701 Pennsylvania Avenue, Ste. 800
Washington, DC 20004–2654
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

AdvaMed
Advanced Medical Technology Association

MBAN - NPRM AdvaMed Reply Comments

Docket FCC 08-59: Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks

4 November 2009

AdvaMed, the Advanced Medical Technology Association, submits these reply comments regarding the subject Docket. AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

1) **MBAN usage scenario**
   a. In the 2360-2390 MHz band, only in-hospital use outside exclusion zones, indoor use only
      MBAN devices can be applied broadly in many hospital patient monitoring situations. General ward monitoring is a significant area where this can reduce cost and improve patient outcome.

   b. In the 2390-2400 MHz band, MBAN devices can be used anywhere, no coordination needed
      i. Significant use cases are Ambulance Emergency monitoring, and Home Care monitoring.
      ii. These solutions can benefit medical care in the military, for emergency monitoring of military personal both on the battlefield and in battlefield hospitals. These small devices can be adapted to meet military needs and enhance care in these critical areas.

   c. Bidirectional communications, an enabler to robust communication
      MBAN devices will use bidirectional communication to achieve a high reliability radio link to meet the needs of critical care monitoring. Temporal and frequency diversity techniques could be applied to enable reliable data transfer. Advanced cognitive protocols as defined in Philips NPRM comments could be applied to achieve the desired link robustness.

   d. Hub devices can control MBAN sensors to move to a new clear channel when necessary.

A variety of architectures can be created for MBAN devices, all of which will enable the individual control of the MBAN device to meet proposed rules. The hub device, as well as other devices that communicate with MBAN devices, can serve this role. In other words, the MBAN devices will be designed within reasonable cost and technical parameters to accommodate whatever rules the Commission issues.

e. Usage for life critical functions is practical with diversity and protocol techniques as well as the addition of advanced cognitive radio technologies, contrary to AFTRCC assertions.
   i. The AFTRCC comments are not applicable to MBAN systems which leverage bidirectional communications, protocol mechanisms for acknowledgement, and auto retransmission of lost data as well as temporal and frequency diversity.
   ii. There are cognitive radio technologies operating in commercial telemetry systems on a secondary basis in the 1.4 GHz WMTS band. They have been deployed for many years without raising any safety concerns. The MBAN devices could use similar cognitive radio technologies. Philips Healthcare has provided a detailed presentation[1] to the FCC on this subject, and GE Healthcare filed a supporting clarification[2].

f. Coordination could be accomplished.
   i. The AdvaMed comments on the NPRM describe how this could be accomplished. In their comments on the Notice, ASHE expressed their interest in participating[3].
   ii. AFTRCC's history of coordinating experimental STA operations with Broadcast Sports Incorporated at higher power than MBANS within the 2360-2395 MHz bands proves that coordination is possible.[4]

g. Operation with mobile AMT is practical with the proposed control process.
   i. The AMT operation will have access to the ASHE database for active MBAN sites, enabling them to choose locations that will avoid conflicts. Mobile AMT systems have good flexibility to choose locations.
   ii. All MBAN sites in the 2360 to 2390 MHz spectrum are proposed to be registered with ASHE and could have electronic control to prevent unauthorized use.

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1 Philips Medical Systems Ex Parte Presentation, WP Docket No.07-100 (dated June 26, 2008)

2 GE Healthcare Ex Parte WP Docket No.07-100 (dated Oct 20,2008)

3 ASHE Comments, ET Docket No. 08-59 (dated, October 5, 2009)

4 GE Healthcare Reply Comments, ET Docket No. 08-59 (dated, November 4, 2009)

iii. Boeing has stated concerns for safety for pilots and people on the ground[5]; therefore it is inconceivable to us that aggressive testing would be conducted over high population density areas. This must also hold true for missile flight tests.

iv. Mobile AMT sites are expected to be located in areas with low population density. Thus, they should have a low probability for conflict with MBAN sites.

v. Hospitals in low population density areas are generally small in size and would have correspondingly small numbers of MBAN devices deployed. This should significantly reduce the management problem.

h. Relatively few hospitals would fall within the exclusion zones needed to protect AMT operations.

i. Only a very small number of hospitals fall within an exclusion zone. From previous GE filing[6], less that 2% of total hospital sites fall within a 10 km exclusion zone around licensed AMT sites. Upon further inspection, the data reveal that more than 94% of all hospitals are more than 50 km from a licensed AMT site. Therefore, the vast majority of hospitals can use the spectrum with no risk. The rules we propose can manage the remaining small percentage of hospital to eliminate interference risks.

ii. This low percentage of hospital within exclusion zones demonstrates that the magnitude of the control problem is small and should be easily handled by coordination described in our comments on the NPRM.

i. A Listen-Before-Talk ("LBT") protocol can be easily implemented with proposed technologies, contrary to the Boeing claims that it will be too expensive.

i. MBAN will leverage technologies used in the 2.4 GHz ISM band. Many of the most popular radio technologies used in the ISM band, e.g., Zigbee (802.15.4) and Bluetooth, already employ LBT protocols at low cost. The cost will continue to fall as the commercial volumes increase.

ii. In the case of Bluetooth radios, adaptive frequency hopping is well established and widely deployed.

j. Licensing

License-by-rule is appropriate. See the GE & Philips comment filings for detailed discussion.

2) The Monte Carlo statistical method is a suitable tool for studying AMT-MBAN coexistence. We believe that the worst-case approach is too conservative and

5 The Boeing Company Comments, ET Docket No. 08-59 (dated, October 5, 2009)

6 GE Healthcare Comments, ET Docket No. 08-59 (dated, October 5, 2009)

impractical, especially considering the limited overlap of healthcare facilities and ATM sites.

a. Significant evidence exists that shows the wide adoption of Monte Carlo method in diverse industries.
b. Monte Carlo is used in life-critical design and risk assessment, e.g. in the aviation industry.
c. See GE & Philips Reply comments filing for detailed analysis.

3) **Exclusion zones of 11.5 km radius are sufficient to protect AMT sites, and the enforcement of exclusion zones (including the indoor use in the 2360-2390 MHz) is feasible and could be done simply and efficiently.**

b. C/(I+N) is an appropriate criterion for a coexistence study to quantify the probability of harmful interference,
c. See Philips NPRM Reply comments for detailed discussion and analysis.
d. AFTRCC tests/analysis did not well represent real MBAN/AMT coexistence scenarios, and their conclusions are questionable and presented without a sufficient level of technical detail and documentation...
e. GE and Philips have conducted extensive simulations with more practical setups. Their results demonstrate exclusion zones with 11.5 km radius are sufficient to protect AMT sites. GE simulations have also addressed separation distances necessary to satisfy the conservative limit of I/N < -3 dB.
f. The MBAN management scheme proposed in the Philips and AdvaMed NPRM comments provides a simple and practical option to enforce exclusion zones and indoor use.
g. See GE and Philips Reply Comments for detailed analyses.

4) **Whether the AMT link is noise-limited or interference-limited is not crucial for the interference probability analysis. Interference from the OOBE of 2.4 GHz devices was not included in GE/Philips analysis.**

a. AMT ambient and noise levels presented by Boeing[7] show they operate well above the thermal noise floor limit.
b. The noise data presented by Boeing show only average noise measurements over their 20 MHz measurement band which understate the real behavior of the noise floor, which is best defined in terms of peak noise levels.
c. See GE and Philips Reply Comments filings for detailed analysis.

5) **Other bands like 2300-2305 and 2390-2400 MHz are not broad enough to support MBAN innovation**[8]

a. The 2300-2305 and 2390-2400 MHz bands is not sufficient bandwidth to meet for MBAN to reach its full potential and cannot support the needs of large hospitals, See Appendix E of Philips Healthcare NPRM comments document) for detailed discussion.

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7 The Boeing Company Comments, ET Docket No. 08-59 (dated, October 5, 2009)

8 ARRL the National association for Amateur Radio Comments, ET Docket No. 08-59 (dated, October 5, 2009)

b. These bands could serve the needs for Ambulance, Home and Small Hospitals, as defined in the usage scenario above.

6) **The FCC's NPRM affords the United States the opportunity to take the lead with driving MBANS technology across the globe. This gives the US a leading edge on new technology application.**
   a. Comments from Zarlink convey a preference for global harmonization.
   b. By proposing this NPRM, the FCC places the United States in a leading position with economic advantage from establishing an MBANS service, leaving other regions in the world to follow the FCC's example.

Respectfully Submitted,

Bernie Liebler
Director
Technology & Regulatory Affairs