A LONG TERM REMOTE INTRAGASTRIC pH, TEMPERATURE, MOTILITY AND ELECTRICAL ACTIVITY MONITORING SYSTEM*

LESLIE WISE, M.D., PAUL W. JONES, B.S.E.E., G. J. WOMACK, M.D. and WALTER F. BALLINGER, M.D.
Department of Surgery, Washington University School of Medicine, St. Louis, Missouri and the Department of Aerospace Medicine, McDonnell Douglas Astronautics Company, St. Louis, Missouri.

SUMMARY The system under development can monitor intragastric physiological changes over time periods exceeding fourteen days. Prior to this development, long term intragastric measurements were impossible in freely mobile subjects.

The electronic instrumentation includes a tethered sensor capsule, automatic titration unit, telemetry system, and data display. The system requires minimal maintenance during the prolonged monitoring period. The sensor capsule utilizes a pH sensitive glass electrode with wet reference, a thermistor, a solid state pressure sensitive transducer, and impedance matching electronics which develop the physically related electrical signals. Signal acquisition is via tether hardline to the multichannel telemetry unit and subsequent RF transmission to a central data receiving system for display and storage. Automatic titration functions, a myograph to record voluntary muscle movement, and the measurement of skin resistance as an indicator of stress, may also be included in the telemetry data. Capsule system tests in vitro indicate these accuracies: ± 0.2 pH units over a range of 1 to 10 pH; ± 0.2°C over a temperature range of 25°C to 45°C; and ± 10% over a pressure range of 0 to 15 inches of water. Life tests of the capsule in vitro show useful life times of the order of 30 days. Preliminary human in vivo experiments have confirmed the capsule sensitivity and stability.

INTRODUCTION Monitoring of intragastric pressure and pH has been accomplished previously with the use of radio capsules in the stomach (1-12). In all these systems either the pH or the pressure, with temperature added in a few cases, was measured. None of these capsules was capable of monitoring pH and pressure simultaneously. Furthermore, in all of these systems the usefulness of the units for long term monitoring of ambulatory subjects was limited by at least one critical parameter such as transmission

* This work was supported by the National Aeronautics and Space Administration under Contract No. NSR-26-008-036.

range, lifetime stability, or accuracy. Our approach utilizes many of the advances made by Maycock and Jones (13), and incorporates additional improvements. The result is a multifunction capsule and supporting signal processing electronics system, which is ideally suited for our long term studies.

SYSTEM DESCRIPTION The system currently being evaluated is shown in Figure 1. The unique part of the system, the sensor capsule, contains a thermistor, pressure transducer and a pair of pH electrodes with associated preamplifier, encapsulated in materials with extremely low moisture absorption. Tethering the capsule allows long term monitoring and the use of an external power source and transmitter. The resulting lifetime and transmission range is limited only by the practical size of the external equipment. Signals representing pH, pressure, and temperature are transmitted via tether wires to the modulation unit where they are sampled and encoded along with input signals from the other sensors. The received pulse train is amplified and demodulated by the receiver; then the data is decoded and displayed. At this point instantaneous values of pH, pressure and temperature are displayed on readout units and if desired, recorded on magnetic tape or stripchart for permanent storage. Provisions have been made for activating an automatic titration unit from the signal conditioning unit at selected intervals. The activation time and the pump running time are included in the transmitted data.

Sensor Capsule The sensor capsule, shown in Figure 2, is capable of measuring pH in the range from pH 1 to pH 10 within an accuracy of ± 0.2 pH units, pressure from 0 to 15 inches of water within an accuracy of ± 10% and temperature from 25°C to 50°C within an accuracy of + 0.2°C. The internal construction of the capsule consists of two submodules encapsulated with polyethylene, beeswax and silicone rubber. The pH submodule is designed to provide a substantial barrier to moisture infiltration. The key to long life lies in the ability to maintain the integrity of all critical moisture seals. The pressure submodule includes a temperature transducer for pressure signal compensation. This submodule is also vented through the tether to provide improved performance and allow for in vivo calibration. The tether is a combined set of polyethylene and silastic tubes. The tubes contain the-power and signal wires, provide for flushing food particles and mucus from the pH electrode, provide-renting for the pressure transducer and provide a conduit for pumping alkaline solution into the stomach.

Data Acquisition System (DAS) The design goals for the DAS include portability, long life with minlIMUM maintenance, data continuity under reasonable ambulatory conditions and resolution compatible with the sensor system. Our early DAS included a two channel telemetry system using pulse rate and pulse width to carry the pH and pressure data respectively.

The expansion of the data requirements to include temperature, titration pump on-off status, movement and stress sensors, dictated a change to a multichannel system with capacity for expansion. Designs for an expanded channel capacity using either standard components or readily available integrated circuits have formerly been too costly in both power consumption and size. The key to the feasibility of a new design providing eight multiplexed digital data channels was the introduction of the new low power, high density COSIMOS series of integrated circuits by the RCA Corporation.

The current system uses a digital encoded pulse train to phase modulate the RF carrier. A block diagram of the instrumentation system is shown in Figure 3. The eight data input lines from the signal conditioner are selected by the multiplexer and presented to the analog to digital converter for digitizing. The digital signal then drives the phase encoder. The output of the phase encoder modulates the RF carrier as a function of the binary state of the date stream. The eight data channels are sampled at a one per second rate with an additional two slots reserved for word synchronization. The resulting frame rate is one per 10 seconds. The word is composed of 10 bits with two reserved for synchronization, one for parity and the remaining seven for data. All of the transmitter digital functions and logic control for deriving bit, word and frame rates, channel selection., analog to digital conversion and parallel to serial conversion, are implemented with the COS/MOS integrated circuits (IC). Total IC package count of 20 for the transmitter is comparable to that of about 25 for a system using the low power TTL integrated circuits. The power consumption, however, has been most significantly reduced to about 100 milliwatts as compared with nearly a watt for the best design using other techniques.

The heart of the demodulation portion of the DAS is the high frequency phase-lock loop and associated logic. An output from the loop provides the master clock drive and the pulse to pulse phase relationship. From these signals we derive the binary coded data and the drive for a low frequency bit synchronization loop. Subsequent processing of the data through the digital to analog converter and demultiplexer is of a routine nature.

The data from the output of the demultiplexer is presented in real time on a multichannel stripchart recorder or recorded on magnetic tape. Pressure, temperature, and pH are also shown on readout indicators with a one minute up-date display cycle.

Automatic Titration Unit The present operational philosophy for the automatic titration unit dictates that the alkaline supply pump be activated at periodic intervals, for example every two hours,. The pump will be deactivated by a signal from the pH signal conditioner when a predetermined pH level is reached in the capsule area. A closed loop electronic flow control provides sufficient regulation of the flow rate to allow the running time of the pump to be used to determine the quantity of alkaline solution infused. The parameters recorded during the automatic titration will permit the mathematical derivation of volumetric gastric acid data.

RESULTS Significant bioengineering advances have been made in this program. These include: extending capsule lifetime, in vivo calibration and completion of several in vivo experiments with both the hardwire and telemetry data acquisition system.

Capsule Lifetime The most significant achievement was the selection of encapsulants and the development of fabrication techniques which provide an extended operational capability. The test procedure was a continuous soak of the capsule. The static conditions were a solution buffered to pH 2 and 2 inches of water pressure. The capsule was periodically cycled through solutions ranging from pH 2 to pH 10, and pressures varying from 2 to 6 inches of water. Temperatures were varied over the design range. All parameters were within the tolerance ranges, except the pressure perturbations caused by changes in temperature. This problem has subsequently been significantly reduced by compensating with the output from the thermistor.

In Vivo Calibration Techniques have been developed to calibrate the pressure and pH transducers in vivo. These procedures provide periodic assurance of the system integrity.

In Vivo Experiments Nine human experiments have been performed since the program began. The significant results include a test of the automatic titration unit shown in Figure 4. The unit was set to cycle on at pH 2 and off at pH 6.5. Figure 5 shows the gastric pH changes during a four hour test on a normal healthy female subject. A hardwired DAS was used. This test demonstrated the effects of eating and drinking a variety of materials on the performance of the sensor capsule. The most serious problem encountered during these early tests was interference with pH electrode function by food particles trapped in the protective basket. A mechanical redesign of the capsule has eliminated this problem. Figure 6 is a segment of in-vivo data acquired with the combined pressure and pH sensors. The relationship is shown between stomach mixing and changes in pH near the capsule. It has been observed that a postprandial sample aspirated from an area only two inches away from the capsule pH electrode, will vary one pH unit or greater from that indicated by the capsule sensor. At the same timeY samples taken from the immediate area of the capsule typically have a value not varying over 0.2 pH units from that measured by the capsule.

In vivo tests using the hardwired DAS have been intentionally limited to four hour periods for subject considerations. These tests included one meal and minimum subject ambulation. The ambulation has been increased during the 12 hour tests with the two channel telemetry system. In this time span three meals were included with some normal activities, such as reading, walking, etc. Problems of correlating subject movement with pressure artifact still limit the freedom of the subject. The development of the multichannel digital telemetry link now provides us with the capability to increase data accumulated during these tests without requiring visual observation of the subject. This should allow the subjects substantial increase in freedom and comfort. The completed system will provide us with the means to accurately monitor under physiological conditions, gastric secretion and motility, as a function of various types of food, drugs, activity, diurnal cycle, stress and fatigue, in both normal subjects and also in patients with various gastric disorders.

REFERENCES.

1. Jacobson, B.: Endoradiosonde Techniques - A Survey. Medical Electronics and Biological Engineering. 1,165, 1963.
2. Farrar, J.T. and Bernstein, J.S.: Recording of Intraluminal Gastrointestinal Pressures by a Radiotelemetering Capsule. Gastroenterology, 35:603, 1958.
3. Farrar, J.T., Zworykin, V.K., and Baum, J.: Pressure-Sensitive Telemetering Capsule for Study of Gastrointestinal Motility. Science, 126:975, 1957.
4. Mackay, R.S.: Radio Telemetry from Inside the Body. New Scientist, 19:650, 1963.
5. Mackay, R.S., and Caceres, C.A.: Biomedical Telemetry. Academic Press, New York, 1965.
6. Russ, R.F., and Wolff, H.S.: Constructional Aspects of Radio Pills Suitable for Mass Production. Third International Conference on Medical Electronics, 27 July, 1960.
7. Watson, B.W., Ross, B. and Key, A.W.: Telemetering from Within the Body Using a Pressure Sensitive Radio Pill. Gut 3:181, 1962 pp.181-186.
8. Nagumo, J., et al.: Echo Capsule for Medical Use (A Batteryless Endoradiosonde). IRE BME-9, 195, 1962. Transactions on Biomedical Electronics.
9. Babskiy, Y.B. et al.: Radiotelemetric Investigation of the pH Content in the Alimentary Canal. NASA TTF-9026, 1964.
10. Kitagawa, Koji et al.: Radiotelemetry of the pH of the Gastrointestinal Tract by Glass Electrode. Gastroenterology 51:368, 1966.
11. Yarbrough, D.R. et al.: Evaluation of the Heidelberg pH capsule. Amer. J. Surg. 117:185, 1969.
12. Neely, J.: The Effects of Analgesic Drugs on Gastrointestinal Motility in Man. Brit. J. Surg, 56:925, 1969.
13. Maycock, B.F. and Jones, P. W.: Proc. Sixth Nat. Biomed. Sc. Instrument. Symp., 1968, Plenum Press, N.Y.

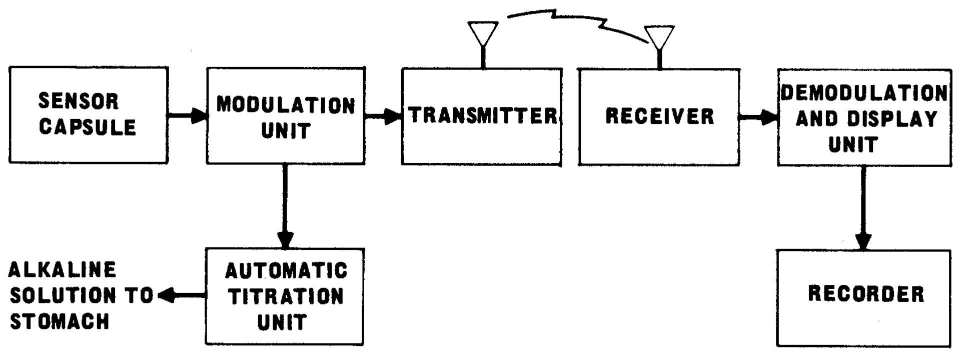

Figure 1. System Block Diagram

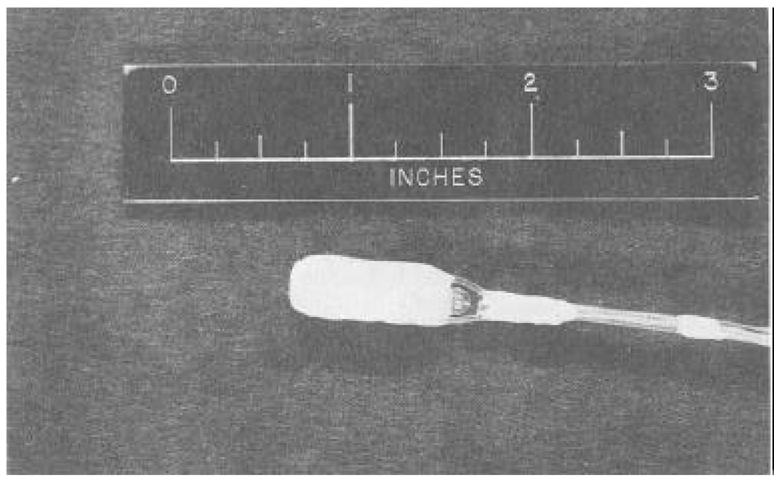

Figure 2. Sensor Capsule

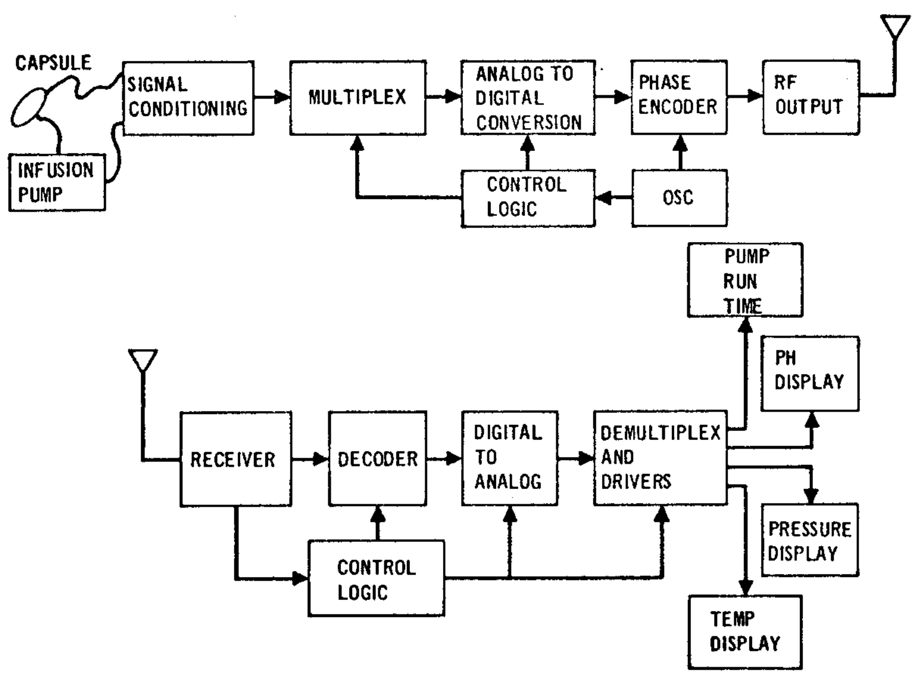

Figure 3. Instrumentation Function Block Diagram

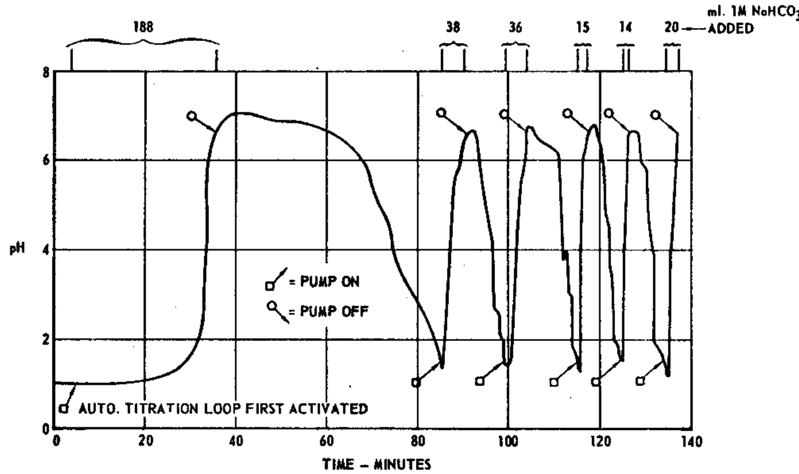

Figure 4. Automatic Titration Test Result

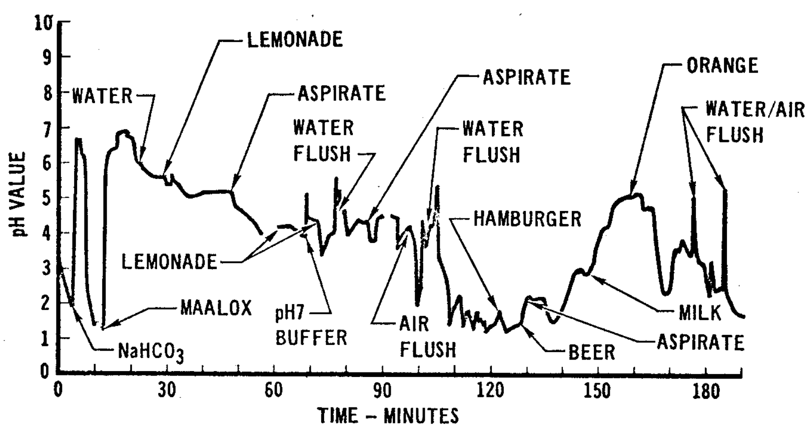

Figure 5. Segment of an In Vivo pH Test Result

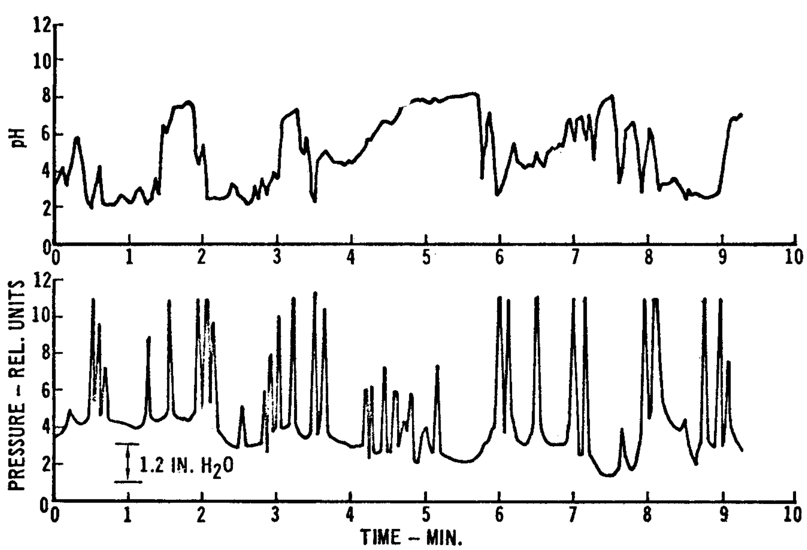

Figure 6. Segment of an In Vivo pH-Pressure Test Result