

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

To the Experimental Licensing Branch,

Biotronik, Inc. seeks experimental licensing for use of the proposed Medical Implant

Communications Service (MICS) band 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 25mWatts. This RF transmission will allow for critical results of a patient's heart condition to be presented to a physician without invasive interrogation.

Detailed Description of System Operation

Biotronik monitoring communications are provided in a series of distinct data transmission steps and electronic systems.

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 $40\text{KHz} + 150\text{KHz} = 190\text{KHz}$. 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.

Scope of Experimentation

The experimental license is being sought to allow for a clinical study to be performed.

Biotronik plans to perform this study with a maximum of 200 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 250 milliseconds. Not all 200 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.

At the conclusion of the experimental phase, application to the Food and Drug Administration will be made.

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@biotronikusa.com.

Sincerely,

Mark Johnson
New Business Development Manager
Biotronik, Inc.