



## Cushion Characterization ISS 2011

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## Presentation Goals



- Update on the cushion characterization project we introduced at last year's ISS
- Share our results, recommendations and proposed next steps
- Obtain your feedback and guidance

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## Project Goals



To develop a method whereby we could:

- Identify the ability of a cushion to be adjusted / readjusted to address changes to weight, shape...
- Identify the skin protecting features of a cushion (e.g. immersion, magnitude and envelopment)
- Identify the ability of an adjustable cushion to maintain equivalent skin protection even when changes to weight, shape, etc. occur

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## History Regarding Cushion Selection and Characterization



Historically the evidence associated with cushion characteristics and performance has been limited and conflicted. But that was OK because...

- **Providers** offered a wide range of products and services to compete for the referral source's business
- **Regulators** - requirements were minimal
- **Payers** "primarily" relied upon clinical judgment

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## The future, unless we have evidence to the contrary:



- Payer – price will be the deciding factor
- Provider – cost will be the deciding factor
- Regulators – more conflicting and inappropriate regulations
- Manufacturers – meet the "minimums" with little incentive to innovate
- Clinicians – diminished authority and selection
- Users – loss of quality and access

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## The future, unless...



**...we find an effective way to categorize seating and full support surfaces based on their characteristics.**

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## Clinical Studies and / or Laboratory Testing???



- Challenges to clinical studies (RCT):
  - Time, \$\$\$ and subjects
  - Diagnosis (primary, secondary, tertiary...)
  - Prognosis
  - Unique individual needs
- Challenges to laboratory testing:
  - Design / Reliability
  - Repeatability / Reproducibility (ability to replicate results)
  - **Clinical relevance / validation**
- That said, we proposed that laboratory testing offer the best chance of success

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## Laboratory Tests Goals:



- To simulate the human condition while eliminating the variables associated with using human subjects.
- To accelerate the collection of data necessary to do analysis and draw conclusions / recommendations
- To evaluate cushion characteristics that are **clinically relevant** / associated with known conditions / risk factors

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## Clinical Relevance and Laboratory Testing:



*“One people separated by a common language...”*

Winston Churchill?

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## Clinically Relevant

### Characteristics / Features:



- Skin Protection (Pressure Management)
  - Immersion
  - Magnitude
  - Envelopment
- Positioning
  - Stability
  - Accommodation
  - Correction
  - Alignment
- Adjustable / Re-adjustable
  - Multiple weights & shapes
  - Full or partial
  - Discrete or continuous
- Micro-climate
  - Heat
  - Moisture
- Durability/Accelerated aging
  - Repetitive Loading
  - Temperature
  - UV
  - Microbial

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## Laboratory Tests Components:



- Define the Activities / risk factors to test
  - Anatomical shapes (‘‘Indenters / mannequins’’)
  - Loads based on positions (seated, supine)
  - Standardized equipment, environment and protocols
  - Standardized data collection and analysis
- Repeatability

...then Reproducibility

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## Indenters, Mannequins and Loads



No two individuals are alike



Size and shape will change over time

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## Indenters, Mannequins and Loads:



Size, shape, materials and weights are dependent upon:

- What characteristics you are evaluating
- What type of surface you are evaluating



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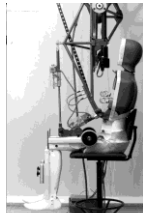
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## Indenters, Mannequins and Loads



Joint Articulation?



Shape?

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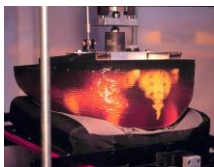
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## Indenters, Mannequins and Loads



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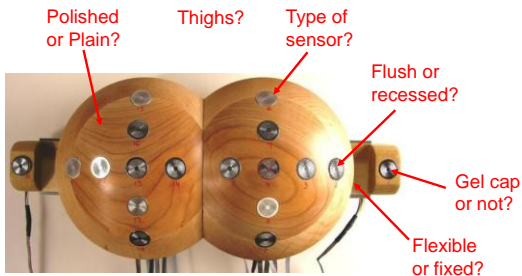
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# Indenters, Mannequins and Loads - Variables



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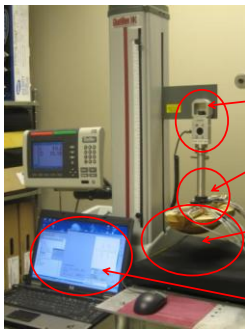
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# Standardized Equipment, Environment and Protocol:



## More Variables

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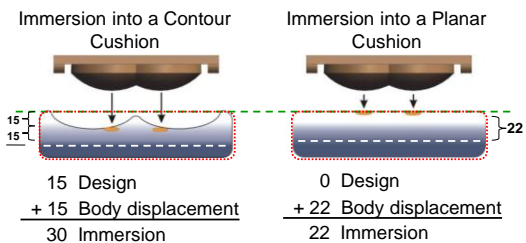
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# Standardized Data Collection / Analysis: ...More Variables



## How do you measure immersion?



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## Standardized Data Collection / Analysis: ...More Variables



What do you measure?

- Peak
- Median
- Average
- Minimum
- Range

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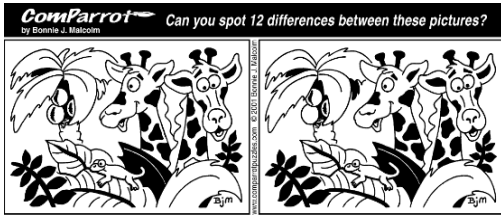
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## Repeatability & Reproducibility:



- Repeatability – consistent data from day to day
- Reproducibility – consistent data from lab to lab




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## Feedback to Date:



- Everyone seems to agree that there is a need to clearly identify what is "adjustable / readjustable"?
  - Full or partial
  - Discreet or continuous
- Everyone seem to agree that clinically relevant skin protecting characteristics for a seat cushion are
  - Immersion
  - Magnitude
  - Envelopment
  - Friction / Shear
  - Micro-climate
- Everyone is afraid of change

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## Next Steps (from Last Year)



- Finalize the review of the data from the initial testing
- Determine any retesting or protocol modification necessary
- Finalize initial lab testing / data
- Duplication of tests at additional lab(s)
- Release of the results and the information necessary to repeat by anyone who is interested (protocols, equipment, etc.)

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## What Has Occurred Since Last Year?

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## Laboratory Test – Our Targets



- **Skin Protection (Pressure Management)**
  - Immersion
  - Magnitude
  - Envelopment
- **Positioning**
  - Stability
  - Accommodation
    - Correction
    - Alignment
- Durability/Accelerated aging
  - Repetitive Loading
  - Temperature
  - UV
  - Microbial
- Micro-climate
  - Heat
  - Moisture

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## Positioning - Stability



### Stability tests conducted

#### 1. Forward sliding test

- Measures
  - The ability of the cushion to prevent forward sliding
  - The ability of the cushion to return the user to the original position once a forward slide has occurred.

#### 2. Lateral lean test

- Measures
  - how well the cushion resists a user's lateral lean
  - The ability of the cushion to return the user to the original position once a lateral lean has occurred.

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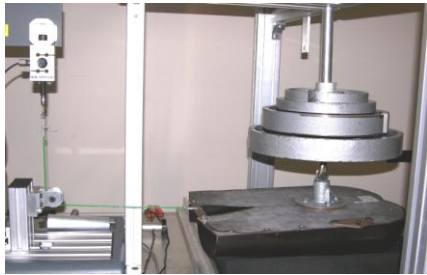
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## Forward Sliding Testing



Based on the ISO horizontal stiffness test

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## Lateral Lean Testing



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## Skin Protection

Important characteristics of a cushions ability to maintain skin integrity



- Immersion
  - Capability of a cushion to allow the body to sink into it.
- Magnitude
  - How much force is concentrated on the bony prominences.
- Envelopment
  - Capability of cushion to deform around and encompass the shape of the body.
- Off-loading
  - Load taken by the trochanters vs. the ITs

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## Skin Protection

Direct Pressure Measurement



- Multiple sizes/shapes and loads to better simulate variation of actual users
  - (22cm & 25.5cm and 97 lb and 116 lb loads)



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## Immersion



- Contact deflection test
  - Instrumented indenter
  - Loaded with 97 lbs or 116 lbs
  - Starting point determined by sensing point at which the indenter began to load (1/2 lb) the cushion

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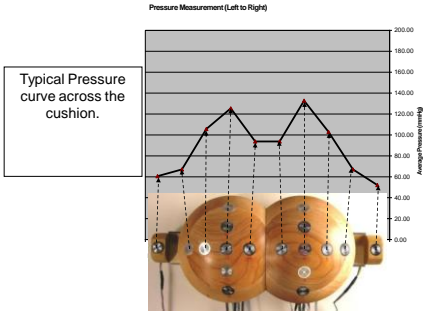
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# Magnitude

## Direct Pressure Measurement Test



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## 2010 Testing Focus



- Demonstrate repeatability and reproducibility of the skin integrity tests
  - *Repeatability* - Produce consistent results at a single lab over several days
  - *Reproducibility* - Produce consistent results at two labs over several days on control sample
  - Demonstrating repeatability and reproducibility was a requisite before revealing results to standards groups
- Originally, data was significantly different between test labs (Sunrise & EC Labs)

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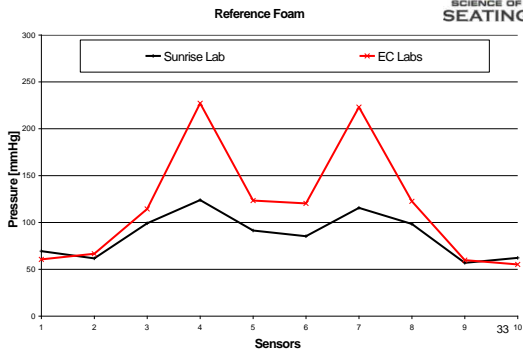
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## Sunrise Data vs. EC Data




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## Additional variables to Control



1. **Position:** Tightly control cushion position relative to indenter.
  - a. 1/2" fore/aft
  - b. 1/2" left/right
2. **Cushion:** Standardized cushion – use the same reference foam for both labs. Eliminate the variables in the process to ensure the measurement tool is robust.
3. **Refresh:** Refresh cushion but do not replace.
4. **Trials:** Increase the number of trials and conduct testing over three days.
5. **Squareness:** Ensure indenter is square to the test surface to eliminate asymmetries as possible.
6. **Calibration:** Calibrate the load cells daily to eliminate possible effect of barometric pressure changes
7. **Gel Interface:** Eliminate the gel medium
8. **Temperature:** Set temperature at 73°F +/- 3°F
9. **Humidity:** Set humidity at 50% +/- 5%
10. **Sensors:** Ensure sensor type is equivalent

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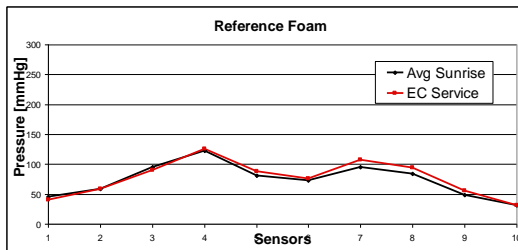
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## Once Variables Were Controlled



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## Findings



- Temperature and Humidity had a significant effect on Repeatability and Reproducibility
- Gel cap sensors seemed to have less variance
- Lower pressure levels had a higher relative variance – as was expected
- Average variance between labs was measured at 7%

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## Analysis of Variance



- EC Labs conducted an analysis of variance study [*contribution of overall variance by different variables*]
- No significant difference was determined between the testing done at Sunrise lab and EC Labs

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## Analysis of Variance Conclusion



- Over all, the test is reproducible between labs.
- The test was able to detect significant differences between cushions.
  - Analysis was done to the 99% confidence level.

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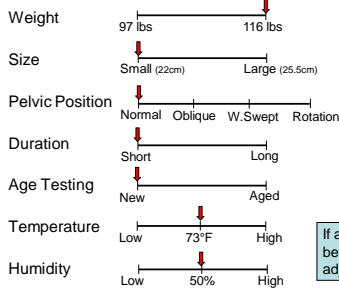
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## Possible Test Variables



**Resulting Values:**

Measured

- Magnitudes
- Immersion

Calculated

- Envelopment
- Off-Loading

If adjustable, tests can be done before adjustments and after adjustments

↓ Indicates initial control condition

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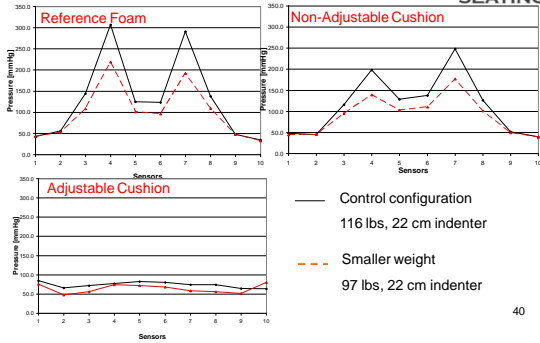
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# Sample Results

Accommodation of weight



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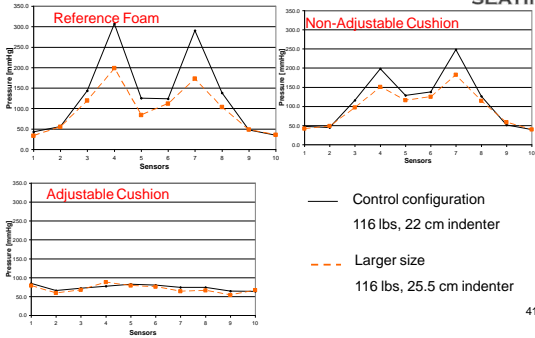
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# Sample Results

Accommodation of size



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# Immersion & Envelopment



|                | Reference Foam          |                      |                        |          |
|----------------|-------------------------|----------------------|------------------------|----------|
|                | Control (116 lbs, 22cm) | Change Size (25.5cm) | Change Weight (97 lbs) | Variance |
| Immersion (mm) | 86.4                    | 83.9                 | 84.3                   | 2.5      |
| Envelopment    | 0.72                    | 0.51                 | 0.58                   | 0.21     |
| Mean (mmHg)    | 108.7                   | 88                   | 87.1                   | 21.6     |

|                | Non-Adjustable Cushion  |                      |                        |          |
|----------------|-------------------------|----------------------|------------------------|----------|
|                | Control (116 lbs, 22cm) | Change Size (25.5cm) | Change Weight (97 lbs) | Variance |
| Immersion (mm) | 76.6                    | 74.5                 | 74.5                   | 2.1      |
| Envelopment    | 0.55                    | 0.43                 | 0.44                   | 0.12     |
| Mean (mmHg)    | 104.4                   | 91.8                 | 85.3                   | 19.1     |

|                | Adjustable Cushion      |                      |                        |          |
|----------------|-------------------------|----------------------|------------------------|----------|
|                | Control (116 lbs, 22cm) | Change Size (25.5cm) | Change Weight (97 lbs) | Variance |
| Immersion (mm) | 74.6                    | 76.9                 | 75.9                   | 2.2      |
| Envelopment    | 0.22                    | 0.21                 | 0.28                   | 0.07     |
| Mean (mmHg)    | 69.2                    | 66.1                 | 58.3                   | 10.9     |

**Note:**  
 • Lower envelopment numbers indicate more even distribution, ideal is 0  
 • Lower variance indicates greater ability to accommodate changes

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## The Remaining Variable

→ **The Cushion** ←



We achieved repeatability and reproducibility in multiple labs, however:

- No two cushions are exactly alike, even foam is never the same.
- For another lab to obtain the same results would require them to used the same equipment, maintain the same environment and use the same products

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## Subsequent Testing



If another facility maintains stringent control over their protocol, equipment and environment...

...then the tests and comparative results of those tests on a specific group of products are valid.

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## We Believe



This test method can:

- Verify / validate the ability of a cushion to be adjusted / readjusted to changes in weight and shape
- Identify and quantify “clinically relevant” skin protecting features of a cushion associated with immersion, magnitude and envelopment.
- Identify and quantify the ability of a cushion with adjustable / readjustable features to maintain consistent skin protecting characteristics even with changes to weight and shape

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## Next Steps



- To identify and address any remaining concerns regarding the use of this test method for identifying and quantifying adjustability and skin protecting features of a cushion.
- To submit this test method to ISO in the hopes that it can become a work item.
- To continue and expand our work relative to other variable changes (angle, asymmetry, temperature, humidity and time)
- To expand our work to positioning characteristics
- Get more folks involved

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## Acknowledgements

Questions

Comments

Recommendations

Feedback

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