Use of Immersion DMA for Biomedical Studies

Problem

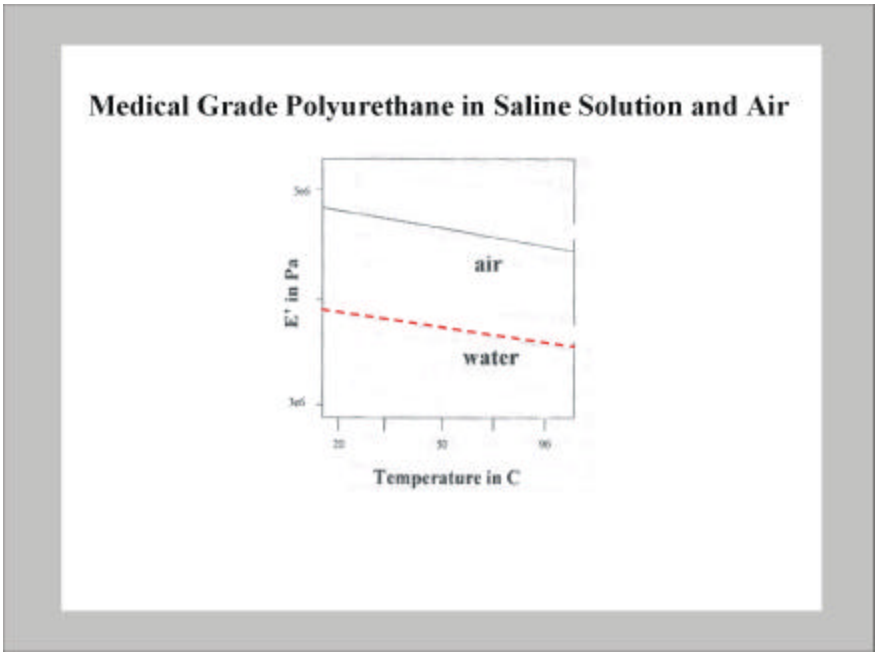
A manufacturer of a heart pacemaker needed to receive approval for the components used in the device. The manufacturer needed to know whether the polyurethane coating on the leads for the pacemaker would become stiffer or not when immersed in bodily saline fluids. If the plastic would become stiffer, then there would be a real danger that the material could tear and damage the heart muscle. Therefore, it was necessary for the manufacturer of the heart pacemaker to prove that the coating would not increase its stiffness once immersed in normal saline solution.

Solution

Dynamic mechanical analysis (DMA) is a very powerful tool for the study of a wide variety of materials, including thermoplastics, thermosets, elastomers, fibers, films, gels and foams. DMA measures important properties including:

- stiffness or storage modulus (E') as a function of temperature
- damping or loss modulus (E")
- coefficient of internal friction or tan delta (E"/E')
- softening temperatures or Tg
- gel times or temperatures
- minimum viscosity of materials
- impact resistance
- brittleness
- aging effects
- creep and stress relaxation

The state of the art PerkinElmer DMA 7e provides an ideal means of characterizing the properties of materials. The important features of the DMA 7e are:



- high sensitivity for the detection of very weak transitions
- ability to immerse samples in a fluid bath, with vertical downward sample mounting, to easily determine long term effects of solvents and fluids
- wide temperature range (-170 to 1000 C) for complete characterization of high performance materials
- stable performance for reliable and reproducible measurements
- unparalleled range of testing probes to handle a wide range of applications and sample geometries ranging from single fibers to composite rods and bars
- ease of sample mounting with *UniMount* measuring technology
- unparalleled temperature performance with *IsoSink* temperature control
- ease of use with Pyris Software for Windows

One of the most powerful applications of DMA is performing immersion studies, where the properties of a sample are studied directly in a solvent or fluid. The long term mechanical performance of polymers can be significantly affected prolonged exposure to a solvent or fluid, and the immersion bath offered with the PerkinElmer DMA 7e provides an

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excellent means of testing these properties. This is especially important for biotechnology applications where polymers, such as those used in a heart pacemaker, for example, are permanently exposed to a saline solution. The downward sample loading of the PerkinElmer DMA 7e makes the analyses of immersed samples much easier and much less troublesome than top loaded DMA instruments, where there is a real danger of the fluid flowing down into the drift shaft and into the force and strain transducers.

In this particular application of the DMA 7e, the polyurethane material, as used with the heart pacemaker, was analyzed in the 3 point bending test apparatus, which was then immersed in a normal saline solution, approximating the saline composition of blood plasma. The test specimen was in the form of a small test bar. The polyurethane material was heated at a rate of 0.5 C/min at a frequency of 1.00 Hz. The sample was also analyzed, under the same conditions, in air, to compare the mechanical properties in solution and in air.

The DMA results on the polyurethane material clearly show that the sample yields a significantly lower modulus, or stiffness, in solution over the complete temperature range of 20 to 90 C. This data proved the point that the polyurethane coating would be safe to use in the heart pacemaker device without a danger of the material puncturing the heart due to a potential higher stiffness in normal saline solution. Indeed, in solution, it was found that the polyurethane coating yielded a significantly lower stiffness, making it all the more acceptable for this particular biomedical application.

Summary

The PerkinElmer DMA 7e provides an excellent means of characterizing the mechanical and viscoelastic properties of a wide range of materials ranging from single fibers to plastic test bars. The characterizing ability of the DMA 7e is further enhanced with the use of a fluids immersion bath, where a sample can be placed into a solvent or solution to determine the long term properties upon exposure to a fluid. This is particularly important for biomedical applications where the mechanical properties of plastics must be established with regards to the exposure of the material to saline solution.

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