Overview: We want to wake people with type 1 diabetes to prevent dead in bed syndrome caused by alarm fatigue leading to unexplained death of a patient with type 1 diabetes—a phenomenon that occurs with the sudden death of type 1 diabetes patients.

Dead in Bed

What is Dead in Bed?
A phenomenon that occurs with the sudden unexplained death of a patient with type 1 diabetes:
- Happens with about 7% of type 1 diabetes patients
- About 5.2% of all US adults reported having type 1 diabetes and using insulin to treat it [1]
- About 22% of all youth diagnosed with diabetes are diagnosed with type 1 [1]
- About 25% of patients on intensive insulin therapy have at least one episode of severe hypoglycemia every year [2]
- Dead in Bed Syndrome is estimated to be the cause of death for about 5% of all type 1 diabetes related deaths
  - Average age ranges between 18 - 31 years [3]
- “Coma can occur at glucose levels in the range of 2.3–2.7 mmol/l (41–49 mg/dl) (9) as well as at lower glucose levels.” [5]

Our Team

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FDA And ISO

FDA Pathway
- 510K - Premarket Notification
  - A premarket submission that does not require companies to provide proof of safety and effectiveness data from clinical trials but does evaluate the effectiveness and safety of the new device through comparison of legally marketed and patented devices currently in the market.
  - Current market devices
    1. Dexcom G6
    2. Medtronic Minimed 770G
    3. Abbott Freestyle Libre
  - Must be submitted 90 days in advance from desired market date

ISO Standards
1. ISO 14971: manufacturers will identify hazards, evaluate the risks associated with use of the device, risk management applies to all stages of the product life cycle.
2. ISO 82366: also known as the human factors engineering standard, it provides guidance on analyzing, developing, and evaluating the usability of the device.
3. ISO 17664: manufacturers will identify hazards, analyze risks, and design and code their device.
4. ISO 20417: information is to be provided by the medical device manufacturer for the processing of non critical medical devices.
5. ISO 13485: quality management of the device

Timeline

Step 1: Take data from CGM.
Step 2: LabView interprets the data from the CGM by reading the voltage input from the sugar pixel and sends signals to our motor, speaker, and fan components to activate our alarms.
Step 3: Motor starts rotating and breaks the ammonia inhalant capsule.
Step 4: Fan is activated, on the side of our alarm we have a compartment for a sugar capsule to be stored for the user to take and restore their glucose levels.

References
[4] Coma can occur at glucose levels in the range of 2.3–2.7 mmol/l (41–49 mg/dl) as well as at lower glucose levels.

Figure 1: Graph Showing a Decrease in the Occurrence of Dead in Bed Syndrome Over Time [4]

Figure 2: Showing Rotation of Capsule Breaking Component