



ORIGINAL
UNITED STATES DEPARTMENT OF COMMERCE
National Telecommunications and
Information Administration
Washington, D.C. 20230
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Federal Communications Commission
Office of the Secretary

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ET Docket No. 06-135

Mr. Julius Knapp
Chief, Office of Engineering and Technology
Federal Communications Commission
445 12th Street, SW
Washington, D.C. 20554

Dear Mr. Knapp:

The National Telecommunications and Information Administration (NTIA) has followed closely the ongoing Federal Communications Commission (FCC) proceeding regarding the establishment of a new Medical Device Radiocommunication Service (MedRadio Service) in the 401-406 MHz frequency band.¹ As you are aware the 401-406 MHz band is used by federal agencies operating over 20,000 Data Collection Platforms transmitting to meteorological satellites and airborne radiosonde transmitters that operate throughout the United States.² In the past, NTIA supported the implementation of the Medical Implant Communications Service (MICS) and NTIA supports the FCC's goal to accommodate new and sophisticated medical devices through sharing spectrum with incumbent services.³ NTIA agrees that these devices have the potential to significantly improve the quality of life for countless Americans living with a variety of medical conditions. However, NTIA believes that medical devices can receive interference from the federal systems operating in the band resulting in disruption of operation for an extended period of time. This concern was raised by NTIA in a letter addressing the Biotronik waiver request.⁴ Radiosonde launches and landings can occur in many parts of the United States on a regular basis. The radiosondes may transmit for a long period of time, possibly exceeding a few hours, resulting in potential interference over fairly large geographic areas around these launch sites.⁵ For this reason, NTIA is

1. See Investigation of the Spectrum Requirements for Advanced Medical Technologies, Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communication Service at 401-402 and 405-405 MHz, DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules, ET Docket No. 06-135, RM-11271, *Notice of Proposed Rulemaking and Notice of Inquiry and Order*, (MedRadio Notice) 21 FCC Rcd 8164 (2006).

2. The 401-406 MHz band is allocated on a primary basis for the meteorological aids, meteorological-satellite, and Earth exploration-satellite services.

3. See Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules, ET Docket No. 03-92, *Order*, 19 FCC Rcd 4208 (2004) at ¶ 3; and DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, ET Docket No. 05-213, *Order*, 21 FCC Rcd 875 (2006).

4. Letter from Fredrick R. Wentland, Acting Associate Administrator, Office of Spectrum Management, to Mr. Edmond J. Thomas, Office of Engineering Technology (May 22, 2003) at 2.

5. Considering the deployment and operational characteristics of radiosondes, given the right circumstances, the potential interference from radiosondes to medical devices operating in the band is very

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concerned about the potential use of this band for time sensitive medical device communications.

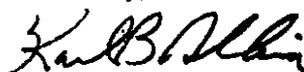
The public comments submitted in response to this proceeding demonstrate that the medical devices envisioned for the MedRadio Service could be used for patient monitoring or therapeutic purposes (e.g., glucose monitoring) where a specific reading can stand to be interrupted without risk to the patient. However, the comments also indicate that other devices could be used for medical applications where, if the transmission is disrupted, patient safety could be compromised (e.g., cardiac defibrillators). NTIA is concerned that the distinction between medical devices used for non-life critical applications that are not time sensitive and devices used for time sensitive applications where patient safety could be compromised was not addressed in the MedRadio rulemaking proceeding.⁶ Given the implications to patient care if a federal system interferes with a MedRadio device, it is in the public interest for NTIA and the FCC to take steps to ensure that manufacturers of MedRadio devices take into account the federal systems operating in the band, particularly when developing medical devices used for time sensitive applications. NTIA recommends that in establishing the service rules for MedRadio devices, the FCC should clearly draw a distinction for time sensitive applications to ensure that the medical community understands the potential risks. Specifically NTIA recommends that the following sentence be added to the MedRadio Service rules addressing channel use:

MedRadio devices should take the necessary steps to prevent the disruption of time sensitive medical communication sessions that could result from interference caused by the federal systems operating in the band.

NTIA welcomes the opportunity to discuss other additions to the service rules that could help bring attention to the current and future radio frequency environment used by time sensitive medical device applications.

If you have any additional questions the NTIA point-of-contact on this issue is Mr. Edward Drocella (202-482-2608; edrocella@ntia.doc.gov).

Sincerely,



Karl B. Nebbia
Associate Administrator
Office of Spectrum Management

real. For example, under worst case conditions the interference range from federal transmitters can be as much as 100 kilometers assuming a 25 Watt radiosonde transmitter a medical device with a 200 kHz receive bandwidth, a noise figure of 4 dB, and an antenna gain of 2 dBi.

6. The parties submitting comments addressed interference to federal systems from the MedRadio devices and interference between different MedRadio device applications.