AdvaMed
701 Pennsylvania Ave., NW – Suite 800
Washington, DC 20004-2654

October 6, 2009

Ms. Marlene Dortch
Secretary
Federal Communications Commission
445 12 Street, S.W.
Washington, DC 20554

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

Dear Ms. Dortch:

I submitted the document below, the AdvaMed comments to this docket, in error to Docket 09-57, due to a mistake transcribing the docket number from the NPRM. The FCC Document Number was unintentionally taken as the Docket number.

As the comments were submitted prior to the comment deadline, and the error was unintentional, I am respectfully requesting that you accept these comments as if they had been submitted directly to the correct docket initially.

Thank you in advance for your cooperation and forbearance in this matter.

Sincerely,

Bernie Liebler
Director
Technology & Regulatory Affairs
AdvaMed

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

October 5, 2009

Ms. Marlene Dortch
Secretary
Federal Communications Commission
445 12 Street, S.W.
Washington, DC 20554

Re: Docket FCC 09-57; Amendment of the Commission's Rules to Provide Spectrum for the Operation of Medical Body Area Networks

Dear Ms. Dortch:

I am writing on behalf of the members of AdvaMed, the Advanced Medical Technology Association. 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.

We are writing to voice our support for this new spectrum allocation. Several of our members are developing products that would operate in this new spectrum band, and we are certain that many more will be entering this area.

We have attached several pages of specific comments that we believe are responsive to the various points and questions raised by the Commission in the NPRM. Should there be questions regarding these comments please direct them to me at bliebler@advamed.org.

Sincerely,

Bernie Liebler
Director, Technology & Regulatory Affairs

Paragraph	COMMENTS
12	MBAN systems could include *medical body-worn devices* as defined in Appendix I to Subpart E of Part 95-Glossary of Terms (FCC 09-23).
13	- Our primary position is a full 40 MHz allocation for MBAN provides the most effective solution to meet the medical needs while allowing for best opportunity for coexistence of this secondary status service with the primary users (AMT and other). We address the significant issues and show how they can be overcome to protect the primary incumbent users. - Our secondary position is a 20 MHz primary allocation will meet the needs of the MBANS systems, with no sharing of the spectrum with AMT users. This would eliminate the need for exclusion zone and simplify management of devices. This would also allow for additional effective home monitoring. - The desired license strategy is part 95 (license-by-rule), more detail is provided under license section 35, 36. - A spectrum allocation of only 10 MHz limits competition and possible applications in hospital of MBANS devices. - A spectrum allocation of only 10 MHz cannot support multiple vendors in a hospital. Therefore, it would drive up cost to customers. -A 10 MHz allocation cannot support all of the currently conceived MBANS device applications, which range from aperiodic parameter communication to full real-time multi-lead ECG communication.
13	- The evidence suggests that 2390-2395 MHz portion of the spectrum is not used by AMT; it is used as a buffer zone against 2.4 GHz ISM devices. This part of the spectrum can therefore be used by MBANS devices, but this spectrum allocation alone is insufficient to meet the overall needs.
13	- The 2400-2483.5 MHz band is heavily used in hospitals for numerous applications. - The 5 GHz band is too costly, has high propagation loss, and high power consumption. - There is no good selection of radio available in the 5 GHz band that can offer low power consumption.
14	Manufacturers should be able to leverage existing industry standards (e.g., IEEE 802.15.4) in the 2400-2483.5 MHz band for MBAN applications as long as applications appropriate for such usage are implemented in light of system reliability factors (e.g., interference).
14	Wireless medical applications, in general (including in principal MBANs), are currently, and should continue to be, permitted to operate on an unlicensed basis under Part 15 rules (see response to paragraph 40 regarding medical device manufactures having the freedom to select, in concert with FDA-required risk management procedures, the appropriate wireless service for a given application). To realize the full benefits envisioned for MBAN applications, there is a need for spectrum in addition to the 2400 MHz band, WMTS, etc. These MBANS applications, which include small, low-cost / disposable, long-run time, sensors for continuous physiological monitoring) without the creation of appropriate new rules, including the allocation of spectrum that allows leveraging available 2.4 GHz electronic technology yet is free from heavy use by ubiquitous higher-powered devices that are likely to be very closely collocated with the MBANs

15	See second Comment on Paragraph 14.
17	AdvaMed agrees with the FCC's assertion that the operation of MBAN devices in the 2360-2400 MHz band would be advantageous because of off-the-shelf component availability and relatively small antenna size.
20	- AdvaMed supports the full 40 MHz allocation; it gives MBANS and AMT system greater ability to avoid each other through frequency separation. - MBANS with contention protocols (e.g. ARQ, frequency hopping, cognitive and adaptive spectrum sensing, etc.) will help to manage the spectrum in the most efficient manor, coupled with exclusion zone to protect incumbent AMT users. So secondary basis is sufficient to meet the clinical needs. - Systems are designed under FDA guidance for wireless systems and have to deal with the case of interference, such as clinical staff notification via the system technical alerts. Additionally there will be suitable protocols used to handle packet loss due to interference so that packet loss will not normally cause application data loss. -The specific link management protocols should be managed by the medical device industry to meet FDA guidance, and should not be a part of the FCC rules.
21	We agree with the assessment from GEHC (GE Healthcare) on the amount of spectrum required. We strongly believe a full 40 MHz allocation as secondary status user provides the optimum sharing of the spectrum. The other possible alternative allocation is a 20 MHz primary allocation with no sharing of the spectrum with AMT users. This is the minimum allocation we believe MBANS needs, but cannot be shared in this case.
22	-MBANS devices should be limited to indoor use in healthcare facilities only in parts of the spectrum used by and allocated exclusively to AMT (i.e. 2360-2390 MHz). -This would allow 10 MHz of the spectrum (2390-2400 MHz) to be used in home monitoring, a growing and important area for patient care that helps hospitals contain costs. This would also allow monitoring in ambulances. The following methods could be deployed to protect incumbent AMT users: - Exclusion zone around AMT sites will protect AMT users - MBANS devices could by default operate only in the unrestricted part of the spectrum, (i.e. 2390 – 2400 MHz) and deliberate user action, which by rule would require prior registration and exclusion zone check, could be required to enable use of the lower 30 MHz. - Alternatively, MBANS systems could potentially employ electronic control to prevent unauthorized transmission when not in hospital; this can be initiated when a hospital site is registered. - For example, an electronic key could be required by the MBANS hub device to authorize use of the 2360-2390 MHz spectrum. - Devices operating without an authorization key would only operate in unrestricted part of the spectrum, 2390 –2400 MHz.

23	MBANS devices can be designed to operate robustly on a secondary basis by employing advanced radio technologies as follows: - Cognitive and Adaptive spectrum sensing to find clear spectrum with LBT protocols. - Error detection and/or error correction, CCA, and ARQ methods. - With a 40 MHz allocation, an MBANS device has higher probability of finding spectrum that is usable.
24	This proposal to utilize two blocks of spectrum separated by 90 MHz may have an impact on antenna tuning and complicate the adaptation of existing off-the-shelf technologies.
24	- An allocation 2300-2305 MHz and 2390-2400 MHz, even on a primary basis, would not be sufficient to meet the needs of hospital usage, where high usage density will occur. - Such a disjoint allocation will be inefficient, as a transition guard band is needed to deal with emission limits, further limiting available radio technologies. - To maintain certain level of competitiveness between medical device manufactures, rules to prevent one vendor, device or device type from consuming a primary allocation should be adopted. The rules that have been used in WMTS can be adopted to facilitate good sharing of primary spectrum allocation.
24	MBANS devices will be able to tolerate interference from Amateur users, the following methods may be employed to achieve co-existence: - Cognitive and Adaptive spectrum sensing to find clear spectrum (e.g. CSMA). - Error detection and/or error correction, CCA, and ARQ methods. - Frequency hopping - ALOHA
24	An *exclusive* primary allocation would permit the allocation of less spectrum (perhaps 20 MHz total) since MBANS devices could rely on the entire allocation always being available. However, a shared co-primary allocation has little potential for reducing the total MBANS allocation. - Co-primary status from MBANS and AMT in the 2390-2395 MHz band can only be shared using geographic separation, as there is not sufficient spectrum to create frequency separation in the services. -While it is highly feasible to define and enforce MBANS exclusion zones around the relatively limited number of AMT received sites, defining and enforcing AMT transmit (i.e. aircraft flight) exclusion zones around each of the 6000-plus hospitals scattered throughout the entire continental US is not feasible.
24	- Contiguous spectrum allocation is best for MBANS solution. - A 15 MHz spectrum allocation would limit the potential of the solution and make it harder for multi-vendor deployment in a hospital site; this would then tend to drive up cost by limiting competition. - With the need to deal with band edge transition, there is further concern that 15MHz will not actually be available for use. Adjacent bands ISM and WCS need to be considered. - A 20 MHz spectrum allocation would be adequate to support available technologies if that spectrum did not need to be shared with AMT. It would allow multi-vendor support at a hospital site. In this case, MBANS needs a primary status to make the allocation work.

25	AdvaMed recognizes the established rights of the incumbent users. Our member companies would only design MBANS devices that can tolerate interference from such users without causing clinical harm to their own medical users. Thus, in our view, this position is acceptable.
26	See second comment for paragraph 14.
28	See section 14, above, detail on issues limiting the use of 2400-2483.5 MHz band In general, MBANS can coexist with incumbent Amateur service, which makes operation in 2390-2400 MHz viable.
29	The ISM bands are used by various wireless medical devices, and some of these devices could also operate in conjunction with an MBAN system. As an example, GE's Dash 5000 monitor and Philips's Intellivue MP40 monitor.
29	There is a large variety of medical use of the ISM band as well as hospital mission critical use. This all add to the spectrum congestion, and with the proximity of high power (100 mW) unlicensed devices, the low power (1 mW) MBANS devices will have significant challenge finding sufficient spectrum to operate effectively.
30	The 5 GHz spectrum is not viable for MBANS from significant technical issues outlined below: The following example illustrates the key physical barriers to using 5 GHz spectrum : 1) 5 GHz band has higher propagation losses, so would require higher transmit power level, which further exacerbates the power consumption problem. 2) Propagation through the body is also a great challenge in the 5 GHz spectrum, Researchers have observed up to 56 dB body absorption loss, a further challenge to this radio link ability to meet the needs. 3) Battery life will be too low to support MBANS use model. 4) Furthermore, developing a specific radio in the 5 GHz band for MBANS will not get to the cost point needed for a low cost disposable solution. We need commercial volume to achieve that goal.
32	The 5150-5250 MHz band will be a very difficult to use for this application, with significant compromises that makes the clinical use model unattractive or even impractical for the MBANS devices to achieve its goals, low cost, and long battery life. See comments in section 30 above for more details.
33	- Licensing MBANS under Part 90 rules is not desirable; we are concerned with the added complexity of this approach. This could pose a significant barrier for efficient system deployment. - Also, where MBANS is used in the home case, this license approach would not be appropriate.

35	- Part 95 rules is desirable, hospitals should register in a similar manner to WMTS but with more robust mechanisms deployed to ensure compliance, as described below. - We suggest that ASHE/Comsearch be the body that manages the registration database, as this infrastructure is in place already. - ASHE is the FCC-designated frequency coordinator for WMTS and Comsearch is ASHE's technical partner. - ASHE should be strongly considered for the MBANS frequency coordinator for the following reasons: 1) Leadership and success in WMTS coordination. 2) Strong representation of hospitals needs where MBANS will be deployed. 3) Can easily leverage existing WMTS registration framework to accommodate MBANS. 4) ASHE's manages advocacy programs to help reach all potential MBANS stakeholders, hospital, and device manufactures. - A possible enforcement mechanism is that MBANS devices would need to recognize a valid site license to become an active transmitter. - In this approach, the hospital infrastructure would carry the site registration information and send an electronic key to the MBANS device to allow authorized transmission in the AMT spectrum, 2360-2390MHz band. - The MBANS devices would by default be configured to operate in the limited part of the spectrum that allow transmission anywhere 2390 -2400MHz if no authorization key available. This would provide the control mechanism to support home usage. - The mechanisms above would most likely require a new Subpart under part 95 of the rules.

36	-AdvaMed suggests that part 95 licensing is a more appropriate for MBANS and should leverage the frequency coordination process established for WMTS operation. - However, improved electronic control methods could be employed to ensure authorized transmission as described in section 35. -A subset of the information that is currently used to manage WMTS via ASHE/Comsearch is sufficient to manage coordination activities. Unlike the WMTS case, there would be no need to register specific frequencies, numbers or type(s) of devices, just site location. -This should be a site registration as done with WMTS, it is a well established process that manufactures and hospitals understand and have trained resources to manage. Today the WMTS devices are registered with ASHE/Comsearch, this could also work in the MBANS case. - Location of AMT sites would need to be disclosed to ASHE/Comsearch. Any sites that are classified as sensitive would need special provision to maintain confidentiality of location, but the exclusion zone can still be determined for these cases. A key output datum is a determination of whether a Hospital is within an exclusion zone and registration data. - For the process to be effective it must be kept as simple as possible and not burden the user. The objective is to create systems that reduce costs.
37	This definition in section 37 is sufficient to describe MBANS, except that “medical sensing device” should read “medical device”, since MBANS applications are not limited to BSNs
38	Medical implant devices should not use 2360-2400 MHz because of operating restrictions for the band. Certainly, the programmer/control transmitter operating under MedRadio rules should be able to connect to other systems operating in the proposed MBAN allocation (2360-2400 MHz).
38	It is not necessary to define other components of an MBANS system. There will be a variety of architectures that can meet the definition, and this flexibility is a key part of the individual manufacturer’s innovation. There is no technical reason why the current definition for MedRadio cannot coexist with MBAN. In addition, allowing communications to an MBANS system would be desirable to help manage data integration of patient data.
39	Permissible Communication and Operator Eligibility - We agree with the proposal to provide flexibility so that MBANS systems can be used for diagnostic or therapeutic function, as well as monitoring functions. - This will be important to have such a provision to support the advancement in the practice of medicine and supporting technologies. - We also accept restriction on non-voice data signals over MBANS systems.

40	- There should be no specific definition within the FCC rules for specific medical application relating to patient risk level, this is a well-understood area within the FDA and among medical device manufactures. - The FDA risk management process and the FDA Guidance for wireless medical systems design are sufficient to control this aspect of MBANS application design. - There are clear guidelines in place under FDA to manage operation of wireless devices for patient risk levels. This is all part of the standard device approval process, where manufactures have to show how interference is managed in the context of a wireless system. These requirements go well beyond what is required to comply with medical EMC standards.
41	- In regard to control transmitters that may be part of an MBANS system, we see no reason to have restrictions on relay of information to receivers that are not part of the system. The control transmitters may well be fully integrated into the MBANS systems and may perform monitoring functions. - This would be too restrictive in MBANS, there needs to be flexibility to use a variety of backhaul radio transmission schemes to achieve the lowest implementation cost. Avoiding this type of restriction allows reuse of existing telecommunication infrastructure, and wireless systems. - The WMTS band can be used in this application to provide backhaul communication to a central station. - The ISM band can also be used, leveraging the hospital wireless infrastructure. - For MBANS in a Home application the ability to use existing radio telecommunication would give greater flexibility to deliver a cost-effective system. - We suggest any communication infrastructure that can be qualified to meet the medical needs can be used for backhaul communication from MBANS devices. These would be approved to meet FDA requirements.
42	- The architecture of MBANS systems should be left to the device manufactures to define based on there understanding of customers and use model. There should be no restrictions in this area of control methods. - We support the most flexible definition possible in how MBANS devices are controlled; this will naturally result in the lowest cost and most innovative implementation.
43	This approach with no specific channel plan is desirable, see section 44 below.

44	- We support the idea that no specific channel plan definition for MBANS be part of the rules, to follow the MedRadio approach or even the WMTS approach. - For example, in the WMTS band, Medical devices vendors have been able to create effective solutions that share the spectrum without a channel plan or bandwidth definition. - It would be acceptable to specify only a maximum permitted bandwidth. - The cognitive mechanisms described and exclusion zone will manage the risk of interference and manage coexistence among different MBANS systems. - Furthermore, allocation of a 40 MHz spectrum will make it much easier for MBANS systems to coexist with other systems without the need to define a channel plan. The possibility of finding clear spectrum is greatly enhanced with 40 MHz allocation.
45	- We propose no specific channel plan is desirable within the FCC rules. This would limit future innovation. The WMTS example has worked effectively. - Less restrictive rules give manufacturers and industry flexibility to develop a variety of standards. Variety helps with completion and cost containment. - We prefer voluntary standards bodies, such as IEEE, to develop standards to address this area of harmonization.
46	We agree with this approach for exclusion zone: - Exclusion zone would apply to 2360-2390 MHz to protect all AMT sites. - The spectrum 2390-2400 MHz should be unrestricted and, therefore, available for home healthcare monitoring, ambulance monitoring, or in hospital monitoring.
52	From a regulatory perspective, exclusion zones are highly feasible for protecting the relatively few AMT sites. This would be very similar to the protection of radio astronomy sites that has worked successfully for WMTS. Definition of exclusion zones and other protection criteria should be based on preventing the reasonable likelihood of actual harmful interference, not based on remote possibilities of interference that would arise only under unrealistic, worst-case assumptions. Thus, as the question is inherently one of probabilities, probabilistic analysis is the appropriate approach. The record contains sound probabilistic analysis showing that modest exclusion zones with radius on the order of 10km would be conservative and make harmful interference negligible. Such zones would leave over 99% of the United States unaffected so the vast majority of hospitals and healthcare facilities would have access to the entire band.
53	The rules should include special provisions to allow for hospitals that fall in the exclusion zone to coordinate with the affected AMT site. In these cases, frequency separation can be used to protect the AMT site. This coordination can be done through ASHE/ Comsearch, similarly to WMTS.

54	We would agree, as a matter of simplicity, to protect all existing AMT sites with exclusion zones regardless of whether or how extensively they currently use the 2360-2390 MHz band. In return, we propose that existing registered 2360-2390 MHz MBANS sites be grandfathered from automatic exclusion when new AMT sites are installed. We expect to use a coordination process based on the site-specific AMT frequency usage to develop appropriate exclusion criteria for the sites. We expect that location of new AMT sites will be quite rare andin remote areas. In addition, AMT will be able to reference a register of active MBANS installations during their planning, which will enable them to enter a coordination on process early.
55	- We suggest the measured distance for MBANS operation be defined from the location of the receiver. For simplicity, in the case of multiple relatively closely-clustered receivers that would result in multiple largely overlapping exclusion zones, a single larger zone with center and radius chosen to exclude the same areas, but not unnecessarily more area, as the multiple individual overlapping zones would be acceptable. - For multiple incumbent sites that are in close proximity, the protected area would be defined by the intersection of circles from the center of each site. Previously-registered 2360-2390 MHZ AMT sites should be grandfathered (see #54 above). - All the site location data would be part of ASHE/Comsearch database.
56	- Frequency Coordination could be included in the rules to deal with hospitals sites that fall inside the exclusion zone if more spectrum efficiency and access to MBANS is desired. However if exclusion zones are small (e.g. 10 km) this would only potentially benefit a small fraction of hospitals. - We envision a process where ASHE/Comsearch is used as the coordinator with AFRACC and NTIA, this may include FCC. ASHE/Comsearch would be the single point of contact for hospitals and medical device manufactures. - Hospitals in the exclusion zone will by default operate with 10MHz spectrum limit (2390-2400 MHz), if that spectrum is not sufficient then coordination through ASHE/Comsearch could be initiated.
57	MBANS registration similar to the WMTS process can work and should be adopted, but some enhanced controls could be employed to avoid unauthorized usage of the AMT band. These controls could be built into the MBANS devices as suggested in section 35.

58	Since MBANS devices would be designed with contention protocols to coexist autonomously, there is no need to for intraservice coordination as occurs with WMTS. - We believe that the process of coordination in the WMTS band for incumbent user can be ready applied to MBANS. - We suggest a coordination service through a body such as ASHE/Comsearch can be used for MBANS. This is a well established process for the medical device manufactures, so would minimize training and logistical support needs. - Location of AMT sites would need to be disclosed to ASHE/Comsearch. Any sites that are classified as sensitive would need special provision to maintain confidentiality of location, but the exclusion zone can still be deermined in this case. Key output dat are a determination of whether a hospital is within an exclusion zone and proviion of a site access key to enable MBANS devices to operate with the AMT band. - The database will contain a very limited subset of the information collected for WMTS. Probably only Hospital site location would be required. - From AMT sites, the following data should be provided: site location, operational frequencies, signal bandwidth, and power level. - For the situation where there may be mobile AMT sites, then more information is needed regarding the range of locations that can be used and exclusion zones established at those locations.
60	We believe that process of coordination in the WMTS band for incumbent user can be readily applied to MBANS and is the preferred approach, but the alternative could be viable. - The Commission and ASHE/Comsearch could work together to resolve sites with coordination problems with NTIA sites. - We would expect that ASHE/Comsearch can easily work directly with AFTRCC to resolve problems. It is not unprecedented for ASHE/Comsearch to work with AFTRCC.
61	- AdvaMed also supports a contention-based protocol for MBANS. However, within the commission's rules this should just be defined as a high-evel requirement with no specific details. - Many of the available radio technologies already deploy such protocols, so picking a specific protocol would not be appropriate. It should be left to the industry and even standards developing bodies to push future developments in this area. The contention protocol definition described here is sufficient, it provides for flexible development of systems.

62	The industry supports LBT in the MedRadio band because the band supports implanted devices that place a premium on low signal strength operation and long battery life,but believes different types of access protocols may be appropriate for MBAN devices operating in other bands. The motivations for requiring contention protocols in MBAN service would be to ensure that MBAN devices are robust to interference from incumbent and other MBAN devices as well as to promote coexistence and band sharing among MBAN devices. Specific contention protocols appropriate and optimized for MBAN applications are expected to be application-dependent so one size will likely not fit all. These may include some form of LBT tailored to the needs of MBAN applications but may include other techniques as well. Any contention protocol requirement for MBAN service should be generic and flexible (see 64) to permit innovation by vendors and standards bodies..
63	Allowing MBANs operation in the 2390-2400 MHz band without geographic coordination would enable important uses of the spectrum for ambulatory systems.
64	- Relative to contention protocol, a more flexible definition gives greater capacity to manage evolving radio technologies. - The specifics of a contention-based protocol should not be defined in the FCC rules.There are existing radios in the adjacent 2.4 GHz ISM band that have already developed such protocols. Some of these could be leveraged for MBANS, thus eliminating the need for significant reengineering. - Standards bodies such as IEEE 802.15.6 (Body Area Network taskgroup) are involved in creation of relevant standards. Those are the appropriate places for this work. - We expect that several protocols should be allowed to be used, to match with available radios in the 2.4 GHz ISM band
66	To be consistent with other international standards (e.g., ETSI), the industry believes the duty cycle should apply to individual MBAN transmitters.
66	- The power limit of 1 mW is acceptable for MBANS operating in the 2360-2390 MHz AMT band. - For the 2390-2400 MHz range, a higher power limit (20 mW) is desirable. The home monitoring application is best served by providing whole house coverage, while keeping those systems simple, and to protect against clinical incidents such as patients falling on the transmitter in an adverse event. This will also help to overcome significant excess noise from adjacent ISM devices that will elevate the noise floor in this part of the spectrum. In this home use case, MBAN duty cycle will be very low (typically 2%) with low frequency of transmission, as real-time monitoring is not needed. This will minimize interference concerns, as these devices will comply with agreed out-of-band emissions limits to not impact AMT users. - In general, for MBANS we can implement power level control to further reduce interference, where highest power is used when the link is significantly impaired. - We seek a higher maximum permitted bandwidth (5 MHz) to allow for future radio technologies. - A 3 MHz bandwidth allows a variety of applicable radio technologies that's are current use in 2.4 GHz ISM band to be leveraged, but allowing a bandwidth up to 5 MHz gives potential for future evolution of technology. Higher bandwidth allows MBANS to use lower duty cycle and support higher data rates that can accommodate future medical devices. In more critical care settings, there is need for more streaming real-time data and improved link robustness, a higher bandwidth allows greater spreading gain, making these links more robust while supporting more clinical data throughput. - We would expect most MBANS devices to use bandwidth up to 3 MHz in less acute care settings.

	This will be the dominant use case. However, there are use cases as cited above where a higher bandwidth is needed. - It must be noted here that with exclusion zone as the key coexistence mechanism, the signal bandwidth is not a factor in interference management with AMT stations. - In the hospital environment, we would expect duty cycle per patient not to exclude 25%. In the home environment, the expected duty cycle per patient is very low, much less than 25% (typically <2% for home monitoring). This allows MBANS in the home to achieve long battery life even with a higher output power limit. - FCC has never allocated any spectrum for the unique case of home monitoring of patients; the above definition provides a more optimum solution for this use case, that will become more important in driving down healthcare costs.
67	- In a channel aggregation scheme, there is no objection to limit aggregation of multiple channels for a single patient to the maximum allowed bandwidth. However, We believe that a 5 MHz aggregation limit would be more appropriate. - The proposed emissions bandwidth of 1 MHz is too restrictive to meet all of the future envisioned MBANS applications and limits the choice in radio technologies that can be leveraged from the adjacent 2.4 GHz ISM band. - A 40 MHz allocation eliminates any aggregation concerns, and in this case may not need to be part of the rules. - A separate Philips response comments filing contains detailed technical analysis to support the technical requirements. In thisanalysis GEHC demonstrates that signal bandwidth up to 5 MHz has no impact on the AMT link performance at the defined exclusion zone.
68	- The general limits applicable to part15 devices used in the adjacent ISM band are acceptable in the case of MBANS, as there is a critical need to leverage radios from the adjacent 2.4 GHz ISM spectrum. So equivalent emission rules would be desirable.
69	- Frequency stability of +/-100ppm is acceptable.
70	- The spectrum from 2360-2390 MHz can be restricted to indoor hospital use to allow for exclusion zone management. For the spectrum 2390-2400 MHz, no antenna location restriction should apply. - We need provisions for outdoor transmitting antenna use outside the 2360-2390 MHz band. This is to allow home and ambulance monitoring to use 2390-2400 MHz spectrum. - To reduce healthcare costs, more care services will be delivered into the home, so it is desirable to have at least 10 MHz of the spectrum unrestricted - 2390-2400 MHz.

71	RF Safety: - We accept the definition of MBANS as portable devices, worn by humans and should be subjected to the RF exposure rules defined in FCC rules section 2.1093 and 1.1307. Note: - MBAN device low duty cycle produce RF exposure that is well under the FCC SAR limits as well as other international exposure limits. With 25% duty cycle exposure is 0.25mW. - MBAN in the home with 20 mW, again the very low duty cycle (<2%, a few seconds of transmission every hour) produce RF exposure that is well under the FCC SAR limits as well as other international exposure limits.
73	Certification is appropriate for MBAN transmitters
74	We have no objection if the commission wants to have a provision to inspect MBAN transmitters in the resolution of interference.
75	- We have no objection to include disclosure statements for MBAN device operation, to accept interference from primary users and not to cause harmful interference to a primary user. - We would eed the option to have such labeling provided in user documentation if the MBAN device is too small to carry a full disclosure statement.
76	- We have no objection to include disclosure statements for MBAN control devices, to accept interference from primary users and not to cause harmful interference to a primary user. - We would need the option to have such labeling provided in user documentation if the MBAN control device is too small to carry a full disclosure statement.
77	Such marketing limitations are acceptable.