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 9, 2008

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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.

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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
 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 <u>while simultaneously complying with strict non-interference guidelines where needed</u>. 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.</p>
- **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 <u>combination of reliability (QoS)</u>, 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 <u>operation on, in or around the</u> <u>human body to serve a variety of applications including medical</u> 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

May 2008

doc.: IEEE 802.15-08-0254-00-0006

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

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. 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: <u>http://www.fcc.gov/cgb/ecfs/</u> or the Federal eRulemaking Portal: <u>http://www.regulations.gov</u>. 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 <u>ecfs@fcc.gov</u>, and include the following words in

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

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).

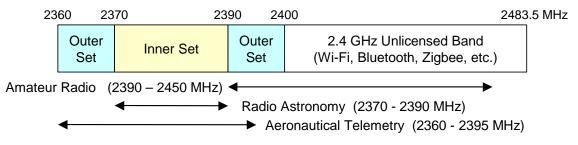
Proposed Part 95 Rules for Medical Body Area Network Service (MBANS)

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

- <u>2370-2390 MHz</u> limited to health care facilities and other environments where health care professionals monitor, diagnose and treat patients, including in ambulances.
- <u>2360-2370 MHz</u> and <u>2390-2400 MHz</u> 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

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

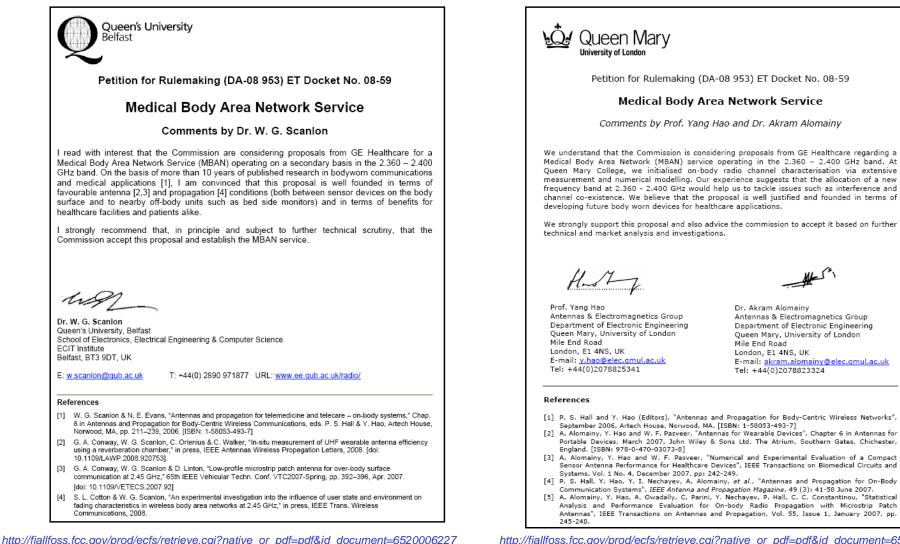
Future of MBANS proposal requires support from academic, industrial and medical communities

How to file comments



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Example comments filed with FCC



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Vote to 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
 - Other points?

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
- Support off 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