to fifty different Man-Pack or Radio Relay transmitters and to convert the received data to an RS232C format which was then sent to WRAIR-supplied personal computers for analysis and storage.

Operating Software The operating software which was developed in Phase II was written in the machine code specific to the Motorola μC ICs in the μRCtl and μDCtl assemblies, via a special software compiler program. The software modules were written to configure the TR6B with the various operating functions previously mentioned.

In Phase III, the software modules which had been written by KI personnel were transferred to WRAIR with the necessary KI consultation and support required to train WRAIR personnel in their operation.

Xilinx Programmable Logic Array Both the μR and μD assemblies were designed to be flexible in operation so as to permit WRAIR personnel to adapt the systems to changing requirements, without the necessity of returning them to KI for rework or redesign. This was accomplished by designing-in the Motorola programmable μCs, and the software programmable logic array from Xilinx.

The Xilinx IC permitted KI designers to reduce the number of digital ICs which would have normally been required in a design of this complexity by incorporating them into the Xilinx IC. This had the additional benefit of allowing for future "hardware" design changes by simply reprogramming the array. Thus the TR6B system allowed for the evolution of the product and its applications without the need to send the units back to the manufacturer.

μRCtl The μRCtl subassembly functioned as the controller for the communications side of the TR6B. It controlled the tuning, transmit, and receive modes of the TXR transceiver subassembly, transferred data from the μDCtl section of the assembly, and could communicate with the "outside world" via RF carrier or conventional RS232C wired cables.

The assembly was packaged as a two-sided, multilayer surface mount printed circuit assembly (surface mount components soldered to both sides of the circuit card) to optimize density/area utilization. Surface mount connector busses at either end and both sides of the assembly connected the μRCtl to other circuit assemblies and to the outside world. Flexibility was designed-in by incorporating a μC and software programmable logic array into the design.

TXR The transceiver (Transmitter/Receiver or TXR) was a miniature, varactor-tuned module capable of tuning from 87 to 110 MHz under control by the μRCtl circuit. The receiver could process both amplitude and frequency information from a received signal. As a result, the TXR could receive both AM RF pulse mode signals from T2D pills and FM Frequency Shift Keyed (FSK) RF information from Man-Pack and Relay Stations.

In the receive mode, the TXR performed the task of converting RF signals from one or more ingestible pills into a digital output which was routed to the μRCtl for data reduction. In the transmit mode, digital modulation from the μRCtl was processed and transmitted as high-level FM FSK signals.

This assembly was also designed as a 2-sided, multilayer surface mount printed circuit assembly with the transmitter on one side of the board and the receiver on the other side. Appropriate shielding was employed to shield the transceiver sections from each other, and from the effects of the RF transmitter.

Power Supply Unregulated DC power was supplied to the TR6B from an external battery pack. The power supply part of the μR Assembly provided regulated power to the entire TR6B. The power supply provided a number of different isolated and regulated power supply busses and reference voltages which were used to power and bias the circuits in the TR6B. In order to increase battery life, extensive use was made of switch-mode voltage regulators and voltage converters. Conversion power efficiencies of about 85% were achieved using this design, about twice what could have been realized with conventional linear voltage regulators.

This assembly was also designed as a two-sided, multilayer surface mount and through-hole printed circuit assembly. Extensive ground and power planes were incorporated to virtually eliminate the noise effects of the switch-mode regulators elsewhere on the rest of the TR6B assembly.

μDCtl The μDCtl subassembly functioned as the controller for the DAS portion of the TR6B. It controlled the sampling format of the analog multiplexer on the DAS board, performed analog to digital conversion of the multiplexed signals via an on-board A-to-D circuit, measured and reduced the digitized signals to numeric equivalents, and stored the data in the logging memory for subsequent relay to the Base Station via the TXR. The μDCtl subassembly could communicate with the outside world via the μR TXR or conventional RS232C wired cables.

The μDCtl was also packaged as a two-sided, multilayer surface mount printed circuit assembly. Surface mount connectors at either end and both sides of the assembly connected the μDCtl to other circuit assemblies and to the outside world. Flexibility was designed-in by incorporating a software programmable logic array.

Logging Memory

The logging memory subassembly was incorporated into the μD subassembly to provide temporary "mass storage" for the reduced data from the μRCtl and μDCtl μCs. The design used two 32K x 8 bit μpower static RAM ICs with appropriate steering logic to create 64K bytes of memory. This assembly was also packaged as a single-sided, multilayer surface mount circuit assembly, with surface mount connection to other circuit assemblies.

Amplifier/Multiplexer/Encoder The Data Acquisition Subassembly (DAS) performed the function of conditioning up to six channels of analog information for interface to the μDCtl A-to-D converter. Circuits on the DAS board provided differential amplification and signal conditioning of small signal inputs such as ECG and EMG biopotentials, as well as providing pulsatile excitation and amplification for devices such as pressure or temperature sensors. (Pulsatile power and signal processing for sensors was used where necessary in order to extend battery life.) The signal conditioning functions were performed by the TO ICs, which were packaged as Quad Ceramic devices for use in the DAS.

The DAS board also incorporated a narrow-bandpass 17 Hz filter, used to extract a heart-rate pulse from the ECG signals. The heart rate pulse was subsequently counted by the μDCtl and stored in the logging memory for packet transmission to the Base Station.

This assembly was also packaged as a two-sided, multilayer surface mount printed circuit assembly. Surface mount connector busses on both sides of the assembly connected the DAS to other circuit assemblies.

A10 Activity Accelerometer A single output, multi-axis accelerometer was designed to be mounted within the case of the TR6B to provide a qualitative indication of soldier activity. In this way, medical staff could correlate temperature and heart rate information with activity information.

The one-channel, *non-directional* accelerometer (an off-balance mass mounted on a single, strain-gaged, cantilever beam) was designed to be sensitive to motion in any direction. A Poisson-type half-bridge was employed so both semiconductor strain gages could be mounted on the same side of the cantilever beam, thus increasing the simplicity and hence reliability of the assembly. Added to this device was circuitry to produce and amplify the resultant electrical signal.

Excitation for the accelerometer was provided by one of the TO instrument amplifiers on the DAS card. The differential signal from the accelerometer was conditioned, quantified by the μDCtl, and stored in the logging memory for packet transmission to the Base Station.

Battery Pack/Auxiliary Logging Module An auxiliary battery pack was designed to provide power to the TR6B and to house a hand-held computer which was selected by WRAIR personnel. The computer was purchased at WRAIR request by KI and modified to WRAIR specifications for installation in the battery pack.

4.0 Post Phase III: Additional Developments.

Several developments which occurred after the completion of the shipment of Phase III hardware are discussed below:

4.1 Operations and Techical Manuals Considerable effort was expended in explaining the Phase III hardware theory of operation, and collecting, upgrading and forwarding system schematics both to the WRAIR COTR and Research Triangle Institute (RTI) personnel. This effort was in support of an RTI, WRAIR-funded, preparation of CDUSS Operations and Technical Manuals, hereby appended. These manuals supported post-contract software and hardware changes made by WRAIR after delivery of all Phase III hardware, as well as relevant portions of the hardware furnished in the original KI Phase III effort.

4.2 FDA Application At the request of WRAIR, and in collaboration with WRAIR's considerable study and effort, KI submitted an FDA 510K application for pill approval. Though the application requested approval of the pill alone, independent of any specific radio receiver, the FDA required both hardware *and* software approval of the TR6B Receiver and its operating software. As TR6B operating software was no longer under KI purview and, further, could be and had to be capable of being revised at WRAIR's will, as operating circumstances required, both WRAIR and KI were in a Catch 22 situation, unable to comply with FDA requirements that 510(k) documentation and approval should precede any operational changes. Hence, KI's 510(k) application was allowed to expire.

Relevant portions of the FDA application are appended as a useful overview of pill operation and history.

4.3 Low Cost Pill At WRAIR's request, KI investigated whether commercially available improvements in the miniaturization and availability of complex surface mount electronic components permitted KI's redesign of the pill without the use of a custom IC. This effort was desireable as minimum production runs of the custom IC had been increased and the cost of moderate changes thereto were becoming prohibitively expensive. The investigation and subsequent redesign effort was successful and resulted in a lower cost device with a smaller overall size than previously attained. Several lots of such pills have since been procured by the Army, with good field results.

4.4 Higher Frequency Operation For another government project, both the pill and the receiving apparatus have been redesigned to operate in the 176-214 MHz commercial TV band. (The CDUSS program utilized the 88-108 MHz commercial FM band.) The higher frequencies of the TV band permit greater efficiencies for the necessarily short Man-Pack antennae. In addition, commercial broadcast RF-quiet regions are easier to find (see TR8 Receiver discussion, below).

4.5 Base Station RF Receiver The equivalent of the CDUSS Program TR5 Base Station Receiver is now available in Dual-TR8 Receivers, packaged so that up to two such receivers (four receiver channels in all) can be inserted in two PC half-height hard disc drive bays. Accessory receiver electronics (demodulators, controllers, etc.) are now packaged as expansion card plug-ins, minimizing external PC Base Station connections. Note: This equipment operates in the 176 to 214 MHz TV broadcast band, not the 88 -108 FM radio broadcast band for the original Phase III CDUSS equipment.

Controlling software (open to the user) is written in Quick Basic, permitting ready field changes if desired. Various versions of the software permits keyboard control of zero (baseline), gain, low and high end frequency roll-offs, plus programmable receiver frequency hopping. This software also includes a spectrum analyzer, permitting on-site, computer screen displayed, visual assessment of RF quiet regions in military field exercise locations.

Similarly, an expanded-capability version of the μR has been developed incorporating two-way voice communication, Base Station RF programming control of individual Man-Pack-equivalent data channel sampling frequencies, frequency roll-offs, and gains, and additional type of sensor input channels. This further development has also been designed and built in modular form, as was the TR6B, so that in future applications investigators can pick and choose functions and modules to be system-integrated as operational tasks require.

5.0 Conclusion

Equipment for ambulatory monitoring of troops in the field, measuring deep body temperature, skin and/or internal suit temperature, heart rate (ECG derived), and activity has been developed. The equipment includes an ingestible temperature pill RF transmitter, body mounted electronics (Man-Pack) to acquire, process and/or store sensor-obtained data, and to transmit such information to Relay and/or Base Stations up to one mile away. Relay and/or Base Stations are software-reconfigured versions of Man-Pack modules, with additional battery, antenna, keyboard-control and display capabilities. The system design permits up to fifty individuals within a one-square mile area of uneven terrain to be monitored by one Base Station with appropriately placed Relay Stations. System design is modular, so various configurations of Man-Packs, Relay Stations, or Base Stations are possible. The system, in various Man-Pack configurations built from KI furnished Phase III modules, has worked well in field exercises.

Recommendations for the future would be conversion of Man-Pack, Relay Station or Base Station RF modules to the 176-214 MHz band, thus increasing antennae efficiency, and taking advantage of the TR8 software programmable capabilities.

APPENDICES

Appendix I

System Analysis Report
Phase I CDUSS

February 7, 1986

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Konigsberg Instruments, Inc.
Pasadena, CA

System Analysis Report

CDUSS Phase I

Prepared For: Director

Walter Reed Army Institute of Research

ATTN: SGRD-UWI-C

Washington, DC 20307

Required By: Contract DAMD17-85-C-5257

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Date: 7 February 1986

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1.0 Statement of The Problem

The general problem, as stated in the contract, is a safe, reliable means of protecting test subject safety by monitoring the test subject's thermoregulation while the subject is wearing a chemical defense suit, either on simulated maneuvers or participating in a prophylactic drug screening program.

The specific requirements of the contract are adequately set forth therein. In this analysis we set forth in general terms (Statement of the Problem) and then again in more specific terms (Analytic Solution) our breakdown in terms of the separate functional tasks, as we see them, and the specific solutions that we envisage.

1.1 Primary and Secondary Sensors

We propose a disposable ingestible radiotelemetry pill, to monitor core body temperature, as our primary sensor. Secondary sensors will be ECG electrodes, a tri-axially sensitive actigraph (accelerometer), an internal suit temperature sensor, and several spare biopotential and/or transducer data acquisition channels.

The principal problems in sensor design are safety (hence no inner ear temperature sensors), comfort and cultural acceptability (hence no reuseable pills or rectal temperature probes), immunity to movement artifact (hence waterproof sensors and interconnects and capacitative ECG electrodes), and freedom from encumbrance (hence strong design effort to confine all external sensors, their interconnects, and the electronic package to miniaturized, light weight units mounted on or very close to a Sam Browne belt).

Secondary problems are that units be easy to use and difficult to misuse, and require little or no field service or logistic support.

1.2 Data Acquisition

Data acquisition must include means of telemetrically acquiring the ingestible pill transmission, regardless of its position or orientation in the body, and the ability to monitor more than one pill at the same time, if need be, without confounding the system.

Data acquisition must also be capable of monitoring up to seven channels of data, four of which are dedicated (core temperature, suit temperature, activity monitor, and ECG). The core temperature channel may monitor more than one transmitter; it is nevertheless classified as one channel with perhaps more than one input. The three undedicated channels may be used for parallel instrumentation efforts in early phases of the development program, to help determine optimum locations of actigraph, ECG lead pair, or suit air temperature sensor by comparing standard with more convenient (packaging, less personnel encumbering) locations.

1.3 Data Interpretation

The primary means of data interpretation will be a pre-arranged algorithm, inserted into the electronic package computer, which will determine the several degrees of danger being encountered. The problems of algorithm development may be summarized as:

1.3 Data Interpretation (con't)

a. Missions may be different, and a low exercise arctic experience may have different requirements than a tropic environment with a high-exertion content. We call this a Mission Calibration Factor (MCF) and each CDUSS unit may be thus programmed. For the present program, only one MCF will be developed.

b. Individuals (or equipages) may be different and the contract specifically calls for a Suit Calibration Factor (SCF). This will permit the algorithm constants to be changed for particular individuals.

c. The specification of an adequate algorithm remains to be determined. Employing the criteria set forth in the Contract is easily done. The determination as to whether an algorithm is suitable depends on several factors. The highest priority needs to be given to safety, but the optimum sensor weighting mix, the establishment of several levels of alarm, and the allowance of easy modification of the algorithm in early trials must be given high priority consideration.

1.4 Data Storage

The contract requirement is that the equipage must be able to monitor the time course of events. Several parallel methods are to be employed: a solid state recorder with three days capacity, an electronic output compatible with WRAIR body mountable tape recorders, and (desireable) the ability to transmit full data or compressed indices thereof to Base. The primary requirement, apart from data storage, is reliability and low power consumption.

1.5 Data Transmission

The requirement is that RF data transmission to Base must cover a one mile radius and must be able to cope with difficult terrain. This makes the use of radio repeaters necessary. All transmissions need to be coded so that the specific identity of the test subject is transmitted along with data and alarm status, if existent.

A corollary of data transmission is radio location. In the event of an alarm status, a trooper's cohorts or the Base must be able to locate the test subject at risk.

Thus data transmission involves not only a suit transmitter, but a repeater, a radio locator, and base station capability. Up to 50 units may be transmitting, and all transmissions will need to be identifiable, yet should conserve RF spectrum and not interfere with each other.

1.6 Base Station

The primary requirement of the base station is that it be able to display the status of 50 test subjects. The greatest degree of flexibility in data presentation is desireable, to permit field commanders to select those parameter displays most meaningful to them for particular missions. We propose a PC based display, using a portable computer, permitting both audio and visual display format without affecting basic signal conditioning equipment, which can remain constant for all missions.

2.0 Auxiliary Statement of the Problem

Section 1.0 has dealt with the sensor, data acquisition, data storage, data transmission, and information display Statement of the Problem. These are basically physiological and/or engineering concerns. There are a whole class of other problems, equally important, which apply to the laboratory or field military environment, and which must be considered.

2.1 Logistics

The primary problem is that of the pill itself. Even though the pill need only be operational for three days, and test programs may only run a few weeks or months, time delay problems inherent in procurement, storage, transhipment, etc. dictate that the life cycle of the pill be long, one year at a minimum.

2.2 Training and Servicing

The CDUSS is a specialty item to be produced in limited quantities. It may be that it will find other applications for military and/or civilian usage, but that eventuality remains to be established.

Accordingly, it seems prudent to make the operation of the unit as simple as possible, suitable for use by non-technically-oriented people, requiring minimal training, few or no adjustments in the field, save in senior-level reprogramming capability or in battery replacement.

To this end, the equipment should be self checking, both for interconnects, sensor and pill operational status, and RF transmit/receive and computer operational status, with adequate alerts to the user of existence and nature of operational deficiencies, if any.

2.3 Generality and Reprocurement

A concomitant of the logistics, training and servicing requirements are the problems of reprocurement, spares planning, and base (or factory) maintenance of equipment. Physiological instrumentation program requirements may change, may be limited in scope, yet ideally should be addressable by variations of the same set of instrumentation elements, in an altered system configuration.

We see the following desiderata for this class of equipment:

a. The RF Receivers and Transmitters should be software controllable to be either body mounted pill receivers and long range transmitters, or repeater stations, base stations, or radio locators.

b. Sufficient generality should be built into the signal conditioning IC's so that the same device can work for a variety of biopotential sensors (ECG/EMG/EEG) or transducers (activity, temperature, pressure), depending on simple external programming by passive components.

c. Sufficient generality should be built into the data acquisition system so that the number and frequency response of its data channels are externally programmable by passive components.

2.4 Environmental Specifications

The contract calls for the standard military environmental requirements suitable for field use. No requirement seems difficult except for high temperature storage for the pill. Batteries available in a size and type suitable for the pill may not meet the high temperature extreme set forth in the specifications. (We do not recommend custom battery development.)

2.5 Effectivity

The size, weight, transmission range, lifetime, storage capacity, etc. of the physical hardware can be defined, engineered, tested, and their effectivity for this mission reasonably well evaluated.

The effectivity of the algorithm assessing a test subject's physiological status is less easy to evaluate. A completely fail-safe system may have too high an incidence of alarms. The predictive value of the particular sensors and their allowable combination of values initially chosen may be inferior to final sensor selections and their algorithm weighting.

At this stage of the design and development process, we would rate the effectivity of the alarm algorithm by how readily medically experienced personnel can alter it in the laboratory or in the field during preliminary trials without recourse to hardware redevelopment or factory reprogramming of the built-in computer.

We would rate effectivity of the Base display the same way: if the originally designed audio and graphics require change, the ease with which Command can change the display format without custom programming would be a good measure of its effectivity.

2.6 Human Use and the FDA

Though we are in the fortunate position of being an FDA-GMP approved facility and of having developed a temperature pill which enjoyed a successful program in a prior study, the social climate and legislation have changed from the time of the previous project, and prudent planning now requires that FDA approval be formally sought and obtained for the ingested device, and perhaps also sought for the other elements of the monitoring system.

University Review Boards as well as WRAIR review will be obtained for initial tests, which because of time constraints will require informed consent release forms, but future project activity should include securing FDA approval for the ingestible temperature pill. We anticipate no difficulties, but we do expect that full and thorough documentation will have to be processed through appropriate regulatory channels, including WRAIR surveillance of our efforts on the program's behalf.

3.0 Preliminary Studies

As part of Phase I, parallel to but not superseding this System Analysis, there is an on-going evaluation and test program designed to take advantage of our existent technology to pre-test significant elements of the CDUSS program prior to their embodiment in "military" hardware. The program consists of the following elements:

3.1 Physiological Consultant Panel

A panel was convened at the University of Oklahoma. Outside consultants included Dr. Bill Williams, EPA and former NASA Scientist for the aforementioned temperature pill clinical test program, Dr. Kenneth Dormer, Director of the University of Oklahoma's Graduate Program in Exercise Physiology, and Dr. Harold Williams, Director of the Oklahoma Center for Alcohol and Drug Related Studies.

Apart from the discussion on temperature and temperature change rate limits which should set alarm levels, two interesting points were developed:

a. It would be useful if the algorithms tentatively adopted for early evaluation were readily changeable by having parameters and their weighting in "spreadsheet form", manipulatable by an ordinary laboratory computer (University of Oklahoma has a PC-XT or equivalent) by means of BASIC or C programming.

b. The expected high quality ECG's to be obtained should permit a PC-XT computer pattern recognition program to identify depressed ST segments. This approach should be useful in determining subject physiological tolerance limits.

3.2 Temperature Pill

A temperature pill with identical size and transmission characteristics (battery, oscillator, pulse width and interval, and transmitting antenna configuration) has been developed and prototype electronics fabricated. It differs from the final embodiment in that it is not disposable (no IC), using discrete components in a simpler circuit.

Tests will be run to determine in vivo the absolute signal strength of the pill and reception requirements. (see Receiver, below).

3.3 Diversity Receiver

A standard-hardware TR4-1 Diversity Receiver will be specially programmed to assess:

a. Signal strength of the pill before and after ingestion and digestive tract traverse.

b. Whether true diversity operation (two receivers) is required or whether one receiver with computer controlled RF switching and diversity antennae will suffice for this application.

c. Whether ECG electrodes can also be used to acquire the RF signal or if not, or for backup receiving capability...

d. What should be the optimum array of RF receiving antennae?

3.3 Diversity Receiver (con't)

The diversity receiver has been laboratory tested for this program, so its characteristics are well defined. Present engineering analysis shows its performance in critical parameters can be duplicated in a smaller package suitable for the CDUSS program, if new state-of-the-art components are used.

We are currently investigating the extent to which the TR4-1 can be controlled by a PC-XT computer, rather than by its built in uP, to give greater flexibility to the direction of the University of Oklahoma algorithm test program.

3.4 Multi-channel Telemetry Transmitter

A six-channel, general purpose physiological telemetry transmitter will be used to acquire the required CDUSS sensor data, and also will be used to test whether the following sensor options are appropriate:

a. Will a shoulder-mounted actigraph provide comparably useful information on subject activity as will a wrist mounted device? (The benefits of a Sam Browne belt mounted unit, being less encumbering to personnel and making for easier sensor installation merits attention.)

b. Will a shoulder mounted internal suit temperature sensor be equally effective as one on or near the back of the head, as specified in the contract? (Less encumbrance, easier installation, and possibility of combination with actigraph sensor are desiderata.)

3.5 ECG Electrodes

Evaluation of optimum ECG electrode pair locations, and evaluation of the suitability of commercially available capacitative electrodes are planned.

3.6 Harness

A preliminary harness will be evaluated.

3.7 Suit Interaction

How radio-opaque is a chemical defense suit, and how will it interact with receiving antennae for the pill?

3.8 Human Factors

Last but definitely not least, a human test protocol will be generated, University of Oklahoma Review Board approval sought, an early review by WRAIR personnel of the proposed test protocol planned, and hands-on experience of the principal physiological consultant (Dr. Kenneth Dormer) and the electronic system Project Engineer (Mr. Timothy Cushing) with an actual suit and heat stress test situation will occur prior to the completion of Phase II development, allowing corrective action if necessary prior to Phase II CDUSS unit testing.

4.0 System Analysis

4.1 The Temperature Pill

The basic pill will be the approximate size of a 500 mgm Vitamin C capsule, and will have the following design approaches.

a. One IC for the basic electronic element, programmable in its basic characteristics (pulse amplitude, pulse width, pulse interval, power output to sensor, etc.) by passive components, either Surface Mounted Devices (SMD's) or laser trimmed hybrid thick film devices, as production quantities and economics dictate.

b. No on-off switches or operation adjustments of any sort. The device will last one year.

c. Encoding will be by means of Pulse Interval Ratio Modulation (PIRM), in which two pulse intervals, one representing temperature, the other representing battery voltage, will be transmitted.

This is a more complex coding than simple Pulse Interval Modulation (PIM) heretofore employed, and is desireable because lifetime of batteries is not determinable to be identical in a production lot. Since the IC needs to be as simple as possible (reliability, yield, size, cost) and the battery as small as possible (a 1.5 V silver oxide unit has been tentatively chosen) it is not practical to incorporate a voltage regulator in the unit. It is not desirable to have to calibrate units in the field. By encoding the battery voltage, changes in calibration due to battery voltage drop are minimized by receiver computer processing.

d. The thermistor bridge will be energized by pulsatile excitation. This is not only a power saving stratagem, well proven in our prior designs, but permits the use of lower impedance thermistor compounds. This promises improved thermistor stability and is also less susceptible to calibration shifts due to high impedance sneak current paths which may develop in ingested units.

e. All pills will radiate at approximately the same radio frequency. The low duty cycle of tranmission will permit several pills to be swallowed, in case "hot spot" alarms (higher metabolic heat generation near the liver) become a problem. The receiver/computer will be able to distinguish betweeen different pills because of minor differences in pulse amplitudes, pulse widths, pulse arrival times, and transmission frequencies (see Computer).

f. Testing of pills prior to deployment will be on a go/no-go basis. The choice as to whether this is done at depot, base, or by the user remains to be determined.

g. The pill will probably be coated with custom compounded dental epoxyacrylate, and will be disposable, eliminating the need for a recovery program.

h. The pills will radiate AM pulses in the 88 to 108 MHz FM band. This band is chosen because transmission characteristics through body tissue in this range, with small antennae, are known to be satisfactory.

i. Problem Area: miniature batteries limit storage temperature to ??/+56 degrees C. The Mil Spec range is -51/+71 C. We recommend against special battery development at this time.

4.2 The Pill Receiving Antenna

The Pill Receiving Antenna configuration will be determined in Phase I test.

4.3 The Receiver

The Receiver will be capable of receiving at two or more RF frequencies, all in the 88-108 MHz band (one frequency for Pill AM reception, the other frequency for long range FM transmission). A broadband RF first stage, and a switchable input through bandpass networks will, with proper computer programming, permit the receiver to be used either as a Pill Receiver, a Retransmitter, a Base Station Receiver, or a Radiolocator. This will achieve economy in design, and certainly in logistics. A receiver can be reprogrammed to other tasks by selecting its frequency of operation, supplying it with an appropriate antenna, and directing it to use one or another of its built-in computer controlled operation programs.

Among the features of the computer control of Receiver operation will be the following:

a. Sample and hold circuitry for AFC and AGC for a particular pill (see below).

b. Storage of pill characteristics (pulse width, amplitude, arrival time, transmission frequency) to enable assignment of AGC and AFC values to a particular pill when more than one pill is being monitored.

c. Sample and hold of pill signal strength and signal to noise ratio for each antenna employed, so that an RF Switch can deploy the best antenna for temperature information acquisition.

d. Alerting the user to the lack of usable signal, whether from equipment failure (pill, antennae, external noise, other), lack of ingestion, excretion (detectable by an algorithm referring pill temperature to suit temperature), or poor pill orientation.

e. Receiver self-monitoring for RF sensitivity through its antenna link (a continuous "housekeeping" function in between data acquisition).

f. Receiver monitoring of the RF signal strength of its long distance transmitter (another "housekeeping" function).

4.4 The Data Acquisition System

This unit is comprised of two integrated circuits, one a 16 channel custom mainframe (prototype PIM IC now in house, ready for evaluation), programmable for any number of channels (1 to 16) working in conjunction with a commercially available IC 16 channel multiplexer.

The mainframe has built-in over- and under-range limits, framing, zero and gain references, voltage regulation, and is modifiable for pulse width, nominal (zero signal) pulse interval, and other functions by the use of passive components. The mainframe can also be externally programmed by passive components to super-commutate or sub-commutate its 16 channels, as the user may elect, for power saving or high frequency response characteristics. The mainframe can also direct amplifier modules to supply pulsatile excitation to strain gage or thermistor based transducers and sensors.

4.4 The Data Acquisition System (con't)

The principal problem area for the mainframe is its PIM operation, which is not suitable for feeding a data stream to a computer. The mainframe can be modified to Pulse Width Modulation (PWM) in which the interval between channels is constant (good for computer handling), and data is encoded by the width of a pulse, within the fixed channel limits, whether by AM or Frequency Shift Keyed (FSK) FM modulation.

In its present embodiment, the PIM mainframe draws less than 1 mA from a 3 V supply. The prime reason for the flexible programmability of the mainframe is so that new instrumentation systems need not be devised for a change in experiment design. The economics even of semi-custom IC devices are such that small production runs are prohibitively expensive or simply not accepted by typical IC semi-custom houses. One quasi-universal design sidesteps this commercial constraint.

4.5 Transducer Driver/Signal Amplifier

For the sake of generality (see discussion above) one semi-custom IC will be able to be used for biopotential signals (ECG, EEG, EMG, EOG), or transducer excitation and output amplification (pressure, acceleration, temperature, force). The IC will be programmable by means of passive outboard components for gain, high frequency roll off, low frequency (to DC) roll-off, and pulsatile excitation duration and levels. The unit is a low noise device; a working breadboard already exists.

4.6 Long Range Transmitter

This transmitter will be identical in both the CDUSS suit systems and the repeater stations. The difference will be in the trasmitting antennae. The suit antenna will, of necessity, be smaller.

Depending on the RF opacity and/or conductivity of the Chemical Defense Suit, and available power for the transmitter, the belt/suit mounted antenna configuration remains to be determined.

All Suit long range transmitters will be crystal controlled and will transmit at the same frequency. Because there are many (50) units, it is impractical to dedicate channels for each transmitter. This would require narrow band FM to place many channels in the target band, would require each unit to be uniquely tuned or programmed, and would require system switching to bands other than those for which there are existing designs and experience.

Many transmitters on the same channel avoid the above problems but require a crash avoidance protocol:

a. There would be pseudo random transmission packet timing, to prevent synchronous interference between different Suit transmissions.

b. Transmission would be in the form of low duty cycle bursts, with transmitter identification, data, and possibly error coding in each burst.

4.6 Long Range Transmitter (con't)

c. Physiologically NORMAL transmission would occupy 1/2000 of individual transmitter time or 2.5% of total available transmission time (50 channels x 1/2000 = .025). RISK transmissions would be at 1/666 of individual transmitter time or 7.5% of total time if all channels were at risk (unlikely), and CRITICAL transmissions would be at 1/200 of individual transmission time or 25% of total time (extremely unlikely), even if all 50 channels were critical. Thus crash avoidance could be maintained and yet give priorities in transmission to test subjects at risk.

The Repeater Stations and the Base Stations would use similar packet-style protocols to reduce redundant channel demands. Repeater Stations might use a different frequency to transmit to the Base Station, or, alternatively, store packet information and transmit to the Base Station in "quiet" time between Suit packet arrivals. The optimum protocol will be determined.

4.7 Computer

The same computer can be used in different operational modes, for different tasks. The probable storage capacity of computer EEPROM plus ROM memory can probably accomodate programs for all tasks in the same unit. The relative advantages of universality (all units have all programs and support all memory requirements, requiring only task selection) versus specificity (each unit is programmed only for what it needs for its function, with unused capacity in reserve for presently unknown requirements) remains to be established. Because computer usage is so intertwined with function and associated hardware, it is advantageous to describe it in terms of multiple usage. This discussion is deferred until the system description is complete.

4.8 Repeaters

Each suit unit must communicate across unknown terrain. One or more repeaters may be required to illuminate terrain RF shadows. The system must provide for multiple paths to the base station. The Repeaters will essentially be Suit devices, not needing specific pill reception and instrument decoding or algorithm processing, but requiring distinct antenna design, packet recognition, and signal buffering. These hardware and software distinctions are set forth in a comparison table elsewhere below.

4.9 Locators

Locators are required to locate distressed (or lost) cohorts. As with Repeaters, these essentially may be Suit devices, without the special Suit hardware and software generally described above, but requiring a portable directional antenna, a packet recognition algorithim (so the Locator only "listens" for the transmitter sought) and a signal strength audio feedback, for operator control. These hardware and software distinctions are set forth in a comparison table elsewhere, below.

4.10 Base Station

The field base station should be capable of displaying alarm conditions, and preferably personnel and equipment status, of all 50 transmitting systems. The display system should show more than alarms alone if medical judgment at base is to be capable of overriding CDUSS computer judgment (whatever the judgment). Since algorithms have not been tested, and it is not clear what data or indices are most useful for transmission to base without overcrowding the RF spectrum, it is vital that the proposed base display allow for easy reconfiguring by any computer operating personnel based on standard (IBM-PC) personal computer operation. This could allow for deluxe graphics, post processing of data if required, and ready output of data to mass storage if desired.

4.11 Diverse Equipment With A Single Basic Instrument

The system we describe has a multitude of functions, as noted above, yet many functions have commonality in both hardware and software. A brief summary follows:

a. Tranceiver hardware/software

Receiver for suits, repeaters, locators, and base

Transmitter for suit, repeaters (optional for locators, base)

Packet protocol for suits, repeaters, locators and base

b. Data processing, data storage, and information disposition

Processing for suit (algorithm), base (data conditioning), locators (feedback)

Data storage for suit time course of data (3 - day), repeaters (packet buffer)

Routing for suit data (transmitter, storage, tape, signal conditioning), Repeaters (transmitters, buffer, data storage), Locators (feedback), and Base (data conditioning, terminal display)

c. User Interfacing

Controls for suits (SCF, flags), Repeaters (configurations), Locators (subject searching for), Base (configuration of Display)

Display for suits (self-test, operating status), and operating indicators for others operative systems.

Ports for the uC for suits (computer configuration such as for MCF), Base (PC terminal interaction).

Antennae connectors, switches, possibly antennae boosters for suits, repeaters, locators, and base.

4.11 Diverse Equipment With a Single Basic Instrument (con't)

d. The hardware/software not common to multiple functions are small, and are mostly in the suit:

Special pulse-processing for pill reception (software; hardware used for packets)

Tunable receiver to allow for pill RF frequency variations (as opposed to selectable frequency channel receiver for all other equipment)

Multichannel analog data acquisition and encoding (for bio-signals)

Multichannel analog data outputs for tape (though this feature may be useful for the base station)

Three day memory capacity (repeater needs only about 10% of this for data buffering).

Specific software algorithms:

Suit: Pill processing; bio-monitoring/alarms; packet transmission and timing

Locator: Packet discrimination and signal strength feedback

Repeater: Packet discrimination and packet buffering until retransmission

Base: Packet discrimination and data decoding

Specific accessory differences:

Suit: Pill receiving antennae, ECG leads, actigraphs, temperature sensor, small long range transmitter antenna, (possibly the same as pill receiving antennae) and audio feedback of alarm status.

Locator: Directional antenna, audio signal strength feedback

Repeater: High gain receiving antennae pair, transmitting antenna

Base: High gain receiving antennae pair, VDT (video display terminal)

e. The inclusion of ALL software modules in each unit requires at most an auxiliary ROM device for all specfic usage application (each application separately addressable).

uC's are EEPROM and can bootstrap any of the ROM stored operation modes into the main program area.

The ROM module is small compared to the overall suit requirements

The EEPROM can assure adequate overhead capacity at almost any desired level.

f. The suit hardware provides functional capability to fill all other hardware needs.

Accessories are all detachable, so can be changed as needed

Suit requirements are overkill for other applications but will none-the-less do

Detachable hardware modules (recorder, batteries, etc) are useable or removable

g. Some constraints multi-purpose integration into all units impose:

Receiver selectivity hardware must cover one broad (or two narrow) bands. We believe a switch band-select filter more economic than an additionally designed fixed frequency receiver.

Pulse acquisition hardware/software must accomodate short, rare pulses (pill) as well as long more frequent pulses (packets).

More complex range control on time measures: the tasking structure for equipment operation monitoring is confined to short "busy" periods

Antennae are probably of different characteristics, depending on task, hence the loading/matching of components will have to be built in as part of the accessory antenna.

All operating program configurations can be stored internal to a ROM memory and will have to be selected by manual keys/switches by the user. Hierarchical user access to determine "mode" of unit may be required.

Configurations can be loaded from base terminal (via serial port or enhanced RF link).

h. The benefits of all functions contained in one suit-unit are:

It will allow a CD user to act as a locator (if logistics permit).

The development program staff and the COTR will have to consider trade-offs between breaching the suit to connect a Direction Finding (DF) antenna to the Suit Receiver, versus the procurement of an extra Receiver for Radio Location equipment. Only those personnel carrying DF antennae can act as locators (but the antenna is relatively low-cost).

With a single basic instrument, only one major piece of hardware need be developed and produced. This avoids the expense of packaging multiple devices, and also avoids the cost of producing only a few special units.

Only one piece of hardware need be maintained and operated. This avoids traing troops on multiple equipment. Any working unit can be substituted for any malfunctioning unit. Only a single operating manual would be required for the entire system (avoiding redundancy). Most importantly, it would eliminate a "single-point-failure" (Base) crashing the entire system until it was repaired.

4.12 Algorithm

We have left the algorithm for last in the analytical solution discussion because, essentially, this is a medical and physiological, rather than an engineering or computational problem. Our objective will be to have a simple fail safe algorithm, embodying at least the specific requirements of the Contract. However we believe the purposes of the program will best be served by providing the "spread sheet" capabilities of a PC controlled algorithm in the early test stages, monitoring actual subject exertion, while observed by medical and physiological personnel, with the results recorded on-line, hard copy and tape recorder monitored for all channels, with algorithms easily varied by operating personnel to find a good match between theory and medically and physiologically qualified observation.

5.0 System Details and Block Diagrams

5.1 Field View of System (Fig. B105010):

a. Base station, for field medics with readout/display of user status transmissions

Uses basic Suit unit, a field-base antenna and portable computer processing and display.

b. Repeater station(s) as required by terrain, to relay user transmissions from RF shadowed areas

Uses basic Suit unit, set to Repeater mode, with high-gain omni-directional receiving antennae

c. Locator units to allow direction finding to users as needed

Uses basic Suit unit, set to Locator mode, with directional (Quagi) antenna

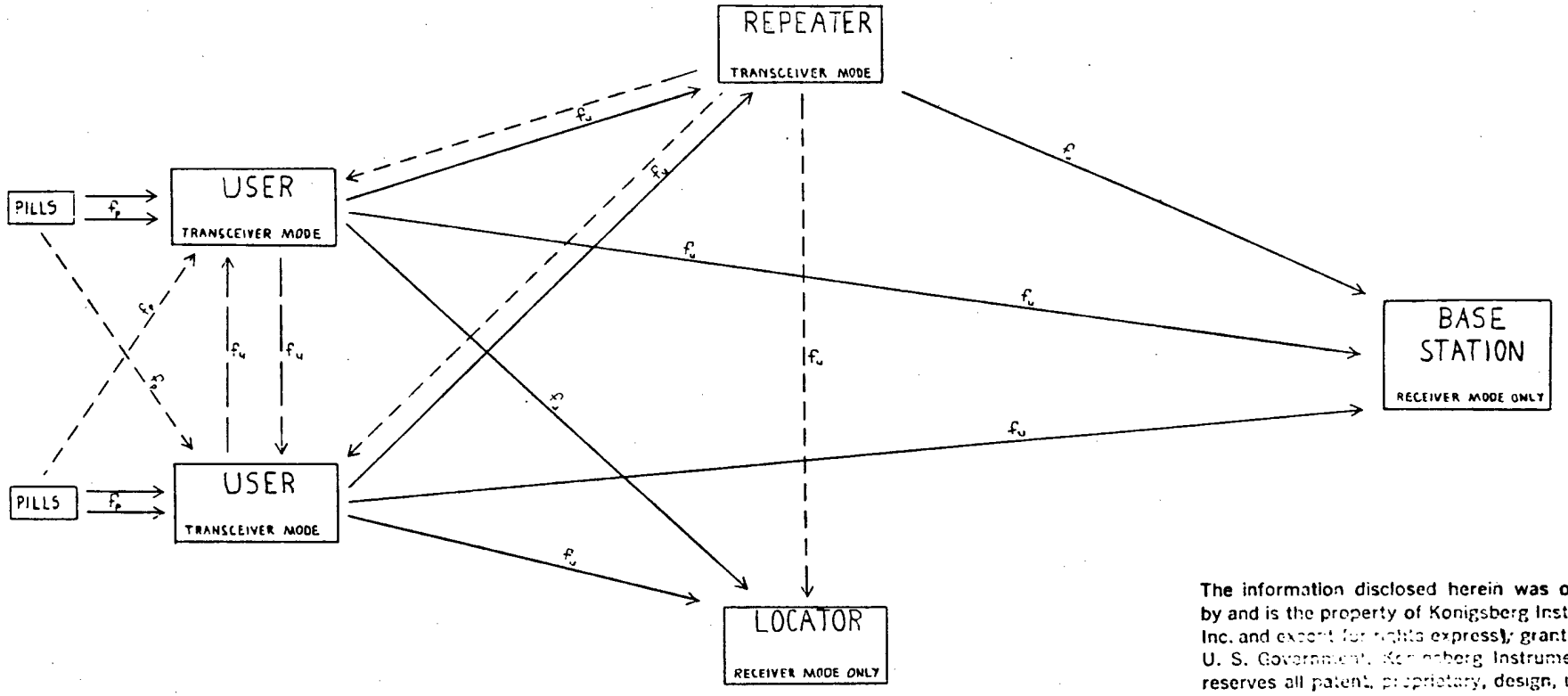
d. Suit units, to monitor User thermoregulatory condition and transmit status to medics

Thermoregulatory algorithm operating in real-time in each Suit unit

e. Temperature Pills to transmit core temperatures to the Suit unit

Disposable pill-transmitters, taken as needed (prompted by Suit unit)

REVISIONS				
ZONE	LTR	DESCRIPTION	DATE	APPROVED



KEY:

DESIRED SIGNAL PATH ——————

INTERFERING SIGNAL PATH — — — — — —

POSSIBLE DESIRED SIGNAL PATH —— —— ——

f_u = USER FREQUENCY

f_p = PILL FREQUENCY

	CDUSS
NEXT ASSY	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES
TOLERANCES ARE:
FRACTIONS DECIMALS ANGLES
± .XX ± ±
.XXX ±

MATERIAL

FINISH

DO NOT SCALE DRAWING

CONTRACT NO.

APPROVALS	DATE
DRAWN EJB	1-10-86
CHECKED	1-10-86

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2000 E. FOOTHILL BL. PASADENA, CA. 91107

RADIO FREQUENCY COMMUNICATION DIAGRAM

SIZE	CODE IDENT NO.	DRAWING NO.	REV.
B		105010	N/R

SCALE NONE SHEET 1 OF 1

5.2 Detail of field base equipment (no Fig.)

a. High-gain (directional, if single Repeater unit) antenna for optimum reception

Use of antenna boosters, etc., may improve overall performance (should not be necessary)

b. Suit unit (in Field Base mode) for receiver and packet processing (see Repeater, below)

Outputs Suit indentification and data for each transmission received (output via serial port)

c. Portable (Mil Qual?) computer (IBM PC/AT compatible) to process Suit identifcation packages

Video display of terminal (PC) provides viewing of Suit status information

PC terminal can be readily programmed for viewing in format desired by customer

d. Large capacity (tape) recording units may be used to collect Suit status, data, etc.

5.3 Detail of Repeater operation (no Fig.)

a. High-gain omni-directional antennae pair mounted for optimum coverage

Use of antenna boosters, etc., may improve overall performance (should not be necessary)

b. Suit unit (in Repeater mode) for receiver, transmitter, and packet processing:

Communication link between Suits and Field Base uses single RF frequency channel for all Suits

Suits transmit occasionally; minimal transmit duration

Repeaters discriminate channel activity for clear Suit transmissions

Suit transmissions accepted by Repeater are re-transmitted to the Field Base

An abreviated form of military "packet" switching protocol will ensure integrity of communication packet data.

c. Re-transmitting antenna(e) may be the same as receiving antenna(e), or may be focused for Field Base

5.4 Detail of Locator operation (no Fig.)

a. Hand-held direction-finding antenna (probably Quagi) for discriminating location of a Suit unit

b. Suit unit (in Locator mode) for receiver, location processing, and feedback to operator

Locator antenna must either be outside the CD suit, requiring a breach of the CDUSS unit inside, or can employ seperate CDUSS unit outside the CD suit. The breach may be in the form of a hermetically sealed RF connector installed in the Suit.

Suit unit in Locator mode will provide audible feedback to the operator of the signal strength of the searched-for Suit (User)

Discrimination processing (as in the Repeater unit) will allow extraction of selected Suit transmission from general Packet transmission activity

5.5 Detail of Suit equipment (Two Fig.: see listings following)

a. Basic Suit unit includes self-contained hardware/software (Fig. B105011):

Receiver with full computer control of tuning, etc.

Antenna interface for multiple and arrayed antennae

Transmitter (adequate for 1 mile) with computer control of tuning, data, etc.

Pulse acquisition/processing capability for multiple simultaneous pill transmissions

Packet discrimination processing for required packet protocol, including Suit identification

Data acquisition for 3 biopotentials, 2 temperatures, and 2 tri-axially sensitive accelerometers

Data processing to reduce raw signals (e.g. ECG, acceleration) into bio-indices, e.g. Heart Rate (HR), Activity Rate (AR)

Data processing to correlate the above per a thermoregulation algorithm (real-time)

Data recording for 72 hours of compressed algorithm indices (physically removable or "data dump" module)

Four analog output channels suitable for tape-recorder inputs (selectable data)

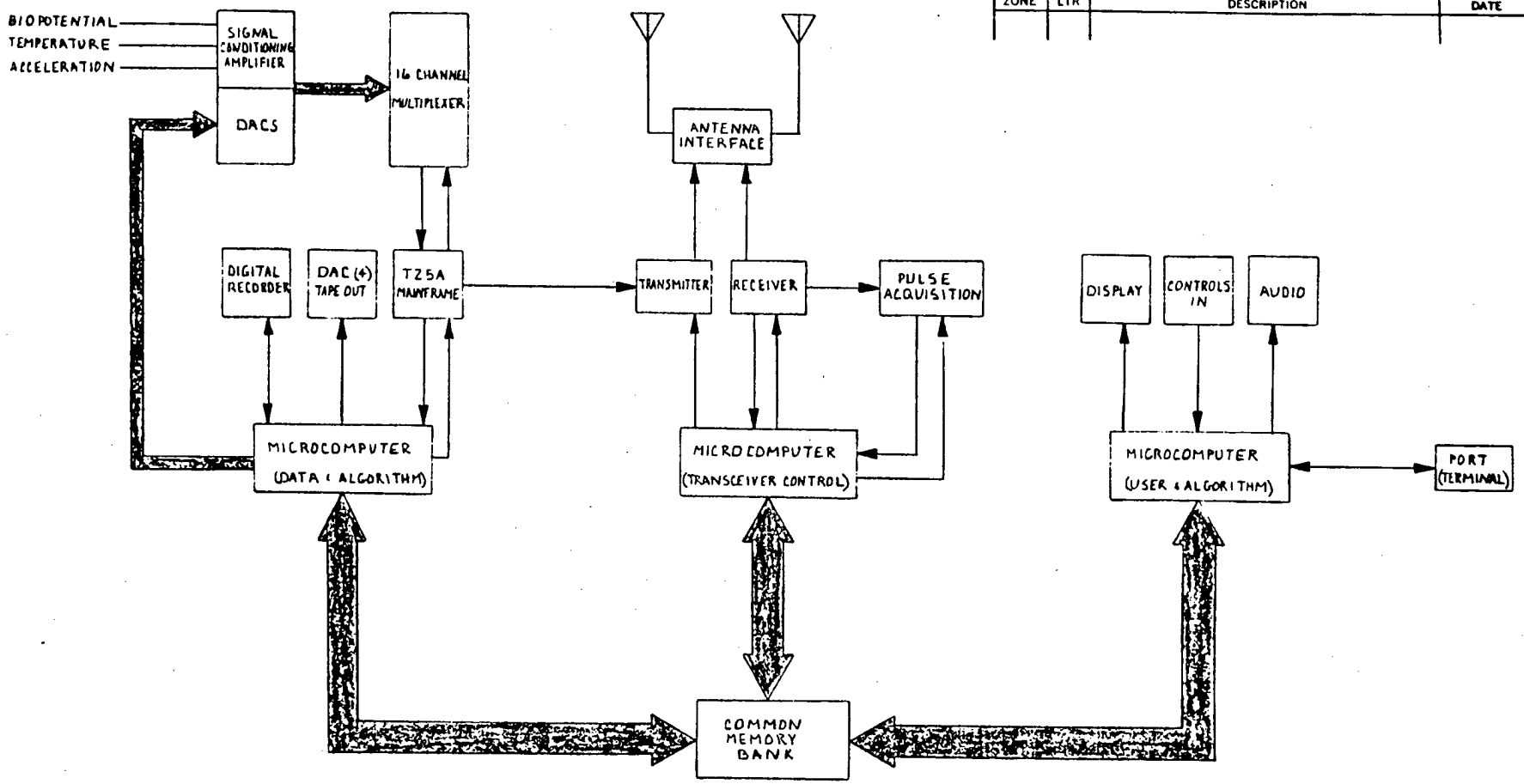
Processing to permit continuous transmission of all raw data acquired

Display of operating mode, unit status, etc, (including self-test status)

User controls for operating mode, SCF, commands, comments, etc.

Audio output for alerts and Locator feedback

Serial port for Field Base and programming purposes



REVISIONS

ZONE	LTR	DESCRIPTION	DATE	APPROVED

NEXT ASSY	USED ON
	CDUSS
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES
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USER SUBSYSTEM DIAGRAM

SIZE	CODE IDENT NO.	DRAWING NO.	REV.
B		105011	M/R

SCALE NONE SHEET 1 OF 1

5.5 Detail of Suit equipment (con't)

b. Accessories to Suit unit for Thermoregulatory monitoring and field usage (Fig. B105016):

1 pair ECG electrodes, capacitative coupling type

2 each tri-axially sensitive accelerometers (1 on right wrist, 1 on right shoulder, for Phase I correlation)

1 each harness (antennae mounts, equipment mounts, connectors, included in a Sam Browne style belt)

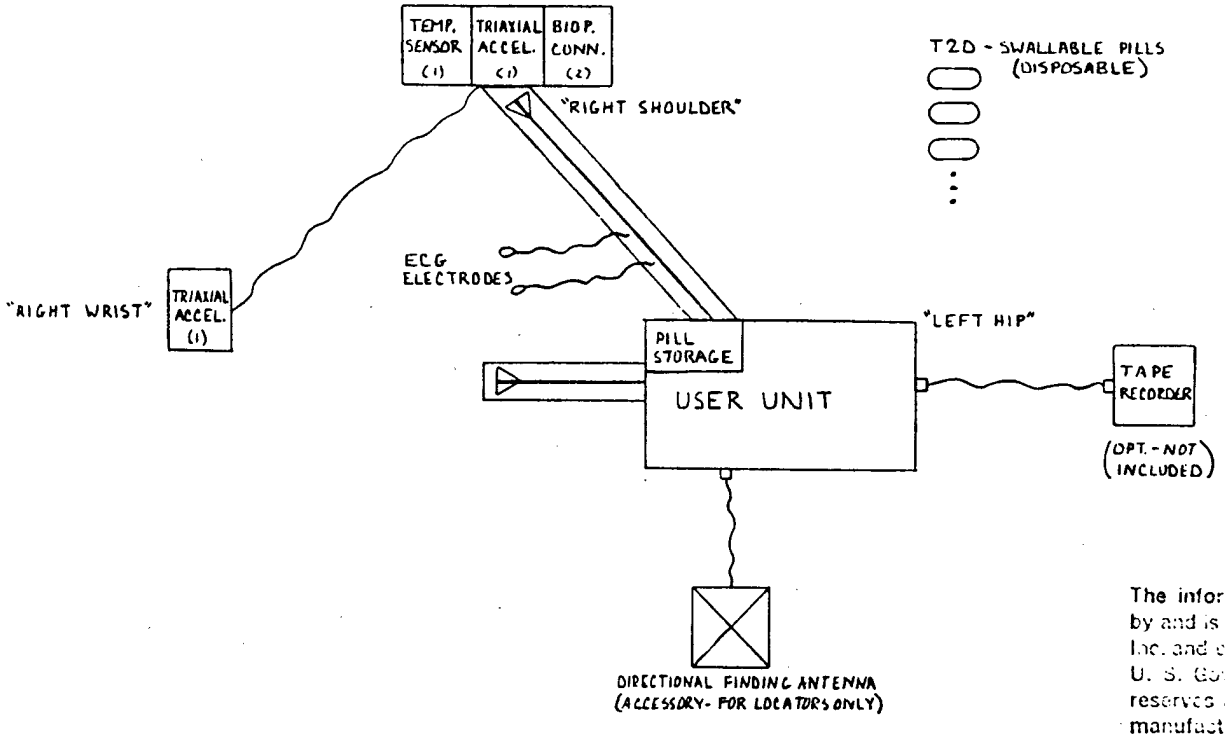
Connections for: 3-biopotential leads, 2-accelerometers, 1-Suit temperature sensor, 1-Suit Electronics unit

Harness mounting for:1 Suit Electronics unit, 1-tape recorder, 1-accelerometer, 1-Suit temperature sensor

3 each/50 direction finding antenna (prob Quagi)

8 each disposable temperature pills

REVISIONS				
ZONE	LTR	DESCRIPTION	DATE	APPROVED



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			APPROVALS / DATE	
			DRAWN SEA 1-11-86	CD USER EQUIPMENT DIAGRAM
		MATERIAL	CHECKED J.C 1-11-86	
		FINISH		SIZE B / CODE IDENT NO. / DRAWING NO. 105016 / REV. M/R
	CDUSS			
NEXT ASSY	USED ON			
APPLICATION		DO NOT SCALE DRAWING		SCALE NONE / SHEET 1 OF 1

5.6 Detail of Thermoregulatory Algorithm (Fig. B105014):

a. Acquire current raw data samples: ECG, Accelerometer, Core Temperature, etc.

b. Convert raw data history into current bio-indices: HR, AR, Temperature, etc.

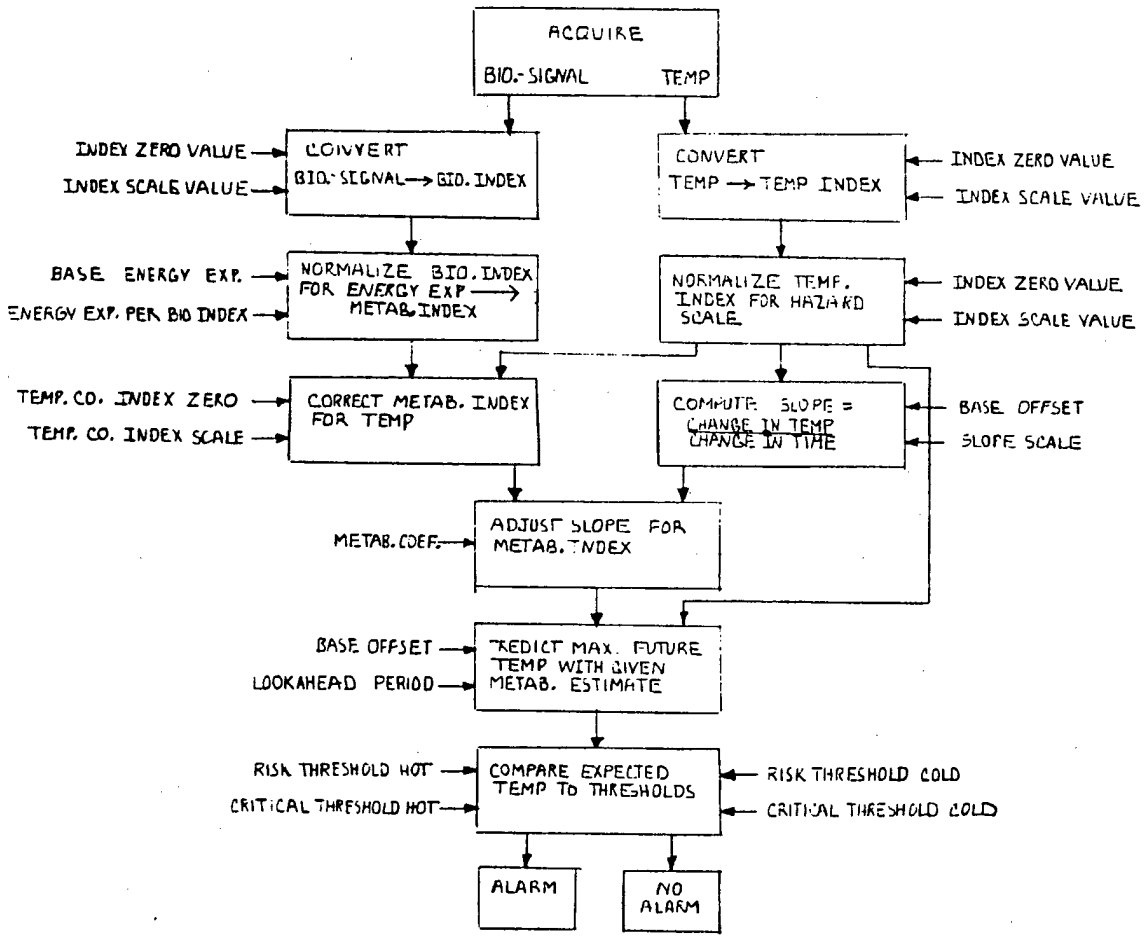
c. Normalize current bio-indices into algorithm indices: Metabolic, Exertion, other

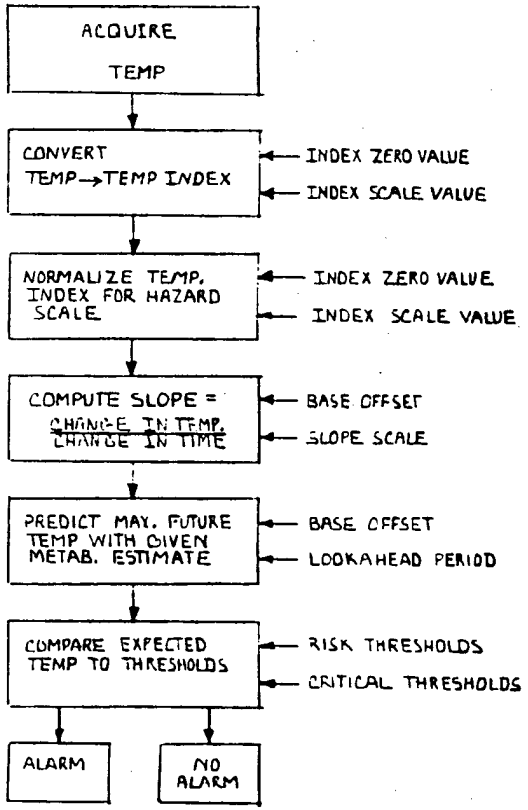
d Correct normalized indices for unwanted cross-effects: Temperature coefficients, User comments, etc.

e. Extrapolate expected time course of body temperature, based on ambient conditions

f. Modify risk/critical thresholds to allow for expected effects of present User behavior

g. Alert/Alarm if body temperature extrapolation crosses modified thresholds





REVISIONS

ZONE	LTR	DESCRIPTION	DATE	APPROVED

NEXT ASSY	USED ON
	CDUSS
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES
TOLERANCES ARE:
FRACTIONS DECIMALS ANGLES
± .XX ± ±
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MATERIAL

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APPROVALS	DATE
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CHECKED JLC	1-10-86

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CDUSS ALGORITHM STRUCTURE

SIZE	CODE IDENT NO.	DRAWING NO.	REV.
B		105014	N/R

SCALE NONE SHEET 1 OF 1

5.7 Detail of Temperature Pill System (Fig. B105012):

a. Transmits brief RF bursts at intervals relative to temperature

Low duty cycle of RF pulses permits seveal pills on the same frequency

Transmitting frequency, pulse amplitude, pulse duration, and pulse arrival time variations between pills effectively "tag" each pulse for a specific ingested pill

b. Calibration stability insured by also transmitting battery level

Computer can correct for gradual battery exhaustion

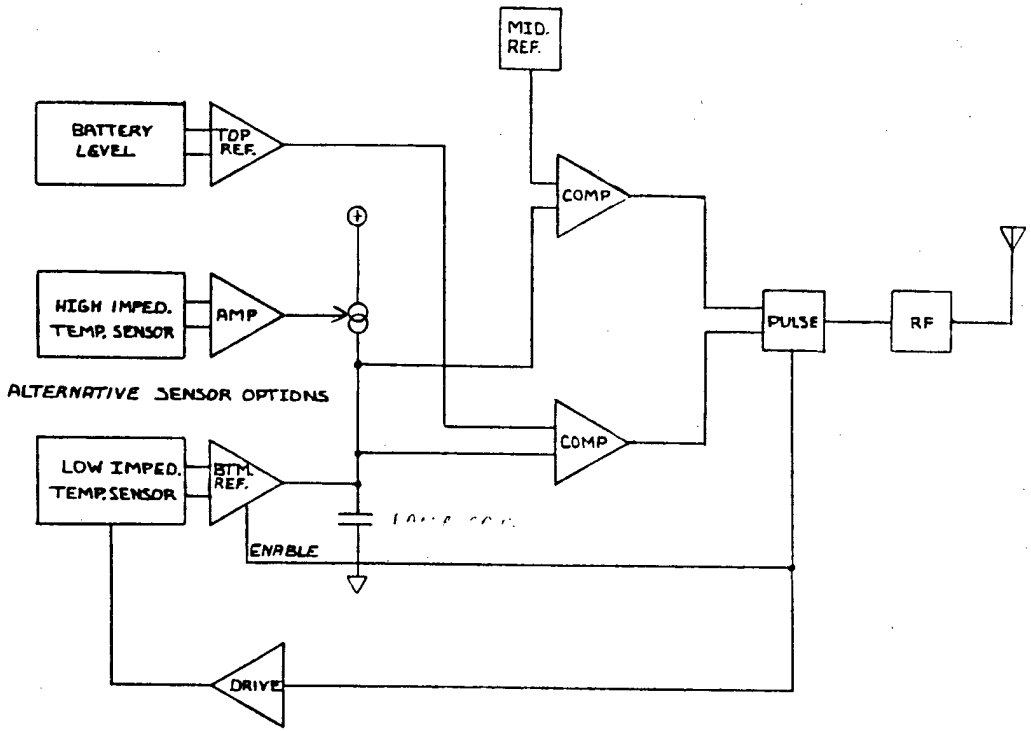
Computer can reject information from pill with inadequate battery voltage (some "default" algorithm backup may be required in such cases).

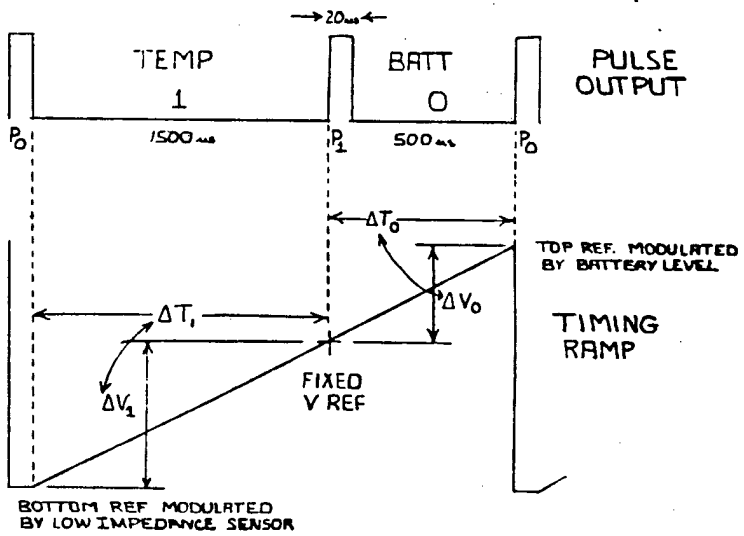
c. Stability and perhaps linearity of thermistor influenced by basic resistivity value of thermistor material

Circuit can accomodate either high or low thermistor resistance values, requirements to be determined

d. Modulating both ends of the ramp, relative to a stable mid-point, permits most efficient use of circuitry and accomodates the limitations of micro-sized batteries (1.5 V)

REVISIONS				
ZONE	LTR	DESCRIPTION	DATE	APPROVED





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		MATERIAL	APPROVALS / DATE: DRAWN R-T 1-10-96; CHECKED MR 1-10-96	TEMPERATURE PILL DIAGRAM
	CDUSS	FINISH		SIZE B; CODE IDENT NO.; DRAWING NO. 105012; REV. N/R
NEXT ASSY	USED ON			SCALE NONE; SHEET 1 OF 1
APPLICATION		DO NOT SCALE DRAWING		

6.0 Fail-Safe Procedural Outline

Fail-operational and safety equipment (self-test)

(User installation at suit entry; reception of temperature pill; acquisition of bio-signals; probable validity of raw data; verification of transmitting to medics; alarm integrity; software integrity (various); self-test of self-test)

a. For safety monitoring, active self-test is necessary to avoid false confidence hazards

Must operate routinely during each use to catch faults that may develop in the field

Must include at least "bottom line" checkout of each component of the algorithm:

-ECG/HR signal appear valid (check for excessive arrythmia, general noise, etc.)
-Core temperature indication believable (if out of range, compare 2nd pill; possible time course of "unbelievable" first temperature pill)
-Suit temperature indication believable (similar criteria to core temperature)
-Acceleration/Activity signal valid (check for none, excessive, etc.)

Checkout of sensors/connections could indicate most expected errors, but would not replace the basic "signal-valid" test, so it is not expected to be used except where a signal is not readily available (as determined in Phase II design).

-A valid accelerometer electrically connected but not mechanically attached to the harness or the wrist will appear OK except for signal
-Improperly placed ECG electrodes will give a legitimate signal, but may not suffice for the algorithm

Thus self-test will be 95% software with only simple hardware allowances for tests

Transmitter may need a power meter, or may listen for repeater/base echo

Receiver may need a harmonic of uC clock, or may listen for repeater/base traffic

Precision voltage references will be needed for testing the Analog to Digital Conversion (ADC) portions of the Data Acquisiton System (DAS)

Scaling the battery voltage to the DAS range will permit a measurement of battery adequacy

Tape outputs will also be routable thru the DAS to verify outgoing data
(no provision for reading from the tape unit is included)

6.0 Fail-Safe Procedural Outline (con't)

a. For safety monitoring, active self test... (con't)

A Computer-Operating-Properly (COP) handshake line between each uC (there will be two or three uC's) to supervise each other (may be implementable in shared memory)

Using feedback from the visual indicators built into the Suits can show faults in the display (in general, including feedback to close all otherwise "open" loops permits tests).

Self-test is limited to system and function testing. It is not feasible to test in adequate depth to reveal partial failures such as loss of any one memory bit.

b. Specifics for general power supply and distribution

Most of the power distribution adequacy will be implied thru tests of various hardware sections

Basic power supply (from battery) will be tested thru simple min/max comparisons thru the uC's (on-chip) ADC (each uC has 8 ADC channels)

Battery voltage will be monitored to observe and alert to impending exhaustion

c. Specifics of basic uC checkout

COP handshake essentially involves each uC checking-in with others at a maximum interval Failures to ROM or uC access to external memory will generally disturb the COP function

RAM test will be routine read-after-write for data throughout the various algorithms Testing can be seldom and still show any overall failure

Testing of various I/O pins will be part of respective function test.

d. Specifics of DAS testing

The uC will output to DAC's zero/scale values: these are routed thru MUX to the T25A encoder (A/PWM) which in turn outputs back to the uC thru its PWM/D conversion. The full DAS loop is thus checked for proper function, calibration and control

Checking of the uC ADC will use zero/scale reference on spare T25A channels (the ADC's are mostly used for various internal functions)

Faults could be isolated to specific blocks by routing the DAC and MUX outputs also to the uC ADC, for comparison with the PWM/D reading of the T25A output. This will be done if spare ADC channels are available, PCB layout permits, and design/software scope is not exceeded (this capability would be useful during development and production troubleshooting, but not essential to self-test for safety).

Tests of the DAS input amplifiers could be made by switching their inputs to a DAC output, and then passing a signal through the system. (This could test gain, frequency filtering, etc.)

If design/software scope permits, this would aid in development and production, but probably would not catch any faults not observed elsewhere. (This type of test would be fault diagnostic, not fault supervisory.)

6.0 Fail-Safe Procedural Outline (con't)

e. Specifics of data record testing

The four analog tape outputs will be routed (possibly switched) to the uC ADC and read

-Two or three uCs allows 16 to 24 ADC channels throughout the unit

Read-after-write verification of the digital record will assure its integrity

-A portion of the record will be set aside for a list of defective locations

-Since the digital record is updated infrequently, a full verification is feasible

-Keeping sliding portion of redundant records (say 10 minutes worth) would allow detecting refresh errors if dynamic memory is used (not needed for ROMs)

f. Specifics of user controls/display testing

Design goal of all control being thru the keypad (for SCF) would allow test during entry of SCF by including each key at least once (test for each at least once)

Switches not in the keypad hinder testing without user interaction (undesireable)

Use of LEDs for display permits checking the display voltage (should be about 2.5 if ON, 0 to 5 would imply a fault; may use ADC or simple logic levels)

LCD may be preferable for other than simple indicators, but would not readily allow testing without user interaction (undesirable)

6.0 Fail-Safe Procedural Outline (con't)

g. Specifics of transceiver testing

Basic receiver tuning and sensitivity may be tested by tuning to a selected harmonic of the uC clock (requires a simple filter circuit and a switch to route the harmonic)

This could also permit testing the RF level meter used for pills and Locating

Routing this harmonic (at very low power) out one antenna while listening at the other would permit verification of the external antennae installation as well

Use of the two uC clock harmonics would permit testing of the Receiver's tuning curve, although having the uC count the receiver's Local Oscillator (LO) output would be more informative, and require little additional hardware.

Tests of selectivity could be made by tuning away from the harmonic and observing the signal loss (tests channel selectivity, image rejection, etc).
This would aid in development and production but is unneccessary for safety confidence

Similar test for AFC, AGC, etc., would be of similar use.

Tests of the pulse acquisition circuitry could be made thru gating the uC harmonic
Probably desireable to ensure proper pill reception/discrimination (acquiring pulse frequency, duration, amplitude, and arrival timing, via sample and hold circuitry)

Transmitter testing cannot use the receiver simultaneously since the receiver LO is used for the transmitting oscillator (buffered with a power amplifier).
Could listen for an echo from base or repeater (occurs at known time)-best but antenna reception properties not in design criteria.

Could simply measure RF power delivered to the antenna (but does not test antenna)

Test of LO (and hence transmit/receive tuning accuracy) can be made by counting the LO output (via a prescaler) to the desired accuracy (necessary to ensure transmitting channel frequency precision)

Appendix II

Report on Phase IA, Section 4 of
the CDUSS subcontract

University of Oklahoma Pill Test

July 1987

Kenneth J.Dormer, Ph.D.

Dept. of Physiology & Biophysics
University of Oklahoma
Oklahoma City, OK

REPORT ON PHASE 1A SECTION 4 OF THE CDUSS SUBCONTRACT TO K.J.D. DORMER

SUBMITTED TO KONIGSBERG INSTRUMENTS ON MARCH, 1987

Final copy submitted July, 1987

OBJECTIVES: In the Phase 1A4.00 section of the CDUSS protocol we were to collect data consisting of heart rate (HR), body core temperature (T_c), skin surface (T_s) or inside suit temperature (T_{suit}) and activity from the wrist-worn accelerometer (Act). These data were to be collected from 2 subjects during quiesence, during exercise without the suit and during exercise while wearing the suit. We also exercised one subject with a 37 lb. backpack on a treadmill. The most rigorous exercise during heat stress was to take the subject to risk conditions, that is requiring behavioral modifications in order to prevent heat stroke or impairment of carrying on required activities in MOP gear.

The final report was delayed because the program formula for data analysis derived at Konigsberg Instruments was late and incompatible with the computer at OUHSC. Calibration curves were also not performed on the telemetry pills before shipping to OUHSC and presented some delays in determining the calibration curves for core temperature.

METHODS: Two subjects were used for the study. Carl Trout, 21 y/o male, wt. 162 lbs., ht. 69 in., no medication, was used in a previous study and had lost weight since that previous study. Ed Loewen is a 22 y/o male, wt. 172 lbs.,

ht. 74 in. and also not on medications. Both signed the patient consent form and both are ROTC from the University of Oklahoma students in good physical condition.

Loewen pill: sn 10 (93.85 Mhz)

Trout pill: sn 13 (104.99 Mhz)

We had one set of capacitative electrodes for the ECG, 2 Sam Brown belts with the antennae, 2 accelerometers and 2 temperature probes. The core temperature was telemetered by the T2C implantable telemetry transmitter and received by the TR4 TD10A programmable diversity receiver. Ts and Act were hard wired into the T41-TD8A multichannel main frame and then multiplexed into the A/D board (IBM) prior to storage on a microcomputer (Tandy 1200 HD). The ECG was hard-wired to a Gould Biotachometer and the heart rate obtained before entering the multiplexer for digital computation of HR. Data obtained were stored in separate files of LabTech Notebook, PH1A400A. This file contained the specifications for data aquisition and graphic presentation of the data. The file was created by Tim Cushing and a copy of the file is enclosed. Data storage files are as follows:

PH1A404 (A-F) quiescent and actively quiescent, both subjects, suited, unsuited.

PH1A405 (A-B) treadmill exercise tolerance tests with a 37 lb. load backpack, unsuited, both subjects.

PH1A406 (A-B) treadmill exercise tolerance tests without a load, suited both subjects.

PH1A406C treadmill exercise tolerance test (ETT) with a load and suited, CT only.

The ETT used was the standard Bruce protocol and the stages used were 1.7 mph at 10% grade, 2.5/12, 3.4/14 for three minute stages.

Additional observers present were Dr. Donna Branson and assistant Maureen Sweeney from the Textiles and Clothing Department of Oklahoma State University. Dr. Branson worked on the chemical defense suit design and testing at the Natick facility of the US Army. Dr. Ron Ratliff is the Director of the Human Performance Laboratory at the University of Oklahoma, Department of Health, Physical Education and Education. Dr. Ratliff is a co-investigator with Dr. Dormer in related studies. Dr. Ricardo Leon, M.D. was present for the treadmill testing to watch for subject stress.

RESULTS: Both pills were taken at 10:25 AM. C. Trout oral temp=97.1 F°: Ed Loewen oral temp=97.3 F°.

C. Trout unsuited, quiescent, actively quiescent (data file PH1A404A) for the first 8 minutes sat quietly in a chair, unsuited. We placed a "tic" on the data files by flipping the cal button on the cardiotachometer. This provided a switching transient, discernable on the data stream. Next for 8.5 min he was walking the floor and a tic was placed before we recorded (for the last 3 minutes) the activity of suiting up. End of file (Figures 1, 3, 4).

C. Trout suited, quiescent (data file PH1A404B). He was suited at 11:15 AM and was quiescent while sitting in a chair. We recorded the temperature

inside the suit with a Yellow Springs thermometer also along with the voltage out of the core temp signal. The room temp was 23.5 C (Figures 5, 7, 8).

Subject was suited up for 20 min, then a tic marks the beginning of the cool down period (after unsuiting) that lasted 10 minutes. There was no remarkable change in HR or temperatures.

T_s	Time	V_{out} core temp
87	11:25	.121
90	11:27	.119
92	11:30	.117
93	11:33	.115
unsuited	11:35	
80	11:36	.110
	11:41	.108
83	11:44	.114

C. Trout suited, actively quiescent (PH1A404C), Room temp 22.3C. Suited up at 11:47 and data aquisition began within 30 sec. Now we added another Yellow Springs thermometer for measuring the skin as well as the temperature just under the chemical defense suit. We then added insulation (1 wool blanket) to see if we could elevate core temperature (Figures 9, 11, 12).

$T_{(skin)}$	$T_{(suit)}$	Time	V_{out}
93	90.5	11:50	.116
93.5	92.5	11:55	.101

blanket placed over subject to add insulation

94.5	93	11:58	.094
94.5	94	12:03	.085
95	95	12:08	.089
95.2	92.2	12:12	.086
95.5	95.5	12:14	.090
95.5	96	12:17	.080

start to unsuit; oral temp 97.2 F

E. Loewen unsuited, quiescent, actively quiescent (PH1A404D). The subject was quiescent for 8.5 min (tic in data) then actively quiescent for 8.5 min (another tic in data) then was suiting up for about 2 min. He was unsuited for most of the time (Figures 2, 3, 4).

HR	T_s	T_{suit}	T_{core}	Time
66-70	88.5	83	.239	12:32
69-71	83	83	.252	12:37
66-71	88.5	83	.260	12:39
68-72	87	83	.260	12:41

start quiescent active period

69-72	87	83	.243	12:43

No remarkable changes in temperature or HR were observed during this time.

Ed Loewen suited, quiescent (PH1A404E). The subject was suited and sitting quietly on a chair then allowed to cool down. The room temp was 72.5 F. Started to record 3 minutes after suiting up.

HR	T_s	T_{suit}	T_{core}	Time
69-72	91	88	.222	13:00
67-72	92	89	.227	13:02
70-74	92.5	90	.234	13:04
67-73	93	90	.240	13:10
69-75	93	91	.241	13:14
70-74	93.5	91	.241	13:16
67-74	92.5	91	.240	13:18

next began the cool down period

65-72	90.5	89.5	.237	13:21
68-73	90	85.5	.228	13:24
67-72	90	86	.230	13:28

In summary the subject was suited for 20 minutes (tic in data record) then he cooled down for 10 min.

Ed Loewen suited, actively quiescent (PH1A404F). Subject was walking the floor with the suit on and 3 sheets on top of MOP suit to increase the insulation. There was no cool down period but we did have noise on the tachometer which caused double triggering in several places. We accepted these data (HR) anyhow. The electrodes were working but apparently had not been in the proper lateral position to get a large R wave (Figures 10, 11, 12).

HR	T_s	T_{suit}	T_{core}	Time
86	90.5	90	.217	13:30

restarted aquisition again about 13:32

85	91.5	92	.270	13:36
85	92	93	.272	13:41
87	92.5	93	.248	13:45
83	92.5	93	.254	13:48
85	93	93.5	.265	13:57
85	97	96	.267	

out of the suit by 1402 hours. His oral temp was 97.7 at the end of 30 min (14:02 hours).

C. Trout, treadmill exercise, unsuited, with load (PH1A405A). The unsuited response to exercise was tested in Carl T. using the Bruce test protocol. He carried a knapsack weighing 37 lbs. Data were collected for 3 min of control (tic on data) 3 min at 1.7 mph/10% grade (another tic on data) 3 min at 2.5/12 (tic) then 3 min at 3.4/14 (tic) then cool down (Figure 13d-16).

Notice that the Borg Relative Perceived Exertion Scale (RPE) is shown along with HR in the following figures. The maximum RPE is 20 and the minimum is 0. Both skin and surface temperatures were recorded, the latter surface temperature was obtained by a Yellow Springs telethermometer placed outside of the clothing but under the Sam Brown belt. Note that the summed biaxial accelerometer signal shows a fair correlation with the level of work being performed on the treadmill.

HR	T_{suit}	T_s	T_{core}	Time
	start control period			14:20
87	91.5	93.5	.200	14:23

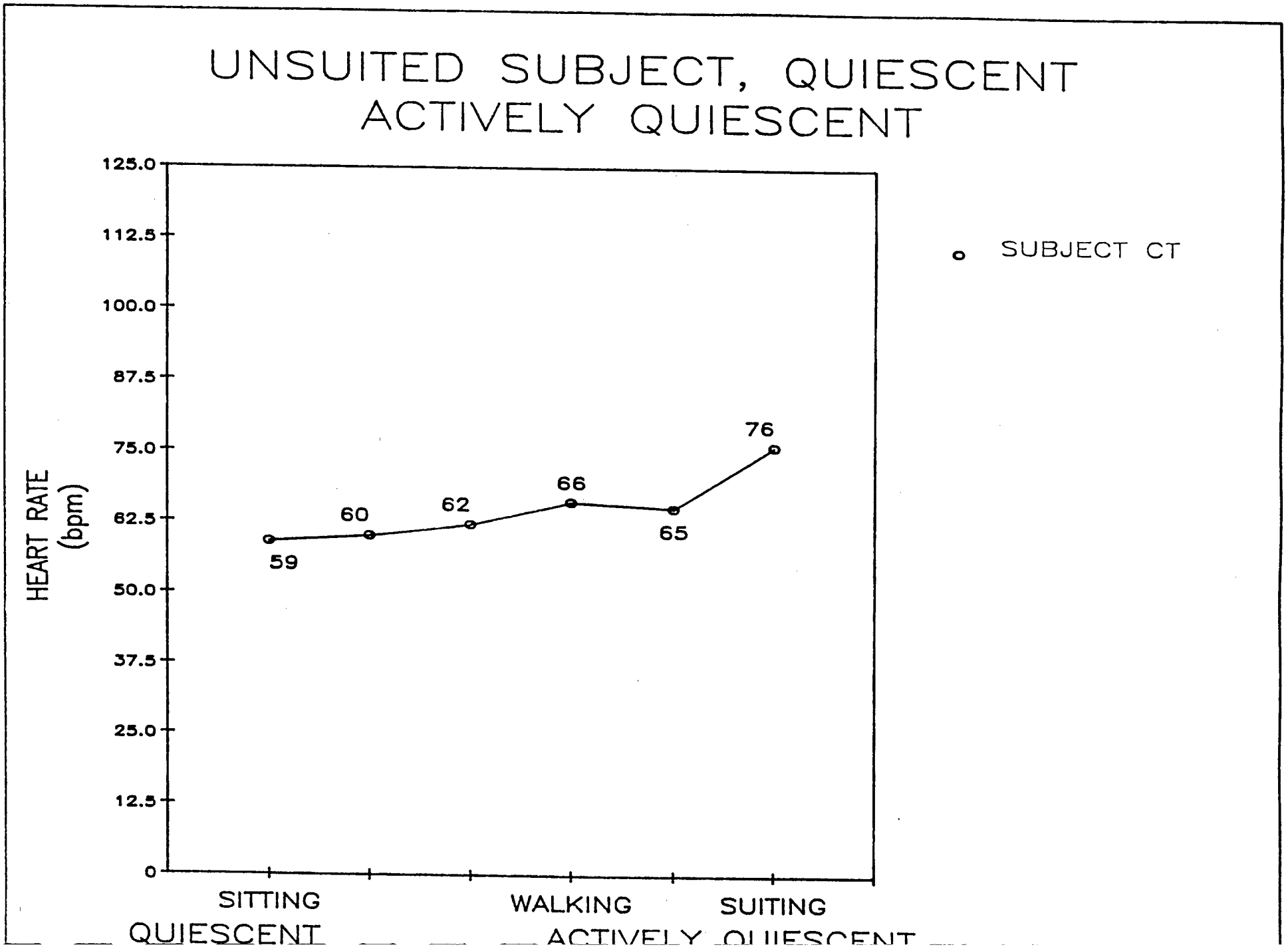

UNSUITED SUBJECT, QUIESCENT
ACTIVELY QUIESCENT
HEART RATE (bpm)
125.0
112.5
100.0
87.5
75.0
62.5
50.0
37.5
25.0
12.5
0
SUBJECT CT
59
60
62
66
65
76
SITTING
WALKING
SUITING
QUIESCENT
ACTIVELY QUIESCENT

Figure 1

Figure 2

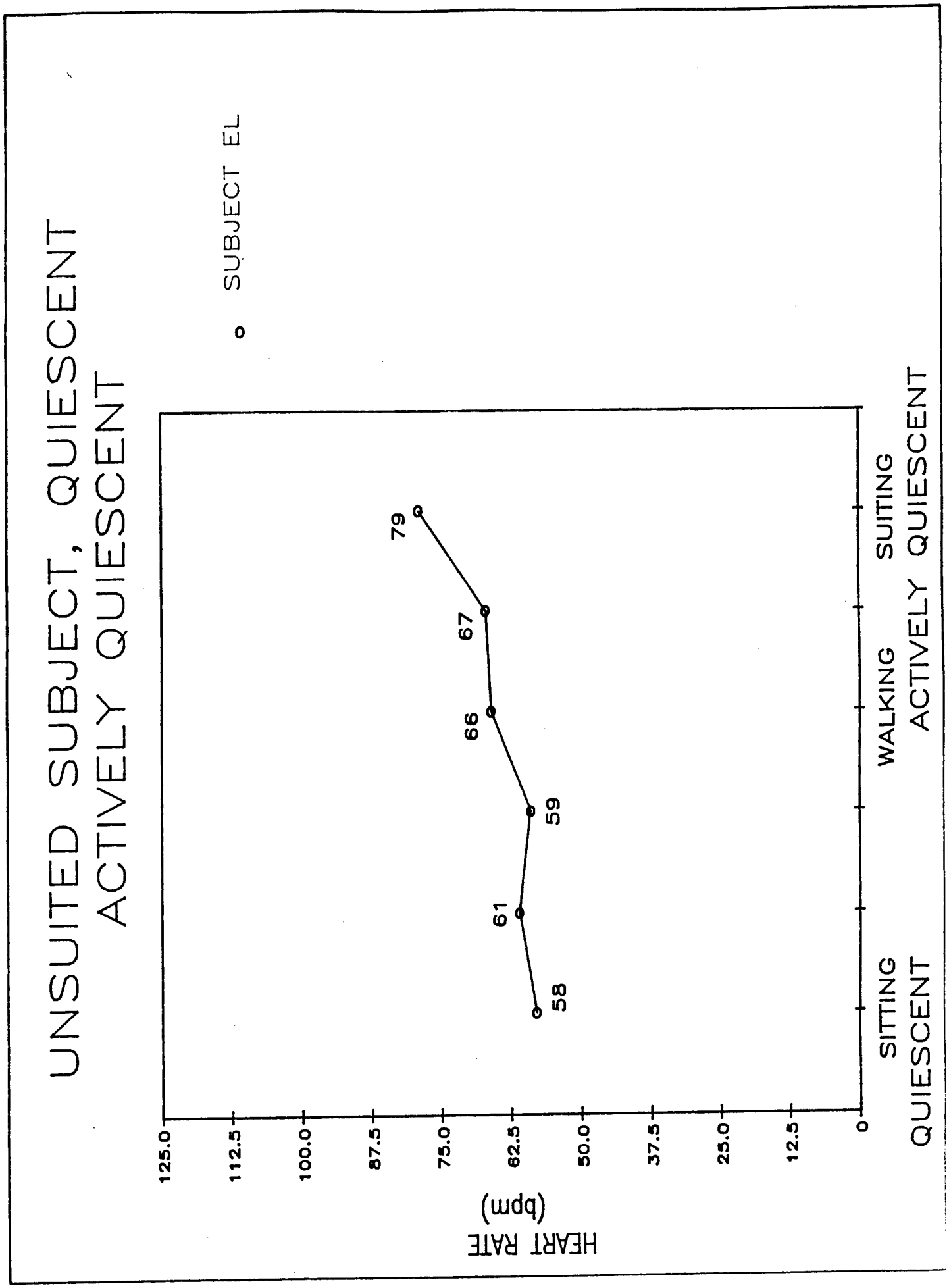

UNSUITED SUBJECT, QUIESCENT
ACTIVELY QUIESCENT
o SUBJECT EL
HEART RATE
(bpm)
125.0
112.5
100.0
87.5
75.0
62.5
50.0
37.5
25.0
12.5
0
79
67
66
59
61
58
SITTING
QUIESCENT
WALKING
ACTIVELY QUIESCENT
SUITING

Figure 3

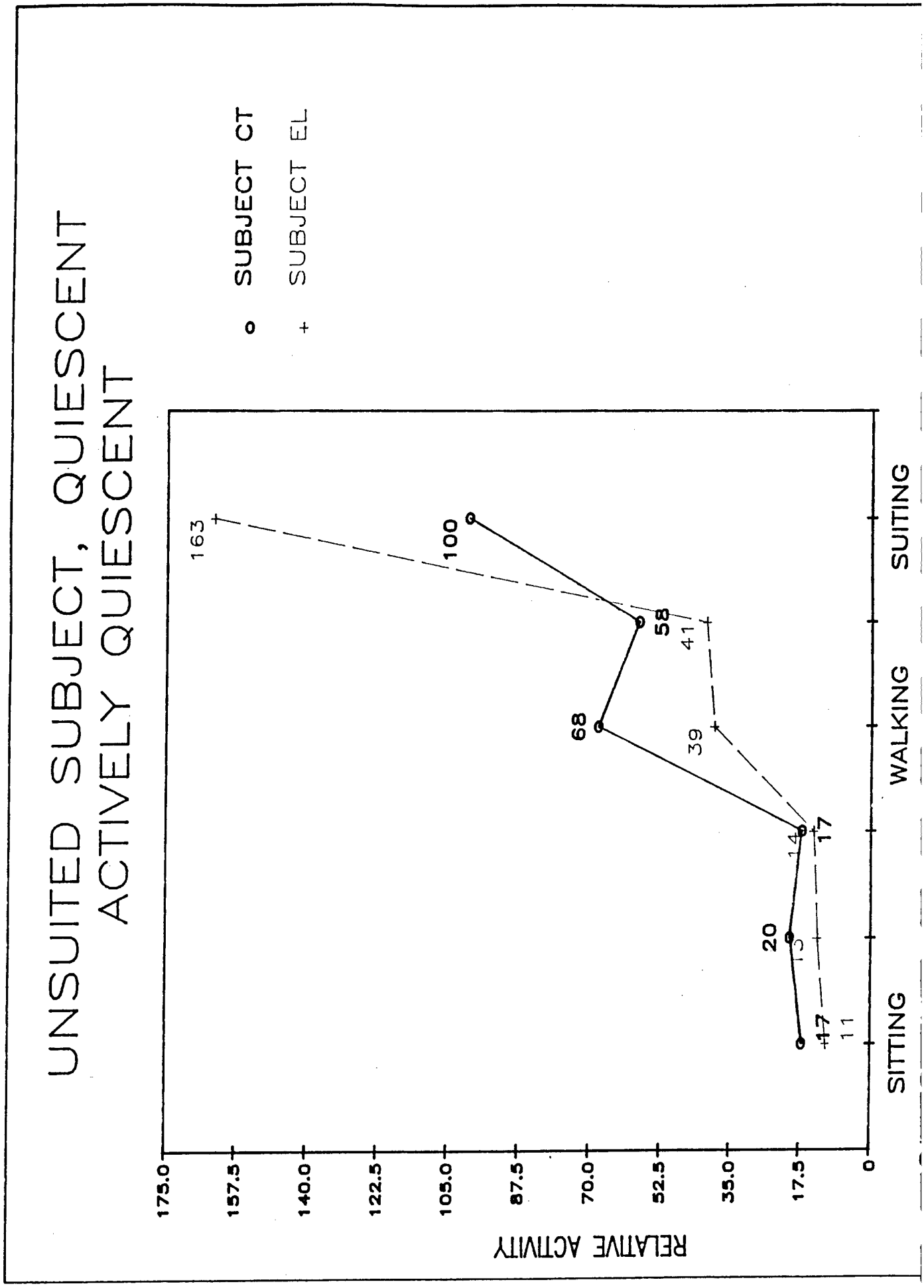
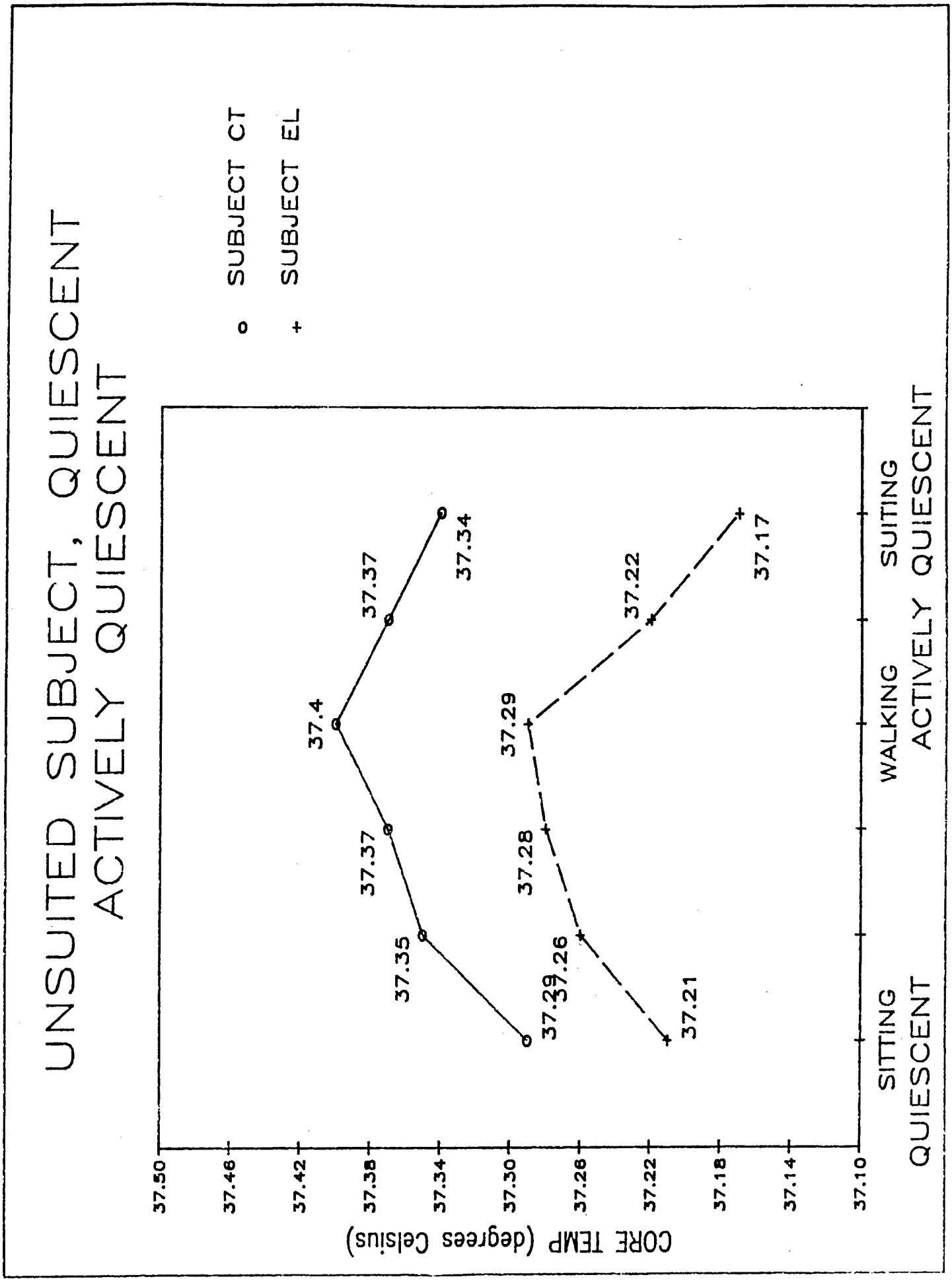

UNSUITED SUBJECT, QUIESCENT
ACTIVELY QUIESCENT
o SUBJECT CT
+ SUBJECT EL
RELATIVE ACTIVITY
175.0
157.5
140.0
122.5
105.0
87.5
70.0
52.5
35.0
17.5
0
SITTING
WALKING
SUITING
163
100
58
41
68
39
20
15
14
17
17
11

Figure 4


UNSUITED SUBJECT, QUIESCENT
ACTIVELY QUIESCENT
o SUBJECT CT
+ SUBJECT EL
CORE TEMP (degrees Celsius)
37.50
37.46
37.42
37.38
37.34
37.30
37.26
37.22
37.18
37.14
37.10
37.4
37.37
37.34
37.37
37.35
37.29
37.22
37.17
37.28
37.26
37.21
SITTING
QUIESCENT
WALKING
ACTIVELY
SUITING
QUIESCENT

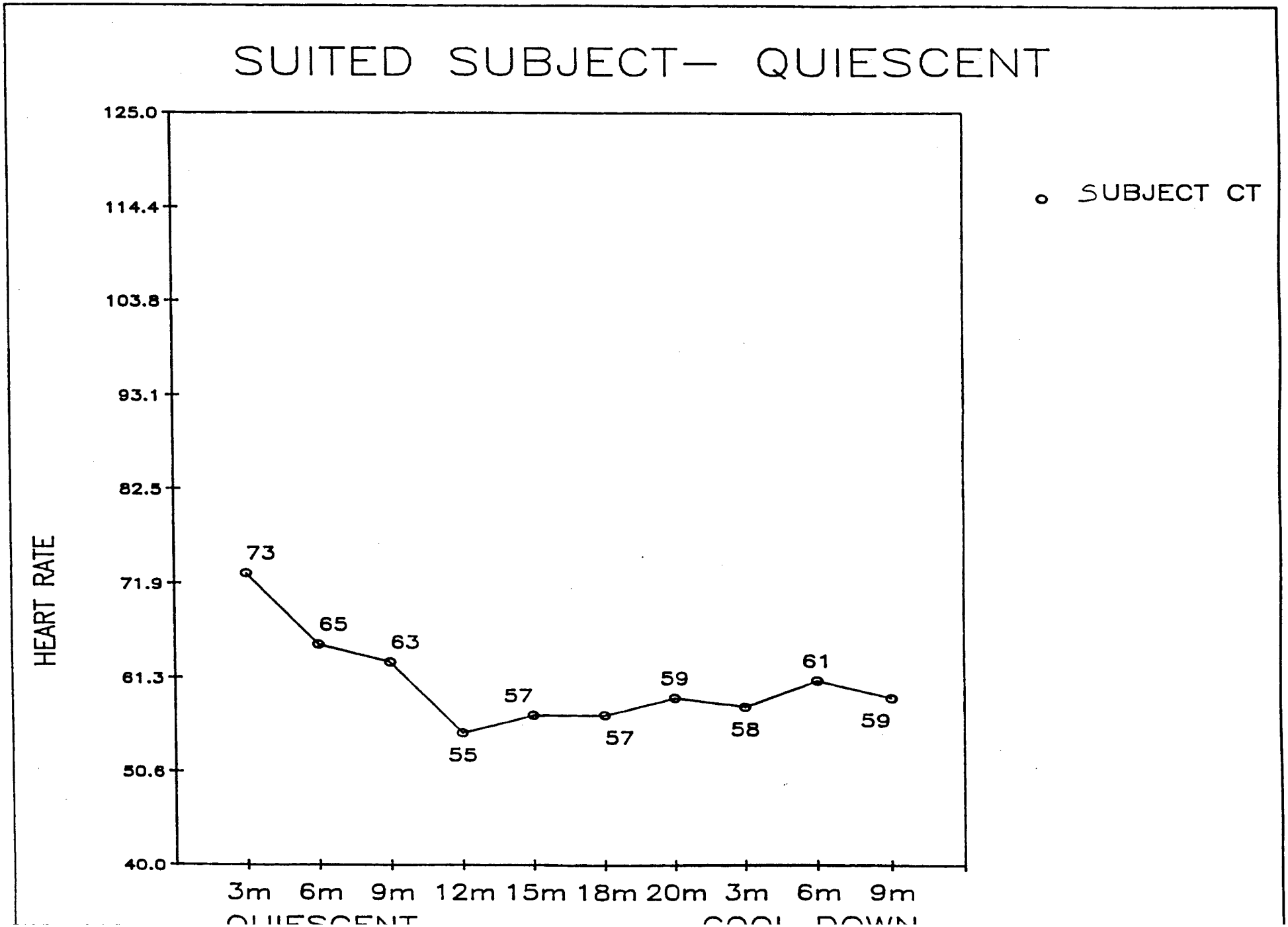

SUITED SUBJECT— QUIESCENT
HEART RATE
125.0
114.4
103.8
93.1
82.5
71.9
61.3
50.6
40.0
SUBJECT CT
73
65
63
55
57
57
59
58
61
59
3m
6m
9m
12m
15m
18m
20m
3m
6m
9m
QUIESCENT
COOL DOWN

Figure 5

Figure 6

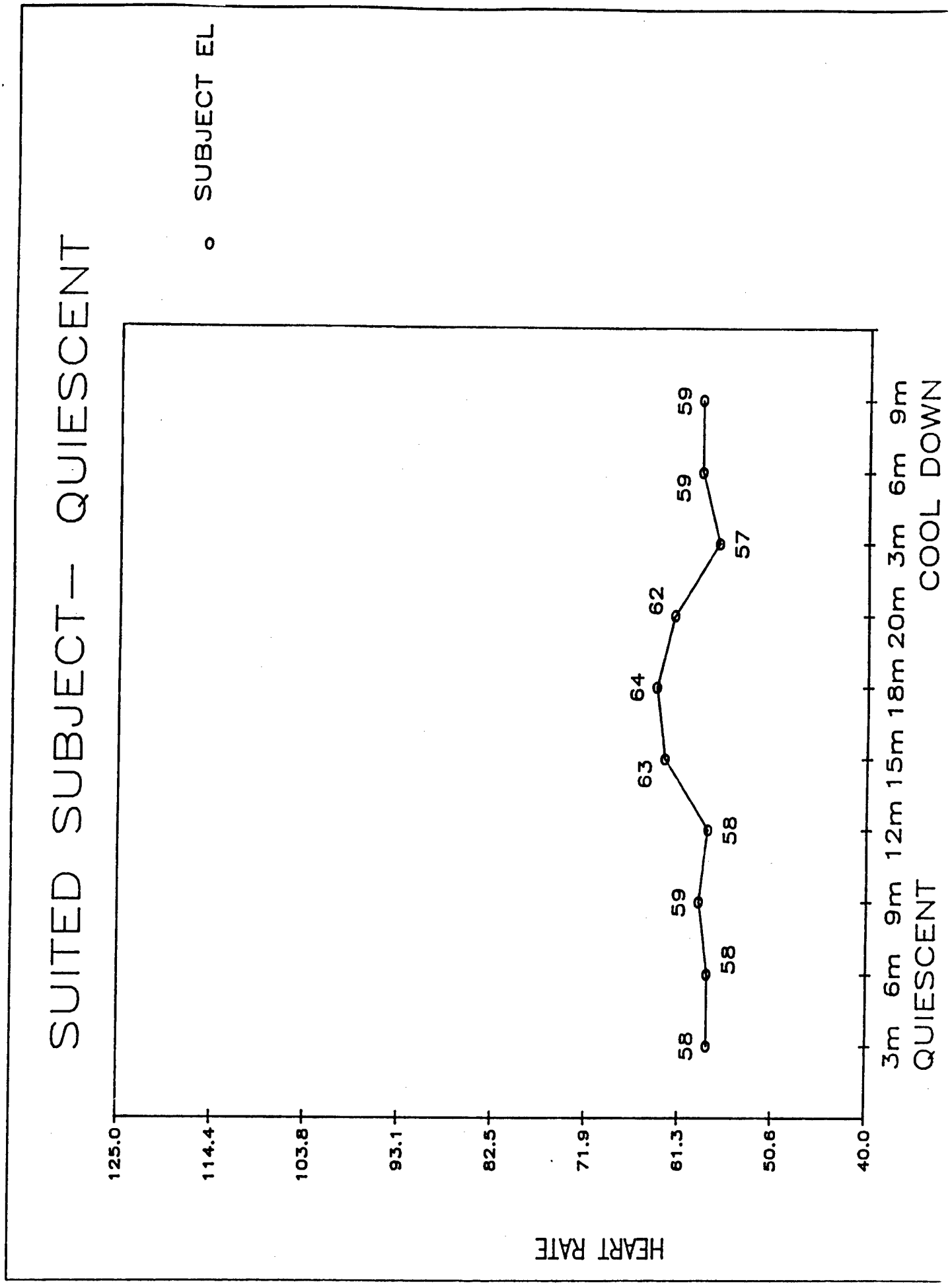

SUITED SUBJECT- QUIESCENT
o SUBJECT EL
HEART RATE
125.0
114.4
103.8
93.1
82.5
71.9
61.3
50.8
40.0
58
58
59
63
64
62
59
59
57
3m 6m 9m 12m 15m 18m 20m 3m 6m 9m
QUIESCENT
COOL DOWN

Figure 7

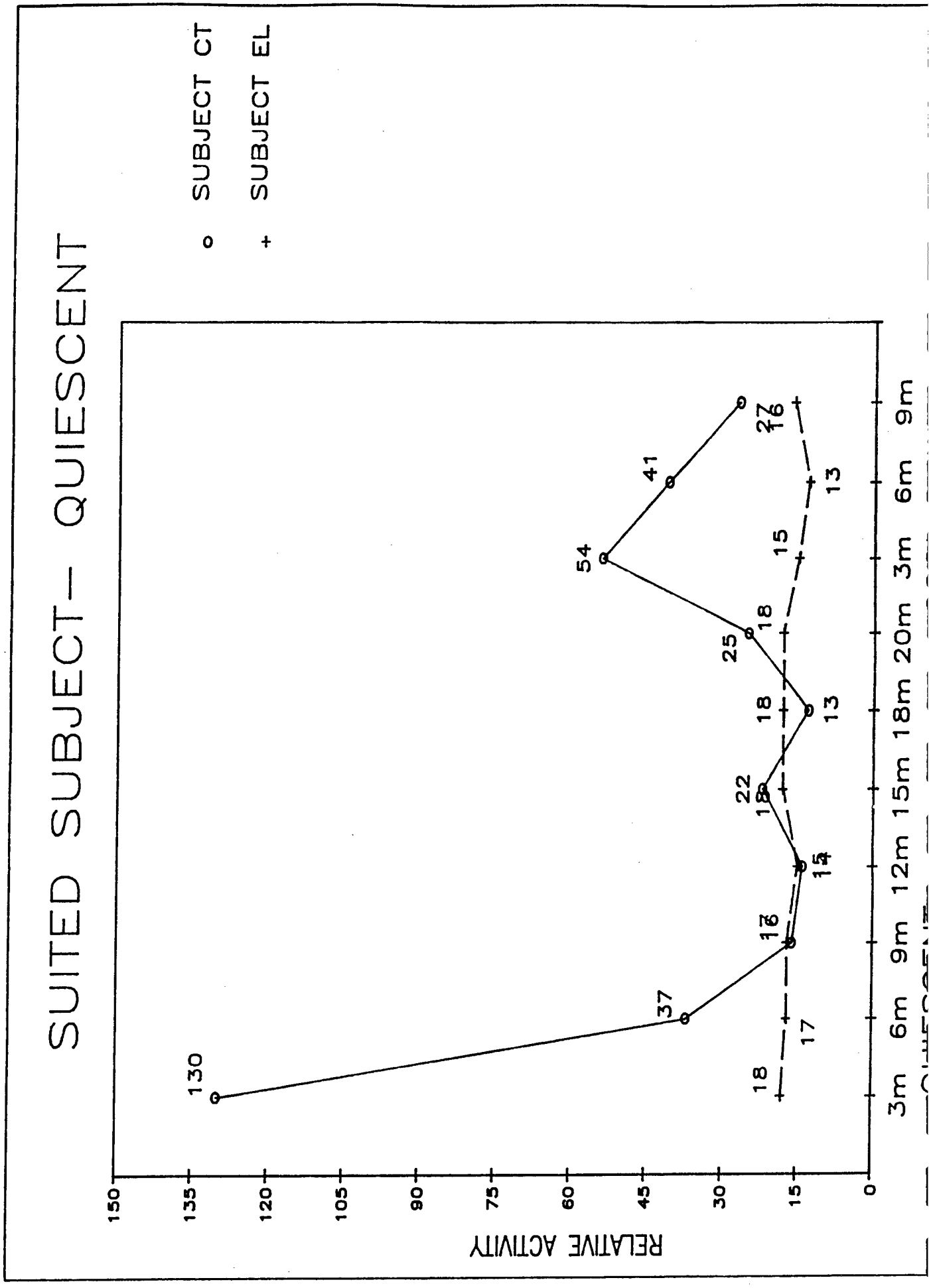

SUITED SUBJECT- QUIESCENT
o SUBJECT CT
+ SUBJECT EL
RELATIVE ACTIVITY
150
135
120
105
90
75
60
45
30
15
0
3m 6m 9m 12m 15m 18m 20m 3m 6m 9m
130
37
18
17
16
15
14
22
18
25
18
54
41
27
16
15
13
13

Figure 8

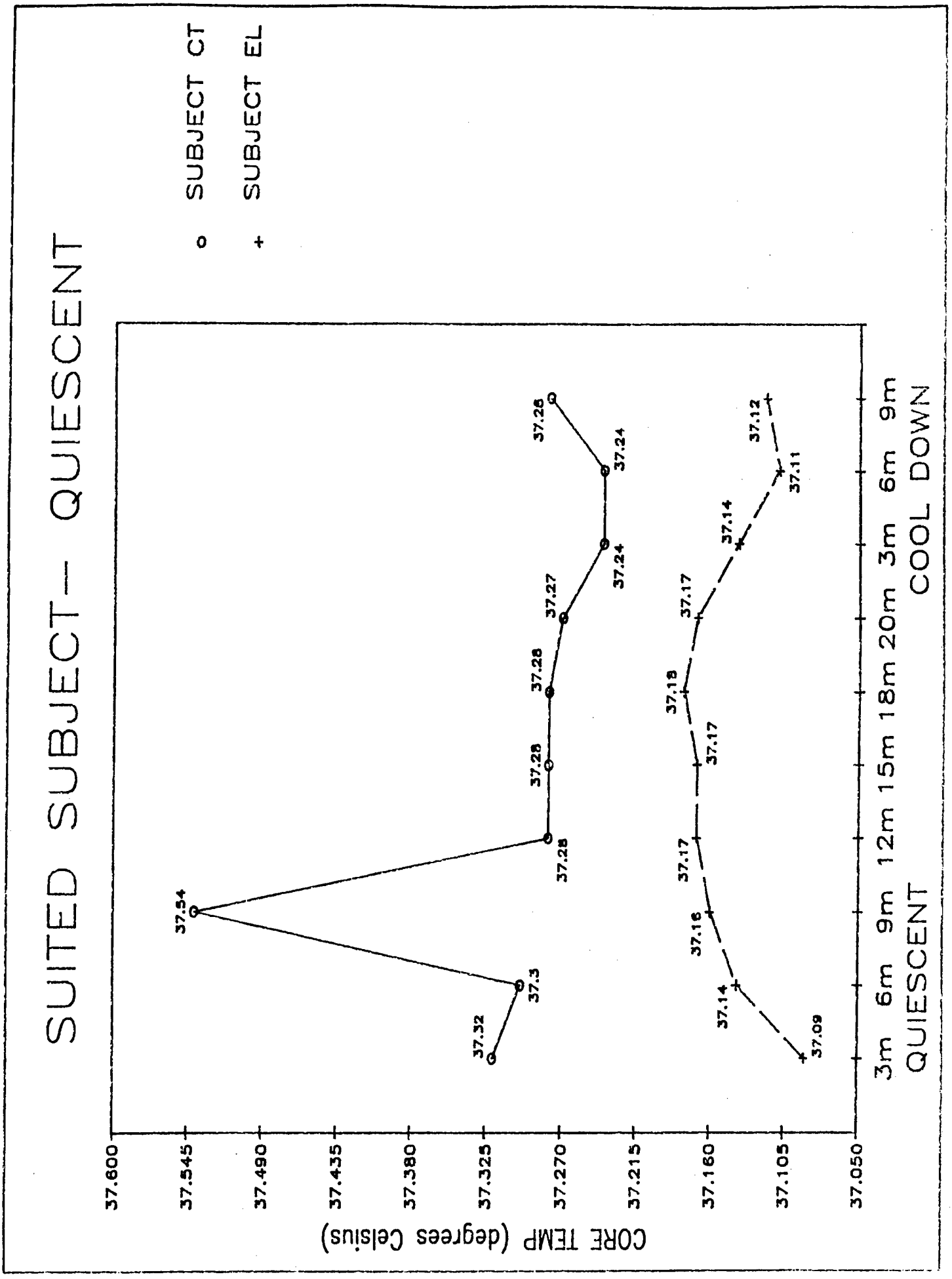

SUITED SUBJECT— QUIESCENT
o SUBJECT CT
+ SUBJECT EL
CORE TEMP (degrees Celsius)
37.600
37.545
37.490
37.435
37.380
37.325
37.270
37.215
37.160
37.105
37.050
3m 6m 9m 12m 15m 18m 20m 3m 6m 9m
QUIESCENT
COOL DOWN
37.54
37.3
37.32
37.28
37.28
37.28
37.28
37.27
37.24
37.24
37.28
37.09
37.14
37.16
37.17
37.17
37.18
37.17
37.14
37.11
37.12

Figure 9

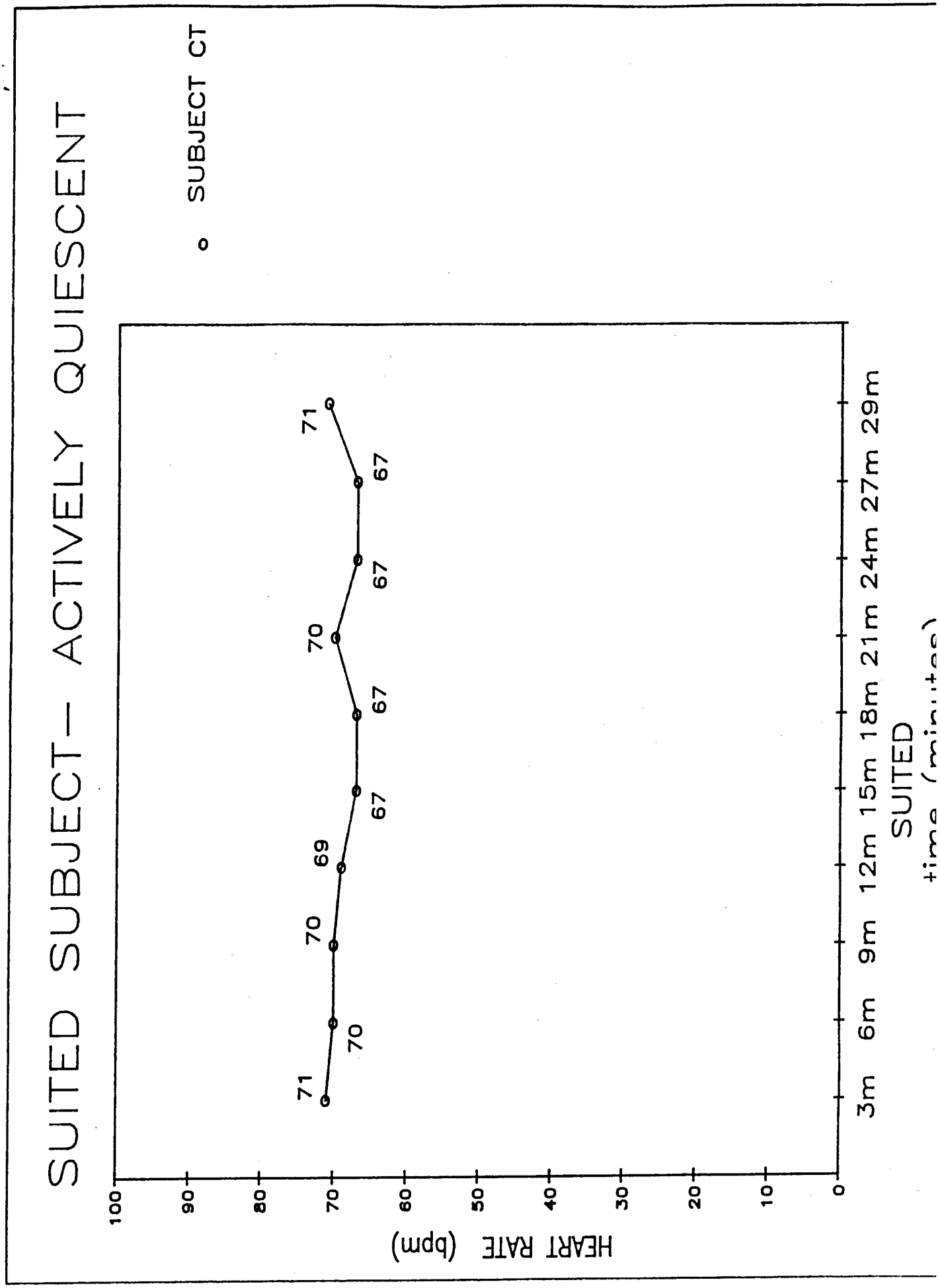
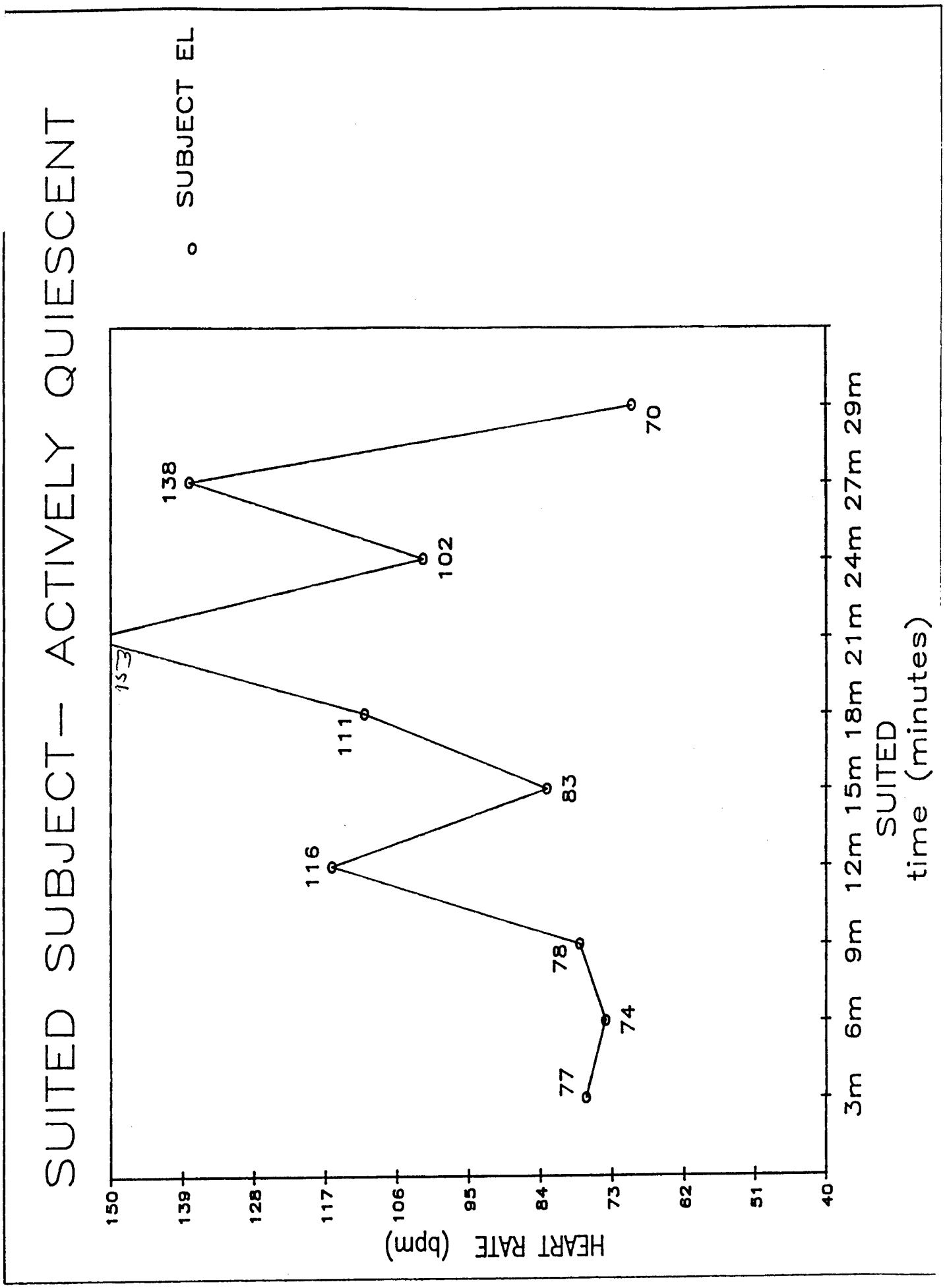

SUITED SUBJECT– ACTIVELY QUIESCENT
o SUBJECT CT
HEART RATE (bpm)
100
90
80
70
60
50
40
30
20
10
0
71
70
70
69
67
67
70
67
67
71
3m 6m 9m 12m 15m 18m 21m 24m 27m 29m
SUITED
time (minutes)

Figure 10


SUITED SUBJECT— ACTIVELY QUIESCENT
o SUBJECT EL
HEART RATE (bpm)
150
139
128
117
106
95
84
73
62
51
40
153
138
102
70
111
83
116
78
74
77
3m 6m 9m 12m 15m 18m 21m 24m 27m 29m
SUITED
time (minutes)

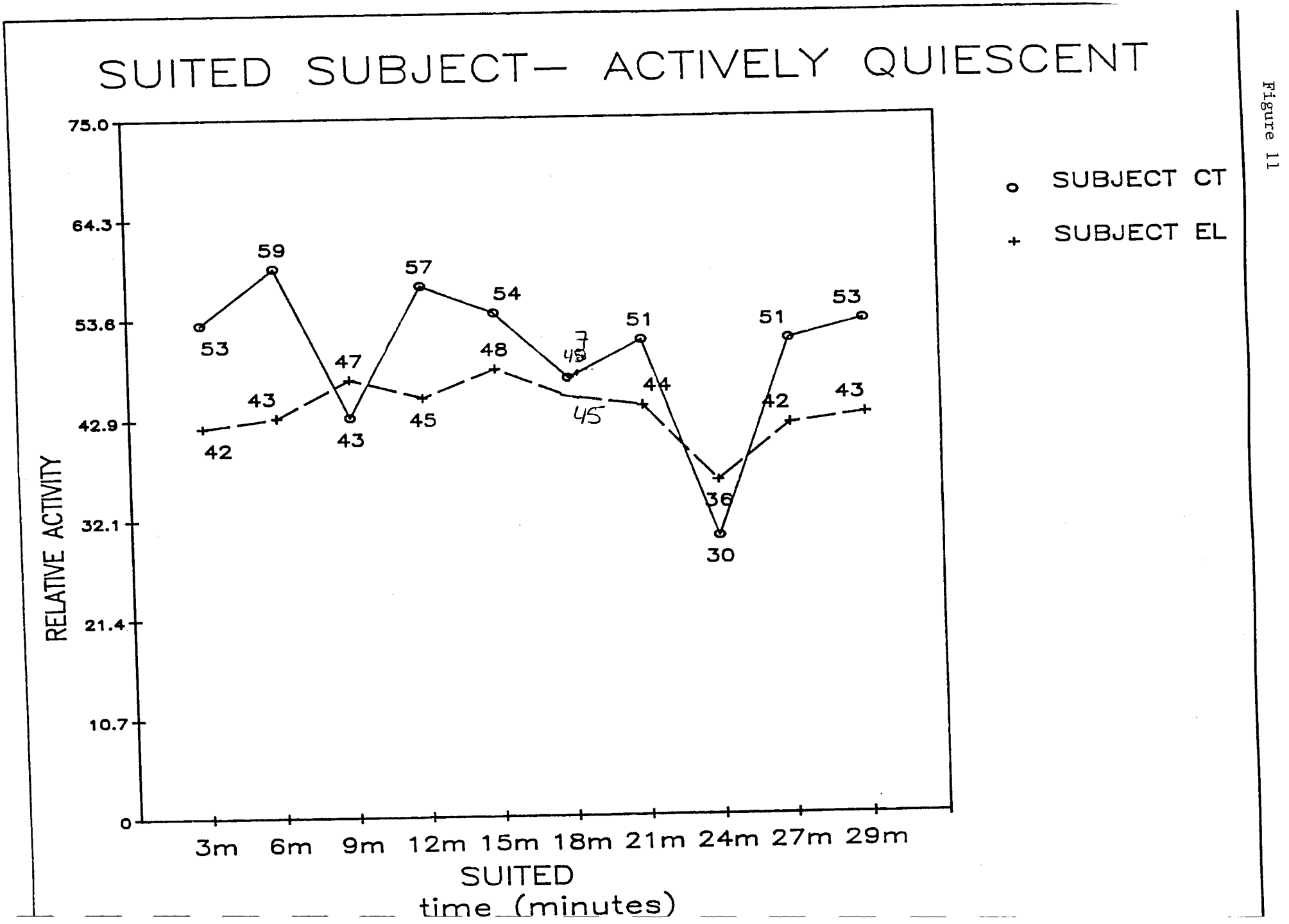
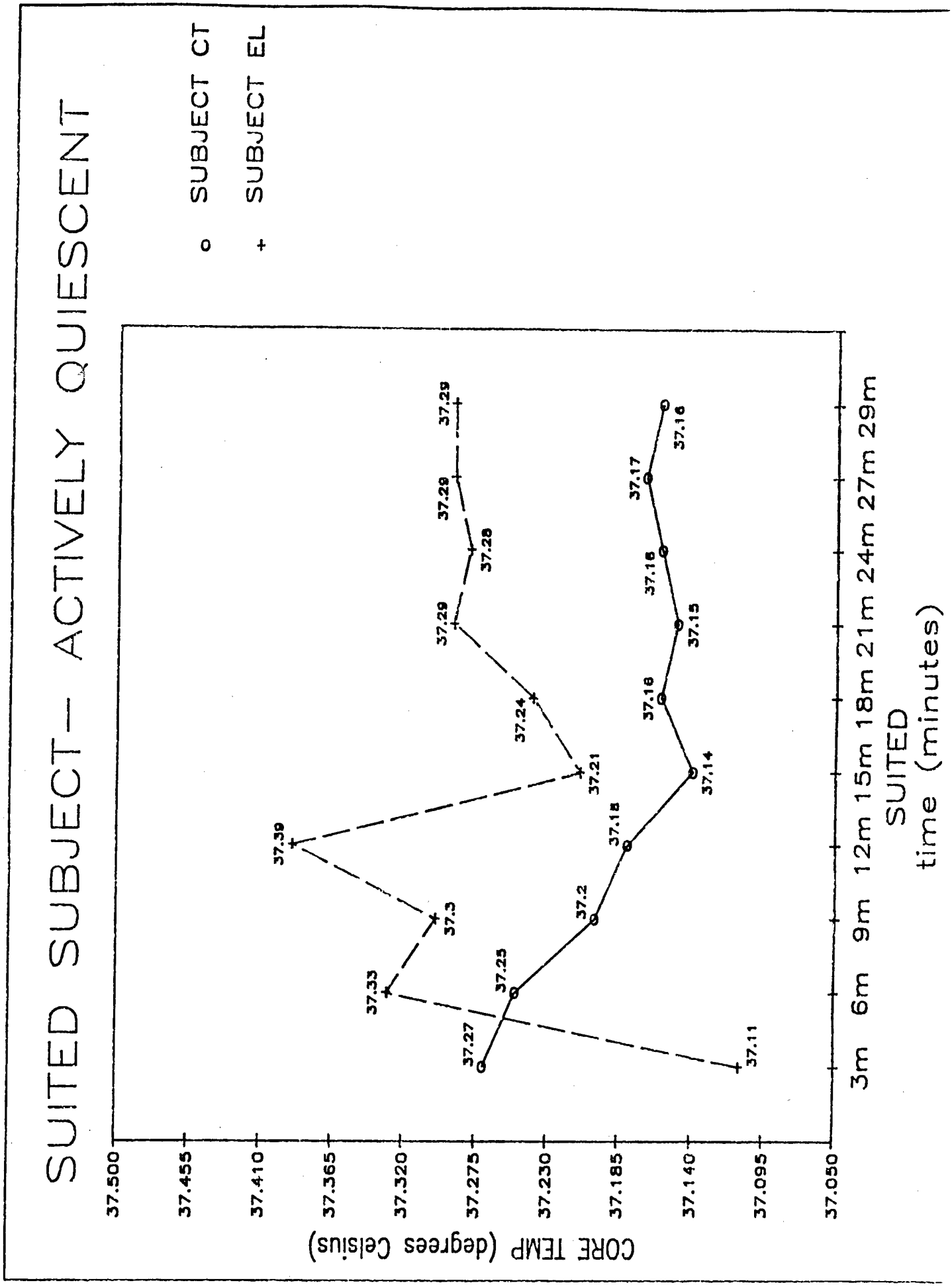

SUITED SUBJECT— ACTIVELY QUIESCENT
75.0
64.3
53.6
42.9
32.1
21.4
10.7
0
RELATIVE ACTIVITY
SUBJECT CT
SUBJECT EL
53
59
43
57
54
47
51
30
51
53
42
43
47
48
45
44
45
36
42
43
3m
6m
9m
12m
15m
18m
21m
24m
27m
29m
SUITED
time (minutes)

Figure 11

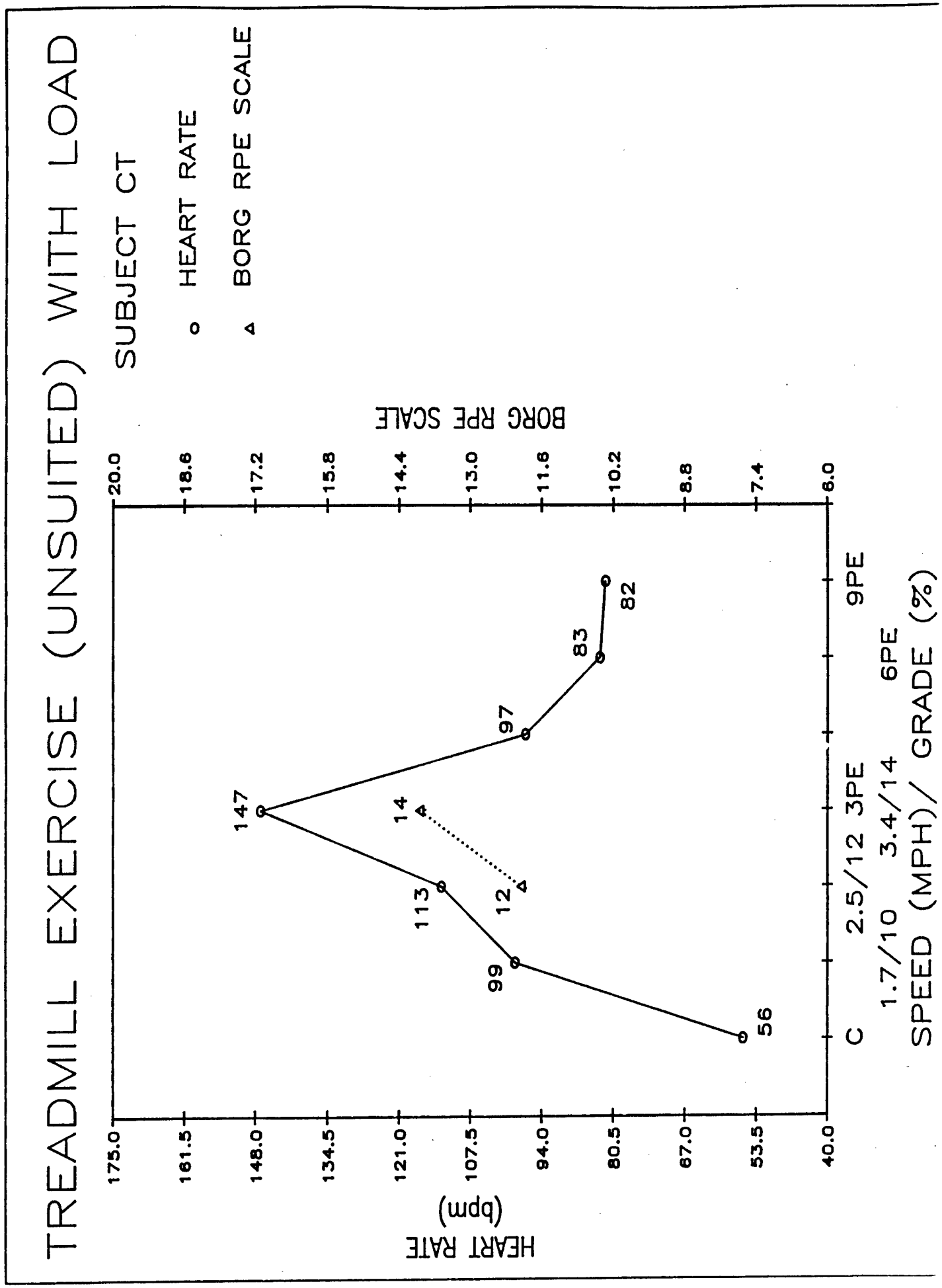
Figure 12


SUITED SUBJECT– ACTIVELY QUIESCENT
o SUBJECT CT
+ SUBJECT EL
CORE TEMP (degrees Celsius)
37.500
37.455
37.410
37.365
37.320
37.275
37.230
37.185
37.140
37.095
37.050
3m 6m 9m 12m 15m 18m 21m 24m 27m 29m
SUITED
time (minutes)
37.39
37.3
37.33
37.27
37.25
37.2
37.18
37.21
37.24
37.29
37.28
37.29
37.16
37.17
37.18
37.15
37.18
37.14
37.11

	end of control period, now go to 1.7/10 stage of Bruce protocol			
111	91	94	.209	14:26
	now go to 2.5/12 stage of Bruce protocol			
125	91.5	95	.219	14:28
	now go to 3.4/14			
158	91.7	96	.223	14:31
	now start to cool down			
118	91.2	97	.236	14:33
95	91.1	97.5	.262	14:35
97	91	97.3	.292	14:37
88	90.2	97.3	.305	14:39
99	90.5	97.2	.302	14:42
91	91	97	.290	14:45
	oral temp 98.5 F			
85	91.5	97.1	.296	14:48

Carl T. thermal stress during exercise, suited (PH1A406A). Suited response to exercise with no extra weight load, following the same Bruce protocol for exercise tolerance testing. Carl began suiting up at 1453 hours. We collected control data for 3 min then (tic) next 3 min at 1.7/10 (tic) then 2.5/12 (another tic) then 3.4/14 for 6 min (tic) (Figures 13-16). Then cool down and recovery. We started control data collection at 1455 hours. The following figures (17-20) show the HR-RPE relationship, core temp, skin vs inside suit (surface) temperatures and relative activity.

Figure 13


TREADMILL EXERCISE (UNSUITED) WITH LOAD
SUBJECT CT
o HEART RATE
Δ BORG RPE SCALE
HEART RATE (bpm)
BORG RPE SCALE
175.0
161.5
148.0
134.5
121.0
107.5
94.0
80.5
67.0
53.5
40.0
20.0
18.6
17.2
15.8
14.4
13.0
11.6
10.2
8.8
7.4
6.0
147
113
99
56
97
83
82
14
12
C
2.5/12 3PE
9PE
1.7/10
3.4/14
6PE
SPEED (MPH)/ GRADE (%)

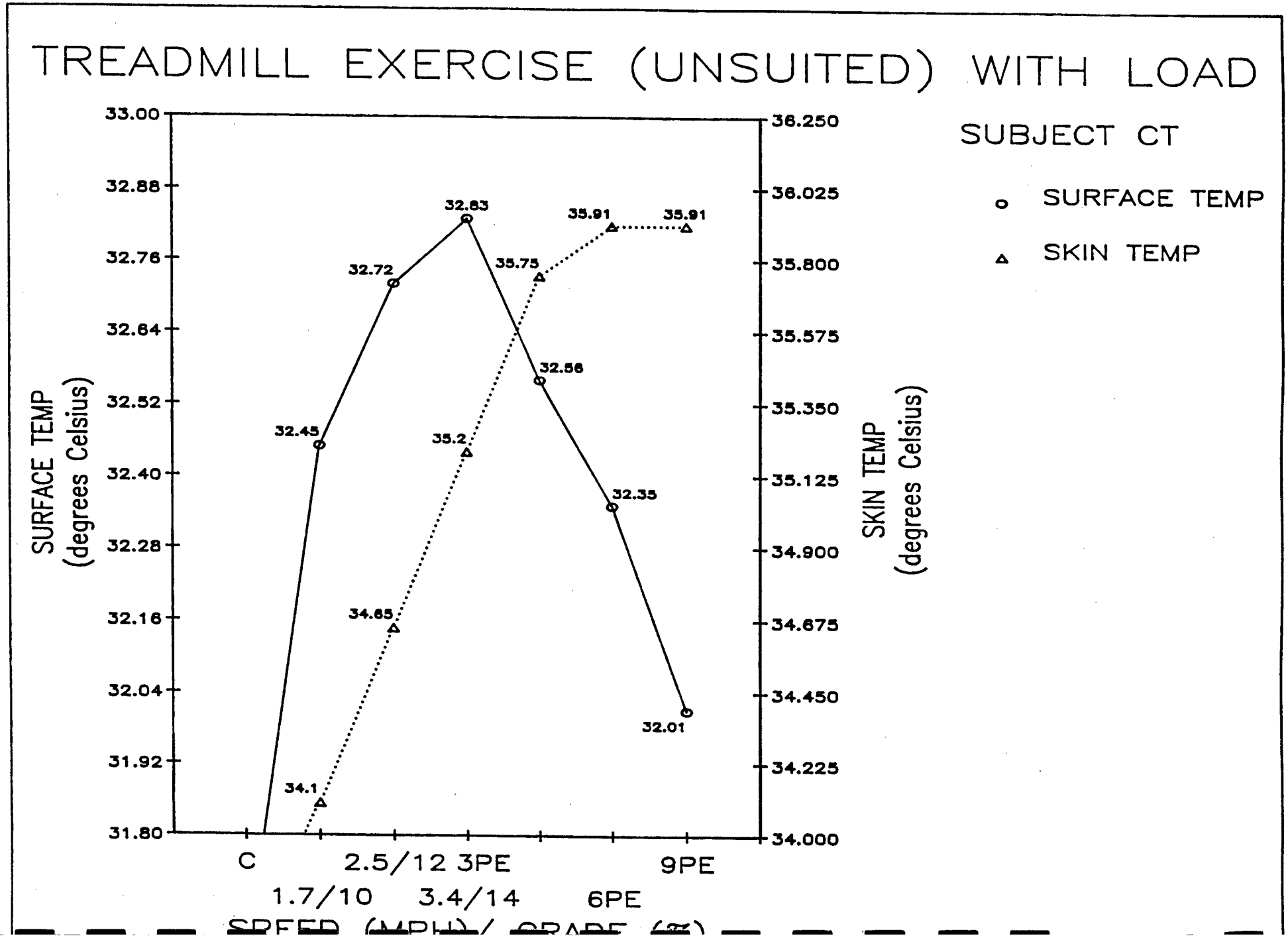

TREADMILL EXERCISE (UNSUITED) WITH LOAD
SUBJECT CT
SURFACE TEMP
SKIN TEMP
SURFACE TEMP (degrees Celsius)
SKIN TEMP (degrees Celsius)
33.00
32.88
32.76
32.64
32.52
32.40
32.28
32.16
32.04
31.92
31.80
36.250
36.025
35.800
35.575
35.350
35.125
34.900
34.675
34.450
34.225
34.000
32.45
32.72
32.83
32.56
32.35
32.01
34.1
35.2
34.65
35.75
35.91
35.91
C
1.7/10
2.5/12
3.4/14
3PE
6PE
9PE
SPEED (MPH)/ GRADE (%)

Figure 14

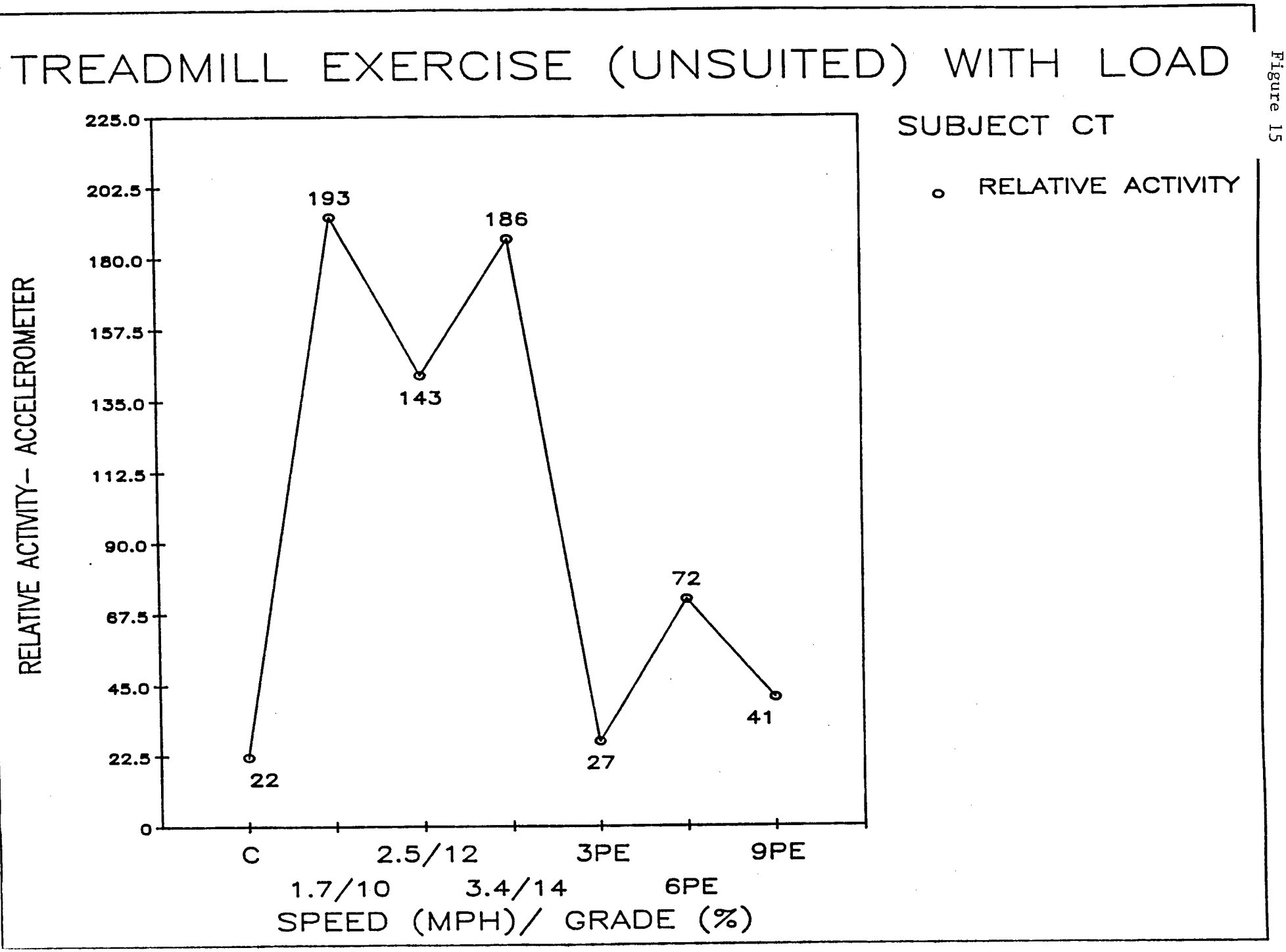

TREADMILL EXERCISE (UNSUITED) WITH LOAD
SUBJECT CT
RELATIVE ACTIVITY
RELATIVE ACTIVITY- ACCELEROMETER
225.0
202.5
180.0
157.5
135.0
112.5
90.0
67.5
45.0
22.5
0
193
186
143
72
41
27
22
C
2.5/12
3PE
9PE
1.7/10
3.4/14
6PE
SPEED (MPH)/ GRADE (%)

Figure 15

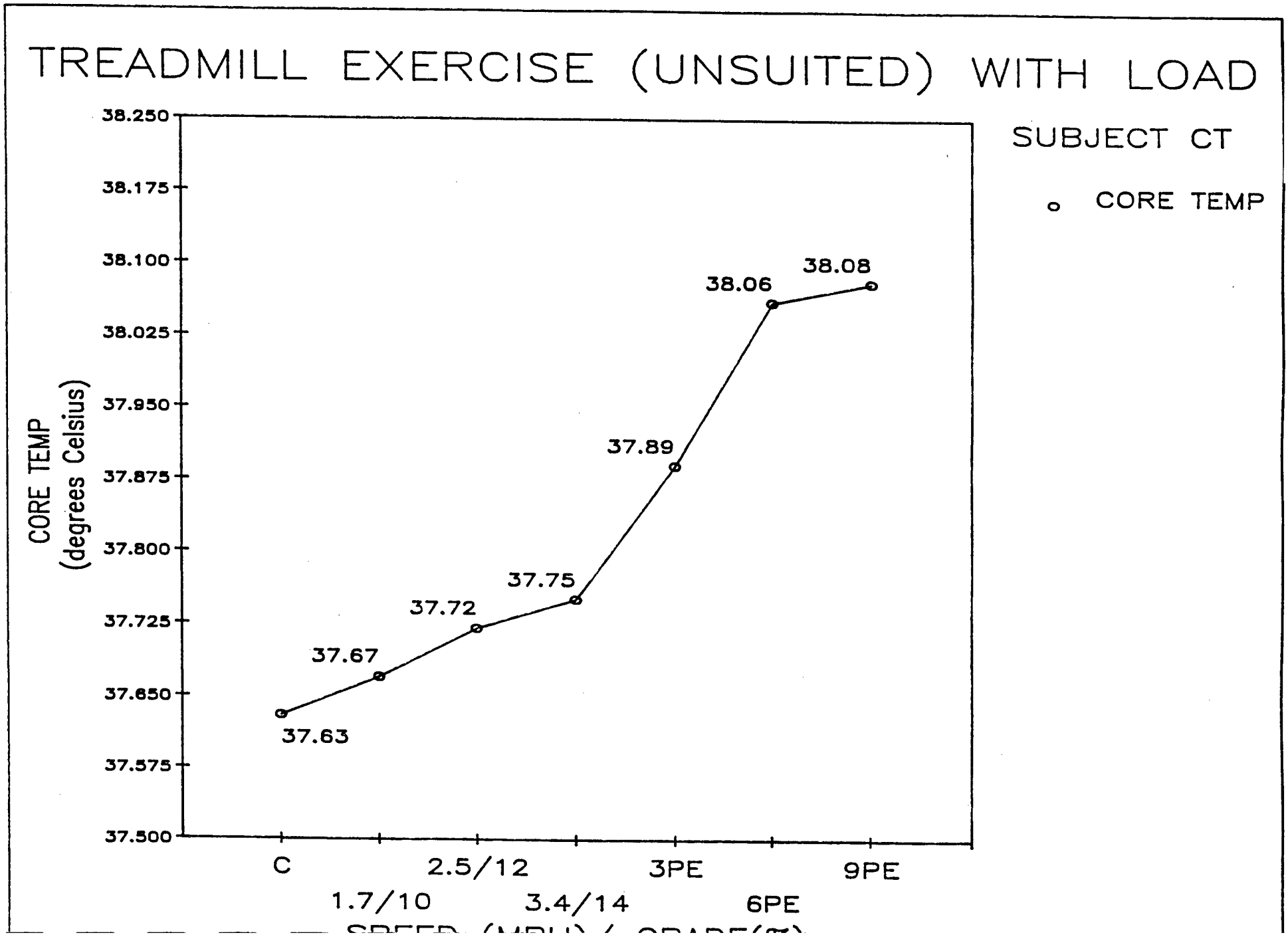
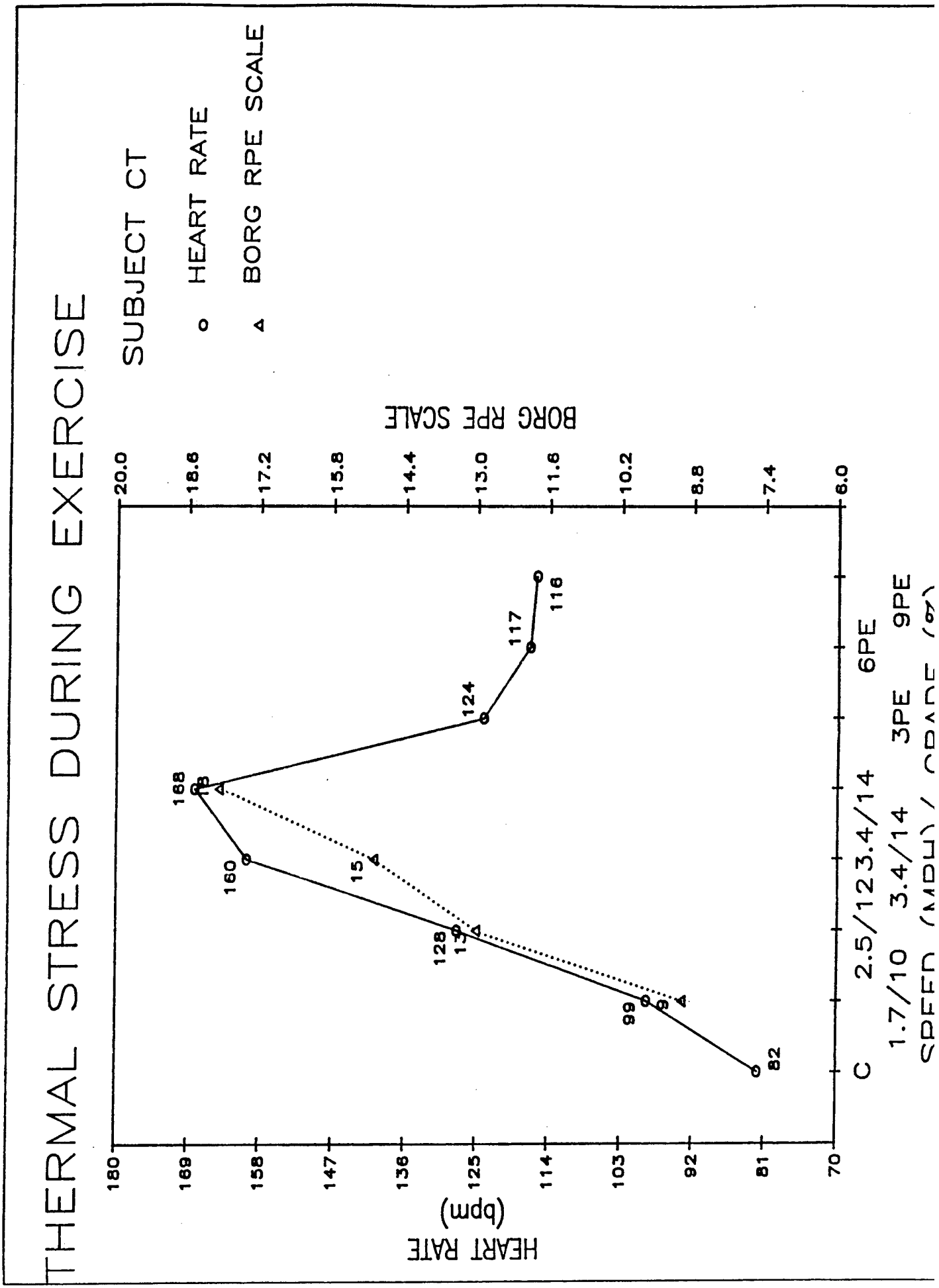

TREADMILL EXERCISE (UNSUITED) WITH LOAD
SUBJECT CT
CORE TEMP
CORE TEMP (degrees Celsius)
38.250
38.175
38.100
38.025
37.950
37.875
37.800
37.725
37.650
37.575
37.500
37.63
37.67
37.72
37.75
37.89
38.06
38.08
C
1.7/10
2.5/12
3.4/14
3PE
6PE
9PE

Figure 16

HR	T_{suit}	T_s	T_{core}	Time
86	82.3	92.2	.311	14:56
97	84.5	93.7	.301	14:58
	started 1.7 mph at 10% grade on the treadmill			
101	87.5	95	.301	15:01
	next go to 2.5/12 stage of Bruce protocol			
133	91	97	.304	15:04
	next go to 3.4/14 stage of Bruce protocol			
174	93	95.5	.314	15:07
177	94	96	.319	15:09
181	94.5	96.5	.320	15:10
184	94	96	.323	15:11
	next cool down without removal of the suit			
143	95.2	97	.341	15:12
135	95	97	.366	15:14
130	94	97	.378	15:16
125	93	97	.377	15:19
123	93	97.5	.359	15:22
126	92.5	97.2	.360	15:25
	oral temp at this time 99.1			

E. Loewen treadmill exercise, unsuited, with load (PH1A405B). Unsuited response to exercise with a 37 lb load on his back. At the beginning of this test his oral temp was 97.9 at 1544 hours. The following figures (21-24) show

Figure 17


THERMAL STRESS DURING EXERCISE
SUBJECT CT
HEART RATE
BORG RPE SCALE
HEART RATE (bpm)
BORG RPE SCALE
180
169
158
147
136
125
114
103
92
81
70
20.0
18.6
17.2
15.8
14.4
13.0
11.6
10.2
8.8
7.4
6.0
188
160
128
99
82
124
117
116
C 2.5/12 3.4/14 6PE
1.7/10 3.4/14 3PE 9PE

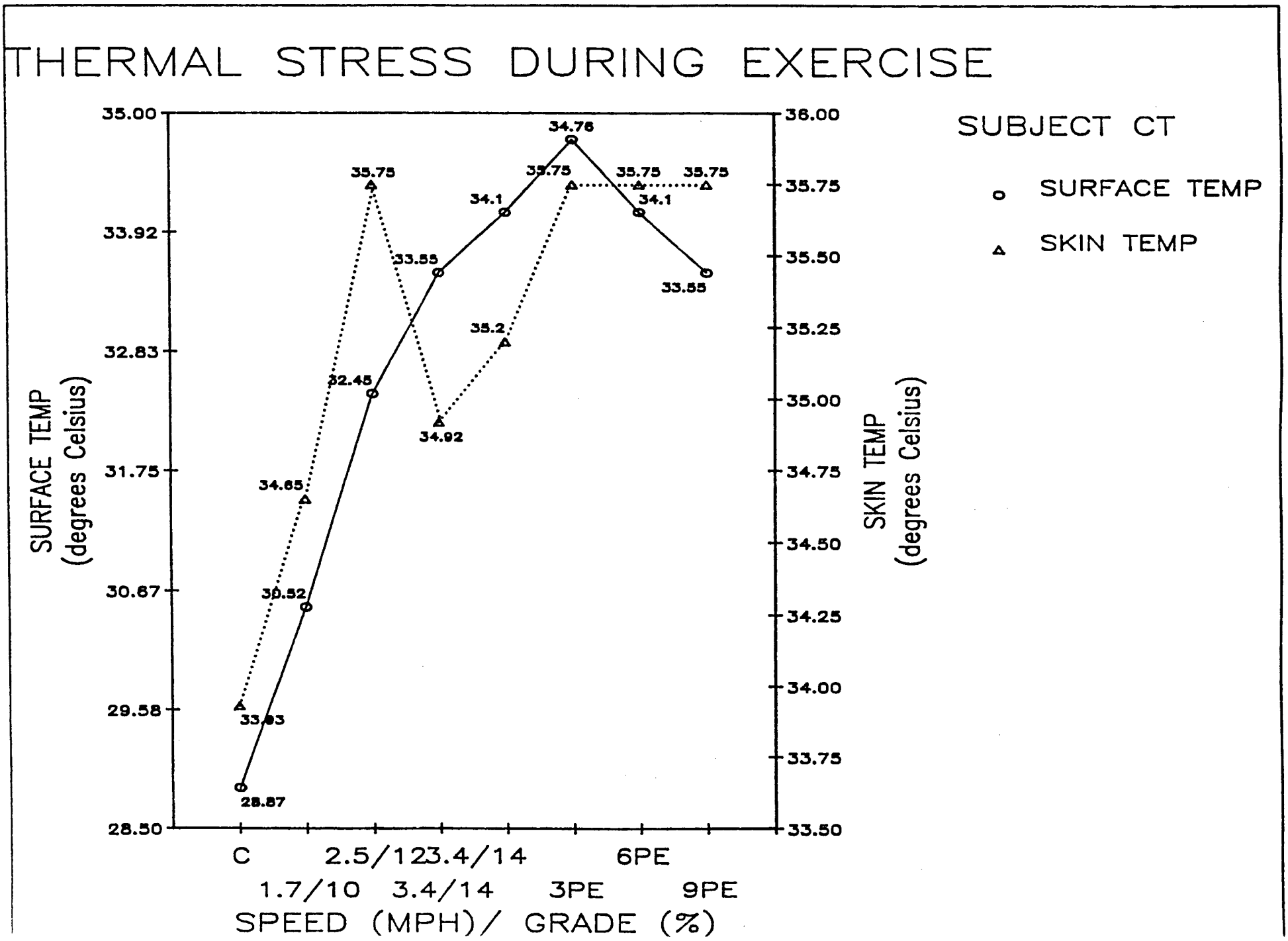

THERMAL STRESS DURING EXERCISE
SUBJECT CT
SURFACE TEMP
SKIN TEMP
SURFACE TEMP (degrees Celsius)
SKIN TEMP (degrees Celsius)
35.00
33.92
32.83
31.75
30.67
29.58
28.50
36.00
35.75
35.50
35.25
35.00
34.75
34.50
34.25
34.00
33.75
33.50
34.76
35.75
35.75
35.75
35.75
34.1
34.1
33.55
33.55
35.2
32.45
34.92
34.65
30.52
33.83
28.87
C
2.5/12
3.4/14
6PE
1.7/10
3.4/14
3PE
9PE
SPEED (MPH)/ GRADE (%)

Figure 18

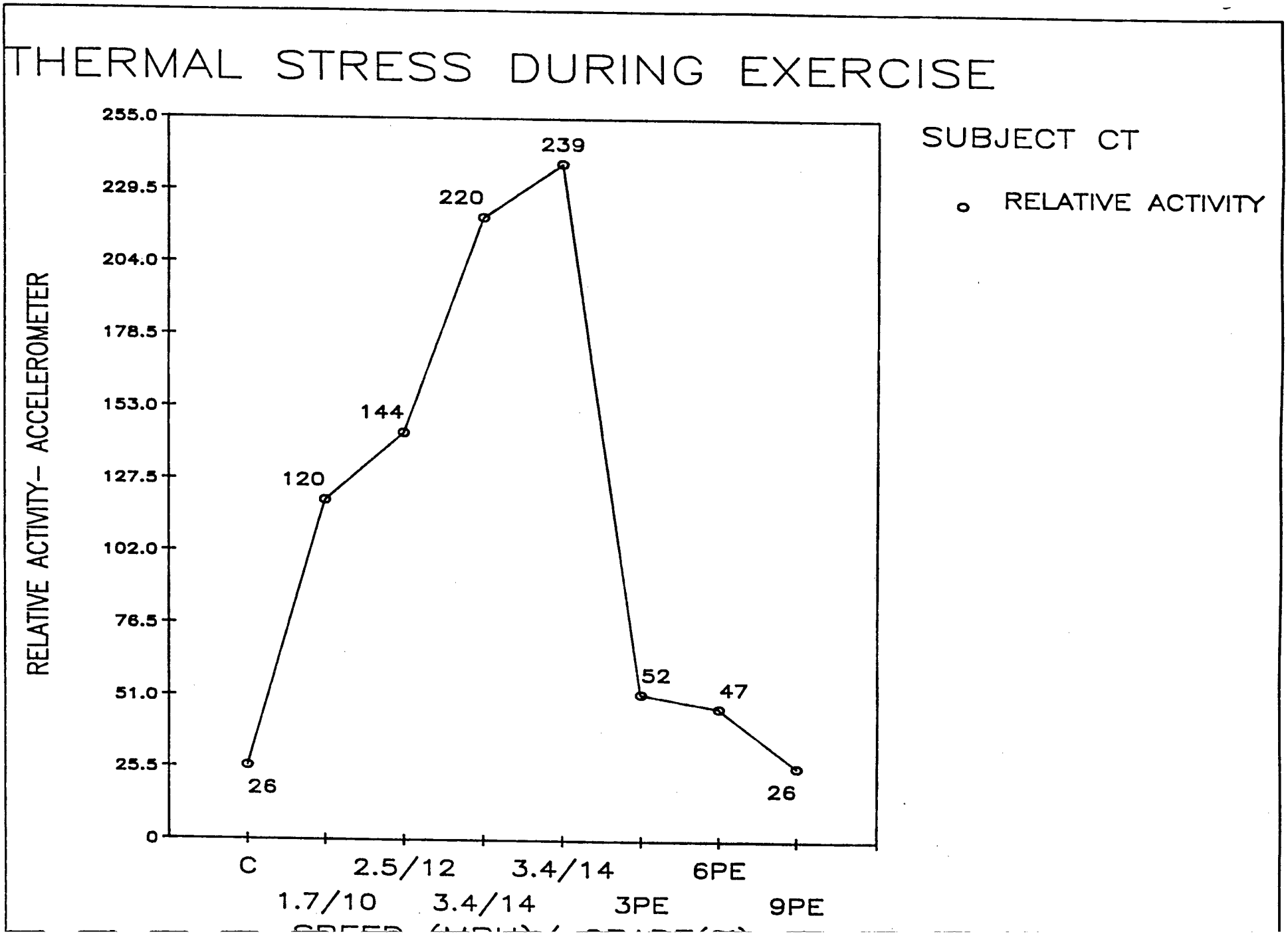

THERMAL STRESS DURING EXERCISE
SUBJECT CT
RELATIVE ACTIVITY
RELATIVE ACTIVITY- ACCELEROMETER
255.0
229.5
204.0
178.5
153.0
127.5
102.0
76.5
51.0
25.5
0
26
120
144
220
239
52
47
26
C
2.5/12
3.4/14
6PE
1.7/10
3.4/14
3PE
9PE

Figure 19

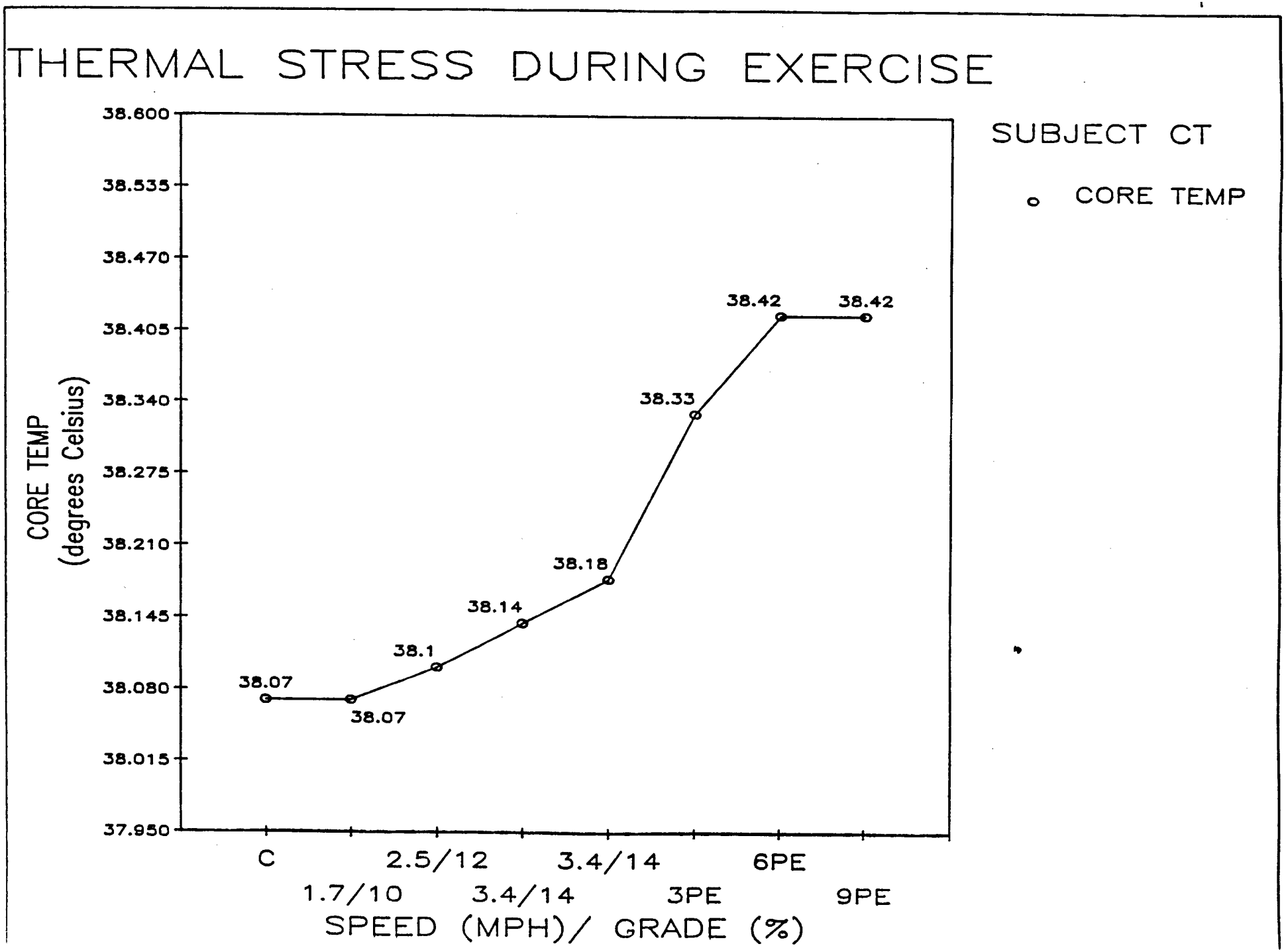

THERMAL STRESS DURING EXERCISE
SUBJECT CT
CORE TEMP
CORE TEMP (degrees Celsius)
38.600
38.535
38.470
38.405
38.340
38.275
38.210
38.145
38.080
38.015
37.950
38.07
38.07
38.1
38.14
38.18
38.33
38.42
38.42
C
1.7/10
2.5/12
3.4/14
3.4/14
6PE
3PE
9PE
SPEED (MPH)/ GRADE (%)

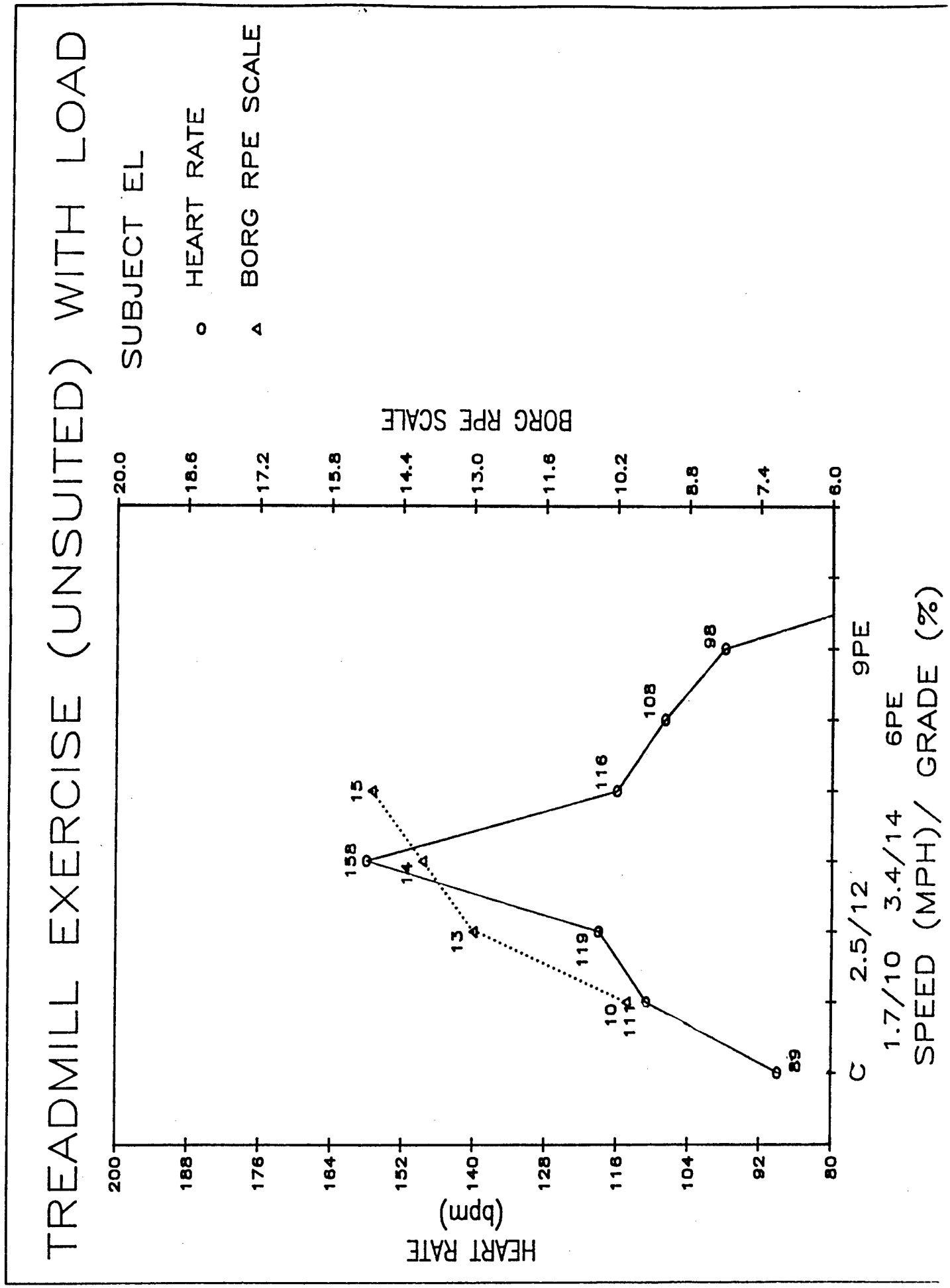
Figure 20

the HR-RPE relationship, skin and surface temperatures, core temperature and relative activity.

HR	T_{suit}	T_s	T_{core}	Time
69	87	92	.288	15:49
89	92	92.5	.288	15:52
begin stage one 1.7/10 on treadmill				
111	94.5	91	.294	15:57
next go to 2.5/12 of Bruce protocol				
119	95.5	90.5	.291	15:60
next go to 3.4/14 of Bruce protocol				
158	97	91	.316	16:02
next stop treadmill and cool down and recovery				
136	97.5	91.5	.331	16:04
116	97.5	91.5	.348	16:05
108	98	92.5	.368	1608
98	98	93	.396	16:10
106	98.2	92.4	.380	16:13
102	98.5	92.5	.390	16:15
100	98.5	92.5	.396	16:18
98	98	92.5	.396	16:20

Thus, this experiment collected data for 3 min of control (tic in data) then 3 min at 1.7/10 (tic) then 3 min at 2.5/12 (tic) then 3 min at 3.4/14 (tic) then cool down and recovery.

Figure 21


TREADMILL EXERCISE (UNSUITED) WITH LOAD
SUBJECT EL
o HEART RATE
Δ BORG RPE SCALE
HEART RATE (bpm)
BORG RPE SCALE
200
188
176
164
152
140
128
116
104
92
80
20.0
18.6
17.2
15.8
14.4
13.0
11.6
10.2
8.8
7.4
6.0
158
116
108
98
89
119
114
15
14
13
10
C 2.5/12 9PE
1.7/10 3.4/14 6PE
SPEED (MPH)/ GRADE (%)

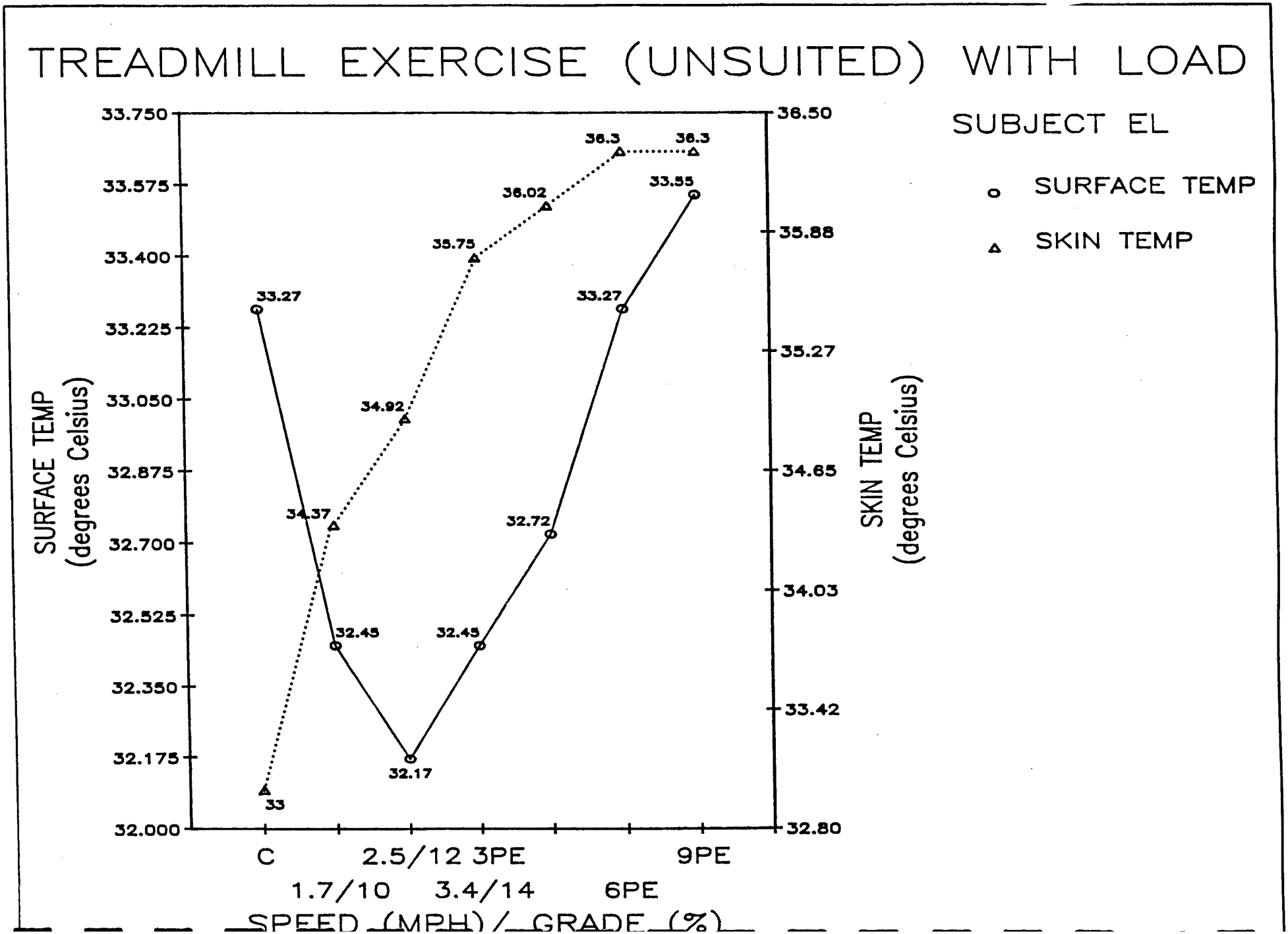

TREADMILL EXERCISE (UNSUITED) WITH LOAD
SUBJECT EL
SURFACE TEMP
SKIN TEMP
SURFACE TEMP (degrees Celsius)
SKIN TEMP (degrees Celsius)
33.750
33.575
33.400
33.225
33.050
32.875
32.700
32.525
32.350
32.175
32.000
36.50
35.88
35.27
34.65
34.03
33.42
32.80
33.27
32.45
32.17
32.45
33.27
33.55
33
34.37
34.92
35.75
36.02
36.3
36.3
C
2.5/12 3PE
9PE
1.7/10
3.4/14
6PE
SPEED (MPH) / GRADE (%)

Figure 22

Figure 23

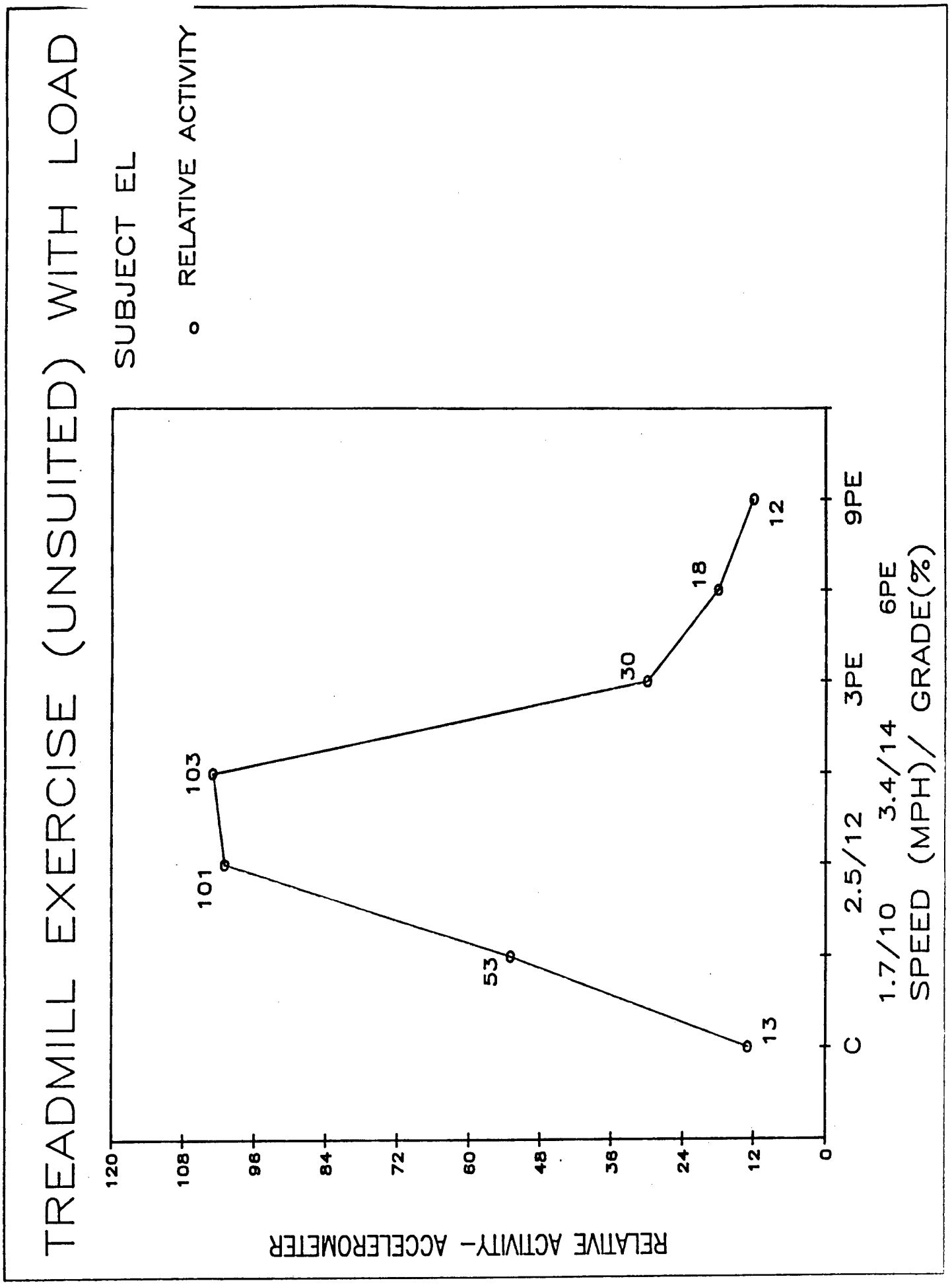
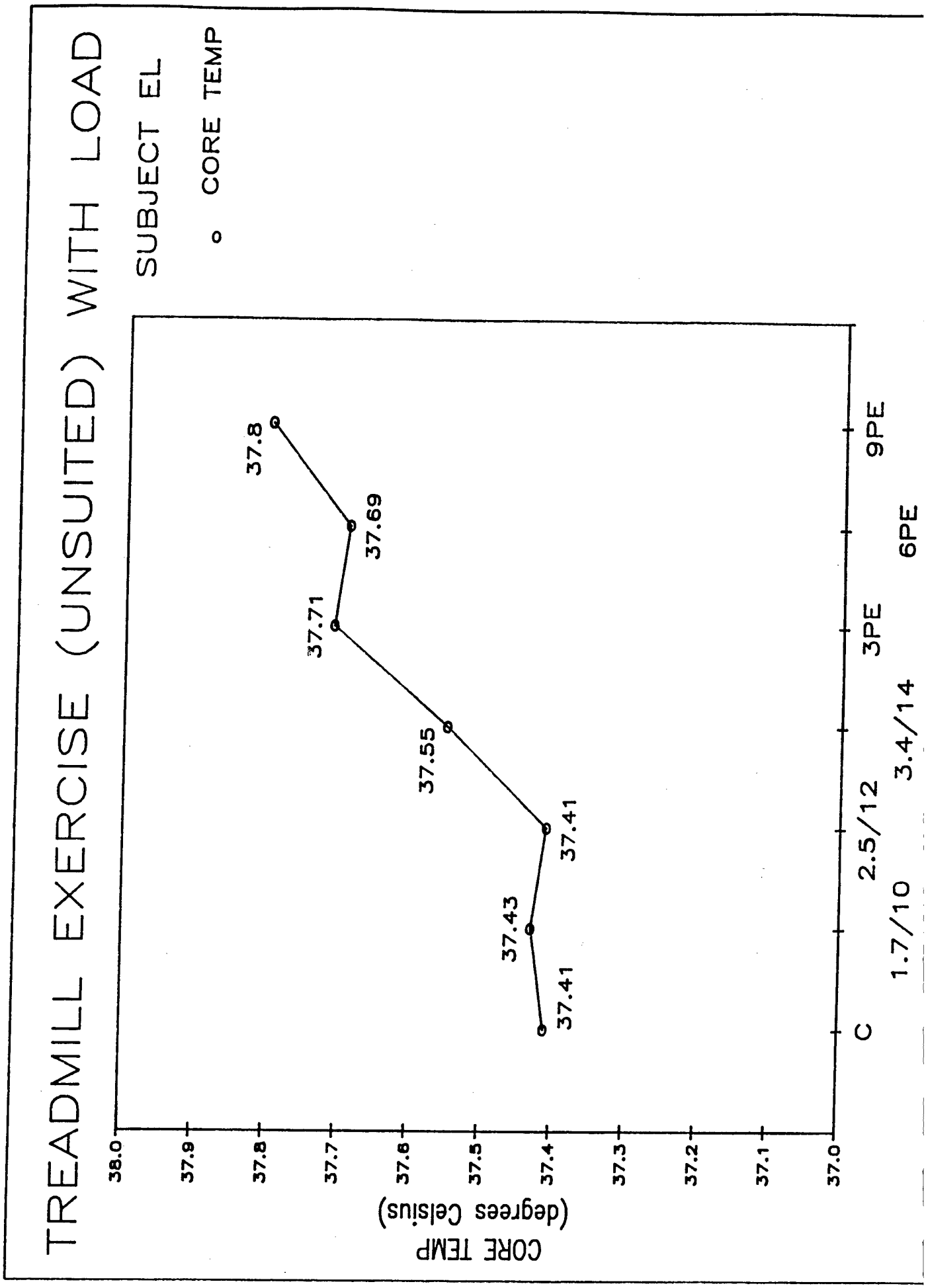

TREADMILL EXERCISE (UNSUITED) WITH LOAD
SUBJECT EL
o RELATIVE ACTIVITY
RELATIVE ACTIVITY- ACCELEROMETER
120
108
96
84
72
60
48
36
24
12
0
103
101
53
13
30
18
12
C
2.5/12
3PE
9PE
1.7/10
3.4/14
6PE
SPEED (MPH)/ GRADE(%)

Figure 24

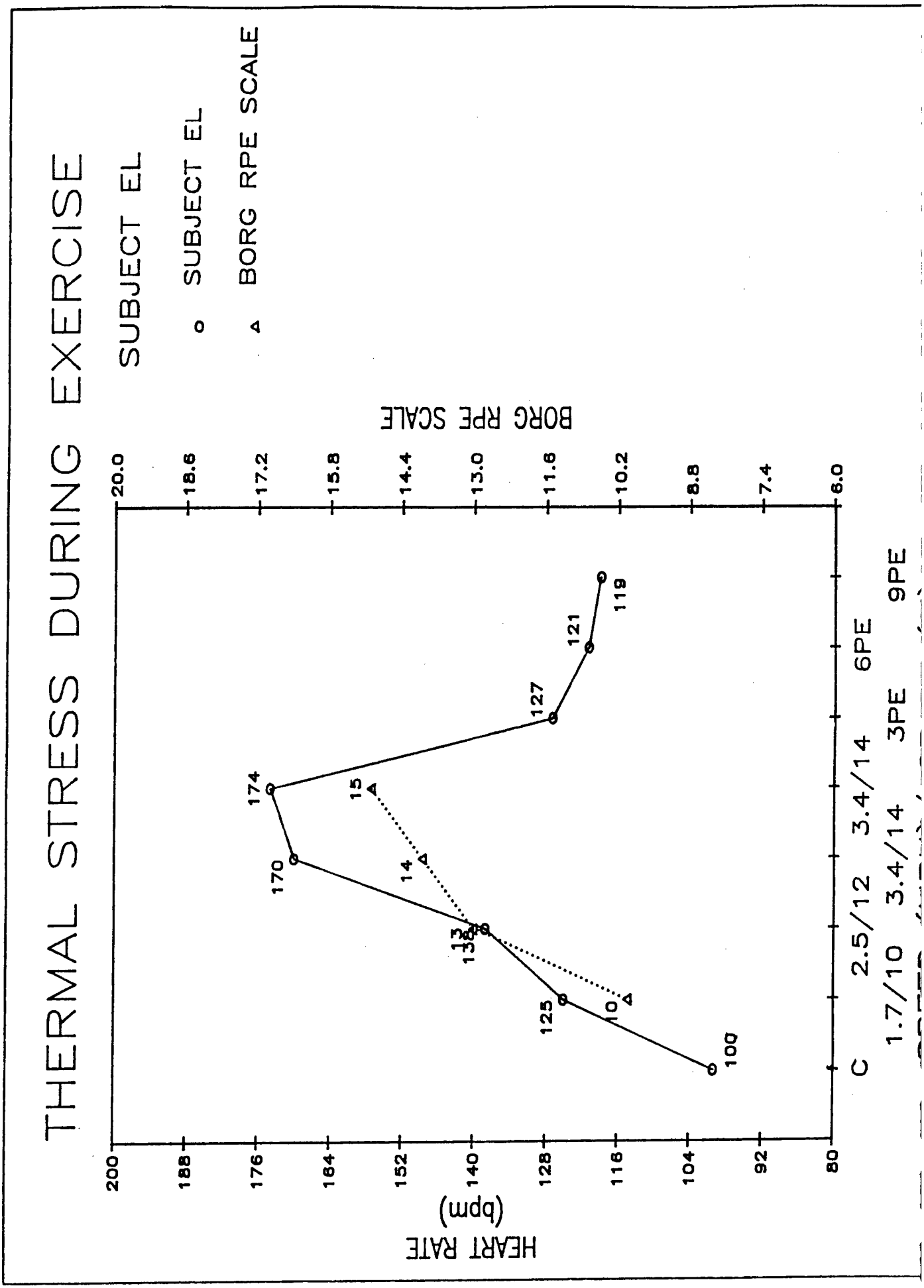

TREADMILL EXERCISE (UNSUITED) WITH LOAD
SUBJECT EL
o CORE TEMP
CORE TEMP
(degrees Celsius)
38.0
37.9
37.8
37.7
37.6
37.5
37.4
37.3
37.2
37.1
37.0
37.8
37.69
37.71
37.55
37.41
37.43
37.41
C
1.7/10
2.5/12
3.4/14
3PE
6PE
9PE

E. Loewen thermal stress during exercise (PH1A406B). Suited exercise with no extra load carried by the subject. Ed suited up at 1621-1630 hours then ran a Bruce protocol starting at 1634 hours. We collected control data for 3 min (tic in data) then he ran at 1.7/10 for 3 min (tic) then he ran at 2.5/12 for 3 min (tic) then he ran for 6 min at 3.4/14 (tic) then he cooled down (Figures 25-28).

One unique observation was that the core temperature dropped at the early stages of exercise, when the subjects were suited. This was attributable to the increased circulation bringing in cooler blood from the extremities. This has been shown or suspected in humans but not demonstrated so clearly. Another component of this dip in core temperature would be the vasoconstriction that occurs during exercise within the splanchnic circulation. The gut is vasoconstricted to provide redistribution of the available cardiac output to the working muscles.

HR	T_{suit}	T_s	T_{core}	Time
97	87.5	94	.416	16:31
100	89	94.5	.410	16:33
next start Bruce protocol 1.7/10				
125	90	96	.384	16:36
next go to 2.5/12 of Bruce protocol				
138	90	96	.382	16:39

Figure 25


THERMAL STRESS DURING EXERCISE
SUBJECT EL
o SUBJECT EL
Δ BORG RPE SCALE
HEART RATE (bpm)
BORG RPE SCALE
200
188
176
164
152
140
128
116
104
92
80
20.0
18.6
17.2
15.8
14.4
13.0
11.6
10.2
8.8
7.4
6.0
174
170
138
125
100
127
121
119
15
14
13
10
C 2.5/12 3.4/14 6PE
1.7/10 3.4/14 3PE 9PE

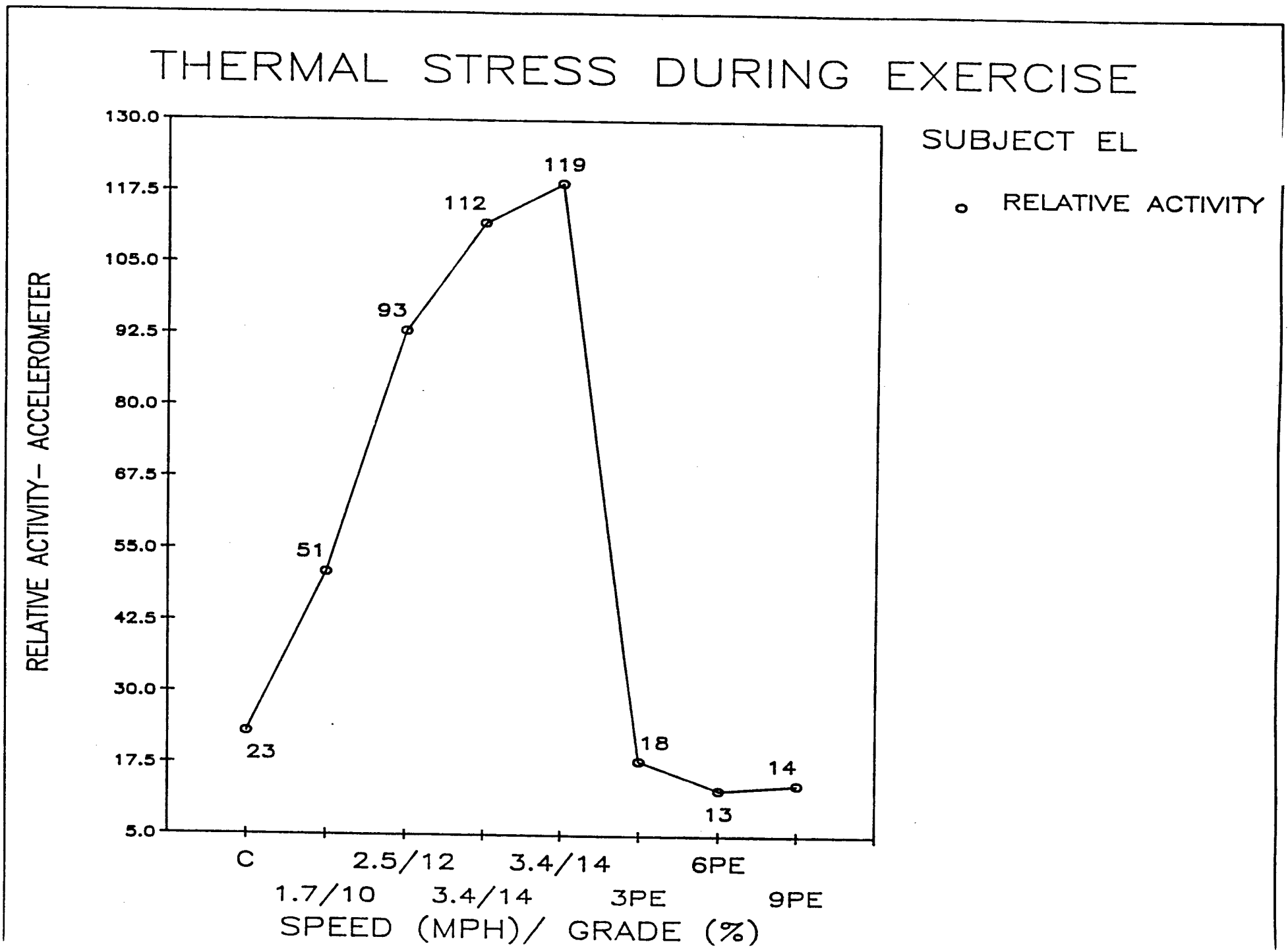

THERMAL STRESS DURING EXERCISE
SUBJECT EL
RELATIVE ACTIVITY
RELATIVE ACTIVITY- ACCELEROMETER
130.0
117.5
105.0
92.5
80.0
67.5
55.0
42.5
30.0
17.5
5.0
23
51
93
112
119
18
13
14
C
2.5/12
3.4/14
6PE
1.7/10
3.4/14
3PE
9PE
SPEED (MPH)/ GRADE (%)

Figure 26

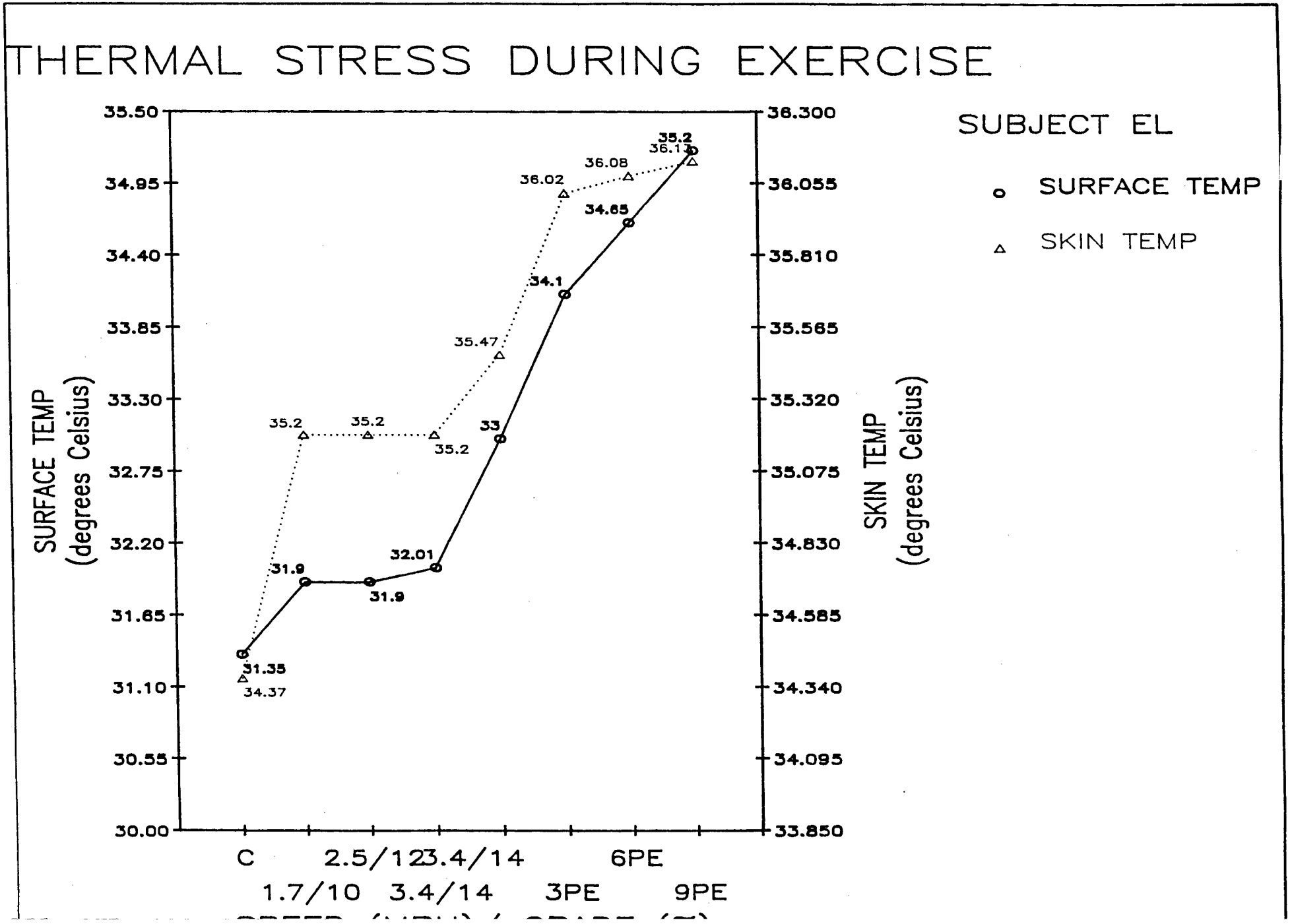
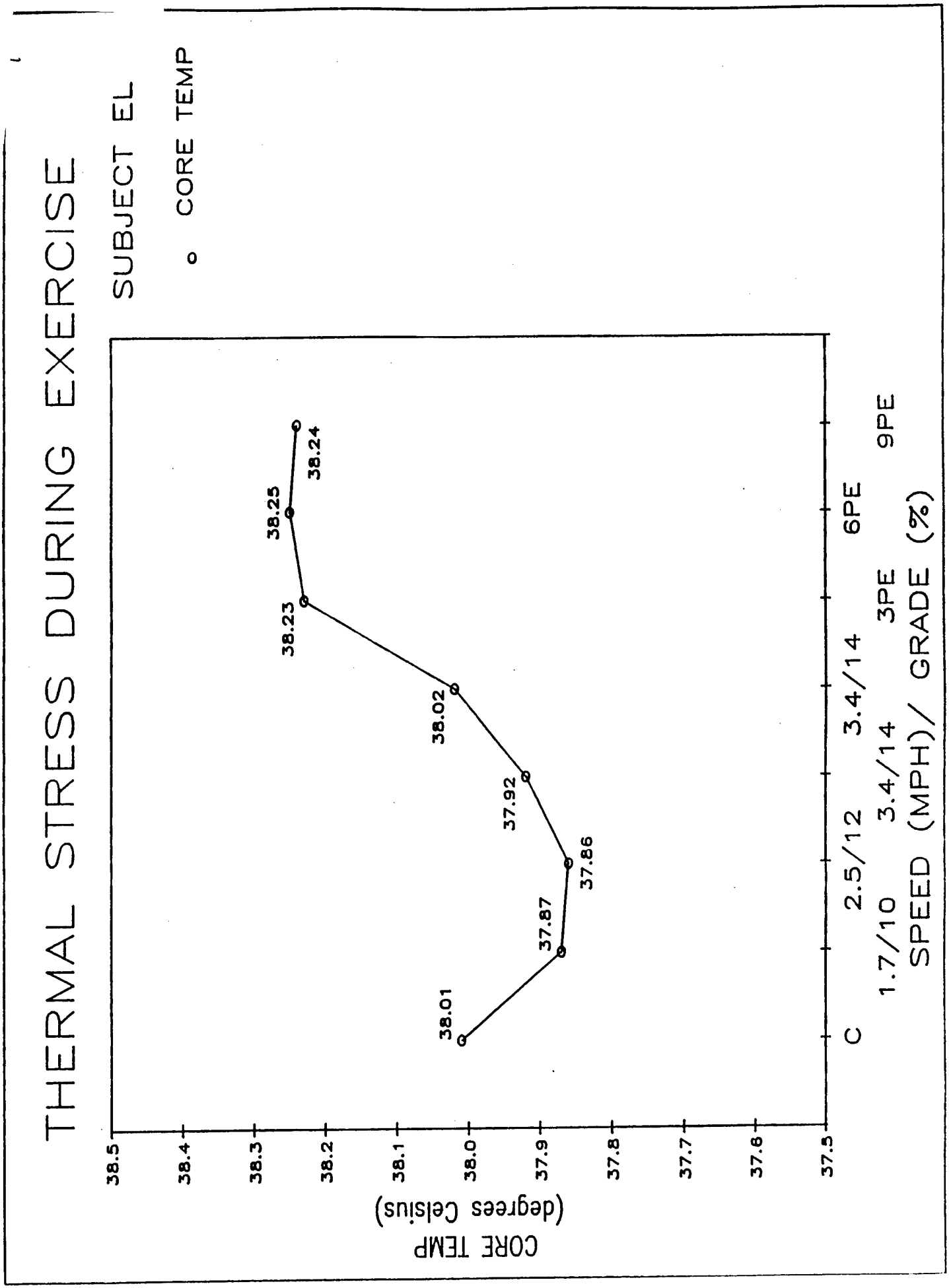

THERMAL STRESS DURING EXERCISE
SUBJECT EL
SURFACE TEMP
SKIN TEMP
SURFACE TEMP (degrees Celsius)
SKIN TEMP (degrees Celsius)
35.50
34.95
34.40
33.85
33.30
32.75
32.20
31.65
31.10
30.55
30.00
36.300
36.055
35.810
35.565
35.320
35.075
34.830
34.585
34.340
34.095
33.850
35.2
35.2
35.2
35.47
36.02
36.08
36.11
35.2
31.9
31.9
32.01
33
34.1
34.65
31.35
34.37
C
1.7/10
2.5/12
3.4/14
3.4/14
3PE
6PE
9PE

Figure 27

Figure 28


THERMAL STRESS DURING EXERCISE
SUBJECT EL
o CORE TEMP
CORE TEMP
(degrees Celsius)
38.5
38.4
38.3
38.2
38.1
38.0
37.9
37.8
37.7
37.6
37.5
38.24
38.25
38.23
38.02
37.92
37.86
37.87
38.01
C
2.5/12
3.4/14
6PE
1.7/10
3.4/14
3PE
9PE
SPEED (MPH)/ GRADE (%)

next go to 3.4/14 of Bruce protocol				
170	90.2	96	.396	16:42
174	92	96.5	.416	16:45
stop and recover and cool down				
141	94	97.5	.435	16:48
127	95	97.6	.467	16:50
118	96	97.7	.460	16:52
121	96	97.7	.439	16:54
123	96	97.5	.457	16:56
119	96	97.5	.460	16:58
119	96	97.5	.462	17:00
118	96	97.5	.464	17:02

Carl T. thermal stress and exercise with load (PH1A406C). Suited response to exercise with extra load of 37 lbs on back. Carl suited up at 1705-1723 and we started to collect control data at 1724.

We collected 3 min of control (tic) then 3 min at 1.7/10 (tic) then 9 min at 2.5/12 until he felt he could not go further. He was definately "at-risk" at the end of this period. Room temp was 23.5 C. His oral temp was 98.2 at the beginning (Figures 29-32).

HR	T_{suit}	T_s	T_{core}	Time
control period/suiting up				
88	83	89.5	.202	17:18
95	90	91.5	.204	17:22

next start the exercise at 1.7/10

108	93	93	.199	17:24

next go to 2.5/12

153	94.5	95	.197	17:27
170	96	95.5	.230	17:30
183	97.5	95.6	.290	17:33
186	98.9	96.4	.369	17:36

next slow down and stop, cool down, took off pack only

167	98	93	.415	17:38
146	94.5	91.5	.442	17:40
145	93	91	.451	17:42
139	93	91	.456	17:44

core temp plateau?

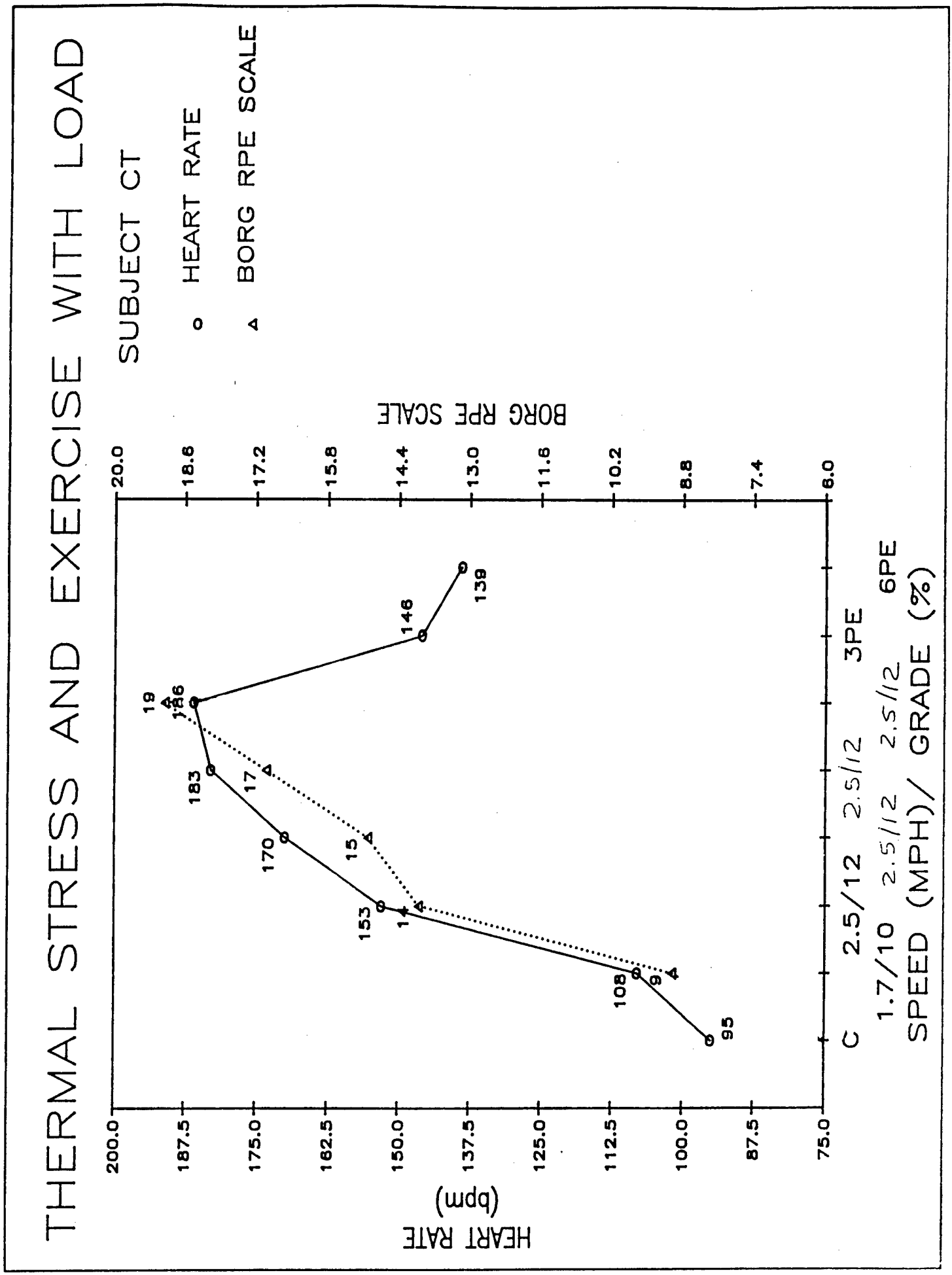
134	93	90	.464	17:47
134	93	89.5	.459	17:50

end of test, subject OK.

The pills were calibrated using a temperature-controlled water bath and returned to KI for examination. The results of the calibration were given to Tim Cushing for the writing of the algorithm. The means for getting the data off of the floppy discs was written by T. Cushing at a later date and the floppy sent to us for data retrieval and completion of this report.

Our examination of the data showed that the core temperature was a good predictor of the at risk alarm and this in combination with the heart rate should be used for alarm detection. Based upon the workload we selected on the treadmill and upon the limited data from two subjects' level of fitness we were able to observe the slope of core temperature rise (degrees C/min) and state that at the particular workload that X minutes could be sustained (accounting for the overshoot of Core temp) before the alarm should be sounded. We extrapolated linearly (not sure of the linearity of heat load accumulation) to also predict a critical alarm. Basically this was about 10 more minutes of the same workload. With these crude approximations we discussed the algorithm with Tim Cushing and he arrived at his own writing of the algorithm.

Figure 29


THERMAL STRESS AND EXERCISE WITH LOAD
SUBJECT CT
o HEART RATE
Δ BORG RPE SCALE
HEART RATE (bpm)
BORG RPE SCALE
200.0
187.5
175.0
162.5
150.0
137.5
125.0
112.5
100.0
87.5
75.0
20.0
18.6
17.2
15.8
14.4
13.0
11.6
10.2
8.8
7.4
6.0
95
108
153
170
183
186
146
139
C 2.5/12 2.5/12 3PE
1.7/10 2.5/12 2.5/12 6PE
SPEED (MPH)/ GRADE (%)

THERMAL STRESS AND EXERCISE WITH LOAD

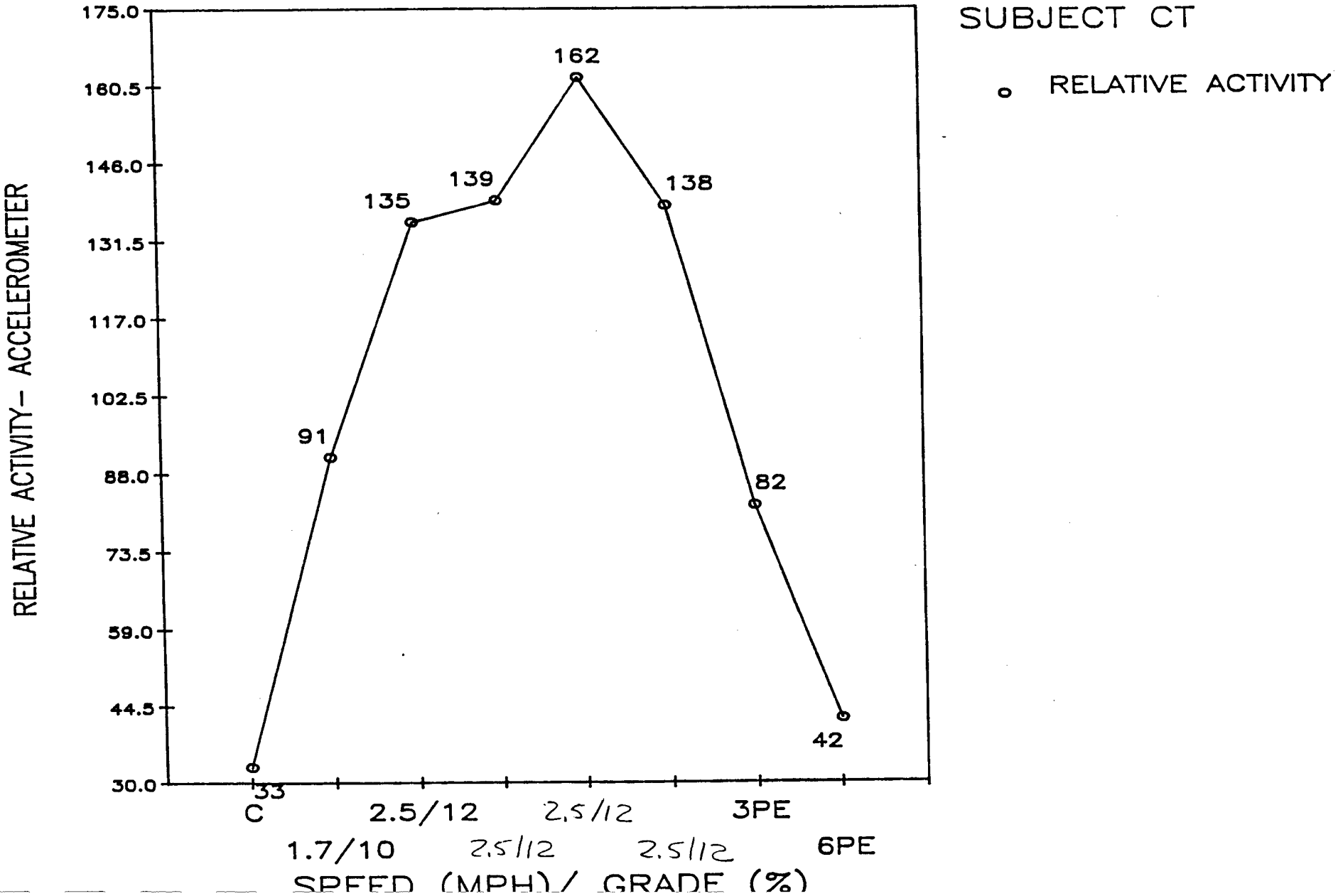
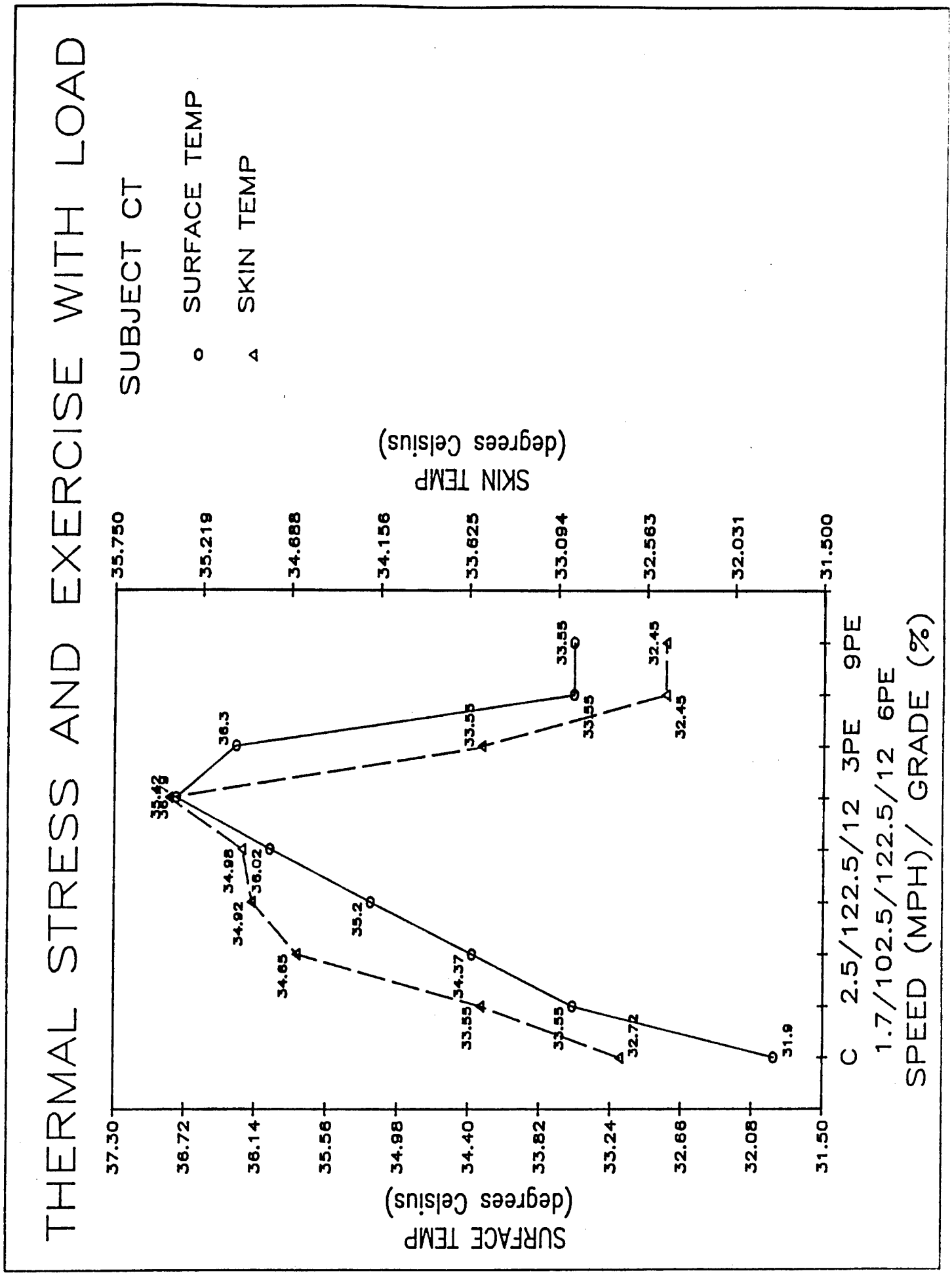


Figure 30

Figure 31


THERMAL STRESS AND EXERCISE WITH LOAD
SUBJECT CT
o SURFACE TEMP
Δ SKIN TEMP
SURFACE TEMP (degrees Celsius)
SKIN TEMP (degrees Celsius)
37.30
36.72
36.14
35.56
34.98
34.40
33.82
33.24
32.66
32.08
31.50
35.750
35.219
34.688
34.156
33.625
33.094
32.563
32.031
31.500
C 2.5/122.5/12 3PE 9PE
1.7/102.5/122.5/12 6PE
SPEED (MPH)/ GRADE (%)

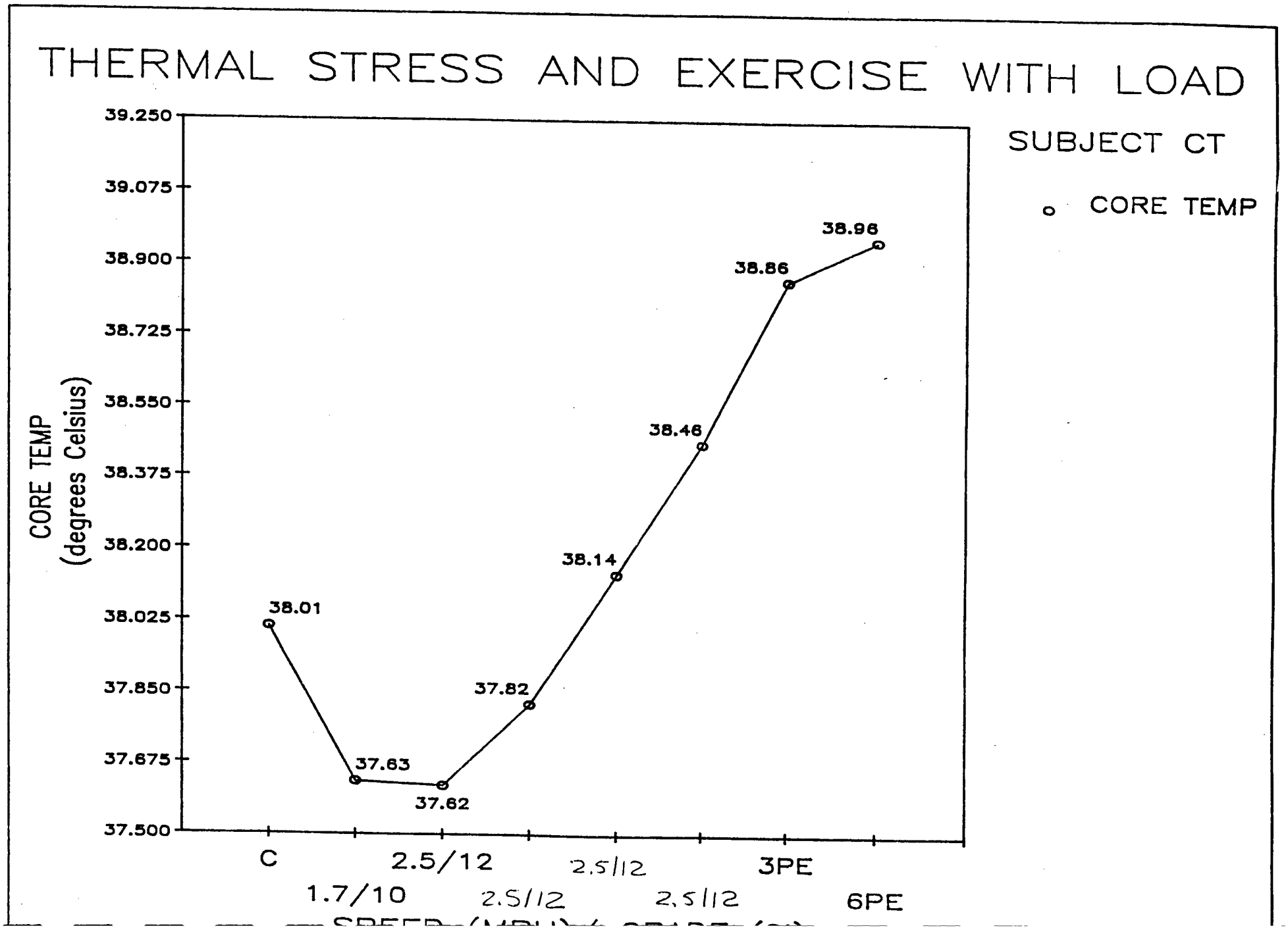

THERMAL STRESS AND EXERCISE WITH LOAD
SUBJECT CT
CORE TEMP
CORE TEMP (degrees Celsius)
39.250
39.075
38.900
38.725
38.550
38.375
38.200
38.025
37.850
37.675
37.500
38.01
37.63
37.62
37.82
38.14
38.46
38.86
38.96
C
1.7/10
2.5/12
2.5/12
2.5/12
2.5/12
3PE
6PE

Figure 32

4/16/87 - Recalibration of Pills from PH1A part 4

K. Dormer
Univ. of Oklahoma

Water Bath	Voltage out	
T°C	Pill #10	Pill #13
35	-0.23	-0.45
35.25	-0.05	-0.24
35.3	-0.19	-0.39
35.4	-0.17	-0.36
36.0	-0.03	-0.24
36.2	-0.05	-0.20
36.25	-0.05	-0.24
36.75	+0.05	-0.14
37.0	+0.00	+0.00
37.3	+0.1	-0.08
37.5	+0.22	+0.02
37.8	+0.23	+0.05
38.0	+0.03	+0.12
38.1	+0.35	+0.18
38.25	+0.23	
38.5		+0.21
38.6	+0.38	+0.22
38.8	+0.48	+0.30
39.0	+0.47	+0.32
39.2	+0.51	+0.35
39.4	+0.55	+0.37
39.5	+0.58	+0.40
39.6	+0.59	+0.38
40.4	+0.72	+0.63

Note: H1B 93.8 mHz - Carl T
94.24

#10 104.99 mHz - Ed L
105.74

Appendix III

BFMS Technical Manual

January 1995
Revision

Prepared for:

Walter Reed Army Institute of Research
Washington, DC

by

Research Triangle Institute

BFMS Technical Manual

Revised 1/95

Prepared for:
Walter Reed Army Institute of Research
Washington, DC

Table of Contents

LIST OF FIGURES

1 INTRODUCTION

In 1985, the U.S. Army Medical Research and Development Command awarded a contract to Konigsberg Instruments, Inc. to develop a system for multi-channel biomedical monitoring in military operational environments. The environment of greatest interest was the chemical defensive posture in which subjects wear restrictive protective clothing but are expected to maintain their task performance and physical activity. Under these conditions heat stress can be a serious problem and it is essential to have a safe and reliable means of monitoring a subject's thermoregulation. The original system developed for this purpose was the Chemical Defense User Safety System (CDUSS). This system used an ingestible radiotelemetry pill as a primary sensor to monitor core body temperature. Secondary sensors measured skin temperature, heart rate, and activity. This system has proven itself in many field studies and with continuing refinements has evolved into its present configuration as the Biomedical Field Monitoring System (BFMS).

1.1 PURPOSE AND GENERAL DESCRIPTION

The Biomedical Field Monitoring System (BFMS) has been developed to provide a practical means of monitoring the physiological status of soldiers under operational conditions. The BFMS is a modular system composed of four major subsystems: 1) biomedical transducers for measuring a variety of physiological parameters; 2) an individually-worn multi-channel data acquisition system; 3) a radio frequency telemetry system; and, 4) a data display and analysis unit ("base station"). Figure 1 illustrates the functional components of the system.

1.2 HISTORY

Work on the BFMS has proceeded in phases. The first phase (IA) began in 1985 with the design of the original CDUSS system by Konigsberg Instruments (KI). The first units consisted of a KI-designed ingestible temperature transmitter (T2A) and a commercial biotelemetry transceiver. The latter consisted of a TR4 diversity receiver, T41A 6-channel

telemetry transmitter, TD10A bench mainframe, PS3A power supply, D4 pill demodulator, CM6 control module, and SC106 signal conditioners. During this phase the integrity of the coating on the T2A pills was tested in dogs and the encapsulating procedure was changed slightly to produce a more uniform coating. The T2A pills utilized a discrete component design which was intended to closely resemble the final design. Tests with human subjects were also conducted. Transmission range of the T2A pills was tested using simple body mounted antennas and found adequate. In addition, computer programs were developed that could successfully predict core temperature rise to above 39 degrees C in a subject engaged in strenuous exercise.

During phase IIA (1987) KI used the T2A temperature pills to test the new TR6A telemetry transceiver. The TR6A was an interim version of the TR6B. It had an LCD readout display for core body temperature, but did not have data acquisition and logging capabilities. It also did not have the RF receiver sensitivity or transmitter power of the later TR6B. The TR6A was tested throughout 1989 at various sites: Walter Reed Army Institute of Research (WRAIR), Aberdeen Proving Grounds, and Fort Knox. The new receiver had adequate sensitivity for picking up pill transmissions, but there were problems with low transmitter power. Power output was estimated at only 20mW instead of the expected 100mW. In addition, antenna problems further limited communication range.

At this stage of the program it became apparent that computer programming of the TR6A pill reception and base station temperature display was heavily "application-sensitive," and was preferably performed at WRAIR. KI was requested to forward existing programming documentation to the Army, which took over further software development. In general, feasibility was established for core temperature acquisition, man-pack transmitter to base station communication, and base station computer temperature display. However, consistency of unattended operation and communication distance between units remained to be improved.

Phase III (1989) saw the introduction of the IC-based T2D temperature pills and the improved TR6B telemetry transceiver. The T2D pill consists of a custom integrated circuit (T0), a micropower RF transmitter, and passive components for programming the IC and RF

transmitter. Physically the pill is similar to the T2A. Electronically the T2D permits the encoding of a pill identification pulse to aid in tracking one pill signal in the presence of many signals. The internal IC was also intended to allow for the simultaneous transmission of ECG and temperature information. However, this function was not implemented in the T2D. 260 T2D pills were manufactured by KI for the phase III tests. These tests were conducted at the Applied Physics Laboratory (APL), Johns Hopkins University, which repeated the pill calibration tests done by the manufacturer (KI). Their results closely matched KI's data. Improvements to the TR6B transceiver included increased power output, simplified circuit board layout, improved power supply, increased receiver sensitivity, and a change in input/output connector design to accommodate a larger data logger memory. Six complete TR6Bs were produced, along with parts for 11 additional units. During initial testing with 4 AA lithium cells an operating lifetime of over 24 hours was achieved and reliable transmission range was found to be 200-750 meters, depending on the antenna used. One serious problem that occurred was a tendency for the TR6Bs to spontaneously reset, interrupting data acquisition. This problem was traced to microprocessor software and a programming change corrected the problem.

In 1990, WRAIR undertook interim refinements of the CDUSS system, renaming it the Biomedical Field Monitoring System (BFMS). The BFMS was based on individual components (of the CDUSS) as delivered by KI, but was repackaged in a smaller case more suitable to immediate application in field studies, which began in Spring 1990. WRAIR was assisted in repackaging and printed circuit fabrication by Precision Control Design, Inc., (PCD) of Fort Walton Beach, Florida.

In 1993 the BFMS was again modified and repackaged as the ATR6B. This new unit is enclosed in a water-tight case and uses an external battery pack. Using external batteries allows the appropriate size batteries to be selected for a given mission while minimizing the total weight of the complete package. The memory board and analog circuitry were also significantly redesigned by PCD to improve performance and allow the complete electronics package to fit into the smaller case. The TR6B receiver was also modified to incorporate a wideband AM detector. This new detector allows improved discrimination of the T2D ID pulses and permits

tracking multiple pills in a subject, although at some cost in power consumption. New lower profile connectors were also selected for the ATR6B, making harness cables less prone to damage.

As of July 1994, three final upgrade revisions were being considered for final closure of the existing system:

1. Since the 1989 delivery of the TR6B tranceivers, a problem with the stability of belt-unit transmissions has been noted, both for carrier frequency and FSK-FM deviations. Application software has been extensively modified to minimize this problem and to assure data telemetry throughput. A hardware revision of the transmitters, at modest cost, has been developed and was incorporated in late 1994.

2. The present battery pack consists of three C-sized lithium cells, but presents a problem of bulkiness and exposure to the elements. A more compact package, based on four 9-volt rectangular batteries, is being designed for applications in late 1994 and 1995.

3. The present microprocessor contains only 2K bytes of programming space (EEPROM), insufficient for certain advanced applications, such as inter-pill discrimination and multi-channel pill applications. A 12K-byte UVEPROM version of the chip is now available, and two prototypes of the TR6B have been built using this microprocessor. Cost-benefit analysis of generalizing this revision is in progress, and such a change will occur in 1995, if at all.

A summary of system development is contained in References 1-8.

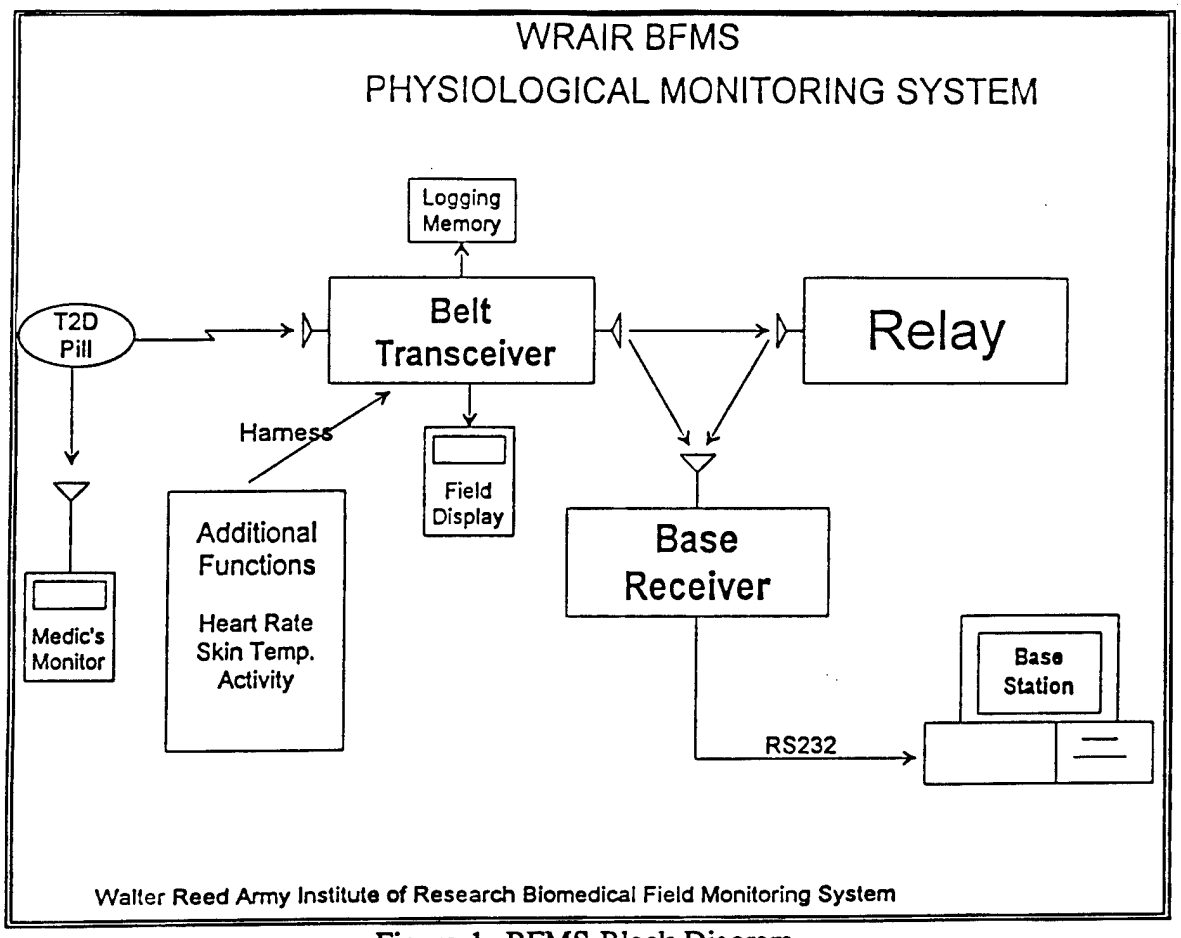


Figure 1 BFMS Block Diagram.

1.3 SUBJECT SAFETY

The ultimate objective of the BFMS is subject safety under adverse, isolated, mobile, or potentially dangerous situations. Safety limits for core temperature, as well as heart rate and skin temperature should be pre-determined for each study, exercise or test. Both absolute levels and trends approaching those limits can be observed with the BFMS in real time, with green/amber/red zones for the base station displays, and auditory signals if desired.

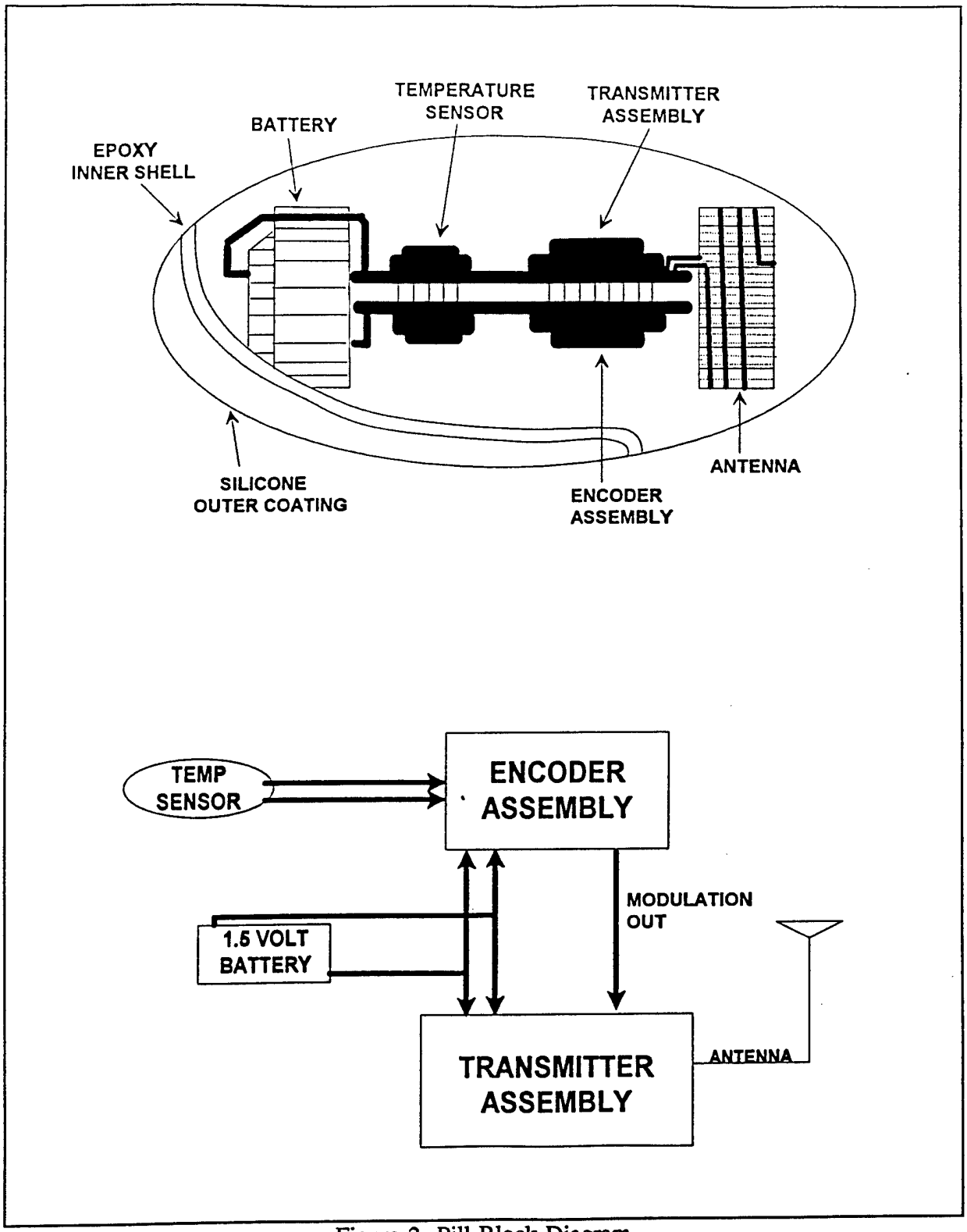


Figure 2 Pill Block Diagram.

2 TEMPERATURE PILL

2.1 GENERAL DESCRIPTION

The T2D "Temperature Pill" is an ingestible sensor/transmitter capsule that emits micro-power radio-frequency (RF) pulses at intervals related to the surrounding temperature (pulse interval modulation).

Data encoding in the T2D is accomplished with a temperature sensor (thermistor) and a semi-custom integrated circuit encoder (T0) which translates temperature information into an equivalent pulse frequency rate. The pulse information is then used to gate an RF transmitter, providing a pulse train of RF transmission decoded by the TR6B transceiver (belt-worn or man-pack). See Figure 2 for a general outline of the pill's structure.

2.2 DETAILED DESCRIPTION

The integrated circuit encoder (T0) translates temperature information, derived from a thermistor, into a train of dual pulses whose pulse-group repetition rate is linearly related to temperature. The nominal pulse frequency is 500 Hz at 37 degrees C, increasing by 20 Hz per increased degree C. This pulse train is used to switch the RF transmitter on and off, which is tuned to emit a pulsed carrier in the band between 88 and 108 MHz, tuned by discrete components at assembly. Because of the brief nature of the pulses (10 to 60 microseconds) and the relatively long interpulse interval (2 milliseconds) the transmitter has a very low duty-cycle which sharply reduces the rate of battery power consumption. Shelf life of an operating pill at ambient temperature (approximately 20-25 degrees C) is approximately three months and can be extended to beyond one year if the pill is kept at 0 degrees C or below. The estimated average input power to the transmitter is 25 microwatts.

2.2.1 Pill ID Encoding

In addition to encoding temperature information the T2D also encodes pill ID information. The T0 integrated circuit generates two narrow pulses in brief succession. The first is a short pulse (P1) of 10 to 22 microseconds. This is followed by an interval (I1) of 10 to 80 microseconds, and then another, longer pulse (P2) of 20 to 105 microseconds. The overall pulse-train interval (beginning of P1 to beginning of P1) is determined by temperature and is about 2 milliseconds. The shorter intervals (P1, I1, and P2) are determined by circuit components and can be preset to represent 8 different pill types. This feature aids the receiver/decoder circuitry in tracking the pill by improving the discrimination of pill signal from sources of pulsatile noise. The dual-pulse scheme is shown in Figure 3.

2.2.2 Physical Characteristics

Physically, the T2D capsule is made up of two printed circuit board assemblies, an antenna assembly, a battery, and hermetic and biocompatible coatings rendering it suitable for ingestion (see Figure 2). The electronic assemblies consist of a thermistor (temperature sensor), an integrated circuit encoder (T0), and a transmitter circuit. The antenna is a wire coil and the battery is a silver oxide button cell. The final assembly is tuned, inserted in a gelatin capsule, and coated with a dental acrylic resin to form a hermetic seal. A unique serial number is inscribed on the pill surface, and it is finally coated with a medical grade silicone elastomer. Each pill is calibrated by measuring the P1-P1 pulse repetition rate at two water bath temperatures (37 and 40 degrees C). The pill is then packaged in a sealed plastic packet along with calibration information and stored at between 0 and 10 degrees C.

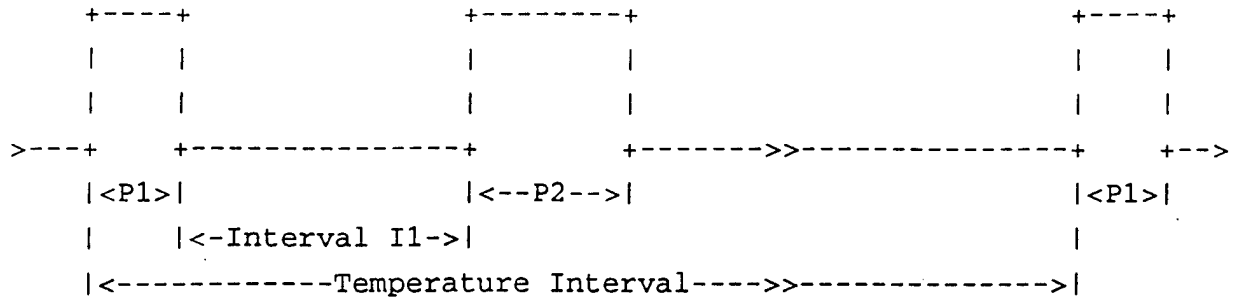


Figure 3: Pulse definition for the T2D Encoder/Transmitter

2.3 T2F PILL DESIGN

Difficulties in manufacturing the T0 integrated circuit in small quantities have made the supply of these parts uncertain. Consequently the T2D has been redesigned to use discrete components in place of the T0 and has been redesignated the T2F. The T2F is functionally equivalent to the T2D, with one exception. The width of the first pulse (P1) is fixed at 16-22 μseconds. ID information is encoded by using two different pulse widths for P2 (20-35 or 36-60 microseconds) and four different I1 pulse intervals (10-23, 23-40, 40-67 and 67-110 microseconds).

2.4 TEMPERATURE PILL SPECIFICATIONS

T2D Temperature Telemetry Transmitter (pill)

Size:	Length = 29 mm (approx.)
	Diameter = 11 mm (approx.)
Weight:	3.9 grams (0.13 oz.)
Temperature sensor:	Bead Thermistor
Pulse frequency:	500 Hz (nominal) at 37 deg. Celsius, +/- 100 Hz
Temperature change:	20 Hz (nominal) per deg. Celsius, +/- 4 Hz
Linearity:	+/- 0.1 deg. between 34 and 40 deg. Celsius
Accuracy:	+/- 0.1 deg. between 34 and 40 deg. Celsius
Transmission method:	Near field pulsed radio frequency
Operating frequency:	86 - 108 MHz (factory set)
Range:	24 inches (typical)
Transmitter duty cycle:	< 5 percent
Transmit power:	Mean (pulsed): < 25 microwatts max.
Power supply:	1.5-volt silver oxide battery (Eveready type 393)
Battery life:	> 3 months at room temperature; > 1 year at 0-10 deg. Celsius
Expected life:	One usage (> 72 hours at 37 deg. Celsius)
Encapsulation materials:	Inner capsule, hermetic seal of electronic components: Lee Pharmaceuticals photo-cure methacrylate resin (dental).
	Outer coating: GE RTV112 silicone sealant
	Overcoating of lettering: Dow RTV734 clear silicone adhesive
	NOTE: The above materials comply with Section 21CFR 177.2600 and Section 21CFR 175.300 of the Food and Drug Regulations.

3.BFMS UNIT - HARDWARE SYSTEM DESCRIPTION

*** THE FOLLOWING TEXT REPRESENTS SEMI-FINAL EDITING OF THIS SECTION BY DPR AND INCORPORATES KI'S REVISIONS. REMAINING FOR THIS SECTION IS A DISCUSSION OF THE ANALOG DATA ACQUISITION BOARD, WHICH CONTAINS THE LOGGER MEMORY AND DISPLAY, AND THE 26 - PIN CONNECTOR AND HARNESS CONNECTIONS. IT MAY BE DESIREABLE, IN THIS PART, TO INCLUDE ILLUSTRATIONS OF THE SUB-CIRCUITS DESCRIBED.

3.1 GENERAL DESCRIPTION

The BFMS hardware unit is based on the Konigsberg Instruments, Inc. TR6B microprocessor controlled radio frequency transceiver, which has been repackaged by WRAIR with some modifications and additional components designed by both Precision Control Design, Inc. and Research Triangle Institute, Inc. This section presents in detail each of the separate components which comprise the BFMS unit. The fundamental building blocks of the hardware system are shown in Figure 4, a block diagram of the various interconnected printed circuit board assemblies (PCBs) of the system.

The most fundamental section is the TR6B, consisting of a radio frequency transceiver (TXR) coupled to and controlled by a microprocessor PCB assembly (uRCTL). The TXR transmits and receives in the 88 to 108 MHz commercial FM broadcast band, and is made up of standard circuit sections typical of any radio, i.e., RF Preamplifier, Local Oscillator(LO), Mixer, IF Amplifier/Detector, IF Gain Control, Modulator network, and RF Power Amplifier. LO frequency is determined by firmware in the uRCTL. In receive mode, LO frequency is set to operating frequency less IF, and the receiver demodulates both AM (for Temperature Pill signals) and FM (for FSK data reception) information from the IF signal. Both AM and FM demodulation signals are fed to uRCTL for processing and Temperature pill data are derived from AM pulse

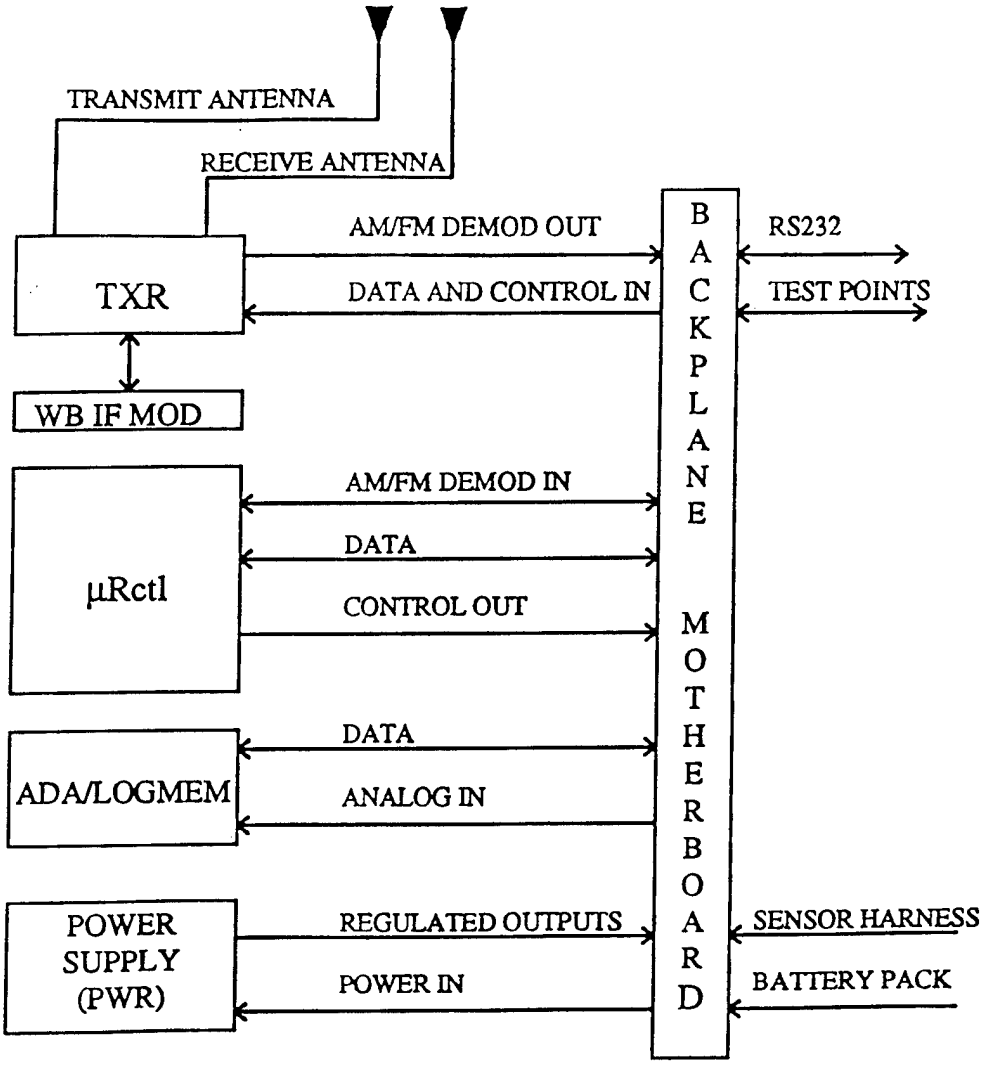


Figure 4. BFMS Hardware

intervals. In transmit mode, the LO determines operating (carrier) frequency for FM-FSK data transmissions.

Data acquisition, from channels other than the Temperature Pill , is accomplished on the Analog Data Acquisition/Logger Memory board (ADA/LogMem PCB) manufactured by Precision Control Design, Inc. Data functions include 1) 4 channels of thermistor drivers for Skin Temperature sensors contained in the harness; 2) a cardiotachometer channel for Heart Rate derived from a chest-strap ECG signal; and 3) body movement data or Actigraphy, derived from an accelerometer mounted on the PCB itself. The ADA/LogMem PCB also contains 128 Kilobytes (Kb) of Static RAM with a back-up battery, for logging of acquired data and off-line retrieval, and a Liquid Crystal Display for external visualization of selected data.

The DC power supplied to each PCB circuit section is conditioned on a single board (PWR) which derives power from the battery pack. Additional components described here include the PCB inter-connections on the backplane or "motherboard," the antenna, harness, and communications connectors, the battery pack options, and the case itself. Finally, two revisions in incomplete or interim implementation are discussed: 1) the Wide-Band IF Strip, and 2) the TX6 transmitter PCB which replaces the transmitter functions of the TXR, for reasons discussed below.

The BFMS unit, by variations and parameter settings of the internal firmware, can be configured for any of three functions: as a man-pack ("belt unit" or wearable instrumentation package), as a relay station (relays signal from a man-pack unit to a base station), or as a base station (logging and PC interface system). Each of these are discussed in separate sections of this manual.

3.2 TRANSCEIVER (TXR)

3.2.1 AM/FM RECEIVER - Detailed Description

Refer to Schematic Drawings TXR1 - TXR3 found in Appendix I.

All three configurations of the TR6B receiver utilize the demodulated AM signal, although only the man-pack actually processes data from the signal. Both base station and relay functions detect the occurrence of incoming data transmissions by awaiting the leading edge of an increase in AM level produced by a remote signal. On the other hand, the belt-unit uses the AM signal to detect the brief RF pulses transmitted by the T2D/T2F temperature pill. The uRCTL processor captures the AM pulses and measures the intervals between them, thus decoding the pulse intervals modulated by temperature (see section 2.0).

Referring to the schematics, the transceiver is switched between receive and transmit modes by manipulating two control lines. One, the Tx Path Inhibit line (also known as OPT6), when asserted, disables the transmit output power amplifier driver U5, silencing the transmitter (see Schematic TXR3). Incoming RF signals are routed from the receiver antenna through a voltage controlled attenuator(VCA) formed by diode D1 and on to the preamplifier Q1. The DACv1 and DACf1 voltages from uRCTL form the second control line and are used to vary the RF impedance of D1 and thus control the amount of signal reaching preamplifier Q1. In transmit mode D1 is strongly reversed biased and protectively isolates the receiver circuitry from the transmitter. In receive mode the D1 acts as a voltage controlled attenuator, and in most usages, it is biased completely on (3v) for maximum receiver sensitivity.

Prior to preamplifier Q1 the signal is filtered by a voltage controlled tuned network (VCF) consisting of Varactor diodes D2 and D3 controlled by the DACv2 voltage level. This provides an 8 MHz passband centered at the operating frequency and -3db gain. Preamplifier Q1 is a conventional common emitter amplifier using a low noise (2dB) UHF transistor (MRF901), providing 16 - 18 db gain. The output from Q1 is coupled to the mixer stage U1 through a top coupled double tuned circuit formed by Varactor diodes D4, D5, D6, and D7. The DACv2 signal is also used here to set the center frequency of the filter, with an 8 MHz passband and 6 db gain. This VCF-Preamp-VCF network greatly reduces the effect of noise and out of band signals on the mixer.

The other input to mixer U1 is the local oscillator (LO) signal from Q6. The mixer U1 multiplies these two signals together and generates sum and difference frequencies. The output tuned circuit (C34, C35, C36, C37, L10, and L11) is adjusted to pass only the difference frequency which is termed the intermediate frequency (IF). The mixer IF output signal, which in this design is set to 10.7 MHz, is then applied to ceramic filter FL1 to further reduce any signals outside the IF passband. The output of filter FL1 is applied to a commercial IF amplifier/demodulator integrated circuit (IC) U2, which here is used only as an IF amplifier gain block. Its output passes to a second IF ceramic filter (FL2), to a second amplifier/demodulator (U3) used as a demodulator. The first stage in U3 further amplifies the IF signal and routes it to a third ceramic filter FL3. From FL3 the signal goes to the output limiter and quadrature detector stages of U3. The detector, along with C58, C59, C60, and L12 form an FM demodulator circuit providing an FM signal (Sig1) which is routed through the motherboard to the uRCTL board.

The AM output signal (Sig0) is derived by summing RSSI (signal strength) outputs from both U2 and U3 which are buffered by operational amplifier U4 and also routed to the uRCTL board.

3.2.2 WIDE-BAND IF STRIP (TR6B Modification)

Refer to diagrams WBIF1 - WBIF3 in Appendix 1.

As described above, the AM detector signal from amplifier/demodulators U2 and U3 does an adequate job of recovering the Temperature Pill interval information encoded by the leading edges of the P1 to P1 interpulse interval (2 milliseconds), sufficient for routine temperature measurement applications. However, this detector circuit has a low-pass characteristic with a bandwidth of only about 100 kHz, which results in somewhat distorted waveforms; trailing edges of both P1 and P2 are slewed to an extent that the short interval between the two ID pulses, and the width of both pulses cannot be accurately determined. Thus, different ID pulse positions and widths cannot be accurately discriminated and different pills in the same individual cannot be

tracked independently. This was an unpredicted result of the circuit design, resulting from the selection of ICs U2 and U3 (NE604) for minimum power consumption.

For limited applications in which accurate pulse discrimination might be required, a circuit providing much greater AM signal bandwidth, about 250 kHz, was designed, fabricated, and installed in the BFMS units. The output of the first Ceramic IF filter, FL1, is routed by coaxial cable to a new PCB called WBIF, mounted on one end of the TXR board. Refering to schematic WBIF1, this circuit consists of two IF gain stages U1 and U2 (MC1350) with a voltage controlled gain of 50dB. Two ceramic filters/matching networks are used to couple the signal from U1 to U2 and from U2 to the AM detector U3 (MC1330). The output of U3 is buffered by amplifier U4B and becomes a new AM video signal. The detector output is also rectified and integrated by amplifier U4A and used to generate an automatic gain control (AGC) signal which controls the gain of the IF stages (U1 and U2). This AGC signal also provides as an output signal which indicated average signal strength.

The WBIF strip and AM detector circuits requires significantly more current, approximately 55 milliamperes at 10.5 volts Vsupply, to operate than the original AM detector on the TXR board. This is an almost 100% increase in power consumption of the overall system, thus halving effective batter life. To provide for extended routine operation of the BFMS, a software controlled power switch was been added to the BFMS to power down the WBIF except during specialized uses. Shown in drawings WBIF2 and WBIF3, this DPDT circuit also switches the AM video line between the new and the original sources of the AM signal, which is then routed as Sig0 to the uRCTL board.

3.2.3 FM-FSK TRANSMITTER

Refer to Schematic Drawings TXR1 - TXR3 and RCTL1 - RCTL4, found in Appendix I

The transmitter in the TR6B is controlled by the 68HC811 processor on the uRCTL

board and operates in the 88 MHz to 108 MHz commercial FM broadcast band. The voltage on the DACv5 line from the uR controller board determines the transmit frequency generated by voltage controlled oscillator (VCO) Q6 (also the local oscillator of the receiver). This voltage varies the capacitance of varactor diodes D11 and D12 in the oscillator tank circuit, which changes the output frequency. In transmit mode, frequency shift keying (FSK) modulation is accomplished by modulating the DACv5 tuning voltage with serial digital data originating as signal TxD at pin 21 of the 68HC811 processor. The digital signal is gated through the Xylinx programmable logic array (PLA) (see RCTL1), scaled and buffered at U202 (see RCTL2), and summed with the DACv5 tuning voltage at amplifier U203. Small changes in VCO control voltage swing Q6 output frequency +/- 100 kHz (approximately) about the chosen center or carrier frequency. Referring to schematic TXR3, the Q6 oscillator output is buffered by FET amplifier Q7 and coupled to amplifier U6, the Prescaler Driver. The output of U6 goes to both the output power amplifier driver (U5) and to the frequency prescaler (U101) shown on RCTL1. The latter, U101, divides the carrier frequency by 64, reducing the frequency to a value countable by the 68HC811 processor (see Section 3.1.5 below for further details of this function). The Power Amplifier Driver amplifier, U5, is controlled by the TX PATH INH line from the uRCTL board. In transmit mode this line is low, which turns on FET switch Q3 which in turn supplies power to U5. This allows U5 to drive output power amplifier Q5. Three additional control lines from the uRCTL board are used to set the output power level by changing the bias on power amplifier Q5. The default setting is 3 mW. This can be changed to nominal values of 10 mW, 30 mW, and 100 mW by turning on the 10, 30, and 100 mW ENABLE lines respectively. The output of power amplifier Q5 is bandpass filtered by the RCL network centered at L15 and finally connected to the output antenna jack.

3.2.4 (DRAFT) TX6 TRANSMITTER (TR6B Modification)

NOTE: THIS MODIFICATION IS NOT IMPLEMENTED AT THE TIME THIS REPORT IS BEING WRITTEN, BUT IS BEING DEVELOPED AND TESTED; THUS FOLLOWING TEXT IS SUBJECT TO CHANGE.

Refer to Schematic Drawings TX61 - TX62.

It has been found in practical applications that the original VCO-TXR design described in Section 3.1.3 above suffers from instability and drift variance of both the carrier frequency, from unit to unit, and within a unit, and the quality of FSK modulation values within the same unit. Although various software adjustments, such as randomly varying DACv5 settings, have ameliorated the problem of maintaining a tuned link between the belt unit senders and the base station receiver, the throughput of data messages is far less than ideal. There is no single source of this problem easily repaired on existing circuits, and probably derives from a combination of 1) noise and/or drift in -2v and -5v reference voltages in the modulation, DAC, and VCO circuits, 2) variable loading by the body-mounted antenna and the prescaler of the complex of driver and output circuits, and 3) variation in the several components involved. Analyses begin with the likelihood that stable frequency determinations using a pure voltage-controlled scheme are simply inferior to designs using either traditional fixed QRLC circuits or crystal controlled or phase-lock-loop technology, a fact reflected in more recent radios produced by Konigsberg Instruments.

In this modification, a manually capacitor-tuned transmitter, the TX6, replaces the transmitter section of the TXR between the Xylinx PLA and the antenna. The tradeoff is the loss of software/controller-tuned frequency selection, but it is the rule that the carrier frequency, once chosen for a given operator location, remains unchanged. Thus frequent adjustments are not required at the base station level. Preliminary tests indicate sufficient stability, up to a temperature of 130 degrees F., to be used in the BFMS FM-FSK application. The TX6 provides a standard FSK signal derived from a serial digital input.

Implementing this change requires the dynamic switching of the ciruit on and off during BFMS operation, and in the present case, it must use the space presently used by if WBIF Mod. Thus, if it isused, the latter will be removed from those units to be applied to long-range telemetry. This modification will be tested, with details described in this space of the report.

3.3 MICROCONTROLLER BOARD (uRCTL)

3.3.1 GENERAL DESCRIPTION

Refer to Schematic Drawings uRCTL1 - uRCTL4 in Appendix 1.

The BFMS microcontroller board has been designed to provide highly versatile digital control of the various functions incorportated in the BFMS. It's centerpiece is the Motorola MC68HC811E2FN (referred to as 68HC811), an 8-bit microcomputer (U106) operating at 8 megahertz, with self-contained analog to digital converters (ADC), 8-bit parallel digital ports, a serial digital port, and various control lines. Supporting circuitry include a XILINX XC2064 (U103) programmable logic array (PLA), a XILINX XC1736 (U102) serial PROM, a Motorola MC12017 (U101) prescaler, a DAC8408 (U107) 8-bit digital to analog converter (DAC), a DAC8221 (U105) 12-bit DAC, a Maxim MAX233 (U104) RS232 interface, and additional interface hardware.

3.3.2 MC68HC811 MICROPROCESSOR

The 68HC811 is the main processing unit of the BFMS since it provides the computational and control functions necessary for pill reception, analog data acquisition, and remote data transmission. The HC811 is configurable as the main processor in an expanded system and theBFMS system uses thise expanded mode, with a capacity for directly addressing 64K of mapped devices through 16 bits of parallel data. Other onboard features include: an 8 channel 8-bit ADC; a 256 byte RAM; a 2K Electrically Erasable Programmable Read Only Memory (EEPROM); a digital pulse accumulator; an asynchronous communications interface; and general purpose timers/counters. The EEPROM contains custom BFMS Programming that is invoked upon application of power to the unit. This firmware provides the necessary routines to interface and control the various hardware functions including Pill reception and tracking, remote data transmssion, data packet reception, and analog data acquisition. The particular mode of operation for any given unit, e.g., whether it is utilized as a man-pack, relay, or base station,

is set by downloading a particular BFMS Program, or selection of particular parameters within a Program, setup at the time of application.

3.3.3 XILINX XC2064 PROGRAMMABLE LOGIC ARRAY

The XC2064 is used to replace several SSI (Small Scale Integration) and MSI (Medium Scale Integration) integrated circuits which would otherwise be required to populate this already dense PCB. The XC2064 is configured into an array of gates, boolian logic functions, latches, and multiplexers, by uploading the contents an 8-pin serial PROM (Programmable Read Only Memory)(U102) each time power is applied to the system. This permits changes in PLA configuration rather than replacement of the 68-pin PLA, should modifications be required.

Details of XILINX functions are given in Appendix _, Xilinx PLA Programming.

3.3.4 RADIO FREQUENCY PRESCALER

The frequency generated by the local oscillator is approximately 100 MHz, which exceeds the capabilities of most conventional logic circuits. Thus, it is necessary to reduce the 100 MHz signal to allow the 68HC811 to monitor the frequency and adjust it accordingly. An RF prescaler is incorporated into the BFMS to accomplish this frequency reduction. A Motorola MC12017 prescaler is configured to divide the frequency by 64. This reduced signal is then input to the XC2064 PLA and is further reduced by a factor of four (4), providing a total reduction factor of 256. This reduced frequency signal is compatible with the the 68HC811 pulse accumulator (PA) in both in format and frequency and can be used to control the RF frequency in the BFMS. The logical sequence for this, described futher under BFMS Programming, is 1) the VCO is turned on with a candidate setting of the control voltage DACv5; 2) VCO output is divided by 256 and inserted into the PA input of the 68HC811; 3) a timed count is obtained and converted into a frequency value; 4) DACv5 is adjusted in the direction of the desired frequency; and 5) the cycle is repeated until stable tuning is obtained.

3.3.5 DIGITAL TO ANALOG CONVERTERS

The digital to analog converters (DAC) are used to set and control the analog voltages used in the BFMS. The 4-channel 8-bit DAC (U107) provides two analog control signals to the TXR: 1) signal DACi1, buffered by U208, becoms DACv1, which is routed to the Voltage Controlled Attenuator (VCA) on the TXR receiver input line; 2) signal DACi2, also buffered at U208, becomes DACv2, which sets the passband of the Voltage Controlled Filter (VCF) of the receiver. The remaining two analog outputs (DACi3 and DACi4) become signals DACv3 and DACv4, and are used to set the threshold voltage levels, AMT and FMT respectively, at analog comparators for AM-level (CMPo0) and FM-level (CMPo1) detection, residing in U211. The AM comparator output is used by an Input Capture line (IC1) of the 68HC811 to detect radio signal amplitude level changes, either the Pill pulses for a belt unit, or the onset of an incoming data signal, in the case of Base/Relay Station configuration. The FM comparator is used to convert incoming FSK signals into digital (0 - 5 v) levels, and routed through the Xilinx to the asynchronous serial input of the 68HC811, RxD, This output (CMPo1) is also routed to an Input Capture line (IC2) of the processor, but this input is not used by current program operations.

The 2-channel 12-bit DAC (U105) is used 1) to control the VCO output frequency via signal DACi5 through voltage follower/buffer U203 to the DACv5 output and 2) to determine the value displayed on the external LCD display via signal DACi6 through U203 to the DACv6 output, which is routed by the motherboard to the Analog/Memory board. The 8-bit DAC provides output voltage step increments of 0.3906% of full scale while the 12-bit DAC provides step increments of 0.0244% of full scale.

3.3.6 RS232 INTERFACE CONTROLLER

The BFMS communicates with the outside world via a standard RS232 serial port. To accomplish this, the digital (0 - 5 v) levels obtained at the 68HC811 asynchronous serial port (TxD and RxD) must first be gated by the Xylinx to the Maxim MAX233 RS232 Interface

Controller (U104), which in turn converts these signals to the voltages (both positive and negative) required by RS232 standards.

3.3.7 DIGITAL CONTROL LINES AND DATA BUS

Parallel Ports "B" and "C" of the 68HC811 comprise 16 bits of digital I/O data and control lines for the various latches and multiplexers of the Xilinx, which are described in more detail in Appendix _. In addition, 13 lines from these ports (PB0-PB4 and PC0-PC7) are routed directly to the Digital to Analog Converters U105 and U107. Three Device Select Lines (DS1 - DS3) from the Xilinx complete the control lines to the DACs. Together, these 16 lines select the particular DAC address and then set its output voltage level.

These same 13 lines from ports B and C are also routed directly to the Motherboard for use as a bus for address and data I/O for the logger memory. Four additional control lines, namely MS1, MS2, CS4, and LOG, emerge from the Xilinx, routed through the Motherboard to the logger memory. Finally, one direct line from the 68HC811, OC2 at pin 28, also termed "OCMP", completes the 18 control/data lines which service thelogger.

Another set of control lines emerge from the Xilinx, named Digital Control Options OPT0 - OPT7, and six of these, OPT1 - OPT6, are passed to the Motherboard. OPT0 is routed to Prescaler Power Switch Q101 and is turned on during frequency calibration episodes. OPT7 passes to digital switch U210, which when asserted disables the DACv1 control line to the Voltage Controlled Attenuator on the TXR Receiver input.

3.4 POWER SUPPLY (PWR)

Refer to Schematic PWR1 in Appendix A.

The power supply board (PWR) in the BFMS is an array of switching type power conditioning circuits, chosen because of higher efficiency than linear type supplies. This board receives its input (Vin) directly from the battery (or a bench source), which should be nominally 9.0 - 12.0 Volts at about 1.25 Watts. Redundant supplies are used for noise isolation between circuit blocks. Five primary regulated outputs are supplied by step-down switching regulators U1 - U5 (Maxim MAX638), each rated at 350 mW. These regulators switch at 65kHz and can achieve efficiencies of 85%:

VTX	Supply for the transmitter output stage Q5 (U1).
+6V	Supply for the analog circuitry on all boards (U4).
+5.0(TX)	Supply for the digital circuitry on the transmitter board (U5).
+5.0(uR)	Supply for the digital circuitry on the uR controller board (U3).
+5.0(uD)	Supply for the digital circuitry on the uR controller board and the battery backed up ram on the analog board(U2).

Besides the primary voltages, the power supply board also generates the following low current reference voltages and a negative power supply voltage:

-6V	Supply for the analog circuitry on all boards (U8).
+5R	Voltage reference for the FM video signal level (U9).
-5R	Voltage reference for the varactor diodes in the VCO (U7).
-2R	Voltage reference for the DAC reference on the uR board (U6).

The -6V supply is generated by an MC7660 charge pump voltage invertor which is connected to the +6V supply. The -5R and -2R voltage references are generated by MC7664 low power negative linear regulators. U9 is a MC7663 low power linear positive regulator which drops the +6V supply voltage down to +5 V. Linear regulators are used here because they are electrically quieter than switching regulators and the circuits they supply require low noise references. Although their efficiency is lower than a switching regulator very little power is lost because the reference currents are very small.

4 SOFTWARE DESCRIPTION

The BFMS software is separated into two major components, the TR6B firmware and the base station software. The TR6B firmware is described in the following sections in a functional manner and it continues to evolve. The base station software is utilized on a DOS compatible PC.

4.1 TR6B FIRMWARE

The software for the TR6B is stored in the 2 Kbyte EEPROM on the HC811 and is used to establish the operating parameters of the TR6B. A complete listing of the latest software is provided in Appendix 4 for user reference. Please note that the firmware provided in the TR6B is not easily user alterable and Appendix 4 is provided only for information.

The TR6B software is written in 68HC811 assembly language and is 'downloaded' to the HC811 EEPROM using the PC program DOWNLOAD.

4.1.1 PILL DATA ACQUISITION

The man-pack starts at entered pill frequency adjusted by an offset. It begins its sweep at this frequency and search for the proper frquency by adjusting the frequnecy up to the ending pill frequency.

The pill acquisition section uses the AM detector output to identify the pill and once it has found it, the receiver section of the man-pack is tuned using local oscillator (ie, VCO in this case) to obtain peak amplitude of the pulses from the pill. In addition the VCO also tunes the bandpass filters to the search frequency.

4.1.2 PILL TRACKING

**optimize signal

a tracking threshold is established for signal tracking

a**pulse width error data is rejected

if signal fades or has inteference so that the pulse pattern is lost

the pill acquisition routines are run to establish new tracking parameters

4.1.3 PACKET TRANSMISSION

[Section to be completed later.]

4.1.4 PACKET RECEPTION

[Section to be completed later.]

4.2 BASE STATION SOFTWARE

The following PC programs comprise the base station software:

KIPILLS,

PCAL,

DISPLAY,

RTITEST,

TESTBM93,

PROISAMD,

LOGPROC93,

DBPROC,

ISAMREPR, and

DOWNLOAD.

These programs are provided to the user in a DOS executable format and must be run on a PC which uses a memory manager. (***** more here ****)

A. Requirements of both processing programs:

1. The presence of LIM 4.0 EMS memory
2. The loading of the TSR program "PROISAMD.EXE"
3. A minimum of an EGA graphics adapter
4. An attached HP LaserJet III or redirect the output to a file.
5. The driver programs below in the same directory:

   drivers.drv

   geograf.bi

   printer.drv

   screen.drv

4.2.1 KIPILLS

KIPILLS.DB (KIPILLS) is the temperature pill database. It stores the calibration information for each temperature pill that will be used in a study. A new pill **must** be entered into the KIPILLS database before it is used. The program PCAL is used for data entry (see below). This pill information is then accessed by the real-time and data processing programs, and must be in the operating subdirectory for those programs.

4.2.2 PCAL

PCAL.EXE (PCAL) is the program used to enter temperature pill data into the KIPILLS database. It provides an entry screen of key parameters to update each new pill. The parameters needed for this update are found on the information insert packed with each pill, and consist of :

- Low calibration temperature (approximately 37° C)
- Low calibration frequency (around 500 Hz)
- High calibration temperature (approximately 40° C)
- High calibration frequency (around 560 Hz)

These parameters should be entered in the upper **and** lower fields of the database screen. Other data may be entered on this screen as desired, but is optional.

4.2.3 DISPLAY

The utility program DISPLAY.EXE (DISPLAY) is used to create the **base, range,** and **scale** variables that generate an accurate display of the pill temperature on the BFMS liquid crystal display. The input data required for DISPLAY is the same as that described above for PCAL (the four temperature/frequency calibrations). These parameters produce a screen listing of the form shown below, in HEX format:

- Base: FD7A
- Range: 6437
- Scale: D6

These values should be recorded for use later when the BFMS unit is set up for operation.

4.2.4 RTITEST

RTITEST.EXE (RTITEST) is the main user interface to the BFMS. This program is used to upload configuration information to the BFMS and to test the operation of the unit. The opening screen presents the main menu, which may be recalled with the "H" command at any time. The main menu screen halts the program in a wait loop which requires hitting any key before interaction begins. The program is exited by hitting the F10 key, CTRL-Break, or "Q".

NOTE: This program may be given a different name and be modified to include special features for a specific study (e.g. SDPO.EXE, OTTER.EXE). Please consult any README files that are included on the program disks for more information.

Main menu screen:

P:= Pause the program

B:= Toggle audible packet signal

L:= Set expected packet length

F10:= Abort this program

K:= Idle CDUSS unit

G:= Reset CDUSS unit

R:= Read loc. in CDUSS unit

W:= Write loc. in CDUSS unit

I:= Read loc. in logger memory

O:= Write loc. in logger memory

C:= Carrier test function

D:= Display test function

X:= Test 64K-byte block of memory

F:= Set operating packet frequency

T:= Set pill frequency

S:= Dump logger to file

Y:= Set display parameters

#:= Set unit ID number

N:= Initialize belt unit

M:= Initialize base monitoring unit

4:= Toggle between heart rate and 4th temp channels

4.2.5 TESTBM93

TESTBM93.EXE (TESTBM93) is the program used for monitoring real time information transmitted from the man-packs and Relays. All monitored information for up to 50 players is displayed on a sequence of screens. These screens show core body temperature, skin temperature, heart rate, activity level, pill tracking status, and whether the information for a given player has been updated in the last minute. The display also prompts the user with warnings

about players whose core temperature, heart rate and activity level may put them at risk of heat related problems. In use, the base station receiver is setup as described later in this section. The receiver antenna should be connected to the base station and the serial interface from the base station connected to the PC. Before this program is run, the program PROISAMD (described below) must be run to provide access to the KIPILLS database.

4.2.6 PROISAMD

PROISAMD.EXE (PROISAMD) is a TSR program which allows the interaction of other programs with the KIPILLS database and the real-time database. It must be started before running TESTBM93, LOGPROC93, or DBPROC.

4.2.7 LOGPROC93

LOGPROC93.EXE processes the binary file (Username.ALD) downloaded from the man-pack data logger. This program first prompts the user for setup information, then prints all the data in tabular form, plots the data, and finally creates two new files, a comma separated file (Username.CSV), and a text file (Username.TXT).

4.2.8 DBPROC

DBPROC.EXE processes the real time data file (Username.DBF) in a manner similar to LOGPROC93. This data file is generated by the monitoring program TESTBM93 and provides a duplicate and/or backup of the man-pack logger data. There will be slight variations between the two data sets due to time base differences in the man-pack data logger and the real-time telemetry system. Like LOGPROC93, DBPROC prints all the data in tabular form, plots the data, and then generates two new files: Name-ID#.TXT and Name-ID#.CSV.

4.2.9 ISAMREPR

ISAMREPR.EXE is a utility for repairing damaged ISAM data base files (KIPILLS.DB or username.DBF). If on accessing any of these files a damage file error message occurs, it can be fixed with this program (type "isamrepr filename"). Some of the data in the file may be lost, be the file should be usable. It is suggested that the damaged file be copied and retained; and that ISAMREPR be run on the copy.

4.2.10 DOWNLOAD

DOWNLOAD.EXE is a self explanatory program that is used to load the machine-code program into the BFMS units. This program is not needed in the normal operation of BFMS unit, but is necessary if the internal program is corrupted. This may occur as a result of incorrectly using the "W" command in RTITEST.

5 BFMS MAN-PACK SYSTEM

The man-pack configuration utilizes the AM receiver section for pill detection, the FM transmitter section for transmitting data packets to either a relay station or a base station, and the RS232 section for program initialization. Figure 5 illustrates the man-pack unit representation. Refer to chapter 3 for specific hardware details.

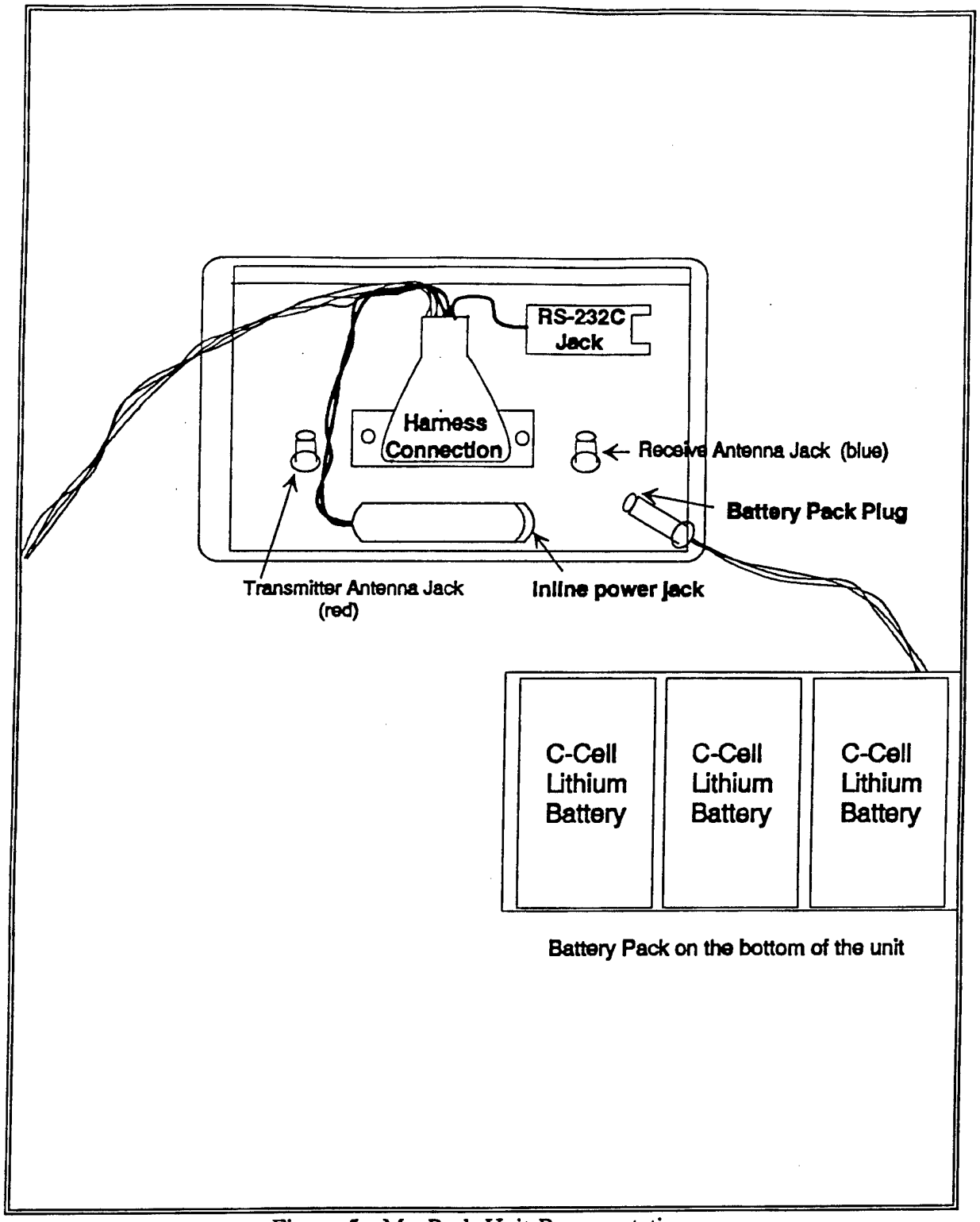


Figure 5. ManPack Unit Representation.

6 BFMS BASE STATION SYSTEM

When the TR6B is used in the base station mode the hardware components are identical to those used in the man-pack system with the exception of antenna and battery. In addition, there is an RS232 communications cable to provide for a link between the base station and a personal computer (PC) system. Figure 6 provides a representation of the base station antenna and cable connections.

Since the base station does not need to be wearable it is possible to utilize a battery with greater capacity. Thus it is possible to utilize any 12 volt battery. This voltage was selected to facilitate the battery selection process since most rechargeable automobile batteries are 12 volts.

The optimum antenna for RF omnidirectional reception is a 5/8 wavelength vertical monopole. To achieve a greater gain or interference rejection it is possible to use Yagis.

The configuration of the TR6B into a base station mode allows it to receive and store packet information received via the RF link (from either a man-pack unit or relay station), reformat the information, and transmit it to the PC via the RS232 link.

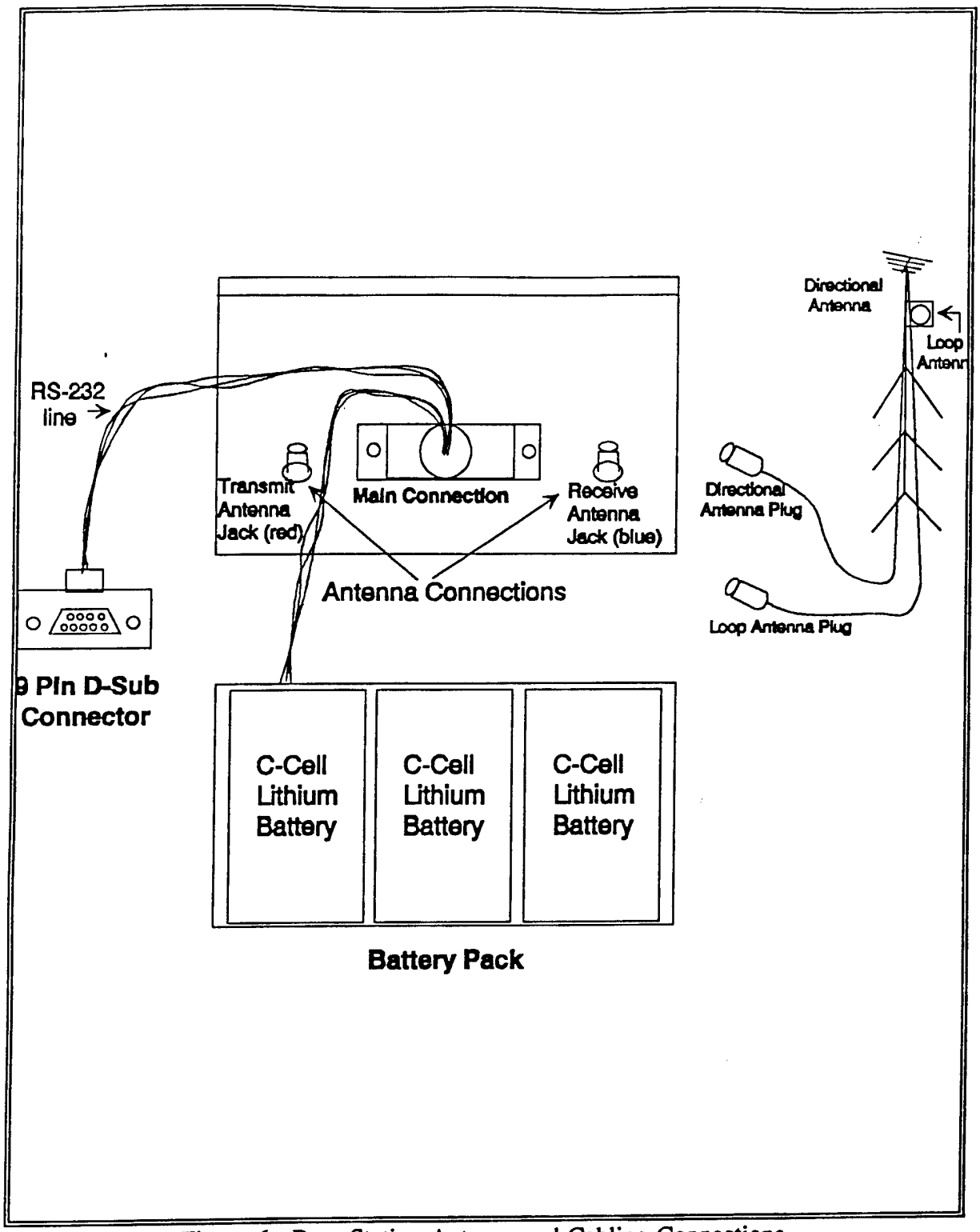


Figure 6. Base Station Antenna and Cabling Connections.

7 BFMS RELAY SYSTEM

When the TR6B is used in the relay mode the hardware is identical to that used in the base station mode, however, the RS232 link is not necessary. The relay station alternates between listening and transmitting data packets. Once a packet is received it is stored until its retransmission time arrives, the relay station reformats the packet, adds its station identification number and the transmits the packet. Figure 7 illustrates the Relay System configuration.

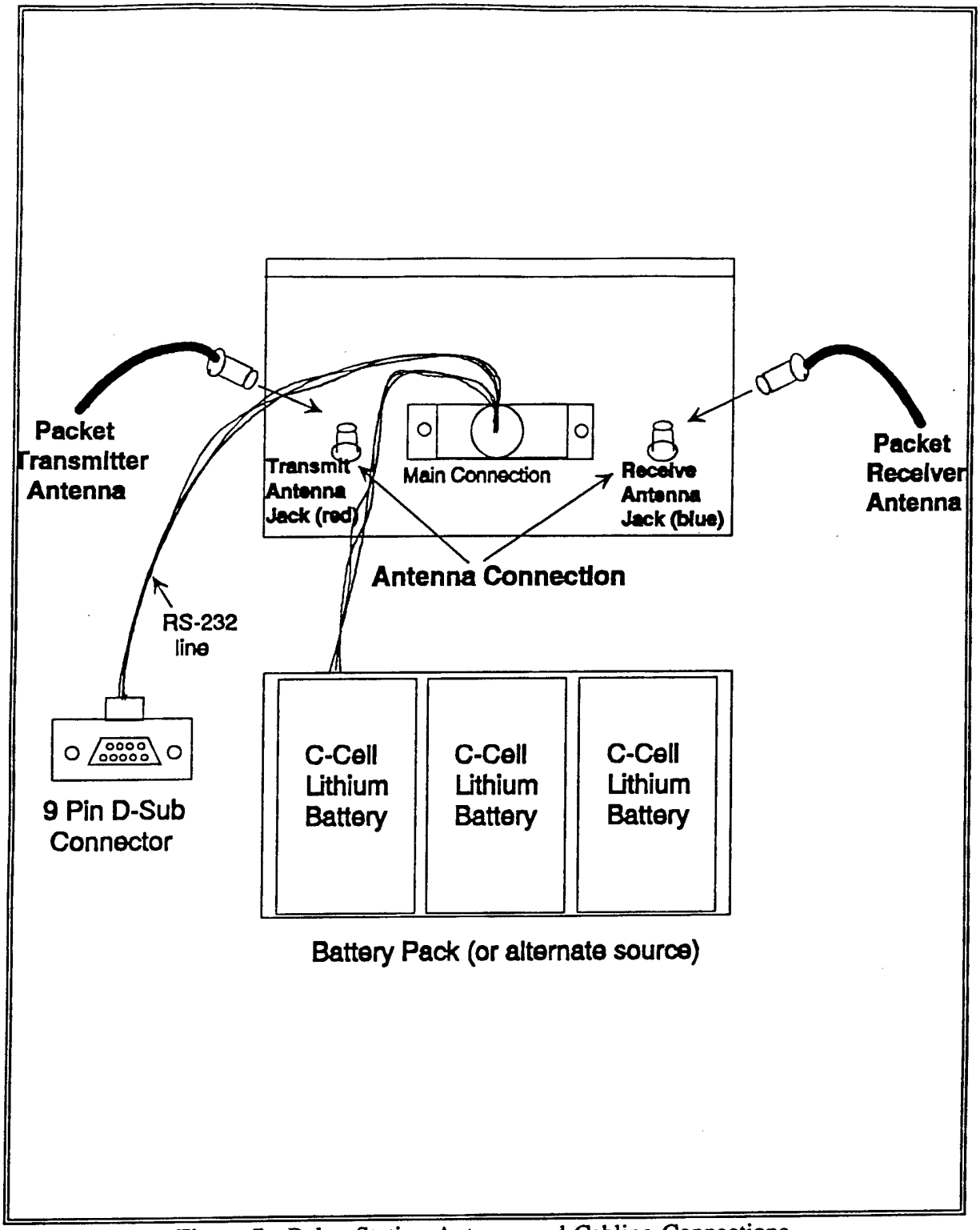


Figure 7. Relay Station Antenna and Cabling Connections.

References

1. Konigsberg, E. and T. Cushing (1986). System analysis report: CDUSS Phase I. Submitted to Walter Reed Army Institute of Research under Contract DAMD17-85-C-5257 by Konigsberg Instruments, Pasadena, CA.

2. Cushing, T. E. (1986). Development Test Plan CDUSS Phase IA. Written for Dr. K. Dormer, Univ. of Okla. Konigsberg Instruments Document No. DTP01110 Rev. A, Pasadena, CA.

3. Dormer, K. J. (1987). Progress reports for development test plan, CDUSS phase Ia, USAMRDC Contract No. DAMD-85C-5257, Ft. Detrick, MD.

4. Dormer, K. J. and R. Ratliff (1988). Validation of ingestible telemetry temperature pill with rectal temperature probe. Research report for USAMRDC Contract No. DAMD17-88M-0035, Ft. Detrick, MD.

5. Eberhart, R. C. (1989). Letter report: Konigsberg ingestible telemetry monitoring system calibration data (June 18, 1989). The Johns Hopkins University Applied Physics Laboratory, Laurel, MD.

6. Redmond, D. P., J. R. Leu, K. A. Popp, P. E. Guitierrez, Jr., and S. W. Hall, Jr. (1990). The Walter Reed temperature pill: evaluations for clinical and investigational usage. WRAIR Tech. Memo BB90-1, Walter Reed Army Institute of Research, Washington, DC.

7. Redmond, D. P., J. R. Leu, K. A. Popp, P. E. Guitierrez, Jr., and S. W. Hall, Jr. (1990). Initial field application and testing. Supplement to WRAIR Tech. Memo BB90-1, Walter Reed Army Institute of Research, Washington, DC.

8. Redmond, D. P., J. R. Leu, K. A. Popp, S. W. Hall, Jr., C. Galinski and P. E. Guitierrez, Jr. (1992). Medical monitoring: assessment of physiological changes in military personnel during field studies. USARIEM Tech. Note 9-42, Special Studies Branch, Dept. of Behavioral Biology, Walter Reed Army Institute of Research, Washington, DC.

Appendix 1 Diagrams and Circuit Board Illustrations

(see following pages)

PARTS LIST

PL - 105081 Rev B

TITLE: CDUSS TRANSCEIVER ASSEMBLY | MODEL # TR68 |

ITEM	QTY	CD	PART NUMBER	INDENTURE 0	1	2	3	4	DESCRIPTION (REFERENCE NUMBERS)	TOTAL QTY	MANUFACTURER/SPEC
1	1	SA	B105081	X					PCA TRANSCEIVER CDUSS	1	KI
2											
3											
4	1	SA	A106792		X				ASSY - TXR I.F. MODIFICATION	1	KI
5											
6											
7	2	MP	B105087		X				SHIELD (-1) Rx AND (-2) Tx	2	KI
8	2	PP	HU6729CB			X			CAN BRASS HOT TIN DIP 2.89 x 1.69 x .25	2	HUDSON CANS
9											
10											
11											
12	2	PP	UPC1651G		X				IC BIPL Si MONO AMP SMD (MACRO-X) (U5-6)	2	NEC
13	1	PP	HA-3-5142A-5		X				IC BIPL DUAL OP AMP DIP-8 (U4)	1	HARRIS
14	1	PP	NE602D		X				IC DBL BAL MIXER & OSC SO-8 (U1)	1	SIGNETIC
15	2	PP	NE604D		X				IC LOW POWER FM IF SYSTEM SO-16 (U2-3)	2	SIGNETIC
16											
17											
18											
19	4	BI	RS1206000085005		X				RES JUMPER 5% 1/8W SMD (R15,26,35,40)	4	.060 x.120
20											
21	2	BI	RS120627R085005		X				RES 27 5% 1/8W SMD (R37-38)	2	.060 x.120
22	1	BI	RS120633R085005		X				RES 33 5% 1/8W SMD (R39)	1	.060 x.120
23	1	BI	RS120668R085005		X				RES 68 5% 1/8W SMD (R42)	1	.060 x.120
24											

PREPARED BY: SEA DATE: 1-5-89

APPROVED BY: WJM DATE: 1-10-89

Rev B: OMITTED C66-67, C75-76, C94, D13-15, & L14. SEA 6-6-94

KONIGSBERG INSTRUMENTS, INC.
2000 FOOTHILL BLVD., PASADENA, CA. 91107

PL - 105081 Rev N/R

PARTS LIST

PL - 105081 Rev B

TITLE: CDUSS TRANSCEIVER ASSEMBLY

MODEL # TR6B

ITEM	QTY	CD	PART NUMBER	INDENTURE					DESCRIPTION (REFERENCE NUMBERS)	TOTAL QTY	MANUFACTURER/S
				0	1	2	3	4			
25	2	BI	RS1206100085005		X				RES 100 5% 1/8W SMD (R6,10)	2	.060 x.120
26	1	BI	RS1206200085005		X				RES 200 5% 1/8W SMD (R43)	1	.060 x.120
27	6	BI	RS1206470085005		X				RES 470 5% 1/8W SMD (R2,11-14,16)	6	.060 x.120
28											
29	2	BI	RS1206100185005		X				RES 1.0K 5% 1/8W SMD (R28,33)	2	.060 x.120
30	1	BI	RS1206150185005		X				RES 1.5K 5% 1/8W SMD (R44)	1	.060 x.120
31	2	BI	RS1206330185005		X				RES 3.3K 5% 1/8W SMD (R31,36)	2	.060 x.120
32											
33	1	BI	RS1206470185005		X				RES 4.7K 5% 1/8W SMD (R46)	1	.060 x.120
34	1	BI	RS1206680185005		X				RES 6.8K 5% 1/8W SMD (R49)	1	.060 x.120
35	3	BI	RS1206100285005		X				RES 10K 5% 1/8W SMD (R3,45,47)	3	.060 x.120
36											
37	2	BI	RS1206300285005		X				RES 30K 5% 1/8W SMD (R22,50)	2	.060 x.120
38	13	BI	RS1206470285005		X				RES 47K 5% 1/8W SMD (R4-5,7-9,27,29-30,) (32,34,48,51-52)	13	.060 x.120
39	2	BI	RS1206820285005		X				RES 82K 5% 1/8W SMD (R24-25)	2	.060 x.120
40											
41	2	BI	RS1206200385005		X				RES 200K 5% 1/8W SMD (R18,20)	2	.060 x.120
42	3	BI	RS1206750385005		X				RES 750K 5% 1/8W SMD (R1,19,21)	3	.060 x.120
43											
44	4	NA	OMITTED		X				RES OMIT 5% 1/8W SMD (R17,23,41,53)	4	.060 x.120
45											
46											
47	1	PP	ST4A-202		X				TRIMPOT 2K 1T SMD (P5)	1	METCOPAL
48	1	PP	ST4A-502		X				TRIMPOT 5K 1T SMD (P6)	1	METCOPAL
49	1	PP	ST4A-103		X				TRIMPOT 10K 1T SMD (P7)	1	METCOPAL
50											
51	2	PP	ST4A-203		X				TRIMPOT 20K 1T SMD (P4,8)	2	METCOPAL

PARTS LIST

PL - 105081 Rev B

TITLE: CDUSS TRANSCEIVER ASSEMBLY | MODEL # TR68 |

ITEM	QTY	CD	PART NUMBER	INDENTURE 0	1	2	3	4	DESCRIPTION (REFERENCE NUMBERS)	TOTAL QTY	MANUFACTURER/SPEC
52	1	PP	ST4A-503		X				TRIMPOT 50K 1T SMD (P3)	1	METCOPAL
53	2	PP	ST4A-104		X				TRIMPOT 100K 1T SMD (P1-2)	2	METCOPAL
54											
55											
56											
57	1	BI	CS0805N1R55017		X				CAP 1.5p ± .25p 50V NPO SMD (C25)	1	.050 x .080
58	4	BI	CS0805N6R85015		X				CAP 6.8p ± .5p 50V NPO SMD (C18,22,38,58)	4	.050 x .080
59	1	BI	CS0805N1805005		X				CAP 18p 5% 50V NPO SMD (C70)	1	.050 x .080
60											
61	2	BI	CS0805N5105005		X				CAP 51p 5% 50V NPO SMD (C71-72)	2	.050 x .080
62	1	BI	CS0805N5605005		X				CAP 56p 5% 50V NPO SMD (C59)	1	.050 x .080
63	3	BI	CS0805N1015005		X				CAP 100p 5% 50V NPO SMD (C85,96-97)	3	.050 x .80
64											
65	2	BI	CS1206N1815005		X				CAP 180p 5% 50V NPO SMD (C101-102)	2	.060 x .120
66	2	BI	CS1206N2715005		X				CAP 270p 5% 50V NPO SMD (C35,37)	2	.060 x .120
67	1	BI	CS1206N3315005		X				CAP 330p 5% 50V NPO SMD (C36)	1	.060 x .120
68	39	BI	CS1206N1025005		X				CAP 1000p 5% 50V NPO SMD (C9-12,14,17,20-21,) (24,26-27,29-30,32-33,63-64,68-69,73-74,81,84,) (87-90,92-93,95,98-100,103-105,107-109)	39	.060 x.120
69											
70	23	BI	CS1206B1035010		X				CAP .01u 5% 50V X7R SMD (C39-46,48-52,54-57,) (61-62,82,86,91,106)	23	.060 x .120
71											
72	17	BI	CS2413T1061620		X				CAP 10u 20% 16V Ta SMD (C1-8,13,31,47,) (53,77-80,83)	17	.130 x .240
73											
74	3	NA	OMITTED		X				CAP OMIT 5% 50V NPO SMD (C15-16,65-67,75-76,94)	3	.060 x .120
75											
76											
77	5	PP	GKX30000		X				TRIMCAP 5-30p 1T SMD (C19,23,28,34,60)	5	SPRAGUE

PARTS LIST

PL - 105081 Rev B

TITLE: CDUSS TRANSCEIVER ASSEMBLY | MODEL / TR68 |

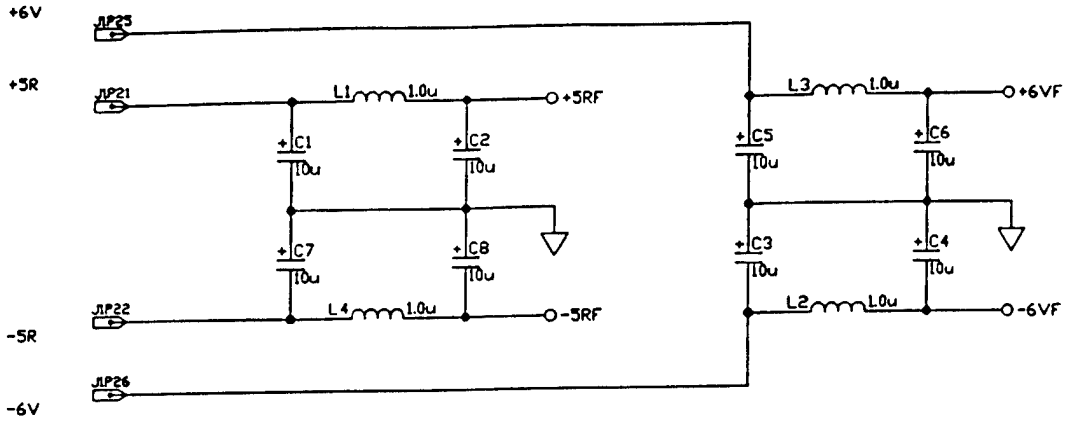
ITEM	QTY	CD	PART NUMBER	INDENTURE 0	1	2	3	4	DESCRIPTION (REFERENCE NUMBERS)	TOTAL QTY	MANUFACTURER/SPEC
78											
79											
80	1	CP	A105085		X				COIL TAPPED TOROID 3T/5T (L22)	1	KI
81	1	PP	T25-12			X			CORE TOROID 12uH/100T .255 dia.	1	MICROMETALS
82	AR	BI	26 AWG			X			WIRE MAGNET	AR	GENERIC
83											
84											
85	1	PP	SM3-047K		X				INDUCTOR .047u 10% SMD (L15)	1	GOWANDA
86	3	PP	SM3-068K		X				INDUCTOR .068u 10% SMD (L7-9)	3	GOWANDA
87	1	PP	SM3-689K		X				INDUCTOR .68u 10% SMD (L20)	1	GOWANDA
88											
89	15	PP	LEM45321ROM		X				INDUCTOR 1.0u 20% SMD (L1-6,10-11,13,16-19,21)	15	TAIYO YUDEN
90	1	PP	LEM45323R3K		X				INDUCTOR 3.3 10% SMD (L12)	1	TAIYO YUDEN
91	1	PP	OMITTED		X				INDUCTOR (L14)	1	
92											
93											
94	3	SD	B105086		X				FILTER 10.7 MHz SELECTED (FL1-3)	3	KI
95	3	PP	SFE10.7MA5-Z			X			FILTER 10.7 MHz x 280 KHz	3	
96											
97											
98											
99	3	PP	MMBD914T		X				DIODE SWITCHING SOT-23 (D8-10)	3	MOTOROLA
100	1	PP	MMBV3401L		X				DIODE PIN SWITCHING SOT-23 (D1)	1	MOTOROLA
101	6	PP	MMBV409		X				DIODE VARACTOR SOT-23 (D2-7)	6	MOTOROLA
102	2	PP	SMV-1202-08		X				DIODE HYPER TUNE VARACTOR SOT-23 (D11-12)	2	ALPHA
103	3	NA	OMITTED		X				DIODE (D13-15)	3	
104											
105											

PARTS LIST

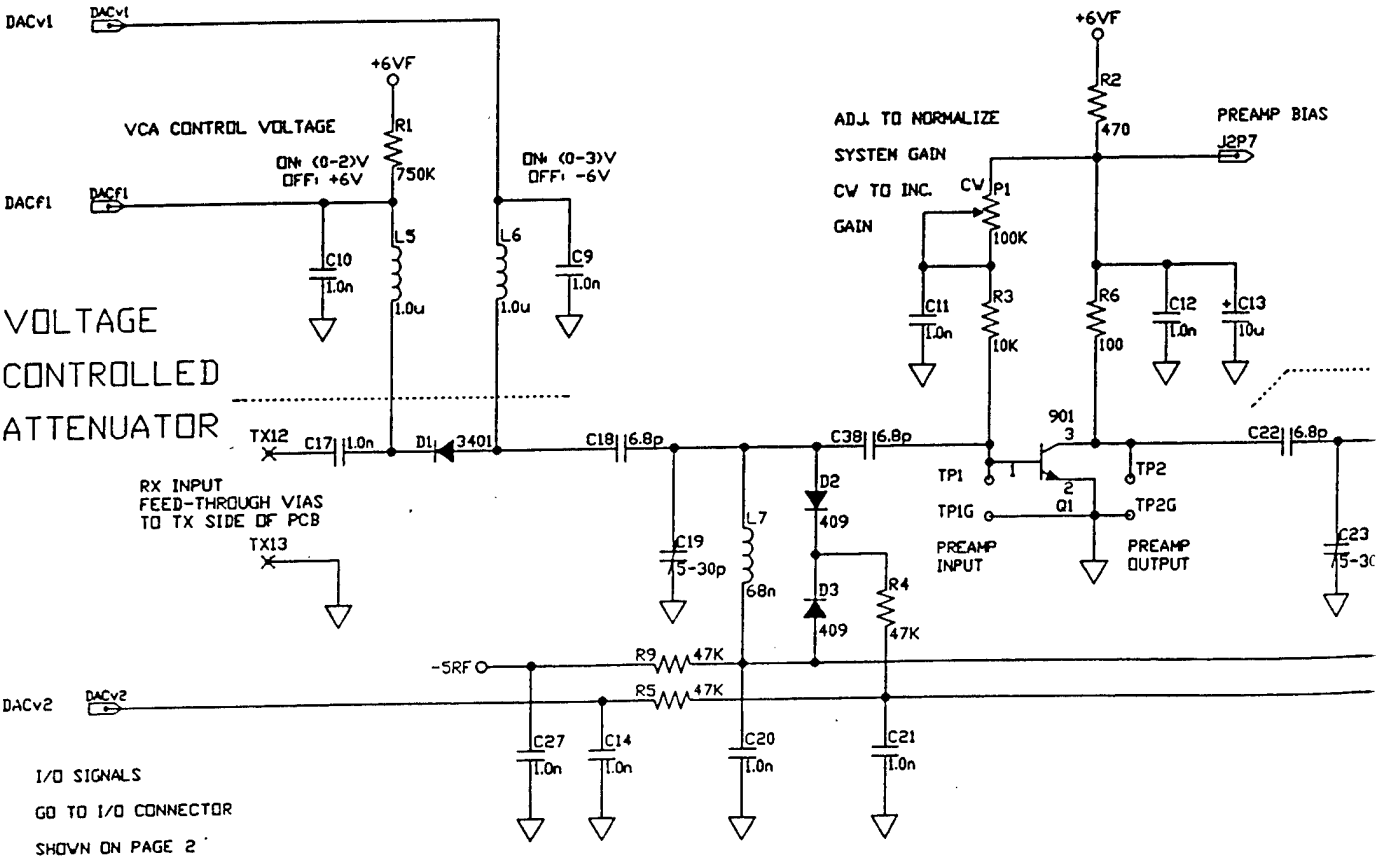
PL - 105081 Rev B

TITLE: CDUSS TRANSCEIVER ASSEMBLY | MODEL # TR6B |

ITEM	QTY	CD	PART NUMBER	INDENTURE					DESCRIPTION (REFERENCE NUMBERS)	TOTAL QTY	MANUFACTURER/SPEC
				0	1	2	3	4			
106	2	PP	MMBR901		X				TRANSISTOR RF BIPL NPN SOT-23 (Q1,6)	2	MOTOROLA
107	1	PP	MFRQ17		X				TRANSISTOR RF BIPL NPN SO-8 (Q5)	1	MOTOROLA
108	3	PP	ZVP3306F		X				TRANSISTOR P-FET 60V SOT-23 (Q2-4)	3	FERRANTI
109											
110	1	NA	OMITTED		X				TRANSISTOR (Q7)	1	
111											
112											
113											
114											
115	1	PP	929647-02-36		X				CONNECTOR 20-PIN MALE VERT. (J2) (DIGI-KEY #929647-02-36-ND, CUT TO LENGTH NEEDED)	1	3M
116	1	PP	SSM-120-S-DH		X				CONNECTOR DUAL 40-PIN FEM HORIZ SMD (J1)	1	SAMTEC
117	4	MP	9619E-SS-0256		X				STANDOFF 3/16 HEX x .625L SWAGE FEMALE	4	AMATOM
118											
119											
120	1	CP	B105080		X				PCB TRANSCEIVER CDUSS	1	KI
121											
122											
123	AR	BI	SN63		X				SOLDER Sn63/Pb37	AR	GENERIC
124											
125											
126	1	RD	B105074		X				SCHEM - TRANSCEIVER CDUSS	1	KI
127											
128											
129											
130											
131											
132											



POWER SUPPLY FILTERING



I/O SIGNALS
GO TO I/O CONNECTOR
SHOWN ON PAGE 2
I/O SIGNALS DACv5, +5V, +VTX, OPT1 - OPT6
ARE SHOWN ON THE TX SCHEM. (PG 3).

INPUT FILTER

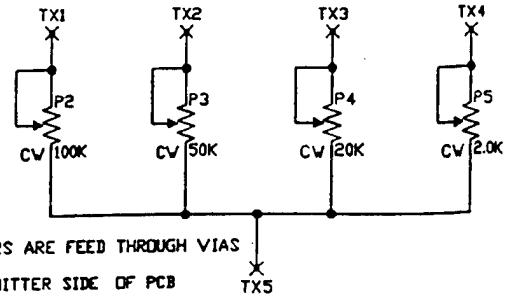
VOLTAGE GAIN > -3db
BW3db = 8MHz

PREAMP

GAIN (16-18)db
NF = 2db

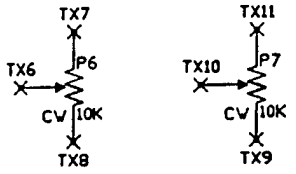
Rev A: See E.O. #91-002. SEA 6-21-91 WJM 6-21-91
Rev B: ON PG. 3, OMITTED C66-67, C75-76, C94, D13-15, & L14. SEA 6-6-94

TRANSMIT POWER ADJUST POTS



TX NUMBERS ARE FEED THROUGH VIAS TO TRANSMITTER SIDE OF PCB

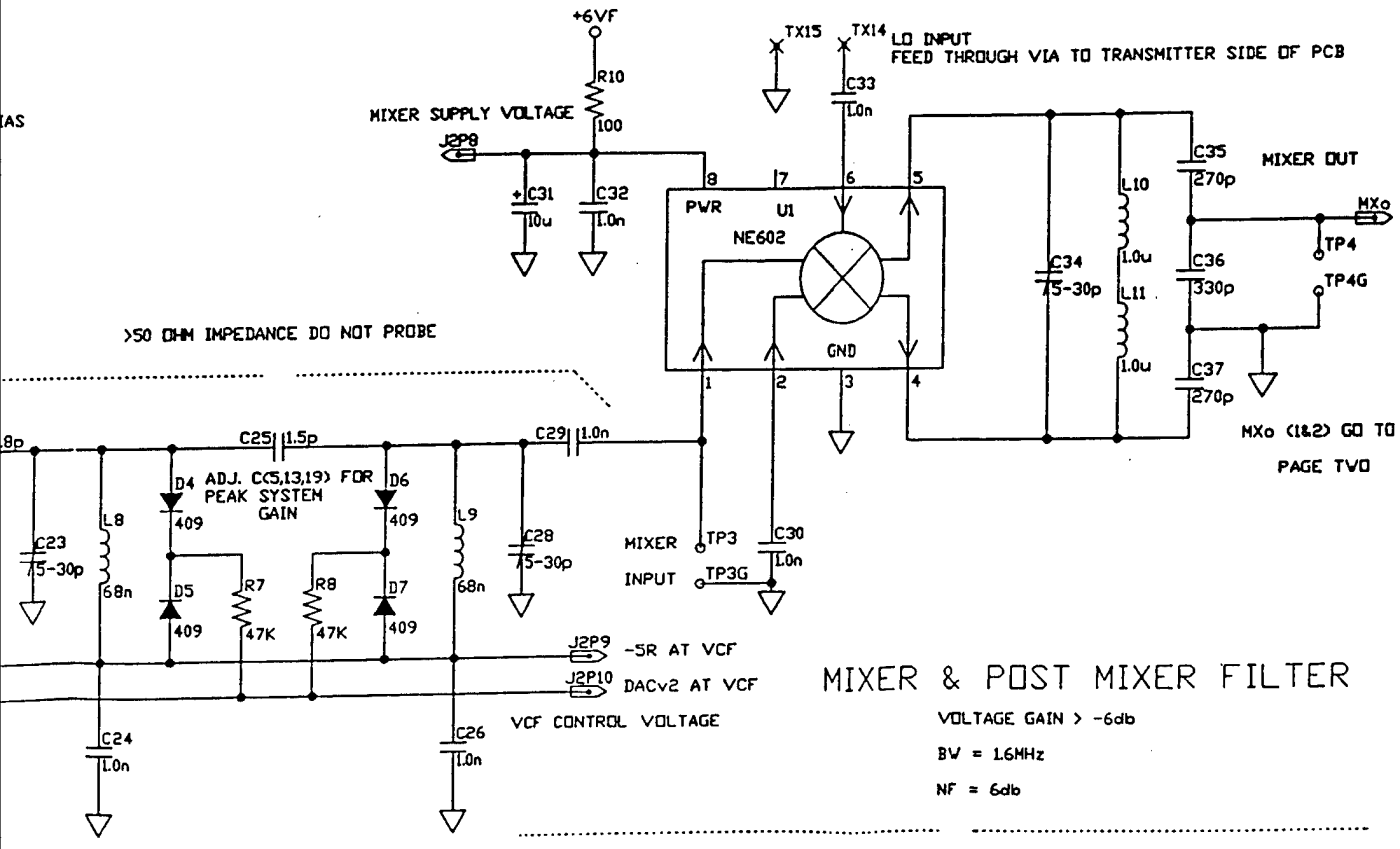
VCO ADJUST POTS



SPAN ADJUST

OFF-SET ADJUST

CW WILL INCREASE SPAN AND OFF-SET



MIXER & POST MIXER FILTER

VOLTAGE GAIN > -6db

BW = 1.6MHz

NF = 6db

POST PREAMP FILTER

VOLTAGE GAIN > 6DB

BW3db = 8MHz

DEVICE NAMES:

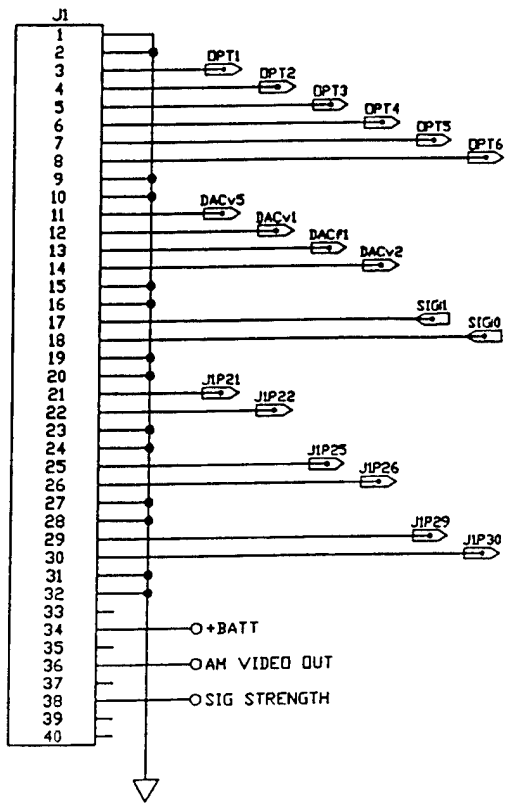
C 1-14,17-38
D 1-7
J 1-2
L 1-11
P 1-7
Q 1
R 1-10
TP 1-4,1G-4G
TX 1-15
U 1

SCHEM - RECEIVER \ TRANSMITTER

B 105074 Rev B

RAA 10/88

(2)



ANT1 CONTROL
ANT2 CONTROL
10mV CONTROL
30mV CONTROL
100mV CONTROL
TRANSMIT ENABLE

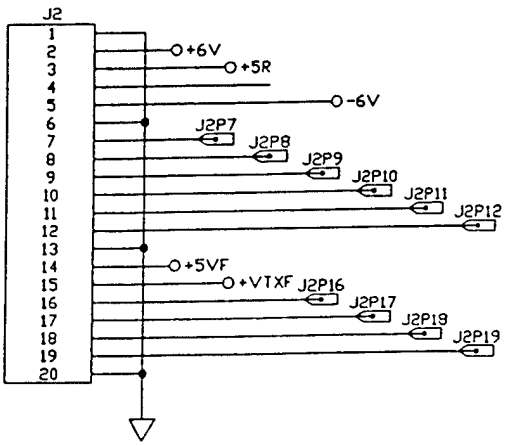
VCO CONTROL VOLTAGE
VCA CONTROL VOLTAGE
VCA CONTROL FEEDBACK
VCF CONTROL VOLTAGE

FM VIDEO OUTPUT
AM VIDEO OUTPUT

+5R = VIDEO REFERENCE
-5R = VCO REFERENCE

+6V = RECEIVER SUPPLY
-6V = VIDEO SUPPLY

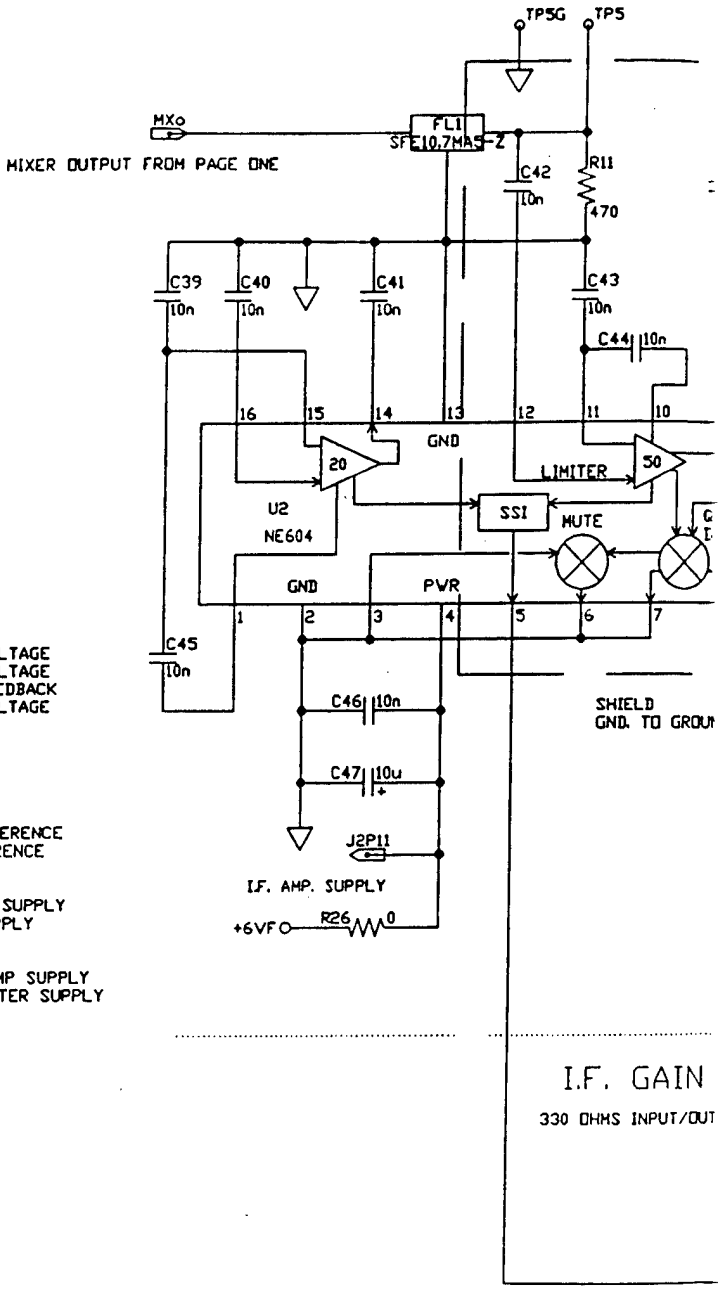
+VTX = POWER AMP SUPPLY
+VCC = TRANSMITTER SUPPLY



+6V ON-BOARD
+5R ON-BOARD
-5R ON-BOARD
-6V ON-BOARD

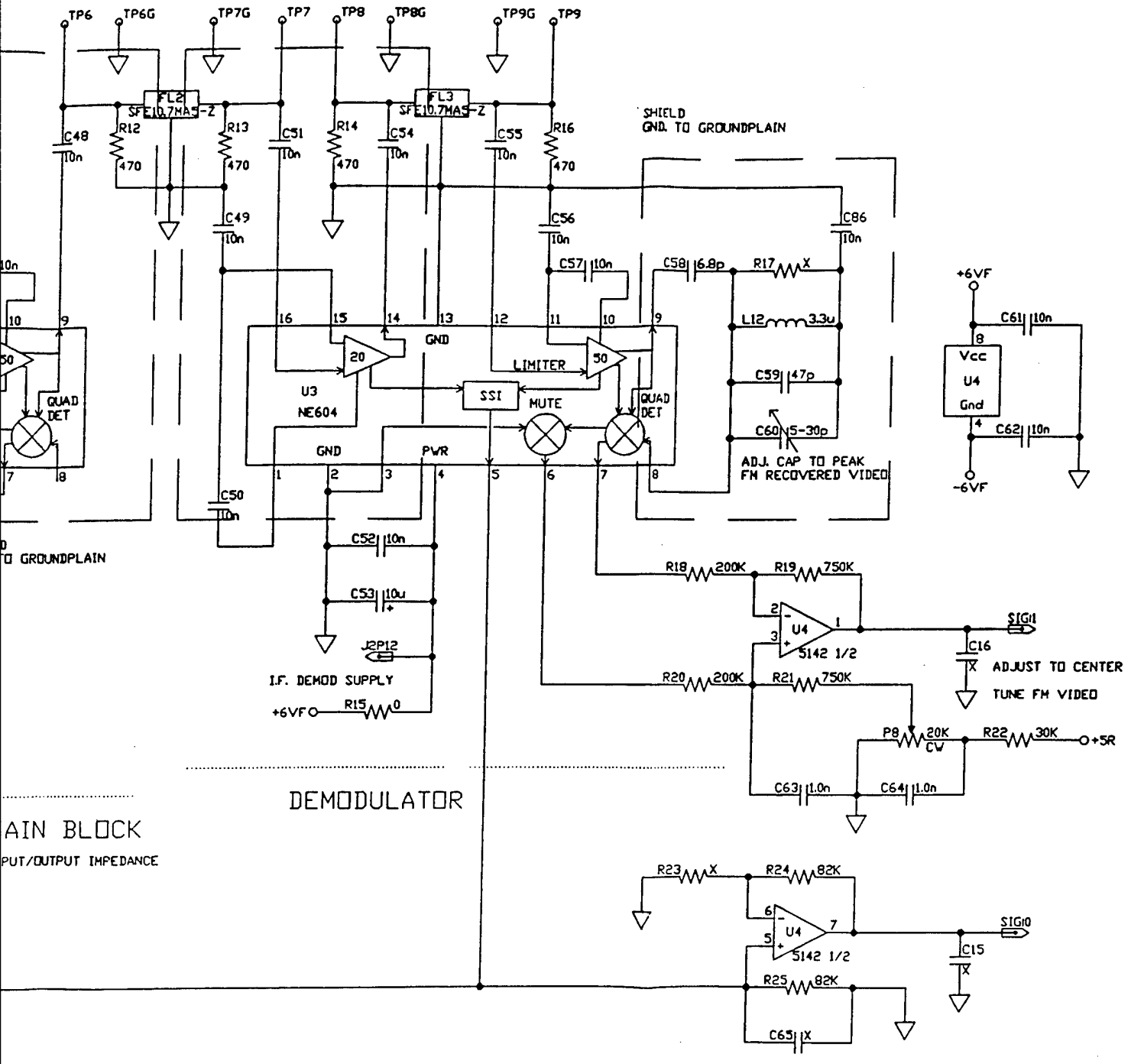
+6V AT RF PREAMP
+6V AT MIXER
-5R AT VCF
DACv2 AT VCF
+6V AT IF GAIN BLOCK
+6V AT IF DEMODULATOR

+5V ON-BOARD
+VTX ON-BOARD
+VTX AT POWER AMP
+5V AT PWR AMP DRIVER
+5V AT PRESCALER DRIVER
LO BIAS LEVEL



I.F. GAIN

330 OHMS INPUT/OUT



DEMODULATOR

AIN BLOCK

PUT/OUTPUT IMPEDANCE

VIDEO SCALING AND TEMP. COMP. CIRCUIT

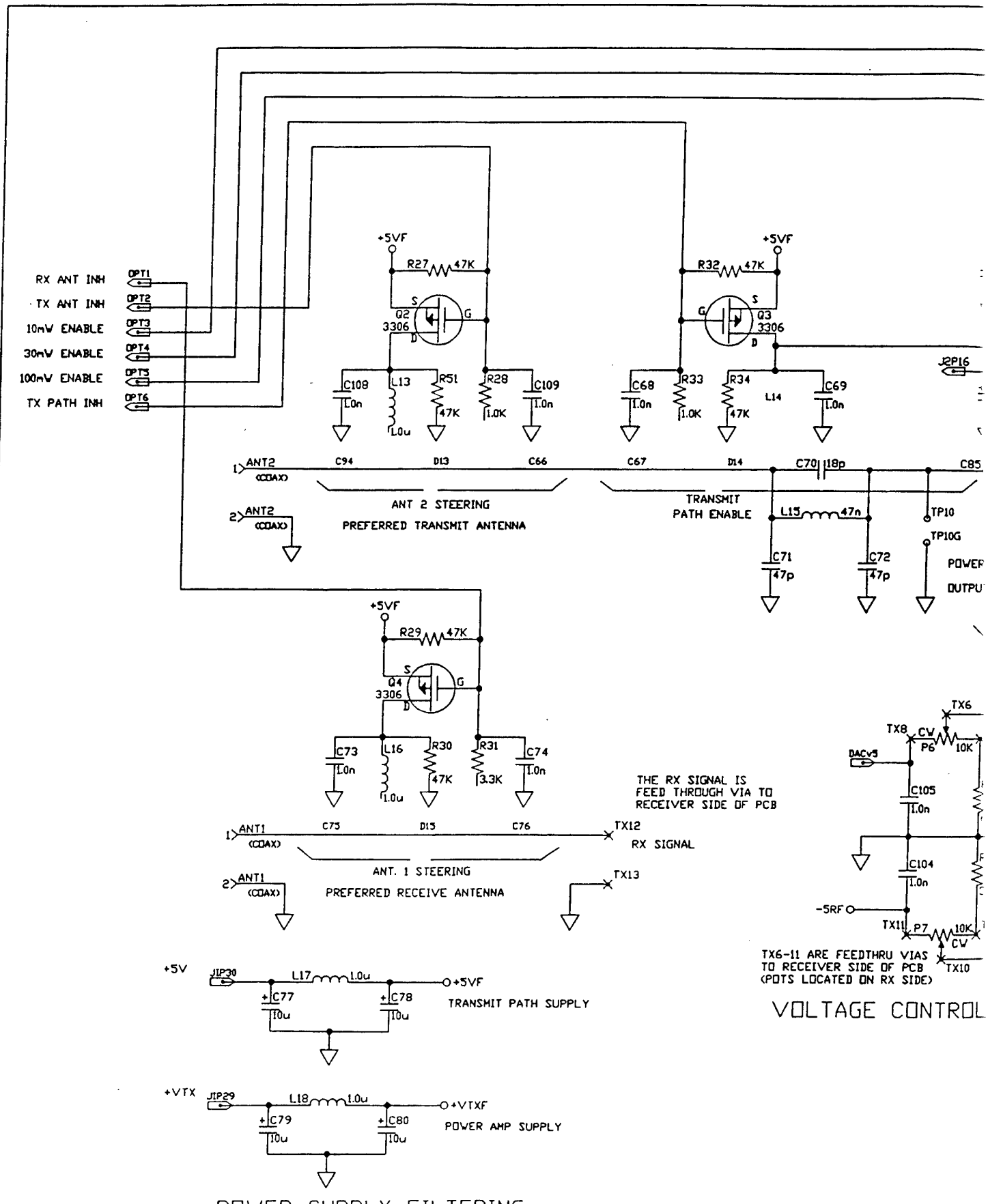
DEVICE NAMES:

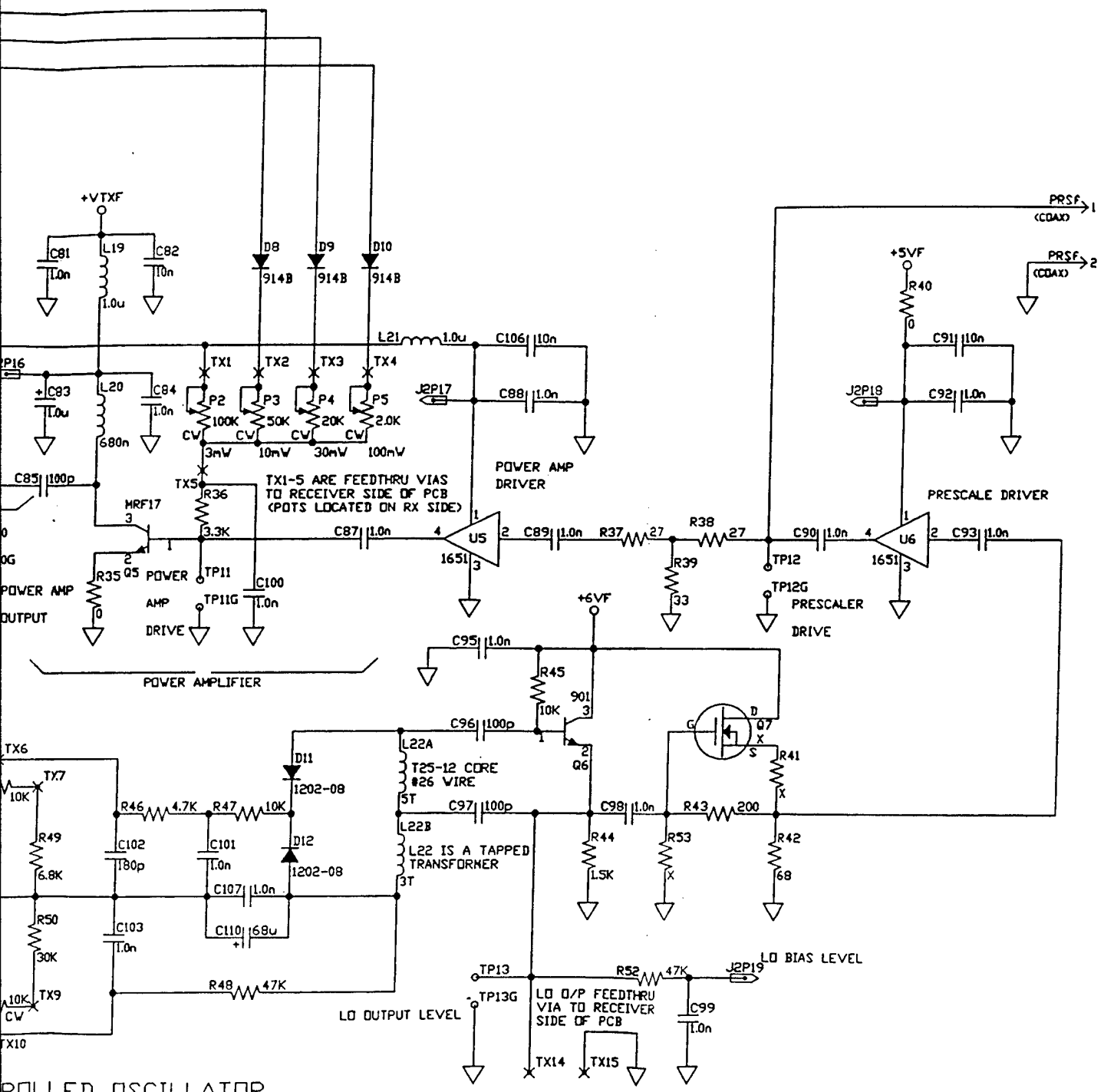
C 15-16,39-65,86
D
FL 1-3
J 1,2
L 12
P 8
Q
R 11-26
TP 5-9,5G-9G
TX
U 2-4

SCHEM - RECEIVER \ TRANSMITTER

B 105074 Rev B

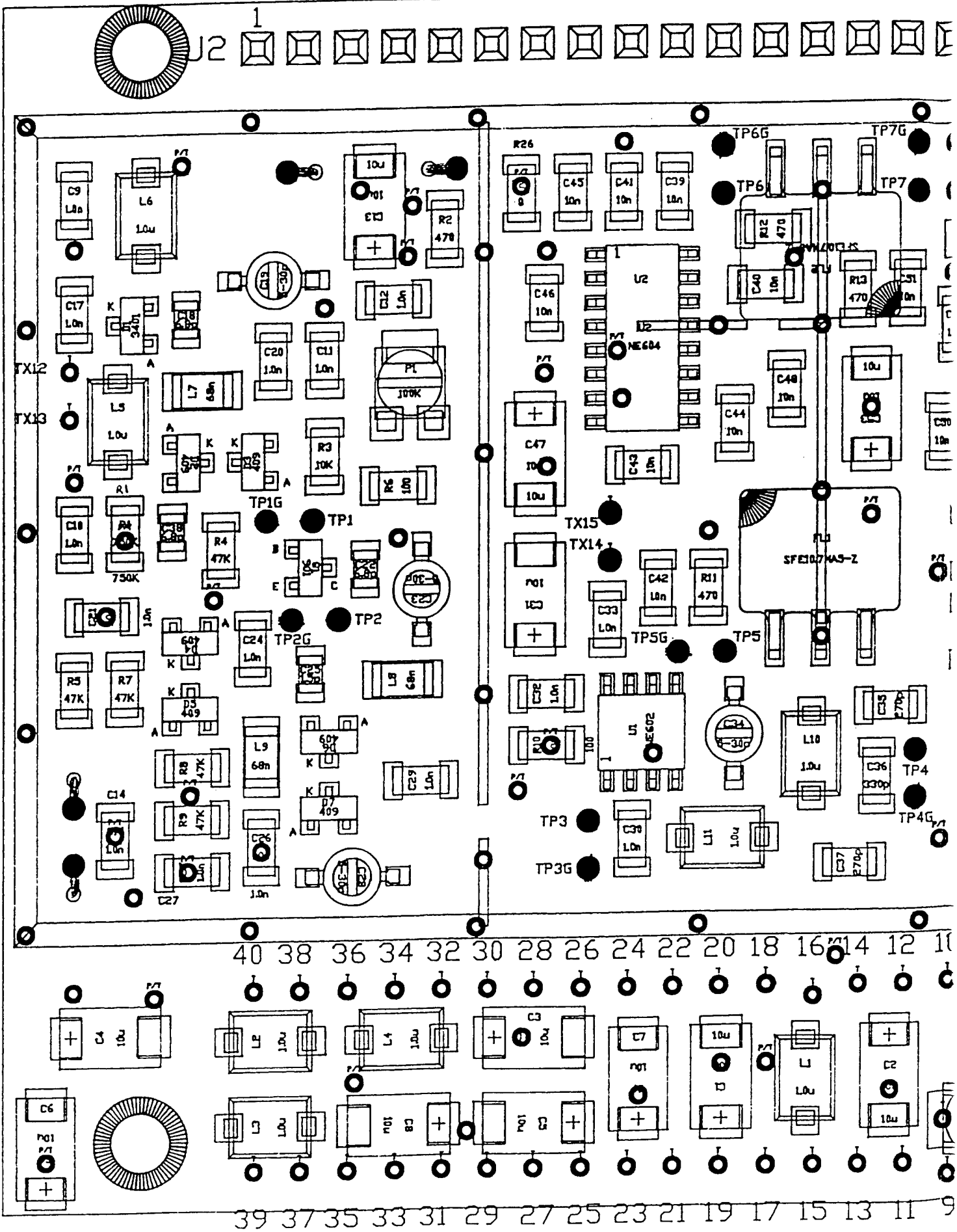
RAA 10/88


RX ANT INH
TX ANT INH
10mW ENABLE
30mW ENABLE
100mW ENABLE
TX PATH INH
OPT1
OPT2
OPT3
OPT4
OPT5
OPT6
+5VF
R27 47K
Q2 3306
C108 1.0n
L13 1.0u
R51 47K
R28 1.0K
C109 1.0n
R32 47K
Q3 3306
C68 1.0n
R33 1.0K
R34 47K
L14
C69 1.0n
J2P16
ANT2 (COAX)
C94
DL3
C66
C67
D14
C70 18p
C85
ANT 2 STEERING
PREFERRED TRANSMIT ANTENNA
TRANSMIT PATH ENABLE
L15 47n
TP10
TP10G
C71 47p
C72 47p
POWER OUTPU
R29 47K
Q4 3306
C73 1.0n
L16 1.0u
R30 47K
R31 3.3K
C74 1.0n
ANT1 (COAX)
C75
D15
C76
TX12
RX SIGNAL
ANT. 1 STEERING
PREFERRED RECEIVE ANTENNA
TX13
THE RX SIGNAL IS FEED THROUGH VIA TO RECEIVER SIDE OF PCB
TX6
TX8
CW
P6
10K
DACV3
C105 1.0n
C104 1.0n
-5RF
TX11
P7
10K
CW
TX10
TX6-11 ARE FEEDTHRU VIAS TO RECEIVER SIDE OF PCB (POTS LOCATED ON RX SIDE)
VOLTAGE CONTROL
+5V
J1P30
L17 1.0u
+5VF
C77 10u
C78 10u
TRANSMIT PATH SUPPLY
+VTX
J1P29
L18 1.0u
+VTXF
C79 10u
C80 10u
POWER AMP SUPPLY
POWER SUPPLY FILTERING

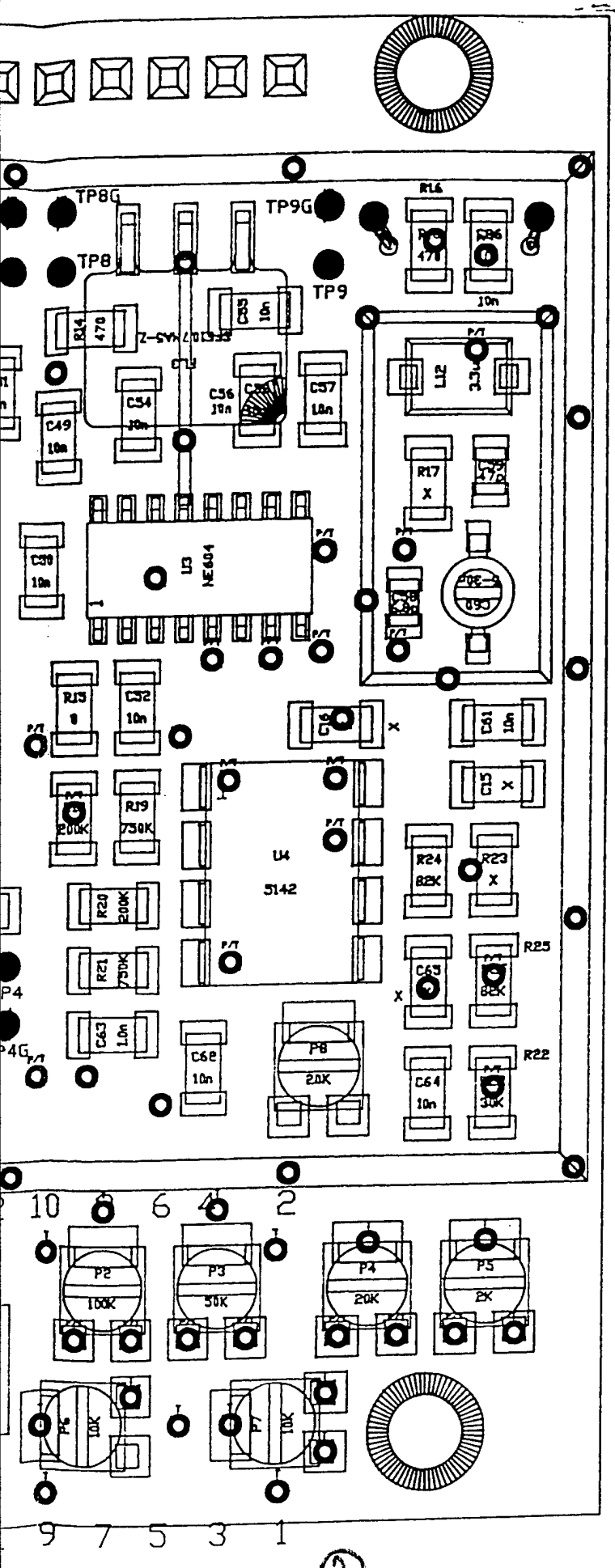


ROLLED OSCILLATOR

DEVICE NAMES:	SCHEM - RECEIVER \ TRANSMITTER
C64-85, 87-110 D 8-15 J 1, 2 L 13-22 P Q 2-7 R 27-53 TP 10-13, 10G-13G TX 1-15 U 5-6	B105074 Rev B
RAA 10/88	PAGE 3 OF 3


U2
1
TP6G
TP7G
TP6
TP7
TX12
TX13
TP1G
TP1
TP2G
TP2
TX15
TX14
TP5G
TP5
TP3
TP3G
TP4
TP4G
U2
NE604
SFE10.7MA5-Z
40 38 36 34 32 30 28 26 24 22 20 18 16 14 12
39 37 35 33 31 29 27 25 23 21 19 17 15 13 11 9

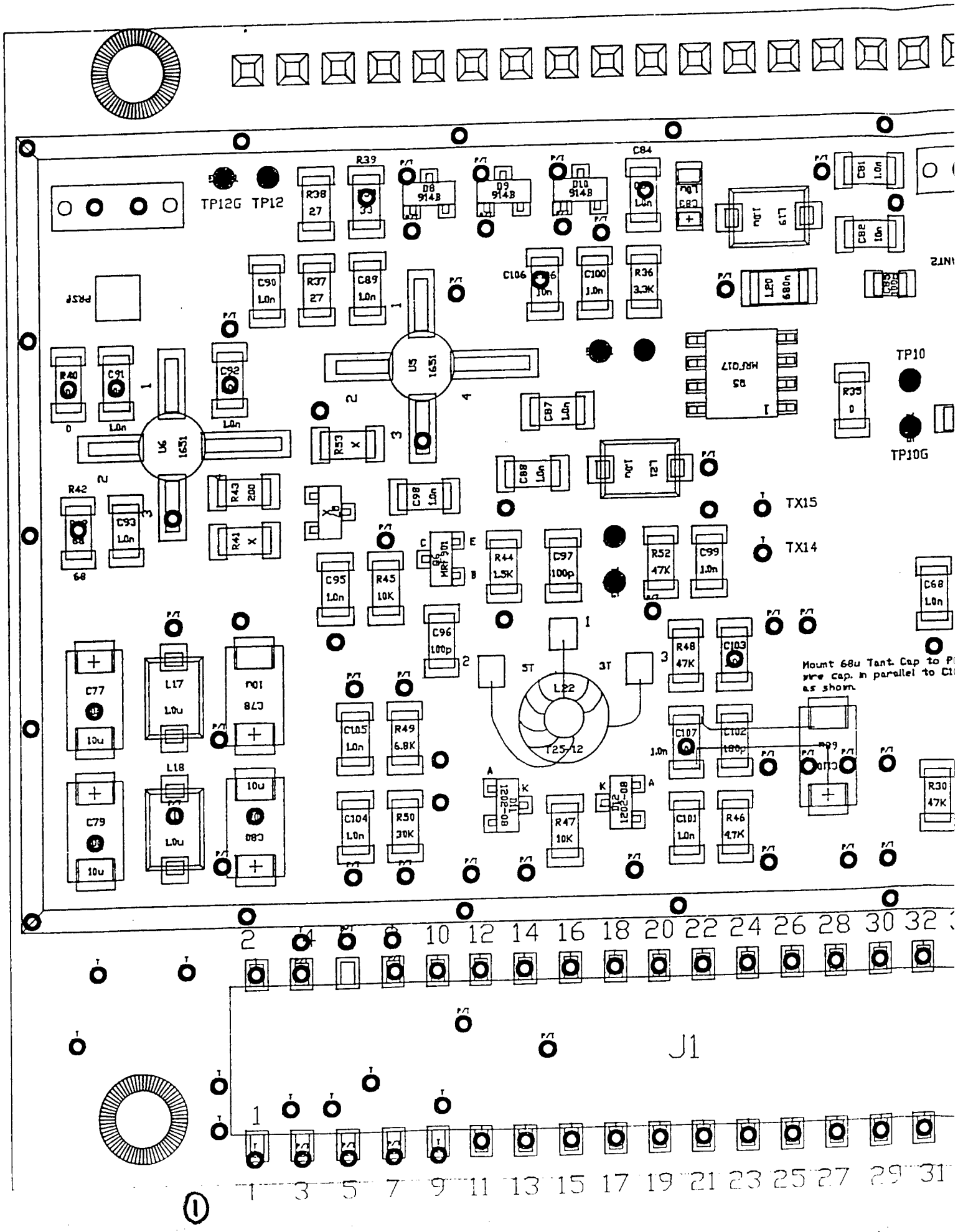
REV. B ON PG 2 - REMOVED C99, C66-67, C75-76, D13-15, & U4.
ADDED 2 JUMPERS TO THOSE AREAS. SEA 6-4-99

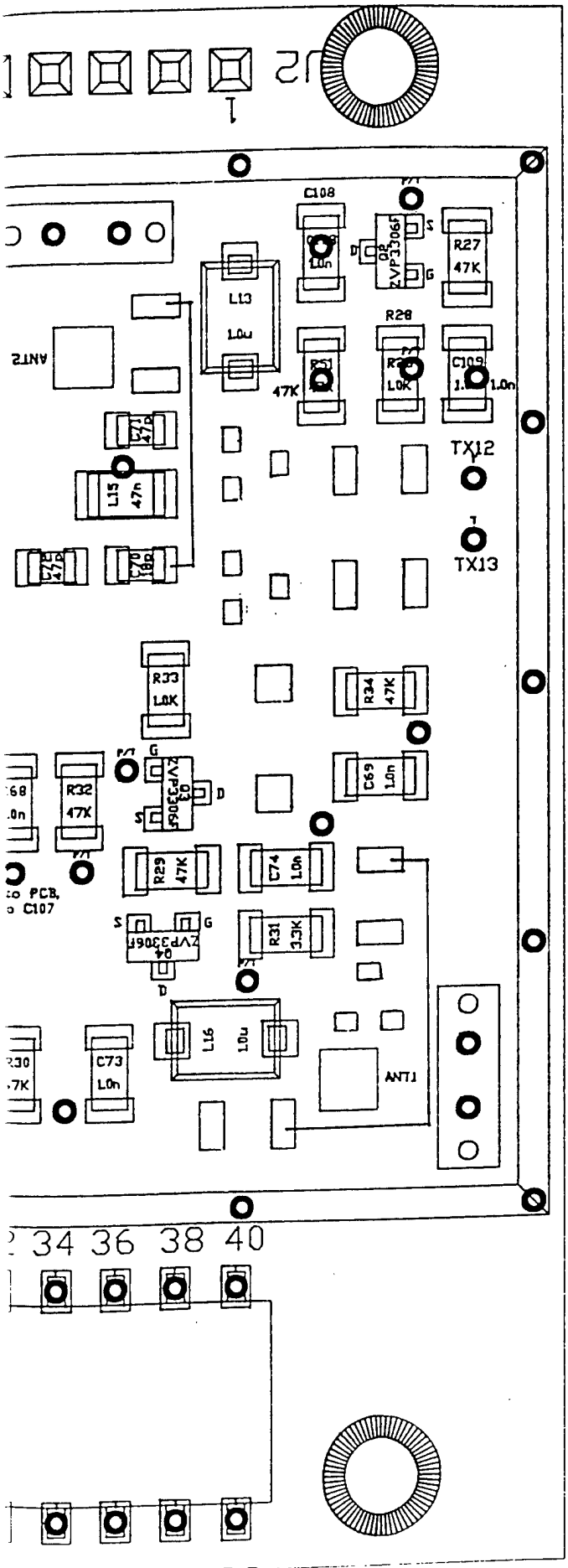


ASS'Y- TXR (RX SIDE)

B.105081 Rev. B

SCALE: — PG. 1 of 2


TP12G
TP12
R39
R38
27
33
D8
914B
D9
914B
D10
914B
C84
C81
1.0n
C82
1.0n
L19
1uH
C83
1.0n
C90
1.0n
R37
27
C89
1.0n
C106
10n
C100
1.0n
R36
3.3K
L20
680n
C85
1.0n
PRSF
U5
1651
MRF017
TP10
TP10G
R35
0
R40
0
C91
1.0n
C92
1.0n
U6
1651
C87
1.0n
R53
X
C88
1.0n
L21
1uH
R42
68
C93
1.0n
R43
200
R41
X
C98
1.0n
TX15
TX14
C95
1.0n
R45
10K
MRF901
R44
1.5K
C97
100p
R52
47K
C99
1.0n
C68
1.0n
C96
100p
R48
47K
C103
1.0n
C77
10u
L17
1.0u
D7
C78
C105
1.0n
R49
6.8K
L22
T25-12
C107
1.0n
C102
100p
R99
0
C79
10u
L18
1.0u
C80
10u
C104
1.0n
R50
30K
BB-202
D11
R47
10K
D12
1202-08
C101
1.0n
R46
4.7K
R30
47K
Mount 68u Tant. Cap to P
wire cap. in parallel to C1
as shown
J1
2 4 6 8 10 12 14 16 18 20 22 24 26 28 30 32
1 3 5 7 9 11 13 15 17 19 21 23 25 27 29 31
1



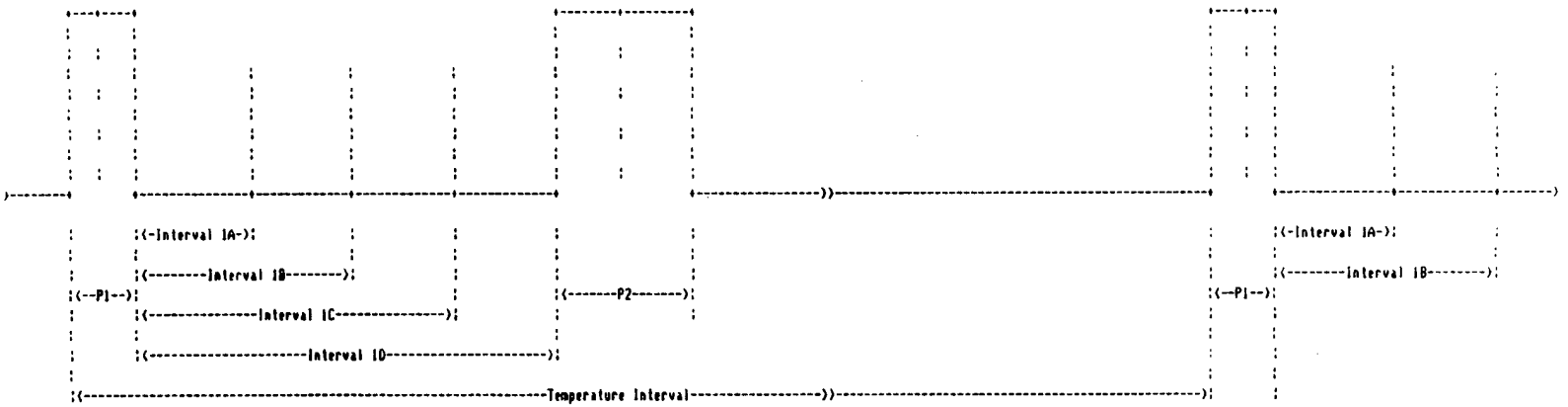
ASS'Y - TXR (TX SIDE

B105081 Rev B

SCALE: — PG. 2 of 2

(2)

REVISIONS				
E.O. #	LTR	DESCRIPTION	DATE	APPROVED
	A	CHANGED TEMP INTERVAL DEF.	22 MAY 89	u/M
	B	CHNGD INT 1 DEF., 34° TO 40° WAS 32°-40°	8 JUN 89	u/M
	C	CHANGED INT 1 DEFINITIONS	10 NOV 89	u/M



Each T2D will be programmed with one of 8 possible Identity Codes. The following definitions may be assumed from 34°C to 40°C:

ID Code #	P1 Pulse Width	P2 Pulse Width	Interval Used	Interval Length 34° C to 40° C	Nominal Int @ 37° C
1	10 uS to 15 uS	20 uS to 35 uS	Interval 1A	10 uS (Int(23 uS	16
2	10 uS to 15 uS	20 uS to 35 uS	Interval 1B	23 uS (Int(40 uS	30
3	10 uS to 15 uS	20 uS to 35 uS	Interval 1C	40 uS (Int(67 uS	52
4	10 uS to 15 uS	20 uS to 35 uS	Interval 1D	67 uS (Int(105 uS	86
5	16 uS to 22 uS	36 uS to 60 uS	Interval 1A	10 uS (Int(23 uS	16
6	16 uS to 22 uS	36 uS to 60 uS	Interval 1B	23 uS (Int(40 uS	30
7	16 uS to 22 uS	36 uS to 60 uS	Interval 1C	40 uS (Int(67 uS	52
8	16 uS to 22 uS	36 uS to 60 uS	Interval 1D	67 uS (Int(105 uS	86

Temperature Encoding is contained in the P1 leading-edge to P1 (or P2 to P2) leading-edge frame.

37 degrees C = 500 Hz +/- 100 Hz (2 mS +500 uS/ -333 uS)

Slope = 20 Hz +/- 4 Hz per degree C

Linearity = within 0.1 degree C from 34 degrees C to 40 degrees C.

NEXT DWG.	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES TOLERANCES ARE:
FRACTIONS DECIMALS ANGLES
± .XX ± ±
.XXX ±

MATERIAL

FINISH

DO NOT SCALE DRAWING

CONTRACT NO.

APPROVALS	DATE
DRAWN u/M	6 APR 89
CHECKED	

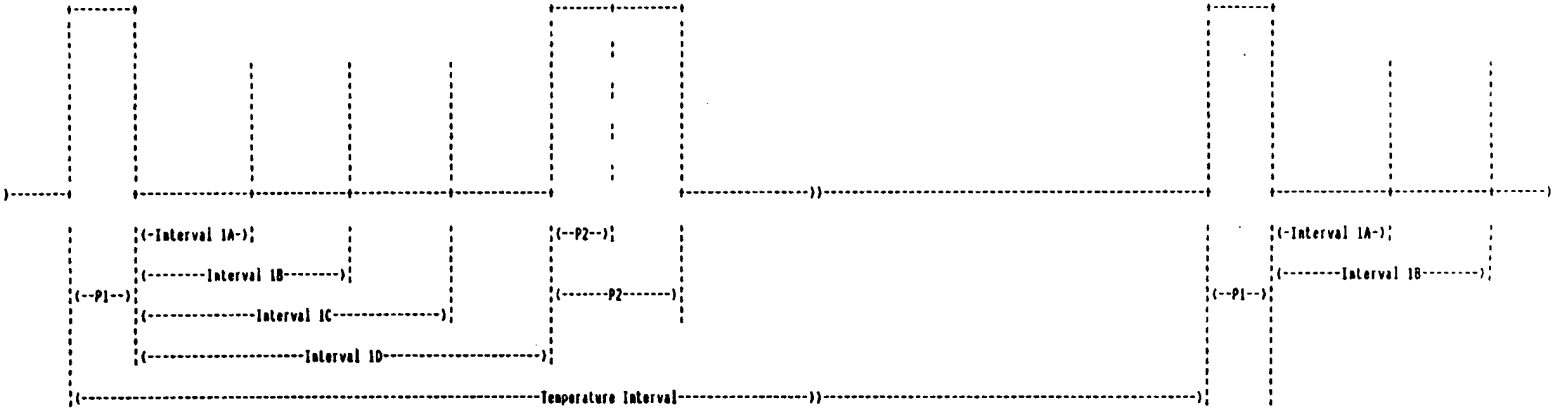
KONIGSBERG INSTRUMENTS INC.
2000 E. FOOTHILL BL. PASADENA, CA. 91107

SPECIFICATION: T2D SYSTEM

SIZE	CODE IDENT NO.	DRAWING NO.	REV
B		105157	C

SCALE SHEET OF

REVISIONS				
E.O. #	LTR	DESCRIPTION	DATE	APPROVED



Each T2F will be programmed with one of 8 possible Identity Codes. The following definitions may be assumed from 34°C to 40°C:

ID Code #	P1 Pulse Width	P2 Pulse Width	Interval Used	Interval Length 34° C to 40° C	Nominal Int @ 37° C
1	16 uS to 22 uS	20 uS to 35 uS	Interval 1A	10 uS to 23 uS	16
2	" "	20 uS to 35 uS	Interval 1B	23 uS to 40 uS	30
3	" "	20 uS to 35 uS	Interval 1C	40 uS to 67 uS	52
4	" "	20 uS to 35 uS	Interval 1D	67 uS to 110 uS	86
5	" "	36 uS to 60 uS	Interval 1A	10 uS to 23 uS	16
6	" "	36 uS to 60 uS	Interval 1B	23 uS to 40 uS	30
7	" "	36 uS to 60 uS	Interval 1C	40 uS to 67 uS	52
8	16 uS to 22 uS	36 uS to 60 uS	Interval 1D	67 uS to 110 uS	86

Temperature Encoding is contained in the P1 leading-edge to P1 (or P2 to P2) leading-edge frame.

37 degrees C = 500 Hz +/- 100 Hz (2 uS +500 uS/ -333 uS)

Slope = 20 Hz +/- 4 Hz per degree C

Linearity = within 0.1 degree C from 34 degrees C to 40 degrees C.

	T2F
NEXT DWG	USED ON
APPLICATION	

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES
TOLERANCES ARE:
FRACTIONS DECIMALS ANGLES
± .XX ± ±
.XXX °

MATERIAL

FINISH

DO NOT SCALE DRAWING

CONTRACT NO.

APPROVALS	DATE
DRAWN	29 NOV 94
CHECKED	3/29/94

KONIGSBERG INSTRUMENTS INC.
2000 E. FOOTHILL BL. PASADENA, CA. 91107

TIMING DIAGRAM - T2F

SIZE	CODE IDENT NO	DRAWING NO.	REV
B		107213	N/R

SCALE —

SHEET 1 OF 1

Appendix 2 Data Packet Format

Byte	Name	Description
1.	Header value always	"0B"
2.	Source	"01" for belt units
3.	UnitNo	e.g., "00" for belt unit #00
4.	Status	"7E" - Pill is not found and the battery is low
		"FE" - Pill is not found and the battery is not low
		"7F" - Pill is found and the battery is low
		"FF" - Pill is found and the battery is not low
5.	HPI	High Order Byte of Pill Data
6.	LPI	Low Order Byte of Pill Data
7.	ACT	Actigraph Data Byte
8.	ST1	Skin Sensor #1 (blue thermistor)
9.	ST2	Skin Sensor #2 (green thermistor)
10.	ST3	Skin Sensor #3 (red thermistor)
11.	ST4	Skin Sensor #4 (red thermistor)
12.	HR	Heart Rate
13.	XOR	Check sum unique for each packet

Appendix 3 Data File Format

The following is the format of the file (username.ALD) created by RTITEST menu option "S".

Start	End	Description
1	4	A four byte number representing the number of seconds elapsed since midnight after belt unit initialization.
5	6	A two byte number indicating the epoch interval of logger recording, 1/100s of a second (e.g., 10 seconds = 1000).
7	8	A two byte number indicating the number of epochs elapsed.
9	12	A four byte number indicating the absolute address of logger memory for the last write.
13	13	The unit identification number.
14	16	Not currently used.

```
American Automation Cross-Assembler 68HC11 9.04.04
Assembly date: 30 Apr 1993
Assembly time: 17:28:32
Options in effect:expand format list macro object xreffile errorfile

0001                        ; Version 306 -- 4/30/93 -- by swh to add SkinTemp4 adc channel.  This
0002                        ;      comes in via SMP2 == ADC ch 2 == PORTE.bit2, which formerly
0003                        ;      carried the signal LOBAT.
0004                        ;      LOBAT now comes via ICAP (IBI) = (ic4/oc5) = PORTA.bit3
0005                        ;      The additional datum (SkinTemp4) is inserted before the Heartrate
0006                        ;      datum in the data packet.
0007                        ;
0008                        ;  NOTE -- need major overhaul of logger update address calculation to
0009                        ;       allow seamless flow of logged packets across the Bank0/Bank1
0010                        ;       boundary, plus a mechanism for supplying bank# for monitor
0011                        ;       logger queries.  THIS VERSION WILL USE ONLY BANK0 AND WILL
0012                        ;       STOP LOGGING WHEN THE NEXT SCHEDULED UPDATE WOULD CAUSE A
0013                        ;       BANK TRANSITION (WHICH WITH THIS CODE, WOULD APPEAR TO BE AN
0014                        ;       IMMINENT WRAPAROUND).
0015
0016                        ; Version 305 -- 5/15/92 by dpr to change method of sweeping vco during
0017                        ;  transmits, for relays as well as belt units.  This is a mod of pt303 and
0018                        ;  pt304, the latter being a change of the relay id tag.  Several default values
0019                        ; are changed for operation at 91 MHz, 9600 baud.
0020
0021                        ; Version 302 -- just like 301 but with corrections to make the base
0022                        ;  station modes work (the problem was improper address info setup
0023                        ;  for "RxMessage" when invoked following OK carrier detect.
0024
0025                        ; VERSION 301 --
0026                        ;  just like version 300, but with changes you asked for implemented.
0027                        ;  Active display datum selection code is removed pending codespace
0028                        ;  availability, which should appear in version 400
0029                        ;
0030
0031                        ; ==>> INVESTIGATE THE FEASIBILITY/DESIRABILITY OF LETTING THE HOST
0032                        ;      HANDLE WHAT WOULD OTERWISE BE COMMANDS 3,4,5 (TOGGLE CARRIER
0033                        ;      INITUNIT&LOGGER, WRITE DISPLAY).  THE HOST, FOR ANY OF THESE FUNCS
0034                        ;      COULD PUT TUHE UNIT IN IDLE MODE, THEN DO THE FUNC BY I-O TO PORTS/
```

```
0035                ;       ADDRESSES (MCU/LOGGER) AS NEEDED, THEN RESET.  THE ONLY DIFFICULTY
0036                ;       WOULD BE DISPATCHING THE TX_DATA SUB-COMMAND OF CMD 3.
0037                ; NOTE TO MYSELF!!!!!!
0038                ;  IN VERSION 400, WHEN NON-REALTIME OPERATIONS (EG, CARRIER TEST, INIT, AND
0039                ;  DISPLAY CALIBRATE) ARE REMOVED FROM THE BFMS MONITOR AND LAID ON THE
0040                ;  HOST AS MACRO-DRIVEN ITERATIONS OF R/W MEMORY OPS, THERE REALLY SHOULD
0041                ;  BE A FLAG TO REMIND THE OPERATOR TO INIT BEFORE STARTING/RESUMING
0042                ;  "NORMAL" OPERATION, SINCE THE RESET-RECOVERY SCHEME OF THE LOGGER
0043                ;  CAN'T HANDLE LONG "TIMEOUTS" FOR OFFLINE ACTIVITIES. !!! IDEA !!!
0044                ;  INCLUDE "SYSCLOCK" IN THE LOGGER PACKETS.  THIS WOULD ALLOW TIMEOUTS OF
0045                ;  UP TO 655.36 SECONDS TO BE ACCOUNTED FOR.
0046
0047                ;TO DO -->> FOR VERSIONS 400+
0048                ;
0049                ;    1. SHOULD OBVIATE NEED FOR "TXVCOFUDGE" IN BASE(/REPEATER) UNITS
0050                ;          A) CENTERTUNE THE FM RECEIVER DURING PREAMBLE          -- OR --
0051                ;          B) DO A PEAK AM AMPLITUDE SEEK DURING THE PREAMBLE
0052                ; TEST -- THE SCI OUTPUT LINE FROM THE XILINX THAT TOGGLES THE VCO
0053                ;       NOW SITS AT ABOUT 2.2 VOLTS WHEN AT REST AND TOGGLES BITS
0054                ;       BETWEEN 0 & 5 VOLTS, AND AT U202 PIN 12, IT SITS AT ABOUT
0055                ;       2.5 VOLTS AND TOGGLES ABOUT +-.5 VOLT, WHICH IS, I THINK, WHAT
0056                ;       WE'VE BEEN SHOOTING FOR.
0057                ;
0058                ;        NOW I NEED TO SET UP A RECEIVER AND LOOK AT THE PACKETS
0059                ;        COMING IN TO SEE IF THEY LOOK RIGHT WHEN SENT CORRECTLY
0060                ;        BY THE TXR.
0061                ;        --> TXR SHOULD SEND A PREAMBLE BEFORE SWITCHING ON THE SCI
0062                ;            THEN SHOULD SEND THE PACKET.
0063                ;        --> RXR SHOULD SHOW THE FM VIDEO FLATTENING OUT OF THE NOISE AT
0064                ;            ABOUT CENTER SCALE, THEN SHIFT TO THE MARKING STATE FOR
0065                ;            AN IDLE BYTE TIME, THEN TOGGLE +/- AROUND THE LEVEL SEEN
0066                ;            DURING THE PREAMBLE.
0067                ;                                 _____   _         _   _
0068                ;            |||(NOISE)|||____|      | | |  ....  | | |  ___/|||(NOISE)|||
0069                ;            |||(NOISE)|||            |_| |_       |_| |_|     |||(NOISE)|||
0070                ;
0071
0072                ; Need to find a way to reflect trk sts for realtime pkts as well]
0073                ; as for logger pkts
0074
0075                ************************************************************************
```

```
0076                ************************************************************************
0077                ************************************************************************
0078                ** Program:  CDUSS firmware for uR standalone                          **
0079                ** Date:     1/31/90                                                 **
0080                ** Author:   Stanley W. Hall, Jr.                                    **
0081                **                                                                   **
0082                **          Special Studies Branch                                   **
0083                **          Department of Behavioral Biology                         **
0084                **          Walter Reed Army Institute of Research                   **
0085                **          Walter Reed Army Medical Center                          **
0086                **          Washington, DC  20307-5100                               **
0087                **          Phone: 301-427-5521                                      **
0088                **                                                                   **
0089                **          ****************************************                 **
0090                ** CAUTION FOR MODIFIERS/MAINTAINERS --                              **
0091                **  Modify at your peril!  To maximize function within minimal       **
0092                **  codespace this code combines extreme nonmodularity with          **
0093                **  flagrant use of beneficial side effects (thus violating every    **
0094                **  premise of maintainable programming.  Thoroughly trace the       **
0095                **  effects of ANY change on preceeding and succeeding code.         **
0096                **                                                                   **
0097                ** =======>>>>> BE SURE TO TRACE THE ACTUAL CODE RATHER THAN         **
0098                **               RELYING EXCLUSIVELY ON COMMENTS/DOCUMENTATION.      **
0099                **               COMMENTS ARE GENERALLY CORRECT AND UP TO DATE       **
0100                **               BUT, DUE TO CONSTANT REVISION, SOME MAY BE          **
0101                **               OUT OF SYNCH WITH ACTUAL CODE.  THIS IS MOST        **
0102                **               TO BE SO IN AREAS WHERE CODE HAS BEEN COMMENTED     **
0103                **               OUT BUT NOT REMOVED.                                **
0104                ************************************************************************
0105                ************************************************************************
0106                ************************************************************************
0107
0108
0109
0110                ; HISTORY --
0111                ;
0112                ; Version 3.00 = "PT3xx.<ext>"
0113                ;  Starting with version 3.00, the LCD data display and the datalogger
0114                ;  are supported.
0115                ;
0116                ;  I. Realtime data transmission
```

```
0117                ;     A.  Data packets transmitted via the radio from LapelUnits contain the
0118                ;         most recently acquired realtime value for each datasource reported.
0119                ;
0120                ;     B.  Transmission intervals are no longer limited to 255 timebase units.
0121                ;         The Tx interval comprises a fixed and a random portion.  The random
0122                ;         portion ranges between 0 and a maximum of 1, 3, 7, 15, 31, 63, 127
0123                ;         or 255 timebase units, depending on the value of "TxRndMsk".  The
0124                ;         fixed portion ("TxMinInt") may then be set between 0 and the 16bit
0125                ;         1's complement of "TxRndMsk".
0126                ;
0127                ;  II. Command monitor changes
0128                ;      A: Changed commands
0129                ;         1. Read/Write Memory (#1/#2) commands now support io to both the
0130                ;            datalogger and MCU memory address spaces.  These commands now
0131                ;            require a 24-bit (ie, 3-byte) address to specify the target byte.
0132                ;            The most-significant-byte MUST have a value of 0 or 1, to select
0133                ;            the MCU or datalogger memory address space, respectively. The
0134                ;            remaining bytes then access an address relative to the selected
0135                ;            address space.  NOTE: DO NOT USE VALUES OTHER THAN 0 OR 1 IN
0136                ;            THE MSB, SINCE UNPREDICTABLE SIDE EFFECTS MAY RESULT.
0137                ;
0138                ;         2. ToggleCarrier command has been changed to require as sequence
0139                ;            of bytes having values of 0 or 1 to turn the TXR off or on,
0140                ;            respectively (NOT the values of ASCII '0' and '1', as previously).
0141                ;            ANY OTHER received value exits the toggle loop via a soft reset.
0142                ;
0143                ;      B. New commands
0144                ;         1. A new command (#4) has been implemented to initialize the
0145                ;            datalogger (see description of datalogger control block under
0146                ;            Datalogger spport below). Proper init values are as follows
0147                ;
0148                ;            LogInitTime: host init time & date when cmd executed
0149                ;            LogEpochLen: Epoch length in 0.01 sec
0150                ;            LogEpochCnt: Current epoch# (-1 [$FFFF])
0151                ;            LogEpochBgn: Epoch# after which to start logging (-1 for immediate)
0152                ;            LoggerAdrs:  Logger address of last written data (8, for immediate)
0153                ;            LogReserved: Reserved bytes (don't care).
0154                ;
0155                ;         2. A new command (#5) has been implemented to facilitate calibrating
0156                ;            the display. This command takes a 12-bit value as argument and
0157                ;            writes the value directly to the display.  To calibrate the
```

```
0158                    ;           display for a given datasource, the unit should first be placed
0159                    ;           into idle mode.  Next, write 0 to the display and adjust the
0160                    ;           "offset" potentiometer to display the minimum value for the data
0161                    ;           source.  Finally, write $FFF to the display and adjust the "scale"
0162                    ;           potentiometer to display themaximum value for the data source.
0163                    ;           NOTE: If coretemp is to be displayed, it may be desirable to use
0164                    ;           a different upper limit in order to minimize error due to integer
0165                    ;           divisions in scaling. See comments at "DisplayData" in the code.
0166
0167                    ;
0168                    ; III. DataLogger support
0169                    ;    A. For LapelUnits datalogger recording is managed using a control
0170                    ;       block maintained both in RAM and as a header in the datalogger
0171                    ;       itself.  The control block is as follows
0172                    ;
0173                    ;       offset   size    contents
0174                    ;       0000     4       Init time/date (Secs past midnite on reference date)
0175                    ;       0004     2       Epoch lenght (in 0.01 sec)
0176                    ;       0006     2       Epoch count (since 0 at reset)
0177                    ;       0008     2       Start time offset from init (in epoch lengths)
0178                    ;       000A     2       Most recently written logger io address
0179                    ;       000C     1       unit id
0180                    ;       000D     3       reserved
0181                    ;
0182                    ;       Initialization is accomplished via a monitor command: initial values
0183                    ;       are loaded from the host to the RAM copy of the control block, copied
0184                    ;       to the battery-backed logger memory header area, and a reset event
0185                    ;       is emulated.  Upon any reset event, the RAM copy of the control block
0186                    ;       is restored from the logger's header area.  At the expiration of each
0187                    ;       epoch, variables are updated as appropriate in the RAM copy which is
0188                    ;       then replicated in the logger's header area.
0189                    ;       Epochal data summaries are recorded following the header for epochs
0190                    ;       after the programmed start epoch until the logger capacity is reached.
0191                    ;       NOTE THAT THIS SCHEME SHOULD MAINTAIN TEMPORAL INTEGRITY OF LOGGED
0192                    ;       DATA ACROSS TRANSIENT RESETS.  HOWEVER, EXTENDED TIMEOUTS (EG, MONITOR
0193                    ;       INTERACTIONS) CANNOT BE ACCOUNTED FOR.
0194                    ;       ==>> ALTHOUGH READ/WRITE OPERATION OF THE DATALOGGER MEMORY HAS BEEN
0195                    ;       TESTED AND VERIFIED, THE INIT FUNCTION HAS NOT BEEN TESTED, NOR HAS
0196                    ;       THE FUNCTIONAL OPERATION OF THE LOGGER CONTROL BLOCK BEEN TESTED.
0197                    ;
0198                    ;    B. It may be possible, codespace permitting, to implement a message
```

```
0199                    ;       buffering function for the datalogger in Base/RepeaterUnits.
0200                    ;
0201                    ;
0202                    ;   IV. Display support
0203                    ;     A. Display management allows any data source to be displayed, although
0204                    ;        hardware calibration of the display meter prevents dynamic switching
0205                    ;        among the various data sources.  The displayed data is updated at
0206                    ;        each realtime data transmission interval.
0207                    ;
0208                    ;     B. Display considerations
0209                    ;        1. There is no way to visually distinguish which data source is
0210                    ;           currently displayed (eg, selective decimal point illumination).
0211                    ;
0212                    ;        2. There is no way to visually indicate whether the unit is operating
0213                    ;           satisfactorily (ie, tracking ok, low battery, etc.)
0214                    ;
0215                    ;        3. Display circuitry hardwires the left-of-hundreds decimal point ON,
0216                    ;           left-of-tens and left-of-units decimal points off. Therefore, all
0217                    ;           displayed values will appear to range from ".vvv" to "V.vv".  For
0218                    ;           temperature data, displayed values should appear as "VV.v".  Heart
0219                    ;           rate and activity data should appear as "VVV".
0220                    ;
0221                    ;        4. The current Xilinx ROM program provides a 2-bit latch, accessible
0222                    ;           via CS3 in it's internal 1/16 select device.  These bits exit the
0223                    ;           Xilinx as signals PMD and FR (formerly used with defunct uD/DAS
0224                    ;           circuitry), and are available to the motherboard at pins 19 and 20
0225                    ;           on connector J103.  These lines could selectively drive a pattern of
0226                    ;           decimal points on the display to convey additional information about
0227                    ;           the data source and/or whole unit.
0228                    ;
0229                    ;   V. Repeater Chatter control
0230                    ;      A.  A new convention has been adopted for controlling repeater chatter
0231                    ;          by preventing repetition of repeated messages.  Now, any message
0232                    ;          rebroadcast by a repeater will have $80 added to its MSGTYP.
0233                    ;          Normally repeaters will not rebroadcast any message received with
0234                    ;          MSGTYP >= $80. If desired/required in a particular setup, this
0235                    ;          feature can be disabled (thus letting ALL Rx'ed messages be
0236                    ;          relayed unmodified) by a one-byte patch that can easily be made
0237                    ;          using the command monitor writemem command.  See the code in the
0238                    ;          "RelayData" function for details.  Host software should simply
0239                    ;          mask off the MSBit of the incoming message byte in the MSGTYPE
```

```
0240                    ;          position before subjecting that byte to any legitimacy tests.
0241                    ;          By convention, legitimate message types will be limited to the
0242                    ;          range $00 -- $7f (0 -- 127).  In fact, for the forseeable future,
0243                    ;          the only defined message type is 1, ie, a data message.  I AM
0244                    ;          CONSIDERING VARIOUS WAYS OF IMPLEMENTING A MORE FLEXIBLE SCHEME
0245                    ;          FOR CONDITIONAL MESSAGE FORWARDING.  ANY SUCH SCHEME WILL LIKELY
0246                    ;          RESULT IN CHANGED USAGE OF THE MSG_TYPE, UNIT_ID AND/OR STATUS
0247                    ;          BYTES.
0248                    ;
0249
0250
0251                    ; Version 2.00 = "PT2xx.<ext>"
0252                    ;     Starting with version 2.00, the following signals are tracked and
0253                    ;     reported by LapelUnits --
0254                    ;    BFMS input          uR_CTL_PCB Signal          '6811 pin
0255                    ;    Rx antenna          SMP0/SIG0/AM_Vid           PORTE.bit0 (ADC ch 0)
0256                    ;                        CMPo0 (PIM Coretemp)       PORTA.bit2 (ic1)
0257                    ;    (Actigraph PCB)     ADC3  (Actigraph)          PORTE.bit4 (ADC ch 4)
0258                    ;    LIN1                ADC0  (Thermistor 1)       PORTE.bit7 (ADC ch 7)
0259                    ;    LIN2                ADC1  (Thermistor 2)       PORTE.bit6 (ADC ch 6)
0260                    ;    ANFEED              ADC2  (Thermistor 3)       PORTE.bit5 (ADC ch 5)
0261                    ;    AAUX                SMP2  (Thermistor 4)       PORTE.bit2 (ADC ch 2)
0262                    ;    ICAP  \------------>SMP3  (Heartrate)          PORTE.bit3 (ADC ch 3)
0263                    ;           \--(unimpl)->ICAP  (IBI)                PORTA.bit3 (ic4/oc5)
0264                    ;    LOBAT               SMP2  (Battery status)     PORTA.bit0 (ic3)
0265
0266                    ;
0267                    ;   --> Data packets comprise the following byte sequence --
0268                    ;         / PacketLength (DATA BYTES ONLY !!!)
0269                    ;        |   /  PacketType
0270                    ;        |   |  UnitID
0271                    ;        |   |  Status              (bit use as shown; bit 7 is battery status)
0272                    ;        |   D  CoretempPill            (status bit 0)
0273                    ;        |   A  Actigraph               (status bit 1)  (<internal>-> ADCi3)
0274                    ;        |   T  Therm4                  (status bit 2)  (AAUX      -> SMPi2)
0275                    ;        |   A  Therm3                  (status bit 3)  (ANFEED    -> ADCi2)
0276                    ;        |   |  Therm2                  (status bit 4)  (LIN2      -> ADCi1)
0277                    ;        |   |  Therm1                  (status bit 5)  (LIN1      -> ADCi0)
0278                    ;        |    \ ECG                     (status bit 6)  (ICAP      -> SMPi3)
0279                    ;         \ Checksum (cumulative XOR of DATA BYTES ONLY !!!)
0280                    ;
```

```
0281                    ; Notes:
0282                    ;    1. Status bytes set_bit/clear_bit = signal_OK/signal_BAD.  At present,
0283                    ;                   only the Coretemp bit (0) and LOBAT (7) bit convey
0284                    ;                   meaningful information.  Bits 1 -- 5 are always set.
0285                    ;
0286                    ;
0287                    ;  Other changes:
0288                    ;   -->> Removed the generic message-formatter dispatcher.  Until otherwise
0289                    ;        decided DATA_MSG_TY (1) and RPTD_MSG_TY (2) are the only possible
0290                    ;        message types.
0291                    ;;;NOTE NO MORE RPTD_MSG_TY
0292                    ; Possible changes to be made:
0293                    ;   -->> Can remove PEM verification stage of pill capture to save about 16
0294                    ;        bytes of code.  However, the resultant reduction of noise rejection
0295                    ;        could be problematic in high noise environments.
0296                    ;   -->> It is likely that some better use can be found for bits 1 - 6 of the
0297                    ;        status byte since there is presently no feasible way to ascertain the
0298                    ;        status of the ADC signal sources in the LapelUnit.
0299
0300
0301                    ; Version 1.xx
0302                    ;  02/05/90 -> Multi-byte FM message transception implemented.  Bench test
0303                    ;              transceptions were highly reliable at 20.833 Kbaud.  Increasing
0304                    ;              baudrate to 31.25 Kbaud degraded performance by at least 30%.
0305                    ;  04/09/90 -> Packet structure changed to use a fixed-length carrier
0306                    ;              preamble regardless of baudrate.  Now all baudrate show
0307                    ;              reliable transception. (Probably the higher bauds provided too
0308                    ;              little time to do carrier verify, FM threshold setting, etc.
0309                    ;              when only 5 bit-periods were allowed.)
0310                    ;  06/29/90 -> Major internal modifications made to "ic1_Isr" pulseframe qual-
0311                    ;              fication processing.  These changes should extend trackability
0312                    ;              to all pills meeting KI's published manufacturing standard.
0313                    ;              The offsetting cost of the changes is slightly decreased noise
0314                    ;              immunity.
0315                    ;  06/29/90 -> Coretemp scaling code and supplementary variables removed from
0316                    ;              the code on assumption that, henceforth, raw data will be sent
0317                    ;              in data messages and all scaling will be done at the host.
0318                    ;
0319                    ; 08/02/90 -> Added variable "TXVCOFUDGE" to allow manual compensation
```

Appendix IV

BFMS Operations Manual

January 1995
Revision

Prepared for:

Walter Reed Army Institute of Research
Washington, DC

by

Research Triangle Institute

BFMS Operations Manual

Revised 1/95

Prepared for:

Walter Reed Army Institute of Research
Washington, DC

BFMS Operator's Manual

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1.0 GENERAL INFORMATION

1.1 Introduction

The Biomedical Field Monitoring System (BFMS) is a wearable instrument for the measurement of core body temperature, regional skin temperature, movement amplitude and heart rate for use in evaluating the health effects of various stressors, such as heat, on military personnel while performing their occupational tasks. The internal body temperature is monitored using the Walter Reed Temperature Capsule, which will be referred to as the "temperature pill" in the remainder of this document.

The BFMS applies an array of instrumentation which has been developed in recent years by the Department of Behavioral Biology, Walter Reed Army Institute of Research (WRAIR), sponsored by the Office of Military Performance Assessment Technology (OMPAT), with further support from the program for Physiological and Psychological Effects of NBC and Extended Operations on Combined Arms Crews (P2NBC2).

The Walter Reed Temperature Capsule (temperature pill) is produced by Konigsburg Instruments, Inc., under contract to the Army. The pill is used for investigational purposes according to Investigational Device Exemption regulations of the FDA.

1.2 Player Safety

The ultimate objective of the BFMS is player safety. Through the use of non-invasive core temperature measurements a player can be monitored under adverse and potentially dangerous situations. If a player's core temperature rises above 40°C, the remote display of his temperature data turns red and the player must be removed from action immediately and be medically checked out. While the player is in the safe zone

his temperature display remains white. As the temperature approaches 38°C the display turns yellow as a warning signal. Finally, at 40°C the display turns red.

1.3 System Description

The BFMS is a modular system comprising four major sub-systems:

- **Biomedical transducers for sensing physiological parameters.**

The physiological transducers allow the core body temperature, skin temperature, ambient or suit temperature, overall activity, and heart rate to be monitored. The core body temperature is transduced non-invasively by using a micro-power disposable telemetry capsule (temperature pill) which eliminates the need for rectal probes. The skin temperature is monitored with attached thermistors. Activity is monitored with a modified version of a psychomotor activity monitor device (Actigraph) previously developed by the Army. A cardiotach (ECG) monitors the heart rate using dry carbon-based electrodes.

- **An individually-worn multi-channel data acquisition system.**

The data acquisition system is designed to be carried on standard Army load-bearing-equipment (LBE) and is entirely self-contained. The module detects, transforms, and stores the data from the temperature, activity, and heart rate sensors. Further processing includes summarizing and formatting of these data for periodic telemetry. The unit can also display core body temperature on a built-in LCD.

- **A radio frequency telemetry system.**

The telemetry system uses a 100-milliwatt, packet-based FM signal to allow real time monitoring from a central site. The telemetry module can be programmed to operate in several modes, including individual transmissions, repeater/amplifier, mobile monitor,

and base-station mode. By using the relay capabilities of the telemetry module, real time monitoring can be accomplished at distances up to several kilometers.

- **A data display and analysis system.**

The BFMS provides a real time display and on-line analysis of the physiological status of the soldiers. The data logger also stores all data in memory.

1.4 Theory of Operation

The BFMS allows mobile and safe monitoring and assessment of physiological parameters under field conditions with a minimum of operational disruptions and personal discomfort. Core body temperature can be measured non-invasively by a soldier swallowing a capsule (temperature pill) which transmits temperature readings to a belt transceiver (man-pack). The transceiver combines the core body temperature measurements with other physiological data and transmits this information to a receiver (base station), either directly or through a relay station. The base station sends this data to the host computer which logs it and displays it to allow real time monitoring of the soldier.

1.5 Specifications

1.5.1 Temperature Pills (type T2D)

Each temperature pill is marked with a unique serial number, placed in an individually sealed plastic bag, and frozen. Each sealed bag contains a package insert providing technical information pertaining to that pill, including calibration specifications. This calibration information must remain with the pill until it is used.

*The temperature pills must be frozen immediately upon receipt and remain frozen to ensure the longevity of the internal battery.

Pill battery life: @ 0° C. - 1 year

@ 20° C. - 3 months

@ 37° C. - >72 hours

Expected life: one usage

1.5.2 Man-pack and Base Station Batteries

Each unit requires three C-cell Lithium batteries (TADIRAN type TL-2200). These batteries should remain frozen until needed. Other battery configurations are being developed.

1.5.3 Main Harness Connected to the Cardiotach and Thermistors

Two of the three thermistors measure skin temperature and the other measures ambient or suit temperature. The cardiotach measures the heart rate of the player.

1.5.4 Cardiotach Batteries

Each unit requires three-volt batteries (RAYOVAC type BR2325). These batteries should remain frozen until needed.

1.5.5 BFMS System Software

The diskettes received should immediately be copied and the original diskettes stored in a safe place.

1.5.6 BFMS TR6B Transceiver

The BFMS transceiver is a microcontroller-based instrument which receives, logs, and transmits core temperature, skin temperature, activity level, and heart rate information. It may be programmed to work in any one of three modes: man-pack, base station, or relay station.

- In the man-pack mode, the system receives signals from the ingested temperature pill, integrates this information with the other sensor data and then transmits the data in radio frequency (RF) packet form, concurrent with companion transceiver RF transmissions, to either relay or base stations.
- In the base station mode, the system receives man-pack or relay station transmissions, decodes them, and communicates via an RS232 link with a PC, either to display the received data, or to receive instructions from the operator.
- In the relay station mode, the system receives man-pack data transmissions and then retransmits the signals to the base station.

1.5.7 Antennas

Two quarter-wavelength flexible wire antennas are provided. One is for pill reception and the other is for man-pack transmission. A high-gain directional antenna (YAGI) is provided, which is suitable for long range telemetry communication with the relay or base stations. A loop antenna is also provided, which is suitable for the local reception of man-pack units.

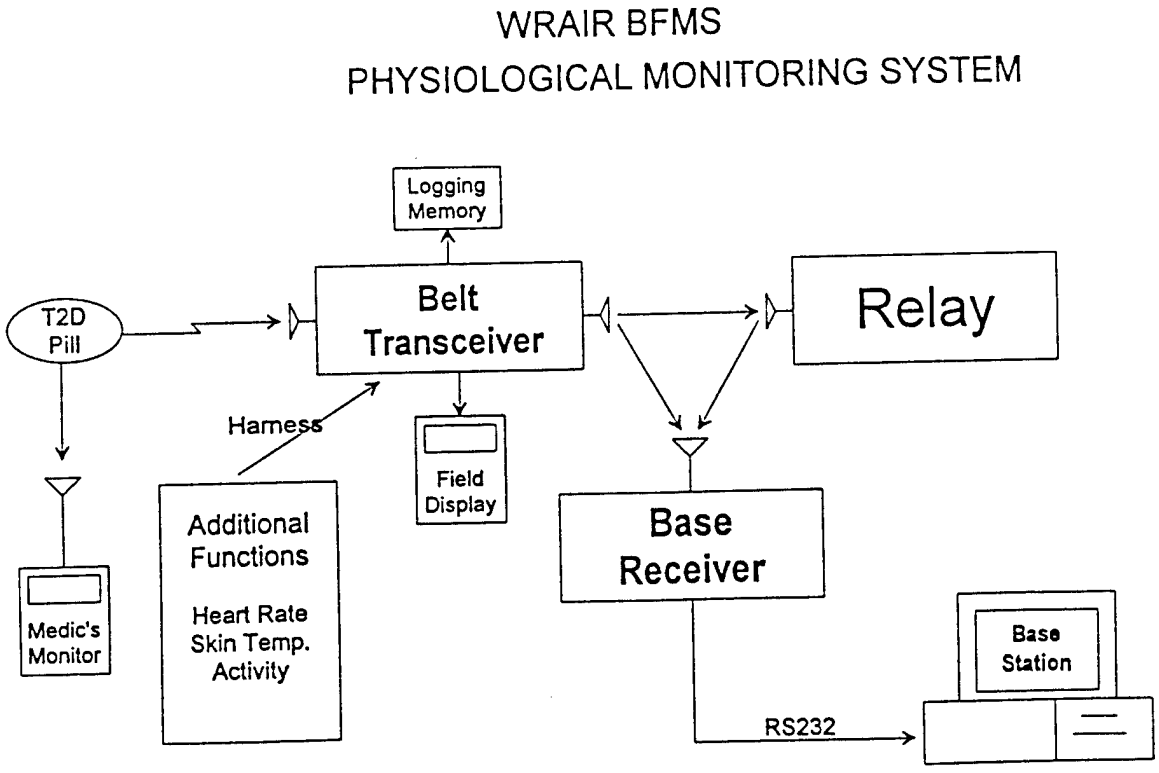
1.5.8 Connectors

A serial communication connection on each BFMS unit is used to communicate with a PC. The man-pack is connected to the PC for setup and for downloading data. The base station unit is connected during data logging so the PC can

monitor the incoming packets for real time monitoring. The man-pack is connected to the PC for setup and to test its operation.

The main harness connector joins the man-pack with the cable to the two skin thermistors, the ambient or suit thermistor, and the cardiotach heart rate monitor. The main connection connects the base unit to the battery pack for a power supply. The main connection also connects the base unit via an RS232 line to a PC serial port to receive packet transmissions. The connection is made with a 9-pin sub-D connector. The 26-pin connector on the top of the unit can be used to supply power to the unit.

Figure 1 **WRAIR BFMS Physiological Monitoring System**



Walter Reed Army Institute of Research Biomedical Field Monitoring System

2.0 MATERIALS

The following materials are needed to operate the Biomedical Field Monitoring System:

- Temperature pills (type T2D)
- BFMS TR6B Transceiver(s)
- Transceiver batteries: 3.6 volt Lithium (TADIRAN type TL-2200) Note: other battery configurations are possible.
- Main harness with cardiotach and 3 thermistors
- Cardiotach batteries: 3 volt Lithium (RAYOVAC type BR2325)
- BFMS system software
- Antennas: Two quarter-wavelength flexible wire antennas.
- RS-232 serial cable configured to run between the computer serial port and the 4-pin Lemo serial connector on the belt-worn transceiver.
- IBM-PC compatible 386 or 486 computer with two externally-accessible serial ports. This computer should be running version 5.0 or later DOS, and version 3.1 or later Windows.
- BFMS Operator's Manual
- BFMS Technical Manual

Upon arrival, the system should be inspected to assure that all materials have been received and are intact.

WARNING!!

It is extremely important that all temperature pills and batteries be frozen immediately upon receipt. Freezing deactivates the pill and batteries and prolongs their shelf life.

3.0 INSTALLATION AND PERFORMANCE CHECK

3.1 Software Installation

Make a backup copy of the two BFMS software diskettes. Insert a formatted 1.44MB 3.5" diskette into drive A or B of the computer and type the following:

A:\>***diskcopy*** or *B:\>**diskcopy***

Diskcopy will only work with removable disks (not hard disk drives) and will prompt you to insert the source (BFMS) and destination (formatted) disks. It will wait for any key to be pressed before continuing.

Install the BFMS software on a hard drive. If the hardware drive letter is other than C, substitute that letter for C in the instructions. Press "enter" after each command which is bold and italicized. The software should be installed into a directory called BFMS or another designated directory. Create the directory and then change to that directory by doing the following:

C:\>***md BFMS*** (make directory BFMS)

C:\>***cd BFMS*** (change to BFMS directory)

C:\BFMS>

To install the software, insert the BFMS backup software diskette into the floppy drive A or B and type:

C:\BFMS> ***copy A: *.**** or C:\BFMS> ***copy B: *.****

The following files should be in the BFMS directory on the hard drive if the diskette was properly copied:

RTITEST.EXE
KIPILLS.DB
PCAL.EXE
DISPLAY.EXE
PROISAMD.EXE
TESTBM93.EXE
LOG93X.EXE
DBPROC.EXE

DR.FNT
DRIVERS.DRV
PLOTTER.DRV
SCREEN.DRV
DOWNLOAD.EXE
ISAMREPR.EXE

Before processing the BFMS data a "system boot disk" must be made if the system is not operating with expanded memory. If you are not sure whether your system is operating with expanded memory, make a system disk. Make a system boot disk by inserting a new blank diskette into the floppy drive (either A or B) and doing the following:

C:\>***format A:/s/u***

C:\>***copy config.sys A:***

C:\>***copy autoexec.bat A:***

Edit config.sys on the floppy and ensure that the memory manager has expanded memory enabled. (e.g., ram and not noems).

3.2 Cable Connections

The RS-232 serial cable links the BFMS unit to the computer for the setup of the unit and the down loading of data. For the man-pack cable setup, see section 5.1.4 and figure 2. For the base station cable setup, see section 5.4 and figure 4. For the relay station cable setup, see section 5.6 and figure 5.

3.3 Antenna Setup

The antenna setup is site specific. The antenna may need to be attached to a wall or ceiling, or a site specific structure may need to be erected for adequate reception. There are various antennas which may be used and are site dependent. There are short and long antennas which may be aimed directly at the remote site depending on the distance from the site. There are also circular systems for sites which are not in a

specific direction. For the man-pack antenna setup see section 5.1.4 and figure 3. For the base station antenna setup see section 5.4 and figure 4. For the relay station antenna setup see section 5.6 and figure 6. For the man-pack and the relay station the receive antenna is connected to the blue port and the transmit antenna is connected to the red port. The base station has only a receive antenna connected to the blue port.

3.4 System Check

Power up the unit after connecting the cables and the antennas. Both the man-pack and the base receiver should display 42.2 if they are receiving battery power. Run RTITEST and verify that the system is operating properly. Check to make sure the man-pack unit is in idle mode by pressing enter and then "R". Read hhll: ***F802***. The correct response for the idle mode is 00. If the response is not 00, then put the unit in the idle mode by pressing "W". Write hhll,val: ***F802,00***, then press "**G**", enter. For more detailed information refer to section 4.2.4.

4.0 SOFTWARE DESCRIPTION

4.1 Software Overview

The BFMS software is implemented in Visual Basic. For a detailed explanation of the software, see the BFMS Technical manual. Following are descriptions of the individual programs.

4.2 Program Descriptions

4.2.1 KIPILLS

KIPILLS.DB (KIPILLS) is the temperature pill database. It stores the calibration information for each temperature pill that will be used in a study. A new pill **must** be entered into the KIPILLS database using the program PCAL for data entry (see below). This pill information is then accessed by the real-time and data processing programs, and must be in the operating subdirectory for those programs.

4.2.2 PCAL

PCAL.EXE (PCAL) is the program used to enter temperature pill data into the KIPILLS database. It provides an entry screen of key parameters to update each new pill. The parameters needed for this update are found on the information insert packed with each pill, and consist of :

- Pill identification number
- Low calibration temperature (approximately 37° C)
- Low calibration frequency (around 500 Hz)
- High calibration temperature (approximately 40° C)
- High calibration frequency (around 560 Hz)

These parameters should be entered twice: once in the upper field and once in the lower field of the database screen. Other data may be entered on this screen as desired, but is optional.

4.2.3 DISPLAY

The utility program DISPLAY.EXE (DISPLAY) is used to create the **base**, **range**, and **scale** variables that generate an accurate display of the pill temperature on the BFMS liquid crystal display. The input data required for DISPLAY is the same as that described above for PCAL (the four temperature and frequency calibrations). The pill information insert contains this data. These parameters produce a screen listing of the form shown below, in HEX format:

- Hexval Base: FD7A
- Range: 6437
- Scale: D6

These values should be recorded on a separate BFMS information sheet, along with the calibration data, for use later when the BFMS unit is set up for operation.

4.2.4 RTITEST

NOTE: This program may be given a different name and modified to include special features for a specific study (e.g. SDPO.EXE, OTTER.EXE). Please consult any README files on the program disks for more information.

RTITEST.EXE (RTITEST) is the main user interface to the BFMS. This program is used to upload configuration information to the BFMS man-pack, and to test the operation of the unit. The opening screen presents the main menu, which may be recalled by pressing "H" at any time. The main menu screen halts the program in a wait loop which requires pressing any key before interaction begins. The program is exited by pressing the F10 key, CTRL-Break, or "Q".

Main menu screen:

P:= Pauses the program

B:= Toggles the audible packet signal (if activated a beep sounds as each new packet appears on the screen)

L:= Sets the expected packet length (should be set to 11)

F10:= Abort & Close this program

K:= Idles the BFMS unit

G:= Resets the BFMS unit

R:= Reads a memory location in the BFMS unit. To verify the unit's mode of operation, the location to read is F802. The response should be 00, 01, or 02, corresponding to the idle mode, transmit mode, and receive mode.

W:= Writes to a memory location in the BFMS unit. The location and data to write are F802,0? (00=idle, 01=transmit, 02=receive) to place the unit into a specific mode. Follow this command with a "G" to reset the unit.

I:= Reads location in logger memory

O:= Writes location in logger memory

C:= Carrier test function

D:= Display the test function (display value between 0 and FFF)

X:= DO NOT USE!! This command locks up the system when used. Test 64K byte Block of Memory (writing / reading sequential numbers to memory).

F:= Sets the operating packet frequency for the man-pack and the receiver, this is always set at 92 mHz. The man-pack and the receiver must be set to the same frequency. This frequency may be changed if a nearby radio frequency is interfering. Remember to change both the transmitter and receiver frequencies.

T:= Sets the pill frequency for the man-pack. The pill has been previously calibrated to this frequency. This information is located on the data insert received with the pill. The low frequency is around 500Hz and the high frequency is around 560Hz.

S:= Dumps the man-pack data logger into a .dbf file after a completed study.

Y:= Sets the display parameters in RTITEST. These parameters were previously recorded from the DISPLAY program. These parameters allow the man-pack unit to accurately display the core temperature on the unit display. If these parameters were not entered into the computer, then the logger will record accurately but the display will not function properly.

#:= DO NOT USE!! This command locks up the system when used. Sets the unit ID number.

N:= Initializes the man-pack unit for operation.

M:= DO NOT USE!! This command locks up the system when used. Initializes the base monitoring unit.

4:= Toggle between heart rate and 4th temp channels

4.2.5 PROISAMD

PROISAMD.EXE (PROISAMD) is a Terminate and Stay Resident (TSR) program which allows the interaction of other programs with the KIPILLS database and the real-time database. It must be started before running TESTBM93, LOG93X, or DBPROC.

4.2.6 TESTBM93

TESTBM93.EXE (TESTBM93) is the program used for monitoring real time information transmitted from the man-pack and the relay unit to the base station. The base station and the man-pack must be functioning properly for incoming packets to be monitored. All monitored information for up to 50 players is displayed on a sequence of screens. These screens show core body temperature, skin temperature, heart rate, activity level, pill tracking status, and whether the information for a given player has been updated within the last minute. The display also prompts the user with warnings about a player's core temperature, heart rate, and activity level.

The program PROISAMD (described below) must be run before TESTBM93 to provide access to the KIPILLS database.

4.2.7 LOG93X

LOG93X.EXE processes the binary file (Username.ALD) downloaded from the man-pack data logger. This program first prompts the user for setup information, then prints all the data in tabular form, plots the data, and finally creates two new files, a comma separated file (Username.CSV), and a text file (Username.TXT).

4.2.8 DBPROC

The program PROISAMD (described above) must be run before DBPROC to provide access to the KIPILLS database.

DBPROC.EXE processes the real time data file (Username.DBF) in a manner similar to LOG93X's processing of the man-pack data. This .dbf data file is generated by the monitoring program TESTBM93 and provides a duplicate and/or backup of the man-pack logger data. There will be slight variations between the two data sets due to time base differences in the man-pack data logger and the real-time telemetry system. DBPROC prints all the data in tabular form, plots the data, and then generates two new files: Name-ID#.TXT and Name-ID#.CSV.

4.2.9 ISAMREPR

ISAMREPR.EXE is a utility for repairing damaged ISAM data base files (KIPILLS.DB or username.DBF). If on accessing any of these files a damaged file error message occurs, the file can be fixed with this program (type "isamrepr filename"). Some of the

data in the file may be lost, but the file should be usable. Make a backup copy of the original file before running ISAMREPR.

4.2.10 DOWNLOAD

DOWNLOAD.EXE is a self explanatory program that is used to load the machine-code program into the BFMS units. This program is not needed in the normal operation of BFMS unit, but is necessary if the internal program is corrupted. This could occur, for example, as a result of incorrectly using the "W" command in RTITEST.

5.0 OPERATION

5.0 BFMS Condensed Operating Instructions

See Appendix 2

5.1 BFMS Man-pack Preparation

Prior to operating the BFMS unit, setups described in sections 5.1.5 and 5.1.6 (cable and antenna connections) should have been performed. This section describes the procedures for performing tests with the BFMS unit.

5.1.1 Date and Time Entry

The time and date on the PC used to initialize the BFMS man-pack must be accurately set before each session. This is important because the PC clock is used to set the time base for the man-pack data logger and for the real time telemetry recordings at the base station. This time information is transfered to the BFMS man-pack when it is initialized.

5.1.2 Pill Data Entry

Pill data must be entered for each new pill using the program PCAL.EXE (PCAL) which provides an input screen for the entry of key calibration parameters. The calibration parameters to be entered are located on the information insert packed with each pill. The data will need to be entered twice, once on the top half of the screen and once on the bottom half. The parameters to be entered are:

1. Pill identification number
2. Transmitter operating frequency (always 92.00 mHz) Occasionally, there are interferring radio station frequencies, and then it may be necessary to change the frequencies in the man-pack and the base station.
3. Low calibration temperature (around 37°C)
4. Low calibration frequency (around 500 Hz)
5. High calibration temperature (around 40°C)
6. High calibration frequency (around 560 Hz)

7. Other information may be added (date of manufacture, date of use, subject number, and study name.)

5.1.3 Display Information

The program DISPLAY.EXE (DISPLAY) is used to generate the **base**, **range** and **scale** variables which are used to calibrate the LCD meter on the BFMS man-pack. These values will be entered during the initialization of the man-pack and assure that the meter accurately displays core body temperature. Just as with the PCAL program (see above), the low and high temperature/frequency calibration parameters for each pill should be entered from the pill data sheet. This will generate the a Hex format screen similar to the following:

Hexval Base: FD7A

Range: 6437

Scale: D6

These three values should be recorded on the BFMS information sheet for later use when the man-pack is set up for operation.

***At this point, information may stay stored in the computer and the pills remain frozen until needed.**

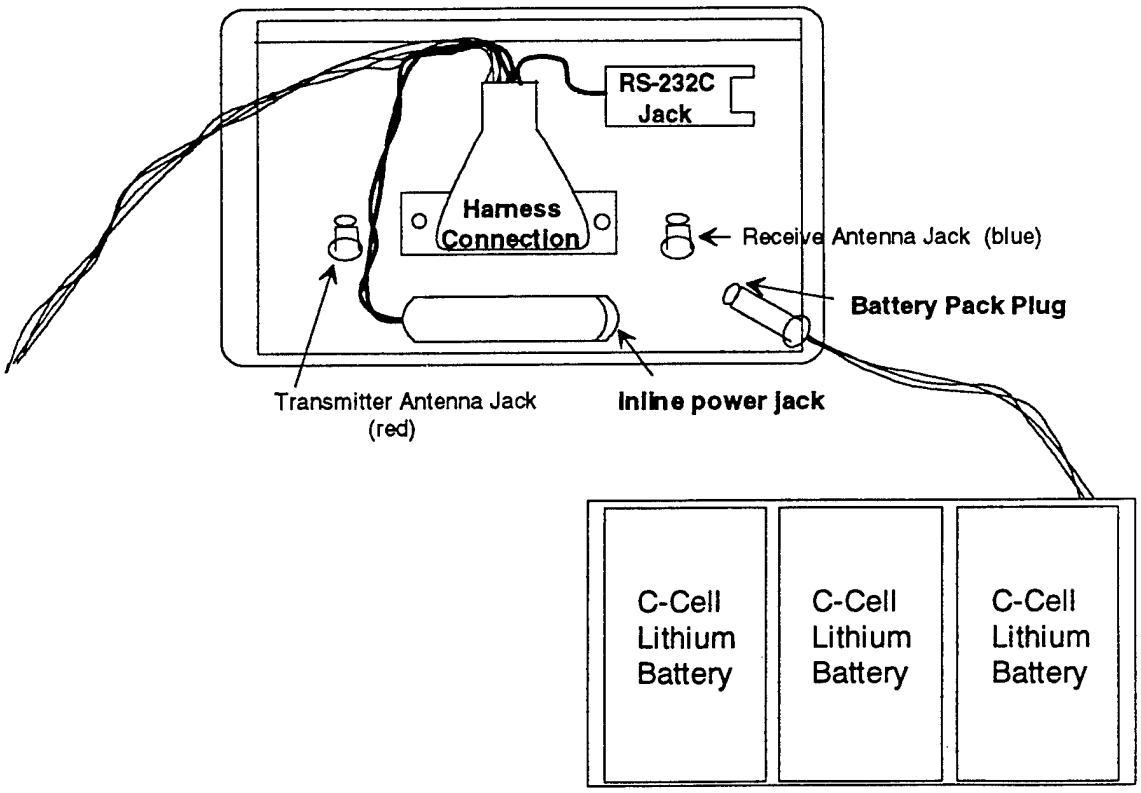
5.1.4 BFMS Man-pack Interface

Prior to starting the program RTITEST.EXE (RTITEST), which is the main user interface to the BFMS man-pack, all cables, antennas, and the serial interface should be connected. The program RTITEST.EXE (RTITEST) presents a main menu screen, which may be recalled with the "H" command at any time. The program is exited by hitting F10, CTRL-Break, or "Q". The menu menu screen halts the program at a wait loop which requires pressing any key before interaction begins.

5.1.5 Man-pack Cable Connections

The RS-232 serial cable links the man-pack to the PC. The main harness connects the man-pack to the cardiotach and thermistors which are then attached to the player. figure 2.

Figure 2 Man-pack Cable Connections



Battery Pack on the bottom of the unit

Serial Communications Connection:
The RS232 line plugs into the man pack for initialization and for downloading data to the computer.

Main Harness Connection:
The main harness connects the two skin thermisters, the ambient or suit thermistor, and the cardiotach heart rate monitor to the man-pack.

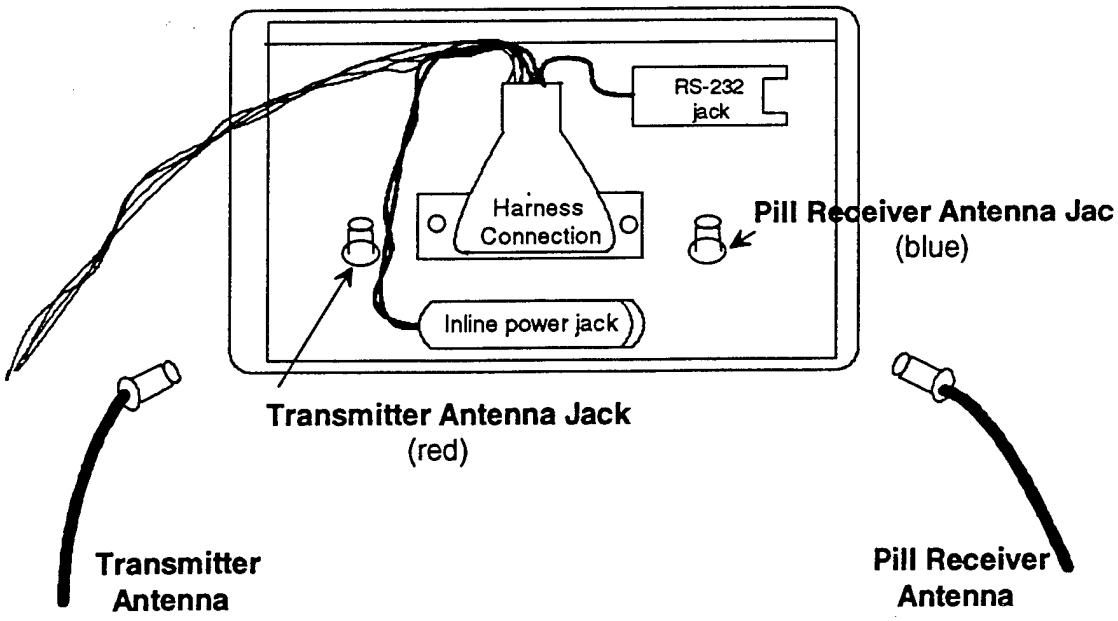
Inline Power Jack:
The inline power jack connects the external power to the man-pack.

Battery Pack Connector:
The battery pack supplies battery power to the main unit when it is plugged into the inline power jack.

5.1.6 Man-pack Antenna Setup

The transceiver has two antenna ports, either of which can be used for receiving or transmitting. In the man-pack mode both antenna ports are used. The antennas are long, fairly flexible cables. One cable is secured around the torso or extended freely down one leg, for the reception of body mounted or ingested sensor/transmitters. The other antenna, used for transmissions, is mounted over the shoulder for communicating with the relay station or the base stations. figure 3

Figure 3 Antenna Connections for the Man-pack



Pill Receive Antenna:
Attach one green wire antenna directly to the man-pack pill receive antenna connector which has a blue ring around the port. After this antenna is connected to the man-pack it should be wrapped around the players waist to pick up the pill, temperature sensor, and cardiotach transmissions. Secure this antenna in place with tape.

Transmitter Antenna:
Attach the other green wire antenna directly to the man-pack transceiver connector which has a red ring around the port. This antenna should then be placed over the players shoulder to transmit data back to the base station or relay station. Secure this antenna in place with tape.

5.1.7 Operation Mode

The man-pack can be either in the idle mode or belt operation mode. The mode state can be determined by reading the location F802 by pressing "R". Read hhll: ***F802***. This should be the first step before setup, both to assure that the unit is idling, and to confirm that communication is established. The reply to "R" F802 should be "00" for the idle mode and "01" for operation mode. If the unit is printing out packets, then it is in the operation mode and should be placed in the idle mode. Put the unit in idle mode by pressing "W". Write hhll,val: ***F802,0,*** then press G, enter. The "K" command, which is not always reliable, may also be used. Recheck the unit with the command "R F802" to assure the unit is in idle mode. If the unit emits "FF" at power on reset, repeat the query. If there is no communication with the unit then reset the unit by uncoupling and recoupling the battery pack connector. Bizarre replies may occur if the unit is in the operating mode and happens to be calibrating the transmitter (such as in the first few seconds of operation after initialization or power-on). If this happens, repeat the query several times.

5.1.8 Parameter Setup

Transmitter operating frequency:

To set the operating frequency press "F" which will display the current parameters and allow them to be changed. The working frequency for telemetry is 92 Mhz. This frequency may be altered if there is interference from a nearby radio frequency.

Pill transmitting frequency:

To set the pill frequency press "T" and change the pill frequency to the frequency on the information insert that comes with that particular pill. This frequency is usually around 88 MHz.

Display parameters:

The command "Y" permits the entry of the three Hex parameters which were previously determined from the DISPLAY program. These parameters should have been recorded on the BFMS information sheet when the system was set up. The parameters to be entered are base, range, and scale. If these parameters are not entered the logger will still acquire data packets but will not display them accurately in real time.

***The unit may be powered down at this point and stored until needed.**

5.1.9 Initialization

Once the above parameters have been set, the unit is ready for operation. The command "N" will start the operation. A table of 16 bytes is written to the unit logger, then checked for validity; the program prompts for an <enter>, which should be pressed right away. This causes a write of "01" to location F802, followed by a software reset, placing the unit into the operation mode. To confirm the operation mode, press "R". Read hhll: ***F802*** and check for a reply of "01". If the reply is the idle mode "00", then re-execute the command "N". If this does not work then use a power-on reset. The operation mode starts to warm up the transmitter and calibrate the unit to the operating frequencies which have been previously entered. This may take several seconds and as long as a minute if the unit is cold. During this time, there is no action on the screen. When start up is complete, the unit begins to emit packets at (about) one second intervals. When operating with the transmit antenna connected, the packets can be heard on the FM radio at 92 Mhz.

****The unit may be powered down or used at this time. If the unit is powered down the time must be recorded because the unit will remember it's original initialization and will not match the computer time.**

5.2 Capsule Preparation

The temperature pill should remain frozen until 30 minutes before ingestion. At this time it should be removed from the freezer and allowed to warm to room temperature before use. The information slip enclosed with the pill should be copied at least twice. One copy must be furnished to WRAIR, along with the date, time, study name, subject ID, and any noted problems.

As the pill approaches room temperature, it should generate an audible tone on a nearby (within 2 feet) FM radio operating on the frequency noted on the data slip. Most pills transmit around 88 MHz but some have been produced around 93 MHz. The signal may also be picked up by a man-pack with its antenna next to the pill.

5.3 Player Preparation

Each player must be given a BFMS unit with a corresponding temperature pill. The player must then have a cardiotach and thermistors attached to his body to record his heart rate and body temperature before going out into the field.

5.3.1 Pill Detection

Prior to swallowing a pill, each player will be checked to verifiy the absence of another pill. To detect the pill, a man-pack will act as a receiver, and a receive antenna will be held near the player's abdomen to see if a pill is detected. A pill is detected if the packet (4) displays "3F", if the pill is detected but there is a low battery then "FF" is displayed. If no pill is detected then "3E" is displayed, if there is no pill and a low battery then "FE" is displayed. If the pill is detected, then the player must have his BFMS unit reprogrammed for the pill which is still present.

If no pill is detected, then the player will be issued a pill and a man-pack unit which has been previously assigned to that particular pill. The player should swallow the pill with ample fluid. After ingestion, the pill signal can be detected by holding a receive antenna near the player's abdomen or bringing a portable FM radio near the body. At body temperature, the pill generates a tone of about 500 Hz.

If the unit was not previously initialized, then the man-pack must be reconnected to the PC and given the command "N" to initialize. If the unit was already initialized (section 5.2.7), reapply power by connecting the battery pack and the unit will start acquiring data. If the unit was previously initialized then note the actual start time because it will not be synchronized with the PC. The pill will begin to telemeter the player's core temperature to the man-pack which will then transmit signals to either a relay station or a base station. The player will have the cardiotach placed around his chest with the red button on the left side to monitor the heart rate. The thermistors monitor the player's skin temperature (blue and green), and ambient or suit temperatures. The pill receive antenna, connected at the blue port, will be wrapped and secured around the players waist to receive pill transmissions. The transmit antenna, connected at the red port, will be secured over the players shoulder, to transmit data from the man pack to the base station or relay station. The player is then ready to be sent into action and monitored noninvasively for external temperatures as well as core temperature and heart rate.

5.3.1 Harness Check

The pill receive antenna should be attached to the unit (blue port), and then brought near the thawed temperature capsule. If the pill is not going to be used, it should be refrozen immediately after testing. The pill is detected when the pill packet status turns to "3F" and the High Order Byte of Pill Data/Low Order Byte of Pill Data (HPI/LPI) assumes a value on the order of "10 00" hex. The Actigraph Data Byte (ACT) should increase upon vigorously agitating the belt unit case. The skin temperature channels should increase individually upon grasping the thermistors between the fingers or otherwise warming them up. The heart rate (HR) is checked by grasping the chest belt electrodes in the palms of both hands, the left hand grasping the red-buttoned side and the right hand grasping the black-buttoned side. The time constant for the HR change is about 20 seconds, and packet data update occurs every 10 seconds, so it may take half a minute or so to observe a significant change. The battery in the HR unit should last about five sessions. It may be changed by removing the unit from the strap, and

carefully removing the eight screws from the rear of the unit. On reassembly, be sure and reapply the strain relief using green tape.

*The unit may be powered down and stored for later use. It is advisable to do the harness check before taking the unit out in the field.

5.4 Telemetry Receiver Setup

The base station stores the packet information received from the RF link, either from the man-pack or the relay station. The transmissions come in at a high baud rate, and are reconfigured into an RS-232 format which is then transmitted at a PC compatible lower baud rate.

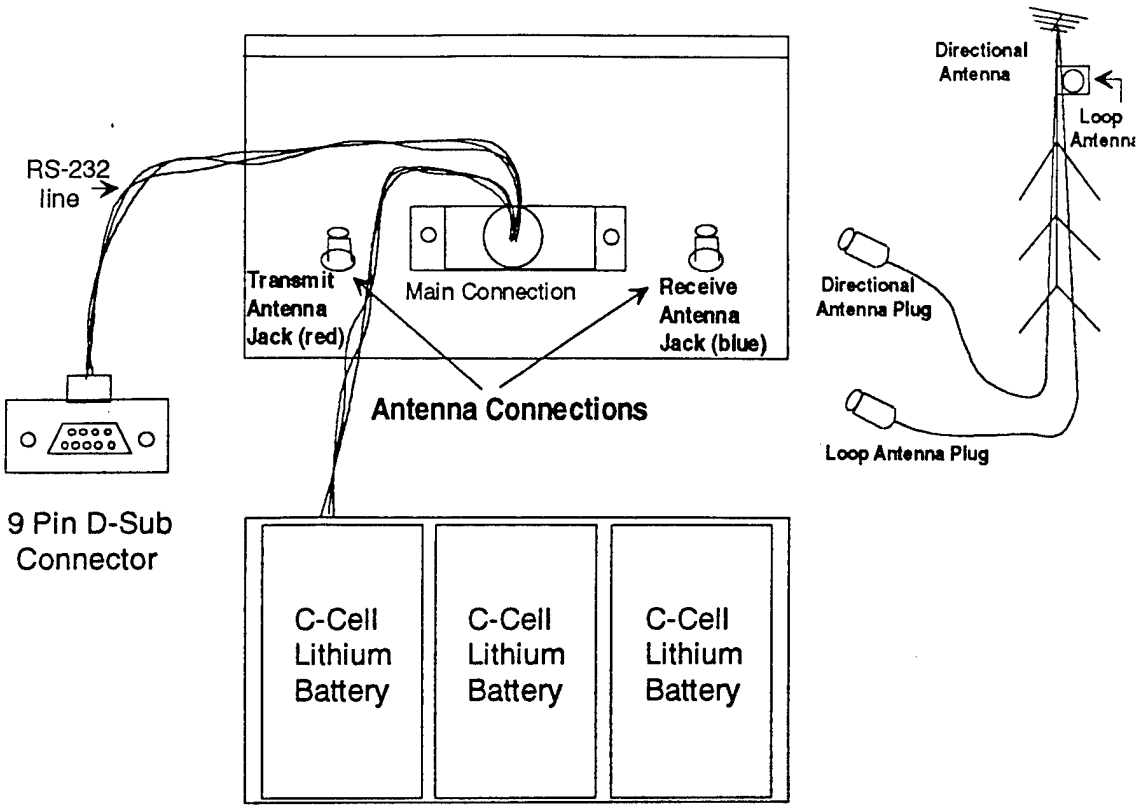
Connect the unit to the PC with the DB-9 connector, check the battery voltage, apply power to the unit and run RTITEST.EXE (RTITEST). The mode byte (at memory location F802) for the telemetry receiver is "02", and this mode begins operation on power-up. Type "R"F802 and check for a response of "00" for idle mode, "01" for tranmitter mode, or "02" for receiver mode. If the unit is not giving a reading, see the trouble shooting section (7.1). Connect the antenna to the receiver (blue port), and the packets should be displayed as if monitored directly as before. If for any reason the unit is taken out of receiver mode, it may be restarted with the command "W(rite) F802, 02" followed by "G(o)". The transmit antenna must be connected for packets to be received from the man-pack.

5.4.1 Base Station Cable Connections

The base-station-mode cable and antenna connections are identical to those used in the man-pack mode. The RS232 line should be connected to the COM1 port of the computer. The power is applied through the battery pack connector. See Figure 4. The antenna should hang in free air space and free from contact with a metal surface. A small ground-plane antenna which can be attached directly to a metal surface must

be used to receive man pack or relay station signals if an antenna cannot be strung in free space. See Figure 4 (next page).

Figure 4 Base Station Cable and Antenna Connections



1. **9 Pin D-Sub Connector:**
   An RS232 line with a miniature 9 pin DB connector links the PC serial port to the receiver serial output at the main connection.

2. **Battery Pack:**
   The battery pack, which consists of fresh 3 C-cell Lithium batteries, is connected at the main connection to supply power to the receiver.

3. **Antenna:**
   A coaxial cable is connected to a remote antenna, usually mast mounted for better reception.

5.5 Setup of Real Time Monitoring

PROISAMD.EXE (PROISAMD) is a TSR program which permits the interaction of other programs with the KIPILLS.DB and the real-time database. Thus, the first step now is to run PROISAMD, with successful installation indicated in reply. A message while running dependent programs "Feature Not Available" indicates that the TSR is not resident.

Next, run TESTBM93.EXE (TESTBM93), which first inquires about the session data.

a. Number of Players, "1 <enter>"

b. Session database file name (BFMSXXX.dbf). Give the database a unique arbitrary name; it should be given the extension ".dbf" for consistency, and the name should be recorded.

c. Pill Number

d. The data monitoring screen, which displays each player appears. This screen allows packet reception to be viewed in real time. The screen updates every 30 seconds. The moniotring screen can be displayed anytime by pressing the F2 key. Other hot keys are as follows: F3, an analog bar graph display of the data. F4, a 30 minute time history of the data. F10, Abort the program. If no packets appear, then check the man pack and base station batteries. If the batteries are low, decimal points will be displayed between each number. Also check the antenna connections.

5.6 Relay Unit Start-up

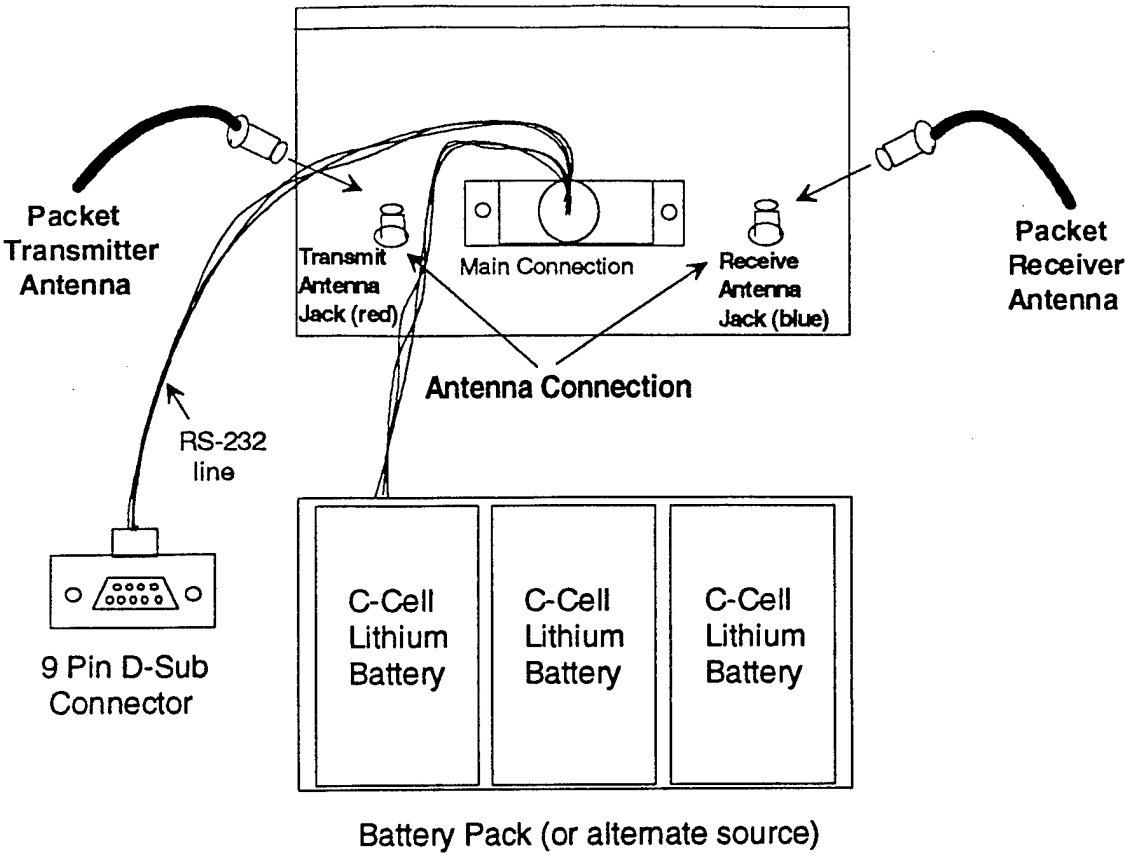
If the terrain has features which inhibit the signal reception, or If the distance between the players and the base station is too great it may be necessary to establish a relay station to establish a reliable communication link. This relay setup will be site specific. The receiving/transmitting antenna for omnidirectional reception is a 5/8 wavelength vertical monopole. A directional antenna, such as yagis, can be used for greater gain

and for direct transmission back to the base station. A circular loop may be set up on a mast antenna or on a truck mirror depending on terrain. This circular loop receives transmissions from players in the immediate vicinity. After aquiring data packets, the unit adds a station identification number and transmits the data packet to the base station via a directional yagis antenna. Only one relay station may be used in relaying the information from the man-pack to the base station, however more than one relay station may receive and transmit the data.

5.6.1 Relay Cable and Antenna Connections

The relay station mode is identical to the man-pack mode except it is programmed to be a relay station. The programming for the relay station is alternate sets of listening and transmitting data packets. The received information is identified and stored until it is retransmitted with station identification added to the information. See Figure 5 (next page).

Figure 5 Relay Station Antenna Connections



5.7 Signal Verification

Once the base station is connected to the PC, packets should begin changing. The heart rate and skin thermistor data packets can be verified by grasping the thermistor or cardiotach and detecting a change in the packet data.

Packet format:

The packet display, in Hex format, consists of 12 bytes of raw data. Each channel of the system can be checked while the unit is still connected to the PC:

Packet format

Byte	Name	Description
1.	Header value always	"0A"
2.	Source	"01" for belt units
3.	UnitNo	"00" for belt unit #00
4.	Status	"3E" or "3F" if the pill is in the track
5.	HPI	High Order Byte of Pill Data
6.	LPI	Low Order Byte of Pill Data
7.	ACT	Actigraph Data Byte
8.	ST1	Skin Sensor #1 (blue thermistor)
9.	ST2	Skin Sensor #2 (green thermistor)
10.	ST3	Skin Sensor #3 (red thermistor)
11.	HR	Heart Rate
12.	XOR	Check sum unique for each packet

5.8 Data Transfer

A. At the end of the session, TESTBM93 should be ended with the F10 key, and the PC re-booted.

B. RTITEST.EXE should be started, and the belt unit, still running but removed from the subject, should be reconnected to the RS232 line of the PC. At this point, the unit should still be emitting packets as before. (If not, there may have been a power failure, however the logger memory should still be in tact and dumpable. Just replace the batteries and resume communications.)

The man-pack should be placed into the idle mode with the "K" command (or "W F802,0" "G"). Once confirmed with the "R F802"=0, the unit is ready for a memory dump.

C. A memory dump is initiated with the "S" command, which should indicate the file name "BFMSO.ALD, with progress indicated by a horizontal bar graph. This procedure can be repeated until completion is successful.

D. At this point, the unit should be in the idle mode and ready for the next session. Uncouple the battery pack connector to turn it off. The file BFMSO.ALD should be renamed uniquely for procession and archival storage (but with the .ALD preserved).

E. The PC should now contain the session's data in two forms: the real time (ISAM/BINARY) data base with the extension ".dbf" and the logger data base of "*.ald" (for ASCII Logger data) form. These are processed separately, but should contain more or less the same data.

5.9 System Shut-down

Once all the data has been down loaded the equipment must be cleaned. This includes the canvas casing for the BFMS unit which are washed, the electrodes, the cardiotach, and the thermistors which are all cleaned thoroughly. The equipment should be disassembled and stored for future use.

6.0 DATA CONVERSION

Requirements of both processing programs:

1. The presence of LIM 4.0 EMS memory
2. The loading of the TSR program "PROISAMD.EXE"
3. An EGA or better screen
4. An HP LaserJet III attached or redirected to file.
5. The driver programs below in the same directory:

   drivers drv

   geograf bi

   printer drv

   screen drv

6.1 Logger Data

LOGPROC.EXE processes the data from the man-pack. The initial screen panel permits the entry of the session information which is self explanatory. The input file name should include the .ald extension (user name .ALD). The second panel allows the review of or the correction of the pill calibration data used during the session. A final panel shows the start and stop times, and the epoch interval, of the logger data set. These may be edited to left and right justify the data to unit hours (e.g., 11:00:00 to 15:00:00), making the hard copy more aesthetic. Epoch interval may be increased (e.g. to 060 seconds) since the fine resolution is not really required. Once this last field is completed, the data are plotted to the screen, and two files are output:

username.TXT

username.CSV

which are both ASCII files (tabular and comma-separated, respectively) suitable for importing into a spreadsheet or other processing). At this point the program pauses at the display. Hitting the space bar causes the screen to clear and output to the printer

to begin. The printed output contains a tabular hard copy of the data, with certain header information, and a graphics printout identical to the screen display. When the PC prompt returns, the processing is finished.

6.2 Real Time Data

DBPROC.EXE performs a very similar operation to that of LOGPROC.EXE. The lead in screen permits up to 4 source files (type *.dbf type) to be linked together. Time interval entry is very similar. It also outputs .TXT and .CSV files and a similar hard copy, with filenames based upon the study name entered at the beginning, plus the unit ID number. The program passes past the display screen without the pause. This processing provides a duplicate and/or backup of the logger data, with slight variations due to the different time base intervals used in the logging and the real-time telemetry systems, respectively.

7.0 MAINTENANCE AND TROUBLESHOOTING

7.1 Failure Mode

7.1.1 Trouble Shooting chart

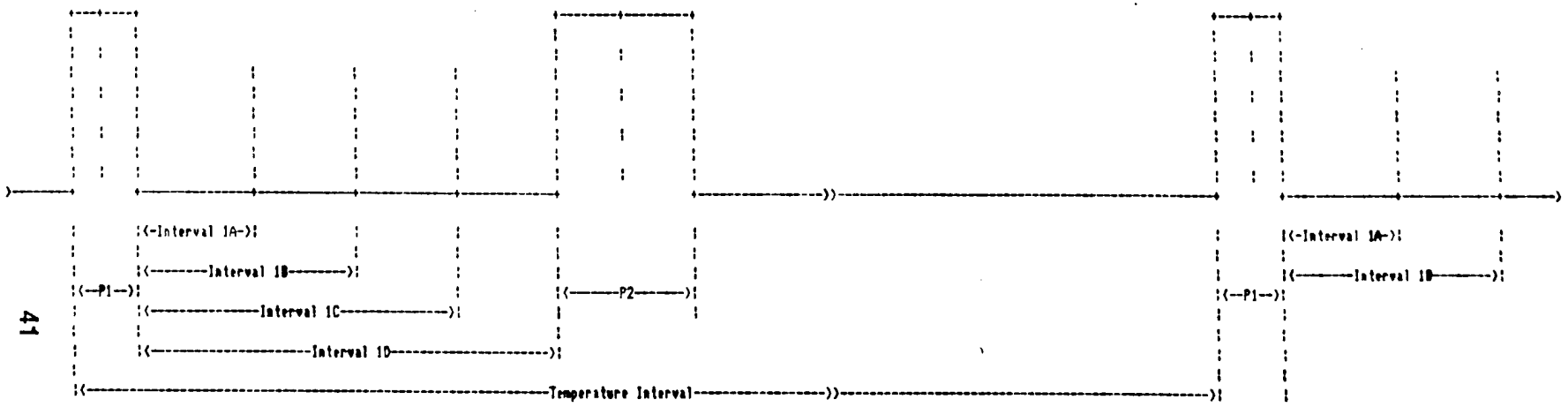
If there is no communication with the unit then reset the unit by uncoupling and recoupling the battery pack connector. Bizarre replies may occur if the unit is in the operating mode and happens to be calibrating the transmitter (such as in the first few seconds of operation after initialization or power-on). If this happens, repeat the query several times. If no packets appear, then check the transmitter and antenna batteries- if the batteries are low then decimal points will be displayed between each number).

7.2 Software Test Modes

See the BFMS Technical Manual for information on software testing.

7.3 Battery Checks

Transmitter batteries should be replaced before every run . The transmitter uses the 3-C-Cell Lithium battery pack and has a nominal voltage of 10.5 volts. The voltage should be at least 9.5 volts for several hours (one session) of operation. If the voltage drops below 8 volts then all three decimal points on the transmitter display light up. Batteries have a life of at least 36 hours. Batteries should remain frozen until needed. Also check the antenna connections.



Each T2D will be programmed with one of 8 possible Identity Codes. The following definitions may be assumed from 34'C to 40'C:

ID Code #	P1 Pulse Width	P2 Pulse Width	Interval Used	Interval Length 34' C to 40' C	Nominal Int @ 37' C
1	10 uS to 15 uS	20 uS to 35 uS	Interval 1A	10 uS (Int(23 uS	16
2	10 uS to 15 uS	20 uS to 35 uS	Interval 1B	23 uS (Int(40 uS	30
3	10 uS to 15 uS	20 uS to 35 uS	Interval 1C	40 uS (Int(67 uS	52
4	10 uS to 15 uS	20 uS to 35 uS	Interval 1D	67 uS (Int(105 uS	86
5	16 uS to 22 uS	34 uS to 60 uS	Interval 1A	10 uS (Int(23 uS	16
6	16 uS to 22 uS	34 uS to 60 uS	Interval 1B	23 uS (Int(40 uS	30
7	16 uS to 22 uS	34 uS to 60 uS	Interval 1C	40 uS (Int(67 uS	52
8	16 uS to 22 uS	34 uS to 60 uS	Interval 1D	67 uS (Int(105 uS	86

Temperature Encoding is contained in the P1 leading-edge to P1 (or P2 to P2) leading-edge frame.

37 degrees C = 500 Hz +/- 100 Hz (2 mS +500 uS/ -333 uS)

Slope = 20 Hz +/- 4 Hz per degree C

Linearity = within 0.1 degree C from 34 degrees C to 40 degrees C.

8.2 Appendix 2 Condensed Operating Instructions

BFMS CONDENSED OPERATING INSTRUCTIONS

BFMSOPER.DOC

A. Preliminary Preparations:

1. Record all pill information from calibration data insert onto a separate BFMS information sheet.
2. Thaw temperature capsule for half an hour before use (only thaw if the capsule is to be used).
3. Check the frequency with a FM radio, if the pill is thawed.
4. Check the computer date and time.
5. Check and record the battery voltage on the transmitter with a voltage meter, if available. (>9.5V=ok) Always use new batteries.
6. Change the directory to BFMS.
7. Run PCAL (all the data to be entered into the computer will come from the pill calibration data insert)
   a. Enter the pill identification number
   b. Enter the transmitter operating frequency (always 92.00 mHz)
   c. Enter Low temp and low frequency (around 37°C and 500 Hz)
   d. Enter High temp and high frequency (around 40°C and 560 Hz)
   e. Enter information on the top and the bottom of the screen.
   f. Enter all information (date of mfg, date of use, subject number, study name)

7. Run DISPLAY (enter information from the pill calibration data insert)
   a. Enter T Low: F Low:
   b. Enter T High: F High:
   c. Record the display parameters on the BFMS information sheet (these will be entered in the computer later.

   Hexval Base:

   Range:

   Scale:

***At this point, information may stay stored in the computer and the pills remain frozen until needed.**

B. Setup BFMS unit:

1. Connect the DB 9-pin, RS-232 serial cable to com1 of a PC (486) from the man-pack.
2. Connect the power supply to the man-pack unit (3 C-cell Lithium battery pack). The BFMS display should read 42.2 (low battery if 3 decimal places are lit).
3. Connect the receive antenna (blue port) and the transmit antenna (red port) to the man-pack unit. The signal may be verified on a FM radio at 92 mHz.
4. Run RTITEST
   a: "H" always returns to the main menu. (Any key must be pressed before a command key will respond)
   b. Check to make sure the BFMS is in idle mode by pressing enter and then "R". Read hhll: ***F802***. The correct response for the idle mode is 00. If the response is not 00, then put the unit in the idle mode by pressing "W". Write hhll,val: ***F802,00***, then press G, enter.
   c. Press "L" to set the length of the packets: ***11***.
   d. Press "F" to set the transmitter operating frequency: always ***92.00 mHz***.
   e. Press "T" to set the pill transmitting frequency: provided on the pill calibration data insert, usually around ***88.00 mHz***.
   f. Press "Y" to set the display parameters: previously recorded on the BFMS information sheet from the DISPLAY program.

***At this point, information may stay stored in the computer and the pills remain frozen until needed.**

   g. Press "N", immediately followed by enter, to START the operation mode,.
   h. Packets should begin to appear on the screen.
   I. Check to verify that the unit is transmitting by the command "R".

Read hhll: ***F802***. The correct response for the idle mode is 01. If the unit is not transmitting, it may be put in the transmitting mode by the command "W". Write hhll,val: ***F802,01***, then press G, enter.

5. Check the pill operation by holding the antenna around the subject's waist and watching the packet data on channel 4.
   FF = system OK, pill detected
   FE = system OK, no pill detected
   7F = low battery, pill detected
   7E = low battery, no pill detected
6. Check the temperature sensors by warming with hands and verifying temperature changes in the packet data.
   blue thermistor=channel 8
   green thermistor=channel 9
   ambient thermistor=channel 10
   thermistor=channel 11
7. Check the cardiotach to monitor the heart rate by the left hand grasping the red button side and the right hand grasping the black button side) = channel 12
8. F10 to quit (H=main menu)
9. Disconnect serial line from the man-pack unit while unit is running.
10. Disconnect the power supply if the unit is **not** going to be used immediately.
11. Unit may be stored until needed in the field.

***At this point, information may stay stored in the computer and the pills remain frozen until needed.**

Once in the field, reconnect the power supply and the man-pack should continue to operate. Since the unit was previously started by pressing "N", there will be a time difference between the actual start up of the unit and the start of the data collection in the field.

C. Player Preparation

1. Check the player for the absence of any other pill. (section 5.3.1)

2. If no pill is detected, issue the player a pill and a corresponding BFMS man-pack. The pill information is specific for this unit and was previously entered in the computer. (above)
3. The player may then swallow the pill.
4. Secure the man-pack with the power supply connected (new batteries) to the player.
5. Attach the thermistors and the cardiotach (red button goes on the left side for heart rate) to each player.
6. Connect the receive antenna to the blue port of the man-pack and secure the antenna around the players waist to receive pill transmissions.
7. Connect the transmit antenna to the red port of the man-pack and secure the antenna over the players shoulder to transmit data back to the base station.

D. Setup Telemetry Receiver (Base Station)

1. Connect the DB9, RS-232 serial cable from the PC to the base station receiver.
2. Check and record the battery voltage on the receiver with a voltage meter. (>9.5V=OK) Always use fresh batteries.
3. Connect power supply (3 C-cell Lithium battery pack).
4. Connect the receive antenna to the blue port on the base station.
5. Run RTITEST
6. Press "L" to set the length of the packets: ***11.***
7. Press "F" to set the transmitter operating frequency: always ***92.00 mHz.*** If the receive frequency needs to be altered due to the interference of a radio station running on the same frequency, it may be done by pressing "F" and entering the operating frequency desired.
8. Check the BFMS unit staus by pressing enter and then "R". Read hhll: ***F802.*** The correct response for the receive mode is 02. The base station is receiving data from the man-pack in mode 02. If the unit is not responding with 02, it may be put in the receive mode by the command "W". Write hhll,val: ***F802,02***, then G enter. Recheck the mode with the command "R". Read hhll: ***F802***, and the response should be 02. It may be neccessary to repeat this step. Packets should begin to appear on the monitor.
9. Check the received packet data to verify the pill (near 37°C), heart rate and temperature status.

11. Press F10 to quit and begin real time monitoring with the programs PROISAMD and TESTBM93 (section E).

E. Setup Real Time Monitoring

1. Run PROISAMD (Response will be that the program was successfully installed).
2. Run TESTBM93
   a. Enter the number of players (1) ** Always enter the number of the unit being tested. Give bogus pill numbers for all unused BFMS units prior to the unit being tested.
   b. Enter the session data base file name, BFMSXXX.dbf (the filename is to be assigned by the user).
   c. Enter the pill number for each player.
   d. The data monitoring screen appears, check to verify that packets are being received. If no packets are being received, check the antenna connections and the transmitter batteries. (if the batteries are low then a decimal point will be displayed between each number) The pill status should be FF and the pill temperature should be near 37°C.

      F1 = **DO NOT USE = the computer **will** lock up.

      F2 = monitoring screen

      F3 = Analog bargraph display

      F4 = 30 min time history

      F10 = quit (end of session)
3. You must reboot the computer after F10.

F. Logger Memory Transfer

1. Remove the BFMS unit from the player.
2. Reconnect the RS-232 serial cable to the man-pack.
3. Run RTITEST
4. Place the unit back in the idle mode by pressing enter and "W".
   Write hhll,val: F802,00 enter, then G enter. Verify that the unit is in idle mode by pressing "R". Read hhll: ***F802***. The correct response is 00. If the unit is still not in the idle mode, retry the "W" command.
5. Press "S" to memory dump (may take 8 minutes) from the man-pack to the PC. Response is BFMS2.ald closed.

Reactivating unit...

Resetting...

Wait...

6. F10 to exit
7. Disconnect the power supply.
8. Rename BFMS0.ald to BFMSXXX.ald (the filename is to be assigned by the user and should have the same filename as the dbf file).

G. Proccessing the Logger Memory Data

1. Verify that the system is set up with expanded memory. If there is no expanded memory, do the following and boot the system to the floppy.
   a. Format a systems disk using the target system. (format a:/s/u)
   b. Copy config.sys to the system floppy.
   c. Copy autoexec.bat to the system floppy
   d. Edit the config.sys on the floppy and ensure that the memory manager has expanded memory enabled. (e.g., ram and not noems)
2. Run PROISAMD
3. Run LOG93
4. Enter the screen information:
   a. Enter name of project or study: BFMS
   b. Enter player's ID code: XXX (the ID code should have the same characters as the filename which was assigned by the user).
   c. Enter pill number:
   d. Enter the date of the study: 00/00/1994
   e. Enter the input file name BFMSXXX.ald (the filename which was previously assigned by the user).
   f. Return past the exit time
   g. Return past the casualty code
5. Verify the pill information
6. Select coordinates and compression: edit the start and stop times to the nearest hour that will include all the data points. Edit the epoch times to 60 secs.
7. Wait for the program to create.CSV and.TXT files.
8. Make sure the printer is attached and working.

9. Hit the space bar to print the data.
10. Press F10 to return to the C:> prompt.

H. Processing Real Time Data

1. Run DBPROC
2. Enter the screen information:
   a. Enter thestudy name: BFMS
   b. Enter the date of data record: 00/00/1993
   c. Enter the input file name: BFMSXXX.dbf (the filename which was previously assigned by the user).
   d. Edit the start and stop times to the nearest hour that will include all data points. Edit the epoch time to 60 secs.
   e. Data will start to print
3. Rename BFMS-1.CSV which was created to BFMSTXXX.CSV (the filename is to be assigned by the user).
4. Rename BFMS-1.TXT which was created to BFMSTXXX.TXT (the filename is to be assigned by the user).

Appendix V

FDA 510(k) Application

Enclosure 1 Product Description and Specification
Enclosure 2 Labeling and Promotional Material
Enclosure 3 Performance Test Data and Safety Analysis
Enclosure 4 Substantial Equivalence - Discussion
Enclosure 5 Encapsulation Material Data Sheets

January 7 1991

Eph Konigsberg

Konigsberg Instruments, Inc.
Pasadena, CA 91107

KONIGSBERG INSTRUMENTS, INC.

2000 Foothill Boulevard Pasadena, California 91107-3294
Telephone: (818) 449-0016 Fax: (818) 449-1086

January 7, 1991

Food and Drug Administration
Center for Devices & Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

RE: 510(k) Notification

This is to notify you of the intention by Konigsberg Instruments, Inc. to manufacture and market the following device:

Classification Name:

General Hospital and Personal Use Monitoring Devices

Classification: II

Common Name: Clinical (Electronic) Thermometer

Proprietary Name: Series T2 Ingestible Temperature Telmeter

Establishment Registration Number: 2020337

Performance Standards: None Established

Labeling/Promotional Material:

Labeling, with application restrictions, enclosed.

Substantial Equivalence:

This product is similar in design and function to two products:

a. The T2T-1 temperature telemeter produced by Konigsberg Instruments, Inc. prior to May 28, 1976. Descriptive documents are enclosed.

b. The CorTemp Temperature Capsule System produced by Human Technologies, Inc., which received 510(k) SE determination on November 2, 1988 (Case # K880639), and which is currently on the market. Comparative material is provided.

The T2D Temperature Telemetry system was developed for, and is supplied to the U.S. Army Medical Research and Development Command, Ft. Detrick, MD, under contract DAMD17-85-C-5257. It is used by them in minimal-risk investigational protocols. Their representatives have been aware of our ultimate intent to market this device for more general and non-investigative applications. However, we consider our current intent to market to be confidential commercial information and request that it be considered as such by the FDA.

Yours truly,

Eph Konigsberg
President

Enclosures:

1. Product Description and Specification
2. Labeling and Promotional Material
3. Performance Test Data and Safety Considerations
4. Substantial Equivalence - Discussion
5. Encapsulation Material Data Sheets

PRODUCT DESCRIPTION Enclosure 1

General Description

The T2D Series Temperature Telemetry System consists of 1) an ingestible sensor/transmitter capsule (or "Temperature Pill") which emits micro-power radio-frequency (RF) pulses at intervals related to the surrounding (gut) temperature, and 2) a suitable receiving module, consisting of antenna, RF tuner/transceiver, digital control, decoding, memory, display, and communications circuits.

T2D Temperature Telemetry Transmitter (Pill)

Assembly. The T2D capsule is made up of two printed circuit board subassemblies, an antenna assembly, the battery, and moisture barrier and biocompatible coatings rendering it suitable for ingestion. (See Fig. 1). The electronic subassemblies consist of a thermistor, a semi-custom integrated circuit (encoder), and a transmitter circuit. The antenna is a wire coil, and the battery is a 1.5 Volt Silver Oxide Battery. The final assembly is tuned, inserted in a gelatin capsule, coated with a dental acrylic resin (for moisture barrier durability) and is finally coated with a medical grade silicone sheathing. A unique serial number is inscribed on the pill surface. Each pill is calibrated by measurement of emitted pulse frequency at each of two water bath temperatures, 37 and 40 degrees Celsius. The pill is then packaged in a sealed plastic packet, which contains labeling information as described in Enclosure 2.

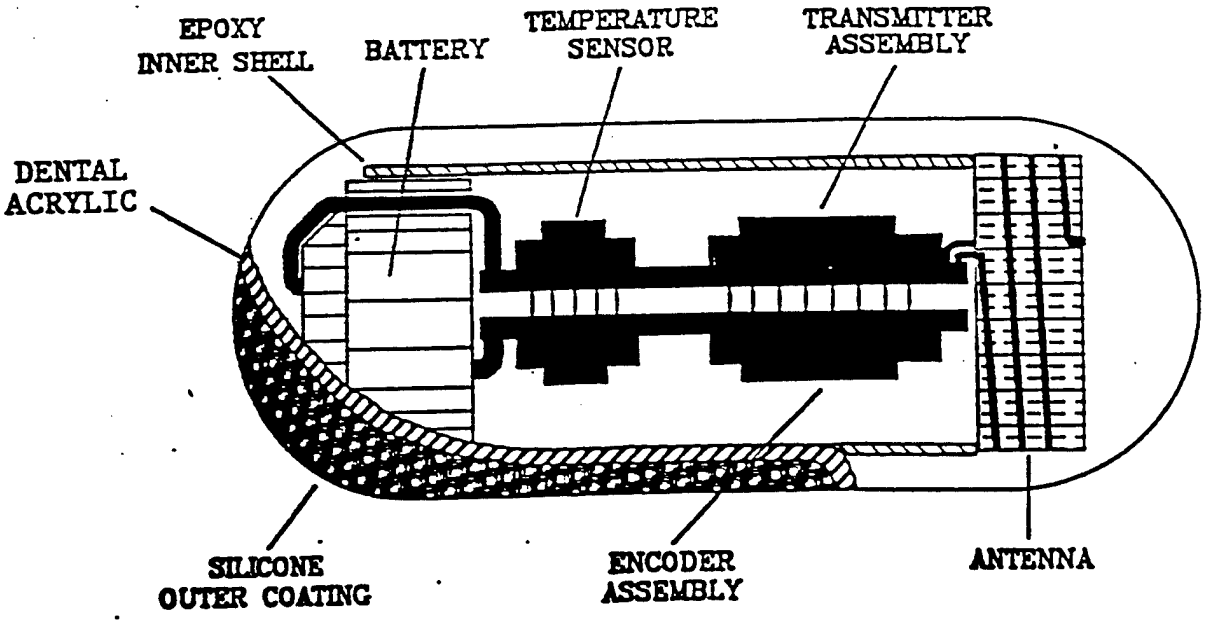


Figure 1. Illustration of T2D Temperature Pill

Theory of Operation. (See Fig. 2). The encoding microcircuit translates temperature information (derived from the thermistor) into a train of pulses (about 10 to 60 microseconds in duration) whose repetition rate (frequency) is linearly related to the temperature. Nominally, the pulse frequency is 500 Hertz at 37 degrees C., increasing 20 Hertz per degree C. This pulse train is then used to switch on and off the RF transmitter, which is tuned to emit a pulsed carrier in the RF frequency band between 86 and 108 Megahertz. This pulsed-transmission feature greatly reduces transmitter duty-cycle, and hence battery drain. Shelf life of the operating pill is about 3 months, and longer with storage in the cold. Estimated battery output power comsumption for operation and transmission is about 25 microwatts.

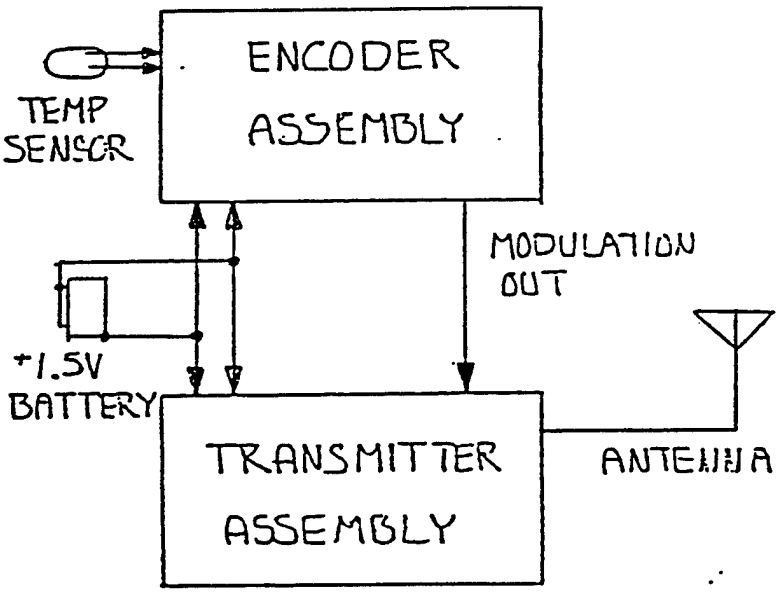
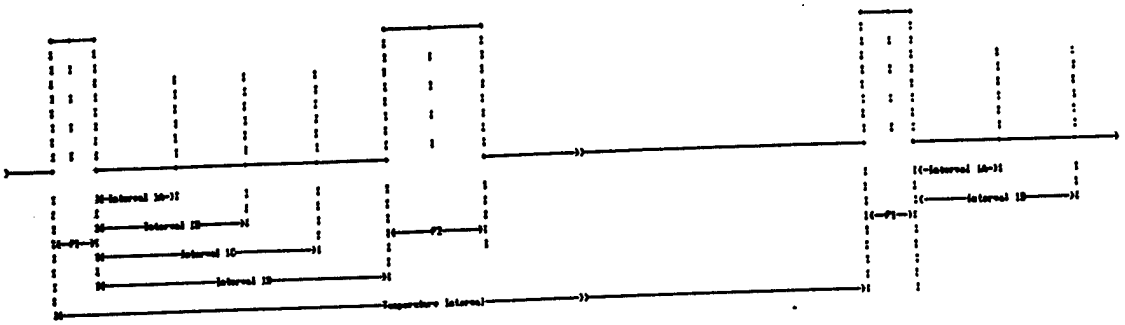


Figure 2. T2D Pill Block Diagram

Dual-pulse encoding: The T2D differs from its predecessors in that the encoding microcircuit emits <u>two</u> pulses in brief succession: a short pulse (P1) of about 10 - 25 microseconds, followed by an interval (I1) of 10 - 80 microseconds, and another, longer pulse (P2) of 20 - 60 microseconds. The overall pulse interval (P1 to P1) is determined by temperature, and is on the order of 2 <u>milli</u>seconds. The shorter intervals (P1,I1, and P2) are determined by the components used at final assembly, at preset values which permit configuration of 8 distinctly different pill types. (See Figure 3).

This feature aids the receiver/decoder circuits described below in discriminating the pill signal from background noise, allowing it to "lock" onto the pill, thus increasing system reliability. This innovation in no way impairs the accuracy of the basic function (temperature measurement), while it permits future development of multi-channel or multi-pill applications.



Each T2D will be programmed with one of 8 possible Identity Codes. The following definitions may be assumed from 34°C to 48°C:

ID Code #	P1 Pulse Width	P2 Pulse Width	Interval Used	Interval Length 34° C to 48° C	Nominal Int @ 37° C
1	10 uS to 15 uS	28 uS to 35 uS	Interval 1A	10 uS (Int(23 uS	16
2	10 uS to 15 uS	28 uS to 35 uS	Interval 1B	23 uS (Int(40 uS	30
3	10 uS to 15 uS	28 uS to 35 uS	Interval 1C	40 uS (Int(47 uS	32
4	10 uS to 15 uS	28 uS to 35 uS	Interval 1D	47 uS (Int(185 uS	86
5	16 uS to 22 uS	36 uS to 48 uS	Interval 1A	10 uS (Int(23 uS	16
6	16 uS to 22 uS	36 uS to 48 uS	Interval 1B	23 uS (Int(40 uS	30
7	16 uS to 22 uS	36 uS to 48 uS	Interval 1C	40 uS (Int(47 uS	32
8	16 uS to 22 uS	36 uS to 48 uS	Interval 1D	47 uS (Int(185 uS	86

Figure 3. Dual Pulse Encoding Scheme

The T2D will be marketed as an electronic thermometer which may be read by a number of different receiver/decoder techniques. As such, the T2D will be manufactured as a finished product; each pill will be shipped with factory calibration data and to guaranteed performance specifications. Field calibration with suitable receiving equipment proximately prior to use is the responsibility of the appropriate administering authority as indicated in Enclosure 2 of this document.

3.0 Specifications

T2D Temperature Telemetry Transmitter (Pill)

Size:	Length = 29 mm (approx.) Diameter = 11 mm (approx.)
Weight:	3.9 Grams (0.13 oz.)
Temperature Sensor:	Bead Thermistor
Pulse Frequency:	500 Hz (nominal) @ 37 Celsius ± 100 Hz
Frequency Change:	20 Hz (nominal) per degree Celsius ± 4 Hz
Non-Linearity:	± 0.1% between 34 and 40 Celsius
Accuracy:	± 0.1% between 34 and 40 Celsius
Transmission Method:	Near Field Pulsed Radio Frequency
Operating Frequency:	86 - 108 MHertz (Factory set)
Range:	24 inches (typical)
Transmitter Duty cycle:	< 5%
Transmit Power:	Mean (Pulsed): < 25 microwatts
Power Supply:	1.5 Volt Silver Oxide Battery (Ray-O-Vac type 393)
Battery Life:	> 3 months at room temperature
Expected Life:	One usage

Encapsulation Materials:

Inner capsule, hermetic seal of electronic components: Lee Pharmaceuticals photo-cure methacrylate resin (dental)

Outer coating: GE RTV112 Silicone Sealant

Overcoating of lettering: Dow RTV734 Clear Silicone Adhesive

The above materials comply with Section 21CFR 117.2600 and Section 21CFR 175.300 of the Food and Drug Regulations.

4.5 **Disposition of data.** Once the basic datum is acquired, the user has four choices for its disposition. First, to transmit the datum directly over a serial-RS232 line to a computer for further storage, analysis, and/or display. Second, to transmit the data through the RF transceiver (using the second antenna port) to a distant station, where the data may be stored, analyzed, and/or displayed. Third, to record, or log, the data in digital memory at preselected intervals, later dumping the data into a personal computer for subsequent analysis and display. And fourth, to immediately display the data, converted to degrees Celsius, on a liquid-crystal display optionally provided with the case. In the first three cases, original interval resolution is retained, while in the fourth, display is limited to the nearest 10th of a degree. All four optional dispositions can be used simultaneously, at varying display/sampling rates determined by user software programming.

4.6 Specifications TR6B Receiver/Decoder Module

Size:	6.8 x 3.6 x 2.5 inches
Weight:	12 oz. (without batteries)
Receiving Antenna:	1/4 wavelength long, insulated wire
Receiver Sensitivity:	1 microvolt
Battery Power:	3 - 3.6 volt Lithium Batteries
Battery Life:	> 24 hours using AA Bateries
Operating Method:	Motorola 68H811E2FN microcomputer controlled radio, analog and digi tal logic functions. Applications software downloaded into non-volatile memory performs specific user-defined operations.
Data Output:	Measured pulse wave interval data passed externally via RS232 serial port, or transmitted via retrans-mission telemetry, or stored in digital memory, or as converted to Temperature (degrees C.),displayed on liquid crystal display screen.

LABELING AND PROMOTIONAL MATERIAL Enclosure 2

The T2D is packaged and delivered within a sealed plastic bag; in this bag is a paper insert containing the following information:

T2D Ingestible Temperature Telemetry Pill

Serial Number:

Date of Manufacture/Calibration:

Calibration Frequency @ 37° C.: @ 40° C.:

Operating Frequency: MHz.

Pulse Configuration Type:

INTENDED FOR CLINICAL OR INVESTIGATIONAL USE AUTHORIZED BY A PHYSICIAN, MEDICAL MONITOR, OR OTHER APPROPRIATE AUTHORITY. NOT FOR USE IN INFANTS, AND NOT IN CHILDREN LESS THAN AGE 16 EXCEPT UNDER DIRECT MEDICAL SUPERVISION. FOR ONE TIME USAGE ONLY.

DO NOT USE IF PACKAGE OPENED OR TAMPERED WITH.

USE ONLY ACCORDING TO DETAILED INSTRUCTIONS PROVIDED WITH SPECIFIC CONFIGURATION OF MONITORING SYSTEM.

<u>CONTRAINDICATIONS</u> TO THE USE OF INGESTIBLE TELEMETRY PILL:

THE T2D TELEMETER SHOULD NOT BE INGESTED ORALLY IN THE PRESENCE OF KNOWN OR SUSPECTED OBSTRUCTIVE DISEASE OF THE GASTROINTESTINAL TRACT INCLUDING BUT NOT LIMITED TO GASTRIC OR DUODENAL ULCERS, DIVERTICULOSIS, APPENDICITIS, BOWEL TUMORS, AND INFECTIOUS OR INFLAMMATORY BOWEL DISEASES OF ANY TYPE; NOR IN ANY PATIENT EXHIBITING OR HAVING A HISTORY OF SWALLOWING DISORDERS OR DISORDERS IMPAIRING THE GAG REFLEX; NOR IN PATIENTS WITH PREVIOUS GASTROINTESTINAL SURGERY; NOR IN ANY PATIENT WHO MIGHT UNDERGO NUCLEAR MAGNETIC RESONANCE (NMR) PROCEDURES DURING THE PERIOD THAT THE TELEMETER IS WITHIN THE BODY.

<u>PRECAUTIONS:</u>

THE T2D TELEMETER MIGHT BE USED AS A RECTAL SENSOR IN THE PRESENCE OF UPPER BOWEL DISEASE, BUT IN THE ABSENCE OF ANAL/RECTAL ABNORMALITY. PEDIATRIC USE SHOULD BE AVOIDED DUE TO ITS SIZE COMBINED WITH THE UNCERTAINTY OF PATENCY IN THE IMMATURE GUT. PATIENTS SHOULD BE INSTRUCTED NOT TO BITE OR CHEW THE CAPSULE, WHICH WOULD RENDER IT USELESS.

REPORT ADVERSE RESULTS AND/OR DIRECT QUESTIONS TO:

Konigsberg Instruments, Inc.
2000 E. Foothill Blvd.
Pasadena, CA 91107
(818) 449-0016

PROMOTIONAL MATERIAL Enclosure 2

PLACE ANY PRODUCT ANNOUNCEMENTS, ETC. HERE

PERFORMANCE TEST DATA AND SAFETY ANALYSIS **Enclosure 3**

This enclosure consists of a Report by COL Daniel P. Redmond, of the Department of Behavioral Biology, Walter Reed Army Institute of Research, who is the Army Technical Representative for the development contract. This report, produced for Army intramural purposes, is a synopsis of various tests of the Konigsberg Instruments T2 Temperature Sensors conducted during the development phase, leading to Army acceptance of the end item. Particular experiences summarized in this report include:

1. Initial dog studies at the University of Oklahoma.

2. Human Temperature Response to Exercise, as assayed with the pill, conducted at the University of Oklahoma.

3. Comparison of Pill Temperature and Rectal Probe, conducted at the University of Oklahoma.

4. Assessment of Accuracy and Linearity of Konigsberg Temperature Pills, <u>In Vitro</u>, from Johns Hopkins University/Applied Physics Laboratory, and from Dr. Redmond's laboratory.

5. A review of Human Use/Safety considerations related to clinical and investigational applications of the pills in Army projects.

THE WALTER REED TEMPERATURE PILL:

EVALUATIONS FOR CLINICAL AND INVESTIGATIONAL USAGE

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AUGUST 1990

THE BRANCH FOR SPECIAL STUDIES
DEPARTMENT OF BEHAVIORAL BIOLOGY
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WALTER REED ARMY INSTITUTE OF RESEARCH
WASHINGTON, DC 20307-5100

TABLE OF CONTENTS

THE WALTER REED TEMPERATURE PILL:

EVALUATIONS FOR CLINICAL AND INVESTIGATIONAL USAGE

1 BACKGROUND

2 Introduction

In 1985, the U. S. Army Medical Research and Development Command awarded a contract to Konigsberg Instruments, Inc. (DAMD17-85-C-5257) to develop a system for multi-channel biomedical monitoring in military operational environments including a chemical defensive posture wherein subjects would wear restrictive protective clothing but would be expected to maintain their task performance and physical activity. A subsystem within this system involved the use of ingestible temperature telemetry allowing monitoring of deep body temperature during periods of heat stress. Ingestible telemetry was chosen because of prior difficulties, especially discomfort and maintenance problems, with the use of rectal probes in such environments. This laboratory had successful results, in constrained environments, using a Canadian temperature capsule, but found certain problems which made it difficult to use in the field. Therefore an effort was made, within this developmental project, to achieve an improved design.

By late 1986, prototype versions of the Temperature Pill were delivered for initial testing and evaluation, and in early 1989, the first lot of the final version, called the T2D Pill, were received. A series of practical tests of performance and operation were conducted here and at other laboratories in order to establish acceptance and suitability of the device for clinical and investigational applications. This report summarizes that evaluation, and favorably concludes that the T2D Pill is both effective and safe for its intended purpose. Conditions of usage, precautions, and contraindications are identified. While it is an Investigational Device (pending FDA clearance), it is considered to pose nonsignificant risk to human subjects, in and of itself. Field applications and further evaluations of the ingestible thermometric system have been planned, under approved protocols, and will be the subject of future reports.

2.1 A Brief History of Ingestible Telemetry

The concept of using ingestible radiotelemeters has developed for over 30 years, coinciding with the development of micro-circuitry and refinement of bio-implantable devices. A technical review of these developments is not appropriate here, but key milestones are tabulated below (see Bibliography for selected references):

Gastrointestinal Pills - Pressure & pH

1957 - Mackay & Jacobson
1957 - Farrar, Zworykin, & Baum
1960 - Noller (Heidelberg)
1975 - Oxford Instruments (USA)
1979 - Colson & Watson (UK)

Thermometric Pills

1961 - Wolfe (UK)
1968 - Mackey (UK)
1972 - Konigsberg (USA)
1973 - Ackles & Kuehn (Canada)
1979 - Walter Reed Army Institute of Research
1986-1989 - Konigsberg (USA)
1987-1989 - NASA/APL/HTI (USA)

The basic design of such devices involves the use of very low power radio frequency signals which are modulated by a transducer or sensor (e.g., pressure, pH, or temperature). Battery and electronics are enclosed in a capsule and coated with an impermeable plastic. The pill is swallowed and eventually excreted in the feces after one transit time (usually 7 -70 hours). While in the gut, the signal is picked up by a body mounted antenna and radio receiver, and demodulated into useful data. Pills are normally discarded after use for aesthetic and ethical reasons. In some studies, pills have been tethered (e.g., to a tooth), or inserted in the rectum or vagina; they have also been implanted in small animals.

Various issues of design and operation have focused on the internal electronics and signal propagation. Signal reception and dropout, battery life, expense, and fabrication difficulties are problems usually addressed. Recently, two pill designs, including the T2D, have been advanced which represent major technical improvements, especially in terms of signal consistency, accuracy, and battery life. A brief review of these follows:

2.1.1. APL/Human Technologies, Inc. (HTI) Pill

This pill was recently cleared by the FDA for marketing and clinical usage. A draft design was developed in 1987 by NASA Goddard, completed under contract by the Applied Physics Laboratory of Johns Hopkins University, and licensed to Human Technologies in 1988. It emits a continuous wave at about 262,000 Hertz, whose frequency is modified by temperature effects on the internal crystal. The receiver consists of an inductive coil antenna and a counter which determines the incoming frequency, converts it to temperature, and stores the data at 30 second intervals in solid-state memory. Temperature is also visible on a display on the belt-worn receiver unit.

The HTI pill is a single channel (temperature only), disposable pill system. Pills are $15-20 apiece, depending on quantity. Current design does not permit re-telemetry of data and there is a possibility of interference (cross-talk) when two or more subjects are in close quarters. Because of the relatively low frequency and inductive link, we have found it sensitive to noise in proximity to computers, heavy vehicles, and other dense electromagnetic fields.

2.1.2 The Walter Reed/Konigsberg Instruments (KI) T2D Pill

This pill has its origins in the Konigsberg T2-T pill developed in 1972 and used by both NASA and the Naval Medical Research Institute. Two subspecies exist: the T2A is a state of the art re-working of the older pill and considered the T2D prototype, used for initial evaluations. The T2D is the Walter Reed pill currently being delivered, and differs from the T2A in terms of its encoding and modulation scheme, which permits three, rather than one, channels of data. This is implemented by using a custom micro-chip for its electronics. Although current usage is limited to temperature only, the T2D has broader potential in future applications. Rather than a continuous high-frequency wave, these pills emit brief bursts or pulses of a radio signal in the FM Broadcast Band (88 - 108 megahertz). The time interval between pulses conveys the temperature information to a belt-worn radio receiver with decoding software. Because of this design, pills with differing frequencies are free from cross-talk, and can be used in several subjects at the same time. Furthermore, the T2D emits two brief pulses in rapid succession, followed by a long pause. The long interval is modulated by temperature, while the short pulse-pair are characteristic for each pill. Thus receiving/decoding software can discriminate the pill in spite of varying amplitude and ambient noise. This permits more avid tracking, reduced dropout, and resistance to interference. Like the HTI pill, the capsule is coated with dual layers of acrylic or epoxy plastic followed by a layer of biocompatible RTV Silicone Compound. At present the cost is about $130 per pill. Technical details of the design are beyond the scope of this report, but are the subject of a Technical Data Package in preparation. See Figure 1.

2.2 Validation

Since the mid-60's, one or another form of ingestible telemeter has been in use in the United Kingdom. Thermal pills were used to assess exercise induced heat stress in British soldiers since the 70's. In Canada, a version of the British temperature pill is used routinely in studies of exposure to cold, especially in naval personnel and divers. Throughout this lengthy experience, no reference is found for a comprehensive comparison of ingested pill data to other methods of measuring human body temperature. One report in the Russian literature (in 1965) maps out gut temperatures in 30 healthy subjects. Otherwise, the

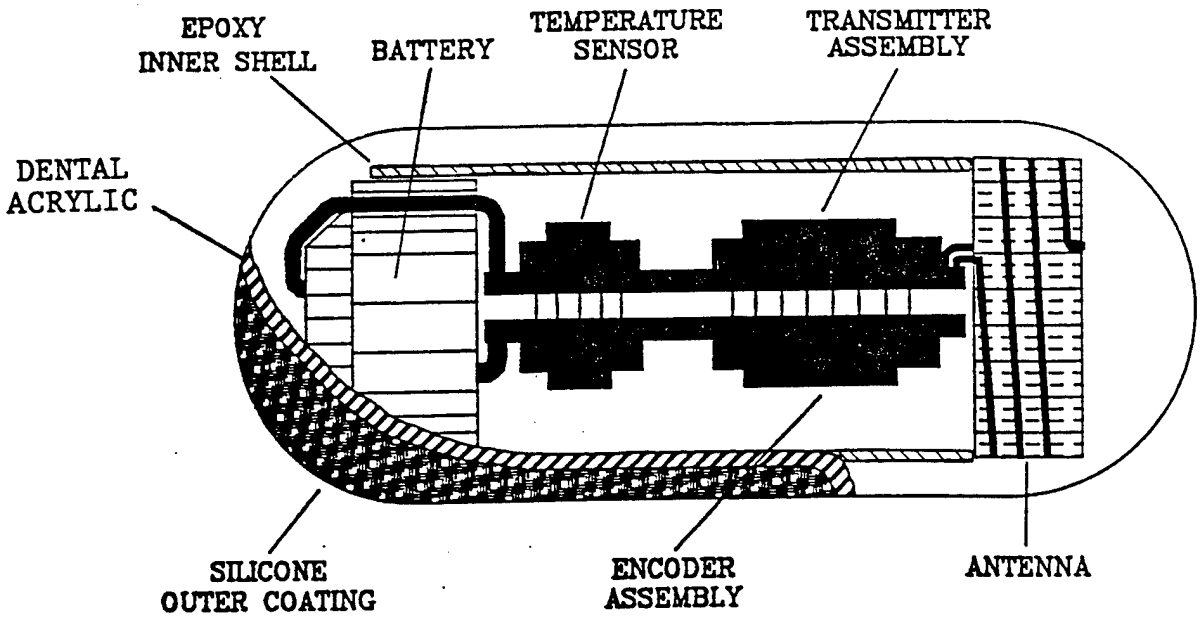


Figure 1. Illustration of T2D Temperature Pill

foreign literature basically assumes 1) that temperature pills are simply thermometers; 2) that they report the temperature at their location, e.g., esophageal if tethered there, rectal if rectally inserted, and somewhere in between if swallowed; and 3) that at any location, thermal measurements obtained from pills are clinically useful for assessing response to either heat or cold stress.

At our laboratory, in 1980-1982, temperature pills were use to track the daily variation (circadian rhythm) of body temperature in laboratory studies concerning jet lag, and produced results comparable to rectal thermometers. However, clinical interpretation of temperature levels was not attempted.

The next section summarizes reports received which serve to validate the T2D as a clinical thermometer. Similar data used to validate the HTI Pill are reported as well, as they are generally applicable to ingestible thermometry. At present, a careful distinction must be drawn between clinical thermometry and measurement of core temperature which might be used in research of thermoregulatory physiology. Present data merely confirm the assumptions of the foreign literature: temperature pills are thermometers which have a clinical application, and they appear to be quite safe. The precise meaning of temperature recorded in the gut remains a question for future research.

3 SYNOPSIS OF TEST AND EVALUATION STUDIES

Most of the following studies were performed by Kenneth J. Dormer at the University of Oklahoma Medical Center, under USAMRDC Contracts DAMD17-85-C-5257 and DAMD17-88-M-0035. Calibrations were performed by the JHU/Applied Physics Laboratory under Navy Omnibus Contract, USAMRDC Project No. 89MM9509. Finally, Dr. Leonard Keilson, of Maine Medical Center, provided us with a copy of his data evaluating the Human Technologies temperature pill. All human studies were performed under appropriate local Human Use Review Committee approval. The summaries below are our own, based on own analyses of original data and other in-house evaluations.

3.1 Canine Pill Passage

3.1.1. Reference. Dormer, Kenneth J., Dept. of Physiology and Biophysics, University of Oklahoma. Letter Report "Preliminary Temperature Pill Studies on Conscious Dogs," October 8, 1986. (Phase IA, Section 2).

3.1.2. Objective. To test integrity of pill coating and electronic function of Konigsberg Instruments T2A pills after passage through the gut of dogs.

3.1.3. Method. Three pills were each passed twice, by insertion in the oropharynx and subsequent retrieval from the stool. On retrieval, pills were examined under the microscope and tested for continued emission of RF signal, then returned to Konigsberg for dissection and examination.

3.1.4. Results. Transit time for each pill passage was about 36 hours. In all six passages, the RTV Silicone coating was intact under the microscope. RF signal remained normal after five of the six passages. One pill, during its second passage, stopped transmitting. Subsequent dissection revealed that its battery had failed; there was no evidence of rupture or leakage of the coating, and it resumed operating when power was applied.

3.1.5. Conclusion. RTV Silicone coating procedures were considered suitable for human use applications.

3.2 Initial Tests In Human Subjects

3.2.1. Reference. Dormer, Kenneth J., Dept. of Physiology and Biophysics, University of Oklahoma. Letter Report "Antennae Reception of Temperature Telemetry Pill," October 24, 1986. (Phase IA, Section 3).

3.2.2. Objective. To test integrity of pill coating and RF propagation of T2A pills during passage through the human gut.

3.2.3. Method. A pill was swallowed by each of two young men, and observations of pill signal and estimated gut temperature were made over a period of about 4 hours. Receiving antenna configurations involving both "rabbit-ear" and quarter wave wires over the chest, shoulder, and waist were evaluated semi-quantitatively from a signal strength meter. Pill signals were tracked and temperature was decoded using a Konigsberg Instruments TR4/T10D benchtop receiver (a functional prototype of the portable TR6 receiver). This was repeated with the subjects wearing chemical-defense protective clothing. Finally, the subjects were tested in various body positions, after drinking hot and cold water, and with calisthenics and brief treadmill exercise. Pills were recovered the following day and examined for integrity of the coating layer.

3.2.4. Results. Pill signal strength at the receiver was considered adequate for tracking (sufficiently above ambient noise levels) at all locations within about 24" from the "rabbit ears", and was consistently tracked using trunk and waist mounted wire antennas, irrespective of position, posture, activity, or clothing. Cross-interference between the two subjects' pills occurred when they were within about 1 foot of each other, using the body mounted wires. Fluctuations in measured temperatures in the order of ± 0.5° C. were observed attendant with the various manipulations of activity. The two recovered pills were intact on microscopic examination and were still functioning.

3.2.5. Conclusions. The pill signal/receiver link was surprisingly robust, and pulse waveforms were well-tracked, even when subjects were wearing chemical protective clothing. Pills appear responsive to hot/cold drinks in the first 2 hours post ingestion, and reflect changes due to exercise. Problem of cross-talk may occur with subjects using same pill carrier frequency, in very close quarters. Pill coating with RTV silicone appears adequate for human use. Additional studies of pill response in humans should proceed.

3.3 Dynamic Response of Gut Temperature to Exercise Heat Stress

3.3.1. Reference. Dormer, Kenneth J., Dept. of Physiology and Biophysics, University of Oklahoma. Letter Report "Multichannel Biomonitor recording of Response to Exercise, wearing Protective Clothing", March 17, 1987. (Phase IA, Section 4).

3.3.2. Objective. The temperature pill was used to track core temperature during exercise, in order to demonstrate systematic dynamic response of the technology to change in the upper ranges of thermal stress. These results would be used to estimate a predictive algorithm relating work load and subsequent gut temperatures, for use in future studies.

3.3.3. Method. Two subjects were studied under five conditions, presented successively with variable "cooling-off" periods:

a. Quiescent without protective overgarment
b. Quiescent with protective overgarment
c. Exercise with 37 lb. backpack load, unsuited
d. Exercise with protective suit, unloaded
e. Exercise with protective suit, loaded

Exercise consisted of a standard Bruce protocol with three stages (1.7 mph/10° grade., 2.5/12, & 3.4/14), with physiological data recorded at 3-minute intervals. The last condition was not tested in the second subject since human-use limits were reached with the first subject. Gut temperature was obtained from Konigsberg T2A pills ingested one hour before protocol started, using the bench-top receiver/decoder used before (TR4/T10D).

3.3.4. Results. Pill temperature data for each condition are tabulated below. The other variables showed expected and corresponding changes during exercise. (*, **, *** = stages of exercise).

Subject CT: Gut Temperature in degrees Celsius. (Figure 2)

CONDITION:	QUIET	QUIET	EXERCISE	EXERCISE	EXERCISE
SUITED:	NO	YES	NO	YES	YES
LOADED:	NO	NO	YES	NO	YES
0 min.	37.9	38.0	38.4	39.0	38.4
3	37.9	38.0	38.4*	38.9	38.4
6	37.9	37.9	38.5**	38.9*	38.4*
9		37.9	38.5***	38.9**	38.4**
12			38.6	39.0***	38.6**
15			38.7	39.0***	38.9**
18			38.9	39.1	39.3**
21			38.9	39.3	39.5
24			38.9	39.3	39.7
27			39.0	39.2	39.8
30				39.2	39.8

Subject EL: Gut Temperature in degrees Celsius.

CONDITION:	QUIET	QUIET	EXERCISE	EXERCISE	EXERCISE
SUITED:	NO	YES	NO	YES	YES
LOADED:	NO	NO	YES	NO	YES
0 min.	37.7	37.6	38.0	38.7	
3	37.8	37.7	38.0	38.7	
6	37.8	37.7	38.0*	38.5*	
9	37.8	37.7	38.0**	38.5**	
12		37.7	38.2***	38.6***	
15		37.7	38.2	38.7***	
18		37.7	38.3	38.8	
21			38.4	39.0	
24			38.6	39.0	
27			38.5	39.0	
30			38.6	39.0	

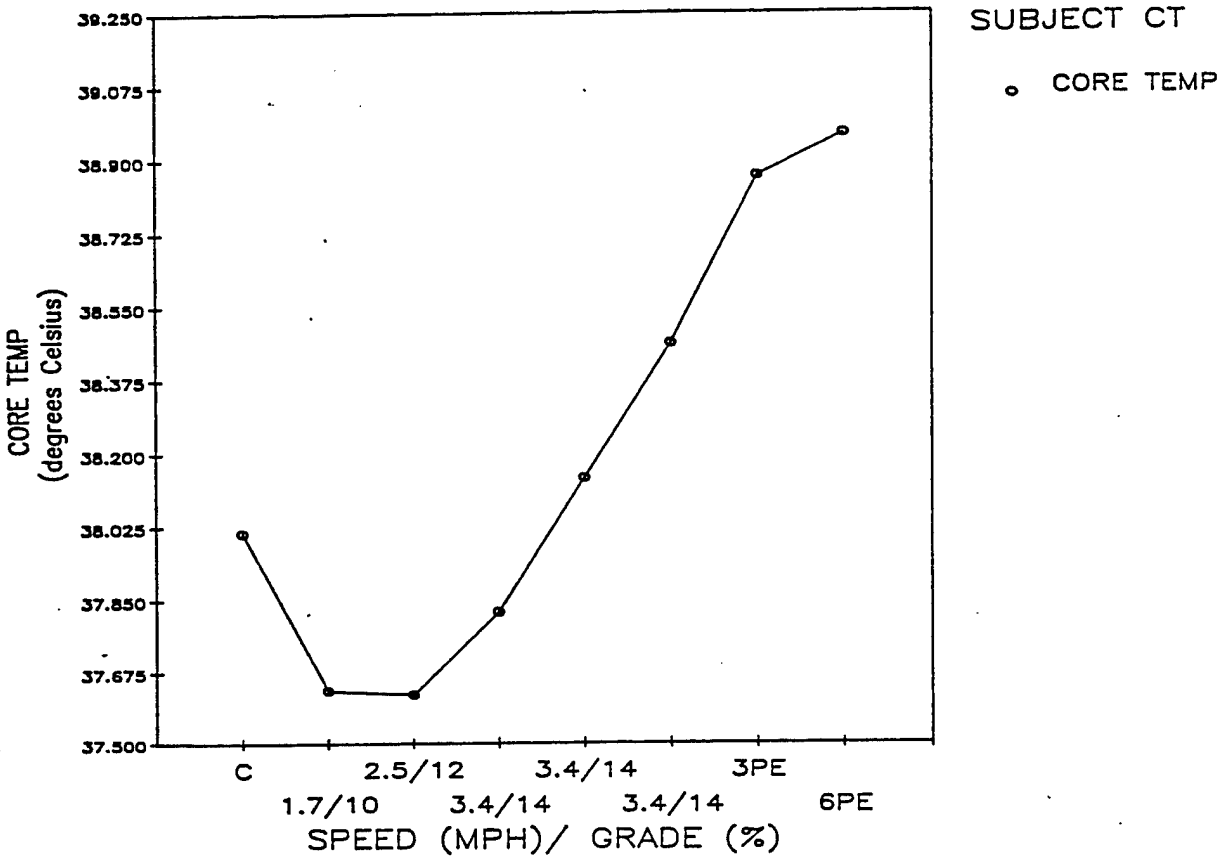


Figure 2. Gut Temperature during Exercise

3.3.5. Conclusions. Although not suitable for statistical inference, these data are interpreted as demonstrating the concept that temperature pill recording will be useful in tracking response to heat stress. The post-challenge overshoot of core temperature is well known, and the consistency of pill temperature response to exercise may permit the development of an algorithm for predicting, hence limiting, that response.

3.4 Predicting Response of Gut Temperature to Exercise

3.4.1. Reference. Dormer, Kenneth J., Dept. of Physiology and Biophysics, University of Oklahoma. Letter Report "Multichannel Biomonitor recording of Response to Exercise, Test of Predictive Algorithm", July 21, 1987. (Phase IA, Section 5).

3.4.2. Objective. Concept demonstration. On repetition of the previous experiment, an algorithm based on the slope of the rise in gut temperature would be tested as predictive of a temperature rise, within 6 minutes, to 39° Celsius, causing cessation of exercise.

3.4.3. Method. Two subjects were exercised with protective overgarment suits and 37-pound backpack load. The Bruce proto-

col was limited to two stages: 1.7/10 and 2.5/12, which was continued until the algorithm predicted a temperature rise to 39 degrees. Skin temperature, between the shoulder blades and within the suit, was recorded along with heart rate.

3.4.4. Results. Data obtained during the two suited exercise trials are tabulated below.

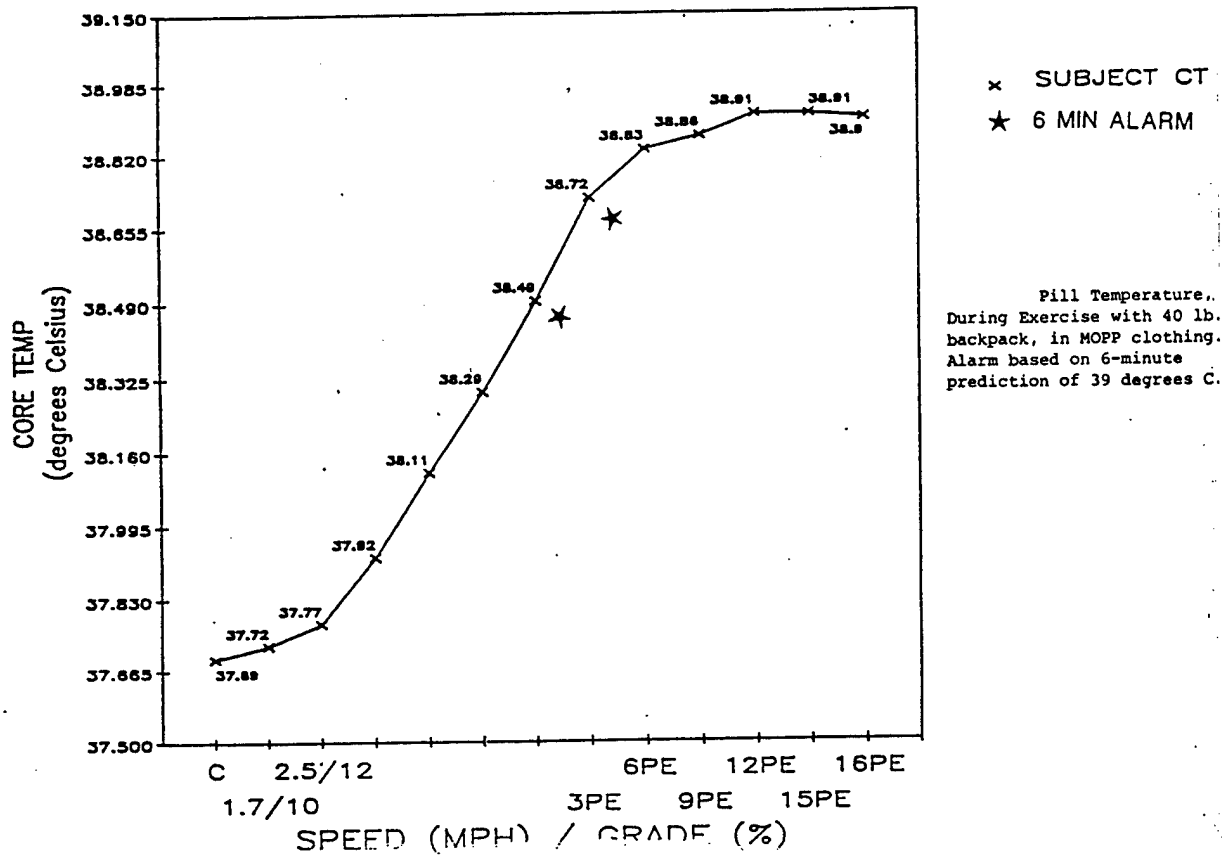
Subject CT: (See Figure 3).

	GUT TEMP	SKIN TEMP	HEART RATE	STAGE	ALARM
0 min.	37.7	32.3	86	0	
3	37.7	34.0	126	*	
6	37.8	35.6	145	**	
9	37.9	36.7	167	**	
12	38.1	37.2	171	**	
15	38.3	37.4	180	**	
18	38.5	37.5	181	**	ON
21	38.7	37.8	173		ON
24	38.8	37.7	135		
27	38.9	37.6	135		
30	38.9	37.4	134		
33	38.9	37.3	139		
36	38.9	37.3	131		

Subject SP:

	GUT TEMP	SKIN TEMP	HEART RATE	STAGE	ALARM
0 min.	38.0	33.2	117	0	
3	38.0	34.6	164	*	
6	38.1	36.2	171	**	
9	38.2	36.6	179	**	
12	38.3	37.2	169	**	
15	38.5	37.2	176	**	
18	38.7	37.0	184	**	ON
21	38.8	37.0	160		ON
24	38.8	37.0	155		
27	38.8	36.7	145		
30	38.8	36.7	148		
33	38.9	36.4	143		
36	38.8	36.3	135		

In one subject (CT), the procedure was repeated without protective clothing. Results were similar, except that skin temperatures were lower (34.9 degrees, maximum), and the alarm occurred 9 minutes later into the exercise test. For subject SP, the test was performed without clothing; oral, rather than gut temperatures were used, and proved too variable to trigger the algorithm.



Pill Temperature, During Exercise with 40 lb. backpack, in MOPP clothing. Alarm based on 6-minute prediction of 39 degrees C.

Figure 3. Warning Algorithm for Exercise Heat Stress

3.4.5. Conclusions. Validation of concept that dynamic response of gut temperature, as measured by the Konigsberg Instruments temperature pill, will be useful in clinical and investigative applications. The consistency of response in these exercise tests indicates that predictive algorithms may be derived for warning or limiting dangerous effects of heat stress.

3.5 Comparison/Validation of Konigsberg Temperature Pill with Rectal Temperature

3.5.1. References.

a. Dormer, Kenneth J., Dept. of Physiology and Biophysics, University of Oklahoma. Letter Report "Validation of Ingestible Telemetry Temperature Pill with Rectal Temperature Probes", May 10, 1988. (USAMRDC Contract DAMD17-88-M-0035)

b. Naramatsu, Kevin, Department of Behavioral Biology, Walter Reed Army Institute of Research, "Comparative Analysis of Core Temperature as Measured by Telemetry Pill and Rectal Probe," August 10, 1988. (In house letter report, summer student project; extended analysis of Dormer data cited above).

3.5.2. Objective. During rest and exercise, a direct comparison of body temperature as measured with a standard rectal probe is made with the Konigsberg Instruments T2A pill 1) inserted into the rectum, and 2) after oral ingestion. The first comparison is to validate the pill as a biothermometer per se, while the second compares and contrasts in-transit gut temperature (location uncertain) with fixed location (rectal) temperature during various manipulations.

3.5.3. Method. Temperature pills and Yellow Springs rectal probes were pre-calibrated in an oil bath over the range of 34 to 40 degrees Celsius. Two male subjects were tested over two days. On one day, a pill was ingested, while on the second day, a pill was inserted rectally. Manipulations during each day were as follows, dispersed over about 7 hours:

a. Resting - 15 minutes
b. Ambulation - 15 minutes
c. Ingestion of iced drink - 30 minutes
d. Ingestion of hot drink - 30 minutes
e. Exercise Tolerance (Treadmill) Test (3-stage Bruce)
f. Recovery period after ETT - 20 - 30 minutes

Temperature data were tabulated every minute as pairings of rectal and pill temperatures, taken to the nearest 1/10th degree Celsius.

3.5.4. Results. Data are summarized below and in Figures 4 and 5.

a. **Rectal Pill vs. Rectal Probe (Day 2)**

The correspondence between the two methods of recording rectal temperature is almost exact, throughout the range of manipulation (See Figure 4):

	Subject IA	Subject TW
N (paired)	132	136
Range (° C.)	37.1 - 38.7	36.9 - 38.9
Correlation (r)	0.984	0.978

Response to hot and cold drinks were barely discernible in the rectal measures.

b. **Ingested Pill vs. Rectal Probe (Day 1)**

The relationship of these data is more complex due to the difference in anatomic location, which in the case of the pill is constantly changing. Unfortunately, for subject TW the pill was operating in the frequency neighborhood of a commercial FM station, resulting in more variable and occasionally spurious readings. Ice cold and hot (65° C.) drinks were delivered 2 - 6 hours after pill ingestion. In both cases changes in pill temperature were sustained for about 15 minutes, with a peak change

of 0.3 to 0.4 degrees C. Both subjects showed a typical response to exercise, which was somewhat attenuated in subject TW.

Paired correlations between rectal and pill temperatures throughout the day were 0.884 for subject IA (N = 136) and 0.643 for TW (N=137). (See Figure 5).

In all cases reported by Dormer, the pills were retrieved from the stool and examined after the study; in no instance was there a failure in the Silicone Coating.

3.5.5. Conclusions. The function of the Konigsberg Temperature Pill as an accurate biothermometer is confirmed by this series of tests by Dormer. In the gut it is responsive to various challenges, especially exercise induced thermal stress, and is suitable for clinical usage. Two caveats emerge from this particular study: First, due to its higher location in the gut, it is more subject than rectal temperature to "artifact" from ingestion of very cold or very hot liquids; during usage, attention should be paid to avoiding these exposures (akin to the problem of using oral thermometers), or at least interpreting data in the light of them. Second, since the FM commercial band is used by these pills, care should be taken to avoid interference induced errors. The improved T2D pill is designed to be more selective in this regard. Finally, the behavior of gut or splanchnic temperature is uncharted territory, and will need to be the subject of future investigation. Dormer concludes that the temperature pill is superior to the rectal probe in both temporal resolution and precision, and will be a useful research tool. The present data confirm its potential clinical value.

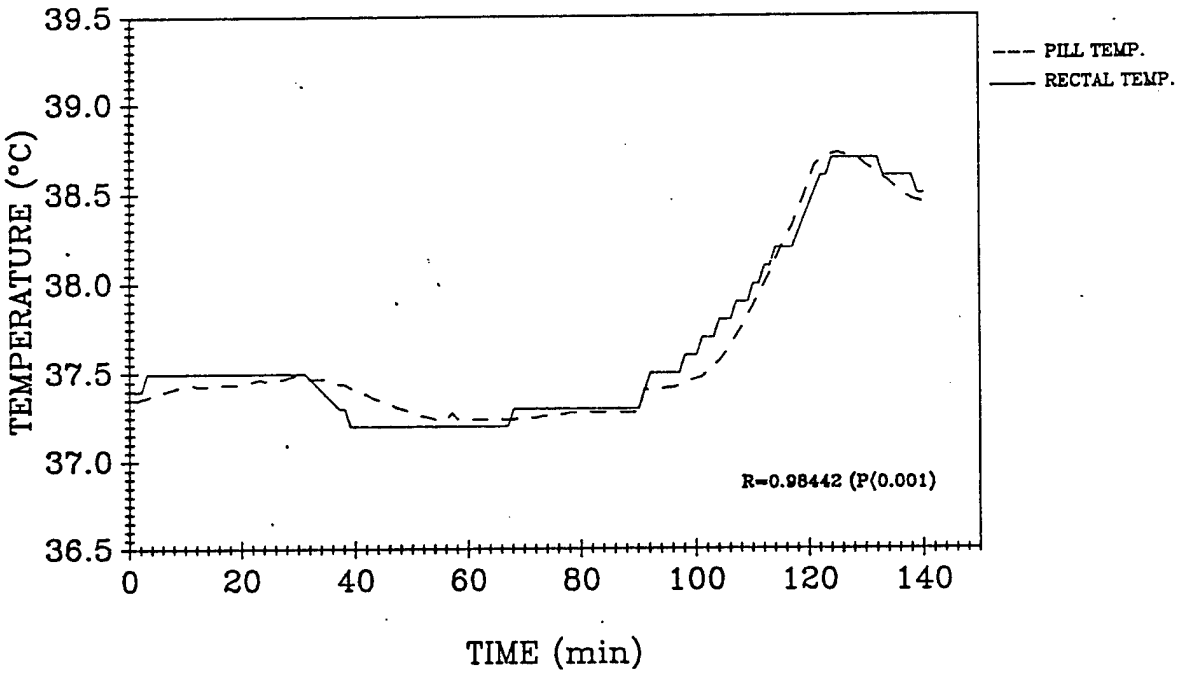


Figure 4. Response of Rectal Pill and Rectal Probe

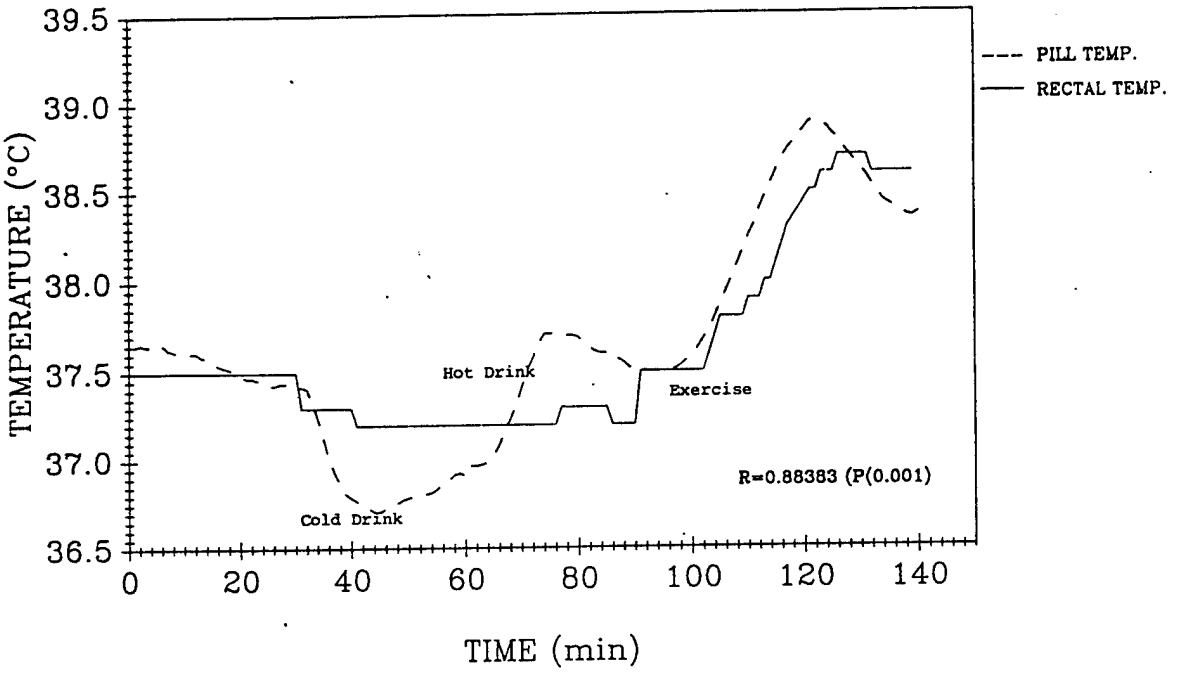


Figure 5. Response of Ingested Pill and Rectal Probe

3.6 Evaluations of Human Technologies Temperature Pill relevant to the Konigsberg Pill

3.6.1. Reference. Keilson, Leonard, Maine Medical Center, Portland, ME. Pre-print manuscript "Evaluation of the Ingestible Telemetry Monitoring System in Humans," August 4, 1988. Provided by courtesy of the author.

3.6.2. Objective. Evaluate orally ingested telemetry thermometer with reference oral and rectal temperatures. (Note: since both types of temperature pills are validated as accurate biothermometers in the rectum, by Keilson and Dormer respectively, then the dynamic performance of one ingested pill in the gut becomes generalizable to the other. Hence, the Keilson data reported below is taken as descriptive of temperature pills in general).

3.6.3. Method. Ten subjects were studied during the period between pill ingestion and pill excretion, using the Human Technologies ingestible telemeter. Simultaneous oral, rectal, and pill temperatures were recorded at varying intervals, from 5 to 7 times per day during waking hours. No systematic manipulations were studied, and readings were "casual" in the sense that they were taken in subjects otherwise at ad libitum activity.

3.6.4. Results. Average transit time was 29.3 hours, ranging from about 7 hours (in a subject with diarrhea) to 70 hours.

A total of 57 observations were made in the 10 subjects. Pooling of the data gives the following results:

	Mean	Minimum	Maximum	Standard Error
Pill	37.46	36.7	38.4	0.31
Oral	36.67	36.0	37.9	0.32
Rectal	37.28	36.6	37.9	0.29

Linear Correlation, Pill vs. Oral Temperature: 0.25
Linear Correlation, Pill vs. Rectal Temperature: 0.51
Linear Correlation, Oral vs. Rectal Temperature: 0.13

Pills were ingested and excreted without incident. Encapsulation of recovered pill was intact.

3.6.5. Conclusions. Gut temperatures tended to be about 0.8 degrees Celsius greater than Oral Temperatures, and about 0.2 degrees higher than rectal temperatures. Correlation between gut and rectal temperatures was modest ($r = 0.51$) due to the different locations and the narrow range of observed temperatures (1.3 degrees, rectal). Keilson concluded pills were sufficiently safe and effective to be utilized as clinical measurement tools.

3.7 In Vitro Validation of the Accuracy and Linearity of the Konigsburg T2D Temperature Pill

3.7.1. Reference. Eberhart, Russell C., Johns Hopkins University, Applied Physics Laboratory, Laurel, MD, Letter Report "Konigsberg Ingestible Telemetry Monitoring System Calibration Data," June 18, 1989.

3.7.2. Objective. Oil Bath calibration of Konigsberg T2D pills. Production pills are specified to be calibrated such that the pulse frequency to temperature transform is accurate to 0.1 degrees Celsius and linear within the physiological range. This effort was to provide calibration data for a shipment of pills and to test the assumption of linearity.

3.7.3. Method. 101 T2D pills were tested in an Applied Physics Laboratory oil bath, and the emitted frequency of each was recorded, to the nearest Hertz, for each of four temperatures: 35.00, 37.00, 40.00, and 42.00 degrees Celsius. A linear equation was computed for each pill based on frequency at 35.00 and 42.00 degrees, and used to calculate temperature estimates at 37 and 40 degrees, based on observations of frequency. These estimates are then compared to the known temperatures.

3.7.4. Results. For all 101 Pills, result_ of observations and calculations are tabulated below:

	Observed				Calculated	
	35°C. Freq.	37°C. Freq.	40°C. Freq.	42°C. Freq.	T37 Est.	T40 Est.
Mean	492.33	531.24	589.35	627.55	37.014	40.023
Min	451	495	550	585	36.919	39.920
Max	518	558	618	656	37.100	40.119
StDeviation					0.032	0.034
StError					0.003	0.003

The average slope of the linear transform was 19.315 Hertz per Degree C. (Range 17.43 - 21.43, St.Dev 0.61).

In none of the 101 cases was the estimated temperature, rounded to the nearest 1/10th, outside the specification, when computed with the linearity assumption.

3.7.5. Conclusions. The T2D production pill is accurate to well within the required 0.1 degree C. when estimated from an observed frequency and computed from two calibration points. In this lot, the variation in slope (range/mean) is about 20%, sufficiently large to indicate that two calibration points should be used. While designed nominally to be 500 Hz at 37° C. with a slope of 20 Hertz/°C., the observed range from pill to pill is great, a result of cumulative errors in components used at fabrication. The key success in the design is the preservation of linearity as shown above, allowing two-point calibration. Additional calibration data, for a narrower human biological range of 36 to 40 ° Celsius, are shown in the next summary.

3.8 Calibration of the Konigsberg T2D Temperature Pill

3.8.1. Reference. Popp, K.A., Leu, J.R., Gutierrez, P.E. and Redmond, D.P., Walter Reed Army Institute of Research. T2D calibrations - data file. In-house file for Chemical Defense User Safety System, DAMD17-85-C-5257.

3.8.2. Objective. Detailed calibration curves were performed on production type T2D Temperature Pills to provide assessment of precision, accuracy, and linearity of Pills.

3.8.3. Method. Pills were immersed in a mineral oil bath, heated to > 40° C., and allowed to cool to 36° C. while bath temperature and pill pulse intervals were measured. A YSI type 407 Reference probe was used, coupled to the Pill with an elastic band, to record pill/bath temperature; the actual variable measured was thermistor probe resistance in ohms. The pill signal

was received with a long wire antenna coupled to a TR6B receiving module configured to track and time pulse intervals in units of 0.5 microseconds. During cooling, at each 1 ohm increase in probe resistance, the pulse interval was recorded. Typically, 212 data points were obtained in the range of 36° - 40°; pulse interval varied by about 270 microseconds. Thus, resolution was limited by the reference probe to about 0.02 degrees.

For analysis, data were paired as Reference (ohms) vs Pill Interval (microseconds) for linear correlation. For more useful plotting, data were then converted to degrees Celsius. First, 15 points (30° - 45°) provided with the reference specifications were used to generate a quadratic-fit transform (r2 = 0.9999) from ohms to degrees C. This reference function was then used to compute Pill Temperature (Tpill) values at each observed pairing. Finally, linear fits were compared between Temperature vs. Interval and the reciprocal function, Temperature vs. Frequency, to determine the optimum transform to use in calibration.

3.8.4. Results. Analyses for 5 pills are tabulated below, with a typical calibration curve shown in Figure 6, and a display of residual errors, over the range of 36° to 40°, is shown in Figure 7.

PILL #:	275	276	277	278	279
No. Observations:	212	212	207	208	207
Ohms vs. μSec.					
R-squared:	0.9998	0.9996	0.9997	0.9997	0.9997
Tpill vs. Int					
R-squared:	0.9987	0.9982	0.9984	0.9983	0.9983
Mean Error:	0.0342	0.0425	0.0391	0.0403	0.0404
Std. Dev:	0.0207	0.0250	0.0231	0.0239	0.0244
Tpill vs. Freq					
R-squared:	0.9999	0.9999	0.9999	0.9999	0.9999
Mean Error:	0.0054	0.0049	0.0057	0.0047	0.0068
Std. Dev:	0.0037	0.0038	0.0039	0.0045	0.0052

3.8.5. Conclusions. Linearity and accuracy of these T2D Pills far exceeds the specification of ± 1/10 degree Celsius in the range of 36° - 40°, and approaches that of the reference standard; it is better than 1/10 degree Fahrenheit (0.056° C.), in fact. The reliability of two point calibration is confirmed. Use of a linear approximation for Temperature vs. Pulse Interval is acceptable, while the inverse transform, Temperature vs. Pulse Frequency, improves the results. Repeat calibrations after long term storage have not yet been performed , but enough variation (due to battery depletion) is expected to indicate that calibrations should be performed within a few days of usage.

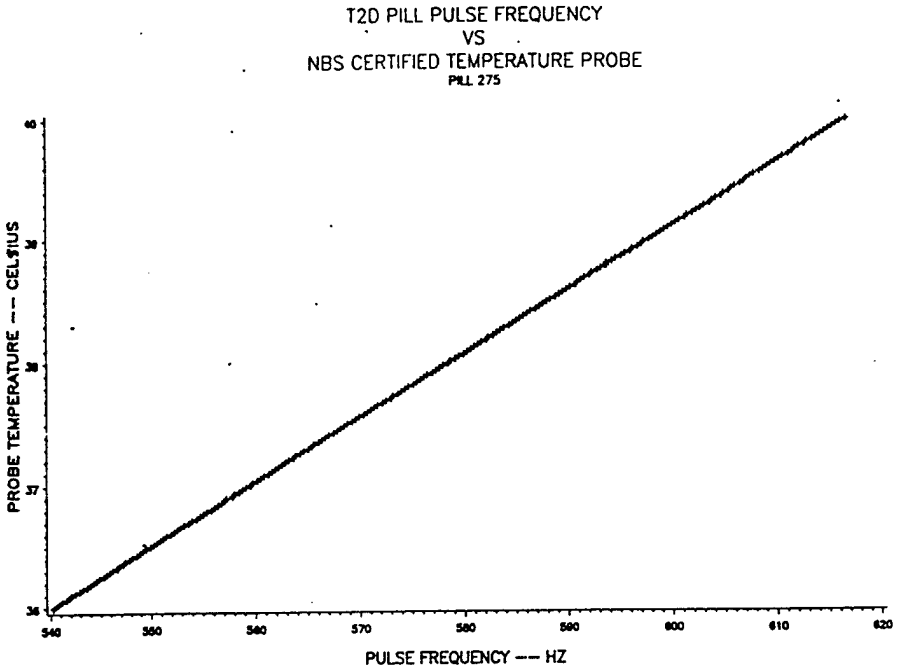


Figure 6. Calibration Curve, T2D Pulse Frequency vs. Temperature

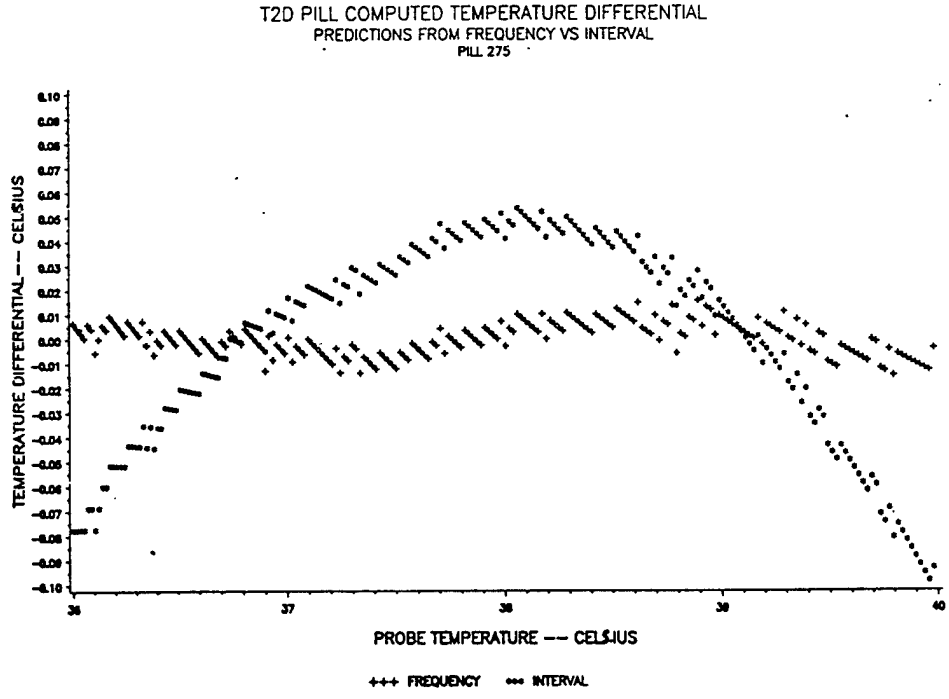


Figure 7. Residual Errors in Linear Fit, Pulse Interval and Pulse Frequency vs. Probe Temperature

4 HUMAN USE AND SAFETY CONSIDERATIONS

4.1 Summary

The Konigsberg Instruments T2D Temperature Pill in and of itself may be considered an "other than significant risk device." That is, the Pill per se poses little if any risk to human subjects. Data reviewed above indicate a level of accuracy and, in comparison to oral and rectal probes, a "substantial equivalency" to other, standard, means of clinically recording body temperature. The Temperature Pill in various forms has been available since well before 1976, and in recent years have been adjudged by Human Use Review Committees as being of non-significant risk. Finally, the FDA, in November 1988, cleared a very similar telemetry device for marketing as a Temperature Monitoring System (Human Technologies, Inc., Case K880639).

In this section, considerations of intrinsic risk factors are discussed item by item, in terms of risk, safeguards, and benefits. This analysis concludes, likewise, that the Pill is a non-significant risk device. The discussion provides the basis for defining Contraindications and Precautions applicable to human applications, whether clinical or investigative, limitations under which the Pill can be considered safe and effective.

4.2 Summary of Human Subject Exclusions and Precautions

4.2.1. Contraindications

- Known or suspected obstructive disease of the bowel, including but not limited to diverticulosis or inflammatory bowel diseases.
- History of gastrointestinal surgery.
- History or symptoms of swallowing disorders or disorders that will impair the gagging reflex.
- (Above restrictions limit usage to rectal insertion).
- Use of Nuclear Magnetic Resonance Scanning during the period while temperature pill is in the body.

4.2.2. Precautions

- Instructions not to chew Pill while ingesting it.
- Administration of Pill under prescription or orders of appropriate medical authority.
- Determination that ambient commercial broadcast stations do not interfere with Pill function.
- Administration at least two hours prior to heat stress exposure.
- Interpretation limited immediately after ingestion of very hot or cold food or fluids.
- Pre-calibration of pills in water baths.
- Monitoring of presence and normal function of telemetry signal.

4.3 History of Regulatory Approval for Usage

4.3.1. Usage under Human Use Review Approved Protocols

NASA used the Konigsberg predecessor to the current pill in a study entitled "Long Term Use of a Swallowable Temperature Transmitter", at the Ames Research Center in 1972.

Army use of Temperature Pills (a design derived from Canadian sources) was approved in a protocol entitled "Health and Effectiveness of Troops Deployed over Long Distances: Countermeasures to Reduce Jet Lag,", Walter Reed Army Institute of Research, 1981, R.C. Graeber, PI. This experience led to program to improve technical design and reliability of pill telemetry systems.

Currently Active Protocols: The following investigational protocols cover recent work performed using either the Konigsberg Instruments or the Human Technologies Temperature Pill designs. In all instances, the respective Human Use Review Boards determined the studies, including the usage of Temperature Pills, to be of less than significant risk.

- "Development of Thermoregulatory Algorithm for Biotelemetry", University of Oklahoma, K.J. Dormer, 1986.

- "Dynamic Temperature Measurement in Clinical Medicine: use of Temperature Telemetry Pills", Maine Medical Center, L. Keilson, 1987.

- "Effects of Antidote/Pretreatment Drugs on Physical Performance", Uniformed Service University of the Health Sciences, P.A. Deuster, 1988.

- "Field Entry/Exit Tests of a Battalion Aid Station," U.S. Army Chemical Research, Development and Engineering Center, W.K. Blewett, 1989.

For this last protocol, the U.S. Army Surgeon General's Human Subjects Research Review Board made an explicit determination that the Konigsberg Temperature Pill posed "nonsignificant risk" to volunteer subjects (HSRRB Minutes, 12 April 1989). Under this determination, the Pill has since been applied in a series of Tests as a nonsignificant risk investigational device.

4.3.2. Status of Ingestible Telemetry under U.S. Food and Drug Administration Regulations

To our knowledge, only two telemetry pill systems are currently marketed in the United States under FDA clearance:

- Oxford Medilog, Inc. pH Pill Telemetry Probe - marketed prior to 1976.

- Human Technologies, Inc. CorTemp temperature pill system with 510(k) clearance for marketing as Class II (No Performance Standards) Device, Nov. 2, 1988.

Konigsberg Instruments, Inc. has to date not applied to the FDA for clearance to market the Temperature Pill, although such clearance could almost certainly be obtained. At present, Konigsberg provides the pill only to the Army and soon to the Navy under limited development contracts. The pills, consequently, are used according to Investigational Device Exemption (IDE) regulations in military research applications.

4.4 Analysis of Risks, Safeguards, and Benefits

4.4.1. Risk Imposed by the Temperature Pill Device

a. Retention in the Bowels (or failure to excrete the Pill).

There are no published reports of adverse effects of telemetry pills in over 30 years of literature. One anecdotal story recurs in conversations, concerning a pill that had to be removed surgically -- in an individual with known obstructive bowel disease. It is prudent to assume that an object of this size (about 2.9 cm. x 1.1 cm diam.) could become lodged in the gut, perhaps causing local inflammation, ischemia, or perforation. Surgical removal might be required. However, the literature of foreign body ingestion indicates that such an event is very rare. For objects less than 1.6 cm. in diameter, streamlined in shape, coated with a "slippery" substance such as Silicone plastic, it is unreported, except perhaps in cases where the gut lumen is normally or pathologically constricted (i.e., children and adults with obstructive bowel disease). See Pellerin, et. al, 1969.

Safeguards The Pill is designed in shape and coating to minimize the probability of being trapped in the gastrointestinal tract. Appropriately, a contraindication for oral pill usage is any bowel disease or surgery which might exist or be suspected, leading to gut constrictions. Likewise, the pill should not be used in children less than fully grown, or if it is, only under direct medical supervision with recognition that risk of entrapment is greater. Note that in such cases and in the absence of ano-rectal disease, the Pill could be used effectively by rectal insertion. In most cases, the pill may be considered a "swallow and forget" item, since in the absence of adverse symptoms it is almost certainly excreted in the stool. Subjects may be advised to examine their stools for positive confirmation if such caution is warranted by the circumstances. Presence of the pill in the body can be confirmed with any FM radio receiver (if it is functioning), and it is radiopaque.

b. Difficulty in Swallowing Pill.

The Pill is no larger than a normal bolus of food, but some may have a subjective aversion to swallowing it. Impairment of the swallowing mechanism or an absent gag reflex could present objective difficulties, in the worst case leading to tracheal inspiration and suffocation.

Safeguards Impairment of swallowing or gag reflex should be a contraindication to oral usage of the Pill. Ingestion of the pill should occur under visual observation of others capable of managing a swallowing problem. The Pill should swallowed with a glass of water.

c. Failure of Pill Coating.

Deterioration of the coating is undesireable because it would lead to exposure to the electronic components within, including the battery and its electrical voltage. The consequences of this are discussed below, but at best it would be an aesthetically unpleasant experience.

Safeguards The coatings used are durable and resistant to decay by stomach and intestinal juices; they consist of biologically inert materials permitted by the FDA in similar applications. The Konigsberg Pills use an outer coating of a rubbery RTV 112 Silicone Compoundor over a hard shell of dental-grade epoxyacrylate plastic. Pills are fabricated in facilities inspected by state and federal authorities for good manufacturing practices, and Konigsberg Instruments, Inc. has a 25-year history of fabricating indwelling, ingestible, and implantable devices for human use. Finally, subjects should be advised not to chew the devices before swallowing. The pills are not reuseable in humans.

d. Exposure to Internal Contents of the Pill.

The main potentially toxic components of the Pill are the traces of lead solder and more importantly, the battery. The battery electrodes present an electrical potential of 1.5 volts, sufficient to cause tissue damage. The battery itself consists of a steel case, silver oxide and zinc amalgam electrodes, and a caustic gel of 45% potassium hydroxide. The remaining contents of the Pill are biologically inert plastics, glass, silicone and carbon electronic materials. Thus, the worst case event of disintegration of the capsule and spillage could conceivably cause serious symptoms or illness due to injury to the gut.

For this reason we undertook a careful review of the literature concerning such exposures to foreign materials, typified by ingestion of coin-type batteries, which included conversations with the National Capital Poison Center. As it happens, the Center has undertaken a National Button Battery Ingestion Study, which provides data on over 2000 cases since 1983. The experience, and their advice, is reassuring. It is their conclusion

that in all but the rarest cases, the ingestion of Silver Oxide batteries is a benign misadventure, attended by few if any symptoms and requiring at most patient clinical observation. The same may be said for the ingestion of minute quantities of metallic lead. It is noted that the serious cases reported consisted of large (>1.6 cm. diameter) batteries, usually Mercury cells, lodged in the esophagus or elsewhere, mainly in children. See Litovitz, 1985, and other references below.

Safeguards The main safeguard is the process by which the Pill is fabricated into a monolithic block of components, encapsulated, and coated, whereby dissolution and fragmentation of components is virtually impossible. Obviously, if a subject experiences gastrointestinal symptoms after ingesting a Pill, it would be advisable to observe him, and to retrieve and examine the pill after voiding. Note that the presence of a functioning pill (FM signal) mitigates strongly against this event.

e. Radio Frequency Radiation.

The Pill transmits a signal in the commercial FM band of 88 to 108 megahertz. The signal is pulsatile, consisting of about 1000 bursts per second of pulses lasting 15 to 50 microseconds each. The estimated power, at the antenna coil, of this signal is less than 25 microwatts. In the worst hypothetical malfunction, if all the battery power were delivered continuously to the antenna coil, about 250 microWatts might be output but would rapidly deplete the battery. In both cases, the power would be dispersed over the surface area of the pill, about 10 square centimeters, yielding a power density of 2.5 to 25 microWatts per square centimeter. This is only about 10 times greater than the density at the body surface of ambient signals from local commercial FM radio stations, and about .25 to 2.5 percent of allowable radio-frequency exposure limits (1 milliwatt/square centimeter at 100 MHz) by Federal standards. Furthermore, since the signal is pulsatile with a duty cycle of at most 5%, under normal operation over time, the average exposure is less than 2/10,000 of that limit. In short, the hazard of radio frequency exposure is negligible.

f. Other Medical Procedures.

Nuclear Magnetic Resonance Scans would likely produce dangerous overheating in the electronic components. This is a contraindication, and in the unlikely event a subject required such a procedure, full medical attendance would be invoked, and the procedure deferred.

4.4.2. Risk Imposed by Usage (Clinical Reliability)

a. Accuracy.

Calibration data indicate that the T2D Temperature Pill has precision, accuracy and linearity far better than the 0.1 degree

C. originally specified. Two point calibration is permitted by the observed linearity, and calibration of pulse frequency to 1/10th of a Hertz assures better than specified accuracy. Thus, it is an accurate thermometer. However, the issue arises as to the validity of temperatures determined in constantly changing gut locations. Available data indicate that gut temperature, except in the rectum proper, tends to be 0.1 or 0.2 degrees C. higher than rectal temperature, irrespective of location. The variance exhibited is no greater than that observed in rectal temperature, while the response to exercise challenge is equal and perhaps more rapid. It is our conclusion that the interpretation of precise gut temperatures is a research issue. From a clinical point of view, rectal and gut temperatures appear nearly equivalent, and both are superior to oral temperatures.

b. Dependability.

At present, there are no data on the long-term survival of battery power and of factory calibration figures. In theory, pills should survive about 3 months at room temperature and perhaps a year stored in the cold. With gradual decay of battery power, calibration figures should change somewhat. Therefore, it is an appropriate precaution that recalibration should occur within about a week of usage. When operating, the presence of a pill is easy to detect due to the presence of an audible signal heard on any FM radio tuned to pill frequency. The receiving/decoding device, furthermore, provides a positive indication to the user as to whether a pill is present and being tracked.

c. Artifact.

The data from the University of Oklahoma indicate a sensitivity of ingested pills to drinking ice-cold water, or hot liquids, in the order of 0.4 degrees C., lasting about 15 minutes. Such artifacts are similar to those occurring with oral thermometry, so the user should be precautioned to interpret temperature readings in the light of a history of such ingestions.

d. Interference.

The presence of a near-by commercial FM radio station, operating at a frequency within about 200 kilohertz of Pill operating frequency may result in RF interference and loss of data. Prior to usage, the location should be surveyed for potentially interfering signals, and pills should be labeled with the operating frequencies set at factory.

e. Alternatives and back-up procedures.

The investigator or clinician observing subjects who are at risk due to thermal stress should not rely on any single measure of temperature (whether obtained from the pill or other sources), but should use all means available and appropriate to the circum-

stances, including direct visual observation. For instance, the overt symptoms of heat strain and injury often become apparent before there is a "trip-wire" elevation of body temperature. The temperature pill, therefore, should be considered only an adjunct in the monitoring of medical safety. Alternate methods, including oral and rectal thermometers should be available in such cases, to provide confirmatory data or to cover transient losses of pill data, if any.

4.4.3. Factors of Benefit

The chief advantage of the Temperature Pill is the comfort and non-intrusiveness it provides to active subjects. It is far more acceptable to subjects than rectal, esophageal, and tympanic probes, especially in long term monitoring. Likewise, it is less likely to interfere with normal or directed activity which might be the object of study or observation. Once ingested, it is not as subject to variation or disruption due to movement or displacement of tethered wires.

4.5 Consent Forms and Subject Notification

In human-use research, AR 70-25 requires that volunteers should be notified, and certain wordings should be contained in the Volunteer Agreement, pertaining to the use of the Temperature Pill, as follows:

To Exclusion Criteria, add:

" Body temperature may be monitored in some or all volunteers with a thermometer which is swallowed (a "Temperature Pill"). Swallowing of this pill cannot be permitted for anyone who has a history of obstructions of the bowels, or of certain illnesses known to cause this, such as stomach or duodenal ulcers, Crohn's Disease, ulcerative colitis, diverticulitis, bowel inflammations, or surgery, gunshot or stab wounds to the gastrointestinal tract. Also, pills may not be swallowed if a person has a history of difficulty with the swallowing or gag mechanism. In these cases, the "Temperature Pill" may still be used by insertion into the rectum, like a suppository, provided no active hemorrhoids, anal fissures or abscesses, or other rectal problems are present."

To Risks or Discomforts, add:

" Test participants will have their internal body temperature monitored frequently in order for the Medical Monitor to detect the threat of injury due to heat (or cold) stress. This monitoring may be accomplished in any of the following ways, depending upon the availability of suitable equipment: 1) Using an electronic temperature probe inserted in the rectum; 2) Using a "Temperature Pill" which is swallowed about 2 hours before the

test, which sends temperature information out by way of a very weak radio signal; or 3) Using oral thermometers at frequent intervals. Rectal probes are considered uncomfortable by some, but are otherwise a safe way of obtaining body temperature. If the "Temperature Pill" is used, it remains in your bowels until it is passed with your next bowel movement. "Temperature Pills" have been used for many years, especially in other countries, and by NASA and at Walter Reed Army Institute of Research in experiments similar to this study. They are generally considered safe, and provide temperature measurements at least as accurate as the rectal probe. They are large capsules, about the size of the largest vitamin capsule available, and may be hard to swallow for some; they should not be used by anyone who might choke on them. Also, they cannot be swallowed by anyone who has problems with bowel obstructions, in case they should become "hung up" instead of excreted in the feces normally. As rectal suppositories, they are more comfortable than the rectal probes, and can be used this way when they can't be swallowed, unless diseases of the anus are present (such as "hot" hemorrhoids or abscesses). In that case, rectal probes should not be used either.

"One type of "Temperature Pill" is called the CorTemp Model 124, produced by Human Technologies, Inc. This pill was recently approved by the Food and Drug Administration (FDA) for sale in the United States for use as a clinical thermometer. Likewise, the Rectal Probe type of monitor is approved for general usage. When you agree to participate in this study, no special or extra approval from you is required to use either method.

(Pending FDA clearance, the following statement should be added):

"A second type of "Temperature Pill" is called the Walter Reed Temperature Pill, produced by Konigsberg Instruments, Inc. under a contract to the Army. This pill is designed to have advanced features over previous pills, and its use in this study will be, in addition to monitoring your temperature, for the purpose of evaluating the Walter Reed Temperature Pill and its performance in this and similar studies. From the outside, the pill differs little from the CorTemp Pill, but it has different internal electronics and data carrying radio signal. However, no approval to sell or generally use this pill has yet been granted by the FDA; instead, we will only use this pill under experimental circumstances. In short, you are advised that using the Walter Reed Pill is experimental. We cannot claim to you that it works, or that it is safe, but instead, you are advised that we are testing it to see if it works, and to make sure that it is safe. Previous tests, conducted at the University of Oklahoma, indicate so far that it is both safe and effective, but more testing, such as this study, is needed to be sure. (Considerations of safety are discussed above, and are the same as those for the CorTemp pill). Therefore, when you volunteer for this study, you will also see a separate statement below that says "I do/do not agree to have my body temperature recorded using the Walter Reed Temperature Pill." Please indicate your choice and initial that statement in the space provided."

ON THE LAST PAGE, BEFORE THE SIGNATURE, add the above statement with space for subject's initials.

Concerning "Hidden Experimental Procedures" add the sentence:

" Special notice and consent is given to permit the use and evaluation of the Walter Reed Temperature Pill (an investigational device) as a means of monitoring temperature."

4.6. Labeling

(Pending FDA clearance, the following statement pertains):

In accordance with FDA regulation, the following Notice is attached to each Pill container:

"CAUTION-Investigational device. Limited by Federal Law to investigational use. To be used only under direct supervision of Department of Defense Research, Development, Test & Evaluation personnel, under procedures indicated by an Approved Protocol, and only with Human Research Volunteer Informed Consent."

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SUBSTANTIAL EQUIVALENCE - A DISCUSSION Enclosure 4

The argument for a finding of Substantial Equivalence for the T2 series, and the T2D Temperature Telemetry Pill in particular, resides in the functional identity with both pre-amendment and currently marketed devices. These are all thermometers which convey their data electronically, and are used for clinical purposes to evaluate human body temperature. They are all ingestible. Dr. Redmond's Report (Enclosure 3) reviews the efficacy and safety, not only for the T2D, but for the general family of ingestible thermo-telemeters.

The T2A and T2D Temperature Pills differ from the others only in the particular electronic design that implements the function. In 1972, Konigsberg Instruments, Inc. produced and marketed the T2-T Pill (see attached data sheet). The current series differs from that species solely by virtue of the advancement in technology allowing design, fabrication, and performance of thermo-telemetric devices. In terms of efficacy, these historical changes have of course enhanced the performance of the thermometer. Dr. Redmond's own data clearly shows the precision and accuracy of the T2D device as a thermometer, and the evaluations he reviewed demonstrate the dynamic response, in vivo, of the pill temperature to clinical challenge.

In 1988, the FDA determined Substantial Equivalence of the Human Technologies, Inc. CorTemp Pill system in a similar application to this one. The Konigsberg Instruments T2 pills differ from that species in terms of the technical implementations of both thermal sensing and telemetry. In terms of their functional classification, Clinical Electronic Thermometers, they are identical. Again, the Army's review demonstrates their effective equivalency.

In terms of Safety, the changes and differences from pre-amendment and currently marketed devices are solely electronic ones contained within the barrier of encapsulation. The historical safety of these ingestible devices has been demonstrated, and is assured by Good Manufacturing Practice to be preserved in the products of Konigsberg Instruments, Inc.

ADVANCE SPECIFICATION

KONIGSBERG INSTRUMENTS, INC.
2000 East Foothill Boulevard Pasadena, California 91107

MODEL T2-T TEMPERATURE TELEMETRY PILL

DESCRIPTION: The T2-T is a temperature telemetry system small enough to be ingested. The entire device--battery, temperature sensor, electronics, and antenna--fits inside a single size "0" capsule. The complete capsule, suitably protected, may be used to monitor deep body temperatures within the digestive tract.

OPERATION: When radiating, the system emits RF bursts in the 88-108 MHz, FM broadcast band. The T2-T employs a Pulse Frequency Modulation (PFM) temperature encoding system. The period between pulses is proportional to the temperature of the pill. This telemetered information can be detected by a suitably modified FM receiver, and decoded by a demodulator, which converts these inter-pulse periods into a DC voltage proportional to temp.

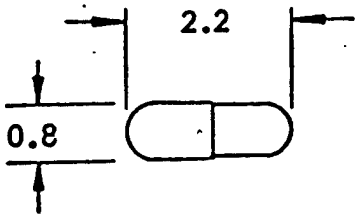
CONSTRUCTION AND SPECIAL FEATURES: The system's electronics are assembled on two printed circuit boards, with the battery and antenna at opposite ends. The entire assembly is then placed in a wax-filled, size "0" gelatin capsule, then wax-dipped, ready for subsequent steps in external sealing.

The system has two significant features. First, the average current is only 14 μA, permitting extended operation between battery replacements. Second, the system ceases to radiate, and current drain is virtually nonexistent when the instrument is refrigerated! Thus the unit may be readily stored in a non-operating condition until needed, with ample remaining life for several application cycles.

SPECIFICATIONS:

Excitation potential	1.35 V	Temperature range	32-42 °C
Battery (or com'l. equiv.)	E212E	Temperature calibration	35, 37, 39 °C
Battery rating	16 mAH	Transmission distance	1-3 m
Current drain (radiating), ave.	14μA	Operating Spectrum	88-108 MHz

ACCESSORIES: The T2-T is designed to be used with the Model R2 FM/AM intermittent pulse mode receiver and the D2-T Temperature Demodulator. The Temp/Pill is only available in the Condition W (wax dipped) and Condition R (refrigeration shipment) modes. The purchaser is advised that further encapsulation, such as a Tygon/Silicone or an Elvax/wax dip may be required to suitably protect the instrument and the experimental subject from adverse interaction effects, or the transmission of infection from one experimental subject to another. This further protective action is left to the user to perform, since experimental conditions will differ.



Dimensions in Centimeters

OBSOLETE
For Historical Interest Only

KONIGSBERG INSTRUMENTS, INC.

2000 East Foothill Boulevard Pasadena, California 91107

DESCRIPTION

1. The T2-T Temperature Pill series of transmitters emit intermittant bursts of R.F. energy. These bursts represent the pulses generated by the sub-carrier oscillator. Its repetition rate is analogous to the temperature being measured.

   The R.F. bursts are treated as an AM signal, as they essentially are an AM signal minus the carrier. It is therefore necessary to use a non-limiting, AM receiving system. The ideal receiver for this is a conventional telemetry receiver capable of receiving pulse or AM information. If a receiver of this type is not available, certain types of commercial FM receivers can be modified to receive this type of signal with satisfactory results.

   The normal operating range of temperature is 35° to 40° C with a demodulated output sensitivity of $1V/^{\circ}C$ from Ø to 5V. The output is self limiting at 10V. If this level is reached, the output is clamped to approximately Ø V and the dropout indicator will light. Should there be a loss of signal to the demodulator input, the output will again clamp to Ø and the dropout indicator will light.

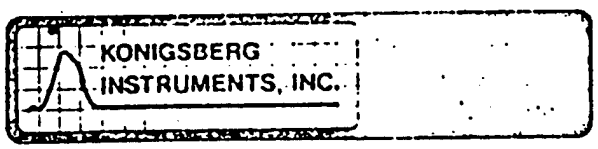
2. The D2-T, T2-T Telemetry system may come to you uncalibrated or already calibrated at your request. The first of the following two sections describes normal operation. The second part is a calibration procedure to be followed should you want to calibrate the system yourself.

OPERATION

1. The D2-T requires a $+2V_p$ minimum signal for proper triggering. This signal, which is taken from the receiver is applied to the BNC jack marked INPUT. The BNC jack marked OUTPUT is where the demodulated temperature signal is taken.

   Each pill will be assigned two numbers which must be dialed in on the controls marked ZERO and GAIN, whenever you are monitoring a particular pill. These controls must be changed to a corresponding set of numbers each time a different pill is tuned.

   The SLOPE control is NEVER adjusted except during calibration as changing its position will completely void any previous calibration.



CORTEMP™

A Major Advance in Technology!

CorTemp Disposable Temperature Sensor - COR-100

Size:	Length = 22.6mm (.89 in) Approximate Diameter = 10.7mm (.42 in) Approximate
Weight:	3.3 Grams (0.11 Oz)
Temperature Sensor:	Quartz Crystal
Operating Frequency:	262,252 Hertz nominal at 37 C
Temperature Change:	9 Hertz per degree Centigrade
Temperature Range:	32 Degrees Centigrade to 44 Degrees Centigrade
Temperature Accuracy:	.1 Degree Centigrade
Temperature Resolution:	.01 Degree Centigrade
Transmission Method:	Near Field Magnetic Link
Transmission Range:	25 cm (minimum)
Power Source:	Ni-Cadmium Battery
Charging Method:	Induction
Charging Time:	12 - 16 Hours
Operating Time:	72 Hours (Minimum when fully charged)
Encapsulation Material:	Dimethly Polysilozane Complies with Section 21CFR 177.2600 and Section 21 CFR 175.300 of the Food and Drug Regulations.
Expected Life:	One Use - 72 Hours Battery Life

CorTemp™ Ambulatory Recorder - COR-124

Size:	127.00mm (5.0 Inches) long 76.0mm (3.0 Inches) wide 51.0mm (2.0 Inches) thick
Weight:	127.6 gms (4.7 ounces) (Without Battery)
Receiving Coil:	228.5 mm (9 inches) Diameter (Approximate)
Power:	9 Volt Alkaline Battery (Mallory MN 1604 or equal)
Battery Life:	24 Hours
Display:	Liquid Crystal Temperature Display
Data Entry:	CorTemp™ Programming Unit COR-120
Data Storage:	Programmable: Standard 2 samples per minute = 24 Hour Data Storage Available 1-5 minutes per sample allows up to 10 day data storage.
Data Output:	1: Through Interface to CorTemp™ Programming Unit (COR-120) A: Directly to Serial Printer B: Directly to a standard ASCII File on MS-DOS XT or AT compatible PC 2: Provisions made for direct output to user provided instrument: A: Analog B: Digital
Operating Range:	0° to 50° C

CorTemp™ Programming Unit - COR-120

Size:	204.0mm (8.0 Inches) long 254.0mm (10.0 Inches) wide 103.9mm (4.1 Inches) high
Weight:	1.8 Kg (4.0 Lb)
Power:	110 - 220 Volt 50/60 Hertz
Computer Compatibility	MS-DOS PC or AT Compatible, 640K Memory
CorTemp™ Ambulatory Recorder Interface	6 Pin Telephone Connector
Computer Interface	RS232 Serial Port
Data Entry:	Keyboard
Data Storage:	Through Computer Hard or Floppy Disk.
Printer Interface	RS 232 Serial

CorTemp™ Bedside Monitor - COR-115

Size:	204.0mm (8.0 Inches) long 254.0mm (10.0 inches) wide 103.9mm (4.1 Inches) high
Weight:	1.8 Kg (4.0 Lbs)
Receiving Coil:	228.5mm (9 inches diameter) Approximate
Power:	110 - 220 Volt 50/60 Hertsz
Computer Compatibility	MS-DOS PC or AT Compatible, 640K Memory
Computer Interface:	RS232 Serial Port
Data Entry:	Keyboard
Data Storage:	Through Computer Hard or Floppy Disk.

REPRESENTED BY:

HUMAN TECHNOLOGIES, INC.

301 3rd Street North • St. Petersburg, FL 33703

813/823-4600 • 800/274-4600 • TELEX 9102509317 HUM TECHUSA

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ENCAPSULATION MATERIAL DATA SHEETS **Enclosure 5**

MATERIAL SAFETY DATA SHEET

May be used to comply with OSHA's Hazard Communication Standard, 29CFR 1910.1200. Standard must be consulted for specific requirements.

Identification Of Product

MANUFACTURER'S NAME LEE PHARMACEUTICALS	EMERGENCY TELEPHONE NO. (818) 442-3141
ADDRESS 1444 Santa Anita Ave., S. El Monte, CA 91733	DATE PREPARED 7-27-87
TRADE NAME AND SYNONYMS Photo-cure methacrylate resin mixture	
CATALOG NUMBER	DOT HAZARD CLASS Combustible Liquid (based on status of ingredient #3 below)

CHEMICAL NAME AND SYNONYMS	CHEMICAL FAMILY	CAS NO.	MOLEC. FORMULA

Hazardous Ingredients

COMPONENT	CAS #	%
1. bisphenol a diglycidyl methacrylate	1564-94-2	50
2. triethylene glycol dimethacrylate	109-16-0	25
3. ethoxylated bisphenol a dimethacylate	24448-20-2	25

COMPONENT	%
4. Camphorquinone	0.3
5. 2-hydroxy-4-methoxybenzophenone	2.0
6. a,a-dimethoxy-a-phenylacetophenone	0.3
7. 2-n-butoxyethyl 4-(dimethylamino)benzoate	0.3

Physical Data

BOILING POINT (°F)

1. gel before boiling
2. 205°
3. No Data
4. N/A
5. N/A
6. No Data
7. 352°

SPECIFIC GRAVITY (H20 = 1)

1. 1.152
2. 1.050
3. 1.11
4. N/A
5. 1.324
6. 1.2
7. 1.043

VAPOR PRESSURE (mm Hg.)

1. <0.1
2. Not Known
3. No Data
4. N/A
5. N/A
6. 8.5 x 10 -6
7.

PERCENT VOLATILE BY VOLUME (%)

1. 0
2. <1
3. negligible
4. N/A
5. negligible
6. <0.5
7. No Data

VAPOR DENSITY (AIR =1)

1. N/A
2. N/A
3. No Data
4. N/A
5. N/A
6. N/A
7. No Data

EVAPORATION RATE

1. N/A
2. N/A
3. N/A
4. N/A
5. N/A
6. N/A
7. N/A

SOLUBILITY IN WATER

1. negligible
2. insoluble
3. insoluble
4. nil
5. nil
6. insoluble
7. insoluble

NOTE: This mixture has not been tested. The best available data for each component has been provided.

APPEARANCE AND ODOR
viscous pale yellow liquid, faintly musty odor

Fire and Explosion Hazard Data

FLASH POINT

1. >240°F
2. 310°F (Cleveland open cup)
3. >310°F (Cleveland open cup)
4. >200°
5. N/A
6. 374°F (Marcusson)
7. >250°C (Closed cup)

FLAMMABLE LIMITS BY VOLUME(%)
N/A

FIRE-EXTINGUISHING MEDIA
Foam, carbon dioxide or dry chemicals

SPECIAL FIRE FIGHTING PROCEDURES
None

UNUSUAL FIRE AND EXPLOSION HAZARDS
High temperatures, exposure to radiation/oxidizers may cause spontaneous polymerization, generating heat,and pressure.

Health Hazards

SUMMARY: This mixture has not been tested but the overall hazard as presented by the major components (1,2,3) are rated slight. The route specific details below are based on the "worst" (3) of the three major components.

ROUTE OF EXPOSURE	SIGNS AND SYMPTOMS
INHALATION	No significant signs or symptoms indicative of an adverse health exposure are expected to occur as a result of inhalation exposure
EYE CONTACT	Although no appropriate human or animal data are known to exist, This material is expected to cause eye irritation.
SKIN ABSORPTION	Although no appropriate human or animal data are known to exist; This material is expected to be a skin irritant/allergic sensitizer.
INGESTION	No data is available although the material is not expected to be particularly toxic by this route. *Note: No data is available for acute or chronic effects of ingestion of polymerized mixture.
CHRONIC EFFECTS	No chronic health effects data are available. If allergic or sensitization reactions are induces they may aggravate systemic disease.

Reactivity Data

CONDITIONS TO AVOID
Heat, oxidizing conditions, direct sunlight, uv radiation

INCOMPATIBILITY (MATERIALS TO AVOID)
Strong oxidizers, free radical initiators, inert gases

HAZARDOUS DECOMPOSITION PRODUCTS
Acrid smoke, fumes, CO/CO2 may be released during fire

HAZARDOUS POLYMERIZATION
May occur

Spill or Leak

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED
Extinguish all ignition sources, soak up small spill, dispose of properly. If spilled on clothing remove saturated clothing immediately, wash affected skin with soap and water.

WASTE DISPOSAL METHOD
If possible polymerize in safe manner. Dispose of liquids in compliance with applicable law

Special Protection Information

RESPIRATORY PROTECTION (SPECIFY TYPE)
No special equipment needed when handling mixture in small quantities. Work in well ventilated area.

PROTECTIVE GLOVES	EYE PROTECTION
Skin should be protected, ie: gloves should normally be worn, keep protective equipment clean.	Chemical splash goggles or a shield is recommended

Special Precautions

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING
None-other than noted above

Disclaimer of Liability

The information in this MSDS was obtained from sources which we believe are reliable. HOWEVER, THE INFORMATION IS PROVIDED WITHOUT ANY WARRANTY, EXPRESS OR IMPLIED, REGARDING ITS CORRECTNESS.

The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. FOR THIS AND OTHER REASONS, WE DO NOT ASSUME REPONSIBILITY AND EXPRESSLY DISCLAIM LIABILITY FOR LOSS, DAMABE OR EXPENSE ARISING OUT OF OR IN ANY WAY CONNECTED WITH THE HANDLING, STORAGE, USE OR DISPOSAL OF THE PRODUCT.

To the purchaser:

Lee Pharmaceuticals has not determined the acute or chronic biological effects of ingestion of the material, ***Photo-cure Methacrylate Resin Mixture.***

It is the responsibility of the users of this material to determine its suitability and safety for the particular purpose they wish to use it and to comply with any regulations which may exist for their product.

MATERIAL SAFETY DATA SHEET

GENERAL ELECTRIC

MANUFACTURED BY:
GENERAL ELECTRIC CO.
SILICONE PRODUCTS DIV.
WATERFORD, NY 12188

EMERGENCY TELEPHONE(24 HRS)
(518) 237-3330
REVISED: 10/21/85
PREPARER:T. LOTT

***** I PRODUCT IDENTIFICATION *****

PRODUCT IDENTIFICATION [RTV112] CHEMICAL FAMILY:POLYSILOXANE SEALANT
CHEMICAL NAME: SILCONE SEALANT FORMULA: MIXTURE

***** II PRODUCT COMPONENTS *****

PRODUCT COMPOSITION	APPROX. %	ACGIH TLV	OSHA PEL	UNITS	CAS REG NO.
A. HAZARDOUS					
METHYLTRIACETOXYSILANE	< 05%	10	10	PPM	4253-34-3*
PROPRIETARY COMPONENT	< 05%	10	10	PPM	
B. NON-HAZARDOUS					

***** III PHYSICAL DATA ******

**PRODUCT INFORMATION

BOILING POINT	N/A (F)	N/A (C)	PHYSICAL STATE	LIQUID	
FREEZING POINT	N/A (F)	N/A (C)	ODOR	ACETIC ACID	
MELTING POINT	N/A (F)	N/A (C)	COLOR	WHITE	
VAPOR PRESSURE (20 C)	N/A	MM HG	PH	N/A	
VAPOR DENSITY (AIR=1)	N/A		ACIDITY/ ALKALINITY	UNK	MEG/G
% VOLATILE BY VOLUME	~5		DENSITY	994	MG/M3
			SPECIFIC GRAVITY (WATER=1)	1.01	
			EVAPORATION RATE (BUTYL ACETATE=1)	>1	

SOLUBILITY IN WATER (20 C) INSOLUBLE
SOLUBILITY IN ORGANIC SOLVENT (STATE SOLVENT): UNK

***** IV FIRE AND EXPLOSION DATA *****

FLASH POINT 162 (F) 72 (C) BY PMCC. IGNITION TEMP UNK (F)UNK(C)
FLAMMABLE LIMITS IN AIR(%): LOWER UNK UPPER UNK
EXTINGUISHING MEDIA:
ALL STANDARD FIREFIGHTING MEDIA
SPECIAL FIREFIGHTING PROCEDURES:
COMBUSTIBLE.

***** V REACTIVITY DATA *****

STABILITY:
X STABLE UNSTABLE

HAZARDOUS:
POLYMERIZATION WILL NOT OCCUR

HAZARDOUS DECOMPOSITION PRODUCTS:
CARBON MONOXIDE.
CARBON DIOXIDE.
SILICON DIOXIDE.
ACETIC ACID.

INCOMPATIBILITY (MATERIALS TO AVOID):
NONE KNOWN.

CONDITIONS TO AVOID:
KEEP AWAY FROM HEAT,SPARKS AND OPEN FLAME.
NONE KNOWN.

***** VI HEALTH HAZARD DATA *****

ACUTE SIGNS/EFFECTS OF OVEREXPOSURE:

INGESTION:
MAY CAUSE STOMACH DISCOMFORT.

SKIN CONTACT:
UNCURED PRODUCT CONTACT WILL IRRITATE LIPS,GUMS AND TONGUE.
UNCURED PRODUCT CONTACT MAY IRRITATE THE SKIN.

INHALATION:
CAUSES MODERATE RESPIRARTORY IRRITATION.
APPLIES ONLY IN UNCURED STATE.

EYE CONTACT:
UNCURED PRODUCT CONTACT IRRITATES EYES.

MEDICAL CONDITIONS AGGRAVATED:
NONE KNOWN.

OTHER:
ACETIC ACID RELEASED DURING CURING.

CHRONIC EFFECTS OF OVEREXPOSURE:
RESPIRATORY AILMENTS.

EMERGENCY AND FIRST AID PROCEDURES:

INGESTION:
RINSE MOUTH WITH WATER SEVERAL TIMES.

SKIN:
TO CLEAN FROM SKIN, REMOVE COMPLETELY WITH A DRY CLOTH OR PAPER TOWEL, BEFORE WASHING WITH DETERGENT AND WATER.

INHALATION:
NONE KNOWN.

EYES:
IN CASE OF CONTACT, IMMEDIATELY FLUSH EYES WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES AND GET MEDICAL ATTENTION IF IRRITATION PERSISTS.

NOTE TO PHYSICIAN:
NONE KNOWN.

TOXICITY: METHYLTRIACETOXYSILANE
ACUTE ORAL LD50 RAT 2060 MG/KG MG/KG
ACUTE DERMAL LD50 NONE FOUND MG/KG
ACUTE INHALATION LC50 NONE FOUND
OTHER NONE.
AMES TEST: UNKNOWN

TOXICITY: PROPRIETARY COMPONENT
ACUTE ORAL LD50 NONE FOUND MG/KG
ACUTE DERMAL LD50 NONE FOUND MG/KG
ACUTE INHALATION LC50 NONE FOUND
OTHER NONE.
AMES TEST: UNKNOWN
PRINCIPAL ROUTES OF EXPOSURE:
EYES.
INHALATION.
PRODUCTS/INGREDIENTS:
THIS SPACE RESERVED FOR SPECIAL USE.

***** VII SPECIAL PROTECTIVE EQUIPMENT *****

RESPIRATORY PROTECTION:
USE IN A WELL VENTILATED AREA.
PROTECTIVE GLOVES:
CLOTH GLOVES.
EYE AND FACE PROTECTION:
SAFETY GLASSES.
OTHER PROTECTIVE EQUIPMENT:
NONE KNOWN.
VENTILATION:
USE ONLY IN WELL VENTILATED AREA.

*** VIII SPILL, LEAK AND DISPOSAL PROCEDURES ***

ACTION TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED:
WIPE, SCRAPE OR SOAK UP IN AN INERT MATERIAL AND PUT IN A CONTAINER FOR DISPOSAL.
WASH WALKING SURFACES WITH DETERGENT AND WATER TO REDUCE SLIPPING HAZARD.
DISPOSAL METHOD:
DISPOSAL SHOULD BE MADE IN ACCORDANCE WITH FEDERAL, STATE AND LOCAL REGULATIONS.
BURY IN A LICENSED LANDFILL OR BURN IN AN APPROVED INCINERATOR ACCORDING TO FEDERAL, STATE, AND LOCAL REGULATIONS.

***** IX SPECIAL PRECAUTIONS *****

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE:
AVOID CONTACT WITH SKIN AND EYES.

CAUTION! COMBUSTIBLE.
REMOVE CONTACT LENSES BEFORE USING SEALANT. DO NOT HANDLE LENSES UNTIL ALL SEALANT HAS BEEN CLEANED FROM THE FINGER-TIPS, NAILS AND CUTICLES. RESIDUAL SEALANT MAY REMAIN ON FINGERS FOR SEVERAL DAYS AND TRANSFER TO LENSES AND CAUSE SEVERE EYE IRRITATION.
PRODUCT RELEASES ACETIC ACID DURING APPLICATION AND CURING. USE MECHANICAL VENTILATION TO STAY BELOW TLV OF 10 PPM ACETIC ACID.
UNCURED PRODUCT CONTACT IRRITATES EYES.
UNCURED PRODUCT CONTACT MAY IRRITATE SKIN.

ENGINEERING CONTROLS:
EYEWASH STATIONS.

** X SHIPPING AND REGULATORY CLASSIFICATION DATA **

DOT SHIPPING NAME: COMBUSTIBLE LIQUID NOS UN/NA NUMBER: NA1993
DOT HAZARD CLASS: COMBUSTIBLE LIQUID
DOT LABEL(S): NONE
EPA HAZARD WASTE: NA
OSHA HAZARD CLASS: COMBUSTIBLE LIQUID
CPSC CLASSIFICATION: NA
TRANSPORTATION CLASS: IMO NA
RID (OCTI) NA
ADR (ECE) NA
RAR (IATA) NA
NFPA/HMIS CLASSIFICATION: FLAMMABILITY 2 , REACTIVITY 0 , HEALTH 2
ADDITIONAL INFORMATION:
THIS PRODUCT OR ITS COMPONENTS ARE ON THE EUROPEAN INVENTORY OF EXISTING COMMERCIAL CHEMICALS (EINECS).
THESE DATA ARE OFFERED IN GOOD FAITH AS TYPICAL VALUES AND NOT AS A PRODUCT SPECIFICATION. NO WARRANTY, EITHER EXPRESSED OR IMPLIED, IS MADE. THE RECOMMENDED HANDLING PROCEDURES ARE BELIEVED TO BE GENERALLY APPLICABLE. HOWEVER, EACH USER SHOULD REVIEW THESE RECOMMENDATIONS IN THE SPECIFIC CONTENT OF THE INTENDED USE.

K R ANDERSON CO INC
2665 S ORANGE AVE
SANTA ANA, CA 92707

DOW CORNING CORPORATION
MATERIAL SAFETY DATA SHEET

MATL NAME: DOW CORNING(R) 734 RTV SELF-LEVEL. ADHESIVE-CLEAR
EMERGENCY TELEPHONE NO. (517) 496-5900

SECTION I - GENERAL INFORMATION

MANUFACTURERS NAME: DOW CORNING CORPORATION
ADDRESS: SOUTH SAGINAW ROAD, MIDLAND MI 48686

PROPER SHIPPING NAME(49CFR 172.101): COMBUSTIBLE LIQUID
D.O.T. HAZARD NAME(49CFR 172.101): SILOXANE
D.O.T. ID NO(49CFR 172.101): N.A. 1993
D.O.T. HAZARD CLASS(49CFR 172.101): COMBUSTIBLE LIQUID (EXEMPT IN PACKAGES OF 110 GALLONS OR LESS)
RCRA HAZARD CLASS(40CFR 261)(IF DISCARDED): NONE
E.P.A. PRIORITY POLLUTANTS(40CFR 122.53): NONE
NFPA = NATIONAL FIRE PROTECTION ASSOCIATION - 704
HEALTH (NFPA): 1 FLAMMABILITY (NFPA): 2 REACTIVITY (NFPA): 1
CAS NO: MIXTURE DOW CORNING WARNING CODE: 57, 84
GENERIC DESCRIPTION: SILICONE

SECTION II - HAZARDOUS INGREDIENT

ACETOXYSILANE % 5 TLV (UNITS): 10 PPM

ONLY THOSE INGREDIENTS LISTED IN THIS SECTION HAVE BEEN DETERMINED TO BE HAZARDOUS AS DEFINED IN 29 CFR 1910.1200. AN INGREDIENT MARKED WITH AN ASTERISK(*) IS ALSO LISTED IN 29 CFR 1910.1200(D) #4 AS KNOWN OR SUSPECTED CARCINOGEN.

COMMENT:TLV FOR ACETOXYSILANE BASED ON ACETIC ACID.

DOW CORNING CORPORATION
MATERIAL SAFETY DATA SHEET

NAME: DOW CORNING(R) 734 RTV SELF-LEVEL. ADHESIVE-CLEAR

SECTION III - EFFECTS OF OVEREXPOSURE

EYES: MAY IRRITATE SERIOUSLY WITH MODERATE CORNEAL INJURY AND CONSIDERABLE REDNESS LASTING A WEEK OR MORE.

SKIN: A SINGLE EXPOSURE FOR SEVERAL HOURS MAY CAUSE SLIGHT REDDENING. LONGER OR REPEATED CONTACTS MAY CAUSE MODERATE IRRITATION AND POSSIBLE A MINOR BURN.

INHALATION: NOSE AND THROAT IRRITATION MAY OCCUR. PROLONGED OR FREQUENTLY REPEATED EXPOSURES MAY CAUSE SLIGHT INJURY.

ORAL: AMOUNTS TRANSFERRED TO THE MOUTH BY FINGERS, ETC., DURING NORMAL OPERATIONS SHOULD NOT CAUSE INJURY.

COMMENT: NO KNOWN ADVERSE CHRONIC HEALTH EFFECTS, BUT UNNECESSARY EXPOSURE TO ANY CHEMICAL SHOULD BE AVOIDED.
THIS PRODUCT, AS WITH ANY CHEMICAL, MAY ENHANCE ALLERGIC CONDITIONS ON CERTAIN PEOPLE. WE DO NOT KNOW OF ANY MEDICAL CONDITIONS THAT MIGHT BE AGGRAVATED BY EXPOSURE TO THIS PRODUCT.

SECTION IV - EMERGENCY AND FIRST AID PROCEDURES

EYES: FLUSH WITH WATER FOR 15 MINUTES.

SKIN: WIPE OFF AND FLUSH WITH WATER.

INHALATION: NO PROBLEM.

ORAL: NO PROBLEM.

COMMENT: NONE

SECTION V - FIRE AND EXPLOSION DATA

FLASH POINT (METHOD USED): OPEN CUP ABOVE 189°F/87°C
AUTOIGNITION: NOT DETERMINED
FLAMMABILITY LIMITS IN AIR : LOWER:N.D. UPPER: N.D.

EXTINGUISHING MEDIA: WATER WATER FOG X CO2 X DRY CHEMICAL X FOAM X OTHER

SPECIAL FIRE FIGHTING PROCEDURES: SELF CONTAINED BREATHING APPRARATUS AND PROTECTIVE CLOTHING SHOULD BE WORN IN FIGHTING FIRES INVOLVING CHEMICALS

UNUSUAL FIRE AND EXPLOSION HAZARDS: NOT KNOWN TO DOW CORNING

COMMENTS: N.D. - NOT DETERMINED

SECTION VI - PHYSICAL DATA

BOILING POINT(@ 760 MM HG): ABOVE 300°F/149°C
SPECIFIC GRAVITY (AT 77 DEG F/25 DEG C): 1.05
MELTING POINT: NOT APPLICABLE
VAPOR PRESSURE (AT 77 DEG F/25 DEG C): LESS THAN 5 MM
VAPOR DENSITY (AIR = 1 AT 77 DEG F/25 DEG C): NOT APPLICABLE
PERCENT VOLATILE BY VOLUME (%): LESS THAN 5%
EVAPORATION RATE (ETHER = 1): LESS THAN 1
SOLUBILITY IN WATER(%): LESS THAN 0.1%
ODOR, APPEARANCE, COLOR: ACETIC ACID-LIKE, PASTE, CLEAR.

NOTE: THE ABOVE INFORMATION IS NOT INTENDED FOR USE IN PREPARING PRODUCT SPECIFICATIONS. CONTACT DOW CORNING BEFORE WRITING SPECIFICATIONS

DOW CORNING CORPORATION
MATERIAL SAFETY DATA SHEET

NAME: DOW CORNING(R) 734 RTV SELF-LEVEL. ADHESIVE-CLEAR

SECTION VII - REACTIVITY DATA

STABILITY: STABLE

INCOMPATABILITY(MATERIAL TO AVOID): OXIDIZING MATERIAL CAN CAUSE A REACTION.

CONDITIONS TO AVOID: AIR OR MOISTURE CAUSES POLYMERIZATION AND FORMATION OF ACETIC ACID VAPORS.

HAZARDOUS DECOMPOSITION PRODUCTS: SILICON DIOXIDE, CARBON DIOXIDE, AND TRACES OF INCOMPLETELY BURNED CARBON PRODUCTS.

HAZARDOUS POLYMERIZATION: WILL NOT OCCUR

CONDITIONS TO AVOID: NOT APPLICABLE

COMMENTS: NONE

SECTION VIII - SPILL, LEAK AND DISPOSAL PROCEDURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED: REMOVE PRODUCT AND USE ABSORBENT MATERIAL TO TAKE CARE OF ANY OIL-LIKE RESIDUES.

PROTECTIVE EQUIPMENT:
EYES: USE PROPER PROTECTION -- SAFETY GLASSES, AS A MINIMUM.

SKIN: AVOID CONTACT BY USING IMPERVIOUS PROTECTIVE CLOTHING" RUBBER OR PLASTIC GLOVES, APRONS, BOOTS, ETC. USE PROTECTIVE GLOVES AS A MINIMUM AND WASH IMMEDIATELY UPON ANY DETECTABLE CONTACT.

INHALATION: USE RESPIRATORY PROTECTION UNLESS LOCAL EXHAUST VENTILATION IS ADEQUATE OR AIR SAMPLING DATA SHOW EXPOSURES ARE WITHIN TLV AND PEL GUIDELINES.

WASTE DISPOSAL METHOD: DOW CORNING SUGGESTS THAT ALL LOCAL,STATE AND FEDERAL REGULATIONS CONCERNING HEALTH AND POLLUTION BE REVIEWED TO DETERMINE APPROVED DISPOSAL PROCEDURES. CONTACT DOW CORNING IF THERE ARE ANY DISPOSAL QUESTIONS.

D.O.T. (49CFR 171.8)/E.P.A. (40CFR 117) SPILL REPORTING INFORMATION
HAZARDOUS SUBSTANCE: NONE REPORTABLE QUANTITY: NOT APPLICABLE
CONCENTRATION OF HAZARDOUS SUBSTANCE: NOT APPLICABLE
REPORTABLE QUANTITY OF PRODUCT: NOT APPLICABLE

COMMENTS: NONE

SECTION IX - ROUTINE HANDLING PRECAUTIONS

PROTECTIVE EQUIPMENT:
EYES: USE PROPER PROTECTION -- SAFETY GLASSES, AS A MINIMUM.

SKIN *: REMOVE CONTAMINATED CLOTHING AND SHOES AT THE END OF THE WORK PERIOD AND THOROUGHLY CLEAN BEFORE REUSE.

INHALATION: USE RESPIRATORY PROTECTION UNLESS LOCAL EXHAUST VENTILATION IS ADEQUATE OR AIR SAMPLING DATA SHOW EXPOSURES ARE WITHIN TLV AND PEL GUIDELINES.

VENTILATION:
LOCAL EXHAUST: RECOMMENDED
MECHANICAL (GENERAL): RECOMMENDED

SUITABLE RESPIRATOR: ACID GAS/ORGANIC VAPOR TYPE.

THESE PRECAUTIONS ARE FOR ROOM TEMPERATURE HANDLING, USE AT ELEVATED TEMPERATURE MAY REQUIRE ADDED PRECAUTIONS.
* GOOD PRACTICE REQUIRES THAT GROSS AMOUNT OF ANY CHEMICAL BE REMOVED FROM THE SKIN AS SOON AS PRACTICAL, ESPECIALLY BEFORE EATING OR SMOKING.
COMMENTS: NONE

DOW CORNING CORPORATION
MATERIAL SAFETY DATA SHEET

NAME: DOW CORNING(R) 734 RTV SELF-LEVEL. ADHESIVE-CLEAR

SECTION X - SPECIAL PRECAUTIONS

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING: STORE BELOW 90F/32C.
PRODUCT IS COMBUSIBLE. USE REASONABLE CARE AND CAUTION.

OTHER PRECAUTIONS: NONE KNOWN TO DOW CORNING.
COMMENTS: NONE

THESE DATA ARE OFFERED IN GOOD FAITH AS TYPICAL VALUES AND NOT AS A PRODUCT SPECIFICATION. NO WARRANTY, EITHER EXPRESSED OR IMPLIED, IS HEREBY MADE. THE RECOMMENDED INDUSTRIAL HYGIENE AND SAFE HANDLING PROCEDURES ARE BELIEVED TO BE GENERALLY APPLICABLE. HOWEVER, EACH USER SHOULD REVIEW THESE RECOMMENDATIONS IN THE SPECIFIC CONTEXT OF THE INTENDED USE AND DETERMINE WHETHER THEY ARE APPROPRIATE.

PREPARED BY: JACK L. SHENEBERGER
LAST REVISION DATE: SEPTEMBER 27, 1985
PREVIOUS REVISION DATE: SEPTEMBER 30, 1983
DATE: NOVEMBER 15, 1985
(R) INDICATES REGISTERED OR TRADEMARK OF THE DOW CORNING CORPORATION.