

1. List two to four Desired Needs of your project that led to your final design objectives. Answer in two to four bullet points or concepts within a sentence or two.

- Personalized treatment plans for diabetic patients
- Demonstrate a pipeline for analyzing CGM data other than standard analysis
- Menstrual rhythm impacts on glucose regulation which should be interpreted in analysis

2. List the major Constraints on your design/project

- a) Safety/Regulatory Affairs: Data leaking without consent from Dexcom/wrong results
- b) Risks: Unaccounted bias in the data and leaking Dexcom data
- c) Global Impact: CGM monitoring is still not as widely used. It is limited to certain socioeconomic groups who can afford the non-permanent CGM monitoring devices.
- d) Manufacturability: The featurization pipeline and data cleaning algorithm should be easily accessible and used across audiences with different backgrounds.
- e) Quality Control/Marketability: Data lacks essential labels (menstrual phase, exercise, sleep, and food intake) so more testing or validation must be done using other datasets

3. List the major Engineering Standards on your design/project

- a) Affected the components used in the device: information security and controlled data handling: ISO/IEC 27001:2022, HIPAA Privacy Rule de-identification standard
- b) Standards that constrain the device and its performance: quality in prediction modeling (end goal): ISO 14971:2019, IEC 62304, IEC 82304-1:2016, ISO 20417:2021
- c) Standards that could be developed from your project: data quality control for CGM data and features to characterize CGM

4. Explain Ethical, Environmental, or Societal concerns for practical applications of your project.

- Not all features apply equally across user groups, creating unreliable analysis for some populations, causing financial and mental burden
- Users put their trust on the prediction model and doesn't seek the consultation of doctors
- CGM devices needs to be switched every 10-15 days, creating waste and financial burden

5. Describe Active Teamwork and Leadership in your design group

- a) Collaboration: Free to debate their opinion on the project, assignments assigned equally and help each other debug code/brainstorm ideas
- b) Leadership: Idea originator leads the subproject, or co-leads if within the same module
- c) Goals & Deadlines: Set big goals weekly, smaller goals to delegate tasks and regroup.
- d) Feedback: Leave feedback in files for others to consider, suggestions during meetings.

6. What were the most significant motivating factors that led you to

- a) Acquire new knowledge: More confidence for the project, skill development for career
- b) Be self-initiating: The desire to develop CGM features that is meaningful
- c) Persist against challenges and setbacks: Help progress women's health

7. What are your most innovative and/or entrepreneurial ideas for this project

- Developing a data cleaning algorithm for CGM datasets. This will be useful for anyone who wants to ensure quality with their data.