Measuring Exercise Systolic Blood Pressure Using Finger Laser Doppler in Kids

Gabrielle Laures - Team Leader
Crystal Jimenez - BSAC/BPAG
Haley Knapp- BSAC
Madison Boston - Communicator
Dr. Allen Wilson - Client
Dr. Paul D. Thompson - Advisor
December 9, 2015

Table of Contents

Abstract

Treadmill stress testing is used on adults and children to check for a variety of health issues in adults and children. The motion incorporated makes it difficult to measure the blood pressure with traditional auscultatory -cuff and stethoscope method especially in children. Due to this difficulty another method has been introduced to measure the blood pressure by reading the waveform of a laser Doppler that measures blood flow in the finger of a patient. However, motion is still an issue in adding noise to the signal that makes it more difficult to read. Dr. Allen Wilson of UW Health Pediatric Cardiology would like to fabricate a motion-stabilizing device, specifically for the thumb or index finger, for increased accuracy of a laser Doppler that indicates when the child's heart is undergoing systolic blood pressure. Other products that measure blood pressure are only used when the patient is not in motion, which allows easier readings for a systolic peak pressure. Therefore, Dr. Allen's experimenting with laser Doppler technology should be considered as novel, and cannot be directly compared with other competing designs. The team designed a finger splint and hand trough to attach to the treadmill to stabilize the signal of the laser Doppler. Testing was done to investigate the improvements that these elements had on the readability of the signal. It was concluded that the splint without the trough was the best method of reducing signal noise.

Problem Statement

A simple auscultatory -cuff method is currently used to measure blood pressure (BP) during treadmill stress testing in adults and kids. With children between the ages of six and twelve, it is often difficult to hear the peak systolic sound that defines systolic pressure. Laser Doppler sampling from the first finger or thumb at rest reads this pressured signal nicely so that it can be used with blood pressure cuffs to find peak systolic BP equivalent. The problem is that laser Doppler signals are motion sensitive. Luckily, when the kids undergo treadmill testing to measure BP, their arms are held off the treadmill. A stabilizing device that holds a laser Doppler probe in place on the first finger or thumb, while stabilizing it from movement that causes artifact on laser Doppler signal, is needed.

Background Information

Project Motivation: Detecting Heart Diseases in Children

According to the Children's Heart Foundation, heart diseases are America's and every other country's number one birth defect, and twice as many children die from congenital heart defects each year than from all forms of childhood cancer combined [1]. Congenital heart diseases are also the most common cause of infant death resulting from birth defects; 27% of infants who die of a birth defect have a heart defect [2]. From an economical standpoint, the cost for inpatient surgery to repair heart defects exceeds to more than $2.2 billion dollars per year [1]. Examples of these diseases include stroke and coronary heart disease. Specifically towards children, hypertension, or high blood pressure, is becoming more and more prevalent within the nation. According to the American Heart Association, BP, pre-HBP and HBP trends in children and adolescents ages 8–17, were downward from 1963–88 and shot upward thereafter [2].

Several methods are used to check for any type of cardiac abnormalities, such as a computed tomography heart scan, x-rays, and stress tests. During these tests, values such as heart rate and blood pressure are measured. The client for this project specifically targets measurement of blood pressure through: treadmill stress testing. Examinations such as these can search for signs of arrhythmias, or irregular heart rhythms, to search for symptoms of more severe causes. As mentioned before, little to no research has been done with detecting types of blood pressure with laser Doppler technology, so a stabilizing device that will reduce noise of finger movement during treadmill stress testing is desired to have more accurate data when testing for heart disease.

Measuring Blood Pressure

To better understand heart activity while it is undergoing physical work, the physiology of heart blood pressure is studied. Blood pressure is written as two numbers with a ratio of systolic to diastolic, where the units are in mmHg which measure pressure. The heart undergoes systolic pressure when it is being contracted. When the heart contracts, it emits an electrical signal that travels from the top to the bottom of the muscle. An auscultatory cuff is typically placed onto a patient and is initially inflated to a level higher than systolic pressure. The cuff pressure is inflated to reach 30 mmHg higher than systolic pressure, and then air is released at a rate of 5 mmHg per second [3]. During compression, the brachial artery being used to measure blood pressure is undergoing turbulent blood flow, or flowing at high velocities, and vibrates to create audible pulses.

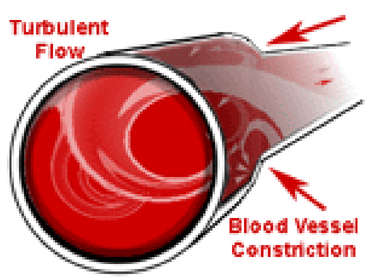


Figure 1: Brachial artery under compression experiencing turbulent flow [3]

Sounds that are heard during this time signal systolic pressure. Once audio beats from the measuring have disappeared, the heart is in diastolic pressure, or relaxed. The actual physics of blood flow was analyzed to have a better understanding of the process (see Appendix A)

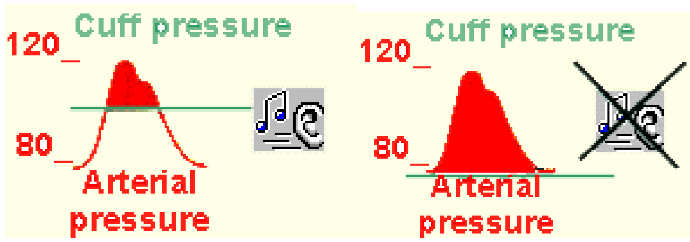


Figure 2: Visual representation of systolic and diastolic pressure. Systolic pressure is the highest pressure at which sounds are first heard [3]

Laser Doppler Flowmetry (LDF)

Laser Doppler flowmetry (LDF) is a method used to assess blood flow. A single-frequency light illuminates the tissue and the frequency distribution of the backscattered light is used to estimate blood perfusion [4]. The probe used by the client is a Perimed Probe 457 Small Angled Thermostatic Probe and gives off a 780 nm wavelength laser with a measuring depth of 0.5-1 mm [5]. The cues for blood pressure events are correlated with the waveform of blood perfusion the laser Doppler creates when applied to the finger. Because of this, the pressure can be read by replacing the auditory cues from the stethoscope with the the visual cues from the waveform.

Treadmill Stress Testing

Treadmill stress testing is conducted to determine how well the patient's heart works and adjusts to different levels of activity. The test involves the usage of an electrocardiogram (ECG) machine, and the patient's blood pressure and ECG are both measured. Before taking the test, patients should not eat or smoke at least two hours prior [6]. One's ECG is measured by applied electrodes, which are cleansed with alcohol, to the user on the targeted skin areas. A total of ten electrodes are applied to the body; the right and left arm electrodes are placed each below each clavicle, and the left and right leg electrodes are placed below the rib cage. The rest of them, labeled "V" electrodes, are placed upon the chest. These electrodes are positioned according to American Heart Association guidelines [7].

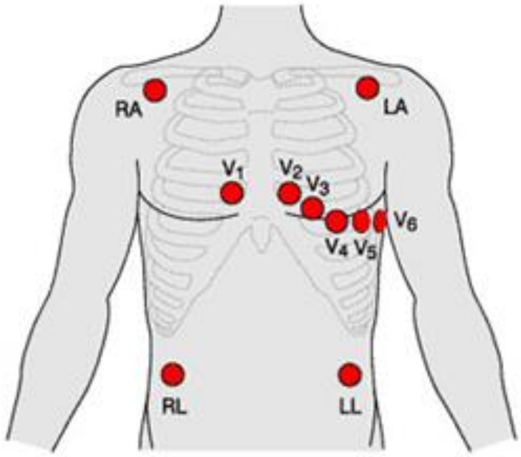


Figure 3: Correct Electrode Placement [6]

The test itself lasts for about ten to fifteen minutes, and the doctor regulates gradual speed or resistance of the treadmill with even intervals. The speed is usually measured in kilometers per hour. The patient will continue running on the treadmill until their specific target heart rate is achieved.

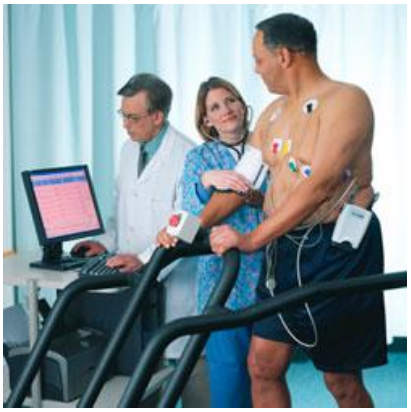


Figure 4: Typical setup during treadmill testing [7]

Current Methods

Treadmill stress testing is currently used in clinical settings with adults. Blood pressure is measured with the traditional cuff and stethoscope. Because of the aforementioned difficulty in hearing auditory pulses in children, a Piezoelectric Pulse transducer is introduced.

When measuring the systolic blood pressure of pediatric patients, the client currently uses a blood pressure cuff to cut off blood flow and watches the signal from the Piezoelectric Pulse Transducer on the oscilloscope to determine when blood flow resumes. Once the signal reappears on the oscilloscope, the test administrator records the pressure measurement on the cuff which corresponds to systolic or peak blood pressure. Currently, the motion due to the treadmill stress test is causing an abundance of noise, making it hard for the test administrator to see when systolic pressure has been reached and flow has begun again.

Design Alternatives

In order to meet the product design specifications, many design options were brainstormed and considered. Three design alternatives were chosen to be included in the team's decision making process and include a splint, splint with bandpass filter, and desk with bandpass filter. After the designs were brainstormed and and discussed with the rest of the team, evaluation using a design matrix was done. The matrix helps to determine which design fits the client's needs best for the project.

Design 1: Splint

Figure 5. The splint design will wrap around the probe along with the wire connecting to the oscilloscope to further prevent any movement by the probe[8].

The first design alternative provides mostly mechanical support for the user. An aluminum bar will be placed along the length of the thumb, restricting any joint movements. The aluminum will be kept in place by a flexible neoprene wrap which will be both comfortable for the user to wear, and allow for easy application and adjustment to different size hands. Velcro will be sewn into the end of the wrap to keep the neoprene in place. The probe will be kept as a separate entity so that the client can easily adjust its placement, but it will be wrapped within the splint to increase stability as shown in figure 5.

Design 2: Splint with Bandpass Filter

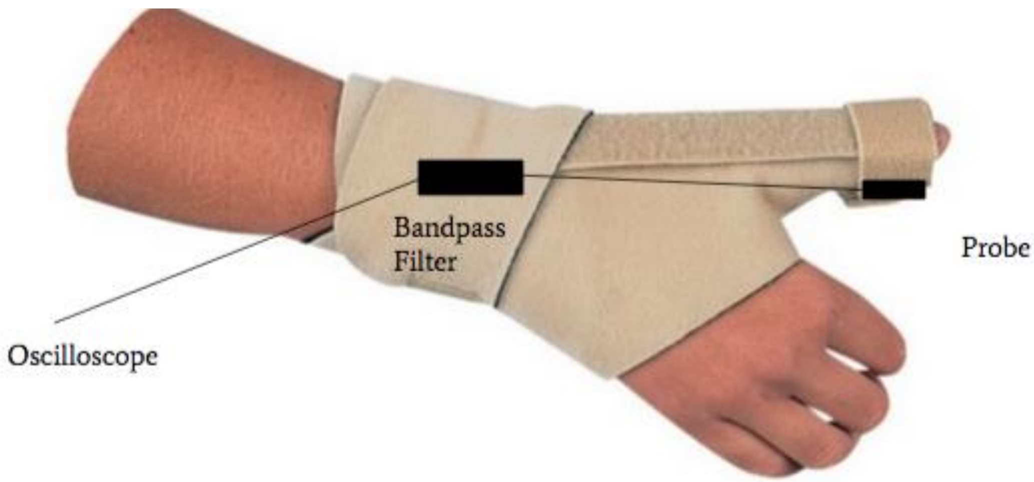


Figure 6. The probe will still be wrapped within the splint, but the signal will first be sent through a bandpass filter to further reduce any potential noise[8].

The second design alternative provides the same mechanical support as the first design, but has the added feature of a bandpass filter to further decrease any noise within the signal. Although the splint decreases the amount of joint movement within the thumb, it will not eliminate it all. After analyzing the signal's noise components, a bandpass filter, which attenuates frequencies outside a selected range, will be added to eliminate the noise found.

Design 3: Desk with Bandpass Filter

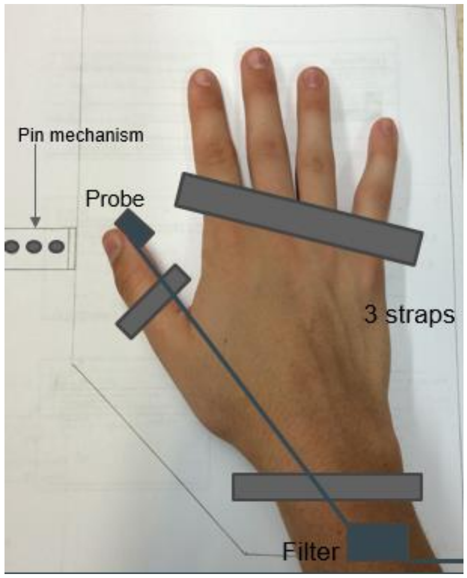


Figure 7. The desk design will provide the necessary mechanical support along with a filter to help eliminate any noise that may be caused by movement of the probe.

The final design alternative provides both mechanical support and a filter for the signal. A 33 x 25 x 2 cm desk will be attached to the preexisting bar of the treadmill, along with a lock and pin mechanism that will move the desk horizontally along the treadmill to a position most comfortable for the user. The desk will have a laminate surface making it waterproof and therefore easy to sanitize. The user's hand will be placed on the desk and held in place by a strap of Velcro across the wrist, upper hand and thumb as shown in figure 7. The probe will be separately velcroed to the user's thumb and the signal will be run through a bandpass filter to eliminate as much noise in the signal as possible.

Design Matrix

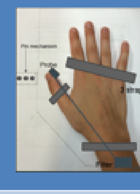
Criteria	Design 1: Splint 		Design 2: Splint with Filter 		Design 3: Desk with Filter 	
Accuracy of Signal (25)	(2/5)	10	(4/5)	20	(5/5)	25
Feasibility (20)	(3/5)	12	(2/5)	8	(4/5)	16
Ease of Use (20)	(3/5)	12	(3/5)	12	(4/5)	16
Safety (15)	(5/5)	15	(4/5)	12	(3/5)	6
Comfort (10)	(4/5)	8	(4/5)	8	(3/5)	6
Cost (10)	(5/5)	10	(4/5)	8	(3/5)	6
TOTAL	67		68		76	

Table 1: Design matrix with winning design prior to preliminary presentations.

In order to select a proposed final design, a design matrix was used to evaluate the designs. In the design matrix, six criteria were assessed: accuracy of signal, feasibility, ease of use, safety, comfort, and cost.

The first and most heavily weighted category was accuracy of signal. This category refers to how well the selected device filters out noise from the Blood Pressure waveform. The Desk with Filter design won this category with 25 points due to its ability to stabilize the thumb and other joints, while including a bandpass filter to further reduce noise from the signal.

The next category to be assessed was feasibility. This category refers to how manageable it will be to manufacture the chosen device. The Desk with Filter design won for this category as well with 16 points because the materials, skills, and time required to fabricate the device are well within the team's capabilities. The feasibility of the splint designs are lower due to the fact that they would require sewing, a skill that requires time and experience to execute properly.

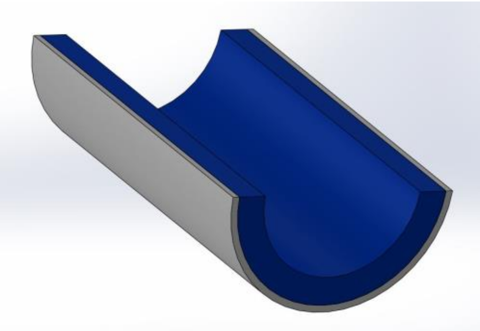
The ease of use category refers to how easy it is for the user to take the device on and off. The Desk with Filter design again won this category with 16 points because the adjustable straps are easy to secure and release the arm. The splint designs would require the user to be manually strapped into the device before each use, which could be tedious and time consuming.

Safety was the next category to be assessed, which focuses on how safe the selected device is for the user. The splint design won for this category with 15 points because it does not incorporate a filter, and through involving circuitry the design poses minor risks such as a shock to the patient. With the desk design, there may also be an increased risk of injury in the event of a fall.

For the comfort category, both the splint and splint with filter designs won with 8 points because the elasticity and flexibility associated with the fabric of these designs would be more comfortable than the materials of the Desk with Filter design.

Lastly, the cost associated with each design was assessed. This category was one of the lowest weighted because it is anticipated that each design will be well below the price limit of $1000. The splint design won this category because it has no circuitry, reducing the overall price to make the device.

Proposed Final Design



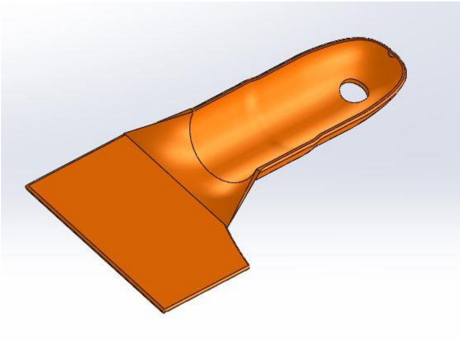


Figure 8: Solidworks images of the trough design (left) and splint design (right).

After discussing the desk idea with our client, the team decided to go with a different design than what was chosen as a result of the design matrix. The final design consists of a splint made of Aquaplast, also known as polycaprolactone, that restricts the joint movement of the right index finger along with a trough to provide mechanical stability while the testing administrator takes the blood pressure. This material is typically used in occupational therapy.

Figure 9: Aquaplast (polycaprolactone) molded for various body parts[9].

A hole for the laser Doppler probe will be cut into the splint and Coban, a self-adherent elastic wrap, will be used to keep the probe and splint in place. A splint was chosen in place of the desk to allow the patient to grip onto the treadmill therefore giving them a more comfortable testing experience.

Once the blood pressure needs to be taken, the patient will place their right hand in the trough, which is designed to provide even more stability to decrease the signal to noise ratio within the reading and allow for the testing administrator to detect when the systolic pressure is reached during the reading. The trough has a lining of foam to absorb noise caused by the movement of the treadmill.

Fabrication/Development Process

There were two main elements to construct in the fabrication process. The first element was the stabilization trough that was to be attached to the treadmill. A 4 in. PVC pipe was chosen to be the base of the trough as it is durable. To acquire the necessary 7 in. length and half-circle shape required, a table saw was used to make the axial and horizontal cuts. Foam and nylon lining was cut and adhered to the PVC with glue. An elastic strap with velcro on either end for fastening was also adhered to the underside of the trough. This provides the mechanism to attach the trough to the handle of the treadmill.

The other element of the fabrication was the Aquaplast for the finger splint. Polycaprolactone was chosen because it has a low melting point and can be molded easily in a warm bath of about 150 degrees Fahrenheit. The heat makes the material pliable and easily molds to hand. After the aquaplast was cut and molded a hole was soldered into the fingertip portion of the mold in order for the probe to make contact with the skin. After this process the splint is attached to the hand using Coban.

Human Factors

For the final design process, human factors and ergonomics were considered. According author C.D Wickens, “The goal of Human Factors and Engineering Psychology is to improve productivity, safety, and comfort” [10]. That being said, it is essential as engineers to evaluate how the overall design is going to impact the user. In this design, children will most likely be the targeted audience. Therefore, simplifying the systolic blood pressure procedure as simple as possible is essential. At an entrepreneur lecture given to the BME department earlier this semester, Doug Dietz emphasized the importance of designing kid-friendly prototypes. By including some type of story or scenario to a design, children will more likely want to behave and follow the procedure asked from them. According to a study involving child interactions with a kinetic structure at Tufts University, “Children provide an interesting dimension to a project because designs must take into account the limited cognitive and motor abilities of children” [10].

One of the main focuses the team established toward Human Factors was including a drawing of a “superhero” named Willy the Supercow. As seen in Figure 10, the team’s drawing demonstrates how Willy’s arm is extended straight to fly into Madison’s sky. Similarly, children will want to extend their arms onto the trough to play along with the story. Prior to testing, a laminated instruction sheet shows a step-by-step process for what the child should do to help the technician running the test, as well as Dr. Wilson reading blood pressure.

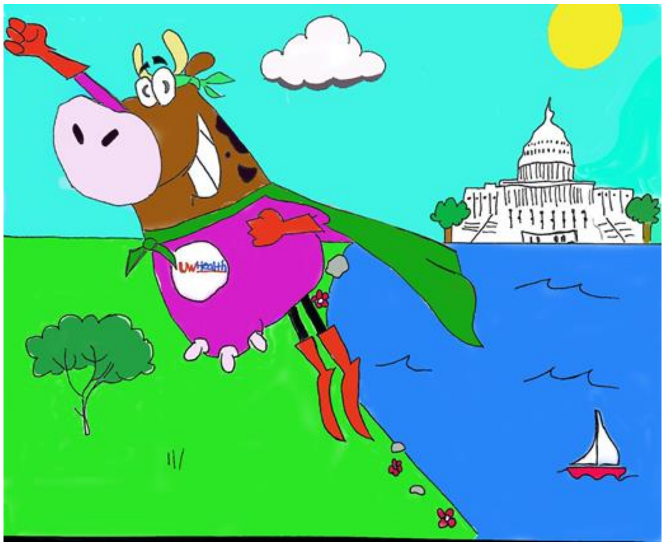


Figure 10: Willy the Supercow shows children how to hold their arms straight and steady.

Materials

In order to transition into a medical setting, materials that come in contact with the skin were chosen to be sterilizable. Nylon and Aquaplast can be sterilized with traditional hospital sterilization processes. Nylon has been used in hospitals because of its resilience, abrasion resistance, and ease of sterilization[11]. Aquaplast, also known as caprolactone, has attractive thermal properties and functions exceptionally well as a molding material and sets upon cooling. The melting point of the material is around 140 degrees fahrenheit which can be easily achieved with a water bath or heat gun.

Costs

Given a budget of $1000, total costs were $35.88. The following table displays costs of fabrication materials such as adhesive spray and Velcro. The *Aquaplast*® material for the splint was provided by the Occupational Therapy Department at UW Health. Laminate for the cartoon was provided by Artist & Craftsman. Other tools such as a hand saw and caliper were provided to the team, so there were no costs there. The overall design is not costly.

Name	Item	Quantity	Cost	Total Cost (with tax)	Date Purchased
NOVEMBER					
Madison Boston	PVC Pipe,	1	$8.23	$10.44	11/15/15
	Large Cable Cuff Clip	1	$1.67		
Gabby Laures	Nylon	1	$2.66	$9.61	11/29/15
	Airtex Foam	1	$3.00		
	Elastic Fabric	1	$3.49		
DECEMBER					
Crystal Jimenez	Silver Metal	1	$4.98	$15.83	12/3/15
	Acrylic Paint 3M Super Adhesive Spray	1	$10.02		
TOTAL COST				$35.88	

Table 2: Cost Analysis for Design Apparatus

Final Prototype

Figure 11. The final prototype of our splint design with the laser doppler and splint held in place by Coban.

Figure 12. The final prototype of the trough element of the design featuring Willy the Supercow.

The final prototype consists of the two previously mentioned element. The trough measures 17.78cm in length and has a diameter of 11.15cm and was cut from PVC pipe with a thickness of .686cm. Foam with a thickness of 1.27cm was used to line the PVC. After the nylon lining was added the inner diameter of the trough measured 7.55cm for hand placement.

The splint made from Aquaplast measures 10.67cm in length. The width of the splint across the palm is 6.35cm and decreases to a width of .63 cm as reaches the index finger. The index portion that the finger rests in has a height of 4.23cm. SolidWorks drawings of both elements can be seen in Appendix C.

Testing

With the fabricated final prototype, testing was performed to determine if the piezoelectric pulse transducer or laser Doppler probe was most effective as well as if the splint and trough designs were effective at reducing noise in the signal. Three subjects were tested under four conditions. These four conditions included the usage of the following:

Condition
1. Piezoelectric transducer without the splint nor the trough
2. laser Doppler probe without the splint nor the trough

3. laser Doppler probe with only the splint
4. laser Doppler probe with both the splint and the trough

Table 3: Different scenarios the three testing subjects underwent to analyze noise activity from oscilloscope.

As mentioned previously in the report, a flatline reading from the laser Doppler reading would indicate that blood flow was completely cut off. Analysis of this flatline signal was conducted under each of the conditions listed above. The main goal of the testing was to determine whether the piezoelectric pulse transducer or the laser Doppler probe had the least amount of noise. Since the signal being analyzed was supposed to be flatlined, the differential of the signal should be zero. Using the differential, the team was able to determine the percentage of data points (frames) that had a change of value between adjacent points. Any nonzero frames correspond to the amount of noise in the signal. The information gathered was then analyzed to determine if there was a significant statistical difference in the amount of noise corresponding to each of the sensors. The differences between the two sensors were also visually analyzed to further determine what probe would be best for reducing noise in the signal.

In order to determine if the splint and trough effectively reduced the noise in the signal, visual analysis was also done on the signals gathered using the laser doppler with only the splint and the laser doppler with both the splint and trough. Examples of a testing protocol were first studied by the team [12].The testing protocol corresponding to the visual test can be found in Appendix D.

Results

Piezoelectric vs Laser Doppler Noise %				
Subject	**Subject 1**	**Subject 2**	**Subject 3**	**Average**
% Frames Nonzero Laser Doppler	35.08%	32.04%	37.19%	**34.77%**
% Frames Nonzero Piezoelectric	48.31%	54.71%	47.91%	50.31%

Table 4. The percentage of data frames which have a nonzero value for the differential.

As shown in Table 4, the piezoelectric pulse transducer had 50.31% of the frames show nonzero values for the differential, while the laser Doppler probe had 34.77% of the frames show nonzero values. A t-test was chosen to analyze the amount of resulting noise because it is commonly used to determine whether or not two sets of data are considered significantly different. The statistical analysis of this data can be found in Appendix E, and shows that the percentage of nonzero frames for the laser Doppler probe is significantly smaller than that of the piezoelectric pulse transducer.

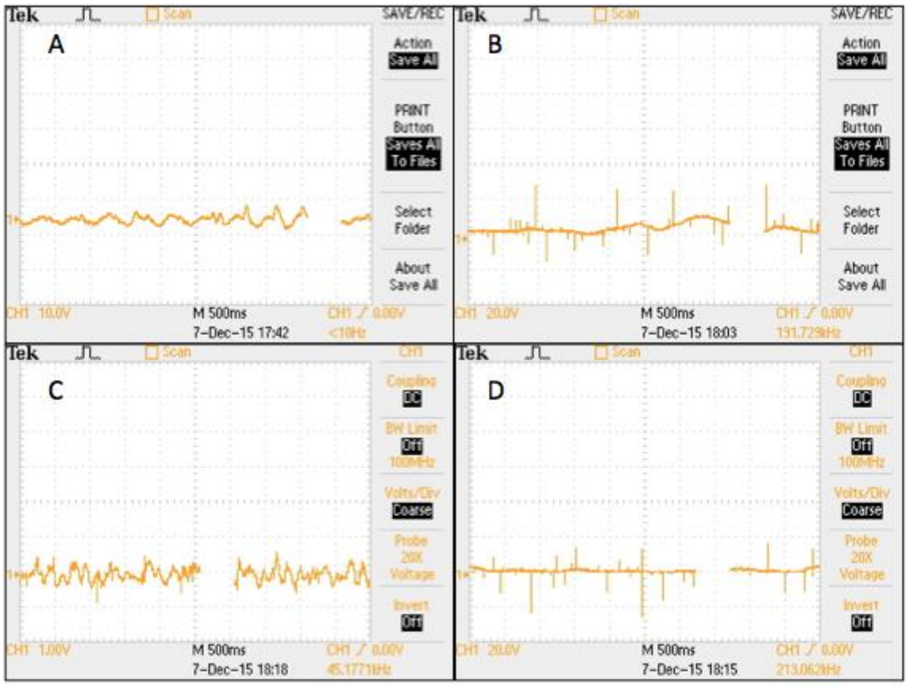


Figure 13. Image A represents the piezoelectric transducer at systolic pressure with a score of 2. Image B represents the laser Doppler at systolic pressure with a score of 4. Image C represents the piezoelectric transducer at flat line with a score of 1. Image D represents the laser Doppler at flat line with a score of 5.

Flat Line for Piezoelectric vs Laser Doppler				
Probe Type	Subject 1	Subject 2	Subject 3	Average
Laser-doppler	5	4	4	**4.33**
Piezoelectric	1	2	2	1.67

Table 5. The visual inspection rating on a scale of 1-5 for when the signal is flat lined.

Systolic for Piezoelectric vs Laser Doppler				
Probe Type	Subject 1	Subject 2	Subject 3	Average
Laser-doppler	3	4	4	**3.67**
Piezoelectric	1	1	2	1.33

Table 6. The visual inspection rating on a scale of 1-5 for when the signal is at systolic pressure.

Upon quantitative evaluation of the piezoelectric pulse transducer and laser Doppler probe, visual inspection was conducted to determine the noise differences at systolic pressure and when the signal has flat lined. The visual inspection for when the signal was flat lined resulted in an average of 4.33 for image quality of the laser Doppler, while the piezoelectric pulse transducer resulted in an average of 1.67, as seen in Table 5. Similar results were observed for when the signal was at systolic peak pressure, with an average image quality of 3.67 for the laser Doppler and 1.33 for the piezoelectric, as seen in Table 6.

These results, along with the visual representations in Figure 13, indicate that a clearer signal is observed using a laser Doppler probe at both systolic and flat lined pressures.

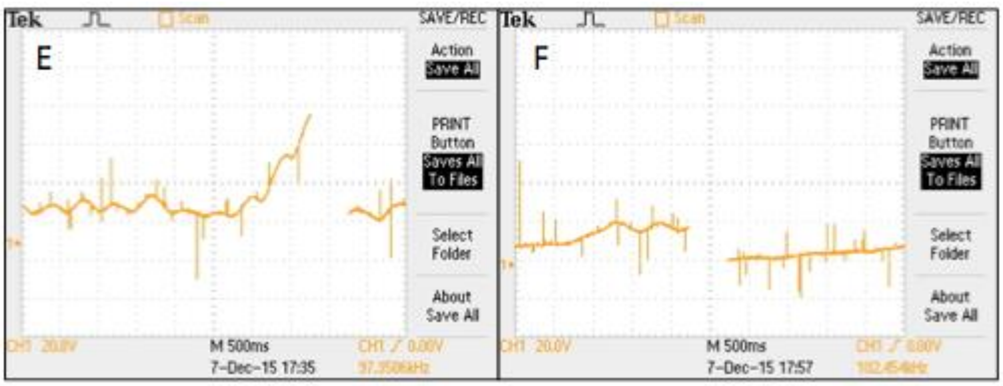


Figure 14. Image E represents the trough with splint at systolic pressure with a score of 1. Image F represents the splint at systolic pressure with a score of 4.

Flat Line for Splint vs Trough with Splint				
Probe Type	Subject 1	Subject 2	Subject 3	Average
Splint	5	4	4	**4.33**
Trough with Splint	1	2	2	1.67

Table 7. The visual inspection rating on a scale of 1-5 for when the signal is flat lined using the splint and trough with splint devices.

Using the laser Doppler, visual inspection of the splint and trough with splint designs was conducted in a similar fashion. Figure 14 shows visual representations of the trough with splint device versus the splint device. For when the signal is at a flat lined pressure, the average image quality rating was 4.33 for the splint device and 1.67 for the trough with splint device. These results indicate that the splint attenuates a greater amount of noise than the trough with splint device.

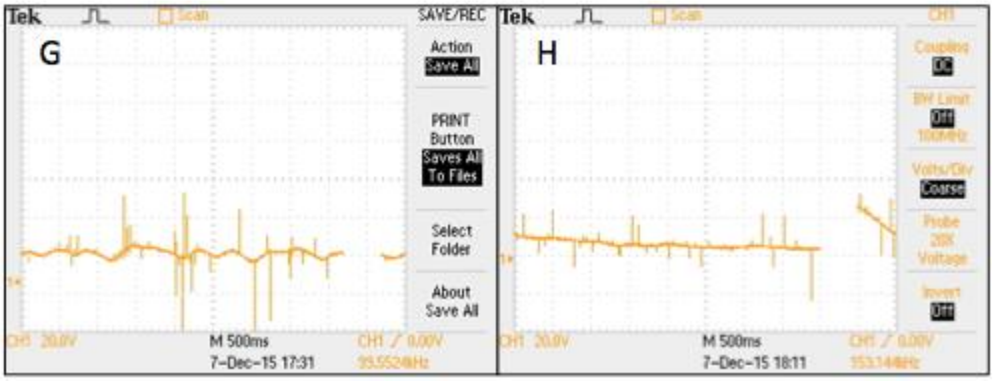


Figure 15. Image G represents the trough with splint at flat line with a score of 1. Image H represents the splint at flat line with a score of 5.

Systolic for Splint vs Trough with Splint				
Probe Type	Subject 1	Subject 2	Subject 3	Average
Splint	5	4	3	4
Trough with Splint	2	3	1	2

Table 8. The visual inspection rating on a scale of 1-5 for when the signal is systolic using the splint and trough with splint devices.

. Lastly, visual inspection was conducted at systolic pressure for the splint and trough with splint devices using the laser Doppler probe. As the representative images in figure 15 indicate, the trough with splint design increased the noise in the signal, making it difficult to identify systolic pressure on the waveform. Results show an average image quality of 4 for the splint device and 2 for the trough with splint device.

Discussion

There were many tests conducted to find the combination of elements that produce the most readable signal for the person running the test. In first comparing the piezoelectric pulse transducer in direct comparison with the laser Doppler the results clearly show that the laser Doppler produces a more stable signal while undergoing movement. In investigating the signals visually on a scale of 5 the laser Doppler received average scores of 4.33 and 3.67 for flatline and systolic periods respectively. The piezoelectric pulse transducer scored 1.33 for both events. When using the laser Doppler the score increased by 63.76% and 69.28% for the two events. To further validate this visual increase of readability with the laser Doppler another test was performed. This test was for the flatline reading to compare the number of adjacent points with nonzero values as for the ideal flatline reading all points should have a differential of zero. In this way the amount of noise produced by movement could be found. In the comparison it was calculated that for the piezoelectric transducer that 50.31% of frames or adjacent points showed nonzero values for their differentials. When compared to the laser Doppler only 34.77% of adjacent points showed nonzero values for their differentials. This evaluation shows that the signal for the laser Doppler was not only visually clearer but the artifact from movement is what is causing the piezoelectric pulse transducer to be noisier and for this reason laser Doppler is chosen as the superior method of viewing blood pressure events.

After concluding the laser Doppler is more effective, testing was done to calculate the improvements that the splint and trough had on further improving the signal. The same visual inspection was used to compare the methods of using the splint alone compared to the splint and trough. These scores showed that for both systolic and flatline the splint alone performed 50.0% and 61.43% better respectively. These numbers disagree with the predicted outcome that the system of both splint and trough would be most effective in reducing noise. This could attributed to the underestimated amount of vibration the trough would receive due to the treadmill and stepping force. During testing, it was clear that the trough took vibrational movement of the treadmill as well as the downward stepping force. The foam did little to absorb this movement so the noise on the reading was increased in comparison with having the hand free during measurements. For this reason the trough portion of the design will be eliminated.

Because the visual inspections are based on subjective viewing, this can cause error in the evaluation of the various elements. Error in the evaluation of nonzero differentials of adjacent points can come from the overgeneralization that the noise in the signal is coming exclusively from movement. With these potential errors considered, the team did its best to present reasonable conclusions using the data collected.

Conclusion

Reading blood pressure in children while performing stress tests on a treadmill is often more difficult because the auditory cues are quieter when using the traditional cuff and stethoscope method. In order to improve this reading the laser Doppler was introduced. To stabilize this signal on the oscilloscope various elements were added to the application of the laser Doppler to the hand as well as to the treadmill. After testing, it was concluded that the finger splint alone was the most promising method to stabilize the signal and that the trough did not contribute to any improvement.

Future Work

In the future, the team will fabricate splints to fit a variety of child’s size hands as well as test and analyze data on children ages 6-12. In order to further improve the signal changes to the splint that limit the movement of the distal phalanx can be made. The team would also like to work with the software Periflux PSW ExM analysis software that comes with the laser Doppler machine to help in further analyzing the data collected. Adding a bioinstrumentation aspect to the design such as an auditory signal or visual output to cue when to take the reading for systolic blood pressure is also something the team wishes to accomplish next semester.

Acknowledgements

The team would like to thank Professor Thompson for his guidance, advice, and assistance throughout the design project. Further thanks goes to the client, Dr. Allen Wilson, for his knowledge of pediatrics and time spent communicating with our team. Much gratitude goes to Lisa Dussault for aiding the team with splint fabrication. Finally, the team would like to thank the University of Wisconsin – Madison Biomedical Engineering department for the opportunity to work on this project and for providing us with the necessary resources to accomplish our design goals.

References

[1] Congenital heart defect fact sheets. (2012). Retrieved October 1, 2015
[2] Youth and cardiovascular diseases. (2013). Retrieved September 28, 2015.
[3] Treadmill stress test. (2002, Mach 3). Retrived September 8, 2015
[6] Cardioperfect exercise ECG quick start guide. (2007). Retrieved September 15, 2015.
[7] Electrocardiograph (ECG,EKG) interpretation. (2009). Retrieved October 3, 2015.
[4] Fredriksson I, Fors C and Johansson J, "Laser Doppler Flowmetry - a Theoretical

Framework", Department of Biomedical Engineering, Linköping University (2007), www.imt.liu.se/bit/ldf/ldfmain.html
[5]Perimed-instruments.com. (2015). *PeriFlux System 5000 - Laser Doppler Perfusion Monitor*. Retrieved 5 December 2015, from https://www.perimed-instruments.com/products/periflux-system-5000-ldpm
[8] DonJoy Universal Thumb/Wrist Splint. (2015). Retrieved September 26, 2015.
[9] Thermoplastic Splint, Hand Splints. (n.d.). Retrieved December 1, 2015, from http://www.rehabmart.com/category/Splinting_Thermoplastics.htm

[10] Kristi, H. (2004). The Human Interface – New Directions for Designing Interactive Systems
[11] Hegde, Kamath. "Nylon Fibers." http://www.engr.utk.edu/mse/pages/Textiles/Nylon Retrieved November 28, 2015.
[12] Wensel, R., Opitz, C.F., Anker, S.D., et. Al (2002). Assessment of survival with primary pulmonary hypertension: importance of cardiopulmonary exercise testing. *Circulation*, 106, 319-324.

Appendix References

[1] Hypothesis Test: Difference Between Means. (2010, April 11). Retrieved December 3, 2015, from http://stattrek.com/hypothesis-test/difference-in-means.aspx?Tutorial=AP

Appendix A: Product Design Specifications

Measuring Exercise Systolic BP Using Finger Doppler in Kids

Contents of PDS- September 18, 2015

Madison Boston, Crystal Jimenez, Haley Knapp, and Gabby Laures

Function: A simple auscultatory-cuff method is currently used to measure blood pressure (BP) during treadmill stress testing in adults and kids. With children between the ages of six and twelve, it is often difficult to hear the peak systolic sound that defines systolic pressure. Laser Doppler sampling from the first finger or thumb at rest reads this pressured signal nicely so that it can be used with blood pressure cuffs to find peak systolic BP equivalent. The problem is that laser Doppler signals are motion sensitive. Luckily, when the BPs of kids are exercised, their arms are held off the treadmill. A stabilizing device that holds a laser Doppler probe in place on that first finger or thumb, while stabilizing it from movement that causes artifact on laser Doppler signal, is needed.

Client requirements:

- The Perimed Probe 457 Small Angled Thermostatic Probe is the preferred probe for usage
- Device must provide oscilloscope with steady BP signal
- Material should be lightweight
- Device should not interfere with stress treadmill testing
- Device should not infringe upon previous patents
- Device should preferably applied onto patient's right hand

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements: This device will be worn by pediatric patients and must be able to resist movement of probe. It must be unaffected by sweat and movement of the child.

b. Safety: This garment or glove should not restrict blood flow and should not in any way irritate the wearer while in use.

c. Accuracy and Reliability: This device must restrict movement of probe in reference to the finger/thumb to a level that provides a clear signal on the oscilloscope. It must also must maintain this level of accuracy regardless of the age or hand size of the wearer.

d. Life in Service: It must be able to maintain its function for one hour each time a test is being performed and must be able to be used repeatedly for different patients over a lifespan of five years.

e. Shelf Life: While there are no perishable items, any materials that include fabric or elastomeric components should last five years from date of manufacturing.

f. Operating Environment: The device will be mainly used for patients while exercising on a treadmill in hospitals due to arrhythmias.

g. Ergonomics: The setup for attaching and removing the device onto the right hand should take no longer than thirty seconds. When the patient is walking with the device on, the acceptable max operation of the thumb when worn is less than 23 kg.

h. Size: The size of the device should wrap to the patient's extremity as a glove would. The material of the glove should at least slip on top of the thumb or first finger. Anthropometric data will be used to determine the average dimensions of children's' fingers between the ages of six and twelve.

i. Weight: To prevent inhibition of the patient's exercise, the weight of the device should be no greater than 2.5 kg.

j. Materials: The material used needs to be both lightweight and comfortable for patient to wear while running on the treadmill. Also, the material of the device should be hypoallergenic.

k. Aesthetics, Appearance, and Finish: The device is not required to be a specific color. The texture should not be uncomfortable when applying to the hand, and should integrate well with the laser Doppler Dr. Wilson will provide.

2. Production Characteristics

a. Quantity: One device will originally be made to hopefully accommodate a range of children's hand sizes.

b. Target Product Cost: The client has a set budget of $1000. This design, however, will most likely spend significantly less when fabricating.

3. Miscellaneous

a. Standards and Specifications: The device must adhere to FDA standards for Class I devices such as general controls to assure quality, suitability of use, and proper labeling. Specific regulatory standards for laser Doppler related devices can be found in Code of Federal Regulations Title 21. 21 CFR 1040.10 and 1040.11 discuss the performance standards for light-emitted products.

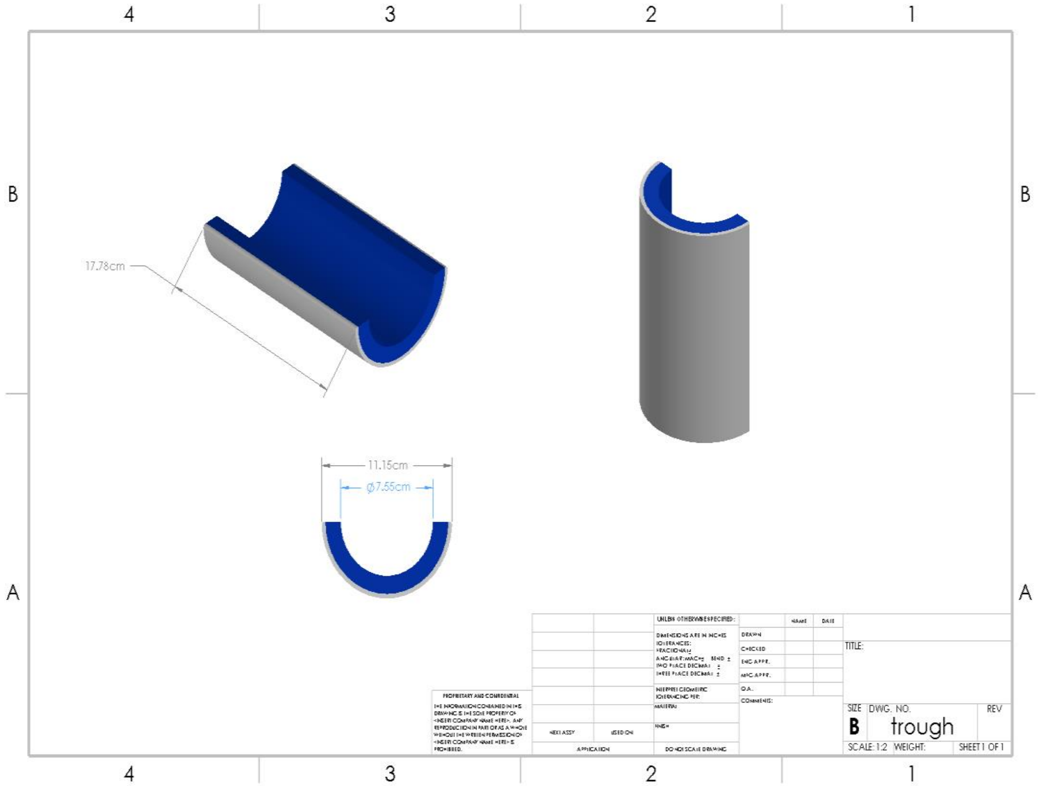
b. Customer: The device will be made to ensure that customer satisfaction is prioritized. This will be achieved through comfortable materials, elasticity and durability of fabrics, and simplistic design concepts for ease of use.

d. Competition: Currently, Dr. Wilson's blood perfusion methods using a laser Doppler are novel, so no competitors exist.

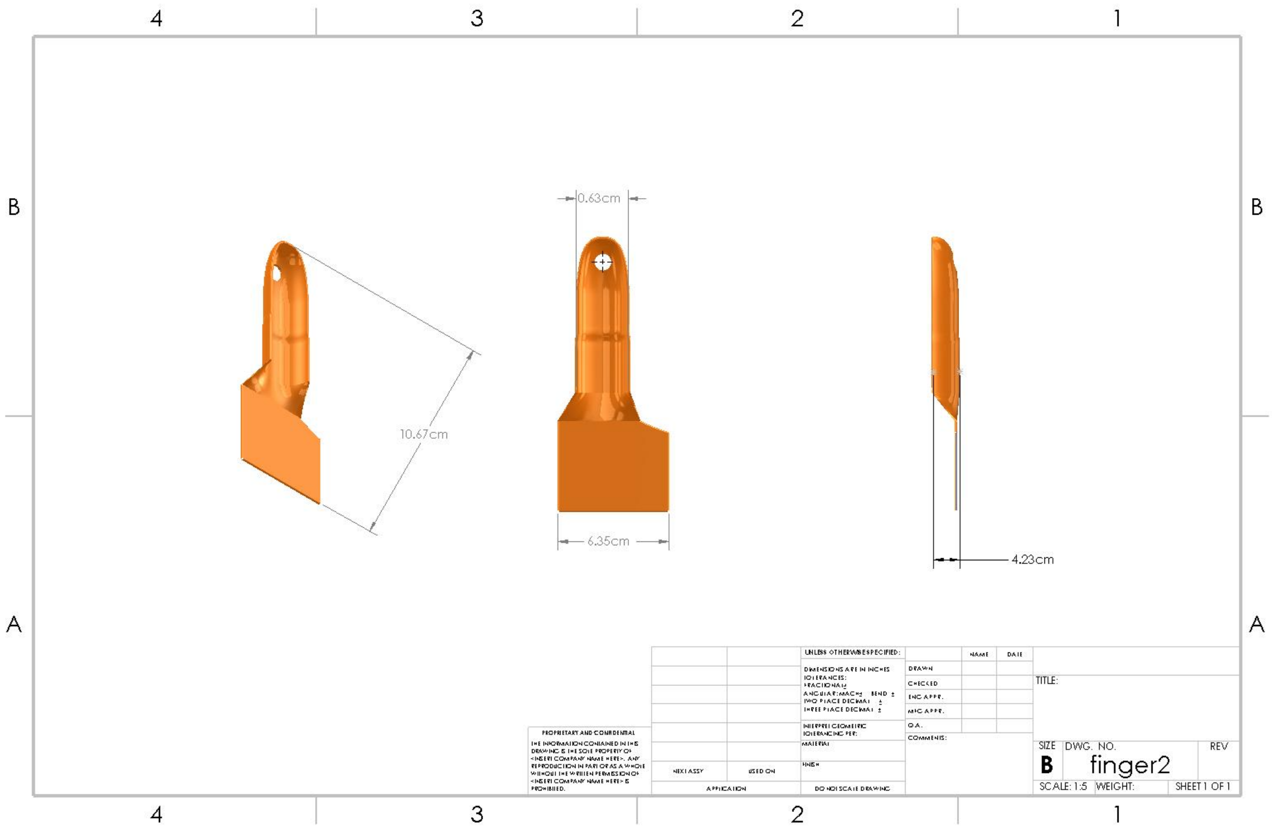
Appendix B: MATLAB Code for Data Analysis

```
%
close all;
clear all;
filename = 'F0013CH1-1.CSV';
M = csvread(filename);
 C1 = M(:,1);
 C2 = M(:,2);
 S1 = C2(1:1008);

 differential = diff(S1);
 absol = abs(differential);
  count=sum(absol~=0);

  average = sum(absol)./sum(absol~=0);
figure;
plot(absol);
xlabel('Time (ms)');
ylabel('Voltage (V)');
title('Time vs. Voltage');
```

Appendix C: SolidWorks Drawings of Prototype



SolidWorks Drawing of Hand Trough



SolidWorks Drawing of Finger Splint

Appendix D: TROUGH STABILIZATION OF LASER DOPPLER VALIDATION PROTOCOL

1.0 Purpose/Scope

1.1 To validate the capability of the trough stabilization device to diminish signal noise in the oscilloscope and allow for a blood pressure reading to occur during a treadmill stress test using laser doppler.

2.0 Reference Documents

2.1 PeriFlux System 5000 Laser Doppler Blood Perfusion Monitoring and tcpO2/tcpCO2 Reference Manual

3.0 Equipment

3.1 Perimed PeriFlux System 5000 Laser Doppler Perfusion Monitor
3.2 Tektronix TDS 2014B Four Channel Digital Storage Oscilloscope
3.3 Perimed PROBE 457 Angled Small Thermostatic Laser Doppler Probe
3.4 GE Treadmill 2100 Series

4.0 Materials

4.1 Trough Stabilization Device
4.2 Blood Pressure Cuff
4.3 Finger splint apparatus: Aquaplast mold and Coban wrapping

5.0 Procedure

5.1 Secure the laser doppler probe to the right index finger of the patient using the Velcro strap.
5.2 Secure the splint over the probe on the right hand/wrist.
5.3 Start the treadmill.
5.4 After the heart rate is increased, instruct the patient to place their right arm in the trough device with their thumb facing the ceiling.
5.5 When the signal is visibly stable, begin filling the blood pressure cuff with air.
5.6 Once the signal on the oscilloscope flatlines, slowly release the air within the blood pressure cuff.
5.7 While releasing the air, identify the first peak systolic blood pressure signal on the oscilloscope.
5.8 Once the signal appears, look at the reading on the blood pressure cuff and record the systolic blood pressure in the table below.
5.9 Repeat steps 6.1-6.8 for each subject.

6.0 Acceptance Criteria

6.1 Visual Inspection

Carefully inspect the signal during the blood pressure reading. The signal should not have a significant amount of noise and should flatline once the blood pressure cuff has cut off circulation in the right arm. Rate each signal from 1 to 5 where:

1 = Poor: Signal cannot be read due to noise
2 = Fair: Signal has a sizable amount of noise, but can still be read
3 = Good: Signal has some noise and can be read
4 = Very Good: Signal has very little noise and can be read easily
5 = Excellent: Signal has no noise and can be read easily

Record results in the table below. The test passes if all seals appear complete and continuous, each group has an average visual rating of ≥ 3, and there are no 1 ratings.

	Reading 1	Reading 2	Reading 3	Reading 4	Reading 5
Subject 1					
Subject 2					
Subject 3					
Subject 4					
Subject 5					

7.0 **Data Analysis Conclusion**

7.1 Data is to be analyzed and reported at the conclusion of testing.

Appendix E: Statistical Analysis of Percent Nonzero Data Frames

Piezoelectric vs Laser Doppler Noise %				
Subject	**Subject 1**	**Subject 2**	**Subject 3**	**Average**
% Frames Nonzero Laser Doppler	35.08%	32.04%	37.19%	**34.77%**
% Frames Nonzero Piezoelectric	48.31%	54.71%	47.91%	50.31%

The percentage of nonzero frames, or frames that did not have a differential of zero were calculated using MATLAB. This analysis was done for each subject that participated in the testing procedure. The mean percentages of nonzero frames for the laser Doppler and piezoelectric transducer were then found to conduct a t-test. A t-test is used for statistical analysis for comparing the means of two "treatments" [1]. A null ($\square_0$) and alternative hypothesis ($\square_\square$)was created for this test with a 99% confidence interval:

- $\square_0$: There is no significant difference in noise activity between the laser Doppler and the piezoelectric transducer.
- $\square_\square$: There ***is*** a significant difference in noise activity between the laser Doppler and the piezoelectric transducer.

By calculating the variance of the difference of the two means (σ^2) the standard deviation of the difference of the two means ($\square = 2.64$)   A t-score is found by subtracting the raw mean scores divided by σ (t= 5.89).

Observing a t-table with degrees of freedom of $(\square_1 + \square_2) - 2$ degrees of freedom is next. $\square_1$ and $\square_2$ represent the sample size for each "treatment" (Piezo vs. laser Doppler). With a confidence interval of 99%, or p = 0.01 and four degrees of freedom (3+3-2), the tabulated score is found to be 4.60 [. Because the calculated t-value exceeds the tabulated value, the null hypothesis can be rejected, confirming that the laser Doppler significantly reduces the amount of noise in the oscilloscope readings.