# DEVELOPMENT OF AN IMPLANTABLE AND PERCUTANEOUS ELECTRICAL STIMULATION SYSTEM FOR GAIT APPLICATIONS IN STROKE AND SPINAL CORD PATIENTS

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## ABSTRACT

Two multichannel electrical stimulation systems, one supporting two eight channel implantable stimulators and the other supporting eight percutaneous or surface electrodes, are being developed at Rancho Rehabilitation Engineering Center to supplement intact neural control of gait in stroke and spinal cord trauma patients. The implantable stimulation system can generate charge balanced biphasic pulses from 0-2.25 mA in sixteen steps. Pulse width is controllable from 30-300 uS in 0.17 uS steps. The percutaneous system generates charge balanced monophasic pulses from 0-20 or 0-100 mA in 256 steps. Pulse width is controllable from 1-300 uS in 1 uS steps. Both systems utilize a battery powered microprocessor based controller that is worn by the patient. Stimulation patterns and operating instructions for this controller may be quickly determined and modified by a laboratory computer with a high resolution color graphics display. A second microprocessor based device, carried by a therapist, permits local modification of stimulation parameters and triggering of stimulation sequences.

## INTRODUCTION

Every year many thousands of people are left paralyzed from accidents or progressive disease. In most of these cases, damage occurs in the brain or spinal cord. Skeletal muscles are paralyzed because neural impulses which normally activate these muscles are unable to pass through the damaged areas in the central nervous system. Since the muscles themselves and their innervating nerves are undamaged, function can be restored if neural impulses are artificially generated in the nervous system beyond the areas where blockage occurs. This can be done with Functional Electrical Stimulation (FES).

Since 1791, when Galvani induced muscle contractions in frogs, it has been known that nerve and muscle tissue can be excited by small pulses of electrical current. Only recently, however, has technology evolved to a point where the instrumentation needed to generate these electrical pulses can be packaged in a small portable unit that can be easily carried by the patient.

Currently available instrumentation has enabled many investigators to demonstrate the feasibility of clinical applications of FES. However, further deployment of the technology to more centers around the world is limited in part because of technological constraints. Specifically, implantable multichannel stimulators are required to overcome the inherent limitations and disadvantages of skin and percutaneous electrodes. The hardware employed must provide sufficient versatility to be used in a variety of neuromuscular deficits, since no two patients have precisely the same combination of voluntary function and deficit. The goal of our laboratory's endeavors is to develop implantable gait stimulation systems which are needed to significantly advance the state-of-the-art and ensure that this promising technology will be made available to thousands of paralyzed individuals. To

bridge the gap between implantable and existing surface stimulation systems, a percutaneous stimulation system is also being developed.

## BACKGROUND

Electrical stimulation has been used to activate appropriate muscles of the lower extremities during ambulation to improve the quality of walking in persons with neuromuscular impairment (1-4). Until recently, control has been "on-off", i.e., stimulus parameters are held constant during each period of stimulation. Stanic et al (5) showed that improved performance could be achieved by modulating stimulation to produce a graded response in the stimulated muscles, in their case, the ankle dorsiflexors. Even greater improvement in walking quality can be expected by using modulated control of the larger muscles of the hip and knee.

Selection of modulated control sequences to optimally assist a person with neuromuscular impairment during walking is far from trivial. Models of bipedal gait are not accurate enough to generate the desired control by computer simulation. This means that appropriate control sequences must be determined experimentally in the laboratory for each individual. To arrive at the control sequences in a straight forward, easy to understand, and flexible method in the laboratory setting where time is limited requires a computer system with enough speed and power to handle a number of complicated tasks. The large number of stimulation channels and the capability of handling complicated control algorithms for the eventual likelihood of the closed-loop control of FES are also very desirable features not easily attained in traditional stimulation systems. Trnkoczy (6,8) and Strojnik (7) have employed microprocessor based stimulators in their research which allow a pulse train to be modulated in several discrete steps, allowing greater control of limb movement compared to "on-off" type stimulators. Thrope (9) and Buckett (10) have refined even more the use of laboratory computer controlled and microprocessor based stimulators which can modulate functional neuromuscular stimulation. The necessity of changing variables of stimulation for each and every single pulse during a train of pulses for modulating the stimulation of a motor group, as in our application, requires microprocessor or computer control to achieve. As reported previously, our laboratory has developed a computer controlled multichannel electrical stimulation system for surface electrodes (11). This system has been successfully been utilized for control and parameter optimization studies aimed at improving the therapeutic and functional application of FES (12-14).

As the efficacy of utilizing multichannel FES continues to increase, so does the need to improve the devices with which it may be applied to spinal cord and head trauma patient population. Clinically, multichannel stimulation has been realized using surface electrodes in two through six channel systems to help patients in gait training programs (2) and through the use of transcutaneous coiled wire electrodes, as many as thirty two channels have been utilized experimentally to help complete paraplegics to take steps, climb and descend stairs (15).

In its development, the use of FES systems for gait assist have encountered a number of problems. One of the problems associated with the use of electrical stimulation in a chronic application is the problem associated with the maintainence of the stimulation system. Electrode lead breakage and other forms of physical damage can lead to a continual and costly operating life for the stimulation system. One of the methods for avoiding this and many other problems is to use implantable electronics and electrodes. Although the body can present a rather harsh internal

environment, it is nonetheless very stable and free from external abuses. It also provides an excellent opportunity for direct interface between the electronics of the stimulus system and the neuromuscular system of the patient, thus greatly improving the level of controllability.

An early attempt to utilize an implantable stimlation system was described by a group at Rancho Los Amigos Hospital (16). A single channel radio frequency (RF) powered device was implanted in the medial thigh of stroke patients and a single bipolar electrode was attached to the post-tibial branch of the peroneal nerve to elicit dorsiflexion of the involved foot during swing phase of gait. This device was successful in that it achieved a great level of function for those patients implanted with the device and provided long term evidence for the safety of the package and electrode configuration.

Recently, multichannel implantable systems have started to appear. At Case Western Reserve University, Peckham et al, have developed an implantable eight channel stimulation system to be used in their upper extremity research (17). Their device can supply twenty milliamps (mA) of current with pulse widths from 0 to 256 microseconds (uSec), the pulse width being controllable via an RF link. A newer version will have five bits of current amplitude control over the RF link as well. Holle et al, have implanted a pair of eight electrode devices in a paraplegic patient with an electrode placement scheme resulting in four separate nerves being controlled (18). The systems of both groups greatly reduce the amount of external devices required to achieve multichannel stimulation.

From the Rancho application we can appreciate the safety and effectiveness of implanted nerve cuff electrodes, and the consistency of the resulting stimulation. Looking to the future we see the need for an ever increasing number of stimulation channels required for effective gait applications and a tremendous need to reduce the external equipment to an absolute minimum. In light of these views, we at Rancho have undertaken the development of the multichannel stimulation systems described here.

## CLINICAL APPLICATION

The clinical applications for a surgically implantable FES system vary widely. Stimulation may be utilized for therapeutic exercise for the purpose of maintaining the size and bulk of the muscles in the lower legs by individuals whose spinal cords are severed. Preservation of the normal muscle mass in the legs serves an important function of protecting the skin from pressure sores. Stimulation can be utilized to move the muscles and joints through their normal range of excursion and prevent the disabling complication of muscle and joint contracture. Cardiovascular benefits of an electrically induced exercise program may provide the paralyzed patient with the same type of benefits as normal exercise. The application of muscle forces may also help reduce severe disuse osteoporosis which commonly leads to fracture in paralyzed patients.

Prevention of muscular atrophy following a spinal cord or brain injury is another important application of electrical stimulation. Following partial paralysis, recovery of neurologic function occurs gradually for up to two years. Prior to the time that recovery occurs, the muscles may undergo atrophy. Electrical stimulation provides a means of maintaining the integrity of muscle until neurologic function returns. Also, stimulation serves as a means of functionally activating the muscles to enable walking. Consequently, gait training may be initiated earlier, prior to the return of

volitional control. By preventing muscle atrophy and enabling earlier gait training, patients can achieve higher ambulatory goals than by standard physical therapy techniques alone.

Finally, electrical stimulation can serve as a permanent method of restoring muscle function in patients who are permanently paralyzed. Research performed in our facility over the last 20 years has led to the development of implanted stimulators which have been in patients as long as 17 years. Single channel electrical stimulators, applied to the peroneal nerve, have enabled correction of footdrop in patients suffering from stroke, head injury and spinal cord injury eliminating the need for externally worn braces (1). Similarly, stimulation applied to the femoral nerve was shown to eliminate the need for extensive bracing from the foot to the thigh in patients with a paralyzed quadricep (19). These applications have proven that not only can braces be eliminated, but dynamic restoration of joint motion can be restored. In addition, these applications have also proven that electrical stimulation via electrodes attached to nerves can be safely tolerated in human subjects for extended periods of time (20).

While the applications above suggest that many patients would be good candidates for implantable stimulation systems, in many instances it may not be appropriate for a patient to receive an implantable device. Patients with short-term dysfunction on the order of a few months tc less than two years but who cannot be helped with surface stimulation due to inaccessibility of deep muscles could very likely benefit from a percutaneous system. Selectivity is another important issue to consider. The short head of the biceps femoris is just such an example where surface electrodes just do not provide enough selectivity, but where surgically implanted epimysial electrodes perform adequately. A percutaneous system would also be an appropriate method of testing a patient to see if sufficient functionality can be achieved with implanted electrodes with eventual implantation of a stimulation system considered appropriate if the patients peripheral nerve status and response to stimulation is successful. Electrodes could be surgically implanted at desired nerve and/or muscle sites, leads and connectors could be brought to a single site where percutaneous leads and connectors would then enable an external system to activate the implanted electrodes. Should, in the case of an implant patient, adequate response be realized, then the percutaneous leads could be removed and an implantable system could then be utilized.

Recently a clinical program at our facility was started in which patients with head trauma, stroke or spinal injury received epimysial electrodes to augment hip and knee stability for stance or to improve limb advancement (21-22). The preliminary results of this program indicate that functional muscle contractions of the deep hip muscles can be obtained with epimysial electrodes. These results have immediate application to short-term therapeutic intervention for patients with upper motor neuron disorders. This program is currently using commercially available two channel stimulators but will utilize the eight channel percutaneous system very shortly.

## LABORATORY DESCRIPTION

An FES laboratory is being developed to support the research with the implantable gait and percutaneous stimulation systems. This laboratory will house all of the equipment and personnel required to train implant candidates prior to and after surgical implantation as well as to determine gait stimulation patterns used by an External Controller to direct the operation

of the implant devices or stimulation via percutaneous leads in all modes of operation. The laboratory equipment directly involved with the implant operation can be divided into three categories: a laboratory computer system, a gait walkway, and an Implant / External Controller / Therapist Control Unit system.

Laboratory Computer

A Digital Equipment Corporation MINC 11/23+ computer is used to formulate control sequences for each of 16 possible channels and to transfer stimulation data table information to the External Controller via a removable hardwire link. While the patient is walking with stimulation, the computer can collect goniometric, electromyographic (EMG), and force data from the patient as he/she proceeds along the gait walkway during experimental runs. This data can then be analyzed and results presented to the clinicians using the laboratory. In this way, parameters for gait stimulation may be quickly determined and analyzed for modification by the clinicians.

To present the results of data analysis in an easily intrepreted manner, and to facilitate the modification of data tables corresponding to gait stimulation parameters, a high speed, high resolution, color graphics display driven by a Parallax 1280Q graphics processor board set, residing on the MINC Q-bus backplane is used. Screen resolution is 1280 by 1024 by 8 with a vector drawing rate of 50,000 vectors/second. Data table information which corresponds to pulse widths for individual pulses within a channel sequence must be presented in an understandable manner to the clinician making decisions about the modification of stimulation parameters for subsequent runs. By utilizing this graphics system, the channel information may be quickly reviewed and modified using a "mouse" and sent to the External Controller. A color hard copier will be purchased to capture the graphics screen information to keep records of patient progress. Support for a Hewlett Packard 7225 plotter is also provided in the system.

Gait Walkway

The gait walkway is approximately ten meters long and has a color video recording system for qualitative patient performance measurement. Force measurements can be obtained from instrumented shoes and canes. Detailed gait analysis complete with EMG measurement is available at the Pathokinesiology Laboratory which is adjacent to the FES Laboratory.

Walking performance is documented by electrogoniometers placed on the knee and ankle and by footswitches that monitor foot/floor contact at the heel, first metatarsal, fifth metatarsal and toe. These data, averaged over one walking trial run, can be displayed on the graphics display along with the control sequences.

IMPLANTABLE STIMULATOR

The implantable stimulator utilizes a three chip set of integrated circuits developed at Stanford University Integrated Circuits Laboratory, the "Stimuliss 8B" (23). These chips were developed to be utilized in Stanford's auditory prosthesis program funded by the National Institutes of Health. Although the chips were incorporated into a working prototype of the cochlear implant, a final application for the chips has yet to be produced. In our application, the chips and their associated electronics are enclosed inside a titanium, hermetically sealed can, with eight tantalum feedthroughs for electrodes and three feedthroughs for antenna connections. A shielding

technique allows the placement of the receiving antenna directly on top of the can, reducing the package size substantially with only small signal loss due to the proximity of receiving coil and metal can. A block diagram of the implantable stimulator may be seen in Figure 1.

The implantable stimulator receives its information and power from a 20 MHz transmitter modulated with an External Timing Control Code, composed of two words, a "Transition" word, and an "Amplitude" word (Fig. 1). Each word uses eleven bits in a bit stream with floating word frames, so the start bit indicates the beginning of a word. A parity bit checks for an odd number of bit errors in a word and thus protects from erratic information being sent to and erroneously acted upon by the implant. An ID bit distinguishes between an Amplitude word and a Transition word. The remaining eight bits contain state commands for the Transition word and current level commands for the Amplitude word.

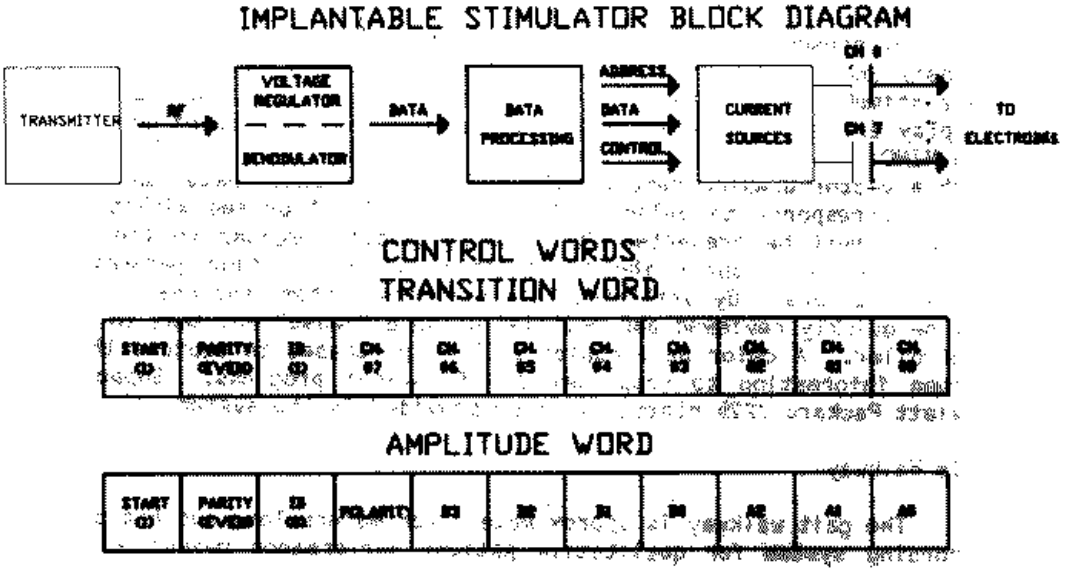


Figure 1. Implantable stimulator block diagram and control word definition. The three chips of the implant are depicted by function above. The implant responds to two control words, the Amplitude word sets current levels for a channel and the Transition word initiates pulse activity.

The Transition word is used to change the state of any of the eight channels. If a one occurs in channel bit positions, then that output cycles to its next state of three states, which are both directions of current, and charge balancing (charge balancing means shorting the electrode to body ground, thereby recovering the residual charge left on the electrode). The Amplitude word selects the current amplitude of the state sequence of a given channel. It has three bits to individually address the eight channels, four bits to adjust the current magnitude, plus one more bit to set the current polarity. The magnitude bits set the peak current of the pulsatile waveforms, while the polarity bit selects one of the two possible pulsatile sequences available for each channel: "sourcing current", "sinking current",

then "charge balancing" or "sinking current", "sourcing current", and then "charge balancing".

A special case of the Transition word, the "Master Reset" word, is used to initialize the implant from time to time and is required by the implant to guarantee the integrity of the incoming information.

The implant package is approximately 1.75 inches in diameter and 0.375 inches thick. Protruding from the edge of the package are eight internal connectors for attachment to the stimulating electrodes. Attached to these connectors are up to eight electrode leads, terminating in monopolar platinum disk nerve cuff electrodes. The platinum disk has a surface area of 1.5 $mm^2$ and an impedance from 1 to 2 KOhm. The implant will be placed surgically in the medial thigh of the patient's leg and transmitting coils will be placed over the device.

In practice the implant will be delivering variable pulse width biphasic pulses, with amplitudes from 100 microamps to 2.25 milliamps. Pulse width is dependent upon the bit transfer rate of the External Controller and the controller's discretion. Using a 6.4 megahertz clock frequency, we are able to attain a 400 kilohertz (KHz) bit transfer rate from the External Controller to the implant devices. This gives us pulse widths ranging from 26 uSec to 300 uSec with a resolution of approximately 156 nanoseconds.

## EXTERNAL CONTROLLER FOR IMPLANTABLE STIMULATOR

Supplying information and power to the implant units will be a microprocessor based External Controller which is worn on a harness by the patient. This controller utilizes a Complementary Metal Oxide Semiconductor (CMOS) microprocessor, the Motorola MC68HC11, for low power portable operation, and circuitry needed to convert stimulation parameter information into the control words required by the implant and the modulation circuitry to implement the transmission process.

The controller has sufficient memory to contain pulse information for sixteen stimulation channels in several modes of operation: transition from sitting to standing, transition from standing to sitting, transition from standing to walking, continuous walking, etc, in the form of data tables. The elements of these tables correspond directly to the pulse widths required for a particular muscle group to produce a desired amount of force. In this manner, a modulated sequence of muscle forces may be defined to realize the desired trajectory of the patient's lower extremities. Additional information is stored for each channel, including pulse amplitude, delay from trigger, etc.

The stimulation patterns utilized by the implantable stimulator are sent via a removable communications link from the laboratory computer. A physical therapist uses a device called the Therapist Control Unit with a high speed serial communication link with the External Controller. Using this device, stimulation modes may be selected and channel data may be adjusted and scaled locally. Prior to a trial run, the stimulation patterns are down-loaded into the External Controller from the laboratory computer. The down-load communication link is then removed and the clinical team begins evaluating the response of the individual to the stimulation. The patterns may then be modified on the graphics monitor, down-loaded, and then evaluated again. The procedure is repeated until desired response has been elicited.

The External Controller is comprised of four subsystems, each on its own circuit board and is housed in a package 2.4" thick by 7.5" wide by 4.4" tall. A strap goes around the back of the individual's neck and the package rests in front at the waist. Cabling to trigger switches, antennas, and miscellaneous analog and digital signals comes from the bottom of the package. There are two telephone style headset jacks which allow the laboratory computer and the Therapist Control Unit to be plugged in. The five subsystems of the External Controller are described below.

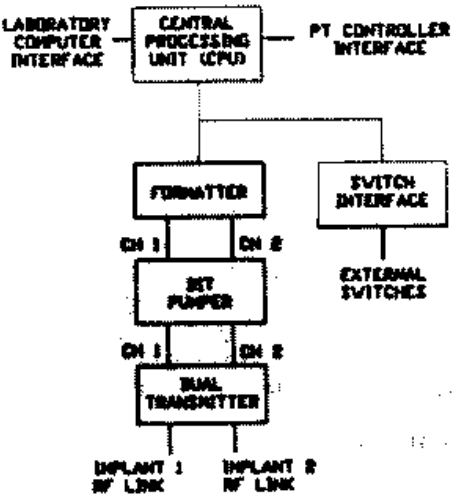


Figure 2. External controller block diagram. Four circuit boards are utilized in the implantable stimulator version of the external controller. Two channels of RF control are supported.

CPU Board

The Central Processing Unit (CPU) board is responsible for data manipulation, subsystem timing, and communication with the laboratory computer and with the Therapist Control Unit. The microprocessor selected for the CPU is the Motorola MC68HC11. A major factor in the selection of the MC68HC11 for this application was its low power consumption due to its fabrication in CMOS and its high level of on-chip integration. On-board the chip is 256 bytes of Random Access Memory (RAM) and 512 bytes of electrically alterable ROM, two serial Input/Output (I/O) ports, an eight channel, eight bit analog to digital converter (A/D), a vectored interrupt processing structure, a clock generator, and a 16 bit timer system with 5 output compare and 3 input capture functions which are utilized for all pulse timing functions.

The on-board asynchronous Serial Communication Interface (SCI) port is interfaced to the laboratory computer system and the synchronous Serial Peripheral Interface (SPI) port is used for the Therapist Control Unit interface. The baud rate of the SCI is 9600. The SPI clock rate is 0.5 Mhz, and so during gait operation commands and responses between the External Controller and Therapist Control Unit may be processed very quickly with little effect on pulse timing.

The RAM requirements for storing the data tables are quite large. Initial estimates of memory requirements to support the stimulation patterns for several modes of operation, 16 channels deep, is greater than 90,000 bytes. To accommodate this, there are four pages of 32K (1K=1024) bytes for a total data memory capacity of 128K bytes. The RAMs are, as is the CPU,

constructed with CMOS technology for low power consumption. In order to achieve the packing density needed because of restricted board size, surface mount 32 kbyte CMOS static RAM chips are utilized with a RAM page mapping register. These devices can be replaced by CMOS EEROM (electrically erasable read only memory) devices when they become available for non-volatile storage in patient maintained devices.

The microprocessor on-board timer is used to provide a time base interrupt that maintains the orderly delivery of sequential stimulation data (pulse amplitude, pulse on/off, channel, right or left transmitter) to the Formatter circuitry. The timer has ten related 16 bit registers for a number of timing functions of critical importance to the External Controller system.

An eight channel digital input interface and an eight channel, eight bit analog to digital converter accept eight external analog inputs and eight external digital inputs which serve as triggers for regulating the delivery of stimulation pulses to the patient's neuromuscular system. Trigger sites used to initiate stimulation sequences will vary from individual to individual depending on their disabilities, so to maintain maximum flexibility, the inputs are configured as generalized inputs which can be defined and configured under program control and direction from the host computer. The analog inputs can also double as quasi digital inputs since the allowable input voltage range is limited from zero to plus five volts and a window can be defined easily to correspond to states of interest.

Formatter Board

The responsibility of the Formatter board is to automatically send eleven bit control words defining the generation of a single stimulus pulse on a single channel for one of the two RF transmitters to the Parallel To Serial Converter and Transmitter Driver Board. As mentioned before, the implant accepts basically two types of information: an 11 bit Transition word and an 11 bit Amplitude word. Transition words contain information about the channel selected, the type of word (a Transition word in this case), and a word transmission error check. It can also contain a Master Reset code. Amplitude words are used to set the amplitude and polarity of the pulses, but they also include a transmission error check and a bit that identifies the word as an Amplitude word. By combining the codes that turn on (or off) the various output driver transistors (polarity control), and by setting the amplitudes on consecutive transmissions, a current waveshape of several possible forms can be generated.

A typical sequence of control words to generate a biphasic pulse would be as follows: 1) Send out a Master Reset word, 2) Send out an Amplitude word that specifies a positive polarity and an amplitude, 3) Send out a Transition word selecting a channel, 4) Send the same Transition word again, reversing the current direction, 5) Send the same Transition word again, causing the stimulator to charge balance the electrode.

The CPU sends the Formatter board two bytes (which makes a 16 bit word of which only 11 bits are used by the Formatter) for each word to be sent to the implant to registers on the Formatter board. Timing information corresponding to word delivery by the Parallel To Serial Converter and Transmitter Driver Board circuitry and pulse width is stored in additional 16 bit registers for Formatter on-board regulation of data transfer timing. A control register on the Formatter board accepts commands from the CPU board to automatically send these stored 11 bit commands to the proper transmitter and informs the CPU when a pulse has been completed. Thus the CPU board has

been relieved of a great deal of critical timing control responsibility in the delivery of high resolution stimulus pulses.

Parallel To Serial Converter and Transmitter Driver Board

The Parallel To Serial Converter and Transmitter Driver Board takes the 11 bit words from the Formatter board and converts them into a pulse width modulation signal which will gate the 20 Mhz carrier from the dual transmitter board giving bursts of 20 Mhz carrier of two precise widths. The output control signals from this board directly control the Dual RF Transmitter board described below.

Dual RF Transmitter Board

The Dual RF Transmitter board simultaneously sends out RF signals to both implants. The bursts of 20 Mhz RF provide both power and stimulation information for the implants. Information to the implant takes the form of narrow pulses of RF representing zeros and wide pulses of RF representing ones.

The RF energy is transferred to the implants via flat disk antennas of coiled wire 2.5 inches in diameter. The antennas are supported directly over the implant and they are tolerant of lateral and vertical misalignment. Each transmitter uses, on the average, 700 milliwatts of power and represents the greatest use of power in the External Controller.

EXTERNAL CONTROLLER FOR PERCUTANEOUS SYSTEM

A second version of the External Controller supports eight channels of percutaneous stimulation. In this configuration, the same CPU board is utilized, but the dual channel RF transmitter, formatter, and Parallel To Serial Converter Boards are replaced by a Percutaneous Driver Board and a Percutaneous Output Amplifier Board. This version supports eight channels of percutaneous leads driving impedances of 1 Kohm each with monophasic pulses with amplitudes in two ranges to 20 or 100 mA and pulse widths ranging from 1 to 300 microseconds. The same protocol for determining stimulation patterns is utilized in this version as are the bulk of the external controller software operating system, however several key driver routines are different to support direct as opposed to RF mediated stimulation.

Percutaneous Driver Board

The Percutaneous Driver Board contains a 16 bit timer, an eight bit pulse amplitude latch and a control register with which the microprocessor can direct the generation of monophasic charge balanced pulses on any of eight leads. The timer uses a 1 MHz time base and can generate pulse widths from 1 to 300 microseconds (the useful range of the output coupling capacitors of the Percutaneous Output Amplifier Board), and generates via an eight bit digital to analog converter control voltage pulses which, when multiplexed, can drive one of eight amplifiers.

Percutaneous Output Amplifier Board

The Percutaneous Output Amplifier Board has eight separate amplifiers and output stages capable of driving 1 KOhm loads with a maximum of either 20 or 100 milliamps of regulated current as directed by a control voltage pulse generated by the Percutaneous Driver Board. Only one channel may be active at a time, as controlled by the multiplexor of the Driver Board.

Output leads are capacitatively coupled with one or two uF ceramic capacitors to isolate the patient from any DC stimulation. Either percutaneous leads and epimysial electrodes may be used with this system, or for evaluation purposes, surface electrodes may be utilized.

## THERAPIST CONTROL UNIT

Communicating to the External Controller worn by the patient will be a Therapist Control Unit. This device is carried by the physical therapist or other clinician walking with the patient during gait runs. With this device, which uses the same CPU board as the External Controller, the therapist is able to locally adjust scale factors for any of the channels of the implanted stimulators, to interrogate the status of the implant system, to trigger or modify the operation of the External Controller, and to generally assist the External Controller in implant or percutaneous system operation. While the External Controller is rather devoid of displays and user modifiable controls, the therapist control unit has a two line, sixteen character alphanumeric liquid crystal display (LCD) and a number of controls which allow extensive interaction between the therapist and the implant/controller system.

## LABORATORY OPERATION

Given a set of control sequences, the patient is asked to walk with the aid of electrical stimulation along the gait walkway. The investigative team, consisting of a clinician with extensive experience in bipedal ambulation and an engineer who is knowledgeable in functional electrical stimulation, will determine what changes should be made in the control sequences to improve walking performance. This decision will be made by observing the patient while he/she is walking and supplementing these observations with the goniometric, footswitch, and when necessary, electromyographic data. Changes to the control sequences are implemented using the graphics terminal and mouse as described above. The patient is then asked to walk again with the assistance of the new set of control sequences. This iterative process is continued until satisfactory performance has been achieved.

Initial estimates of the control sequences can be obtained in one of two ways. One method is to simply draw "a priori" sequences on the graphics display based upon electromyographic records from normals and from ambulatory patients with similar neuromuscular impairments. A second method is to have a physical therapist trained in gait applications of FES to select appropriate on-off controls for the patient by adjusting the stimulus amplitude, delay from trigger and duration of stimulus train for each stimulation channel via a Therpist Control Unit communicating with the implant External Controller during gait. This procedure is used routinely at our facility with multichannel surface electrode stimulators used clinically for gait training. When the "best" set of stimulation parameters has been determined by the therapist, they are transferred to the laboratory computer and used as a starting point for determination of the modulated sequences.

## DISCUSSION

The implantable stimulation system and laboratory described above comprise the latest efforts of Rancho Rehabilitation Engineering Center in the area of gait assist. The system is able to accommodate implantable stimulators, percutaneous leaded electrodes driven by external systems and surface electrodes for the evaluation, therapy, training and functional

application of Functional Electrical Stimulation in patients suffering from spinal cord injury and other related disabilities.

The technology behind the advances made thus far in FES research has taken us from very primative beginnings just twenty-five or so years ago to the threshold of some very exciting and beneficial applications, with the potential to help thousands of patients afflicted with neuromuscular disorders. Technology must now make a quantum leap in much the same manner that cardiac pacemakers did when they matured from transcutaneous external stimulation system to the completely implantable, battery powered, microprocessor controlled devices we see in use today. The efforts of many researchers today to develop the implantable functional neuromuscular stimulators of tomorrow is a very necessary development. The limitations and inherent problems exhibited by surface and transcutaneous stimulation systems must be relegated to those applications which due to cost, or short-lived usefulness cannot benefit from implanted technology.

The system being developed in our facility will hopefully fulfill many of the clinical dreams we have for rehabilitation engineering research. Custom fitting the operation of the implants to the needs of the patients and requirements of future research studies will be a valuable asset to this new and important development in functional electrical stimulation gait assist research. We hope that the flexibility and power of this system will allow research in this vital area to continue at our facility and allow us to make invaluable contributions to this field.

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