Bruxism Biofeedback Device

by

Isabelle A. Starr

Errin S. Abasolo

Claire A. Dossey

College of Engineering
California Polytechnic State University
San Luis Obispo
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Executive Summary

This paper aims to summarize the design process for a biofeedback bruxism device, covering the necessary background research, engineering requirements, design process, prototyping, manufacturing, and testing for the device. The purpose of this project was to design an engineering solution for the treatment of bruxism. This entails both measuring and significantly reducing clenching and grinding during sleep, as many current solutions may reduce symptoms of the disorder, but do not treat bruxism itself. Engineering requirements included biocompatibility, size and weight, electrical safety, and ease of use and comfort. Many design options were proposed, and a Pugh Matrix was used to help choose the best design, given customer and engineering requirements. The selected conceptual design includes a pressure sensor embedded in a custom mouthguard that communicates using radiofrequency (RF) to a haptic feedback module in a headset to alert the user when they are clenching. This feedback device activates above a bite force threshold–effectively treating bruxism with classical conditioning, pairing a haptic response with the action of unclenching. The design went through several rounds of prototyping to make circuit alterations and manufacturing changes, while attempting to verify the device efficacy. A final proof-of-concept product was presented to the sponsor, including two functional circuits that are able to 1) sense pressure using a pressure sensor embedded in silicone, 2) send a signal using an RF transmitter to a receiver connected to the haptic circuit, and 3) trigger the haptic response module to vibrate, with a minimal response lag time between force being applied and response triggering. The result of this project produced a proof of concept circuit for both the sensing and responding circuits. A final conceptual design is proposed for the ideal circuits and mouthguard design, including manufacturing and testing plans. Next steps are outlined to aid in the continuation of this project in future years.
1. Introduction

Bruxism is a disorder that causes involuntary clenching and grinding of the jaw and teeth, typically during sleep. The symptoms of bruxism include teeth grinding, increased tooth pain and sensitivity, jaw, neck, and face pain, headaches, and trouble sleeping [1]. Many of those who struggle with bruxism have side effects such as jaw tension and tightness, headaches, and tooth-root damage, and they are typically recommended nightguards, occlusal splints, or pain-reducing medications, however, these solutions do not stop the jaw from clenching, or effectively reduce the effects of the clenching. Mouthguards offer protection from chipping and cracking to the surface of the teeth, while splints were designed to reduce vertical tension between the top and bottom of the mouth, but, neither reduce the pressure and tension from jaw clenching [2]. Our goal as a team was to create a solution to bruxism that can both measure and significantly reduce the frequency and level of jaw clenching.

Stakeholders in this project included those who suffer from bruxism—specifically Sandra Lee—and professionals in the dental field who have patients with the disorder or interest in progressing the treatment options for bruxism. Additional stakeholders in the course of the project included our team—Claire Dossey, Errin Abasolo, and Isabelle Starr—and Karla Carichner, the project advisor. As the design team, we worked diligently to produce a viable product that reduces bruxism and meets our customers' needs. The designed device could be used to diagnose the severity of the bruxism, as well as treat the symptoms and prevent further damage to the patient’s teeth. The main customer was our sponsor, Sandra Lee, who personally suffers from bruxism and is dissatisfied with the current solutions on the market, like many in her situation.

Our goal as a team was to create a device that first measures the level and frequency of jaw clenching, and then significantly reduces the level of bruxing. Because bruxism cannot be linked to one specific cause, our design applies to anyone experiencing symptoms of the disorder, regardless of the reason. The design process was guided by our customer requirements based on our conversations with our sponsor, as well as research on current solutions. Our device includes a measuring device that can quantify the amount of jaw clenching occurring during sleep, as bruxism most commonly occurs during sleep for those with the disorder [2]. The measuring device is made of a piezoelectric pressure sensor embedded in a wearable night guard and connected to a radio frequency receiver. The measurement device sends a signal to a haptic response device worn by the user. The device then alerts the user when a bruxism event is occurring, eventually breaking the habit developed and reducing symptoms through classical conditioning.
I. Background

Sleep Bruxism is classified as a sleep-related movement disorder that encompasses the actions of clenching, grinding, and tapping of the teeth during sleep. It is an involuntary oral habit that is often spasmodic or rhythmic and involves mechanical movements of the jaw, not for mastication [3]. During clenching or grinding, many different muscles in the head and neck have been shown to be active, with several different mandibular movement patterns present; however, no significant patterns of movement have been detected. Some studies demonstrate that specific muscles are more active than others during clenching versus grinding or tapping [4].

Common signs of bruxism include tooth damage such as fractures, flattened edges, chips, root damage, and increased pain in the teeth. Other signs of bruxism may include pain in the jaw or neck, headaches, issues with sleep, and being conscious of bruxism habits. Known causes of bruxism include psychosocial, pathophysiological, and peripheral factors. Psychosocial risk factors are stress, anxiety, or recent mood changes. Pathophysiological factors are when a separate disease or disorder is the cause of bruxing. Examples of peripheral factors include medications such as antidepressants or psychiatric drugs, genetics, age, personality, and lifestyle choices, including the intake of caffeine, tobacco, recreational drugs, and alcohol [3].

Most scientists believe that sleep bruxism is heavily related to sleep and can be associated with the arousal phase of REM [3]. Transient arousals recur at between 20-40 second intervals in non-REM sleep and occur in a cyclic alternating pattern. A published study in the Journal of Dental Research found that bruxism activity was equally distributed between non-REM and REM sleep, and always occurs during transient arousal. The cyclic pattern suggests a link between sleep bruxism and arousal-related phenomena [5].

In the study of sleep bruxism, it is important to differentiate between the disorder being studied and similar disorders. Although the broad term bruxism encompasses daytime and sleep bruxism, the two disorders are classified and treated differently. While sleep bruxism is considered a sleep disorder, daytime bruxism is often more preventable—as individuals are awake and conscious when they clench or grind their jaw. Daytime bruxism is also believed to be caused by stress, anxiety, lifestyle, and genetics, but in evaluating treatment, there is no obstacle of sleep involved. In comparison, disorders of the temporomandibular joint (TMJ) are often related to genetics, injury, overuse, and musculoskeletal issues. Disorders of the TMJ (TMD) are common, with the prediction that 11-12 million adults within the United States have TMD [6]. Although disorders of the TMJ and bruxism can be differentiated by their causes, many of the current physical treatment options are similar and can be used to treat the whole branch of disorders.

To understand how sleep bruxism can be treated, the anatomy, physiology, and mechanics of the jaw must be evaluated. The primary muscles involved in clenching, grinding, and tapping are the muscles of mastication: the masseters, medial and lateral pterygoids, and temporals.
**Figure 1:** The muscles of mastication include the masseter, temporalis, lateral pterygoid, and medial pterygoid, on both the left and right side of the head. The lateral and medial pterygoids are deep to the masseters [15].

The most current research shows that the masseter muscles are the primary muscles involved in the action of clenching. The masseters originate from the temporal process and arch of the zygomatic bone, as shown in Figure 1. There are both deep and superficial portions of the masseter muscle that insert on the angular and lateral surfaces of the ramus. In a paper published in 2009, a research group studied the activity of the four sets of muscles of mastication during sleep bruxism-associated clenching and grinding. They identified that the masseter muscles were contracting, on average, 35.6% of the time during sleep, for subjects who have sleep bruxism. The force exerted by masseter muscle contractions on the teeth and jaw is capable of causing extreme damage to teeth and the TMJ joint [7].

One research study through Tohoku University [8] sought to measure the bite force during maximum intercuspation, along with simplifying the results into an equivalent force couple system with a single line of action. They found the most significant force was located at the molars, rather than the premolar and anterior teeth. The bite forces were found to be in a range from 246.9-2091.9 N, where the bite force was slanted favoring an anteroposterior distribution. It is noted that the line of action of the bite force was almost perfectly perpendicular to the mandibular occlusal plane. This particular study is measuring jaw pain, but it is helpful to examine the forces exerted during clenching to properly design a mechanical device.
Another research group through the Medical University of Vienna did research into how clenching forces affect the temporomandibular joint (TMJ) [9]. This group created a dynamic model to measure the forces on the jaw while clenching. This was done by creating a musculoskeletal model and performing finite-element analysis in a simulation. To simplify the simulation, forces were modeled as a wrench – meaning the resultant force acts with a moment arm and along a certain line of action. The results show that increasing the inclination of the jaw decreases TMJ loading while clenching. This study concurs with the previous, stating the highest bruxing force is at the molar, with a max force of 317.24 N, with a 2-degree inclination. However, the author states change in inclination provides a wide range of the mean bruxing force. It is worth noting that the max force was calculated for a shallow incline. Logic lines up with this finding, as the force vector becomes almost parallel to the closing muscle, allowing for the muscle to be highly active.

This study found the limit to determine bruxing force is 20% of the max bite force. It then follows that the temporal muscle on the ipsilateral side is strongly activated during all cases, while the ipsilateral anterior compartment (LAT) is most active during shallow simulations, while the lateral pterygoid muscle (LIP) is most active during steep simulations, and the ipsilateral superficial masseter (LSM) is activated for all cases. TMJ loading becomes slightly more complicated. It is observed that TMJ experiences the least amount of stress for a steep inclination, the angle of the teeth will affect how impacted it will be. Wear facet position causes little effect on bruxing forces, but the impact on the TMJ is highly correlated. The author concludes that canine bruxing simulation showed higher loading on the TMJ than molar simulations with the same inclination. This suggests a connection between tooth shape and mandibular biomechanics.

During jaw clenching, signaling must occur from the brain, to stimulate the contraction of the muscles of mastication. Electrical signals travel from the brain through nerves to reach the muscle at neuromuscular junctions, where the excitation of muscle fibers occurs. The muscles of mastication are innervated by
cranial nerve V, the trigeminal nerve. Most actions associated with movement of the jaw (specifically in the cases of clenching, grinding, and tapping) rely on motor signals from the trigeminal nerve; sensory input from the face also travels to the brain through the trigeminal nerve. The mandibular branch of the trigeminal is responsible for delivering motor commands to the lower jaw—the signaling pathway needed during clenching [7].

Figure 3: The mandibular branch leaves the trigeminal nerve at the temple, directly in front of the ear, innervating the muscles of mastication [10]

Many solutions have been proposed, patented, or commercialized to treat bruxism and the symptoms of bruxism including mouth guards, mouth splints, biofeedback devices, psychotherapy, pain medications, and sleep aids; however, few methods of treatment have shown to be successful in preventing the action of clenching or grinding the jaw, unconsciously during sleep, and most solutions target to treat the impacts to the teeth or pain in the jaw and head.

Classical conditioning is a physiological method that involves using a positive stimulus, paired with an expected signal, to condition a specific response in an individual, when the signal occurs. It has been studied for more than 100 years in the field of psychology, for the treatment of undesired habits. The general paradigm for classical conditioning is described with the example of a dog, food as positive stimuli, and the ringing of a bell as a paired signal. When the bell is rung, the food is given to the dog, so the dog begins to associate the bell ringing with food, causing the dog to salivate simply when the bell is rung. Research has shown that classical conditioning is successful in treating drug addictions and other habit-related issues. As sleep bruxism is considered a habitual disorder, classical conditioning could be applied similarly to train individuals to stop bruxing, treating the root of the issue—the habit—rather than just treating the symptoms, as the current treatment methods do. Biofeedback devices are used to treat a variety of medical issues such as headaches, hypertension, urinary and fecal incontinence, and anxiety, by measuring a biological metric, and applying a stimulus that targets the autonomic nervous system to form new neural pathways, correcting the habit. Few feedback devices have been patented or marketed for the
treatment of bruxism; however, the relevant research supporting classical conditioning in the form of biofeedback for other conditions supports its application to the treatment of sleep bruxism. A biofeedback device to treat sleep bruxism would need to include a method of sensing a biological metric and a response mechanism that pairs the positive event of unclenching with a response signal. This combination would result in a classical conditioning apparatus that could be used to re-train the autonomic activity of the patient to unclench the jaw when the response mechanism occurs [31, 32].

In order to measurably reduce clenching, a device must—both—sense clenching and reduce it. Several mechanisms can be used to sense muscle activity or that could relate to clenching detection, so they must first be outlined to understand the full device designs.

For a bruxism treatment design, a pressure sensor to measure forces between the teeth could be used. There are three main types of pressure sensors—capacitive, piezoelectric, and piezoresistive sensors [28]. All three are made of materials that experience the piezoelectric effect but are measured in different ways. Piezoelectric pressure sensors release a charge when pressure is applied, while piezoresistive increases in resistance and capacitive sensors increase in capacitance [29]. Capacitive sensors are used for highly sensitive circumstances, like on phone screens or in veins to measure blood pressure [28]. Piezoelectric sensors have similar applications but aren’t as sensitive as their capacitive counterparts. This allows them to be much more accessible and cost-effective, as well as easier to work with as they are commonly used in tandem with Arduino circuit boards, which will be utilized in this project [28, 29].

For designs that involve sensors within a mouthguard, a signal may need to be transmitted from within the mouthguard, to an outer source. To communicate that there has been a pressure change, two possible communication methods are possible options: radio frequency communication (RF) and Bluetooth. Bluetooth typically has higher power requirements than RF and is more complicated than RF, requiring a microcontroller to send signals. RF is a method of transmitting information, ranging from location to electrical signals [30]. It works by communicating a signal from a transmitter to a receiver, which is constantly waiting to read a signal from the transmitter. In a bruxism mouthguard, RF could communicate pressure changes in a mouthguard to a haptic response device that the user is clenching, and activate the vibrational response until the user can stop the bruxing.

The following list gives an overview of current patents found associated with bruxism solutions:

1. **Method and apparatus for protecting teeth, preventing the effects of bruxism, and protecting oral structures from sports injuries [P1]**
   
   This solution focuses on utilizing a current mouthguard already on the market, called a boil and bite mouthguard. Using this product makes the mouthpiece customizable to the customer. It is a multi-layer design that includes four springs connecting the top and bottom pieces as shown in Figure 4 below. The concept also includes a tough layer of silicone and rubber on the outside, with a metal mesh reinforcing the outer layer. Under that, a gel layer connects to a soft silicone inner layer, which is molded to the teeth.
2. *Bruxism Detection System With Chin-Mounted Accelerometer Sensor* [P2]

This design utilizes an accelerometer mounted on a person’s chin to detect clenching and tapping of the teeth. The process is described in Figure 5 below.

![Figure 5: Interface for accelerometer design [P2]](image)

The accelerometer is described to be reusable and portable, so any person could take the device and potentially acquire a bruxism diagnosis. It is not clear how the accelerometer is attached, but it is
connected to an energy source and local processing system, which transfers data remotely to another computer to be processed. The processing method is not discussed in detail, though the movement at the beginning and end of clenching is what would lead to a bruxism diagnosis. Other movements during the night such as turning the head and swallowing are said to have their own signature and can be filtered out. The signatures associated with bruxism are shown in the waveform, frequency, average acceleration, and pattern over the x, y, and z-axis. Generally, this interface detects motion associated with bruxism in five-second intervals. This patent claims an accelerometer is superior to an EMG sensor because the accelerometer has a stronger signal than electrical activity would provide. They also claim this concept is superior to intraoral systems due to reduced complications involving safety, size, and power consumption. Accelerometers are also mass-produced, thus a cheaper solution than an EMG sensor.

3. **Bruxism Protective Device [P3]**

Another design to treat bruxism utilizes a mouthguard-inspired concept. The design can be seen below in Figure 6.

![Figure 6: Patent for Bruxism Protective Device [P3]](image)

This invention focuses on reducing grinding damage. There are two-bite pads that rest over the back teeth, which are connected by an elongated band. This design can be worn on the upper or lower teeth. If worn on the upper teeth, there is a notch to avoid irritating the frenulum. The bite-pads are made of deformable material to reduce forces on the teeth, and there are several configurations of the bite-pads depending on customer needs. The configurations include a ribbed pattern longitudinally, transverse, diagonal, and parallel, along with circular and other random patterns. The purpose of the bite-pads is to be deformable and absorb cyclic forces while being strong enough to not snap under the same conditions. The author describes the device as “preferably a one-piece molded plastic”, which leaves room for interpretation of the material properties. The author also goes on to state the device is suitable for many different mouth shapes and does not need direct clinical supervision.

4. **Bruxism monitoring and prevention system [P4]**

This is attempting to reduce bruxism using a device partially in the ear canal. The device can be pictured in Figure 7 below. The concept of this design is to detect a “bruxism event”, which will send a signal to the earpiece, which generates a sound to alert the user they are clenching. The author lists several ways to detect a bruxism event, which include using a microphone to listen for a particular sound produced by
teeth grinding, measuring the force of the jaw muscle with an electromyographic sensor or pressure sensor, and measuring the decrease in ear canal diameter while clenching.

![Figure 7: Depiction of ear canal sensor and mouth guard sensor [P4]](image_url)

A micro-electro-mechanical (MEM) system is also mentioned, but has a narrower scope and requires specific conditions. The earpiece emitting the alert sound can also double as a pressure sensor. Initial data is needed to evaluate the resting and clenching size of the ear canal for accurate results.

5. Bruxism tracking and reduction device and methods [P5]
The next patent uses an optical muscle activity sensor and prediction-based biofeedback method to monitor and reduce bruxism. The concept is shown in figure 8 below.

![Figure 8: Design concept and process [P5]](image_url)
This design both monitors and provides feedback to the temporalis muscle - which is located at the temple, and secured in place by a headband. The concept of this invention is to sense bruxism-related activity and provide feedback to the user before clenching begins during the night. The inventor claims if the user is already clenching it is too late to stop. The device is made of opaque material to protect the photosensor, which can be a CMOS camera or photodiode to measure light intensity. There is an infrared light source that targets the temporalis muscle and is placed one centimeter away from the photosensor. In addition, there is a visual light source to stimulate the user's optic nerve through the skull. Vibration is also used as a stimulus in some cases. The assembly is connected to a processor – in this case, a low-power microcontroller with memory included. This processor is what controls the current in the light source. A motion sensor is also included in the form of a MEMS sensor, which includes a gyroscope and accelerometer. Altogether the device measures several biological signals such as muscle activity, pulse rate, and motion to detect bruxism activity, and then provides feedback to the user.

6. Wearable device capable of having sensor for detecting biological signal attached thereto or detached therefrom and method of controlling the wearable device [P6]
Like the previous patent, This device is wearable and capable of detecting biological signals through a detachable sensor.

![Figure 9: A wearable device to detect biological signals [P6]](image)

While this device is not targeted towards bruxism, the patent holds elements about a potential bruxism solution. This particular device is capable of communicating with a smartphone to provide the user feedback on the biological signal they are monitoring.

7. Devices and method for bruxism management [P7]
This design utilizes a dielectric substrate with an integrated circuit and or electric lines, along with a grounding pad, a sensor pad, and a shielding pad. The concept is shown in Figure 10 below.
This design states that incorporating a sensing region into a dielectric substrate that is one piece enables the use of an integrated circuit, thus reliably being able to detect biting parameters. The inventors address materials such as prostheses, or contact with the human body, that can make measurements less accurate – which is why they included the electronic shield and grounding pads. The housing for the sensor is made with a dielectric substrate housing, which makes the product elastic enough to protect the inner technology from the biting force. The device can detect the clenching force and send the data externally to be examined for patterns related to bruxism. The author claims this device collects more accurate data than other existing solutions, concerning mechanical tolerances, electronic noise level, and reproducibility. One reason for such a claim is the use of a shielding pad. The data was drastically improved with its addition to the product, as the electrical field around the conductive patch is preserved.

8. **Sensing system and method for detecting occlusal force of 3D printing implant [P8]**

An invention from China utilizes a 3D printed dental implant with an embedded sensor to collect data on the user's jaw clenching habits.
This technology works using an RFID embedded in the dental crown, which is activated from pressure-sensitive materials plated in the false tooth. The RFID sends a signal to a mobile device. The 3D-printed tooth is coated with a titanium paste, but this design decision does not have a detailed description or is lost in translation.

9. **Wireless battery-free diagnostic mouth guard [P9]**
This patent is designed to monitor bruxism using a mouthguard and a piezoelectric film.

![Figure 12: Wireless battery-free mouthguard [P9]](image)

This design works using a battery-free mouthguard configuration that includes a piezoelectric film as a bite force voltage transducer. A wireless sensor and transmitting antenna are used to communicate the sensor data. The voltage created from the bite force on the piezoelectric film can bias a varactor diode loaded on the wireless sensor, which has a response frequency tuned to a capacitance change of the character diode. In the configuration described in the patent, the creator uses a split ring resonator as the sensor, though multiple sensors can be used.

10. **Smart wearable that monitors jaw movement in ear [P10]**
This product is wearable in ear and has sensing and feedback mechanisms built in.

![Figure 13: SOVN in-ear wearable sensor/feedback device [P10]](image)
This device uses AI-driven microsensors that detect jaw movement, and respond with vibration. The product claims to be backed with research that it is shown to work, but gives no sources. It is accompanied by an app so the user can track their data on their smartphone. This product is in its BETA launch, so reviews are limited.

11. **SleepGuard headband measures biofeedback with EMG and provides an auditory response**

This product is a wearable headband device that measures clenching through EMG in the muscles in the head (on the temples). It provides a very subtle auditory response to alert the individual that they are clenching. It is intended to be practiced during the day to get the subconscious brain to recognize the quiet sound and respond with unclenching, without the user having to wake up.

![Image of SleepGuard headband biofeedback bruxism treatment device](image.jpg)

**Figure 14:** SleepGuard headband biofeedback bruxism treatment device

While this product has been FDA approved, the product relies on EMG to accurately sense clenching through the muscles on the temples. While some research has suggested that it is possible to measure muscle activity related to clenching through EMG, most research suggests that it is not very accurate or consistent in recording a clenching or grinding event [P11, 7].

The solutions and measurement concepts relating to bruxism above are all inventions pertaining to physical or mechanical devices. While this is the focus of our project, it is worthwhile to mention other, non-mechanical solutions to bruxism have worked for patients in the past. Bruxism has been shown to be linked to sleep issues, especially snoring. Doing a sleep study could provide the necessary feedback to start working toward a solution. Bruxism has also been linked to stress, so lifestyle changes, therapy, or a change of diet are other more holistic solutions, which may or may not be effective, depending on the person. The cause of bruxism is not generally known, so the solution could differ with each case. While the causation is not known, we plan to find a solution that does not require the source of the condition to be known.

The solutions discussed have been successful for many patients in protecting teeth and reducing the symptoms tied to bruxism, but there are no commercialized products found that can prevent clenching of the jaw during sleep. Several of the outlined patents are promising for the prevention of bruxism, but none of the proposed designs have been made into commercial devices. We hypothesize that the lack of commercialized devices is due to the difficulty of accurately measuring jaw-clenching activity, especially because the tie between bruxism and sleep patterns has not been thoroughly studied. We have aimed to design a product that may have similar intentions as the given patents while ensuring no patents are violated and the challenge in measuring bruxism is tackled. To design a device that prevents sleep bruxism, required engineering specifications and codes must be followed.
According to the FDA, mouthguards and orthodontic mouthpieces are classified as Class I medical devices, indicating that they have low to moderate risk to the patient. Although Class I medical devices have looser testing and FDA filing requirements than Class II or III devices, several biocompatibility tests must still be performed and codes must be adhered to. ISO 10993 is a document formalized by the International Standard Organization that specifies the required specifications for biocompatibility that medical devices must meet. A device for bruxism that goes internally, inside the mouth, requires a higher level of sterility and biocompatibility than is necessary than for a device that remains external to the mouth, but still, contacts skin [16,17].

For the purpose of design, a higher bar for sterility and biocompatibility has been set. ISO 10993 was used to quantify sensitization rating, irritation requirements, and cytotoxicity, based on Safety Data Sheets for all device components [16,17,18]. Another similar specification is the sterility assurance level, which is a measurement of detecting viable microorganisms on the device after it has been sterilized [19]. Additionally, if any electrical components are included in a device, the electrical leakage current must be tested and be within a specific range to be safe [21]. Another requirement for devices with electrical components is that the surface temperature of the device must always remain under 43 degrees celsius for any medical device that comes in contact with skin or tissue membranes to ensure that the device does not overheat and burn a patient [22].
II. Functional Requirements and Specifications

The main objective of this project is to design, develop, prototype, manufacture, and test a device that can measurably decrease clenching at night— with the ability to both measure the level of clenching and respond with a treatment that reduces the level of clenching. We have worked to fully satisfy the customer’s requirements for the project to the best of our ability.

Our primary customer from this project is Sandra Lee, and the course of the project has depended on her customer needs for a device. The secondary customers for the product are other individuals who also have bruxism and suffer from similar pain and symptoms. Sandra Lee would like to continue this project and turn it into a marketable product if it is successful, and Sandra will own all ideas, designs, and products of the project. We formulated a list of customer requirements that aims to cover all needs voiced by the customer. It also includes some requirements that are given constraints in designing a device for bruxism and in the jaw region. Table 1 below includes the customer requirements for the project, in no specific order.

<table>
<thead>
<tr>
<th>Requirement #</th>
<th>Parameter Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Comfortable</td>
</tr>
<tr>
<td>2</td>
<td>Affordable Price</td>
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<tr>
<td>3</td>
<td>Durable</td>
</tr>
<tr>
<td>4</td>
<td>Safe to Use</td>
</tr>
<tr>
<td>5</td>
<td>Measures Clenching</td>
</tr>
<tr>
<td>6</td>
<td>Reduces Clenching</td>
</tr>
<tr>
<td>7</td>
<td>Reduces Teeth Damage</td>
</tr>
<tr>
<td>8</td>
<td>Reduces Pain</td>
</tr>
<tr>
<td>9</td>
<td>Compact Design</td>
</tr>
<tr>
<td>10</td>
<td>Sound</td>
</tr>
</tbody>
</table>

In order to design a device to meet the customer requirements, engineering specifications must be met that both—help the product meet each customer requirement, and ensure that the product will be clinically and commercially marketable, with FDA regulations met. Table 2 below illustrates the necessary engineering specifications, drawn from the customer requirements.
<table>
<thead>
<tr>
<th>Spec. #</th>
<th>Parameter Description</th>
<th>Requirement or Target</th>
<th>Tolerance</th>
<th>Risk</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cost to Manufacture</td>
<td>$3000</td>
<td>max</td>
<td>L</td>
<td>A</td>
</tr>
<tr>
<td>2</td>
<td>Shelf Life</td>
<td>1-year</td>
<td>min</td>
<td>L</td>
<td>A,T,S</td>
</tr>
<tr>
<td>3</td>
<td>Meets Sensitization per ISO 10993</td>
<td>Average rating 1</td>
<td>max</td>
<td>H</td>
<td>T, I</td>
</tr>
<tr>
<td>4</td>
<td>Meets irritation per ISO 10993</td>
<td>Average rating 1</td>
<td>max</td>
<td>H</td>
<td>T</td>
</tr>
<tr>
<td>5</td>
<td>Cytotoxicity per ISO 10993</td>
<td>Level 2</td>
<td>max</td>
<td>H</td>
<td>T</td>
</tr>
<tr>
<td>6</td>
<td>Sterility Assurance Level (SAL)</td>
<td>10^-3 SAL</td>
<td>max</td>
<td>H</td>
<td>T</td>
</tr>
<tr>
<td>7</td>
<td>Size of components internal to mouth</td>
<td>0.5 in^3</td>
<td>max</td>
<td>M</td>
<td>I, A</td>
</tr>
<tr>
<td>8</td>
<td>Size of components external to mouth</td>
<td>2.5 in^3</td>
<td>max</td>
<td>M</td>
<td>I, A</td>
</tr>
<tr>
<td>9</td>
<td>Weight (Wearable)</td>
<td>1 lb</td>
<td>max</td>
<td>M</td>
<td>A, T, S</td>
</tr>
<tr>
<td>10</td>
<td>Weight (Non-Wearable)</td>
<td>10 lb</td>
<td>max</td>
<td>L</td>
<td>A, T, S</td>
</tr>
<tr>
<td>11</td>
<td>Maximum Sound Level (White Noise of Device)</td>
<td>55 dB</td>
<td>max</td>
<td>L</td>
<td>A, T, I</td>
</tr>
<tr>
<td>12</td>
<td>Maximum Sound Level (Alert)</td>
<td>70 dB</td>
<td>max</td>
<td>L</td>
<td>A, T, I</td>
</tr>
<tr>
<td>13</td>
<td>Surface Temperature per IEC 60601-2-37 during normal operation</td>
<td>43 degrees C</td>
<td>max</td>
<td>H</td>
<td>A, S</td>
</tr>
<tr>
<td>14</td>
<td>Electrical leakage current during normal operation per AAMI IEC 60601-2</td>
<td>100 microA</td>
<td>max</td>
<td>H</td>
<td>A, S</td>
</tr>
<tr>
<td>15</td>
<td>Accurately detects occurrence of jaw clenching forces</td>
<td>95%</td>
<td>min</td>
<td>H</td>
<td>A, T, S</td>
</tr>
<tr>
<td>16</td>
<td>Accurately measures jaw clenching forces</td>
<td>90%</td>
<td>min</td>
<td>H</td>
<td>A, T, S</td>
</tr>
<tr>
<td>17</td>
<td>Accurately signals to a response mechanism when clenching is detected</td>
<td>90%</td>
<td>min</td>
<td>H</td>
<td>A, T, S</td>
</tr>
<tr>
<td>18</td>
<td>Accurately delivers a feedback mechanism to prevent clenching</td>
<td>80%</td>
<td>min</td>
<td>H</td>
<td>A, T, S</td>
</tr>
</tbody>
</table>
A House of Quality was used to aid in creating engineering specifications to meet each of our customer requirements and is included in the Appendix A. Additionally, the House of Quality helps us to rank each engineering specification by how successfully it meets our customer requirements, and how much of a risk there is in meeting each engineering specification. Risk is based on a scale of Low (L), Medium (M), or High (H), with high-risk specifications needing more focus, to ensure that they are met. Compliance demonstrates how each engineering requirement will be met, with possible methods of compliance: analysis (A), testing (T), similarity to existing designs (S), and inspection (I). The Weighting column indicates the importance of each customer requirement, and the level to which engineering requirements meet customer requirements is demonstrated with the 1-9 rating system. Each engineering specification will be discussed, demonstrating how it will be qualitatively and quantitatively measured. More specific testing procedures are outlined later in the paper.

1. **Cost to Manufacture**
The cost to manufacture is important, as this device could eventually be put on the market if successful. However, the effectiveness of the device is of more importance to our sponsor, so the price limit has been set to $3000 to allow for necessary research, prototyping, and production costs. If successful, more affordable solutions could be produced based on the final designs and concepts.

2. **Shelf Life**
Durability is also important to the design, especially at the price point set. Durability will be measured through the material properties of the design, as well as long-term testing of the prototypes created by the team.

3. **Meets Sensitization per ISO-10993**
In ISO-10993, Sections 10 and 12 rate sensitization, which is the level to which a device contacts the size and the associated cutaneous reactions. A safe device will meet the requirement and not cause a hypersensitive reaction, such as redness or swelling near the points of contact with the device [16,17,18,20].

4. **Meets Irritation per ISO 10993**
A measure of irritation is also outlined by sections 10 and 12 of ISO-10993. It is a measurement of how a medical device irritates the tissue that it contacts, tested on a scale that compares control sites to reaction sites from an intracutaneous reactivity study. The average irritation level must be below 1, and if the requirement is met, it indicates that extracts from the test material will not cause harm or skin irritation if the extracts were to enter the body internally [16,17,18,20]

5. **Cytotoxicity per ISO 10993**
Cytotoxicity was measured and tested with ISO 10993-1. Section 1 of ISO 10993 states the requirements for cytotoxicity—the degree to which something can cause harm to cells, generally being measured on a grading scale from 0 to 4, with levels below grade 2 generally being acceptable for medical devices [16,17,18,20]
6. **Meet Sterility Assurance Level (SAL)**  
Another similar specification is the sterility assurance level (SAL), which is a measurement of detecting viable microorganisms on the device after it has been. For medical devices, the acceptance criteria is between one in a thousand and one in a million probability of detecting a microorganism–also referred to as $10^{-3} - 10^{-6}$ probability. For the medical device in this project, a probability $<10^{-3}$ is necessary, for a medical device that contacts bodily fluids but is not implanted. When a device meets the SAL, it indicates that the device has been thoroughly sterilized and is safe to reuse [19].

7. **Size of components internal to mouth**  
The size of the components in the mouth is extremely important to the comfort level the user experiences and has been limited to 0.5 in$^3$ maximum. A small, compact design will create an overall better experience for the user.

8. **Size of components external to mouth**  
The size of the components outside of the mouth is also very important to the comfort level the user experiences and has been limited to 2.5 in$^3$ in area maximum. If the device has any components outside of the mouth, they will need to be small enough to not cause any extra disturbances to the user’s sleep.

9. **Weight (Wearable)**  
Like the size requirements, weight is also an important factor that can help quantify the comfortability of the device. Wearable weight is limited to 1 pound but will be minimized as much as possible to avoid any extra pressure on the jaw or head.

10. **Weight (Non-Wearable)**  
The non-wearable weight is a requirement aimed at ensuring the portability of the system so that the customer can easily move it. The non-wearable weight is limited to 10 pounds, however, it will be reduced as much as possible to ensure that customers who cannot lift weight will still be able to use the product.

11. **Maximum Sound Level (White Noise of Device)**  
Because bruxism is typically a sleep disorder, adding extra possible distractions to the user’s sleep cycle is to be avoided. The device’s overall noise level should be less than 55 dB if any motors or noise-producing mechanics are a part of the final design.

12. **Maximum Sound Level (Alert)**  
This project strives to interrupt the clenching while it is occurring, so there is a possibility of an alarm being used to accomplish that. The alarm function will not reach over 70 dB if any alarm is used.

13. **Surface Temperature <43 degrees C per IEC 60601-2-37 during normal operations**  
Another requirement for devices with electrical components is that the surface temperature of the device must always remain under 43 degrees celsius for any medical device that comes in contact with skin or tissue membranes to ensure that the device does not overheat and burn a patient [22].
14. **Electrical leakage current <100μA during normal operation per AAMI IEC 60601-2**

If any electrical components are included in a device, the electrical leakage current must be tested and within a specific range to be safe. The American National Standards Institute Association for Advancement of Medical Instrumentation (AAMI) IEC 60601-2 is the group that regulates electrical components. Medical devices that contain electrical equipment are required to achieve specific leakage current and surface temperature requirements. For the device to operate under expected conditions, the leakage current has to be less than 100 μA. The leakage current is an important metric in determining device safety by ensuring electrical shock will not occur [21].

15. **Accurately detects the occurrence of jaw clenching forces**

This requirement relates to the measuring aspect of the device. Whether the device measures sound from teeth grinding or muscle activity, it must be able to accurately detect the frequency of jaw clenching while the user is utilizing the device. This would be measured through a sensor and should be able to perform its function at a 95% accuracy level.

16. **Accurately measures jaw clenching forces**

The device will most likely include a sensor that quantifies either the pressure between the teeth or the force of the jaw muscles on the mouth. This will identify the level of bruxism the patient is experiencing and will allow the device to trigger the feedback mechanism. It should be able to perform its function at a 90% accuracy level.

17. **Accurately signals to a response mechanism when clenching is detected**

The device should also be able to detect what is jaw clenching as a result of bruxism and differentiate between other movements and activities during sleep (i.e. sleep talking, pressing on the face with hands, unusual jaw position, etc). If a pressure sensor is a part of the design, there would be a minimum pressure force necessary to trigger the device, and it would not disturb the user in other instances. It should be able to perform its function at a 90% accuracy rate.

18. **Accurately delivers a feedback mechanism to prevent clenching**

This requirement will be measured through user feedback. The device should identify when the jaw clenching is occurring, trigger the feedback device, and halt the user during the clenching episode. This could be quantified in either the reduction of symptoms after the user has awoken or by the number of times the user was awoken during the night. It should be able to perform its function at a 90% accuracy rate.

Based on these requirements, our team moved onto the ideation phase of our design, and we began developing our conceptual design, always keeping in mind our customer and engineering requirements.
III.  Design Development: Conception Generation
The team went through an extensive ideation phase which included researching current solutions, brainstorming all possible design options, and rapid prototyping upwards of thirty different designs to ensure that all pathways for the product were explored. Ideation for the design was divided into three categories: the sensing portion of the product that senses clenching, the stimuli portion that responds to clenching and reduces it, and the combination of how the two aspects of the product will work together. We brainstormed for the separate designs first and then discussed how the components could work together. Our four best sensing and four best stimuli designs are outlined below.

A. Sensing Clenching Designs

1. Piezoelectric Pressure Sensor
The piezoelectric pressure sensor would include a piezoelectric material embedded into a customized mouthguard that most patients with bruxism already use. When the user clenches, the piezoelectric sensor would measure bite force between the teeth based on the pressure between the teeth. It would include an RF system that records the information from the sensor to provide feedback to the stimuli portion of the device. With this design, the electrical components would need to be fully sealed inside the mouthguard to ensure safety for the user in that no electrical leakage occurs. The design would also need to be very compact, as it is fully inside the mouth. To embed all components within the mouthguard, we would need collaboration with the mouthguard company to obtain materials for testing and to determine how we can properly attach the components to the mouthguard, but a possible idea is biocompatible adhesives.

Figure 15: A sketch of the pressure sensor depicting the combination of the mouthguard, pressure sensor, and Bluetooth device.
2. Capacitive Pressure Sensor
The capacitive pressure sensor would work very similarly to the piezoelectric pressure sensor outlined above, except that the capacitance is being measured rather than resistivity. As discussed in the background, capacitive pressure sensors work by reading the capacitance of the sensor, with increasing capacitance as the distance between plates decreases. The same system for embedding the capacitive pressure sensor and the RFID device within the mouthguard would be applied and all safety concerns still apply.

![Figure 16: A sketch of the piezoelectric mouthguard sensor shows the combination of mouthguard, piezoelectric material, and Bluetooth device.](image)

3. Electromyography (EMG) Muscle Sensor
The electromyography (EMG) muscle sensor would include sticky EMG patches that attach to the skin on the jaw at the location of the masseter muscles and would measure muscle activity through the electrical signals within muscles that are present during muscle contraction. The signals would be transmitted through wires to an Arduino that would signal to the feedback element that a clenching event is occurring. This sensing device would need to be programmed to only count electrical signals of a certain range as proof of clenching, to ensure that small muscle contractions are not counted. The sticky patches would be made with an adhesive that can be reused many times with a simple cleaner.

![Figure 17: A sketch of the EMG sensor shows the measurement pads on the face of the user, connected to a non-wearable data hub](image)
4. Muscle Movement Measurement

This measurement device would require a headset to be kept in place and would measure the muscle displacement from a calibrated datum based on a person's features when the user is relaxed. When a person is clenching, the masseter muscle bulges outward, and the device would sense that movement with an accelerometer. This design would become complex in coding for precision, in addition to accounting for movement in sleep.

Figure 18: A sketch of the muscle movement device shows the device on the face of user

B. Reducing Clenching Stimuli Designs

1. Vibration

The first stimulus is a vibration or haptic response which would be attached to the user's face, likely near the jaw muscle or ear area. Our design includes some sort of wire, similar in design to typically wired earbuds, which would increase comfortability for the user. The vibration would work as a way to notify the user of a clenching event, and possibly to relax the muscle (this would need to be verified with testing). Vibration is a good choice as it is effective, but not as disruptive to the user's sleep as an alarm, for example.
2. Low-Voltage Electrical Stimulation

The low-voltage electrical stimulation response device would have a similar design to the previously mentioned haptic response—in that it would contact the skin on the jaw and have wires connecting the stimulation point to the Arduino and communication system. It would have adhesive patches with low-voltage electrical current applied to the user to stimulate the muscles of mastication to unclench when a bruxism event is occurring. Several studies have shown that low-voltage electrical current is not painful or harmful to the patient and that it can be successful in stimulating muscles, as it is used for treating muscle injuries and reducing muscle spasms [7, 26].

Figure 19: A sketch of the vibration response device shows the device on the face of the user.

Figure 20: A sketch of the low-voltage electrical stimulation response shows the device on the face of the user, as well as a remote controller.
3. Mechanical Response
The mechanical response feedback mechanism would be very similar in purpose to the haptic (vibrational) response, to alert the user that they are clenching—either consciously or not. It would apply a small tap inwards on the jaw muscles when a clenching event takes place, continuing until the sensing clenching device stops signaling to the response element to fire. Including a headband-like design for comfort, the device would sit on either side of the face and the “tapping” pieces would rotate inwards to apply the stimulation.

![Figure 21](image1.png)

**Figure 21:** A sketch of the mechanical response shows the device on the face of the user

4. Sound
Another conceptual idea for a feedback response is sound stimulation such as a beeping or an alarm of the user’s choosing. This feedback mechanism would be most beneficial if the user does not respond to less disruptive stimuli options mentioned above like haptics or low-voltage electronics. The sound stimuli would cause the user to wake up when they begin clenching so that they can consciously unclench their jaw. The project sponsor mentioned that she wouldn’t mind being woken up to unclench, and eventually, the habit of unclenching could be trained. The Bluetooth signaling and processing methods would be the same as mentioned above.

![Figure 22](image2.png)

**Figure 22:** A sketch of the sound response shows the device connected to the Bluetooth receiver in the mouthguard
IV. Design Development: Idea Selection

To evaluate all possible device designs, we used three Pugh Matrices. A Pugh Matrix is a criteria-based decision matrix that uses a scoring system to compare each design to a datum, which is pre-decided. The datum is the design that is assumed to be the optimal option, and each other design is compared to it. They are ranked on the criteria of how well each design meets the customer's requirements. Designs can either be the same (S), better (+), or worse (-) than the datum at meeting the customer requirements. We used one Pugh Matrix to evaluate design options for sensing clenching and we used one to evaluate design options for responding to clenching (the stimuli to reduce clenching). Each member of the team individually ranked all design options. Then, the team re-grouped, discussed, and re-ranked the designs as a team to ensure that each person had thought about the pros and cons of designs and to reduce biases.

Next, we created a Pugh Matrix with sixteen of the best possible combinations of sensing and reducing clenching from the original matrices, and we ranked the combinations. After completing the ranking process, we used the Pugh Matrices and discussion to decide on our final concept. The combined group Pugh Matrices can be found in Appendix B, C, and D.

As stated, our first goal is to create a way to measure the frequency and level of jaw clenching from the user. This will allow us to understand the severity of the condition, as well as the effectiveness of our device. After researching current patents and solutions, we have found there are many approaches to measuring clenchings, such as pressure sensors, sound measurements during sleep, and muscle activity measurements on the face and head. Because there is no current effective solution to the disorder, all of these methods are being considered in our research. The second aspect would be reducing symptoms of the disorder. Based on feedback from our sponsor and research on others’ experiences, the device should interrupt clenching as it is happening, rather than attempting to alleviate symptoms.

We chose the pressure sensor over other designs based on our key criteria. Motion tracking would be expensive, complicated, and potentially less effective. Several of the other options such as EMG, EKG, and heart rate included wiring that would likely reduce comfortability. Measuring muscle movement as a source of sensing clenching was decided to be too complicated for the scope of this project. The movement would be subtle, so the sensors would have to be incredibly sensitive. This sensitivity could be thrown off by movement during sleep. In the end, we decided a pressure sensor best met our most important customer requirements, which included comfortability, affordability, safety, and accuracy in sensing clenching.

As for the feedback mechanism, we decided vibration was the option most suited to our design requirements. This decision was made with driving factoring including simplicity, comfortability, and affordability. In comparison to other designs, it is affordable, and most likely to be reliable. A simple haptic module can be integrated into a wearable wireless headpiece that will alert the user when the sensing mechanism detects clenching. Light and air blasts as feedback mechanisms are less likely to wake the user during sleep, thus being less effective. Using an external device to tap or put pressure on the user would likely be bulky and reduce comfort during sleep. And lastly, the flavor packet and strong smell were novel ideas, but required trial and error, and would not be as effective for some users as they would be for others. The combined Pugh matrix took our top four designs as a combination and compared them to other combinations of sensing and responding. This method yielded the same result as the individual matrices, for similar reasoning.
V. Design Development: Prototyping

After selecting the optimal bruxism treatment design, a series of prototypes were built, tested, and altered before reaching the final design. The initial set of prototype circuits was built on breadboards with ‘tinker kit’ Arduino Unos in order to try different circuit designs, test circuit elements, learn how to code with Arduino IDE, and have the ability to easily switch out circuit components without having to sauder/de-sauder each time the circuit design changed.

A. Initial Prototype Design

The initial prototype design for the device consisted of the combination of the two best choices from our ideation phase, which were the piezoelectric pressure sensor and haptic response, using RF to communicate between the two. In Figure 23, a layout drawing of our conceptual design is depicted. This is our first iteration of a prototype body design. It consists of an over-the-counter moldable night guard that has the circuit design on the outside of the body. To waterproof the circuit, a casing would be placed on the outside, which would be encased in silicone. The haptic response would rest on the sides of the jaw to indicate a clenching event. The location of the haptic response was chosen because the face is a sensitive area, which is more likely to gain a reaction from the user. Figure 23 below depicts a conceptual design of this initial prototype.

Figure 23: Conceptual design 3D model
This design was iterated and defined in greater detail. The nightguard will have the pressure sensor encased in silicone for waterproofing with the circuit embedded in the custom mouthguard, and the pressure sensor will trigger the RF transmitter when the force between the teeth, from clenching or grinding, is above a predetermined minimum bite force. Figure 24 outlines the design of circuit components in the mouth for this prototype. Once the signal is sent, an RF receiver in the feedback device will activate the vibration using a microcontroller. The haptic response will stop alerting the user when the clenching is no longer occurring. This new iteration of the design will have the circuit components of the feedback mechanism housed behind the ears instead of behind the head to increase comfort for the user. The inspiration for this design is shown in Figure 25, which illustrates a headphone set with a similar housing design that lays on the top of the ears and wraps around the back of the head/upper neck. The power of the vibration will be determined in our testing phase. A detailed outline of the device logic is shown in Figure 26, and the full details of the manufacturing process will be outlined in a later section.

Figure 24: Functional prototype design for night guard with integrated circuit [39]

Figure 25: Inspiration for the functional prototype design for feedback mechanism [40]
**Figure 26:** Block Diagram of signaling between sensing and stimulation portions of the feedback mechanism.

### B. First Physical Prototype

Our first attempt at creating this design resulted in using a voltage comparator to activate the RF module from the pressure sensor. The initial design can be seen in **Figures 27 and 28**, which illustrates the wiring diagrams for both the mouthguard and the haptic feedback response headset. The mouthguard circuit is simple – the pressure sensor input was taken into the microcontroller and sent to the transmitter. The receiver then decided if the value was above 0, and if it was, it would activate the two haptic motors via a PWM pin. There are also two additional circuit features, a capacitor, which lowers noise from the power source to the transceiver, and a 10K ohm resistor, which acts as a voltage regulator for the pressure sensor.

**Figure 27:** Pressure sensing mouthguard wiring diagram
After using this circuit, we discovered our signal was unreliable. It would cut in and out and wasn’t activating the haptic motors accurately. The cause of these complications involved not being able to control the voltage. The circuit as it was required a lot of power for all the large parts, and we are trying to use as little power as possible because the batteries will be single-use due to being embedded in the mouthguard. For our product to last long enough to use, we needed a voltage comparator to act as an open circuit when the pressure sensor is not detecting a force, utilizing the batteries only when pressure was detected instead of constantly waiting for input. Because of this, we first tried a voltage comparator IC but found it was too large and overcomplicated for our circuit. We then turned to the PNP transistor. This design is much more desirable for several reasons. First, this is capable of operating by switching between rails. Our top rail is our power source, 3.3V, and the bottom rail is ground. Another that made this the preferable choice moving forward was its simpler design, which included only 3 pins instead of 8. And lastly, a transistor is already much smaller than a voltage comparator, even without custom ordering the parts, thus better meeting our design criteria.

C. Mouthguard prototyping and adapting the acrylic manufacturing process

In order to achieve the intended design for the device, various options were evaluated to build the custom mouthguard to house the pressure sensor circuit and protect the patient’s teeth from clenching and grinding behavior. The custom mouthguard material needed to have a high enough tensile strength to withstand clenching forces and protect the circuit components, while still being ductile enough to prevent breakage, and not too rigid to prevent teeth damage. Materials that are used for custom bruxism mouthguards and splints were considered, with research being applied from dental labs and previous bruxism mouthguard research. Common materials that are used in bruxism mouthguards include medical-grade acrylics, silicones, and thermoplastics. Since a strong, but semi-ductile material was desired, acrylics were most heavily considered. Another major requirement for the mouthguard was that it

Figure 28: Haptic feedback response wiring diagram
could coat and embed the pressure sensor circuit components, without overheating the circuit. Therefore, common materials used for bruxism mouthguards such as heat-cured acrylics are not as applicable to this project because they require temperatures greater than 300 degrees C to be molded and cured, which could damage the circuit components. Instead, cold cure acrylic resins were used [43, 44, 45].

In order to manufacture a custom mouthguard, dental impressions must be taken, followed by the creation of a mold of the teeth, which can then be used to mold the mouthguard. The three-step process was adapted from typical dental lab manufacturing processes. The dental impression material is composed of sodium alginate, which is pliable and allows for direct molding of the teeth that don’t have bubbles and reproduces impressions that mirror the teeth. Then, a dental stone is mixed with water to create a paste that is poured into the teeth impressions. The mold is agitated to remove any air bubbles, and any overflowing stone is removed. After 10-15 minutes, the stone has hardened, and the mold can be removed from the impressions to be used for molding the mouthguard.

The acrylic molding step required the testing of various different solvent to solute ratios, external mold options (to injection mold, the teeth mold is only half of the mold), mixing conditions of the acrylic, and optimal processes for encasing the circuit in the acrylic, given that the acrylic hardens quickly and is permanent once it hardens. The initially chosen acrylic was a denture acrylic with strength and ductility suitable for a bruxism mouthguard. The acrylic is only intended to be used for dental applications, so it is fully biocompatible, in accordance with ISO 10993 once it is fully cured, and does not leak harmful chemicals. Being a cold cure acrylic, it was sold as a powder and liquid combination that upon combining in the optimal ratio, became a honey-like consistency that could be poured. It took 10-20 minutes to harden, and 24-48 hours in a ventilated area to fully cure. The acrylic is made of methyl methacrylate and N, N-Dimethyl-p-Toluidine, which react when mixed to form the solution that can be poured. Separately, these components are hazardous, but the chemical reaction and curing phase makes them non-toxic and biocompatible [44, 45].

Although this acrylic was about to be poured and molds to the shape of the mouth guard, the material properties of the mouthguard were harder than expected, and working with the acrylic was not easy. It had to be handled in a well-ventilated area with gloves and a mask, and the consistency of the acrylic once the solute and solvent were combined was not viscous enough to hold a shape that could be easily controlled. Therefore, there was low consistency between each trialed mouthguard, and the external mold was not preferable. As seen in Figure 29, the acrylic had rough edges and air bubbles. After thorough consideration, it was decided that this particular cold cure acrylic option would not work for the entire mouthguard. Instead, we pivoted to using a moldable silicone mouthguard with the circuit embedded in silicone for the final proof of concept. As discussed further on in the report, another acrylic, such as EVA (ethylene vinyl acetate), would be preferable for the body of the mouthguard, while still embedding the circuit in this cold cure acrylic.
Figure 29. Example of a molded mouthguard with the cold-cure acrylic.

Taking the changes for the circuit design, we iterated our prototype to produce a “final proof of concept” which is our last design iteration before our final design was implemented. This circuit served as a verification that the basis of our communication between circuits is applicable. While embedding in the mouthguard was not achieved, we will outline plans that would have been implemented if the project continued.
VII. Final Proof of Concept Prototype
From our prototyping designs, we developed a circuit that can accurately deliver a haptic response using the flow chart shown in Figure 26. This circuit worked as our proof of concept for the circuit design but does not meet our size requirements to fit in a mouthguard. This design consists of two NRF24L01+ RF Transceiver modules connected to their own Arduino Unos. The details of each circuit are shown below.

D. Pressure Sensor Circuit

![Pressure Sensor Circuit Diagram]

This circuit is representative of the sensing circuit that would be in the mouthguard once the components are sized down. This design works using a PNP transistor to compare the input voltages. The PNP transistor works by connecting the input voltage to the pressure sensor across a resistor. The pressure sensor is then connected to the base terminal, and the emitter terminal is connected to the power rail. The collector terminal is connected to the base with a 12KΩ resistor. The pressure sensor acts as a variable resistor, where no pressure corresponds to a resistance of 1MΩ. As pressure increases, the resistance drops. When the resistance drops below the threshold of 12kΩ, the PNP transistor switches from ground to our rail voltage of 3.3 V, allowing this voltage to send a signal through the collector to the Arduino. When the Arduino sees this voltage-activated, it is coded to send a signal to the haptic circuit using the NRF24L01+ Modules. The code used can be seen in Appendix J.

Figure 30: Pressure sensing mouthguard wiring diagram

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E. Haptic Feedback Circuit

The haptic circuit detects an incoming signal from the sensing circuit using the NRF24L01+ module and will alert the Arduino. This controller is programmed to set the PWM to 255, turning on the haptic motors to their maximum speed. When this signal is no longer detected, the Arduino turns off the motors. The code that controls this circuit can be seen in Appendix J. The circuit diagram can be seen below in Figure 31.

![Figure 31: Haptic feedback response wiring diagram](image)

F. Manufacturing Proof of Concept

The proof of concept circuit was built on a breadboard using the NRF24L01+ transceiver for communication. The FlexiForce pressure sensor, the Boffintropics haptic motors, and other circuit components can be seen in Figures 30 and 31. The manufacturing for the prototype was just a matter of putting the circuits into the breadboards and connecting the circuits to the two RF modules and Arduino.
G. Proof of Concept of custom mouthguard with silicone-embedded pressure sensor circuit

To prove the components of the circuit for the mouthguard, the circuit was built on a flex PCB board and coated in silicone on a “boil-and-bite” mouthguard, and molded to the mouth of our sponsor, Sandra. This can be seen below in Figure 32. Although this specific mouthguard didn’t hold a working circuit, it proved that our conceptual design could fit inside the mouthguard, and demonstrates visually what the mouthguard would look like if encased in acrylic with a silicone coating.

Figure 32: Sensing Circuit on Mouthguard

H. Cost of Proof of Concept
The costs in Table 3 are only for the prototype presented at the senior design exposition – the actual price of the working circuit is outlined in further sections.

<table>
<thead>
<tr>
<th>Component</th>
<th>Product</th>
<th>Units</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcontroller</td>
<td>Arduino Uno</td>
<td>2</td>
<td>60</td>
</tr>
<tr>
<td>RF Transceiver</td>
<td>NRF24L01+</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Pressure Sensor</td>
<td>FlexiForce Pressure Sensor - 100 lb</td>
<td>1</td>
<td>16</td>
</tr>
<tr>
<td>User Feedback</td>
<td>Boffintronics Haptic Feedback Module</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Circuit Board</td>
<td>Breadboard</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Circuit Components</td>
<td>Resistors, Transistor, wires</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total Cost</strong></td>
<td></td>
<td></td>
<td><strong>$99</strong></td>
</tr>
</tbody>
</table>
I. Proof of Concept Design Validation

Our design was validated through a combination of manufacturer-provided tests (given in Safety Data Sheets) and tests we performed on our proof of concept prototype. The tests that would be necessary to fully validate a final design if the product was to be FDA approved are outlined in the DV&P (See Appendix F), however, given that the culminating product for our team is proof of concept, and is not ready to be used by patients, not all testing was performed. Validation that was possible is outlined in this section.

Design validation was achieved through the manufacturer’s SDSs for the biocompatibility of materials that are in contact with bodily fluids (i.e. saliva). Since all circuit components were encased in biocompatible, medical-grade silicone, which is an insulator, the silicone insulation around the electrical components is able to ensure that other engineering requirements are met as well. Table 4 below outlines the engineering requirements and design validation that is necessary, that have been met, and how it was achieved.

<table>
<thead>
<tr>
<th>Engineering Requirement</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biocompatibility per ISO 10993: Sensitization, Irritation, and Cytotoxicity</td>
<td>Per DenSurefit product’s intended use as a medical-grade silicone, the embedding material is biocompatible per ISO 10993 [42]</td>
</tr>
<tr>
<td>Electrical Leakage Current</td>
<td>Silicone embedding insulates the electrical components preventing any potential electrical leakage current.</td>
</tr>
<tr>
<td>Surface Temperature</td>
<td>SDSs for electrical components and insulating characteristic of silicone prevent the surface temperature of electrical components from being above 43°C</td>
</tr>
</tbody>
</table>

To validate how our design was functional after being manufactured, we tested the essential function of the device to ensure the circuits themselves and the code we wrote using the Arduino interface worked as intended. To start, we did a series of trials timing the lag time between pressing the pressure sensor, and the motors turning on. The average time was found to be 0.62 seconds, which can be seen in Table 5 below.
Table 5: Testing RF Communication Lag Time

<table>
<thead>
<tr>
<th>Trial</th>
<th>RF Lag Time (s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.70</td>
</tr>
<tr>
<td>2</td>
<td>0.73</td>
</tr>
<tr>
<td>3</td>
<td>0.88</td>
</tr>
<tr>
<td>4</td>
<td>0.00</td>
</tr>
<tr>
<td>5</td>
<td>1.11</td>
</tr>
<tr>
<td>6</td>
<td>0.98</td>
</tr>
<tr>
<td>7</td>
<td>0.00</td>
</tr>
<tr>
<td>8</td>
<td>0.93</td>
</tr>
<tr>
<td>9</td>
<td>2.09</td>
</tr>
<tr>
<td>10</td>
<td>0.00</td>
</tr>
<tr>
<td>11</td>
<td>0.00</td>
</tr>
<tr>
<td>12</td>
<td>0.53</td>
</tr>
<tr>
<td>13</td>
<td>0.00</td>
</tr>
<tr>
<td>14</td>
<td>0.00</td>
</tr>
<tr>
<td>15</td>
<td>0.86</td>
</tr>
<tr>
<td>16</td>
<td>0.79</td>
</tr>
<tr>
<td>17</td>
<td>0.89</td>
</tr>
<tr>
<td>18</td>
<td>0.91</td>
</tr>
<tr>
<td>19</td>
<td>0.90</td>
</tr>
<tr>
<td>20</td>
<td>0.00</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td><strong>0.62</strong></td>
</tr>
</tbody>
</table>

This average response time was found to be acceptable for our design purposes. Individuals with bruxism tend to clench their teeth for minutes at a time. Because of this, the team decided approximately 3 seconds of response time is our acceptance criteria. As can be seen above, all trials were within an acceptable range.

Our next test consisted of testing the accuracy of the RF communication. We performed fifty trials and recorded when the signal was properly sent and received, thus activating the haptic motors. This data can be seen in **Figure 33** below, where it was found that the motors responded accordingly 94% of the time.
Test 2: Accuracy of RF Communication

![Pie Chart]

- Motor Activity 94%
- No Motor Activity 6%

**Figure 33**: Testing accuracy of NRF24L01+ communication and motor response

Our third test consisted of measuring the resistance of the pressure sensor with varying forces applied. This test was relevant because our threshold changed from the expected values based on the resistance in our circuit. The data sheet for the pressure sensor is provided in the chart seen in **Figure 34** below for comparison.

![Graph]

**Figure 34**: Resistance vs. applied force graph given in pressure sensor datasheet
**Figure 35** depicts the test results we obtained for our sensing circuit. The resistances chosen were set to have a slight tolerance to account for the user lightly biting without a full bruxing event taking place. Every individual with bruxism has varying clenching forces, so this tolerance could be optimized through testing with multiple participants.

![Test 3: Resistance vs Force Applied on Pressure Sensor](image.png)

**Figure 35:** Tested resistance vs. applied force for sensing circuit

The data shown above in **Figure 35** was obtained by stacking weights onto the sensor to have a known metric to plot the resistance against. This test shows the effectiveness of the added resistance, as compared to the datasheet graph provided.

While this design sends and receives data accurately, it does not fit our design requirements, as the nRF transceiver module is too large to fit inside the mouthguard comfortably. Given this, we were led to our final design concept, which uses small enough components to fit comfortably in a mouthguard.

With the knowledge gained from our iterative prototyping process, we developed our final design concept.
VIII. Final Design Concept

The final design concept consists of a piezoelectric resistive pressure sensor embedded in a nightguard, paired with a wearable haptic response. The night guard will be made out of ethylene vinyl acetate (EVA), with a low VA percentage of 10-15%. The full circuit will be encased inside the EVA. The night guard will be completely custom with sized-down circuit components, thus increasing the comfort and effectiveness of our design.

The most prominent design update from our previous iteration is the change in RF communication module. The AT-MT1 transmitter was chosen for its size. This transmitter measures 10x14x3.3 mm, whereas the previous RF module measured 15.2x29x4.6 mm. Not only is this a significant size difference in the module itself, but using the AT-MT1 allowed us to eliminate the need for a microcontroller. The AT-MT1 only has two pins – one is both data input and power, and the other is ground. The NRF24L01+ is a transceiver, meaning it can both send and receive data. For either side of the data transmission, the chip required a microcontroller to operate. This is due to the Serial Peripheral Interface (SPI) of the module, which is a much more complicated system of communication, where one “leader” device sends packets of data to other receiving devices. In our application, there would only be one transmitter and one receiver, so the AT-MT1 was better suited to our project in that aspect as well. The AT-MT1 and its corresponding receiver are able to communicate just based on a signal being active. The threshold of pressure is controlled by the circuit itself using the PNP transistor and a threshold resistor. This part of the circuit is unchanged from our previous prototype, where it is described in greater detail. This circuit diagram can be seen below in Figure 36, and the working circuit can be seen in Figure 37.

A. Sensing Circuit
   1. Circuit Design

![Figure 36: Final design: sensing circuit diagram](image-url)
B. Feedback Circuit

The haptic circuit uses the same principle outlined in our prototyping section with an Arduino Pro Mini and two haptic motors to alert the user to a bruxing event. The updated component in this circuit the receiver used, is now the Abacom ARX-433-ULC Ultra Low Power AM receiver module. This receiver was chosen because it can pair with the AT-MT1, which both operate using a radio frequency of 433MHz. There was a lot of time put into troubleshooting this device and its corresponding transmitter because the data sheets (found in Appendices L and M) provide very little information, and there are not many users who have put these in projects found online. However, the datasheet for the receiver does state that when a transmitted signal is not being sent, the module will see noise from other signals. It provides that a resistor can be connected between the test pin and ground to reduce the device sensitivity to solve this issue. A plot for gain loss per mega ohm of resistance is provided. A 10MΩ resistor corresponds to -1dB of gain loss. This is where we started, but went down to 2MΩ of resistance, which correlates to approximately -9dB of gain loss. From experimenting with this resistance value with our circuit, we determined this loss filters out all noise, but not the transmitting signal from the sensing circuit. This stops the motors from turning on randomly. The circuits are within close enough range that the signal is read clearly and the motors respond at the appropriate times. Depicted in Figure 38 is our circuit diagram and Figure 39 depicts the functional circuit.
1. Circuit Diagram

![Circuit Diagram]

**Figure 38:** Final design: haptic circuit diagram

![Functional Haptic Circuit Final Design]

**Figure 39:** Functional Haptic Circuit Final Design
B. Power Requirements

The last component of the design is the power supplies. The total amperes necessary to run each circuit were summed. It was found that the mouthguard circuit necessitates 5 mA when operating while the headpiece required 505.7 mA.

To choose batteries based on this information, we had to find batteries that were size and power efficient. Choosing the battery for the mouthpiece required a very small power source that would not be able to be accessed again after construction. Using the assumption that the average person clenches a maximum of 40 minutes a night, and based on classical conditioning studies discussed in the background, the effects of the mouthguard should take around 2 months to work [31, 32]. Giving ourselves a bit of extra time to be safe, the mouthguard would need to last 3 months or 60 hours of clenching time. Equation 2 calculates the lifetime of a power source based on the current requirements of the circuit. Using this equation, we found two batteries that would power the mouthguard for approximately 64 hours and the headpiece for approximately 1.89 hours. These calculations are based on the fact that the average person with bruxism clenches for approximately 40 minutes total in one night.

\[
\text{Battery Lifetime} = \frac{\text{current capacity [mAh]}}{\text{current drawn [mA]}}
\]  

The mouthguard will feature 2 1.5 V 357 Silver Oxide button batteries. They will be aligned in parallel and series to meet voltage and current requirements. The battery has a current capacity of 160 mAh, meeting our current requirements. The headpiece will feature a 3.7 V CR 2450 coin cell battery, with a current capacity of 600 mAh. The design requires the user to replace the battery on the headpiece about every other night. The mouthguard batteries cannot be recharged or replaced once the acrylic is poured, but if the device isn’t working at that point, it may not be the correct solution for the user, and other methods should be considered.

2. Mouthguard Manufacturing

In choosing a material for the mouthguard, the most important factors were biocompatibility, material strength, and stiffness, how it will be manufactured, and similarity to other dental mouthguards used for bruxism, as we want to avoid straying too far from the characteristics and fit of our customer’s current mouthguard (Sandra Lee). Ethylene-vinyl acetate (EVA), with a low percentage of VA, is one of the most common materials used for hard mouthguards. It is a copolymer that’s material characteristics change based on the composition of VA, versus ethylene. When the material has a higher percentage of VA (40-60%), the material is more rubber-like and optimal for softer athletic mouthguards. As the percentage of VA decreases, the material becomes harder and more rigid, which is better for hard, bruxism mouthguards [34]. Additionally, EVA is known to be one of the most biocompatible copolymers, making it safe for biomedical devices. It also is extremely low-toxic and easy to recycle, as its only degradation products are CO2 and H2O (see also IX. C. Sustainability) [35].

The mouthguard for our device would be made of EVA at 10-15% VA, which is commonly used for bruxism mouthguards, as its hardness protects the teeth from damage and reduces wear [34]. Two 2 mm
thick pieces of EVA will be layered to sandwich the circuit components within the mouthguard, with an opening for the pressure sensor on the bottom surface, touching the teeth. To ensure that the circuit is not overheated in the mouthguard thermoforming process, the circuit will be encased in cold-cure acrylic resin prior to sandwiching it between the EVA sheets for molding. After molding, the mouthguard would be trimmed and coated in a 1 mm thick layer of silicone to waterproof the pressure sensor.

**Figure 40** below illustrates how the circuit components fit into a custom mouthguard. Although this prototype is made out of silicone, it demonstrates how the circuit components would fit and where they would be placed within the acrylic mouthguard. The pressure sensor circuit was encased using a flex PCB board, with all circuit components, showing that the PCB board was flexible enough to mold to the curve of the mouthguard. It also showed that the circuit components were not too large to be placed on the outside of the teeth, rather than the roof of the mouth, and how tall the PCB board could be to fit the circuit on the outside of the mouthguard. Because of this restriction, we laid out the circuit being long in the horizontal direction.

![Figure 40: Silicone mouthguard with circuit embedded, visually depicting what the custom mouthguard would look like and how the components would fit if it were made of acrylic](image)

### 3. Wearable Casing Manufacturing

The most updated version of the haptic casing is shown below. **Figure 41** shows a detailed drawing of the haptic casing, and **Figure 42** shows how the haptic circuit would fit, along with how they are connected. The casing is 3D Printed using PMMA. The part that would sit on the left side of the head is on the left side of the drawing and can hold the RF receiver and the Arduino Pro Mini in the large casing. One haptic motor sits in the small box next to the ear on both sides of the head. On the right side of the head, there is room for one battery and one haptic motor. The design choice was made to only include one battery to increase the comfort of the user. A previous design iteration that has room for two batteries can be seen in Appendix H. Making this design choice entails recharging the battery more often, but comfort during sleep was decided to be the driving factor of the design. A 1/16th inch foam pad was attached to the back of the housing to also increase comfort. These modules sit on the ears and are attached by a flexible rubber tube that allows the circuit to be completed.
Figure 41: 3D Drawing of Final Haptic Casing Design

Figure 42: Haptic casing with components inside
A. Design Satisfying Project Requirements
The chosen conceptual design satisfies the project requirements by fulfilling all of the engineering specifications and the corresponding customer requirements. As outlined in the design development section, the Pugh Matrices demonstrated how each customer requirement could be met with the engineering requirements. The three Pugh matrices for idea decision can be found in Appendix B, C, and D. The project sponsor, Sandra Lee, is most concerned with the design satisfying the requirements of safety, and comfort, and successfully measuring and reducing clenching. The safety of the device will be discussed further in the next section, and the accuracy of the device in measuring and reducing clenching will be further outlined in the testing section.

a. Customer Comfort
To ensure user comfort, the engineering requirements considered were size of components (internal to mouth and external on the face), weight (wearable), and the biocompatibility of the chosen materials. To reduce the size of components inside the mouth, electrical components for the pressure sensor circuit were selected primarily based on size, to ensure that they could fit comfortably within a custom mouthguard. The components for the haptic response headset were also selected to be as small as possible, but it was not quite as essential. Because all components of the device are wearable, the wearable weight of all device components was also important to the design. The size of each component housed within the mouthguard and haptic feedback headset and corresponding weights are outlined further in the Design Verification section.

The biocompatibility of the materials that sit against the face and that interact with the inside of the mouth, and saliva, were also important aspects in the comfort of the design. These aspects will be discussed in the Safety section.

IX. Cost Analysis
Outlined in Table 3 are the components required for the conceptual design. The significant changes from the proof of concept prototype are the microcontroller model and the RF modules. For the haptic circuit, the microcontroller still uses the same interface but is a smaller version to miniaturize our circuit design. The compatibility does not change, and the code we validated will work for any Arduino board. The most significant change is the RF modules. In the proof of concept design, we used the NRF24L01+, which would be too large to fit in a mouthguard and requires a microcontroller. For our final conceptual design, we use the AT-MT1 and its corresponding receiver because of the significant size decrease. This transmitter consists of only two pins – one of which is power and data input on the same pin, and the other is ground. This change in radio communication module effectively simplifies the circuit design to fit our size requirements.

The mouthguard will be custom using dental impressions. The cost estimate is presented below including the impressions kit, epoxy resin for the mold, and the Acrylic resin for the night guard. This cost estimation was made from purchasing individual components, so we believe making this into a product where you can buy in bulk for mass manufacturing will greatly reduce the cost per unit. However, with labor and equipment taken into account, we believe the costs will be similar to what is outlined below.
### Table 6: Components and cost breakdown of Conceptual Design

<table>
<thead>
<tr>
<th>Component</th>
<th>Product</th>
<th>Units</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcontroller</td>
<td>Arduino Pro Mini 328 – 3.3V</td>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td>RF Transmitter</td>
<td>AT-MT1</td>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td>RF Receiver</td>
<td>ARX-433-ULC</td>
<td>1</td>
<td>26</td>
</tr>
<tr>
<td>Pressure Sensor</td>
<td>FlexiForce Pressure Sensor - 100 lbf.</td>
<td>1</td>
<td>16</td>
</tr>
<tr>
<td>User Feedback</td>
<td>Boffintronics Haptic Feedback Module</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>Voltage Regulator</td>
<td>220pF Capacitor</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td>Resistors</td>
<td>50Ω, 10 kΩ, 12kΩ, 1MΩ</td>
<td>4</td>
<td>1.5</td>
</tr>
<tr>
<td>Circuit Board</td>
<td>Flex PCB Board</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Mouthguard Battery</td>
<td>357 Silver Oxide Button Cell</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Haptic Battery</td>
<td>CR 2450</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Battery Holder</td>
<td>CR2450 &amp; 357/303 Holder</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Haptic Casing</td>
<td>3D Printed</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Dental Impressions</td>
<td>Sentinel Mouthguards Impression Kit (sodium alginate)</td>
<td>1</td>
<td>7.5</td>
</tr>
<tr>
<td>Dental Stone</td>
<td>Gypsum Type III Dental Yellow Buff Stone</td>
<td>1</td>
<td>0.5</td>
</tr>
<tr>
<td>Acrylic Cast</td>
<td>Self Curing Denture Acrylic Powder + Liquid</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Silicone</td>
<td>DenSureFit Denture Reline Kit</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td><strong>$ 136</strong></td>
</tr>
</tbody>
</table>

**J. Safety**

The primary safety concerns for the device design were electrical leakage, surface temperature, biocompatibility, jaw and tongue position, and mouthguard personalization. The first three concerns are mostly due to the risks associated with implementing electrical components into a mouthguard that will remain inside the mouth for long periods, and with the chosen material for a custom mouthguard. To ensure that the device is fully safe, all components that are on the external of the device, including
adhesives, are biocompatible according to ISO 10993, in cytotoxicity, irritation, and sensitization, and it will be sterilized according to the sterility assurance level (SAL) of $10^3$, which is required for medical devices that are not implanted but still contact parts of the body that are internal. To reduce the potential for electrical leakage, the material used for the mouthguard is an electrically insulating material, acrylic, that will protect the user from electrical leakage and provide a barrier from saliva in the mouth. The total voltage will be limited to prevent high surface temperatures [25]. These biocompatibility and electrical requirements were met by each part individually, as the suppliers provided proof of safety requirements in their Safety Data Sheets (SDSs) (see Appendix Q).

As for factors that affect our particular device design, tongue positioning is a concern because if components in the mouth were to be placed on the roof of the mouth, the space for tongue positioning would be changed from natural tongue positioning. This can have an effect on teeth arrangement in the mouth and have very negative effects on dental health [27]; therefore, we decided to place the Arduino and communication components on the outer side of the mouthguard, rather than on the roof of the mouth. In addition to tongue positioning, the mouthguard that an individual uses impacts teeth and jaw health. We intend to eventually implement our bruxism device into mouthguards that are specially designed for people with bruxism so that we are not altering the teeth structure and support that the individual already has in place. Using simple store-bought mouthguards runs the risk of being non-patient specific and forcing teeth to shift, so we plan to use moldable mouthguards that will still interface well with the teeth. In addition to being custom, the mouthguard also needs specific material characteristics, as outlined previously, in order to prevent the teeth from being damaged. To be safe for the user, the mouthguard should be an acrylic that is strong enough to prevent breakage from intense clenching, but ductile and not too hard in order to absorb the force of clenching and prevent teeth chipping.

b. Product and Material Decisions
We chose the components of our device through pugh matrices, but also through consideration of what would be the most feasible and cost-efficient, to ensure that the customer's requirement of cost was met. The piezoelectric pressure sensor, for example, is not as sensitive to pressure changes or as low-power as the capacitive pressure sensor, but the price difference was significant enough that it made more sense to go with the piezoelectric sensor. We did not use a Pugh matrix to decide on RF communication over Bluetooth, but rather through research on the two options. RF requires less electrical work in the circuit design and is more cost-efficient as well. Lastly, haptic feedback was chosen over other responses because it was the most comfortable and feasible option for our sponsor.

Beyond customer requirements, there are a few engineering requirements that required further analysis. First, temperature requirements according to IEC 60601-2-37 state that surface temperature must remain below 43 degrees Celsius during normal operation. Reading the data sheets for each component, both inside the mouthguard and in the external headpiece, no component reaches above this temperature. These data sheets can be referenced in Appendix L, M, and N. Next, current leakage was an important safety aspect due to our design being inside the mouth. Per AAMI IEC 60601-2, current leakage should not be greater than 100 microamps. Our entire design will be encased inside Ethylene-vinyl acetate which is an insulator, so current leakage is not possible outside of the mouthguard.
B. Repairs and Maintenance

As the core of the mouthguard is made out of EVA, a strong and durable material, material breakage prior to its intended lifetime is unlikely, but it will be dealt with accordingly. Small chips in the mouthguard may be repaired with spot-fixing with EVA or silicone. Larger cracks in the mouthguard core will warrant the need for a newly manufactured mouthguard., with the patient's dental molds reused to reduce material consumption.

As for the maintenance of the electronics, the haptic response circuit will be able to be opened and fixed if necessary. The user has to do no other maintenance other than changing the battery if it dies. As for the mouthguard, once the acrylic is poured the circuit cannot be changed as the structural integrity of the acrylic would be decreased if cut open. However, the intended use time for the device being less that 2 months indicates that the mouthguard will not need to have a long lifetime.

X. Future Final Design Manufacturing

To begin testing our prototype, we must first begin a manufacturing plan. Now that we have a final design, we will order any extra parts for our prototype, and keep testing circuit designs to ensure our design logic works. We can then begin construction of the compartment for the circuit that goes inside the mouth, as well as the haptic response mechanism which will be worn by the user. Both of these components will require work in Mustang 60 machine shop, and we are planning on obtaining our red tags before manufacturing begins.

A. Circuit Manufacturing
All circuit components will be soldered together on a flex PCB board. The design is verified on a breadboard, and now just needs to be miniaturized even further, and combined. It will then be placed in the mouthguard mold before the acrylic pour.

B. Mouthguard Manufacturing
The manufacturing of embedding the electric components into a functional mouthguard will be a three-part process including performing dental impressions, creating a cast model of the teeth, and molding the mouthguard from the cast. Dental impressions are a common method used by dental experts to create bruxism or athletic mouthguards, dentures, crowns, and at-home teeth whitening kits. We will implement this method for the manufacturing of our mouthguard, with a few alterations. To ensure that the mouthguards are manufactured safely and effectively, we will follow the advice of experts in the field of dentistry.

First, we will perform dental impressions, with a sodium alginate impression kit purchased externally. Once the impressions are ready, we will pour the heated epoxy resin into the impressions to cast a model of the teeth. Once the model has fully cooled and hardened, the mouthguard can be molded (see Figure 43). Ethylene vinyl acetate will be used as the material for the mouthguard, which will be manufactured using thermoforming. EVA comes in “sheets” that are placed over the mold, heated, and pressed into the desired shape. A liquid separator will be applied to the teeth model to provide a small tolerance, and the
The first sheet of EVA (2 mm) will be placed over the model. The heat-protected circuit system will then be placed along the side of the model (to sit along the side of the teeth), and another sheet of EVA (2 mm) will be placed on top of the first, sandwiching the components. A small slit will be cut in the EVA top layer before heating, for the pressure sensor. The material will be heated to approximately 320 degrees Celsius, at which point it is moldable. Then, a vacuum will be applied to mold the material to the model. While still pliable, the material will be trimmed to the proper dimensions that border the gingiva (lighter pink portion of the gums) [34, 36, 37].

**Figure 43:** Process of creating mouthguard

C. **Sustainability**

To ensure that our device is manufactured sustainably, the “design for the environment” recommendations were considered. Our major sustainable goal is to design for energy efficiency. To achieve this, our mouthguard and haptic response electronic elements will be designed to use as little energy as possible. The aspects of the design that make it low energy are the RF signal transmission and retrieval method, the on/off element of the haptic module, and the nature of the device only being necessary for a short lifespan (<1 year). RF is inherently low-energy because radio frequency is a longer wavelength, which is on the low-energy side of the electromagnetic spectrum, which is a non-ionizing radiation type, meaning that it has insufficient energy to remove electrons from atoms. This level of energy is sufficient for transmitting the small amount of data that needs to be sent in our design, including only the pressure measured in the piezoresistive pressure sensor. Additionally, because the device only transmits pressure data when it is above the clenching threshold, the RF and haptic modules are in a “sleep” mode, where they are using very little energy, while a clenching event is not occurring. Lastly, the intended need for the device is short-term, meaning that it should take less than a year for an individual with bruxism to use the device to resolve their condition and rewire their neural pathways with classical conditioning to stop clenching. The short lifetime will mean that the need for device replacement, battery replacement, or device repair will be very low [32, 33].

Our device was also designed to “minimize hazardous materials” and for recycling. The material chosen for the mouthguard, ethylene vinyl acetate (EVA), is very non-toxic in manufacturing, its usable state, and
recycling. It does not leach any harmful chemicals when it is thermoformed for manufacturing, and it is very stable once hardened, supporting its biocompatibility. If the product is to be discarded, PVA is incredibly safe to recycle, as its only byproducts are CO2 and H2O, and it can be melted down to be reused [35].

**XI. Final Design Verification**

When the circuit was complete, we then needed to encase the components in the nightguard. To ensure the components could withstand this process, we needed to perform a thermal cycle and humidity test. The thermal cycle test exposes the circuit to a wide variety of temperatures to ensure the circuit can withstand the thermal stress from temperature changes. The humidity test will be exposed to high humidity. The circuit should be observed to ensure it performs adequately during these tests. This will confirm the circuit is resilient enough to encase in EVA. This phase of testing will need to be completed in further iterations of the project.

Human trials begin once the first functional prototype is validated. Before we would have begun, the team must obtain a human testing certification. Once that is finished, we would start gathering baseline data for a person with bruxism. This would be done using EMG. We could collect muscle activity data from several nights before our device is used, giving us a datum to compare to. The device could then be used by a person with bruxism. Once the device is in use, we would collect EMG data at several intervals to determine the validity of the design concept. The purpose of the design is to use classical conditioning to train the habit of clenching/teeth grinding out of the user. This hypothesis will either be confirmed or denied based on the collected data. If the muscle activity is reduced in duration, amplitude, or instances by a significant amount, the design will be considered a success. Significance can be calculated by performing a statistical analysis. This phase of testing will need to be completed in further iterations of the project.

**XII. Next Steps**

As of now, the project is close to being a fully-functioning prototype, with the sensing and haptic circuits fully working outside of the mouthguard. The main goal is to make a comfortable and effective solution to bruxism, and with some adjustments, the project has a lot of potential going forward.

To bring the project to a point of the ideal conceptual design, there are a few modifications that can be made to the design. First, the sensing circuit outlined in the final design concept needs to be miniaturized. To do this, the circuit could be custom ordered and printed onto a flexible PCB board, similar to the one in figure 44. Each of the parts (PNP transistor, resistors, etc) could be custom ordered to sizes as small as half a millimeter. The AT-MT1 used in the final design is the smallest commercially available RF our group could find, but smaller chips are available if specially ordered. The FlexiForce pressure sensor used could easily be connected to the board with the right design.
As for power requirements, the batteries we chose for our final design concept fit the power requirements, they were too large for the mouthguard in the application. Multiple alternative options are possible, including printed batteries, medical grade coin cell batteries (i.e. hearing aid batteries), or even moving the mouthguard design to be rechargeable using Qi charging. The design is relatively low power, so finding a power alternative for the mouthguard that fits both size and power is possible. The haptic feedback headset also required a larger power source than what the sponsor preferred. As of the final design, the coin cell batteries would be swapped out nightly, and placed in a coin cell recharger every other night. However, the headset design is well suited for recharging, so that could be a way to greatly decrease size and weight.

On that note, the haptic headset could also be adjusted in a few ways. First, the circuit could also be custom ordered and sized down, as well as the battery as previously mentioned. In that case, the whole size of the headset would be reduced and more comfortable to wear in sleep. We originally chose the headset because 1) the face is very sensitive, thus the user is more likely to react to stimuli, and 2), the signal between circuits is the shortest possible distance, thus sustaining a more reliable connection. An alternative to that design included a vibrating bracelet, which our sponsor showed interest in. Considering this design will most likely decrease the device sensitivity, but could increase user comfort, which is especially critical for sleep. We are excited to see where this design process goes should a future senior project group continue our work.
XII. Acknowledgements

We would like to thank Dr. Vladimir Prodanov, as we would not have been able to complete this project without his guidance and expertise.

Special thanks to our advisor Karla Carichner for guiding us through this design process.

Thank you to Sandra Lee for sponsoring this project and giving us this opportunity to learn.

We would also like to thank Dr. Eric Espinoza-Wade, Dr. Tali Freed, and David Laiho, for providing their expertise and assistance on this project.

And thank you to Ryan Johnson and Eric from Coast Electronics Radio Shack for their help manufacturing our circuits.
XIII. Appendices:

Appendix A: House of Quality
Appendix B: Pugh Matrix of Sensing
Appendix C: Pugh Matrix of Stimuli for Reducing Clenching
Appendix D: Pugh Matrix of Combined Designs
Appendix E: Gantt Chart
Appendix F: Design Development: Testing Plan
Appendix G: Bill of Materials with cost breakdown and links to retailers
Appendix H: Haptic Casing iteration
Appendix I: Detail drawing of final haptic casing
Appendix J: Transmitter and Receiver Code for Proof of Concept
Appendix K: Final Code for Abacom Receiver
Appendix L: Transmitter Datasheet
Appendix M: Receiver Datasheet
Appendix N: Arduino Data Sheet
Appendix O: Pressure sensor Datasheet
Appendix P: Methods for mixing the acrylic resin for the mouthguard prototyping
Appendix Q: SDSs for acrylic resin for prototyping
Appendix R: Management Plan from Project
Appendix S: User Guide
### Appendix A: House of Quality

#### Engineering Requirements (HOWS)

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<th>Accuracy: detection of jaw clamping forces</th>
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**Concept Selection Legend**
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- Same: S
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**Summary**
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Appendix C: Pugh Matrix of Stimuli for Reducing Clenching

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| Sum of Sames     | 9 | 8 | 7 | 6 | 5 | 7 | 2 | 6 | 5 | 4 | 6 | 4 | 3 | 4 | 3 |
### Appendix E: Gantt Chart

**Dental Detectors Gantt Chart**

- **Assign**
  - Update PDF for Conceptual Design Report
  - Update Introduction
  - Update Background
  - Add more information on other patients to background
  - Update Specifications
  - Update Method of Approach
  - Concept generation
  - Idea Selection
  - Final Concept
  - Engineering principles, models, cost, feasibility of conc...
  - Submit COR
  - Task [Milestone] Group of Tasks

- **Progress**
  - October 2022
  - November 2022
  - December 2022

- **Tasks Completed**
  - Claire Dossay
  - Izzy Starr
  - Eri, Izzy Starr

- **Tasks Ongoing**
  - Claire Dossay
  - Izzy Starr

- **Tasks to be Completed**
  - Eri, Izzy Starr
  - Claire Dossay
  - Izzy Starr

- **Pending Tasks**
  - Claire Dossay
  - Izzy Starr

- **Notes**
  - Review designs with team
  - Update progress report
  - Finalize project timeline
  - Prepare final presentation
  - Submit final report

---

**Detailed Design**

- **Assign**
  - Deep dive research on design options
  - Contact Sander’s mouthguard company about obtaining...
  - Decide on method of combining piezoelectric material...
  - Decide on piezoelectric shape and dimensions
  - Decide on vibrational system method and placement o...
  - Decide on Bluetooth system design
  - Decide on method of power source
  - Decide on method of data collection and storage

- **Progress**
  - October 2022
  - November 2022
  - December 2022

- **Tasks Completed**
  - Claire Dossay
  - Izzy Starr

- **Tasks Ongoing**
  - Claire Dossay
  - Izzy Starr

- **Tasks to be Completed**
  - Claire Dossay
  - Izzy Starr

- **Pending Tasks**
  - Claire Dossay
  - Izzy Starr

---

**COD Presentation**

- **Assign**
  - Divide work between team
  - Decide on theme
  - Decide which student is speaking when
  - Fill in powerpoint with info
  - Write what we will say per slide
  - Time our entire planning
  - Present!

- **Progress**
  - October 2022
  - November 2022
  - December 2022

- **Tasks Completed**
  - Claire Dossay, Izzy Starr

- **Tasks Ongoing**
  - Claire Dossay, Izzy Starr

- **Tasks to be Completed**
  - Claire Dossay, Izzy Starr

- **Pending Tasks**
  - Claire Dossay, Izzy Starr

---

---

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<thead>
<tr>
<th>Task</th>
<th>Assigned</th>
<th>Progress</th>
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<tr>
<td>Plan electronic components needed for device to function...</td>
<td>Clare Dossouy, Emm, Izzy Starr</td>
<td>100%</td>
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<tr>
<td>Create detailed CAD designs</td>
<td>Emm</td>
<td>100%</td>
</tr>
<tr>
<td>CIR Presentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Divide work between team</td>
<td>Clare Dossouy, Emm</td>
<td>100%</td>
</tr>
<tr>
<td>decide on theme</td>
<td>Izzy Starr</td>
<td>100%</td>
</tr>
<tr>
<td>decide who is speaking when</td>
<td>Clare Dossouy, Emm</td>
<td>100%</td>
</tr>
<tr>
<td>Fill in powerpoint with info</td>
<td>Clare Dossouy, Emm</td>
<td>100%</td>
</tr>
<tr>
<td>Write what we will say per slide</td>
<td>Clare Dossouy, Emm</td>
<td>100%</td>
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<td>Time alignment planning</td>
<td>Clare Dossouy, Emm</td>
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<td>Present</td>
<td>Clare Dossouy, Emm</td>
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<tr>
<td>Critical Design Report</td>
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<tr>
<td>Divide work for report</td>
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<td>Work on Critical Design Report</td>
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<td>Add final models</td>
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<td>100%</td>
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<td>Turn in Critical Design Report</td>
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<tr>
<td>Prototype</td>
<td></td>
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<tr>
<td>Create basic prototype for proof of concept</td>
<td>Clare Dossouy, Emm</td>
<td>100%</td>
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<tr>
<td>Create detailed design through drawings/3D modeling</td>
<td>Clare Dossouy, Emm</td>
<td>100%</td>
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<tr>
<td>Split up parts of design that must be constructed</td>
<td>Clare Dossouy, Emm</td>
<td>100%</td>
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<tr>
<td>Write software</td>
<td>Clare Dossouy, Emm</td>
<td>100%</td>
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<tr>
<td>Build Circuits</td>
<td>Clare Dossouy</td>
<td>100%</td>
</tr>
<tr>
<td>Mold Mouthguard</td>
<td>Izzy Starr</td>
<td>0%</td>
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<tr>
<td>New Mastic 3D model</td>
<td>Emm</td>
<td>100%</td>
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<tr>
<td>Consult Sandie/Decide to pivot</td>
<td>Clare Dossouy, Emm</td>
<td>100%</td>
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<tr>
<td>Finish Prototype Construction</td>
<td>Clare Dossouy, Emm</td>
<td>50%</td>
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<tr>
<td>Present Functional Prototype</td>
<td>Clare Dossouy, Emm</td>
<td></td>
</tr>
<tr>
<td>Hardware &amp; Software Demo</td>
<td>Clare Dossouy, Emm</td>
<td></td>
</tr>
<tr>
<td>Test</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Get human testing certification</td>
<td>Clare Dossouy, Emm</td>
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<tr>
<td>Decide on testing methods</td>
<td>Clare Dossouy, Emm</td>
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Source: ENGR 459-461 Interdisciplinary Senior Project, Fall/Winter/Spring 2022-2023
### Appendix F: Design Development: Testing Plan

<table>
<thead>
<tr>
<th>Task No</th>
<th>Test Description</th>
<th>Acceptance Criteria</th>
<th>Test Stage</th>
<th>Start date</th>
<th>Finish date</th>
<th>Test Result</th>
<th>Notes</th>
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<tbody>
<tr>
<td>1</td>
<td>Circuit 1 Validation: Mouthguard</td>
<td>Pressure sensor responds and activates RF transceiver</td>
<td>EIC</td>
<td>CV</td>
<td>3</td>
<td>A</td>
<td>2/6/2023</td>
</tr>
<tr>
<td>3</td>
<td>Pressure Sensor Testing: Minima/Maxima</td>
<td>Pressure sensor activates above max threshold</td>
<td>EIC</td>
<td>CV</td>
<td>3</td>
<td>B</td>
<td>3/1/2023</td>
</tr>
<tr>
<td>4</td>
<td>Circuit Communication: Validate the circuits communicate</td>
<td>RF transceiver and receiver are accurately and efficiently communicating</td>
<td>EIC</td>
<td>DV</td>
<td>3</td>
<td>B</td>
<td>3/1/2023</td>
</tr>
<tr>
<td>5</td>
<td>Heating validation</td>
<td>The circuit can withstand adequate temperatures to be encased in tight guard</td>
<td>EIC</td>
<td>DV</td>
<td>3</td>
<td>B</td>
<td>3/1/2023</td>
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<tr>
<td>6</td>
<td>Moisture validation</td>
<td>The circuit can withstand adequate humidity during encapsulation</td>
<td>EIC</td>
<td>DV</td>
<td>3</td>
<td>B</td>
<td>3/1/2023</td>
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<td>7</td>
<td>Testing Design Intent: Baseline drilling data</td>
<td>Data is interpretable</td>
<td>EIC</td>
<td>PV</td>
<td>3</td>
<td>C</td>
<td>4/25/2023</td>
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<tr>
<td>8</td>
<td>Testing Design Intent: Interim drilling data with device use</td>
<td>Data is interpretable and significantly different from baseline data</td>
<td>EIC</td>
<td>PV</td>
<td>3</td>
<td>C</td>
<td>4/25/2023</td>
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</table>
**Appendix G: Bill of Materials with cost breakdown and links to retailers**

<table>
<thead>
<tr>
<th>Component</th>
<th>Product</th>
<th>Screenshot</th>
<th>Unit Price</th>
<th>Units</th>
<th>Total Price</th>
<th>Link</th>
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</thead>
<tbody>
<tr>
<td>Microcontroller</td>
<td>Arduino Pro Mini 328 – 3.3V</td>
<td><img src="image" alt="Microcontroller Screenshot" /></td>
<td>$15</td>
<td>1</td>
<td>$15</td>
<td>Microcontroller</td>
</tr>
<tr>
<td>RF Transmitter</td>
<td>Miniature AM RF Transmitter Module (AT-MT1)</td>
<td><img src="image" alt="RF Transmitter Screenshot" /></td>
<td>$15</td>
<td>1</td>
<td>$15</td>
<td>Transmitter</td>
</tr>
<tr>
<td>RF Receiver</td>
<td>Ultra Low Current AM RF Receiver Module (ARX-433-ULC)</td>
<td><img src="image" alt="RF Receiver Screenshot" /></td>
<td>$26</td>
<td>1</td>
<td>$26</td>
<td>Receiver</td>
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<tr>
<td>Pressure sensor</td>
<td>FlexiForce Pressure Sensor - 100lbs.</td>
<td><img src="image" alt="Pressure Sensor Screenshot" /></td>
<td>$16</td>
<td>1</td>
<td>$16</td>
<td>Pressure Sensor</td>
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<tr>
<td>Haptic response</td>
<td>Boffintronics Haptic Feedback Module</td>
<td><img src="image" alt="Haptic Response Screenshot" /></td>
<td>$4</td>
<td>2</td>
<td>$8</td>
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</tr>
<tr>
<td>Category</td>
<td>Item Description</td>
<td>Price</td>
<td>Quantity</td>
<td>Total</td>
<td>Additional Notes</td>
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<td>-----------------------</td>
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<td>----------</td>
<td>--------</td>
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<td>Mouthguard Battery</td>
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<td>$2</td>
<td>2</td>
<td>$4</td>
<td>Battery-Mouthguard</td>
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<td>Haptic Battery</td>
<td>CR 2450</td>
<td>$3</td>
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<td>$3</td>
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<td>Mouthguard</td>
<td>Cold Cure Resin</td>
<td>$10</td>
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<td>$10</td>
<td>Cold Cure Resin</td>
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<td>Waterproofing</td>
<td>Silicone - DenSureFit, denture resin in preloaded applicators</td>
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<tr>
<td>Dental Impressions</td>
<td>Sodium Alginate - dental impression kit</td>
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<td>0.5</td>
<td>$7.5</td>
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<tr>
<td>Item</td>
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<td>-------------------------------</td>
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<td>--------</td>
<td>----------</td>
<td>------------</td>
<td>-----------------------------</td>
<td></td>
</tr>
<tr>
<td>Haptic Casing</td>
<td>3D Printing: PLA</td>
<td>$2</td>
<td>1</td>
<td>$2</td>
<td>Mustang 60 Machine shop</td>
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<tr>
<td>Circuit Board</td>
<td>Flex PCB Board</td>
<td>$5</td>
<td>2</td>
<td>$10</td>
<td>PCB Board</td>
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<tr>
<td>Circuit Components</td>
<td>Resistors, transistor, battery holder, wires, capacitor</td>
<td>$5</td>
<td>1</td>
<td>$5</td>
<td>Owned</td>
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<tr>
<td><strong>Total estimated cost per unit:</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>$136</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix H: Haptic Casing iteration
Appendix 1: Detail drawing of final haptic casing
Appendix J: Transmitter and Receiver Code for Proof of Concept

Transmitter

```cpp
#include <SPI.h>
#include <RF24.h>
#include <nRF24L01.h>
RF24 radio(9, 8); // CE, CSN
const byte address[10] = "ADDRESS01";
const int analogPin = A0;

void setup() {
  Serial.begin(9600);
  radio.begin();
  radio.openWritingPipe(address);
  radio.setPALevel(RF24_PA_LOW);
}

void loop() {
  int sensorValue = analogRead(analogPin);
  int dataToSend = map(sensorValue, 0, 1023, 0, 255);
  radio.write(&dataToSend, sizeof(dataToSend));
  Serial.println("Data Sent: " + String(dataToSend));
  delay(1000); // Delay between each transmission
}
```
**Receiver**

```c
// Include necessary headers
#include <SPI.h>
#include <RF24.h>
#include <nRF24L01.h>

RF24 radio(9, 8); // CE, CSN
const byte address[10] = "ADDRESS01";
const int motorPin = 5;

void setup() {
    Serial.begin(9600);
    pinMode(motorPin, OUTPUT);
    radio.begin();
    radio.openReadingPipe(1, address);
    radio.setPALevel(RF24_PA_LOW);
    radio.startListening();
}

void loop() {
    if (radio.available()) {
        int receivedData;
        radio.read(&receivedData, sizeof(receivedData));
        Serial.println("Data Received: ");
        Serial.println(String(receivedData));
        if (receivedData >= 1 && receivedData <= 160) {
            analogWrite(motorPin, 255);
        } else {
            analogWrite(motorPin, 0);
        }
    }
}
```
Appendix K: Final Code for Abacom Receiver

```cpp
const int motorPin = 5; // PWM output pin to haptic motor
const int rfReceiverPin = A1; // RF receiver pin
const int debounceDelay = 50; // Debounce delay in milliseconds

bool isSignalActive = false; // Flag variable to track signal state
bool lastSignalState = LOW; // Previous signal state
bool motorOn = false; // Flag variable to track motor state
unsigned long lastDebounceTime = 0; // Last time the signal was stable

void setup() {
    Serial.begin(9600);
    pinMode(rfReceiverPin, INPUT);
    pinMode(motorPin, OUTPUT);
}

void loop() {
    int rfsignal = digitalRead(rfReceiverPin); // Read the RF receiver signal

    // Debounce the signal
    if (rfsignal != lastSignalState) {
        lastDebounceTime = millis(); // Update the debounce time
    }

    if ((millis() - lastDebounceTime) > debounceDelay) {
        // The signal has been stable for the debounce delay
        if (rfsignal != isSignalActive) {
            isSignalActive = rfsignal; // Update the active signal state

            if (isSignalActive) {
                // Toggle the motor state when the signal becomes active
                motorOn = !motorOn;
                digitalWrite(motorPin, motorOn ? HIGH : LOW);
            }
        }
    }

    lastSignalState = rfsignal; // Update the last signal state
}
```
Appendix L: Transmitter Data Sheet

AT-MT1-xxx Miniature AM Transmitter Module

The AT-MT1 miniature UHF RF transmitter modules are well suited to applications where size constraints are dominant. Employing OOK modulation, the AT-MT1 transmits the carrier only when the data input signal is at a high level.

Low current consumption and OOK modulation yield excellent power conservation characteristics making the AT-MT1 an ideal RF transmitter module for portable battery powered wireless applications.

The AT-MT1 will suite one-to-one and multinode wireless links in applications including security, RKE, robotics, wireless data acquisition, remote control etc. and may be driven directly by microcontrollers and data encoders such as the DPC-2400, HT12E, and the MC145026.

Features
- Miniature two pin package
- SAW resonator stability
- Data rates up to 2400bps
- Optimal range 300ft
- 418MHz, 433.92MHz and 916.5MHz versions
- CMOS / TTL compatible input
- Low current (typ. 5mA)
- Wide power supply range 1.5-13V
- Compatible with our AM receiver modules

Application Information
Antenna Design

The design and positioning of the antenna is as crucial as the module performance itself in achieving a good wireless system range. The following will assist the designer in maximizing system performance.

The antenna should be kept as far away from sources of electrical interference as physically possible. If necessary, additional power line decoupling capacitors should be placed close to the module.

The antenna ‘hot end’ should be kept clear of any objects, especially any metal as this can severely restrict the efficiency of the antenna to transmit power. Any ground planes restricting the radiation path to the antenna will also have the same effect.

Best range is achieved with either a straight piece of wire, rod or PCB track. Further range may be achieved if the 1/4 wave antenna (15.5cm @ 433.92MHz) is placed perpendicular in the middle of a solid ground plane measuring at least 16cm radius. In this case, the antenna should be connected to the module via some 50Ω characteristic impedance coaxial cable such as RG174U or RG38U.

When designing a PCB loop antenna, the inside area of the loop must be kept clear of any other components, as well as the area surrounding the loop. In other words the loop antenna must occupy an area of the PCB which is allocated to the antenna only. In some cases where PCB real estate is at a premium, the loop may be designed as a discrete component which soldered onto the board. The tuning capacitor is usually a variable capacitor which may be replaced with a fixed value capacitor once the tuned value has been determined. Provision can be made in the PCB layout to accommodate for this.

For the 916.5MHz AT-MT1 transmitter modules, the variable capacitor value is typically very low, in the region of 0.5pF and the loop area will also be smaller than for the lower UHF devices. The value of the capacitor will be a function of the loop size and electrical dimensions as applies to any tuned circuit.

Data Encoding

Data encoding and decoding is invariably required for successful RF data communications.

Encoders which interface suitably with the ATMT1 RF transmitter modules such as Holtek’s HT12E, Motorola and National Semiconductor’s MC145026 and Microchip’s Kielq devices, are typically used for data encoding in remote control...
Appendix M: Receiver data sheet

ARX-433-ULC Ultra Low Power AM Receiver Modules

The ARX-433-ULC AM receiver modules include SAW front end filtering and shielding can for high selectivity and high immunity to electromagnetic fields. These receiver modules offer ultra low current consumption making them a perfect choice for portable battery powered applications.

Features

- 5V operation
- Ultra low current consumption: 0.07mA
- High selectivity SAW front end filter
- EMI-RFI Shielding
- Wide operating temperature range
- Small size and low profile
- Compatible with our AM RF transmitter modules such as the AM-RT4/S, ATM1, ATX-433A and AM-TXHP

<table>
<thead>
<tr>
<th>CHARACTERISTICS</th>
<th>MIN</th>
<th>MAX</th>
<th>UNIT</th>
<th>TYP</th>
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<tbody>
<tr>
<td>Supply Voltage</td>
<td>2.75</td>
<td>3.6</td>
<td>Vdc</td>
<td></td>
</tr>
<tr>
<td>Supply Current</td>
<td>0.07</td>
<td></td>
<td>mA</td>
<td></td>
</tr>
<tr>
<td>Receive Frequency</td>
<td>433.92</td>
<td></td>
<td>MHz</td>
<td></td>
</tr>
<tr>
<td>RF Sensitivity</td>
<td>-64</td>
<td></td>
<td>dBm</td>
<td></td>
</tr>
<tr>
<td>Interference Rejection</td>
<td>&gt;80</td>
<td></td>
<td>dB</td>
<td></td>
</tr>
<tr>
<td>Square Wave Output</td>
<td>0.4</td>
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<td>Output High Voltage</td>
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<td>3</td>
<td>V</td>
<td></td>
</tr>
<tr>
<td>Output Low Voltage</td>
<td>GND+0.4</td>
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<td>V</td>
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<td>Antenna RF Emission</td>
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<td>dBm</td>
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<td>Operating Temperature</td>
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<td>+80</td>
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<table>
<thead>
<tr>
<th>Model</th>
<th>Loss (-1dB)</th>
<th>Loss (-3dB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARX-433-ULC</td>
<td>Rx = 10M</td>
<td>Rx = 5.5M</td>
</tr>
</tbody>
</table>

Squelch threshold adjustment

To achieve highest sensitivity, the ARX-433-ULC receivers exhibit random digital noise on the data output pin in the absence of a transmission. This is entirely normal operation, however, some applications may find this undesirable. In such cases, this noise level can be reduced by adding a resistor between Test Point (pin 13) and GND, with the trade-off of reducing the sensitivity of the receiver. As an example, a resistor value of 10M will result in (~1dB) loss in receiver sensitivity, but will result in a noise reduction at the data output. This noise reduction is often desired for microcontroller interfaces where a wakeup interrupt is required. The following information shows the loss in sensitivity of the receiver with different resistor values.

Receiver Block Diagram
Appendix N: Arduino Data Sheet

Arduino Pro Mini (DEV-11114)
Programmed as Arduino Pro Mini w/ ATmega328
8MHz / 3.3V

Power
- Raw: 3.3V-16V (4V-12V recommended)
- VCC: 3.3V
- Maximum current: 150mA @3.3V

ATmega328P
- Absolute maximum VCC: 6V
- Maximum current for chip: 20mA
- Maximum current per pin: 40mA
- Recommended current per pin: 20mA
- 8-bit Reset Alrm
- Flash Program Memory: 32kB
- EEPROM: 1kB
- Internal SRAM: 2kB
- ADC: 10-bit
- PWM: 8-bit

LEDs
- Power: Red
- User (D13): Green
Appendix O: Pressure sensor Datasheet

**FlexiForce™ Standard Model A301**

The A301 design is optimized for high-volume manufacturing and is ideal for embedding into products and applications. This sensor is available in low and high quantities off-the-shelf, ideal for an easy proof of concept. The A301 can be used with our test & measurement, prototyping, and embedding electronics, including the FlexiBoard Sensor Characterization Kit, FlexiForce Prototyping Kit, FlexiForce Developer Board, and the ELF™ System. You can also use your own electronics or multimeter.

**Physical Properties**
- Thickness: 0.250 mm (0.008 in.)
- Length: 25.4 mm (1 in.)**
- Width: 14 mm (0.55 in.)
- Sensing Area: 9.53 mm (0.375 in.) diameter
- Connector: 2-pin Male Square Pin
- Substrate: Polyester
- Pin Spacing: 2.54 mm (0.1 in.)

**Benefits**
- Small size is ideal for prototyping and integration
- Available with Enhanced Stability Series (ESS) pressure sensitive ink for high-temperature and high-humidity environments
- Thin and flexible
- Easy to use

*Sensor will require an adapter/holder to connect to the ELF System. Contact your Tekscan representative for assistance.

**Recommended Circuit**

\[ V_{OUT} = -V_{REF} \times \frac{R_F}{R_S} \]

- **VDD** = V\_SUPPLY
- DC 0.25V - 1.25V
- **VSS** = Ground
- **REFEEDBACK**
- **C1** = 47 pF
- 100kΩ POTENTIOMETER

- **R_Feedback** (R_F) = 100kΩ

**Recommended Values**

- V\_out must be opposite the polarity of V\_supply.
- Sensor Resistance R_S at no load is typically >1MΩ
- Max recommended current is 2.5mA

**Data Sheet**

*All data above was collected utilizing an Op Amp Circuit (shown on the next page). For your application cannot allow an Op Amp Circuit, visit www.tekscan.com/tekscan-integration-guides, or contact a FlexiForce Applications Engineer.

---

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Appendix P: Methods for mixing the acrylic resin for the mouthguard prototyping

Self Curing Denture Acrylic Resin

Intended Purpose
Fabrication of dentures by a dental professional

Other Materials / Equipment Needed
1. Liquid Foil (Tin foil substitute solution)
2. Stainless steel spatula
3. Flask
4. Aquapress® (Pressure curing unit), optional

Instructions for Use
For consistent results always shake liquid before use.

1. Prepare and invest the case in the usual manner, using Liquid Foil as a separating medium. After wax boil out, cool invested case to room temperature before continuing.
2. Using a stainless steel spatula, mix approximately 5 parts Self Curing Denture powder to 2 parts Self Curing Denture liquid. Vibrate mixture, if necessary, to remove trapped air. Pour mixture into flask, including along periphery and undercuts, until flask is slightly over-filled.
3. Place the top half of the flask into position with light hand pressure only. Keep flask in this position, applying no pressure, for 3 minutes. Do not open flask at any time after closing it. Trial packing is not necessary.
4. Then with full pressure, close flask completely. Allow an additional 20 minutes for complete curing. Bench cure at room temperature or, for better results, cure in a pressure pot at 30 psi.
5. Remove flask from case. Trim and polish in normal manner.

May cause respiratory irritation.
Wear protective gloves/protective clothing/eye protection/face protection.
Keep material in original container, tightly closed, in upright position. Store in a well-ventilated place. Keep cool.

Disposal
Dispose of contents and container in accordance with all local, regional and national regulations.

Warranty
Manufacturer warrants this product to be free from manufacturing defects for one year from date of purchase only from an authorized reseller. Warranty is void if product is not used for intended purpose, not used as instructed or not stored in original container.

Lang Dental Mfg. Co., Inc.
175 Messner Dr
Wheeling, IL 60090 USA
www.langdental.com
Ph. +1 847-215-6622
Fax +1 847-215-6678
Made in USA

EC REP
MediMark® Europe
11 rue E. Zola
38100 Grenoble
France

Note: Any serious incident that has occurred in relation to this device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
Appendix Q: SDSs for acrylic resin for prototyping

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines
Consideration should be given to the work procedures involved and the potential extent of exposure as they may determine whether a higher level of protection is required. The following information is given as general guidance.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH</th>
</tr>
</thead>
<tbody>
<tr>
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<td>STEL: 100 ppm</td>
<td>TWA: 50 ppm</td>
<td>TWA: 100 ppm</td>
</tr>
<tr>
<td></td>
<td>TWA: 50 ppm</td>
<td>TWA: 410 mg/m³</td>
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</tr>
</tbody>
</table>

ACGIH = American Conference of Governmental Industrial Hygienists / OSHA = Occupational Safety and Health Administration
PEL = Permissible Exposure Levels / STEL = Short Term Exposure Limit / TLV = Threshold Limit Value / TWA = Time Weighted Average

Appropriate engineering controls
For bulk size: Use local explosion-proof ventilation that is adequate to keep employee exposure to airborne concentrations below exposure limits.

Individual protection measures, such as personal protective equipment

Eye / face protection
Depending on the use of this product, safety glasses or goggles may be worn. If necessary, refer to US OSHA 29 CFR SS1910.133. Canadian standards or the European Standard EN 166. Ensure that an eyewash station, sink or washbasin is available in case of exposure to eyes.

Skin and body protection
If anticipated that prolonged and repeated skin contact will occur during use of this product, wear gloves for routine industrial use. If necessary, refer to US OSHA 29 CFR SS1910.138 or the appropriate standards of Canada or the EC member states. Wear suitable protective clothing.

Respiratory protection
No special respiratory protection is required under typical circumstances of use or handling. If necessary, use only respiratory protection authorized per US OSHA requirement in 29 CFR SS 1910.134, or applicable US state regulations, or the appropriate standards of Canada, its provinces, or the EC member states. VENTILATION: Local exhaust at processing equipment.

General hygiene considerations
Handle in accordance with good industrial hygiene and safety practice. Wash thoroughly after handling. Food, beverages and tobacco products should not be carried, stored, or consumed where this material is in use. Wash hands thoroughly before eating, drinking, or smoking.

9. PHYSICAL AND CHEMICAL PROPERTIES

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<thead>
<tr>
<th>Property</th>
<th>Values</th>
<th>Remarks / Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
<td></td>
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<tr>
<td>Appearance</td>
<td>Liquid</td>
<td>Odor threshold</td>
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<tr>
<td>Color</td>
<td>Clear</td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>Not determined</td>
<td></td>
</tr>
<tr>
<td>Melting point / Freezing point</td>
<td>Not determined</td>
<td></td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>101°C / 214°F</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
<td>12°C / 54°F</td>
<td></td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not determined</td>
<td></td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>n/a (liquid)</td>
<td></td>
</tr>
<tr>
<td>Flammability limits in air</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Upper flammability limit</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Lower flammability limit</td>
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<td></td>
</tr>
<tr>
<td>Specific gravity</td>
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<td>Water = 1</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>421°C / 790°F</td>
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</tr>
<tr>
<td>Other information</td>
<td></td>
<td></td>
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<tr>
<td>Density</td>
<td>0.949 g/mL</td>
<td></td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Reactivity
Unstable/Reactive upon depletion of inhibitor.
Chemical stability: Stable under recommended storage conditions.
Possibility of hazardous reactions: None under normal processing.
Hazardous polymerization: Hazardous polymerization may occur.

Incompatible materials:
- Strong oxidizing agents, strong reducing agents, free-radical generators, inert gases, oxygen scavengers.
- Material has strong solvent properties and can soften paint and rubber.

Hazardous decomposition products: Carbon oxides

11. TOXICOLOGICAL INFORMATION

Mixture Toxicity:
- Inhalation Toxicity: 4,632 mg/L.

Component Toxicity:
- No data available.

Routes of Exposure:
- No data available.

Target Organs:
- Eyes, Skin, Respiratory System.

- Inhalation: Harmful if inhaled.
- Eye contact: Causes severe eye irritation.
- Skin contact: Causes skin irritation. May be harmful in contact with skin.
- Ingestion: May be harmful if swallowed.

Product Components Listed as Carcinogenic: None

12. ECOLOGICAL INFORMATION

Ecotoxicity

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Algae / aquatic plants</th>
<th>Fish</th>
<th>Toxicity to microorganisms</th>
<th>Crustaceans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl Methacrylate 80/32-8</td>
<td>170/96 h</td>
<td>246-275 96 h Pimephales promelas mg/L</td>
<td>-</td>
<td>69-48 h Daphnia magna mg/L</td>
</tr>
<tr>
<td></td>
<td>Pseudokirchneriella subcapitata mg/L LC50</td>
<td>LC50 flow-through;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>125.5-190.7 96 h Pimephales promelas mg/L LC50 static;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>170-206 96 h Lepas macronius mg/L LC50 flow-through;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>336.4-436 9.96 h Pocilia reticulata mg/L LC50 static;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;75 96 h Oncorhynchus mykiss mg/L LC50 flow-through;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;75 96 h Oncorhynchus mykiss mg/L LC50 static</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Disposal of wastes:
- Follow all local and national government regulations in disposing material or contaminated packaging.
- For U.S.: Dispose of in accordance with federal, state and local regulations. When discarded, it is considered a hazardous waste by the EPA under RCRA. The reportable quantity for methyl methacrylate is 1000 lb. (40 CFR Part 302). Add excess inhibitor before disposing.
- Contaminated Packaging: Reuse of empty drums or containers is not recommended. Employees should be advised of the potential hazards due to residual material associated with empty containers. Dispose of all empty containers in accordance with local and national government regulations.

14. TRANSPORTATION INFORMATION

DOT:
- UN / ID No: UN1993
SAFETY DATA SHEET
Version 5

1. IDENTIFICATION

Product Identifier
Product Name
SELF CURING DENTURE LIQUID

Other means of identification
SDS# 014
UN No. UN1993
Product Code
0804, 0805, 0807, 0808, 0834, 0856

Recommended use of the chemical and restrictions on use
Recommended Use
Self-curing acrylic resin

Details of the supplier of the safety data sheet
Supplier Address
Lang Dental Mfg. Co., Inc.
175 Messner Dr.
Wheeling, IL 60090
USA

Emergency telephone number
Company Phone Number +1-847-215-6829
Emergency Telephone (INFOTRAC) +1-332-323-3550 (International)
800-535-6953 (North America)

Authorized European Representative
Medmark Europe SARL
11, rue Emile Zoéa BP 2332
38033 Grenoble Cedex 2
France
Tel: +33 476 96 43 22
Fax: +33 476 17 15 82
Email: info@medmark-europe.com

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

<table>
<thead>
<tr>
<th>Flammable liquids</th>
<th>Category 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Corrosion / Irritation</td>
<td>Category 2</td>
</tr>
<tr>
<td>Skin Sensitization</td>
<td>Category 1</td>
</tr>
<tr>
<td>Specific Target Organ Toxicity - Single Exposure (Respiratory)</td>
<td>Category 3</td>
</tr>
</tbody>
</table>

Signal word
Danger

Hazard statements
H225 Highly flammable liquid and vapor.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.

Appearance
Clear
Physical state
Liquid
Odor
Acrid
Precautionary Statements – Prevention
P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P220 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ventilating/lighting equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P251 Avoid breathing dust/dust/fumes/gas/mists/vapors/spray.
P254 Wash hands thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P272 Contaminated clothing should not be allowed out of the workplace.
P290 Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary Statements – Response
P303+P361+P335 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P334+P310 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P312 Call a POISON CENTER or doctor/physician if you feel unwell.
P333+P313 IF SKIN IRRITATION or rash occurs: Get medical advice/attention.
P392 Take off contaminated clothing and wash before use.
P507+P378 In case of fire: Use CO2, for extinguishing.

Precautionary Statements – Storage
P235 Keep cool.
P403+P233 Store in a well-ventilated place. Keep container tightly closed.

Precautionary Statements – Disposal
P501 Dispose of contents/container in accordance with local regulation.

Hazardous component(s) for labeling
Contains methyl methacrylate

3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No</th>
<th>Weight - %</th>
<th>Trade Secret</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methyl Methacrylate</td>
<td>81-62-5</td>
<td>&gt;50</td>
<td>*</td>
</tr>
<tr>
<td>N,N-Dimethyl-p-Toluene</td>
<td>98-87-3</td>
<td>&lt;1</td>
<td>*</td>
</tr>
</tbody>
</table>

Specific chemical weight has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures
Inhalation
Remove victim to fresh air. Keep at rest in a position comfortable for breathing. Seek immediate medical attention.
Eye contact
Rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. If irritation persists, call a physician immediately.
Ingestion
If ingested, do not induce vomiting. Drink plenty of water or milk immediately. If vomiting, continue to offer water or milk. Never give anything by mouth to an unconscious person. Call a physician or poison control center immediately and provide an estimate of when and how much material was ingested. Seek immediate medical attention.
Skin Contact
Wash with soap and water. If irritation, redness or swelling persists, call a physician immediately. Take off contaminated clothing and wash before reuse.

Most important symptoms and effects, both acute and delayed
Symptoms
No information available.

Indication of any immediate medical attention and special treatment needed

Notify physicians
Treat symptomatically.
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10. STABILITY AND REACTIVITY

Reactivity
Unstable/Reactive upon depletion of inhibitor.

Self Curing Denture Liquid 644 v.5
Appendix R: Management Plan from Project
Appendix S: User Guide

Instructions on using Biofeedback Device with Wearable Haptic Response

1. Make teeth impressions to get custom fitting mouthguard
2. After mouthguard has been manufactured, put mouthguard in mouth before going to sleep
3. Put on wearable haptic on your head by resting the housing on your ears
4. The wearable haptic headset will alert you when a bruxing event occurs
5. Change wearable haptic battery every other night by removing the top cover of the right side housing. Rechargeable batteries and their chargers are included
XV. Works Cited


Patents:


