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THE INGESTIBLE THERMAL MONITORING SYSTEM

Under NASA/Goddard Space Flight Center sponsorship, APL designed and developed an ingestible pill that allows the body core temperature to be monitored by a telemetry link. The device has potential applications for divers, astronauts, soldiers in combat, and people with hypothermia or hyperthermia.

INTRODUCTION

The body core temperature can be accurately measured in only a few locations without implanting a sensor into the body. Most commonly, a rectal thermometer is used for core temperature measurement. However, this method is inconvenient in many applications. The oral temperature, which is also frequently used, is a quite unreliable measure of core temperature because of variations due to breathing and to ingesting hot or cold liquids. The ingestible thermal monitoring system (ITMS) consists of an ingestible pill, a battery recharger, and a receiver. The pill senses the temperature at its location (e.g., the stomach or small intestine) and transmits the temperature out of the body by a magnetic inductive telemetry link.

Ingestible pills have been used for monitoring pressure,[1-3] temperature,[4] and radiation dosage.[5] However, the pill described here is unique in that it is both commandable and rechargeable; that is, the pill will only send out temperature telemetry briefly after receiving a command so that battery power is conserved, and the pill can be recharged before use, which results in a very long shelf life.

ITMS has potential applications for people with hypothermia (low body temperature) or hyperthermia (high body temperature). Both conditions require careful and frequent monitoring of body core temperature. In addition, continuous monitoring of body temperature is desirable for several types of professionals, such as divers and astronauts. ITMS may also be used to monitor the body temperatures of soldiers in combat to detect changes resulting from the use of chemical or biological warfare agents. For these applications, an external receiver worn by the user can sound an alarm if the body temperature is too high or too low.

PILL ELECTRONICS

Design of a commandable pill began at APL in mid-1986 after a usable quartz temperature-sensing tuning fork and a small nickel–cadmium cell were identified. Several design iterations produced the circuit discussed here and also resulted in the use of the oscillator and charging circuit as a rechargeable, continuously transmitting pill.

The pill electronics consists of a battery power source, a crystal-controlled oscillator that drives a small air coil, and a command detection circuit. The resulting 262-kHz magnetic field can easily be detected up to 1 m away from the pill. The ability of the pill oscillator to function at voltages less than 1 V allows the use of a single nickel–cadmium battery, which is rechargeable. The pill can also be recalibrated periodically to compensate for long-term drift. These two features permit the pill to be reused over long periods of time in animal research.

The continuously transmitting pill draws an average current of 100 μA and exhausts the battery in about 72 h, whereas the commandable pill provides several hundred hours of shelf life after charging and maximizes in-use duration. A commandable pill also minimizes cross talk when several units are used in the same room.

Circuit design uses the single 1.2-V nickel–cadmium cell to minimize volume and eliminate the reverse-charge problem common in multicell batteries. This low voltage requires careful circuit configuration since the silicon transistors require a 0.6-V base bias.

The oscillator is the heart of the pill. A schematic of the oscillator is shown in Fig. 1. It is stable from 1 V to 2 V, starts reasonably fast (0.4 s), and uses little power (1.2 V $\times$ 100 μA = 120 μW). It has a thermal transfer function of about 9 Hz/°C and a repeatability of $\pm$1 Hz over its battery range. Each oscillator is individu-

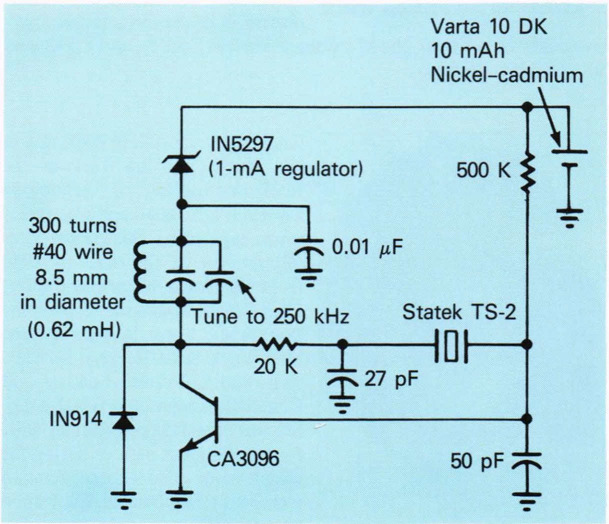

Figure 1—Schematic of oscillator.

ally calibrated to eliminate the ±3° absolute variation of production quartz tuning forks. The coil produces an induction field used for remote sensing as generated by its nominal 1-mA circulating current. The coil has a swing of twice the battery voltage.

The oscillator uses one negative doping/positive doping/negative doping (NPN) transistor of the CA3096 array to drive a tuned coil and a feedback network that contains the quartz resonator in its series mode. The coil is tuned to 250 kHz to maximize command sensitivity and ensure a capacitive load for the collector current. A DC base drive of 1 μA or more at turn-on ensures excess gain and reliable start-up.

The control circuitry for command requires 10 additional transistors. The commandable pill uses RCA CA3046 and CA3096 five-transistor arrays to obtain eight NPN transistors and two positive doping/negative doping/positive doping (PNP) transistors. One additional discrete PNP transistor is used to make a complementary amplifier without the parasitic problems inherent in the arrays.

The coil provides three functions: (a) a tuned load for oscillation (with generation of an induction field for readout), (b) command sensing, and (c) voltage during charging. Packaging is critical: the battery and circuitry within the coil must be configured for minimum field loading.

Figure 2a is a block diagram that illustrates the commandable pill. Commands induce a peak-to-peak voltage of 500 mV or greater in the coil. The voltage is detected by a command receiver circuit, which then discharges the 10-s timing capacitor. Induced voltage is attenuated to 0.14 times the coil magnitude at the receiver input.

The first receiver stage is biased to allow detection of a peak-to-peak voltage of 70 mV at its input. The rest of the circuit is turned off until detection to save power. When a command is received, the receiver resets a timer that produces a 10-s timing pulse. The timer drives a Schmitt trigger that controls the oscillator bias. Detection removes the clamp from the oscillator base to initiate oscillator start-up. It takes about 0.4 s to achieve full voltage at the oscillator collector. Command detection continues during this turn-on transient time until the oscillator voltage reaches 0.6 V peak.

The receiver is muted after a PNP transistor detects coil voltages greater than 0.6 V peak. The muting circuit disables the receiver to prevent the readout oscillation from self-commanding the pill. Without the circuit, the pill would run continuously after the first turn-on command is sent. The 10-s timing begins when the receiver is disabled.

The pill returns to standby when the timing capacitor charges up to 550 mV. This triggers the Schmitt trigger, which clamps the oscillator off. The crystal continues to vibrate for several seconds; however, the oscillator base clamp prevents any drive. The muting circuit continues to operate for 1 s, after which time the receiver is again activated and a new "on" command can be accepted. The delay ensures that the coil oscillations, shown in Fig. 2b, have ceased before the receiver is reenabled. Muting also occurs during charging to keep the pill in standby after one 10-s readout. The large charging voltage keeps the receiver clamped off so that less power is consumed.

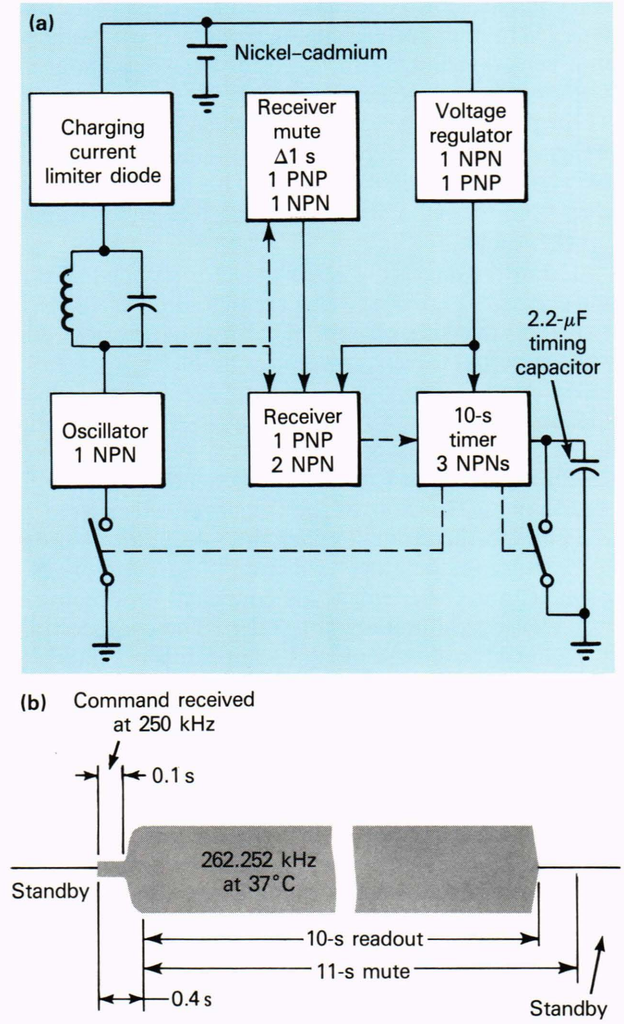

Figure 2—(a) Block diagram of commandable pill and (b) waveform at coil.

Nominal standby current drain is 20 μA; readout draws about 100 μA. Standby discharge occurs over about 500 h. The commandable pill may be charged several days before use and still have approximately 50 operating hours when activated. Human retention of the pill is expected to be 1 to 2 days.

The pills were tested between 0.6 and 3.0 V to prove the design. The design goals were met, and the design provided for a reasonable manufacture of the device requiring one tailor operation (tuning the coil to 250 kHz) plus temperature calibration.

EXTERNAL RECEIVER

The pill receiver is designed to provide a signal to a standard frequency counter and to provide the operator with a signal strength indication. The pickup coil has two configurations: one is 5 cm in diameter, and the other is 23 cm in diameter. The smaller coil is easily placed in a person's garment or taped to the skin without interfering with movement and allows for easier location of the pill. The larger coil is used when a person cannot wear a coil and the coil must be mounted on the side of a bed or in a mattress cover. This coil is much farther from the pill and therefore must be larger to pick up the signal.

The external coils are either tuned or untuned. If tuning capacitors are used, they are placed on the coils so that the same receiver can be used with any coil. The voltage across the external coil is amplified by a field-effect transistor amplifier. The amplifier is tuned to have maximum gain at 262 kHz. The gain of the amplifier is 70 dB, and this gain provides a pickup range of 25 cm, as shown in Fig. 3. The frequency of the amplified signal is the same as the frequency telemetered by the pill and therefore contains the information needed to measure temperature. The amplified signal drives a counter, and the frequency is converted to a temperature by using calibration data collected before ingestion.

Figure 4 is a cross section of a three-dimensional field, showing that if the coils are axially aligned, the maximum flux is linked. Coil A is an example of an axially aligned coil that links maximal flux. Coils C, D, and E link no net flux because all linked field lines cross the loop twice in opposite directions. Coil C is aligned at the same angle as coil A, but it will not produce a reading because there is no net flux through it. Coil F is at the same distance as coil A but links less flux because of its angle with respect to the axis of the pill. Thus, position as well as angle is important for receiving a strong signal. A planned three-coil receiver would solve the pickup problem for automated data collection. A receiver with three orthogonally positioned coils will not have any positions where the field of the pill cannot be detected.

With a gain of 70 dB, the pill can be detected from 1 m. A plot of amplifier output versus distance is shown in Fig. 5. The top trace shows data for axially aligned coils. If the axis of the pill coil does not coincide with the axis of the external coil, the maximum flux linkage is not achieved and the output signal is attenuated. The other traces show the output for coils that are aligned at an angle with the pill coil. The middle trace is for coil F in Fig. 4. The coupling is a cosine function of the angle between the coils.

The present system has only a single coil receiver. A field-strength circuit, which informs the operator of the strength of the received signal, is built into the receiver. The operator moves the coil around the person who has ingested the pill until the field-strength indicator gives a valid reading. The pill-receiver system specifications are summarized in Table 1.

RECHARGER

The pill can be recharged before use by placing it in a recharging fixture. The same coil that is used to telemeter data from the pill is used to extract power from an externally generated field to recharge the nickel-cadmium battery in the pill. The pill coil is tuned with a capacitor to 250 kHz, and that frequency is used to charge and command the pill. A tuned coil extracts maximum energy from a field at its resonant frequency and thus yields the fastest charge rate and longest command range. The 250-kHz frequency is used for two reasons: (a) it is 10 kHz less than the oscillator frequency and therefore provides a capacitive load to the oscillator, and (b) the charging and command frequencies are easy to separate from the data frequencies.

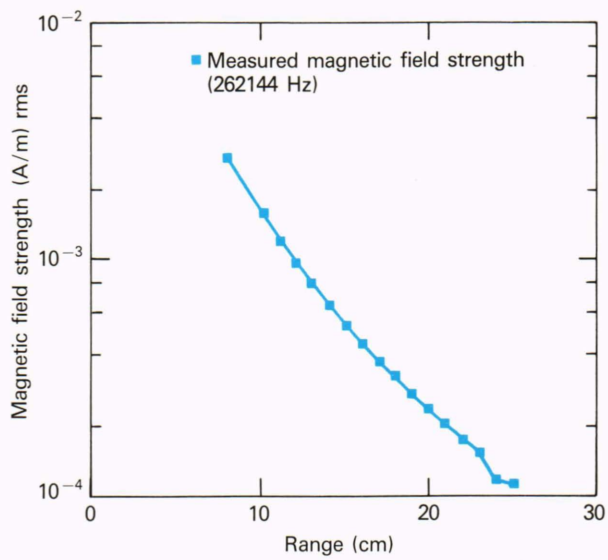

Figure 3—Measured field strength from fully charged pill.

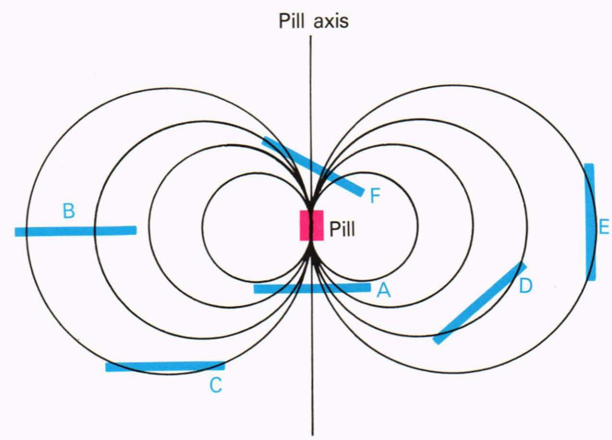

Figure 4—Field lines from the pill with possible positions for receiver coils.

The pill electronics contains a current-limiting diode to protect the battery from overcharging. The inductor in the charger is a specially wound air-core coil that has an internal diameter of 1.25 cm. The ITMS pills fit into these inductors, and this pill-charger configuration provides the maximum flux to be linked from the recharger coil to the pill coil.

The current-limiting diode in the pills has a 1-mA operating point. This current is equal to one-tenth of

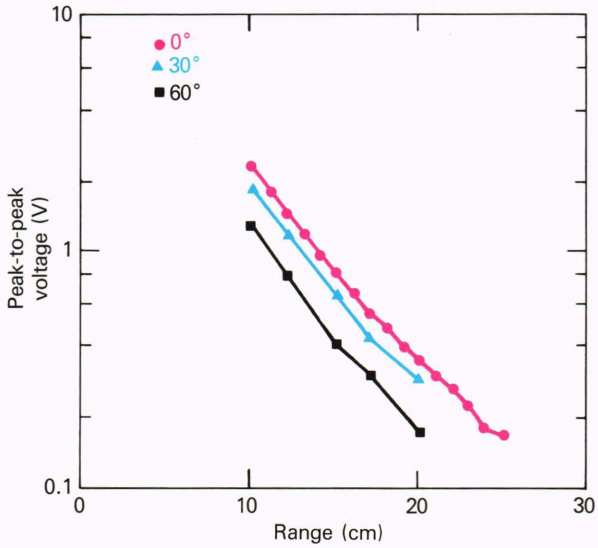

Figure 5—Receiver output for coils on the pill axis aligned at 0°, 30°, and 60° to the pill axis. The pickup coil area is 0.002 m^2.

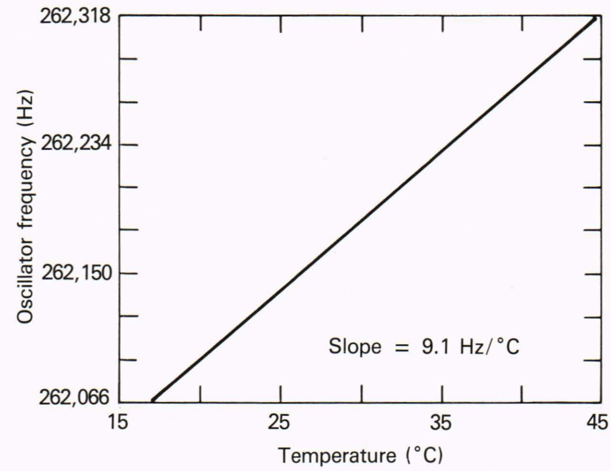

Figure 6—Crystal frequency versus temperature.

Table 1—Specifications of ITMS.

Size	10.7 mm in diameter, 22.6 mm in length
Readout field	0.4 × 10^{-3} (A/m) rms at 15 cm and 262144 Hz
Command range	15 cm with current equipment
Readout range	25 cm
Lifetime	100 h (reading once per minute)
Power drain	20 μA at 1.2 V (standby) and 100 μA at 1.2 V (readout)
Output duration	8 ± 4 s
Charge time	14 h
Crystal	Statek TS-2
Frequency	262252 ± 27 Hz at 37°C (body temperature)
Expected frequency range from 32 to 44°C	262180 to 262342 Hz
Nominal temperature coefficient	9 Hz/°C
Potting materials	3M Scotch-Weld #1838 B/A epoxy adhesive
Coil	300 turns, #40 gauge, 8.5 mm in diameter, inductance = 0.62 mH
Battery	Varta 10 DK, single 10 mAh, nickel-cadmium

the 1-h discharge capacity of the battery and is the specified charging current for the battery. A fully discharged battery requires 14 h to become fully charged again.

CRYSTALS

The crystal selected for the ITMS pill is the model TS-2 from Statek. The crystal is specified to measure temperature to 0.1°C resolution with an uncalibrated accuracy of ±3°C. Each crystal undergoes calibration to meet the 0.1°C accuracy specification for the pill.

The crystals are calibrated in the oscillator circuit against a temperature reference. A forced dry-air, heating and cooling environmental test chamber that can provide temperatures from −65 to +125°C is used to test the pill. The system can hold a given temperature with an accuracy of ±0.5°C, measure the temperature of the environment to a resolution of ±0.1°C, and be computer controlled to automate testing.

The test setup for calibrating the crystals consists of the environmental test chamber, an HP 9000 series model 520 computer, a pill oscillator, a frequency counter, and a current meter. The computer controls all the other equipment and collects data from the counter and current meter. The automated test setup permits calibration of crystals at night so that the test setup can be used for other tasks during the day.

The crystals are calibrated by cycling them through a range of temperatures from 15 to 45°C in 5°C steps. The tester spends 20 min at each step and records the frequency and temperature once every minute. The 20-min dwell time is to allow the temperature reference and the TS-2 crystal to reach thermal equilibrium. These devices have different thermal time constants; therefore, the tester must wait for the parts to reach the same temperature.

Figure 6 is a plot generated by the automated test system. The plot contains data that were collected over 15 h, the time required to put the crystal through three complete cycles from 15 to 45°C and back to 15°C. The crystals show no hysteresis during the cycles.

FABRICATION AND PACKAGING

The task of packaging the ITMS pill was challenging because of the small final size of the device and the environment in which the device had to work. The final size of the pill is 10.7 mm in diameter and 22.6 mm in length. Four circular ceramic multilayer boards, one of which is shown in Fig. 7a, are used for the circuitry be-

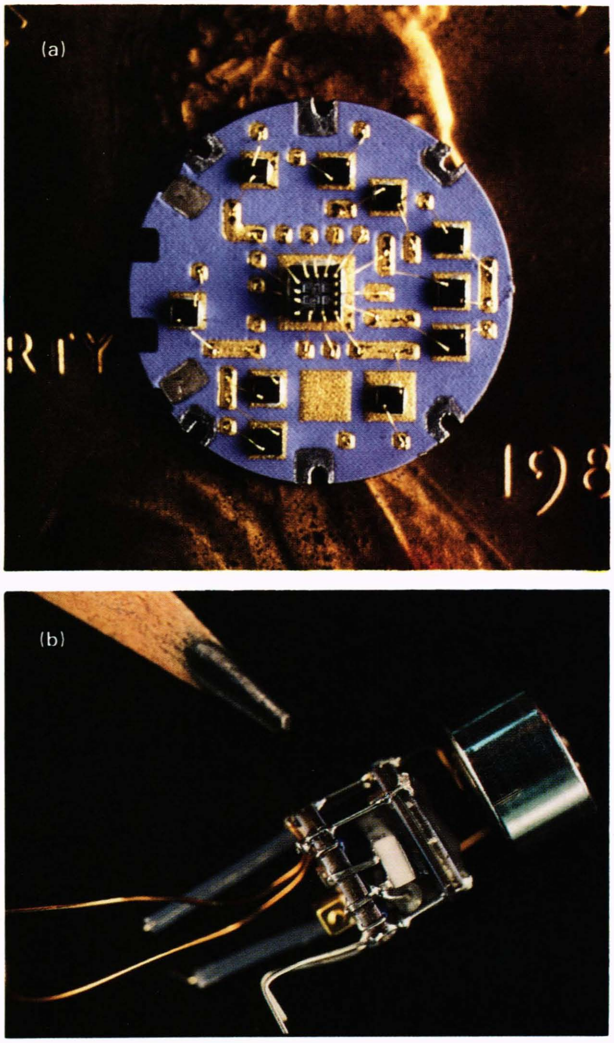

Figure 7—(a) Ceramic multilayer circuit board and (b) unpotted pill electronics assembly.

cause circular boards yield the smallest possible envelope dimensions for later packaging. The boards are made by using thick-film technology on the ceramic furnace in APL's Microelectronics Group.[6] The boards are cut from a ceramic base with a laser machining tool, and each board has two or three conducting layers. Four boards are epoxied back-to-back to form two sets, and these are connected by wires at the outer perimeters of the boards, as shown in Fig. 7b. Grooves are then cut in the boards to allow the wires to sit properly and not add to the diameter of the pill. The limiting factor in determining the pill diameter is the diameter of the nickel–cadmium battery, which is 7.6 mm. The circuit boards are made the same diameter as the battery to use all available space.

The fabrication of the pill is shown in Fig. 8. The first step is making the boards. A ceramic base (Fig. 8a) is cut into nine copies of each board (Fig. 8b). The pill contains four different boards, each 7.6 mm in diameter. After the boards are cut out, they are populated with chips, resistors, and capacitors, as shown in Fig. 7a. Figures 8c and 8d are the Statek TS-2 crystal and the

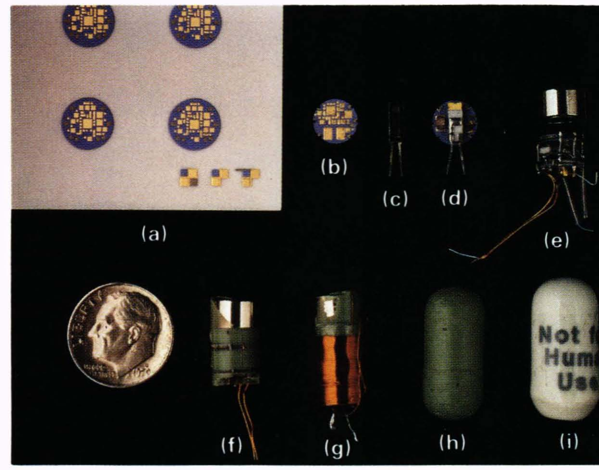

Figure 8—Packaging sequence.

crystal mounted on its substrate. After the appropriate substrates are mounted back-to-back, they are assembled with a battery into a pill, as shown in Figs. 8e and 7b. In Fig. 7b, one can see the battery connections and the wires that run between the substrates.

The next step is potting the pill with epoxy, as shown in Fig. 8f. All leads are removed except for the copper leads used to attach the coil and tuning capacitor. The potted pill is then wrapped in heat-shrink tubing to extend its length and provide a smooth coil form. The end of the pill where the coil leads come out is now hollow, and the tuning capacitor is placed there. The extra length also keeps the battery as far away from the end of the 300-turn coil as possible. This step is shown in Fig. 8g. After the tuning capacitor has been chosen and soldered into place, the whole pill is placed in a different mold and given a second potting (Fig. 8h). The second potting holds the coil in place, provides extra protection for the electronics, and gives the pill the familiar capsule-like shape.

The outer layer of the pill, shown in Fig. 8i, is the critical layer, which must be resistant to degradation by the contents of the digestive tract as well as be biocompatible. For this layer, silicone rubber was selected. A review of the literature on ingestible pills yielded silicone rubber[1-4,7] and polytetrafluoroethylene[1,5] as materials that have been used for encapsulation. Silicone rubber was chosen for the pill because it is the most proven of the materials in addition to being the easiest with which to work. The pills are encapsulated by dipping them into a solution in which silicone rubber is dispersed in cyclohexane. The cyclohexane then evaporates, allowing the silicone to polymerize. Three dippings are necessary to obtain the desired 0.5-mm coating for the ITMS pill.

SUMMARY AND FUTURE WORK

A rechargeable and commandable ingestible pill for measuring core body temperature was developed and successfully tested at APL. The pill uses magnetic induction for command and telemetry as well as for recharging. A follow-on program supported by NASA/

Goddard Space Flight Center is under way to design a pill that will measure pH, temperature, electrocardiogram, and pressure in one device. This device will likely require custom-integrated circuits as well as new packaging techniques to allow the sensing electrodes to lie on the surface without letting moisture into the package.

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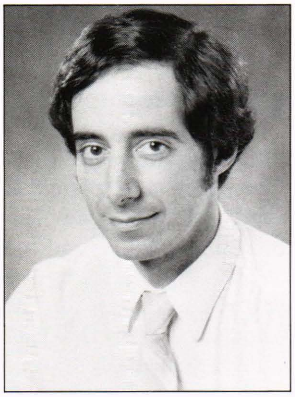

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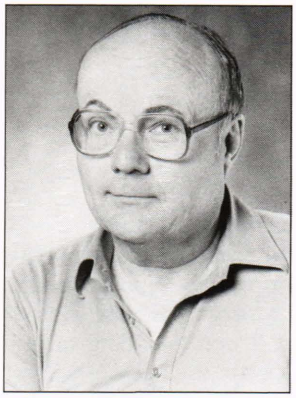

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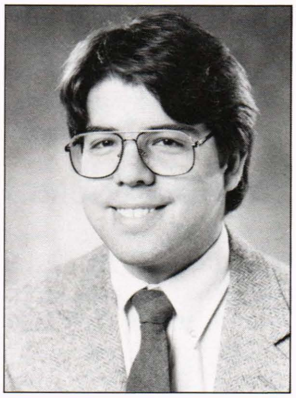

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