Project: IEEE P802.15 Working Group for Wireless Personal Area Networks (WPANs)

Submission Title: FCC Public Notice 2360 to 2400 MHz MBANS Proposal Update

Date Submitted: July 14, 2008

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Re: IEEE P802.15-08-0108-01-0006, IEEE P802.15-08-0254-02-006

Abstract: This presentation provides an update on responses submitted to the FCC in response to its public notice regarding GE Healthcare's proposal to create a new Medical Body Area Network Service

Purpose: To inform TG6 of the FCC's public notice. To obtain TG6 support via vote to engage IEEE 802.18 to file comments on behalf of TG6.

FCC Public Notice - 2360 to 2400 MHz MBANS Proposal Update

David Davenport

GE Global Research

RF and Photonics Laboratory

802.15.6 PAR defines need for reliable links for medical body area devices

5.2 Scope: This is a standard for short range, wireless communication in the vicinity of, or inside, a human body (but not limited to humans). It can use existing ISM bands as well as frequency bands approved by national medical and/or regulatory authorities. Support for Quality of Service (QoS), extremely low power, and data rates up to 10 Mbps is required **while simultaneously complying with strict non-interference guidelines where needed**. This standard considers effects on portable antennas due to the presence of a person (varying with male, female, skinny, heavy, etc.), radiation pattern shaping to minimize SAR* into the body, and changes in characteristics as a result of the user motions. *SAR (Specific Absorption Rate) measured in (W/kg) = (J/kg/s). SAR is regulated, with limits for local exposure (Head) of: in US: 1.6 W/kg in 1 gram and in EU: 2 W/kg in 10 gram. This limits the transmit (TX) power in US < 1.6 mW and in EU < 20 mW.

5.4 Purpose: The purpose is to provide an international standard for a short range (ie about human body range), low power and highly reliable wireless communication for use in close proximity to, or inside, a human body. Data rates, typically up to 10Mbps, can be offered to satisfy an evolutionary set of entertainment and **healthcare services**. Current Personal Area Networks (PANs) do not meet the medical (proximity to human tissue) and relevant communication regulations for some application environments. They also do not support the **combination of reliability (QoS), low power, data rate and noninterference** required to broadly address the breadth of body area network applications.

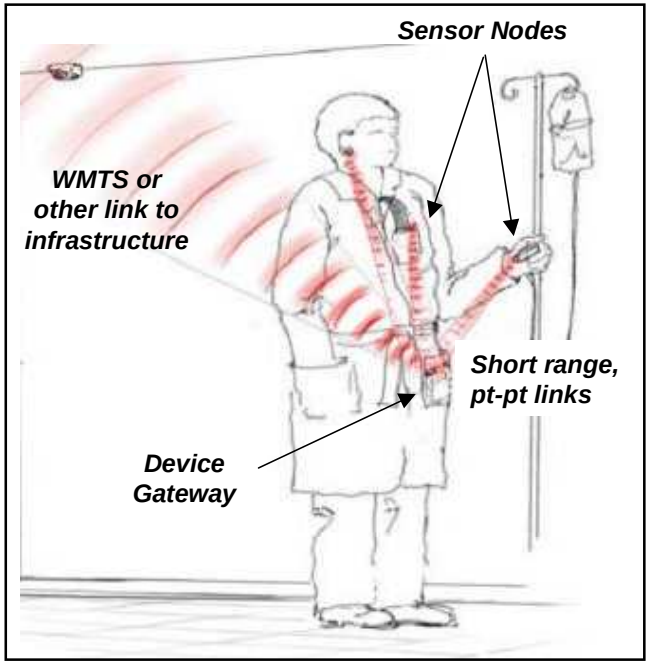
5.5 Need for the Project: There is a need for a standard optimized for ultra low power devices and **operation on, in or around the human body to serve a variety of applications including medical** and personal entertainment. Examples of the applications served by the proposed standard are: Electroencephalogram (EEG), Electrocardiogram (ECG), Electromyography (EMG), vital signals monitoring (temperature (wearable thermometer), respiratory, wearable heart rate monitor, wearable pulse oximeter, wearable blood pressure monitor, oxygen, pH value , wearable glucose sensor, implanted glucose sensor, cardiac arrhythmia), wireless capsule endoscope (gastrointestinal), wireless capsule for drug delivery, deep brain stimulator, cortical stimulator (visual neuro-stimulator, audio neuro stimulator, Parkinson's disease, etc…), remote control of medical devices such as pacemaker, actuators, insulin pump, hearing aid (wearable and implanted), retina implants, disability assistance, such as muscle tension sensing and stimulation, wearable weighing scale, fall detection, aiding sport training. This will include body-centric solutions for future wearable computers. In a similar vein, the same technology can provide effective solutions for personal entertainment as well. The existence of a body area network standard will provide opportunities to expand these product features, better healthcare and well being for the users. It will therefore result in economic opportunity for technology component suppliers and equipment manufacturers.

Reference = https://development.standards.ieee.org/P625900033/par

Body Sensor Network (BSN) for Medical Monitoring

A wireless network of sensors around a patient providing multiple clinical benefits

- Patient mobility, comfort, infection control
- Monitoring flexibility and scalability
- Extension of monitoring into care areas that are currently unmonitored
- Reduced clinical errors
- Reduced overall monitoring costs



** Reference = Medical Body Area Network Application, 15-08-0108-01-0006-medical-body-area-network-application.pdf*

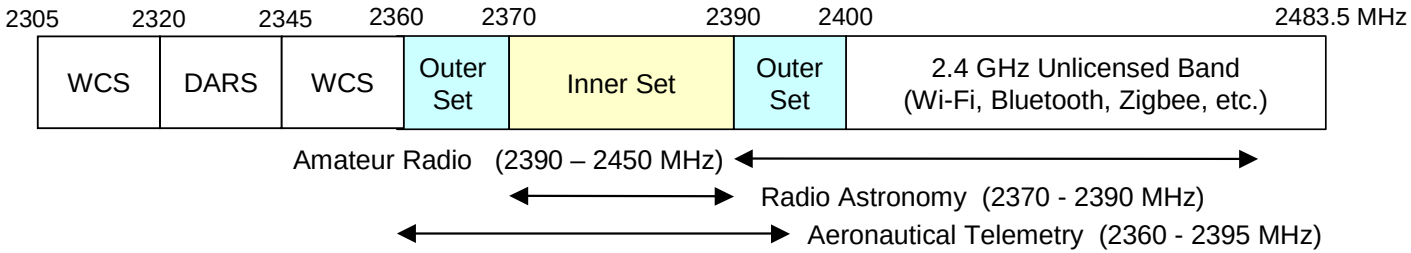
Proposed Part 95 Rules for Medical Body Area Network Service (MBANS)

Eligibility & Permissible Communications

- Licenses by rule operations by authorized health care professionals and by any other person, if such use is prescribed by a health care professional. Limited to transmission of data (no voice) used for monitoring, diagnosing or treating patients.

Frequencies & Authorized Locations

- 2370-2390 MHz limited to health care facilities and other environments where health care professionals monitor, diagnose and treat patients, including in ambulances.
- 2360-2370 MHz and 2390-2400 MHz operations permitted anywhere CB radios may operate.



Technical Parameters

- All stations must employ unrestricted contention-based protocol.
- Maximum emission bandwidth of 1 MHz.
- Maximum EIRP not to exceed the lesser of **1 mW** or 10 log $BW_{20dB\ MHz}$ dBm.
- Same out-of-band (more than 500 kHz outside of band) field strength limits as apply to MICS.

Reference = http://fjallfoss.fcc.gov/prod/ecfs/retrieve.cgi?native_or_pdf=pdf&id_document=6519820996

PUBLIC NOTICE

Federal Communications Commission
445 12th St., S.W.
Washington, D.C. 20554

News Media Information 202 / 418-0500
Internet: http://www.fcc.gov
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DA 08-953
April 24, 2008

OFFICE OF ENGINEERING AND TECHNOLOGY TO TREAT *EX PARTE* COMMENTS OF GE HEALTHCARE AS PETITION FOR RULE MAKING AND SEEKS COMMENT

ET Docket No. 08-59

Comment Date: May 27, 2008
Reply Comment Date: June 11, 2008

On December 27, 2007, GE Healthcare (GEHC) filed *ex parte* comments in ET Docket No. 06-135 in response to a *Notice of Inquiry* (*NOI*) in the pending *MedRadio Proceeding*.[1]

In the *MedRadio Proceeding*, the Commission adopted a combined *Notice of Proposed Rulemaking* (*NPRM*) and *NOI*. In the *NPRM*, the Commission proposed to allocate additional spectrum in the 400 MHz band for implanted and body-worn medical devices using wireless radiofrequency (RF) technologies that are used for diagnostic and therapeutic purposes in human patients.[2] More specifically, the *NPRM* explored expanded use of such devices in the existing Medical Implant Communications Service (MICS) 'core' band at 402-405 MHz, as well as in the proposed new MedRadio 'wing' bands at 401-402 MHz and 405-406 MHz.

In the *NOI*, the Commission sought comment on the anticipated developments in the medical devices field and the resulting spectrum requirements of such devices that might use radio frequency (RF) transmitters. More particularly, the Commission asked for detailed comment on new implant and body-worn medical radiocommunication technologies and how their operation could be accommodated.

Responding to the call for comments in the *NOI*, GEHC proposes the allocation of spectrum on a secondary basis in the 2360-2400 MHz band and for the adoption of service rules under Part 95 for the operation of wireless medical 'body sensor networks' - or BSNs. As described by GEHC, Wireless BSN sensors would be used to replace the present generation of physiological body sensors (often used with patients in hospitals, for example) that rely upon wired cables connected to bedside monitoring equipment. GEHC states that a key benefit of eliminating the wired link with wireless BSN technology would be to reduce the chances of body sensors becoming unintentionally disconnected, thereby enhancing the safety, quality and mobility of patient care. GEHC thus requests that the Commission issue a further rule making notice in order to consider its proposal.

Although the GEHC submission is styled as an *ex parte* comment, we conclude that it provides sufficient basis to be treated as a petition for rulemaking under Section 1.401 of the Commission's rules. Among other factors, it sets forth a comprehensive proposal for a new allocation in a specific frequency band and for service rules for a new Medical Body Area Network Service under Part 95, issues that are not presently under consideration in the *MedRadio Proceeding*. Thus, in order for the Commission to determine if there are sufficient reasons for instituting a rulemaking proceeding, we are treating the GEHC *ex parte* filing as a petition for rulemaking and seek comment on GEHC's request. To the extent the *ex parte* comment also discusses issues in the pending rulemaking, this public notice is issued without prejudice to the Commission's ability to address issues pending from the *NPRM* in the existing rulemaking. We deem the proceeding, for *ex parte* purposes, as "permit-but-disclose" in accordance with Section 1.1200(a) of the Commission's rules, subject to the requirements under Section 1.1206(b).

Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR §§ 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) the Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings*, 63 FR 24121 (1998).

- Electronic Filers: Comments may be filed electronically using the Internet by accessing the ECFS: http://www.fcc.gov/cgb/ecfs/ or the Federal eRulemaking Portal: http://www.regulations.gov. Filers should follow the instructions provided on the website for submitting comments.
  - For ECFS filers, if multiple docket or rulemaking numbers appear in the caption of this proceeding, filers must transmit one electronic copy of the comments for each docket or rulemaking number referenced in the caption. In completing the transmittal screen, filers should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions, filers should send an e-mail to ecfs@fcc.gov, and include the following words in

[1] *See* "Investigation of the Spectrum Requirements for Advanced Medical Technologies, Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405-406 MHz, DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules, Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules," ET Docket No. 06-135, RM-11271, *Notice of Proposed Rulemaking and Notice of Inquiry and Order, (MedRadio Proceeding)* 21 FCC Rcd 8164 (2006).

[2] The most common examples in present day use include cardiac pacemakers and blood glucose monitors. Commenters envision the use of such wireless devices in the treatment of many other medical conditions.

Reference = http://www.fcc.gov/Daily_Releases/Daily_Business/2008/db0424/DA-08-953A1.pdf.

How will MBANS coexist as a secondary service?

1. Physical separation of low power MBANS devices and incumbent receivers

   Location of airborne vehicle testing “is often restricted to areas over water or uninhabited land in order to preclude danger to life or property in case of catastrophic failure of the vehicle being tested…” Recommendation ITU-R M.1459, 2000, Section 2.2.2

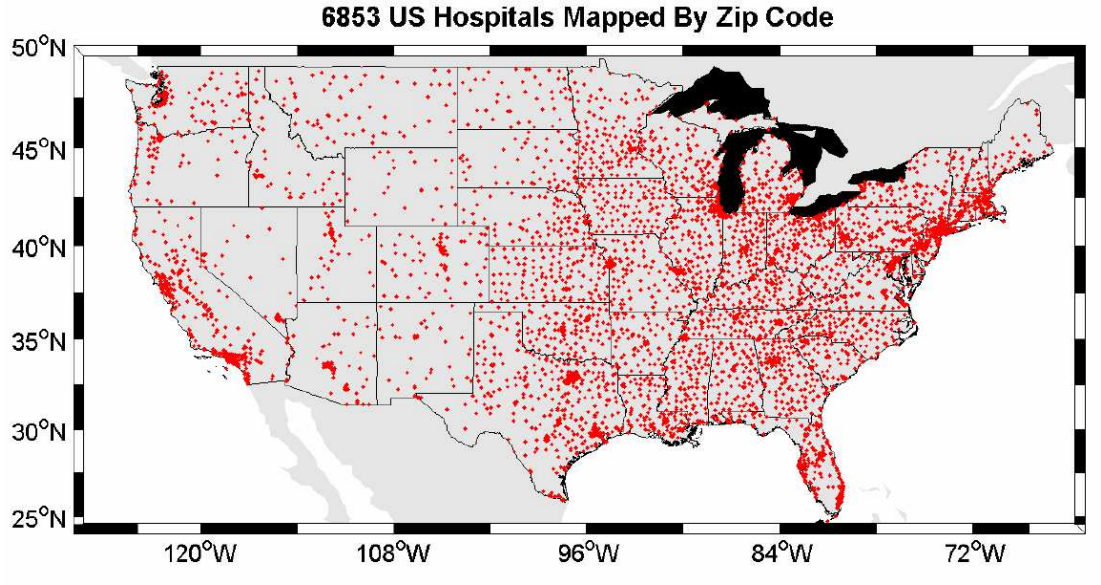
2. Adoption of contention-based protocols

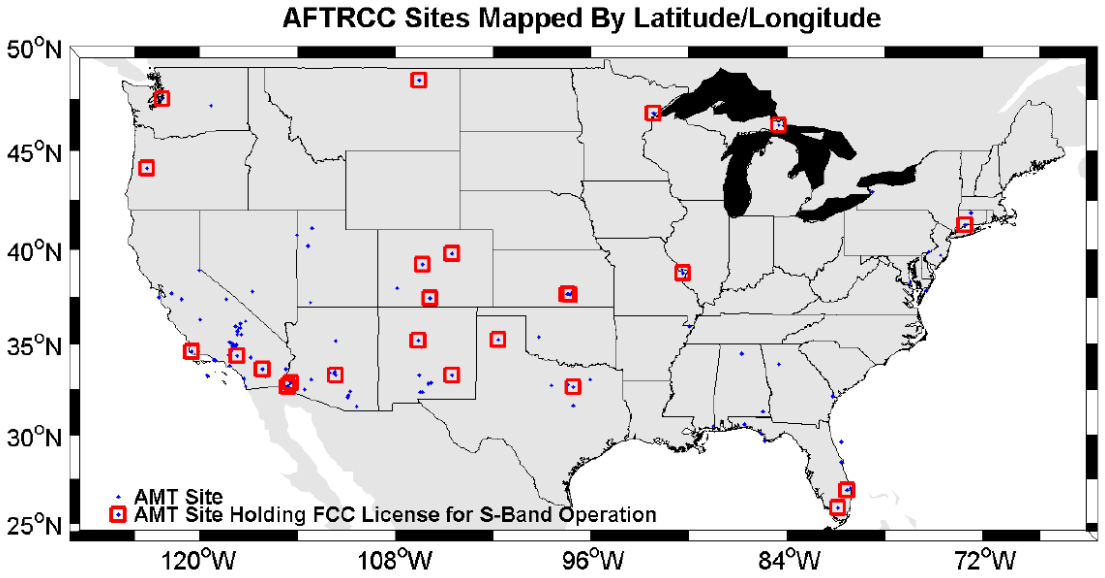
   Frequency agility and hopping, listen-before-talk are effective and proven mechanisms

   - Avoids transmitting on the same frequency as nearby, high power incumbents
   - Permits spectrum sharing with other MBANS devices

** Reference = Medical Body Area Network Application, 15-08-0108-01-0006-medical-body-area-network-application.pdf*

Spatial separation between US hospitals and aeronautical mobile telemetry (AMT) test sites





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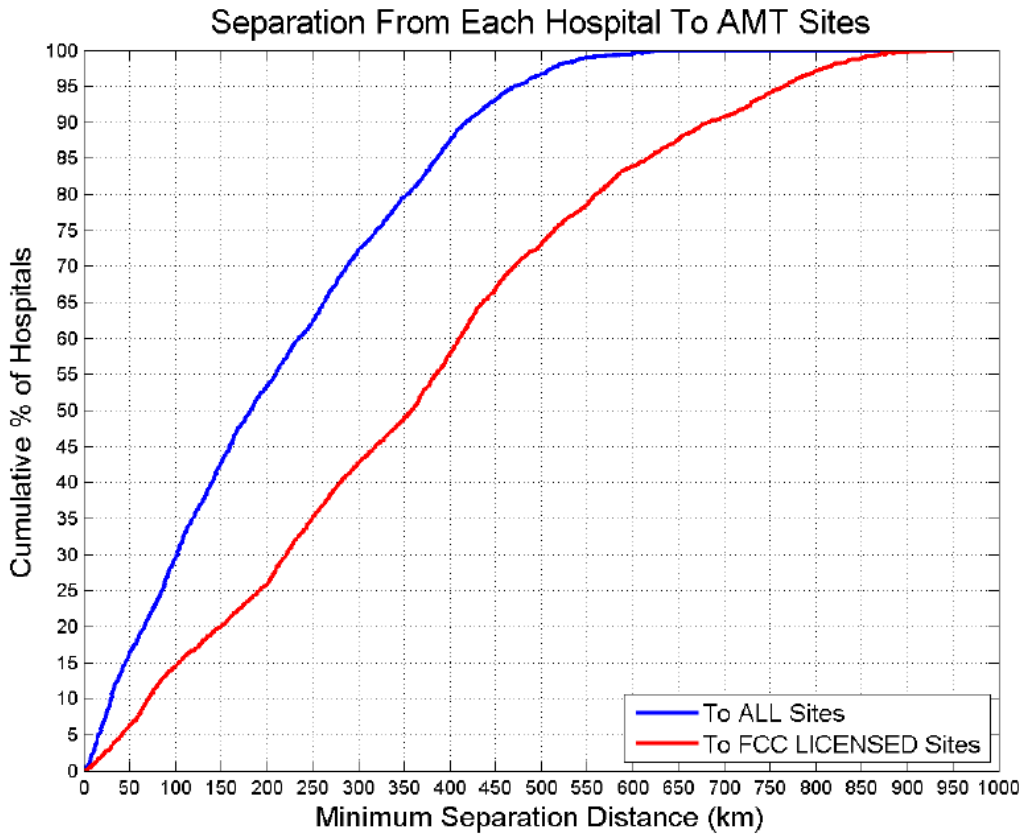
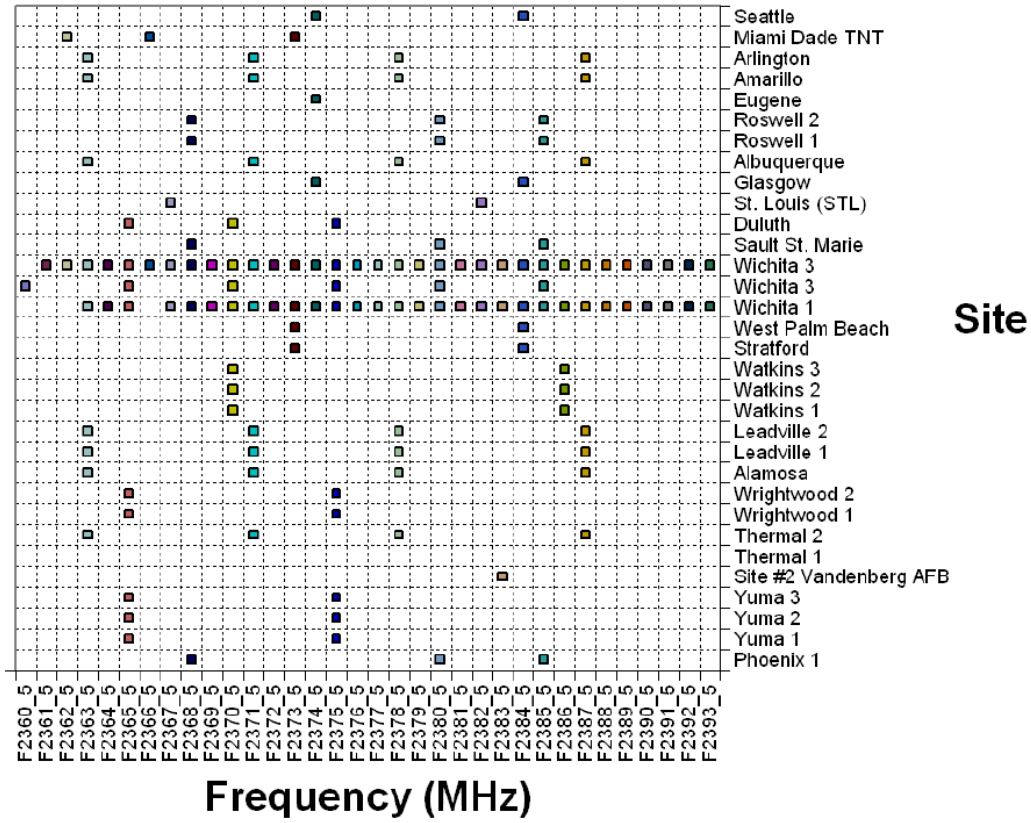


Only 6.1% of hospitals are located < 20 km from any AMT site

Reference = http://fjallfoss.fcc.gov/prod/ecfs/retrieve.cgi?native_or_pdf=pdf&id_document=6520028374

Licensed aeronautical mobile telemetry frequencies per FCC ULS search of June 5, 2008

FCC licenses reflect sparse utilization of frequency band at majority of sites



Reference = http://fjallfoss.fcc.gov/prod/ecfs/retrieve.cgi?native_or_pdf=pdf&id_document=6520028374

Outline of FCC Process Going Forward

- After June 11 comment deadline on MBANS Public Notice, anyone may still file *ex parte* comments or schedule *ex parte* meetings with the FCC to lobby for their interests.
- FCC will eventually decide whether go ahead with a rulemaking proceeding. If they decide to proceed the would issue a Notice of Proposed Rule Making (NPRM) which:
  - Could adopt all of GEHC's MBANS proposal, propose few specifics, or anything in between.
  - Would likely seek comment on a number of specific questions, many of which would likely be driven by the concerns raised by previously submitted comments on GE Healthcare petition.
  - Will have its own comment and reply comment deadline.
- After NPRM comment deadlines, anyone may still engage in oral or written *ex parte* communications with the FCC for as long as the rule making proceedings are still pending, no decision has been released and the FCC has not put a decision in the proceedings on its agenda for its official monthly meeting.
  - Lobbing phase may last many months (e.g. docket still open for July 2006 MedRadio NPRM).
- The rule making proceeding would conclude with a when the FCC adopts a final Ruling and Order establishing new rules.

Conclusion

- BSNs hold significant promise for health care quality and efficiency.
- FCC's consideration of MBANS proposal represents opportunity for 802.15.6 to achieve coexistence and noninterference for medical BSNs
  - The incumbent services in the proposed band are well suited to coexistence with low-power short range BSNs.
  - The proposed band has many other desirable properties (e.g. proximity to 2.4 GHz Part 15 band).
  - The proposed band is, by any objective measure, sparsely utilized over most of the USA at any instant in time.
- Support of MBANS proposal required via filing of *ex parte* comments with FCC
- Engage 802.18 TAG to convey objectives of 802.15.6 and benefit of MBANS proposal

Motion for 802.15.6 to support MBANS Proposal

Move that 802.15.6 and 802.15 WG vote to engage 802.18 TAG to file ex parte comments to the FCC stating:

- Scope, purpose and need of 802.15.6 to develop an international standard for body area networks (sections 5.2, 5,4, 5.5 of PAR)
- There is a benefit of specialized protected spectrum for coexistence and noninterference of medical body area networks.
- Support of Medical Body Area Network Service proposal
- Encourage the Commission to move expeditiously towards an NPRM, to make the next generation of wireless medical devices a reality