A FES DEVICE DEVELOPED FOR TREATING DROP FOOT

by

Aykut YAVUZ

B.S., E.E., Yıldız Technical University, 2002

Submitted to Institute of Biomedical Engineering

in partial fulfillment of the requirements

for the degree of

Master of Science

in

Biomedical Engineering

Boğaziçi University

February 2006

ACKNOWLEDGMENTS

I would like to take this opportunity to acknowledge those who have provided the help and guidance to complete this work.

First and foremost I would like to thank to my supervisor Assoc. Pr. Dr. H. Özcan Gülçür for his help and support. I am very grateful for his encouragement, motivation and patience throughout my thesis work

I am also grateful to Prof. Dr. Ömer Cerid and Assist. Prof. Dr. Can Yücesoy for their vital suggestions and for being a member of my thesis committee.

I would like to thank to Gülay Gül and N. Ekin Akalan for sharing their experience and giving helpful suggestions.

I also would like to thank to Ömer Şaylı and O. Serdar Doğruluk for their help and support.

Finally, I would like to thank my family for their endless support, encouragement and patience.

ABSTRACT

A FES DEVICE DEVELOPED FOR TREATING DROP FOOT

Multiple sclerosis, stroke and peripheral neural disorders affect the central nervous system and cause various nervous and muscular disabilities. One of these disabilities is called drop foot, which prevents the patient from raising the foot at the ankle and effectively swinging the leg when walking. This situation can be corrected by using muscle stimulators and synchronizing functional electrical stimulation of the common peroneal nerve to the swing phase of the gait cycle.

This thesis presents a portable, two channels, functional electrical stimulator that was designed and developed to assist drop foot patients during walking. The device has two independently programmable constant current outputs, which can produce biphasic pulses having pulsewidth up to 350 μs and amplitude up to 100 mA. A microcontroller core controls all of the parameters. A new program code has been written for controlling stimulation parameters and storing them for a future application. The system can be programmed using pushbuttons and an LCD display. A foot switch worn by the patient, under the heel, is used for getting feedback control for stimulation timing during the gait cycle. This foot switch triggers the output channels to stimulate the related muscles through electrodes that are placed over the nerves. Various tests have shown that our system is reliable and the performance of the design is satisfactory enough.

Keywords: Functional electrical stimulation, drop foot, muscle stimulation.

ÖZET

DÜŞÜK AYAK TEDAVİSİ İÇİN GELİŞTİRİLEN İŞLEVSEL UYARI CİHAZI

Multipl skleroz, felç ve periferik sinirlerde zedelenme gibi bozukluklar merkezi sinir sistemini etkilemekte ve çeşitli sinirsel ve kassal sakatlıklara sebep olmaktadır. Bu sakatlıklardan biri, hastanın ayağını ayak bileğinden yukarıya kaldıramaması, yürüme sırasında bacağın etkili bir biçimde salınmasının engellenmesidir. "Düşük ayak" olarak adlandırılan bu durum kas uyarıcıları kullanılarak ve peroneal sinirin, yürüme döngüsüne göre zamanlanmış işlevsel elektrik uyarımı ile düzeltilebilmektedir.

Bu tezde, düşük ayaklı hastaları yürüme sırasında desteklemek amacıyla tasarlanıp geliştirilmiş portatif, 2 kanallı bir sistem sunulmaktadır. Cihazda birbirinden bağımsız olarak programlanabilen, genişliği 350 mikro saniyeye ve genliği ise 100 mili ampere kadar çıkabilen çift yönlü darbeler üreten, sabit akım çıkışları bulunmaktadır. Tüm parametreler merkezdeki bir mikro denetleyici ile yönetilmektedir. Uyarı parametrelerinin kontrolü ve bu parametrelerin gelecekte tekrar kullanımı için saklanabilmesini sağlayan yeni bir program kodu yazılmıştır. Sistem bir sıvı-kristalli ekran ve basmalı düğmeler yardımı ile programlanabilir. Yürüme evresi içerisinde uyarıların ve denetimin uygun biçimde zamanlanabilmesi için topuk altına yerleştirilmiş bir "ayak anahtarı" geri besleme denetimi için kullanılmıştır. Bu ayak anahtarı, sinirler üzerine yerleştirilen elektrotlar aracılığı ile ilgili kasları uyarmak üzere çıkış kanallarını tetikler. Yapılan deneysel testler cihazın güvenilir olduğunu ve tasarımın performansının yeterince memnun edici olduğunu göstermektedir.

Anahtar kelimeler: İşlevsel elektrik uyarımı, düşük ayak, kas uyarımı

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

A/D	Analog-to-Digital
Ach	Acetylcholine
AFO	Ankle foot orthoses
DC	Direct current
DFS	Drop foot stimulator
DIP	Dual in-line package
EEPROM	Electrically erasable programmable read-only memory
EMF	Electromotive force
FES	Functional electrical stimulation
GND	Ground
GRF	Ground reaction force
HS	Heel strike
I/O	In/Out
ICD/ICSP	In-circuit serial programming/In-circuit debugger
LCD	Liquid crystal display
O2CHS	Odstock two channel stimulator
ODFS	Odstock dropped foot stimulator
PWM	Pulse width modulation
R/W	Read/Write
RAM	Random access memory
TO	Toe off

1. INTRODUCTION

Drop foot is a problem that disables a person's ability to raise the foot by moving the ankle. Generally, these patients are unable to move the foot inward or outward and point the toes toward the body. This situation prevents the patient from effectively swinging the leg when walking. Patients slap the foot on the floor or their toes drag on the ground. This leads to an inefficient and unsafe gait. They either develop a high stepping gait or drag the foot and toes on the ground when walking. The increased effort involved not only means that walking is slow, tiring and unsafe but also leads to further increase in spasticity. Drop foot is not a disease but a symptom of another problem. It is a common problem for stroke patients or patients with other neurological conditions including incomplete spinal cord injuries, multiple sclerosis and traumatic brain injury. It is caused partly by poor active motor control of the anterior tibial muscles and partly by spasticity of the calf muscles. An important feature of this situation is that the electrical excitability of the associated peripheral nerves is still intact, thus facilitating the use of functional electrical stimulation (FES) to restore or enhance gait [1]-[2]-[3]. Using FES for the correction of drop foot has been used since early 1960s when Liberson proposed application of electrical stimulation to the common peroneal nerve [4].

1.1 Motivation

The most important motivation is to assist people who are having gait disabilities and minimize the effect of their disabilities in everyday life. The main goal of this thesis is to apply engineering principles and current microcontroller technology to develop a FES system with feedback control to assist drop foot gait. This system would be able to sense the phases in the gait cycle and produce dorsiflexion of the foot by the electrical stimulation of the common peroneal nerve. Microcontroller technology is preferred in this application instead of a hard-wired FES because it offers a user-friendly, programmable implementation of multichannel stimulation. Moreover, it simplifies circuit design and results in reduced overall cost. Another advantage is the flexibility of the stimulator circuit, since it has the capability to be programmable. Different algorithms would require only software change; no hardware changes would be necessary.

1.2 Outline of the Thesis

Chapter 2 provides a detailed background and literature review of topics that are related to this thesis. Basic theory of muscle and nerve physiology, that are relevant to the studied topic and human gait properties are explained in the first part of this chapter. Then the *drop foot* problem and current technologies for assisting this problem are reviewed. Chapter 3 describes the hardware design of the Functional Electrical Stimulator (FES) developed. General properties of the designed stimulator and the system components are explained in detail. Chapter 4 describes the software developed for Pic16f876 microcontroller used in this design. Program architecture and stimulation routines are described. In chapter 5, experimental results that were recorded from artificial body loads are given to be able to evaluate the output characteristics of the designed stimulator. Chapter 6 discusses the results and conclusions of this work and provides recommendations for future work.

2. BACKGROUND

This chapter provides the background information on topics on the basic physiological structures that takes part in muscle stimulation and their electrical properties. An overview of human gait, the effects of drop foot and a brief history of technologies used for treating drop foot are summarized.

2.1 Physiological Background

For a skeletal muscle fiber to contract, it must be stimulated by a nerve ending and must propagate an electrical current, or action potential, along its sarcolemma. This electrical event causes a transient rise in intracellular calcium ion levels, which is the final trigger for contraction [5].

2.1.1 Muscle fiber

Skeletal muscle is made up of cylindrical muscle fibers (Figure 2.1). Each skeletal muscle fiber is a long cylindrical cell with multiple nuclei arranged just beneath its plasma membrane surface. Multiple nuclei arise from the fact that each muscle fiber develops from the fusion of many cells (called myoblasts). Each muscle fiber contains thousands of myofibrils, which are the contractile elements of skeletal muscle cells. Bundles of muscle fibers are called fascicles.

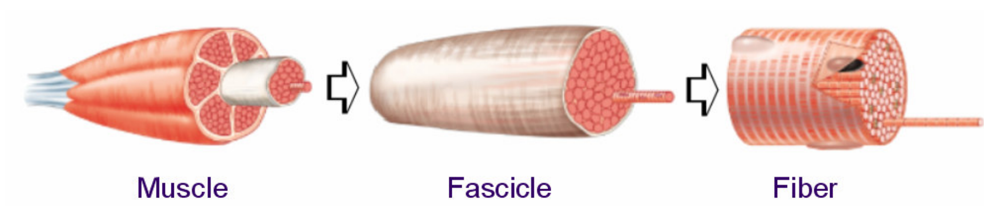


Figure 2.1 Structure and organization levels of a skeletal muscle [5].

Since a muscle fiber is not a single cell, its parts are often given special names such as sarcolemma for plasma membrane, sarcoplasmic reticulum for endoplasmic reticulum, sarcosome for mitochondrion and sarcoplasm for cytoplasm (Figure 2.2).

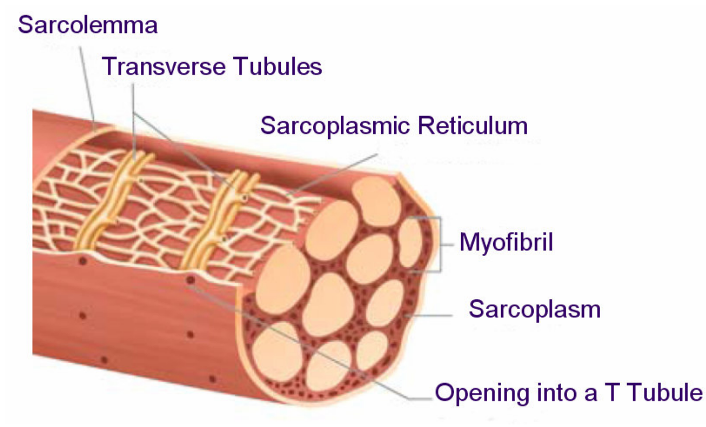


Figure 2.2 Components of a skeletal muscle fiber [5].

2.1.2 Neurons

Neurons are the basic structural and functional units of the nervous system. They are specialized to respond to physical and chemical stimuli, conduct electrochemical impulses, and release chemical regulators. Neurons have three principal regions: A cell body, dendrites, and an axon (Figure 2.3).

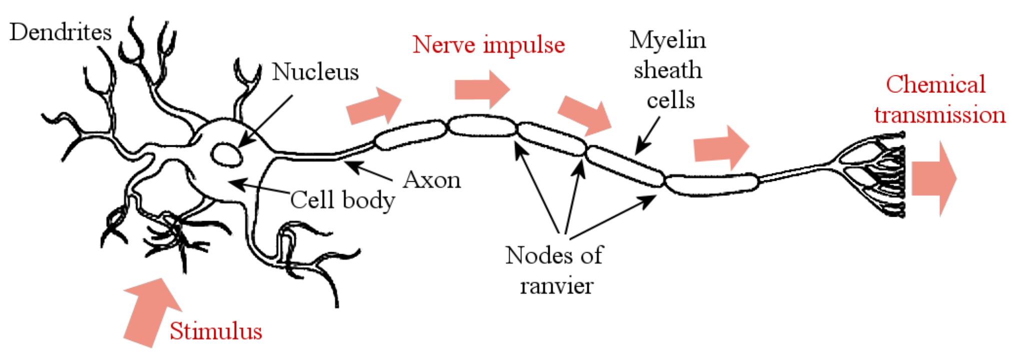


Figure 2.3 Structure of a typical spinal motor neuron [6].

The cell body contains a nucleus; it is the nutritional center of the neuron where macromolecules are produced. Dendrites provide a receptive area that transmits electrical impulses to the cell body. The axon is a longer process that conducts impulses away from the cell body. The axon terminal takes part in chemical transmission by releasing neurotransmitters [7].

2.1.3 Regulation of contraction

Although motor neurons reside in the brain or spinal cord, their axons travel, bundled within nerves, to the muscle cells they serve. Each muscle fiber receives a single axon terminal from a somatic motor neuron. These types of neurons are responsible for both reflex and voluntary control of skeletal muscles. One motor neuron can innervate one or multiple fibers [5]. The axon of each motor neuron divides profusely as it enters the muscle, and each of these axonal endings forms a branching neuromuscular junction with a single muscle fiber. Each muscle fiber has only one neuromuscular junction in its approximate middle (Figure 2.4).

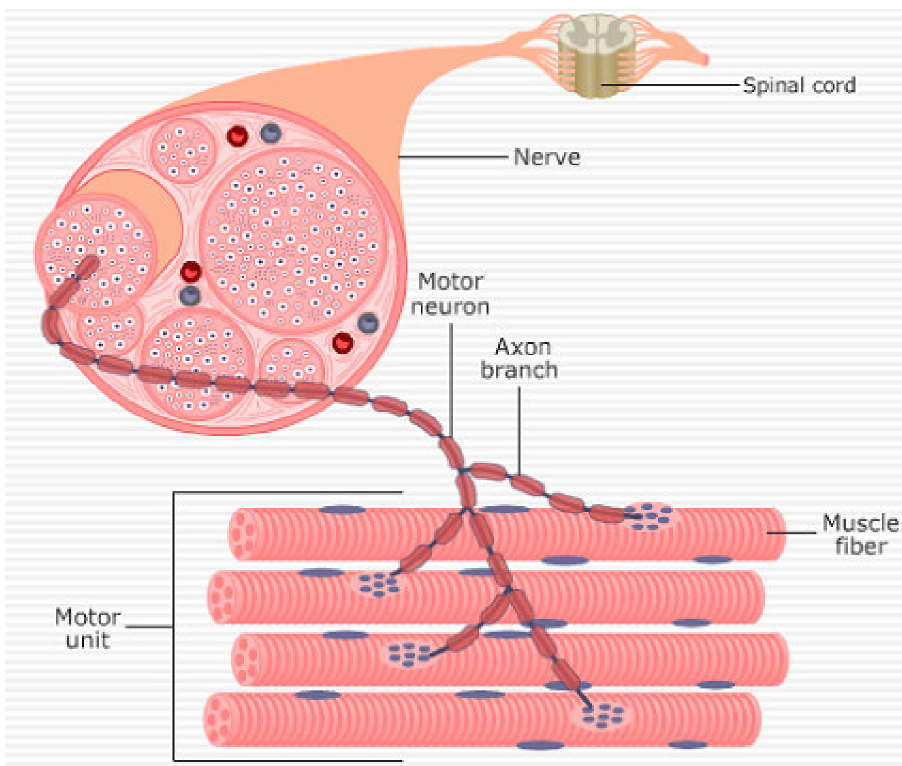


Figure 2.4 The motor unit. Each motor unit consists of a motor neuron and all of the muscle fibers it innervates [8]

Although axonal ending and the muscle fiber are exceedingly close, they do not touch, but remain separated by a space called the synaptic cleft (Figure 2.5). The synaptic cleft is filled with a basal lamina, which is a substance rich in glycoprotein. Within the axonal endings are synaptic vesicles containing a neurotransmitter called acetylcholine (Ach) [5].

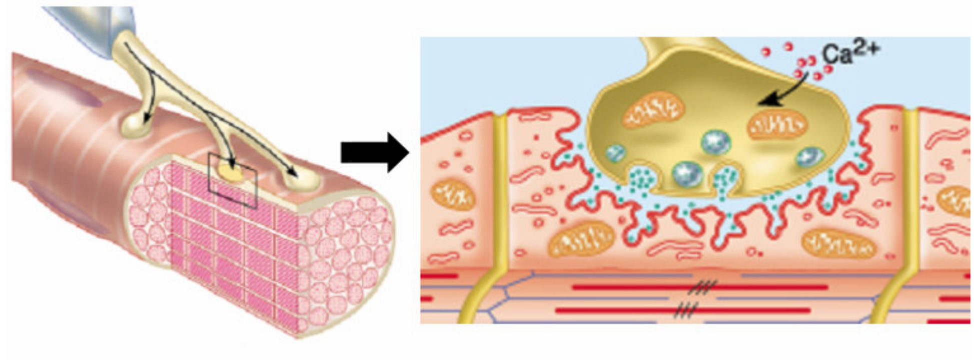


Figure 2.5 The neuromuscular junction and the axonal ending of a motor neuron forming a neuromuscular junction with a muscle fiber [5].

When a nerve impulse reaches the end of an axon, voltage-regulated calcium channels in its membrane open; allowing calcium to flow in from the extra cellular fluid. Once inside the axon terminal, calcium causes some of the synaptic vesicles to fuse with the axonal membrane and release Ach into the synaptic cleft by exocytosis. Ach diffuses across the cleft and attaches to Ach receptors on the sarcolemma.

Like the plasma membrane of all cells, a resting sarcolemma is polarized as seen in Figure 2.6. There is a voltage across the membrane and the inside is negative. Binding of Ach molecules to appropriate receptors on the sarcolemma opens chemically regulated ion gates and leads to transient permeability changes in the sarcolemma. The result is a change in membrane potential such that the muscle cell interior becomes slightly less negative; an event called depolarization [5]-[7].

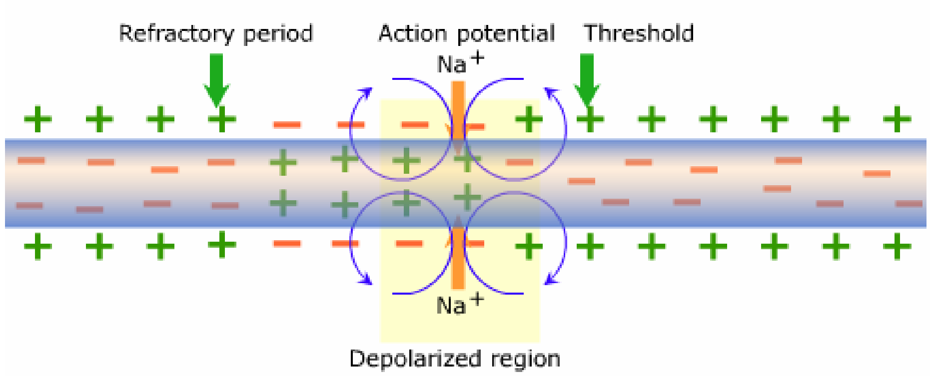


Figure 2.6 Events in the generation and propagation of an action potential in a skeletal muscle fiber [9].

Initially, depolarization is occurring only at the receptor site. But if the nerve stimulus is strong enough, an action potential is generated that passes in all directions from the neuromuscular junction across the sarcolemma (Figure 2.7).

Immediately after depolarization, repolarization occurs, which restores the sarcolemma to its initial polarized state. During repolarization, a muscle fiber is said to be in refractory period, because the cell is insensitive to further stimulation until repolarization is complete. Action potentials then stimulate the release of calcium ions into the sarcoplasm. This effect causes the shortening of the muscle fibers, and the muscle contracts.

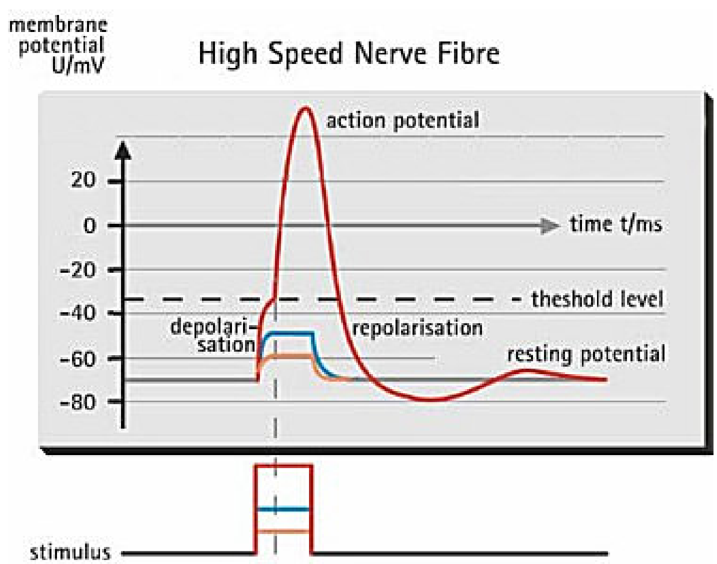


Figure 2.7 Recording of an action potential indicating the timing of periods. A subthreshold stimulus does not generate an action potential at all, but once threshold voltage is reached, the stronger stimulus is generated [10].

When the muscle is stimulated with a single electric shock of sufficient voltage, it quickly contracts and relaxes. This response is called a *muscle twitch* (Figure 2.8). Increasing the stimulus voltage increases the number of motor units activated and that increases the strength of the twitch, up to a maximum.

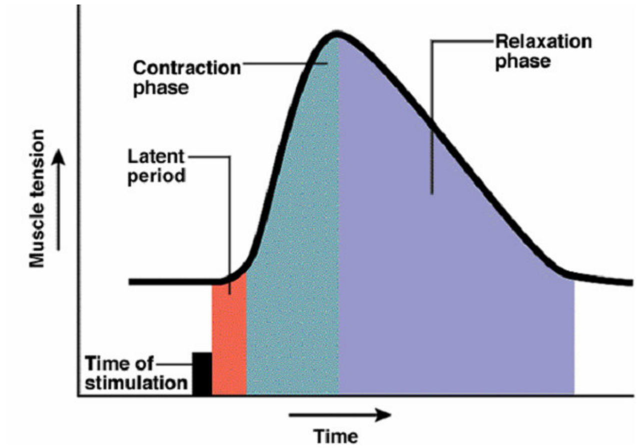


Figure 2.8 The muscle twitch. The latent period is the few milliseconds following stimulation when excitation-contraction coupling is occurring. The contraction phase is the time from the onset of shortening to the peak of tension development and in the relaxation period, muscle tension gradually decreases to zero [11].

If a second electric shock is delivered immediately after the first, it will produce a second twitch that may increase the contraction force. This phenomenon, called a wave, or temporal, summation, occurs because the second contraction is induced before the muscle has completely relaxed after the first (Figure 2.9).

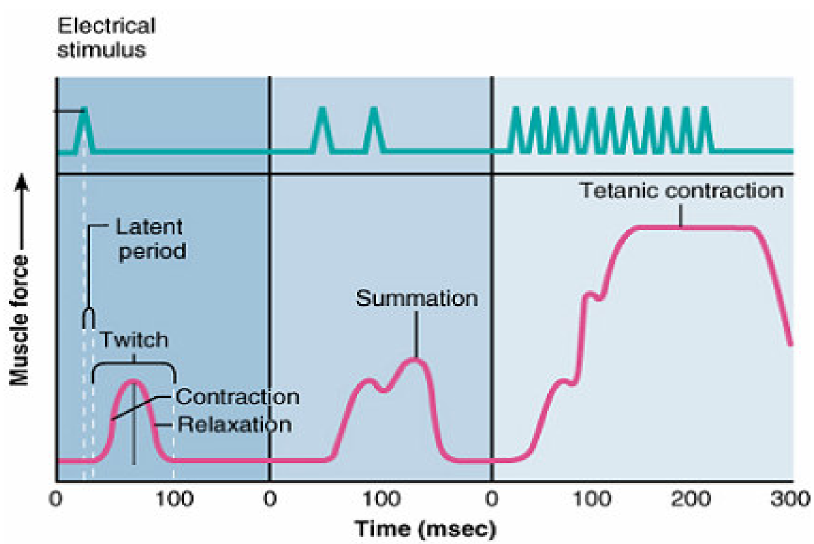


Figure 2.9 Wave summation and tetanus. A whole muscle's response to different stimulus frequencies is shown [11].

If the stimulus is held constant and the muscle is stimulated at an increasingly faster rate, the relaxation time between the twitches becomes shorter and shorter, and the degree of summation greater and greater. Finally, all evidence of muscle relaxation disappears and the contractions fuse into a smooth, sustained contraction called tetanus.

Tetanus reflects the usual manner of muscle contraction in the body. That is, motor neurons usually deliver impulses in rapid succession rather than single impulses that result in twitch contraction.

2.2 Gait Cycle

A single gait cycle, also called stride, is the period of time between two successive occurrences of one of the repetitive events of walking. It is usually measured from an initial heel contact, termed heel strike (HS), of one foot to the subsequent heel strike of the same foot [12].

There are many types of gait including walking, running, skipping, and many pathological gaits. The focus of this thesis, however, is specifically on walking.

The terms *dorsiflexion* and *plantar flexion* are used for the rotation of the ankle in the sagittal plane (a vertical plane through the longitudinal axis dividing the body into left and right portions.) towards or away from the body, respectively [13]-[5].

The gait cycle consists of the stance and swing periods. Swing designates the time the foot is in the air for limb advancement. Stance is the period where the foot is in contact with the ground.

Walking can be further defined as being comprised of initial double support, single limb support, terminal double support and swing. Stance comprises sixty percent of the walk cycle, where each double support interval is ten percent and single limb support is forty percent. The remaining forty per cent is swing as shown in Figure 2.10. Single limb support of one limb is equal to swing of the other, as they are occurring at the same time [14]-[15].

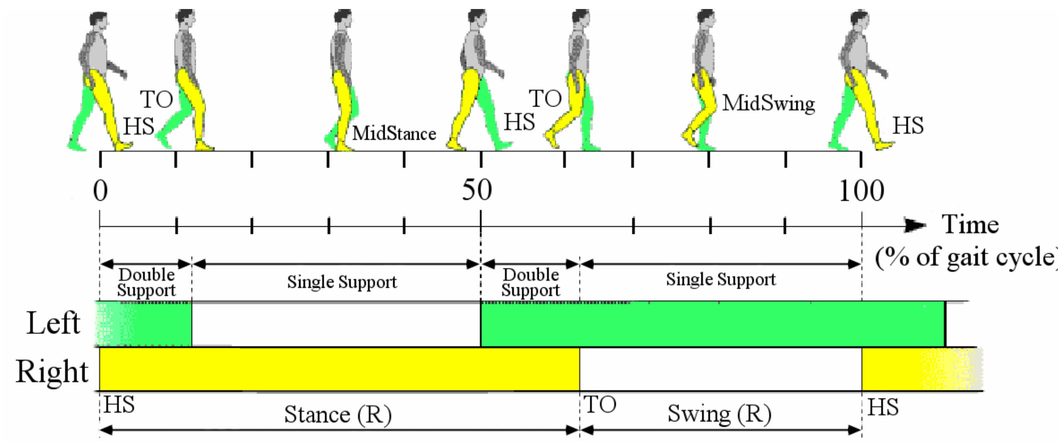


Figure 2.10 Gait phase diagram showing the phases and events of a gait cycle [16].

The gait cycle can be divided into eight phases, as shown in Figure 2.11, which enable the limb to accomplish three basic tasks: weight acceptance, single limb support and limb advancement [15].

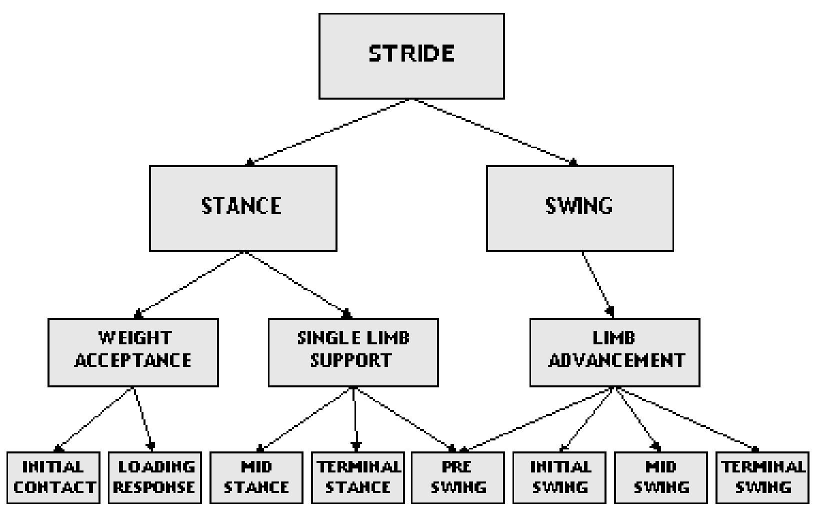


Figure 2.11 Divisions of the gait cycle [17].

Weight acceptance is the most demanding task in the walk cycle since it requires shock absorption of the free-falling body, initial stabilization of the stance limb and preservation of forward momentum. This task comprises the first two walk phases;

initial contact and loading response. Stance continues with single limb support, comprising the mid-stance and terminal stance phases. During this task, the stance limb has total responsibility for supporting body weight, while the other limb is in swing. Limb advancement begins in the final phase of stance, pre-swing, and continues through the three phases of swing: initial swing, mid-swing and terminal swing (Figure 2.12) [13].

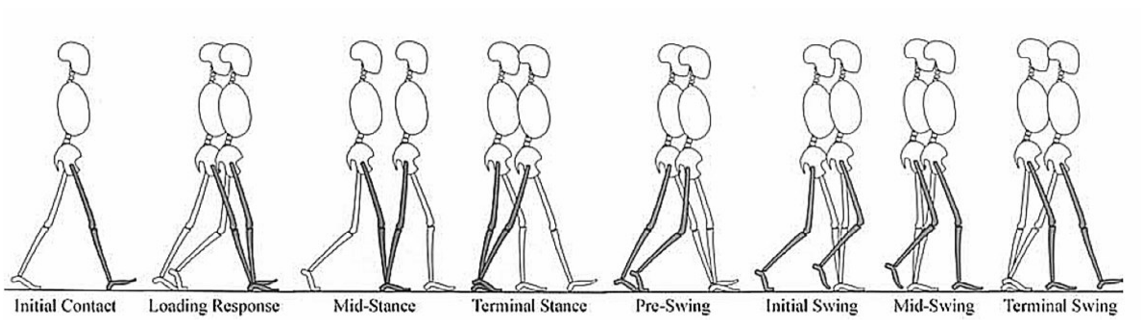


Figure 2.12 Phases of the gait cycle [15]

2.2.1 Physiology of gait

The easiest way of looking at gait is to analyze each joint individually. There are three joints that are involved in human gait: hip, knee and ankle joints [5]. Active muscles controlling these joints during a gait cycle are shown in Figure 2.13.

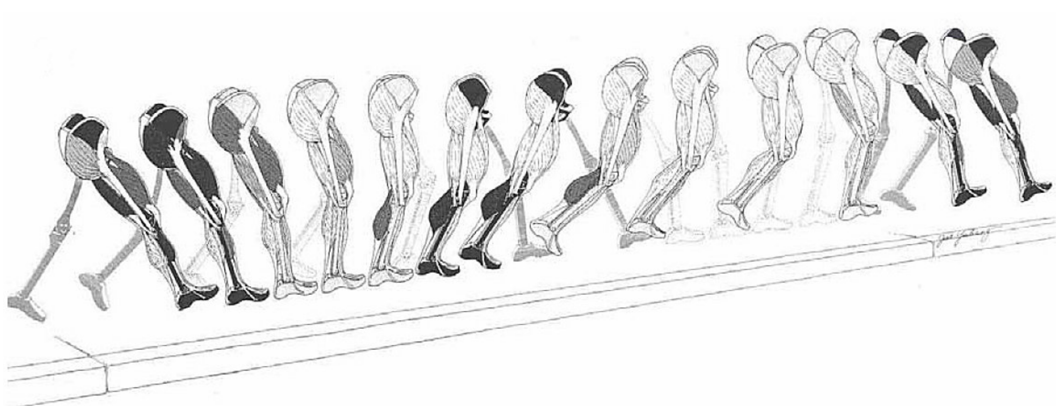


Figure 2.13 Muscle activation pattern of gait (the active muscles are darkened) [18].

Hip: The hip provides the connection between the dynamic lower body and the almost stationary upper body. The hip moves through only two arcs of motion during a normal stride: extension during stance and flexion in swing. During stance, the primary role is stabilization of the trunk; while during swing, it is control of the limb [15].

Knee: The knee is the basic determinant of limb stability during stance. In swing, knee flexibility is the primary factor in the limb's freedom to advance.

Ankle: The arcs of ankle motion are not large, but they are critical for shock absorption and progression during stance. Momentum is preserved by creation of pivotal system in the heel, ankle and forefoot that allow the body to advance while the knee maintains an extended posture, as shown in Figure 2.14. In swing, ankle motion contributes to limb advancement [13].

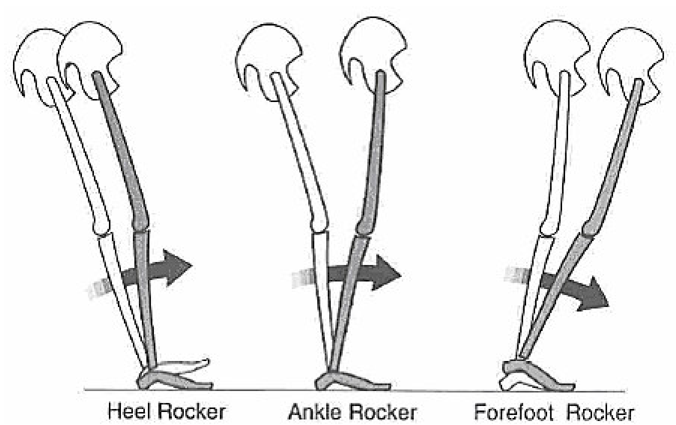


Figure 2.14 Heel, ankle and forefoot rockers used for body advancement [15].

Initial contact occurs when the heel contacts the floor with the ankle in neutral position pulled by the tibialis anterior. A heel rocker is used to keep the body moving forward without interruption. Rapid loading of the limb generates a plantar flexion moment that drives the foot toward the floor. The external plantar flexion moment is resisted by the internal dorsiflexion moment of the pretibial muscles (tibialis anterior, extensor digitorum longus, and peroneus tertius) as they provide for a controlled, eccentric contraction [14]. This extends the heel support period, draws the tibia forward, and rolls the body weight forward on the heel. This also provides shock absorption for the brief period when the body weight free falls before heel strike [13].

Ankle motion during mid stance serves as an ankle rocker to continue progression. The displacement of the body over the foot creates an increasing dorsiflexion moment that rolls the tibia forward from an initial eight degrees of plantar flexion to five degrees dorsiflexion, while the foot remains in contact with the floor [15]. The gastrocnemius and soleus muscles slow the rate of tibial advancement until the end of midstance to restrain the forward movement of the tibia on the foot. Soleus activity is the dominant decelerating force because of its larger size and its direct attachment between the tibia and calcaneus [19].

By the end of midstance, the ankle is locked by the gastrocnemius and soleus, and the heel rises due to continued tibial advancement. This makes the forefoot the only source of foot support and creates a forefoot rocker to allow for forward progression. During terminal stance, a combination of limited ankle dorsiflexion and heel rise places the ground reaction force (GRF) anterior to the source of foot support. As the GRF moves more anterior to the metatarsal head axis, the foot rolls with the body, leading to a greater heel rise and an increasing dorsiflexion moment. This creates a free forward fall situation that passively generates the major progression force used in gait. The ground reaction force created is greater than body weight and varies with gait velocity. By the end of terminal stance, there is no stabilizing force within the foot, so it is free to plantar flex in response to the triceps surae muscle [13]-[15].

Following the onset of double limb support, the body weight is transferred to the other limb in preparation for pre-swing. Peak soleus and gastrocnemius activity only support a heel rise and accelerate advancement of the unloaded limb. The tibia moves forward as the toe is stabilized by floor contact and the knee flexes in preparation for swing.

During toe-off, the ankle is plantar flexed approximately 20 degrees. The pretibial muscles increase their intensity in initial swing to dorsiflex the foot to neutral by the time the swing foot is opposite the stance limb. The dorsiflexion moment decreases in mid swing since only an isometric force to support the foot at neutral or slightly plantar flexed is required. During terminal swing, pretibial muscle activity increases to assure the ankle is at neutral position for optimal heel contact and in preparation for the increased force requirement of initial contact [14].

2.3 Drop Foot

Drop foot is a general term that describes loss of the ability to raise the foot at the ankle. This leads to difficulty in walking and a floppy-appearing foot [2]. When walking, the patient's foot drops and the toes drag on the floor. It is impossible for them to make the heel strike the ground first. To compensate, the patient develops a high stepping gait, raising the foot as high as necessary to prevent the toes from hitting the ground. The patient also walks with a distinctive "clop" because the foot comes down suddenly.

There are many causes, but injury to the peroneal nerve is a very important reason for drop foot. This nerve supplies the tibialis anterior muscle, which is responsible for lifting the foot; injury to the nerve results in drop foot (Figure 2.15).

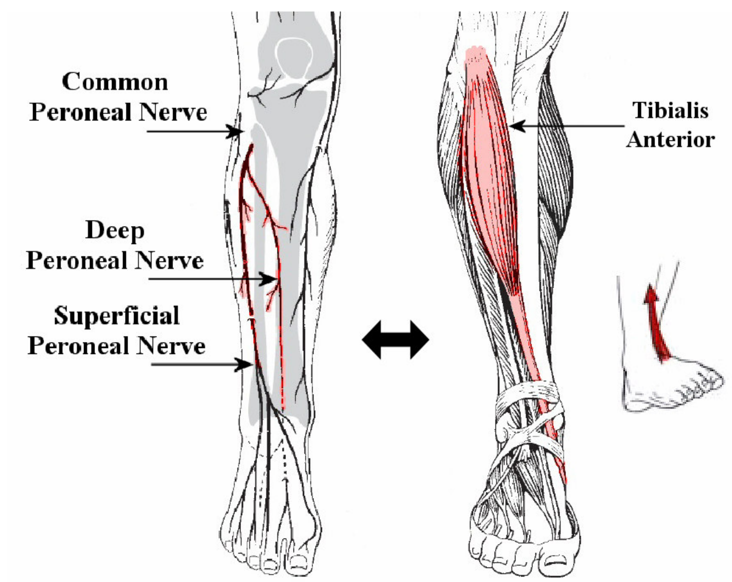


Figure 2.15 Common peroneal nerve and tibialis anterior muscle. They are shown in isolation to allow visualization of its origins and insertions [5].

The common peroneal nerve leaves the popliteal fossa between the tendon of biceps femoris and the lateral head of gastrocnemius (Figure 2.15). It crosses behind the head of the fibula and passes laterally around the neck of the fibula [20]. The nerve pierces the peroneus longus muscle to divide into deep and superficial branches. The deep peroneal nerve supplies the muscles of the anterior compartment. The superficial peroneal nerve supplies the muscles in the lateral compartment and the skin over the anterior lower leg and dorsum of the foot [20].

This nerve is the most vulnerable nerve to be injured in the lower limb due to its superficial position as it winds around the fibular nerve. The nerve may be severed during a fracture of the fibular neck or stretched when the knee joint is injured or dislocated. The severance of the common fibular nerve results in a paralysis of all muscles in the anterior and lateral compartments of the leg. The loss of aversion of the foot and dorsiflexion of the ankle causes drop foot [2].

Other reasons for such problem can be stroke, spinal cord injury, multiple sclerosis, cerebral palsy or head injury [3]. When there is damage only to the central nervous system, the muscle and its nerve supply remain healthy. An important feature of these situations is that electrical excitability of the associated peripheral nerves is still intact, thus facilitating the use of functional electrical stimulation (FES) to restore or enhance gait for some of these cases. The reason they don’t work is that they are cut off from the command signals coming from the brain. FES applied near the muscle or nerve can substitute artificial electrical signals for the missing normal motor signals. The artificial impulses make the muscle contract. For drop foot to be correctable using portable FES, suitable for take home use, sufficient muscle function must remain to enable the subject to stand and walk, even though the walking gait is significantly disturbed [3]-[21].

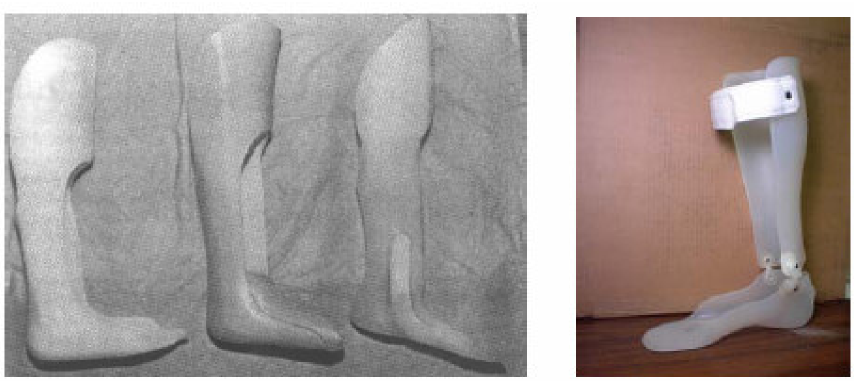
By provision of dorsiflexion and aversion, the foot clears the ground in the swing phase more easily. This reduces the effort of gait, reducing compensatory activities such as hip hitching and circumduction. Reduction in effort will lead to a reduction of associated reactions and result in a general lowering of tone [22]. Repeated use of the stimulator may then lead to a pattern of normal walking being relearned centrally and long term potentiation of the required pattern of synapses may lead to a reinforcement of this pattern of walking. However, a more immediate benefit from the orthotic use of the device is that walking is easier and safer and therefore confidence will improve leading to an extension of mobility range and an overall improvement in quality of life.

2.4 Current Technologies

The current medical technologies available are ankle foot orthoses (AFO) or functional electrical stimulation (FES) of the peroneal nerve. Both technologies have helped many clinical users around the world.

2.4.1 Ankle-Foot Orthosis (AFO)

An ankle foot orthosis (AFO) is a medical mechanical device to support and align the ankle and foot, to suppress spastic and overpowering ankle and foot muscles, to assist weak and paralyzed muscles of the ankle and foot, to prevent or correct ankle and foot deformities, and to improve the functions of the ankle and foot [23]. Traditional ankle foot orthoses were double-metal upright braces with leather bands that attached to a pair of shoes. They are still utilized in cases of fluctuating peripheral edema or in situations where patients prefer the metal braces usually because they have worn the braces for years and are accustomed to them [13]. However, they have virtually been replaced by plastic, or polypropylene, braces, shown in Figure 2.16. The major advantages of polypropylene AFOs are that they distribute pressure over a larger surface area of the limb resulting in less discomfort, are lighter than metal braces, more cosmetically appealing, and can be worn with a variety of shoe types [24]. They are also stable and resistant to damage by water or solvents.



(a) (b)

Figure 2.16 Polypropylene ankle-foot orthosis (AFO) (a) and Tamarack FlexureTM joint (b) [13].

Polypropylene AFOs are fabricated by making a cast of the patient's leg below the knee, then molding the polypropylene over it. This ensures a close fit for improved pressure distribution. The AFOs are divided into rigid and flexible types. Rigid AFOs, seen in Figure 2.16 (a), are utilized when more control is needed such as with poor ankle control, spasticity or clonus. Flexible AFOs, seen in Figure 2.16 (b), are utilized to assist the patient who may need dorsiflexion assistance. AFOs are prescribed to protect the extremity from injury, to correct abnormal posturing, and to aid in the development of efficient and safe gait [13].

2.4.2 Functional Electrical Stimulation (FES)

FES is a method of applying low-level electrical current pulses to the body to restore or improve function [6]. These pulses generate action potentials in motor neurons attached to a muscle [25]. The stimuli then propagate along ramified pathways of the nervous system and cause that muscle to contract. In this way, electrical pulses can influence almost any organ of the human body.

In order to achieve a continuous muscle contraction, also called tetanization, the FES system must produce pulses at a minimum of 20 Hz. Otherwise, the muscle twitches continuously and does not generate a steady output force [26]-[27]. Both monophasic and biphasic current or voltage pulses can be used to stimulate motor neurons. The common belief, however, is that the injected charge should be removed from the body and not allowed to accumulate. Most surface electrodes use biphasic current pulses, which changes the positions of the anode and cathode during stimulation [13].

The main components of an FES system are the electrodes, the stimulator, and sensors or switches. The stimulator controls the strength and timing of the low-level pulses that flow to the electrodes. The sensors or switches control the starting and stopping of the pulses supplied by the stimulator.

The use of a portable stimulator to stimulate the common peroneal nerve for real-time correction of drop foot was first proposed by Liberson in 1961 [4]. Prior to the Liberson’s paper, electrotherapy was only used for therapeutic purposes, such as muscle repair following injury [3].

His concept was that by applying electrical stimulation to paralyzed muscles, functional movement could be produced, providing the user with a useful orthotic device. Liberson's device was a portable neuromuscular stimulator which produced pulses of durations between 20 and 250μs at a frequency of 30-100Hz and current amplitudes of up to 90mA. Stimulation was timed using a switch placed under the heel of the affected side. When weight was taken from the switch, stimulation was delivered to carbon rubber electrodes placed over the common peroneal nerve as it passes over the head of fibula, causing dorsiflexion. Liberson reported that the gait of hemiplegics was significantly improved by the use of the device and that on several occasions users acquired the ability of voluntary dorsiflexion for short periods after its use.

In 1965, Vodovnik, Dimitrijevic, Prevec, and Logar evaluated the influence of stimulation parameters on stimulation pain and after completing a series of tests, proposed pulse duration of 300 μs and a pulse frequency range of 30–60 Hz as the most comfortable range of stimulation parameters [28]. These findings on comfort have since been replicated by several researchers [29]-[30]-[31].

Some researchers, in the following decades, suggested refinements to the basic single channel hard-wired *drop foot stimulator* (DFS) systems. Pedersen, Petersen, Hansen and Klemar, from Arhus in Denmark, described the clinical evaluation of a single channel DFS device [32]. The DFS used was described as a heel wedge with built-in contacts to trigger application of stimulation. They presented data on the experience of 46 patients treated with the DFS and reported that after one year, the majority of the patients reported that the DFS had become an integral part of their lives and that the stimulator activated dorsiflexion in all subjects and hip and knee flexion in 50% of the subjects. Since that time several groups have developed similar systems and the devices have received some clinical use but the most frequently used stimulator is the Odstock Dropped Foot Stimulator (ODFS).

2.4.3 ODFS

In 1997, Burridge, Taylor, Hagan, and Swain described the use of a single-channel hard-wired stimulator, the ODFS (Odstock Drop Foot Stimulator), with several clinically useful features [33].

ODFS was a single channel, foot switch triggered stimulator designed to elicit dorsiflexion and eversion of the foot by stimulation of the common peroneal nerve, (max. amplitude 100mA, 350μs pulse, 40 Hz). It was a development of the device first described by Liberson. Skin-surface electrodes were placed, typically, over the common peroneal nerve as it passes over the head of the fibula and the motor point of tibialis anterior (Figure 2.17). If greater knee flexion was required, the indifferent electrode can be placed over the common peroneal nerve as it passes through the popliteal fossa, eliciting a withdrawal reflex.

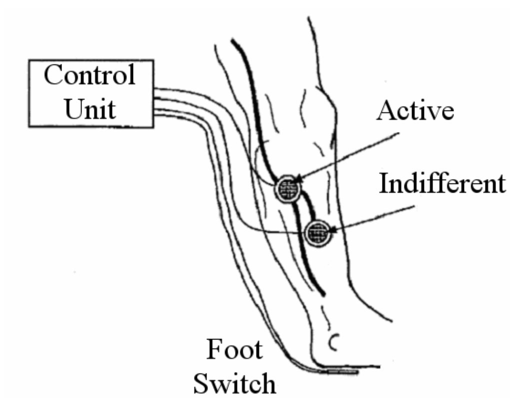


Figure 2.17 Electrode positioning during stimulation [34].

Stimulation of the hemiplegic leg could be controlled by a heel-switch worn on either the hemiplegic or nonhemiplegic side. When the switch was on the nonhemiplegic side, stimulation was initiated by heel strike and terminated by heel rise. When the switch was on the hemiplegic side, this was reversed. This option was important because using the nonhemiplegic side for controlling stimulation is preferred when patients are unable to achieve a reliable heel-strike, usually because of either contracture or poor balance and controlling stimulation from the hemiplegic side is preferable because it encourages the patient to weight-bear on that side during the stance phase.

The other feature was the incorporation of miniature potentiometers to allow adjustment of both the rate at which stimulus was ramped up at toe-off and the rate at which stimulus was ramped down at heel-strike.

The adjustment of ramp-up time can be very important in subjects with calf muscle spasticity. The adjustment of the ramp-down time is used to avoid foot-flap or foot-slap, where termination of stimulation immediately on heel-strike causes the foot to fall rapidly. The ramp-down time maintains stimulation until the center of gravity is forward over the forefoot. Studies of normal muscle activation patterns during walking have shown that the tibialis anterior activation peaks between heel and toe strike.

There was also a facility to add an extension to the stimulation envelope after heel strike, which mimics the natural activity of the anterior tibialis muscle which contracts eccentrically lowering the foot to the ground.

In the 1990's, a portable, two-channel drop foot stimulator was developed using hard-wired technology by the group at Salisbury District Hospital, UK [35]. The device was called O2CHS. It was a very flexible 2-channel stimulator allowing a wide range of independent triggering options for the two channels of stimulation. However, setting up different stimulation options on the O2CHS was achieved using a complex combination of DIP switches and miniature potentiometer settings that were quite difficult for the therapist to initially set up. The implementation of multichannel systems using hard-wired technology resulted in systems which were difficult to configure, and highlighted the need for microcontroller technology to enable a more user-friendly, programmable implementation of multichannel stimulation.

In this thesis, the stimulator design ODFS, made by Ian Douglas Swain and Paul Nicholas Taylor, is taken as a reference because its output is known to be safe and effective in clinical use.

3. DESIGN

A portable, battery powered, microcontroller based, programmable stimulator system has been designed and implemented to assist drop foot patients during a gait cycle.

3.1 System Components

The designed system consists of a stimulator, a foot switch, electrodes and connection cables. A picture of the system realized is shown in Figure 3.1.

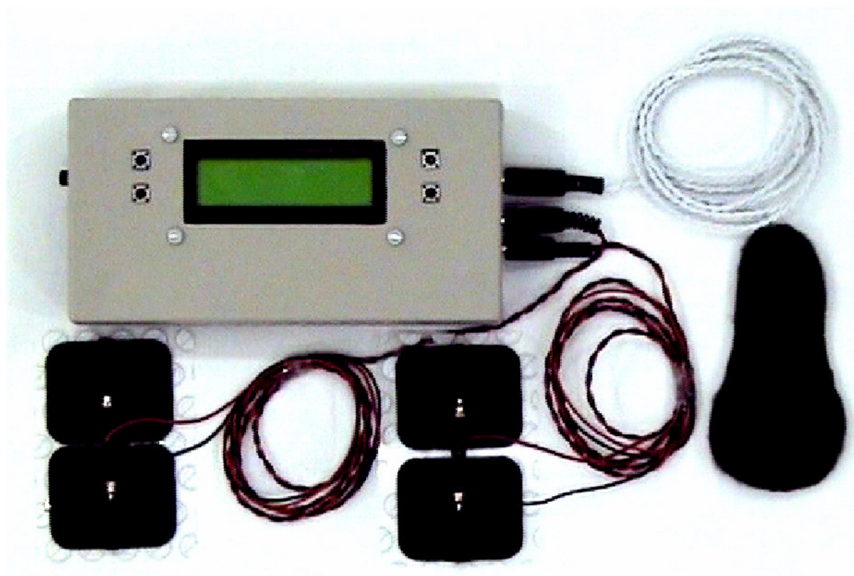


Figure 3.1 The FES device developed for treating drop foot.

Electrodes are reusable and self-sticking to the skin. They conduct the stimulation current through the skin into the appropriate nerves and the muscles. The foot switch is placed in the shoe, under the heel to turn the stimulation on and off in time while the patient is walking.

The stimulator's main function is to generate the electrical stimulation. It is lightweight, battery operated and small sized. The unit is 15 cm x 8 cm with a profile of

4.5 cm. On the front panel there is an LCD display and 4 pushbuttons. Electrodes and the foot switch are can be connected to the jacks on the right side and the On/Off switch of the unit is on the left side (Figure 3.2).

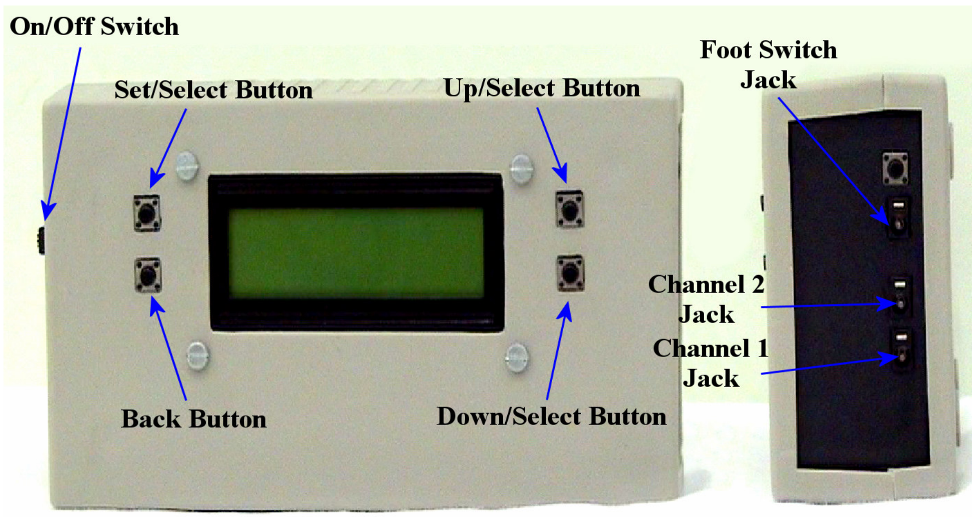


Figure 3.2 Front and right side view of the stimulator.

Stimulation is applied to the tibialis anterior or peroneal nerves. An active electrode must be placed over the common peroneal nerve just below the head of the fibula and an indifferent electrode must be located about 5cm below and slightly medially of the active electrode over the motor point of the anterior tibialis, as shown in Figure 3.3. This is a standard position to produce a flexion withdrawal response.

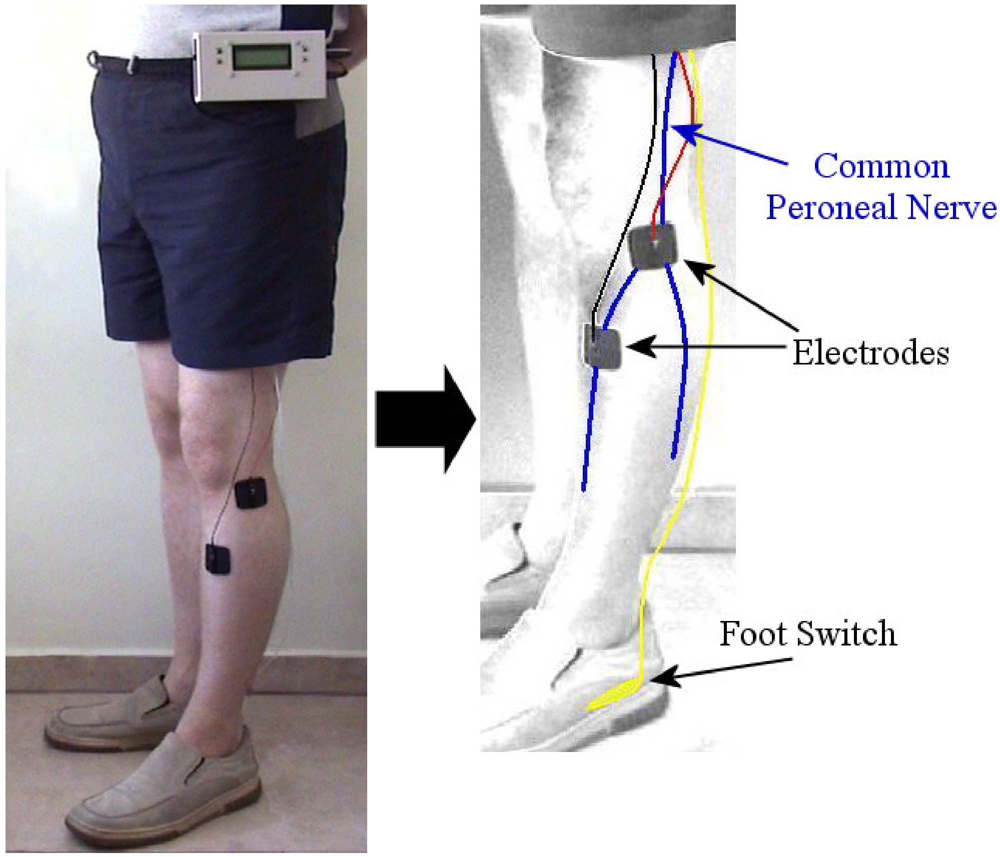


Figure 3.3 Placement of the electrodes and the foot switch.

3.2 Circuit Design

Since setting up different stimulation options on the ODFS was achieved using a complex combination of DIP switches and miniature potentiometer settings, they were quite difficult to initially set up. To make a more user-friendly and flexible device, we realized the stimulator using microcontroller technology. This technology allows the system to run software-based control algorithms. To run different algorithms requires only changes in the software; no hardware changes are necessary.

The block diagram of the system realized is shown in Figure 3.4.

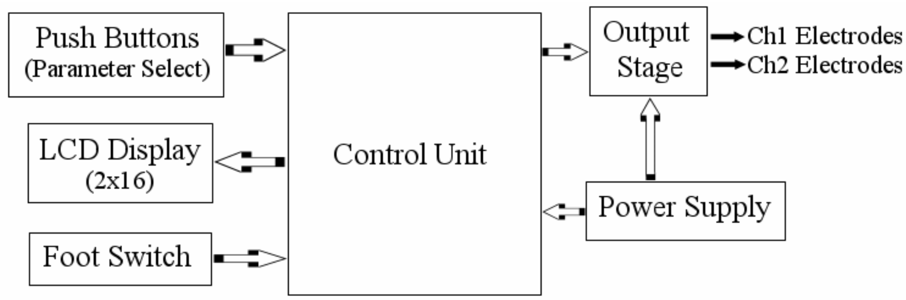


Figure 3.4 The block diagram of the stimulator.

Basic functions of the system are as follows:

- Stimulation parameters can be selected by using push buttons and an LCD display. When the device is energized, the microcontroller first runs the parameter selection program. By tracking the LCD display and selecting desired stimulation values by using the push buttons, the device can be setup.

- A resistive pressure switch, positioned under the heel, is being used to control the timing of stimulation. By sensing the state of this switch, foot rise and fall actions are detected and stimulation pulses are sent to the leg electrodes according to these states.

- The power supply unit of the device is designed to supply power to the electronic circuits and to generate the necessary DC voltage levels for the circuit elements and the output stage.

- The designed stimulator has two stimulation channels, which can be controlled with a foot switch. The parameters of these channels can be independently adjusted.

- All of the blocks are controlled by a PIC16F876 microcontroller.

Table 3.1 shows some of the parameters that can be configured.

Table 3.1
The Range and Resolution of the Stimulation Parameters.

	Minimum	Maximum	Resolution
Pulse Rate (Hz)	20	60	5
Pulse Duration (us)	15	350	5
Pulse Interval (us)	10	350	5
Amplitude (mA)	20	100	1
Ramp Up Time Duration (s)	0	4	0,1
Ramp Down Time Duration (s)	0	4	0,1
Extension Time Duration (s)	0	2	0,1
Fixed Time Duration (s)	0,5	6	0,1
Delay Time for CH2 (s)	0	2	0,1

The other parameters include monophasic/biphasic waveform selection, fixed or adaptive timing selection, and heel-rise/heel-strike mode selection (stimulation starts after heel rise or heel strike).

Following either release or pressure on the footswitch, stimulation begins with a ramping of the amplitude. The rate of the ramp can be adjusted from 0 to 4 seconds. The stimulation then remains at a fixed level, until either there is a change in the footswitch state or after a fixed time chosen between 0.5 - 6 seconds. In fixed timing mode, stimulation will end after a chosen time; but if the adaptive timing mode is selected, the output remains on until the foot switch state changes. An extension can be added to the stimulation period to extend the stimulation time past the change in foot-switch state. This will provide an eccentric contraction of the tibialis anterior after heel strike, lowering the foot to the ground. Finally, there is a descending ramp that can be used to prevent sudden fall of the foot. A delay time can also be added at the beginning of the stimulation process to adjust the stimulation time. These stages are shown in Figure 3.5.

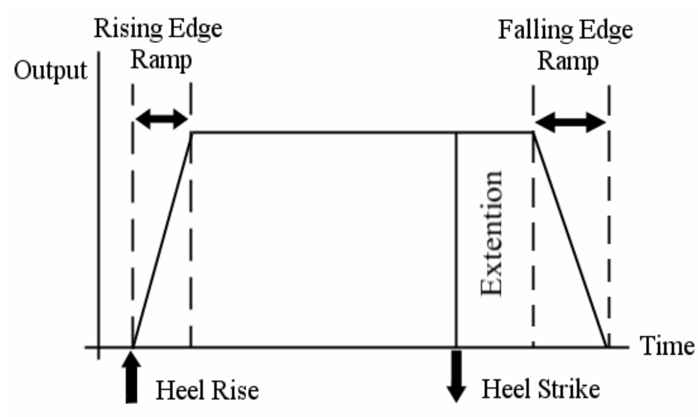


Figure 3.5 Stimulus intensity during a gait cycle. The intensity envelope in drop foot stimulators is trapezoidal in shape, with a ramp–up time at the beginning of swing.

The current amplitude and the pulse width control the charge, which in turn affect the number of stimulated muscle fibers. Intensity change during a stimulation cycle is obtained by changing the pulse width value of the signal (Figure 3.6).

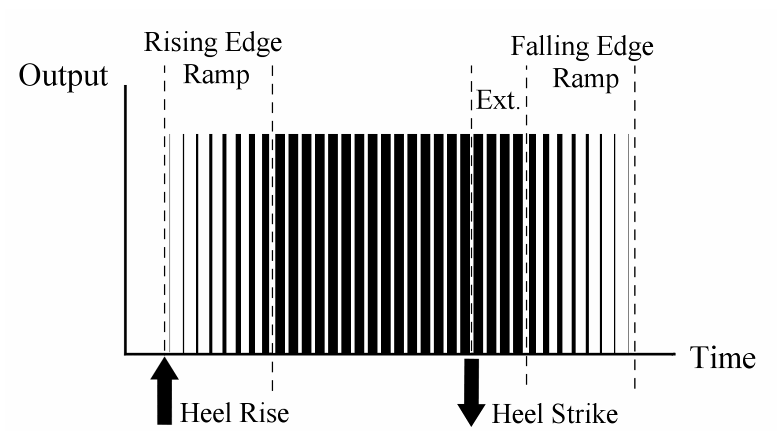


Figure 3.6 Pulse width change during a gait cycle.

Figure 3.7 represents the types of waveforms that can be created by the device. There are two types of signals mostly used in electrical stimulation: monophasic and biphasic. Although a monophasic signal is enough for obtaining a muscle contraction, this type of pulses can cause ionic charge and skin irritation. To eliminate these effects, biphasic signals can be used.

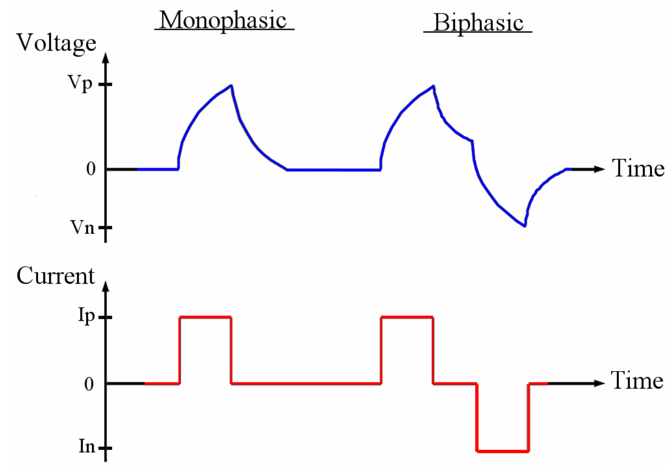


Figure 3.7 Representative diagrams of monophasic and biphasic waveforms.

Both of the channels have the same configuration. By changing the related parameters, the second channel can be timed to give outputs at another time in the gait cycle. This way, when the first channel is being used for common peroneal stimulation to produce dorsiflexion, the second channel can stimulate another muscle.

3.2.1 Control unit

The basic function of the control unit is to drive output stages with the specified pulse duration and frequency. In addition, it must do the gait detection, user interface control and timing control (Figure 3.8).

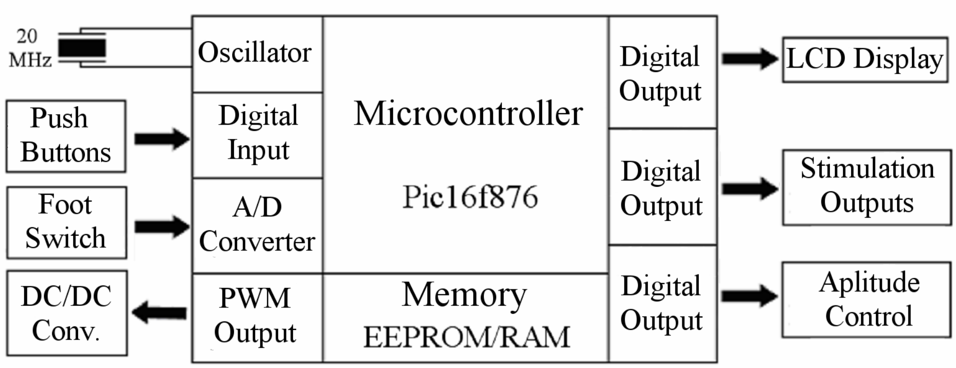


Figure 3.8 Block diagram of the control unit, based on PIC16F876 microcontroller.

The PIC16F876 microcontroller, produced by Microchip Technology Inc., is chosen for the present design. This microcontroller features 256 bytes of EEPROM data memory, 8K FLASH program memory, self-programming, ICD/ICSP capability, 5 channels of 10-bit Analog-to-Digital (A/D) converter, 3 timers, integrated watch-dog, 2 capture/compare/PWM functions and a synchronous serial port. All of these features make this microcontroller ideal for this application.

The oscillator of the controller is a 20 MHz crystal and two 22pF capacitors. Since the speed at which the microcontroller operates depends heavily on the frequency of the oscillator, all of software timing calculations and loops are based on this frequency.

Five ports of this microcontroller are configured as inputs. Four of these inputs are digital ports for detecting the state of the four push button switches; the fifth port is an analog port for 8 bit A/D conversion.

To be able to synchronize the stimulation output with user's gait cycle, the control unit must detect heel rise and fall times. When a load is applied to the foot switch, the resistance value of the force sensitive resistor decreases. This causes the voltage level to change on the microcontroller's analog port. Since this change is an analog value, the control unit is configured to convert it to digital form by using the built-in A/D converter. This option eliminates the need for using an external converter and simplifies the circuit.

One other important feature of this microcontroller is that it has two hardware PWM modules. A typical output signal of these ports is shown in Figure 3.9.

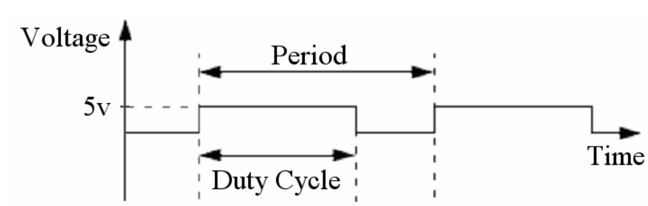


Figure 3.9 A typical PWM signal output.

The PWM period is set by writing to the PR2 register ; the PWM duty cycle is set by writing to the CCPR1L register and the CCP1CON<5:4> bits. Writing to the T2CON register enables Timer2. When the port is enabled, it starts to produce a train of pulses in the background while the controller performs other tasks.

In our design, one of the PWM ports of the microcontroller is assigned for driving the DC/DC converter stage at 50 KHz.

A digital potentiometer is used for changing the output current level. Communications from the controller to the digital potentiometer is accomplished using the SPI serial interface. Three of the digital output ports are assigned for this purpose.

Four digital ports are set for controlling the stimulation pulses. The voltage level of these ports (high or low) change in synchronism with the frequency of the signal for the appropriate channel output.

The remaining ports are used for controlling the LCD Display and reading the states of the push buttons.

3.2.2 Power

A 9V battery provides the main power for the unit. A 7805 regulator provides the main digital supply of 5V (Figure 3.10).

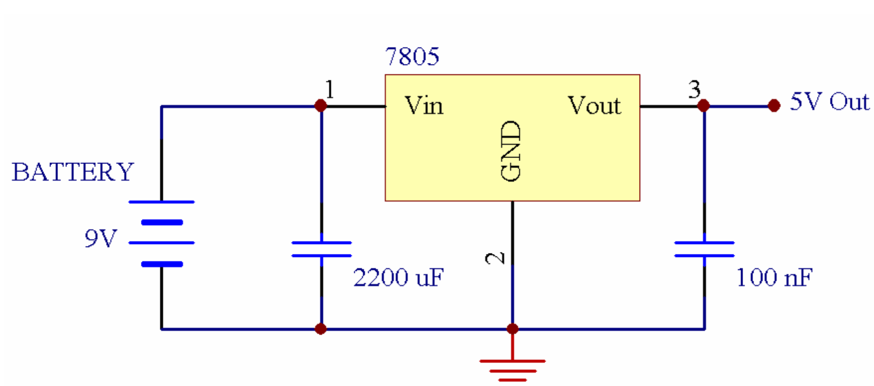


Figure 3.10 The main power supply unit for the digital circuitry.

The power supply of the output channels is based on a flyback DC/DC converter topology (Figure 3.11). This circuit generates four isolated 100V outputs (two for each channel).

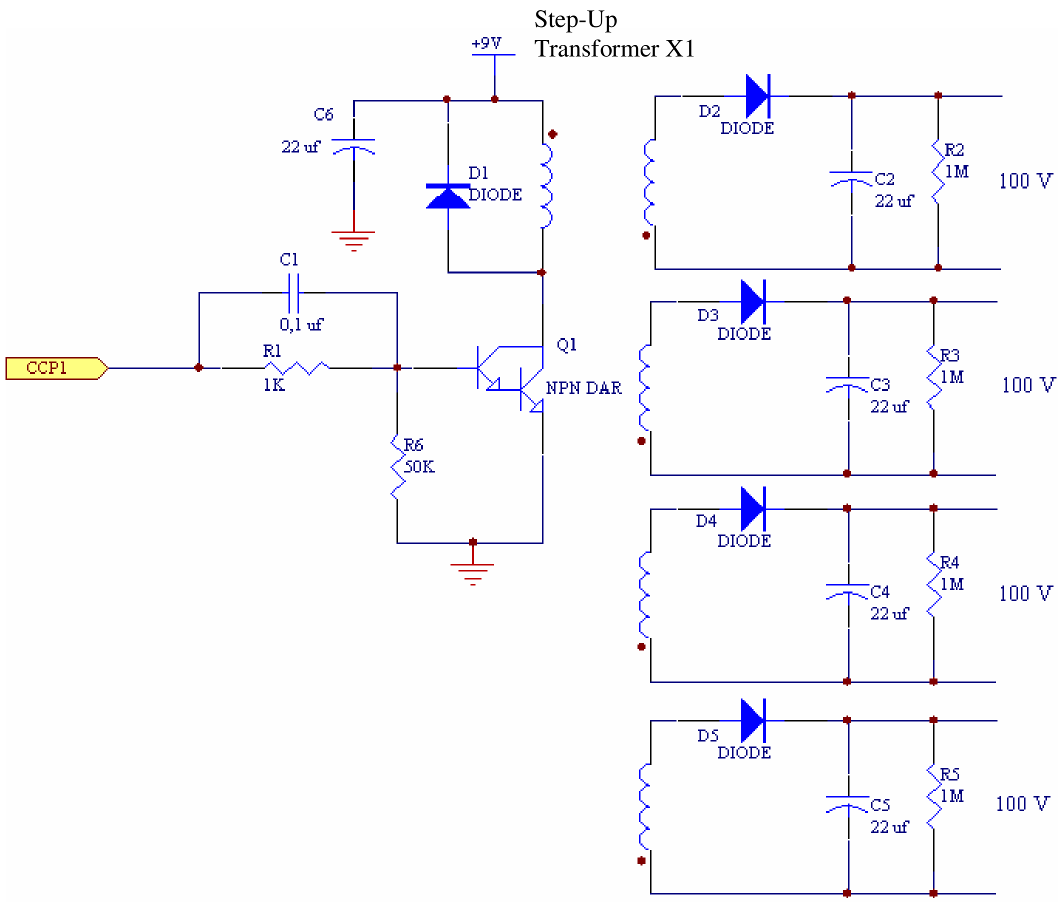


Figure 3.11 Power supply circuit of the output stage.

The PWM output of the microcontroller is set to generate a square wave voltage at 50 KHz. A Darlington transistor is being driven by this output to supply energy to the isolation and step-up transformer X. Capacitor C1 speeds up the transistor and diode D1 acts as a flyback diode to prevent EMF from damaging Q1. The outputs from the transformer are connected to the constant current output stages for creating stimulation pulses.

During stimulation, when the pulses are being created, the output of the PWM port is disabled for a duration equal to the signal’s pulsewith. This is done to eliminate the spike effects on the output signal caused by the transformer. After the creation of pulses is finished, the PWM operation starts again.

The stimulator consumes about 1.8 W of power from a 9 V battery at the maximum output (both channels are active at highest current level). When the device is in standby mode, the power consumption decreases to 0.27 W.

3.2.3 Foot switch

The foot switch consists of a force-sensitive resistor. FlexiForce Sensor Model A201 (Figure 3.12) is chosen for this circuit because of its thin and flexible structure.

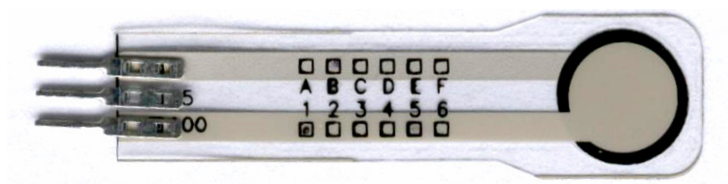


Figure 3.12 FlexiForce Sensor Model A201**.**

The "active sensing area" is a 0.375 inch diameter circle at the end of the sensor. It is constructed from two layers of substrate, such as a polyester film. On each layer, a conductive material (silver) is applied, followed by a layer of pressure-sensitive ink. Adhesive is then used to laminate the two layers of substrate together to form the sensor. The silver circle on top of the pressure-sensitive ink defines the active sensing area. It extends from the sensing area to the connectors at the other end of the sensor, forming the conductive leads. FlexiForce sensors are terminated with a solderable male square pin connector, which allows them to be incorporated into a circuit. The two outer pins of the connector are active and the center pin is inactive.

The sensor acts as a variable resistor in an electrical circuit. When the sensor is unloaded, its resistance is very high (greater than 5MΩ); when a force is applied to the sensor, the resistance decreases to a minimum of about 20KΩ. The switch circuit is a potential divider (Figure 3.13). When there is no load, the output level of the divider is high. If a force is applied to the sensor, the voltage level starts decreasing. Then the A/D converter port of the controller converts this to a digital value. If it is below our threshold value, the switch is said to be "ON". Otherwise it is considered as "OFF".

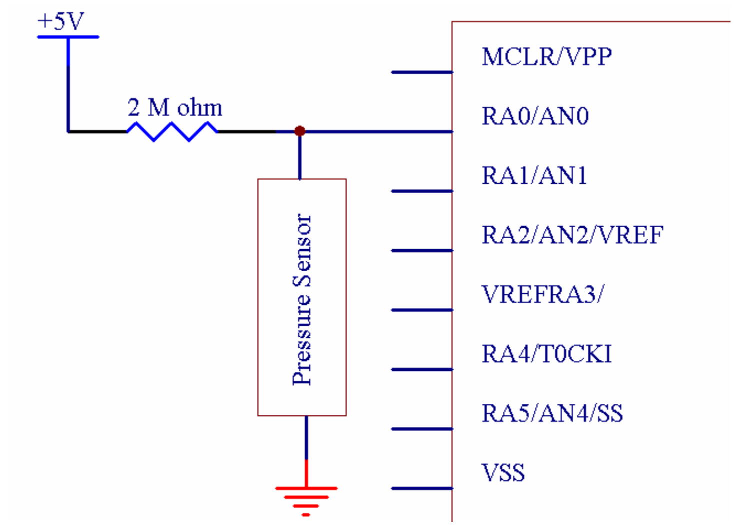


Figure 3.13 The foot switch circuit.

3.2.4 LCD display

The LCD Display has two lines of 16 characters, which can be both numeric and alphanumeric. It is controlled in a four-bit mode, to be able to save other ports of the microcontroller for other purposes. Port B4 to B7 of the controller is connected to the DB4-DB7 of the LCD module. Through these connections all control characters are sent. Connections of the LCD Display is presented in Figure 3.14.

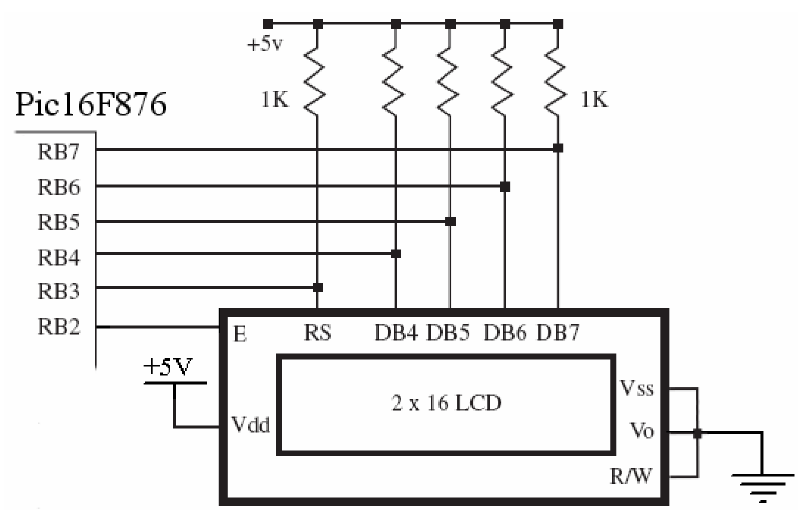


Figure 3.14 LCD display driving circuit .

The I/O ports have pull-up resistors to guarantee a logic high level. The LCD has the R/W port grounded, which limits it to write-only mode. The V0 controls the contrast level of the LCD. By grounding, we set it to maximum contrast. The RS pin is used to tell the LCD if a character or LCD command is coming from the PIC.

3.2.5 Output stage

The output stage is designed to generate constant current stimulation pulses (Figure 3.15). All of the parameters of these pulses are controlled by the microcontroller.

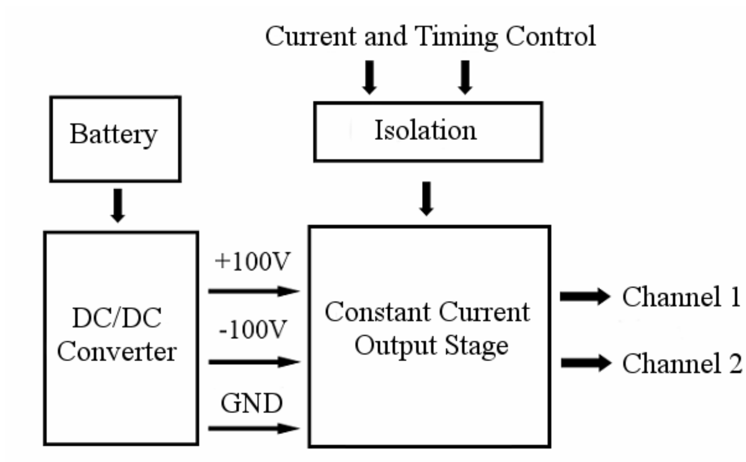


Figure 3.15 Block diagram of the output stage.

As previously mentioned, a battery powered DC/DC converter generates two 100V outputs for each channel. The output stage is controlled by digital signals from the controller. These signals are isolated from the output by using optocouplers. This way the control circuit is protected from the high voltages generated by the DC/DC converter and also the output channels are separated from each other and the main circuit.

The detailed circuit diagram of the constant current output stage for one of the channels can is presented in the Figure 3.16.

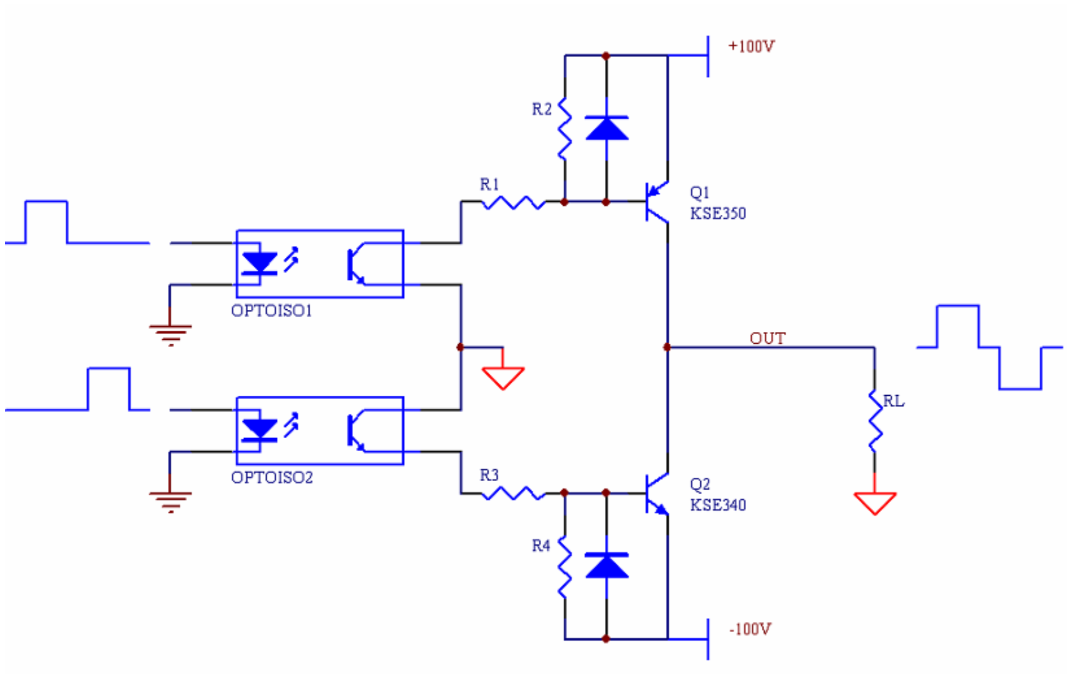


Figure 3.16 Detailed circuit schematic of the constant current output stage.

This stage is designed using high voltage transistors that are driven by optocouplers. The input current of the optocouplers determines the bias current of the transistors, hence the amplitude of the output current.

The current control is done by using MCP42100 digital potentiometers and HEF4016 quadruple bilateral switches. MCP42100 has two integrated 100 kΩ digital potentiometers and can be controlled by a microcontroller using the SPI interface. The value of the potentiometers can be changed from 0 to 100 in 256 steps. HEF4016 has four independent analogue switches. Each of these switches has two input/output terminals and an active high enable input. When “E” is connected to VDD a low impedance bi-directional path between the terminals is established (ON condition). When “E” is connected to VSS, the switch is disabled and a high impedance between the terminals is established (OFF condition). Figure 3.17 shows the configuration of these components in the circuit.

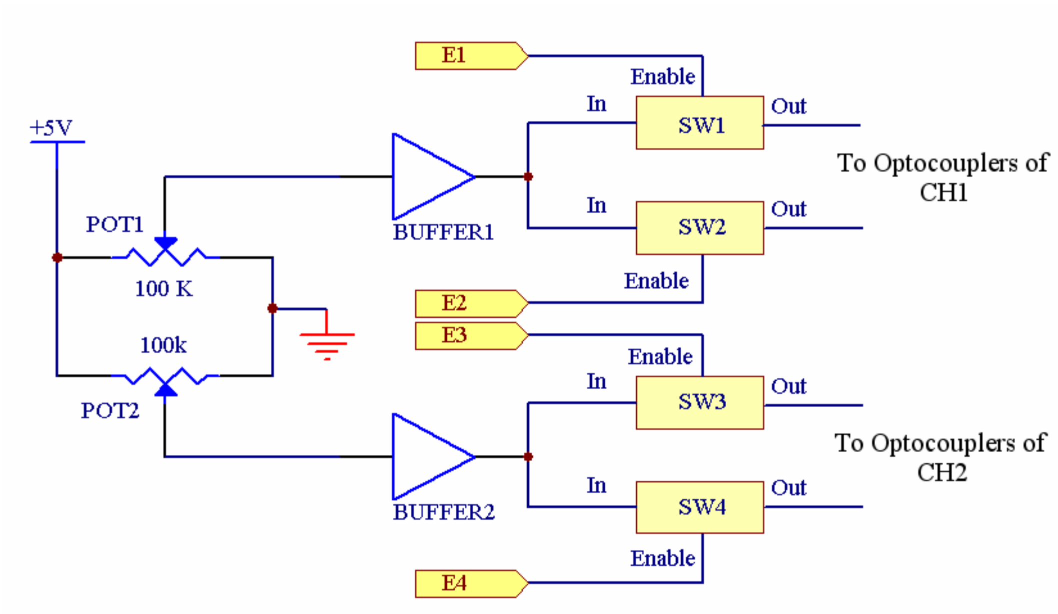


Figure 3.17 Current amplitude control circuit.

When the user selects a current value from the menu, the microcontroller sets the related potentiometer to a matching predefined value. This value changes the voltage value of the buffer output, hence the switch input. When the microcontroller enables the related switch during stimulation, this affects the current input of the optocoupler. Finally, as explained before, the output current from the channel is released according to this input current.

4. SOFTWARE

The program code has been written using the PicBasic Pro programming language because of the simplicity of the language and the complexity of the program. In the designed system, the microcontroller does many operations like creating stimulation pulses, current control, A/D conversion, configuring potentiometer by serial communication, and controlling the LCD display. PicBasic makes it easier to configure these processes.

There are two main parts of the program. These are labeled as "Options", and "Start".

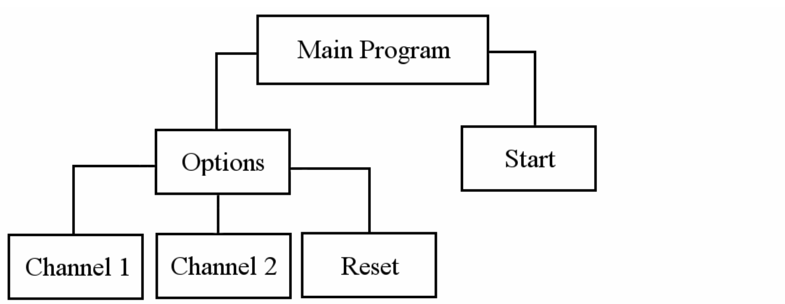


Figure 4.1 Main parts of the software program.

4.1 Options Menu

When the device is switched on and the microcontroller starts to execute the designed software, the first thing done is the configuration of the microcontroller parameters. Upon power-up, the program configures the I/O pins, A/D conversion set up, defines LCD control pins, sets PWM parameters and configures the timer parameters. The program then opens the options menu. By selecting this menu, the user can configure the stimulator features for each channel.

Four push buttons and an LCD display enables the interactive control of the system. By moving up and down through the menu, each parameter can be selected for configuration. When the desired value is chosen, that value can be saved and then the display shows the next parameter to be selected.

The parameters of both channels can be configured and stored separately. A memory space has been assigned to each configuration option. During option selection cycles, selected values are saved in these memory addresses to store the stimulation information for future use.

The reset option resets all of the stimulator parameters to predefined values.

4.2 Stimulation Process

The second part of the program is responsible from the stimulation process. When all the variables are entered and stimulation start is selected from the menu, first the calculation routine runs. All of the variables and constants used in the stimulation process are read from the memory and calculated in this routine. The program then enters a loop; as long as the user does not exit by selecting “Back”, stimulation continues. In this loop, the previously configured A/D input is used for checking the foot switch and a predefined register is changed according to the switch. The timing variables are then compared with the constant values. Throughout the loop, by using the switch status and timing comparisons, the output pulses of each channel are controlled (Figure 4.2(a)).

When the stimulation start is selected, the interrupt subroutine that occurs in every 2 ms is also enabled in the background (Figure 4.2(b)). At every cycle of the interrupt subroutine, variables that were used for time tracking are increased. When these variables reach for a certain predefined value and if enough number of loop cycles is passed since the last pulse generation, the program jumps to another subroutine for pulse creation. After the pulses are created, the program returns to the main loop. This way, the time interval between pulses is maintained to match the selected signal frequency.

The pulse duration is controlled by software loops. Therefore, pulses at different output channels cannot be generated simultaneously; they appear in sequence. But this is not noticeable by the user.

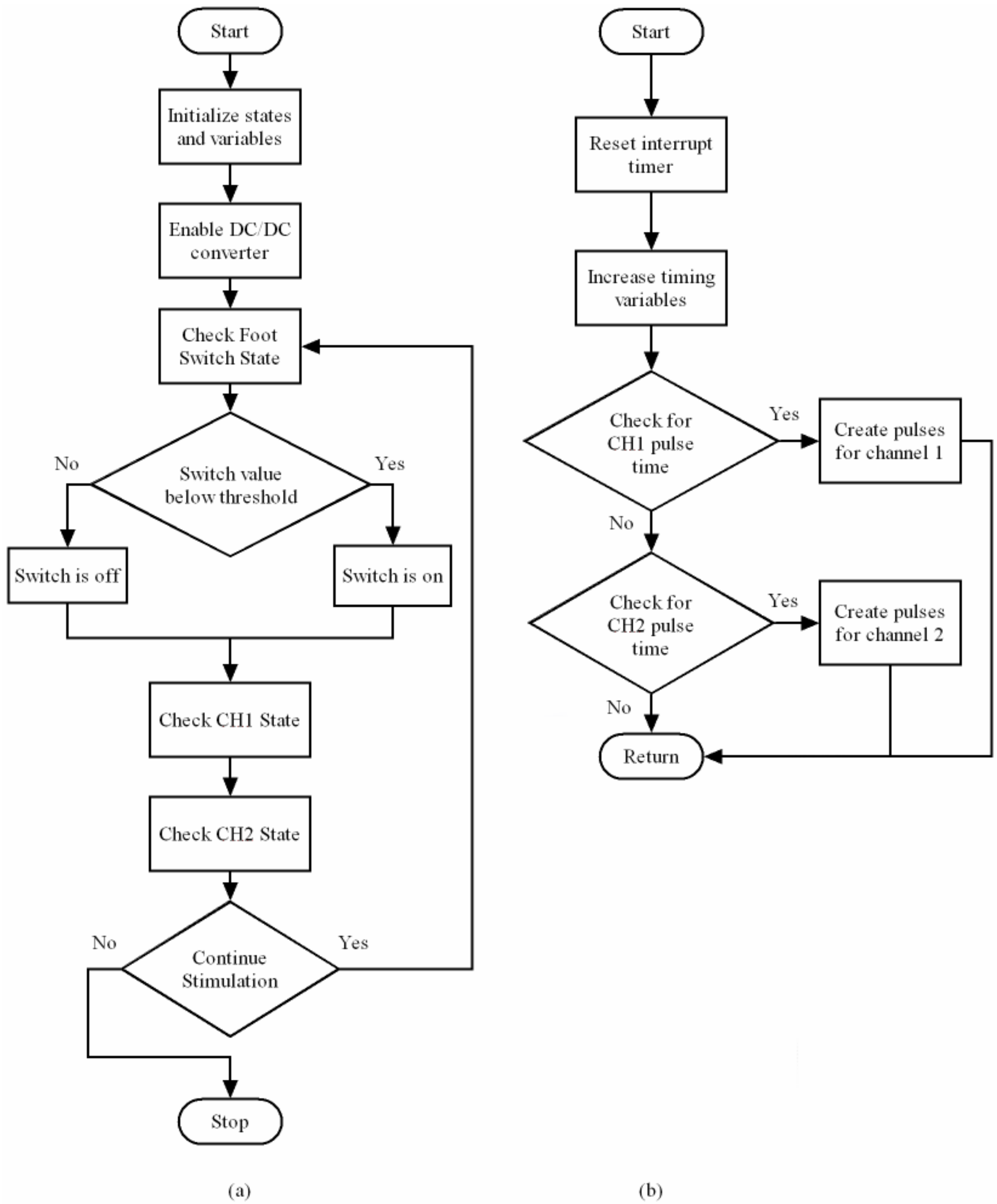


Figure 4.2 Flow charts for the stimulator (a) and interrupt (b) subroutines.

5. TEST RESULTS

In order to evaluate the performance of the designed drop foot stimulator, the channel outputs were tested under load conditions.

5.1 Experimental Methods

The experimental setup consisted of the stimulator, a circuit to simulate the characteristics of a human load, an oscilloscope and a PC.

The stimulator's output electrodes were connected to a test load circuit. During the stimulation process, a *Tektronix TDS1000 Series* oscilloscope was used to record the current and voltage waveforms over this load and the RS232 output port of the oscilloscope was connected to a PC running *WaveStar Software for Oscilloscopes* for saving the recorded waveforms.

The voltage was measured by the oscilloscope's Channel 1 with one probe connected across the electrodes, while the current was measured by Channel 2 with another probe as the voltage across a 1 Ω series resistor. Since the voltage level vas above the oscilloscope's limits, the probe was set to "x10" value. This means that, to be able to read the actual value from the graphs, Channel 1 values must be multiplied by 10.

In the graphs, Channel 1 of the oscilloscope is presented in blue color while Channel 2 is presented in red. Channel number, seen on the left side of the graph, indicates the ground level for the corresponding channel.

The vertical axis of the graph shows the time change in microseconds and the horizontal axis shows the voltage change in volts. The colored notes at the bottom give the scaling values of these axes.

Two types of loads were used during these tests. The circuit diagrams of these loads and oscilloscope connections can be seen in Figure 5.1.

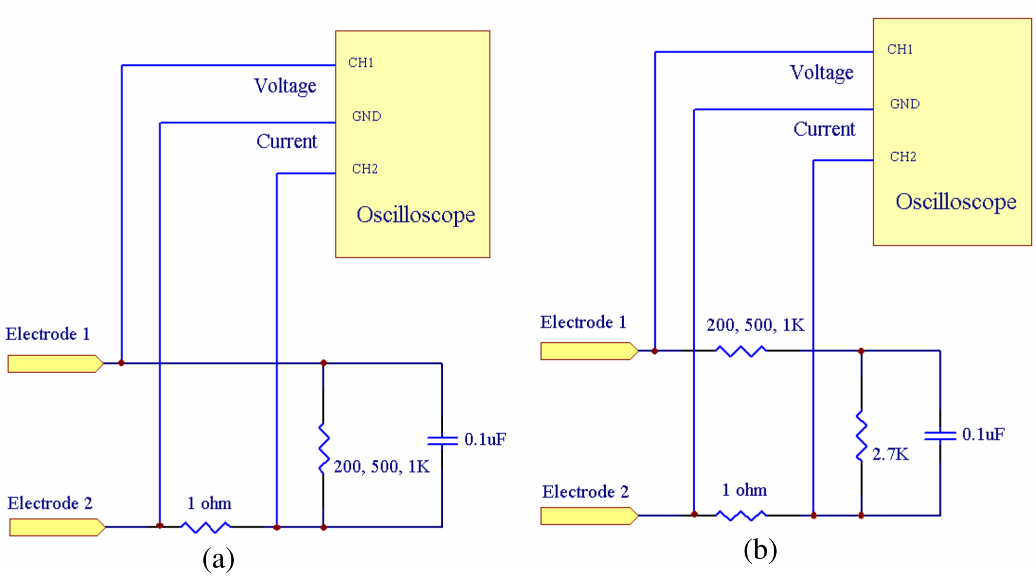


Figure 5.1 (a) Circuit schematics for a typical test load. (b) The standard test load (Specified by The American Standard for Transcutaneous Electrical Nerve Stimulators).

The test load in Figure 5.1(a) is a circuit commonly used by stimulator designers to test the output characteristics of their stimulators. This circuit is composed of a 1 KΩ resistor in parallel with a 100nf capacitor. These components represent the average resistive and the capacitive property of human body during stimulation. The other test load, shown in Figure 5.1(b), is an artificial test load specified by The *American Standard for Transcutaneous Electrical Nerve Stimulators* (ANSI/AAMI NS4-1985). Both of the circuits also have a 1-ohm resistor for measuring the amount of current released from the channels. This way both the voltage and the current change can be seen at the same time.

During tests, both channels of the stimulator were set to amplitudes of 50mA, pulsewidth to 250 µs and frequency to 40 Hz. For biphasic pulses, the pulse interval was set to 10µs.

5.2 Results

To be able to understand the behavior of the stimulator output on different loads, recordings were taken for 200 Ω, 500 Ω and 1 KΩ loads.

Figures from 5.2 to 5.13 show the waveforms taken from the test load shown in Figure 5.1(a), and Figures from 5.14 to 5.25 show the waveforms taken from the test load shown in Figure 5.1(b).

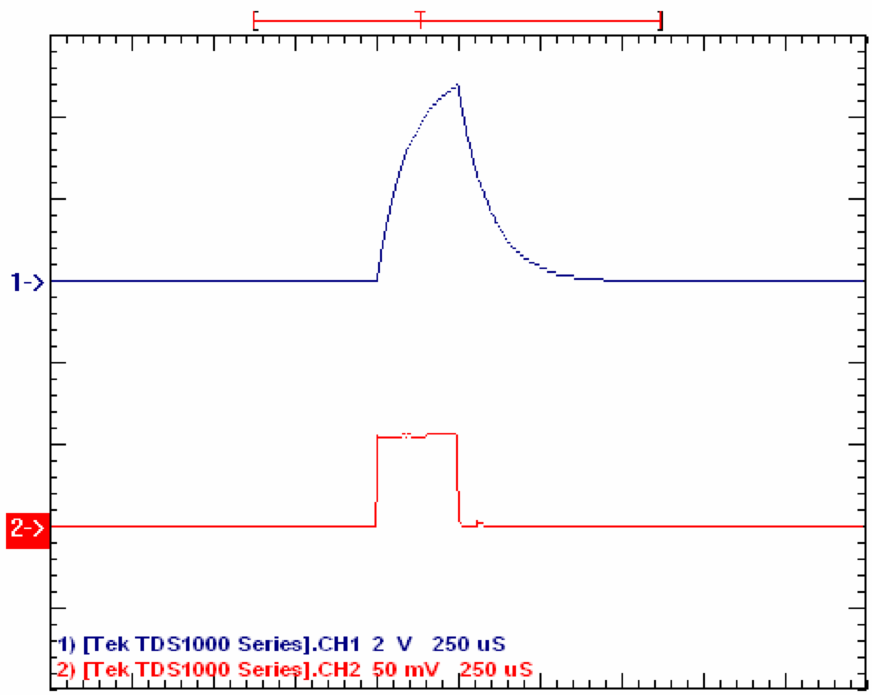


Figure 5.2 Monophasic signal output from Channel 1 for a 1KΩ load.

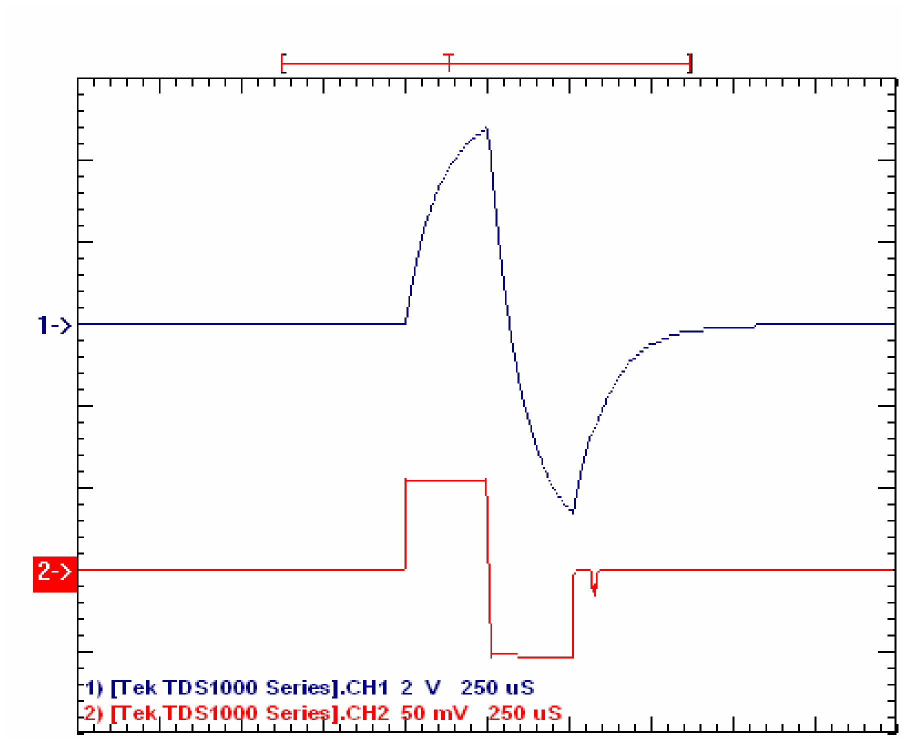


Figure 5.3 Biphasic signal output from Channel 1 for a 1KΩ load.

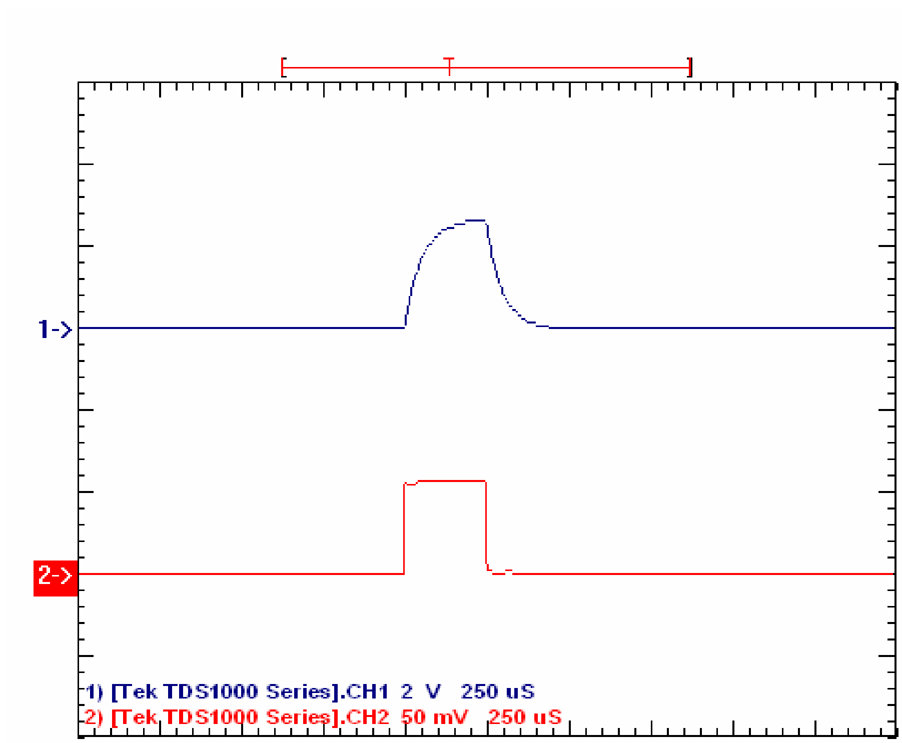


Figure 5.4 Monophasic signal output from Channel 1 for a 500Ω load.

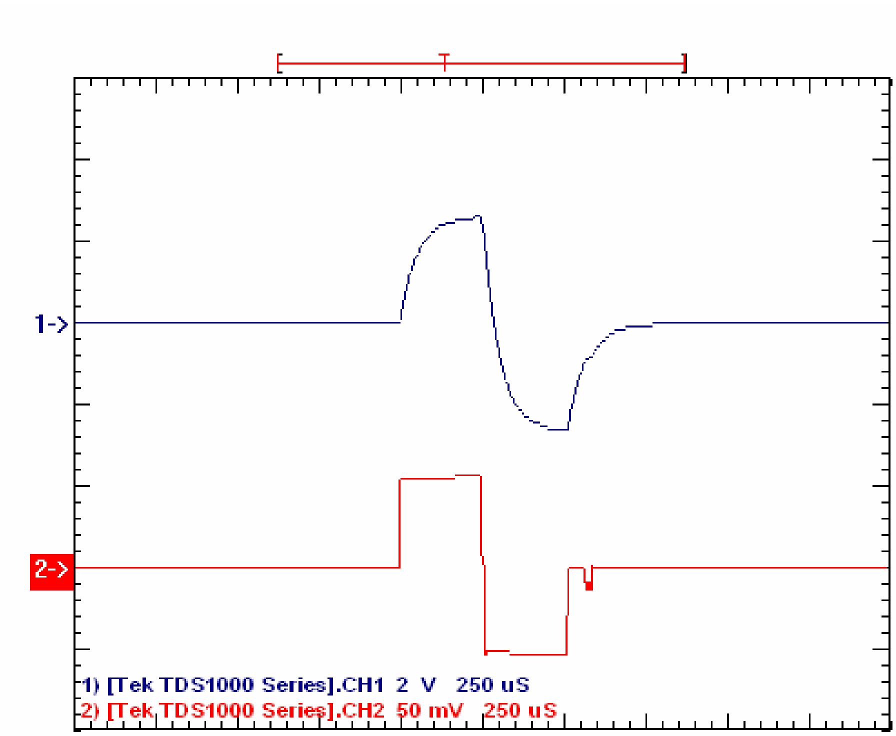


Figure 5.5 Biphasic signal output from Channel 1 for a 500Ω load .

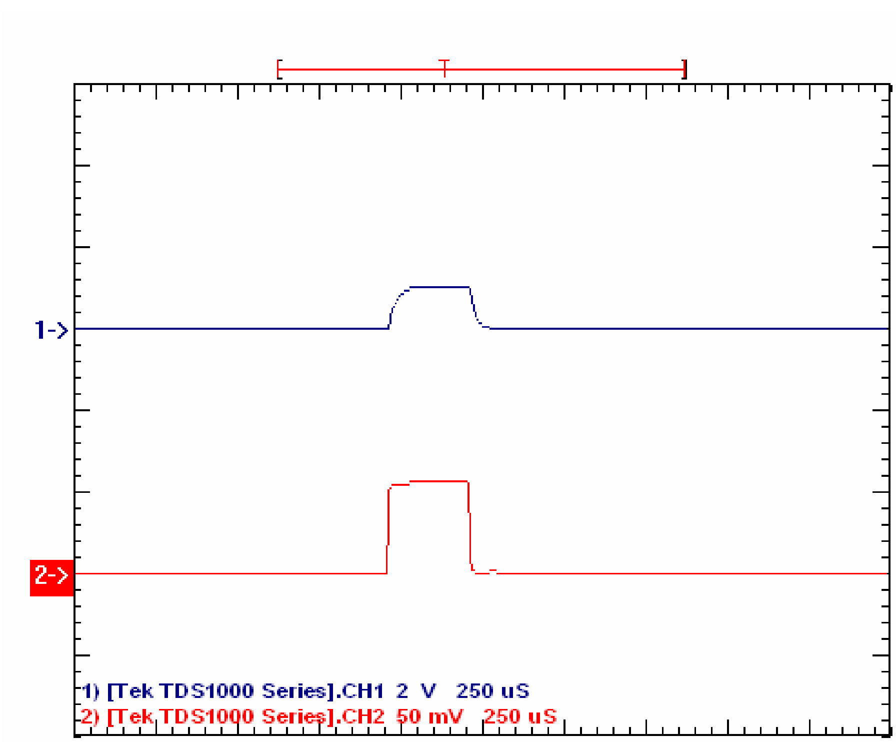


Figure 5.6 Monophasic signal output from Channel 1 for a 200Ω load.

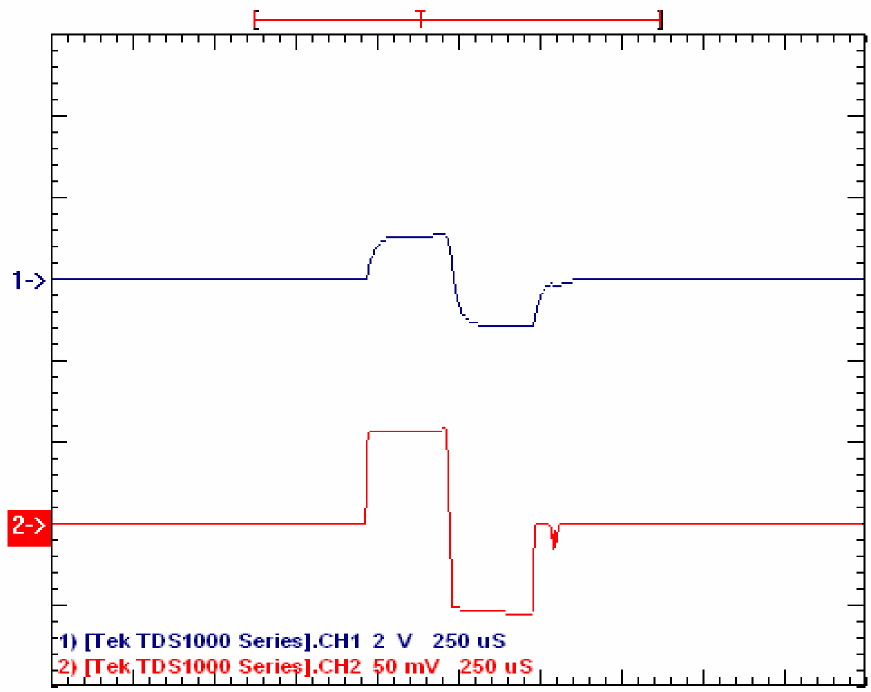


Figure 5.7 Biphasic signal output from Channel 1 for a 200Ω load.

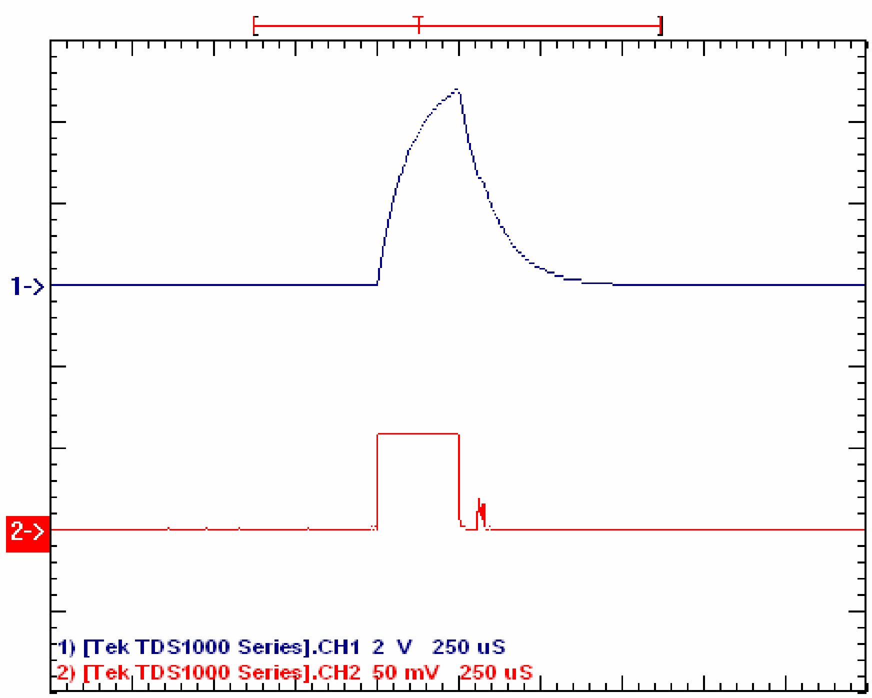


Figure 5.8 Monophasic signal output from Channel 1 for a 1KΩ load.

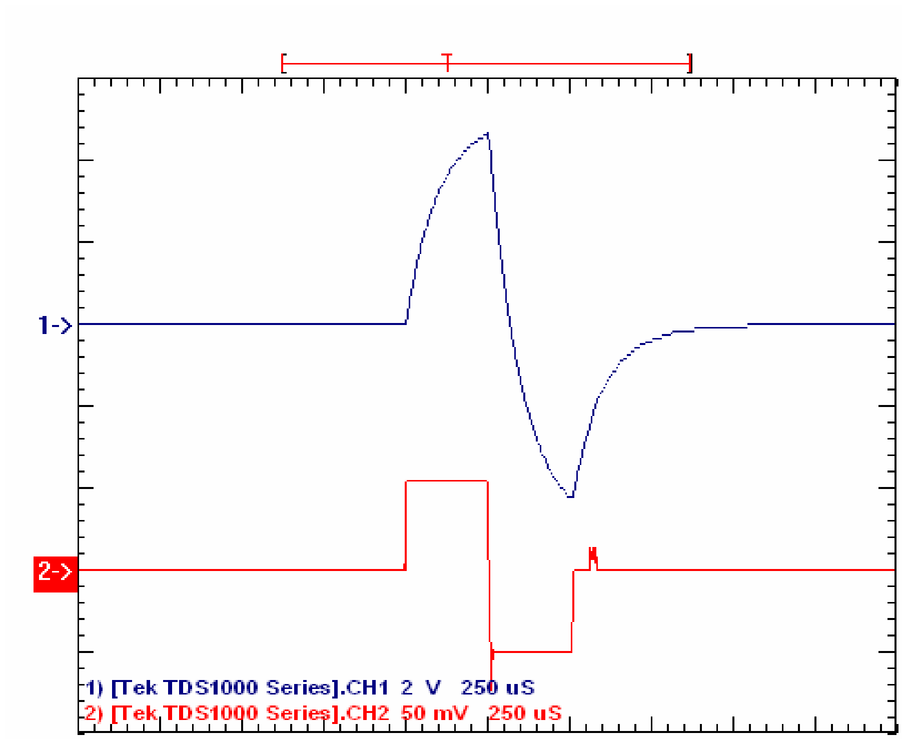


Figure 5.9 Biphasic signal output from Channel 2 for a 1KΩ load.

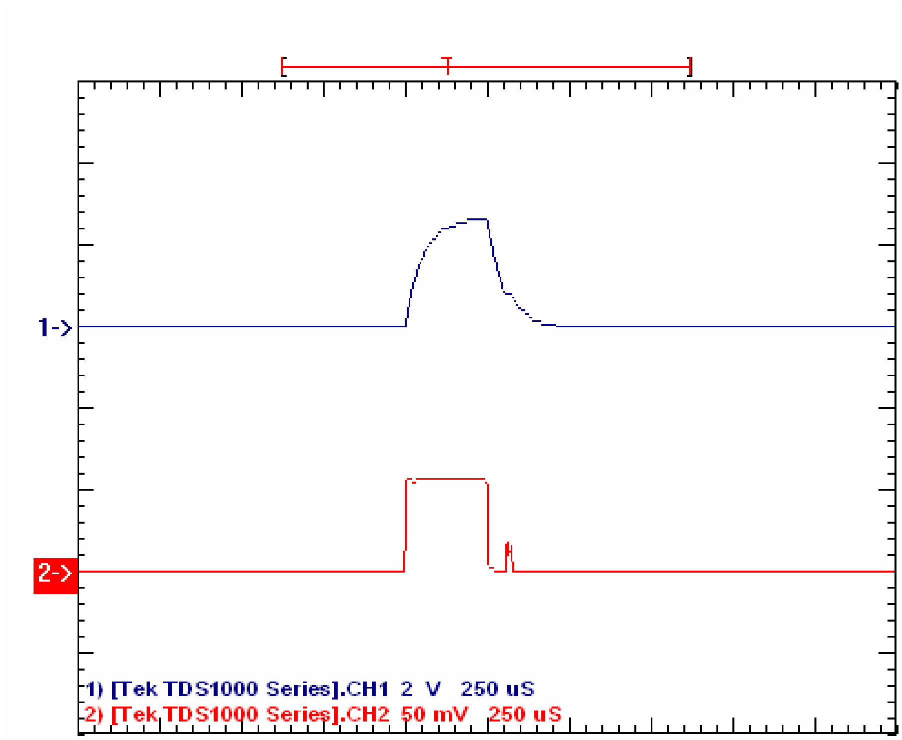


Figure 5.10 Monophasic signal output from Channel 1 for a 500Ω load.

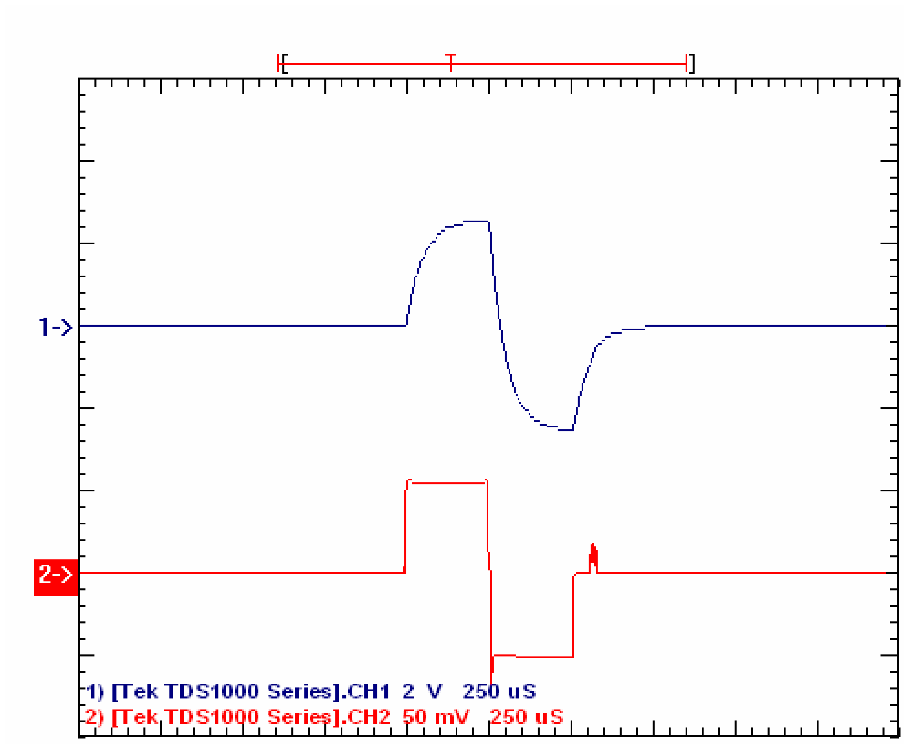


Figure 5.11 Biphasic signal output from Channel 2 for a 500Ω load.

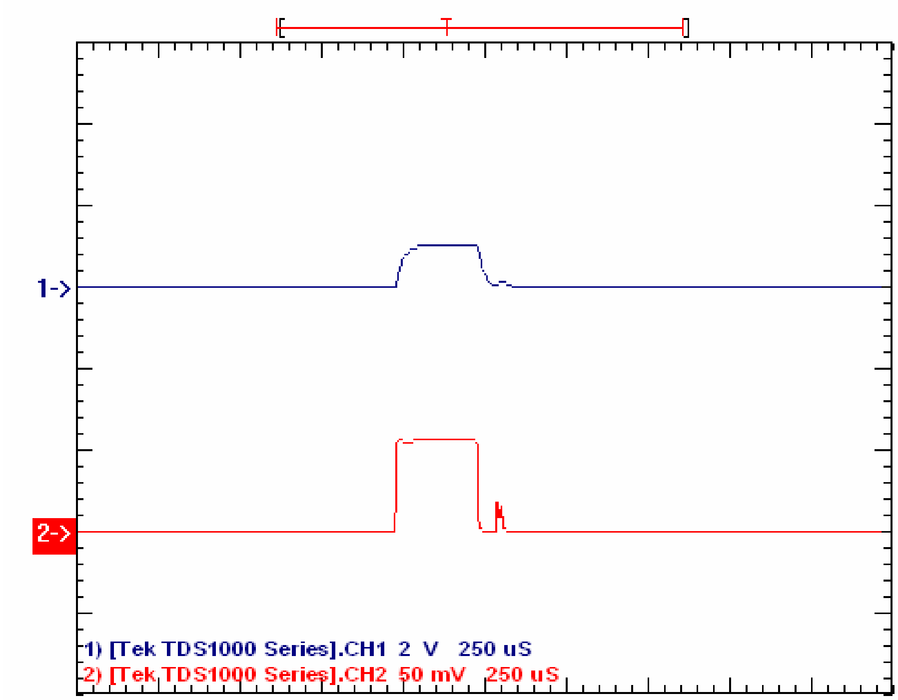


Figure 5.12 Monophasic signal output from Channel 1 for a 1KΩ load.

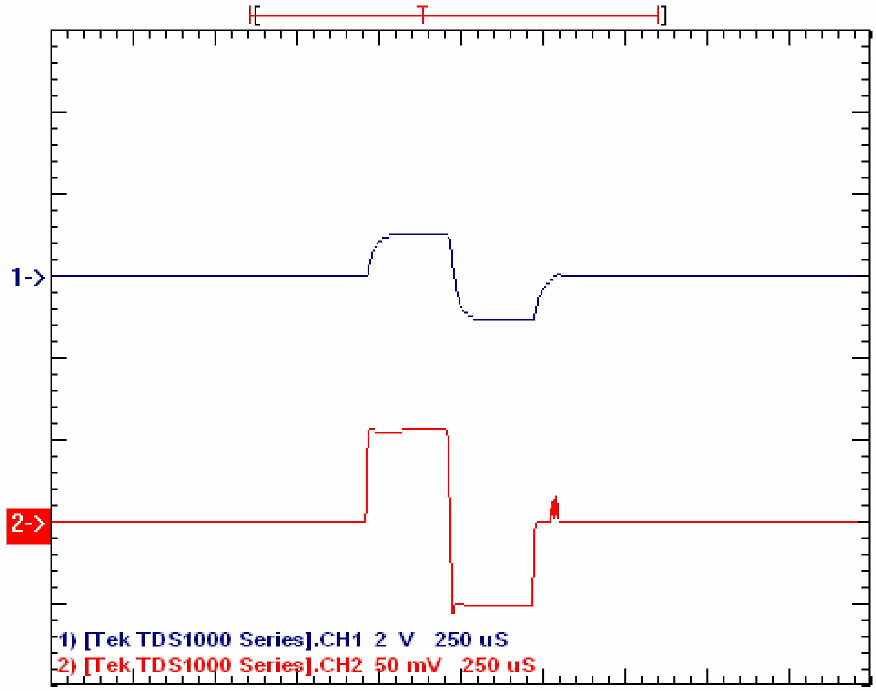


Figure 5.13 Biphasic signal output from Channel 2 for a 200Ω load.

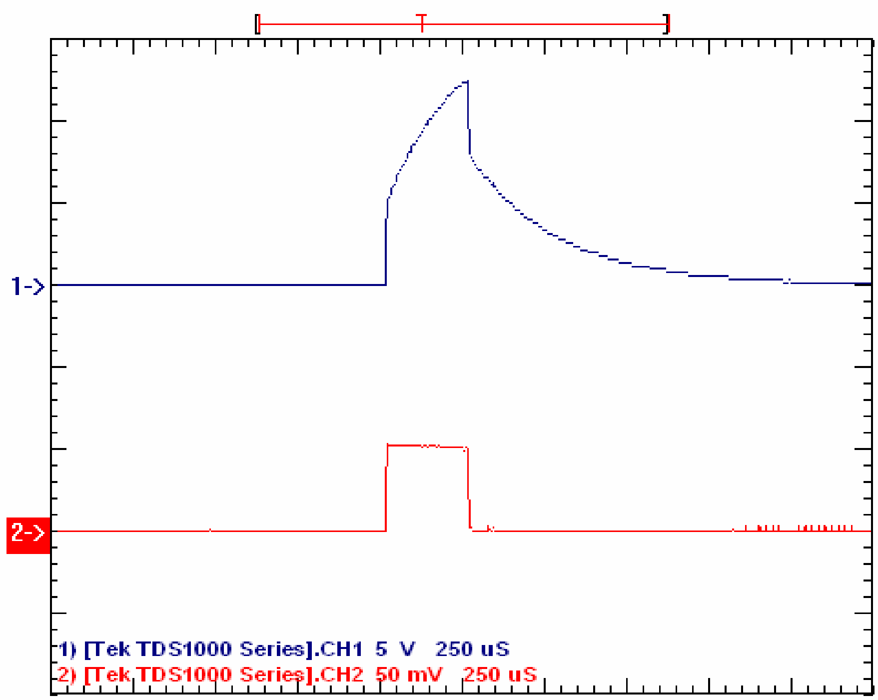


Figure 5.14 Monophasic signal output from Channel 1 for a 1KΩ load.

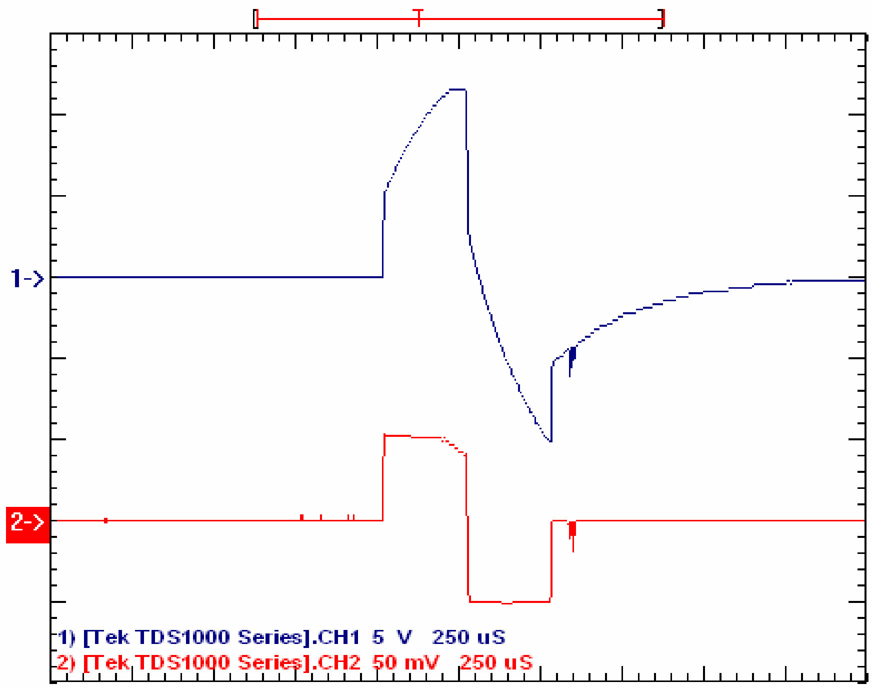


Figure 5.15 Biphasic signal output from Channel 1for a 1KΩ load.

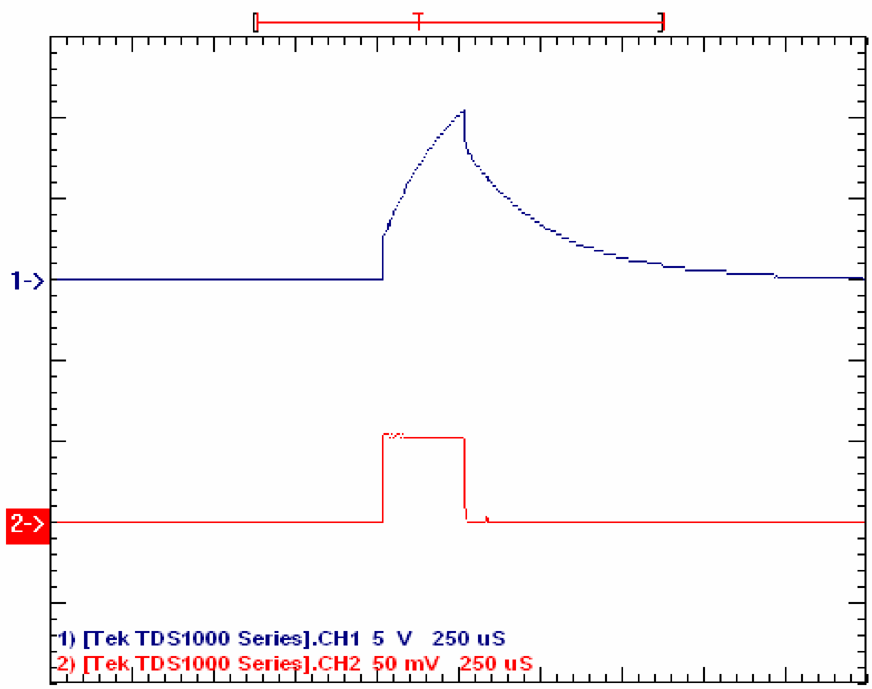


Figure 5.16 Monophasic signal output from Channel 1 for a 500Ω load.

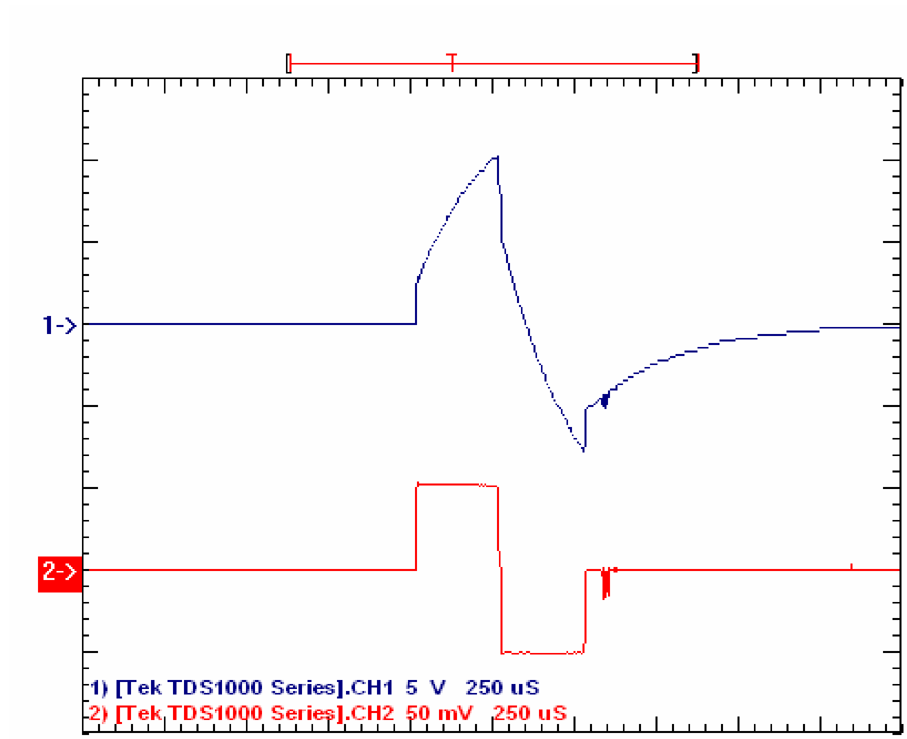


Figure 5.17 Biphasic signal output from Channel 1 for a 500Ω load.

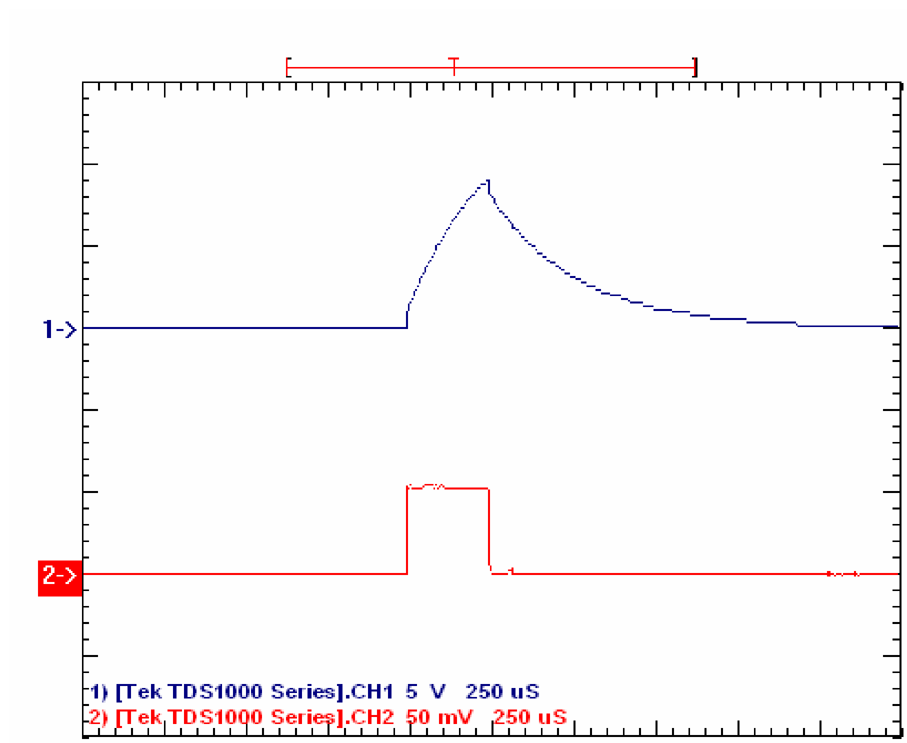


Figure 5.18 Monophasic signal output from Channel 1 for a 200Ω load.

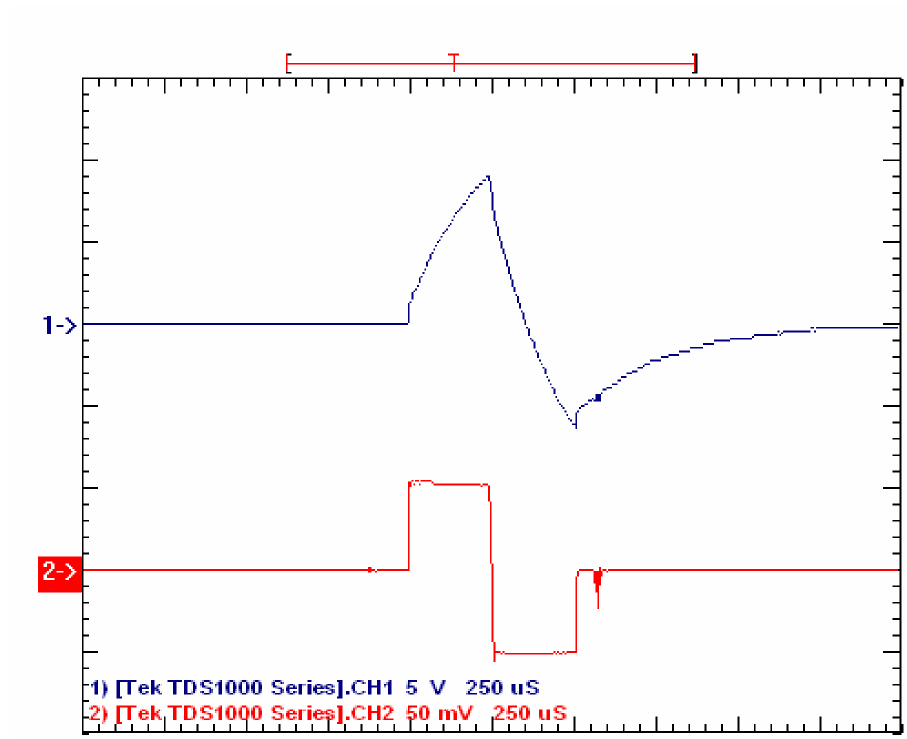


Figure 5.19 Biphasic signal output from Channel 1 for a 200Ω load.

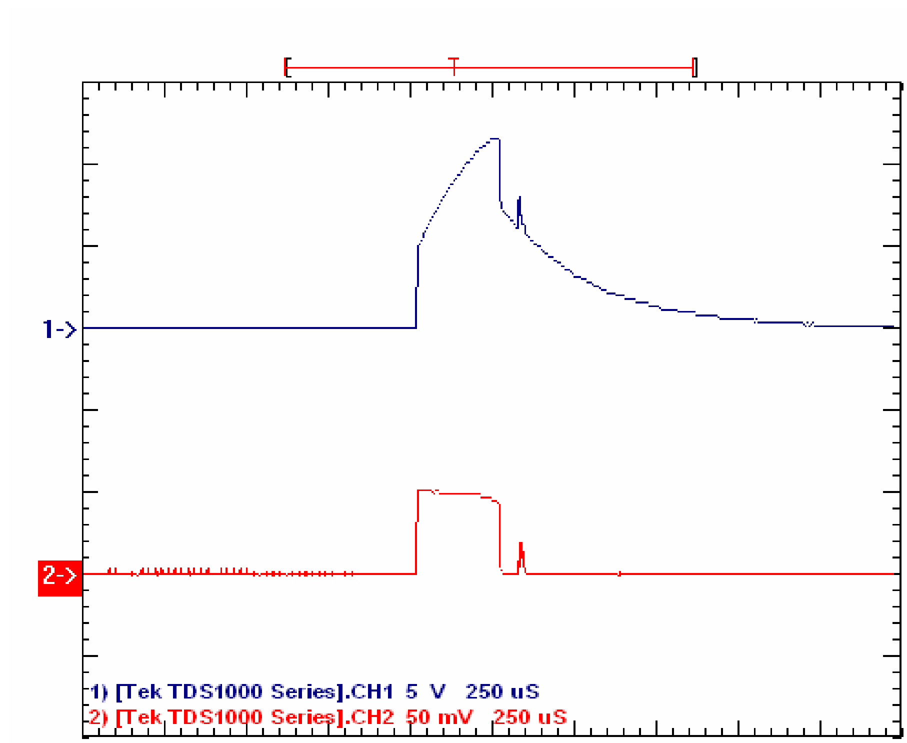


Figure 5.20 Monophasic signal output from Channel 1 for a 1KΩ load.

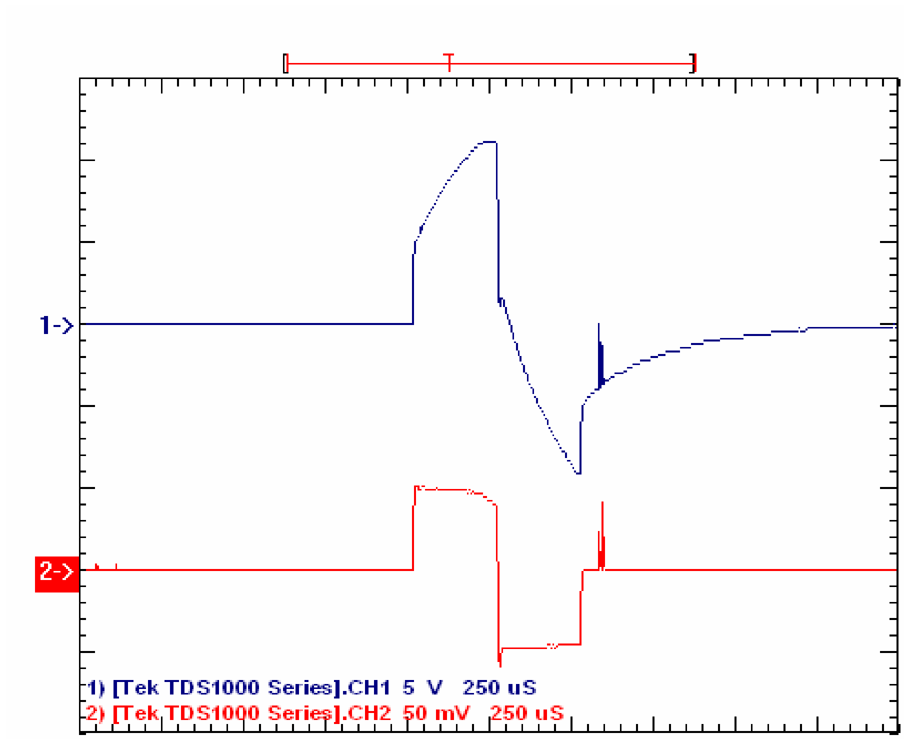


Figure 5.21 Biphasic signal output from Channel 2 for a 1KΩ load.

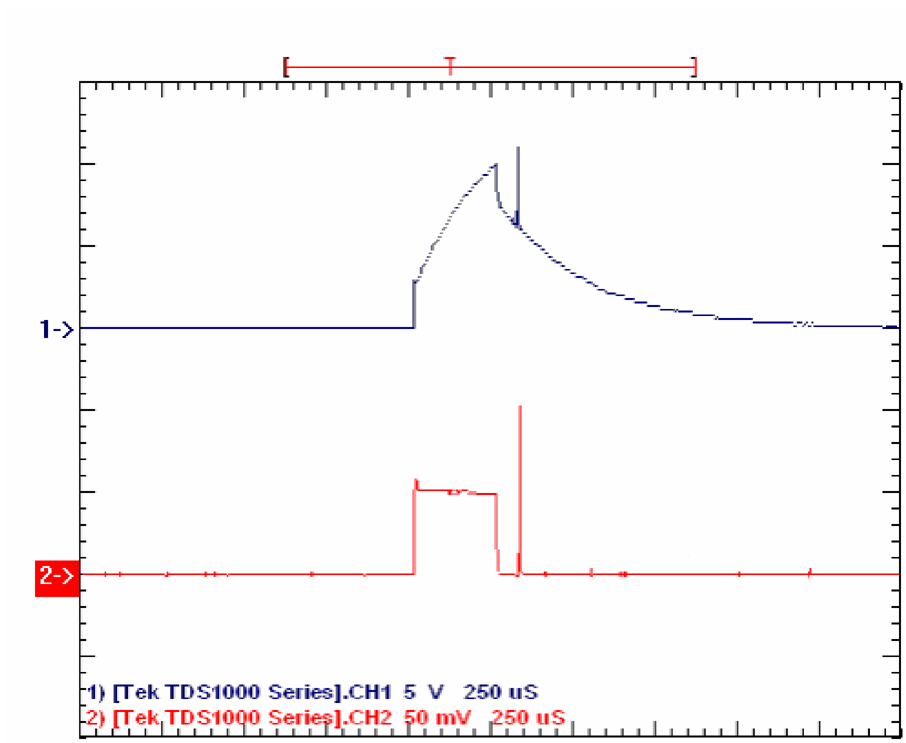


Figure 5.22 Monophasic signal output from Channel 2 for a 500Ω load.

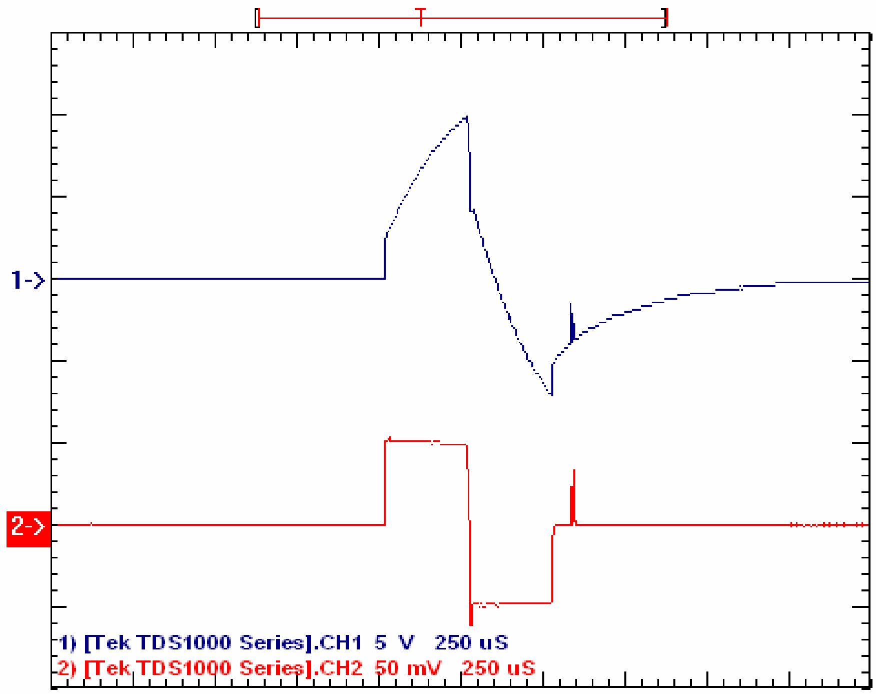


Figure 5.23 Biphasic signal output from Channel 2 for a 500Ω load.

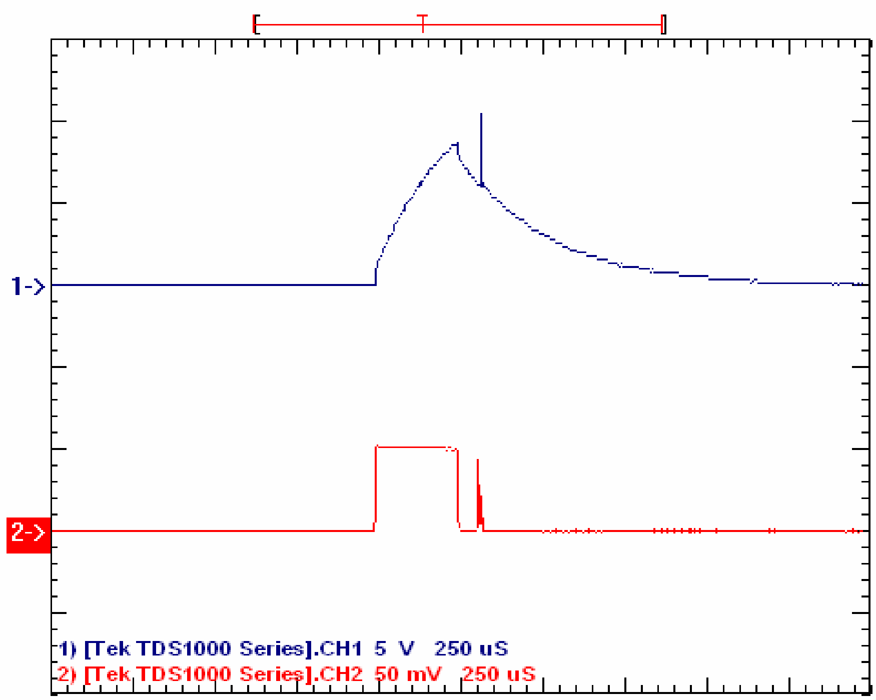


Figure 5.24 Monophasic signal output from Channel 2 for a 200Ω load.

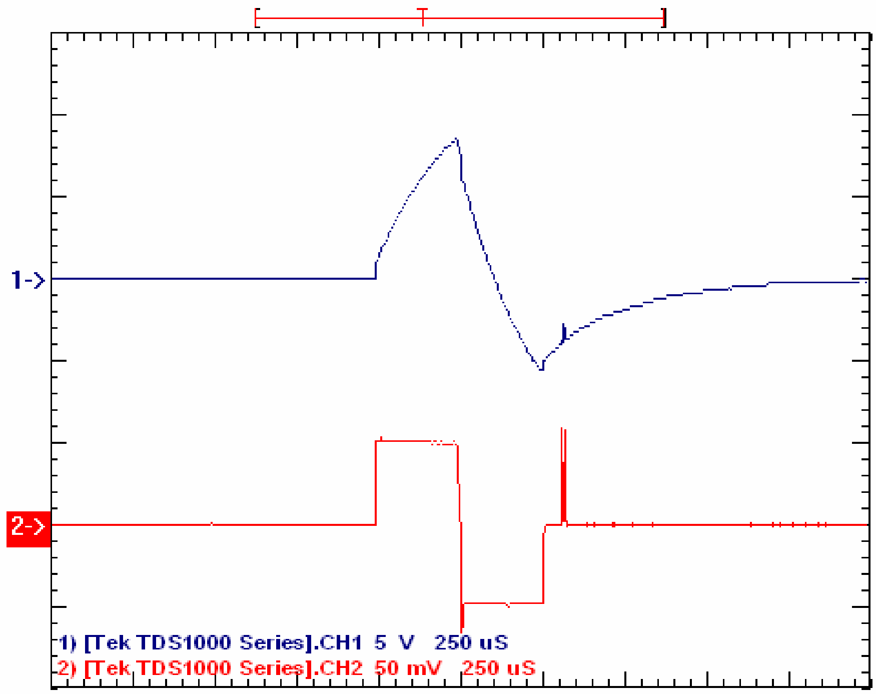


Figure 5.25 Biphasic signal output from Channel 2 for a 200Ω load.

These traces demonstrate that the stimulator can produce balanced, rectangular pulses while driving a load. The current output from the channels stay constant even if the resistive component in the load is different. It is possible to create positive and negative pulses at desired levels.

Recorded waveforms show that a spike occurs after each pulse. Since the DC/DC converter is being stopped during the creation of pulses, when we enable the converter after each pulse, this causes a spike signal in the waveform. However. because this is for a very short time, it doesn't affect our stimulation output.

To illustrate the behavior of the stimulator during an open-circuit state, a couple of other recordings were taken for a 100 kΩ resistive load. These waveforms are shown in Figures from 5.26 to 5.29.

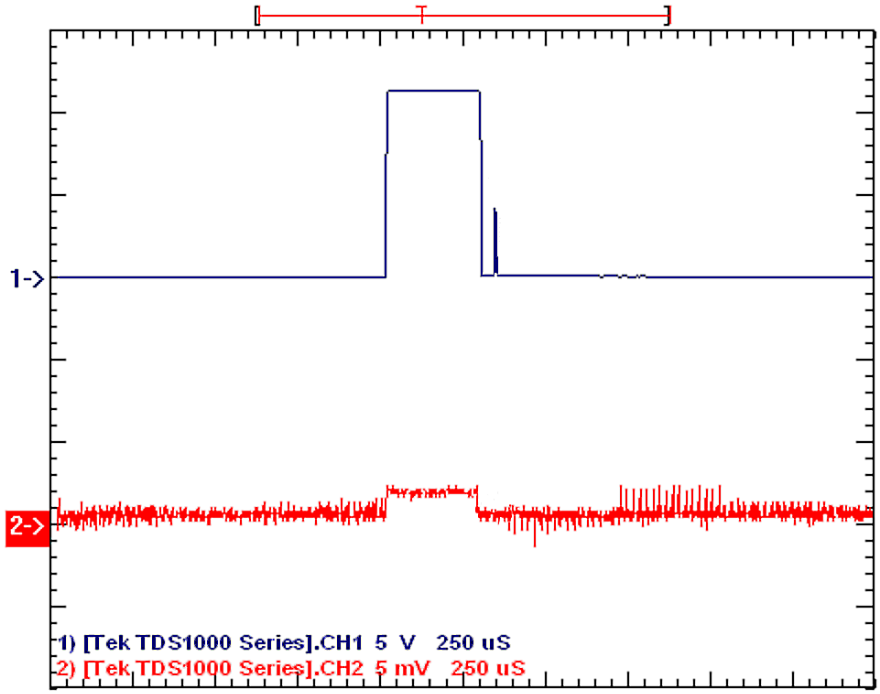


Figure 5.26 Monophasic signal output from Channel 1 for a 100kΩ load.

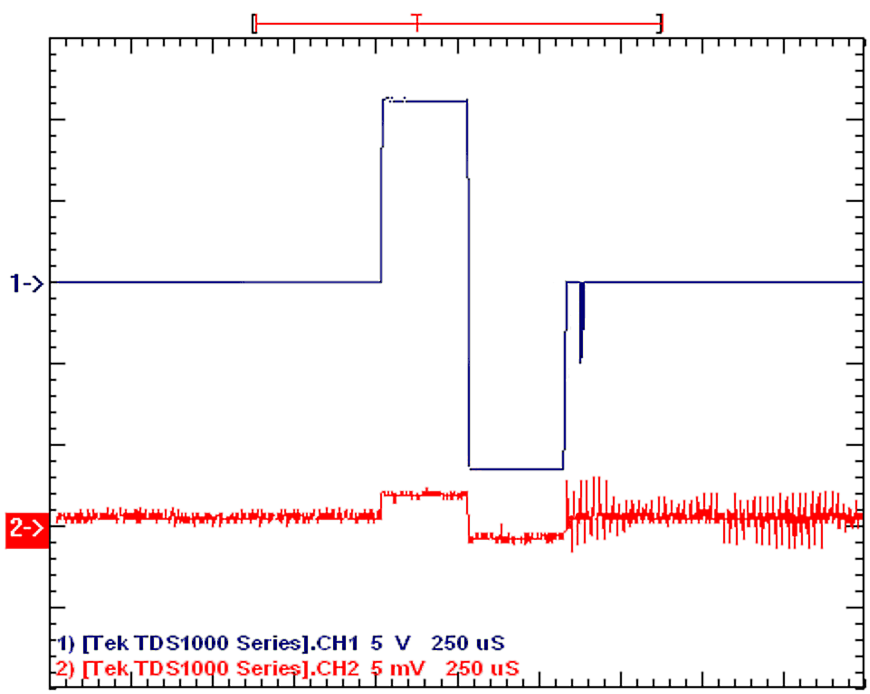


Figure 5.27 Biphasic signal output from Channel 1 for a 100kΩ load.

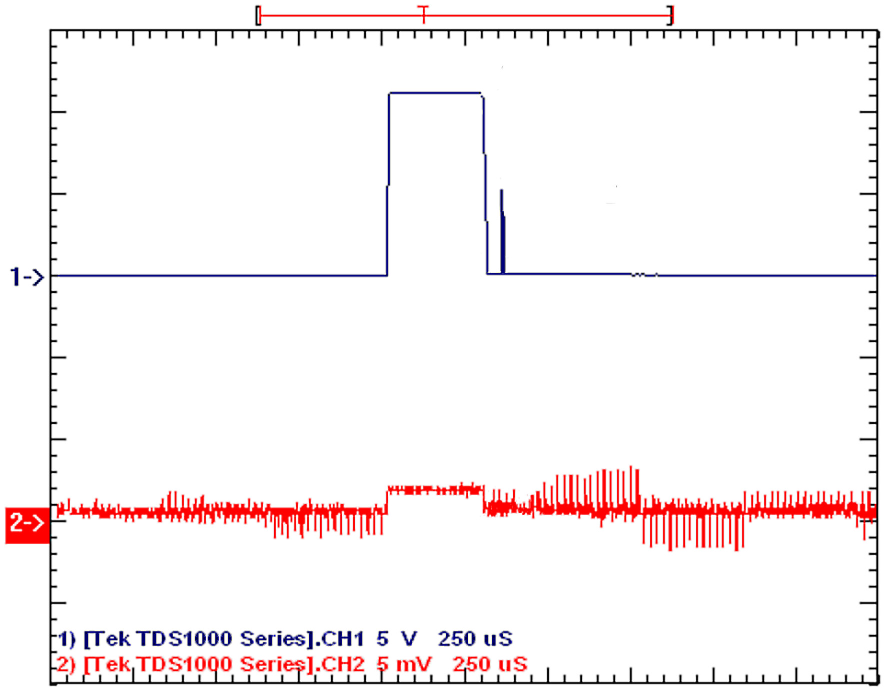


Figure 5.28 Monophasic signal output from Channel 2 for a 100kΩ load.

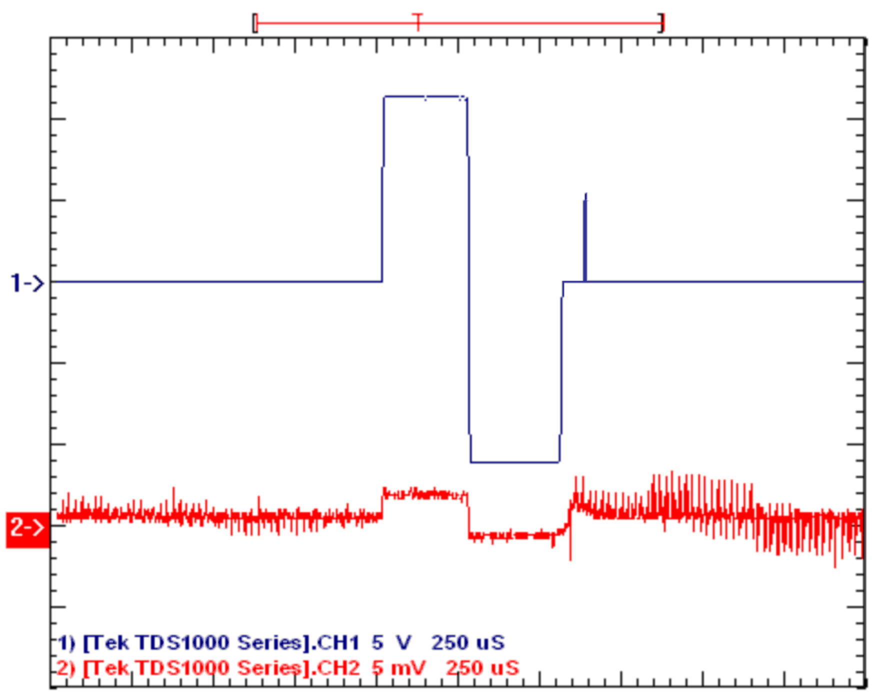


Figure 5.29 Biphasic signal output from Channel 2 for 100kΩ load.

Figures from 5.26 to 5.29 show that the maximum voltage across the electrodes is equal to the DC/DC converter's output voltage. The high frequency signal seen in these waveforms is because of the effect of the transformer.

To compare the selected current values of the stimulator to the actual values seen on the test loads, current output levels were recorded at different configurations for each channel. Figures 5.26 and 5.27 show these recordings.

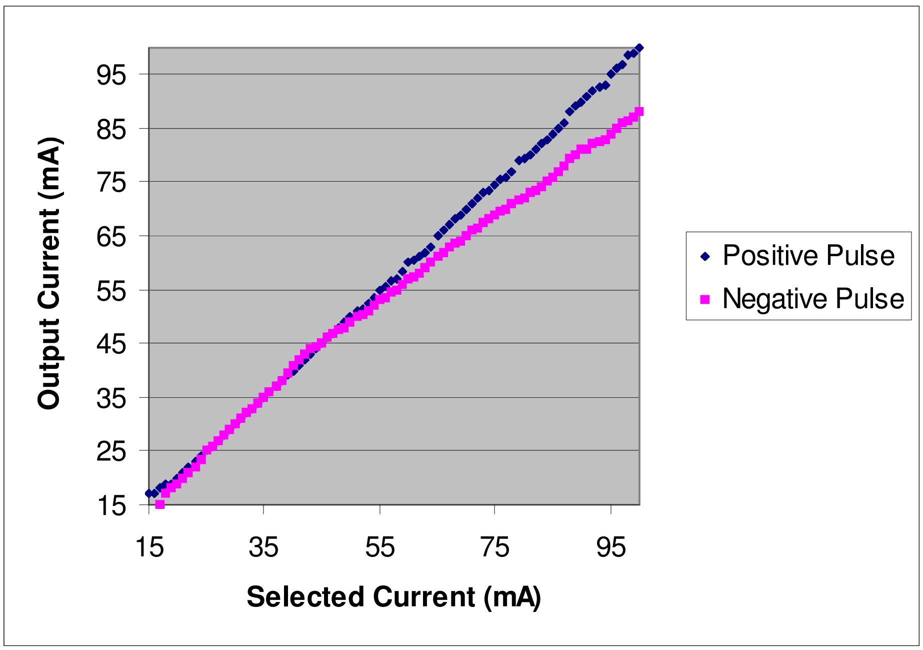


Figure 5.30 Graph of current output levels vs. configured values for Channel 1

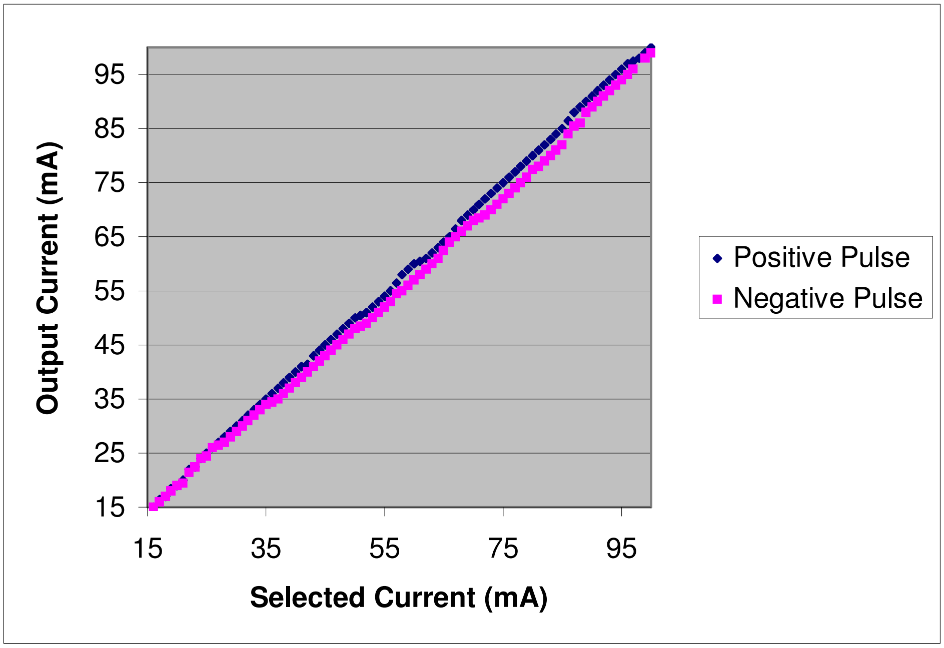


Figure 5.31 Graph of current output levels vs. configured values for Channel 2

These recordings show that the output levels of the channels are at the targeted values. There is a maximum %5 error caused by the tolerance of the circuit components. This error is mostly because of the non-linearity of output current vs. input current characteristic of the optocouplers.

6. DISCUSSIONS AND CONCLUSIONS

This thesis describes the design and development of a portable, user-friendly, programmable, two-channel FES system to assist Drop Foot patients.

6.1 General Discussions

Drop foot is a general term that describes loss of the ability to raise the foot at the ankle. When walking, the patient's foot drops and the toes drag on the floor. It is impossible for them to make the heel strike the ground first. To compensate, the patient develops a high stepping gait, raising the foot as high as necessary to prevent the toes from hitting the ground. The patient also walks with a distinctive “clop” because the foot comes down suddenly.

Drop foot is not a disease but a symptom of another problem. It is a common problem for stroke patients or patients with other neurological conditions including incomplete spinal cord injuries, multiple sclerosis and traumatic brain injury. It is caused partly by poor active motor control of the anterior tibial muscles and partly by spasticity of the calf muscles.

The current medical technologies available are ankle foot orthoses (AFO) or functional electrical stimulation (FES) of the peroneal nerve. Both technologies have been used by many clinical users around the world.

FES is a method of applying low-level electrical current pulses to the body to restore or improve function. These pulses generate action potentials in motor neurons attached to a muscle. The stimuli then propagate along ramified pathways of the nervous system and cause that muscle to contract.

Drop foot can be corrected by using muscle stimulators and synchronizing functional electrical stimulation of the common peroneal nerve to the swing phase of the gait cycle. But for drop foot to be correctable using portable FES, suitable for take home use, sufficient muscle function must remain to enable the subject to stand and walk, even though the walking gait is significantly disturbed.

By provision of dorsiflexion and eversion, the foot clears the ground in the swing phase more easily. This reduces the effort of gait, reducing compensatory activities such as hip hitching and circumduction. Reduction in effort will lead to a reduction of associated reactions and result in a general lowering of tone. Repeated use of the stimulator may then lead to a pattern of normal walking being relearned centrally and long term potentiation of the required pattern of synapses may lead to a reinforcement of this pattern of walking. However, a more immediate benefit from the orthotic use of the device is that walking is easier and safer and therefore confidence will improve leading to an extension of mobility range and an overall improvement in quality of life.

Using FES for the correction of drop foot has been used since early 1960s. Since that time many groups have developed stimulator systems and the devices have received some clinical use but the most frequently used stimulator was the Odstock Dropped Foot Stimulator (ODFS).

Although ODFS was a popular stimulator, there have been some difficulties with the configuration of the device. Since it was a hard-wired design, setting up different stimulation options was achieved using a complex combination of DIP switches and miniature potentiometer settings that were quite difficult to initially set up.

6.2 Conclusions

During the design process, the first thing done was to explore the surface FES stimulator technologies found in the literature since 1960s. This research helped to determine the necessary features that should be in the designed stimulator. These features include the stimulation signal parameters, application timing parameters, necessary feedback controls and user configuration options.

After the main targets of this thesis were determined, a microcontroller was selected as the core component. The PIC16F876 microcontroller was selected because of its in-built A/D converter, PWM output, 8K FLASH program memory and small size. To be able to collect the feedback information during a gait cycle, a pressure sensor was selected next. The FlexiForce Sensor Model A201 was chosen for the circuit because of its thin and flexible structure. The other components were chosen one by one during the design process.

In order to program the microcontroller, a program code has been written in PicBasic Pro programming language. This language has been chosen because of the simplicity of the language and the complexity of the program. In the designed system, the microcontroller does many operations like creating stimulation pulses, current control, A/D conversion, configuring potentiometer by serial communication, and controlling the LCD display. PicBasic made it easier to configure these processes.

After the software and hardware developments were finished, components were placed on a printed circuit board and packaged into a housing.

The main components of the implemented FES system are the electrodes, the stimulator, and sensors or switches. The stimulator controls the strength and timing of the low-level pulses that flow to the electrodes. The sensors or switches control the starting and stopping of the pulses supplied by the stimulator.

The device has two independently programmable constant current outputs, which can produce biphasic pulses having pulsewidths up to 350 µS and amplitudes up to 100 mA. A microcontroller core controls all of the parameters. A new program code has been written for controlling stimulation parameters and storing them for a future application. The system can be programmed using pushbuttons and an LCD display. A foot switch worn by the patient, under the heel, is used for getting feedback control for stimulation timing during the gait cycle. This foot switch triggers the output channels to stimulate the related muscles through electrodes that are placed over the nerves.

The experimental tests explained in Chapter 5 shows that the system is reliable and the performance of the design is satisfactory. The device works according to the stated specifications. It is possible to obtain constant current stimulation pulses at the desired amplitude and frequency from the output channels.

Although the proposed targets are mostly reached, some arrangements can be made to improve the performance of the stimulator as described in the following section.

6.3 Future Work

One of the main problems with the portable stimulators is the power consumption. To be able to achieve high level stimulation outputs for more than a couple of hours, long lasting rechargeable batteries (like lithium-ion batteries) can be integrated into these systems.

In some cases, a simple foot switch may not meet the needs of a patient. This may result in the need of an advanced sensor system that can sense the events of a gait cycle. These sensors can have multiple sensors to measure the pressure applied to any part of the foot or the information can be taken from the neural activity in the related parts.

There are some disadvantages of using surface electrodes. For example the patient needs to position the electrodes on a daily basis. Surface electrodes can cause skin allergy and they need to be changed frequently. New implanted systems would solve some of these problems.

A cosmetic improvement can also be important for the device to be acceptable by the users. It is always better to have a small size and weight. A PC-based user interface can be added to make it easier to configure.

APPENDIX A

SETUP MANUAL

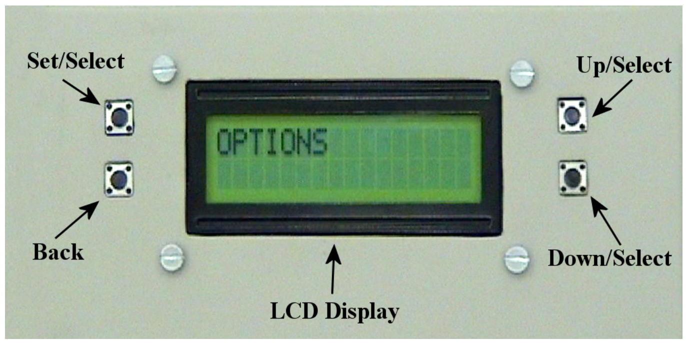


Figure A.1 Front panel of the stimulator

The FES can be configured by selecting the desired options from the menu. LCD display shows the part of the program the user is currently in. By selecting any of the four pushbuttons, user can go to another part of the menu.

There are four pushbuttons. These are:

- **Set/Select:** This is the main button for setting the stimulation parameters and storing them in the memory.
- **Up/Select:** The main function of this button is to increase a variable or move up in the menu. But in some cases it can also be used to select an option to configure. When in the LCD display, option name points to this button, pushing this button will select that part of the menu.
- **Down/Select:** This button's function is similar to Up/Select button. But this button is mainly used to decrease a variable's value or move down in the menu.
- **Back:** This button brings the previous menu.

The architecture of a channel menu is shown in the figure A.2.

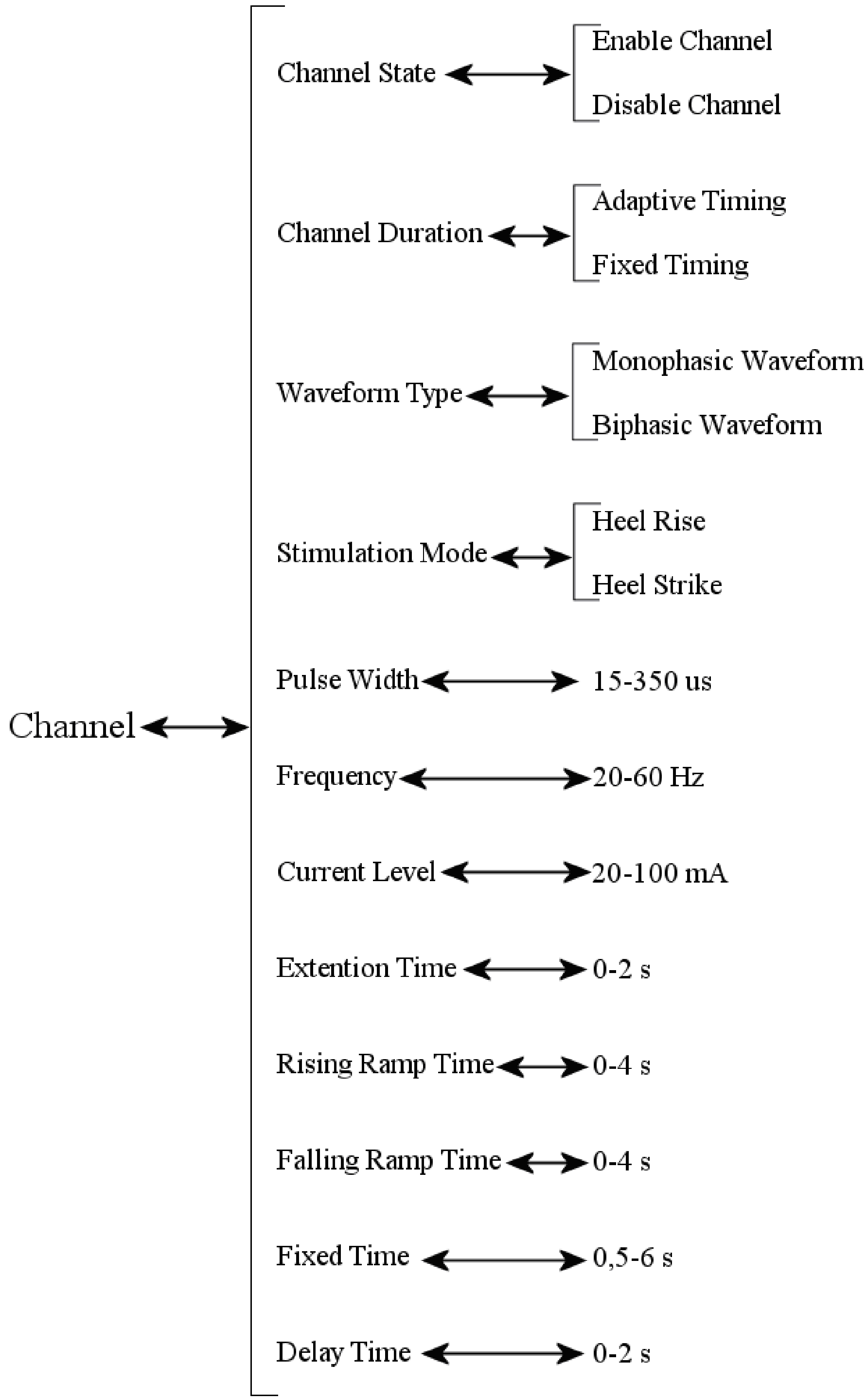


Figure A.2 Options that can be selected under a channel menu.

When the device is powered up, it opens with the options menu. By following the LCD display, desired option can be selected. An example is shown in Figure A.3.

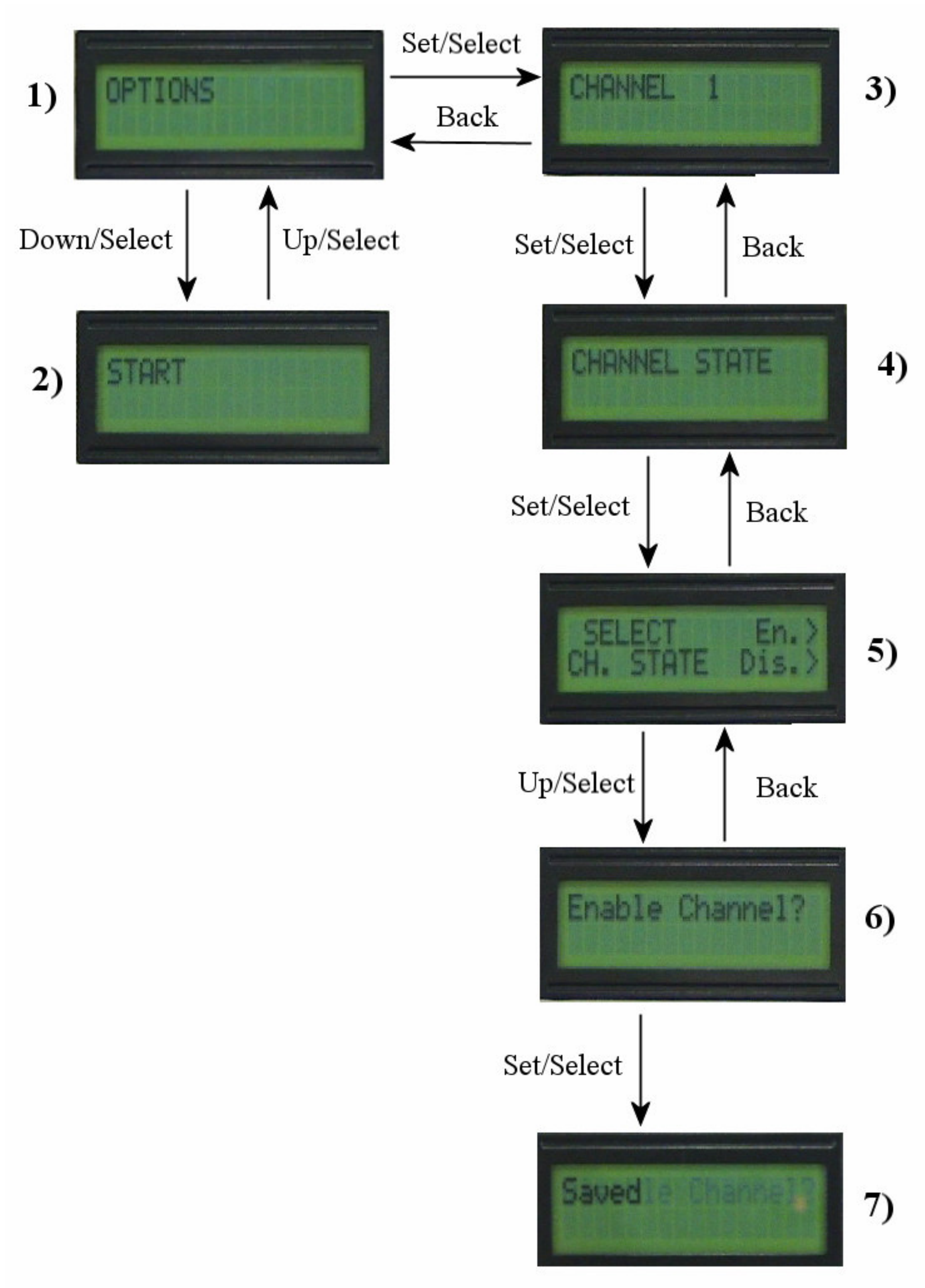


Figure A.3 Steps for enabling Channel 1.

APPENDIX B
THE SOFTWARE

The software is included in the CD-ROM attached to the back cover of the thesis.

APPENDIX C

CONNECTION DIAGRAM OF THE CIRCUIT

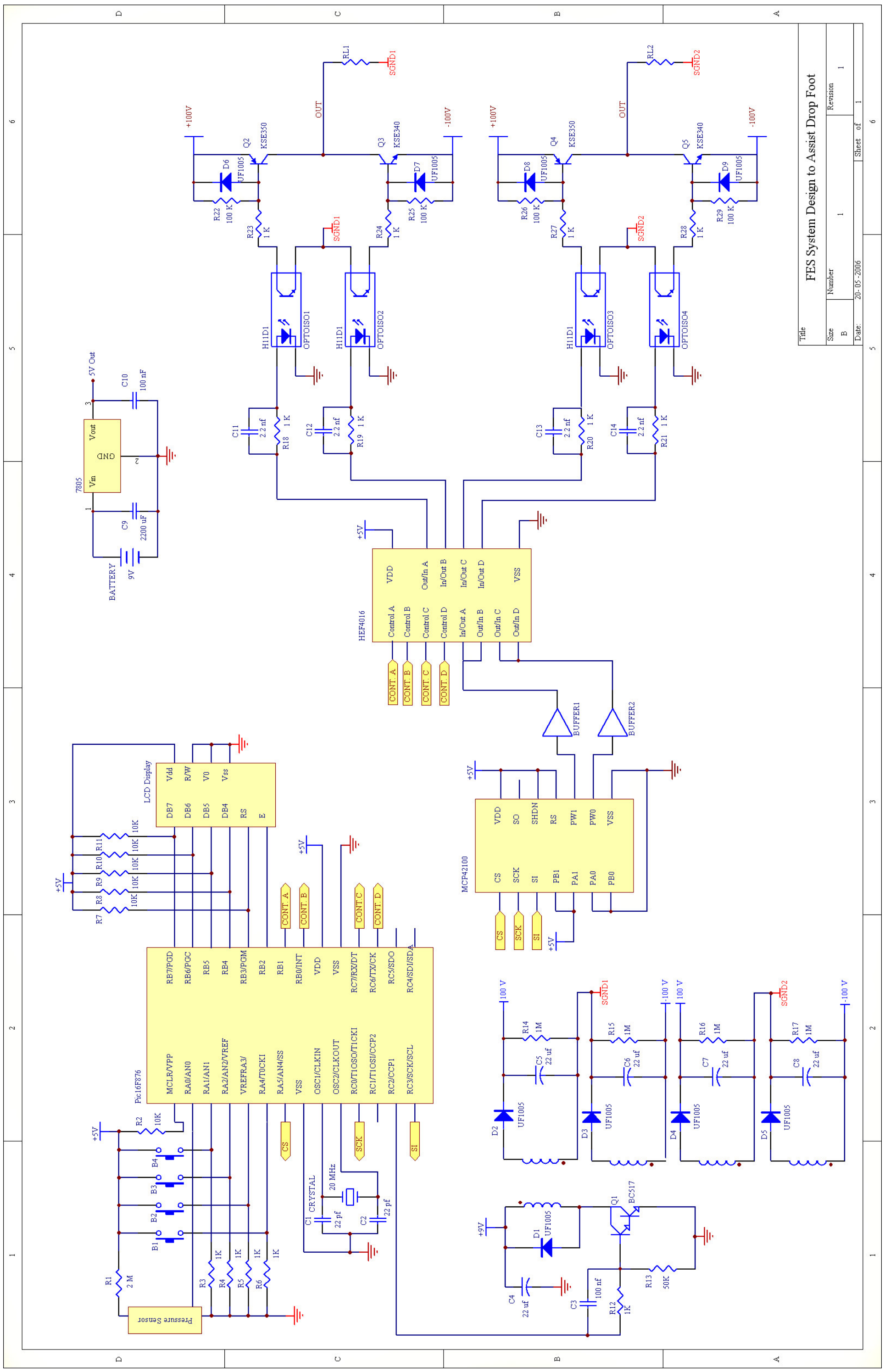


Figure A.4 Connection Diagram of the Circuit

APPENDIX D

SPECIFICATIONS OF THE PRESSURE SENSOR

A201 Sensor	
Physical Properties	
Thickness	0.008" (.208mm)
Length	8" (203mm) 6" (152mm) 4" (102mm) 2" (51mm)
Width	0.55" (14mm)
Sensing Area	0.375" diameter (9.53mm)
Connector	3-pin male square pin
Thickness	0.008" (.208mm)
Typical Performance	
Linearity Error	<+/-5%
Repeatability	<+/-2.5% of full scale (conditioned sensor, 80% force applied)
Hysteresis	<4.5% of full scale (conditioned sensor, 80% force applied)
Drift	<5% per logarithmic time scale (constant load of 90% sensor rating)
Response Time	<5 microseconds
Operating Temperatures	15°F to 140°F (-9°C to 60°C)
Force Ranges	0-1 lb. (4.4 N) 0-25 lbs. (110 N) 0-100 lbs. (440 N)
Temperature Sensitivity	Output variance up to 0.2% per degree F (approximately 0.36% per degree C)

APPENDIX E

DATASHEET OF THE PIC16F876 MICROCONTROLLER

The datasheet of the PIC16F876 microcontroller is included in the CD-ROM attached to the back cover of the thesis.

APPENDIX F
DATASHEET OF THE MCP42100 DIGITAL POTENTIOMETER

The datasheet of the MCP42100 digital potentiometer is included in the CD-ROM attached to the back cover of the thesis.

REFERENCES

1. Swain, I.D., Taylor, P.N., Burridge, J.H., Hagan, S.A., Wood, D.E., *Common Peroneal Stimulation For The Correction Of Drop-Foot*. Report To The Development Evaluation Committee, 1996.

2. Rahul Nath M.D., *Information About Foot Drop*, Texas Nerve And Paralysis Institute, Available: http://www.drnathfootdrop.com/

3. Lyons, G.M., Sinkjaer, T., Burridge, J.H., Wilcox, D.J., "A review of portable FES-based neural orthoses for the correction of drop foot", *IEEE Transactions on Neural systems and Rehabilitation Engineering*, Vol. 10, No. 4, pp. 260-279, December 2002.

4. W. T. Liberson, H. J. Holmquest, D. Scott, and M. Dow, "Functional Electrotherapy in stimulation of the peroneal nerve synchronized with the swing phase of gait in hemiparetic patients," *Arch. Phys. Med. Rehabil.*, vol. 42, pp. 101–105, 1961.

5. Elaine N. Marieb, R.N.,Ph.D., *Human Anatomy and Physiology, 3rd Edition*, The Benjamin/Cummings Publishing Company Inc., 1995.

6. Charand, K.X., "Nerve Cell", *HyperPhysics*, Georgia State University, Atlanta, 2005. Available: http://hyperphysics.phy-astr.gsu.edu

7. Fox, Stuart Ira, *Human Physiology, 7th Edition*, McGraw-Hill, 2002

8. Sheffield, S., *An Online Examination of Human Anatomy and Physiology*, 2005. Available: http://www.getbodysmart.com/

9. Matthews, Gary G., *Neurobiology: Molecules, Cells, and Systems*, Blackwell Science Inc., 2000.

10. Technical Aspects of Peripheral Electrical Nerve Stimulation, B. Braun, Medical Inc., 2002. Available: http://www.bbraunusa.com

11. Kenneth & Saladin, Anatomy and Physiology: The Unity of Form and Function, The McGraw-Hill Companies Inc., 1998.

12. Winter, D.A., *The Biomechanics and Motor Control of Human Gait Normal, Elderly and Pathological*, University of Waterloo press, 1991.

13. Blaya, Joaquin A., *Force Controllable Ankle Foot Orthosis (AFO) to Assist Drop Foot Gait,* Master's Thesis, Massachusetts Institute of Technology, USA, February 2003.

14. Gage, J.R., *Gait Analysis and Cerebral Palsy,* (McKeith Press) Blackwell, Oxford/UK & Cambridge University Press, Boston/New York, 1991.

15. Perry, J. *Gait Analysis: Normal and Pathological Function*, Slack Inc., New Jersey, 1992.

16. D. Maxwell, N. Barr, *Functional Anatomy & Biomechanics*, 1996, Available: http://www.gla.ac.uk/ibls/fab/

17. Molson Medical Informatics Project, *Normal Gait*, May 15, 1999 Available: http://sprojects.mmip.mcgill.ca/gait/normal/intro.asp

18. Inman, V. T., Ralston, H. J., and Todd, F., *Human Walking*, Williams & Wilkins, Baltimore. 1981.

19. Whittle, M., *Gait Analysis: An Introduction*, Butterworth-Heinemann Ltd., Boston, 1991.

20. McNamara, Brian, "Anatomy primer: Foot drop", *Advances in Clinical Neuroscience and Rehabilitation* Vol. 3 Issue 1 March/April, 2003

21. Berns, Paul, Douglas, Roy, *FES Resource Guide*, The Society to Increase Mobility Inc., 2004. Available: http://fescenter.case.edu

22. Taylor, P.N., "The use of electrical stimulation for correction of dropped foot in subjects with upper motor neuron lesions". *Advances in Clinical Neuroscience and Rehabilitation*, 2(1): 16-18, 2002.

23. Wu, K.K., *Foot Orthoses: Principles and Clinical Applications*, Williams & Wilkins, Baltimore, 1990.

24. Good, D. G., and Supan, T. J. "Basic principles of orthotics in neurologic disorders." *Orthotics in Neurologic Rehabilitation*, M. L. Aisen, ed., Demos Publications, New York, 1989.

25. Popovic, M., Keller, T., Pappas, I. P. I., Vietz, V., and Morari, M, "Surface-stimulation technology for grasping and walking neuro-prosthesis." *IEEE Engineering in Medicine and Biology*, 82-93, 2001

26. Guyton A, Hall J, *Textbook of Medical Physiology 9th Ed.* W. B. Saunders Company, 1996.

27. Bajd, T., Kralj, A., Stefancic, M., and Lavrac, N. "Use of functional electrical stimulation in the lower extremities of incomplete spinal cord injured patients." *Artificial Organs,* 23(5), 403-409, 1999.

28. L. Vodovnik, M. R. Dimitrijevic, T. Prevec, and M. Logar, "Electronic walking aids for patients with peroneal palsy," *Proc. Europ. Symp. Med. Electron.*, 1965, pp. 58–61.

29. B. R. Bowman and L. L. Baker, "Effects of waveform parameters on comfort during transcutaneous neuromuscular electrical stimulation," *Ann. Biomed. Eng.*, vol. 13, pp. 59–74, 1985.

30. F. Gracanin, F. Trnkcozy, and A. Trnkcozy, "Optimal stimulus parameters for minimum pain in the chronic stimulation of innervated muscle," *Arch. Phys. Med. Rehab.*, vol. 56, no. 6, pp. 243–249, 1975.

31. M. Milner, A. O. Quanbury, and J. V. Basmajian, “Surface electrical stimulation of the lower limb,” *Arch. Phys. Med. Rehab.*, vol. 51, pp. 540–548, 1970.

32. E. Pedersen, T. Petersen, C. Hansen, and B. Klemar, “Clinical experience with new peroneal stimulator,” *Ugeskrift for Laeger,* vol. 148, no. 21, pp. 1272–1275, 1986.

33. J. Burridge, P. Taylor, S. Hagan, and I. Swain, “Experience of clinical use of the Odstock Dropped Foot Stimulator,” *Artific. Organs*, vol. 21, pp. 254–260, 1997.

34. Swain, I. Douglas, Taylor, P. Nicholas, “Electric leg stimulator for treating foot drop”, *UK Patent Application GB 2368017 A, 2000.*

35. K. Takebe, C. Kukulka, M. G. Narayan, M. Milner, and J. V. Basmajian, “Peroneal nerve stimulator in rehabilitation of hemiplegic patients,” *Arch. Phys. Med. Rehab.*, vol. 56, pp. 237–240, 1975.