

## 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.

- Need for a cuff design that distributes urethral compression more uniformly to reduce ischemia, erosion, and atrophy on urethral tissue
- Need for real-time, quantitative pressure and flow measurement to establish performance baselines for comparative design testing

### 2. List the major Constraints on your design/project

- a) **Safety/Regulatory:** Must comply with FDA PMA requirements and ISO 10993 biocompatibility standards
- b) **Risks:** Cuff erosion, urethral atrophy, fluid leakage, and urinary retention from closed failure mode
- c) **Global Impact:** Improved AUS could reduce reoperation rates and healthcare burden globally
- d) **Manufacturability:** T-spline model is static and does not simulate dynamic inflation/deflation behavior
- e) **Quality Control:** Chamber pressure distribution must be consistent and match AMS 800 mechanical survival rates (~72–79% at 5 years)

### 3. List the major Engineering Standards on your design/project

- ISO 10993: Biocompatibility evaluation of medical devices; governed material selection for Ecoflex 00-30 silicone and any implant-adjacent components
- FDA PMA P000053: Regulatory standard under which the AMS 800 is approved; any proposed design modification must demonstrate non-inferiority to the existing device
- ISO 13485: Quality management systems for medical device design and manufacturing processes

### 4. Explain Ethical, Environmental, or Societal concerns for practical applications of your project.

- MRI imaging data raises considerations around patient data privacy and informed consent in the design process.
- Societally, urinary incontinence disproportionately impacts quality of life and mental health in prostate cancer survivors, a population that is aging and growing globally
- PLA for 3D printed components offers a more sustainable fabrication pathway compared to traditional machining

### 5. Describe Active Teamwork and Leadership in your design group

- a) **Collaboration:** The project was divided into parallel workstreams, such as benchtop model fabrication, sensor integration, CAD design, and FEA.
- b) **Delegation:** Leadership on subprojects was distributed by technical expertise in each subproject.
- c) **Goals and deadlines:** Iterative milestones were set around key deliverables, with final presentation serving as the culminating deadline
- d) **Feedback:** Constructive feedback was incorporated at each design iteration through team member reflection and also input from our stakeholders and mentors.

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

- a) **Acquiring new knowledge:** The outdated AMS 800 design motivated the team to independently develop new skills across FEA simulation, silicone molding, and embedded systems programming.
- b) **Self-initiating:** Independent analysis of 500 FDA MAUDE complaints provided original evidence to justify focusing the project on cuff redesign.
- c) **Persisting against challenges:** Repeated setbacks (failed sensor approaches and insufficient cuff geometry) each directly informed a stronger final solution.

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

1. The 15-chamber cuff design is a novel pressure redistribution approach not found in any commercial AUS device, presenting a potential IP opportunity pending FEA and physical validation
2. The Arduino-Python monitoring system is a low-cost, open-source platform packageable as a standardized testing toolkit for future AUS design teams