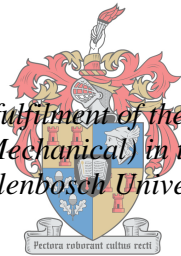


An affordable robotic-assisted rehabilitation device for the treatment of stroke and spinal cord injury

by
Ariël Basson

Thesis presented in partial fulfilment of the requirements for the degree of Master of Engineering (Mechanical) in the Faculty of Engineering at Stellenbosch University



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March 2018

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Abstract

An affordable robotic-assisted rehabilitation device for the treatment of stroke and spinal cord injury

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A prototype robotic-assisted pedalling device for stroke and spinal cord injury (SCI) treatment was produced. The device had to be more affordable than current technology, such as the MOTomed leg trainer, and capable of facilitating functional recovery through active-assisted motion.

The prototype uses a servomotor to indirectly drive or assist pedal motion through a planetary gear box (PGB). The planet-arm and sun gear shaft of the PGB are respectively driven by the motor and pedal inputs. A friction brake loads the planetary ring gear in such a way that slight movement of the ring gear is still possible. This allows more power to be transferred from the motor to the pedals, without causing a direct drive between the pedals and the motor. Releasing the friction brake from the ring gear disconnects the motor drive to the pedals. This serves as a mechanical safeguard against unexpected motor behaviour.

A rotary encoder measures the actual pedalling speed that is achieved during training sessions with the device. The control system regulates the motor speed according to the magnitude of the error between the actual pedalling speed, and a target pedalling speed of 40 rpm. A negative error indicates that the user is struggling to reach or maintain the target speed. Consequently, the control system increases the motor input for more assistance. Similarly, the motor speed is reduced when a positive error exists, so as to increase the pedalling resistance. The device includes a pushbutton user interface with an LCD screen, which displays training time and pedalling speed during operation.

A randomised controlled study was conducted on two stroke inpatients and two stroke outpatients admitted to Vincent Pallotti Hospital's rehabilitation unit. No SCI patients were available to participate in the study. Both the

control and test group received conventional therapy either two or five times a week. Additionally, test subjects completed 60 minutes of device training every week, for four consecutive weeks. Functional outcome measures related to muscle strength (LEMS), spasticity (MAS), sit-to-stand time and over ground walking ability (TUG test and WISCI II) were evaluated throughout the study.

All the participants showed functional improvement in their muscle strength and sit-to-stand times. Outpatient results indicated favour towards training with the device. In contrast, inpatient results showed more improvements after conventional therapy alone. The results were inconclusive, and the intended test procedures for the study could not be implemented. A larger scale study is needed to confirm the efficacy of device treatment for functional improvement after stroke and SCI. Future studies need to eliminate differing variables and unequal treatment times among participants.

Uittreksel

'n Bekostigbare robot-geassisteerde rehabilitasietoestel vir die behandeling van beroerte en rugmurgbesering

(“An affordable robotic-assisted rehabilitation device for the treatment of stroke and spinal cord injury”)

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Departement Meganiese en Megatroniese Ingenieurswese

Tesis: MIng (Meg)

Maart 2018

'n Prototipe van 'n robot-geassisteerde traptoestel vir die behandeling van beroerte en rugmurgbesering is geproduseer. Die toestel moes goedkoper wees as huidige tegnologie, soos die MOTOMed beenrehabiliteerder, en daartoe in staat wees om die herstel van funksionaliteit deur aktief-geassisteerde beweging te bevorder.

Die prototipe maak gebruik van 'n servomotor om die trapaksie indirek deur 'n planetêre ratkas aan te dryf of te assisteer. Die planeet-arm en sonratas van die planetare ratstelsel word onderskeidelik deur die motor en inset vanaf die pedale aangedryf. 'n Wrywingsbriek rem die planetare ringrat op so 'n manier dat effense beweging van die ringrat steeds moontlik is. Dit laat toe dat meer drywing vanaf die motor na die pedale oorgedra word, sonder dat die motor die pedale direk aandryf. Die kraguitset vanaf die motor na die pedale word ontkoppel deur die wrywingsbriek vanaf die ringrat te lig. Hierdie dien as meganiese beskerming teen 'n onverwagse kraginset vanaf die motor.

'n Enkodeerder meet die werklike trapspoed wat gehandhaaf word tydens oefensessies met die toestel. Die beheerstelsel reguleer die spoed van die motor na gelang van die grootte van die verskil tussen die werklike trapspoed en 'n teikentrapspoed van 40 revolusies per minuut. 'n Negatiewe verskil dui daarop dat die gebruiker sukkel om die teikenspoed te haal of te handhaaf. Derhalwe verhoog die beheerstelsel die motorinset vir meer bystand. Soortgelyk word die motorspoed verminder wanneer 'n positiewe verskil ontstaan, sodat die weerstand teen trap verhoog word. Die toestel sluit 'n drukknop-gebruikerskoppelvlak met 'n LCD skerm in wat die oefentyd en trapspoed tydens werking vertoon.

'n Ewigkansige gekontroleerde studie is uitgevoer op twee binnepatiënte en twee buitepatiënte wat by Vincent Pallotti Hospitaal se rehabilitasie-eenheid opgeneem is. Geen pasiënte met rugmurgbesering was beskikbaar vir deelname aan die studie nie. Beide die kontrole- en toetsgroep het konvensionele terapie twee of vyf keer 'n week ontvang. Aanvullend tot dit, het toetspatiënte weekliks 60 minute van oefening met die toestel voltooi, vir vier weke aaneenlopend. Funksionele uitkomsmaatstawwe wat verband hou met spiersterkte (LEMS), spastisiteit (MAS), sit-tot-staan tyd en oorgondse loopvermoëns (TUG-toets en WISCI II) is ondersoek tydens die studie.

Al die deelnemers het funksionele verbetering in hul spiersterkte en sit-tot-staan tye getoon. Buitepatiënte se resultate het daarop gedui dat dit gunstig is om met die toestel te oefen. In teenstelling hiermee het binnepatiënte se resultate meer verbetering getoon na slegs konvensionele terapie. Die resultate was onoortuigend en die voorgenome toetsprosedures vir die studie kon nie toegepas word nie. 'n Groot-skaalse studie is nodig om die bevoegdheid van behandeling met die toestel vir verbetering in funksionaliteit na beroerte en rugmurgbesering te bevestig. Toekomstige studies moet uiteenlopende veranderlikes en ongelyke behandelingstye onder deelnemers uitskakel.

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Abbreviations

AIS	ASIA impairment scale
ANOVA	Analysis of Variance
ASIA	American Spinal Injury Association
BWSTT	Body-weight Supported Treadmill Training
CNS	Central Nervous System
CW	Clock-wise
CCW	Counter Clockwise
FES	Functional Electrical Stimulation
FFBD	Functional Flow Block Diagram
HREC	Health Research Ethics Committee
ICCP	International Campaign for Cures of Spinal Cord Injury Paralysis
ICRR	Indirect Cost Recovery Rate
LCD	Liquid Crystal Display
LE-FMA	Lower Extremity subscale of the Fugl-Meyer Assessment
LEMS	Lower Extremity Motor Score
MAS	Modified Ashworth Scale
NINDS	National Institute of Neurological Disorders and Stroke
PGB	Planetary Gear Box
PPR	Pulses per Revolution
PT	Physical Therapy
RAGT	Robotic-assisted Gait Training

ABBREVIATIONS

xv

RMSSE	Root Mean Square Standardized Effect
SCI	Spinal Cord Injury
TIA	Transient Ischaemic Attack
TUG	Timed-Up-and-Go
WCRC	Western Cape Rehabilitation Centre
WHO	World Health Organisation
WISCI	Walking Index for Spinal Cord Injury
10MWT	10-meter Walk Test

Chapter 1

Introduction

There is a need to address the socio-economic issues associated with personal and functional losses that accompany stroke and spinal cord injury (SCI). Effective treatment of stroke and SCI through robotic-assisted technology is a means to address this issue. However, the majority of South African clinics are unable to afford this technology for patient treatment. This report documents a proof of concept study that aimed to produce a robotic-assisted device that is more affordable for South African clinics. The report is submitted in partial fulfilment of a Master in Mechanical Engineering degree at Stellenbosch University, South Africa.

1.1 Background

According to the National Institute of Neurological Disorders and Stroke (NINDS), stroke and SCI are classified as two of 400 possible neurological disorders that affect the central nervous system (brain and spinal cord) [1]. The effects vary depending on the type and severity of the injury or stroke, but typically it causes either complete or partial loss of the motor function that is needed to walk [2, 3]. Restoring gait through rehabilitation is, therefore, a high priority after stroke and SCI, which greatly impacts social and professional reintegration [4]. On the other hand, treating stroke and SCI is costly from an individual, family and societal perspective [5, 6].

An international comparison of stroke cost studies showed that, on average, national health systems spent 0.27% of gross domestic product (GDP) on stroke care. This accounted for approximately 3% of total health care expenditures [5]. In rural South Africa, the direct costs related to caring for stroke patients in the public health sector was estimated to be ZAR2.5 - ZAR4.2 million (US\$283,500 - US\$485,000) in 2012. This represented 1.6 - 3% of the sub-district health expenditure for the year [7]. Direct costs of treatment typically include health and rehabilitation services, transportation, and special diets or personal assistance, whereas indirect

costs refer to both economic and non-economic costs such as lost productivity due to premature death or disability [8].

There is limited information available about the economic burden of SCI globally or in South Africa, but reports in Canada showed an estimated annual economic burden of US\$2.67 billion (41.2% indirect costs) associated with 1,389 new persons with traumatic SCI in 2011 [9]. From a patient perspective, indirect costs related to a loss of income can easily exceed direct costs. The World Health Organisation (WHO) (2013) found a 6-fold difference between the direct costs (average of US\$239) and indirect costs (US\$1360, including the sum of income lost) among 34 individual with SCI in Nigeria. Ultimately, the total cost of treatment was the equivalent of more than 50% of the annual income for participants [8].

These figures demonstrate that stroke and SCI result in devastating personal losses and societal burdens on a global scale (for both developed and developing countries). There is a need for effective treatment methods that can enhance the recovery rate after stroke and SCI, to reduce costs associated with prolonged treatment (from a patient and a government perspective) and facilitate quicker reintegration into society.

A newly developed gait-training strategy known as body-weight supported treadmill training (BWSTT), has led to more recovery of functionality in neurologic patients [10]. The method involves using a harness system to support a percentage of a patient's body weight as he/she trains to walk on a treadmill with manual assistance from therapists when needed [10]. Today, advanced robotic-assisted technology, such as the Gait Trainer GT I (Reha-Stim Inc., Berlin, Germany) or MOTomed leg trainer (RECK-Medizintechnik GmbH & Co. KG, Betzenweiler, Germany), combines the concept of assisted gait training (with less human resources needed) and conventional physical therapy (PT) to excel the recovery rate of both stroke and SCI patients [11, 12, 13, 14].

Unfortunately, these devices are costly and few South African clinics (especially state clinics) are able to afford this or similar technology. For example, the Gait Trainer GT I costs €56,000.00 (ZAR859,615.82) [15]. However, a state clinic such as the Western Cape Rehabilitation Centre (WCRC) typically has a maximum of ZAR30,000.00 available for a new rehabilitation device (and that is only if the hospital board is convinced it is a necessity) [16]. The majority of South African centres, therefore, rely on mainly conventional PT to treat stroke and SCI [16], which limits the amount of functional recovery achievable.

1.2 Motivation

Stroke and SCI cause personal and societal burdens that need to be addressed on a global scale. Modern robotic-assisted technology offers a feasible solution to promote functional recovery, which can potentially help mitigate the socio-economic issues associated with these disorders.

Current robotic-assisted devices are too expensive for South African clinics that have budget limits of ZAR30,000.00 for rehabilitation devices, which forces them to rely on mainly PT treatment. This limits the recovery rate that patients can achieve after stroke and SCI and contributes to the socio-economic burden in South Africa. Evidently, there is a need for a cost-effective alternative to current robotic-assisted devices that can be used in South Africa.

1.3 Research Aim and Objectives

The research project aimed to produce a more cost-effective robotic-assisted training device that could be used for stroke and SCI treatment in South Africa. The device had to be (1) more affordable than current technology, (2) able to recover functionality in stroke and SCI patients, and (3) safe to use with both stroke and SCI patients without increasing the risk of injury.

Table 1.1 summarises the list of requirements that were needed to meet the project aim or objectives.

The requirements were formulated based on feedback from a team of clinicians that formed part of the research team for this project. Appendix A summarises the researchers, clinicians and affiliations that were involved with this research project.

1.4 Report Outline

Chapter 2 provides a literature review on stroke and SCI classification and current rehabilitation devices. Chapter 3 then provides a detailed discussion about the design concept that was manufactured into a working prototype for testing. Chapter 4 outlines the ethically approved study protocol that had to be adhered to during clinical testing of the device, whereas Chapter 5 summarises the results recorded during testing. The results are discussed and interpreted in Chapter 6, before Chapter 7 concludes on the project aim and objectives that were satisfied and recommendations for future work.

Table 1.1: Project requirements

#	Requirement	Necessity
1.	The device must include gait-related, passive, active and active-assisted training modes	To compete with current robotic-assisted devices and accommodate varying (patient) muscle strengths
2.	Device cost should be close to ZAR30,000.00	To be less expensive than current technology and in a price range that is more affordable for South African clinics
3.	The device must be able to accommodate unpredictable limb spasms	To accommodate secondary symptoms of stroke and SCI
4.	The device must include an emergency stop mechanism	To ensure patient safety against unexpected device behaviour
5.	The device needs to be tested on selected stroke and SCI patients	To determine if the device can safely train stroke and SCI patients
6.	The intended test procedures must be ethically approved	To ensure fair and safe treatment of patients
7.	The study must use outcome measures that reflect or relate to the functional abilities of stroke and SCI patients	To determine if treatment contributed toward improved functionality after stroke and SCI

Chapter 2

Literature Review

The literature review summarises the medical classification and effects associated with stroke and SCI. It also explains the principle of neuroplasticity and how it relates to task-orientated therapy. The chapter includes a review of renowned robotic-assisted devices that can be used for task-orientated training, and to what extent training with the devices has contributed to functional improvement in previous stroke and SCI patients.

2.1 Medical Classification and Effects

2.1.1 Stroke

A stroke occurs when the blood supply to part of the brain is suddenly interrupted, or when a blood vessel in the brain unexpectedly bursts. This kills or damages brain cells when there is a shortage of oxygen and nutrients in the brain due to reduced blood supply, or when the pressure build up in the brain damages cells [17].

The American Stroke Association classifies stroke into one of three categories; ischaemic, haemorrhagic or transient ischaemic attack (TIA) [18]. Ischaemic strokes are the result of blood clots or debris that obstruct arteries and interrupt blood supply to the brain. The underlying condition for this type of obstruction is the development of fatty deposits lining the vessel walls. Haemorrhagic strokes occur when a weakened blood vessel ruptures. The most common cause of hemorrhagic stroke is uncontrolled hypertension (high blood pressure). Lastly, TIA strokes are similar to ischaemic strokes in that blood clots or debris obstruct blood flow to the brain, but the clot (and stroke) is only temporary. TIA strokes, therefore, serve as warning signs for partially blocked arteries or clot sources near the heart, which must be treated to avoid a severe ischaemic stroke [18, 19].

The effects of a stroke depend on several factors including the location of the

obstruction, and how much brain tissue is affected [20]. Because of how the brain and nerves throughout the body interact, damage on the left side of the brain affects the right side of the body, whereas damage to the right side of the brain affects the left side [21].

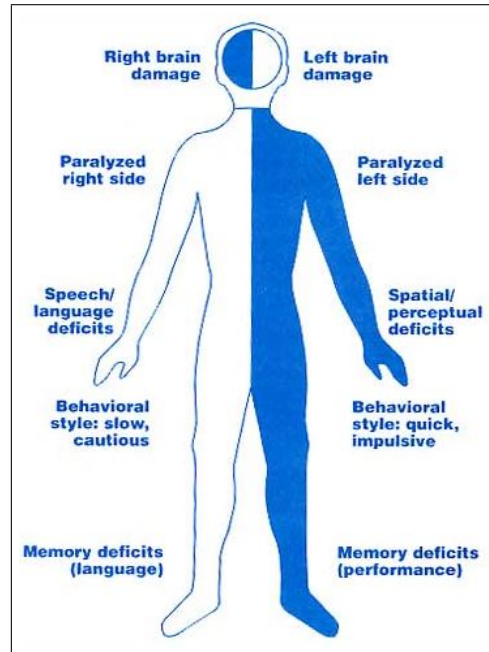


Figure 2.1: Symptoms associated with right or left brain injury [20]

A stroke that affects the right side of the brain can cause vision problems, difficulty controlling emotions, impulsive behaviour, memory loss and complete or partial paralysis on the left side of the body (Figure 2.1). On the other hand, a stroke on the left side of the brain can cause speech problems, slow or cautious responses, memory loss, and paralysis on the left side of the body [20, 22]. Complete paralysis of half of the body is otherwise known as hemiplegia, whereas partial paralysis of one side of the body is called hemiparesis [18, 23].

After a stroke, the brain must learn to readjust and account for the death or reduction of cells in the affected area of the brain. Stroke recovery occurs in three phases; acute, subacute and chronic. The acute phase (a few hours to a week after stroke) is characterised by cell death, brain swelling, and deactivation of poorly-oxygenated brain cells surrounding the dead core. This is followed by the subacute phase, which lasts up to six months after stroke. During this time, brain swelling and inflammation gradually subside, and the central nervous system (CNS) starts to reorganise neural pathways (naturally or with proper stimulation through rehabilitation) [24].

In the chronic stage that follows (more than six months after stroke) patients demonstrate a “plateau” or deceleration of motor recovery, which often leads to early discharge from PT. However, training induced improvements are still possible during the chronic stage of stroke [25].

2.1.2 Spinal Cord Injury

Spinal cord injury is associated with a blow to the spine that fractures or dislocates vertebrae, which compresses vertebrae and/or damages axons (nerve cells that carry information between the brain and the rest of the body) [26]. Alternatively, SCI can also arise from naturally occurring conditions. SCI is, therefore, classified as either traumatic or non-traumatic [8].

Traumatic SCI is caused by external forces that occur due to incidences such as falls, vehicle accidents, occupational and sports injuries, and violence. On the other hand, non-traumatic SCIs are caused by infections of the spinal nerve cells, cysts or tumours that press on the spinal cord, or congenital (present at birth) medical conditions [8, 27]. SCI can then be further classified as either tetraplegia (meaning the loss of function in all four limbs and the trunk area) or paraplegia (complete or partial paralysis of the trunk, legs and pelvic organs). This sub-classification of SCI depends on the location of the lesion [27, 28].

Figure 2.2 illustrates the four neurological levels of the spinal column (cervical, thoracic, lumbar and conus/sacral) and the mobility impairment that is typically associated with damage to each level.

Damage to the cervical vertebrae (C1 - C8) is the most severe SCI. It results in tetraplegia and the need for 24-hour assistance with daily activities such as eating or sometimes breathing. These individuals are usually confined to a motorised wheelchair after injury [29]. Thoracic level injuries (T1 - T12) also result in tetraplegia, but the injury is less severe and typically it does not affect the upper body as much. Individuals with thoracic injuries maintain moderate ability to control the trunk while seated or standing with or without assistance. They have little control over bowel or bladder movement, but patients are usually able to drive a modified car or use a manual wheelchair after injury [29].

On the other hand, lumbar level injuries (L1-L5) cause paraplegia with losses of functionality in the hips and leg areas. However, patients with lumbar injuries are more likely to walk with braces or assistance after injury. Lastly, sacral or conus level (S1 - S5) injuries are the least severe and patients typically do not need braces or assistance to walk after injury [29].

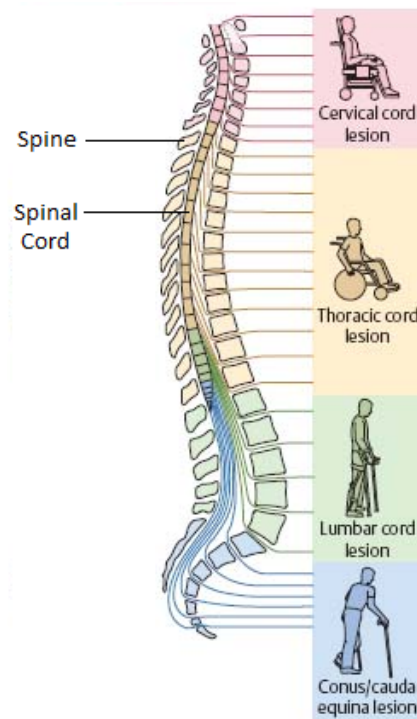


Figure 2.2: Neurological levels of the spinal cord [30]

To conceptualise the severity of a SCI, the American Spinal Injury Association (ASIA) developed a “completeness” scale that classifies the motor and sensory function preserved below the level of injury [27]. The medical dictionary defines sensory function as the ability to correctly sense skin stimulation, sounds, taste, smell, and visual images [31], whereas motor function refers to the ability to perform muscle contractions that facilitate movement [32]. Figure 2.3 summarises the levels of functionality associated with each of the five possible completeness scales; ASIA impairment scale (AIS) grade A, B, C, D or E [27, 33].

Motor function is physically measured by a therapist (through a series of passive exercises) in terms of the ASIA motor score scale. The motor score represents muscle strength and involves rating 10 key muscles (at least one at each neurological level) on a scale of zero (total paralysis) to five (active movement) [33]. A muscle grade of three as referred to in Figure 2.3 represents a muscle that can be active against gravity during measurements [33].

After SCI, the acute phase of recovery is characterised by continued haemorrhage, increasing edema (swelling due to excess fluid in body tissue), inflammation and secondary processes that contribute to axonal injury and cell death. The subacute stage is mainly associated with the onset of repair

ASIA Impairment Scale (AIS) category	Description
AIS A- <i>Complete</i>	No preserved sensory or motor function in the sacral segments.
AIS B- <i>Incomplete</i>	Sensory but not motor function is preserved, at least partially, below the neurological level, including the sacral segments.
AIS C- <i>Incomplete</i>	Motor function is partially preserved below the neurological level, with more than half the key muscles having a power grade less than 3.
AIS D- <i>Incomplete</i>	Motor function is partially preserved below the neurological level, with more than half the key muscles having a power grade equal or greater than 3.
AIS E- <i>Normal</i>	Normal sensory and motor functions.

Figure 2.3: ASIA impairment scale (AIS) classification of SCI [27].

mechanisms, whereas (similar to stroke) the chronic stage is characterised by inhibited recovery due to a gradual maturation of the lesion [34]. However, Yang and Musselman (2012) found that early treatment of SCI (using walking as the active ingredient) could still result in improved walking ability in both subacute and chronic stage SCI patients [6].

Although the mechanism of injury in stroke and SCI differs (ischaemia versus trauma) the rehabilitation methods for both set a high priority to restore gait [2, 4] by facilitating neuroplasticity [35, 36].

2.2 Neuroplasticity and Task-Specific Training

Neuroplasticity refers to the reorganisation of spared neural connections in the central nervous system (CNS), as well as the formation of new connections to compensate for functional impairments caused by injury or stroke [35, 36].

Neuroplasticity can lead to a surprising degree of spontaneous recovery when temporarily blocked or damaged nerves naturally heal [35, 37]. Typically, most spontaneous recovery occurs within the first three months after stroke. Thereafter, it gradually depreciates until it is non-existent during the chronic stage [35]. According to Wahl and Schwab (2014), spontaneous recovery also varies among patients. Patients with milder deficits tend to achieve more spontaneous recovery in a shorter time frame compared to patients with more severe deficits [37].

Task-specific training has been identified as a rehabilitative means to enhance the neuroplasticity that patients can experience after stroke and SCI [36, 38]. There is no conclusive definition of task-specific training, but in general, it refers to repetitive motor training that focusses on a particular goal/task related to the functional needs of patients, such as walking [36, 38]. Interventions like conventional PT, body-weight supported training (BWSTT), bicycling programmes, sit-to-stand exercises, and robotic gait training are considered to be task-specific training methods [36].

BWSTT is a training method that enhances the ability to walk through repetitive practice of complex gait cycles on a treadmill [36]. Intensive BWSTT in addition to conventional PT has shown significantly improved gait ability and daily living competence in subacute stroke patients compared with PT alone [11]. However, Duncan *et al.* (2011) found that among a sample size of 408 stroke patients, the benefits of BWSTT was not superior to conventional PT. There were multiple reports of falls during training, especially among acute patients with more severe walking impairments [39]. What is more, BWSTT requires more resources and assistance than conventional PT. At least two therapists are needed to manually adjust paretic limbs or help with weight shifting during training. This is strenuous for therapists and reduces training efficiency [2, 11].

Robotic-assisted gait training (RAGT) offers an alternative means of task-orientated training. RAGT devices are externally paced and controlled by one therapist. It provides electro-mechanically assisted training that can maintain constant gait patterns [4]. These devices can be individually tailored to patients so that it encourages active involvement for increased neuroplasticity [35]. Furthermore, RAGT devices provide a safer training environment for stroke or SCI patients with more severe hemiparesis [2, 35]. RAGT, therefore, holds many advantages over BWSTT including less effort and assistance from therapists, longer training times, higher training intensities, and the possibility to measure patients' movement performance over the course of rehabilitation [4, 12, 35].

The Lokomat (Hocoma Inc., Zurich, Switzerland) and Gait Trainer GT I (Reha-Stim Inc., Berlin, Germany) are two commercial RAGT devices that have shown functional improvement in both stroke and SCI patients in the past [4, 11].

2.3 Robotic-assisted Gait Trainers

The Gait Trainer GT I (Figure 2.4) consists of two motorised foot plates that simulate the stance and swing phases of gait [4]. The device includes a removable multifunctional display that gives feedback about the duration of

training, number of steps, velocity, and amount of body weight support. The step length and gait speed are also continuously adjustable to fit the device to the individual needs of patients [40].



Figure 2.4: Gait Trainer GT I [40]

Skvortsova *et al.* (2008) investigated the effect of training with the Gait GT I trainer among 50 subacute stroke patients (30 test, and 20 control subjects). Both groups received conventional PT and the test group completed 8 to 10 additional sessions of training with the Gait trainer. Both groups showed significant improvements in standing ability, walking, and self-care skills. However, no significant differences were detected between the two groups [41].

On the other hand, the Lokomat system uses a gait-orthosis (exoskeleton) combined with a treadmill, a body weight support system, and actuators at the hip and knee joints (Figure 2.5). The exoskeleton and the hip and knee joint angles are adjustable to suit the individual needs of patients. Speed, loading, and robotic support can also be adjusted to optimise the shape and intensity of training. Furthermore, the system includes an augmented performance feedback (APF) that enhances the effect of Lokomat training. Game-like exercises motivate patients by adjusting training speed and gait patterns according to patients' performance in a game [42].

Husemann *et al.* (2007) conducted a pilot study on 30 subacute stroke survivors. The test group received 30 minutes of training with the Lokomat (five days a week), whereas the control group received 30 minutes of

conventional PT. Both groups received 20 treatment sessions (test and control treatment) with an additional 20 sessions of conventional PT. Outcome measures included gait independence, gait speed and parameters, and body tissue composition. Although there was no statistically significant difference between the group results, the Lokomat group showed more improvement in gait abnormality and body tissue composition compared to the PT group [2].



Figure 2.5: Lokomat [43]

Benito-Penavla *et al.* (2012) conducted the largest SCI study on 105 patients (subacute and chronic) who were randomly assigned to either a Lokomat, or a Gait Trainer GT I group. Both groups had to complete conventional PT in addition to their respective RAGT sessions, five days a week, for eight weeks. Of the 105 patients, a subgroup of 24 traumatic AIS grade C and D patients were matched with a historical control group that received only conventional PT at another treatment centre in the past. The patients were matched in terms of gender, age, AIS scale, cause of injury, and their lower extremity motor scores (LEMS) at three months post-injury. Both devices were safe for SCI treatment and there were significant gains in motor function for all the SCI patients involved (with no dominance of one robotic device over the other). Furthermore, incomplete SCI patients that received training earlier after injury showed more improvement, and AIS grade D lesions showed more significant ambulatory gains than AIS grade C injuries. This suggests that the effectiveness of RAGT is related to the time when training starts, as well as the severity of an injury [4].

Neither the stroke or SCI studies reported adverse effects or injury due to falls. RAGT devices like the Lokomat and Gait Trainer, therefore, resolve the issue regarding increased risk of injury and therapist exertion associated with BWSTT. However, both devices are costly in comparison to conventional treatment.

In 2017 Rhe-Stim and Hocoma, respectively, confirmed that the Gait Trainer GT I costs €56,000.00 [15], whereas the Lokomat can cost €181,000.00 to €434,420.00 (without packaging or shipping to South Africa) [44]. This is exceptionally high costs compared to the ZAR30,000.00 budget implemented at some state rehabilitation centres in South Africa.

Fortunately, the MOTomed Viva2 leg trainer (RECK-Medizintechnik GmbH & Co. KG, Betzenweiler, Germany) is an alternative task-specific pedalling device that is less expensive than the Lokomat and Gait Trainer [45].

2.4 MOTomed Viva2 Trainer

The MOTomed Viva2 trainer is a robotic-assisted bicycle ergometer (an apparatus that measures work or energy expended during physical exercise [46]) designed to promote walking ability, activate residual muscle strength and reduce spasticity [47].



Figure 2.6: Upper and lower limb trainer [47]



Figure 2.7: Lower limb trainer [47]

The device includes an electronic servomotor that assists pedalling motion. There are two different designs or trainers available; one that allows for assisted upper- and lower extremity training (Figure 2.6) and one that allows for only assisted lower limb training (Figure 2.7). Patients can train while seated in their wheelchairs with their feet, calves and/or hands securely strapped onto the device [48].

The trainer includes three different training modes; passive, active-assisted and active (Figure 2.8). In active-assisted mode, the user can have minimal muscle strength and the motor will increase its input to assist any active pedalling movement that is present. In active mode, users train actively against finely adjustable resistance levels that range from easy to difficult. When a patient is tired or fatigued, he/she can relax and the motor will automatically switch to passive training of upper and/or lower limbs. This allows for some degree of oxygen and nutrition supply to affected areas even when patients are too tired to pedal actively [47].



Figure 2.8: MOTomed Viva2 training modes [47]

In addition to this, the device continuously monitors pedalling speed, resistance, and muscle conditions to detect any sign of a muscle spasm. If/when a spasm is detected, a *SpasmControl* feature automatically changes the rotational direction of the pedals until the spasm is relieved. This response relates to the therapeutic principle of antagonistic inhibition; a bending spasm is relieved by stretching, and a stretching spasm is relieved by bending [47, 48]. Furthermore, the user display provides feedback regarding the duration of training, pedalling speed, performance (Watt), cycling distance and symmetry display. The symmetry display is a percentage comparison of the respective right and left leg power that is exerted on the pedals [48, 49].

Yang *et al.* (2013) conducted a cross over study on 31 stroke patients using the MOTomed leg trainer. One group received four weeks of conventional PT followed by another four weeks of MOTomed training (five days a week, 30 minutes at a time). The other group received the same treatment only in the reverse order. The results showed significantly greater improvements in muscle strength (LE-FMA), spasticity (MAS), and walking ability (10MWT) during the cycling period compared to the non-cycling period. They concluded that visual feedback of cycling parameters and symmetry played an important role in patients learning how to adjust bilateral control of the lower extremities [49].

The review process could not identify publications regarding the effects of MOTomed training on SCI patients, but some studies did use the MOTomed

trainer in conjunction with functional electrical stimulation (FES). FES refers to the process of applying small electrical pulses to affected muscles in an attempt to initiate a muscle contraction that the brain can recapture [50]. Kuhn *et al.* (2014) investigated the functional improvements in SCI patients after MOTomed training combined with FES. The study included 30 subacute SCI patients who received 20-minute FES-cycling sessions, two days a week, for four weeks. Changes in muscle cross-section, muscle and limb circumference, spasticity level, and walking ability were measured throughout the study. The results showed that FES cycling in combination with task-oriented PT had a positive influence on spasticity, walking ability, and muscular reactivation [13].

Regarding cost, Mediatronics, an internationally accredited supplier of rehabilitation equipment in South Africa, confirmed that a new MOTomed upper and lower extremity trainer costs ZAR98,000.00, whereas the lower limb trainer costs ZAR65,000.00 [51].

In conclusion, training with the MOTomed Viva2 trainer is safe and capable of facilitating functional recovery in stroke and SCI patients. It is less expensive than the Lokomat or Gait Trainer RAGT devices, with the same added benefits of biofeedback and fewer resources or assistance needed. However, its effects without FES are unknown for SCI, and the cost of purchasing a MOTomed trainer remains well above the ZAR30,000.00 budget of state clinics in South Africa.

Therefore, this project had the opportunity to design a more affordable alternative to the MOTomed trainer, and determine the effects of MOTomed training without FES in SCI patients.

Chapter 3

Prototype Development

The prototype development process involved establishing design requirements, generating feasible concepts, and manufacturing a working prototype of the final concept. Additionally, this chapter explains the control system design and approach implemented, and how the device performed during preliminary tests.

3.1 Concept Generation

3.1.1 Design Requirements

To satisfy the project requirements identified in Chapter 1, design concepts had to adhere to the design requirements listed in Table 3.1.

Table 3.1: Design requirements

#	Requirement
1.	The device must have gait-related, passive, active and active-assisted training modes
2.	The device cost should be close to ZAR30,000.00
3.	The device must be able to accommodate unpredictable limb spasms
4.	The device must have an emergency stop mechanism

The MOTomed Viva2 trainer (from here on referred to as the MOTomed or MOTomed trainer) was identified as a popular and cost-effective competitor in the field of stroke and SCI rehabilitation devices. The MOTomed was selected as the benchmark for the concept generation phase. The phase focused on producing concepts that are less expensive than the MOTomed, yet able to improve limb functionality after stroke and SCI. Assisted pedalling motion

was, therefore, selected as the gait-related training technique that concepts had to include to satisfy the first design requirement.

Concepts were limited to lower extremity training only. Restoring gait is the top priority of stroke and SCI treatment which significantly impacts reintegration into society. Conventional treatment during the first five to six weeks of recovery (typically the inpatient therapy period) is aimed at rehabilitating the lower limbs for gait training. Once significant gait is restored, or inpatient treatment is complete, outpatient therapy is designed to refine patients' gait patterns and start restoring upper extremity movement (apart from upper body strength training for people with paraplegia which occurs during inpatient therapy). Therefore, the proof of concept study restricted its focus to producing a lower limb rehabilitation device that could excel the rate of gait recovery during in- or outpatient treatment. Future work can include upper body training if a need is identified and if it does not compromise the affordability of the device.

With the aim and requirements of the design process known, concept generation commenced with a functional decomposition of the device to be designed.

3.1.2 Functional Decomposition

Figure 3.1 shows the functional flow block diagram (FFBD) of an active-assisted pedalling device to be designed.

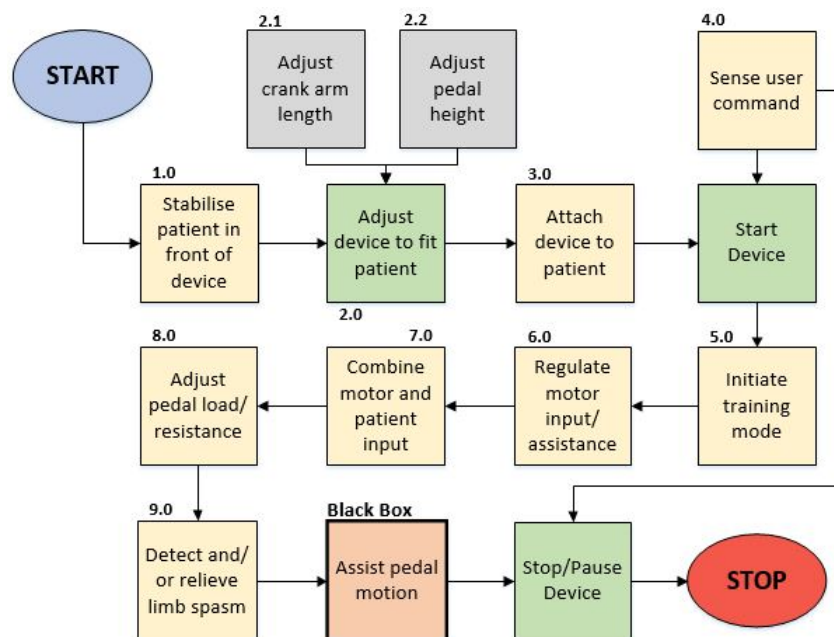


Figure 3.1: Functional flow block diagram (FFBD) of the required device

Each numbered block represents a function or need that design concepts had to be able to satisfy. The ‘black box’ refers to the single function that describes the purpose of the device as a whole, which is to assist pedalling motion. Design concepts that could satisfy the functional blocks, automatically qualified as concepts that could meet the black box and the design requirements listed in Table 3.1 [52]. A morphological analysis was conducted to identify feasible design concepts for the system.

3.1.3 Morphological Analysis

A morphological analysis involves identifying one or more solutions for each function block in an FFBD. The set of functional solutions are then organised into a large table called a morphological chart. The table simplifies concept generation as different combinations of functional solutions from the chart form different design concepts for the system [52].

Appendix B provides a morphological chart of solutions identified for the function blocks in Figure 3.1. Two different combinations of solutions from the chart formed two design concepts for the prototype pedalling device. Appendix B provides the combination of solutions that formed each concept. After comparing the advantages and disadvantages associated with the concepts, it was concluded that Concept 1 showed more promise to meet the functional needs and requirements of the system. The concept required fewer components and expenses (more likely to meet device cost target of ZAR30,000.00) and less complicated control. Concept 1 was, therefore, selected as the prototype design that was to be manufactured. A detailed discussion of the design will now follow.

3.2 Prototype Design

Figure 3.2 illustrates a three-dimensional (3D) model of the prototype design. Inventor Professional 2017 design software (Autodesk, California, Unites States) was used to generate the detailed design model.

The main components of the device include a sheet-metal housing, pushbutton user interface, adjustable pedal assemblies, a flywheel, and two timing belt drive systems that connect pedals and a servomotor to separate ends of a planetary gear box (see Figure 3.3). Patients must pedal the device (actively) as best they can to overcome the flywheel load and reach a preselected target pedalling speed. If they struggle to achieve the target speed, the device automatically regulates the motor input to assist pedalling motion as needed.

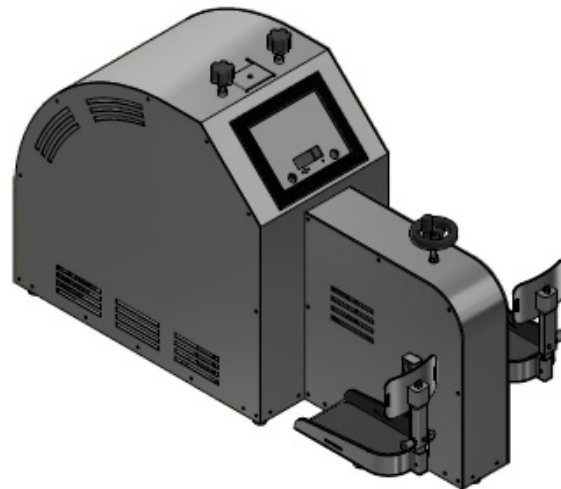


Figure 3.2: Three-dimensional model of prototype design

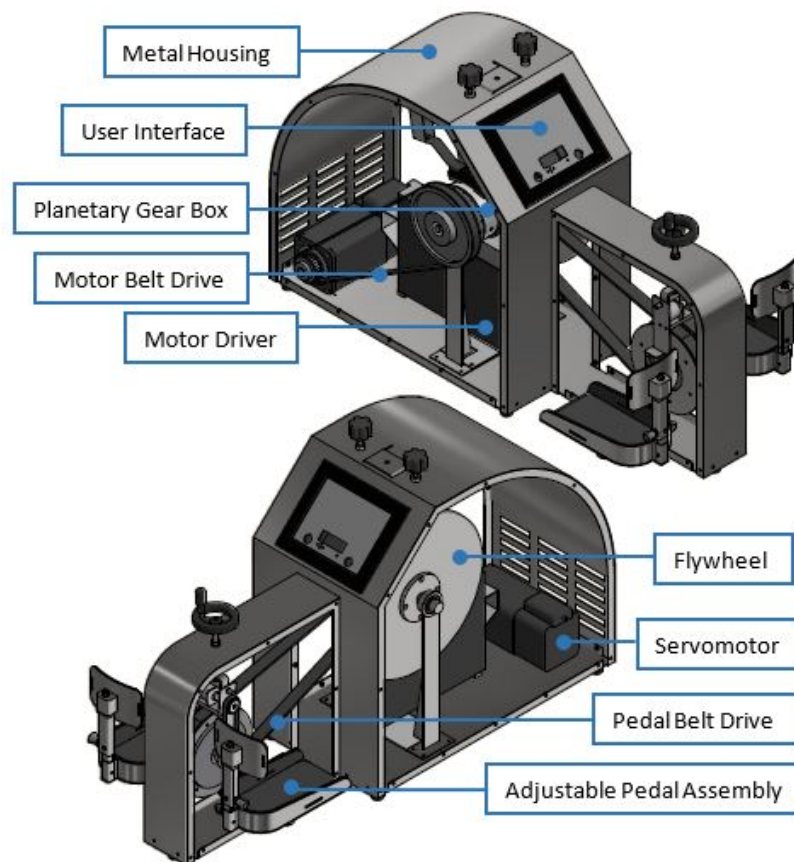


Figure 3.3: Main components of prototype design

The device is adjustable to accommodate varying leg lengths by (1) moving patients closer or further away from the device, (2) adjusting the height of the pedals, or (3) adjusting the crank arm length (to be explained).

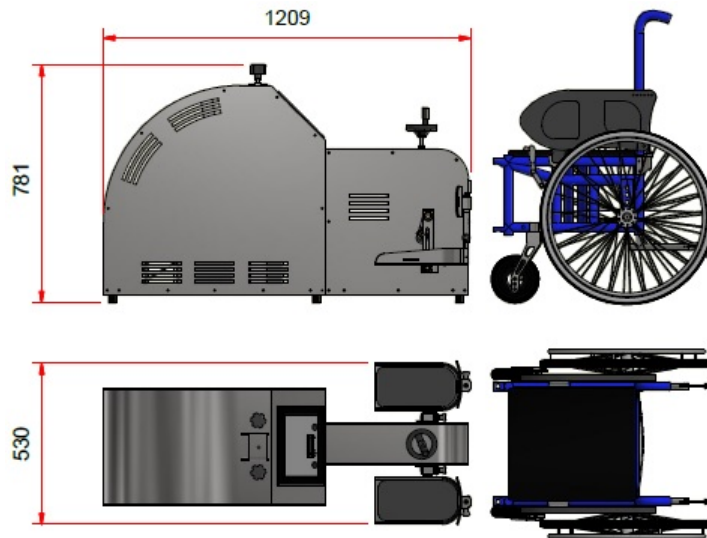


Figure 3.4: Device dimensions (mm) with a standard wheelchair to scale

Firstly, patients can train while seated in their wheelchairs¹ as illustrated in Figure 3.4. This way, it is easy to move patients to and from the device, and wheelchair brakes prevent patients from moving or falling over during training. Patients can also train with customised seat cushions (if they have any) that are designed to help maintain the correct posture in the seated position. This is especially important for SCI patients to avoid uneven pressure distributions that can cause skin damage, muscle imbalances or contracture development (shortening and hardening of muscles, tendons, or other tissue) [16]. The only down side to this approach is that wheelchairs must have removable footrests to move patients close enough to the device to train. Alternatively, patients can move (or be moved) to an armchair or a wheelchair with removable footrests, before training.

Secondly, rotating the hand wheel of the pedal shaft support arm (shown in Figure 3.5) adjusts the pedal height. The pedal shaft (to which the pedal assemblies are connected through keys) is supported by two plates that hinge on an intermediate shaft. The intermediate shaft is indirectly linked to the hand wheel that adjusts pedal height. The threaded rod of the hand wheel turns inside a nut welded to the inner roof of the housing (not visible in Figure 3.5). This means clockwise (CW) rotation of the hand wheel lowers the

¹If patients do not have or use a wheelchair, they can train while seated in a standard arm chair

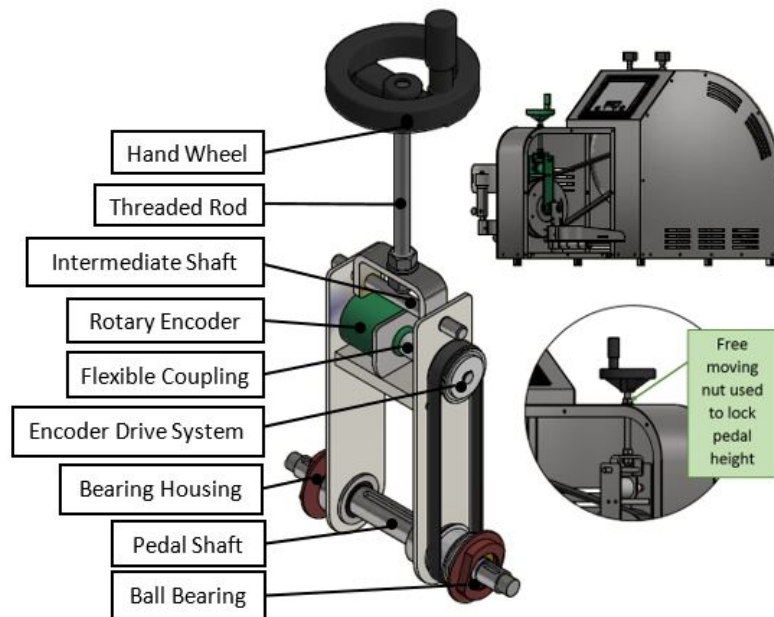


Figure 3.5: Pedal shaft support arm

entire support arm (and thereby pedals), whereas counter-clockwise (CCW) rotation lifts the pedals.

Radial slots guide the movement of the pedal shaft during pedal height adjustments. The customised bearing housings shown in Figure 3.5, slide along radial slots located on the side of the machine (see Figure 3.6). The slots have the necessary radii to ensure that the belt drive connecting the pedal shaft to the flywheel remains tensioned as the pedal shaft moves. The deep-groove ball bearings fitted inside the housings, therefore, allow the pedal shaft to rotate freely at the desired pedal height. The pedal height is locked in place by tightening a free moving nut on top of the device as shown in Figure 3.5. Refer to the drawing pack in Appendix C for more detailed information about the components that were used in the assemblies mentioned in this section.

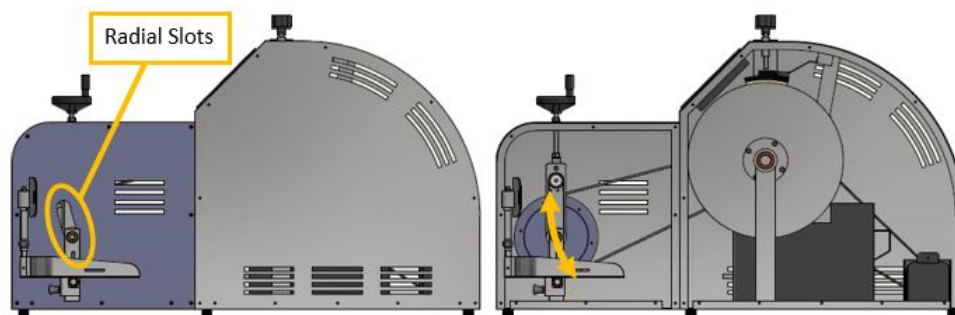


Figure 3.6: Radial slot design used to maintain pedal belt drive tension

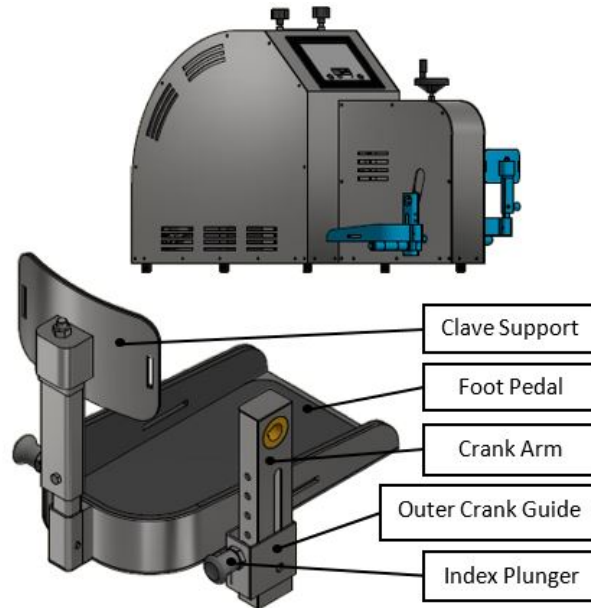


Figure 3.7: Left pedal assembly with calve support

Thirdly, Figure 3.7 demonstrates the pedal assembly which includes the crank arm. The crank arm refers to the arm to which the foot pedals are attached (like with a bicycle). In this case, the crank arm connects the foot pedals to the pedal shaft at a certain length/distance. Depending on a patient's leg length, it might be more comfortable to pedal the device with a longer or shorter crank arm length. The outer crank guide in Figure 3.7 (to which a foot pedal is attached) is manually moved along the crank arm to one of five possible indexes that range from 60 mm to 135 mm crank arm lengths. Once a length is selected, an index plunger is used to lock the pedals in place.

Each pedal assembly is also equipped with a removable calve support. The support was included to help stroke or SCI patients with a common secondary condition known as drop foot. Drop foot occurs when a neuromuscular disorder weakens the muscles that usually allow for flexing of the ankles and toes. Individuals with drop foot tend to drag their feet while walking [53]. In this case, patients cannot control dorsi- and plantar flexion during pedalling [16]. However, some stroke and SCI patients with drop foot find it easier to pedal while wearing a 90° foot brace [16]. Therefore, the calve support was placed at the back of the pedals to imitate a foot brace that maintains an approximate right angle between the foot and shin during training. The height of the calve supports is then also adjustable using a method similar to that of the crank arm adjustment mechanism.

When patients can comfortably pedal the device after the necessary adjustments have been made, non-invasive velcro straps (with cushioning)

are used to strap patients' feet and calves to the device for training.

3.2.1 Assistive Drive Train

A planetary gear box (PGB) and two synchronous belt drives form the assistive drive train that transmits power from the motor to the pedals to achieve assisted motion.

A planetary gearbox is a continuously variable transmission (CVT) that uses gears to achieve different speed ratios between two rotating shafts [54]. Figure 3.8 illustrates the three elements of a simple planetary gear set; a sun gear, a large ring gear, and two or more small planet gears that are in constant mesh with the sun- and ring gear. Although the planet gears are free to rotate about their axes, they are attached to a common carrier arm referred to as the planet-arm [55].

Depending on the application, any one of the elements (sun, ring or planet-arm) can be used as an input to or an output from the gear set. This means a PGB can combine two inputs to drive a single output, or drive two outputs from a single input. Different speed/gear ratios can also be achieved by fixing (zero or constant speed) one or more elements. A PGB, therefore, offered a feasible solution to combine the motor and patient inputs to drive a flywheel load output.

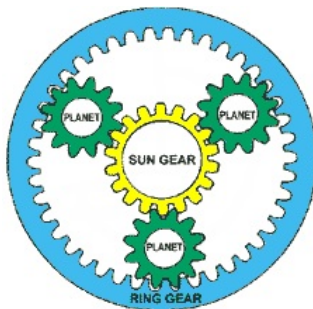


Figure 3.8: Typical planetary gear box (PGB) design [55]

A PGB that was readily available at the university was used to reduce project costs. Agenbach (2015) developed the gear set as part of his final year project. The gears are manufactured from Nylon 6 plastic (which avoids the need for gear lubricant), and the planet-, sun- and ring gears have 15, 30 and 60 gear teeth, respectively. Agenbach determined that the gear box has an overall transmission efficiency of 87.58% to 80.03% for a ring gear output and sun gear input (stationary planet-arm). The power output was measured using a custom braking mechanism that slowed the ring gear output by applying weights ranging from 0.2kg to 0.6kg to a belt system. The results showed that the efficiency of the gear set decreased as the ring gear load increased.

Furthermore, the gear set was limited to a maximum power transmission of 1 kW and operating temperatures of less than 70°C to avoid potential gear failure [56]. These limitations were taken into consideration when the planetary gear set-up was selected.

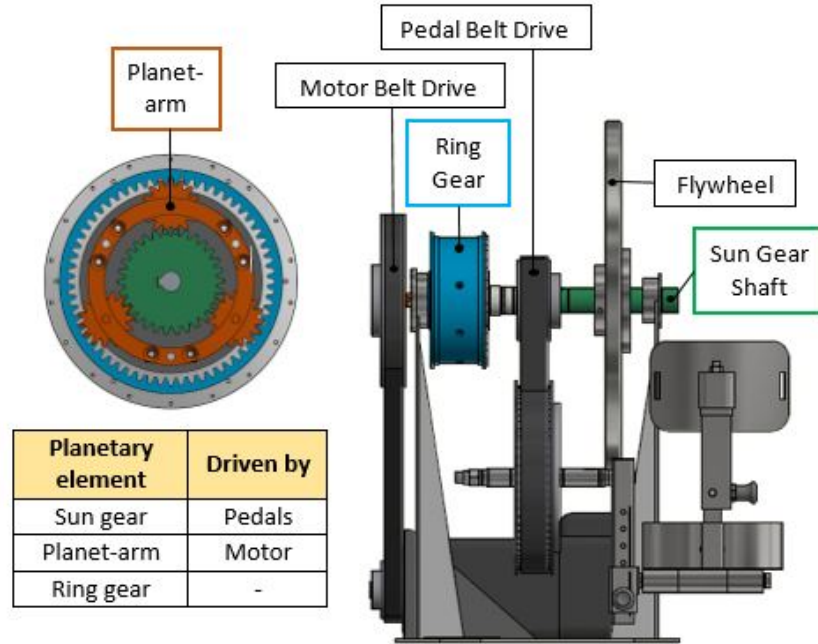


Figure 3.9: Planetary gear box (PGB) set-up with motor and pedal inputs

Figure 3.9 illustrates the PGB set-up used in the design. The motor drives the planet-arm (through the motor belt drive), and the pedals drive the sun gear shaft to which the flywheel is attached. Although the ring gear appears free to rotate in this image, it is in fact loaded by a friction brake as will be discussed shortly.

Ideally, the flywheel would have been attached to the ring gear so that the motor and pedal inputs could be combined to drive the flywheel load. However, based on Agenbach's findings, the additional weight of a solid Ø400 mm metal wheel on the ring gear would have significantly reduced the efficiency of the planetary gear set. Instead, the flywheel was attached directly to the sun gear shaft to serve as a load that patients must overcome to pedal the device. A percentage of the motor torque and speed applied at the planet-arm is, therefore, transferred to the sun gear shaft to help overcome the flywheel load. Theoretically, the amount of motor assistance provided could be enhanced by keeping the ring gear stationary.

$$\omega_{sun} = \left(\omega_{arm} \left(1 + \frac{N_{sun}}{N_{ring}} \right) - \omega_{ring} \right) \left(\frac{N_{sun}}{N_{ring}} \right)^{-1} \quad (3.1)$$

$$\omega_{sun} = \left(\omega_{arm} \left(1 + \frac{30}{60} \right) - 0 \right) \left(\frac{30}{60} \right)^{-1} = 3 (\omega_{arm}) \quad (3.2)$$

Equation 3.1 shows the relationship between the sun-, ring- and planet-arm speeds for a sun gear output. This equation was derived from first principles using the tabular analysis method provided in Appendix D. Equation 3.1 demonstrates that a sun gear output (ω_{sun}) will rotate faster for a fixed/stationary ring gear input ($\omega_{ring} = 0$). More specifically, given the PGB gear teeth of $N_{sun} = 30$ and $N_{ring} = 60$, a sun gear output (pedals and flywheel) will rotate three times faster than the planet-arm input (motor) as shown in Equation 3.2. Therefore, a fixed ring gear maximises the speed ratio and the amount of assistance provided during assisted training.

At the same time, a fixed ring gear creates a direct drive between the motor and the pedals. This increases the risk of injury if the motor behaves unexpectedly. What is more, it restricts the pedalling speed to a corresponding sun gear speed that is three times the planet-arm speed at all times. In other words, patients will only be able to train passively if/when the ring gear is fixed and the motor is active (no active-assisted motion). An alternative means to transfer maximum motor assistance through the PGB, without restricting pedalling speed was devised.

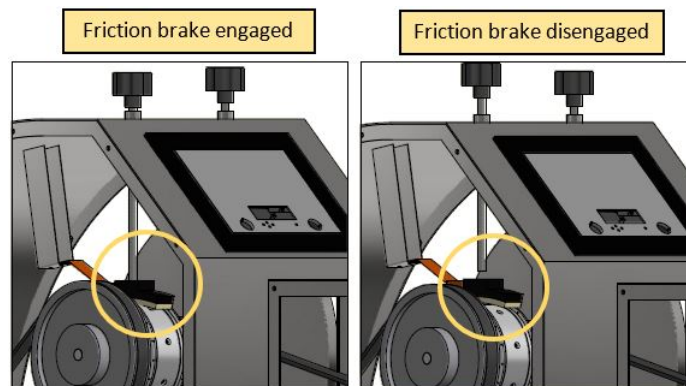


Figure 3.10: Ring gear brake modes for active-assisted training (left) and a mechanical emergency stop (right)

A friction brake was used to load the ring gear in such a way that the gear is just able to move if/when the sun gear speed (driven by the pedals) is not three times the planet-arm speed. The brake is manually adjusted by turning a brake knob that engages or disengages the brake as shown in Figure 3.10. The brake is locked in place by tightening a free moving nut to the housing (similar to the pedal height lock mechanism used in Figure 3.5).

During preliminary testing (to be discussed in Section 3.5) it was confirmed that when the brake is disengaged, the combined weight of the flywheel, pedal belt drive and patient limbs at the sun gear end of the PGB is too large for the motor to turn. Instead, the ring gear rotates faster as the motor speed increases and the sun gear acts as a stationary input. This serves as a mechanical safeguard against unexpected motor behaviour. It also shows that an engaged ring gear brake maximises the amount of assistance that the device provides, without creating a direct drive between the motor and pedals.

Although the PGB set-up (motor to planet-arm and pedals to sun gear) achieves a greater speed ratio, it also results in less torque transfer to the pedals (torque ratio of $\frac{1}{3}$). Alternatively, the motor could drive the sun gear shaft instead and achieve a torque ratio of three through the PGB. Nevertheless, the set-up would not affect the amount of assistance that the device could provide in the form of power (torque \times speed). For negligibly small losses in the synchronous drive systems, the same amount of motor power (after the PGB efficiency) is transferred to the pedals irrespective of the PGB set-up. With the implemented set-up (motor to planet-arm) the speed ratio achieved through the PGB means that the power transferred to the pedals will consist of more speed than torque. On the other hand, the torque ratio achieved with the alternative set-up would mean that the same amount of power could be transferred to the pedals, but the power would consist of more torque than speed. Both PGB set-ups would, therefore, be able to provide the same amount of power and assistance, only with different torque to speed ratios in each case.

If future applications need a greater mechanical advantage through the system (torque applied versus torque delivered at the pedals), the alternative set-up would be more beneficial. However, the specifications for this system and application required only a certain amount of power at the pedals (as discussed next) and the motor selected was able to provide the necessary power with the PGB set-up implemented.

3.2.2 Motor and Belt Drive Selection

Before an appropriate motor could be selected for the device, the maximum load conditions (torque and speed) expected at the pedals had to be calculated.

A dynamic analysis of the pedal load case was conducted. Figure 3.11 illustrates the free-body diagram that was used for the analysis. The maximum torque (M_p) applied at the pedal shaft (P) would be calculated for one crank arm revolution (from here on referred to as a pedal cycle).

It was assumed that the maximum load would occur during passive training. In passive training, the motor needs to overcome and drive the total weight



Figure 3.12: Gravitational effect during assisted motion (adjusted from [47])

in Equation 3.3, the estimated load conditions corresponded to a maximum power of 703.72 W that was needed to move a 100 kg user's limbs passively at 70 rpm with the device.

$$Power = M_p \times \left(\omega_{rpm} \times \frac{\pi}{30} \right) = 96 \times \left(70 \times \frac{\pi}{30} \right) = 703.72 \text{ W} \quad (3.3)$$

Assuming the PGB achieved a transmission efficiency of 80 % (as calculated by Agenbach for a slightly loaded ring gear application [56]) and losses across the synchronous drive systems were negligibly small, this requirement translated to a motor power requirement of 879.65 W. Table 3.2 summarises the maximum load conditions and motor requirement for the system.

Table 3.2: System requirements calculated for maximum load case

Maximum Parameter	Unit	Magnitude
Pedal torque	N m	96
Pedal speed	rpm	70
Power at pedals	W	703.72
Motor power	W	879.65

It was not necessary to experimentally determine the efficiency of torque or speed transfer through the PGB, to determine the corresponding motor speed and torque values associated with the motor power requirement. This is because the control and operation of the device did not require the motor to be able to counteract the maximum torque applied to the pedals (prevent further rotation of the pedals). In other words, there was no need for a motor torque (or speed) requirement for this application, only a motor power requirement. Any motor with a rated power output equal to or more than

the motor requirement for the system, would have been able to train a 100 kg user's limbs passively at 70 rpm.

The prototype was limited to using a Bosch Rexroth servomotor (MKD701B-061-KG0-KN) and driver (DKC 11.3-040-7-FW). It was the only servomotor that was available at the university (to save project cost) that satisfied the system requirement and could be powered from a single-phase (220 V) power supply (even though it is a three-phase motor). Single-phase power supply was necessary because the rehabilitation clinic where the device would be tested did not have three-phase power supply outlets. Table 3.3 summarises the rated specifications of the Rexroth motor.

Table 3.3: Bosch servomotor specifications [58]

Rated Output	Unit	Magnitude
Power	kW	1.8
Torque	Nm	6.8
Speed	rpm	2000

The motor was programmed to have a speed limit of 1000 rpm. If the motor exceeded this speed, it would automatically execute an emergency stop. Given the motor's speed capacity and the estimated speed increase through the PGB, the speed limit was an automated safety measure against unexpected motor behaviour. Furthermore, this corresponded to a maximum power output of 712.10 W at rated torque, which prevented the motor from exceeding the 1 kW power constraint of the PGB designed to avoid planetary gear failure. Although this limit was below the estimated motor power requirement, preliminary tests showed that the device could still meet the system requirement despite the speed limit. Therefore, the speed limit was not increased to satisfy an overestimated power requirement.

The servomotor offered precision control of the motor speed or torque and satisfied the system requirements. At the same time, the motor was over-designed for the system, with a power output of more than double what was needed and various advanced control features that were irrelevant for this application. This reflected in the high cost associated with the motor and driver. Future projects can significantly reduce device cost by looking at less expensive servo-, DC- or stepper motors that meet the system requirement.

From here, timing belts and pulleys capable of transferring the maximum system power to and from the PGB were selected. Compared to chains, belts are less expensive, require no lubrication, and cause little wear on pulleys or sprockets [59]. Timing belts, in particular, are thin, flexible, less prone to

slip, and (apart from direct drive) the most efficient means to transmit power through a system [60]. However, timing belts are also more expensive than flat/V-belts, and it can generate belt noise that increases exponentially with speed and pitch [59, 60]. Fortunately, this was considered to be a low-speed application (due to limited muscle strength in participants), and the need to efficiently transfer motor and limited patient power through the system outweighed the potential increase in cost.

Appendix F shows the belts and pulleys that were selected according to the SKF power transmission selection procedure [61, 62]. Initially, the drive ratios were iteratively selected to minimise the motor torque needed (because motors with higher torque output are generally more expensive). This resulted in large pulley diameters that were not a standard size for most suppliers, and increased project cost to obtain the pulleys. Because the device was then limited to the Bosh servomotor, and any motor with sufficient power output could in fact be used, smaller pulleys could have been selected. Future projects are, therefore, advised to reduce project cost with smaller pulleys if the same approach applies (any motor with sufficient power is satisfactory).

3.3 Control System Design

The control system had to determine the amount of motor assistance needed, and communicate it (along with user interface commands) to the driver to generate the correct device response. Figure 3.13 illustrates the feedback control system used for the device.

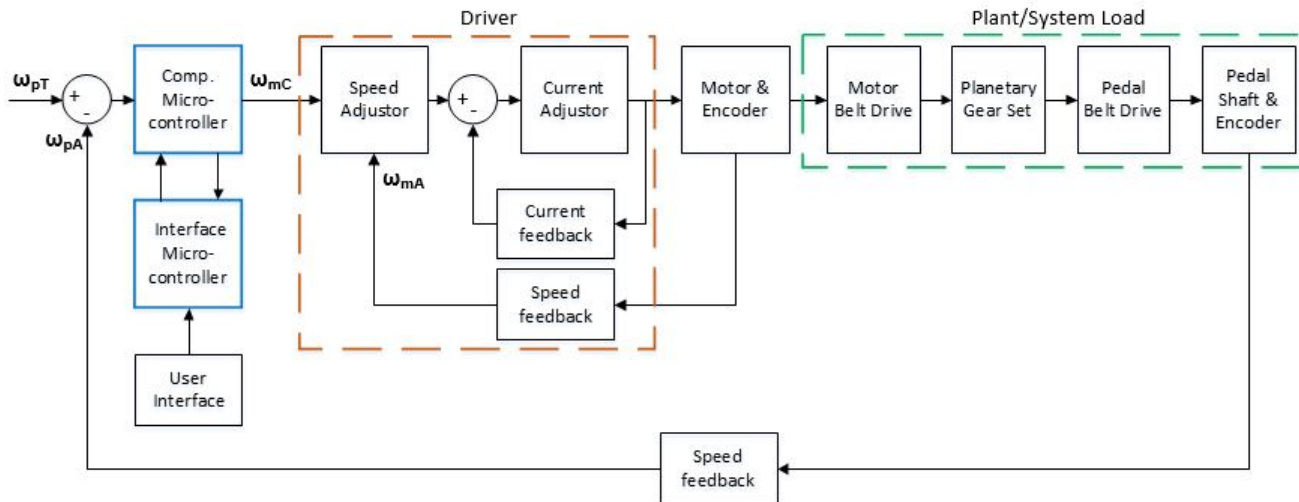


Figure 3.13: Feedback control system block diagram

The system consisted of a user interface, two Arduino Uno microprocessors (from here on referred to as microprocessors or processors) and a motor

driver. The user interface received commands and communicated it to the microprocessors. The microprocessors calculated a motor speed command (ω_{mC}) and relayed the speed command, as well as user interface commands, to the driver. The driver then controlled the motor to achieve the desired response. The actual pedalling speed (ω_{pA}) was, therefore, monitored during training so that processors could regulate the motor input based on the error between the actual- and a target pedalling speed (ω_{pT}).

This section will explain how the control components interacted to meet the control objectives. Figure 3.14 lists the additional electrical components that were used in the control system, which will be referred to throughout this section. Appendix G provides a Fritzing (Friends of Fritzing e.V., Berlin, Germany) schematic of the control circuit for future reference.

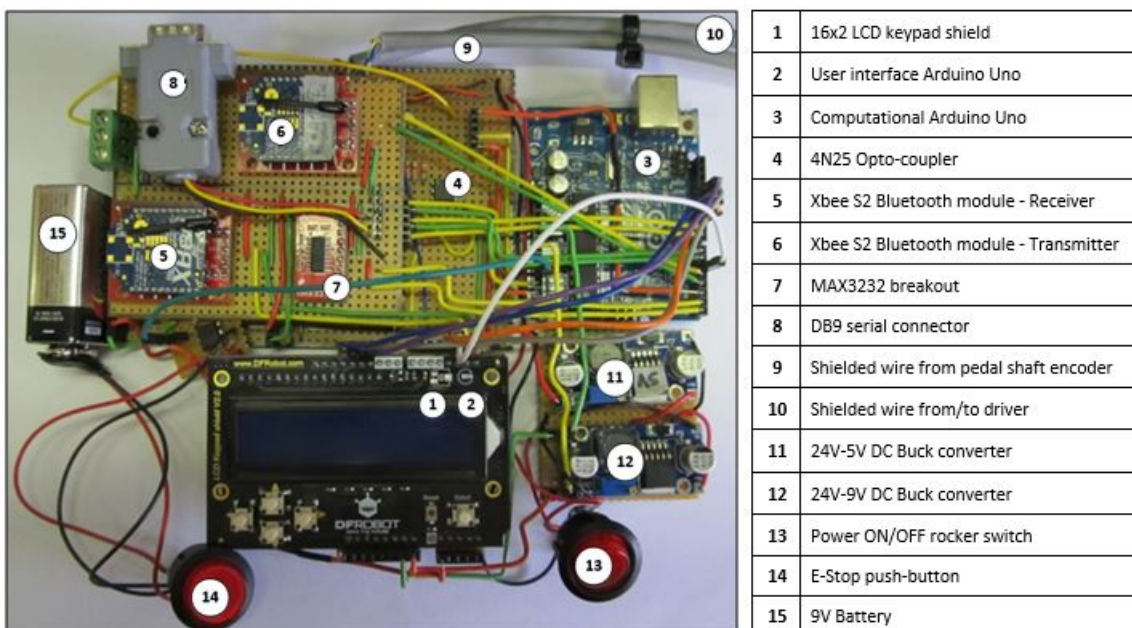


Figure 3.14: List of electrical components used for the control system

3.3.1 User Interface

The user interface included the seven commands shown in Figure 3.15. It consists of a 16x2 LCD keypad shield that fits onto the interface microprocessor (item 1 and 2, Figure 3.14). The interface asked/guided the user for the sequence of interface commands that were needed to initiate training. During training, the training-time and real-time pedalling speed was displayed on the LCD.

The power switch supplied 9V power to the microprocessors through their respective V_{in} pins. 9V is a standard supply voltage. It is also more than the

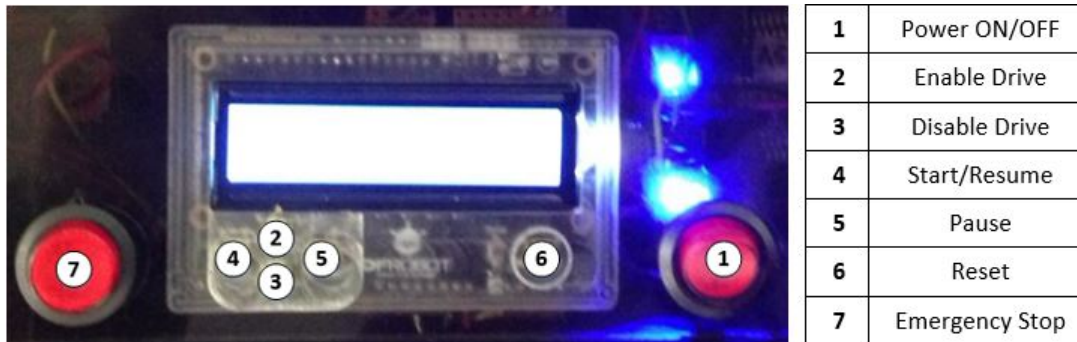


Figure 3.15: User interface display and commands

minimum input voltage (6.2V) that is needed to power a 5V Arduino board through its linear voltage regulator (which has a voltage drop of 1.2V). A buck converter (item 12, Figure 3.14) was used to convert a 24V supply from the driver, to the 9V supply that was needed for the microprocessors. This avoided the use of batteries to power the microprocessors, which reduced device maintenance. The driver received its 24V supply from an external power supply (not visible in Figure 3.14) that was powered by the same wall outlet that powered the servomotor. The device could, therefore, be conveniently powered from a single (220V) wall outlet.

After receiving a 24V control voltage, the driver had to be enabled before it could execute any commands. The enable and disable commands, therefore, activated or de-activated the driver as was needed. Once the motor and driver were correctly powered and enabled, the driver returned a ready signal that was processed by the microprocessors, and displayed on the interface to show that the device was ready for training.

The start/resume command initiated a training session by sending an internal command to the computational microprocessor to start calculating and sending a motor speed command to the driver. The pause command activated the drive halt function, which brakes/holds the motor until the function is de-activated. This meant a session could be momentarily interrupted (with the pause command) to relieve a spasm or make a device adjustment before training could commence with the start/resume command.

On the other hand, when the emergency stop was activated the device had to be reset (to clear the emergency stop from the driver) before the motor would be able to operate again. Appendix H provides a visual illustration of the driver pin layout that accompanied these interface commands. From a safety perspective, a sudden stop of the motor did not result in an equally sudden stop of the pedals. This is because the pedals were not directly driven by the motor. If the motor was fixed (stationary) due to an emergency stop, the ring gear could still move, and the pedals was still able to rotate. This

meant patients could stop pedalling the device at their own pace if/when the emergency stop (or pause) was activated.

The control was simplified by not including commands that control the training modes (active, passive or active-assisted). Instead, the control was designed to automatically transition between active-assisted and passive training modes as needed. Active training could then be achieved by not enabling the driver before training. If the driver was not enabled, the motor could not operate, and patients could pedal the device with speed and training-time feedback on the LCD. A second friction brake was added on top of the flywheel (similar to the ring gear brake, Figure 3.10) so that pedalling resistance could be adjusted (manually) during active training.

A single Arduino processing board did not have enough digital and analogue pins to communicate interface commands to the driver, in addition to receiving encoder signals and controlling the LCD keypad. The computational microprocessor was, therefore, added to provide more pins and form the link between the user interface and the motor driver.

3.3.2 Computational Microprocessor

The responsibilities of the computational microprocessor could be summarised in the following five functions:

1. Receive and communicate user interface commands to the driver,
2. Receive and process motor and pedal shaft rotary encoder signals,
3. Send the measured pedalling speed to the user interface for display,
4. Calculate the motor speed command,
5. Communicate the motor speed command to the driver.

Figure 3.16 illustrates the communication pathway between the user interface and the driver. The interface processor sent user commands to the computational processor as 0-5 V digital signals. Once the computational processor received the signals, it activated 0-5 V output signals that relayed the commands to corresponding digital input pins on the driver.

In order for the driver to register the command signals, the 0-5 V signals had to be converted to 0-24 V signals using optocouplers (item 4, Figure 3.14). Optocouplers are electrical devices that convert energy from a voltage input at one side of the coupler to light directed toward a phototransistor at the other end. The phototransistor turns the light energy back into an electrical signal [63]. This means optocouplers isolate electrical signals on opposite sides of the coupler, and prevents voltage spikes or reverse currents from damaging

components on either side. Refer to the W9XT web site for a helpful guide on how to select appropriate resistors for optocoupler circuits [64].

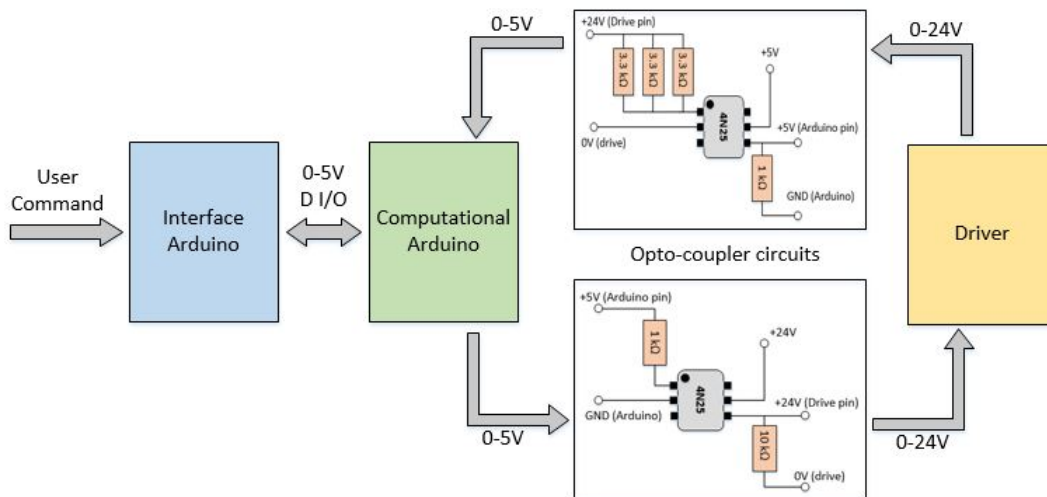


Figure 3.16: Communication pathway between the interface and motor driver

A 5 V quadrature encoder was attached to the pedal shaft via a 1:1 ratio pulley system to measure the pedalling speed (refer to Figure 3.5). The encoder could provide both pedalling speed and direction through two pulse signals (channel A and B), that are 90° out of phase as shown in Figure 3.17. The number of channel A pulses (high to low) per second indicates rotational speed, whereas channel B provides rotational direction as CW if channel B is high when A is low, or CCW if channel B is low when A is high.

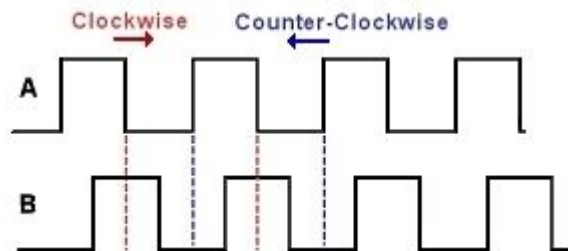


Figure 3.17: Quadrature encoder pulse signals for CW or CCW rotation

The pedal direction was not measured as patients did not need to pedal backwards (even though they could) and the encoder could provide the correct pedalling speed irrespective of the direction signal. Therefore, only channel A was tracked through an interrupt pin on the computational processor. The pin was programmed to detect both the rising and falling edges of each encoder pulse, where this particular encoder generated 500 pulses per revolution (PPR). Equation 3.4 was used to calculate the

pedalling speed in revolutions per minute. $D = 2$ represented the number of changes/counts (high to low, or low to high) detected per pulse, and C represented the number of counts per second. This is known as 2x decoding, which increases the resolution of the speed measurement as 1000 *counts* per revolution were detected as opposed to 500 *pulses* per revolution.

$$\omega_{pedal} = \frac{C}{(D \times PPR)} \times 60 \quad (3.4)$$

Similar to this, analogue pins 3 and 4 of the computational processor were masked to act as interrupt pins that could process 5V motor encoder signals received directly from the driver (refer to Appendix H). The motor direction was included, because it could be used to increase pedalling resistance by rotating the motor in the opposite direction to pedalling. Equation 3.4 was, therefore, adjusted for $D = 4$ (because two signals were tracked), and the PPR of the motor encoder was reduced to 1024 pulses per revolution. The latter setting enabled the microprocessor pins to sample fast enough to accurately detect the encoder counts per second. DriveTop Version 16VRS software (Bosch Rexroth, Lohr am Main, Germany) was used to pre-program the motor for application specific requirements such as the reduced PPR or speed limit (1000 rpm) mentioned earlier.

To display the pedalling speed on the interface LCD, the measured/calculated speed (not motor speed) was sent to the interface processor through serial communication using XBee Bluetooth modules (item 5 and 6, Figure 3.14). Wireless communication was necessary because there were not enough board pins to hardwire a serial communication between the two microprocessors. X-CTU version 6.3.8 software (Digi International, Minnesota, United States) was used to set-up the bluetooth modules using the settings outlined in Table 3.4. This configuration allowed the modules to successfully communicate information from the transmitting module (connected to the computational processor) to the receiving module (connected to the interface processor).

Table 3.4: Bluetooth module settings for successful wireless communication

Module	X-CTU Settings
Transmitter	Router AT, PAN ID = 885, JV = Enable, LH = 0
Receiver	Coordinator API, PAN ID = 885, LH = 1

Typically, the hardware serial ports on an Arduino (TX and RX pins) are used for wireless communication. However, these pins were already used to communicate to the driver (as explained later). Therefore, *digital* pins 3 and

4 of the computational processor were programmed to be software serial ports that could communicate to the interface processor. The interface processor was then programmed to extract and display the pedalling speed on the LCD during training. Appendix H provides a summary of the pin layouts for each microprocessor to avoid confusion.

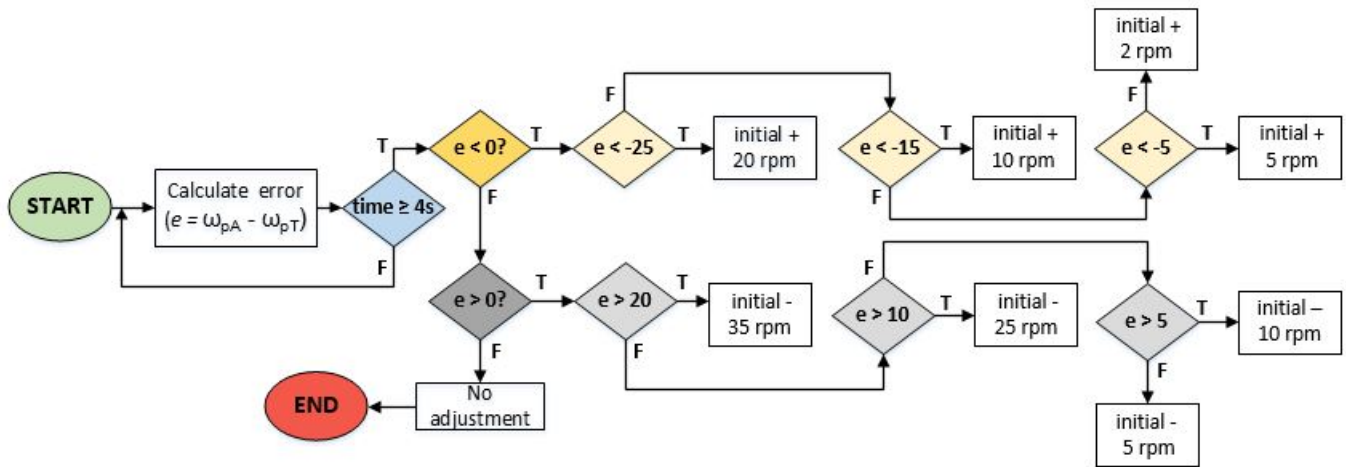


Figure 3.18: Control logic used to calculate the motor speed command

To calculate the motor speed command to be sent to the driver, the computational logic illustrated in Figure 3.18 was used. The speed error between the actual pedalling speed (ω_{pA}), and a target pedalling speed of 40 rpm (ω_{pT}) was calculated. The magnitude of the error determined with how much the motor speed was adjusted/incremented compared to the previous (initial) motor speed command. If the error was negative, it meant that the patient was pedalling below the target speed and more assistance was needed. The motor speed was then increased based on the magnitude of the error; the greater the error, the greater the increment size. Similarly, if the error was positive, the patient was capable of pedalling above the target speed and the motor speed had to be decreased. This approach encouraged active participation and higher training intensities for more improvement in patient functionality.

As shown in Figure 3.18, the motor speed was only adjusted every four seconds. This provided enough time for patients to experience the adjustment in assistance (or resistance). They could then try to reach/maintain the target speed before another adjustment occurred. The four second time lapse and increment sizes used were iteratively selected until a gradual increase or decrease of assistance (or resistance) was achieved. This explains why there was no need for a controller (such as a PID controller) designed to zero the system error in the shortest amount of time (as most controllers do). The control system merely needed to monitor real-time

pedalling speed, so that the error could be used to gradually assist pedalling motion; there was no need to zero the pedal error for operation.

Finally, the motor speed command was serially communicated to the driver through the hardware serial pins (TX and RX) of the computational microprocessor. The hardware serial command (“S-0-0036,7,w”) correctly communicated the speed command to the driver, where ‘w’ represented the speed command in rpm. Before the motor could respond to any speed command from the processor, the command “BCD:01” had to be sent to the driver to enable it for serial communication. Similar to the user interface commands, the serial command signal from the microprocessor had to be converted to a signal that the driver could register.

The serial port of the Arduino microprocessor complied with TTL (Transistor-Transistor Logic) serial communication, whereas the driver serial port operated with RS232 (Recommended-standard 232) telecommunication standards. This meant the logic high and logic low voltages of the ports differed. The driver port registered a logic high at negative voltages ranging from -3 to -25 V and a logic low at +3 to +25 V. On the other hand, the Arduino serial pins had a logic high of 5 V and a logic low of 0 V [65]. The MAX3232 breakout board (item 7, Figure 3.14) was used to convert the processor’s TTL signals to the RS232 signals needed at the driver. Figure 3.19 shows how the breakout board was connected to the processor and a DB9 connector, which was connected to the driver’s serial port using a serial cable (DB9 to DB15).

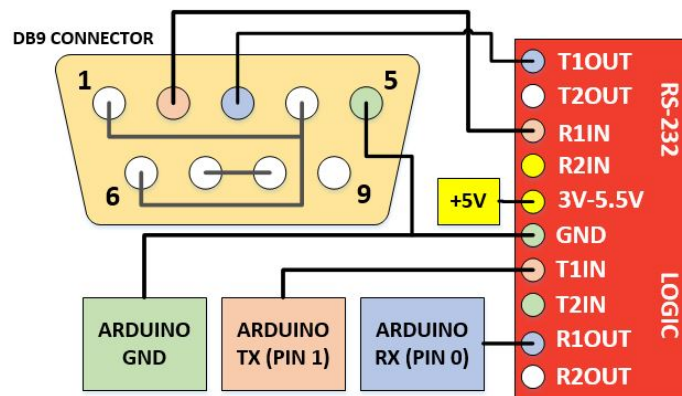


Figure 3.19: MAX3232 and DB9 connector layout for serial conversion between processor and driver

Note that the 5 V power supply referred to in Figure 3.19 was also converted from the 24V power supply of the driver (using a second buck converter). This was necessary to avoid using a 5 V supply pin from one of the microprocessors to power the breakout board and external circuitry (bluetooth modules and the 5 V sides of the optocoupler circuits). If a voltage regulator of either one

of the microprocessors had to supply enough current to the board pins as well as the external circuit connected to the 5 V pin, it could have damaged the processor or caused momentary blackouts in the system. Therefore, a separate 5 V supply was created for the external circuit.

From here, all that remained was for the driver to generate the correct motor response according to the speed command it received.

3.3.3 Driver

The Rexroth driver offered both speed and torque control options. Speed control was selected, because it was easier to relate a motor speed to the measured pedalling speed, compared to relating a motor torque value to the pedalling speed. There was also no measurement of the patient's torque input to which motor torque could be linked alternatively. Excluding torque measurements at the pedals was, however, deliberate, to avoid increased device cost and control complexity associated with incorporating wireless force or pressure sensors at the pedals.

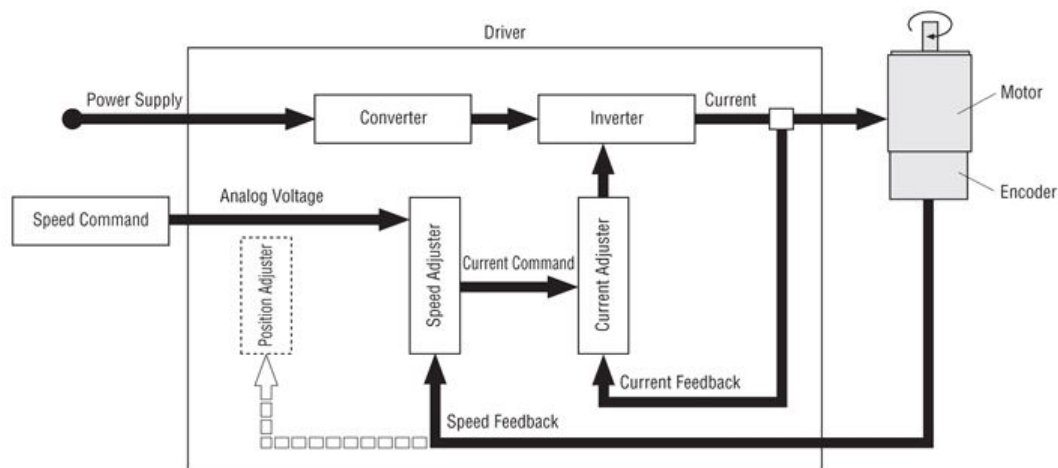


Figure 3.20: Driver speed control mechanism [66]

Figure 3.20 shows a simplified illustration of how the driver used two internal controllers to control the motor speed. When the driver received a speed command from the Arduino, it translated it into a current command that was sent to the motor to invoke a response. The current feedback was then internally (to the driver) monitored in the first closed-loop controller. If/when the current feedback differed from the target value, a rectifying current command was initiated. At the same time, the motor speed (encoder) feedback was monitored in the second closed loop controller. If a speed error occurred, the controller determined the motor torque needed to

rectify the response. Because current is directly proportional to torque, this translated to another rectifying current command sent to the motor [66].

The driver, therefore, offered reliable feedback control of the motor speed and there was no need to include an additional (external) feedback controller to achieve the desired motor response. Because the motor speed was not used for either motor speed command calculations or feedback control of the motor, future work can save computational time and microprocessor pins by not measuring the motor speed (if the same approach is used). Alternatively, motor speed measurements can be used for data logging if future projects want to capture the amount of assistance provided during training.

Furthermore, future work can consider using one large Arduino Mega processor instead of two Arduino Uno processors. The Mega board will have enough pins to eliminate the need for two microprocessor, which means wireless communication will not be necessary and device costs can be reduced. Alternatively, the bluetooth modules implemented can be used to achieve remote control over user interface commands. This was identified as an opportunity for improvement during clinical testing of the device, which will be elaborated on at a later stage.

3.4 Device Specifications

Table 3.5 summarises the final device specifications regarding size, training loads and -features, and built-in fail safe mechanisms.

The device and testing procedures discussed in Chapter 4 were ethically approved by the Health Research Ethics Committee (HREC) of Stellenbosch University. The committee approves testing on human subjects in accordance with the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice, and the Medical Research Council (MRC) Ethical Guidelines for Research. The guidelines include principles regarding the safety of patients during experimental testing. Approval from the committee, therefore, confirmed that the device conformed to safety standards/measures outline in these three ethical guidelines.

Table 3.5: Summary of device specifications

Specification	Unit	Magnitude
Dimensions	m	1.209 x 0.53 x 0.781
User weight	kg	0 - 100
Training speeds	rpm	0 - 70
Power consumption	W	0 - 800
Training modes	-	Active, Passive, Active-assisted
Display	-	16x2 LCD display (colourless) Push-button user interface
Feedback display	-	Real-time pedalling speed Training time
Fail safe mechanism(s)	-	Manual and automated emergency stop & Mechanical disengage of motor drive to pedals

3.5 Preliminary Testing

Before the device was tested on selected stroke and SCI patients, preliminary tests were conducted to refine the device response and eliminate any unexpected device behaviour. Figure 3.21 illustrates the prototype training device that was produced for testing.

The device was first tested without a user to determine how much of the motor input was transferred to the pedals. The serial port of the driver was connected to the serial port of a computer, and DriveTop software was used to send speed commands to the motor. After the motor reached the desired speed (as monitored on DriveTop software), the corresponding pedalling speed displayed on the LCD screen was recorded. This was repeated 29 times for motor speeds ranging from 0 to 200 rpm. Figure 3.22 illustrates the results captured, to which a linear regression model with an R-squared value of 0.997 was fitted.

For each measurement, the motor speed was translated to the corresponding planet-arm speed (for negligibly small losses in the motor belt drive) by dividing by the motor belt drive ratio of 3.27 (Equation 3.5).

$$\omega_{arm,i} = \frac{\omega_{motor,i}}{3.27} \quad (3.5)$$



Figure 3.21: Prototype training device used for testing

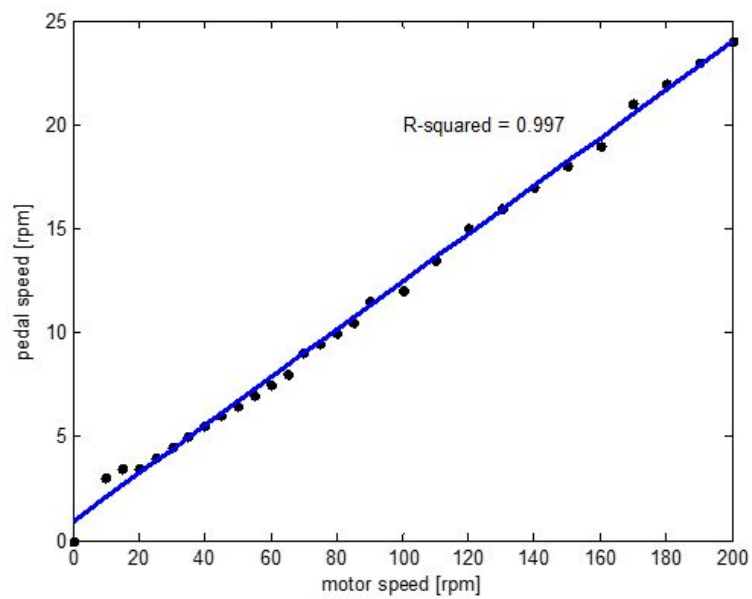


Figure 3.22: Pedal speed output for motor speed inputs without a user load

Similarly, the pedal speed was translated to the corresponding sun gear speed by multiplying with the pedal belt drive ratio of 2.5 (Equation 3.6).

$$\omega_{sun,i} = 2.5 \times \omega_{pedal,i} \quad (3.6)$$

The speed ratio for each measurement was then calculated by dividing the sun gear speed with its corresponding planet-arm speed. Taking the average of all the speed ratios calculated provided an estimate of the actual speed ratio achieved, which was calculated to be 1:1.14 from the planet-arm to the sun gear.

This did not correspond with the approximate ratio of 1:3 that was expected for the loaded ring gear PGB setup. This suggests that either the assumption that the PGB set-up would behave similar to a fixed ring gear design was incorrect, or the efficiency of the PGB was reduced due to the brake load applied at the ring gear (or both). Nevertheless, the device was able to invoke an assisted response at the pedals, albeit less efficient than what the design approach intended for.

Two healthy volunteers were recruited to test the device. These tests would determine if the device responded correctly to user interface commands, and if it could still train a 100 kg user passively at 70 rpm (without activating the automated emergency stop) despite the less than expected speed ratio.

The volunteers weighed 107 kg and 60 kg, respectively, with body heights of 1.8m and 1.5m. Both were asked to pedal the device three times, for 20 - 30 minutes at a time. The volunteers had to test all three training modes (active, passive and active-assisted) more than once during each training session. The device was also repeatedly stopped and started during sessions (including emergency stop) to test the interface commands.

The device responded as expected for each user interface command (without any delay) and neither volunteer reported discomfort or pain during training. Both volunteers could train passively at 70 rpm without activating the automated emergency stop. Furthermore, the volunteers confirmed that they experienced gradual assistance before 40 rpm was reached, and gradual resistance increase as 40 rpm was exceeded.

This confirmed that the device behaved as expected and that it was ready to be clinically tested on stroke and SCI patients.

Chapter 4

Clinical Testing

This chapter outlines the protocol according to which the effects of the device were to be tested on selected stroke and SCI patients. It includes the intended study design, outcome measures selected, inclusion/exclusion criteria and statistical analysis approach. The protocol was approved by the Health Research and Ethics Committee (HREC) of Stellenbosch University in May 2017 (ethics reference: S16/09/176).

4.1 Study Design

The device was to be tested at the Life Rehabilitation unit of Vincent Pallotti Hospital, Cape Town, using a randomised controlled study design. This meant stroke and SCI patients that qualified to participate in the study (per the inclusion/exclusion criteria in Section 4.4) would be randomly assigned to one of two study groups; a test group, or a control group.

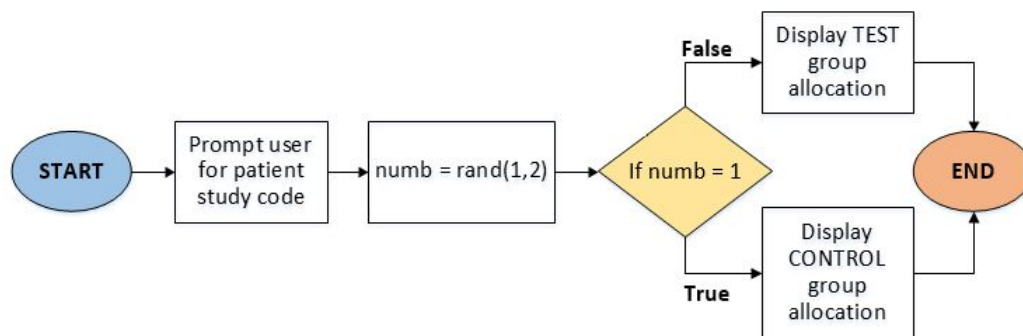


Figure 4.1: Flowchart of group allocator program algorithm

To maintain anonymity, patient identities had to be replaced with unique patient study codes. A group allocator program was designed to randomly assign each patient to a study group using the patient study codes. Figure 4.1 illustrates a flowchart of the algorithm used for the allocator

program. A uniform number generator assigned either a one or a two to each study code received, which determined patients' group allocation (1 = control, 2 = test). Matlab software (Mathworks, Massachusetts, United States) was used to generate the group allocator program.

Both study groups were to receive conventional physical therapy (PT) available to stroke or SCI patients at the clinic. In addition to this, test subjects had to complete three, 20-minute training sessions with the device (weekly) using the set-up shown in Figure 4.2. Control patients then had to receive 3 x 20-minute sessions of additional PT as well. This way, both groups could benefit from conventional therapy and receive the same amount of treatment time every week. Any difference in improvements detected between the groups would then indicate the effects of training with the device, and not the effects of more treatment time. Alternatively, equal training times could be achieved by making device training sessions part of test subjects' PT sessions (if they would allow it).



Figure 4.2: Test group set-up for device training

An eight week study period was selected. SCI patients were to complete all eight weeks of the study, whereas stroke patients only needed to complete four weeks. It has been shown that a minimum period of eight weeks is adequate for SCI patients to show measurable improvements after RAGT [4], whereas stroke patients can show improvement after as little as two weeks [14].

Patients would be invited to participate in the study during interview sessions with the primary researcher (Ms Basson) and a physical therapist before treatment started. To maximise the sample size, two additional days of interviews with stroke patients were scheduled at 2-week intervals as illustrated in Figure 4.3. This meant three different groups of stroke patients could complete the study instead of only one or two.

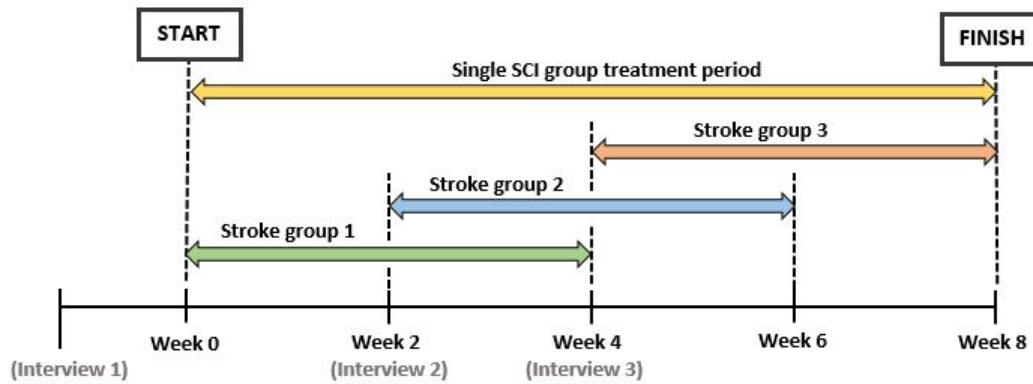


Figure 4.3: Stroke and SCI treatment groups with scheduled interview rounds

During device training, test subjects had to try and achieve a Borg rating scale of 12 - 14, while maintaining a pedalling speed of 40 rpm or more for each session. The Borg scale is a perceived measure of exertion during training, and a score of 12 - 14 corresponds to the target heart rate zone for extensive exercise (recovery within 24 hours) in most adults younger than 65 years [67]. The scale would be measured through verbal communication between the patient and the primary researcher who would supervise device training sessions. The Borg rating was, however, only an indication of training intensity and did not form part of the outcome measures of the study.

4.2 Outcome Measures

Functional recovery in stroke and SCI patients would be measured in terms of muscle strength, muscle spasticity, and daily activities of sit-to-stand and over ground walking. It was decided to simplify the analyses procedure by using the same outcome measures for both stroke and SCI patients. Clinicians supported this decision and agreed that the outcome measures selected would be able to show functional improvement in both stroke and SCI patients.

4.2.1 Muscle Strength

The ASIA lower extremity motor score (LEMS) was selected to assess muscle strength improvements. The scale involves assigning a rating of zero to five, to each of the five key lower extremity muscles shown in Table 4.1. A positive change in a patient's combined LEMS would then indicate improved muscle strength in his/her legs.

As part of the assessment method described later, an external physiotherapist, Ms Maclachlan, would grade each key muscle (left and right) according to the international standards for neurological classification of SCI motor scores

[68]. Typically, the motor scores of stroke patients are measured according to the lower extremity subscale of the Fugl-Meyer assessment (LE-FMA). Future studies can decide if they would prefer to incorporate separate motor score measures for stroke and SCI patients.

Table 4.1: Key muscles for lower extremity motor score (LEMS) using ASIA muscle grades [69]

Key muscle	Left (max)	Right (max)
Hip flexors (iliopsoas)	5	5
Knee extensors (quadriceps)	5	5
Ankle dorsiflexors (tibialis anterior)	5	5
Long toe extensors (extensor hallucis longus)	5	5
Ankle plantar flexors (gastrocnemius, soleus)	5	5
Total motor score per limb	25	25
Combined LEMS	50	

Muscle grades: 0 = total paralysis; 1 = palpable or visible contraction; 2 = active movement, gravity eliminated; 3 = active movement, against gravity; 4 = active movement, against some resistance; 5 = active movement

4.2.2 Muscle Spasticity

The Modified Ashworth Scale (MAS) was selected to evaluate muscle spasticity on a scale of zero to four; the higher the score, the more spasticity detected in muscle tissue. Table 4.2 summarises the key muscles that would be evaluated and the maximum MAS score that could be achieved.

Unlike the LEMS, the MAS measure is the primary outcome measure for muscle spasticity in patients with neurological conditions, including both stroke and SCI [69, 71]. The scale determines the amount of resistance felt during passive displacement of a limb, but it does not consider the velocity of a stretch, which can vary among investigators [69]. This causes general concern about the inter-rater reliability (degree of agreement among investigator) of the MAS. Therefore, only one (and the same) investigator would measure patients' MAS scores throughout the study.

MAS scores are then also measured through a series of lower limb passive movements conducted by the investigator (see Figure 4.4).

Table 4.2: Key muscles and maximum scoring for MAS measure [70]

Key muscle	Left (max)	Right (max)
Hip flexors	4	4
Hip abductors	4	4
Hamstrings	4	4
Gastrocnemius	4	4
Rectus femoris	4	4
Total MAS per limb	20	20
Combined MAS score	40	

**Figure 4.4:** 'Blinded' investigator measuring participant LEMS or MAS

4.2.3 Sit-to-Stand

The sit-to-stand outcome measure was included as a means to test and compare functional improvement in daily activities of patients that cannot walk (with or without assistance).

**Figure 4.5:** Example of one participant's sit-to-stand

The measure required patients to move from the seated position as shown in Figure 4.5 (with their feet comfortably flat on the floor) to the standing position where they had to wait for two seconds before sitting down. They could execute this exercise with or without assistance. The time taken to complete the task would then be recorded, and a video of each sit-to-stand exercise would be recorded for visual illustrations of significant improvement (if any).

4.2.4 Over Ground Walking

The final outcome measures included a Timed Up-and-Go (TUG) test combined with a Walking Index for SCI (WISCI II). Both measures were selected to evaluate functional improvements in patients that can walk (with or without assistance).

The TUG test would require patients to stand from a standard-arm chair (or wheelchair), walk three meters, turn around, walk back to the chair, and sit down again. Figure 4.6 illustrates the set-up that would be used to complete this task/test. As soon as the patient starts to rise from the chair, a timer would be started and the time it takes a patient to complete the exercise (until comfortably seated again) would be recorded.



Figure 4.6: TUG test set-up to be implemented

Additionally, a walking index score would be assigned to each patient based on the amount of assistance they use during the TUG test. The walking index scale ranges from zero (when patients cannot walk) to 20 (if patients can complete the six-meter exercise with no assistance). The amount of assistance is measured in terms of the devices (parallel bars, walkers, crutches or canes),

leg braces (short or long), or assistance from one or more persons needed to complete the task [72].

The TUG test is commonly used for both stroke and SCI patients. However, the WISCI is typically used only for SCI patients. Future studies might prefer replacing the WISCI II with an alternative measure such as the 10-meter walk test (10MWT), which assesses walking performance in terms of over ground walking speed.

In addition to these functional outcome measures, test subjects would be requested to complete the custom device questionnaire provided in Appendix I. The questionnaire evaluates the device's safety and operability from a patient's perspective. It requires of patients to rate statements about the device on a scale of one (strongly disagree) to four (strongly agree). Furthermore, clinician feedback about the potential value of the device would be collected during discussions about study results once the study is complete.

4.3 Assessment Method

An external physiotherapist not affiliated with Vincent Pallotti Hospital (Ms Maclachlan) would measure each of the outcome measures (excluding the device questionnaire) with the help of the primary researcher. Measurement sessions/days were scheduled to occur every two weeks. To avoid muscle fatigue that could influence the results, measurements had to be taken before conventional PT or device training sessions would occur on the day of measurements. SCI patients would, therefore, have five sets of measurement data after the study (1 x baseline, 3 x intermediate and 1 x final) and stroke patients would have only three (baseline, intermediate and final).

To ensure that the physiotherapist's judgement of improvements could not be impaired, she was not allowed to know the study group identities (which patients receive device treatment or not). Patients would be instructed not to reveal their group identities (or that of other patients at the clinic) to the investigator. This is known as a single-blinded outcome assessment, which improves the reliability of measurements [33].

Not revealing group identities to the investigator is the type of information that the informed consent document would communicate to patients. Per ethics requirements, the document had to inform patients of all the intended methods and procedures, as well as any potential risks or benefits associated with the study. Patients had to sign the document before they could take part

in the study. Reliable consent was, therefore, part of the selection criteria that would determine if patients could participate.

4.4 Inclusion and Exclusion Criteria

Table 4.4 and 4.3 summarise the selection criteria for SCI and stroke patients, respectively. The criteria were based on clinician feedback [16], criteria from previous stroke studies [73, 74], and recommendations from the ICCP (International Campaign for Cures of Spinal Cord Injury Paralysis) [69].

Table 4.3: SCI inclusion/exclusion criteria

Inclusion	Exclusion
Subacute AIS grade B to D spinal injuries	Musculo-skeletal or neuromuscular disorders that effect lower extremity functionality such as pressure sores, pathological fractures, osteoarthritis, and motor neuron disease (MSD)
18 - 70 year of age	Concomitant brain injuries or psychotic illness like psychosis, schizophrenia or depression unresponsive to medication
Lumbar level injuries	SCI at multiple levels of the spinal cord
Subacute stage of recovery	Medical problems like heart surgery or joint replacements in the past year
Able to travel to testing facility for exercise sessions (sufficient means of transport)	Pregnancy and alcohol or substance abuse in the last six months
Informed consent from participant	Current participation in another ongoing study or clinical trial
In-or outpatient therapy treatment	

The criteria aimed to ensure patient safety and avoid confounding results (confusing or not according to expectation). Because the criteria could still fail to consider all the possible medical issues or conditions, a physician had to clear each patient for participation beforehand. The inpatient therapy doctor at Vincent Pallotti rehabilitation unit (Dr Baalbergen) agreed to determine if patients were fit to participate. He would have access to both in-

Table 4.4: Stroke inclusion/exclusion criteria

Inclusion	Exclusion
Subacute ischaemic or haemorrhagic stroke	Progressive stroke or a previous stroke within the last 12 months
18 - 70 year of age	Medical problems such as acute renal failure, unstable cardiovascular condition or serious cardiac conditions like heart surgery within the last six months
Ability to sit for 20 minutes (with or without support)	Musculo-skeletal problems that cause restricted passive motion in lower extremities
Barthel index $\leq 65^*$	Neurological co-morbidities like Parkinson's disease, multiple sclerosis or non-neurological heart failure
Able to travel to testing facility for exercise sessions (sufficient means of transport)	Psychiatric illness like bipolar affective disorder, psychosis or suicidality unresponsive to medication
Informed consent from participant	Pregnancy and alcohol or substance abuse in the last six months
In-or outpatient therapy treatment	Current participation in another study or clinical trial

* Barthel index is a measure available on patient medical records that indicates the extent to which a patient functions independently.

and outpatients' medical records and would be able to make an informed decision about whether it is safe for patients to participate. Dr Baalbergen would convey his decision on the medical clearance form provided in Appendix I. With reliable patient consent and medical clearance, patients would be free to participate in the study.

Given the study design and assessment method selected, the following statistical analysis approach would be implemented to evaluate the results.

4.5 Statistical Analysis

Stroke and SCI results would be analysed separately. An analysis method that compares the average change in outcome measures between study groups would be implemented.

This approach corresponds to the respective null (H_0) and alternative (H_I) hypotheses summarised in Table 4.5 (the subscript ‘ i ’ represents an i^{th} outcome measure). An analysis of variance (ANOVA) test would then be used to determine the significance of treatment by either proving or disproving the null hypothesis for stroke and SCI treatment.

Table 4.5: Study hypotheses

Hypothesis	Description	Expression
$H_{0,Stroke/SCI}$	No detectable difference between study groups	$\mu_{T,i} = \mu_{C,i}$
$H_{I,Stroke/SCI}$	A detectable difference between study groups in favour of test group	$\mu_{T,i} > \mu_{C,i}$

The ANOVA test would calculate a unique probability value (p -value) for each pair of test and control group results. The p -value would indicate if either a statistically significant ($p \leq 0.05$) or insignificant ($p > 0.05$) difference was detected between the study groups. If a significant difference is detected, the null hypothesis can be rejected and the difference detected is due to the treatment interventions and not due to chance [75].

On the other hand, the ability of the study to reject the null hypothesis would remain dependant on the number of subjects (sample size) tested. If the sample size is too small, the study would not be able to detect a small/significant difference if one exists. This means an analysis of the results could fail to reject the null hypothesis when it should be rejected (otherwise known as a Type II error). Professor Nel (statistician) was consulted to determine a sufficient sample size for the study.

4.5.1 Sample Size

Statistica data analysis software (StatSoft, Oklahoma, Unites States) was used to calculate an adequate sample size through a power analysis of the proposed study design.

Figure 4.7 shows the power versus sample size graph that was generated. Power goal (x-axis) refers to the probability of the study detecting a statistically significant difference if/when one exists. Table 4.6 clarifies the other power analysis parameters (visible above the graph) that were used to generate the graph.

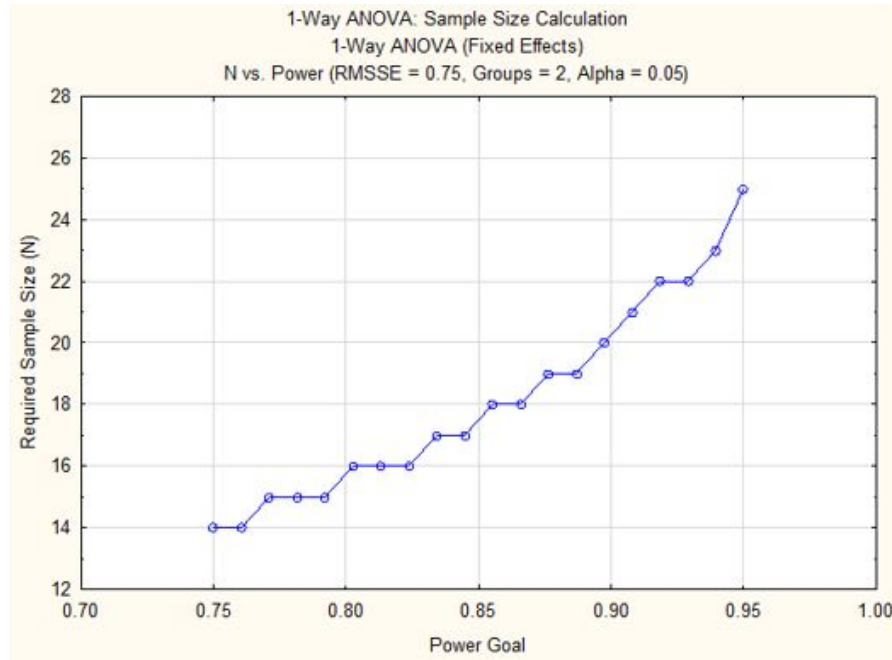


Figure 4.7: Power versus sample size results

Table 4.6: Power analysis parameters used in *Statistica* software

Parameter	Name	Description	Value
ANOVA	Analysis of Variance	Statistical method used to test differences between two or more means	-
RMSSE	Root Mean Square Standardized Effect (effect size)	Smallest detectable size of difference between study groups. For example, RMSSE of 25% means the study can detect a $\frac{1}{4}$ of a standard deviation's difference between group results	75 %
Groups	-	Number of independent study groups being analysed i.e. test and control group	2
Alpha	-	Probability of a Type I error: rejecting H_0 when it should not be rejected	5%

According to Figure 4.7, 20 patients per study group would give the study a 90% chance of detecting a 75% effect size (see Table 4.6). This is commonly referred to as a 90% confidence level, which is ideal for reliable results. However, it was unlikely that the study would be able to obtain enough patients for even a 75% confidence level (14 stroke and SCI patients per

study group). The sample size would be subject to the amount of stroke and SCI patients (which is naturally more scarce) available for testing at Vincent Pallotti Hospital during the limited study period. Fortunately, this was only a proof of concept study. Any number of participants would, therefore, be satisfactory to obtain an indication of the potential results that future (larger-scale) studies could expect to see.

Chapter 5 will now reveal the sample size and clinical test results obtained throughout the study.

Chapter 5

Results

This chapter summarises the patient demographic and functional outcome measurements recorded throughout the study. Additionally, it includes patient- and clinician feedback about the device's safety and operability, as well as a life cycle cost analysis of the manufactured prototype.

5.1 Patient Demographic and Treatment

Eleven prospective participants were interviewed at the in- and outpatient centres of the Life Rehabilitation unit of Vincent Pallotti Hospital, Cape Town. Only one patient was a SCI patient, and although she gave consent to participate, she was discharged from the inpatient centre two weeks after her interview. She could not return to the clinic for further testing. Similarly, a stroke patient who agreed to participate was suddenly discharged due to personal reasons and could not continue with testing. Two other stroke patients declined to participate in the study, and another patient was too cognitively impaired to give consent or participate. Two more patients were excluded because they had too little functional impairment (more cognitive than physical) and their therapist(s) advised that they would not be able to show measurable improvements in the selected study outcomes. Ultimately, only four stroke patients were able to participate and complete the study. Table 5.1 summarises the patient demographic and clinical data of each participant at the time when baseline measurements were taken. All four patients had either complete or partial paralysis on the left side of their body.

Three rounds of interviews with patients were conducted as planned. The first series of interviews identified the two inpatients listed in Table 5.1. The second set of interviews produced no new participants, whereas the two outpatients consented to participate during the final round of interviews. Inpatients completed the study as part of their stay at the inpatient centre, whereas outpatients completed treatment during bi-weekly visits to the outpatient centre. The inpatients were treated during the first four weeks of

the eight-week study (19 June-17 to 14 July-17), and the outpatients were treated during the remaining four weeks of the study (17 July-17 to 11 Aug-17).

Table 5.1: Patient demographic and clinical data at the time of baseline measurement

Patient Code	Age (years)	Gender	Type of stroke	n th Stroke	Time since stroke	Patient Centre	Study Group
S-01	46	Male	Ischaemic	1 st	4 weeks	Inpatient	Test
S-02	52	Male	Ischaemic	1 st	2 weeks, 5 days	Inpatient	Control
S-04	57	Female	Haemorrhagic	2 nd	11 weeks, 3 days	Outpatient	Test
S-07	32	Female	Ischaemic	2 nd	15 weeks, 2 days	Outpatient	Control

Despite the intended methods discussed in Chapter 4, treatment times and frequencies differed among study groups and in- and outpatient centres. Conventional inpatient therapy included five, 45-minute physical-, occupational-, and speech therapy sessions a week. The test group inpatient received the standard inpatient treatment, with three, 20-minute device training sessions a week as planned. However, due to high workload and back-to-back appointments, physical therapists were unable to provide additional 20-minute PT sessions to the control inpatient. The test subject also preferred not to shorten his PT sessions to include device training as part of PT therapy.

On the other hand, the outpatients received two, 60-minute physical-, occupational- and speech therapy sessions a week. The test subject received an additional 30-minute device training session during each visit. Similarly, outpatient therapists could not administer additional 30-minute PT sessions to the control subject, and the test subject was reluctant to make device training part of her PT sessions. Consequently, both test subjects received 60 minutes more treatment than control subjects every week.

With regards to the study outcomes, Ms Maclachlan measured the outcomes every two weeks as planned. Measurement sessions were, however, subject to the availability of both the patient and Ms Maclachlan on the day. This meant measurements were sometimes taken during or after conventional therapy, and not consistently beforehand as planned.

Furthermore, the sample size was too small compared to the 14 subjects needed per group for a confidence level of 75%. A statistical analysis of the

results would not have produced meaningful and reliable conclusions about the significance of device treatment. Consequently, the results were not statistically analysed. Instead, this chapter provides the outcome measurements and patient and clinician feedback recorded throughout the study. The results will then be discussed in Chapter 6 to establish its clinical value for future research.

5.2 Functional Outcome Measurements

For convenience, the S-0X study codes listed in Table 5.1 are now replaced with T-0X or C-0X for test- and control subjects, respectively.

All four participants showed an overall improvement in their lower extremity motor scores (LEMS) from baseline to final measurements as shown in Table 5.2. Baseline scores of the inpatients (top two codes) differed by 11 scores, whereas that of outpatients (bottom two codes) differed by only one. After four weeks of treatment, the control inpatient (C-02) showed a greater improvement than the test inpatient (T-01). On the other hand, the test outpatient (T-04) showed more improvement than all four participants including the corresponding control outpatient (C-07). Furthermore, both control subjects showed no change in motor score from week 2 to week 4, whereas the test subjects showed positive changes after each measurement session.

Table 5.2: Combined LEMS for participants (out of a possible 50)

Patient Code	Baseline	Intermediate (week 2)	Final (week 4)	Total change
T-01	25	29	30	+5
C-02	36	43	43	+7
T-04	36	42	45	+9
C-07	35	37	37	+2

Three of the four subjects showed reduced spasticity (MAS) scores after treatment as demonstrated in Table 5.3. Both test subjects showed more improvement than their respective control subjects. Baseline MAS scores differed by three scores for the inpatients, whereas the outpatients started with equal MAS scores before treatment. During treatment, both outpatients showed an unexpected increase in their score from week two to week four, and the control inpatient (C-02) showed no change in his MAS score after week two.

Table 5.3: Combined MAS for participants (out of a possible 40)

Patient Code	Baseline	Intermediate (week 2)	Final (week 4)	Total change
T-01	7	7	5	-2
C-02	4	3	3	-1
T-04	6	4	5	-1
C-07	6	5	6	0

Table 5.4 summarises the sit-to-stand times recorded. It shows that all the participants had faster sit-to-stand times by the end of treatment. The control inpatient (C-02) showed more improvement than the test inpatient (T-01), whereas the outpatients showed negligibly small improvements in comparison to one another and the inpatients. Before treatment, the test inpatient (T-01) was not able to execute the sit-to-stand exercise. This changed after two weeks when he was able to complete the exercise with assistance from a physical therapist. Similarly, control subject (C-02) and (C-07) needed assistance from a therapist and a balancing stick, respectively, to perform the exercise before treatment. In both cases, the patients were able to complete the sit-to-stand task without assistance by week four. The sit-to-stand measurements were, however, subject to variability because patients executed different standing times (despite instructions to stand for two seconds).

Table 5.4: Sit-to-stand exercise times (in seconds)

Patient Code	Baseline	Intermediate (week 2)	Final (week 4)	Total change
T-01	NT	15.07 (WA)	13.70 (WA)	-1.37
C-02	10.30 (WA)	6.30 (NA)	6.17 (NA)	-4.13
T-04	4.77 (NA)	4.64 (NA)	4.20 (NA)	-0.57
C-07	3.87 (WA)	3.23 (NA)	3.67 (NA)	-0.20

NT = Not Testable (due to functional incapability), WA = With Assistance (brace, crutches, parallel bars or person), NA = No Assistance

Lastly, Table 5.5 and 5.6 respectively summarise the Timed Up-and-Go (TUG) test and Walking Index (WISCI II) scores for each participant. Due to limited functionality, the test inpatient (T-01) could not complete the TUG test at any time during his four-week treatment. This automatically corresponded to a constant walking index score of zero. On the other hand, the control inpatient

(C-02) was able to complete the TUG test for his final measurement session when he received a walking index score of 19 out of a possible 20 (he was able to complete the six-meter exercise using only a cane).

Both outpatients were able to complete the TUG test for all three measurement sessions. However, neither showed a change in their walking index scores. To complete the TUG test, both patients needed assistance from a foot-brace on their affected side, and the control patient (C-07) required a balancing stick as well. This was the case for each measurement session. Ultimately, the test patient (T-04) showed an improved TUG time after treatment, whereas the control patient showed a surprisingly slower time than her baseline measurement.

Table 5.5: Timed Up-and-Go (TUG) test times (in seconds)

Patient Code	Baseline	Intermediate (week 2)	Final (week 4)	Total change
T-01	NT	NT	NT	-
C-02	NT	NT	41.20 (WA)	-
T-04	27.47 (NA)	27.58 (NA)	24.55 (NA)	-2.92
C-07	40.47 (WA)	44.95 (WA)	45.23 (WA)	+4.76

NT = Not Testable (due to functional capabilities), WA = With Assistance (brace, crutches, parallel bars or person), NA = No Assistance

Table 5.6: Walking Index (WISCI II) scores

Patient Code	Baseline	Intermediate (2 weeks)	Final (4 weeks)	Total change
T-01	0	0	0	0
C-02	0	0	19	19
T-04	18	18	18	0
C-07	15	15	15	0

To summarise, Table 5.7 shows which patients demonstrated some improvement (+), a deterioration (-), or no change (0) in their respective outcome measures after treatment.

Table 5.7: Summary of participant change in outcome measures

Patient Code	LEMS	MAS	Sit-to-stand Time	TUG Time	WISCI II
T-01	+	+	+	N.A*	0
C-02	+	+	+	N.A*	+
T-04	+	+	≈ 0	+	0
C-07	+	0	≈ 0	-	0

*N.A = Not Applicable. No baseline and/or intermediate and final measurements to compare

5.3 Device Safety and Operability

Both test subjects completed the device questionnaire at the end of treatment to rate the device's safety and operability based on their experience. Figure 5.1 and 5.2 respectively show the device safety- and operability feedback received.

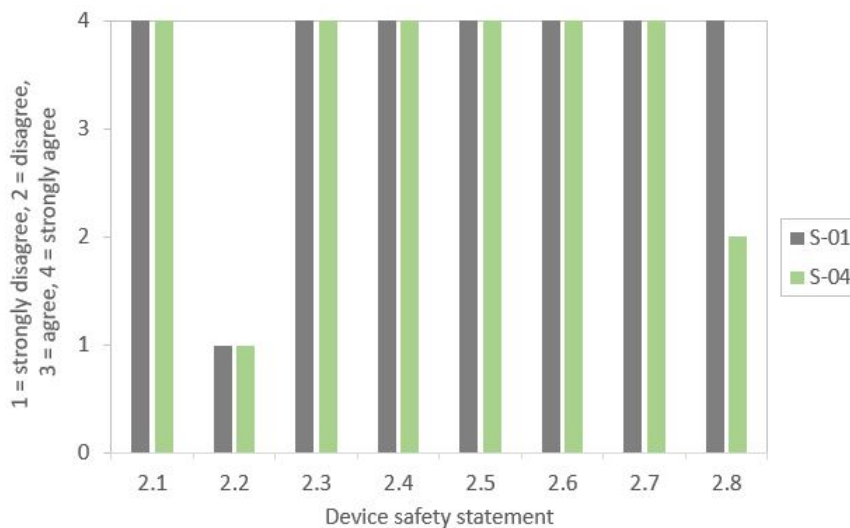


Figure 5.1: Patient feedback regarding device safety

Both patients strongly agreed that they felt safe and comfortable while training with the device (statement 2.1 and 2.6, Figure 5.1). They also felt that the device behaved as expected and responded well to interface

commands such as the emergency stop or pause command (statement 2.3 to 2.5). Both patients would feel safe to train with the device on their own at the clinic (statement 2.7), but patient S-04 would prefer to have an assistant or clinician near while training (statement 2.8). Furthermore, by strongly disagreeing with statement 2.2, both patients confirmed that the device did not hurt or injure them before, during or after training.

Regarding operability, the patients agreed that the device is easy to use if an assistant or clinician is present (statement 1.1, Figure 5.2). However, they found it difficult to operate the device without an assistant or clinician (statement 1.2). This was because they could not reach the user interface from the seated position to control the device themselves. On the other hand, they thought the user interface was easy to understand (statement 1.3) and would like to train with the device as part of their treatment at the clinic (statement 1.4). Patient S-01 stated that he does not have a desire to purchase this (or a similar device) for home-use (statement 1.5), whereas patient S-07 said that she would like to purchase such a device for home training (if she could afford it).

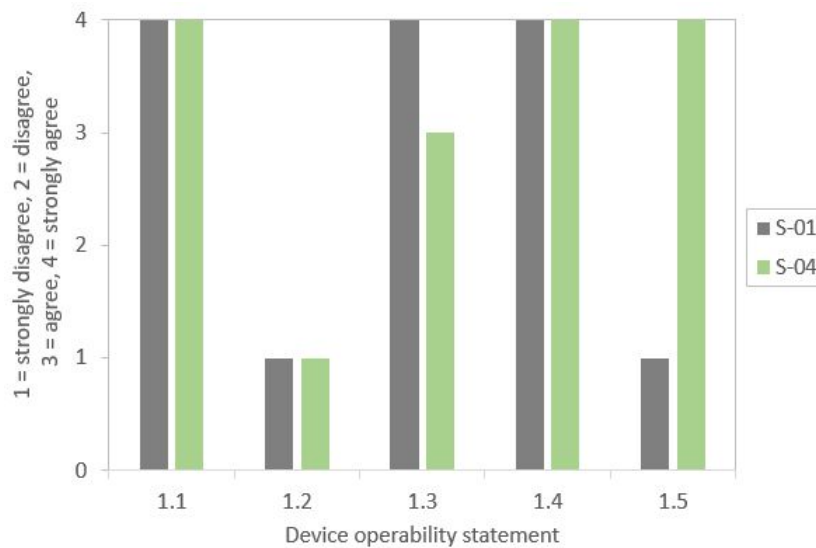


Figure 5.2: Patient feedback regarding device operability

In addition to this feedback, patient S-04 suggested that the calve supports should be moved to the side of the pedal assembly. She found it difficult to put her left (affected) foot onto the pedal with the calve support located at the back of the pedals. Clinicians at the rehabilitation unit agreed that the device was safe for stroke treatment, and easy to operate once the commands were explained. However, powering the device posed a problem, as it could not work on the office circuit line without disconnecting some kitchen appliances

first. The device was also heavy and could not be easily moved if/when needed. Clinicians felt these are issues that need to be addressed in future designs.

5.4 Life Cycle Cost Analysis

A conservative approach was used to estimate the life cycle cost associated with the prototype device. The assessment considered costs related to the resources (material and hardware), manufacturing, distribution, use, and end-of-life cycle phases. Table 5.8 summarises the outcome of the cost analysis. Refer to Appendix J for a summary of how these values were calculated.

Table 5.8: Estimated life cycle cost associated with the prototype

Life Cycle Phase	Includes	Cost (ZAR)
Resources	Material and hardware	40,000.00
Manufacturing	Labor, equipment and indirect cost	25,000.00
Prototype cost	Direct and indirect costs	65,000.00
Distribution	Transport and installation	6,500.00
Use	Maintenance and power	68,000.00*
End of Life	Disposal plan	≈0

*Annual estimated cost for 500 patients that complete three, one-hour training sessions per week (52 weeks)

The resource cost refers to the list of components that were used for the mechanical and control design of the prototype. These components are physically visible on the final device, and it includes the Rexroth servomotor and driver. The resource cost of ZAR40,000.00 represents the reduced material cost of the prototype. This is the cost that can be achieved if unnecessary components such as the over-designed Rexroth servomotor and driver are replaced with less expensive alternatives per recommendations made throughout Chapter 3. Appendix J explains which component costs could be reduced or eliminated.

The manufacturing cost includes the direct costs associated with equipment use (not electricity costs) and labour needed to manufacture the device. The labour cost corresponds to 100 working hours that a skilled artisan required to produce the prototype. Indirect manufacturing costs such as facility usage (water and electricity) and administrative salaries were difficult to estimate for the prototype alone. This is because the workshop that produced the device was responsible for manufacturing multiple other devices at the same time.

Nevertheless, indirect manufacturing cost was estimated as 20 % of direct costs (material, labour and equipment) per Stellenbosch University guidelines.

Distribution costs to Western Cape facilities were considered negligibly small compared to direct and indirect costs. The device could be transported to Vincent Pallotti Hospital using a rented vehicle and two people for a travel distance of less than 100 km. No installation process was required upon arrival because the device merely connects to a single phase outlet for use. However, distributing devices across South Africa would involve greater distribution costs. National distribution cost associated with the prototype was estimated to be 10 % of the prototype cost.

It was confirmed that, given the operating conditions and application of the device, the motor and driver is likely to last 10 to 15 years without maintenance [76]. The only other maintenance requirements would involve changing the friction brake pads and emergency stop button battery once or twice a year (depending on use), meaning no specialists are required to conduct maintenance on the prototype. Therefore, maintenance costs associated with the device life cycle was considered negligibly small.

Furthermore, it was assumed that the device would not exceed a rated power output of 800 W to train patients (due to the motor speed limit and rated torque output discussed in Chapter 3). Based on the business rate of Eskom electricity for 2017/2018 (ZAR1.09/kWh), and a usage cycle of three, one-hour device training sessions per week, an annual power cost of ZAR136.00 was estimated per patient. If 500 patients were to train with the device annually using these frequencies, it would accumulate to an annual power cost of ZAR68,000.00.

Lastly, the end-of-life plan could involve donating or selling the device to educational institutions such as Stellenbosch University. The materials and components used in the device can be reused or disassembled for use in future research projects. Therefore, there are no expenses associated with the end-of-life plan for the prototype.

The test and cost analysis results will now be discussed.

Chapter 6

Discussion

This chapter evaluates in-and outpatient results separately and discusses the device cost analysis. The chapter concludes on the clinical value of the results, and the potential value of the device for rehabilitation centres in South Africa.

6.1 Inpatient Results

Both patients showed improved muscle strength (LEMS), muscle spasticity (MAS), and sit-to-stand ability after treatment. Because the test subject received 60 minutes more treatment than the control subject every week, it was expected that the test subject would show the most improvement. Surprisingly, the test subject showed less improvement. Five differentiating factors among the patients that could have contributed toward the unexpected outcome was identified.

The control subject started his study treatment two weeks after stroke, whereas the test subject started four weeks after his stroke as shown on the inpatient timeline in Figure 6.1. Literature showed that earlier treatment in the subacute stage could lead to greater functional improvements [4], and spontaneous recovery also contributes toward improvements in the first few weeks of recovery [37]. It is possible that the control subject experienced more functional improvement (which occurred mainly during the first two weeks) because he was experiencing more spontaneous recovery and benefits due to earlier treatment after stroke.

On the other hand, this phenomenon changed after two weeks. The control subject showed less (if any) improvement than the test patient during the last two weeks of the study. For the control patient, the change in improvement occurred at the same post-stroke time that the test subject started with (four weeks). This suggests that the effects of earlier treatment and spontaneous recovery began to depreciate at four weeks post-stroke. Device training could, therefore, have contributed toward the continued improvements seen in the

test subject, which occurred despite less spontaneous recovery and more injury stabilisation later after stroke.

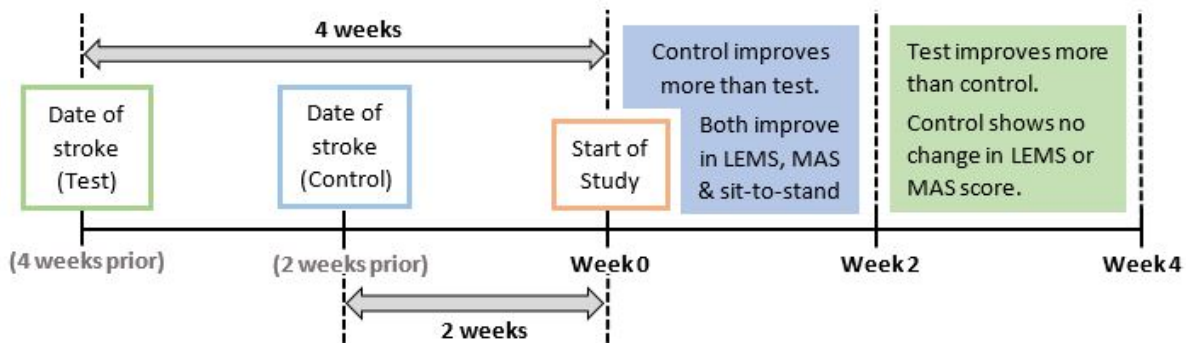


Figure 6.1: Timeline summary of inpatients' improvements after stroke

The patients demonstrated differing baseline values for the LEMS (muscle strength) and MAS (spasticity) measures before treatment. This had an impact on the patients' functional capabilities and PT treatment goals, which would have influenced the results.

The difference in baseline LEMS values shows that the control subject had more muscle strength in his left leg than the test subject. In fact, the test subject had no movement or muscle strength in his affected leg before treatment. Increased muscle strength meant that the control subject's PT treatment could focus on advanced exercises that were designed to restore limb functionality. The test subject would not have been able to execute the same exercises with his more severe hemiplegia. At the same time, the test subject showed greater muscle spasticity (MAS) before treatment. As he was not physically able to do much else until he regained some muscle strength, his conventional PT mainly focused on reducing muscle spasticity. This would explain why the test subject showed greater improvement in spasticity despite showing less improvement than the control subject in all the other outcomes.

The effect of differing baseline measures or treatment goals can also be seen in the sit-to-stand and TUG test results. Neither subject could walk (with or without assistance) before treatment. By the end of treatment, the control subject was able to complete the TUG test using only a cane for support. The control subject could also complete the sit-to-stand exercise for each measurement session, which improved from 'with assistance' to 'without assistance' after treatment. In contrast, the test subject needed two weeks before he could execute sit-to-stand (with assistance), and he was never able to complete the TUG test before his study treatment ended. The control subject was, therefore, better equipped (physically) to practice more

advanced exercises (like sit-to-stand) earlier in recovery, which would have helped him to show more functional improvement.

Apart from treatment time post-stroke, PT goals/focus, and differing baseline measurements, the patients' attitude could also have influenced the results. Feedback from the patients' physical therapists established that the control patient was very motivated and hard working during training. In contrast, the test subject was more easily distracted and had the tendency to stop a task before it was finished. This corresponds with the results as the more committed and hard working patient showed greater improvement.

Furthermore, there was no control over the type or amount of additional training that patients completed outside of the study. Hospital regulations prevented the restriction of any additional training that patients might want to complete in their spare time. This means both patients had access to the inpatient gymnasium during their stay, and given the patients' attitudes toward training, it is probable that the control subject did more training in his spare time.

Finally, compared to literature, Skvortsova *et al.* (2011) and Dobke *et al.* (2011) found significant differences in favour of active-assisted training in subacute stroke patients (using a MOTomed trainer) [14, 77]. This means device factors such as the lack of symmetry or biofeedback, which Yang *et al.* (2013) found to be important features for more functional improvement [49], could have resulted in the test subject showing less improvement than expected. Alternatively, training frequency (3 x 20 minutes a week), or the fact that intensity (Borg rating) was monitored through patient feedback instead of a heart rate monitor, resulted in insufficient training intensities that could not produce more measurable improvements in four weeks. However, the latter possibilities seemed less plausible when outpatient results showed favour toward device training.

To summarise, the results showed that there are no adverse effects associated with device treatment. Although the test subject showed less improvement than the control, the unexpected result was assumed to be the cause of differentiating factors that inhibited the test subject's ability to show more functional improvement. The factors identified in this regard include; (1) treatment time post-stroke, (2) differing baseline measurements, (3) different PT goals, (4) patient attitude, and (5) control over additional training. Fortunately, some of these factors were avoided with outpatient treatment, which showed more favourable results.

6.2 Outpatient Results

Both outpatients showed improved muscle strength, sit-to-stand time, and walking performance after their four-week treatment. The test subject showed greater improvements than the control, which corresponds to the expected results as explained before. Fortunately, the test conditions for the outpatients were more controlled, and there were less confounding variables that could have influenced the results.

The patients demonstrated similar and/or equal baseline measurements for both muscle strength (LEMS) and muscle spasticity (MAS). Their outpatient therapy was focussed on the same goal, namely to restore proper gait, and neither admitted to completing additional treatments outside of the study (excluding home exercises prescribed by therapists for conventional therapy).

This eliminates three of the five potentially influential factors identified with inpatient treatment (differing baseline measurements, differing PT goals, and no control over extra training). On the other hand, both patients were being treated for their second reoccurring stroke. Usually, reoccurring strokes can be added to the list of influential factors. However, for this particular case, it was not relevant. Neither patient suffered their first stroke within a year before the study, and both recovered well after their first stroke with no physical impairments or functional dependencies before their second stroke.

Surprisingly, therapists described the test subject's attitude towards training as despondent (low spirited due to a loss of hope), whereas the control subject appeared to be very motivated and hard working. This could suggest that the device helped overcome the potentially adverse effects of a less positive attitude, or the effects of near chronic stage recovery inhibited the control subject's ability to show more improvement as explained next.

The test subject started the study close to three months after her stroke, compared to the control subject who started treatment more or less four months post-stroke (see Figure 6.2). The test subject showed more improvement during both two-week intervals of the four-week treatment, whereas the control subject showed little to no improvement (if not deterioration) after treatment. As explained with the inpatient results, earlier treatment after stroke could have contributed toward greater improvements for the test subject. On the other hand, the control subject was more or less one month away from the chronic stage of recovery by the end of treatment. Literature associates the chronic stage with a sharp decay or stagnation in improvement. It is, therefore, possible that the control subject showed little improvement because she was nearing the chronic stage of recovery. Extended tests would have been necessary to confirm this notion.

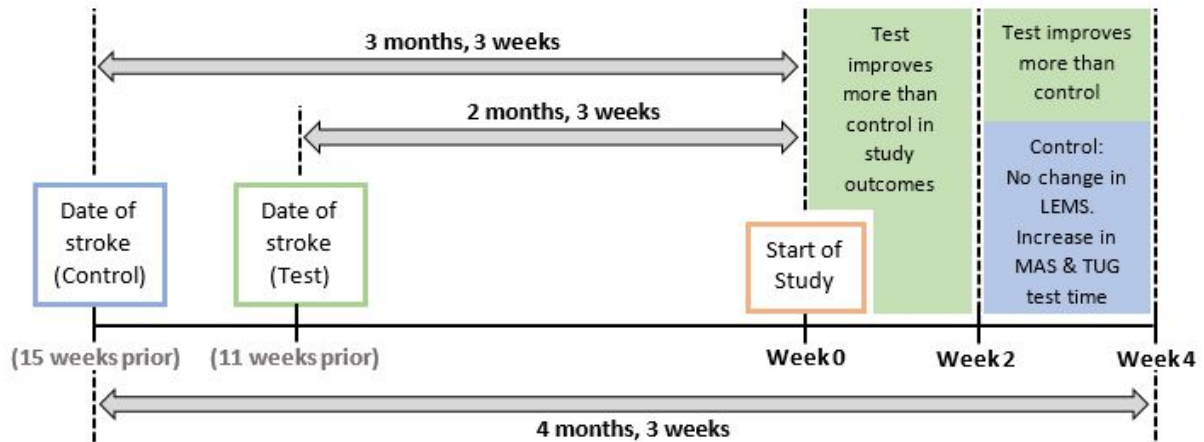


Figure 6.2: Timeline summary of outpatients' improvements after stroke

The test subject showed greater improvements in both her muscle strength and spasticity measures after treatment. Because baseline LEMS and MAS scores were either very similar or equal, it is reasonable to assume that greater improvements were due to additional treatment with the device. However, because the control subject did not receive additional 30-minute PT sessions as planned, it cannot be known if the difference in improvement is due to additional treatment with the device or simply due to more treatment in general. Future studies need to rectify this error if/when possible to generate more conclusive results. Nevertheless, the effect of improved muscle strength and spasticity was visible in the test subject's walking performance as measured by the TUG test time.

The test subject's TUG time reduced by almost three seconds after treatment, which suggests that her walking speed and/or over ground walking ability improved significantly. This corresponds with her considerable increase in muscle strength (most of all the participants) that made it easier for her to complete and excel at the exercise. Surprisingly, the control subject's TUG time increased after treatment. This would mean that her over ground walking deteriorated despite using the same amount of assistance for each TUG test, and despite experiencing some increase in muscle strength which should have facilitated walking. The most reasonable explanation for this is the potential effect that weather conditions, and the time at which measurements were taken had on results.

On cold days, the control subject demonstrated less mobility and often referred to increased muscle pain and spasticity. This would have had an adverse effect on the patient's walking performance for TUG test measurements. Coincidentally, the weather was cold and rainy on both the intermediate and final measurement days (but sunny during baseline measurements). This corresponds to the measurements that showed

deteriorated performance and/or spasticity in the control subject, which suggests that weather conditions played a part. However, the test subject was exposed to the same weather conditions during measurements, and she too mentioned increased muscle pain on colder days, but she still showed improvement in her TUG test time.

This was likely a due to device treatment combined with inconsistent times at which measurements were taken. The test subject's measurements were always taken after a device training session and before conventional therapy. Device training, therefore, acted as a brief warm-up for the patient, which would have benefitted her outcome measurements (especially on colder days). In contrast, the control subject's measurements were taken at the end of her three, one-hour treatment sessions for the day (physical-, occupational-, and speech therapy). This would have made her more fatigued during measurements, which would have influenced her results.

Regarding the remaining outcomes of sit-to-stand and walking index (WISCI II) scores, the patients demonstrated negligibly small improvements in their sit-to-stand times, and no change in their index scores. Negligibly small change in sit-to-stand times is understandable because prior inpatient therapy required of patients to execute sit-to-stand (with or without assistance) before discharge. This meant there was little room for improvement in patients' sit-to-stand times to begin with. On the other hand, the walking index was not a sensitive enough measure of walking performance for this study. The amount or type of assistance that either patient used for their TUG tests never changed. Therefore, the walking index (which considers only support used and distance travelled) could not detect improved (or deteriorated) walking performance in participants. Future work can consider replacing the walking index with an alternative measure like the 10-meter walk test (10MWT) that measures walking speed instead.

Overall, the outpatient results correspond more with the positive influence of device training that Skvortsova *et al.* (2011), Dobke *et al.* (2011) and Yang *et al.* (2013) found. It suggests that training with the device (in conjunction with conventional PT) can achieve more functional improvements without the need for symmetry and biofeedback features on the device. However, the true effects of device training can only be known after a larger scale study is conducted, where control subjects receive the same amount of treatment time as test subjects every week. Also, equal warm-up times before measurements and consistently taking measurements before conventional treatment or fatigue, are two more factors that future studies should consider.

6.3 Cost Analysis

The cost analysis showed that the unit production cost of the prototype device is equal to the purchasing cost of a new MOTomed leg trainer, namely ZAR65,000.00.

It is a well-known fact of the economics of scaling that the average cost per unit output decreases as the volume of production increases [78]. Therefore, on a larger production scale, the cost of this prototype device will be less than that of the competing MOTomed leg trainer. However, because many factors influence scaled production, it is unknown to what extent scaling can/will reduce the prototype cost.

A detailed scaling analysis was not part of the scope of this research project. The objectives required (among other) that the research must show if the training device produced could be more affordable than current technology. The cost analysis indicates that this objective was satisfied, but the potential scaled cost of the device remains unknown. To ensure that the device is competitive regarding cost, future research need to conduct a scaling analysis to determine with how much the device cost can reduce.

If the scaled device cost is significantly less than the MOTomed trainer, the main difference in cost will be due to features that are included or excluded in each device. The prototype device includes the bare minimum of features. In contrast, the MOTomed includes functional features such as biofeedback and symmetry display, as well as other convenient features such as a colour screen display, 32 languages, and interactive games for training [47]. It is possible that the prototype device can achieve similar recovery rates than the MOTomed without including these elaborate features. Larger scale studies will need to compare the devices to indicate the worth of the features (and increased or reduced cost) in terms of how much more it contributes to functional recovery.

Clinicians confirmed that, if future research can show that the scaled prototype's cost can be within ZAR40,000.00 - ZAR50,000.00, and that the device can enhance functional recovery in the form of over ground walking, centres like Vincent Pallotti Life rehabilitation unit would prefer to buy a prototype device rather than a ZAR65,000.00 or ZAR98,000.00 MOTomed trainer [79].

A summary of the clinical value of the results and the potential value of the device for South African clinics will now be provided.

6.4 Clinical Value of Results and Device

Inpatient results show that three, 20-minute training sessions with the device (combined with conventional PT) contributes toward functional improvement in muscle strength, spasticity and sit-to-stand activity. However, the method is not superior to five, 45-minute conventional therapy sessions a week, and there were confounding variables that influenced the results.

Outpatient results suggest that bi-weekly, 30-minute training sessions with the device (combined with conventional PT) is superior to two, one-hour conventional therapy sessions a week. Nevertheless, the results are not reliable due to different treatment times among test and control subjects.

The results are inconclusive about the superiority of device treatment. This is because only four stroke patients completed the study, and control subjects did not receive the additional 60-minutes of conventional therapy as the study protocol intended. Consequently, the results can only indicate potential results that future studies can expect to see, but in this case, it cannot be known if the results were due to device training specifically, or due to more treatment time, or external factors. A larger scale study with equal treatment times (and less confounding variables) is needed to produce more conclusive results about the effects of device treatment.

On the other hand, the study was able to identify seven differentiating factors that can influence test results (apart from unequal treatment time). Future studies can use this information to avoid potentially confounding results, by refraining from comparing patients that differ with regards to these factors. Researchers can decide what an acceptable amount of difference for each factor is, but ideally, there should be little to no difference to produce more reliable results. Refer to Table 6.1 for the list of the factors identified.

Patient feedback (Figure 5.1 and 5.2, Chapter 5) established that the device is safe and sufficient for post-stroke treatment, which clinicians corroborated. Their feedback identified three design areas that can be improved, namely (1) the location of the calve support which makes it difficult to place feet on the pedals, (2) power supply problems to the machine when there are too many appliances connected to the office circuit-line, and (3) the fact that patients cannot operate the interface while they are seated in front of the device.

Future development can, therefore, refine the design by (1) moving the calve supports to the side of the pedal assemblies, (2) using a smaller motor and/or changing the PGB set-up for more mechanical advantage (meaning less motor torque and current consumption), and (3) adjusting the control system to incorporate wireless or remote control of user interface commands. With the latter improvement, patients will be able to train with the device without

assistance from any therapists or staff members. Currently, one therapist or assistant is needed to initiate training sessions (and stop/pause when needed), but once the session starts, patients can train safely without the constant supervision of a therapist.

Table 6.1: Differentiating factors identified among participants

Factor	Description
1	Time after stroke when the study is started
2	Baseline values for study outcome measures
3	Main goal or priority for PT during the study, for example, restoring proper gait technique or reducing spasticity
4	Patient attitudes towards treatment
5	Control over additional treatment/training outside of the study
6	Warm-up time (if any) prior to measuring study outcomes
7	When study outcomes are measured. Preferably before conventional treatment and/or after equal warm-up time.

Finally, the cost analysis revealed that, if the prototype can be produced on a larger scale, it will be more affordable than the MOTomed leg trainer. Future investigations on scaling are needed to establish how competitive the unit cost of the prototype can be. Nevertheless, Vincent Pallotti agreed that if the unit cost of the device can be less than, or equal to ZAR50,000.00, and if the efficacy of the device can be assured for improved over ground walking, clinics would prefer to purchase the more affordable device as opposed to the competing MOTomed trainer.

In conclusion, the study established that the experimental device can be more affordable than current technology. Also, 60-minutes of active-assisted training with the device (with conventional PT) can contribute to functional improvements, with minimal assistance from therapists. Therefore, the main advantages of the device for South African clinics would be its potentially reduced cost and ability to contribute toward functional recovery with minimal input from therapists with high work loads.

Chapter 7

Conclusion

The project produced a motor-assisted pedalling device that can be less expensive than the current MOTomed Viva2 leg trainer after larger scale production. Preliminary results indicate that the device may contribute toward functional recovery with minimal assistance from therapists. It may, therefore, provide a treatment method that can benefit both patients and therapists. Additionally, the device has the potential to excel the functional recovery rate achievable after in- or outpatient therapy. If future research can demonstrate a distinct advantage of device treatment, the device offers a potential solution for the current socio-economic need for a cost-effective means to enhance recovery and quality of life after stroke and SCI. The project demonstrates the merit for further evaluation in a larger scale clinical trial.

The prototype design incorporated an innovative means to achieve active-assisted training motion by integrating motor and patient inputs through a planetary gear box. The device was successfully tested on stroke patients during a proof of concept study that demonstrated no adverse effects associated with device treatment. Unfortunately, circumstances prevented SCI patients from testing the device, and a cost analysis of the device could only determine a device cost of ZAR65,000.00 for unit production. It is unknown whether the cost of the device can be close to ZAR30,000.00 for larger scale production. Detailed scaling analyses are needed to determine the cost competitiveness of the device. Treatment centres would prefer to purchase this device rather than the MOTomed trainer, if its scaled unit cost can be less or equal to ZAR50,000.00, and if/when there is proof of its efficacy for functional recovery.

In conclusion, the project satisfied the research aim and objectives listed in Chapter 1, and all but one of the project requirements as shown in Table 7.1. Future research can be guided by the findings of this proof of concept study for the potential commercialisation of a more affordable active-assisted training device for stroke and SCI treatment in South Africa.

Table 7.1: Project requirements satisfied

#	Requirement	Satisfied	Extent of satisfaction
1.	The device must include gait-related, passive, active and active-assisted training modes	Fully satisfied	The device uses motor-assisted pedalling motion that can achieve all three training modes
2.	The device cost must be close to R30,000.00	Unknown	It is unknown if larger scale production of the prototype can reduce the unit cost close to the the target cost
3.	The device must be able to accommodate unpredictable limb spasms	Fully satisfied	The device includes a reliable stop/pause function that allows for time to relieve a spasm
4.	The device must have an emergency stop mechanism.	Fully satisfied	The device includes two manual E-stop mechanisms (push button & release of ring gear friction brake) and an automated stop (for motor speed > 1000 rpm)
5.	The device must be tested on selected stroke and SCI patients	Partly satisfied	Four sub-acute stroke patients tested the device as part of a proof of concept study No SCI patients could participate in the study
6.	The intended test procedures must be ethically approved	Fully satisfied	The Health Research Ethics Committee (HREC) of Stellenbosch University approved the intended study protocol
7.	The study must use outcome measures that reflect or relate to the functional abilities of stroke and SCI patients	Fully satisfied	The study included outcome measures that relate to muscle strength, muscle spasticity, and daily activities like sit-to-stand and over ground walking

7.1 Project Limitations

The project was limited to a small sample size when initial arrangements for a testing facility and subjects from the Western Cape Rehabilitation Centre (WCRC - the largest rehabilitation unit for post-stroke and SCI treatment in the Western Cape) failed to realise. Fortunately, Vincent Pallotti Hospital was able to assist, but only a small group of stroke patients (and no SCI patients) could complete the study in the limited time that was available. Due to limited departmental funding, the design was also limited to using readily available equipment from the university where possible. External project funding and more project time for extended tests at the WCRC should resolve these limitations for future studies.

7.2 Recommendations for Future Work

Future work can refine the prototype design by moving the calve supports to the side of the pedal assemblies, incorporating remote control of user interface commands, and using a smaller motor (with the necessary power output) to drive the planetary sun gear for more mechanical advantage. Patient heart rate feedback from the device can also be considered to help maintain sufficient training intensities and enhance functional recovery. Additionally, torque and force measurements obtained through affordable slip rings and Arduino strain gauges can add value to the device as a research machine that provides additional information to correlate progress against. The intended study protocol of this report can be used to test the device on a larger sample size of stroke and SCI patients that avoid the differentiating factors identified in this research project.

Appendices

Appendix A

Research Team

Table A.1: Research team



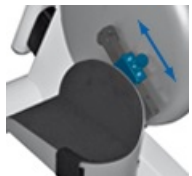

Member	Job Title/Affiliation	Project Role
Ariël Basson	Postgraduate student	Primary researcher
Dr. JH Müller	Senior lecturer and biomedical engineer	Stellenbosch University supervisor
Mechanical & Mechatronic Workshop	Stellenbosch University	Primary Manufacturers
-	Vincent Pallotti Hospital Life rehabilitation unit	Collaborators for test facility and patients
Ms Mirda Maclachlan	WCRC physiotherapist	Consulting therapist and outcome investigator
Ms Denette Swart	Therapy services coordinator for Vincent Pallotti Life rehabilitation unit	Primary organiser of tests at Vincent Pallotti Hospital
Ms Elmarie du Preez	Physiotherapist for Vincent Pallotti Life rehabilitation unit	Consulting therapist and co-organiser of tests at Vincent Pallotti Hospital
Dr. Candace Vermaak	WCRC biokineticist	Consulting clinician
Dr. Ed Baalbergen	Rehabilitation doctor for Vincent Pallotti Life rehabilitation unit	Practitioner for participant medical clearance
Professor Daan Nel	Centre for statistical consultation	Consulting statistician

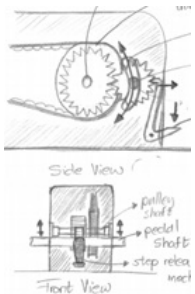



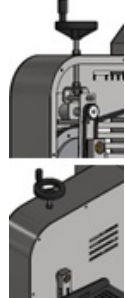
Appendix B




Concept Generation and Selection

Table B.1 provides the morphological chart of solutions identified for the function blocks outlined in Figure 3.1.

Table B.1: Morphological chart

Function	Solution				
	1	2	3	4	5
1.0	 <p>Adjustable seat fixed to device</p>	 <p>Patient wheelchair with brakes</p>	-	-	-
2.1	 <p>Using square tubing + index plunger</p>	 <p>Using square linear guides + index plunger</p>	Using solution 1 or 2 with rounded tubing or guides	-	-

<p>2.2</p>	 <p>Manually slide pedal shaft along radial slots and gears with a release mechanism</p>	 <p>Manually lift and adjust device with bar-and-hook mechanism</p>	 <p>Manually lift and adjust pedal shaft on radial slots with reverse bar-and-hook mechanism</p>	 <p>Similar to solution 3 but with closed-roof alternative</p>	 <p>Manually 'pull' pedal shaft along radial slots using rotating hand wheel</p>
<p>3.0</p>	<p>Attach feet only using velcro straps</p>	<p>Attach feet and calves using velcro straps</p>	<p>Feet and calves using velcro straps with padding</p>	<p>Feet and calves using specialised rehabilitation straps</p>	<p>-</p>
<p>4.0</p>	<p>Pushbutton user interface (on device)</p>	<p>Touch screen user interface (on device)</p>	<p>Remote controlled interface</p>	<p>-</p>	<p>-</p>
<p>5.0</p>	<p>Automatically through control system</p>	<p>Manually through user interface</p>	<p>-</p>	<p>-</p>	<p>-</p>
<p>6.0</p>	<p>Regulate motor input based on force/torque applied at pedals</p>	<p>Regulate motor input based on pedalling speed</p>	<p>Regulate motor input based on patient heart rate</p>	<p>-</p>	<p>-</p>
<p>7.0</p>	<p>Bicycle freewheel</p>	<p>Nuvinci Continuous Variable Transmission (CVT)</p>	<p>Planetary CVT</p>	<p>-</p>	<p>-</p>

8.0	 Manual adjustment of brake shoe on flywheel	 Manual adjustment of brake clamp on flywheel	 Manual adjustment of magnetic brake on flywheel	Automated control over solutions 1,2 or 3	
9.0	Detect spasm through pressure sensors at pedals and automatically stop device	Detect spasm through pressure sensors on pedals and reverse pedalling direction	Manually activate stop/pause option on interface and wait for spasm to relieve	-	-

Two different sets of solutions were combined two form two feasible design concepts. Table B.2 summarises the combination of solutions for each concept.

Table B.2: Combination of functional solutions for two respective design concepts

	Function block	Concept 1	Concept 2
Solution	1.0	2	1
	2.1	1	2
	2.2	5	1
	3.0	3	3
	4.0	1	2
	5.0	2	1
	6.0	2	1
	7.0	3	2
	8.0	1	4
	9.0	3	1

Table B.3: Advantages and disadvantages of Concept 1

Advantage	Disadvantage
Easy to move patient to device and adjust pedal height and crank arm length with less components needed to do so	Less smooth movement of crank arm adjustment without linear guides
Reduced device cost and simplified control system with a pushbutton interface on the device (compared to wireless control)	Need to control or operate device from the device panel
Can achieve all three training modes with less control commands that need to be incorporated	Can only transition automatically between active-assisted and passive modes. Need to set device for active training beforehand
Requires only a rotary encoder to regulate motor input, which does not have to be wireless to measure pedalling speed	No knowledge/measurements about the patient input at the pedals
PGB can combine motor and patient input with no need to adjust speed ratios during operation. Also a PGB readily available at university (reduced project cost)	Fixed speed ratios between motor and pedals based on gear ratios in PGB
Reduced device cost with simpler mechanism to adjust pedalling resistance	Pedalling resistance must be manually adjusted through friction brake.
Can accommodate muscle spasms with less expenses and complicated control	Device must be manually stopped by patient or assistant if spasm occurs
Can achieve all the functional needs and design requirements of the system with less components, less expenses and a more simplified control system	Likely to require the assistance of a therapist or assistant to initiate training and adjust resistance, but continuous supervision is not necessary

Table B.4: Advantages and disadvantages of Concept 2

Advantage	Disadvantage
Easy to move patient to device and adjust crank arm length	Requires more complicated mechanism (more components) to adjust pedal height
Can control/operate device from a distance with remote control	More expenses needed and complicated control to achieve remote control
Patient can select or change to preferred training mode during training	More complicated control to include training commands and correct system response
There is knowledge/measurements of the patient input (torque) at the pedals	Requires more expensive wireless force or pressure sensors at the pedals to regulate motor input
Device can offer various speed ratios between motor and pedal inputs which can also be used to control the amount of assistance provided	Requires automated mechanism that can adjust the idler shaft of a NuVinci CVT for different speed ratios with remote adjustment command (to keep with remote control feature)
Can control pedalling resistance from remote control	More complicated control and mechanisms needed that can adjust a brake based on remote command
Automated spasm detection for quick system response to stop training	Requires more complicated control to detect spasm through wireless sensors on pedals
Can satisfy the functional needs of the system and potentially all the design requirements with no assistance needed from staff or therapists	More complicated control and project expenses to include convenient features. Less likely to meet the ZAR30,000.00 device cost target

Concept 1 was considered to be the superior design. It is more likely to meet the device cost target of ZAR30,000.00 for South African rehabilitation centres, and it requires less complicated control and components. This was more suitable for a project with limited funding and time.

Appendix C

Drawing Pack

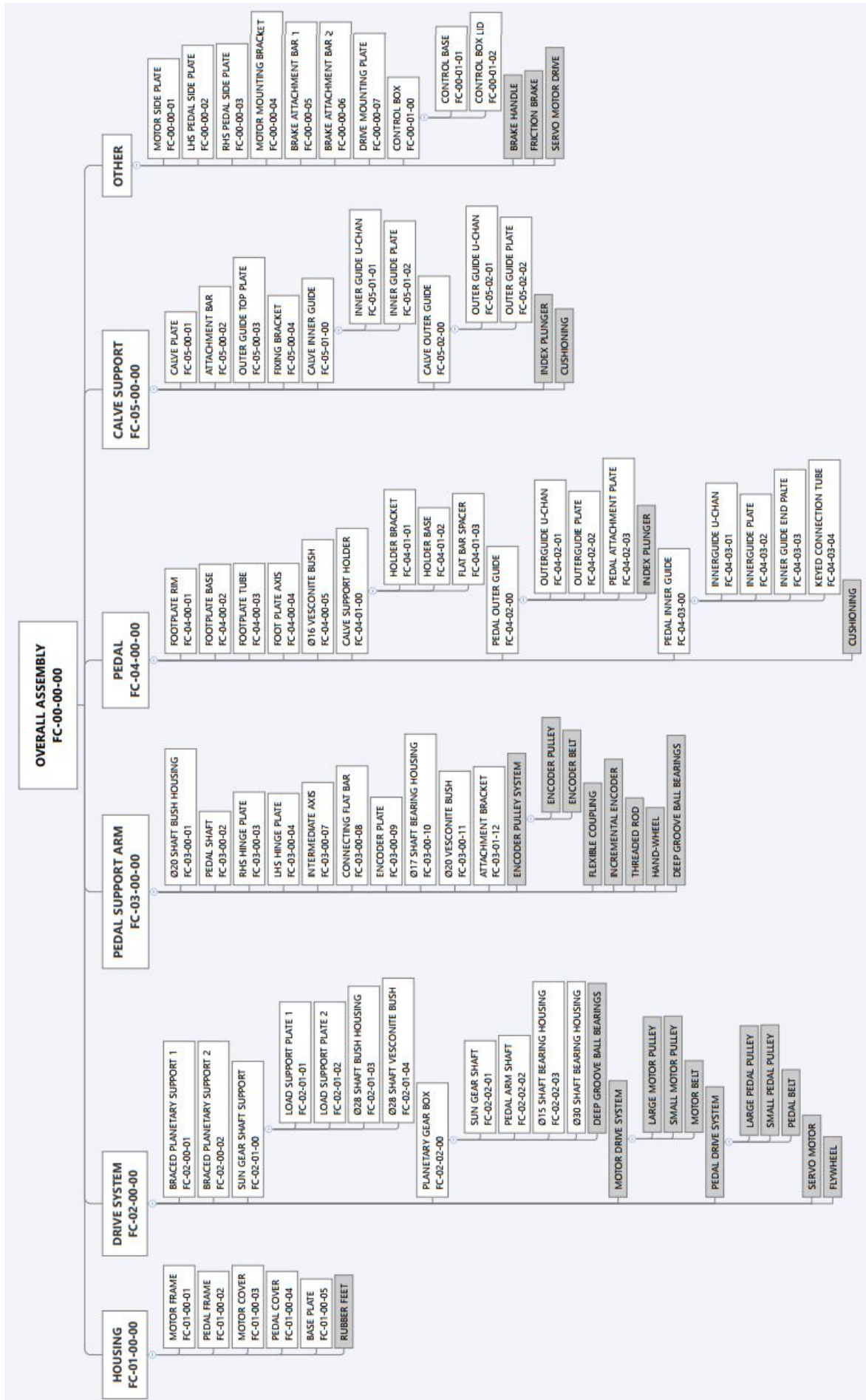


Figure C.1: Drawing Tree

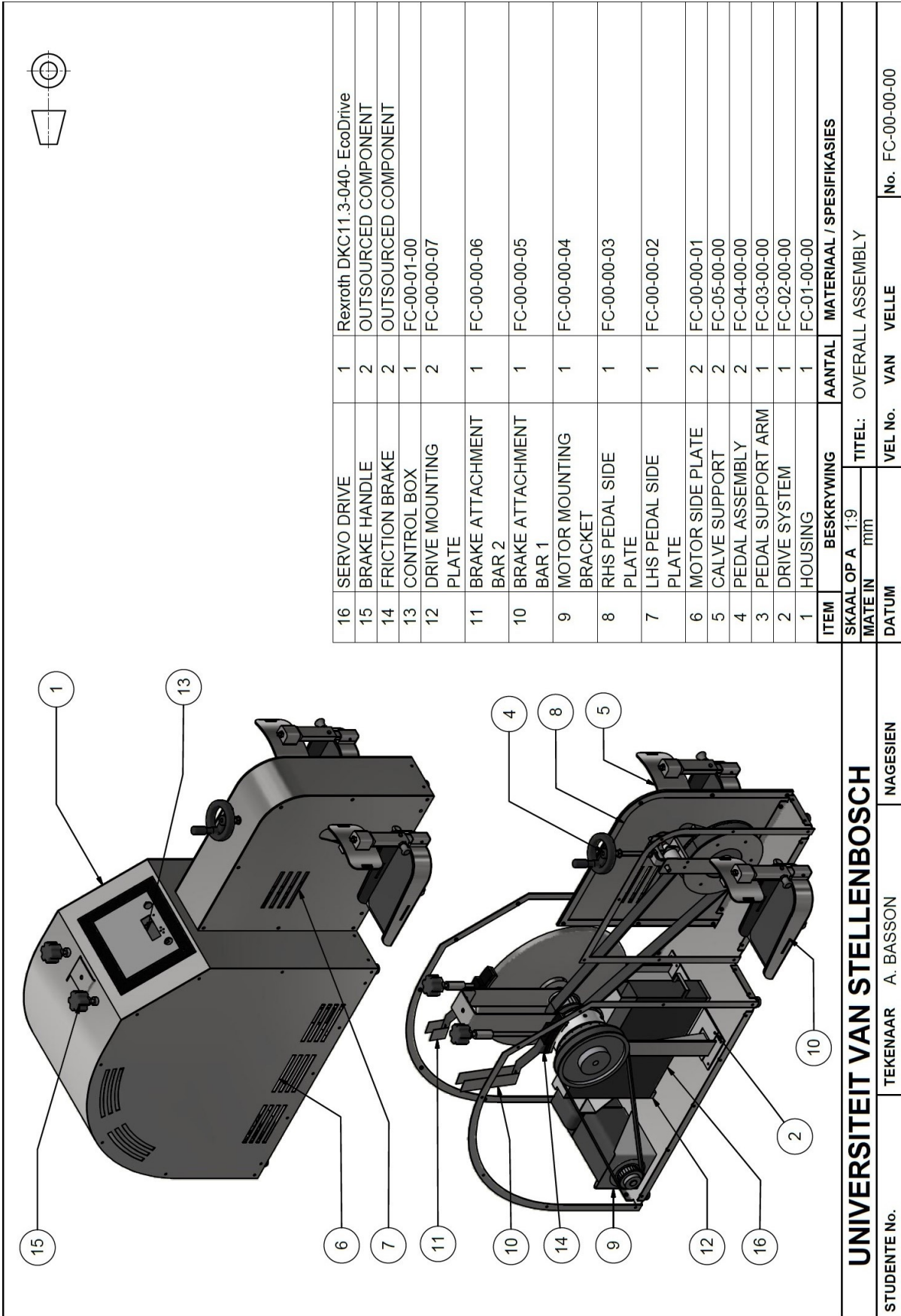


Figure C.2: Overall assembly

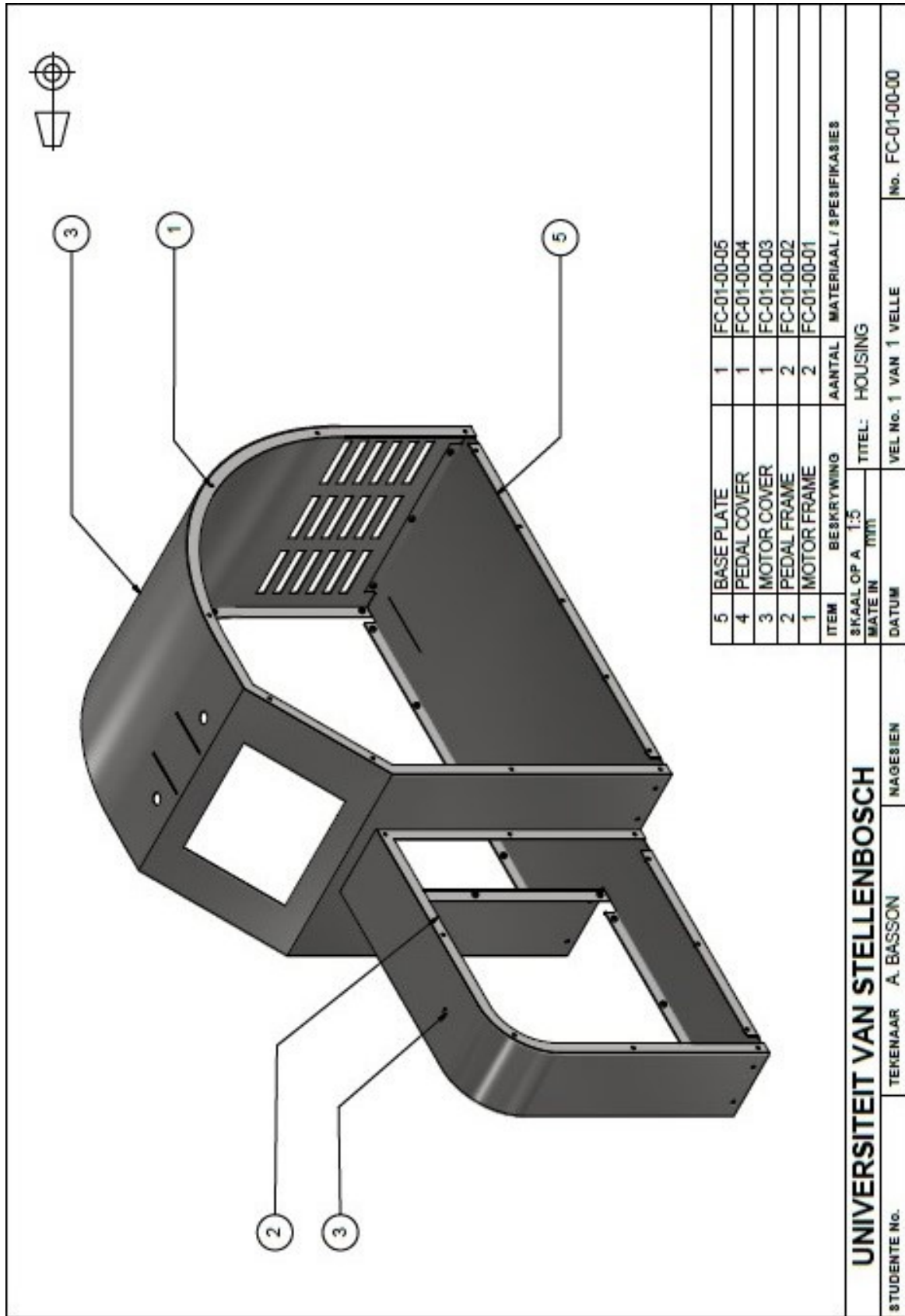


Figure C.3: Housing assembly

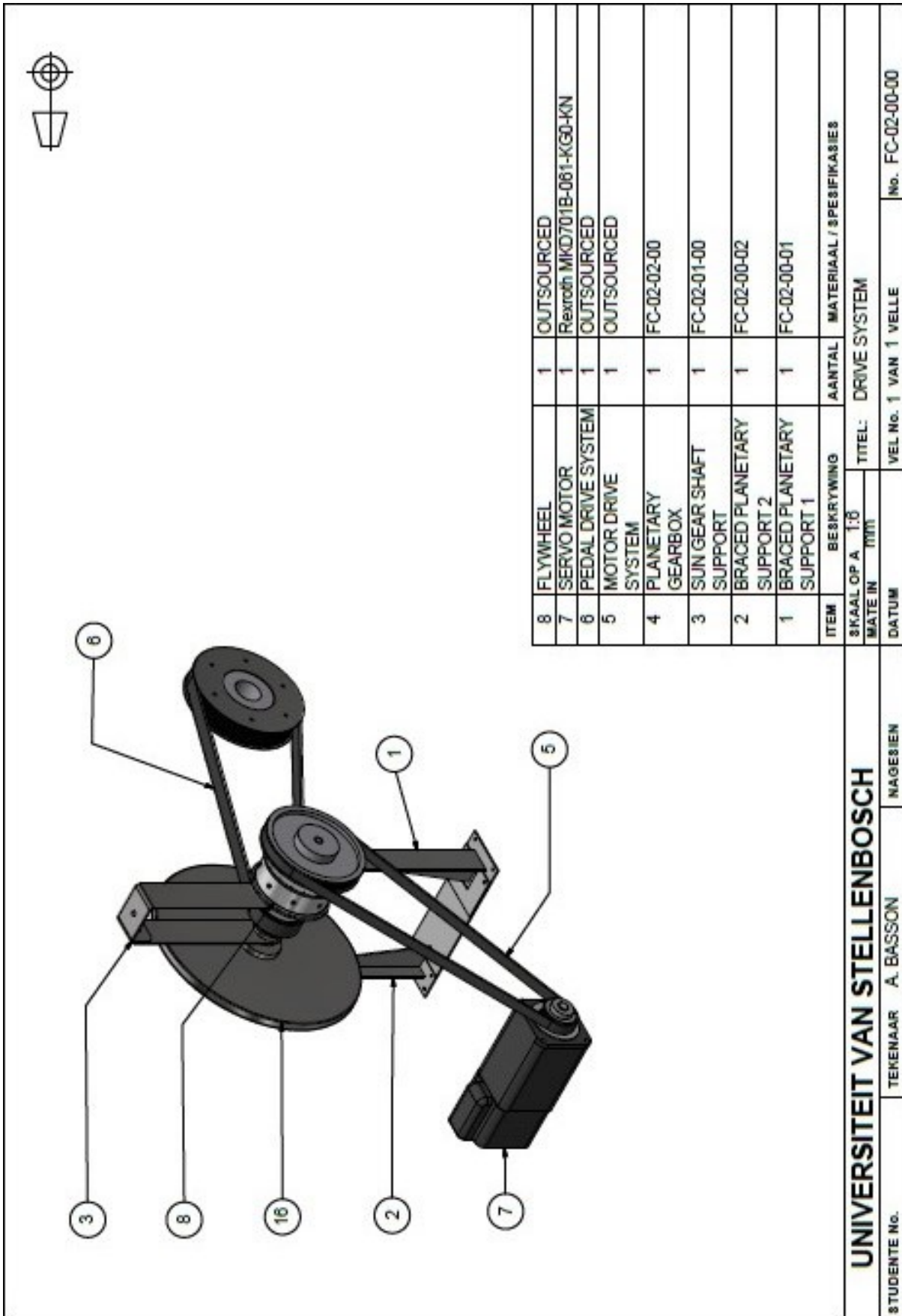


Figure C.4: Drive system assembly

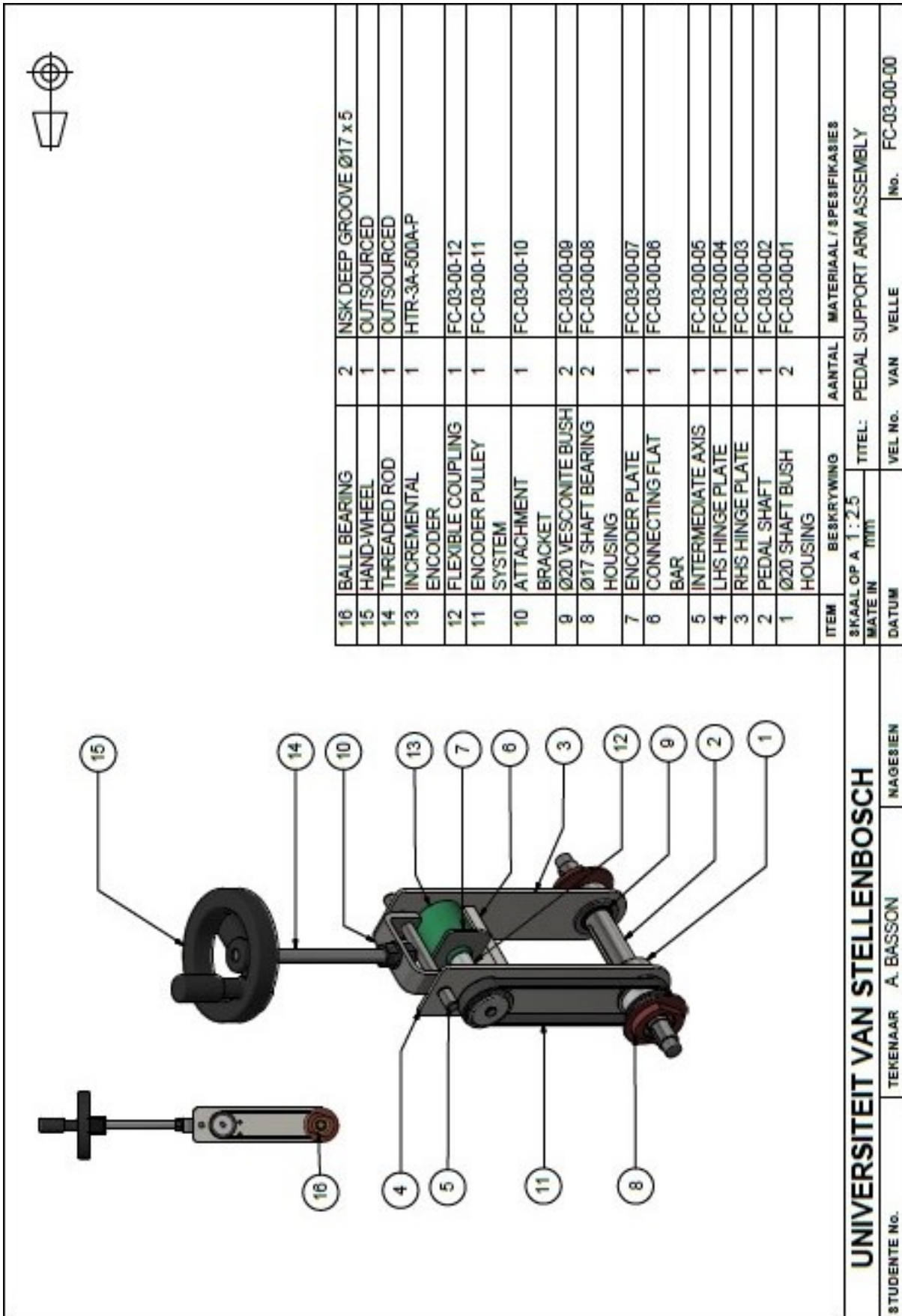


Figure C.5: Pedal support arm

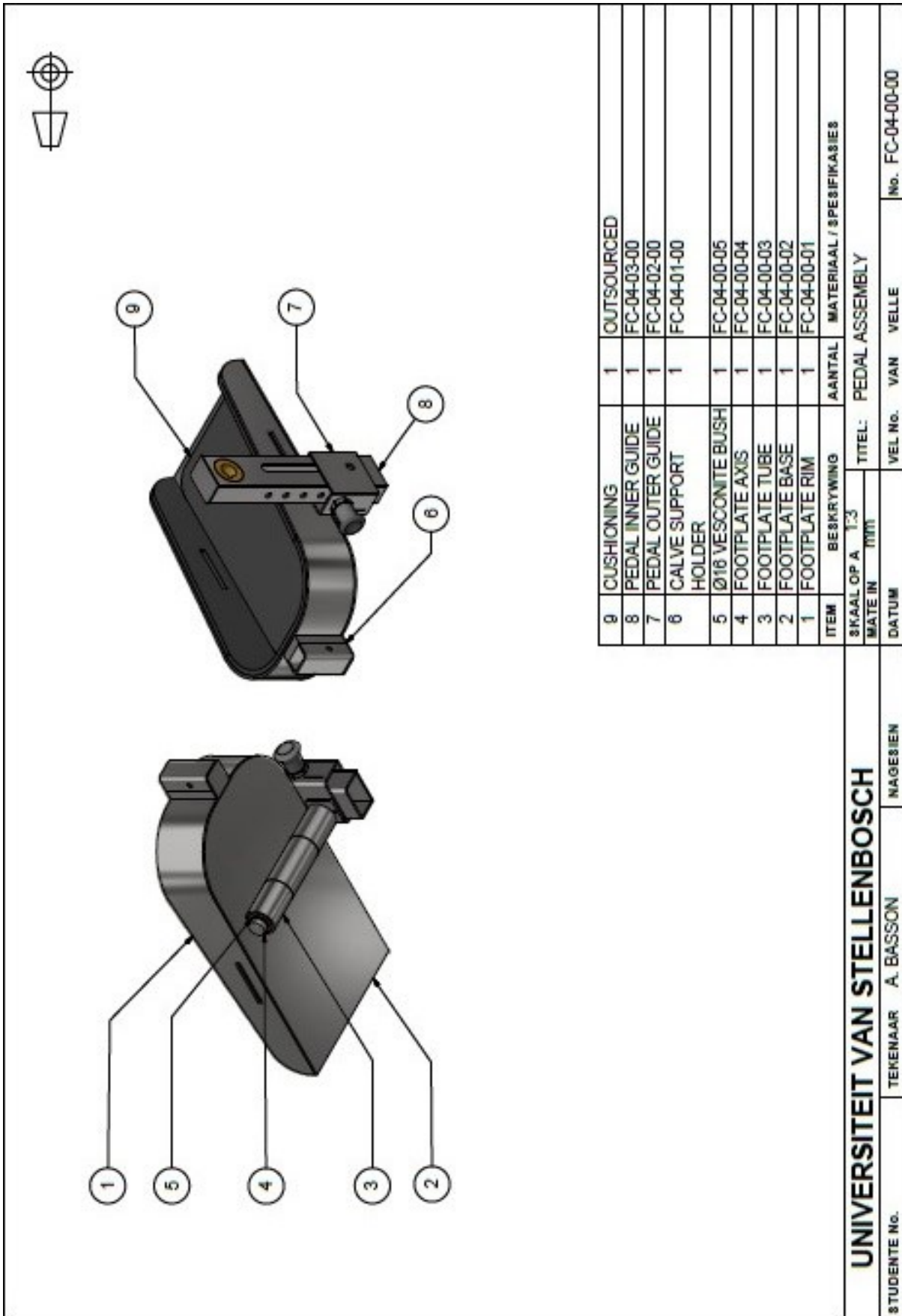


Figure C.6: Pedal assembly

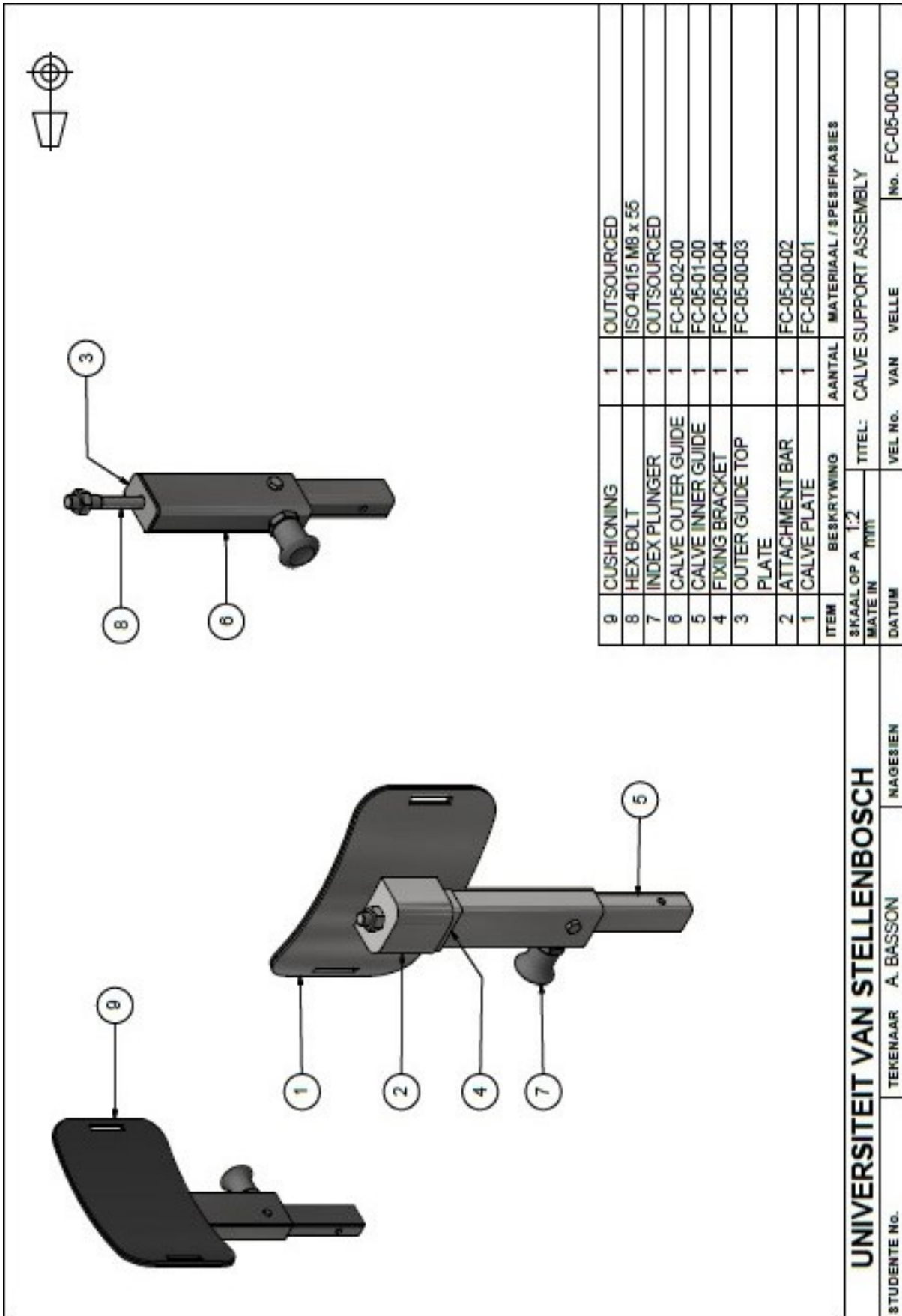


Figure C.7: Calve support assembly

UNIVERSITEIT VAN STELLENBOSCH

STUDENTE No.

TEKENAAR A. BASSON

NAGESIEN

SKAAL OP A 1:2
DATE IN mm

TITEL: CALVE SUPPORT ASSEMBLY
VEL No. VAN VELLE No. FC-05-00-00

Appendix D

Tubular Analysis of Planetary Gear Set

The tabular analysis method as outlined by Uicker et al (2011) was used to derive the relationship between the ring-, sun-, and planet gear speeds in a planetary gear set. Table D.1 summarises the tubular analysis approach.

Table D.1: Tabular Analysis

	Sun	Ring	Planet	Arm
Rotate gearbox by x rotation	x	x	x	x
Fix planet-arm and rotate sun by y rotation	y	$-y \cdot \frac{N_{sun}}{N_{ring}}$	$-y \cdot \frac{N_{sun}}{N_{planet}}$	0
Total	$x + y$	$x - y \cdot \frac{N_{sun}}{N_{ring}}$	$x - y \cdot \frac{N_{sun}}{N_{planet}}$	x

Equations D.1 to D.3 are derived from Table D.1.

$$x = \omega_{arm} \quad (D.1)$$

$$\omega_{ring} = x - y \left(\frac{N_{sun}}{N_{ring}} \right) \quad (D.2)$$

$$\omega_{sun} = x + y \quad (D.3)$$

Rearranging equation D.3:

$$\omega_{sun} = x + y \quad (D.4)$$

And substituting equation D.1 and D.4 into D.2 before re-arranging gives:

$$\omega_{ring} = \omega_{arm} \left(1 + \frac{N_{sun}}{N_{ring}} \right) - \omega_{sun} \left(\frac{N_{sun}}{N_{ring}} \right) \quad (D.5)$$

Equation D.5 represents the relationship between the ring-, sun- and planet gear speeds for a ring gear output. Equation D.5 can then be re-arranged to express a sun gear output in terms of a ring- and planet-arm input (Equation D.6), or a planet-arm output for a sun- and ring gear input (Equation D.7).

$$\omega_{sun} = \left(\omega_{arm} \left(1 + \frac{N_{sun}}{N_{ring}} \right) - \omega_{ring} \right) \left(\frac{N_{sun}}{N_{ring}} \right)^{-1} \quad (D.6)$$

$$\omega_{arm} = \left(\omega_{ring} + \omega_{sun} \left(\frac{N_{sun}}{N_{ring}} \right) \right) \left(1 + \frac{N_{sun}}{N_{ring}} \right)^{-1} \quad (D.7)$$

Appendix E

Maximum Load Case Calculations

In the seated position in front of the device, the legs are more or less in 70° knee flexion and 0° hip flexion as it rests on the pedals (see Figure E.1). For one revolution of the pedal crank arm, it is assumed that the hip and knee flexion angles would range from $0^\circ - 20^\circ$, and $0^\circ - 90^\circ$, respectively. On the other hand, the dorsi- and plantar flexion of the ankle was considered small during pedalling motion and the calve supports maintained more or less a 90° angle between the shin and foot. Therefore, the ankle was modelled in 0° flexion at all times.

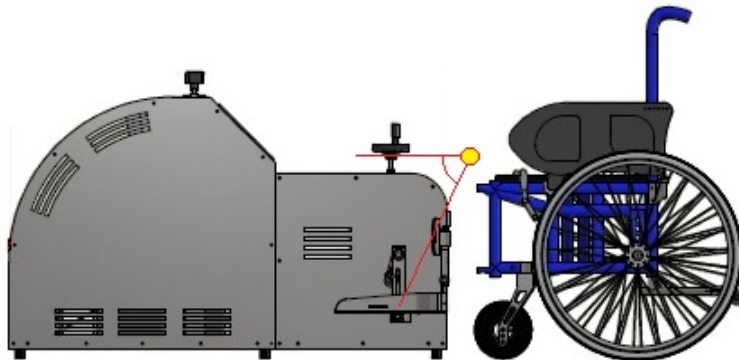


Figure E.1: Rested leg position while seated in front of prototype

Figure E.2 provides a free body diagram of the 2-dimensional dynamic model of the pedal load case. The leg segments are modelled as rigid structures with their centre of gravity, and the hip and pedal shaft is modelled as a pin connection and a fixed support, respectively. Having a right sin-to-foot angle simplifies the model to only three different reference frames; the hip (purple), pedal (orange), and global (red) reference frame.

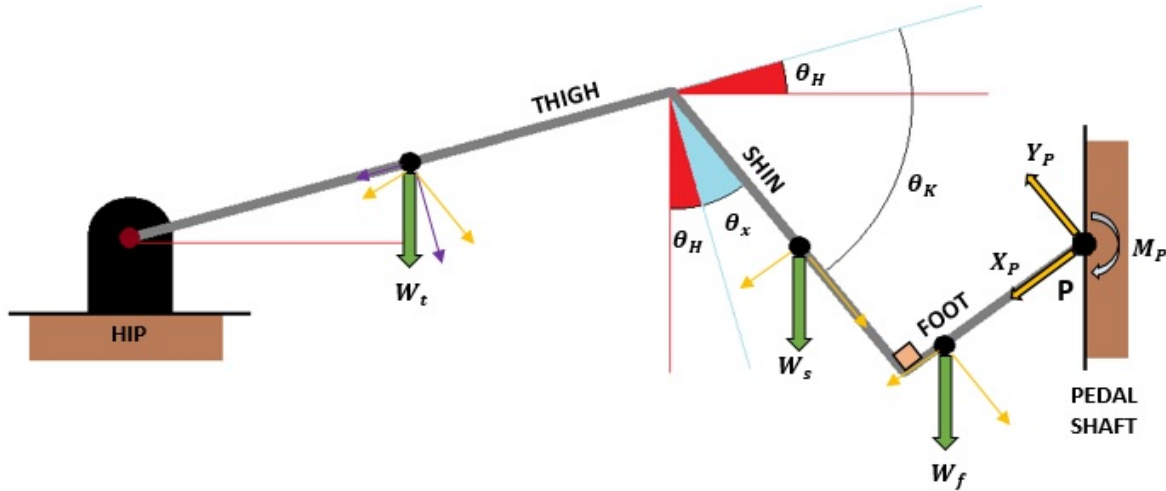


Figure E.2: Free body diagram of the pedal load case

When the origin of a reference frame accelerates and translates relative to a fixed origin of another reference frame, it is referred to as a *non-inertial* reference frame. For instance, in Figure E.2 the movement of the knee reference frame relative to either the hip or the pedal shaft axes illustrates a non-inertial reference frame. However, Newton II for rotational movement (Equation E.1) that can be used to calculate the moment about the pedal shaft (P), is only applicable to *inertial* reference frames (frame origins that do not accelerate or are stationary) such as the hip and pedal reference frame. If non-inertial reference frames are present, Newton II must be adjusted to include complex fictitious forces associated with non-inertial reference frames, otherwise known as *Coriolis forces* [80].

$$\sum M_p = I\alpha \quad (\text{E.1})$$

Fortunately, Coriolis forces can be avoided if the system is analysed relative to an inertial reference frame, and if any forces or moment arms in non-inertial reference frames are translated to the inertial reference frame beforehand. In this case, moments about the pedal reference frame was evaluated to calculate the maximum moment (M_p) about the pedal shaft. θ_H and θ_K represent the respective hip and knee flexion angles. Therefore, θ_x represents the transformation angle that transforms forces and moment arms from the hip reference frame to the pedal reference frame (Equation E.2), whereas θ_s (see Equation E.3) transforms gravitational forces (green arrows) from the global reference frame to the pedal reference frame.

$$\theta_x = 90^\circ - \theta_K. \quad (\text{E.2})$$

$$\theta_s = \theta_x + \theta_H = 90^\circ - \theta_K + \theta_H. \quad (\text{E.3})$$

Furthermore, it was assumed that patients would only be able to increase their pedalling speed at a slow pace to either achieve a maximum pedalling speed of 70 rpm (7.33 rad/sec) or reduce their speed to zero when training is done. Therefore, the angular acceleration of each limb segment was considered to be negligibly small during training. This simplified Newton's law to Equation E.4 for rotational equilibrium about the pedal shaft (P).

$$\sum M_p = 0 \quad (\text{E.4})$$

After the gravitational forces and respective moment arms to each leg segment's centre of gravity were transformed to the pedal reference frame, the maximum moment about the pedal shaft for one revolution of the crank arm was calculated. A Matlab R2017a (MathWorks, Massachusetts, United States) script was written to calculate the maximum moment (M_P). Figure E.5 provides a flowchart of the algorithm that was used whereas Table E.1 provides the constant parameters that were defined/used in the script.

Figure E.3 and E.4 provide the Matlab output which identified a maximum pedal moment of 72 N m when the hip and knee are more or less in 14.5° and 65° flexion, respectively. If a safety factor of 1.33 is added to account for the simplifications made, a maximum pedal torque of 96 N m was calculated at the pedal shaft.

Table E.1: Constant parameters defined in Matlab algorithm for pedal moment calculation

Parameter	Description	Magnitude
M	Maximum patient weight	100 kg
H	Maximum patient height	1.8 m
L_p	Crank arm length	0.135 m
M_t	Weight of thigh segment	$0.1M$ [81]
M_s	Weight of shin segment	$0.0465M$ [81]
M_f	Weight of foot segment	$0.0145M$ [81]
L_t	Typical thigh length	$(0.53 - 0.285)H$ [81]
L_s	Typical shin length	$0.285H$ [81]
L_f	Typical foot length	$0.152H$ [81]

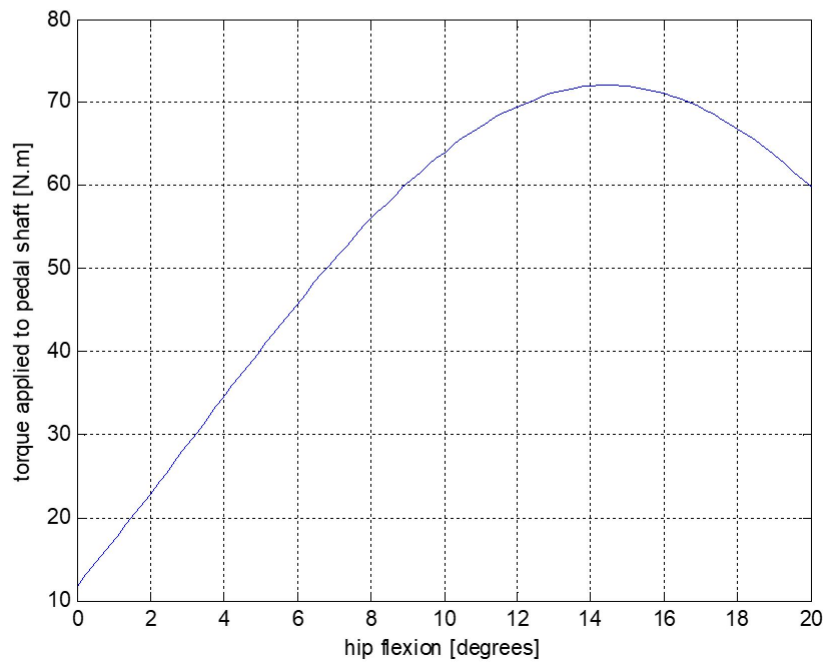


Figure E.3: Pedal Moment vs Hip Flexion

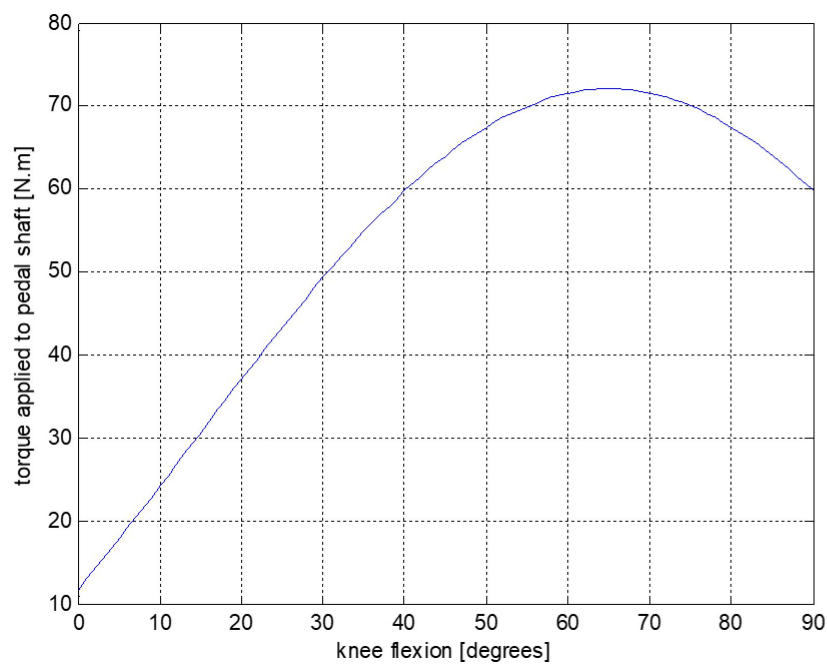


Figure E.4: Pedal Moment vs Knee Flexion

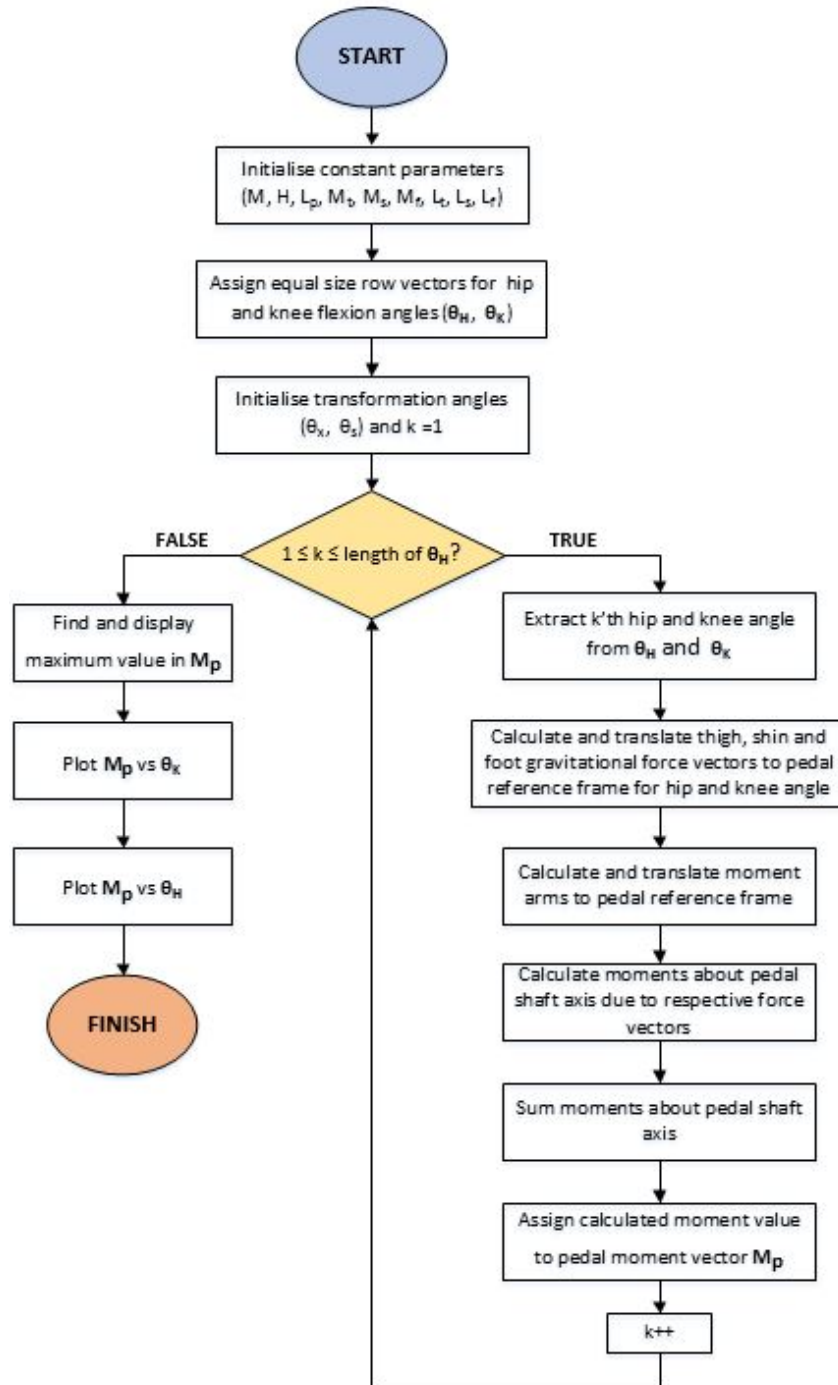


Figure E.5: Matlab algorithm used to calculate maximum pedal load

Appendix F

Belt and Pulley Selection

Pulley System 2: Load to Motor Shaft

$$\eta_m = 3.27 \quad \omega_3 = \left(\frac{1}{3} \cdot \omega_2 \text{ radps} \right) \quad \omega_4 \text{ radps} = \eta_m \cdot \omega_3 = 19.9753$$

$$T_2 = \left(\frac{1}{\eta_p} \right) \cdot T_1 = 39.04 \text{ Nm} \quad T_3 = 3 \cdot T_2 \quad \eta_{\text{PGB}} = 80$$

$$T_4 = \left(\frac{1}{\eta_m} \right) \cdot T_3 = 35.8165 \text{ Nm} \quad P_2 = P_1 \cdot \left(\frac{100}{\eta_{\text{PGB}}} \right) = 894.3067 \text{ W}$$

SKF Belt Catalogue Steps

Service Factor: $f_{s2} = 1.8 \cdot 1.18 = 2.124$ p.108, Table 1, 2 & 3

Design Power: $P_{d2} = f_{s2} \cdot P_2 = 1899.5074$

Belt Pitch: 8M SKF Classic Belt p.109, Figure 1

Pulley Selection: $N_3 = 72$ $N_4 = 22$ p.116, HTD 8mm Drive Selection
 $D_1 = 183.35 \text{ mm}$ $d_1 = 56.02 \text{ mm}$

Basic Power: $P_{B2} = 3.8325 \text{ kW}$ p.141, Power Ratings for 8M Belt

Centre Distance: $c_2 = 528.2 \text{ mm}$ p.113

Pitch Length: $L_{\text{pitch}2} = 1440 \text{ mm}$ p.160

$N_{\text{belt}} = 150$ p.163

$\text{delta} = D_1 - d_1 = 0.1273 \text{ m}$

Teeth = $\left(0.5 - \left(\frac{\text{delta}}{6 \cdot c_2} \right) \right) \cdot N_4$ Teeth = 10.1161

Belt Length Correction Factor: $C1 = 1$ p.130, Table 6 and 7
 $C4 = 1$

Corrected Power Rating: $P_{\text{corr}1} = C1 \cdot C4 \cdot P_{B2} = 3832.5 \text{ W}$

Required Power Rating:

$$P_{\text{req}1} = \frac{P_{d2}}{C1 \cdot C4} = 1899.5074$$

Belt Width Factor: $f_{w2} = 0.633$ P141

Actual Power Rating: $P_{a2} = P_{B2} \cdot f_{w2} = 2425.9725 \text{ W}$

Belt Width: $b2 = 20 \text{ mm}$ p.141

SKF TIMING BELT SELECTION PROCEDURES

Pulley System 1: Pedals to Load Shaft

$$\eta_p = 2.50 \quad \omega_{1\text{revpm}} = 70 \quad \omega_{2\text{revpm}} = \eta_p \cdot \omega_{1\text{revpm}} = 175$$

$$\omega_{1\text{radps}} = \omega_{1\text{revpm}} \left(\frac{2 \cdot \pi}{60} \right) = 7.3304 \quad \omega_{2\text{radps}} = \omega_{2\text{revpm}} \left(\frac{2 \cdot \pi}{60} \right) = 18.326$$

$$T_p = 96 \text{ Nm} \quad T_1 = T_p + 1.6 = 97.6 \text{ Nm} \quad P_1 = \omega_{1\text{radps}} \cdot T_1 = 715.4454 \text{ W}$$

SKF Belt Catalogue Steps

Service Factor: $f_{s1} = 1.8 \cdot 1.18 = 2.124$ p.108, Table 1, 2 & 3

Design Power: $P_{d1} = f_{s1} \cdot P_1 = 1519.606$

Belt Pitch: 8M SKF HiTD Belt p.109, Figure 1

Pulley Selection: $N_1 = 80 \quad N_2 = 32$ p.115, HTD 8mm Drive Selection
 $D_1 = 203.72 \text{ mm} \quad d_1 = 81.48 \text{ mm}$

Basic Power: $P_{B1} = 2.6078 \text{ kW}$ p.141, Power Ratings for 8M Belt

Centre Distance: $c_1 = 572.7 \text{ mm}$ p.115

Pitch Length: $L_{\text{pitch}1} = 1600 \text{ mm}$ p.115

$N_{\text{belt}} = 160$ p.163

$\text{delta} = D_1 - d_1 = 0.1222 \text{ m}$

Teeth = $\left(0.5 - \left(\frac{\text{delta}}{6 \cdot c_1} \right) \right) \cdot N_2$ Teeth = 14.8616

Belt Length Correction Factor: $C1 = 1.1$ p.130, Table 6 and 7
 $C4 = 1$

Corrected Power Rating: $P_{\text{corr}1} = C1 \cdot C4 \cdot P_{B1} = 2868.58 \text{ W}$

Required Power Rating:

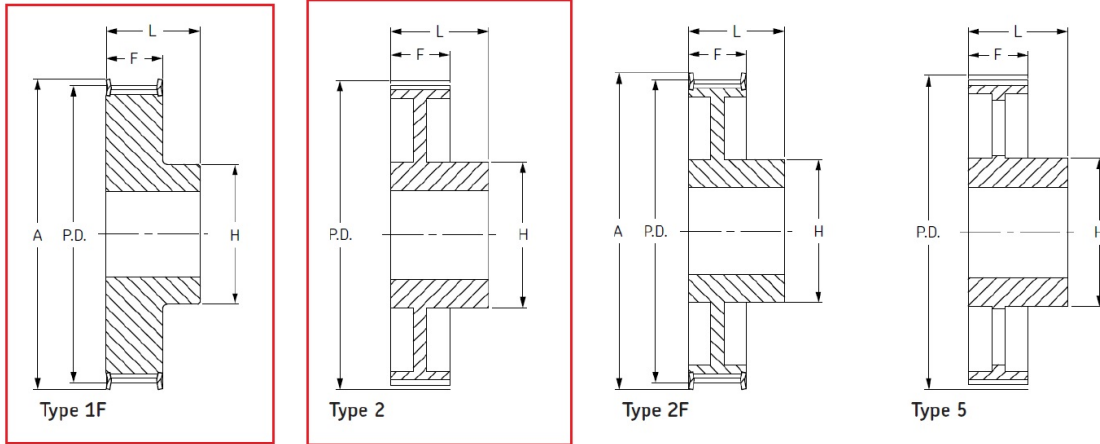
$$P_{\text{req}1} = \frac{P_{d1}}{C1 \cdot C4} = 1381.46$$

Belt Width Factor: $f_{w1} = 1$

Actual Power Rating: $P_{a1} = P_{B1} \cdot f_{w1} = 2607.8 \text{ W}$

Belt Width: $b1 = 30 \text{ mm}$ p.141

8 mm Pitch

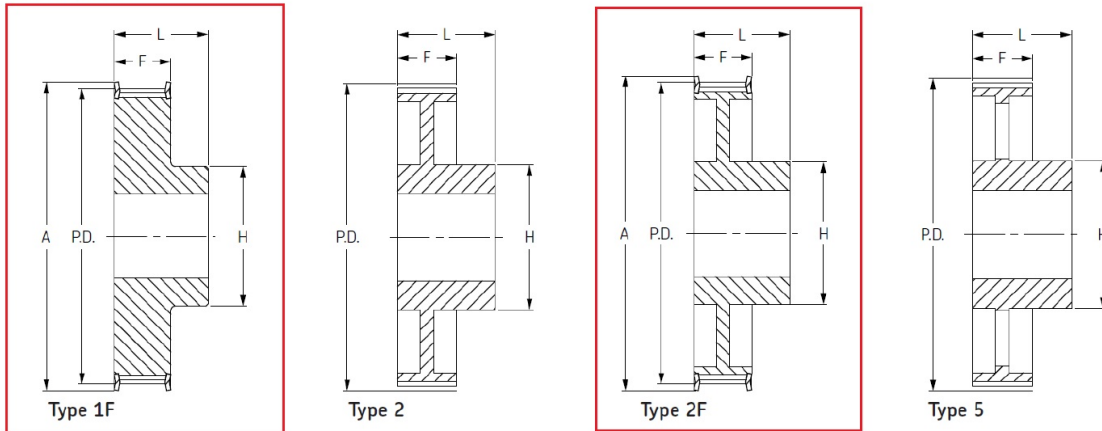


Belt Width 30 mm

No. Teeth	Diameter		Type	Bore		Dimensions					Weight kg	Designation	
	P.D.	O.D.		A	Min	Max	F	K	L	M			H
20	50,93	49,56	60	1F	12	25	38	-	48	-	38	0,54	PHP 20-8M-30RSB
21	53,47	52,10	62	1F	12	27	38	-	48	-	40	0,62	PHP 21-8M-30RSB
22	56,02	54,65	65	1F	12	29	38	-	48	-	43	0,69	PHP 22-8M-30RSB
23	57,57	57,20	65	1F	12	30	38	-	48	-	45	0,77	PHP 23-8M-30RSB
24	61,12	59,75	70	1F	12	30	38	-	48	-	45	0,84	PHP 24-8M-30RSB
25	63,66	62,28	71	1F	12	31	38	-	48	-	50	0,92	PHP 25-8M-30RSB
26	66,21	64,84	75	1F	12	32	38	-	48	-	50	1,00	PHP 26-8M-30RSB
27	68,75	67,39	75	1F	12	33	38	-	48	-	50	1,06	PHP 27-8M-30RSB
28	71,30	70,08	80	1F	15	34	38	-	48	-	50	1,12	PHP 28-8M-30RSB
30	76,39	75,13	85	1F	15	36	38	-	48	-	55	1,32	PHP 30-8M-30RSB
31	78,94	77,65	87	1F	15	38	38	-	48	-	55	1,42	PHP 31-8M-30RSB
32	81,49	80,16	90	1F	15	40	38	-	48	-	60	1,53	PHP 32-8M-30RSB
33	84,03	82,58	90	1F	15	42	38	-	48	-	60	1,64	PHP 33-8M-30RSB
34	86,58	85,22	95	1F	15	44	38	-	48	-	70	1,80	PHP 34-8M-30RSB
35	89,13	87,76	95	1F	15	45	38	-	48	-	70	1,90	PHP 35-8M-30RSB
36	91,67	90,30	100	1F	15	46	38	-	48	-	70	1,99	PHP 36-8M-30RSB
38	96,77	95,39	105	1F	15	50	38	-	48	-	75	2,27	PHP 38-8M-30RSB
40	101,86	100,49	110	1F	15	50	38	-	48	-	75	2,40	PHP 40-8M-30RSB
42	106,95	105,58	111	1F	15	50	38	-	48	-	75	2,60	PHP 42-8M-30RSB
44	112,05	110,67	121	1F	15	50	38	-	48	-	75	2,80	PHP 44-8M-30RSB
45	114,59	113,22	121	1F	15	50	38	-	48	-	75	2,90	PHP 45-8M-30RSB
48	122,23	120,86	131	1F	15	50	38	-	48	-	75	3,20	PHP 48-8M-30RSB
50	127,32	125,95	131	1F	15	50	38	-	48	-	75	3,30	PHP 50-8M-30RSB
52	132,42	131,05	140	1F	15	60	38	-	48	-	90	3,40	PHP 52-8M-30RSB
56	142,60	141,23	151	2F	15	60	38	-	48	-	90	3,60	PHP 56-8M-30RSB
60	152,79	151,42	168	2F	15	60	38	-	48	-	90	3,95	PHP 60-8M-30RSB
64	162,97	161,60	172	2F	15	60	38	-	48	-	90	4,30	PHP 64-8M-30RSB
72	183,35	181,97	192	2F	15	63	38	-	48	-	95	4,80	PHP 72-8M-30RSB
80	203,72	202,35	-	2	15	60	38	-	48	-	100	5,10	PHP 80-8M-30RSB
90	229,18	227,81	-	2	15	60	38	-	48	-	100	5,70	PHP 90-8M-30RSB
112	285,21	283,83	-	5	18	60	38	-	48	-	100	6,80	PHP 112-8M-30RSB
144	366,69	365,32	-	5	20	60	38	-	48	-	100	9,30	PHP 144-8M-30RSB
168	427,81	426,44	-	5	20	60	38	-	48	-	100	11,40	PHP 168-8M-30RSB
192	488,92	487,55	-	5	20	60	38	-	48	-	100	16,00	PHP 192-8M-30RSB

Figure F.1: Pedal belt drive pulleys [62]

8 mm Pitch



Belt Width 20 mm

No. Teeth	Diameter			Type	Bore		Dimensions					Weight kg	Designation
	P.D.	O.D.	A		Min	Max	F	K	L	M	H		
20	50.93	49.56	60	1F	12	25	28	-	38	-	38	0.43	PHP 20-8M-20RSB
21	53.47	52.10	62	1F	12	27	28	-	38	-	40	0.49	PHP 21-8M-20RSB
22	56.02	54.65	65	1F	12	29	28	-	38	-	43	0.54	PHP 22-8M-20RSB
23	58.57	57.20	65	1F	12	29	28	-	38	-	45	0.60	PHP 23-8M-20RSB
24	61.12	59.75	70	1F	12	30	28	-	38	-	45	0.65	PHP 24-8M-20RSB
25	63.66	62.28	71	1F	12	31	28	-	38	-	45	0.73	PHP 25-8M-20RSB
26	66.21	64.84	75	1F	12	32	28	-	38	-	50	0.80	PHP 26-8M-20RSB
27	68.75	67.39	75	1F	12	33	28	-	38	-	50	0.84	PHP 27-8M-20RSB
28	71.30	70.08	80	1F	15	34	28	-	38	-	50	0.87	PHP 28-8M-20RSB
29	73.85	72.62	85	1F	15	35	28	-	38	-	55	0.95	PHP 29-8M-20RSB
30	76.39	75.13	85	1F	15	36	28	-	38	-	55	1.02	PHP 30-8M-20RSB
31	78.94	77.65	87	1F	15	38	28	-	38	-	55	1.11	PHP 31-8M-20RSB
32	81.49	80.16	90	1F	15	40	28	-	38	-	60	1.20	PHP 32-8M-20RSB
33	84.03	82.68	90	1F	15	42	28	-	38	-	60	1.30	PHP 33-8M-20RSB
34	86.58	85.22	95	1F	15	44	28	-	38	-	70	1.40	PHP 34-8M-20RSB
35	89.13	87.76	95	1F	15	45	28	-	38	-	70	1.48	PHP 35-8M-20RSB
36	91.67	90.30	100	1F	15	46	28	-	38	-	70	1.55	PHP 36-8M-20RSB
38	96.77	95.39	105	1F	15	50	28	-	38	-	75	1.65	PHP 38-8M-20RSB
40	101.86	100.49	110	1F	15	50	28	-	38	-	75	1.74	PHP 40-8M-20RSB
42	106.95	105.58	111	1F	15	50	28	-	38	-	75	1.92	PHP 42-8M-20RSB
44	112.05	110.67	121	1F	15	50	28	-	38	-	75	2.10	PHP 44-8M-20RSB
45	114.59	113.22	121	1F	15	50	28	-	38	-	75	2.19	PHP 45-8M-20RSB
48	122.23	120.86	131	1F	15	54	28	-	38	-	75	2.44	PHP 48-8M-20RSB
50	127.32	125.95	131	1F	15	54	28	-	38	-	75	2.48	PHP 50-8M-20RSB
52	132.42	131.05	140	1F	15	54	28	-	38	-	80	2.52	PHP 52-8M-20RSB
56	142.60	141.23	151	2F	15	54	28	-	38	-	80	2.60	PHP 56-8M-20RSB
64	162.97	161.60	172	2F	15	54	28	-	38	-	80	2.90	PHP 64-8M-20RSB
72	183.35	181.97	192	2F	15	54	28	-	38	-	80	3.10	PHP 72-8M-20RSB
80	203.72	202.35	-	2	15	54	28	-	38	-	90	3.80	PHP 80-8M-20RSB
90	229.18	227.81	-	2	15	54	28	-	38	-	90	4.20	PHP 90-8M-20RSB
112	285.21	283.83	-	5	18	54	28	-	38	-	90	5.20	PHP 112-8M-20RSB
144	366.69	365.32	-	5	20	54	28	-	38	-	90	7.50	PHP 144-8M-20RSB
168	427.81	426.44	-	5	20	60	28	-	38	-	100	10.00	PHP 168-8M-20RSB
192	488.92	487.55	-	5	20	60	28	-	38	-	100	14.40	PHP 192-8M-20RSB

Figure F.2: Motor belt drive pulleys [62]

Appendix G

Control System Schematic

Appendix H

Arduino and Driver Pin Layout

Interface Arduino	
Hardware Serial Port	
0 (RX)	Xbee Receiver TX - DOUT
1 (TX)	Xbee Receiver RX - DIN
Digital Pins	
2 I	<i>Ready</i> feedback from computational Arduino
3 O	Reset (Select keyboard button)
4	LCD
5	LCD
6	LCD
7	LCD
8	LCD
9	LCD
10	LCD
11 O	Drive Enable (Up keyboard button)
12 O	Start/Resume (Left keyboard button)
13 O	Stop/Pause (Right keyboard button)
Analog Pins	
0	LCD
1 I	Emergency stop push button (+5V)
2	
3	
4	
5	
Power Pins	
Vin	+9V (DC buck converter)
GND 1	0V (DC buck converter)

Computational Arduino	
Hardware Serial Port	
0 (RX)	Breakout MAX3232 pin 9
1 (TX)	Breakout MAX3232 pin 7
Digital Pins	
2 I	Signal A (white wire) Pedal Rotary Encoder
3	Software Serial RX (Xbee Transmitter TX - DOUT)
4	Software Serial TX (Xbee Transmitter RX - DIN)
5 O	<i>Ready</i> feedback output to interface Arduino
6 O	Reset (Clear error) signal to driver
7 O	Stop/Pause (Drive Halt) signal to driver
8 O	Emergency stop signal to driver
9 O	Drive Enable signal to driver
10 I	Reset command from interface Arduino
11 I	Stop/Pause command from interface Arduino
12 I	Start/Resume command from interface Arduino
13 I	Drive Enable command from interface Arduino
Analog Pins	
0	
1 I	Emergency stop push button (+5V)
2 I	<i>Ready</i> Feedback from driver
3	X9_lgsUA1+ driver incremental encoder signal
4	X9_lgsUA2+ driver incremental encoder signal
5	
Power Pins	
Vin	+9V (DC buck converter)
GND 1	0V (DC buck converter)

Figure H.1: Arduino Uno microprocessor board pin layouts

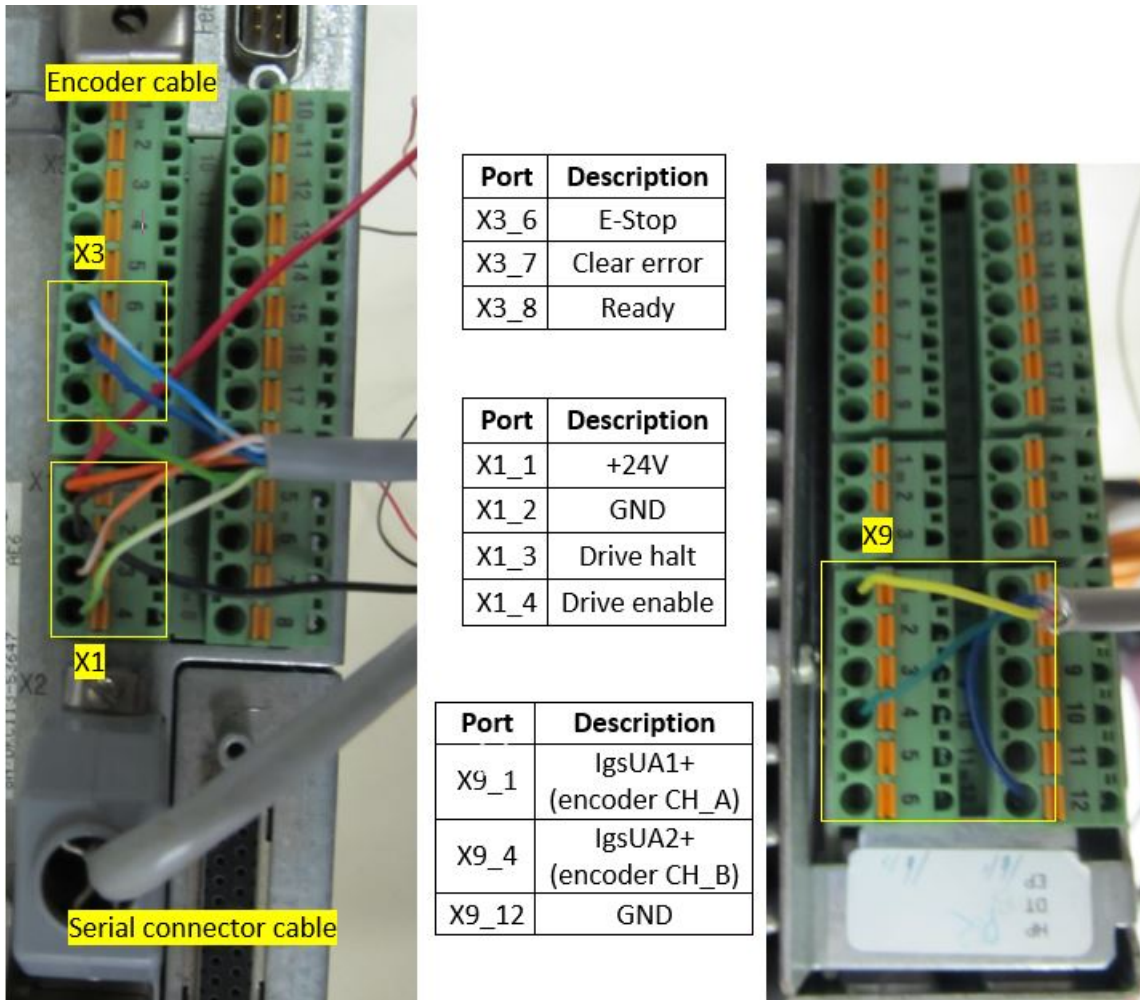


Figure H.2: Driver pin set-up for user interface commands and encoder feedback

Appendix I

Clinical Study Documents

I.1 Medical Clearance Form

PROOF OF CONCEPT STUDY OF AN AFFORDABLE LOWER LIMB REHABILITATION DEVICE

Researcher: Ariël Basson, [REDACTED]

Dear Doctor

Your patient, _____, wishes to participate in the postgraduate research project to be conducted at Vincent Pallotti's Life Rehabilitation Unit from June - August 2017.

This study has been approved by the Health Research Ethics Committee at Stellenbosch University and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for

Objective: The study aims to design a low-cost alternative for the *MOTomed Viva2* rehabilitation device that will be more affordable for state clinics, safe for sub-acute phase stroke and (incomplete) spinal cord injury (SCI) treatment, and capable of improving lower limb functionality in stroke and SCI patients. Please refer to the respective stroke and SCI inclusion/exclusion criteria at the back of this form.

Method: Participants will be assigned to a control or device study group. Control groups must complete 60 minutes of conventional therapy available to patients at Vincent Pallotti, plus an additional 20 minutes of the same conventional therapy. Device groups, must complete the same 60 minute conventional therapy sessions, in addition to a 20-minute training session with the experimental device. SCI patients must complete three, 80-minute sessions per week, for 8 consecutive weeks, and stroke patients must complete three sessions per week, for 4 weeks.

Device: Device training sessions consist of patients pedalling a motor-assisted pedalling device, at a constant speed of 40 rpm (as best they can) for 20 minutes. The device is minimally invasive and attaches to the feet and calves using material straps. Depending on the actual pedalling speed achieved, the motor-input automatically increases or decreases to assist 40 rpm motion. The device is adjustable for unilateral or bilateral training modes, and if fatigued, the device can train patient's limbs passively while they rest. A BORG intensity rating of 13 will be encouraged, but patients can pedal at which ever intensity is most comfortable to them at the time.

Physician Recommendations:

With the above information, do you consider it is safe for your patient to participate in this study given his/her current medical condition(s)? Please select one:

	Yes, I considered it is safe for my patient to participate.
	Yes, I considered it is safe for my patient to participate, <i>as long as</i> :
	No, I do not considered it safe for my patient to participate <i>because</i> :

Physician Signature	Physician Name (print)	Date

I.2 Device Questionnaire

PATIENT FEEDBACK

Patient Study Code: _____ Interviewer: _____

Date: _____

Please note that your answers will not have any effect on your current, or any of your upcoming treatments. You will also be answering this questionnaire anonymously. Furthermore, please note that, although there is a possibility that your answers/feedback can be used in project related reports or articles, we will make sure that it cannot be directly linked to you.

If you are informed and comfortable with this information, please answer the following questions about the project device, and feel free to ask the primary researcher (Ms A Basson) if you need any assistance.

1. On a scale of 1 to 4, please answer the following questions about the device's user-friendliness by marking the appropriate box with an X.

#	QUESTION	1. STRONGLY DISAGREE	2. DISAGREE	3. AGREE	4. STRONGLY AGREE
1.1	The device is easy to use and operate with a clinician or assistant.				
1.2	The device is easy to use and operate without a clinician or assistant.				
1.3	The user interface is easy to understand.				
1.5	The device is too complicated to train with.				
1.6	I would like to train with this device when I visit the clinic.				
1.7	I would like to have this device at home.				

2. On a scale of 1 to 4, please answer the following questions about the device's safety by marking the appropriate box with an X.

#	QUESTION	1. STRONGLY DISAGREE	2. DISAGREE	3. AGREE	4. STRONGLY AGREE
2.1	I felt safe training with the device.				
2.2	Parts of the device cut/bruised me before, during or after I trained with the device.				
2.3	The device did exactly what I was told it would do.				
2.4	The device responded very well to my instructions/requests on the user board.				
2.5	The device was easy to stop when/if I had a spasm during the session.				
2.6	I felt uncomfortable training with this device.				
2.8	I would feel safe training with this device on my own at home or the clinic.				
2.9	I will would prefer to train with this device if an assistant or clinician is close by.				

3. What was the easiest part about this training session?

4. What was the hardest part about this training session?

5. Is there anything different or new to the device since you last used it? (Explain briefly)

6. What can we change or improve on the device?

INTERVIEWER

I, _____, (Name & Surname) hereby confirm that these are the answers and opinions of the patient alone, and that as _____, (role) for the project, I did not manipulate or convince the patient otherwise during the completion of this questionnaire.

INTERVIEWER SIGNATURE

PATIENT SIGNATURE

Appendix J

Life Cycle Cost Analysis

The cost associated with the resources, manufacturing, distribution, use, and end-of-life life cycle phases of the prototype device was calculated or estimated as shown in this appendix.

J.1 Resources

The resource cost referred to the direct cost of material and hardware that was used in the final prototype. This included components used for the mechanical and control design of the prototype. Figure J.1 shows the corresponding bill of materials for the prototype device. Green costs represent all component costs that can be reduced or eliminated in future work.

The total resource/material cost of the prototype comprised of ZAR54,700.00. However, this included the use of unnecessary components such as (1) two Arduino Uno boards instead of one Arduino Mega board, (2) two Bluetooth modules that accompany the use of two Arduino Uno boards, (3) excessively large diameter pulleys, and (4) and over-designed servomotor and driver (with cable accessories). Table J.1 provides product details of an alternative Schneider servomotor and driver set that is suitable for this application (power output and speed control) at a significantly reduced cost.

The material cost of the device can, therefore, be significantly reduced by replacing or eliminating unnecessary costs. It was estimated that the pulleys and housing costs shown in Figure J.1 could be reduced by 20% and 10%, respectively if a smaller motor and pulleys are used. Furthermore, the cost of two Arduino Uno boards and the Bluetooth modules (with accompanying breakout boards) could be replaced with the cost of a single Arduino Mega board. The motor costs listed in Table J.1 would also replace the corresponding motor costs shown in Figure J.1. With these replacements, the total material cost of the prototype reduced to ZAR39,844.32.

Motor Selection & Accessories	Cost (ZAR)	Mechanical Design Component	Cost (ZAR)
Rexroth DKC11.3-040-7-FW Eco-Driver	11761.71	Deep groove ball bearings	422.00
Rexroth MKD-701B-061-KG-KN motor	15663.04	Spray Paint (silver)	360.00
24V power supply	1000.00	Pedal cushioning	32.00
Motor power cable	1867.41	Fixed wheels	140.00
Motor feedback & control cable	957.04	Rubber lugs for feet	18.75
Triple pole 32 amp circuit breaker	319.83	Hontko rotary encoder (HTR-3-500A-P)	1862.76
Motor Selection Total	31569.03	Encoder pulleys	602.90
		Fabrinox sheet metal parts	3843.98
Control Design Component	Cost (ZAR)	Velcro straps	20.00
MAX3232 breakout module	114.00	Flexible coupling	634.98
Xbee Bluetooth modules	1137.72	Index plungers	717.61
DC-DC buck converters	127.90	Perspex sheets	122.57
Power ON/OFF rocker switch	39.95	Hand wheel	347.75
Emergency push button	40.00	Taper locks	339.05
9V Battery connector	4.95	Cable hooks	100.00
Vero board	71.98	Threaded rod	35.00
Female headers	30.00	Mild steel handle	24.00
Male headers	30.00	Friction brakes	138.80
Optocouplers	23.40	Timing belts and pulleys	3609.63
Xbee breakout boards	451.44	3D Printed interface box	1021.00
16x2 LCD keypad shield V2 for Arduino	239.40	Encoder pulley belt	100.00
9V Battery	140.00	Planetary gear set	4806.61
Male jumper wires	13.68	Workshop material (fasteners, paint etc.)	867.48
Arduino Uno microcontroller buddy pack	450.30	Mechanical Design Total	20166.87
Jumper wires	20.00		
Ethernet cable (R308 per 100m)	4.00		
Shielded cable (per meter)	4.62		
Control Design Total	2943.34		
		Total cost of resources	Cost (ZAR)
			54679.23736

Figure J.1: Bill of materials used in final prototype

Table J.1: Alternative Schneider servomotor and driver for prototype

Component	Part Number	Cost (ZAR)
Servomotor	BCH2LF0733CA5C	6,524.57
Driver	LXM23AU04M3X	10,269.65
Power cable	VW3M5111R30	513.83
Encoder cable	VW3M8121R30	805.58

J.2 Manufacturing

The prototype was manufactured by the Mechanical and Mechatronic engineering workshop of Stellenbosch University. According to the workshop records, the cost of equipment used to produce the prototype (excluding electricity and/or water) accumulated to ZAR881.44.

Direct labour costs comprised of a skilled artisan who required 100 working hours to manufacture the prototype. With a tariff of ZAR200/hour, the labour

costs associated with the prototype accumulated to ZAR20,000.00. Table J.2 summarises the manufacturing costs for the prototype.

There were no accurate estimations for the indirect costs (electricity usage, water consumption, administrative salaries and so forth) associated with manufacturing. This is because, at the time of manufacturing, the workshop was responsible for manufacturing multiple devices at the same time. Running costs could, therefore, not be accurately allocated the project specifically. Stellenbosch University allocated an indirect cost rate return (ICRR) of 20 % on direct costs of third party activities (such as research) in 2012 [82]. Indirect manufacturing cost was, therefore, estimated as 20 % of the direct cost (material, labour and equipment).

Table J.2: Manufacturing cost associated with the prototype

	Cost (ZAR)
Equipment	881.44
Labor	20,000.00
Indirect costs	4,176.29
Total	25,057.73

J.3 Distribution

A suitable vehicle was rented to transport the prototype to Vincent Pallotti Life rehabilitation unit at ZAR500. This required little expenses as less than 100 km were travelled to deliver the prototype. Upon arrival, the assistance of one person was needed to move the device to the testing facility. No installation process was required because the device could simply be connected to a single phase outlet before use.

The distribution and installation costs associated with delivering the device in the Western Cape was, therefore, considered to be negligibly small compared to the material and manufacturing cost. However, for national distribution of the device in South Africa, the distribution cost was estimated to be 10 % of the total (direct and indirect costs) of the device.

J.4 Use

The power consumption of the device was first calculated based on the test procedures implemented, meaning one hour of device training per patient, per week ,for four weeks. The speed limit programmed into the motor

(100 rpm) corresponded to a power output of 712 W at the rated motor torque output. The device was able to train a 100 kg user passively at 70 rpm without activating the emergency stop. Therefore, a conservative assumption was made that the rated power output of the device would not exceed 800 W during life time operation.

According to Eskom, the electricity rates for non-local authorities or businesses in 2017/2018 is ZAR1.09/kWh (VAT included) [83]. Therefore, the cost associated with powering the device for one patient, one hour per week over the course of four weeks was calculated to be a mere ZAR3.49 (Equation J.1).

$$C_{power} = 4 \text{ weeks} \times \frac{1 \text{ hour}}{\text{week}} \times 0.800 \text{ kW} \times \frac{\text{ZAR}1.09}{\text{kWh}} = \text{ZAR}3,49 \quad (\text{J.1})$$

This corresponds to an annual (52 weeks) cost of ZAR45.37 per patient. If the training frequency is increased to three, one-hour training sessions a week, it still corresponds to an annual power cost of only ZAR136.03 per patient.

Regarding maintenance, Tectra Automation (South African supplier accredited by Bosch Rexroth group for the repair and testing of its drive and control products) confirmed that for the low speed, -shaft load, -vibration, and low temperature operating conditions of this application, the servomotor should not require maintenance throughout a 15-year life cycle [76]. There is also limited maintenance required throughout the rest of the system. The friction brake pads and 9 V battery for the emergency stop might need to be replaced once or twice a year (depending on the use cycle). Maintenance costs are, therefore, considered to be negligibly small throughout the device life cycle.

J.5 End of Life

When rehabilitation centres would like to replace or dispose of the device, they can sell or donate the device to educational institutions such as Stellenbosch University. The device consists of components and materials that can be disassembled and reused in future research projects. Similarly, companies such as Tectra Automation also accept old motors and drivers for internal tests and research being conducted. The end-of-life plan of the device is, therefore, associated with little to no effort and expenses for rehabilitation centres.

List of References

- [1] NINDS, “Neurological Diseases & Disorders A-Z from NINDS,” n.d., [Accessed on 10 July 2017]. [Online]. Available: <http://www.brainfacts.org/diseases-disorders/diseases-a-to-z-from-ninds/>
- [2] B. Husemann, F. M’uller, C. Krewer, S. Heller, and E. Koenig, “Effects of Locomotion Training With Assistance of a Robot-Driven Gait Orthosis in Hemiparetic Patients After Stroke,” *Stroke*, vol. 38, pp. 349–354, 2007.
- [3] D. Kuhna, V. Leichtfriedb, and W. Schobersbergerb, “Four weeks of functional electrical stimulated cycling after spinal cord injury: a clinical cohort study,” *International Journal of Rehabilitation Research*, vol. 37, pp. 243–250, 2014.
- [4] J. Benito-Penalva, D. Edwards, E. Opisso, M. Cortes, R. Lopez-Blazquez, N. Murillo, U. Costa, J. Tormos, J. Vidal-SamsÃs, J. Valls-SolÃl, and J. Medina, “Gait Training in Human Spinal Cord Injury Using Electromechanical Systems: Effect of Device Type and Patient Characteristics,” *Archives of Physical Medicine and Rehabilitation*, vol. 93, pp. 404–412, March 2012.
- [5] “Human and economic burden of stroke,” *Age and Ageing*, vol. 38, no. 1, pp. 4–5, 2009.
- [6] J. Yang and K. Musselman, “Training to achieve over ground walking after spinal cord injury: A review of who, what, when, and how,” *The Journal of Spinal Cord Medicine*, vol. 35, no. 5, pp. 293–304, 2012.
- [7] M. Maredza and L. Chola, “Economic burden of stroke in a rural south african setting,” *eNeurologicalSci*, vol. 3, pp. 26–32, 2016.
- [8] World Health Organisation, “International Perspectives on Spinal Cord Injury,” Tech. Rep., 2013.
- [9] H. Krueger, V. Noonan, L. Tremaman, P. Joshi, and C. Rivers, “The economic burden of traumatic spinal cord injury in canada,” *Chronic Diseases and Injuries in Canada*, vol. 33, pp. 113–121, 2013.
- [10] H. Barbeau and M. Visintin, “Optimal Outcomes Obtained With Body-Weight Support Combined With Treadmill Training in Stroke Subjects,” *Archives of Physical Medicine and Rehabilitation*, vol. 84, pp. 1458–1465, 2003.

- [11] M. Pohl, C. Werner, M. Holzgraefe, G. Kroczeck, J. Mehrholz, I. Wingendorf, G. Hölig, R. Koch, and S. Hesse, "Repetitive locomotor training and physiotherapy improve walking and basic activities of daily living after stroke: a single-blind, randomized multicentre trial (deutsche gangtrainerstudie, degas)," *Clinical Rehabilitation*, vol. 21, pp. 17–27, 2007.
- [12] I. Schwartz, A. Sajina, N. Neeb, I. Fisher, M. Katz-Luerer, and Z. Meiner, "Locomotor training using a robotic device in patients with subacute spinal cord injury," *Spinal Cord*, vol. 49, pp. 1062–1067, 2011.
- [13] D. Kuhna, V. Leichtfriedb, and W. Schobersberger, "Four weeks of functional electrical stimulated cycling after spinal cord injury: a clinical cohort study," *International Journal of Rehabilitation Research*, vol. 37, no. 3, pp. 243–250, 2014.
- [14] V. Skvortsova, G. Ivanova, N. Rumyantseva, A. Staritsyn, E. Kovrazhkina, and A. Suvorov, "Current approaches to restoring walking in patients during the acute phase of cerebral stroke," *Neuroscience and Behavioral Physiology*, vol. 41, no. 5, pp. 536–541, 2011.
- [15] Reha Stim, "Gait Trainer GT I Quotation," E-mail Correspondance, June 2017.
- [16] M. Maclachlan and C. Vermaak, "Research Project Scope and Objectives," Interview, June 2016, physiotherapist and Biokineticist at Western Cape Rehabilitation Centre.
- [17] NINDS, "Stroke," n.d., [Accessed on 29 August 2017]. [Online]. Available: <http://www.brainfacts.org/diseases-disorders/diseases-a-to-z-from-ninds/stroke/>
- [18] American Stroke Association, "Types of Stroke," n.d., [Accessed on 29 August 2017]. [Online]. Available: http://www.strokeassociation.org/STROKEORG/AboutStroke/TypesofStroke/Types-of-Stroke_UCM_308531_SubHomePage.jsp
- [19] J. McIntosh. (2016, April) Stroke: Causes, Symptoms, Diagnosis and Treatment. [Accessed on 17 May 2017]. [Online]. Available: <http://www.medicalnewstoday.com/articles/7624.php>
- [20] Milka Clarke Stroke Brain Trauma Foundation. (n.d.) Effects of stroke. [Accessed on 29 August 2017]. [Online]. Available: <http://www.milkaclarkestrokefoundation.org/effects-of-stroke.html>
- [21] Saebo. (2016, August) Important Facts Of The First Stage Of Stroke Recovery. [Accessed on 29 August 2017]. [Online]. Available: <https://www.saebo.com/important-facts-first-stage-stroke-recovery/>
- [22] American Stroke Association. (2012, November) Effects of Stroke. [Accessed on 3 June 2017]. [Online]. Available: http://www.strokeassociation.org/STROKEORG/AboutStroke/EffectsofStroke/Effects-of-Stroke_UCM_308534_SubHomePage.jsp

- [23] Flint Rehab, "Hemiplegia vs Hemiparesis after Stroke," September 2015, [Accessed on 11 June 2017]. [Online]. Available: <https://www.flintrehab.com/2015/hemiplegia-vs-hemiparesis-after-stroke/>
- [24] Stroke Recovery. (n.d.) Optimal stroke recovery with hyperbaric oxygen therapy. [Accessed on 29 August 2017]. [Online]. Available: <http://baromedical.ca/medical-stroke-recovery.php>
- [25] J. Moore, E. Roth, C. Killian, and T. Hornby, "Locomotor Training Improves Daily Stepping Activity and Gait Efficiency in Individuals Poststroke Who Have Reached a Plateau in Recovery," *Stroke*, vol. 41, pp. 129–135, 2010.
- [26] NINDS, "Spinal Cord Injury," n.d., [Accessed on 29 August 2017]. [Online]. Available: <http://www.brainfacts.org/diseases-disorders/diseases-a-to-z-from-ninds/spinal-cord-injury/>
- [27] C. Joseph, "Traumatic Spinal Cord Injury in South Africa and Sweden: Epidemiologic Features and Functioning," PhD, Karolinska Institute, Stockholm, 2016.
- [28] Mayo Clinic, "Diseases and Conditions Spinal cord injury: Symptoms," October 2014, [Accessed on 4 June 2017]. [Online]. Available: <http://www.mayoclinic.org/diseases-conditions/spinal-cord-injury/basics/symptoms/con-20023837>
- [29] Shepherd Center, "Understanding Spinal Cord Injury: Levels of Injury," n.d., [Accessed on 19 June 2017]. [Online]. Available: <http://www.spinalinjury101.org/details/levels-of-injury>
- [30] Atlas of Anatomy. (n.d.) Brain & Spinal Cord. [Accessed on 4 June 2017]. [Online]. Available: <http://doctorlib.info/medical/anatomy/41.html>
- [31] Medical Dictionary, "Sensory function," n.d., [Accessed on 10 July 2017]. [Online]. Available: <http://medical-dictionary.thefreedictionary.com/sensory+function>
- [32] Medical Dictionary, "Motor function," n.d., [Accessed on 10 July 2017]. [Online]. Available: <http://www.dictionary.com/browse/motor-skills>
- [33] J. Steeves, D. Lammertse, A. Curt, F. J.W., M. Tuszynski, J. Ditunno, P. Ellaway, M. Fehlings, J. Guest, N. Kleitman, P. Bartlett, A. Blight, V. Dietz, B. Dobkin, R. Grossman, D. Short, M. Nakamura, W. Coleman, M. Gaviria, and A. Privat, "Guidelines for the conduct of clinical trials for spinal cord injury (SCI) as developed by the ICCP panel: clinical trial outcome measures," *Spinal Cord*, pp. 1–16, 2006.
- [34] J. Rowland, G. Hawryluk, and M. Kwon, B. Fehlings, "Current status of acute spinal cord injury pathophysiology and emerging therapies: promise on the horizon," *Neurosurgical Focus*, vol. 25, no. 5, 2008.

- [35] V. Dietz and K. Fouad, "Restoration of sensorimotor functions after spinal cord injury," *Brain*, vol. 137, pp. 654–667, 2014.
- [36] N. Takeuchi and S. Izumi, "Rehabilitation with Poststroke Motor Recovery: A Review with a Focus on Neural Plasticity," *Stroke Research and Treatment*, vol. 2013, 2013.
- [37] A. Wahl and M. Schwab, "Finding an optimal rehabilitation paradigm after stroke: enhancing fiber growth and training of the brain at the right moment," *Frontiers in Human Neuroscience*, vol. 8, pp. 1–13, 2014.
- [38] C. Morawietz and F. Moffat, "Effects of Locomotor Training After Incomplete Spinal Cord Injury: A Systematic Review," *Archives of Physical Medicine and Rehabilitation*, vol. 94, no. 11, pp. 2297–2308, November 2013.
- [39] P. Duncan, K. Sullivan, A. Behrman, S. Anzen, S. Wu, S. Nadeua, B. Dobkin, D. Rose, J. Tilson, S. Cen, and S. Hayden, "Body-Weight-Supported Treadmill Rehabilitation after Stroke," *The New England Journal of Medicine*, vol. 364, pp. 2026–2036, 2011.
- [40] B. D. Brandl-Hesse, "Gait Trainer GT I," n.d., [Accessed on 30 August 2017]. [Online]. Available: <http://www.reha-stim.de/cms/assets/files/Flyer/Gait%20Trainer%20GT%20I%20Flyer%20Englisch%202012.pdf>
- [41] V. Skvortsova, G. Ivanova, E. Kovrazhkina, N. Rumiantseva, A. Staritsyn, A. Suvorov, and E. Sogomonian, "The use of a robot-assisted Gait Trainer GT I in patients in the acute period of cerebral stroke: a pilot study," *Zhurnal Nevrologii I Psikhiatrii Imeni S.S. Korsakova*, vol. 23, pp. 28–34, 2008.
- [42] Hocoma Inc., "Advantages of Lokomat Therapy," n.d., [Accessed on 30 August 2017]. [Online]. Available: <https://www.hocoma.com/us/solutions/lokomat/>
- [43] PT.Airindo Sentra Medika, "Lokomat," n.d., [Accessed on 16 June 2017]. [Online]. Available: <http://airindo.com/product/lokomat/>
- [44] Hocoma AG, "Lokomat Quotation," E-mail Correspondance, July 2017.
- [45] D. Swart and E. du Preez, "Research Project Scope and Objectives," Interview, March 2017, therapy Services Co-ordinator and Physiotherapist for Vincent Pallotti Life Rehabilitation Unit.
- [46] English Oxford Dictionary. (2017) Ergometer. [Accessed on 21 June 2017]. [Online]. Available: <https://en.oxforddictionaries.com/definition/ergometer>
- [47] MOTomed, "MOTomed Movement Therapy," Brochure, n.d. [Online]. Available: <http://abilityinmotion.com.au/wp-content/uploads/2010/11/Brochure-Neurological-Condition.pdf>
- [48] A. Kamps and K. Schüle, "Cyclic movement training of the lower limb in stroke rehabilitation," *Journal of Neurologic Rehabilitation*, vol. 11, no. 5, pp. S1–S12, 2005.

- [49] H. Yang, C. Lee, R. Lin, M. Hsu, C. Chen, J. Lin, and S. Lo, "Effect of biofeedback cycling training on functional recovery and walking ability of lower extremity in patients with stroke," *Kaoshiun Journal of Medical Sciences*, vol. 30, pp. 35–42, 2014.
- [50] American Stroke Association, "Functional Electrical Stimulation," March 2013, [Accessed on 14 June 2017]. [Online]. Available: http://www.strokeassociation.org/STROKEORG/LifeAfterStroke/RegainingIndependence/PhysicalChallenges/Functional-Electrical-Stimulation_UCM_310628_Article.jsp#.WUGC2miGNpk
- [51] Mediatronics, "MOTOmed Viva2 Quotation," Interview, June 2016.
- [52] B. Fabrycky, *Systems Engineering and Analysis*, 5th ed. Pearson Education Limited, 2014.
- [53] WebMD, "Foot Drop," n.d., [Accessed on 8 July 2017]. [Online]. Available: <http://www.webmd.com/a-to-z-guides/foot-drop-causes-symptoms-treatments>
- [54] Dictionary.com, "Continuously Variable Transmission," n.d., [Accessed on 11 July 2017]. [Online]. Available: <http://www.dictionary.com/browse/continuously-variable-transmission>
- [55] C. Ofria, "A Short Course on Automatic Transmissions," n.d., [Accessed on 20 November 2016]. [Online]. Available: <http://www.carparts.com/transmission.htm>
- [56] C. Agenbach, "The Design and Testing of a Continuous Variable Transmission," Stellenbosch University, Tech. Rep., October 2015.
- [57] H. Yang, C. Lee, R. Lin, M. Hsu, C. Chen, J. Lin, and S. Lo, "Effect of biofeedback cycling training on functional recovery and walking ability of lower extremity in patients with stroke," *Koasiung Journal of Medical Sciences*, vol. 30, pp. 35–42, 2014.
- [58] Bosch Rexroth, "Rexroth MKD Synchronous motors: Project Planning Manual," n.d., [Accessed on 10 November 2016]. [Online]. Available: http://www.magnaproducts.com/content/file/MKD_PR07.pdf
- [59] T. Hechler and S. Anderson, "The noise about synchronous belts," n.d., [Accessed on 10 July 2017]. [Online]. Available: <http://www.machinedesign.com/technologies/noise-about-synchronous-belts>
- [60] Machine Design, "Synchronous Belts," November 2002, [Accessed on 10 July 2017]. [Online]. Available: <http://www.machinedesign.com/basics-design/synchronous-belts>
- [61] SKF, "SKF Power Transmission belts," 2011, [Accessed on 1 September 2016]. [Online]. Available: http://www.skf.com/binary/21-268672/Catalogue---SKF-Power-Transmission-belts---06875_3-EN.pdf

- [62] SKF, “Pulleys,” n.d., [Accessed on 1 September 2016]. [Online]. Available: <http://www.bearing.net.au/wp-content/uploads/2014/07/SKF-Pulley-Catalogue.pdf>
- [63] Sunpower, “Optoisolator,” July 2014, [Accessed on 30 July 2017]. [Online]. Available: <http://www.sunpower-uk.com/glossary/what-is-an-optoisolator/>
- [64] W9XT Web Site, “Microcontroller Interfacing - Part 11: Using Optoisolators for Inputs,” n.d., [Accessed on 10 February 2017]. [Online]. Available: http://www.w9xt.com/page_microdesign_pt11_opto_inputs.html
- [65] Sparkfun, “RS-232 vs. TTL Serial Communication,” November 2010, [Accessed on 08 August 2017]. [Online]. Available: <https://www.sparkfun.com/tutorials/215>
- [66] O. motor. (n.d.) Servo Motor Features Overview. [Accessed on 9 July 2017]. [Online]. Available: <http://www.orientalmotor.com/servo-motors/technology/servo-motor-features.html>
- [67] Harvard T.H. Chan, “The Borg Scale of Perceived Exertion,” n.d., [Accessed on 23 August 2017]. [Online]. Available: <https://www.hsph.harvard.edu/nutritionsource/borg-scale/>
- [68] ASIA, “International Standards for Neurological Classification of Spinal Cord Injury,” Reference Manual, 2003.
- [69] M. Tuszynski, J. Steeves, J. Fawcett, D. Lammertse, M. Kalichman, C. Rask, A. Curt, J. Ditunno, M. Fehlings, J. Guest, P. Ellaway, N. Kleitman, P. Bartlett, A. Blight, V. Dietz, B. Dobkin, R. Grossman, and A. Privat, “Guidelines for the conduct of clinical trials for spinal cord injury as developed by the ICCP Panel: clinical trial inclusion/exclusion criteria and ethics,” *Spinal Cord*, pp. 1–10, 2006.
- [70] Rehabilitation Measures Database, “Ashworth Scale or Modified Ashworth Scale,” n.d., [Accessed on 22 August 2016]. [Online]. Available: <http://www.rehabmeasures.org/Lists/RehabMeasures/PrintView.aspx?ID=902>
- [71] Stroke Engine, “Modified Ashworth Scale,” n.d., [Accessed on 22 August 2016]. [Online]. Available: <https://www.strokengine.ca/assess/mashs/>
- [72] Thomas Jefferson University, “Walking Index for Spinal Cord Injury II (WISCI II),” Instructions for Use, March 2005.
- [73] A. Fl’oel, C. Werner, U. Grittner, S. Hesse, M. J’obges, J. Knauss, M. Seifert, E. Steinhagen-Thiessen, M. G’overcin, C. Dohle, W. Fischer, R. Schlieder, A. Nave, A. Meisel, M. Ebinger, and I. Wellwood, “Effect of Locomotor Training on Motor Recovery and Walking Ability in Patients with Incomplete Spinal Cord Injury: A Case Series,” *Trials*, vol. 15, p. 45, 2014.

- [74] S. Billinger, A. Mattlage, A. Ashenden, A. Lentz, and G. Harter, "Aerobic Exercise in Subacute Stroke Improves Cardiovascular Health and Physical Performance," *Journal of Neurologic Physical Therapy*, vol. 36, no. 4, pp. 159 – 165, 2012.
- [75] M. Zint, "Power Analysis, Statistical Significance, & Effect Size," n.d., [Accessed on 22 August 2017]. [Online]. Available: <http://meera.snre.umich.edu/power-analysis-statistical-significance-effect-size>
- [76] Tectra Automation, "Study sample size calculation," Consultation with Georg Venter, September 2017.
- [77] B. Dobke, K. Schüle, W. Diehl, and T. Kaiser, "Use of an assistive movement training apparatus in the rehabilitation of stroke patients," *Journal of Neurologic Rehabilitation*, vol. 16, no. 4, pp. 173–185, June 2011.
- [78] R. B. Chase, N. Aquilano, and F. Jacobs, *Operations Management for Competitive Advantage*, 10th ed. McGraw-Hill Irwin, 2004.
- [79] E. du Preez and M. M., "Results discussion and clinician feedback," Interview, August 2017.
- [80] P. Ryder, *Classical Mechanics*. Aachen Shakerl, March 2007.
- [81] D. Winter, *Biomechanics and Motor Control Human Movement*. John Wiley & Sons Inc, 2009.
- [82] Stellenbosch University, "The indirect cost recovery rate (ICRR) on third stream income: interim information to faculties," Letter to Faculties, Stellenbosch University, Stellenbosch Central, Stellenbosch, 7599, South Africa, 2012.
- [83] Eskom, "Tariffs and Charges 2017/2018," April 2017. [Online]. Available: http://www.eskom.co.za/CustomerCare/TariffsAndCharges/Pages/Tariffs_And_Charges.aspx