A programmable implantable neuromuscular stimulator with novel features

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ABSTRACT

The design of versatile implantable neuromuscular stimulators has been greatly facilitated by the availability of low-power microcontrollers. Such devices normally operate with a fixed output voltage, motor unit recruitment being varied when necessary by modulating the stimulus duration. When control of stimulus amplitude is also required it is usual to include an off-chip digital-to-analog converter. However, this approach adds considerably to overall power consumption. Here we present an alternative off-chip solution. A Field-Programmable Gate Array is used to control the amplitude in steps by generating a high-frequency pulse-width-modulated train. Each output pulse is an envelope formed by integrating a burst of these high-frequency pulses. The microcontroller is used to determine output pulse duration, interpulse interval, burst duration and interpulse interval and controls output pulse amplitude via the FPGA. These parameters are set up on a Personal Computer and transferred to the implanted device via an optical or radiofrequency communication link. Once programmed, the device continues to deliver stimulation with the specified timing and amplitude parameters. Preliminary tests on nerve-muscle preparations indicate that the response to pulse-width-modulated stimuli is consistent with the expected physiological behaviour.

INTRODUCTION

When a muscle is activated by electrical stimulation of its motor nerve, the number of motor units recruited, and therefore the magnitude of contraction, depends on two factors: the duration of the stimulus and its 'strength' or amplitude. (Since the device described in this paper is voltage-controlled, stimulus strength will be expressed in volts.) There is a value for stimulus voltage (rheobase) below which it is not possible to elicit contraction, whatever the conditions. As the voltage increases above rheobase, contraction can be elicited by stimuli of progressively shorter duration (Figure 1). Stimulation apparatus that is designed for the laboratory bench usually incorporates facilities for varying both stimulus voltage and duration. Devices that are designed for implantation usually operate with a fixed output voltage that is at or near the supply voltage, and motor unit recruitment is varied, where necessary, by modulating the stimulus duration in the sub-millisecond range. This approach lends itself more readily to implantable circuitry, which must meet tight specifications, including a very low power consumption (Jarvis & Salmons, 2001).

There are, however, applications in which the contributions of different nerve branches to an overall contraction need to be more finely balanced. In these cases it is desirable to have control of stimulus amplitude as well as duration. An example of this is sequential stimulation, in which separate nerve branches innervating a muscle are stimulated asynchronously in order to achieve a steady contraction at a lower frequency of stimulation (Rack & Westbury, 1969) and to minimise the fatigue that would otherwise occur in continuously active muscles (Zonnevijlle et al., 2000).

The advent of low-power microcontrollers has made it possible to design highly versatile implantable neuromuscular stimulators (Gunning et al., 1996; Salmons, 2001; Salmons et al., 2001). When it is necessary to extend the functionality of these devices to include amplitude control this is usually achieved by adding a digital-to-analog (D-to-A) converter. This solution, however, adds considerably to the overall power consumption of the device. In this paper we wish to suggest an alternative off-chip solution, based on a Field-Programmable Gate Array (FPGA).

CIRCUIT DESCRIPTION

The operating principle may be stated simply: each output pulse is an envelope formed by integrating a burst of high-frequency pulses, and amplitude is controlled in steps by pulse-width modulation (PWM) of the high-frequency train. Although this principle has been employed in other engineering applications, this is, to our knowledge, the first time that it has been applied to the design of implantable stimulators.

A schematic diagram of the implantable portion of the device is seen in Figure 2. It incorporates two 4-bit counters, each of which increment their value on the rising edge of an input pulse. Counter A receives input pulses from a high-frequency source, and counts continuously. Counter B has a fixed value that determines the amplitude of the output. This is set by the microcontroller, which zeroes Counter B and then delivers a predetermined number of pulses to increment it to the fixed value. The two counts are compared in a comparator. For as long as the value in Counter B exceeds that in Counter A, the output is logic high. The output switches to logic low when the value in Counter A exceeds that in Counter B. This results in a pulse whose length can be adjusted in 15 steps, and the output of the comparator is a sequence of such pulses, which comprise the pulse-width modulated train.

An output pulse is generated by gating the PWM train for the required duration, and this is achieved by a pulse delivered by the microcontroller to an AND gate. Figure 3 shows four examples of the output voltage for a gating pulse of 20 μs duration. The insets illustrate the PWM produced by counts of 1, 7, 13 and 15. The output voltage was recorded between two electrodes that had been placed on a frog sciatic nerve in a classical frog sciatic nerve–gastrocnemius muscle preparation. Note that the ripple virtually disappears at the maximum amplitude, corresponding to 15 on the 4-bit counter, because the output of the comparator then maintains a continuous logic high.

Embedded code within the microcontroller determines not only the amplitude and duration of the output pulse but also the interpulse interval, burst duration and interburst interval. The operator sets up these parameters on a Personal Computer (PC) using a Graphic User Interface that has been realised in Borland Delphi. The parameter set is then transferred from the PC to the implanted device via an optical or radiofrequency communication link. A common data structure allows patterns of considerable complexity to be specified without exceeding the on-board memory limitations of the PIC microcontroller. Once programmed, the device continues to deliver stimulation with the specified timing and amplitude parameters without further reference to the external PC. The stimulator can deliver bursts of up to 255 pulses, within which up to 15 of the interpulse intervals can be specified individually from 1 ms to 255 ms. Interburst intervals can be varied from 100 ms to 25 s. Pulse duration can be varied from 20 μs-100 ms.

EXPERIMENTAL EVALUATION

Although the traces recorded in Figure 3 appear to show a considerable degree of ripple it should be borne in mind that these transitions are of short duration compared with the normal events governing the excitation of a nerve. Nonetheless it was necessary to evaluate the effect of such an output on a biological system. The two key questions were:

1. Would pulse-width-modulated stimuli elicit the same response from a biological system as conventional stimuli?

2. Would the response of the biological system follow normal ‘strength-duration curve’ behaviour?

These questions were addressed, at least in a preliminary way, by using the frog sciatic nerve–gastrocnemius muscle preparation already mentioned. The same nerve electrode pair was connected in turn to the output of the pulse-width-modulated stimulator and to the output of a conventional bench stimulator (Devices Ltd., Isolated Stimulator Mk IV). There appeared to be no difference between isometric twitch contractions elicited by stimulus pulses from the two different sources (results not shown).

In a second test we examined the effect of various stimulus pulse durations on the isometric twitch contractions elicited by the pulse-width-modulated stimulator. Stimulus pulses of short duration required larger stimulus amplitudes than pulses of longer duration to produce the same peak twitch force (Figure 4). This behaviour is entirely consistent with expected physiological behaviour, illustrated by the simulated strength-duration curve in Figure 1.

CONCLUSIONS

We have shown that the stimulus amplitude generated by a neuromuscular stimulator can be varied by integrating a pulse-width-modulated train. This approach appears to offer a viable solution to the problem of amplitude control in an implantable stimulator. It can be implemented with an off-chip FPGA, a solution that adds less to the overall power consumption of the device than a D-to-A converter. The prototype device produced the expected physiological effects when tested at the laboratory bench on a frog sciatic nerve–gastrocnemius muscle preparation.

The operating principle embodies certain trade-offs. Elevating the pulse frequency underlying the PWM train would reduce the ripple on the output, but would increase the current drain of the device. Replacing the 4-bit counters with 3-bit counters would also reduce ripple, at the expense of providing fewer amplitude steps. Increasing the time constant for integration would reduce ripple, but would lengthen the rise-time of the output pulses. A suitable compromise has to be reached and this optimization will occupy the next phase of the design process. We will also be undertaking *in-vivo* tests on rabbit hind limb muscles. Finally the device will be constructed and packaged in a form that is acceptable and reliable for implantation (Jarvis & Salmons, 2001).

ACKNOWLEDGEMENTS

The work was supported by the European TMR Research Network ‘NEUROS’ (FMRX-CT96-0021), the European RTD Action ‘RISE’ (QLRT-2000-02191), and the British Heart Foundation (Programme Grant RG/97001).

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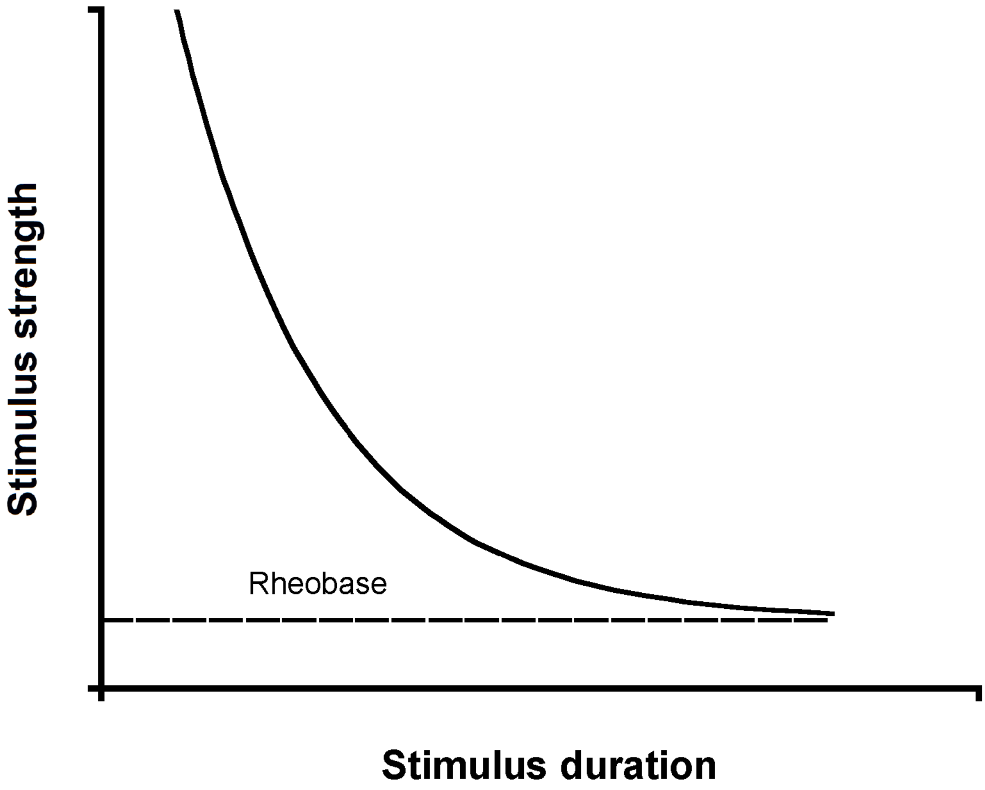
FIGURE LEGENDS

Figure 1. Simulated strength-duration curve for the contractile response of a muscle to stimulation of its motor nerve.

Figure 2. Schematic diagram of stimulator circuit, showing the microcontroller and off-chip elements used to provide control of stimulus amplitude by pulse-width modulation.

Figure 3. Output of the PWM stimulator, recorded between the two nerve electrodes in a frog sciatic nerve-gastrocnemius muscle preparation. Four amplitude steps are illustrated, corresponding to counts of 1, 7, 13, and 15 on the 4-bit counter (insets). Pulse duration is 20 µs.

Figure 5. Twitch contractions of isolated frog gastrocnemius muscle elicited by applying PWM stimuli to the attached sciatic nerve. When the stimulus pulse duration is shorter (upper panel) a larger stimulus amplitude (step number) is required to produce the same contractile response, consistent with the strength-duration behaviour illustrated in



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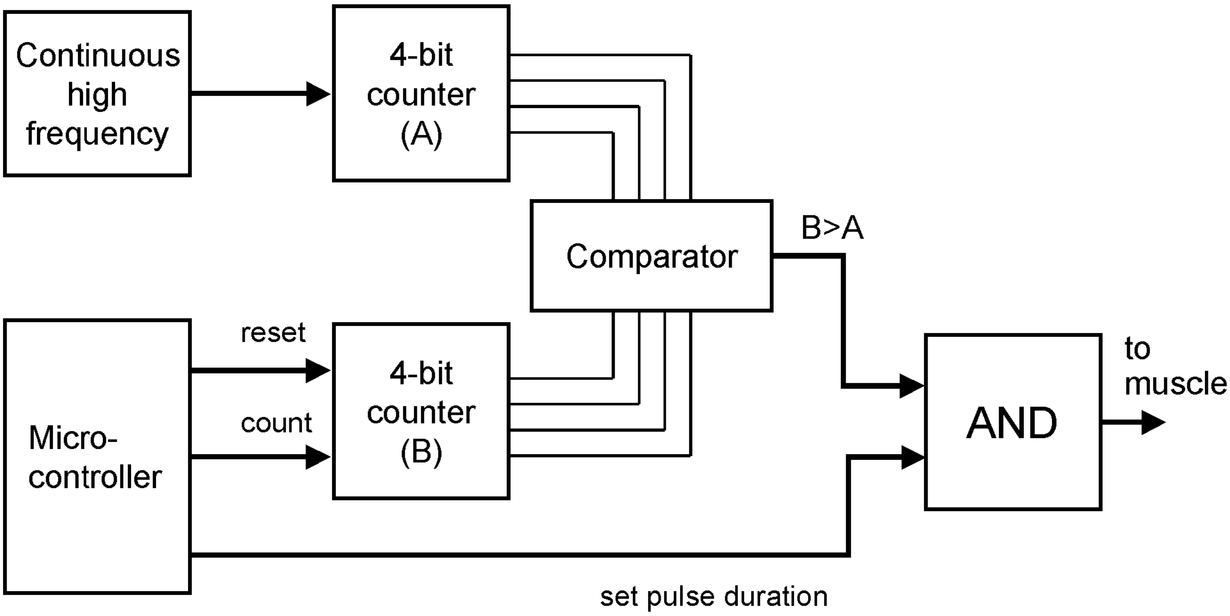

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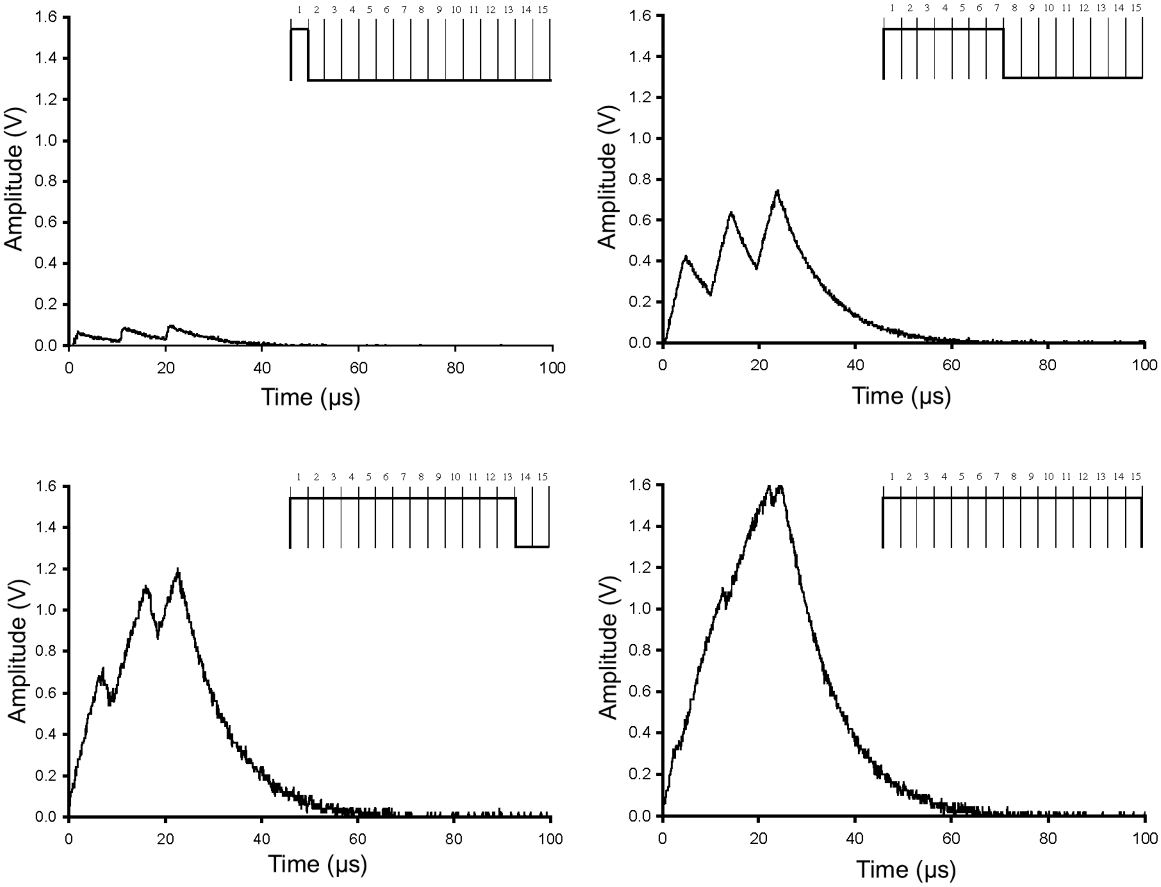

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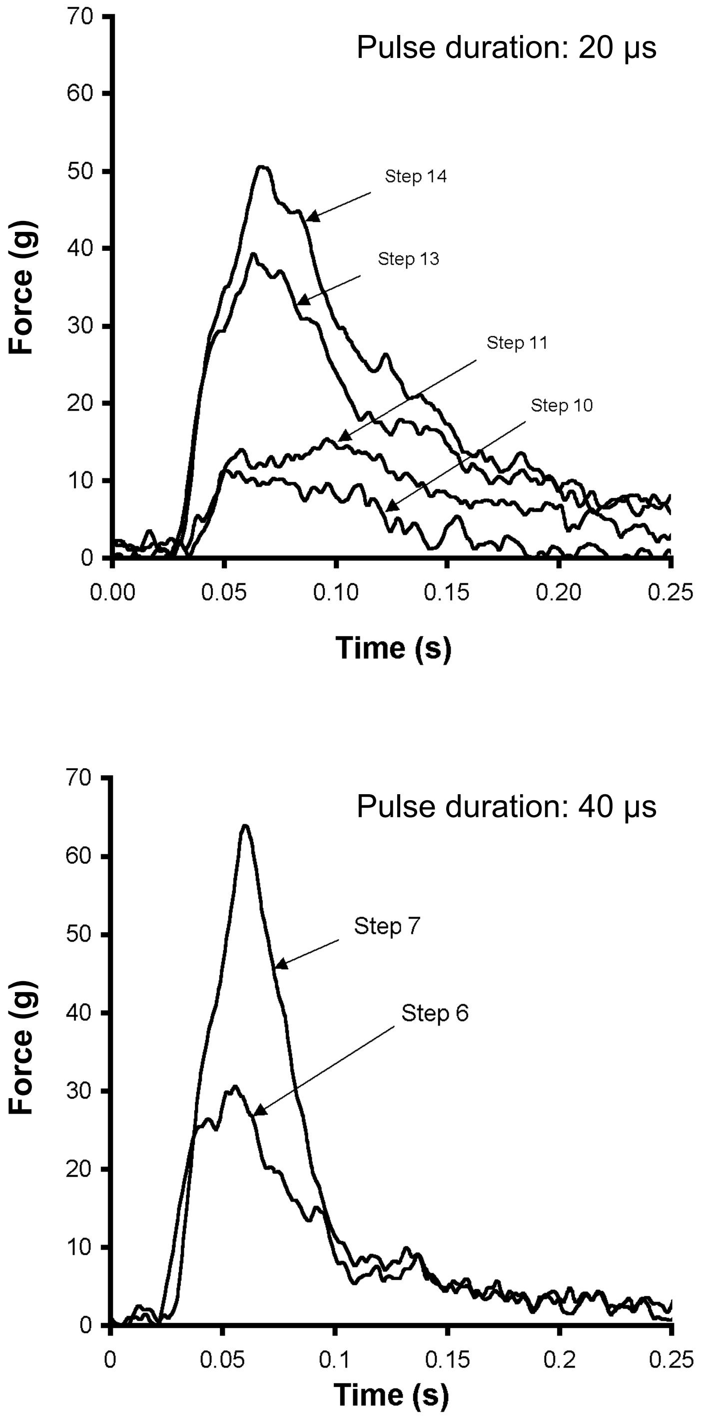

Figure 4. Twitch contractions of isolated frog gastrocnemius muscle elicited by applying PWM stimuli to the attached sciatic nerve. When the stimulus pulse duration is shorter (upper panel) a larger stimulus amplitude (step number) is required to produce the same contractile response, consistent with the strength-duration behaviour illustrated in Figure 1.