

Lifespan Evaluation Group – LEG  
Minutes: Meeting #4  
Meeting Location: Las Vegas  
Meeting Date: April 27, 2003

---

The attendees to the meeting included:

Scott Haynes (R)  
Lydia Biggie (M)  
Jeanne Perla (M)  
Jim Collins (M)  
Shaunda Gross (CI)  
Erik Larsen (M)  
Mike Lipp (M)  
Chuck Gokoo (M)  
p.r.n., Stephen Sprigle (R) and David Brienza (R)

Manufacturing (M), Clinician (CI), Researcher (R)

Changes to the minutes from previous meeting included the correction that Scott Haynes was listed as Manufacturing (M) and should be listed as Research (R)

Discussed the mission and scope of LEG.

The mission statement used in the PowerPoint presentation in the opening session stated:

*LEG Mission:*

*Identify metrics and methods for demonstrating the changing condition of a support surface (due to fatigue in regular use, damage by customer, or environmental effects) relative to its “out-of-the-box” design specifications.*

The term “demonstrating” relates to the need to develop some reporting guidelines. These guidelines would help improve consistency in the information that is disclosed by the Manufacturer to the clinician.

Scott used the analogies of an Oral-B® Indicator™ toothbrush and a jar of Play-Doh® to demonstrate aspects of the LEG mission. The toothbrush has colored bristles that wear away as the product is used. When the color has worn a way to a pre-determined amount, it indicates the need to replace the toothbrush. The group discussed the benefits of being able to provide indicators, which would signal the need to repair or replace support surfaces as well. It was decided that the identification of such indicators should come as a Phase II effort, following the development of standard measures and test methods.

The Play-Doh® was used to demonstrate the changes in product attributes due to damage by customer or environmental effects (e.g. drying out when exposed to air) or fatigue in regular use (e.g. color changes when colors are mixed). It was also used as an example of product “knock-offs” in that there are many different “Playdough” recipes

available for home production. Standard measures and test methods will help ensure product quality.

The phrase “damage by customer” was dropped as being beyond the scope and resources of the LEG at this time. However, LEG may pursue a search of FDA/MedWatch data if time and resources permit.

LEG reaffirmed the proposed outcomes as

1. Develop Measurements and Test Methods to:
  - a. Establish Critical Performance/design measures
  - b. Simulate Use
  - c. Quantify change in performance over time
2. Identify Key Indicators to:
  - a. Signal performance drop below design parameters
  - b. ~~Predict “Lifespan” for a given condition of use~~

The sub-bullet, “Predict ‘Lifespan’ for a given condition of use,” listed under the second major outcome was dropped. It was decided that the prediction of lifespan tied too closely with the statement of product warranty, which would raise liability issues.

LEG reviewed the stated goal for 2003:

*“Establish draft test methods for Lifespan Evaluation variables and begin to test the test methods.” – S3I Annual Report 2002*

It was agreed that manufacturers involved with LEG would provide the working group with information relating to their facility’s testing capacity and their company’s test methods. This is contingent on the signing of appropriate non-disclosure agreements. The information collected would then be stripped of identifiers and used to help establish a set of standard measures and test methods that more closely represents current industry practice.

LEG identified three sub-task groups based on the three broad categories established by the Powered/Non-powered and Active/Passive definitions (recognizing that there is not a possibility for an Active/Non-powered system). Each task group reviewed the list of product characteristics compiled in a previous LEG meeting and identified those which may change and have an effect on therapy. (See attached flip chart notes.)

The task groups and group leaders are as follows:

Passive and Non Powered – Jeanne Perla

Passive and Powered – TBD (Ron Dziedziula was nominated but was not present to accept)

Active and Powered – Lydia Biggie

In spite of the different product types reviewed by each task force, there was duplication in the characteristics that were identified. The combined list, with brief descriptions, was as follows:

- Internal Pressure (High and Low) – refers to the pressure inside the support surface
- Weight Capacity: TIG + extra weight – refers to the potential change in measured performance when a surface is loaded to its stated capacity after much regular or simulated use. It was thought that LEG may be able to modify future TIG test methods by increasing the weight used from a nominal value to a value at maximum stated capacity.
- MVTR: TIG – refers to the change in permeability (relative to air, moisture, microbes, etc.) of the support surface. It was decided that LEG would follow TIG’s test method development efforts in this area.
- Air Distribution within non-powered – refers to the ability to identify restricted air/fluid flow in a passive / non-powered support surface, e.g. if a connecting tube or valve becomes clogged.
- Temperature and Ambient Pressure – refers to the potential change in measured performance for a support surface that experiences extreme changes in temperature or ambient pressure between manufacture and delivery for clinical use.
- Time: duration and frequency of pressure changes – refers to the characteristics used to define Alternating Pressure and rotating support surfaces. It was decided that LEG will follow T&D’s efforts to define these terms.
- Dimensions – refers to the potential change in measured performance as indicated by a change in the overall support surface dimensions (i.e. thickness, width, or length).
- Rotation – refers to the need to quantify claims that a support surface is able to “rotate” the patient from side to side.

#### NEXT STEPS:

1. Search for existing measures and test methods consistent with characteristics identified by the established LEG task groups.
2. Schedule virtual meetings to discuss progress.
3. Establish non-disclosure agreements with manufacturers interested in sharing information related to their facility’s testing capacity and their test methods.
4. Coordinate with TIG and T&D in their development of test methods that relate to characteristics identified by LEG.
5. Draft test methods for characteristics not currently being tested and not related to TIG or T&D efforts.

FLIP CHART NOTES:

Opening Session, recommended agenda items:

Test Methods

- Accelerated use / Simulated use

Reporting Guidelines

- Change in TIG variables
- Markers that indicate need to replace / repair
- Mechanism of Failure

Breakout Session

Task Groups: assignments and objectives

- I. Passive / Non-Powered: Jim, Jeanne, Shandra
- II. Passive / Powered: Eric, Scott
- III. Active / Powered: Chuck, Mike, Lydia

Objectives:

- [List] Characteristics that may change AND are important to therapy
- [Identify] Task Group Objectives
- [Identify] Task Group Leader

Task Group Notes – Passive / Non-Powered:

Fatigue:        -Foam        }  
                  -Air         } Welding glue tensile and compression strength  
                  -Cover      }

Degradation: -Foam        -Height  
                                 -Firmness  
                                 -Memory / Return force

Mode of Failure:    -Valve        }  
                          -Hose         } AIR DISTRIBUTION  
                          -Manifold    }  
                          -Chambers   }

Weight limit / Capacity

Fabric / Covering:    -Moisture     }  
                             -Air            } TIG  
                             -H<sub>2</sub>O entry pressure  
                             -Infection microbial

Temperature / Environmental

- Sensitivity (Extremes)
- Ambient Pressure

Task Group Notes – Passive / Powered

e.g. Fluidized Air, Static Air, Combination Air / Foam

Characteristics that may change

- Dimensions (length, width, thickness)
- Internal Pressure (Inlet Pressure)
- Weight Capacity → TIG+
- Foam ILD (comb.)
- Fabric Resistance to Bacteria → Pore Size → TIG
- Dead Spots?

Team Leader: Ron D.

Objectives Identify Standards / Test Methods

Task Group Notes – Active / Powered

(i.e. Alt. Press, Rotation)

Characteristics that could change over time and effect therapy

1. Pressure – High Press & Low Press / Air cell
2. Time – Duration at H[igh]/L[ow], Frequency
3. MVTR – Coverlet / different materials

**Could fail / degrade**

Pump / Blower  
Connection / hose / valves  
Air sacs  
Timing / timer / ON-OFF  
Filters (Dirt)

**Tests**

Factory Specs (Rated hours)  
Factory Specs (Rated hours)  
Leaks → Burst Strength Seam Strength  
--  
--  
Manometer test – Pressures (Water column)