Mr. Steve Dayhoff
Federal Communications Commission
Application Processing Branch

BIOTRONIK

April 10, 2001

Dear Mr. Dayhoff:

I am responding to your two questions the Biotronik application FCC ID PG6BA0T, correspondence reference number 18687731, confirmation number EA100044.

Response to Question 1. The chemical formula for the tissue substitute material used in the radiation emissions testing comes directly from the paper referenced in Part 95.639(g)(2)(ii). The reference paragraph is in the box below.

> **§ 95.639 (g) (2) (ii)** A formula for a suitable tissue substitute material is defined in the paper ``Simulated Biological Materials for Electromagnetic Radiation Absorption Studies" by G. Hartsgrove, A. Kraszewski, and A. Surowiec as published in ``Bioelectromagnetics 8:29-36 (1987)".

The tissue model assumed was muscle, which surrounds the area of the implanted pacemaker (5cm under skin directly below the collarbone). The chemicals in the simulation tank were mixed as follows (from Table 1(A) of the referenced paper).

Material	% by Weight
Water	52.4
Salt (NaCl)	1.4
Sugar	45.0
Hydroxyetheylcellulose (HEC)	1.0
Bacteriacide	0.1

The dielectric constant and conductivity values for this tissue substitute material are also given in the reference paper. At 400MHz frequency, the values are $\varepsilon' = 62.5$ **and** $\sigma = 9.0$.

Response to Question 2. The Biotronik communications system is a unidirectional transmitter, which is embedded in an implantable pacemaker. The external receiver has no capability to transmit back to the implanted device.

For this reason, Part 95 Section 628 (b) applies which states that paragraph (a) of the section is not applicable (see below). Therefore, the Biotronik communications system has no frequency monitoring mechanism.

> **§ 95.628 (b)** MICS communications sessions initiated by a medical implant event are not required to use the access criteria set forth in paragraph (a) of this section.

If there are any further questions regarding the Biotronik request for confidentiality, please contact Mark Johnson at (503) 675-2187 or maj@biotronikusa.com.

Sincerely,

Mark Johnson
Biotronik, Inc.