

Bioengineering Day - ABET Addendum

1. List two to four desired needs of your project that led to your final design objectives.

- Diagnostic gap in dysphagia, patients with swallowing difficulty frequently show normal findings on conventional HRIM creating a need for more sensitive tools.
- Quantitative biomechanical metric: A need to translate raw pressure and impedance waveforms into a clinically meaningful measure, esophageal mechanical work

2. List the major constraints on your design/project

- Safety/Regulatory Affairs: patient data handling must comply with HIPAA; any future clinical implementation would require FDA approval
- Risks: algorithmic errors in mechanical work computation could yield false-negative diagnoses, delaying treatment.
- Global Impact: EoE and dysphagia affect millions worldwide, a validated non-invasive computational tool could improve diagnostic equity
- Manufacturability: the system is software-based which minimizes manufacturing barriers and gel portion is also simple ingredients easy to obtain.
- Quality Control: validation against established clinical metrics (eosinophil counts, patient symptom scores) is essential.

3. Major Engineering Standards

- IEC 60601-1 (medical electrical equipment safety)
- ISO 10993 (biocompatibility for patient-contacting devices).
- ISO 10993-1 - biocompatibility standards for conductive gel or bolus material introduced into the body.
- This work could inform new consensus metrics for biomechanical HRIM analysis, potentially extending the Chicago Classification framework with work-based parameters

4. Ethical, Environmental, and Societal Concerns

- Patient privacy and informed consent are most important
- Algorithmic bias must be monitored training on a limited cohort
- Environmental impact is minimal given the software-only nature of the tool with no additional disposable hardware.

5. Active Teamwork and Leadership

- Team members with backgrounds in signal processing, physiology, and clinical data analysis each contributed knowledge

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- Subproject were assigned for data pipeline development, clinical data acquisition coordination, statistical analysis, and gel reformulation to each member
- Interim results were presented to our mentor, feedback on metric selection and statistical approach

6. Motivating Factors for Growth

- The need to model esophageal mechanics required learning mechanics and impedance beyond normal coursework, which motivated by its clinical significance
- No existing open-source tool combined HRIM pressure and impedance into a mechanical work

7. Innovative and Entrepreneurial Ideas

- Extension to other esophageal and GI motility disorders (achalasia, GERD, gastroparesis) where biomechanical work metrics could reveal dysfunction invisible to standard manometry