BME 4800C SENIOR DESIGN PROJECT
DESIGN HISTORY FILE

Seismocardiogram Sensor

Submitted in partial fulfillment of the
requirements for the degree of

BACHELOR OF SCIENCE
in
BIOMEDICAL ENGINEERING

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Section 1.1 - Clinical Research

The heart is one of the most important organs in the body, with the primary function of pumping blood throughout the body. The heart consists of four main chambers made out of muscle and powered by the brain and nervous system through electrical impulses. The heart chambers are separated into the atriums located at the top of the heart and the ventricles located at the bottom of the heart. Deoxygenated blood enters the right atrium by the superior and inferior vena cava to pump blood into the right ventricle. The right ventricle pumps blood through the lungs and then transferred to the left atrium by the pulmonary veins. The left atrium pumps the blood to the left ventricle which sends the blood to the rest of the body.

Blood is transferred to each chamber through different valves of the heart. The heart consists of four main valves that allow blood to flow. The Tricuspid valve allows blood to transfer between the right atrium and right ventricle. The Mitral valve allows blood transfer between the left atrium and left ventricle. The Aortic valve allows blood flow from the left ventricle to the aorta. The Pulmonary valve allows blood flow from the right ventricle to the pulmonary arteries. These valves are associated with the two main heart sounds heard from a stethoscope.

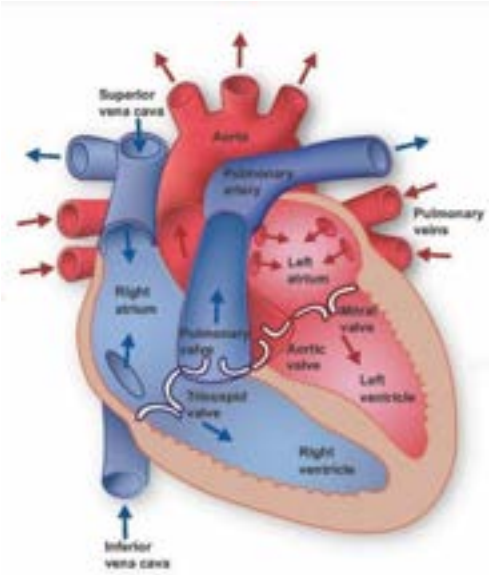

Fig. 1 Main Chambers of the Heart Depicting Direction of Blood Flow [1]

Every part of the heart is important; if one of these chambers, valves, arteries, or veins becomes damaged, it can affect the organ system as a whole and cause serious problems. Atrial fibrillation occurs when the electrical impulses are rapidly fired at once instead of rhythmically, producing bpm's of 300 to 600, leading to stroke and heart failure. Coronary artery disease (CAD) is the plaque buildup of coronary arteries caused by atherosclerosis, resulting in weakness, chest discomfort, and in severe cases death by heart failure. These are just a few examples out of the many cardiovascular diseases (CVD) that exist. [2]

Early detection of these diseases is crucial for treating patients with cardiovascular disease. The most common method of detection for CVD is by using an electrocardiogram (ECG). ECGs are able to record electrical signals from the heart to test for different heart conditions a person could have. However, ECG is unable to detect problems associated with mechanical problems of heart valves or the chambers of the heart. Seismocardiography (SCG) is the recording of vibrations of the body caused by the heart. These vibrations correlate to the blood flow through the vessels as the aortic and mitral valves open and close. Therefore, SCG contains crucial information on cardiac mechanics, such as heart sounds and cardiac output. SCGs are currently being improved upon for more reliable detection of various cardiovascular diseases, including CAD.

Patients with higher cholesterol levels are more vulnerable to this type of heart condition since CAD is associated with atherosclerosis, as previously stated. As a person's cholesterol begins to increase, it allows the cholesterol-containing deposits (plaque) to accumulate on the walls of the arteries. This buildup leads to the narrowing of the blood vessels thus reducing blood flow to the heart and forcing it to work harder. Men starting at around age 40 are more prone to CAD, more specifically when looking at its main associated risk. The figure below demonstrates which populations are affected by high levels of bad cholesterol. It can be seen that within the United States Hispanic males show the most cases. Therefore, this would be the target audience to develop a medical device that allows for the monitoring of CAD.

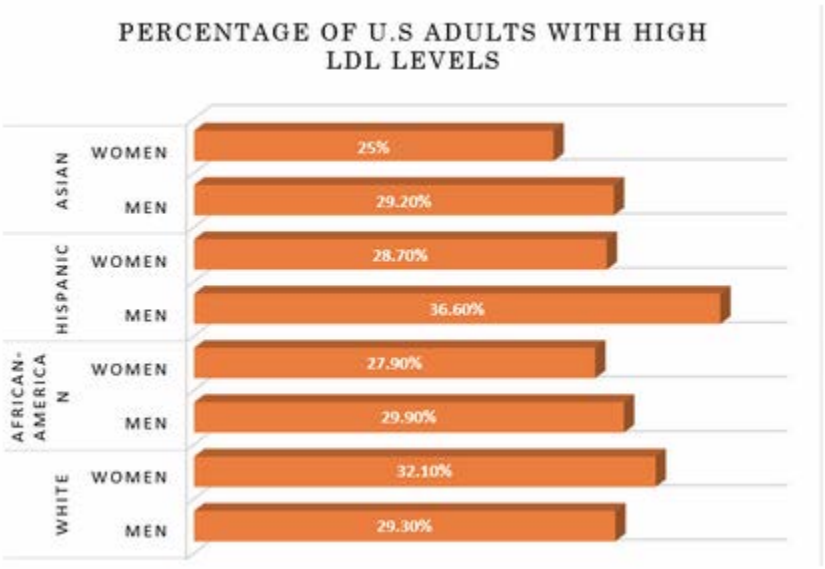

Fig. 2 Percentage of adults in the US with LDL levels higher than 130 [3]

Section 1.2 - Interviews & Surveys

Advances in wireless sensors and digital technologies have led to a proliferation of wearable healthcare devices with which users can monitor their physiological conditions. Advantages of wearable healthcare devices are noninvasive, autonomous, and wearable with fixed sensors to collect physiological information. According to estimates, the market for wearable healthcare devices in 2018 was $24.57 billion and was expected to grow 24.7% annually to $139.35 billion by 2026.[4]

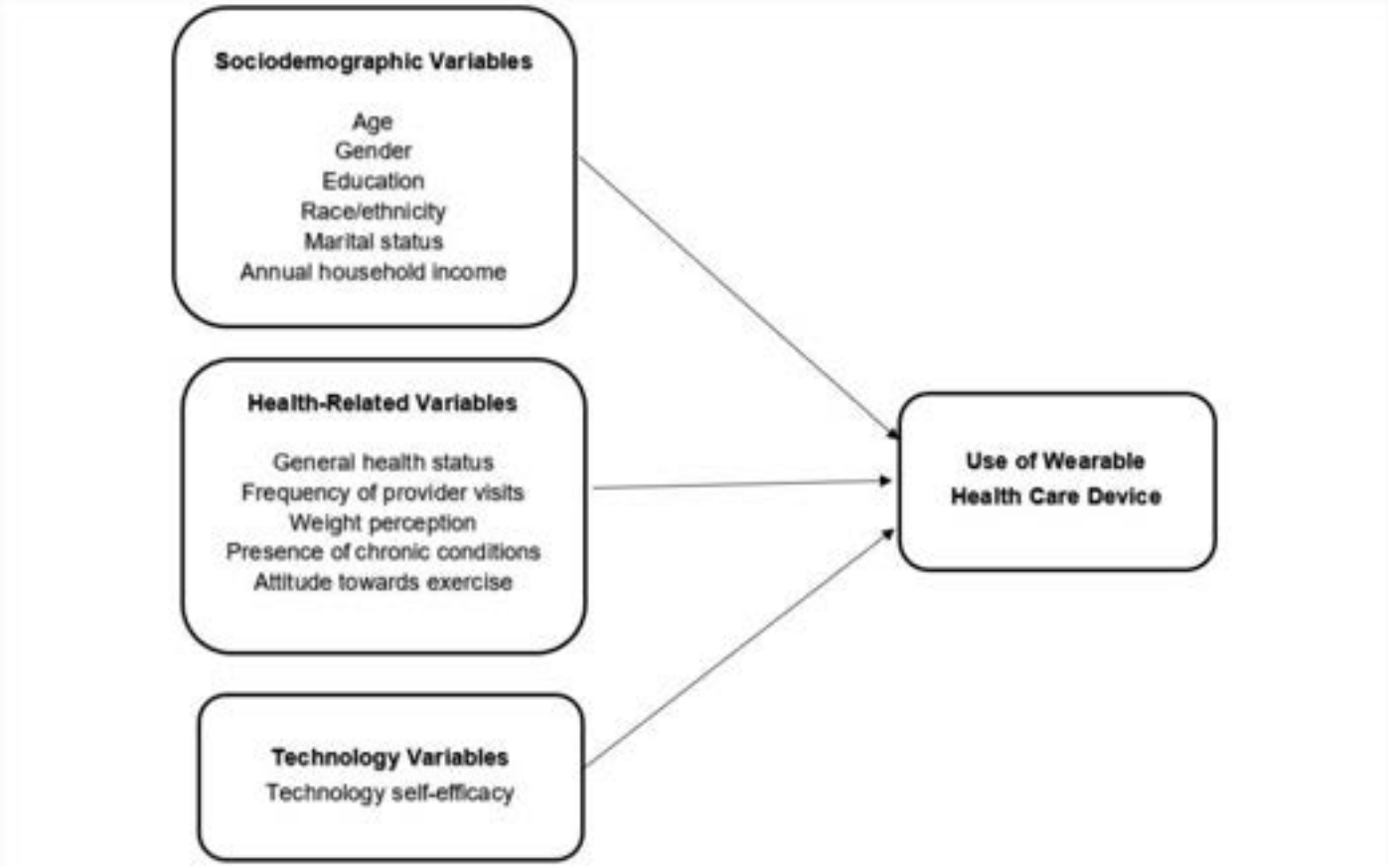

Fig. 3 Key predictors of wearable healthcare devices.[3]

According to Health Information National Trends Surveys (HINTS), data collected from January 2019 to April 2019 through self-administered mailed questionnaires for US adults ≥18 years-old. Of the 4,551 respondents, 29.95% indicated using healthcare wearable devices in the past 12 months. Of the adaptors, 47.33% used it every day, and 24.85% indicated using the device almost every day. And 82.38% indicated their willingness to share data from wearable devices with their healthcare provider. To break it down in more detail, women (16.41%), white individuals (19.74%), adults aged 18-50 years (19.52%) were most likely to use wearable medical devices. [1] In the more specific case of wearable healthcare devices, wearable devices in cardiovascular disease prevention, diagnosis, and management need well-designed trials to

establish their advantages. For example, a TIM-HF2 trial was randomly assigned 1,571 patients with NYHA class II-III and a left ventricular ejection fraction ≤ 45% to usual care plus remote management or to usual care only. A structured intervention consisted of a multicomponent system with a three-channel ECG, a BP device, a weight scale, and an oxygen saturation device. The intervention was associated with a smaller proportion of days lost from unplanned HF-related hospital admissions and had a lower all-cause mortality after 393 days of follow up.[5]

Section 1.3 - Market Data

As of 2019, the global diagnostic electrocardiograph market was at **$7.5 billion**, but is projected to reach **$10.3 billion** by 2024.[6] Ambulatory monitoring devices are opening a new window to healthcare by collecting long-term data for reliable diagnostics. As mentioned before, these devices are becoming popular for continuous monitoring of cardiac disease. The recent advancements are inclusive of affordable and reliable monitoring devices while coexisting with other devices nearby for patients. Early detection of important physiological events by wearable cardiac devices lead to timely alerts for seeking medical attention. Some ambulatory cardiac monitoring devices such as ECG, photo-plethysmography (PPG), or accelerometers have been developed for wearable, smart-phone or other mobile devices aiming to improve cardiac monitoring. The table below, shows a few cardiac monitoring wearable devices and their clinical applications.[7]

Device Name	**Device Type**	**Clinical Applications**	**Image of the Device**
Zio Patch	Patch	ECG monitoring, arrhythmia detection	
NUVANT MCT	Patch	ECG monitoring, arrhythmia detection	

Apple iwatch	Wristwatch	ECG monitoring, AF detection	
Kardia Mobile	Smartphone case	ECG monitoring, AF detection	
ECG Check	Smartphone case	ECG monitoring	N/A
cvrPhone	Smartphone app	ECG monitoring, arrhythmia detection, ischemia, and apnea detection	N/A

Table 1. A list of current cardiac monitoring devices in different types.

As shown in the above table, all popular current cardiac monitoring devices are recording ECG and are ambulatory. Wearable sensor systems can help reduce the costs associated with high-quality and continuous healthcare monitoring by reducing unnecessary hospital admissions and length of stay. With all the advancements and technologies on wearable monitoring devices, there is very limited data on clinical accuracy. Yet, remote monitoring devices for cardiac disorders are showing great promise for the early detection of life-threatening conditions.[7]

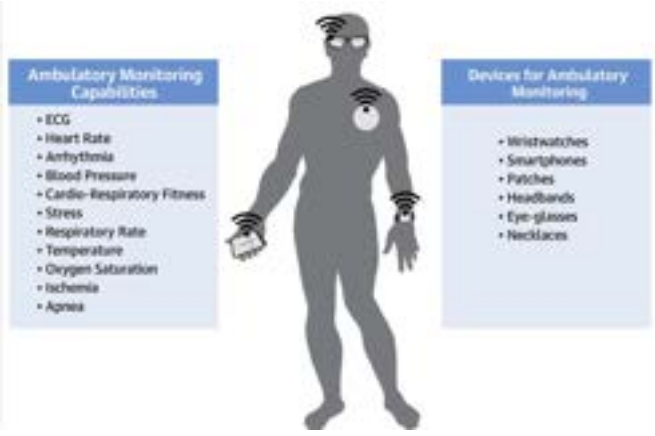

Fig. 4 Wearable monitoring devices advancement for continuous cardiac activities monitoring via smart-phone based solutions.[7]

Section 1.4 - Market Requirements

Our market requirements were created with a focus on solely one component of the final SCG patch, the sensor. These are related to the component's features such as signal sensitivity for detection, signal conversion, placement, and size. The ordering of said requirements reflects the priorities for the final product, which was a joint decision of the team, sponsor, and advisor.

➔ ***November 1, 2021,***

Market Requirements
Device should be battery-free without continuous charging
Device should be ambient assisted
Device should be lightweight and small in size
The device functionality shouldn't be affected by any other nearby devices
The device should be minimally abrasive
Device should be inexpensive
The device should be flexible and wearable
The device must be contactless

➔ ***Revision - November 3, 2021,***

Market Requirements
The device should be able to communicate wirelessly.
The device should be able to function without any wires or cords attached.
The device should be battery-free without continuous charging.
The device should not be affected by any other nearby devices.
The device should be lightweight and small in size.
The device should be flexible and wearable.
The device should be comfortable.
The device must be inexpensive.

➔ ***Revision - November 5, 2021,***

Market Requirements
The device should be able to communicate and function wirelessly.
The device should be battery-free without continuous charging.
The device should not be affected by any other nearby devices.
The device should be lightweight and small in size.
The device should be flexible and wearable.
The device should be comfortable.
The device must be inexpensive.

➔ ***Revision - November 8, 2021,***

Market Requirements
The device should be able to communicate wirelessly and function without any wires or cords attached.
The device should be battery-free without continuous charging.
The device should not be affected by any other nearby devices.
The device should be lightweight and small in size.
The device should be flexible and wearable.
The device should be comfortable.
The device must be inexpensive.

➔ ***Revision - November 9, 2021,***

Market Requirements
The device should be able to receive and process body vibrations within the chest wall
The device should be in contact with the skin and be biocompatible
The device should be able to communicate wirelessly and function without any wires or cords attached.
The device should be battery-free without continuous charging.
The device should not be affected by any other nearby devices.
The device should be lightweight and small in size.

The device should be flexible and wearable.
The device should be comfortable.
The device must be inexpensive.

➔ ***Revision - November 13, 2021,***

Market Requirements
The device should be placed on the chest wall and detect low cardiac vibrations.
The device should be able to communicate and function wirelessly, allowing the patient to be ambulatory.
The device should be wearable and composed of adhesive material that will avoid skin irritation.
The device should function independently of a battery.
The device should be able to function without the interference of any other nearby devices or instruments.
The device should be compact and lightweight.

➔ ***Revision - November 17, 2021,***

Market Requirements
The device should be able to adhere to the chest.
The device should non-invasively record the vibrational signals from the heart in respect to its amplitude normal range of ± 20 mG.
The device should be able to maintain a low signal-noise ratio (SNR).
The device should be inclusive of an antenna tag creating passive communication between the device and an external reader.
The device should be able to function independently of a battery for continuous monitoring.
The device should be able to function without interference from any other nearby devices or instruments.
The device should be compact and lightweight.

➔ ***Revision - November 19, 2021***

Market Requirements
The device should be able to adhere to the chest for up to 3 days.
The device should be able to non-invasively record the vibrational signals from the heart in respect to its amplitude normal range of ± 20 mG.
The device should be able to maintain a low signal-noise ratio (SNR).
The device should be able to function independently of a battery for continuous monitoring.
The device should be inclusive of an antenna tag creating two-way transferring of data between the device and an external reader.
The device should be able to function without the interference of nearby devices or instruments.
The device should be compact.
The device should be lightweight

➔ ***Revision - November 23, 2021,***

Market Requirements
The device should be able to non-invasively record the vibrational signals from the heart with respect to its amplitude normal range of ± 20 mG.
The device should be able to minimize mechanical noise caused by a sinusoidal force of 1.5 N/m^2.
The device should be able to function independently of a wired power source with continuous monitoring.
The device should be inclusive of an antenna tag creating two-way transferring of data between the device and an external reader.
The device should be able to function without the interference of nearby devices or instruments.
The device should be able to adhere to the chest for up to 3 days
The device should be compact.
The device should be lightweight

➔ ***Revision - December 5, 2021,***

Market Requirements
The device should be able to non-invasively record the vibrational signals from the heart in respect to its amplitude normal range of ± 20 mG.
The device should be sensitive to a uniaxial force of 1.5 N/m^2.
The device should be able to function independently of a battery for continuous monitoring.
The device should be inclusive of an antenna tag creating two-way transferring of data between the device and an external reader.
The device should be able to function without the interference of nearby devices or instruments.
The device should be able to adhere to the chest for up to 3 days hence minimizing any mechanical noise.
The device should be compact.
The device should be lightweight

➔ ***Revision - January 31, 2022,***

Market Requirements
The device should be capable of converting low cardiac vibration into electrical voltage in order to read the mechanical vibration input from the sternum.
The device should be able to non-invasively recognize the vibrational signals from the heart with an amplitude range of ± 20 mG, given the signal range of SCG.
The device should be sensitive to uniaxial tension of 1.5 Pa, because of the uniaxial nature of the pulsation experienced by the sternum.
The device should be able to adhere to the chest for up to 3 days hence minimizing mechanical noise produced by the skin elasticity.
The device should be able to function independent of battery and powering cables, for ease of consumer use.
The device should be inclusive of an antenna tag creating two-way transferring of data between the device and an external reader, to display the readings on a mobile device.
The device should be compact, to cater to the user's comfort.
The device should be lightweight, to cater to the user's comfort.

➔ ***Revision - February 2, 2021,***

Market Requirements
The device should be able to non-invasively recognize the vibrational signals from the heart, in a uniaxial direction.
Device should be able to convert cardiac vibration to electrical voltage.
Device must comply with the skin's elasticity on the chest.
The device should be compact, to cater user's comfort.

➔ ***Final Revision - February 6, 2021***

Market Requirements
The device should be able to non-invasively recognize the vibrational signals from the chest, in a uniaxial direction.
Device should be able to convert cardiac vibration to electrical voltage.
Device must comply with the skin's elasticity on the chest.
The device's dimensions should comply with the size of the apex of the sternum.
The device should be compatible with the patch's wireless power transfer design.

References

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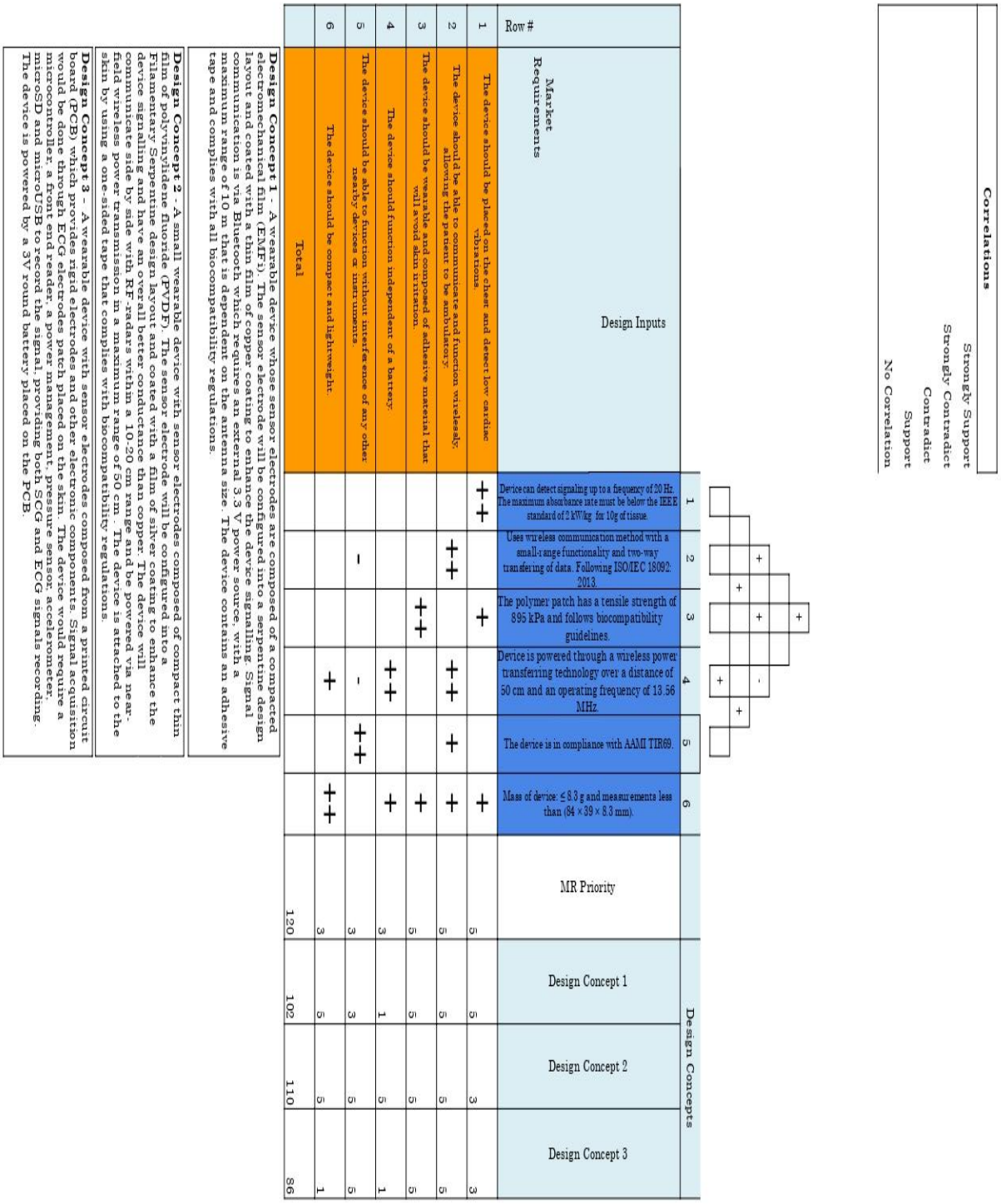
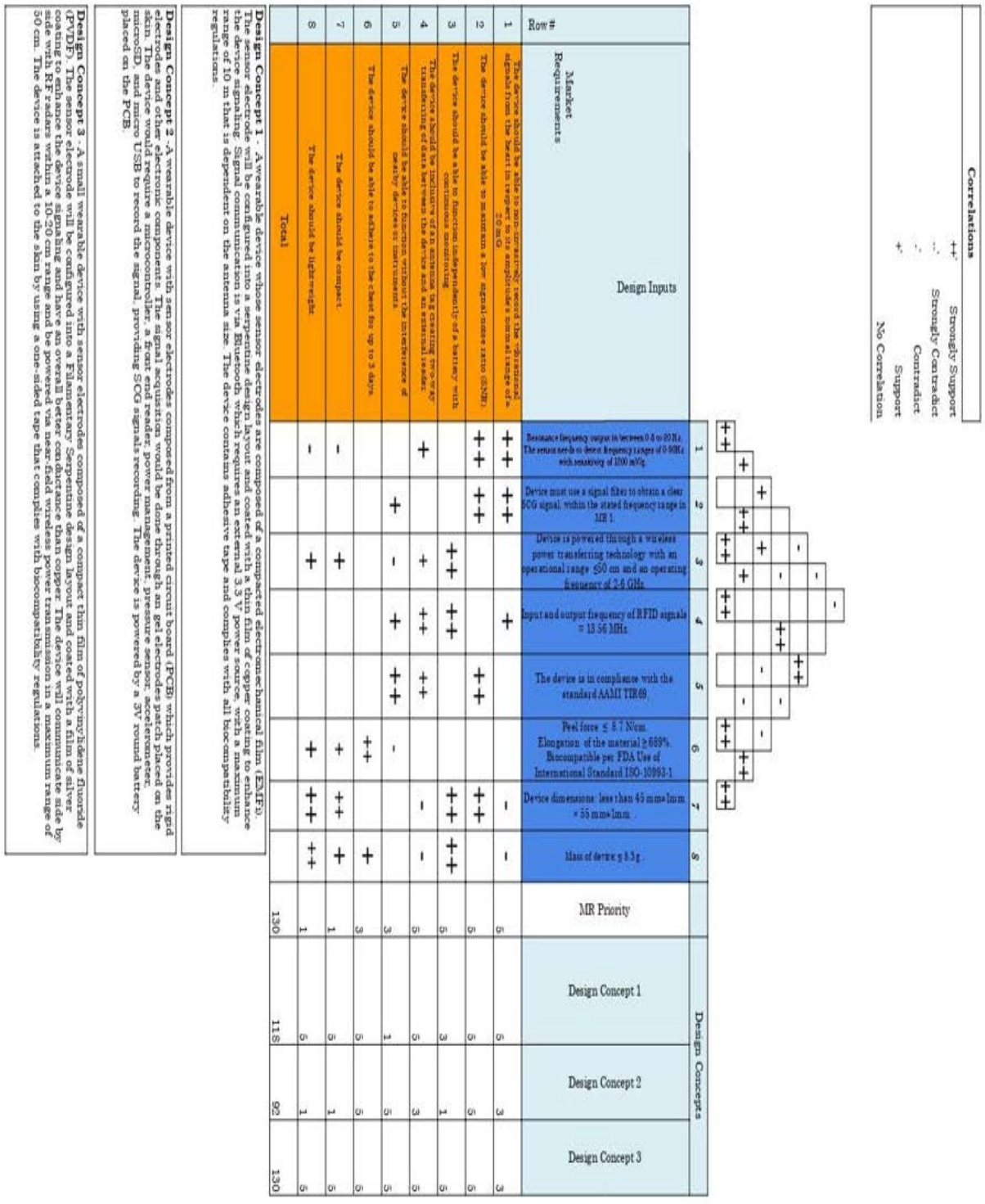
Section 2 - Design Inputs

Section 2.1 - Quality Function Deployment (QFD) Analysis

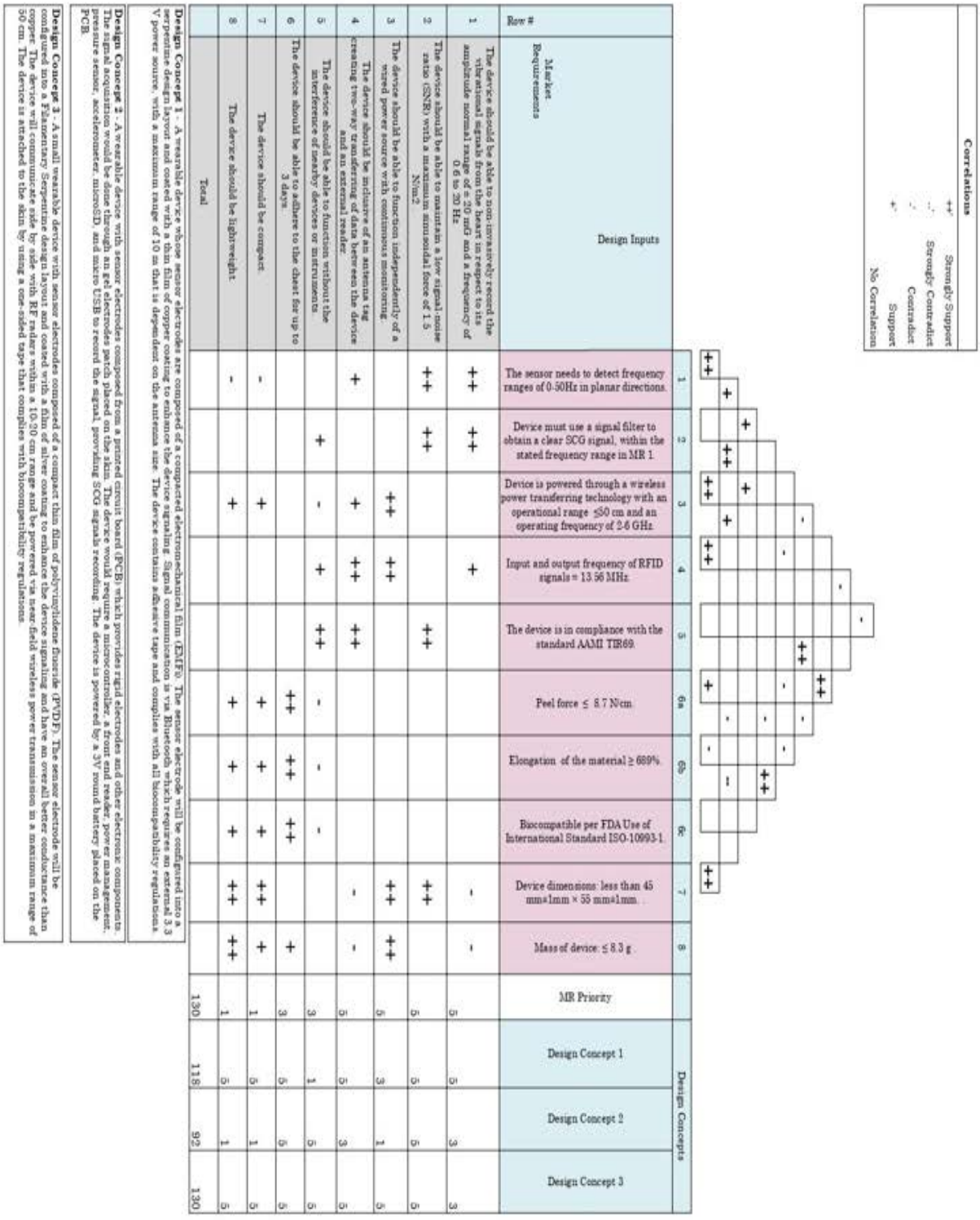
➔ ***November 15, 2021***



➔ ***Revision - November 20, 2021***



➔ ***Revision - November 21, 2021***



Correlations	
++	Strongly Support
-	Strongly Contradict
-	Contradict
+	Support
	No Correlation

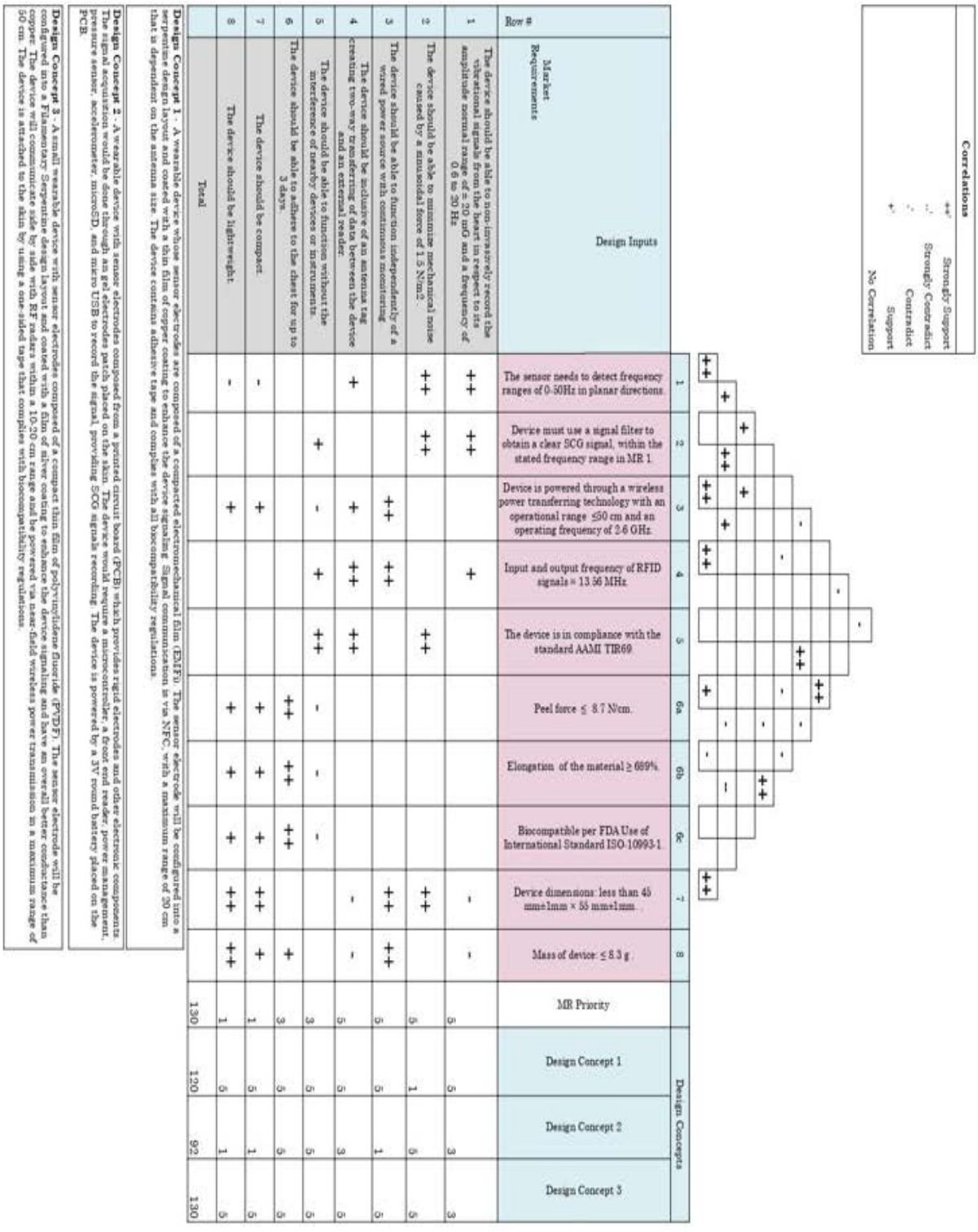
Row #	Market Requirements	Design Inputs	1	2	3	4	5	6a	6b	6c	7	8	MR Priority	Design Concepts		
														Design Concept 1	Design Concept 2	Design Concept 3
1	The device should be able to non-invasively record the vibrational signals from the heart in respect to its amplitude normal range of ≤ 5.0 mG and a frequency of 0.6 to 30 Hz	The sensor needs to detect frequency ranges of 0-50Hz in planar directions.	++									-	5	5	3	3
2	The device should be able to maintain a low signal-noise ratio (SNR) with a maximum sinusoidal force of 1.5 N/m2	Device must use a signal filter to obtain a clear SCG signal, within the stated frequency range in MR 1.	++	++			++				++		5	5	3	3
3	The device should be able to function independently of a wired power source with continuous monitoring	Device is powered through a wireless power transferring technology with an operational range ≤50 cm and an operating frequency of 2.6 GHz.			++						++		5	5	1	5
4	The device should be inclusive of an antenna tag creating two-way transferring of data between the device and an external reader.	Input and output frequency of RFID signals = 13.56 MHz.	+		+	++							5	3	1	5
5	The device should be able to function without the interference of nearby devices or instruments	The device is in compliance with the standard AAMI TIR69.		+	-	+	++				-	-	3	1	5	5
6	The device should be able to adhere to the chest for up to 3 days.	Peel force ≤ 8.7 N/cm						++	-	-		+	3	5	5	5
7	The device should be compact	Elongation of the material ≥ 689%.	-		+			+	++				1	5	1	5
8	The device should be lightweight	Biocompatible per FDA Use of International Standard ISO-10993-1.	-					+	+	+			1	5	1	5
	Total	Device dimensions: less than 45 mm×1mm × 55 mm×1mm.											130	118	92	130

Design Concept 1 - A wearable device whose sensor electrodes are composed of a compacted electromechanical film (EMFi). The sensor electrode will be configured into a serpentine design layout and coated with a thin film of copper coating to enhance the device signaling. Signal communication is via Bluetooth which requires an external 3.3 V power source, with a maximum range of 10 m that is dependent on the antenna size. The device contains adhesive tape and complies with all biocompatibility regulations.

Design Concept 2 - A wearable device with sensor electrodes composed from a printed circuit board (PCB) which provides rigid electrodes and other electronic components. The signal acquisition would be done through an gel electrodes patch placed on the skin. The device would require a microcontroller, a front end reader, power management, pressure sensor, accelerometer, microSD, and micro USB to record the signal, providing SCG signals recording. The device is powered by a 3V round battery placed on the PCB.

Design Concept 3 - A small wearable device with sensor electrodes composed of a compact thin film of polyvinylidene fluoride (PVDF). The sensor electrode will be configured into a Filamentary Serpentine design layout and coated with a thin of silver coating to enhance the device signaling and have an overall better conductance than copper. The device will communicate side by side with RF readers within a 10-20 cm range and be powered via near field wireless power transmission in a maximum range of 50 cm. The device is attached to the skin by using a one-sided tape that complies with biocompatibility regulations.

➔ ***Revision - November 23, 2021***



➔ ***Revision - December 5, 2021***

Correlations	
++	Strongly Support
-	Strongly Contradict
-	Contradict
+	Support
	No Correlation

Row #	Market Requirements / Design Inputs	1	2	3	4	5	6a	6b	6c	7	8	MR Priority	Design Concept 1	Design Concept 2	Design Concept 3
1	The device should be able to non-invasively record the vibrational signals from the heart in respect to its amplitude normal range of ± 20 mG and a frequency of 0.6 to 20 Hz	++	++							-	-	5	5	3	3
2	The device should be sensitive to uniaxial force of 1.5 N/m^2	++	++			++				++		5	5	3	5
3	The device should be able to function independently of a wired power source with continuous monitoring			++	++					++	++	5	5	1	5
4	The device should be inclusive of an antenna tag creating two-way transferring of data between the device and an external reader	+		+	++	++				-	-	5	5	3	5
5	The device should be able to function without the interference of nearby devices or instruments		+	-	+	++	-	-	-			3	5	5	5
6	The device should be able to adhere to the chest for up to 3 days hence minimizes any mechanical noise						++	++	++		+	3	5	5	5
7	The device should be compact.	-		+			+	+	+	++	+	1	5	1	5
8	The device should be lightweight	-		+			+	+	+	++	++	1	5	1	5
	Total											130	120	92	130

Design Concept 1 - A wearable device whose sensor electrodes are composed of a compacted electromechanical film (EMF). The sensor electrode will be configured into a serpentine design layout and coated with a thin film of copper coating to enhance the device signaling. Signal communication is via NFC, with a maximum range of 20 cm that is dependent on the antenna size. The device contains adhesive tape and complies with all biocompatibility regulations.

Design Concept 2 - A wearable device with sensor electrodes composed from a printed circuit board (PCB) which provides rigid electrodes and other electronic components. The signal acquisition would be done through an gel electrodes patch placed on the skin. The device would require a microcontroller, a front end reader, power management, pressure sensor, accelerometer, microSD, and micro USB to record the signal, providing SCG signals recording. The device is powered by a 3V round battery placed on the PCB.

Design Concept 3 - A small wearable device with sensor electrodes composed of a compact thin film of polyvinylidene fluoride (PVDF). The sensor electrode will be configured into a Filamentary Serpentine design layout and coated with a film of silver coating to enhance the device signaling and have an overall better conductance than copper. The device will communicate side by side with RF readers within a 10-20 cm range and be powered via near-field wireless power transmission in a maximum range of 50 cm. The device is attached to the skin by using a one-sided tape that complies with biocompatibility regulations.

➔ ***Revision - February 15, 2022***

Correlations	
++'	Strongly Support
--'	Strongly Contradict
-'	Contradict
+'	Support
	No Correlation

										Design Concepts	
										Design Concept 1	
										Design Concept 2	
										Design Concept 3	
	Row #	Design Inputs	1	2	3	4	5	MR Priority			
	1	Market Requirements The device should be able to non-invasively recognize the vibrational signals from the chest, in a uniaxial direction.	++	+	+	+		5		1	5	5
	2	Device should be able to convert cardiac vibration to electrical voltage.	+	++				5		5	5	5
	3	Device must comply with skin's elasticity on the chest.	+	+	++			5		3	3	5
	4	The device's dimensions should comply with the size of the apex of the sternum.	+	+		++		5		5	5	5
	5	The device should be compatible with the patch's wireless power transfer design.					++	3		5	5	5
		Total						115		85	105	115

Design Concept 1 - A small thin sensor composed of a metalized polypropylene film (electromechanical film (EMFi™)) with a Hilbert-curve pattern. The polymer came metallized with a carbon conductive paint to provide conductive properties.

Design Concept 2 - A small sensor composed of a thin film of metallized polyvinylidene fluoride (PVDF) with a Kirigami pattern. The material is metallized with silver ink to provide conductive properties.

Design Concept 3 - A small sensor composed of a thin film of metallized polyvinylidene fluoride (PVDF) with a filamentary serpentine pattern. The material is metallized with silver ink to provide conductive properties.

Section 2.2 - Design Inputs by Functions

Once the final market requirements were determined, the corresponding design inputs were intended to fulfill as a baseline for the design as well as to achieve the project's objectives. The design inputs were expected to be measurable and verifiable, as they would be necessary values for when developing the verification protocols. To better understand the team's thought process, the rationale behind each final design input was included.

➔ ***November 5, 2021***

Market Requirements	**Design Inputs**
The device should be able to communicate and function wirelessly.	Uses a wireless communication method with a small-range functionality and two-way transferring of data. Following ISO/IEC 14493 type B and 15693 standard.
The device should be battery-free without continuous charging.	
The device should not be affected by any other nearby devices.	AAMI TIR69
The device should be lightweight and small.	Density of ___ and volume of ___ , lower compared to our competitors
The device should be flexible and wearable.	Young's Modulus of range ____
The device should be comfortable.	Rigid characteristics
The device should be inexpensive.	Cost ___ , lower compared to our competitors

➔ ***Revision - November 8, 2021***

Market Requirements	**Design Inputs**
The device should be able to communicate wirelessly and function without any wires or cords attached.	Uses a wireless communication method with a small-range functionality and two-way transferring of data. **Following ISO/IEC 18092:2013.**
The device should be battery-free without continuous charging.	**Device is powered through a wireless power transferring technology.**

The device should not be affected by any other nearby devices.	The device is in compliance with AAMI TIR69
The device should be lightweight and small.	**Mass Density of patch ≤ 1.8 g/cm^3 and volume of ≤ 2000 mm^3**
The device should be flexible and wearable.	**Young's Modulus of range 0.00200 - 10.2 GPa**
The device should be comfortable.	Rigid characteristics
The device should be inexpensive.	Cost ___ , lower compared to our competitors

➔ ***Revision - November 15, 2021,***

Market Requirements	**Design Inputs**
The device should be placed on the chest and detect low cardiac vibrations.	**Device can detect signaling up to a frequency of 20 Hz. The maximum absorbance rate must be below the IEEE standard of 2 kW/kg for 10g of tissue.**
The device should be able to communicate and function wirelessly, allowing the patient to be ambulatory.	Uses a wireless communication method with a small-range functionality and two-way transferring of data. Following ISO/IEC 18092: 2013.
The device should function independently of a battery.	**Device is powered through a wireless power transferring technology over a distance of 50 cm and an operating frequency of 13.56 MHz.**
The device should be able to function without the interference from any other nearby devices or instruments.	The device is in compliance with AAMI TIR69.
The device should be wearable and composed of adhesive material that will avoid skin irritation.	**The polymer patch has a tensile strength of 895 kPa and follows biocompatibility guidelines.**
The device should be compact and lightweight.	**Mass of device: ≤ 8.3 g and measurements less than (84 × 39 × 8.3 mm).**

➔ ***Revision - November 19, 2021,***

Market Requirements	**Design Inputs**

The device should be able to adhere to the chest for up to 3 days.	Peel force ≤ 8.7 N/cm.
	Elongation of the material ≥ 689%.
	Biocompatible per FDA Use of International Standard ISO-10993-1
The device should be able to non-invasively record the vibrational signals from the heart in respect to its amplitude normal range of ± 20 mG.	Uses a wireless communication method with a small-range functionality and two-way transferring of data. Following ISO/IEC 18092: 2013.
The device should be able to maintain a low signal-noise ratio (SNR).	
The device should be able to function independently of a battery for continuous monitoring.	Device is powered through a wireless power transferring technology with an operational range <50 cm and an operating frequency of 2-6 GHz
The device should be inclusive of an antenna tag creating two-way transferring of data between the device and an external reader.	**Input and output frequency of RFID signals = 13.56 MHz**
The device should be able to function without the interference of nearby devices or instruments.	The device is in compliance with the standard AAMI TIR69.
The device should be compact.	Measurements less than 45 mm±1 mm × 55 mm±1mm.
The device should be lightweight	Mass of device: ≤ 8.3 g

➔ ***Revision - November 20, 2021***

Market Requirements	**Design Inputs**
The device should be able to non-invasively record the vibrational signals from the heart with respect to its amplitude normal range of ± 20 mG.	**Resonance frequency output in between 0.6 to 20 Hz.**

	The sensor needs to detect frequency ranges of 0-50Hz with a sensitivity of 1200 mV/g
The device should be able to maintain a low signal-noise ratio (SNR).	**Device must use a signal filter to obtain a clear SCG signal, within the stated frequency range in MR 1.**
The device should be able to function independently of a battery for continuous monitoring.	Device is powered through a wireless power transferring technology with an operational range <50 cm and an operating frequency of 2-6 GHz
The device should be inclusive of an antenna tag creating two-way transferring of data between the device and an external reader.	Input and output frequency of RFID signals = 13.56 MHz
The device should be able to function without the interference of nearby devices or instruments.	The device is in compliance with the standard AAMI TIR69.
The device should be able to adhere to the chest for up to 3 days.	Peel force ≤ 8.7 N/cm.
	Elongation of the material ≥ 689%.
	Biocompatible per FDA Use of International Standard ISO-10993-1
The device should be compact.	Measurements less than 45 mm±1 mm × 55 mm±1mm.
The device should be lightweight	Mass of device: ≤ 8.3 g

➔ ***Revision - November 21, 2021,***

Market Requirements	**Design Inputs**
The device should be able to non-invasively record the vibrational signals from the heart with respect to its amplitude normal range of ± 20 mG.	**The sensor needs to detect frequency ranges of 0-50Hz in planar directions.**

The device should be able to maintain a low signal-noise ratio (SNR).	Device must use a signal filter to obtain a clear SCG signal, within the stated frequency range in MR 1.
The device should be able to function independently of a battery for continuous monitoring.	Device is powered through a wireless power transferring technology with an operational range <50 cm and an operating frequency of 2-6 GHz
The device should be inclusive of an antenna tag creating two-way transferring of data between the device and an external reader.	Input and output frequency of RFID signals = 13.56 MHz
The device should be able to function without the interference of nearby devices or instruments.	The device is in compliance with the standard AAMI TIR69.
The device should be able to adhere to the chest for up to 3 days.	Peel force ≤ 8.7 N/cm.
	Elongation of the material ≥ 689%.
	Biocompatible per FDA Use of International Standard ISO-10993-1
The device should be compact.	Measurements less than 45 mm±1 mm × 55 mm±1mm.
The device should be lightweight	Mass of device: ≤ 8.3 g

➔ ***Revision - November 23, 2021,***

Market Requirements	**Design Inputs**
The device should be able to non-invasively record the vibrational signals from the heart with respect to its amplitude normal range of ± 20 mG.	The sensor needs to detect frequency ranges of 0-50Hz in planar directions.
The device should be able to minimize mechanical noise caused by a sinusoidal force of 1.5 N/m^2.	Device must use a signal filter to obtain a clear SCG signal, within the stated frequency range in MR 1.

The device should be able to function independently of a battery for continuous monitoring.	Device is powered through a wireless power transferring technology with an operational range <50 cm and an operating frequency of 2-6 GHz
The device should be inclusive of an antenna tag creating two-way transferring of data between the device and an external reader.	Input and output frequency of RFID signals = 13.56 MHz
The device should be able to function without the interference of nearby devices or instruments.	The device is in compliance with the standard AAMI TIR69:2017/(R2020).
The device should be able to adhere to the chest for up to 3 days.	Peel force ≤ 8.7 N/cm.
	Elongation of the material ≥ 689%.
	Biocompatible per FDA Use of International Standard ISO-10993-10:2021.
The device should be compact.	Measurements less than 45 mm±1 mm × 55 mm±1mm.
The device should be lightweight	Mass of device: ≤ 8.3 g

➔ ***Revision - December 5, 2021***

Market Requirements	**Design Inputs**
The device should be able to non-invasively record the vibrational signals from the heart in respect to its amplitude normal range of ± 20 mG. [1]	The sensor needs to detect frequency ranges of 0-50Hz in planar directions. [2]
The device should be sensitive to uniaxial force of 1.5 N/m^2. [3]	**The sensor needs to be a uniaxial sensor sensitive to force up to 1.5 N/m^2 within the stated frequency range in MR 1.**
The device should be able to function independently of a battery for continuous monitoring.	Device is powered through a wireless power transferring technology with an operational range <50 cm and an operating frequency of

	2-6 GHz [4]
The device should be inclusive of an antenna tag creating two-way transferring of data between the device and an external reader.	Input and output frequency of RFID signals = 13.56 MHz [5]
The device should be able to function without the interference of nearby devices or instruments.	The device is in compliance with the standard AAMI TIR69:2017/(R2020).
The device should be able to adhere to the chest for up to 3 days hence minimizes any mechanical noise.	Peel force ≤ 8.7 N/cm. [6]
	Elongation of the material ≥ 689%. [6]
	Biocompatible per FDA Use of International Standard ISO-10993-10:2021.
The device should be compact.	Measurements less than 45 mm±1 mm × 55 mm±1mm. [3]
The device should be lightweight	Mass of device: ≤ 8.3 g [7]

➔ ***Revision - January 31, 2022***

Market Requirements	**Design Inputs**
The device should be capable of converting low cardiac vibration into electrical voltage in order to read the mechanical vibration input from the sternum.	**The sensor needs to have a low voltage output of 1-3 mV peak-peak, given the normal range for an adult.**
The device should be able to non-invasively recognize the vibrational signals from the heart with an amplitude range of ± 20 mG, given the signal range of SCG.	**The sensor needs to detect frequency ranges of 10-40 Hz in planar directions, to capture the nature of the signal.**
The device should be sensitive to uniaxial tension of 1.5 Pa, because of the uniaxial nature of the pulsation experienced by the sternum.	**The sensor needs to be a uniaxial sensor sensitive to force up to 1.5 Pa within the stated frequency range and amplitude in MR 2.**
The device should be able to adhere to the chest for up to 3 days hence minimizes	**Peel force ≤ 8.7 N/cm, to securely attach to the skin for the specified time.**

mechanical noise produced by the skin elasticity.	**Biocompatible per FDA Use of International Standard ISO 10993-10:2021.**
The device should be able to function independent of battery and powering cables, for ease of consumer use.	**Device is powered through a wireless power transferring technology with an operational range ≤ 50 cm and an operating frequency of 2-6 GHz.**
The device should be inclusive of an antenna tag creating two-way transferring of data between the device and an external reader, to display the readings on a mobile device.	**Input and output frequency of RFID signals = 13.56 MHz .**
The device should be compact, to cater to the user's comfort.	**Device dimension: less than 45 mm±1mm × 55 mm±1mm.**
The device should be lightweight, to cater to the user's comfort.	**Mass of device: ≤ 25 g**

➔ ***Revision - February 2, 2021***

Market Requirements	Design Inputs	Rationale
The device should be able to non-invasively recognize the vibrational signals from the heart, in a uniaxial direction.	**The sensor needs to be uniaxial and detect frequency ranges of 10-40 Hz in planar directions with an amplitude range of ± 20 mg.**	**The nature of a typical SCG signal is characterized by these parameters.**
Device should be able to convert cardiac vibration to electrical voltage.	**The sensor needs to have a low voltage output of 1-3 mV peak-peak, given the normal range of an adult.**	**The sensor must have piezoelectric characterics that creates a voltage output that corresponds to an SCG signal.**
Device must comply with skin's elasticity on the chest.	**The sensor's elastic modulus needs to range from kPa to MPa.**	**The sensor complying with skin's elastic modulus would allow for a closer interface, minimizing unwanted mechanical noise.**
The device should be compact, to cater user's comfort.	**Device dimension: less than 45 mm±1mm × 55 mm±1mm.**	**Compared to competitors, our device should be equal or less than specified measurements.**

➔ ***Final Revision - February 6, 2021***

Market Requirements	Design Inputs	Rationale
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.	The nature of a typical SCG signal is characterized by these parameters.
Device should be able to convert cardiac vibration to electrical voltage.	The sensor needs to convert a minimum cardiac pressure of (x) Pa to a minimum voltage output of 1mV peak-peak.	The sensor must have piezoelectric characterics that creates a voltage output that corresponds to an SCG signal.
Device must comply with the skin's elasticity on the chest.	The sensor's elastic modulus needs to range from 130 kPa to 20 MPa.	The sensor complying with skin's elastic modulus would allow for a closer interface, minimizing unwanted mechanical noise.
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.	The sensor's dimensions must comply with anatomical constraints for targeted market.
The device should be compatible with the patch's wireless power transfer design.	Device is powered through a 3 - 5V wireless power source.	Device's power is constrained to allow for the patch to be wireless.

Section 2.3 - Design Concepts

Visual representations of the device were constructed to reflect the user's needs and the market requirements stated in a previous section. Analysis for each concept was made to determine whether met the requirements accordingly and show the comparison between concepts. From the final revisions, design concept 3 was chosen for development as a result of this analysis and demonstrated the best fit for the project's objective.

➔ ***November 15, 2021***

Design Concept 1
Description: A wearable device whose sensor electrodes are composed of a compacted electromechanical film (EMFi). The sensor electrode will be configured into a serpentine design layout and coated with a thin film of copper coating to enhance the device signaling. Signal communication is via Bluetooth which requires an external 3.3 V power source, with a maximum range of 10 m that is dependent on the antenna size. The device contains an adhesive tape and complies with all biocompatibility regulations.

Design Concept 2
Description: A small wearable device with sensor electrodes composed of compact thin film of polyvinylidene fluoride (PVDF). The sensor electrode will be configured into a Filamentary Serpentine design layout and coated with a film of silver coating to enhance the device signaling and have an overall better conductance than copper. The device will communicate side by side with RF-radars within a 10-20 cm range and be powered via near-field wireless power transmission in a maximum range of 50 cm . The device is attached to the skin by using a one-sided tape that complies with biocompatibility regulations.

Design Concept 3
Description: A wearable device with sensor electrodes composed from a printed circuit board (PCB) which provides rigid electrodes and other electronic components. Signal acquisition would be done through ECG electrodes patch placed on the skin. The device would require a microcontroller, a front end reader, a power management, pressure sensor, accelerometer, microSD and microUSB to record the signal, providing both SCG and ECG signals recording. The device is powered by a 3V round battery placed on the PCB.

➔ ***Revision - November 20, 2021***

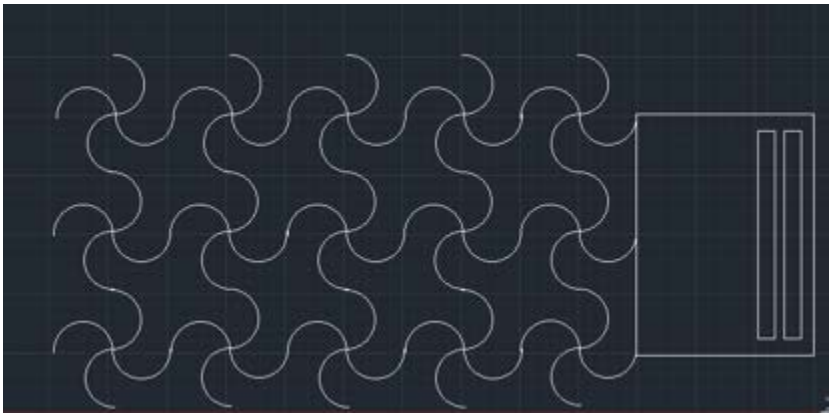
Design Concept 1

Description:
A wearable device whose sensor electrodes are composed of a compacted electromechanical film (EMFi). The sensor electrode will be configured into a serpentine design layout and coated with a thin film of copper coating to enhance the device signaling. Signal communication is via Bluetooth which requires an external 3.3 V power source, with a maximum range of 10 m that is dependent on the antenna size. The device contains adhesive tape and complies with all biocompatibility regulations.

Design Concept 2

Description:
A wearable device with sensor electrodes composed from a printed circuit board (PCB) which provides rigid electrodes and other electronic components. The signal acquisition would be done through a gel electrode patch placed on the skin. The device would require a microcontroller, a front end reader, power management, pressure sensor, accelerometer, microSD, and micro USB to record the signal, providing SCG signals recording. The device is powered by a 3V round battery placed on the PCB.

Design Concept 3



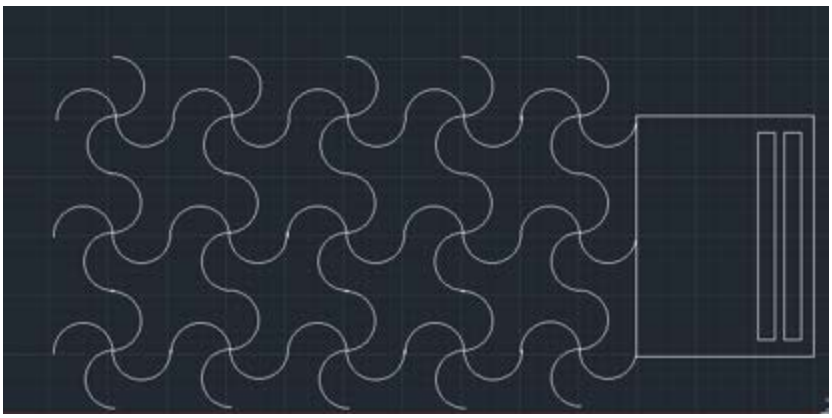
Description:
A small wearable device with sensor electrodes composed of a compact thin film of polyvinylidene fluoride (PVDF). The sensor electrode will be configured into a Filamentary Serpentine design layout and coated with a film of silver coating to enhance the device signaling and have an overall better conductance than copper. The device will communicate side by side with RF radars within a 10-20 cm range and be powered via near-field wireless power transmission in a maximum range of 50 cm. The device is attached to the skin by using a one-sided tape that complies with biocompatibility regulations.

➔ ***Revision - November 21, 2021***

Design Concept 1	
Description: A wearable device whose sensor electrodes are composed of a compacted electromechanical film (EMFi). The sensor electrode will be configured into a serpentine design layout and coated with a thin film of copper coating to enhance the device signaling. Signal communication is via Bluetooth which requires an external 3.3 V power source, with a maximum range of 10 m that is dependent on the antenna size. The device contains adhesive tape and complies with all biocompatibility regulations.	
Pros	**Cons**
● Non-invasive ● Wireless ● Batteryless ● Large Operational range ● Compact	● Prone to interference ● External battery source required for functionality

Design Concept 2	
Description: A wearable device with sensor electrodes composed from a printed circuit board (PCB) which provides rigid electrodes and other electronic components. The signal acquisition would be done through a gel electrode patch placed on the skin. The device would require a microcontroller, a front end reader, power management, pressure sensor, accelerometer, microSD, and micro USB to record the signal, providing SCG signals recording. The device is powered by a 3V round battery placed on the PCB.	
Pros	**Cons**
● Non-invasive ● Wireless ● Wearable	● Dependent of a battery ● Bulky ● Rigid ● Increased weight and size

Design Concept 3

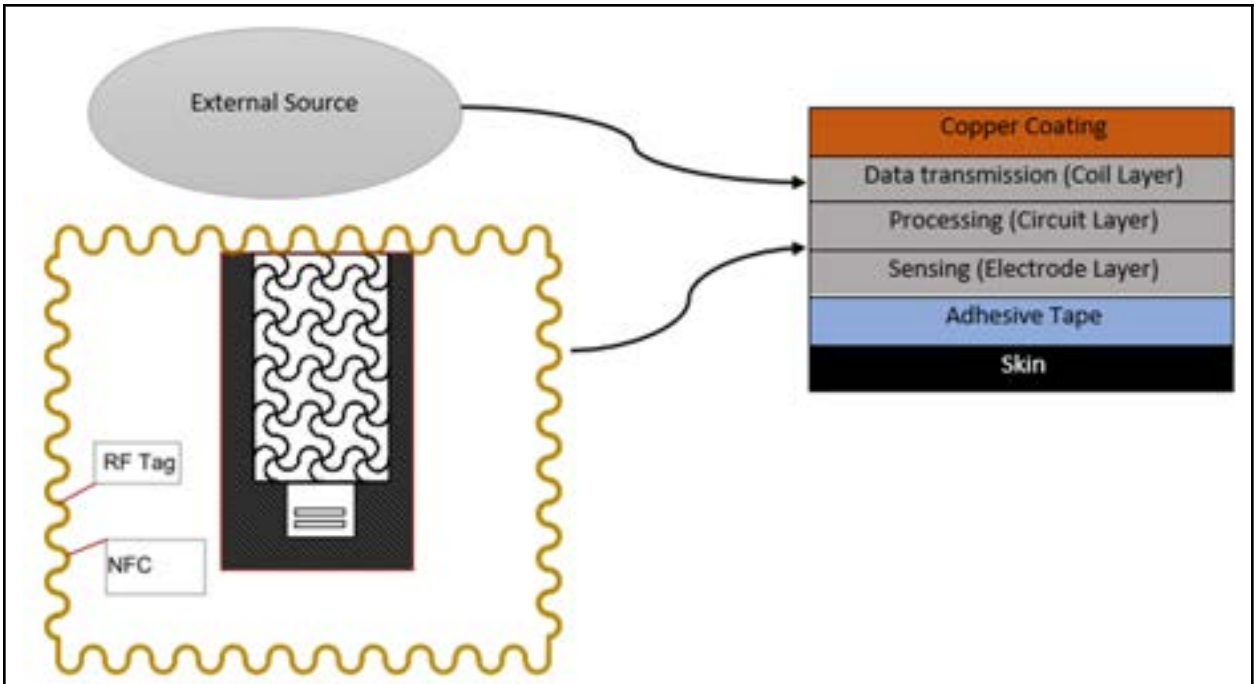


Description:
A small wearable device with sensor electrodes composed of a compact thin film of polyvinylidene fluoride (PVDF). The sensor electrode will be configured into a Filamentary Serpentine design layout and coated with a film of silver coating to enhance the device signaling and have an overall better conductance than copper. The device will communicate side by side with RF radars within a 10-20 cm range and be powered via near-field wireless power transmission in a maximum range of 50 cm. The device is attached to the skin by using a one-sided tape that complies with biocompatibility regulations.

Pros	**Cons**
● Non-invasive ● Wireless ● Independent of Battery ● Low probability of interference ● Wearable ● Compact ● Lightweight	● Low functional range ● External battery source required for functionality

➔ ***Revision - November 23, 2021***

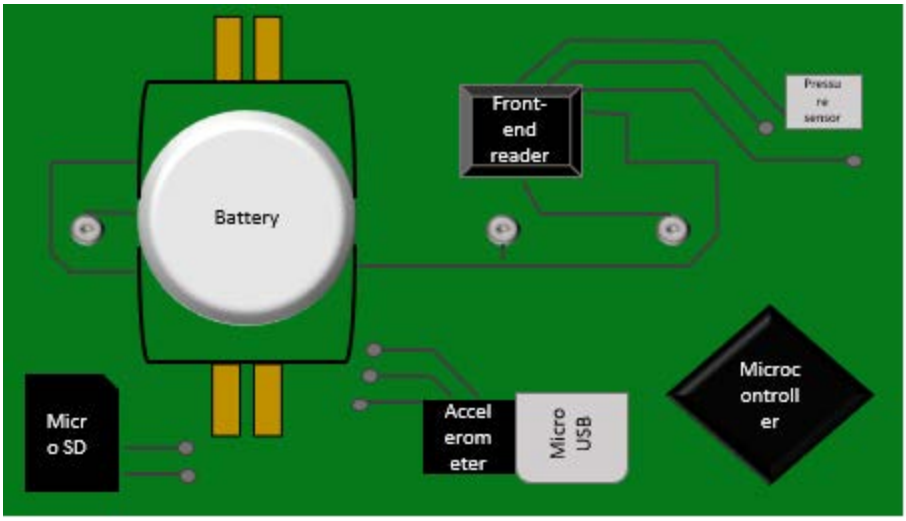
Design Concept 1



Description:
A wearable device whose sensor electrodes are composed of a compacted electromechanical film (EMFi). The sensor electrode will be configured into a serpentine design layout and coated with a thin film of copper coating to enhance the device signaling. Signal communication is via NFC, with a maximum range of 20 cm that is dependent on the antenna size. The device contains adhesive tape and complies with all biocompatibility regulations.

Pros	Cons
• Non-invasive • Low probability of interference • Wireless • Wearable • Compact • Inexpensive • Low Young's modulus	• Not sensitivity to planar forces • External source required for functionality

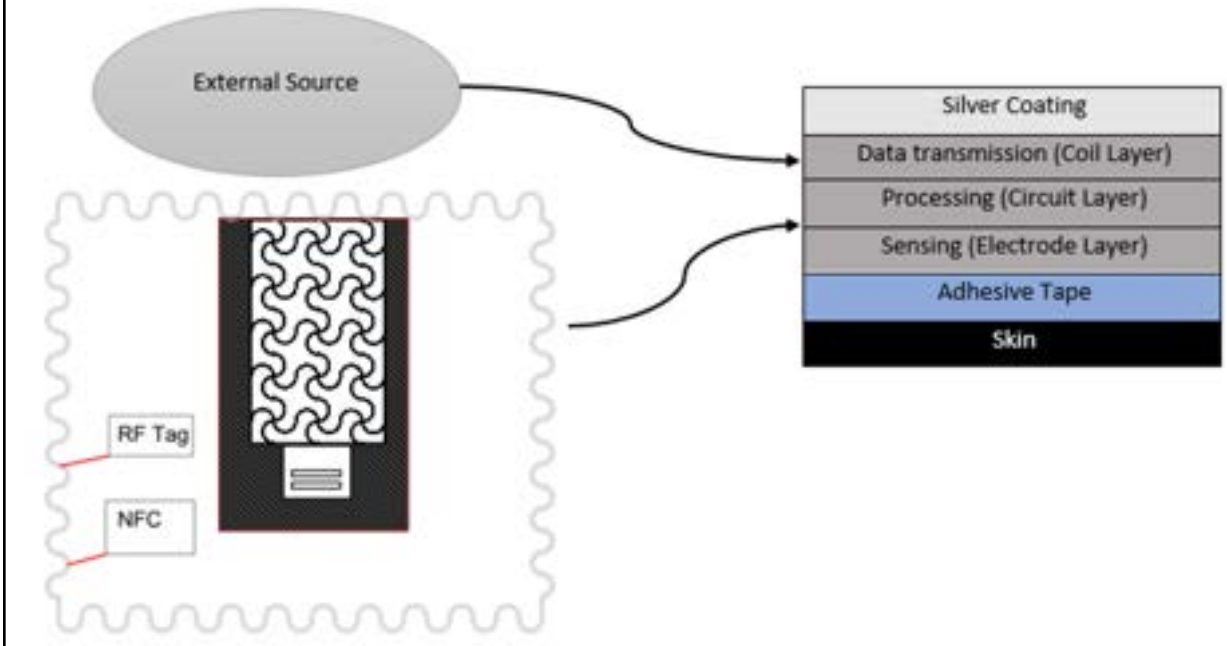
Design Concept 2



Description:
A wearable device with sensor electrodes composed from a printed circuit board (PCB) which provides rigid electrodes and other electronic components. The signal acquisition would be done through a gel electrode patch placed on the skin. The device would require a microcontroller, a front end reader, power management, pressure sensor, accelerometer, microSD, and micro USB to record the signal, providing SCG signals recording. The device is powered by a 3V round battery placed on the PCB.

Pros	Cons
• Non-invasive • Wireless • Wearable	• Battery dependent • Bulky • Rigid • Increased weight and size

Design Concept 3

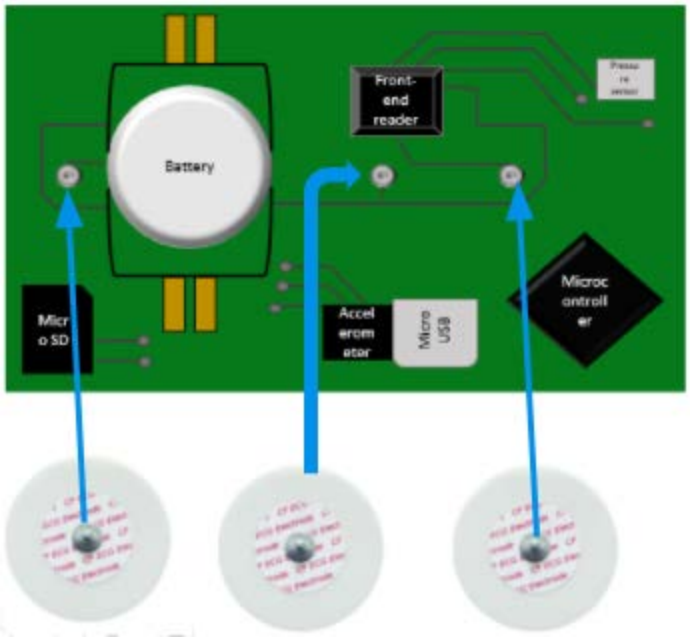


Description:
A small wearable device with sensor electrodes composed of a compact thin film of polyvinylidene fluoride (PVDF). The sensor electrode will be configured into a Filamentary Serpentine design layout and coated with a film of silver coating to enhance the device signaling and have an overall better conductance than copper. The device will communicate side by side with RF radars within a 10-20 cm range and be powered via near-field wireless power transmission in a maximum range of 50 cm. The device is attached to the skin by using a one-sided tape that complies with biocompatibility regulations.

Pros	Cons
● Non-invasive ● Wireless ● Independent of Battery ● Low probability of interference ● Wearable ● Compact ● Lightweight	● Low functional and powering range ● External source required for functionality

➔ ***Revision - February 6, 2022***

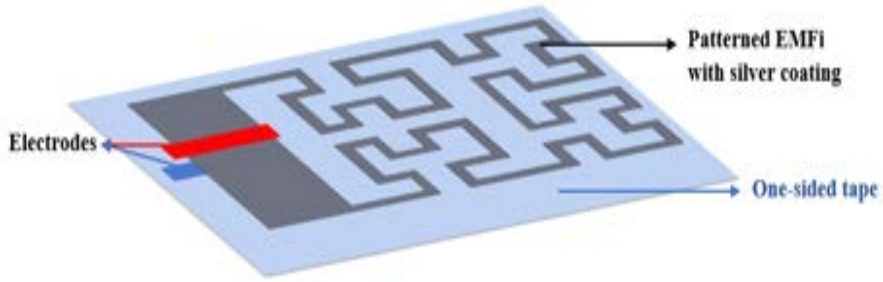
Design Concept 1

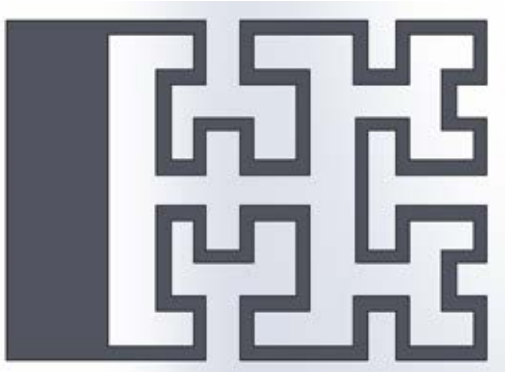


Description:
A wearable sensor composed from a printed circuit board (PCB) which provides rigid electrodes and other electronic components. The signal acquisition would be done through a gel electrode patch placed on the skin. The device would require a microcontroller, a front end reader, power management, pressure sensor, accelerometer, microSD, and micro USB to record the signal, providing SCG signals recording. The device is powered by a 3V round battery placed on the PCB.

Pros	**Cons**
• Non-invasive • Converts cardiac vibration to electrical voltage via an accelerometer. • Uniaxial accelerometer sensitive to planar forces. • Wireless • Wearable • No need of external source for data recording or processing. • Easy to pattern and manufacture	• Bulky (Inclusive of a battery) • Rigid (No Young's modulus to modify) • Increased weight and size

Design Concept 2

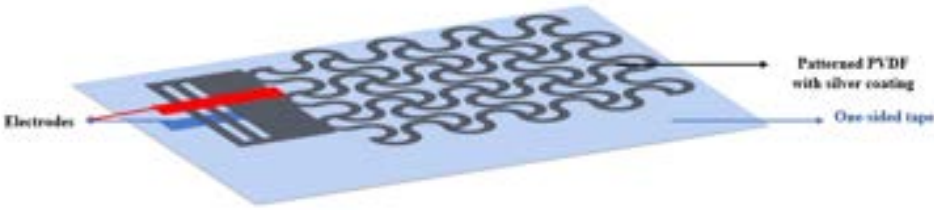




Description:
A small thin sensor composed of a metalized polypropylene film (electromechanical film (EMFi™)) with a Hilbert-curve pattern. The polymer came metallized with a carbon conductive paint to provide conductive properties.

Pros	Cons
• Non-invasive • Converts cardiac vibration to electrical voltage via a piezoelectric component. • Wireless • Wearable • Conformal • Low Young's modulus	• Not sensitive to planar forces. • External source required for reading of data. • Challenging to pattern and manufacture.

Design Concept 3

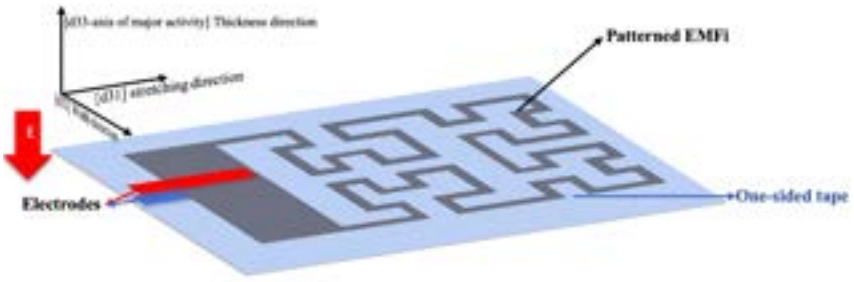


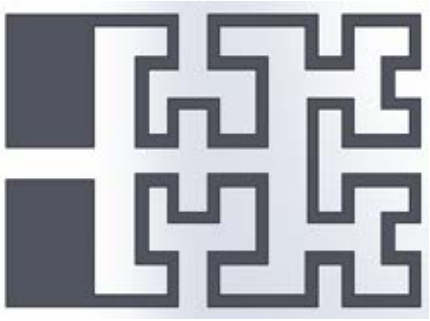
Description:
A small sensor composed of a thin film of metallized polyvinylidene fluoride (PVDF) with a filamentary serpentine pattern. The material is metallized with silver ink to provide conductive properties.

Pros	Cons
● Non-invasive ● Converts cardiac vibration to electrical voltage via a piezoelectric component ● Wireless ● Wearable ● Conformal ● Lightweight ● Low Young's modulus ● Unchallenging to pattern and manufacture.	● External source required for reading of data

➔ ***Final Revision - February 15, 2022***

Design Concept 1

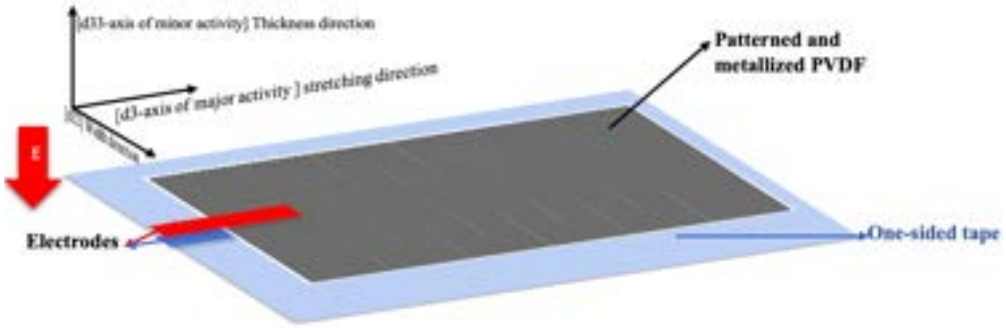


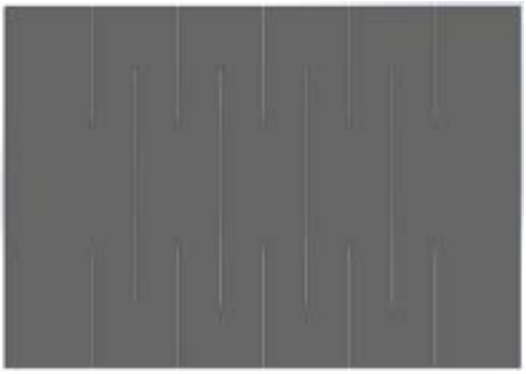


Description:
A small thin sensor composed of a metalized polypropylene film (electromechanical film (EMFi™)) with a Hilbert-curve pattern. The polymer came metallized with a carbon conductive paint to provide conductive properties.

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' compliance with skin is compromised by the rigid geometric configuration

Design Concept 2

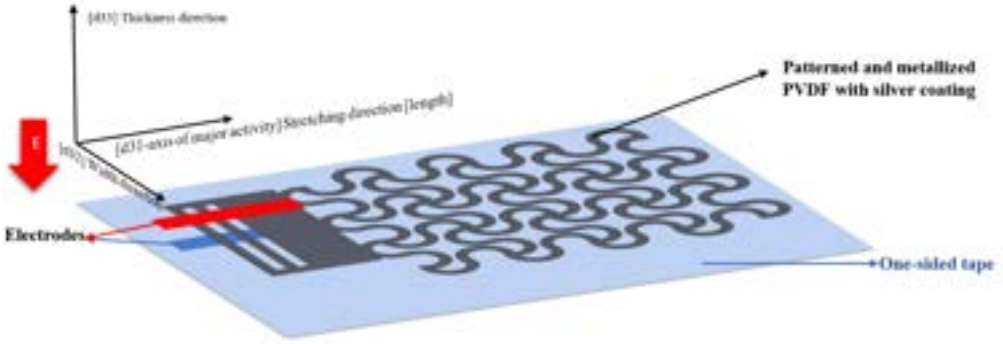




Description:
A small sensor composed of a thin film of metallized polyvinylidene fluoride (PVDF) with a Kirigami pattern. The material is metallized with silver ink to provide conductive properties.

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 metallized polyvinylidene fluoride (PVDF) with a filamentary serpentine pattern. The material is metallized 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.	● N/A as per our market requirements

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Section 3 - Feasibility Assessment

Section 3.1 - Technology Assessment

➔ ***November 9, 2021***

Material	Pros	Cons
PVDF (poly-vinylidene fluoride)	● Heat and corrosion resistance. ● For use outdoors. ● Flexible and stretchable.	● Low impact strength. ● Lower sensitivity in compared to other materials such as EMFi
PCB (Printed Circuit Board)	● Easy to repair. ● Little to no electric noise. ● Fixed components.	● Rigid. ● Bulky. ● Battery dependent.
NFC (Near Field Communication)	● Battery-less, wireless, and wearable. ● Low-cost. ● Real-time biosignal continuous monitoring. ● Comfortable and seamless to touch of skin.	● Short distance communication. ● Challenging manufacturing on soft substrate.

➔ ***Revision - November 20, 2021***

Material	Pros	Cons
PVDF (poly-vinylidene fluoride)	● Heat and corrosion resistance. ● For use outdoors. ● Flexible and stretchable.	● Low impact strength. ● **Lower sensitivity in comparison to EMFi.**
PCB (Printed Circuit Board)	● Easy to repair. ● Little to no electric noise. ● Fixed components.	● Rigid. ● Bulky. ● Battery dependent. ● ***not applicable for SCG coated***
NFC (Near Field Communication)	● Battery-less, wireless, and wearable. ● Low-cost. ● Real-time biosignal continuous monitoring. ● Comfortable and seamless to touch of skin.	● Short distance communication. ● Challenging manufacturing on soft substrate.

➔ ***Revision - November 21, 2021***

Material	Pros	Cons
PVDF (poly-vinylidene fluoride)	● Heat and corrosion resistance. ● Sensitive to vibration and lateral forces. ● Flexible.	● Low impact strength. ● Lower sensitivity in comparison to EMFi.
PCB (Printed Circuit Board)	● Easy to repair. ● Little to no electric noise. ● **Easy to design.**	● Rigid. ● Bulky. ● Battery dependent. ● Not sensitive to vibration.
EMFi (electromechanic film)	● **5 times more sensitive than PVDF.** ● **Flexible.** ● **Ability to convert mechanical signals to electrical signals.**	● **Sensitivity depends on the load of the film.** ● **Very sensitive to thickness change.** ● **Not sensitive to lateral forces.**
Gelled Electrodes	● **Low electrical noise.** ● **Reusable as long as the gel is fresh.** ● **Non-polarized.**	● **Higher chance of skin irritation.** ● **Bulky.** ● **Sensitive to electrical signals only.**
Bluetooth	● **Wireless** ● **Wider range of communication (up to 10m).** ● **A feature available in most devices.**	● **Require a low power source.** ● **Could be power draining.** ● **Compatibility issues.**
NFC (Near Field Communication)	● Battery-less ● Wireless ● Real-time biosignal continuous monitoring.	● Short distance communication. ● Challenging manufacturing on soft substrate.

➔ ***Revision - November 23, 2021***

Material	Pros	Cons
PVDF (poly-vinylidene fluoride)	● Heat and corrosion resistance. ● Sensitive to vibration and lateral forces. ● Flexible.	● Low impact strength. ● Lower sensitivity in comparison to EMFi.

PCB (Printed Circuit Board)	• Easy to repair. • Little to no electric noise. • Easy to design.	• Rigid. • Bulky. • Battery dependent. • Not sensitive to vibration.
EMFi (electromechanic film)	• 5 times more sensitive than PVDF. • Flexible. • Ability to convert mechanical signals to electrical signals.	• Sensitivity depends on the load of the film. • Very sensitive to thickness change. • Not sensitive to lateral forces.
Gelled Electrodes	• Low electrical noise. • Reusable as long as the gel is fresh. • Non-polarized.	• Higher chance of skin irritation. • Bulky. • Sensitive to electrical signals only.
NFC (Near Field Communication)	• Battery-less • Wireless • Real-time biosignal continuous monitoring.	• Short distance communication. • Challenging manufacturing on soft substrate.

➔ ***Revision - November 28, 2021***

Material	Pros	Cons
PVDF (poly-vinylidene fluoride)	• **Withstand mechanical force of 1.5 N/m2.** • Sensitive to lateral forces • Flexible. • **Lightweight/compact**	• Lower sensitivity to mechanical vibration. • **High Young's modulus. Needs to be pattern to lower Young's modulus and increase sensitivity.**
PCB (Printed Circuit Board)	• Little to no electric noise. • Easy to design.	• Rigid and bulky • **Require accelerometer** • Battery dependent. • Not sensitive to vibration. • **Depends on gel electrodes for attachment.**
EMFi (electromechanic film)	• 5 times more sensitive than PVDF. • Flexible. • Ability to convert mechanical signals to electrical signals. • **Lightweight/compact**	• Sensitivity depends on the load of the film. • Very sensitive to thickness change. • Not sensitive to lateral forces.

Gelled Electrodes	• Low electrical noise. • Reusable as long as the gel is fresh.	• Higher chance of skin irritation. • Bulky. • Sensitive to electrical signals only.
Polyurethane Tape	• **Biocompatible** • **Have peel force of ≤ 8.7 N/cm** • **Elongation of ≥ 689%** • **Flexible**	• **Sensitive to moisture.** • **Requires a partial pressure to adhere.** • **There is a chance of skin irritation**
NFC (Near Field Communication)	• Battery-less • Wireless • Real-time biosignal continuous monitoring. • **Operating frequency of 13.56 MHz** • **Apply a filter to remove unwanted noise**.	• Short distance communication. • Challenge in manufacturing on soft substrate.

➔ ***Revision - December 06, 2021***

Material	Pros	Cons
PVDF (poly-vinylidene fluoride)	• Sensitive to lateral forces. • Flexible. • Lightweight/compact • **Ability to convert. mechanical signals to electrical signals.**	• Lower sensitivity to mechanical vibration. • High Young's modulus. Needs to be pattern to lower. Young's modulus and increase sensitivity.
PCB (Printed Circuit Board)	• Easy to design. • **No Young's modulus needs to be taken into account.**	• Rigid/bulky. • Battery dependent. • Not sensitive to vibration. • **Need an accelerometer to convert mechanical to electrical signals and capture lateral forces.**
EMFi (electromechanic film)	• 5 times more sensitive than PVDF. • Flexible. • Ability to convert mechanical signals to electrical signals. • Lightweight/compact.	• Sensitivity depends on the load of the film. • Not sensitive to lateral forces.

Gelled Electrodes	• Reusable as long as the gel is fresh. • **Biocompatible.**	• Higher chance of skin irritation. • Bulky. • Sensitive to electrical signals only. • **Not flexible.** • **Lower peel force.** • **Low elongation.**
Polyurethane Tape	• Biocompatible. • **Higher peel force.** • Elongation of ≥ 689% • Flexible. • **Lower chance of skin irritation.** • **Compact.**	• Sensitive to moisture. • Requires a partial pressure to adhere. • **Not reusable.**
NFC (Near Field Communication)	• Battery-less • Wireless • Real-time biosignal continuous monitoring. • Operating frequency of 13.56 MHz • Apply a filter to remove unwanted noise.	• Short distance communication. • Challenge in manufacturing on soft substrate.

➔ ***Revision - February 7, 2022***

Material/Technology	Pros	Cons
Gelled Electrodes (Ag/AgCl)	• Reusable as long as the gel is fresh. • Biocompatible. • Low impedance. • Pass current without interference.	• Higher chance of skin irritation. • Bulky. • Not flexible. • Lower peel force.
Polyurethane Tape	• Biocompatible. • Higher peel force. • Flexible. • Lower chance of skin irritation. • Compact.	• Sensitive to moisture. • Requires a partial pressure to adhere. • Not reusable.
PVDF	• Compact • Sensitive to uniaxial stress • Convert mechanical vibration to electrical (voltage)	• Sensitivity reduction after patterning..

Accelerometer	• Uniaxial. • Sensitive to stress. • Convert mechanical vibration to electrical (voltage).	• Rigid. • Bulky.
EMFi	• More sensitive compared to PVDF. • Stretchable. • Convert mechanical vibration to electrical signals.	• Not sensitive to lateral forces. • Challenging to manufacture.

➔ ***Revision - March 17, 2022***

Material/Technology	Pros	Cons
Tegaderm Tape	• Biocompatible. • Higher peel force. • Flexible. • Lower chance of skin irritation. • Compact.	• Sensitive to moisture. • Requires a partial pressure to adhere. • Not reusable.
PVDF	• Compact • Sensitive to uniaxial stress • Convert mechanical vibration to electrical (voltage)	• Sensitivity reduction after patterning..
EMFi	• More sensitive compared to PVDF. • Stretchable. • Convert mechanical vibration to electrical signals.	• Not sensitive to lateral forces. • Challenging to manufacture.

Section 3.2 - Cost Assessment

➔ ***November 8, 2021***

- ◆ ***Product***

Unit Cost at volume 100 = ~$180
- Material = $34.89 (for 1 unit)
  - PVDF = $10.93 for 1ft and 0.003" thickness
  - Silver coating with Premion = $10.80
  - photosensitive dry film = $0.16
  - One-sided polyurethane tape = ~$13
- Labor* = $100
- Overhead** = $44.88 ($40+$4.88)

*Labor: $25 per hour (4 workers) x 40 hours weekly x 23 weeks
**Calculated overhead (40% of Labor + 14% of Material)

- ◆ ***Project***

Total Budget Requested = $xxxxxxx
- Material = $150.52
  - PVDF = $10.93 for 1ft and 0.003" thickness
  - Silver coating with Premion = $111
  - photosensitive dry film = $15.59
  - One-sided polyurethane tape = ~$13
- Lab Cost = $???
- Technology = $??
- Consulting = $0
- Certifications = $0
- Labor = $0 (Provided at zero cost by the team)

➔ ***Revision - November 22, 2021***

- ◆ ***Product***

Unit Cost at volume 100 = ~$180
- Material = $252.91 (for 1 unit)
  - PVDF = $10.93 for 1ft and 0.003" thickness
  - Silver coating with Premion = $10.80
  - photosensitive dry film = $0.16
  - One-sided polyurethane tape = $64.50
  - Adhesive transfer tape = $8
- Labor* = $57.81
- Overhead** = $ ($22.40+$35.41)

*Labor: $14 per hour (4 workers)
**Calculated overhead (40% of Labor + 14% of Material)
make table format

Product Cost Assessment (for volume 1000)		
Expense	Description	Cost (USD)
Assembly Labor		
Materials		
Overhead (Facilities, Utilities, Equipment, Indirect labor, certification, and licenses).	40% labor +14% materials	
Total		

◆ ***Project***

Total Budget Requested = $1500
Material = $462.93
PVDF = $10.93 for 1ft and 0.003” thickness
Silver coating with Premion = $111
photosensitive dry film = $15.59
One-sided polyurethane tape =$64.50
Adhesive transfer tape = $8
Lab Cost = $???
Technology = $783.50
Consulting = $0.00 (Provided by Sponsor/Faculty Advisor)
Certifications = $0.00 (No certifications needed)
Labor = $0 (Provided at zero cost by the team)

Project Cost Assessment			
Expense	Description / Use	Cost in USD	Actual Cost to Sponsor
Material Costs			
Polyvinylidene fluoride (PVDF)	**Description:** Thin-film piezoelectric polymer sheet 0.003" Thick, 24" Wide, 1 ft. Length with high tensile strength, low thermal resistance, **Use:**	$11	$11
Silver coating	**Description:** Silver foil, 0.025mm (0.001in) thick, annealed, Premion®, 99.998% (metals basis) 50x50mm **Use:**	$111	$111
Photosensitiv	**Description:**	$16	$16

e dry film	**Use:**		
One-sided polyurethane tape	**Description:** 3M Single Sided Transparent Polyurethane Tape 30 cm × 46 cm, 0.20 mm **Use:** Adheres the patch to user's skin	$65	$65
Adhesive transfer tape	**Description:** **Use:** Laminates the patch and allows for adhesion to	$8	$8
NFC tag	**Description:** **Use:**		
Front end tag	**Description:** **Use:**		
Arduino Uno M	**Description:** A microcontroller board based on the ATmega328P **Use:** Provides an electromagnetic field that will stimulate the	$20	$0 (provided by the team)
Equipment Costs			
Desktop Cutting Machine	**Description:** **Use:** Cutting the PVDF sheet into the desired geometric configuration	$300	
Multifunctional DAQ			
Thermal Laminator		$84	
Labor	$0		
Regulatory requirements			
ISO/IEC 18092:2013	**Description:** Information technology — Telecommunications and information exchange between systems — Near Field Communication — Interface and Protocol (NFCIP-1) **Use:**	$170	
AAMI TIR69:2017/(R2020)	**Description:** Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems. **Use:**	$250	

ASTM D3359	**Description:** Standard Test Methods for Measuring Adhesion by Tape Test **Use:**	$64	
ISO 10993-10:2021	**Description:** Biological evaluation of medical devices in relation to skin reaction. **Use:**	$170	
IEC 60601-1-11:2015	**Description:** Medical electrical equipment safety and essential performance **Use:**	$333	

➔ ***Revision - November 23, 2021***

- ◆ ***Product***

Unit Cost at volume = ~$94.36
Material = $14 (for 1 unit)
Labor* = $56
Overhead** = $24.36

*Labor: $14 per hour (4 workers)
**Calculated overhead (40% of Labor + 14% of Material)

Product Cost Assessment		
Expense	**Description**	**Cost (USD)**
Assembly Labor	$14 hours (4 workers)	$56
Materials		
Polyvinylidene fluoride (PVDF)	**Description:** Thin-film piezoelectric polymer sheet 0.003" Thick, 24" Wide, 2.4” Length with high tensile strength, low thermal resistance, **Use:** Sensing mechanical vibration and translating to electrical waveforms	$2
Silver coating	**Description:** Silver foil, 0.025mm (0.001in) thick, annealed, Premion®, 99.998% (metals basis) 50x50mm **Use:** aids in the electrical conductivity of the patch.	$11
Photosensitive dry film	**Description:** Color: blue Material: Plastic Dimension: 30cm*500cm / 11.8*197in Weight: approx. 150g **Use:** aids in the fabrication of the circuit and coil layer.	$1

One-sided polyurethane tape	**Description:** 3M Single-Sided Transparent Polyurethane Tape 30 cm × 46 cm, 0.20 mm **Use:** Adheres the patch to the user's skin	$1
Adhesive transfer tape	**Description:** TransferRite Ultra Clear 1310 Medium Tack Transfer Tape 10 yd x 6 in **Use:** Laminates the patch	$1
NFC tag	**Description:** for 5 units **Use:** Two-way data transfer and power	$1
Arduino Uno Microcontroller	**Description:** A microcontroller board based on the ATmega328P **Use:** Provides an electromagnetic field that will stimulate the power of the device	$20
Overhead (Facilities, Utilities, Equipment, Indirect labor, certification, and licenses).	40% labor +14% materials	$28
Total		$121

- ***Project***

  Total Budget Requested = $1,152.66
  Material = $169.12
  Lab Cost = $0
  Technology/Equipment = $983.54
  Consulting = $0 (Provided by Sponsor/Faculty Advisor)
  Certifications = $0 (No certifications needed)
  Labor = $0 (Provided at zero cost by the team)

Project Cost Assessment			
Expense	Description / Use	Cost in USD	Actual Cost to Sponsor
Materials Cost			
Polyvinylidene fluoride	**Description:** Thin-film piezoelectric polymer sheet 0.003" Thick, 24" Wide, 1 ft.	$11	$11

(PVDF)	Length **Use:** Sensing mechanical vibration and translating to electrical waveforms		
Silver coating	**Description:** Silver foil, 0.025mm (0.001in) thick, annealed, Premion®, 99.998% (metals basis) 50x50mm **Use:** aids in the electrical conductivity of the patch.	$111	$111
Photosensitive dry film	**Description:** Color: blue Material: Plastic Dimension: 30cm*500cm / 11.8*197in Weight: approx. 150g **Use:** aids in the fabrication of the circuit and coil layer. [4]	$16	$16
One-sided polyurethane tape	**Description:** 3M Single-Sided Transparent Polyurethane Tape 30 cm × 46 cm, 0.20 mm **Use:** Adheres the patch to the user's skin	$20	$20
Adhesive transfer tape	**Description:** TransferRite Ultra Clear 1310 Medium Tack Transfer Tape 10 yd x 6 in [7] **Use:** Laminates the patch	$8	$8
NFC tag	**Description:** for 5 units **Use:** Two-way data transfer and power [5]	$3	$3
Arduino Uno Microcontroller	**Description:** A microcontroller board based on the ATmega328P **Use:** Provides an electromagnetic field that will stimulate the power of the device	$20	$0
Technology/Equipment Cost			
Desktop Cutting Machine	**Use:** Cutting the PVDF sheet into the desired geometric configuration [1]	$300	$300
Multifunctional DAQ	**Use:** For simultaneous recordings of SCG and ECG when testing the signal recording capability [6]	$600	$600

Thermal Laminator	**Use:** For precise lamination of the different foils and dry films [3]	$84	$84
Labor	$25 per hour (4 workers) x 40 hours per week x 14 weeks	$56,000	$0
Regulatory requirements			
ISO/IEC 18092:2013	**Description:** Information technology — Telecommunications and information exchange between systems — Near Field Communication — Interface and Protocol (NFCIP-1) **Use:** Active-passive data transfer via NFC and coupled device at a frequency of 13.56 MHz	$170	$0
AAMI TIR69:2017/ (R2020)	**Description:** Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems. **Use:** Device communication functionality in the coexistence of medical devices	$250	$0
ASTM D3359	**Description:** Standard Test Methods for Measuring Adhesion by Tape Test **Use:** To test the adhesion of the patch on the skin	$64	$0
ISO 10993-10:2021	**Description:** Biological evaluation of medical devices in relation to skin reaction. **Use:** Minimize skin adverse events to the product	$170	$0
IEC 60601-1-11: 2015	**Description:** Medical electrical equipment safety and essential performance **Use:** Safety of electrical component use in medical device	$333	$0
Total		$58,160	**$1153**

➔ ***Revision - February 26, 2021***

- ◆ ***Product***

  Unit Cost at volume = ~$92.62
  Material = $12.47 (for 1 unit)

Labor* = $56
Overhead** = $24.15

*Labor: $14 per hour (4 workers)
**Calculated overhead (40% of Labor + 14% of Material)

Product Cost Assessment		
Expense	**Description**	**Cost (USD)**
Assembly Labor	$14 hours (4 workers)	$56
Materials		
Polyvinylidene fluoride (PVDF)	**Description:** Thin-film piezoelectric polymer sheet 0.003" Thick, 24" Wide, 2.4’’ Length with high tensile strength, low thermal resistance, **Use:** Sensing mechanical vibration and translating to electrical waveforms	$2
CI-1036 Highly Conductive, Highly Flexible Silver Ink	**Description:** Silver conductive ink designed for superior durability and crease resistance along with low resistance and long screen residence time. **Use:** Screen printing the sensor and aids in the electrical conductivity of the PVDF.	$9
TransferRite Ultra (3M™ -582U) Medium Tack Transfer Tape	**Description:** TransferRite Ultra (3M™ -582U) Medium Tack Transfer Tape 6 in x 10 yd **Use:** Placing the metallized PVDF on the cutting board.	$1
3M™ Tegaderm™ Transparent Film Roll	**Description:** One-sided medical grade transparent polyurethane film 2 in x 11 yd **Use:** Substrate to encase the PVDF	$1
Mueller® Quick Drying Adherent Spray	**Description:** Colorless tape adherent you apply to skin before taping 4 oz can **Use:** Adhere sensor to artificial human skin	$1
Overhead (Facilities, Utilities, Equipment,	40% labor +14% materials	$24

Indirect labor, certification, and licenses).		
Total		$94

- ***Project***

  Total Budget Requested = $1,106.09
  Material = $105.10
  Lab Cost = $0
  Technology/Equipment = $1,000.99
  Consulting = $0 (Provided by Sponsor/Faculty Advisor)
  Certifications = $0 (No certifications needed)
  Labor = $0 (Provided at zero cost by the team)

Project Cost Assessment			
Expense	Description / Use	Cost in USD	Actual Cost to Sponsor
Materials Cost			
Polyvinylidene fluoride (PVDF)	**Description:** Thin-film piezoelectric polymer sheet 0.003" Thick, 24" Wide, 1 ft. Length **Use:** Sensing mechanical vibration and translating to electrical waveforms	$11	$11
CI-1036 Highly Conductive, Highly Flexible Silver Ink	**Description:** Silver conductive ink designed for superior durability and crease resistance along with low resistance and long screen residence time. **Use:** Screen printing the sensor and aids in the electrical conductivity of the PVDF.	$63	$63
TransferRite Ultra (3M™ -582U) Medium Tack Transfer Tape	**Description:** TransferRite Ultra (3M™ -582U) Medium Tack Transfer Tape 6 in x 10 yd **Use:** Placing the metallized PVDF on the cutting board.	$6	$6
3M™	**Description:** One-sided medical grade	$20	$20

Tegaderm™ Transparent Film Roll	transparent polyurethane film 2 in x 11 yd **Use:** Substrate to encase the PVDF		
Mueller® Quick Drying Adherent Spray	**Description:** Colorless tape adherent you apply to skin before taping 4 oz can **Use:** Adhere sensor to artificial human skin	$6	$6
Technology/Equipment Cost			
Cameo Silhouette 4 Cutting Machine	**Use:** Cutting the PVDF sheet into the desired geometric configuration [1]	$300	$300
Vibration Generator	**Use:** Generate vibrations mechanically with frequency range of 0 - 20 kHz	$260	$260
Circular Chladni Plate	**Use:** Place on vibration generator to vibrate	$51	$51
Accelerometer, ICP® (MODEL:352C65)	**Use:** Detect SCG signals	$390	$390
Labor	$25 per hour (4 workers) x 40 hours per week x 14 weeks	$56,000	$0
Regulatory requirements			
ISO 16063-32:2016	**Description:** 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 **Use:** Detailed specification for instruments and procedures of testing the frequency and the phase response of accelerometers by means of shock excitation.	$73	$0
ISO 527-1:2019	**Description:** Plastics — Determination of tensile properties — Part 1: General principles	$149	$0

	Use: Specifies the general principles for determining the tensile properties of plastics and plastic composites under defined conditions		
ISO 16063-21:2003	**Description:** Methods for the calibration of vibration and shock transducers — Part 21: Vibration calibration by comparison to a reference transducer **Use:** Specifies procedures for performing calibrations of rectilinear vibration transducers by comparison in the frequency range from 0.4 Hz to 10 kHz	$175	$0
ISO 10993-10:2021	**Description:** Biological evaluation of medical devices in relation to skin reaction. **Use:** Minimize skin adverse events to the product	$170	$0
IEC 62353:2014	**Description:** Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment **Use:** Defines the requirements for electrical safety testing of medical electrical (ME) equipment and systems during routine intervals.	$320	$0
Total		$57,994	**$1,107**

➔ ***Revision - April 14, 2022***

◆ ***Product***

Unit Cost at volume = ~$110.30
Material = $27.98 (for 1 unit)
Labor* = $56
Overhead** = $26.32

*Labor: $14 per hour (4 workers)
**Calculated overhead (40% of Labor + 14% of Material)

Product Cost Assessment		
Expense	**Description**	**Cost (USD)**
Assembly	$14 hours (4 workers)	$56

Labor		
Materials		
Polyvinylidene fluoride (PVDF)	**Description:** Thin-film piezoelectric polymer sheet 28UM, 60C ANN, PLSM 16.14" W with high tensile strength, low thermal resistance **Use:** Sensing mechanical vibration and translating to electrical waveforms	$18
CI-1036 Highly Conductive, Highly Flexible Silver Ink	**Description:** Silver conductive ink designed for superior durability and crease resistance along with low resistance and long screen residence time. **Use:** Screen printing the sensor and aids in the electrical conductivity of the PVDF.	$9
TransferRite Ultra (3M™ -582U) Medium Tack Transfer Tape	**Description:** TransferRite Ultra (3M™ -582U) Medium Tack Transfer Tape 6 in x 10 yd **Use:** Placing the metallized PVDF on the cutting board.	$1
3M™ Tegaderm™ Transparent Film Roll	**Description:** One-sided medical grade transparent polyurethane film 2 in x 11 yd **Use:** Substrate to encase the PVDF	$1
Overhead (Facilities, Utilities, Equipment, Indirect labor, certification, and licenses).	40% labor +14% materials	$24
Total		$93

- ***Project***

  Total Budget Requested = $1,407.28
  Material = $416.29
  Lab Cost = $0
  Technology/Equipment = $1,000.99
  Consulting = $0 (Provided by Sponsor/Faculty Advisor)
  Certifications = $0 (No certifications needed)
  Labor = $0 (Provided at zero cost by the team)

Project Cost Assessment			
Expense	Description / Use	Cost in USD	Actual Cost to Sponsor
Materials Cost			
Polyvinylidene fluoride (PVDF)	**Description:** Thin-film piezoelectric polymer sheet 28micron thick, 60C ANN, PLSM 16.14" W **Use:** Sensing mechanical vibration and translating to electrical waveforms	$203	$0
Pre-metallized Polyvinylidene fluoride (PVDF)	**Description:** Thin-film piezoelectric polymer sheet 28micron metalized with silver ink and dimensions of 8” x 11” **Use:** Sensing mechanical vibration and translating to electrical waveforms	$317	$317
CI-1036 Highly Conductive, Highly Flexible Silver Ink	**Description:** Silver conductive ink designed for superior durability and crease resistance along with low resistance and long screen residence time. **Use:** Screen printing the sensor and aids in the electrical conductivity of the PVDF.	$63	$63
TransferRite Ultra (3M™ -582U) Medium Tack Transfer Tape	**Description:** TransferRite Ultra (3M™ -582U) Medium Tack Transfer Tape 6 in x 10 yd **Use:** Placing the metallized PVDF on the cutting board.	$6	$6
3M™ Tegaderm™ Transparent Film Roll	**Description:** One-sided medical grade transparent polyurethane film 2 in x 11 yd **Use:** Substrate to encase the PVDF	$20	$20
Mueller® Quick Drying Adherent Spray	**Description:** Colorless tape adherent you apply to skin before taping 4 oz can **Use:** Adhere sensor to artificial human skin	$6	$0
Technology/Equipment Cost			
Cameo Silhouette 4	**Use:** Cutting the PVDF sheet into the desired geometric configuration [1]	$300	$300

Cutting Machine			
Vibration Generator	**Use:** Generate vibrations mechanically with frequency range of 0 - 20 kHz	$260	$260
Circular Chladni Plate	**Use:** Place on vibration generator to vibrate	$51	$51
Accelerometer, ICP® (MODEL:352C 65)	**Use:** Detect SCG signals	$390	$390
Labor	$25 per hour (4 workers) x 40 hours per week x 14 weeks	$56,000	$0
Regulatory requirements			
ISO 16063-32:2016	**Description:** 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 **Use:** Detailed specification for instruments and procedures of testing the frequency and the phase response of accelerometers by means of shock excitation.	$73	$0
ISO 527-1:2019	**Description:** Plastics — Determination of tensile properties — Part 1: General principles **Use:** Specifies the general principles for determining the tensile properties of plastics and plastic composites under defined conditions	$149	$0
ISO 16063-21:2003	**Description:** Methods for the calibration of vibration and shock transducers — Part 21: Vibration calibration by comparison to a reference transducer **Use:** Specifies procedures for performing calibrations of rectilinear vibration transducers by comparison in the frequency range from 0.4 Hz to 10 kHz	$175	$0

ISO 10993-10:2021	**Description:** Biological evaluation of medical devices in relation to skin reaction. **Use:** Minimize skin adverse events to the product	$170	$0
IEC 62353:2014	**Description:** Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment **Use:** Defines the requirements for electrical safety testing of medical electrical (ME) equipment and systems during routine intervals.	$320	$0
Total		$58,503	**$1,407**

Section 3.3 - Risk-Hazard Analysis

➔ ***November 15, 2021***

Potential Hazard	Generic Cause	Specific Cause	Probability	Severity	Control Mode	Control Method
Electric Shock	Wrong design	Current flow exceeds 0.01A	Reasonably Remote	Negligible	Design	
Outside Elements Damaging Device	Humidity and temperature	Excess body perspiration (sweat)	Remote	Negligible	Design	Provide proper sealing between the interfaces
Skin Irritation	Patch in contact with skin	Skin allergic reaction to one-sided 3M tape	Reasonably Remote	Marginal	Design	*Listing of materials used in device label*
Electromagnetic interference	Low signal to noise ratio	Disturbance between RF antenna and NF tag	Extremely Remote	N/A		develop three schemes that prevent real-time packet classification by combining cryptographic primitives with physical-layer attributes. They are Strong Hiding Commitment Schemes (SHCS), Cryptographic Puzzles Hiding

						Schemes (CPHS), All-Or-Nothing Transformation Hiding Schemes (AONTS-HS).
NFC Radiation			Remote	Negligible	Design	*Uses a shielding material*

➔ ***Revision - November 21, 2021***

Potential Hazard	Generic Cause	Specific Cause	Probability	Severity	Control Mode	Control Method
Electric Shock	Faulty Circuitry	Current flow exceeds 0.01A	Remote	Negligible	Design	Proper insulation
Outside Elements Damaging Device	Humidity and tempera-ture	Excess body perspiration (sweat)	Remote	Negligible	Design	Provide proper sealing between the interfaces
Electro-magnetic interference (EMI)	Low signal to noise ratio	Distur-bance between RF antenna and NF tag	Extreme- ly Remote	Negligible	Design	Use of Pasive Filters for EMI
Skin Irritation	Patch in contact with skin	Skin allergic reaction to one-sided 3M tape	Extreme- ly Remote	Marginal	Design	Follow EHS Guidelines

➔ ***Revision - November 22, 2021***

Potential Hazard	Generic Cause	Specific Cause	Probability	Severity	Control Mode	Control Method
Skin Irritation	Patch in contact with skin	Skin allergic reaction to one-sided 3M tape	Extreme- ly Remote	Marginal	Design	Follow EHS Guidelines, Confirm Allergies with patients.

*Outside Elements Damaging Device
*Electromagnetic interference (EMI)
*Electric Shock

➔ ***Revision - November 29, 2021***

Potential Hazard	Generic Cause	Specific Cause	Probability	Severity	Control Mode	Control Method
Skin Irritation	Patch in contact with skin	Skin allergic reaction to one-sided 3M tape	Extreme- ly Remote	Marginal	Design	Follow EHS Guidelines, Confirm Allergies with patients.

Section 3.4 - Regulatory Assessment

➔ ***November 7, 2021***

- FDA Classification: Class II Device
  - General controls and special controls

- Regulatory path: 510(k) clearance needed
  - Device must be proven to be safe and effective before being introduced to the market

- Exempt from: PMA and IDE .
  - Rationale:
    - It is not a Class III device hence PMA is not applicable.
    - No clinical study will be conducted

The FDA classification of this device is considered to be a Class II medical device, which requires general controls and special controls. It is exempt from premarket approval (PMA) and investigational (IDE) but required a 510(k) as it must be proven to be a safe and effective device before being introduced into the market.

➔ ***Revision - November 21, 2021***

- FDA Classification: Class II Device
  - General controls and special controls

- Regulatory path: 510(k) clearance needed
  - Device must be proven to be safe and effective before being introduced to the market

- Exempt from: Premarket approval (PMA) and investigational device exemption (IDE) .
  - Rationale:
    - It is not a Class III device hence PMA is not applicable.
    - No clinical study will be conducted.

The FDA classification of this device is considered to be a Class II medical device, which requires general controls and special controls. It is exempt from premarket approval (PMA) and investigational (IDE) but required a 510(k) as it must be proven to be a safe and effective device before being introduced into the market.

- Relevant Standards
  - ISO/IEC 18092:2013 Information technology — Telecommunications and information exchange between systems — Near Field Communication — Interface and Protocol (NFCIP-1)
  - AAMI TIR69:2017/(R2020) Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems.
  - ASTM D3359 Standard Test Methods for Measuring Adhesion by Tape Test
  - ISO 10993-10:2021 Biological evaluation of medical devices in relation to skin reaction.
  - IEC 60601-1-11:2015 Medical electrical equipment safety and essential performance

➔ ***Revision - November 21, 2021***

- FDA Classification: Class II Device
  - General controls and special controls

- Regulatory path: 510(k) clearance needed
  - Device must be proven to be safe and effective before being introduced to the market

- Exempt from: Premarket approval (PMA) and investigational device exemption (IDE).
  - Rationale:
    - It is not a Class III device hence PMA is not applicable.
    - No clinical study will be conducted.

The FDA classification of this device is considered to be a Class II medical device, which requires general controls and special controls. It is exempt from premarket approval (PMA) and investigational (IDE) but required a 510(k) as it must be proven to be a safe and effective device before being introduced into the market.

- Relevant Standards
  - 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

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[2] *ATSAML10E14A-MU Microchip Technology | Integrated Circuits (ICs) | DigiKey*. (2021). Digikey.com. https://www.digikey.com/en/products/detail/microchip-technology/ATSAML10E14A-MU/9360524

[3] *Laminador térmica A4 Laminador de documentos quente e frio 480W*. (2021). Cablematic.com; Cablematic. https://cablematic.com/en/products/thermal-laminator-a4-hot-and-cold-document-laminator-480w-OF04300/

[4] *PU Film Skin Protector Tape Aftercare Waterproof Transparent Adhesive Tape Bandage Roll*. (2021). Walmart.com. https://www.walmart.com/ip/PU-Film-Skin-Protector-Tape-Aftercare-Waterproof-Transparent-Adhesive-Tape-Bandage-Roll/996739270?wmlspartner=wlpa&selectedSellerId=18988

[5] *ST25DV04K-IER6S3 STMicroelectronics | RF/IF and RFID | DigiKey*. (2020). Digikey.com. https://www.digikey.com/en/products/detail/stmicroelectronics/ST25DV04K-IER6S3/6691417

[6] *T7 | LabJack*. (2021). Labjack.com. https://labjack.com/products/t7

TransferRite Ultra Clear 1310 Medium Tack Transfer Tape. (2021). USCutter. https://uscutter.com/Transferrite-Ultra-Clear-1310-Medium-Tack-Transfer-Tape-100Yd-Rolls/

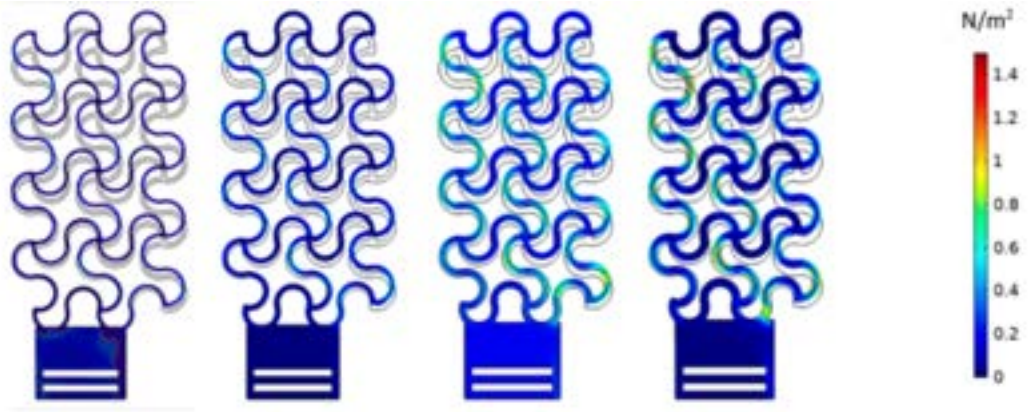
Section 4 - Design

Section 4.1 - Simulation Results

SOLIDWORKS MECHANICAL SIMULATIONS

➔ ***February 7-11***

- **Objective**: determine the relationship between AD value and stress experienced in the design.
- **Reference**: (values were scaled with AD) [Contactless, Battery-free, and Stretchable Wearable for Continuous Recording of Seismocardiograms. (2021). ACS Applied Electronic Materials. https://pubs.acs.org/doi/10.1021/acsaelm.0c00768?ref=pdf]
  - A force of 1.5 N was applied to the boundary on the top while the bottom was fixated.



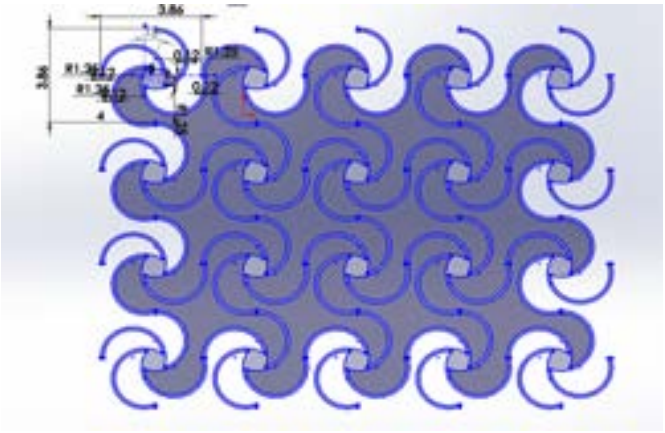
- **Expected result** = lower applied stress is expected with a higher AD value.
  - **Obtained result** = An AD 50% showed the minimum feasible parameters since with higher Ads the structure would have overlapped.
    - **A force of 1.5 Pa was applied to the boundary on the right of the design, with the same direction of the plane, while the left boundary was fixed.**

Calculations and results

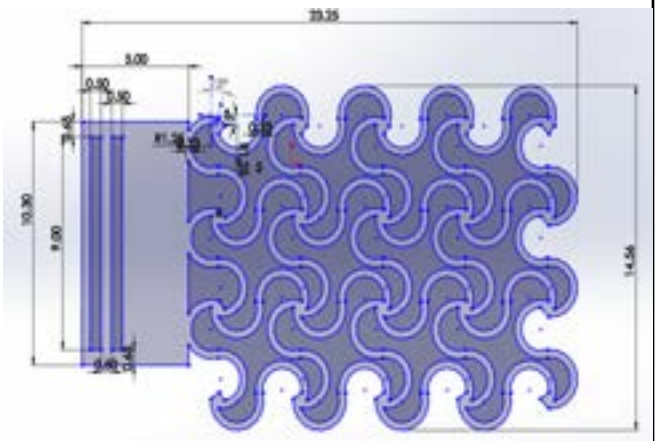
AD	10%	30%	40%	50%	60%	70%
Width (mm)	0.12	0.33	0.42	0.50	0.58	0.65

❖ Design

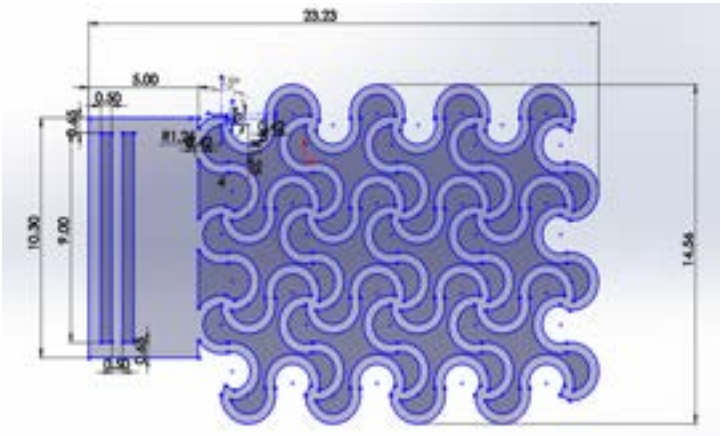
10%



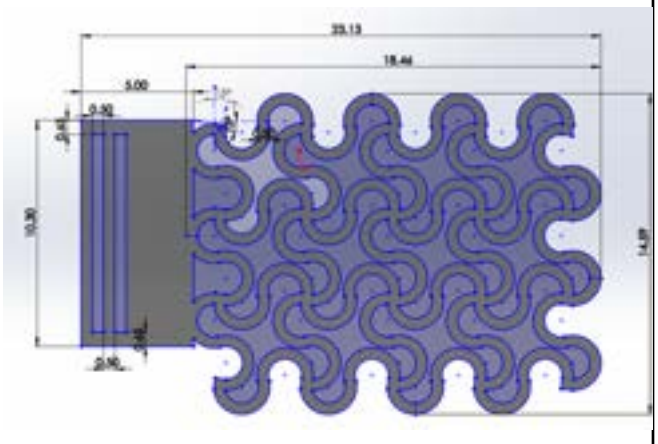
30%



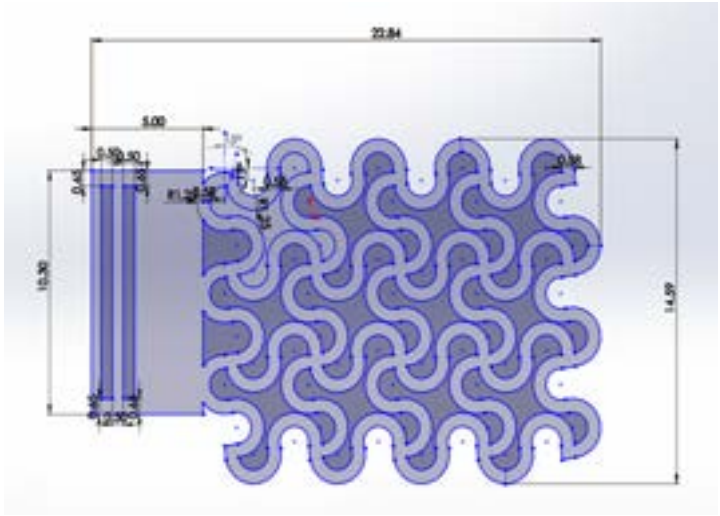
40%



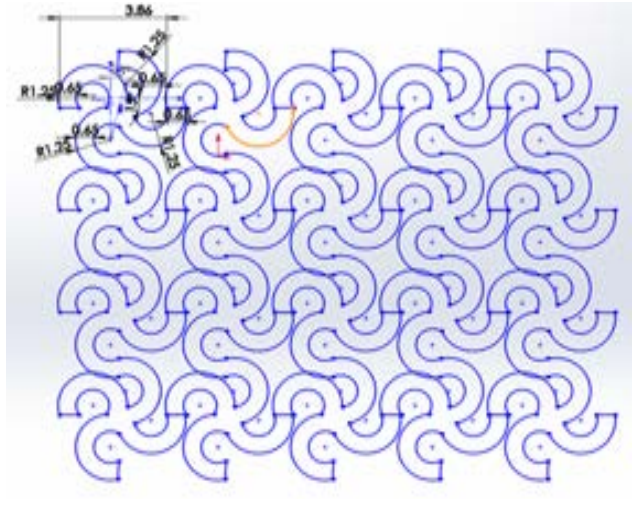
50%



60%

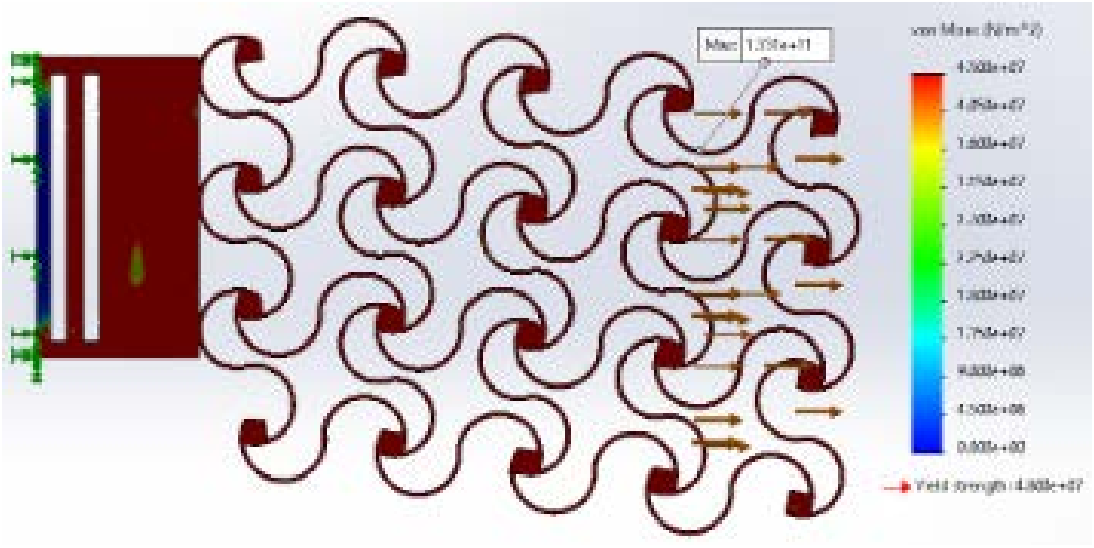
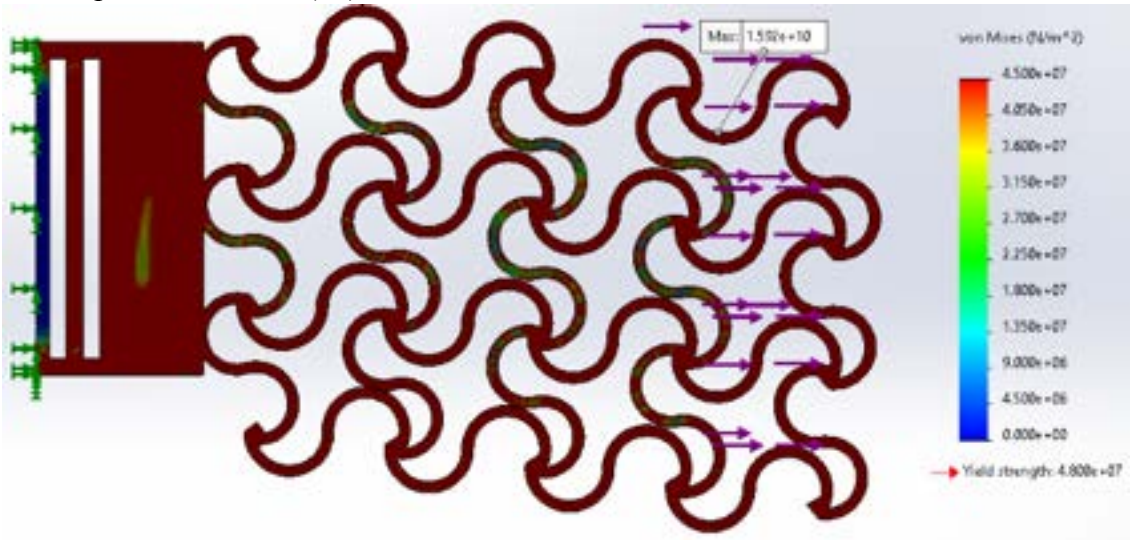


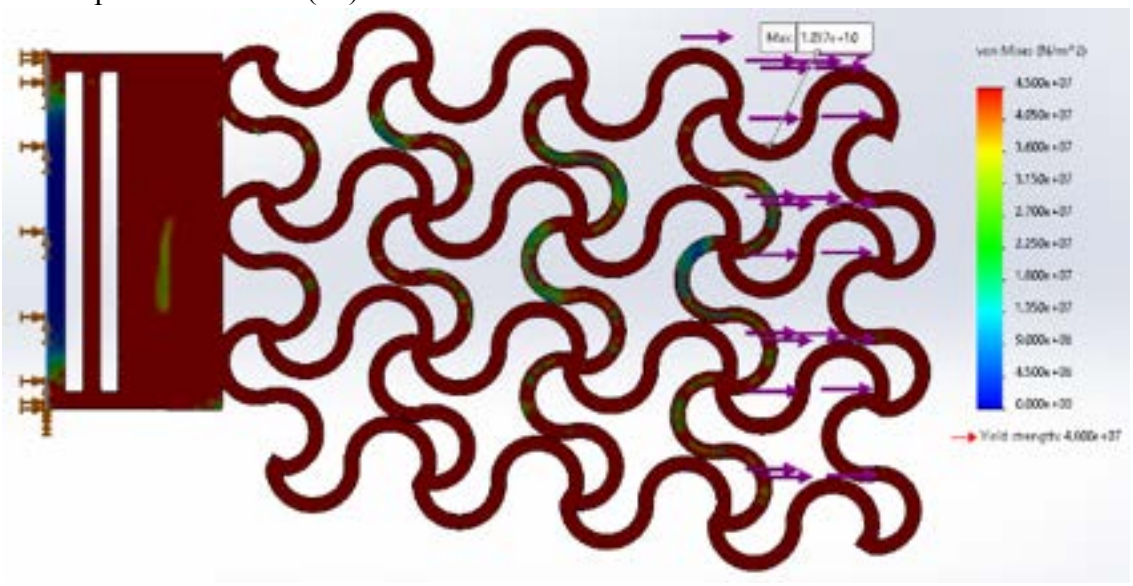
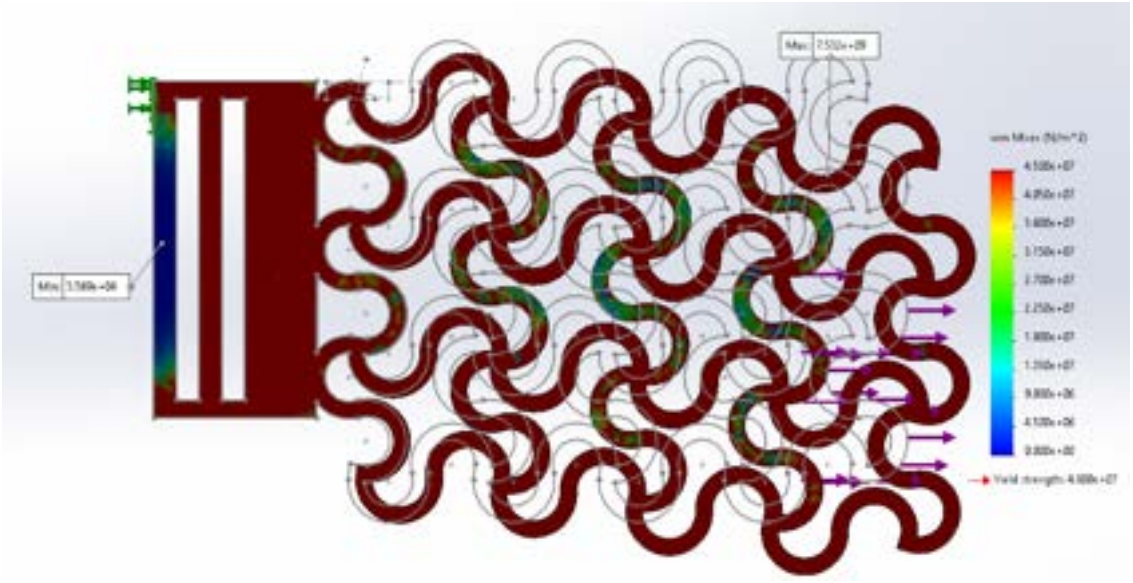
70%

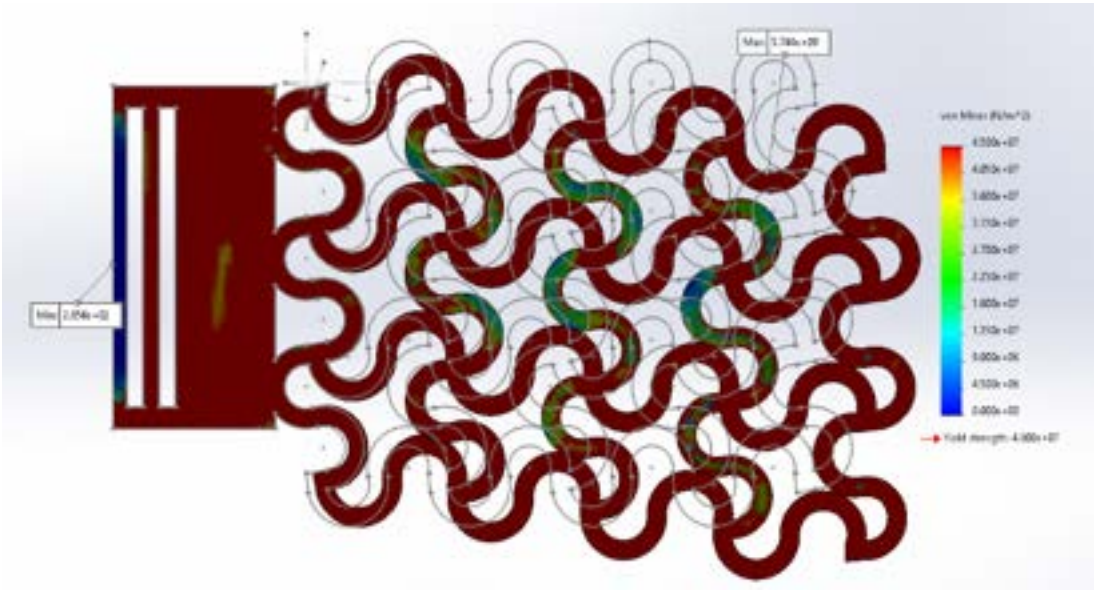
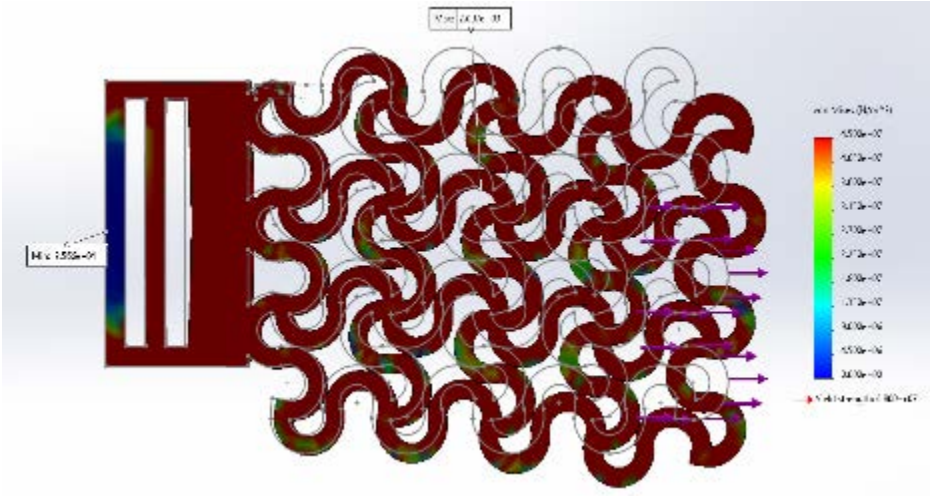


❖ Simulation

➢ Trend = as AD value increases, the maximum stress experienced decreases.

10%	Max experienced stress (Pa): 1.331e+11 
30%	Max experienced stress (Pa): 1.592e+10 

40%	Max experienced stress (Pa): 1.037e+10 
50%	Max experienced stress (Pa): 7.532e+09 

60%	Max experienced stress (Pa): 5.744e+09 
70%	Max experienced stress (Pa): 2.097e+09 

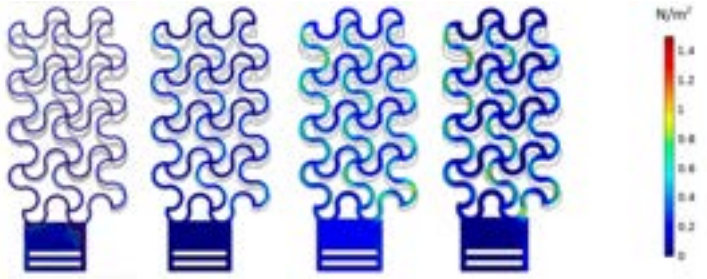
- *The scales were normalized with respect to the yield strength of PVDF, which is 4.8e+07 (the max stress was defined as 4.5e+07)

- The result matched the expected results. **An AD of 50% showed the least applied stress while showing no overlap, or clear proximity, of the outer circles.** The figure above shows how the pattern shifted during the simulation compared to the original pattern.

➔ ***February 14-25, 2022***

- **Objective**: Based on the results from the previous simulation, an AD of 50% was chosen. For these simulations three dimensions were compared to determine which dimensions showed the most stress-relieving structure.

- **Reference**: (values were scaled with AD) [Contactless, Battery-free, and Stretchable Wearable for Continuous Recording of Seismocardiograms. (2021). ACS Applied Electronic Materials. https://pubs.acs.org/doi/10.1021/acsaelm.0c00768?ref=pdf]
  - A force of 1.5 N was applied to the boundary on the top while the bottom was fixated.

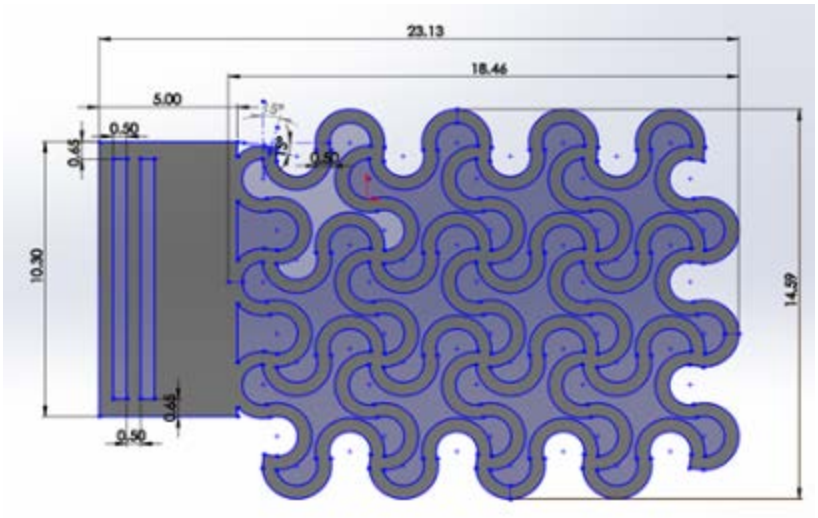
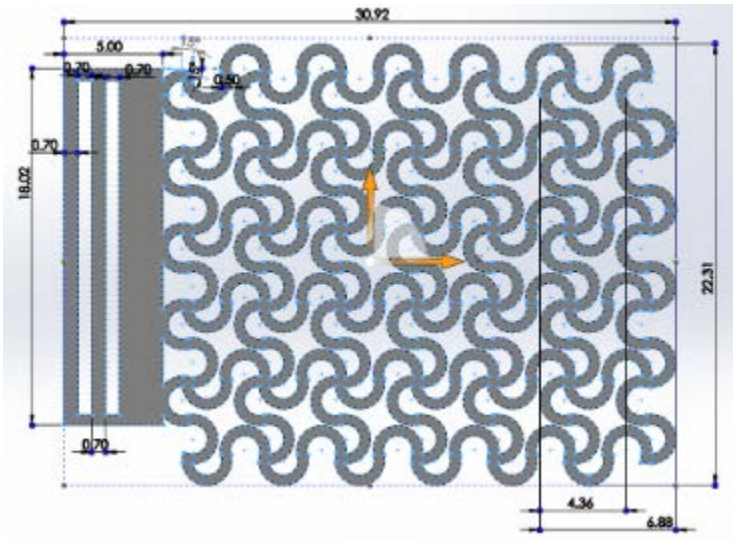


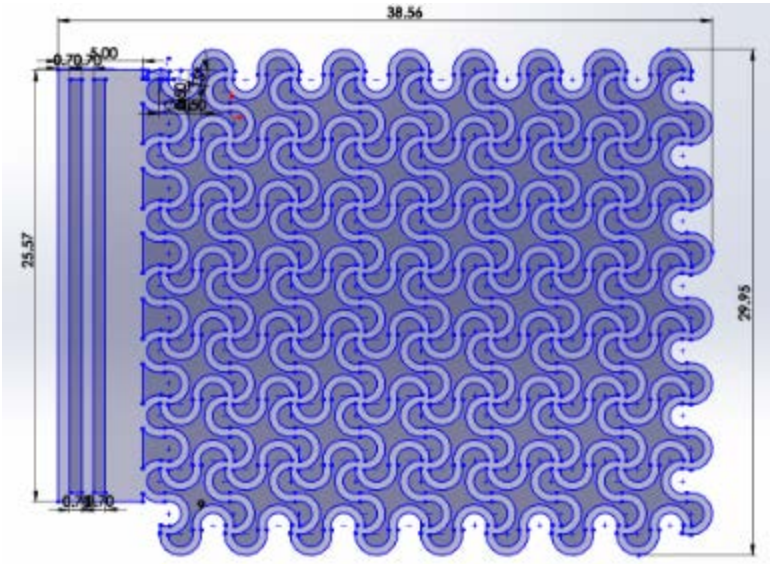
- **Expected result** = lower applied stress is expected with higher dimensions.
  - **Obtained result** = An dimension of 22.31mmX30.92mm [W(mm)xL(mm)] showed the lowest maximum experienced stress.
    - **A force of 1.5 N was applied to the boundary on the right of the design, with the same direction of the plane, while the left boundary was fixed.**

Calculations and results

	Repeating Unit [W x L]	Size [W(mm) X L(mm)]	Maximum Experienced Stress Value [N/m2]
Design 1	3x4	14.59 x 23.13	7.532e+09
Design 2	5x6	22.31 x 30.92	6.931e+09
Design 3	7x8	29.95 x 38.56	8.681e+09

❖ Design

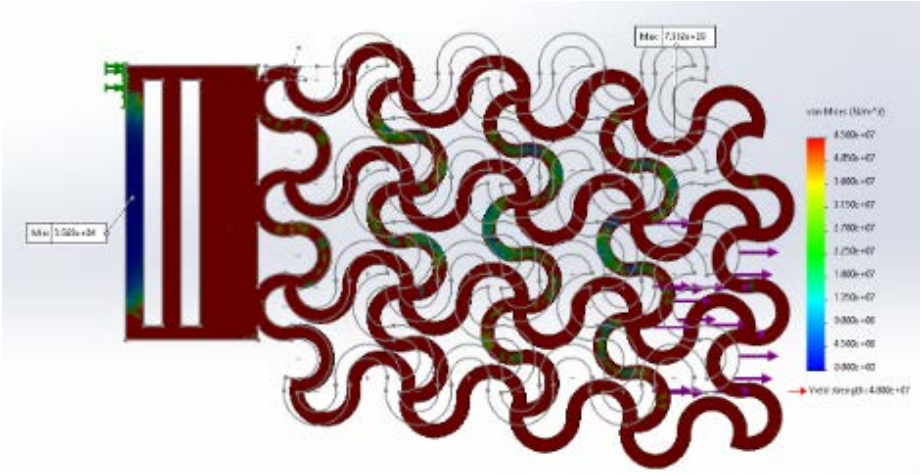
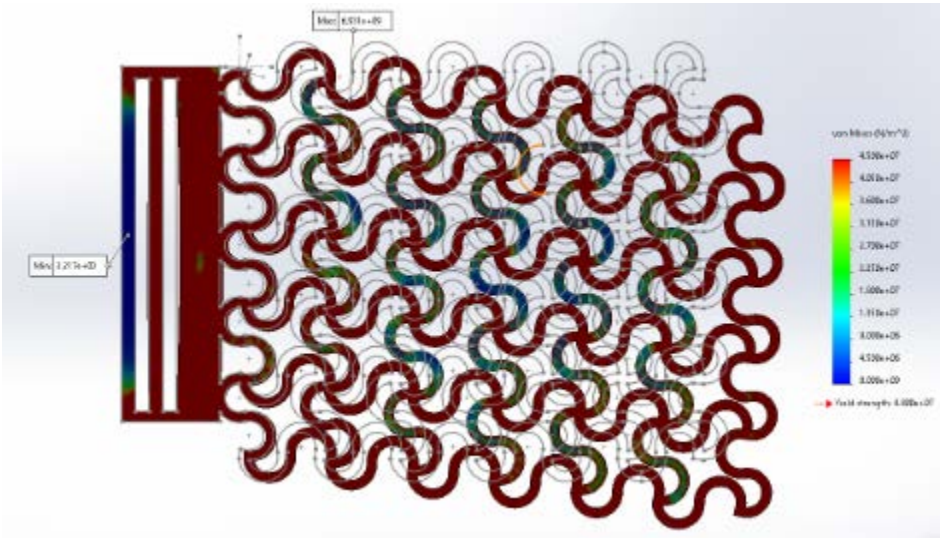
Design 1	
Design 2	

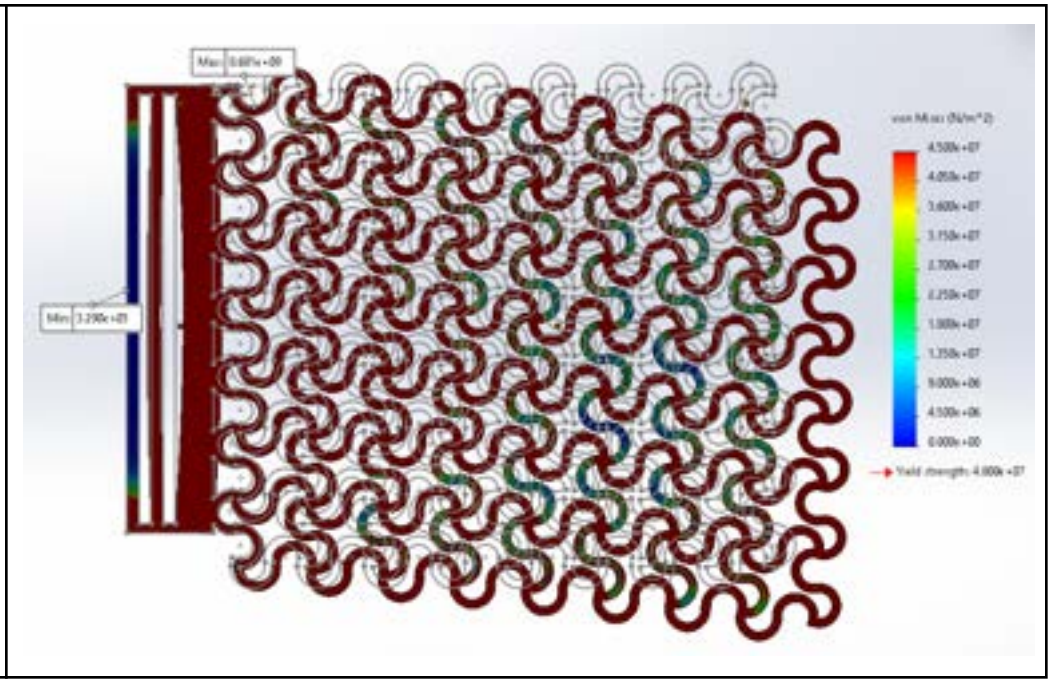
Design 3	

❖ Simulation

➢ Trend = as AD value increases, the maximum stress experienced decreases.

Design 1	Max experienced stress (Pa): 7.532e+09

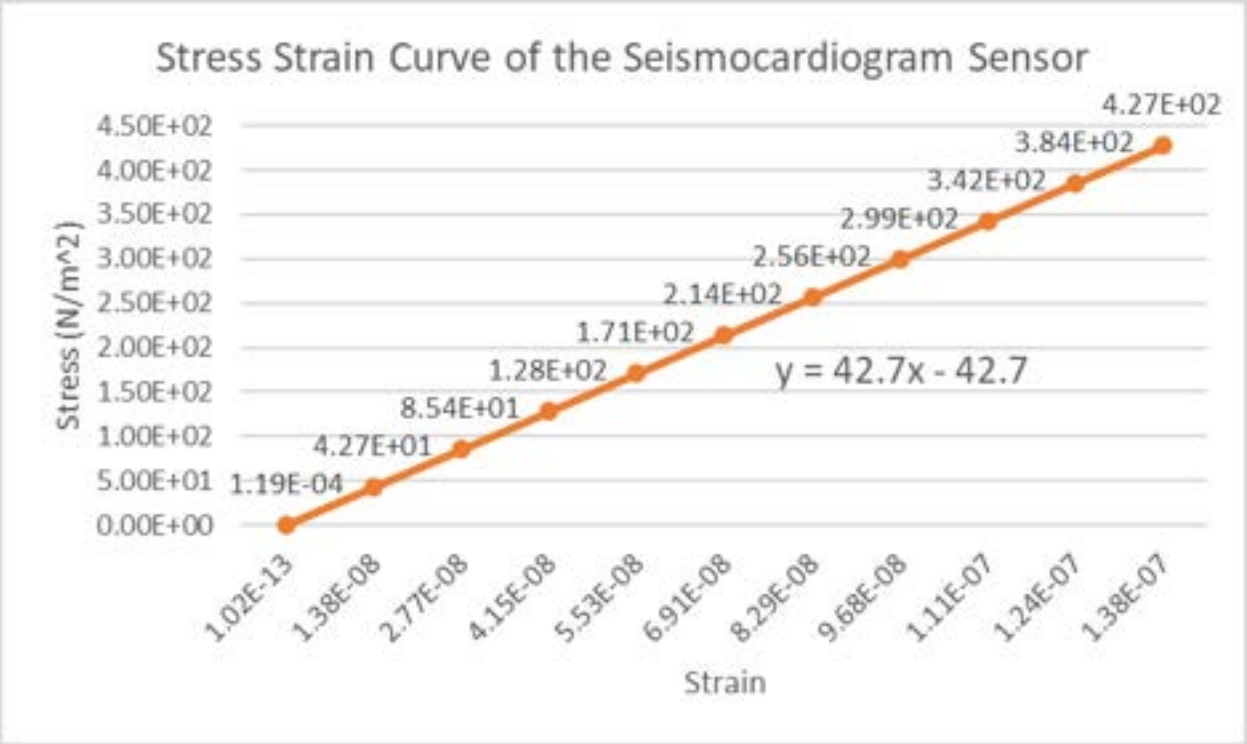
	
Design 2	Max experienced stress (Pa): 6.931e+09 
Design 3	Max experienced stress (Pa): 8.681e+09



- *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)

- All structures were stress relieving and provide stretchability [significantly higher than needed]. The size 22mmx31mm, with repeating units 5x6 [middle picture], was chosen for manufacture since it is within the width limitations and has the lowest max experienced stress value.

The above images are the results of a Solidworks simulation for a force of 1.5 N acting along the edges on the right side of the pattern. This simulation displayed that the most stress and strain are experienced along the inner curves of the pattern. In terms of displacement due to the location of the applied pressure, most displacements were expected on the left side of the pattern. This was supported by the results since a clear gradient was seen, with the left side having higher values than the fixed right side.



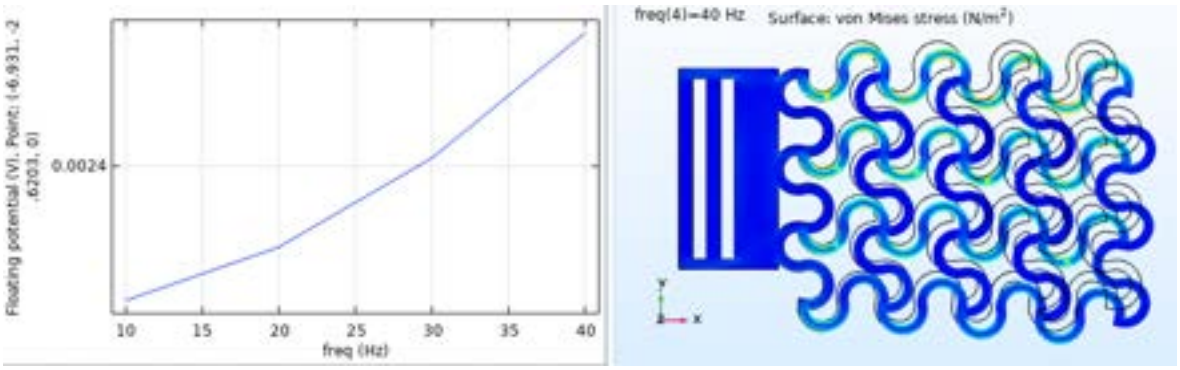
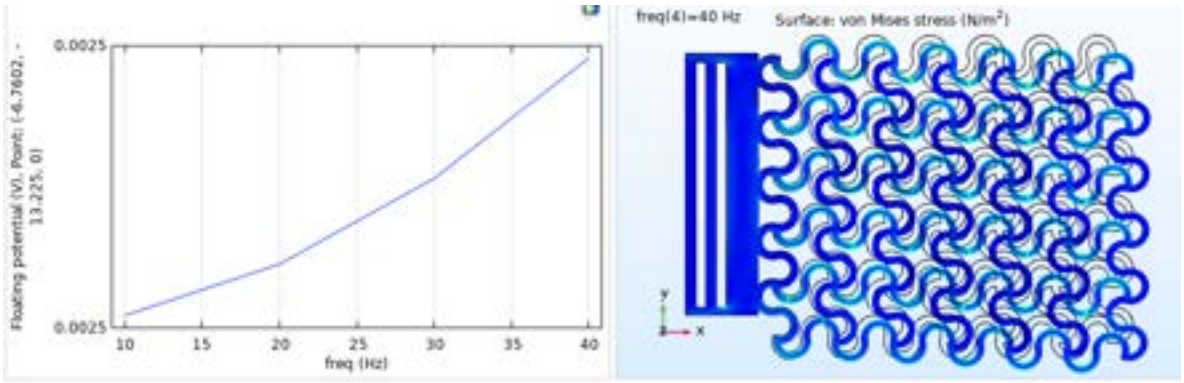
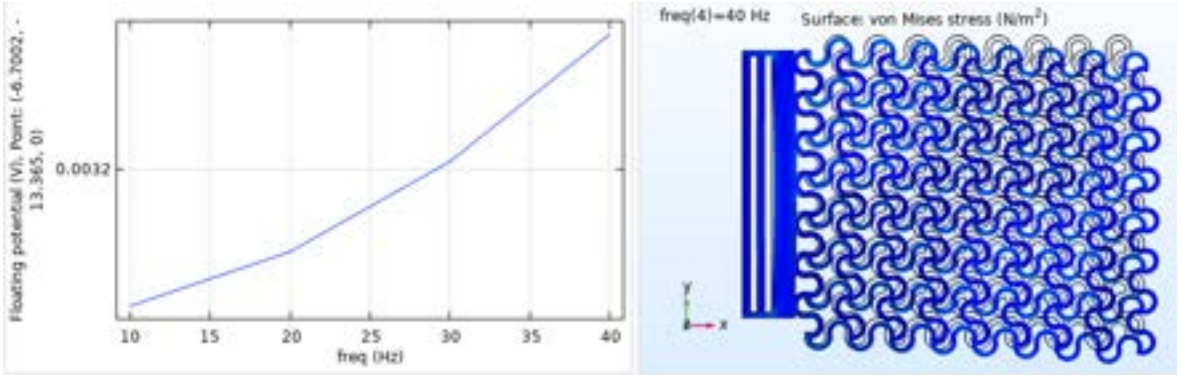
Using the stress and strain values resulting from the simulation, the following stress-strain curve was developed. This information was necessary to calculate the sensor's elastic modulus and compare its precision to that of skin. According to the graph, the patterned sensor has an elastic modulus of about 43 Pa, but from one of the previously stated design inputs, the young's modulus should range from 130 kPa to 20 MPa. Further simulations would need to be done in order to understand the source of error.

COMSOL PIEZOELECTRIC SIMULATIONS

- Using COMSOL, a force per area 1.5 N/m2 was applied to the SolidWorks design and the following voltages were produced,
  - The PVDF sensor dimensions 15 x 23 mm the voltage output was about 2.38 mV (top figure)
  - **Our PVDF sensor dimensions 23 x 31 mm the voltage output was about 2.49 mV (center figure)**
  - The PVDF sensor dimensions 30 x 39 mm the voltage output was about 3.20 mV (bottom figure)
- The analysis was similar to that of the mechanical analysis where a fixed boundary was placed on the far left face of the design and the applied load was on the outer far right curve. The floating potential was taken from the bottom face of the design to the top to simulate the electrical potential from the skin to the sensor.
- Hypothesis: Increasing the sensor's size wouldn't significantly improve its elasticity but it possibly can improve its voltage output
- As the size of the sensor increases, we do see a slight increase in the output voltage

➢ The voltage is still within the range given by design input #2

❖ Conclusion: Increasing the sensor size does increase its voltage output slightly but would need further testing for whether it provides significance to the device's functionality

Dimension: 15 x 23 mm	
Dimension: 23 x 31 mm	
Dimension: 30 x 39 mm	

COMSOL Piezoelectric Analysis Data Collection				
Patterned PVDF Sensor Size		Patterned PVDF Sensor		Patterned PVDF Sensor

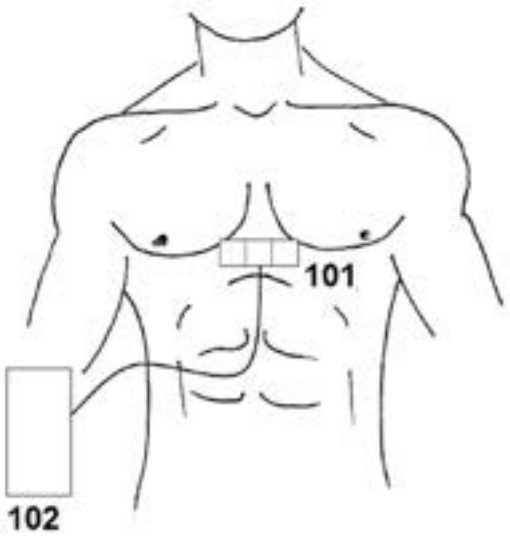
[15x23]			Size [23x31]			Size [30x39]	
Frequency (Hz)	Voltage Output (mV)		Frequency (Hz)	Voltage Output (V)		Frequency (Hz)	Voltage Output (V)
10	2.3811		10	2.4892		10	3.2019
12	2.3812		12	2.4894		12	3.2023
14	2.3812		14	2.4896		14	3.2028
16	2.3814		16	2.4898		16	3.2034
18	2.3815		18	2.4901		18	3.204
20	2.3816		20	2.4904		20	3.2047
22	2.3817		22	2.4907		22	3.2055
24	2.3819		24	2.4911		24	3.2064
26	2.3821		26	2.4915		26	3.2073
28	2.3822		28	2.4919		28	3.2083
30	2.3824		30	2.4924		30	3.2094
32	2.3827		32	2.4928		32	3.2106
34	2.3829		34	2.4934		34	3.2118
36	2.3831		36	2.4939		36	3.2131
38	2.3834		38	2.4945		38	3.2145
40	2.3836		40	2.4951		40	3.216

Section 4.2 - Prototype Sub-System Tests

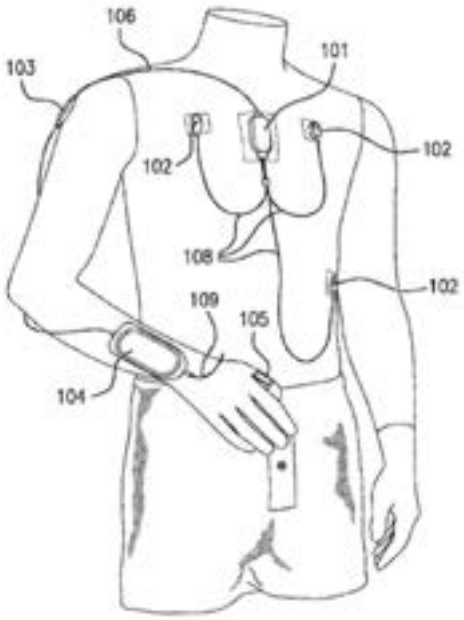
**The project prototype is composed of only one system that needs to be designed. Hence this section was intentionally left blank.*

Section 4.3 - Patent Search Results

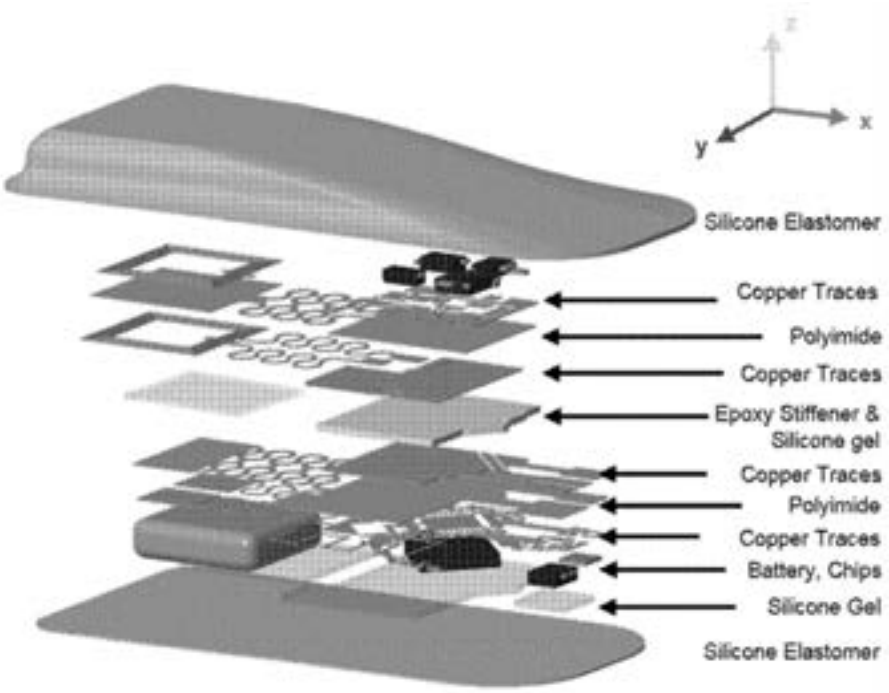
- Method and apparatus for estimating myocardial contractility using precordial vibration. (US20150038856A1). [3]
    - Published: 2015
    - Assignee: Heart Force Medical Inc, Vancouver (CA)
    - Abstract: A method and apparatus for assessment of cardiac contractility in a subject by recording precordial acceleration signals. This includes, but is not limited to, the method and apparatus of seismocardiography (SCG).



- Body-worn system for continuous, noninvasive measurement of vital signs. (US20210177281A1) [5].
    - Published: 2021
    - Assignee: Sotera Wireless, Inc., San Diego, CA (US)
    - Abstract: The invention provides methods and systems for continuous noninvasive measurement of vital signs such as blood pressure (cNIBP) based on pulse arrival time (PAT). The invention uses a body-worn monitor that recursively determines an estimated PEP for use in correcting PAT measurements by detecting low-frequency vibrations created during a cardiac cycle, and a state estimator algorithm to identify signals indicative of aortic valve opening in those measured vibrations.



- Wireless medical sensors and methods. (US20210113099A1) [4].
    - Published: 2021
    - Abstract: Provided herein are medical sensors and related methods for measuring a real-time personal metric. The medical device may comprise an electronic device having a sensor comprising an accelerometer and a bidirectional wireless communication system electronically connected to the electronic device for sending an output signal from the sensor to an external device and receiving commands from an external controller to the electronic device.



- Cardiac Performance monitoring system for use with mobile communications devices. (US8700137B2) [1].
    - Published: 2014
    - Assignee: AliverCor, Inc. San Francisco, CA (US)
    - Abstract: Described herein are apparatuses (e.g., devices, systems, software), and methods for monitoring the cardiac health of a patient. The apparatuses and methods may include a smartphone or handheld computing device having an accelerometer. The apparatus may also include a device with a plurality of electrodes integral with or attached to the smartphone. The devices can be placed on a patient's chest to measure electrical signals and vibrations on the chest caused by the heartbeat. The measurements can generate a seismocardiogram (SCG) and in some variations an electrocardiogram (ECG). The apparatuses and methods can analyze the data in the SCG to produce a measure of cardiac function. Changes in such measures can provide an early warning for potential cardiac problems and signal the need for the patient to seek treatment before a fatal cardiac event.

- System and method for indicating coronary artery disease risk based on low and high-frequency bands. (US9451921B2) [2].
    - Published: 2016
    - Assignee: Acarix A/S, Lyngby (DK)

- Abstract: A system and method for diagnosing coronary artery disease (CAD) comprise an acoustic sensor to be placed on the chest of a patient to generate acoustic signals SA: a control unit adapted to receive said acoustic signals SA, the control unit comprising: an identification unit to identify diastolic or systolic periods in a predetermined period and to generate a period signal SP; a filtering unit adapted to apply a filter to said identified periods to generate a low-frequency band signal SLFB and a high-frequency band signal SHFB of said identified periods; and a calculation unit, to calculate a low-frequency power measure SLFP and a high-frequency feature measure SHFF. A risk-determining unit provides a risk-of-CAD signal based on the low-frequency power measure and the high-frequency feature measure. The invention also relates to a stethoscope and a method for the detection of low-frequency power.

Section 4.4 - Animal and/or Cadaver Tests

The project scope does not include any animal and/or cadaver tests. Hence this section was intentionally omitted.

Section 4.5 - ALT Results

This was not applicable to the project scope hence this section was intentionally left blank.

Section 4.6 - Reliability Determination

This section was intentionally left blank.

References

[1] *US8700137B2 - Cardiac performance monitoring system for use with mobile communications devices - Google Patents*. (2013, August 30). Google.com. https://patents.google.com/patent/US8700137B2/en?oq=US8700137B2

[2] *US9451921B2 - System and method for indicating coronary artery disease risk based on low and high-frequency bands - Google Patents*. (2015, May). Google.com. https://patents.google.com/patent/US9451921B2/en?oq=US9451921B2

[3] *US20150038856A1 - Method and apparatus for estimating myocardial contractility using precordial vibration - Google Patents*. (2012, May 2). Google.com. https://patents.google.com/patent/US20150038856A1/en

[4] *US20210113099A1 - Wireless medical sensors and methods - Google Patents*. (2019, February 15). Google.com. https://patents.google.com/patent/US20210113099A1/en?oq=US20210113099A1

[5] *US20210177281A1 - Body-worn system for continuous, noninvasive measurement of vital signs - Google Patents*. (2020, December 7). Google.com. https://patents.google.com/patent/US20210177281A1/en?oq=US20210177281A1

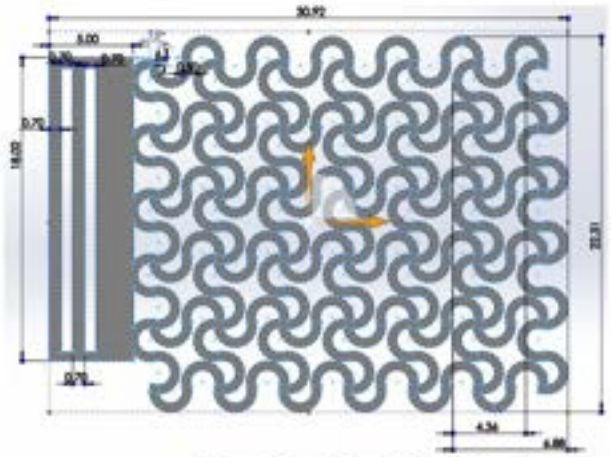
Section 5 - Design Outputs

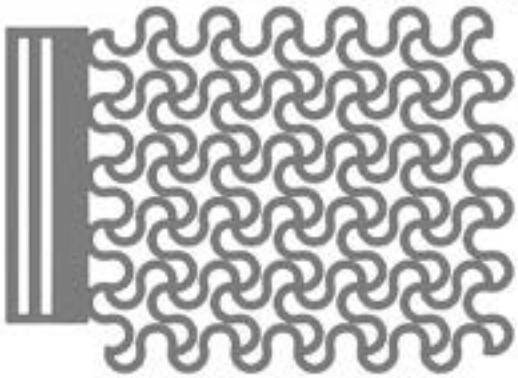
Section 5.1 - Engineering Drawings

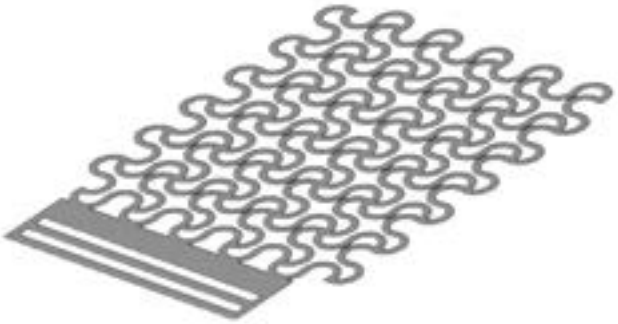
Seismocardiogram Sensor

FIU Senior Design Team 1 – Spring 2022

[Measures in mm]







Section 5.2 - Material Specifications

➔ ***March 6, 2022***

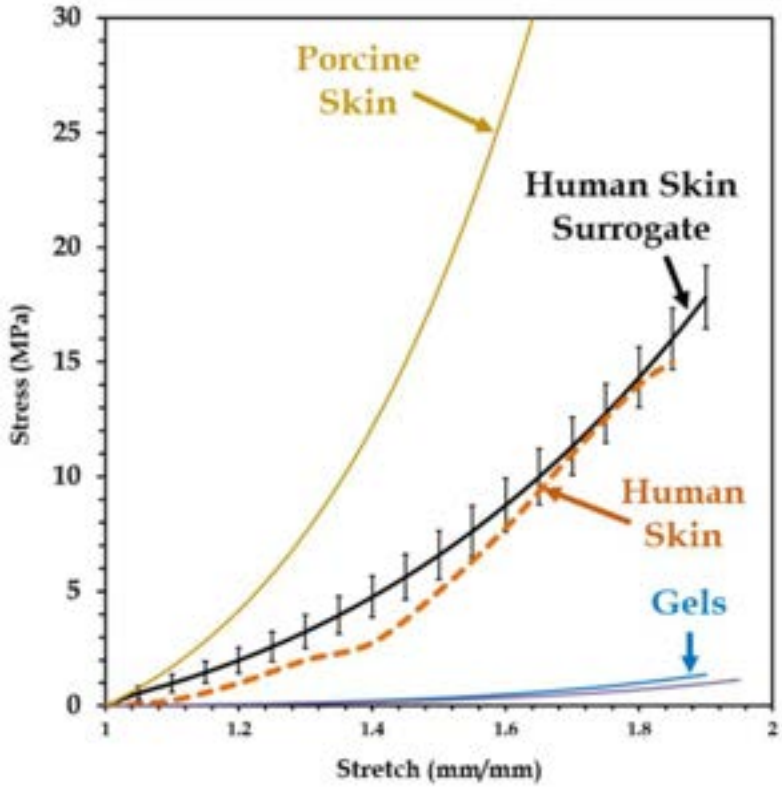


Fig. Surrogate human skin model which is a better model in artificial pulses simulation, testing PVDF sensitivity to SCG signals.[1]

Fig. Artificial skin with 3 layers epidermis, dermis, and subcutaneous.[2]

Piezoelectric Analysis:

Property	Unit	Materials		
		PVDF	PZT	Quartz
Density	kg/m3	**1780**	7600	2650
Young's Modulus	GPa	**2-4**	63	77
Electromechanic Constant	Unitless	0.12	0.36	0.10
Tensile Strength	MPa	**53.5**	28	48
Piezoelectric voltage constant	Vm/N	0.12	12.4	0.5
Piezoelectric constant	pC/N	23	175	2.3

Table. Piezoelectric polymers which can be used as transducers as well. [3][4]

Materials	Application
PVDF	Sensing
Silver Ink	Screen printing the sensor
Weak Adhesive Tape (3M-582U)	Placing the metalized PVDF on the cutting board
Medical Grade Tape (Tegaderm)	One-sided tape as a substrate to encase the PVDF
Artificial Human Skin	Biomechanical modeling of human skin
Medical Grade Adhesive Spray	Adhere sensor to artificial human skin

Table. Materials required to fabricate the PVDF and place on skin/artificial skin

➔ *April 14, 2022*

Piezoelectric Analysis:

Property	Unit	Materials		
		PVDF	PZT	Quartz
Density	kg/m3	**1780**	7600	2650
Young's Modulus	GPa	**2-4**	63	77
Electromechanic Constant	Unitless	0.12	0.36	0.10
Tensile Strength	MPa	**53.5**	28	48
Piezoelectric voltage constant	Vm/N	0.12	12.4	0.5
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Silver Ink	Screen printing the sensor
Weak Adhesive Tape (3M-582U)	Placing the metalized PVDF on the cutting board
Medical Grade Tape (Tegaderm)	One-sided tape as a substrate to encase the PVDF

Table. Materials required to fabricate the PVDF sensor

*Due to issues with the product being back-ordered, the artificial skin do not arrive on time to be used for testing so it was removed from the scope

Section 5.3 - Procedures

Screen-Printing Procedure

1/28/22

1. Cut a 28 um PVDF film in 20x20 cm2
2. Place the film on a paper.
3. Smear the silver ink evenly on the film until there is no excess ink or blank spots on the film.
4. Place the film and the paper (to cure) in the oven at 60C for 9-10 hours.
5. Repeat the same procedure for the other side of the film.

Two sheets were prepared, the same procedures were followed for the other side of the films on 1/29/22.

- The cured film was wrinkled and rolled over.
- Resistance was uneven throughout the pattern.

- The circuit was not isolated on both sides of the.

2/8/22

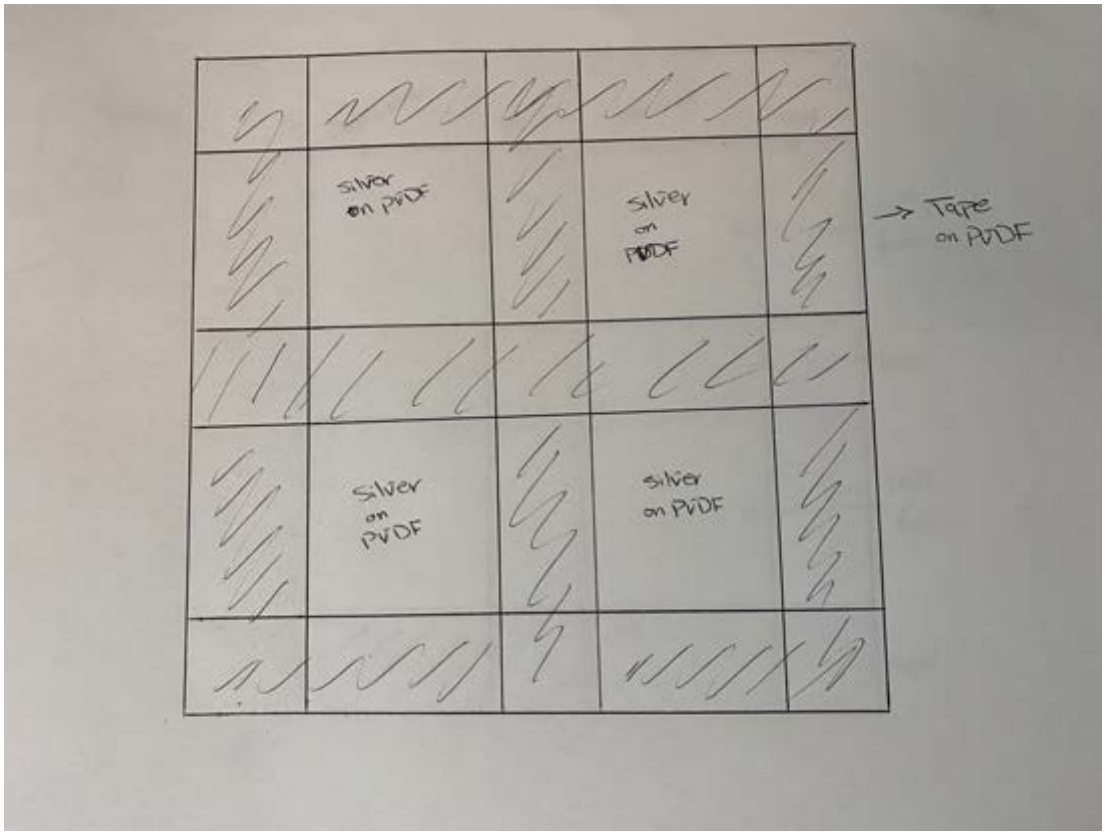
1. Cut a 28 um PVDF film in 18x18cm.
2. Place the film on a paper and tape each side of the film to the paper to secure it.
3. Smear the silver ink evenly on the film until there is no excess ink or blank spots on the film.
4. Place the film and the paper (to cure) in the oven at 50C for 16-17 hours.
5. Repeat the same procedure for the other side of the film.

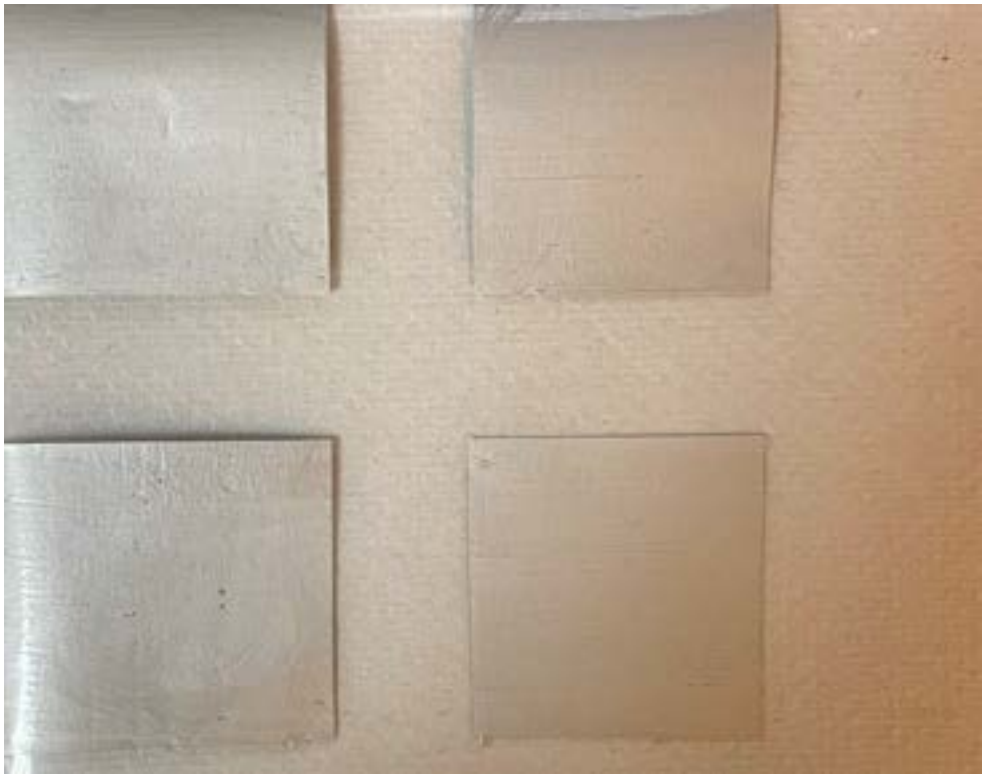
- Surface was more even and straight.

- Back and front circuit was open and continuous.
- Continuous circuit on each side.

2/14/22

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.





- One sample was closed circuit but others were open circuit.
- Faced issues during cutting the samples, realized the blade had silver residue on it.

2/28/22

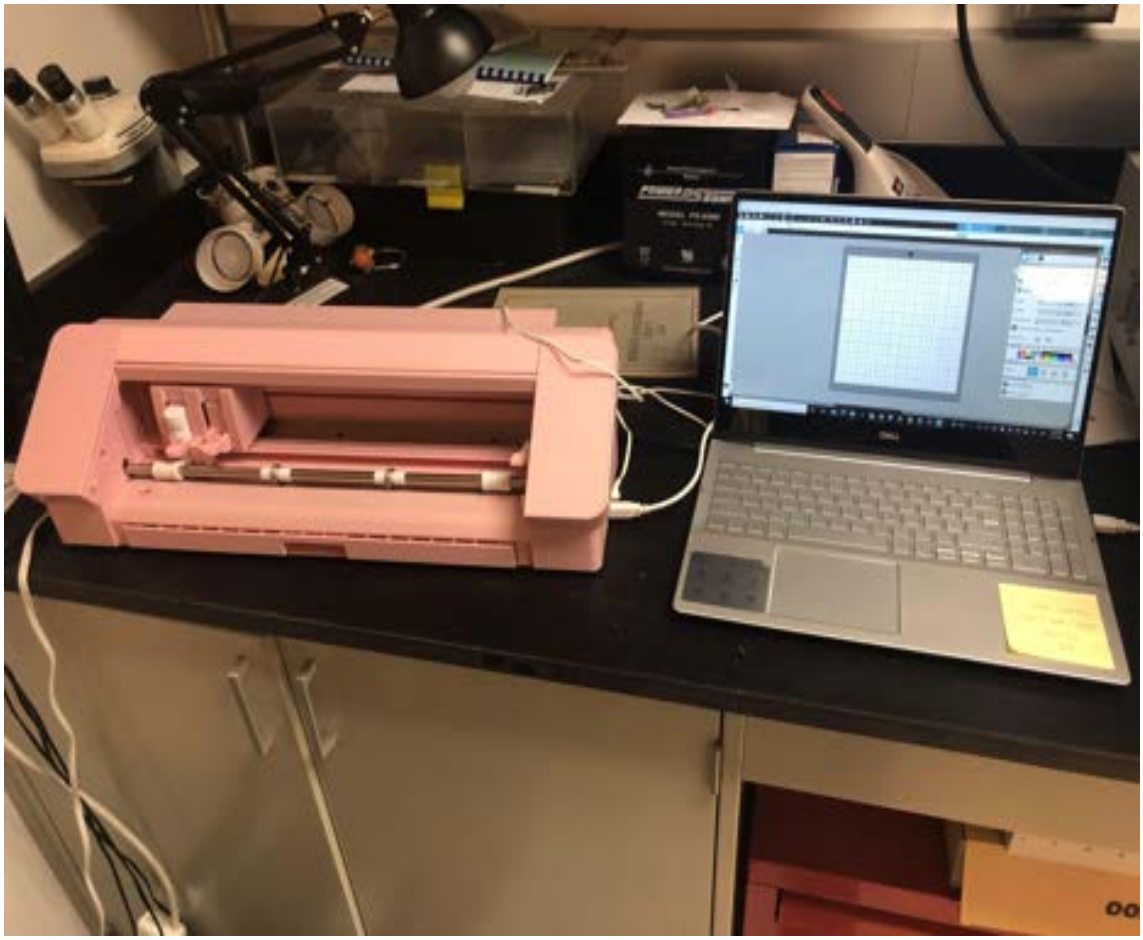
1. Cut a 28 um PVDF film in 12x12cm.
2. Place the film on a paper and tape each side of the film to the paper to secure it.
3. Smear the silver ink evenly on the film until there is no excess ink or blank spots on the film.
4. Place the film and the paper (to cure) in the oven at 50C for 16-17 hours.
5. Repeat the same procedure for the other side of the film.

Two sample films were prepared and on 3/1/22 the other side of the films were cured.

Cutting Procedure:

Trial #	Blade Depth	Speed	Passes	Force	PVDF Cut Through Without Cutting the tape ?
1	1 mm	5 cm/s	5	10 N	No, cut the tape too
2	2 mm	5 cm/s	5	10 N	No, cut the tape too
3	2 mm	5 cm/s	1	10 N	No, cut the tape too
4	1 mm	5 cm/s	3	10 N	No, cut the tape too
5	3 mm	1 cm/s	5	10 N	Yes, PVDF was almost cut through
6	**3 mm**	**1 cm/s**	**6**	**10 N**	**Yes**

1. Obtain a sample of metallized PVDF and place onto the weakly adhesive side of the medical tape.
2. Gently place medical tape with metallized PVDF onto the cutting board; Make sure to place onto board gently and smoothly to not produce any air bubbles.
3. Slide cutting board into cameo silhouette machine. Press the “Up arrow” on the machine to feed the cutting board into the machine.
4. Open Cameo Silhouette software on computer.
5. Download PVDF shapes that will be cut.
6. Adjust dimensions of material to users needs.
7. Apply setting to cut 28 um thick PVDF (Blade Depth=2, Speed=1, Force=10)
8. Run the machine
9. When the machine finishes, press the “Down arrow” to eject the cutting board.
10. Separate the PVDF material from the medical tape using a small pair of tweezers



LAB Data 1/27/22

-Begin setting up the CAMEO 4
  - Added blades, and software
-Since it's the first lab, tried different setting
  - Devices to use Vinyl setting to cut PVDF (Force = 10, Speed = 5)
-Tried to cut PVDF into a baseball (to test the limit of how precise the machine is)
with various blade depths (2,3,4)
-Realized the blade wasn't placed correctly
  - Fixed blade positioning, and noticed Blade Depth above 1 was cutting into the board.
-Tried cutting the PVDF with the weakly adhesive tape attached
- Using blade depth 1, Force 10, Speed 5, we noticed that the PVDF wasn't cutting all the way through
  - Kept blade depth at 1 but increased number of passes to 3
  - PVDF didn't cut through completely but with additional force from hand, the design came out perfectly
  - Acquired PVDF Baseball

LAB Data 2/2/22

-Begin with 28um PVDF and 582U tape

- 1st trial with leaf design
  -Design looked successful but machine jammed
  - Blade depth 1 and 5 Passes, Force= 10, Speed = 5
- 2nd trial with hot air balloon
  - Blade depth 1 and 5 Passes, Force= 10, Speed = 5
  - Half of the PVDF remained and other half did not cut through properly
- 3rd trial, this time just a geometric circle shape with a spiral to test blade depth.
  - Blade depth 2 and 5 Passes, Force= 10, Speed = 5
  - Blade depth 2 allows for complete cut of PVDF, however also cuts through the tape
- 4th trial, Repeat
  - Same Result
- 5th trial, same as 3, but with only 1 pass.
  - Same result
- 6th trial, 1 blade depth, 3 passes and only PVDF material
  - Almost cut through completely
- 7th trial, same as 6 but 5 passes
  - Almost cut through completely

- Conclusion, cutting without tape is easier and increasing Passes will ultimately result in the desired cut

LAB Data 2/10/22

Begin trials with metallized PVDF with Silver

- From knowledge from E-tattoo paper, setting are changed to Blade depth 2, Speed 1, Force 10 (default)

, and passes to 5

trial 1

- Success, able to cut out PVDF pattern
- Also able to remove tape from PVDF as well, with a bit of work

trial 2: increase pass number to 6 for easier removing of the tape

- Success, much easier to remove PVDF from tape.

trial 3: trying without tape, placed on paper

- Failed, the paper was too thick and messed up the design.

Measuring Capacitance

- Using a 1 * 1 cm square of metallized PVDF and copper tapes

Testing if Voltage would change capacitance

- 20 uA and 1 Khz

Capacitance measurements

- 1V = 9.16 pF
- 2V = 9.16 pF
- 3V = 9.18 pF
- 10V = 9.18 pF
- 20V = 9.17 pF

Average = 9.17 pF

- Measured Resistance of trial 1
  - Noticed that one side was open when it should have been closed
    - Possible error due to cutting or in curing.
- Measured Resistance of trial 2
  - Better, but similar result.

LAB Data 2/15/22

Cut two samples in different sizes of 40.34x29.11 mm and 65.13x47mm.
Blade depth 3, force 10, pass 6, speed 1.

LAB Data 02/16/22

Wanted to test if CAMEO can cut small enough sample for PVDF (22.31 mm W, 30.92 mm L)

- Trail 1, using paper to not waste PVDF
  - Shape was successful, however paper is not a good example to use (easily broke)

Metalized more PVDF

-Applied Silver ink to 2nd side of 1 sheet

-Applied Silver ink to 1st side of another sheet for more samples
-A Lab member will place them in the oven @ 50 degrees C for ~17 hrs.
-Thursday @ 4 Antonio and Haniyeh will remove samples from the oven to begin cutting.

LAB Data 02/17/22

Acquired 2 PVDF samples, one with both sides metallized and a smaller one with only one side metallized
- Noticed that smearing silver ink is not very effective as it leaves gaps in the PVDF
- Considering buying PVDF already metallized

Will cut out a few samples of PVDF from the 2-sided metalized PVDF

Trial 1: Cut out of 23.12 mm W and 14.59 mm L, Blade depth 2, Speed 1, Force 10 (default), and passes to 6
- There is a possible error point on one of the serpentine designs but otherwise came out clean and with no problems.

Testing for closed and open connections

- Same problem as last time, with a closed surface when there shouldn't be
-Possible error due to incomplete smearing.

Trial 2: Cut out of 30.92 mm W and 22.31 mm L, Blade depth 2, Speed 1, Force 10 (default), and passes to 6
-Hard to remove without breaking PVDF but still able to remove tape.

Testing for closed and open connections

- Same problem as last time, with a closed surface when there shouldn't be

Trial 3: Cut out of 30.92 mm W and 22.31 mm L, Blade depth 2, Speed 1, Force 10 (default), and passes to 6
-Success

Testing for closed and open connections

- Same problem as last time, with a closed surface when there shouldn't be

-Decided that the curing was the issue, as some of the surface of the original sheet was not open.

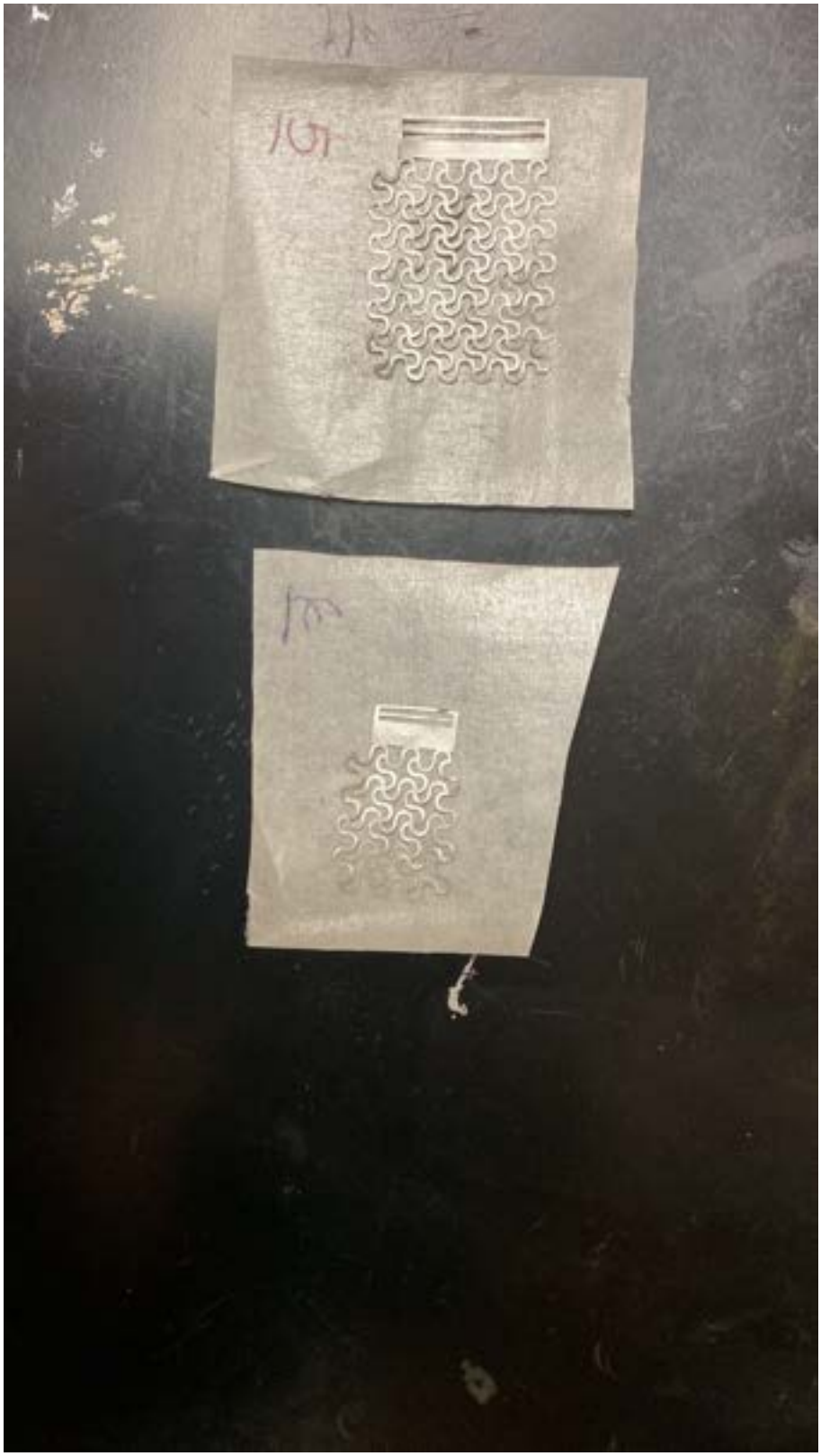


Fig. Sample 5 is the actual size and sample 6 is the prior pattern size.

Fig. Different trials and sizes of the sensor.

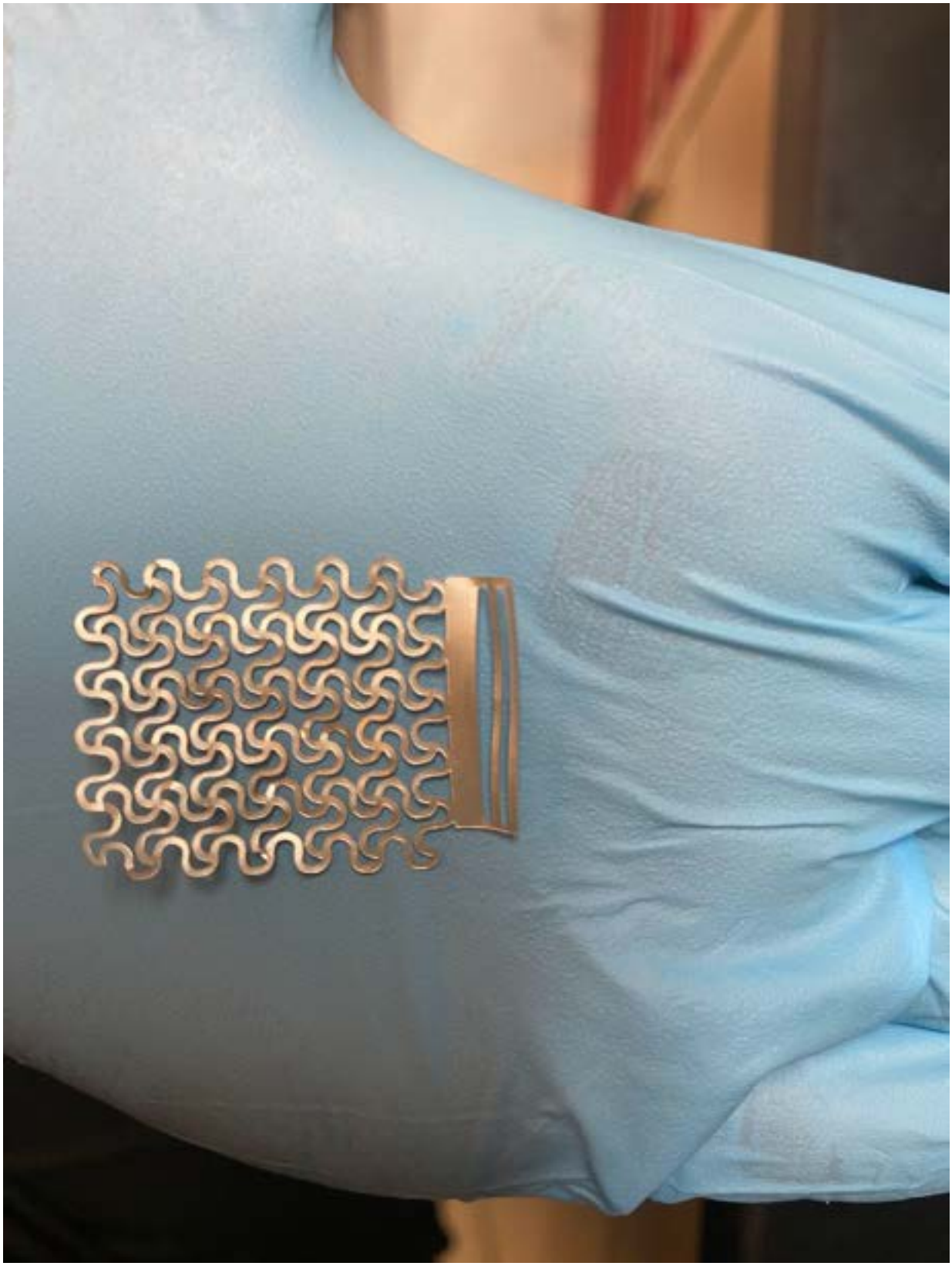
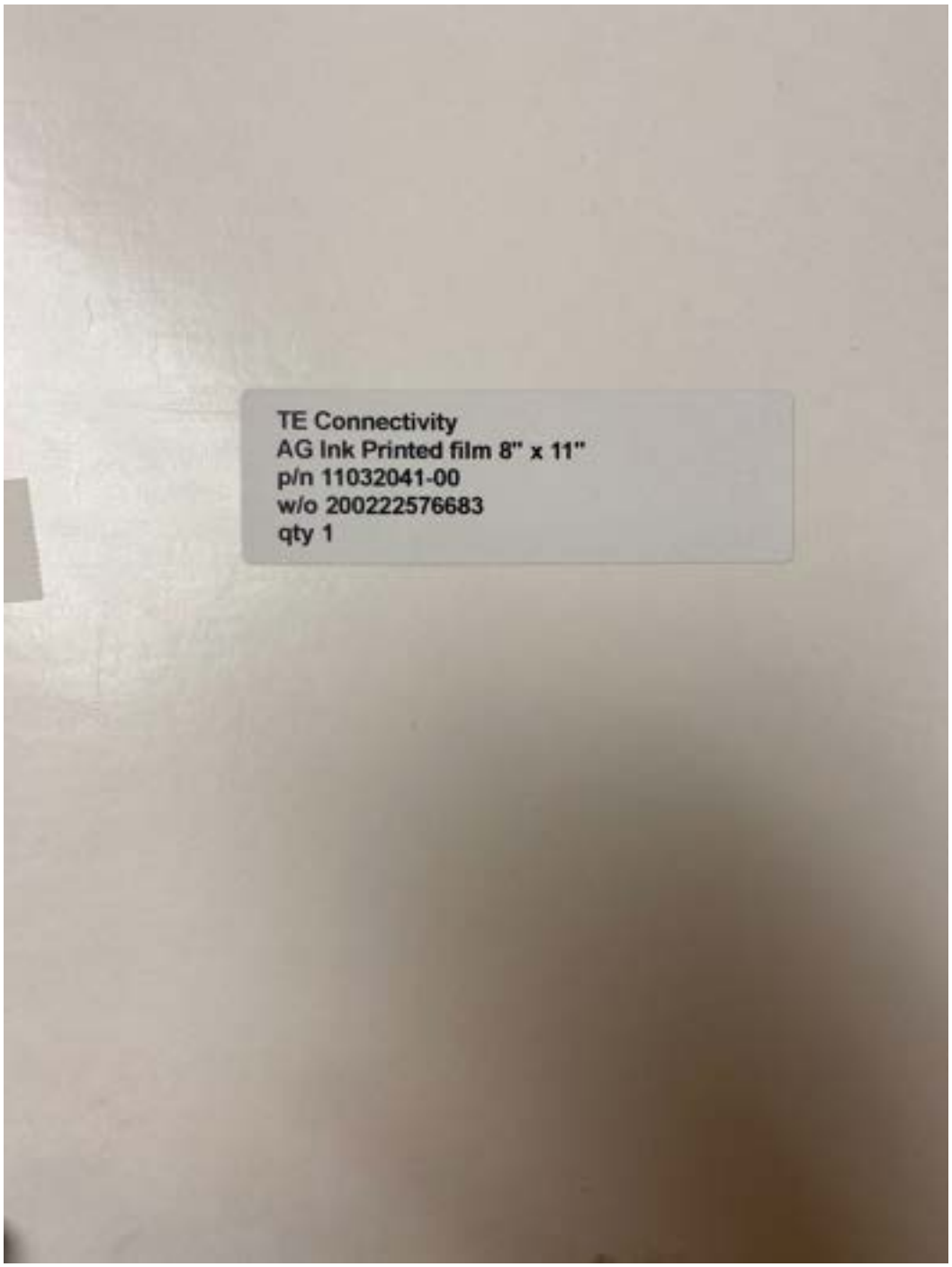


Fig. The actual size of the sensor.

As an alternative/secondary manufacturing method, a commercially available silver screen-printed PVDF film was purchased by the sponsor, Jabil. A few attempts were made to cut the design with Cameo machine on this film, but the attempts were unsuccessful.



Total samples & their serial numbers:

Image				
Part Number	S1-1	S1-2	S2	S3
Dimensions [W(mm) x L(mm)]	29.58 x 46.87	29.58 mm x 46.87	29.11 mm x 40.34	47 mm x 65.13
Electrically Functional? (Y/N)	N	N	N	N
Notes	Conversion from (in) to (mm) in wrong scale in the software. Adjusting cutting settings.	Conversion from (in) to (mm) in wrong scale in the software. Adjusting cutting settings.	Conversion from (in) to (mm) in wrong scale in the software. Adjusting cutting settings.	Conversion from (in) to (mm) in wrong scale in the software. Adjusting cutting settings.

Image					
Part Number	S4-1	S4-2	S4-3	S4-4	S4-5
Dimensions [W(mm) x L(mm)]	22.3 x 31.3	22.6 x 32.1	22.7 x 30.5	22.1 x 30.9	21.9 x 30.9

Electrically Functional? (Y/N)	N	N	Y	N	N
Notes	Optimal setting cut. No damage to the design. Un-patterned PVDF not electrically functional.	Optimal setting cut. No damage to the design. Un-patterned PVDF not electrically functional.	**MVP**	Electrically functional electrically functional but design didn't cut well. Difficulties removing the mesh.	Electrically functional electrically functional but design didn't cut well. Difficulties removing the mesh.

Image					
Part Number	S5-1	S5-2	S6	S7-1 → S7-6	S7-7
Dimensions [W(mm) x L(mm)]	14.6 x 23.7	14.8 x 23.5	NA	NA	NA
Electrically Functional? (Y/N)	N	N	N	N	N
Notes	Out of curiosity, testing the capability of the machine for cutting smaller samples and details	Out of curiosity, testing the capability of the machine for cutting smaller samples and details. Design broke.	The machine started giving difficulties in cutting samples. Needed to purchase a new blade	Commercial metallized PVDF to obtain electrical functional samples. Attempted different settings.	Attempted different setting yet not getting results.

Pre-metallized PVDF with Silver					
Part Number	L1	L2	L3	L4	L5
Dimensions [W(mm) x L(mm)]	22.2 x 31.1	22.4 x 31	22.1 x 31	22.7 x 31.8	22.7 x 31.1
Date of Manufacturing	04/01 - 04/06	04/01 - 04/06	04/01 - 04/06	04/01 - 04/06	04/01 - 04/06
Electrically Functional? (Y/N)	N	N	N	N	N
Notes	The outer edges of the design are very smooth and precise, but the inner edges are a bit frayed.	The cutting was more rough around the edges. The outer edges were less smooth while the inner edges remained frayed.	The sample appeared similar to Sample #2, but contained a broken piece towards the center of the sample.	The outer edges of the design are smooth and precise, but we observed that the inner edges were less frayed than Sample #1. The sample also contained a broken piece within the center.	Showed smooth outer and inner edges, but there were still certain areas of the inner edges that were slightly frayed. This sample showed better precision of cutting around the edges , but not as good as Sample #1.

Section 5.4 - Test Procedures

Test Protocol #1	
Project Description: Seismocardiogram Sensor	**REVISION NO.: 3**
Team: Raquel Bojorquez , Haniyeh Alirezaei , Antonio Fernandez , and Alessandra Jimenez	**Page** 1 of 3
TITLE: *Artificial Pulse Generator via a Phantom Test*	

1. PURPOSE

To artificially simulate the vibrations from the heart in order to verify the sensor's sensitivity to SCG signals. This test will also be classified as the project's killer test to determine if the success factors were met.

2. SCOPE

This procedure concerns the device sensor's sensitivity to small vibrations with a frequency range of 10-40Hz.

3. REFERENCE DOCUMENTS

- Castiglioni, P., Faini, A., Parati, G., & Di Rienzo, M. (2007). Wearable Seismocardiography. *2007 29th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*. https://doi.org/10.1109/iembs.2007.4353199
- *Simulation of the Human Heart Rate | Dewesoft*. (2020). Dewesoft.com. https://dewesoft.com/case-studies/human-heartbeat-simulation
- Taebi, A., Solar, B., Bomar, A., Sandler, R., & Mansy, H. (2019). Recent Advances in Seismocardiography. *Vibration*, *2*(1), 64–86. https://doi.org/10.3390/vibration2010005
- 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

4. OVERVIEW/BACKGROUND

Since human or animal testing is requires a deep signal processing which is out of the scope of the verification process, an artificial stimulus will be required to determine the functionality of the device. A pulse generator is an electronic device that can be programmed to generate rectangular pulses with SCG signal characteristics, which can be similar to those

created from the heart. The vibrations created from the pulses hitting the surrounding surfaces are the desired input for the device's sensor. From this, the test can determine whether the sensor's sensitivity is high enough to detect the low vibrational frequencies.

5. OBJECTIVES

The objective of this procedure is to verify the sensor's ability to detect the seismocardiogram signals, with respect to detecting frequencies in the range of 10-40 Hz in the planar direction.

6. TEST EQUIPMENT

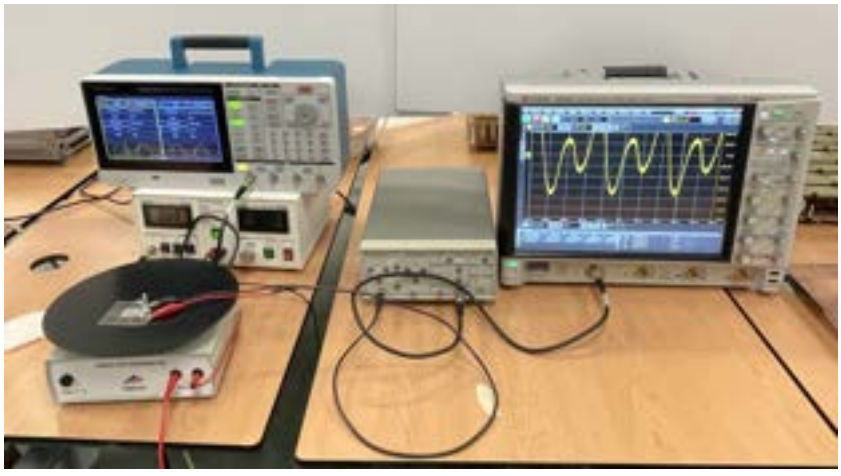
- Function Generator
- Waveform Amplifier
- Vibration Generator
- Low-noise Preamplifier
- Digital Oscilloscope
- Alligator Clips
- BNC to BNC cables
- BNC to alligator clips cable

7. MATERIAL

- Wireless Seismocardiogram Sensor (PVDF)
- Medical grade one sided tape (Tegaderm 3M)

8. SETUP

The function generator was connected to the waveform amplifier, which was connected to the vibration generator. The PVDF sensor was placed on the surface of the vibration generator and its electrodes were connected to the low-noise amplifier. Lastly, the low-noise amplifier directed the signal to the oscilloscope. The setup of the procedure can also be found in the image below.



9. **SAMPLE SIZE***

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours(9.488)/(3650 hours)*2

Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result from this test is that the device is able for the sensor to detect seismocardiogram signals frequencies from 10 to 40 Hz and show a difference in the output voltage, compared to control settings. The control setting was defined as the setup not being connected to the sensor.

11. **PROCEDURE**

The seismocardiogram sensor would be placed on top of the vibration generator. The desired signal for the sensor to detect was first imported into the acquisition software which will be replay for a set time. The frequency of the signal delivered should be set to 10-40 Hz.

12. **DATA COLLECTION SHEET**

*** Completed only 10 trials instead of testing 11 samples. Decided that due to the limited resources available to us as well as the complex process of learning how to create these samples, 10 trials of the electrical functional sample would be appropriate for statistical analysis tests such as t-test.**

Voltage Calculation (mV) Initial Amplitude: 1V					
Trial Number	Control Group	10 Hz	20 Hz	30Hz	40Hz

Test Protocol #2

Project Description: Seismocardiogram Sensor	**REVISION NO.: 3**
Team: Raquel Bojorquez , Haniyeh Alirezaei , Antonio Fernandez , and Alessandra Jimenez	**Page** 1 of 3
TITLE: *Uniaxial Tensile Test for the verification of the PVDF's sensitivity to uniaxial forces and its young's modulus for electromechanical sensitivity.*	

1. PURPOSE

The purpose of this protocol is to determine if the sensing component of the device, the poly-vinylidene fluoride (PVDF), is sensitive to uniaxial forces and that its young's modulus is within the acceptable range to capture the heart's vibration.

2. SCOPE

The protocol ensures that the young's modulus of the PVDF is within 130 kPA - 20 MPa, complying with skin's young's modulus.

3. REFERENCE DOCUMENTS

- Ha, T., Tran, J., Liu, S., Jang, H., Jeong, H., Mitbander, R., Huh, H., Qiu, Y., Duong, J., Wang, R. L., Wang, P., Tandon, A., Sirohi, J., & Lu, N. (2019). A Chest‐Laminated Ultrathin and Stretchable E‐Tattoo for the Measurement of Electrocardiogram, Seismocardiogram, and Cardiac Time Intervals. *Advanced Science*, *6*(14), 1900290. https://doi.org/10.1002/advs.201900290
- Hu, Y., Kang, W., Fang, Y., Xie, L., Qiu, L., & Jin, T. (2018). Piezoelectric Poly(vinylidene fluoride) (PVDF) Polymer-Based Sensor for Wrist Motion Signal Detection. *Applied Sciences*, *8*(5), 836. https://doi.org/10.3390/app8050836
- ISO 527-1:2019 Plastics — Determination of tensile properties — Part 1: General principles

4. OVERVIEW/BACKGROUND

In order to verify the device's ability to detect seismocardiogram (SCG) signals, the properties of the sensor have to be evaluated. The sensor, PVDF, will be patterned which will reduce its young's modulus. A high young's modulus around the threshold of 2-4 Gpa would result in a non-stretchable patch, hence compromising the signal noise due to mobility of the patch. In addition, the overall sensitivity of the device to the SCG signals is dependent on its ability to sense planar forces. Both of these properties can be assessed with a uniaxial tensile test, which measures material's properties such as young's modulus and yield strength based on the force applied in a single direction.

5. **OBJECTIVES**

- Validate that the young's modulus of the PVDF is within 130 kPA - 20 MPa.

6. **TEST EQUIPMENT**

- MTS Criterion Electromechanical Universal Test System
- MTS Test Suite Software

7. **MATERIAL**

Patterned PVDF sensor of dimensions 22.31 mm x 30.92 mm x 0.028 mm capsulated with Tegaderm tape

8. **SETUP**

The setup involves placing the PVDF sample that has been patterned onto the testing machine and slowly extending it until a strain of about 10% is reached. Elongation of the sample is recorded and uploaded to a MTS Test Suite Software for data processing. The software is able to compute the sample's elastic modulus and produce the appropriate stress-strain curve with the user's desired units.

9. **SAMPLE SIZE***

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours(9.488)/(3650 hours)*2

Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result is for the patterned PVDF to experience a Young's Modulus to be within 130 kPA - 20 MPa and approach a value of around 8.5 MPa for the material to be stretchable and appropriate for SCG measurements.

11. **PROCEDURE**

The patterned PVDF will be placed on the MTS Criterion Electromechanical Universal Test System. The device will clamp both sides of the PVDF and begin to elongate the material at a

speed of 0.05 mm per second. Before starting the test, the width and thickness was inputted as 23mm and 0.142 mm (sum thickness of PVDF, silver ink, and Tegaderm tape). The software will be used for stress and strain calculation while the test is being run. The test will run until the strain reaches about 10% or is applied about 3N force. Young's Modulus will be calculated with analyzed stress and strain to confirm if E is 8.5MPa ±.5MPa. Repeat for four trials of the sample.

12. **DATA COLLECTION SHEET**

*** Completed only 4 trials instead of testing 11 samples. Decided that due to the limited resources available to us as well as the complex process of learning how to create these samples, 4 trials of the electrical functional sample would be appropriate for statistical analysis tests such as t-test.**

Trial Number	Young's modulus

Test Protocol # 3

Project Description: Seismocardiogram Sensor	**REVISION NO.: 3**
Team: Raquel Bojorquez, Haniyeh Alirezaei, Antonio Fernandez, Alessandra Jimenez	**Page** 1 of 2
TITLE*: Measurement Confirmation of SCG Patch*	

1. PURPOSE

To confirm the size of the patch to be based on the design inputs to be less than 27.7 ± 4.1 mm for width and 154.1 ± 13.1mm for length.

2. SCOPE

This procedure relates to the verification of the Wireless Seismocardiogram device size.

3. REFERENCE DOCUMENTS

- Taebi, A., Solar, B. E., Bomar, A. J., Sandler, R. H., & Mansy, H. A. (2019, January 14). *Vibration | free full-text | recent advances in ... - MDPI*. MDPI. Retrieved October 20, 2021, from https://www.mdpi.com/2571-631X/2/1/5
- AI;, A. S. D. M. U. (2018, January 18). *Evaluation of the morphological characteristic and sex differences of sternum by multi-detector computed tomography*. Folia morphologica. Retrieved February 22, 2022, from https://pubmed.ncbi.nlm.nih.gov/29345718/

4. OVERVIEW/BACKGROUND

There is a lack of commercially available seismocardiograms (SCGs) that are for everyday use. The latest SCG measurement devices are mostly bulky and uncomfortable for prolonged use. Wearable ECGs have been made compact and lightweight for everyday patient use. To compete with these lightweight ECGs, a device with similar dimensions will be made.

5. OBJECTIVES

The objective is to measure the dimensions of the PVDF sensor and ensure it is within acceptable range of similar ECG and SCG devices.

6. TEST EQUIPMENT

- Caliper

7. **MATERIAL**

Seismocardiogram sensor

- PVDF material: 22.31 mm x 30.92 mm

8. **SETUP**

Once the SCG sensor has been cut to the specific shape by the CAMEO silhouette machine, the SCG sensor will be placed onto the table and measured with a ruler capable of measuring millimeters. The goal is to ensure the device has the proper dimensions stated previously.

9. **SAMPLE SIZE***

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours(9.488)/(3650 hours)*2

Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result is that the patch will be the correct dimensions of 22.31 mm x 30.92 mm.

11. **PROCEDURE**

1. Lay PVDF sensor onto flat surface
2. Using a caliper, measure the length and height of the sensor
3. Compare if results match the expected size and if size is less than sternum measurements stated in market requirements.

12. **DATA COLLECTION SHEET**

*** Completed only 4 samples instead of 11. Decided that due to the limited resources available to us as well as the complex process of learning how to create these samples, 4 samples would be appropriate for statistical analysis tests such as t-test.**

Sample Number	Width [mm]	Length [mm]

Test Protocol #4

Project Description: Seismocardiogram Sensor	**REVISION NO.:2**
Team: Raquel Bojorquez , Haniyeh Alirezaei , Antonio Fernandez , and Alessandra Jimenez	**Page** 1 of 3
TITLE: *Comparison of accelerometer and piezoelectric sensor*	

1. PURPOSE

The purpose is to compare the measurements of seismocardiogram signals obtained with an accelerometer and a PVDF sensor to test PVDF sensing capabilities.

2. SCOPE

This procedure bases on comparing accelerometer and the PVDF sensor seismocardiogram (SCG) signals, to show the efficacy of the two sensors in capturing significant information related to cardiovascular health via the chest wall's vibrations.

3. REFERENCE DOCUMENTS

- Ha, T., Tran, J., Liu, S., Jang, H., Jeong, H., Mitbander, R., Huh, H., Qiu, Y., Duong, J., Wang, R. L., Wang, P., Tandon, A., Sirohi, J., & Lu, N. (2019). A Chest‐Laminated Ultrathin and Stretchable E‐Tattoo for the Measurement of Electrocardiogram, Seismocardiogram, and Cardiac Time Intervals. *Advanced Science*, *6*(14), 1900290. https://doi.org/10.1002/advs.201900290
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- ISO 16063-21:2003 Methods for the calibration of vibration and shock transducers — Part 21: Vibration calibration by comparison to a reference transduc

4. OVERVIEW/BACKGROUND

In order to verify the functionality and accuracy of the sensor of detecting SCG signals, its measurements have to be evaluated. An accelerometer is a device that measures either static or dynamic acceleration (vibration) of a structure. Accelerometers have been extensively used to record SCG signals, hence being the standard method of measurement. SCG signals are characterized for their output voltage, regardless of the method of measurement. Hence, by comparing the results from an accelerometer with the manufactured sensor, it can be

confirmed that the sensor can generate a voltage output that corresponds to an SCG signal based on its piezoelectric characteristics

5. **OBJECTIVES**

- The sensor needs to convert a minimum cardiac pressure of (x) Pa to a minimum voltage output of 1mV peak-peak.

6. **TEST EQUIPMENT**

- Manufactured PVDF sensor
- An accelerometer (model)

7. **MATERIAL**

- Manufactured PVDF sensor (reusable)

8. **SETUP**

The wireless seismocardiogram sensor and the accelerometer would be placed on the surface of the artificial pulse generator. Both are connected to an acquisition software and the obtained signal is obtained for later comparison.

9. **SAMPLE SIZE**

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours(9.488)/(3650 hours)*2

Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result from this test is that the sensor is able to detect seismocardiogram signal that match the characteristics and pattern of those obtained with the accelerometer.

11. **PROCEDURE**

For this procedure a manufactured pulse generator with Polydimethylsiloxane (PDMS) layers will be used to mimic a human chest. First, the accelerometer will be placed on top of the middle point of the pulse generator and the PVDF sensor will be below the accelerometer.

Both were attached using medical tape. After placing both sensors, the pulse generator will be powered for # minutes (or cycles), taking measures continuously. The raw SCG signal from the PVDF sensor will be filtered with a 4th order Butterworth filter of 12-40 Hz bandwidth. Finally, the SCG signal from the PVDF sensor will be compared with the signal from the accelerometer.

12. DATA COLLECTION SHEET

The desired accelerometer had not arrived. An alternative accelerometer was used but due to its structure, it was not possible to mount it with stability on the setup. Therefore, this verification testing was not completed.

Test Protocol #5

Project Description: Seismocardiogram Sensor	**REVISION NO.: 2**
Team: Raquel Bojorquez, Haniyeh Alirezaei, Antonio Fernandez, Alessandra Jimenez	**Page** 1 of 2
TITLE: *Measuring the power source voltage used via voltmeter*	

1. PURPOSE

The purpose is to verify that the sensor can be powered by the patch's power supply and deliver an output voltage of 1-3mV as stated in the design input.

2. SCOPE

The protocol will demonstrate how the power source of the patch will be compatible with the sensor. A voltmeter will be used to measure that the sensor has a reasonable output voltage after receiving power from the patch's power supply.

3. REFERENCE DOCUMENTS

- Leitão, F., Moreira, E., Alves, F., Lourenço, M., Azevedo, O., Gaspar, J., & Rocha, L. A. (2018). High-Resolution Seismocardiogram Acquisition and Analysis System. Sensors (Basel, Switzerland), 18(10), 3441. https://doi.org/10.3390/s18103441
- IEC 62353:2014 - Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment

4. OVERVIEW/BACKGROUND

The sensor created is just one part of the overall final device, but it should be compatible with its other components. In order for the patch to function properly, it needs a source of power and the sensor should be able to function with this same source. Therefore, if the manufactured sensor doesn't comply with the given requirements then it won't fulfill its purpose of detecting SCG signals. So, it is necessary to measure if the sensor is capable of using the same power supply as the patch and still producing the necessary output voltage to function.

5. OBJECTIVES

- The sensor should be powered with a 3 - 5V power source and deliver an output voltage of 1-3mV.

6. TEST EQUIPMENT

- FLUKE (R) Fluke-115/CZWG Series, Compact - Basic Features, Digital Multimeter

7. **MATERIAL**
   - Manufactured PVDF sensor

8. **SETUP**

   The seismocardiogram sensor with the attached copper coils will be connected to the transducer that is powered by an Arduino microcontroller. The multimeter will be set to the voltmeter feature to measure the sensor's output voltage.

9. **SAMPLE SIZE**

   The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

   Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

   Sample size = 8766 hours(9.488)/(3650 hours)*2

   Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

    The expected result from this test is that the sensor is able to function with the provided input voltage of the patch's power supply.

11. **PROCEDURE**

    1. The manufactured PVDF sensor will be connected to the patch's power source.
    2. The black probe of the multimeter is attached to the "COM" port and the red probe will be attached to "VΩ" port
    3. The multimeter will be set to the mode of 20V under the section of the V with a straight line to measure DC voltage. The section knob is set to 20V so that the multimeter can read a range up to 20V.
    4. Connect the red probe to the positive side of the sensor and the black probe to the other side of the sensor.
    5. Read the value on the display.

12. **DATA COLLECTION SHEET**

    Due to late arrival of the piezo-transducer and time constraint, the verification testing setup was unsuccessful. Therefore, this verification is not completed.

Section 5.5 - Patent Opportunities

This section was intentionally left blank.

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Section 6 - Design Verification

Section 6.1 - Design Verification Tests

Artificial Pulse Generator via a Phantom Test

Purpose: To artificially simulate the vibrations from the heart in order to verify the sensor's sensitivity. This test will also be classified as the project's killer test to determine if the success factors were met.

Design Input: The sensor needs to detect frequency ranges of 0-50Hz in planar directions.

Uniaxial Tensile Test for the verification of the PVDF's sensitivity to uniaxial forces and its young's modulus for electromechanical sensitivity.

Purpose: The purpose of this protocol is to determine if the sensing component of the device, the poly-vinylidene fluoride (PVDF), is sensitive to uniaxial forces and that its young's modulus is within the acceptable range to capture the heart's vibration.

Design Input: The sensor needs to be a uniaxial sensor sensitive to force up to 1.5 N/m^2 within the stated frequency range in MR 1.

Mass Confirmation of SCG Patch

Purpose: To confirm the weight of the patch to be based on the design inputs to be less than 8.3 g.

Design Input: Mass of device: ≤ 8.3 g

➔ ***Revision - February 15, 2022***

➔ ****Changed mass confirmation to size confirmation***

Artificial Pulse Generator via a Phantom Test

Purpose: To artificially simulate the vibrations from the heart in order to verify the sensor's sensitivity. This test will also be classified as the project's killer test to determine if the success factors were met.

Design Input: The sensor needs to detect frequency ranges of 0-50Hz in planar directions.

Uniaxial Tensile Test for the verification of the PVDF's sensitivity to uniaxial forces and its young's modulus for electromechanical sensitivity.

Purpose: The purpose of this protocol is to determine if the sensing component of the device, the poly-vinylidene fluoride (PVDF), is sensitive to uniaxial forces and that its young's modulus is within the acceptable range to capture the heart's vibration.

Design Input: The sensor needs to be a uniaxial sensor sensitive to force up to 1.5 N/m^2 within the stated frequency range in MR 1.

Size confirmation of SCG sensor

Purpose: The device should be within the dimensions stated in the Design Input for best signal quality.

Design Input: Sensor dimensions should be within 27.7 ± 4.1 mm for width and 154.1 ± 13.1mm for length.

➔ ***Revision - February 24, 2022***
Added more Verification Tests

Artificial Pulse Generator via a Phantom Test

Purpose: To artificially simulate the vibrations from the heart in order to verify the sensor's sensitivity. This test will also be classified as the project's killer test to determine if the success factors were met.

Design Input: The sensor needs to detect frequency ranges of 0-50Hz in planar directions.

Uniaxial Tensile Test for the verification of the PVDF's sensitivity to uniaxial forces and its young's modulus for electromechanical sensitivity.

Purpose: The purpose of this protocol is to determine if the sensing component of the device, the poly-vinylidene fluoride (PVDF), is sensitive to uniaxial forces and that its young's modulus is within the acceptable range to capture the heart's vibration.

Design Input: The sensor needs to be a uniaxial sensor sensitive to force up to 1.5 N/m^2 within the stated frequency range in MR 1.

Size confirmation of SCG sensor

Purpose: The device should be within the dimensions stated in the Design Input for best signal quality.

Design Input: Sensor dimensions should be within 27.7 ± 4.1 mm for width and 154.1 ± 13.1mm for length.

Sensor Comparison with Accelerometer

Purpose: Check if the PVDF sensor is less than, greater than, or equal to the sensing capabilities that are shown in modern accelerometers.

Design Input: The sensor needs to convert a minimum cardiac pressure of (x) Pa to a minimum voltage output of 1mV peak-peak.

Measuring Power Source Voltage using a Voltmeter

Purpose: Verify that the device altogether has the capability of a wireless power source that can be implemented in the future.

Design Input: Device is powered through a 3 - 5V wireless power source.

Section 6.2 - Design Verification Protocols

Test Protocol #1

Project Description: Seismocardiogram Sensor	**REVISION NO.: 1**
Team: Raquel Bojorquez, Haniyeh Alirezaei, Lizette Avila, Antonio Fernandez, and Alessandra Jimenez	**Page** 1 of 2
TITLE*: Artificial Pulse Generator via a Phantom Test*	

1. PURPOSE

To artificially simulate the vibrations from the heart in order to verify the sensor's sensitivity. This test will also be classified as the project's killer test to determine if the success factors were met.

2. SCOPE

This procedure concerns the device sensor's sensitivity to small vibrations in the range of 10-50 mg.

3. REFERENCE DOCUMENTS

- Castiglioni, P., Faini, A., Parati, G., & Di Rienzo, M. (2007). Wearable Seismocardiography. *2007 29th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*. https://doi.org/10.1109/iembs.2007.4353199
- *Simulation of the Human Heart Rate | Dewesoft*. (2020). Dewesoft.com. https://dewesoft.com/case-studies/human-heartbeat-simulation
- Taebi, A., Solar, B., Bomar, A., Sandler, R., & Mansy, H. (2019). Recent Advances in Seismocardiography. *Vibration*, *2*(1), 64–86. https://doi.org/10.3390/vibration2010005

4. **OVERVIEW/BACKGROUND**

Since human or animal testing is out of the scope of the verification process, an artificial stimulus will be needed to determine the functionality of the device. A pulse generator is an electronic device that can be programmed to generate rectangular pulses, which can be similar to those created from the heart. The vibrations created from the pulses hitting the surrounding surfaces are the desired input for the device's sensor. From this, the test can determine whether the sensor's sensitivity is high enough to detect the low vibrational frequencies.

5. **OBJECTIVES**

The objective of this procedure is to verify the sensor's ability to detect the normal range of seismocardiogram signals (± 20 mG or ± .02 G), with respect to detecting frequencies in the range of 0-50 Hz in the planar direction.

6. **TEST EQUIPMENT**

- Artificial pulse generator
- Acquisition software with a function generator compatible with the pulse generator

7. **MATERIAL**

- The device (Wireless Seismocardiogram)

8. **SETUP**

The wireless seismocardiogram device should be placed on the surface of the artificial pulse generator. The acquisition software replays a reference signal of the heart programming a shaker creating the necessary mechanical vibrations for the sensor to detect.

9. **SAMPLE SIZE**

The MTTF (Mean Time To Failures) is estimated to be 1 years (8766 hours) along with 3 months(2191.5 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours*(9.488)/(2191.5 hours)*2

Sample size = 19 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result from this test is that the device is able to receive seismocardiogram signals from 0 to ±20 mG of amplitude. The data received will be similar to what is expected from a standard seismocardiogram.

11. **PROCEDURE**

The seismocardiogram patch would adhere to the surface of the shaker containing the artificial pulse generator. To replicate the placement of the device and how noise can affect the signal, the distance between the device and the pulse generator was 32.1 +/- 7.9 mm. The desired signal for the sensor to detect was first imported into the acquisition software which will be replay for a set time. The frequency of the signal delivered should be set to 0-50 Hz.

12. **DATA COLLECTION SHEET**

This section was intentionally left blank.

➔ ***Revision - March 5th, 2022***

Test Protocol #1

Project Description: Seismocardiogram Sensor	**REVISION NO.: 2**
Team: Raquel Bojorquez , Haniyeh Alirezaei , Antonio Fernandez , and Alessandra Jimenez	**Page** 1 of 3
TITLE: *Artificial Pulse Generator via a Phantom Test*	

1. PURPOSE

To artificially simulate the vibrations from the heart in order to verify the sensor's sensitivity to SCG signals. This test will also be classified as the project's killer test to determine if the success factors were met.

2. SCOPE

This procedure concerns the device sensor's sensitivity to small vibrations in the amplitude range of ± 20 mg and frequency range of 10-40Hz.

3. REFERENCE DOCUMENTS

- Castiglioni, P., Faini, A., Parati, G., & Di Rienzo, M. (2007). Wearable Seismocardiography. *2007 29th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*. https://doi.org/10.1109/iembs.2007.4353199
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4. OVERVIEW/BACKGROUND

Since human or animal testing is requires a deep signal processing which is out of the scope of the verification process, an artificial stimulus will be required to determine the functionality of the device. A pulse generator is an electronic device that can be programmed to generate rectangular pulses with SCG signal characteristics, which can be similar to those created from the heart. The vibrations created from the pulses hitting the surrounding surfaces are the desired input for the device's sensor. From this, the test can determine whether the sensor's sensitivity is high enough to detect the low vibrational frequencies.

5. OBJECTIVES

The objective of this procedure is to verify the sensor's ability to detect the seismocardiogram signals (± 20 mg or ± .02 g), with respect to detecting frequencies in the range of 10-40 Hz in the planar direction.

6. **TEST EQUIPMENT**

- Piezoelectric Transducer
- Microcontroller (Arduino)
- PDMS (artificial skin)
- Acquisition software with a function generator compatible with the pulse generator

7. **MATERIAL**

- Wireless Seismocardiogram Sensor (PVDF)
- Medical grade one sided tape (Tegaderm 3M)

8. **SETUP**

The PVDF covered with Tegaderm tape on both sides (top and bottom) will be placed on the surface of the PDMS. The PVDF will be secured on the PDMS by a medical grade tape spray. Then this setup will be placed on a piezoelectric pulse generator transducer. The transducer is connected to an Arduino, and the Arduino to a computer. The Arduino will be programmed in a way to create SCG signals via the transducer.

9. **SAMPLE SIZE**

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours(9.488)/(3650 hours)*2

Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result from this test is that the device is able to receive seismocardiogram signals from 0 to ±20 mG of amplitude. The data received will be similar to what is expected from a standard seismocardiogram.

11. **PROCEDURE**

The seismocardiogram patch would adhere to the surface of the shaker containing the artificial pulse generator. To replicate the placement of the device and how noise can affect the signal, the distance between the device and the pulse generator was 32.1 +/- 7.9 mm. The

desired signal for the sensor to detect was first imported into the acquisition software which will be replay for a set time. The frequency of the signal delivered should be set to 10-40 Hz.

12. **DATA COLLECTION SHEET**

This section was intentionally left blank.

➔ ***Revision - April 14, 2022***

Test Protocol #1	
Project Description: Seismocardiogram Sensor	**REVISION NO.: 3**
Team: Raquel Bojorquez , Haniyeh Alirezaei , Antonio Fernandez , and Alessandra Jimenez	**Page** 1 of 3
TITLE: *Artificial Pulse Generator via a Phantom Test*	

1. PURPOSE

To artificially simulate the vibrations from the heart in order to verify the sensor's sensitivity to SCG signals. This test will also be classified as the project's killer test to determine if the success factors were met.

2. SCOPE

This procedure concerns the device sensor's sensitivity to small vibrations with a frequency range of 10-40Hz.

3. REFERENCE DOCUMENTS

- Castiglioni, P., Faini, A., Parati, G., & Di Rienzo, M. (2007). Wearable Seismocardiography. *2007 29th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*. https://doi.org/10.1109/iembs.2007.4353199
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- 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

4. OVERVIEW/BACKGROUND

Since human or animal testing is requires a deep signal processing which is out of the scope of the verification process, an artificial stimulus will be required to determine the functionality of the device. A pulse generator is an electronic device that can be programmed to generate rectangular pulses with SCG signal characteristics, which can be similar to those created from the heart. The vibrations created from the pulses hitting the surrounding surfaces are the desired input for the device's sensor. From this, the test can determine whether the sensor's sensitivity is high enough to detect the low vibrational frequencies.

5. OBJECTIVES

The objective of this procedure is to verify the sensor's ability to detect the seismocardiogram signals, with respect to detecting frequencies in the range of 10-40 Hz in the planar direction.

6. TEST EQUIPMENT

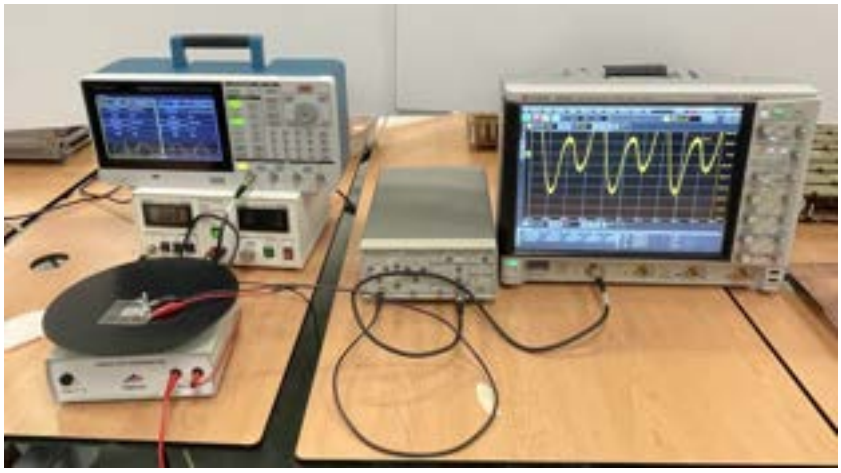
- Function Generator
- Waveform Amplifier
- Vibration Generator
- Low-noise Preamplifier
- Digital Oscilloscope
- Alligator Clips
- BNC to BNC cables
- BNC to alligator clips cable

7. MATERIAL

- Wireless Seismocardiogram Sensor (PVDF)
- Medical grade one sided tape (Tegaderm 3M)

8. SETUP

The function generator was connected to the waveform amplifier, which was connected to the vibration generator. The PVDF sensor was placed on the surface of the vibration generator and its electrodes were connected to the low-noise amplifier. Lastly, the low-noise amplifier directed the signal to the oscilloscope. The setup of the procedure can also be found in the image below.



9. **SAMPLE SIZE***

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours(9.488)/(3650 hours)*2

Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result from this test is that the device is able for the sensor to detect seismocardiogram signals frequencies from 10 to 40 Hz and show a difference in the output voltage, compared to control settings. The control setting was defined as the setup not being connected to the sensor.

11. **PROCEDURE**

The seismocardiogram sensor would be placed on top of the vibration generator. The desired signal for the sensor to detect was first imported into the acquisition software which will be replay for a set time. The frequency of the signal delivered should be set to 10-40 Hz.

12. **DATA COLLECTION SHEET**

*** Completed only 10 trials instead of testing 11 samples. Decided that due to the limited resources available to us as well as the complex process of learning how to create these samples, 10 trials of the electrical functional sample would be appropriate for statistical analysis tests such as t-test.**

Voltage Calculation (mV) Initial Amplitude: 1V

Trial Number	Control Group	10 Hz	20 Hz	30Hz	40Hz
S4-3 Trial 1	900.5	1831	2007	2484	2593
S4-3 Trial 2	1358	1746	2207	2525	2673
S4-3 Trial 3	1510	1773	2282	2558	2836
S4-3 Trial 4	1515	1749	2492	2488	2746
S4-3 Trial 5	1393	1751	2226	2506	2784
S4-3 Trial 6	1337	1771	2672	2560	2746
S4-3 Trial 7	1369	1763	2197	2519	2849
S4-3 Trial 8	1338	1798	2408	2513	2773
S4-3 Trial 9	1338	1825	2778	2469	2687
S4-3 Trial 10	1356	1776	2733	2351	2746

Test Protocol #2

Project Description: Seismocardiogram Sensor	**REVISION NO.: 1**
Team: Raquel Bojorquez, Haniyeh Alirezaei, Lizette Avila, Antonio Fernandez, and Alessandra Jimenez	**Page** 1 of 2
TITLE: *Uniaxial Tensile Test for the verification of the PVDF's sensitivity to uniaxial forces and its young's modulus for electromechanical sensitivity.*	

1. PURPOSE

The purpose of this protocol is to determine if the sensing component of the device, the poly-vinylidene fluoride (PVDF), is sensitive to uniaxial forces and that its young's modulus is within the acceptable range to capture the heart's vibration.

2. SCOPE

The protocol ensures that the young's modulus of the PVDF is within 2-4 GPa so that it facilitates the patterning that also results in reducing the young's modulus and softening the PVDF. Moreover, measure the area density (AD) of the PVDF with a uniaxial force of 1.5 N/m2.

3. REFERENCE DOCUMENTS

- Ha, T., Tran, J., Liu, S., Jang, H., Jeong, H., Mitbander, R., Huh, H., Qiu, Y., Duong, J., Wang, R. L., Wang, P., Tandon, A., Sirohi, J., & Lu, N. (2019). A Chest‐Laminated Ultrathin and Stretchable E‐Tattoo for the Measurement of Electrocardiogram, Seismocardiogram, and Cardiac Time Intervals. *Advanced Science*, *6*(14), 1900290. https://doi.org/10.1002/advs.201900290
- Hu, Y., Kang, W., Fang, Y., Xie, L., Qiu, L., & Jin, T. (2018). Piezoelectric Poly(vinylidene fluoride) (PVDF) Polymer-Based Sensor for Wrist Motion Signal Detection. *Applied Sciences*, *8*(5), 836. https://doi.org/10.3390/app8050836

4. OVERVIEW/BACKGROUND

In order to verify the device's ability to detect seismocardiogram (SCG) signals, the properties of the sensor have to be evaluated. The sensor, PVDF, will be patterned which will reduce its young's modulus. A high young's modulus around the threshold of 2-4 GPa would result in a non-stretchable patch, hence compromising the signal noise due to mobility of the patch. In addition, the overall sensitivity of the device to the SCG signals is dependent on its ability to sense planar forces. Both of these properties can be assessed with a uniaxial tensile test, which measures material's properties such as young's modulus and yield strength based on the force applied in a single direction.

5. OBJECTIVES

- Validate that the young's modulus of the PVDF is below 2-4 GPa.
- Determine the optimal AD value of the PVDF for sensing a uniaxial force of 1.5 N/m2.

6. **TEST EQUIPMENT**

- Universal Testing Machine
- Digital Image Correlation Software

7. **MATERIAL**

Patterned PVDF sheet of varying ratios of width to the radius.

8. **SETUP**

The setup involves placing the PVDF sample that has been patterned onto the testing machine and slowly extending it until a fracture occurs. Elongation of the sample is recorded and uploaded to a Digital Image Correlation Software for data processing. The software is able to calculate the amount of strain at different locations of the material to determine where failure would occur.

9. **SAMPLE SIZE**

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 3 months(2191.5 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTBF goal(X^2α;2)/(testing time)*2

Sample size = 8766 hours(9.488)/(2191.5 hours)*2

Sample size = 19 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result is for the patterned PVDF to experience a Young's Modulus to be much less than 2 GPA and approach a value of around 8.5 MPa for the material to be stretchable and appropriate for SCG measurements.

11. **PROCEDURE**

The patterned PVDF will be placed on the Universal Testing Machine. The device will clamp both sides of the PVDF and begin to elongate the material. The software will be used for stress and strain calculation while the test is being run. The test will run until material failure. Young's Modulus will be calculated with analyzed stress and strain to confirm if E is 8.5MPa ±.5MPa. Repeat for each prototype.

12. **DATA COLLECTION SHEET**

This section was intentionally left blank.

➔ ***Revision - February 25th, 2022***

Test Protocol #2

Project Description: Seismocardiogram Sensor	**REVISION NO.: 2**
Team: Raquel Bojorquez , Haniyeh Alirezaei , Antonio Fernandez , and Alessandra Jimenez	**Page** 1 of 3
TITLE: *Uniaxial Tensile Test for the verification of the PVDF's sensitivity to uniaxial forces and its young's modulus for electromechanical sensitivity.*	

1. PURPOSE

The purpose of this protocol is to determine if the sensing component of the device, the poly-vinylidene fluoride (PVDF), is sensitive to uniaxial forces and that its young's modulus is within the acceptable range to capture the heart's vibration.

2. SCOPE

The protocol ensures that the young's modulus of the PVDF is within 2-4 GPa so that it facilitates the patterning that also results in reducing the young's modulus and softening the PVDF. Moreover, measure the area density (AD) of the PVDF with a uniaxial force of 1.5 N/m2.

3. REFERENCE DOCUMENTS

- Ha, T., Tran, J., Liu, S., Jang, H., Jeong, H., Mitbander, R., Huh, H., Qiu, Y., Duong, J., Wang, R. L., Wang, P., Tandon, A., Sirohi, J., & Lu, N. (2019). A Chest‐Laminated Ultrathin and Stretchable E‐Tattoo for the Measurement of Electrocardiogram, Seismocardiogram, and Cardiac Time Intervals. *Advanced Science*, *6*(14), 1900290. https://doi.org/10.1002/advs.201900290
- Hu, Y., Kang, W., Fang, Y., Xie, L., Qiu, L., & Jin, T. (2018). Piezoelectric Poly(vinylidene fluoride) (PVDF) Polymer-Based Sensor for Wrist Motion Signal Detection. *Applied Sciences*, *8*(5), 836. https://doi.org/10.3390/app8050836

4. OVERVIEW/BACKGROUND

In order to verify the device's ability to detect seismocardiogram (SCG) signals, the properties of the sensor have to be evaluated. The sensor, PVDF, will be patterned which will reduce its young's modulus. A high young's modulus around the threshold of 2-4 Gpa would result in a non-stretchable patch, hence compromising the signal noise due to mobility of the patch. In addition, the overall sensitivity of the device to the SCG signals is dependent on its ability to sense planar forces. Both of these properties can be assessed with a uniaxial tensile

test, which measures material's properties such as young's modulus and yield strength based on the force applied in a single direction.

5. **OBJECTIVES**

- Validate that the young's modulus of the PVDF is below 2-4 GPa.
- Determine the optimal AD value of the PVDF for sensing a uniaxial force of 1.5 N/m2.

6. **TEST EQUIPMENT**

- Universal Testing Machine
- Digital Image Correlation Software

7. **MATERIAL**

Patterned PVDF sheet of varying ratios of width to the radius.

8. **SETUP**

The setup involves placing the PVDF sample that has been patterned onto the testing machine and slowly extending it until a fracture occurs. Elongation of the sample is recorded and uploaded to a Digital Image Correlation Software for data processing. The software is able to calculate the amount of strain at different locations of the material to determine where failure would occur.

9. **SAMPLE SIZE**

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours(9.488)/(3650 hours)*2

Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result is for the patterned PVDF to experience a Young's Modulus to be much less than 2 GPA and approach a value of around 8.5 MPa for the material to be stretchable and appropriate for SCG measurements.

11. **PROCEDURE**

The patterned PVDF will be placed on the Universal Testing Machine. The device will clamp both sides of the PVDF and begin to elongate the material. The software will be used for stress and strain calculation while the test is being run. The test will run until material failure. Young's Modulus will be calculated with analyzed stress and strain to confirm if E is 8.5MPa ±.5MPa. Repeat for each prototype.

12. **DATA COLLECTION SHEET**

This section was intentionally left blank.

➔ ***Revision - April 12, 2022***

Test Protocol #2

Project Description: Seismocardiogram Sensor	**REVISION NO.: 3**
Team: Raquel Bojorquez , Haniyeh Alirezaei , Antonio Fernandez , and Alessandra Jimenez	**Page** 1 of 3
TITLE: *Uniaxial Tensile Test for the verification of the PVDF's sensitivity to uniaxial forces and its young's modulus for electromechanical sensitivity.*	

1. PURPOSE

The purpose of this protocol is to determine if the sensing component of the device, the poly-vinylidene fluoride (PVDF), is sensitive to uniaxial forces and that its young's modulus is within the acceptable range to capture the heart's vibration.

2. SCOPE

The protocol ensures that the young's modulus of the PVDF is within 130 kPA - 20 MPa, complying with skin's young's modulus.

3. REFERENCE DOCUMENTS

- Ha, T., Tran, J., Liu, S., Jang, H., Jeong, H., Mitbander, R., Huh, H., Qiu, Y., Duong, J., Wang, R. L., Wang, P., Tandon, A., Sirohi, J., & Lu, N. (2019). A Chest‐Laminated Ultrathin and Stretchable E‐Tattoo for the Measurement of Electrocardiogram, Seismocardiogram, and Cardiac Time Intervals. *Advanced Science*, *6*(14), 1900290. https://doi.org/10.1002/advs.201900290
- Hu, Y., Kang, W., Fang, Y., Xie, L., Qiu, L., & Jin, T. (2018). Piezoelectric Poly(vinylidene fluoride) (PVDF) Polymer-Based Sensor for Wrist Motion Signal Detection. *Applied Sciences*, *8*(5), 836. https://doi.org/10.3390/app8050836
- ISO 527-1:2019 Plastics — Determination of tensile properties — Part 1: General principles

4. **OVERVIEW/BACKGROUND**

In order to verify the device's ability to detect seismocardiogram (SCG) signals, the properties of the sensor have to be evaluated. The sensor, PVDF, will be patterned which will reduce its young's modulus. A high young's modulus around the threshold of 2-4 Gpa would result in a non-stretchable patch, hence compromising the signal noise due to mobility of the patch. In addition, the overall sensitivity of the device to the SCG signals is dependent on its ability to sense planar forces. Both of these properties can be assessed with a uniaxial tensile test, which measures material's properties such as young's modulus and yield strength based on the force applied in a single direction.

5. **OBJECTIVES**

- Validate that the young's modulus of the PVDF is within 130 kPA - 20 MPa.

6. **TEST EQUIPMENT**

- MTS Criterion Electromechanical Universal Test System
- MTS Test Suite Software

7. **MATERIAL**

Patterned PVDF sensor of dimensions 22.31 mm x 30.92 mm x 0.028 mm capsulated with Tegaderm tape

8. **SETUP**

The setup involves placing the PVDF sample that has been patterned onto the testing machine and slowly extending it until a strain of about 10% is reached. Elongation of the sample is recorded and uploaded to a MTS Test Suite Software for data processing. The software is able to compute the sample's elastic modulus and produce the appropriate stress-strain curve with the user's desired units.

9. **SAMPLE SIZE***

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours(9.488)/(3650 hours)*2

Sample size = 11 samples

10. EXPECTED RESULTS/HYPOTHESIS

The expected result is for the patterned PVDF to experience a Young's Modulus to be within 130 kPA - 20 MPa and approach a value of around 8.5 MPa for the material to be stretchable and appropriate for SCG measurements.

11. PROCEDURE

The patterned PVDF will be placed on the MTS Criterion Electromechanical Universal Test System. The device will clamp both sides of the PVDF and begin to elongate the material at a speed of 0.05 mm per second. Before starting the test, the width and thickness was inputted as 23mm and 0.142 mm (sum thickness of PVDF, silver ink, and Tegaderm tape). The software will be used for stress and strain calculation while the test is being run. The test will run until the strain reaches about 10% or is applied about 3N force. Young's Modulus will be calculated with analyzed stress and strain to confirm if E is 8.5MPa ±.5MPa. Repeat for four trials of the sample.

12. DATA COLLECTION SHEET

*** Completed only 4 trials instead of testing 11 samples. Decided that due to the limited resources available to us as well as the complex process of learning how to create these samples, 4 trials of the electrical functional sample would be appropriate for statistical analysis tests such as t-test.**

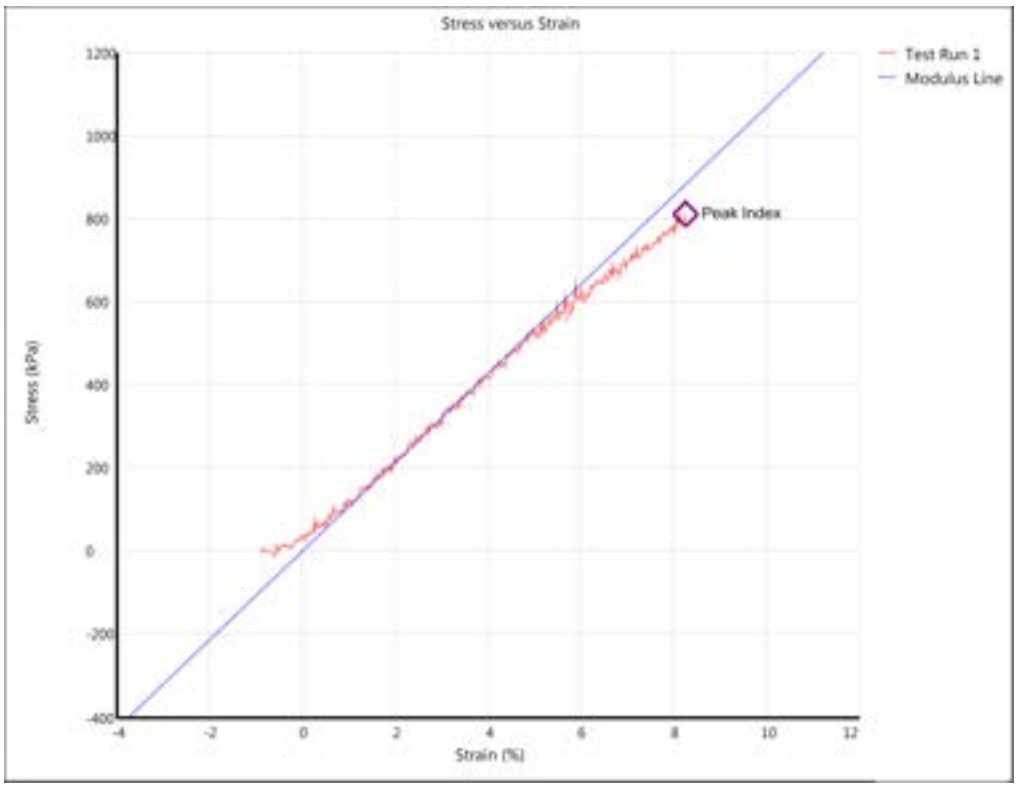
Solidworks Tensile Test Data

Patterned [23x31mm]	
Strain	Stress Data (Pa)
1.02E-11	0.00E+00
1.38E-06	4.50E+06
2.77E-06	9.00E+06
4.15E-06	1.35E+07
5.53E-06	1.80E+07
6.91E-06	2.25E+07
8.29E-06	2.70E+07
9.68E-06	3.15E+07
1.11E-05	3.60E+07
1.24E-05	4.05E+07
1.38E-05	4.50E+07

Experimental Data

Trial Number	Young's modulus
S4-1 Trial 1	10.6 MPa
S4-1 Trial 2	10.532 MPa
S4-1 Trial 3	10.317 MPa
S4-1 Trial 4	10.374 MPa

Corresponding Experimental Stress-Strain Curve



Test Protocol #3

Project Description: Seismocardiogram Sensor	**REVISION NO.: 1**
Team: Raquel Bojorquez, Haniyeh Alirezaei, Lizette Avila, Antonio Fernandez, and Alessandra Jimenez	**Page** 1 of 2
TITLE*: Mass Confirmation of SCG Patch*	

1. PURPOSE

To confirm the weight of the patch to be based on the design inputs to be less than 8.3 g.

2. SCOPE

This procedure relates to the verification of the Wireless Seismocardiogram device mass.

3. REFERENCE DOCUMENTS

- Choi, W., Kim, S. H., Lee, W., Kang, S. H., Yoon, C. H., Youn, T. J., & Chae, I. H. (2020). Comparison of continuous ECG monitoring by wearable patch device and conventional telemonitoring device. Journal of Korean medical science, 35(44).

4. OVERVIEW/BACKGROUND

There is a lack of commercially available seismocardiograms (SCGs) that are for everyday use. The latest SCG measurement devices are mostly bulky and uncomfortable for prolonged use. Wearable ECGs have been made compact and lightweight for everyday patient use. To compete with these lightweight ECGs, a device with similar dimensions will be made.

5. OBJECTIVES

The objective is to measure the weight of the entire seismocardiogram including all the components such as silver coil coating, poly-vinylidene fluoride (PVDF), polyurethane tape, and NFC (Near Field Communication) tag.

6. TEST EQUIPMENT

Scientific weight scale

7. MATERIAL

Seismocardiogram patch

- Silver coil: 0.32g for 50x50mm
- PVDF: approximately .0187g for 35mm x 10mm x .028mm of material in patch
- Polyurethane tape: .091g for 45mm * 55mm * .03mm
- Transfer tape: approximately .3g for 45mm * 55mm * .11mm
- Electronics: approximately 7g

The SCG patch prototype will be placed on the weight scale to obtain the overall weight for the assembled patch.

9. SAMPLE SIZE

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 3 months(2191.5 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTBF goal*(X^2α;2)/(testing time)*2

Sample size = 8766 hours*(9.488)/(2191.5 hours)*2

Sample size = 19 samples

10. EXPECTED RESULTS/HYPOTHESIS

The expected result is that the patch will weigh less than 8.3 g

11. PROCEDURE

1. Zero the scale
2. Place the patch on the scale
3. Record the weight of the prototype
4. Remove the patch from the scale
5. Repeat the steps for each prototype
6. Average the weight of all measured prototypes.

12. DATA COLLECTION SHEET

This section was intentionally left blank.

➔ ***Revision - February 25th, 2022***

Test Protocol # 3

Project Description: Seismocardiogram Sensor	**REVISION NO.: 2**
Team: Raquel Bojorquez, Haniyeh Alirezaei, Antonio Fernandez, Alessandra Jimenez	**Page** 1 of 2
TITLE*: Measurement Confirmation of SCG Patch*	

1. PURPOSE

To confirm the size of the patch to be based on the design inputs to be less than 27.7 ± 4.1 mm for width and 154.1 ± 13.1mm for length.

2. SCOPE

This procedure relates to the verification of the Wireless Seismocardiogram device size.

3. REFERENCE DOCUMENTS

- Taebi, A., Solar, B. E., Bomar, A. J., Sandler, R. H., & Mansy, H. A. (2019, January 14). *Vibration | free full-text | recent advances in ... - MDPI*. MDPI. Retrieved October 20, 2021, from https://www.mdpi.com/2571-631X/2/1/5
- Al;, A. S. D. M. U. (2018, January 18). *Evaluation of the morphological characteristic and sex differences of the sternum by multi-detector computed tomography*. Folia morphological. Retrieved February 22, 2022, from https://pubmed.ncbi.nlm.nih.gov/29345718/

4. OVERVIEW/BACKGROUND

There is a lack of commercially available seismocardiograms (SCGs) that are for everyday use. The latest SCG measurement devices are mostly bulky and uncomfortable for prolonged use. Wearable ECGs have been made compact and lightweight for everyday patient use. To compete with these lightweight ECGs, a device with similar dimensions will be made.

5. OBJECTIVES

The objective is to measure the dimensions of the PVDF sensor and ensure it is within an acceptable range of similar ECG and SCG devices.

6. TEST EQUIPMENT

Ruler/measuring tape

7. **MATERIAL**

   Seismocardiogram sensor

   - PVDF material: 22.31 mm x 30.92 mm

8. **SETUP**

   Once the SCG sensor has been cut to the specific shape by the CAMEO Silhouette machine, the SCG sensor will be placed onto the table and measured with a ruler capable of measuring millimeters. The goal is to ensure the device has the proper dimensions stated previously.

9. **SAMPLE SIZE**

   The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

   Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

   Sample size = 8766 hours(9.488)/(3650 hours)*2

   Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

    The expected result is that the patch will be the correct dimensions of 22.31 mm x 30.92 mm

11. **PROCEDURE**

    1. Lay PVDF sensor onto flat surface
    2. Using a ruler or measuring tape, measure the length and height of the sensor
    3. Compare if results match the expected size and if the size is less than sternum measurements stated in market requirements.

12. **DATA COLLECTION SHEET**

    This section was intentionally left blank.

➔ ***Revision - April 12, 2022***

Test Protocol # 3

Project Description: Seismocardiogram Sensor	**REVISION NO.: 3**
Team: Raquel Bojorquez, Haniyeh Alirezaei, Antonio Fernandez, Alessandra Jimenez	**Page** 1 of 2
TITLE*: Measurement Confirmation of SCG Patch*	

1. PURPOSE

To confirm the size of the patch to be based on the design inputs to be less than 27.7 ± 4.1 mm for width and 154.1 ± 13.1mm for length.

2. SCOPE

This procedure relates to the verification of the Wireless Seismocardiogram device size.

3. REFERENCE DOCUMENTS

- Taebi, A., Solar, B. E., Bomar, A. J., Sandler, R. H., & Mansy, H. A. (2019, January 14). *Vibration | free full-text | recent advances in ... - MDPI*. MDPI. Retrieved October 20, 2021, from https://www.mdpi.com/2571-631X/2/1/5
- AI;, A. S. D. M. U. (2018, January 18). *Evaluation of the morphological characteristic and sex differences of sternum by multi-detector computed tomography*. Folia morphologica. Retrieved February 22, 2022, from https://pubmed.ncbi.nlm.nih.gov/29345718/

4. OVERVIEW/BACKGROUND

There is a lack of commercially available seismocardiograms (SCGs) that are for everyday use. The latest SCG measurement devices are mostly bulky and uncomfortable for prolonged use. Wearable ECGs have been made compact and lightweight for everyday patient use. To compete with these lightweight ECGs, a device with similar dimensions will be made.

5. OBJECTIVES

The objective is to measure the dimensions of the PVDF sensor and ensure it is within acceptable range of similar ECG and SCG devices.

6. TEST EQUIPMENT

- Caliper

7. MATERIAL

Seismocardiogram sensor

- PVDF material: 22.31 mm x 30.92 mm

8. **SETUP**

Once the SCG sensor has been cut to the specific shape by the CAMEO silhouette machine, the SCG sensor will be placed onto the table and measured with a ruler capable of measuring millimeters. The goal is to ensure the device has the proper dimensions stated previously.

9. **SAMPLE SIZE***

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours(9.488)/(3650 hours)*2

Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result is that the patch will be the correct dimensions of 22.31 mm x 30.92 mm.

11. **PROCEDURE**

1. Lay PVDF sensor onto flat surface
2. Using a caliper, measure the length and height of the sensor
3. Compare if results match the expected size and if size is less than sternum measurements stated in market requirements.

12. **DATA COLLECTION SHEET**

*** Completed only 4 samples instead of 11. Decided that due to the limited resources available to us as well as the complex process of learning how to create these samples, 4 samples would be appropriate for statistical analysis tests such as t-test.**

Samples used for measurement confirmation

Example on how to measure

Experimental Data

Sample Number	Width [mm]	Length [mm]
Solidworks Design	22.31	30.92

S4-1	22.3	31.3
S4-2	22.6	32.1
S4-3*	22.7	30.5
S4-4	22.1	30.9
S5-5	21.9	30.9

*Electrically Functional Sample, MVP

Test Protocol #4

Project Description: Seismocardiogram Sensor	**REVISION NO.:2**
Team: Raquel Bojorquez , Haniyeh Alirezaei , Antonio Fernandez , and Alessandra Jimenez	**Page** 1 of 3
TITLE: *Comparison of accelerometer and piezoelectric sensor*	

1. PURPOSE

The purpose is to compare the measurements of seismocardiogram signals obtained with an accelerometer and a PVDF sensor to test PVDF sensing capabilities.

2. SCOPE

This procedure bases on comparing accelerometer and the PVDF sensor seismocardiogram (SCG) signals, to show the efficacy of the two sensors in capturing significant information related to cardiovascular health via the chest wall's vibrations.

3. REFERENCE DOCUMENTS

- Ha, T., Tran, J., Liu, S., Jang, H., Jeong, H., Mitbander, R., Huh, H., Qiu, Y., Duong, J., Wang, R. L., Wang, P., Tandon, A., Sirohi, J., & Lu, N. (2019). A Chest‐Laminated Ultrathin and Stretchable E‐Tattoo for the Measurement of Electrocardiogram, Seismocardiogram, and Cardiac Time Intervals. *Advanced Science*, *6*(14), 1900290. https://doi.org/10.1002/advs.201900290
- Shandhi, M. M. H., Semiz, B., Hersek, S., Goller, N., Ayazi, F., & Inan, O. T. (2019). Performance Analysis of Gyroscope and Accelerometer Sensors for Seismocardiography-Based Wearable Pre-Ejection Period Estimation. IEEE Journal of Biomedical and Health Informatics, 23(6), 2365–2374. https://doi.org/10.1109/jbhi.2019.2895775
- ISO 16063-21:2003 Methods for the calibration of vibration and shock transducers — Part 21: Vibration calibration by comparison to a reference transduc

4. OVERVIEW/BACKGROUND

In order to verify the functionality and accuracy of the sensor of detecting SCG signals, its measurements have to be evaluated. An accelerometer is a device that measures either static or dynamic acceleration (vibration) of a structure. Accelerometers have been extensively used to record SCG signals, hence being the standard method of measurement. SCG signals are characterized for their output voltage, regardless of the method of measurement. Hence, by comparing the results from an accelerometer with the manufactured sensor, it can be

confirmed that the sensor can generate a voltage output that corresponds to an SCG signal based on its piezoelectric characteristics

5. **OBJECTIVES**

- The sensor needs to convert a minimum cardiac pressure of (x) Pa to a minimum voltage output of 1mV peak-peak.

6. **TEST EQUIPMENT**

- Manufactured PVDF sensor
- An accelerometer (model)

7. **MATERIAL**

- Manufactured PVDF sensor (reusable)

8. **SETUP**

The wireless seismocardiogram sensor and the accelerometer would be placed on the surface of the artificial pulse generator. Both are connected to an acquisition software and the obtained signal is obtained for later comparison.

9. **SAMPLE SIZE**

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours(9.488)/(3650 hours)*2

Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result from this test is that the sensor is able to detect seismocardiogram signal that match the characteristics and pattern of those obtained with the accelerometer.

11. **PROCEDURE**

For this procedure a manufactured pulse generator with Polydimethylsiloxane (PDMS) layers will be used to mimic a human chest. First, the accelerometer will be placed on top of the middle point of the pulse generator and the PVDF sensor will be below the accelerometer.

Both were attached using medical tape. After placing both sensors, the pulse generator will be powered for # minutes (or cycles), taking measures continuously. The raw SCG signal from the PVDF sensor will be filtered with a 4th order Butterworth filter of 12-40 Hz bandwidth. Finally, the SCG signal from the PVDF sensor will be compared with the signal from the accelerometer.

12. DATA COLLECTION SHEET

The desired accelerometer had not arrived. An alternative accelerometer was used but due to its structure, it was not possible to mount it with stability on the setup. Therefore, this verification testing was not completed.

Test Protocol #5

Project Description: Seismocardiogram Sensor	**REVISION NO.: 2**
Team: Raquel Bojorquez, Haniyeh Alirezaei, Antonio Fernandez, Alessandra Jimenez	**Page** 1 of 2
TITLE: *Measuring the power source voltage used via voltmeter*	

1. PURPOSE

The purpose is to verify that the sensor can be powered by the patch's power supply and deliver an output voltage of 1-3mV as stated in the design input.

2. SCOPE

The protocol will demonstrate how the power source of the patch will be compatible with the sensor. A voltmeter will be used to measure that the sensor has a reasonable output voltage after receiving power from the patch's power supply.

3. REFERENCE DOCUMENTS

- Leitão, F., Moreira, E., Alves, F., Lourenço, M., Azevedo, O., Gaspar, J., & Rocha, L. A. (2018). High-Resolution Seismocardiogram Acquisition and Analysis System. Sensors (Basel, Switzerland), 18(10), 3441. https://doi.org/10.3390/s18103441
- IEC 62353:2014 - Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment

4. OVERVIEW/BACKGROUND

The sensor created is just one part of the overall final device, but it should be compatible with its other components. In order for the patch to function properly, it needs a source of power and the sensor should be able to function with this same source. Therefore, if the manufactured sensor doesn't comply with the given requirements then it won't fulfill its purpose of detecting SCG signals. So, it is necessary to measure if the sensor is capable of using the same power supply as the patch and still producing the necessary output voltage to function.

5. OBJECTIVES

- The sensor should be powered with a 3 - 5V power source and deliver an output voltage of 1-3mV.

6. TEST EQUIPMENT

- FLUKE (R) Fluke-115/CZWG Series, Compact - Basic Features, Digital Multimeter

7. **MATERIAL**

- Manufactured PVDF sensor

8. **SETUP**

The seismocardiogram sensor with the attached copper coils will be connected to the transducer that is powered by an Arduino microcontroller. The multimeter will be set to the voltmeter feature to measure the sensor's output voltage.

9. **SAMPLE SIZE**

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours(9.488)/(3650 hours)*2

Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result from this test is that the sensor is able to function with the provided input voltage of the patch's power supply.

11. **PROCEDURE**

1. The manufactured PVDF sensor will be connected to the patch's power source.
2. The black probe of the multimeter is attached to the "COM" port and the red probe will be attached to "VΩ" port
3. The multimeter will be set to the mode of 20V under the section of the V with a straight line to measure DC voltage. The section knob is set to 20V so that the multimeter can read a range up to 20V.
4. Connect the red probe to the positive side of the sensor and the black probe to the other side of the sensor.
5. Read the value on the display.

12. **DATA COLLECTION SHEET**

Due to late arrival of the piezo-transducer and time constraint, the verification testing setup was unsuccessful. Therefore, this verification is not completed.

Section 6.3 - Equipment Calibration Information

Equipment Model	Equipment Description	Next Calibration Due Date	Calibration Required? Yes / No / N/a	Rationale for No Calibration
SILH-CAMEO-4-PNK-4T	CAMEO Silhouette 4 cutting machine	N/A	No	Self-diagnostic and calibration upon startup
N/A	Oven	N/A	N/A	Temperature determined by mercury thermometer
1000701	3B Scientific Vibration Generator	N/A	N/A	Dependent on the function generator for power?
Fluke-115/CZW G Series	FLUKE ® Compact - Basic Features, Digital Multimeter	8/2022 (Annually)	Yes	
Model 41	MTS Criterion Electromechanical Universal Test System	8/2022 (Annually)	Yes	
AFG31000 Series	Tektronix Arbitrary Function Generator	1/2023 (Annually)	Yes	
MSOS254A	Keysight Mixed Signal Oscilloscope	1/2023 (Annually)	Yes	
Model SR560	Stanford Research Systems Low-Noise	1/2023 (Annually)	No	New product that is already calibrated from the manufacture

	Preamplifier			
TS250	Accel Instruments Waveform Amplifier	1/2023 (Annually)	No	New product that is already calibrated from the manufacture

Section 6.4 - Test Deviations

6.4: Template

I. Perform a Root Cause Analysis
II. Determine the possible root cause (s)
III. If failure were due to overly stringent Design Inputs, provide a scientific basis/rationale for changing the Design Inputs.
IV. Redo verification tests
V. Complete verification report
VI. If design was incorrectly implemented, perform a redesign of applicable component or sub-assembly
VII. Perform design simulations
VIII. Remanufacture device or system component
IX. Redo verification tests
X. Analyze data
XI. Complete verification Report

6.4.1: Verification Test: Artificial Pulse Generator

I. Root Cause Analysis: Signal amplitude is not in the range desired. Causes could be too much noise from the machine, incorrect placement of sensor for measurement. Signal processing with filters could significantly improve results.
II. Possible Root Cause: System has too much noise, attempt to reduce with a faraday cage. Signal Processing and the use of filters could improve our results
III. Design Input change: Decided that our goal was to determine if the sample was able to be detected, therefore the value we were expecting does not have to match any set value. Change design verification to test if the sample can generate voltage in the range of 10-40 Hz.
IV. Verification tests are redone with the goal of only detecting voltage in 10-40 Hz.

V. ***N/A***

VI. ***N/A***

VII. **Simulation Data:**

Force applied: 1.5 Newtons/m^2

Patterned [23x31mm]	
Frequenc	Voltage Output (V)
10	2.4892
12	2.4894
14	2.4896
16	2.4898
18	2.4901
20	2.4904
22	2.4907
24	2.4911
26	2.4915
28	2.4919
30	2.4924
32	2.4928
34	2.4934
36	2.4939
38	2.4945
40	2.4951

VIII. ***N/A***

IX. ***N/A***

X. Data Analysis: Different voltages can be detected from ranges of 10-40 Hz, ultimately proving that the sensor is sensitive to SCG signals.

XI. ***Refer to 6.2.1***

6.4.2: Verification Test: Comparison of accelerometer and PVDF

I. The accelerometer requested by faculty was not shipped on time. The team attempted to use a much cheaper accelerometer on arduino setup.

II. Other accelerometers used were not compatible with the Arduino system.

III. Decided that comparing with an accelerometer would have looked better in the presentation, but it is not required. The team deviated from this Verification test.

IV. ***N/A***
V. ***N/A***
VI. ***N/A***
VII. ***N/A***
VIII. ***N/A***
IX. ***N/A***
X. ***N/A***
XI. ****Refer to 6.2.4***

6.4.3: Verification Test: Measuring Power source voltage

I. ***N/A***
II. ***N/A***
III. Decided that this verification test was not required as it did not reflect the scope. The team deviated from this Verification test.
IV. ***N/A***
V. ***N/A***
VI. ***N/A***
VII. ***N/A***
VIII. ***N/A***
IX. ***N/A***
X. ***N/A***
XI. ****Refer to 6.2.5***

Section 6.5 - Design Verification Reports

Test	Protocol Step	RQ#	Acceptance Criteria	Result	Deviation Reference
Voltage Generated from Artificial Pulse Generator	6.1.1.1		The sensor needs to be uniaxial and detect frequency ranges of 10-40 Hz in planar directions with an amplitude range of ± 20 mg.	**F**	**6.4.1 Amplitude of the sensor was not correct. Removed Amplitude Requirement for future testing.**
Voltage Generated from Artificial Pulse Generator	6.1.1.2		The sensor needs to be uniaxial and detect frequency ranges of 10-40 Hz in planar directions	**P**	
Uniaxial Tensile Test	6.1.2.1		The sensor's elastic modulus needs to range from 130 kPa to 20 MPa	**P**	
Dimension Confirmation of Sensor	6.1.3.1		Sensor dimensions should be within 27.7 ± 4.1 mm for width and 154.1 ± 13.1mm for length.	**P**	
Accelerometer vs. PVDF Comparison	6.1.4.1		The sensor needs to convert a minimum cardiac pressure of (x) Pa to a minimum	**F**	**6.4.2 Materials were not shipped on time. Not compatible with**

			voltage output of 1mV peak-peak.		**Arduino. Not a necessary verification test.**
Measuring of Power Source Voltage	6.1.5.1		Device is able to be powered through a 3 - 5V wireless power source.	**N/A**	**6.4.3 Deviated away from this verification**

Section 6.6 - Test Data and Data Evaluation

Size Confirmation of SCG Sensor

Sample Number	Width [mm]	Length [mm]
Solidworks Design	22.31	30.92
S4-1	22.3	31.3
S4-2	22.6	32.1
S4-3*	22.7	30.5
S4-4	22.1	30.9
S5-5	21.9	30.9

Uniaxial Tensile Test

Trial Number	Young's modulus
S4-1 Trial 1	10.6 MPa

S4-1 Trial 2	10.532 MPa
S4-1 Trial 3	10.317 MPa
S4-1 Trial 4	10.374 MPa

Killer Test: Phantom Test via Artificial Pulse Generator

Collected Data

Voltage Calculation (mV) Initial Amplitude: 1V					
Trial Number	Control Group	10 Hz	20 Hz	30Hz	40Hz
S4-3 Trial 1	900.5	1831	2007	2484	2593
S4-3 Trial 2	1358	1746	2207	2525	2673
S4-3 Trial 3	1510	1773	2282	2558	2836
S4-3 Trial 4	1515	1749	2492	2488	2746
S4-3 Trial 5	1393	1751	2226	2506	2784
S4-3 Trial 6	1337	1771	2672	2560	2746
S4-3 Trial 7	1369	1763	2197	2519	2849
S4-3 Trial 8	1338	1798	2408	2513	2773
S4-3 Trial 9	1338	1825	2778	2469	2687
S4-3 Trial 10	1356	1776	2733	2351	2746

Data Evaluation

Number of Groups (k): 5

Number of Trials per Group (n): 10

Total Number of Trials(N):50

Control Group: Device placed onto static Vibrator (not turned on)

One-Way Anova Test @ α=.05	Degrees of Freedom	Sum of Squares (SS)	Mean Square (MS)	F-Ratio	F-Critical	Conclusion
Between Groups	4	13,269,518	3317380	**154.9169**	**~ 2.57**	F >> F-Critical The voltages acquired are significant from each other **Design Input: Passed**
Within Groups (Error)	45	963,627	21414			
Total	49	14,233,145				

Means from each Frequency	Control	10 Hz	20 Hz	30 Hz	40 Hz
Average (mV)	1342	1778	2400	2497	2743

Killer Test: Observing Input Amplitude Affecting Output Voltage

Collected Data

Different Control Settings

Trial Number	Device Not Attached, only Clips (mV)	Device Attached, Hanging in Air (mV)	Device Attached, on Static Vibrator (mV)
S4-3 Trial 1	188.7	236.8	900.5
S4-3 Trial 2	188.7	242.9	1358
S4-3 Trial 3	172.4	276.6	1510

S4-3 Trial 4	191.4	228.5	1515
S4-3 Trial 5	202.7	223.8	1393
S4-3 Trial 6	208.5	207.1	1337
S4-3 Trial 7	188.7	250.3	1369
S4-3 Trial 8	193.4	220.1	1338
S4-3 Trial 9	175.7	204.4	1338
S4-3 Trial 10	187.6	212.2	1356

Means	Not Attached	Attached, Contact with Air	Attached, Contact with Plate
Average (mV)	187.3	230.0	1342

Different Initial Amplitude Settings

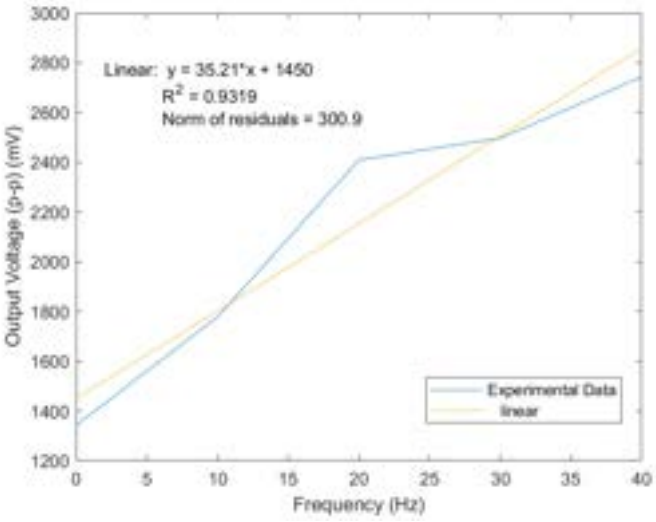
Trial Number	Initial Amplitude: 1mV	Initial Amplitude: 3mV	Initial Amplitude: 10mV
S4-3 Trial 1	1394	1656	2033
S4-3 Trial 2	1377	1356	1996
S4-3 Trial 3	1291	1510	2203
S4-3 Trial 4	1804	1407	2097
S4-3 Trial 5	1585	1599	2137
S4-3 Trial 6	1521	1729	2157
S4-3 Trial 7	1804	1986	2139
S4-3 Trial 8	1441	1486	2154

S4-3 Trial 9	1439	1466	2104
S4-3 Trial 10	1535	1981	2158

Means	1mV	3mV	10mV
Average (mV)	1519	1618	2118

Data Evaluation

Linear Correlation of Original Data
(P-Value <.01)
(Correlation Coefficient R: .9654)



Conclusions:

- Original Data has a positive linear trend
- Device is VERY Sensitive
- A higher Initial Amplitude results in a greater Voltage Reading
    - System contains significant noise
    - Better testing procedures required to improve result

References

[1] Castiglioni, P., Faini, A., Parati, G., & Di Rienzo, M. (2007). Wearable Seismocardiography. *2007 29th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*. https://doi.org/10.1109/iembs.2007.4353199

[2] *Simulation of the Human Heart Rate | Dewesoft*. (2020). Dewesoft.com. https://dewesoft.com/case-studies/human-heartbeat-simulation

[3] Taebi, A., Solar, B., Bomar, A., Sandler, R., & Mansy, H. (2019). Recent Advances in Seismocardiography. *Vibration*, *2*(1), 64–86. https://doi.org/10.3390/vibration2010005

[4] Ha, T., Tran, J., Liu, S., Jang, H., Jeong, H., Mitbander, R., Huh, H., Qiu, Y., Duong, J., Wang, R. L., Wang, P., Tandon, A., Sirohi, J., & Lu, N. (2019). A Chest‐Laminated Ultrathin and Stretchable E‐Tattoo for the Measurement of Electrocardiogram, Seismocardiogram, and Cardiac Time Intervals. *Advanced Science*, *6*(14), 1900290. https://doi.org/10.1002/advs.201900290

[5] Hu, Y., Kang, W., Fang, Y., Xie, L., Qiu, L., & Jin, T. (2018). Piezoelectric Poly(vinylidene fluoride) (PVDF) Polymer-Based Sensor for Wrist Motion Signal Detection. *Applied Sciences*, *8*(5), 836. https://doi.org/10.3390/app8050836

[6] Choi, W., Kim, S. H., Lee, W., Kang, S. H., Yoon, C. H., Youn, T. J., & Chae, I. H. (2020). Comparison of continuous ECG monitoring by wearable patch device and conventional telemonitoring device. Journal of Korean medical science, 35(44).

Section 7 - Project Plan

ID	Task Mode	Task Name	Duration	Start	Finish	Predecessors	Resource Names	Qtr 3, 2021 Jul
1		**Senior Design Project**	**179 days?**	**Mon 8/16/21**	**Thu 4/21/22**			
2		**First Semester**	**90 days?**	**Mon 8/16/21**	**Fri 12/17/21**			
3		Receive Project Approval	50 days	Mon 8/16/21	Fri 10/22/21		Team	
4		Determination of need	14 days?	Mon 11/1/21	Thu 11/18/21	3	Team	
5		Determine Design Inputs	10 days?	Fri 11/19/21	Thu 12/2/21	4	Team	
6		Develop Design Concepts	11 days?	Fri 12/3/21	Fri 12/17/21	5	Team	
7		**Feasibility Analysis**	**32 days?**	**Mon 10/11/21**	**Tue 11/23/21**	6		
8		Technology Assessment	11 days?	Mon 11/8/21	Mon 11/22/21		HA	
9		Risk Assessment	10 days?	Tue 11/9/21	Mon 11/22/21		AF	
10		Cost Assessment	11 days?	Tue 11/9/21	Tue 11/23/21		RB,AJ	
11		Regulatory Assessment	6 days?	Mon 10/11/21	Mon 10/18/21		AF	
12		Project Proposal Presentation	17 days?	Mon 12/20/21	Tue 1/11/22	3,4,5,6,7	Team	
13		**Second Semester**	**74 days?**	**Mon 1/10/22**	**Thu 4/21/22**			
14		**Phase 1- Research Design and Materials**	**6 days?**	**Mon 1/10/22**	**Mon 1/17/22**			
15		**Physiology**	**6 days**	**Mon 1/10/22**	**Sun 1/16/22**			
16		Coronary Artery Disease	6 days	Mon 1/10/22	**Sun 1/16/22**		AF	

Project: Project plan-team1
Date: Sun 3/6/22

Task		Manual Summary	
Split		Start-only	[
Milestone	◆	Finish-only	]
Summary		External Tasks	
Project Summary		External Milestone	◇
Inactive Task		Deadline	✦
Inactive Milestone		Path Predecessor Milestone Task	◆
Inactive Summary		Path Predecessor Summary Task	
Manual Task		Path Predecessor Normal Task	
Duration-only		Progress	
Manual Summary Rollup		Manual Progress	

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ID	Task Mode	Task Name	Duration	Start	Finish	Predecessors	Resource Names	Qtr 3, 2021 Jul
17		CAD and Heart Sounds in terms of nature of the signals (comparison between SCG and ECG)	6 days	Mon 1/10/22	**Sun 1/16/22**		HA	
18		**Mechanical and eletrical signals of the heart**	**6 days**	**Mon 1/10/22**	**Sun 1/16/22**			
19		How each signal can be detected	6 days	Mon 1/10/22	**Sun 1/16/22**		AF	
20		**Nature of SCG signals**	**6 days**	**Mon 1/10/22**	**Sun 1/16/22**			
21		Frequency and amplitude	6 days	Mon 1/10/22	**Sun 1/16/22**		AF	
22		Locations on the chest where SCFG signals can be detected	6 days	Mon 1/10/22	**Sun 1/16/22**		AF	
23		Direction of the SCG signal	6 days	Mon 1/10/22	**Sun 1/16/22**		AF	
24		**Material and Equipment**	**6 days**	**Mon 1/10/22**	**Sun 1/16/22**			
25		**Piezoelectric Polymers**	**6 days**	**Mon 1/10/22**	**Sun 1/16/22**			
26		**PVDF**	**6 days**	**Mon 1/10/22**	**Sun 1/16/22**			
27		Piezoelectricity/Piezoelc coefficient.	6 days	Mon 1/10/22	**Sun 1/16/22**		HA	

Project: Project plan-team1
Date: Sun 3/6/22

Task		Manual Summary	
Split		Start-only	[
Milestone	◆	Finish-only	]
Summary		External Tasks	
Project Summary		External Milestone	◇
Inactive Task		Deadline	✦
Inactive Milestone		Path Predecessor Milestone Task	◆
Inactive Summary		Path Predecessor Summary Task	
Manual Task		Path Predecessor Normal Task	
Duration-only		Progress	
Manual Summary Rollup		Manual Progress	

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ID	Task Mode	Task Name	Duration	Start	Finish	Predecessors	Resource Names	Qtr 3, 2021 Jul
28		Stress/strain, Young's modulus, capacitance, elastic modulus.	6 days	Mon 1/10/22	**Sun 1/16/22**		HA	
29		**Patterning**	**6 days**	**Mon 1/10/22**	**Sun 1/16/22**			
30		How to reduce PVDF's Elastic Modulus to comply with skin	6 days	Mon 1/10/22	Sun 1/16/22		RB,AJ	
31		How is sensitivity affected by the patterning?	6 days	Mon 1/10/22	Sun 1/16/22		RB,AJ	
32		What parameters can be changed for optimal shape/dimensions for quality signaling	6 days	Mon 1/10/22	Sun 1/16/22		AJ,RB	
33		Determine parameters to increase stretchability	6 days	Mon 1/10/22	Sun 1/16/22		AJ,RB	

Project: Project plan-team1
Date: Sun 3/6/22

Task		Manual Summary	
Split		Start-only	[
Milestone	◆	Finish-only	]
Summary		External Tasks	
Project Summary		External Milestone	◇
Inactive Task		Deadline	◆
Inactive Milestone	◇	Path Predecessor Milestone Task	◆
Inactive Summary		Path Predecessor Summary Task	
Manual Task		Path Predecessor Normal Task	
Duration-only		Progress	
Manual Summary Rollup		Manual Progress	

ID	Task Mode	Task Name	Duration	Start	Finish	Predecessors	Resource Names	Qtr 3, 2021 Jul
34		**Frabrication Equipemt/ Software**	**7 days**	**Mon 1/10/22**	**Tue 1/18/22**		**Team**	
35		**Silhouette Cameo machine.**	**1 day**	**Mon 1/10/22**	**Mon 1/10/22**			
36		Understand how to use the machine	5 days	Mon 1/10/22	Fri 1/14/22		HA,AF	
37		Purchase machine	11 days	Tue 1/18/22	Tue 2/1/22		Dr.RAJ	
38		Tensile test machine.(Universal testing machine)	3 days	Sat 1/15/22	Tue 1/18/22		HA,AF	
39		Artificial pulse generator machine	3 days	Sat 1/15/22	Tue 1/18/22		AF,HA	
40		Understand Autocad/Solidwords methodology	7 days	Mon 1/24/22	Tue 2/1/22		AJ,RB	
41		**Coating for the sensor**	**2 days**	**Thu 1/13/22**	**Fri 1/14/22**			
42		Benefits of coating PVDF with silver	2 days	Thu 1/13/22	Fri 1/14/22		RB	
43		Complete Phase 1	0 days	Mon 1/17/22	Mon 1/17/22	14		
44		**Phase 2 - Design**	**16 days?**	**Tue 1/18/22**	**Tue 2/8/22**			
45		**Dimension of the PVDF**	**10 days**	**Tue 1/18/22**	**Mon 1/31/22**			

Project: Project plan-team1
Date: Sun 3/6/22

Task		Manual Summary	
Split		Start-only	[
Milestone	◆	Finish-only	]
Summary		External Tasks	
Project Summary		External Milestone	◇
Inactive Task		Deadline	◆
Inactive Milestone	◇	Path Predecessor Milestone Task	◆
Inactive Summary		Path Predecessor Summary Task	
Manual Task		Path Predecessor Normal Task	
Duration-only		Progress	
Manual Summary Rollup		Manual Progress	

ID	Task Mode	Task Name	Duration	Start	Finish	Predecessors	Resource Names	Qtr 3, 2021 Jul
46		**Create design on autocad/solidworks**	**10 days**	**Tue 1/18/22**	**Mon 1/31/22**	**43**		
47		**Rough draft of sensor 1**	**4 days**	**Tue 1/18/22**	**Fri 1/21/22**			
48		Design Filamentary Serpentine Pattern	4 days	Tue 1/18/22	Fri 1/21/22	19,21,22,23,27,28	RB,AJ	
49		**Rough draft sensor 2**	**6 days**	**Mon 1/24/22**	**Mon 1/31/22**	**47**		
50		Understand math for AD	3 days	Mon 1/24/22	Wed 1/26/22		AJ	
51		Show rotational angle	6 days	Mon 1/24/22	Mon 1/31/22		RB,AJ	
52		**Simulations**	**41 days?**	**Tue 2/1/22**	**Tue 3/29/22**			
53		**Determine best Area density(AD) of the sensor.**	**6 days**	**Tue 2/1/22**	**Tue 2/8/22**	**49**	**RB,AJ**	
54		Simulation of varying parameters that affect AD	6 days	Tue 2/1/22	Tue 2/8/22			
55		**Observe Stress and Strain Based Desired Applied Pressure**	**8 days**	**Wed 2/9/22**	**Fri 2/18/22**	**53**	**AJ,RB**	
56		Develop Stress-Strain Curve	3 days	Mon 2/21/22	Wed 2/23/22		RB	

Project: Project plan-team1
Date: Sun 3/6/22

Task		Manual Summary	
Split		Start-only	[
Milestone	◆	Finish-only	]
Summary		External Tasks	
Project Summary		External Milestone	◇
Inactive Task		Deadline	◆
Inactive Milestone	◇	Path Predecessor Milestone Task	◆
Inactive Summary		Path Predecessor Summary Task	
Manual Task		Path Predecessor Normal Task	
Duration-only		Progress	
Manual Summary Rollup		Manual Progress	

ID	Task Mode	Task Name	Duration	Start	Finish	Predecessors	Resource Names	Qtr 3, 2021 Jul
57		Observe Piezoelectric Properties with Desired Pressure	2 days	Fri 3/4/22	Mon 3/7/22	55	RB	
58		**Final design of sensor**	**12 days**	**Mon 1/24/22**	**Tue 2/8/22**	**47**		
59		Fixate dimensions and units	12 days	Mon 1/24/22	Tue 2/8/22	47		
60		Complete Phase 2	0 days	Wed 2/9/22	Wed 2/9/22	44		
61		**Phase 3 - Fabrication**	**20 days**	**Tue 2/1/22**	**Mon 2/28/22**			
62		**Fabrication of PVDF.**	**20 days**	**Tue 2/1/22**	**Mon 2/28/22**			
63		**Patterning PVDF**	**20 days**	**Tue 2/1/22**	**Mon 2/28/22**			
64		Use Cameo Silhouette machine to cut out PVDF	20 days	Wed 2/9/22	Tue 3/8/22	58,35	AF	
65		Apply silver ink to PVDF	20 days	Tue 2/1/22	Mon 2/28/22	64	HA	
66		Complete Phase 3	0 days	Tue 3/1/22	Tue 3/1/22	61		
67		**Phase 4- Verification Testing**	**19 days?**	**Mon 3/7/22**	**Thu 3/31/22**			
68		**Uniaxial Tensile Test**	**4 days**	**Tue 3/8/22**	**Fri 3/11/22**		**HA,AF**	
69		Gather Testing Equipment	1 day	Tue 3/8/22	Tue 3/8/22			

Project: Project plan-team1
Date: Sun 3/6/22

Task		Manual Summary	
Split		Start-only	[
Milestone	◆	Finish-only	]
Summary		External Tasks	
Project Summary		External Milestone	◇
Inactive Task		Deadline	◆
Inactive Milestone	◇	Path Predecessor Milestone Task	◆
Inactive Summary		Path Predecessor Summary Task	
Manual Task		Path Predecessor Normal Task	
Duration-only		Progress	
Manual Summary Rollup		Manual Progress	

ID	Task Mode	Task Name	Duration	Start	Finish	Predecessors	Resource Names	Qtr 3, 2021 Jul
70		Begin Test Run 1	1 day	Tue 3/1/22	Tue 3/1/22	66		
71		**Phantom Test via a Artificial Pulse Generator**	**7 days?**	**Mon 3/14/22**	**Tue 3/22/22**		**Team**	
72		**Assembly of the phantom test**	**12 days**	**Tue 3/29/22**	**Wed 4/13/22**		**Team**	
73		Find material with similar properties of skin	3 days	Mon 2/21/22	Wed 2/23/22			
74		Gather Testing Equipment	2 days	Mon 3/14/22	Tue 3/15/22			
75		Begin Test Run 1	7 days	Mon 3/14/22	Tue 3/22/22	66		
76		**Comparison of accelerometer and piezoelectric sensor**	**4 days**	**Thu 3/17/22**	**Tue 3/22/22**		**Team**	
77		Gather Testing Equipment	1 day	Thu 3/17/22	Thu 3/17/22			
78		Begin Test Run 1	4 days	Wed 3/23/22	Mon 3/28/22	66,71		
79		**Measurement Confirmation of SCG Sensor**	**1 day**	**Tue 3/8/22**	**Tue 3/8/22**		**AF**	
80		**Begin Test Run 1**	**1 day**	**Tue 3/8/22**	**Tue 3/8/22**	**66**		

Project: Project plan-team1
Date: Sun 3/6/22

Task		Manual Summary	
Split		Start-only	[
Milestone	◆	Finish-only	]
Summary		External Tasks	
Project Summary		External Milestone	◆
Inactive Task		Deadline	◆
Inactive Milestone	◆	Path Predecessor Milestone Task	◆
Inactive Summary		Path Predecessor Summary Task	
Manual Task		Path Predecessor Normal Task	
Duration-only		Progress	
Manual Summary Rollup		Manual Progress	

ID	Task Mode	Task Name	Duration	Start	Finish	Predecessors	Resource Names	Qtr 3, 2021 Jul
81		Measure sample sensors and compare to the design input	1 day	Tue 3/8/22	Tue 3/8/22			
82		**Measuring the power source voltage used via voltmeter**	**1 day?**	**Mon 3/14/22**	**Mon 3/14/22**		**HA**	
83		Gather Testing Equipment	1 day	Mon 3/14/22	Mon 3/14/22			
84		Begin Test Run 1	1 day?	Mon 3/14/22	Mon 3/14/22	66		
85		Complete Phase 4	0 days					
86		**Presentation**	**73 days**	**Mon 1/10/22**	**Wed 4/20/22**			
87		**Documentation**	**70 days**	**Mon 1/10/22**	**Fri 4/15/22**		**Team**	
88		**DHF Draft**	**6 days**	**Mon 2/28/22**	**Sun 3/6/22**	**43,60,66,67**	**Team**	
89		Revise Meeting Minutes	41 days	Mon 1/10/22	Sun 3/6/22		Team	
90		Project Report Draft	6 days	Mon 2/28/22	Sun 3/6/22	43,60,66,67	Team	
91		DMR Draft	6 days	Mon 2/28/22	Sun 3/6/22	43,60,66,67		
92		Final DHF	70 days	Mon 1/10/22	Fri 4/15/22			
93		Final DMR	70 days	Mon 1/10/22	Fri 4/15/22			
94		**Presentation**	**13 days**	**Mon 4/4/22**	**Wed 4/20/22**			

Project: Project plan-team1
Date: Sun 3/6/22

Task		Manual Summary	
Split		Start-only	[
Milestone	◆	Finish-only	]
Summary		External Tasks	
Project Summary		External Milestone	◆
Inactive Task		Deadline	◆
Inactive Milestone	◆	Path Predecessor Milestone Task	◆
Inactive Summary		Path Predecessor Summary Task	
Manual Task		Path Predecessor Normal Task	
Duration-only		Progress	
Manual Summary Rollup		Manual Progress	

ID	Task Mode	Task Name	Duration	Start	Finish	Predecessors	Resource Names	Qtr 3, 2021 Jul
95		Power Point Presentation	13 days	Mon 4/4/22	Wed 4/20/22			
96		Project Poster	13 days	Mon 4/4/22	Wed 4/20/22			
97		Presentation day	0 days	Thu 4/21/22	Thu 4/21/22			

Project: Project plan-team1
Date: Sun 3/6/22

Task		Manual Summary	
Split		Start-only	
Milestone		Finish-only	
Summary		External Tasks	
Project Summary		External Milestone	
Inactive Task		Deadline	
Inactive Milestone		Path Predecessor Milestone Task	
Inactive Summary		Path Predecessor Summary Task	
Manual Task		Path Predecessor Normal Task	
Duration-only		Progress	
Manual Summary Rollup		Manual Progress	

Section 8 - Meeting Minutes

Section 8.1 - Design Review Meeting Minutes

Agenda for Design Review Meeting

01/18/2022

Meeting Goals

- ➢ Review what the team has done thus far
- ➢ Receive advice towards how the team should be moving forward

Discussion Topics	Comments and Questions
Brief Summary of Project	● Synopsis of problem statement, solution, and project scope ● Explain the physiological significance of the device ○ How it would benefit patients with coronary artery disease ● Explain how PVDF would be the material of choice to convert mechanical signal to electrical ● Look also into different copolymers of PVDF and refresh into the principles of piezoelectricity
Project Plan	● Emphasis on the errors of the current project plan ● Plan must contain more detailed tasks/subtasks, who's assigned what tasks, what happens if a task is not completed or it passes the due date ● Don't include class assignments to the plan ● MS Project must be used to create the project plan

Key Decisions

- ➢ Change the format of the current project plan to include solely detailed tasks that help the project move forward
- ➢ Use MS Projects to revised project plan format
- ➢ Assigned Alessandra to manage the project plan

Action Item	Person Responsible	Due Date
Send reference papers to Dr. Christie about the project's physiology and signalling with PVDF via email	Antonio Fernandez	01/18/22
Revise project plan on MS	Alessandra Jimenez, Raquel	01/20/22

Projects	Bojorquez, Haniyeh Alirezaei, Antonio Fernandez	
Put together team's accomplishments, what are their next steps, threats they can face, and what's their mitigation plan	Raquel Bojorquez, Haniyeh Alirezaei, Antonio Fernandez, Alessandra Jimenez	02/01/22
Create proper agenda and DRM minutes	Raquel Bojorquez	02/01/22

Design Review Meeting Team #1

01/18/2022, 1:30pm - 2:05pm

I. Call to order

Dr. Christie called to order a design review meeting of Team 1 of BME4908 at 1:30pm January 19, 2022, via Zoom.

II. Roll call

Raquel Bojorquez assured a roll call, in which the following persons were present: Raquel Bojorquez, Dr. Michael Christie, Haniyeh Alirezaei, Antonio Fernandez, and Alessandra Jimenez

III. Approval of minutes from last meeting

The minutes were not discussed with the advisor at the time, but unanimously approved by the team prior.

IV. Open Issues

1. Synopsis of Team 1's problem statement, solution, and project scope
    A. Raquel presented a quick synopsis to Dr. Christie explaining the team's desires
        a. Dr. Christie asked the team questions focusing on the physiology, device signalling, and materials
            i. Team provided an explanation of how the physiology of the coronary artery disease is expressed and detected by the device would be important
            ii. Haniyeh provided an explanation of how PVDF would be the material of choice to convert mechanical signal to electrical

1. Dr. Christie suggests to look also into different copolymers of PVDF and refresh into the principles of piezoelectricity

b. Antonio was assigned to send reference papers to Dr. Christie about the project's physiology and signalling with PVDF via email

V. New business

1. Revision of project plan
   A. Dr. Christie emphasizes the importance of format of the plan
      i. Should be more detailed with subtasks, who's assigned what tasks, what happens if a task is not completed or it passes the due date
         1. It's not necessary to add class assignments to the plan only tasks that help the project move forward
      ii. An emphasis was made to construct the plan using MS Projects
         1. Alessandra was designated to manage the project plan but the team will assist in creating it
   B. Dr. Christie instructed for the team to submit a revised project plan by Thursday 1/20 at 3:30pm via Canvas email
2. Preparing for the following design review meeting
   A. Dr. Christie wants the team to present him with a proper agenda, meeting minutes, and revised project plan
      i. The suggestion was made to research how to write up a proper agenda
   B. Team must concern what are their accomplishments, what are their next steps, threats they can face, and what's their mitigation plan
      i. These points should be evidence-based and data-driven

VI. Adjournment

Dr. Michael Christie adjourned the meeting at 2:05pm
Minutes submitted by: Raquel Bojorquez

Agenda for Design Review Meeting
02/01/2022

Meeting Goals

- ➢ Review Market Requirements and Design Inputs
- ➢ Revised Project Plan Approval
- ➢ Review Project Success Factors

Discussion Topics	Comments and Questions
Market Requirements	• Discuss what the desired tangible output would be and how

	the team can achieve it ○ Should the market requirements include out of scope items?
Project Plan	● Explain the reasoning behind the structure of the plan ○ The subtasks for each phase ○ The dates for fabrication and verification testing are rough estimates ○ Is the structure of the project plan acceptable or should we continue to revise it?
Accomplishments, Next Steps, Threats, Mitigations	● Explain the team has accomplishments the past week ○ Raquel and Alessandra has developed the PVDF design on SolidWorks ○ Antonio has worked with Yeahia to learn how to use the Cameo Silhouette cutting machine ● Discuss what the team plans to do this following weeks ○ Raquel and Alessandra will work toward simulating a tensile strength test with the PVDF design ○ Antonio and Haniyeh will work with Yeahia using the Cameo Silhouette and practicing with the tensile strength test

Key Decisions

➢

Action Item	Person Responsible	Due Date
Present revised project plan on MS Projects	Alessandra Jimenez	02/01/22
Present team's accomplishments, what are their next steps, threats they can face, and what's their mitigation plan	Raquel Bojorquez	02/01/22
Present team's market requirements and design inputs	Raquel Bojorquez, Haniyeh Alirezaei, Antonio Fernandez, Alessandra Jimenez	02/01/22

Design Review Meeting Team #1

02/01/2022, 1:30pm - 2:00pm

I. Call to order

Dr. Christie called to order a design review meeting of Team 1 of BME4908 at 1:30pm February 1, 2022, via Zoom.

II. Roll call

Raquel Bojorquez assured a roll call, in which the following persons were present: Raquel Bojorquez, Dr. Michael Christie, Haniyeh Alirezaei, Antonio Fernandez, and Alessandra Jimenez

III. Approval of minutes from last meeting

The minutes were approved by Dr. Christie during the meeting and by the team prior

IV. Open Issues

1. No open issues were discussed this meeting, centered around new business.

V. New business

1. Changes to Market Requirements
    A. Team discusses concerns with Market Requirements
        i. Questions about adding and removing certain Market Requirements, to properly reflect the team's project scope.
            1. Beginning with MR #1, Dr. C recommended to split it up into 3 separate MR's, reflecting detection, reading, and conversion
            2. MR # 2, mentioning the amplitude range is redundant and should instead be in the Design Input.
            3. Similar with MR # 3, mention the pressure of Uniaxial Tension of 1.5 Pa in Design Input.
            4. MR# 5 regarding two-way transferring of data with an antenna shouldn't be mentioned in MR, but rather in Design Concept.
        ii. All Design Concepts and Verification Tests should have explanation as to why it was chosen
        iii. Christie brought up that Market requirements should only include what is reflected in the project scope.
            1. The team expressed that they will only be working on the sensor and not the entire device

2. MR #5 shouldn't be a market requirement as it does not involve the sensor

2. Final Thoughts
   A. Recommends team to look over the MR's and make sure they reflect the project scope.
      i. Dr. Christie set up an Ad Hoc meeting for Thursday the 3rd at 3:00 pm to see if the team was able to fix their market requirements.
         1. Meeting rescheduled for Friday the 4th at 1:00 p.m.

VI. Adjournment

Dr. Michael Christie adjourned the meeting at 2:05 p.m.
Minutes submitted by: Antonio Fernandez

Agenda for Ad Hoc Design Review Meeting

02/01/2022

Meeting Goals

- ➢ Review New Market Requirements and Design Inputs.
- ➢ Review Design concepts

Discussion Topics	Comments and Questions
Market Requirements	● Revised Market Requirements based on Dr. Christie's inputs ○ Focused on Market Requirements that are reflected from the project scope, revised market requirements in more specifics about the sensors and its requirements to function in ○ Added references for Design Inputs and Verification Tests with proper explanation as to why we chose these DI's and VT's.
Accomplishments, Next Steps, Threats, Mitigations	● Explain the team has accomplishments the past week ○ Alessandra has developed the design concept 2 on SolidWorks ○ Antonio and Haniyeh have worked with Yeahia to learn how to use the Cameo Silhouette cutting machine and made a protocol. ● Discuss what the team plans to do this following weeks ○ Raquel and Alessandra will work toward simulating a tensile strength test with the PVDF design as well as attempting to transfer the Solidworks design into the

	Cameo Silhouette. ○ Antonio and Haniyeh will work with Yeahia with the PVDF using the Cameo Silhouette cutting the rough pattern and practicing with the tensile strength test.

Key Decisions

➢ Removed all market requirements that don't relate to the project scope

Action Item	Person Responsible	Due Date
Present team's new market requirements and design inputs and design concepts based on Friday inputs.	Raquel Bojorquez, Haniyeh Alirezaei, Antonio Fernandez, Alessandra Jimenez	02/07/22

Ad Hoc Design Review Meeting Team #1
02/04/2022

I. Call to order

Dr. Christie called to order a team meeting of Team 1 of BME4908 at 1:00pm February 04, 2022 in person

II. Roll call

Dr. Christie assured a roll call, in which the following persons were present: Dr. Christie, Raquel Bojorquez, Haniyeh Alirezaei, Antonio Fernandez, and Alessandra Jimenez

III. Approval of minutes from last meeting

The minutes were not discussed at the time, but unanimously approved by the team prior.

IV. Open Issues

1. Finalize market requirements
2. Assure each DI has a verification and a reasoning.

V. New business

1. Dr. Christie says to clarify what using a phantom test will accomplish
   - To properly detect the mechanical signals of the heart
   - Add standards to Uniaxial test, (ISO and ect.)
2. Re-states to not mix Market Requirements
   - Not mix phantom test and Uniaxal test
3. Relating to PVDF, Uniaxial tension test is to strech PVDF to increase the piezoelectric constant.
   - When subjecting PVDF to a charge, the dipoles allign
   - Metallize the PVDF

- Attach electrodes to the mettalized PVDF
- When PVDF is Uniaxial modulated, it will have a higher Elastic Modulus.

4. Relating to MR #3, when looking at the range for skin's elastic modulus, compare to Elastic modulus of similar texture skin parts.
5. MR #4, change wording, device must fit to overall device size. Device must be compatable with patch. Device must not be a bother to person.
   - Split into two different conditions, one for size, one for comfort.
6. Back to MR #1.5, suggestion is just to remove it to avoid redundancies.
   - Sensor needs to be attached to electrode leads for the device to work.
   - Voltage created must be transfered to the circuit on the patch.
7. Homework was assigned to the team to identify what the sensor needs for it to work
8. Have design concepts ready for the next meeting.
9. Scheduled another meeting for Monday the 7th at 10:30 am.

VI. Adjournment

Dr. Christie adjourned the meeting at 1:40pm
Minutes submitted by: Antonio Fernandez

Ad Hoc Design Review Meeting Team #1

02/07/2022, 10:30am - 11:00am

I. Call to order

Dr. Christie called to order a design input review meeting of Team 1 of BME4908 at 10:30am February 7, 2022, via Zoom.

II. Roll call

Haniyeh Alirezaei assured a roll call, in which the following persons were present: Raquel Bojorquez, Dr. Michael Christie, Haniyeh Alirezaei, Antonio Fernandez, and Alessandra Jimenez

III. Approval of minutes from last meeting

The minutes were approved by Dr. Christie during the meeting and by the team prior

IV. Open Issues

1. No open issues were discussed this meeting, centered around new business.

V. New business

1. Changes to Design Inputs
   A. Dr. Christie reviewed the DIs and made the following comments.

i. DI #2 which conveys the conversion factor:
    1. The team should add a range for the vibration of the heart.
        a. Ex. The sensor should be able to convert minimum vibration (unit) to minimum electrical voltage.
ii. DI #3 which conveys the skin elastic compliance:
    1. Reasoning for DI 3 needs to be reworded.
        a. Ex. Use ‘maintain contact’ instead of ‘skin deformation’.
    2. Skin’s Young’s modulus needs to have a range.
iii. DI #4 which conveys the sensor’s compatible to the patch:
    1. Sensor needs to fit within the bond of the patch. How much room needs to be left in the patch? How much room is needed for the sensor to fit in the patch?
        a. What is a sufficient size?
        b. Check standards for TAPPI (packaging standards organization)
iv. DI #5 which conveys the powering of the sensor:
    1. Must identify the minimum voltage needed.
        a. Ex. Sensor should function with a power supply of a minimum (x) V and maximum of 5V.

2. Final Thoughts
    A. Recommends the team to look over the DIs and ensure they are clear to the reader and measurable within a range.
    B. Once team has finalized the MRs and DIs, they’re free to begin designing concepts

VI. Adjournment

Dr. Michael Christie adjourned the meeting at 11:00 a.m.
Minutes submitted by: Haniyeh Alirezaei

Agenda for Design Review Meeting

02/15/2022

Meeting Goals

- ➢ Review Design Concepts
- ➢ Finalize Market Requirements and Design Input

Discussion Topics	Comments and Questions

Design Concepts	● Present the three design concepts based on the finalized market requirements ● Explain how each design reflects each market requirements ● Discuss the rationale between each design by using the pros and cons table ○ Would we need to provide simulations for each design concept as an additional form of rationale?
Market Requirements	● Present the final cut of market requirements and design inputs ○ The final cut only reflects the team's scope of designing a SCG sensor ● Discuss the range value necessary for each design input and how the evidence is based on the attached references ● Clarify that the verification protocols for the recent changes will be added before starting any method of verifications ○ Is it required for each method of verification to include a testing standard? ■ Do we need to include a standard for measuring dimensions or comparing the function of two devices?

Key Decisions

➢ Changed market requirement about complying with patch's dimensions to reflect the dimensions of the desired placement

➢ Adjust design concept 1 & 2 from Senior 1 to reflect the recent changes to the market requirements

Action Item	Person Responsible	Due Date
Research and finalize the missing design inputs	Raquel Bojorquez, Haniyeh Alirezaei, Antonio Fernandez, Alessandra Jimenez	2/15/2022
Using SolidWorks to sketch out the design concepts	Raquel Bojorquez, Alessandra Jimenez	2/15/2022

Section 8.2 - Sponsor and Advisor Meeting Minutes

Peer Advisor Meeting Minutes Team #1

01/11/2022, 2:00 pm - 4:00pm

VII. Call to order

Raquel Bojorquez called to order a team meeting of Team 1 of BME4908 at 2:00pm January 19, 2022 in person

VIII. Roll call

Raquel Bojorquez assured a roll call, in which the following persons were present: Raquel Bojorquez, Haniyeh Alirezaei, Antonio Fernandez, and Alessandra Jimenez

IX. Approval of minutes from last meeting

The minutes were not discussed at the time, but unanimously approved by the team prior.

X. Open Issues

1. Prepare a presentation of up-to-date work for Girish and Dr. Christie.
2. Discuss the project scope and adjustments of the market requirements.

XI. New business

10. Put together two separate powerpoints for Dr. Christie presented our project scope and accomplishments.
11. Create a simple powerpoint presentation summarizing the work completed last semester for Girish.

XII. Adjournment

Raquel Bojorquez adjourned the meeting at 4:00pm
Minutes submitted by: Haniyeh Alirezaei

01/14/2022, 6:00pm - 7:00pm

I. Call to order

Raquel Bojorquez called to order a team meeting of Team 1 of BME4908 at 6:00pm January 14, 2022, via Zoom.

II. Roll call

Raquel Bojorquez assured a roll call, in which the following persons were present: Raquel Bojorquez, Haniyeh Alirezaei, Antonio Fernandez, and Alessandra Jimenez

III. Approval of minutes from last meeting

The minutes were reviewed and unanimously approved by the team.

IV. Open Issues

1. Check the powerpoint to present to Dr. Christie.
2. Discuss the project plan and phases.
3. Setting a set date for weekly group meetings.

V. New business

1. Update the project plan.
2. Finalize the powerpoint presentation for Dr. Christie

3. Adjournment

Raquel Bojorquez adjourned the meeting at 7:00pm
Minutes submitted by: Haniyeh Alirezaei

01/15/2022, 10:00am - 11:00am

I. Call to order

Raquel Bojorquez called to order a team meeting of Team 1 of BME4908 with sponsor Girish Wable and faculty mentor Dr. Raj at 10:00am January 15, 2022, via Zoom.

II. Roll call

Raquel Bojorquez assured a roll call, in which the following persons were present: Raquel Bojorquez, Dr. Markondeyaraj Pulugurtha, Yeahia Been Sayeed, Haniyeh Alirezaei, Antonio Fernandez, and Alessandra Jimenez

III. Approval of minutes from last meeting

The minutes were not discussed with the advisor at the time, but unanimously approved by the team prior.

IV. Open Issues

1. Review the accomplishments thus far.
2. What is the plan for this semester?
3. Set a schedule for weekly meetings.

V. New business

1. Update the powerpoint and make it more detailed and clear.
2. Partner with Yeahia for material and fabrication process.
3. Prepare the project plan.
4. Assign each person to a specific area of the project such as quality, design, manufacturing.

VI. Adjournment

Raquel Bojorquez adjourned the meeting at 11:00am
Minutes submitted by: Haniyeh Alirezaei

01/21/2022, 6:00pm - 10:00pm

I. Call to order

Raquel Bojorquez called to order a team meeting of Team 1 of BME4908 with peer advisor Yeahia Been Sayeed at 6:00pm January 21, 2022, via Zoom.

II. Roll call

Raquel Bojorquez assured a roll call, in which the following persons were present: Raquel Bojorquez, Yeahia Been Sayeed, Haniyeh Alirezaei, Antonio Fernandez, and Alessandra Jimenez

III. Approval of minutes from last meeting

The minutes were not discussed with the advisor at the time, but unanimously approved by the team prior.

IV. Open Issues

1. Presenting information to Yeahia's questions last week
    A. Haniyeh presented information regarding the comparison of different piezoelectric material and showing why PVDF was the better choice
        a) Relation to the mechanical properties
    B. Antonio presented slides on what can affect the quality of signal that the PVDF can collect
        a) Molecular Weight, Thickness, Stretching ratio, Positioning

V. New business

1. Sensor Design
    A. Alessandra presented the sketch of the PVDF on SolidWorks and explained how the next step would be to simulate the changes in area density would vary with the width
        i. It was explained that the only value not expressed in the sketch was the rotational angle, but Raquel and Alessandra would work on it for the new sketch
2. Verification Testing
    A. Artificial Pulse Generator
        i. Haniyeh asked if it were possible to perform the verification test on a human subject since all members are certified
            1. Yeahia sees no problem, but the team first needs to consult Dr. Christie, Girish, and Dr. Raj
        ii. Yeahia also gave the suggestion to modify a small pulse generator that he can provide to fit the project's criteria
    B. Tensile Strength Test
        i. Yeahia has a friend that can supply the machine for the test and he would let the team know when it's possible to use it
            1. He suggests one person accompany him, so Raquel suggests for Antonio to join since he is Head of Quality
3. Preparing for the following meeting

A. Yeahia asks if meetings can be moved for Mondays at 6:30pm and team unanimously agreed
B. Modify the market requirements to focus mainly on the sensor and adhere of the device
    i. Wireless communication may be included but won't be part of the team's scope

VI. Adjournment

Raquel Bojorquez adjourned the meeting at 10:00pm
Minutes submitted by: Raquel Bojorquez

Peer Advisor Meeting Minutes Team #1

01/24/2022, 6:30pm - 8:30pm

I. Call to order

Raquel Bojorquez called to order a team meeting of Team 1 of BME4908 with peer advisor Yeahia Been Sayeed at 6:30pm January 24, 2022, via Zoom.

II. Roll call

Alessandra Jimemez assured a roll call, in which the following persons were present: Raquel Bojorquez, Yeahia Been Sayeed, Haniyeh Alirezaei, Antonio Fernandez, and Alessandra Jimenez

III. Approval of minutes from last meeting

The minutes were reviewed and unanimously approved by the team.

IV. Open Issues

1. Determine meeting dates to work on understanding the tensile testing machine
    A. Meeting date on 1/25/2022 at 3:00 pm in Yeahia's cubicle
2. Discussed the layers of the prototype
    A. Agreed to show a cross-sectional view instead of a top view
3. Discussed reasoning for prototype design's parameters
4. Discussed phase 1
    A. For the materials research it was discussed that it is better to mention weak medical grade adhesive tape instead of "tape"
    B. The sensor characteristics were modified for compliance and stretchability

5. Haniyeh updated the piezoelectric analysis to showcase the properties related to the project scope.

V. New business

1. Antonio suggests to move meets for **Mondays at 7:00pm** and there was an unanimous agreement
2. Showcase angle of rotation in the design
    A. Alessandra and Raquel will work on adding the angle to the design as well as working on the simulation.
3. Preparing for the following meeting
    A. The team agreed on holding a meeting on **1/28/2022** at 1to review the changes in the powerpoint before sending it to Yeahi for review.
    B. Haniyeh will research possible methods to use as the artificial pulse generator, update the piezoelectric analysis, and add research on materials needed for the sensor.
    C. Raquel will convert the project phases to a table format for clarity.
    D. Alessandra will update the design of the patch
    E. Antonio will add the research behind the location of the sensor and factors that affect the sensor's sensitivity.

VI. Adjournment

Raquel Bojorquez adjourned the meeting at 8:30pm
Minutes submitted by: Alessandra Jimenez

Sponsor Meeting Minutes Team #1

01/29/2022, 10:00am - 11:00am

I. Call to order

Raquel Bojorquez called to order a team meeting of Team 1 of BME4908 with sponsor Girish Wable and faculty mentor Dr. Raj at 10:00am January 29, 2022, via Zoom.

II. Roll call

Raquel Bojorquez assured a roll call, in which the following persons were present: Raquel Bojorquez, Girish Wable, Dr. Markondeyaraj Pulugurtha, Yeahia Been Sayeed, Reshmi Banerjee, Haniyeh Alirezaei, Antonio Fernandez, and Alessandra Jimenez

III. Approval of minutes from last meeting

The minutes were not discussed with the advisor at the time, but unanimously approved by the team prior.

IV. Open Issues

1. Revised Master Review Presentation
    A.

V. New business

1. Changes and additions needed for the Master Presentation
    A.
2. Raquel proposed to Girish and Dr. Raj if the sponsor meeting could be held biweekly to provide a better tangible output and progress
    A. Both parties agreed but would like the presentation to be sent via email weekly to remain informed
3. Preparing for the following sponsor meeting
    A. Team will meet in person on Tuesday 02/01 at 4:00pm to look over how to modify given miniature pulse generator
        i. Observe how to mimic the pulse generator using an Arduino board and possibly be useful for future projects
    B. Alessandra and Raquel will continue to work towards resolving the issue with the SolidWorks simulation to display desired output
    C. Antonio will meet with Yeahia to continue working with the Cameo Silhouette machine

VI. Adjournment

Raquel Bojorquez adjourned the meeting at 11:00 am
Minutes submitted by: Raquel Bojorquez

01/31/2022, 7:00pm-8:00pm

I. Call to order

Raquel Bojorquez called to order a team meeting of Team 1 of BME4908 with peer advisor Yeahia Been Sayeed at 4:00pm February 1, 2022, via Zoom.

II. Roll call

Raquel Bojorquez assured a roll call, in which the following persons were present: Raquel Bojorquez, Yeahia Been Sayeed, Haniyeh Alirezaei, Antonio Fernandez, and Alessandra Jimenez

III. Approval of minutes from last meeting

The minutes were not discussed with the advisor at the time, but unanimously approved by the team prior.

IV. Open Issues

1. Discussed Market Requirement suggestions brought up by Dr. Christie

V. New business

1. Remove MR's not relating to final design
2. Convey information of Sponsor and BME faculty advisor Dr. Raj.
3. Review verification protocols, specifically of artificial pulse generator

VI. Adjournment

Raquel Bojorquez adjourned the meeting at 5:00pm
Minutes submitted by: Antonio Fernandez

02/01/2022, 4:00 pm-5:00pm

VII. Call to order

Raquel Bojorquez called to order a team meeting of Team 1 of BME4908 with peer advisor Yeahia Been Sayeed at 7:00pm January 1st, 2022, via Zoom.

VIII. Roll call

Raquel Bojorquez assured a roll call, in which the following persons were present: Raquel Bojorquez, Yeahia Been Sayeed, Haniyeh Alirezaei, Antonio Fernandez, and Alessandra Jimenez

IX. Approval of minutes from last meeting

The minutes were not discussed with the advisor at the time, but unanimously approved by the team prior.

X. Open Issues

1. Reviewed Market Requirements

XI. New business

1. Reviewed Ventriject device for SCG signals and vibrational shakers
   - Not really an option due to them being stationed in Europe.
2. Gave contact information to Yeahia to discuss with Dr. Raj and Girish Sponser
   - Haniyeh wanted to participate in Cameo experiments, Wednesday in the Afternoon
3. Look into Hemotag
4. Discussed Medical Grade Tapes
   - 3M Kind Removal Silicon Tape, Transpore and Blenderm Surgical Tape are all effective for skin.
5. Discussed Machines and Devices
   - Pulse/Vibrator Machine could be bought at Walmart perhaps?
6. Ansys structure still needs to be downloaded

7. Another model using Double Helix structure was considered to be worked on after this project
8. Analyzed Solidworks model, more work to be done there
   - try with 50um thickness
   - compare both values using a t-test

XII. Adjournment

Raquel Bojorquez adjourned the meeting at 8:00pm
Minutes submitted by: Antonio Fernandez

02/07/2022, 7:00pm - 8:30pm

XIII. Call to order

Raquel Bojorquez called to order a team meeting of Team 1 of BME4908 with peer advisor Yeahia Been Sayeed at 7:00pm February 7, 2022, via Zoom.

XIV. Roll call

Raquel Bojorquez assured a roll call, in which the following persons were present: Raquel Bojorquez, Yeahia Been Sayeed, Haniyeh Alirezaei, Antonio Fernandez, and Alessandra Jimenez

XV. Approval of minutes from last meeting

The minutes were not discussed with the advisor at the time, but unanimously approved by the team prior.

XVI. Open Issues

1. Review Design Concepts with Yeahia to get his feedback on the patterns, pros and cons, and selected materials as a sensor.
2. Yeahia explained and summarized what does metallizing mean and what is the purpose of it.

XVII. New business

1. Specify possible output for each design concept.
2. Design Concept 2, make the material highly compliant to the tissue.
3. Narrow down the width of Design Concept 3.
4. Use “Conformal” instead of “Compact” for the size.

XVIII. Adjournment

Raquel Bojorquez adjourned the meeting at 8:30pm
Minutes submitted by: Haniyeh Alirezaei

02/12/2022, 10:00am - 11:30am

I. Call to order

Raquel Bojorquez called to order a team meeting of Team 1 of BME4908 with peer advisor Yeahia Been Sayeed, Dr. Raj, and the sponsor Girish Wabble at 10:00am February 12, 2022, via Zoom.

II. Roll call

Haniyeh Alirezaei assured a roll call, in which the following persons were present: Raquel Bojorquez, Yeahia Been Sayeed, Haniyeh Alirezaei, Antonio Fernandez, and Alessandra Jimenez

III. Approval of minutes from last meeting

The minutes were not discussed with the advisor at the time, but unanimously approved by the team prior.

IV. Open Issues

1. Review the work progress of the team in fabrication and screen-printing the PVDF.
2. Went over the slides from the beginning.

V. New business

1. Slide 1 → Add 2-3 pictures of ECG multilayer patches and wrist watch.
2. Slide 1 → What are the limitation factors on ECG devices.
3. Slide 4 → Add a block diagram to show how SCG works.
4. Slide 5 → Why Hispanics? "Hispanics" needs to go on top with the first sentence.
5. Slide 6 → Mention which market research firm? Show 2-3 more firms.
6. Research for Phillips multi lead ECG.
7. Use appropriate terminology in the manufacturing section.

VI. Adjournment

Raquel Bojorquez adjourned the meeting at 11:30am

Minutes submitted by: Haniyeh Alirezaei

02/28/2022, 7:00pm - 7:40am

VII. Call to order

Raquel Bojorquez called to order a team meeting of Team 1 of BME4908 with peer advisor Yeahia Been Sayeed at 7:00pm February 28, 2022, via Zoom.

VIII. Roll call

Raquel Bojorquez assured a roll call, in which the following persons were present: Raquel Bojorquez, Yeahia Been Sayeed, Haniyeh Alirezaei, Antonio Fernandez, and Alessandra Jimenez

IX. Approval of minutes from last meeting

The minutes were not discussed with the advisor at the time, but unanimously approved by the team prior.

X. Open Issues

1. Finish meeting minutes
2. Finish DHF
3. Finish Project Statement

XI. New business

1. Discussed materials that will be needed for testing
   - Tensile testing confirmed for next week after Spring Break
   -Phantom vibration machine still being acquired
2. Materials confirmed with Yeahia
   -Yeahia stepped out at 7:40pm
3. Team decided to focus on completing meeting minutes, DHF, and Project Statement

XII. Adjournment

Raquel Bojorquez adjourned the meeting at 8:40am
Minutes submitted by: Antonio Fernandez

Section 8.3 - Team Meeting Minutes

Meeting Date: November 5, 2021

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P
Antonio Armando Fernandez	P
Alessandra Jimenez	P
Lizette Avila	A

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Raquel Bojorquez Note Taker: Antonio Armando Fernandez Timekeeper: Antonio Armando Fernandez

Topics Discussed:

Discussion Points	Comments
Design Inputs	● After interpreting the sponsor's interests into market requirements, the team began working on design inputs o Focus first on the characteristics of the device rather than the design of how the device will function o Research was done so that the design inputs could be measurable and verifiable
End of Meeting	

Updates needed:

- ❏ Continue working on proposal presentation
- ❏ A further meeting is needed to continue working on market requirements and design inputs.

Meeting Date: November 8, 2021

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P
Antonio Armando Fernandez	P
Alessandra Jimenez	P
Lizette Avila	A

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Raquel Bojorquez Note Taker: Alessandra Jimenez Timekeeper: Alessandra Jimenez

Topics Discussed:

Discussion Points	Comments
Overall Proposal Presentation	● Went over the progress made in the PowerPoint ○ Problem Statement, BME acumen, Business Need, current modalities, success factors, regulatory assessment, and relevant standards.
Cost Analysis	● What materials are needed? ○ PVDF, silver coating, photosensitive dry film, one-sided polyurethane film. ● Where will the materials be bought? ○ Suggestion: Mcmaster and Amazon
Design Inputs	● How to define the wireless communication, battery-less, interference, size, flexibility, and wearable characteristics of the device.
End of Meeting	

Updates needed:

- ❑ Continue working on proposal presentation
- ❑ A further meeting is needed to continue working on market requirements and design inputs.

Meeting Date: November 14, 2021

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P
Antonio Armando Fernandez	P
Alessandra Jimenez	P
Lizette Avila	A

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Team
Note Taker: Haniyeh Alirezaei
Timekeeper: Haniyeh Alirezaei

Topics Discussed:

Discussion Points	Comments
What are the market requirements (MR) based on the project scope.	● Research conducted on: o Market data. o Current devices. o Clinical need. o Surveys on wearable medical devices. o SCG concept

Fill in the House of Quality (HOQ) excel sheet	● Put together the MR and on the HOQ.
End of Meeting	

Updates needed:

- ❑ Send the MR's to Dr. Shahrestani for additional feedback if there is any need for an update.
- ❑ Send the MR's to Jabil for feedback and each MR priority.

Meeting Date: November 15, 2021

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P
Antonio Armando Fernandez	P
Alessandra Jimenez	P
Lizette Avila	A

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Team Note Taker: Raquel Bojorquez Timekeeper: Raquel Bojorquez

Topics Discussed:

Discussion Points	Comments
Finalizing the design inputs	● The first draft of design inputs were finalized and sent for feedback to Dr. Shahrestani
Beginning the House of Quality	● Concerns were discussed because there was little correlation between the market requirements and design inputs when beginning the HOQ ○ For this reason the team leader emailed Dr. Shahrestani for clarification ○ The section involving the design concept was not completed until feedback for the design inputs were received
End of Meeting	

Updates needed:

- ❑ Continue working on completing proposal presentation
- ❑ Feedback from Dr. Dr. Shahrestani for first draft of design inputs

Meeting Date: November 16, 2021

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P

Antonio Armando Fernandez	P
Alessandra Jimenez	P
Lizette Avila	A

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Team Note Taker: Raquel Bojorquez Timekeeper: Raquel Bojorquez

Topics Discussed:

Discussion Points	Comments
Revised MR based on Dr. Shahrestani and Jabil's feedback	● Revised the MR's based on the feedback provided by Dr. Shahrestani. o Clarified SCG signals characteristics such as amplitude and frequency.
End of Meeting	

Updates needed:

❑ Send the revised MR's to Dr. Shahrestani for feedback.

Meeting Date: November 19, 2021

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P
Antonio Armando Fernandez	P
Alessandra Jimenez	P
Lizette Avila	A

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Team Note Taker: Raquel Bojorquez Timekeeper: Raquel Bojorquez

Topics Discussed:

Discussion Points	Comments
Design Input Revision	● Revisions were made based on the comment Dr. Shahrestani made stating that the current design inputs are appropriate ● More research was done to understand the features needed for the device such SCG signal sensitivity, NFC characteristics, and properties of the necessary adhesive material
End of Meeting	

Updates needed:

- ❏ Revise House of Quality based on the revised design inputs
- ❏ Feedback from Dr. Dr. Shahrestani about revised design inputs

Meeting Date: November 20, 2021

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P
Antonio Armando Fernandez	P
Alessandra Jimenez	P
Lizette Avila	A

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Team Note Taker: Raquel Bojorquez Timekeeper: Raquel Bojorquez

Topics Discussed:

Discussion Points	Comments
Design Inputs Revision	● Based on the advice from our sponsor Girish, the design inputs regarding the sensor detect and accuracy were revised o Numerical rationale and references were added to the revised design inputs #1, #2 o All design inputs were rearranged to demonstrate the team's priority for the final device
House of Quality Revision	● Concerns were discussed if one market requirement could have multiple design inputs after completing the revisions ○ The HOQ was completed as if only a single design input could be used, but Dr. Shahrestani was contacted for clarification
End of Meeting	

Updates needed:

- ❏ Continue working on completing proposal presentation
- ❏ Start developing the pros and cons and the visual representation for each design concept.
- ❏ Finalize the HOQ depending on response from Dr. Shahrestani

Topics Discussed:

Discussion Points	Comments
Design Inputs	● Presented design inputs to Girish ● Revised Design Inputs o Added references o Removed size and weight of the device
House of Quality (Design Concepts)	● Developed Design Concepts o Defined each concept based on their sensors, on relying on EMFi, one on PCB, and one on PVDF

Overall Proposal Presentation	● Technology assessment o Further work on the analysis of PVDF, PCB, EMFi, gelled electrodes, Bluetooth, and NFC.
End of Meeting	

Updates needed:

- ❏ Continue working on proposal presentation
- ❏ Start developing the pros and cons and the visual representation for each design concept.
- ❏ Finalize the HOQ

Meeting Date: November 21, 2021

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P
Antonio Armando Fernandez	P
Alessandra Jimenez	P
Lizette Avila	A

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Team Note Taker: Raquel Bojorquez Timekeeper: Raquel Bojorquez

Topics Discussed:

Discussion Points	Comments
House of Quality Revision	● Based on Dr. Shahrestani's advise, the design inputs for market requirement #6 was separated into multiple design inputs o The newly added design inputs were added to the House of Quality and the analysis was repeated
End of Meeting	

Updates needed:

- ❏ Visual representations of design concepts need to be developed.

Topics Discussed:

Discussion Points	Comments
House of Quality (Design Concepts)	● Market requirements with multiple design inputs were separated o Went over the newly added design inputs
Overall Proposal Presentation	● Slides 1-11 were revised based on Dr. Shahrestani

End of Meeting

Updates needed:

- ❏ Visual representations of design concepts need to be developed.
- ❏ Further meeting needed to go over the division of the presentation for the oral presentation

Meeting Date: November 22, 2021

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P
Antonio Armando Fernandez	P
Alessandra Jimenez	P
Lizette Avila	A

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Team Note Taker: Alessandra Jimenez Timekeeper: Alessandra Jimenez

Topics Discussed:

Discussion Points	Comments
Finalize visual representation of design concepts	● Design concepts were revised o The first design concept was fixed to be NFC-based instead of Bluetooth. o The design concepts were finalized, and the representation was developed by Haniyeh and Alessandra
Overall Proposal Presentation	● The presentation was revised and finalized ▪ Only skin irritation as a hazard ▪ Bluetooth
Cost Analysis	● The materials needed were further analyzed (Raquel)
End of Meeting	

Updates needed:

- ❏ Overlook the proposal presentation
- ❏ Record the presentation for the committee
- ❏ Cost Analysis needs to be finished

Meeting Date: November 23, 2021

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P

Antonio Armando Fernandez	P
Alessandra Jimenez	P
Lizette Avila	A

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Team Note Taker: Alessandra Jimenez Timekeeper: Alessandra Jimenez

Topics Discussed:

Discussion Points	Comments
Finalize design inputs and House of Quality	● Before completing the final proposal video presentation the design inputs and design concepts were reviewed ○ Due to missing rationale and to avoid confusion, design input #2 was changed to specified mechanical noise instead of focusing on signal-noise ratio ● House of Quality was revised to follow the current revisions
Finalize visual representation of design concepts	● Design concepts were revised o The first design concept was fixed to be NFC-based instead of Bluetooth. o The design concepts were finalized, and the representation was developed by Haniyeh via KiCAD and Alessandra via AUTOCAD
Overall proposal presentation	● The PowerPoint presentation was finalized and the oral presentation was practiced and recorded.
End of Meeting	

Updates needed:

- ❏ Send the recording to the committee
- ❏ Further work on the DHF and written proposal

Topics Discussed:

Discussion Points	Comments
Cost assessment	● The product and project costs was finalized
Overall Proposal Presentation	● The presentation was finalized and the oral presentation was practiced and recorded.
End of Meeting	

Updates needed:

- ❏ Send the recording to the committee
- ❏ Further work on the DHF and written proposal

Meeting Date: November 28, 2021

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P
Antonio Armando Fernandez	P
Alessandra Jimenez	P
Lizette Avila	A

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Team Note Taker: Alessandra Jimenez Timekeeper: Alessandra Jimenez

Topics Discussed:

Discussion Points	Comments
Overall Proposal Presentation	● The presentation was edited and re-recorded based on the professor's comment
End of Meeting	

Updates needed:

- ❏ Send the recording to the committee
- ❏ Further work on the DHF and written proposal

Meeting Date: November 29, 2021

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P
Antonio Armando Fernandez	P
Alessandra Jimenez	P
Lizette Avila	A

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Team Note Taker: Antonio Fernandez Timekeeper: Antonio Fernandez

Topics Discussed:

Discussion Points	Comments
Written Proposal	● Team Leader Raquel Bojorquez sent an email to the BME faculty about our video proposal and when to hold a Q&A session ● Began to assign work for the written proposal ○ Raquel is assigned to 2a, 2b, and 5 ○ Alessandra is assigned to 4

	○ Haniyeh is assigned to 1 and 2c ○ Antonio is assigned to 3 Decided to do Q&A questions Tuesday at 12:00 p.m.
End of Meeting	

Updates needed:

- ❏ Practice session for Q&A session
- ❏ Work on DHF and written proposal

Meeting Date: December 5, 2021

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P
Antonio Armando Fernandez	P
Alessandra Jimenez	P
Lizette Avila	A

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Team
Note Taker: Antonio Armando Fernandez
Timekeeper: Antonio Armando Fernandez

Topics Discussed:

Discussion Points	Comments
Verification testing for design inputs	● Continued working of the DHF ○ Verification Protocols for design inputs #1, #2, #7 ■ Phantom Test with an Artificial Pulse Generator, an Uniaxial Tensile Test, and Mass Confirmation Assessment
Design inputs and House of Quality	● Design input #1 and #2 were reworded based on the comments made during the Q&A session ● House of Quality was revised to follow the current revisions
End of Meeting	

Updates needed:

- ❏ Finalize verification protocols
- ❏ Further work on written proposal (Section 2, 5, 6)
- ❏ Further work on DHF (Section 1, 6)

Topics Discussed:

Discussion Points	Comments

● DHF	● Assigned work for the Design History File.
● Protocol Verification	● Afterwards began working on Test Protocol_Verification for the verification tests ○ Two main tests will be used: Phantom Test with an Artificial Pulse Generator and an Uniaxial Tensile Test ■ Weight test was added later. ● Reworded market requirements and verification tests for a clearer description.
End of Meeting	

Updates needed:

- ❏ Finilaze DHF for review and submission.

Meeting Date: December 6, 2021

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P
Antonio Armando Fernandez	P
Alessandra Jimenez	P
Lizette Avila	A

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Team
Note Taker: Antonio Fernandez
Timekeeper: Antonio Fernandez

Topics Discussed:

Discussion Points	Comments
Design History File	● Continued working of the DHF ○ Verification Protocols
Written Proposal	● What materials are needed? ● Revised each written part ○ Finalized section 6 (Engineering Analysis and Decision-Making)
Technology Assessment	● Fixed technology assessment based on Q&A Feedback ○ Made the comparison more cohesive
End of Meeting	

Updates needed:

- ❏ Further work on written proposal
- ❏ Finalize DHF
- ❏ Finalize meeting minutes for the DHF

Meeting Date: January 21, 2022

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P
Antonio Armando Fernandez	P
Alessandra Jimenez	P
Yeahia Been Sayeed	P

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Raquel Bojorquez
Note Taker: Raquel Bojorquez
Timekeeper: Raquel Bojorquez

Topics Discussed:

Discussion Points	Comments
Overall Update Presentation	● Went over the comparison between different piezoelectric materials ○ Relation to the mechanical properties ● Antonio presented slides on what can affect the quality of signal that the PVDF can collect ○ Molecular Weight, Thickness, Stretching ratio, Positioning
Design	● Alessandra presented the sketch of the PVDF on SolidWorks and explained how the next step would be to simulate the changes in area density would vary with the width ○ It was explained that the only value not expressed in the sketch was the rotational angle, but Raquel and Alessandra would work on it for the new sketch
Verification Testing	● Artificial Pulse Generator ○ Haniyeh asked if it were possible to perform the verification test on a human subject since all members are certified ■ Yeahia sees no problem, but the team first needs to consult Dr. Christie, Girish, and Dr. Raj ■ Yeahia also gave the suggestion to modify a small pulse generator that he can provide to fit the project's criteria ● Tensile Strength Test ○ Yeahia has a friend that can supply the machine for the test and he would let the team know when it's possible to use it ■ He suggests one person accompany him, so Raquel suggests for Antonio to join since he is Head of Quality
End of Meeting	

Updates needed:

- ❏ Further work on the simulations
  - ❏ A meeting will be arranged with Yeahia, Alessandra, and Raquel to further discuss the simulations

- ❏ The market requirements need to be updated to show a focus on the sensor
    - ❏ Wireless communication may be included but won't be part of the team's scope

Meeting Date: February 01, 2022

Attendees	
Raquel Bojorquez	P
Alessandra Jimenez	P

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Raquel Bojorquez Note Taker: Alessandra Jimenez Timekeeper: Alessandra Jimenez

Topics Discussed:

Discussion Points	Comments
Design	● Alessandra and Raquel worked on defining the direction of the applied pressure and the fixed face. ○ It was concluded that the fix will be on the left face of the design while the pressure would be applied to the outer faces on the right in the same direction as the plane.
End of Meeting	

Updates needed:

- ❏ Alessandra and Raquel will continue working on the simulations and present the current status to the rest of the team.

Meeting Date: February 5th, 2022

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P
Antonio Armando Fernandez	P
Alessandra Jimenez	P

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Raquel Bojorquez Note Taker: Antonio Fernandez Timekeeper: Antonio Fernandez

Topics Discussed:

Discussion Points	Comments

Powerpoint Presentation update	● Decided to go through entire powerpoint slide by slide to make sure everything is good. ○ Reworded problem statement to remove confusion. ○ Thought about changing the chart in background information to reflect only the sensor and not the whole device. ● Added ISO regulation of Design Inputs based on Christie's restrictions. ● Researched what the sensor needs in order to transfer voltage to the electrical components. ● Looked into conductance ● Decided to keep market requirements as is and argue why we think we won't need anymore.
End of Meeting	

Updates needed:

- ❏ Talk to Dr. Christie about what would be the next step
  - ❏ Discuss Design Concepts and Verification Testing.
- ❏ Finalize Market requirements

Meeting Date: February 6th, 2022

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P
Antonio Armando Fernandez	P
Alessandra Jimenez	P

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Raquel Bojorquez Note Taker: Antonio Fernandez Timekeeper: Antonio Fernandez

Topics Discussed:

Discussion Points	Comments
Finalize design concepts	Meeting began at 11:00 am. ● Goal was to look over and finalize design concepts ○ LDV isn't specific to SCG, so it will be removed from current modalities ○ Antonio will add Ventriject device for current modalities ○ Raquel was assigned to fix business needs ● Did research to see if a copolymer of PVDF(TFE) was better ○ Researched EMFI again as well ● For design concept 1, added the PCB board with the accelerometer idea. ● For design concept 2, added the EMFI sensor from the previous powerpoint. ● For design concept 3, kept the PVDF sensor from the previous powerpoint. ● Antonio will add data about what has been happening in the lab

	● Alessandra and Raquel will try to finalize Solidworks creation and convert the device into a DXF file. ● Future meeting plans involve discussing technology assessment. Meeting ended at 4:30
End of Meeting	

Updates needed:

- ❏ Talk to Dr. Christie to determine if these Design concepts are good
- ❏ Follow up with Verification testing and manufacturing questions for next meeting

Meeting Date: February 08, 2022

Attendees	
Raquel Bojorquez	P
Alessandra Jimenez	P

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Raquel Bojorquez Note Taker: Alessandra Jimenez Timekeeper: Alessandra Jimenez

Topics Discussed:

Discussion Points	Comments
Design	● Alessandra presented the measurements needed to generate the AD values of 10%, 30%, 40%, 50%, 60%, and 70%. ○ Alessandra and Raquel discussed that it is needed to show the simulation results for all the mentioned AD and compared their stress values.
End of Meeting	

Updates needed:

- ❏ Alessandra and Raquel will develop a simulation results report
  - ❏ Alessandra will develop the results for AD values of 50%, 60%, and 70%
  - ❏ Raquel will develop the results for AD values of 10%, 30%, and 40%.

Meeting Date: February 16, 2022

Attendees	
Raquel Bojorquez	P
Alessandra Jimenez	P
Yeahia Been Sayeed	P

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Raquel Bojorquez Note Taker: Alessandra Jimenez Timekeeper: Alessandra Jimenez

Topics Discussed:

Discussion Points	Comments
Simulation status	● Discussed the results for stress, strain, and displacement ○ Alessandra and Raquel presented the simulation process to Yeahia ○ **Yeahia raised a question about the possibility of obtaining a stress-strain curve from the simulation results.**
End of Meeting	

Updates needed:

- ❏ Raquel will work on developing the stress-strain curve.
- ❏ Alessandra will develop the design with the new dimensions.

Meeting Date: February 21, 2022

Attendees	
Haniyeh Alirezaei	P
Raquel Bojorquez	P
Antonio Armando Fernandez	P
Alessandra Jimenez	P
Yeahia Been Sayeed	P

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Raquel Bojorquez
Note Taker: Raquel Bojorquez
Timekeeper: Raquel Bojorquez

Topics Discussed:

Discussion Points	Comments
Manufacture status	● Metallized PVDF versus manually metalizing PVDF ○ The team and Yeahia discussed the benefits and disadvantages of both processes, along with the current results obtained with manually metalizing PVDF. The main issue discusses was that with manually applying the silver ink, close to no samples have shown closed circuits, hence it was decided to buy metalized PVDF
Simulation status	● Alessandra and Raquel provided a summary of the results of the simulations ○ A meeting for February 22, 2022, at 3:00 pm between Alessandra, Raquel, and Yeahia was established to further discuss the simulations. ○ Raquel explained the status of the stress-strain curve

Status of purchased parts	● Yeahia directed the team to follow up with Dr.Raj
Discusses updated master presentation slides	● Updated the flowchart of the proposed solution ● Reworded the target patients to be general adult males instead of specifying the sensor to be for Hispanic adult males.
Discussed the pre-manufacturing agreement	● Materials and primary manufacturing method need to be updated
End of Meeting	

Updates needed:

- ❏ Alessandra and Raquel will meet with Yeahia on February 22, 2022, to discuss the results of the simulation.
- ❏ Arrange a meeting with Dr. Hutcheson
- ❏ The materials and primary manufacturing method of the pre-manufacturing agreement have to be updated.
- ❏ The team will contact Dr.Pala about the possibility of him having an artificial pulse generator
- ❏ The team will work on finalizing the test protocols to start test verifications.

Meeting Date: February 22, 2022

Attendees	
Raquel Bojorquez	P
Alessandra Jimenez	P
Yeahia Been Sayeed	P

P = Present L = Late AE = Absent (Excused) A = Absent

Facilitator: Raquel Bojorquez Note Taker: Raquel Bojorquez Timekeeper: Raquel Bojorquez

Topics Discussed:

Discussion Points	Comments
Simulation status	● Compare the results of the design dimensions (15 mmx23 mm vs 23mm x31 mm) ○ The team had previously agreed to go with 23 mm x 31 mm, given the better results obtained in the simulation, which Yeahia agreed on. ● Understand the pressure value of 1.5 Pa ○ Yeahia and the team discuss the lack of support for the value found through research due to seismocardiograms sensors being a newly studied area. ■ Yeahia suggested discussing the value with Dr. Hutcheson ● Correlation to the results of the main reference paper

	○ Yeahia and the team discussed that while the simulations showed the same trend as the paper, the values differ given the scaling of the paper. ■ Due to the lack of explanation within the paper, the team agreed to only relate the trend with the paper ● Can we obtain the young's modulus? ○ Raquel discussed a potential method of calculating the young's modulus from the stress and strain values of the simulation.
Yeahia showed a new potential design	● The team discussed its potential result and agreed that it might provide less stretchability than the current design, filamentary serpentine.
End of Meeting	

<u>Updates needed:</u>

- ❏ Alessandra and Raquel will update the simulation results based on the new dimensions.
- ❏ Alessandra will perform the simulation for the new design Yeahia provided.
- ❏ Alessandra will update the presentation to show only the trend compared with the reference paper.
- ❏ Raquel will work on obtaining a stress-strain curve to show the young's modulus of the patterned PVDF.

Appendix

Matlab Code

Senior Project Graphs

```
clc
clear all
close all
```

Simulations: COMSOL Piezoelectric Analysis

```
%Patterned [15x23] Data
Patterned1_VData = xlsread('Piezo Data.xlsx','A3:B18');
Freq_P1 = Patterned1_VData(:,1);
Volt_P1 = Patterned1_VData(:,2);
%Patterned [23x31] Data
Patterned2_VData = xlsread('Piezo Data.xlsx','D3:E18');
Freq_P2 = Patterned2_VData(:,1);
Volt_P2 = Patterned2_VData(:,2);
%Patterned [30x39] Data
Patterned3_VData = xlsread('Piezo Data.xlsx','G3:H18');
Freq_P3 = Patterned3_VData(:,1);
Volt_P3 = Patterned3_VData(:,2);

figure(2)
plot(Freq_P1,Volt_P1,Freq_P2,Volt_P2,Freq_P3,Volt_P3)
xlabel('Frequency (Hz)')
ylabel('Voltage Output (mV)')
title('Piezoelectric Analysis of Patterned PVDF Sensor' )
legend('Size: 14.59 x 23.13 mm','Size: 22.31 x 30.92 mm','Size: 29.95 x 38.56 mm')
```

Linear Correlation For Phantom Test

```
x = [0, 10, 20, 30, 40];
y = [1342, 1778, 2409, 2497, 2743]
plot(x,y)
xlabel("Frequency (Hz)")
ylabel("Output Voltage (p-p) (mV)")
legend("Experimental Data")
```

Lab Engineering Notebook

TITLE Size Verification

Project No. 2

Book No.

Confidential

From Page No.

Objective: to confirm the size of the sensor is less than 27.7 ± 4.1 mm for width and 154.1 ± 13.1 for length.

Materials: PVDF - Sensor
Caliper

Data Collection
* measurements were taken in 'mm' range.

Sample Number	Width (mm)	Length (mm)
1	21.1	30.6
2	22.7	30.5
3	22.0	31.6
4	22.6	30.8
5	~~30.7~~ 22.1	30.7

To Page No.

Witnessed & Understood by me.

Date 03/30/22

Invented by: Raquel G. and Alessandra

Recorded by: Alessandra G.

To Page No.

Date 03/30/22

TITLE Killer test: Artificial Pulse Generator Project No. 3 5

Book No. Confidential

From Page No.

Objective: Artificially simulate the vibrations from the heart to verify the sensor's sensitivity to ~~SCF~~ SCG signals.

Materials: Function Generator
Waveform amplifier
Vibration Generator
Digital Oscilloscope
Alligator Clips
BNC to BNC cable
PVDF Sensor

Note: This day only the setup was developed since some cables were missing (BNC-BNC cables and BNC-alligator clip cable). Yet, the vibration generator was tested and it worked properly.

Set up: Function generator connected to the waveform amplifier. The amplifier was connected to the vibration generator. The oscilloscope was directly connected to the sensor.

Data: Only noise data was recorded. No data was saved.

Conclusions: • Carry the experiment again once the cables are obtained.

To Page No. | Date

Witnessed & Understood by me. | Date 04/05/22

Invented by: Raquel B., Antonio F., and Alessandra J. | Recorded by: Alessandra J | Date 4/05/22

6

Project No. 3

Confidential Book No.

TITLE Killer test: Artificial Pulse Generator

From Page No. 5

Materials: Function Generator
Waveform Amplifier
Vibration Generator
Low-noise Preamplifier
Digital Oscilloscope
Alligator Clip
BNC to BNC Cables
PVDF Sensor
BNC to alligator clip cable

Set up: The function generator was connected to the waveform amplifier. ~~The~~ This was connected to the vibration generator. The + electrodes of the sensor were directed to the low-noise Pre amplifier, which was connected to the oscilloscope.

* The Pre-amplifier was configurated with a "x10" factor of magnitude.

~~Note:~~

Data: A sinousoidal wave was seen on the oscilloscope, matching the input from the function generator. However, only ~~noisy~~ noisy data was shown.

Note: It was noted that regardless of the input signal from the function generator, the oscilloscope ~~w~~ showed a sinousoidal wave.

To Page No.

Witnessed & Understood by me.

Date 04/06/22

Invented by: Raquel B, Hamych A, and Alessandra J

Recorded by: Alessandra J

Date 4/6/22

Project No. 3 7

TITLE Killer test: Arboval Pulse Generator Book No. Confidential

From Page No. 5

Note: Materials and set up were kept from last report.

Objective: Attempt to understand more the oscilloscope and see if an SGG data can be imported into the function generator.

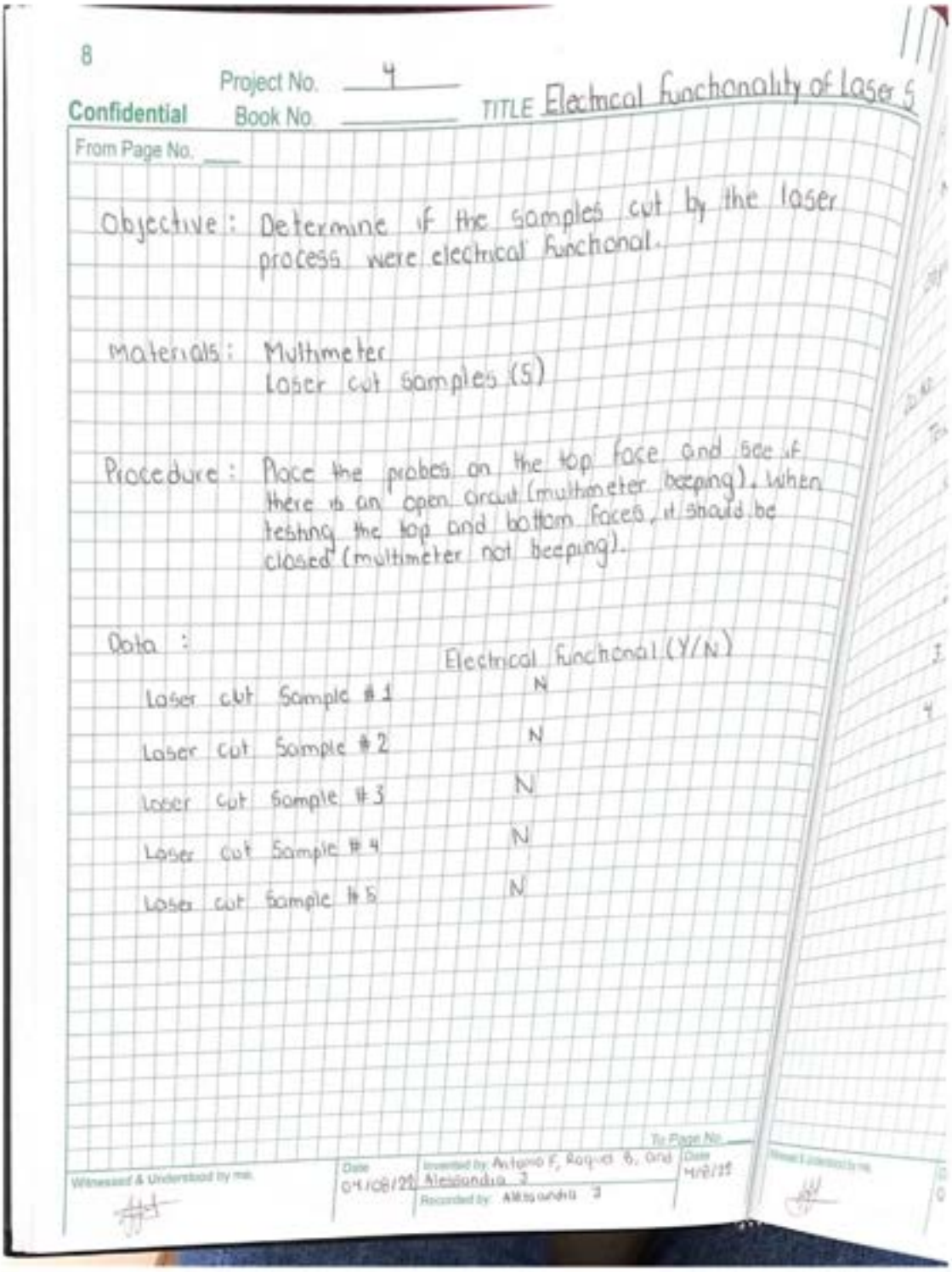
Note: The data was not able to be imported into the function generator. The oscilloscope still showed a sinousidal wave output, but this was distorted when the input wave was changed.

To Page No.

Witnessed & Understood by me. Date 04/04/22

Invented by: Raquel S. and Alessandra Date 4/3/22

Recorded by: Alessandra Z



8

Project No. 4

Confidential Book No. _____ TITLE Electrical Functionality of Laser 5

From Page No. ___

Objective: Determine if the samples cut by the laser process were electrical functional.

Materials: Multimeter
Laser cut samples (5)

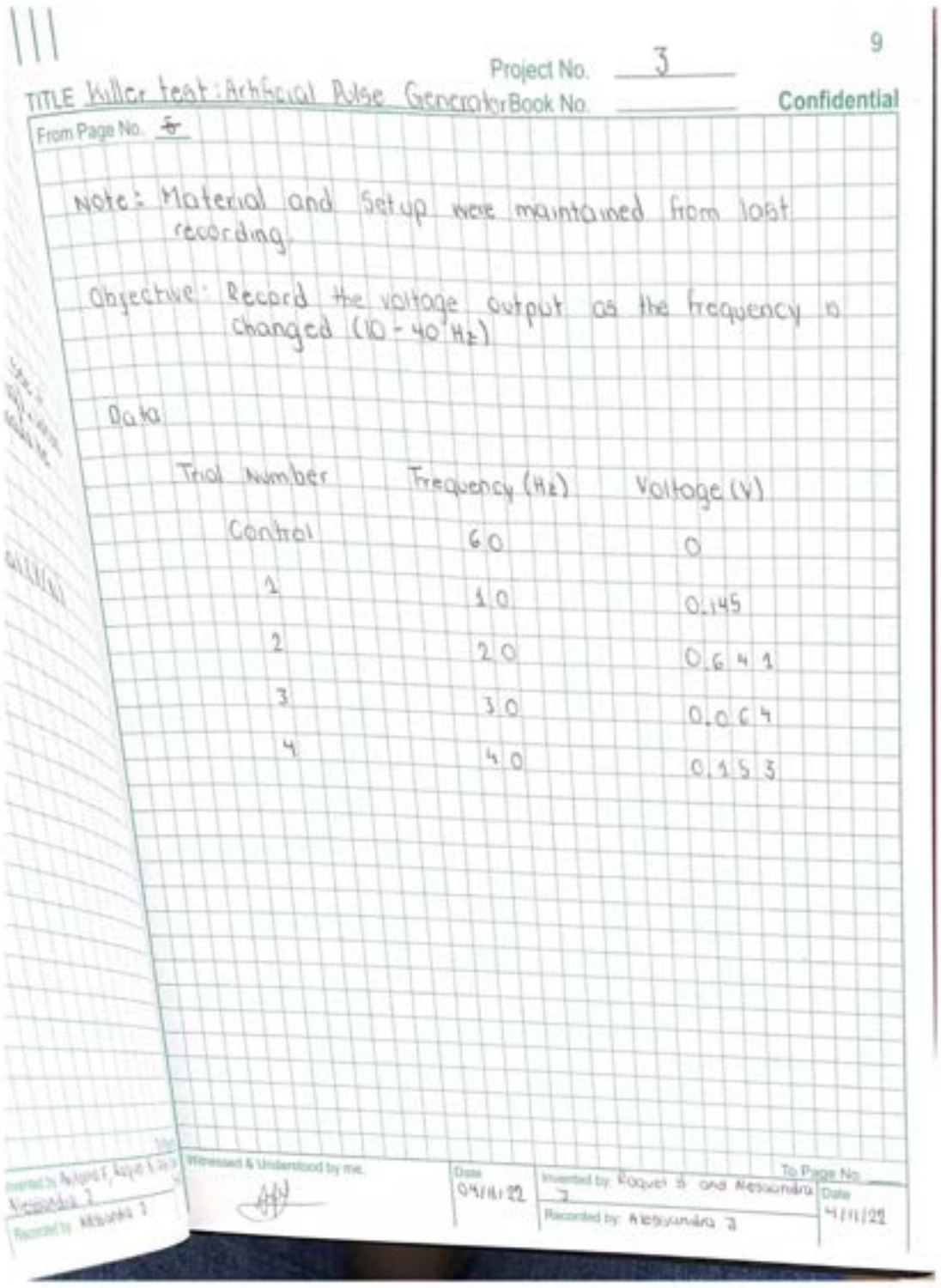
Procedure: Place the probes on the top face and see if there is an open circuit (multimeter beeping). When testing the top and bottom faces, it should be closed (multimeter not beeping).

Data:

	Electrical Functional (Y/N)
Laser cut Sample # 1	N
Laser cut Sample # 2	N
Laser cut Sample # 3	N
Laser cut Sample # 4	N
Laser cut Sample # 5	N

To Page No. ___

Witnessed & Understood by me. Date 04/08/25 Invented by: Antonio F, Raquel B, and Alessandra J Recorded by: Alessandra J Date 4/8/25



Project No. 3 — 9

TITLE Killer test: Artificial Pulse Generator Book No. — Confidential

From Page No. 5

Note: Material and Setup were maintained from last recording.

Objective: Record the voltage output as the frequency is changed (10 - 40 Hz)

Data

Trial Number	Frequency (Hz)	Voltage (V)
Control	60	0
1	10	0.145
2	20	0.641
3	30	0.064
4	40	0.153

Witnessed & Understood by me. — Date 04/11/22 — Invented by: Raquel S. and Alessandra J. — Recorded by: Alessandra J. — Date 4/11/22 — To Page No.

10 Project No. 3

Confidential Book No.

TITLE Killer test: Artificial [illegible]

From Page No. 5

* Note: Same setup and procedure as last recording. 10 data values were recorded for each case.

All data was recorded with the one electrical functional sample (Sample 4-3).

~~Trial~~

Data

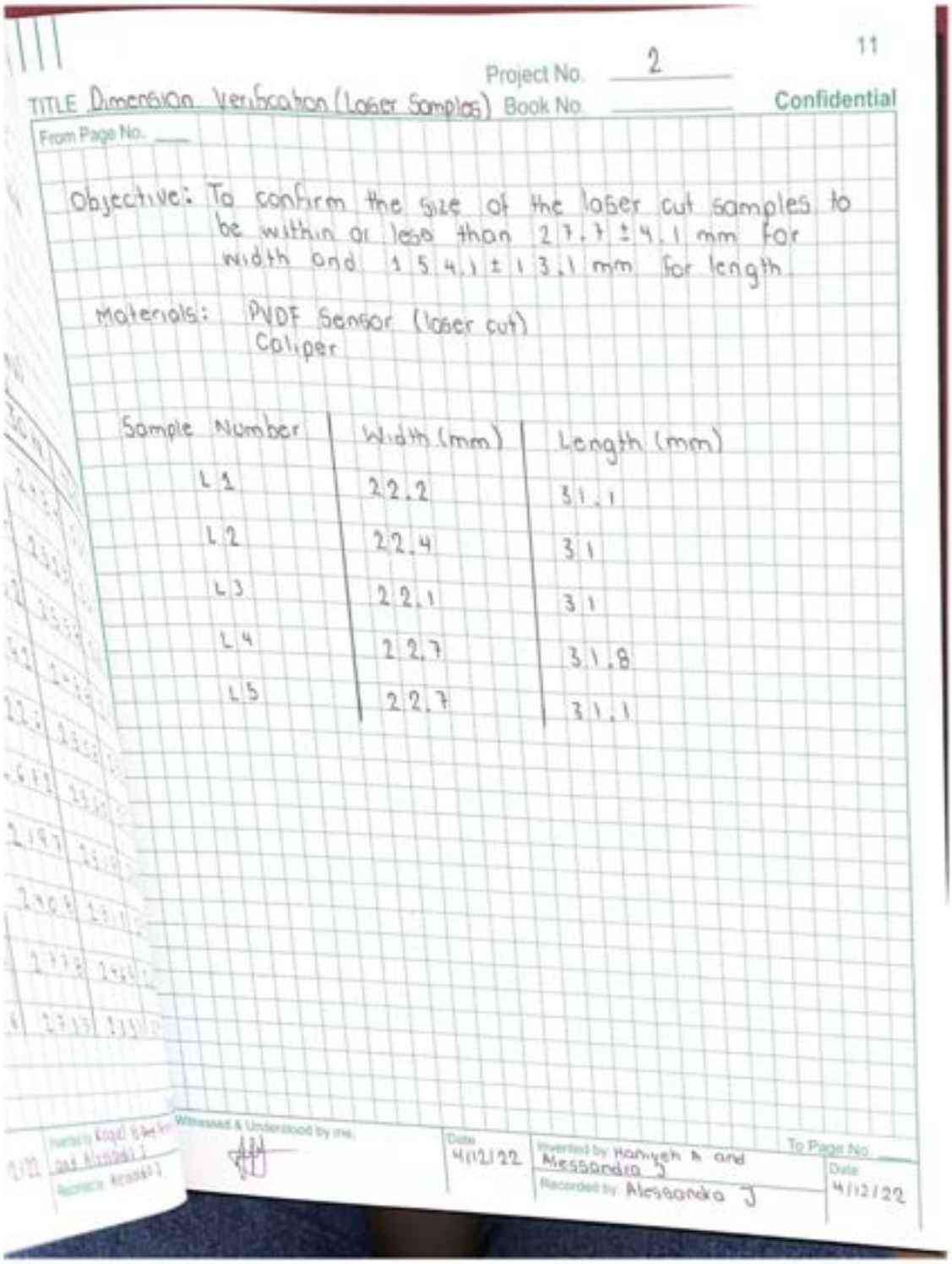
Trial #	Voltage Calculation (mV) Initial Amplitude: 1 V				
	Control	10 Hz	20 Hz	30 Hz	40 Hz
1	900.5	1831	2007	2484	2593
2	1358	1746	2207	2525	2673
3	1510	1773	2282	2556	2836
4	1515	1749	2492	2488	2746
5	1393	1751	2226	2506	2784
6	1337	1771	2672	2560	2746
7	1369	1763	2197	2519	2849
8	1338	1798	2408	2513	2773
9	1338	1825	2778	2469	2687
10	1356	1776	2733	2351	2746

To Page No.

Witnessed & Understood by me. Date 4/12/22

Invented by: Raquel B and, Antonio F and Alessandra J Date 4/12/22

Recorded by: Alessandra J



Project No. 2 11

TITLE Dimension Verification (Laser Samples) Book No. Confidential

From Page No.

Objective: To confirm the size of the laser cut samples to be within or less than 27.7 ± 4.1 mm for width and 154.1 ± 13.1 mm for length.

Materials: PVDF Sensor (laser cut)
Caliper

Sample Number	Width (mm)	Length (mm)
L1	22.2	31.1
L2	22.4	31
L3	22.1	31
L4	22.7	31.8
L5	22.7	31.1

Witnessed & Understood by me.

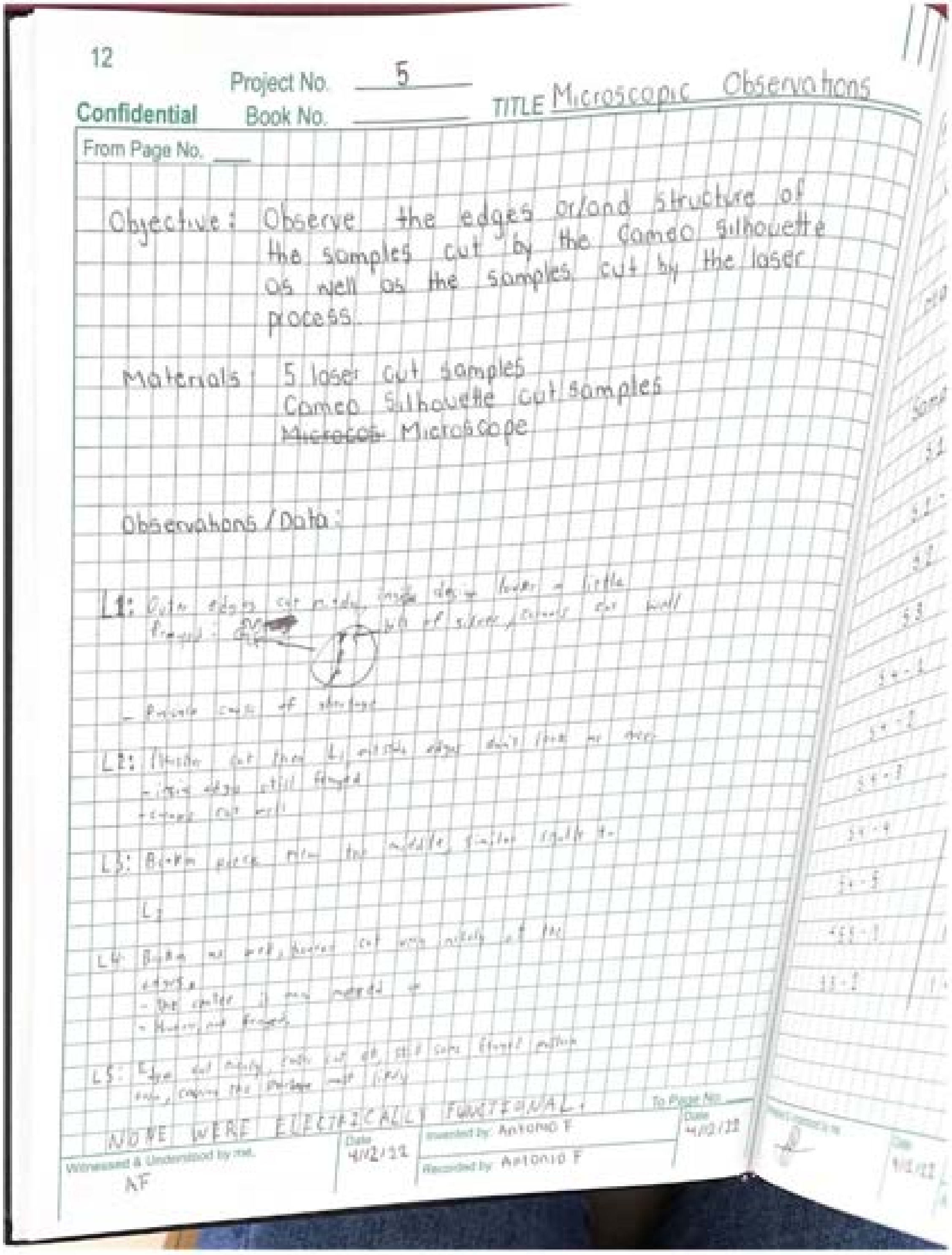
Date 4/12/22

Invented by: Hamyeh A and Alessandra J

Recorded by: Alessandra J

To Page No.

Date 4/12/22



12

Project No. 5

Confidential Book No. ______ TITLE Microscopic Observations

From Page No. ___

Objective: Observe the edges or/and structure of the samples cut by the Cameo Silhouette as well as the samples cut by the laser process.

Materials: 5 laser cut samples
Cameo Silhouette cut samples
~~Microcos~~ Microscope

Observations / Data:

L1: [illegible] edges cut [illegible] design [illegible] a little [illegible] cut well
[illegible]

- [illegible]

L2: [illegible] cut [illegible] edges [illegible]
- [illegible] still [illegible]
- [illegible] cut well

L3: [illegible] piece [illegible] middle [illegible]

L4: [illegible] cut [illegible]
- the center [illegible]
- [illegible]

L5: [illegible]
[illegible]

NONE WERE ELECTRICALLY FUNCTIONAL.

To Page No. ___

Witnessed & Understood by me, AF | Date 4/2/22 | Invented by: Antonio F | Recorded by: Antonio F | Date 4/2/22

TI

13

TITLE Dimensions Verification

Project No. 2

Book No.

Confidential

From Page No.

Objective: To confirm the size of the sensor is within or less than 27.7 ± 4.1 mm for width and 154.1 ± 13.1 mm for length.

Materials: PVDF Sensor
Caliper

Sample Number	Width (mm)	Length (mm)
S1 - 1	29.58	46.87
S1 - 2	29.58	46.87
S2	29.11	40.34
S3	47	65.13
S4 - 1	22.3	31.3
S4 - 2	22.6	32.1
S4 - 3	22.7	30.5
S4 - 4	22.1	30.9
S4 - 5	21.9	30.9
S5 - 1	14.6	23.7
S5 - 2	14.8	23.5

To Page No.

Witnessed & Understood by me.

Date 4/12/22

Invented by: Haniyeh A and Alessandra J

Recorded by: Alessandra J

Date 4/12/22

14

Confidential Project No. 6 Book No. _____ TITLE Killer test: Artificial Pulse Generator

From Page No. 14

Objective: Determine if there is a correlation between the frequency the machine operated in and the peak voltage that was being generated.

Note: Material and setup were kept from last recording.

* Sample 54-3 was used (only electrical functional sample)

Data: Different Control Settings

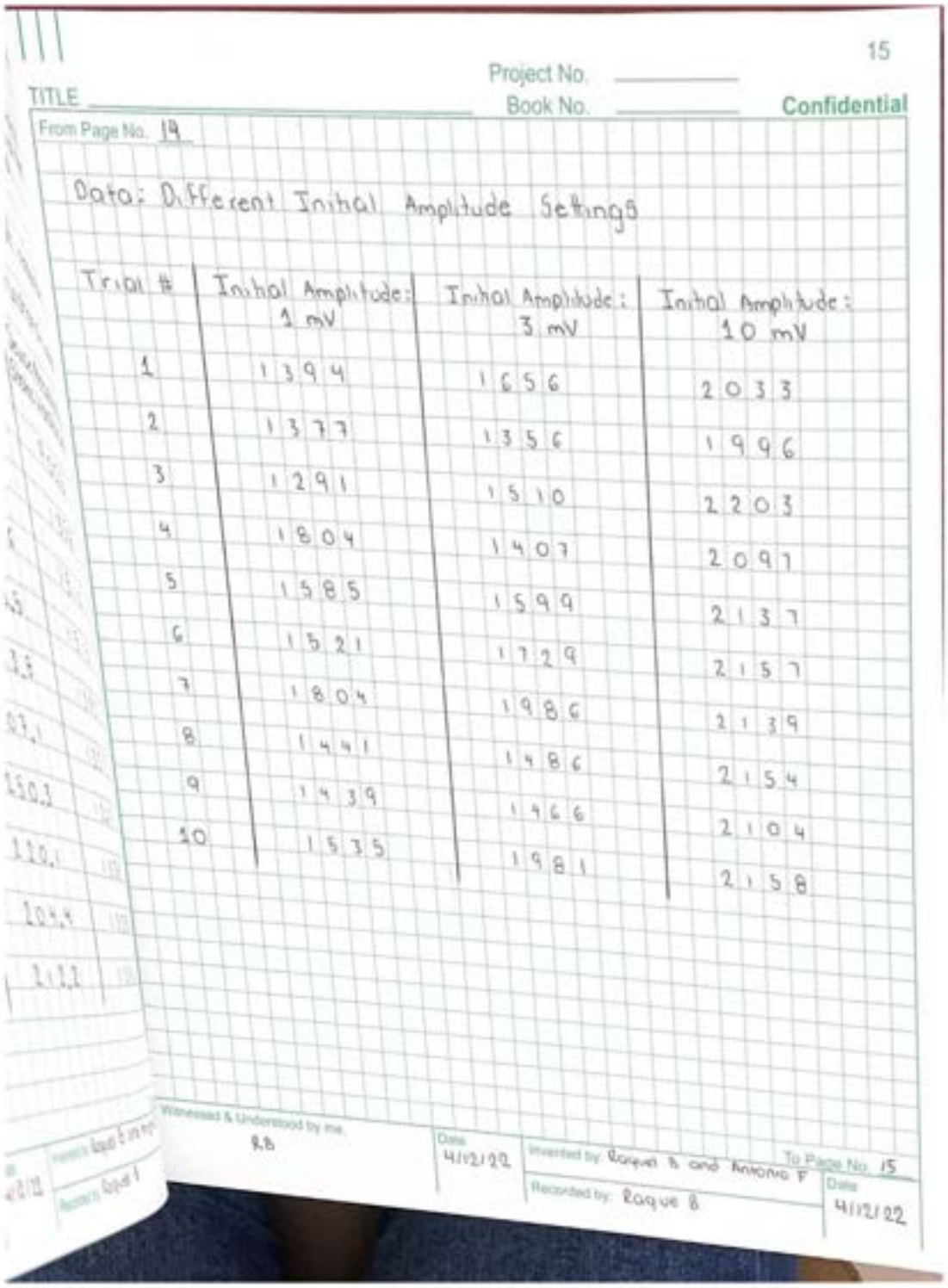
Trial #	Device Not Attached, only Clips (mv)	Device Attached. Hanging in Air (mV)	Device Attached, on Static Vibrator (mV)
1	188.7	236.8	900.5
2	188.7	242.9	1358
3	172.4	276.6	1510
4	191.4	228.5	1515
5	202.7	223.8	1393
6	208.5	207.1	1337
7	188.7	250.3	1369
8	193.4	220.1	1338
9	175.7	204.4	1338
10	187.6	212.2	1356

To Page No. 15

Witnessed & Understood by me. RB Date 4/12/22

Recorded by: Raquel B and Antonio F Date 4/12/22

Recorded by: Raquel B



15

Project No. _____

TITLE _____ Book No. _____ Confidential

From Page No. 14

Data: Different Initial Amplitude Settings

Trial #	Initial Amplitude: 1 mV	Initial Amplitude: 3 mV	Initial Amplitude: 10 mV
1	1394	1656	2033
2	1377	1356	1996
3	1291	1510	2203
4	1804	1407	2097
5	1585	1599	2137
6	1521	1729	2157
7	1804	1986	2139
8	1441	1486	2154
9	1439	1466	2104
10	1535	1981	2158

Witnessed & Understood by me: RB

Date 4/12/22

Recorded by: Raque B

Recorded by: Raque B and Antonio F

To Page No. 15

Date 4/12/22

BME 4908 SENIOR DESIGN PROJECT
DEVICE MASTER RECORD

Seismocardiogram Sensor

Submitted in partial fulfillment of the
requirements for the degree of

BACHELOR OF SCIENCE
in
BIOMEDICAL ENGINEERING

April 14, 2022

Project Team 1
Raquel Bojorquez
Haniyeh Alirezaei
Alessandra Jimenez
Antonio Fernandez

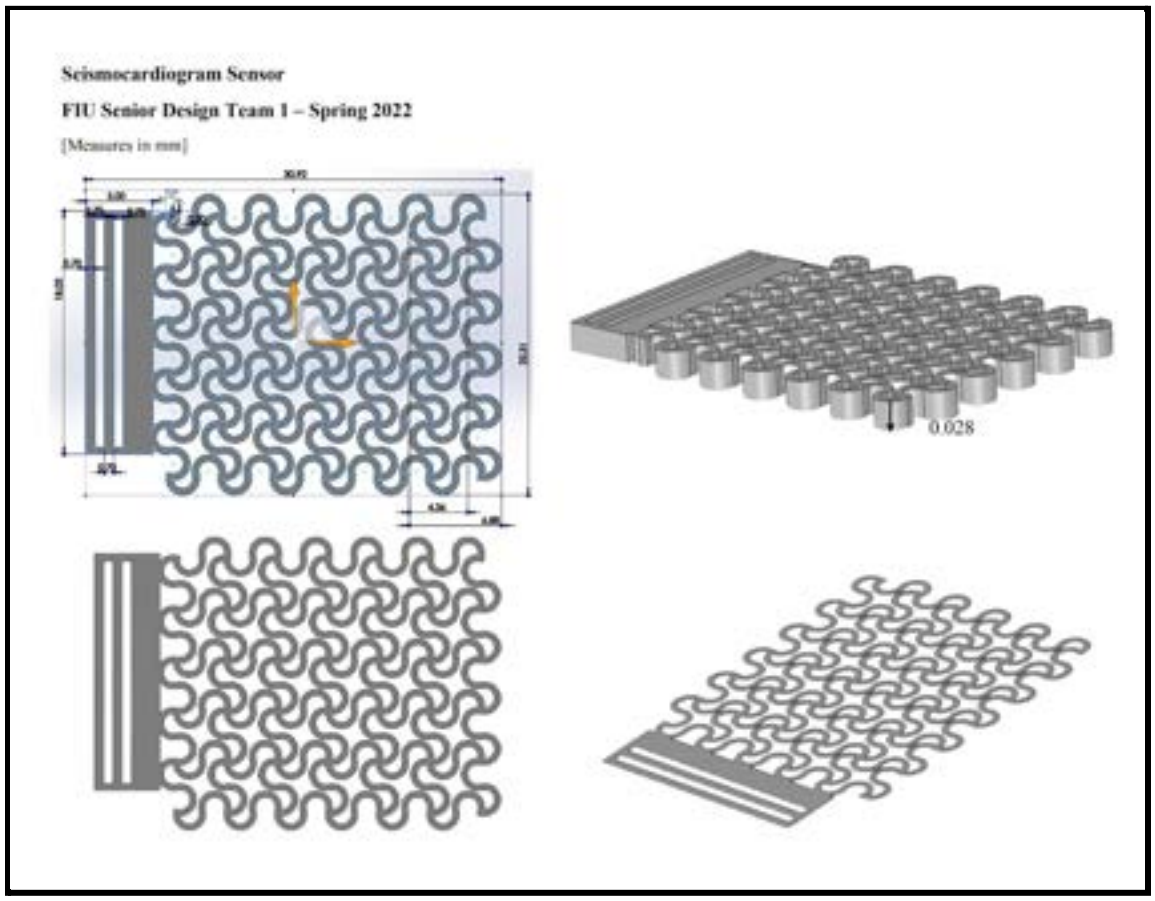
Sponsor: Girish Wable from Jabil, Inc.
Faculty Advisor: Dr. Markondeya Raj Pulugurtha

Table of Contents

Section 1 - Design Specifications

Section 1.1 - Engineering Drawings

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.



Section 1.2 - Formulations

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.

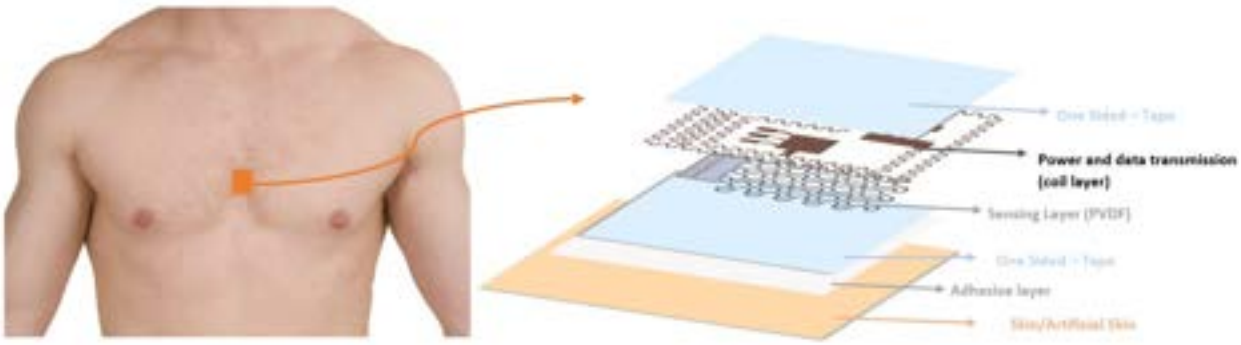
$$AD = \frac{\text{mesh area}}{\text{square area}} = \frac{4\pi[R^2-(R-W)^2]\left(1-\frac{180-2\theta}{360}\right)}{\{2[R\cos\theta+(R-W)\cos\theta]\}^2} = \frac{\pi\left(\frac{1}{2}+\frac{\theta}{180}\right)}{\left(\frac{2R}{W}-1\right)\cos^2\theta} \qquad (1)$$

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

Section 1.3 - Materials Specifications

The final sensor will also include a coil layer to enhance the power and data transmission. In addition, other layers will include an adhesive layer and one sided-tape layers. The complete composition of the sensor is shown below.



Materials	Description	Application
Polyvinylidene fluoride (PVDF) (TE Connectivity)	Thin-film piezoelectric polymer sheet 28UM, 60C ANN, PLSM 16.14" W with high tensile strength, and low thermal resistance.	Sensing mechanical vibration and translating to electrical waveforms
Silver Conductive Ink (NAGASE CHEMTEX AMERICA CORP)	Silver ink that is designed for superior durability, extreme flexibility, low resistance, long screen residence time, and high conductance.	Screen printing the sensor and aiding in the electrical conductivity of the PVDF.

Table. Materials required to fabricate the seismocardiogram sensor.

Purchase References

[1] https://www.te.com/usa-en/product-11028415-00.html
[2] https://www.environmental-expert.com/files//download/308546/1-1.pdf

Research References

[1] Eyvazi Hesar, M., Khan, D., Seyedsadrkhani, N. S., & Ingebrandt, S. (2020). Contactless, Battery-free, and Stretchable Wearable for Continuous Recording of Seismocardiograms. *ACS Applied Electronic Materials*, *3*(1), 11–20. https://doi.org/10.1021/acsaelm.0c00768

[2] Luo, N., Ding, J., Zhao, N., Leung, B. H. K., & Poon, C. C. Y. (2014). Mobile Health: Design of Flexible and Stretchable Electrophysiological Sensors for Wearable Healthcare Systems. *2014 11th International Conference on Wearable and Implantable Body Sensor Networks*. https://doi.org/10.1109/bsn.2014.25

Section 2 - Production Process Specifications

Section 2.1 - Equipment Specifications

Materials	Description	Application
TransferRite Ultra (3M™ -582U) Medium Tack Transfer Tape	TransferRite Ultra (3M™ -582U) Medium Tack Transfer Tape 6 in x 10 yd	Placing the metallized PVDF on the cutting board
3M™ Tegaderm™ Transparent Film Roll	One-sided medical grade transparent polyurethane film 2 in x 11 yd	Substrate to encase the PVDF - contact material for the entire patch
Cameo Silhouette 4 Desktop Cutter	Electronic cutting machine with ability to cut various materials such as vinyl.	Cutting the PVDF sheet into the desired geometric configuration

Section 2.2 - Production Methods

- Screen-printing: Apply a layer of silver ink to the plain PVDF film and cure it at a set temperature (50C) for 16-17 hours.
- Use a desktop cutting machine capable of cutting materials such as vinyl.

Section 2.3 - Production Procedures

1. Cut a 28 um PVDF film in 12x12cm.
2. Place the film on a paper and tape each side of the film to the paper to secure it.
3. Smear the silver ink evenly on the film until there is no excess ink or blank spots on the film.
4. Place the film and the paper (to cure) in the oven at 50C for 16-17 hours.
5. Repeat the same procedure for the other side of the film.
6. Obtain a sample of metallized PVDF and place onto the weakly adhesive side of the medical tape.
7. Gently place medical tape with metallized PVDF onto the cutting board; Make sure to place onto board gently and smoothly to not produce any air bubbles.
8. Slide cutting board into cameo silhouette machine. Press the “Up arrow” on the machine to feed the cutting board into the machine.
9. Open Cameo Silhouette software on computer.
10. Download PVDF shapes that will be cut.
11. Adjust dimensions of material to users needs.
12. Apply setting to cut 28 um thick PVDF (Blade Depth=3, Speed=1, Force=10)
13. Run the machine
14. When the machine finishes, press the “Down arrow” to eject the cutting board.
15. Separate the PVDF material from the medical tape using a small pair of tweezers.
16. Apply copper contact on the PVDF.
17. Encase top and bottom of the patterned PVDF with the Tegaderm tape.

Research References

[1]. Ha, T., Tran, J., Liu, S., Jang, H., Jeong, H., Mitbander, R., Huh, H., Qiu, Y., Duong, J., Wang, R. L., Wang, P., Tandon, A., Sirohi, J., & Lu, N. (2019). A Chest‐Laminated Ultrathin and Stretchable E‐Tattoo for the Measurement of Electrocardiogram, Seismocardiogram, and Cardiac Time Intervals. *Advanced Science*, *6*(14), 1900290. https://doi.org/10.1002/advs.201900290

Purchase References

[2] https://uscutter.com/Transferrite-Ultra-582U-Medium-Tack-Transfer-Tape-100-Yard/
[3]https://www.amazon.com/dp/B006VZHQG4
[4]https://www.silhouetteamerica.com/featured-product/cameo

Section 3 - Quality Assurance Specifications

Section 3.1 - Quality Assurance Equipment

Materials	Model Number	Description	Application
Vibration Generator	1000701	Vibration generator for exciting oscillating and waves mechanically.	Generate vibrations mechanically with frequency range of 0 - 20 kHz.
Circular Chladni Plate	1000705	Metal plate for generating acoustically excited figures in media.	Place on vibration generator to vibrate
Carbon Fiber Composites Digital Caliper	SL01 SL53	A device with a digital display marked with units of lengths	Measure the sensor's size.
FLUKE ® Compact - Basic Features, Digital Multimeter	Fluke-115/CZ WG Series	Electronic measuring instrument that includes features such as capability of measuring voltage, current, and resistance.	Determine if there is a current on both sizes of the metallized PVDF during fabrication.
Tektronix Arbitrary Function Generator	AFG31000 Series	Waveform generator 25 MHZ 2CH	Produce SCG waveforms
MTS Criterion Electromechanical Universal Test System	Model 41	Equipment made for applying mechanical forces onto an object such as compression and tension	Test the material's elasticity via cycles of loading and unloading
Keysight Mixed Signal Oscilloscope	MSOS254A	A device used in display for electrical signals	Measure output voltage fluctuation
Stanford Research Systems Low-Noise Preamplifier	Model SR560	A device used in amplifying subtle signals before sending it to the amplifier	Boost the desired SCG signal since the environment was very noisy.
Accel Instruments Waveform	TS250	A device capable of increasing the signal power	Empowering the SCG signal to be able to

Amplifier			differentiate it from the environmental noise.

Section 3.2 - Acceptance Criteria

Frequency Ranges	10-40 Hz
Amplitude range	± 20 mg
Minimum amount of stress converted to voltage	1.5 Pa
Elastic Modulus of PVDF	130kPa-20MPa
Size of the sensor	27.7 ± 4.1 mm for width and 154.1 ± 13.1mm for length.

Section 3.3 - Quality Assurance Procedures

Test Protocol #1	
Project Description: Seismocardiogram Sensor	**REVISION NO.: 3**
Team: Raquel Bojorquez , Haniyeh Alirezaei , Antonio Fernandez , and Alessandra Jimenez	**Page** 1 of 3
TITLE: *Artificial Pulse Generator via a Phantom Test*	

1. PURPOSE

To artificially simulate the vibrations from the heart in order to verify the sensor's sensitivity to SCG signals. This test will also be classified as the project's killer test to determine if the success factors were met.

2. SCOPE

This procedure concerns the device sensor's sensitivity to small vibrations with a frequency range of 10-40Hz.

3. REFERENCE DOCUMENTS

- Castiglioni, P., Faini, A., Parati, G., & Di Rienzo, M. (2007). Wearable Seismocardiography. *2007 29th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*. https://doi.org/10.1109/iembs.2007.4353199
- *Simulation of the Human Heart Rate | Dewesoft*. (2020). Dewesoft.com. https://dewesoft.com/case-studies/human-heartbeat-simulation
- Taebi, A., Solar, B., Bomar, A., Sandler, R., & Mansy, H. (2019). Recent Advances in Seismocardiography. *Vibration*, *2*(1), 64–86. https://doi.org/10.3390/vibration2010005
- 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

4. OVERVIEW/BACKGROUND

Since human or animal testing is requires a deep signal processing which is out of the scope of the verification process, an artificial stimulus will be required to determine the functionality of the device. A pulse generator is an electronic device that can be programmed to generate rectangular pulses with SCG signal characteristics, which can be similar to those

created from the heart. The vibrations created from the pulses hitting the surrounding surfaces are the desired input for the device's sensor. From this, the test can determine whether the sensor's sensitivity is high enough to detect the low vibrational frequencies.

5. OBJECTIVES

The objective of this procedure is to verify the sensor's ability to detect the seismocardiogram signals, with respect to detecting frequencies in the range of 10-40 Hz in the planar direction.

6. TEST EQUIPMENT

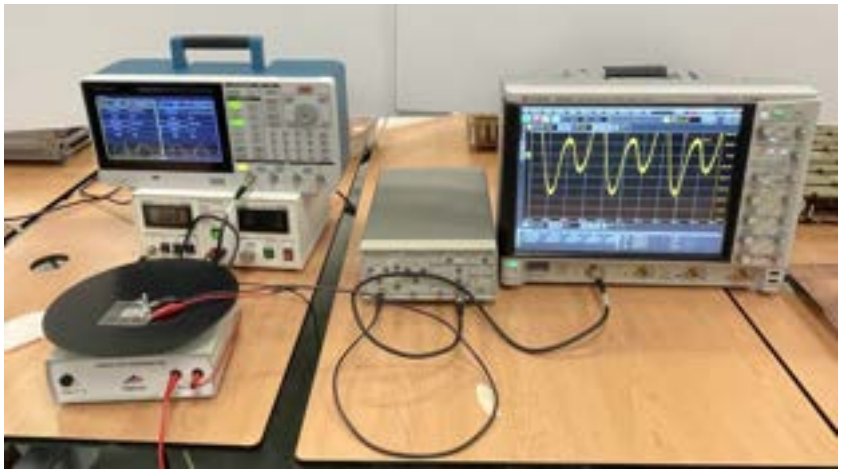
- Function Generator
- Waveform Amplifier
- Vibration Generator
- Low-noise Preamplifier
- Digital Oscilloscope
- Alligator Clips
- BNC to BNC cables
- BNC to alligator clips cable

7. MATERIAL

- Wireless Seismocardiogram Sensor (PVDF)
- Medical grade one sided tape (Tegaderm 3M)

8. SETUP

The function generator was connected to the waveform amplifier, which was connected to the vibration generator. The PVDF sensor was placed on the surface of the vibration generator and its electrodes were connected to the low-noise amplifier. Lastly, the low-noise amplifier directed the signal to the oscilloscope. The setup of the procedure can also be found in the image below.



9. **SAMPLE SIZE***

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours(9.488)/(3650 hours)*2

Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result from this test is that the device is able for the sensor to detect seismocardiogram signals frequencies from 10 to 40 Hz and show a difference in the output voltage, compared to control settings. The control setting was defined as the setup not being connected to the sensor.

11. **PROCEDURE**

The seismocardiogram sensor would be placed on top of the vibration generator. The desired signal for the sensor to detect was first imported into the acquisition software which will be replay for a set time. The frequency of the signal delivered should be set to 10-40 Hz.

12. **DATA COLLECTION SHEET**

*** Completed only 10 trials instead of testing 11 samples. Decided that due to the limited resources available to us as well as the complex process of learning how to create these samples, 10 trials of the electrical functional sample would be appropriate for statistical analysis tests such as t-test.**

Voltage Calculation (mV) Initial Amplitude: 1V					
Trial Number	Control Group	10 Hz	20 Hz	30Hz	40Hz
S4-3 Trial 1	900.5	1831	2007	2484	2593
S4-3 Trial 2	1358	1746	2207	2525	2673
S4-3 Trial 3	1510	1773	2282	2558	2836
S4-3 Trial 4	1515	1749	2492	2488	2746
S4-3 Trial 5	1393	1751	2226	2506	2784

S4-3 Trial 6	1337	1771	2672	2560	2746
S4-3 Trial 7	1369	1763	2197	2519	2849
S4-3 Trial 8	1338	1798	2408	2513	2773
S4-3 Trial 9	1338	1825	2778	2469	2687
S4-3 Trial 10	1356	1776	2733	2351	2746

Test Protocol #2

Project Description: Seismocardiogram Sensor	**REVISION NO.: 3**
Team: Raquel Bojorquez , Haniyeh Alirezaei , Antonio Fernandez , and Alessandra Jimenez	**Page** 1 of 3
TITLE: *Uniaxial Tensile Test for the verification of the PVDF's sensitivity to uniaxial forces and its young's modulus for electromechanical sensitivity.*	

1. PURPOSE

The purpose of this protocol is to determine if the sensing component of the device, the poly-vinylidene fluoride (PVDF), is sensitive to uniaxial forces and that its young's modulus is within the acceptable range to capture the heart's vibration.

2. SCOPE

The protocol ensures that the young's modulus of the PVDF is within 130 kPA - 20 MPa, complying with skin's young's modulus.

3. REFERENCE DOCUMENTS

- Ha, T., Tran, J., Liu, S., Jang, H., Jeong, H., Mitbander, R., Huh, H., Qiu, Y., Duong, J., Wang, R. L., Wang, P., Tandon, A., Sirohi, J., & Lu, N. (2019). A Chest‐Laminated Ultrathin and Stretchable E‐Tattoo for the Measurement of Electrocardiogram, Seismocardiogram, and Cardiac Time Intervals. *Advanced Science*, *6*(14), 1900290. https://doi.org/10.1002/advs.201900290
- Hu, Y., Kang, W., Fang, Y., Xie, L., Qiu, L., & Jin, T. (2018). Piezoelectric Poly(vinylidene fluoride) (PVDF) Polymer-Based Sensor for Wrist Motion Signal Detection. *Applied Sciences*, *8*(5), 836. https://doi.org/10.3390/app8050836
- ISO 527-1:2019 Plastics — Determination of tensile properties — Part 1: General principles

4. OVERVIEW/BACKGROUND

In order to verify the device's ability to detect seismocardiogram (SCG) signals, the properties of the sensor have to be evaluated. The sensor, PVDF, will be patterned which will reduce its young's modulus. A high young's modulus around the threshold of 2-4 Gpa would result in a non-stretchable patch, hence compromising the signal noise due to mobility of the patch. In addition, the overall sensitivity of the device to the SCG signals is dependent on its ability to sense planar forces. Both of these properties can be assessed with a uniaxial tensile test, which measures material's properties such as young's modulus and yield strength based on the force applied in a single direction.

5. **OBJECTIVES**

- Validate that the young's modulus of the PVDF is within 130 kPA - 20 MPa.

6. **TEST EQUIPMENT**

- MTS Criterion Electromechanical Universal Test System
- MTS Test Suite Software

7. **MATERIAL**

Patterned PVDF sensor of dimensions 22.31 mm x 30.92 mm x 0.028 mm capsulated with Tegaderm tape

8. **SETUP**

The setup involves placing the PVDF sample that has been patterned onto the testing machine and slowly extending it until a strain of about 10% is reached. Elongation of the sample is recorded and uploaded to a MTS Test Suite Software for data processing. The software is able to compute the sample's elastic modulus and produce the appropriate stress-strain curve with the user's desired units.

9. **SAMPLE SIZE***

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours(9.488)/(3650 hours)*2

Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result is for the patterned PVDF to experience a Young's Modulus to be within 130 kPA - 20 MPa and approach a value of around 8.5 MPa for the material to be stretchable and appropriate for SCG measurements.

11. **PROCEDURE**

The patterned PVDF will be placed on the MTS Criterion Electromechanical Universal Test System. The device will clamp both sides of the PVDF and begin to elongate the material at a

speed of 0.05 mm per second. Before starting the test, the width and thickness was inputted as 23mm and 0.142 mm (sum thickness of PVDF, silver ink, and Tegaderm tape). The software will be used for stress and strain calculation while the test is being run. The test will run until the strain reaches about 10% or is applied about 3N force. Young's Modulus will be calculated with analyzed stress and strain to confirm if E is 8.5MPa ±.5MPa. Repeat for four trials of the sample.

12. **DATA COLLECTION SHEET**

*** Completed only 4 trials instead of testing 11 samples. Decided that due to the limited resources available to us as well as the complex process of learning how to create these samples, 4 trials of the electrical functional sample would be appropriate for statistical analysis tests such as t-test.**

Trial Number	Young's modulus
S4-1 Trial 1	10.6 MPa
S4-1 Trial 2	10.532 MPa
S4-1 Trial 3	10.317 MPa
S4-1 Trial 4	10.374 MPa

Test Protocol # 3

Project Description: Seismocardiogram Sensor	**REVISION NO.: 3**
Team: Raquel Bojorquez, Haniyeh Alirezaei, Antonio Fernandez, Alessandra Jimenez	**Page** 1 of 2
TITLE*: Measurement Confirmation of SCG Patch*	

1. PURPOSE

To confirm the size of the patch to be based on the design inputs to be less than 27.7 ± 4.1 mm for width and 154.1 ± 13.1mm for length.

2. SCOPE

This procedure relates to the verification of the Wireless Seismocardiogram device size.

3. REFERENCE DOCUMENTS

- Taebi, A., Solar, B. E., Bomar, A. J., Sandler, R. H., & Mansy, H. A. (2019, January 14). *Vibration | free full-text | recent advances in ... - MDPI*. MDPI. Retrieved October 20, 2021, from https://www.mdpi.com/2571-631X/2/1/5
- AI;, A. S. D. M. U. (2018, January 18). *Evaluation of the morphological characteristic and sex differences of sternum by multi-detector computed tomography*. Folia morphologica. Retrieved February 22, 2022, from https://pubmed.ncbi.nlm.nih.gov/29345718/

4. OVERVIEW/BACKGROUND

There is a lack of commercially available seismocardiograms (SCGs) that are for everyday use. The latest SCG measurement devices are mostly bulky and uncomfortable for prolonged use. Wearable ECGs have been made compact and lightweight for everyday patient use. To compete with these lightweight ECGs, a device with similar dimensions will be made.

5. OBJECTIVES

The objective is to measure the dimensions of the PVDF sensor and ensure it is within acceptable range of similar ECG and SCG devices.

6. TEST EQUIPMENT

- Caliper

7. **MATERIAL**

Seismocardiogram sensor

- PVDF material: 22.31 mm x 30.92 mm

8. **SETUP**

Once the SCG sensor has been cut to the specific shape by the CAMEO silhouette machine, the SCG sensor will be placed onto the table and measured with a ruler capable of measuring millimeters. The goal is to ensure the device has the proper dimensions stated previously.

9. **SAMPLE SIZE***

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours(9.488)/(3650 hours)*2

Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result is that the patch will be the correct dimensions of 22.31 mm x 30.92 mm.

11. **PROCEDURE**

1. Lay PVDF sensor onto flat surface
2. Using a caliper, measure the length and height of the sensor
3. Compare if results match the expected size and if size is less than sternum measurements stated in market requirements.

12. **DATA COLLECTION SHEET**

*** Completed only 4 samples instead of 11. Decided that due to the limited resources available to us as well as the complex process of learning how to create these samples, 4 samples would be appropriate for statistical analysis tests such as t-test.**

Samples used for measurement confirmation

Example on how to measure

Sample Number	Width [mm]	Length [mm]
Solidworks Design	22.31	30.92

S4-1	22.3	31.3
S4-2	22.6	32.1
S4-3*	22.7	30.5
S4-4	22.1	30.9
S5-5	21.9	30.9

*Electrically Functional Sample, MVP

Test Protocol #4

Project Description: Seismocardiogram Sensor	**REVISION NO.:2**
Team: Raquel Bojorquez , Haniyeh Alirezaei , Antonio Fernandez , and Alessandra Jimenez	**Page** 1 of 3
TITLE: *Comparison of accelerometer and piezoelectric sensor*	

1. PURPOSE

The purpose is to compare the measurements of seismocardiogram signals obtained with an accelerometer and a PVDF sensor to test PVDF sensing capabilities.

2. SCOPE

This procedure bases on comparing accelerometer and the PVDF sensor seismocardiogram (SCG) signals, to show the efficacy of the two sensors in capturing significant information related to cardiovascular health via the chest wall's vibrations.

3. REFERENCE DOCUMENTS

- Ha, T., Tran, J., Liu, S., Jang, H., Jeong, H., Mitbander, R., Huh, H., Qiu, Y., Duong, J., Wang, R. L., Wang, P., Tandon, A., Sirohi, J., & Lu, N. (2019). A Chest‐Laminated Ultrathin and Stretchable E‐Tattoo for the Measurement of Electrocardiogram, Seismocardiogram, and Cardiac Time Intervals. *Advanced Science*, *6*(14), 1900290. https://doi.org/10.1002/advs.201900290
- Shandhi, M. M. H., Semiz, B., Hersek, S., Goller, N., Ayazi, F., & Inan, O. T. (2019). Performance Analysis of Gyroscope and Accelerometer Sensors for Seismocardiography-Based Wearable Pre-Ejection Period Estimation. IEEE Journal of Biomedical and Health Informatics, 23(6), 2365–2374. https://doi.org/10.1109/jbhi.2019.2895775
- ISO 16063-21:2003 Methods for the calibration of vibration and shock transducers — Part 21: Vibration calibration by comparison to a reference transduc

4. OVERVIEW/BACKGROUND

In order to verify the functionality and accuracy of the sensor of detecting SCG signals, its measurements have to be evaluated. An accelerometer is a device that measures either static or dynamic acceleration (vibration) of a structure. Accelerometers have been extensively used to record SCG signals, hence being the standard method of measurement. SCG signals are characterized for their output voltage, regardless of the method of measurement. Hence, by comparing the results from an accelerometer with the manufactured sensor, it can be

confirmed that the sensor can generate a voltage output that corresponds to an SCG signal based on its piezoelectric characteristics

5. **OBJECTIVES**

- The sensor needs to convert a minimum cardiac pressure of (x) Pa to a minimum voltage output of 1mV peak-peak.

6. **TEST EQUIPMENT**

- Manufactured PVDF sensor
- An accelerometer (model)

7. **MATERIAL**

- Manufactured PVDF sensor (reusable)

8. **SETUP**

The wireless seismocardiogram sensor and the accelerometer would be placed on the surface of the artificial pulse generator. Both are connected to an acquisition software and the obtained signal is obtained for later comparison.

9. **SAMPLE SIZE**

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours(9.488)/(3650 hours)*2

Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result from this test is that the sensor is able to detect seismocardiogram signal that match the characteristics and pattern of those obtained with the accelerometer.

11. **PROCEDURE**

For this procedure a manufactured pulse generator with Polydimethylsiloxane (PDMS) layers will be used to mimic a human chest. First, the accelerometer will be placed on top of the middle point of the pulse generator and the PVDF sensor will be below the accelerometer.

Both were attached using medical tape. After placing both sensors, the pulse generator will be powered for # minutes (or cycles), taking measures continuously. The raw SCG signal from the PVDF sensor will be filtered with a 4th order Butterworth filter of 12-40 Hz bandwidth. Finally, the SCG signal from the PVDF sensor will be compared with the signal from the accelerometer.

12. DATA COLLECTION SHEET

The desired accelerometer had not arrived. An alternative accelerometer was used but due to its structure, it was not possible to mount it with stability on the setup. Therefore, this verification testing was not completed.

Test Protocol #5

Project Description: Seismocardiogram Sensor	**REVISION NO.: 2**
Team: Raquel Bojorquez, Haniyeh Alirezaei, Antonio Fernandez, Alessandra Jimenez	**Page** 1 of 2
TITLE: *Measuring the power source voltage used via voltmeter*	

1. PURPOSE

The purpose is to verify that the sensor can be powered by the patch's power supply and deliver an output voltage of 1-3mV as stated in the design input.

2. SCOPE

The protocol will demonstrate how the power source of the patch will be compatible with the sensor. A voltmeter will be used to measure that the sensor has a reasonable output voltage after receiving power from the patch's power supply.

3. REFERENCE DOCUMENTS

- Leitão, F., Moreira, E., Alves, F., Lourenço, M., Azevedo, O., Gaspar, J., & Rocha, L. A. (2018). High-Resolution Seismocardiogram Acquisition and Analysis System. Sensors (Basel, Switzerland), 18(10), 3441. https://doi.org/10.3390/s18103441
- IEC 62353:2014 - Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment

4. OVERVIEW/BACKGROUND

The sensor created is just one part of the overall final device, but it should be compatible with its other components. In order for the patch to function properly, it needs a source of power and the sensor should be able to function with this same source. Therefore, if the manufactured sensor doesn't comply with the given requirements then it won't fulfill its purpose of detecting SCG signals. So, it is necessary to measure if the sensor is capable of using the same power supply as the patch and still producing the necessary output voltage to function.

5. OBJECTIVES

- The sensor should be powered with a 3 - 5V power source and deliver an output voltage of 1-3mV.

6. **TEST EQUIPMENT**

- FLUKE (R) Fluke-115/CZWG Series, Compact - Basic Features, Digital Multimeter

7. **MATERIAL**

- Manufactured PVDF sensor

8. **SETUP**

The seismocardiogram sensor with the attached copper coils will be connected to the transducer that is powered by an Arduino microcontroller. The multimeter will be set to the voltmeter feature to measure the sensor's output voltage.

9. **SAMPLE SIZE**

The MTTF (Mean Time To Failures) is estimated to be 1 year (8766 hours) along with 5 months(3650 hours) for testing time. Using a 95% confidence level with $\alpha = 0.05$ and $r = 2(1) + 2 = 4$, assuming 1 failure, we can calculate the sample size by looking at the Chi-square chart. We obtain a value of 9.488. Final sample size:

Sample size = MTTF goal*(X^2α;2)/(Testing time)*2

Sample size = 8766 hours(9.488)/(3650 hours)*2

Sample size = 11 samples

10. **EXPECTED RESULTS/HYPOTHESIS**

The expected result from this test is that the sensor is able to function with the provided input voltage of the patch's power supply.

11. **PROCEDURE**

1. The manufactured PVDF sensor will be connected to the patch's power source.
2. The black probe of the multimeter is attached to the "COM" port and the red probe will be attached to "VΩ" port
3. The multimeter will be set to the mode of 20V under the section of the V with a straight line to measure DC voltage. The section knob is set to 20V so that the multimeter can read a range up to 20V.
4. Connect the red probe to the positive side of the sensor and the black probe to the other side of the sensor.
5. Read the value on the display.

12. **DATA COLLECTION SHEET**

Due to late arrival of the piezo-transducer and time constraint, the verification testing setup was unsuccessful. Therefore, this verification is not completed.

Purchase References

[1] https://www.muellersportsmed.com/b2c-us/en/c/Quick-Drying-Adherent/p/170201

[2]https://www.3bscientific.com/us/vibration-generator-1000701-u56001-3b-scientific,p_576_1977.html?utm_source=google&utm_campaign=gmc_feed

[3]https://www.3bscientific.com/us/chladni-plate-circular-1000705-u56005-3b-scientific,p_576_1981.html

[4]https://www.digikey.com/en/products/detail/rigol-technologies/DG1022Z/10468126?utm_adgroup=Test%20and%20Measurement&utm_source=google&utm_medium=cpc&utm_campaign=Shopping_DK%2BSupplier_RIGOL%20Technologies&utm_term=&utm_content=Test%20and%20Measurement&gclid=CjwKCAiAvOeQBhBkEiwAxutUVJkH66ytK5sQ_Y8Lq6B0gzzge1kBmox9DbdDCLt2p5iDXSSQypRUFxoC6CoQAvD_BwE

[5] https://www.iso.org/standard/75824.html

[6] https://www.iso.org/standard/40382.html

[7] https://www.iso.org/standard/27053.html

[8] https://webstore.iec.ch/publication/6913