AN IMPLANTABLE STIMULATOR FOR ALL SEASONS

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ABSTRACT

This paper describes an implantable electrical stimulator with a large span of stimulating parameters that can satisfy almost every application need. Its features include 16 stimulation channels, two way communication, small size and channel expansion capabilities. Monopolar and bipolar stimulation modes can be programmed. Monophasic, biphasic, and biphasic waveforms with interphase delay are available. All stimulation waveforms are charge balanced. The outputs have a constant current nature and are capacitively coupled. Maximum output current is 10 mA with the compliance voltage of 10 V. The electronic circuitry is environmentally protected by a package made of a biocompatible and RF-transparent ceramic.

KEY WORDS: Multichannel implantable stimulator, FES, FNS.

INTRODUCTION

In recent years, there has been an increased interest in implantable multichannel stimulation systems. This can be attributed to the advances in FES research in general as well as to the particular results obtained by multichannel stimulation using surface, percutaneous, and implantable stimulation of paraplegic and tetraplegic patients. The majority of applications have focused on the functional neural stimulation of upper and lower extremities. However, the stimulation of sensory inputs, as is the case in cochlear stimulation, has also provided significant results.

We will now describe a general purpose implantable stimulator. It has been designed as an FES enhanced version of a multichannel cochlear stimulator. Its design concept, however, makes it possible for it to be used as a multichannel FNS device with an extremely wide range of stimulation parameter settings.

DESIGN STRATEGY

The weaknesses of multichannel surface stimulation are well known as are the difficulties associated with percutaneous systems, even though they have been used with some success (1,2). The need for a multichannel implantable FES system has been explicitly expressed by a number of investigators and there has been a formal request for a Feasibility Study for the Development and Manufacture of a Functional Electrical Stimulation (FES) system which was released by NASA in 1985 (3).

Unfortunately, there seemed to be a communication problem between those who were able to manufacture FES implant hardware on a commercial basis and the potential users of such systems. The users were not able to agree on a set of stimulation parameters that would be appropriate for every possible application. On the other hand, manufacturers were unwilling to venture into the expensive and not very well defined area of the implantable FES. As a result, many FES researchers have been forced to develop their own multichannel implant systems designed specifically to meet their particular research needs (4,5,6,7).

The lack of agreement on the specifications of FES parameters has prompted us to design and develop a "transparent" implantable multichannel stimulator that is not locked to any single set of stimulation parameters but can be adapted to virtually any stimulation strategy and application. The block diagram of the system is shown in Fig.1.

ENERGY AND DATA TRANSMISSION

Inductive coupling is established between the external controlling device and the implant. Amplitude modulation of a 49 MHz carrier is used to transfer data into the implant with a information transfer rate of 1.1 Mbit/sec. The power supplies for the implant circuitry as well as for the stimulation current are derived from the same 49 MHz signal.

TIMING MANAGEMENT

The data transferred into the implant is organized in "words", each of which is 9 bits long. Nine words in sequence constitute a "frame". The first eight words contain stimulus amplitude and polarity data. Eight bits define the output current amplitude and the last bit defines the polarity. The "ninth word" in the frame contains commands that define stimulation parameters other than amplitude or polarity and also provides a means for setting the configuration and functionality of the implant.

Most ninth words are organized as three subwords that define three types of data: "function", "channel", and "value". The "function" may be a global one, common to all channels, or it may provide control for each individual channel, activate back telemetry, define the maximum output voltage, or define the stimulus pulse-width. The "channel" subword defines the channel number to which the rest of the command refers. The "value" data selects subfunctions of a major function and is interpreted in the context of the overall command of which it is part.

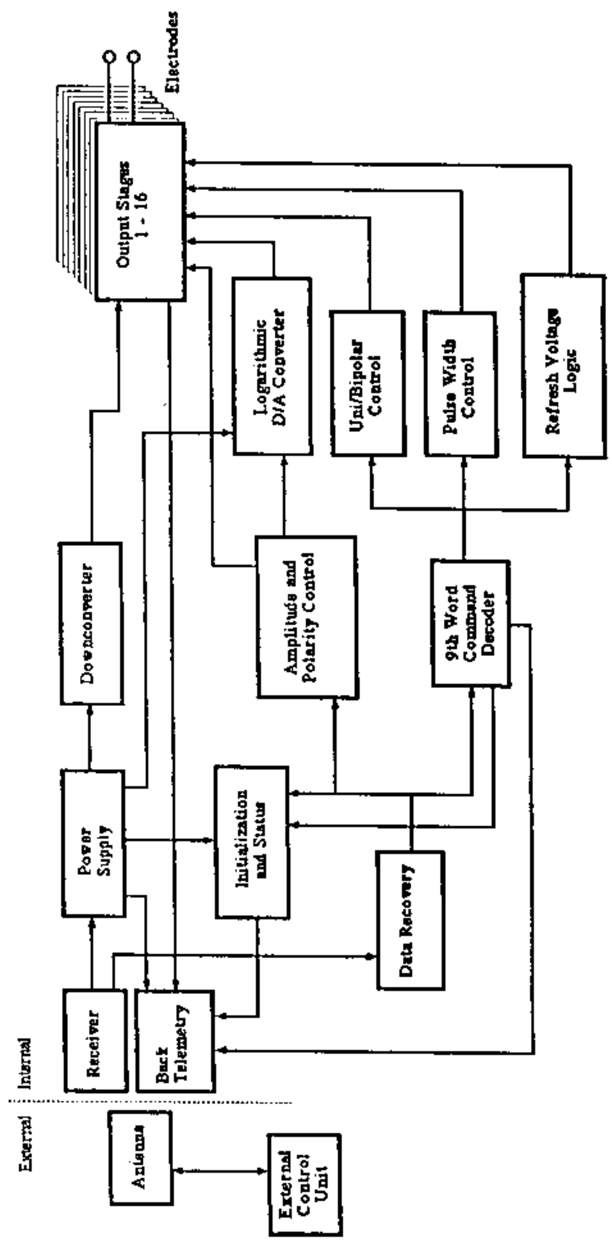

Fig.1: Block diagram of the system electronic circuitry

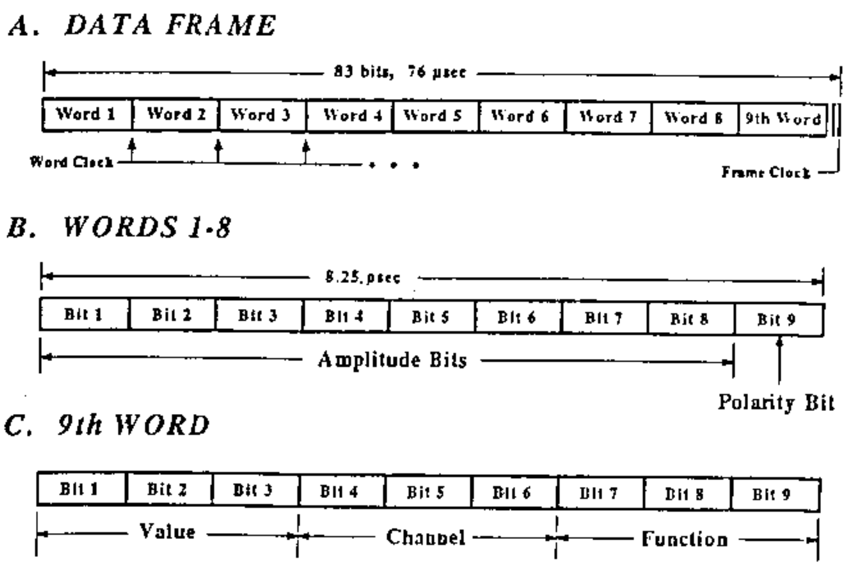

Fig.2: Timing diagram of a typical data frame (A), amplitude data words(B) and a typical ninth word (C)

Finally, the frame terminates with a group of pulses that define the "frame pulse". Its occurrence defines both the end of the frame and beginning of the next. A frame pulse may be inserted following any of the "words", thus shortening the frame time.

BACKTELEMETRY

The implant can communicate with the external device using a separate telemetry channel. It operates at 10.7 MHz and employs frequency modulation. It operates in two modes. The carrier is turned on as soon the implant receives enough power for operation and the data are received correctly from the external control unit. The presence of this carrier tells the external device that the implant is operating correctly. If the implant detects an error in the forward transmission it turns off the backtelemetry carrier, which causes the external device to restart the turn-on procedure.

The second mode is a data transmission mode. The implant circuitry contains a digital voltmeter circuit that is connected, via a multiplexer, to a number of internal nodes of the circuitry. This mode is activated by certain ninth word commands. Signals which may be monitored include the stimulus output voltages and currents as well as power supply levels. Other commands are used to turn the a/d converter on and off to conserve power, and to set the gain of the a/d preamplifier stages. Five different gains from x1 to x100 can be programmed. The A/D subsystem has 6 bits of resolution and at maximum gain, the resolution is 2 mV. Transmission of backtelemetry data is synchronized with the incoming frame pulses, with one bit of information sent per word time.

ELECTRONIC CIRCUITRY

The implant is activated by receiving a special string of bits which powers up the implant and synchronizes an internal oscillator to the bit rate of the incoming data. After the internal voltages have reached the required values and the transmission is recognized as valid, the actual stimulus control information is sent to the implant. Each word is transferred to a parallel buffer through a serial to parallel converter. The parallel data is then sent to an 8 bit logarithmic D/A converter. The logarithmic relation is shown in Fig.3. The analog output current data are multiplexed to the output stages. The amplitude value is stored and is operative until the next data for a particular channel are received and converted.

The ninth word is transferred into a different parallel buffer and is decoded so that the commands come into effect during the next frame time.

The output stages are isolated from each other and from the rest of the circuitry most of the time, except for when the amplitude data is transferred to them.

Compliance voltage control

An important property of our implant device is the stimulus power conservation feature. The amplitude of the voltage source powering each output channel can be set to an appropriate value by the use of ninth word commands. This reduces the power dissipation in the internal current control devices and thus minimizes the energy drawn from the external transmitter. The four possible compliance voltage levels are 10.0 V, 7.5 V ,5.0 V, and 2.5 V. They are provided by the refresh voltage control using a downconverter circuit.

Output stage

The output stage is a current source or sink that can provide currents between 4 uA and 10 mA. Each one can be configured as a monopolar source/sink, or, in conjunction with another electrode, as a bipolar source/sink. At a given time, any two electrodes may be configured as an electrode pair. The current magnitude can be set to any value with a resolution of 3.4%. In addition, an internal discharge resistor can be connected across the outputs on each of the channels, and each channel can be individually disconnected from the external electrodes. The coupling between the output stages and the electrodes is made via a coupling capacitor.

Output control is used to select the connection mode of the outputs on a channel-by-channel basis. The output connectivity can be made monopolar with respect to the "A" electrode, monopolar with respect to the "B" electrode, or bipolar using both "A" and "B" electrodes. Connection of the Indifferent Electrode is also controlled. The block diagram of the output stage is shown in Fig.4.

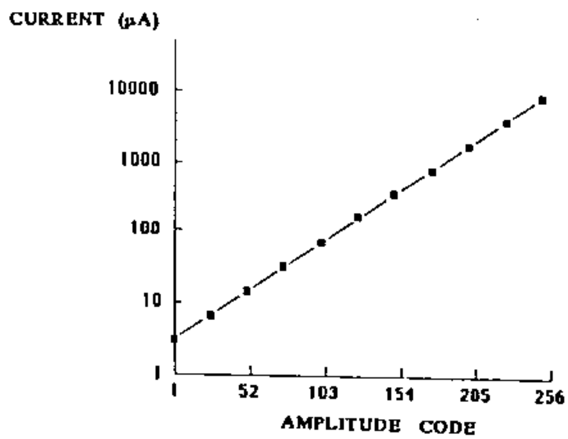

Fig.3: The output current increases logarithmically with amplitude binary code

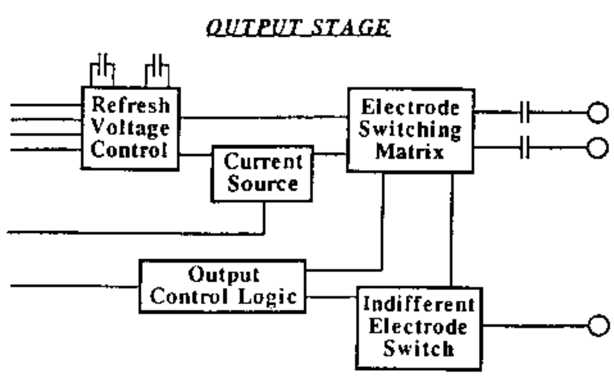

Fig.4: Output stage block diagram

At this time, we plan to provide the output connection but not the final electrode assemblies. The requirements of each application must be met by the custom electrode configuration which is appropriate for that particular need.

Pulse width control

The pulse duration can be set in 1 μs increments. The pulse amplitude and polarity are controlled in the normal way by the value sent out during the appropriate word time for the channel being controlled.

HERMETIC PACKAGING

The implant circuitry is positioned on a ceramic substrate. The heart of the system is a full- custom CMOS ASIC chip, containing approximately 10,000 transistors.

The implant electronics and the antennas are contained in a hermetic ceramic package. Four hermetic feedthroughs, each containing four mutually insulated conductors, are used to connect the 16 electrode leads to the electronic circuitry. The size of the hermetic package including feedthroughs and the indifferent electrode band is 4.0 x 2.5 x 0.6 cm (1.6" x 0.98" x 0.24"). It weighs approximately 14 grams (0.5 oz).

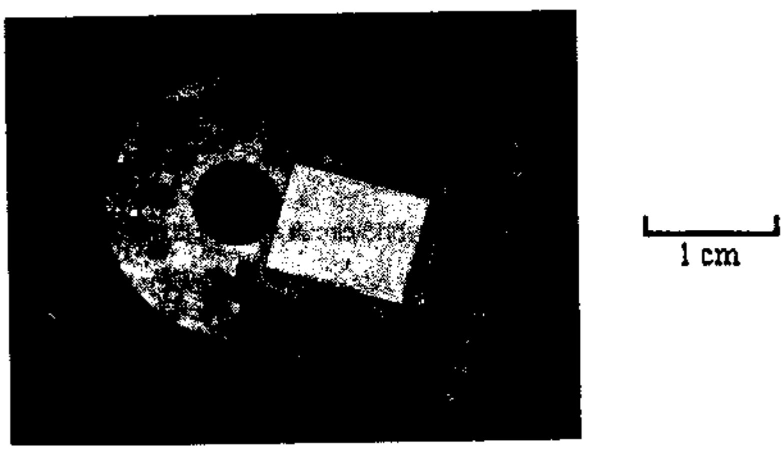

Fig.5: Implant hybrid circuit. Antennas are on the back surface of the substrate.

EXTERNAL CONTROL UNIT

The implant is powered and controlled via an antenna which is connected to the external control unit through a connecting cable.

A semicustom gate array serves as the formatter for the transmitted data. It is in turn controlled by a CMOS digital signal processor with a 8 kbytes EPROM on board. A great number of arbitrary stimulation patterns and pulse-forms can be programmed into the EPROM memory, depending on the requirements of a particular application. Programming is carried out by means of a modified AT-class personal computer.

Fig.6: Three steps in implant production: hybrid circuit alone, with feedthroughs attached, and the completed hermetic package.

SUMMARY OF PARAMETERS

The pertinent parameters are shown in Fig.7 below. Other arbitrary waveforms can be generated, limited only by the update interval of 76 microseconds.

OUTPUT PARAMETERS

Peak Voltage:	3.5, 7, 10.5 or 14 volts
Current:	0 to 10 mA in 256 steps, 3.4% each
Frequency:	0 to 270 Hz
Pulsewidth:	0 to 500 µsec, 0.9 µsec resolution
Waveforms:	

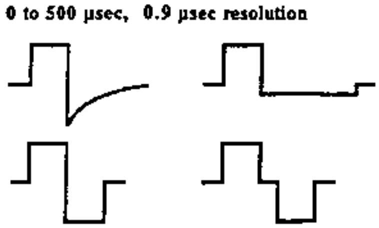

Fig.7: Brief summary of output parameters

EXPANSION CAPABILITY

The implant chip design allows for three expansion schemes. The first scheme uses a circuit in the front end of the chip which allows for ganging of several chips into one functional unit by making one chip the master device and the others slaves. A large, perhaps unlimited number of chips can be connected together, forming a system with an enormous number of channels. The upper limit is set by the data rate since the frequency at which each device is updated decreases with the number of channels. Only after the update rate for a particular application becomes well defined can the maximum number of the ganged chips be determined.

The second expansion scheme is realized by utilizing one or more of the stimulation channels as a power supply for some other implanted device, for example an implanted sensor. In this case, the backtelemetry feature can be utilized as well. Powering up and measuring the sensor's response can provide the feedback we need in a closed-loop FES application.

The third expansion scheme uses up to eight different carrier frequencies to support 8 implants simultaneously, thus providing up to 128 stimulation channels.

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