BME 4908 SENIOR DESIGN PROJECT REPORT

Seismocardiogram Sensor

Submitted in partial fulfillment of the
requirements for the degree of

BACHELOR OF SCIENCE
in
BIOMEDICAL ENGINEERING

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Executive Summary

An overview of the project. Marketing background, the need, and its social impact. Also clearly specify what the project will deliver as a tangible output.

Wearable medical devices, especially cardiac monitoring, have a growing demand and market due to their convenient use such as visibility, size, and ease of interpretation for consumers. The overview of the project is to design a wireless sensor that can be compatible with a wearable patch for patients with coronary artery disease (CAD) that recognizes cardiac mechanical signals that are produced by the vibration on the chest.

Jabil, a manufacturing company that is interested in minimizing wearable medical devices, showed interest in our proposed device and gave us sponsorship to fulfill our senior design project. The tangible output is a small skin-wear sensor that is capable of capturing SCG frequencies (up to 40 Hz), converting the mechanical signal to electrical, and recording real-time data.

1. Recognition of Need/Opportunity

What clinical problem is being addressed? Is anything currently being used to address this problem? What opportunities exist to improve clinical outcomes, cost management, or ease of use? What are the particular needs of the customer? How have these needs been identified and defined?

Cardiovascular disease (CVD) has one of the highest mortality rates in the United States. CAD is the leading cause of death in CVD. About 18.2 million adults are affected by CAD, mainly caused by high cholesterol levels, which is predominant in males in the age range of 40-60 years old.

The best way of diagnosing CAD currently is cardiac catheterization also known as coronary angiography which is a minimally invasive approach. An alternative approach is an electrocardiography (ECG) which is a noninvasive approach. ECG only records electrical signals traveling through the heart due to repolarization and depolarization of the valves, but CAD can be diagnosed more accurately from mechanical vibrations with seismocardiogram (SCG) signals. ECG devices are advancing in minimizing size and weight, portability and mobility, wireless functionality, ease of use and interpretation for consumers, and incorporating in other wearable devices such as smartwatches. The price of current wearable wireless ECG devices varies from $100-$400, depending on the manufacturing company.

ECG results are not precise in the detection of CAD. Therefore, the problem is the lack of SCG devices to detect CAD noninvasively, especially in early stages. Based on the current ECG devices, the prototype is aiming to be skin-wear, wireless, compact, and lightweight while being able to record SCG signals continuously.

2. Problem Formulation

Includes the conversion of customer requirements to functional, performance, and interface design specifications, and all engineering standards that must be met and other design constraints (should be multiple).

a. Project Objectives:

Is the objective a device, system, component, or process? What can be specifically accomplished in the allotted time and with the allotted resources?

In order to meet the deadline of completion for April 2022 and fulfill the wishes of the sponsor, the senior design team will design and develop a small wireless component capable of detecting SCG signals. The component will be constructed in the form that it's compatible with a wearable patch that can be placed on the user's sternum to sense the vibrations produced by blood flowing through the heart chambers as the cardiac valves open and close. Said vibrations have fairly low frequencies and amplitudes therefore the sensor will be made of a high compliance piezoelectric polymer to focus on the sensor's sensitivity and an adhesive polymer to minimize unwanted mechanical noise. Also, in order for the full system to function properly, the sensor will be constructed so that it may comply with the patch's power source. The project will be completed using available funding of $3000 for any necessary manufacturing and verification testing.

b. Design Specifications:

How were the customer needs converted into specific design specifications? What are the criteria for success in meeting those specifications? How will they be measured?

To initial the design process of the SCG sensor, the team developed well-defined market requirements based on the sponsor's interest in wearable or flexible medical devices used in health monitoring. The market requirements related to the component's features such as signal sensitivity for detection, signal conversion, placement, and sizing. During this process, the main focus was creating a device that can provide better outcomes than the current modalities and fulfill the targeted market's needs. The table below shows how the team constructed the device's market requirements, based on the sponsor's interests, to create design inputs for executing the intended output. Also, the success of meeting these design inputs will be based on the results from the verification tests listed. The protocols for each method of verification can be found in the design history file with further details and rationale for the selection.

Market Requirements	Design Inputs	Method of Verification

The device should be able to non-invasively recognize the vibrational signals from the chest, in a uniaxial direction.	The sensor needs to be uniaxial and detect frequency ranges of 10-40 Hz in planar directions.	Phantom test via an artificial pulse generator.
Device should be able to convert cardiac vibration to electrical voltage.	The sensor needs to convert a minimum cardiac pressure of 1.5 Pa to a minimum voltage output of 1-3mV peak-peak.	Comparison of accelerometer and piezoelectric sensor.
Device must comply with skin's elasticity on the chest.	The sensor's elastic modulus needs to range from 130 kPa to 20 MPa.	Uniaxial Tensile Test - load/unload cycles.
The device's dimensions should comply with the size of the apex of the sternum.	Sensor dimensions should be within 27.7 ± 4.1 mm for width and 154.1 ± 13.1mm for length.	Dimensions confirmation of SCG sensor.
The device should be compatible with the patch's wireless power transfer design.	Device is powered through a 3 - 5V wireless power source.	Measuring the power source voltage used via voltmeter.

c. Engineering Standards

What engineering standards were considered? These could be regulatory standards, design standards, testing standards, and safety standards. If none were considered, provide the reason.

Below are standards that the device must comply with:

- ISO 16063-32:2016 Methods for the calibration of vibration and shock transducers — Part 32: Resonance testing — Testing the frequency and the phase response of accelerometers by means of shock excitation
- ISO 527-1:2019 Plastics — Determination of tensile properties — Part 1: General principles
- IEC 62353:2014 Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment
- ISO 10993-10:2021 Biological evaluation of medical devices in relation to skin reaction.
- ISO 16063-21:2003 Methods for the calibration of vibration and shock transducers — Part 21: Vibration calibration by comparison to a reference transducer

d. Constraints and other considerations

What economic, environmental, social, political, ethical, safety, manufacturability, or sustainability constraints exist?

One of the main constraints regarding this project is socioeconomic such that one of the main requirements is maintaining the manufacturing cost of the device as low as possible so that the manufacturing company, Jabil, can provide the device at a lower cost of current wearable cardiac monitoring devices such as ECG to patients with CAD.

Another major constraint is the fact that our constructed component is intended to be only one part of a device. The design of the sensor needs to depend on the given patch dimensions and be compatible with the other features of the device, such as communication and power. The design constraints also revolve around the placement of the device as the sponsor's request for the device to be placed on the skin in the chest area. In order for the sensor to maintain direct contact with the skin, it needs to have a similar elastic modulus which depends on the configuration of the material.

The main parts of the sensor are Polyvinylidene Fluoride (PVDF) and polyurethane film, which is considered recyclable materials and gives a great advantage of using such materials. While remaining environmentally conscious, PVDF is not a biodegradable material and polyurethane film is susceptible to biodegradation naturally. Additionally, the film tape is very thin which has a negligible effect on the sensor sensitivity.

Considering the points mentioned, the component that we're constructing is safe to use and has no safety concern except a possible skin reaction to the polyurethane film. Also what can possibly cause irritation to the user may be the adhesive methodology of the final patch in the form of an adhesive spray. Lastly, the device components do not require any sterilization, hence less steps of manufacturing.

3. Solution Formulation: Conceptualization and Creativity (Alternative Solutions)

What are all the possible ways the objectives could have been accomplished? What methods were used to foster and optimize creativity? What engineering solutions were formulated or adapted to meet the customer needs?

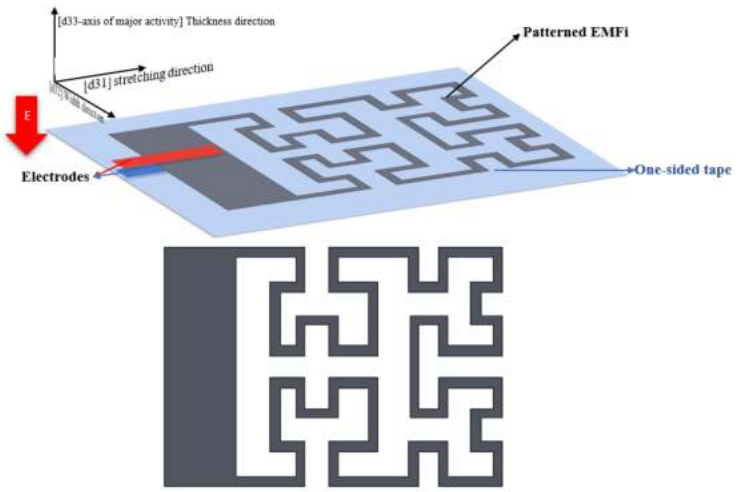
Based on the aforementioned priorities, the team carried Method 635 and Delphi techniques to develop the conceptualization of the device. These techniques involved the group members building their ideas off one another and consulting outside experts. When attempting the creation of a device that meets the user's needs, the market requirements, design inputs, and current modalities were taken into consideration.

Firstly, the team discussed the sensitivity of the sensor and how it could sense SCG signals. The use of PVDF was the material we decided to be the best. PVDF is a piezoelectric polymer both lightweight and compact while being sensitive to lateral forces for SCG measurements. However, unpatterned PVDF has a very high Young's Modulus (3.6 GPa) and makes it non-stretchable. Research shows that a filamentary serpentine design of PVDF will allow for the material to be stretchable and usable in our medical component.

Other possible materials and geometric configurations were also taken into account in the analysis of the optimal design. For example, metalized polypropylene film (electromechanical film (EMFi™)) is a useful material as it is very sensitive while still being flexible, lightweight, and compact. The main downside of EMFi resulting in the team going in a different direction is due to EMFi not being sensitive to lateral forces, which are important for SCG measurements. The team also researched different designs that could optimize the material's piezoelectric properties such as the Hilbert-curve pattern and Kirigami pattern. Both designs are known to provide a desirable elastic modulus to the material, but the disadvantage is it doesn't reach the range for skin that the team needs. If the sensor doesn't have great contact with the skin then it may affect the quality of the signal detected. These combinations of materials and methodologies allow for the final product to compete and even outperform with wearable, wireless ECG's currently in the market as SCGs can provide data to monitor patients with CAD.

The design concepts created to satisfy the market requirements, as well as the rationale of each, are displayed in the table below. Design concept 3 was chosen for development as a result of this analysis.

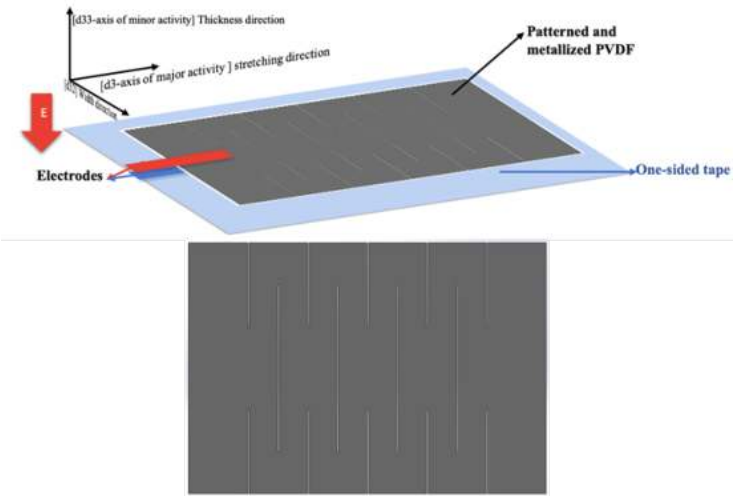
Design Concept 1



Description:
A small thin sensor composed of a metalized polypropylene film (electromechanical film (EMFi™)) with a Hilbert-curve pattern. The polymer came metalized with a carbon conductive paint to provide conductive properties.

Pros	Cons
• Non-invasive • Converts cardiac vibration to electrical voltage via a piezoelectric component. • Wireless • Wearable • Conformal	• Not sensitive to planar forces. • Low patterning and manufacturing feasibility. • The device's compliance with skin is compromised by the rigid geometric configuration

Design Concept 2

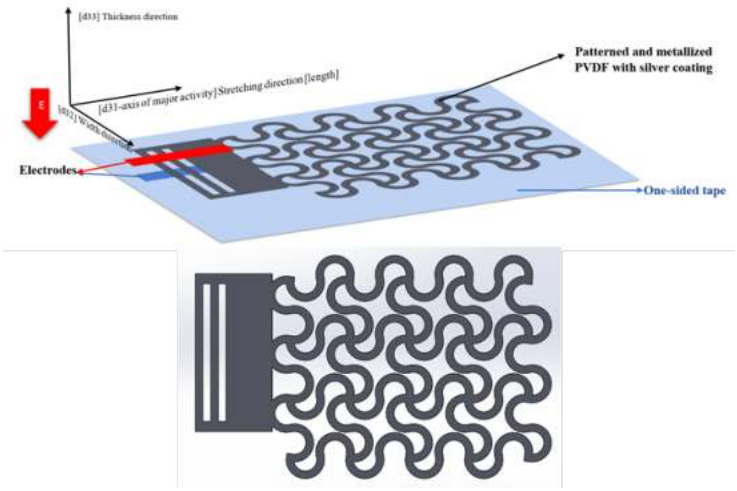


Description:
A small sensor composed of a thin film of metalized polyvinylidene fluoride (PVDF) with a Kirigami pattern. The material is metalized with silver ink to provide conductive properties.

Pros	Cons

• Non-invasive • Converts cardiac vibration to electrical voltage via a piezoelectric component • Low Young's modulus • Wireless • Wearable • Conformal • Lightweight • High patterning and manufacturing feasibility.	• Compromises interface of skin and sensor

Design Concept 3



Description:
A small sensor composed of a thin film of metalized polyvinylidene fluoride (PVDF) with a filamentary serpentine pattern. The material is metalized with silver ink to provide conductive properties.

Pros	Cons
• Non-invasive • Converts cardiac vibration to electrical voltage via a piezoelectric component • Low Young's modulus • Wireless • Wearable	• N/A as per our market requirements

• Conformal • Lightweight • High patterning and manufacturing feasibility.	

4. Feasibility Assessment (Proposed Solution)

What criteria did you use to choose the solution method that you did? Is this solution the most feasible based on technical, operational, schedule, and economic considerations? What impact might each possible solution have on society in a global and contemporary context?

The team was approached with the project of designing a wearable wireless device for heart activity monitoring. Market and clinical research were conducted, and the team concluded on focusing on CVD monitoring. Many patients with CAD are asymptomatic, meaning there is a need for a technology that is accurate and easy to use to reduce the mortality of the disease. Most patients are diagnosed by using either ECG or coronary angiography. ECG modalities require further tests to assess the location and degree of the occlusion, given that one can have a normal ECG and still have a heart attack. Furthermore, the standard technique for diagnosis of CAD, which is coronary angiography, is expensive and only available in hospitals. One alternative has been to use the sound of turbulent blood flow that is induced by the presence of coronary stenosis. Seismocardiogram is a non-invasive recording of chest vibrations due to the heartbeat and contains information on heart sounds and cardiac activities such as aortic and mitral valves opening and closure, rapid inflow, and atrial systole. This analysis shows that SCG is an appealing methodology to investigate changes with coronary artery stenosis and ischemia due to a decrease in coronary blood flow, hence detecting CAD.

The technology assessment provides information regarding evaluating the materials to be used in sensory function. Although accelerometers have the ability to convert mechanical movements to electric charges, piezoelectric transducers have such ability as well. Piezoelectric such as lead zirconate titanate (PZT) despite being stretchable, contains hazardous substances, is expensive, and naturally brittle. On the other hand, polyvinylidene fluoride (PVDF) is biocompatible, durable, and commercially available. An unpatterned PVDF has Young's modulus of 3.6 GPa, therefore not stretchable. However, patterned PVDF becomes stretchable due to its reduction in Young's modulus. In order to increase the sensor's conductivity and stretchability, silver screen-printed PVDF film is the ideal option in comparison to nickel screen-printed film which is brittle and not as stretchable.

A flexible biocompatible adhesive substrate needs to be applied to the patterned PVDF to encase the sensor. It is crucial the adhesive layer Young's modulus be close to the skin Young's modulus in order for the sensor to compress and decompress as much

skin does, and also be extremely thin to not dampen the signals. The chosen adhesive tape is a one-side adhesive Tegaderm tape.

In accordance with the potential project budget of $3000 provided by Jabil, the cost assessment was performed. Based on the projected selected materials and equipment needed, the total project cost was estimated to be $1,407.28.

The hazard analysis performed included an analysis of possible risks associated with the use of the device. Given that the device will be wearable, compact, and exclude a battery, no major complications were determined except the possibility of skin irritation due to the adhesive material. Moreover, the regulatory assessment classified the device as a Class II with the need of 510(k) clearance but excluding Premarket approval (PMA) and investigational device exemption (IDE).

Providing a miniature skin-wear heart monitoring device that is based on a seismocardiogram would have a positive impact in reducing the mortality of CAD. From an economic standpoint, a wearable SCG is more appealing than a wearable ECG. ECG wearable devices record and process the electrical signals, and are bulky. Market research was conducted to compare the proposed methodology with either current devices or prototypes by research groups. Through this, it was concluded that the solution suggested is unique and the most feasible, given its focus on sensitivity and simplified fabrication.

5. Project Management: Organization/Work Breakdown Structure

What activities were done to accomplish the project? Who performed what tasks? What was the time frame for the completion of each task, and then the entire project? What project management software was utilized? Did the team work together in a professional and ethical manner?

After seeking a design project and receiving the proposal on October 08, 2021, the team began researching together with the significance of seismocardiography in regards to the clinical need and market need. During this time, the current modalities were researched as well to find areas of improvement and possible ideas for design concepts. The team worked together with their contact at Jabil to determine the device's market requirements to be able to develop the corresponding design inputs to execute the desired output. Following the configuration of the possible design concepts for the final product, the necessary feasibility assessments (technology, cost, regulatory, and risk-hazard) and verification test designing were accomplished. These critical tasks were done prior to the video presentation of the project proposal and the accompanying Q&A session, which took place on November 23, 2021, and December 1, 2021, accordingly. During the Q&A session, the team answered questions regarding their project proposal presented to a committee of Florida International University faculty which included Professor Hamid Shahrestani, Dr. Anuradha Godavarty, and Dr. Markondeya Raj Pulugurtha.

The majority of project tasks were executed with the full team's participation. In meetings, project decisions, and workload distribution, every member's opinion was always valued and taken into account. Raquel, the project manager, created a shared Google Drive to allow for the organization of the necessary documents and facilitate team collaboration during project assignments. Each group member was then given an assigned assignment to complete in order to finish the project on time. For example, regarding the feasibility assessments, Antonio led the regulatory and risk-hazard assessments, Alessandra and Raquel led the product and project cost assessment, and Haniyeh led the technology assessment, however, the entire group reviewed, discussed, and made any necessary adjustments.

To complete the first half of the project by early December 2021, the team made a real effort to attend periodic meetings, whether in person or remotely. In Microsoft Project, a project plan was created that showed detailed milestones and activities that must be fulfilled as part of the project's scope. In the project plan, the time duration to complete each task was an approximation, as a result, it was proposed that larger jobs be given extra time to have enough time for quality level completion. In addition, a design history file (DHF), an organized record, was created to give documentation of the project's progress and any revisions made during the two semesters.

The final half of the project was expected to be completed by early April 2022 when the team was responsible for the device's design, simulation, manufacturing, and verification. Each member was assigned a role by the project manager based on these phases of the project, for example, Alessandra was Head of Design, Haniyeh was Head of Manufacturing, and Antonio was Head of Quality. The first step of the second part of the project phase was for Alessandra and the team to finalize any changes to the design concepts based on changes to the project scope discussed after the feedback from the committee. Once all changes were made, Alessandra and Raquel worked to complete the simulations to prove design concept 3 was the concept to be manufactured. The main simulations involved adequate forces that could be applied to the sensor to simulate the stresses sustained when placed on the skin. Also, from these same forces, it was necessary to observe how they would stimulate the PVDF’s piezoelectric properties and if the output satisfied the respective design input. Afterward, Haniyeh and Antonio worked with Yeahia Been Sayeed to manufacture the first prototype. Haniyeh was able to develop a protocol that consisted of the cutting process of the material, applying the conductive ink, adding the electrodes, and then encapsulating the sensor with a thin polymer adhesive film. As the final prototypes are being constructed to reach the desired sample size, Antonio was organizing all protocols and procedures needed for verification testing. The main verification testings that were performed for the samples produced were a dimensions confirmation, uniaxial tensile test, and our killer test which involved an artificial pulse generator. A root cause analysis was constructed when there were complications during manufacturing and verifications to show where the possible error arises from. After all verification testing was completed, the team organized all

their information for their oral presentation and poster that was scheduled for April 21, 2022 and April 22, 2022, respectively.

6. Engineering Analysis and Decision-Making

What kind of engineering analysis was required to make the design decisions? How was the analysis performed, and what was the result? What application of mathematical, physical, and life sciences was used in the engineering analysis? What modern engineering tools (including, for example, modeling software) were used for the analysis? On what basis were design decisions made? For example, what criteria were used for materials choices? If experiments were performed, how was data measured, analyzed, and interpreted to assist in design decisions?

To effectively make the design decisions, the team needed to focus on what materials and setup would produce the intended output. The following criteria needed to be considered: receiving a mechanical signal, converting it to an electrical signal, not compromising skin elasticity, complying with the size of the apex of the sternum, and being compatible with the patch's wireless power transfer design. From the design inputs mentioned in Section 2, the team constructed design concepts that best satisfy these requirements. Performing the quality function deployment analysis validated which design concept will be chosen for this project, which is emphasized in Section 3. Once the concept was selected, material analysis was conducted, with cost consideration.

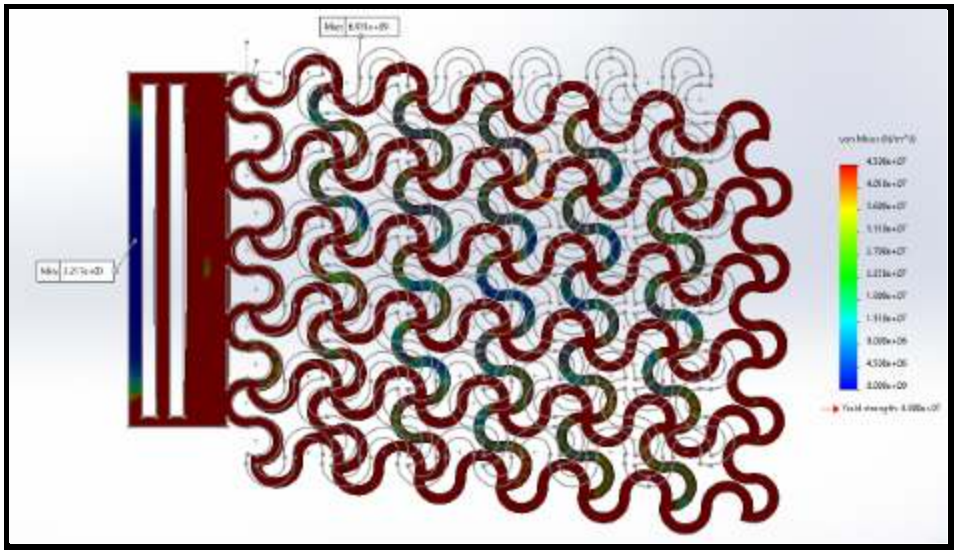
To visually represent the chosen design concept Solidworks was used, and the interconnected designs were developed. To enhance the PVDF's ability to sense cardiac vibrations it needs to be patterned. Analysis of different patterns was conducted, and a filamentary serpentine was chosen, as mentioned in Section 3. However, this decision requires further analysis on determining the optimal area density (AD) or contact area between the sensor and skin, based on varying ratios of weight to the radius. The contact area of the electrodes with the body affects the quality of the signal detected, with a larger contact area meaning less dependence on the placement of the sensor and a higher signal to noise ratio. The general formula used in the analysis is shown below, where 'θ' is the rotation angle, 'R' is the outer circle radius, and 'W' is the curve width.

$$AD = \frac{\text{mesh area}}{\text{square area}} = \frac{4\pi[R^2-(R-W)^2]\left(1-\frac{180-2\theta}{360}\right)}{\{2[R\cos\theta + (R-W)\cos\theta]\}^2} = \frac{\pi\left(\frac{1}{2}+\frac{\theta}{180}\right)}{\left(\frac{2R}{W}-1\right)\cos^2\theta} \quad (1)$$

To determine the most feasible design, simulations were performed with AD values of 10%, 30%, 40%, 50%, 60%, and 70%. In the simulation, R was set to 1.25 mm, and θ was set to 15º due to the resolution of the cutting machine that was used (Silhouette CAMEO 4), while W was varied. The values for the varying W are shown below.

AD	10%	30%	40%	50%	60%	70%
Width (mm)	0.12	0.33	0.42	0.50	0.58	0.65

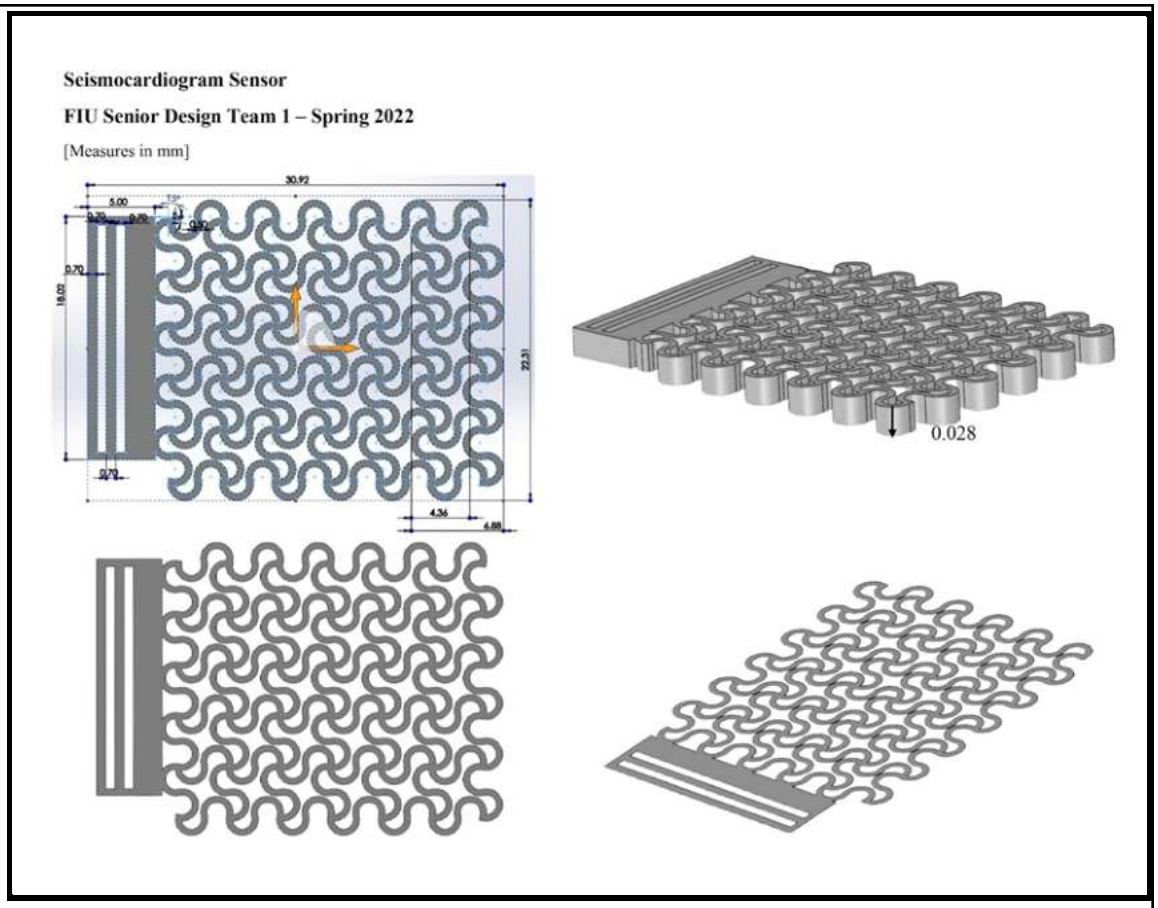
A force of 1.5 N was applied to the boundary on the right of the design, with the same direction of the plane, while the left boundary was fixed. The expected result was that lower applied stress would be seen with higher AD value, and the most feasible design would be the one with the lowest applied stress and no overlap or clear proximity. This was supported by the simulation results, which showed that as AD value increases, the maximum stress experienced decreases. The result matched the expected results. It was concluded that an AD of 50% showed the least applied stress while showing no overlap, or clear proximity, of the outer circles. The stress result for an AD of 50% is shown below, having a maximum stress of 6.931e+09 (Pa). *The scales were normalized with respect to the yield strength of PVDF, which is 4.8e+07 (the max stress was defined as 4.5e+07)



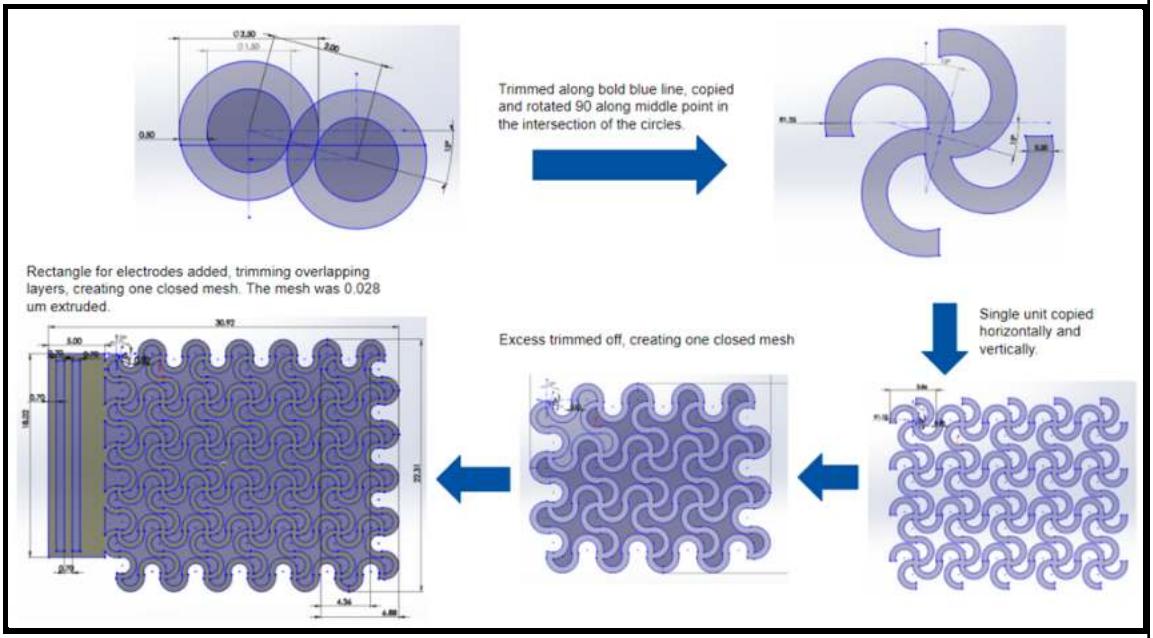
Further, a protocol was developed, based on the uniaxial tensile test, and will be carried out in March 2022. Once the optimal AD for the patterned PVDF was determined, the sensitivity of the patch to normal SCG signals (10-40 Hz) will be assessed. To carry out this verification, the team designed a test protocol based on phantom testing. The overall test focuses on artificially simulating the vibrations from the heart to verify the sensor's sensitivity, which will be completed in the verification phase of Senior 2. Given the results of the two verification tests, the functionality of the design would be assessed.

7. Detail Design

Should include all production specifications, such as machine drawings, assembly drawings, material and process specification, work instructions, etc.



The design was based on utilizing a filamentary serpentine pattern and was designed using Solidworks. The repeating unit of the design was constructed from two circles that are in contact with each other at a specific rotation angle (θ). A rectangle was constructed based on the center of the circles and the θ was specified based on the diagonal connection and the top horizontal line. Based on the vertical line, a middle point line was constructed, which the circles are then cut along said line. The now connected wavy pattern was rotated 90º along the intersection of the circles to create the repeating unit. This unit is then repeated horizontally and vertically to achieve the final filamentary serpentine pattern. Once finalized the pattern, a rectangle with two openings was added to the left side of the design to facilitate the placement of the electrodes. Lastly, the mesh was extruded 0.028 mm to match the thickness of the chosen PVDF. The final design has a width of 22.31 mm, a length of 30.92 mm, and a thickness of 0.028 mm. This whole process is shown below.

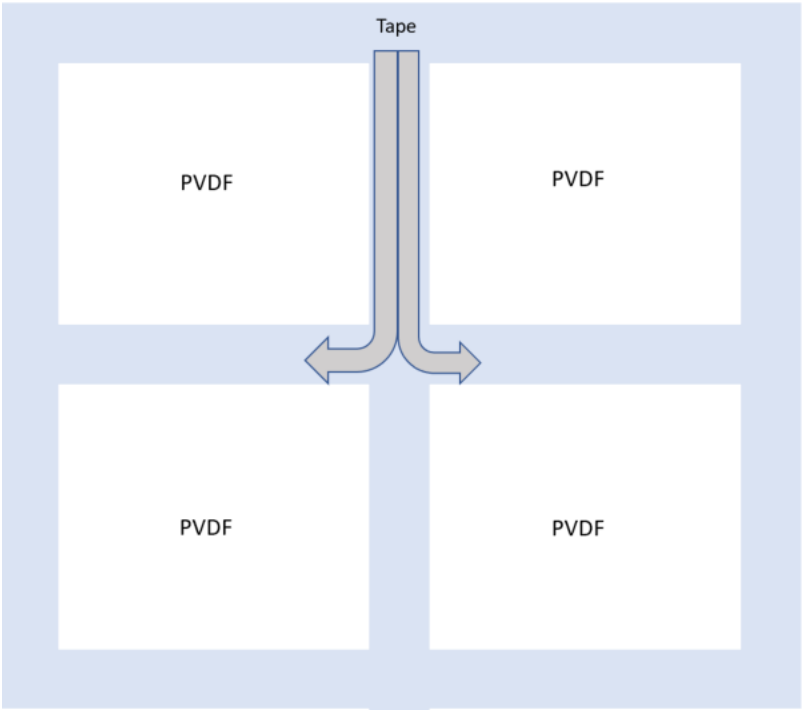


8. Construction

How was it constructed? By whom? Using what manufacturing techniques, tools and processes? What problems were overcome?

With consideration of sample size, waste reduction of material and time, and the size of the sensor, the preparation includes the steps below:

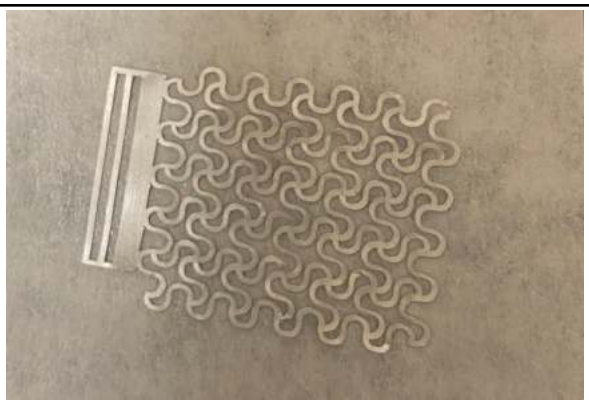
1. Cut the PVDF film in a proper size.
2. Smear silver ink (CI-1036) with a squidgy on the PVDF sample.
3. Set the oven temperature to 50C.
4. Place the sample in the oven for 16-17 hours to cure it.
5. Repeat steps from 2-4 for the other side of the sample.



The size of the sample film needs to be smaller than the oven plate, and also two blocks are required to be placed on two sides of the sample to ensure during curing the PVDF is not warping and wrinkling, therefore a 12x12 cm sample was cut. This sample is taped on an aluminum board and sectioned into a 4 square base pattern 3x4 cm (1cm2 larger than the sensor size) creating a fiducial section.

With a multimeter, the resistance of each side of the screen-printed samples is measured to ensure the resistance is below 50 ohms and it is continuous. The top and bottom of each sample are measured as well to ensure the circuit is not continuous.

Each sample is cut and placed on a weak adhesive tape (3M-582U) in order to prepare it for the next step of printing/cutting the design. The small samples are in the size of 3x4 cm, slightly larger than the sensor. Cameo Silhouette is the desktop cutter used in carving the pattern on the metalized sample and cutting it. Also, Cameo Studio is software used in displaying the design and optimizing the cutting setting such as blade depth, force, speed, and a number of passes of the blade.



The optimal setting first was set to 10N force, 1cm/s speed, 5 passes, and 2mm blade depth. The carved pattern was not cut through on the edges. After increasing the blade depth to 3mm and the passes to 6, the pattern was cut thoroughly and with tweezers, it was gently removed from the weak adhesive tape.

9. Testing

How was verification testing designed and conducted? How was validation testing designed and conducted? What application of mathematical (including statistics), physical, and life sciences was used in the analysis? What modern engineering tools (including, for example, sophisticated testing and analytical equipment) were used for the testing and analysis? What were the results?

For the verification of the PVDF sensor, five protocols were created to ensure the device meets the market requirements stated: Sensitivity test utilizing artificial pulse generator, uniaxial tensile test, dimension confirmation, comparison with an accelerometer, and testing for voltage from an external power source. The sensitivity test involves using an artificial pulse generator *(3B Scientific Vibration Generator)* to phantom test the device. The device will be placed onto the machine and measure the output voltage that would be generated by standard SCG frequencies. These frequencies usually range from 10Hz to 40Hz. The uniaxial test will allow for the determination of the young's modulus of the patterned PVDF. The goal is to have the PVDF sensor stretch with the skin, and as such the young's modulus of skin and the sensor should be similar. The dimension confirmation relates to the length and height of the device. The width is 28um, and the length and height of the sensor should be below the range stated in the design inputs (27.7 ± 4.1 mm for length and 154.1 ± 13.1mm for height). Based on work that has been done so far, the measurements for fully cut samples have been around the range set by the machine of 30.92 mm in height and 22.31 mm in length, which is good. Confirmations have been done in both the CAMEO silhouette software and in the lab physically using a caliper. For the test utilizing an accelerometer, the goal is to compare the signal values that each one would produce. Most SCG devices use an accelerometer and have lately been experimenting with MEMS accelerometers, so this is to prove an effective and lightweight alternative. This verification test has been omitted due to timing constraints and it being not focused on our design inputs. Finally, the device as a whole should be able to be powered wirelessly in the future, so this protocol is to show that voltage from an external power source can be wirelessly

introduced. The test was also not completed as it is not necessary for our design inputs. Software such as Ansys structure and COMSOL are softwares to further solidify verification results. SOLIDWORKS has been extensively used for stress analysis and measurement confirmation.

10. Evaluation

What application of mathematical (including statistics), physical, and life sciences was used to analyze and interpret the results? Was a statistical software package, or other modern engineering tool, was used to assist in data interpretation? What were the specific evaluation criteria? Were they met?

As mentioned previously, statistical tests such as ANOVA and t-test can be used to test for if there are any significant differences betweens samples based on young's modulus or for sensitivity. Size verification analysis was accomplished with a standard t-test and 95% Confidence level. Uniaxial tensile testing was also confirmed with a standard t-test and 95% Confidence. For our killer test, one-way ANOVA analysis was conducted with 95% confidence. All three verification tests were passed. Sensing of the PVDF can be shown if it is able to detect the vibrations that will be produced by the pulse generator and analyzed by the appropriate software. More testing would have to be done to accomplish this as these tests were fairly sensitive to noise Software that has been used for analysis so far is only SOLIDWORKS, with Ansys structure and COMSOL as possibilities not explored yet. The criteria stated in the design inputs were met.

Design History File (DHF) and Device Master Record (DMR)

DHF -
https://docs.google.com/document/d/1E5Ra9M6KsWELaNnDbt9-in9qFIJ7wseucA6Pssvrroc/edit?usp=sharing
DMR -
https://docs.google.com/document/d/1E5Ra9M6KsWELaNnDbt9-in9qFIJ7wseucA6Pssvrroc/edit?usp=sharing

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