Design Document: Wearable Heart Rate and Blood Pressure Monitor

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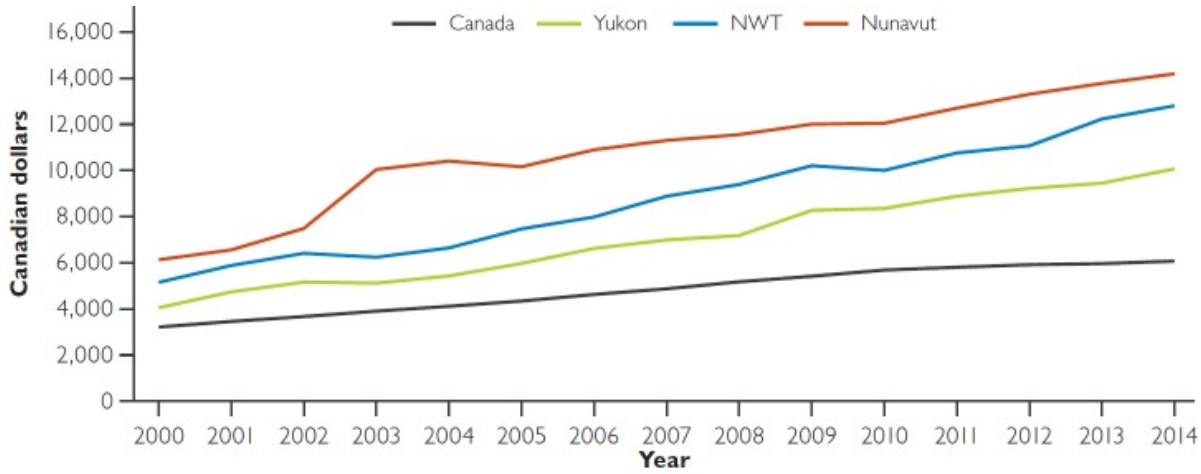
Our design is a wearable heart rate and blood pressure monitor intended for regular use throughout the day. Due to our customer base being the residents of Nunavut where they live in relatively isolated communities, it is important that our design is long-lasting and relatively lightweight so it can be used at any time. Individuals who leave medical problems in their vascular system untreated for a prolonged period of time can suffer from health complications to the heart, brain, kidneys, and more. Therefore, it is important to be educated on how to recover from illnesses and when it's necessary to receive medical attention from a trained professional.

Client/Customer Definition:

"Low health status in Nunavut is strongly influenced by comorbidities that result from the severe socio economic strain" [1]. Nunavut, with a population of approximately 40,000, is facing increasingly alarming issues regarding accessible healthcare. The medical resources that are available to Indigenous communities and others that live in Northern Canada are scarce despite the low population density. Oftentimes, residents have to relocate or travel in order to receive medical attention because there aren't hospitals or enough working staff in close proximity. In Iqaluit, the capital of Nunavut, it was found that people there are generally sicker for longer periods of time as their health concerns often go undiagnosed or untreated. Most Nunavut communities are only accessible through air transport, so even non-urgent medical travel is done by plane [2]. Around 86% of residents in Nunavut don't have a regular healthcare provider and without a clear, long-term solution, Nunavut patients will become sicker and sicker, raising a major health concern for those living in the region [3]. Furthermore, Northern Canada's per capita total health expenditures fall behind compared to the rest of Canada, especially Nunavut whose graphical trend showed to be 2.3 times larger than the national average, as seen in *Fig. 1* [4].



Source: Figure drawn from data in the Canadian Institute of Health Information's *National Health Expenditures Trends 1975–2015* report.

Fig. 1: *Data from the Canadian Institute of Health Information Comparing Nunavut's Health Expenditures to Other Regions*

However, the government believes that these costs are justifiable given the need to deliver goods and offer services to widely scattered communities with geographical barriers. If these people were to reside in another province, perhaps Eastern or Western Canada, there would certainly be a decrease in their spendings in relation to medication and medical transportation. Overall, the lack of healthcare available to Indigenous communities and other Nunavut residents contributes to socio-economic

difficulties and health disparities, which can perpetuate cycles of limited economic opportunities, addiction, and poverty.

Competitive Landscape:

Digital Blood Pressure Monitors:

A pre-existing technological system that addresses our problem with blood pressure are the widely sold digital blood pressure monitors. They include inflatable cuffs that wrap around an individual's upper arm that register systolic, diastolic, and pulse measurements onto an LCD screen [5]. Digital blood pressure monitors measure a patient's blood pressure; they are portable and can be used regularly, which eliminates the need for travel to see a doctor regarding these issues. However, without proper prior knowledge on the data displayed by the monitor, an individual may not interpret their data correctly which can put their safety at risk. This system can't replace in-person doctor health consultations for this reason. In comparison with our design, it is less lightweight which can make its portability less efficient given its weight as well.

Fig. 2: *Blood Pressure Monitor*

Society of Rural Physicians Canada:

A social system, or program, in place that advocates for and provides specialized training for doctors to work in rural areas is the *Society of Rural Physicians Canada* [6]. The advocacy program and its benefits give doctors working in rural areas a reliable support network. This ensures their success which limits the turnover of doctors working in Northern Canada. It is essential to persuade doctors to take work opportunities in regions such as Nunavut, so this program is a great way to entice medical professions to relocate [7]. Nevertheless, although it may contribute to a higher influx of doctors coming to Nunavut, it is not guaranteed that they will stay long-term as many may prefer to only work there for short-term. Environment and social factors may be part of the reason since Nunavut has a harsh climate and it is located in a remote location which may be difficult to adapt to.

Grants to the Government of the Northwest Territories and the Government of Nunavut for Health Care of Indians and Inuit:

An economic system in place to aid Nunavut's healthcare system is their annual funding that contributes to improving hospital facilities and services, physician services, and helping medical practitioners in the region. Given the money provided by the Canadian government, the Government of Nunavut can allocate funds to improving their healthcare and the medical resources available to the population of Nunavut. It could also stabilize their healthcare facilities and allow for expansion. A challenge with this system is that it won't necessarily help alleviate the cost of travel for many who do not reside in close proximity to a hospital and it doesn't guarantee an increase in long-term hospital staff either. An increase in funding could be beneficial to improving eligible expenditures. Under the *Hospital and Physician Services Grant* program, as of April 14, 2020, there is an allocated maximum

of $30.8 million for Nunavut for health and social services preparations and response and up to $5 million for air services [8].

Requirement Specifications:

1. In order to prevent damage to the device and its components as well as avoid any discomfort or safety risks to the user, there should be no exposed circuits or wires in the final prototype. Electrical safety must be taken into consideration to stop any potential harm to the user including burns or shocks [9]. This can be accomplished by 3D printing a case for the portable heart rate monitor and ensuring that all electrical components are inside the case.

2. The wearable device strap should be adjustable to fit wrists of a variety of sizes - the width of the strap should be 20-22 cm to comply with the average size of standard wristwatches [10]. Additionally, the length of the strap should be around 115% of the wrist circumference for the strap to sit comfortably (not too loosely or too tightly) around the wrist [11]. Since the average wrist size is between 14.43 - 18.25 cm (taking into account both male and female wrists) [12], we can perform the following calculation:
   $18.25 \times 1.15 \approx 20.99\ cm$ *(rounded to 2 decimal places)*
   Thus, the length of the strap should be 21 cm long, and should be able to be adjusted to wrap around the wrist from 14.43 cm to 18.25 cm.

3. The device will check the heart rate continuously when the user activates the device. The heart rate will be calculated 4 times per minute to allow for a 15 second pause between checks. This frequency will allow the device to store data and gather insight into trends with the user's heart rate [12][13].

4. The device should light up green when there are no health risks, yellow when there are mild risks/fluctuations, and red when there are high risks [14]. There are studies surrounding the psychology of colours and how the brain interprets them with meanings. A prime example of this phenomenon is how red is seen as a color that not only signifies danger but also health [15]. In wavelengths, red can be quantified as 650-700 nm while yellow and green are 580-600 nm and 550-580 nm respectively [16]. The visible spectrum of light is the range of electromagnetic waves that can be perceived as colors.

5. For the vibration option, for mild risks, there will be vibrations separated by periods of 10 seconds until the user presses a button to turn the vibrations off. For high risk, there will be vibrations every 5 seconds (vibrations more often due to higher risk) until the button is pressed to turn vibrations off. This feature is not only to ensure that the customer is aware of their heart rate/blood pressure but also allows the technology to be more accessible. This is similar to Apple's Smartwatch that offers VoiceOver, a function to help the visually impaired navigate the device [17].

Design

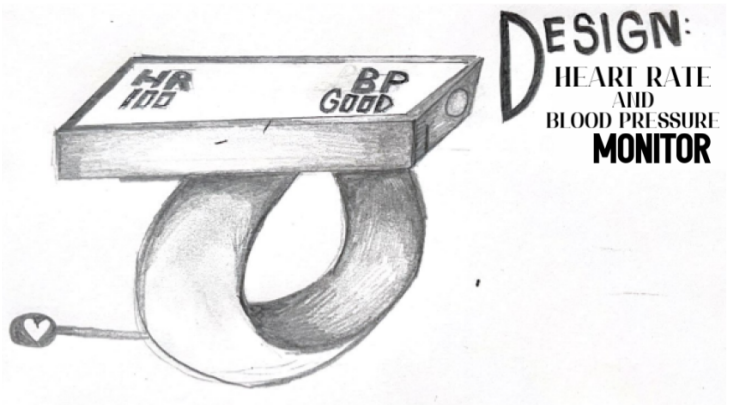


Fig. 3: *Sketch of Final Design Including Case, Display, Strap, and Pulse Sensor*

The foundation of our wearable heart monitor is our microcontroller, the STM32 Nucleo-64 Board and the pulse sensor, SEN-11574. The microcontroller will allow us to implement various applications and interface with different electronic components like our pulse sensor. The sensor can detect a change in blood volume, which occurs whenever the heart beats, due to an LED that emits light transmitted through the skin. It also uses a photodiode, a component that consumes light energy to produce an electric current, to detect the amount of light reflected back after being passed through the skin. The change in blood volume directly affects the amount of light able to be reflected back, as when it is high, it indicates a heartbeat. This process is scientifically referred to as "Photoplethysmogram" [18].

The device uses circuit components, such as resistors, wires, and more, to connect all parts of the device and ensure proper functionality. The battery, which is a laptop connected by USB to the STM32 Nucleo-64 board (STM32F401), supplies the current needed to power the device. The STM32 can hold a maximum current of 300 mA. In order to determine how much power is being supplied to the board and to all the components used in the device, we require the use of Ohm's Law. For example, if we needed to determine how much voltage is being supplied by an LED to the board, we can use $V = IR$. As an example, the PA10 pin has a resistor of around 7 kΩ, and a typical LED uses a current of 30 mA, so we can perform the following calculation:

$$V = IR$$
$$V = (30 \times 10^{-5})(7 \times 10^{3}) = 2.1\,V$$

So, the battery must supply 2.1 V to this specific pin with the LED.

The STM32's IDE analyzes the heart rate data sent from the pulse sensor and converts it into a blood pressure range. This is possible since there exists a directly proportional relationship between heart rate and blood pressure. For every extra heartbeat that the pressure sensor detects, the SBP (systolic blood pressure) increases by around 0.090 mmHg for males and 0.063 mmHg for females, and the DBP (diastolic blood pressure) increases by around 0.179 mmHg for males and 0.161 mmHg for females [19]. Since a normal resting heart rate is between 60 - 100 bpm (beats per minute) [20], we take the average of this, 80 bpm, to be the average heart rate. Accordingly, a normal SBP is around 90-120 mmHg, and a normal DBP is around 60-90 mmHg. The SBP range can then be calculated as follows:

$$SBP_{min} = 90 + (0.090 \times (RHR - 80)),\ SBP_{max} = 120 + (0.090 \times (RHR - 80))$$

for males, and

$$SBP_{min} = 90 + (0.063 \times (RHR - 80)),\ SBP_{max} = 120 + (0.063 \times (RHR - 80))$$

for females.

Meanwhile, the DBP is calculated as follows:

$$DBP_{min} = 60 + (0.179 \times (RHR - 80)),\ DBP_{max} = 90 + (0.179 \times (RHR - 80))$$

for males, and

$$DBP_{min} = 60 + (0.161 \times (RHR - 80)),\ DBP_{max} = 90 + (0.161 \times (RHR - 80)).$$

Using this mathematical relationship, the blood pressure range can be predicted to a fairly high degree of accuracy.

Next, the device will turn on the coloured LED that reflects the state of the user's vascular system. Green is associated with good health, while yellow and red are indicators of moderate and dangerous levels of health concern, respectively. In order to determine when a specific LED is turned on, we use the Heaviside function to represent the behavior of the voltage running through each light. For example, when the device determines that a no risk level heart rate is now mild risk at t = 3, the following Heaviside functions will display the behavior of the LEDs:

Fig. 5: *Green LED's Heaviside Function with Equation* $H(t) = \{t < 3{:}1,\ t \geq 3{:}0\}$

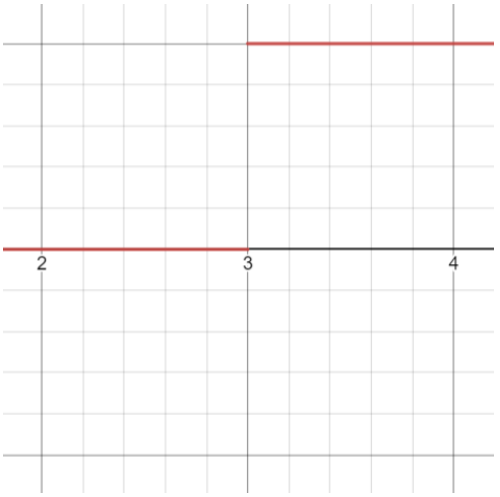


Fig. 6: *Yellow LED's Heaviside Function with Equation* $H(t) = \{t < 3{:}0,\ t \geq 3{:}1\}$

As modeled by the functions above, the green LED will turn off while the yellow LED will turn on at t = 3.

Lastly, the device's motor will vibrate once every 10 seconds if it receives a signal for mild risks, and once every 5 seconds if it receives a signal for high risks. The device also includes a transistor, a component that acts as a switch to control current flow in the circuit. The transistor will be used to stop the current motor's current once an on/off switch is pressed, so that the user can control whether the device continues vibrating or not.

Table 1: *Anticipated Outputs Based on Heart Rate*

Heart Rate (Beats Per Minute)	**State of Vascular Health**	**Output (LED Colour)**
<40	Extremely Low HR, Dangerous	Red
40-59	Low HR, Moderate	Yellow
60-100	Normal HR, Healthy	Green
101-179	High HR, Moderate	Yellow
180+	Extremely High HR, Dangerous	Red

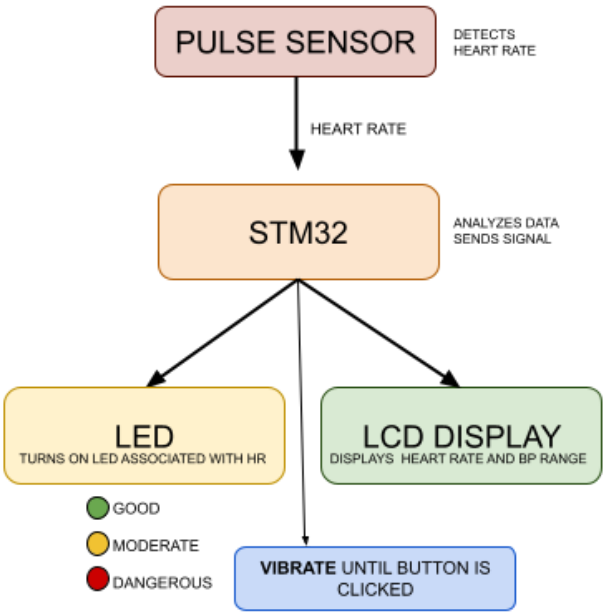


Fig. 7: *Flowchart Modeling Device's Behavior*

Finally, the LCD display will show the user their quantified heart rate and blood pressure range. Given that the LCD display only allows for a minimal amount of characters, the display will be user-friendly: all displayed metrics will be clearly visible to the client by using a large font size, an easy-to-read font, and a font color that contrasts with the screen background. This is all in compliance with usability standards to ensure legibility and readability as per the UX Design Handbook [21].

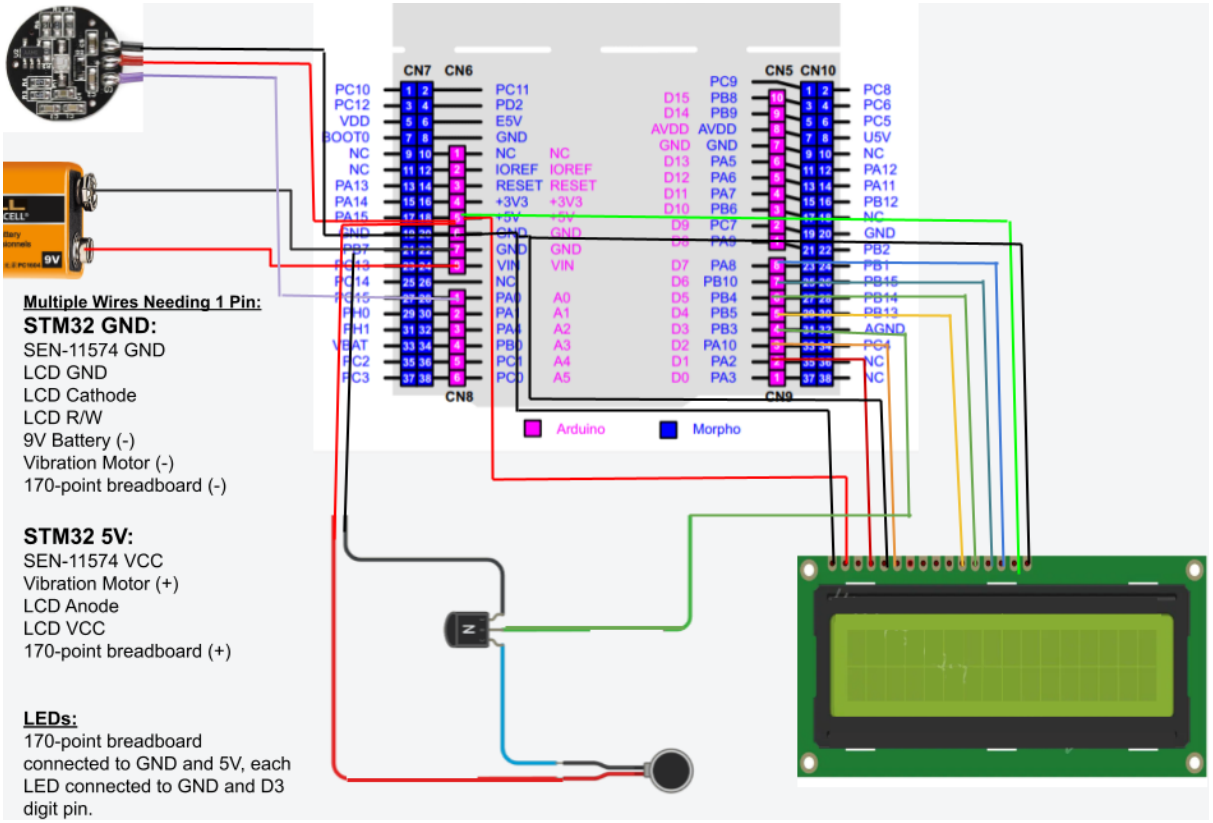


Fig. 8: *Basic Layout layout of the Wiring According to STM32 Pins*

Scientific and Mathematical Principles (3):

Ohm's Law:

Ohm's Law defines that 'the current flowing in a circuit is directly proportional to the applied potential difference and inversely proportional to the resistance in the circuit' [22]. This can also be written as:

$$V = IR$$

This principle will be applied when designing and constructing the circuits in the battery powering the wearable device.

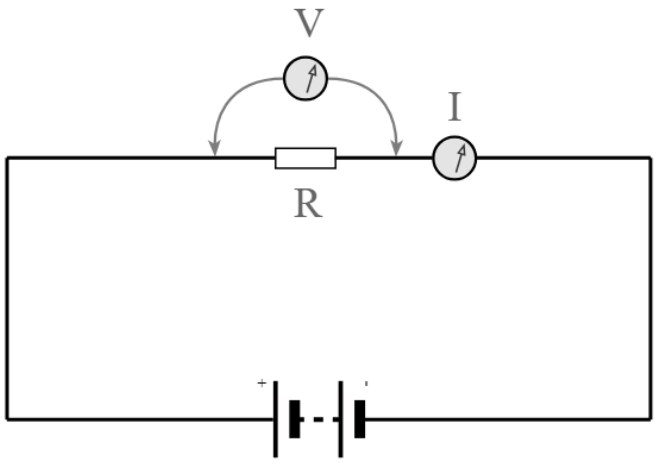


Fig. 9: *A Simple Circuit Utilizing the Relationships Between V (voltage), I (current), and R (resistance) [22]*

Understanding the principle of Ohm's Law is crucial when dealing with circuitry and different electronic components, it provides a fundamental framework for circuit design. It's an important way

to relate the voltage, current, and resistance as well as determine and regulate the amount of electric current that passes through the monitor itself. In order to achieve the desired electrical characteristics in our circuit, Ohm's Law can determine what types of resistors, diodes, or capacitors need to be used to maximize the design but also stay within guidelines regarding the total amount of voltage permitted.

As per the project requirements, the design must not consume, transfer, discharge, or expend more than 30W of power or store more than 500mJ of energy. The circuit must be oriented in a way that these regulations aren't exceeded.

Heaviside Function:

The Heaviside function, denoted as $H(x)$, is stated as 'a discontinuous function whose value is zero for negative arguments $x < 0$ and one for positive arguments $x > 0$ [23]. This principle will be used when designing the on/off switch pressed by the user to stop vibration/audio alerts. It can also potentially be used to signal when light-emitting diodes should be turned off or on depending on the user's heart rate. By making ranges that relate to different health states like an abnormal heart rate or hypertension, heaviside functions can be implemented to say that a certain LED should light up depending on the data sent by the SEN-11574.

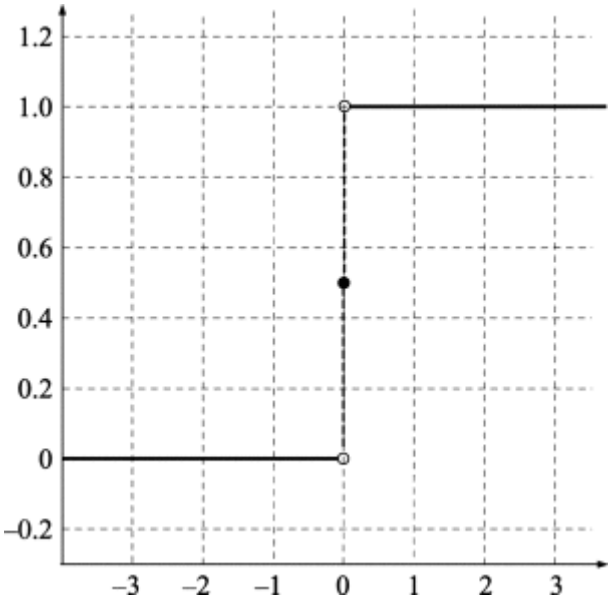


Fig. 10: *Graph of $H(x)$: the Heaviside "Step" Function [23]*

Pressure and Flow in the Circulatory System:

Blood pressure is related to the circulatory system as it's the pressure of fluid around the blood vessels and it can be influenced by a variety of factors [24]. These factors can include lifestyle, diet, stress levels, and other unhealthy habits like smoking or alcohol consumption. A study that tested the systolic and diastolic blood pressure of the Inuit population in the Arctic referred to the aforementioned factors to deduce why an individual had higher blood pressure [25].

	Systolic (mm Hg)		Diastolic (mm Hg)
Normal	< 120	*and*	< 80
Elevated	120 – 129	*and*	< 80
Hypertension			
Stage 1	130 – 139	*or*	80 – 89
Stage 2	≥ 140	*or*	≥ 90

adapted from ACC Guidelines

Fig. 11: *Table of Safe and Unsafe Systolic and Diastolic Blood Pressures*

The device will send out appropriate signals according to the severity of the user's condition according to this chart. It will be important that it may differ based on an individual's age as health risks are increased in older people. For specific calculations and ranges, refer to a site that offers readings based on gender and age [26]. Understanding the ranges for healthy blood pressures will allow us to quantify ranges that are unhealthy and dangerous; therefore, this principle will be helpful in approving our system's accuracy in giving appropriate alerts. Knowing the physiology of blood pressure levels and the workings of blood flow is crucial.

As the sensor is detecting heart rate from the radial artery, it is important that the degree of varying heart rates as well. This will be used to determine the state of the user's overall vascular health. Once again, similar to blood pressure, heart rate can be impacted by many factors including the user's level of physical activity, age, emotions like anxiety, and certain medications.

Age (years)	Target heart rate (50% to 85%) (bpm)	Average maximum heart rate (bpm)
20	100 to 170	200
30	95 to 162	190
35	93 to 157	185
40	90 to 153	180
45	88 to 149	175
50	85 to 145	170
55	83 to 140	165
60	80 to 136	160
65	78 to 132	155
70	75 to 128	150

Fig. 12: *Table of Target Heart Rates by Age [27]*

This principle will be used in our device as when the pulse sensor detects the number of pulses within a minute and quantifies it as BPM (Beats per Minute), the STM32 can put it into a range to determine the overall state of vascular health and blood pressure.

Table 2: *Manufacturing Costs for Project*

ITEM	**PRICE**	**QUANTITY**	**PURCHASE LOCATION**
STM32 Nucleo-64 Board	$34.99	1	WStore, University of Waterloo. Waterloo,

			ON, Canada
Light Emitting Diode, Red	$0.20	1	RigidWare, E7 1419. Waterloo, ON, Canada
Light Emitting Diode, Yellow	$0.20	1	RigidWare, E7 1419. Waterloo, ON, Canada
Light Emitting Diode, Green	$0.20	1	RigidWare, E7 1419. Waterloo, ON, Canada
LCD Display	$5.75	1	RigidWare, E7 1419. Waterloo, ON, Canada
Switch/Button	$0.60	1	RigidWare, E7 1419. Waterloo, ON, Canada
Breadboard 170 Point	$1.30	1	RigidWare, E7 1419. Waterloo, ON, Canada
Pulse Sensor (SEN-11574)	$38.06	1	Mouser Electronics, Website. Kitchener, ON, Canada
DC Vibration Motor	$1.87	1	Digikey DC Motor. Thief River Falls, Minnesota, USA
Wrist Strap (Velcro)	$4.50	1	EPOXY SEA Wrist Strap, Amazon
9V Battery Connector	$1.00	1	XMSILIMEIG Battery Connector, Amazon
9V Battery	$4.62	1	Duracell Battery, Amazon. Chicago, Illinois, U.S., Bethel, Connecticut
NPN Transistor	$1.54	1	Digikey NPN Transistor Thief River Falls, Minnesota, USA

Implementation Costs

User Guide:

This heart rate and blood pressure monitor is designed to fit all customers' wrists and provide accurate results. Each device has an adjustable velcro strap to securely and comfortably fasten it to its users wrists as well as LCD display that will show the current state of your vascular health. On the left side of the display, it will display the heart rate, and on the right it will show the state of your blood pressure as low, good, or high.

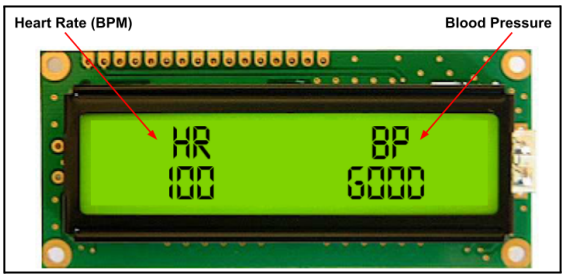


Fig. 13: *Desired Display for Device Including Heart Rate and Blood Pressure Level*

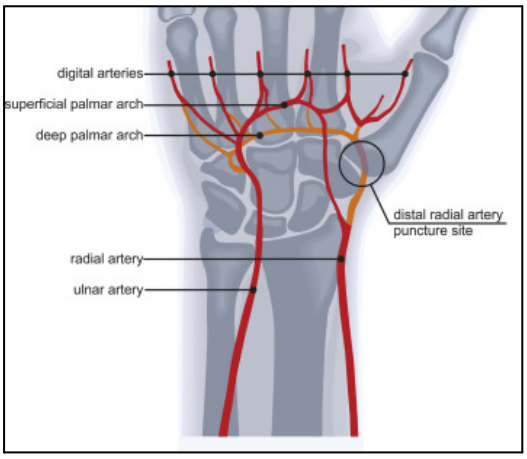


Fig. 14: *Radial Artery Diagram from Journal of Vascular and Interventional Radiology [28]*

To improve the accuracy of this device, proper calibration is required. Therefore, ensure that the pulse sensor aligns with the radial artery in your wrist. This can simply be done using the visual indicator on the device that will help aid you in the process of alignment. This indicator should be lined up relative to the ideal placement of the device [29].

The device will also vibrate to indicate that it's completed the first check cycle. The vibrations can be turned off by clicking on the button on the device. To optimize the accuracy of readings, remain in a resting position and breathe steadily. This will eliminate a lot of root causes for errors.

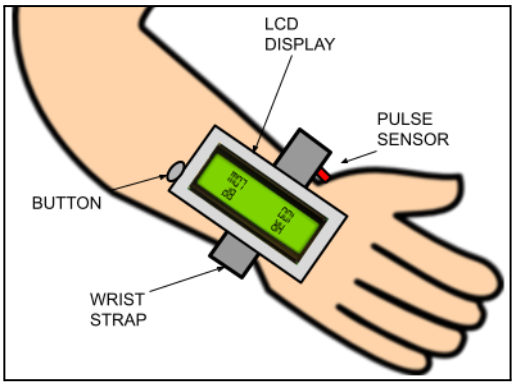


Fig. 15: *Drawing Showing How the Device Fits on the Wrist*

Installation Manual:

Our device's main components are its microcontroller, the STM32F401, and the associated pulse sensor, SEN-11574.

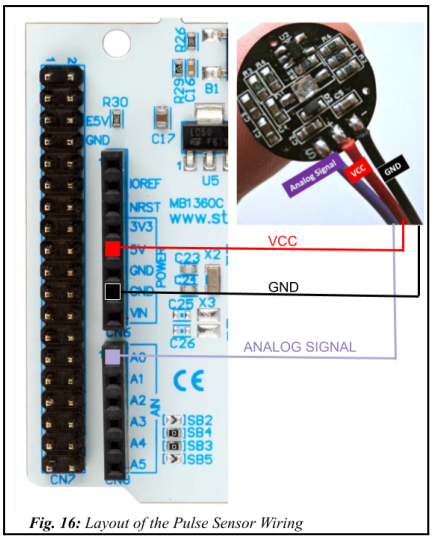


Fig. 16: Layout of the Pulse Sensor Wiring

The pulse sensor, SEN-11574, consists of 3 pins: GND, VCC, and Analog Signal.

GND: Supplies ground to the sensor and is connected to the source ground pin.

VCC: Supplies power to the sensor, this one in particular needing 3.5V-5V.

A0 (Analog Signal): An analogue pin that receives analogue signals. It sends its output in the form of voltage.

The output of a pulse sensor is an analog signal that corresponds to the monitored heart rate. Inside the Arduino's IDE, there are programs that convert the analog signal into its corresponding heart rate and blood pressure that is then sent out to the LCD Display to turn on an LED as well. These checks occur once every 15 seconds, or four times a minute. In order for this to happen, the device must have the necessary firmware to complete these actions.

To access the microcontroller's IDE, a USB-A or USB-B type cable is needed. Once connected to a computer port, it can be programmed to receive the sensor's analog signal, process it and send the needed instructions. The device can use either the USB cable or a battery as its power source.

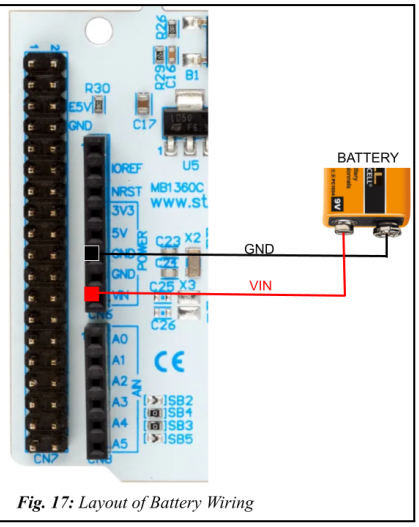


Fig. 17: Layout of Battery Wiring

Additionally, the device's vibration motor needs to be wired onto three pins on the STM32. However, in order to accommodate for all three connections and the action of turning on and off the motor's current, an NPN transistor is needed. Therefore, the red wire needs to be attached to the 5V pin while the black wire is connected to the NPN transistor that branches off into two additional wires. One of the wires is connected to the GND pin and the other to the D3 digital pin as shown in *Fig. 8*.

In order to power the device using a battery, the battery itself must supply the 5V pin with enough voltage so, a 7-12V battery would suffice. It is recommended to not use a battery beyond 12V because it can cause the voltage regulator to overheat and eventually damage the board [30]. Place the black wire from the battery connector to an empty GND (Ground) pin and the red wire to the VIN pin.

The 16 by 2 character LCD display also needs to also be connected to the STM32 using the corresponding pins:

-Digital pins D4 to D7 will be connected to the microcontroller's digital pins 4 to 7.

-The GND pin, R/W pin, and Cathode pin will need to be connected to a GND pin.

-The Enable pin and RS pin will be wired to the digital pins 2 and 1 respectively.

-The VCC pin and Anode pin will be wired to the 5V power.

-Vo adjusts the contrasts of the LCD display and can be wired to a potentiometer or PWM capable pin [31].

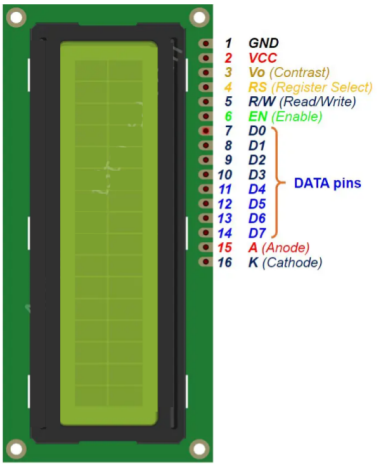


Fig. 18: LCD Display Pins

Energy Analysis

Power (W) = voltage (V) x current (I)

Our device can be classified as a medical device as its main function is to analyze its users vital signs. The International Electrotechnical Commision (IEC), IEC 60601, specifies safety and performance requirements for medical devices and our device must perform within these regulations. For example, this standard addresses electromagnetic compatibility (EMC) and ensures that the medical device is designed to operate safely in environments with electromagnetic interference [32]. Our device is meant to be a medical device to assess its users vitals therefore, it would have to a the IEC 60601 reference standard.

The STM32F401 operates with a 3.3V supply however, due to the on-board voltage regulator, the VIN pin, it can accommodate a wider voltage range (7-12V) that our battery satisfies.
As stated before, our device will likely run using a 9V battery which aligns with the safe voltage range of our microcontroller of 3.3V to 12V. The project requirements state that our design cannot exceed 30W of power consumption. It can be rest assured that our device doesn't surpass this amount due to the on-board regulator that regulates the voltage supply to the microcontroller and other components of the board to 5V. Given that 30W is the maximum amount of power, there would have to be 6000mA of current in the device to reach that limit and even more needed to exceed this threshold.

Our 16 by 2 character LCD display requires 1mA of current within its operating voltage of 4.7-5.3V and our pulse sensor, the SEN-11574, requires 4mA of current while operating at 5V. Each LED operates at a maximum of 20mA at its brightest, 3 LEDs would require approximately 60mA at most [33]. Our vibration motor requires 3V and 80mA of current and the 170-point breadboard needs 1000mA of current. The microcontroller itself requires 160mA according to its datasheet making the total power consumption of all necessary components 6.365W [34]. However, if the device opts to have its power source be from a PC through a USB connector, then the maximum current would be 300mA which makes the total power consumption 7.065W [35].

Table 3: *Components Used in Device and their Corresponding Electrical Data*

Component	Current (mA)	Power (W)
LCD Display	1	0.005
SEN-11574	4	0.02
LED (3)	60	0.3
170-point Breadboard	1000	5
Vibration Motor 3V	80	0.24
STM32F401	160/300	0.8/1.5

Energy Storage

A component in our device that stores energy would be our 9V battery. A typical 9V alkaline battery can store up to 600mAh or 2.16Wh which is a lot of energy when converted to Joules. However, the maximum current drawn from the batteries onto the board shouldn't exceed 100mA, or 0.1A, so it will not store a significant amount of energy beyond 500mJ.

LEDs emit infrared light when current flows through them, through the principle of electroluminescence. Electroluminescence is one of the instances where electric energy is converted into visible light, therefore, LEDs act as semiconductors. Semiconductors are designed to facilitate the transfer of energy and they aren't designed to store energy. Therefore, the LEDs and the NPN transistor do not store energy.

The LCD display's energy consumption is related to the screen brightness. It doesn't store energy but requires a constant source of power in order to maintain the display. The pulse sensor and vibration motor don't store any energy as they draw power from the microcontroller while the microcontroller relies on the external power source to supply all the energy they require to operate.

We ensure that our medical device and all its components are within regulations in relation to limits on power and energy while keeping it efficient and safe for any potential user. We can conclude that the design absolutely minimizes the amount of energy being stored, with the maximum stored energy being 500mJ from the battery.

Risk Analysis

Safety:

There are possible negative consequences regarding safety from using our product, one of which is eye strain from the LEDs. If the user finds themself exposed to these lights for excessive periods of time, they could become light sensitive and may cause negative effects on the user's eye health due to degradation after constant usage [36]. The device is meant to be used as a medical device, and not as a toy. The misuse of the device by using it as a toy and not its intended purpose can cause the child to injure themselves. Although the electrical components won't be visible, it is still inevitable that some problems will occur.

If the design is not placed on the intended area of the body, the data that it displays won't be accurate and could make the user misinterpret the state of their vascular health. This can impact their safety if it prevents them from potentially being able to make an early diagnosis of a medical condition. This would render the device useless and its purpose is to aid Nunavut residents in determining their bodies' condition. Our device doesn't fully replace the services and quality of treatment that a doctor can provide so, even while using this device, it is recommended to take precautions and seek medical attention when needed.

If used incorrectly, the design could have a negative impact on the user's ergonomics. An example of this would be tightening the device strap to the point where wearing the monitor becomes uncomfortable for the user. This would put pressure on the user's arm and could even cause strain, soreness, irritation, redness, and more [37]. Additionally, according to the U.S. Department of Health and Human Services, it is recommended that blood pressure devices be only used on people three years of age or older [38], and there are other specialized methods of measuring infants' heart rates [39]. The device built in this project is not designed for infant use, and failure to follow this recommendation can result in physical harm.

Environment:

There are negative consequences pertaining to the environment that arise from the use of the device. It includes the fact that most batteries are made of lithium, a resource that uses a lot of water and energy to extract [40]. Even the extraction of lithium has caused many ethical issues to arise like child labour

and modern slavery as well as concerns regarding poor environmental and ecological pratices [41]. Our design would incorporate a potentially unethically harvested source of lithium. In addition, lithium mining endangers natural ecosystems due to the vast amount of air and water pollution that's produced, including the emission of greenhouse gasses [42][43].
The incorrect use of the device regarding proper disposal methods can also have negative consequences on the environment. In particular, if the lithium battery is incorrectly disposed of, it can end up in landfills and leak toxic chemicals into the soil, causing soil erosion, and harm wildlife [37]. In general, a discarded product with a battery that contains hazardous materials can pose a severe risk to humans and overall environmental health. Many components in the device could be salvaged and recycled to limit electronic waste. Avoiding lithium's non-biodegradable nature can prevent it from accumulating in the surrounding environment and affecting the quality of water, air, and soil [44].

Failure Mechanisms:
This device could malfunction in various ways that could hinder its ability to deliver precise results [45]. If the device is used in an environment with wind, or objects in the surrounding environment move and create wind, the device can malfunction [46]. If the user uses the device while exercising, the heart responds to high-intensity movement and delivers oxygen-rich blood throughout the body. This elevated heart rate due to muscles needing oxygen for energy might take a while to return to normal again [47]. Therefore, readings during this time may not always indicate your current health as there are other factors contributing to your heart rate. This phenomenon can also occur when the user is asleep or has just woken up; according to studies, sleeping tends to lower heart rate [48].

In relation to the pulse sensor, its accuracy varies depending on the LED light passing through the skin and the photodiode's ability to capture any reflected light. Our natural skin pigment, melanin, is very good at absorbing green light. Therefore, an increased amount of melanin in your skin decreases the accuracy of a pulse sensor that's dependent on infrared green light. The sensor has also been reported to have problems with dark tattoos, sweat, and arm hair [49][50]. In addition, bright ambient lighting in the surrounding environment can dilute the infrared rays and make it challenging for the proper amount of reflected light to be collected. Probe placement is crucial too, it should be securely fixed to either the wrist near the radial artery or the finger to increase the device's prognosis [51].

If the readings are inaccurate, their vitals won't be displayed correctly. In extreme cases, this can lead to safety issues if the machine indicates the wrong state of health during an emergency situation where they should seek immediate medical attention. On the other hand, for example, if the LED turns red while a user is exercising and believes that their life is at risk when in actuality it's not, this would cause the user unnecessary stress and travel costs in order to go see a doctor.

Test Plan

Test 1:
Test setup
In order to prevent damage to the device and its components as well as avoid any discomfort or safety risks to the user, there should be no exposed circuits or wires in the final prototype. Electrical safety must be taken into consideration to stop any potential harm to the user including burns or shocks [9]. This can be accomplished by 3D printing a case for the portable heart rate monitor and ensuring that the final product is well put together. In order to test the electrical safety of the device, the device will be placed flat on the table in the lab room and a pair of rubber gloves will be used to conduct an inspection of the device to prevent physical injury from possible stray wires or other electrical components that could be sharp or harmful when touched with bare skin.

Environmental parameters

To ensure that all areas of the device can be inspected, the lab room will be well-lit. The room will remain lit up for the length of the test, and all doors, windows, and other regions through which light could pass must be closed so that all light is blocked out of the room. This is to ensure that the amount of lighting in the room does not change throughout the length of the test, which prevents difficulty of seeing all components due to fluctuation in lighting.

Test inputs

The person doing a physics inspection will wear the rubber gloves and pick up the device. The person will run their gloved hands over the sides of the case, rotating the case with the other hand. Next, the person will run their hands over the top and bottom of the case, as well as over the device's strap. Then, a visual inspection will be conducted to attempt to find any stray electrical components. The device will be rotated from a variety of angles so that all of the sides of the case are scanned over.

Measurement standard

All electrical components should be inside the case. There should be no electrical components on the exterior of the case.

Pass criteria

a) There are no exposed circuits, wires, or other electrical components on the exterior of the device.

Test 2:

Test setup

The wearable device strap should be adjustable to fit wrists of a variety of sizes - the width of the strap should be 20-22 mm to comply with the average size of standard wristwatches [10]. Additionally, the length of the strap should be around 115% of the wrist circumference for the strap to sit comfortably (not too loosely or too tightly) around the wrist [11]. Since the average wrist size is between 14.43 - 18.25 cm (taking into account both male and female wrists) [12], we can perform the following calculation:

$$18.25 \times 1.15 \approx 20.99\ cm$$ *(rounded to 2 decimal places)*

Thus, the length of the strap should be 21 cm long, and should be able to be adjusted to wrap around the wrist from 14.43 cm to 18.25 cm. In order to test the adjustability of the device's strap, we will use hollow cylinders made of flexible poster board with varying diameters to simulate the human wrist. The first cylinder will have a circumference of 14.43 cm, and the second cylinder will have a circumference of 18.25 cm, to ensure that the strap can be adjusted to fit the maximum and minimum wrist sizes as stated in Requirement #1. In order to make these cylinders, two rectangles of length 14.43 and 18.25 cm, and of height 15 cm (to ensure width of strap will fit on the cylinder) will be measured with a standard ruler and cut out. Then, each rectangle will be curved lengthwise into a hollow cylinder shape, and will be taped so that the cylinder shape stays.

Environmental parameters

In order to reduce error in results, the same piece of poster board will be used to create both hollow cylinders.

Test inputs

To test the device's strap, the first hollow cylinder will be placed on the table while the strap of the device is wrapped under and over around the diameter of the cylinder. Then, the strap will be tightened and attached around the diameter of the cylinder, ensuring that the cylinder does not get crumpled or damaged in the process to secure the most accurate results possible. This process will be repeated in its entirety with the second hollow cylinder.

Measurement standard

Input:	**Expected output:**
Wrap strap around cylinder with circumference 14.43 cm	Strap is able to fit around circumference of cylinder without falling off
Wrap strap around cylinder with circumference 18.25 cm	Strap is able to fit around circumference of cylinder without falling off

Pass criteria

a) The strap must be 22 mm wide.
b) The strap must be 21 cm long.
c) The strap must be able to attach around the cylinder with a 14.43 cm diameter without falling off.
d) The strap must be able to attach around the cylinder with a 18.25 cm diameter without falling off.

Test 3:

Test setup

The device will check heart rate continuously when the user activates the device. The heart rate will be calculated 4 times per minute to allow for a 15 second pause between checks. This frequency will allow for the device to store data and gather insight into trends with the user's heart rate [12][13]. To ensure that the device is able to check the user's heart rate continuously, we will use an empty plastic water bottle, and an online timer will be set up before the testing begins.

Environmental parameters

Testing will be done in a lab room that is well-lit, since the heart rate sensor relies on changes in light to work. The room will remain lit up for the length of the test, and all doors, windows, and other regions through which light could pass must be closed so that all light is blocked out of the room. This is to ensure that the amount of lighting in the room does not change throughout the length of the test, so that the sensor is able to read information properly. Additionally, the device should be set up in an environment that maximizes (as much as possible) the chance for the vitals to be read as accurately as possible. Hence, the testing will be done in a lab room with a sealable entrance (ie. door that can be closed), and any other openings in the room, such as windows, should be closed before commencing testing, so that the environment is completely isolated. This controls the temperature and pressure inside the room, preventing it from fluctuating throughout the testing. It also ensures that there is no wind that is able to enter the testing room from the outside, and that the noise levels remain quiet in the testing room. This is all to prevent external factors from influencing the accuracy of the device testing.

Test inputs

To test that the device checks for heart rate continuously and properly, the device will be placed on the table while the water bottle will be held over the sensor, at a small distance away from the sensor. Once the device is activated, the timer will be started and the water bottle will be repeatedly swung over the sensor from left to right, then from right to left. This action will happen once every second according to the timer in order to mimic an average heart rate for a human being, around 60 bpm. This action will continue to happen until the timer reaches 1 minute, at which time the device is stopped. This test will be done twice to ensure that the test results are accurate.

Measurement standard

Input:	**Expected output:**
Check if device records heart rate at 0 s	Device checks for heart rate at 0 s
Check if device records heart rate at 15 s	Device checks for heart rate at 15 s
Check if device records heart rate at 30 s	Device checks for heart rate at 30 s
Check if device records heart rate at 45 s	Device checks for heart rate at 45 s
Check if device records heart rate at 60 s	Device checks for heart rate at 60 s

Pass criteria

a) The device should check and perform heart rate calculations every 15 seconds.

Test 4:

Test setup

The device should light up green when there are no health risks (60-100 bpm), yellow when there are mild risks (50-60 bpm or 100-110 bpm), and red when there are high risks (under 60 bpm or over 100 bpm) [14]. There are studies surrounding the psychology of colours and how the brain interprets them with meanings. A prime example of this phenomenon is how red is seen as a color that not only signifies danger but also health [15]. In wavelengths, red can be quantified as 650-700 nm while yellow and green are 580-600 nm and 550-580 nm respectively [16]. The visible spectrum of light is the range of electromagnetic waves that can be perceived as colors. To test that the device's LEDs light up according to the appropriate health risks identified based on the user's heart rate and blood pressure measurements, we will place the device on the lab room table so that the LED colors are clearly visible. We will also use the plastic water bottle and an online timer to simulate a human heart beat.

Environmental parameters

The testing will be done in a lab room that is well-lit, since the heart rate sensor relies on changes in light to work. The room will remain lit up for the length of the test, and all doors, windows, and other regions through which light could pass must be closed so that all light is blocked out of the room. This is to ensure that the amount of lighting in the room does not change throughout the length of the test, so that the sensor is able to read information properly. Additionally, the device should be set up in an environment that maximizes (as much as possible) the chance for the vitals to be read as accurately as possible. Hence, the testing will be done in a lab room with a sealable entrance (ie. door that can be closed), and any other openings in the room, such as windows, should be closed before commencing testing, so that the environment is completely isolated. This controls the temperature and pressure

inside the room, preventing it from fluctuating throughout the testing. It also ensures that there is no wind that is able to enter the testing room from the outside, and that the noise levels remain quiet in the testing room. This is all to prevent external factors from influencing the accuracy of the device testing.

Test inputs

Once the device is activated, the timer should be run and the water bottle should be swung repeatedly from left to right, and then right to left, for one minute. This will be done five times, and each time, the water bottle will be swung at a different rate to test all three different risk levels, low, medium, and high. The tests will be as follows:

1. Once every two seconds (30 bpm), indicating high level risk
2. Five times every six seconds (50 bpm), indicating mild risk
3. Once every second (60 bpm), indicating no health risks
4. Six times every five seconds (108 bpm), indicating mild risk
5. Twice every second (120 bpm), indicating high level risk

Measurement standard

Input:	**Expected output:**
Heart rate of 30 bpm	The
Heart rate of 50 bpm	
Heart rate of 60 bpm	
Heart rate of 108 bpm	
Heart rate of 120 bpm	

Pass criteria

a) The LCD screen should light up red for the heart rate of 30 bpm.
b) The LCD screen should light up yellow for the heart rate of 50 bpm.
c) The LCD screen should light up green for the heart rate of 60 bpm.
d) The LCD screen should light up yellow for the heart rate of 108 bpm.
e) The LCD screen should light up red for the heart rate of 120 bpm.

Test 5:

Test setup

To test that the device performs vibrations correctly, we will use an online timer to record the intervals between motor vibrations, as well as a water bottle to mimic a human heart beat, as used in previous tests.

Environmental parameters

The device should be placed in a lab room at room temperature so that the motor is less likely to overheat or malfunction.

Test inputs

After the device is activated, the water bottle will be used to mimic a human heart beat beating at 50 bpm (mild risk) with the same process as stated in Test 4. After the first motor vibration, the timer will be started and the time interval between vibrations will be kept track of. This will be repeated with the water bottle being used to mimic a heart beat at 120 bpm (high risk). The amount of passed and failed tests will be kept track of in order to prevent malfunction, and ensure product quality and customer satisfaction.

Pass criteria

a) The vibrations must be separated by 10 second intervals for a heart rate of 50 bpm.
b) The vibrations must be separated by 5 second intervals for a heart rate of 120 bpm.

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