UNIVERSITY OF ILLINOIS CHICAGO

Richard and Loan H[illegible] of Biomedical Engin[illegible]

Development of a Domain-Agnostic Standards Curriculum in Partnership with a Medical Device Manufacturer

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Richard and Loan Hill Department of Biomedical Engineering

- Standards in Biomedical Engineering
- Hip Joint Arthroplasty Device Example
- Study Aims
- Module Contents
- Project Schedule

AGENDA

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Standards in Biomedical Engineering

Standards Organizations:

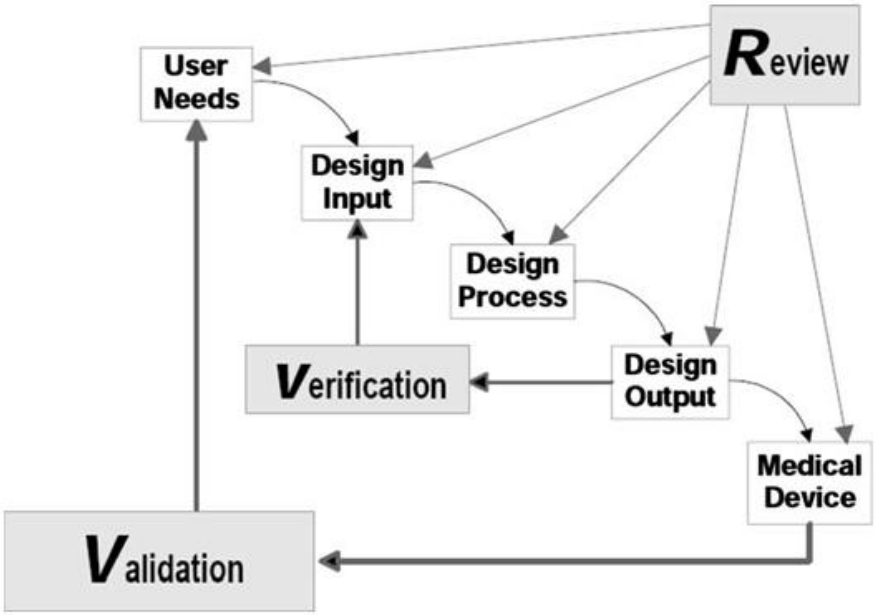
ISO, ASTM, IEEE, etc.

Frequently Taught Standards:

ISO 13485:2016 Quality Management Systems

ISO 10993-1:2018 Biological evaluation of medical devices

ISO 14971:2019 Medical devices — Application of risk management to medical devices



Hip Joint Arthroplasty Device Example (slide 1 of 2)

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Device: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented

Regulation Description: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.

Product Code: LZO

Regulation Number: 888.3353

Device Class: 2

DePuy EMPHASYS Dual Mobility

https://www.jnjmedtech.com/en-US/product/emphasys-dual-mobility

Hip Joint Arthroplasty Device Example (slide 2 of 2)

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56 Total FDA Recognized Consensus Standards:

ISO 21535 Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants

ASTM F2345-21 Standard Test Methods for Determination of Cyclic Fatigue Strength of Ceramic Modular Femoral Heads

ISO 13779-4 Implants for surgery - Hydroxyapatite
Part 4: Determination of coating adhesion strength

DePuy EMPHASYS Dual Mobility

https://www.jnjmedtech.com/en-US/product/emphasys-dual-mobility

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Study Aims

MODULE 1
Introduction to the fundamentals of performance standards and organizations using ASTM Compass.
Blooms Taxonomy: recognition and understanding

MODULE 2
Students will learn to write accurate testing protocols based on requirements set in technical standards.
Blooms Taxonomy: application

MODULE 3
Students will experience the process to revise and update performance standards through activities.
Blooms Taxonomy: analyze and evaluate

MODULE 4
Immersion in the technical challenges and ethical dilemmas in the creation of new consensus standards.
Blooms Taxonomy: evaluate and create

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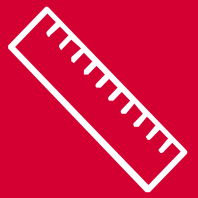
Sourcing and appropriate selection of standards (slide 1 of 2)

Incorporation into Capstone Senior Design and “FDA and ISO Requirements for Medical Devices” Courses to develop and extract performance requirements

Course Goals and Learning Outcomes

After the completion of the course, students will be able to:

1. Describe and discuss federal and international standards for quality assurance in the medical device development and manufacture process.
2. Identify and interpret appropriate standards (both general and specific) for medical devices design and testing.
3. Draft the types of documentation required for quality assurance controls in industry.
4. Identify points in the design and manufacture of a medical device that must be compliant with federal and international guidance documents.



MODULE 1

Introduction to the fundamentals of performance standards and organizations using ASTM Compass.

Blooms Taxonomy: recognition and understanding

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Sourcing and appropriate selection of standards (slide 2 of 2)

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Technical Standards: Home

Home | Locating Technical Standards | Standard Equivalents: What Are They? | Accessing Standards Through the University Library

Standards Overview

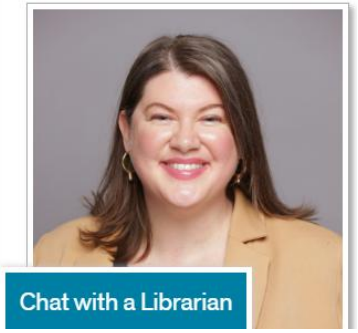
According to the National Institute of Standards and Technology (NIST), technical standards:

- provide a common language to measure and evaluate performance,
- make interoperability of components made by different companies possible, and
- protect consumers by ensuring safety, durability, and market equity.

Standard Development Organizations (SDO), such as the International Organization for Standardization (ISO) or the International Electrotechnical Commission (IEC), create and update existing standards. ISO encourages users to "think of them as a formula that describes the best way of doing something." Our goal at the University Library is to connect you to the resources you need and we are proud to provide access to the following SDOs:

- UNE/ISO equivalents
- ASTM

Assistant Professor and Reference & Liaison Librarian (STEM)



Kristyn Caragher
Assistant Professor and Reference & Liaison Librarian (STEM)

MODULE 1

Introduction to the fundamentals of performance standards and organizations using ASTM Compass.

Blooms Taxonomy: recognition and understanding

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Writing of protocols to comply with standards (slide 1 of 2)

Team-based assignments to write then execute detailed protocols to test previously identified requirements using performance standards

MODULE 2

Students will learn to write accurate testing protocols based on requirements set in technical standards.

Blooms Taxonomy: application

Writing of protocols to comply with standards (slide 2 of 2)

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PRD Item	Design Criteria Item	PRD Class I-IV	Quantifiable Requirement	Units	Standard, Reference, Calculation, or Data	Verification Method
A	3,6	I, IV	**An impedance value less than 5kΩ but more than 100Ω.** **We will verify this requirement in the protocol below.**	Ohms (Ω)	[1] In this source, electrode contact that resulted in an impedance below 5kΩ proved to provide viable signals. Below 10kΩ was also acceptable but anything below 100Ω was unacceptable because it indicated a shunt or short.	Measure the impedance between the electrode and the scalp. Verify that the impedance falls within the defined range. No electrolyte solution needed. Impedance will be measured by varying the frequency and measuring input/output voltages with a known resistor in series.

https://www.sciencenews.org/article/electrodes-brain-waves-eeg-black-african-american-natural-hair

8. Find Scalp Impedance: Repeat steps 3-7 by placing the same two electrodes on the scalp a few centimeters apart on F3 and F4, according to the 10-20 electrode system [9,10,13].

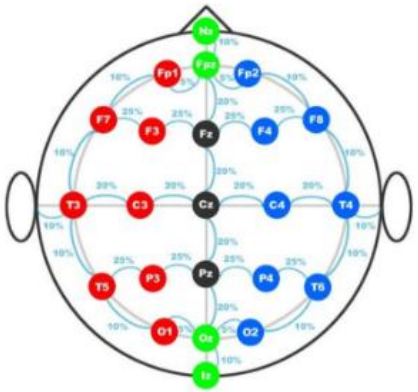

Figure 3: Illustration of standard 10-20 system electrode placement for EEG data collection [13].

9. Record the output voltage on oscilloscope.
10. Find Average Scalp Impedance: Repeat steps 8-9 five more times, remove electrodes, and place the electrodes in the same location, as defined in step 8.
    a. It is assumed that contact was applied to the best of the tester's ability.
11. Calculate electrode impedance using equations provided in section 3.1 for both the scalp and forearm.
12. Find the average of the scalp impedances.
13. Repeat steps 3-12 for five subjects from each bin defined in step 1.

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Blooms Taxonomy: application

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The revision of consensus standards (slide 1 of 4)

Adulterated Modulus of Elasticity Exercise

This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Designation: BME410 – 24

Standard Test Methods for Biomedical Engineering Class 410 Thermoplastics — Tension[1]

This standard is modified using the designation BME410 the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

This standard has not been approved for use by agencies of the U.S. Department of Defense.

1. Scope

1.1 These test methods cover procedures used to evaluate the tensile (tension) properties of vulcanized thermoset rubbers and thermoplastic elastomers. These methods are not applicable to ebonite and similar hard, low elongation materials. The methods appear as follows:

Test Method A—Dumbbell and Straight Section Specimens
Test Method B—Cut Ring Specimens

NOTE 1—These two different methods do not produce identical results.

1.2 The values stated in either SI or non-SI units shall be regarded separately as normative for this standard. The values in each system may not be exact equivalents; therefore each system must be used independently, without combining values.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This internal standard was based on approved standards and was made in accordance with ineeds for the University of Illinois Chicago (UIC) Biomedical Engineering Department (BME) 410 class on FDA and ISO standards for the development and manufacturing of medical devices. It is not intended to be used or shared outside the UIC BME program.*

D3182 Practice for Rubber—Materials, Equipment, and Procedures for Mixing Standard Compounds and Preparing Standard Vulcanized Sheets
D3183 Practice for Rubber—Preparation of Pieces for Test Purposes from Products
D4483 Practice for Evaluating Precision for Test Method Standards in the Rubber and Carbon Black Manufacturing Industries
E4 Practices for Force Verification of Testing Machines

2.2 *ASTM Adjunct:*
Cut Ring Specimens, Method B (D412)[3]

2.3 *ISO Standards:*
ISO 37 Rubber, Vulcanized and Thermoplastic Determination of Tensile Stress-Strain Properties[4]

3. Terminology

3.1 *Definitions:*

3.1.1 *tensile set*—the extension remaining after a specimen has been stretched and allowed to retract in a specified manner, expressed as a percentage of the original length. (D1566)

3.1.2 *tensile set-after-break*—the tensile set measured by fitting the two broken dumbbell pieces together at the point of rupture.

3.1.3 *tensile strength*—the maximum tensile stress applied

Chara Nunnally
MS Thesis Graduate
UIC Biomedical Engineering

MODULE 3

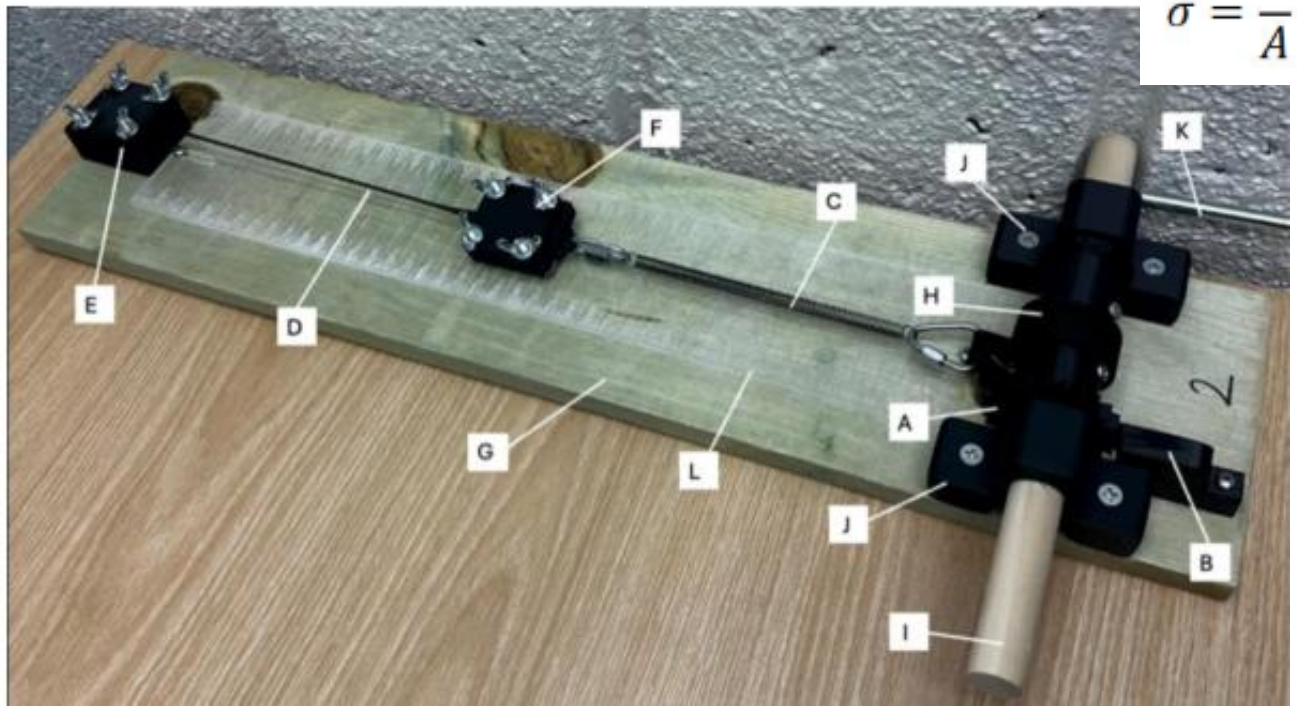
Students will experience the process to revise and update performance standards through activities.

Blooms Taxonomy: analyze and evaluate

The revision of consensus standards (slide 2 of 4)

Adulterated Modulus of Elasticity Exercise

$$\sigma = \frac{F}{A} = \frac{kx}{A} = E\varepsilon_{sample}$$



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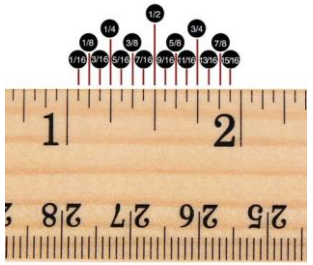
The revision of consensus standards (slide 3 of 4)

Device and Team Numbers	Resolution	Spring Constant	Material Durometer	Adulteration Status
1 & 2	1/16th in	1.5 lbs/in	40 A	Reference – unadulterated
3 & 4	1/4th in	1.5 lbs/in	40 A	Adulterated measurement resolution
5 & 6	1/16th in	1.0 lbs/in	40 A	Adulterated spring constant
7 & 8	1/16th in	1.5 lbs/in	60 A	Adulterated material



Device and Team Number	Adulteration	Identification of Resolution Adulteration	Identification of Spring Adulteration	Identification of Material Adulteration	Total Adulteration Identification Score
1	None	1	1	0.5	2.5
2	None	0	0	0	0
3	Resolution	1	1	0.5	2.5
4	Resolution	0	0	0	0
5	Spring	0	0.5	0	0.5
6	Spring	0	0.5	0	0.5
7	Sourcing	1	1	0.5	2.5
8	Sourcing	0	1	0.5	1.5
		0.4±0.5	0.6±0.4	0.3±0.3	1.3±1.1

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The revision of consensus standards (slide 4 of 4)

c. ASTM Standard Revision (Angle of Material Grain Direction)

i. Original section of ASTM Standard (Section 11.1.3):

"11.1.3 All specimens shall be cut so that the lengthwise portion of the specimens is parallel to the grain unless otherwise specified. Refer to 7.1.1 regarding anisotropy or grain directionality."

"7.1.1 Since anisotropy or grain directionality due to flow introduced during processing and preparation may have an influence on tensile properties, dumbbell or straight specimens should be cut so the lengthwise direction of the specimen is parallel to the grain direction when this direction is known."

ii. Revision and Rewritten ASTM Standard (Section 11.1.3):

"11.1.3 All specimens shall be cut so that the lengthwise portion of the specimens is parallel to the grain unless otherwise specified. Grain directionality must be specified and recorded based on supplier material properties to ensure consistent and accurate results. Grain directionality should be visually assessed between each sample for consistency. Refer to 7.1.1 regarding anisotropy or grain directionality."

iii. Rationale for new ASTM Standard (Section 11.1.3):

The importance of grain directionality in tensile properties is well-documented, as emphasized by D.I. James and J.S. Gilder [1]. Specimens cut parallel to the grain exhibit a higher modulus and greater tensile strength than those cut perpendicular to the grain. This adjustment to the protocol aims to standardize and confirm the grain alignment, reducing measurement variability and enhancing the accuracy of tensile results. Ensuring that all test samples are cut in the correct grain directionality is essential to obtain accurate tensile measurements. Observations during in-class testing have demonstrated that samples with grain direction aligned parallel to the length have a higher elastic modulus than those cut at a 45-degree angle. By strictly controlling grain direction, we eliminate a significant source of error that could otherwise result in skewed tensile properties.

Improvements:

- Extend duration
- More "hand holding"
- Pre & post analysis

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Blooms Taxonomy: analyze and evaluate

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The creation of new consensus standards (slide 1 of 4)

Murder Mystery Themed Activity

- "Death" of *Billy Boingz*, professional pogo sticker
- Teams worked in companies to c a new ISO standard for pogo stick
- Company and individual personas
- Moderation by standards rep
- Working groups collaborated to create draft standard

MODULE 4

Immersion in the technical challenges and ethical dilemmas in the creation of new consensus standards.

Blooms Taxonomy: evaluate and create

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The creation of new consensus standards (slide 2 of 4)

Companies with in-process development (ethics)

The AeroPulse 9000 by PogoElite Manufacturing

- **Primary Design Goal:** Maximum efficiency and agility for competitive pogo athletes focusing on speed runs and technical skills.
- **Key Components:**
  - **Carbon Nanotube Spring System:** Advanced carbon nanotube technology enables high-energy rebound with minimal energy loss, allowing for controlled but rapid bounces.
  - **Titanium Frame with Weight Reduction Ribs:** The frame uses lightweight titanium with reinforcement ribs for durability without sacrificing maneuverability, meeting high-stress competition demands.
  - **Torsion-Control Handles:** Handles designed to absorb torque, reducing wrist strain during high-intensity jumps and maneuvers.
  - **Flexible Footplate:** The footplate is made from a composite material that flexes slightly upon landing, providing a greater feel and enhancing control for athletes performing precision tricks.
- **Notable Internal Concerns:**
  - **Spring Consistency Issues:** The nanotube spring system is challenging to manufacture with uniformity, causing some slight variation in bounce height and force.
  - **Weakness at Torsion Joints:** The torsion control handles have multiple moving parts that can wear out over time, compromising handle stability.

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The creation of new consensus standards (slide 3 of 4)

Individuals with personal biases and conflicts

Lacy Rocketbounce, Junior Biomechanist, SkyBound Innovations

- **Public Bias:** Believes standards must support ergonomic design to reduce user injuries, particularly for beginners.
- **Hidden Info:** Hates pogo sticking and finds it "dangerous for fun." Wants high safety barriers that make sticks harder to market.

Stanley Grip, Industrial Designer, SkyBound Innovations

- **Public Bias:** Prioritizes flexibility in designs so companies like SkyBound can remain competitive.
- **Hidden Info:** Had a falling-out with Willie Jumpster over materials selection; resents any push for more expensive materials.

Nina Skyhops, Marketing Strategist, SkyBound Innovations

- **Public Bias:** Thinks industry should be self-regulated to keep the sport exciting and appeal to thrill-seekers.
- **Hidden Info:** Struggling to gain traction with the community; sees standards as a way to force customers toward products they don't truly want.

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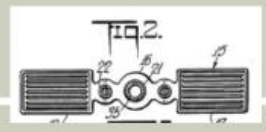
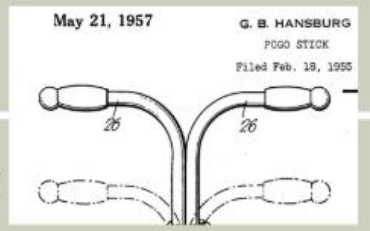
The creation of new consensus standards (slide 4 of 4)

3.4 Requirements for grips





[US 2793036]

3.3.1 *Retention*

The pogo stick hand and foot grips shall be secure against removal force of no less than 66.8N (15lbf). This requirement applies whether the grips are slip on or directly adhered to the hand and foot bars. (Refer to test method.) The same standard for grip retention should be applied to all use cases due to potential danger to user if grips are removed. *ASTM F2793-14(2023)*

3.3.2 *Durability*

3.3.2.1 *Heat and cold resistance*

The pogo sticks hand and foot grips shall be resistant to temperatures in the range of 5-33 C. That is the grips shall not experience any significant decline in material property within this temperature range.

3.3.2.2 *Wear from normal use*

Under beginner use the grips shall not visually degrade due to normal wear for a period of up to 1 year. Under Intermediate use the grips shall not degrade visually for a period of up to 6 months. Under advanced use the grips shall not visually degrade for a period of up to 1 month.

3.3.3 *Compression of grip*

3.3.3.1 *Compression Set*

The pogo stick hand and foot grips compression set range shall fall within the range of 20-30%. Compression set shall be measured as a percentage of the original thickness. (Refer to test method.) *ASTM D395-18 (2018).*

3.3.3.2 *Thickness and Use Cases*

The pogo stick hand and foot grips shall vary in thickness correlating to the use case. Beginner use shall have grips no thinner than 4mm. Intermediate use shall have grips no thinner than 8mm. Advanced use shall have grips no thinner than 1.2mm.

3.3.4 *Surface Friction*

The pogo stick foot and hand grips shall provide a coefficient of friction no less than 0.9 for dry conditions, and 0.5 for wet conditions. The coefficient of frictions stated should be applied to all use cases due to the danger of lost grip.

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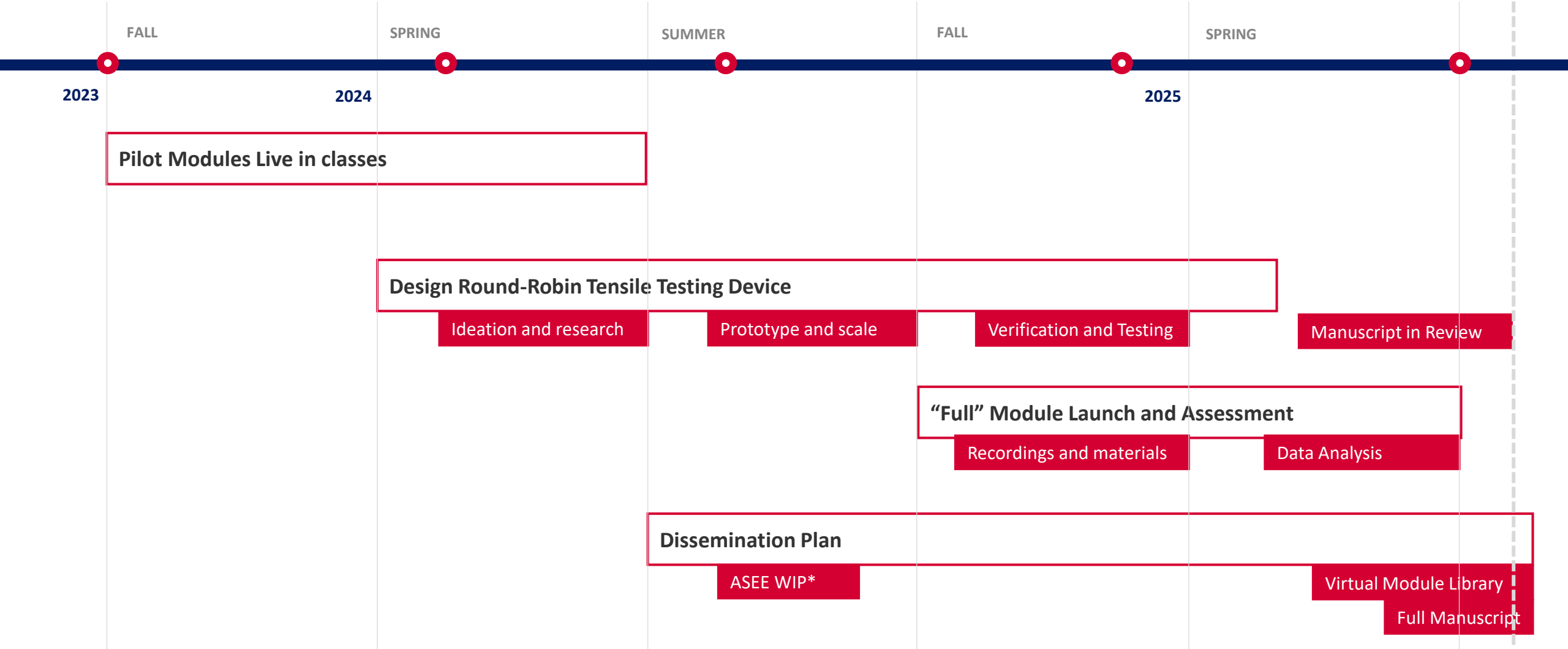
Project Schedule



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Richard and Loan Hill Department
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Anthony Felder Ph.D.
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Adrian Defante Ph.D.
Hollister Inc.

Thank you!

Michael G. Browne Ph.D.

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