



Posture and Wheeled Mobility 2010 Abstract

Changes in Properties with Use, Aged to Perfection, or, it's All Down Hill From Here

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Summary

Some products perform better with use, others are on a slow decline from the moment that they are put into service. All cushions come to the point of no return (to use). Here we discuss what we know, what we don't, how to fill the gaps.

Aims and Objectives

Teach clinicians and designers the signs of cushion fatigue, and what are the current best practices in ensuring that the cushion is not contributing to tissue breakdown. Present the current gaps in knowledge about the aging of cushions and how age related changes impact cushion performance. Discuss the current ISO Changes in properties draft.

Background, Technique, Standards, Clinical Detail, Results and Testing

Lecture, open discussion and circulation of sample swatches will be used to present the signs and indications of aging of wheelchair cushions and the materials of construction. The meaning of the term "Failure" and its determination based on "Obviousness" and Risk Analysis will be reviewed. The results of testing performed on the laboratory bench and limited results from the field will be presented.

Following the outline of the ISO CD for Changes in Properties with use, examples of test selection, test performance and the results of these test are provided.

The use of the Buckling Column Test demonstrates a reduction in cushioning properties of some cushions, while others initially perform better following an initial use period.

Aging tests cause a reduction in physical dimension (compression set) in foam based products. Each foam type responds to this challenge in a different manner, but PU foams can reduce by 70% in physical thickness as a result of exposure to the cushion aging processes defined.

Results of testing on products containing hydrogels demonstrate that some tests can not be appropriately applied to some products. Out-gassing under some conditions renders the cushion untestable and unfit for use by any user.

Significance of each of the various challenges demonstrates that the washing and disinfection process is the most

significant of the aging processes impacting cushion life. Soiling, aging in the presence of artificial feces and bacteria create the second most important challenge to product life and performance over their life.

Test selection based on the unique characteristics of the materials of construction and the cushion architecture is demonstrated by the failure of cut away cushions to register results in the typical test listed in the standard. In these cases, the manufacturer is responsible to identify the proper tests and properly apply them in cushion evaluation.

Discussion

Differentiating between new and used cushions is not particularly easy but using existing tests we are beginning to be able to determine when a cushion is performing adequately and when it is no longer able to do the job it is intended to do.

Manufacturers should be willing to provide adequate information about their products to guide clinicians and users as to when their cushion should be removed from service. In some cases, simple user evaluations can make this determination, in others technical guidance from knowledgeable individuals is required.

The process of challenging cushions using the outlined method will give us the tools necessary to properly scrutinize the life of products and improve the quality of care for the user by the eliminate of functionally expired product from service.

References

ISO 16840-7 (CD) Changes in Properties with Use.

ANSI/AAMI/ISO 14971:2000, Medical Devices-Application of Risk Management to Medical Devices.

ASTM D3574:2008, Standard Test Methods for Flexible Cellular Materials—Slab, Bonded, and Molded Urethane Foams.

ASTM D3884:2007, Standard Guide for Abrasion Resistance of Textile Fabrics.

ASTM D4266:1998, Standard Guide for Evaluating Stain Removal Performance in Home Laundering.

ISO 554:1976, Standard atmospheres for conditioning and/or testing — Specifications

ISO 13427:1998, Geotextiles and geotextile-related products -- Abrasion damage simulation (sliding block test).

ISO 7176-8:1998, Wheelchairs — Part 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths.

JIS K 6400:2004, Flexible cellular polymeric materials -- Determination of physical properties.

NOTE: Among those documents listed are ASTM test methods which have been adopted to replace specific test methods from:

Federal Test Method Standard (FTMS) No. 101, Test Procedures for Packaging Materials;

FTMS No. 147, Tape, Packaging, Adhesive and Gummed;

Method of Inspections, Sampling, and Testing;

FTMS No. 406, Plastics: Methods of Testing;

FTMS No. 601, Rubber: Sampling and Testing.

Budruga, P. Thermal lifetime evaluation of polymeric materials exhibiting a compensation effect and dependence of activation energy on the degree of conversion. *Polymer and Degradation and Stability*. 50:2 (1995): 241-46.

Celina, M., K. T. Gillen, and R.A. Assink. Accelerated aging and lifetime prediction: Review of non-Arrhenius behaviour due to two competing processes. *Polymer and Degradation and Stability*. 90:3 (2005): 395-404. (An Elsevier Journal. Scandia National Laboratories)

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Press. ISBN 0849319102, 2003.

Nakajima- Kame, T. Microbial degradation of polyurethane, polyester polyurethanes and polyether polyurethanes. *Applied Microbial Biotechnology*. 51 (1999): 134-140.

Wise, J, KT Gillen, and RL Clough. An ultrasensitive technique for testing the Arrhenius extrapolation assumption for thermally aged elastomers. *Polymer and Degradation and Stability*. 49:3 (1995): 403-18.

AATCC test method 147-2004: Antibacterial Activity Assessment of Textile Materials: Parallel Streak Method

To Be Considered For: Platform