Lecture 01: Class Introduction and Overview

- Business Items
    - Bryan Research Building parking is available with Duke Card after 4:00 PM, so we can start lab on time (4:40 PM).
- Group project assignments
    - Non-exclusive team roles
        - *Electronic hardware:* Design and build electronic hardware, including theory behind design, circuit schematics, printed circuit boards, etc.
        - *Software:* Work closely with the hardware team member to write software for the microcontroller (and tablet), including analysis of the theoretical algorithmic approach, logical flowcharts, software fault tolerance and software tests.
        - *Physical design:* Design and construct all physical aspects of the device that are not associated with the electronic hardware, including the selection and integration of the transductive elements. Prepare 2D and 3D mechanical drawings (SolidWorks) for parts and enclosures, and utilize the machine shop and 3D printer to professionally-fabricate all parts. The physical design should be robust to handle being dropped from a specified height, handle water / humidity exposure (if applicable) and be bio-compatible (if applicable). Electrical safety must also be specifically addressed.
        - *Testing, Validation & Safety:* Delineate all functional specifications of the device, and design test fixtures, instruments, independent measurement protocols to test and validate the function and safety of the device. Specify what other team members should achieve for functional and safety validation, and prepare formal documentation of passing all validation and safety tests.
    - All team members will contribute to:
        - Device and sub-system planning, specifications, and block diagrams, including definition of the clinical / community / research need for the device.
        - Defining the market for the device, including patent searches for existing technology, competition in this field, advertising, presentations and reports.
        - Defining the price point for the device, development costs, and production costs.
        - Developing a regulatory plan, including definition of FDA device class, studies for device approval, etc.
    - Choose team name and develop a team logo
- ELN / LabArchives Overview
    - The FDA requires formal documentation of device design, fabrication and testing to be available for review.
    - Block diagrams of the device and sub-modules in the device should be presented and updated as the device evolves throughout the semester.
    - Signal processing and software algorithm logic should be documented, and the associated code should be specifically referenced by the appropriate git repository URL and SHA1 hash(es). Utilize flowcharts and other graphical means to demonstrate logical progression of algorithms.
    - Choice of electronic components should be supported by an analysis (when appropriate) that includes considerations such as power, bandwidth, SNR, etc. that could impact performance of your device.
    - Formal circuit schematics should be drawn and properly annotated for all electronic circuits.

- Component datasheets, user manuals, etc. should be included.
- Mechanical drawings (e.g., SolidWorks) in 2D and 3D should be included. Final drawings of all physical components will need to be provided in your final reports.
- All measurements made during debugging and testing should be recorded with the appropriate precision, units, and estimates of uncertainty. These measurements should be accompanied by a motivation for making them, along with a summary of your interpretation of the data.
- A copy of all reports and slides should be saved.
- All software associated with your device, along with relevant documentation, should be maintained in your group's git repository. A tar / zip archive of your final software repository should be saved in your ELN.
- Your ELN should be able to audited and have your device be replicated without any other information.
- We will utilize team ELNs in class, that Dr. Palmeri, Matt Brown and Dongwoon will all have access to throughout the semester.
- All pages should be electronically signed when complete, and an entry should indicate what team members contributed to that effort when a single person is making an entry.
- Dr. Palmeri will provide feedback in the ELN on at least a weekly basis.
- Part ordering will occur through your ELN (order template to be provided).