Waking Dead in Bed

Team: Adam Peters, Angélica Esteves-Manzo, Siana Jimenez, Leslie Rangel, Rebeca Silva

Project Advisor: Elliot Botvinick

UCI Samueli School of Engineering | Department of Biomedical Engineering

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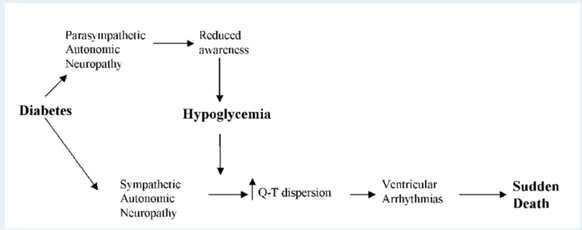
Overview : We want to wake people with type 1 diabetes to prevent dead in bed syndrome caused by alarm fatigue leading to the lack of emergency glucagon administration that prevents death.

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 one 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 - 31.5 years [3]**



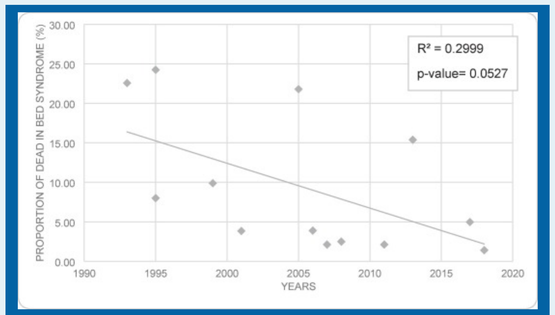


Figure 1: Graph Showing a Decrease in the Occurrence of Dead in Bed Syndrome Over Time [4]

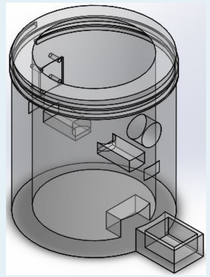
- **"Coma can occur at glucose levels in the range of 2.3–2.7 mmol/l (41–49 mg/dl) (9) as well as at lower glucose levels." [5]**

Our Device

The purpose of our project is to wake type 1 diabetics from their sleep before entering a hypoglycemic state that has the potential to cause coma and even death. This device would alternate through various auditory alarms, as well as an olfactory alarm, which would avoid causing alarm fatigue within the patients.

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, and sends the ammonia inhalant aroma to the user, which will wake them up.

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.

Figure 2: Showing Rotation of Capsule Breaking Component

References

Our Team

Adam Peters
Biomedical Engineering
Team Lead
Project manager in charge of ensuring all deadlines are met and responsible for 3D printing of the device.

Contact Information: petersan@uci.edu

Angelica Esteves-Manzo
Biomedical Engineering
Designer
Utilizes SolidWorks and LabView to design and code the device.

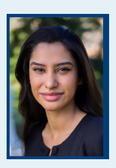
Contact Information: estevesa@uci.edu

Siana Jimenez
Biomedical Engineering
Manufacturer
In charge of overall fabrication of device through physical and mechanical means.

Contact Information: scjimene@uci.edu

Leslie Rangel
Biomedical Engineering
Facilitator
Facilitates expansion of the device by providing support to all areas of device development and production.

Contact Information: lgrangel@uci.edu



Rebeca Silva
Biomedical Engineering
Marketing Advisor
Provide insights and recommendations to comnpany's marketing initiatives.

Contact Information: rebecas2@uci.edu

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 62366-1: also known as the human factors engineering standard, it provides guidance on analyzing , developing , and evaluating the usability of the device.**
3. **ISO 17664-2 & ISO 20417 : information is to be provided by the medical device manufacturer for the processing of non critical medical devices**
4. **ISO 13485: quality management of the device**
5. **ISO 15223-1 : manufacturer will specify the symbols used to express certain information they supply on their device and will be placed on packaging or device itself**

Timeline