



Federal
Communications
Commission

FCC's Role in Promoting Innovation & Safety in Connected Health

NAS

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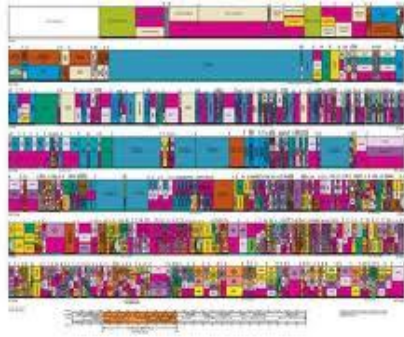


FCC Role in Connected Health

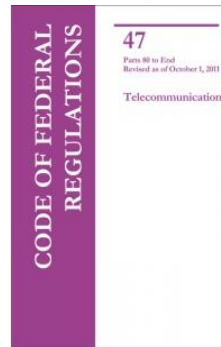
- Broadband: Advances both wireline and wireless communications services and technologies, thus enabling many medical and medical-associated applications.
- Federal Communications Commission (FCC) manages use of the radio spectrum by the private sector:
 - First, the Commission establishes technical regulations (frequency allocation, emission, etc.) for transmitters and other equipment to minimize their potential for causing interference to radio services.
 - Second, the Commission administers an authorization program to ensure that equipment reaching the market complies with the technical requirements. (Part 2 J)



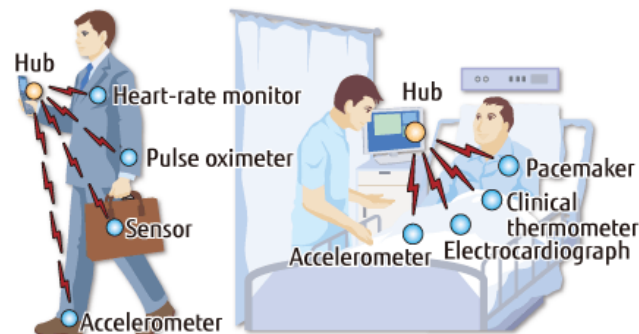
FCC as Enabler of Wireless Technologies in Connected Care



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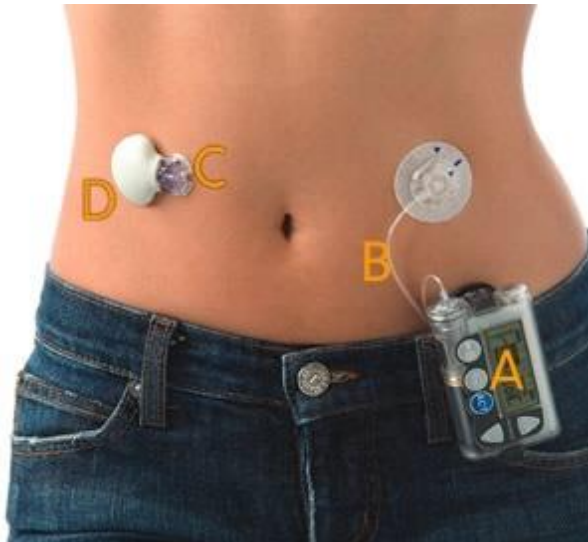


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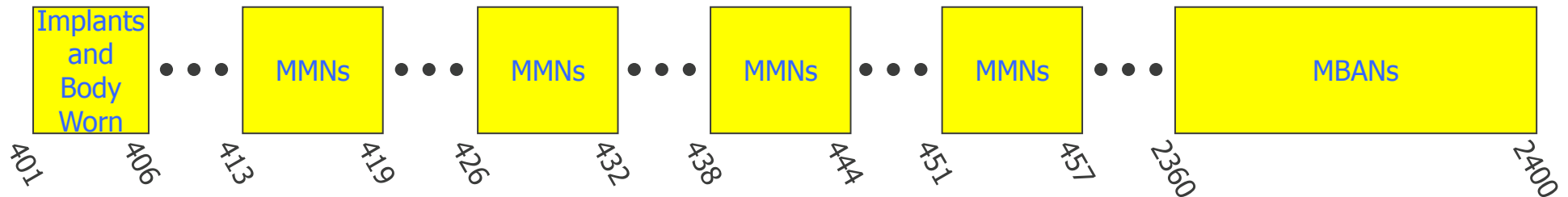
Wireless Medical Devices and Applications are Emerging



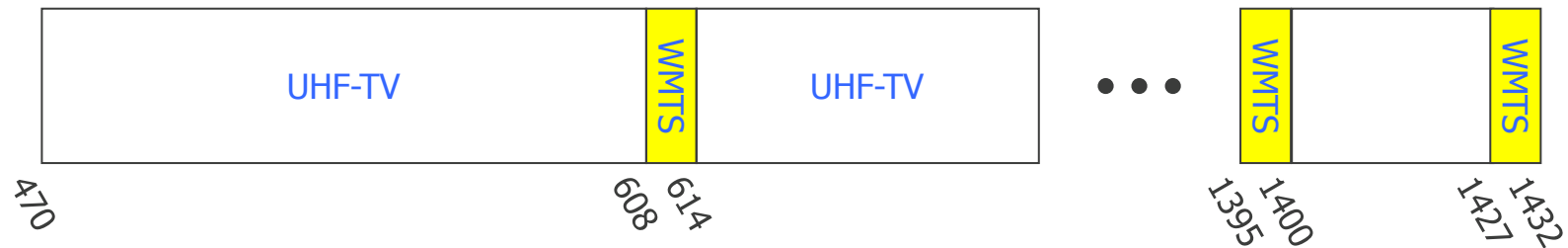


Spectrum for Medical Devices

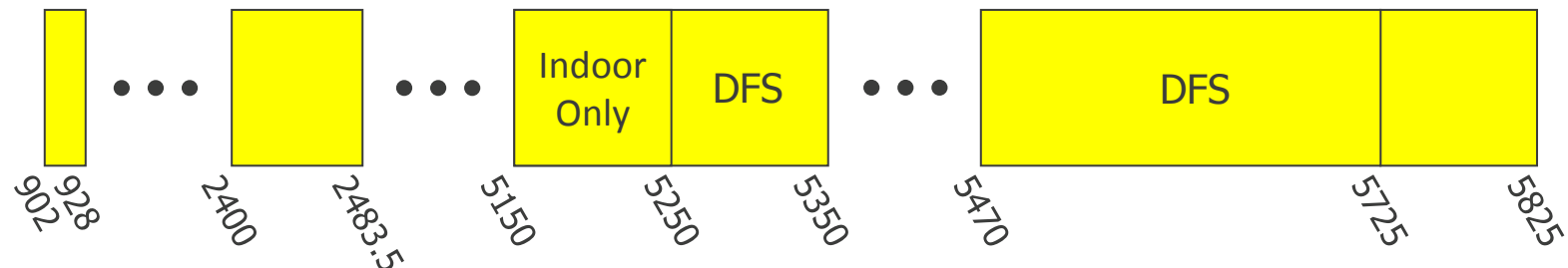
Medical Radiocommunications Service



Wireless Medical Telemetry Service



ISM & UNII Bands (Unlicensed Devices)





Equipment Authorization Required

- Multi-tiered equipment authorization program - - many devices self-declared
- Most transmitters must be certificated by FCC or telecommunications certification body
- Equipment may not be imported or marketed until certificated
- Check label for FCC ID
- Grants of certification available on FCC web site



See
<http://www.fcc.gov/oet/ea/>

FCC Id: XXXYYYY





Recent FDA Final Guidance on Wireless Medical Devices (Aug 13, 2013)

- **Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff**
- Addresses considerations that may affect the safe and effective use of medical devices that incorporate RF wireless technology (wireless medical devices), including:
 - Selection of wireless technology, quality of service, coexistence, security, and EMC.
- Such RF wireless technologies operate under a grant of certification and/or issuance of a license from the Federal Communications Commission (FCC).

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077210.htm>



FDASIA Workgroup Recommendations

FCC Issues

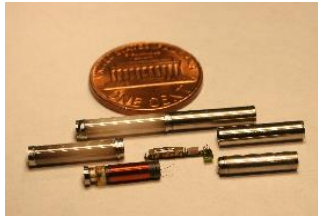
A = Ambiguous and B = Broken at the written law level

Item	Issue: A or B	Description of challenge
Pre-Installation Assessment	A	Planning for deployment of wireless technologies is difficult in spectrum-crowded, interference-prone environments (i.e. most hospitals). Pre-clinical test and evaluation tools and environments could help manufacturers and healthcare delivery organizations. (FCC “wireless test bed” initiative)
Post-installation Surveillance	A	Spectrum management and identification, diagnosing, and resolving wireless co-existence/Electromagnetic Compatibility (EMC) problems that affect HIT and medical device performance (in healthcare facilities and mHealth environments)

- Strategies for mitigating and troubleshooting risk ²⁷
- Wireless Test Bed Workshop
- Close collaboration with FDA (and ONC)



Recent FCC and Actions



- **Retinal Implants, November 2011:** granted a waiver to Second Sight Medical Products, Inc. of Section 15.209(a) of the Commission's rules
- **Medical Body Area Networks (MBANs), May 2012 and Aug 2014:** Order to allocate spectrum for Medical Body Area Networks, making the U.S. the first country in the world to make spectrum available for this specific usage. MBANs are networks of wireless sensors which transmit data on a patient's vital health indicators to their doctor or hospital.
- **Experimental Licensing Order, January 2013:** Order to promote expanded opportunities for radio experimentation and market trials, including medical devices
- **Participation in FDASIA, MOU with FDA and ONC, 2014**
- **Incentive Auctions, 2015**



CONNECT2HEALTH^{FCC} Task Force

- Bring together the expertise of the FCC on the critical intersection of broadband, advanced technology, and health
- Chairman Wheeler announced Michele Ellison as Chair
- Will consider ways to accelerate the adoption of health care technologies by leveraging broadband and other next-gen communications services.

“The Commission’s top priority must be to make networks work for everyone. Broadband itself is not the goal – it’s what broadband enables. We must leverage all available technologies to ensure that advanced health care solutions are readily accessible to all Americans, from rural and remote areas to underserved inner cities. By identifying regulatory barriers and incentives and building stronger partnerships with stakeholders in the areas of tele-health, mobile applications, and tele-medicine, we can expedite this vital shift.”

– FCC Chairman Tom Wheeler