New Microprocessor-Based Insulin Controller

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Abstract—We have previously defined the requirements of an elegant, simple waveform for intravenous insulin delivery in insulin-dependent diabetes [7]. This waveform consists of a constant basal rate and three sequential pulses which are adapted for each meal. Under the direction of a diabetologist, the basal rate is adjusted for fasting normal blood glucose levels, and the meal pulses are configured according to two parameters per pulse (flow rate and time duration) so that blood glucose after the meal is also normalized. We here describe a new microprocessor-based insulin controller which exploits this knowledge.

The device incorporates a complementary metal oxide semiconductor (CMOS) microprocessor which operates on a wake-up cycle every 2.86 ms. To drive the insulin pump, it generates a 1.37 Hz pulsewidth-modulated output signal, the on-time of which is varied according to an 8 bit word. Filtering of this pulse with a CMOS operational amplifier and 1.5x dc driver provides motor voltages linearly variable from 0 to 7.5 V in 29.41 mV increments.

Output current to the motor is monitored, and the device signals overcurrent and undercurrent according to a linear threshold dependent on output voltage. The total device current is 2.5 mA, excluding motor current drain. Power is provided from seven rechargeable nickel-cadmium cells, rated at 0.5 AH. The total weight of the controller is 475 g. The motor current is 3-20 mA, and the rotation rate is linearly related to applied voltage from 0.3 to 7.5 V. In conclusion, this external insulin controller is simple to program and simple to operate, yet provides enormous flexibility to the diabetic in terms of meal selection, exercise accommodation, and inherent safety. These features are a direct benefit of the recent availability of CMOS microprocessor and electrically programmable read-only memory chips. This device is a unique research tool. Its clinical application is generating important data on the response to physiologic insulin infusions in diabetic patients. Such new knowledge will pave the way to an implantable device.

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INTRODUCTION

INSULIN is the main anabolic hormone of the body. Appropriate insulin release in the healthy organism is capable of accommodating in its entirety all of the metabolic adaptations needed for feasting or fasting. In the absence of adequate insulin, body tissues (muscle and fat, in particular) are broken down and some of their products are converted into blood sugar. Such excess sugar is lost via the urine, and thus improperly metabolized, while excess fat released from peripheral adipose tissue contributes to acetone formation in the liver until life-threatening ketoacidosis prevails. The process of body wasting will continue until death. Exogenous insulin replacement, even by the simple expedient of one subcutaneous injection a day, will restore a sufficient amount of insulin to prevent this wasting of body protein and minimize the loss of glucose in the urine, while simultaneously promoting the storage of fat and the building of muscle.

Unfortunately, insulin replacement by a single injection a day under the skin fails to simulate the normal release of the hormone from the pancreas in keeping with the metabolic challenges of meals, fasting, and exercise. As a result, the metabolism of the diabetic individual is discordant with the hormonal milieu, and fuel is frequently released when it should be stored and stored when it should be released. It is plausible, but not proven, that this asynchrony of anabolism and catabolism and the production of high circulating levels of precursors of various protein, fat, and carbohydrate moieties results in their inappropriate deposition in nerves and blood vessels, and therefore may account for the long-term debilitating consequences of the disease. In an attempt to avert these complications, the artificial endocrine pancreas has as its goal the more effective distribution of insulin so that the benefits of a closer approximation to normal metabolism can accrue on

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a daily basis. If such a device can be realized and effectively used in the treatment of diabetes mellitus, it is anticipated that the long-term complications of the disease will be significantly reduced, if not completely prevented.

The requirements for intravenous insulin replacement in diabetes have been studied in depth in both man and animals [1]-[6]. In addition to a background or basal rate of insulin infusion, delivery of the hormone must be accelerated at meal time to accommodate nutrient intake according to the size and caloric distribution of the meal. This can be done in man with a simple, yet elegant three-pulse waveform [7]. Physical exercise during the meal absorption period allows meal insulin requirements to be reduced [8].

In this paper, we describe the design details and characteristics of a new microprocessor-based insulin flow rate controller incorporating these features. It uses only newly available CMOS chips, consumes a minimum amount of energy, and is portable.

Materials

The flow rate controller is shown in Fig. 1. It is provided with a pushbutton for each of "breakfast," "lunch," "dinner," "snack" and three size selections ("large," "regular," small"). When the patient is about to eat, he actuates in sequence the appropriate size and meal buttons, and the pump then operates at the prescribed elevated speeds corresponding to that meal until the enhanced meal infusion is complete, at which point it automatically reverts to the basal rate. If the patient is about to undertake significant exercise while a meal infusion is in progress, he may actuate the "exercise" button, which reduces the infusion to basal rate until a "stop exercise" button is depressed, returning the infusion to the point in the schedule that it would have reached if there had been no interruption [8]. A light-emitting diode adjacent to each button indicates on demand the current infusion status.

The controller is provided with alarms to indicate open-circuit, short-circuit, and overload conditions. In addition to the conservative failsafe design, the patient is instructed to activate at bedtime a "day-night" switch to protect against the very remote possibility of catastrophic malfunction resulting in a runaway pump during sleep, when he is most vulnerable. In the "night" position, there is insufficient energy available for a runaway failure to be catastrophic.

A flow diagram of the microprocessor-based insulin flow rate controller is shown in Fig. 2. The microprocessor is a CMOS single chip device (MC146805E2, Motorola, Austin, TX) operated from a crystal clock at a frequency of 3.579 MHz and connected to either a 512 or 1024 byte EPROM memory chip (IM6654 or IM6658, Intersil, Cupertino, CA) which contains the programming instructions for the controller. Parameters for a given patient's insulin profile are transmitted to the random access memory (RAM) in the microprocessor using a two-way link to a programming terminal consisting of a modified hand-held calculator (HP4ICV, Hewlett-Packard, Corvallis, OR). Verification is returned via a modified optical reading wand (HP82153A, Hewlett-Packard, Corvallis, OR). When the programming calculator is disconnected, the microprocessor is activated as required by the patient via the pushbuttons whose

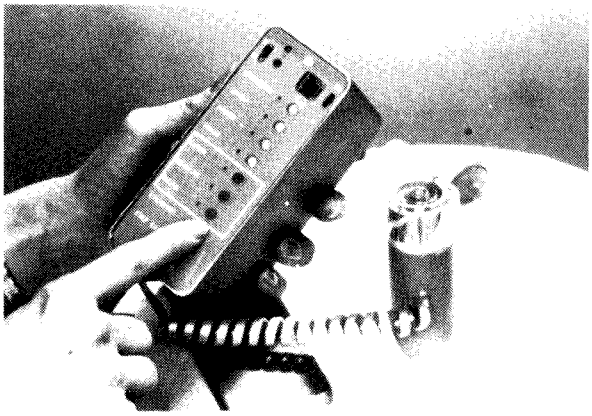

Fig. 1. Insulin flow rate controller device weighs 475 g, includes rechargeable batteries and a CMOS microprocessor, and EPROM memory chips. Patient activates the device at meal or exercise times using the pushbuttons shown. The device controls insulin infusion directly into a vein on a minute-by-minute basis, and can be programmed by a diabetologist to normalize the blood sugar of Type I diabetics. The miniature peristaltic pump and silicone rubber insulin reservoir have been previously described [11].

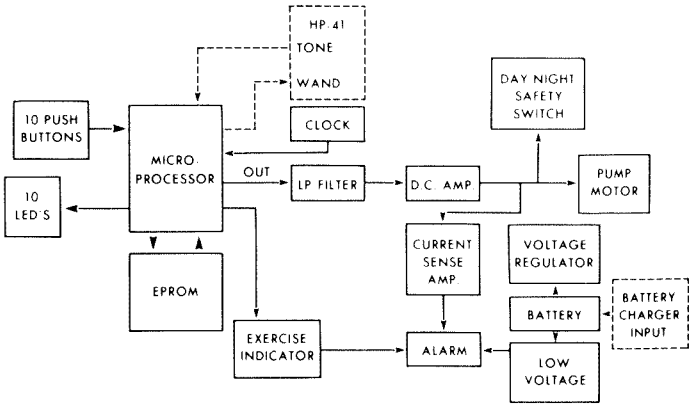

Fig. 2. Schematic flow diagram of CMOS microprocessor and CMOS EPROM-based insulin flow rate controller. Broken lines outline the information flow paths between the controller and the HP41CV hand-held calculator. The latter is the programming terminal used by the diabetologist.

status are indicated by their corresponding light-emitting diodes (LED's). In the "exercise" mode of operation, the microprocessor briefly actuates the alarm every 60 s as a reminder to the user of this condition.

The main output from the microprocessor is a software-defined pulsewidth-modulated binary signal which is fed to a low-pass filter. The resulting analog voltage is amplified and used to drive the pump motor over the range of 0.3-7.5 V dc. Concurrently, output current to the motor is monitored for either overcurrent, short-circuit, undercurrent, or open-circuit conditions. Any of these actuates an alarm, but only the overcurrent or short-circuit conditions result in output voltage foldback.

Power for the motor drive circuit is not regulated, and is derived directly from seven rechargeable nickel-cadmium batteries (VR.5AA, Saft Batteries Ltd., Scarborough, Ont., Canada), while power for the microprocessor is regulated to 5.04 V. Total dc current drain is 3-20 mA for the motor (depend-

ing on its applied voltage), 0.1 mA for the voltage regulator, and typically 2.4 mA for the microprocessor, but excluding current for the LED indicators. When these are interrogated by the patient, the dc current drain increases by 1.5 mA only, due to their pulsed mode of operation. A low voltage condition due to the failure or premature discharge of any one or more batteries is detected and the alarm is activated well before inadequate operating voltage is available to the microprocessor. Internal battery power is adequate for about two days of operation. The batteries must thus be recharged on a daily basis while a second identical device is used by the patient. Thus, each patient must have two of the flow rate controller devices shown in Fig. 1.

The day-night safety switch limits output voltage simply by placing a power diode directly across the motor voltage terminals. In this way, any output condition greater than about 0.55 V activates the overcurrent detection circuits and sounds the alarm, while clamping the voltage to this value.

METHODS

In the following subsections, we describe the strategy used in selecting a suitable microprocessor, the simple method for motor voltage control using a software digital-to-analog converter, the details of the motor drive circuitry including the overcurrent/undercurrent detection circuits, the battery failure detection circuit, and the interfacing with the hand-held programming terminal.

Selection of Available Microprocessors

A complementary metal oxide semiconductor (CMOS)-type microprocessor having low energy consumption and sufficient power to efficiently perform the required tasks was sought. Two suitable devices were becoming available at that time, the Intel 80C35 series and the Motorola MC146805E2. Both are "single chip" designs (with CPU, RAM, and I/O on one dice) capable of being operated with external program ROM during the design and debug phases. In high volume production, they are inexpensive due to their lack of architectural sophistication (with consequent enhanced device reliability).

Only the MC146805E2 has low power consumption (4 mA at full speed operation), provided low clock frequencies are used. However, both have power-down modes where the processor consumes little power (0.6 mA), "waking up" only to service interrupts. The internal timer, which runs even though the CPU is "asleep," keeps track of the system task interval and energizes the CPU when it is necessary to perform further scheduling.

Although we had some previous design experience with the 80C35 as a portable infusion controller [9], the MC146805 was chosen primarily because of its symmetrical addressing structure (on most of the common instructions). This reduces the possibility that software "bugs" will remain hidden in the program beyond the initial design phase of the project. Furthermore, there had been one electronic failure during clinical tests with the 80C35 infuser, apparently due to the complex interrupt handling procedures of that CPU. This failure mode was sufficiently complex to defy simulation in the lab and was never really identified.

The 80C35 has only eight general-purpose registers accessible via the direct addressing mode. All other RAM's are accessed indirectly with the pointer registers $R0$, $R1$. Thus, a program can only access six general-purpose registers (other than $R0$, $R1$) without destroying the previous contents of $R0$, $R1$. When an 80C35 interrupt occurs, it is usually necessary to switch register banks as most or all of those six available registers will be used by the main program. With the alternate register bank selected, a new set of eight registers becomes available, but it is the responsibility of the programmer to switch back to the main bank before returning from the interrupt. This structure severely limits the utility of the RAM provided in the 80C35. The more RAM that is used, the greater the chance that the programmer will lose track of register allocation and overwrite wanted data.

The MC146805 has direct addressing capability for page 0 (the first 256 memory locations), although only 112 bytes of RAM are provided internally in the processor. The stack takes some of these (building downwards from the top). Nevertheless, a contiguous addressed RAM block is available starting at 10H and extending to 80H, which can be accessed with both the direct and indirect addressing modes. This enhances a programmer's ability to write reliable interrupt-driven code. The only conflict to be resolved when using maximal RAM is the number of bytes used by the stack.

One disadvantage of the MC146805 was that the manufacturer did not adequately support it (at that time) with development tools. Consequently, an in-circuit emulator (ICE) was designed and constructed [10]. This provided the capability to download a newly assembled program into RAM and execute it with breakpoints and register display. An assembler (written in Fortran) was purchased and commissioned. This was hosted on a Z80-based CP/M® system (DPS-1, Ithaca Intersystems, Ithaca, NY) with two 8 inch floppy disk drives (DT/8, QUME, San Jose, CA).

The MC146805 assembly code was written on the host using a video editor, assembled, and the hexadecimal code file down loaded serially to the emulator. The emulator control program placed the hex into the appropriate RAM locations for the ICE MC146805 to execute. The program execution could then be carefully traced and debugged before the CMOS EPROM was programmed (by the emulator). This EPROM was then transferred to the controller hardware for final testing.

Digital-to-Analog Conversion

The infusion pump motor speed was determined by a variable voltage (0-5.00 V dc) applied to its control electronics. The simplest way to achieve this would have been to use a digital-to-analog converter (DAC). However, a method was devised for achieving this function with software. It required only a low-pass filter (LPF) external to the microprocessor. The total power consumption and chip count of the circuitry was thus reduced. The technique, using pulse width modulation, is generally applicable, and will thus be examined in greater detail as follows.

The microprocessor is operated from a 3.57 MHz quartz crystal, yielding a machine cycle time of 1.40 μs. It has an internal timer which is programmed to provide an interrupt

every 128 cycles (179 μs) while an infusion is in progress. Whenever this interrupt occurs, an 8 bit register is incremented (cycling in value from 0 to 255 to 0 to 255, etc.) and the new value is compared to that in the dosage register (also a value from 0 to 255). Whenever the cycling counter is less than (unsigned 8 bit comparison) the value in the dosage register, the PWM output line is asserted true (+5 V); otherwise, it is reset (0 V). The second-order CMOS low-pass filter has a cutoff frequency of approximately 2 Hz, which is sufficiently low to make the (179 μs $\times$ 256 = 45.8 ms) ripple component negligibly small.

DC Motor Drive Circuitry

Rather than an operational amplifier, a comparator was used in the motor drive control circuit because it has very high gain and reasonably wide bandwidth. Also, the chip can be operated from a single voltage supply and draws a total quiescent current of only 200 μA/unit. Further, in this regard, the LM139 series (National Semiconductor, Santa Clara, CA) consists of four independent voltage comparators in one package. One of them (D) is used in conjunction with an output p-n-p transistor to drive the pump as shown in Fig. 3. In operation, the output of comparator D supplies the base of transistors $Q2$ and $Q3$. A capacitor $C1$ is used to filter the output. Motor voltage is 1.50 times the input from the low-pass filter (LPF), this being defined by voltage feedback resistors $R3$, $R4$ (1 percent). Because of the high loop gain inherent in a comparator, excellent regulation against load variation is achieved.

Overcurrent Detecting Circuits

The circuit in Fig. 3 is designed to detect both overcurrent and undercurrent conditions. Transistor $Q3$, which operates in parallel with motor driver transistor $Q2$, essentially senses the motor current and generates an output voltage $V2$ proportional to the instantaneous motor current.

If $R6 = R7$ and $\Delta VBE = VE2 - VE3$, then

$$V2 = IM \times R5 + \Delta VBE \tag{1}$$

where IM is the motor current and VM is the motor voltage.

Comparator C is used to compare $V2$ to $V1$ and detect the condition $V2 > V1$, the motor overcurrent (or output short-circuit condition). Under these conditions, comparator C sounds the alarm, and via $Q1$, clamps the noninverting input to D to V^+. Since $V^+ > 5.0$ V (the maximum output voltage from LPF), comparator D shuts off $Q2$, protecting the driving transistor from overload and making $VM = 0$. Automatic recovery for the circuit occurs when $VM = 0$ because IM goes to zero, which permits the output current to flow again. The circuit repeats the above behavior if the overcurrent condition persists. A linear threshold dependent on VM is established by this circuit, as shown in Fig. 4.

Undercurrent Detecting Circuit

When IM reaches a previously defined small value, comparator A activates the alarm to indicate that the load current is unduly small, perhaps due to disconnection of the pump from the controller. Comparator A activates the alarm if $V3 > V2$. Again, a linear threshold relationship between undercurrent and motor voltage is established, as shown in Fig. 4.

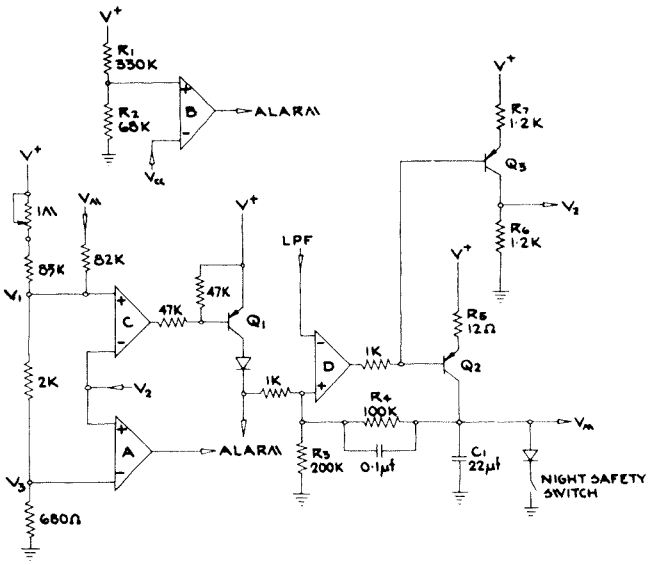

Fig. 3. Salient circuit elements of the dc motor drive, overcurrent, and undercurrent detectors used in the microprocessor-based insulin pump controller.

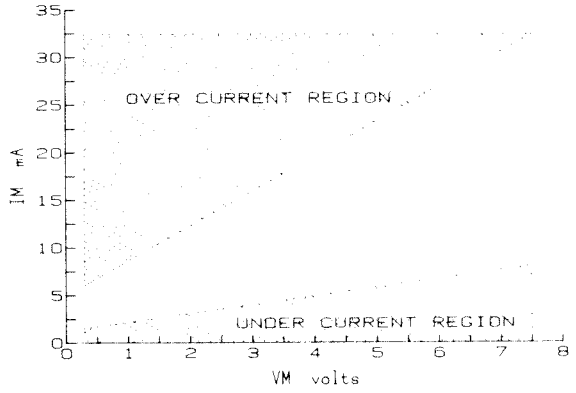

Fig. 4. Alarm thresholds established by the circuit in Fig. 3. When motor current IM exceeds the threshold at the boundary between the operating region and the overcurrent region (stippled area), both an alarm is sounded and the voltage VM is folded back, thus protecting the motor drive circuitry against overcurrent or short circuit. When the motor current is less than the linear threshold between the operating region and the undercurrent region (lower stippled area), only an alarm is sounded, indicating motor failure or open circuit. Motor operating voltage is from 0.3 to 7.5 V.

The region between the undercurrent zone and the overcurrent zone is the acceptable operating range. This was chosen to accommodate the range of motor characteristics usually encountered (see Fig. 5). Twenty motors were so characterized, and the thresholds of overcurrent and undercurrent were defined to accommodate the worst case characteristics.

Low Voltage Detecting Circuit

Comparator B (Fig. 3) is used to detect battery failure in the power supply. The (-) input of the comparator is taken from

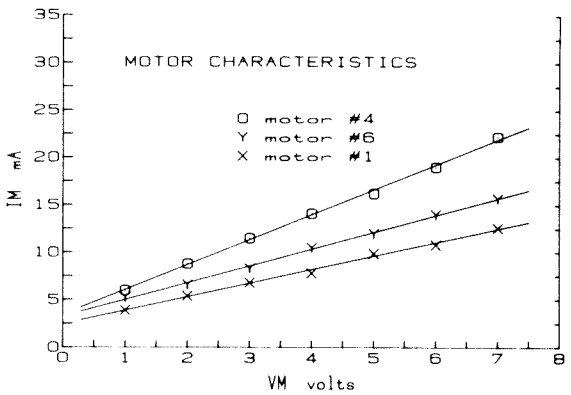

Fig. 5. Motor characteristics showing armature current *IM* as a function of applied voltage *VM*. Of 20 motors, the characteristics of 3 are shown, spanning the ranges observed. Note the linear relationship between *IM* and *VM*. Overcurrent and undercurrent thresholds shown in Fig. 4 were based on these data.

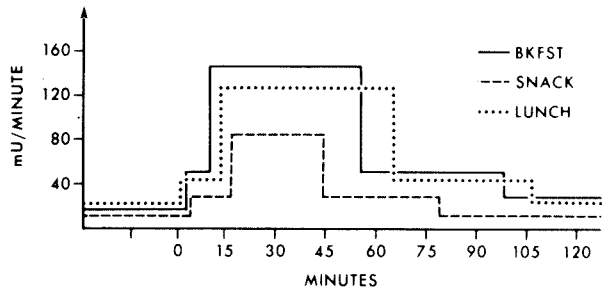

Fig. 6. Three-pulse insulin infusion waveform found suitable for normalizing blood sugar excursions after meals [7]. Typical waveforms for breakfast, snack, and lunch are shown. The parameters (rate, duration) of each pulse are programmed into the microprocessor-based flow rate controller by the diabetologist using the programming terminal as shown in Fig. 7.

Fig. 7. New microprocessor-based insulin controller and physician programming terminal. Patient parameters are stored on magnetic cards.

VCC, which is equal to 5.04 V and is constant because it is derived from the voltage regulator elsewhere in the circuit. The rechargeable batteries used can be completely discharged to zero output voltage. They can also be inverted if over discharged. With seven batteries, V^+ is 7 X 1.24 V or 8.68 V. *R*1 and *R*2 were selected so that the comparator would detect the total discharge, failure, or inversion of one or more batteries. When this happens, comparator *B* activates the alarm.

Programming Terminal

Once the diabetologist has estimated the patient's insulin requirements for basal and meal infusion, and has decided on the amplitude in mU/min and duration in minutes of the three possible postprandial pulses for each meal (typical examples of which are shown in Fig. 6), the information is keyed into the HP41CV programmable hand-held calculator equipped with a magnetic card reader (HP821041, Hewlett-Packard, Corvallis, OR) and a peripheral printer (HP82143A, Hewlett-Packard, Corvallis, OR) (see Fig. 7). Other essential information includes only the concentration of the insulin solution in U/ml, the flow rate of the pump in μl/min at a given voltage, and the scaling factors for the large and small meals in percent (range 0-200), relative to the regular meal taken to be 100 percent. These scaling factors apply to the time and duration parameters of the second and third pulses, but not the first of each meal profile. The calculator is used to prompt data from the physician, process them to hexadecimal form, send them to the MC146805, receive back diagnostic data, process and print them, and store the patient data on its magnetic card reader.

No suitable hardware interface to the HP41CV was then available, so novel means for transmitting and receiving the information were devised. The only wire leads available for modification on the calculator PC board were those leading to the tone generator. External access to the tone generator circuit was established through unused battery-charging contacts, and the tone functions of the calculator were then used to transmit the insulin profile data in octal form. In this regard, the HP41CV tone function has a selectable frequency with fixed duration. Tone 9 has a frequency of approximately 1200 Hz, while that of Tone 6 is about 600 Hz. Data are therefore transmitted to the infuser in binary form by frequency shift keying (FSK). Although it is very slow (fewer than 10 bits/s, limited by the HP41CV), it has proven reliable and effective. Data transmission from the HP41CV to the MC146805 takes 5 min.

Data are returned to the HP41CV via its bar code reading wand. The MC146805 is programmed to generate bar code data sequences in the form recognized by the HP41CV. Initially, data were returned by flashing an infrared light-emitting diode, but later a direct connection to the bar wand electronics module was used to bypass the LED. Data transfer via the wand is fast, typically taking less than 1 s. The binary data are sent to the wand bit serially, with a narrow gap signifying a binary 0 and a wide gap a binary 1. Details of the format for the data exchange can be found in Table I. Full handshaking is used in the data transfer to synchronize the MC146805 with the much slower HP41CV which emits a "beep" after it has accepted valid data from the wand. This is ignored by the MC146805. The HP41CV software then checks that the data values returned from the MC146805 are the same as those it

TABLE I
DATA FORMAT USED TO COMMUNICATE WITH THE HP41CV BAR CODE READER

Preamble: Gap, Narrow Bar, Space, Narrow Bar, Space
Data Field: Narrow Bar for logical 0, Wide Bar for logical 1
Postamble: Space, Wide Bar, Space, Narrow Bar, Gap

where
Gap is a 46 ms pulse
Narrow Gap is a 5.4 ms delay
Wide Gap is a 10.8 ms delay
Space is a 5.4 ms interbit space pulse
Narrow Bar is a 5.4 ms pulse

previously sent. It then generates a Tone 6 or else a Tone 9 "beep" for the handshake. The tone decoding software in the MC146805 is used to distinguish the return status. If any of the data values echoed by the MC146805 do not match those transmitted to it, then the entire data transfer must be restarted manually (when the HP41CV returns an error status tone); otherwise, it proceeds to completion. Both of these interfaces require no hardware in the controller in addition to the use of two of the 16 available I/O pins.

DISCUSSION

Successful control of diabetes mellitus depends on a balance of many factors. Of primary importance among these are the energy supply or food intake, the energy expenditure or level of activity, and the effective storage of energy or its utilization at the cellular level. It is only the latter which is dependent on insulin, but insulin requirements depend on the first two. Therefore, new methods of insulin administration should not only be able to finely control the rate of delivery of the hormone, but should also be capable of accommodating changes in the other major components. Thus, the new microprocessor-based flow rate controller described in this paper can elegantly accommodate meals of varying size and composition, as well as physical exercise occurring either in the fasting state or shortly after meal ingestion.

In order for such an electromechanical drug delivery device to be clinically acceptable as well as effective, it must satisfy several strict requirements including reliability, programmability, simplicity, durability, and safety. The present model flow rate controller has to date been used on eight patients, each for 18-60 days. The simplicity of its operation was demonstrated by the fact that activation of a meal cycle required no extra tools once the meal and its size were determined. Also, the last meal profile activated could always be identified by the indicating LED's, a useful feature with forgetful patients. The controller was routinely replaced once daily with a similar unit which had been fully charged over the previous 24 h. Dropping the instrument accidentally on a terrazo floor did not result in malfunction or failure and attested to its durability, although more rigorous tests in this regard were not done.

The safety alarms incorporated in the unit proved effective. Accidental disconnection of the controller from the pump on several occasions was detected and signaled appropriately by the undercurrent detecting circuit. As well, a motor failure was signaled by the overcurrent detecting circuit. One of the major safety concerns with such devices is its ability to prevent increased voltage output resulting in increased insulin infusion and subsequent dangerously low blood sugar levels, especially at night. The simply activated day-night switch which limits voltage output would prevent and signal any accidental activation of a meal profile and many, if not all, single failures in the electronics which would result in a runaway situation.

The reliability of the unit was greatly enhanced by the fact that no manual switches, potentiometers, or other wiping contacts were involved in setting the amplitude or duration parameters of the basal and meal infusion rates or the time durations of the latter. The programmability of the unit using the simple hand-held terminal proved to be elegant, both in its flexibility and simplicity. Although the time involved in defining the diurnal profile and transmitting it from the programming terminal to the controller was rather long initially (10 min), once the patient's requirements were determined, small changes to the profile took shorter times (5 min) and were done less than once per day. The permanent printout of all the information transmitted and the read-back nature of the program contributed significantly to the physician's confidence in the unit. Any discrepancies between the desired data and those recorded in the memory of the controller were immediately detected and signaled. In well over a year of use with ten such units, no failures of any sort have occurred.

Patient acceptance was high. All were enthusiastic about participation in the research protocols of which this controller was an essential component. Training time to operate the device was trivial, and the patients all felt physically and mentally well once insulin requirements were established so that normal blood sugar levels prevailed and neither abnormally high nor low blood sugar levels were encountered. The major shortcoming of the controller was a lack of audible verification that the device had been activated. As a consequence, several patients forgot to activate the controller at meal time. As a result, the CMOS chip was reprogrammed to include a subroutine that briefly sounded the alarm to signal the meal cycle activated, and patients are now instructed not to eat until they hear the beep!

For reasons of size, cost, and availability, a 3.58 MHz colorburst-type crystal was used, but the microprocessor was programmed to operate predominantly in a wait mode where current drain is only 1.9 mA due to the high speed of operation of the clock. Upon awakening, however, full speed operation with a machine cycle time of 1.40 μs ensured that necessary tasks and computations were rapidly completed. The average dc current drain of the microprocessor, its voltage regulator, the A-D conversion, and the low-pass filter totaled only 2.5 mA. This was less than the power drawn by the motor at its lowest operating voltage. Clearly, this system has not been optimized with respect to the current drain in light of the inherent capabilities of CMOS microprocessor technology in this regard. However, should extended operation without recharging be required at some future date, then it is a simple matter to change the clock frequency by substituting a lower fre-

quency crystal and modifying the software. Current drain in this device is virtually proportional to clock frequency.

In conclusion, this external insulin controller is simple to program and simple to operate, yet provides enormous flexibility to the diabetic in terms of meal selection, exercise accommodation, and inherent safety. These features are a direct benefit of the recent availability of CMOS microprocessor and electrically programmable read-only memory chips. This device is a unique research tool. Its clinical application has generated important data on the response to physiologic insulin infusions in diabetic patients and new knowledge which will pave the way to more sophisticated implantable devices.

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