

# Exhibit # 1



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FEDERAL COMMUNICATIONS COMMISSION  
Experimental Radio Service  
P.O. Box 358320  
Pittsburgh, PA 15251-5320

To the Experimental Licensing Branch,

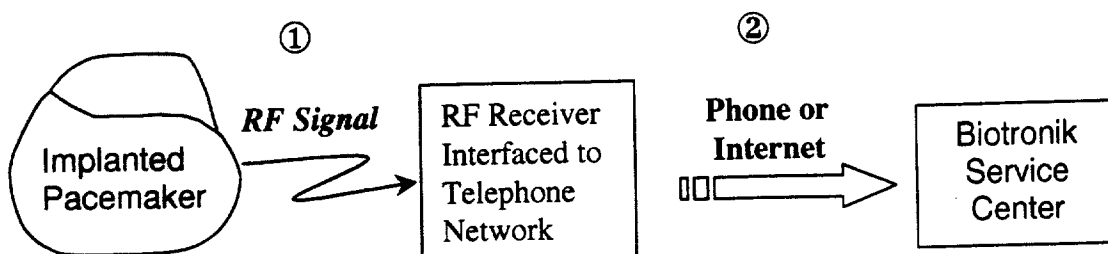
I am submitting this narrative statement in response to line item 10 of form 442.

Biotronik, Inc. seeks experimental licensing for use of the proposed Medical Implant Communications Service (MICS) band, which is slated as a secondary user within the 400 – 406MHz Meteorological Service band. The Notice for Proposed Rule Making (NPRM) # 99-23 will allow for medical device manufacturers to provide RF transmissions within this bandwidth for implantable life support products. Biotronik is a leading manufacturer of implantable pacemaker and defibrillator electronics, and wishes to initiate evaluation and development of RF communications from the implant to an external receiver.

Biotronik has designed a Colpitts oscillator transmitter, which will be integrated into pacemaker and defibrillator electronics products. This transmitter will provide critical patient data to a mobile receiver 2 to 3 meters from the source. The maximum output power of the transmitter will not exceed 25 $\mu$ Watts. This RF transmission will allow for critical results of a patient's heart condition to be presented to a physician without invasive interrogation. Further details of the rationale for use are presented in the NPRM 99-23 and comments from industry filed in response.

## Detailed Description of System Operation

Biotronik monitoring communications are provided in a series of distinct data transmission steps and electronic systems. A block diagram of the transmission path is shown below.



- ① Communication starts with the implant, which activates an RF transmitter at 403.65MHz +/- 75KHz carrier frequency. The bandwidth is 40KHz. The maximum deviation of the carrier is 40KHz + 150KHz = 190KHz. The transmitter circuitry is integrated within the pacemaker electronics. Data is transmitted at a distance of two to three meters to a bedside receiver, which is interfaced to a telephone network.
- ② The patient is equipped with a receiver centered at 403.65MHz with a 300KHz bandwidth to accept the incoming data. The receiver is interfaced to a telephone network, which provides a means for transmission of data via telephone to the Biotronik service center. Specialized analysts at the Biotronik Service Center receive incoming data and generate a summarized report, which is forwarded to the physician.

Note: Each transmitter will have a unique serial number that will be transmitted as part of the data stream. This identifier can be used in the absence of a call sign for station identification (line item 14).

### **Scope of Experimentation**

The experimental license is being sought to allow for a clinical study to be performed. The protocol for this study is part of a requirement by the Food and Drug Administration (FDA) and is termed an Investigational Device Exemption (IDE) study.

Biotronik plans to perform this study with a maximum of 100 experimental systems under clinical evaluation. Each transmitter/receiver will provide less than or equal to 10 transmissions per day. The duration of each transmission is approximately 70 milliseconds. Not all 100 systems will be operational concurrently, but the entire study will have a duration of less than the 2 years allotted by the experimental license.

The implanted units are obviously mobile, as is the receiver station. Sites for the study have yet to be determined, but will be in various clinical locations throughout the United States. The exact geographical coordinates during operation is presently unknown (requirement of line item 5c). Such information can be provided to the FCC once clinical sites have been established.

At the conclusion of the experimental phase, application to the Food and Drug Administration will be made with the summary results of the study. Formal license application will be filed with the FCC assuming the Medical Implant Communications Service (MICS) as proposed by NPRM #99-23 has been accepted.

If there are any further questions regarding the specific objectives sought with this experimental license, please contact me at (503) 675-2187 or E-mail: [maj@bioregon.com](mailto:maj@bioregon.com).

Sincerely,



Mark Johnson  
New Business Development Manager  
Biotronik, Inc.