Tsubasa Kitada

1. **Desired Needs**
    a) The device must maintain a constant force on the testing subject.
    b) The device must achieve biaxial compression by integrating into the larger UTS testing device.
    c) The device must be affordable, fitting within the ~5.5k budget.
2. **Major Constraints**
    a) **Safety/Regulatory Affairs** – Exposed electrical contacts present a shock hazard during operation. The mechanical components introduce physical pinch points, as well.
    b) **Risks** – False validation is a major risk, as if the system records inaccurate force data, it would lead to the passing of a structurally compromised medical device in preclinical trials.
    c) **Global Impact** – To ensure global accessibility, our design was constrained by cost, aiming to democratize medical R&D by enabling validation of orthopedic implants without high costs.
    d) **Manufacturability** – Easy to manufacture, as each device part can easily be purchased or machined.
    e) **Quality Control/Marketability** - The device is both affordable (~$500) and small enough that a company could deploy multiple units in parallel.
3. **Major Engineering Standards**
    a) **affected the components used in the device –** Load cell was calibrated to ASTM E74. The actuator meets IEC 60529. Arduino/motor driver comply with CE/FCC EMC requirements.
    b) **standards that constrain the device and its performance** – ASTM F1717 and ISO 12189 outline force magnitudes and other performance criteria the fixture must meet.
    c) **standards that could be developed from your project** – New protocols could be developed for active force control systems, and for testing spinal devices which are able to change dimensions.
4. **Ethical, Environmental, or Societal concerns for practical applications**
    - **Ethical** – Users must properly calibrate the load cell and tune the control loop, as not addressing anomalies in the active feedback system could result in patient harm during surgery.
    - **Societal** – Enabling accurate, dynamic testing of expandable cages, contributes to the development of more reliable spinal implants, leading to better patient outcomes.
    - **Environmental** – The device minimizes waste by having completely reusable components.
5. **Active Teamwork and Leadership**
    a) **collaboration and inclusion of diverse opinions** – Initially each member would work independently on their own ideas. We would then meet to discuss the ideas and collaborate.
    b) **delegation of leadership on subprojects** – We divided major subprojects within the group, each member taking a leadership role in each. Other members still contributed to the other subprojects as well.
    c) **establishing and reaching goals and deadline**s – We communicated amongst our group and coordinated to get everything done before the deadline.
    d) **received or given constructive feedback** – We would talk within the group to find better solutions when necessary. Our mentor would also give us general guidance and advice, while mostly hands-off.
6. **Motivating Factors**
    a) **acquire new knowledge** – I chose this project originally because I felt that this project had many components that I was originally unfamiliar with, so I was motivated to acquire new knowledge and skills. Most significant was learning SolidWorks and CAD design.
    b) **be self-initiating** – For the subproject I was leading (3D design), I had to take ownership and start the work, and it would be the same for the other members.
    c) **persist against challenges and setbacks** –Regardless of manufacturing bottlenecks or technical setbacks, we were highly motivated by the professional obligation to deliver a fully functional, tested prototype.
7. **Most Innovative and/or Entrepreneurial Ideas**
    - The system can measure force on an expandable spinal cage in real time during expansion or retraction, which is currently not possible in standard passive fixtures. The setup also costs around $500, enabling biaxial testing much cheaper than existing machines.