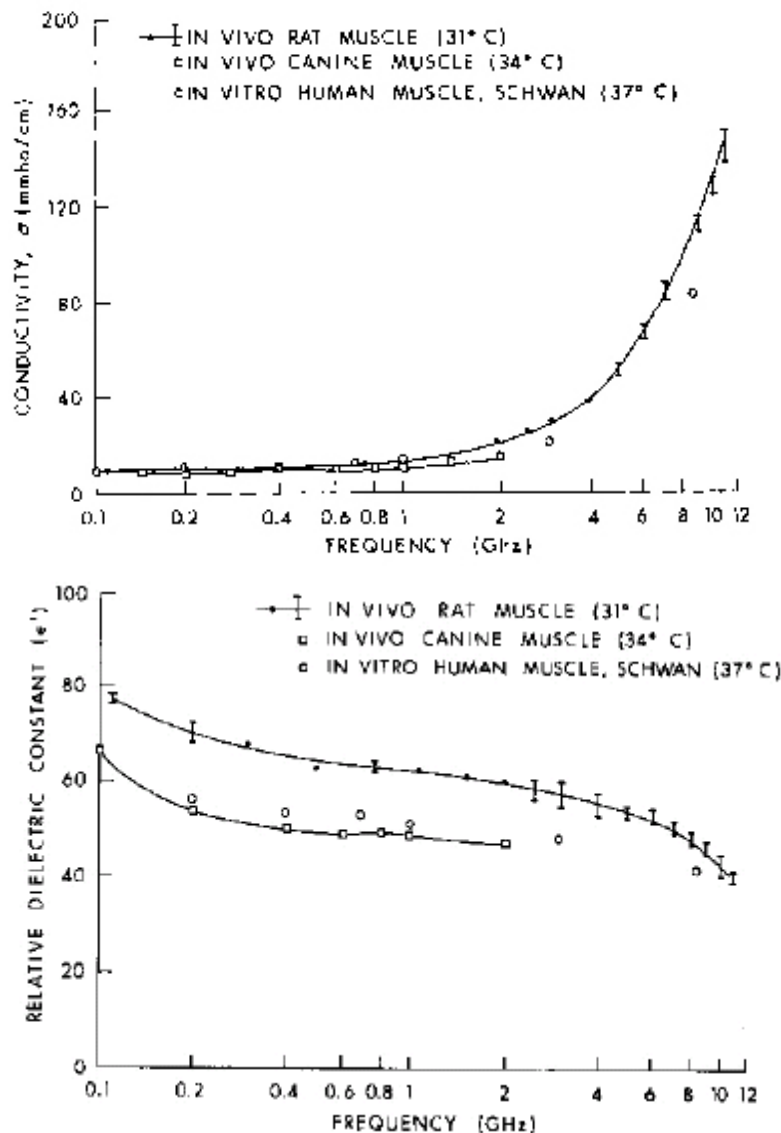


COVER LETTER ADDRESSING THE TISSUE MATERIAL

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The formula for mixing the tissue material used in the container to simulate an actual usage scenario for the implant was found in the RADIOFREQUENCY RADIATION DOSIMETRY HANDBOOK. This handbook contained the following graphs comparing muscle tissue characteristics across a frequency range from 100 kHz to 12 GHz. The comparison is made for conductivity and dielectric constant for three species, rats, canines, and humans. At a frequency of 1000 MHz these graphs show very little or no variation (<5%) between humans and canines. Based on this the tissue parameters from the FCC website for a frequency of 916 MHz were obtained. The values used for muscle are; conductivity - 1.001396, dielectric constant - 56.842484.



DSI contracted with a local chemical supply house (XXXX) to provide a mixture having the above properties based on the chemical makeup and formula described in the literature by G. Hartsgrove*, A. Kraszewski, and A. Surowiec. The table in OET 65 Supplement C is also a source providing guidance on providing such a mixture. The mixture used to simulate canine tissue is the equivalent material normally used to simulate human tissue at a frequency of 916 MHz.

The container chosen was selected as a suitable size for the purpose of representing the torso of a typical canine. The container plastic material dielectric constant and conductivity are very close to those of Plexiglas and therefore would have essentially the same effect on the radiated field strength as Plexiglas that is the material recommended by the FCC for use as torso simulators.

The simulator is standard plastic polyethylene bucket commonly available in multiple outlets. This material has essentially identical dielectric and conductivity properties to the Plexiglas torso container specified by Part 95 of the FCC rules and also specified in ETSI 301-839-1 which is recognized by Industry Canada as the suggested type of container for making field strength measurements for human implants. The FCC actually specified the use of Plexiglas for 916 MHz for testing an implant manufactured by Guidant as well as for DSI or their subsidiary at the time, Transoma Medical. Thus because the material RF characteristics are essentially identical between Plexiglas and Polyethylene , one can conclude that the attenuation characteristics of Plexiglas and Polyethylene are essentially identical.

Testing of the implant requires use of a liquid torso simulation fluid and its cylindrical container. The container bale or handle in the instant case was removed.

Sincerely yours,

Perry Mills, VP