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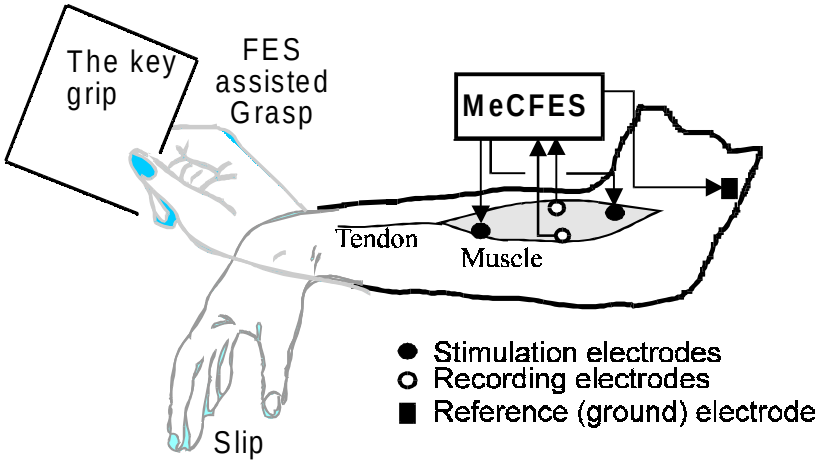
Restoration of Hand Function in Tetraplegics Using Myoelectrically Controlled Functional Electrical Stimulation of the Controlling Muscle



by

Rune Thorsen

Asah Medico A/S, Denmark

Center for Spinal Cord Injured,
Copenhagen University Hospital, Denmark

Department of Mathematical Modeling,
The Technical University of Denmark, Denmark

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Abstract

This Ph.D. dissertation treats the development of a device that can enhance the force of a paretic muscle. The device is a Myoelectrical Controlled Functional Electrical Stimulator (**MeCFES**). The MeCFES is a small portable device that can be carried in a pocket. It is the intention that the device is to be used by peoples paralyzed by a cervical spinal cord lesion (tetraplegics). The primary aim has been to re-establish a useful grip in tetraplegics with C5/6 lesion.

The MeCFES records the myoelectrical signals (EMG) resulting from volitional contraction of a muscle. The muscle in question is the wrist extending muscle: Musculus Extensor Carpi Radialis (longus and/or brevis) ECR. This signal is transformed into a control signal for the intensity of functional electrical stimulation of the controlling muscle. The controlling muscle, the ECR, may be paretic (partly paralyzed) to a degree where only a fraction of the volitional power is remaining.

The unique feature of the device is its capability to simultaneously stimulate the same muscle as the one which controls the stimulation. It allows the use of surface electrodes (electrodes placed on the skin) for both recording of myoelectric signals and electrical stimulation of the same muscle. An essential quality of using of surface electrodes is that no implanted electrodes are required to use the system. It is thus not involving 'modifications' of the user to apply the device. It can thus be tested by the user without any inconvenience or obligations.

A theory of myoelectrical controlled stimulation of the controlling muscle is evolved and summarized into a model of the recorded signal. This uncovers the problems in transforming the recorded signal into a control signal for the electrical stimulation. The model is used to set the technical specifications of the developed hardware. Methods for filtering of the recorded signals are discussed and a new technique for evaluation of the voluntary myoelectrical signal has been suggested and implemented in the device. A new method of suppressing artifacts in recording of bio-potentials has been developed. This has resulted in an invention of a dedicated amplifier. The features are a fast DC offsets compensation and stimulation response suppression of the input signal.

The MeCFES has been tested and evaluated on a voluntary panel of tetraplegics. It has been found that the device can increase the isometric force of the paretic muscle. It can increase the range of controlled wrist extension against gravity for extensor carpi radialis muscles with strength from 1 to 3. Thus a useful grip has been achieved in some tetraplegics. Stimulation of the thumb flexion controlled by the ECR in some experiments has provided an enhanced hand function. The restoration of the key grip (lateral pinch grip) and the volar grip has been achieved by this use of the MeCFES.

Abstract (Dansk)

Denne Ph.D. afhandling omhandler udvikling af et apparat der kan øge muskelstyrken af en paretisk muskel. Apparatet kaldes en Myoelektrisk Kontrolleret Funktionel Elektrisk Stimulator (**MeCFES**). Dette er et lille bærbart apparat, der kan være i en lomme. Formålet med MeCFESen er at den skal kunne bruges af mennesker der er lammede pga. en hals rygmarvsskade (tetraplegikere). Det primære mål har været at reetablere et brugbart greb hos tetraplegikere med C5/6 læsion.

MeCFESen måler myoelektriske signaler (EMG) stammende fra viljestyret kontraktion af en muskel. Denne muskel er den håndledsløftende muskel: Musculus Extensor Carpi Radialis (longus og/eller brevis) ECR. Signalet omdannes til et kontrol signal for styrken af funktionel elektrisk stimulation af den styrende muskel. Den styrende muskel, ECR, kan være paretisk (delvist lammet) i en grad hvor kun en brøkdel af den voluntære kraft er tilbage.

Det unikke ved apparatet er dets egenskab til at stimulere den samme muskel som stimulationen er styret af. Tillige bruges der overflade elektroder (elektroder placeret på huden) til både stimulation og måling af det myoelektriske signal fra samme muskel. En væsentlig egenskab anvendelsen af overflade elektroder er at at systemet kan bruges uden behov for implantering af elektroder. Der kræves således ikke 'modifikationer' af brugeren for at kunne anvende apparatet. Det kan således uforpligtende afprøves af brugeren uden ulemper.

En teori for myoelektrisk kontrolleret stimulation af den kontrollerende muskel er udviklet og samlet til en model af det målte signal. Den afdækker problemerne ved at omdanne det målte signal til et kontrol signal for den elektriske stimulation. Modellen danner grundlag for specifikationerne til det udviklede elektriske udstyr. Metoder til filtrering af de målte signaler er behandlet og en ny teknik til evaluering af de voluntære myoelektriske signal er foreslået og implementeret i systemet. En ny metode til undertrykkelse af stimulations responser ved måling af bio-potentialer er blevet udviklet. Dette har resulteret i opfindelsen af en dedikeret forstærker med hurtig kompensation af DC offset af input signalet og undertrykkelse af stimulations responser.

MeCFES systemet er blevet evalueret ved at teste det på et frivilligt forsøgspanel bestående af tetraplegikere. Ved brug af MeCFES systemet er der opnået en øget isometrisk muskel kraft af den paretiske muskel. Det kan også give en kontrolleret øget ekstension af håndleddet mod tyngden ved muskelstyrke 1 til 3. Systemet har således givet et greb hos nogle tetrapegikere. Eksperimenter med at stimulere tommel og finger fleksion, styret af extensor carpi radialis musklen, har givet et anvendeligt greb. Både et nøglegreb og et cylindergreb er genetableret ved denne brug af MeCFES systemet.

Table of Content

Preface

This thesis is part of the requirements for obtaining the Ph.D. degree as an Industrial Ph.D. Fellow, conferred by the Technical University of Denmark. The work has been carried out for Asah Medico A/S, Denmark in affiliation to The Department of Mathematical Modeling, The Technical University of Denmark (IMM,DTU) and the Center for Spinal Cord Injury, Copenhagen University Hospital (Rigshospitalet), Denmark.

During the 90'es the former Electronics Institute, DTU has been collaborating with the Center of Spinal Cord Injury, Rigshospitalet in projects with the aim of restoring motor functions in spinal cord injured.

In 1994 Asah Medico A/S initiated the project: "EMG Signals from Paretic Muscles Controlling Electrical Stimulation of the Same Muscle" in collaboration with Center of Spinal Cord Injury, Rigshospitalet (DK); Consort Engineering Ltd (UK); Jones & Hunt, Orthopaedic Hospital (UK); Roessingh Research and Development (NL) and The Danish Paraplegic Association (DK).

The present thesis describes the research and development of electronics related subjects, carried out in the position as an Industrial Ph.D. Fellow.

The work was conducted under the supervision of Steffen Duus Hansen Ph.D. M.Sc.E.E. (DTU), Ole Trier Andersen Ph.D. M.Sc.E.E. (DTU), Fin Biering-Sørensen Ph.D. M.D. (Rigshospitalet), Olav Balle-Petersen M.Sc. E.E. (Asah Medico A/S).

I wish to thank The Danish Academy of Technical Sciences (ATV) for enabling and supporting the project and their representative Dr. Bodil Norrild (The Panum Institute) for attending the project.

I am deeply grateful to the following people who have been very helpful:

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Rune Thorsen, M.Sc.EE, Industrial Ph.D. Fellow

Asah Medico A/S
Valseholmen 11-13
DK-2650 Hvidovre
Denmark

1. Introduction

This chapter describes briefly the objective of the project and some essentials of the established knowledge. The sections *1.1* to *1.4* explains the **motivation** for the project and section *1.5* reviews the **state of the art**. A basic description of the relevant **physiology** is presented in section *1.6*. Section *1.7* defines the (MRC) scale that is used to describe the **muscle strength** of muscles. Finally the sections *1.8* through *1.12* summarizes some **basics** of the muscle, nerve, electrical muscle stimulation and recording of myoelectrical signals. This knowledge will be used in **Chapter 2** for the development of models and methods for recording the muscle signals and applying stimulation. Here the conditions for the development of a system named **MeCFES** is stated. **Chapter 3** describes the developed MeCFES system and the test setup used for the recordings in **Chapter 4**. Finally there is the conclusion of the project in **Chapter 5**. As part of the development of the MeCFES as a commercial device a marketing analysis is made. **Appendix A** is a revised version of this **marketing analysis.**

1.1 Objective

The aim of this project has been to develop and test an aid, the MeCFES (Myoelectrically Controlled Functional Electrical Stimulator), for use by people with a certain physical disability involving the loss of hand function. This can be due to an upper motor neuron lesion, such as a cervical spinal cord lesion, causing paralysis of the hand. This can be the case for a C5/6 lesion tetraplegic which usually involves paralysis of the trunk and lower limbs, the hands and **partial paralysis,** i.e. paresis, of the forearms. For these people, restoration of the hand-function will provide more independence to perform activities of daily living (eating, drinking, writing etc.) thereby increasing their **quality of life** significantly. The approach is to use the electrical signal from that part of a paretic muscle that is under volitional control, as a control for electrical muscle stimulation. This

myoelectrical signal[1], is recorded using surface electrodes. It is used to control electrical stimulation of the same muscle (and/or other muscles) to generate or augment the muscle contraction. When the controlling muscle and the stimulated muscle is the same the result is an **amplification of the muscle strength** (Figure 1.1-1).

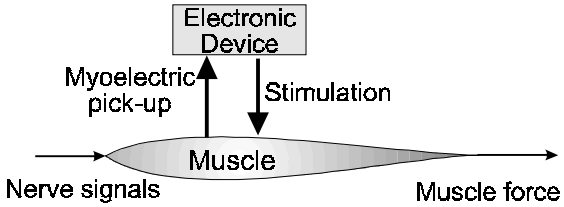

Figure 1.1-1 Amplifiaction of muscleforce

This method of muscle amplification is applied to the paretic wrist extensor muscle as the first step towards obtaining a feasible grasp (involving the tenodesis function).

1.2 Users

The primary target group of users are **C5/6 tetraplegics** (see *1.6.2 C5/6 Lesion* later on). Tetraplegics are very limited in their capability to perform **activities of daily living** due to the paralysis of the lower limbs, trunk, hands and paresis of the forearms. They are therefore are highly dependent on help from other people. Traumatic spinal cord lesion involves **12-17 persons/million/year in Europe**. The most common cause is traffic accidents. Tetraplegics are the spinal cord lesioned individuals in most need of personal assistance for activities of daily living. Please refer to **Appendix A** for a more details on the market needs. Secondary users can be patients with other damages in the central nervous system e.g. some patients with multiple sclerosis and cerebrovascular diseases. Since these people in addition can have cognitive disabilities that can complicate the experiments, this group has not been involved. The precondition for the MeCFES is that a paresis is due to an upper motor neuron lesion. This will be explained further in this chapter.

[1] A myoelectric signal is the electrical potentials caused by contraction of a muscle. Often the term EMG, an abbreviation for electromyogram, is used for the same signal. It is my opinion that the EMG is the result of plotting the myoelectric signal in a graph. For that reason, the term ‘myoelectric’ is used for the electrical muscle signals in this thesis.

1.3 The Tetraplegic's Grasp

One of the most useful methods of grasp, is the key-grip or the lateral pinch grip. This is a grip where the object is held between the thumb and the index finger (Figure 1.3-1). It is useful for holding smaller objects such as paper, pencil etc. It can be used in several variants as for example for holding a mug with the thumb in the handle. For holding larger objects such as a bottle, the palmar pinch grip (thumb, index and middle fingers) or a variant, the volar grip (all fingers) is used. These grasps can be used when the wrist extending muscle, **extensor carpi radialis** has a sufficient strength and there are proper contractures of the fingers.

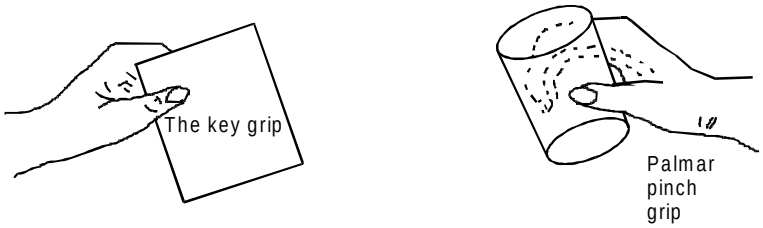

Figure 1.3-1 Key grip

Under these circumstances the **tenodesis function** is providing a passive flexion of the fingers and thumb as a result of wrist extension (dorsiflexion), due to the counteracting force in the finger flexor tendons. [Smith 1996]. The force of this tenodesis grip can be enhanced by shortening the finger flexion tendons. This can either be done by surgery or by fixating the fingers in a position like a clenched fist. The latter method is most often used and will cause the desired contractures of the fingers.

Once the conditions for the tenodesis function is present the next step in obtaining this grip is to establish a controlled extension of the wrist. If the tenodesis grip at full wrist extension does not have sufficient strength; it might be necessary to improve the strength of the grip, mainly by increasing the force between the index finger and the thumb. **This thesis proposes stimulation of muscles in the hand**, in particular the thumb flexor muscle as described in ***2.8.3 Hand Stimulation Technique***, using the extensor carpi radialis as control.

The forearm contains several muscles that control the hand. An **anatomical drawing** of the superficial muscles in the dorsal side of the forearm can be found in **Appendix C**. In normal subjects, wrist extension is controlled by coactivation of the muscles: extensor

carpi radialis longus (**ECRL**), extensor carpi radialis brevis (**ECRB**) and extensor carpi ulnaris (**ECU**). Only the ECRB provides a pure wrist extension whereas the other two muscles gives respectively radial and ulnar flexion in addition to the wrist extension [Gray 1973]. The ECRL is partially covering the ECRB and is for this reason most easy to stimulate. There will not be distinguished between ECRL and ECRB since they can not be stimulated individually by surface electrodes. As it appears on the drawing, the finger extensors are located between ECR and ECU and partially overlapping both. For this reason it is **difficult to avoid undesired stimulation of the finger extension**. On the radial side of the ECR the brachio radialis muscle and the supinator muscle are located. Accidental stimulation of these will also impede a useful grip.

1.4 The Basic Principle

The MeCFES requires **5 surface electrodes placed on the skin** above the muscle. The electrodes are two stimulation electrodes, two recording electrodes and one for active electrical ground (negative feedback of common mode potential). From the recording electrodes the signal is fed to the electronic part of the device, which will estimate the voluntary activity in the muscle. This estimate controls the amplitude of a stimulation signal that is fed to the stimulation electrodes. The user thus **controls the stimulation** intensity **by the voluntary contraction** of the controlling muscle.

When the muscle in control is the same as the stimulated, (extensor carpi radialis stimulation) the two types of electrodes are placed over the muscle belly (see *2.8 Electrode Usage*).

The **choice of surface electrodes** and not implanted electrodes was **decided** in the proposal for the project. The **reasons** for using surface electrodes are several. The principal reason is that implantation of the electrodes can be avoided. The use of surface electrodes is safe (apart from possible skin injury) and eliminates the risk of infections or other possible complications of implanted electrodes. The use of surface electrodes leaves the person participating in the test unaffected. The person does not have to be ‘modified’ prior to the test. Implanting electrodes and removing them again are time consuming, difficult, requires surgeons and can be troublesome for the test person with the risk of permanent injury. The use of **surface electrodes** eliminates these problems and **facili-**

tates easy and quick testing on both normal and tetraplegics. On the economical side the resources needed for testing or applying the system using surface electrodes are less than when using implanted electrodes. When it comes to **marketing** of the product, the use of surface electrodes offers a possibility for the customer of easy testing of functional electrical stimulation as an aid, before deciding. The use of **surface electrodes** also gives rise to **many problems**. This is essential in the technical solution presented in this thesis. In the first instance there are the signal processing problems presented in Chapter 2. Then comes the problems of mechanical reliably placing of the electrodes, their selectivity and the cosmetic appearance of the electrode system. **Surface electrodes are thus not an ideal replacement for implanted electrodes by rather an alternative to or a stage before deciding for implanted electrodes.**

1.5 State of the art

In 1992 **Haxthausen** [Haxthausen 1992;Haxthausen, et al. 1991] obtained the Ph.D. degree for the work: ”Restoration of Wrist Extension using Functional Electrical Stimulation Controlled by the Remaining Voluntary EMG from the Stimulated Muscles”. The thesis proved that it was possible to record the voluntary myoelectrical signal from a paretic muscle that simultaneously was stimulated using **surface electrodes**, i.e. **the recorded signal controlled the stimulation**. The target muscle was the extensor carpi radialis, which extends the wrist. With a differential amplifier made up of leaded components and utilizing fast recovery current conveyers, he recorded the myoelectrical signal. The amplifier was basically of the same topology as what is called a conventional amplifier in the chapter *2.5 Signal Amplification (Figure 2.5-3)* in this thesis. Switches were used to shut down the last stage of the amplifier during stimulation. The stimulation pulse was biphasic, 300µs/phase with inter pulse interval 300µs (see Figure 1.11-3 in *1.11 Electrical Stimulation)*. The reason for this pulse type, was to avoid skin damage. After amplification the signal was sampled by a computer (PC) and processed. The signal processing strategy was as follows: The stimulation response was suppressed by blanking and filtering using a **3rd** order transposed **elliptic** comb **filter** with stop bands at multiples of the stimulation frequency. Then the average (bin integrated) rectified value (**ARV**) was calculated. The stimulation amplitude was directly proportional to this ARV. The amplifier was closed by the analogue switches during the stimulation pulse and a

number of following signal samples were blanked (put to zero). The system was tested in faraday shielded premises using a force- and angle- tracking test (similar to the later described). **It was found that C6/7 lesioned tetraplegics got an enhanced force in the wrist when using the system.** The system was extensive, involving 2 Personal Computers, the amplifier and stimulator were both voluminous and required special surroundings. The results were evaluated with respect to muscle force and angle of wrist extension against gravity. A tracking test was used. The test is described and used later in the present thesis. It was concluded that it is a feasible method to obtain a key grip, but that the system needed to be brought down to a portable size and that the signal processing needed improvement.

In 1994, Thorsen [Thorsen 1994], in his M.Sc.EE. graduation project, made a microprocessor based stand-alone system for research purposes based on the specifications by Haxthausen. It had enhanced noise immunity on the amplifier side. The system was enclosed in a 19" rack making it moveable and independent of external computers.

This equipment was used by **Sennels** [Sennels 1996;Sennels, et al. 1997] in his Ph.D. project in the investigation of the use of **adaptive filters** to reduce stimulation artefacts. He made optotracking recordings of the movement of the fingers during stimulation of the extensor carpi radialis and found that the **stimulation had a tendency to affect the finger extensors**. Thereby **counteracting on the tenodesis function** and thus making it **difficult to obtain a useful key grip**. A control strategy using finite-state control was proposed. It was assumed that the tetraplegics could only control the myoelectrical signal in discrete levels. For two tetraplegics it was found that only two levels (on/off) of stimulation could be controlled. A third tetraplegic could control a finite-state control of four levels. Adaptive filters were compared to fixed finite impulse response (FIR) filters. **Filters with 1 coefficient** had **same noise power reduction** of **14dB for both the adaptive and the fixed filter**. Increasing the number of non-zero coefficients gave improvement of the noise reduction for the adaptive filter. An adaptive filter with **6 coefficients** was found to have **optimal filterlength**. The noise power reduction was **23dB**.

For the above described and the present project, the most essential feature difference is the control strategy combined with the use of surface electrodes. This is what differenti-

ates them from other attempts to restore the hand function. The control strategies from five of the most closely related or important works are:

- A two-channel, **portable**, battery operated system for enhancement of grasping in tetraplegics [Saxena, et al. 1995]. **Surface electrodes are used** for recording and stimulation. This system is meant for tetraplegics capable of grasping by tenodesis. Candidates for this system must retain some wrist extension, and have paralyzed but innervated finger flexors, and nearly normal shoulder and elbow coordination within the working space. The **myoelectric signal** from the **wrist extensors** is used for control. This turns the **stimulation** of forearm finger and thumb **flexors on and off.** The detection of the threshold of the amplified, rectified, and integrated myoelectric signal is used as control. The device was tested on subjects with tetraplegia, and the general conclusions are: The system **increases the strength of the grasp, no side effects** or related problems were noticed, the training period is short and the reliability of the operation is good. Functional tests of the system showed that some of the study subjects did not benefit from this approach due to disuse and denervation types of muscle atrophy of their finger flexors, lack of controllable wrist extension, curled resting position of distal and proximal interphalangeal joints, and/or inability to bring the thumb in the opposition of fingers The difference between this system and the MeCFES is that **the controlling muscle differs from the controlled muscle and that the control is on/off and not proportional as in the MeCFES**.
- The **NESS Handmaster** (NESS Ltd. Israel) [Handmaster 1996]. It was launched into the market in 1995. This device comprises a nice designed **splint** that can be placed on the paretic forearm-hand and a **control box**. The targeted users are tetraplegics or hemiplegics. The control box is connected to the splint by an electric wire. The splint can be donned and doffed by the user without assistance. Electrodes for stimulation of the finger extension, **finger flexion thumb adduction and thumb flexion** are mounted in the splint. A complete system for wetting the electrodes are supplied with the system. The stimulation strategy is a finite state strategy where different modes can be selected. There is an exercise mode for therapeutic use and a functional mode for grasp. The grasp mode is selected by pressing buttons on the control box. A **trigger button** is located on the control box and a button with same

function is located on the splint. When pressing the button first time a **grasp sequence** will start after a few seconds. First the finger extensors are stimulated. After a moment this is replaced by finger flexor and thumb stimulation and the grasp is established (key grip or volar grip). The stimulation continues until the trigger button is hit second time. Then the release sequence will begin by stimulating finger extension and then stop all stimulation. It is reported that users benefit from the device [IJzerman, et al. 1996]. **The control is on/off triggered by a button.** The control thus requires and takes up a movement that **is not a natural part of the grasp** movement. This limits the feasibility of the device. It has been observed that the task is slowed down by the time delay of the grasp sequence. An example of a situation were this has significance is the use of a cash dispenser, where the transaction will be canceled before the cash or credit card is seized. The system has a lot of nice mechanical solutions and would be fit for a myoelectrical signal controlled strategy.

- The **BIONIC Glove** [Prochazka, et al. 1997;Prochazka and Wieler 1994;Seymour 1996]. It uses a **mechanical sensor** to record wrist movement. It is not released for the market yet. This device controls **stimulation of finger flexion/extension**. The device comprises a garment containing electrodes and the electronic control box. The garment is donned to the forearm and closed by Velcro. The device requires a sufficient wrist extension and can be used by hemiplegics and tetraplegics. A wire is connecting the mechanical sensor in the control box on the middle of the forearm with the back of the hand. It thus can sense the wrist angle. When the wrist is extended to a certain angle, the sensor triggers the stimulation. **The control is a natural part of the movement. It requires strong wrist extension and does not provide proportional control.**
- The **Freehand system** [Keith, et al. 1996;Keith, et al. 1996;Kilgore, et al. 1996; Mulcahey, et al. 1997], is a commercialized implant system. This system is launched on the market and requires implanted electrodes. A grasp mode is selected and the stimulation is controlled by a position transducer. This is mounted between the chest and the shoulder. The shoulder movement is thus used to control the stimulation. The system consists of an external power-and-control device and an eight channel implanted stimulator. The energy for stimulation and stimulation control is transmitted

electro-magnetically (RF transmission) from the external system to the stimulator. Thus a wired interface through the skin and thereby a source of infections is avoided. **The system provides the user with several useful grips and is hidden, which is a very attractive feature.** It differs from the present project by the control strategy, which is not a natural part of the movement, and the use of implanted electrodes. It thus requires 'modification' of the user before it can be tested and used.

1.6 Tetraplegia

Total or partial paralysis of all four limbs and the trunk, denoted as **tetraplegia,** can have several causes. In this thesis the term will exclusively be used for paralysis caused by a cervical spinal cord lesion. The physiological cause and consequences is summarized in the next subsections. This should explain why some muscles, e.g. the wrist extensor muscles, are left only paretic and not totally paralyzed by the cervical spinal cord lesion.

1.6.1 Brain-Muscle Nerve Path

Voluntary movements are caused by contraction of the skeletal muscles under the control of the brain. The normal regulation of the muscle contraction is involving a complicated network of motor and sensory nerves in the body. This transmits control signals and sensory feedback signals between the brain and the muscle. These signals are necessary for the accurate and complicated movements that able bodied humans can perform. The motor neurons are transmitting the nerve signal that controls muscle contraction. (This nerve path from the motor cortex to the muscle is described in a simplified form. The interaction with sensory nerves in the spinal cord is omitted for the simplicity). This nerve signal is transmitted in two tempi. From the motor cortex the signal is transmitted by the first motor neuron to a second motor neuron, also called the **lower motor neuron**. Each lower motor neuron **innervates** (i.e. is connected to) a group of muscle fibers. This is called a **motor unit**. The first motor neuron, also called **upper motor neuron**, has its nucleus in the motor cortex and the fiber, the axon, is running down through the spinal cord. The spinal cord can be divided into segments where upper motor neuron nerve ends connect to their corresponding lower motor neurons. These segments are in succession from the cranium: The 8 cervical segments C1-C8, the 12 thoracic T1-T12, the lumbrical L1-L5 and final the sacral S1-S5 segments [Netter 1996]. The muscles of

the forearms are innervated by lower motor neurons having their cell bodies in segments C4 to T2. The lower motor neurons are intermingled in the **brachial plexus** and collected in nerves containing motor neurons (and sensory nerves) from different segments. One of these nerves is the **radial nerve**. The wrist extensor muscle, extensor carpi radialis muscle, is innervated by lower motor neurons in the radial nerve [Netter 1996]. There are several motor units comprised within this muscle. The cell bodies of the lower motor neurons belonging to these motor units are distributed in the spinal cord segments C5 to C7, (C8) [Kendall, Kendall et al. 1983]. Some motor units are innervated from C5, others from C6 and so on. The extensor carpi radialis muscle is thus not only innervated from one segment but from more segments[1].

1.6.2 C5/6 Lesion

A damage of the signal path, blocking the motor nerve impulses will paralyze the corresponding motor unit (from now on mainly referring to only the muscle fibers). The paralysis can be due to a lesion of the upper motor neuron and/or a lesion of the lower motor neuron. A nerve signal in an intact lower motor neuron will cause the motor units to contract. Such a signal can be evoked artificially in the neuron by electrical stimulation. It requires that the lower motor neurons are intact to make the motor units of the muscle contract by electrical surface stimulation[2].

If a lower motor neuron is severe damaged, the motor unit will be **denervated** and paralyzed and thus **not perceptive to electrical stimulation**. In case of a lesion of the upper motor neuron, and if the lower motor neuron is intact, the motor unit (the muscle fibers) is innervated but paralyzed. In this case electrical stimulation can be used to control contraction of the muscle fibers in the motor unit.

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[1] The same principle applies to the lower limb where the lumbarsacral plexus combines nerve fibers from T12, the lumbar and sacral segments to nerves innervating the muscles in the legs [Netter 1996].

[2] It is possible to stimulate the muscle fibres directly but the current threshold is much higher than for stimulating nerves. Applying the stimulation through the skin, surface stimulation, it will actually be a nerve stimulation. Although it is called muscle stimulation the muscle is thus not be stimulated directly.

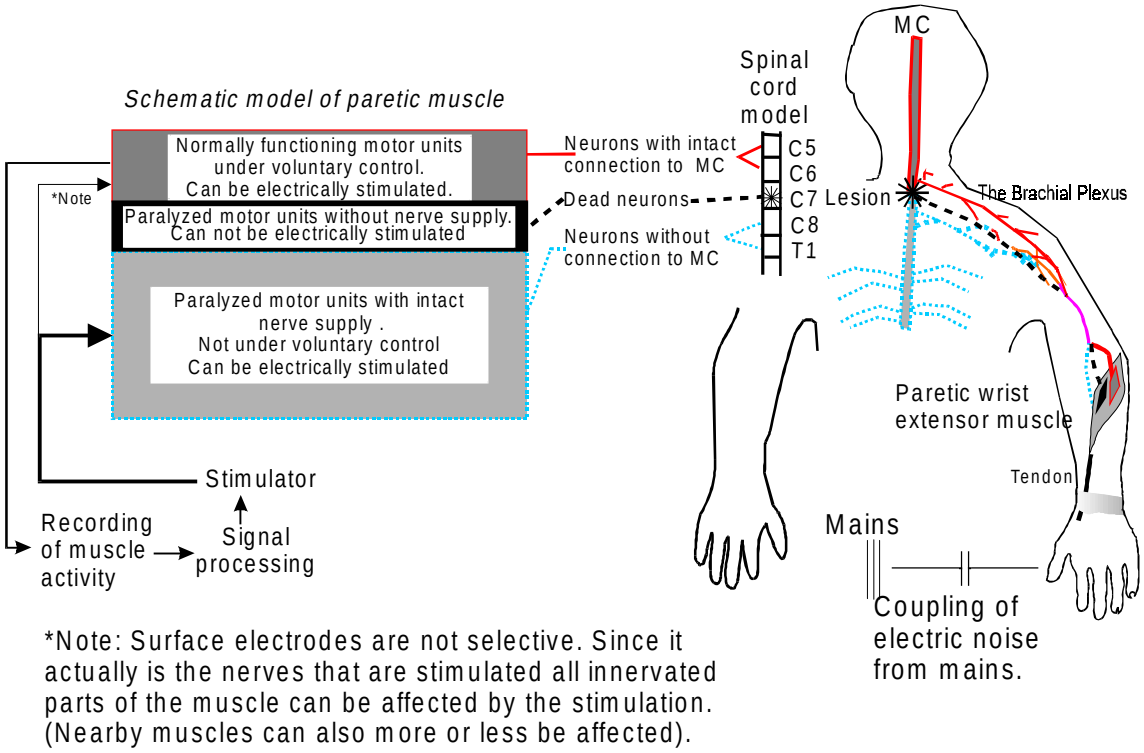


Figure 1.6-1 Tetraplegic with complete C6 lesion

Tetraplegia due to a spinal cord lesion is primarily a lesion of upper motor neurons. Lower motor neurons will often be damaged too. The situation is shown in Figure 1.6-1. For simplicity an example of a complete C6 lesion is illustrated[1]. In the C6 lesion example, the segments C1 to and including C6 are intact, C7 is damaged and C8, T1 -T12 etc. are intact. Muscles innervated from C1 to C6 are unaffected and have normal function. Muscles normally innervated from C8 and down will still be innervated but totally paralyzed due to the lesion of the corresponding upper motor neurons in C7. Both types of muscles can be stimulated since they are fully innervated. Muscles that prior to the lesion was innervated from segments above, in and below the lesion will be paretic i.e. partly paralyzed. The total available muscle strength will for that reason be reduced. Such a muscle (among several) is the wrist extensor muscle, extensor carpi radialis muscle. As illustrated schematically, the muscle will contain motor units affected by the lesion in 3

[1] Spinal cord lesions are normally much more complicated than in the example. The lesion can include several segment and be more or less complete. For the functionality of the MeCFES the worst case is a complete lesion. If the lesion in addition extends to more segments denervating the rest of the muscle the principle will not be functional. Spinal cord lesions are categorized as complete or incomplete and the last intact segment [Biering-Sørensen].

different ways. The normally innervated motor units that are under voluntary control and can be stimulated. The motor units that are denervated due to lesion of their lower motor neurons in C7. These are paralyzed and can not be stimulated. Finally there are the motor units that are paralyzed due to the lesion of the upper motor neuron, but are innervated and can thus be stimulated due to the intact lower motor neuron. **The result is a muscle with some voluntary control having paralyzed and non paralyzed parts that can be stimulated electrically**. This situation is **a criterion for the MeCFES principle to be feasible**. (Other reasons than a spinal cord lesion can cause this type of paresis as mentioned in *1.2 Users*.)

Spinal cord lesions are never identical. There is always differences in the motor function capabilities in the population of tetraplegics. Even if the level of lesion is the same and the diagnosis is for example complete C5 lesion, they might have different abilities to use their hands. The reason is presumably variations in the extend of the lesion, that the lesion anyhow is not 100% complete and maybe anatomical variations in the nerve paths. The complete C5 tetraplegic can have different strength of the extensor carpi radialis as the data in *2.1 Test Panel* illustrates. The effect of the lesion is not even symmetric but the two forearms of a C5 tetraplegic can have different wrist extension force. The determination of the level of lesion is clinically done by examining muscle forces and the extent of skin sensation [Biering-Sørensen]. For that reason the level of lesion does not define the exact capabilities but rather indicates which muscles that might be affected. To determine whether a certain tetraplegic will benefit from the MeCFES, it is thus not sufficient to know the level of lesion, but the person must be tested using functional electrical stimulation.

1.7 Muscle Strength

When discussing the capabilities of a certain muscle the strength of a muscle is defined in Table 1.7-1 below. It is a subjective measure that can vary slightly with the persons judging the strength. It is often referred to as the medical research council (MRC) scale. It is a judgment of the force the muscle can provide on the joint. In this case it is the wrist.

Strength	Description
0 - none	Totally paralyzed muscle
1 - trace	Muscle contraction is only just visible or palpable but the muscle cannot produce any movement
2 - poor	Movement of the joint possible only when gravity is eliminated (movement perpendicular to gravity)
3 - fair	Movement of the joint against gravity just possible
4 - good	The muscle can move the joint against gravity and some extra force.
5 - normal	Normally innervated muscle that can exert normal force.

Table 1.7-1 Muscle strength definition interpreted from Kendall [Kendall, Kendall et al. 1983]

This graduation is commonly used. The C5/6 lesioned in the test panel have strength of the extensor carpi radialis in the range 1-4.

1.8 Nerve and Muscle Fibers

A fundamental characteristic of both a nerve and a muscle is that once initiated, an action potential will propagate along the fiber to the fiber endings. An **action potential** is a local discharge of the fiber due a local ion transport through the cell membrane (see Figure 1.8-1). In brief it consists of an absolute and a relative refractory period. In the absolute refractory period the nerve can not be excited by stimulation where as it in the relative refractory period can be excited by a stimulation, but with a higher threshold. (A more extensive explanation can be found in many textbooks on physiology e.g. [Schmidt and Thews 1983])

Normal action potentials in the lower motor neurons are propagating in only one direction; from the cell body in the spinal cord to the motor unit. Each neuron divides into the terminal nerve branch before connecting, via the endplates, to the muscle fibers of the motor unit. Here the nerve signal is initiating a new action potential in the fibers of the innervated motor unit. These endplates are placed near the middle of the muscle fibers. Here the action potential will propagate in both directions towards the ends of the muscle fiber.

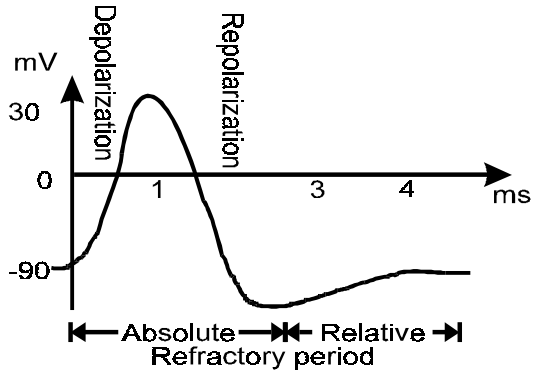


Figure 1.8-1 Illustration of an action potential as function of time.

The motor nerve is myelinated, i.e. it is surrounded by a sheath that is electrically isolating. The myelin sheath provides a fast conduction velocity for the nerve signals. The nerve is unmyelinated in the last part before it attaches to the muscle fibres. An unmyelinated nerve will be more easy to excite by electrical stimulation than a myelinated nerve due to the resistance of the sheath. This may be considered when applying stimulation electrodes and finding adequate positions (the motor points).

The fiber behaves in an all or nothing fashion, which means that the nerve impulse are like a binary signal. No intermediate levels are possible. This is the ‘all or nothing’ law that applies both to nerve and muscle fibers. When a nerve/muscle fiber is stimulated above a certain threshold it will fire, which means that the action potential will start propagation. The ‘all or nothing’ law is not equivalent to a constant level of the action potential since the amplitude can vary slightly with fatiguing of the fiber or in case of neurological deficiencies [Stålberg and Trontelj 1994].

1.9 The Muscle

Besides from being the force generating element of movements, the muscle is also a source of an electrical signal, the myoelectric signal. This is of significance for the way it can be controlled by electrical stimulation, and for the use of the myoelectric signal for control.

The muscle can be regarded as a collection of elements, the motor units comprising the muscle fibers, that behaves according to the all or nothing law. These motor units can thus either contribute to the muscle force with a twitch of full contraction or nothing. The muscle fibers can be of different types. These types behave differently with respect to their endurance and force output. The **fast glycolytic** fibers (FG) can be recruited at a high frequency up to 100 Hz and generate high force. The staying power of these fibers is short. The purpose of these fibers is to generate a short powerful contraction. The **fast oxidative** fibers (FO) generate a smaller force but have a longer endurance. And finally there are the **slow oxidative** (SO) fibers which can sustain a moderate force for a long time (Figure 1.9-1). These fibers are of special interest for the stimulation of hand-function, since holding typically requires a moderate near constant force for several seconds up to minutes. The central nervous system normally recruits the slow oxidative units by **low frequency (<10Hz) nerve signals**.

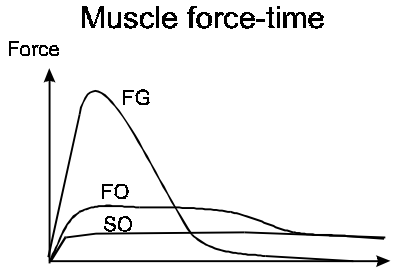


Figure 1.9-1 Fiber types vs. endurance/force [Mortimer 1984]

The muscle fibers belonging to a motor unit is of the same fiber type [Schmalbruch 1985]. The fibers of different motor units are intermingled in the muscle but fibers belonging to the same motor unit have the highest density in the center of the motor unit [Buchthal and Schmalbruch 1980].

Only few data are available on the size and topology of different types of motor units in the muscles in humans. This may be due to the fact that it is difficult to determine which muscle fibers a particular motor neuron is connected to. Motor units of human upper limb muscles have an average **territory of 5-10 mm in diameter**. In such an area there are typically fibers from 15-30 different motor units [Buchthal and Schmalbruch 1980; Schmalbruch 1985]. The number of muscle fibers in the motor units varies between motor units within the same muscle and more widely from muscle to muscle [Buchthal and Schmalbruch 1980]. For human brachioradialis muscle there are around 350 motor units with an average of more than 410 fibers per unit. 1'st Dorsal interosseus and 1'st lumbricalis (muscles in the hand) have about one hundred motor units with respectively 340 and 100 fibers per motor unit [Feinstein et al. 1954; Schmalbruch 1985].

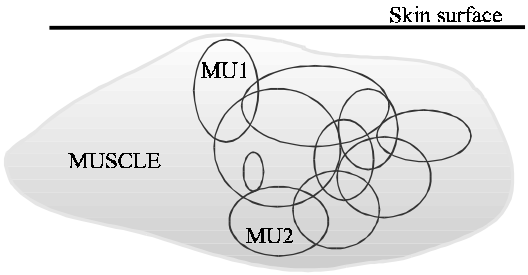


Figure 1.9-2 Tentative model of the cross-section topology of motor units in a muscle. Two motor units MU1 and MU2 are not in the same distance from the skin.

These informations about the topology of the motor units can be interpreted to form the model in Figure 1.9-2 where the motor units are intermingled but located to different compartments of the muscle. The **number** of motor units and their **type** is significant for the **myoelectric signal** and for the **force properties** of the muscle using electrical stimulation. .

1.10 Myoelectric signals

The control signal of electrical stimulation is obtained from the signal recorded on the skin over the muscle. The following is a discussion of the nature of the control signal and some of the noise components. It is assumed that the voluntary contraction of the paretic muscle is under full control of the conscious mind. The problem is to extract information of the voluntary contraction from the recorded signal. The sum of action potentials from the muscle fibres of a motor unit generates an electrical field. This is the **motor unit**

action potential (MUAP). The **myoelectrical signal** is composed of such MUAPs. A MUAP can be caused by other things than voluntary contraction. It is for that reason important to distinguish between **voluntary** MUAPs and MUAPs with other causes. These reflections are used in the model proposed in the section *2.4 Components of the Recorded Signal.*

Voluntary contraction of a muscle is controlled by the central nervous system by modulation of the number of motor units recruited and the **firing** rate, which is the frequency of the motor nerve signals. This results in voluntary MUAPs and make up the **voluntary** myoelectrical signal.

Surface stimulation causes MUAPs synchronized by the stimulation pulses. These correlated MUAPs are denoted as the **compound motor unit action potential (CMUAP)**. The CMUAP is by nature **non-voluntary**. This is a significant component in the recorded signal from a stimulated muscle.

Other types of MUAPs can theoretically occur as a side effect of electrical stimulation due to two phenomena: The possibility of exiting the **H-wave** and the **F-wave** by the stimulation. The H-wave is MUAPs caused by stimulation of the **H-reflex**. This is a monosynaptic reflex caused by stimulation of sensory nerves (the Ia afferent neurons) in the muscle. These run from the muscle to the spinal cord where they directly stimulate the motor neurons of the same muscle[1] [Schmidt and Thews 1983]. The latency of the H-wave in the hand muscles is typically 15ms [Tarkka 1986]. The **F-wave** is a recurrent discharge of the motor neuron due to the electrical stimulation described by [Stålberg and Falck 1993]. The F-wave follows the CMUAP (the stimulation response) and occurs only in a small fraction of the stimuli (5%). The H-wave has in contrast to the F-waves constant shape and latency.

In addition to the above mentioned spontaneous MUAPs can occur independently of voluntary contraction and stimulation. In its extreme this can be spasms. A recorded

[1] Lesion of the spinal cord can also affect the H-reflex belonging to the different spinal cord segments. Without going into details it should be mentioned that the lesion can result in changed excitability or absence of the H-reflex.

myoelectrical signal from a provoked spasm in a muscle is presented in section *2.4.4 Spasticity*.

The CMUAPs, H-waves, F-waves and spontaneous MUAPs are non voluntary and are regarded as noise. The voluntary MUAPs is the desired signal.

The voluntary MUAPs from a single voluntary contracted motor unit are fairly regular but the intervals between them are not constant. There is a tendency of a long MUAP interval to be followed by short [Andreassen et.al. 1980]. This interval between MUAPs is regarded as **a stochastic process** and the Cauchy distribution with a standard deviation of 20% has been proposed for modeling the process . The mean interval is typically in the range of 50-150ms, depending on the voluntary contraction [Andreassen 1978]. An example of a MUAP recorded by needle electrodes can be seen in Figure 1.10-1

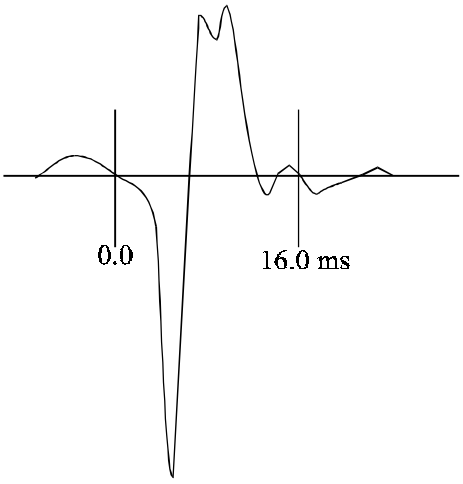


Figure 1.10-1 Single MUAP [DeLuca 1993]

The fibers of a motor unit discharge synchronously since they are innervated by the same motor neuron, but the action potentials are not initiated simultaneously. This is due to variations in the length and conduction velocity of the fibers in the terminal nerve branch [Schmalbruch 1985] the action potentials will be shifted in time. This gives a dilatation of the MUAP and interference between the fiber action potentials. The size of the action potentials decreases rapidly with increasing distance between the generating muscle fibers and the recording electrode. Therefore for a given electrode location, the myo-electrical signal consists of large and small MUAPs with temporal dispersion. Each MUAP will have a **characteristic shape** [Schmalbruch 1985]. To obtain the best results, the electrodes should be placed over the middle of the muscle belly where the distance to

the motor units is minimal. If the muscle is shortened, the motor unit action potential duration decreases and the amplitude increases [Stålberg and Falck 1993].

In the previous section (*1.9 The Muscle*) it was argued that the motor units were distributed in different territories. Consider each motor unit as an electrical generator surrounded by conductive tissue as in Figure 1.10-2, where the tissue is a non-homogeneous volume conductor that attenuates and filters the signals from the generators. The figure serves to illustrate the complexity of the field from the motor units. It illustrates that the MUAPs contribute with a different amplitude depending on the depth in the tissue and their orientation.

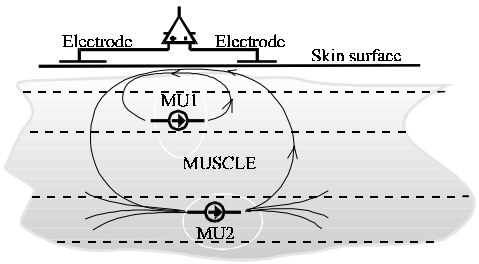


Figure 1.10-2 Tentative illustration of the motor units as electrical generators in a volume conductor

The orientation of the generators will depend on the resulting electrical vector from the depolarization pattern of the muscle fibers involved. Since the currents in the tissue are very small it is reasonable to assume linearity. Thus the electric signal arising from all the MUAPs can be modeled as a sum of impulse generators. Each has a different transfer functions between generator and the electrodes. Figure 1.10-3 shows the model as reviewed in [Merletti, Knaflitz et al. 1992]. The firing pattern of the motor units are represented by the impulse trains. These are stochastic distributed in time. Each impulse generates a MUAP. The transfer function $h_n(s)$ is representing the shape of each MUAP and the sum of these are constituting the myoelectric signal. **Assuming** that the shape of the action potential of each muscle fiber and conduction time in the terminal branches are not changing over time $h_n(s)$ should be an **unique fixed function for each motor unit**. The amplitude A_n of each MUAP is dependent on the attenuation of the MUAP due to distance from recording electrode and the motor unit and the size of the motor unit (in terms of number of fibers). Changes in the amplitude of action potentials of the muscle fibers (e.g. fatiguing) will also result in a change in amplitude.

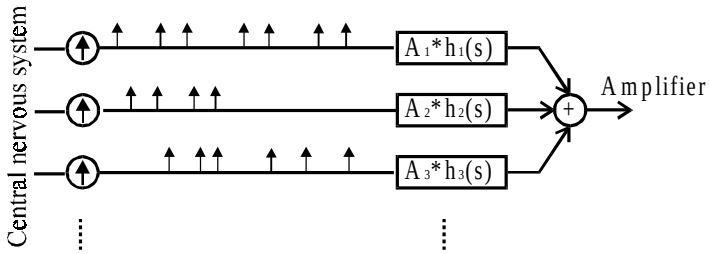


Figure 1.10-3 The signal at the electrodes can be regarded as a sum of different motor units. (Tentative model).

The goal is to transform the voluntary contraction of the muscle into a well defined control signal. Based on the reflections in this section it has been decided that: **The control signal for the MeCFES should be the total number of voluntary MUAPs (motor unit action potentials) in average per time unit.** The problem is then, how to transform the myoelectrical signal to an estimate of such a **MUAP activity** measurement, when the signal is noisy and the power of each MUAP is differing. A method is proposed in *2.7.3 MUAP Activity Calculation.*

1.11 Electrical Stimulation

In the development of a system for controlled contraction by the use of functional electrical stimulation, it is of value to have knowledge about some of the mechanisms involved. A comprehensive practical textbook on the topic of functional electrical stimulation is written by Benton [Benton, et al. 1981].

When stimulating the muscle using surface electrodes, the stimulation current is flowing through the skin and the underlying tissue. The current will spread in the volume between the electrodes and can affect both nerves and muscle fibers. **Muscle fibers** require around ten times greater stimulation current to be excited [Mortimer 1984] than nerves. For that reason the **stimulation will predominantly be nerve stimulation**. For the same reason it is assumed that **denervated motor units are not susceptive to surface stimulation**. Since it is the muscles that are the target for the stimulation the phrase **'muscle stimulation'** will be used despite it should be called transcutaneous electrical motor neuron stimulation. (This phrase is often used and abbreviated to TENS).

As a result of the 'all or nothing' law applying to the motor units, **the only way to control the muscle force, is by modulation of the number of motor neurons stimulated**

and/or by the excitation frequency. The stimulation current threshold for a neuron is depending of the diameter of the neuron. The larger the diameter, the lower the threshold [Mortimer 1984]. It is believed that this is the reason that the muscle contraction can be modulated by controlling the stimulation current amplitude.

Activation of the different motor units, when controlled by the central nervous system, is asynchronous in both space and time [Merletti, et al. 1992]. In this way a steady smooth contraction can be maintained at a low firing rate for the individual motor units (Figure 1.11-2). By surface electrical stimulation it is not possible to stimulate the motor units individually. The MUAPs from the motor units stimulated will be synchronized. Each stimulation pulse will cause a twitch of force in the muscle generated by the motor units activated. To fuse the twitches to a smooth contraction it is **necessary to raise the stimulation frequency above the natural level**. The frequency depends on the mechanical properties of the joint in question. For the wrist extensor it is found empirically that the stimulation frequency should be above 10Hz to obtain a smooth contraction. (The Freehand system for hand function uses 12.5 Hz with implanted electrodes). This implies fatigue of the muscle. Increasing stimulation intensity will recruit more motor units besides the motor units stimulated at the low intensity. Thus the only way to enable these motor units to recover is to turn the stimulation of the muscle off.

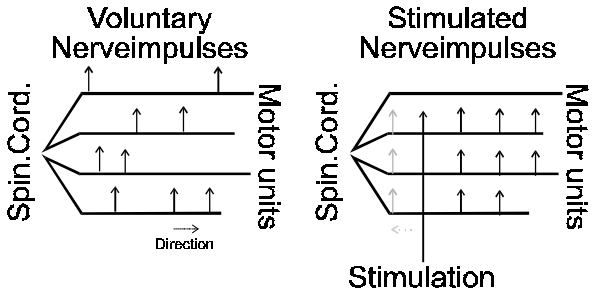


Figure 1.11-2 Tentative model of nerve impulses' distribution. Voluntary impulses are non correlated (left) and stimulated impulses are correlated (right). [Merletti, Knaflitz et al. 1992]

1.11.1 Stimulation Safety

When stimulating tissue the pulse shape should be considered for safety reasons. Introducing a current in the electrolyte will result in electrochemical processes. Depending on the current density, the electrochemical processes can be reversible or irreversible. The irreversible region is entered when the net charge density exceeds a certain limit. When the irreversible process occurs free radicals can be created. These may be toxic. Therefore the charge density in the tissue should be kept in the reversible region. To comply with this, it is commonly recommended to **use a bi-phasic** pulse shape, see Figure 1.11-3, instead of a mono-phasic [Mortimer 1984]. The bi-phasic pulse is charge balanced. In that way no direct current will push the processes out into the irreversible area. There is an interpulse interval (IPI) between the two phases to reduce the annihilation of the initiated action potential. As it will become clear in *2.4.7 Stimulation Response* it is of importance that there are no remaining charge after the end of the pulse and that the total duration of the pulse is kept as short as possible.

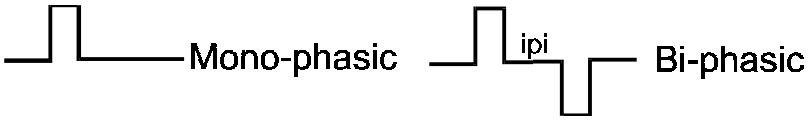


Figure 1.11-3 Stimulation pulse types

For these reasons **a bi-phasic charge balanced pulse is used** to avoid skin/tissue irritation. The shape of the pulse is chosen to be rectangular as shown in Figure 1.11-3 with a 0.3ms pulse width/phase. This is the shape that Haxthausen [Haxthausen, et al. 1991] used and is assumed adequate for minimizing pain [Gracanin and Trnkoczy 1975]. Based on preliminary experiments, 50mA is assumed to be absolute maximum stimulation amplitude needed for upper extremity stimulation.

Only a few reports on negative side effects of functional electrical stimulation have been found (only temporary skin burn). Shannon [Shannon 1992] has proposed a model based upon data from cortical stimulation. (Although this stimulation is very different from muscle stimulation this is used as an indicator for tissue damage. A formula for surface stimulation has not been found in the litterature).

The current limit should not exceed a maximum value in mA given by

$$I = \frac{d_e}{2t_{ph}}\sqrt{\pi 10^k} \qquad \text{Eq.1.11}$$

where d_e is the diameter of a circular electrode in cm, t_{ph} is the duration of each phase in the simulation pulse in ms and k is a constant. For k less than 2, stimulation is regarded safe and k=1.5 is regarded as a conservative limit. (This model is based upon animal experiments of cortical surface stimulation). Using this formula on k=[1.5;2], t=0.3ms and I=50 one obtains a stimulation electrode **diameter of 17-30mm**.

The recommendations and regulations in the International Standard IEC 601-2-10 (Medical Electrical Equipment Part2: Particular requirements for the Safety of Nerve & Muscle Stimulators; 1997) should be observed. Of special interest is that it is advised to keep the **current density < 2mA/cm^2**. (It is assumed that this is the effective value of the current although it is not explicitly stated). A biphasic pulse with a 2 x 0.3ms pulse with and 16Hz repetition frequency and electrode diameter 17mm, the root mean square value of the current density will yield the current density.

$$\sqrt{\frac{0.6}{60}} * \frac{50\text{mA}}{\pi(½ \cdot 17\text{mm})^2} = 2.2\text{mA} / \text{cm}^2$$

Using electrodes with greater diameter than 17mm is then in accordance to the directive.

1.11.2 Control of Contraction

An important issue is to control the force and position of the joint on which the stimulated muscle is acting, since this is the purpose of it all. The stimulation input versus muscle output, the so-called recruitment curve, is non-linear [Hines, et al. 1992]. The recruitment has been investigated and the results can be found in *4.2 Recruitment Curve* where it will be demonstrated that it is non-linear and not a constant relation. For this reason it is necessary to have some contraction information feedback to the controller of the stimulation. Such closed loop systems are a important topic and often discussed topic of functional electrical stimulation. A way to provide this information is by the use of the natural sensors. An example can be the recording of the sensory nerve signals from the receptors [Haugland and Hoffer 1994;Haugland, et al. 1994;Haugland and Sinkjær

1995;Popovic, et al. 1993;Yoshida and Horch 1996] or as is the case with the MeCFES the visual feedback to the user. It can be discussed whether this is an open or closed loop.

1.12 Electrodes

To transmit the myoelectric signals from the muscle to the amplifier and the stimulation current to the muscle surface electrodes are used. There are some general requirements that the electrodes must fulfill and when stimulation and recording is performed in the same area extra constraints apply to the electrodes. A discussion of general requirements for electrodes can be found in [Crago, Peckham et al. 1974; Tam and Webster 1977; Webster 1984; Webster 1992].

The electrodes should provide the following properties:

- A good electrical contact to the skin
- Low impedance
- Bio-compatibility, i.e. cause no skin irritations during long term use
- Easy to apply.

1.12.1 Stimulation Electrodes

In the previous section was found a recommended size for the stimulation electrodes. A choice of **30mm in diameter is be regarded safe** based upon the findings in *1.11.1 Simulation Safety*. The electrodes must ensure good uniform skin contact. In theory the stimulation should be applied where the nerve enters the muscle or over the endplate zone of the muscle. This zone is where the terminal nerve branches attaches to the muscle fibers. Since the nerve fibers here are unmyelinised they are more easily stimulated. Ag-AgCl electrodes was used for stimulation in the work of Haxthausen [Haxthausen 1992]. Personal communications (name unknown) have advised not to use Ag-AgCl electrodes for stimulation since they may cause permanent tattoos to the skin. For this reason, this type of (recording) electrode can not be used for stimulation. The **stimulation electrodes** used in this project are silicone-rubber-carbon electrodes from

ASAH Medico A/S Denmark. The electrodes are coated with a conductive gel that makes them adhesive.

1.12.2 Recording Electrodes

To record myoelectrical signals Ag-AgCl electrodes can be used. These are made of silver with a thin layer of silver-chloride on the surface. A discussion of the features of these electrodes can be found in [Webster 1992]. The electrodes used in this project are Ag-AgCl electrodes (Blue sensor from Medicotest A/S, Denmark). Electrode paste are applied to the electrodes. This paste and the gel on the stimulation electrodes serves as an ionic carrier between the skin and the electrode.

The type of electrodes used for stimulation and recording in the project has been chosen since they are easy available, inexpensive, easy to use and fulfilled the demands. The electrode types are very commonly used and could be supplied by second souce.

1.12.3 Motion Artefacts

The electrical conditions of an electrode are very complex. A simplified model can be seen in Figure 1.12-1. Especially the **half-cell potential** (the potential occurring from the dissolution of metal ions into the electrolyte) is significant for the recording electrodes. This potential depends on the equilibrium of the different ions.

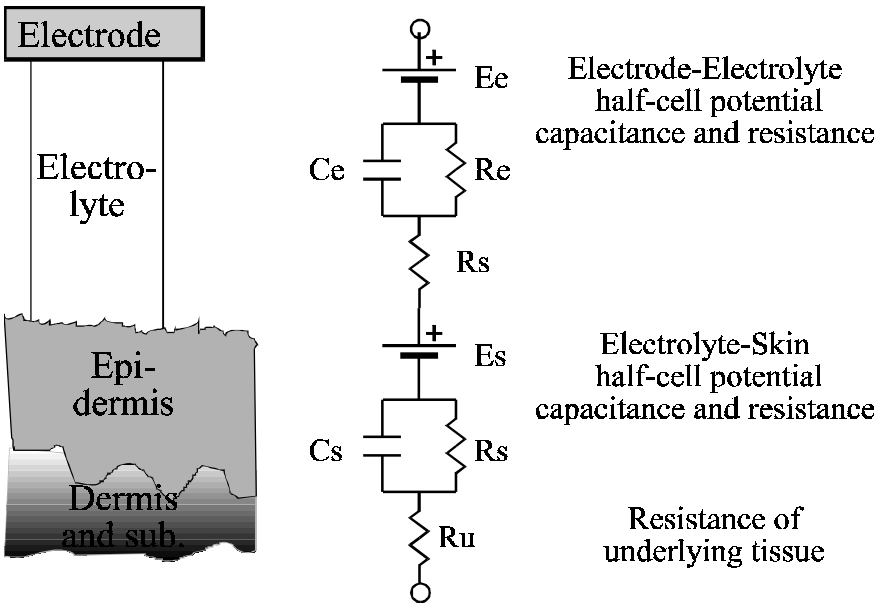


Figure 1.12-1 Simplified model of the electrode body interface [Webster 1992]

When the skin or the recording electrode is stressed the electrolytic equilibrium is shifted and thus the half-cell potentials (Figure 1.12-1) are changed [Webster 1992]. This may be the case if, for instance, the electrode is tapped, twisted or changing shear forces are applied. These actions will disturb the equilibrium states of the electrode-electrolyte, electrolyte-skin and the electrolytes in the epidermis. If the reference electrode does not experience the exact same changes, then the result will be a rapid change in the potential between the electrodes. This signal is termed **motion artefacts**. The shape of the motion artefacts is dependent on the mechanical action on the electrodes, the type of electrodes and the involved electrolytes. The motion artefacts will be occurring at random times depending on the conditions under which the electrodes are used. **Stretching the skin can give rise to up to 10mV motion artefacts** [Webster 1984], which should be compared to a typical peak value of 1mV in myoelectric signals.

Due to the stochastic nature of the myoelectrical signal it is believed that it is not easy to filter out the motion artefacts. For this reason **the electrodes must be protected from mechanical influences and stretching of the skin must be avoided.**

2. Theory, Models and Methods

This chapter describes development of the theoretical models and methods. This is based upon the established knowledge reviewed in Chapter 1 and experimental results. Initially the **test panel** of voluntary participants in the experiments is presented in section *2.1*. The measurements in section *2.2,* of **electrode impedance and noise**, are used in section *2.3* for the choice of **stimulator principle** and in section *2.5* for specifying the amplifier constraints. A **model of the recorded signal** is evolved in section *2.4.* This model is used when discussing **signal amplification** in section *2.5,* defining the signal to noise ratio in section *2.6* and choosing the **signal processing** methods in section *2.7*. Section *2.8* is describing the **electrodes** used, their placement and **suggest a electrode-mount**, making electrode application easy for the user.

2.1 Test Panel

Myoelectrical signals from normal and paretic muscles will be presented in the following sections. In Chapter 4 results from evaluation of the MeCFES performance will be presented. For these tests a number of volunteers have participated. Those, which results are presented in this report are listed in Table 2.1-1 below. For the tetraplegics the selection criteria has been that they were willing to participate, were spinal cord lesioned at a level that resulted in paresis of the extensor carpi radialis, had the time and lived in a reasonable traveling distance from the laboratory in Copenhagen. More than 5 other tetraplegics have been tested but will not figure in this dissertation.

The muscle strength is not exact, but may change a single level depending on the person, who is judging the force and when the muscle is tested. As for all muscles the condition of training or fatigue is influencing on the force. Generally, the right hand is tested since the participants were right handed before injury. Subject EG had had a muscle transfer in the right hand and had a good tenodesis function in that hand. For that reason the left hand had been used in the tests. On subject RAT (the author) the left hand has been used for testing, leaving right hand free for working. Subjects OBP and CD has only been tested once for recording of the recruitment curve.

Subject ID	Lesion	ECR strength (MRC)	Sex	Date of Injury	Date of Birth
AA	C5	4 (Right)	F	95.01.17	1917
EG	C5	4 (Left)	F	84.02.13	1955
FB	C5	4 (Right)	M	59.07.29	1942
HSJ	C5	2 (Right)	M	94.05.14	1955
JBS	C5	1 (Right)	M	94.07.16	1953
LP	C5	2 (Right)	M	92.05.22	1967
KGN	C5	1 (Right)	M	84.04.14	1965
KN	C5	2-3 (Right)	F	93.12.28	1965
RAT	NONE	5 (Left)	M	NA	1967
OBP	NONE	5(Left)	M	NA	1957
CD	NONE	5(Left)	M	NA	1966

Table 2.1-1 The test panel

Testing and myoelectrical signal recording is carried out with the forearm resting on a horizontal support with the palm down. Since the MeCFES should enable the user to extend the wrist against gravity, the angle or force of this movement is often used as a measure for muscle contraction.

As with most cases of tetraplegia the subjects are influenced differently. Only a few remarks shall be made to some of the test persons.

Subject AA needs typically more than 30mA to generate wrist extension. This is a high current compared to the other subjects. She has a weak voluntary grip and is using the tenodesis function in small extent. She is generally difficult to stimulate to a good wrist extension.

Subject EG has limited used of the left hand. It is easier to stimulate to a wrist extension than in the case of subject AA. She has a good tenodesis flexion of the fingers.

Subject KGN has much spasticity in general, and the fingers are stretched when stimulating the extensor carpi radialis muscle.

Subject KN has strong contractures in the supinators, which is resulting in a tendency to hold the hands in a ‘begging position’. She has no grip at all. Using special tools mounted to her hand she can use a computer.

2.2 Electrode Characteristics

Since the electrodes constitutes the electrical interface to the muscle, it is of interest to have an idea of the impedance of the recording electrode as well as the stimulation electrodes.

The electrodes used for recording are Ag-AgCl electrodes with electrode paste (Blue sensor from Medicotest A/S, Denmark). These are a commonly used electrode type for EEG and EMG recordings. The **recording electrodes** have an **effective diameter of 7mm, but physical diameter is 30mm** due to the adhesive non conducting backing material. The **stimulation electrodes** are silicone-rubber-carbon (from ASAH Medico A/S Denmark) with approximately **30mm effective diameter equal to the physical diameter**. This type are commonly used for transcutaneous electrical nerve stimulation (TENS). The electrodes are coated with a conductive gel that makes them adhesive.

These electrode types are used for all the measurements presented in this work. The following recordings are carried out at a normal subject (subj.: RAT).

2.2.1 Recording Electrode Characteristics

The impedance of the recording electrodes is important for the design of the amplifier. Tree sets of electrodes have been tested. Each set was applied 3 times. A total of 9 recordings was thus made. Prior to the measurements the skin was washed with tap water. According to the recommended use on the electrodes, electrode gel (from Medicotest A/S, Denmark) was applied before the electrodes were applied. The distance between the electrodes was varied between 4-10cm. A 300mV sine generator was used for all the measurements (Selected as the minimum allowed by the noise level and the available equipment). This impedance recordings used the setup illustrated in Figure 2.2-1.

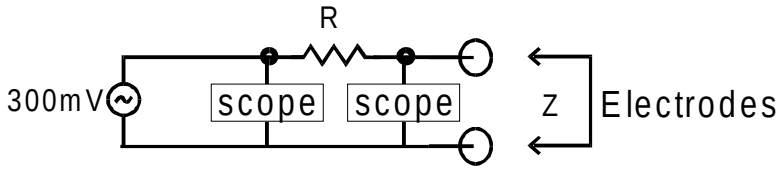


Figure 2.2-1 Measurement set-up

As it can be seen in Table 2.2-1, the measurements have a high deviation. The impedance varies from placement to placement and over time. The impedance can decrease nearly a decade over the first a quarter of an hour after application on dry skin. The distance between electrodes seemed not to have significant influence on the electrode impedance. Table 2.2-1

shows minimum and maximum values of the measured electrode impedance magnitudes $|Z|$ at frequencies f, which are relevant for the recording of myoelectrical signals.

f(Hz)	|Zmin|(kΩ)	|Zmax|(kΩ)
10	30	100
50	22	78
100	13	68
500	11	30
1000	17	20

Table 2.2-1 Electrode impedance recordings

It should be noted that this impedance may not be the same as for recording myoelectric signals. Applying a current in the electrodes may change the impedance due to chemical reactions.

The noise from electrodes mounted on the skin above inexcitable tissue, the bony prominence of ulna, is $\mathbf{4\mu V_{RMS}} \pm 1\mu V$. These measurements are performed with the MeCFES amplifier which will be described in Chapter 3. When tapping the electrodes with a finger, **motion artefacts of 5-10mV** peak can be caused (Applying firm pressure can cause greater motion artefacts). These motion artefacts are recorded direct by an oscilloscope (10 MΩ input impedance). The skin has not been prepared by e.g. removing the epidermis (outermost dead layer of the skin), since this is not realistic for daily use of the MeCFES device. Placing the electrodes on each other gives an impedance recording of the pair of electrodes of less than 1kΩ.

In section *2.8.5 Electrode Embodiment* an electrode concept is presented. Wet shammy is used as contact medium. For this reason impedance of Ag-AgCl electrodes with wet shammy as contact medium has been measured. The electrodes have been placed with direct contact to each other with the leather in between. The results are shown in Table 2.2-2.

Impedance (kΩ)	Noise(RMS)	Motion Artefacts
0.9@50Hz 0.75@200Hz 0.6@500Hz	<8μV	<50mV (Recorded by oscilloscope)

Table 2.2-2 Electrode pair with wet shammy leather as contact medium.

As it may be noted the motion artefacts are significantly higher. The impedance is very low compared to the recordings in Table 2.2-1. On that basis it can be concluded that the greater part of the electrode impedance is due to the skin, since the recording in **Table 2.2-2 does not imply the human tissue**. When applying the shammy covered recording electrodes on the skin, the impedance is in same magnitude as in Table 2.2-1. However the motion artefacts are still in the magnitude of **10-50mV**

2.2.2 Stimulation Electrode Characteristics

When designing a stimulator it is important to know the impedance of the stimulation electrodes. For a current output stimulator the electrode impedance determines the voltage range for the output.

The significance of chemical reactions in the electrode interface is different for the stimulation electrodes. In the recording electrodes the current in the electrolyte is vanishing in comparison to the several milliampere of the stimulation pulse. The area and material of the stimulation electrodes also differs from the recording electrodes. The impedance is recorded using the set-up shown in Figure 2.2-2. A set of stimulation electrodes are applied to the skin of a test subject (subj.: RAT). A current generator, which is the stimulator Type 1 (described in *Chapter 3*), is connected to the terminals *T1* and *T2*. The current is observed using the 100Ω resistor in series with the electrodes and the voltage over the electrodes are recorded simultaneously.

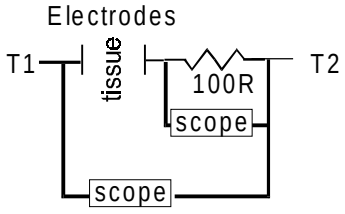


Figure 2.2-2 Test set-up

The voltage and current can be seen in Figure 2.2-3 and voltage versus the current is shown in Figure 2.2-4. A stimulation amplitude of 17mA was tolerable and resulted in full wrist

extension. The current drop in the negative pulse phase (Figure 2.2-3)are due to imperfections in the stimulator. As it can be seen, the **capacitance of the electrodes are not negligible,** but causes a long **transient** after end of the stimulation pulse**.**

Measuring capacitance and resistance with a LCR meter (3kHz, 7V) yields a **capacitance in the range 10-50nF and resistance in the range 3-10kΩ** (depending on the pressure on the electrodes. High pressure gives lower values). Like the recording electrodes the electrode impedance is expected to be non linear, depending on the current applied.

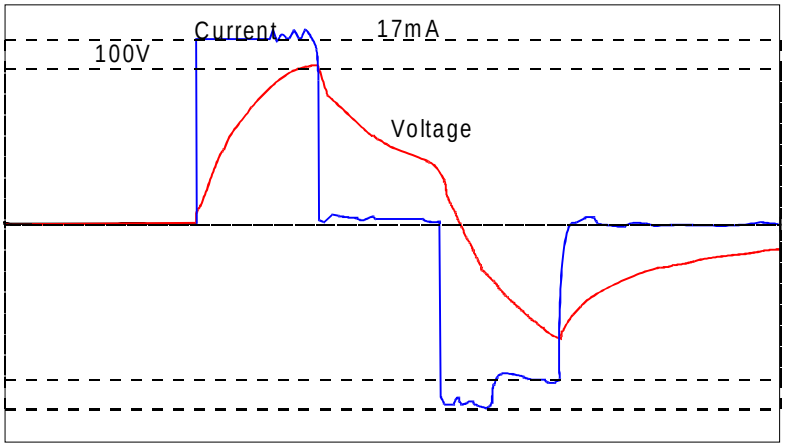


Figure 2.2-3 Voltage and current in stimulation electrodes

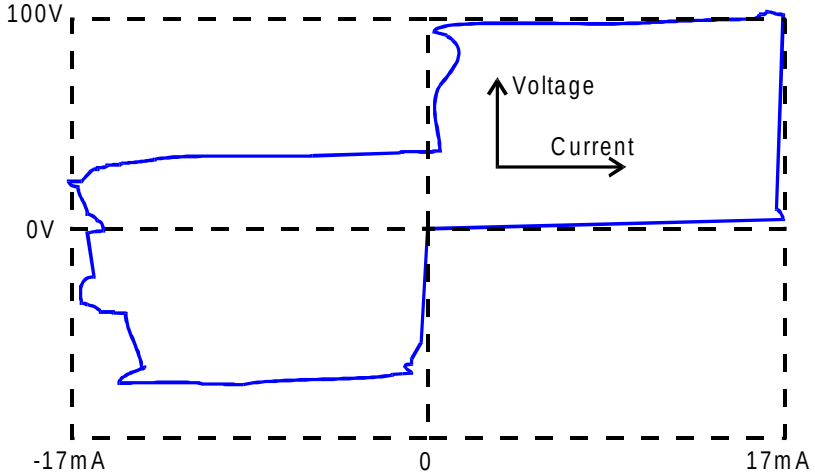


Figure 2.2-4 Voltage vs. current in stimulation electrodes (same data as Figure 2.2-3)

2.3 Stimulator Principles

The stimulator must be able to deliver the stimulation current needed to provide desired muscle contraction. The experiments have shown that a 40 mA biphasic pulse amplitude is ample for contraction of the extensor carpi radialis, where 20mA has been sufficient for most of the persons in the test panel. (The necessary maximal stimulation is found by trial in respect to the tetraplegics well-being and under advise from occupational therapists). From the previous section, the impedance of the stimulation electrodes was in the range 3-10kΩ. An impedance of 5kΩ requires 200V differential voltage over the stimulation electrodes if e.g. 40mA is to be delivered into the tissue.

As described in section *1.11 Electrical Stimulation*, a bi-phasic charge balanced pulse shape is chosen. **Each phase is selected to endure 300µs with a 300µs inter pulse interval**. This complies with the work of Haxthausen [Haxthausen et al. 1991; Haxthausen 1992].

To minimize artefacts the stimulator **output must be zero immediately** after the end of the stimulation pulse. Furthermore, the **output must be bi-phasic** so that no net charge flows though the tissue. A **monophasic pulse will** charge the recording electrodes and thus give rise to **blocking of myoelectric recording**. As discussed in *2.4.7 Stimulation Response* the stimulator output must be balanced to make the sum of the currents in the two stimulation electrodes equal to zero. Otherwise stimulation artefacts will be enlarged.

The stimulator can either be realized with a transformer in the output stage to provide the high voltage or it can be realized as an electronic output stage supplied with the needed high voltage. The principle of the first type, called Type 3, is illustrated in Figure 2.3-1. (Three types of stimulators are developed in the hardware section).

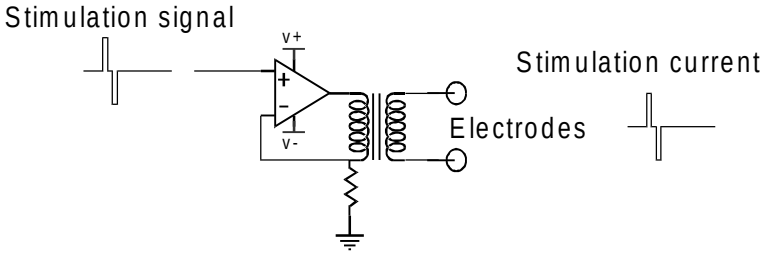


Figure 2.3-1 Type 3 stimulator. Output through transformer.

The **advantages** for the **Type 3** stimulator are a galvanic separation and that the control electronics is at the low-voltage side, which simplifies the design. The galvanic separation ensures that the output is fully charge balanced and that the stimulator outputs are floating

with respect to the amplifier ground (re discussion in *2.4.7 Stimulation Response*). The **drawbacks** are that a transformer adds both weight and volume to the system. It has a low efficiency if the stimulation is not maximal[1]. Driven from a battery, the design of the driver circuit for the primary side of the transformer is critical if a good efficiency is desired. It is desired that the transformer has a small size. This implies reduced area of the copper and consequently a resistance of the windings that can not be neglected. A high current is required in the primary side (in the range of an Ampere) and thus resistance in the primary side and the driving circuit may represent major power loss. The limited transformer size also implies that it can not be regarded as an ideal transformer, but parameters such as saturation, series inductance, parasitic capacitance etc. must be considered. This implies that the output current is not directly proportional to the input current, and thus the characteristics of the output current may differ from the expected. In *4.1.5 Type 3 Performance* the output current for such a stimulator design is shown. Another drawback of the transformer coupled stimulator is that the capacitance of the electrodes and the series self-induction of the transformer will form a resonating circuit that can disturb picking up of the myoelectric signal. It has been observed, when using a stimulator with a large transformer (used by Haxthausen [Haxthausen et al. 1991]) , that **oscillations are present** after stimulation pulse. This has also been reported by personal communication [Sennels 1996].

In the concept shown in Figure 2.3-2 a step up DC-DC converter, supplied by the battery, is generating an adjustable high voltage. (According to the prior calculation this voltage should be up to ±100V). The voltage supplies the output stage of a current output amplifier. The supply voltage is adjusted to match the actual electrode impedance and stimulation current requirements. Thus, the voltage drop over the output transistors can be minimized and thereby increase the efficiency.

The **advantage,** beside high efficiency, is that the transformer can be omitted. Thereby overall size and weight can be reduced. The transistor output stage gives the possibility of a better control of the output current. This is the principle in the stimulators called **Type 1 and Type 2.** The **drawback** is that there will be no galvanic separation, which requires ideal

[1] A simple example will illustrate this: If 50% of the maximum stimulation output is required, there will be only 50% of maximum voltage over primary side of the transformer (assuming a resistive load). Thus there will be a 50% voltage drop in the driving circuit from output to the power supply. The power dissipation is thus 50% in the driving circuit and 50% in the tissue, i.e. only 50% efficiency.

matched current generators. This makes the stimulator as well as the power supply circuit more complicated than the one needed for the Type 3 stimulator.

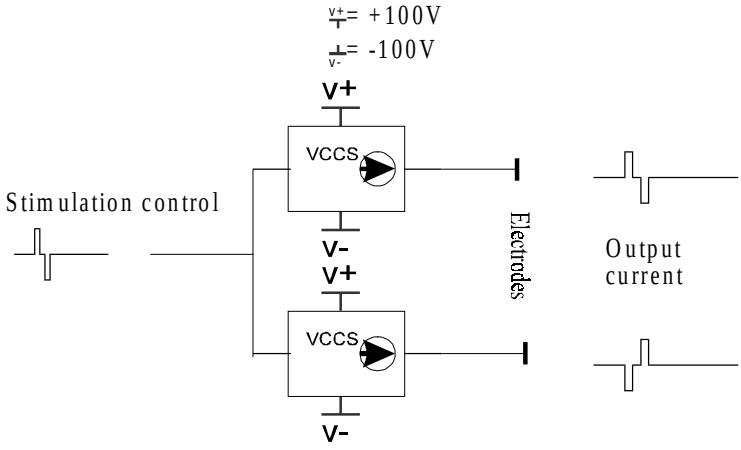


Figure 2.3-2 Type 1 and Type 2 stimulator. Voltage controlled current source (VCCS)

To reduce the influence of a noisy stimulator output stage on the myoelectrical recording, diodes can put in series with the output as shown in Figure 2.3-3. Thus noise levels below the diodes on voltage will not disturb the recording. (The resistor provides a well defined voltage at the current generator output).

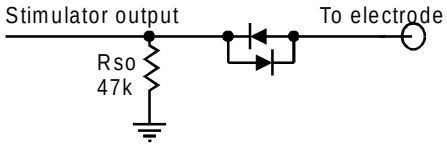


Figure 2.3-3 Diodes in output

Another possibility is to add switches that can short circuit the stimulator output after the stimulation pulse. The drawback of this solution is that the switches have to be reed-relays. No analogue switches can handle the high voltages, when supplied by ±3V. These relays are noisy, power consuming and voluminous. Both these methods has been tested. The **reed-relay solution is used for the Type 3** stimulator. **The diode solution has been tested with the Type 1 stimulator**, but has not implied significant improvement of the myoelectrical signal recording.

2.4 Components of the Recorded Signal

The myoelectric signal consists of signals from several motor unit action potentials. The central nervous system can control the number of motor units, and the rate at which they are

activated. Although there are indications that the central nervous system can control the individual motor units selectively [Rushton 1997], it is assumed that there is no voluntary control over which motor units is activated in the muscle. For that reason the control property is desired to be the number of voluntary motor unit action potentials per time: **The MUAP activity.**

An example of a myoelectrical signal (subj.: KN) from a voluntarily contracted paretic extensor carpi radialis, recorded with the MeCFES amplifier using surface electrodes, is shown in Figure 2.4-1. Hum is filtered out as described in *2.7 Signal Processing*.

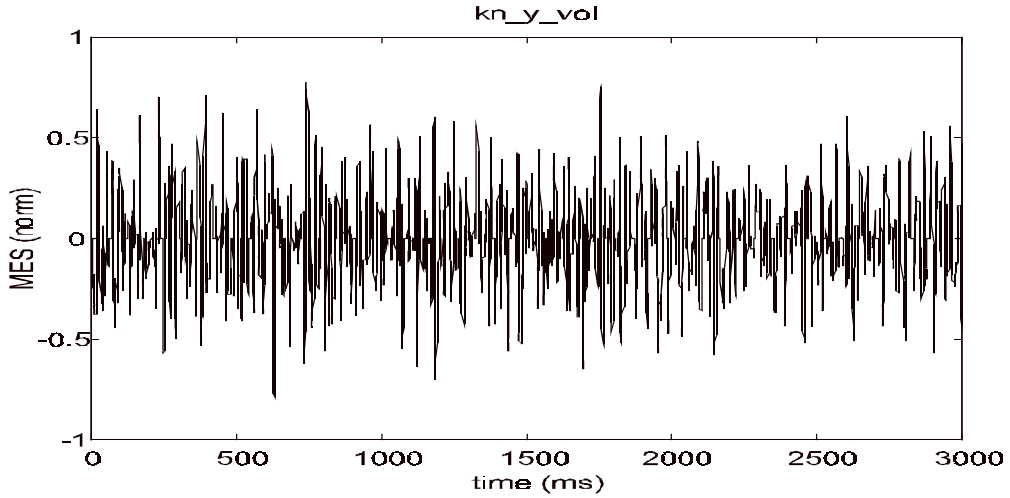


Figure 2.4-1 Myoelectrical signal (subj.: KN)

It shows a stochastic signal over 3sec from a muscle of strength 2-3. Full range is ± 300μV.

2.4.1 Variation in Myoelectrical Signal

In signal processing, the question of stationarity of the signal in question is often of interest. To illustrate how the signal changes in time the RMS (root mean square) value of some myoelectrical signals (subj.: JBS) from a stimulated muscle is shown in Figure 2.4-2. On the upper graph the subject attempts no voluntary contraction and on the lower graph a maximum voluntary contraction is attempted. The signals are filtered by the first order transformed FIR filter presented in *2.7 Signal Processing*. It shows that the change in RMS level when stimulation is applied is minor but present. It is possible that the stimulation triggers the reflex arch as discussed in *1.10 Myoelectric Signals*. This could produce a stochastic component in the signal that is impossible to reduce by linear filtering. (The RMS window is sliding over the signal and calculated at each sample. The RMS is not valid for the first 0.3 sec.)

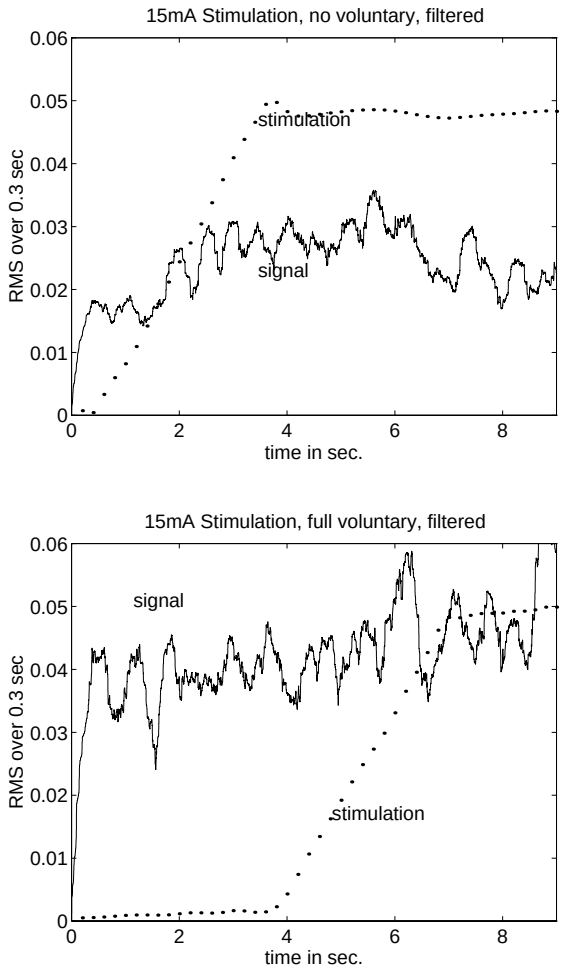


Figure 2.4-2 RMS values for signals from a relaxed and voluntarily contracted muscle.

Stimulation is applied according to the dotted curve from 0-15mA. The subject has muscle-strength 2 in the extensor carpi radialis.

It can bee seen that the signal has not a constant RMS value and is therefore not stationary [Møller and Sørensen 1992]. Voluntary contraction results in a doubling of the RMS value of the signal. Also it can be seen that the RMS level rises slightly when stimulation is applied.

2.4.2 Motor Unit Distribution Model

For the selection of a control strategy for the stimulation, it is of interest to know how many motor units that are under volitional control. Most important are the number of voluntary controlled motor units since they determines the statistical properties of the recorded myoelectrical signal, this number are determinant for the motor unit action potential activity. The myoelectrical signal from a normal muscle can be assumed to be band-pass filtered white

noise if the number of MUAPs (motor unit action potentials) is large [Graupe and Kohn 1987]. This assumption might not be valid for a paretic muscle of e.g. force 3 since the number of motor units are expected to be few as exemplified in the following.

In a normal ECR (extensor carpi radialis muscle) the number of motor units is expected to be of the order of one hundred motor units (The extensor digitorum longus muscle has 130 motor units [Buchthal and Schmalbruch 1980]). If the strength of a paretic ECR is *Q*% of the normal muscle and if the paralysis has affected small and large motor units equally, then it is assumed that *Q*% of the motor units are under voluntary control.

The weight of a normal hand (subj.: RAT) is measured to be approximately 0.5kg. The centre of mass is estimated to be 10cm from the rotation point at the wrist. The torque needed to extend the wrist against gravity is then: N_{par}= 0.5Nm. A normal person should be able to exert a force of at least 10kg at center of mass. This means that the torque for the normal joint is: N_{norm}=10Nm. For a subject with the ability to extend the wrist just against gravity (muscle force 3) the percentage of motor units according to the former should be approximately

$$Q\% = N_{par}/N_{norm} * 100\% = 5\% \qquad \text{Eq. 2.4-1}$$

Assuming that the paralysis has affected motor units of different size and type equally, it is believed that the percentage of intact motor units is equal to the percentage of remaining force. Based on this theory the number of voluntary innervated motor units should be 5% of the total motor units before lesion for a muscle force of 3. This will then, based on the assumption of a hundred motor units in ECR, be around **five motor units at muscle force 3**, which probably is too low due to some degree of atrophy in the untrained paretic muscle. The conclusion is that the **number of volitionally controlled motor units is very low** in the weak paretic muscles. **The single MUAPs should thus be recognizable in the myoelectrical signal.**

2.4.3 Antidromic Nerve Block Theory

It can be (and has been) questioned whether the MeCFES principle is possible. The concern has been that the stimulation initiated nerve impulses propagates in the 'wrong' direction and block the voluntary nerve signals, i.e. antidromic nerve blocking. In the following it will be discussed that this phenomena will only reduce the voluntary myoelectrical signal slightly.

Since the nerve axon is locally symmetrical there is in theory no constraints on which direction an action potential in the nerve will propagate. The direction of propagation is thus determined by the way the nerve is exited. If the action potential originates in the end of the axon it will propagate towards the opposite end. If the nerve fiber is exited in-between the ends it will propagate in opposite directions towards both ends.

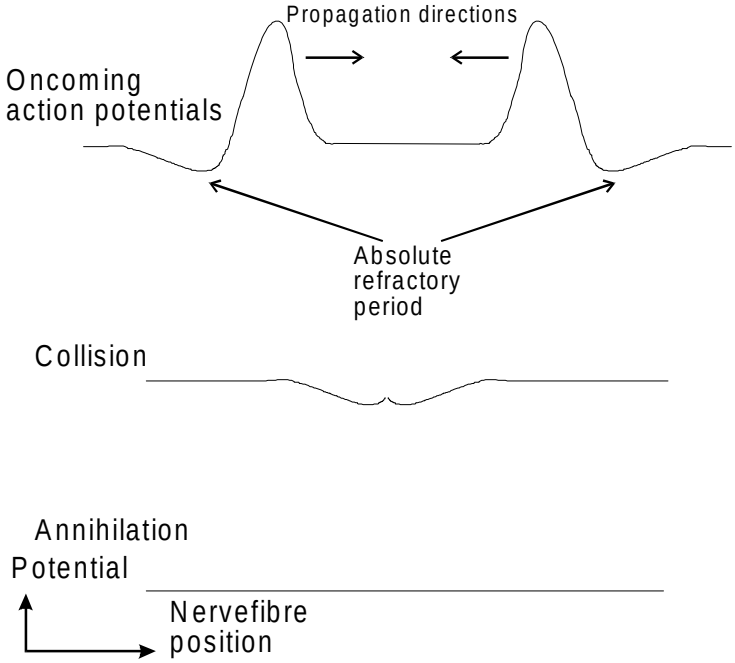


Figure 2.4-3 Theory of the collision block phenomena

When the nerve is stimulated near the muscle two action potentials will be initiated. One that propagates towards the muscle and will cause a twitch and the other that will propagate antidromic towards the cell body in the spinal cord. A voluntary action potential will be coming from the cell body and propagate towards the muscle. If it encounters the antidromic action potential then the result will, as depicted in Figure 2.4-3, be an annihilation of both signals. Both the oncoming nerve signals are succeeded by an absolute refractive period, where the nerve at that location can not be stimulated or in this case pass the action potential on. After the refractory period has passed, other nerve signals can be transmitted again. This collision

block or antidromic nerve blocking effect will thus only affect the first coming voluntary initiated nerve impulse.

The time interval where the antidromic nerve blocking will be able to annihilate a voluntary nerve impulse is dependent on the nerve fiber length and the conduction velocity. The conduction velocity (CV) is defined as the speed of a propagating action potential in the nerve. The total time of propagating of the antidromic nerve impulse is the distance from the origin of excitation to the nucleus of the nerve cell or the first oncoming action potential divided by the conduction velocity. The conduction velocities of the motor nerves n.ulnaris and n.medianus for adults typically be in the range 50-60 m/s [Stålberg and Falck 1993; Falck et al. 1994]. If the nerve is 0.5m-0.7m (estimated as the distance from the wrist to the spinal column in anatomical normal position). The maximum time of antidromic propagation is then in the range of 8-14ms. In comparison the stimulation pulse interval at 16Hz is 60ms.

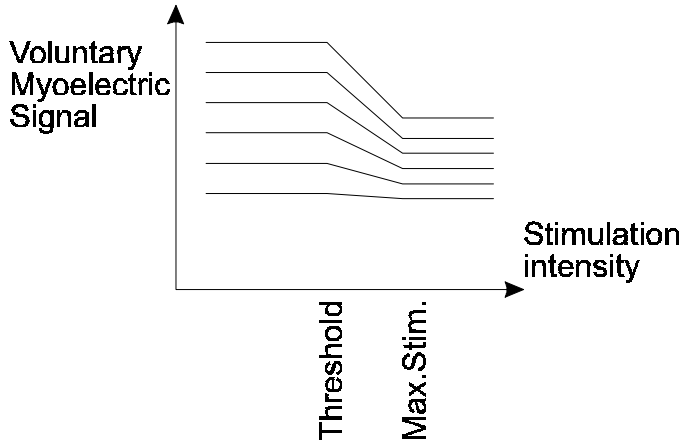


Figure 2.4-4 Tentative illustration of the influence of the stimulation activity on the voluntary myoelectric signal

When a nerve fiber is stimulated the corresponding motor unit will contract and create a motor unit action potential. In the duration of the motor unit action potential voluntary action potentials transferred to the motor unit will have no affect. The stimulation will thus overrun later coming voluntary motor unit action potentials in the refractive period of the muscle fibers. The stimulation activity has to exceed a threshold level before nerve fibers are stimulated. From that level increasing stimulation activity will recruit more nerve fibers until the **supra maximal stimulation**, where all fibers are stimulated, is reached. In this interval the increasing stimulation will lead to decreasing recorded voluntary myoelectric signal activity due to the antidromic nerve blocking effect as well as muscle response and stimulation artefacts. A tentative illustration of the situation is illustrated in Figure 2.4-4.

The effect of stimulation and the effect of antidromic collision block can be seen by investigating Figure 2.4-5 and Figure 2.4-6. The first graph shows stimulation where the subject tries to relax. The second is of the same recording at a time where the subject (subj.: JBS) tries to contract the muscle voluntarily. The subject has an extensor carpi radialis muscle of strength 1, one year after injury, when the recording took place.

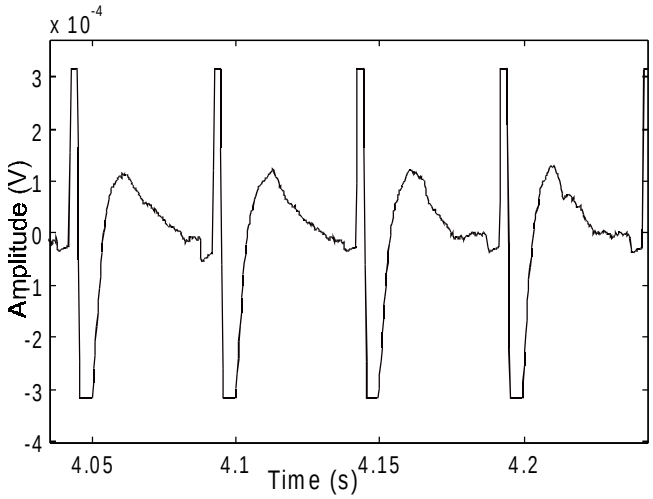


Figure 2.4-5 Voluntarily relaxed with 15mA stimulation (subj: JBS)

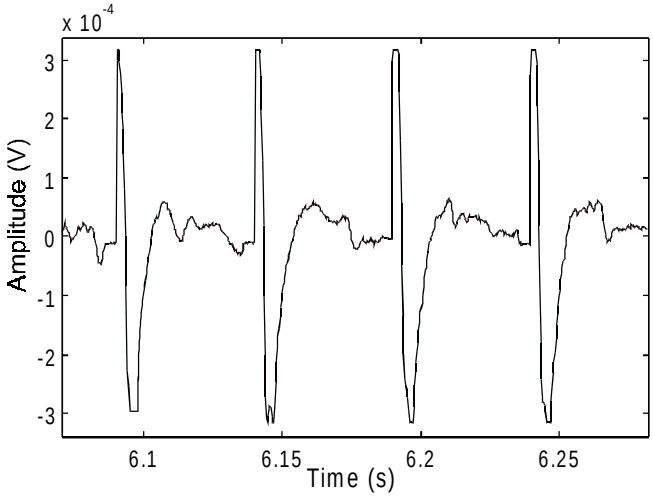


Figure 2.4-6 Voluntary contraction with 15mA stimulation

The stimulation amplitude is 15mA, which produces a strong force (it is not evaluated whether supra maximal stimulation is achieved). On the first graph the stimulation responses are seen as a regularly train of similar shape. Comparing the two graphs it can be seen that voluntary myoelectric activity is present after 20 ms. The first 20ms after the pulse is dominated by the stimulation response. This implies that the antidrome nerveblock is not preventing the voluntary nerve signals to be recorded. The conclusion is that antidromic nerve

blocking does not obstruct recording of voluntary myoelectric signals (from the upper limb) at low stimulation frequency but must be considered, and that the **stimulation will have an inhibiting effect on the voluntary myoelectrical signal.**

2.4.4 Spasticity

Detecting whether the myoelectrical signal is originated by a spasm or voluntary contraction is a severe problem. The myoelectrical signal from spasms is alike the voluntary myoelectrical signals. Signals from spasms tend to be very strong (based on two persons, who are able to provoke a spasm). One example from subject LP, can be seen in Figure 2.4-7 that can be compared with Figure 2.4-8, where a pure voluntary contraction is showed (The signal is blanked as described in *2.7 Signal Processing*. The signals are normalized with same factor).

Spasms will therefore be interpreted by the MeCFES as a voluntary control signal and cause high stimulation. This might provoke the spasm further more resulting in an uncontrollable stimulation. This can only be stopped by turning the device off.

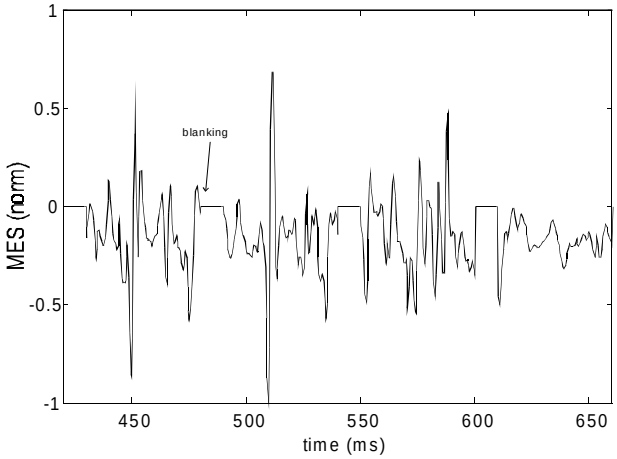


Figure 2.4-7 Spasm from LP

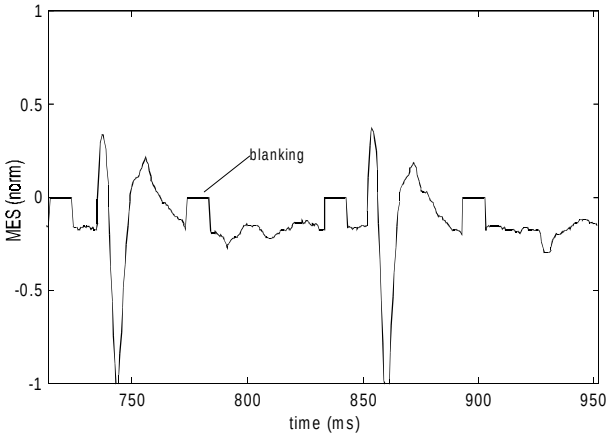


Figure 2.4-8 Voluntary contraction from LP

There are two things that must be investigated if spasms show out to be a major problem. If the myoelectrical signal from spasms is significant higher than voluntary myoelectrical signal, then the control algorithm could be modified to turn off stimulation when the myoelectrical signal activity exceeds a threshold, typically for spasms. Another possibility is that that functional electrical stimulation tends to reduce spasticity as it has been reported [Petersen and Klemar 1988].

2.4.5 Motion Artefact Recordings

The conditions under which the amplifier is to be used imply that the recording electrodes are exposed to mechanical actions. Mechanical actions on the electrodes, such as varying pressure against the skin [Webster 1984], are causing **motion artefacts** due to changes the half-cell potential. To illustrate this Figure 2.4-9 shows the signal from a relaxed muscle (subj.: RAT) where the one electrode is tapped with a finger (at approximately time marks

900,1600 and 2400ms). The recording is made 5 minutes after electrode application using the MeCFES amplifier.

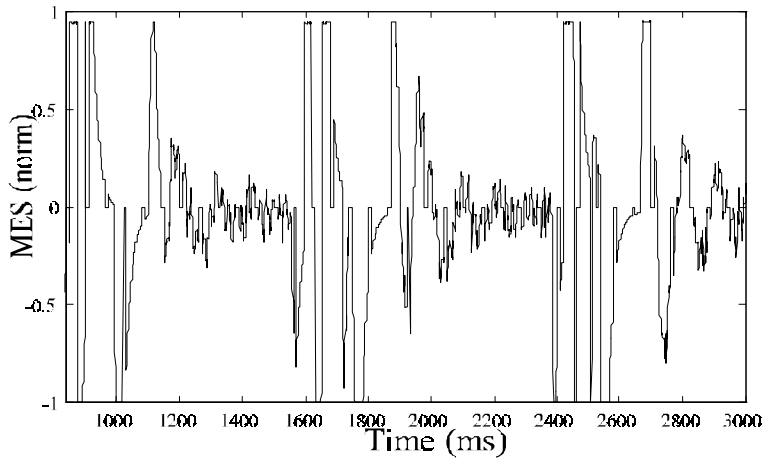


Figure 2.4-9 Motion artefacts (Ag-AgCl electrodes)

Recalling section *2.2 Electrode Characteristics*, the motion artefacts can have peak value that exceeds the ±600μV input range for the amplifier by at least ten times. The recorded signal is, for that reason, clipped.

2.4.6 Spontaneous Activity

It has been noted that in recording signals from a relaxed muscle, (subj.: JBS), there are some single signal spikes or impulses. These seem to occur spontaneously.

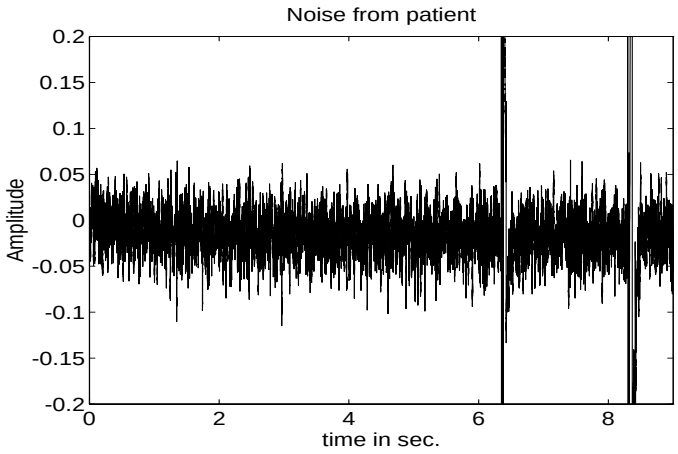


Figure 2.4-10 Background noise with electrodes

As it can be seen at Figure 2.4-10 large bursts appears at the time marks 6.3 and 8.2-8.5 seconds (no blanking is used). A zoom at these bursts can be seen in Figure 2.4-11. This recording was made using the amplifier developed by Sennels [Sennels 1996]. By observing the signal over longer periods it seems that these bursts appears at random intervals. It is not

known whether or not it is external noise or signals from the subjects muscles is not certain. It is known that the subject has spasms and it seems most likely that it is spontaneous activity in the muscles, although it cannot be excluded that the bursts are due to motion artefacts.

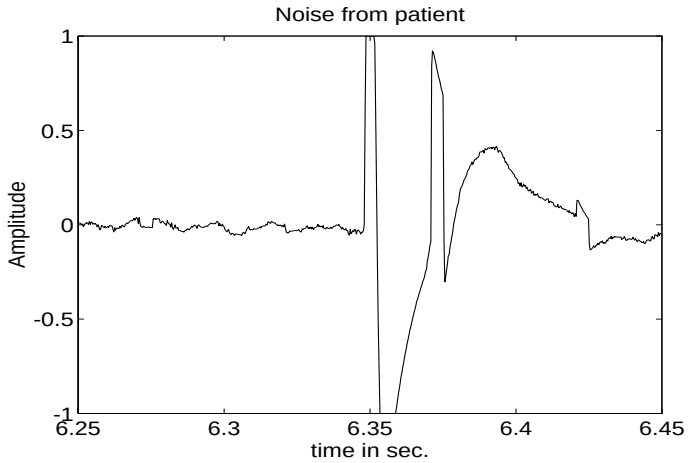


Figure 2.4-11 Zoom at first noise pulse

This phenomenon has been noticed in another tetraplegic but has not been investigated further.

2.4.7 Stimulation Response

The recording electrodes are located in the same area as the stimulation electrodes. For that reason the stimulation will result in a signal component at the recording electrodes known as **stimulation artefacts** [Merletti et al. 1992]. The stimulation initiates a synchronized contraction of a number of motor units the **compound motor unit action potential (CMUAP),** which is the muscles electrical response to the stimulation. The CMUAP can be a magnitude higher than the myoelectrical signal but may vary due to fatigue. (That property can be used as a fatigue indicator [Mizrahi et al. 1994]). The simulation artefact and the CMUAP are mixed and synchronized . The combination is denoted in this text as the **stimulation response**.

The large ratio between the stimulation response and the myoelectrical signal is a problem for the recording of the myoelectrical signal. The magnitude of the myoelectric signals typically less than 0.5mV. The stimulation current can cause voltages at the recording electrodes up to magnitudes of 100V in the worst case. When special care is taken to minimize the fault current from the stimulation electrodes to the recording electrodes (see *2.8.1 Electrode Placing*) the stimulation response can be reduced. Careful electrode placing can bring it below 0.5V at 15mA stimulation. The simulation artefact is thus the dominating component in

the stimulation response. The conclusion is that the stimulation response can be at least 60dB above the myoelectrical signal level. For that reason **the amplifier must have a fast recovery from overloading of an impulse at the input.**

To protect the input of the myoelectric amplifier the inputs are clamped to a level near zero (the MeCFES amplifier is clamped to ±3V) with a resistor in series. This implies the possibility for the stimulation current to flow through the recording electrodes via the clamping circuit to the return ground. A model of the configuration is illustrated in Figure 2.4-12.

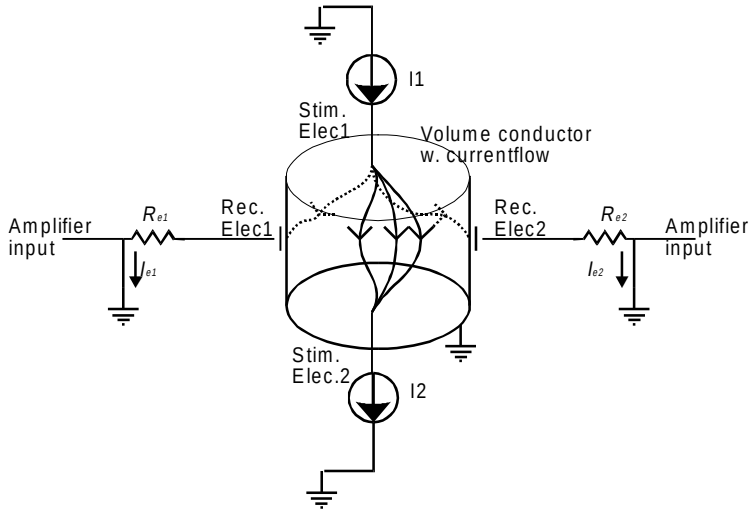


Figure 2.4-12 Simplified model of the stimulation current flow

The two current generators I_1 and I_2 are representing the stimulator output. If the voltage at the recording electrodes exceeds the clamping voltage, the amplifier input will be equivalent to impedance in the current return path. (There will be a return path for the current from one electrode to another. This path might be the common ground for the system as well as the power supply. The model is simplified by using ground as return path). Two cases are considered:

In the first case we assume that the two current generators are not perfectly matched i.e. $I_1 \neq -I_2$. Since the sum of currents in a closed system is zero, the current difference must be equal to the current flowing into the electrodes and through the return path to ground: $I_1 - I_2 = I_{e1} + I_{e2}$. If $I_{e1} = I_{e2}$ we can call it a **common mode stimulation artefact**.

In the second case we assume that $I_1 = I_2$.but the current flow in the tissue, in conjunction with the electrode placement, results in a potential difference of the recording electrodes exceeds the clamping voltage. In this case there will flow a current through the one recording

electrode to the return path (e.g. ground) and out of the other electrode. That means that I_{e1}=-$I_{e2.}$ We can call this a **differential mode stimulation artefact**. Worst case is where the recording electrodes are placed on a line between the stimulation electrodes.

The Type 3 stimulator is a method to realize the current generator that **avoid common mode stimulation artefacts.** The output is galvanic separated from common ground. (The two generators are realized as one current generator). **Elimination of difference stimulation artefacts**, by adjusting the electrode positions, has turned out **not** to be **possible in practice.** The dimension of the electrodes and the physiological demands limits the freedom of the electrode placing. (The stimulation electrodes must be placed on the right motor points and the recording electrodes must be placed where the desired myoelectrical signal is present).

If current flows into the electrodes these will be charged due to the change of half cell potential and the capacitance (see *1.12 Electrodes*). This will prolong the stimulation artefacts since the electrodes will behave like the high pass filter described in *2.5 Signal Amplification.* If the part of the stimulation current that flows into the recording electrode is not charge balanced the result, as illustrated in Figure 2.4-13, recording of the myoelectrical signal will be impossible as long as the electrode potential saturates the amplifier.

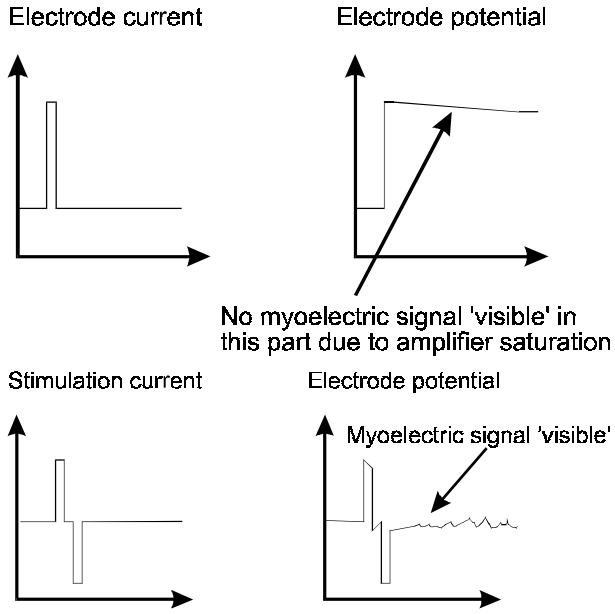


Figure 2.4-13 Transients in electrodes caused by stimulation responses of different shapes. Some can saturate the amplifier.

The figures show that if the stimulation artefact is monophasic the transient in the electrodes can saturate the amplifier and thus temporarily disable amplification of the myoelectrical signal. For a perfect charge balanced biphasic stimulation artefact this effect is reduced (but not

eliminated). **This is an important technical argument for using a biphasic charge balanced stimulation pulse form.**

If the half-cell potential of the electrodes are uneasily changed due to a low solubility product of the ions and the capacitance is low, which is the case with Ag-AgCl electrodes, the decay time for the transient is reduced. The properties (impedance & half cell potential) of the recording electrode pair when applied to human skin will not be identical. As described in *2.5 Signal Amplification*, common mode stimulation artefacts can converted to a difference signal due to different transient courses for the electrodes). For that reason **common mode stimulation artefacts must be avoided** despite the amplifier has a high common mode rejection ratio.

In summary the stimulation current is a serious noise source. To reduce the noise and ensure proper amplification of the myoelectrical signal the following must apply for the stimulator and the electrodes.

The stimulation impulses must be charge balanced and biphasic.

The stimulator outputs must be floating, i.e. have infinite impedance to common ground.

The stimulator outputs must be very near identical ideal current generators.

The recording electrodes must be placed in a way that differential mode stimulation artefacts are reduced and the **recording and stimulation electrodes can not be the same**.

2.4.8 Inherent Noise

Both the electrodes and the amplifier generates filtered white noise. For the MeCFES amplifier the inherent noise when the inputs are short-circuited to ground is $0.4\mu V_{RMS}$(Figure 2.4-14). This is 20dB less than the noise from Ag-AgCl electrodes, which is approximately $4\mu V_{RMS}$ (described in *2.2 Electrode Characteristics*).

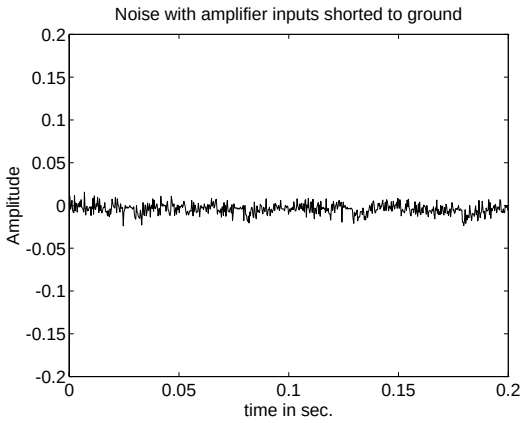


Figure 2.4-14 Inherent noise from the MeCFES amplifier when inputs are connected to ground (amplitude in mV).

In other words. The inherent noise from the electrodes is dominant.

2.4.9 Signal Model

The previous findings can be collected to a simple model of the signals included in the recorded signal. Only the **voluntary myoelectrical signal** is of interest why all the other signal components are regarded as noise. The signal from the electrodes can be modeled as coming from six sources (Figure 2.4-15). Some of those sources are representing different processes but are having the same characteristics and can for that reason, to

simplify the model, be regarded as one source. This applies to the sources V_s, V_n and V_{sp}, where these can be divided into two sources in order to obtain a more elaborate model.

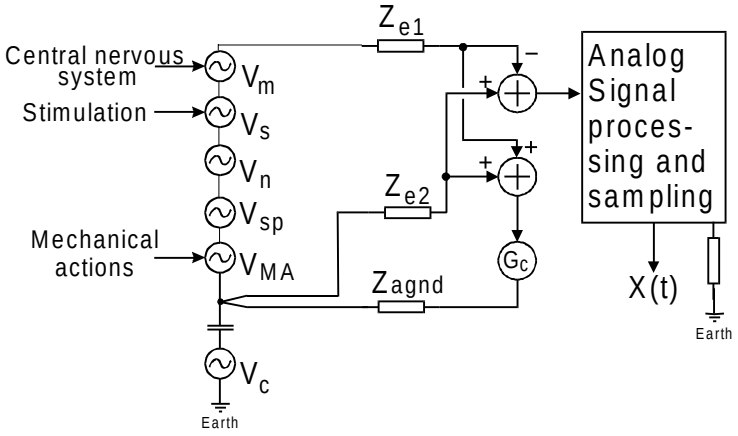


Figure 2.4-15 A simple signal model

The signal sources and their expected values are:

V_m: The voluntary myoelectric signal. This is a stochastic signal controlled by the central nervous system. The typical amplitude for a paretic muscle is below **$0.5mV_{peak}$**.

V_s: Stimulation response. This is a periodic signal with an amplitude depending on the stimulation intensity and the electrode placement. It comprises both the compound motor unit action potential and the stimulation artefacts. The compound motor unit action potential is depending on the stimulation amplitude as well as the state of the muscle, which for example can be how fatigued the muscle is. This stimulation artefacts are increasing with increasing stimulation amplitude and is also affected by the electrode mounting and the characteristics of the stimulation pulse (see discussion in 2.4.7 Stimulation Response. An example of magnitude is a measurement of the stimulation response amplitude of **0.5V at 15mA** stimulation. Careful rearranging of the electrodes can give lower values.

V_n : Inherent noise. This includes the inherent (thermal) noise from both the electronics and the electrodes. This is a strictly stationary stochastic signal. (This implies that is has a constant level). For the given MeCFES amplifier it is recorded to **$4\mu V_{RMS}$** when using Ag-AgCl electrodes.

V_{sp} : Spontaneous noise. This includes all kinds of stochastic non-stationary noise from the muscle. This applies mostly to signals arising from spasms. They are expected to be a strong intermittent signal. From provoked spasms the level is far above the level of a voluntary contraction. (It is estimated that levels can be up to **10mV**$_{peak}$ in worst case, these levels will cause clipping of the signal by the amplifier.

V_{MA}: Motion artefacts. This is transients caused by mechanical influences on the electrodes. This is a intermittent signal and therefore a non-stationary signal. As discussed in 1.12.3 Motion Artefacts they can be up to 10mV$_{peak}$ regardless of the electrodes.

V_c: Common mode signal. This is a **50Hz (60Hz) distorted sine** appearing at the electrodes as a common mode signal. The origin is the capacitive coupling from mains to the user. If the MeCFES's common ground is coupled direct to the earth, the level at the amplifier input will be higher than when the MeCFES is 'floating' with respect to the electrical earth. With the common ground connected the electrical earth an amplitude of 0.2V$_{RMS}$ is measured.

Noise from the mains is capacitive coupled to the person and will be present as a common mode signal at recording electrodes. The common ground for the MeCFES is coupled to the electrical earth. (The impedance of the latter coupling is depending on which devices the MeCFES has electrical connection to. For example a computer). To reduce the **common mode signal** the signal is amplified G_c times with a 180 degrees phase shift and **fed back to the body** through the ground electrode (with impedance Z_{agnd}).

The model is simplified and does not include the input impedance of the amplifier (which can cause conversion of some of the common mode signal into a difference signal, if the electrode impedance Z_{e1} and Z_{e2} are not equal).

2.5 Signal Amplification

The amplifier is a critical component since it provides the first processing of the weak high impedance myoelectrical difference signal. Therefore some aspects in designing the stimulator will be discussed in the following.

In normal surroundings there is a powerful electrical field from the mains that surrounds us. This 50Hz (in Europe) field may create common mode signals, from the user, of several volts. To suppress this field it is necessary to have **a high common mode rejection** in the amplifier. It is well known [Webster 1992] that the common mode signal can be suppressed by amplifying and feeding it back to a grounding electrode, on the subject, with a phase shift of π. This is called **active ground**.

The input impedance (common- and differential mode) must be very high since the myo-electrical signal has a high impedance. If the electrode impedance is unequal then common mode signals will be converted to difference mode signals. The amplifier is a three terminal device on the input side with the two inputs and the ground as in Figure 2.5-1 with respect to the common mode signal. For a common mode signal the electrode impedance, **convert common mode noise to difference mode noise** which can disturb myoelectrical signal measurement.

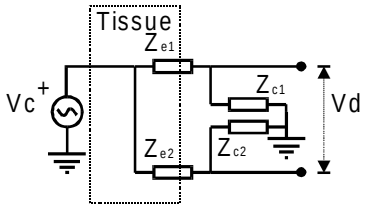


Figure 2.5-1 Simplified equivalent diagram of amplifier input

The difference signal V_d arising from the common mode signal V_c is

$$V_d = V_c\left(\frac{Z_c}{Z_c+Z_{e1}} - \frac{Z_c}{Z_c+Z_{e2}}\right) \approx V_c \frac{Z_{e2}-Z_{e1}}{Z_c} \qquad \textbf{Eq. 2.5-1}$$

Where Z_c is the common mode impedance of the amplifier (including cables) and Z_{e1} and Z_{e2} are the electrode impedance. For the approximation it is assumed that the common mode impedance is much larger than the electrode impedance, $Z_e << Z_c$.

To amplify the less than 0.6mV myoelectrical signal to a level that can match a 3V analog - digital converter, the **amplification** of the amplifier must be in the range of at least 74dB.

The **inherent-noise** of the amplifier related to input must be less than the inherent noise from the electrodes (less than 4μV).

Since the inputs of the amplifier is so easy accessible, these must be protected from **electrostatic discharging** as illustrated in Figure 2.5-2. This protection must, when inactive, have an impedance in same magnitude as the input impedance of the amplifier to leave the myoelectrical signal undisturbed.

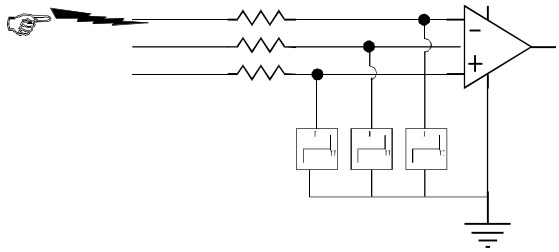


Figure 2.5-2 Protecting inputs from electrostatic discharge

This will also protect the inputs against signals from the high-voltage stimulator output. The protection can be provided by clamping the inputs. Diodes are suitable for that purpose. Clamping to ground, using common diodes, should be avoided due to difference in dynamic resistance, R_d, given by Eq.2.5-2.

$$R_d = \frac{V_t}{I_0(\exp(\frac{V_d}{V_t}) - 1)} \qquad \textbf{Eq. 2.5-2}$$

Where V_t =26mV and I_0 in the range of nA-μA are diode specific constants. If the electrode half cell potential V_d=1-10mV the dynamic resistance can be less than one MΩ. This can cause **conversion of common mode noise to differential mode noise** according to Eq.2.5-1 using the diodes dynamic resistance as the amplifier input impedance. Therefore clamping to power supply is more attractive. However the reverse current in the diodes must then be considered.

As discussed in the previous section the signal at the amplifier input is mixed with pulses of far greater amplitude than the myoelectrical signal of interest. A typical electromyography amplifier is configured as shown in Figure 2.5-3 [Hall and Munday 1994;Saridis and Goothe 1982;Ylvisaker 1986].

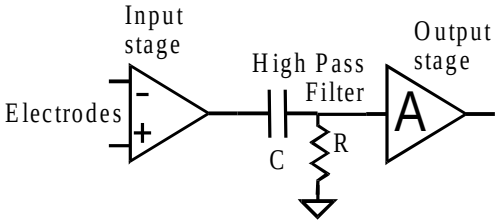


Figure 2.5-3 Simplified schematic of a typical conventional myoelectric amplifier

It comprises of a differential input stage, a high pass filter to remove DC-offset and a high gain output stage. Stimulation artefacts will flow into the high-pass filter and the transients created here can cause saturation of the second stage and thus extend the duration of the stimulation artefacts. The recovery time is here defined as the time from the amplifier input is exposed by a pulse till the amplifier output reaches the active area (i.e. between the supplies:- 3 to 3V). The test pulse, after 20dB amplification in the input stage, is defined as an 1V, 1ms wide rectangular pulse[1]. For an amplifier as in Figure 2.5-1, with gain 74dB, the response would be determined from the equation derived from adding the RC circuit response from two step functions.

$$V_0 = A \cdot V_i (\exp(-\frac{t}{\tau}) - \exp(-\frac{t-1\text{ms}}{\tau}) \qquad \text{for } t > 1\text{ms} \qquad \text{Eq. 2.5-3}$$

For A=500 this yields

$$V_0 < -3\text{V} \quad \text{for} \quad t < 43\text{ms} \quad \text{at} \quad \tau = \frac{1}{8}\text{s})$$
$$V_0 < -3\text{V} \quad \text{for} \quad t < 10\text{ms} \quad \text{at} \quad \tau = \frac{1}{80}\text{s}) \qquad \text{Eq. 2.5-4}$$

Therefor the **recovery time would take most of the inter stimulation period**. To deal with this problem a switch [Minzly, et al. 1993;Mizrahi, et al. 1994] or a sample-hold circuit [Babb, et al. 1978;Howson and Heule 1980] can be applied before the filter. As an alternative the filter cut-off frequency can be raised (1kHz) well above the stimulation frequency [Haugland and Hoffer 1994]. CMOS switch and sample-hold circuits causes a charge injection in the signal path which give rise to new artefacts. Furthermore a high cut off frequency is inadequate for recording surface myoelectric signals for which it is commonly

[1] According to *2.4.9 Signal Model* stimulation response could be up to 0.5V. With a gain of 10 in the input stage, the 1V pulse is a low choice of amplitude.

accepted that the information is present in the frequencies below 500Hz [Bilodeau, et al. 1993;Kwatny, et al. 1970]. Choice of the cut off frequency is a compromise between minimizing the recovery time from stimulation artefacts and the recovery time from changing the DC offset. The recovery time is here defined as the time from the end of a stimulation pulse until the circuit is no longer saturated.

Reduction of artefact transients in the amplifier circuit is essential for subsequent processing. As long as the signal is not clipped or by other means distorted in the analogue circuits, further suppression of artifacts can be done by means of digital signal processing. This can be done by blanking [Holländer 1987;Kitzenmaier and Boenick 1993;Nikolic, et al. 1994;Popovic, et al. 1993] and filtering [Haxthausen, et al. 1991;Sennels, et al. 1995].

This artefact problem has been leading to the development of the MeCFES amplifier as described in Chapter 3.

2.6 Signal to Noise Ratio Definition

To evaluate the efficiency of different signal processing methods a measure of the signal to noise ratio (SNR) is required. The dilemma is that the signal is never known because we only have access to the output of the system and the applied stimulation pulses, by which it is influenced. The input signal is the "decision" which the subject is controlling. (This reflects the desire for a movement). This is not possible to measure objectively. An illustrative input-output model (Figure 2.6-1) can be seen as a black box with the inputs: mental decision and electrical stimulation. The output is the resulting myoelectric signal. The only exact measurable signals are the stimulation and the output.

As described in the *2.4.3 Antidromic Nerve Block Theory* and *2.4.7 Stimulation Response* the stimulation will have an inhibitory effect on the voluntary myoelectrical signal and add more noise to the output signal with increasing stimulation amplitude. It is therefore reasonable to define the signal to noise ratio at a fixed stimulation level. First we assume that the noise is non-correlated with the signal, (which not applies to the part of the stimulation that inhibits the signal i.e. the following is only an approximation). Then assuming that when the subject is relaxing the muscle, the output (M_{rel}) is representing only the noise component. When the subject concentrates on full contraction of the muscle the output (M_{vol}) comprises the sum of the noise and the signal. Then the signal to noise ratio (S/N) can be defined as

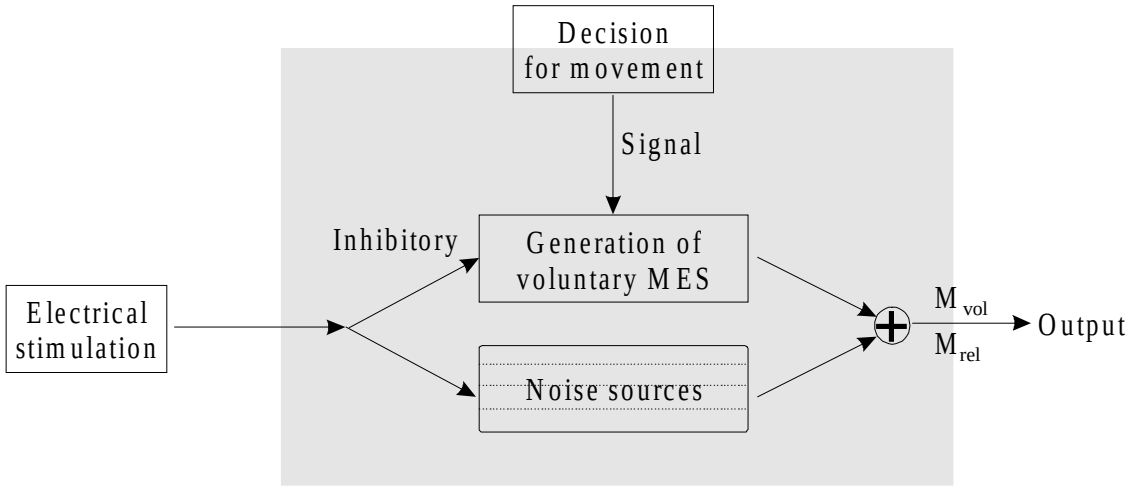


Figure 2.6-1 Input-output model. The voluntary myoelectrical signal (MES) is generated in the voluntary controlled motor units.

$$S/N = \sqrt{\frac{RMS^2(M_{vol}) - RMS^2(M_{rel})}{RMS^2(M_{rel})}} \qquad \text{Eq. 2.6-1}$$

where M_{vol} is the myoelectrical signal measured under full voluntary contraction and M_{rel} is the signal from the voluntarily relaxed muscle. The root mean square value of the signal is denoted by RMS.

A feasible way to measure this has been found (by experiments). The participant is asked to perform maximal contraction and then the stimulation is applied. M_{vol} is recorded immediately after the onset of the stimulation. Immediately after recording M_{vol} , the subject is asked to relax. Then M_{rel} can be recorded. To avoid the effect of fatigue the two measurements should be accomplished within a few seconds.

2.7 Signal Processing

This section describes the signal processing for the MeCFES.

2.7.1 Analogue Signal Conditioning

The signal processing starts in the amplifier where the signal is amplified and filtered using the MeCFES amplifier, which is described in detail in section *3.2 Amplifier Circuit.* The amplifier is designed to minimize the stimulation responses by having a fast recovery time and clip signals levels exceeding ±600µV. A change in the electrode offset exceeding ±0.1mV starts the fast offset compensation. In this way both motion artefacts and stimulation responses are reduced.

The filtering of the myoelectrical signal is determined from the following observations of the frequency content. A typical frequency spectrum (FFT) of a myoelectrical signal is shown in Figure 2.7-1 using an amplifier with 0-1.5kHz bandwidth and sampling at 3.3kHz. Here it can be seen that frequencies above 500Hz are below -20dB.

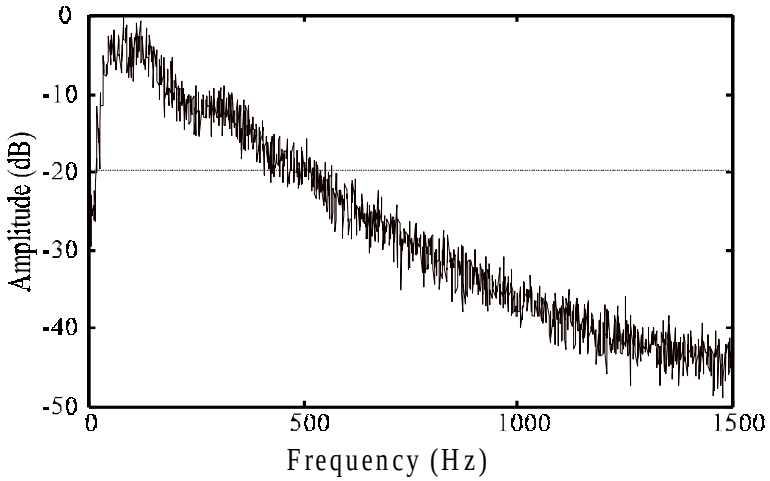


Figure 2.7-1 Frequency spectrum of a myoelectrical signal (normalized by peak value. Subj.: RAT)

Applying stimulation to the full voluntary contracted muscle results in the spectrum seen in Figure 2.7-2

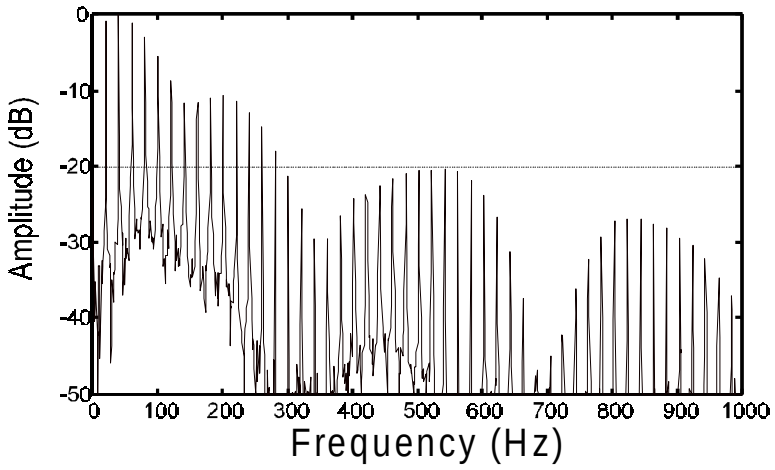


Figure 2.7-2 Myoelectrical signal and stimulation (Normalized)

As it can be seen the harmonics of the stimulation response are dominating at frequencies above 500Hz. To comply with the Nyquist criterion before sampling it has been chosen to provide the MeCFES amplifier with a **500Hz 2nd order low pass filter** to reduce the frequency components above 500Hz. The signal is then **sampled at 2kHz** without significant aliasing since the signal at 1kHz (half the sampling frequency) will be further damped 12 dB by the filter. Since the recorded signals contains impulses it is important that the filter has the best possible impulse reproduction. **A Bessel-filter is chosen** since this filter complies with this requirement [Langvad 1987].

2.7.2 Sampling and Pre-filtering

After being amplified and processed by the amplifier the signal is **sampled at 2kHz**. The **SNR** (signal to noise ratio) of the amplifier can be at the most 60dB (maximal input signal level is $600\mu V_{peak}$ and the noise is $0.4\mu V_{RMS}$ excluding electrodes and $4\mu V_{RMS}$ including electrodes). For that reason a **10 bit resolution** (60dB) is sufficient for the myoelectrical signal sampling.

In Figure 2.7-3 the stimulation response (subj.: JBS) from a voluntarily relaxed, but stimulated muscle is shown. The stimulation pulse starts at the time zero and has a total duration of 900µs. As it can be seen that the amplifier is saturated for approximately 10ms after the initiation of the stimulation pulse. This is a typical response. Since this interval does not contain information of the voluntary myoelectrical signal the samples are **blanked** in this interval i.e. values are put to zero. In the signal processing the **10ms blanking** is equal to discarding 20 samples. This reduces the samples by 20% and thereby saves computing resources without loss of information.

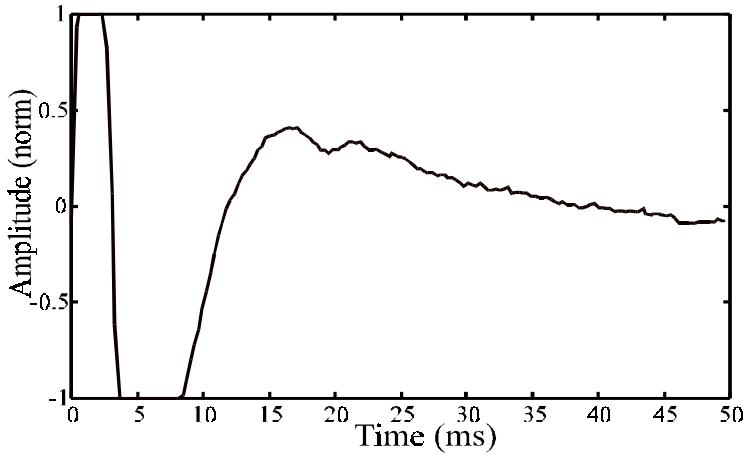


Figure 2.7-3 Stimulation response (subj.: JBS)

In Figure 2.7-4 the subject performs voluntary contraction during the stimulation. The subject has a very weak muscle of force 2. Comparing with Figure 2.7-3, one finds that the voluntary myoelectric part is much smaller than the stimulation response.

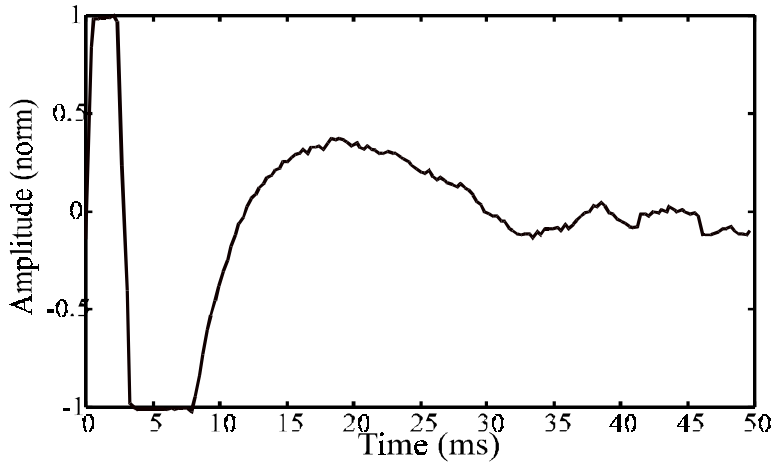


Figure 2.7-4 Mixed signal (subj.: JBS).

To remove stimulation responses a linear filter is applied. Haxthausen [Haxthausen et al. 1991; Haxthausen 1992] used a transformed 3rd order elliptical filter for the suppression of the stimulation response. It has been found [Thorsen 1994] that this filter does not improve the SNR much compared to a fixed FIR (finite impulse response) filter (Eq. 2.7-1). Sennels [Sennels et al. 1997] compared adaptive filters to fixed FIR filters. It was found that adaptive filters with 6 non zero coefficients gave some improvement of the SNR compared to a fixed FIR filter.

The drawback of adaptive filters is that they require significant more computation than a fixed FIR filter. Considering the SNR improvement it has been decided to use a transformed first

order FIR filter which requires minimal computation. The filtered myoelectric signal *m* is given by the difference equation

$$m_n = (x_n - x_{n-p}) / \sqrt{2} \qquad \text{Eq. 2.7-1}$$

where *n* is the sample number, *x* is the sampled signal and *p* the number of samples in the period between consecutive stimulation pulses is *p*. (Gain factor $1/\sqrt{2}$ leaves the RMS (root mean square) value unchanged for a stochastic signal).

By selecting the stimulation frequency to be an integer fraction of the power supply net frequency (which in Europe is 50Hz) we get the double advantage of the comb filter. It thus **both suppress stimulation signals and 50 Hz hum**. Experiments have shown that the stimulation frequency should be above 10Hz to obtain a constant muscle contraction. It is desirable to keep the stimulation frequency as low as possible, since the amount of valid samples of the myoelectrical signal is increasing with decreasing stimulation frequency. For these reasons **the 16.6Hz stimulation frequency has been chosen** , a third of the mains frequency. (For countries with 60Hz mains frequency a fourth i.e. 15Hz will be suitable).

If the signal is contaminated by a high level of hum from mains the difference in the energy before and after comb filtering is high. This is used **for detecting if the signal is too noisy.** This will be the case if the recording electrodes does not have proper skin contact. Then one or both the electrodes will have a high impedance which may cause common mode hum to be converted to a differential signal as described in *2.5 Signal Amplification.*

2.7.3 MUAP Activity Calculation

After the signal to noise ratio has been improved by filtering, the myoelectrical signal can be converted into the control signal. This is done by estimating the **MUAP activity**, defined as the average voluntary MUAPs (motor unit action potentials) from the controlling muscle over time. Some different techniques for estimating the control signal have been considered e.g. autoregressive models [Hefftner et al. 1988] or the use of neural networks [Costa and Gander 1993]. It is the believe that the advantages of such methods does not match the need for computation. For that reason, simple methods based on the energy of the voluntary myoelectrical signal have been chosen. Assuming that the myoelectrical signal is a white noise signal from a high number of independent generators with a stochastic distribution of the firing interval, an **ARV** (average rectified value) of the signal is often used. The use of

ARV has a historic reason, since it was simple to realize in analogue electronic circuits. With the introduction of low cost digital signal processors the RMS value of an interval (sliding window) of the signal has become another often used measure. In the context of signal processing, the RMS of the myoelectrical signal is more attractive since it applies to the common calculation of the signal-noise relation. Which of the two measures are used is not important since the RMS and ARV can be considered proportional [Hermens 1991]. Haxthausen [Haxthausen et al. 1991; Haxthausen 1992] used the ARV as a measure for the MUAP activity.

In this **work has been chosen to use the RMS** of segments of the myoelectrical signal as **one method for estimation of the MUAP activity**. It is practical to calculate the RMS for a block of samples, where **a block is defined as the samples between two consecutive stimulation pulses**. The control signal is estimated by low-pass filtering of the RMS (in quadratic sense). A method using ARV instead of RMS has been implemented in the MeCFES for compatibility with the work of Haxthausen.

A different approach will be described in the following. This is an ad-hoc method for estimation of the MUAP activity. As discussed in *2.4.2 Motor Unit Distribution Model* the number of MUAPs are few. From *1.10 Myoelectric Signals* it is known that the different MUAPs do not contribute equally to the myoelectrical signal. The RMS value will be differently affected by different motor units and might thus not reflect the number of MUAPs per time in the muscle, but rather which motor units are currently recruited. The argument is thus that if the MUAPs are few and changing in origin then the RMS over a short time interval of the signal will not be an accurate estimate for the firing activity. It is desired to keep this interval short to minimize the total delay of the system.

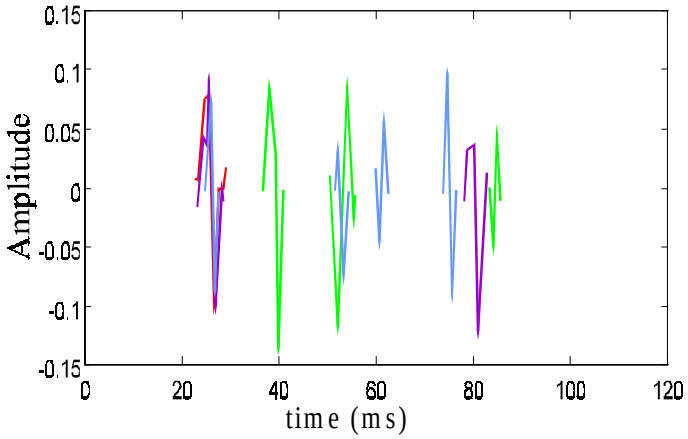


Figure 2.7-5 Selected MUAPs

Figure 2.7-5 shows MUAPs from a normal muscle (subj.: RAT) at a very weak contraction (RMS of myoelectrical signal = 6µV) selected by visual inspection. The duration of the MUAPs is in the range of 6-10ms. According to *1.10 Myoelectrical Signals*, the electrical properties of the motor unit does not change over time. At this low level of MUAP activity, the individual MUAPs are visible in the electromyogram as discrete action potentials. At levels of 20µV the hand starts extension against gravity.

Let $S=(s_0,s_1,s_2,\ldots,s_{m-1})$ be the MUAP that is going to be detected. If the MUAP occurs at different times in the signal *m* and if the MUAPs do not overlap, then the MUAP can be detected using a filter with the impulse response $h=a(s_{m-1},s_{m-2},\ldots,s_0)$ [Justesen and Forchhammer 1992].

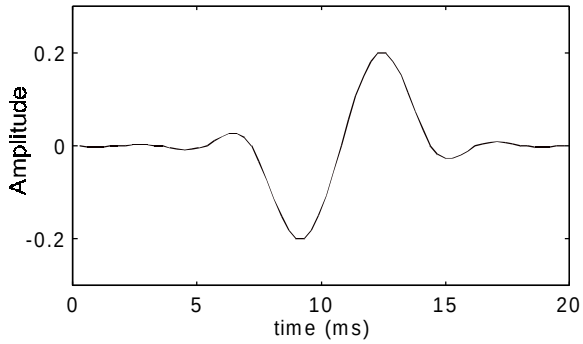


Figure 2.7-6 Idealized MUAP

A standard MUAP is generated by smoothing the sequence [0,-1,0,1,0] (using the MATLAB™ interpolation command *interp*). This representation is arbitrary chosen, based on inspection of the recorded MUAPs. A time interval of 3msec between the bottom and the top of the pulse is used. The frequency response for the filter together with the spectrum of a $20\mu V_{RMS}$ myoelectrical signal is shown in Figure 2.7-7.

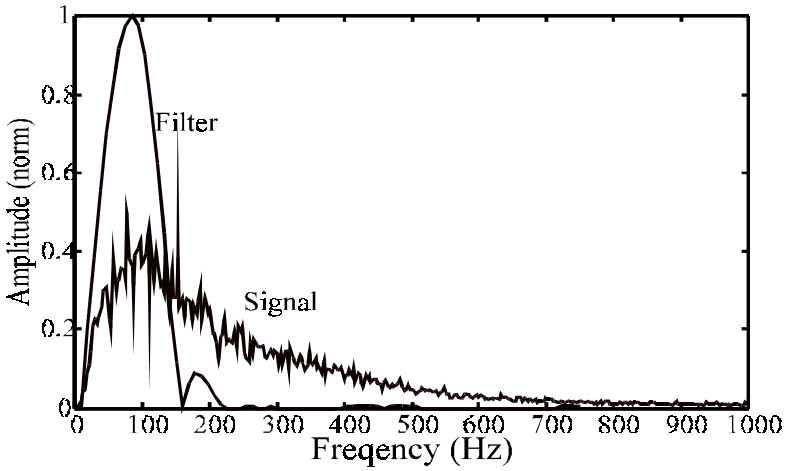


Figure 2.7-7 Frequency response for filter and signal spectrum

As it can be seen in Figure 2.7-7, the filter is a band pass filter. If the filter output us an extreme of a certain level, it is assumed that a MUAP is encountered. Finding local extremes is not a trivial computing task. To simplify the computation the MUAP activity was chosen to be calculated as the number of samples in the filtered signal with a magnitude that exceeded a certain threshold *tr* according to Eq. 2.7-2

$$TC(m,tr) = \frac{1}{N}\sum_{N} u(y(n),tr) \quad , \quad u(y,tr) = \begin{cases} 1, & |y| \geq tr \\ 0, & |y| < tr \end{cases} \qquad \text{Eq. 2.7-2}$$

where *y* is the filtered myoelectrical signal *m* and *N* is the number of samples in the block.

The following results are based on weak contractions of a normal muscle (subj.: RAT). The signals are produced by measuring the RMS value of the myoelectrical signal from the muscle. The subject tries to retain a steady contraction with the visual feedback from a RMS meter at different RMS levels of the myoelectrical signal.

In Figure 2.7-8 the threshold counting method is compared to the RMS value. The values are calculated over 3 seconds of the most constant contraction. The left curve shows the relation between the attempted contraction and the actual root mean square value of the myoelectrical signal RMS(*m*) . The right curve shows the TC value (TC(*m*)) of the same myoelectrical signal *m* where the threshold *tr* is arbitrary chosen to two times the RMS of the inherent noise (which is 4μV).

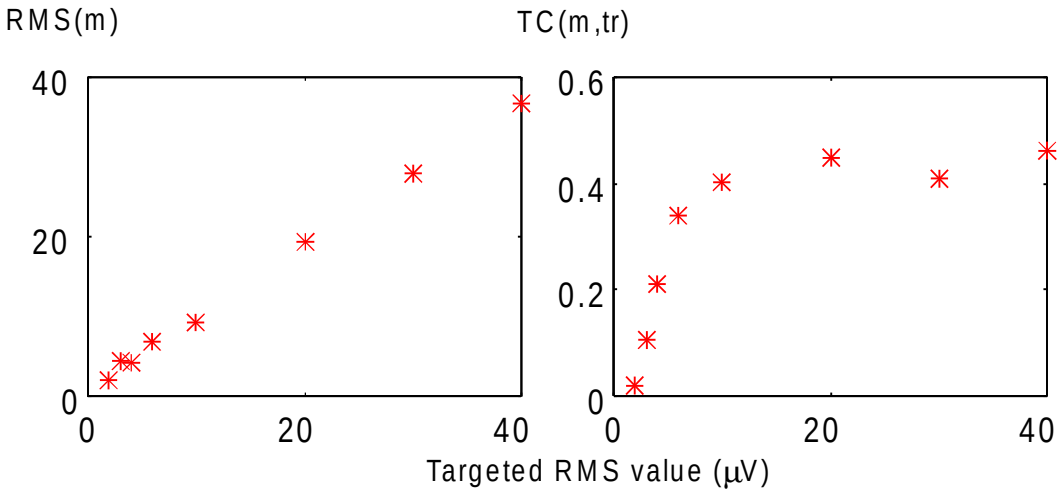


Figure 2.7-8 RMS values compared to the threshold counting (TC)

The noise immunity of the two methods are compared at low myoelectrical signal levels. Figure 2.7-9 shows the RMS values of filtered myoelectrical signals (*m*) added with noise. The RMS values of *m* are 4,6,8,12,20,40,60 and 80 μV_{RMS}. The noise is the recorded inherent noise amplified to 0,10,20,30,40 μV_{RMS}. Figure 2.7-10 shows the TC values with threshold 60μV of the same signals. The five noise levels are seen as the five curves with increasing level.

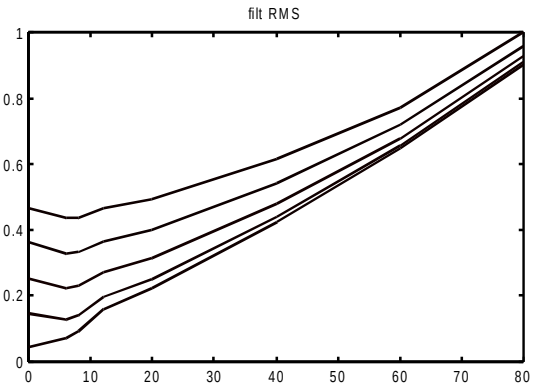


Figure 2.7-9 RMS(m+noise) vs RMS(m)

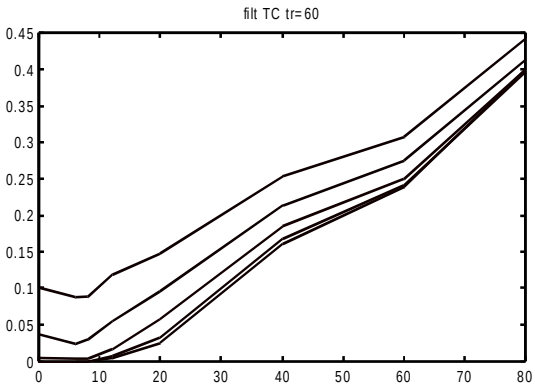


Figure 2.7-10 TC(m+noise,60) vs. RMS(m)

At low levels, the TC is more noise suppressing than the RMS method as illustrated by Figure 2.7-11. Here the level of noise+signal relative to the signal is calculated for the $6\mu V_{RMS}$ and $12\mu V_{RMS}$ signals. The horizontal axis shows the noise relative to the signal. On the vertical axis the RMS of the filtered noisy signal or the TC of the noisy signal is relative to the pure signal.

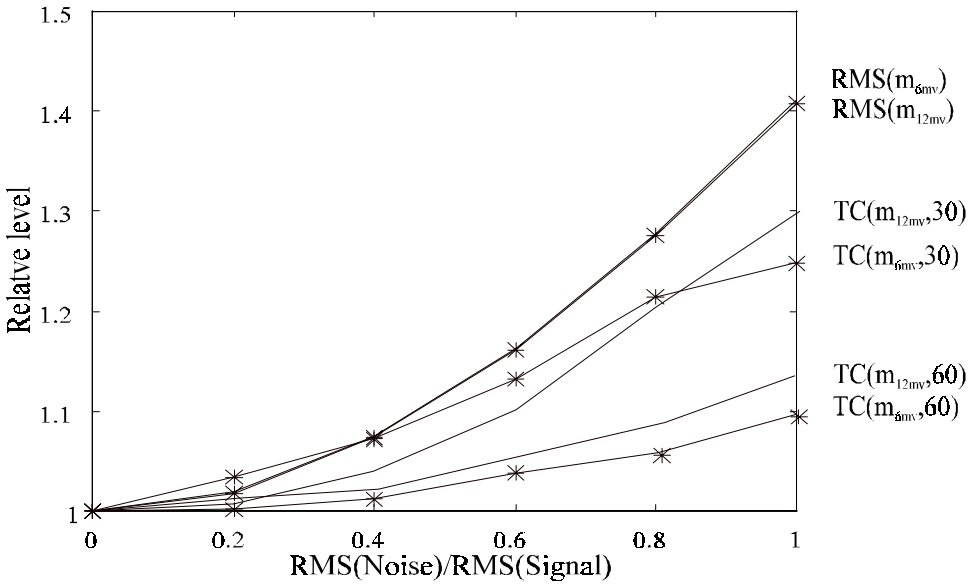


Figure 2.7-11 Noise immunity

The TC method is calculated with thresholds 30μV and 60μV. When the MUAP activity is low, this method is better in suppressing the noise. Finding the threshold is done by trial and error.

The threshold counting method is implemented in the developed device as another method of estimating MUAP activity . The method is applied to each block of samples.

2.7.4 Calculation of Stimulation Amplitude

The MUAP activity is calculated over each block of data. A block is defined as the signal between two consecutive stimulation pulses. The MUAP activity is filtered by a low pass filter. The filter used calculates the mean value over 20 stimulation periods (corresponding to 1.25sec) of the MUAP activity.

Alternatively an IIR (infinite impulse response) low-pass filter can be used. The implemented filter has the form:

$$y_n = a_0 x_n + b_1 y_{n-1} \qquad \text{Eq. 2.7-3}$$

(Where y is the output and x the input, n denotes the sample number, a and b are constants determining the gain and frequency response).

The stimulation amplitude is calculated by a piece-wise linear function.

$$IAmp = \begin{cases} IOfs+(Z-MAofs)*IGain & for\ Z>MAOfs \\ 0 & otherwise \end{cases} \qquad \text{Eq. 2.7-4}$$

Here *Z* is the filtered muscle activity, *MAofs*, *IGain* and *IOfs* are constants that can be adjusted by trial and *IAmp* is the stimulation amplitude. The amplitude is limited by *IMax* for safety reasons.

2.7.5 Summary of Signal Processing

One of the signal processing configurations is illustrated in Figure 2.7-12. The left column is showing different stages of the signal processing and the right column is an corresponding example of the signal. The recording electrodes are placed in a way that the stimulation response are minimized. The amplifier band pass filters the signal and suppresses stimulation responses before sampling. The comb filter removes the stimulation responses and the 50Hz periodic hum from the mains. Then the signal is transformed into a control signal for the amplitude of the stimulator, which outputs a pulse with 60ms interval. In the shown control signal, formed by RMS method the, signal to noise relation is only 5dB.

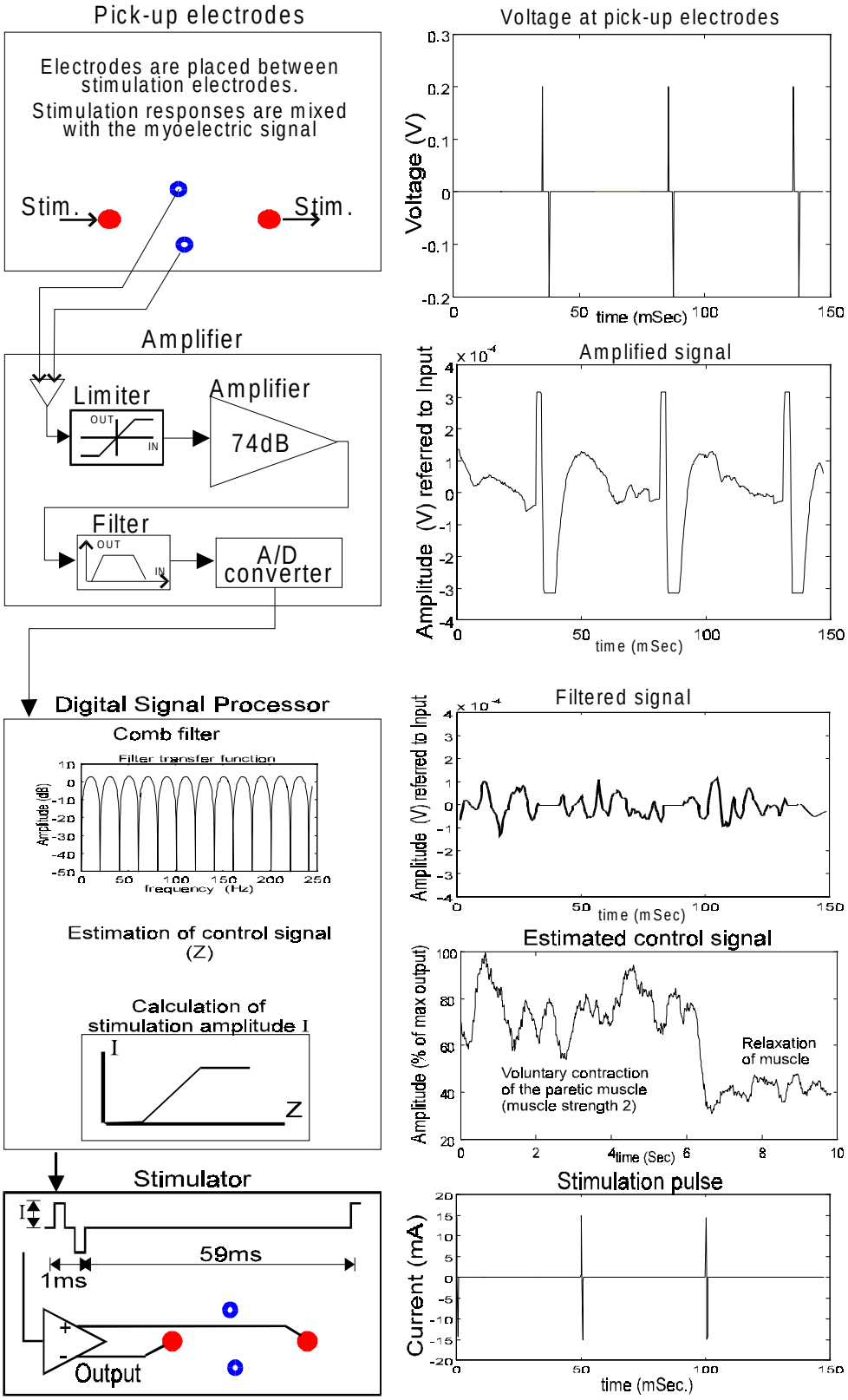


Figure 2.7-12 Signal flow

2.8 Electrode Usage

This section describes the electrodes and their use in the experiments. Furthermore a suggestion for a electrode-mount is presented.

2.8.1 Electrode Placing

The electrodes used for **recording are Ag-AgCl electrodes** with electrode paste (Blue sensor from Medicotest A/S, Denmark) and the **stimulation electrodes are siliconerubber-carbon** (from ASAH Medico A/S Denmark). Electrodes are placed as shown in Figure 2.8-1. The stimulation site is found by trial and error where the best compromise between a strong wrist extension and a minimal finger extension. The distance between the electrodes have been varying from 5 to 10 cm. The exact placing is individual and varies from person to person and must be found by trial and error. Precise **positioning** of **stimulation electrodes** is very important if a pure wrist extension is desired. Electrode displacement of more than a few millimeters can cause undesired stimulation of finger extensors.

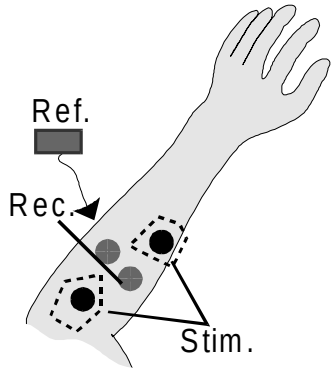


Figure 2.8-1 Electrode position

After these motor points have been found the recording electrodes are placed perpendicular to a line between the stimulation electrodes. This is a compromise between placing them in equal distance from the stimulation electrodes and being able to record the myoelectrical signal. This is also done by trial and error. In practice the **area** in which the recording electrodes can be placed **is limited** by the geometry of the arm and size of electrodes. If large stimulation artefacts occur the recording electrodes may be repositioned.

To **reapply** the electrodes an overhead transparency is used with advantage. The natural brown spots in the skin are suitable as fix-points for the transparent where both spots and electrode position is transferred to, using an overhead pen. The **active ground electrode** is

placed anywhere away from the area bounded by the other electrodes. A suitable site is at the flexor side of the arm or the elbow.

It is very important that the recording electrodes have matched impedance. Otherwise there will be a risk that common mode signals will be transformed into difference mode signals. Especially at 50 Hz, where the common mode noise is high this can cause problems. The difference signal will approximately be the difference in electrode impedance($\approx 10^4\Omega$) divided by the input impedance (>10GΩ common mode for the used amplifier) times the common mode signal as discussed in *2.5 Signal Amplification.*

The coupling from mains to the electrode wires is assumed to be negligible compared to the coupling to the body. Thus wire impedance should be included in amplifier impedance.

2.8.2 Connections

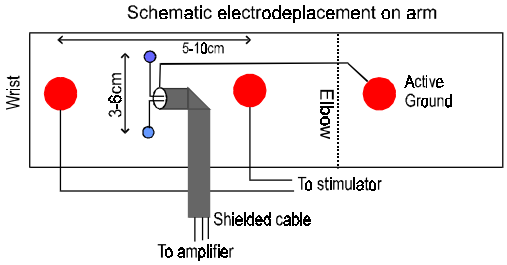


Figure 2.8-2 Schematic drawing of the electrode placement and the cabling

It is important that the recording electrodes are connected via a shielded cable to the amplifier. Any unshielded sections of the cable is twisted in order to reduce noise. The shield of the cable can be used as lead for active reference (ground). This is negative feedback of the common mode signal from the amplifier and as such not is to be connected to the actual ground or frame of the electronics. The principle in the connection is outlined in Figure 2.8-2.

2.8.3 Hand Stimulation Technique

Stimulation of the hand can be accomplished as shown in Figure 2.8-3 whereby the hand closes as a clenched fist. One electrode is placed over the pisiform bone and the other is placed on the back of the hand over the thenar space at the dorsal side of the hand. The first electrode stimulates the palmar branch of nervus ulnaris which controls the small finger flexors of the hand. The second stimulates the flexion of the thumb (Flexor pollices muscle, adductor pollices muscle etc.).

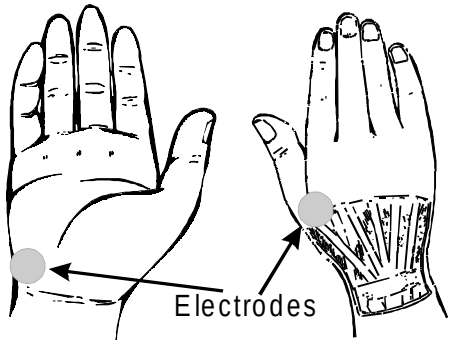


Figure 2.8-3 Hand stimulation

This electrode configuration has been evolved during the work with the functional electrical stimulation experiments. It requires that the adductor pollices and I. interossi muscles, in particular, are innervated.

2.8.4 Electrode-mount

The concept of using adhesive electrodes is not very feasible for a device which is supposed to be **used on daily basis**. It is desirable to have a device that holds the electrodes on the right position. This **electrode-mount should be easy to put on and off.** Preferably by the tetraplegics themselves. It should place the five electrodes and hold them firmly to the skin. The wires to the electrodes should be hidden in the electrode-mount and connected to the MeCFES by a single wire.

The hand stimulation results (see Chapter 4) have shown such good results that it has been decided to look for a solution that can place two stimulation electrodes on the hand as shown in Figure 2.8-3. One between the thumb and index finger on the back of the hand and one at the end of ulna on the palmar side of the hand.

The electrode-mount shall put the recording electrodes over the extensor carpi radialis and optionally also the stimulation electrodes for same muscle as in Figure 2.8-1.

The electrode-mount is intended as a splint that covers the electrode placement sites including part of the hand. This requires a linkage at the wrist. Designer Marianne Thorsen, Danmarks Designskole (Danish School of Design) has been a great help with the design of a concept for the electrode-mount. A **model** made of Aqua plast™ is **shown in Appendix D**. This material is available in plates. It can be formed at temperatures above 60 degrees Celsius. Hot water is suitable for the heating. After cooling it maintains the form.

It is composed around a straight rectangular piece, Figure 2.8-4, the back-piece that runs along ulna. At the proximal end there is a plate formed around the arm. This part contains the recording electrodes and optional stimulation electrodes. A strip that wraps around the arm just above the wrist serves for stabilization. The distal end of the back-piece is connected with a hinge to the hand part of the electrode-mount. This wraps around the middle part of the hand from the thenar space and into the palm, covering the pisiform bone. It locates an electrode at the thenar space and near the pisiform bone.

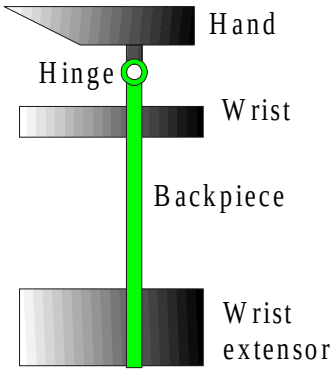


Figure 2.8-4 Components of electrode-mount

The construction has an important feature. When laying the electrode-mount on a table **it turns with the back-piece down**, due to its center of mass. In this position the arm and hand can be put into the electrode-mount since the electrode-mount is an open construction. The arm must be partly supinated. This movement can be done by a tetraplegic (subj.: KN). (See test subject description later on). The electrode-mount is lined with soft water rejecting foam to avoid wetting when the electrodes are wetted. (Electrodes has not been incorporated in the prototype, but the electrodes from first subsection has been taped in for the test).

The electrode-mount needs a closing mechanism to hold the electrodes firmly to the skin and maintains the position. One solution is to lace it up with elastic lace. A ring attached on the lace with a size so it can be caught by a paralyzed thumb (or index finger).

The ring is used to guide the lace around knobs on both side of the opening of the electrode-mount and finally used for tightening of the lace around the last knob. This requires some control of the position of the opposite hand and the ability to catch the ring. This action has not been possible for KN for which the electrode-mount was designed. It has unfortunately not been possible within the economical frame of the project to have a prototype with electrodes produced.

A design student (Birgitte Bennike, Danmarks Designskole) has designed a electrode-mount with a more attractive cosmetic design. This is supposed to be produced in a stronger type of plastic. **Photos of the model can be seen in Appendix D**. The outline for the box containing the MeCFES is included as well.

2.8.5 Electrode Embodiment

A suggestion for electrode incorporation in the electrode-mount is as follows (Figure 2.8-3). Each electrode is placed between the lining and the electrode-mount shell. For this long term use of the electrodes it is important, besides the properties discussed in *1.12 Electrodes* that the electrode material is bio-compatible, chemically and mechanically stable (e.g. corrosion could lead to decreased performance). There must be a hole (Ø5mm recording and Ø20mm stimulation) in the lining over the electrode. The electrode can be covered by a water absorbing material being in between the skin and the electrode. The water serves as a conductor (electrolytic carrier) between the electrode and the skin. Tests have shown that shammy is good for that purpose. I has a long dry-up time and is a good skin interface.

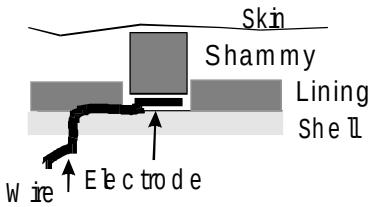


Figure 2.8-5 Electrode build in

The material should perform a spring-like pressure on the skin and provide good contact. If the lining is not waterproof, the material should be surrounded by a rubber ring (gasket) to impede drying up and preventing the lining from getting wet.

3. Hardware and Software

This chapter describes the **hardware and software developed** and the **test set-up**

The keywords for the design of the electronic parts of the system besides functionality, are minimum size, weight and a low power consumption. Power consumption is closely connected to the size and weight since it determines volume of batteries which are among the heavy and space consuming parts. To minimize the size it has been attempted to use few components and choose the most power efficient techniques as possible. The availability of low price components limits the design possibilities.

Through several test circuits and three prototypes, the system has been evolving to comprise an amplifier, stimulator, digital signal processor (**DSP**), power supply/battery manager including rechargeable batteries and wires for electrodes. This system is called **MeCFES (Myoelectrical Controlled Functional Electrical Stimulator)**. There are four different printed circuit boards which are the amplifier-, the stimulator-, the digital signal processing (DSP)- and the power supply- board. Especially for the DSP system, state of the art devices has been used causing some problems with faulty devices and supplier problems. Developing, manufacturing and testing the hardware and software has been occupying more than 2/3 of the project period leaving only half a year for systematic trials with tetraplegics. Sections *3.1* through *3.5* are describing the **MeCFES hardware**. Section *3.6* describes the **method and set-up** for the evaluating the performance of the MeCFES. The **software** developed for the system is described in section *3.7* and *3.8.* It consists of a **DSP program** for the MeCFES and a **host program** for occasional communication with the DSP. Only a brief description is provided for this comprehensive work to preserve proprietary rights. Finally section *3.9* is a **summary of the MeCFES specifications**.

3.1 Interface

Tetraplegics have very limited possibilities to turn knobs and push buttons to operate the MeCFES. To comply with this, it has been decided that the device shall have **only one push-button**, by which the user can operate the MeCFES. To inform the user of

changes in the states of the device a **sound transducer** is used. Figure 3.1-1 shows the on/off procedure using the button.

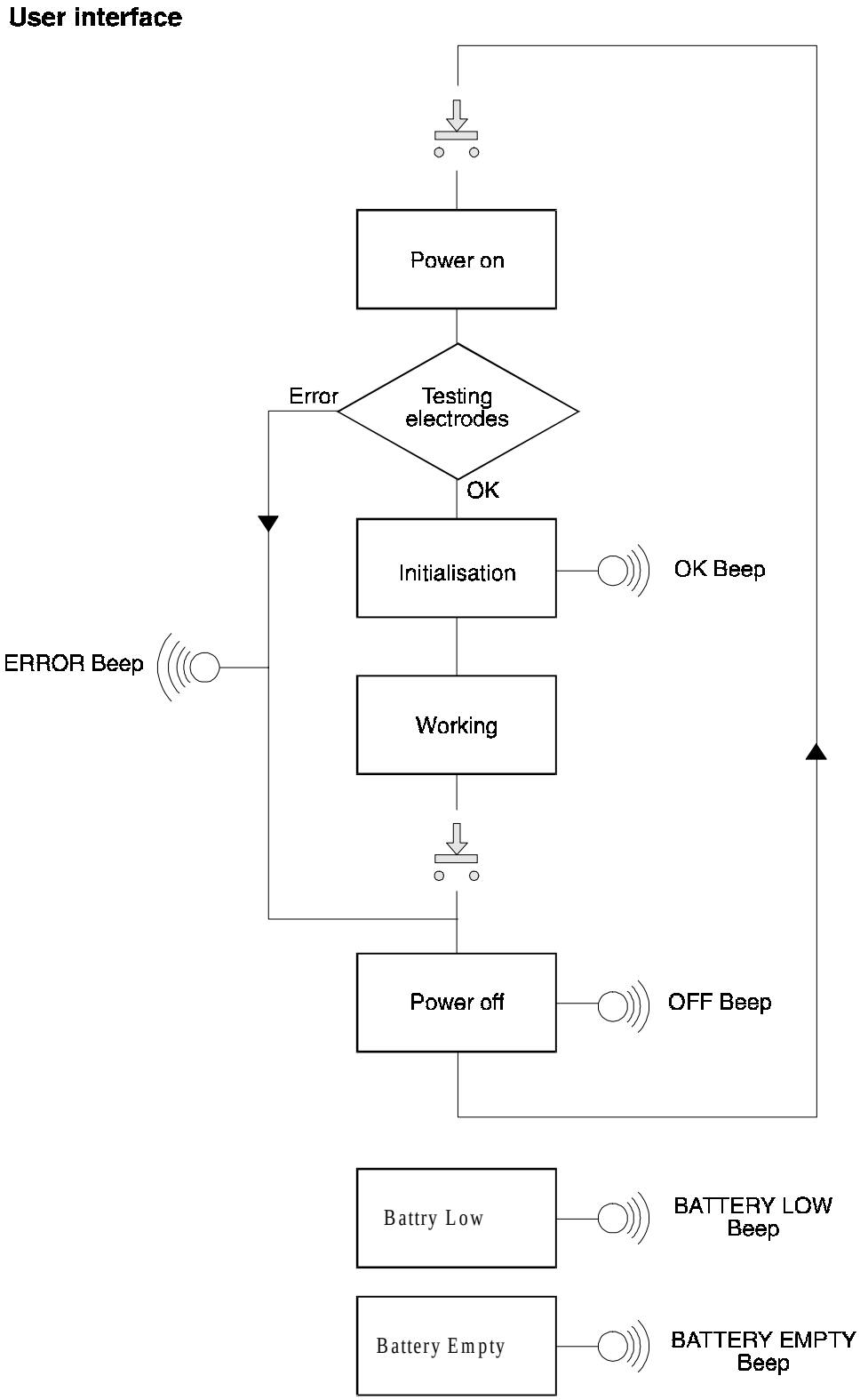


Figure 3.1-1 Start-up procedure

Sound signals with different characteristics informs the user as listed in Table 3.1-1.

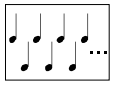
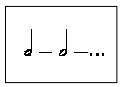
	Single tone	The device is turning on and initializing
	Rising scale of tones	The device goes ready and operating
	Descending scale of tones	The device is shutting down
	Two alternating tones repeating	An error has occurred. Turn off the device. Try again, recharge batteries or call service.
	Repeated buzz	Battery low. Shut off the system and recharge batteries.

Table 3.1-1 Sound signals

This restricted user interface implies that no adjustments of parameters can be done. These adjustments must be done initially with a connected host computer as described later. The demands for stimulation intensity and myoelectrical sensitivity might change from time to time. For that reason the program has been prepared for implementation of an automatic calibration procedure. This should be executed during the initialization phase after power up of the device. A suggestion for the auto calibration procedure is follows.

After the button is pressed, system powers up and starts a self-test. If the test is passed, an initialization mode is entered and the user is informed by a sound signal whereupon the stimulation increases slowly (limited by a pre-set maximum value). The user observes when the maximum contraction is achieved and confirms by pressing the button and the stimulation stops. This procedure will set the stimulation gain and the MeCFES will confirm this by a sound signal.

There is an option of connecting a host computer (BM PC) to the MeCFES. This requires a special cable from the parallel port of the host computer to the MeCFES. Communication with the MeCFES is then possible using the developed host computer software. After the manufacturing of the MeCFES the DSP program has to be downloaded to the device from a host computer. The program is then stored in the FLASH memory

(an erasable non volatile integrated memory circuit) of the MeCFES. Once programmed, the system will not need the host connection to operate.

The host interfacing option gives access to the following actions:

- Future upgrading of the signal processing software in the FLASH memory
- Changing reading data in the RAM (random access memory used for variable data)
- Changing user specific parameters
- Exchanging signals, values and parameters for research
- Controlling performance and testing of sub-circuits
- Setting/reading serial numbers, user ID and other information
- Getting an activity logbook of the systems use

3.2 Amplifier Circuit

As described in *2.5 Signal Amplification* the amplifier is the most important link in the signal processing. The developed amplifier is patent pending and a complete schematic can be found in Appendix B. The special property of the amplifier is that **high-pass filtering** is achieved using a non-linear feedback loop.

3.2.1 Amplifier Principle

Figure 3.2-1 is a model showing the principles of the amplifier. The electrodes, denoted by (1), pick up the signal. Each of the electrode signals are limited (2) to reduce stimulation artefacts and to protect the pre-amplification circuit (3). The pre-amplifier (3) has a difference gain of A_1 and transforms the high impedance difference signal into a low impedance signal. The pre-amplifier output (3) is added (4) with the negative output (12) from the feed-back network which provides an estimate of the DC-offset at the pre amplifier output (3). The offset regulated signal from the addition (4) is fed to a post-amplifier (5) with gain A_2.

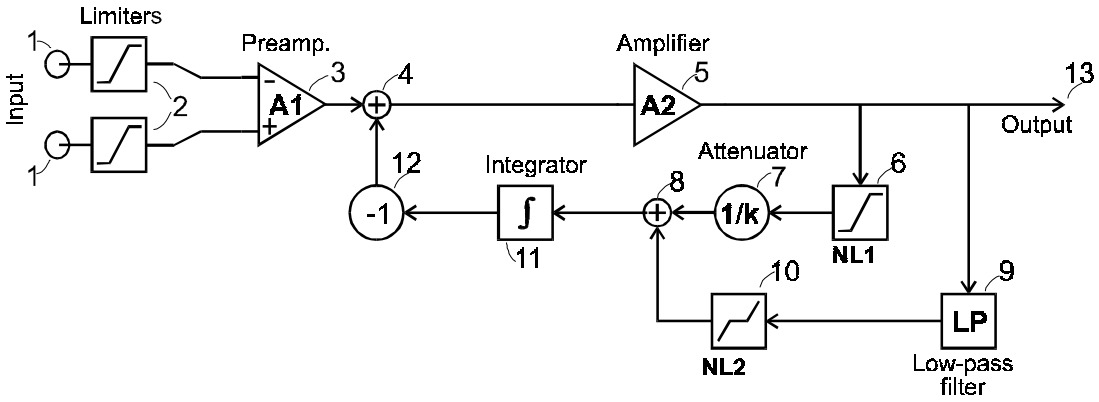


Figure 3.2-1 Principle of the amplifier

The feedback network is divided in two parallel paths to accommodate different behavior to small signal as to large signal offsets.

High-pass Filter:

Small signal feedback (6-7-8-11-12-4) realizes the high-pass filter. The output from the post-amplifier (5) is limited by a non-linear function *NL1* (6). *NL1* has the input output relation illustrated in Figure 3.2-2. Clipping the signal in *NL1* reduces the influence of impulses in the subsequent circuit. After clipping (6) the signal is attenuated (7) by a factor *k*, where *k* is determined by the amplification A_2 and the desired overall high-pass cut off frequency. (see subsection *3.2.2 Realization* for details). Hence the signal is integrated (11) and phase shifted π (12). (The integrator (11) is a linear element and the processing of the signals from the added (8) outputs form the attenuation (7) and the non-linear function *NL2* (10) does not influence on each other). This part of the signal path provides linear high-pass filtering of small signals.

DC-offset Compensation:

Large signal feedback (9-10-8-11-12-4) provides the offset compensation. The output from the post amplifier (5) is low-pass filtered (9). The cut off frequency of the filter (9) determines the overall recovery time for the MeCFES amplifier. The filtered signal is fed to a non-linear function *NL2* (10). The *NL2* has the I-O relation illustrated in Figure 3.2-2. Only if the absolute value of the input of *NL2* exceeds a threshold the output of *NL2* is non-zero. In this case the signal will run through the adder (8) to the integrator (11) and thus fast establish the offset compensation. It is this part of the circuit that provides the fast recovery time of the entire circuit.

Thresholds for *NL1* (6) and *NL2* (10) should be equal with characteristics as shown in Figure 3.2-2.

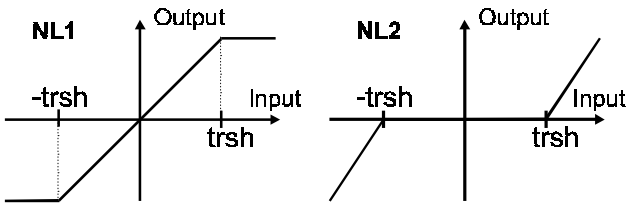


Figure 3.2-2 Non-linear functions

3.2.2 Realization

The embodiment of the amplifier is shown in the simplified schematic Figure 3.2-1 with the main component values. It is designed as a ±3V system with a total gain of **74dB** and a small signal high-pass filter cut off frequency at 8Hz. DC-offset compensation is starting after 50ms (significantly longer than the expected muscle response). At the output there is a second order low-pass Bessel filter (not shown) with a cut off frequency of 500Hz.

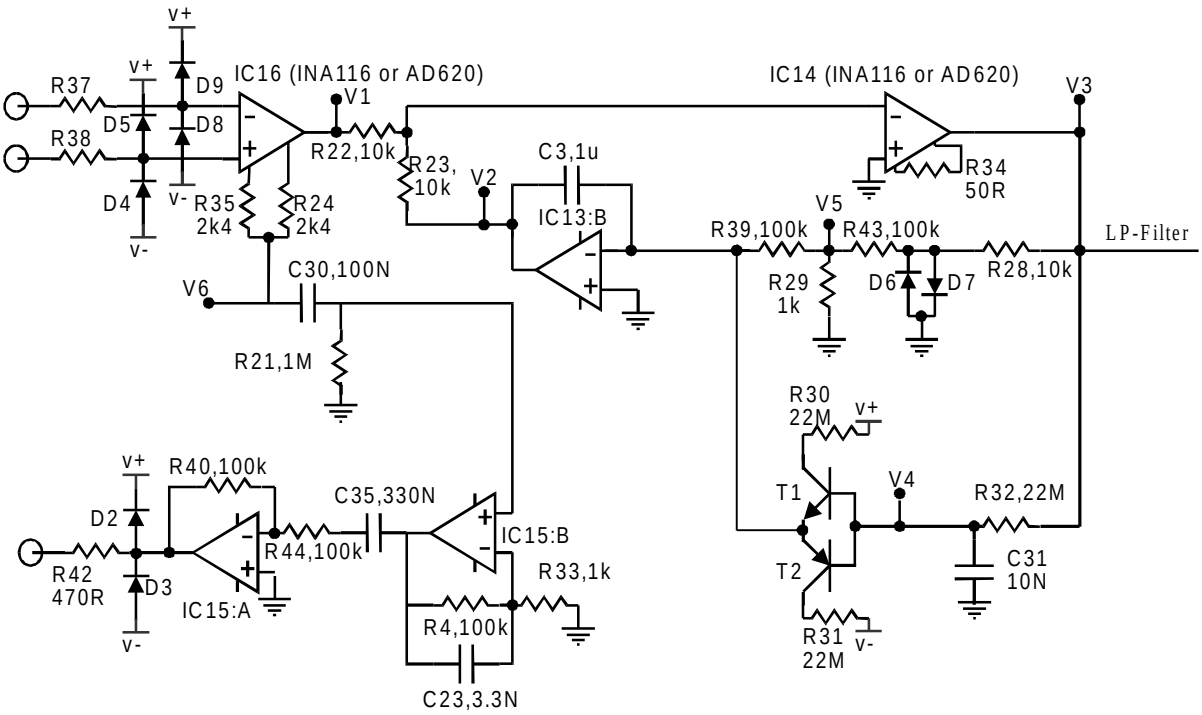


Figure 3.2-3 Simplified schematic of the MeCFES Amplifier

The signal from the electrodes is clamped between the power supplied through a resistor-diode network to protect the instrumentation amplifier *IC16*. This device is one of

the critical parts since it determines the **common-mode rejection ratio** and the **input impedance of the MeCFES amplifier**. The output of *IC16* is divided by 2 by the identical resistors R_{22} and R_{23}. Operational amplifier *IC13B* 'mirrors' the DC offset at the output of *IC16*.

The ***IC16* is selected to have a gain of 20dB**. This allows a differential offset of the electrode potentials of up to 0.3V without saturation of the amplifier. The stimulation artefacts are saturating both *IC16* and *IC14* which for the same reason are chosen be fast recovery circuits (<10µs). The **gain in *IC14* is selected to 60dB** to obtain a total signal gain of 74dB.

DC-offset Compensation

To find the time constant $R_{32}C_{31}$ of the low-pass filter (*LP*) it is assumed that the transistors are switches that are open below the $V_{be,on}$ voltage of about ±0.6V. If a DC-offset saturates the amplifier, V_3 will be clamped to ±3V, and the voltage at V_4 will change accordingly to the formula

$$V_4 = V_3(1 - \exp(-t / R_{32}C_{31})) \qquad \textbf{Eq.3.2-1}$$

Setting V_4 to the 0.6V $V_{be,on}$ voltage then, with the time of 50ms, Eq 3.2-1 yields a time constant of 220ms.The transistors realizes the non-linear function (*NL2*). It is assumed that the basis current in the transistors can be neglected. When the transistors are active they feed current into the capacitor C_{34}. Saturation[1] of *IC14* (post amplifier) calls for at least 3V/500=6mV compensation at V_2. When the transistor is on, a current of $3V/R_{30}$ flows into C_3, giving a change in V_2: of

$$\Delta V_2 = \frac{V_3}{R_{30}C_3}t \qquad \textbf{Eq. 3.2-2}$$

where it is desired to have a recovery time t=50ms. The values of R_{30} (=R_{31}) can calculated using Eq. 3.2-2 and should not be greater than R_{32}. With C_3=1µF the result will be R_{30}≈25MΩ. Because of the non-linearity of this circuit there is a potential danger of instability but, with the chosen components, it has proven to be stable.

[1] R_{22} and R_{23} bisects the signal. Thus the gain is divided by 2

High-pass Filter:

The diodes (*NL1*) D_6 and D_7 clamps the input of the linear filter to the range ±0.6V. This minimizes the effects of transients from stimulation responses. Resistor network (attenuator), R_{39}, R_{43} and R_{29}, attenuates the signal. The transfer function of the entire high-pass filter is derived using the following three equations, derived from the circuit in Figure 3.2-3:

$$V_3 = G_{IC14}(V_1 - V_2)/2 \qquad \textbf{Eq. 3.2-3}$$

$$V_2 = V_5 \big/ sC_3R_{39} \qquad \textbf{Eq. 3.2-4}$$

$$V_5 = V_3/K \quad , \quad K = (R_{43}+R_{28})(1/R_{29}+1/R_{39})+1 \qquad \textbf{Eq. 3.2-5}$$

Here G_{IC14} is the gain of *IC14* (1000 times). Combining Eq. 3.2-3, Eq. 3.2-4 and Eq. 3.2-5 yields the transfer function for the post-amplifier stage.

$$H(s) = \frac{V_3}{V_1} = \frac{s(KC_3R_{39})}{1 + s \cdot 2KC_3R_{39}/G_{IC14}} \qquad \textbf{Eq. 3.2-6}$$

Multiplying this with the gain of the pre-amplifier (which is 10 times) yields the small-signal transfer function of the two first stages of the MeCFES amplifier circuit in Figure 3.2-3.

3.2.3 Common-mode Feedback

The common-mode signal is provided by *IC16*. It is amplified 40 dB and band-pass filtered from 5Hz to 500Hz. This suppresses the harmonics of the hum in the bandwith of the amplifier. The output from *IC16* has an offset that is removed by R_{21} and C_{30} before amplification.

3.2.4 Low-pass Filter

The amplifier is ended with a low-pass filter to comply with the Nyquist criterion before sampling. A simple RC high-pass filter is applied before the low-pass filter to remove offsets. The 2nd order low-pass filter is configured as a multiple feedback Sallen-Key filter, using a single operational amplifier (Figure 3.2-4). The transfer function for the filter can be found to

$$H(s) = \frac{Output}{Input} = -\frac{R_{26}}{R_{25}} \frac{(R_{26}R_{27}C_{32}C_{33})^{-1}}{s^2 + s(R_{25}^{-1} + R_{26}^{-1} + R_{27}^{-1})C_{33}^{-1} + (R_{26}R_{27}C_{32}C_{33})^{-1}} \quad \textbf{Eq. 3.2-7}$$

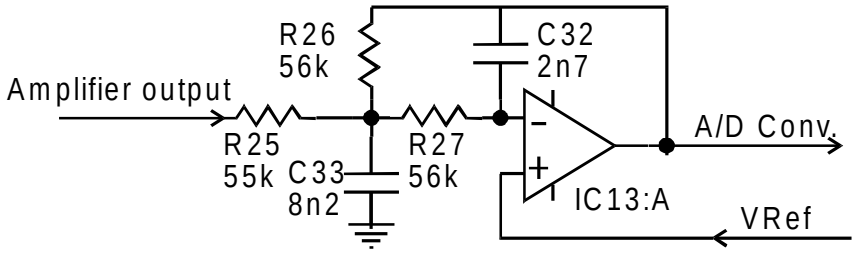


Figure 3.2-4 Low-pass filter

Bessel filter type is selected and the gain is chosen to unity The denominator for the second order transfer function must be of the form s^2+3s+3 [Jensen 1987] By normalizing s with respect to the 3db cut off frequency being unity, the transfer function for the Bessel filter becomes

$$H(s) = -A\frac{b/\omega_0^2}{(s/\omega_0)^2 + a\,s/\omega_0 + b} \quad , \quad where \quad a = 2.20320 \quad b = 1.61803 \quad \textbf{Eq. 3.2-8}$$

From Eq.3.2-7 the gain A can be found to be equal to

$$A = \frac{R_{26}}{R_{25}}. \quad \textbf{Eq.3.2-9}$$

Comparing Eq. 3.2-8 and Eq.3.2-9 the capacitors can be calculated

$$C_{33} = \frac{R_{25}^{-1} + R_{26}^{-1} + R_{27}^{-1}}{2\pi f_0 a} \quad \textbf{Eq .3.2-10}$$

$$C_{32} = ((2\pi f_0)^2 b \cdot C_{33} \cdot R_{26} \cdot R_{27})^{-1} \quad \textbf{Eq .3.2-11}$$

Setting $R_{25} \approx R_{26}$, the gain becomes one and to obtain a cut-off frequency f_0 close to 500Hz, selecting C_{33}=8.2nF, C_{32}=2.7nF (type 1% np0 SMD), the resistors can be calculated to:R_{27}=56kΩ (1%), R_{25}=55kΩ (1%), R_{26}=56kΩ (1%)

The realization of the Bessel filter is sensitive to the component values. The single operational amplifier configuration has been selected to minimize the number of required components.

3.3 Digital Signal Processor Unit

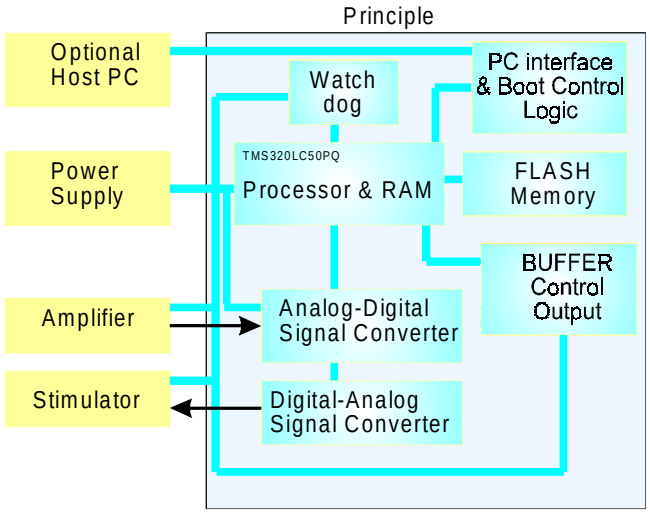


Figure 3.3-1 DSP board

The digital signal processor unit (**DSP**) is the core of the system and is outlined in Figure 3.3-1. Special attention has been paid to power consumption and size. Schematic of the digital signal processor board can be found in Appendix B. The central unit is the TMS320LC50 signal processor from Texas Instruments. It was in 1995 the commercial **available processor with least power consumption** with respect to calculation capabilities[1] (Figure 3.3-2). It contains 10kWords on chip RAM that can be used for both data and program memory, has sufficient calculation capacity and is available in small quantities. The processor takes care of data communication with A/D (analogue-digital) and D/A (digital-analogue) converters as well as miscellaneous controls of the subsystems (amplifier, stimulator and power supply).

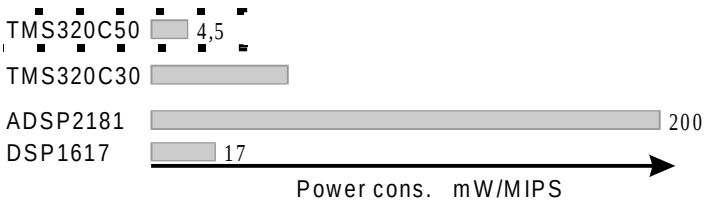


Figure 3.3-2 Power consumption of common DSP's

[1] The TMS320LC50 is declared obsolete in 1997 (Maybe because of hardware errors). A compatible successor is expected.

The DSP board is equipped with an AT29LV1024 FLASH memory from Atmel. This device has 64k*16bit non-volatile memory. It is used for storage of the program, parameters and miscellaneous information. It can be programmed in sectors of 128 words. The lifetime is more than 1000 write cycles in each sector and a data retention time of more than ten years. The advantage is that it can be **programmed 'on board'** without the need for a programming voltage other than the 3.3V power supply. The power consumption is low (5mA @ 1MHz) compared to other ROM (read-only memory) circuits. The FLASH is connected to the program data bus of the TMS320 so the **program can be run directly**. Special commands in the TMS320 provides access to both **reading and writing of the FLASH**.

Since the FLASH will contain no information after assembly of the DSP, it must be programmed. For this purpose the board has been equipped with a **boot-load** control logic. It controls the mode in which the TMS320 will start in after reset (power up). In **stand-alone** mode the program execution will begin from the FLASH. In boot-load mode it will execute the Texas build in boot load program[1] to start reading from the serial port[2]. Thus a communication program can be transmitted from the host computer to the program RAM of the TMS320, using four wire serial communication. Afterwards the entire program can be transferred via the TMS320 to the FLASH. This start up mode is determined by the host computer. If no host computer is connected the stand alone mode is automatically selected.

The choice of converters was at the time of system design very limited by the low-power 3.3V constraint with serial interface. **The A/D converter** is the TLV1543C from Texas Instruments with **10 bit resolution** and 11 channels. This samples the myoelectric signal, battery level, stimulation voltages etc.

For **D/A conversion** the only available device fulfilling the demands was the LTC1452 from Linear Technology. It is a **12bit converter** with one channel output. It generates the analogue stimulation signal. The output is besides the stimulator also fed to the A/D

[1] Note that the TMS320C50 User's Guide is erroneous in the description of the bootmode selection.

[2] The processor has a hardware bug in the serial port 1. The opreation after booting is not according to the manual.

converter for self-testing purpose. For safety reasons to prevent erroneous function a **watch dog** has been implemented. If a control signal line is not toggled within 50ms power to the entire system will be shut off. This and other controls are interfaced by the 6 line output buffer. If the system thus executed invalid code the watch dog will turn the system off to **protect the user** against uncontrolled stimulation. (An example of such a situation can be if the program is changed due to external noise)

It will be outside the scope of this report to give an extensive description of the DSP board but a few remarks are made. The figures are subsections of the full DSP schematic in Appendix B.

The host computer interface is shown in Figure 3.3-3. All signals are **ESD protected** by the *D1* and buffered by the *IC9*. The clock *PClk*, frame synchronization *PFS* and transmit data *PX* are outputs from the computer and the data receive is the input to the computer. The receive signal is buffered by a transistor to match a 5V low impedance input of the parallel port of the host computer. The actual operation of the serial ports of the TMS320, after reset, is not in agreement with the description in the user's guide Resistors R_{151} and R_{150} in the DSP circuit compensates for this.

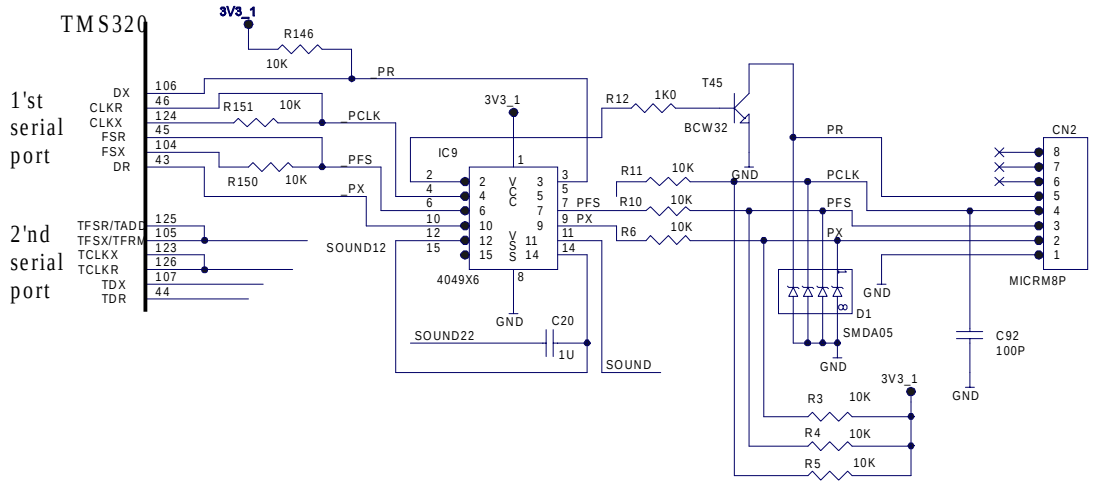


Figure 3.3-3 Host computer interface subcircuit

Since the **2'nd serial port**, connecting to the A/D and D/A converters, can be configured before it is enabled the receive (*TFSR* and *TCLKR*) can be connected directly to the transmit (*TFSX* and *TCLKX*) of the frame sync and clock signals.

The serial port is not directly compatible with the converters, why the interfacing counter (pleas refer to Appendix B, *IC31*) and gates are necessary to generate the chip enable signals for the converters, using the frame sync and clock signals from the 2'nd serial port.

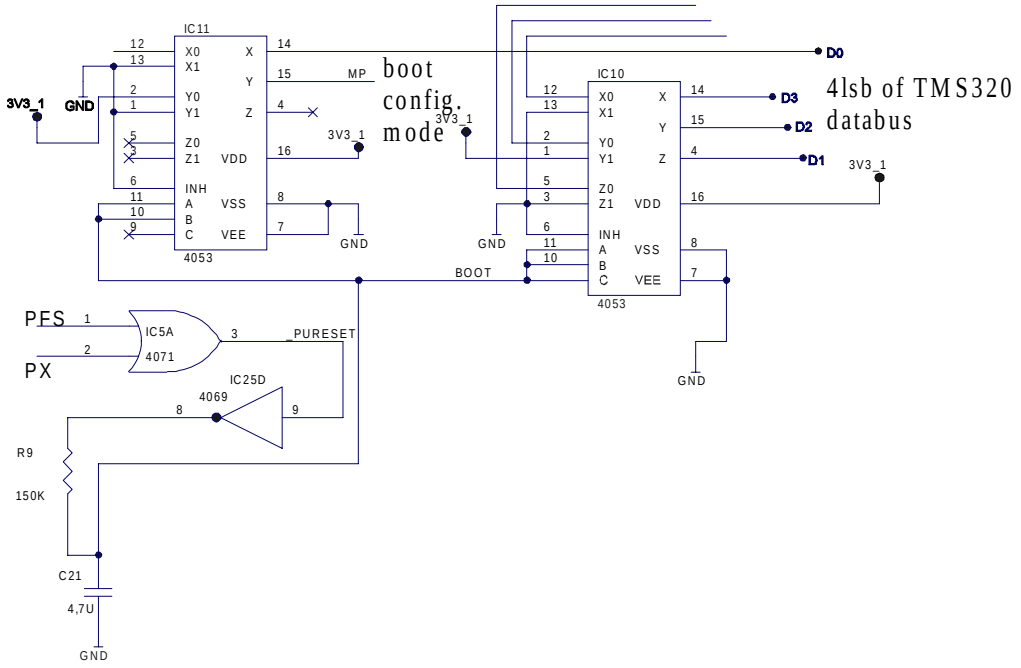


Figure 3.3-4 Boot control subcircuit

The system is reset when both *PFS* and *PX* are low (Figure 3.3-4). The duration of the low pulse determines whether stand-alone mode or boot-load mode is initiated. A long pulse will charge C_{21} and thus setting the *boot* signal. This signal is used for the input of *IC11* and *IC10* that will put the '16 bit serial boot-load mode command' (binary xxxx xxxx xxxx 0100) pattern on the data bus and set the *MP* low (starting the on-chip factory programmed boot loader). As the last thing it shall be mentioned that patches has been made to enable the on off button to interface the signal processor and at the same time be able to turn the system on/off. These are not in full agreement with the schematic.

3.4 Stimulator circuits

Two different stimulator concepts (**Type 1 and Type 2**) have been designed based on a high voltage supplied transistor output stage. A third stimulator concept **(Type 3)** based on the transformer output has been developed and produced. The aim is to create the most ideal current generator according to the discussion in *2.3 Stimulator Principle*, with a very low quiescent power consumption, optimal efficiency and the desired pulse form.

The concept of Type 1 and Type 2 provides the opportunity to improve efficiency and size of the stimulator. The advantages of avoiding connection, to the stimulation electrodes, through a transformer is described in *2.3 Stimulator Principles*.

The specifications set for the stimulators are:

- Input control signal V_i in the range ±3V
- A biphasic pulse form of duration <1ms
- Output current controlled by:$I_o=V_i$*20mA/V
- $|V_{out}|$<0.1V between stimulation (50ms).

3.4.1 Stimulator Type 1 Design

The following describes the design of the Type 1 stimulator. The full schematic is in Appendix B. The following calculations applies to Figure 3.4-3.

There are **four identical current generators** configured as in the illustrative model Figure 3.4-1. The current generators are **active in pairs**. The a positive control signal controls generator number 1 and 3 while number 2 and 4 are off. In the negative stimulation period number 1 and 3 are off while 2 and 4 are on. (If the current in the generators is not identical, the result will be the fault current in the recording electrodes as described in *2.4.7 Stimulation Response*).

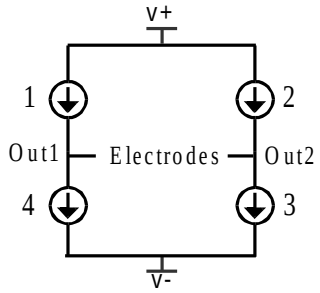


Figure 3.4-1 Illustrative model of stimulator configuration

Each current generator is realized as outlined as in Figure 3.4-2 where a voltage controlled current generator (VCCG) is determining the current in the resistor R_{49}. If the transistors are identical then the basis emitter voltage must be identical and thereby the voltage over R_{51} must equal the voltage over R_{49}. This yield a current gain when idealizing the transistors

$$I_{out} \approx I_{R51} \approx I_{R49} \frac{R_{49}}{R_{51}}$$ Eq. 3.4-1

To obtain a high efficiency the resistor R_{51} should be much lesser than the electrode impedance and the ratio of R_{49}:R_{51} should be high to minimize the power loss in R_{49}. The value chosen for resistor R_{51} is 100ω and the current gain is selected to 10.

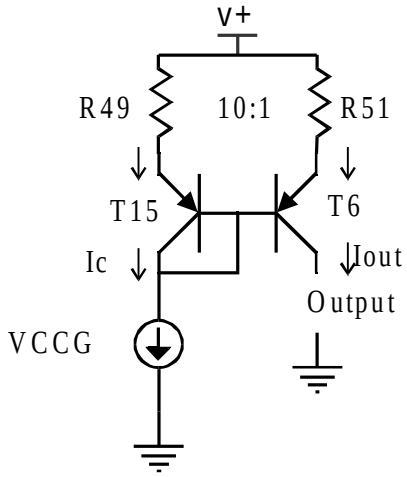


Figure 3.4-2 Current amplification

Since high voltage transistors must be used (which are not ideal and usually have a low gain), it is of interest to include the gain (β) and the basis emitter voltage $V_{be,on}$ in the calculations. Let ΔV_{be} be the difference in the basis-emitter voltage, V_{be}, for the two transistors. The current output of the transistors are given by

$$I_o = I_{R51}(1+1/\beta_{T15}) \qquad \text{Eq. 3.4-2}$$

$$I_c = I_{R49}(1+1/\beta_{T6}) \qquad \text{Eq. 3.4-3}$$

The difference basis-emitter voltage difference provides the currents in the resistors

$$\Delta V_{be} = I_{R49}R_{49} - I_{R51}R_{51} \qquad \text{Eq. 3.4-4}$$

Combining these equations yields

$$I_o = I_c \frac{1+1/\beta_{T6}}{1+1/\beta_{T15}} \frac{R_{49}}{R_{51}} + \frac{\Delta V_{be}}{R_{51}} \qquad \text{Eq. 3.4-5}$$

From this it appears that the output current is sensitive to ΔV_{be} and difference in β for the transistors. To minimize the consequence of a ΔV_{be} the resistor R_{51} must not be too small. Typical (50-200) variations in β can give rise to an error on the current gain of some percent. For the selected transistor type the V_{be} can vary 0.1V in worst case and thus give rise to significant offset approaching a milliampere if R_{51}=100Ω.

Figure 3.4-3 shows a section of the schematic including generator 1 and 4.

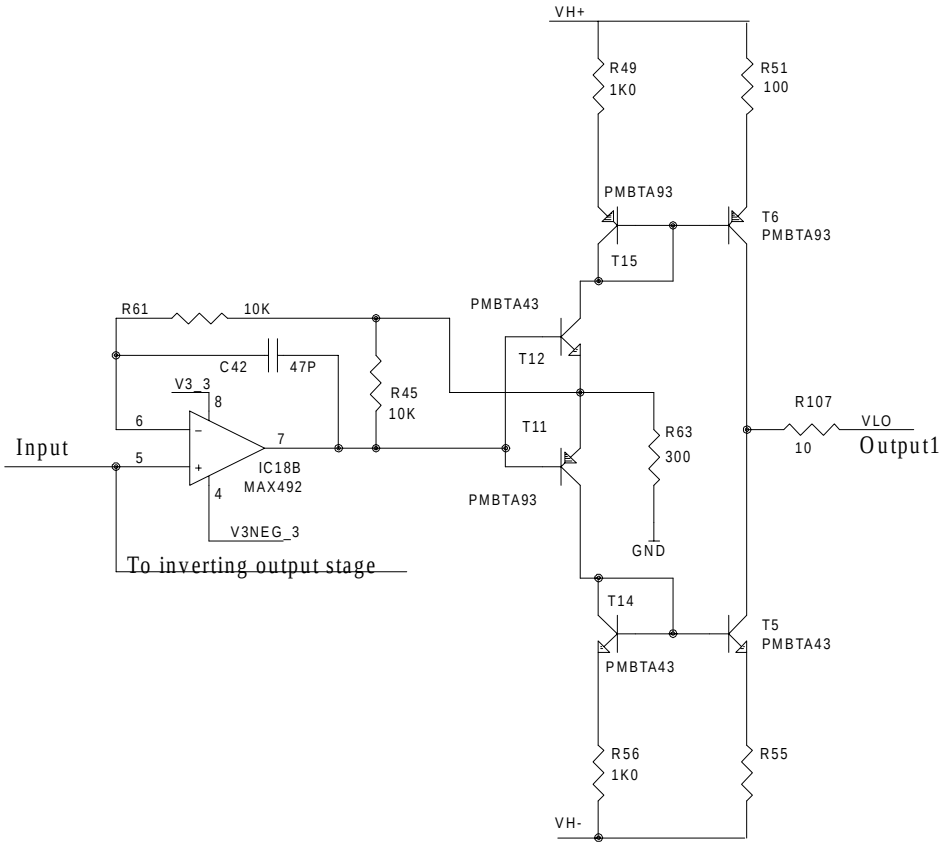


Figure 3.4-3 Section of schematic

The VCCG in Figure 3.4-2 is realized by the transistor T_{12} (and in the negative pulse period T_{11}) and operational amplifier IC_{18B} which controls the current in the resistor R_{63}. This current will (when neglecting the basis current in T_{12}) be supplied by the transistor T_6. The coupling of this transistor results in a 'shut down' feature. When the input to the stimulator is near zero (the 10 bit D/A converter will have a certain noise level at the output of at least±5mV) the current generators will effectively be shut off leaving the stimulator output in a current-less high impedance state. The stimulator will thus be 'silent' and not disturb myoelectrical signal recording and the power consumption will be reduced to the quiescent power consumption of the operational amplifiers.

This on/off threshold is determined by

$$V_{input,threshol} = V_{be,on}\frac{R_{63}}{R_{45}} \qquad \text{Eq. 3.4-6}$$

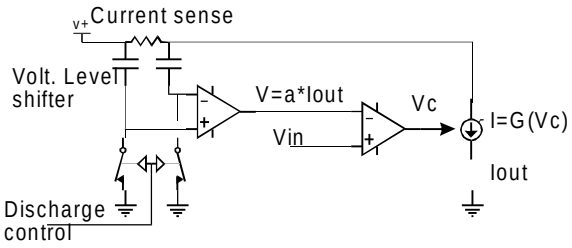
where $V_{\text{be,on}}$ of T_{12} can be set to 0.6V and $V_{input,threshol}$ is the input to the stimulator. In summary the transfer function for the stimulator is

$$I_o = \begin{cases} 0 & \text{for } |V_{\text{input}}| < V_{\text{be,on}} \dfrac{R_{63}}{R_{45}} \\ \dfrac{R_{49}}{R_{54}} \left(\dfrac{V_{\text{input}}}{R_{63}} - \dfrac{V_{\text{be,on}}}{R_{45}} \right) & \text{for } |V_{\text{input}}| > V_{\text{be,on}} \dfrac{R_{63}}{R_{45}} \end{cases}$$

Eq. 3.4-7

3.4.2 Stimulator Type 2 Design

It was found that the stimulator Type 1 is sensitive to the matching of the transistors. In order to improve the performance of the stimulator design an approach to use a different technique is attempted. This circuit (Figure 3.4-4) makes use of a current sensor that feeds back to the control sub circuits. This makes a closed loop control of the output current. This should in theory give very accurate balanced stimulation output. A full schematic can be found in Appendix B.



x2

Figure 3.4-4 Principal function of Type 2

The concept is build up upon the idea of letting the high level voltage across the current sensing resistor be transformed down to a level of ±3V using capacitors (see Figure 3.4-4). Then an instrumentation amplifier amplifies this differential signal, representing the current flowing into the electrode (when using FET transistors in the output). The capacitors low side must have equal voltage before the stimulation pulse starts. This voltage must not exceed the active region of the instrumentation amplifier input. This is ensured by switches. The output is switched between the two electrodes depending on the phase of the stimulation pulse. A matching circuit is providing the negative counterpart to the in Figure 3.4-5 shown circuit.

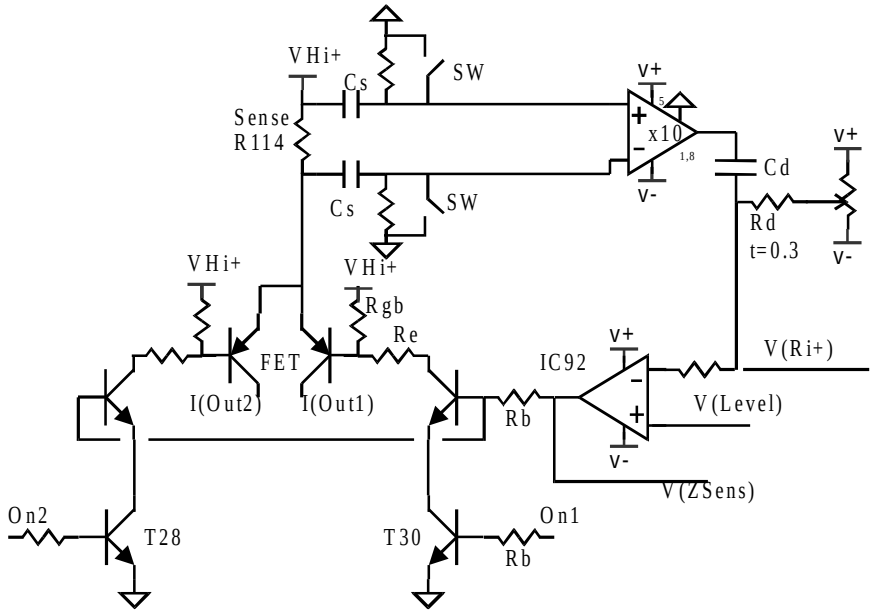


Figure 3.4-5 Principle of stimulator Type 2

The switching between the diodes are demanding two logical signals On_2 and On_1 controlling the phase (see Figure 3.4-5). Stimulation form/amplitude is send to the positive part of the circuit V_{level}. This is inverted as the actual current in the positive part V_{Ri+} and fed to the negative stimulator part as the control signal. This ensures that the current in the negative output mirrors the positive output current. The following calculations refers to Figure 3.4-5.

Desired precision of I_{Out1} and I_{Out2} is determined by the precision of the sensing resistors. The voltage drop over the resistor is chosen to 0.5V at 50mA, i.e. R_{114}=10Ω.

The high voltage is stored in capacitors in the power supply. Selecting a 0.5V margin to the ±3V rated input of the instrumentation amplifier the allowable voltage drop of V_{hi} is 2V over 2*300µs. (the selected type of integrated circuits INA118 or AD620 are internally protected at the inputs to ±40V)

The impedance for the instrumentation amplifier is 10^{10}Ω which can be neglected. The leakage current is 10nA. This implies a possible DC offset error on V_{Ri} of ±30mV corresponding to an error in the stimulation current balance of 3%. This is removed by a high-pass filter. The resistor R_e is limiting the current output from *IC92* when V_{Hi} is low. The resistor R_{cb} is removing charge from the gate. Transistors T_{28} and T_{30} are enabling the outputs and selecting which of the two electrodes the output current is applied to.

3.4.3 Stimulator Type 3 Design

The Type 3 stimulator is made by Miguel Hermann at Asah Medico A/S and the schematic can be found in Appendix B. The circuit is controlling the current in the primary side of an 1:20 transformer. It needs 9V battery supply. It is thus assumed that the transformer is ideal and that the current in the secondary side is proportional to the current in the primary side. This stimulator needs a modified power supply.

3.5 Power Supply Unit

The power supply circuit can be found in Appendix B and the functions is illustrated in Figure 3.5-1. The power supply part of the system is taking care of

- Charging of the battery
- Generating ±3V for the analogue circuits
- Generating 3.3V for the digital circuits
- Generating 0-±75V for the stimulator circuit, using switch mode power supply technique.
- Starting/stopping the system

It comprises the push button control, the sound source and a watchdog. The power will be shut down if the unit does not receive a signal for the watchdog .

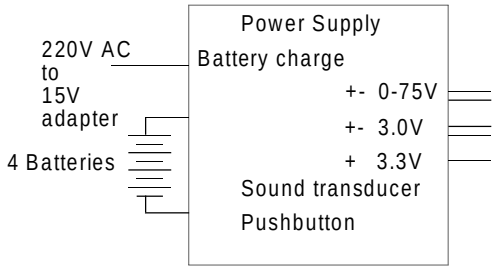


Figure 3.5-1 The power supply unit

The high voltage is generated by a switch-mode fly back converter. The DSP can control the voltage level by turning the converter on/off. To protect the circuit components, a feedback loop in the converter ensures that the voltage does not exceed ±75V.

3.6 Evaluation Method

The first step in evaluation of the MeCFES performance is the enhancement of the muscle force and wrist movement. This is evaluated by the **tracking test** (used by Haxthausen [Haxthausen, et al. 1991]). The next step is evaluation of the functional benefits of that enhancement. This is done by a hand function test has been developed by the occupational therapists at the Center for Spinal Cord Injury, Copenhagen University Hospital, Rigshospitalet, Denmark. The hand function test has been conducted by an occupational therapist. It is described along the conclusion of the results in 4.6 Functional Evaluation.

3.6.1 Tracking Test Description

The tracking test is recording **isometric wrist force** or the **wrist extension angle against gravity** with the purpose of being an objective repeatable test of the MeCFES. The test is modified and extended by an endurance measurement. The evaluation thus comprises three types of tests: A **force** tracking test, an **angle** tracking test and an **endurance** tracking test. All measurements are using the same set-up which is described last in this section. In addition to the tracking test where the test participant is controlling the stimulation, the set-up is used for recording of recruitment curves (the current-muscle output).

In the tracking test, a target, a course of desired muscle output is displayed on a computer screen. The subject being tested is supposed to track this target as close as possible. The track is representing either an **isometric force** or **the angle of the wrist extension against gravity**. The recorded parameter will be displayed, real time, with a moving marker on the computer screen together with the target. In the force and angle tests the target is a trapezoid with a duration of 20 seconds, see Figure 3.6-1. Muscle contraction is required in **16 seconds**. The target **maximum value is 90%** of the maximal MeCFES assisted contraction. The **endurance test** is a modified tracking test where the participant is supposed asked to keep a **50% force** for **200 seconds**, see Figure 3.6-2. The vertical axis is normalized with the maximum contraction.

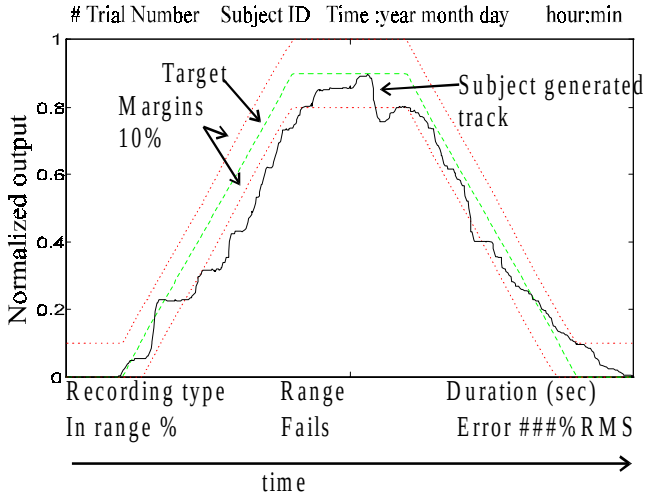


Figure 3.6-1 Example of a tracking test

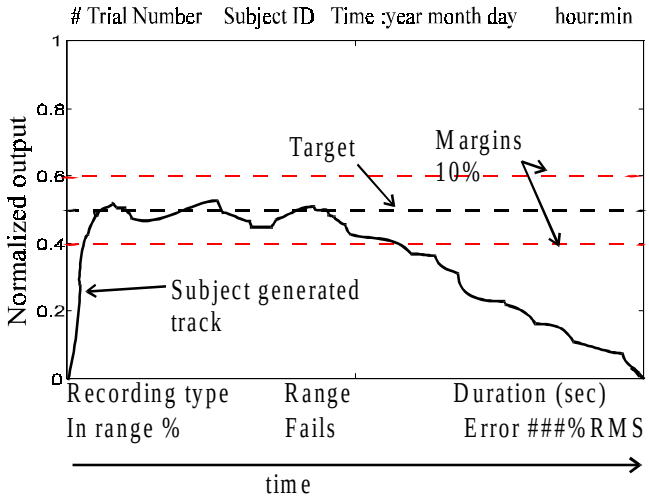


Figure 3.6-2 Endurance Test example.

Three different means of evaluating the performance are chosen. A **10% margin** for the track, is shown on each side of the target according to the precision needed to perform a given task. If the tracking is outside the margin once, then the task has failed. The 10% margin is arbitrarily chosen.

In range: A normal subject can easily keep the track within this margin. The time the track is outside this margin is shown as the percentage of the total time. No contraction and normal tracking will yield respectively: In range 23% and In range 100%.

Fails: This is the number of times the track exceeds the margin. This is a measure for the reliability of the movement, since it only takes a short failure of contraction for a cup of coffee to end on the lap. For a reliable system a fail should not occur.

Error: This is the value used by Haxthausen. It is the root mean square (RMS) value of the vertical distance between the target and the tracking (used by Haxthausen). No contraction will yield: Error 60% RMS.

Recording of the **recruitment curves** are using the **same set-up**. The **current** is not controlled by the myoelectrical signal but is **controlled by the computer**. It is direct proportional with the target used in the tracking tests. The target is providing the percentage of maximum stimulation (determined by the participant). The curves can be recorded as stimulation-angle or stimulation-isometric force curves. The corresponding recording to endurance test is the stimulation-endurance curve, where a constant stimulation of 90% maximum stimulation is applied for 200 seconds.

3.6.2 Calibration Procedure

The parameters for the MeCFES are set by trial and error, using the settings from previous experiments as a starting point. When this is finished the tracking test set-up is calibrated. The offset (relaxed non stimulated) and maximal MeCFES assisted contraction is measured at the start of the test. For adjustment of the MeCFES system and train the patient the Angle Tracking Test is used. This test is used maximally 10 times before commencing the measurements.Performing the tracking test comprises of the following steps:

I. Finding maximal stimulated contraction angle and force
II. Tuning the MeCFES parameters using Angle Tracking Tests. Maximally 10 times.
III.Angle Tracking Test is performed without MeCFES.
IV.Angle Tracking Test is performed with MeCFES.

V. Force Tracking Test is performed without MeCFES.

VI.Force Tracking Test is performed with MeCFES.

VII.Endurance test is performed without MeCFES.

VIII.Endurance test is performed with MeCFES.

The procedure is not followed strictly due to practical reasons during the actual test situation. The deviations are on the order of using MeCFES and some times a test has been restarted or repeated.

3.6.3 Tracking Test Set-up

The set-up for the tracking tests is comprising a device illustrated in Figure 3.6-1 and a electronic circuit, **the transducer interface board, that can be found in Appendix B.** The circuit consists of two amplifier circuits, one for the force transducer and one for the angle transducer. These two signals are converted by two separate analog-digital converters, enabling sampling on a PC (IBM compatible personal computer). The connection to the computer is using some of the free pins on the same parallel port as is used by the MeCFES. This enables simultaneous sampling of either force or angle and monitoring of the MeCFES processing. The force signal is provided by a **strain-gauge bridge** and the angle by a linear single turn **potentiometer**. Both the control of the MeCFES and the tracking test is integrated in the MeCFES host program.

The **mechanical set-up** consists of a plate mounted with a lever, see Figure 3.6-1. The forearm is intended to be placed on the plate in such way that the lever rests on the back of the hand over the knuckles. The plate is mounted on a flexible arm to provide the opportunity to place the plate in the most comfortable position for the test person.

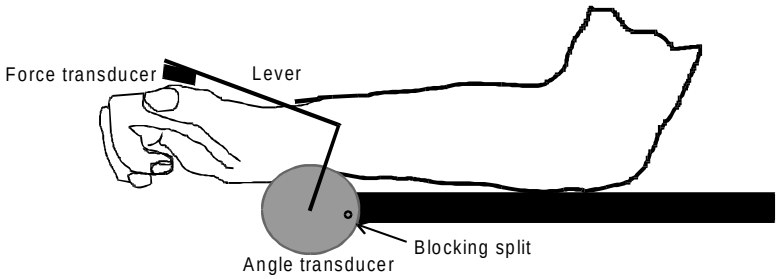


Figure 3.6-1 Angle and force measurement set-up

The rotation axis of the lever is parallel to the rotation axis of the wrist and the angle is recorded by a mechanical connected potentiometer. The wrist extension angle, where

gravity is the only force reacting on the hand, is recorded for the **Angle Tracking Test.** The movement is a **dynamic movement** that allows concentric and eccentric contraction that is comparative to the conditions under which the hands is used when grasping and lifting objects.

The lever can be blocked by a split as seen in Figure 3.6-1. The **Wrist Force Tracking Test** and **Endurance Test** are performed by fixing the lever at a position where the wrist is parallel to the arm (normal anatomical position). The contraction will then be an **isometric contraction**. A force transducer is mounted on end of the lever that rests on the knuckles and by blocking the lever the isometric force is recorded providing a well defined reproducible measurement. Note that the **force of gravity is not eliminated**. In all tests the hand is taped to the lever. This is necessary since the attempt of wrist extension in all the participants was accompanied by some supination of the wrist.

3.7 DSP Software

The DSP (digital signal processor) is taking care of: Sampling and filtering, output of stimulation pulse, calculation of stimulation output and miscellaneous control tasks.

The software for the DSP is coded in the TMS320C50 assembly language consists over 2000 codelines. Besides the signal processing it enables communication and data exchange capabilities to the optional host computer. The program provides different signal processing strategies, which can be changed by the host computer. A combination of the following signal processing steps are possible: The functions in italics are the default, Mode1.

Signal name	**Processing**		
X=	*Sampling of amplified signal*		
Y=	*Stimulation response suppression filter (1.order transposed FIR-filter)*		
Noise indication	*Noise detection*		
MES=	*Filtering the blocs of data (Changeable coefficients)*		
MA=	*Counting samples above a threshold*	Rectified mean value	Root mean square
M=	*FIR low-pass filtering*	IIR low-pass filter	
I=	*Stimulation amplitude = Piece-wise linear function*	Constant stimulation	

Table 3.7-1 Signal processing

The filters with changeable coefficients are using a lookup table for the coefficients. At assembly time different tables can be used/created. The sampling frequency is set to 2kHz but can be changed in the source code for the program (it then has to be reassembled). Of the total stimulation interval, which is 60ms, the first 10ms is blanked, i.e. they are implicitly set to zero. The block length (samples in-between stimulation) is 100 samples. This is equivalent to 50ms of the myoelectrical signal.

The stimulation pulse is given by a sequence of 10 interrupt routines with an interval of 0.1ms. This gives the opportunity to select an arbitrary stimulation pulse with a duration of 1ms with a resolution of 0.1ms. The used stimulation from is a biphasic pulse with equal positive, inter- and negative pulse have a duration of 0.3ms each. The execution of these tasks are illustrated in Figure 3.7-1

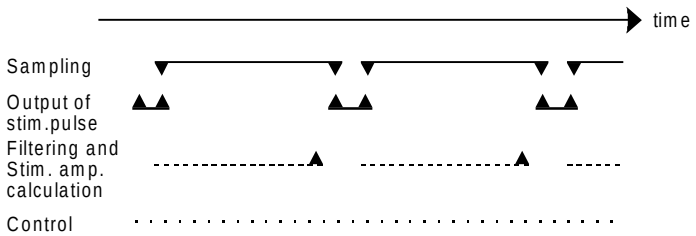


Figure 3.7-1 Timing of program

The sampling and output of the stimulation pulse have the first priority since they demand precise timing. Calculation of the new stimulation amplitude can be performed in

parallel with the sampling. It must be completed before the stimulation starts. The signal processing flow is illustrated in Figure 3.7-2.

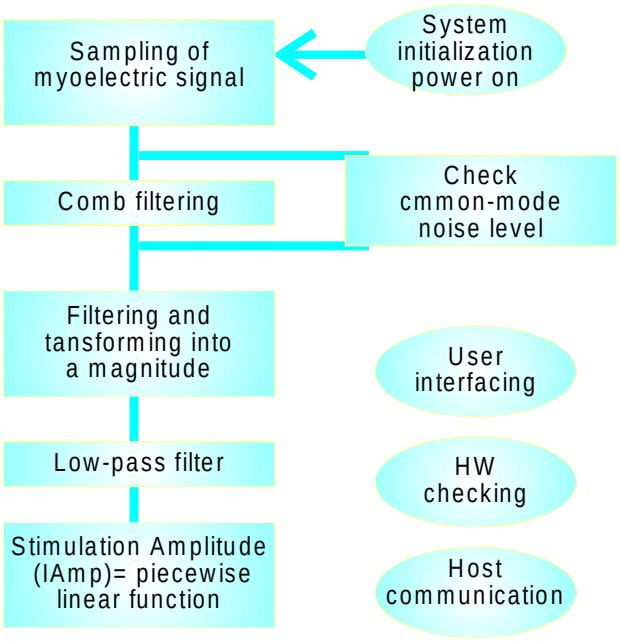


Figure 3.7-2 Flow of the signal processing

The control tasks can be executed asynchronously in parallel with the two other processes as indicated on the timing diagram Figure 3.7-1. These three classes of processes are controlled by pointers. The pointers are: *SamplingStateSel_M*.which takes care of the sampling, *ProgramModeSel_M* selecting the signal processing of the blocks. Finally there are two background process pointers *BackProcessSel_MeCFES* and *ComModeSel_M* for the asynchronous tasks.

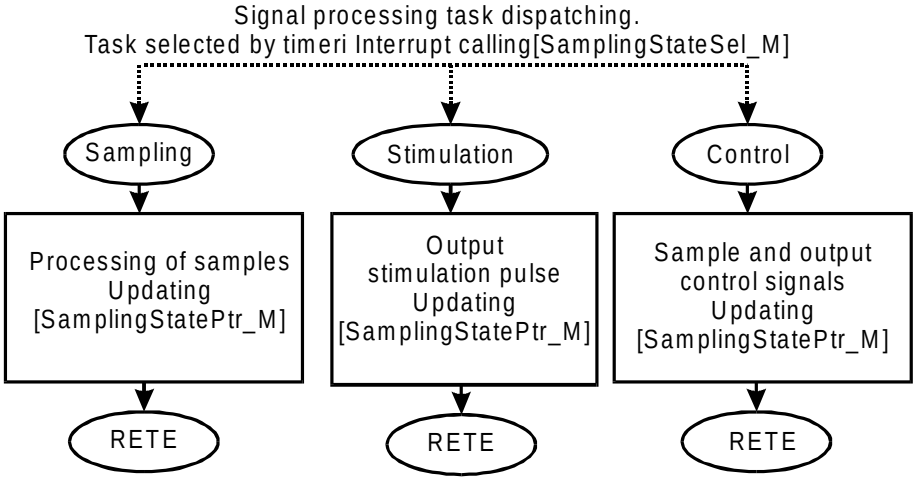


Figure 3.7-3 Task dispatching

The pointer, *SamplingStateSel_M*, is controlling the sampling process using the timer interrupt, as shown in Figure 3.7-3. After 100 samples the pointer is being changed to the stimulation process and then again after 1ms to the control process during the blanking of 10ms. Totally a stimulation period of 60ms. Changing the stimulation period from 16.66Hz to 15Hz it is done by extending the blanking time by 6.66ms. This can be done by correcting a fine-tuning parameter called *PeriodTune_k* that extends the control process.

A feature that recently has been implemented in the program is a mode for data logging of a myoelectrical signal. This can be used to **register spasticity** in a muscle over 24hours. In this mode, *SpasmRecord*, the stimulator module is not used. The program calculates the RMS value of the myoelectrical signal in blocks of 6 seconds. These values are saved in the FLASH and can be downloaded to the host computer after the end of the recording period.

3.8 Host Computer Software

A range of data exchange options can be accessed by connecting a host computer (80386 IBM compatible PC or higher) to the MeCFES. The host computer program, containing over 3000 code lines, is written in Turbo Pascal as a DOS application. The primary purpose of the program is to program and test the DSP. The features are:

- Initializing the DSP

- Programming the memory circuit (FLASH memory)
- Verifying the program
- Testing different sub-circuits in the system
- Writing serial numbers, version and other information in memory for service purposes
- Downloading data and signals from the DSP to the PC-disk drive., for later examination of the performance and control of myoelectric signals.
- Monitoring the signals in different states of signal processing on the screen. This serves for controlling the quality of the Myoelectric signals.
- Changing signal processing parameters.
- Reprogramming the DSP to upgrade the program.
- Real time debugging the DSP program and tracing the execution of the DSP program in single steps as well as free run.

In addition the program performs the **tracking tests, endurance tests and the recruitment measurements**.

3.9 Summary

This section gives a summary of the specifications for the hardware. The hardware is produced in surface mount technology, minimizing size and weight

The MeCFES system, comprising stimulator, DSP and power supply, is build into a **11cm x 7cm x 3.5cm box with a total weight of 200g**. The box is intended to be placed e.g. in a pocket A flat cable connects it to the amplifier which is intended to be placed near the recording electrodes. The amplifier is build into a 5mm x 45mm x 35mm box. The bottom of the box is mounted with the reference electrode. It is the intention to have the amplifier enclosed in the electrode-mount (described in *2.8.4 Electrode-mount*) near by the recording electrodes. The system is powered by 4x1.2V rechargeable NiCd batteries with a total capacity of min 2Wh.The measured power consumption of the four parts is

DSP (executing signal processing.)	26mW @ 3,2MHz clock. (3.3V)
Amplifier	18mW. (±3V)
Stimulator (Type1)	10-150mW stimulation dependent
Power supply	Not available (unstable efficiency)

Some of the following measurements are described in detail in section *4.1 Hardware Performance.*

3.9.1 Amplifier Specifications

The produced amplifier has an artefact suppressing construction and needs no shut-down during stimulation.

Power supply	±3V
Active current*	6mA
Input impedance**	>10GΩ common mode >10GΩ differential mode
Gain*, Input range	74dB, ±600µV
Frequency range*	10-500Hz
Filter	Low pass: 2 order Bessel High pass: Non-linear feedback
Common-mode rejection**	>110dB + active grounding of patient
Noise related to input*	400nV(RMS) or 3mV(peak-peak
Recovery time@10mV step as differential input(2)	50ms-100ms
Offset compensation activation level	±0.1mV
ESD & Stimulation artefact protected	

* Measured

** Specified by IC manufacturer

3.9.2 Digital Signal Processor Specifications

Power supply	3.3V
Active current	8 mA
Microprocessor	TMS320LC50
Speed	1,6 MIPS (Million Instructions Per Sec.)
FLASH Memory	64kWords
RAM	10kWords
A/D converter	10bit >10kHz, 11 channels
D/A converter	12bit >100kHz serial
Logic outputs	6
Serial communication port for host computer connection	

Digital signal processing is fully software controlled. The signal processor program has a mean execution time of : 0.788MIPS with a peak at 0.972MIPS during data acquisition and host communication. The DSP takes care of all control and signal processing tasks.

3.9.3 Stimulator

The stimulator is converting the signal from the DSP to a current. The shape of the stimulation signal is controlled by the DSP. The Type 1 stimulator is used.

Power supply	±3V and Variable -75V
Typical output power	14mW @ 15mA, 2kΩ load,16Hz
Pulse shape	Biphasic with interpulse interval. (DSP controlled). Current forced to zero in inter stimulation period.
Pulse width	0.9mSec (DSP controlled)
Current output amplitude	<50mA
Pulse repetition rate	Arbitrary

A power efficient concept for the stimulator has been chosen. It is based upon a switch mode DC-DC converter to produce high voltage. This voltage is controlled by the DSP. In this way the voltage for the stimulator output stage is kept as low as possible in order to increase efficiency. A transistor based output stage provides the stimulation current.

3.9.4 Power Supply

The system is powered by build in batteries. The power supply for the Type1 stimulator is taking care of: Charging of the battery, Sound module, push button and generation of 5 different voltage levels.

Power supply	4x1,2V NiCd batteries
Output voltages	±3V for analog circuits 3.3V for digital circuits 0-±75V for stimulator circuit
Charging input	1A @ 10-20V AC or DC
High voltage output efficiency	<40% @ 70V,0.3mA_{mean} output

High voltages are generated using switch mode power supply technique.

4. Results

This chapter evaluates the developed hardware, the MeCFES. First the main **electrical specifications** of the MeCFES is verified in section 4.1. The **recruitment curves**, i.e. the stimulation-muscle output relation, recorded in section 4.2 serves to explain the problem of muscle control. The findings regarding muscle **endurance** in section 4.3 provides information of the effect of fatigue on the tracking test and section 4.4 shows the effect of **habituation** to the MeCFES. The **tracking test results** in section 4.5, for five tetraplegics, together with the **functional evaluation**, section 4.6, are the main results of the functionality of the MeCFES. At last section 4.7 is evaluating a way to **enhance the grip** further by use of the MeCFES.

4.1 Hardware Performance

The hardware developed in Chapter 3 has been tested to find what specifications have been achieved. Since the bottlenecks of the analogue part of the signal processing are the amplifier and the stimulator, emphasis has been put on the measurement of the performance of these parts.

4.1.1 Amplifier Performance

The amplifier has been tested by computer simulation and by **measurements on the produced prototype**. The computer **simulation** has been used to control the amplifiers response to a signal mixed with stimulation artefacts and DC transients. This simulation allows a more noise free measurement than what the available laboratory facilities could offer.

The test signal for the simulation can be seen in Figure 4.1-1. This represents a worst case signal comprising monophasic stimulation responses and an offset change. The test signal is a sum of:

- 0.1mV, 200Hz sine wave representing the myoelectric signal
- -0.1V, 500ms pulse representing a change in electrode offset
- 1V, 2ms pulse repeated 20times/sec representing the stimulation artefacts

Due to the graphic resolution the sine wave can not be seen.

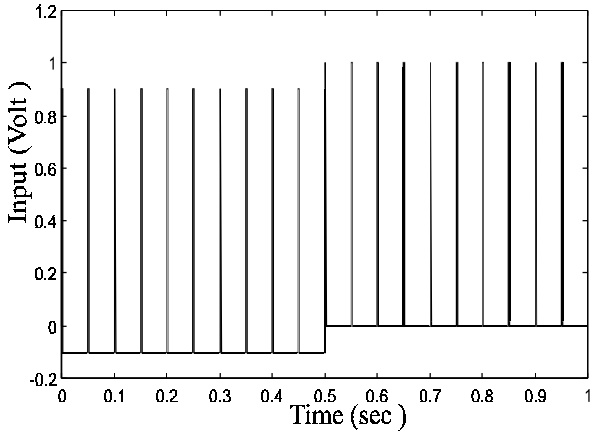


Figure 4.1-1 Excitation test signal

The simulations are made with SPICE (computer program for analysis of electronic circuits). The Instrumentation amplifiers are modeled as ideal amplifiers with a rail-to-rail output limitation. For comparison a simulation on a conventional amplifier as shown in Figure 4.1-2 can be seen on Figure 4.1-3. The amplifier has a 15Hz cut off high-pass filter to remove DC offset. It has the same gain as the MeCFES amplifier

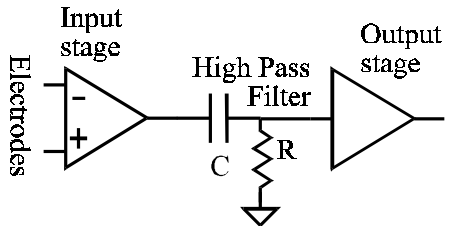


Figure 4.1-2 Simplified schematic of a typical conventional myoelectric amplifier

Most of the 200Hz signal is blocked due to saturation of the amplifier from the stimulation pulses. The amplifiers are simulated as being powered by ±5V. This distortion of the signal makes it unsuitable for the myoelectric control.

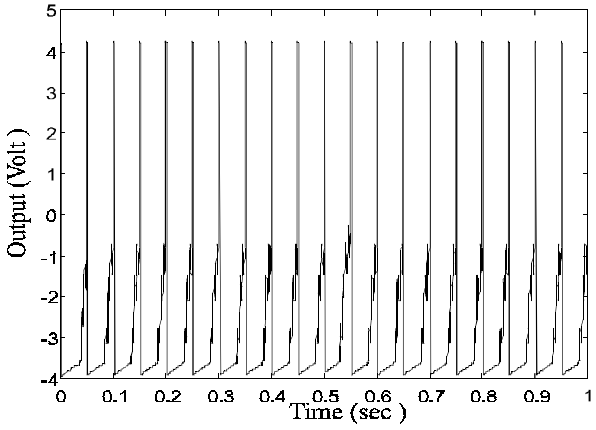


Figure 4.1-3 Response from a conventional amplifier

With the same test signal on the input of the MeCFES amplifier the output is displayed in Figure 4.1-4. The stimulation pulses are suppressed and causes significantly less distortion of the sine. Immediately after the end of the stimulation pulses the sine is amplified unaffected. The change of DC offset is causing transients that only saturate the amplifier for 50-100ms after the transient corresponding the loss of one or two blocks of myoelectrical signal. After that the sine is amplified but superimposed with the remaining transient.

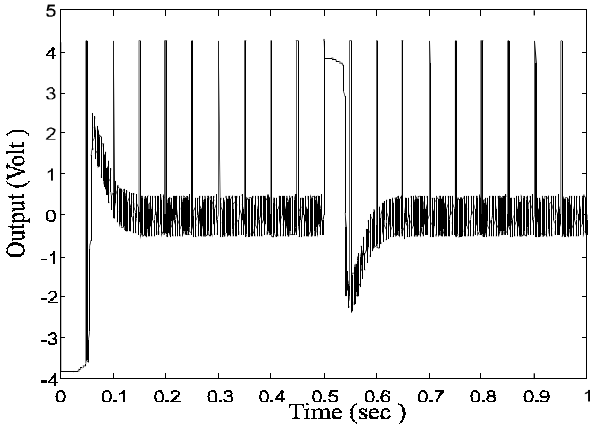


Figure 4.1-4 Output from the MECFES-Amplifier

In comparison with the conventional amplifier the **MeCFES amplifier suppresses both the stimulation pulses and the offset change**, permitting amplification of the myoelectric signal. The output is shown in Figure 4.1-4. The adjustment of the offset change begins after 50ms and is completed within 100ms. This allows myoelectric signals to pass through the amplifier only 150 ms after an offset change. This is off-course dependent on the magnitude of the change. A zoom at the output, Figure 4.1-5, shows that the stimulation actually does not affect the following signal after the transient.

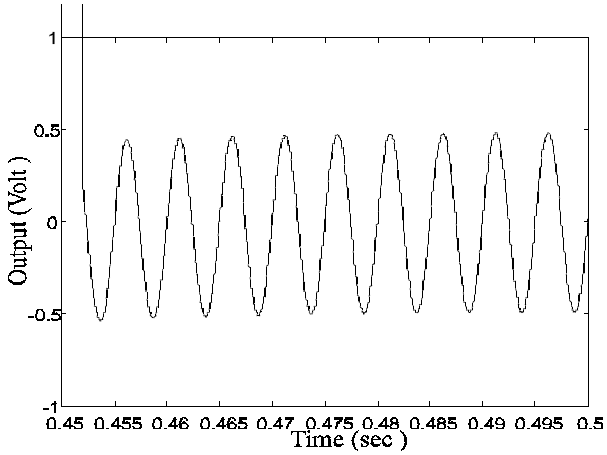


Figure 4.1-5 Zoom of the output from the MeCFES amplifier

The theoretical and simulated results of the MeCFES amplifier are verified by a measurement of the output from the hardware realized amplifier. Adding the signals from a sine generator and two pulse generators produces the test signal. The amplifier output has been sampled at 2kHz with 10bit and an example is reproduced in Figure 4.1-6. The equipment used for generating the test signal gave rise to some noise, mainly 50Hz hum. The slight distortion of the signal shown is due to interference between noise in the experimental set-up and the sampling interval resolution. Overlooking this disturbance the recording proves that the amplifier possesses the desired characteristics of being stimulation response suppressing and fast recovering. Regarding DC offset compensation experiments has shown that as long as the DC change does not saturate the second instrumentation amplifier, the recovery is according to the simulation. The instrumentation amplifier (INA118) is reversing the output when saturated. Thus if the DC offset is saturating the amplifier, the MeCFES amplifier becomes unstable.

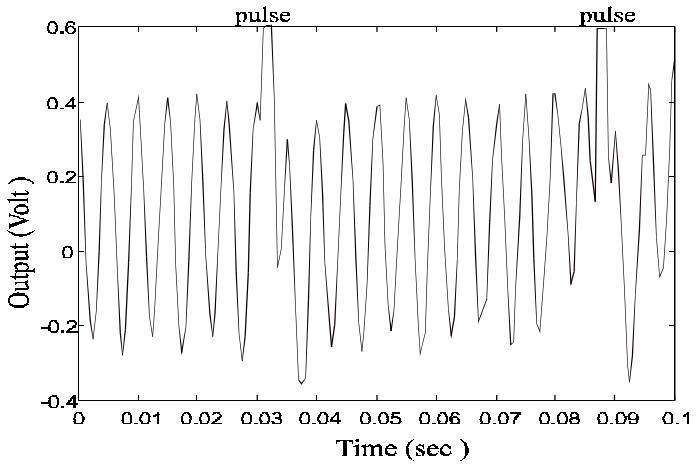


Figure 4.1-6 Measured output from the MECFES-Amplifier (fsam=2kHz)

The following data has been measured:

- Supply current 6mA
- Frequency range 10-500Hz
- Common-mode rejection >110dB exclusive active ground
- Gain 74dB
- Noise related to input 400nV(RMS) or 3mV(peak-peak

In conclusion the MeCFES amplifier is an AC-signal amplifier which does not saturate by short stimulation artefacts. Changes in the DC-offset at the input are compensated within a short period determined by the time constant of a RC circuit.

4.1.2 Power Supply Performance

On four fully charged 400 mAh batteries the entire system can be powered for 15-30 hours when no stimulation takes place. The switch mode power supply is not optimized and it has therefore a low efficiency. It has not been possible to obtain an efficiency of more than 40% at a power output of 22mW in 70V. This means that the estimate runtime on batteries is decreased significantly during stimulation.

4.1.3 Type 1 Stimulator Performance

The output from the stimulator is tested using the resistor network in Figure 4.1-7.

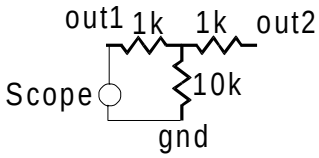


Figure 4.1-7 Test set-up

For the Type 1 stimulator outputting 25mA the positive pulse is not equal to the negative pulse. The variation in amplitude for three Type 1 prototype stimulators under these circumstances is up to 20%. The Type 1 stimulator has been used for all the stimulation tests which proves that the imperfection of the stimulator is not fatal but might cause degeneration of the performance of the complete system. Of the three stimulators the best matched has an output at 17mA as shown in Figure 4.1-8. This stimulator is used in the tracking tests.

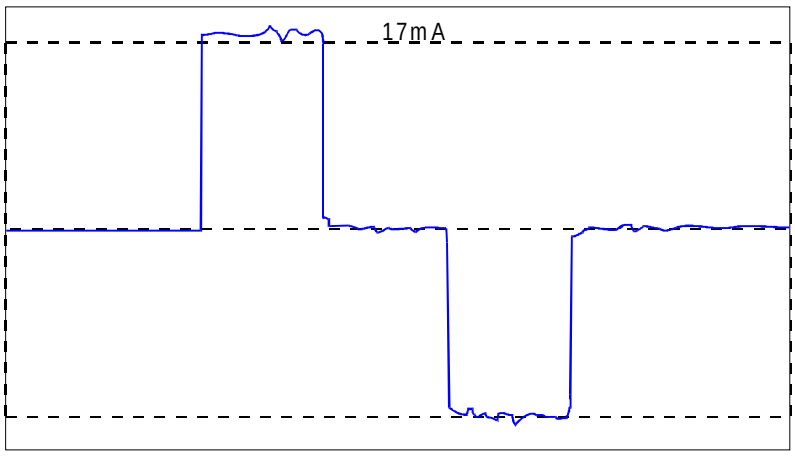


Figure 4.1-8 Current through 5kΩ resistor, Type 1 stimulator.

As it may be noticed this stimulator type has a fast risetime and a stable level of current compared to the Type 3 which will be described in subsection *4.1.5 Type 3 Stimulator Performance*. Measuring at the equilibrium point over the 10kΩ resistor (see Figure 4.1-

7), the results varies between the three prototypes. For the best matched an example is shown in Figure 4.1-9 . This is equal to a fault current in the 10kΩ resistor of up to 2mA. Part of the reason has been traced to be imperfect balance in the power supply. Another explanation is variation in the transistor parameters in the output stage of the stimulator.

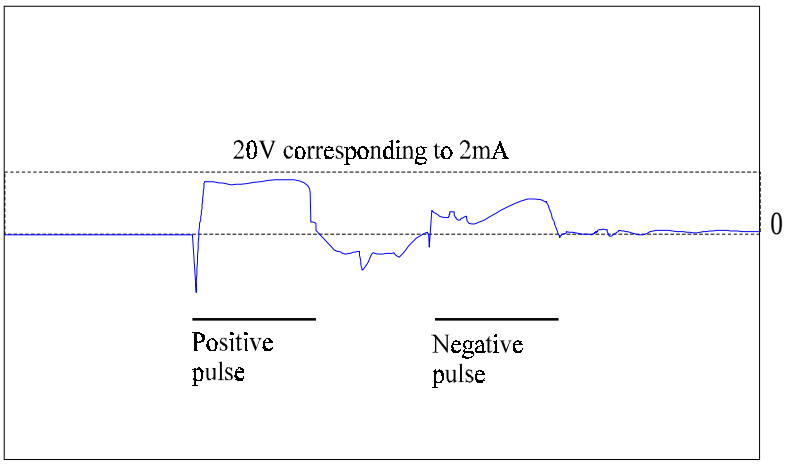


Figure 4.1-9 Fault current

This implies that the stimulation can not be expected to be balanced as described in the demands for stimulators in *2.4.7 Stimulation Response.* These current shapes also yields when the output is loaded by applied stimulation electrodes as can be seen in *2.2 Electrode Characteristics.*

4.1.4 Type 2 Stimulator Performance

This stimulator has turned out to be unstable. It is oscillating at a frequency of 1MHz. Adding frequency limitations in the feedback loop decreases the slew-rate of the output below tolerable limits. SPICE simulation has shown good performance. This leads to the assumption that the circuit concept has the potential to be very well suited for the purpose once the instability problem is solved.

4.1.5 Type 3 Stimulator Performance

The transformer coupled Type 3 stimulator needs a 9V battery voltage to be efficient. The output is symmetric between out1 and out2. As it can be seen on, Figure 4.1-10 there is a decay in the current during the pulse. It may also be noticed that current in the inter-pulse interval is not zero. The same applies to the period after the second pulse.

This was brought below the limit of measure (less than 0.1mA) 10ms after the pulse, due to the clamping circuit. Efficiency of the circuit is not measured.

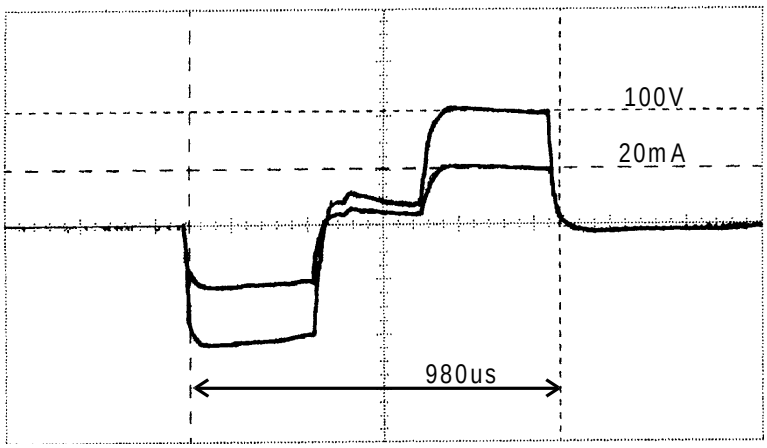


Figure 4.1-10 Output through resistor, Type 3

The circuit has shown to have problems coping with the electrode capacitance. Current through and voltage across a pair of stimulation electrodes is shown in Figure 4.1-11

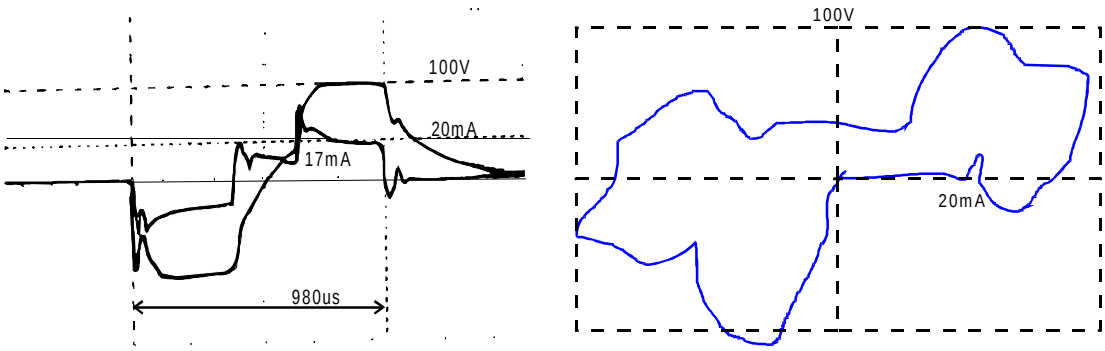


Figure 4.1-11 Type 3 loaded with stimulation electrodes. Left: Current and voltage. Right: Current vs. voltage

For comparison with the Type 1, please refer to section *2.2 Electrode Characteristics* for a similar measurement.

4.1.6 Digital Signal Processor Unit Performance

The DSP Unit is operating properly. At full signal processing, the supply current has a mean value of 8mA. The execution speed is 1,6MIPS (million instructions per second). The required speed for the signal processing is 0.79MIPS, leaving capacity for host communication. A communication speed with the host has been estimated to at least 4000 data words per second, enabling transferring the full recorded myoelectrical signal to the host.

4.1.7 Conclusion of the Hardware Performance

If the Type 1 stimulator concept is going to be feasible, it calls for significant improvement of the DC converter efficiency as well as the performance of the stimulator outputs. Both Type 1 and Type 3 stimulator concept has advantages and drawbacks, which may counterbalance each other. For small size, the Type 1 is preferable but Type 3 may be better suited for minimization of the stimulation artefacts. The amplifier concept is very well suited for the application together with the microprocessor solution. It has potential for significant miniaturization and has satisfactory power consumption.

4.2 Recruitment Curve

The recruitment curve is measured, as the stimulation intensity needed to generate a given muscle output, using the set-up described in *3.6 Evaluation Method.* This relation has been recorded in 7 subjects, three normal subjects (subj.: RAT, OBP, CD) and 4 tetraplegics (subjects: HSJ,JBS,KN,EG). It is recorded as the relation stimulation - wrist angle and stimulation - wrist force. The current is following the same course as the target in the tracking test (Figure 4.2-1).

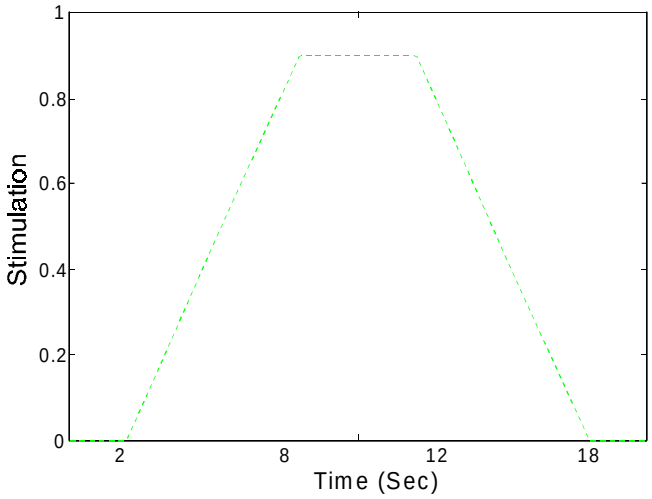


Figure 4.2-1 Stimulation versus time

An example of a typical recruitment curve can be seen in Figure 4.2-2 (subj.: HSJ). Full stimulation (15mA) gives full extension of the wrist. Without stimulation, the subject could voluntarily lift the wrist to an angle of 0.3, where 1 is the angle of full extension by stimulation without voluntary extension.

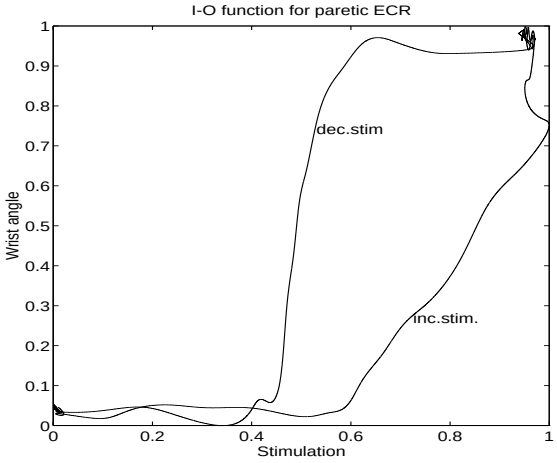


Figure 4.2-2 Wrist-angle vs. stimulation amplitude

As it can be seen, the relation between stimulation and wrist angle is strongly non-linear. The wrist angle shows not only to be dependent on the actual stimulation amplitude, but also whether the amplitude is increasing or decreasing. Amplitude-angle relation shows a hysteresis function. This applies to all the tested subjects

For a normal subject (subj.: RAT) the recruitment curves appear as in Figure 4.2-3 and Figure 4.2-4 for angle and Figure 4.2-5 and Figure 4.2-6 at isometric force recording. This recording shows the same shape of non-linearity. The same type of recordings are shown in Figure 4.2-7 to 4.2-14 for two tetraplegics; KN and EG.

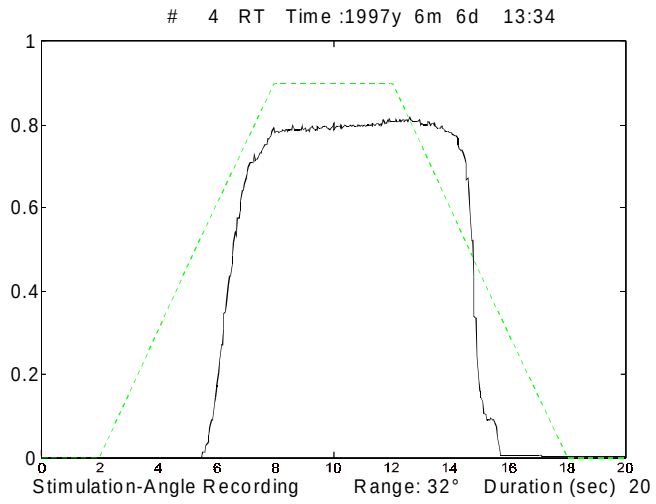


Figure 4.2-3 Subj.: RAT. Full range=15mA

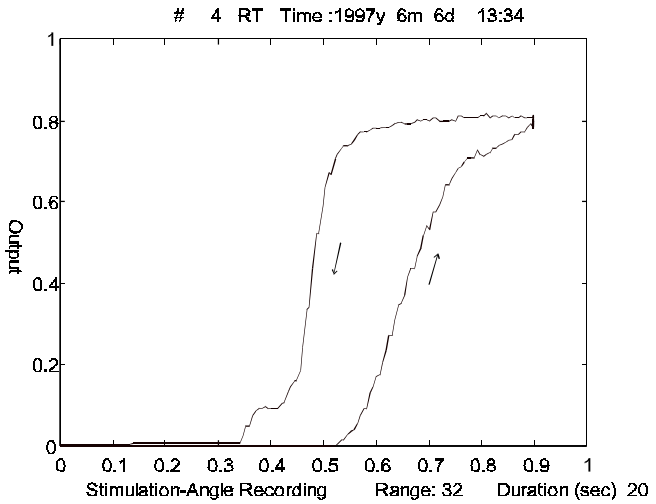


Figure 4.2-4 Subj.: RAT Current vs. Angle

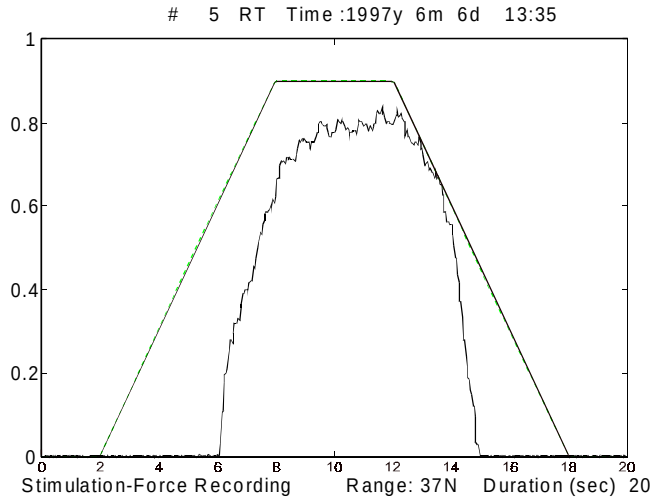


Figure 4.2-5 Subj.: RAT. Full range=15mA

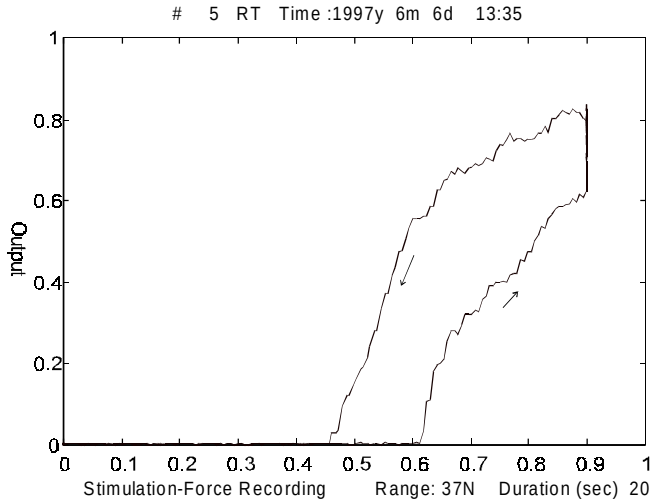


Figure 4.2-6 Subj.: RAT Current vs. Force

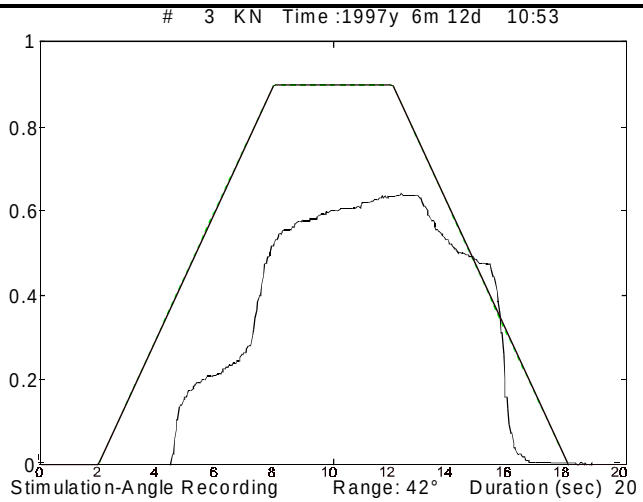


Figure 4.2-7 Subj.: KN. Full range=20mA

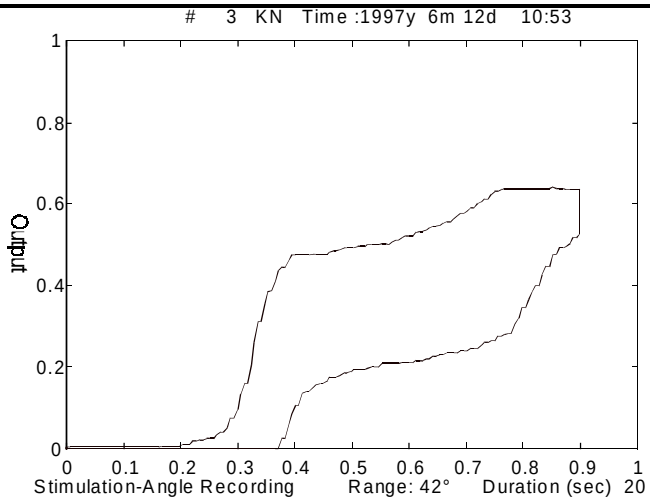


Figure 4.2-8 Subj.: KN Current vs. Angle

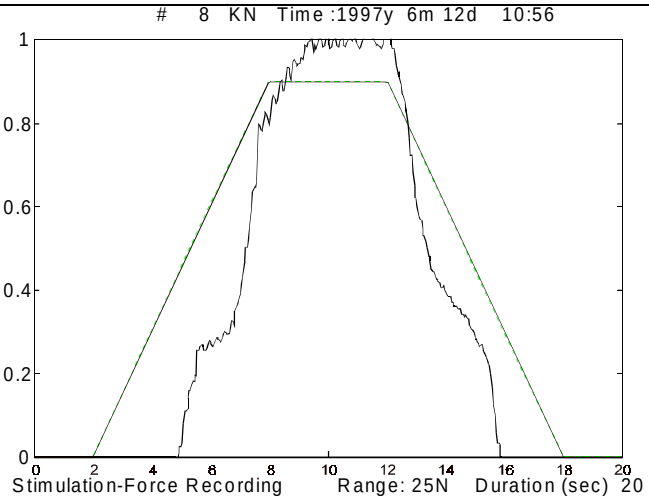


Figure 4.2-9 Subj.: KN. Full range=25mA

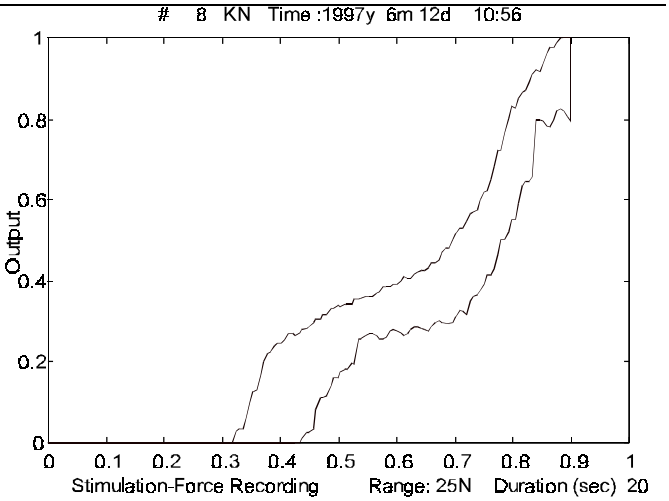


Figure 4.2-10 Subj.: KN Current vs. Force

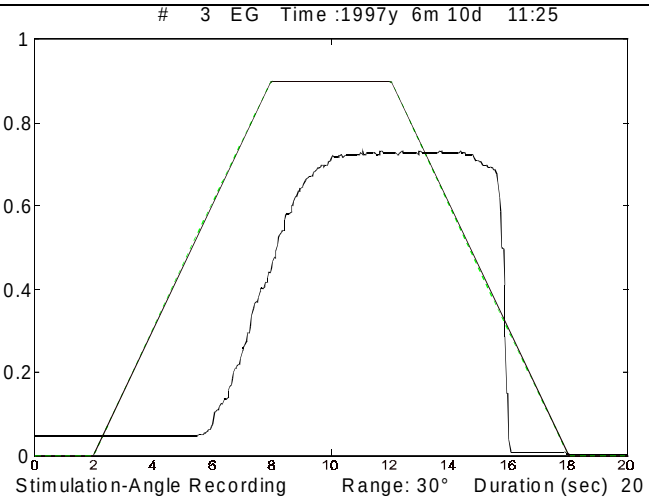


Figure 4.2-11 Subj.: EG. Full range=30mA

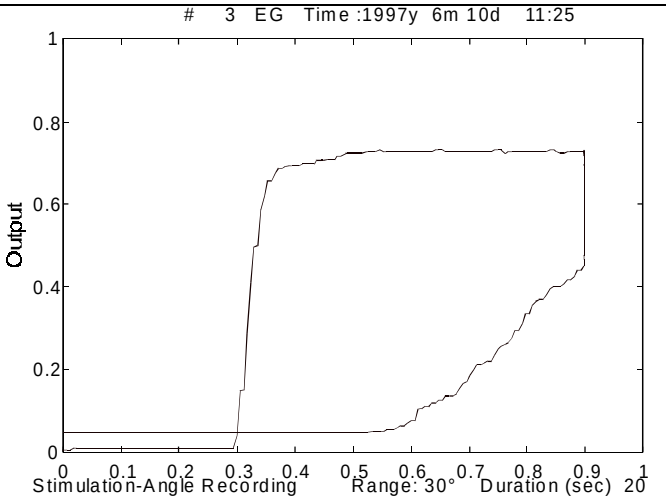


Figure 4.2-12 Subj.: EG Current vs. Angle

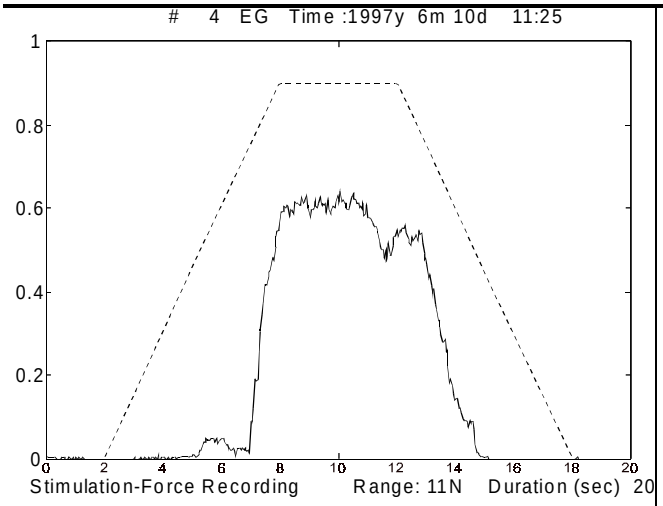


Figure 4.2-13 Subj.: EG. Full range=30mA

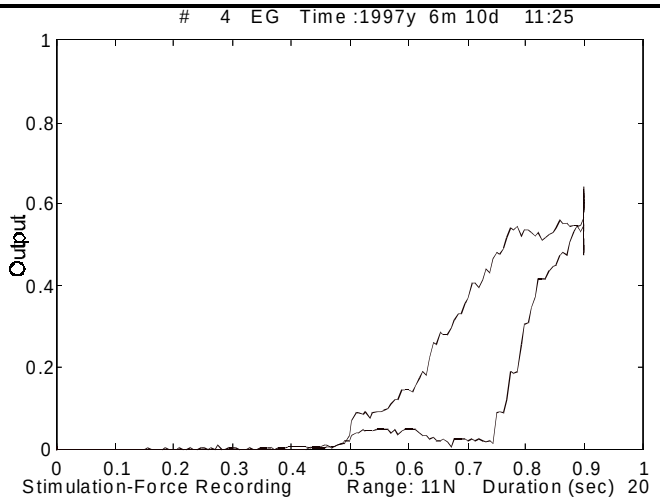


Figure 4.2-14 Subj.: EG. Current vs. Force

This **hysteresis** like shape of the **recruitment curve** applies to **angle and isometric force** measurements for the tested **tetraplegics and normal** subjects. The **shape varies** from person to person but it is also important to notice that the shape changes between two identical consecutive tests as illustrated by comparing Figure 4.2-14 and Figure 4.2-15.

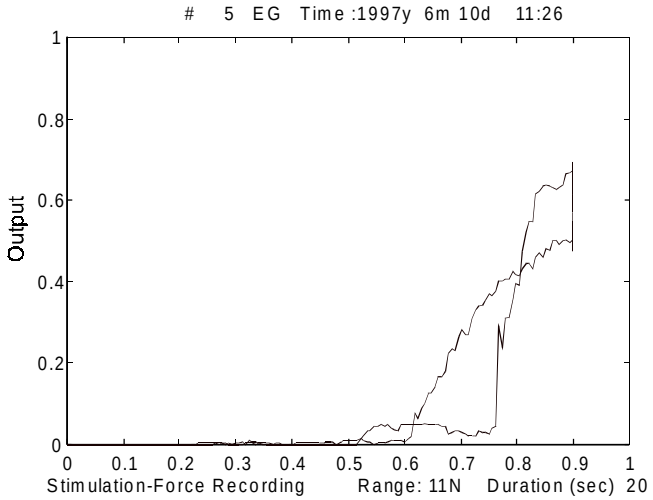


Figure 4.2-15 Subj.: EG. Current vs. Force #2

The **conclusion** is that the **recruitment curve** (relation between stimulation current and muscle force output) is **non linear and history dependent**. This relation is **not the same** for consecutive recordings nor for different subjects. It applies both to isometric contractions as well as to movements.

4.3 Endurance

Except for participants: HSJ, JBS and LP, the tetraplegics in the test panel have been involved in a conditioning project. The outcome of the project was that training with electrical stimulation enhanced the endurance [Hartkopp 1996]. To have an idea of what influence fatigue would have on the tracking tests the participants EG and KN were stimulated with a constant amplitude of 22mA over 200s using the stimulation-endurance recording described in *3.6 Evaluation Method*. The results are given in Figure 4.3-1 and Figure 4.3-2.

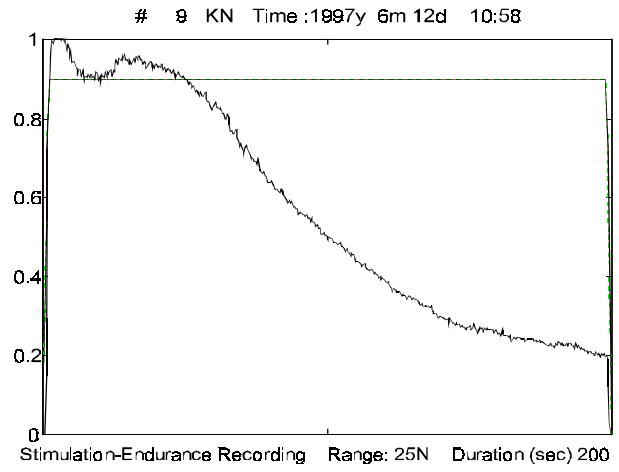


Figure 4.3-1 Force endurance (Subj.: KN)

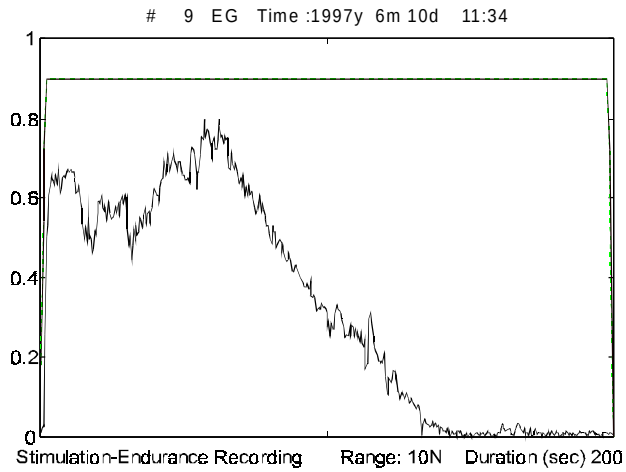


Figure 4.3-2 Force endurance (Subj.:EG)

None of these subjects have been using functional electrical stimulation for training for the past half year and must be considered unconditioned. The graphs show the course of the force during 200 seconds of constant stimulation. For both subjects the force begins to **decline after a minute**. Participant EG could feel the fatigue for around 5 minutes after the test. Since the tracking tests have a duration of 20 seconds with only 8 seconds of full stimulation, **fatigue will not influence the tracking test**, but may be considered when carrying out consecutive tests.

4.4 Habituation

The system requires adjustment of several parameters. The main parameters are IGain, Trsh and IMax. This is an iterative process where the tracking test is used for the optimization. This leads to better results as the parameters are adjusted towards their best values. At the same time, it has been experienced that the test subject is becoming better for the control of the system. These effects is a habituation to the system for both the user and the experimenter The following two series of figures shows this in two different subjects using the angle tracking tests. Since the setup is calibrated for the maximum range before each trial, the range differs from the measurements. As it can be seen this variation is significant. The range should have been kept constant, but the habituation phenomena seems demonstrated anyway.

The first series is performed by participant KN. Without stimulation the wrist can **voluntary be extended 8 degrees** against gravity.

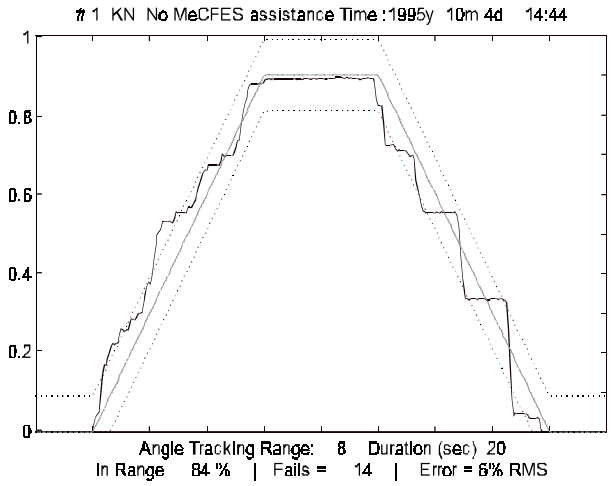


Figure 4.4-1 Subj.:KN. No stimulation. Max extension 8 degrees

Within the very limited range the tracking is good. (A normal subject will be able to keep the entire track inside the 10% margin (dotted lines)).

With the MeCFES the wrist can be fully extended against gravity i.e. a 58-66 degrees movement. (Offset position is slightly below zero angle extension i.e. back of the hand parallel with forearm.)

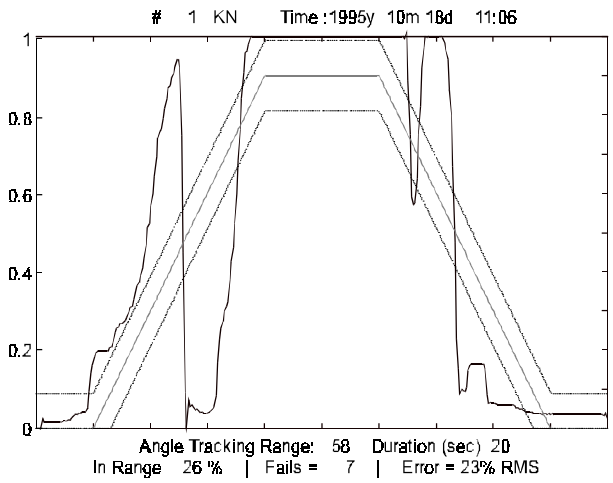


Figure 4.4-2 Subj.: KN. First trial after system adjustment

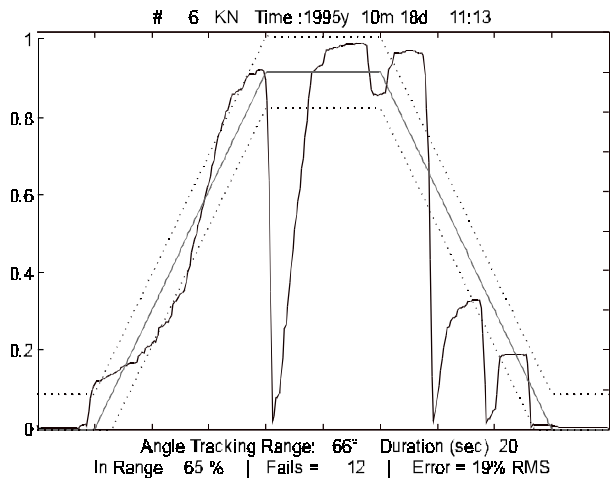


Figure 4.4-3 Subj.: KN. Sixth test

The subjects has already gained some experience with the system, before the first trial, during the parameter adjustment. After six consecutive tests, without changing the parameters, the result, shown in Figure 4.4-3, is obtained. It has a better *in range time* and a lower *Error* score than the first test in Figure 4.4-2. This person has been participating in most tests and has thus during the project gained experience with the device. In the last part of the project a test has shown a performance as seen in Figure 4.4-4

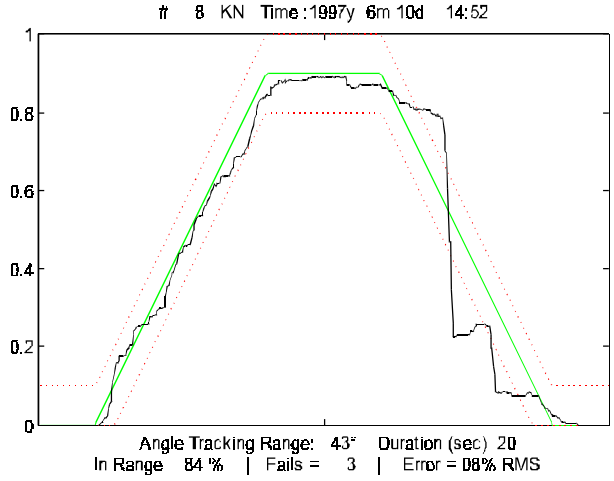


Figure 4.4-4 Subj.: KN. 1½ year later

In the passing time the parameters have been optimized, the person has gained experience and the system has been improved.

The second series is recorded from a person with much weaker extensor carpi radialis muscle. Without stimulation the subject (KGN) is not capable of showing any movement against gravity. A qualified guess on the parameters has been made and it has briefly been tested that the subject was able to start and stop stimulation. The first trial is seen on Figure 4.4-5.

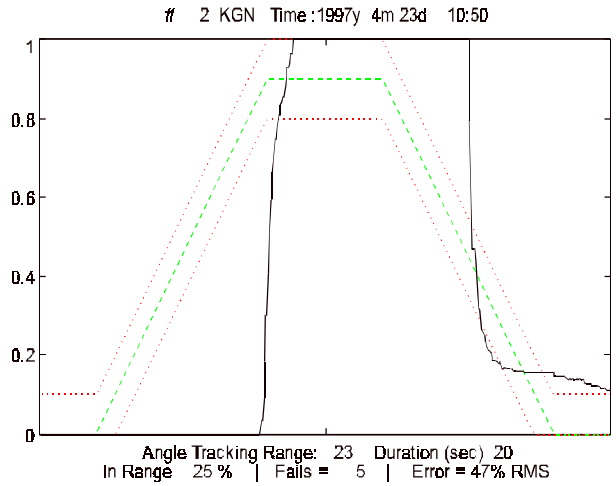


Figure 4.4-5 Subj.: KGN. First trial

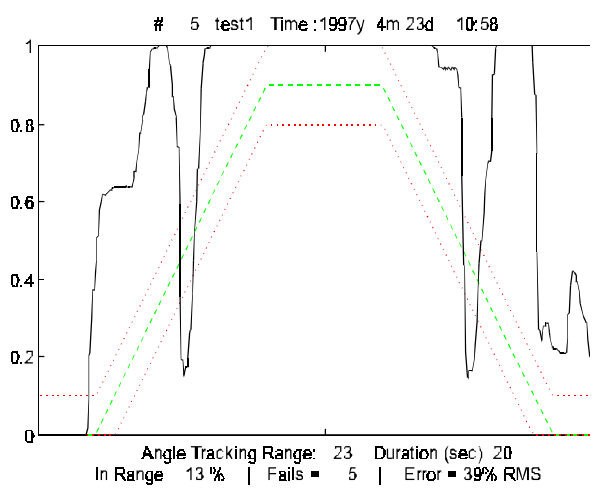


Figure 4.4-6 Subj.: KGN. Fifth trial

As it can be seen the tracking is very poor. The gain was adjusted since the subject did not seem to be able to obtain full stimulation. After five trials without adjustments the result was as in Figure 4.4-6.The performance has been better for each trial. This has continued until the ninth trial (Figure 4.4-7), where it was decided to continue with the other tests (in respect of the persons time schedule). (The eighth trial was without stimulation).

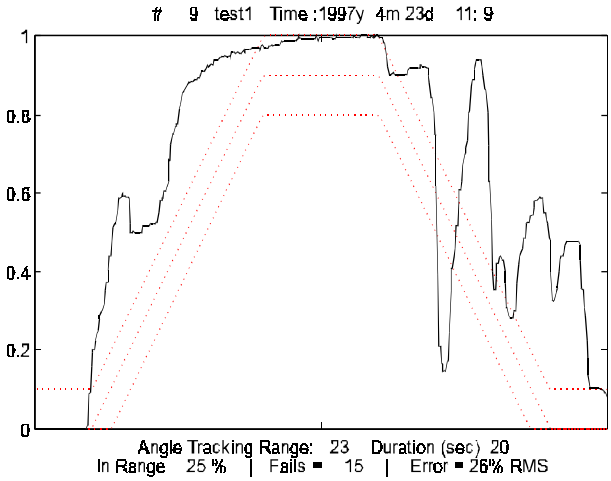


Figure 4.4-7 Subj.: KGN. Ninth trial

These tests indicate that the performance might increase with the habituation to the device. There has not been a systematic comparison of the three different signal evaluation methods; threshold, RMS and ARV due to the impact with the habituation effect. Sporadic tests with the RMS and ARV have indicated slightly poorer performance. An example is Figure 4.4-8 that shows the performance using ARV after adjustment of parameters (IGain & IMax) and 3 trials with further adjustment. This is recorded in continuation of the trial in Figure 4.4-3. It shows a higher RMS error and lesser in range time than the threshold counting method trial.

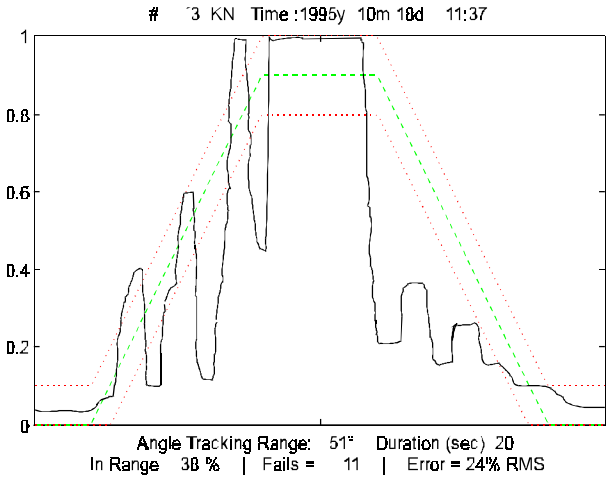


Figure 4.4-8 Subj.: KN. ARV method

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4.5 Tracking test results

This section describes the results of the tracking tests for five tetraplegics with muscle strength in the range 1-4. The tests are performed using the set-up described in *3.6 Evaluation Method.* The participants in the test are AA, EG, FB, KGN and KN from the test panel described in *2.1 Test Panel*. Following the description of the performance of each participant, 6 graphs are collected in a scheme with two columns and 3 rows (see example Table 4.5-1).

The **first column** is the performance **without** the MeCFES and the **second column** is **with** the **assistance of the MeCFES**. **First row is the angle tracking test, Second row is the force tracking test and the last row is the endurance tracking test**. After the parameters had been adjusted the trials were carried out consecutively.

Unassisted	MeCFES assisted
Angle tracking	Angle tracking
Force tracking	Force tracking
Endurance	Endurance

Table 4.5-1 Format for the result schemes

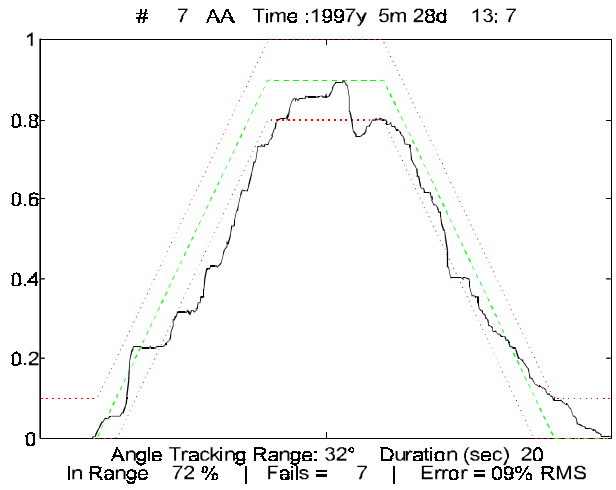
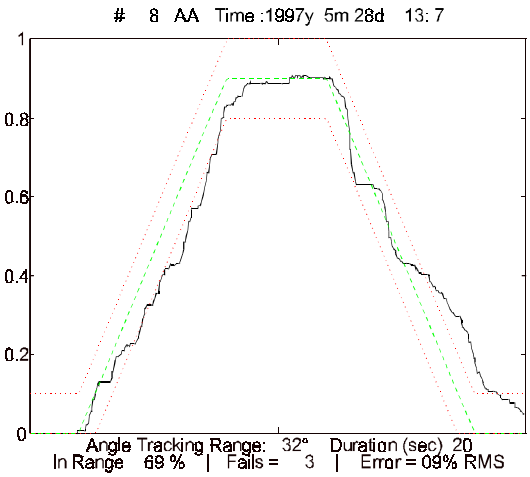
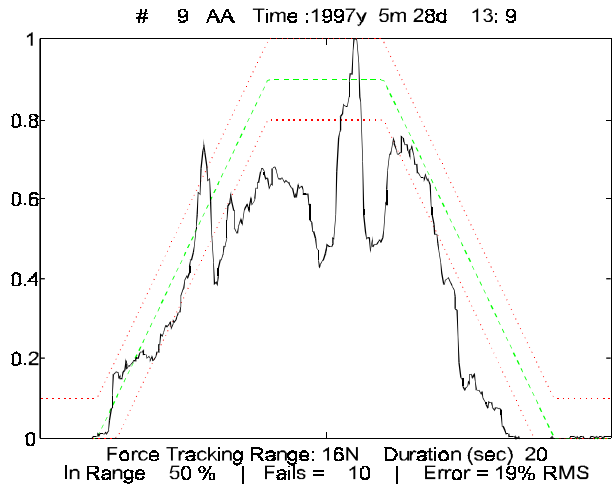
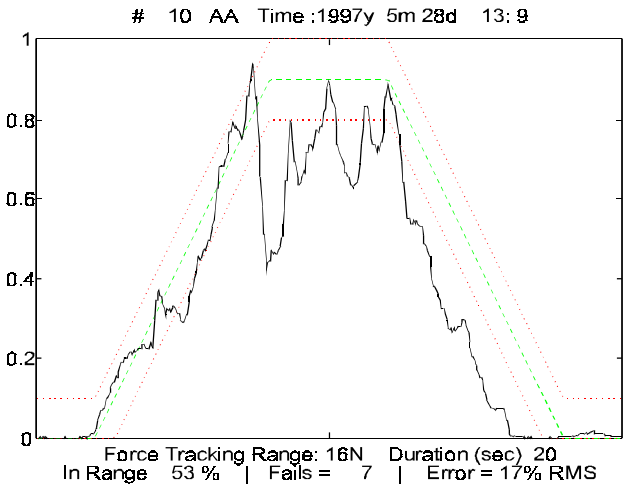
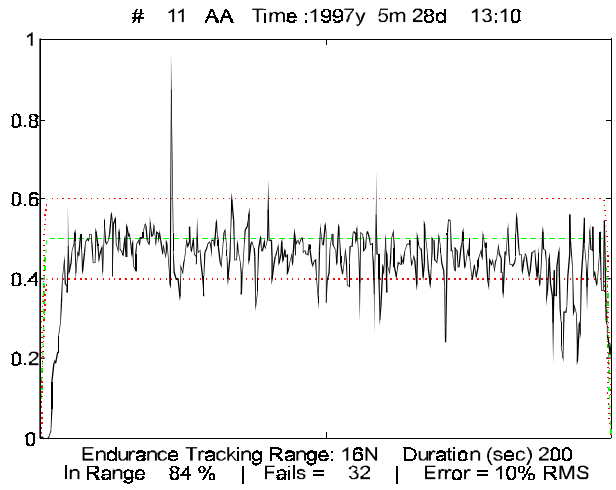
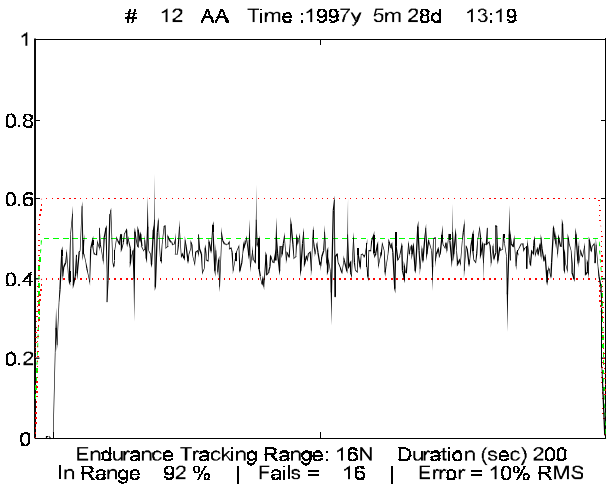
Recording of the isometric force is performed with the hand positioned in parallel with the forearm. In the angle recordings the angle is measured from the resting position of the hand. This position changed from participant to participant since it was necessary to place a pillow between the lap and the recording equipment for the comfort of the participant. The hand was thus resting in a of slightly flexed position.

4.5.1 Participant AA

This is the first time AA tries the system. It has been difficult to reproduce electrode placing since her skin is very loose and can slide several centimeters with respect to the muscle. In general it was difficult to maintain the electrodes in a position, giving a good wrist extension. High skin impedance resulted in a low level of the voluntary myoelectrical signal.

Her voluntary force is sufficient to produce full wrist extension against gravity and electrical stimulation is thus not increasing the angle. The day the tracking test was performed the maximal voluntary contraction was approximately 30N (peak). Stimulating the voluntary relaxed muscle with the maximum current for the MeCFES (which is about 30mA) resulted in a contraction of only 16N. Since the stimulated force is only half of the voluntary the force amplification is small as it also appears from the graphs on the next page. The endurance is unaffected by the stimulation.

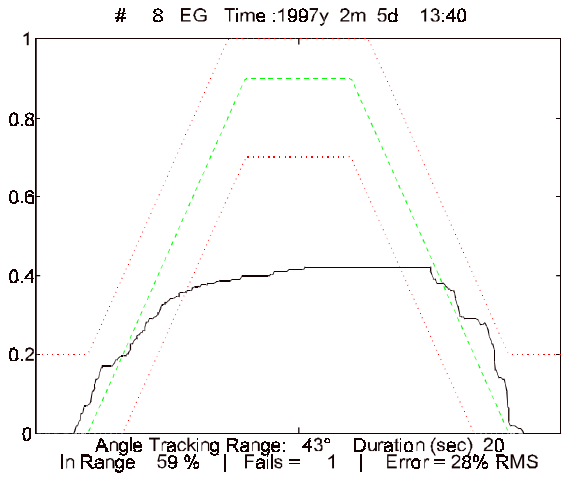
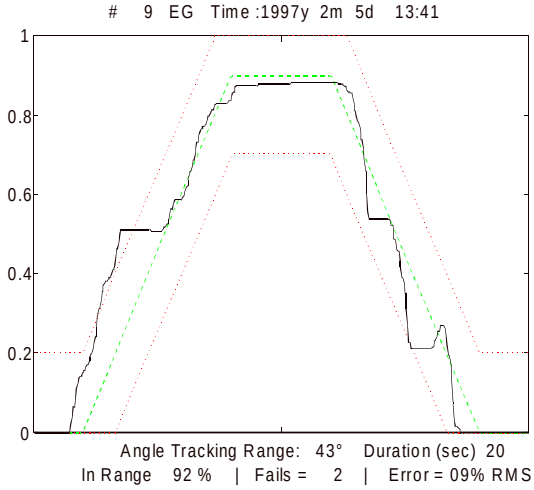
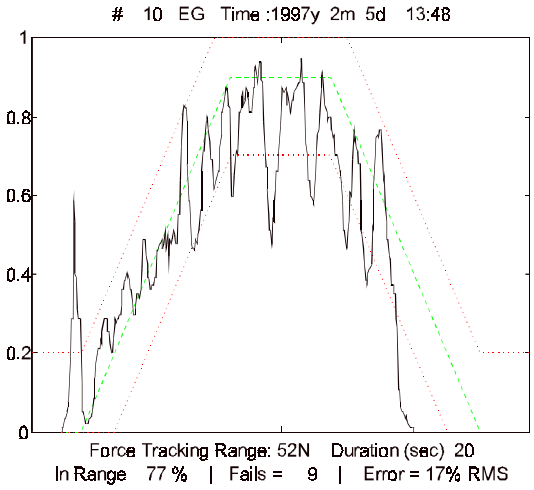
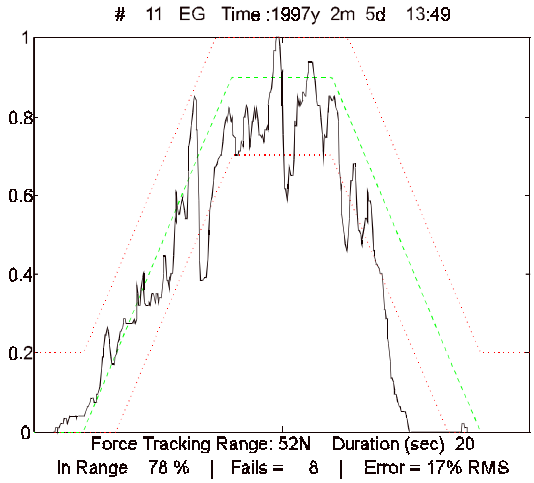
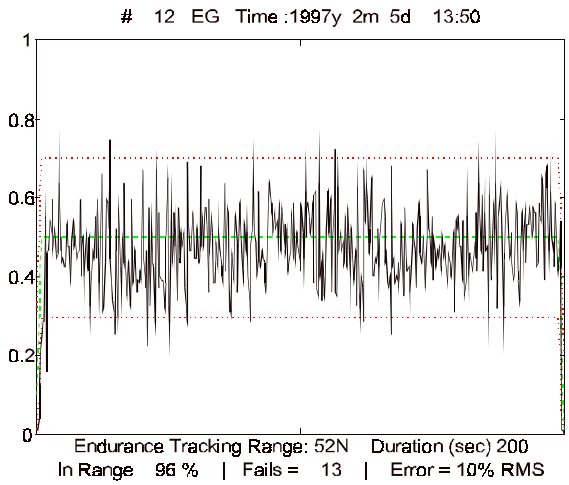
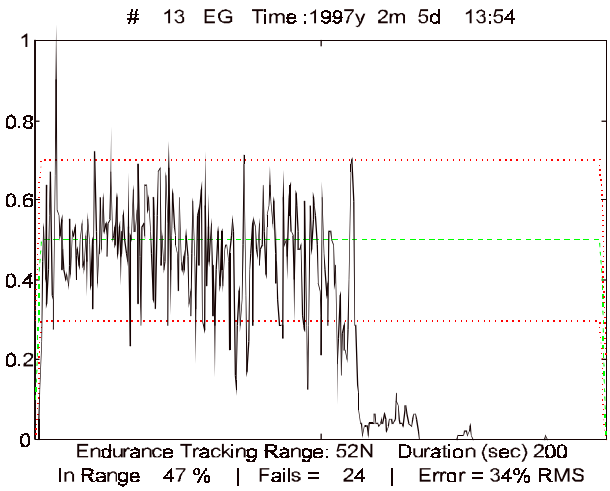
The conclusion for AA is that the MeCFES will only give a insignificant improvement of the wrist extension.

Subj.: AA. Unassisted performance	MeCFES assisted
	
	
	

4.5.2 Participant EG

Participant EG has tested the MeCFES only once before this first tracking test. The left hand is used for the test since the right hand has a muscle transfer and is regarded too strong. She can extend the left wrist against the gravity. As it can be seen on the force tracking test, on next page, she has a good voluntary force of 52N in the wrist extension. This force is not increased significantly by the functional electrical stimulation where she allowed a maximum current of 25mA. Only in the angle test there is a significant difference when using the MeCFES. The span of the wrist angle is about doubled with the MeCFES assistance. The angle tracking test has shown some improvement of the range. The endurance test has shown ability to voluntarily keep 50% maximal contraction for 200 seconds. The endurance test shows a fatigue after 110sec of stimulation. As the time stamp reveals there has been no resting period after the first non MeCFES assisted endurance test. Therefore no conclusion can be made whether the fatigue was induced by the functional electrical stimulation. It was the first time in the course of the project that the endurance test had been applied. On the other endurance tests shown, there has been a resting period between the endurance tests. (Note that the margin is 20% and not 10% as for the other participants.)

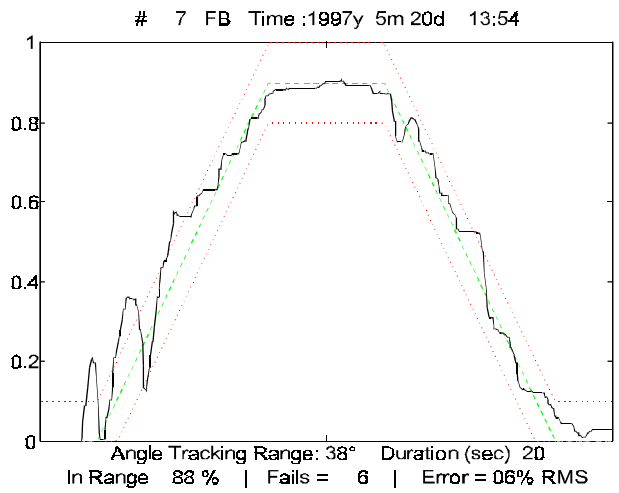
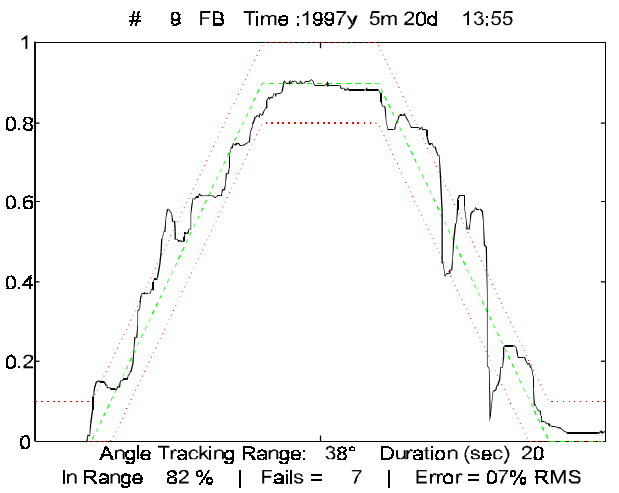
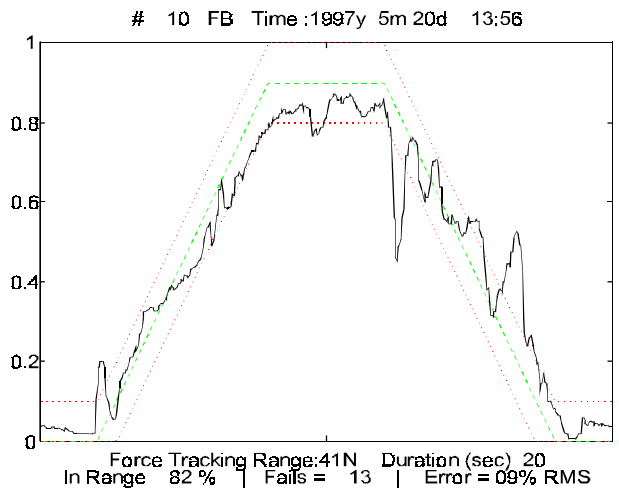
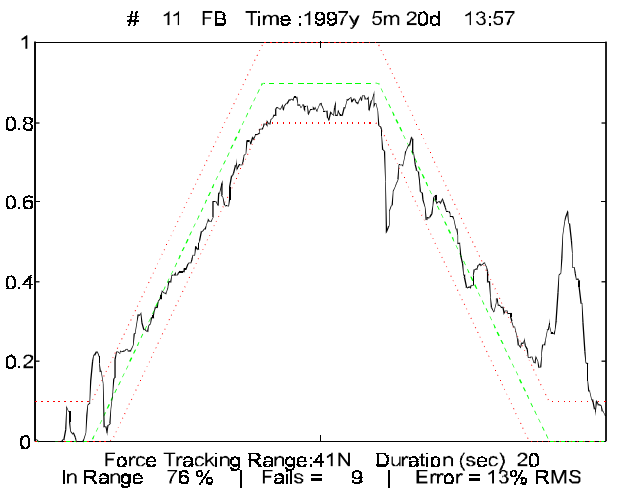
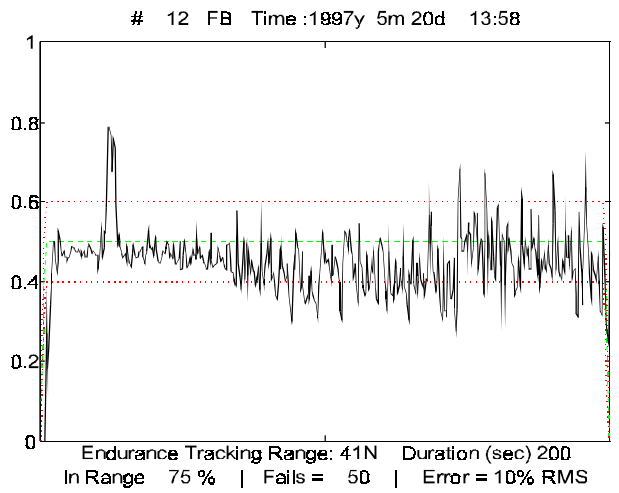
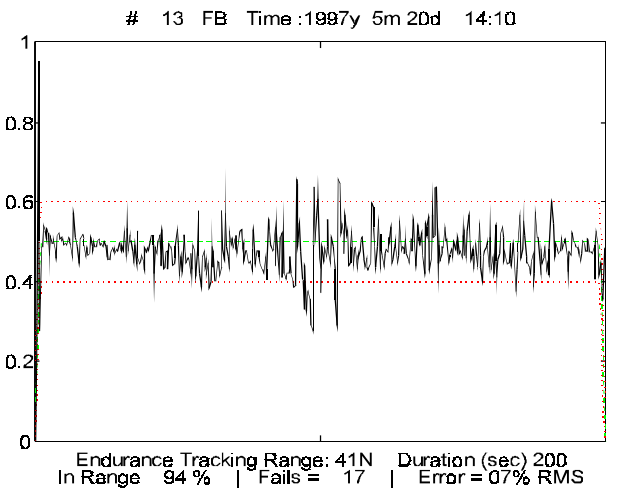
The conclusion for EG is that the MeCFES increases the range of motion for the wrist but force tracking test has no significant improvement.

Subj.:EG. Unassisted performance	MeCFES assisted
	
	
	

4.5.3 Participant FB

It is the first time FB tries the MeCFES. The device has been applied to the left wrist which is the weakest. A voluntary unassisted wrist force of 41N can be exerted by FB by voluntary extension of the wrist. A high stimulation current (>40mA) is required to give any movement which is above the capability of the MeCFES. The tissue showed a high impedance and thus it was not possible to stimulate to a significant force using the MeCFES. As a result there is no difference with the use of the MeCFES as it can be seen on next page.

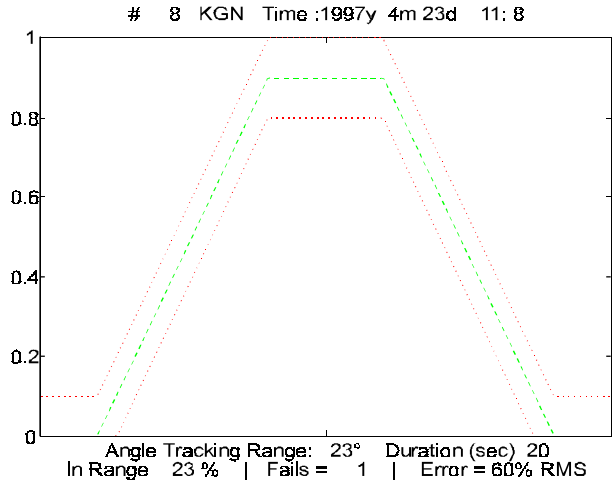
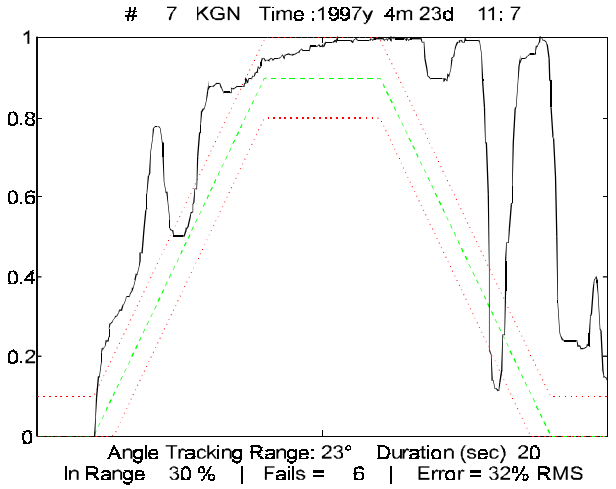
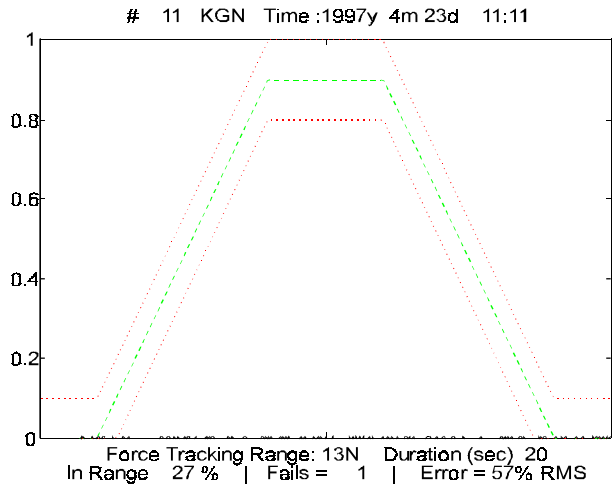
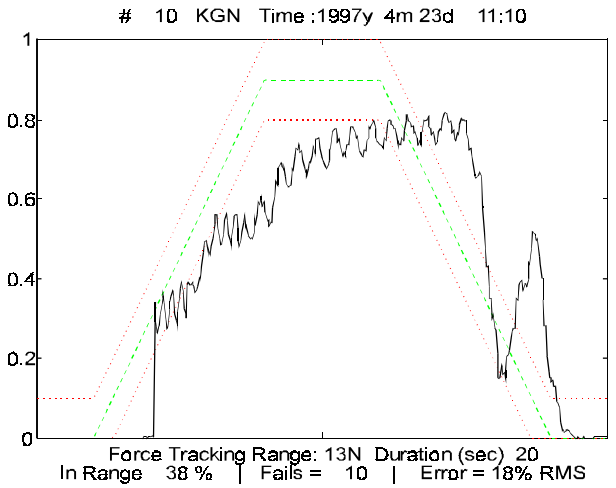
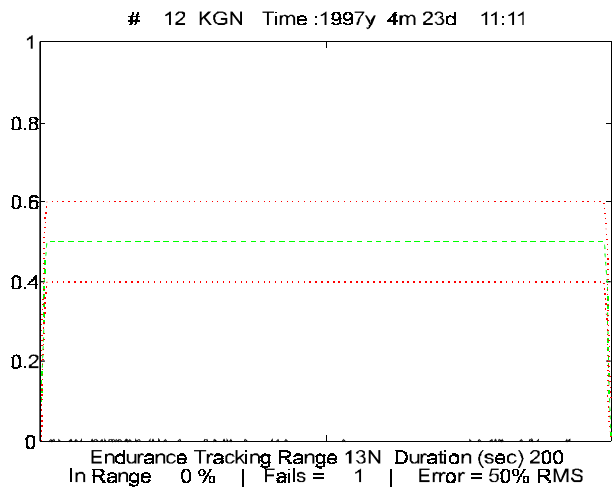
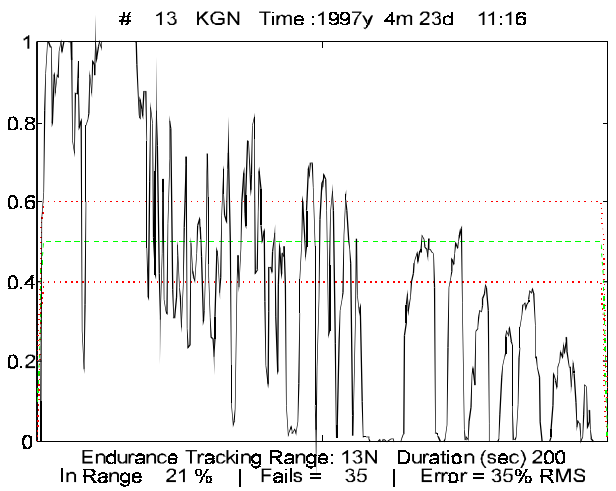
The conclusion for FB is that the MeCFES can not provide the sufficient current.

Subj.: FB. Unassisted performance	MeCFES assisted
	
	
	

4.5.4 Participant: KGN

This is the first time KGN tries the device. He has a very weak right wrist extension and can not perform any movement against gravity. The arm is skinny and a good recording of the myoelectrical signal is possible. There is evidence of very few motor units in the electromyogram. A maximum stimulation current of 20mA was allowed by the participant. The stimulation was affecting the finger extensors and it can be discussed whether it is the finger extensors or the wrist extensors that gives the majority of the wrist extension. The stimulation gave a maximum wrist angle range of 23° and a force of 13N. Spasticity was limiting the range of motion for the wrist. As it can be seen on the next page there is a very significant improvement of the wrist extension by the use of the MeCFES. It is possible for the person to move the wrist 23 degrees with the assistance of the MeCFES. Due to the low MUAP activity the gain is set at such high level that it approaches on/off control as it can be seen on the tests. The endurance test shows that the control is poor and fatigue occurred after 110sec.

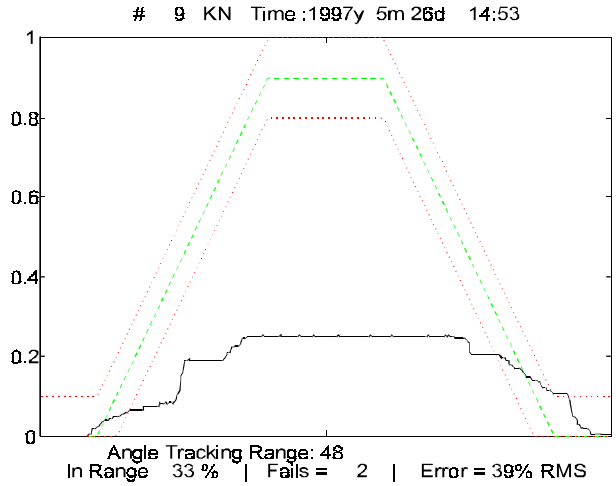
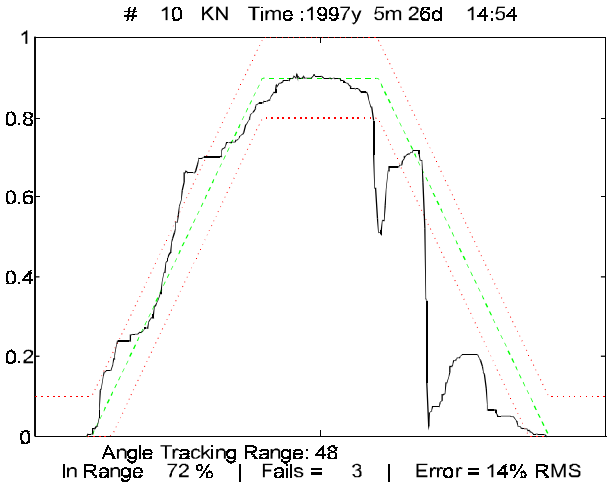
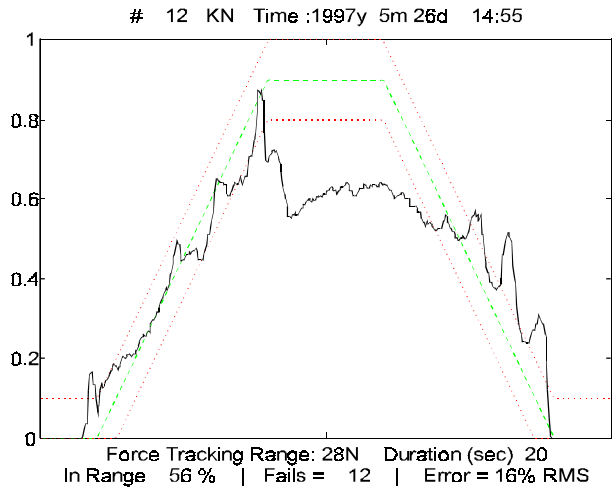
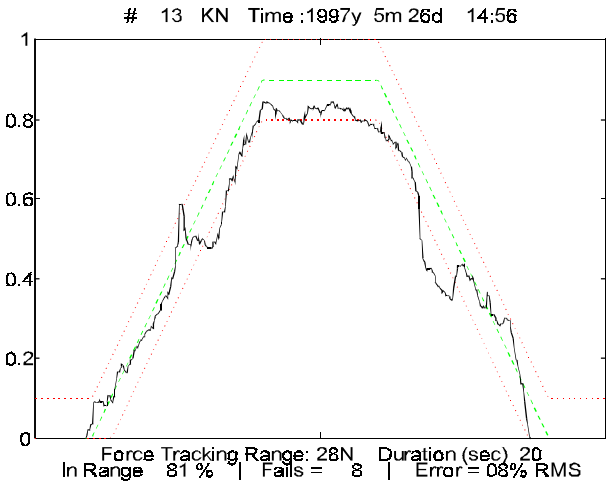
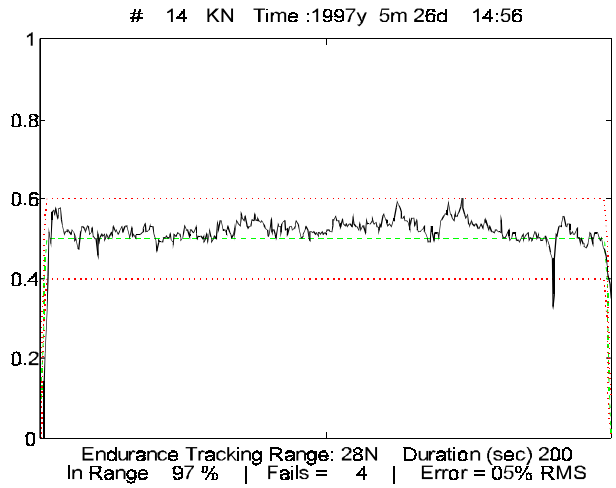
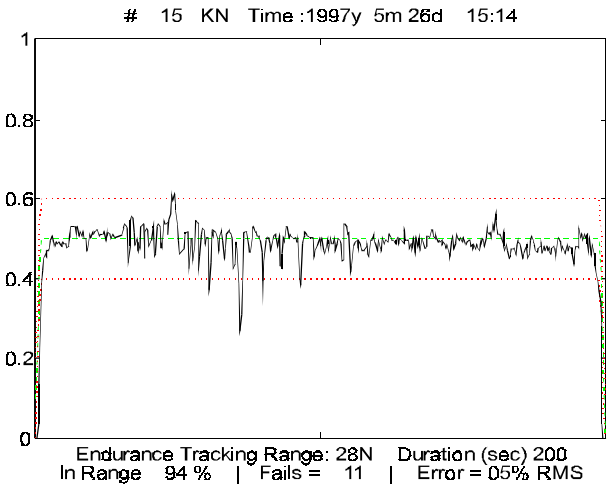
The conclusion for KGN is that the MeCFES gives a movement and force of the wrist that otherwise is not present.

Subj.: KGN. Unassisted performance	MeCFES assisted
	
	
	

4.5.5 Participant: KN

Participant KN has been testing the MeCFES several times during the development process of the system during the project period. She thus has some experience in performing the tracking tests. The experience is that the wrist force is changing somewhat during the years depending on how much she has been training and she has a very mobile wrist. At the time of this test she has a fairly strong voluntary wrist force. The arm is skinny and wrist extension is easily stimulated. She permitted a maximum current of 15mA which gave a force close to the voluntary force. As it appears from the results on next page, it is the angle tracking test where the improvement is significant. In this test she is able to extend the wrist 48 degrees against gravity. Without the MeCFES the maximum angle is 20% of the MeCFES stimulated angle. The force is also increased using the MeCFES. Without the MeCFES she is not able to follow the track above 60% maximum MeCFES stimulated contraction. Looking at the 'In Range' times there is a significant improvement for the angle and force tracking using the MeCFES. On the endurance test there is no significant difference between with or without the MeCFES. This may be due to the fact that the participant is capable of maintaining the 50% by pure voluntary contraction.

The conclusion for KN is that there is a significant improvement of the wrist extension angle and some improvement of the force.

Subj.: KN. Unassisted performance	MeCFES assisted
	
	
	

4.5.6 Summary of Tracking Tests

The endurance test has not been providing much information. It should be set at a higher level than the 50% of maximal contraction. There is a problem in comparing two endurance tests (without- and with- MeCFES) that are done after each other. Fatigue occurring from the first test will influence the second. For this reason the endurance test can not be used in its present form to determine whether the functional electrical stimulation is fatiguing the muscle excessively.

For those tetraplegics with **weak wrist extensors** there is a clear **improvement of the wrist extension** against gravity and isometric wrist force when using the system. Depending on the training and the capabilities of the user this control **is ranging from on/off control to proportional control.**

4.6 Functional Evaluation

When stimulating the wrist extensors in normal subjects it is possible (4 subjects) to find motor points where only the wrist extensor muscle is activated. The findings for normal subjects are, that it is possible to stimulate the wrist extensors selectively without stimulation of the finger extensors. It is thus **possible to obtain the tenodesis** effect where the wrist extension leads to passive flexion of the fingers. For normal subjects, a wrist extension against gravity is obtained at a lower stimulation level than for tetraplegics. Since the **stimulation disturbs the proprioceptive sensation** it is not possible to feel if voluntary contractions are involved. It is for that reason not guaranteed that the muscles in the forearm is fully voluntary relaxed when stimulation is applied.

For most of the tetraplegic participants, a **high stimulation is needed for stimulation** compared to the normal subjects. Their arms, in general, are more skinny with smaller wrist extensors than normal subjects due to atrophy of the muscles. This makes it more difficult to find the motor points for the wrist extensors without undesired stimulation of other muscles. When placing the electrodes where a good wrist extension is obtained, the stimulation usually also affects the finger extensors. As it can be seen in *Appendix C* the extensor carpi radialis (longus/brevis) is located close to the extensor digitorum. This implies the even if the extensor carpi ulnaris is targeted for the wrist extension then the stimulation can effect the finger extensors. This has been found to be the case when

targeting the extensor carpi ulnaris muscles at several tetraplegics. Only in participant EG this stimulation has succeeded without finger extension but resulting in a pronounced sideways extension of the wrist which is not compatible with a grasp.

Since the aim is to used the tenodesis function it is unwanted to stimulate the finger extensors because the use of the tenodesis function requires a flexion of the fingers during extension of the wrist. The finger flexion of the tenodesis function is weak and is easily overrun by **finger extension stimulation**, and thus **prevent the grip**. A way to cope with this can be to cut the tendons of the finger extensors and attach them to the wrist like the way the extensor carpi radialis brevis are naturally attached. This will in addition enhance the stimulated wrist extension force.

By moving the electrodes more towards the radial side the stimulation of the finger extensors can be minimized. The drawback is that the brachioradialis may be affected. This causes supination of the wrist, which is adverse for the lateral pinch grip. This is particularly a problem if the pronating muscles are paralyzed, which they often will be for the tetraplegics and the problem may be even worse if the hand is supinated by contractures. During trials on the test panel it has been observed that, when using adhesive electrodes, pro- and supination can be done without significant change of the stimulated muscle contraction. This is important since this is a unavoidable movements when manipulating objects.

Hand-function tests have been carried out for the five tetraplegics AA, FB, EG, KGN and KN [Asah Medico A/S (DK) et al. 1997]. The hand function test consisted of the task of picking up 6 different types of objects. See Table 4.6-1

Task number	Task	Used grip
1	3 different coins	Key grip
2	A sheet of paper	Key grip
3	An ordinary pencil and writing	Abnormal grip
4	One dining spoon, a fork and a knife	Abnormal grip
5	An Electrical toothbrush	Volar grip
6	A 25cc bottle with water.	Volar grip

Table 4.6-1 The six tests to be performed

None of the participants could use the key grip with MeCFES assistance, using stimulation of the wrist extension.

Participant **AA** could perform task 1-3 and 5 without MeCFES assistance. Unfortunately she became permanently ill and dropped out of the test panel. For that reason only a sporadic hand functions has been evaluated with MeCFES assistance, which showed no functional key grip.

Participant **EG** could only perform task 2 without MeCFES assistance. This could also be performed with MeCFES assistance. **The MeCFES made task 5 and 6 possible**. The bottle was too heavy to carry out drinking but she was **able to take the toothbrush to the mouth and perform brushing of teeth with MeCFES stimulation of the wrist**. This was possible due to the strong tenodesis flexion of the fingers.

The participant **FB could not perform any task without stimulation. By the MeCFES enhanced wrist extension he could perform task 5 and 6.** Again the bottle was too heavy for the tenodesis flexion of the fingers to hold it in drinking position.

Participants **KGN and KN could not perform any task** neither with or without the MeCFES assisted wrist extension. When applying stimulation to the wrist extension an extension of the fingers was not possible to avoid.

The conclusion of the hand function evaluation is that the MeCFES provides two participants with a grip which is the volar grip. The stimulation of the wrist extensor is not sufficient to establish a key grip using the tenodesis function.

4.7 Hand Stimulation Results.

It has been found that stimulation of the hand as described in *2.8.3 Hand Stimulation Technique* flexes the thumb and the fingers in a **useful way**. This stimulation technique has been tested on all tetraplegics and gives a **firm pressure** between the thumb and the index finger. It also gives firm flexion of the 2nd to 5th finger.

Participants EG, KGN and KN have been tested where the hand stimulation was controlled by the extensor carpi radialis muscle using the MeCFES. In all subjects the stimulation resulted in a key-grip. **Using this stimulation method KGN was able to pick up the electric toothbrush using the palmar pinch grip**. It was not attempted to put it to the mouth. In the same way participant **EG** was able to **pick up the electric toothbrush** and put it to her mouth. She **could** take a pencil and **write** her first name (left hand), picking up paper and pick up **cutlery using the lateral pinch grip**. **These tasks were not possible without the MeCFES for hand stimulation**.

With the **stimulation current shared between the hand electrodes and the wrist extension electrodes KN was able to pick up cutlery, a mug and holding paper**. Due to paresis of the rotator muscles in the shoulder she was not able to pass the hand to the mouth but she could carry both the cutlery and the mug towards the mouth.

This configuration, where the wrist extension is controlling the hand stimulation and optionally the extensor carpi radialis muscle, has thus been very successful.

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5. Discussion and Conclusion

5.1 Résumé

The development of a small portable, battery powered device, the MeCFES has been described. The primary goal has been to establish a grip in cervical spinal cord lesioned with paralysis of the hand and paresis of the wrist extensor muscles. By enhancing the wrist extension force the tenodesis function can be used for the key grip. The MeCFES can record the voluntary myoelectrical signal from a muscle and use it for control of functional electrical stimulation of **the same muscle**. The size is 11cm x 7 cm x 3.5cm with a weight of 200g and the device is rechargeable. For a paretic wrist extensor muscle the MeCFES will provide an amplification of the muscle contraction. Both for recording of the myoelectrical signal and for the electrical stimulation surface electrodes attached to the skin are used. A model of the recorded signal has been developed identifying the signal and the sources of noise. It is used to specify the demands to the hardware and software. **The system has been tested by C5 spinal cord lesioned tetraplegics** and the performance has been evaluated by tracking tests and functional tests on 5 tetraplegics.

A pair of **surface recording electrodes** placed over the muscle picks up the signal including the **voluntary myoelectric signal**. This is fed to the MeCFES that amplifies, filters and converts the signal to a control for **the amplitude of a 16Hz biphasic stimulation current**. The stimulation current is applied to the same muscle using a pair of stimulation electrodes. The muscle must have innervated motor units. A part of these can be paralyzed. The muscle must be superficial so it can be reached electrically by the surface electrodes.

5.2 The Technological Context

By the start of the project in 1994 there were found no commercialized products for restoration of the hand function in tetraplegics. Since then, the Handmaster™ from NESS ltd. Israel and the Freehand™ system from NeuroControl Corp.,USA has been launched. The Bionic Glove from University of Alberta, Canada is in approach. None of these systems are using the myoelectric signal as control.

The **Freehand™** system is using implanted electrodes, which give an accurate selective stimulation. Another advantage is that it is an "invisible" system. The MeCFES approach can bee seen as a safe method of testing a functional electrical stimulation (FES) system without having implants. This applies for the user prior to selecting or purchasing a FES system and to the investigation of control/stimulation strategies. **The MeCFES is thus an alternative or supplement to an implanted system**. It may also be seen as the first step towards a MeCFES similar control strategy for an implanted system.

The Handmaster™ and Bionic Glove are both non-invasive systems using surface electrodes for stimulation. Both uses on/off control of the stimulation but, where the Handmaster™ uses a grasp program started by a push button, the Bionic Glove uses a mechanical wrist extension sensor for the control. The control movement for the Bionic glove is then similar to the MeCFES apart from the control being not linear. The MeCFES approach is from the user point of view assumed to be the most convenient control method offering a control of the force. The drawbacks are that the myoelectric signal as a control signal is more unreliable than the movement as a control signal and as it appears from the experiments only few tetraplegics have the type of muscle paresis that is required for the functionality of the MeCFES.

5.3 Progress of the Project

The MeCFES concept was developed and proved feasible by E-U. Haxthausen at The Technical University of Denmark (DTU) in 1992 [Haxthausen 1992]. In continuation S. Sennels, DTU has refined the signal processing and control strategy [Sennels 1996]. Both have provided test results from tetraplegics using the concept. This projects uses the same principles as developed by Haxthausen. The tracking test method used by Haxthausen, has been used as a part of the evaluation of the MeCFES.

The contributions from this project have been:

- Development of minimized dedicated hardware to form a software programmed MeCFES system that can be in a pocket.
- Determining the specifications for MeCFES systems to meet functional and safety requirements. A model for the recorded signal has been proposed and stimulation electrode requirements have been calculated.
- Developing a new type of artefact suppressing amplifier.
- Developing a new stimulator concept.
- Extended evaluation of the MeCFES including hand function test.
- A stimulation method to establish/enhance the key- and volar- grip.
- An electrode mount concept for applying electrodes.

5.3.1 Hardware and Software Evolution

The system used by Haxthausen was non portable since it was designed for research only. The system comprised an amplifier, stimulator as separate units powered by mains supplied power supplies. Signal processing was taken care of by a personal computer. The developed MeCFES is a system where amplifier, stimulator, signal processor unit and power supply is minimized in size. This has required a totally different design of all parts. Special attention has been paid to minimizing the power consumption. The system is now portable and powered by batteries. The software program for the device has been written and control/programming software running on a PC platform has been developed.

5.3.2 Model Evolution

In the minimization of the hardware design, there has been a need for knowing the specifications that the system has to meet. Since the aim is a system for functional use the reliability of the system should be optimal. These items have led to the development of a model of the recorded signal from a stimulated muscle. This reveals the possible problems and demands to the signal processing.

5.3.3 Signal Processing Evolution

The digital signal processing is using a more simple filter than Haxthausen proposed. A new method (threshold counting) for converting the voluntary myoelectric signal to a control for stimulation is proposed and used. No objective measurements on whether this method is better than the average rectified value method used by Haxthausen (and many others), has been performed by experiments on tetraplegics.

5.3.4 Amplifier Enhancement

Typical amplifiers as well as the one designed by Haxthausen or Sennels have a high-pass filter that can prolong the stimulation artefacts as described in section *2.5 Signal Amplification.* Since a low voltage amplifier is more sensitive to this problem it has been necessary to find a solution. **A novelty in the hardware design is the MeCFES amplifier.** It is different from other amplifiers in the way the high pass filtering is achieved. **The MeCFES amplifier is a stimulation artefact suppressing fast recovery amplifier** that enables the recording of the myoelectrical signal in the presence of short pulses that are several orders of magnitude larger than the desired signal. Another feature of the amplifier is the fast recovery from DC offset changes in the input signal. This can be caused by a change in the half-cell potential of the recording electrodes due to mechanical actions. SPICE™ simulations of the conventional amplifier and the MeCFES amplifier have shown that the MeCFES amplifier is better suited for the purpose. Recordings on the amplifier have verified the simulation result.

5.3.5 Stimulator Development

The low size and low power consumption demands could not be met by the stimulator design used by Haxthausen. For that reason the stimulator has been totally redesigned Three different concepts have been developed and tested.

5.3.6 New Experiments

The tracking test performed on the 5 tetraplegics has the same concept as used by Haxthausen but has been expanded by the endurance test.

The tracking tests showed that there is a better control of an increasing force or angle than of a decreasing force or angle, where the angle is the angle of wrist extension against gravity. The participants with high muscle strength have better control than those with low muscle strength. A participant (subj.: KGN) with the weakest voluntary unassisted wrist extension which was less than a 2° angle against gravity obtained a 23° angle against gravity by use of the MeCFES. For the same person the MeCFES amplified the isometric muscle force from 1N to 13N. The **force/angle amplification** ranged from 1 (i.e. no improvement) for the strongest participant to a magnitude of 10 times for the weakest participant.

The results in form of the root mean square of the error are summarized in Table 5.1. An error of 57% is corresponding to no movement at all. First number is the tracking error without the MeCFES and second number is with use of the MeCFES.

Subj:	AA	EG	FB	KGN	KN
Angle range	32°	43°	38°	23°	48°
Error % RMS	9 | 9	28 | 9	8 | 7	60 | 32	39 | 14
Force range	16N	52N	41N	13N	28N
Error % RMS	19 | 17	17 | 17	9 | 13	57 | 18	16 | 8
Endurance	50% 16N	50% 52N	50% 41N	50% 13N	50% 28N
Error % RMS	10 | 10	see *4.5.2*	10 | 7	50 | 35	5 | 5

Table 5.1 Summary of the tracking test results. Results without | with the MeCFES.

Only in the subjects EG, KGN and KN the MeCFES gives an improvement of the movement. As found by Haxthausen and Sennels it is difficult for the tetraplegics to control the stimulation of an accurate movement. Sennels has shown that a reason for this is that the myoelectric signal is not a reliable control signal. Control appears to be particularly difficult for a decreasing muscle contraction.

The degree of precision depends on the subject, the remaining voluntary muscle strength and how well the various signal processing parameters are adjusted. The condition of the

subject (concentration, fatigue etc.) affects the performance and must thus be considered. A conclusion of the tracking tests is that the precision of the MeCFES assisted movement is history dependent. **An increasing contraction is more accurately controlled than a decreasing contraction**. This is explained by the non-linearity of the muscle. To further clarify the reasons for control difficulties, recordings of the recruitment curves (stimulation vs. muscle contraction) have been performed. **It is found that the recruitment curve has a hysteresis-like shape**, where the gradient of the current-output relation for an increasing current differs from a decreasing current. The decreasing slope is very steep. Less current is required to generate a certain muscle contraction from a previous high contraction than from a low contraction. This phenomena is assumed to be the main problem in controlling a moderate contraction. The control problem is not only the reliability of the myoelectric signal but also due to this recruitment curve.

This project presents the first evaluation of the MeCFES principle by functional tests. The conclusion of functional tests is that stimulating the wrist extensor solely provides no pinch grip due to finger extension but can provide a volar grip in 2 out of the 5 tetraplegic participants. This is in accordance to the movement analysis performed by Sennels, where it was concluded that the pinch grip is not feasible to obtain only by surface stimulation of the extensor carpi radialis muscle.

5.3.7 New Stimulation Approach

As a spin off from the experiments, an efficient method of stimulating the hand muscles to obtain both key grip and volar grip has been found. This stimulation method has been possible on all participants. It has been found that the stimulation is suited for control by the wrist extension. Letting the wrist extensor controlled MeCFES stimulate the hand muscles, a **useful grip** was established **in 3 out of 3** tetraplegic participants.

5.3.8 Electrode mount

A concept for a electrode mount, allowing easy placement of the electrodes has been designed. Together with the MeCFES the electrode mount will comprise the complete system that can be used at home by tetraplegics. The electrode mount is not tested.

5.4 Future Aspects of the MeCFES

Letting the MeCFES control stimulation of the muscles in the hand provides a good controlled grip. This stimulation can be a supplement to the stimulation of extensor carpi radialis to augment wrist extension. A way to compensate for this is to stimulate thumb flexion and finger flexion controlled by the MeCFES. Wrist extension will then control a functional electrical stimulation enhanced tenodesis function, which provides the user with a useful grasp**. The conclusion is that the MeCFES should additionally stimulate selected muscles in the hand**. In general the **MeCFES can be used for all muscles** where the voluntary myoelectrical signal can be recorded and the muscle can be stimulated by use of surface electrodes. The device has in its present state one channel for recording and one for stimulation, but can be extended to more channels by adding stimulator modules, amplifier modules and a minor software modification.

The principle of the MeCFES has advantages and disadvantages. It is a supplement to existing and future devices for hand function restoration. For the Handmaster™ that is using surface electrodes and has a well functioning electrode mount system, the MeCFES principle would be well suited. Instead of the trigger button, the wrist extensor muscles could control the stimulation. The muscles stimulated are near the controlling muscle, which requires the same stimulation artefact suppressing features as in the original MeCFES principle. This would provide the user with better control of the grasp and faster grip release opportunity. For the Bionic Glove, which already uses the wrist extension, the MeCFES approach will be less attractive, but can maybe be used as an alternative to the mechanical wrist angle transducer.

The system has been developed for restoration of wrist extension but there is reason to assume that the methods are **applicable to all paretic muscles**. It may therefore in addition be used in **paraplegia and hemiplegia** to **assist lower limb movements**. Such applications could be a foot-drop stimulator control and hip extension/flexion in standing and walking. If the method shows feasible in longer terms of use, it can be used for control of implanted systems as well. For example the Freehand™ implant system could be controlled by use of the MeCFES principle, forming a hybrid using both surface electrodes and implanted electrodes.

Besides for the MeCFES application, the **amplifier** relates generally to the field of recording biopotential signals from tissue that is simultaneously stimulated and thus **extends to other applications** than the MeCFES. An example could be recording of electrocardiograms during electroshock and evoked potentials e.g. from brain stimulation.

As a further result of the MeCFES development, the system can be used for acquisition of myoelectrical signals in general. The system can thus be used for a recording of spasticity in a muscle. This is an application that might find its use in clinical evaluation of a range of patients besides the spinal cord lesioned.

5.5 General Discussion

For a reliable system it might be inadequate to maintain the linear control, since this is not a robust control as found by Sennels or Saxena. These and other works have proposed a finite state control i.e. the myoelectric signal is classified in different levels, where the most simple is the on/off control. Functional tests of a MeCFES using linear control and a MeCFES using on/off (maybe intermediate states) control should be compared.

The MeCFES must be expanded to stimulate the hand to the grip. This approach should be tested on several tetraplegics and the fraction of the population of tetraplegics that can benefit from the device must be found. The tests must be compared to the tests of the Handmaster™.

In this project the threshold count method of processing of the myoelectric signal should have been compared systematically to the use of average rectified value. The choice of signal processing is important to obtain best possible result and must therefore be investigated further.

The hardware needs too many corrections in its present form. The efficiency of the power supply and the performance of the stimulator are insufficient. The software is not easy to use for non-engineers and calls for a user-friendly interface.

The design and testing of an cosmetic acceptable and easy-to-use electrode mount is essential for the success of the system.

5.6 Market needs

The tentative marketing analysis shows a need for 400 devices/year in Europe and 500 in USA. The function of the device is very attractive for the users. The **use of surface electrodes is essential** and provides an alternative to surgical implanted electrodes. It will be relatively simple to apply to the customer and easy to service since it is a non-invasive system.

5.7 Conclusion

The development of a myoelectrical controlled functional electrical stimulator has resulted in a functional prototype, a portable MeCFES device. Its ability to enhance wrist extension has been tested on 5 tetraplegics with muscle strength in the range from 1 to 4 (MRC scale). The tests have shown that the MeCFES gives an **enhanced force and movement range of the wrist to which it is applied**. The technique is most feasible for tetraplegics with a weak wrist extension. Tracking tests have shown that a MeCFES assisted movement can be controlled, but not with the same precision as a normal voluntary movement. The precision ranges from nearly normal control to on/off control.

The conclusion is that the **MeCFES is a feasible concept for restoration of hand function in spinal cord lesioned persons**. It is a technological platform from which there are possibilities for further evolution of functional electrical stimulation aids for disabled. **It offers a complimentary solution to implanted systems**, allowing the potential recipients of this device to test the benefits from functional electrical stimulation, **in a simple non-invasive way**, before making a decision for a permanent functional electrical stimulation system. There are on the other hand still many practical problems that have to be solved before the MeCFES can be commercialized. This applies especially to the design of the electrode mount and the robustness of the device.

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Literature

Andreassen, S., *Interval Pattern of Single Motor Units*, Aalborg,Denmark: Aalborg Universitetsforlag, 1978.

Asah Medico A/S (DK), SCI-centre Copenhagen University Hospital (DK), Consort Engineering (UK), and O.R.L.A.U. Jones&Hunt Hospital (UK), "Final Report, EPCES Project no 1083 of the TIDE programme,EEC.," Danish Technological Institute, Taastrup, Denmark 1997.

Babb, T. L., E. Maiani, G. M.Strain, J. P. Lieb, H. V. Soper, and P. H. Crandall, "A Sample and Hold Amplifier System For Stimulus Artifact Suppression," *Electroencephalography and Clinical Neurophysiology*, vol. 44, pp. 528-531, 1978.

Benton, L. A., L. L. Baker, B. R. Bowman, and R. L. Waters, *Functional Electrical Stimulation - a practical clinical guide*, 2 ed. Downey: Rancho los Amigos Hospital, 1981.

Bilodeau, M., M. Cincera, S. Gervais, A. B. Arsenault, D. Gravel, Y. Lepage, and P. McKinley, "Variations in the shape of the EMG power spectrum during an increasing force level," *Proceedings of the Annual Conference on Engineering in Medicine and Biology*, vol. 15, pp. 1206, 1993.

Biering-Sørensen, F. (Personal communication) 1994-1997.

Buchthal, F. and H. Schmalbruch, "Motor Unit of Mammalian Muscle," *Physiological Reviews*, vol. 60, pp. 90-131, 1980.

Crago, P. E., P. H. Peckham, J. T. Mortimer, and J. P. Van der Meulen, "The choice of pulse duration for chronic electrical stimulation via surface, nerve, and intramuscular electrodes," *Ann.Biomed.Eng.*, vol. 2, pp. 252-264, 1974.

DeLuca, C. J., "Precision Decomposition of EMG Signals," *Methods in Clinical Neurophysiology*, vol. 4, pp. 1-28, 1993.

Falck, B., E. Stålberg, and C. Bischoff, "Sensory Nerve Conduction Studies with Surface Electrodes," *Methods in Clinical Neurophysiology*, vol. 5, pp. 1-20, 1994.

Feinstein, B., B. Lindeg†rd, E. Nyman, and G. Wohlfart, "Morphologic studies of motor units in normal human muscles," *Acta Anatomica*, vol. 23, pp. 127-141, 1954.

Gracanin, F. and A. Trnkoczy, "Optimal stimulus parameters for minimum pain in the chronic stimulation of innervated muscle," *Arch.Phys.Med.Rehabil.*, vol. 56, pp. 243-249, 1975.

Graupe, D. and K. H. Kohn, "A critical review of EMG-controlled electrical stimulation in paraplegics," *Critical Reviews In Biomedical Engineering*, vol. 15, pp. 187-210, 1987.

Gray, *Gray's Anatomy*, 35 ed. London: Longmann, 1973.

Hall, H. E. and W. A. Munday, "Electromyographic Treatment Device," in *US Patent*, 1994.

Handmaster, *Clinical Handbook (users manual)*. Israel: Ness Ltd., 1996.

Hartkopp, A., "Personal Communication," , 1996.

Haugland, M. and J. A. Hoffer, "Slip Information Provided by Nerve Cuff Signals: Application in Closed-Loop Control of Functional Electiical Stimulation," *IEEE Transactions on Rehabilitation Engineering*, vol. 2 No. 1, pp. 29-36, 1994.

Haugland, M. K. and J. A. Hoffer, "Artifact-free sensory nerve signals obtained from cuff electrodes during functional electrical stimulation of nearby muscles," presented at IEEE Transactions on Rehabilitation Engineering, 1994.

Haugland, M. K. and T. Sinkjær, "Cutaneous Whole Nerve Recordings Used for Correction of Footdrop in Hemiplegic Man," *IEEE Transactions on Rehabilitation Engineering*, vol. 3, No.4, pp. 307-317, 1995.

Haugland, M. K., A. Hoffer, and T. Sinkjaer, "Skin contact force information in sensory nerve signals recorded by implanted cuff electrodes," *IEEE Transactions.on.Rehabilitation.Engineering.v.2.n.1.Mar.1994.*, pp. 28, 1994.

Haxthausen, E.-U., "Restoration of wrist extension using functional electrical stimulation controlled by the remaining voluntary EMG from the stimulated muscles," in *Electronics Institute*. Lyngby: The Technical University of Denmark, 1992, pp. 140.

Haxthausen, E.-U., F. Biering-Sørensen, K. Dahl, S. D. Hansen, and O. T. Andersen, "Restoration of key grip in SCI patients, An attempt using FES controlled by emg from the stimulated muscle," presented at New theoretical and applied approaches in the restoration of impaired motor control, Milano, 1991.

Hermens, H. J., "Surface EMG," . Enchede: Universiteit Twente, 1991, pp. 111.

Hines, A. E., N. E. Owens, and P. E. Crago, "Assessment of input-output properties and control of neuroprosthetic hand grasp," *IEEE Transactions on Biomedical Engineering*, vol. 39, pp. 610-623, 1992.

Holländer, H. J. e. a., "An EMG Controlled Multichannel Stimulator," presented at The Ninth Int. Symp. on External Control of Human Extremities, Belgrade, 1987.

Howson, D. C. and J. E. Heule, "Electronic Circuit Permitting Simultaneous use of Stimulating and Monitoring Equipment," in *US Patent*, 1980.

IJzerman, M. J., T. S. Stoffers, F. A. C. G. i. t. Groen, M. A. P. Klatte, G. J. Snoek, J.H.C.Vorsteveld, R.H.Nathan, and H.J.Hermens, "The NESS Handmaster orthosis: restoration of hand function in C5 and stroke patients by means of electrical stimulation," *Journal of rehabilitation sciences*, vol. 9, pp. 86-89, 1996.

Jensen, A. F., *Filterteori I*, Lyngby: Institute of Circuit Theory and Communication, Technical University of Denmark, 1987.

Justesen, J. and S. Forchhammer, "Signalanalyse," in *Instituttet for Teleteknik*. Lyngby,Denmark: Technical University of Denmark, 1992.

Keith, M. W., K. L. Kilgore, and P. H. Peckham, "Tendon Transfers amd Functional Electrical Stimulation for Restoration of hand Function in Spinal Cord Injury," , 1996.

Keith, M. W., P. H. Peckham, and Thrope Geoffrey B., "Implantable functional neuromuscular stimulation in the tetraplegic hand," *Journal of Hand Surgery*, 1996.

Kendall, F. P., H. O. Kendall, and E. K. McCreary, *Muscles Testing and Function*, Baltimore: Williams & Wilkins, 1983.

Kilgore, K. L., P. H. Peckham, and M. W. Keith, "An Implanted Upper Extremity Neuroprostehesis: A Six Patient Follow-up," *Journal of Bone and Joint Surgery*, 1996.

Kitzenmaier, P. and U. Boenick, "Möglichkeiten der Störsignalerkennung und -unterdrueckung in EMG- Signalen," *Biomedizinische Technik*, vol. 38, pp. 219-223, 1993.

Kwatny, E., D. H. Thomas, and H. G. Kwatny, "An application of signal processing techniques to the study of myoelectric signals," *IEEE.Trans.Biomed.Eng.*, vol. 17, pp. 303-313, 1970.

Langvad, J., *Aktive filter, Sådan laves de*, København: Teknisk Forlag A/S, 1987.

Merletti, R., M. Knaflitz, and C. J. DeLuca, "Electrically evoked myoelectric signals," *Crit.Rev.Biomed.Eng.*, vol. 19, pp. 293-340, 1992.

Minzly, J., J. Mizrahi, N. Hakim, and A. Liberson, "Stimulus artefact suppressor for EMG recording during FES by a constant-current stimulator," *Med.Biol.Eng.Comput.*, vol. 31, pp. 72-75, 1993.

Mizrahi, J., M. Levy, H. Ring, E. Isakov, and A. Liberson, "EMG as an indicator of fatigue in isometrically FES-activated paralyzed muscles," *IEEE Transactions on Rehabilitation Engineering*, vol. 2, pp. 57-65, 1994.

Mortimer, J. T., "Motor prosthesis," in *Handbook of Physiology I, The nervous system*, Williams and Wilkins, Eds., Am. Physiol. Society, 1984, pp. 155-187.

Mulcahey, M. J., R. R. Betz, B. T. Smith, A. A. Weiss, and S. E. Davis, "Implanted Functional Electrical Stimulation Hand System in Adolescents With Spinal Injuries: An Evaluation," *Arch Phys med Rehabil*, vol. 78, pp. 597-607, 1997.

Møller, P. K. and J. A. Sørensen, "Adaptiv Signalbehandling," in *Elektronisk Institut*. Lyngby: Danmarks Tekniske Højskole, 1992.

Netter, F., "Musculoskeletal System," in *THE CHIBA COLLECTION OF MEDICAL ILLUSTRATIONS*, vol. 8, *The Ciba Colletion of Medical Illustrations*. New Jersey: CIBA-Geigy corporation, 1986.

Netter, F., "Nervous System," in *THE CHIBA COLLECTION OF MEDICAL ILLUSTRATIONS, Vol 1.*: CIBA, 1986.

Nikolic, Z. M., D. B. Popovic, R. B. Stein, and Z. Kenwell, "Instrumentation for ENG and EMG recordings in FES systems," *IEEE Transactions on Biomedical Engineering*, vol. 41, pp. 703-706, 1994.

Petersen, T. and B. Klemar, "Electrical Stimulation as a Treatment of Lower Limb Spasticity," *Neuro Rehab*, vol. Vol.2, No.3,, pp. 103-108, 1988.

Popovic, D. B., R. B. Stein, K. L. Jovanovic, R. Dai, A. Kostov, and W. W. Armstrong, "Sensory nerve recording for closed-loop control to restore motor functions," *IEEE.Trans.Biomed.Eng.*, vol. 40, pp. 1024-1031, 1993.

Prochazka, A. and M. Wieler, "The Bionic Glove:Information Sheet," 1994. Correspondance.

Prochazka, A., M. Gauthier, M. Wieler, and Z. Kenwell, "The Bionic Glove: An Electrical Stimulator Garment That Provides Controlled Grasp and Hand Opening in Quadriplegia," *Arch Phys Med Rehabil*, vol. 78, pp. 608-614, 1997.

Rushton, D., "CNS can control motor units individually" : Personal Communication, 1997.

Saridis, G. N. and T. P. Goothe, "EMG Pattern Analysis and Classification for a Prosthetic Arm," *IEEE Transactions on Biomedical Engineering*, vol. 6, pp. 403-412, 1982.

Saxena, S., S. Nikolic, and D. Popovic, "An EMG-controlled grasping system for tetraplegics," .*J Rehabil.Res.Dev.*, vol. 32, pp. 17-24, 1995.

Schmalbruch, H., *Handbook of Microscopic Anatomy:Vol.II/6:Skeletal Muscle*, Berlin: Springer-Verlag, 1985.

Schmidt, R. F. and G. Thews, *Human Physiology*, 20 ed: Springer-Verlag, 1983.

Sennels, S., "Functional Electrical Stimulation for Rehabilitation of an EMG-Controlled Lateral Pinch Grip," The Technical University of Denmark, Lyngby,Denmark, Ph.D Thesis. 1996.

Sennels, S., F. Biering-Sørensen, O. T. Andersen, and S. D. Hansen, "Functional Neuromuscular Stimulation Controlled by Surface Electromyographic Signals Produced by Volitional Activation of the Same Muscle: Adaptive Removal of the Muscle Response from the Recorded EMG-Signal," *IEEE Transactions on Rehabilitation Engineering*, vol. 5, pp. 195-206, 1997.

Sennels, S., R. Thorsen, F. Biering-Sørensen, S. D. Hansen, and O. T. Andersen, "EMG-Controlled Wrist Extension," *5th Vienna Int. Workshop Func. Elect. Stim.*, pp. 417-420, 1995.

Seymour, L., "Bionic glove's Home Page (http://www.srv.ualberta.ca/~aprochz/bg.html)," *World Wide Web*, 1996.

Shannon, R., "A Model of Safe Levels for Electrical Stimulation," *IEEE Transactions on Biomedical Engineering*, vol. 39, pp. 424-427, 1992.

Smith, B. T., "Quantitative comparison of grasp and release abilities with and without functional neuromuscular stimulation in adolescents with tetraplegia.," *Paraplegia*, vol. 34, pp. 16-23, 1996.

Stålberg, E. and B. Falck, "Clinical Motor Nerve Conduction Studies," *Methods in Clinical Neurophysiology*, vol. 4, pp. 61-80, 1993.

Stålberg, E. and J. Trontelj, *Single Fiber Electromyography, Studies in Healthy and Diseased Muscle*, 2 ed. New York: Raven Press, 1994.

Tam, H. W. and J. G. Webster, "Minimizing Electrode Motion Artifact by Skin Abration," *IEEE Transactions on Biomedical Engineering*, vol. 24, pp. 134-139, 1977.

Tarkka, I. M., "Short and Long Latency Reflexes in Human Muscles Following Electrical and Mechanical Stimulatation," *Acta Physiologica Sacnsinavica*, vol. Supp. 557, pp. 5-28, 1986.

Thorsen, R., "Elektrisk stimulation af lammede muskler, Hovedrapport," in *Electronics Institute*, 1 ed. Lyngby, Denmark: Technical University of Denmark, 1994.

Webster, J. G., "Reducing Motion Artifacts and Interference in Biopotential Recording," *IEEE Transactions on Biomedical Engineering*, vol. 31, pp. 823-826, 1984.

Webster, J. G., *Medical Instrumentation*, 2 ed. Boston: Houghton Mifflin, 1992.

Ylvisaker, C. J., "Patient Inititiated Response Method," in *US Patent*, 1986.

Yoshida, K. and K. Horch, "Closed-Loop Control of Ankle Position Using Muscle Afferent Feedback with Functional Neuromuscular Stimulation," *IEEE Transactions on Biomedical Engineering*, vol. 43, pp. 167-175, 1996.