



December 4, 2006

Federal Communications Commission  
Authorization and Evaluation Division  
7435 Oakland Mills Road  
Columbia, Maryland 21046

To Whom It May Concern:

Biotronik would like to request that some of the information provided in our submission for a license for the RF transmitter embedded in our Stratos pacemaker product remain confidential. The confidential documents in this submission should include:

1. Antenna Information.pdf
2. Block Diagram.pdf
3. Operational Description.pdf
4. Internal Photos.pdf
5. Schematics.pdf
6. Parts List.pdf
7. Test Procedure. pdf

The reasons for requesting confidentiality of these items are that this transmitter circuitry and its performance are Biotronik proprietary designs.

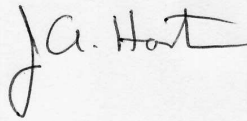
- If disclosed, this information would result in substantial competitive harm. Utilizing RF communications in pacemakers is a novel approach, which Biotronik seeks to exploit as a competitive advantage.
- Design and development efforts were substantial, and if provided to competitors would create an unfair market advantage to those gaining the information.
- Biotronik feels that this feature will provide first-to-market advantage that will provide financial gains of millions of dollars. These gains would be greatly diminished if such proprietary information was made publicly available to competitors.
- The internal photos will also reveal information about non-radio design elements that are also Biotronik proprietary designs and if disclosed would result in substantial competitive harm.
- Note: The Stratos devices are implantable pacemaker/CRT devices. These devices are not allowed (by law) to be sold in a store or pharmacy to the public. Therefore it is not possible to buy such a device in a public store. A Biotronik representative usually participates during the operation and in most cases brings the device with him to the operation. Until operation/implantation the device is stored in a non-re-sealable semi-opaque sterile container. The housing of the device itself is made of titanium that is fully laser welded. It is not possible to open the device without destroying it. Therefore, before implantation it is impossible for anyone outside Biotronik personnel to have the opportunity to open the device in order to get the information that Biotronik requests to be held confidential.

The user's manual does include an X-ray picture, as required by international studies. This X-ray picture does not show detailed information of the inner assembly since it is only a two-dimensional figure. Because of the nature of X-ray pictures, it does not show all used materials, parts and details.

It should also be noted that as this is a medical communications device, Biotronik has designed this pacemaker communications system to meet the patient's privacy regulations provided by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Digital data transmitted with this system is encrypted using techniques to assure privacy of patient data. Specific information regarding the design of this system is revealed in the schematics, descriptions, and photographs. Disclosure of these documents may reduce the effectiveness of the designs for privacy that Biotronik has developed.

If there are any further questions regarding the Biotronik request for confidentiality, please contact Jim Horton at (503) 387-2640 or [jim.horton@biotronik.com](mailto:jim.horton@biotronik.com)

Sincerely,

A handwritten signature in black ink, appearing to read "Jim Horton". The signature is stylized, with the first letters of the first and last names being prominent.

Jim Horton  
Senior Project Manager  
Biotronik, Inc.