A NEW MULTIPLEXED STIMULATOR FOR FNS

Donaldson N. de N.

M.R.C. Neurological Prostheses Unit, London, ENGLAND.

ABSTRACT

A new inductively-powered stimulator for FNS has been designed which has 32 outputs and is intended for exciting electrodes with access resistances of about 220 . The chief objective of the design was to allow a wide range of transmitter coil position while retaining the highest possible efficiency. Several novel methods have been employed in the design: these are briefly described and justified. An outline of the electrical design of the stimulator is presented; also the architecture of the FNS control systems of which it will be part.

KEY WORDS: Implantable stimulator, Logarithmic coding, Handshaking, Humidity monitoring, Coupling compensation.

1. INTRODUCTION

In the MRC Neurological Prostheses Unit, we have been working on the restoration of motor function by FNS since 1977. The first devices used arrays of 5 or 6 receivers [1] and the results were so encouraging that the development of multiplexed stimulators began in 1979. The Mark I was implanted in 1981 but after three implantations, fractures of wires occurred in two of the devices. The design was improved to prevent this type of failure [2] and since 1983, Mark II devices [3] have been implanted for breathing, in a C2 SCI patient with a damaged phrenic nerve [4], for grasp in a C7 tetraplegic, and for standing and walking in several paraplegics. Infection of the implants has been a problem with the paraplegics despite the use of methods similar to those used with Sacral Anterior Root Stimulators [5,6]. Electrodes and cables have broken. D.N. Rushton has presented a new method which may ease these difficulties [7]. No implanted stimulator has yet failed.

The Marks I and II multiplexed stimulator have a shortcoming which was apparent long ago: that position tolerance of the transmitter coil was small [8]. Lateral movements of only 12 mm in the worst direction, caused the stimulator to cut off. As the stimulator is sited over the lower ribs, it is difficult to maintain the transmitter in position this accurately, particularly on a fat subject, trying to stand up. These devices used two inductive links with morphognostic coils [9] to reduce cross-talk. The position tolerance is poor because the coupling coefficient between the "Figure-8" coils falls

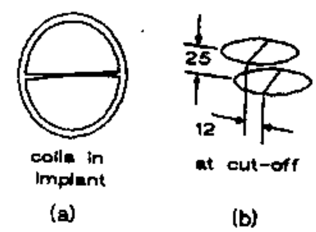


Figure 1.

rapidly with sideways movement. In these designs, one receiver supplied the power to the implant and synchronised the demultiplexor, while the other carried the trains of stimulating pulses. This division of the energy transfer for the two destinations meant that designing so that the deviser was energy-efficient was largely a matter of the design of the inductive links [8].

The position tolerance could only be substantially improved, given the diameter of the implant, and therefore the receiving coil(s), by jettisoning the "Figure-8" coil, and sending all the energy and the signal via one pair of circular coils. The chief design challenge was then how to utilise a single inductive link in such a way that accurate stimuli could be delivered over a wide range of coupling coefficient (coil position) with reasonable efficiency. Efficiency is important because the access resistance of our electrodes in typically no more than about 220 Ω *in vivo*. Many authors have addressed the subject of inductive links, in steady state, supplying power to a fixed load resistance [8,10,11, 12] but there is little in the literature on how best to obtain a stabilised voltage within the implant as the coupling changes, or how the signal should be modulated on the carrier, given that the carrier must also deliver all the energy to the device. As an example of a design which seems strange in this respect, Smith *et al.* [13] define their

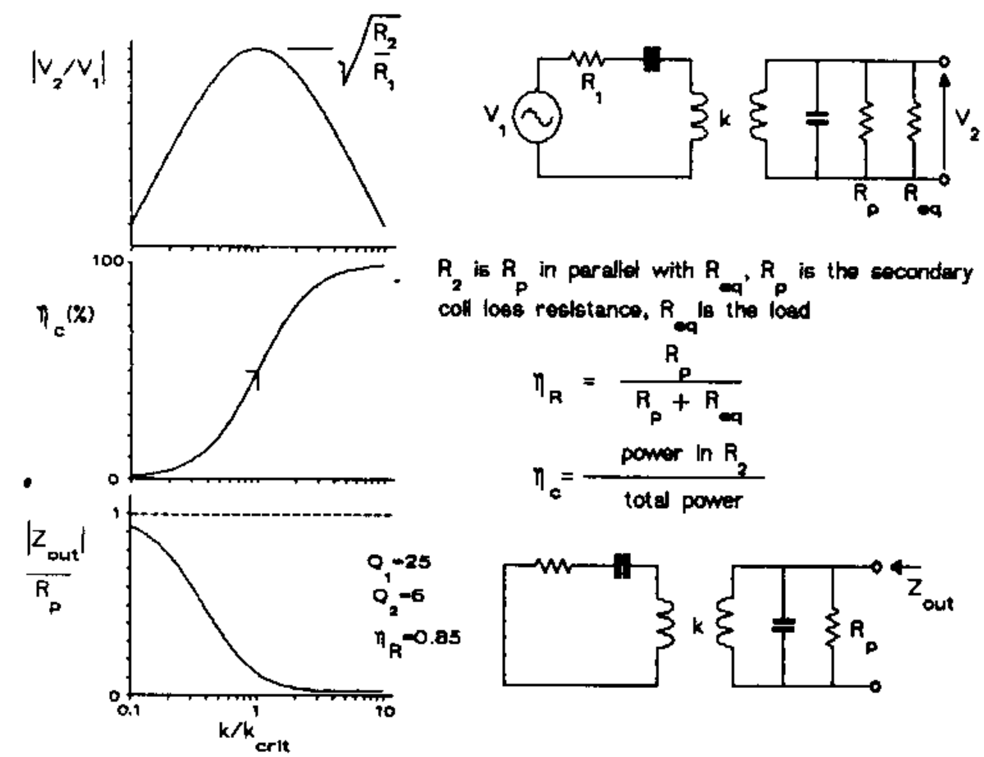


Figure 2. Brief summary of inductive coupling.

pulse lengths by an interval in the carrier, so that the command to expend more energy in a longer pulse, itself reduces the time that the inductive link can convey energy.

Taking these matters into consideration, I have designed a Mark III stimulator which is outlined at the end of this paper. Five aspects of the design are considered in the following sections. The design of the inductive link is not discussed but Figure 2 presents some of the relevant facts.

2. STIMULATOR OUTPUTS

Most designs of implantable stimulator use blocking capacitors in series with the electrodes [13,14]. Several reasons have been given for this; one is that the capacitor will prevent net charge transfer and will therefore reverse electrochemical changes at the tissue interface. Brummer & Turner [15] argued that this was not necessarily true. However of the capacitor will maximise the charge which can be passed per stimulus pulse before gas evolution [16]. A separate reason is the capacitor prevents direct current flowing through the electrodes if a fault occurs in the stimulator. Referring to Figure 3, direct current will flow through the electrodes if the transistor breaks down (short-circuit) or if the circuits which drive the transistor base fail so that the transistor is held "on". The presence of a capacitor in the position shown will limit the charge to CV. Unfortunately, this measure can not be guaranteed to work. The implanted device is under attack be water which, if it penetrates an "hermetic" enclosure, is likely to let metal dendrites grow in the electric fields across insulators between adjacent conductors [17]. Conducting bridges may then form across the switch transistor or across the blocking capacitor.

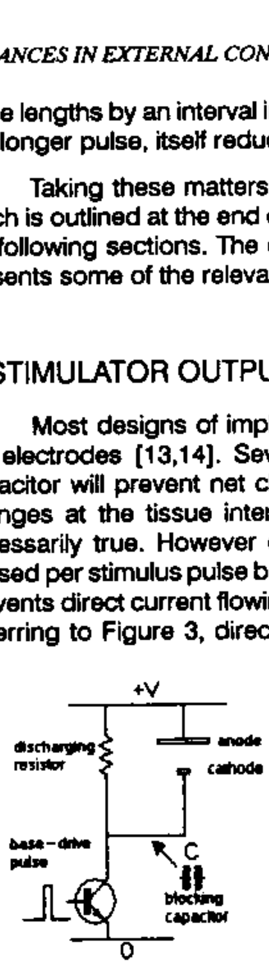


Figure 3.

The Mark II stimulator had no blocking capacitors because the volume of 24 of them would have been to great. The capacitance of the Pt/tissue interface was relied upon the balance the charge. Stimulation thresholds have not been closely monitored but we have not noticed rises after periods of use, as would be expected if the electrodes were evolving toxic products. The Mark III uses a commercial multiplexer chip [18] with 32 outputs; again, lack of space prohibits the use of blocking capacitors if all these outputs are to be employed. On the other hand, monitoring the humidity inside the "hermetic" enclosures requires little space using hygrometric chips [19] but a method is required to relay the signals from the implant. If humidifies are observed to rise beyond a safe limit (perhaps 30% RH [19]), then the device would be considered unsafe and no longer used. Of course, dry failures may still occur which cause electrolysis. Excessive damage can then only be prevented by regular observation of the effects of using the stimulator.

Most stimulators have controlled-current outputs, on the grounds that this will determine the charge densities on the electrodes (if the real areas of the electrodes are known). What happens if an electrode is broken or reduced in size by corrosion? The charge density is then inversely proportional to the remaining area and may become high enough to be dangerous without this being observable. In contrast, if a controlled-voltage output is used, the charge density will be much less dependent on the area and for some shapes of electrode will tend to be independent of it (e.g. long parallel wires losing length). For this reason, controlled-voltage outputs are safer under fault conditions. The charge density can only be calculated if the access resistance is known, but this can be measured in saline in order to predict, with reasonable accuracy, the value *in vivo*.

3. PROVISION OF A STABILISED VOLTAGE.

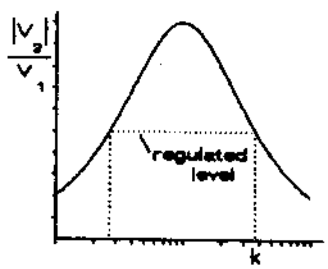


Figure 4.

The obvious way to provide a stabilised voltage in the implant is to place a regulator after the inductive link. The effect of this is to truncate the top of the gain curve, as illustrated by Figure 4: the lower the regulated level, the wider is the range of k over which regulation is maintained. There are three types of regulator: shunt, series and voltage convertor. More or less practical forms of these are shown in Figure 5. To see how these alternatives affect the efficiency, when supplying a fixed load, I used mathematical models [21]. Figure 6 compares the efficiencyversus coupling functions for the three methods. The efficiency improves as the complexity of the regulator rises but even a loss less voltage step-down across the convertor, its input impedance is high, and larger voltages appear across the receiving coil which increases the loss in its own resistance (R of Figure 2). In all three methods, an increase in the range of k over which the voltage is regulated will raise the losses.

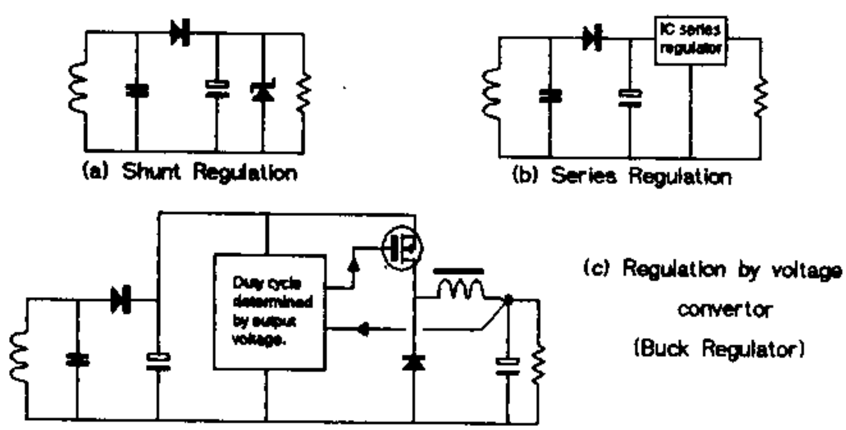


Figure 5. Types of regulator

This conflict is avoided if the voltage convertor (now probably a switch-mode voltage booster) is placed before the transmitter (Figure 7). The efficiency is then simply

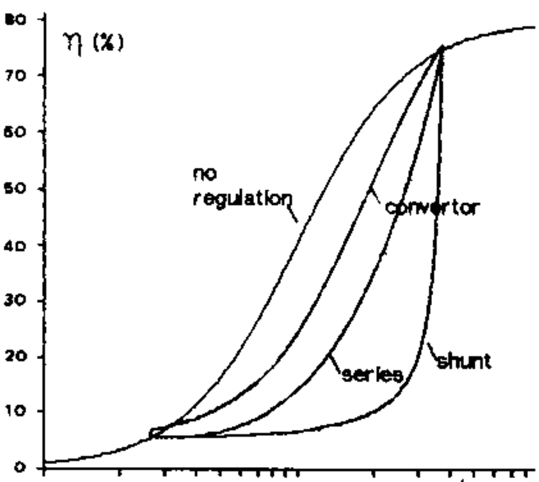


Figure 6.

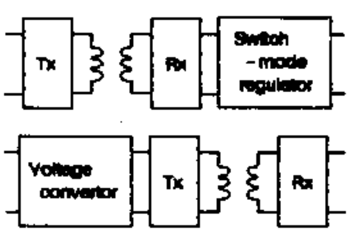


Figure 7.

the product of the convertor efficiency (which may in practice be 80-90%) and the link efficiency (h in Figure 2). This will be higher than the efficiency with regulators in the implant unless the regulated range of k is narrow. A bonus of this arrangement is that a battery with a few cells can be used with a step-up convertor. This facilitates protection of the cells of rechargeable batteries from damage due to overdischarging weak cells [22].

How is the conversion ratio to be adjusted to stabilise the voltage in the receiver? There are two alternatives, either the voltage can be fed back be telemetry to the control box, or, the coupling coefficient can be continually measured and this used to compensate for the changes in link gain with coupling [23]. The latter method has been adopted, partly because of the collateral benefits which are described in the next section.

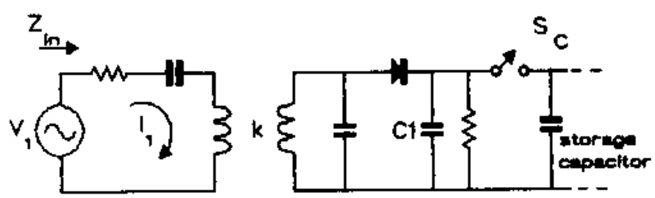
4. STIMULATION CUT-OFF

If the transmitter coil is moved away from the implanted receiver, a coupling must eventually be reached at which accurate stimulation can no longer be maintained. It may be that synchronisation will be lost causing unpredictable excitation of the nerves. This may be dangerous besides being unpleasant for the user. it is desirable that before this occurs, the stimulation should be completely cut off.

Effecting this is not easy. Suppose that the receiver delivers charge to a large (storage) capacitor, from which it is paused to the electrodes; and suppose that the voltage across this capacitor were used to test whether the transmitter is adequately coupled. When the voltage falls below threshold, the stimulation stops. However, because of the high output impedance of the link when the coupling is weak (Figure 2), the capacitor will then recharge, eventually restarting the stimulation while the transmitter coil is in the same position. In this case, stimulation may occur in bursts. More subtle circuits could avoid this but a better alternative is to measure the coupling externally and do the decision-making in the control box. This has several advantages.

1. Power is not wasted in the transmitter while the coupling is too low.
2. The same measurement can be used for the coupling compensator.
3. The problem of stimulation bursts is avoided.
4. An alarm can be sounded to warn the user if the coupling is getting weak but before stimulation cut-off, allowing the transmitter position to be improved.
5. The coupling can be displayed to the user so that he can maximise it.

The coupling can be measured from the transmitter, from the total impedance in the primary circuit, *if the secondary impedance is known.* Generally the secondary impedance is unknown because it varies with the charge on the storage capacitor. However by placing a switch between the receiver and the storage capacitor (S), and opening this at predetermined periods, the measurement is achieved (Figure 8).



$k = f(Z_{in})$ if S_C is open and the voltage across C1 has settled.

Figure 8.

5. MODULATION

The following points were considered before deciding on a method of modulation.

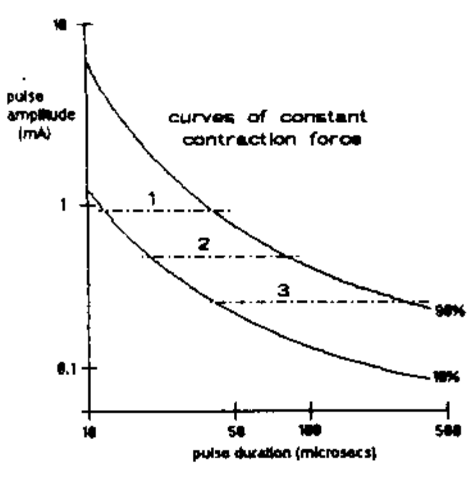


Figure 9.

a. Constant amplitude, variable width pulse can be delivered most efficiently because the electrodes can be connected directly to the regulated voltage supply without further voltage drop.

b. Goreman & Mortimer [24] and McNeal et al. [25] have performed experiments with cuff electrodes to determine what is the best operating line on the strength-duration curves. A central idea is that the recruitment should not be too steep, lest the contraction can not be set at a reasonable number of levels within the range of force. However, consider Figure 9 which is a sketch of a figure from McNeal et al.: here the axes are logarithmic. I have drawn on three possible operating lines. The length of these increases as the pulse amplitude decreases, but not very fast. So long as the amplitude is not too low, the length of the lineas from 10 to 90% force is fairly constant, *on a log scale*, and therefore the ratio of pulse lengths at 10 and 90% force, is not strongly dependent on the amplitude.

c. Using Lapique's formula for the strength-duration curve function [26], the charge needed to excite the nerve is least if the stimulating pulses are short. At chronaxie, the charge is double that of a infinitely short pulse. Above chronaxie, charge is proportional to length. It is charge per pulse which determines the limit of safety for the electrodes.

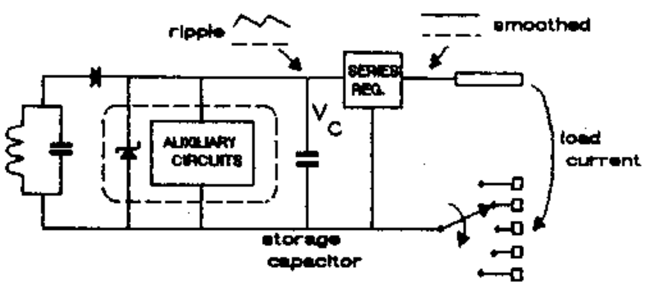


Figure 10.

d. Although the coupling compensator (section 3) is efficient, it can only compensate slowly for changes in coupling. The storage capacitor will have some ripple across it as the demultiplexing switch operates (Figure 10): if this is not to appear at the electrodes, regulation is required to remove it. In theory, so long as V_C is always greater than the drop-out voltage for the regulator and the auxiliary circuits draw negligible current, the efficiency is constant, at any k, however long the transmitter is excited compared to the time that the de-multiplexer switch allows load current to flow. In practice, letting V_C rise above the drop-out voltage will increase the dissipation in any auxiliary circuits (Figure 10) and, if it rises too far, power must be lost in the zener which protects the other components from exceeding their voltage ratings.

e. Practical-sized storage capacitors can only store enough charge for a few long stimulating pulses. It follows that this capacitor can not "average out" the charge required over many stimulus pulses and therefore, that sufficient should be transferred in the signal for each stimulation pulse. To reduce the ripple on the storage capacitor, induction should coincide with stimulation.

f. An inductive link which is optimised for power efficiency has a transient response which depends strongly on the coupling coefficient. Figure 11 shows the expected build-up of the alternating voltage across the receiver coil (before the rectifier which supply the storage capacitor begins to conduct). These responses are calculated using Laplace Transforms for k at likely extremes of its range. From these responses, and given a carrier frequency of 3.5 MHz, the accuracy with which periods of transmission may be conveyed to the implant is +/- 1μs.

Taking all these points into consideration, the method of modulation I have adopted is what I call Logarithmic Pulse Interval Modulation (LPIM). Outputs are not

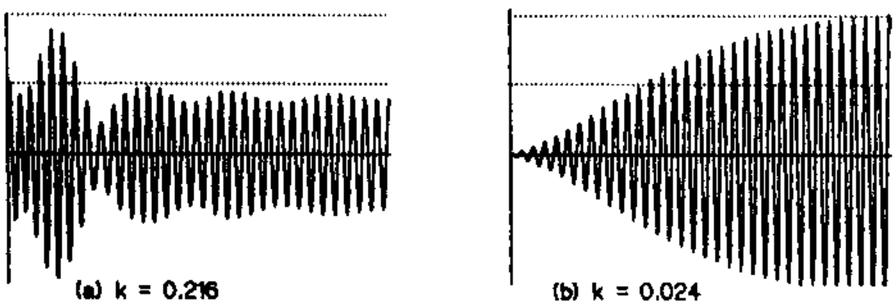


Figure 11.

addressed but used sequentially. Every output has an associated interval-plus-pulse in a pulse train which may be up to 32 pulses long with one demultiplexor chip [18]. The interval t is timed in the implant by counting at 500 kHz. After the interval, there is a pause at the beginning of the period of induction, when, because no stimulation current is flowing, the storage capacitor is charged up and CMOS logic of a gate array calculates T, the stimulus pulse length, from the preceding interval. This takes 30 μs. The stimulus pulse is then delivered (but see below) for T μs, or until the end of the induction period if this is insufficiently long. The relationship between t and T is approximately exponential, with T increasing in 6% steps from 2.125μs to 992μs (Figure

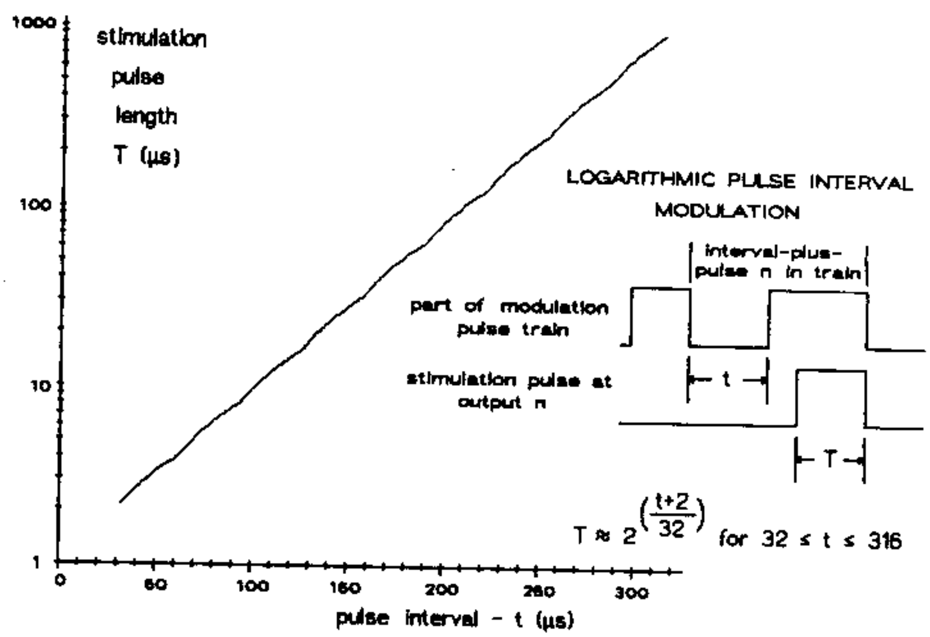


Figure 12.

12). This gives 142 strengths over a range of nearly nine octaves, or no pulse, if the interval is less than 32 μs.

6. HANDSHAKING & HUMIDITY MONITORING

The Coupling Compensator can only work for one value of the electrode access resistance. In setting up the look-up table for the Compensator, any value could be used but the obvious choice is that of the most-used type of electrode. If, in use, a

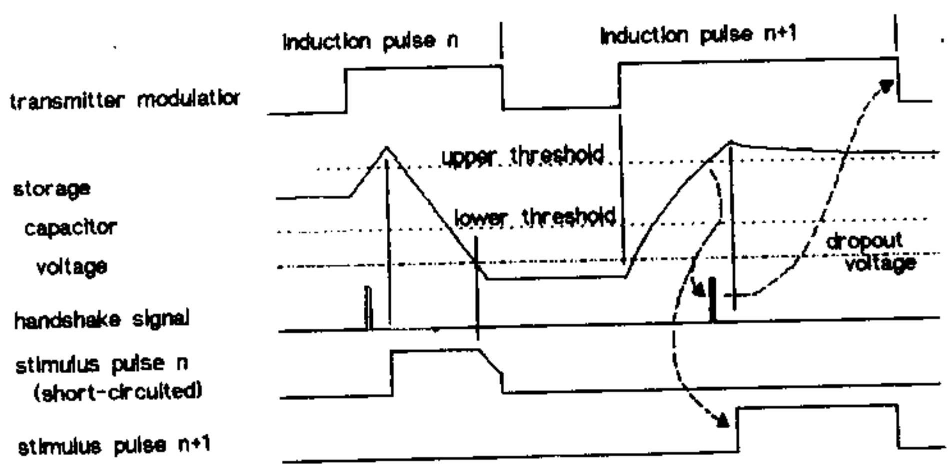


Figure 13. Handshaking

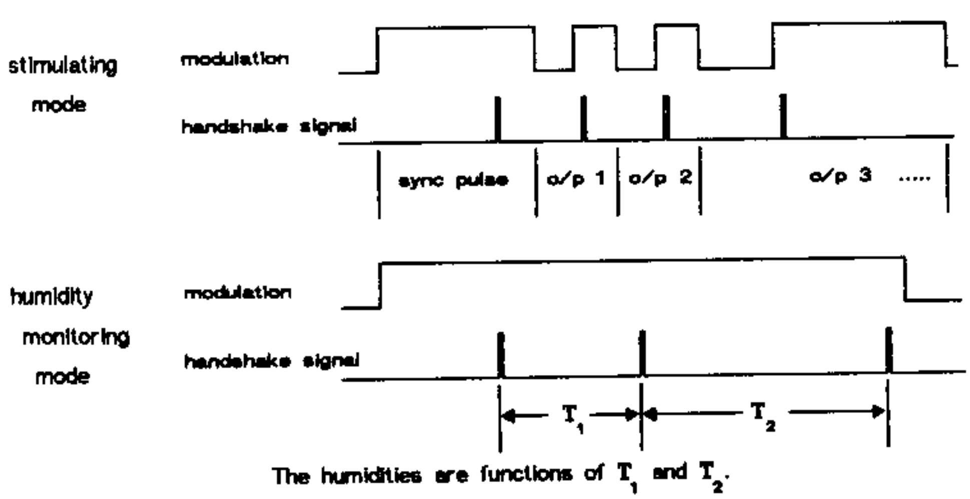


Figure 14.

particular electrode has a lower resistance, or there is a low-resistance fault, such as a short-circuit between two cores of a cable, the storage capacitor may be discharged below the dropout level of the regulator (Figure 10) and, consequently, the stimulating pulse from the next output in the sequence may be of reduced amplitude. (The current through a short-circuit is limited by the regulator.) To prevent this happening, handshaking is used. The stimulus pulse (Figure 12) is not delivered until the storage capacitor is adequately charged. In order that the period of induction continues for at least T ms after this instant, a signal is sent to the external control box at the start of each period of induction or when the capacitor has had time to charge. The effect of this is to "stretch" the transmitted pulse train when the stimulator is heavily loaded.

A method of passive signalling is used [27] so that no power is transmitted from the implant. The same techniques is used in a different operating mode to relay the internal humidifies within the gas-filled chambers of the implant (section 2). Signals in the two modes are shown in Figure 14.

7. SYSTEM

Figure 15 is a schematic diagram of the implanted stimulator. Inputs to the gate array are A, the demodulated carrier, and B, the storage capacitor voltage. Three of the outputs operate the UCN5832 demultiplexor. Three more, C.D. and E. actuate the semiconductor switches S , S and S respectively. The purposes of these switches are: to permit coupling measurement while the switch (C) is open for a few hundred microseconds; to send a handshake signal when the switch (D) closes for a few microseconds; and (E) to prevent the storage capacitor discharging through the series regulator during the milliseconds between pulse trains. The timing of the stimulus pulses is derived from the 8 MHz crystal which is connected to the gate array.

The external part of the system is being developed at present. Figure 16 is a block diagram which shows the Coupling Compensator, which draws power from the battery (not shown) and delivers current to the transmitter at a voltage which is specified from a look-up table by the Link Processor. The handshake signal is detected at the

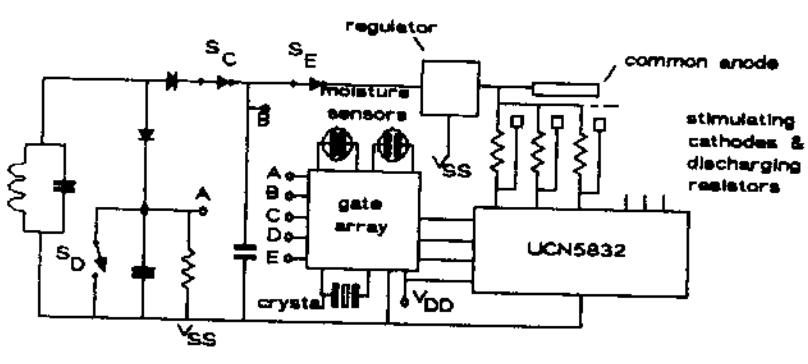


Figure 15.

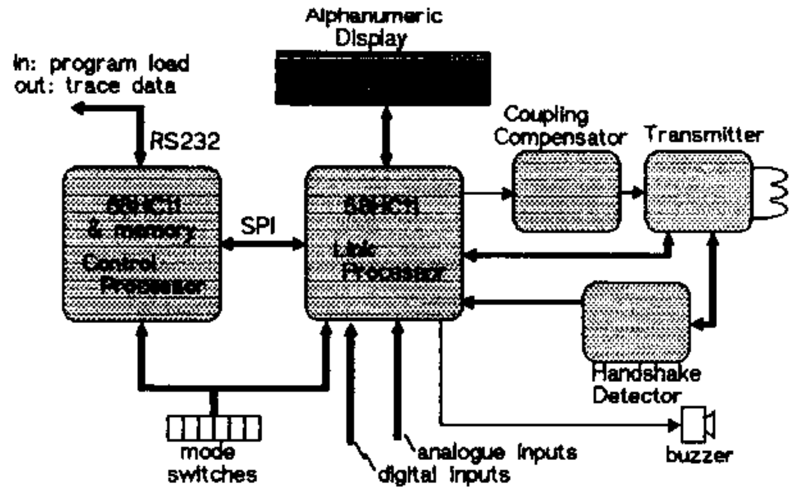


Figure 16.

transmitter, changed to a logic-level pulse and sent to a "input capture" pin of the processor. The (analogue) coupling-measurement voltages are also extracted in the Handshake Detector and fed to an A/D input on the processor.

The stimulator is only part of an FNS control system: the "control box" which the user carries will also have analogue and digital inputs for sensors, a 32-character alphanumeric LCD display and an alarm buzzer. There are two 68HC11 processors. The "Link" Processor is an embedded microcontroller which generates the pulse train to modulate the transmitter, measures the coupling, measures the sensor inputs, writes messages to the display, et cetera: its program is permanent. This leaves the "Control" Processor unencumbered by these tasks. It determines the stimulus strengths by some program written as the occasion requires. This writing will be greatly facilitated by programming in FSDL [28]. The stimulus strengths are sent to the Link Processor via a high-speed serial interface (SPI). The asynchronous (RS232) interface is used for downloading the program from a PC and may be used for sending out "trace" data from the FNS controller to the video recorder.

Measurements made on the bench prototype show that, at the moment, the stimulator is neither as accurate nor as efficient as it could be with this design concept. A small modification is needed to prevent the stimulus pulse length changing by 2-3 steps over the extreme range of working conditions. Several improvements are needed to raise the efficiency with which power is transferred continuously from the battery to a resistance representing the electrode access resistance. At present, this is 13% when the coils are at 27 mm coaxial spacing, which could be raised to over 30%. With modulation and the demultiplexor switch operating, the energy efficiency approaches the power efficiency during continuous induction for long pulse trains, which is good, but falls for short trains. Improvements here are possible but will probably require more customised silicon. With the coils of the inductive link separated by 25 mm (a likely spacing in use), a radial movement of 30 mm is needed to cause cut-off.

8. SUMMARY

A new multi-channel stimulator has been developed which can be the basis for FNS control systems. Cathodal stimulating current can be passed to 32 monopolar cathodes or "pseudo-tripoles" (tripoles with common anodes). The chief objective of the design has been that stimulation should be possible over a wide range of coil positions while retaining the best possible efficiency.

As far as I know, the following features have not been used before in implantable stimulators.

1. Logarithmic coding of the pulse length. A digital circuit generates stimulus pulses whose lengths are approximately exponentially related to the preceding interval.
2. Handshaking: to ensure that the implant is ready before delivering each stimulus pulse.
3. Monitoring of the humidity within the gas-filled enclosures of the implant, before and after implantation.
4. Coupling compensation: feedback from the measured coupling to the transmitter voltage.
5. The decision to cut off the stimulation is taken in the external equipment.
6. Display of the coupling to the patient and an alarm to worm him if the coupling is close to cut-off.

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