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

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

Date Submitted: May 14, 2008

Source: David Davenport, GE Global Research

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Re: IEEE P802.15-08-0108-01-0006

Abstract: This presentation summarizes the FCC's 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 show how individuals may file comments to the FCC. 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 Service Proposal

David Davenport

GE Global Research

RF and Photonics Laboratory

Agenda

- FCC Public Notice
  - Review
- Submission of Comments to FCC
  - File
- Engaging 802.18 TAG
  - Discuss & Vote

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

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
TTY: 1-888-835-5322

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.

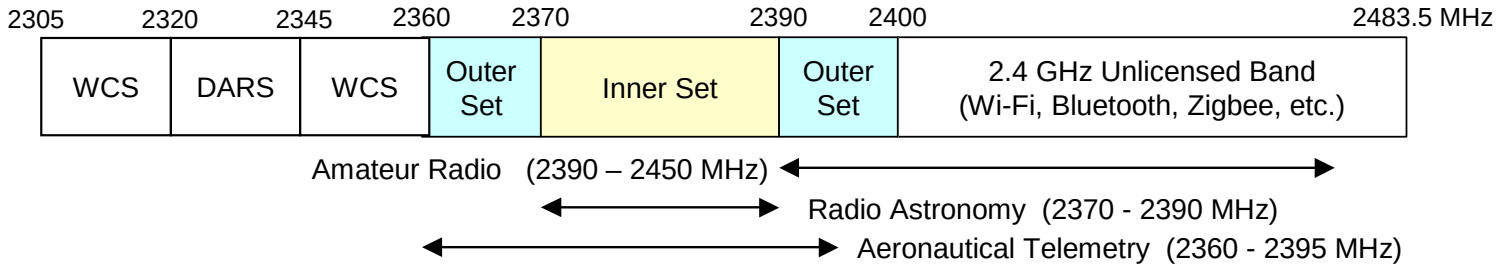
Proposed Part 95 Rules for Medical Body Area Network Service (MBANS)

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

Why 2360 to 2400 MHz?

Medical BSNs require new, protected spectrum for clinical applications *

- Leverage 2.4 GHz off-the-shelf component integration, capability and volume costs
- Suitable on-body propagation characteristics similar to 2.4 GHz
- Permits small, efficient antennas
- Allows high symbol rate for low duty cycle and short bursts

- Consultation with NTIA
- Incumbent Aeronautical Telemetry and Amateur operations are good candidates for coexistence

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

Medical BSNs require new, protected spectrum for clinical applications

Unlicensed Bands

- Lack reliability needed for unprocessed, life-critical monitoring data
- Fully utilized by hospital WLAN for mission-critical applications

400 MHz MedRadio, Part 95

- Duty cycle limits force BSN to 3 MHz center of MedRadio band
- 3 MHz insufficient for BSN patient population within hospital

WMTS, Part 95

- Limited and disjointed spectrum bands
- Heavily utilized by hospitals for existing telemetry applications
- “Command and control” channel coordination
- Prohibits use in ambulance, home, office

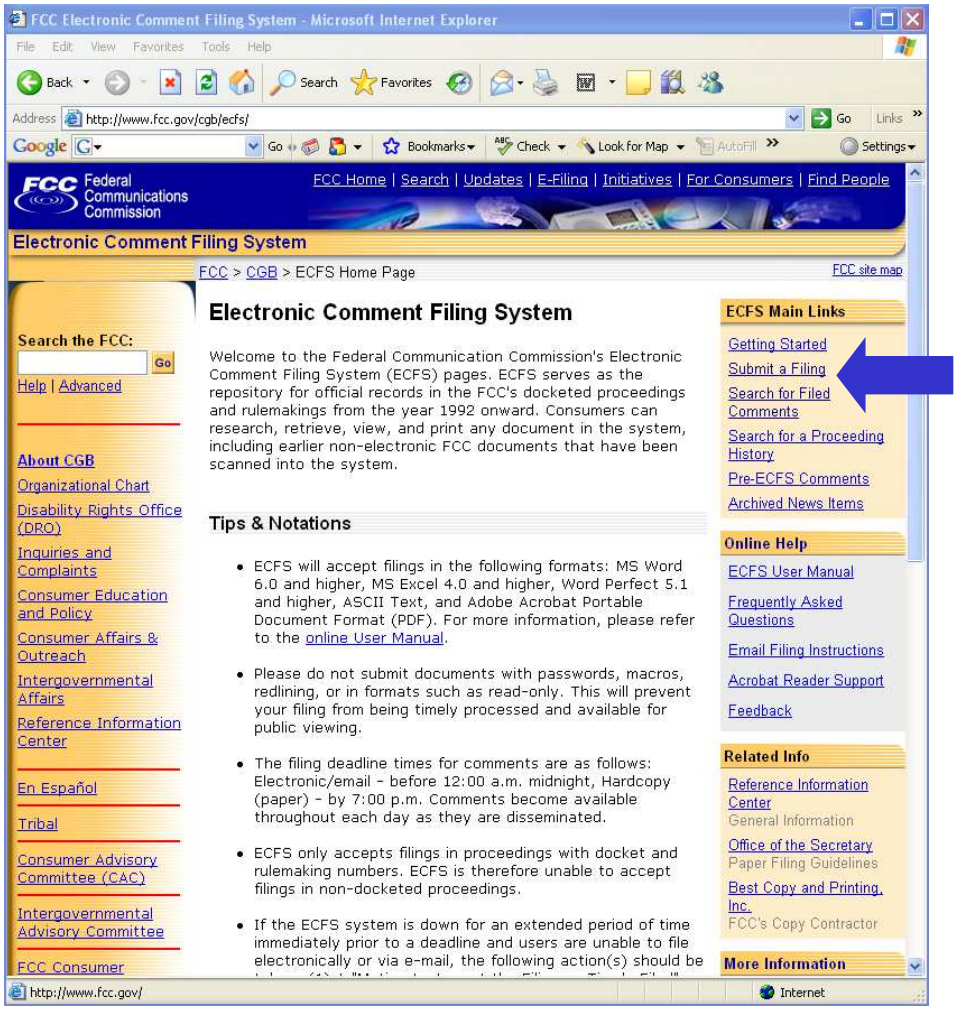
FCC petition for rule making presents opportunity for TG6 to achieve its PAR purpose

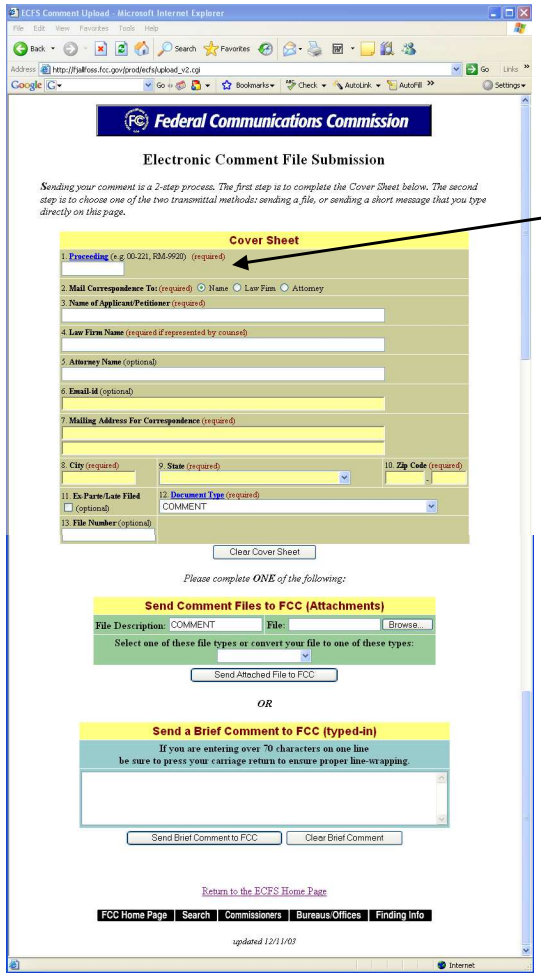
- Opportunity for spectrum affording reliable physical layer for medical devices
- Adjacent to 2.4 GHz ISM band for entertainment and non-medical devices
  - [Texas Instruments] and other vendors design and manufacture a wide variety of low power transceiver chips for the 2400 MHz band that support various standards including Bluetooth, WiFi and ZigBee, and that can support contention based protocols. These chips can be modified to operate in the 2360 – 2400 MHz band. As a result, it is expected that medical devices incorporating these chips could benefit from economies of scale -- and the corresponding cost-effective prices -- and from the ready availability of essential components.
    Reference = http://fjallfoss.fcc.gov/prod/ecfs/retrieve.cgi?native_or_pdf=pdf&id_document=6519838779

Future of MBANS petition for rule making requires support from academic, industrial and medical communities

How to file comments

www.fcc.gov/cgb/ecfs/





08-59

Example comments filed with FCC

Queen's University Belfast

Petition for Rulemaking (DA-08 953) ET Docket No. 08-59

Medical Body Area Network Service

Comments by Dr. W. G. Scanlon

I read with interest that the Commission are considering proposals from GE Healthcare for a Medical Body Area Network Service (MBAN) operating on a secondary basis in the 2.360 – 2.400 GHz band. On the basis of more than 10 years of published research in bodyworn communications and medical applications [1], I am convinced that this proposal is well founded in terms of favourable antenna [2,3] and propagation [4] conditions (both between sensor devices on the body surface and to nearby off-body units such as bed side monitors) and in terms of benefits for healthcare facilities and patients alike.

I strongly recommend that, in principle and subject to further technical scrutiny, that the Commission accept this proposal and establish the MBAN service.

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References

[1] W. G. Scanlon & N. E. Evans, "Antennas and propagation for telemedicine and telecare – on-body systems," Chap. 8 in Antennas and Propagation for Body-Centric Wireless Communications, eds. P. S. Hall & Y. Hao, Artech House, Norwood, MA, pp. 211–239, 2006. [ISBN: 1-58053-493-7]

[2] G. A. Conway, W. G. Scanlon, C. Orlenius & C. Walker, "In-situ measurement of UHF wearable antenna efficiency using a reverberation chamber," in press, IEEE Antennas Wireless Propagation Letters, 2008. [doi: 10.1109/LAWP.2008.920753].

[3] G. A. Conway, W. G. Scanlon & D. Linton, "Low-profile microstrip patch antenna for over-body surface communication at 2.45 GHz," 65th IEEE Vehicular Techn. Conf. VTC2007-Spring, pp. 392–396, Apr. 2007. [doi: 10.1109/VETECS.2007.92]

[4] S. L. Cotton & W. G. Scanlon, "An experimental investigation into the influence of user state and environment on fading characteristics in wireless body area networks at 2.45 GHz," in press, IEEE Trans. Wireless Communications, 2008.

http://fjallfoss.fcc.gov/prod/ecfs/retrieve.cgi?native_or_pdf=pdf&id_document=6520006227

Queen Mary University of London

Petition for Rulemaking (DA-08 953) ET Docket No. 08-59

Medical Body Area Network Service

Comments by Prof. Yang Hao and Dr. Akram Alomainy

We understand that the Commission is considering proposals from GE Healthcare regarding a Medical Body Area Network (MBAN) service operating in the 2.360 – 2.400 GHz band. At Queen Mary College, we initialised on-body radio channel characterisation via extensive measurement and numerical modelling. Our experience suggests that the allocation of a new frequency band at 2.360 - 2.400 GHz would help us to tackle issues such as interference and channel co-existence. We believe that the proposal is well justified and founded in terms of developing future body worn devices for healthcare applications.

We strongly support this proposal and also advice the commission to accept it based on further technical and market analysis and investigations.

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References

[1] P. S. Hall and Y. Hao (Editors), "Antennas and Propagation for Body-Centric Wireless Networks", September 2006, Artech House, Norwood, MA. [ISBN: 1-58053-493-7]

[2] A. Alomainy, Y. Hao and W. F. Pasveer, "Antennas for Wearable Devices", Chapter 6 in Antennas for Portable Devices, March 2007, John Wiley & Sons Ltd, The Atrium, Southern Gates, Chichester, England. [ISBN: 978-0-470-03073-8]

[3] A. Alomainy, Y. Hao and W. F. Pasveer, "Numerical and Experimental Evaluation of a Compact Sensor Antenna Performance for Healthcare Devices", IEEE Transactions on Biomedical Circuits and Systems, Vol. 1 No. 4, December 2007, pp: 242-249.

[4] P. S. Hall, Y. Hao, Y. I. Nechayev, A. Alomainy, *et al.*, "Antennas and Propagation for On-Body Communication Systems", *IEEE Antenna and Propagation Magazine*, 49 (3): 41-58 June 2007.

[5] A. Alomainy, Y. Hao, A. Owadally, C. Parini, Y. Nechayev, P. Hall, C. C. Constantinou, "Statistical Analysis and Performance Evaluation for On-body Radio Propagation with Microstrip Patch Antennas", IEEE Transactions on Antennas and Propagation, Vol. 55, Issue 1, January 2007, pp. 245-248.

http://fjallfoss.fcc.gov/prod/ecfs/retrieve.cgi?native_or_pdf=pdf&id_document=6520009145

Engage IEEE 802.18 to file comments on behalf of 802.15.6

- Need vote at 802.15 TG6 and 802.15 WG to engage 802.18 TAG

- IEEE 802.18 Radio Regulatory TAG to prepare and file comments including:
  - 802.15.6 scope, purpose, need (sections 5.2, 5.4, 5.5 of PAR)
  - Benefit of licensed spectrum for medical body area network coexistence and noninterference
  - Balance interests of other 802 groups, including 802.16

Conclusion

- FCC public notice issued treating MBANS proposal as petition for rule making
- MBANS proposal represents opportunity for 802.15.6 to achieve coexistence and noninterference for medical applications
- Support of MBANS proposal required via filing of comments with FCC
- Engage 802.18 TAG to convey objectives of 802.15.6 and benefit of MBANS proposal