Jenna Cecil

Bioengineering Day Poster Addendum (ABET questions)

1. Desired Needs
    a. The most critical goal of this design is to maximize urethral safety, the current AUS systems frequently cause infection and erosion due to, for example, excessive or uneven cuff pressures.
    b. The system should leverage contemporary manufacturing methods and materials to reduce failure modes while maintaining simplicity.
2. **Constraints**

a) Safety/Regulatory: Device materials must meet ISO 10993 biocompatibility requirements and any design modifications must satisfy FDA PMA non-inferiority standards relative to the AMS 800

b) Risks: Primary patient-facing risks include urethral erosion from over-occlusion, persistent incontinence from under-occlusion, and device failure requiring revision surgery

c) Global Impact: Post-prostatectomy incontinence affects hundreds of thousands of men annually worldwide;

d) Manufacturability: Silicone casting and 3D printing allow rapid low-cost iteration

e) Quality Control: Occlusion pressure must remain consistently within 60–80 cm H_2O across repeated actuation cycles

3. **Engineering Standards**

ISO 10993: Governs biological evaluation of implantable materials; directed selection of Ecoflex 00-30 for the urethral model and informed material constraints for any future implant-grade cuff prototypes

FDA PMA P000053: Establishes the regulatory approval basis for the AMS 800; proposed cuff modifications must demonstrate equivalent or superior safety and efficacy before clinical translation

ISO 13485: Defines quality management requirements for medical device development; guided documentation, calibration protocols, and reproducibility standards throughout the project

Ethical, Environmental, or Societal concerns

- Stress urinary incontinence carries a significant psychological burden, including depression, social withdrawal, and loss of independenceUse of PLA filament for 3D-printed mold components and reusable silicone castings reduces material waste compared to single-use machined tooling, reflecting a more sustainable prototyping approach

5. Describe **Active Teamwork** and **Leadership** in your design group
    a) Collaboration: Mechanical fabrication, sensor integration, CAD modeling, and FEA we done together, with regular team meetings
    b) Delegation: I sublead on fabrication of model, Mya Verrett and Selena Cao on sensing and calibration, and Kate Reimold on cuff design
    c) Goals and deadlines: The team used a Gantt chart to set milestones
    d) Feedback: Clinical mentors at Naval Medical Center San Diego and industry mentor Moreed Khosravanipour provided design critique at key checkpoints
6. What were the most significant motivating factors that led you to
    a) Acquiring new knowledge: LearnedCAD, circuit design, embedded systems, silicone casting
    b) Self-initiating: Reviewing over 500 FDA MAUDE adverse event reports
    c) Persisting against challenges: Sensor signal variability
7. Most **innovative and/or entrepreneurial ideas** for this project:
    - In the future potentially having a cuff that is magnetic and works without a hydraulic pump, and that is connected to some sort of controller.