

JEDIGLOVE - A New Way of Seeing Blindness

by

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## Biomedical Engineering, NUI Galway

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## **ABSTRACT**

Navigating from one point to another has always been a big challenge for blind people. Previously used traditional technologies such as white canes and guide dogs have proved to be useful for blind individuals to some extent only. The drawbacks include colliding with objects of high level and having no information for guiding in an unknown environment remains hazardous. The ergonomic JediGlove is a novel solution to these problems using engineering skills of electronics and combining them with software programming. The evaluation of the JediGlove was completed by 10 participants including a blind female. The participants were required to navigate in a room with obstacles in it to reach the target point using the glove prototype. The user feedbacks of 9 blindfolded participants and a blind female participant were in favour of using the JediGlove for navigation with some enhancement.

## **ACKNOWLEDGEMENT**

On the very outset of this report, I would like to extend my sincere and heartfelt obligation towards all the personage who have helped me to complete this Master's thesis entitled ' A new way of Seeing Blindness – JediGlove' throughout these 9 months.

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Thanking You

Mouzzam Husain

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## CHAPTER 1 – INTRODUCTION

### **1.1 BACKGROUND STUDY**

According to the global data of World Health Organization (WHO), the approximated statistics for the visual impairment for the year 2010 deduced from various countries concluded that on global level, there are roughly 285 million visually impaired people consisting of all ages. Among these people, 39 million are blind. Furthermore, of all the blind individuals, 82% have the ages of 50 and above [\[1\]](#). Without medical advancements and efficacious inventions the number of blind people worldwide is estimated to escalate to 76 million by 2020 provided the existing run continues. [\[2\]](#).

In medical definition, Blindness corresponds to loss of sense of light or vision. In addition, No Light Perception (NLP) is another term used for the absolute blindness [\[3\]](#). However, a person is called as legally blind if the field of view is constrained to 20° or less or having a visual acuity of 20/200 or poor than that with the possible rectification method for the better eye [\[4\]](#). There are four main causes of visual impairment and absolute blindness namely:

**Glaucoma** - It starts developing with the escalating intra-ocular pressure (IOP) within the eyes. Consequently, the elevated pressure affects the optic nerve causing sight loss. However, its progression could be hindered with the application of eye drops or laser surgery. Early diagnosis is critical in this case.

**Diabetic Retinopathy** - The initiation of this disorder is because of problems in blood vessels throughout the body including the eyes. Moreover, it is a complication of diabetes, in which the blood vessels in the rear side of the eyes, on the retina gets damaged. Nevertheless, the cause could be cured via laser surgery but the damage done is permanent.

**Age Related Macular Degeneration (AMD)** - The most common cause of vision loss which usually occurs after the age of 60. It destroys macula; which is centrally located at retina that helps in focusing. However, it is not the main cause of total blindness.

**Cataract** - This involves painless cloudy lens in the eyes which is the reason for blurry vision. It advances with age. The prime reasons for cataract involve diabetes, trauma, some medications and excessive UV light exposure. Cataract can be effectively treated by eye glasses and laser surgeries.

Although, total vision loss could be slowed down but the mutilation done could not be reversed. Nonetheless, numerous low technological and high technological devices are available in the markets which have proved to be of great assistance for sightless individuals.

## **1.2 PROBLEM STATEMENT**

The first assistance for blind people goes back to 1920's which is claimed to be the time for invention of 'white cane'. A whole decade after the first sighting of white cane, sightless individuals started to use it. This soon became an identifier for blind people [5]. Following the increased usage of white canes, guide dogs became a new helping hand for the blinds. Till date both of these traditional assistances are used all over the world.

In the 21<sup>st</sup> century, with the advancement of the technology, numerous devices have modelled for blind people. These established technologies may be further divided on basis of the type of activities an individual performs. Firstly for activities involving *motion assistance* and secondly the tasks that requires *details transmission*. However, plethora of problems accompanies these advancements. Problems with details transmission generally involve reading and word identification. On the other hand, challenges with motion assistance consist of more complex issues related to mobility and navigation. In addition, these devices are considered costly. The complications of the existing technologies do need a new change with high reliability and efficacy which would be beneficial for visually impaired people.

The JediGlove with its ergonomic and user- friendly design will prove to be of great aid for blind people in their daily lives for commuting from one place to another. With its low cost, low-power consumption and easy use; the navigation would not be a bigger problem for the people with low/no vision.

## **1.3 OBJECTIVES**

1. To design a functioning glove prototype for navigation.
2. To create a glove for blind people that will be less costly, low power consuming and easy to use.
3. Minimizing the problems present with devices already available in market.



## **1.4 SCOPE OF STUDY**

There are various popular facilities in market available for assisting blind people to make their life as normal and simple as possible. Generally speaking, there are certain long-established and proven supports for sightless people such as canes and trained guide dogs. On the contrary, some high tech gadgets are also available providing a relief to blind individuals. These includes Finger Reader [7], Ultrasonic Blind stick with GPS system [8], Smart walking stick [9], Automated walk in assistant for blind [10] and many more which will bediscussed later in this report. However, certain complications are involved in both the above stated resources. This project will be engaging such a high technological glove for their everyday use making the navigation more secure and reliable. Furthermore, minimising the complexity offered by the available technologies.

The project consists of designing and fabricating of a glove which can be used by the blind people for navigation purpose. The glove is named as JediGlove (as an analogy of a Star Wars [20]movie where an individual can feel a force in his/her hand). After the completion of the JediGlove, the testing was carried out with the help of 8 people including a blind person with their consent. Subsequently, feedbacks from all of these individuals were recorded and an analysis report on basis of the feedback was generated. The duration of the whole project was of nearly 9 months having a breakdown of 6-7 months of project and device fabrication while roughly 2 months of testing. For the purpose of testing, obstacles along the path where created and the person wearing the glove needs to complete the full path distance. The time and number of collisions with the obstacles were also recorded proving a feedback on its accuracy.

The JediGlove is a programmed device which uses the ultrasonic technique for distance detection in synchronization with five vibration motors vibrating on basis of the detected object distance. An accelerometer is also used for constraining the usage of device in appropriate situation only. The microprocessor used is ATmega382P in Arduino UNO which is the heart of the circuitry. The report will discuss the methodology and theories of all the sensors and electronic components used in designing of the JediGlove.

## CHAPTER 2: LITERATURE REVIEW

### 2.1 HISTORY OF TRADITIONAL EQUIPMENTS

The history of solutions for the blind individuals was started from biblical period where the sticks were used for the unaccompanied travel. For centuries, the canes were used by the blind to sense the obstacle in their path when they used to travel. This usage of canes became a symbol in the 20<sup>th</sup> century that gave others the hint that the person is blind. In 1921, a 'white cane' came in existence that is claimed by James Biggs of Bristol. He used the white cane for commuting through traffic of vehicles and alerting the motorists coming his way. It roughly took 10 years for the white cane to create its presence in the society. Soon after the World War II, Doctor Richard Hoover developed the "long cane" or "Hoover" method of cane travel. These Hoover canes were created in such a manner that they can be used as mobility equipments. However, the cane remained the identification for blind person [5].

Another vital source of assistance for blind came from the most faithful animal. The use of guide dogs by blind started in the year 1931 by two British, Muriel Croke and Rosamund Bond. They were the first to train four guide dogs in Wallasey, Merseyside [6]. Since then guide dogs have established their utility as an aid to the blind for travelling and avoiding collisions from the foreign objects in their surroundings.

These conventional sources for blind people were of great help in the past. However, with the rise of demand for automobiles and the construction due to increasing population, walking on roads is not the same as it was in the previous centuries. There are two main limitations of using white canes. Firstly, the objects at the height of head cannot be judged. This may result in massive head injuries. Secondly, the range of the cane is restricted to its length due to which the person may tumble or fall. Furthermore, the guide dogs for blind have proven to be better than using white canes. Nevertheless, they have their own drawbacks. Many dogs of different breeds were considered as not fit for becoming the guide dogs because of their frightened behaviour in public environment. In other cases, distractions from the other dogs became the reason to stop use guide dogs. Apart from these, the excited characteristics of various dog breeds made it difficult for the blind person to control it which may result in accident [7].

## **2.2 PRE-EXISTING TECHNOLOGIES**

Tremendous high tech aids developed with help of electronic configuration and software programming showed a better alternative to the traditional ones. Some of these technologies are detail transmission such as Finger Reader [8] while others are motion assistance devices like Ultrasonic Blind stick with GPS system [9], Smart walking stick [10], Automated walk in assistant for blind [11], Guide Dog Robot [12], etc. Numerous equipments use ultrasound sensors and detectors whereas others use haptic feedback in their working.

Finger Reader (Figure 1 (a)) is basically a device which allows a sightless person to read in any non-ideal condition whether it may while going somewhere or may due to variations in alignment of lines. The device can be worn over the finger with camera installed on it and can be used while reading. A person wearing that only need to move his finger and device would then accordingly scan the text and words are heard as synthesized speech. It has limitations in terms of technicality as autofocus of camera does not work making it difficult to adjust according to finger length [8]. Ultrasonic cane are a type of cane having inbuilt ultrasonic system that will sense the object in its way and give a feedback via GPS system. The main purpose of such cane is to act as a better navigation tool. Sensors are used for detection of objects. A vital feature on this device is that an individual can locate its stick with the aid of RF technology built remote. On pressing the remote, the cane will start to vibrate. The main drawback of this device is the cost involved and it cannot predict accurately rough terrain [9]. Smart walking stick for visually impaired uses a similar technology as ultrasonic blind stick. But the main difference here is the usage of various other sensors such as pit sensors, water sensors, GPS with memory having pre-programmed routes, level controller and PIC controller. This device solves the problem of rough terrain present in ultrasonic blind stick, but the cost increases in comparison to the same. However, if the budget is reduced, the performance needs to be comprised [10]. Automated walk-in assistant for blinds consists of a spectral glass embedded with obstacle deflection module and an alarm generator. The obstacle deflection module has range of 3m and an angle of 60° to detect the objects. It weighs 165gm and is temperature resistant [11]. The main disadvantage of this device is that for objects at close proximity, the desired accuracy was found out to be much lower. Moreover, the complexity of the glasses that one needs to wear due to its circuitry. Guide Dog Robot is a type of electronic travel assist. It works on the principle of Kinect sensors to

navigate its environment. Radar and ultrasound technologies are used in this device. Guiding the blind walking person is its main objective which is achieved by the ultrasonic sensor, by which it detects the obstacle and sends signals to blind for a safe walk. Nonetheless, the output of this robotic dog reduced if the surface is uneven. In addition, the cost of this device is quite high [12].

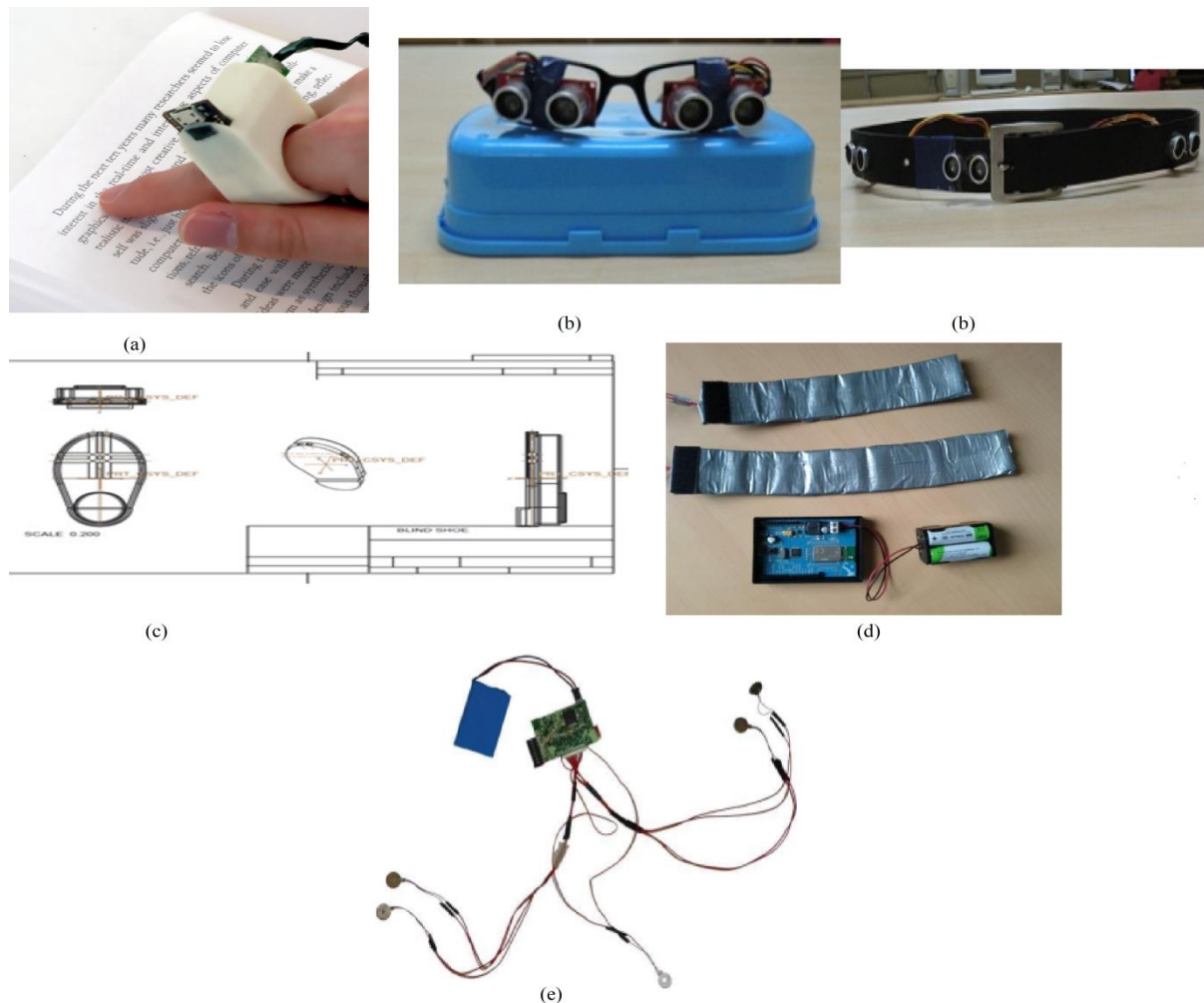


Figure 1 : (a) Finger Reader [8]; (b) Ultrasonic spectacles and waist belt [14]; (c) Blind Shoe Design [18]; (d) Wrist bands with vibration actuator connected via Bluetooth and Arduino[16]; (e) Vibrotactile actuator [13]

There are some of the recent devices that use the principle of ultrasonic emitter and detection techniques with some other programmed circuits. Ultrasonic Spectacles and Waist-belt for Visually Impaired and Blind Person [14] (Figure 1 (b)) is an example of above stated

principles. In this equipment, five ultrasonic sensors were used having a breakdown in two on head and three on waist attached to a belt. The data is collected every 20 msec. By these five sensors and is then is sent to the microcontroller AT89S52, all in real time. Following it, processing is done by microcontroller and the speech messages are then utilised which are stored in flash memory. After processing this data, microcontroller invokes relevant speech message stored in flash memory. The variable duration of the speech messages are 60 sec. Although, all the three directions are covered with this device, the detection of obstacle below the waist level cannot be done which can lead to fatal injuries [\[14\]](#). Design and Fabrication of Blind Shoe using ATmega328P Microcontroller and Vibration motor [\[18\]](#) (Figure 1 (c)) is another idea utilising concepts of vibration motor and ultrasonic sensor. In this project, ultrasonic sensor and motor is installed in a shoe that could be worn by the blind. It is portable and consumes low power but the main problem with this idea is the need of different shoe sizes for different people. Also, the comment on comfort level of the shoe cannot be justified [\[18\]](#). The haptic feedback in the device is the most recent version of devices available in market. One such device is Guiding Blind people with Haptic Feedback [\[16\]](#) (Figure 1 (d)) in which two vibration actuators are used in connection with Bluetooth Arduino card. This design enables the users for easily setting up and using the haptic system to receive feedback on their path. The actuators allow us to control the frequency, duration and interval between stimuli. The design is portable and easy to interact. However, the main attention in this prototype was on feedback from the surroundings and not on the localization techniques [\[16\]](#). A Remote guidance system for blind and visually impaired people via Vibrotactile Haptic feedback [\[13\]](#) (Figure 1 (e)) is a system which requires a blind user and a remote operator. The blind wears a camera glasses and a pair of vibratactile bracelets. The guidance is given by the operator via the haptic feedback in the bracelets. The camera glasses are connected with the USB which is in connection with Laptop via a Bluetooth module. The video is captured and seen using Skype by the remote operator. The operator can activate the vibration motors in the wrists and can give commands for the movements. Both of the motors can function independently using the Bluetooth communication [\[13\]](#). The drawback of this system is the possible risks of misunderstanding that persists because of the haptic feedback of the operator. A cost-effective indoor Vibrotactile Navigation system for Blind [\[15\]](#) is another such modelling using the vibration motor technique. It comprises of four main components; the localization engine, a compass module, the haptic node (vibrotactile actuator), and the navigation engine.

The navigation engine is the main part of the system. It receives input from all functioning blocks. The coordination between navigation system and the compass module is driving the vibration actuator in loop. Magnetometer module is also connected with the microcontroller that helps the blind to navigate through their path. Given the location and the orientation it can send the correct instructions to the vibrotactile actuator. Five vibration motors are used one on chest in centre, two motor on left shoulder while the remaining two on the right shoulder. When the motor activates for the chest move forward while for left and right vibrations, proceed in left and right direction respectively [15]. The disadvantage with this system is that the objects near the ground level cannot be detected.

On 23<sup>rd</sup> July 2020, RTEplayer featured a series called as ‘BigLifeFix’. In one of its episode, a novel engineering solution was remarkably implemented for an old lady named Maureen who is blind in one eye and has only 10% vision in the other. She is a walker and has walked for as long as 700kms. For her vision problems, engineers associated with this program designed a novel idea of friend recognition aid. Initially, using RFID technique coupler with ultrasonic sensors and headphone, as soon as someone approaches her she gets a voice message in her ears with the aid of headphone stating distance, direction and person entering her zone. However, due to the big size of the prototype it was difficult to use. The next idea was to make a jacket that would alert Maureen if someone’s coming from back using ultrasonic sensor and at the back integrated with the haptic feedback that creates a vibration. In addition, for the recognition purpose instead of RFID, Bluetooth module was used that increased the range and accurately giving voice message in the headphone of if a known person enters in Maurine’s room [19].



[19]Figure 2 : (a) Logo of BIG LIFE FIX; (b) shows the wearable jacket with Haptic Feedback; (c) reveals the technology behind this novel idea

## CHAPTER 3: MATERIALS AND METHODS

The ergonomic design of JediGlove is constructed with the help of four major components. These are namely HC-SR04 Ultrasonic Sensor, Grove- Vibration motor, Arduino UNO and GY291 ADXL345 3-Axis Digital Acceleration. Apart from the stated elements, a glove, 9V battery, battery snap connector, breadboard, jump wires and a box for protecting the circuitry from the surrounding.

### **3.1ELECTRONIC COMPONENTS OF JEDIGLOVE**

1. Ultrasonic sensor is an electronic device which measures the distance of the obstacle within its range. It consists of four pins that are for power supply, trigger, echo and ground respectively. The trigger pin emits ultrasonic sounds waves which on reflection from the object are converted into an electrical signal. The trigger pin or the transmitter uses piezoelectric crystal for emitting the waves.

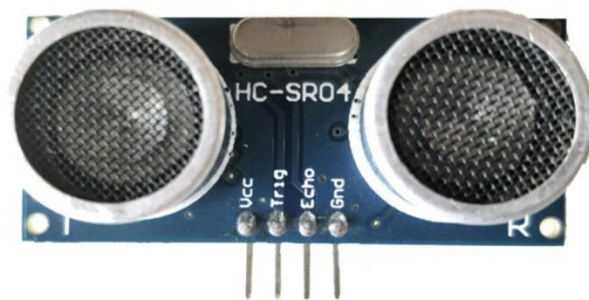


Figure 3: Ultrasonic sensor with its four pins.

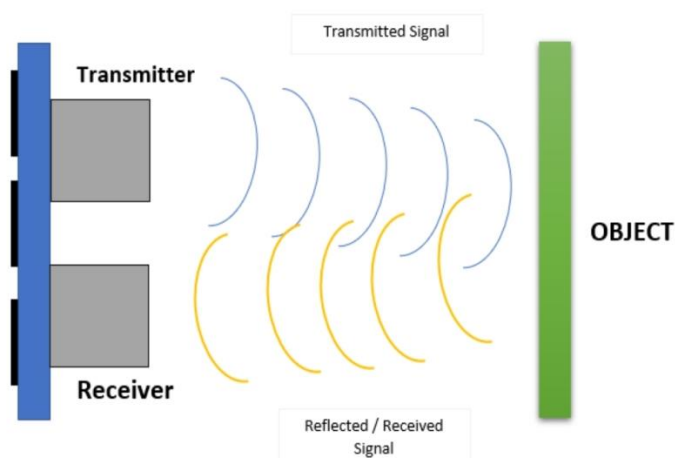


Figure 4: Schematic of principle of ultrasonic sensor.



(A) General Specifications of the Ultrasonic sensor:

- ❖ Working Voltage: 5V.
- ❖ Working Static current: Less than 2mA.
- ❖ Sensor angle: Not greater than 15 degrees.
- ❖ Precision: Up to 3mm.
- ❖ Detection Range: 2cm to 450cm (approx.).
- ❖ Input trigger signal: 10μs impulse TTL

(B) Output Signals:

- ❖ Electric Frequency signal: HIGH=5V, LOW=0V.
- ❖ Echo signal: PWM signal with proportional to measured distance.
- ❖ Transmitter output: Eight 40KHz pulses.

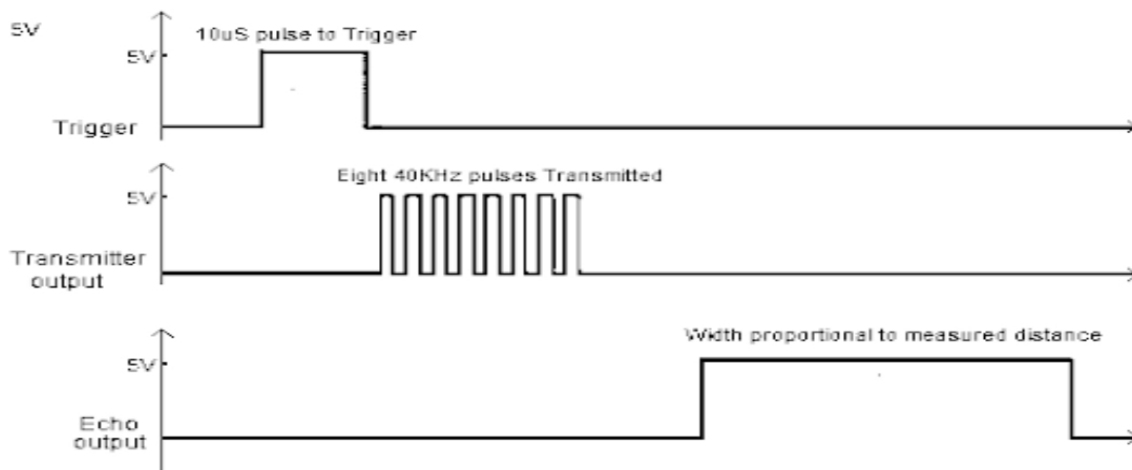


Figure 5: Ultrasonic sensor Timing diagram.

(C) Distance Calculation: The distance is calculated by using the formula mentioned below.

$$Distance = \left( \frac{traveltime}{2} \right) * speedofsound$$

Where speed of sound  $\approx 340\text{m/s}$

2. The Grove Vibration motor consists of a one coin type motor which is a Permanent Magnet coreless DC motor. Vibrations are observed when the input is logic HIGH. This vibration motor is non-audible and consumes very low power. It has four coloured wires attached directly to the pins. The red wire is for the power supply whereas the black is



designated for the ground. The pin with yellow wire acts as a connecting interface. However, the fourth white wired pin is not connected in the circuit.

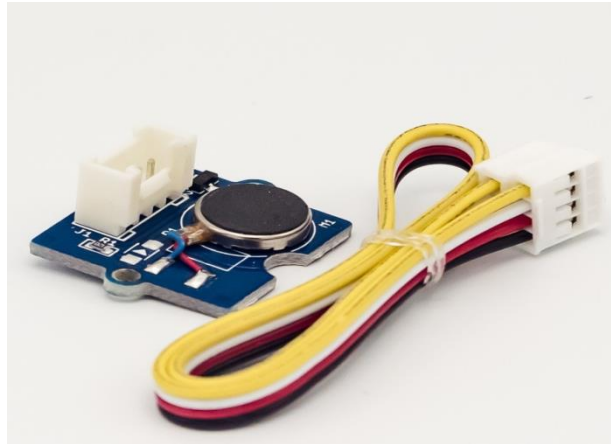


Figure 6: Grove Vibration Motor.

(A) Specifications of Grove Vibration motor:

- ❖ Supply Voltage: 3.3/5V.
- ❖ Rated speed: 9000rpm.
- ❖ Interface: Digit port.

3. The ADXL345 3-axis Digital Acceleration is a type of accelerometer sensor that can sense 3-axis acceleration. It detects static acceleration of gravity in tilt-sensing. In addition, the dynamic acceleration can be also be sensed resulting from shock or motion. The ADXL345 consists of 8 pins in which two are power supply (VCC) and ground (GND). CS pin stand for Chip select while INT1 and INT2 are the interrupts output. SDO pin is serial data output. SDA and SCL are Serial Data and Serial communication clock respectively. SDA and SCL are mainly used for the programming of JediGlove.

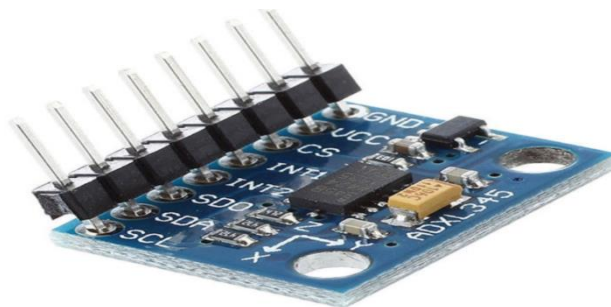


Figure 7: ADXL345 3-axis Digital Acceleration Sensor.

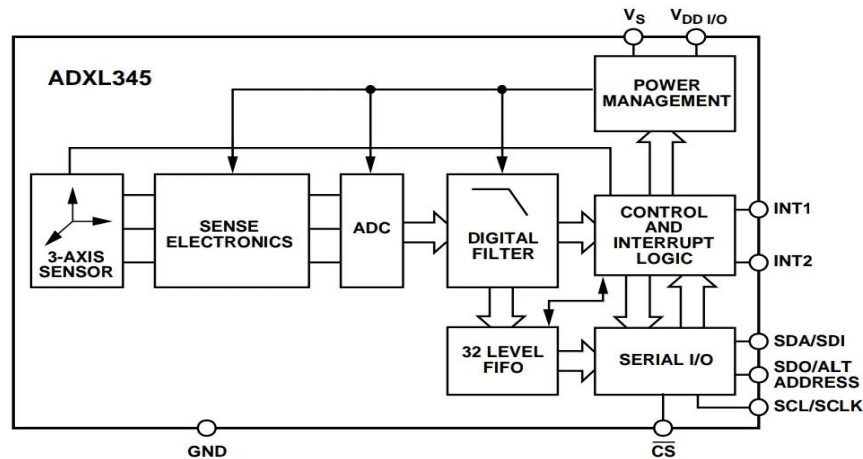


Figure 8: Functional Block diagram of ADXL345

(A) Specifications of ADXL345 3- axis Digital Acceleration sensor:

- ❖ Power Supply: 3-5V.
- ❖ Means of Communication: IIC/SPI communication protocol.
- ❖ Measuring Range:  $\pm 2g$ ,  $\pm 16g$  (where 'g' is in terms of acceleration due to gravity).
- ❖ High Resolution: 3.9mg/LSB.
- ❖ Measures inclination changes of less than 1.0 degrees.

4. Arduino UNO is the heart of JediGlove. It is a microcontroller board based on ATmega328P. It contains 14 digital input/output pins among which 6 can be used as PWM outputs. In addition, Arduino UNO supports 6 analog inputs. Also, a 16MHz ceramic resonator is attached to the board and is supported by a USB connection. USB connection can be used for powering up the board as well as for programming it.



Figure 9: Arduino UNO

(A) Specifications of ATmega328P microcontroller based Arduino UNO:

- ❖ Operating Voltage: 5V.
- ❖ Input Voltage: 6-20V (limit).
- ❖ Flash Memory: 32KB (ATmega328P) of which 0.5KB used by bootloader.
- ❖ SRAM: 2KB (ATmega328P).
- ❖ EEPROM: 1KB (ATmega328P).
- ❖ Clock Speed: 16MHz.

5. Battery used in Jediglove is a PP3 9V Zinc Chloride. This is suitable for heavier duty high-drain applications.

### **3.2 BLOCK DIAGRAM OF THE PROTOTYPE**

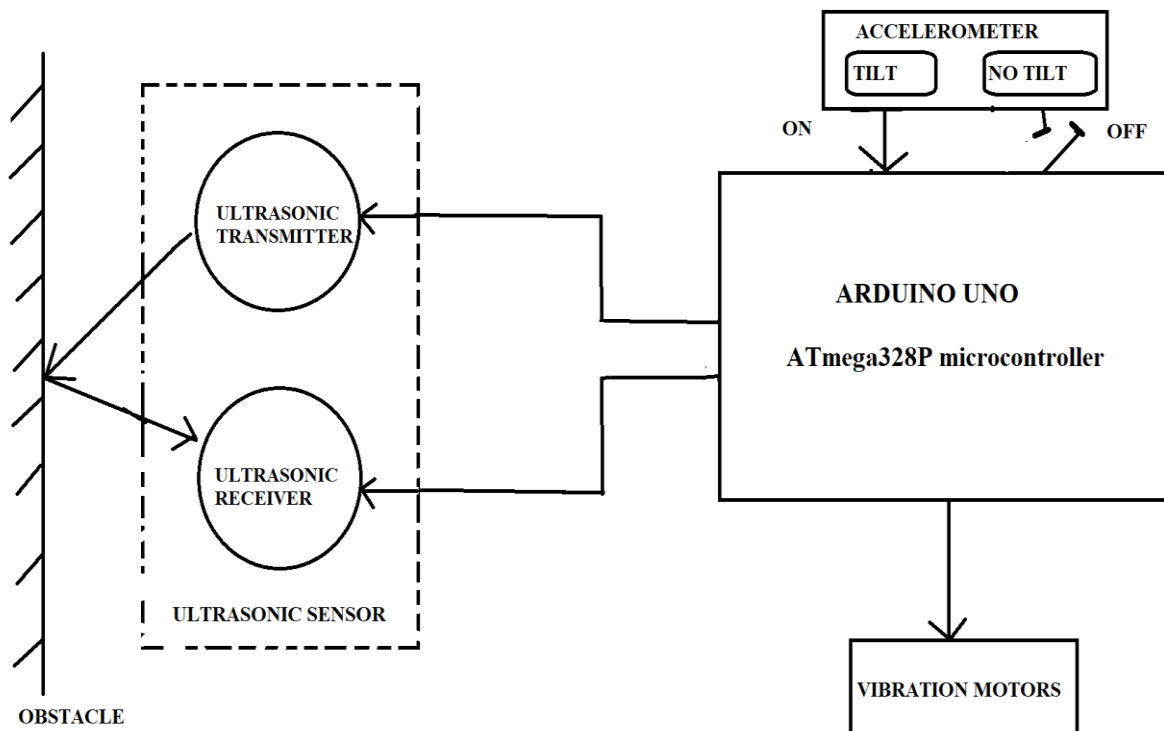


Figure 10: Working of JediGlove in Block Diagram

The block diagram in Figure 10 depicts the simple functioning of the JediGlove. The accelerometer depending on the position of hand will connect the power supplied to the arduino UNO. The microcontroller follows commands for ultrasonic sensor which transmits the wave towards the object and is received at the echo pin of the sensor. The distance is then

computed by microcontroller. Consequently, the distance will decide for which vibration motor (among five motors attached near the tips of hand) to switch on.

### **3.3 RESEARCH METHODOLOGY**

The initial approach for the designing of glove prototype or the JEDIGLOVE was by using one Ultrasonic sensor, two Vibration motors and ATmega328P microcontroller. The bread board implementation was carried out. The idea was to detect objects via ultrasonic module and with the aid of programming in microcontroller controlling the vibration motor. The first design can be seen in Figure 11.

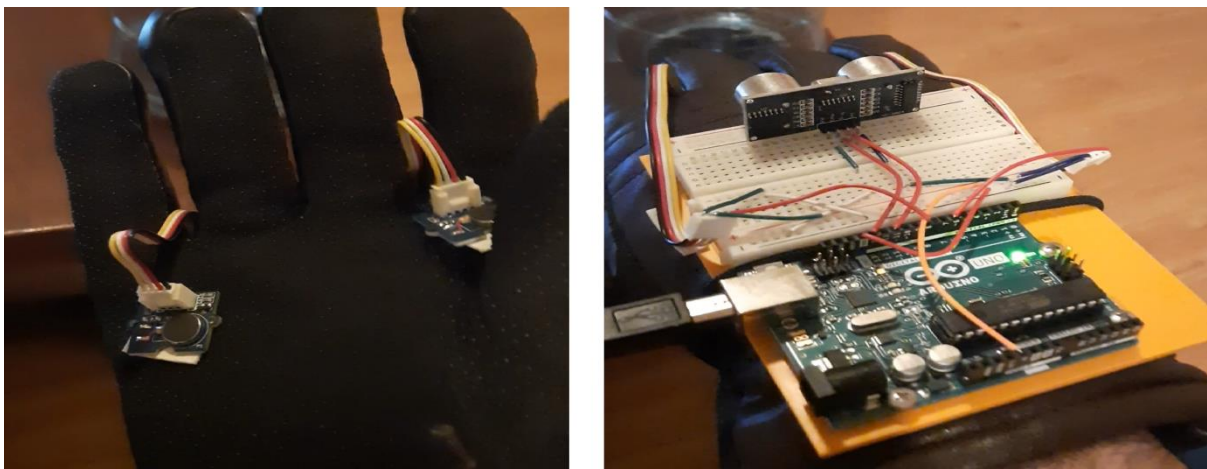


Figure 11: Initial design approach of JediGlove

The programming was executed in such a manner that the vibrations from the motors totally depended on the distance between the obstacle and JediGlove. The idea was to alert the blind by increasing the frequency of vibrations if they get really close to the object. The role of ultrasonic sensor was just to calculate the distance. The distance was interpreted by the ATmega328P microcontroller. The microcontroller then gave command to either one of the vibration motor or both of the motors according to the value of distance. If the distance was less than 150cm only one vibration motor switches ON to vibrate. However, if the distance between the target and the glove becomes less than 50cm; both the motors start to vibrate. Thus, alerting the blind person that the object is too close with high intensity of vibrations that could be felt in the hand. The prototype was working well. Nevertheless, after discussing the initial design with the supervisor, two main limitations were observed. Firstly, the range

was too less. Secondly, the circuitry became slightly big in size. So, to fit it in a box for protection purpose was an issue.

The changes were implemented in the JediGlove after considering with supervisor. The new modelling was done. In this new approach, one ultrasonic sensor and five vibration motors were integrated along with the microcontroller. The changes in programming were completed. The new programming commands worked on the same principle of vibration in accordance with distance. However, this time each vibration motor corresponded to a particular distance range. These vibration motors were placed in such a manner that all the fingers and a thumb were designated one vibration motor each. Figure 12 depicts the second prototype of JediGlove.

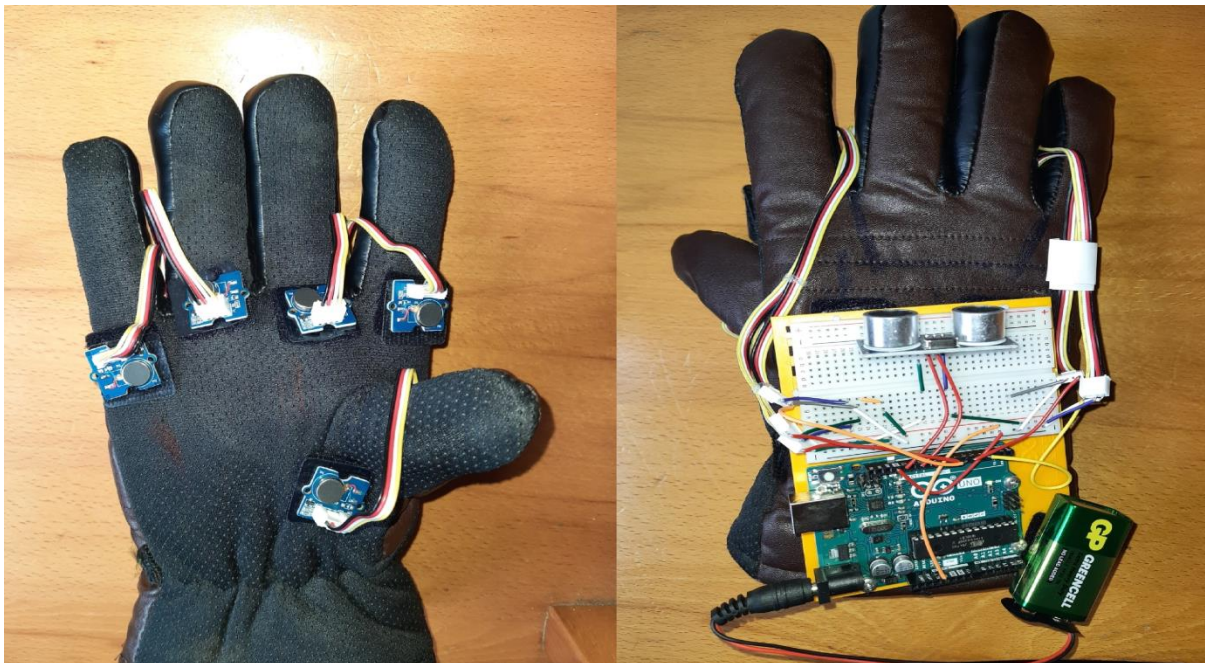


Figure 12: Images after alteration in Design

Consequently, the vibration motors became distinctive. The command was executed by microcontroller again depending on the distance. The coding was done in such a manner that the 1<sup>st</sup> vibration motor glued at the thumb vibrated when the distance is less than 70cm. Similarly, the 2<sup>nd</sup> vibration motor at the index finger switches on when the range of distance becomes 71-150cm and so on. Table 1 reveals the designated vibration motor fingers and the distance. Consequently, every finger will now be representing a distance. So for instance, if the blind is 100cm far from an object only 2<sup>nd</sup> motor vibrates. As soon as the person gets



closer to it and the distance becomes less than 70cm, the 1<sup>st</sup> motor starts to vibrate. Subsequently, vibrations can be felt around the thumb alerting person that the distance is too close.

Designated Positions	Vibration motor number	Distance Range(cm)
Thumb	1	Less than 70cm
Index Finger	2	71 - 150
Middle Finger	3	151 - 250
Ring Finger	4	251 - 350
Little Finger	5	351 - 400

Table 1: Range of Distance with respect to haptic feedback from motors in different fingers

The implementation was successfully completed. The limitations of the previous design were overcome. The range was increased to 400cm from 150cm giving a more knowledge of surrounding. Placing the whole circuitry in junction boxes were quite a challenge as the ultrasonic module needs no hindrance ahead of it or else it kept on vibrating. For this problem, a box with high insulation and temperature resistant characteristic was chosen. Subsequently, certain modifications on the box were made to make it more easy to use. In addition, the ultrasonic sensor was placed carefully so that it performs its role accurately.

Although, the JediGlove was working effectively, there were still two major issues with the prototype. The first was with the intensity of vibrations around the distinctive fingers as it may confuse the person. Furthermore, the vibrations should stop when the hand is in resting phase near the leg. Vibrations are unwanted at the time. Therefore, the whole system must work only if the blind uses his hand for navigation purpose.

The discussions on the standing limitations were made with the supervisor and changes were executed. The positioning of the vibration motor was changed and repositioned near the tips of each fingers and a thumb. Therefore, the intensity of vibrations increased significantly. The other potential challenge was overcome by using the ADXL345 3-axis Digital

acceleration. The coding was altered according to the requirement of accelerometer. The ADXL345 works with respect to the acceleration due to the gravity ( $g=9.8\text{m/s}^2$ ). Subsequently, the two gravitational values in two positions for the entire three axes were checked and then coded accordingly. The range of the acceleration of any axis ranges from  $+2g$  to  $-2g$  (where  $g$ = acceleration due to gravity). Figure 13 shows the two different positions of hands. In (a) the Jediglove is in working state along with values of acceleration of the 3-axis while in (b) the glove is in OFF state.



Figure 13: (a) ON state of glove ; (b) OFF state of glove

### **3.4 PROGRAMMING -ATmega328P MICROCONTROLLER**

The ATmega328P microcontroller integrated on Arduino Uno is coded using C++ language. However, the environment is limited so not all C/C++ features are used. The Arduino language can be divided into three main parts: function, values (variables and constants) and structure. The high-level programming language used in programming was compiled via Arduino compiler for any debug.

The coding of JediGlove has basically three essential points. First is the programming the ultrasonic sensor for calculation of distance shown below.

Code:

```
digitalWrite(trigPin, LOW);
delayMicroseconds(2);
digitalWrite(trigPin, HIGH);
delayMicroseconds(10);
digitalWrite(trigPin, LOW);
duration = pulseIn(echoPin, HIGH);
distance = duration*0.034/2; // distance calculation
```

Secondly, the coding related ADXL345 3-Axis Digital Acceleration for the purpose of controlling the vibrations from the motors with respect the positioning of the arm. Lastly, operating range with various vibration motors.

For instance, If the distance detected by the ultrasonic sensor is 125cm. After executing of the main part of the coding once, the loop portion initiates. According to the value of distance and acceleration due to gravity in Z-axis, the conditional statement in the coding is executed. Therefore, for the distance 125cm and acceleration in Z-axis in range, the following code will be implemented.

Code:

```
if(Z_g > 0.40 && Z_g <= 0.94) // conditional statement for positioning of hand in working
{
    // state
    if(distance >=71&& distance <=150){
        digitalWrite(motor2, HIGH); // Index finger motor will vibrate
    }
    else{
        digitalWrite(motor2, LOW);
    }
}
```

For the complete programming of JediGlove refer to Appendix A on this report.



## **CHAPTER 4: TESTING PROCEDURE**

### **4.1 TESTING OF JEDIGLOVE**

After the successful completion of fully working prototype of JediGlove, the testing was propagated. The testing on people was divided into two phases: the 1<sup>st</sup> phase was the evaluation of design and working by the people which have no major vision problem and 2<sup>nd</sup> phase consisted of user feedback from a blind person. The testing was carried out over 10 people including an impaired vision person. The testing phase continued for 1-2 months.

The 1<sup>st</sup> phase testing comprises of walking through a path which contains various obstacle in it with the help of glove. A brief description about the vibrations and distance ranges were given. At all times, the blindfolded person was accompanied by a person for safety reasons but no hindrance or help was created by the same person. At the end of the evaluation, the feedback in a form of questionnaire was provided to all the 10 people.

In case of 2<sup>nd</sup> phase testing, same process was performed. However, the patient here was a blind. Consequently, she was made aware with the ethical review information sheet process. As the results in this project are completely based on the evaluation and user feedback, the patient was given the ethical sheet to make her aware about the user testing. Furthermore, information sheet was developed according the norms of university hospital. To view the Ethical Review sheet, please refer to appendix B.

For final evaluation of the JediGlove, a class room was used as a set up. This class room was organized with various obstacles such as desks, chairs, round table etc. The corridor connecting to the door of class room was the starting of the path that was needed to be navigated. The main task for this evaluation was to reach to the target point which was the door where all the participants have to start. There two paths created which could have been used to complete the navigation. A descriptive map of the classroom from the table with the obstacles and paths can be seen in figure 14.

The 1<sup>st</sup> testing phase that included 9 blindfolded participants was the first group to try the test. For 2<sup>nd</sup> phase testing, a young female patient suffering from legal blindness due to diabetes complication was asked for evaluate the working of the glove and her feedback as a user was recorded. She can use white cane but she does not use it in public as it makes her

conscious of other people will be watching her. This motivated her to try the ergonomic Jediglove.

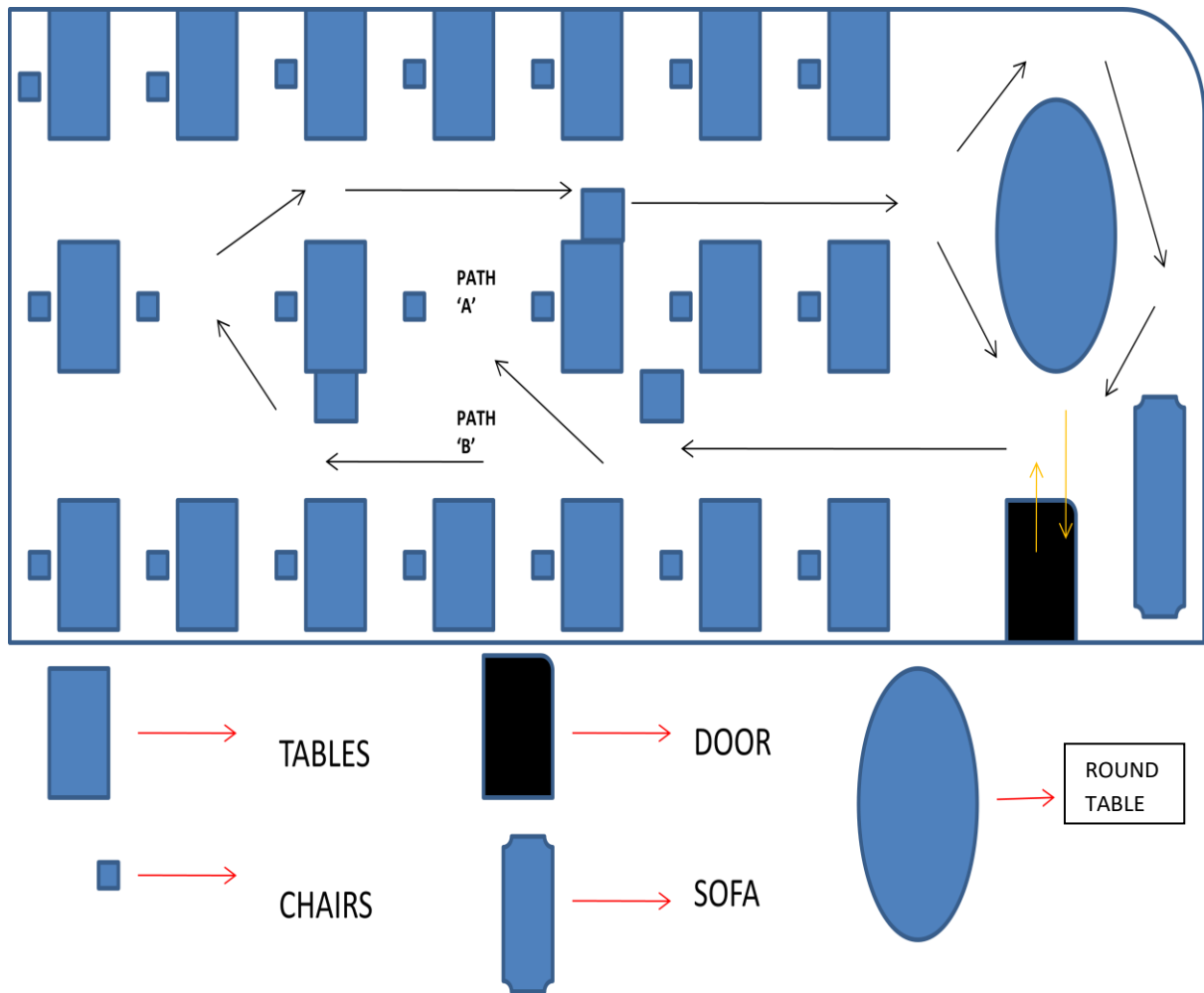


Figure 14: Top-View of the Classroom

With her permission to proceed, she was given the JediGlove to get familiar with the technology before using it for actual paths containing obstacles. Also, the evaluation was under the supervision of many people present there including her mother. The final look of JediGlove before user testing can be seen in figure 15.



Figure 15: Final Prototype of JediGlove

The outcome of the testing was quite successfully by all the 10 participants and the navigation was performed by using the glove by walking through the paths following the different vibration feedbacks on glove.

#### **4.2EXPERIMENTAL QUESTIONNAIRE**

Various questions were clubbed together which checked the usage, comfort and accuracy of the JediGlove. Table 2 below shows the statements asked in the questionnaire for the feedbacks from all the participants.

Q. No.	Question
1	Was it easy to use the JediGlove?
2	Did you feel any hindrance using the glove?
3	Did you feel any hindrance by the sound of vibration motor?
4	Were the vibrations made by the vibration motor easy to feel?
5	Was the system comfortable to use and wear?
6	Was the usage of JediGlove safe?
7	Was it tiring at the end of experiment?
8	Would I wear the JediGlove in public?
9	Did your target point reached?
10	Were you relied more on vibrations rather than vibration sounds?

Table 2: Questionnaire for the Feedback

## CHAPTER 5: RESULTS AND DISCUSSION

### 5.1 RESULTS

The testing comprising both the phases was completed after duration of 1-2 months. The valuable feedbacks from the 9 participants of the 1<sup>st</sup> testing phase were recorded and vital alterations were made throughout the 1<sup>st</sup> testing phase. Also, for the improved navigation for the 2<sup>nd</sup> testing phase on the blind which was the main objective. Table 3 shows the evaluation and feedbacks results from the 9 participants.

Participant Number and Gender	Path chosen for completion of evaluation	Frequency of collision with any of the obstacle	Percentage of <i>POSITIVE</i> Feedback on basis of questionnaire
1 (Male)	Path 'A'	8	80%
2(Male)	Path 'B'	10	70%
3(Male)	Path 'B'	12	60%
4(Female)	Path 'A'	9	80%
5(Male)	Path 'A'	7	80%
6(Female)	Path 'A'	7	70%
7(Male)	Path 'B'	10	70%
8(Male)	Path 'B'	8	70%
9(Female)	Path 'B'	6	90%

Table 3: Results of 1<sup>st</sup> Testing Phase

Here a positive answer to a question comprises of 10% of the total questionnaire. For instance, if a participant answers “YES” to the first question of the questionnaire which is “Was it is easy to use the JediGlove?” the feedback is considered as positive. So, for participant 9 (Female), 9 on 10 feedbacks were positive which was the highest in 1<sup>st</sup> testing phase. On the contrary, the participant 6 (Male) was the only person who did not reach the target point.

The feedback from the 2<sup>nd</sup> testing phase was 80% positive on basis of the questions asked. The blind female chose the path 'B' to reach the target point. Furthermore, the frequency of collision with the obstacle was recorded as 15.

## **5.2 DISCUSSION**

The users feedbacks from the 1<sup>st</sup> testing phase in which 9 participants were blindfolded were positive as majority of the people favoured in wearing the glove in public after certain enhancement. The feedbacks from all the 9 people allowed for the improvising the glove prototype for the 2<sup>nd</sup> testing phase. One such feedback was differences in sizes of hand. In general, the hands of females are small when compared to males. This feedback helped to change the positioning of the vibration motor from the tips of hand to the middle length of each finger. Due to another feedback, the material of the glove was altered. Initially the glove used was of wool quality which was later changed to leather.

Majority of the feedbacks were concerned related to the size of junction box in which the electronic elements were integrated. Nevertheless, this challenge could be overcome by using the surface mount technology that will ultimately reduce the size of the circuitry. In addition, many participants felt that they needed to be cautious for using the Jediglove for the first time. However, after getting familiar of the vibrations, almost every participant in the 1<sup>st</sup> testing group found the glove comfortable and easy to use.

Prof Sean Dinneen, a senior lecturer in Medicine, NUI Galway, Consultant Endocrinologist and National Lead for the Diabetes Clinical Programme gave his important feedback after evaluating which will be a potential challenge with this glove prototype. The technology involving vibrations in hand or feet could not be sensed by the blind patient suffering from Diabetes Neuropathy. In this disease, the nerves in hand and legs are damaged that causes numbness and loss of sensation [21]. This feedback helped in identification of a drawback of the JediGlove.

In case of the blind female, the feedbacks were optimistic. She established that the JediGlove was easy to use and did not over any hindrance. Also, the vibrations of the motor were straightforward in terms of sensations. In addition, she felt more freedom in using the JediGlove in comparison to white cane. She told that the JediGlove can be moved in all the directions to navigate was not possible with many of the major high technologies like Ultrasonic Spectacles and Waist-belt for Visually Impaired and Blind Person [14] and A Remote guidance system for blind and visually impaired people via Vibrotactile Haptic feedback [13]. Moreover, she implied that while using white cane, the obstacle above certain

level of ground can be judged whereas she was successfully able to figure out the obstacle in front of her reaching from ground level to her head.

In her feedback, she faced two main problems while using the JediGlove. Firstly, the vibrations in the little finger could be felt properly. Secondly, the reduced size of the box on top of the glove would make it easier to wear in public without noticing by the people around her.

### **5.3 FUTURE WORK**

In Future work, the development of multiple glove prototypes could be done which will increase the covering area. The next step to the JediGlove is to implement the principles of this glove into a “Vest” system. This vest can have haptic or vibration feedback on chest, both the shoulders and at the back side. In addition, this technique will also be able to help the blind people due to diabetic neuropathy as the patient loses glove and stocking sensations. However, an approach to use the concepts of JediGlove can be executed above the elbow level around the biceps.

Apart from the above stated, a proper clinical study evaluation of ‘JediGlove’ and ‘White Cane’ can be implemented. In this study, a number of participants (people suffering from vision loss) can use white cane initially for a certain period of time. Following it, the same group of people must use JediGlove for the same amount of time. Subsequently, a long study would be more beneficial in providing feedback and evaluation of glove extensively.

## CHAPTER 6: CONCLUSION

The JediGlove is a perfect example of coupling electronics, mechanical and software skills to create a successful navigation system glove prototype. The glove was successfully tested on 9 blind folded subjects and 1 blind female subject in an indoor environment. The prototype with a sufficient practice can be used for outdoor navigation also. The JediGlove is a complete and fully working prototype with positive evaluation and user feedback.

Advantages:

- Detection of obstacle in all the directions according to movement of hand.
- Can detect object below waist level.
- Non-invasive and minimal tiring.
- The time required for training is less.
- Low power consuming.
- Light in weight and low in cost.

Limitation:

- Will not work in case of diabetic neuropathy.
- Cannot identify the obstacle in the path.
- Cannot recognize colour.

In consideration of requirements by an impaired person, the JediGlove is an exceptional prototype that is low power consuming, light in weight, easily portable and integrated with high tech sensors and haptic feedbacks which will make lives of blind independent for navigational purposes. Further, the integrated circuit and junction box on top of glove can be replaced with the surface mounting technology. Thereby, reducing the complexity of circuit and making it lighter. Furthermore, all the files related to the JediGlove have been uploaded on the *GitHub* under the name of *JediGlove* as an *open source* material so it could be accessed by anyone and could be used to contribute in any new novel technologies.

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## APPENDIX A

### **Full Program of JediGlove:**

```
/* JediGlove - A new way of seeing Blindness

by Mouzzam Husain (19234423)

MSc in Biomedical Engineering

(Thesis Project)

*/

#include<Wire.h> // Wire library- used for I2C communication

int ADXL345 = 0x53; //I2C address of ADXL345

float X_g, Y_g, Z_g; // outputs

const int trigPin = 11; // Trigger pin of Ultrasonic sensor

const int echoPin = 13; // Echo pin of ultrasonic sensor

const int motor1 = 4; // Signal pin of vibration motor 1

const int motor2 = 9; // Signal pin of vibration motor 2

const int motor3 = 7; // Signal pin of vibration motor 3

const int motor4 = 8; // Signal pin of vibration motor 4

const int motor5 = 3; // Signal pin of vibration motor 5

long duration;
```

```

int distance;

void setup() {

pinMode(trigPin, OUTPUT); // output of ultrasonic sensor

pinMode(echoPin, INPUT); // input to ultrasonic sensor


pinMode(motor1, OUTPUT); // output of motor 1

pinMode(motor2, OUTPUT); // output of motor 2

pinMode(motor3, OUTPUT); // output of motor 3

pinMode(motor4, OUTPUT); // output of motor 4

pinMode(motor5, OUTPUT); // output of motor 5

Serial.begin(9600); // Initiate serial communication for

        //printing the results on serial monitor

Wire.begin();    // initiate the wire library

        // set ADXL345 in measuring mode

Wire.beginTransmission(ADXL345); //Start communicating with the device

Wire.write(0x2D);        // access to power control register-0x2D

Wire.write(8);           // (0000 1000) binary bit D3 high for measuring enable

Wire.endTransmission();

delay(10);

}

void loop() {

```

```

digitalWrite(trigPin, LOW);

delayMicroseconds(2);

digitalWrite(trigPin, HIGH);

delayMicroseconds(10);

digitalWrite(trigPin, LOW);

duration = pulseIn(echoPin, HIGH);

distance = duration*0.034/2; // distance calculation

Serial.print("Distance: ");

Serial.println(distance);

Wire.beginTransmission(ADXL345); // read accelerometer data

Wire.write(0x32);           //start with register 0x32

Wire.endTransmission(false);

Wire.requestFrom(ADXL345, 6, true); // read 6 registers total, each axis value is stored in 2
register

X_g = (Wire.read()|Wire.read() << 8); // X-axis value

X_g = X_g/256;

Y_g = (Wire.read()|Wire.read() << 8); //For a range of +2g to -2g,

//we need to divide the new values by 256

//according to the datasheet

Y_g = Y_g/256;           // Y-axis value

Z_g = (Wire.read()|Wire.read() << 8); // Z-axis value

Z_g = Z_g/256;

```

```

if(Z_g > 0.40 && Z_g <= 0.94){ // conditional statement for positioning of hand in working
state

if(distance >=351 && distance <=400){

    digitalWrite(motor5, HIGH); // Little finger motor will vibrate

}

else{

digitalWrite(motor5, LOW);

}

if(distance >=251 && distance <=350){

digitalWrite(motor4, HIGH); // Ring finger motor will vibrate

}

else{

digitalWrite(motor4, LOW);

}

if(distance >=151 && distance <=250){

digitalWrite(motor3, HIGH); // Middle finger motor will vibrate

}

else{

digitalWrite(motor3, LOW);

}

if(distance >=71 && distance <=150){

digitalWrite(motor2, HIGH); // Index finger motor will vibrate

```

```

}

else{

digitalWrite(motor2, LOW);

}

if(distance<=70){

digitalWrite(motor1, HIGH); // Thumb finger motor will vibrate

}

else{

digitalWrite(motor1, LOW);

}

}

else if(Z_g > -0.08 && Z_g <= 0.30){ // condition for position of hand in rest state

digitalWrite(motor1, LOW);

digitalWrite(motor2, LOW);

digitalWrite(motor3, LOW);

digitalWrite(motor4, LOW);

digitalWrite(motor5, LOW);

}

else{ // if neither of above are true

digitalWrite(motor1, LOW);

digitalWrite(motor2, LOW);

digitalWrite(motor3, LOW);

```



```
digitalWrite(motor4, LOW);  
  
digitalWrite(motor5, LOW);  
  
}  
  
delay(500);  
  
}
```

## APPENDIX B

### **Ethical Review Standard Application Form:**

# STANDARD APPLICATION FORM

ADAPTED VERSION (AUGUST 2018)

EDITED (31 August 2018)

For the Ethical Review of  
Health-Related Research Studies, which  
are not Clinical Trials of Medicinal  
Products For Human Use  
as defined in S.I. 190/2004

DO NOT COMPLETE THIS APPLICATION FORM  
IF YOUR STUDY IS A CLINICAL TRIAL OF A MEDICINAL PRODUCT

Title of Study: a new way seeing Blindness -  
JediGlove\_\_\_\_\_

Application Version No: \_\_\_\_\_

Application Date: \_\_\_\_\_

For Official Use Only – Date Stamp of Receipt by REC:

TABLE OF CONTENTS	MANDATORY /OPTIONAL
SECTION A GENERAL INFORMATION	MANDATORY*
SECTION B STUDY DESCRIPTORS	MANDATORY*
SECTION C STUDY PARTICIPANTS	MANDATORY*
SECTION D RESEARCH PROCEDURES	MANDATORY*
SECTION E DATA PROTECTION	MANDATORY*
SECTION F HUMAN BIOLOGICAL MATERIAL	(OPTIONAL)
SECTION G RADIATION	(OPTIONAL)
SECTION H MEDICAL DEVICES	(OPTIONAL)
SECTION I MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS	(OPTIONAL)
SECTION J INDEMNITY AND INSURANCE	MANDATORY*
SECTION K COST AND RESOURCE IMPLICATIONS, FUNDING AND PAYMENTS	MANDATORY*
SECTION L ADDITIONAL ETHICAL ISSUES	(OPTIONAL)

This Application Form is divided into Sections.

**\*Sections A, B, C, D, E, J and K are Mandatory.**

(Sections F, G, H, I and L are optional. Please delete Sections F, G, H, I and L if these sections do not apply to the application being submitted for review.)

**IMPORTANT NOTE:** Please refer to **Section I** within the form before any attempt to complete the Standard Application Form. **Section I** is designed to assist applicants in ascertaining if their research study is in fact a clinical trial of a medicinal product.

**IMPORTANT NOTE:** This application form permits the applicant to delete individual questions within each section depending on their response to the preceding questions. Please respond to each question carefully and refer to the accompanying *Guidance Manual* for more in-depth advice prior to deleting any question.

**PLEASE ENSURE TO REFER TO THE ACCOMPANYING GUIDANCE MANUAL  
WHEN COMPLETING THIS APPLICATION FORM.**

**SECTION A GENERAL INFORMATION**

**SECTION A IS MANDATORY**

**A1 Title of the Research Study:**

A new way of Seeing Blindness - JediGlove

**A2 (a) Is this a multi-site study?**

If you chose 'yes' please delete questions A2 (e) and (f), If you chose 'no' please delete Questions A2 (b) (c) and (d)

**A2 (e) If no, please name the principal investigator with overall responsibility for the conduct of this single-site study.**

**Title:**

**Name:** Derek O' Keeffe

**Qualifications:** Answer

**Position:** Answer

**Dept:** Answer

**Organisation:** Answer

**Address:** Answer

**Tel:** Answer

**E-mail:** Answer

**A2 (f) For single-site studies, please name the only site where this study will take place.**

University Hospital Galway

**A3. Details of Co-investigators:**

**Name of site (if applicable):** Answer

**Title:**

**Name:** Answer

**Qualifications:** Answer

**Position:** Answer  
**Dept :** Answer  
**Organisation:** Answer  
**Address:** Answer  
**Tel:** Answer      **E-mail:** Answer  
**Role in Research e.g. statistical / data / laboratory analysis:** Answer

**A4. Lead contact person who is to receive correspondence in relation to this application or be contacted with queries about this application.**

**Name:** Answer  
**Position:** Answer  
**Organisation:** Answer  
**Address for Correspondence:** Answer  
**Tel (work):** Answer      **Tel (mob.):** Answer      **E-mail:** Answer

**A5 (a) Is this study being undertaken as part of an academic qualification?**

If answer is No, please delete remaining questions in Section A

**A5 (b) If yes, please complete the following:**

**Student Name(s):** Mouzzam Husain  
**Academic Course:** MSc in Biomedical Engineering  
**Academic Institution:** National University of Ireland Galway

**A5 (c) Academic Supervisor(s):**

**Title:**       **Name:** Ted Vaughan  
**Qualifications:** Answer  
**Position:** Answer  
**Dept:** Answer  
**Organisation:** Answer  
**Address:** Answer  
**Tel:** Answer      **E-mail:** Answer

## SECTION B      STUDY DESCRIPTORS

SECTION B IS MANDATORY

**B1. What is the anticipated start date of this study?**

**B2. What is the anticipated duration of this study?**

9 month

**B3. Please provide a brief lay(plain English) description of the study. Please ensure the language used in your answer is at a level suitable for use in a research participant information leaflet.**

The project for Masters comprises of designing a working glove prototype that would help blind people in navigation eliminating the use of conventional white canes and guide dogs. The project is an evaluation and user feedback type.

**B4. Provide brief information on the study background.**

On global level, there are roughly 285 million visually impaired people consisting of all ages. Without medical advancements and efficacious inventions the number of blind people worldwide is estimated to escalate to 76 million by 2020 provided the existing run continues. There are for main causes of blindness that are glaucoma, diabetic retinopathy, age related macular degeneration and cataract. Numerous low technologies and high technologies devices are available in the markets which have proved to be of great assistance for sightless individuals. However, plethora of problems accompanies these advancements. Problems with details transmission generally involve reading and word identification. On the other hand, challenges with Motion assistance consists of more complex issues.

**B5. List the study aims and objectives.**

To design a functioning glove prototype for navigation. Furthermore, to create a glove for blind people that will be less costly, low power consuming and easy to use. In addition, minimizing the problems present with devices available in market.

**B6. List the study endpoints/ measurable outcomes (if applicable).**

**B7. Provide information on the study design.**

The designing of JediGlove is done with help of four main components that are ultrasonic sensor, vibration motors, accelerometer and AT328P microcontroller integrated in Arduino UNO.

**B8. Provide information on the study methodology.**

The microcontroller is programmed in such a manner that it will detect the distance via ultrasonic sensor and vibration is produced in the fingers/thumb according to the distance with help of vibration motors. The accelerometer is used to cut off the circuit when not in a running state.

**B9. Provide information on the statistical approach to be used in the analysis of your results (if appropriate) / source of any statistical advice.**

Answer

**B10 (a) Please justify the proposed sample size and provide details of its calculation (including minimum clinically important difference).**

Answer

**B10 (b) Where sample size calculation is impossible (e.g. it is a pilot study and previous studies cannot be used to provide the required estimates) then please explain why the sample size to be used has been chosen.**

Answer

**B11. How many research participants are to be recruited in total?**

10 participants.

**B12 (a) How many research participants are to be recruited in each study group (where applicable)? Please complete the following table (where applicable).**

Name of Study Group:	Name of Study Group:	Name of Study Group:	Name of Study Group:	Name of Study Group:
1 <sup>st</sup> testing Phase	2 <sup>nd</sup> testing phase	Answer	Answer	Answer
Number of Participants in this Study Group:	Number of Participants in this Study Group:	Number of Participants in this Study Group:	Number of Participants in this Study Group:	Number of Participants in this Study Group:
9	1	Answer	Answer	Answer

**B12 (b) Please provide details on the method of randomisation (where applicable).**

Answer

**B13. How many research participants are to be recruited at each study site (where applicable)? Please complete the following table.**

Site:	Number of Research Participants at this site:
UNIVERSITY HOSPITAL GALWAY	10

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## SECTION C STUDY PARTICIPANTS

### SECTION C IS MANDATORY

#### C1 PARTICIPANTS – SELECTION AND RECRUITMENT

##### C1.1 How will the participants in the study be selected?

The participants are selected on basis of their vision level.

##### C1.2 How will the participants in the study be recruited?

The emphasis of the project is to design a glove for blind individuals. Therefore, participants with very less vision are recruited.

##### C1.3 What are the inclusion criteria for research participants? (Please justify, where necessary)

Answer

##### C1.4 What are the exclusion criteria for research participants? (Please justify, where necessary)

Answer

##### C1.5 Will any participants recruited to this research study be simultaneously involved in any other research project?

#### C2 PARTICIPANTS – INFORMED CONSENT

##### C2.1 (a) Will informed consent to take part in the research be obtained?

C2.1 (b) If no, please justify. You must provide a full and detailed explanation as to why informed consent will not be obtained. Please note explicit consent to process personal data for research purposes is mandatory under the Data Protection Act 2018 (Section 36 (2)) (Health Research) Regulations unless the data is anonymous or a 'consent declaration' has been obtained.

The consent is not required in this project as it mainly includes an evaluation and user feedback of a glove prototype for blind people. However, all the participants were made aware of the ethical information and guidelines.

**C2.1 (c) If yes, please outline the consent process in full. (How will consent be obtained, when, by whom and from whom etc.)**

Answer

**C2.2 (a) Will participants be informed of their right to refuse to participate and their right to withdraw from this research study?** ☒ Yes

**C2.2 (b) If no, please justify.**

Answer

**C2.3 (a) Will there be a time interval between giving information and seeking consent?** ☐ No

**C2.3 (b) If yes, please elaborate.**

Answer

**C2.3 (c) If no, please justify and explain why an instantaneous decision is reasonable having regard to the rights of the prospective research participants and the risks of the study.**

The using time of the device is very less. Thereby, feedback required will be very quick. Consequently, instantaneous decision is reasonable.

### **C3 ADULT PARTICIPANTS (AGED 18 OR OVER) - CAPACITY**

**C3.1 (a) Will all adult research participants have the capacity to give informed consent?** ☒ Yes

### **C4 PARTICIPANTS UNDER THE AGE OF 18**

**C4.1 (a) Will any research participants be under the age of 18 i.e. Children?** ☐ No

### **C5 PARTICIPANTS - CHECKLIST**

**C5.1 Please confirm if persons from any of the following groups will participate in this study. This is a quick checklist to assist research ethics committee members and to identify whether study participants include persons from vulnerable groups and to establish what special**



**arrangements, if any, have been made to deal with issues of consent. It is recognised that not all groups in this listing will automatically be vulnerable or lacking in capacity. Please refer to the HSE's National Consent Policy, particularly Part 3, Section 5.**

**Committees are particularly interested to know if persons in any of these groups are being targeted for inclusion, as per the inclusion criteria.**

**(a) Healthy Volunteers**

**(b) Patients**

- **Unconscious patients**
- **Current psychiatric in-patients**
- **Patients in an emergency medical setting**

**(c) Relatives / Carers of patients**

**(d) Persons in dependent or unequal relationships**

- **Students**
- **Employees / staff members**
- **Persons in residential care**
- **Persons highly dependent on medical care**

**(e) Intellectually impaired persons**

**(f) Persons with a life-limiting condition**

*(Please refer to guidance manual for definition)*

**(g) Persons with an acquired brain injury**

**C5.2 If yes to any of the above, please comment on the vulnerability of the research participants, and outline the special arrangements in recognition of this vulnerability (if any).**

**C5.3 Please comment on whether women of child-bearing potential, breastfeeding mothers, or pregnant women will be included or excluded in this research study.**

## SECTION D IS MANDATORY

**D1 (a) What activities, procedures or interventions (if any) are research participants asked to undergo or engage in for the purposes of this research study?**

Participants are asked to wear a device which is of a glove type and walk through a path including some obstacles blindfolded using it.

**D1 (b) What other activities (if any) are taking place for the purposes of this research study e.g. chart review, sample analysis etc?**

The feedbacks on basis of using the glove prototype are collected.

**D2. Please provide details below of any potential harm that may result from any of the activities, procedures, interventions or other activities listed above.**

All the participants, at all times were under supervision. However, collision with an obstacle may take place but the risk major harm is not present.

**D3. What is the potential benefit that may occur as a result of this study?**

The positive feedbacks from this study may lead to development of a next level vest prototype for blind people which will use the same technology and principle as the JediGlove.

**D4 (a) Will the study involve the withholding of treatment?**

Non-applicable

**D4 (b) Will there be any harms that could result from withholding treatment?** No

**D4 (c) If yes, please elaborate.**

Answer

**D5 (a) How will the health of participants be monitored during the study, and who will be responsible for this?**

All the participants while doing their task were accompanied by me or my supervisor. This is a solo project. I am solemnly responsible.

**D5 (b) How will the health of participants be monitored after the study, and who will be responsible for this?**

Initially, just after the experiment the health was monitored. However, after the study the participants are responsible for themselves.

**D6 (a) Will the interventions provided during the study be available if needed after the termination of the study?**

**D6 (b) If yes, please state the intervention you are referring to and state who will bear the cost of provision of this intervention?**

Answer

**D7. Please comment on how individual results will be managed.**

The results in this project are the feedbacks from the participants. Individual questionnaire will be provided.

**D8. Please comment on how aggregated study results will be made available.**

The thesis of this project will be available on open source.

**D9. Will the research participant's general practitioner be informed that the research participant is taking part in the study (if appropriate)?**

**D10. Will the research participant's hospital consultant be informed that the research participant is taking part in the study (if appropriate)?**

## SECTION E DATA PROTECTION

SECTION E IS MANDATORY

### E1 DATA PROCESSING - CONSENT

**E1.1 (a) Will explicit consent be sought for the processing of data?**

**E1.1 (b) If no, please elaborate. Please note explicit consent is mandatory under the Data Protection Act 2018 (Section 36 (2)) (Health Research) Regulations 2018 unless the data is anonymous or a 'consent declaration has been obtained'**

The study is an evaluation and on feedback based.

**YOU MUST ANSWER ALL QUESTIONS IN THIS SECTION AS THEIR FULFILLMENT IS A MANDATORY REQUIREMENT UNDER THE DATA PROTECTION ACT 2018 (SECTION 36(2)) (HEALTH RESEARCH) REGULATIONS 2018**

**E2.1 Please specify which arrangements are in place to ensure that personal data will be processed as is necessary; a) to achieve the objective of the health research and; b) to ensure that shall not be processed in such a way that damage or distress to the data subject?**

N/A

**E2.2 Please specify the data controller; joint data controllers (if applicable) and any data processors involved in the research.**

N/A

**E2.3 Please specify any person or organisation who provides funding for, or otherwise supports, the project.**

N/A

**E2.4 Please specify any person other than the named data controller, joint controllers or processors with whom it is intended to share any of the personal data collected (including where it has been pseudonymised or anonymised) and the purpose of such sharing.**

N/A

**E2.5 The provision of training in data protection law and practice to anyone involved in carrying out the health research is a mandatory legal requirement. Please specify the provision of training.**

N/A

**E2.6 Has a "risk assessment" and/or "data protection impact assessment" been carried out, taking in to account local policy and/or legal requirements?**

N/A

**E2.7 Please specify the measures in place that demonstrate compliance with the data minimisation principle (Is it adequate, relevant and limited to what is necessary?)**

N/A

**E2.8 Please specify the controls in place to limit access to the personal data undergoing processing in order to prevent unauthorised consultation, alteration, disclosure or erasure of personal data.**

N/A

**E2.9 Please specify the controls in place to log whether and by whom personal data has been consulted, altered, disclosed or erased.**

N/A

**E2.10 Please specify measures to protect the security of the personal data concerned.**

N/A

**E2.11 Please specify the arrangements to anonymise, archive or destroy personal data once the health research has been completed.**

N/A

**E.2.12 Please specify other technical and organisational measures designed to ensure that processing is carried out in accordance with the Data Protection Regulation, together with processes for testing and evaluating the effectiveness of such measures.**

N/A

**E2.13 Please specify which arrangements are in place to ensure that personal data is processed in a transparent manner.**

N/A

## **E3 DATA PROCESSING - GENERAL**

**E3.1 What media of data will be collected?**

N/A

**E3.2 (a)** Would you class the data collected in this study asanonymous, pseudonymised, coded or identifiable data?

N/A

**E3.2 (b)** If '**PSEUDONYMISED**', please confirm who will retain the 'key' to re-identify the data?

N/A

**E3.3** Where will data which is collected be stored?

N/A

**E3.4 (a)** Will data collected be at any stage leaving the site(s) of origin?

Yes / No

**E3.4 (b)** If yes, please elaborate.

N/A

**E3.5** Where will data analysis take place and who will perform data analysis (if known)?

N/A

**E3.6(a)** After data analysis has taken place, will data be retained?

No

**E3.6(b)** If **yes**, for how long, for what purpose, and where will it be retained?

N/A

**E3.7** Please comment on the confidentiality of collected data.

N/A

**E3.8 (a)** Will any of the interview data collected consist of audio recordings / video recordings? Yes

**E3.9(a)** Will any of the study data collected consist of photographs/ video recordings? Yes

**E3.9 (b) If yes, please elaborate.**

Video recording of working of the glove prototype.

**E4 ACCESS TO HEALTHCARE RECORDS**

**E4.1 (a) Does the study involve access to healthcare records (hard copy / electronic)?**

If answer is No, please delete remaining questions in Section E3

Consent is required from the patient to access healthcare records for research purposes unless a 'consent declaration' has been granted or the records are anonymous

If answer is Yes, please delete remaining questions in Section E3

**SECTION F HUMAN BIOLOGICAL MATERIAL**

**F1 BODILY TISSUE / BODILY FLUID SAMPLES - GENERAL**

**F1 1 (a) Does this study involve human biological material?**

If the answer is No, please delete Section F

**SECTION G RADIATION**

**G1 RADIATION – GENERAL**

**G1.1 (a) Does this study/trial involve exposure to radiation?**

**SECTION H MEDICAL DEVICES**

**H1 (a) Is the focus of this study/trial to investigate/evaluate a medical device?**

If answer is No, please delete remaining questions in Section H.

**H1 (b) If yes, what is the name of the medical device or device nomenclature (system of naming the medical device)?**

JEDIGLOVE

**H1 (c) If yes, please provide a general description of the medical device.**

The device contains an integrated circuit mounting on a glove inside a junction box to protect the circuit from outer environment. From this box an ultrasonic module and five vibration motors are bulging out. The inside of box has a battery, an Arduino UNO, a bread board for connections and an accelerometer.

<b>H2 (a) Does the device have a CE mark?</b>	
No	
<b>H2 (b) If the device has a CE mark, is it proposed to use the device within the terms of its CE mark or outside the terms of its CE mark?</b>	<b>H2 (e) If the device does not have a CE mark, is this study being undertaken for the purposes of obtaining a CE mark?</b>
Within / Outside	No
<b>H2 (c) If outside, please elaborate:</b>	
Answer	
<b>H2 (d) CE MARK NUMBER:</b>	
Answer	

**H3 (a) Is this an application to conduct a clinical investigation of a medical device?** No

**H3 (b) If yes, will the Medical Devices section of the Health Products Regulatory Authority (HPRA) be reviewing this study?** No

## SECTION I MEDICINAL PRODUCTS / COSMETICS / FOOD AND FOODSTUFFS

### I.1 NON-INTERVENTIONAL TRIALS OF MEDICINAL PRODUCTS

**I1.1 (a) Does this study involve a medicinal product?** No

**I1.2 (a) Is this an application to conduct a non-interventional trial of a medicinal product?** No



**I1.2 (b) Is this trial a post-authorisation safety study?**

## **I.2 COSMETICS**

**I2.1 (a) Does this study involve a cosmetic?**

If the answer is No, please delete remaining questions in subsection I2

## **I.3 FOOD AND FOOD SUPPLEMENTS**

**I3.1 (a) Does this study involve food or food supplements?**

If the answer is No, please delete remaining questions in subsection I3

## **SECTION J INDEMNITY AND INSURANCE**

### **SECTION J IS MANDATORY**

**J1 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study at each site.**

N/A

**J2 Please confirm and provide evidence that appropriate insurance/indemnity is in place for this research study for each investigator.**

N/A

**J3.1 Please give the name and address of the organisation / or individual legally responsible for this research study?**

N/A

**J3.2 Where an organisation is legally responsible, please specify if this organisation is:**

**A pharmaceutical company**

**A medical device company**

**A university**

**A registered charity**

**Other**  **If yes, please specify:**

**J3.3 Please confirm and provide evidence of any specific additional insurance / indemnity arrangements which have been put in place, if any, by this organisation / or individual for this research study?**

N/A

## SECTION K COST AND RESOURCE IMPLICATIONS, FUNDING AND PAYMENTS

### SECTION K IS MANDATORY

#### K1 COST AND RESOURCE IMPLICATIONS

**K1.1 Please provide details of all cost / resource implications related to this study (e.g. staff time, office use, telephone / printing costs etc.)**

N/A

#### K2 FUNDING

**K2.1 (a) Is funding in place to conduct this study?**

No

**K2.1 (b) If no, has funding been sought to conduct this study? From where? Please elaborate.**

N/A

**K2.1 (c) If yes, please state the source of funding (industry, grant or other), the name of the funder, the amount of funding and duration of funding.**

<b>Source of funding (industry, grant or other):</b>
N/A
<b>Name of Funder:</b>
<b>Amount of Funding:</b>
<b>Duration of Funding</b>

**K2.1(d) Please provide additional details in relation to management of funds.**

N/A

**K2.1(e) Is the study funded by a 'for profit' organisation?**

**K2.2 (a) Do any conflicts of interest exist in relation to funding or potential funding?**

**K2.2 (b) If yes, please elaborate.**

N/A

### K3 PAYMENTS TO INVESTIGATORS

**K3.1 (a) Will any payments (monetary or otherwise) be made to investigators?**

**K3.1 (b) If yes, please provide details of payments (including amount).**

N/A

### K4 PAYMENTS TO PARTICIPANTS

**K4.1 (a) Will any payments / reimbursements (monetary or otherwise) be made to participants?**

**K4.1 (b) If yes, please provide details of payments / reimbursements (including amount).**

N/A

## SECTION L ADDITIONAL ETHICAL ISSUES

**L1 (a) Does this project raise any additional ethical issues?**

If answer is No, please delete remaining questions in Section L.

PLEASE ENSURE THIS APPLICATION FORM IS FULLY COMPLETED AS INCOMPLETE SUBMISSIONS WILL NOT BE REVIEWED.

We acknowledge the work of the Beaumont/RCSI Ethical Committee and Ms. Mary Kirwan in updating this application form.

## APPENDIX C

### **Bill of Materials:**

PARTS NAME	STOCK NUMBER	PRICE	QUANTITY
Seed studio 1010200010 Ultrasonic Ranger for Gove system	RS electronics- 1743238	€ 15.29	1
Grove- Vibration Motor	RS electronics- 1845108	€ 3.20	5
Arduino Yno DIP V3 Arduino starter Kit- K000007	RS electronics- 7617355	€94.66	1
GY291 ADXL345 3- Axis Digital Acceleration	Irish Electronics- GY291	€ 4.69	1
PP3 9V Battery clip Snap on connector 145mm cable lead	Irish Electronics- PP3 9V Battery clip	€ 0.50	1
Zinc Chloride PP3 battery	Irish Electronics- 2211	€ 0.90	1
GW 44206 150X110X70 IP56 BOX	Product code- 0640122	€ 6.40	1