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Development of an equipment to detect and quantify muscular spasticity

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Development of an equipment to detect and quantify muscular spasticity

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ABSTRACT

Spasticity consists of a muscular tonus alteration caused by a flawed central nervous system which results in a hypertonic phenomenon. The presence of spasticity is normally noticeable by the appearance of a denoted velocity dependent "rigidity" throughout the passive mobilization of an affected limb which can be a potential source of constraints in subject independency by negatively affecting the accomplishment of daily basic tasks.

Spasticity treatment usually comprises high cost methods and materials. There is also a strict relation between the spasticity grade and the dose that has to be applied to attain the desired effective result. These two facts justify the need for a more precise equipment to detect and quantify muscular spasticity.

In the present days, three main groups of spasticity quantification methods coexist: the clinical scales, electrophysiological measurements and the biomechanical measurements. The most used ones are the clinical scales, especially the Modified Ashworth Scale. These scales quantify spasticity based on the perception of muscular response sensed by an operator. In a different field of approach, many instruments have been built to quantify biomechanical magnitudes that have shown direct relation with spasticity. Unfortunately, most of these instruments had either inappropriate size for clinical use, weak result correlation both inter and intra-subject, or a noticeable result dependence on the operator.

The objective of this project was to create a reliable method for spasticity detection and quantification that could: be of easy and fast application, have no need for a specialized operator, be portable and present good repeatability and independency from the operator in the produced results. The resulting prototype, named *SpastiMed*, is a motorized and electronically controlled device which through analysis of the produced signal presented irrefutable proof of its capacity to detect and possibly quantify spasticity while gathering the important characteristics mentioned.

Keywords: Biomedical Engineering, Medical device, Biomechanics, Muscular tonus, Spasticity assessment.

RESUMO

A espasticidade é um fenómeno de hipertonia muscular causada por um funcionamento incorreto do sistema nervoso central. É normalmente percetível, aquando da mobilização passiva do membro afetado, pelo aparecimento de uma "rigidez" dependente da velocidade. A espasticidade pode afetar negativamente a vida do doente, comprometendo a sua independência, ao dificultar ou impossibilitar o desempenho de tarefas básicas.

A necessidade de um aparelho mais preciso na deteção e quantificação da espasticidade é justificada pelo facto de o tratamento da espasticidade compreender tratamentos de elevado custo e pela estreita relação de dependência entre o grau de espasticidade presente no músculo que se pretende tratar e a dose e efetividade resultante do tratamento a aplicar.

Para efeitos de quantificação existem atualmente 3 classes de métodos: escalas clínicas, medições eletrofisiológicas e medições biomecânicas. O método mais utilizado são as escalas clínicas, com especial relevância para a Modified Ashworth Scale, que tem como base a perceção, por parte do operador, da resposta muscular aquando da mobilização passiva do membro. Paralelamente, no plano da quantificação de grandezas biomecânicas como potenciais quantificadores de espasticidade, tem-se verificado o aparecimento de vários instrumentos desenvolvidos. Infelizmente, a maioria, peca pelas dimensões pouco apropriadas ao ambiente clínico, pela fraca correlação de resultados inter ou intra-doente, ou pela dependência dos resultados gerados para com o operador do instrumento.

O objetivo deste projeto era criar um método fiável na deteção e gradação da espasticidade fácil e rápido de aplicar, que não necessite de um operador especializado, seja transportável e que apresente uma boa reprodutibilidade e independência do operador nos resultados produzidos. O protótipo desenvolvido, apelidado de *SpastiMed*, é um dispositivo motorizado e eletronicamente controlado. Através da análise do sinal por este produzido foram obtidas provas da capacidade para detetar e possivelmente quantificar espasticidade muscular sem abdicar das características chave referidas anteriormente.

Palavras-Chave: Engenharia Biomédica, Dispositivos médicos, Biomecânica, Tónus Muscular, Avaliação da Espasticidade.

TABLE OF CONTENTS

AKNOWLEDGEMENTS	i
ABSTRACT	iii
RESUMO	v
FIGURE INDEX	xi
TABLE INDEX	xiii
SYMBOLS AND NOTATIONS	xv
INTRODUCTION	1
1. THEORETICAL STUDY AND STATE OF THE ART	3
1.1 Spasticity	3
1.1.1 Clinic and etymologic definition	3
1.1.2 Epidemiology and impact	3
1.1.3 Treatments	4
1.2 Spasticity assessment methods	5
1.2.1 Clinical Scales	5
1.2.2 Electrophysiological measurements	7
1.2.3 Biomechanical measurements	7
1.2.3.1 Spasticity Measurement System	9
1.2.3.2 On-line spasticity measurement system	9
1.2.3.3 Portable system with force transducer	10
1.2.3.4 Portable Spasticity Assessment Device	10
1.2.3.5 Myotonometer [™]	11
1.2.3.6 Isokinetic Dynamometers (Biodex multi-joint System [™] and	
Kincom 500H)	11
1.2.3.7 Instrument developed by Inês Clemente – "The Glove"	13
1.3 Project motivation and contextualisation	14

2. BUILDING AND DEVELOPING SPASTIMED	15
2.1 Mechanical Part	16
2.1.1 Introductory considerations	16
2.1.2 Conic Gears	17
2.1.3 Motor	18
2.1.4 Metallic parts	19
2.2 Electronics	20
2.2.1 Current Sensor	20
2.2.2 Angular position Sensor	22
2.2.3 Safety switches	23
2.2.4 Motor Control driver	23
2.2.4.1 Motor velocity control	24
2.2.4.2 Control of the direction of rotation of the motor	25
2.2.5 Microcontroller	26
2.2.5.1 Choosing an appropriate sampling rate for data acquisition	26
2.2.5.2 Communication with the LabVIEW® interface	26
2.2.5.2.1 Communication from the microcontroller to the LabVIEW® interface	26
2.2.5.2.2 Communication from the LabVIEW® interface to the microcontroller	27
2.2.5.3 Analogic Signal Acquisition	29
2.2.5.4 Push buttons actions	30
2.2.5.5 Motor control	30
2.2.5.6 Microcontroller programming	32
2.3 LabVIEW® Interface	33
2.3.1 Graphical User Interface	33
2.3.2 Communication configuration	33
2.3.3 Interpretation of the received data	34
2.3.3.1 Angular position value	34
2.3.3.2 Consumed current value	35

3. SPASTIMED ASSESSMENT ROUTINE	37
3.1 Pre-Calibration process	37
3.2 R.O.M definition Routine	38
3.3 Data Acquisition Routine	38
4. RESULTS	39
4.1 Obtained signals	39
4.1.1 Unloaded Device	39
4.1.2 Healthy relaxed subject arm	40
4.1.3 Healthy subject arm inducing opposing force	41
4.1.4 Spastic subjects arms	42
4.2 Signal analysis	43
5. CONCLUSIONS AND FUTURE DEVELOPMENTS	45
5.1 Prototype Improvements	46
5.2 Future Perspectives	48
6. REFERENCES	51
7. APPENDICES	55

FIGURE INDEX

Figure 1.1 – Subjects that present spasticity in flexor muscles around the elbow and the wrist junctions ^[25,26] .	3
Figure 1.2 – SMS – Spasticity Measurement System – Explanatory scheme of the measuring equipment ^[17] .	9
Figure 1.3 – Mechanical structure of the On-line spasticity measurement system. The arrows indicate the possible adjustments that can be made to the motor position ^[15]	9
Figure 1.4 – Scheme of the portable system with a force transducer [7].	10
Figure 1.5 – Portable Spasticity Assessment Device scheme [18].	11
Figure 1.6 – BIODEX MULTI-JOINT SYSTEM–PRO ^[21] used in the study made by Supraja e Singh ^[10] .	12
Figure 1.7 – KinCom 500H ^[13, 22-24] .	12
Figure 1.8 – Spasticity measurement device developed by <i>Inês Clemente</i> ^[16] . A) Inside view of the glove (plastic water sac inserted between the glove and the yellow tissue). B) Outside view ((1) back of the hand (2) and palm of the hand) of the Glove when correctly strapped on an examiner's hand ^[16] .	13
Figure 2.1 – Block Diagram representation of the SpastiMed device.	15
Figure 2.2 – Final state of the mechanical part of the <i>SpastiMed</i> device. A) Top View when attached to a subject arm. B) Side View when attached to a subject arm. C) View of the device without the plastic protective caps. a) DC motor. b) arm metallic part. c) forearm metallic part. d) bigger conic gear. e) smaller conic gear. f) splint parts to help locking the device in position on top of an arm.	16
Figure 2.3 – Schematic drawing of a cut view of the gears used in the mechanical part of the <i>SpastiMed</i> . All the specifications, lengths and sizes of the used set of gears can be found in Table 2.2.	17
Figure 2.4 – Schematic of all the electronics integrated in the SpastiMed device	20
Figure 2.5 – Schematic of the Current Sensor developed and used in the SpastiMed	21
Figure 2.6 – Schematic of the Angular position sensor circuit	22
Figure 2.7 – Motor consumed current signal when supplying the motor with a 12V Pulse Width Modulated line. Time scale is in cs.	24
Figure 2.8 – Schematic of the digitally controlled motor velocity control circuit developed for SpastiMed.	24
Figure 2.9 – Schematic of the circuit used to control the direction of rotation of the motor presented in 2.1.3.	25
Figure 2.10 – Block diagram of the "computersaid" function responsible by the interpretation of the information sent by the LabVIEW®.	28
Figure 2.11 – Block diagram of the "vel_ctrl" function responsible by the control and adjustment of the motor velocity according to the reference (ANGVEL).	31
Figure 2.12 – Block diagram of the "SpastiMed-main-pic" function which works as the "brain" of the device.	32
Figure 2.13 – Picture of the LabVIEW® graphical user interface. A – "Calibrate" button. B – Pre-Calibration movement push-buttons. C – Calibration results. D – Save to file button. E – Assessment Start/Stop button. F – "Number of Cycles" box. G – Warning lights panel. H – Angular position plot. I – Consumed current plot.	33
Figure 2.14 – Picture of the LabVIEW® graphical user interface communication configuration boxes.	33

Figure 2.15 – Metallic arm with the angular position referential in yellow.
Figure 2.16 – Values acquired to establish a linear relation between the angular position and the ADC values.
Figure 3.1 – Explanatory diagram of the <i>SpastiMed</i> routine used to assess and quantify spasticity.
Figure 4.1 – Consumed current signals (A) obtained from the current sensor circuit with an unloaded device at A) – 25° /s, B) – 45° /s, C) – 60° /s and D) – 90° /s. The horizontal axis is displaying the number of acquisitions which can be converted to time (s) by simply dividing by 100.
Figure 4.2 – Consumed current signals (A) obtained from the current sensor circuit with <i>SpastiMed</i> applied on a healthy and relaxed upper limb mobilized at A) – 25° /s, B) – 45° /s, C) – 60° /s and D) – 90° /s. The horizontal axis is displaying the number of acquisitions which can be converted to time (s) by simply dividing by 100.
Figure 4.3 – Consumed current signals (A) obtained from the current sensor circuit with <i>SpastiMed</i> applied on a healthy upper limb mobilized at A) 25°/s and B) 60°/s. In the square-boxes, the reaction of the device to a small opposing force is easily noticeable. The horizontal axis is displaying the number of acquisitions which can be converted to time (s) by simply dividing by 100.
Figure 4.4 – Consumed current signals (A) obtained from the current sensor circuit with <i>SpastiMed</i> applied on a healthy upper limb mobilized at 25°/s. In the square-boxes, the reaction of the device to intense opposing forces is easily noticeable. The horizontal axis is displaying the number of acquisitions which can be converted to time (s) by simply dividing by 100.
Figure 4.5 – Consumed current signals (A) obtained from the current sensor circuit with <i>SpastiMed</i> applied on "Subject A" upper limb mobilized at A) – $45^{\circ}/s$, B) – $90^{\circ}/s$. The horizontal axis is displaying the number of acquisitions which can be converted to time (s) by simply dividing by 100.
Figure 4.6 – FFT of two signals obtained during extension movements at the velocity of 90°/s with the device: A) unloaded. B) attached to a relaxed healthy upper limb. C) attached to "Subject A" upper limb.
Figure 5.1 – Custom made upper limb sustentation tool used in <i>Centro de Medicina e Reabilitação de Alcoitão</i> to nullify the effect of gravity in the rehabilitation of some upper limb movements.
Figure 5.2 – Custom made upper limb sustentation tool used in <i>Centro de Medicina e Reabilitação de Alcoitão</i> with an upper limb suspended on it.

TABLES INDEX

Table 1.1 – Modified Ashworth Scale used in clinical environment to assess spasticity [7]	6
Table 1.2 – Modified Tardieu Scale used in clinical environment to assess spasticity ^[12] .	6
Table 2.1 – Expected mass and length of the different segments of a human upper limbfrom a subject with a total mass of 100kg and a total height of 1m [42].1	17
Table 2.2 – Specifications of the set of gears used in the mechanical part of the <i>SpastiMed.</i> All the lengths and sizes in the table are expressed in millimetres and are related to the ones presented in Figure 2.2 (adapted from ^[44]).1	18
Table 2.3 – Specifications from the motor used in <i>SpastiMed</i> 's mechanical part (adapted from ^[44]). 1	19
Table 2.4 – Motor direction control state with the change of the inputs (IN1 and IN2) of the circuit presented in Figure 2.9.	25
Table 2.5 – Communication code from the microcontroller to the LabVIEW® interface regarding the push of the safety buttons. 2	27
Table 2.6 – Communication code from the microcontroller to the LabVIEW® interfaceregarding the acquired sensor data communication. The information sent in byte1 andbyte2 corresponds respectively to the microcontroller's ADRESH e ADRESL registries.	27
Table 2.7 – Communication code from the microcontroller to the LabVIEW® interface regarding other types of warnings.	27
Table 2.8 – Communication code from the LabVIEW® interface to the microcontroller regarding hardware action commands. 2	29
Table 2.9 – Communication code from the LabVIEW® interface to the microcontroller regarding the configuration of the motor movement. 2	29
Table 2.9 – Motor motion control macros. 3	30
Table 5.1 – Achievement table for all of the relevant spasticity assessment methods presented in CHAPTER 1. regarding the 5 fundamental key-features on a spasticity assessment device/method. The symbols are explained as follow: \checkmark - the method fully possesses the feature; \checkmark/\varkappa - the method partially possesses the feature or presents small flaws and/or limitations either for scientific or clinical use; \varkappa - the method does not possess the feature; $?$ – not enough information to conclude if the method possesses the feature or not.	45

SYMBOLS AND NOTATIONS

CNS	Central Nervous System
MAS	Modified Ashworth Scale
MTS	Modified Tardieu Scale
AS	Ashworth Scale
TS	Tardieu Scale
MMAS	Modified Modified Ashworth Scale
PROM	Passive Range of Motion
EMG	Electromyography
RPM	Rotations Per Minute
ADC	Analogic-to-Digital Converter
IC	Integrated Circuit
DAC	Digital-to-Analogic Converter
UI	User Interface
ADRESH	A/D Result High
ADRESL	A/D Result Low
FFT	Fast Fourier Transform
PCB	Printed Circuit Board

INTRODUCTION

Spasticity consists of a muscular tonus alteration caused by a flawed central nervous system (CNS) which leads into a hypertonic phenomenon ^[1-4]. The presence of spasticity is normally noticeable by the appearance of a denoted velocity dependent "rigidity" throughout the passive mobilization of the affected limb ^[1, 3]. Spasticity is a potential source of constraints in subjects' independency by negatively affecting the accomplishment of daily basic tasks ^[5].

To quantify spasticity physicians usually recur to the clinical scales ^[6-10] from which the most used ones are the Modified Ashworth Scale (MAS) ^[7-9, 11, 12] and the Modified Tardieu Scale (MTS) ^[6, 10]. Both these scales quantify spasticity based on the perception of muscular response sensed trough the passive mobilization by an operator with no resource to any advanced measuring tools ^[6, 7-10, 12]. In a different field of approach, many instruments have been built based on the quantification of biomechanical magnitudes that have shown direct relation with spasticity ^[7, 9, 10, 13-24]. Even so, most of these instruments had either inappropriated size for clinical usage, weak result correlation both inter and intra-subject, or a noticeable result dependence on the operator [7, 9, 10, 13-24].

Another problem associated with spasticity is the fact that the treatment methods usually comprise high costs ^[2, 5-7]. Also, the relation between the quantity of spasticity and the dose that has to be applied to attain an effective and desired result is known to be very strict. These two facts combined justify the need for a more precise equipment to quantify muscular spasticity ^[2, 5-7].

The main objective of this project was to create a reliable device to detect and quantify spasticity that can simultaneously: be of easy and fast application, have no need of a specialized operator, be portable, present a good result repeatability and good independency from the operator in the produced results.

This paper is divided in five chapters. In Chapter 1 the pathology and the ways to detect and quantify it are reviewed. This review lead to the development of a new device which is explained throughout Chapter 2. In Chapter 3 the routine through which the device assesses spasticity is explained. In Chapter 4, the results are exposed and commented leading to Chapter 5 where a small set of conclusions and the future perspectives are presented.

1. THEORETICAL STUDY AND STATE OF THE ART

1.1 Spasticity

1.1.1 Clinic and etymologic definition

Spasticity is commonly described as a simple type of muscular "rigidity" ^[1, 4]. However, clinically and scientifically, this designation is inappropriate and incorrect as muscular rigidity designates a different pathology with only a few similar effects ^[1]. Unlike muscular rigidity, spasticity is defined as velocity dependent effect, positively affected by the increase of movement speed ^[1, 3]. Physiologically, it consists of an abnormal skeletal muscle tonus ^[1, 2] which causes this type of muscular hypertonia ^[3]. As a result of this phenomenon, subjects usually express permanent or intermittent ^[2] muscular contractions (Figure 1.1) which can be sensed and quantified by passively mobilizing the affected limb ^[3].

Spastic muscular hypertonia results directly from a malfunction in the central nervous system (CNS) ^[3], more precisely, by the loss of the natural equilibrium between muscular activation and inhibition ^[1]. This kind of disorder is typically connected to superior motor neuron lesions ^[1-4]. Among a vast group of lesions the most relevant ones are spastic diplegia, motor neuron disease, multiple sclerosis ^[1, 3, 4, 6], vertebro-medullary lesions, encephalic lesions, tumours, stroke and cerebral palsy ^[1, 3, 4].



Figure 1.1 – Subjects that present spasticity in flexor muscles around the elbow and the wrist junctions [25,26].

1.1.2 Epidemiology and impact

The main causes of muscular spastic hypertonia are considerably common ^[27]. For example, according to studies carried in United States of America, the actual incidence of cerebral palsy is around 36 cases by each 10000 births ^[27] affecting mostly male subjects in a ratio of 14:10 ^[27]. On its own, accidentally inflicted spinal cord injuries contribute with around 30 to 60 persons with non-lethal acquired lesion per million of inhabitants which sums on 10000 new subjects with this type of lesions per year ^[28]. And finally, multiple sclerosis has an incidence of 42 cases per million of inhabitants, being female subjects the most affected in an approximate ratio of 2:1 ^[29].

Statistically, muscular spasticity is present in 77% of cerebral palsy subjects, 65 to 78% of the persons with non-lethal spinal cord lesions ^[5] and around 90% of the subjects with multiple sclerosis ^[30]. Apart from these 3 main causes in number of subjects to spastic subjects pool, other lesions like stroke (39% of all cases turn into spastic subjects) ^[31] and cranio-encephalic injuries (50%) ^[32] also contribute with a considerably high number of subjects.

The consequential impact of muscular spasticity on the daily life of spastic subjects is very variable and influenced by both the grade of spasticity and the region where the affected muscles are located. Spasticity negatively impacts the subjects independency to do their personal hygiene, it interferes in their walking pattern and in a group of other daily simple tasks ^[5], commonly causes pain in the affected limbs as well as other secondary complication like contractures, pressure ulcers, fatigue and sleep disorders ^[5]. Therefore, the negative effect on subjects' daily life is an undeniable fact which degree depends on the subject needs and on the number and type of barriers that arise with the acquired spasticity (architectural barriers and others). However, spasticity can lead into some positive impacts such as the increase of venous return ^[5, 6], the increase of subject stability while standing or seating ^[5, 6, 31], muscular growth and the increase in strength of spastic muscles ^[5].

1.1.3 Treatments

As previously mentioned, acquired spasticity results in a group of good and bad effects. Those effects should always be correctly compared and weighted to decide if a clinical treatment is needed and how it will improve subjects' life quality. Consequently, the decision should not only be supported by the grade of muscular spasticity presented by the subject but as well by the increase in subjects' life quality that treatment could turn into ^[5, 11]. Even though this has been a conclusion of many authors ^[2, 5, 6, 31], in the present days there is still no clinical method that shows sensitivity to this aspect.

The 3 main goals of clinical treatment are: to improve the subject performance and adaptation to his surroundings, to reduce the risk on the appearance of secondary complications and to appease the pain ^[2].

There are various types of treatments and/or strategies of application. The first line of treatments are the most conservative ones, such as the case of the rehabilitation therapies. If later a need for a more acute type of treatment arises, the subject is prescribed a set of drugs. Those, if needed, can be followed by intrathecal injections. Finally, and only as a last resort if everything else fails, surgery can be administered ^[2, 5].

The most used drugs are: baclofen, diazepam, dantrolene, clonazepam, phenol and BTX-A (botox – botulinum toxin) ^[2, 5-7]. In the surgery technics field, the commonly used ones are: rear

and front rhizotomy to unlock jammed nerves and microsurgeries to purposely cause lesions on the motor nerve that causes the hypertonia ^[2].

1.2 Spasticity assessment methods

1.2.1 Clinical Scales

The clinical scale assessment methods are based on protocols that qualitatively grade the sensed muscular response during the passive mobilization of a limb according to a pre-defined scale ^[6, 7-10]. Among all the existent scales, the most used one is the MAS ^[7-9, 11, 20] followed by the Ashworth Scale (AS), the Tardieu Scale (TS) and the MTS ^[6, 10].

The AS and MAS (Table 1.1) are based on the quantification of the perceived resistance during the passive mobilization of a limb or segment. The magnitude of that resistance is then graded in 5 different levels with the AS (grade 0 to 4) and 6 levels with the MAS ^[6]. The MAS just as the name denotes is a modified version of the AS where the lower grades were revised to turn the boundaries between them less diffuse. To do so, a new 1+ grade was introduced ^[8]. Even though this new grade slightly improved the results, the main problem of the MAS is still the result clustering effect in the lowest grades of the scale ^[9]. To complete, the MAS is still unable of providing any type of biomechanical information related to the components of the muscular tonus like the viscoelastic component or the reflex activation of the contractile elements ^[9].

The TS and MTS (Table 1.2) evaluate the passive range of motion (PROM) at different movement velocities, the quality of the reaction and the angular position where the first muscular response, which is called "catch", is perceived during a limb extension done at a high angular velocity ^[12, 33-35]. Usually the velocities used in MTS spasticity assessment are the ones corresponding to a movement of extension or flexion done in one second and in half a second ^[12]. While assessing, the examiner should collect two catch angles, R1 and R2 which correspond to the angle at the higher movement velocity and the one at lower velocity, respectively ^[35]. The presence of a considerably high difference between R1 and R2 values evidences the presence of a velocity dependent resistance which is usually associated to muscular spasticity ^[35] and a small difference can evidence the absent of spasticity or that the perceived resistance is non-velocity dependent ^[35].

There are still other scales like the "Priebe and Penn", based on the assessment of the frequency of spasms ^[6, 12] and, more recently, *Ansari et al.* developed the Modified MAS (MMAS) as a result of a study which concluded that this new scale as a better result repeatability for the same examiner but, unfortunately, a weak correlation in the results from different examiners ^[11]. The differences when compared to the MAS are the abolition of the grade 1+ and the redefinition of the grade 2 ^[11, 12].

Grade	Explanation
0	No increase in muscle tone;
1	Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion;
1+	Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder of the range of motion;
2	More marked increase in muscle tone through most of the range of motion, but affected limb is easily moved;
3	Considerable increase in muscle tone, passive movement is difficult;
4	Affected limb is rigid in flexion or extension.

Table 1.1 - Modified Ashworth Scale used in clinical environment to assess spasticity [7].

Table 1.2 - Modified Tardieu Scale used in clinical environment to assess spasticity ^[12].

Grade	Explanation
0	No resistance throughout the course of the passive movement;
1	Slight resistance throughout the course of the passive movement, with no clear catch at precise angle;
2	Clear catch at precise angle, interrupting the passive movement, followed by release;
3	Fatigable clonus (<10s when maintaining pressure) occurring at precise angle;
4	Continuous clonus (>10s when maintaining pressure) occurring at precise angle.

All these scales, even if highly subjective, represent useful tools extremely used both in clinical procedure and in scientific studies to obtain qualitative information concerning muscular spasticity. However, some studies revealed the low reliability and low sensitivity to small spasticity variations ^[8, 10, 13]. In addition it is notorious that the results are substantially dependent on the examiner ^[6]. Removing this dependency was one of the main goals of the tool developed during this project.

Like previously mentioned for the treatments, authors ^[36] defend that the quantification of spasticity should also take into account the effect of the disease in the subject life quality ^[36]. As a matter of fact, with that goal, some authors developed some questionnaires which unfortunately remain unused ^[6, 36].

To conclude, even though these scales present a limited ability to quantify spasticity, they will surely remain used ^[14] due to their simplicity, inexistent usage cost and their relatively satisfactory results.

1.2.2 Electrophysiological measurements

This type of measurements is nearly never used in clinical procedure because the produced results are hard to analyse, the devices needed are very expensive and because a few methods require invasive procedures ^[7, 37].

One example of this type of measurements is the usage of electromyography (EMG) to estimate muscular reflexes during the passive mobilization of a limb, to study the amplitude and the duration of those reflexes ^[34] and to categorize them in spastic or non-spastic ones ^[38]. Another example is the measurement of the H-Reflex (Hoffmann Reflex) which is produced by electrically stimulating a muscle and measuring the M-wave (muscular response wave) given by the muscle ^[39]. This method is capable of identifying a "shorter" excitability of the synapsis caused by an alteration of the synaptic excitation threshold ^[37]. Even though both the H-Reflex and the ratio H-max/M-max present higher values in the presence of spasticity when the objective is to quantify spasticity, those values have shown to be highly variable and with diffuse or no dependence at all to the spasticity grade ^[37]. In fact, during a cross study with MAS, subjects with different clinical scale results presented similar H-Reflex amplitudes, and subjects with similar grades of spasticity presented very different H-Reflexes ^[37]. Similar results were found for the H-max/M-max ratio ^[37].

The main problem associated with the application of EMG technics is the irrefutably high dependence on factors such as: subject subcutaneous fat, skin resistance and muscle fibbers orientation in the spot where the electrodes are attached ^[34] as these factors substantially contribute to the previously mentioned variability in results.

To conclude, the main advantage in the usage of EMG in new studies is the fact that it can be used to monitor and easily detect subjects' voluntary muscular contractions and avoid "false positive" results when assessing or quantifying spasticity ^[34].

1.2.3 Biomechanical measurements

In the last few years, many authors developed and described various methods, tools, devices and instruments created to measure biomechanical magnitudes with a direct relation with spasticity which can be described and understood in such a way that quantification is described through a physical or mathematical model ^[9, 14].

The recent technical and technological developments in the area of biomechanical measurements have evidenced the huge potential these methods possess to quantify spastic hypertonia with much more precision and liability than the clinical scales ^[7, 14, 37]. Even so, this methods remain unused in clinical procedure and most of the authors' point the main causes as being the necessity of specialized instruments and personal to operate it, the high costs of these equipment and the very tight security rules to be authorised in clinical use ^[7].

One of the oldest biomechanical tests to assess and quantify spasticity is the Wartenberg Pendulum Test, which was described in 1951 by the author with the same name as being a simple method with a good liability ^[9, 36]. In this test, the examiner extends the leg of a subject seating or laying down on the edge of a litter and then drops the leg and lets it oscillate ^[9, 36]. Wartenberg described that a non-spastic leg oscillates smoothly, just like a pendulum ^[9], 6 times in average, before it stops ^[36]. However, in a spastic leg, the oscillation is affected by the abnormal viscoelastic properties and the exaggerated extensive reflexes of the limb ^[9]. As a result, the number of oscillations is reduced in proportion to the grade of spasticity in the limb ^[36]. More recent studies concluded that the observation of the first oscillation, in opposition to the simple evaluation of the number of oscillations, could be a better solution to assess and quantify spasticity in a subject limb ^[36].

The Wartenberg Pendulum test is commonly used in studies of spasticity in subjects of various ages with cerebral palsy, victims of stroke and others ^[9, 40]. It is highly accepted as a method capable of differentiating healthy subjects from subjects with spasticity in the extensor muscles of the knee ^[36] and able to distinguish subjects with spasticity and parkinsonian rigidity ^[41]. However, the Wartenberg is more and more seen as an imprecise method for spasticity quantification ^[40].

Recently the combined use of the Wartenberg Pendulum test with EMG technics demonstrated much better results than the simple older test with a considerably higher sensitivity in spasticity quantification for flexor muscles in the knee even in extreme cases like 2 years and a half old children ^[9] and on elder subjects ^[41].

In the literature, there are numerous examples of instruments used in biomechanical quantification and, in the last few years, many new solutions have emerged ^[9]. These instruments recurred to mechanical tools and data acquisition instruments to be more precise than the clinical scales in the identification of the characteristic aspects of spasticity ^[38]. Most of these methods have been mainly used to quantify neuromuscular activity, muscular resistance (force and torque measuring tools), muscular rigidity, elasticity, viscosity, etc. ^[38]. Below are some concrete examples that through their limitations and achievements relevantly contributed to the concept behind the prototype developed during this project.

1.2.3.1 Spasticity Measurement System

The *Spasticity Measurement System*^[17] (Figure 1.2) consists of a mechanical machine capable of producing movements of sinusoidal oscillation in the hip (with frequencies in between 3 and 12Hz) by simply moving a foot correctly attached to a platform which is moved by an electric motor. The system is completed by an acquisition and registry module responsible for collecting the torque response and the angular position of the foot during the evaluation time and an EMG system for muscular reflex monitoring ^[17]. The results presented by the author regarding the detection of muscular spasticity are satisfactory ^[17]. Even so, there were no further studies to proof it was capable of quantifying spasticity.

Finally, the main problem found in this system was the inappropriate size for clinical use as well as the restrict applicability to the lower limb only.

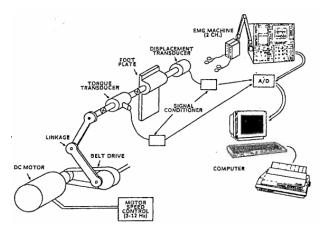


Figure 1.2 – SMS – Spasticity Measurement System – Explanatory scheme of the measuring equipment [17].

1.2.3.2 On-line spasticity measurement system

The *On-line spasticity measurement system* (Figure 1.3) is divided in 3 subsystems: mechanical structure, acquisition electronics/sensors and a control subsystem. The function of the device was to induce passive movement of a body segment around a specific joint while measuring the sensed muscle torque during the mobilization. The applicability of the instrument was very wide covering a vast range of joints and limb sizes ^[15].

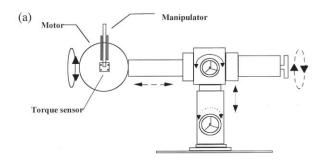


Figure 1.3 – Mechanical structure of the On-line spasticity measurement system. The arrows indicate the possible adjustments that can be made to the motor position ^[15].

The results obtained by this instrument were highly satisfactory in distinguishing spastic from non-spastic limbs. The only flaw it presented was the inadequate size for clinical use. This fact was promptly pointed by the authors and justified by the purpose for which this device was built. That purpose was to perform a group of scientific studies that could lead into a bigger and better understanding of the biomechanical parameters associated with spasticity without any human interference in the system. The final goal of these authors was to develop a clinically accepted portable system based on this system with high precision in assessment and quantification ^[15].

1.2.3.3 Portable system with force transducer

This portable system (Figure 1.4) is composed by a force transducer and one flexible electrogoniometer. The instrument is to be held by an examiner that passively mobilizes the limb of a subject while the instrument does the acquisition of angular position and applied force on the transducer ^[7]. From the data acquired the "Resistance to Passive Motion" is calculated and used to quantify spasticity ^[7]. Even so, this parameter ended up showing small correlation with the results obtained with the MAS especially in the grades 1, 1+ and 2. For that same reason, it was declared as possibly inefficient to quantify spasticity but highly effective in detecting its presence ^[7].

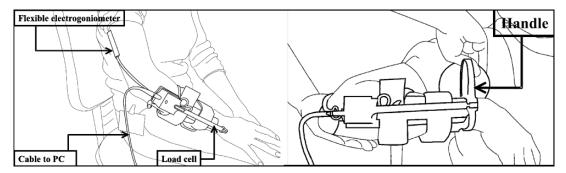


Figure 1.4 – Scheme of the portable system with a force transducer [7].

1.2.3.4 Portable Spasticity Assessment Device

The *Portable Spasticity Assessment Device* (Figure 1.5) is divided in 2 main parts: the air cushions, used to sense muscle response torque, and an angular position sensor to monitor and register the instant angle of the limb that is being assessed ^[18]. The air cushions are strapped in both sides of the wrist (for the upper limb) and, the cushions, are connected to a differential pressure sensor that communicates with a personal computer ^[18]. The results obtained with this instrument showed good correlation with MAS results specially when executing the movement at a high frequency (>1.5Hz) ^[18, 38]. The constant need of monitoring by a trained operator that could interpret the results, turned into a major limitation of this device ^[18].

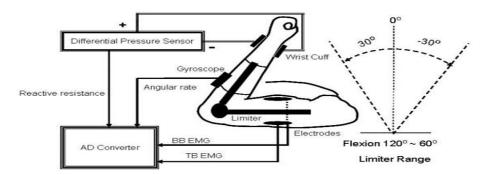


Figure 1.5 – Portable Spasticity Assessment Device scheme [18].

1.2.3.5 Myotonometer[™]

The *MyotonometerTM* function is to measure the rigidity (or viscosity) of a muscle with simple non-invasive contact with the skin ^[19, 20]. This device is composed by a line of transducers that measure the quantity of tissue moved when an external force is applied by a probe over the muscle that is being tested. The resulting value has a linear relation with the muscle tonus of a relaxed muscle ^[20] and so, it can be used to measure alterations in the tonus such as spasticity. This device wasn't as successful as expected in quantifying spasticity in accordance with the MAS ^[20]. In the reviewed literature, the authors also presented results based on statistics that can be considered biased and impartial.

1.2.3.6 Isokinetic Dynamometers (Biodex multi-joint System[™] and Kincom 500H)

The isokinetic dynamometry is a method extensively used in the last decade mainly in computer controlled machines and instruments ^[22] especially in the areas of physiotherapy and in some scientific studies ^[21, 22]. Some of the most technologically advanced instruments ^[10, 13, 21-23] can record and determine a huge set of parameters simultaneously with relevance in spasticity assessment like instant velocity, angular position, muscular applied force, etc. Also very important is the fact that they can be used in a high variety of muscles and articulations ^[10, 13, 21-23].

Among all the devices available in the market, there are two with more relevant results in spasticity assessment which are the *Biodex multi-joint System*^{TM [10, 21]} (Figure 1.6), which is mainly used in rehabilitation and the *KinCom 500H* ^[13, 22-24] (Figure 1.7) which can be described as a device capable of inducing movements at a constant velocity with a coupled force transducer as main source of data ^[24].

The use of these devices is usually explained by the inner curiosity that some authors express in understanding and studying the two components of muscle resistance (reflex component and non-reflex component) as well as their dependence with the velocity of the movement ^[13].



Figure 1.6 - BIODEX MULTI-JOINT SYSTEM-PRO^[39] used in the study made by Supraja e Singh^[10].



Figure 1.7 - KinCom 500H [13, 22-24].

There is a considerably high amount of studies where this kind of devices were used ^[21-23, 39] and, generally, the results are quite satisfactory in detecting the presence of spastic hypertonia. The quantification results have shown good correlation with the MAS with imprecise results only in separating slightly spastic subjects and non-spastic ones ^[13, 21-23].

To conclude, the main and big advantage of this devices is the fact that they have multiple applications ^[10, 21] but, they also have a big disadvantage in the fact that they are quite big and heavy ^[10, 21].

1.2.3.7 Instrument developed by Inês Clemente et al. - "The Glove"

The main objective of this project was to build the prototype of an instrument capable of assessing and quantifying spasticity with simplicity of use and a low cost of production ^[16]. The development team had members who were also involved in the *SpastiMed* project.

The final prototype (Figure 1.8) is composed by a glove with a water sac which is connected to a pressure transducer and an acquisition system which communicates with a personal computer where the data is processed and shown to the operator.



Figure 1.8 – Spasticity measurement device developed by *Inês Clemente* ^[16]. A) Inside view of the glove (plastic water sac inserted between the glove and the yellow tissue). B) Outside view ((1) back of the hand (2) and palm of the hand) of the Glove when correctly strapped on an examiner's hand ^[16].

To use this device, the physician would just have to wear the glove and execute a similar protocol to the one usually used to assess spasticity on a limb ^[16]. In the mentioned project, only the arm was studied (elbow junction).

The prototype showed satisfactory ability to differentiate the spastic subjects from the healthy subjects seen that 82% of the non-spastic cases and 89% of the spastic ones were identified in accordance with the physician diagnostic obtained using a custom clinical scale ^[16]. Even so, during the development and validation of this prototype, a high result dependency on the examiner was detected. To contour this limitation the examiner that operated the instrument was always the same. The study of all the information and notes left by the author also lead to the conclusion that a limitation that should be corrected urgently was the lack of velocity monitoring to avoid producing different spasticity grade results even in the same subject only caused by a variation in the limb mobilization velocity. All these conclusions were taken highly into account during the development of the *SpastiMed* device.

1.3 Project motivation and contextualisation

The main reasons that justify the search for a more precise equipment in spasticity assessment are the fact that the regularly used treatments present high costs and the very strict relation between the degree of spasticity, the dose and the consequent effectiveness of the applied treatment.

The objective of this project is centred around the scientific and clinic urgency in creating a method for spasticity assessment and quantification that can gather simultaneously a set of key points like being of easy and fast application, no need for a specialized operator, being portable, present a good result repeatability and a good independency from the operator in the results produced.

After an extended literature review this research team took part in a mini-intern course lectured in *Centro de Medicina de Reabilitação de Alcoitão* in which the main team members could understand and contact with the pathology and its effects, observe the clinical procedure of spasticity quantification by MAS and the administration of botulinic toxin. Later on, the team idealized a new device that could gather the previously referred key points and that could be an attractive alternative solution to the use of the clinical scales in daily clinical procedure. This new device was given the name of <u>SpastiMed</u>.

2. BUILDING AND DEVELOPING SPASTIMED

The *SpastiMed* device is divided in 3 parts (Figure 2.1). The mechanical part is composed by an articulated metallic arm on top of which a high current input brushed DC motor and a set of gears are attached. These last two are responsible by passively mobilizing the metallic arm and the subject limb while the second part, composed by the control and acquisition electronics, is collecting real-time data like the angular position of the arm and the motor consumed current, which is proportional to the motor torque output. In this prototype system, a few sensors are responsible for supervising subject security during the procedure. The third and last part is a user interface developed in LabVIEW® which is responsible for the storage and treatment of the acquired data.

A diagram that summarises this last paragraph is shown in the Figure 2.1.

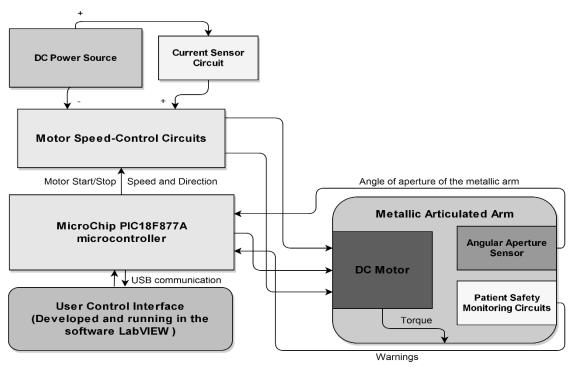


Figure 2.1 – Block Diagram representation of the SpastiMed device.

This prototype was developed with the goal of assessing and quantifying spasticity in the upper limb (elbow joint). However, in concept, this prototype can be adapted to nearly any articulation with a simple redesign of the fixation method over a specific joint (straps, etc.) and, if needed, a resizing of the mechanical part.

2.1 Mechanical Part

The obvious main goal of the mechanical part of the prototype was to passively mobilize a subject upper limb. The final state of the prototype can be seen in Figure 2.2. The bigger sized conic gear (Figure 2.3 - C) - d)) is fixed tightly with the metallic part that lays over the subject forearm (Figure 2.3 - C) - d) and is supposed to sit over the subject joint. Over the second metallic part (Figure 2.3 - C) - d), the one that lays over the patient arm, is screwed a DC motor (Figure 2.3 - C) - d) to which is fixed a smaller sized conic gear (Figure 2.3 - C) - d). The size ratio between the referred conic gears is 2:1.



Figure 2.2 – Final state of the mechanical part of the *SpastiMed* device. A) Top View when attached to a subject arm. B) Side View when attached to a subject arm. C) View of the device without the white plastic protective covers. a) DC motor. b) arm metallic part. c) forearm metallic part. d) bigger conic gear. e) smaller conic gear. f) splint parts to help locking the device in position on top of an arm.

2.1.1 Introductory considerations

To establish the design sizes of the metallic parts (Figure 2.3 - C) – b) and Figure 2.3 - C) – c)) and the minimum specifications of the motor that could be used (Figure 2.3 - C) – a)) an extreme standard case ^[42] of a very short (1m tall) and heavy (100kg total mass) person was considered. The segments that the *SpastiMed* device passively mobilizes are the ones presented in Table 2.1 (adapted from ^[42]).

These segments can be seen as a cylinder with a total mass of nearly 4.9kg and 47.5cm of length. Considering this cylinder uniform in density it has its centre of gravity at nearly 23.75cm from the joint central point. As a result, the chosen size for the forearm metallic part was 25cm from the metallic articulation axis point and the extremity with an expected maximum mass of 300g.

Segment	Mass (kg)	Length (cm)
Arm	5.26	33.5
Forearm	3.64	28.0
Hand	1.26	19.5

 Table 2.1 – Expected mass and length of the different segments of a human upper limb from a subject with a total mass of 100kg and a total height of 1m ^[42].

Therefore, all the previously mentioned data can be condensed to a simple problem of classic physics of a metallic rod with 25cm and 5.2kg, fixed on one of the extremities, to which is applied a perpendicular force to its rotation axis over the free extremity. Thus, the moment of inertia of the rod can be calculated using the Eq.1.

$$I = \frac{1}{3}ML^2 \qquad Eq. 1$$

The obtained result is *I*=0.108(3)kg.m².

2.1.2 Conic Gears

The selection of these components was mainly based on the set of choices available in the market suppliers.

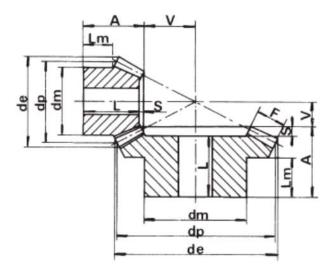


Figure 2.3 – Schematic drawing of a cut view of the gears used in the mechanical part of the *SpastiMed*. All the specifications, lengths and sizes of the used set of gears can be found in Table 2.2 (adapted from ^[43]).

Table 2.2 – Specifications of the set of gears used in the mechanical part of the *SpastiMed*. All the lengths and sizes in the table are expressed in millimetres and are related to the ones presented in Figure 2.2 (adapted from ^[43]).

Nº de Teeth	dp	A+V	dm	Bore	F	Α	de	S	Lm
15	22.5	32.0	16	6	17.23	17.23	26.11	1.73	7.88
30	45.0	25.0	25	8	17.85	45.88	45.88	2.85	9.00

2.1.3 Motor

Based on the previously described classic physics problem and adding the facts that the prototype was expected to achieve an angular velocity of ω =90°/s, that the range of painless motion of a spastic member is usually around the 70° and that the acceleration should be made in around 0.1s then, the angular acceleration α applied to accelerate the previously described rod from 0 to 90°/s can be determined through one of the cinematic equations of a movement with constant acceleration (*Eq.2*).

$$\omega(t) = \omega_0 + \alpha t \qquad Eq.2$$

From which results that α =900°/s² or, converting from grades to radians, α =15.71s⁻².

Using *Eq.3*, it is now possible to determine the fragment of the range of motion "lost" in the acceleration process from 0 to 90° /s.

$$\Delta\theta(t) = \omega_0 t + \frac{1}{2}\alpha t^2 \qquad Eq.3$$

The result is $\Delta \theta = 4.5^{\circ}$.

Seen that both the acceleration and the moment of inertia are now known, the torque can now be obtained through the use of the *Eq.4*.

$$\tau = I\alpha$$
 Eq. 4

The result is $\tau = 1.7$ N.m.

Considering now that the point of application of the corresponding force is R=25cm and recurring to the known torque relation with force and radius (*Eq.5*) the force applied in the gear at 2.25cm can be calculated.

$$\tau = FR \qquad Eq.5$$

The magnitude of that force is F=75.(5)N and consequently, it is now possible to, once more through the use of *Eq.5*, calculate the torque output exerted by the selected motor through the gear with R=1.125cm. Therefore, the torque output value is $\tau = 0.85$ N.m.

In the considered ideal case scenario, the limb would not produce any kind of resistance to the acceleration or to the passive mobilization. In a real case scenario this resistance can't be ignored and will surely play a considerably relevant role in the motor load stress. For that reason, while choosing an appropriate motor a security factor (four times) was applied to the motor torque output.

The second fundamental parameter that had to be defined was the motor output in rotations per minute (RPM). As previously mentioned, the metallic arm should be mobilized with angular velocities in between 0 and 90°/s, what corresponds to 15RPM. Remembering that the size ratio between gears is 2:1 then, the motor speed output will have to be 30RPM and, for the same reason as the mentioned before, the chosen motor had an unloaded maximum speed output nearly four times bigger than this value.

The motor seen in Figure 2.3 - C(-a) was chosen based on these two fundamental specifications (output torque and speed). All of its specifications are shown in Table 2.3.

Parameter	minimum			Maximum
DC Supply Voltage (V)	4.5	6.0	12.0	15.0
Consumed Current with no load (A)	-	0.45	0.52	-
Consumed Current with load (A)	-	2.10	2.85	-
Rotation Speed with no load (RPM)	40	53	106	132
Peak Stall Torque (Nm)	-	9.72	14.50	-

Table 2.3 - Specifications from the motor used in SpastiMed's mechanical part (adapted from [44]).

2.1.4 Metallic parts

With the specifications obtained in 2.1.2 and 2.1.3, with special focus on the gears chosen (Figure 2.3 - C) – d) and Figure 2.3 - C) – e)), the metallic parts presented in Figure 2.3 - C) – b) and Figure 2.3 - C) – c) were designed in the 3D graphic design software *SolidWorks*®. The resulting drawings were then presented to a machining engineer. The team gave him total

freedom to manipulate the drawings to obtain the best possible result. The parts were machined from a block of aluminium to obtain a light prototype with good mechanical properties. To achieve the best result in the articulation between the two metallic parts and having a precise and solid angular position measuring tool, both the motor holding plate and the gears were considerably modified from their stock state.

2.2 Electronics

The second part of the *SpastiMed* device is composed of all the control and acquisition electronics being these divided in five sub-parts: current sensor, angular position sensor, the motor driver circuitry and the microcontroller. In the next few steps all these sub-parts will be extensively described to clarify their construction as well as their role in the device.

The complete schematic of all the electronics integrated in the *SpastiMed* device can be seen in Figure 2.4.

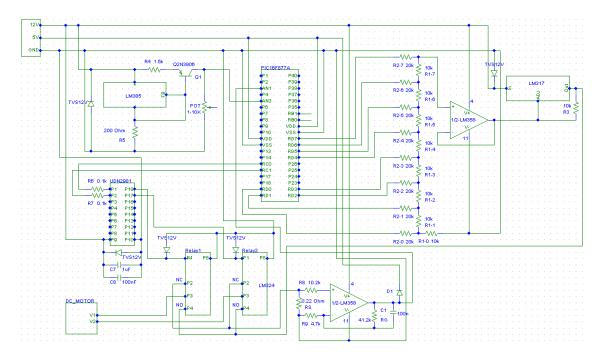


Figure 2.4 – Schematic of all the electronics integrated in the SpastiMed device.

2.2.1 Current Sensor

SpastiMed's spasticity assessment method is based on the relation between the motor torque output and its linear relation with the consumed current as a measure of the resistance to passive motion. It turns out obvious that a good current sensor circuit had to be developed so that this motor consumed current could be measured and monitored through the use of a microcontroller.

Considering the DC motor previously described, the expected consumed current should be normally ranged in between 0 and 2.5A. With that in mind and based on the specifications of the Analogic-to-Digital Converter (ADC) module of the chosen microcontroller, the goal in this step was to build a circuit capable of linearly converting a current value in those referred ranges to a voltage value in between 0 and 5V while producing the smallest alteration possible to the motor supply voltage.

The schematic of the developed circuit can be seen in Figure 2.5. This small circuit is based on the simple theory behind the Ohm's Law and can measure the current passing through a small ohmic value resistance (RS<1 Ω) by amplifying the small electrical potential difference with an Operational Amplifier (Op-Amp).

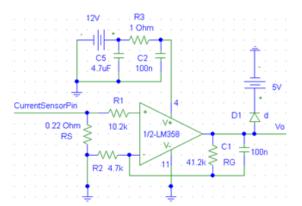


Figure 2.5 – Schematic of the Current Sensor developed and used in the SpastiMed.

To determine the value of the sensing resistance (RS) the desired maximum electrical potential difference in between the resistance terminals was defined as 0.5V. Therefore, seen that this maximum should correspond to the previously mentioned maximum current value of 2.5A, using the Ohm's Law the value of RS is RS=0.2 Ω . With such high value of current (2.5A), one big concern in the component choice was the dissipative potency, which had to be at least P_{RS}=1.25W. Within the choices available the used resistance was the closest to this specifications RS=0.22 Ω with P_{RS}=6W.

The values of RG and R2 were determined through the use of the equation of the gain of an Operational Amplifier in non-inverting amplifying mode (*Eq.*6) and by defining the gain value (*G*) as being 10 or lower so that the output would never exceed the 5V that the microcontroller can safely read.

$$G = \frac{(R2 + RG)}{R2} \qquad Eq. 6$$

The result for RG was RG \leq 42,3k Ω . Based on the material available the used resistance was the one with the closest ohmic value (RG=41.2k Ω).

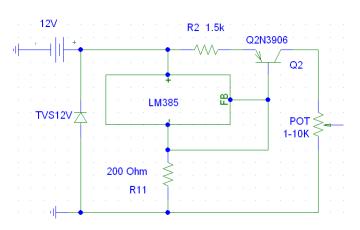
In the final circuit a couple of $1k\Omega$ resistances were connected from the non-used amplifier input pins to the ground line, like suggested in the Op-Amp LM358 datasheet ^[45].

2.2.2 Angular position Sensor

The second relevant magnitude in *SpastiMed*'s spasticity assessment routine is the angular position of the metallic arm. In the final prototype, the fundamental component to achieve that goal was a linear high-precision potentiometer which was fixed tightly inside the bigger gear bore, parallel to its axis of articulation. With this design, a linear relation between the resistance value of the potentiometer and the angular position of the metallic arm was achieved.

Similarly to what was described in 2.2.1, the objective was to develop a circuit that would linearly convert a resistance value that would range from nearly 0 to nearly $10k\Omega$ in a voltage value from 0 to 5V. The simpler and most logic solution was the use of a current regulator which to keep a constant current in the potentiometer and consequently keeping the voltage value linearly related to the resistance at every instant (Ohm Law).

The schematic presented in Figure 2.6 is based on a common current regulator circuit ^[46] with a Zener diode that was replaced by LM385 which is an adjustable high precision Zener diode. The Zener voltage was fixed at V_Z =1.24V in between the (+) and (-) terminals. As a result, in theory, R2 will define the current value (I_L) just like described in *Eq.*7.



$$V_Z - V_{EB} = I_L R2 \qquad Eq. 7$$

Figure 2.6 – Schematic of the Angular position sensor circuit.

According to the datasheet ^[47] of chosen transistor (Figure 2.7 – Q2) at a temperature of 25°C, V_{BE} is approximately 0.65V and it will slightly decrease with an increase of the component temperature. For that and for safety reasons, the value of the used R2 was 1.5k Ω instead of the 1.2k Ω obtained through Eq.7.

2.2.3 Safety switches

One on/off button switch was integrated on the system so it could be held by the subject under evaluation so that he/she could stop the motor movement of the device at any moment. Another on/off button switch is placed on the top of a hardtop case inside which all of the electronic circuits are placed. This second button has the same working pattern.

Finally, one push button is present on the hardtop case which possesses a vital role in the calibration of the *SpastiMed* device by helping in the definition of the painless range of motion before the assessment and quantification procedure is made.

In the code developed for the microcontroller (7. Appendices) a few other button actions were left on a dormant state for further developments of the *SpastiMed* device.

2.2.4 Motor control driver

During the development of all the hardware and circuits present in this prototype, the development of an appropriate motor driver circuit was the longest and more complex step. This step arose numerous problems and required a group of slight adjustments to the conceptual idea itself.

The desired motor driver should have the role of controlling both the velocity and the direction in which the motor will rotate. To do so, our first choice fell on the commonly used Full H-Bridge motor drivers on a single Integrated Circuit (IC). Unfortunately, this approach had to be abandoned based on the fact that this type of component revealed itself very sensitive to some characteristics of the used motor that would lastly cause a few of these ICs to burn down during the device development. Another flawed relevant fact was that the velocity control on the chosen IC motor driver had to be done through the use of a Pulse Width Modulated (PWM) input in the motor which was causing undesirable oscillations in the motor consumed current (Figure 2.7) "polluting" the most relevant signal to this study.

The final solution to these problems was based on a motor characteristic that allows its speed to be controlled through the variation of the DC Voltage Supply value. As a consequence, much of the previously presented calculations to determine the specifications of the mechanical parts of *SpastiMed* may seem slightly unjustified when observing the final prototype and the way it works. Even so, and seen that those calculations reflect the exact way through which those specification were determined, they were kept unaltered.

The motor driver in its final state has two separate circuits: a "motor velocity control" circuit and a "direction of rotation of the motor control" circuit.

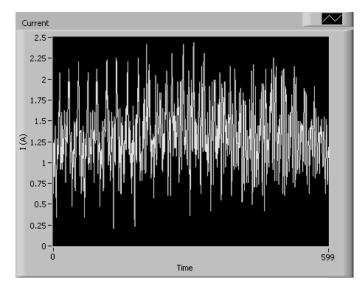


Figure 2.7 – Motor consumed current signal when supplying the motor with a 12V Pulse Width Modulated line. Time scale is in cs.

2.2.4.1 Motor velocity control

Based on the previously mentioned objective of controlling the motor speed through the value of its supply voltage, the goal in this step was to create a digitally controlled voltage regulator. To do so, two components were combined: a Digital-to-Analogic Converter (DAC) based on the R/2R ladder theory and a standardly used analogic adjustable voltage regulator (LM317) supplied by a 12V DC line with a maximum current supply of 6A. To control this remotely, the DAC was connected to the PORTD of the microcontroller, like shown on Figure 2.8.

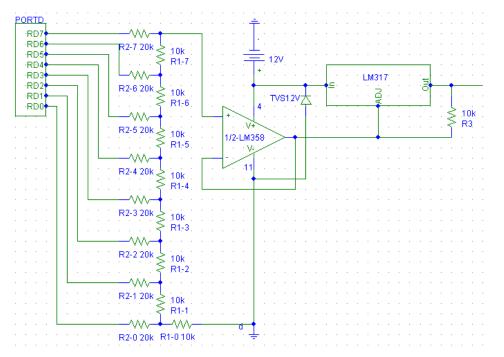


Figure 2.8 – Schematic of the digitally controlled motor velocity control circuit developed for SpastiMed.

2.2.4.2 Control of the direction of rotation of the motor

To control the direction in which the motor rotates a small circuit was developed with two high current relays and a relay driver IC. This relay driver IC was responsible for receiving input from the microcontroller and drive the relays according to those. The microcontroller outputs used were the RC0 (IN1) and RC1 (IN2) which were responsible for controlling the Relay1 and Relay2 respectively. The complete circuit schematic can be seen in the Figure 2.9.

Different combinations of the relay driver inputs produce different motor motion directions. All the possible combinations of logic inputs as well as the corresponding effect in the metallic arm movement can be seen in Table 2.4.

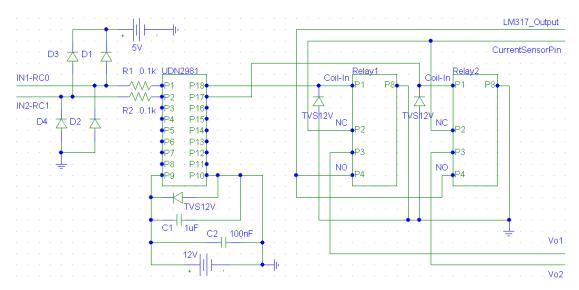


Figure 2.9 – Schematic of the circuit used to control the direction of rotation of the motor presented in 2.1.3.

IN1	IN2	Motor state
0	0	Turned Off
0	1	Moves the metallic arm Clockwise
1	0	Moves the metallic arm Counter-clockwise
1	1	Turned Off

 Table 2.4 – Motor direction control state with the change of the inputs (IN1 and IN2) of the circuit presented in Figure 2.9.

2.2.5 Microcontroller

In this project the microcontroller was used as the "brain" responsible by controlling the way all the hardware behaves. It is responsible by the control of all the electronics, acquiring data from the sensors and communicating with the User Interface (UI) developed in LabVIEW®.

2.2.5.1 Choosing an appropriate sampling rate for data acquisition

In this project there are two directly measureable magnitudes: angular position and consumed current. However, there is a third fundamental magnitude that needs to be constantly monitored and adjusted which is angular velocity.

To get a good amount of samples per second the rate had to be as high as possible but, seen that the communication has its speed limits, through extensive experimentation the highest sampling rate that was generating the best overall quality of communication was 100Hz. This is the same as saying that one acquisition of the angular position and the consumed current is made and transmitted every 0.01s. The angular velocity is calculated in the microcontroller as the angular displacement during the time period in between two acquisitions. For that reason, the angular position sampling rate sets a maximum sampling rate for this calculated velocity sampling of 100Hz as well.

In the way this project is implemented, when the velocity is calculated, if it is slightly deviated from what it was supposed to be, the motor speed driver is commanded to adjust. Seen that there is a small delay in between the communication and the moment the response perceived on the motor velocity, such high sampling rate for angular velocity could not be used because it would cause a phenomenon of "over-acceleration" or "over-deceleration" that would lead to a non-stabilising oscillation in the velocity of the movement. Trough simple value experimentation, the sampling rate for the calculated velocity had to be 20Hz or lower to prevent the referred phenomenon from happening. Therefore, the velocity sampling rate used in this project was 20Hz to, once again, keep it as high as possible.

2.2.5.2 Communication with the LabVIEW® interface

All the communication between the microcontroller and the LabVIEW[®] interface is made through a physical RS232-USB cable.

2.2.5.2.1 Communication from the microcontroller to the LabVIEW® interface

Although a total of 4 warning push buttons were programed, only one of them is used in the final prototype which is the push button responsible for the device calibration.

All the communication codes from the microcontroller to the LabVIEW® are presented in Table 2.5, Table 2.6 and Table 2.7.

Table 2.5 – Communication code from the microcontroller to the LabVIEW® interface regarding the push
of the safety buttons.

Safety push button warnings	
Code	Meaning
S3	The operator/physician button was pushed.

 Table 2.6 – Communication code from the microcontroller to the LabVIEW® interface regarding the acquired sensor data communication. The information sent in byte1 and byte2 corresponds respectively to the microcontroller's ADRESH e ADRESL registries.

Communication of acquired sensor data from the microcontroller to the LabVIEW® interface		
Code	Meaning	
I [byte1] [byte2]	Instant voltage value read from the current sensor circuit.	
P [byte1] [byte2]	Instant voltage value read from the angular position sensor circuit.	
FA [byte1] [byte2]	Calibration routine: angular position 1.	
FB [byte1] [byte2]	Calibration routine: angular position 2.	

 Table 2.7 – Communication code from the microcontroller to the LabVIEW® interface regarding other types of warnings.

Other warning codes		
Code Meaning		
EN	The movement of the motor was stopped.	
FC	The microcontroller warns that the calibration is proceeding.	

2.2.5.2.2 Communication from the LabVIEW® interface to the microcontroller:

The microcontroller has a specific function which role is to interpret the incoming information ("strings") from the LabVIEW[®]. That function can be easily understood through the block diagram in Figure 2.10.

Similarly as presented in 2.2.5.2.1, all the communication codes from the LabVIEW[®] to the microcontroller are presented in Table 2.8 and Table 2.9.

function "computersaid"

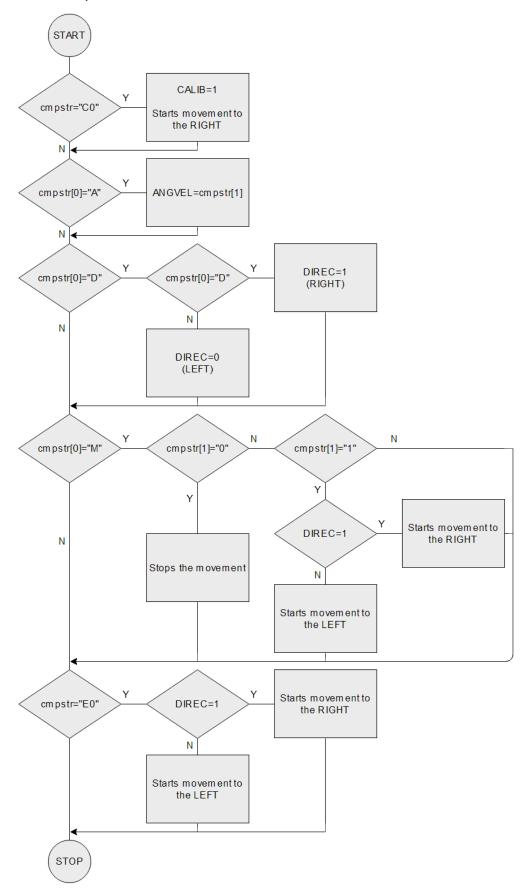


Figure 2.10 – Block diagram of the "computersaid" function responsible by the interpretation of the information sent by the LabVIEW®.

Commands		
Code	Meaning	
C0	Commands the start of the calibration routine.	
E0	Commands the start of the assessment routine at a specified movement speed.	
M0	Commands the motor to be stopped.	
M1	Commands the motor to start moving.	

Table 2.8 – Communication code from the LabVIEW® interface to the microcontroller regarding hardware
action commands

 Table 2.9 – Communication code from the LabVIEW® interface to the microcontroller regarding the configuration of the motor movement.

Configuration of the motor movement		
Code	Meaning	
DD	Indicates that the metallic arm shall move clockwise.	
DE	Indicates that the metallic arm shall move counter-clockwise.	
N [byte1]	Indicates the number of cycles (byte1) that shall be done at each angular velocity during the assessment routine.	
A [byte1]	Indicates the angular velocity at which the arm shall move (byte1).	

2.2.5.3 Analogic Signal Acquisition

The acquisition of the signals provided by the sensors described in 2.2.1 and 2.2.2 is done through the microcontroller ADC module. This module is capable of safely reading voltage values in between 0 to 5V from one origin at a time converting that same value into a digital 10bits binary value which is equivalent to saying that it can obtain a digital value in between 0 and 1023. The result of the acquisition is registered in two 8bit registry variables, ADRESH (Analogic to Digital conversion RESult High) and ADRESL (Analogic to Digital conversion RESult Low). In the microcontroller configuration the ADC 10bits are right justified, which means that the eight less significant bits are in the ADRESL registry and the two more significant bits are in the bit 1 and 0 of the ADRESH registry while all the other bits (7 to 2) are filled with zeros.

The 2 inputs used were RA1 and RA3 for Current sensor and the Angular position sensor respectively.

2.2.5.4 Push button action

The developed program makes use of an input (RB0) of the microcontroller MicroChip® PIC16F877A to receive information from a button which is available to the operator on the hardtop electronics case.

This button acts in different ways depending on the stage of *SpastiMed* assessment process. In the stage of pre-calibration it produces no reaction on the whole system. In the calibration stage this button is fundamentally responsible for the definition of the starting and stopping angles of the spasticity assessment passive mobilization (for more information see 3.2). Lastly, during the assessment phase, this button can stop the movement of the metallic arm at any moment if pushed.

2.2.5.5 Motor control

The motor control is completely done through microcontroller outputs. In this prototype, the 8bit PORTD is responsible for defining the velocity of the motor rotation while the RC0 and RC1 outputs are responsible for defining the direction in which the motor will rotate.

In the programmed code, the adjustment of the velocity is made by a specific function, "vel_ctrl" (Figure 2.11), which role is to adjust the angular velocity by changing the PORTD variable.

For the direction and to start/stop the motor motion 3 macro commands were defined. Their names and meanings can be seen on Table 2.10.

Motor actuation configuration		
Code	Meaning	
RIGHT	Sets the motor in motion making the metallic arm move to the right.	
LEFT	Sets the motor in motion making the metallic arm move to the left.	
STOP	Makes the motor stop.	

Table 2.10 - Motor motion control macros.

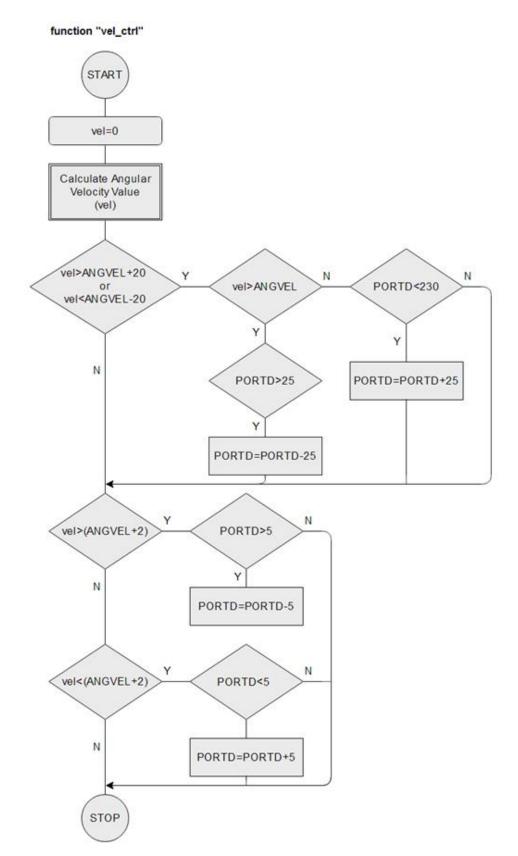
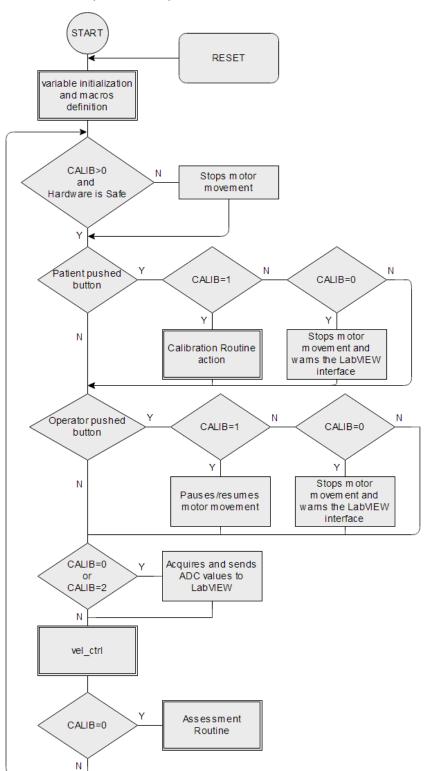


Figure 2.11 – Block diagram of the "vel_ctrl" function responsible by the control and adjustment of the motor velocity according to the reference (ANGVEL).

2.2.5.6 Microcontroller programming

As a conclusion and agglutination of the previous 4 steps (2.2.5.1 to 2.2.5.4) the "SpastiMedmain-pic" program is presented in the Figure 2.12 as a block diagram explaining the way the microcontroller will act and react. The complete code (in C language) can be seen in Chapter 7.



function "SpastiMed-main-pic"

Figure 2.12 – Block diagram of the "SpastiMed-main-pic" function which works as the "brain" of the device.

2.3 LabVIEW® Interface

2.3.1 Graphical User Interface

The final look of the graphical UI developed in LabVIEW[®] can be seen in Figure 2.13. It was designed to provide information in a simple way so it could be easy to interpret by any operator. The look itself aimed to be sober and formal with only the fundamental buttons needed to make the device work in the front panel. There is a second Tab where all the configuration of the microcontroller communication protocol is saved and can also be altered.

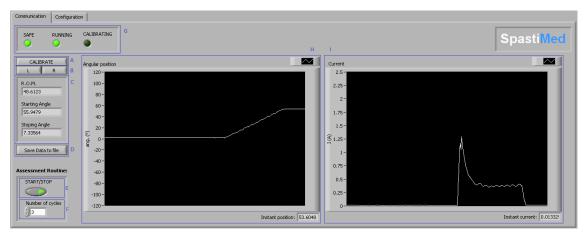


Figure 2.13 – Picture of the LabVIEW® graphical user interface. A – "Calibrate" button. B – Pre-Calibration movement push-buttons. C – Calibration results. D – Save to file button. E – Assessment Start/Stop button. F – "Number of Cycles" box. G – Warning lights panel. H – Angular position plot. I – Consumed current plot.

2.3.2 Communication configuration

When the user opens up the configuration Tab a group of boxes is presented (Figure 2.14). The input values define the RS232 configuration. For a correct understanding between the microcontroller and the interface, the configuration has to be done in the exact same way in both. The rest of the boxes refer to "wait timers" responsible for achieving a good communication flow. The defaulted values on the application (Figure 2.14) were the ones that produced a good communication both in sending/receiving data to/from the microcontroller. The alteration of these values can produce unexpected results.

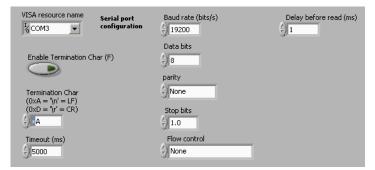


Figure 2.14 – Picture of the LabVIEW® graphical user interface communication configuration boxes.

2.3.3 Interpretation of the received data

Like previously mentioned, the bytes sent by the microcontroller to the LabVIEW[®] interface correspond to the ADRESH and ADRESL registry values which can simply be converted into a single integer value through the use of *Eq.8*.

$$ADC = 255 \times ADRESH + ADRESL \qquad Eq. 8$$

2.3.3.1 Angular position value

To convert the ADC values into angular position values there had to be a pre-definition of some fundamental angular positions. The referential through which the angular position of the metallic arm is expressed is represented in Figure 2.15. For ease of use and simplicity in further explanations, the positive position angles correspond to the use of the *SpastiMed* on a left upper limb and the negative ones to the use on a right upper limb.

Through the use of an angle measuring tool, the metallic arm was placed in the three angular positions -90, 0 and 90° (Figure 2.15) while the signal from the angular position sensor was acquired and tabled. A linear fitting curve was applied to those values to obtain a linear relation between the ADC values and the angular position values (Figure 2.15). This obtained values are then shown on the Angular Position Plot (Figure 2.16).

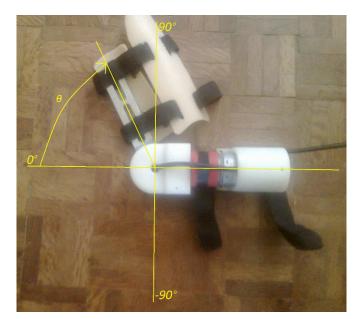


Figure 2.15 – Metallic arm with the angular position referential in yellow.

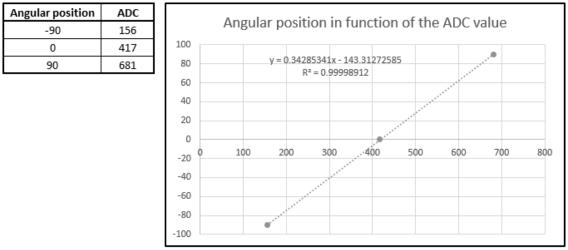


Figure 2.16 – Values acquired to establish a linear relation between the angular position and the ADC values.

Seen that the obtained r^2 value is very close to 1, the potentiometer presents a good linearity. As a further test to this linear relation the metallic arm was set at a few random position angles and the result obtained through the sensor ADC and with a standard analogic measuring tool were compared. The result of 20 random angles had the biggest deviation of 1° which is considered very satisfactory. Consequently, this relation was accepted and implemented in the LabVIEW[®] interface as expressed on *Eq.9*.

 $\theta = 0.34285341 \times ADC - 143.31272585 Eq.9$

2.3.3.2 Consumed current value

Unlike the angular position values, there was actually no fundamental need to make a conversion from ADC values to consumed current values (in Ampere). The reason is that, in this case, what is fundamental is the evolution over time of the signal as well as the relative alterations (ratios and/or percentages) the signal suffers when mobilizing a subject's limb. Even so, for a proper scientific presentation and an easier understanding of what is being displayed, the values in the Current Plot (Figure 2.13 - I) are displayed in a range of 0 to 2.5A according to what the sensor circuit had previously been dimensioned to be able to read. Even so, and very importantly, these values are just averagely around the expected real value and there wasn't any kind of confirmation or attempt at fitting this displayed values to the real ones.

The implementation in the interface was made according Eq. 10.

$$I = ADC \times 2.5 \div 1023 \qquad Eq. 10$$

3. SPASTIMED ASSESSMENT ROUTINE

The assessment routine is divided in 3 main stages: calibration on the subject limb, data acquisition and finally the quantification of the muscular spasticity grade. This last stage was not among the objectives of the project phase this paper refers to. For that reason it is mentioned but it shall be part of a following study with *SpastiMed* prototype.

A short resumed explanation of the Assessment Routine steps can be seen in the Figure 3.1.

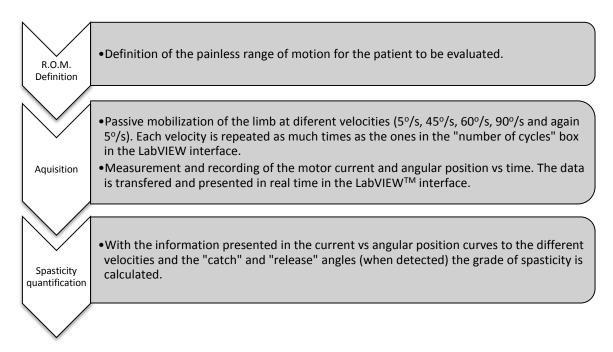


Figure 3.1 - Explanatory diagram of the SpastiMed routine used to assess and quantify spasticity.

3.1 Pre-Calibration process

After the UI application is started and the communication is established, the interface has a set of two buttons (Figure 2.13 - B) which make the metallic arm move either right or left at low velocity (25° /s) to help in the process of conveniently attaching the device to the subject limb.

After the metallic arm is correctly attached to the subject arm, for safety reasons, the operator should adjust the metallic arm position to somewhere near the middle of the range of motion of the subject arm. After that, the conditions for a correct calibration process are met.

3.2 R.O.M definition Routine

This R.O.M definition process exists with the fundamental purpose of letting the operator directly define in between which angular positions *SpastiMed* will passively mobilize the subject limb so that the mobilization can feel as comfortable and painless as possible.

In a resumed way, the R.O.M. definition routine proceeds as follow:

- 1. The "Calibrate" (Figure 2.13 A) button in the LabVIEW[®] interface is pushed.
- 2. The motor mobilizes the metallic arm clockwise.
- 3. When the physician considers that the device is reaching a point where some pain is being felt by the subject or the joint range limit is being reached, he should push the button on the device electronics hardtop case to stop the movement and to define the 1st limit angle.
- 4. When the subject feels ready to proceed with the R.O.M. definition the physician should push the button again ordering the device to proceed with the calibration by making the motor move slowly in counter-clockwise direction.
- 5. When the physician considers that the device is reaching a point where some pain is being felt by the subject or the joint range limit is being reached, he should push the button again to stop the movement and to define the 2nd limit angle.
- **6.** The starting angle, stopping angle and R.O.M. are presented in their corresponding boxes in the LabVIEW[®] interface (Figure 2.13 C).
- **7.** Calibration process is finished and the metallic arm position is set to the position where the movement of limb extension should start.

3.3 Data Acquisition Routine

To start the assessment routine and data acquisition process the operator must push the "START/STOP" button (Figure 2.13 – E). When that happens, the routine is started and proceeds as follow:

- 1. Device starts the extension movement at an angular velocity of 25°/s while recording all the data acquired from the sensors. When the safety limit point is reached the movement is stopped and a waiting period is started in the microcontroller.
- After the waiting target time is reached, the flexion movement is made in a similar way. The two movements are repeated as much times as the "Number of cycles" box (Figure 2.13 F) value.
- **3.** When the number of cycles is complete, the angular velocity is changed to 45°/s. The movement is started and the routine explained in points 1. and 2. is repeated.
- 4. Point 3. is repeated with the angular velocity of 60 °/s.
- 5. Point 3. is repeated with the angular velocity of 90 °/s.
- 6. Finally, point 3. is repeated again with the angular velocity of 25 %.

4. RESULTS

After completing the development of the hardware and software, the *SpastiMed* device was tested to determine its sensitivity as a spasticity assessment tool. For this purpose, a few healthy and spastic subjects were evaluated to collect small sets of data. From these, we expected to find clear evidences that the presence and degree of muscular spasticity would produce some detectable influence in the obtained signals.

4.1 Obtained signals

4.1.1 Unloaded Device

At first, the consumed current (Figure 4.1) and angular position signals produced with the device unloaded were acquired and observed.

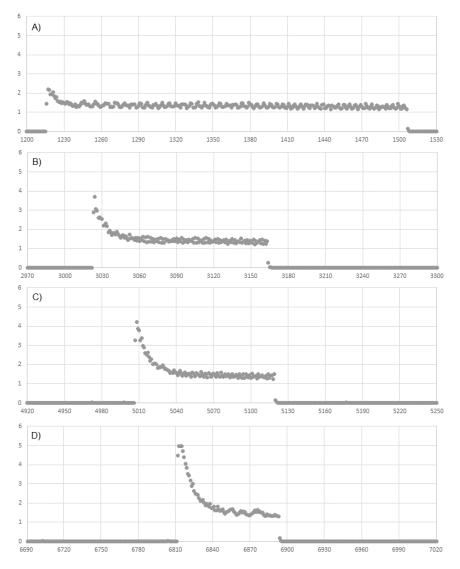


Figure 4.1 – Consumed current signals (A) obtained from the current sensor circuit with the device unloaded at A) – 25°/s, B) – 45°/s, C) – 60°/s and D) – 90°/s. The horizontal axis is displaying the number of acquisitions which can be converted to time (s) by simply dividing by 100.

The obtained consumed current signals can be roughly described as: similar to a "Step Function" with an initial spike with similar behaviour to an "Exponential Function".

The example presented in Figure 4.1 is representative of all signals acquired, either in shape, duration and amplitude. This leads to the conclusion that, in these conditions, the device presents linearity and repeatability in the produced results. Another very important conclusion is that, when unloaded, an increase in the movement velocity does not affect the consumed current base level.

4.1.2 Healthy relaxed subject arm

Next, the device was attached to a relaxed healthy left upper limb from a subject with no clinical record of any type of muscular hypertonia. The resulting signals can be seen in Figure 4.2.

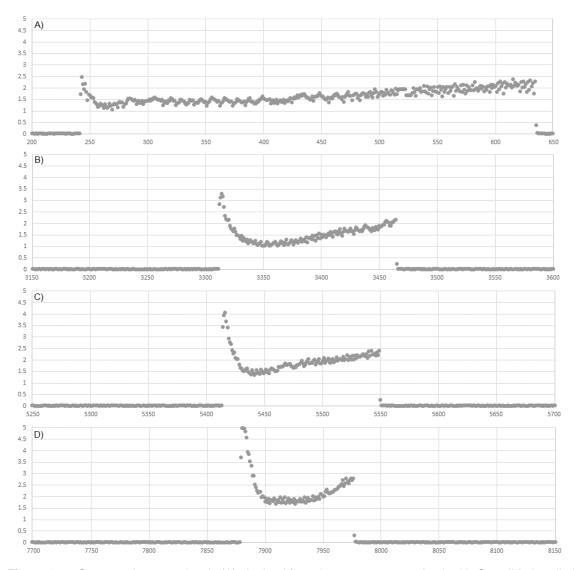


Figure 4.2 – Consumed current signals (A) obtained from the current sensor circuit with SpastiMed applied on a healthy and relaxed upper limb mobilized at A) – 25°/s, B) – 45°/s, C) – 60°/s and D) – 90°/s. The horizontal axis is displaying the number of acquisitions which can be converted to time (s) by simply dividing by 100.

The first conclusion is that the signals in Figure 4.2 show clear similarity in shape and duration compared to the ones previously presented in Figure 4.1. However, in Figure 4.2 a small increase in resistance to passive mobilization is noticed near the end of the range of motion. This phenomenon is especially visible in the Figure 4.2 plot D), and it was found in all the evaluated healthy subjects. Another very relevant conclusion resides in the fact that the increase of movement velocity does not produce an increase in the base level amplitude of the motor consumed current signal.

4.1.3 Healthy subject arm inducing opposing force

In a third step, the objective was to understand if the device was sensitive and capable of detecting opposing forces to the induced movement. For this purpose, the subject tested in 4.1.2 was asked to react during the induced passive movement, by inducing opposing force spikes. Representative signals, in which some of these small intensity and short in duration force spikes were produced, are presented in Figure 4.3. The force spikes were identified in the mentioned figures through the use of square boxes. Finally, the subject was asked to produce short but intense opposing force spikes which resulted in signals similar to the presented in Figure 4.4.

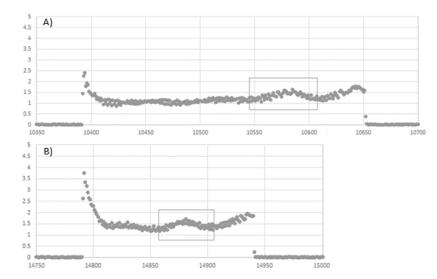


Figure 4.3 – Consumed current signals (A) obtained from the current sensor circuit with *SpastiMed* applied on a healthy upper limb mobilized at A) 25°/s and B) 60°/s. In the square-boxes, the reaction of the device to a small opposing force is easily noticeable. The horizontal axis is displaying the number of acquisitions which can be converted to time (s) by simply dividing by 100.

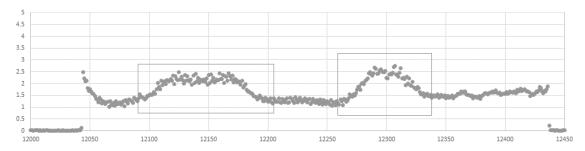


Figure 4.4 – Consumed current signals (A) obtained from the current sensor circuit with *SpastiMed* applied on a healthy upper limb mobilized at 25°/s. In the square-boxes, the reaction of the device to intense opposing forces is easily noticeable. The horizontal axis is displaying the number of acquisitions which can be converted to time (s) by simply dividing by 100.

Collectively, these results represent a clear evidence that this device has good sensitivity. However, for further scientific validation, the device sensitivity should be defined in terms of a standard physical magnitude such as torque (N.m) or force (N).

4.1.4 Spastic subjects arms

Finally, the device was tested on spastic subjects, courtesy of *Centro de Medicina e Reabilitação de Alcoitão*. All the evaluated subjects acquired muscular spastic hypertonia on their left upper limb as a consequence of right brain lobe injury ^[48]. For that reason and given that their speech and understanding was not affected ^[48] they were able to express their full consent and collaboration during the procedure. A very relevant criteria during subject selection resides in the shared lack of voluntary muscular contraction.

The obtained results from "Subject A" can be seen in Figure 4.5. This subject was graded by two trained physician as "grade 1" in the MAS scale in his extensor muscles.

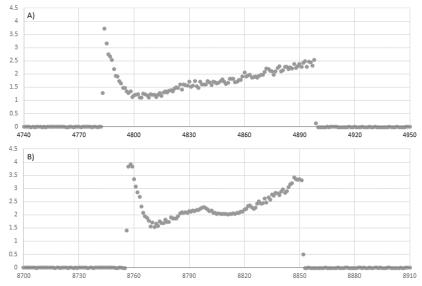


Figure 4.5 – Consumed current signals (A) obtained from the current sensor circuit with *SpastiMed* applied on "Subject A" upper limb mobilized at A) 45°/s, B) 90°/s. The horizontal axis is displaying the number of acquisitions which can be converted to time (s) by simply dividing by 100.

The small increase in resistance to passive mobilization that the limb expresses near the end of the range of motion is again visible in Figure 4.5, and so we conclude that it is a common effect found on upper limb muscles during passive extension movements. Very relevant to this device validation is the fact that, like expected from a spastic limb, the increase in movement velocity resulted in a clear increase in motor consumed current signal base level amplitude.

4.2 Signal analysis

To find a distinctive characteristic between the obtained signals in 4.1.1, 4.1.2 and 4.1.4, the signal was processed in MatLAB® with the "Fast Fourier Transform" (FFT) function available in MatLAB®'s function library. With this method, the signal is "converted" to its "fingerprint" in the frequency domain. The FFT of the extension movement signals done at 90°/s presented bigger differences, like expected from a velocity dependent effect. The FFT from the unloaded, healthy and spastic upper limb signals are presented in Figure 4.6. A), B) and C), respectively.

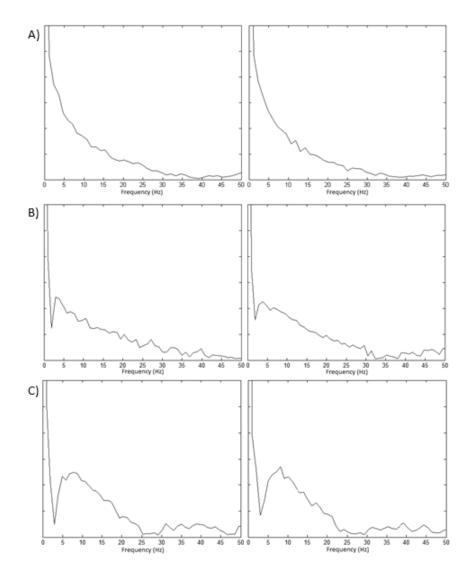


Figure 4.6 – FFT of two signals obtained during extension movements at the velocity of 90°/s with the device: A) unloaded. B) attached to a relaxed healthy upper limb. C) attached to "Subject A" upper limb.

The distinction between the different FFTs is notorious especially on the frequency ranges of 2 to 25Hz and 30 to 45 Hz. Additionally, the similarities observed between the two different signals acquired in each condition are evidence of result repeatability (Figure 4.6). Further studies with a statistically relevant number of subjects with different degrees of spasticity could possibly lead to a relation between subject spasticity grade and variations in specific frequency ranges. As an example, the "catch" is expected to be a high frequency phenomenon which we are lead to assume, from what is presented in Figure 4.6, that would be increasingly detected with the increase in spasticity degree.

5. CONCLUSIONS AND FUTURE DEVELOPMENTS

The accurate measurement of muscular spasticity has been an area of growing interest in the last few decades ^[16, 18, 26, 33, 34, 35, 36]. Consequently, many examples of tools to attempt spasticity assessment and quantification were developed ^[16, 26, 33, 34, 35, 36]. Some of those presented surprisingly good result, while some other, even with disappointing results, served as major contributions by pointing the right path to follow for upcoming attempts by other authors.

Table 5.1 – Achievement table for all of the relevant spasticity assessment methods presented in CHAPTER 1 regarding the 5 fundamental key-features on a spasticity assessment device/method. The symbols are explained as follow: ✓ - the method fully possesses the feature; ✓/× - the method partially possesses the feature or presents small flaws and/or limitations either for scientific or clinical use; × - the method does not possess the feature; ? – not enough information to conclude if the method possesses the feature or not.

Assessment Method	Feature					
	Easy and Fast Application	No need for a specialized operator	Portable	Operator independent results	Result Repeatability	Refs.
Clinical Scales	~	×	✓	×	√/×	
Electrophysiological Measurements	×	×	√/×	\checkmark	√/×	
Spasticity Measurement System	×	×	×	\checkmark	\checkmark	[17]
On-line spasticity measurement system	×	×	×	✓	✓	[15]
Portable System with Force Transducer	\checkmark	√/×	√	✓	√/×	[7]
Portable Spasticity Assessment Device	✓	√/×	~	\checkmark	\checkmark	[18]
Myotonometer™	×	×	√/x	\checkmark	×	[19, 20]
Biodex multi-joint System™	×	√/×	×	√	\checkmark	[10, 21]
Kincom 500H	×	√/×	×	\checkmark	\checkmark	[13, 22-24]
"The Glove"	\checkmark	√/×	~	×	√/×	[16]
SpastiMed	√/×	\checkmark	~	\checkmark	?	

To organize all the information about the methods, tools and devices developed to assess and quantify spasticity presented in Chapter 1, a table of key-feature achievements is presented in Table 5.1. In the bottom of that table, *SpastiMed* was scored based on the conclusions presented in Chapter 4.

To conclude, the obtained prototype is capable of inducing movements at any fixed and controlled velocity inside a tested range of 25°/s to 90°/s. It has a safe range of motion of 180° (Figure 2.15) making it usable for either right or left upper limbs. The software automatically detects if the device is being used on a right or left arm depending on the starting and stopping angles defined through the calibration phase and adapts its actuation accordingly. Finally, the data obtained from the Consumed Current and Angular Position sensors achieved a valuable very low level of noise coupled with a high degree of sensitivity. These facts dramatically contribute to the expectations deposited in this device. Based on these significantly relevant characteristics and all the results previously presented, we can affirm that the developed device has undeniable potential to detect spasticity and that it can possibly quantify it.

5.1 Prototype Improvements

During the construction and testing of this prototype many points of improvement were detected from which the most relevant ones are presented next.

Hardware improvements:

During some concept design modifications previously mentioned, the team had no choice but to supply the motor with a voltage value bellow the one recommended by the manufacturer ^[45]. The smallest velocity attainable (25°/s) was higher than the team intended it to be in concept (5°/s), but even in such conditions, the referred under-voltage supply, cause the motor maximum torque output to be undesirably low and sometimes unable to start the movement even on spastic subjects with MAS medium grades of spasticity. To contour that problem the movement at 25°/s was sometimes aided and when done so, the signal obtained at those small velocities was not considered or used to take any of the before mentioned conclusions. For all these combined reasons, a stronger, smaller and lighter motor with a higher torque at lower rotation speed would certainly improve the results quality and make the device easier to use.

The solution used to attach the device on a subject arm is one of the hardware parts that could be considerably improved to attain better results and more comfort to the subjects during the assessment routine. One suggestion is to create some "attaching solution" that could also serve as an auxiliary tool for upper limb sustentation like the one in Figure 5.1 and Figure 5.2. The sustentation could not only result in a more pleasant assessment routine but also produce more controlled results.



Figure 5.1 – Custom made upper limb sustentation tool used in *Centro de Medicina e Reabilitação de Alcoitão* to nullify the effect of gravity in the rehabilitation of some upper limb movements.



Figure 5.2 – Custom made upper limb sustentation tool used in *Centro de Medicina e Reabilitação de Alcoitão* with an upper limb suspended on it.

In the complete angular range of motion, the metallic arm presented some regions with considerably higher friction which could be removed or somehow balanced out to obtain a smoother and closer to inexistent friction profile during the entire range of motion.

Software improvements:

The interface developed in LabVIEW®, in its final state, was a stable and effective control graphical interface with an intuitive data display. However, one very relevant matter that should be addressed is to revise the save data mechanism to be simpler and less prone to human failure. One important matter in this field would be to create a data pre-treatment algorithm to avoid saving a lot of information with no practical use in spasticity quantification or any other type of muscular evaluation.

A more accurate velocity control algorithm would result in more uniformity in the produced results as sometimes, due to a very sudden increase of resistance (i.e. "catch" phenomenon) coupled with a "slow" device response, produces a movement which duration is bigger than expected, considering the defined movement velocity.

5.2 Future Perspectives

My suggestions on future developments to the *SpastiMed* device are: to replace the RS232-USB communication cables by wireless communication (Bluetooth or Wi-Fi); to replace the use of a personal computer by the use of a Tablet Computer and its touchpad to obtain a more "user friendly" and attractive graphical UI; to replace the Voltage Regulator, DAC, Current Regulator and Motor Driver circuits built specifically to *SpastiMed* by similar ones with smaller dimensions available in the market either in Printed Circuit Board (PCB) or IC format; to rebuild the angular position sensor circuit which presented some component heating problems in the Current Regulator circuit and finally, to create a good looking enclosure for all the electronics.

Finally, the safety features and mechanisms should be of primary importance as soon as the device proves that it can correctly quantify spasticity. For that matter, one relevant fact is that in the early stages of the software development the actuation of 4 safety switches were implemented and left dormant both the microcontroller code and the LabVIEW® interface code. For that reason, they can be used in further safety solutions which can be created in further developments.

The next step on the *SpastiMed* device development is to collect a big amount of data from a big number of spastic subjects previously evaluated with MAS and MTS (as a reference) and then study those results to obtain a biomechanical or mathematical model that can automatically quantify spasticity through the data obtained with this prototype. After that, *SpastiMed* should be scientifically validated by comparing its results with the "gold-standards" results like the ones obtained through MAS and MTS.

Based on its potential, other types of use for this device should be considered and explored.

To conclude, *SpastiMed* could turn into a valuable muscular tonus evaluation device, which could be of enormous use in spasticity quantification especially because of its undeniable operator independency and its tight control over the relevant examination conditions (velocity control, angular position monitoring, etc.). Even though this device will never be a method to quantify spasticity faster than the use of the MAS by a specialist, it outshines any clinical scale for being clearly more objective and for the fact that it requires no specialized operator and has no human dependence or tendency in the produced results.

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7. Appendices

Complete microcontroller code:

//* Includes: * #include "pic.h" #include "string.h" #include "stdio.h" #include "math.h" //* Variables initialization: //Motor State Variables: int DIREC = 1; //1 -> right | 0 -> left int RUNNING = 0; int INST_POS = 0; int $PREV_POS = 0;$ int HOLD_POS = 0; //Motor movement characteristics: int ANGVEL = 0; int ROM = 0; int STRT_POS = 0; int END_POS = 0; int SFTYn = 140; int SFTYp = 695; int mPOINT = 420; /*420 is the read for angle 0^{0*} / //Calibration Auxiliary Variables: int CALIB = 2; //2 - pre-calibration; 1 - calibration; 0 - assessment. int ang 1 = 0; int ang 2 = 0; int repos = 0;//Assessment Auxiliary Variables: int nCYCLES = 3; int WAIT = 7888; //2s wait. int WAITFLAG = 0; int ASSESS = 0; //Received Text Memory: char cmpstr[2]; //Time cycle counter: int CTR = 0; int CTR2 = 0;int CTR3 = 0: int CTR4 = 0; int LCTR = 39; // corresponds to 0.01s || LCTR = 1972 corresponds to a reading every 0.5s. int LCTR2 = 195; // (LCTR * 5) number of steps in between every velocity check step. //Angular Sensor Calibration constant: //* Macro Definition: #define RELAY1 RC0 #define RELAY2 RC1

```
#define RIGHT
                                  RELAY1 = 0; RELAY2 = 1; RUNNING = 1;
#define LEFT
                                  RELAY1 = 1; RELAY2 = 0; RUNNING = 1;
#define STOP
                                  RELAY1 = 0; RELAY2 = 0; RUNNING = 0;
#define PATBTON
                                          !RB0 //Constructed button circuit works as a pull up voltage
button instead of the common pull down ones.
#define CLIBTON
                                          RB1
#define SAFE1
                                  RB4
#define SAFE2
                                  RB5
#define BLINK
                                  RC3
//The only thing "hardcoded" is the analogic ports reading commands.
//* Received Text interpretation function:
//****
void computersaid(void)
{
  //Calibration commands:
                                                                                    (cmpstr=='C*')
        if(cmpstr[0]=='C' && cmpstr[1]=='0')
        {
                 ANGVEL=5;
                cmpstr[1]='a'; //clears memo and avoids repitition of this command unless if it is rewritten.
                //Calibration Stage Flags:
                CALIB=1;
                ang1=1; //Flags that Calibration and assessment of the first angle is on the go.
                ang2=1; //Flags that Calibration and assessment of the second angle is on the go.
                DIREC=1;
                 RIGHT:
        }
        //Computer sets Angular velocity:
                                                                   (cmpstr=='A*')
        else if (cmpstr[0]=='A' && cmpstr[1]!=ANGVEL)
        {
                 ANGVEL=cmpstr[1];
                 PORTD=(ANGVEL*2);
        }
        //Computer sets the number of assessment cycles:(cmpstr=='N*')
        else if (cmpstr[0]=='N')
        {
                nCYCLES=cmpstr[1];
        }
        //Computer sets the direction of movement:
                                                           (cmpstr=='D*')
        else if (cmpstr[0]=='D')
        {
                if(cmpstr[1]=='D') {DIREC=1;} //Right
                 else if(cmpstr[1]=='E') {DIREC=0;} //Left
        }
        //Computer orders motor to move or stop:
                                                           (cmpstr=='M*')
        else if (cmpstr[0]=='M')
        {
                if (RUNNING==0 && cmpstr[1]=='1') //starts motor;
                {
                         cmpstr[1]='a'; //clears the memo preventing the motor from restarting after shut
down and before a new starting order is sent.
                         if (DIREC==1) { RIGHT; }
                         else { LEFT; }
                }
                 else if (cmpstr[1]=='0') //stops motor;
                 {
```

```
cmpstr[1]='b'; //clears the memo.
                     STOP;
                     TXREG='E';
                     while(TRMT==0) {}
                     TXREG='N';
                     while(TRMT==0) {}
              }
       }
       //Computer orders the system to do the Assessment Routine:
       else if (cmpstr[0]=='E' && cmpstr[1]=='0' && CALIB==0)
       {
              cmpstr[1]='b';
              if (DIREC==1) { ASSESS=1; RIGHT; }
              else { ASSESS=1; LEFT; }
       }
}
//* Interrupt handler:
void interrupt interrupt_handler(void)
{
       if(T0IF)
       {
              TOIF = 0;
              CTR++;
              CTR2++;
              if (WAITFLAG==1) { CTR3++; }
              CTR4++;
              if (CTR4>1971) { CTR4 = 0; BLINK=!BLINK; }
       }
       if (RCIF==1)
       {
              RCIF=0;
              cmpstr[0]=cmpstr[1];
              cmpstr[1]=RCREG;
              computersaid();
       }
}
//* ADC Reading and Sending by USART:
                                   *
void read_adc(void)
{
       //Reads RA1 - motor current
       ADCON0=0x49;
       int count = 0;
       while(count<25) {count++;}
       ADCON0=0x4D;
       while(ADCON0==0x4D) {}
       int mine1 = ADRESH;
       int mine2 = ADRESL;
       if (CALIB!=1)
       {
              //Sends the reading:
              while(TRMT==0) {}
              TXREG='I';
              while(TRMT==0) {}
              TXREG=mine1;
              while(TRMT==0) {}
```

```
TXREG=mine2;
             while(TRMT==0) {}
      }
       //Reads RA3 - angular position
       ADCON0=0x59;
       count = 0;
       while(count<25) {count++;}
       ADCON0=0x5D;
       while(ADCON0==0x5D) {}
       int mine1 = ADRESH;
       int mine2 = ADRESL;
       HOLD_POS = 255*ADRESH + ADRESL;
       if (CALIB!=1)
       {
             //Sends the reading:
             while(TRMT==0) {}
             TXREG='P';
             while(TRMT==0) {}
             TXREG=mine1;
             while(TRMT==0) {}
             TXREG=mine2;
             while(TRMT==0) {}
      }
}
//* Regular Button push function:
                              *
                        *****
//***
void buttonpush(char ch)
{
       if (CALIB==0)
       {
             if (RUNNING==1)
             {
                    TXREG='S';
                    while(TRMT==0) {}
                    TXRÈG=ch;
                    while(TRMT==0) {}
             STOP;
             TXREG='E';
             while(TRMT==0) {}
             TXRÈG='N';
             while(TRMT==0) {}
      }
}
//****
void calib_button (void)
{
       if(ang1==1 && ang2==1)
       {
             ADCON0=0x59;
             int count = 0:
             while(count<25) {count++;}
             ADCON0=0x5D;
             while(ADCON0==0x5D) {}
             int mine1 = ADRESH;
```

```
int mine2 = ADRESL;
        //Flags the sending of the first calibration angle
        while(TRMT==0) {}
        TXREG='F';
        while(TRMT==0) {}
        TXRÈG='A':
        //and then sends it
        while(TRMT==0) {}
        TXREG=mine1;
        while(TRMT==0) {}
        TXREG=mine2;
        while(TRMT==0) {}
        STRT_POS= mine1*255 + mine2;
        ang1=0;
        STOP:
        TXREG='E';
        while(TRMT==0) {}
        TXREG='N';
        while(TRMT==0) {}
        DIREC=0;
}
else if(ang1==0 && ang2==1 && RUNNING==0)
{
        //Flags that the motor is allowed to proceed
        while(TRMT==0) {}
        TXREG='F';
        while(TRMT==0) {}
        TXREG='C';
}
else if(ang1==0 && ang2==1 && RUNNING==1)
{
        ADCON0=0x59;
        int count = 0;
        while(count<25) {count++;}
        ADCON0=0x5D;
        while(ADCON0==0x5D) {}
        int mine1 = ADRESH;
        int mine2 = ADRESL;
        //Flags the sending of the second calibration angle
        while(TRMT==0) {}
        TXRÈG='F';
        while(TRMT==0) {}
        TXREG='B';
        //and then sends it
        while(TRMT==0) {}
        TXREG=mine1;
        while(TRMT==0) {}
        TXREG=mine2;
        while(TRMT==0) {}
        END_POS= mine1*255 + mine2;
        ang2=0;
        CALIB=0;
        STOP:
        TXREG='E':
        while(TRMT==0) {}
        TXREG='N';
        while(TRMT==0) {}
        DIREC=1;
        repos=1;
        int midle = 0;
        CLRWDT();
```

```
midle = (END_POS+STRT_POS)/2;
                //Few resets for a correct working of the system:
                CTR2=0:
                INST_POS=0;
                read_adc();
                if (midle > mPOINT) /*430 is the read for angle 0°*/
                {
                        CLRWDT();
                        RIGHT;
                        END_POS=END_POS+10;
                        STRT_POS=STRT_POS-10;
                }
                else
                {
                        CLRWDT();
                        RIGHT;
                        int aux = END_POS;
                        END_POS=STRT_POS+10;
                        STRT_POS=aux-10;
                }
       }
}
//* Velocity Control:
*****
void vel_ctrl(void)
{
        CLRWDT();
        double vel;
        vel = 0;
        vel = INST_POS - PREV_POS; // Delta ADC
        vel = ASC*vel; // ADC to ° (grades)
        vel = vel/(LCTR2); //step1
        vel = vel*1972*2; //step2 conv. to %
        //absolute value step:
        if (vel < 0) { vel = - vel; }
        if (vel > 2) {
                if (vel > (ANGVEL + 20) || vel < (ANGVEL - 20))
                {
                        //bluky velocity adjustments:
                        if (vel > ANGVEL)
                        {
                                if (PORTD>25) { PORTD = PORTD - 25; } // 25 is an arbitrary value.
might need to be improoved trough adjustment
                        }
                        else if (vel < ANGVEL)
                        {
                                if (PORTD<230) { PORTD = PORTD + 25; } // 25 is an arbitrary value.
might need to be improoved trough adjustment
                        }
                }
                else
                {
                        //slight velocity adjusments:
                        if (vel > (ANGVEL + 2))
                        {
                                if (PORTD>5) { PORTD = PORTD - 5; } // 5 is an arbitrary value. might
need to be improoved trough adjustment
                        else if (vel < (ANGVEL - 2) ) //1.5 -> delta theta of 2º
```

```
{
                                 if (PORTD<250) { PORTD = PORTD + 5; } // 5 is an arbitrary value.
might need to be improoved trough adjustment
                         }
                }
        }
}
//* Main Program:
                                      *
.vial
//******
                                        ******
                                   ******
void main(void)
{
        T0IF=0;
        T0IE=1;
        PEIE=1;
        RCIE=1; //receiving is enabled.
        GIE=1; //global interrupts are enabled.
        OPTION_REG=0x08;
        //ports configs:
        //External input/outputs Port:
        TRISB=0xFF;
        PORTB=0x04;
        //PORTC config:
        TRISC=0xF0;
        RC0=0;
        RC1=0;
        //DAC Port:
        TRISD=0x00;
        PORTD=0x00;
        TXSTA=0x26; //transmiting config: asynchronous mode at high speed.
        RCSTA=0x90; //receiving config
        //ADC config:
        ADCON1=0x84; //right justified; ports RA0, RA1 and RA3 are analog;
        ADCON0=0x49; //fosc/8; reads port RA1.
        SPBRG=0x0C:
        //local aux variables:
        int push = 0;
        int cycles = 0;
        do
        {
                CLRWDT();
                //These 2 safe switches are not used but are programed for future use in a mechanical
                //safety system.
                //safes (1 and 2):
                /* if (SAFE1==0 && push==0) //safe-1 = RB4
                {
                         push=1;
                         buttonpush('1');
                }
                else if (SAFE2==0 && push==0) //safe-2 = RB5
                {
                         push=1;
                         buttonpush('2');
                } */
```

//Push button Safes (3 and 4):

```
if (PATBTON==0 && push==0) //safe-3 = RB0 - patient safe/calib button.
                {
                        push=1;
                        if (CALIB==1)
                        {
                                 calib_button();
                        }
                        else if (CALIB==0) { buttonpush('3'); }
                }
                else if (CLIBTON==0 && push==0) //safe-4 = RB1 - physician safe button.
                {
                        push=1;
                        if (CALIB==1)
                        {
                                if (RUNNING==1) { STOP; }
                                else
                                {
                                         if (DIREC==1) { RIGHT; }
                                         else { LEFT; }
                                }
                        }
                        else if (CALIB==0) { buttonpush('4'); }
                }
                //push reset:
                if (SAFE1==1 && SAFE2==1 && PATBTON==1 && CLIBTON==1 && push==1)
                {
                        push=0;
                }
                //Hardware Safety:
                if (CALIB>0)
                {
                        if ((HOLD_POS<SFTYn && RELAY1==1) || (HOLD_POS>SFTYp &&
RELAY2==1))
                        {
                                 STOP;
                                 TXREG='E';
                                while(TRMT==0) {}
                                 TXREG='N';
                                 while(TRMT==0) {}
                        }
                }
                //automated motion after calibration is finished.
                else if (CALIB==0)
                {
                        if (STRT_POS>END_POS) //left arm
                        {
                                 //ROM safety AND Repositiong
                                if ((HOLD_POS<END_POS && RELAY1==1) ||
(HOLD_POS>STRT_POS && RELAY2==1))
                                 {
                                         repos=0;
                                         STOP:
                                         if (ASSESS==0)
                                         {
                                                 TXREG='E';
                                                 while(TRMT==0) {}
                                                 TXREG='N';
                                                 while(TRMT==0) {}
                                         if (DIREC==1) { DIREC=0; }
                                         else { DIREC=1; }
                                }
```

```
//Timer for small pause in between movements.
```

```
if ((HOLD_POS<(END_POS+10)) && ASSESS==1 && RELAY2==0)
                               {
                                       WAITFLAG=1;
                                       if (CTR3>WAIT) { CTR3=0; WAITFLAG=0; RIGHT; }
                               }
                               else if ((HOLD_POS>(STRT_POS-10)) && ASSESS==1 &&
RELAY1 == 0)
                               {
                                       WAITFLAG=1;
                                       if (CTR3>WAIT) { CTR3=0; WAITFLAG=0; LEFT; cycles++; }
                                       if (cycles==nCYCLES)
                                       {
                                              cycles=0;
                                              ASSESS=0;
                                              STOP;
                                              TXREG='C';
                                              while(TRMT==0) {}
                                              TXREG='Y';
                                              while(TRMT==0) {}
                                      }
                               }
                       }
                       else //right arm
                       {
                               //Repositioning.
                               if (repos==1 && HOLD_POS>STRT_POS)
                               {
                                       repos=0;
                                       STOP;
                                       TXREG='E';
                                       while(TRMT==0) {}
                                       TXREG='N';
                                       while(TRMT==0) {}
                               }
                               //ROM safety.
                               if ((HOLD_POS<STRT_POS && RELAY1==1) ||
(HOLD_POS>END_POS && RELAY2==1))
                               {
                                       STOP;
                                       if (DIREC==1) { DIREC=0; }
                                       else { DIREC=1; }
                               }
                               if ((HOLD_POS>(END_POS-10)) && ASSESS==1 && RELAY1==0)
                               {
                                       WAITFLAG=1;
                                       if (CTR3>WAIT) { CTR3=0; WAITFLAG=0; LEFT; }
                               }
                               else if ((HOLD_POS<(STRT_POS+10)) && ASSESS==1 &&
RELAY2==0)
                               {
                                       WAITFLAG=1;
                                       if (CTR3>WAIT) { CTR3=0; WAITFLAG=0; RIGHT; cycles++;
}
                                       if (cycles==nCYCLES)
                                       {
                                              cycles=0;
                                              ASSESS=0;
                                              STOP;
                                              TXREG='C';
                                              while(TRMT==0) {}
                                              TXREG='Y';
                                              while(TRMT==0) {}
                                      }
                               }
                       }
```

63

}