BENG Senior Design — ABET Addendum

Umair Mahmood | Insulin Potency Detection Device (Group #10)

1. Desired Needs

a. Develop an accurate and reliable fluid draw mechanism for insulin sampling that enables consistent detection of fibrillation through optical analysis.

b. Design an intuitive UI/UX and supporting software to evaluate optical analysis against gold-standard testing, displaying results and usage history in a clear, easy-to-navigate interface.

2. Major Constraints

a. Safety/Regulatory: The device is classified as a Class II medical device under FDA regulation.

b. Risks: Minimizing false positives and negatives that could misrepresent insulin potency, erode user trust, or lead to patient hyperglycemia and unnecessary waste. Contamination and user error during operation must also be mitigated.

c. Global Impact: Addresses a critical need in regions with unreliable cold-chain storage infrastructure. Reduces global insulin waste and helps prevent diabetes-related hospitalizations.

d. Manufacturability: Use of standard, commercially sourced components enables consistent assembly, scalability, lower unit costs, and improved profit margins while maintaining sterility.

e. Quality Control/Marketability: Target insulin-dependent diabetics and clinical users with a mobile-compatible interface that delivers real-time insights and is built to a marketable standard.

3. Engineering Standards

a. Optical components must comply with IEC 60825-1 laser safety standards.

b. As a Class II device, the design must satisfy applicable performance requirements, including design history file (DHF) documentation and manufacturing quality management standards.

c. A standardized spectroscopic profile for rapid insulin assay must be developed, as no established standard currently exists for spectroscopic signatures of insulin degradation.

4. Ethical, Environmental, and Societal Considerations

a. Ensure device accessibility for users lacking proper storage infrastructure, minimize environmental waste from discarded insulin, and reduce the broader societal burden of preventable hospitalizations.

5. Active Teamwork and Leadership

a. Leverage diverse perspectives across multiple disciplines (mechanical, software, and biotech specializations). Assign subprojects based on individual interest, availability, and expertise, while maintaining weekly milestones with built-in flexibility and incorporating regular feedback from teammates and mentors.

6. Significant Motivating Factors

a. Drive project progression through iterative research and development, take ownership of subproject leadership, collaborate effectively across the team, and develop creative solutions to technical challenges that work synchronously with other subprojects, informed by ongoing feedback.

7. Most Innovative and/or Entrepreneurial Ideas

a. The most innovative part of this device was the overall mechanical design which leveraged a cam reducing the necessary vertical space for the fluid draw mechanism whilst allowing this internal mechanism to have an extremely long lifecycle. Then all of the more complex moving parts were moved

to the cartridge which have to be replaced each use no matter what, so to maintain accuracy in fluid draw, this design allows for that possibility with no maintenance.