GNG5140: Engineering Design

Deliverable B: Design Research

Submitted by

Team Opioid Overdose

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Abstract

The GNG5140 project utilizes a brownfield design approach, meaning that previous work is built upon and elaborated on to recreate and improve the product. This report first introduces opioids and opioid overdose. It then outlines the group’s understanding of previous work, listing multiple previous prototypes, their key concepts, benefits, and drawbacks. The report then outlines a set of benchmarking criteria, under-which the prototypes will be graded. The design specifications were then used to set targets for the product according to specifications needed for the application, and all prototypes were graded according to these targets. A testing plan was then laid out to acquire and process testing data.

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List of Acronyms

|  |  |
| --- | --- |
| **Acronym** | **Definition** |
| WHO | World Health Organization |
| OD | Opioid overdose |
| CDC | Center for Disease Control and Prevention |
| SpO2 | Oxygen saturation |
| RR | Respiratory rate |
| PHO | Public Health Ontario |
| HR | Heart rate |
| BPM | Breaths per minute |
| ABS | Acrylonitrile butadiene styrene |
| TPV | Thermoplastic vulcanizates |
|  |  |
|  |  |

# Introduction

## What is an opioid?

The term “opioids” includes the natural opiates extracted from poppy seeds as well as semisynthetic and synthetic compounds that are similar in structure and effect on the body [1]. Opioids are commonly used for pain relief and sedation, and include substances such as morphine, fentanyl, oxycodone, and heroin. Recreational or unsupervised use of opioids can lead to opioid dependence and tolerance which can increase the likelihood of an OD [2].

## What is an opioid overdose?

An OD is defined as an injury to the body occurred when a substance, often a drug, is taken in excessive amounts [3]. Symptoms of an OD can vary depending on the amount and the substance taken. Common symptoms of OD include [4]:

* Slow, weak or no breathing
* Blue lips or nails
* Dizziness and confusion
* Can’t be woken up
* Choking, gurgling, or snoring sounds and
* Drowsiness or difficulty staying awake

There are also signs that can be easily measured to determine if someone is overdosing, such as [1]:

* SpO2 below 90%
* RR below 10 breaths per minute

## Treatments for an Opioid Overdose

The antidote for an OD is naloxone or Narcan. It can reverse an OD, helping the user breathe normally and regain consciousness if administered immediately. Naloxone can be administered via an injection or a nasal spray [5].

## Who is affected by Opioid Overdose?

WHO [2] estimates that approximately 115,000 people died of OD in 2017. In Canada, there were 13,900 opioid-related deaths between January 2016 and June 2019 [1]. Approximately 75% of opioid-related deaths were male, and 53% were between the ages of 25 to 44. About 75% of lived in a private residence, 62% in large urban centres, and 32% in areas with high material deprivation. Nearly 50% of the deceased were unemployed and only 18% were employed at the time of their death. Among those with employment, construction was the most common industry at 31% [6]. It is also reported that nearly 50% of the deceased were alone at the time of the incident and 60% of them occurred in their own home [1]. Therefore, developing an effective OD monitoring device can be vital in potentially saving thousands of lives.

# Design Review

There are past attempts of this project available on the MakerRepo website (https://makerepo.com/) for review. From eleven past attempts on MakerRepo, three were selected for review. There are also existing devices that perform similar tasks available on the market, such as QardioCore and Fitbit Sense.

## Save your Sole [7]

*Save your Sole* is one of the past attempts at designing an OD monitor available on MakerRepo. The most stand-out feature of this project is that all the hardware components were placed on a sole in order to take the measurements from the user’s foot.

To set up the device, the user must connect a 9V battery to the device and connect it to the smartphone in the app. Once the devices are connected, the data collected is displayed on the phone showing HR and SpO2. In the app, the user can add or remove emergency contacts from their phone’s contact list.

The user can send a text message, along with their current location, to all of their emergency contacts. If the device detects an OD, it will first alert the user that an OD has been detected. The user can verify the OD, but the device will automatically send a text message if the user does not respond in 30 seconds.

### Potential Issues or Risks

A major issue of this project is the location of the measurement. For an accurate SpO2 measurement, the sensor must be in contact with bare skin. The accuracy of the measurements can be severely compromised if the user is wearing socks before the measurements are taken. Also, this device was designed to be placed on the sole of a shoe. If the user were in an environment where they would not be wearing shoes i.e., indoors, the device would not be able to take accurate measurements.

### Areas for Improvement

While this project shows plenty of promise, there are areas where some improvements can be made. One such area is the interface between the sensor and the user’s foot. A component that could physically hold the sensor in contact with the foot such as a strap instead of being placed in a sole could eliminate the issue of indoor measurements mentioned above.

Another area for improvement is the power system. Currently, the device is turned on/off by connecting/disconnecting a 9V battery to it. A more convenient method of powering the device such as a switch would improve the quality for the user.

## O2-POD [8]

*O2-POD* is another past attempt at an OD monitor available on MakerRepo. Unlike *Save your Sole*, this device uses an ear-clamp to measure SpO2. The device also includes earbuds for a more discreet design, as it will appear as if the user is wearing regular earbuds and listening to music.

To setup the device, the user must first install the smartphone app then connect to the device with the GPS and cellular service enabled. After charging and turning on the power bank, the user can provide the phone number of the emergency contact.

When the device detects an OD, it sends a text to the emergency contact to notify them along with the location of the user. It will also play an intervening sound in an attempt to assist the user regain their consciousness.

### Potential Issues or Risks

Similar to *Save your Sole*, a potential issue lies with the location of measurements with this project. Since the measurements are taken from the earlobe, the sensor can be exposed to different light sources that could affect the accuracy of the measurements.

### Areas for Improvement

*O2-POD* has features that are desirable for any future attempts at developing an OD monitor such as active intervention via sounds. However, there are some areas for improvement that would a huge upgrade. Currently, the user must enter the phone number of only one emergency contact. By being able to select multiple emergency contacts from the user’s list of contacts, it would not only make the app easier to use but also increase the likelihood of the user receiving help during an OD.

## OP-Watch [9]

*OP-Watch* is another OD monitor available on MakerRepo. Unlike the first two devices, *OP-Watch* is placed on the wrist for SpO2 measurements. The device also includes watch straps to physically hold the sensor in contact with the user’s skin and to disguise the device as a watch.

To setup the device, the mobile app must be installed and paired with the user’s smartphone. The app starts tracking the GPS location upon launching, but it must be connected to the device to display the SpO2 measurements.

When the device detects an OD, the device emits a sound and vibrates. The user can press a button on the side if a false positive occurs. If the OD is real, the device contacts the emergency contact along with the GPS location.

### Potential Issues or Risks

One of the feedbacks received from the client was that the measurements were fluctuating violently. This issue must be addressed so that the device does not repeatedly detect an OD when there is not one, or worse, does not detect an OD when the user is overdosing.

Another feedback from the client was that the sensor was overheating. Allowing the sensor to cool down would be useful in not only improving battery life but the lifespan of the sensor as well.

### Areas for Improvement

While *OP-Watch* seems like a promising device, there are areas where it must be improved. The precision of the measurements stated above must be improved for it to be a viable OD monitor. Another area for improvement is to be able to stop the measurements, either by setting a measurement period or an on/off switch. Being able to stop measuring will not only improve the battery life of the device, but also allow the sensor to cool down, thereby reducing the overheating issue mentioned above.

# User Needs

The client meeting was established to gather information about the needs of the user as the user of the device and the client are different. Various criteria were discussed, and potential issues were put forward.

## Software Requirement

The following are program requirements expected from the device:

* 1. The device detects an OD within 3 minutes of an overdose.
	2. The device intimates the user about the alert message that will be sent to the emergency contact upon detecting an overdose.
	3. Customization for setting up an alert for emergency contact or 911 can be done.
	4. User privacy will be maintained with discrete but strong alerts.
	5. Customization for constant or periodic monitoring is available for the user.

## Hardware Requirement

The following hardware requirements are expected from the device:

* 1. It is externally activated by the user before the intended usage.
	2. The device stays in contact with user’s skin always while it is monitoring the symptoms and will be comfortably wearable for long periods of time.
	3. The size of the device will be small and discrete, and performance will be hands free.
	4. Cost of the device is below $ 200.
	5. Device connects to a smartphone to alert the emergency contacts.

## Performance Requirement

* 1. Device will display the SpO2 measurements and monitor drops in readings less than 90% [1].
	2. Device will display the respiratory rates measurements and monitor drops in readings less than 10BPM [1].
	3. A predefined message is displayed to the emergency upon activation of the alert.

##  Life Cycle Requirement

* 1. The device can work through the night without recharge for continuous monitoring mode.

##  Prioritized List of Needs

Based on the user’s needs, a list of requirements for this project was generated. Each requirement was ranked on a scale from 1 to 5, with **5** being **most** important and **1** being the **least** important. Table 1 shows the list of user requirements and their priority for this project.

Table 1. Prioritized User Requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **Need #** | **User Requirement** | **Description** | **Priority** |
| **1.** | **Cost efficient** | Cost of the device is below $200 so that its accessible to our target customer, middle to lower class men. |  **4** |
| **2.** | **Measure SpO2** | Device will display the SpO2 measurements and monitor drops in readings. | **5** |
| **3.** | **Measure respiratory rate** | Device will display the respiratory rates measurements and monitor drops in readings. | **5** |
| **4.** | **Hands free** | The user will not be able to use their hands for operating the devise while using substance hence the device is hands free. | **4** |
| **5.** | **Discrete** | Target customer does not want to be noticed wearing this device in public. | **4** |
| **6.** | **Customizable** | Option to change the contacts that needs to be alerted for faster response in case of OD. | **3** |
| **7.** | **Quick response** | OD detection and generating alert is very quick as the user only has 3 minutes of consciousness left. | **5** |
| **8.** | **Long battery life** | For overnight or continuous monitoring, frequent charging is not required. | **3** |

From the user needs, the project metrics and how they will be measured can be generated. Table 2 shows the project metric and what user need they are based on, along with their units of measurements and priority.

Table 2. Project Metrics

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Metric #** | **Need #** | **Metric** | **Importance** | **Unit** |
| 1. | 1. | Unit manufacturing cost | 4 | CAD |
| 2. | 2. | Oxygen saturation | 5 | % percentage |
| 3. | 3. | Respiratory rate | 5 | BPM |
| 4. | 5. | Device size | 4 | cm × cm × cm |
| 5. | 5. | Device weight | 4 | g |
| 6. | 7. | Overdose response time | 5 | minutes |
| 7. | 8. | Battery charging time | 3 | minutes |
| 8. | 8. | Battery capacity | 3 | mAh |

# Technical and User Benchmarking

Benchmarking can be used to compare the specifications and performance different products. It also allows for generating a range of specification for a project design. For this project, the three past attempts that were selected as well as QardioCore will be used for benchmarking. Table 3 shows the specifications of each device compared to the others.

Table 3. Specification of Existing Devices

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Monitoring Device /Specifications** | Save your Sole | O2-POD | OP-Watch | QardioCore |
| **Company** | GNG1103 Section C01 Group 3 | GNG1103-C Team 6 | GNG1103-C Team 7 | Qardio |
| **Cost** | 90.50 CAD | 70.17 CAD | 55.86 CAD | €500 (775CAD) |
| **Material** | Plastazote | Plastic | Metal, rubber | ABS and TPV |
| **Shape/concept** | Sole | Earbud | Wristwatch | Chest strap |
| **Size** | 32 × 11 × 3 | 19 × 9 × 5 | 5 × 2.5 × 2 | 19 × 10 × 1 |
| **Weight** | Unknown | Unknown | 145 | 130 |
| **Method of OD detection** | SpO2 < 90% | SpO2 < 90% | SpO2 < 90% | N/A |
| **Method of alerting someone** | Call multiple emergency contacts | Call emergency contact & Play intervening sounds | Call emergency contact & Vibrate/ play sounds | N/A |
| **Battey life** | ~30 hrs | Unknown | Unknown | 24 hrs |
| **Non-invasive** | YES | YES | YES | YES |

## Design Criteria

Table 4 depicts the design criteria required for the device:

Table 4. Project Design Criteria

|  |  |  |
| --- | --- | --- |
| **No.** | **Need** | **Design Criteria** |
| 1. | **Cost efficient** | Below 100 CAD |
| 2. | **Measure SpO2** | Reliably detect if blood oxygen level is less than 90% and sharp drops in level |
| 3. | **Measure respiratory rate** | Detect if respiratory rate is less than 10 BPM |
| 4. | **Does not interfere with activities** | Hands free |
| 5. | **Maintains privacy** | Discrete and light weight |
| 6. | **Ability to edit emergency contact information** | Customizable |
| 7. | **Quick response** | Activate alert within 3 minutes of OD detection accurately |
| 8. | **Long battery life** | ~40 hrs |

## Design Constraints

The following design constrains might be posed while implementing the monitoring device:

* 1. Durability
	2. Development cost, unit cost and operational cost
	3. Structure and size of the device to fit in a discrete and sensitive area
	4. Comfort of wearing the device and using it

## Project Specifications

Table 5 shows the marginal and ideal values for each specification for this project that were generated using the design criteria and constraints discussed above.

Table 5. Marginal and Ideal Values of Metrics

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Metric** | **Unit** | **Marginal Value** | **Ideal Value** |
| 1. | Unit manufacturing cost | CAD  | < 200 | < 100 |
| 2. | Oxygen saturation accuracy | % | ±5 | ±2 |
| 3. | Respiratory rate accuracy | % | ±10 | ±5 |
| 4. | Device size | cm × cm × cm | 19 × 9 × 5 | 5 × 2.5 × 2 |
| 5. | Device weight | g | 200 | 130 |
| 6. | Overdose response time | minutes | 3 | 1 |
| 7. | Battery charging time | minutes | 120 | 60 |
| 8. | Battery capacity | mAh | 1000 | 1500 |

 Table 6 shows the final specifications of this project. Note that the value are labeled as “Under Design Process” as it was decided to choose the final values later in the design process.

Table 6. Final Specifications

|  |  |  |  |
| --- | --- | --- | --- |
| **SNo.** | **Metric** | **Unit** | **Value** |
| 1. | Unit manufacturing cost | CAD | Under Design Process |
| 2. | Oxygen saturation accuracy | % | Under Design Process |
| 3. | Respiratory rate accuracy | % | Under Design Process |
| 4. | Device size | cm × cm × cm | Under Design Process |
| 5. | Device weight | g | Under Design Process |
| 6. | Overdose response time | minutes | Under Design Process |
| 7. | Battery charging time | minutes | Under Design Process |
| 8. | Battery capacity | mAh | Under Design Process |

# Test Plan for Existing Prototypes

## Data Acquisition

The test plan first begins with the analysis of the prototype design as per the metrics defined by the team. As seen in Table 4, there are 8 metrics by which the product will be judged. For unit manufacturing cost, the costs presented in each prototype user manual will be researched and listed. Oxygen and respiratory rate accuracy can be found by sensor data sheets. Utilizing the provided documentation on existing prototypes, the data sheets will be found, and sensor accuracy will be listed. It is also worth considering the location of the device, as this could affect accuracy of the measurement. Device size, weight, overdose response time, battery charge time, and battery capacity values will be taken directly from the provided documentation.

## Methods to Compare Performance

Since all values are quantifiable, a numeric approach can be utilized to assess prototype performance. A decision matrix can be developed to select the optimal prototype/prototypes. To compare the performance of the protype against target specifications and performance requirements, the team will utilize a grading scale. The percentage difference between the target specification and prototype specifications will be calculated. Values exceeding expectations will be given a positive percentage and values that do not meet the requirements will be given a negative percentage. The values will then be offset by the lowest value, meaning that all values will vary from 0 to infinity. Once these values are formed for each design criterion, they will be multiplied by their respective importance values specified in Table 2. This weights each design aspect by importance. The total sum of all weighted performance criteria values will then be added together for each prototype, giving the final values to select a prototype to base the preliminary design on.

# Conclusions and Recommendations for Future Work

 The first step in the design process is to get a clear set of requirements. The client portrayed a clear insight into the need of an opioid overdose monitor for thousands of opioid users. She also provided a very clear set of requirements for this project.

 Since this project was attempted before, three of those past prototypes available on MakerRepo were studied extensively. While all three of them showed promise, they all had areas in which the prototypes could be improved. A list of design metrics, project specifications and constraints were generated using the data acquired during the research. A test plan for these prototypes were also generated, but a physical test was deemed not possible due to the current situations of a raging pandemic.

 Future works would involve finalizing the specification values, conducting physical tests for each prototype and beginning the designing of the project: mainly what to measure and how they will be measured. While there is still a long journey ahead, the team feels that this is a right step forward.

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