Insulin Delivery System

At right, Robert E. Fischell of The Johns Hopkins University Applied Physics Laboratory (APL) is seen holding a Programmable Implantable Medication System (PIMS) which, when implanted in the human body, delivers precise preprogrammed amounts of insulin over long periods of time. Fischell, a staff physicist and chief of technology transfer of APL's Space Department, headed the initial development of PIMS as a technology utilization project sponsored by Goddard Space Flight Center. MiniMed Technologies of Sylmar, California, licensee of the technology, has been refining the design of PIMS since the initial development at APL. The photo at right shows a closeup of the PIMS implantable pump and catheter.

PIMS is currently rounding out its second year of clinical trials as a human-implanted system, following five years of preclinical testing under the direction of Dr. Christopher D. Saudek, director of The Johns Hopkins Diabetes Center. PIMS is also undergoing trials at a second implant center, the University of California, Irvine. It is estimated that one million insulin-dependent diabetics in the United States will benefit from implantable infusion systems because they will not have to inject themselves daily with the pancreatic hormone.

Almost a decade in development, PIMS is an outstanding example of how space technology offers special utility in medical systems. PIMS employs several technologies derived from R&D work on NASA and military space systems, including a tiny, microminiaturized fluid control system initially used in life search experiments aboard two NASA Viking spacecraft that landed on Mars.

The Johns Hopkins Medical Institutions (JHMI) also collaborated with NASA and APL in the PIMS program. JHMI has teamed with APL since 1965 in a continuing effort to apply APL technology acquired in defense and space programs to the solution of biomedical problems.

Corporate participants in addition to Minimed Technologies include Wilson Greatbatch Company, Buffalo, New York, makers of the lithium battery; Hoechst-Roussel Pharmaceuticals, Somerville, New Jersey, which developed a special, highly concentrated type of insulin for PIMS; the Bio-medical Group of Parker-Hannifin Corporation, Irvine, California, producer of the key microminiaturized fluid control system and infusion pump; and Teledyne Microelectronics Division, Los Angeles, California, makers of the electronics.

The size of a hockey puck and encased in a titanium shell, PIMS holds about two and a half teaspoons of insulin at a programmed basal rate. If a change in measured blood sugar level dictates a different dose, the patient can vary the amount of insu-
lin delivered by holding a small radio transceiver over the implanted system and dialing in a specific program held in the PIMS computer memory. A miniature two-way communications system, based on the space technology of telemetry, sends signals from the implant with operating information such as insulin usage and pump performance. When an insulin refill is needed, about four times a year, it is accomplished without surgery by a special hypodermic needle.

In laboratory tests, the implant's lithium battery and micropower circuits have demonstrated a lifetime capability of more than five years; new batteries in development have potential for a 10-year lifetime.

The first PIMS unit was surgically implanted in the abdomen of F. Jackson Piotrow, a professor at American University, on November 10, 1986 at The Johns Hopkins Hospital, Baltimore, Maryland. At left, Piotrow is shown prior to the implantation with nurse Roslyn Polk (center) and Dr. Saudek. Since then there have been 17 additional implants.

The PIMS development program continues to inspire additional spinoff products for health care. MiniMed Technologies' work on PIMS led to development and manufacture of the MiniMed Implantable Pump system (below), a second generation implantable, programmable pump with physician and patient controllers which will be implanted beginning in late 1988. In addition, Parker Hannifin's Biomedical Group is producing an external delivery device; called the Parker Micro-pump, it is a pocket-sized micropump for infusion of chemotherapeutic, antibiotic and anti-pain medication.