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Bioengineering Day Poster Addendum (ABET questions)

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.
   - Develop a quantitative and objective assessment of swallowing disorders by utilizing both pressure and impedance data from High Resolution Impedance Manometry (HRIM) rather than relying primarily on qualitative interpretation.
   - Extract clinically meaningful biomechanical metrics such as cross-sectional area, stress-strain relationships, stiffness (modulus), work, and power to better characterize esophageal function.
   - Create a more standardized and reliable bolus medium to improve impedance signal consistency and reduce variability in HRIM measurements.

2. List the major **Constraints** on your design/project
   a) Safety/Regulatory Affairs
      a. The project involves clinical HIRM data and potential patient interaction requiring compliance with HIPAA, IRB protocols, and patient privacy protections.
      b. Any future clinical implementation would need to comply with FDA medical device regulations and IEC/ISO safety standards.

   b) Risks
      a. Variability in impedance measurements due to air bubbles, bolus inconsistencies, or catheter positioning may affect data accuracy.
      b. Misinterpretation of biomechanical metrics could impact clinical decision-making if not properly validated.

   c) Global Impact
      a. Dysphagia affects diverse patient populations worldwide making improved diagnostics globally relevant.
      b. Accessibility and affordability of advanced HRIM analysis tools may limit adoption in lower-resource healthcare systems.

   d) Manufacturability
      a. Standardizing the conductive gel composition and maintaining reproducible conductivity and viscosity may be challenging at large scale.
      b. Integration of software analysis pipelines into existing clinical HRIM systems must remain compatible with current medical institution workflows.

   e) Quality Control/Marketability
      a. Reliable calibration and repeatability of pressure and impedance measurements are critical for clinical acceptance.

b. The project must demonstrate improved diagnostic utility compared to existing HRIM analysis methods to encourage adoption by clinicians.

3. List the major **Engineering Standards** on your design/project
   a) affected the components used in the device, and/**or**
   b) standards that constrain the device and its performance, and/**or**
   c) standards that could be developed from your project

- IEC 60601-1-11:2015 - standards for medical electrical equipment used in healthcare environments, relevant to future clinical implementation of HRIM-based systems.
- IEC 60601-1-2:2014 - electromagnetic compatibility requirements for medical devices to ensure accurate sensor measurements without interference.
- ISO 10993-1:2018 - biocompatibility standards relevant to any conductive gel or bolus material introduced into the body.
- Clinical interpretation standards such as the Chicago Classification v4.0 constrain how HRIM metrics are interpreted and compared clinically.

4. Explain **Ethical, Environmental, or Societal concerns** for practical applications of your project.
   - Protecting patient confidentiality and properly handling de-identified clinical data are major ethical responsibilities.
   - False diagnoses in swallowing disorder diagnosis could impact patient treatment plans and quality of life.
   - Increased diagnostic precision could improve healthcare equity by helping patients who are currently underdiagnosed using conventional methods.
   - Development of disposable conductive gels or catheters may contribute to medical waste creating environmental concerns for future large-scale use.

5. Describe **Active Teamwork** and **Leadership** in your design group
   a) **collaboration** and inclusion of diverse opinions?
      - Team members contributed perspectives from bioengineering, clinical medicine, and data analysis, to guide both technical and clinical aspects of the project.
      - Regular meetings with mentors and collaborators encouraged open discussion and incorporation of feedback.
   b) **delegation** of leadership on subprojects?
      - Responsibilities were divided among data processing, MATLAB analysis, literature review, experimental testing, and presentation preparation.
      - Individual members took leadership roles based off of personal strengths while maintaining collaborative communication.

c) establishing and reaching **goals and deadlines**?

- Weekly progress discussions helped maintain accountability and adjust timelines when challenges arose.
- The team established milestones for orientation training, data analysis pipelines, biomechanical modeling, and presentation preparation.

d) received or given **constructive feedback**?

- Team members continuously reviewed MATLAB outputs, graphs, and interpretations together to improve accuracy and clarity.
- Mentor feedback helped refine experimental design, improve data interpretation, and strengthen clinical relevance.

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

a) acquire **new knowledge**

- Learning how pressure and impedance data can be combined to model esophageal biomechanics motivated deeper exploration into HRIM analysis and tissue mechanics.
- Exposure to clinical dysphagia cases highlighted the importance of translational bioengineering research.

b) be **self-initiating**

- The open-ended nature of the project required independent learning in MATLAB programming, signal processing, and biomechanical modeling.
- Troubleshooting experimental and coding challenges encouraged initiative and problem-solving skills.

c) **persist** against challenges and setbacks.

- Variability in HRIM signals and difficulties with data interpretation required repeated troubleshooting and refinement of analysis methods.
- Maintaining progress despite technical issues strengthened persistence and adaptability within the team.

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

- Developing a standardized conductive gel bolus that improves impedance signal quality while remaining patient-friendly and clinically practical.
- Creating software tools that automatically extract biomechanical metrics such as stress-strain loops and modulus from routine HRIM studies.
- Expanding HRIM analysis beyond traditional pressure measurements to provide more comprehensive and quantitative swallowing assessments.
- Potentially integrating quantitative HRIM biomechanics into future personalized treatment planning and disease monitoring for dysphagia and EoE patients.