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Regulatory

New Medical Body Area Network (MBAN) Service – First Report and Order (Order) and Further Notice of Proposed Rulemaking (FNPRM) Issued by the Federal Communications Commission (FCC)

On May 24, 2012, the FCC released the above-referenced Order and FNPRM to allocate 40 MHz of spectrum between 2360-2400 MHz on a secondary basis for a new Medical Body Area Network (MBAN) service.[1] New spectrum rules will allow healthcare professionals to interact with patients through wireless body sensors to monitor, diagnose and control patient therapies remotely without the use of restricting cables, and to aggregate data from the sensors for backhaul to monitoring stations.[2] MBANs will consist of multiple body-worn sensors and a transmitter/hub (*i.e.*, a type of "base station") that controls sensor communications. MBANs will be connected to other telecommunications systems (*e.g.*, local area networks (LANs) such as Ethernet and Wi-Fi links) using spectrum outside the 2360-2400 MHz band. The Order represents the culmination of years of FCC study and of negotiations between supporters of the spectrum allocation for MBAN (such as GE Healthcare and Philips Healthcare) and existing licensees in the spectrum (*e.g.*, Aeronautical Mobile Telemetry (AMT)) over potential interference concerns.[3]

The Order creates a regulatory framework to deploy and operate medical devices associated with MBANs including (i) service rules including operator eligibility, permissible communications, authorized locations, and equipment authorizations; (ii) technical rules involving authorized bandwidth, channel aggregation, transmitter operation and power limits, radiofrequency (RF) safety, and unwanted emissions; and (iii) registration and coordination requirements.

A few highlights of the new MBAN regulations include the following:

- MBAN medical devices are eligible for "license-by-rule" operation pursuant to Part 95 of the FCC's Rules on a shared, non-exclusive basis with respect to each other and without the need for the MBAN to be individually licensed.[4]

- MBAN operations in the 2360-2390 MHz band are limited to indoor locations within health care facilities, while MBAN operations in the 2390-2400 MHz band are permitted in any location.[5]

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[1] In the Matter of Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks, *First Report and Order and Further Notice of Proposed Rulemaking,* ET Docket No. 08-59 (rel. May 24, 2012).

[2] The FCC Rules, as revised by the Order, define MBAN as "a low power network consisting of a MedRadio programmer/control transmitter and multiple medical body-worn devise 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." Order at ¶ 31.

[3] *See, e.g.,* 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 Radiocommunication Service at 401-402 and 405-406 MHz, ET Docket No. 06-135, *Notice of Proposed Rulemaking, Notice of Inquiry, and Order,* 21 FCC Rcd 8164 (2006).

[4] *See* Order at ¶ 29.

[5] *See Id.* at ¶ 40.

- MBAN operations in the 2360-2390 MHz band are subject to registration and coordination requirements (a process whereby a health care facility must register with a third party "MBAN coordinator(s)" before operating an MBAN), while MBAN operations in the 2390-2400 MHz band are not subject to either the registration or coordination requirements.[6]

- Health care facilities will probably be unable to deploy MBANs using the 2360-2390 MHz band until June 2013 (*i.e.,* the date by which the FCC selects the MBAN coordinator(s) to oversee the registration and coordination requirements).[7]

Below is a more complete summary of these and other MBAN requirements together with our thoughts on issues which medical device manufacturers should consider as they develop devices and related networks.

MBAN REQUIREMENTS

1. **Service Rules**. (Order at ¶¶ 33-43.) The FCC will regulate MBAN devices under its existing MedRadio service-related rules[8] subject to certain modifications. Below are specific service parameters applicable to MBAN.

    a. Operator Eligibility. (Order at ¶¶ 33-35.) MBAN devices may be operated by duly authorized health care professionals and by persons operating transmitters at the direction of a duly authorized health care professional. Manufacturers and their representatives may also operate MBAN devices for the purpose of demonstrating such equipment to duly authorized health care professionals.

    Observations and/or Recommendations

    - Vendors may demonstrate equipment as representatives of a manufacturer.

    - Manufacturers cannot rely upon this rule to operate MBAN devices for developing and testing purposes. The FCC's experimental licensing rules provide the appropriate process for such use by manufacturers. It is not entirely clear how Section 2.803 (which governs pre-compliant RF device operations) impacts these requirements.

    b. Permissible Communications. (Order at ¶¶ 35-38.) An MBAN (which utilizes spectrum within 2360–2400 MHz) must consist of a single programmer/control transmitter (or

[6] *See Id.* at ¶ 58.

[7] The FNPRM requested public comment on a number of issues related to designating the MBAN coordinator(s) for the 2360-2390 MHz band including the following: (i) whether there should be one or multiple MBAN coordinators; (ii) the type of minimum criteria that should be established for selecting an MBAN coordinator(s); and (iii) the type of fees that the MBAN coordinator(s) should be permitted to charge for coordination and registration services. Comments responsive to the FNPRM were due in early September 2012.

[8] The MedRadio service provides "an umbrella framework to regulate the operation of both implanted and body-worn wireless medical devices used for diagnostic and therapeutic purposes in humans. MedRadio uses spectrum in the 401-406 MHz, 413-419 MHz, 426-432 MHz, 438-444 MHz, and 451-457 MHz bands, all on a secondary basis." Order at ¶ 3.

hub) that controls multiple non-implanted sensor devices. Direct communications between body-worn sensors or direct communication between hubs is not permitted. Hubs will be able to interconnect multiple patients and can interconnect with other telecommunications systems (*e.g.,* LANs, Wi-Fi links, etc. which do not use spectrum within 2360-2400 MHz). The FCC does not believe that specific protocols should be associated with sensor/Hub transmissions.

Observations and/or Recommendations

- The FCC indicated that it may revisit the restrictions on sensor-to-sensor and hub-to-hub communications as it gains more experience with MBAN operations. Manufacturers should consider this as they develop MBAN devices.

- Manufactures should carefully analyze the Order since the FCC provides insight about other permissible communications that might impact a manufacturer's product development.

- MBANs include body-worn sensor devices, not implanted devices. However, it is unclear whether implanted devices could be linked to body-worn sensors (which are part of an MBAN).

- The Order indicates that body-worn sensors can be used to deliver medical therapy which, presumably, can be done upon direction from the hub.

c. Authorized Locations. (Order at ¶¶ 39-40.) MBAN operations in the 2360-2390 MHz band are limited to indoor locations within health care facilities as a way to limit potential interferences between MBAN and AMT users.[9] MBAN operations in the 2390-2400 MHz band are not subject to this location restriction.

Observations and/or Recommendations

- Health care facilities can consider using MBAN devices that are capable of shifting to the 2390-2400 MHz band in those emergency situations where, for example, some patients in a health care facility must be temporarily moved outdoors where operation on the 2360-2390 MHz is not allowed (unless a temporary waiver for such operation is obtained).

d. Equipment Authorization. (Order at ¶¶ 41-43.) MBAN programmer/controller transmitter devices are generally subject to the same equipment authorization requirements, disclosures statements, and labeling requirements as those set forth in the MedRadio rules.[10] There are a few variations of these requirements applicable to

[9] AMT licensees use this spectrum on a primary basis.
[10] Certification requirements and procedure for MedRadio equipment are currently contained in 47 C.F.R. Sections 95.603(f) and 95.605, while disclosure policies, labeling requirements and marketing limitations are contained in 47 C.F.R Sections 95.1215, 95.1217, and 95.1219, respectively.

MBAN devices including the following: (i) only individual MBAN programmer/controller transmitters need to have, and be labeled with, a unique serial number -- individual MBAN body-worn sensor devices do not need have a unique serial number; and (ii) the FCC ID number associated with the MBAN hub and the information required by Section 2.925 of the FCC's Rules can be placed in the hub's instruction manual rather than directly on the transmitter.

Observations and/or Recommendations

- The FCC has comprehensive requirements governing the equipment authorization process. Manufacturers hoping to market MBAN devices for use in June 2013 should be sure to consider this process (including the timing it will take to obtain an equipment authorization) as they develop their marketing and deployment plans.

- MBAN programmer/control transmitters must include (either on a label or in the instruction manual) a statement that the device may not interfere with stations authorized to operate on a primary basis in the 2360-2400 MHz band.

2. **Technical Rules.** (Order at ¶¶ 44-55.) The FCC will regulate MBAN devices under its existing MedRadio technical rules subject to certain modifications. Below are specific technical parameters applicable to MBAN.

   a. Authorized Bandwidth and Channel Aggregation. (Order at ¶¶ 44-46.) MBAN devices may use up to a 5 MHz bandwidth. Device manufacturers can aggregate multiple transmission channels in a single device, as long as the total emission bandwidth used by all devices in any single patient MBAN communication session does not exceed the maximum authorized bandwidth of 5 MHz.

   Observations and/or Recommendations

   - By adopting a maximum bandwidth, the rules accommodate MBAN devices that use a smaller bandwidth (e.g., 1 MHz) and give flexibility for the development of MBAN devices that can use higher data rates and that have higher throughput for applications that require larger amounts of data.

   - The new rules do not define what constitutes a "single patient MBAN communication session"

   b. Transmitter Operation and Power Limits. (Order at ¶¶ 46-49.) Generally, there is a maximum EIRP of 20 mW measured over the frequency band of operation for the 2390-2400 MHz band, and a maximum EIRP of 1 mW over the frequency band of operation for the 2360-2390 MHz band. MBAN programmer/controller transmitters must be capable of receiving and complying with a control message specifying its particular

operating parameters within the band.[11] Specifically, an MBAN programmer/control transmitter may not commence operation and must automatically cease operating in the 2360-2390 MHz band if it does not receive a control message.

Observations and/or Recommendations

- The FCC recognizes that each health care facility's communications infrastructure and physical layout will present unique capabilities and challenges and, therefore, the FCC did not establish any requirements for how control messages are distributed within a health care facility. However, the FCC expects that the control message will be an electronic message since it is expected to be sent using the health care facility's LAN. Manufacturers may want to develop alternative, turn-key "options" from which health care facilities can select to comply with this control message requirement.

c. RF Safety. (Order at ¶ 52.) MBAN devices are subject to Section 2.1093 of the FCC's Rules, pursuant to which an environmental assessment concerning human exposure to RF electromagnetic fields must be prepared under Section 1.1307.

d. Unwanted Emissions. (Order at ¶ 50.) According to Section 95.635 of the FCC Rules, "In the first 2.5 MHz beyond any of the frequency bands authorized for MBAN operation, the EIRP level associated with any unwanted emission must be attenuated within a 1 MHz bandwidth by at least 20 dB relative to the maximum EIRP level within any 1 MHz of the fundamental emission."

3. Registration and Coordination Requirements. (Order at ¶¶ 56-74.) The FCC has adopted registration and coordination requirement for MBAN devices operating in certain portions of the 2360-2400 MHz band. Below is an overview.

a. Overview. MBAN operations in the 2360-2390 MHz band are subject to registration and coordination requirements (which are two separate, but related processes). Essentially, a health care facility that intends to operate an MBAN in the 2360-2390 MHz band must register the MBAN with the MBAN frequency coordinator. By registering, the location of the MBAN operations will be recorded in a database. As part of the coordination process, the MBAN coordinator will determine if a proposed MBAN is within line-of-sight of an AMT receiver. If it is, the MBAN and AMT coordinators will assess the interference risk.

Observations and/or Recommendations

- Health care facilities (which are responsible for registration and coordination) will probably be unfamiliar with these regulatory requirements and/or may not have the resources to devote to FCC compliance. Therefore, manufacturers should develop

[11] The FCC adopted this requirement, in part, to ensure compliance with its restrictions on 2360-2390 MHz band operations outside a health care facility.

turn-key compliance plans and procedures to make it as easy as possible for health care facilities to satisfy their responsibilities. For example, manufacturers might want to develop forms, modules and training materials that are designed to minimize the compliance burden on health care facilities.

b. Required Registration Information. As part of the registration process, health care facilities must provide the following information (and other information) to the MBAN coordinator: (1) specific frequencies or frequency ranges to be used within the 2360-2390 MHz band; (2) number of programmer/controller transmitters to be used including manufacturer name(s), model numbers and FCC identification number; (3) legal name of the health care facility; (4) location of programmer/controller transmitters; (5) point of contact for the health care facility; (6) contact information for party responsible for ensuring proper MBAN operations within the health care facility; and (7) whether MBAN operations are capable of defaulting to the 2390-2400 MHz band or to other hospital systems.

Observations and/or Recommendations

- The party/person responsible for ensuring proper MBAN operations would typically be an employee of the health care facility or a contractor. Manufacturer should consider preparing written training materials to assist health care facilities comply with these requirements. Manufacturers may also want to consider whether to provide oversight services on a contractor basis.

- Health care facilities have an ongoing responsibility to ensure that the information provided to the MBAN coordinator is accurate and up to date.

Please contact us with any questions or comments.

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