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Development and Validation of a Recumbent Patient Weighing Scale

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DEVELOPMENT AND VALIDATION OF A RECUMBENT PATIENT WEIGHING SCALE

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RECUMBENT PATIENT WEIGHING SCALE

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ABSTRACT

Today, most medications are administered according to a standard amount or based on the patient's weight (weight-based). For emergency departments and emergency medical services, weight-based medications are difficult to administer as medical personnel do not have a means to obtain accurate patient weights. Paramedics generally rely on visual estimation for adults and height- or age-based estimation tools for children in order to obtain weight.

Over the past year, a team of biomedical engineering students, including the present author, worked to design and fabricate a weighing device for in-ambulance use. This device consists of three separate scales, wired together as one, that attach to the base of an ambulance stretcher. Each scale consists of a platform of syntactic foam and four strain gauge load sensors. An Arduino is used to combine the three weight measurements and display the total weight on a liquid crystal display.

Validation testing was performed. The first test was an accuracy test where the device was compared to the standard (standing) weight of each participant. For children, estimations using the Broselow tape and Pedi-Wheel were also recorded. The data was used to determine if the device was reading accurately, as well as to see if the device is better than the current methods used by paramedics. After the device was working properly, it was tested by paramedics, allowing them to provide feedback regarding the accuracy, usefulness, and durability of the device. From this, necessary changes were made in order to better the prototype.

The results indicated that this prototype works as well as, if not better than, the Broselow tape and Pedi-Wheel. Paramedics provided positive feedback on the idea, but there were some concerns expressed, durability and reliability being the most common. Future modifications to the scales, including changes to the material, can help to improve the durability, and further calibration can help to improve reliability.

Keywords: Recumbent Weighing Scale, Weight-Based Dosing, EMS

ACKNOWLEDGEMENTS

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LIST OF ABBREVIATIONS

ADE	adverse drug events
ASTM	American Society for Testing and Materials
EMS	Emergency Medical Services
FDA	Food and Drug Administration
FEA	finite element analysis
IRB	Institutional Review Board
LCD	liquid crystal display
MMP	minimum marketable product
MVP	minimum viable product
PCB	printable circuit board
PVA	polyvinyl alcohol
UAB	University of Alabama at Birmingham

INTRODUCTION

Medications

At some point in life, almost everyone will be in a situation that requires them to take medication. Medications can be used for a plethora of reasons, whether it's to maintain health, to cure a disease, to recover from surgery, etc. There are many different types of medications that can be used for different situations, and there are multiple medications that can be used for the same situation. There are four dominant methods for classifying medications: (1) their therapeutic use and the conditions they treat, (2) their mechanism of action and the reaction that occurs, (3) their mode of action and how one's body responds, and (4) their chemical structure.[1] Medications can fall into one classification or multiple. The Anatomical Therapeutic Chemical (ATC) Classification System categorizes medications into five levels:

- Level 1 – describes the organ system the drug treats
- Level 2 – describes the drug's therapeutic effect
- Level 3 – describes the mechanism/mode of action
- Level 4 – describes the general chemical properties of the drug
- Level 5 – describes the chemical components that make up the drug

Doctors and pharmacists use this system to ensure appropriate use and administration, as it allows them to classify the active ingredient of the drug.

Along with various types of medications, there are also several routes they can be administered. Medications are either given via intravenous (IV) injection or an extravascular route.[2] Some of the more common forms of extravascular administration include:

- Buccal – held inside the cheek
- Inhalation – breathed in through a tube or mask
- Intramuscular – injected into muscle
- Ophthalmic – given into eye
- Oral – swallowed by mouth
- Subcutaneous – injected just under skin
- Transdermal – given through a patch placed on skin

Medication Dosing

Pharmacokinetics and pharmacodynamics play a major role in determining the correct dose for a medication. Pharmacokinetics is what the body does to the medication, which includes absorption, distribution, metabolism, and excretion. Pharmacodynamics is what the medication does to the body, which includes its potency and efficacy. One's age, weight, and various health conditions are the major factors that doctors take into consideration when determining the correct dosage.[2] Another factor that plays a role is the medication's half-life; this is the time it takes for the concentration of medication in the blood plasma to fall by 50%. A medication's half-life is used to determine timing which a medication should be taken; medications can be once-a-day, once in the morning and once at night, three times a day, every four to six hours, etc. For the medication to stay within its safe, therapeutic range, the drug-plasma concentrations must stay within certain ranges and taking a medication too often or not often enough could cause serious side effects.

Typically, medications are either given in a standard amount or the dose is weight-based. Weight-based dosing means that a certain amount of the medication is given based on the individual's body weight, for example 1 mg/kg. In an emergency, weight-based dosing is required for various types of medication prior to life-saving intervention. When working with pediatric cases, typically children eighteen years of age or younger, it is especially crucial to know an accurate weight.[3] With these types of medications, even the smallest amount over the recommended dose could be life threatening. In the case of recumbent (unable to stand) or unconscious individuals, patient weights are obtained via visual estimation made by medical personnel.

The American Academy of Pediatrics published a guideline for emergency medication dosing. This document contains a list of various, common medications used when caring for pediatric patients.[4] All of the medications listed have a 'per kilogram' based dose, with some being stricter than others. Depending on the effects of the medication, some have strict instructions of how they should be administered, and some have a maximum dose that should not be exceeded no matter what the weight is. Table 1 shows a few examples of the medications listed in this guideline, along with their use and dosage. Hospitals are required to have a policy specifying a weight-based dosing strategy for particular medications, especially for pediatric and elderly patients.

Table 1. *Uses and Recommended Dosage for Various Drugs* [4]

Drug	**Use**	**Pediatric Dosage**
Benadryl	Allergic Reactions	IV 1-2 mg/kg
Epinephrine	Anaphylactic Shock	0.01 mg/kg
	Infusion	0.6 * BodyWeight (kg)
	Cardiac Arrest	0.01 mg/kg
Lidocaine	Anesthetic	5 mg/kg
	Ventricular Fibrillation	0.5-1 mg/kg Max: 5 mg/kg
Nitroprusside	Lower Blood Pressure	0.0005 mg/kg/min Max: < 0.002 mg/kg/min

Medical personnel in all fields should use a specific dosing system whenever possible. However, following a weight-based dosing system is challenging because medical personnel are lacking proper weighing processes. While a vast majority of medications perform better when administered according to a weight-based system, there are other ways to dose a medication.[5] One study comparing height- and weight-adjusted dosing versus fixed-dosing of anesthesia found that fixed dosing during cesarean sections led to more frequent hypotension, as well as more pronounced nausea and vomiting. Patients with height- and weight-adjusted dosing typically suffered less hypotension (30%), as well as less nausea and vomiting, than those with fixed-dosing (64%). For children with acute lymphoblastic leukemia, a pharmacokinetic model was created to compare weight-adjusted dosing to body surface area-adjusted dosing of methotrexate. The results from this model showed that weight-adjusted doing could achieve a better outcome than body surface area-adjusted dosing. While weight-based dosing is typically the most effective method, there are some situations where fixed dosing might be better. For adults, a fixed-dose regimen may be better when administering cyclosporine for psoriasis treatment.

Tools for Ambulatory Setting

For Emergency Medical Services (EMS) personnel, it is difficult to obtain accurate patient weights. Ambulances do not have any form of a weighing scale in them, and often times the patient is either recumbent (unable to stand) or unconscious. Therefore, EMS personnel must estimate weights when administering medications that are weight-based, which includes all medications for children and a handful for adults. When caring for an adult patient, medical personnel rely on their own visual estimations. When caring for pediatric patients, there are some tools available that provide weight estimates and pre-calculated medication doses. These tools can include the Broselow tape, the Pedi-Wheel, CrashCards, or mental memorization of weights, such as the Handtevy method.

The Broselow tape (Fig. 1) is a color-coded measuring tape that is stretched along the length or height of a child; whichever colored box the child's feet end in corresponds to a pre-determined weight range.[6] The colors of the tape specify the amount of various medications to give for that weight range, as well as equipment size for performing emergency resuscitation. The Broselow tape is intended to be used for children up to the age of twelve. However, if a child is taller than the tape is long (58 inches), it will not be applicable. The Pedi-Wheel (Fig. 2) is an age-based estimation tool. On one side, the dial can be turned to the patient's age.[7] This window will then provide an average weight, blood pressure, heart rate, respiratory rate, and suggested sizes and lengths for endotracheal tubes. On the other side, the dial can be turned to the patient’s weight. This window provides pre-calculated doses for the more common medications that might be needed. CrashCards are similar to the Broselow tape and Pedi-Wheel. These cards are color-coded to correspond to the tape system, and they include pre-calculated doses and other information based on weight and age. There are also various memorization tricks that can be used. One example, the Handtevy method (Fig. 3), is a weight estimation based on age.[8] Using one’s hand, one can assign each finger a chronological odd number (start with one), as well as counting up by five’s, starting with ten.

Figure 1. *Broselow tape which would be stretched along the height of a child.*

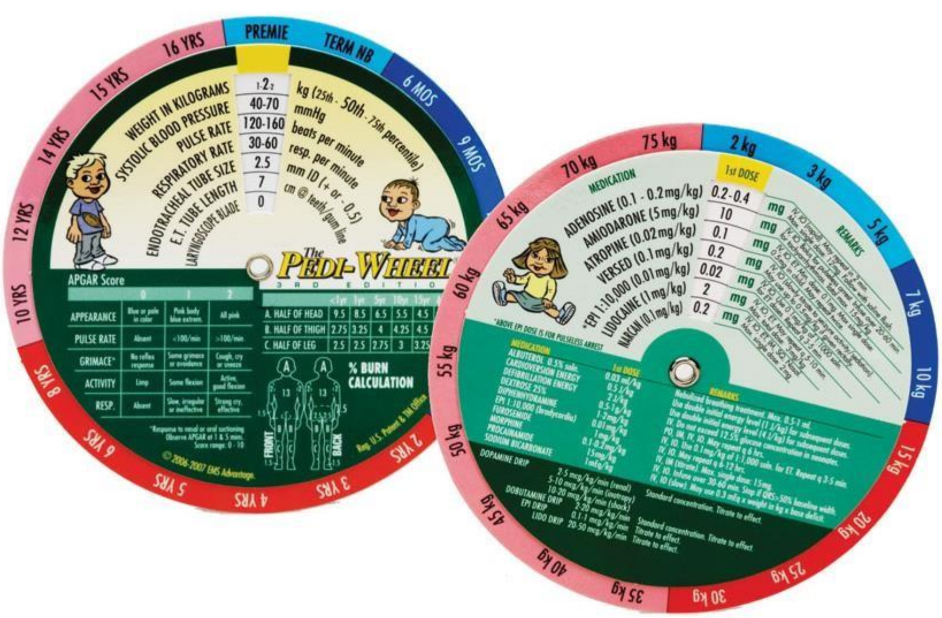

Figure 2. *Age and weight sides of the Pedi-Wheel.*

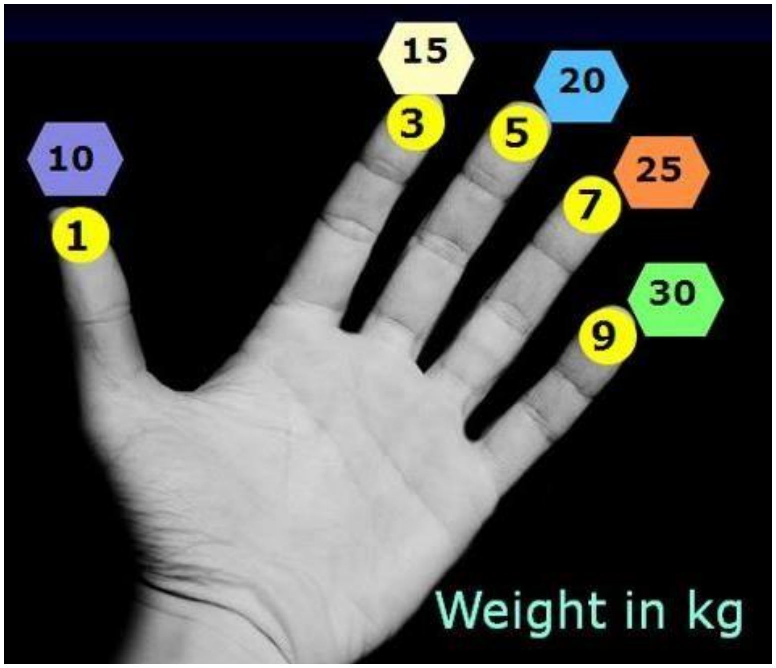

Figure 3. *Handtevy method, showing how to estimate pediatric weights with one's hand.*

Medication Errors

"It is estimated that medication errors cost billions of dollars and harm 1.5 million people per year".[9] Many of these medication errors come from weight-based dosing errors. In 1999, there was a study conducted looking at 10,788 medication orders written over a 36-day period. There were 616 medication errors accounted for by 320 patients; 64 patients had three or more errors.[10] There were also 26 adverse drug events (ADEs), which are injuries resulting from the use of a drug. Of these 26, five were preventable. There were 115 potential ADEs, which were either intercepted before reaching the patient or the error did not cause the patient any harm.

While weight-based dosing is crucial for pediatrics, studies have shown that in some pediatric emergency departments as few as two percent of children are actually weighed, while the rest have their weight estimated.[11] In some pediatric emergency departments, tenfold deviations were observed in one of every 766 prescriptions, corresponding to 1000% of the recommended dose. In a simulated resuscitation situation, this number was as many as one of every 32 prescriptions containing a tenfold deviation. Out of 360 prehospital prescriptions, 35% showed medication errors. Within these errors, doses of epinephrine had an average tendency to be 808% of the recommended dose.

While a potential 1.5 million people are harmed by a medication error every year, it is estimated between 44,000 and 98,000 die from a medication error every year.[12] An estimated 15% of all medication errors are accounted for by incorrect dosing. After observing 2,213 prescriptions written in a California pediatric emergency department, it was found that 33% contained dosing errors. A study consisting of 396 patients, seventeen years of age or older, found that an average of 33.5% of physicians and nurses were capable of estimating a person's weight within 5%, and only 21.5% of paramedics had this capability. In estimation errors greater than 20% of the actual weight, physicians and nurses were more likely to over or underestimate than paramedics.

Estimation Accuracy in Adults

In 2001 and 2002, 33 health care providers from different levels of training were asked to estimate patient weights; a total of 494 estimations were recorded.[13] These health care providers consisted of paramedics, emergency medicine residents and faculty, medical students, nurses, and interns. Only 28.1% of estimations were within ± 5kg (11 lbs). When compared to the rest of the groups, the accuracy of paramedics was worse (19.4%). Emergency medicine faculty and paramedics were more likely to underestimate weights, while interns and medical students were more likely to overestimate. This study also found that health care providers under the age of thirty were almost twice as likely to estimate weights more accurately than those over the age of thirty.

In a study including 458 patients, only half of nurses and physicians were able to estimate weights within 10% of the patient's actual weight.[14] The physicians who participated had a mean estimate of 11.1 pounds below the actual patient weight. The definition of accuracy is subject to change for different people. If accuracy is defined as being within 10% of a person's actual weight, between 48 to 58% of EMS, emergency department nurses, and emergency physicians were correct.[15] If the scope of accuracy is broadened, almost all medical personnel are capable of estimating patient weights within 20%. However, if the scope of accuracy is narrowed to 5%, the number of medical personnel capable of correctly estimating weights is even smaller; only 28% of medical personnel can estimate within 5% of a patient's actual weight.[13,16] When looking at estimations made by paramedics, only 19% were able to estimate within 5% of the patient's actual weight. The specific accuracy which medical personnel need to be within varies for each medication. Ideally, medical personnel want to use the patient's exact weight in order to avoid under- or over-dosing. Under-dosing can result in the medication not working effectively and exacerbation of the patient's condition. Over-dosing can result in longer patient recovery and even death.

Nomograms and equations using anthropometric parameters (mid-arm circumference, knee height, and other body measurements) have been created to estimate weight; however, these are not ideal for emergency situations as they are time consuming. A study conducted in 2010 compared various estimation techniques involving anthropometric parameters, as well as visual estimation, for 198 patients.[17] The Lorenz equation (Eqns. 1 & 2) utilized body height (BH), waist circumference (WC), and hip circumference (HC), and the Crandall equation (Eqns. 3 & 4) utilized height (HT) and mid-arm circumference (ARM). All height and circumference measurements were in centimeters. The Lorenz equation had a tendency to over and underestimate patient weights; it overestimated about 33% and underestimated about 10% of patient weights. This method was accurate within 10% of the actual weight for 110 (56%) patients. The Crandall equation had a tendency to overestimate patient weights; it was within 10% of the actual weight for only 67 (34%) patients.

Lorenz Equations

$$weight_{male} = -137.432 + (BH * 0.60035) + (WC * 0.785) + (HC * 0.392) \quad \text{(Eqn. 1)}$$

$$weight_{female} = -110.924 + (BW * 0.4053) + (WC * 0.325) + (HC * 0.836) \quad \text{(Eqn.2)}$$

Crandall Equations

$$weight_{male} = -93.2 + (3.29 * ARM) + (0.43 * HT) \quad \text{(Eqn. 3)}$$

$$weight_{female} = -64.6 + (2.15 * ARM) + (0.54 * HT) \quad \text{(Eqn. 4)}$$

Estimation Accuracy in Pediatrics

While most studies tend to use adults for weight estimations, similar estimation accuracies are made for children as well. In prehospital settings, the risk of medication errors is even greater, as these situations are typically more time sensitive. A survey completed by just over one-thousand paramedics showed that 43% of respondents were familiar with a case when a medication error was administered to a child.[18] Of these respondents, 35.5% indicated that they do not obtain any weight for pediatric patients; they just give them a smaller dose.

For paramedics, as well as emergency doctors, the most accurate estimation tool used is a Broselow tape. Studies have shown that this tape is only accurate within 10% for just over half of the children it is used on.[19] While there have been a few changes to the tape over the years, evidence shows that the accuracy has of the tape has not significantly improved. Some question if the tape has successfully adapted to the changing populations or not. The 2011 version of the tape was more inaccurate than older versions when using it in low- and middle-income countries, as the weights were based on growth data for high-income countries. The highest weight range on this tape is 30 to 36kg (66 to 79 pounds). According to Cincinnati Children's Hospital, the average weight range for a twelve-year-old female of age is 68 to 136 pounds.[20] For a twelve-year-old male, the average weight range is 66 to 130 pounds. If the Broselow tape were used on children at the upper end of these weight ranges, their estimated weight could be twenty pounds, or more, less than their actual weight.

PURPOSE AND GOALS

Purpose

Today's technology is constantly changing and improving. Despite this, EMS agencies still lack the appropriate tools needed to obtain accurate patient weights. The purpose of this study is to develop a recumbent patient weighing scale. While there have been some advances to help with the ease of the job, this new weighing scale will help with the efficiency of the job. By assisting paramedics to more efficiently do their jobs, this device can lead to an improvement in the quality of pre-hospital care. This can also decrease the overall number of medication errors.

Hypotheses and Specific Goals

The first hypothesis was that this new weighing scale would provide more accurate weight measurements than existing solutions, specifically for children. Weight measurements from the weighing scale were compared to the standard (standing) weight, as well as to the Broselow tape and Pedi-Wheel, in order to test the hypothesis that the new weighing scale will be more accurate than the Broselow tape and Pedi-Wheel. Since there are no tools for obtaining adult weight within an ambulance, the weighing scale was only compared to the standard standing weight for its accuracy.

In addition to testing the weighing scale's accuracy, feedback from EMS personnel was another aspect of this project. A key factor to consider when creating a new product is whether there is a market for that product; this can be tested through customer discovery. Customer discovery allows one to meet with potential users of a product and design that product to their specific needs. To determine if this weighing scale is something truly needed or if the tools they already have are enough, meetings were conducted with paramedics and their feedback was obtained. The feedback from demonstrations and user testing was beneficial in assessing what changes needed to be made for future prototypes.

METHODS

Design Process

Customer-Centered Design

Mr. Jason Bowman and Dr. Linda Thompson were the main clients throughout the design process of this project. Mr. Bowman is an EMS manager at Alton Memorial Hospital in Illinois; he expressed the original need for a way to obtain weight of stroke patients within ambulances. Mr. Bowman was consulted periodically throughout the planning and design of the weighing scale. Preliminary ideas were conveyed with Mr. Bowman in order to get his perspective on whether or not various designs would be a good fit. Once a preliminary prototype was completed, it was shown to Mr. Bowman for feedback.

Dr. Linda Thompson is an associate professor within the Department of Emergency Medicine at UAB. Dr. Thompson expressed the need for a way to study the effects of emergency medication dosing. When presented with the design for an ambulance weighing scale, Dr. Thompson helped to plan ways for testing. She helped plan a comparison test to the Broselow tape, as well as a user study with a handful of EMS agencies within the Birmingham area.

For the first prototype, meetings were held with paramedics in Tuscaloosa. These paramedics helped with ideas and feedback regarding the first prototype that was made. For the second prototype, an initial meeting with EMS personnel within the Hoover Fire Department Station 4 was conducted, where 20 paramedics were present. Design plans were discussed with them in order to gain initial feedback. Throughout the designing process of the second prototype, there were multiple meetings with EMS personnel in the Hoover and Birmingham fire departments, as well as members within the Birmingham Regional Emergency Medical Services System (BREMSS). From these meetings, feedback was obtained from roughly 35 EMS personnel. Throughout the building of this weighing scale, the clients and paramedics were consulted to ensure that the scale suited their needs. It became apparent that there is a need for a lightweight device for obtaining patient weights in emergency situations. Based on feedback from the clients and paramedics, a list of design constraints and requirements was formed.

Device Constraints

The three main constraints for this weighing scale were overall weight, cost, and functionality of the design. Alone, an ambulance stretcher can weigh between 100 and 125 pounds. Typically, one person, sometimes two, is lifting, lowering and maneuvering this stretcher. If a 200-pound person is placed on top, plus the oxygen tank that is always on it, that is just over 300 pounds that two people have to lift into the back of an ambulance. Upon knowing this, the weight requirement for this scale was set at 20 pounds or less. EMS personnel do not want a device that adds an unnecessary amount of weight to their already labor-intensive routine.

Most EMS agencies are funded by service reimbursement and/or fundraising; some agencies working within big cities can also receive local tax subsidies. EMS agencies bill patients for their services, which is paid for either by the insurance companies or the patient. Many smaller agencies in rural areas rely on fundraising to cover the costs of maintaining ambulances and equipment. Because EMS budgets are just big enough to cover the cost of ambulance and equipment maintenance, the overall cost of materials and manufacturing of a weighing scale must be kept to a minimum so that a potential selling price is no more than $1,000.

After consulting with various EMS agencies, it was observed that Stryker and Ferno EMS are the two main manufacturers for ambulance stretchers, with Stryker being the more popular option. While the two have some differences, the main base which a patient is placed on had the same concept: three sections so that the head and/or legs could be raised depending on the situation. The Stryker and Ferno stretchers can be seen in Figures 4a and 4b, respectively. These three sections played an immense role in the overall design and functionality of the weighing scale. The scale must comply with the set-up of the base, and it cannot hinder the natural motion of the stretcher.

Figure 4a (left). *Stryker stretcher.*
Figure 4b (right). *Ferno EMS stretcher.*

Device Requirements

There were other requirements for this weighing scale as well. One requirement was that the scale needed to be accurate. While EMS personnel noted that pediatrics were the most important population requiring weight-based dosing, the team wanted the weighing scale to work for persons of all ages. The initial goal was set for the scale to be within ± 2.5 kilograms (±5 lbs.) of a person's true weight. Upon further discussions with paramedics, the goal was changed to ± 1.5 kilogram (±3 lbs.). While paramedics want to be as accurate as possible, their main focus is to keep the patient stable during transport to the hospital. The scales also need to be durable. Durability for the weighing scale is twofold: (1) the scales themselves need to be able to withstand the rough terrains that stretchers are rolled across, as well as constant loading and unloading, and (2) the material for the scales needs to be able to handle a maximum load of 650 pounds. Another requirement for the weighing scale is that it needs to comply with the US Food and Drug Administration (FDA) regulations. The scale would need to be purple-top safe, as well as waterproof. Purple-top safety refers to the capability of being wiped with Sani-Cloth disinfectant wipes.

Previous Prototype

The original idea for this project came about as a senior design project at The University of Alabama. A group of mechanical engineering students, which included the present author, spent their senior year on designing and fabricating a weighing scale for ambulance use. This prototype (Fig. 5) consisted of two scales. Each scale consisted of two pieces of acrylic, with the top piece being slightly thicker than the bottom. The bottom acrylic was used to keep the sensors from falling into the holes of the stretcher base; the thickness was minimal as it was being supported by the base of the stretcher. Each scale included four load sensors, configured into a Wheatstone bridge. An Arduino was used to add the two measurements and display the total weight on a liquid crystal display (LCD).

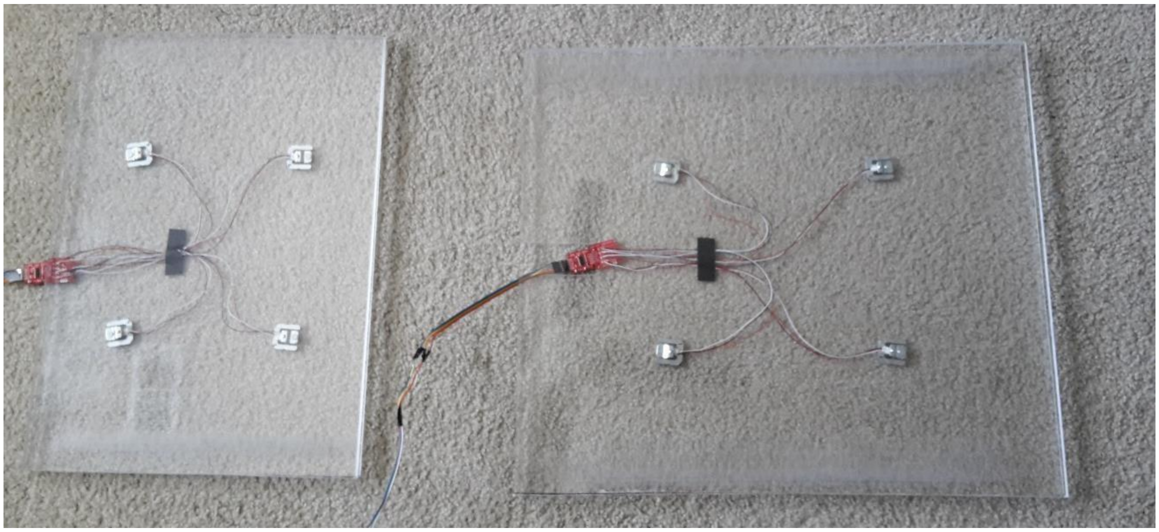

Figure 5. *First prototype consisting of 2 scales.*

This prototype worked, but it was not ideal. The four sheets of acrylic that were used made the weighing scale heavier than the 20-pound constraint. Additionally, smaller details regarding the attachment of the weighing scale to the stretcher, protection for the wires, and housing for the Arduino and LCD had not been finalized. In using two pieces of acrylic with only sensors in between, it still needed to be determined how to keep the acrylic from sliding apart without pre-inducing a load. This also led to the difficulty of determining how to best attach the scales to the stretcher. With the sides being open, this prototype was not waterproof. While this first prototype had many flaws, it aided in the design of the second prototype.

Fabrication of Second Prototype

Throughout two school semesters, a team of three biomedical engineering students, including the present author, worked together to complete a preliminary prototype as their project in the BME 630 (Engineering Design and Commercialization) and EGR 695 (Innovation-Commercialization Project) courses at UAB. Designing and planning the project were completed in the Fall 2018 semester, and then the device was built in the Spring 2019 semester. Preliminary calibration and testing of fellow classmates were completed prior to the end of the course.

Completion of Prototype

The following were the major milestones throughout this design project. After looking at the base of the ambulance's stretchers, the team felt it necessary to model the base in order to determine the best design for the weighing scale. Once 3D models were completed, they were shown to paramedics to obtain feedback and approval. Once a final design was chosen, various materials had to be tested in order to choose that which best fit the design requirements: lightweight and low cost. After material testing and finite element analyses (FEA), the first prototype was built and preliminary calibration and testing were done.

<u>Modeling</u>

The first model that needed to be created was one of the stretcher's base. With this model, the team was able to determine the best design for the weighing scale. Figures 6a and 6b show the geometries of the base of a Stryker stretcher and the weighing scale, respectively. All models were created using SolidWorks. Once the final design was chosen, more intricate 3D models were created to later perform finite element analyses for choosing a material. An exploded view of the foam padding, three scales, and stretcher base can be seen in Figure 7.

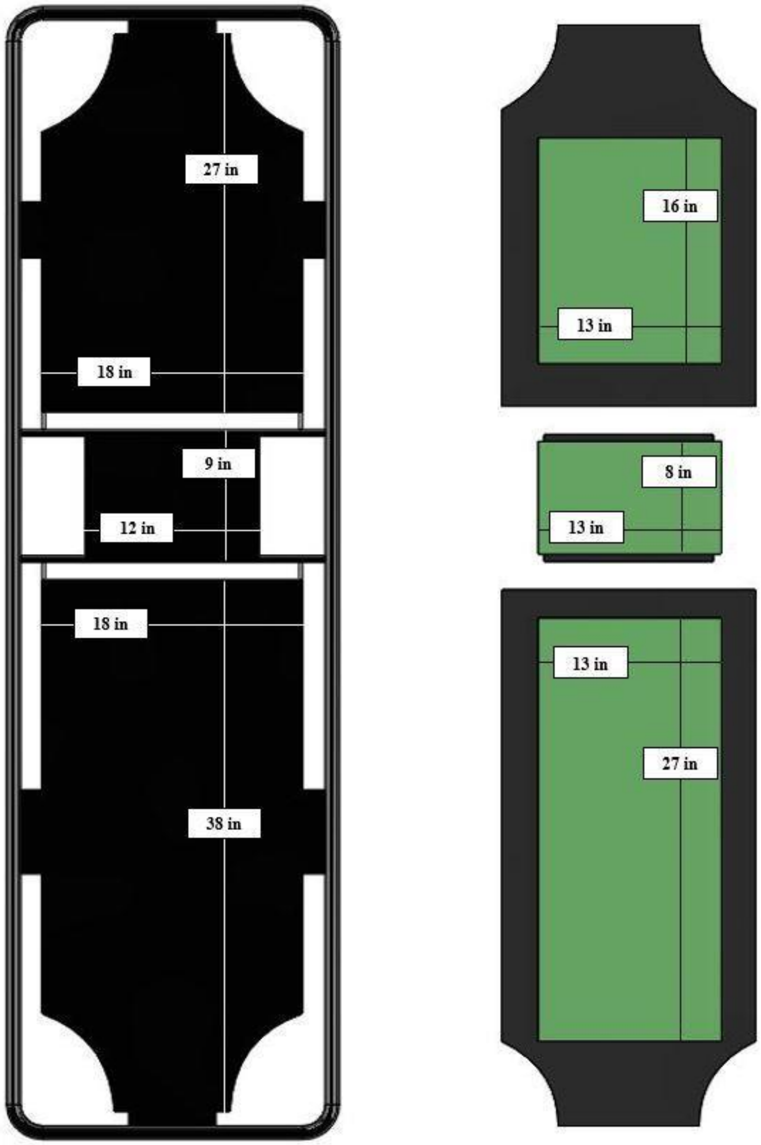

Figure 6a (right)*. Stretcher base geometry, upon which a foam padding is placed.* ***Figure 6b (left)****. Base with scales (green) placed on each section.*

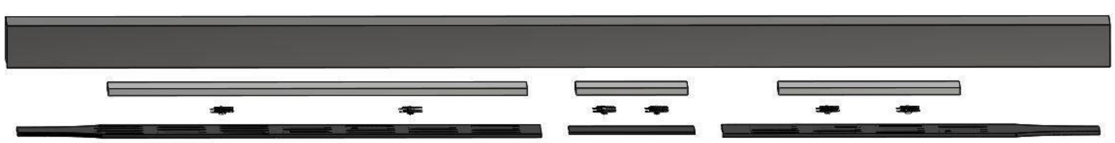

Figure 7*. Side view of foam pad, syntactic foam platforms, load sensors, and stretcher base.*

Material Testing

When determining the best material option, acrylic, sandwich composite, and syntactic foam were the top possibilities. Since this device is being used in emergency, medical situations, it must comply with FDA regulations and cannot be absorbent in case liquids come into contact with it. It must also be purple-top safe, meaning the material can withstand being wiped with Sani-Cloth disinfectant wipes. Due to its weight, acrylic was eliminated from the list, leaving sandwich composites and syntactic foam.

A sandwich composites consist of stiff "skins" attached to a lightweight core; combinations of glass- and carbon-fiber skins vacuum-sealed to a polyurethane core were made. Data from three-point bending tests conducted by other students, according to the American Society for Testing and Materials (ASTM) standards, was obtained in order to calculate the mechanical properties of various samples. Syntactic foam consists of a metal, ceramic, or polymer matrix mixed with small, hollow spheres for reinforcement. For this project, samples made with epoxy resin and 3M's K-series glass bubbles were tested. The team performed four-point bending tests, according to ASTM standards, in order to obtain mechanical properties of the syntactic foam. The set-up for the four-point bending tests can be seen in Figure 8, and the samples of syntactic foam can be seen in Figure 9. The data from the tests was used to calculate the maximum flexural stress, maximum strain, and flexural modulus of elasticity (Eqns. 5-7). A force versus displacement graph from one of the samples can be seen in Figure 10, which was used to obtain the maximum force, displacement, and slope of the secant line for calculations. Table 2 shows the calculated values for each sample.

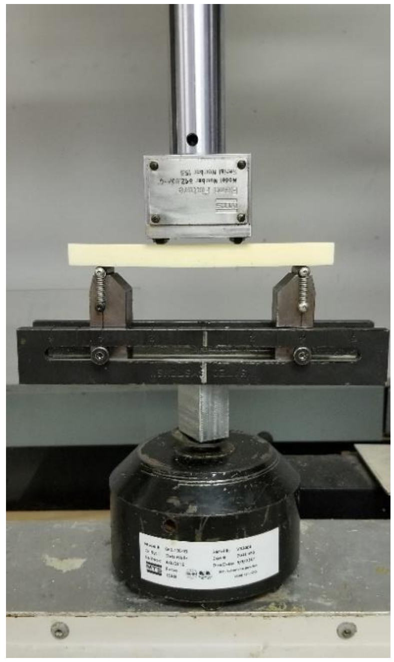

Figure 8. *MTS set-up for four-point bending tests utilizing a 15kN load cell.*

Figure 9. *Three samples of syntactic foam used for four-point bending tests.*

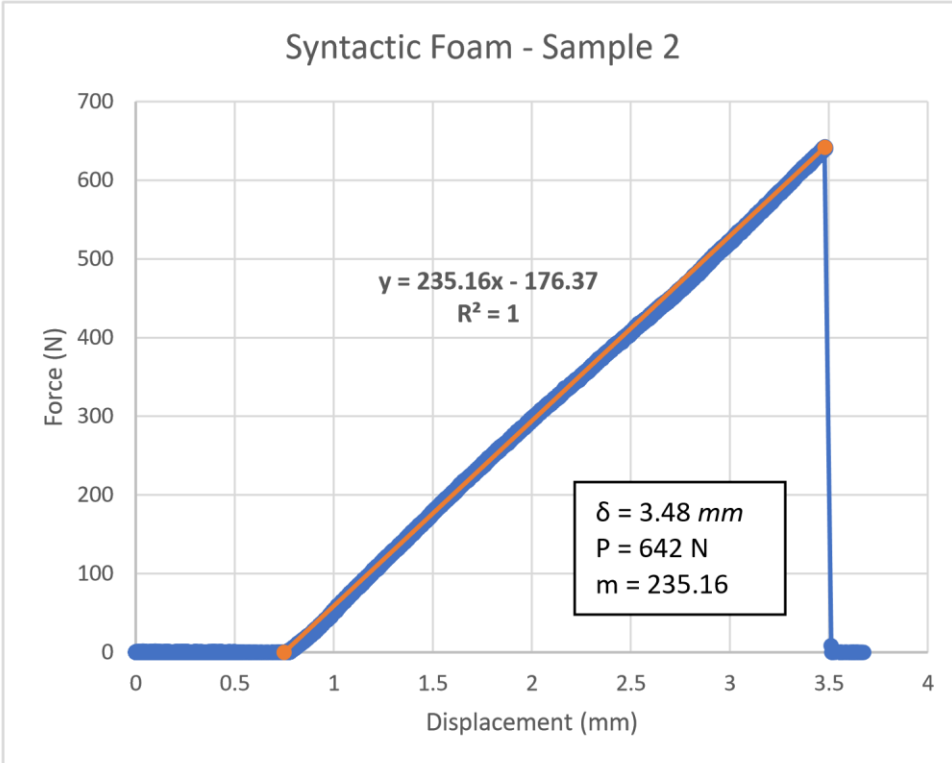

Figure 10. *Force vs Displacement graph from sample 2.*

Stress $$\sigma = \frac{3PL}{4bh^2}$$ (Eqn. 5)

Strain $$\varepsilon = \frac{4.36\delta h}{L^2}$$ (Eqn. 6)

Elasticity $$E = \frac{0.17L^3 m}{bh^3}$$ (Eqn. 7)

P = applied load (N)
L = support span (mm)
b = specimen width (mm)
h = specimen thickness (mm)
δ = mid-span deflection of specimen (mm)
m = slope of the secant of the load-deflection curve

__Table 2__. Material Properties for Syntactic Foam

Sample	Stress (MPa)	Strain	Elastic Modulus (GPa)
1	9.67	0.011	1.01
2	14.76	0.015	1.21
3	13.72	0.023	0.63
4	9.72	0.011	0.93
5	14.40	0.016	1.10
Average	12.45	0.015	0.98

From the sandwich composite testing, the average stress was 12.10 MPa and the elastic modulus was 2.54 GPa. While the strength of each material is equivalent, the stiffness of sandwich composites is great than the syntactic foam. Once the properties for each were calculated, FEA tests were done utilizing SolidWorks. From these analyses, the deflection was the main focus. The sensors provide about a 7mm clearance when attached to the bottom of the scales. If the deflection of either material were more than 7mm, it would result in the scales bottoming out.

For these analyses, the top scale was constructed with load sensors underneath, and a load was applied to the top. The analyses resulted in minimal deformations for each material when a 300-pound force was applied. It is estimated that 50% of a person’s body weight lies within the trunk region: chest, back, and abdomen. For Stryker stretchers, the maximum weight capacity is 600 pounds; therefore, 300 pounds would be the trunk region of a 600-pound person being placed on the stretcher. Figure 11 shows the distribution of the 300-pound load, automatically chosen by SolidWorks FEA. Figures 12a and 12b show the displacement results for sandwich composite and syntactic foam, respectively. The maximum deflection for the sandwich composite and syntactic foam was 0.85mm and 2mm, respectively. While the sandwich composites were a stiffer material, the deflection of the syntactic foam was still minimal. Since cost was one of the design constraints, the team chose syntactic foam because it was much cheaper. Sandwich composites were going to be $550 for a 16x16 inch square, but the materials to make all three platforms out of syntactic foam only costed about $135.

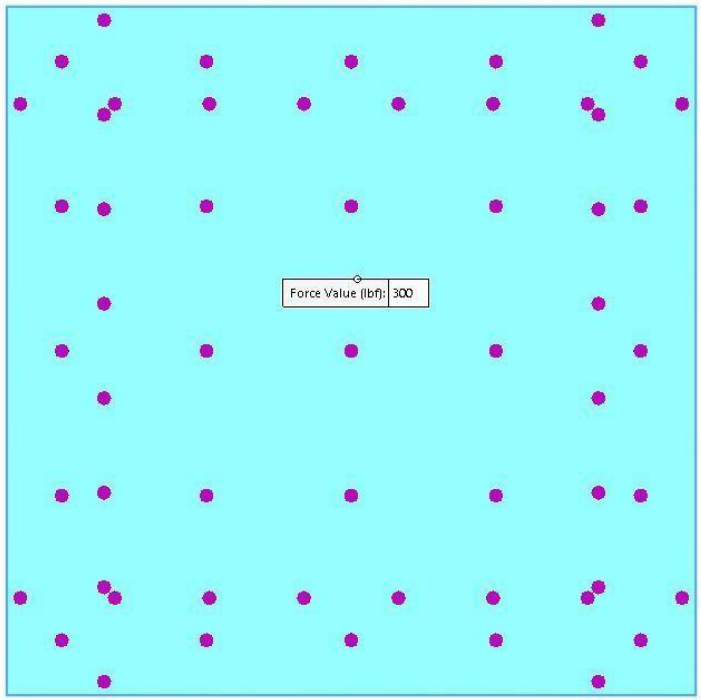

Figure 11*. SolidWorks' distribution of 300lb load on top scale.*

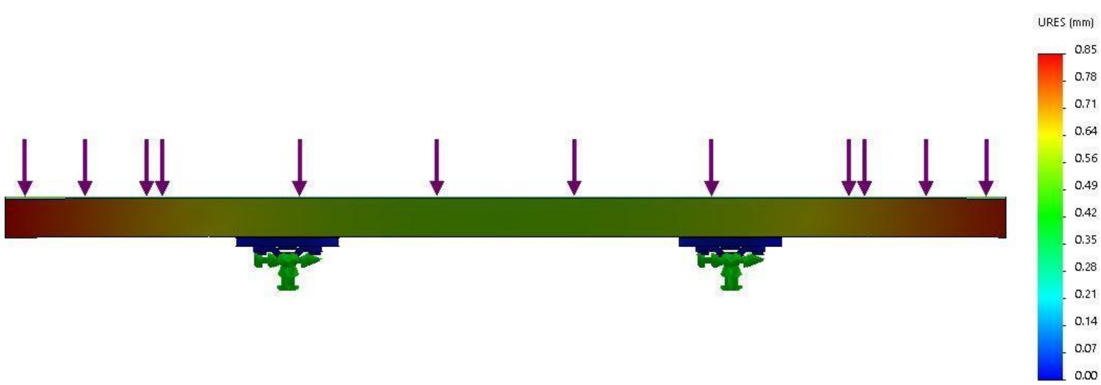

Figure 12a*. Displacement of sandwich composite with 300lb force applied to top.*

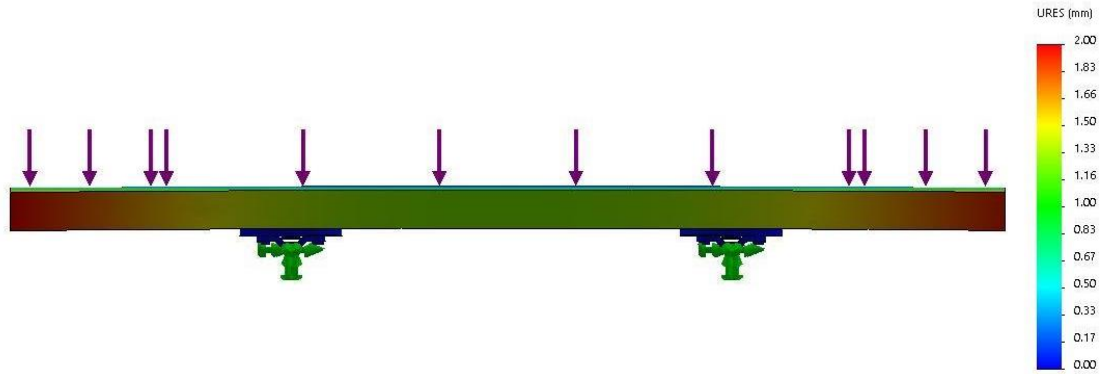

***Figure 12b**. Displacement of syntactic foam with 300lb force applied to top.*

<u>Build</u>

Once syntactic foam was chosen as the material, molds for each scale had to be made. For a single prototype, it was sufficient for the team to use plywood to build the molds. The wood was cut and nailed together to form the molds. To ensure that the epoxy would not cure and stick to the wood, a thick layer of wax needed to be applied; after watching tutorial videos, a carnauba-based car wax was chosen, which helped to create a non-stick surface. Multiple layers of polyvinyl alcohol (PVA) were then coated on top of the wax to ensure easy release from the wood. These molds can be seen in Figure 13.

***Figure 13**. Wood molds used for casting platforms of syntactic foam.*

Once the molds were dry and ready, the team mixed together equal volumes of epoxy part A, part B, and glass bubbles. Once thoroughly mixed, the syntactic foam was poured into the molds in thin layers, and a heat gun was used to diminish any air bubbles that formed during the mixing process. Once all of the syntactic foam was poured into the molds, they were left to cure for at least 24 hours before being taken out. Once the platforms were ready, the preliminary prototype was built.

To determine what load cells to use, a stand-on bathroom scale was purchased and taken apart. It was found that these scales use four strain gauge load sensors, wired to a custom printable circuit board (PCB), as seen in Figure 14. This PCB configured the sensors into a Wheatstone bridge to calculate the total measurements, and then displayed the final weight on an LCD. These load sensors (Fig. 15) could measure up to 100 pounds (50 kg) each and had a low comprehensive error of 0.05 mV/V. The nonlinearity (maximum deviation from the straight line), repeatability (ability to maintain consistent outputs for identical loads), and creep (change in output over 3 minutes) were all 0.03%, which was about average when compared to other types of load cells. These factors relate to the sensors' abilities to accurately read within ± 0.034 pounds (±0.0156 kg). It was decided to use the same type of load sensors for this project as what was in the bathroom scale.

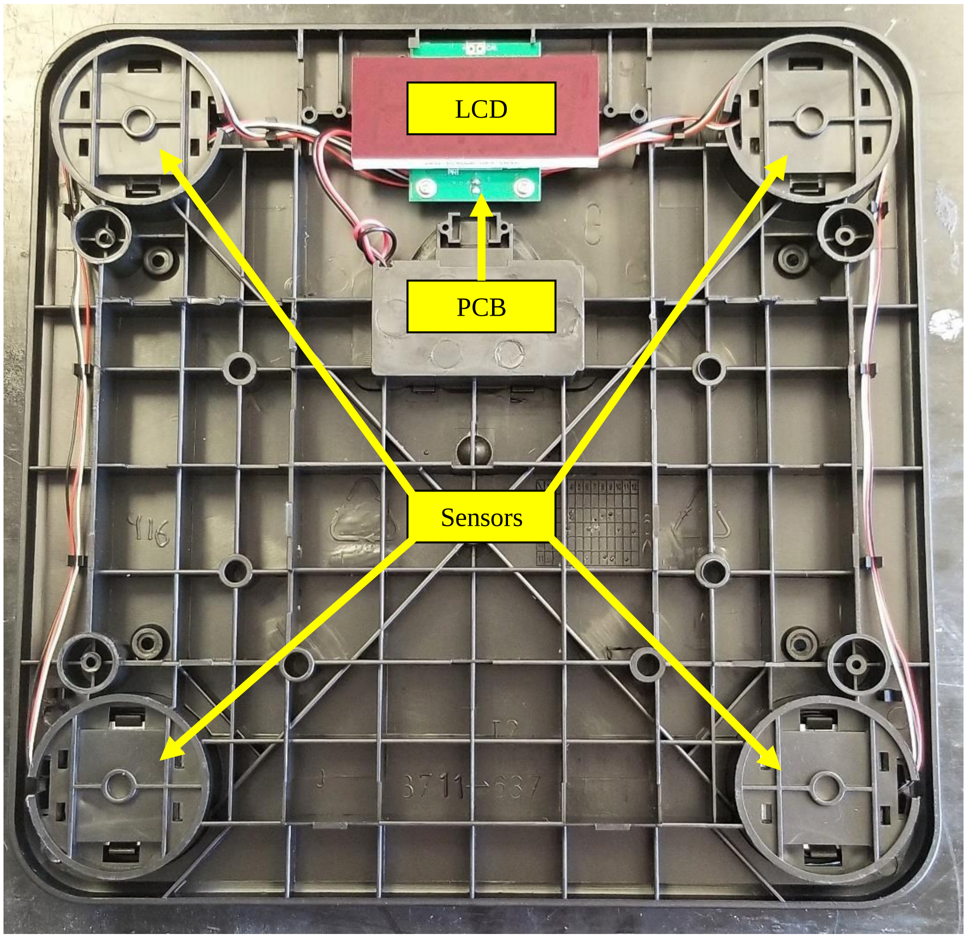

Figure 14. *Sensor placement and wiring inside a bathroom scale.*

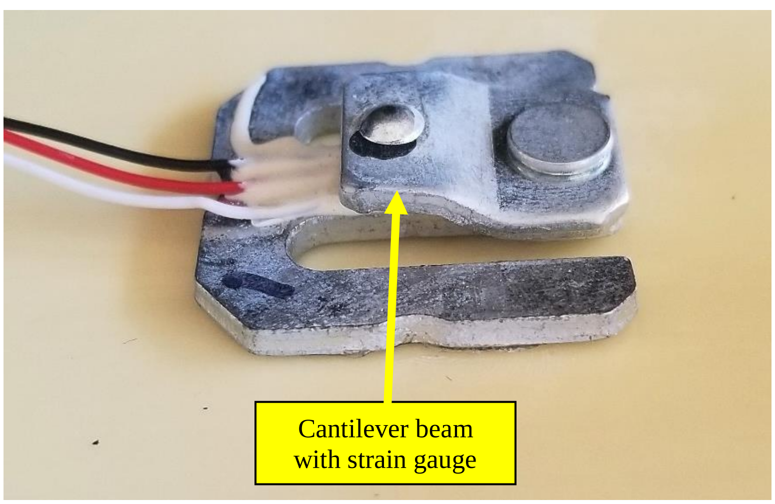

Figure 15. *Strain gauge load sensor used in bathroom scale.*

Once the load sensors were chosen, it needed to be determined where they should be placed on each scale. The load sensors were initially taped to the bottom of each platform to determine their best placement; they were then secured to the bottom of each platform. To determine how to wire the sensors together for each scale, the SparkFun "Load Cell Amplifier HX711 Breakout Hookup Guide" was used.[21] This tutorial provided step-by-step instructions for wiring the four load sensors to a combinator, which was then attached to an HX711 amplifier and then the Arduino. Throughout the wiring process, a multimeter was used to ensure free-flowing current through all wires and connections. Additionally, time was taken to ensure that all solder connections were secure and there were no loose wires; these connections were periodically checked throughout the build and testing of the device.

The use of a combinator helped to easily configure the sensors into a Wheatstone bridge. With the combinator, two of the sensors are variable while the other two are constant values. The combinator was attached to an amplifier, which then sends the signal to the Arduino. An HX711 amplifier was used to increase the signal from the load sensors so it can be easily read by the Arduino. This amplifier includes an optional connection that helps to ground any outside electromagnetic interference; this connection was used. Additionally, the wires used to connect the combinator to the amplifier was a 6-conductor coiled cord, 5 wires and a copper shield wire in an outer jacket. The extra copper shielding within the wire also helps to cancel out potential noise or interference. This circuit can be seen in Figure 16. The Arduino, a programmable microcontroller, was used to calibrate the sensors and add the weight measurements together.

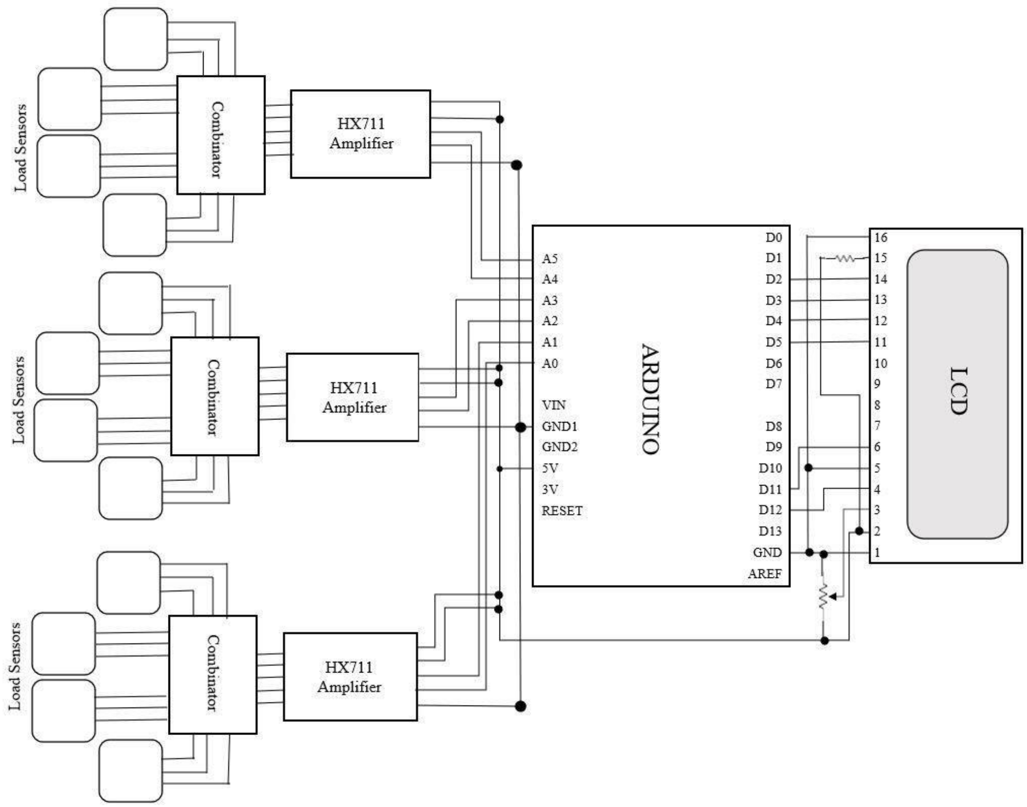

***Figure 16**. Circuit schematic for the device.*

The SparkFun tutorial also included two samples codes, one for calibration and one for final use. These codes were modified to include the three scales. The final code was written so that the total weight is the summation of the three individual measurements, allowing the scales to work independently or together. For example, if the patient is a small child, the paramedics could place them solely on the bottom scale and the Arduino would add zero pounds for the top and middle scales. The total weight would only be that which was placed on the bottom scale. Contrarily, if an adult is lying across all three scales, the Arduino will take measurements from each scale and add them together for a total weight. Once the total weight is calculated, the Arduino displays the reading on the liquid crystal display.

Calibration

The calibration code was written so that each scale had its own calibration factor. To determine that correct calibration factor, a weight was placed on one of the scales. Depending on whether the reading was higher or lower than the actual weight, the calibration factor was changed accordingly. This was done for each scale individually to establish a baseline. Once each calibration factor was determined, the scales were coded together are recalibrated all together. Once the best calibration factors were determined, they were added into the final code for full testing.

Calibration of each scale was first done separately using small weights. Five- and ten-pound weights were used for the initial calibration, before using 35- and 45-pound weights. Once each scale was calibrated individually, they were then programmed and calibrated together. With the scales programmed together and the foam padding on top, known weights were again used prior to testing people. Throughout the calibration, the weights were moved across the scales to ensure that all points on the stretcher would read similarly. With the foam padding distributing the weight across the scales, it could be seen that the scales were a little sensitive to where the weight was placed. Calibration measurements can be seen in Table 3 for various weights used and where the weight was relative to the scales. While the readings are not exact, the three calibration factors used to obtain these values were the best of the combinations tested.

Table 3. *Initial Calibration Readings*

Placement on Pad	Known Weight (lb)	Reading (lb)
Scale 1 (top)	10	9
	45	47
	90	93
	180	184
Between 1 & 2	10	7
	45	49
	90	95
	180	186
Scale 2 (middle)	10	10
	45	45
	90	92
	180	182
Between 2 & 3	10	8
	45	43
	90	87
	180	175
Scale 3 (bottom)	10	11
	45	41
	90	89
	180	178

Once the calibration was complete, the scales were ready to be tested with people. Table 4 shows the recorded measurements of a few classmates who volunteered to help. These peers were asked to lay on the stretcher in order to obtain the 'scale weight'. They then stood on a calibrated bathroom scale to obtain the 'standing weight'. Half of these measurements were within the ± 1.5-kilogram goal. As it can be seen in the table, some measurements were over, some under, and one exact. One preliminary explanation for this was that each person's body weight is distributed differently. As mentioned, it could be seen during calibration that the scales were sensitive to placement. With the foam pad distributing each person's weight onto the scales, it could be seen that the readings were slightly different for persons of varying body types.

Table 4. *Preliminary Testing of Scale Accuracy*

Gender	Height	Standing Weight (lb)	Scale Weight (lb)	Difference (lb)	Difference (kg)
Female	5' 5"	130	131	+1	+0.45
Female	5' 5"	135	133	-2	-0.91
Male	5' 10"	219	214	-5	-2.27
Female	5' 9"	188	190	+2	+0.91
Female	5' 4"	112	116	+4	+1.82
Male	6' 3"	210	208	-2	-0.91
Male	6' 0"	226	230	+4	+1.82
Female	5' 6"	144	148	+4	+1.82
Male	5' 10"	186	186	0	0
Male	5' 8"	165	160	-5	-2.27

Final Prototype

An Arduino is currently being used to power and run the weighing scale, with an LCD attached to display the total weight. Within the code that was written, the Arduino takes each of the three weight measurements, adds them together to obtain a total weight, and then displays that total on the LCD. A preliminary housing box containing the electrical components, Arduino, and LCD was constructed from wood in order to determine its best size, where holes need to be made for wires coming in/out, and to ensure that it will conveniently fit somewhere on the stretcher frame for paramedics to see the LCD. This was since replaced with a more durable plastic box. Figure 17 shows the scales and pad on top of the stretcher and the LCD housing box attached to the side.

Figure 17. *Final prototype placed on a Stryker stretcher.*

To ensure that the sensors would not fall into the holes that are present on the base of the stretcher, a thin sheet of plastic was attached to the bottom side of each scale. This plastic was attached using strips of rubber foam weather seal. The material used for attaching the plastic needed to be easily compressible so that it did not take away any of the load from the sensors. With the use of the foam strips, it also helped to make the scales waterproof.

Along with the smaller electrical components, the device needed a power source. One option that was explored was using a portable, rechargeable battery. In order to recharge the battery, EMS personnel can use the power source that is in the back of the ambulance. However, it was determined that this option would not be best for keeping everything waterproof and easily accessible. Instead, a battery was wired to the Arduino shield, powering the weighing scale with a 9-volt battery. This battery fits in the housing box with the rest of the electronics.

Indications of Use

This weighing scale is indicated for use in the emergency medical field during the transportation of recumbent patients who require drug dosing. A recumbent patient could be someone experiencing cardiac arrest, seizure, or any kind of trauma which inhibits them from standing on a scale or effectively communicating their own weight. For these specific situations, there are a number of drugs that might be administered; specific drug administration depends on each individual situation. The scale is made complimentary to the ambulance stretcher and will attach to the base of the stretcher. This project is directly targeted to improve patient care during an emergency medical situation requiring drug dosing by providing an instant weight reading. Medical personnel can dose drugs more accurately and prevent patient injury and complications.

Intended Use

The weighing scale is intended for paramedics to obtain accurate patient weights during emergency situations. The scale will allow for medical personnel to accurately dose a patient by providing an instant weight of the patient when placed upon the stretcher. Ideally, the most accurate measurement will be taken when the stretcher and the patient are both still. With the use of a programmable microcontroller, one can program the code to filter out any noise that might occur due to any movement. Since the scale will be attached to the ambulance stretcher's base, regardless if the patient needs drug dosing or not, it will provide a weight. Once the patient has been removed from the stretcher, the scales will automatically calibrate back to zero. This scale will be able to accurately measure patients of all weight and heights.

Verification

Material Testing

As mentioned, the ASTM D7264 standard was used to ensure the proper procedure for conducting four-point bending tests.[22] A sample calculation for the maximum flexural stress, maximum strain, and flexural modulus of elasticity can be seen in Appendix A. In a large-scale manufacturing environment, syntactic foam could be manufactured more consistently through the use of vacuum degassing and an intricate mold design to reduce imperfections. Due to limited resources available to a student design team, the syntactic foam might not be of the best quality that it could be because of air bubbles that formed during the mixing and pouring processes. The heat gun was used to eliminate as many air bubbles as possible, but vacuum degassing would be better. Also, the wood molds used can be reconstructed to use again, but silicone or polyurethane molds would be better and would last longer. The composite could also be analyzed through many non-destructive evaluation (NDE) tests such as visual inspection and liquid penetration testing in order to verify its consistency.

Codes and Standards

The International Electrotechnical Commission (IEC) has created a set of standards for the safety and performance of medical equipment with electrical components. The IEC 60601-1 (*Medical Electrical Equipment – General Requirements*) standards serve as a requirement for the commercialization of medical equipment; these standards were consulted throughout the design process of this project.[23] Another standard that the team took note of is the Ground Vehicle Standard (GVS) for Ambulances, which was created by the Commission on Accreditation of Ambulance Services (CAAS). In section C.10 – Ambulance Body and Patient Area, it specifies the general construction of the patient area: interior dimensions, body structure, doors, and flooring. Based on these standards, the weighing scale cannot be integrated into the floor. It also states that there must be a certain amount of open room for paramedics to work; therefore, the scale must be contained within the size of the stretcher.

Validation

Validation of the code and a working prototype was done through the aforementioned calibration and testing. In order to conduct full tests, Institutional Review Board (IRB) submissions were completed and approved. The first validation testing that needed to be done was to compare this weighing scale to the Broselow tape in order to prove that this would be the more accurate solution. Also, user testing was done in order to gain feedback from local paramedics; this feedback helped to better the device so that it totally suits their needs. For the comparison test, it was determined that at least 33 participants were needed. Equation 8 shows the statistical analysis used to determine this sample number. Currently, most medical personnel are off by roughly 8kg when visually estimating a person's weight; the goal for this device is to only be off by 1.5kg, giving a δ value of -6.5. The t-values are based on α, β, and ν, and they can be found using t-tables. To find the sample size needed, one must assume an n value, which gives ν = n-1. As higher n values are assumed, the calculated n values begin to converge to one number. These calculations can be seen in the appendix.

$$n = 2 * \left\{\frac{\sigma}{\delta}\right\}^2 * \left\{t_{\alpha,\nu} + t_{\beta,\nu}\right\}^2 \qquad \text{(Eqn. 8)}$$

n	=	sample size
σ	=	population standard deviation (8 kg)
δ	=	difference desired to detect (-5.5 kg)
α	=	desired significance level (0.05)
β	=	desired type II error rate (0.1 or 0.2)
ν	=	degrees of freedom (varying factor to determine n)

Risk Analysis

After conducting a Risk Priority Number matrix, it was found that the weighing scale can be considered a safe supplement for determining recumbent weight during an emergency situation. There are currently indirect solutions on the market that use mechanical and electrical components in an attempt to report recumbent patient weight; however, they have not implemented the technology into an ambulance stretcher. This is due to the complex nature relating to a high-risk priority number. This simple design has similar features to the indirect, existing solutions in which it utilizes load sensors, a programmable device, and light weight material. The Critical Risk Priority Number

Analysis was performed considering two assemblies: Assembly 1 (load sensor assembly) and Assembly 2 (Attachment to the base).

Assembly 1 had two parts: Part A (electrical component placement) and Part B (the scale). Part A components included the load sensors, the wires/electrical connections, and the Arduino, while Part B components included the scale material and the casing of the connections. The first major hazard was the electrical components of the weighing scale. Although the electrical circuit of this design is covered with insulation and waterproof material, there is a risk of electroshock and system failure due to electroshock if the scale is tampered with. Additionally, if a scale falsely reports the weight of an individual, serious medical implications could occur. False reading is an extreme situation that would be caused by human tampering of the electrical components. These two scenarios in Assembly A can be controlled by providing a safety information sheet for the handling of the device, conducting monthly maintenance inspection checks, and providing proper training.

The second hazard included the mechanical components (the building of the material). A source of failure could come from the dimensions of the weighing scale. The scale should provide adequate area to support the patient; however, failure to support adequate portions of the body could lead to inaccurate patient weighing. Thus, the maximum load of the scale must be considered to prove that the loads sensors can withstand average patient weight given by the CDC.

When considering hazards related to the use of the device by medical personnel, it is vital to measure the weight of the weighing scale and cover all exposed wire. The weight of the scale had to be light enough as to not add unnecessary weight to the stretcher. If the scale is dropped, there could be damage to it and strain on the medical personnel. If wires are exposed, medical personnel, as well as the patient, are both at risk for electroshock. Often, exposed wires are caused by improper handling of device. For this reason, training protocols will be heavily implemented to show proper use and handle of the scale.

Hazards that arise from maintenance and aging could include over-used load sensors and worn out wire insulation. The programmed load sensor assembly must be reprogrammed to maintain baseline values; the scale will be reset at certain time periods to ensure correct readings. The insulation of the electrical wires may experience wear and tear, and this could be hazardous to patients and medical personnel if they come into direct contact with the wiring. However, the maximum voltage through the electrical components is five volts; therefore, this would cause only minimal injury.

Calibration checks should be performed monthly by the paramedics to ensure weight readings are accurate. It is recommended that paramedics test the weighing scale weekly, or at least once a month, by weighing themselves; this can be done at the fire station. Records of these tests can be used to ensure that the scale is still within the ± 1.5kilogram range of actual weight measurements. If the scale is off by more than this, the paramedics will be advised to contact the manufacturer and have it serviced.

This weighing scale is simply for displaying the weight of a recumbent patient in emergency situations; however, multiple energy hazards could arise and must be noted. For example, if a patient must go through CPR, the vibrations of the compressions could interfere with the scale. In instances like this, the scale will be turned off to avoid system failure and patient injury. If a defibrillation system is in use, the scale will be turned off to avoid interference with device and electrical shock waves.

After completing the risk analysis documentation (DFMEA), this weighing scale does not exceed a risk priority number of 16.

Assembly 1						
Assembly	**Failure and Effect**	**S1**	**O1**	**D1**	**RPN Before**	**Preventative Measures**
Part A (Load Sensor)	Sensor	1	3	2	6	Provde training and protocol for use Protocol for monthly calibration
	Connections	1	3	2	6	Use of a covering to ensure water resistance and avoid electroshock
Part B (Scale)	Arduino	2	3	2	12	Regular claibration to ensure accuracy
	Scale Material	3	2	1	6	Material will need to withstand loading up to 600 lbs
	Casing	3	3	1	9	Must be corrosion-resistant and waterproof

Figure 18. *Risk analysis of assembly 1.*

Assebly 2						
Assebly 2	**Failure and Effect**	**S1**	**O1**	**D1**	**RPN Before**	**Preventative Measures**
Part A (Attachment)	Velcro	3	2	1	6	Scale will be secured to the base Pad will be secured to the scale
	Materials	3	2	1	6	Materials will be compatible with sanitizing agents for cleaning

Figure 19. *Risk analysis of assembly 2.*

Action Plan	
Electrical Component Testing	A. Post prototype manufacturing, cover all electrical components with electrostatic coverings B. Test electrostatic properties on an electrstatic workbench C. Test for waterproof properties
Mechanical Component Failure Testing	Test mechanical properties by simulating wear and tear - use MTS for cyclic loading
Usage Testing	Use MTS to apply multiple, varing loads to determine maximum number of loading before failure
Chemical Resistance Testing	Verify no erosion when wiping with Sani-Cloth disinfectant wipes

Figure 20. *Risk analysis action plan for the device.*

Accuracy Testing

After obtaining IRB approval, testing the accuracy of the weighing scale was the first things that needed to be done. After initial testing was completed in the lab to ensure the scale was reading accurately, the real testing was conducted at Prince of Peace Catholic Church in Hoover, Alabama. A stretcher and the scale were set-up in a common area of the church and volunteers were asked to participate. Each volunteer was asked to first lay on the stretcher and then stand on a calibrated scale. If the volunteer was a child, a Broselow tape was stretched alongside them as they were laying on the stretcher; their age was also noted in order to record the weight measurement from the Pedi-Wheel. All weight measurements were recorded in pounds. Over a period of two days, 53 children under the age of eighteen and 23 adults above the age of eighteen participated.

For participants under the age of eighteen, four data measurements were recorded: standing weight (using a calibrated bathroom scale), recumbent estimation (laying on weighing scale), Broselow estimation, and Pedi-Wheel estimation. Using the standing weight as the theoretical value, the percent errors for the recumbent, Broselow and Pedi-Wheel measurements were calculated. The differences between the three estimations and the standing weight were calculated. The differences were used to find the mean and standard deviation for each of the estimations, as well as to create Bland-Altman plots. For the Bland-Altman plots, the standing weight is plotted on the x-axis and the difference on the y-axis. Paired t-tests were done in Excel to determine if there was a significant difference between each estimation and the standing weight.

For participants above the age of eighteen, the standing weight and recumbent estimation were recorded. The percent error was calculated with the standing weight as the theoretical value. Similar to the under eighteen group, the difference was calculated and used to determine the mean and standard deviation, as well as create Bland-Altman plots. Lastly, a paired t-test was done in Excel to determine if there was a significant difference between the two values.

User Testing

Once data regarding the accuracy of the device was collected, the next step was to gain feedback from potential users. While IRB approval for full user testing was pending, mock tests with a couple EMS agencies was done. Meetings were scheduled with a fire station in both Mountain Brook and Vestavia Hills, Alabama. For each of these meetings, the device was set up on their stretcher and an explanation of how it works was given. After this, available personnel could volunteer to lay on the stretcher and have their weight measured. Throughout the setup and testing, personnel were asked to provide feedback regarding the device and if it is something that they would find useful.

After obtaining IRB approval, a meeting was set up with the chief of Hoover Fire Department. During this meeting, the device was set up and an explanation of how everything works was given. After discussing the prototype and expressing some concerns, it was determined that Hoover Fire Department would not perform the user testing, as they were not comfortable with using the device. These concerns and other feedback from the personnel were recorded to help with bettering the prototype.

RESULTS

Accuracy

Pediatrics

It should first be noted that, of the 53 participants under the age of eighteen, the Broselow tape estimation was only applicable for 32. While the participants' ages range from a few months old to fifteen years old, the Broselow tape was not applicable for any children over the age of ten; an estimation was obtained for two of the seven participants at the age of nine and one of the seven participants at the age of ten. While the tape is designed to be used for children up to the age of twelve, most children around the age of nine are starting to be taller/longer than the tape. Because the Broselow tape was not applicable for all of the children, the data was split into two sets: (1) comparing all three estimations for 32 participants, and (2) comparing the recumbent and Pedi-Wheel estimations for all 53 participants.

The first data set compared all three estimations (recumbent, Broselow, and Pedi-Wheel) for the 32 participants that they all applied to. To calculate the percent error for each of the estimations, the standing weight was used as the theoretical value. Using Excel to calculate the error for each participant and then the average, the recumbent estimation has the lowest average error compared to the Broselow tape and Pedi-Wheel. The average percent error for the recumbent estimation, Broselow tape, and Pedi-Wheel are 13.6%, 13.9%, and 15%, respectively. Next, the difference between each estimation and the standing weight was calculated, with a positive difference meaning that the estimation was higher than the standard weight; the mean and standard deviation of the differences was calculated using the absolute value of the difference. The recumbent estimation had a mean difference of 6.53 ± 3.89 pounds, while the Broselow tape and Pedi-Wheel had mean differences of 6.67 ± 4.06 and 7.87 ± 6.03, respectively. It could be seen that the recumbent estimation and the Broselow tape estimations were typically higher than the standing weight, while the Pedi-Wheel estimation was typically lower.

The differences were also used to create Bland-Altman plots in order to compare the difference to the standing weight. If the two measurements are in agreement, the data points will lie along the horizontal line close to zero; if one measurement is biased, the points will be shifted away from the horizontal line. Figure 21 compares all three estimations, and Figures 22-24 show the individual plots for the recumbent estimation, Broselow tape, and Pedi-Wheel. As mentioned, the recumbent estimation and Broselow tape were typically higher than the standing weight and the Pedi-Wheel was typically lower. For the recumbent scale, the differences between the recumbent estimations and the standing weights cluster between positive two and positive fifteen pounds. For the Broselow tape, the differences between the estimation and the standing weight grows more positive as the weight of the participant increases. This would indicate that the Broselow tape is not as accurate for heavier children. For the Pedi-Wheel, a majority of the differences cluster between zero and negative fifteen pounds. Contrary to the Broselow tape, the Pedi-Wheel estimations grow more negative as the weight of the participant increases. This would indicate that the Pedi-Wheel is more accurate for smaller children.

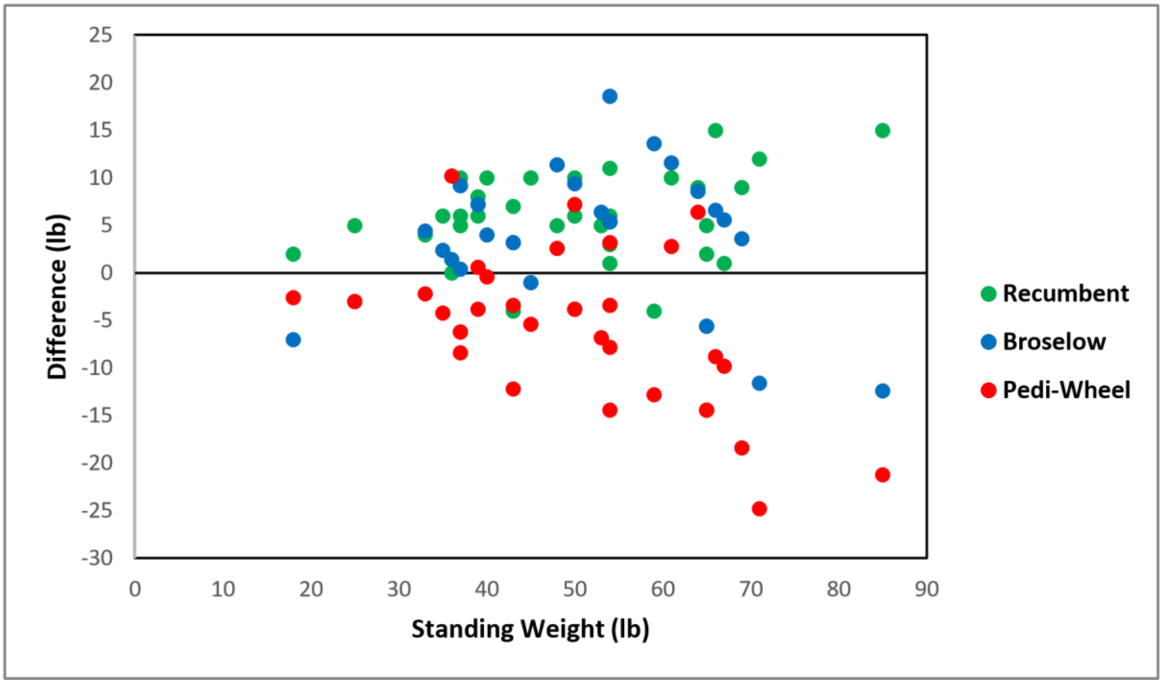

Figure 21. *Bland-Altman plot comparing all three estimation differences.*

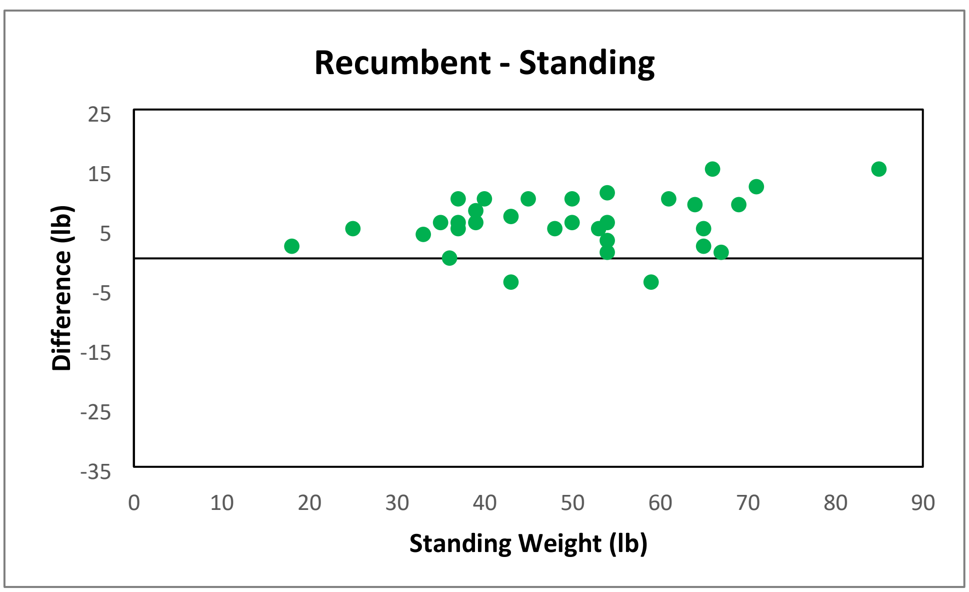

Figure 22. *Bland-Altman plot comparing the recumbent and standing weights.*

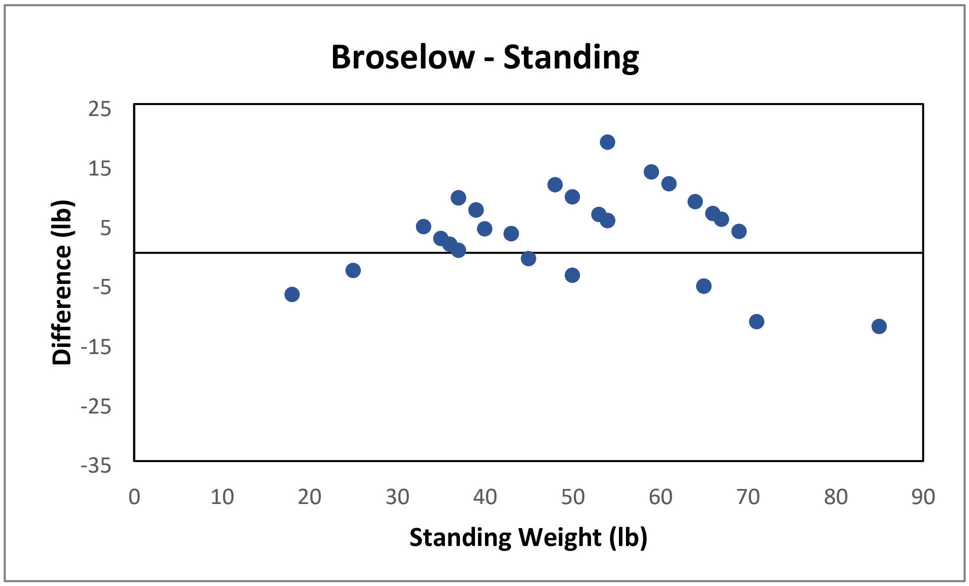

Figure 23. Bland-Altman plot comparing the Broselow and standing weights.

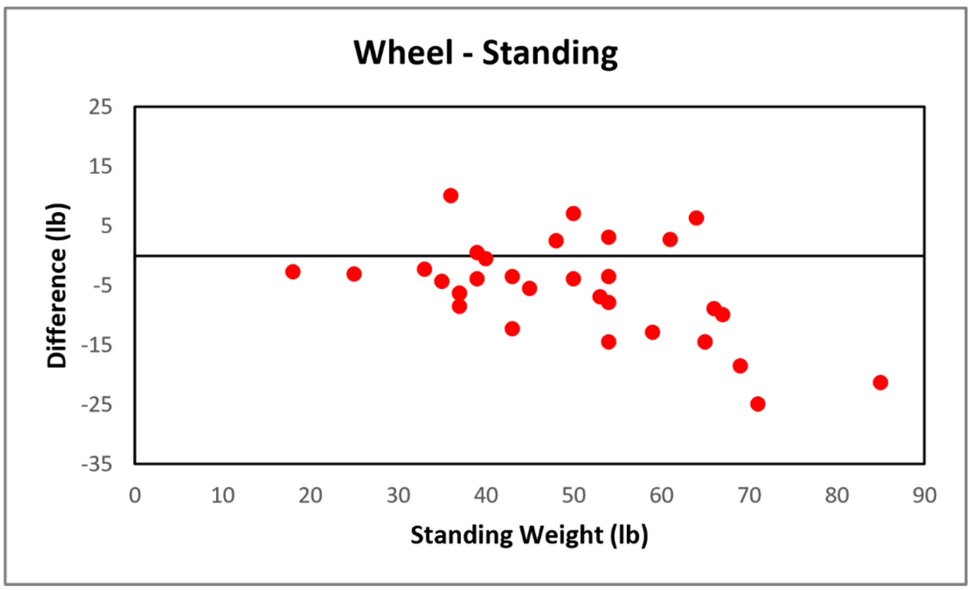

Figure 24. Bland-Altman plot comparing the Pedi-Wheel and standard weights.

After looking at the percent errors and Bland-Altman plots, paired t-tests were done using Excel to determine if there is a significant difference between the recumbent estimation, Broselow tape, and Pedi-Wheel and the standing weight. For each test, the null hypothesis was that the estimation (recumbent, Broselow, Pedi-Wheel) and the standing weight are equal and there is no significant difference. The p-values obtained from these tests for the recumbent estimation, Broselow tape, and Pedi-Wheel were < 0.000001, 0.0077, and 0.00031, respectively. Since all of the p-values are less than the significance level ($\alpha = 0.05$), the null hypothesis is rejected, and it can be stated that there is a significant difference between each of the estimations and the standing weight. For the recumbent scale, 6 of the 32 recumbent estimations were within the ± 1.5-kilogram goal. For the Broselow tape and Pedi-Wheel, 7 of the 32 Broselow estimations and 8 of the 32 Pedi-Wheel estimations were also within ± 1.5 kilograms.

The second set of data compared the recumbent estimation and Pedi-Wheel estimation for all 53 participants. The same procedures were used for this set of data. The average percent error for all of the recumbent estimations was 11.5%, and the average percent error for all of the Pedi-Wheel estimations was 16.6%. The absolute value for the mean difference and standard deviation for the recumbent and Pedi-Wheel estimations were 7.11 ± 4.14 pounds and 13.13 ± 13.72 pounds, respectively. The average difference between the recumbent estimations and standing weight was high by 5.87 pounds, and the average difference for the Pedi-Wheel estimations was low by 11.72 pounds. Figure 25 shows the Bland-Altman plot comparing all of the recumbent and Pedi-Wheel estimations, and Figures 26 and 27 show the individual plots for the recumbent and Pedi-Wheel estimations, respectively.

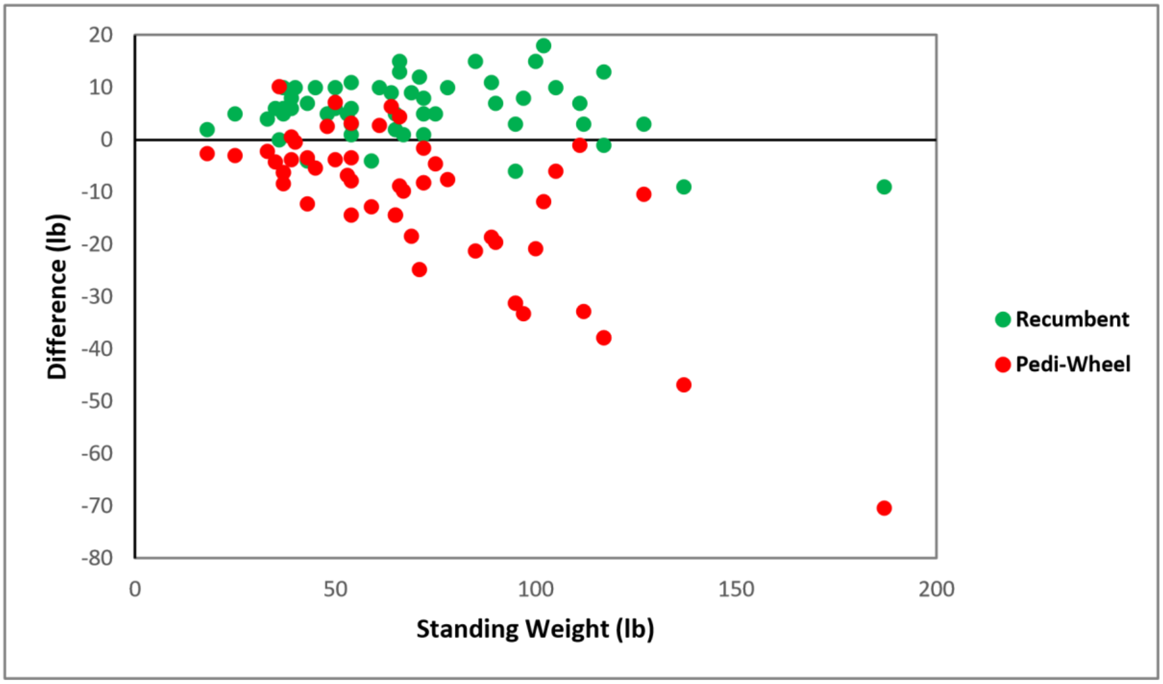

Figure 25. *Bland-Altman plot comparing the recumbent and Pedi-Wheel estimations.*

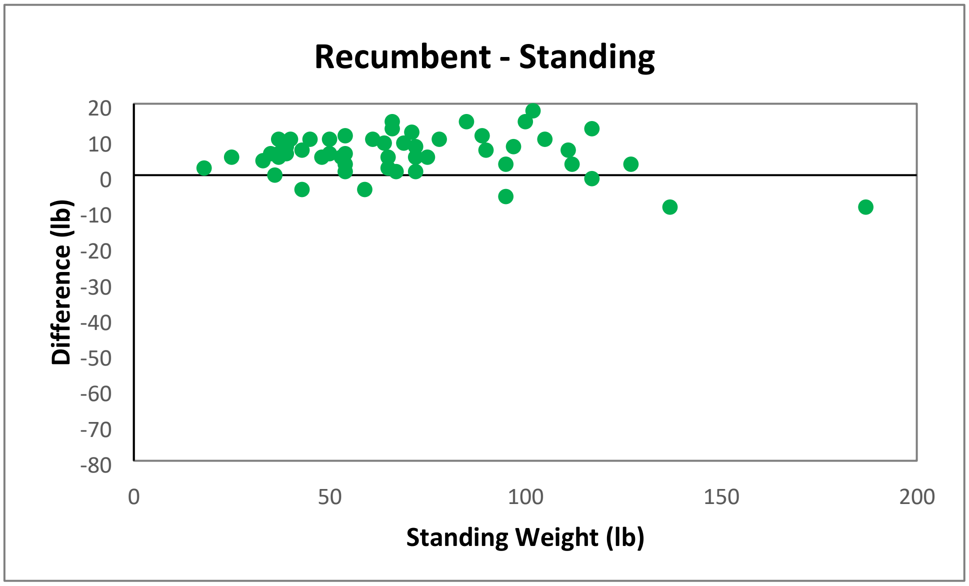

Figure 26. *Bland-Altman plot for all of the recumbent estimations.*

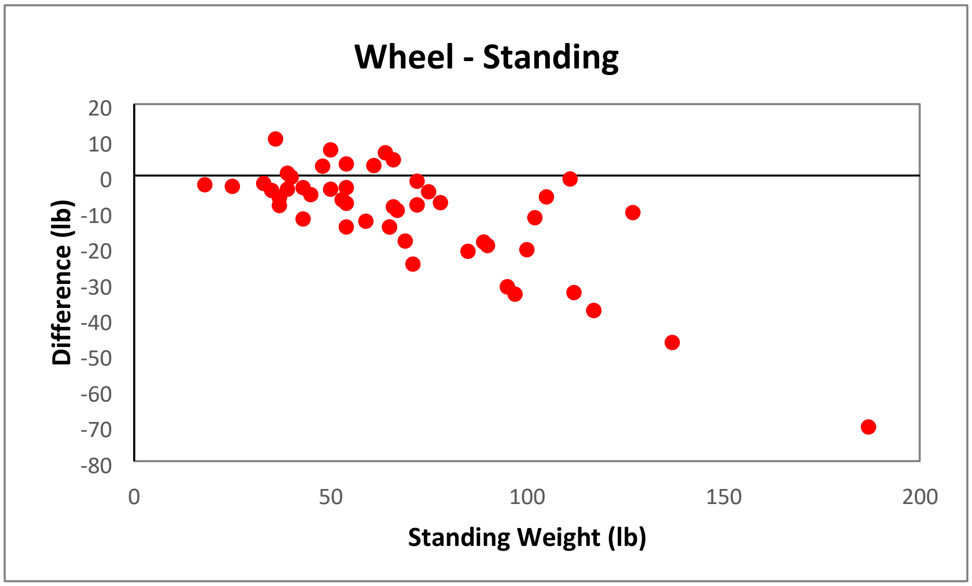

Figure 27. *Bland-Altman plot for all of the Pedi-Wheel estimations.*

The two Bland-Altman plots for the recumbent estimations are very similar; in both, the data clusters between positive two and positive fifteen pounds. When looking at the Bland-Altman plot for all of the Pedi-Wheel estimations, a majority of the differences cluster between positive five and negative twenty-five pounds. It can be seen more clearly in the second Pedi-Wheel plot that the estimations grow more negative as the weight of the participant increases. For this second set of data, the paired t-tests gave p-values of < 0.000001 for both the recumbent and Pedi-Wheel estimations. When looking at the data for the weighing scale, 11 of the total 53 recumbent estimations were within the ± 1.5-kilogram goal. For the Pedi-Wheel, only 10 of the total 53 estimations were within ± 1.5 kilograms.

Adults

For participants above the age of eighteen, the standing and recumbent weight measurements were recorded. The same procedures were done for this data set as what was done for the under eighteen data. The average percent error between the recumbent and standard weight was 7.65%, with a mean difference of 16 ± 16.76 pounds. The Bland-Altman plot for this data can be seen in Figure 28. When looking at the plot, the differences between the recumbent estimation and standing weight grow more negative as the weight of the participant increases. This would indicate that the recumbent scale is not as accurate for heavier participants. From the paired t-test, a p-value of 0.0037 was obtained, indicating that there is a significant difference between the recumbent and standing weights. Of the 23 estimations, only 8 were within the ± 1.5-kilogram goal.

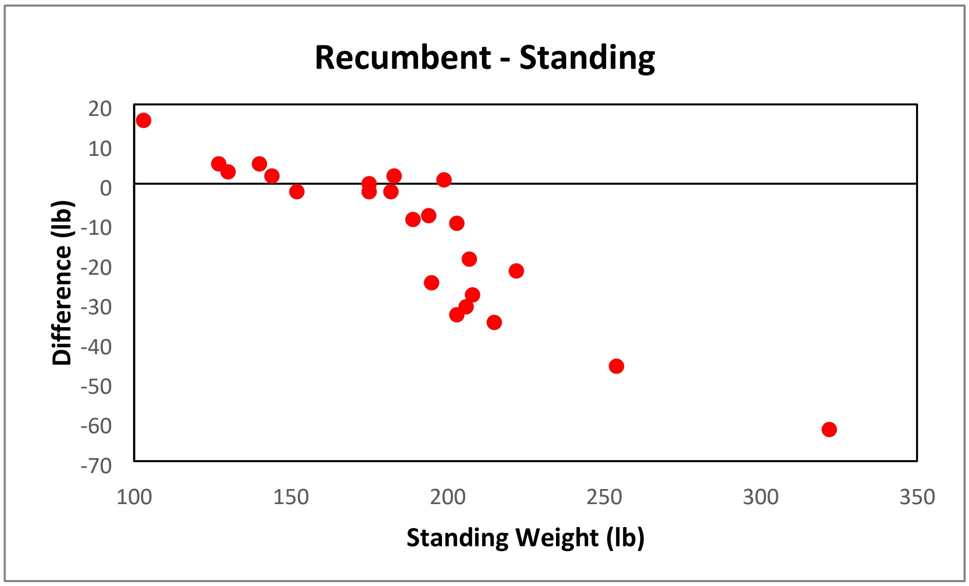

Figure 28. *Bland-Altman plot comparing the adult recumbent and standing weights*.

User Feedback

Meetings with fire departments in Mountain Brook, Vestavia Hills, and Hoover, Alabama were conducted to obtain feedback from the paramedics. During these meetings, an explanation was given throughout the setup and testing of the weighing scale. Paramedics were free to comment during any part of it; these comments were recorded by the present author. All of the participants gave positive feedback regarding the idea of a weighing scale for stretchers. They commented that this would greatly help them in their jobs and to better care for patients; they would definitely benefit from a weighing scale that can provide accurate patient weights.

Along with the positive feedback, some concerns were raised. The most common concerns were regarding the durability and the accuracy/reliability of the weighing scale. For the durability, paramedics asked if the scale would be able to withstand the harsh wear and tear that their equipment experiences on a daily basis. In many situations, the stretcher can be taken across rough terrains. In a time-sensitive situation, the weight of the patient might need to be taken while the stretcher is in motion; paramedics asked if this would affect the readings in any way. The scales should keep an accurate weight even when the stretcher is moving; however, true testing of this had not been done. The weighing scale would also experience constant loading and unloading of patients, for which the material cannot wear out quickly. Another concern was the reliability of the weighing scale. For a couple of the meetings, issues with the accuracy of the scale arose. While the weighing scale would work in the lab that morning, it would not work properly after being transported and setup on another stretcher. One problem was that their stretcher was a newer version than the one being used in the lab, so the scales didn't sit properly on the base.

A couple minor details that were also questioned were the location of the LCD and whether the weighing scale was waterproof. At one of the meetings, it was mentioned that psychiatric patients will try to grab at various objects. The placement of the LCD on the side of the stretcher might be a position for someone to try and grab at it. Also, in this situation, if psychiatric patients become restless or violent, the paramedics will need to constrain them with straps. These straps would typically go where the LCD was located.

Alternate locations for the LCD were then discussed, and the foot of the stretcher seemed to be the best potential position. However, this situation was brought up when meeting with a different group of personnel, and they said they think the side is the best place for the LCD. While it is true that psychiatric patients might try to grab at things, as long as the housing box is secure, it should be fine. Also, they thought it would be rather difficult to see the LCD if it is placed at the foot of the stretcher. While also discussing the LCD, questions regarding the waterproofing of the housing box arose. At the time of the meetings, the housing box being used was not waterproof.

DISCUSSION

As mentioned, the Broselow estimations were typically higher than the standing weight, and the Pedi-Wheel estimations were typically lower than the standing weight. For the recumbent scale, the recumbent estimations in children were typically higher than the standing weight, while the estimations for adults were typically lower. One observation that was made throughout the testing was that the readings from the recumbent scale were sensitive to a person's position on the pad. For the calibration and testing, a piece of tape was placed across the pad to indicate where one's bottom should go. If a person was slightly higher or lower than the tape, the recumbent scale would read a little differently. This sensitivity could account for some of the error in the recumbent estimations.

During the user testing, it could be seen that the plastic underneath the sensors was starting to flex from the sensors not being on a solid section of the stretcher base. To add support for the sensors, a thin strip of aluminum was added inside the plastic. This aluminum helped to keep the sensors on a solid surface and prevent them from misreading if the sensor was over one of the holes in the stretcher's base. After this aluminum was added, the recumbent scale started to read a little more consistently. To determine if the aluminum truly helps the accuracy and reliability of the scales, further testing would need to be done. This could be one possible solution to the reliability concern that paramedics had.

Recalibration

After analyzing the data, it was noted that the weighing scales were rather inconsistent, as measurements differed for persons of varying sizes. There are many variables that affect the accuracy of these scales, including (1) each person's body composition, (2) weight distribution through the foam pad, and (3) calibration of the scales. In a typical situation, a person stands on one scale. However, in this situation, a person is laying on a foam pad across three scales. Each person's body composition can affect how accurately the scales read; whether the person is tall or short, lean or stocky, has more muscle or more fat all play a part. In addition to this, that person is laying on top of a foam pad, which is then distributing their weight onto three scales. These were observations made in both the initial calibration and the testing.

Originally, each scale was initially calibrated individually before being programmed together. Each of the three scales had its own calibration factor and was calibrated to read individual weights. When the scales were all wired together, it could be seen that, while a weight was placed directly over one scale, the foam pad would distribute some of that weight to the other scales. For example, when a 45-pound plate was placed on the pad over the middle scale, the middle scale would read 45 pounds, but the top scale would also be reading 10 pounds, giving a total weight of 55 pounds. To fix this issue, the Arduino code was changed so that all three scales were calibrated as one, using only one calibration factor instead of three.

For the new calibration method, a long piece of wood was placed across all three scales; this was used to establish a baseline for the calibration factor before the foam pad was added. Once the foam pad was placed on top of the scales, a similar approach was taken as the initial calibration process: weights were placed on top of the scales and the calibration factor was changed accordingly until the scales were reading the known weight that was placed on top. Ten- and forty-five pounds weights were used for calibration. Table 5 shows the readings from the new calibration process, after the proper calibration factor was determined. Figure 29 compares the readings from the first and second calibration methods, showing that the new calibration is not as sensitive to placement as the first.

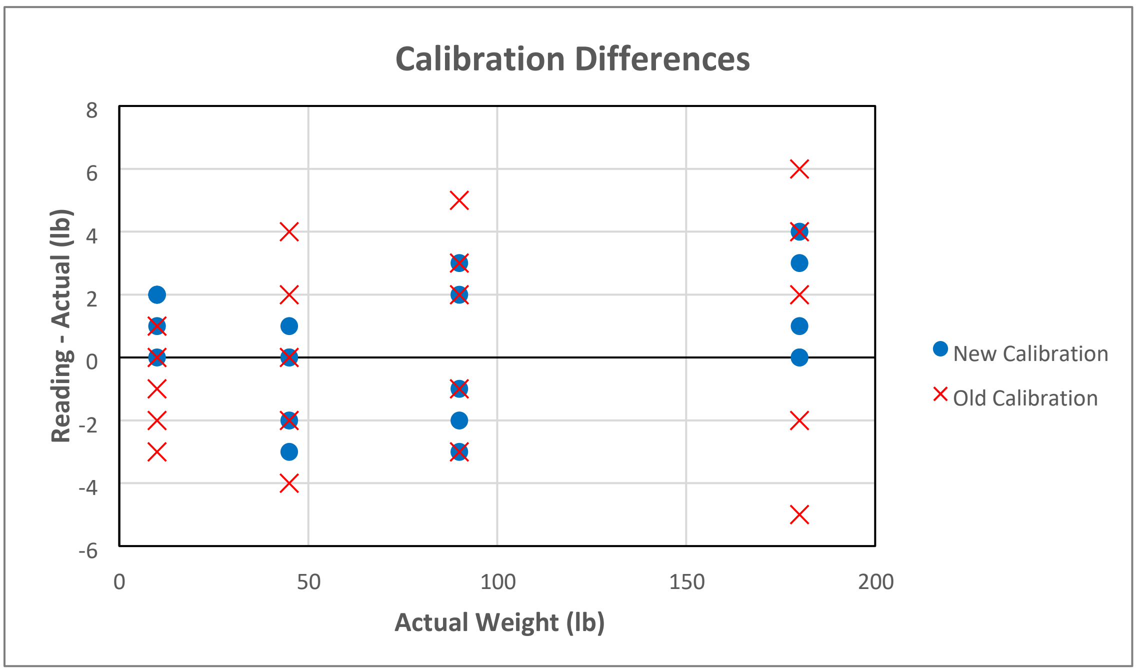

Figure 29. *Differences between the scale reading and actual weight for the old and new calibration methods.*

Table 5. *New Calibration Readings*

Placement on Pad	Known Weight (lb)	Reading (lb)
Scale 1 (top)	10	11
	45	45
	90	89
	180	180
Between 1 & 2	10	12
	45	43
	90	93
	180	180
Scale 2 (middle)	10	12
	45	45
	90	87
	180	183
Between 2 & 3	10	10
	45	42
	90	88
	180	181
Scale 3 (bottom)	10	12
	45	46
	90	92
	180	184

Business Model

Throughout various business and engineering courses, a fictitious business model was prepared for if a company was created in order to sell this new weighing scale. While developing this business model, approval from the Food and Drug Administration (FDA) and potential reimbursement options were explored. Product marketability and manufacturing needs are discussed, as well as on-going research and development. The information from the business model is then condensed into a business model canvas, which is used in the lean start-up method by entrepreneurs and small start-ups.

FDA

This stretcher scale system is a Class I medical device and falls under the FDA's exemptions as defined in 21 CFR Parts 862-892. A premarket notification application and FDA clearance is not required before marketing the device in the United States; however, the device must be registered with the generic category or classification name. The generic classification is a patient scale, regulation number 880.2720. This classification is 510(k) exempt. The manufacturing company and device will have to follow Current Good Manufacturing Practices (CGMPs) established by the FDA, and the company will have to renew the device filing annually with the FDA.

Reimbursement Process

Developing a reimbursement strategy includes the following steps: (1) become fluent in medical billing-medical coding systems, (2) understand payer's considerations when issuing new coverage, and (3) understand the needs of stake holders. There are various codes used for billing of inpatient and outpatient procedures. Ambulance and transport services and supplies lie in the HCPCS (Healthcare Common Procedure Coding

System) code range of A0021-A0999.[24] The codes that relate to this project are listed below.

1. A0425 – Ground Mileage
    a. Quantity is per mile, and the reimbursement for mileage is generally based on the insurance company's perception of who is the closest appropriate provider.
2. A0426 – Advanced Life Support Level 1, Non-Emergency
    a. This code includes transportation by ground ambulance medically necessary supplies for nonemergency situations. The response personnel must document an ALS (Advanced Life Support) assessment and provide at least one ALS intervention.
3. A0427 – Advanced Life Support Level 1, Emergency
    a. This code includes the provision of ALS1 services as an emergency response applies.
4. A0428 – Basic Life Support, Non-Emergency
    a. This code indicates transportation by ground ambulance vehicle, as well as BLS (Basic Life Support) services. The ambulance must be staffed by a qualified EMT. Coding for these services depends on state regulations and the ambulance provider's assurance. Any procedure conducted by an EMT using approved medical Class I and class II devices will be covered.
5. A0429 – Basic Life Support, Emergency
    a. This code includes the provision of BLS services as an emergency response applies.

6. A0432 – Paramedic Intercept
    a. This code applies to rural areas in which transports are furnished by a volunteer ambulance company. These volunteer companies are prohibited by state law from billing third party payers.
7. A0433 – Advanced Life Support Level 2, Emergency or Non-Emergency
    a. This code requires three or more different administrations of medications by IV push/bolus or by continuous infusion or medically necessary ground transportation, supplies and services, and the provision of at least one ALS procedure depending on state.

The above codes apply to each call an ambulance service attends to and how they are reimbursed for patient transportation. However, there are no codes regarding the financial aspect of maintaining each ambulance, which includes supplies and equipment. Therefore, there are no reimbursement codes that apply to features within ambulance equipment. As of now, our device would be considered a feature, as it is not a standard necessity.

Marketable Product

As detailed in this document, a minimum viable product (MVP) has been created. The next step is to create a minimum marketable product (MMP). In addition to the MVP that strictly had to be lightweight, work reliably, and provide accurate weights, the MMP must be cost effective and ready for commercialization. In order to reach commercialization, ways to replace the Arduino have been researched. With the use of syntactic foam, the MVP is cost effective. This MMP has a projected production cost of $450, but it is only be viable for Stryker ambulance stretchers due to the specific dimensions. The production cost is an estimate based on what was spent to produce one prototype; this amount could vary if any changes or additions are made to the scale.

Manufacturing Feasibility

Large scale manufacturing of the current prototype would require a large amount of space to run production in parallel. Due to the extensive time required for the epoxy resin to cure, many samples must be run simultaneously to upkeep production. Epoxy resin adheres to most materials; however, epoxy resin does not bond to some materials such as wax, polyvinyl alcohol, and silicone. While the method for the current prototype is cost effective for singular production, it is time consuming for consistent production. The sealed wood molds will have to be coated in wax and polyvinyl alcohol for every casting, which takes several hours. This process could be eliminated through the use of silicone molds, which would only require a mild mold release spray to prolong the life of the molds, eliminating hours from the process for each casting. The epoxy resin currently utilized has a workable pot life of 3 hours and reaches full cure in 24 hours at room temperature. In large scale manufacturing, this process could be expedited through the addition of fast curing agents and raising the cure temperature; however, these additions generally lower the strength of the final product and will require testing. In order to minimize casting defects, a vacuum system could be implemented to aid the casting process in reducing air bubble voids in the part. Reducing voids would greatly improve the strength of the cured product.

By utilizing four identical load sensors per scale, the sensors could be potted into the curing resin or attached following full cure. Each subsystem can be assembled before integration with the scale. The composite plates can be manufactured alone, and the

Wheatstone bridge wiring configuration, Arduino, and LCD display can be preassembled in bulk in preparation to be attached to the composite plates.

Research and Development

Immediate research and development goals need to be implemented to expand market penetration. The current marketable design is only usable with Stryker ambulance stretchers. Although Stryker holds the majority of the ambulance stretcher market, there are other manufacturers in use by many EMS agencies such as Ferno EMS. The main difference between the Stryker and Ferno Stretchers are the dimensions of the stretcher frame; both can handle approximately the same weight. Producing versions of the MMP for use with each major ambulance stretcher in use in the United States would be priority. Following adoption of the MMP and expansion into other United States' ambulance stretcher requirements, future development of a more advanced product would be looked at. A future version of the weighing scale could include age and height inputs to provide a calculated color-coded display that correlates with the current Broselow system for pediatrics. Additionally, a future version could be programmed to Bluetooth to the personnel's laptops that are used with the ambulance; with the weight, their computer system could pre-calculate doses of medications for the personnel.

Refinements in production with vacuum systems and molds could allow glass fiber reinforcement, which could reduce material costs, product size, and expedite construction. Refining this process would take significant time and resources over casting the current syntactic foam, but it could significantly increase profitability and visual appeal of a more refined product.

Business Model Canvas

All of the information above regarding the operating plan and market strategy for the business can be complied into a Business Model Canvas (Fig. 30). The need statement for this project was expanded upon to create the company’s value proposition. Despite having spoken with various groups of paramedics, the exact process that is followed by EMS agencies for purchasing materials for ambulance is still unknown. As of right now, it is believed that direct sales through a company website would be the most convenient; this could be subject to change in the future. It is also believed that it will be beneficial, at least in the beginning, to send a sales representative to each customer; this could change over time after the company and product become more recognized.

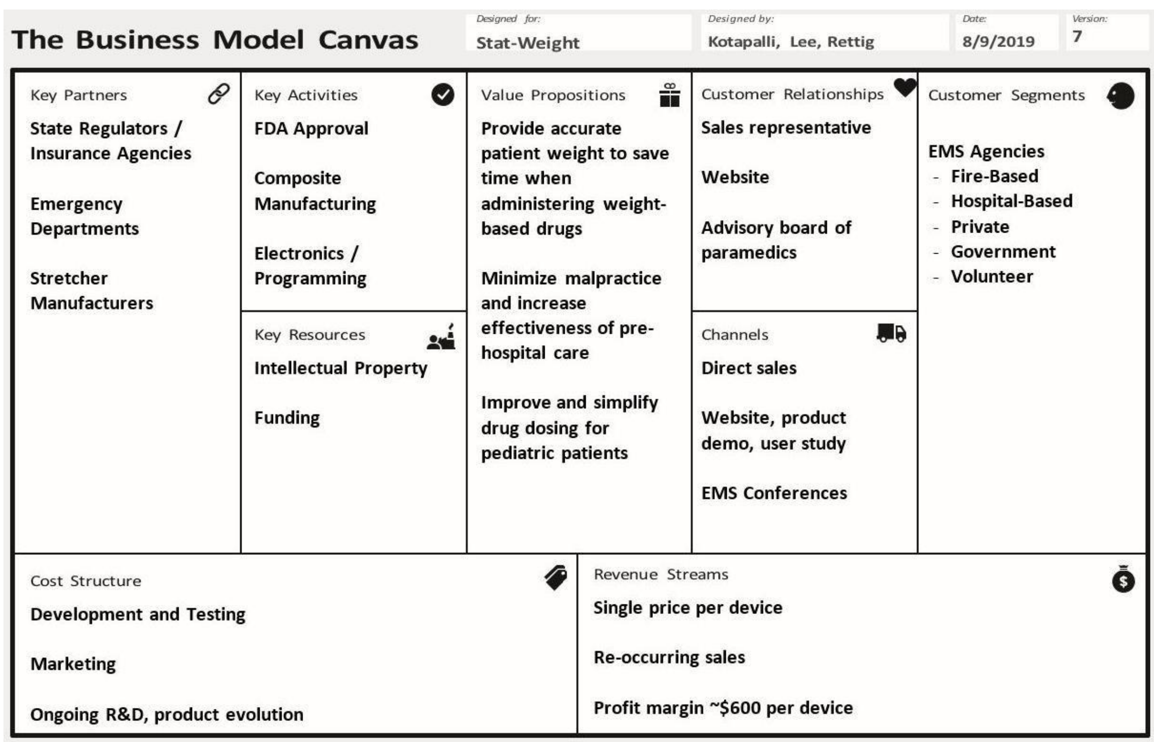

Figure 30. *Business model canvas created based on the business model.*

Future Work

There are a handful of modifications that could be made to the weighing scale in order to improve its quality. A couple minor changes include how the scale displays the final weight. Currently, the code is written to take ten measurements and average them for each scale, and then the Arduino adds these averages together to give the total weight. With the current code, the Arduino and LCD are constantly displaying a running number of weights. For a marketable product, the weighing scale would need to be programmed similar to a bathroom scale, where it only displays one weight. Throughout the testing of the weighing scale, weight measurements were recorded and displayed in pounds. For ease of the job, paramedics have also asked that the final weight be in kilograms. Since the medications they use are dosed according to milligram per kilogram, it would be easier and quicker for the paramedics to be given the weight in kilograms so they do not have to take the time to convert pounds to kilograms on their own.

It was observed throughout the testing that the syntactic foam was prone to warping. If the material was left in the heat, it would soften and begin to curl a little. This was mostly present in the bottom scale, as it is much longer than the other two. This could be a simple fix by adding small aluminum rods within the syntactic foam to act as rebar. Another solution might be to change the material all together. While older versions of stretchers required manual lifting, most of today's stretchers are automatic and include a button that is pushed for raising and lowering it. Since paramedics do not have to manually lift the stretchers anymore, a heavier, more durable material could be used for the scales. When looking into materials, it should also be noted that some of the new Stryker stretchers have bases with four sections, instead of the three-section design that was used throughout this project. These stretchers now allow for bending at the knee. With this new base design, the current weighing scale prototype will not be applicable for these stretchers.

The biggest modification that should be made to the weighing scale is to replace the Arduino with a custom PCB. In order to market the weighing scale, it should not include an Arduino, as the Arduino is not a marketable component. While the design for a PCB was explored in this project, the final design or product was not reached. Since the combinators and HX711 amplifiers are already PCBs in themselves, it will be easiest to design a PCB where the amplifiers connect onto it. The combinators can stay on the bottom side of the scale, with the sensors, and then a single, 5-strand wire can be connected from each scale to the PCB; this would help keep the number of exposed wires to a minimum. With a custom PCB, one can also order a custom box for the electrical components. There are many options for these custom boxes, one being waterproof. Costs of having a PCB made vary based on the number of layers, complexity of the schematic, what's mounted to it, the size/area of the board, and the number of holes. One website gave estimated costs to produce PCBs based on the quantity and the features.

- Simplest option: 2 layers, 100x100mm, 1.6 thickness, lead-free, 1oz copper ○ Quantity of 5 = $7.30 total
- More complicated option: 6 layers, 100x100mm, 2 thick, lead-free, 2oz copper ○ Quantity of 5 = $205.30 total

Another addition to the weighing scale would be to use Bluetooth to send the final weight directly to the paramedics. In one of the meetings, it was mentioned that it would be beneficial to them if the weighing scale could Bluetooth the weight to the paramedic's laptop. With sending the weight to their laptop or phone, the app could pre-calculate medication doses based on the person's weight. This addition would help to save the paramedic's time and better care for the patients. For this feature, a Bluetooth module can be purchased for $10. This small module is attached to the Arduino and can communicate between the Arduino and one's phone or computer. A separate code is written which controls the Bluetooth module, allowing it to communicate between the Arduino and one's phone or computer. One the device of choice (phone or computer), the paramedics would need to have Bluetooth turned on and connect with the module. Once the devices are connected, the Bluetooth module communicates with their device via a web-based application that would need to be downloaded.

Future Operating Plan

Along with the business model, an operating plan was created for a future company, including details regarding the key business members. The target market and customer are detailed, along with how the product would be promoted and the channels that could be used for selling. This business model also includes a detailed cost projection for the first year of operations, with estimated numbers for salaries, operating expenses, supplier and marketing costs, overall costs, and revenue forecasts.

In order to succeed as a company, a stringent operating plan must be implemented. The mission of this company would be to provide methods for medical professionals to improve the quality of treatment will begin with this scale system. The scale system will provide a way for medical personnel within EMS agencies to obtain recumbent patient weight in order to decrease inaccurate medication dosing.

The following plan is for an initial start-up consisting of a four-member team, including the three design engineers and one individual with a business/marketing background. An operating space would need to be leased or purchased and function primarily as a manufacturing center. The company would begin by targeting EMS agencies in the Birmingham metropolitan area and then expand via physical visitation to EMS conferences and centers in the region, as well as nationally. Online sales will be active. Based on the potential fixed costs of salaries and operating costs, an aggressive growth rate and large margin will be necessary until sales reach a turnover point to produce enough revenue to exceed expenditures. Within the first year, the company will need to have penetrated a significant portion of the South-east, as well as offer devices for all models of ambulance stretchers to make enough sales to impact the industry and grow. Later growth can expand into new devices and markets. Growth, market, and other projections are outlined below.

Business Members

In order to maintain a strong growth rate with sales, a quality product is vital. Of the potential four-member team, three members should have engineering backgrounds and one member with a business background; each team member will have a specific job. One member of the team will function full time as a quality control engineer in order to test the devices for defects. Many non-destructive evaluation tests of materials can be implemented, such as visual inspection and liquid penetrant testing to check for part defects. A manufacturing engineer will manage day to day production in tandem with the quality engineer. As sales grow, so will manufacturing demands. As revenue is gained, production methods can be modified to improve quality, lower costs, and expedite production. The manufacturing engineer and quality control engineer will work together to design and prototype new products as shown below in the manufacturing feasibility and research and development portions of the report. The third engineer will manage day to day operations and accounting to ensure that the company is following all local, state, and federal regulations, in addition to budgetary management. This member will help implement a set of quality standards with the engineers, a risk management plan, and monitor progress by key performance indicators.

In addition to the three engineers, acquisition of a fourth member to help with the business and marketing of running a company will be necessary. In order to expand sales, this member will function for distribution and sales. This employee will manage online sales, in addition to acting as a sales representative. The representative will travel to local EMS agencies to display the product, and if purchased, will install and train professionals in its use, as well as service any damaged products. As the company grows, the representative will attend regional and national EMS conferences.

Market Model

Target Market and Customer Archetype

The type of market that this product would fall into is a single-sided market, with the target being medical personnel. This can be broken into three segments: EMS agencies (paramedics), pediatric doctors, and emergency departments. EMS agencies are the most attractive segment since they currently have no way to obtain accurate patient weight. Emergency departments would be the next segment to look at, but they are not as attractive as the EMS agencies. Pediatric doctors are an attractive segment, but they are the least attractive of the three. For pediatric doctors, most of their patients can communicate their own weight and these situations are not as time-sensitive as it is for the other two.

A study done in 2016 stated that the EMS product market size was valued at 8 billion dollars, and it is expected to rise at a compound annual growth rate of 7.2% between 2018 and 2025.[25] This product market is expected to reach 15 billion dollars by 2025. This growth is based on an increase in trauma cases as well as growing healthcare spending to decrease time spent in a hospital. As of 2016, life support and emergency resuscitation held the largest share in the EMS product market; other shares included monitoring systems, wound care consumables, patient handling equipment, infection control supplies, and other EMS products. The end-users of these products were segmented into fire departments, government/third-party, private transport, hospital owned, public utility, volunteer, and other. Fire departments held the largest share in product use, as they are the first ones to attend casualties when responding to accident sites. Emergency departments have also been increasing over the years; use of emergency departments has steadily increased at a rate faster than the Unites States' population growth.

For both EMS agencies and emergency departments, there is no way to obtain an accurate patient weight, especially if the patient is unable to stand on a scale. This problem is crucial when dealing with children, as they have stricter medication dosing systems than adults. With existing solutions, medical personnel can approximate weights, but never obtain an accurate weight. Studies have shown that in pediatric emergencies, 1 of every 766 children were given ten times the correct amount, correlating to 1,000% of the recommended dose.[11] One study observing the medication errors in the pediatric inpatient setting reviewed 10,778 medication orders.[10] Of these orders, 616 were medication errors, 115 were potential ADEs, and 26 were ADEs. Of the 26 ADEs, 5 were preventable. After talking with various paramedics and emergency doctors, most have expressed a dissatisfaction with current products. If a new, more accurate device were to be presented, they would love to have it.

The typical customer would be a paramedic. Since fire departments have the largest share in EMS product use, fire departments integrated with EMS agencies would be the ideal customer that would be targeted. While transporting patients to medical care facilities, paramedics are put into very time sensitive situations. Many of these situations involve trauma victims, which is the fourth leading cause of death. Roughly ten percent of all transports involve children under the age of sixteen. For these pediatric cases, the only solution is to use the Broselow tape, even though it has been proven to be at least 30% inaccurate. Of 1,000 paramedics included in a study, about 35% said they do not get a weight for toddlers/infants; they just give them a smaller dose.[18]

In order to introduce a new product into this market, one must first gain FDA approval. There are different FDA classes that products can fall into, depending on whether the product is basic and not life-threatening or if it is a product to be implanted in one’s body. After gaining FDA approval, the device must be tested to prove that it works properly. For a new weighing scale, a test utilizing people of various sizes would be performed to show that it can be accurate for a wide range of weights. The next step would be looking into patentability. If a patent is obtained, one could license their device or create a business and sell directly to customers.

The customer archetype includes individuals that:

a. hope to decrease malpractice insurance

b. want to provide better emergency patient care

c. have seen incorrect dosing and the repercussions of it

This customer archetype illustrates an individual that cares not only about patient care, but also about the agencies it can help. Multiple individuals make up these EMS agencies, all with the goal to decrease injury at the emergency site prior to reaching the hospital. All these individuals work daily to optimize emergency patient care, and this future company could help with their goal.

Positioning

The Broselow tape is currently the most commonly used method of indicating a pediatric patient's weight, but the stretcher scale will accurately weigh each patient with no guessing or calculating involved. An LCD screen will display the exact weight of the person on the stretcher so that precise dosing of medications can be given based on the medical emergency at hand. In 2008, the estimated total cost of measurable medical errors in the United States was $17.1 billion, and of all errors that were discovered the most frequent were adverse events where drugs were administered.[26] About 30-35% of these costs are paid for by the hospitals, accounting for about $5 billion annually spent each year fixing preventable medical errors. By incorporating this device into everyday use for EMS teams throughout the country, these numbers have the possibility of dropping drastically. On top of the monetary benefit of the stretcher scale, the ability to give an accurate dose of medicine to a critical patient helps EMS personnel do their jobs better and more efficiently. These are benefits that cannot be touted by competitors because of their inaccuracy.

Promotional Strategy

By conducting a study comparing this device to the Broselow tape, it is possible to show that this device is more accurate. This will help to convince EMS agencies that they should choose this device. It is known within the medical world that weight-based dosing is very important, especially for children. With an accurate weight, medical personnel will be able to provide better quality care to their patients. Not only will they be able to administer the correct doses, they will also be able to care for their patients in a timelier fashion. With this device, they will not have to take the time to visually estimate or use the Broselow tape.

The study will be submitted to various medical journals for publication, which would help to generate awareness among medical personnel. Along with the comparison study, the company could create a product video showing the accuracy of the device. This video could be uploaded to the company's website, as well as YouTube. The company will want to create a website, which can then have the results of the study and video, as well as other information regarding the device. By consulting with the clients and paramedics throughout the design process, there is already initial awareness for this device. For more exposure, members of the company could also attend various EMS conferences. There are many global and local conferences and symposiums which are attended by medical personnel and first responders.

Channel Strategy

Table 6. *Channel Selection Matrix*

	Will Customers Use This Channel?	Strategic Fit	Product Fit	Financial Fit
Medical Distributors	No	No	No	No
Stretcher Companies (selling as add-on)	Maybe	No	Yes	No
Direct Sales	Yes	Yes	Yes	Yes

A future company will need to answer the following questions regarding different channels before choosing the best option: (1) will customers use this channel to buy the device, (2) does this channel fit within our first year's strategy, (3) does our product fit with these channels in our first year, and (4) do these channels provide a financial benefit? If the company were to go with the Medical Distributor route (Stryker, Medtronic, etc.), customers would have a hard time buying from the distributor due to increase cost based on profit margin. If the company were to sell to the stretcher companies as an add-on to stretchers, sales might be lower. It is rare that EMS agencies buy new stretchers every year; the stretchers they do buy are usually refurbished and still expensive. Having stretcher manufacturers sell the device as an add-on would be another expense for EMS agencies and would cut profits for a potential business. For this reason, direct sales would be the best option. The company can have its own website, through which the customers can purchase the weighing scale. The website could include a 3D rendering of the device, a virtual demo of how the product fits on the stretcher, and an instructional manual.

In the first year, the company could set up demos at various EMS agencies, fire stations, and emergency departments. The importance of this demo is to prove that this device is an easy to use, lightweight solution that will not interrupt patient care. Another benefit of providing demos is building a client base. The company will need to build a client base that will: (1) increase the referral rate to various organizations, (2) aid in the innovation and development of a newer version of the device and other products, and (3) increase the sales and open channels with various customers. Thus, the company would be selling directly to the customer. The members of the business could start out manufacturing the devices at The University of Alabama (UAB) in the Materials Processing and Applications Development Laboratory for a cost. A heavy-duty transportation service will not be needed to deliver the device since the device is portable and light; this will allow the company to transport the device in their own vehicle. After one year of sales, if demand projections are high, the company could use a device manufacturer such as Medtronic or Stryker to help meet the demand. Per a survey with local EMS agencies in the Birmingham Metro area, nearly all ambulance stretchers are manufactured by Stryker. There are a few older stretchers made by Ferno, however these stretchers are becoming scarce.

In order to start selling within the first year, the company could donate a few of its devices to volunteer EMS agencies and fire stations. Giving these devices to volunteer organizations will allow future, paying customers to see its benefits; the company will also be able to collect data and feedback for future improvements. Prior to donating the devices, user testing will be conducted with local EMS agencies in order to ensure that the design is satisfactory. This initial testing will also help to generate awareness of the device and company.

Cost Projections

Each unit costs $400 to manufacture and would retail at $1000, offering a margin of $600 per unit. The four members would each take a salary of $20,000 plus 9% benefits. The company should aim to keep operating expenses under $22,000 per year and spend no more than $12,000 in the first year with marketing. Assuming that 10 units can be sold in the first month and the company can grow at a pace of 5%, there is a potential to sell 186 devices in 2020, offering a break-even point in August and year end net loss of $11,200.

The company could aim to generate revenue solely through sales with a medical sales representative approach of traveling to clients and displaying the product with service, instruction, and installation provided. In addition to a localized sales representative approach, the company should aim to pursue internet sales by selling directly through the website or through distributors.

Salaries/Staffing

With four employees each making a base salary of $20,000 per year with 9% benefits, the monthly salary expenditure would be $1816.67 each, for a total of $7266.67. The combined yearly salary amounts to $87,200. The four members would have four distinctive roles in manufacturing, quality control, distribution/sales, and management/accounting. As the company grows, additional members would be added to aid in production and business strategizing.

Operating Expenses

In order to maintain production and house the business, the business should look into leasing an office in the Birmingham area. As a new company, they should aim to spend no more than $1500 a month, or $18,000 per year. In the model created, there is an additional budget of $300 per month/$3600 per year in operating expenses directly related to the facilities. The total operating expense amounts to $21,600 for the first year.

Supplier Services

The device costs about $400 per unit to manufacture. In addition to the materials costs, the company should budget $2000 per year for additional supplier and/or legal services. The model projects that selling 10 units in the first month would require $4,166.67. With a 5% growth rate, this quickly turns into a cost of $13,700 in the first quarter, $17,300 in the second quarter, $20,900 in the third quarter, and $24,500 in the fourth quarter, for a grand total of $76,400 in the first year.

Marketing

In addition to the localized sales representative approach, the company should budget $1,000 per month for advertisement/acquisitions to increase internet-based sales and cover local travel expenses. The first-year projection is to spend $12,000 on marketing.

Total Costs

The grand total of costs sums up to $197,200 for the first year, with an average burn rate of $16,433.33 per month. Our costs for each quarter are $43,900, $47,500, $51,100, and $54,700.

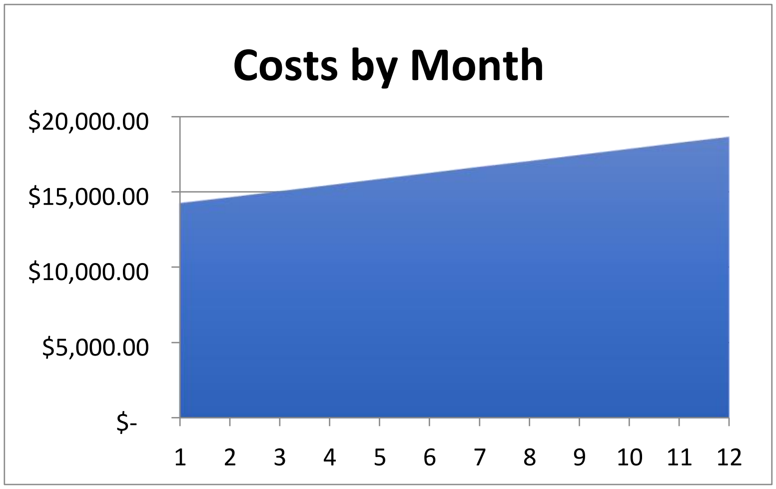

Figure 31. *Total expenditures for each month within the first year.*

Revenue

If the company can sell 10 units in the first month with a growth rate of 5%, this results in 186 devices sold in the first year. With a profit of $600 per unit sold, the company would sell $109,600 worth of devices in the first year. After subtracting costs, quarter one, quarter two, and quarter three projections show losses of $10,900, $5,500, and $100, respectively. The company would see a turn-around point in September and a quarter four profit of $5,300. The company would see an overall loss of $11,200 after the first year of business.

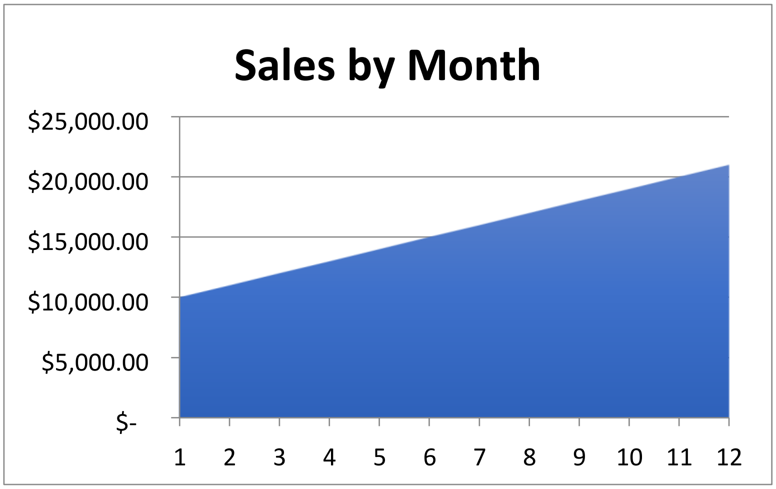

Figure 32. *Total sales by month for the first year.*

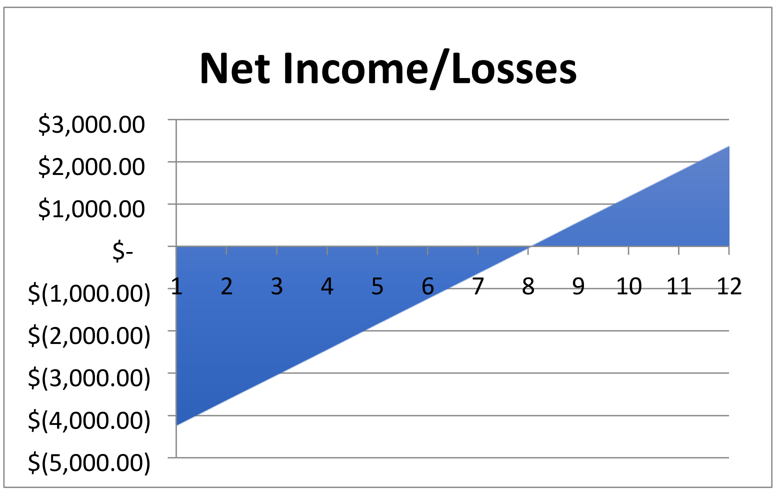

Figure 33. *Monthly net income and losses for the first year.*

CONCLUSION

While the device does need more work, there is a proof-of-concept. It is possible to create a weighing scale for recumbent patients. A device like this will help medical personnel across many fields in better caring for patients. A device like this can be more accurate than both the Broselow tape and Pedi-Wheel. This will also be more reliable than asking family or friends how much a patient weighs. For paramedics, having a device that can automatically display the weight of the person will save them time. When dealing with children, paramedics will ask the parents how much their child weighs, and the parents will give them an answer in pounds. The paramedics then have to take a small amount of time to convert this to kilograms in order to determine the correct amount of medications to administer. This device can help in these time-sensitive situations, and it will provide accurate weight measurements instead of estimations.

REFERENCES

[1] Bihari, M, 2019, “Drug Classes: Making Sense of What Medication Classifications Mean,” *Verywell Health*.

[2] Case-Lo, C, 2019, “Administration of Medication: Taking Drugs the Right Way,” *Healthline.*

[3] O’Hara, K, 2016, “Paediatric Pharmacokinetics and Drug Doses,” *Aust Prescr*.

[4] “Emergency Drug Doses for Infants and Children,” 1988, *American Academy of Pediatrics*.

[5] Pan, S et al, 2016, “Weight-Based Dosing in Medication Use: What Should We Know?” *Patient Preference and Adherence*.

[6] DeBoer, L et al, 2019, “A Tale of Two Tapes: Broselow-Luten Tapes,” *JEMS*.

[7] Emergency Medical Products: “EMS Advantage Pedi-Wheel.” https://www.buyemp.com/product/ems-advantage-pedi-wheel

[8] Antevy, P, 2013, “Handtevy Method Helps Providers Rapidly Calculate Pediatric Drug Dosages,” *JEMS*.

[9] Lin, BW et al, 2008, “A Better Way to Estimate Adult Patients’ Weights,” *American Journal of Emergency Medicine*.

[10] Kaushal, R et al, 2001, “Medication Errors and Adverse Drug Events in Pediatric Inpatients,” *JAMA*.

[11] Kaufmann, J et al, 2012, “Medication Errors in Pediatric Emergencies,” *Dtsch Arztebl Int*.

[12] Anglemyer, BL et al, 2004, “The Accuracy of Visual Estimation of Body Weights in the ED,” *American Journal of Emergency Medicine*.

[13] Hall, W et al, 2004, “Errors in Weight Estimation in the Emergency Departments: Comparing Performance by Providers and Patients,” *Journal of Emergency Medicine*.

[14] Corbo, J et al, 2004, “Who Should be Estimating a Patient’s Weight in the Emergency Department?” *Academic Emergency Medicine*.

[15] Axelband, J et al, 2004, “Can Emergency Personnel Accurately Estimate Adult Patient Weights,” *Annals of Emergency Medicine*.

[16] Menon, S et al, 2005, “How Accurate is Weight Estimation in the Emergency Department?” *Emergency Medicine Australasia*.

[17] Darnis, S et al, 2012, “Estimation of Body Weight in Hospitalized Patients,” *QJM*.

[18] Hoyle, JD et al, 2017, “Pediatric Prehospital Medication Dosing Errors: A National Survey of Paramedics,” *Prehospital Emergency Care*.

[19] Wells, M et al, 2017, “The Accuracy of the Broselow Tape as a Weight Estimation Tool and a Drug-Dosing Guide,” *Resuscitation*.

[20] Cincinnati Children’s Hospital: “Growth, Range of Height and Weight,” 2016. https://www.cincinnaticildrens.org/health/g/normal-growth

[21] SparkFun Electronics: “Load Cell Amplifier HX711 Breakout Hookup Guide,” https://learn.sparkfun.com/tutorials/load-cell-amplifier-hx711-breakout-hookup-guide?_ga=2.243518214.24057899.1574387854-743326138.1540850573

[22] ASTM International: “D7264/D7264M-15 Standard Test Method for Flexural Properties of Polymer Matrix Composite Materials,” 2016. https://doi.org/10.1520/D7264_D7264M-15

[23] IEC: “60601-1 Medical Electrical Equipment – General Requirements for Basic Safety and Essential Performance,” 2005. https://webstore.iec.ch/publication/2612

[24] HCPCS: “A-Codes – Transportation Services Including Ambulance, Medical & Surgical Suppliers,” 2019. https://hcpcs.codes/a-codes/

[25] Grand View Research: “U.S. EMS Product Market Worth $15.09 Billion by 2025 | CAGR 7.2%,” 2018. https://www.grandviewresearch.com/press-release/us-emergency-medicalservices-ems-products-market-analysis

[26] Bos, J et al, 2011, “The $17.1 Billion Problem: The Annual Cost of Measurable Medical Errors,” *Health Affairs.*

APPENDIX A

EQUATIONS AND CALCULATIONS

Sample Material Property Calculations

a. Maximum Flexural Strength

$$\sigma = \frac{3PL}{4bh^2} = \frac{3(642)(101.6)}{4(30.56)(10.414)^2} = 14.76\ MPa$$

b. Maximum Strain

$$\varepsilon = \frac{4.36\delta h}{L^2} = \frac{4.36(3.48)(10.414)}{(101.6)^2} = 0.015$$

c. Flexural Modulus of Elasticity

$$E = \frac{0.17L^3 m}{bh^3} = \frac{0.17(101.6)^3(235.16)}{(30.56)(10.414)^3} = 1.215\ GPa$$

Statistical Analysis Calculations

a. n = 25 → ν = 24, α = 0.05, β = 0.1, σ = 8, δ = -6.5

i. From t-tables: $t_{\alpha,\nu} = 2.064$ $t_{\beta,\nu} = 1.318$

$$n = 2 * \left\{\frac{8}{-6.5}\right\}^2 * \{2.064 + 1.318\}^2 = 34.65$$

b. n = 50 → ν = 49, α = 0.05, β = 0.1, σ = 8, δ = -6.5

i. From t-tables: $t_{\alpha,\nu} = 2.01$ $t_{\beta,\nu} = 1.30$

$$n = 2 * \left\{\frac{8}{-6.5}\right\}^2 * \{2.01 + 1.30\}^2 = 33.19$$

c. n = 100 → ν = 99, α = 0.05, β = 0.1, σ = 8, δ = -6.5

i. From t-tables: $t_{\alpha,\nu} = 1.987$ $t_{\beta,\nu} = 1.291$

$$n = 2 * \left\{\frac{8}{-6.5}\right\}^2 * \{1.987 + 1.291\}^2 = 32.55$$

d. n = 150 → ν = 149, α = 0.05, β = 0.1, σ = 8, δ = -6.5

i. From t-tables: $t_{\alpha,\nu} = 1.983$ $t_{\beta,\nu} = 1.290$

$$n = 2 * \left\{\frac{8}{-6.5}\right\}^2 * \{1.983 + 1.290\}^2 = 32.45$$

APPENDIX B

COMPARISON TESTING DATA AND SAMPLE CALCULATIONS

Data

Under 18 years of age – all weight measurements in pounds (lbs)

Age	Standing	Recumbent	Broselow	Pedi-Wheel
< 1	18	20	11	15.4
1	25	30	22	22
3	33	37	37.4	30.8
3	37	42	37.4	30.8
3	43	39	46.2	30.8
3	35	41	37.4	30.8
3	37	43	46.2	28.6
3	37	47	46.2	30.8
4	39	45	46.2	35.2
5	45	55	44	39.6
5	40	50	44	39.6
5	43	50	46.2	39.6
5	54	57	59.4	39.6
5	39	47	46.2	39.6
6	53	58	59.4	46.2
6	59	55	72.6	46.2
6	36	36	37.4	46.2
6	54	65	72.6	46.2
6	50	56	59.4	46.2
6	71	83	59.4	46.2
7	65	70	59.4	50.6
7	54	60	59.4	50.6
7	65	67	59.4	50.6
7	69	78	72.6	50.6
7	48	53	59.4	50.6
8	54	55	59.4	57.2
8	67	68	72.6	57.2
8	66	81	72.6	57.2
8	50	60	46.2	57.2
9	95	89		63.8
9	85	100	72.6	63.8
9	97	105		63.8
9	95	98		63.8
9	61	71	72.6	63.8
9	72	77		63.8
9	72	73		63.8
10	78	88		70.4
10	64	73	72.6	70.4
10	72	80		70.4
10	89	100		70.4
10	66	79		70.4
10	75	80		70.4
10	90	97		70.4

Age	Standing	Recumbent	Broselow	Pedi-Wheel
11	117	116		79.2
11	117	130		79.2
11	100	115		79.2
11	112	115		79.2
12	137	128		90.2
12	102	120		90.2
13	105	115		99
14	111	118		110
15	187	178		116.6
15	127	130		116.6

Above 18 years of age – all weight measurements in pounds (lbs)

Standard	*Recumbent*
208	180
215	180
127	132
203	193
195	170
194	186
254	208
183	185
207	188
175	173
182	180
203	170
144	146
206	175
140	145
322	260
103	119
175	175
189	180
152	150
222	200
130	133
199	200

Percent Error Calculation

$$\% = \frac{|standing - estimation|}{standing} * 100\% \qquad \text{(Eqn. 9)}$$

Paired t-test

1. First set of data (32 of 53 children)

   a. Standing vs. Recumbent (pediatric)

t-Test: Paired Two Sample for Means

	Recumbent	*Standing*
Mean	56.000	49.875
Variance	285.355	220.242
Observations	32.000	32.000
Pearson Correlation	0.966	
Hypothesized Mean Difference	0.000	
df	31.000	
t Stat	7.501	
P(T<=t) one-tail	0.000	
t Critical one-tail	1.696	
P(T<=t) two-tail	< 0.000001	
t Critical two-tail	2.040	

b. Standing vs. Broselow Tape

t-Test: Paired Two Sample for Means

	Standing	*Broselow*
Mean	49.875	53.419
Variance	220.242	245.820
Observations	32.000	32.000
Pearson Correlation	0.895	
Hypothesized Mean Difference	0.000	
df	31.000	
t Stat	-2.850	
P(T<=t) one-tail	0.004	
t Critical one-tail	1.696	
P(T<=t) two-tail	0.0077	
t Critical two-tail	2.040	

c. Standing vs. Pedi-Wheel

t-Test: Paired Two Sample for Means

	Standing	*Pedi-Wheel*
Mean	49.875	44.069
Variance	220.242	161.589
Observations	32.000	32.000
Pearson Correlation	0.839	
Hypothesized Mean Difference	0.000	
df	31.000	
t Stat	4.060	
P(T<=t) one-tail	0.000	
t Critical one-tail	1.696	
P(T<=t) two-tail	0.00031	
t Critical two-tail	2.040	

2. Second set of data (all 53 children)

a. Standing vs. Recumbent (pediatric)

t-Test: Paired Two Sample for Means

	Recumbent	*Standing*
Mean	75.906	70.038
Variance	1022.202	1059.306
Observations	53.000	53.000
Pearson Correlation	0.984	
Hypothesized Mean Difference	0.000	
df	52.000	
t Stat	7.368	
P(T<=t) one-tail	0.000	
t Critical one-tail	1.675	
P(T<=t) two-tail	< 0.000001	
t Critical two-tail	2.007	

b. Standing vs. Pedi-Wheel

t-Test: Paired Two Sample for Means

	Standing	*Pedi-Wheel*
Mean	70.038	58.321
Variance	1059.306	527.490
Observations	53.000	53.000
Pearson Correlation	0.912	
Hypothesized Mean Difference	0.000	
df	52.000	
t Stat	5.701	
P(T<=t) one-tail	0.000	
t Critical one-tail	1.675	
P(T<=t) two-tail	< 0.000001	
t Critical two-tail	2.007	

3. Standing vs. Recumbent (adult)

t-Test: Paired Two Sample for Means

	Standing	*Recumbent*
Mean	188.174	175.130
Variance	2099.241	888.482
Observations	23.000	23.000
Pearson Correlation	0.958	
Hypothesized Mean Difference	0.000	
df	22.000	
t Stat	3.249	
P(T<=t) one-tail	0.002	
t Critical one-tail	1.717	
P(T<=t) two-tail	0.0037	
t Critical two-tail	2.074	

APPENDIX C

IRB APPROVAL

Comparison Testing Approval

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Office of the Institutional Review Board for Human Use

470 Administration Building
701 20th Street South
Birmingham, AL 35294-0104
205.934.3789 | Fax 205.934.1301 | irb@uab.edu

APPROVAL LETTER

TO: Rettig, Kayla

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance # FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)

DATE: 12-Aug-2019

RE: IRB-300003291
Recumbent Patient Weighing Scale

The IRB reviewed and approved the Initial Application submitted on 10-Jul-2019 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

Type of Review: Expedited
Expedited Categories: 1, 4, 7
Determination: Approved
Approval Date: 12-Aug-2019
Approval Period: Expedited Status Update (ESU)
Expiration Date: 11-Aug-2022

Although annual continuing review is not required for this project, the principal investigator is still responsible for (1) obtaining IRB approval for any modifications before implementing those changes except when necessary to eliminate apparent immediate hazards to the subject, and (2) submitting reportable problems to the IRB. Please see the IRB Guidebook for more information on these topics.

The following populations are approved for inclusion in this project:

- Children – CRL 1

The IRB 02 met on August 7, 2019 and approved the use of the Stretcher Scale device for this protocol. The IRB also determined that the Stretcher Scale device meets the criteria for a non-significant risk device as used in the above-referenced protocol.

Documents Included in Review:

- flyer.190411
- devicereview.190411
- hsp.clean.190710.pdf
- assent.190513
- pptcomms(handout).clean.docx
- children.190513
- consent.clean.190513

User Testing Approval

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Office of the Institutional Review Board for Human Use

470 Administration Building
701 20th Street South
Birmingham, AL 35294-0104
205.934.3789 | Fax 205.934.1301 | irb@uab.edu

APPROVAL LETTER

TO: Rettig, Kayla

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance # FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)

DATE: 24-Sep-2019

RE: IRB-300003475
Recumbent Patient Weighing Scale - User Study

The IRB reviewed and approved the Initial Application submitted on 09-Sep-2019 for the above referenced project. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services.

Type of Review:	Expedited
Expedited Categories:	4, 7
Determination:	Approved
Approval Date:	24-Sep-2019
Approval Period:	Expedited Status Update (ESU)
Expiration Date:	23-Sep-2022

Although annual continuing review is not required for this project, the principal investigator is still responsible for (1) obtaining IRB approval for any modifications before implementing those changes except when necessary to eliminate apparent immediate hazards to the subject, and (2) submitting reportable problems to the IRB. Please see the IRB Guidebook for more information on these topics.

The IRB determined the Stretcher Scale meets the criteria for a Non-Significant Risk (NSR) device as used in the above referenced protocol.

Documents Included in Review:

- surveyquest.190517
- devicereview.clean.190909
- hsp.clean.190909.pdf
- consent.clean.190918