Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

In the Matter of	)	
	)	
Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks	)))	ET Docket No. 08-59

To: The Commission

COMMENTS OF GE HEALTHCARE

Neal Seidl
Wireless System Architect
GE Healthcare
8200 W. Tower Avenue
Milwaukee, WI 53223
(414) 362-3413

David Davenport
Electrical Engineer
GE Global Research
1 Research Circle
Niskayuna, NY 12309
(518) 387-5041

Ari Q. Fitzgerald
Hogan & Hartson L.L.P.
555 13th Street, N.W.
Washington, DC 20004
(202) 637-5423

October 5, 2009

TABLE OF CONTENTS

PAGE

INTRODUCTION AND SUMMARY 1

I. MBAN TECHNOLOGY HOLDS GREAT PROMISE FOR IMPROVING THE EFFICIENCY AND QUALITY OF HEALTH CARE DELIVERY AND AN MBAN ALLOCATION IS IN THE PUBLIC INTEREST 2

II. ISM AND U-NII SPECTRUM DO NOT MEET THE NEEDS OF MBAN DEVICES 6

III. ALLOCATION OF THE ENTIRE 2360-2400 MHZ BAND FOR MBAN OPERATIONS ON A SECONDARY BASIS IS THE BEST WAY TO MAKE MBAN PRODUCTS TECHNICALLY, CLINICALLY AND ECONOMICALLY VIABLE.....7

IV. A SECONDARY ALLOCATION IN 2360-2400 MHZ FOR MBAN OPERATIONS IS CONSISTENT WITH SOUND SPECTRUM POLICY CONSIDERATIONS.....11

V. THE POTENTIAL FOR HARMFUL INTERFERENCE FROM MBAN DEVICES TO INCUMBENT SERVICES IN THE 2360-2400 MHZ BAND IS NEGLIGIBLE.....14

VI. MBAN DEVICES WOULD BE ABLE TO OPERATE SAFELY AND EFFECTIVELY ON A SECONDARY BASIS IN THE 2360-2400 MHZ BAND.....17

VII. OTHER ISSUES.....23

CONCLUSION.....31

APPENDIX A.....A-1

APPENDIX B.....B-1

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

In the Matter of	)	
	)	
Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks	)))	ET Docket No. 08-59

To: The Commission

COMMENTS OF GE HEALTHCARE

INTRODUCTION AND SUMMARY

GE Healthcare ("GEHC") hereby submits these comments in response to the Commission's Notice of Proposed Rulemaking ("NPRM")[1] in this proceeding. GEHC applauds the Commission for recognizing that wireless Medical Body Area Network ("MBAN") technology would serve the public interest and for consequently taking this important step towards allocating the spectrum necessary to make MBAN devices a reality. Clearly, this action underscores the Commission's continuing desire to promote the development of advanced wireless medical devices that promise not only to improve the health and well-being of the American public, but also to play a key role in improving the efficiency of health care delivery in the United States.

[1] *See 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) ("*MBAN NPRM*").

I. MBAN TECHNOLOGY HOLDS GREAT PROMISE FOR IMPROVING THE EFFICIENCY AND QUALITY OF HEALTH CARE DELIVERY AND AN MBAN ALLOCATION IS IN THE PUBLIC INTEREST

In the *MBAN NPRM*, the Commission sought comment on its tentative conclusion that "[g]iven the significant health care benefits offered by MBAN systems, . . . providing spectrum for MBAN operations would serve the public interest."[2] GEHC wholeheartedly agrees with the Commission's tentative conclusion. As reflected by comments filed previously in this docket, MBAN technology holds great promise for improving the quality and efficiency of health care delivery.[3] MBAN technology offers many compelling benefits for both clinical quality and provider workflow, including infection control, patient mobility, ease of patient transport and flexible acuity monitoring. MBAN technology would replace wired connections to patients, enable disposable, patient-worn devices and, as a result, reduce the risk of infection and avoid time consuming and potentially imperfect sterilization procedures. A patient that is not encumbered by monitoring wires and cables is able to move more freely than one that is. Such mobility improves patient comfort and can contribute to better outcomes, faster recovery times and reduced lengths of hospital stays for hospital patients.

Transporting a patient between areas of the hospital often requires caregivers to move monitoring equipment along with the patient or to disconnect and reconnect the patient to the equipment. As an example, consider a patient who is transported from a cardiac recovery floor to the radiology department or a patient in labor who is moved from the delivery room to a surgical suite. Device management during patient transport is a time-consuming process that

---

[2] *Id.* at 9596, ¶ 20.

[3] *See, e.g.*, Comments of Marilyn Rantz, RN, PhD, FAAN, Professor, Sinclair School of Nursing, University of Missouri, ET Docket No. 08-59 (May 22, 2008); Comments of Lisa Gaudet, ET Docket No. 08-59 (May 23, 2008); Comments of Dr. David Pugliese, ET Docket No. 08-59 (May 29, 2008); Comments of Dr. Michael Shabot, M.D., ET Docket No. 08-59 (June 3, 2008; Comments of Kim Bonzheim, Director, Cardiac Services, William Beaumont Hospital, ET Docket No. 08-59 (June 4, 2008).

introduces gaps in data monitoring. With MBAN technology, caregivers would no longer need to disconnect and reconnect wires, allowing for enhanced data continuity. Furthermore, the data stream could be captured in the patient's electronic medical record without the need for manual data entry and the associated risk of human input errors.

In today's largely wired environment, many patients are treated in specific care areas based solely upon their monitoring needs. MBAN technology would afford hospitals greater monitoring flexibility and scalability, potentially allowing caregivers the ability to safely monitor more patients with fewer staff. MBAN technology would also allow health care providers to quickly add or remove physiological parameter sensors as patients' medical conditions warrant and to integrate and evaluate these multiple parameters to make informed treatment decisions. Additionally, MBAN technology would allow caregivers to wirelessly monitor many parameters outside of specialized care areas. For example, EEGs, a measure of brain electrical activity, could be measured outside a hospital's neurology unit.

To further appreciate the importance of MBAN technology to improving health care delivery and efficiency, consider the National Health Expenditure ("NHE") data compiled by the Department of Health and Human Services. The NHE fact sheet[4] includes the following statistics:

- NHE grew 6.1% to $2.2 trillion in 2007, or $7,421 per person, and accounted for 16.2% of Gross Domestic Product ("GDP").
- Medicare spending grew 7.2% to $431 billion in 2007, or 19% of total NHE.
- Private spending grew 5.8% to $1.2 trillion in 2007, or 54% of total NHE.

---

[4] U.S. Dep't. of Health & Human Serv., Centers for Medicare and Medicaid Services, National Health Expenditure (NHE) Data – Fact Sheet, http://www.cms.hhs.gov/NationalHealthExpendData/25_NHE_Fact_Sheet.asp#TopOfPage (last accessed Sept. 28, 2009).

- Hospital expenditures grew 7.3% in 2007, up from 6.9% in 2006.
- Growth in NHE is expected to remain steady at 6.1% in 2008 and average 6.2% per year over the projection period (2008-2018).
- The health share of GDP is projected to reach 16.6 % in 2008 and 20.3 % by 2018.
- Spending on hospital services is projected to grow 7.2% in 2008 to $747 billion.
- Average growth of 6.4% per year is expected for the entire projection period.

In gauging the potential positive impact of MBAN technology, it is also important to understand the scope and breadth of the health care industry in terms of its workforce and consumers. The American Hospital Association ("AHA") 2009 Chartbook addresses trends affecting hospitals and health care delivery systems. Chapter 5 of the Chartbook[5] lists statistics for 2007, including the employment of 4,465,028 full-time equivalent employees in hospitals and a total of 1,191,200 registered nurses. Chapter 3 of the Chartbook[6] indicates that in 2007 there were 35,345,986 inpatient admissions and 603,300,374 outpatient visits at community hospitals. An MBAN allocation would help to improve, and reduce the costs associated with, this critically important activity and ultimately improve the health and well-being of a large segment of the American population.

The capabilities and benefits of MBAN technology are also needed to address the country's aging population and its increasing demand for health care. Hospital acuity is rising due to nearly 80 million baby boomers in the US population. As this population ages, the

---

[5] American Association of Hospitals, 2009 Chartbook – Trends Affecting Hospitals and Health Systems, Chapter 5, *available at* http://www.aha.org/aha/research-and-trends/chartbook/ch5.html (last accessed Sept. 28, 2009).

[6] *Id*. at Chapter 3, *available at* http://www.aha.org/aha/research-and-trends/chartbook/ch3.html (last accessed Sept. 28, 2009).

average acuity of hospitalized patients is projected to grow rapidly.[7] As baby boomers are aging and retiring, so are nurses and physicians. The growth and aging of the population will contribute to a 22% increase in the demand for physician services between 2005 and 2020. Growth in demand will be highest among specialties that predominantly serve the elderly (*e.g.*, cardiology, internal medicine, and most surgical specialties),[8] where patient monitoring is often most needed. The current registered nurse shortage is expected to continue to grow in severity, and the demand for registered nurses in hospitals is projected to increase 37% from 2000 to 2020.[9] If allowed to operate, MBAN technology could be used to address many of these challenges and enable care givers to better manage a growing population of sicker patients.

As the discussion above makes clear, by allocating the spectrum required to enable MBAN devices and establishing sensible rules regarding their use, the Commission would be taking a major step in fostering revolutionary advances in patient monitoring and health care delivery and thereby making an important contribution to health care reform. Therefore, the Commission's final order in this proceeding should confirm its tentative conclusions regarding the "significant health care benefits offered by MBANS systems."[10]

---

[7] U.S. DEP'T OF HEALTH & HUMAN SERV., HEALTH RES. & SERV. ADMIN., THE CRITICAL CARE WORKFORCE: A STUDY OF THE SUPPLY AND DEMAND FOR CRITICAL CARE PHYSICIANS, REQUESTED BY: SENATE REPORT 108-81, *available at* http://bhpr.hrsa.gov/healthworkforce/reports/criticalcare/default.htm (last accessed Sept. 28, 2009).

[8] U.S. DEP'T OF HEALTH & HUMAN SERV., HEALTH RES. & SERV. ADMIN., THE PHYSICIAN WORKFORCE: PROJECTIONS AND RESEARCH INTO CURRENT ISSUES AFFECTING SUPPLY AND DEMAND (2008), *available at* http://bhpr.hrsa.gov/healthworkforce/reports/physicianworkforce/default.htm (last accessed Sept. 28, 2009).

[9] U.S. DEP'T OF HEALTH & HUMAN SERV., HEALTH RES. & SERV. ADMIN., WHAT IS BEHIND HRSA'S PROJECTED SUPPLY, DEMAND, AND SHORTAGE OF REGISTERED NURSES? (2004), *available at* http://bhpr.hrsa.gov/healthworkforce/reports/behindrnprojections/index.htm (last accessed Sept. 28, 2009).

[10] *See MBAN NPRM* at 9596, ¶ 20.

II. ISM AND U-NII SPECTRUM DO NOT MEET THE NEEDS OF MBAN DEVICES

In the *MBAN NPRM*, the Commission seeks comment on whether, as an alternative to the 2360-2400 MHz band, MBAN devices could potentially operate, either as Part 15 or Part 95 devices, within the 2400-2483.5 MHz and 5150-5250 MHz bands.[11] For a number of reasons, however, the alternative bands mentioned are not well-suited to accommodating MBAN devices.

First, these bands are quite noisy due to the emissions of a variety of unlicensed intentional radiators and, in the case of the 2400-2483.5 MHz band, Part 18 ISM devices already operating in the band. For example, 802.11 Wi-Fi, operating in both the 2400-2483.5 MHz and 5150-5250 MHz U-NII bands, has become pervasive in hospitals and is increasingly being used for life- and mission-critical applications. Moreover, due to high utilization, demanding throughput and latency and reliability requirements, dense Wi-Fi access point ("AP") deployments are very common. Also, in some cases, instead of traditional one-channel-per-AP deployments, multiple channels are "layered" across all APs,[12] effectively consuming, for instance, the entire 2400-2483.5 MHz ISM band in all areas. On top of all this, the latest 802.11n standard doubles the maximum Wi-Fi channel bandwidth to 40 MHz, compared to the 20 MHz channels employed by the earlier 802.11a/b/g standards. These Wi-Fi APs, and the numerous client devices that they serve, transmit at up to 100 mW and can be expected to come into very close proximity to MBAN devices, which, in order to achieve satisfactory battery life, would transmit at only 1mW or less.

In addition to Wi-Fi devices, an almost unlimited variety of other devices – both devices deployed deliberately by hospitals and devices carried in by patients, visitors, doctors and staff – employing Bluetooth, ZigBee and a host of proprietary wireless technologies make use of the

---

[11] *See id*. at 9598-99, ¶¶ 28-32.

[12] *See, e.g.*, Meru Networks, Channel Layering, http://www.merunetworks.com/technology/rflayer/layering.php (last accessed Oct. 5, 2009).

2400-2483.5 MHz band in hospitals. Here again, many of these devices transmit at substantially higher power than MBAN devices, with their stringent power consumption requirements, would be able to transmit.

Finally, there are additional issues with respect to the 5150-5250 MHz U-NII band in particular that would impede the development of MBAN products for that band and perhaps make MBAN products in that band technically and/or economically infeasible. For example, the substantially higher propagation and implementation losses associated with the 5150-5250 MHz band would drive the need for higher transmit power and, consequently, result in higher power consumption and shorter battery life. Also, unlike the situation with the 2360-2400 MHz band and 2400-2483.5 MHz band components, GEHC is not aware of any 5150-5250 MHz off-the-shelf chip solutions that could be used without modification or with slight modification for MBAN devices. The need for chip vendors to create new silicon is a significant barrier that would, at a minimum, increase MBAN costs and introduce significant development delays if the 5150-5250 MHz band were used.

III. ALLOCATION OF THE ENTIRE 2360-2400 MHZ BAND FOR MBAN OPERATIONS ON A SECONDARY BASIS IS THE BEST WAY TO MAKE MBAN PRODUCTS TECHNICALLY, CLINICALLY AND ECONOMICALLY VIABLE

In the *MBAN NPRM*, the Commission seeks comment on the appropriateness and feasibility of creating a secondary allocation for MBAN devices in the 2630-2400 MHz band, consistent with a proposal for sharing the band supported by GEHC and other parties to the proceeding.[13] GEHC proposed allocation of the entire 2360-2400 MHz band to the MBAN service on a secondary basis after carefully taking into account a number of considerations and,

[13] *See MBAN NPRM* at 9597-98, ¶¶ 21-25.

as explained below, GEHC continues to believe that this is the best approach to enabling MBAN devices.

One advantage of the proposed allocation that cannot be overemphasized is that it would allow use of the abundant and low cost electronic components that are currently available, and are continually being developed, for the adjacent 2400-2483.5 MHz ISM band. While, as described above, the large number of consumer and other devices that currently operate in the 2400-2483.5 MHz ISM band make it a poor choice for MBAN operations, the demand for such devices has nevertheless driven the development and availability of useful electronic components to volumes and price points that MBAN devices alone could likely never justify. Many of these components will work "off-the-shelf" in the 2360-2400 MHz band, and others with only minor modification.

Operating MBAN devices in the 2360-2400 MHz offers the best of both worlds – it allows MBAN devices to leverage the many electronic components, standards and other technologies developed for the adjacent ISM band, while at the same time avoiding the difficulties, explained above, of coexisting in the same band as ubiquitous, higher power unlicensed ISM devices. For example, the Body Area Network standard currently under development by IEEE 802.15 Task Group 6 has identified the 2400-2483.5 MHz ISM band for consumer applications and 2360-2400 MHz band for medical applications. Undoubtedly, high-volume consumer applications will drive the development of 802.15.6 integrated circuits, but MBAN applications will also benefit by being able to take advantage of those same chips.

Another important advantage of the 2360-2400 MHz band is that it is a candidate for international harmonization and was included in the technical requirements developed by ETSI ERM TG30 – Medical Devices (TR102 655). The ETSI ERM TG30 group independently identified the 2360-2400 MHz band as a candidate band. The potential for international

harmonization further bolsters the likelihood of widespread adoption and economies of scale necessary for MBAN viability.

GEHC believes that allocation of the entire 2360-2400 MHz band on a secondary basis is the most advisable approach to facilitating MBAN technology. Such an allocation would maximize the likelihood of MBAN devices being able to operate reliably across all conceivable scenarios in the vast majority of US hospitals, where most or all of the band would be available for use.

An examination of MBAN spectrum requirements, including the peak MBAN device densities that could arise at certain locations in hospitals, likely protocol overhead (*e.g.*, frame sync preambles, media access control ("MAC") layer information, error detection and correction schemes, etc.), contention protocol inefficiencies (*e.g.*, collision rates, etc.) and modulation spectral efficiency, suggests that 10-20 MHz of available spectrum would be required for the densest deployments of collocated MBAN devices. Appendix B provides further discussion of MBAN bandwidth requirements, as well as simulation results of MBAN performance considering several MAC protocol mechanisms.

It would, of course, be ideal if 20 MHz of suitable spectrum (*i.e.*, spectrum having the virtues of chip availability, etc.) were available for exclusive primary allocation to the MBAN service. However, a primary allocation of that amount of spectrum does not appear possible. Nevertheless, because the 2360-2400 MHz band is extremely sparsely utilized, a secondary allocation of the entire band would, as a practical matter, provide as much, or more, available spectrum to MBAN devices at most locations in the US.

Allocation of the entire 40 MHz block on a secondary basis would also provide meaningful frequency diversity, which is important for combating multipath and strong signal blocking effects, without requiring additional transmit power.

The *MBAN NPRM* described an alternate proposal to allocate some of the spectrum in the 2360-2400 MHz band (specifically 2390-2395 MHz) for MBAN device operations on a shared co-primary basis with aeronautical telemetry.[14] While a co-primary allocation for MBAN would certainly be acceptable, unlike an *exclusive* primary allocation, a co-primary allocation would *not* have the effect of reducing the amount of spectrum allocation needed to ensure sufficient spectrum is actually available for MBAN device use after sharing with incumbents. Regardless of whether the MBAN allocation is co-primary or secondary, the proposed MBAN devices would need to be designed to tolerate, and operate robustly in the presence of, interfering signals from higher powered incumbent services. Thus, the MBAN allocation would still need to be large enough to provide a high likelihood of sufficient spectrum being available for opportunistic MBAN devices to successfully operate in the band.

The Commission also seeks comment on the possibility of allocating 2300-2305 MHz for MBAN devices as a way of reducing the amount of 2360-2400 MHz spectrum that would have to be allocated.[15] GEHC believes that this would be of very limited value for several reasons. First, because this block would be separated from the rest of the MBAN allocation, and thus would introduce the need for two additional band edges, close to which MBAN devices would not be able to transmit, the 2300-2305 MHz band would not contribute a full 5 MHz of useful spectrum to the MBAN allocation. Second, the substantial frequency separation from the 2400-2483.5 MHz ISM frequencies, which extends well beyond 2483.5 MHz in many countries, would mean that many of the electronic components designed for use at or above 2483.5 MHz would not be useable for 2300-2305 MHz. Indeed, unlike for 2360-2400 MHz, GEHC is not aware of any current radio frequency transceiver chips that operate in the 2300-2305 MHz band

---

14 *See id.* at 9597-98, ¶ 24.

15 *See id*.

and expects that, even if this block were allocated to the MBAN service, chip vendors would decide to omit support for it from future chips due to technical challenges. Finally, MBAN use of 2300-2305 MHz and 2390-2400 MHz (the feasibility of which the Commission also asked commenters to consider)[16] would provide no "incumbent service diversity" for MBAN devices. Amateur radio is the incumbent service in both the 2300-2305 MHz and 2390-2400 MHz bands. These bands could fail to offer sufficient vacant spectrum in many areas where heavy Amateur activity is present.

IV. A SECONDARY ALLOCATION IN 2360-2400 MHZ FOR MBAN OPERATIONS IS CONSISTENT WITH SOUND SPECTRUM POLICY CONSIDERATIONS

As the Commission is aware, there exists virtually no unallocated spectrum below 3 GHz. Therefore, unless incumbent services are reallocated, any new services below 3 GHz will have to share spectrum with incumbents. The Commission's ground-breaking 2002 Spectrum Policy Task Force Report ("SPTFR") on spectrum efficiency recognized this situation, stating:

> [M]ost prime spectrum has already been assigned to one or more parties, and it is becoming increasingly difficult to find spectrum that can be made available either for new services or to expanding existing ones. . . . [T]o ensure that existing services can continue to grow to accommodate marketplace needs, and that new services have a chance to take hold and grow, it is important that the Commission continue to promote efficient access to and use of the radio spectrum.[17]

Currently, by any objective measure, the 2360-2400 MHz band is extremely sparsely utilized in geography, frequency and time. For example, a 2004-2005 study conducted by the Shared Spectrum Company for the National Science Foundation found that the 2360-2390 MHz band was largely fallow.[18] There is only one radio astronomy site using the band. All

---

16 *Id.*

17 Spectrum Policy Task Force Report, ET Docket No. 02-135 (Nov. 15, 2002), at 14-15.

18 *See* Shared Spectrum Company, Spectrum Occupancy Measurements, http://www.sharedspectrum.com/measurements/ (last accessed Oct. 5, 2009); Mark A. McHenry et al., *Shared Occupancy Measurements Chicago, Illinois November 16-18, 2005*, SHARED SPECTRUM

indications are that utilization by Amateur Radio is also quite limited and, at worst, can only occupy up to one quarter of the proposed band. And details regarding the sparse nature of aeronautical mobile telemetry ("AMT") operations in the band are provided below.

Figure 1 in Appendix A maps all 157 AMT receive locations, both government and commercial, that are registered with Aerospace and Flight Test Radio Coordinating Council ("AFTRCC") for the continental US. Many of these sites are closely clustered (*e.g.*, 13 at Edwards Air Force Base, etc.). There are 6,867 hospitals located within the continental US.[19] These hospitals are also mapped in Figure 1 of Appendix A. A visual comparison of the hospital and AMT receive site map demonstrates the substantial opportunity for spatial reuse of 2360-2400 MHz for MBAN operations. A quantitative statistical examination of the minimum separation distance between each hospital and the AMT sites is depicted in Figures 2 and 3 in Appendix A. Only 2.4% of hospital sites are located within 9.7 km of any AMT site.

Indeed, according to comments made by the aeronautical telemetry community to the ITU Radiocommunication Study Group 8B, the overwhelming amount of AMT operations occur away from densely populated areas, where hospitals tend to be located:

> Testing of aircraft in the US is conducted at remote inland sites (Nevada, the California deserts, Washington State, and Montana, to name a few), as well as offshore, over the Atlantic and Pacific Oceans as well as the Gulf of Mexico . . . .
>
> Flight tests are already conducted subject to numerous "keep-out" zones. This is true, for example, at Atlantic Coast ranges that are not far from metropolitan areas such as Washington, D.C. or Baltimore, Maryland. Flight testing at these ranges is conducted towards the east, over the Ocean. For ranges in the Southwestern

---

COMPANY (2005), *available at* http://www.sharedspectrum.com/measurements/download/NSF_Chicago_2005-11_measurements_v12.pdf. The study, which considered seven locations across the United States, found that the 2360-2390 MHz band was only 6.31% and 0.02% utilized in two locations and 0% utilized in the other five locations, amounting to only a 2.5% observation-time-weighted average utilization for the seven locations overall.

[19] SDI Health (www.sdihealth.com) is one of the major providers of health care information and services. SDI Health offers a commercial database of hospitals, which was used by GEHC for this effort.

United States, flight tests are conducted away from populated areas like Los Angeles.[20]

By contrast to special purpose medical spectrum,[21] which, despite having tens of thousands of users, currently totals only 21 MHz scattered over four disjointed spectrum bands, all of which is not available in any one location, AMT, despite having only a tiny fraction of users, has a total of 150 MHz allocated to it — most of it on an exclusive primary basis.[22] This is a truly remarkable amount of spectrum to be exclusively allocated for a handful of part-time users that are tightly clustered in just a few select areas. It is simply not in the public interest for this much spectrum to be left lying fallow in the majority of the US at any given time (and, in fact, 100% of the time over much of the US) when a compelling, compatible and socially productive potential new use such as MBAN exists.

As suggested above, Amateur operations are permitted on a primary basis in 2390-2400 MHz, but the Commission has stated that Amateur use of at least the 2390-2395 MHz portion "appears to be relatively light."[23] Moreover, GEHC has uncovered no information that would suggest that the 2395-2400 MHz portion of the band is not also lightly used.

---

[20] Response to the Liaison Statement From WP-8D Concerning Sharing Between Aeronautical Mobile Telemetry and GSO MSS Systems, United States of America, Document 8B/283-E, International Telecommunications Union Radiocommunication Study Groups (Sept. 6, 2002).

[21] MedRadio at 400-405 MHz and WMTS at 608-614, 1395-1400 and 1427-1432 MHz.

[22] In addition to the 35 MHz primary 2360-2395 MHz allocation at issue here, Part 87 provides AMT an additional primary allocation of 90 MHz at 1435-1525 MHz as well as a secondary allocation of 25 MHz within 2130-2320 and 2345-2360 MHz. AMT will also benefit from WRC-07's allocation of an additional 1374 MHz of additional bandwidth within 4400-4940 MHz, 5091-5150 MHz and 5925-6700 MHz band, as described by Int'l Telecomm. Union, *World Radiocommunication Conference Provisional Final Acts* (2007), *available at* http://www.telemetryspectrum.org/docs/Extract_Final_Acts_Prov.pdf (last accessed Sept. 3, 2008).

[23] *See Amendment of Part 2 of the Commission's Rules to Allocate Spectrum Below 3 GHz for Mobile and Fixed Services to Support the Introduction of New Advanced Wireless Services, Including Third Generation Wireless Systems*, ET Docket No. 00-258, Seventh Report and Order, 19 FCC Rcd 21350, 21373, ¶ 47 (2004) ("*New Advanced Wireless Services Seventh R&O*").

Finally, although a radio astronomy site operates at 2380 MHz near Arecibo, Puerto Rico, that is the only radio astronomy site at which the frequency is used. If necessary, this site could easily be protected by an exclusion zone similar to those proposed for AMT.[24]

Given the sparseness of incumbent operations in the spatial and frequency domains and their inherently intermittent nature, the 2360-2400 MHz band presents an excellent opportunity for shared use by opportunistic, frequency-agile MBAN devices. Clearly, allocation of 2360-2400 MHz for MBAN use on a secondary basis is consistent with the progressive spectrum policy recommendations of the SPTFR. In creating the WMTS, the Commission took a grossly underutilized spectrum block (*i.e.*, 16 MHz previously used only by a handful of radio astronomy and government radar sites) and made it available at substantial public benefit with few, if any, problems occurring in the almost nine years since. A similarly compelling opportunity exists for MBAN devices in 2360-2400 MHz.

V. THE POTENTIAL FOR HARMFUL INTERFERENCE FROM MBAN DEVICES TO INCUMBENT SERVICES IN THE 2360-2400 MHZ BAND IS NEGLIGIBLE

In the *MBAN NPRM*, the Commission seeks comment on the potential for harmful interference from MBAN devices to incumbents in the 2360-2400 MHz band.[25] Of course, the Commission should only concern itself with assessing the potential for harmful interference from MBAN devices to primary services in the band. What actually constitutes *harmful* interference is service-dependent. Received interference energy that is theoretically measurable but insufficient to cause actual outages (*e.g.*, causes a marginal increase in the noise floor of a victim receiver when the victim link still has ample margin to operate reliably) cannot by definition be

---

[24] The Arecibo antenna is located remotely and is permanently pointed skyward. According to SDI Health, the nearest hospital is Dr Cayetano Coll y Toste, which is over 14km away. *See* SDI – Innovations in Healthcare Analytics, http://www.sdihealth.com/ (last accessed Oct. 5, 2009).

[25] *See, e.g.*, *MBAN NPRM* at 9603-06, ¶¶ 46-55.

harmful and therefore should not be of interest to the Commission. In addition, it is certainly true that in many cases actual outages will not be harmful if they are sufficiently brief and/or infrequent. Thus, the intrinsic link performance of an incumbent service in the absence of interference provides a very good indication of the level of interference-induced outages, if any, that can be tolerated by that service without harm. Finally, after determining what actually constitutes harmful interference, the Commission should make its assessment by considering the actual *probability* – rather than merely the theoretical possibility – of it occurring.

The probabilistic analysis of interference to AMT operations previously provided by GEHC[26] is consistent with industry practice and is guided by all of the above principles. This analysis shows that modest (*e.g.*, 9.7 km for AMT sties using up to 8-foot parabolic dish antennas)[27] exclusion zones around AMT receive sites would protect AMT operations from harmful interference even under very conservative assumptions.[28]

By contrast, static minimum coupling loss ("MCL") analysis, as has been provided by AFTRCC, is overly simplistic, unrealistic and fails to achieve the purpose of providing a reasonable assessment of actual probability of harmful interference. AFTRCC's analysis and conclusions are belied by numerous counter examples of existing, widespread interference sources, including many common consumer wireless devices transmitting energy into the 2360-

---

[26] *See* Letter from GE Healthcare to Marlene Dortch, Federal Communications Commission, ET Docket No. 08-59 (Sept. 18, 2008), at Appendix A ("GE Healthcare Sept. 2008 *Ex Parte*").

[27] The *MBAN NPRM* states that "GEHC recommends an exclusion zone radius of 11.5 km." *See MBAN NRPM* at 9603, ¶ 47. This 11.5 km figure appears to be taken from the legend of the figure contained on page 14 of the March 3, 2009 presentation by GEHC to the Commission and originated in a preliminary analysis from 2008. However, GEHC's final analysis yielded an exclusion zone of 9.7 km and this is the only value that GEHC has ever actually recommended. *See* GE Healthcare Sept. 2008 *Ex Parte* at 12, n. 41; Letter from GE Healthcare to Marlene Dortch, Federal Communications Commission, ET Docket No. 08-59 (Mar. 13, 2009), at 3.

[28] The analysis assumed a hospital with many MBAN devices located directly in the main beam of the AMT antenna; very low AMT receive noise figure; and no interference from other existing sources, which can often be expected to be the limiting factor in AMT performance.

2400 MHz band.[29] If AFTRCC's analysis is to be believed, these interference sources should already be crippling AMT, which obviously is not the case.

Although it is unnecessarily conservative, a static MCL analysis is nevertheless satisfied in the case of Amateur Radio. According to the Amateur Radio Relay League ("ARRL"), the band is designated for fast-scan TV, high-rate data, packet, and control and auxiliary link transmissions.[30] GEHC's coexistence analysis shows that at 100 meters separation, MBAN signals are at least 6 dB below the noise floor of Amateur FS-TV and Amateur packet/control receivers.[31]

Apparently, the ARRL agrees with GEHC's conclusion, as it has already commented that it "does not, frankly, expect a significant amount of harmful interference to Amateur operations at 2390-2400 MHz" from GEHC's proposed MBAN devices.[32] In addition, expert representatives in the Amateur community have previously commented that their point-to-point relay systems have good potential for sharing with commercial and even unlicensed services. For example, the Southern California Repeater and Remote Base Association ("SCRRBA") has stated that "[w]e can visualize how amateur fixed point-to-point services might effectively use the same spectrum as low power spread spectrum or medium bandwidth digital commercial

---

[29] *See, e.g.*, Reply Comments of GE Healthcare, ET Docket No. 08-59 (Jun. 1, 2008), at 21-22; Letter from GE Healthcare to Marlene Dortch, Federal Communications Commission, ET Docket No. 08-59 (Oct. 30, 2008).

[30] AMERICAN RADIO RELAY LEAGUE, FCC RULE BOOK 4-26 (13 ed. 2004). Like some of the other candidate bands, this band is allocated to the amateur service in many countries, which would aid international harmonization.

[31] *See* Letter from GE Healthcare to Marlene Dortch, Federal Communications Commission, ET Docket No. 06-135 (Dec. 27, 2007) ("GE Healthcare Dec. 2007 *Ex Parte*").

[32] Comments of American Radio Relay League, The National Association for Amateur Radio, ET Docket No. 08-59 (May 27, 2008), at 2.

devices intended for localized areas,[33] and that Amateur point-to-point relay systems are generally located on commercial communications sites which provide physical isolation that would facilitate potential sharing with Part 15 users.[34] MBAN devices would have similar (or likely less) transmit power and ubiquity as the unlicensed Part 15 devices contemplated in the context of those comments.

ARRL has also stated that wideband systems with low duty cycles and spread spectrum techniques are best suited to share the band with Amateurs.[35] MBAN devices satisfy this description. Notably, ARRL favorably cited the former UPCS as "a compatible arrangement . . . negotiated to permit the use of the 2390-2400 MHz band by both Amateur Radio Service and Part 15 Asynchronous UPCS."[36] The UPCS rules incorporated a listen-before-talk ("LBT") mechanism that was analogous to the unrestricted contention-based protocol requirement proposed by GEHC for MBAN. Also, in comparison to UPCS devices, MBAN devices would operate over shorter distances, use significantly lower power and would be no more ubiquitous than UPCS devices were envisioned to become when ARRL commented favorably on the UPCS allocation.

VI. MBAN DEVICES WOULD BE ABLE TO OPERATE SAFELY AND EFFECTIVELY ON A SECONDARY BASIS IN THE 2360-2400 MHZ BAND

In the *MBAN NPRM*, the Commission sought comment on whether health care professionals and medical device manufactures, in concert with FDA-required risk management

---

[33] Comments of Southern California Repeater and Remote Base Association, ET Docket No. 94-32 (June 14, 1994), at 11 (attached to comments filed Dec. 17, 1994).

[34] Reply Comments of Southern California Repeater and Remote Base Association, ET Docket No. 94-32 (June 29, 1994), at 9 (attached to comments filed Dec. 17, 1994).

[35] NTIA, SPECTRUM REALLOCATION FINAL REPORT, NTIA SPECIAL PUBLICATION 95-32 (1995), at Section 2.

[36] Comments of American Radio Relay League, RM-10166 (Aug. 1, 2001), at 8, n. 7 (Opposition to petition for rulemaking filed by AeroAstro).

processes, should determine whether MBAN devices should be used for life-critical and time-sensitive applications even though these devices would not receive interference protection from primary incumbent services,[37] and also on the ability of MBAN devices to operate in the 2360-2400 MHz band without suffering harmful interference from incumbents in the band.[38] For a number of reasons, GEHC believes that MBAN devices with secondary status in the 2360-2400 MHz band would be able to operate safely and effectively as required by the FDA.

GEHC and any other medical device manufacturers seeking to develop equipment consistent with the MBAN rules would need to build robust products in order to satisfy FDA requirements and to ensure customer acceptance. Indeed, medical device manufacturers have every incentive to develop reliable products and GEHC would not be proposing secondary status for MBAN operations in the 2360-2400 MHz band unless it was confident that MBAN devices could be designed to operate safely and effectively on a secondary basis. GEHC's request for allocation of 40 MHz is based on the approach of time and frequency diversity, where frequency agility can be used to find and use unused frequencies.

In a 2004 order, the Commission described the characteristics of AMT operations and determined that such operations could share the 2390-2395 MHz band with Amateurs (primarily fast-scan amateur TV).[39] Specifically, the Commission explained that:

> [A]eronautical mobile use of the band will likely be predominantly at remote facilities. . . . We observe that the potential for interference from amateur operations, even directional point-to-point operations, to flight testing operations, would be small, due to the high altitudes of aeronautical mobile flight testing transmitters, and the correspondingly high elevation and off-axis attenuation of high gain flight testing receive antennas on the ground. Although . . . we cannot rule out the possibility of interference to flight testing from amateur operations, we believe

---

37 *See, e.g.*, *MBAN NPRM* at 9597, ¶ 40.

38 *See id*. at 9597, ¶ 23.

39 *See New Advanced Wireless Services Seventh R&O*, *supra* note 23.

> the likelihood of such an occurrence is limited by the remoteness of flight testing facilities . . . .[40]

For similar reasons, the Commission reasoned that AMT operations would not cause interference to Amateur receivers due to large separation distances. The Commission observed that "aeronautical mobile operations will not be widespread and will often occur in the vicinity of test ranges. Thus, it is expected that there normally would be large separation distances between aeronautical mobile transmitters" and victim receivers.[41] These same factors reduce the potential for AMT signals to affect MBAN devices operating in health care facilities.

In addition, previous comments of AFTRCC acknowledge the negligible likelihood of interference from an aeronautical flight test transmitter to an omnidirectional, terrestrial receiver, such as a satellite DARS or the proposed MBAN receiver. Specifically, AFTRCC has stated:

> As explained in the attached Engineering Statement from Daniel G. Jablonski, Johns Hopkins University Applied Physics Lab, a combination of factors, operational and technical, precludes the risk of flight test interference to DARS reception. Among other things, when an aircraft is visible during a flight test, such as at a higher altitude (say, 20,000 feet), an extremely high gain antenna (20 to 40 dBi) is required to pick up the telemetry signal. By contrast, DARS antennas are omnidirectional, that is zero gain, meaning that their susceptibility to a telemetry signal is virtually nil.
>
> On the other hand, when an aircraft is at low altitude, ground attenuation and geographic separation between members of the general public and flight test operations ensures that the telemetry signal will be attenuated.[42]

MBAN devices, like satellite DARS receivers, would employ omnidirectional, body worn antennas and, as explained by AFTRCC, "susceptibility to a telemetry signal is virtually nil."

---

[40] *Id*. at 21373, ¶ 47.

[41] *Id*. at 21374, ¶ 48.

[42] *See* Reply Comments of the Aerospace and Flight Test Radio Coordinating Council, ET Docket No. 00-258 (Dec. 1, 2003), at 3.

Furthermore, the shadowing of the human body provides a random variable serving to further reduce reception of aeronautical telemetry signals.

The AFTRCC analysis noted above went further to convey the negligible probability of interference from AMT transmitters to terrestrial satellite DARS receivers in the Engineering Statement:

> In order to successfully receive flight test telemetry signals, high gain parabolic dish antennas (G = 20 – 40 dBi) must be used. One way to look at the issue is that, if interference to DARS reception were a realistic possibility, flight test ranges would be able to use roof-top automobile antennas instead of large dishes. But of course, this is not the case. . . . Separation distances as low as 1400 feet between aircraft and DARS receivers are theoretically possible during low level flight or take-off and landing operations. However, under these circumstances, public access to areas where flight test operations are conducted will be restricted.
>
> For example, runways at Edwards AFB are 10 miles or more from the base perimeter. Even at Patuxent River Naval Air Station, the public is not allowed within 1 – 3 miles of the nearest runways. Under these circumstances, ground attenuation effects and line of site limitations further reduce the possibility of interference to members of the public who happen to be using DARS during off-base activities.[43]

For all these same reasons, MBAN devices will experience a very low likelihood of interference from AMT transmitters.

The AFTRCC Engineering Statement also provides useful quantification of the aeronautical telemetry signals presented to a terrestrial receiver such as a satellite DARS or MBAN device:

> For an aircraft transmitting 10 watts in a 2 MHz bandwidth at an altitude of 20,000 feet, the maximum received power density is –80 dBW/m^2/MHz. [AFTRCC Footnote 1: The maximum power received by a DARS unit will occur when the DARS receiver is directly beneath the aircraft . . . power levels seen by a DARS receiver will typically be much lower than this conservative estimate.] . . . For a 3 dBi antenna the gain G is, in non-logarithmic units, equal to 2. Thus, the effective area of a DARS receive antenna is approximately . . . -25 dB-m^2.[44]

---

43 *Id.* at 6-7.

44 *Id.*

Using AFTRCC's conservative, free space numbers, MBAN receivers operating within a 1 MHz channel bandwidth and with a 3 dBi omnidirectional antenna will see approximately -105 dBW = -75 dBm from an aeronautical telemetry transmitter passing directly overhead. A MBAN receiver within a hospital will benefit from an estimated 10 dB or more of building material attenuation, yielding an AMT signal level of –85 dBm, equivalent to the sensitivity level of narrowband, 2400-2483.5 MHz off-the-shelf transceivers. In addition, the AMT power actually falling in the channel bandwidth of the MBAN receiver is expected to be even lower, as AMT transmissions often spread their power over much wider channels (*e.g.*, 5 to 15 MHz).

In the rare instance where aeronautical telemetry signals are even detectable by a MBAN device, the MBAN frequency agility and contention based protocol characteristics, along with the 40 MHz frequency allocation, will permit transmission of data on another channel in which aeronautical telemetry signals are absent.

AFTRCC has cited the future use of "100 watts and possibly much higher" uplink transmissions from AMT ground stations to aircraft for dynamic spectrum control,[45] but has not provided specific, technical details of this future functionality. GEHC notes that Part 87.131 of the Commission's rules limit flight test land stations in the band to only 25 watts conducted antenna input power. AFTRCC does not explicitly state that this uplink will reside within the 2360-2390 MHz band. Such an AMT, high-power, uplink transmission within the 2360-2900 MHz band would certainly raise the noise floor of any proximate AMT receivers much more than would any low-power, MBAN device at a distance of 9.7 km. Furthermore, such an in-band 2360-2900 MHz uplink would consume the precious spectrum that AMT claims is already fully utilized.

---

[45] *See* Comments of Aerospace and Flight Test Radio Coordinating Council, ET Docket No. 08-59 (May 27, 2008), at 11, n. 16.

Despite the apparent inconsistencies and limited details of AFTRCC's reported future uplink signal, physical separation and MBAN contention-based protocols would minimize the probability of harmful interference from AMT uplink operations to MBAN systems. As AFTRC has commented, it is appropriate to include ground propagation effects between a MBAN transmitter and an AMT receiver using an exponential path loss factor of n = 2.4.[46] Such a n = 2.4 path loss would also apply to propagation from an AMT terrestrial uplink transmitter into an MBANS receiver. Given a separation of only 1 km, a 100 watt AMT uplink transmitter would be attenuated by 120 dB, presenting a –70 dBm signal level to the MBAN receiver. In addition, this future, AMT terrestrial signal would experience additional attenuation due to building structures and body shadowing, reducing the received signal to levels at or below the –85 dB sensitivity level of narrowband, 2400-2483.5 MHz off-the-shelf transceivers. The n=2.4 path loss model is also applicable to Amateur transmissions, which typically would be lower in power than 100 watts.

For both AMT and Amateur high-power, terrestrial transmissions, modest physical separation would serve to reduce the radiated signals to levels approaching or below the MBAN receiver sensitivity. In the rare instance where a future, AMT uplink signal or Amateur transmission is detectable by a MBAN device, the MBAN frequency agility and contention-based protocol characteristics, along with the 40 MHz frequency allocation, would permit transmissions of data on another channel in which these incumbent service signals were not present. Based on these factors, MBAN devices would experience a very low likelihood of harmful interference from future, AMT uplink or Amateur transmitters.

---

[46] *See id*. at Engineering Statement, Appendix C, page 3.

Finally, GEHC notes that consistent with FDA-required risk management processes [47], MBAN devices would need to incorporate appropriate risk mitigations to address service disruptions, regardless of the cause (*e.g.*, dead battery, device failure, radio interference, etc.). Typically with wireless patient monitoring systems, for example, if the signal is not received, a technical alarm is generated to alert clinicians to the loss of monitoring. For this reason, it is important to note that the maximum acceptable likelihood of occurrence of MBAN outage due to interference need not actually be zero, but should instead be determined by risk management on a device-by-device basis.

VII. OTHER ISSUES

Definitions and Permissible Communications

The definitions proposed in the *MBAN NPRM* for "medical body area network," "MBAN transmitter" and "MBAN control transmitter"[48] are generally appropriate. However, the proposed definition for "medical body area device" includes the term "medical sensing device," which is too narrow in scope and should be replaced with "medical device" to broaden its applicability. With this relatively minor change, the definitions proposed in the *MBAN NPRM* would suffice to capture the salient functional elements for MBAN operations and, therefore, no further identification or definition of other components is necessary. There is also no need to include medical implant devices as part of MBAN systems, as they are adequately treated in the Commission's MedRadio rules.

---

[47] *See, e.g.*, 21 CFR § 820.30(g); *Recognition Number 5-40: ISO 14971:2007, Medical Devices - Application of risk management to medical devices, available at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/simplesearch.cfm?db=std&id=19639 (last accessed Oct. 5, 2009).

[48] *See, e.g.*, *MBAN NPRM* at 9601, ¶ 37.

GEHC agrees with the Commission that it would be prudent to provide flexibility such that MBAN systems can be used for monitoring, diagnostic or therapeutic functions.[49] In addition, GEHC agrees with the Commission's conclusion in the MedRadio proceeding that "the ultimate decision on which frequency band to use for each type of application [should be] left to health care professionals and medical device manufacturers, in concert with FDA-required risk management processes . . . ."[50] As such, the Commission should allow for medical device manufacturers and health care professionals to decide whether and how to utilize MBAN devices for life-critical applications and other risk management issues.

The Commission's MBAN rules should allow MBAN control transmitters to relay data from body-worn sensors to a receiver that is located off the patient's body. Examples of such off-body receivers include a WMTS backhaul network distributed across a hospital facility or a short-range link to a bedside receiver. Such a bedside receiver could link to a hospital Ethernet network or to one or more MBAN control transmitters using MBAN transmissions.

Certain MBAN applications might benefit from communications between MBAN body sensors within a single MBAN network. As such, communications between MBAN body sensors or other intra-MBAN network communications should be allowed. There is no need to limit external MBAN control transmitters to controlling the body sensor transmitters for only a single patient. Certain applications with limited patient mobility might benefit from one MBAN controller managing multiple patient networks to promote spectral efficiency – a possible example might be monitoring proximate newborn incubators.

---

49 *See id.*

50 *Id.* at 9602, ¶ 40.

Contention-Based Spectrum Access Protocols

Mandatory contention-based protocols were proposed by GEHC to provide for efficient spectrum sharing and coexistence amongst MBAN devices. Contention-based protocols would afford protection for MBAN devices from high-power, incumbent signals. However, contention-based protocols are not intended as the mechanism for preventing interference from MBAN devices to incumbent users. GEHC believes that the definition of contention-based protocol recently adopted by the Commission for the operation of wireless devices in the 3650-3700 MHz band is appropriate for MBAN.[51] In particular, the definition's inclusion of "rules by which a transmitter provides reasonable opportunities for other transmitters to operate" is of critical importance. The low-power operation of MBAN devices, along with their limited duty cycle, short message "on-time" and ability to change frequency channels, are characteristics which enable such reasonable opportunities for transmitters of separate MBAN networks to operate without the need for complex synchronization between networks.

GEHC recognizes however, that a wide array of specific techniques (*e.g.*, CSMA / listen-before-talk, Frequency Hopping, ALOHA, etc.) could arguably satisfy such a requirement and that, while allowing considerable flexibility, a relatively open-ended, unrestricted contention-based protocol requirement could pose practical challenges for equipment certification. While GEHC would not favor overly-prescriptive service rules that effectively define a single MAC protocol for MBAN devices, less subjective approaches than explicitly requiring devices to implement an unrestricted contention protocol could potentially provide a greater level of certainty with respect to the equipment certification process, without significantly reducing manufacturer flexibility. For example, a possible alternative to a relatively open-ended unrestricted contention-based protocol requirement would be to define a few basic technical

[51] *See* 47 C.F.R. § 90.7.

characteristics and parameters for MBAN devices, such as maximum channel bandwidth (which is already incorporated into GEHC's MBAN proposal), maximum channel occupancy time, minimum number of hop channels, etc.

In any event, GEHC believes that the technical rules for MBAN service must remain flexible enough to allow for international standards bodies, such as the IEEE 802.15 task group 6, as well as individual vendors, to design contention-based protocols appropriate for specific MBAN applications. MBAN applications will likely differ from other radio services due to patient movement throughout the health care facility. Ambulatory patient movement and changes in body posture yield a dynamic radio propagation channel. Movement of patients also results in a changing interference environment where a given MBAN network observes different neighbor MBAN networks over the course of time. These factors militate in favor of more generic technical rules.

The LBT frequency monitoring defined for the MedRadio service[52] is ill-suited to the use of MBAN devices within an ambulatory patient environment. The MedRadio service's LBT requires 10 msec monitoring of a selected channel within 5 seconds of the intended use of that channel for a communication session. This 10 msec may be much longer than the time for a MBAN transmitter to send a data message at a 1 Mbps data rate. Furthermore, a 5 second silent period ends a MedRadio communication session and requires a new LBT activity for subsequent communication sessions. Applications exist where a network of MBAN devices would sleep in a silent, battery saving mode for five or more seconds. A requirement to perform LBT for each wake-up could add significant complexity for MBAN devices having to re-discover the operating frequency channel each time they awaken. For these reasons, GEHC prefers that the Commission issue generic technical rules for contention-based protocols where statistical

---

52 *See id*. §§ 95.628(a), 95.1209(b).

opportunities for transmitter operation are afforded by limiting the duty cycle of MBAN transmitters on any given channel.

Continuous monitoring of ambulatory patients is well served by the use of time division multiple access ("TDMA") techniques with dedicated time slots allocated to MBAN devices by the MBAN controller. Such a TDMA approach provides for power-efficient operation of MBAN devices, an opportunity to employ automatic repeat request ("ARQ") methods for robust data transfer, as well as temporal determinism to limit data latency. A MBAN controller can manage a listing of operating frequency channels and share such listing with its associated MBAN devices to provide frequency diversity and robustness at any time in the future without the spectral and power consumption burden of regularly changing such a listing. Episodic sensing applications such as alarms or event-driven conditions are well served by a purely contention-based access method. Carrier sense and collision avoidance can be used to ensure that when a short episodic event must be communicated within a MBAN network, the communication is successful. Combinations of these access methods have been proposed and are being considered by the IEEE 802.15 task group 6.[53]

Limiting the aggregate duty cycle of a MBAN network to no more than 25% would provide flexibility for a variety of access methods to satisfy the various continuous and periodic MBAN applications. Such a limit could alternately be constructed as limiting the aggregate transmissions from all members of a given MBAN network to no more than 25 out of 100 milliseconds, averaged over any 1 second interval. Such a definition considers only the active transmissions and excludes any brief silent periods between packet transmissions. An MBAN

[53] Proposals available via the Internet. In particular, see proposals from MedWiN (https://mentor.ieee.org/802.15/dcn/09/15-09-0326-01-0006-medwin-mac-and-security-proposal-presentation-part-1-mac.pdf), as well as NICT (https://mentor.ieee.org/802.15/dcn/09/15-09-0346-01-0006-nict-s-mac-proposal.pdf) and Samsung (https://mentor.ieee.org/802.15/dcn/09/15-09-0315-01-0006-samsung-mac-proposal-part-1-a-power-efficient-mac-for-ban.ppt).

network could attempt to transmit data on one or more alternate frequency channels to realize frequency diversity gain and combat short-term fading. The 25% duty cycle limit would apply to all transmissions on all frequency channels in aggregate. Considering this limit over a 1 second interval accommodates infrequent occurrences of increased data traffic which may occur when a new MBAN device is added to a network or under worst-case fading when multiple retransmissions are necessary.

Channelization and Antenna Locations

Consistent with the approach taken for MedRadio, technical rules for MBAN operations need not define a particular channel plan but specify only the maximum permitted bandwidth. Such an approach affords flexibility for the development of standards, such as those being developed by IEEE 802.15 task group 6.

GEHC supports limiting MBAN transmitter operation within the 2360-2390 MHz band to indoor operations within health care facilities as an additional interference avoidance protection.[54] However, GEHC believes that outdoor operation should be permitted in the 2390-2400 MHz band to support various application use-case environments, including ambulances.

Transmitter Power, Emission Bandwidth, and Channel Aggregation

GEHC continues to believe that a power limit of 1mW EIRP per megahertz of bandwidth is sufficient for MBAN devices. However, it is possible that future MBAN applications could benefit from somewhat higher limits. If higher EIRP limits are allowed they should scale with channel bandwidth and be limited to the upper, 2390-2400 MHz band, which is already encumbered by more severe OOBE from the adjacent 2400-2483.5 MHz ISM band, so that 2360-2400 MHz MBAN exclusion zones that would be used to protect AMT receivers would not need to be any larger than what would be required for 1 mW MBAN transmissions.

---

[54] *See MBAN NPRM* at 9609, ¶ 70.

Limiting the aggregate duty cycle of a MBAN network to 25% is discussed in more detail above. With respect to channel aggregation, GEHC agrees with the approach of limiting simultaneous MBAN transmissions (*e.g.*, full-duplex) on multiple channels. However, non-simultaneous transmissions by a MBAN network on more than one channel should not be viewed as an aggregate channel. For example, in situations where a MBAN network that transmits a series of messages on a first channel and then tunes to a second channel to retransmit any messages that were not delivered on the first channel, each channel should be able to satisfy the 1 MHz emission bandwidth limit. GEHC believes that such a non-simultaneous sequence of frequency channel agility should not be subject to a simultaneous channel aggregation limit.

Unwanted Emissions, Frequency Stability and RF Safety

The limits imposed by the Commission for unwanted emissions, both in-band and out-of-band, should balance the mechanisms defined for MedRadio with those of Part 15 devices used in the adjacent, 2400-2483.5 MHz ISM band, given the critical need for MBAN devices to leverage integrated radio technology and chips developed for use in the 2400-2483.5 MHz ISM band. As such, GEHC would prefer that the Commission establish unwanted emission limits for MBAN devices that resemble those for Part 15 devices. GEHC notes that the general limits put forth in the *MBAN NPRM*[55] are consistent with those in GEHC's initial proposal.[56] Frequency stability of +/- 100 ppm is an acceptable limit for MBAN devices. GEHC also supports the definition of MBAN devices as portable devices, worn by humans and subject to the RF exposure rules defined in sections 2.1093 and 1.1307 of the Commission's rules.

---

55 *See MBAN NPRM* at 9609, ¶ 68.

56 *See* GE Healthcare Dec. 2007 *Ex Parte*, *supra* note 31.

Miscellaneous Provisions

In the MBAN NPRM, the Commission also sought comment on equipment certification issues.[57] Certification of MBAN transmitters is appropriate for any MBAN device marketed for use and operated in the US. Non-implanted MBAN transmitters should be subject to the same provisions as MedRadio transmitters with respect to availability for inspection by an authorized Commission representative and reasonable cooperation. Requiring manufacturers of MBAN transmitters to include an appropriate disclosure statement analogous to that of MedRadio transmitters with each MBAN transmitting device is also appropriate. Given the likelihood of small MBAN device form factors for body-worn applications, any device labeling and disclosure statement requirements should allow for off-device labeling on product packaging or user manuals. It would not be appropriate to require that individual MBAN transmitters be equipped with a unique serial number, given the fact that individual sensor nodes may be disposable. Labeling with FCC-ID per transmitter certification rules would be appropriate, even for disposable devices. Finally, GEHC agrees that the Commission's rules should specify that MBAN transmitters should be "marketed and sold only for those permissible uses" discussed in the *MBAN NPRM*.[58]

---

57 *See MBAN NPRM* at 9610, ¶ 73.

58 *See id.* at 9611, ¶ 77.

CONCLUSION

GEHC appreciates the Commission's decision to issue a NPRM in this proceeding and urges the Commission to move expeditiously to final MBAN rules. Such action would create the proper conditions for development of the next generation of potentially ground-breaking, advanced wireless medical devices.

Respectfully submitted,

/s/ Neal Seidl

Neal Seidl
Wireless System Architect
GE Healthcare
8200 W. Tower Avenue
Milwaukee, WI 53223
(414) 362-3413

/s/ David Davenport

David Davenport
Electrical Engineer
GE Global Research
1 Research Circle
Niskayuna, NY 12309
(518) 387-5041

/s/ Ari Q. Fitzgerald

Ari Q. Fitzgerald
Hogan & Hartson L.L.P.
555 13th Street, N.W.
Washington, DC 20004
(202) 637-5423

Counsel to GE HEALTHCARE

October 5, 2009

APPENDIX A

Map of US Hospitals and AFTRCC Reported Government and Civilian Flight Test Locations

Figure 1 contains a map of 6,867 hospitals located in the continental US. Hospital latitude and longitude location information was obtained from a commercial database product from SDI Health.[59] Figure 1 also shows 157 flight test sites, both government and civilian. The flight test site listing, including latitude and longitude information, was provided to GE Healthcare by AFTRCC during January 2008.[60]

The separation distance between each of the 6,867 hospitals and the 157 AMT sites was computed using the Haversine formula on a spherical earth of radius 6378.137 km. The separation from each hospital to the closest AMT site was stored. In addition, the separation from each hospital to the closest AMT site actually holding an FCC license for S-band operation was stored.[61] Figure 2 plots the cumulative distribution functions of the minimum hospital to AMT site separation considering all AMT sites (blue curve) or only FCC licensed AMT sites (red curve). Figure 3 shows these cumulative distribution functions of minimum separation distance for a limited range of interest, namely 0 to 20 km.

---

59 *See* SDI – Innovations in Healthcare Analytics, http://www.sdihealth.com (last accessed Oct. 5, 2009).

60 *See* Reply Comments of GE Healthcare, ET Docket 08-59 (June 11, 2008), at A-8.

61 *Id*. at A-1.

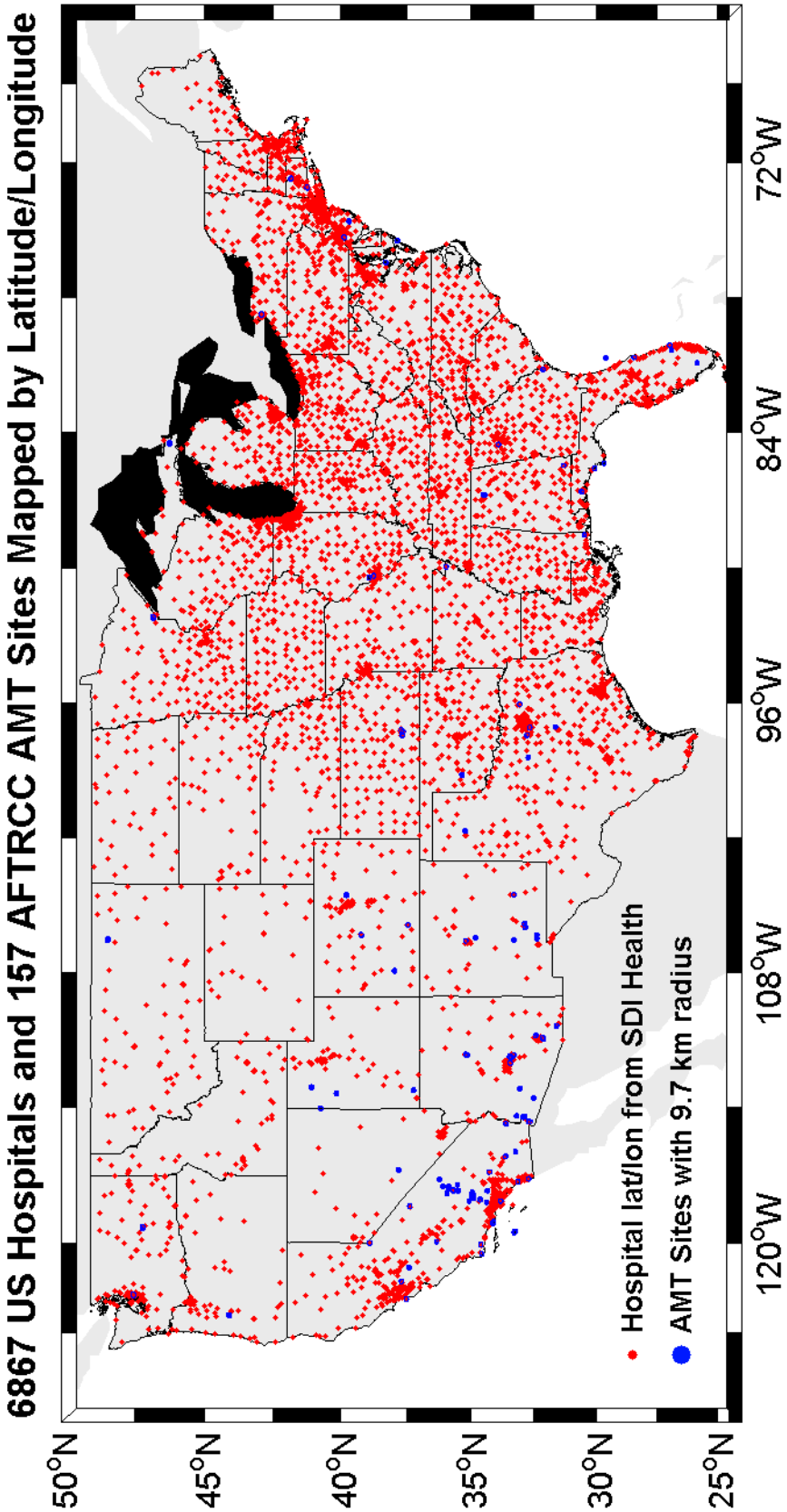
6867 US Hospitals and 157 AFTRCC AMT Sites Mapped by Latitude/Longitude
Hospital lat/lon from SDI Health
AMT Sites with 9.7 km radius
50°N
45°N
40°N
35°N
30°N
25°N
120°W
108°W
96°W
84°W
72°W

Figure 1

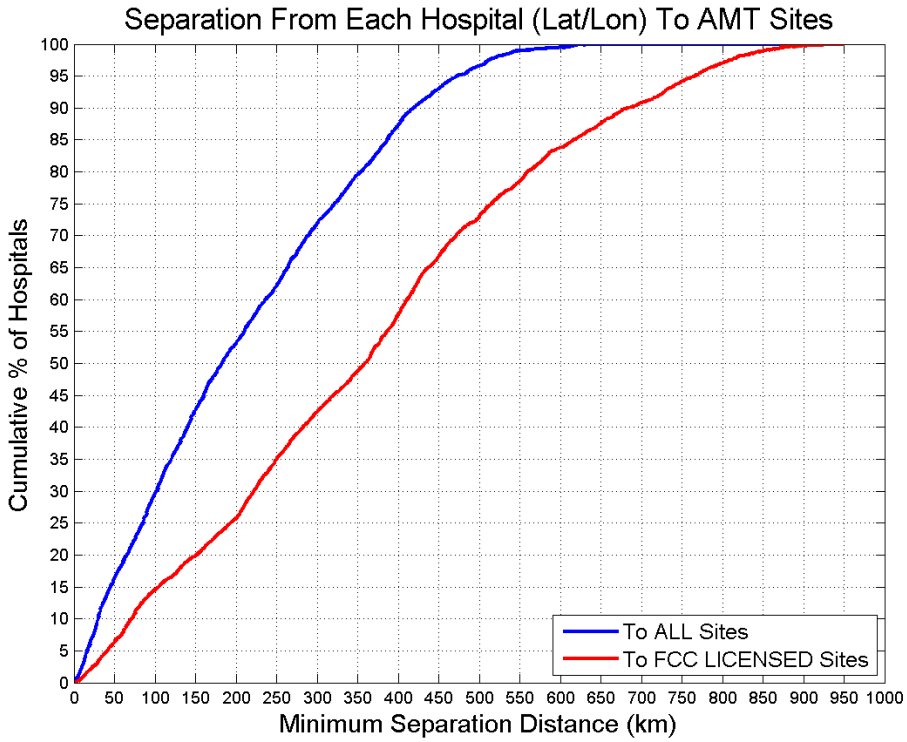

Figure 2

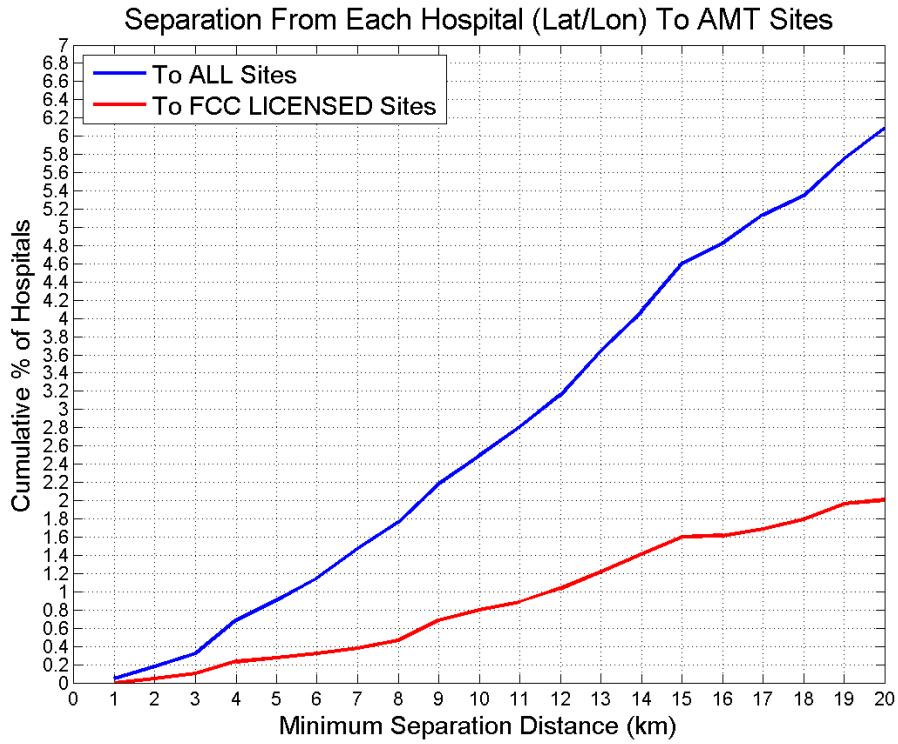

Figure 3

APPENDIX B

Medical Body Area Network Bandwidth Requirements[62]

GE Healthcare has proposed maximum emission bandwidth of 1 MHz. Such a bandwidth permits transmission of data at 1 Mbps using GFSK or other modulation techniques instantiated in commercially available transceiver products. Operation at higher data rates (*i.e.*, 500 kbps and 1 Mbps) enables transmission of temporally short data bursts and low-duty cycle operation. Low duty-cycle operation facilitates low power consumption and long battery life. Low duty-cycle operation also promotes coexistence among MBAN systems and other radio devices. Operation at 1 Mbps data rate over-the-air allows transfer of 32 byte data messages in approximately 256 microseconds. With such short data bursts, multiple packets can be exchanged, including acknowledgements and retransmissions, while maintaining a low duty cycle.

The retransmission of short data packets on multiple frequency channels is an effective diversity technique that is readily implemented using commercially available transceiver chips. Transmitting on a second frequency allows an MBAN system to combat any frequency specific attenuations resulting from the propagation environment or body posture. Coherence bandwidth is a measure representing the range of frequencies over which two frequency components have a strong potential for amplitude correlation. GE Global Research measurements of on-body and body-coupled propagation with body-worn, printed antennas reveal coherence bandwidths of approximately 6 to 10 MHz, respectively. These coherence bandwidths are derived with respect to a 0.9 threshold on the correlation function between path gain measurements of 1 MHz channels ranging between 2400 and 2500 MHz.

---

[62] This appendix provides an update to the material originally presented by GE Healthcare in December 2007. *See* GE Healthcare Dec. 2007 *Ex Parte* at 29.

Detailed simulations were created and evaluated to assess the impact of various protocol mechanisms on MBAN coexistence and reliability. Implementations of frequency hopping, frequency diversity, LBT, and ARQ were considered. Our simulation scenario consisted of MBAN body sensor network (BSN) equipped patients moving within an area of 10 by 10 feet. Each BSN implements a TDMA network among its hub and sensors. The protocol mechanisms were implemented using Network Simulator NS2. Each scenario was evaluated multiple times with random patient positions and motion. For each protocol case considered, a total of 50 trials were conducted. Each trial included 10 hubs each with 10 sensors. Each trial represented a unique, random draw of time and frequency parameters and lasted for $1x10^5$ frames. Trials were evaluated using a printed monopole antenna propagation model, 32 byte messages and 1 Mbps data rate. The aggregate duty cycle for each of the ten BSNs used was approximately 10 to 15%.[63]

During each TDMA frame (*i.e.*, beacon period), a single packet is transmitted by the hub and each sensor node on a designated frequency channel. The frequency of each medical BSN changes periodically in an uncoordinated and asynchronous manner (across BSNs) to reduce collisions. Upon successful reception of the hub's beacon message, each sensor node sends a single packet in an allocated time slot. The dual frequency mechanism causes every packet to be sent twice within each frame, using a different frequency and hop pattern for the second, redundant transmission. Enabling ARQ ensures that a sensor's redundant transmission is sent only if its hub failed to receive the first attempt in that frame. With LBT each transmission is subject to a fixed, time deferral if the device observes other BSN activity during the beginning of

---

[63] *See* David M. Davenport et al., *Wireless Propagation and Coexistence of Medical Body Sensor Networks for Ambulatory Patient Monitoring, Wearable and Implantable Body Sensor Networks*, SIXTH INT'L WORKSHOP ON WEARABLE & IMPLANTABLE BODY SENSOR NETWORKS, at 41-45 (2009).

its time slot. The deferred transmission still occurs within the TDMA slot assigned to that device. Regardless of the protocol mechanisms, a redundant, retransmitted message is sent on a second frequency for diversity gain. These protocol concepts are but a few examples of the various mechanisms which might be applied to improve coexistence and reliability of BSN traffic given proximate MBAN systems.

Figure 4 shows the average 3-sequence error rate from these simulations as a function of the number of available channels (i.e. bandwidth). This 3-sequence error represents the probability of a sensor failing to transmit its data message to its hub within three sequential TDMA frame periods, considering any redundant transmissions. Increasing the number of 1 MHz channels available to the BSN networks decreases the probability of 3-sequence frame loss.

The simulation results of Figure 4 show that for the 10 patient/10 sensor scenario considered, 15 channels represents a performance threshold with respect to orders of magnitude average 3-sequential error rate as well as the slope of the response curves. It must be noted that the results of Figure 4 apply to short, 32 byte messages. Satisfaction of the IEEE 802.15 Task Group 6 Body Area Network requirements for < 10% packet error rate with 256 byte packets as well as scalability for many more than 10 sensor nodes per BSN will require the availability of additional frequency channels.[64] Furthermore, the simulation assumes channels free of other radio services or otherwise available after avoiding frequencies in use by other services (i.e. incumbents) within a shared band.

[64] B. Zhen et al., *TG6 Technical Requirements Document*, IEEE 802.15 Document Number 15-08-0644-09-0006 (Nov. 2008).

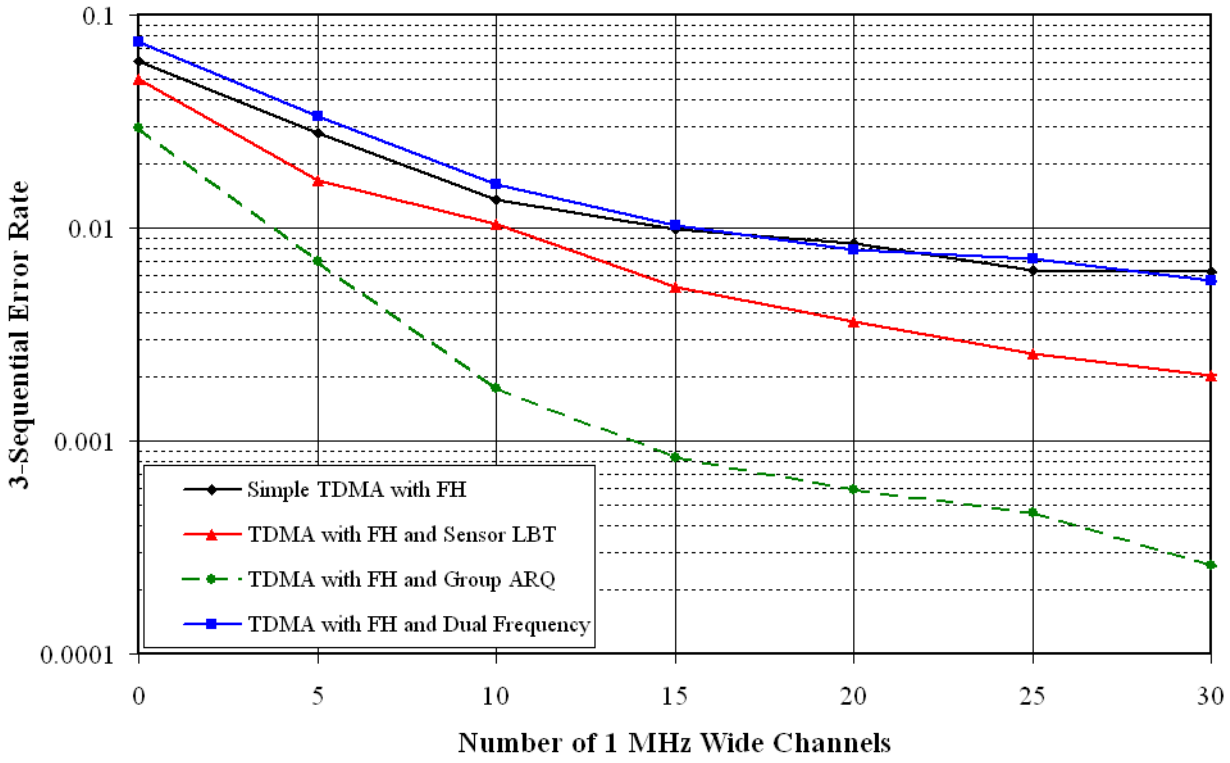
0.1
0.01
0.001
0.0001
3-Sequential Error Rate
0
5
10
15
20
25
30
Number of 1 MHz Wide Channels
Simple TDMA with FH
TDMA with FH and Sensor LBT
TDMA with FH and Group ARQ
TDMA with FH and Dual Frequency

Figure 4