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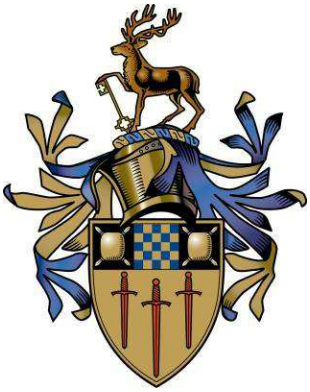

Real-time Electro-tactile Biofeedback for Amputee Gait Re-Training

by

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Presented as part of the requirements for
the Degree of
Doctor of Philosophy

4.4 Design and Development of Electro-tactile Stimulator

4.4.1 Requirements

The stimulator was required to deliver a sensory stimulation waveform with an output current and voltage range that would elicit the expected physiological response from perception to discomfort. Since the physiological response is also a function of electrode geometry, the required ranges were not known. So the design was based on a muscle stimulator design, with the assumption that the output would have a sufficient range for more sensitive sensory stimulation. Therefore the stimulator was required to provide a maximum current output of ± 120 mA, a maximum output voltage range of ± 120 Va.c., an off resistance ≥ 100 MΩ and on resistance ≤ 10 Ω, with no distortion to the waveform, based on Odstock Medical Ltd (2006). An adjustable pulse width was also required (ranging from 1 to 300 μs) as was an adjustable pulse repetition frequency (ranging from 1 to 300 Hz). Electrical stimulators can operate as constant current or constant voltage devices. In the presence of high impedance loads (resulting from poor electrode contact) constant current devices increase the applied voltage to maintain current density, this has potential to produce localised high current densities at the low impedance areas under the electrode, which can cause discomfort. The stimulator was therefore required to operate as a constant voltage device, in which the applied current is reduced. To limit the transfer of ions across skin-electrode interface, the device was required to use a bi-phasic waveform.

A minimum of 8 channels of stimulation were required to provide the spatially symmetrical resolution of the chosen electrode array (in practice a 16 channel device was developed to provide greater flexibility for future work). An interrupt-based emergency stop button was required for the reassurance of the user. To ensure the operator or user had physical control of the output, the stimulation amplitude was to be controlled manually via potentiometers. A PC-based user interface was required to enable control of the stimulator independent of the feedback system, for development and testing purposes. Real-time manual operator control was required to incorporate control of the active electrode selection and the ability to sweep through the electrodes, control the waveform pulse width, frequency and start/stop functions and indication of system status through lights or

PC messaging. As a failsafe measure, handshaking was required between the device and controlling PC to ensure stimulation was stopped in the event of a physical or software fault. To reduce the risk of electric shock from the device while in use, the device was required to incorporate patient isolation and be powered by a battery. The device was designed to comply with BS-EN 60601-1:2006 Medical Electrical Equipment – Part 1: General requirements for safety and BS-EN 60601-2-10:2001: Medical electrical equipment – Part 2.10: Particular requirements for the safety of nerve and muscle stimulators.

4.4.2 Circuit design

The pulse amplifier circuit from an FES stimulator (Odstock Medical Ltd) shown in Figure 29, was used to generate the stimulation waveform. A positive square pulse is delivered to the base of a Darlington driver, via a resistor network. The resistors provide an adjustable base bias to the driver and control the stimulus amplitude. The Darlington pair acts as a current amplifier and switches a 9 Volt supply across the transformer (TR1). TR1 steps up the voltage, providing a voltage controlled stimulus which discharges through the electrodes. A fast switching diode (D1) protects the Darlington driver when the primary field collapses.

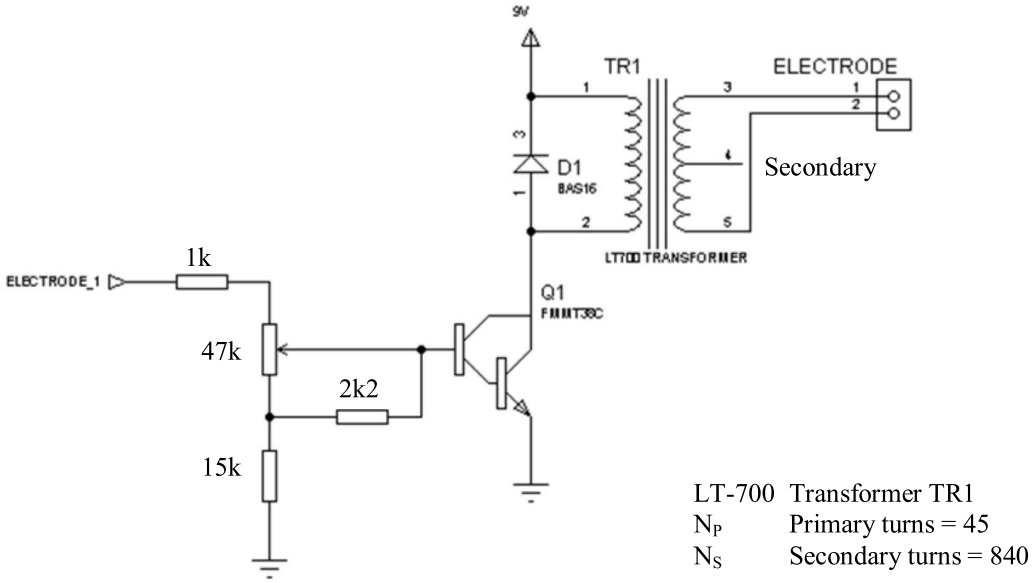

Figure 29 Pulse amplifier circuit

Assuming a purely resistive load of 1kΩ across the electrodes(Grimnes 1983), the reflected impedance (R'_{LOAD}) seen at the primary coil is given by:

$$R'_{LOAD} = R_{LOAD} . \left(\frac{N_P}{N_S}\right)^2 \quad \text{Equation 1}$$

$$= 1000(45/840)^2 = 3\Omega$$

Assuming no heating losses in the iron core, the voltage transformation provided by TR1 is:

$$V_S = V_P . \left(\frac{N_S}{N_P}\right) \quad \text{Equation 2}$$

Where V_P = 9 V minus one diode drop across the Darlington driver

$$= 8.4 \left(\frac{840}{45}\right) = 156.8 \text{ V}$$

The required peak collector current (I_C) is therefore:

$$I_C = \left(\frac{V_P}{R'_{LOAD}}\right) \quad \text{Equation 3}$$

$$= \left(\frac{8.4}{3}\right) = 2.8\text{A}$$

This is switched to the transformer primary by the Darlington driver. From the 5V regulated supply, the base current and voltage are controlled via a potentiometer across the resistor network giving:

$$V_B = \text{Vs} - 1.4 \quad \text{Equation 4}$$

$$= 0 \text{ to } 3.6 \text{ V}$$

and $I_B = 0$ to 3 mA

The required 2.8 Amp collector current is produced (with h_{FE} = 1000). The resulting waveform, shown later in Figure 36, is biphasic and asymmetrical due to first order RL characteristics of TR1.

The current transformation across Tr1 is:

$$I_S = I_P . \left(\frac{N_P}{N_S}\right) \quad \text{Equation 5}$$

$$= 2.8 \left(\frac{45}{840}\right) = 150 \text{ mA}$$

The Darlington driver has a rated peak current of 800 mA, however since the waveform is pulsed at a maximum of 300µs the device does not overheat. If a fault were to occur the Darlington would act as a fuse and prevent longer pulses being delivered to the patient.

Control was provided by a PIC16F876a microcontroller (Microchip, Arizona USA). The circuit outline is shown in Figure 30 (schematics are included in Appendix E1). The 16F876a is an 8-bit CMOS microcontroller in the mid-range family of Microchip products. It has 8 kBytes of enhanced flash program memory which enabled programming and debugging in-circuit, using a 35-word instruction set.

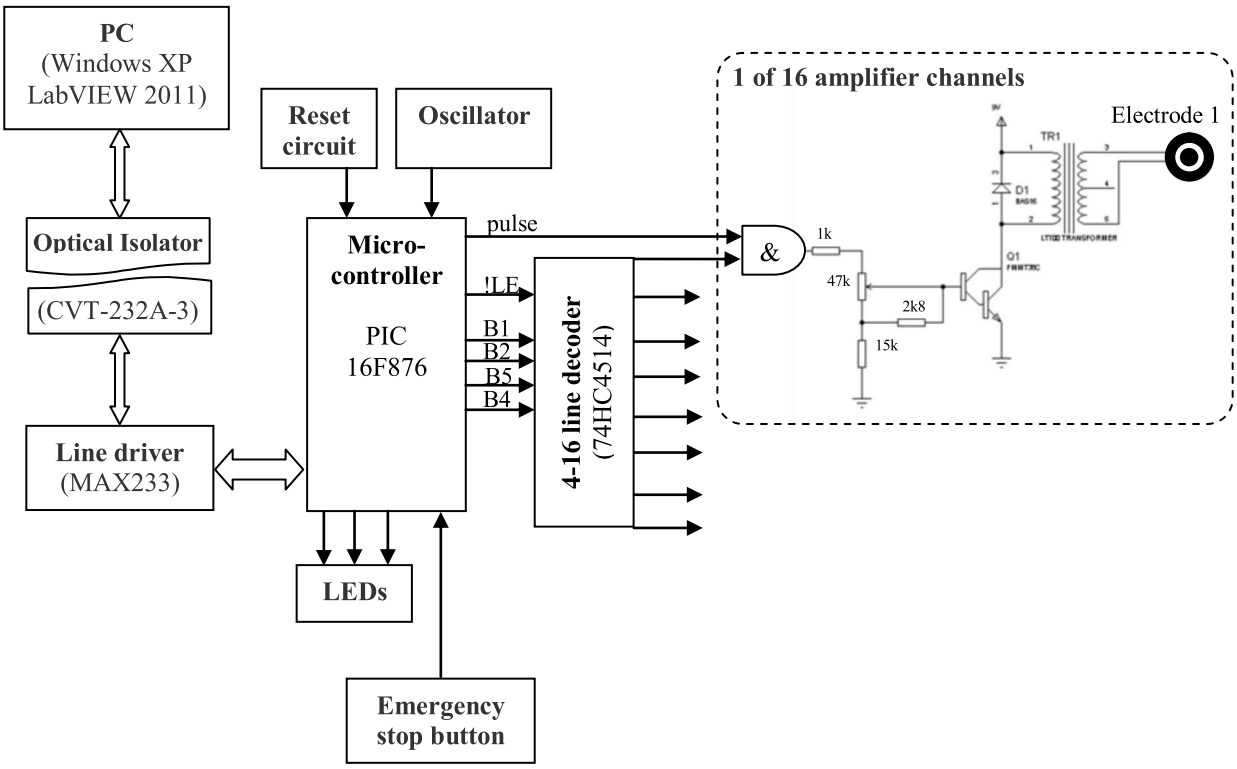

Figure 30 Stimulator control circuit

The stimulator was not required to store or transmit large pages of data, so the memory requirement was minimal. The 16F876a provided 256 Bytes of EEPROM for data and 368 Bytes of SRAM organised into 4 banks, it contained general purpose and special function registers. An external crystal oscillator (IQXO-22) was provided to enable the PIC to operate at 20 MHz. An instruction cycle (one fetch-execute cycle) takes 4 clock pulses, so 20 MHz provided an internal clock of 5 MHz (or 0.2 μs instructions).

The device has a 22 I/O channels arranged in 3 ports (2x8-bit and 1x6-bit port) that include a number of secondary features: 2 10-bit analog-to-digital converters, 2 timers and 2 capture/compare/PWM functions, in addition to a number of firmware and hardware interrupts. 4 pins from port B were de-multiplexed using a 74HC4514 4-to-16 line decoder, to provide the channel selection signals. These were then AND'd with a pulse generation signal (using a 74HCT08 quad 2-input AND gates) to provide the switching signals required by the Darlington drivers.

The PIC has a synchronous serial port which can be configured as a Serial Peripheral Interface or an Inter-Integrated Circuit bus, and a Universal Asynchronous Receiver Transmitter (USART). A USART was defined and connected to a line driver (MAX 233) to convert between TTL and RS232 signal levels (unlike the MAX232, the MAX233 does not require any external components). An interrupt pin (using a change on rising edge) was used as an input for a manual push button, which was used as an emergency stop. Three LEDs provided an indication of system status – red indicted a positive supply voltage, green gave an output according to the serial communication and hence indicated communication was taking place, and a blue LED was provided for development and debugging use. Remaining pins were set as outputs and connected to header pins.

Power was provided by an 8.4 Volt 1/3Ah PP9 Ni-Cd battery (RS229-059), which was regulated using a series positive voltage regulator (MC78M00). Use of a battery eliminated connection to a mains power supply. Patient isolation was also achieved by isolating the stimulator from the computer using a RS-232 optical isolator (CVT-232A-3 CommFront Communications, Singapore). The isolator was rated at 2500 Vrms for 1 minute. During

development and testing the stimulator was mains powered and isolated using a residual current device.

The circuit functions were split across two single-sided printed circuit boards: one contained the digital control functions, the other contained the analogue amplifiers. They were housed in a large instrumentation case, with the LEDs and potentiometers accessible to the operator, as shown in Figure 31. One of the output header pins emerged through the case for use as a test pin.

Figure 31 Completed stimulator, front (top) and back (bottom)

4.4.3 Firmware implementation

Code was developed using the MPLAB v.8.0 Integrated Development Environment (IDE) (Microchip Technology Inc. Arizona, USA) and the CCS c compiler (Custom Computer Services Inc., Wisconsin USA). Both of which are dedicated for the PIC range of microcontrollers. A PICSTART Plus Programmer was used to program the microcontroller. The organisation of programming elements and associated files is shown below (Figure 32).

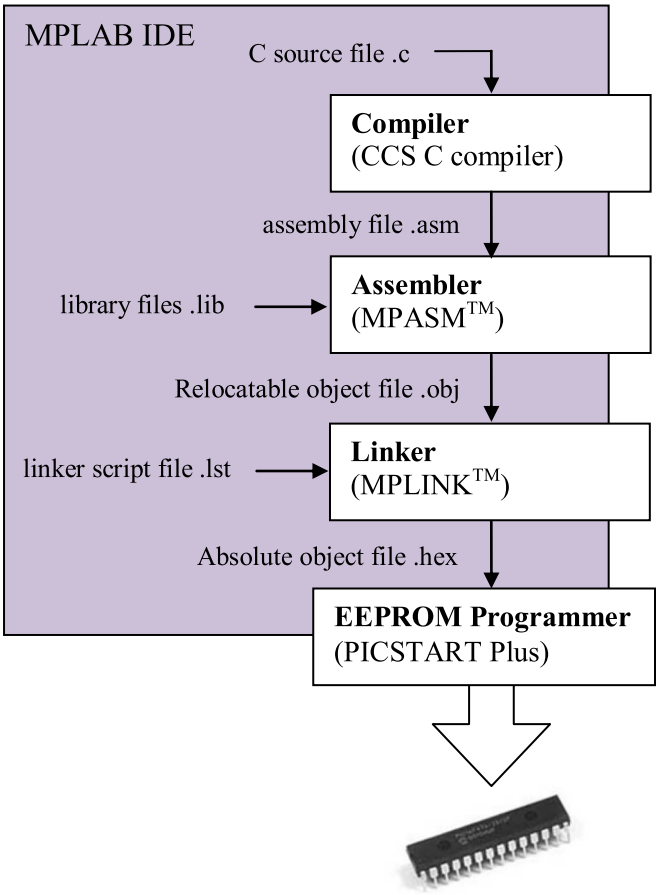

Figure 32 Programming flow for the PIC microcontroller

On power up the stimulator outputs are held low to ensure no transient outputs are sent to the Darlington driver bases prior to operation. To ensure clarity in the code, a simple state machine was used with two states: "`STIMULATING`" and "`STOPPED`", as shown in Figure 33. The stimulator initially enters the `STOPPED` state following power up and

during operation remains in either state until a new command is received by the PC, or via the emergency stop button.

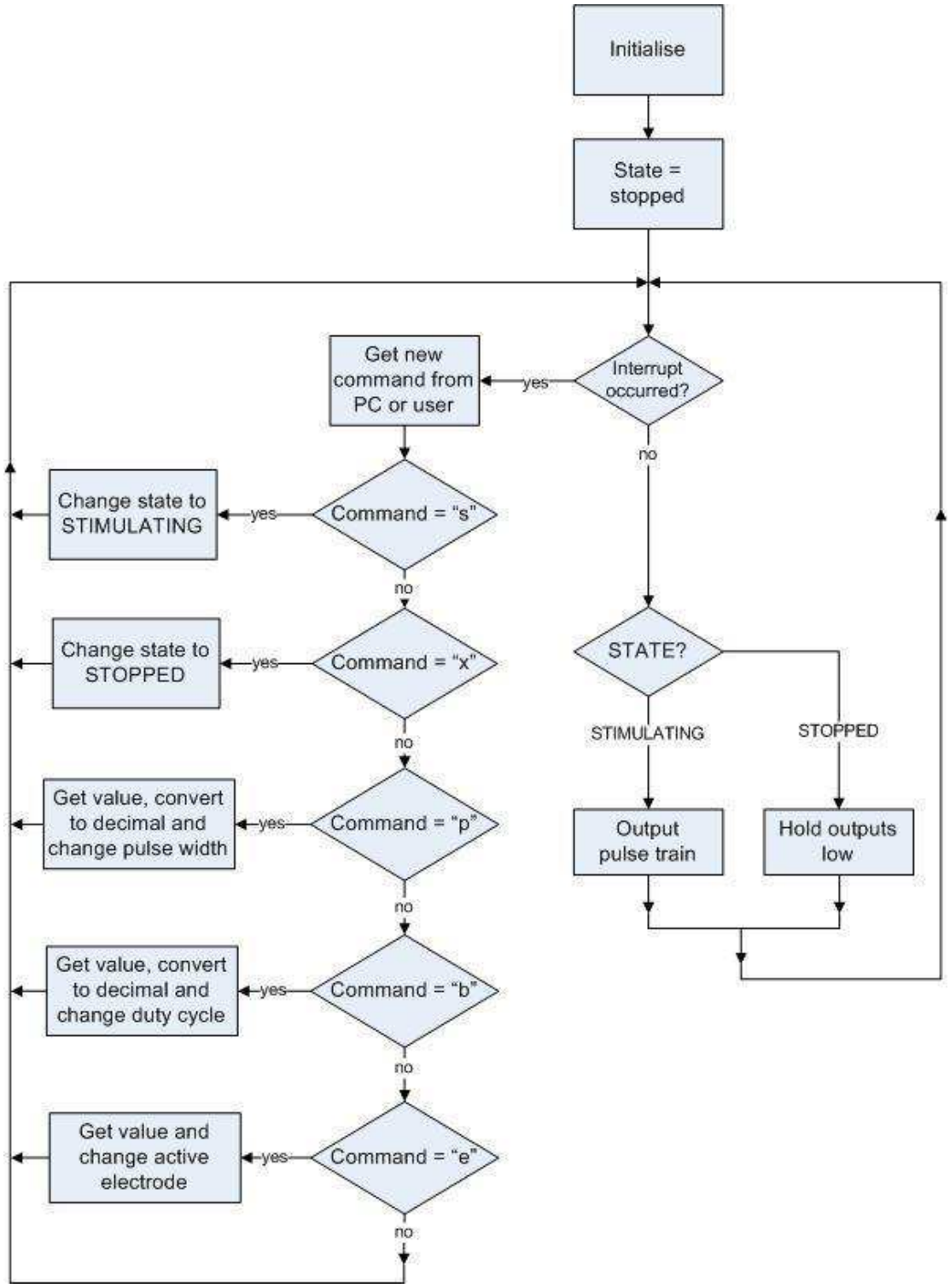

Figure 33 Microcontroller code flow

Commands were received via the onboard USART port using an interrupt. Valid commands were identified as ASCII characters followed by the requested value (Table 5).

Table 5 Communications protocol: Codes sent from PC to the microcontroller

ASCII code	Associated Value	Command
"h"	None	'Say Hello' to PC
"s"	None	Start stimulation
"x"	None	Stop stimulation
"p"	0-300 (μs)	Change pulse width on time
"b"	0-999999 (μs)	Change pulse train off time
"e"	0-99	Change active electrode

The "s" command places the stimulator in the `STIMULATING` state, whereupon the output is pulsed if valid waveform parameters have been provided (by commands "p", "b" and "e"). The "x" command and the emergency stop button place the stimulator back in the `STOPPED` state. A character is sent back to the PC when the emergency stop button is used, to inform the operator. The following ASCII characters are sent to the PC to inform the user of system operation (Table 6).

Table 6 Communications protocol: Codes sent from the microcontroller to the PC

ASCII code	Associated Value	Output
"A"	none	Device is in the `STIMULATING` state
"B"	none	Device is in the `STOPPED` state
"C"	none	Emergency stop button pressed
"D"	0-99	Active electrode in use*
"H"	none	The text "Hello"is sent

* Used only during system development, confirmation of electrode number unnecessary in normal operation

Handshaking - occurred between the PC and microcontroller to ensure the user had control of the stimulator. After initialization, a flag was set true each time a valid command was received by the stimulator and set false after 500 ms had expired. Between sending waveform parameter commands the PC sent "h" commands to the stimulator to ensure the timer did not expire and the microcontroller responded with "H". If, for example, the RS232 cable was accidentally detached or a power fault occurred that prevented communication, the timer expired, the stimulator would enter the "`STOPPED`" state and the PC would inform the user. Stimulation would therefore only be delivered if the valid

waveform parameters had been received, the start command had been given and a valid command was received every 500 ms.

Timing – A baud rate of 38400 bps was chosen, which was found to be sufficiently high, permitting enough time for approximately 1000 electrode location changes per second (i.e. 38400 bps = 26 µs per bit, one electrode change command required 40 bits = 1ms, including parity and data bits).

4.4.4 Stand-alone PC code implementation

LabVIEW 2010 (National Instruments, Texas, USA) was used to develop the PC-based user interface, as shown below (Figure 34). The user had control of the pulse repetition frequency (from 1 to 100 Hz), the pulse width (from 1 to 300 µs) and selection of the active electrode. Electrode selection was either manually controlled using a dial to allow continuous transitions between electrodes; or through a pre-set routine that allowed the user to set clock-wise or anti-clockwise movement of the stimulus at user-defined speeds. Connection status was displayed, as were the commands sent to and from the stimulator (if enabled) for development.

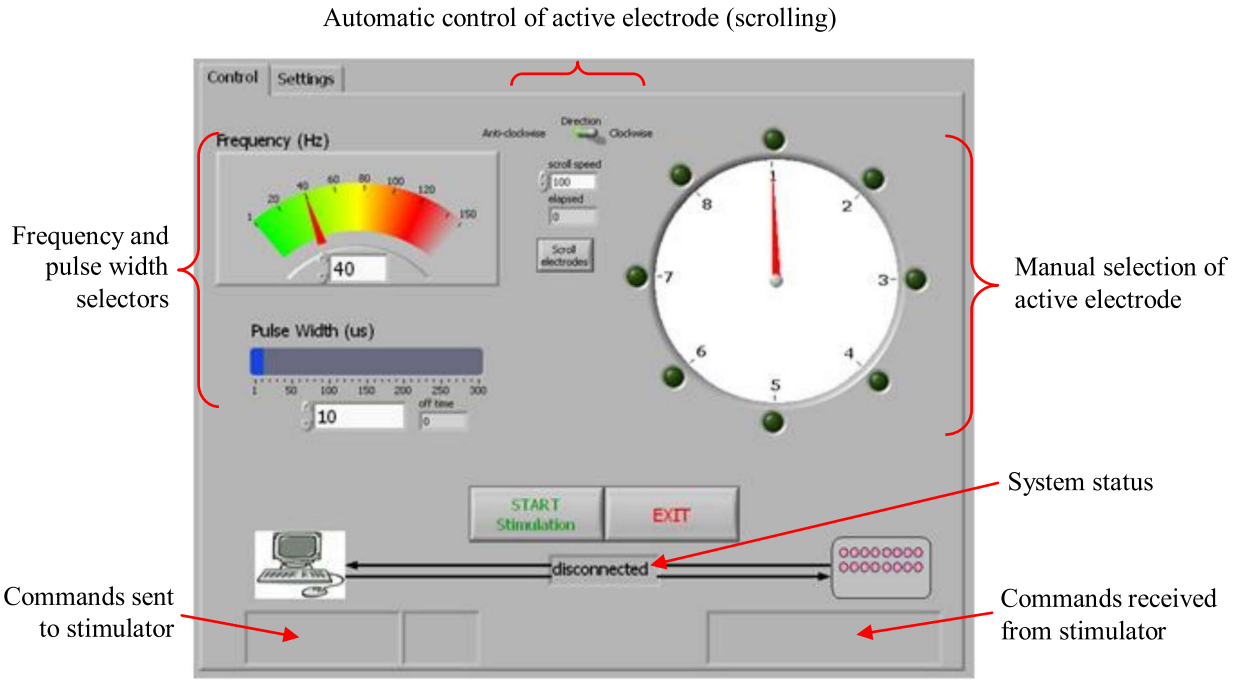

Figure 34 Stimulator graphical user interface

The software used an event-driven producer/consumer design pattern, to ensure the user interface and communication functions operated concurrently and in a controlled manner. Referring to Figure 35, after initialisation (1) an event structure responds to user interaction (buttons presses and mouse movements) by placing each event on a queue (2) thus *producing* internal commands. Events are read or *consumed* from the queue in parallel to this, and the appropriate communication takes place with the stimulator (3). Continuous and independent handshaking occurs throughout (4).

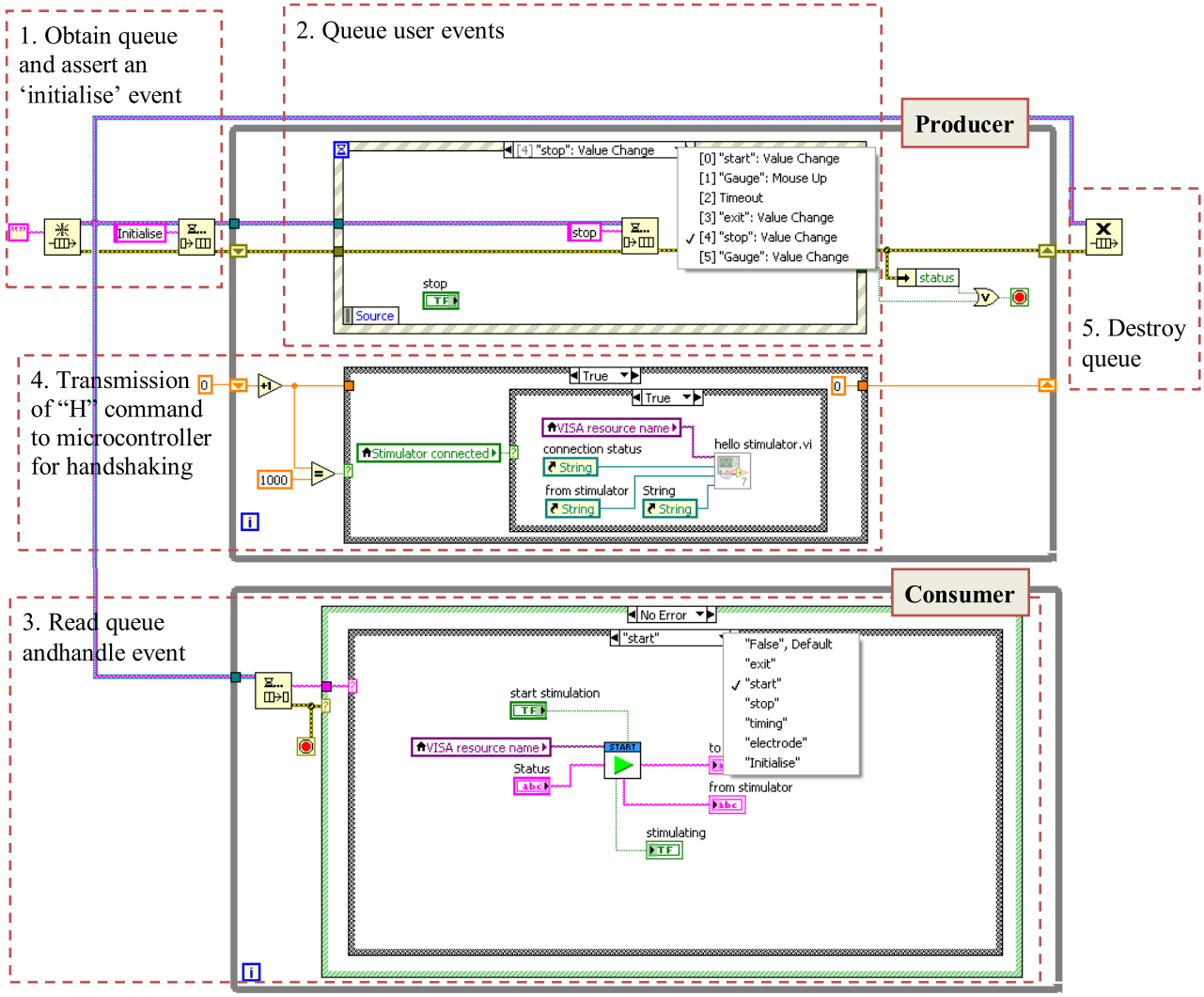

Figure 35 Software control of stimulator

4.5 Stimulator Testing

Electrical testing -Before use with subjects the circuit boards were electrically tested. To then determine the consistency of the outputs across each stimulation channel, a 1kΩ purely resistive load was applied across each channel. The stimulator was set to output a 40 Hz pulse with a width of 300 µs and the amplitude was manually set to a maximum. The output across each electrode load was captured and the pulse widths, peak amplitudes and frequency were measured. Figure 36 shows the output from each of the 16 channels. Table 7 shows the measured values for pulse width and peak amplitude. The frequency was found to be consistently 40 Hz as expected.

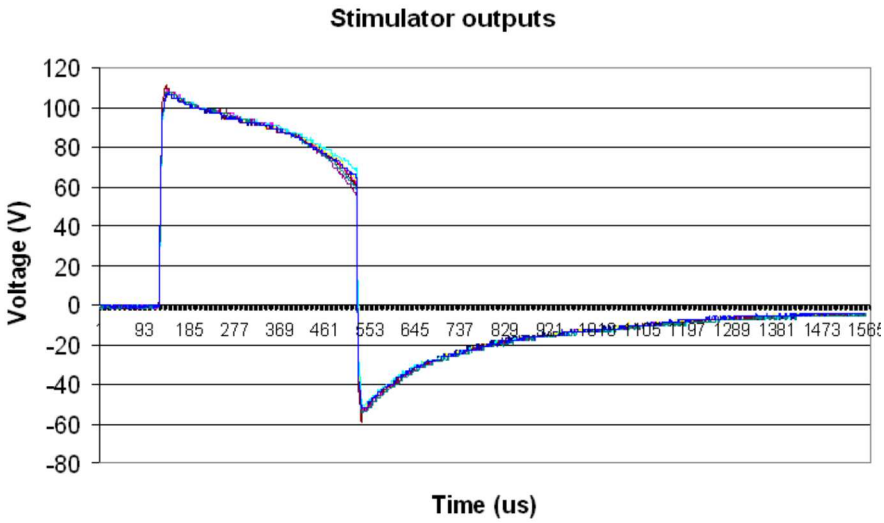

Figure 36 Output from stimulator across 1kOhm load (all 16 channels are shown superimposed)

Table 7 Waveform characteristics for each channel across a 1kOhm load

Channel	1	2	3	4	5	6	7	8
Pulse width (µs)*	299	299	299	299	299	299	299	299
Amplitude (V)	121.3	109.2	109.2	107.7	107.7	110.7	107.7	107.7

The pulse width was consistently measured to be 299 µs. Measurements were made using the digital oscilloscope PC-based software Picoscope 5.21 (Pico Technology Ltd, UK). The available resolution with the cursor on screen in this case only permitted accuracy within 2 or 3µs, and approximately 2 V (when the zoom window covered the complete signal). The amplitude ranged from 107.7 to 121.3 V, which is a difference of 13.6 Volts or 6 % variation across all channels. Again given the grouping of the values around 107.7

and 109.2, it is possible this falls within the achievable precision of the measurement software. The shape of the waveforms remained consistent and as predicted. Finally to ensure no cross-talk between channels, each stimulator output was viewed whilst adjacent electrodes became active. No cross-talk was found.

Software testing– In addition to a firmware loop-back test, a number of software checks were carried out. The function of each operator command was checked whilst observing the pulse trains of commands sent to and from the stimulator (known as white box testing). Attempts were then made to cause software faults through robustness testing. Operator functions were rapidly and repeatedly called, and in random order. Non-valid fields were entered into all controls, for example the pulse-width values were limited to prevent the Darlington drivers overheating. To ensure the likelihood of stimulation being delivered on start-up, the start-up process was carried out under a number of different fault and false conditions. For example: without PC control. The system was found to perform as expected, and found to be robust to unplanned operation. This is in part due to the tight control of the user interface (user buttons were only made visible and active when appropriate, and all controls had pre-set limits defining their range of operation), and in part due to the combination of using a state machine in the microcontroller and an event-driven producer/consumer design pattern, both of which force a clear path through the code without the use of ambiguous `goto` commands or program branches.

Safety testing – Medical devices are required to comply with the EU harmonised standard BS-EN60601. Whilst the stimulator is not a medical device, it is important to ensure comparative safety testing was carried out before the stimulator was used with human participants. In addition to the functional tests described above, a visual inspection was carried out internally and externally to identify faults. The inspection included a check of the following and no faults were found: Damage or cracks to the enclosure; cuts in the cabling, misconnections, exposed wires or incorrect colour coding, marking and labelling, integrity of the fascia, the integrity of or obstructions to the electrode connectors and emergency stop button.