



Medical Body Area Networks (MBANs)

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MBANs Report and Order

- The FCC released a R&O and FNPRM (FCC 12-54) in May, 2012 that expands the Part 95 Medical Radio (MedRadio) rules to permit the development and operation of wireless Medical Body Area Networks (MBANs)
- MBANs are low power networks that support wireless non-voice data communications between body-worn medical sensor (client) devices and a dedicated programmer/control (P/C) device
 - The body-worn sensor devices measure patient physiological information and/or perform diagnostic and therapeutic functions and then wirelessly transmit the associated data to the P/C device.
 - The P/C device aggregates the patient data and transmits it to one or more monitoring stations via the hospital's local area network (LAN).



MBAN System Components

- **Body-worn sensor/actuator devices**
 - Body-worn (or body-proximity) sensors/actuator devices measure and collect the individual patient data for transmission to their dedicated P/C device.
- **Programmer/controller (P/C) devices**
 - The portable programmer/controller device manages the transfer of data between the sensor devices and the facility LAN.
 - The P/C device also receives a control message from the Control Point (via the facility LAN) and uses the embedded information to enable the associated sensors to operate on coordinated frequencies in the 2360-2390 MHz band segment.
 - In the event of a failure to receive a control message, the P/C device must immediately inform its sensor devices to cease transmission on frequencies within the 2360-2390 MHz.



Authorized MBAN Frequencies

- The R&O authorizes the 2360-2400 MHz frequency band for use by MBANs
 - Use of frequencies in the 2360-2390 MHz is subject to coordination with Aeronautical Mobile Telemetry (AMT) licensees.
 - Frequencies in the 2390-2400 are available for use by MBANs without the need for coordination.



MBAN Frequency Coordination Requirements

- **§ 95.1223 Registration and frequency coordination in the 2360-2390 MHz Band.**
 - A health care facility must register all MBAN devices it proposes to operate in the 2360-2390 MHz band with a frequency coordinator designated by the FCC under §95.1225.
 - Operation of MBAN devices in the 2360-2390 MHz band is prohibited prior to the MBAN coordinator notifying the health care facility that registration and coordination is complete.
 - The required registration information is listed in §95.1223(a)
 - The frequency coordinator will determine if an MBAN is within the line of sight of an AMT receive facility and notify the health care facility when it may begin MBAN operations in the 2360-2390 MHz Band according to the procedures listed in §95.1223(c).



MBAN Control Point

- The Control Point receives communications from the MBAN Frequency Coordinator (via secure E-Key, email, telephone, fax, etc.) informing what, if any, frequencies within the 2360-2390 MHz band are available at that particular location/facility.
 - This information is used to generate a control message that is provided to the P/C devices in the MBAN (via facility LAN) notifying them of those frequencies available for use.
 - There is typically only one Control Point per coordinated facility.
 - The Control Point is technically not a part of the MBAN; however, the control messages generated by a Control Point are necessary for testing MBAN functionality.



MBAN Technical Requirements

- **§95.628(c) Requirements for Medical Body Area Networks.**
 - A MedRadio 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, a MedRadio 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.
- **§95.628(d) Frequency Stability Requirements**
 - All MBAN devices must maintain a frequency stability of ± 100 ppm over a temperature range of 0-55 degrees Celsius



MBAN Technical Requirements

(continued)

● §95.633(e) Emission Bandwidth Limits

- All transmissions associated with an MBAN are limited to an emission bandwidth (EBW) of less than or equal to 5 MHz, where the EBW is determined by measuring the width of the signal between points, one below the carrier center frequency and one above the carrier center frequency, that are 20 dB down relative to the maximum level of the modulated carrier.
- Multiple transmission channels from a single device are permitted 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.



MBAN Technical Requirements

(continued)

- **§95.639(f) Maximum Transmitter Power Limits**
 - (3) MBAN transmissions in the 2360-2390 MHz frequency band are limited to a maximum equivalent isotropic radiated power (EIRP) that shall not exceed the lesser of 1 mW (0 dBm) or $10\log(\text{EBW})$ dBm, where EBW is expressed in MHz.
 - (4) MBAN transmissions in the 2390-2400 MHz frequency band are limited to a maximum EIRP that shall not exceed the lesser of 20 mW (13 dBm) or $16 + 10\log(\text{EBW})$ dBm, where EBW is expressed in MHz.
 - (5) The antenna associated with any MedRadio transmitter must be supplied with the transmitter and shall be considered part of the transmitter subject to equipment authorization.



MBAN Technical Requirements

(continued)

● §95.635(d) Unwanted Radiation

- (7) In the first 2.5 megahertz 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 (i.e., 20 dBc).



MBAN Technical Requirements (continued)

● §95.635(d) Unwanted Radiation (continued)

- (1)(v) Emissions from a MedRadio transmitter shall be attenuated to a level no greater than the field strength limits shown below when they are more than 2.5 MHz outside of the 2360- 2400 MHz band when measured at a distance of 3 meters:

30-88 MHz	100 μ V/m
88-216 MHz	150 μ V/m
216-960 MHz	200 μ V/m
960 MHz and above	500 μ V/m

- (2) The emission limits above are based on measurements employing a CISPR quasi-peak detector except that above 1 GHz, the limit is based on measurements employing an average detector. Measurements above 1 GHz shall be performed using a minimum resolution bandwidth of 1 MHz.
 - A peak detector is an acceptable alternative for either the quasi-peak or the average detector
- (3) The emissions from a MedRadio transmitter must be measured to at least the tenth harmonic of the highest fundamental frequency designed to be emitted by the transmitter.



Standard Compliance Test Considerations

- Bandwidth, transmitter power, unwanted emission levels and frequency stability can be measured using the standard guidance provided in KDB 971168.
 - Measurements of peak radiated field strength are the most effective means of measuring the above parameters to demonstrate compliance
 - Integral antennas are likely to be utilized, particularly with respect to body-worn sensor/actuator devices
 - Limits are expressed in terms of both EIRP (output power) and field strength (unwanted emissions beyond 2.5 MHz)
 - KDB 971168 provides guidance for performing radiated measurements and mathematical conversion factors for converting the measured field strength levels to EIRP when necessary to compare to the limit
 - Testing may necessitate establishment of a communications link between the P/C and sensor device(s)
 - Compliance tests performed on body-worn sensors may require human body simulation. If this becomes necessary:
 - Use a phantom (artificial human body) as described in ETSI TR 102 273-7
 - Use the liquid tissue solution for 2450 MHz as defined in Appendix C of Supplement C to OET Bulletin 65



Unique Tests to Validate Requirements of §95.628(c)

- **Verify that P/C transmitter does not transmit on frequencies within the 2360-2390 MHz band until a valid control message is received**
 - Set up a LAN connection between the MBAN P/C device under test (DUT) and the simulated control point.
 - Note that the simulated control point must be capable of generating a valid control message, utilizing the applicable network protocols, and delivering it to the MBAN P/C device via a local area network connection for the purpose of enabling or restricting operation on frequencies within the 2360-2390 MHz band.
 - The simulated control point shall provide the ability for test personnel to set relevant control message parameters (e.g., channel frequency list, available or restricted sub band list, transmitter power, etc.) in order to facilitate testing.
 - Test reports must clearly describe the how the control point is simulated and used to generate the control message to facilitate the compliance measurements.
 - Disable the control message to the DUT.
 - Apply power to DUT.
 - Verify that DUT does not commence transmissions on frequencies in the 2360-2390 MHz band.



Unique Tests to Validate Requirements of §95.628(c)

(continued)

- **Verify that P/C transmitter operates on frequencies in the 2360-2390 MHz band only in accordance with instructions contained within a valid control message.**
 - Establish LAN connection between DUT and simulated control point.
 - Set control message frequency/channel/sub band parameters to enable operation as per manufacturer definition.
 - Verify that DUT transmissions in the 2360-2390 MHz band are in accordance to the control message specifications.
 - Reset control message to prohibit operation on frequencies within the 2360-2390 MHz band.
 - Verify that DUT ceases transmission on frequencies within the prohibited band with a latency period not exceeding the maximum control message periodicity.
 - Reset control message to enable DUT operation on frequencies within the 2360-2390 MHz band.
 - Verify that the DUT resumes transmitting on frequencies within the 2360-2390 MHz band.
 - Disrupt (disable) the control message.
 - Verify that DUT ceases all transmission on frequencies within the 2360-2390 MHz band.



Unique Tests to Validate Requirements of §95.628(c)

(continued)

- **Verify that body-worn sensor transmitters cease transmitting in 2360-2390 MHz band when connection is lost with the associated P/C device.**
 - Establish a LAN connection between the MBAN P/C device and the simulated control point.
 - Establish connection between the MBAN P/C and the body-worn sensor device under test (DUT).
 - Configure the control message to enable operation in the 2360-2390 MHz band.
 - Verify that transmissions between DUT and its associated MBAN P/C are consistent with the control message configuration.
 - Interrupt the wireless connection between the P/C and the sensor.
 - Verify that the DUT ceases transmission in the 2360-2390 MHz band.



Certification Considerations

- At this time, MBAN devices are on the TCB Exclusion List
 - Application for certification must be filed directly with the FCC
- The MBAN operational description shall clearly define how communications with the Control Point/Frequency Coordinator will be managed.
- A complete description of the communications protocol shall be provided for review.
- Detailed compliance measurement guidance will be forthcoming, initially as a draft KDB for public comment.



Questions and Answers

Thanks!