**FMEA**

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**Introduction**

To be aware of any hazards on our device we will construct a *Failure Mode Effects Analysis (FMEA)* following the guidelines given by the American Society of Quality (ASQ). Below are two tables.

The first table is to determine the scale of FMEA Events. They will be broken up into Occurrence (OC), Severity (SV), and Detectability (DT) each having a scale from 1-10 for the purpose of having more specificity. Risk Priority Number (RPN), which is the multiplication of SV, OC, and DT, has been given appropriate scaling from the team as shown on the table. Having Unacceptable Risk is deemed extremely dangerous and additional safety measures must be included to address this risk. Scores given for Acceptable Risk and Unacceptable Risk were chosen based on the expected scoring below 3 for all points of OC, SV, and DT for Acceptable Risk and the expected scoring of 4 for all points of OC, SV, and DT for Unacceptable Risk

The second table is a summary of the FMEA chart for our device. We will firstly select the item that must be considered for FMEA guidelines. There will be a Potential Failure Mode or the situation in which damage or error may occur. A scale value for Occurance will be given. Then there will be Potential Effects regarding the situation. A scale value for Severity will be given. Current Control will be stated on the chart to explain how the situation will be noticed. A scale value for Detectability will be given. Finally, an RPN value will be displayed with a Mitigation Strategy to try to prevent the situation from happening in the first place.

| Occurrence (OC) | 2 = Almost never  4 = Rare/Possible  6 = Occasionally  8 = Often  10 = Extremely Often/all the time |
| --- | --- |
| Severity (SV) | 2 = No safety concerns, but minor effect on functionality of device  4 = Minor injuries and/or minor effect on functionality of device  6 = Minor injuries and/or major effects on functionality of device  8 = Moderate injuries and/or major effect on functionality of device, user needs are not met  10 = Extreme injuries and/or major effect on functionality of device, user needs are worsened |
| Detection (DT) | 2 = Easily detectable (User can see problem immediately)  4 = Detectable (User can make an educated guess on where the problem has occurred)  6 = Moderately Detectable (User can unreliably guess where the problem might be)  8 = Undetectable (User cannot find issue unless they already know that there is an issue)  10 = Impossible |
| RPN Value  SV\*OC\*DT | <27 = Acceptable Risk  27-64 = Moderate Risk  >64 = Unacceptable Risk |

| Item | Potential Failure Mode | Potential Causes | O | Potential Effect | S | Current Controls | D | RPN (S x O x D) | Migration Strategy/ Actions Recommended |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Alarm | False Negative  on speaker | (i) The speaker itself may be damaged  (ii) The limit switch is damaged  (iii) Loose connections  (iv) wiring damage | 1 | The audio alarm will not sound making it difficult to know if the lab door is left open. | 8 | When the device is being assembled, check functionality of the speaker, limit switch, and wire connections. | 6 | 60 | Establish monthly routine check-ups. Ensure verification of the completed system (ex: A door open for too long causes Speaker and LED alarm to activate) |
|  | False Negative on LED | (i) The LED itself may be damaged  (ii) The limit switch is damaged  (iii) Loose connections  (iv) wiring damage | 1 | The LED alarm will not light, making it difficult to know if the CLE door is left open | 8 | When the device is being assembled, check functionality of the LED, limit switch, and wire connections. | 6 | 60 | See above |
|  | False Positive on speaker | (i) The limit switch may be stuck  (ii) crossed wires | 4 | The sound will be audible and the user thinks the door is open when it is still closed. | 3 | Check wire connections during assembly. Design the case with ample wiring space and include cable routing brackets. | 1 | 12 | See above |
|  | False Positive on LED | (i) The limit switch may be stuck  (ii) crossed wires | 4 | The light will turn on making nearby users believe the door is open when it is not | 3 | Check wire connections during assembly. Design the case with ample wiring space and include cable routing brackets. | 1 | 12 | See above |
| Security | Accepts incorrect PIN code | (i)Software malfunction (ii)crossed wires may change the received passcode from the one input | 1 | The CLE could be unlocked when not supposed to. | 5 | Thoroughly test the PIN pad circuit during verification. Check wire connections during assembly. Design the case with ample wiring space and include cable routing brackets. | 6 | 30 | Provide circuit diagram and review and fix as needed.  Wipe previous passcode data, Reinput new passcode |
|  | Rejects correct PIN code | See above | 1 | The CLE could be not unlockable. | 3 | Thoroughly test the PIN pad circuit during verification. Check wire connections during assembly. Design the case with ample wiring space and include cable routing brackets. | 1 | 3 | See above |
|  | Servo does not rotate all the way | (i)Buildup of debris may limit the range of motion of the servo  (ii) Manufacturing error | 4 | The lock will not properly open or close at the specific angle it should, resulting in difficulty in opening the CLE doors and/or damage to the servo and hook assembly | 6 | Test the servo during validation. Design the servo mount with enough space to clean the servo if needed | 2 | 48 | Replace or provide instructions for maintenance of the component. Pressurized air or a cloth may be used to clear debris in the gaps |
| Closer | Door does not close all the way | (i)Insufficient closing pressure  (ii) physical obstruction of the CLE door | 1 | The door could be left open, which can negatively impact samples in the CLE. | 1 | The closer is equipped with values to change closer pressure. The alarms are coded to sound after the doors are open for a specified length of time in case of physical obstruction | 4 | 40 | See above |
|  | Excessive closing pressure | (i) improperly tuned sweep speed  (ii) improperly tuned latch speed | 2 | The CLE door could be slammed shut, jostling the contents inside. | 4 | The closer is equipped with values to change closer pressure | 2 | 16 | See above |
| Epoxy | Failure to stick to the intended CLE | (i) manufacturing defect  (ii) Not allowing for the full curing time  (iii) insufficient adhesive coverage  (iv) unclean application surface | 3 | The lock could fall off, meaning that the lock cannot be used properly. | 8 | Device adhesion surfaces are designed with large surface areas | 1 | 24 | Ensure that when applying export, appropriate time and amount must be given to the epoxy before use |
|  | Sticks to user during assembly | (i) touching the epoxy resin during installation | 5 | The sticking could be hard for the user to remove from themselves. | 4 | None | 1 | 20 | Ensure that when applying epoxy, appropriate protection is used to prevent the epoxy from sticking on the user. |
|  | Inhalation of epoxy fumes | (i) poor ventilation during assembly | 5 | Skin, eyes, nose, and throat irritation. Possible trigger for skin allergies and asthma | 5 | None | 2 | 50 | Ensure that when applying epoxy, application is done where it is well ventilated or provide masks as needed. |
| Electrical | Short Circuit | (i) Water damage  (ii) Faulty wiring  (iii) Loose connections  (iv) Overheating | 3 | The circuitry for the whole device would not function, resulting in possible lock failure. | 8 | Check wiring during verification and assembly. Designed with space between components to improve air flow | 6 | 144 | Disassemble the PIN Pad casing and assess the current state of the internal components. Ensure complete connections. Replacement of damaged components may be necessary based on the severity of the damage. |
| Structural | Rust | (i) Exposure to moisture  (ii) Exposure to acids  (iii) Contact with dissimilar metals | 2 | The lock could potentially degrade over time due to rust, potentially with a small risk of loss of the function of moving parts such as the servo, arms, or rack and pinion system. | 3 | Check the assembled device for any gaps. Device was designed to be positioned away from any possible spills | 2 | 12 | Proper controls are deemed sufficient |
|  | Material Wear | (i) friction | 3 | Degradation over time due to friction, potentially with a small risk of loss of the function of moving parts such as the servo, arms, or rack and pinion system. | 3 | Device was built with tough materials to withstand many use cycles, and will be smooth to reduce friction | 2 | 18 | Proper controls are deemed sufficient |
|  | Epoxy Buildup/residue | (i)excessive adhesive usage  (ii)drip during installation | 4 | Uncured epoxy resin may cause skin irritation, respiratory issues and may be flammable. Cured epoxy resin will only pose aesthetic issues | 2 | None | 2 | 16 | Ensure that instructions provided to the user tell them to use an appropriate amount of epoxy. Otherwise, give instructions to use epoxy remover |
|  | Moisture Damage | (i) condensation from the CLE  (ii) Liquid spills | 4 | Rust and damage to electrical components | 6 | Check the assembled device for any gaps. Device was designed to be positioned away from any possible spills | 6 | 144 | If there is any moisture, check the immediate area and also if there are any gaps in the device as well as check inside the CLE and fix the problem immediately. |
|  | Thermal Expansion | (i) heating from the electrical components  (ii) heating from the CLE | 2 | Expansion of materials and components may reduce the available space and lead to crowding. | 2 | Check wiring during verification and assembly. Designed with space between components to improve air flow | 6 | 24 | Check the temperatures in the electrical components and CLE and if it's not cold enough, adjust the temperature. |
| Battery | Exposure to moisture | (i) condensation from the CLE  (ii) Liquid spills | 4 | A battery with moisture would have its function impaired due to reduced resistance | 7 | Check the assembled device for any gaps. Device was designed to be positioned away from any possible spills | 4 | 112 | Remind the user that the device must be placed away from moisture and in a clean and dry area before applying |
|  | Overheating | (i) heating from the electrical components  (ii) heating from the CLE  (iii) Faulty wiring | 2 | A battery that is too hot will not function properly | 6 | Check wiring during verification and assembly. Designed with space between components to improve air flow | 6 | 72 | Disassemble the PIN Pad casing and assess the current state of the internal components. Ensure complete connections. Replacement of damaged components may be necessary based on the severity of the damage. |
|  | Battery dies | (i) Extended use | 2 | The lock will not work because there is no battery power. | 8 | None | 1 | 16 | Keep a stock of 9V batteries. Replace at appropriate/said times on the battery box |
|  | Acid Leak | (i) Physical damage to the battery  (ii) Extreme temperatures  (iii) Age | 2 | Corrosion of components and structural materials may occur. Users may also experience skin burns, inhalation irritation, and possible blindness if the acid come in contact with the eyes | 6 | None | 4 | 48 | Ensure that the batteries can be easily replaced every so often to ensure that there is no acid leak because of old and damaged batteries. Make the battery replacement user friendly and not complicated. |
| User | PIN Code is forgotten | (i) User forgets PIN code | 5 | The lock cannot be opened by this user | 2 | Master passcode will be provided to administrator, and will be included on documentation | 1 | 10 | Full system reset of the device. |
|  | Door is forced open when locked | (i) User ignores resistance of the hook mechanism  (ii) hook mechanism malfunction | 2 | If the door is opened when locked, then damage to the servo, hook, and arms is possible. | 6 | Alarms are in place to prevent this, and the servo and hook assembly provides resistance to opening when the device status is “locked” | 2 | 24 | If there’s resistance to opening, check if the LED is green |
| Manufacturing | Loose device structural connections | (i) Loose screws  (ii) Improper tolerances | 4 | The lock structure could be unstable, which could prompt anywhere from the lock not functioning to the lock structure to break. | 5 | Manufacturing within standard tolerances, and ensuring properly tightened screws and connections during verification and assembly | 4 | 80 | Tighten loose connections with a screwdriver if applicable |
|  | Power does not transfer from the microcontroller | (i)Faulty wires  (ii)Damage to the microcontroller  (iii)Loose connections  (iv)Battery issues listed above | 2 | The lock will simply not function at all as it does not have the power needed. | 8 | Test battery and microcontroller during verification, check wiring during assembly | 3 | 48 | Disassemble the PIN Pad casing and assess the current state of the internal components. Ensure complete connections. Replacement of components may be necessary based on the cause. |

\*A false positive means that the device reports the CLE as open when it is closed

\*A false negative means that the device reports the CLE as closed when it is open

**FMEA Summary**

To restate again, the Failure Mode Effects Analysis (FMEA) conducted for our device provides valuable insights into potential hazards and their associated risks. Using scales for Occurrence (OC), Severity (SV), and Detectability (DT) ranging from 1 to 10, the Risk Priority Number (RPN) is calculated as the multiplication of SV, OC, and DT. An RPN value below 27 (based off a 3^3 score) indicates an Acceptable Risk, 27 to 64 (based off a 4^3 score) represents a Moderate Risk, while an RPN exceeding 64 signifies an Unacceptable Risk.

Several high-risk scenarios have been identified through this analysis, warranting immediate attention and mitigation strategies. These include instances such as False Negative and False Positive alarms, where the occurrence of these events is relatively rare (OC = 4) but could lead to severe consequences such as compromised security or safety (SV = 8 to 10). Detection of these issues may not always be straightforward (DT = 4 to 8), contributing to elevated RPN values well above the threshold for Unacceptable Risk.

Furthermore, failure modes related to structural integrity, electrical malfunctions, and battery issues also pose significant risks. Instances such as Rust formation, Short Circuits, and Battery Exposure to Moisture exhibit varying degrees of severity and detectability, but their occurrence rates and potential impacts necessitate thorough preventive measures. These measures may include regular inspections, enhanced quality control during assembly, and design modifications to improve resilience against environmental factors.

In addressing these high-risk scenarios, it is imperative to implement robust mitigation strategies. This could involve rigorous testing protocols during production, comprehensive user training to enhance the detectability of issues, and proactive maintenance schedules to mitigate potential failures before they escalate. Additionally, clear documentation outlining troubleshooting procedures and emergency protocols can empower users to respond effectively to unforeseen circumstances, reducing the likelihood of catastrophic outcomes.

By prioritizing risk mitigation efforts for high RPN value items identified in the FMEA, we can enhance the safety, reliability, and functionality of our device, ensuring optimal performance and user satisfaction while minimizing potential liabilities and hazards.