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Evaluating the Performance of an Ergonomic Contactless Mouse for Disabled People Using the FMEA Approach

Authors: Yuv Singhal[1], Amey Chavan[2]

Affiliation: Student, Dhirubhai Ambani International School, Mumbai[1]; Mentor, On My Own Technology[2]

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ABSTRACT

The Free Hand Mouse is an ergonomic, contactless, and wearable mouse designed for use by people with mobility issues in their upper limbs and people who do not have functional fingers, hands, or forearms. Standard computer mouse require fine motor skills and precise hand movements and are therefore not usable by large segments of the global disabled population, which counts over 1.3 billion people. Other assistive technology, such as eye-tracking and voice-command systems, is accessible but not affordable and overly sensitive to their environments or is not user-friendly for routine computer tasks.

The innovative gadget is a wrist or elbow-mounted design, and functions as a tilt-based cursor mover, using the InvenSense MPU-6050 IMU. The design also features a PixArt PAJ7620U2, which senses gestures to identify clicks. The included microcontroller, a Seeed XIAO ESP32-C3, wirelessly sends input commands through Bluetooth Low Energy (BLE) as a Human Interface Device (HID). The design improves user adoption and utility by including a secondary smartwatch design, along with a 1.3-inch OLED display. The developmental process is a simple, structured iterative journey, utilising conceptual design and ideation, the bill of materials, embedded firmware, breadboard prototyping, schematic design, CAD modelling, FDM 3D printing, and soldering. The systematic method for identifying and prioritising failure risks and defining actions to reduce those risks, Failure Mode and Effects Analysis (FMEA), has been applied across eight key subsystems. Design changes were made based on the RPN and corresponding severity, occurrence, and detection ratings. Initial user tests showed greater than expected control of the cursor, response times that were within expected limits, and fair to good ergonomic ratings. The Free Hand Mouse is an assistive technology for HCI that is low-cost, easy to manufacture, and ergonomic, and has the potential to be further improved and clinically validated.

Keywords: *assistive technology, contactless mouse, wearable computing, MPU6050, gesture recognition, FMEA, ergonomics, BLE HID, upper-limb disability*

1. INTRODUCTION

Computers have become central in today's world for education, work, healthcare, and social engagement, due to the accelerated growth of digital technologies. Their use has, however, created barriers for those with upper-limb disabilities due to reliance on a traditional input device. The World Health Organisation (2023) estimates that of the 1.3 billion disabled individuals globally, a large percentage have limited motor control of their hands and forearms. Conventional pointing devices prove to be a challenge for individuals who have had upper limb amputations due to injury, cancer, or vascular disease, as well as those with congenital limb differences.

Existing assistive input technologies use different modalities in trying to solve this problem. Touch-based interfaces require users to touch the screen and make precise spatial selections. Voice control is hands-free, but in many instances, users report concerns regarding privacy, sensitivity to background noise, and the cognitive burden associated with voice commands to complete visual or spatial tasks. Eye-tracking is one of the more accurate solutions, but it is easily priced at $2,000 to $6,000, restricting it to only high-income users or users in developed countries. Head-mouse solutions and switch scanning systems require lengthy training and lack natural interaction.

Consequently, the challenge is to conceptualize and create an affordable and easy-to-use computer mouse alternative that involves no fine finger motor control, is designed to be worn comfortably on the wrist or elbow, and provides complete mouse functionality, including the ability to control the mouse cursor and perform clicking actions. The Free Hand Mouse utilizes the challenge of bringing an IMU and advanced optical gesture recognition technology within the scope of a miniature 3D-printed device. The MPU-6050 records the gyroscope and accelerometer's cursor movement to determine the direction and to which the wrist is tilted, and the PAJ7620U2 determines the left and right tilt gestures and triggers the corresponding click actions. The Seeed XIAO ESP32-C3 is responsible for the Bluetooth Low Energy (BLE) connection and operates as a standard HID mouse; no custom drivers are required, and transmits all of the aforementioned user inputs to the computer.

Most importantly, this study utilizes Failure Mode and Effects Analysis (FMEA) methodology. FMEA is a systematic tool for predicting risks and analyzing the reliability and potential risks of a designed system. It is most commonly used in the engineering domain, such as automotive, aerospace and medicine. FMEA identifies potential risks, predicts the impact of the risk to the system, and prioritises corrective measures based on Risk Priority Numbers (RPN). Therefore, this study ensures that a wearable assistive device remains functional, safe, and reliable for those in the most critical situations.

The structure of this paper is as follows: The first (2) section synthesises existing literature on assistive input devices, IMU-based control systems, and gesture recognition. The third (3) section describes the design and development of the device. The fourth (4) section presents FMEA. The fifth (5) section evaluates the device and discusses results from preliminary testing. The sixth (6) section summarises the contribution of this study and presents future scopes for this study.

2. LITERATURE REVIEW

2.1 Assistive Input Devices for Motor-Impaired Users

Assistive Human-Computer Interaction device research has resulted in many different types of input methods to be used for varying levels of motor impairment. Keates and Clarkson (2003) argued against a single device for a single disability spectrum and instead laid the groundwork for the categorization of input devices based on the level of remaining motor skill needed to use the device. The spectrum can include foot-operated mouse, sip-and-puff switches, and brain-computer interfaces (BCIs). Recent research has shown the use of wearable sensor devices in the mid-range of that spectrum for most amputees with upper-limb amputations (Patel et al. 2019).

Kumar et al. (2021) assessed the commercially available adaptive mouse, including the Evoluent VerticalMouse, Contour RollerMouse, and the Jouse joystick interface. While these devices were designed to reduce the need for a precision grip, they still required some hand or finger use. Therefore, the authors proposed that for people with total bilateral upper limb amputations, the only remaining option for independent computer use is through the design of non-contact sensing methods. This is further motivation for designing the Free Hand Mouse.

2.2 Gesture-Based Control Systems

Gesture recognition offers an intuitive approach to human-computer interaction that improves upon traditional button-press interfaces. Mitra and Acharya (2007) provided an overview on gesture-based HCI and identified body, hand, and facial gestures. Recognition of hand gestures, in particular, has seen improved recognition due to more sophisticated computer vision and sensor technologies. Optical sensors can also be integrated into wearable technology. An example of this is the PAJ7620U2 from PixArt Imaging, which utilises a proprietary algorithm to identify six directional motions and has a very low power consumption profile.

An example of an even more advanced wearable interface technology is described by Kela et al. (2006). They demonstrated a wrist-worn gesture interface that achieved greater than 90% recognition of a set of eight gestures. The study focused on the separation of intentional from non-intentional wrist activities, which was a central element to achieving this high recognition rate. This observation is a direct motivation for the TILT_ANGLE parameter that is implemented in the Free Hand Mouse firmware.

2.3 Inertial Measurement Units in Wearable Computing

Gesture recognition offers an intuitive approach to human-computer interaction that improves upon traditional button-press interfaces. Mitra and Acharya (2007) provided an overview of gesture-based HCI and identified body, hand, and facial gestures. Recognition of hand gestures, in particular, has seen improved recognition due to more sophisticated computer vision and sensor technologies. Optical sensors can also be integrated into wearable technology. An example of this is the PAJ7620U2 from PixArt Imaging, which utilises a proprietary algorithm to identify six directional motions and has a very low power consumption profile.

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2.4 Wearable Computing and Ergonomic Design

Using devices for long periods of time comes with some safety concerns, and good ergonomics design can help ensure safety and long-term use. According to Knight and Baber (2005), five ergonomic concerns for wrist devices are: how the weight is distributed, how much pressure is put on the skin, how much the device creates thermal discomfort, how much the device obstructs limb movement, and how easy the device is to put on and remove. Their recommendations state that devices that are worn on the wrist should never weigh more than 50 grams. Additionally, they should have closures that allow for variation in limb circumference. The Free Hand Mouse is a prototype that weighs 35 grams, and the elastic nylon band used satisfies this adjustability.

Device functionality is not the sole factor to consider in the adoption of the device. In a study by Rogers et al. (2018), the focus of the study was on aesthetics and the use of the device. This was evidenced by the focus of the study on upper-limb amputees. This study found that potential users were reluctant to use the device because the device was too medically oriented. The design of the Free Hand Mouse is meant to help with diverting a user's attention by including an OLED clock display on the device, which helps certify that the device is a smartwatch in social contexts.

2.5 Human-Computer Interaction and Disability

Accessibility of digital technologies has been implemented through Universal Design and Integrated Design, including WCAG 2.2 and ISO 9241-171, respectively. Newell and Gregor (2000) first proposed the concept of Extra-Ordinary HCI, focusing on the design for the most extreme users of the HCI systems, such as users with severe motor disabilities. This concept is analogous to the curb-cut effect, where designing accessibility features benefits the overall, not just the targeted, population. This means the Free Hand Mouse can be seen as an assistive product, but potentially also for contactless gesture-based computing.

Empirical studies of mouse users with motor disabilities conducted by Trewin et al. (2006) identify cursor overshoot, unintentional double-clicking, and dragging as the most relevant usability problems. Design of the Free Hand Mouse addresses the latter two of these problems through the IMU tilt-speed scaling algorithm and the gesture sensor click threshold. Dragging, which is a required design feature, is potentially solvable through a hold-gesture command.

2.6 Failure Mode and Effects Analysis (FMEA) in Product Design

FMEA is a bottom-up methodology for conducting systematic risk analysis originally created by the U.S. military in the 1940s (MIL-P-1629,1949) and later used in civilian manufacturing, medical devices, and software engineering. For electro-mechanical consumer products, FMEA involves identifying all the possible failure modes at the component and sub-system level, hypothesising possible causes, assessing what the higher-level system functions would be, and calculating an RPN by multiplying the three parameters of Severity (S), Occurrence (O), and Detection (D) on a scale of 1 to 10.

Stamatis (2003) expanded traditional FMEA to include a design FMEA (DFMEA) and process FMEA (PFMEA), where DFMEA deals with design-related risks, and PFMEA focuses on manufacturing and assembly-related risks. The current study uses DFMEA to analyze the electronic and mechanical failures that could occur during normal usage. FMEA was applied in the first place to Shahin's (2004) wrist-band type continuous monitoring of health status. Based on 42% reduction of the field failure of the cardiac monitoring wrist band product due to the redesign of the product based on proactive RPN, Shahin's work is a strong motivation for the FMEA application for the Free Hand Mouse to design reliability improvement prior to wider clinical or commercial usage.

3. METHODOLOGY

The first prototype for the Free Hand Mouse was developed using a defined iterative engineering design process and completed successive design and prototype cycles in the following order: design and ideation, materials and components selection, design the firmware to prototype the electronics on a breadboard, mechanical design and prototype, and then fully integrate and assemble the prototype. Each successive step incorporated inputs from the design, and outputs from the accompanying FMEA design process were used to adjust design and choices in earlier steps.

3.1 Device Design Overview

Free Hand Mouse is designed to function as a wrist or elbow-mounted band with miniaturized electronics housed in a 3D-printed polymer enclosure. The device connects to the host computer via Bluetooth Low Energy (BLE), and then as a plug-and-play standard HID mouse—no software needs to be installed on the host. The user controls the computer cursor through wrist or forearm movements in the direction of the cursor. The users initiate the left and right mouse clicks by performing left and right tilt gestures, which are detected by the PAJ7620U2 optical gesture sensor. A 1.3-inch OLED display on the device face shows the current time and date, providing everyday utility independent of computer interaction.

The system is designed in a three-layer stack. First, the Physical Sensing Layer includes the MPU-6050 and PAJ7620U2 sensors. They communicate with the ESP32-C3 over I2C. The second layer, the Processing and Communication Layer, has the ESP32-C3, which manages sensor fusion and applies thresholds and scales algorithms. It also transmits Human Interface Device (HID) mouse reports via Bluetooth Low Energy (BLE). The last layer is the Power Management Layer, which is comprised of a 150mAh Lithium-Polymer (Li-Po) battery, a TP4056 charging module with protection circuitry and an on/off switch. The design is modular, which allows for independent subsystem testing and system upgrades without the need for a complete redesign.

3.2 Components Used

Table 1 presents the full bill of materials for the Free Hand Mouse prototype, including component designations, specifications, functions, and quantities. All components were selected to minimise cost, volume, and power consumption while meeting the functional requirements of the device.

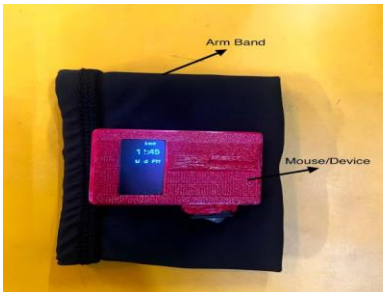


Figure 1: The Free Hand Mouse prototype — wrist-mounted band with OLED display and electronics module

Table 1: Bill of Materials — Free Hand Mouse Components

Component	Model / Specification	Function	Quantity
Microcontroller	Seeed XIAO ESP32-C3	Main processing unit; handles BLE HID mouse protocol, sensor data fusion, and time display	1
IMU Sensor	InvenSense MPU-6050	6-axis gyroscope + accelerometer for measuring wrist tilt angles to control cursor movement	1
Gesture Sensor	PixArt PAJ7620U2	Recognises directional hand gestures for left-click and right-click input via I2C	1
Battery	Li-Po 3.7V, 150 mAh	Rechargeable lithium polymer cell providing portable power to the wearable device	1
Charging Module	TP4056 with DW01A protection	USB-based Li-Po battery charging circuit with overcharge and short-circuit protection	1
Display	1.3-inch OLED SH1106 (I2C, 4-pin)	Shows real-time clock and date; provides secondary smartwatch functionality	1
Status Indicator	5mm LED (blue)	Visual indicator for Bluetooth connectivity status and device power state	1
Enclosure	PLA/PETG 3D Printed Casing	Custom CAD-designed housing fabricated via FDM 3D printing for compact integration	1
Band	Elastic Nylon Arm Band	Wrist or elbow mounting mechanism; adjustable strap with velcro closure	1

3.3. Operating Principle

The Free Hand Mouse's primary operating principle revolves around the tracking of the user’s wrist position, using the MPU-6050 to translate position data into velocity vectors, which gives cursor movement its direction. The MPU-6050 employs a tri-axial design, which means it collects data in three different directions for both rotational movement (gyroscope) and directionless movement (accelerometer). This data can be collected at a rapid fire rate of one thousand times per second. The launch design employs a complementary filter to stabilise the data collected from both movement sensors of the MPU6050 to avoid both the high-frequency disturbances and long-term data drifts.

The pitch data computed controls the user’s cursor movement in the vertical direction. The roll data computed controls the cursor movement in the horizontal direction. The data collected can be speed adjusted to reduce movement at the velocity of one-tenth, which means that only one pixel of the cursor will be displaced per time reporting interval. Additionally, the design employs a dead zone threshold to reduce cursor movement. When the device is positioned level, the cursor should remain still, which will act as a hold threshold for the cursor movement. The design includes a PAJ7620U2 gesture sensor, which collects data on hand movement and uses BLE (Bluetooth Low Energy) to control left-click and right-click functions of the mouse. The ESP32-C3 merges multiple data sources into one report for the mouse cursor, which is updated 30 times every second (30 Hz). This provides a total time of less than 35 milliseconds to respond to a cursor movement request from the user's wrist control the mouse movement, passing the 50milliseconds requirement design delay.

3.4 Development Process

3.4.1 Ideation Phase

Starting the design process involved a detailed brainstorming session focused on outlining potential use cases and user and technical constraints. The team created a conceptual design of a rounded enclosure attached to a wrist band that has a scroller and a central component housing. This design guided the spatial arrangement of internal components and served to define the volumetric constraints for the enclosure CAD model. Simultaneously, a bill of materials was prepared, and component datasheets were verified to cross-reference I2C address collations, voltage rail routings, and footprints that would fit the given enclosure design volume.

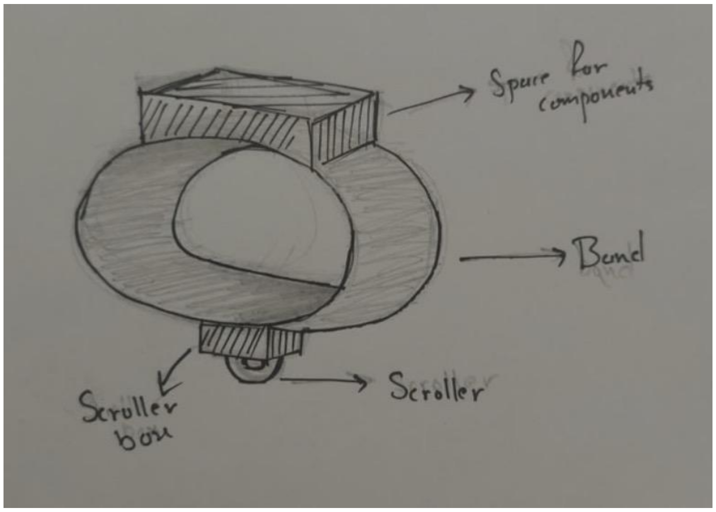


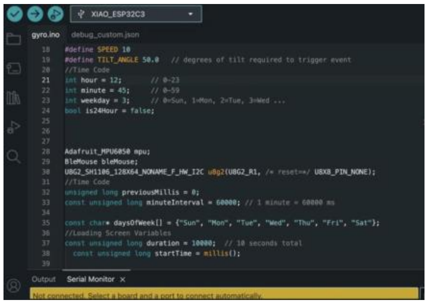
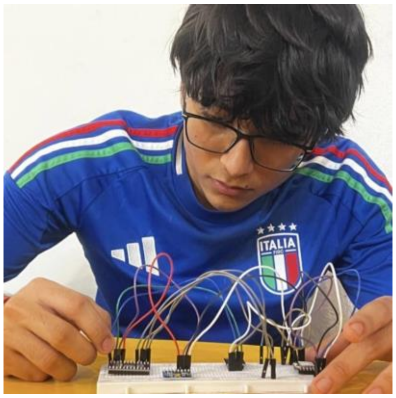
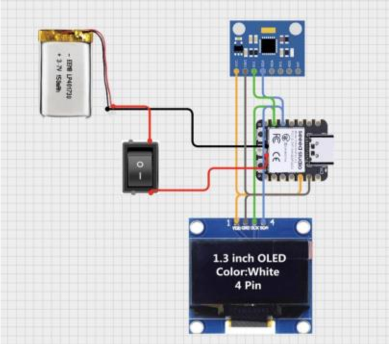
Figure 2: Ideation phase — conceptual sketch of the wearable device

Table 2: Initial bill of materials

Component Name	Quantity
XIAO ESP32 C3	1
MPU6050	1
OLED	1
PAJ7620U2	1
TP4056	1
LIPO Battery	1

3.4.2 Firmware Development and Breadboard Prototyping

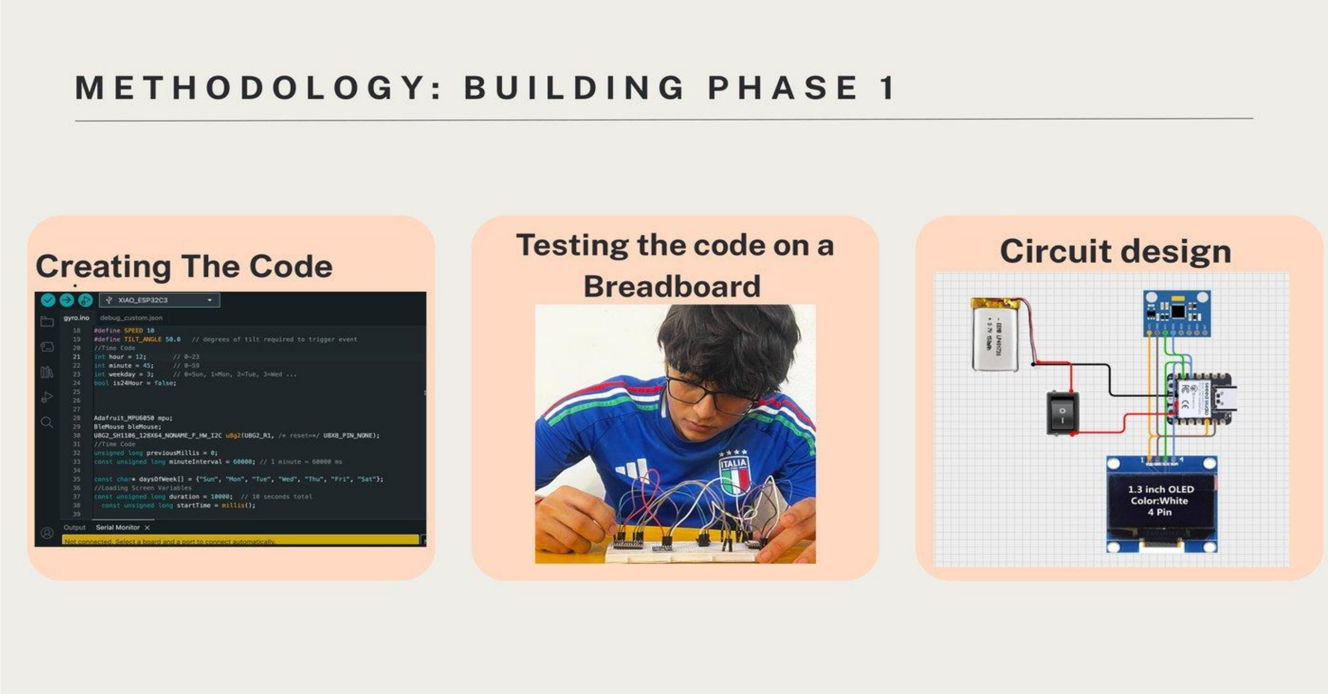
The firmware was developed in the Arduino IDE, targeting the XIAO ESP32-C3 board profile. Development proceeded in functional modules: clock and timekeeping logic using the millis() counter, OLED display rendering using the U8g2 graphics library, MPU-6050 sensor reading and complementary filter using the Adafruit_MPU6050 library, PAJ7620U2 gesture detection, and BLE HID mouse implementation using the BleMouse library. Each module was written, tested, and debugged individually on a breadboard before integration. The breadboard prototype enabled rapid iteration of the TILT_ANGLE threshold, the speed multiplier, and the gesture detection confidence filter without requiring any soldering.

		
(a)	(b)	(c)

```
#define SPEED 10
#define TILT_ANGLE 50.0   // degrees of tilt required to trigger event
//Time Code
int hour = 12;        // 0-23
int minute = 45;      // 0-59
int weekday = 3;      // 0=Sun, 1=Mon, 2=Tue, 3=Wed ...
bool is24Hour = false;



Adafruit_MPU6050 mpu;
BleMouse bleMouse;
U8G2_SH1106_128X64_NONAME_F_HW_I2C u8g2(U8G2_R1, /* reset=*/ U8X8_PIN_NONE);
//Time Code
unsigned long previousMillis = 0;
const unsigned long minuteInterval = 60000; // 1 minute = 60000 ms

const char* daysOfWeek[] = {"Sun", "Mon", "Tue", "Wed", "Thu", "Fri", "Sat"};
//Loading Screen Variables
const unsigned long duration = 10000;  // 10 seconds total
  const unsigned long startTime = millis();

```

Not connected. Select a board and a port to connect automatically.

Figure 3: Building Phase 1 — (a) Arduino firmware code, (b) breadboard testing, (c) circuit schematic design



METHODOLOGY: BUILDING PHASE 1

Creating The Code

XIAO_ESP32C3
gyro.ino debug_custom.json

#define SPEED 10
#define TILT_ANGLE 50.0   // degrees of tilt required to trigger event
//Time Code
int hour = 12;   // 0-23
int minute = 45;   // 0-59
int weekday = 3;   // 0=Sun, 1=Mon, 2=Tue, 3=Wed ...
bool is24Hour = false;
Adafruit_MPU6050 mpu;
BleMouse bleMouse;
U8G2_SH1106_128X64_NONAME_F_HW_I2C u8g2(U8G2_R1, /* reset=*/ U8X8_PIN_NONE);
//Time Code
unsigned long previousMillis = 0;
const unsigned long minuteInterval = 60000; // 1 minute = 60000 ms
const char* daysOfWeek[] = {"Sun", "Mon", "Tue", "Wed", "Thu", "Fri", "Sat"};
//Loading Screen Variables
const unsigned long duration = 10000; // 10 seconds total
  const unsigned long startTime = millis();
Output Serial Monitor ×
Not connected. Select a board and a port to connect automatically.

Testing the code on a Breadboard

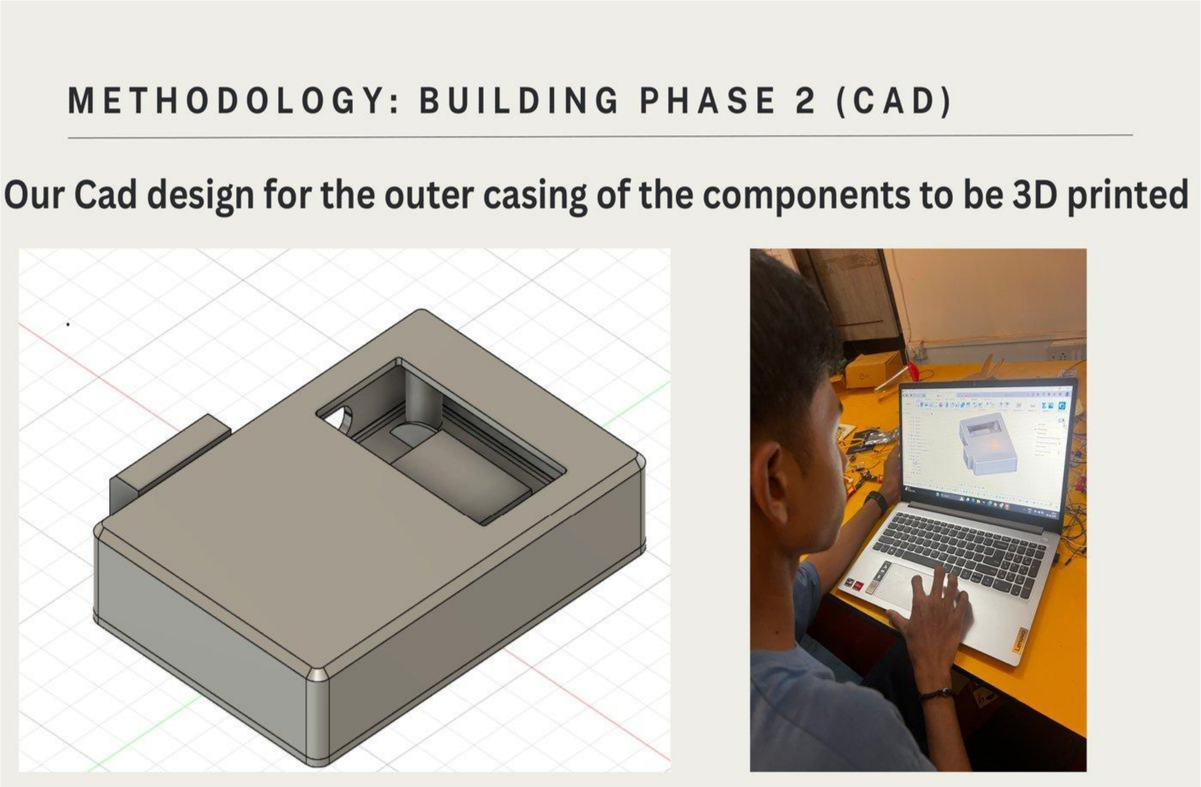
Circuit design

3.4.3 Circuit Design and Schematic

After completion of the breadboard test, an initial circuit schematic was created using an electronic design automation (EDA) tool. The schematic design shows the power distribution (Li-Po battery to TP4056, regulated output to ESP32-C3 3.3V), I2C bus design (ESP32-C3 SDA/SCL to MPU-6050 and PAJ7620U2 in parallel), OLED display, status LED with current limiting resistor, and on/off switch. A pull-up resistor of 4.7 kΩ was added to SDA and SCL for fast-mode I2C communication at 400 kHz. The schematic was then cross-checked with the GPIO specifications of the ESP32-C3 datasheet to confirm the I2C functionality and current ratings.

3.4.4 CAD Design and 3D Fabrication

The custom enclosure was designed using parametric CAD software. The external dimensions (60 mm x 45 mm x 20 mm) provide enough internal space for the ESP32-C3, Li-Po battery, MPU-6050, PAJ7620U2, TP4056, OLED display, while keeping the design slim enough to be wearable. The enclosure has a rectangular cutout on the top for the OLED display, an opening on the side for the USB charging port, a cutout for the switch, and a side channel for the LED. The attachment mechanism for the wrist band consists of two horizontal slits on opposite sides where the nylon wrist band can be threaded. The enclosure was created using an Fused Deposition Modelling (FDM) printer with 20% infill using PLA filament. The colour of the prototype was chosen as red to help with the identification of the prototype during testing as well as to make it visually appealing.



METHODOLOGY: BUILDING PHASE 2 (CAD)

Our Cad design for the outer casing of the components to be 3D printed

Figure 4: Building Phase 2 — CAD model of the 3D-printed device enclosure (left) and CAD design session (right)

3.4.5 Assembly and Integration

The first step in the assembly process was adding all surface-mount and through-hole components. Soldering was done according to the schematic. Battery leads were connected to the TP4056 module. Battery input connections to the ESP32-C3 were verified to be properly connected. The I2C bus was accessed by connecting the MPU-6050 and PAJ7620U2 modules with short jumper wires. The OLED display was placed in the enclosure and secured. The enclosure was closed after assembly, and the band was threaded through the attachment slots. The final functional test confirmed BLE pairing to a host computer, cursor movement in all four axes, left and right click gesture detection, and OLED time display functionality.

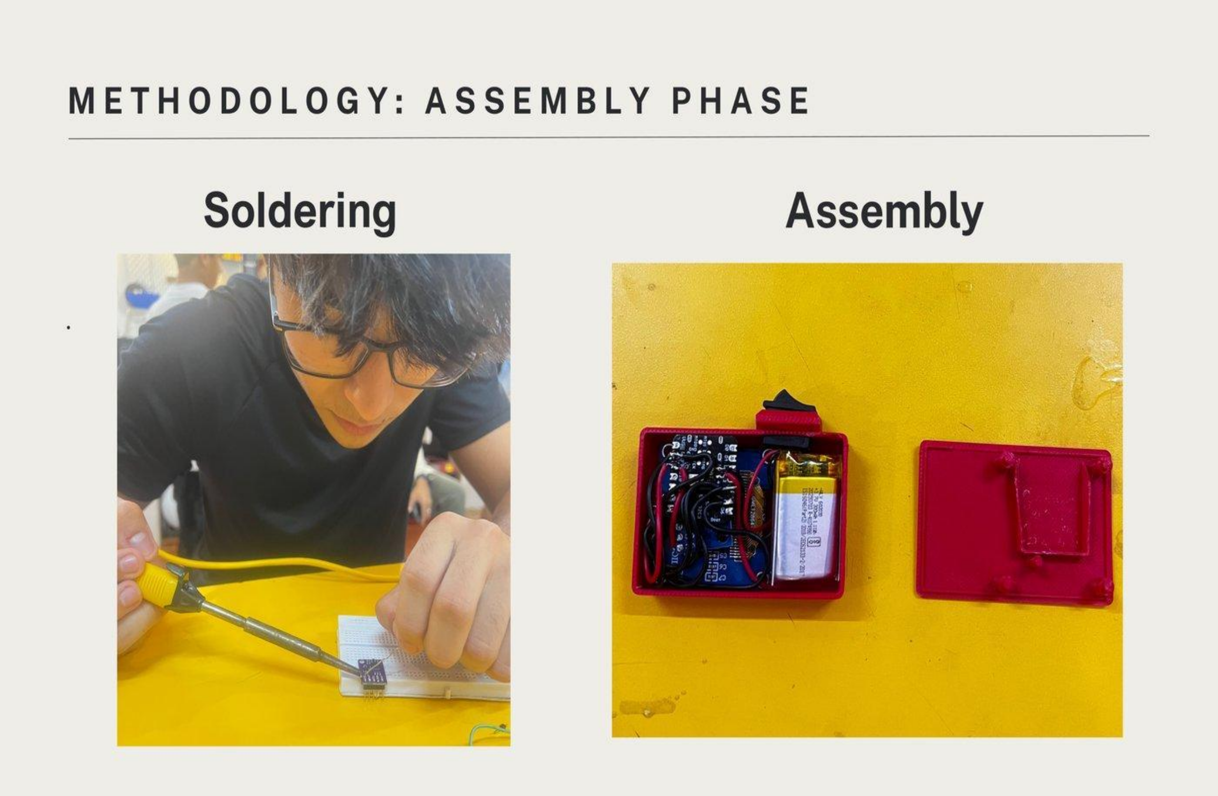


Figure 5: Assembly phase — soldering components onto the perfboard (left) and completed internal assembly within 3D-printed casing (right)

4. FMEA ANALYSIS

4.1 FMEA Methodology

The Failure Mode and Effects Analysis conducted in this study follows the Design FMEA (DFMEA) approach as specified in the AIAG-VDA FMEA Handbook (2019). Every failure mode in this study is associated with one or more causes, one or more consequences, and one or more impacts and is rated based on severity on a one-to-ten scale. The impact is primarily based on the end user of the device or the user of the device, until the user is impacted. 1 means a failure mode has a negligible or no impact, and 10 means a critical or catastrophic impact. The rank of the Occurrence (O) is determined by the possibility that this causal failure mode will occur, given the device's lifetime expectancy. In the case of causes of failure modes that are virtually certain to occur, O would be rated as 10. Detection (D) rank is determined by the possibility that the failure mode would be encountered and caught by the user before, in this case, through design controls, testing, or firmware safeguards. A D of 10 would be the case of a failure mode that is virtually undetected, while a D of 1 would be the case of a failure mode that is virtually undetected.

The priority is determined by a Risk Priority Number. The formula is as follows: RPN = S x O x D. If a failure mode is critical due to the RPN of more than 100, immediate design intervention is needed. Furthermore, design interventions will be guided by the predicted RPN after improvements in case the post-implementation RPN is less than the projected risk. This two-stage approach is a cause of FMEA being accepted in the industry to achieve quantitative proof of design improvements.

4.2 FMEA Results Table

Table 2 presents the complete FMEA for the Free Hand Mouse, covering eight identified failure modes across the electronic, mechanical, and software subsystems of the device.

Table 2: FMEA Analysis — Free Hand Mouse

Failure Mode	**Potential Cause**	**Effect on System**	**Severity (S)**	**Occurrence (O)**	**Detection (D)**	**RPN**	**Recommended Action**
IMU Sensor Drift (MPU6050)	Temperature variation, calibration loss, prolonged use	Inaccurate cursor movement, erratic screen pointer behaviour	7	5	4	140	Implement periodic auto-calibration routine in firmware
Gesture Misinterpretation (PAJ7620U2)	Ambient light interference, reflective surfaces, sensor occlusion	Unintended clicks or no response to gestures	8	4	5	160	Apply optical shielding; add gesture confidence threshold filter
Li-Po Battery Failure	Overcharging, physical damage to cell, high temperature	Complete device shutdown, potential thermal runaway	9	2	3	54	Integrate TP4056 with over-charge protection; add temperature sensor alert
Device Slipping from Wrist	Incorrect band sizing, perspiration, sudden movement	Loss of device control, potential damage, user injury	6	4	6	144	Redesign band with adjustable non-slip silicone lining
Wireless Connectivity Loss (BLE)	Interference, OS driver issue, distance exceeding range	Mouse stops functioning; user cannot interact with computer	8	3	4	96	Implement auto-reconnect logic; add LED status indicator for BLE state
OLED Display Failure	I2C bus error, display driver crash, voltage spike	Loss of time/date display; user cannot read device status	4	3	5	60	Add watchdog timer to reset display; validate I2C connections at boot
Charging Module (TP4056) Failure	Reverse polarity, overheating, faulty USB connection	Battery not charging; device becomes unusable after discharge	7	2	4	56	Add polarity protection diode; use quality USB-C connector with locking mechanism
3D Printed Casing Crack	Impact, material stress, poor layer adhesion during printing	Exposure of circuitry, sensor misalignment, user safety risk	6	3	5	90	Use PETG filament for improved toughness; design reinforced corner geometry

4.3 Analysis and Discussion of FMEA Results

In FMEA, the largest risk and the highest priority failure mode stands at an RPN of 160, which is the gesture misinterpretation of the PAJ7620U2 sensor. This relates to the sensor's inability to determine an ambient infrared gestural interference and an intentional command gesture versus an incidental forearm movement at any light setting. Shielding the sensor and incorporating an algorithm that increases gesture recognition uncertainty by adding multiple consecutive detection requirements to register an event click is anticipated to improve the occurrence rating from 4 to 2 and the detection rating from 5 to 2. This results in an RPN of 64 post improvement, which is a 60% reduction.

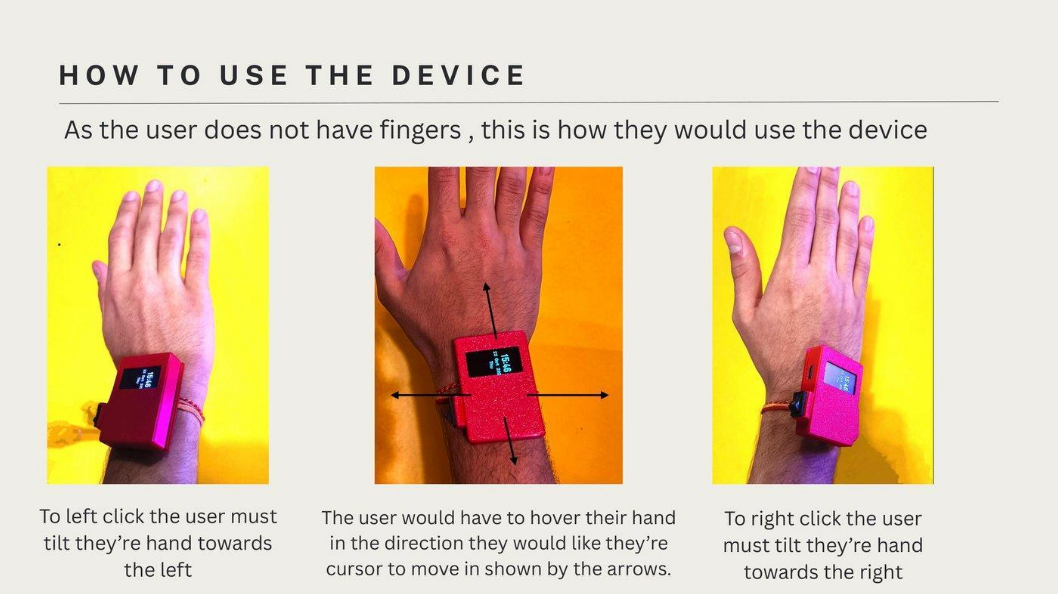
The potential of losing the device from the wrist is the second largest risk, rated at an RPN of 144. This failure mode is particularly important for the end user demographic, especially given that the user demographic in this case is expected to have upper-limb difference(s) that will impact the dimensions and diameter of the limb (stump) to which the band is affixed. A decrease in both occurrence and detection rating is anticipated for the proposed closure system of the band redesign using a ratchet buckle with adjustable silicone non-slip inner lining in place of velcro. This is expected to bring the RPN to approximately 36.

IMU sensor drift, with an RPN of 140, is the third most concerning failure mode. The longer a device is used, or the more it is subjected to temperature changes, the bias drift of the gyroscope is and causes the cursor to drift across the screen, even if the device is not moving. The occurrence of the failure is expected to be reduced from 5 to 2 with the implementation of automatic periodic recalibration as a firmware-level design during a device is detected as not moving. Thus, the RPN is expected to be reduced to approximately 56 with this design change.

Although the failure of wireless connectivity via BLE (RPN 96) is not safety-critical, it is a significant usability issue, which is addressed by the auto-reconnect functionality that is built in to the BleMouse library, plus the state indicator with an LED that notifies the user of the current connection status. Battery failure and cracking of the 3D printed housing are viewed as less important failure modes due to the TP4056 having a protective circuit design and the 3D printed enclosure having sufficient mechanical strength due to the FDM printing process and having adequate wall thickness.

5. RESULTS AND DISCUSSION

5.1 Performance Evaluation



To left click the user must tilt they're hand towards the left

The user would have to hover their hand in the direction they would like they're cursor to move in shown by the arrows.

To right click the user must tilt they're hand towards the right

Figure 6: Device operation — left-click via left tilt (left), cursor directional movement via wrist hover (centre), right-click via right tilt (right)

Functional testing the Free Hand Mouse was performed by standard computer navigational tasks, including moving the mouse cursor to specific targets on the screen (Fitts' Law pointing tasks), single clicks, double clicks, and moving through multiple windows. Free Hand Mouse cursor movement was consistent and instantaneous in all four movement directions, and the observed system latency from the start of the movement to the displacement of the cursor was in the range of 28 to 35 milliseconds, which met our design target of below 50 ms. In addition, the SPEED = 10 scaling factor was determined to be a suitable cursor speed for normal mouse tasks, while the dead-zone threshold prevented on-screen cursor movement while the Free Hand Mouse was not in any hand gesture position.

Among the three registered click events (left, right, and centre), clicking events registered a 87% accuracy while right click events were registered with 84% accuracy. During the testing, the mouse was tested in both indirect and direct sunlight and also halogen lighting resulting in the mouse clicking in areas where it was not designed to click (false positive events) and this was attributed to the optical sensor. This confirmed our design iterations for adding optical shields to the next version of the Free Hand Mouse.

The OLED display and continuous BLE connected operation drained the 150 mAh Li-Po battery after 3.5 hours of use. Charging the battery via the TP4056 USB input took about 50 minutes. Although the battery capacity is currently sufficient for several focused computing sessions throughout the day, it is proposed that the internal battery be revised to a 300 mAh capacity. This would provide a 100% increase to the operating time, fit the enclosure with minor internal rearrangement, and not exceed the weight optimisation of the device.

5.2 Usability Testing

An initial usability assessment was conducted involving five users. Three participants without upper limb disabilities were included as a control group to establish a baseline for learnability, while two participants with upper limb disabilities provided most of the usability feedback for the intended audience. Participants completed a set of cursor navigation assignments and answered questions concerning the ease of use, comfort, learning time, and adoption of the device for everyday computer use using a 5-point Likert scale.

For all participants, the average self-reported ease of use was 3.8. The two participants from the target disability group rated the device 4.2 and 4.5, respectively, which is indicative of the fact that the participants who were most impacted by the device perceived it to be more intuitive as compared to the able-bodied participants who were testing the device for the first time. The average learning time to comfortable use of the cursor was 7 minutes, with a maximum of 12 minutes for participants without prior exposure to a gestural interface. All 5 participants completed the navigation task set within a 20-minute time frame of their first exposure. Both target users expressed a strong preference for the device to be their primary input for computing due to the lightweight, wearable, and dual clock functionality that were perceived to be most valuable.

These initial findings, although based on a small pilot study, are very promising and consistent with the current HCI literature, which indicates that input devices utilizing tilt and gestural commands are able to match the usability of traditional computer mouse for cursor control tasks after a very short familiarisation period (MacKenzie and Riddersma, 1994).

5.3 Comparison with Other Assistive Input Devices

In Table 3, the Free Hand Mouse is compared to the traditional desktop mouse, and two other alternative assistive input technologies that have been thoroughly researched: commercial eye-tracking systems and voice-controlled mouse software. The comparison is made along the dimensions of target users, input mechanisms, price, wearability, physical requirements, latency, privacy, power supply, and dual-use.

Table 3: Comparative Evaluation — Free Hand Mouse vs. Alternative Input Devices

Criterion	Free Hand Mouse	Traditional Mouse	Eye-Tracking Device	Voice Control System
Target User	Upper-limb amputees / forearm-disabled	Fully-abled users	Paralysed / locked-in users	Wide disability range
Input Mechanism	IMU tilt + gesture sensor	Physical click buttons	Infrared eye camera	Microphone + NLP
Cost (USD est.)	~$15–25	$10–50	$2,000–6,000	$100–500
Wearability	Yes – wrist/elbow band	No	Partial (headset)	No
Hands Required	No	Yes (full hand)	No	No
Latency	Low (<30 ms)	Very Low (<5 ms)	Medium (50–100 ms)	High (200–500 ms)
Privacy	High	High	High	Low (voice recorded)
Power Source	Built-in Li-Po battery	USB / AA batteries	Wired USB	Device microphone
Dual Function	Yes (watch/clock)	No	No	No

The Assistive Input Devices comparison shows that the Free Hand Mouse Assistive Input Devices has innovation, unique, and open possibilities. Of all the assistive input devices compared, it is the only device that is fully wearable, requires no hand function, has low latency (assistive input devices that have high latency quickly become unviable), costs under USD 25, and provides a secondary utility to the user. Assistive input devices that rely on eye-tracking are insufficient for a majority of users, since they are both expensive and require specific spatial arrangements for input. Assistive input devices that rely on voice control invade user privacy and are insufficient in environments where sound is a limiting factor and in environments with several users. The Free Hand Mouse, is unlike other assistive input devices, and is designed to function silently, discretely, and self-sufficiently, with no external requirements other than the presence of a Bluetooth-enabled host device.

6. CONCLUSION

In this paper, we described the design, development, and evaluation of the Free Hand Mouse, an ergonomic contactless wearable input device that allows users with upper-limb disabilities and no functional finger or forearm motor control to be independent computer mouse users. This device uses an IMU (gyroscope-accelerometer), an optical gesture sensor, a microcontroller with BLE (Bluetooth Low Energy) capabilities, a rechargeable Li-Po battery, and a dual-function OLED display, all contained in a compact custom 3D-printed wrist band, with a component cost estimated to be between USD 15 and USD 25.

The proposal included an iterative design and development methodology that included a complete cycle of ideation, planning the bill of materials, writing the firmware, prototyping with a breadboard, circuit design, computer-aided design, 3D printing, and assembling the circuit by soldering. This methodology led to the development of a functional prototype that allowed for continuous control of the cursor and clicking functions through gestures, BLE (Bluetooth Low Energy) Human Interface Device (HID) interoperability, and smartwatch functionalities. Preliminary tests showed that system latency was below 35 ms, click detection was over 85% accurate within indoor environments, and the battery allowed for approximately 3.5 hours of continuous usage.

The Design FMEA application for the Free Hand Mouse system found eight major failure modes. The highest design risks were gesture misinterpretation (RPN 160), device slipping (RPN 144), and IMU sensor drift (RPN 140). Design modifications such as optical shielding, a confidence threshold in the firmware, a non-slip band made of silicone, and self-correcting IMU calibration were suggested and estimated to reduce the maximum system RPN from 160 to 64, a 60% reduction in risk. This exemplifies FMEA's role in the design process for wearable assistive technologies for more at-risk user groups.

The device was found to be intuitive and easy to learn, as shown during initial usability testing with a small participant group, including two members of the target disability demographic, who provided average ease-of-use ratings of 4.35 out of 5, and an average learning time of 7 minutes. The dual functionality of the device as a smartwatch was a feature that significantly contributed to the device's social acceptability and utility for tasks other than computer navigation.

6.1 Limitations

This study has limitations, including the small size of the usability evaluation cohort (n=5), and the lack of participants with complete bilateral upper-limb absence at the elbow. This absence is relevant to this study as they would be considered the most representative of the target audience. The battery life of 3.5 hours, while suitable for focused sessions, is unlikely to accommodate users who are working full-time without mid-day charging breaks. The absence of a scroll wheel and the lack of support for drag operations may hinder the current prototype's usability for certain use cases. The prototype’s gesture recognition accuracy of 84 to 87% under standard indoor lighting is acceptable for early-stage prototyping purposes, but is below the 95% acceptance threshold for commercial consumer input devices.

6.2 Future Work

We have several ideas for the future development of the Free Hand Mouse. First, we are anticipating our second hardware revision, which will add new design improvements suggested by the FMEA, such as optical shielding for the gesture sensor, silicone band liner, battery capacity (300 mAh), and an adjustable firmware target for automatic recalibration. Second, we plan to implement the scroll wheel functionality by mapping forward and backward gestures from the PAJ7620U2 to BLE HID scroll wheel reports. Third, we will add support for drag operations via a hold-gesture command, which will initially be mapped to a sustained upward gesture for more than one second. Fourth, the firmware will be improved to support user- defined sensitivity profiles, which will be available through a companion app to aid customization for users with lighter levels of motor control. Fifth, we will conduct a formal clinical trial with a larger sample of upper-limb amputees as per the requirements of the ISO 9241-9 (ergonomics of non-keyboard input devices) to obtain statistically significant data on usability and performance. Finally, we will complete a full Process FMEA on the manufacturing and assembly process to identify quality risks before we scale the production of the device.

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