DESIGN, DEVELOPMENT, AND VERIFICATION OF AN AUTOMATED PAIN MEASUREMENT DEVICE

by

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Design, Development, and Verification of an Automated Pain Measurement Device

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Abstract

The focus of this study is the redesign, development, fabrication, and initial evaluation of an automated pain measurement device. The redesign will focus on improving the original Computer Controlled Pressure Algometer, designed by Zimkowski in 2010. Pain measurement is very difficult to accurately accomplish, and current methods are limited to subjective techniques such as pain rating scales and handheld algometry. These subjective methods of pain measurement have many shortcomings that render them inadequate at reliably assessing an individual's pain. Large variability has been shown with these testing methods, which can be prone to error due to test administrator, environmental and psychological conditions, and individual patient factors. This study hypothesizes that by creating an automated device, these sources of variability may be minimized. The improved automated pain measurement device enhances usability, functionality, and aesthetics compared to the original device – these improvements will enable more practical clinical studies. Furthermore, the addition of biometrics could introduce an objective measure of pain. By creating an automated pain measurement device with integrated biometrics, both subjective and objective pain response data could be collected for each patient, eventually establishing a personalized pain scale for each patient. These personalized pain scales could then be used to better assess, diagnose, and treat ailments which cause chronic and acute pain.

Acknowledgements

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The support and encouragement from my family have made this endeavor possible. They have always encouraged me to pursue my dreams and believed that I would achieve them, and for that I am so grateful.

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Glossary

Term	Definition
Algometer	A device used to measure sensitivity to an applied pain stimulus
Pressure Algometer	An algometer that applies pressure as the applied pain stimulus
Pressure Pain Threshold (PPT)	The moment a patient begins to perceive pain and not just pressure
Pressure Pain Tolerance (PPTol)	The moment the applied pain is perceived to be intolerable
AmP-MeD	The Automated Pain Measurement Device developed and discussed in this paper
CCPA	The Computer Controlled Pressure Algometer developed by M. Zimkowski in 2010

Chapter 1

Introduction

Pain is extremely difficult to accurately measure, as is evidenced by the lack of sufficient pain measurement tools used today. The subjective nature of pain poses the primary challenge in pain measurement, as subjective responses vary depending on the patient and how he/she reacts to environmental, psychological, physical, and physiological influences.

Current pain measurement methods include visual, numerical, verbal, and behavioral pain rating scales as well as the use of handheld algometers. Typically, a physician will use a pain rating scale to assess a patient's pain level (see Section 2.1 Current Pain Measurement Methods for an outline of how each pain rating scale is used). The use of algometers is restricted mostly to research but does exist sparingly in clinics. While pressure algometers present an advantage over pain rating scales since they enable a clinician to establish a more precise pain scale of an individual patient, they have significant shortcomings as well.

The most noteworthy shortcoming of existing pain measurement techniques is that both pain rating scales and pressure algometers are limited to the measurement of a patient's subjective response to pain and do not allow any objective measures. This limits the clinician to interpreting the patient's mental response to the pain stimulus (either clinically applied pain or accidental acute or chronic pain) rather than his/her bodily response.

Pain measurement techniques also lack accuracy, precision, and repeatability. Pain rating scales have as few as four markers for patients to choose from, which can result in very

imprecise pain perception approximations. Pressure algometers increase the precision of pain measurement by allowing the patient to indicate his/her threshold and tolerance at any time. However, the clinician is then responsible for quickly stopping the pain stimulus. The delay between patient indication and test administrator recognition can cause vast discrepancies in the load readings provided by the pressure algometers. The accuracy, precision, and repeatability of handheld pressure algometers can also be compromised by test administrator techniques such as angle and rate of pressure application.

Finally, it is evident that environment can play a large role in pain perception. A human test administrator can influence a patient's perception, and the use of multiple clinicians on one patient can introduce large variability. For example, if a unique clinician visits a patient every hour to assess his/her pain, the patient may respond differently to each clinician. This shortcoming is applicable to both pain rating scales as well as handheld pressure algometer readings.

To improve upon the shortcomings exhibited by current pain measurement techniques, an automated pressure algometer has been developed. It is hypothesized that an automated pressure algometer maintains the benefits of a handheld algometer (creating an individual patient pain scale by recording threshold and tolerance) while introducing novel pain measurement techniques. The automated pressure algometer developed will integrate the patient's subjective pain response (threshold and tolerance) with objective pain response (physiological signals linked to pain). The combination of both subjective and objective data paired with the ability to consistently test patients using the same method and device

(thus minimizing variability caused by environmental discrepancies) could be a significant advance in pain measurement.

Improvements in pain measurement could lead to exciting clinical benefits such as improved pain diagnosis, more accurate pain medication dosing, pain management and treatment, and measurement of chronic and acute pain for both communicative and non-communicative patients alike.

An individual pain scale could be developed per-patient and measured in the clinic at the same time as other vital signs such as blood pressure and pulse. This individual pain scale would facilitate the dosing of pain medications in the future for the patient, improve the assessment of pain, and quantify the success of treatments prescribed to alleviate said pain. In a clinical sense, an automated pressure algometer would improve clinicians' abilities to better treat patients – thus improving the quality of life of pain-sufferers around the world. In an academic sense, the use of this automated pressure algometer could enable accurate research of the relationship of psychological and physiological responses to pain. This understanding would be a significant advance in psychology, physiology, and medicine that could lead to exciting new frontiers.

Chapter 2

Background and Motivation

Pain is defined by the International Association for the Study of Pain as *an unpleasant sensory and emotional experience associated with actual or potential tissue damage* [1]. This *unpleasant sensory and emotional experience* is extremely difficult to measure, and presents a significant challenge to researchers and clinicians alike.

There are many contributing factors that render pain such a difficult entity to measure. Different patients perceive pain differently depending on race, sex, ethnicity, and between individuals [1]. Pain perception can furthermore depend on an individual's conditioning, personality, past experiences, present experiences, and training [1]. Additionally, patients express their pain perception differently through facial expressions, verbal communication, vocalization, and physical expression [2]. To add to the challenge, certain patients do not respond to pain normally (e.g. those that are critically ill, those with brain and spinal cord injuries, and those with mental illness) but the need to assess these patients' pain levels remains essential [3].

The difficulty of pain measurement is certainly an interesting challenge, but it is extremely important to pursue a solution. The Medical Expenditure Panel Survey of 2008 studied 100 million Americans, and determined that additional health care costs due to pain ranged from $261 to $300 billion in the USA, amounting to an average increase in healthcare cost per-person of 6.6%. These substantial costs are greater than the average costs due to heart disease, cancer, and diabetes [4]. Clearly the considerable cost of pain treatment and the

significant decrease of quality of life caused by inadequate pain treatment calls for a better method to measure and diagnose pain. Because of this clear need, the Joint Commission on Accreditation of Healthcare Organizations recognized pain as a fifth vital sign in addition to pulse, blood pressure, temperature, and respiration [5]. This recognition of the importance of pain further emphasizes the need to develop an adequate pain measurement technique.

2.1 Current Pain Measurement Methods

Multiple pain measurement techniques have been developed over the past decades, in addition to techniques that have been implemented for centuries. The most popular pain measurement techniques involve a clinician asking the patient to indicate his/her perception of the level of pain that he/she is experiencing – self reporting is still the "gold standard" of pain measurement according to the guidelines of the International Association for the Study of Pain [6]. These types of pain measurement are called pain rating scales, and include the Verbal Rating Scale, Visual Analog Scale, Numeric Rating Scale, Faces Rating Scale, and the Oswestry Disability Index. In cases where the patient is unable to reliably report his/her own pain, the Behavioral Pain Scale is utilized [3]. In research applications and in some clinics, the Quantitative Sensory Testing Method as well as handheld algometers are used to assess a patient's pain threshold and/or tolerance.

While these pain measurement techniques do provide useful information to clinicians, they have significant limitations. All of these current pain measurement techniques rely completely on patient feedback. They are thus limited to subjective interpretation of pain; this interpretation can be influenced by many factors and is likely not the best option for assessing pain responses in patients.

2.1.1 Verbal Rating Scale

The Verbal Rating Scale provides only five points for a patient to select to describe his/her pain level – no pain, mild, moderate, severe, or pain as bad as it could be (see Figure 1). This scale is simple to use, but does not provide adequate resolution. Although patients may make a mark anywhere on the line, 73% chose one of the defined positions [1].

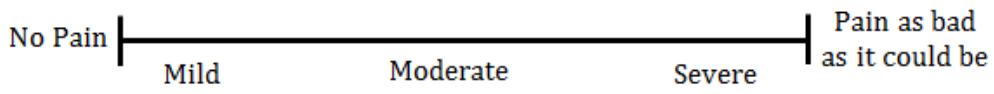

Figure 1: Verbal Rating Scale

2.1.2 Visual Analog Scale

In order to improve upon the resolution of the Verbal Rating Scale, the Visual Analog Scale was developed (see Figure 2). The "mild", "moderate", and "severe" markers are removed, allowing patients to choose any point on the line. While this method does increase the amount of choices given to the patient, it does not successfully provide a measurable marker for the clinician. Sometimes, however, clinicians will measure the length of the line and the location of the patient-indicated marker to determine a numerical assessment [1].

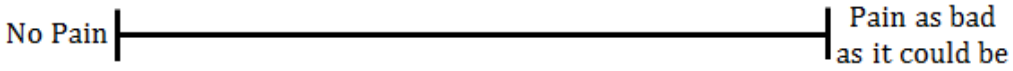

Figure 2: Visual Analog Scale

2.1.3 Numeric Rating Scale

The Numeric Rating Scale builds on the Visual Analog Scale by adding numbers zero through ten on a line to indicate pain level choices for a patient (see Figure 3). This scale is a slight variation on the Visual Analog Scale and Verbal Rating Scale, and does not present significant advantages or disadvantages over either. Some sources indicate that associating a number to an abstract idea such as pain is not a logical method, as the left brain analyzes the numbers while the right brain analyzes the pain sensation and perception.

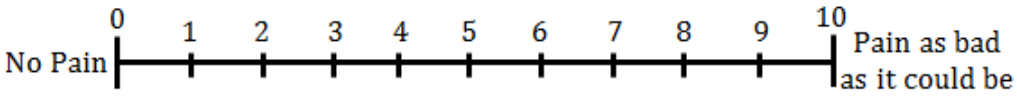

Figure 3: Numeric Rating Scale

2.1.4 Faces Rating Scale

The Faces Rating Scale was developed for the self-assessment of pain severity in children, but it is also used widely on the elderly [7]. The clinician describes each level of pain to the patient and then the patient indicates which level of pain they are experiencing via the pain scale pictured in Figure 4. The Faces Rating Scale presents an advantage over the other methods discussed for children and cognitively impaired adults, since they are able to relate more easily to graphical descriptors than to number or word descriptors. Again, with only six choices to describe their pain, a patient is limited and the resolution of the feedback is greatly limited.

Figure 4: Faces Rating Scale [A]

2.1.5 Oswestry Disability Index

The Oswestry Disability Index is a very popular method for pain assessment. It uses a series of questions to rank a patient from zero to one-hundred (higher scores indicate greater disability) [8]. This questionnaire method of testing is more thorough than the methods previously outlined, but it still limited to subjective feedback from patients. Version 2 of the Oswestry Disability Index can be found in the appendix, Section Appendix 11.1 Oswestry Disability Index.

2.1.6 Behavioral Pain Scale

In order to assess the need to measure pain in patients who are unable to communicate their pain effectively, the Behavioral Pain Scale was developed [3]. To use this pain assessment method, the clinician observes the patient for one minute, recording pain markers such as facial expression, upper limb movements, and compliance with mechanical ventilation (if applicable); each subscale is scored from 1 (no response) to 5 (full response) [10]. An example of a clinician evaluation sheet used with the Behavioral Pain Scale is shown in Figure 5.

Characteristic	Evaluate	Points
Alertness	Deeply asleep	1
	Lightly asleep	2
	Drowsy	3
	Awake and alert	4
	Hyper-alert	5
Agitation	Calm	1
	Slightly anxious	2
	Anxious	3
	Very anxious	4
	Panicky	5
Respiratory response	No coughing	1
	Spontaneous respiration with little response to ventilation	2
	Occasional coughing with little resistance to the ventilator	3
	Active breathing against the ventilator	4
	Actively fighting the ventilator and coughing	1
Physical movements	None	1
	Occasional, slight movements	2
	Frequent, slight movements	3
	Vigorous movements of extremities only	4
	Vigorous movements of extremities, torso, and head	5
Blood pressure (mean)	Below baseline	1
	Normal	2
	Infrequent elevations of 15% or more	3
	Frequent elevations of 15% or more	4
	Sustained elevation greater than or equal to 15%	5
Heart rate	Below baseline	1
	Normal	2
	Infrequent elevations of 15% or more	3
	Frequent elevations of 15% or more	4
	Sustained elevation greater than or equal to 15%	5
Muscle tone	Relaxed/none	1
	Reduced muscle tone	2
	Normal muscle tone	3
	Increased tone/flexion-fingers/toes	4
	Extreme rigidity/flexion-fingers/toes	5
Facial tension	Facial muscles relaxed	1
	Normal tone	2
	Some tension	3
	Full facial tension	4
	Facial grimacing	5

Figure 5: Behavioral Pain Scale [B]

2.1.7 Quantitative Sensory Testing Method

The Quantitative Sensory Testing Method (QST) was developed to assess clinical pain by defining the stimulus type and the response. This test is psychophysical and typically implements a thermal pain stimulus, but other types of pain stimulus such as pressure, pin pricks, and electrical signals are used as well. With a gradual increase of the stimulus, the

patient can indicate his/her pain threshold and pain tolerance [11]. With these measures, a more quantifiable indication of perceived pain is available.

A result of the QST methods, the introduction of pain threshold and pain tolerance was an important advancement in pain measurement. Pressure Pain Threshold (PPT) and Pressure Pain Tolerance (PPTol) have been used to collect meaningful data from pain patients in many studies. The data collected has been shown to be reliable and has provided important clinical value. However, one criticism of PPT and PPTol measurements is that they are not valid unless the patient is fully cooperative [12]. These important markers are used with pressure algometry, and will be discussed in depth in Section 2.2 Pressure Algometers.

2.2 Pressure Algometers

The pressure algometer was first developed by Keele and Fisher in 1954, and has been used widely in research since then. Preliminary research investigated standard values of pressure thresholds as well as their validity and reproducibility in healthy patients [13]. Subsequent studies have evaluated standard values of pressure pain threshold and/or pressure pain tolerances in healthy versus unwell patients [3], [7], [10]. Studies have also been conducted on the difference of pain response according to body location and body side [14], [15], [16]. The use of pressure algometers is mainly limited to a $1cm^2$ (and sometimes a $0.5cm^2$) rubber tipped probe. The pressure application tip makes perpendicular contact with the skin and applies pressure to induce deep muscle pain in the subject [17].

As the body of research on pressure algometers has grown, these devices have also been improved and evaluated. Some studies evaluate the variability of patient response of pressure threshold and/or tolerances over multiple trials in the same location – some of these studies have found minimal variability while others have found significant differences between tests [17]. Other studies have evaluated the efficacy of pressure algometers by using them in conjunction with traditional pain measurement techniques such as the techniques described in Section 2.1 Current Pain Measurement Methods [17].

Many of these studies acknowledge the possibility that test administrator differences introduce variability in results [18], [19], [20], [21]. Few sources indicate that reasonable reliability may be maintained between test administrators after sufficient training, although they acknowledge that if multiple test administrators are used, complete randomization within testing should be used [19]. This evidence supporting inter-test-administrator differences in pressure pain thresholds and/or tolerances supports the hypothesis presented in this thesis that an automated pressure algometer could greatly reduce the variability introduced by multiple test administrators.

2.2.1 Market Algometers

Wagner Instruments is a principal provider of both digital and analog algometers, along with Fisher and US Neurologicals. Figure 6 through Figure 11 show typical handheld algometers on the market today.

Figure 6: Wagner "Pain Test" FPK Algometer, *Force Dial [C]*

Figure 7: Wagner "Pain Test" FPX Algometer, *Force Ten [C]*

Figure 8: Wagner "Pain Test" FPIX Algometer, *Force One [C]*

Figure 9: Somedic Algometer [D]

Figure 10: JTech Commander Algometer [E]

Figure 11: JTech Tracker Freedom Wireless Algometry Device [E]

The Wagner algometers pictured (as well as the Somedic Algometer) utilize both digital and analog methods of force sensing. The test administrator uses the handheld algometer to apply pressure to the patient, who then verbally marks his/her pressure pain threshold and/or tolerance. Upon the patient's notification, the test administrator then "immediately" notes the pressure reached at the point of notification and releases pressure. The *Force One* algometer is capable of storing the maximum force read, and thus the test administrator does not have to note this force until the test is complete. The Somedic Algometer offers pressure application rates as an additional metric.

The JTech Commander operates similarly to the Wagner and Somedic Algometers, but incorporates its own data analysis tool which facilitates statistical analysis of tests. The most advanced option listed on the market is arguably the JTech Tracker Freedom Wireless Algometer. This tool automatically collects data via wireless communication with a personal computer. To address the variability introduced due to test administrator inconsistency of pressure application rate, the software displays "pressure pacer" technology to assist the test administrator in using constant pressure application rates. Furthermore, since the software is displayed real time on a personal computer, the patient can directly press "enter" to indicate that he/she has reached the pain threshold and/or tolerance.

While these options are widely used in clinics and generally accepted methods of pain measurement, they still have major shortcomings. Even the JTech Tracker Freedom Wireless Algometer which takes measures to resolve identified issues lacks a true solution to test administrator discrepancy and inaccuracy in application rates.

2.2.2 Devices Developed for Research Purposes

The literature provides an interesting and diverse basis of novel pain measurement techniques. Xiong *et al.* developed a device to study measurement reliabilities associated with pressure thresholds while determining the effects of stimulus characteristics such as stimulus area and indentation speed [22]. They also evaluated how the mechanical properties of the tissue tested (in this case, the foot) is important for measurement of pain threshold [23]. Extensive studies have been documented which investigate test-retest repeatability and/or reliability of pressure algometers [24], [25], [26], [27], [28], [29], [30]. Furthermore, studies have been developed to better understand the relationship between pain responses in tender versus non-tender areas of the body, between different locations in the body, and between patients suffering from chronic pain versus healthy patients [27], [31], [32], [33], [34], [35], [36], [37].

Perhaps the most relevant to this research is an experiment comparing an automated pressure algometer to a handheld algometer [38]. Koo *et al.* developed a computer controlled pressure algometer and tested it in comparison with a handheld algometer to determine reliability, repeatability, and sensitivity. The device used is pictured in Figure 12. The group investigated the hypothesis that an automated algometer could reduce the effects of operator reaction time, operator anticipation, indenter alignment error, and variation in indentation rate on pain-pressure threshold [38]. Surprisingly, the group discovered more reliable results with the handheld algometer despite the advantages offered by the automated algometer. They hypothesize two reasons for the unexpected results: that the loading rate and loading mode between the two algometers differed in their experiment, and that deformation control and load control are not equivalent.

Furthermore, they acknowledge that "load-controlled indentation protocol appears to be better than deformation-controlled protocol for PPT measurements" [38].

Figure 12: Koo *et al.* Automated Deformation-Controlled Indentation Algometer – testing performed on *erector spinae* muscles

2.3 Limitations of Current Pain Measurement Techniques

As has been mentioned briefly, handheld algometers are prone to inconsistency and inaccuracy due to application rate, test administrator psychological effects, and other sources of error. Like pain rating scales, handheld algometers are easy to use, relatively inexpensive, and do not require extensive training or time to administer. However, the shortcomings shared by all current pain measurement techniques provide significant and noteworthy limitations to pain measurement and analysis.

2.3.1 Application Rate

Application rate is perhaps one of the dominating sources of error seen with handheld algometers. Research reports a large range of pressure application rates (normally between 0.05 to 20 N/s) [17]. Higher PPT scores are often correlated with higher application rates, since the patient has less time to react and thus a "false" or "exaggerated" PPT is recorded [17]. Handheld algometers offer little to no control over application rate. While some models like the JTech Tracker Freedom Wireless Algometer offer visual feedback to the test administrator, it is still largely dependent on administrator tendencies and training.

2.3.2 Test Administrator Psychological and Environmental Effects

Environmental, cultural, psychological, and emotional factors play significant roles in a patient's pain response. These factors are difficult to identify and even more difficult to measure. It is understood that pain responses differ between males and females, with males consistently reporting higher PPT values [39]. Research also acknowledges that "gender warrants much more thoughtful attention in healthcare and in pain research not as a demographic variable but as a factor that may significantly affect all aspects of clinical pain experience" [39]. Pain responses between men and women are not the only gender-related cause of discrepancy – interactions between male patients and female test administrators may result in skewed findings [18]. Furthermore, examiner expectancy of inflicted pain may significantly affect findings – Ohrbach *et al.* hypothesize that measurement order and knowledge of measurement site characteristics can influence obtained PPT measurements [18].

2.3.3 Other Sources of Error

It is widely acknowledged that test administrator training is essential to providing reliable and repeatable results [40]. While some research indicates that sufficient training yields reliable and repeatable results between test administrators, other research indicates that test administrator variability is significant [38]. These conflicting results may indicate that the specific test administrator may have more influence on repeatability and reliability than the effect of training on any individual. Furthermore, interactions between patients and test administrators may contribute to psychological influences on reported PPT or PPTol. Finally, habituation may play a large role in a patient's subjective response to pain, and many studies have documented the effects of repeated measurements of PPT and PPTol [41], [42], [43], [44].

2.4 Physiological Signals Correlated to Pain Response

Perhaps the most important shortcoming of current pain measurement techniques is that they lack a method to objectively quantify pain. Relying only on a patient's subjective response to pain introduces a number of psychological factors that are impossible to measure and control, and which may drastically influence his/her pain response.

In order to introduce an objective measure of pain, one may measure physiological signals that have been correlated with pain response via research. There are a number of physiological signals with documented relationships to pain – blood pressure, heart rate, skin impedance, pupil dilation, and respiratory rate to name a few.

2.4.1 Relationship between Blood Pressure and Pain Response

A direct correlation between blood pressure and pain response has been established in humans. Hypertension is linked to a decreased sensitivity to pain, and hypotension is linked to an increased sensitivity to pain [45]. Furthermore, systolic blood pressure may be inversely related to pain ratings in normotensive male patients [46]. Because of the established relationships between blood pressure and pain response, this physiological signal could be used to predict pain.

2.4.2 Heart Rate

The relationship between heightened states of arousal and sympathetic nervous system activity has been clearly documented and is well understood. Since the sympathetic and parasympathetic nervous systems control heart rate, it is obvious to assume that a pain stimulus (which raises arousal) would increase sympathetic nervous system action and thus increase heart rate. Tousignant-Laflamme and Marchand investigated this hypothesis and confirmed that a relationship exists between pain and heart rate variability in low back pain patients [47]. They also confirmed that heart rate increases as pain stimulus is applied and increased, but if the stimulus remains constant over time (approximately 30 seconds) the heart rate drops presumably to due to parasympathetic nervous system activity [47]. This research indicates that heart rate may be used to identify pain stimuli in patients, but only if the pain stimuli is increasing or recently begun.

2.4.3 Skin Impedance

Skin impedance is essentially the fall of resistance caused by sweat gland activity. Measurement of skin impedance is commonly used to measure peripheral sympathetic responses to stress and pain [8]. Fujita *et al.* observed a strong correlation of strain on a joint (pain stimulus) to decreased skin impedance proportional to baseline skin impedance [48].

2.4.4 Pupil Dilation

Bertrand *et al.* studied the relationship between pupil dilation, anxiety, and pain stimulation in ninety-six healthy patients. They found that there was a significant increase in pupil diameter upon pain stimulation, and that this increase was greater in patients who reported anxiety before testing, regardless of gender [49]. Pupil dilation may be an easy-to-measure physiological response to pain, and could be used to indicate an objective response to pain and to evaluate anxiety levels before pain stimulation.

2.4.5 Respiratory Rate

It is commonly assumed that respiratory rate increases with pain. This assumption is backed up in literature, but is not widely studied as it may be considered "obvious". Borgbjerg *et al.* determined that pain stimulation does act as a respiratory stimulant in humans [50]. Respiratory rate is easily monitored and could be an indicator of objective pain response in humans.

2.4.6 Body Mass

Although body mass is not a physiological signal, it has been shown to be an indicator of a patient's pain scores. Wood *et al.* reported that in a study of nearly 200 patients (1/3 of

whom were obese), the relationship between pain as a continuous variable and BMI approached significance (P=0.098) [45]. They found that the BMI of persons with lower pain scores was significantly different than those with higher pain scores [45]. This could mean the relationship of high BMI and increased pain level among patients with chronic pain could be an important indicator, along with the other physiological bio-indicators discussed above.

2.5 Towards an Ideal Pain Measurement Device

Current market algometers provide significant advantages when compared to traditional pain assessment techniques, and when used in conjunction with these techniques. They provide a quantifiable measure of pressure pain threshold (PPT) and pressure pain tolerance (PPTol). However, these systems are inherently reliant on subjective patient feedback and are susceptible to many sources of error such as application rate and angle, psychological effects, test-administrator variability and dependence on training, etc.

The ultimate pain measurement device would combine the strengths that currently exist in handheld pressure algometers and pain assessment techniques (*i.e.* easy, inexpensive, clinic-friendly, etc.) while eliminating or greatly reducing the downfalls of these devices.

First, the device should be automated to reduce the variability in application rate and angle performed by human test administrators. Application rates should be precisely controlled and monitored – both displacement/time and pressure/time are important markers and can influence a patient's response [38]. The slower the application rate, the more time the patient has to react, resulting in more sensitive and precise PPT and PPTol readings [17].

Furthermore, the automated control of pressure application creates a possibility to further study the relationship between perceived pain and pain application method. Pressure algometers are typically used with a ramped pressure/time application. An automated device could explore this relationship with other pressure/time application modes such as step functions, sine or square waves, etc. Relationships between perceived pain and application modality could potentially lead to a better understanding of pain.

If an understanding of the relationship between biometrics (blood pressure, heart rate, skin impedance, pupil dilation, or respiratory rate) and pain response was developed, a future automated algometer could rely solely on these inputs and require no subjective feedback from the patient. Therefore a pain scale per patient could be easily measured in conjunction with vital sign measurement.

The ultimate pain measurement device would successfully measure a personal pain scale per patient to determine that patient's response to pain stimulus. This personalized pain scale could be used to properly dose pain medications, aid in treatment options decision making (surgery versus therapy versus medication), and better diagnose ailments associated with pain. The advantages offered by an idealized pain measurement device would ultimately lead to an important increase in quality of life and quality of care for patients worldwide.

Chapter 3

Pain Measurement Device Design

3.1 Zimkowski CCPA

In 2010, Michael Zimkowski designed, developed, fabricated and evaluated an initial prototype of a computer-controlled pressure algometer (CCPA) [9]. The CCPA created was an important proof-of-concept that a computer controlled device could eliminate or greatly reduce the variability factors given to a hand-held device, thus improving sensitivity and reliability. In collaboration with Dr. Patel and Dr. Lindley (principal and co-investigators, respectively) the following specifications were outlined for the device: it must be at least as accurate as hand-held algometers but allow the integration of heart rate, blood pressure, and any other useful physiological measures. The device must also work seamlessly with QST and Numerical Rating Scale methods [8].

The final Zimkowski design incorporated a load frame, laptop computer and data acquisition, control box, air compressor, algometer actuator assembly, 24 Volt DC power supply, and a physiological data collection system as pictured in Figure 13. The load frame was made to be placed on a clinic bed with the patient's legs over the foam-padded base. The laptop computer was used as actuator control and data acquisition. The control box housed the pneumatic control mechanisms such as air regulators, release valves, etc. and was used in combination with a large industrial air compressor to power the pneumatic mechanism. The actuator assembly was custom built and housed on the top arm of the

load-frame. Physiological data was integrated from standard monitoring equipment to a DAQ which relayed the information to the laptop.

Figure 13: Zimkowski CCPA Design –load frame with patient control remote, physiological data monitoring equipment, laptop computer and control box. Photo omits air compressor and all electrical connections (wiring).

As reported in Zimkowski's thesis, the device was tested on human patients and displayed slightly lower and more variable PPT results as compared to the Wagner FPIX Digital Algometer. When tested on ten patients in the absence of physiological data integration, the CCPA recorded average threshold pressure as compared to the recorded PPT using the handheld Wagner device (summarized in Table 1).

Testing Phase	CCPA Results	Wagner Results
Open Loop Testing - PPT	4.42 ± 1.65 kg	6.20 ± 2.02 kg
Closed Loop Testing - PPT	3.90 ± 1.12 kg	4.50 ±1.04 kg

Table 1: CCPA versus Wagner ForceOneTM Results [8]

While the Zimkowski CCPA did provide useful clinical data and introduced the ability to correlate patient pain threshold and tolerance to physiological markers (blood pressure and heart rate), it did have significant shortcomings. Firstly, the patient and user-interfaces with the device were cumbersome and intimidating. The machine was not transportable or easily used in a clinical setting (weighing over 144 lbf). Setup and takedown were intricate processes and often required repair before and between tests.

Secondly, the device had some mechanical issues. In using pneumatically powered actuation, the CCPA sacrificed the ability to measure application tip displacement – an important measure correlated with patient pain response [38]. The load cell used did not provide adequate accuracy at low forces, and the laptop control would sometimes time out, resulting in loss of data and possibly unnecessary patient discomfort.

Finally, the design of the device was not streamlined. This resulted in an intimidating appearance to the patient as well as an unreliable setup (due to oversized wiring, controls, and interfaces). Table 2 summarizes the hardware used in the CCPA device design, and can later be compared to Table 5 which summarizes the hardware used in the AmP-MeD design. Many of the hardware components used in the design of the CCPA are not ideally fitted to the device. This causes over-complication, unnecessary amount of parts, and an overall loud, bulky, and cumbersome appearance.

Part #	Hardware	Use/Description	Comments
1	Laptop Computer	Computer control	Antivirus software caused timeouts
2	USB-6008 Data Acquisition System	Computer control	
3	Normally Retracted Spring Return Air Cylinder	Actuator	Impossible to measure displacement
4	Load Cell	Force Measurement and Feedback	Lack of resolution at lower forces
5	Air Solenoid	Emergency Stop	Simple emergency stop system that works well to automatically kill applied pressure upon activation
6	Electronic Pressure Regulator	Control of air pressure actuator	
7	Operational Amplifier	Facilitates Operation Electronic Pressure Regulator	
8	Electronic Pressure Gauge	Pressure Feedback to computer	
9	Momentary Switches	PPT and PPTol marker buttons	Cumbersome and potentially confusing for patient to use multiple buttons
10	Two Automotive Switches	Test administrator and patient emergency stop	Cumbersome and potentially confusing for patient to use multiple buttons
11	24V DC Power Supply	Main power source	Cumbersome, bulky, and heavy
12	Air Compressor	Supplies air to Normally Retracted Spring Return Air Cylinder	Loud, cumbersome, bulky, heavy, and intimidating to patient
13	Load Frame	Supports Actuation System and Patient	Large and difficult to adjust

Table 2: Main Hardware Components Associated with CCPA

3.2 Overall CCPA Design

Overall, the CCPA accomplished important achievements but also had significant shortcomings. Most importantly, the CCPA succeeded in integrating blood pressure and heart rate measurements from medical equipment through the LabView interface. The integration of these physiological signals to the automated device is a huge accomplishment, and the strategy used to accomplish this will be used on the AmP-MeD. The shortcomings of the CCPA led to the goals of the AmP-MeD development, which are discussed in Section 4.1 AmP-MeD Goals.

Chapter 4

AmP-MeD Design

4.1 AmP-MeD Goals

A new device has been developed to address the shortcomings of the CCPA and to add additional benefit over both the Zimkowski CCPA and handheld pressure algometers on the market today – it will be referred to throughout this document as the AmP-MeD, or the ***A**uto**m**ated **P**ain **Me**asurement **D**evice*. The primary goal of the AmP-MeD is to improve sensitivity and reliability. This is accomplished by eliminating variability due to a human test administrator, increasing sensitivity by controlling pressure application rates, and minimizing psychological effects on the patient experience. While the Zimkowski CCPA made significant steps towards achieving these goals (as compared to a hand-held pressure algometer), the primary goals may still be refined. Important secondary goals of the AmP-MeD (as compared to the Zimkowski CCPA) are to improve usability, functionality, and aesthetics.

The design of the AmP-MeD with regards to *usability* will focus on improving the user interface, the actuation method usefulness, transportability, and adjustability. The improved user interface will provide the test administrator with a streamlined, intuitive platform in which to conduct the test with minimal variability caused by complex test administration. The actuation method will be simple, effective, and efficient. The device will

be easily transported as it may be used in multiple clinics or multiple rooms of one clinic. Finally, the device will be simple and easy to adjust for different patients.

The design of the AmP-MeD with regards to *functionality* will focus on improving the reliability, safety, accuracy, and precision of the device. This will be accomplished in the physical structure of the device, the actuation mechanism, and the control mechanism.

The design of the AmP-MeD with regards to *aesthetics* will focus on minimizing the size and weight of the device, improving upon the administrator and patient interfaces, and providing comfort to the patient (with the exception of the intentional induced pain). Patient intimidation, expectation, and fear of pain have been strongly correlated with patient pain responses [51]. Thus, multiple steps will be taken to both reduce the device's intimidation level and control the variability of perceived "fear" between patients. This will be achieved by reducing the size of the device, increasing patient comfort and perception of safety, and streamlining all human interfaces.

4.2 Geared-Motor Actuation System

A geared-motor approach to pressure-actuation was chosen because it is more precisely and accurately controlled, and it offers the ability to measure displacement as well as applied load/pressure. Furthermore, the geared-motor approach drastically decreases the size and weight of the device. In the CCPA, the pneumatic actuation system involved custom built piston housing, air tubing, a large control box, and an industrial air compressor. This setup was cumbersome, complicated to setup, prone to breaking, and intimidating to the patient. It did, however present a significant advantage – in the case of a power outage or a short in the system, the pressure would automatically diminish, discontinuing any applied

pressure to the patient. The geared motor approach, however, needs a signal to retract the piston (as the motor must be powered to reverse). For this reason, three levels of safety have been implemented, and are explained in Section 4.6 Safety and Emergency Stops.

The geared-motor approach was designed and built to take advantage of the compact, light-weight volume while retaining high accuracy and precision in measurement and control. A Pololu 67:1 Metal Gearmotor with a 64 CPR Encoder (pictured in Figure 14) was chosen for its favorable specifications (listed in Table 3). The geared motor is used in conjunction with a series of gears that act as a linear actuator, as depicted in Figure 15.

Figure 14: Pololu Motor used in AmP-MeD motorbox

Specification	Attributes	Comments
Size	2.62 L * 1.45 D [in]	Compact
Weight	7.7 oz	Lightweight
Encoder	4331 counts per revolution	Extremely precise control capability
Gear Ratio	67:1	Allows precise control capability and adequate stall torque in small size
Stall Torque	200 oz-in	Provides appropriate maximum pressure applied when used in conjunction with linear actuator gearing system

Table 3: Pololu Motor Specifications

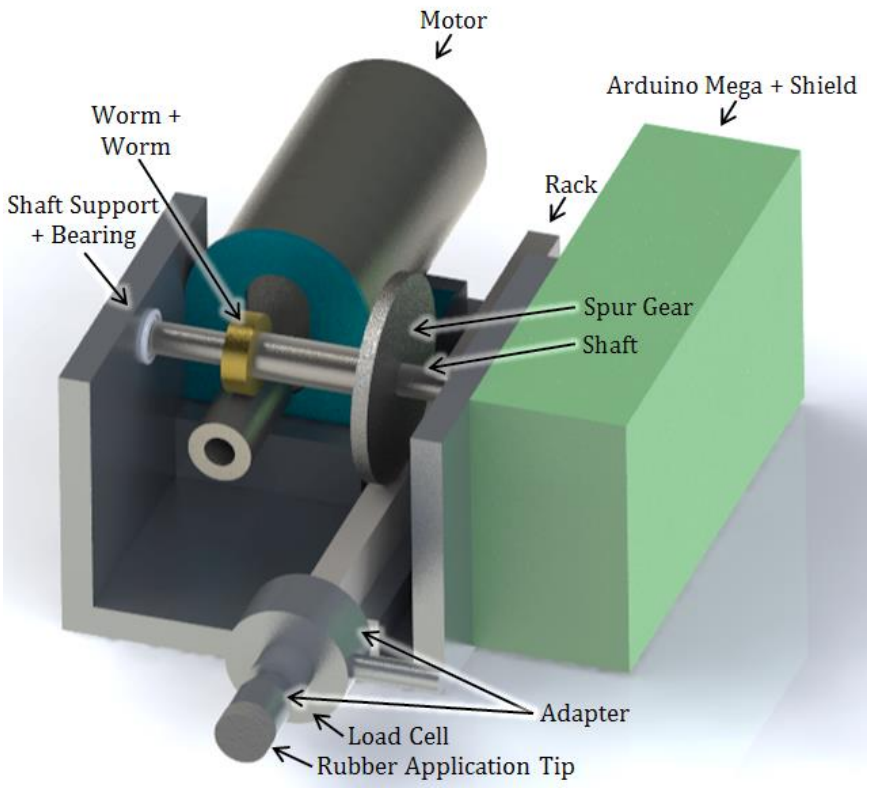

Figure 15: Linear Actuator Gearing Assembly used for AmP-MeD Actuation System

The sizes of the gears were determined via calculations that optimized desired maximum force, desired linear speed, and desired minimum volume, as shown in Equation (1) through Equation (6).

$$Desired\ Force\ Output: F_{out} = 160\ N \tag{1}$$

$$Needed\ Motor\ Torque: T_{motor} = \left(\frac{\omega_{spur}}{\omega_{motor}}\right) * T_{spur} \tag{2}$$

$$\omega_{spur} = \frac{V_{out}}{r_{spur}} \tag{3}$$

$$\omega_{motor} = \omega_{w.wheel} * t_{w.wheel} \tag{4}$$

$$T_{spur} = F_{out} * r_{spur} \tag{5}$$

$$\omega_{motor,RPM} = \omega_{motor,\frac{rad}{s}} * \left(\frac{60\frac{s}{min}}{2\pi}\right) \tag{6}$$

The input parameters were chosen based on future testing needs. Linear speeds as low as 0.1 cm/s and as high as 10 cm/s are desired for future testing (for investigations of the relationship between application rate and pain response). An output force of 160 N was chosen for these calculations, though the practical use case will employ a maximum of 80 N for safety and average use case parameters. The 80 N safety cutoff will be employed to ensure no tissue damage (bruising) occurs during testing. In previous tests conducted by Zimkowski, few patients could tolerate forces exceeding 80 N (unpublished results). However, the AmP-MeD will be designed so that patients with PPTol marks above 80 N may choose to undergo additional testing that will apply up to 160N (this way, the PPTol on patients exceeding 80 N of force may be recorded).

4.2.1 Load Cell

A 100 lbf force load cell was chosen for force measurement and force feedback. The load cell uses a Wheatstone Bridge sensor and implements a threaded force sensing tip which enables an easy and secure fit with the rubber application tip. Furthermore, the load cell is compact yet accurate (See the Appendix, Section Appendix 11.2 Load Cell Datasheet).

4.2.2 Application Tip

In order to maintain correlation to previous studies, a $1cm^2$ rubber application tip (identical to that in the Wagner ForceOne™ and to the CCPA) is used to apply pressure to the patient's tibialis anterior (shown in Figure 16). This rubber application tip is attached to the rack via a simple linear assembly, as depicted in Figure 17. A load cell adapter was machined to mount the load cell flush to the end of the rack. The rubber application tip is then mounted flush to the load cell via the threaded force sensing tip on the load cell (the attachment does not affect load measurements).

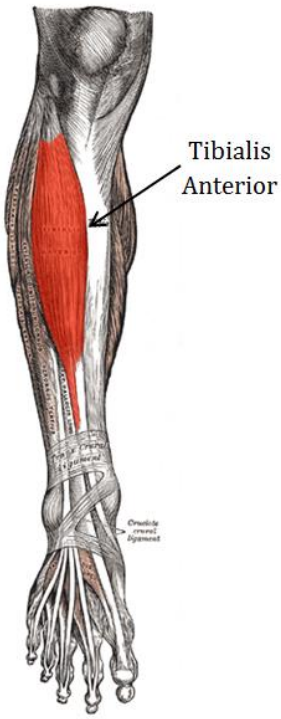

Figure 16: Location of AmP-MeD test site - Tibialis Anterior [F]

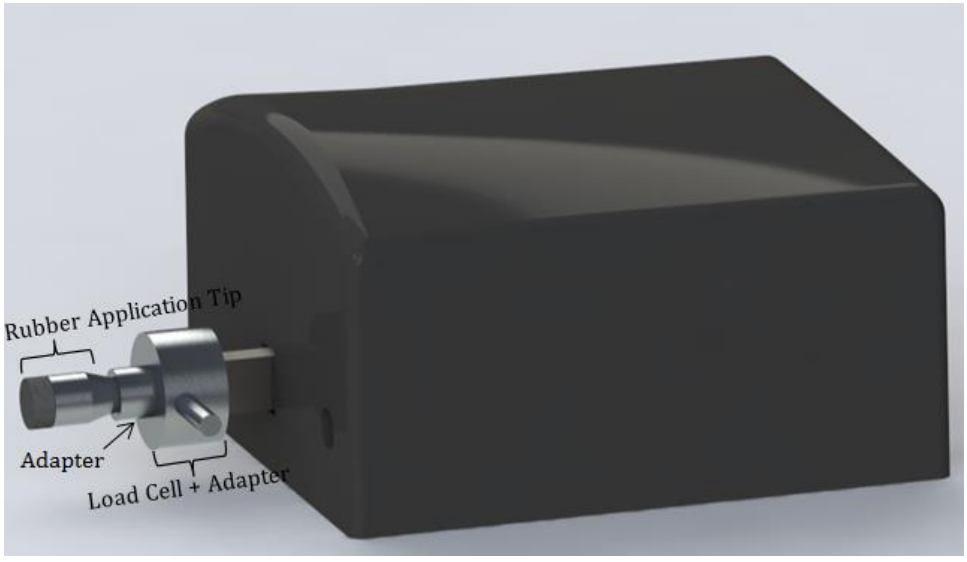

Figure 17: Application Tip Connection Assembly to Rack for AmP-MeD Actuation

4.3 Electronics

The electronic components included in the device design consist of the power supply, Arduino Mega with Motor Driver Shield, and Tablet PC. The power supply used is a lightweight, compact 100V-240V to DC 12V 5A Switching Power Supply Adapter (pictured in Figure 18). This power supply is based off of a "laptop charger" system, and provides power to the Arduino which regulates power delivery to the other hardware. Power is supplied to the load cell and motor. This system streamlines power supply and regulation via the Arduino, which facilitates the simple (and easy to repair or modify), compact design, as seen in Figure 19.

Figure 18: AmP-MeD Power Supply

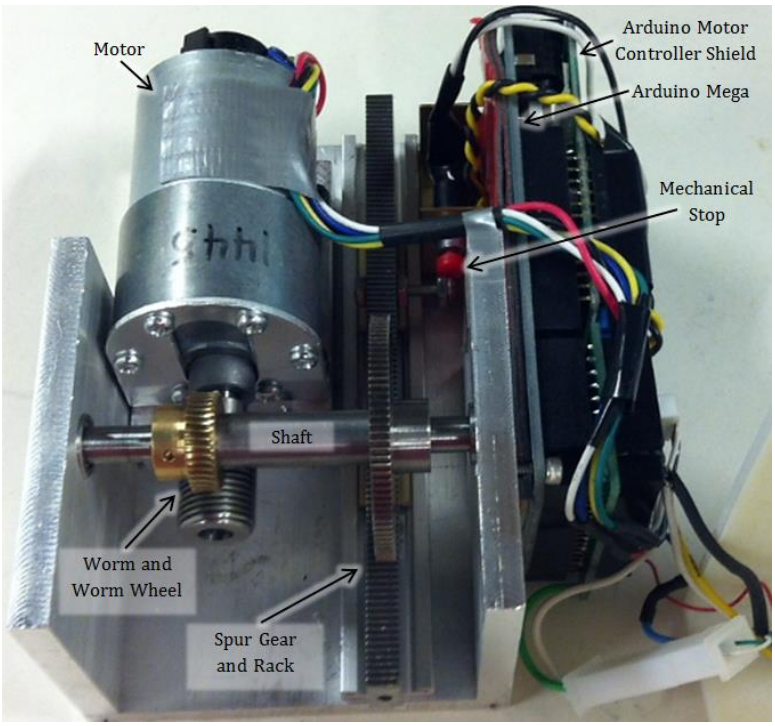

Figure 19: Motorbox with Wired Arduino Control Boards – photo of interior

4.4 Software (Actuation and Control Methods)

An Arduino Mega 2560 R3 with a Pololu Dual VNH5019 Motor Driver Shield for Arduino is used as the input and output for the control system (see Figure 19). The physiological data will be collected via a DATAQ DI-720. All data and testing is controlled by LabVIEW software, which also acts as the graphical user interface.

4.4.1 Data Acquisition

The Arduino Mega plus Motor Driver Shield provide both digital and analog inputs and outputs. The analog inputs are used for the load cell and motor, and the analog outputs provide linear 0-5V output control for the motor. The digital inputs provide the threshold and tolerance markers.

Although physiological input has not been implemented at this time, the Zimkowski design will be outlined in this paper, as it was a robust design that will work well for the AmP-MeD [8]. The DATAQ DI-720 will have three channels for analog input from the physiological measurements for input into LabVIEW.

4.4.2 LabVIEW Software

The use of LabVIEW in the AmP-MeD system enables control from any Windows based computer. The LabVIEW program consists of three case scenarios which control the motor via force feedback from the load cell. First, the code resets the encoder to determine the zero position. The user may then control the system manually or use the automatic control by setting parameters such as the rate of the piston, the safety cutoff, etc. The desired speed is linked to the position measurements, as each rotation of the motor equates to exactly the same displacement of the piston.

The automatic control consists of three cases – motor is not activated, motor is activated and test is running, and motor is in full reverse to initial position. When the motor is not activated, it will sit at the last position it was stopped at unless instructed to "return to home". When a test is running, the motor will meet its desired speed (slowing as it approaches the cutoff force to avoid an overshoot) and continue as the patient presses the "threshold" button. When the patient presses the "tolerance" button, the motor will back up at high speed to stop any applied pressure to the patient; this is the third case. When the patient presses the button the first time (indicating he/she has reached his/her threshold), LabVIEW writes the load and position to a specified file. When the patient presses the button the second time (indicating he/she has reached his/her tolerance), LabVIEW writes

the load and position to the specified file and immediately reverses the motor back to its starting position. Copies and screenshots of the LabVIEW code can be found in the Appendix, Section Appendix 11.3 LabVIEW Code.

The force feedback works through a PID (Proportional-Integral-Derivative) controller within LabVIEW. The PID control has been tuned to work with very good accuracy and precision. A linear control is implemented currently, but ramped and stepped functions would be simple to implement for future testing.

The user manipulates the front panel, where the controls are located. In the *manual control* area, the user may move a knob from 0-100% of motor speed in either the forward or backward position. The user may also reset the encoder (override the automatically set zero position which works with a mechanical stop within the motorbox) and return the motor to "home". In the *automatic test* area, the user may set a desired speed (mm/s), a maximum return speed (% of full speed), and a load cutoff (kg) before enabling the control and starting the test. During the automatic control test, the user can see an indicator which shows whether the patient has pressed the button zero, one, or two times. The user is also able to visualize the position of the pressure application tip, the speed at which it is travelling, and the force it is exerting on the patient through graphs (as shown in Figure 20 and Figure 21).

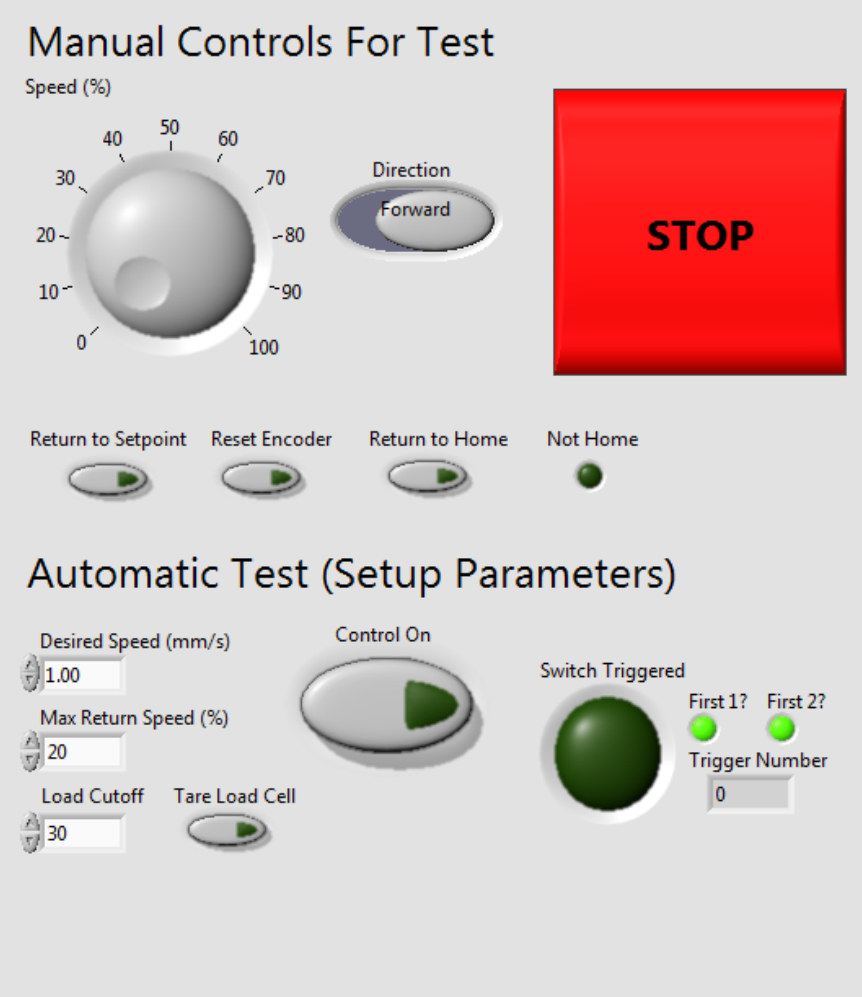

Figure 20: LabVIEW User Graphical Interface – User Inputs Area

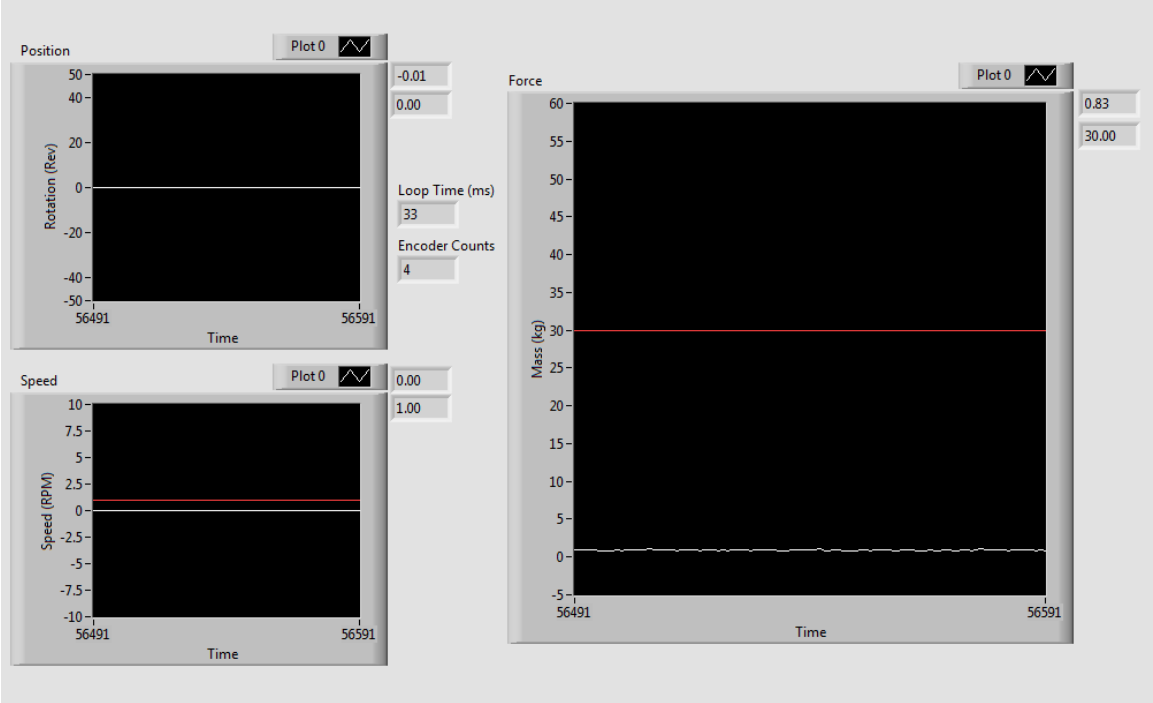

Figure 21: LabVIEW User Graphical Interface - User Visualization Area

4.5 Frame Design

The AmP-MeD device has an improved custom-built frame that allows the patient to sit in a chair rather than lay in a clinic bed. The primary advantage of this change is that not all clinics have beds available, but nearly every medical clinic has a chair in every room. These chairs are usually used to take the patient's vital signs; of which "pain scale" will eventually be supplemented. Secondly, the new frame is drastically smaller than the previous CCPA frame, and weighs significantly less. The CCPA weight is compared to the AmP-MeD weight in Table 4 below, which shows that the AmP-MeD weighs roughly 11% the weight of the CCPA. This compacted design presents the advantage of easy transportation from clinic room to clinic room, or even from clinic to clinic. Thirdly, a sedentary patient is thought to be more at-ease than a patient made to lie in a bed. His/her sense of security and control is

elevated in a sedentary position as opposed to a prone patient. Fourthly, the AmP-MeD frame is modular, and could easily be modified to test other locations on a patient - the motorbox is easily removed, and could be used on frames made for testing other areas of the body such as the erector spinae muscles or other locations often documented in literature. Finally, the AmP-MeD frame, although custom built at this stage of research, would be easily and inexpensively manufactured in larger volumes as it is mainly comprised of simple planar aluminum parts (see Appendix Section Appendix 11.4 SolidWorks Part Drawings for Frame Fabrication).

	CCPA (lbf)	**AmP-MeD (lbf)**
Air Compressor	54.08	N/A
Control Box	17.74	2.58
Frame	40.04	11.00
Laptop	6.96	1.92
Power Supply	25.00	0.60
TOTAL	**143.82**	**16.10**

Table 4: CCPA versus AmP-MeD Component and Total Weights

The frame consists of a structural assembly and an adjustable assembly. The main structural assembly is made up of the base, back, and front parts, while the adjustable assembly is made up of the rod, ring, and arm. The assembly of the frame is shown in Figure 22.

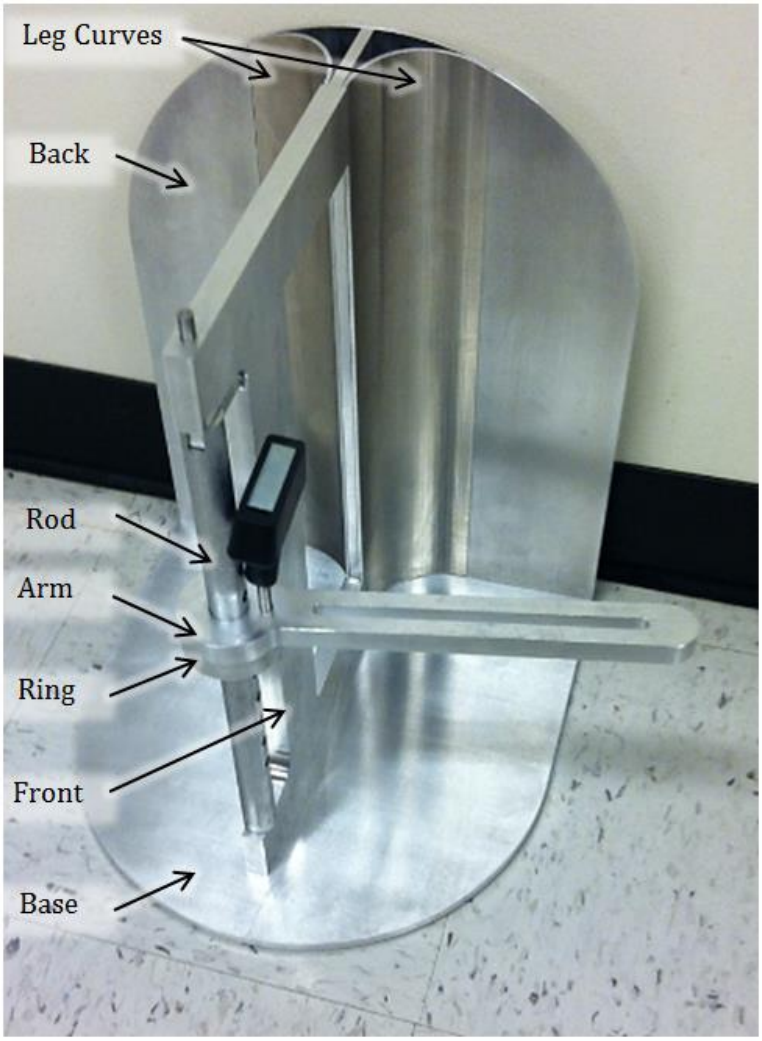

Figure 22: AmP-MeD Frame - Structural and Adjustable Assemblies

Easy adjustability is an important factor of the AmP-MeD frame, as a maintaining a perpendicular interface of the pressure-application tip and the patient's skin is important in accurate measurement (a major shortcoming of handheld algometers) [52]. There are a series of easy to make adjustments to ensure a proper fit before testing begins. Firstly, the ring and arm can be slid up/down the rod to adjust for height. After the correct height is selected, the test administrator places a pin into the rod that constrains the ring and arm

from falling. Secondly, the rotational position of the arm is adjusted by rotating the arm about the rod and ring (the ring and rod do not rotate – they are constrained by key slots). Once the proper angular position of the arm is found (placing the motor box in proximity to the tibialis anterior), the emergency release pin is placed into the ring and arm, constraining any rotation. Finally, the motorbox may be adjusted linearly and angularly by sliding it along the trough of the arm. After the correct position is found (the pressure-application tip is touching the patient's leg perpendicularly), the wing nut is tightened to secure the motorbox to the arm. Proper adjustment is an easy three step process, and requires zero effort from the patient and minimal effort from the test administrator. This is a significant improvement from the original CCPA, where the patient needed to "scoot" up or down the bed, aid in medial and/or lateral rotation of the lower leg, and the test administrator needed to exert significant strength to move the forty-pound frame under the patient for new test locations.

4.6 Safety and Emergency Stops

The AmP-MeD was designed for patient safety. A maximum level of the pressure pain stimulation is set based on published data- an automatic motor-reversal mechanism will be switched on through feedback control if the pressure exceeds this set limit. The patient input is the first safety stop, and if the patient exceeds the set limit, the device will also retract.

During testing, the subject has immediate access to a simple emergency stop switch. The patient only has one button to press – he/she is instructed to press the button the first time when the pain threshold is experienced and a second time when the tolerance is reached.

When the button is pressed the first time, pressure data is logged and the test continues, but when the button is pressed for the second or subsequent times, the motor will automatically reverse at full speed, retracting the rubber pressure application tip and rod into the motorbox housing and away from the patient. This simplified mechanism reduces risk of patient confusion or panic. In previous testing with the CCPA, patients became confused as to which button to press at what time, and if they pressed a button more than once, a malfunction would possibly occur.

Furthermore, there is a mechanical emergency release designed into the AmP-MeD in the instance of a panicked patient or a power outage. The test administrator simply needs to reach down and turn the wing-nut securing the motor, which will disengage the motor's connection to the arm and thus to the patient. The motorbox may then be rotated or lifted away from the patient. This will stop the pressure applied to the patient, and allow the patient to stand up and remove their legs easily from the device.

This triple redundant safety system uses feedback control to limit the pressure applied, a patient input to stop the pressure when they reach a tolerance, and a mechanical stop in the case of an "all-else-fails" incident. The three implemented safety systems ensure patient safety at all times and release all applied loads within milliseconds of triggering. Additionally, in most cases the patient would be able to simply remove his/her leg, since the patient is sedentary and able to stand and/or move the leg laterally out of the machine.

4.7 Physiological Data Integration

The Zimkowski CCPA design for physiological data integration was a strong design, and therefore the AmP-MeD will use these specifications for its design as well. The following section is adapted directly from Zimkowski's thesis [8].

A DATAQ DI-720 will serve as a digital to analog converter and integrates information from the ECG signals (heart rate) and the Finapress BP Monitor (blood pressure). The ECG enables post-processing calculations of heart rate fluctuations during testing. The Finapress BP monitor records blood pressure in real-time and enables post-processing calculations in blood pressure during testing. Both devices are shown in Figure 23.

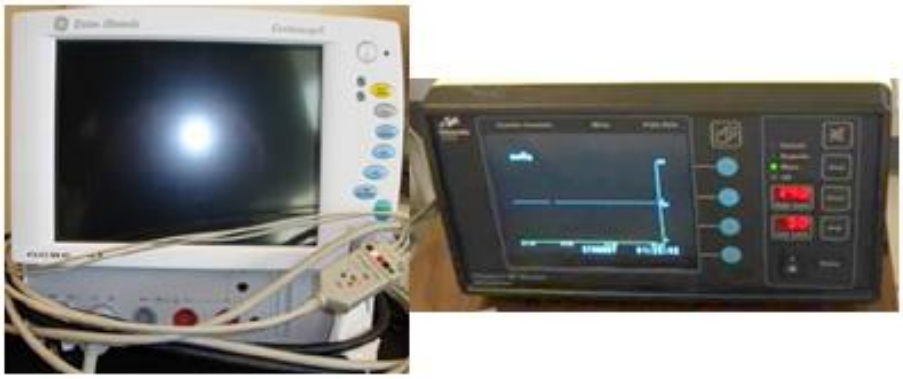

Figure 23: ECG Signal Monitor (Left) and Finapress BP Monitor (Right)

There are drawbacks to these physiological data integration methods, unfortunately. The ECG monitoring system can result in a loss of signal resolution when the signal is relayed from the machine to the Windows-based operating system [8]. Zimkowski suggests implementing a real-time operating system on a programming logic controller to correct the problem. Furthermore, the real-time blood pressure monitoring system via a finger-cuff

can be highly unreliable due to arm position with relation to the heart [8]. Unfortunately the best way to accurately measure blood pressure real-time is with an arterial measurement line – this not a practical solution for this study [8].

In order to mitigate these drawbacks, practical solutions are implemented that are within scope of this study. The real-time processing issues related to the ECG monitor will be minimized by using the PC Tablet which runs Windows software, but without any antivirus or background checks – this will enable data integration to be more streamlined without timeouts that can result in lost data. The real-time blood pressure monitoring system will be calibrated with a traditional blood pressure cuff before testing begins for each patient. This quick calibration will enable the test administrator to position the patient's hand (and finger) in a desirable location (likely on the chair's armrest) which will result in accurate blood pressure measurements for the duration of the test.

4.8 Test-Administrator Interface

The test administrator interface has been drastically simplified from the CCPA design. Test setup is completed by following the simple instructions (see Section Appendix 11.5 AmP-MeD Testing Procedure). Once testing has been set up, the test administrator uses the tablet to conduct testing, by simply pressing the START TEST button. Parameters like rate of pressure application (mm/s) and maximum force (lbf) may also be adjusted prior to testing.

A tablet computer was chosen in order to simplify the test-administrator interface. The tablet will not be equipped with any internet capabilities, and therefore will not have the time-out issues presented with the first CCPA due to antivirus software. Furthermore, the

tablet allows a more transportable platform for the test administrator interface – it's lightweight and wireless. The total setup only involves two wires – a USB to mini-USB from the tablet to the motorbox and a laptop style charger from the motorbox to a standard wall outlet.

4.9 Patient Interface

As briefly described in the *Electronics and Emergency Stops* section, the patient will hold a remote with one button in his/her hand. The remote (pictured in Figure 24) controls data collection as well as retraction of the piston when the tolerance is met (or when the patient presses the button more than once, if he/she wants pressure-application to cease immediately). This simple "one-button" model reduces stress and/or confusion in the patient.

Figure 24: AmP-MeD Patient Interface - Handheld Remote

The patient will also be connected to physiological data collection devices. The physiological data collection methodology is based on Zimkowski's design [8], and is described more fully in Section 4.7 Physiological Data Integration. ECG leads will be adhered to the patient's torso, and the blood pressure monitor will be a finger-cuff on the opposite hand used to operate the handheld remote.

4.10 Overall AmP-MeD System

The AmP-MeD has been designed for simplicity. The level of complication, number of parts, and setup processes have all been streamlined and minimized, as is evidenced in Figure 25, a photo of the complete test setup. Table 5 summarizes all components required in the AmP-MeD.

Part #	Hardware	Use/Description	Comments
1	PC Slate Tablet	Computer control	No antivirus software
2	Arduino Mega + Motor Controller Shield	Computer control	Simple, compact interface
3	Motorbox	Actuator	Displacement and force easy to control and accurately measure
4	Load Cell	Force Measurement and Feedback	Accurate and precise measurement
5	Patient Remote Switch	PPT and PPTol marker buttons	One-switch design introduces more simplicity for the patient
6	100V-240V to DC 12V 5A Switching Power Supply Adapter (laptop charger)	Main power source	Compact and lightweight
7	AmP-MeD Frame	Supports Actuation System and Patient	Easily transported and adjusted

Table 5: AmP-MeD components

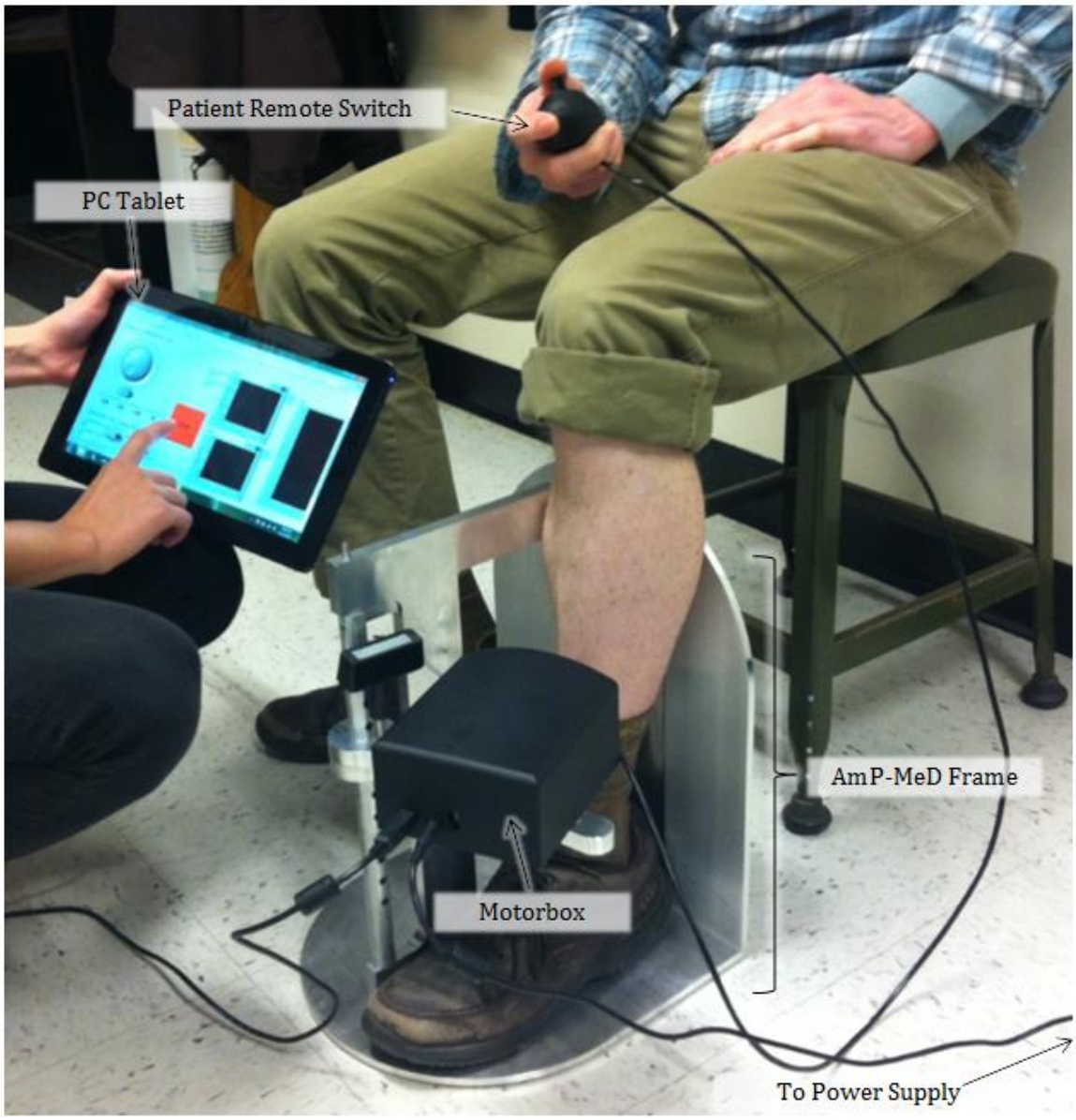

Figure 25: Complete AmP-MeD Test Setup

Chapter 5

Results

5.1 AmP-MeD in comparison to Wagner and CCPA Devices

In order to assess the design of the AmP-MeD testing platform in comparison to the CCPA and Wagner ForceOne™ (the chosen market device), a series of methods may be used. To standardize and simplify the comparison, a Quality Function Deployment (QFD) was used. User interface (ease of setup and use, cost, weight, and size of the device), patient interface (comfort and safety), and data capabilities (usefulness, accuracy, precision and reliability of data), and were analyzed in the QFD. While the Wagner ForceOne™ presents advantages in simplicity and ease of use, it does not provide adequate results. The CCPA provides the advantages of an automated device, but is not streamlined or user-friendly. The AmP-MeD provides a combination of advantages between the handheld and automated designs, incorporating simplicity and usability with high data capabilities. Figure 26 shows a summary of the QFD performed.

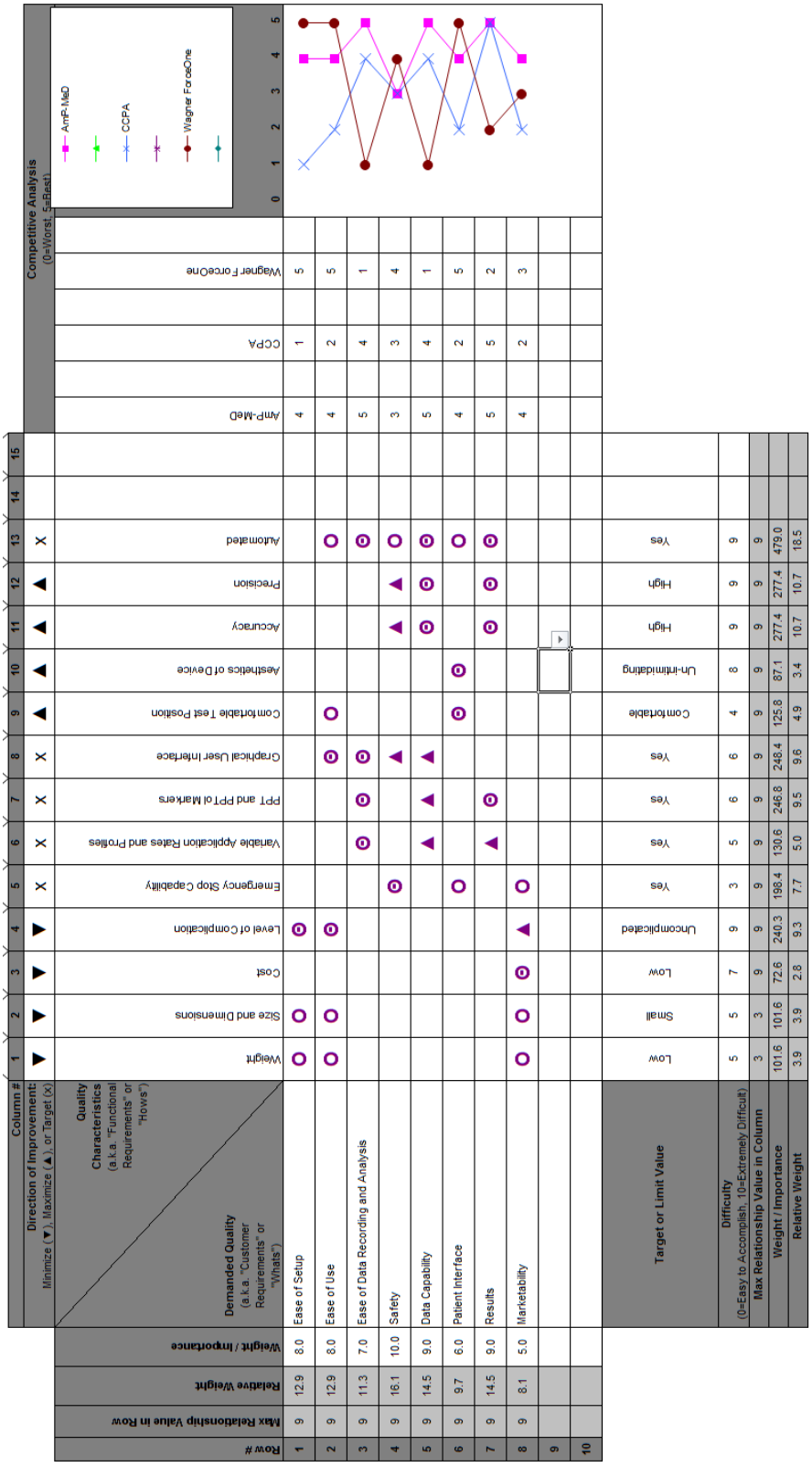

Figure 26: QFD Analysis of AmP-MeD in comparison to the CCPA and Wagner devices

In order to more specifically assess the strengths and shortcomings of each device, some metrics may be analyzed. While the Results Chapter assesses the data capability of the AmP-MeD device, the ease of setup and ease of use may be compared between the three devices. The average time to setup each device was chosen as a metric that would adequately describe the ease of setup. This metric is compared in Table 6, where it is evident that the AmP-MeD device setup is vastly minimized compared to the CCPA and comparable to the Wagner handheld device.

Device	Average Setup Time
Wagner	3 minutes
CCPA	30-45 minutes
AmP-MeD	5 minutes

Table 6: Average Device Setup Time summary of Wagner, CCPA, and AmP-MeD devices

In order to assess ease of use, the time necessary to record data and cycle through one test may be used as a metric, in combination with the simplicity level of the test-administrator and patient interfaces with the machines. Table 7 summarizes the assessment of ease of use between the three devices.

Device	Average Data Recording Time per Test	Test-Administrator Interface Simplicity Level	Patient Interface Simplicity Level
Wagner	5 minutes	Medium	Simple
CCPA	Automatic	Complex	Complex
AmP-MeD	Automatic	Simple	Simple

Table 7: Average recording time per test and simplicity levels of test-administrator and patient interfaces compared between Wagner, CCPA, and AmP-MeD devices.

5.2 Engineering Experimental Results

Engineering tests were performed on the AmP-MeD device before initial subject testing to ensure that it functioned properly. The load cell was calibrated and the control system was analyzed.

5.2.1 Load Cell Calibration

The load cell described in Section 4.2.1 Load Cell was calibrated using known weights to ensure that the correct measurements were being obtained. The linear regression from the calibration of the load cell is integrated into the main LabVIEW code so that the program uses the calibration values of the load cell upon initialization. If the load cell needs to be recalibrated, this can be done with ease and the new linear regression values may be resubmitted to the LabVIEW code. Figure 27 shows the linear regression of the load cell calibration.

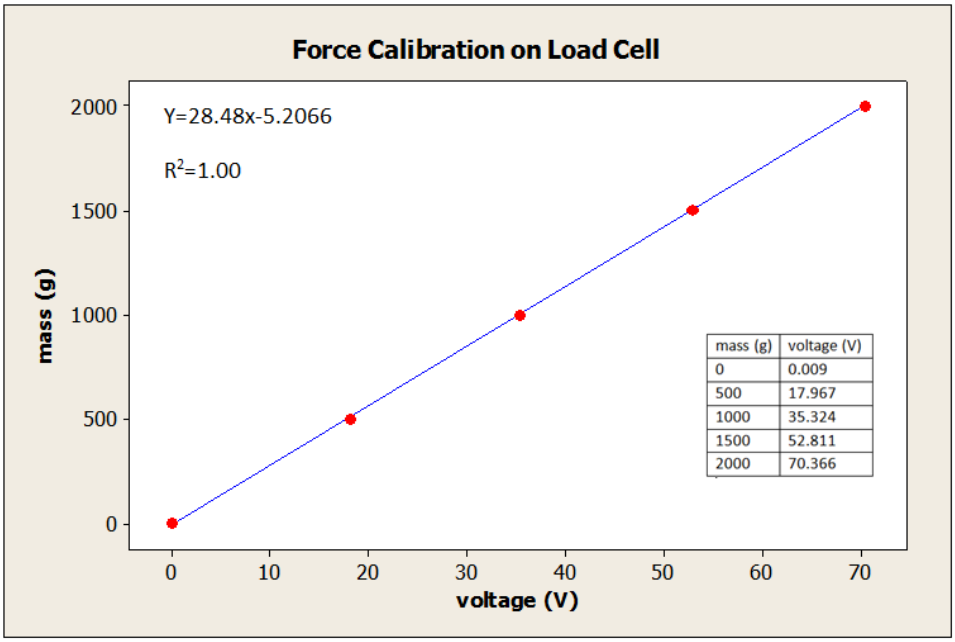

Figure 27: Load Cell Calibration in AmP-MeD Device

5.2.2 Control Loop Evaluations

The control loop implemented in the code was evaluated both on a synthetic leg and in testing on study participants. The initial testing was performed using a padded aluminum tube roughly the same diameter of a human leg. The AmP-MeD was used on this synthetic leg to ensure that the control system behaved properly during human testing. After this initial stage, participants from the test-group were tested. Figure 28 shows an example of a force control loop on a test participant. The vertical green lines have been added after testing analysis to indicate when the participant pressed the trigger to indicate his PPT and PPTol. The white line is the ramped force from the pressure application tip (measured by the load cell), and the red line is the safety cutoff. When the participant pressed the tolerance button, the pressure application was immediately ended.

The force and position control is also evidenced in Figure 29, depicting the position and application speed graphs. When the participant pressed the tolerance button, the piston automatically retracted at full speed to the initial set-point position. The PID control system is tuned for maximum retraction speed, which results in some overshoot. This explains the oscillations seen in the bottom plot of the figure. The PID could be tuned to minimize these oscillations, but that would mean a slower retraction speed, and this is considered less desirable for safety reasons.

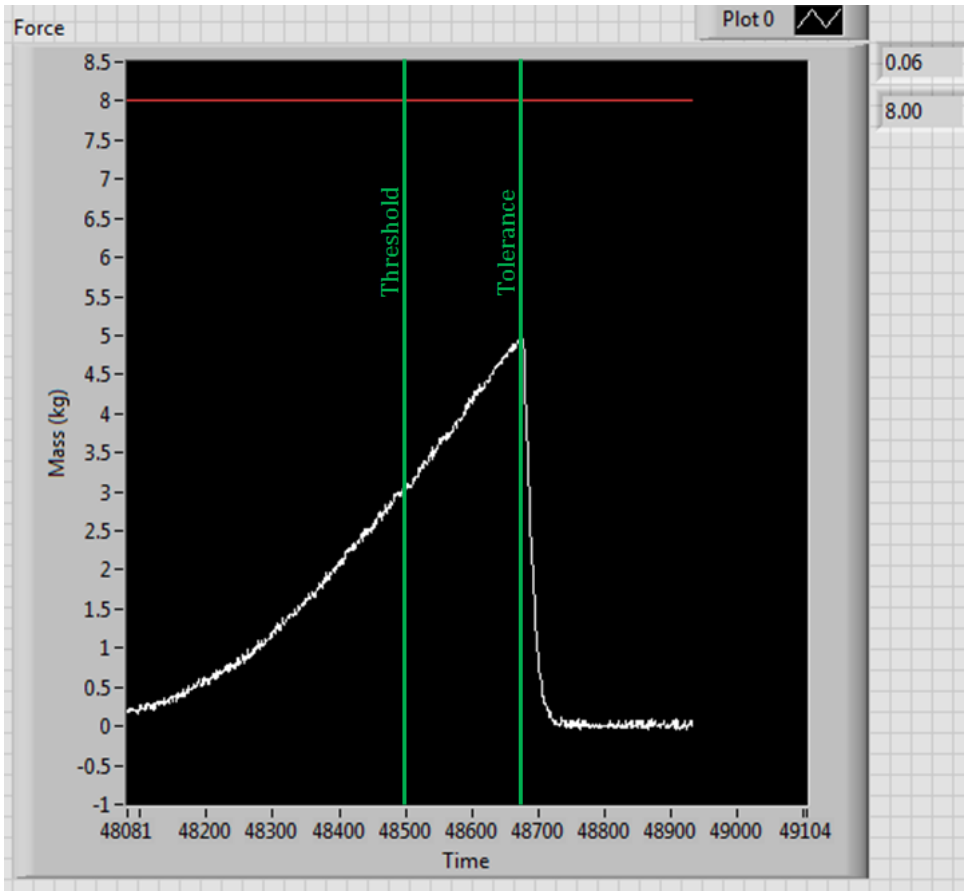

Figure 28: Force Feedback control on participant - characteristic example. Graph is of force applied (in kgf units) versus time. The white line follows the force-application path over time, while the red line is the force limit safety cutoff. The green *threshold* and *tolerance* lines have been added to indiate where the participant indicated PPT and PPTol, respecively, during this test run.

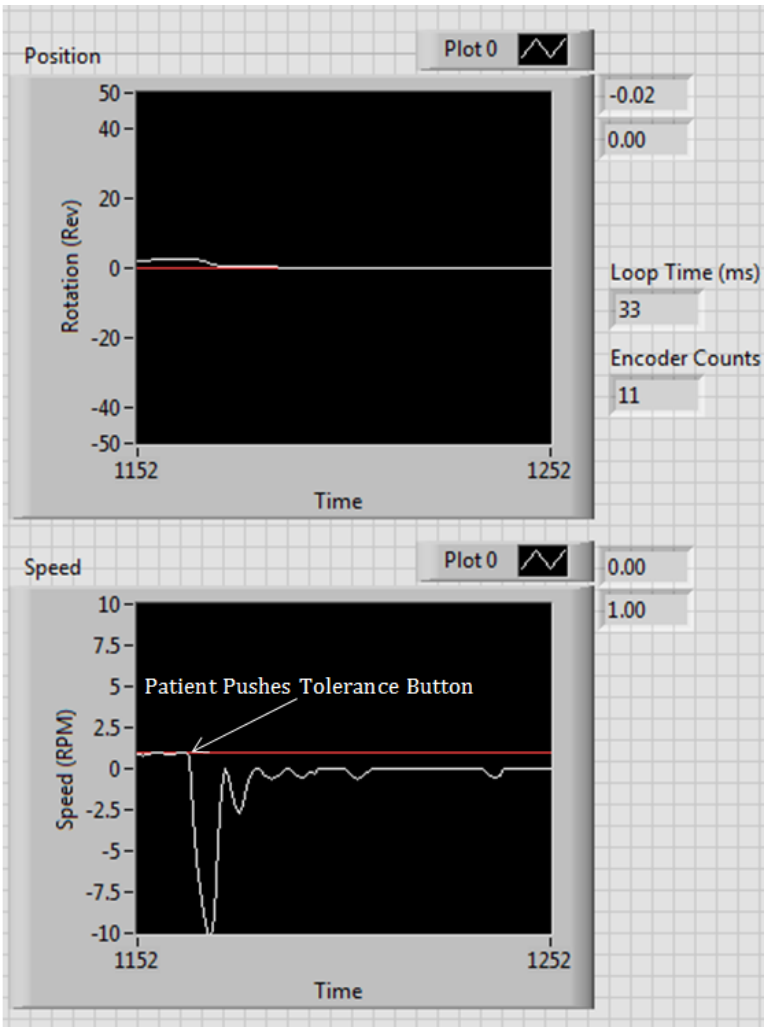

Figure 29: Force Feedback control on participant – characteristic example. The top plot represents motor position in revolutions per time. The white line is the position of the motor, and the red line is the zero position of the motor. The bottom plot represents motor speed in revolutions per minute per time. The white line is the motor speed and the red line is the set point speed. The motor is operating at set point speed until the participant presses the remote the second time (indicating PPTol), then the motor rapidly backs out and shoots toward a 0 rpm speed, with significant overshoot (to maximize retraction speed of the rubber application tip).

5.3 Subject Experimental Results

5.3.1 Initial Study Results

An initial study was performed on a test group of nine participants to compare recorded PPT from the AmP-MeD versus the Wagner device. Each test participant was instructed to indicate his/her pressure-pain threshold during each test. Three measurements were taken with each device: the right leg was tested using the Wagner device and the left leg was tested with the AmP-MeD. Testing order was not randomized, as the literature supports consistency between pain ratings on corresponding left and right sides of the body [13].

For the AmP-MeD testing, test subjects were instructed to sit on a chair behind the device, resting both legs comfortably against the back of the device, as shown in Figure 30. The participant was given the handheld button and instructed to hit the switch when PPT was experienced, and to hit the switch the second time on a chosen fraction of PPTol (in order to end the test). PPTol was not measured in preliminary testing in order to avoid inflicting unnecessary levels of pain.

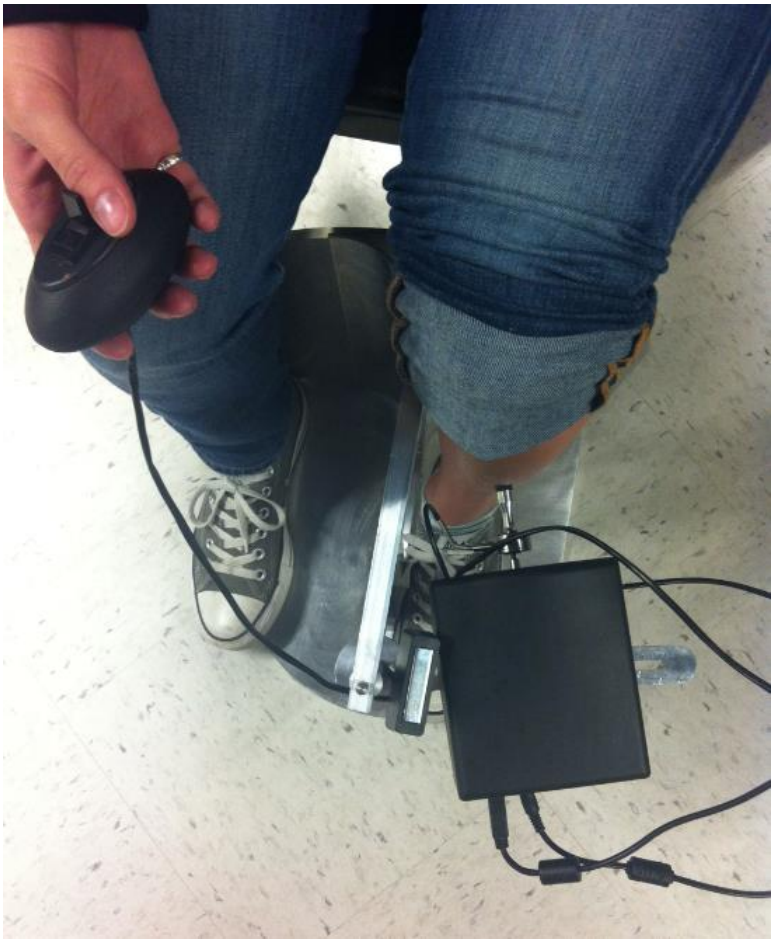

Figure 30: Top-down view of setup for AmP-MeD testing

For the Wagner device testing, the participant remained seated in the chair, and rested his/her leg horizontally on another platform (shown in Figure 39). The test administrator then selected tests sites equivalent to the test sites measured on the opposite leg with the AmP-MeD and attempted to apply pressure at a constant rate similar to 1mm/s (the rate at which the AmP-MeD applies pressure). PPT was then recorded.

Figure 31 summarizes the results of the preliminary study. The boxplot is divided by participant (separated by vertical dotted lines) and device used to record PPT (green

versus blue boxes). Two trends are immediately obvious; firstly, the data collected with the Wagner device appears significantly higher than the data collected with the AmP-MeD device. This trend was anticipated from results reported by Zimkowski [8]. Secondly, the figure shows less spread between the datasets recorded using the AmP-MeD for most participants (with the exception of participants four and eight). This observation is an important indicator that the automated device may be capable of recording more reliable and repeatable results than the handheld device.

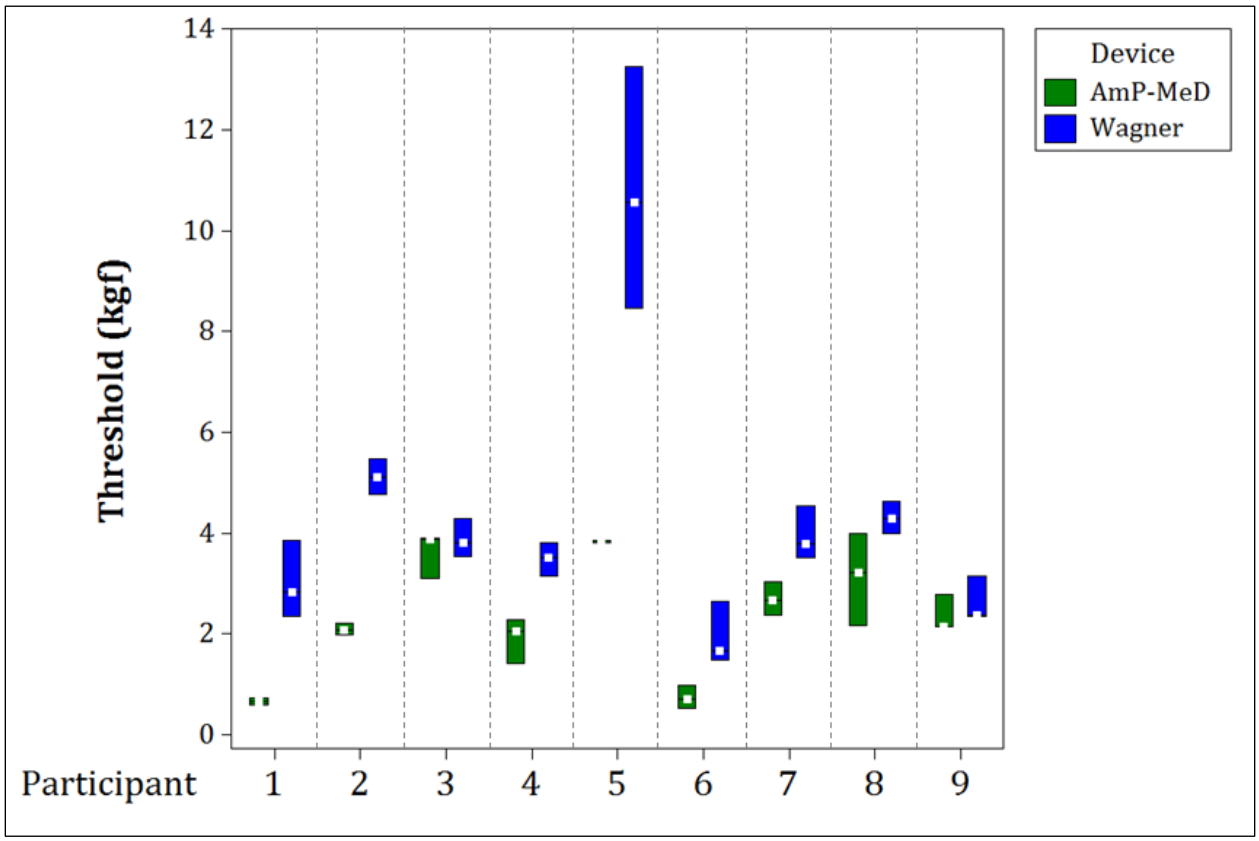

Figure 31: Initial Study Results Boxplot – separated by participant (1-9, dashed lines between) and device (green boxes indicate AmP-MeD and blue boxes indicate Wagner). White squares in individual boxes represent median values of that test group.

Participant number 5, as shown in Figure 31, reported low and consistent values for the AmP-MeD device but high and inconsistent values for the Wagner device. This participant shows both trends extremely well, but had a different magnitude of results from the other participants. For this reason, the other eight participants' data is more closely examined in Figure 32. This figure further indicates both trends are present – lower and more consistent readings appear for the AmP-MeD device for most patients.

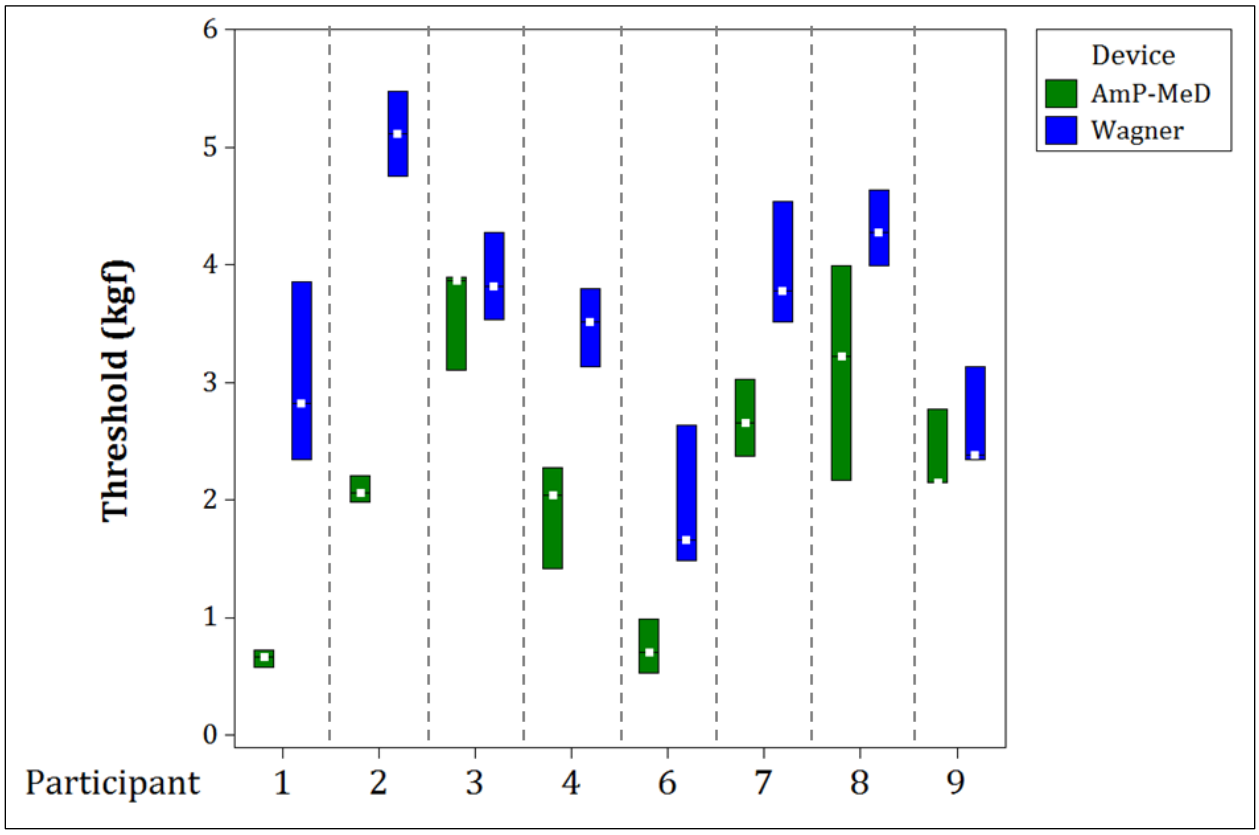

Figure 32: Trimmed Data from Initial Study – Patient 5 omitted to view magnitude and variation within and between groups more closely. Separated by participant (1-9, omitting 5, dashed lines between) and device (green boxes indicate AmP-MeD and blue boxes indicate Wagner). White squares in individual boxes represent median values of that test group.

5.3.2 Study Results

While the initial study was valuable in that it provided trends and added evidence to the existing hypotheses, it only incorporated three data points per device from each participant. In order to increase the power of the results, a second study was performed. This study used the same test setup and instructions as outlined in the initial study (Section 5.3.1 Initial Study Results), but nine data-points were measured and recorded for PPT using each device. Therefore, a total of 18 PPT measurements were recorded for each of the 10 participants. Participants were tested on the right leg using the Wagner device first, then on the left leg using the AmP-MeD device. Each participant was tested in three locations, with three measurements recorded at each location for each measurement technique - Figure 33 diagrams the test locations on each leg. The test locations on the left and right leg were considered equivalent, as supported by literature [13]. Furthermore, the three test locations (A, B, and C, not distinguished per leg) were not randomized, as literature supports that test site sensitivity does not vary in the muscle belly [53].

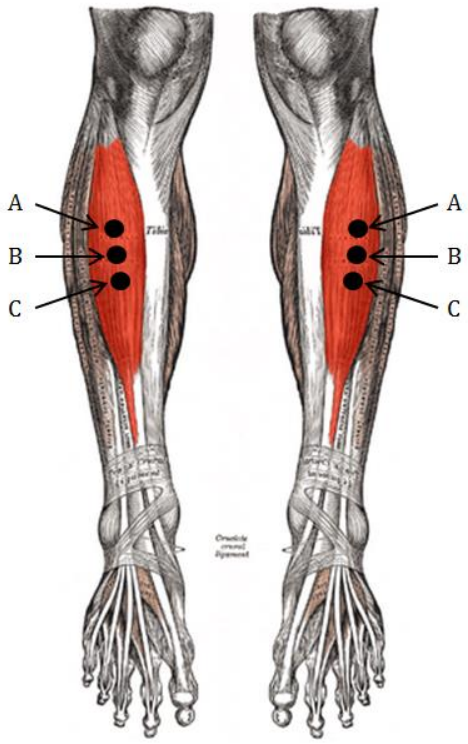

Figure 33: Test Locations for the Study, modified from [F]

This increased sample size gives more data to analyze, makes trends more apparent, and adds the possibility of statistical analysis. The increased study size enables us to examine trends within groups as well as between groups. Figure 34 and Figure 35 show the results from this study. The boxplot shown in Figure 34 is separated by patient and device, while the boxplot shown in Figure 35 is separated by patient, device, and test location (which of the 3 locations on each leg the test was administered).

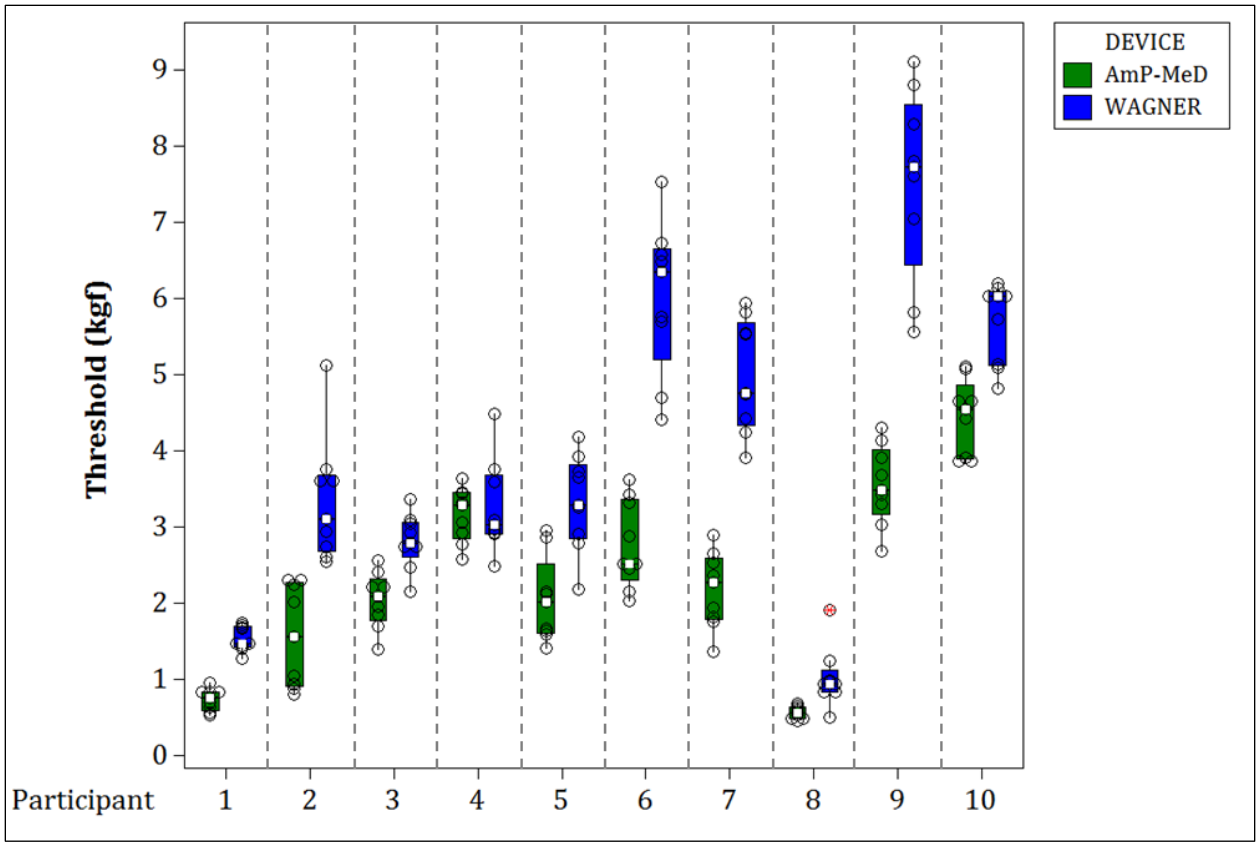

Figure 34: Study Results – Separated by participant (1-10, dashed lines between) and device (green boxes indicate AmP-MeD and blue boxes indicate Wagner). White squares in individual boxes represent median values of that test group, individual data points marked by black circles. Participant 8 includes an outlier, marked by the black circle with a red cross on one Wagner measurement.

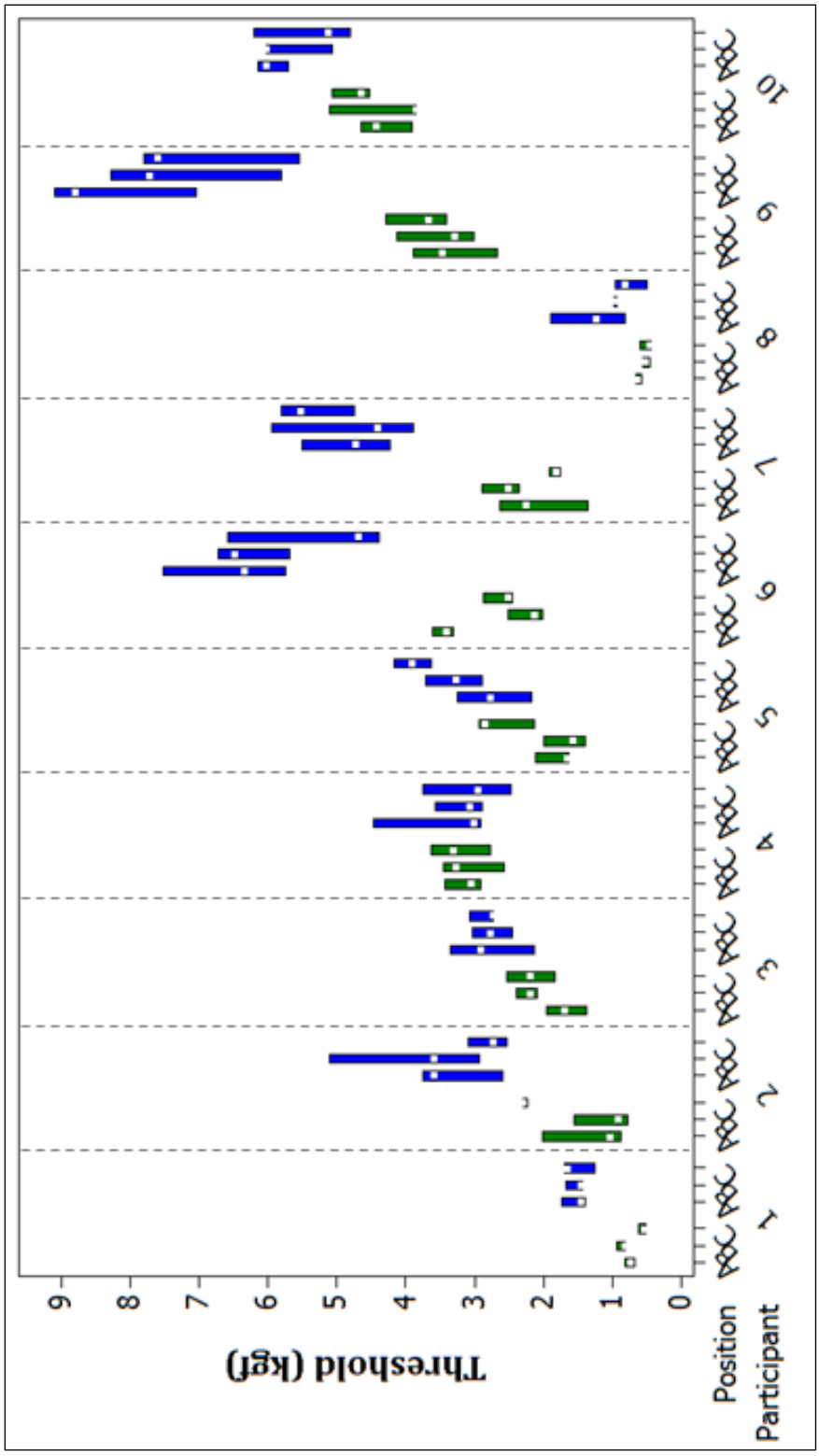

Figure 35: Study Results - Separated by participant (1-10, dashed lines between), device (green boxes indicate AmP-MeD and blue boxes indicate Wagner), and test location (A, B, and C, as depicted in Figure 33). White squares in individual boxes represent median values of that test group.

Statistical analysis supports the visually identified trends. Analysis was performed on all test participants between PPT measurements made by the AmP-MeD device and by the Wagner device to maximize the amount of data analyzed and to assess the differences in each pain measurement device. A summary of the descriptive statistics is shown in Table 8 and Table 9.

Device	Total Count (N)	Mean PPT	StDev PPT
AmP-MeD	90	2.302	1.240
Wagner	90	3.946	2.077

Table 8: Descriptive Statistics Summary. Mean and Standard Deviation (StDev) PPT measurements made on *all* (grouped) test participants by AmP-MeD and Wagner devices.

Device	Participant	Total Count (N)	Mean PPT	StDev PPT
AmP-MeD	1	9	0.731	0.145
	2	9	1.562	0.660
	3	9	2.036	0.363
	4	9	3.160	0.350
	5	9	2.041	0.551
	6	9	2.764	0.574
	7	9	2.172	0.492
	8	9	0.554	0.081
	9	9	3.543	0.520
	10	9	4.452	0.490
Wagner	1	9	1.533	0.166
	2	9	3.333	0.810
	3	9	2.807	0.357
	4	9	3.242	0.599
	5	9	3.318	0.626
	6	9	6.022	0.994
	7	9	4.987	0.739
	8	9	1.011	0.386
	9	9	7.542	1.214
	10	9	5.684	0.527

Table 9: Descriptive Statistics Summary. Mean and Standard Deviation (StDev) PPT measurements made on *each* (separated) test participant by AmP-MeD and Wagner devices.

First, a test for normality was performed on the two groups to assess the assumptions of an ANOVA test. A Ryan-Joiner Test for normality produces a correlation coefficient near 1, so the populations of each group are likely to be normal. However, an Anderson-Darling test produces a P-value below 0.05 for each group. Figure 36 displays the probability plots for each test group, where it is seen that the data deviates from normal at the front-end. Because of the relatively small sample sizes and variations between test participants, this deviation from normality will be considered minimal, and the data will be assumed normal for statistical analysis.

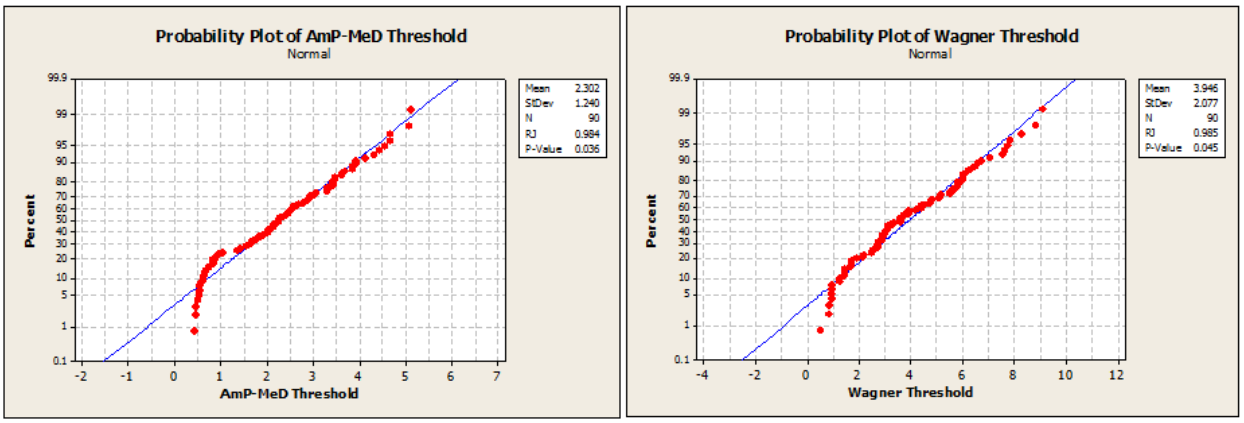

Figure 36: Probability Plots for Normally Distributed Data: separated into PPT measurements made by the AmP-MeD and the Wagner Devices.

In order to statistically assess the trends that were determined with visual analysis, two tests were performed. First, an ANOVA was performed to assess the difference in mean PPT measurements made by either the AmP-MeD or the Wagner device. A P-Value of 0.000 was determined, strongly indicating that there is a significant difference in the mean PPT measurements between devices. Subsequently, a Tukey Test was performed to assess which device measured higher PPT measurements. The test confirmed the visual analysis that the Wagner device measured significantly higher PPT values for all patients than the AmP-MeD. Figure 37 summarizes these statistical results.

```
Source   DF      SS      MS      F      P
DEVICE    1  121.72  121.72  41.60  0.000
Error   178  520.85    2.93
Total   179  642.57

S = 1.711   R-Sq = 18.94%   R-Sq(adj) = 18.49%


                          Individual 95% CIs For Mean Based on
                          Pooled StDev
Level     N   Mean  StDev  --------+---------+---------+---------+-
AmP-MeD  90  2.302  1.240  (-----*-----)
WAGNER   90  3.946  2.077                              (-----*-----)
                          --------+---------+---------+---------+-
                                2.40      3.00      3.60      4.20

Pooled StDev = 1.711


Grouping Information Using Tukey Method

DEVICE    N   Mean  Grouping
WAGNER   90  3.946  A
AmP-MeD  90  2.302    B

Means that do not share a letter are significantly different.
```

Figure 37: ANOVA Results of PPT measurements made by Wagner and AmP-MeD show that there is a significant difference in PPT measured with Wagner versus AmP-Med (P=0.000) and that the Wagner measurements are significantly higher (groups A and B).

In order to assess the trend that there was less variation in PPT measurements made by the AmP-MeD than the Wagner device, a Test for Equal Variance was performed on all PPT measurements made by each device. With a low ratio of variance, P-Values less than 0.05 for both the F-Test and Levene's Test, it is highly likely that the variance of PPT measurements made by Wagner is significantly higher than the variance of PPT measurements made by the AmP-MeD device. Figure 38 summarizes the Test for Equal Variance statistics.

Method

Null hypothesis: Sigma(AmP-MeD) / Sigma(WAGNER) = 1
Alternative hypothesis: Sigma(AmP-MeD) / Sigma(WAGNER) not = 1
Significance level: Alpha = 0.05

Statistics

DEVICE	N	StDev	Variance
AmP-MeD	90	1.240	1.538
WAGNER	90	2.077	4.314

Ratio of standard deviations = 0.597
Ratio of variances = 0.357

95% Confidence Intervals

Distribution of Data	CI for StDev Ratio	CI for Variance Ratio
Normal	(0.484, 0.736)	(0.235, 0.542)
Continuous	(0.483, 0.736)	(0.233, 0.542)

Tests

Method	DF1	DF2	Test Statistic	P-Value
F Test (normal)	89	89	0.36	0.000
Levene's Test (any continuous)	1	178	21.20	0.000

Figure 38: Test for Equal Variance of PPT Measurements made by AmP-MeD and Wagner devices. The low ratio of variance and the low P-values indicate that the Wagner device made measurements with significantly higher variance than the AmP-MeD Device.

Chapter 6

Discussion

From both the initial study and the expanded study, evident trends are observed which support original hypotheses that an automated device may be more desirable than a handheld device.

6.1 Difference in PPT Magnitude between Automated and Handheld Devices

It is clear that the measurements made with the AmP-MeD device are significantly (P=0.000) and systematically lower than the measurements made with the Wagner handheld device. There are multiple reasons for this result which introduce interesting hypotheses that further indicate the advantages of an automated device. Firstly, it is hypothesized that patients trust a human test administrator more than a machine, and since there is a sense of distrust with an automated device, a patient will indicate a PPT or PPTol value earlier than with a handheld device, thus buying time to "escape" or stop the test if the machine does not respond as expected. This psychological effect could play a role in the magnitude discrepancy between the measurement results. However, all participants tested thus far have been Mechanical Engineering students who are familiar with the device and research– thus they have reported little intimidation or "fear" of the device, and certainly less than a non-technical, less informed participant may be.

While this psychological effect may still be present, it is consistent throughout all ten participants tested – this may indicate that the psychological effects of the automated

device are more consistent from participant to participant than the psychological effects of the handheld device. This hypothesis is further backed by the observations that the automated device is exactly the same in every test – the testing environment can be closely controlled, and the patient-machine interface remains constant in every test with the AmP-MeD. However, a handheld device may be operated in many different environments with many different test administrators. This inconsistency in testing environment creates large variation between testing sessions, which makes psychological and psychosocial factors virtually impossible to monitor, and thus impossible to minimize. With the consistent testing environment provided by an automated device, psychological and psychosocial factors are still present, but they are constant between testing sessions and between patient and test administrators; thus, they are more easily monitored and minimized, and variation of these factors between tests is nearly eliminated.

Secondly, and very importantly, the difference in magnitude between the PPT measurements is likely due to sensitivity of the automated device. When the participant indicates PPT or PPTol by a button press during an automated-device test, the machine immediately records the applied force within a millisecond. When the participant indicates PPT or PPTol by verbal communication with the test administrator during a handheld device test, the time between the participant's decision that s/he has reached PPT or PPTol, the participant's verbalization of this information, the test administrator's recognition of the information, and the test administrator's action of stopping the test and recording the force at that time is significant. This lost time results in increased PPT and PPTol measurements with handheld measurements, as the pressure is still being applied while

this time is lost. For these reasons, we may hypothesize that the AmP-MeD device successfully increases measurement sensitivity.

6.2 Less Variation in Measurements with Automated versus Handheld Device

It is observed that there is less variation in measurements made by the AmP-MeD versus the handheld Wagner device. Minitab analysis determined that there is a significant difference in the variances between measurements made by the AmP-MeD and Wagner devices, with the AmP-MeD measurements showing significantly less variance than the Wagner measurements. This smaller variance indicates that measurements made using the automated device are more reliable and more repeatable than measurements made using the handheld device – a significant improvement which could lead to improved understanding of pain measurement.

6.3 AmP-MeD versus CCPA

As discussed in Section 5.1 AmP-MeD in comparison to Wagner and CCPA Devices, the AmP-MeD device offers significant benefits over the original CCPA. Namely, the usability, functionality, and aesthetics have been drastically improved. This goal was further validated by the testing, where it was evident that the improvements featured in the AmP-MeD make an enormous difference in both the test administrator and patient experience. A second test administrator was briefly trained for this testing to assess the ease of use of the device. The simplicity of the setup and ease of use of the operating system were immediately apparent. The data recording and analysis was also perceived as streamlined and clear. The size/weight/aesthetics of the device each contribute to the ease of use, as well as the multiple safety mechanisms (outlined in Section 4.6 Safety and Emergency

Stops). Overall, the streamlined design improves the usability, functionality, and aesthetics of the device such that all users are positively impacted.

6.4 Participant and Test Administrator Feedback

Many of the participants from the study provided feedback which may enable future enhancements of the device and test methods. Firstly, a couple of participants commented that that outstretched, horizontal testing position for the handheld device test, pictured in Figure 39, stretched his/her hamstring. This may have introduced a secondary source of pain, which has been shown to affect pain measurement. Secondly, some participants reported that they felt more sensitive on the third PPT measurement in one location than on the first or second. This increased sensitivity could be attributed to sensitization, although the opposite (habituation) is also thought to occur simultaneously. Participants also reported the different test locations to feel more/less sensitive than others, although the test locations were separated by one inch and were all along the belly of the tibialis anterior (as pictured in Figure 33). One participant noted that if the pressure application tip was angled upward, it may produce a more perpendicular contact with the tibialis anterior, as the leg diameter increases the more proximal to the body. This feedback will be considered in the future work of the device in order to improve the device and testing methods. Finally, one participant remarked that if the test administrator touched him in another location close to the test site (in the handheld device testing), he became confused as to which sensation was which for PPT measurements. This situation is pictured in Figure 40, where the test administrator may rest a hand on the participant's leg to stabilize the testing.

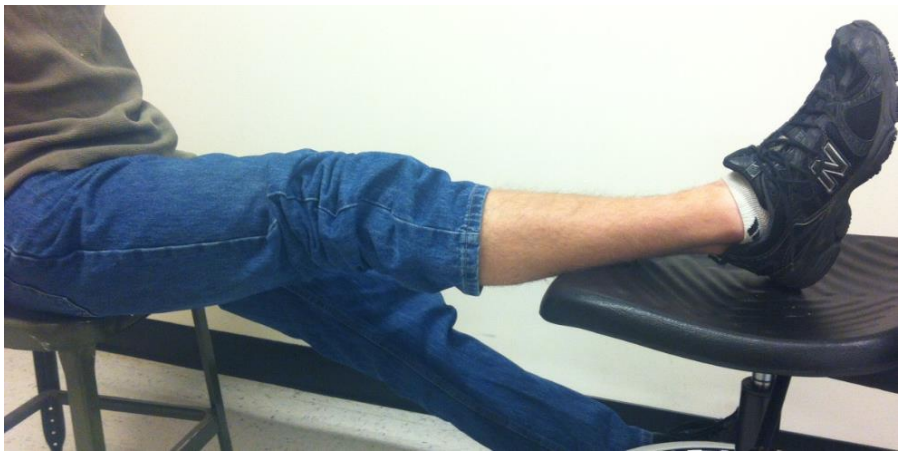

Figure 39: Wagner Handheld Device Testing Position

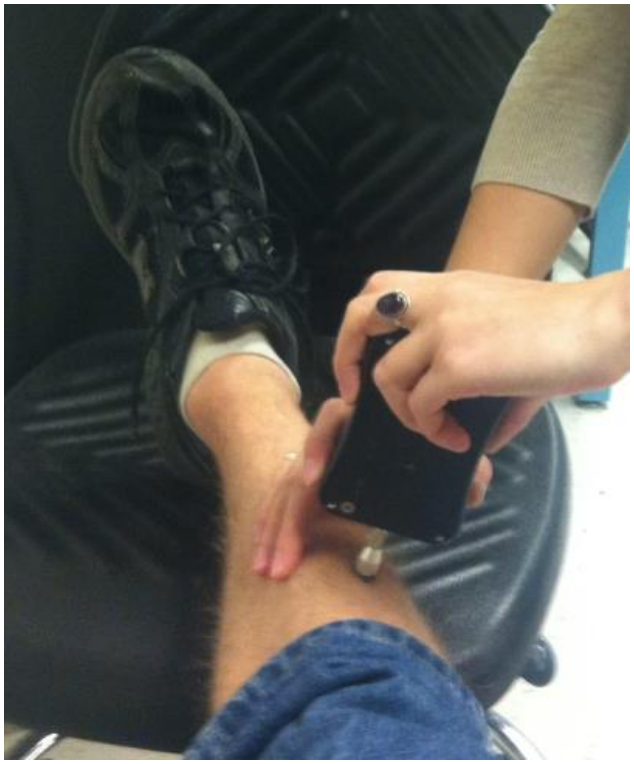

Figure 40: Wagner Testing, with Test Administrator's Right Hand Making Contact with Participant

One participant that was tested was involved in the CCPA testing with Zimkowski, and had valuable comments on the differences between the two test experiences. Firstly, it was noted that the AmP-MeD device was much less intimidating than the CCPA because of size, design, and actuation method (the loud air compressor used with the CCPA was intimidating and bulky). Secondly, it was noted that safety enhancements were obvious with the AmP-MeD and the testing seemed much more reliable. Thirdly, the ease of use for the operator and the participant were noted as being vastly improved. The fact that the participant was not required to help with leg positioning (as in the CCPA where scooting up and down in the frame with internal/external rotation of the leg was necessary) and that the testing setup was short and simple made the testing experience easier on the participant. However, some shortcomings were noted that could contribute to future work goals. First, it was noted that the test administrator must bend down to adjust the device before and between tests. While this is not an issue for a young and able-bodied test administrator, some individuals may find this uncomfortable and inconvenient. Secondly, it was observed that the arm of the device can deflect away from the participant at higher forces (this was observed with PPTol measurements only), as shown in Figure 41, which may result in inaccurate displacement measurements. This observation will be taken into account if a second-generation AmP-MeD is created, and if PPTol measurements are made.

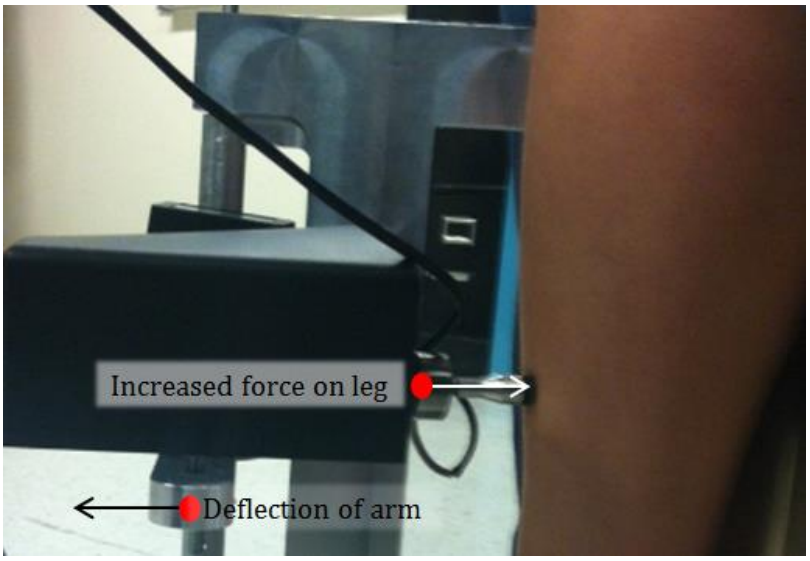

Figure 41: Deflection of AmP-MeD Arm at High Forces

Chapter 7

Future Directions

Now that a successful device has been designed, developed, and validated, it must be integrated with physiological data measurements in order to conduct larger studies. The integration with physiological data was not a focus of this project, as it has already been achieved by Zimkowski [9]. The physiological data integration will follow the methodology outlined in Zimkowski's thesis and other documentation, and no significant changes are anticipated.

Once physiological data is successfully measured with the AmP-MeD, a larger study will be possible. If ~50 participants were tested using the device, research analysis could be performed to investigate the correlation of the objective physiological data with the subjective participant input data.

If the relationship between objective and subjective pain responses is established, it will be possible to measure a personalized pain scale at any clinic using typical vital sign measurement devices. Although this relationship may be difficult to fully understand, personalized pain scales may still be easily measured in any clinic using the AmP-MeD in addition blood pressure and heart rate measurement equipment. The integration of the AmP-MeD device into a clinic could be streamlined easily, as vital signs are typically already measured at the beginning of any clinic exam. With the data collected on blood pressure and heart rate, the pain data would be easily integrated into digital medical records, establishing a pain scale over time for each patient.

Chapter 8

Conclusion

Although future work is necessary to accomplish a better understanding of pain, the work described in this thesis takes us one step closer to accomplishing improved pain measurement techniques. The design, development, and verification of the AmP-MeD summarized in this thesis shows that the device is a novel tool for pain research that may provide insight into the understanding of pain.

Using the AmP-MeD device in the future to enable personalized pain scales to be measured in clinics would help clinicians to better understand pain, more accurately diagnose it, and more appropriately treat it. With the improved understanding and treatment of pain, millions of people around the globe would experience less hardship due to chronic and acute pain; resulting in higher qualities of life, lower costs of healthcare, a reduced burden of pain and pain medications in the daily lives of people around the world.

Chapter 9

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Chapter 10

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Chapter 11

Appendices

Appendix 11.1 Oswestry Disability Index

Section 1: Pain Intensity
□ I can tolerate the pain I have without having to use pain killers. [0 points]
□ The pain is bad but I manage without taking pain killers. [1 point]
□ Pain killers give complete relief from pain . [2 points]
□ Pain killers give moderate relief from pain. [3 points]
□ Pain killers give very little relief from pain. [4 points]
□ Pain killers have no effect on the pain and I do not use them. [5 points]

Section 2: Personal Care
□ I can look after myself normally without causing extra pain. [0 points]
□ I can look after myself normally but it causes extra pain. [1 point]
□ It is painful to look after myself and I am slow and careful. [2 points]
□ I need some help but manage most of my personal care. [3 points]
□ I need help every day in most aspects of self care. [4 points]
□ I do not get dressed wash with difficulty and stay in bed. [5 points]

Section 3: Lifting
□ I can lift heavy weights without extra pain. [0 points]
□ I can lift heavy weights but it gives extra pain. [1 point]
□ Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned for example on a table. [2 points]
□ Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned. [3 points]
□ I can lift only very light weights. [4 points]
□ I cannot lift or carry anything at all. [5 points]

Section 4: Walking
□ Pain does not prevent me walking any distance. [0 points]
□ Pain prevents me walking more than 1 mile. [1 point]
□ Pain prevents me walking more than 0.5 miles. [2 points]
□ Pain prevents me walking more than 0.25 miles. [3 points]
□ I can only walk using a stick or crutches. [4 points]
□ I am in bed most of the time and have to crawl to the toilet. [5 points]

Section 5: Sitting
□ I can sit in any chair as long as I like. [0 points]
□ I can only sit in my favorite chair as long as I like. [1 point]
□ Pain prevents me sitting more than 1 hour. [2 points]
□ Pain prevents me from sitting more than 0.5 hours. [3 points]
□ Pain prevents me from sitting more than 10 minutes. [4 points]
□ Pain prevents me from sitting at all. [5 points]

Section 6: Standing

□ I can stand as long as I want without extra pain. [0 points]
□ I can stand as long as I want but it gives me extra pain. [1 point]
□ Pain prevents me from standing for more than 1 hour. [2 points]
□ Pain prevents me from standing for more than 30 minutes. [3 points]
□ Pain prevents me from standing for more than 10 minutes. [4 points]
□ Pain prevents me from standing at all. [5 points]

Section 7: Sleeping
□ Pain does not prevent me from sleeping well. [0 points]
□ I can sleep well only by using tablets. [1 point]
□ Even when I take tablets I have less than 6 hours sleep. [2 points]
□ Even when I take tablets I have less than 4 hours sleep. [3 points]
□ Even when I take tablets I have less than 2 hours of sleep. [4 points]
□ Pain prevents me from sleeping at all. [5 points]

Section 8: Sex Life
□ My sex life is normal and causes no extra pain. [0 points]
□ My sex life is normal but causes some extra pain. [1 point]
□ My sex life is nearly normal but is very painful. [2 points]
□ My sex life is severely restricted by pain. [3 points]
□ My sex life is nearly absent because of pain. [4 points]
□ Pain prevents any sex life at all. [5 points]

Section 9: Social Life
□ My social life is normal and gives me no extra pain. [0 points]
□ My social life is normal but increases the degree of pain. [1 point]
□ Pain has no significant effect on my social life apart from limiting energetic interests such as dancing. [2 points]
□ Pain has restricted my social life and I do not go out as often. [3 points]
□ Pain has restricted my social life to my home. [4 points]
□ I have no social life because of pain. [5 points]

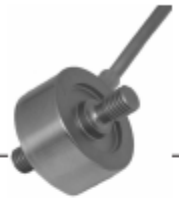
Section 10: Travelling
□ I can travel anywhere without extra pain. [0 points]
□ I can travel anywhere but it gives me extra pain. [1 point]
□ Pain is bad but I manage journeys over 2 hours. [2 points]
□ Pain restricts me to journeys of less than 1 hour. [3 points]
□ Pain restricts me to short necessary journeys under 30 minutes. [4 points]
□ Pain prevents me from traveling except to the doctor or hospital. [5 points]

Appendix 11.2 Load Cell Datasheet

Honeywell

Model 31 Mid

Mid Range Precision Miniature Load Cell



DESCRIPTION

Model 31 mid range precision miniature load cells measure both tension and compression load forces of 1000 g to 1000 lb. These models are our highest accuracy, rugged miniature load cells. Model 31's welded, stainless steel construction is designed to eliminate or reduce to a minimum, the effects of off-axis loads. (The internal construction assures excellent long-term stability for ranges 1000 grams and above.) A modification permits this model to be completely welded for underwater applications.

The Model 31 tension/compression load cell has male threads attachments. High accuracies of 0.15 % to 0.25 % full scale are achieved. Each bonded strain gage unit is built of welded 17-4 PH stainless steel for additional ruggedness. All load cells with ranges from 1 kg to 10 lb have an electrical balance module in the lead wire (approximately 1 in x .087 in thick). This balance module does not have to be the same temperature as the transducer.

FEATURES

- 1000 g to 1000 lb
- mV/V output
- Stainless steel
- Miniature design

Model 31 Mid

PERFORMANCE SPECIFICATIONS

Characteristic	Measure
Load ranges[4]	1000 g, 5 lb, 10 lb, 25 lb, 50 lb, 100 lb, 250 lb, 500 lb, 1000 lb
Linearity 1000 g to 250 lb	±0.15 % full scale
Linearity 500 lb to 1000 lb	±0.2 % full scale
Hysteresis 1000 g to 250 lb	±0.15 % full scale
Hysteresis 500 lb to 1000 lb	±0.2 % full scale
Non-repeatability 1000 g	±0.1 % full scale
Non-repeatability 5 lb to 1000 lb	±0.05 % full scale
Tolerance on output 1000 g	1.5 mV/V (nominal)
Tolerance on output 5 lb to 1000 lb	2 mV/V
Operation	Tension/compression [3]
Resolution	Infinite

ENVIRONMENTAL SPECIFICATIONS

Characteristic	Measure
Temperature, operating	-53 °C to 121 °C [-65 °F to 250 °F]
Temperature, compensated	15 °C to 71 °C [60 °F to 160 °F]
Storage temperature	-73 °C to 148 °C [-100 °F to 300 °F]
Temperature effect, zero	0.005 % full scale/°F
Temperature effect, span	0.005 % full scale/°F

ELECTRICAL SPECIFICATIONS

Characteristic	Measure
Strain gage type	Bonded foil
Excitation (calibration) 1 kg to 10 lb	5 Vdc
Excitation (calibration) 25 lb to 1000 lb	10 Vdc
Insulation resistance	5000 Mohm @ 50 Vdc
Bridge resistance	350 ohm
Zero balance	1 % max.
Electrical termination (std)	Teflon cable (1524 mm [60 in])

MECHANICAL SPECIFICATIONS

Characteristic	Measure
Maximum allowable load	150 % FS[1]
Weight	See table
Material	17-4 PH stainless steel
Deflection full scale	See table
Natural frequency	See table

RANGE CODES

Range codes	Range
AR	1000 g
AT	5 lb
AV	10 lb
BL	25 lb
BN	50 lb
BR	100 lb
CN	250 lb
CR	500 lb
CV	1000 lb

WIRING CODES

Cable	Unamplified
Red	(+) excitation
Black	(-) excitation
Green	(-) output
White	(+) output

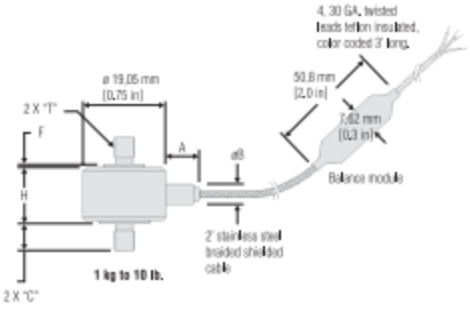
DEFLECTIONS AND RINGING FREQUENCIES

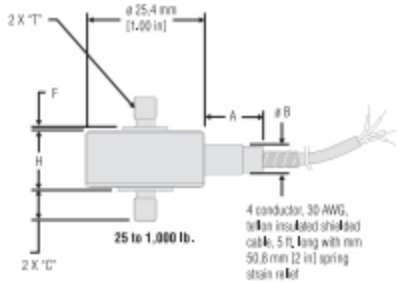
Capacity (lb)	Deflection at full scale (in)	Ringing frequency (Hz)	Weight (g)
1000 g to 10 lb	0,03 mm [0.001 in]	3000 Hz	21 g
25 lb to 100 lb	0,03 mm [0.001 in]	10000 Hz	63 g
250 lb to 1000 lb	0,04 mm [0.0015 in]	12000 Hz	80 g

Mid Range Precision Miniature Load Cell

MOUNTING DIMENSIONS

Ranges (lb)	T	H	C	F	A	B
1000 g, 5 lb, 10 lb	#6-32 UNC	11,43 mm [0.45 in]	6,35 mm [0.25 in]	1,27 mm [0.05 in]	7,87 mm [0.31 in]	4,83 mm [0.19 in]
25 lb, 50 lb, 100 lb	#10-32 UNF	13,21 mm [0.52 in]	6,35 mm [0.25 in]	0,76 mm [0.03 in]	12,7 mm [0.50 in]	6,35 mm [0.25 in]
250 lb, 500 lb, 1000 lb	1/4-28 UNF	13,21 mm [0.52 in]	9,65 mm [0.38 in]	0,76 mm [0.03 in]	12,7 mm [0.50 in]	6,35 mm [0.25 in]





OPTION CODES

	Many range/option combinations are available in our quick-ship and fast-track manufacture programs. Please see http://sensing.honeywell.com/TMsensor-ship for updated listings.
Load range	1000 g, 5 lb, 10 lb, 25 lb, 50 lb, 100 lb, 250 lb, 500 lb, 1000 lb
Temperature compensation	1a. 60 °F to 160 °F 1b. 30 °F to 130 °F 1c. 0 °F to 185 °F 1d. -20 °F to 130 °F 1e. -20 °F to 200 °F 1f. 70 °F to 250 °F 1g. 70 °F to 325 °F 1h. 70 °F to 400 °F 1i. -65 °F to 250 °F 1j. 0 °C to 50 °C 1k. -20 °C to 85 °C 1m. -25 ° to 110 °C
Internal amplifiers	2u. Unamplified, mV/V output
Overload stops	4a. Overload stops
Electrical termination	6a. Bendix PTIH-10-6P - 6 pin (max. 250 °F)[5] 6d. Microtec DR-4S-4H 4 pin 6e. Integral cable: Teflon 6f. Integral cable: PVC 6h. Integral cable: Silicone 6i. Integral underwater cable (max. 180 °F) 6v. Phoenix connector on end of cable 15d. Connector on end of cable
Special calibration	9a. 10 point (5 up/5 down) 20 % increments @ 20 °C 9b. 20 point (10 up/10 down) 10 % increments @ 20 °C
Special calibration	30a. Compression only calibration, positive in compression 30b. Tension and compression calibration, positive in tension 30c. Compression only calibration, negative in compression
Shock and vibration	44a. Shock and vibration resistance
Interfaces[4]	53e. Signature calibration[7] 53t. TEDS IEEE 1451.4 module

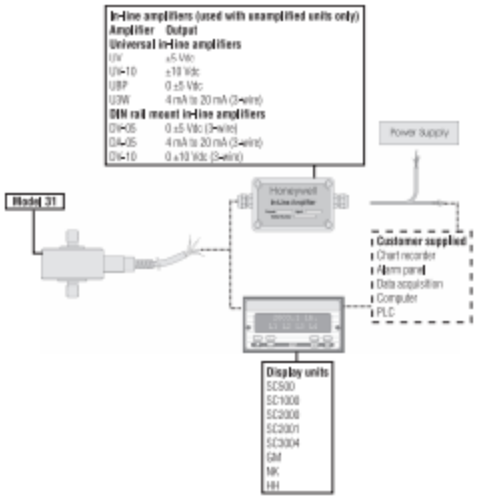
Model 31 Mid

Mid Range Precision Miniature Load Cell

NOTES

1. Allowable maximum loads - maximum load to be applied without damage. [2]
2. Without damage - loading to this level will not cause excessive zero shift or performance degradation. The user must consider fatigue life for long term use and structural integrity. All structurally critical applications (overhead loading, etc.) should always be designed with safety redundant load paths.
3. Standard calibration for tension/compression load cells is in tension only.
4. TEDS available with integral cable units only.
5. Availability varies with range.
6. This unit calibrated to Imperial (non-Metric) units.
7. Signature calibration only available as inline module.

TYPICAL SYSTEM DIAGRAM



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May 2008

Appendix 11.3 LabVIEW Code

AmP_MeD.lvproj

11.3.1 Motor Encoder Reset, Button and Load Cell Control

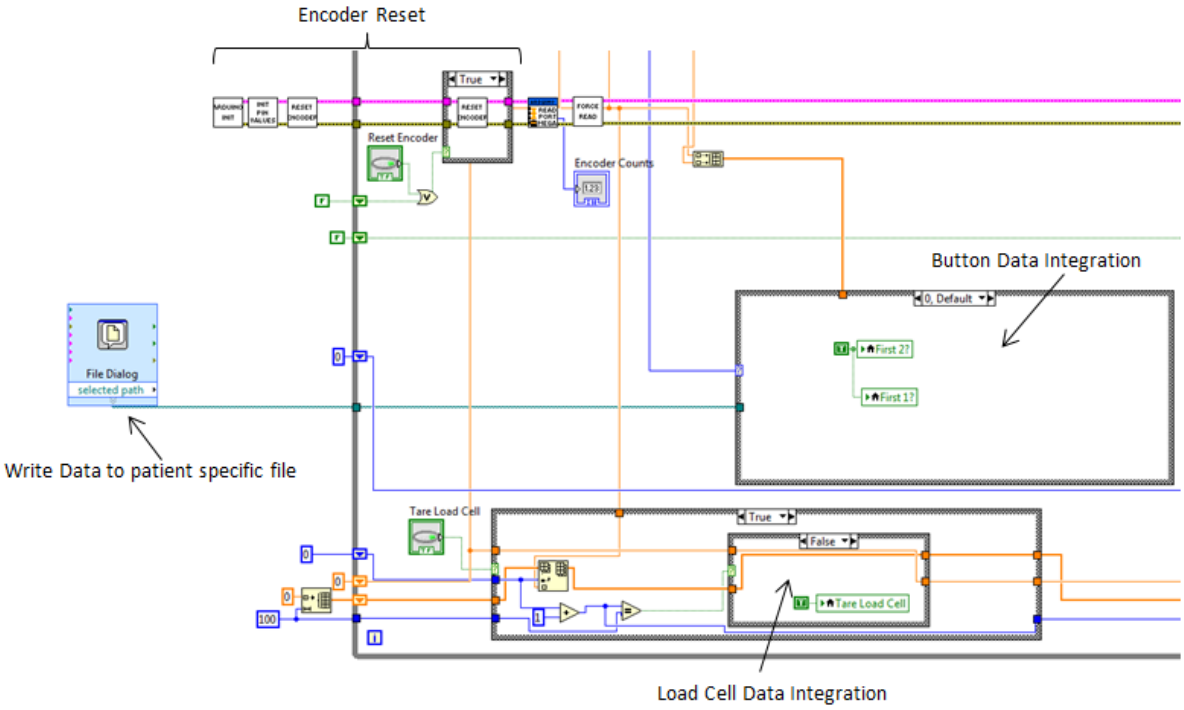


Figure 42: LabVIEW Code - Motor Encoder Reset, Button and Load Cell control

11.3.2 Automatic Control (Case 0)

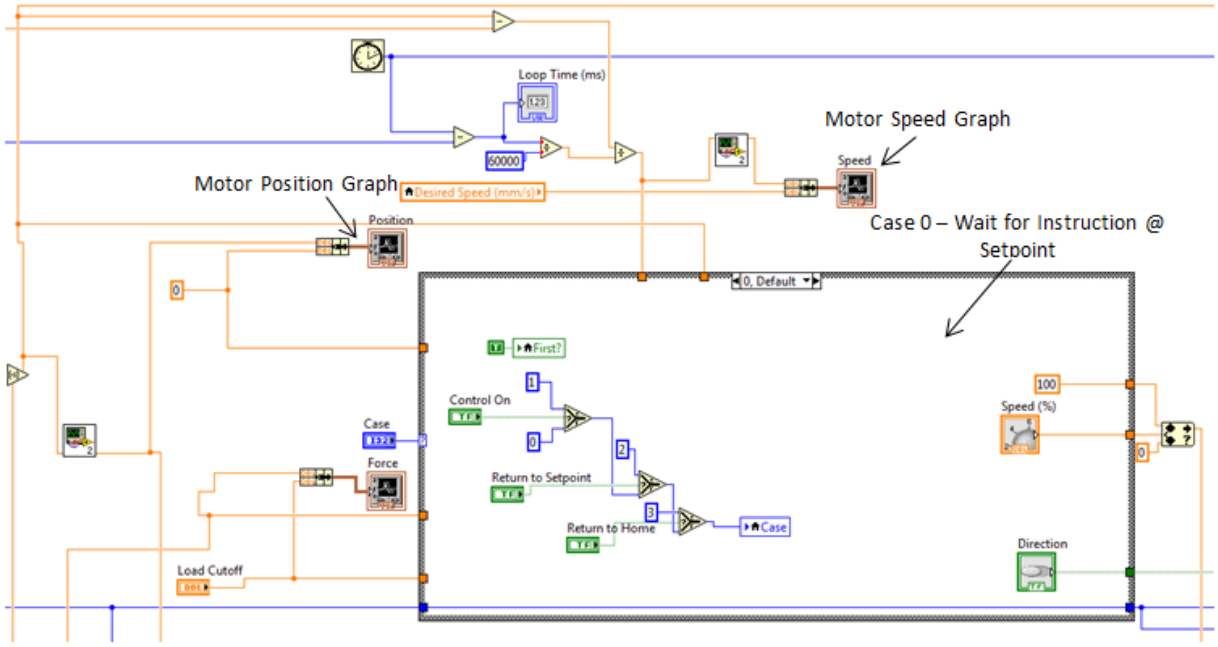


Figure 43: LabVIEW Automatic Control (Case 0)

11.3.3 Automatic Control (Case 1)

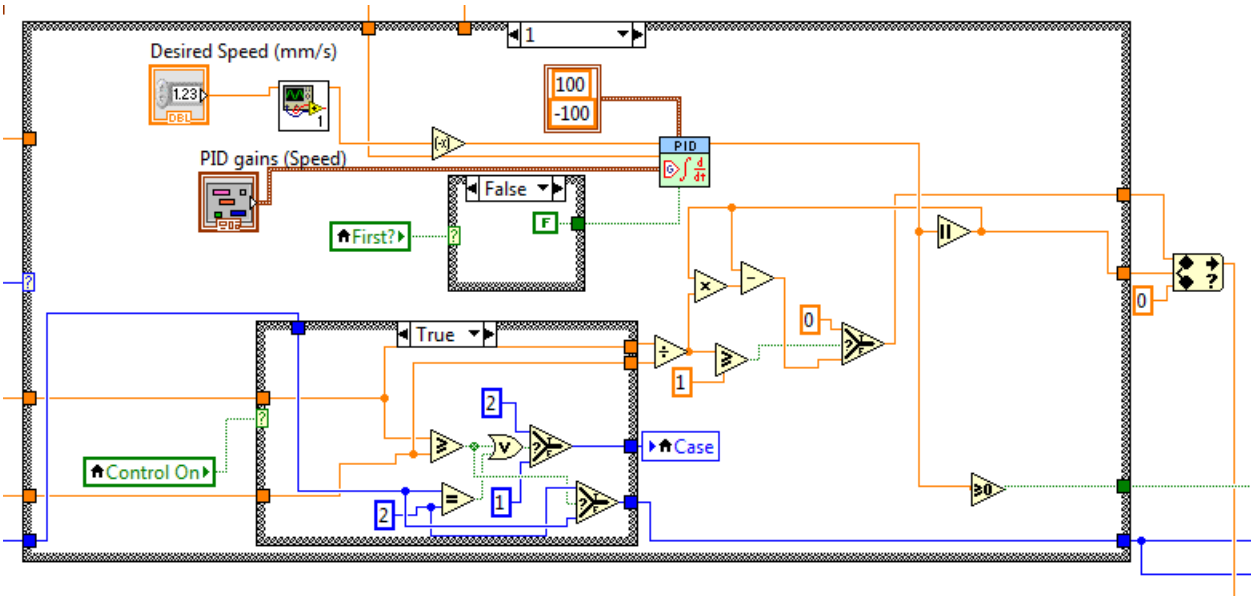


Figure 44: LabVIEW Automatic Control (Case 1)

11.3.4 Automatic Control (Case 2)

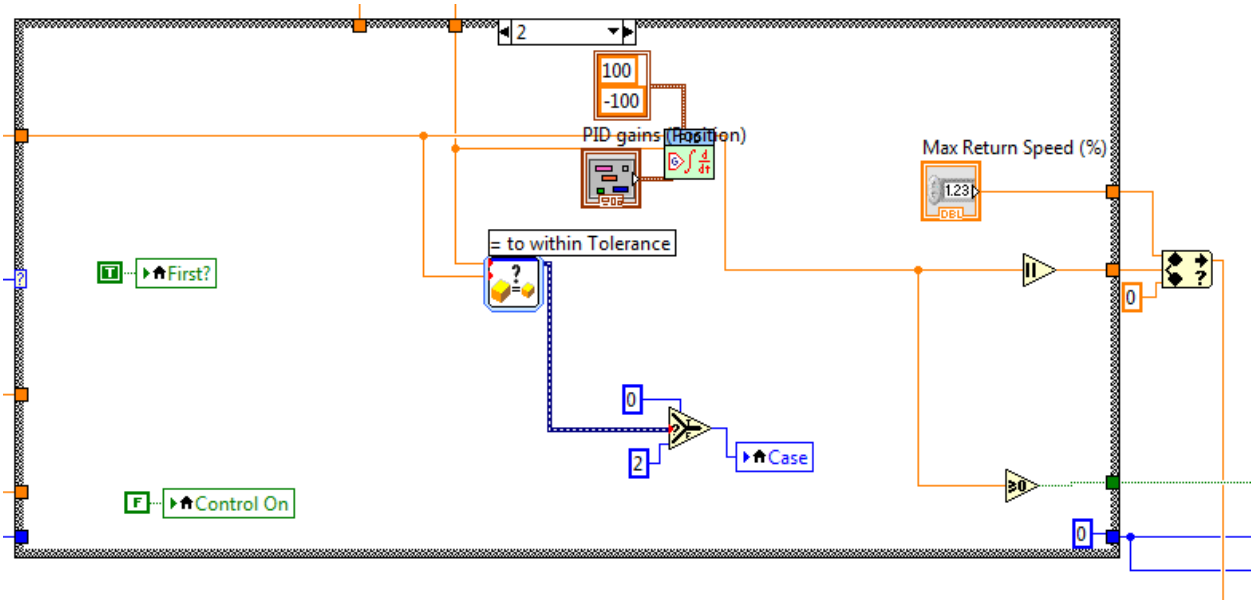


Figure 45: LabVIEW Automatic Control (Case 2)

11.3.5 End of Control Loop – Integration with Mechanical Safety Stop

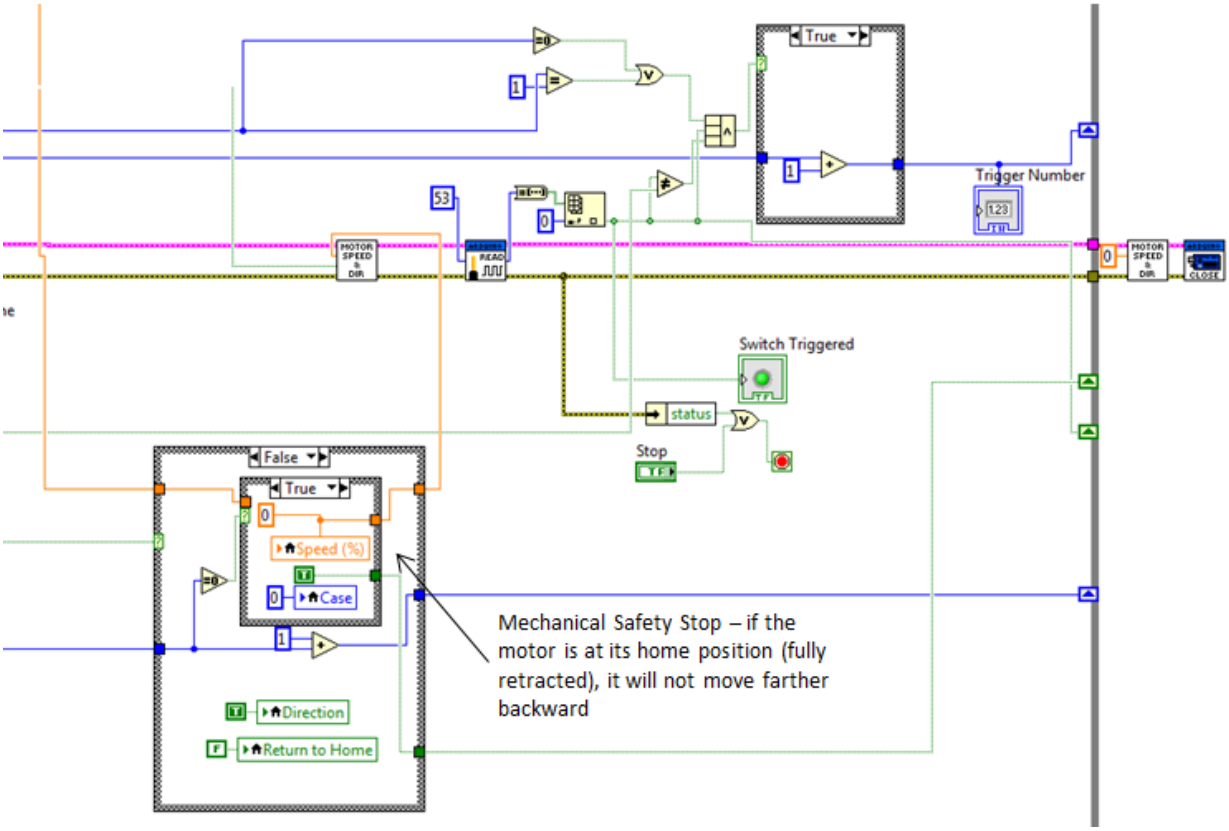
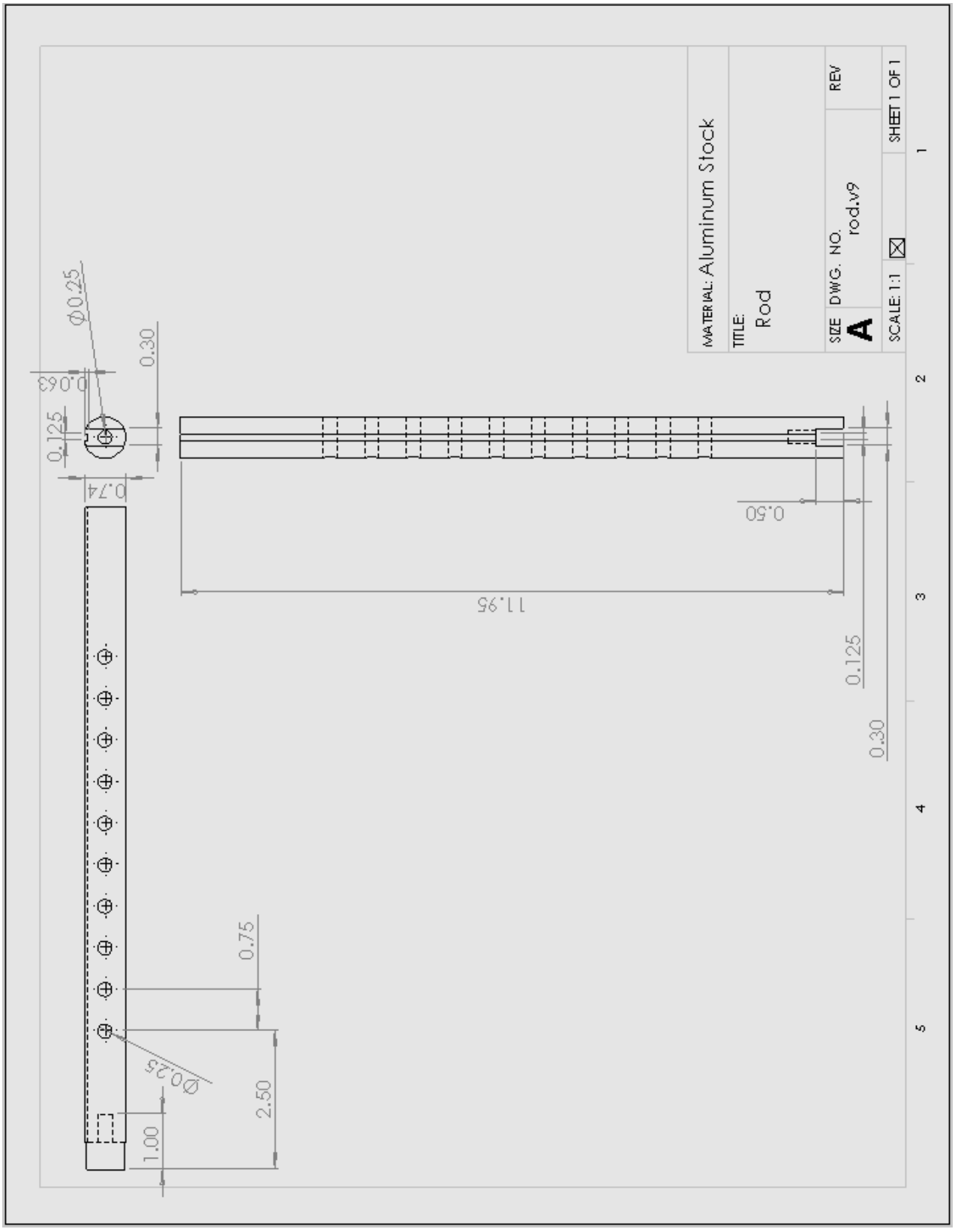
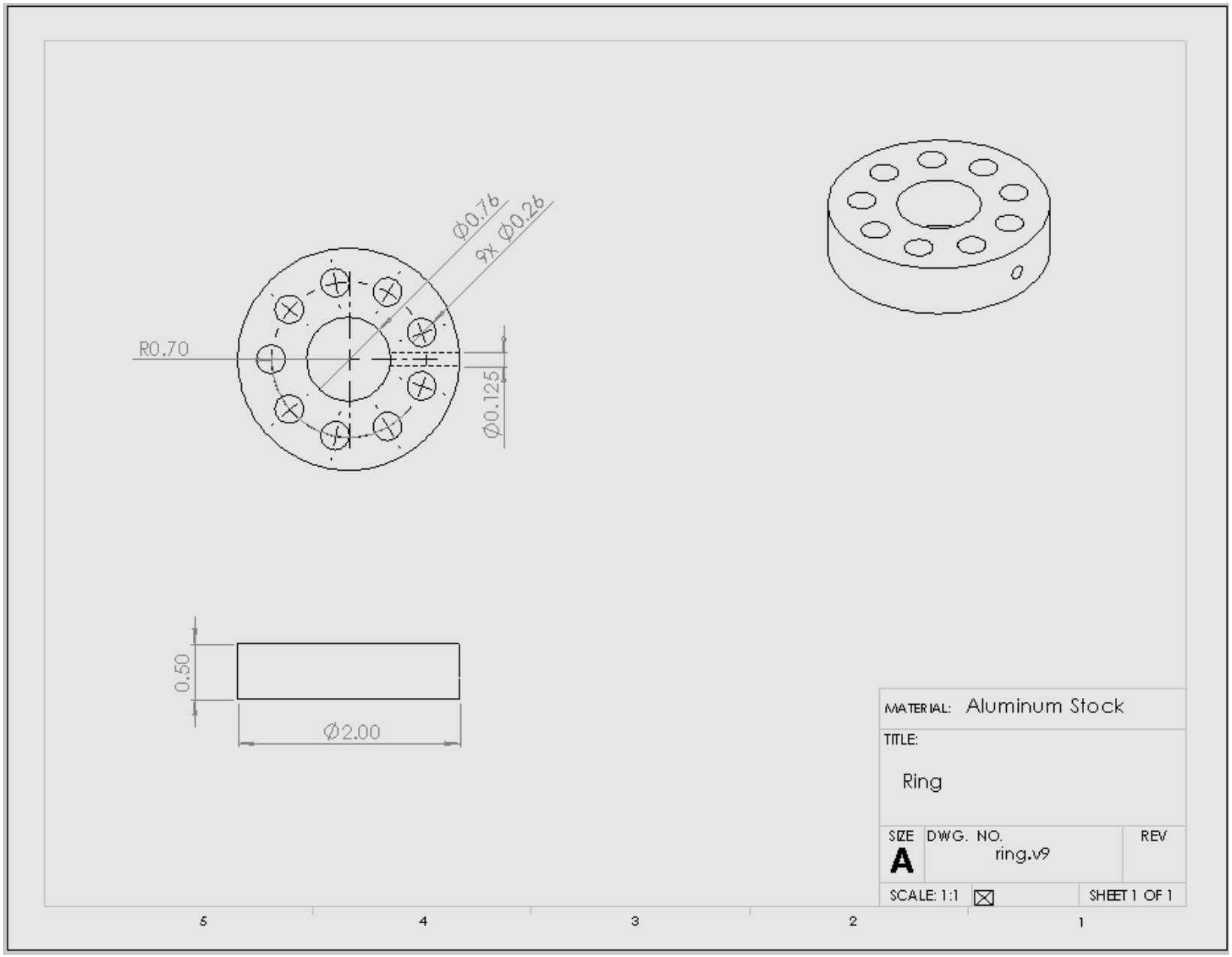


Figure 46: LabVIEW End of Control Loop - Integration with Mechanical Safety Stop

Appendix 11.4 SolidWorks Part Drawings for Frame Fabrication




Ø0.76
9x Ø0.26
R0.70
Ø0.125
0.50
Ø2.00
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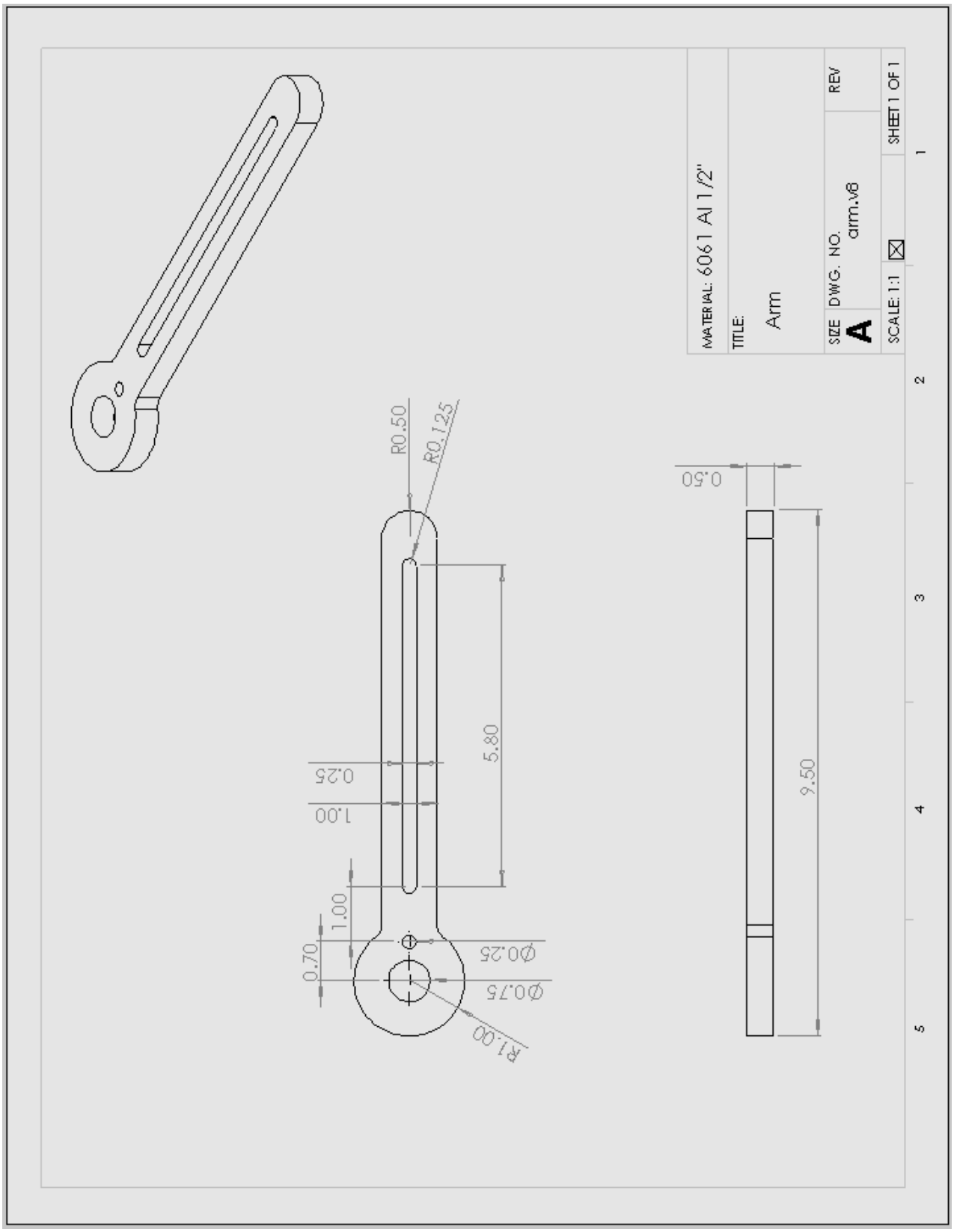
DWG. NO.
ring.v9
REV
SCALE: 1:1
SHEET 1 OF 1
5
4
3
2
1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TITLE:
Arm
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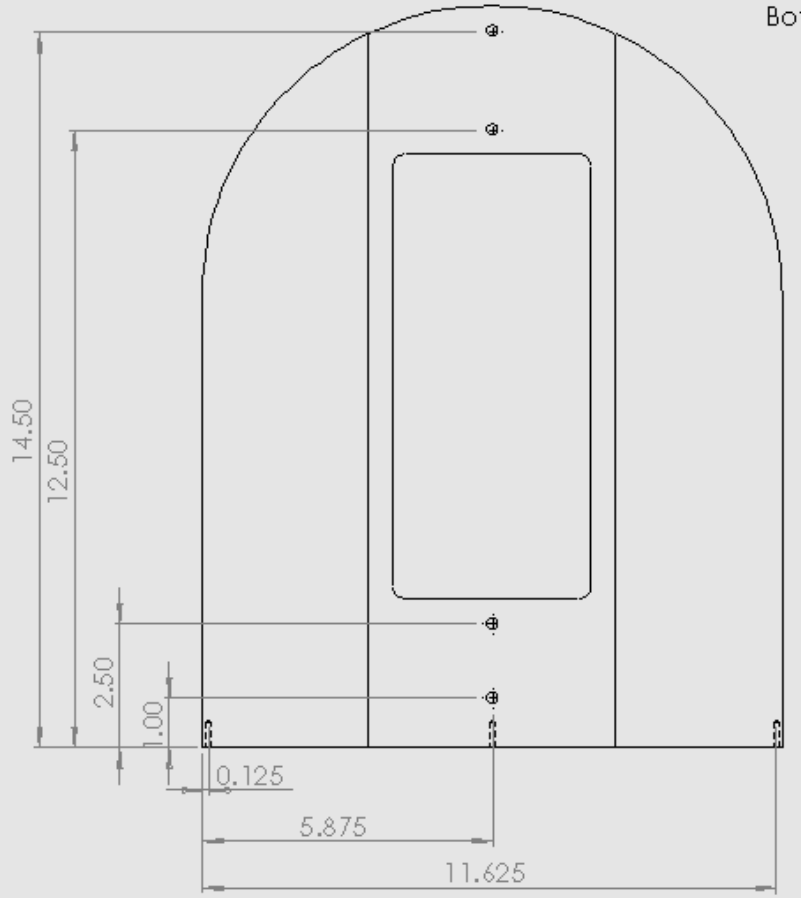
A
DWG. NO.
arm.v8
REV
SCALE: 1:1
SHEET 1 OF 1
R0.50
R0.125
5.80
0.25
1.00
1.00
0.70
Ø0.25
Ø0.75
R1.00
0.50
9.50

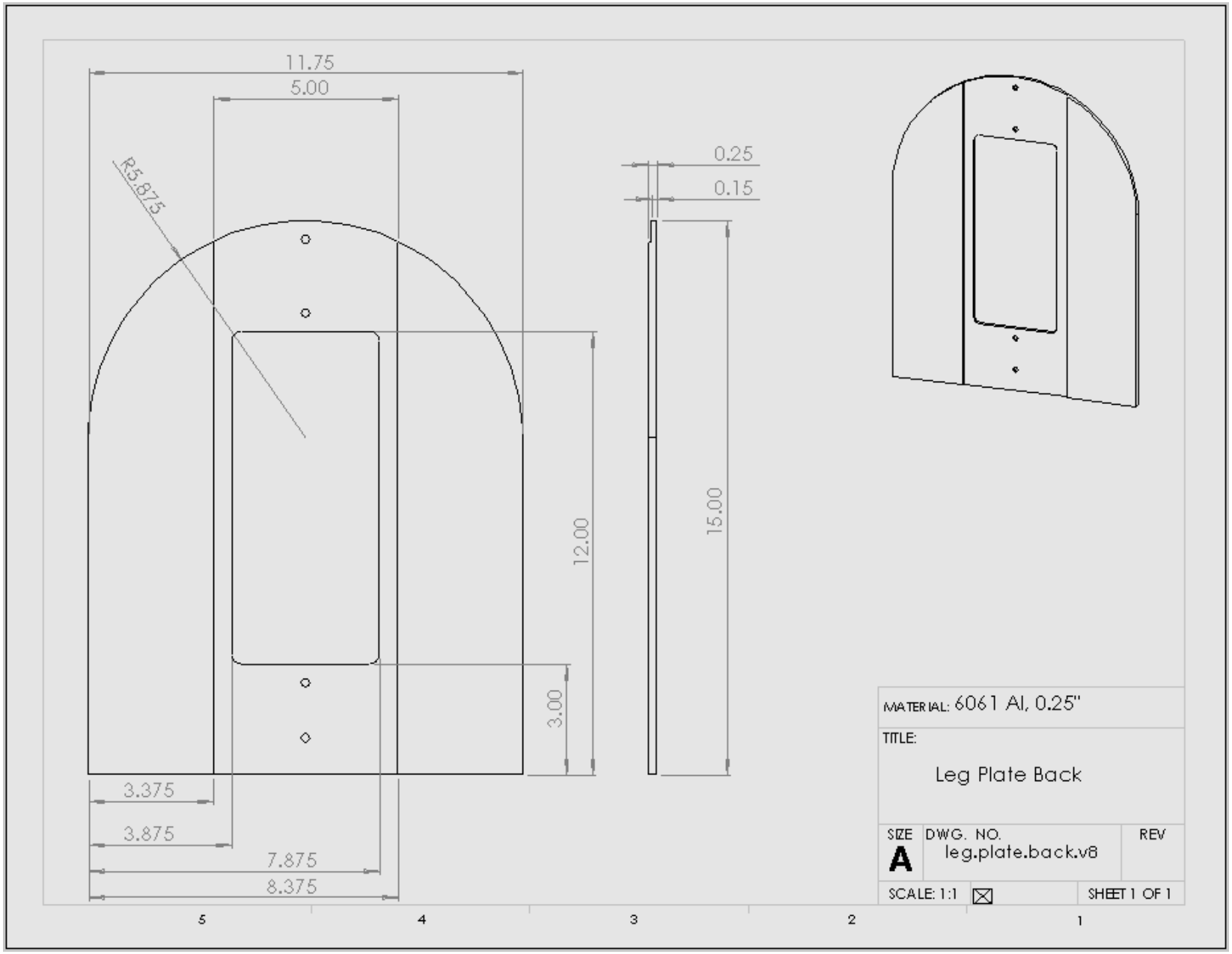
Front Holes are Counter-Sunk for 6/32 Screws

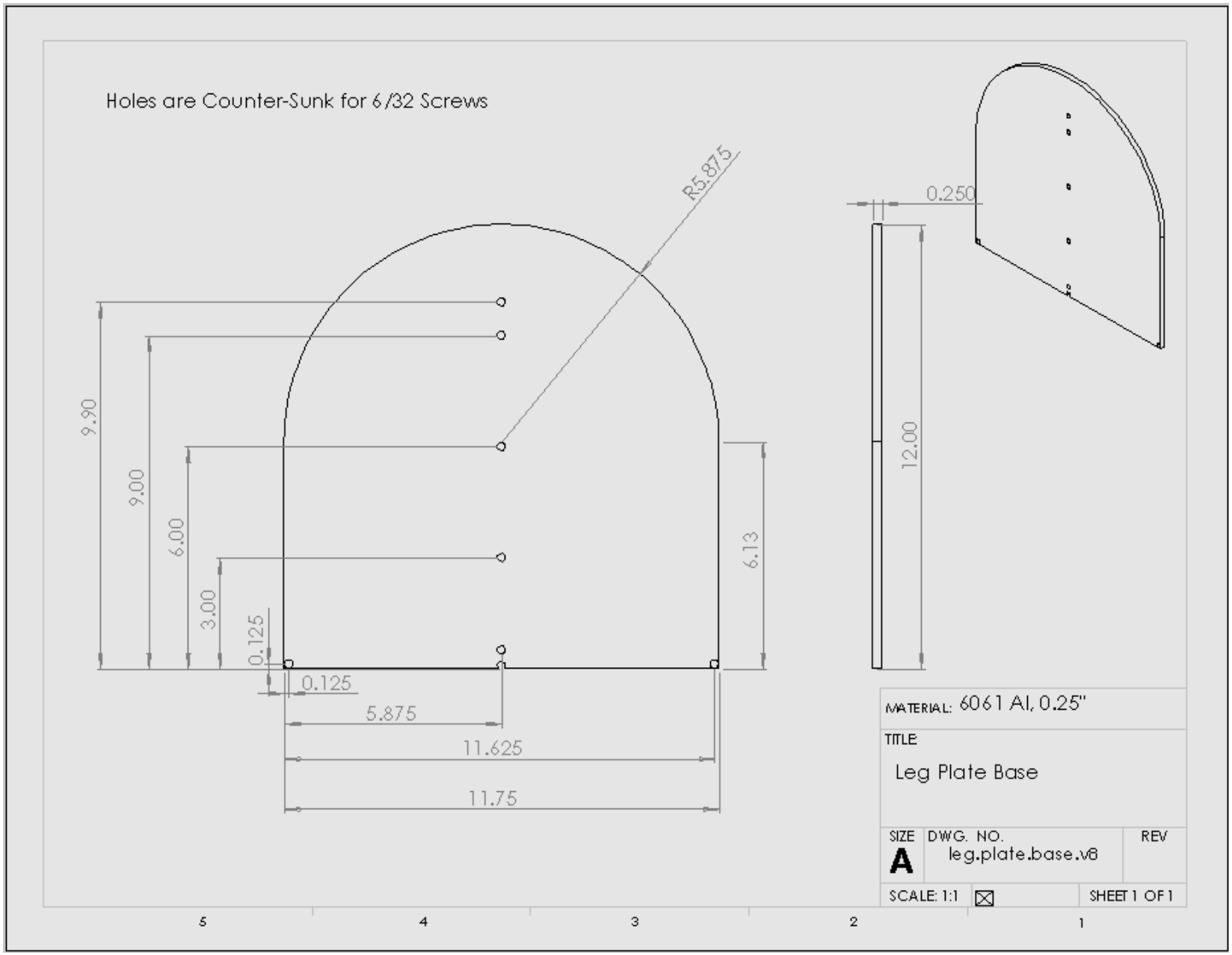
Bottom Holes are Tapped for 6/32 Screws x 1/2"

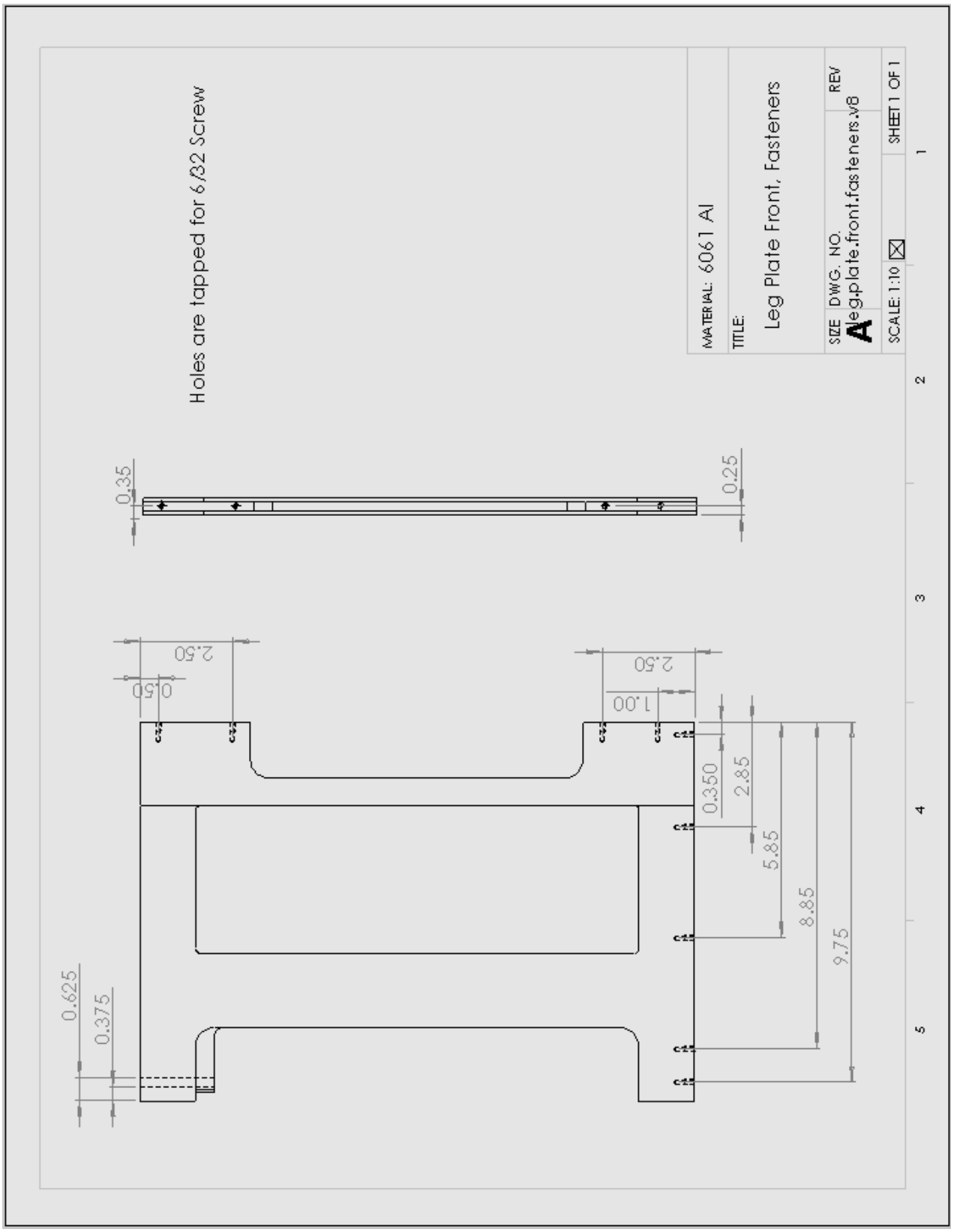


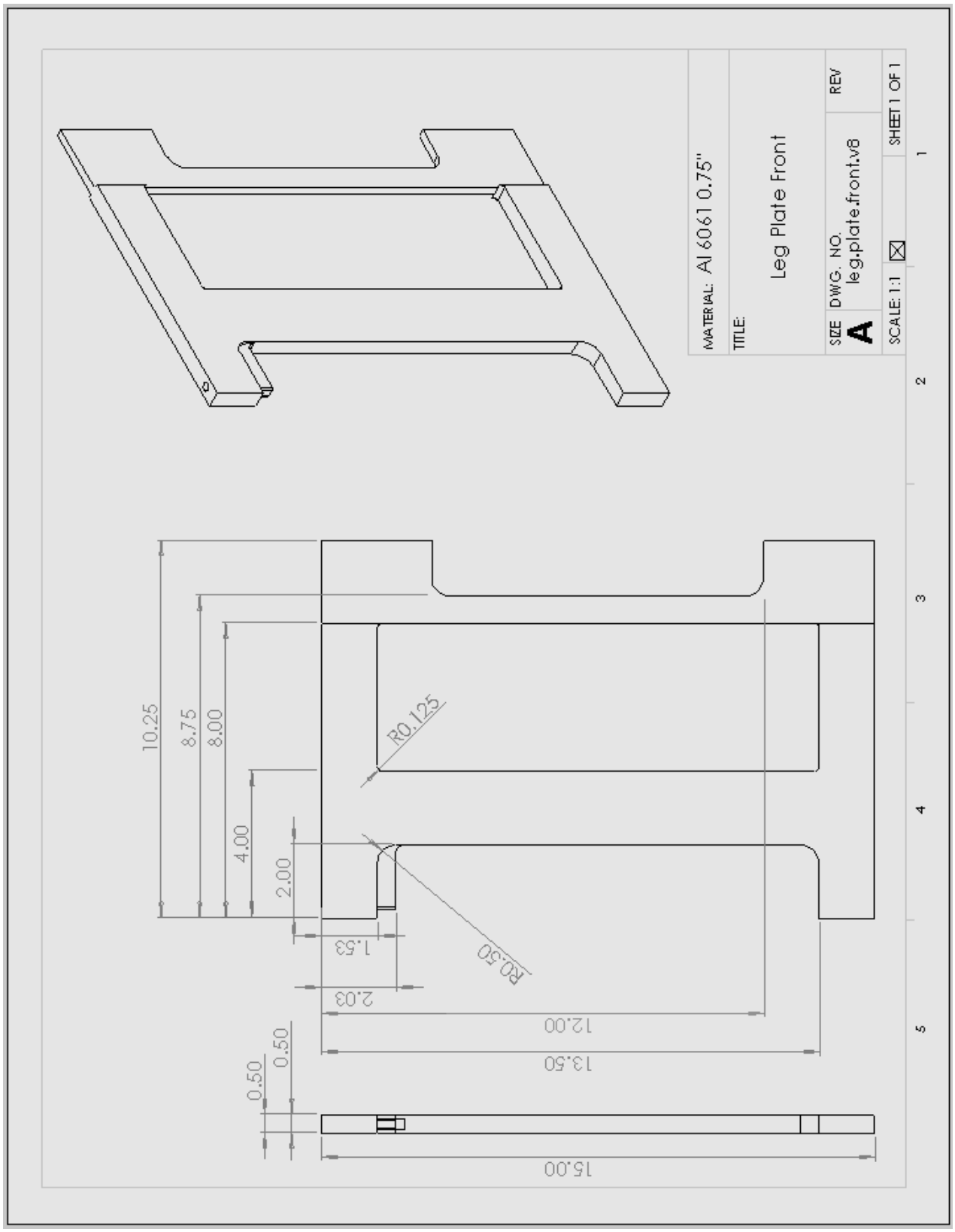
MATERIAL:	60601 Al
TITLE:	Leg Plate Back, Fasteners
SIZE: A	DWG. NO.: leg.plate.back.fasteners.v8
REV	
SCALE: 1:5	SHEET 1 OF 1

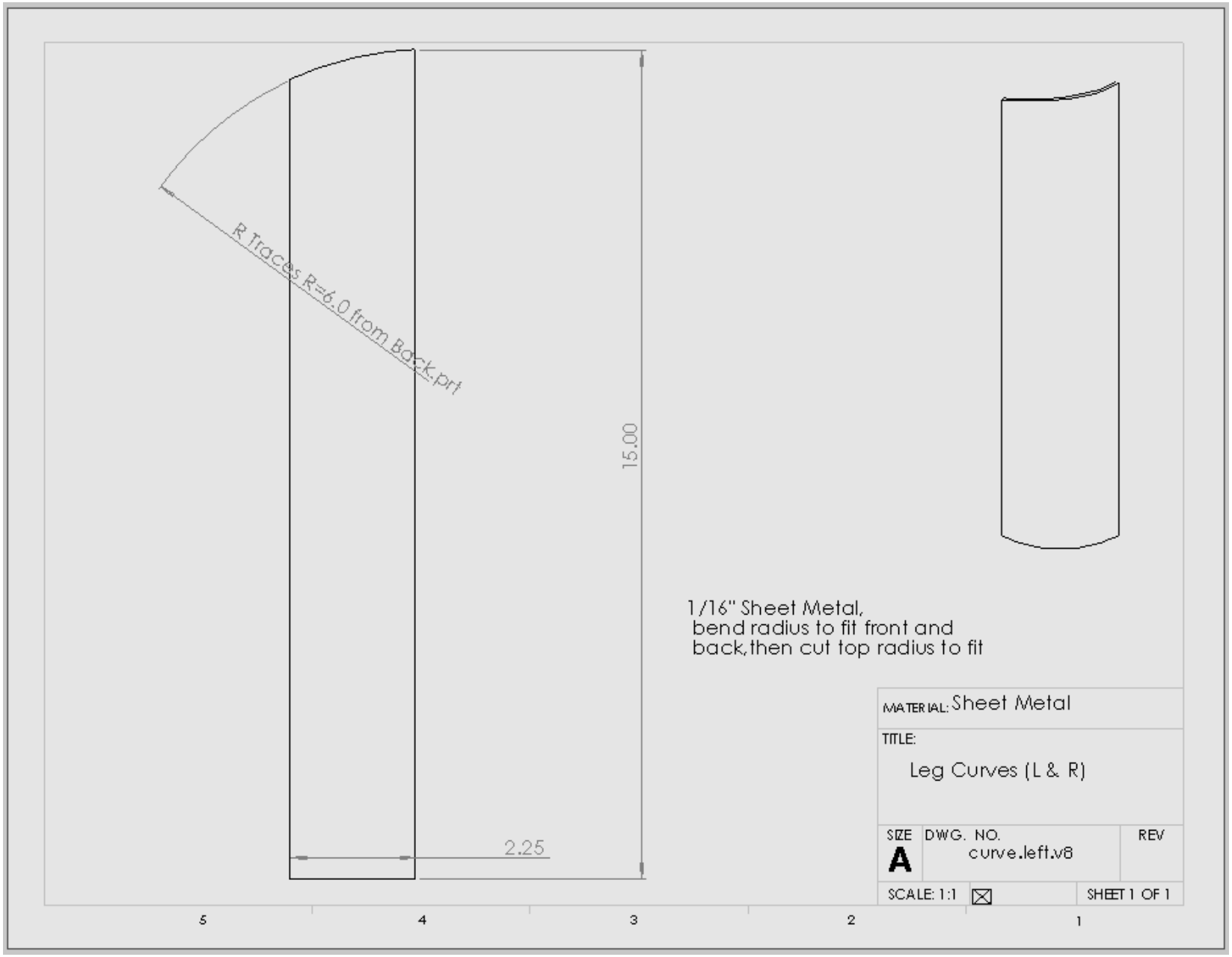
5 4 3 2 1


11.75
5.00
R5.875
0.25
0.15
12.00
15.00
3.00
3.375
3.875
7.875
8.375
MATERIAL: 6061 Al, 0.25"
TITLE:
Leg Plate Back
SIZE
A
DWG. NO.
leg.plate.back.v8
REV
SCALE: 1:1
SHEET 1 OF 1
5
4
3
2
1


Holes are Counter-Sunk for 6/32 Screws
R5.875
0.250
9.90
9.00
6.00
3.00
0.125
6.13
12.00
0.125
5.875
11.625
11.75
MATERIAL: 6061 Al, 0.25"
TITLE
Leg Plate Base
SIZE
A
DWG. NO.
leg.plate.base.v8
REV
SCALE: 1:1
SHEET 1 OF 1
5
4
3
2
1


Holes are tapped for 6/32 Screw
MATERIAL: 6061 Al
TITLE:
Leg Plate Front, Fasteners
SIZE A
DWG. NO. leg.plate.front.fasteners.v8
REV
SCALE: 1:10
SHEET 1 OF 1
0.35
0.25
2.50
0.50
2.50
1.00
0.350
2.85
5.85
8.85
9.75
0.625
0.375


MATERIAL: Al 6061 0.75"
TITLE:
Leg Plate Front
SIZE A
DWG. NO. leg.plate.front.v8
REV
SCALE: 1:1
SHEET 1 OF 1
10.25
8.75
8.00
4.00
2.00
R0.125
1.53
R0.50
2.03
12.00
13.50
0.50
0.50
15.00


R Traces R=6.0 from Back.prt
15.00
2.25
1/16" Sheet Metal,
bend radius to fit front and
back, then cut top radius to fit
MATERIAL: Sheet Metal
TITLE:
Leg Curves (L & R)
SIZE
A
DWG. NO.
curve.left.v8
REV
SCALE: 1:1
SHEET 1 OF 1
5
4
3
2
1

Appendix 11.5 AmP-MeD Testing Procedure

AmP-MeD Test Procedure

Setup

1. Attach the motorbox to the arm
   A) Tighten the threaded bolt into the bottom of the motor box
   B) Pass the threaded bolt through the slot in the arm and screw on the wing nut below the arm
   C) Lightly tighten the wing nut to secure the box
2. Plug in the motorbox
   A) Plug the laptop power cable into a wall outlet
   B) Plug the USB cable into the tablet
   C) Plug the mini USB into the back-right corner of the motorbox
   D) Plug the power cable into the back of the motorbox
3. Adjust the AmP-MeD to the patient
   A) Have the patient sit in a chair positioned over the AmP-MeD. The AmP-MeD should be aligned with the front of the chair, as shown in Figure 47.

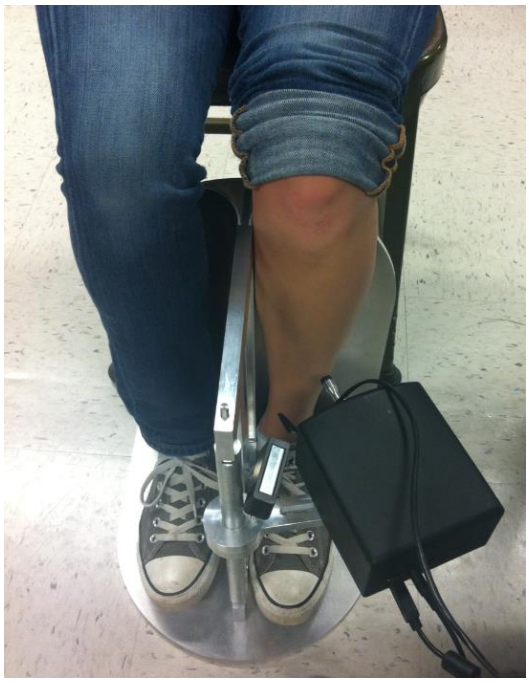


Figure 47: Patient Positioning with AmP-MeD

   B) The patient's legs should be placed on either side of the middle-divider on the AmP-MeD frame, as shown in Figure 47. The patient's calves should be resting comfortably on the curved leg supports on the back of the AmP-Med.
   C) Adjust the height of the arm to select a proper test location, see Figure 48.

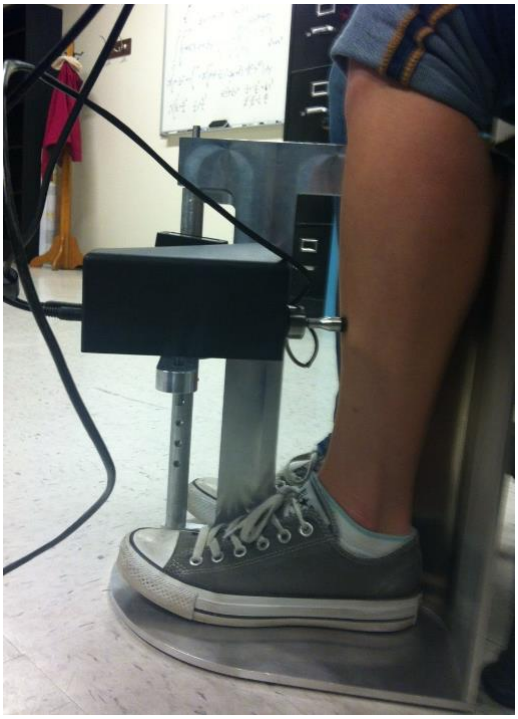


Figure 48: Proper Height adjustment for test location

i) Slide the ring and arm together up/down the rod until the preferred height is found.
ii) Insert a horizontal pin through the rod to support the ring and arm.

D) Adjust the angle of the arm to select a proper fit for the patient's leg size, see Figure 49.

Figure 49: Proper angular adjustment for leg size

i) Swing the arm toward/away from the patient's leg so that the pressure application tip is close to touching the patient's leg
ii) Place the emergency release pin vertically through the arm and ring to select a proper arm angle for the patient's leg size

E) Adjust the angle and position of the motorbox to acquire a perpendicular fit at the tibialis anterior (see Figure 49).
i) The motorbox may pivot about the threaded bolt in the arm slot
ii) The motorbox may slide horizontally along the arm slot
iii) Tighten the wing nut when the proper location is determined. The rubber application tip should be resting very close to the patient's skin at a perpendicular angle.

Data Recording Setup

1. Open the Template.xls file from the AmP-MeD Testing Data folder, and save a copy for the specific patient, in the format

Patient Initials_PatientNumber_Date.xls

2. Run the AmP-MeD program
   A. On the desktop, select the AmP-MeD folder
   B. Run the AmP_MeD project
   C. Run the PID.ArduinoMega.Main.vi
   D. Start the .vi by clicking on the white arrow in the top left corner
   E. Provide a filename for the results to be stored. Use the format:

Patient Initials_PatientNumber_Date.txt

3. Set the Desired Speed to 1.00 mm/s
4. Set the Load Cutoff to 4 lbf for preliminary testing
5. Ensure that the Max Return Speed is set at 50%
6. Tare the Load Cell by clicking the *tare load cell* button
7. Observe that the patient's switch has is not activated (the large *switch triggered* indicator should be dim, and both small *first 1?* and *first 2?* indicators should be lit). If this is not the case, physically activate the switch (remote patient held button) once or twice to reset the test.

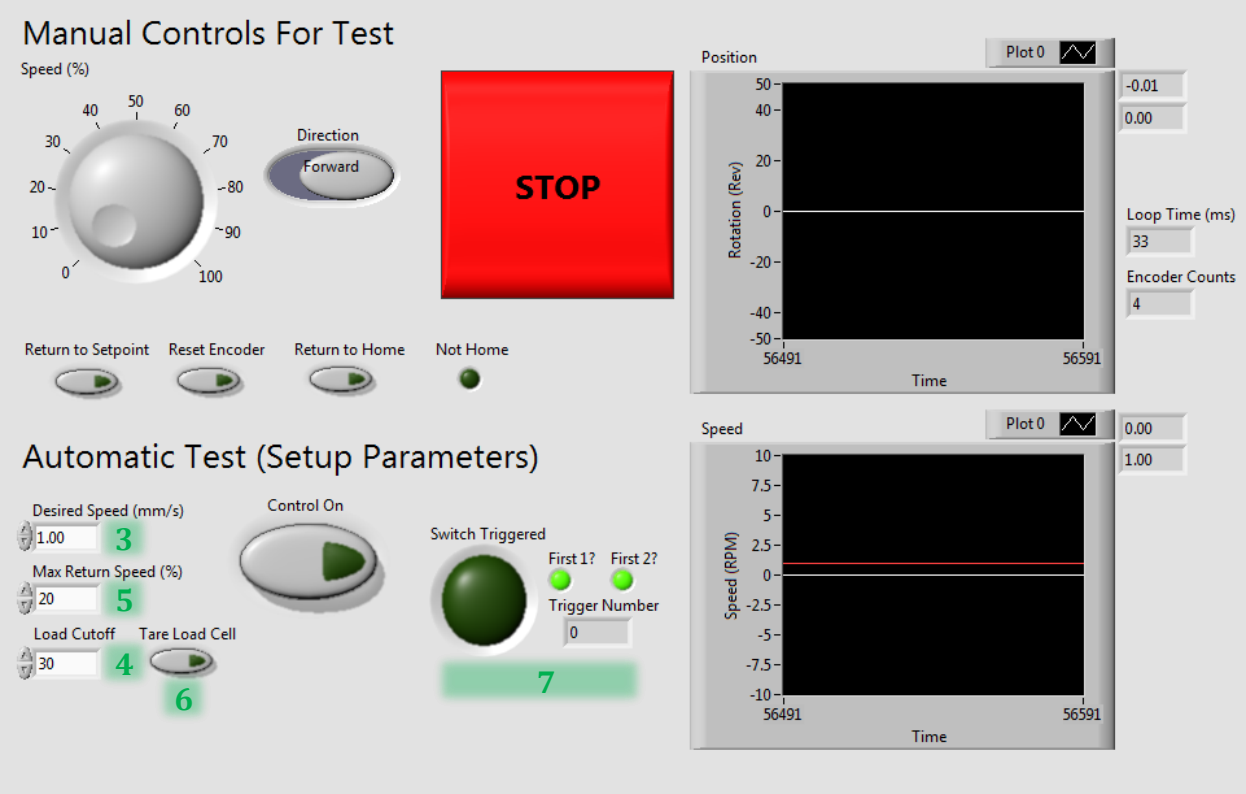


Figure 50: Test Administrator Interface - Test Setup steps have been highlighted in green

Preliminary Testing

1) Inform the patient that you will run a "practice test". The safety cutoff is very low for this (4 lbf) so they should feel no or very little pain. Explain that if they press the button more than one time, the pressure application tip will immediately and swiftly reverse to stop any applied pressure or pain. You will run the test, and they will press the threshold and tolerance button whenever they feel like it – this is just an example, so they may not actually feel their threshold and tolerance.
2) Press the "control on" button, and watch the patient run through the test. If he/she becomes confused or panics, manually reverse the piston to its original position and hit the big red "stop" button.
    a) To manually reverse the piston:
        i) Ensure that the manual direction is set to *reverse*
        ii) Turn the *speed (%)* dial clockwise, as pictured in Figure 51.

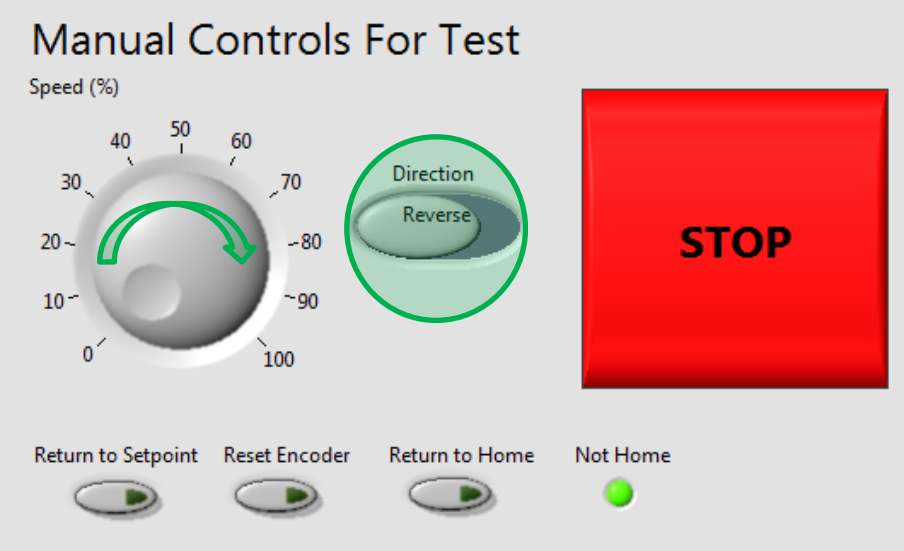


Figure 51: Manual Control - Manual reverse steps are highlighted in green

3) Discuss the preliminary test with the patient and clear up any confusion or worries he/she may have.

Testing

1) Reset the "load cutoff" to 8.0 kg (~80N, ~18 lbf)
2) Explain the definition of PPT and PPTol to the patient:

   PPT = Pressure Pain Threshold - the minimum pressure stimulus at which you begin to feel pain

   PPTol = Pressure Pain Tolerance – the maximum pressure stimulus that you can tolerate

   **The PPTol we would like to record for this test is what you perceive to be a pain level of about 5/10. This will enable us to record the data without subjecting you to too high a pain level.*

3) Instruct the patient to press the button the first time when they feel a sensation of not only pressure but pain, and the second time when they feel they have met their tolerance and want the test to end.
4) Push the "control on" button to run the test.
5) After the first test is complete, move the arm up/down one location to perform the test on a new location. Run the test again.
6) Repeat the test 3 times, or as many as the patient is comfortable with.
7) Click on the large red *stop* button to end the program.

Recording

1) You should keep notes as the test is conducted to record any observations.
2) After the test is complete, record this info in the patient's .xls file.
   a) Open the patient's .txt file, and copy the data into the .xls file, as shown in Figure 52 and Figure 53.

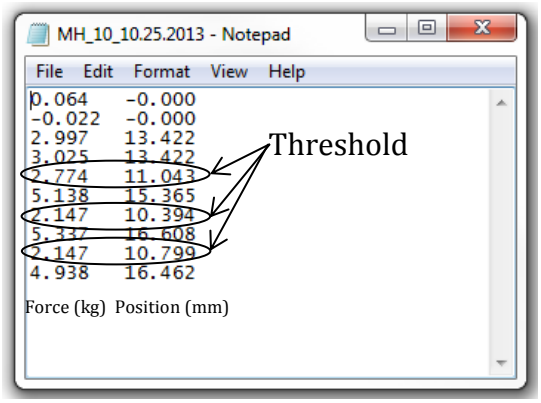


Figure 52: Force (left column) and Position (right column) data from AmP-MeD test. First two rows are from program initiation. 3rd and 4th row are from the "practice test". Rows 5-10 are test data, alternating between threshold and tolerance measurements.

	AmP-MeD			
	Threshold		Tolerance	
	Force	Position	Force	Position
1	2.774	11.043	5.138	15.365
2	2.147	10.394	5.337	16.608
3	2.147	10.799	4.938	16.462
4				
5				
6				
7				
8				
9				
10				

Figure 53: Data copied into Patient's Excel File

Wagner Device Testing Procedure

1) Turn on the Wagner device, and scroll through the "peak" button until you reach the option where maximum force remains displayed on the screen.
2) Ensure that the units are in kgf (kilogram-force)
3) Have the patient rest his/her leg on a chair or platform so that it is relaxed and horizontal.
4) Notify the patient that you will first measure threshold, record the data, and then measure tolerance in the same location.
5) Select a test location on the tibialis anterior lateral to the tibial ridge.
6) Apply steady, slow pressure until the patient notifies you that he/she has reached his/her threshold.
7) Record this data in the patient's excel file.
8) Zero the recorded max force on the Wagner device, and measure tolerance in the same location.
9) Repeat steps 5-8 on a new location for 3 trials (or as many as the patient is comfortable with).

Appendix 11.6 Minitab Results Analysis

Minitab Project Report

Descriptive Statistics: Threshold

Results for DEVICE = AmP-MeD

Variable	Patient	N	N*	Mean	SE Mean	StDev	Minimum	Q1	Median
Threshold	1	9	0	0.7309	0.0482	0.1446	0.5190	0.5900	0.7470
	2	9	0	1.562	0.220	0.660	0.790	0.903	1.559
	3	9	0	2.036	0.121	0.363	1.381	1.765	2.093
	4	9	0	3.160	0.117	0.350	2.575	2.845	3.287
	5	9	0	2.041	0.184	0.551	1.408	1.607	2.006
	6	9	0	2.764	0.191	0.574	2.027	2.298	2.511
	7	9	0	2.172	0.164	0.492	1.358	1.785	2.270
	8	9	0	0.5541	0.0270	0.0811	0.4430	0.4720	0.5570
	9	9	0	3.543	0.173	0.520	2.676	3.160	3.474
	10	9	0	4.452	0.163	0.490	3.854	3.883	4.538

Variable	Patient	Q3	Maximum
Threshold	1	0.8320	0.9460
	2	2.271	2.299
	3	2.306	2.549
	4	3.443	3.628
	5	2.505	2.946
	6	3.365	3.622
	7	2.583	2.896
	8	0.6285	0.6710
	9	4.015	4.300
	10	4.865	5.108

Results for DEVICE = WAGNER

Variable	Patient	N	N*	Mean	SE Mean	StDev	Minimum	Q1	Median
Threshold	1	9	0	1.5333	0.0553	0.1658	1.2600	1.4200	1.4600
	2	9	0	3.333	0.270	0.810	2.540	2.670	3.100
	3	9	0	2.807	0.119	0.357	2.140	2.600	2.780
	4	9	0	3.242	0.200	0.599	2.480	2.910	3.020
	5	9	0	3.318	0.209	0.626	2.180	2.840	3.280
	6	9	0	6.022	0.331	0.994	4.400	5.200	6.340
	7	9	0	4.987	0.246	0.739	3.900	4.330	4.760
	8	9	0	1.011	0.129	0.386	0.500	0.820	0.940
	9	9	0	7.524	0.405	1.214	5.560	6.430	7.720
	10	9	0	5.684	0.176	0.527	4.820	5.110	6.020

Variable	Patient	Q3	Maximum
Threshold	1	1.6900	1.7400
	2	3.680	5.120
	3	3.060	3.360
	4	3.670	4.480
	5	3.820	4.180
	6	6.650	7.520
	7	5.680	5.940
	8	1.110	1.900
	9	8.540	9.100
	10	6.080	6.200

Test and CI for Two Variances: Threshold vs DEVICE

```
Method

Null hypothesis         Sigma(AmP-MeD) / Sigma(WAGNER) = 1
Alternative hypothesis  Sigma(AmP-MeD) / Sigma(WAGNER) not = 1
Significance level      Alpha = 0.05

Statistics

DEVICE    N  StDev  Variance
AmP-MeD  90  1.240     1.538
WAGNER   90  2.077     4.314

Ratio of standard deviations = 0.597
Ratio of variances = 0.357

95% Confidence Intervals
                                 CI for
Distribution   CI for StDev      Variance
of Data            Ratio           Ratio
Normal        (0.484, 0.736)  (0.235, 0.542)
Continuous    (0.483, 0.736)  (0.233, 0.542)


Tests
                                          Test
Method                          DF1  DF2  Statistic  P-Value
F Test (normal)                  89   89       0.36    0.000
Levene's Test (any continuous)    1  178      21.20    0.000
```

One-way ANOVA: Threshold versus DEVICE

```
Source   DF      SS      MS      F      P
DEVICE    1  121.72  121.72  41.60  0.000
Error   178  520.85    2.93
Total   179  642.57

S = 1.711   R-Sq = 18.94%   R-Sq(adj) = 18.49%


                          Individual 95% CIs For Mean Based on
                          Pooled StDev
Level     N   Mean  StDev  --------+---------+---------+---------+-
AmP-MeD  90  2.302  1.240  (-----*-----)
WAGNER   90  3.946  2.077                            (-----*-----)
                          --------+---------+---------+---------+-
                                2.40      3.00      3.60      4.20

Pooled StDev = 1.711


Grouping Information Using Tukey Method

DEVICE    N   Mean  Grouping
WAGNER   90  3.946  A
AmP-MeD  90  2.302    B

Means that do not share a letter are significantly different.
```

Tukey 95% Simultaneous Confidence Intervals
All Pairwise Comparisons among Levels of DEVICE

Individual confidence level = 95.00%

DEVICE = AmP-MeD subtracted from: