

1. Desired Needs
  - a. Create an accurate and reliable method for fluid draw of insulin that ensures proper detection of fibrillation via the optical analysis.
  - b. Create a clean UI/UX and software to properly evaluate optical analysis against gold standard testing and display results and history to users that is easy to navigate.
2. Major Constraints
  - a. **Safety/Regulatory Affairs:** Class II medical device under FDA
  - b. **Risks:** reducing the number of false positives/negatives incorrectly indicating insulin potency, reducing user trust, patient hyperglycemia, and waste. Contamination and user error when using the device.
  - c. **Global Impact:** Provides a vital check in regions where "cold chain" storage is unreliable. Reduces global insulin waste and prevents hospitalizations.
  - d. **Manufacturability:** Component sourcing and standard parts allows for consistent assembly and scalability which allows lower cost parts and higher profit.
  - e. **Quality Control/Marketability:** Make the device marketable to insulin dependent diabetics and clinicians. The development of a mobile friendly and device interface with real time insights to their data.
3. Engineering Standards
  - a. The optical component standards must comply with IEC 60825-1.
  - b. The performance constraints as Class II devices and the design history and manufacturing management.
  - c. Standardized spectroscopic profile for rapid insulin assay since there is no standard of spectroscopic signatures for insulin degradation.
4. Ethical, Environmental, or Societal concerns
  - a. Ensure device is accessible to those with improper storage methods, reduce environmental waste, societal burden of hospitalizations
5. Active Teamwork and Leadership
  - a. Diverse opinions from BTECH and BENG and software backgrounds, subprojects based on interest and time, weekly deadlines that allows for wiggle room, team feedback and mentor-feedback weekly
6. Significant motivating factors
  - a. Acquire new knowledge through trial and error necessary for the progression of the project, take leadership for subprojects and work with and around team members, create innovative ways to deal with challenges and acquire feedback.
7. Most innovative and /or entrepreneurial ideas
  - a. At home potency check that allows a shift from lab testing and allows for real time potency dash board and creates a method that allows testing without destroying a large portion of the medication.