Federal Communications Commission
Washington, D.C. 20554

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Small Entity Compliance Guide

Medical Body Area Networks

Report and Order
FCC 12-54
ET Docket No. 08-59
Released: May 24, 2012

This Guide is prepared in accordance with the requirements of Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. It is intended to help small entities—small businesses, small organizations (non-profits), and small governmental jurisdictions—comply with the new rules adopted in the above-referenced FCC rulemaking docket(s). This Guide is not intended to replace the rules and, therefore, final authority rests solely with the rules. Although we have attempted to cover all parts of the rules that might be especially important to small entities, the coverage may not be exhaustive. This Guide may, perhaps, not apply in a particular situation based upon the circumstances, and the FCC retains the discretion to adopt approaches on a case-by-case basis that may differ from this Guide, where appropriate. Any decisions regarding a particular small entity will be based on the statute and regulations.

In any civil or administrative action against a small entity for a violation of rules, the content of the Small Entity Compliance Guide may be considered as evidence of the reasonableness or appropriateness of proposed fines, penalties or damages. Interested parties are free to file comments regarding this Guide and the appropriateness of its application to a particular situation; the FCC will consider whether the recommendations or interpretations in the Guide are appropriate in that situation. The FCC may decide to revise this Guide without public notice to reflect changes in the FCC's approach to implementing a rule, or to clarify or update the text of the Guide. Direct your comments and recommendations, or calls for further assistance, to the FCC's Consumer Center:

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Medical Body Area Networks

1. Objectives of the Proceeding

In the *First Report and Order* adopted May 24, 2012 in ET Docket 08-59, the Commission amended the Part 95 rules governing MedRadio devices to enable networks of body-worn medical devices called medical body area networks. Medical body area networks, or MBANs for short, are networks of devices worn on the human body that communicate with a programmer/controller device outside the body using a wireless communication link. MBANs are used for the purpose of measuring and recording physiological parameters and other patient information or for performing diagnostic or therapeutic functions, primarily in health care facilities.

The existing MedRadio rules under Part 95 of the Commission's rules allow implanted and body-worn medical devices to operate in discrete bands within the 401-457 MHz spectrum. The *First Report and Order* amends the MedRadio rules to allow MBANs to operate in the 2360-2400 MHz frequency band on a secondary basis. This frequency band is used for other purposes on a primary basis, such as Federal government and private aeronautical mobile telemetry (AMT) transmissions, amateur radio, and radio astronomy. Because MBANs will operate on a secondary basis, they may not cause interference to and must accept interference from primary users of these frequency bands. MedRadio device use of this frequency band is limited to MBANs.

A copy of this *First Report and Order* is available at:
http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-12-54A1_Rcd.pdf

2. Definitions

MBANs are defined in the Part 95 rules as follows:

> A low power network consisting of a MedRadio programmer/control transmitter and multiple medical body-worn devices all of which transmit or receive non-voice data or related device control commands for the purpose of measuring and recording physiological parameters and other patient information or performing diagnostic or therapeutic functions via radiated bi- or uni-directional electromagnetic signals.

3. Restrictions on MBAN Operation

Use of MBANs must comply with the following restrictions:

- MBANs can be used only for diagnostic and therapeutic purposes.
- MBANs must be provided to a patient only under the direction of a duly authorized health care professional.
- MBANs may not cause harmful interference to other authorized stations operating in the 2360-2400 MHz band.
- MBANs must accept interference from other authorized stations operating in the 2360-2400 MHz band.
- MBAN devices may not be used to relay information to other devices that are not part of the MBAN using the 2360-2400 MHz frequency band.

- In order to protect AMT operations, there are additional restrictions placed on MBAN operation in the 2360-2390 MHz band: operation within this band may only occur indoors at an authorized healthcare facility (as defined in the Part 95 MedRadio Rules); and operation may only occur upon completion of registration, and, if necessary, coordination with an authorized MBAN frequency coordinator.
- MBAN body-worn devices may only communicate with the programmer/controller for their MBAN. An MBAN body-worn device may not communicate directly with another MBAN body-worn device.
- MBAN transmitters must be certificated by the FCC or a Telecommunications Certification Body (TCB) designated by the FCC. To obtain certification, the manufacturer must submit a certification application accompanied by a measurement report showing compliance with the FCC technical requirements to the Commission or TCB. See 47 C.F.R. § 2.1033 for the certification application requirements or http://www.fcc.gov/encyclopedia/equipment-authorization-procedures for more information.
- MBAN devices are licensed by rule and, as such, individual licenses are not required for MBAN use.

4. Technical Requirements

MBANs must comply with a number of technical requirements designed to allow them to share the 2360-2400 MHz frequency band with primary users and other MBANs. Specifically, these requirements are that:

- An MBAN programmer/control transmitter shall not commence operating and shall automatically cease operating in the 2360-2390 MHz band if it does not receive, in accordance with the protocols specified by the manufacturer, a control message permitting such operation Additionally, an MBAN programmer/control transmitter operating in the 2360-2390 MHz band shall comply with a control message that notifies the device to limit its transmissions to segments of the 2360-2390 MHz band or to cease operation in the band.
- MBAN transmitters are allowed a maximum emission bandwidth of five megahertz.
- MBAN transmitters operating in the 2360-2390 MHz band are allowed a maximum EIRP over the frequency bands of operation that shall not exceed the lesser of 1 mW or 10*log (B) dBm, where B is the 20 dB emission bandwidth in MHz.
- MBAN transmitters operating in the 2390-2400 MHz band are allowed a maximum EIRP over the frequency bands of operation that shall not exceed the lesser of 20 mW or 16+10*log (B) dBm, where B is the 20 dB emission bandwidth in MHz.
- In the first 2.5 megahertz beyond the 2360-2400 MHz band, the EIRP level associated with any unwanted emission must be attenuated within a 1 megahertz bandwidth by at least 20 dB relative to the maximum EIRP level within any 1 megahertz of the fundamental emission. In addition, emissions from an MBAN transmitter that are more than 2.5 megahertz beyond any of the frequency bands authorized for MBAN operation must be less than field strength limits specified in the Part 95 rules.
- Each MBAN transmitter must maintain a frequency stability of ±100 ppm of the operating frequency over the range 0 °C to 55 °C.

5. Labeling and Other Requirements

MBANs must comply with a number of other requirements designed to inform medical professionals about the secondary status of MBANs and allow the Commission to enforce the Part 95 rules governing MBAN operation:

- All MBAN devices must be made available for inspection upon request by an authorized FCC representative.
- Persons operating body-worn MBAN transmitters are required to cooperate reasonably with duly authorized FCC representatives in the resolution of interference.
- A disclosure statement as specified in the Part 95 rules must be included with each MBAN transmitting device. This disclosure statement warns that the device must accept interference from and not cause interference to primary users sharing the same frequency bands. The statement also warns that there is no guarantee that the MBAN device will not receive interference.
- MBAN programmer/control transmitters must be labeled with a statement as specified in the Part 95 rules. The statement warns that the device may not cause interference to and must accept interference from devices that are operating on a primary basis in the same frequency bands as the MBAN programmer/control transmitter. The statement may be placed in the instruction manual for the transmitter where it is not feasible to place the statement on the device.
- MBAN programmer/controller transmitters must be identified by a serial number that is assigned by the device manufacturer. This serial number may be placed either on the device or in the instruction manual for the transmitter.

6. Weblink and Citations

The *First Report and Order* adopted May 24, 2012: Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks, ET Docket No. 08-59, *First Report and Order and Further Notice of Proposed Rulemaking,* 27 FCC Rcd 6422 (2012). Available at: http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-12-54A1_Rcd.pdf

The *Notice of Proposed Rulemaking* that preceded the May 24, 2012 *First Report and Order*: Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks, ET Docket No. 08-59, *Notice of Proposed Rulemaking*, 24 FCC Rcd 9589 (2009). Available at: http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-09-57A1_Rcd.pdf.

The *Notice of Inquiry* regarding medical devices which proceeded the *Notice of Proposed Rulemaking*: Investigation of the Spectrum Requirements for Advanced Medical Technologies, ET Docket Nos. 06-135, 05-213, 03-92, *Notice of Proposed Rulemaking, Notice of Inquiry, and Order*, 21 FCC Rcd 8164 (2006). Available at: http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC-06-103A1.pdf

A previous small business compliance guide addressing the previous amendment to the MedRadio rules is available at: http://hraunfoss.fcc.gov/edocs_public/attachmatch/DA-11-912A1.doc