MEDICAL RELATED WIRELESS STANDARDS

RONG ZHENG

OUTLINE

Basics of wireless communication

Spectrum allocation for medical applications

Wireless body area networks (WBANs)

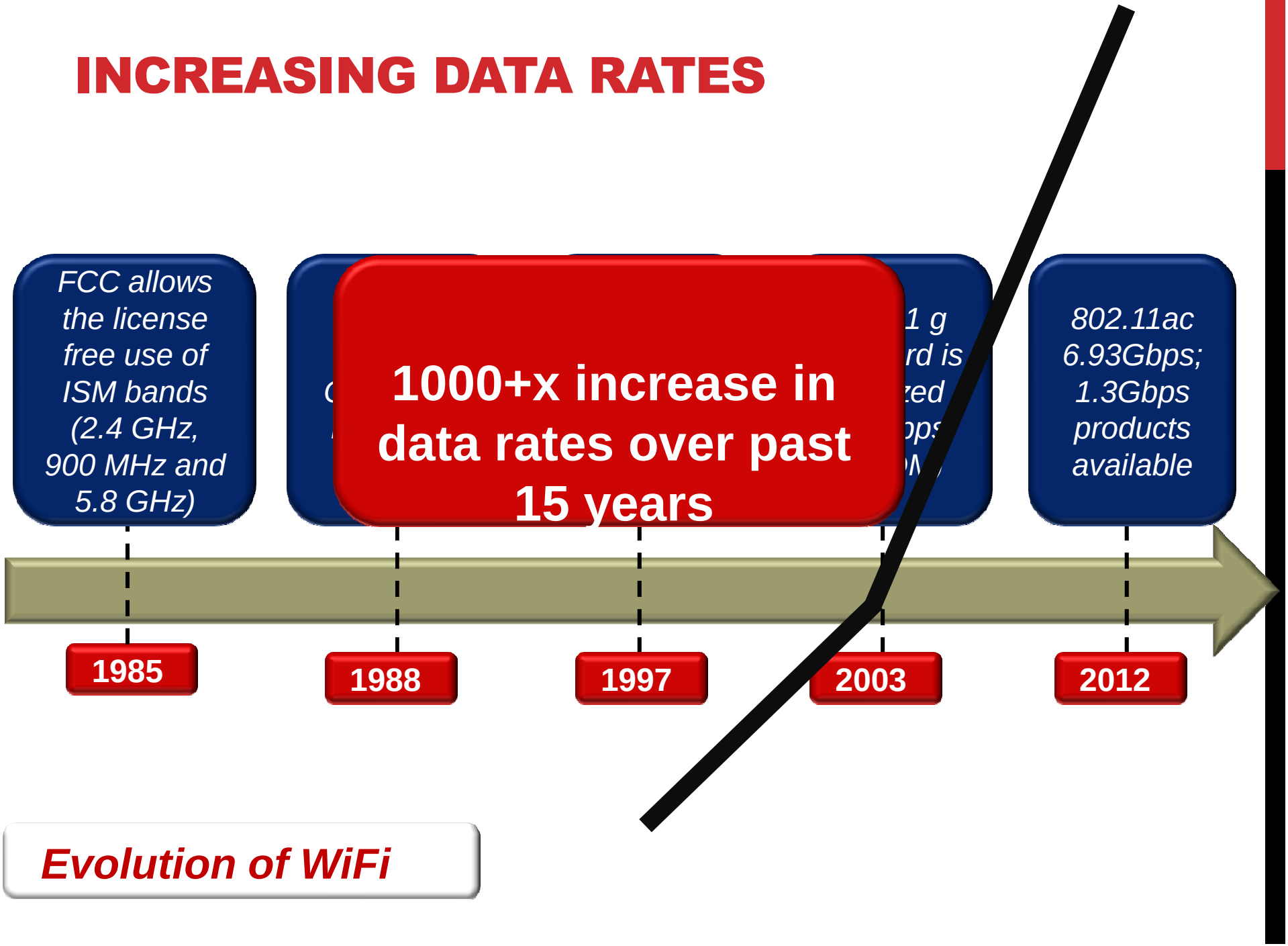
Wireless Co-existence

IT'S A WIRELESS WORLD!

Wireless, Mobile everywhere

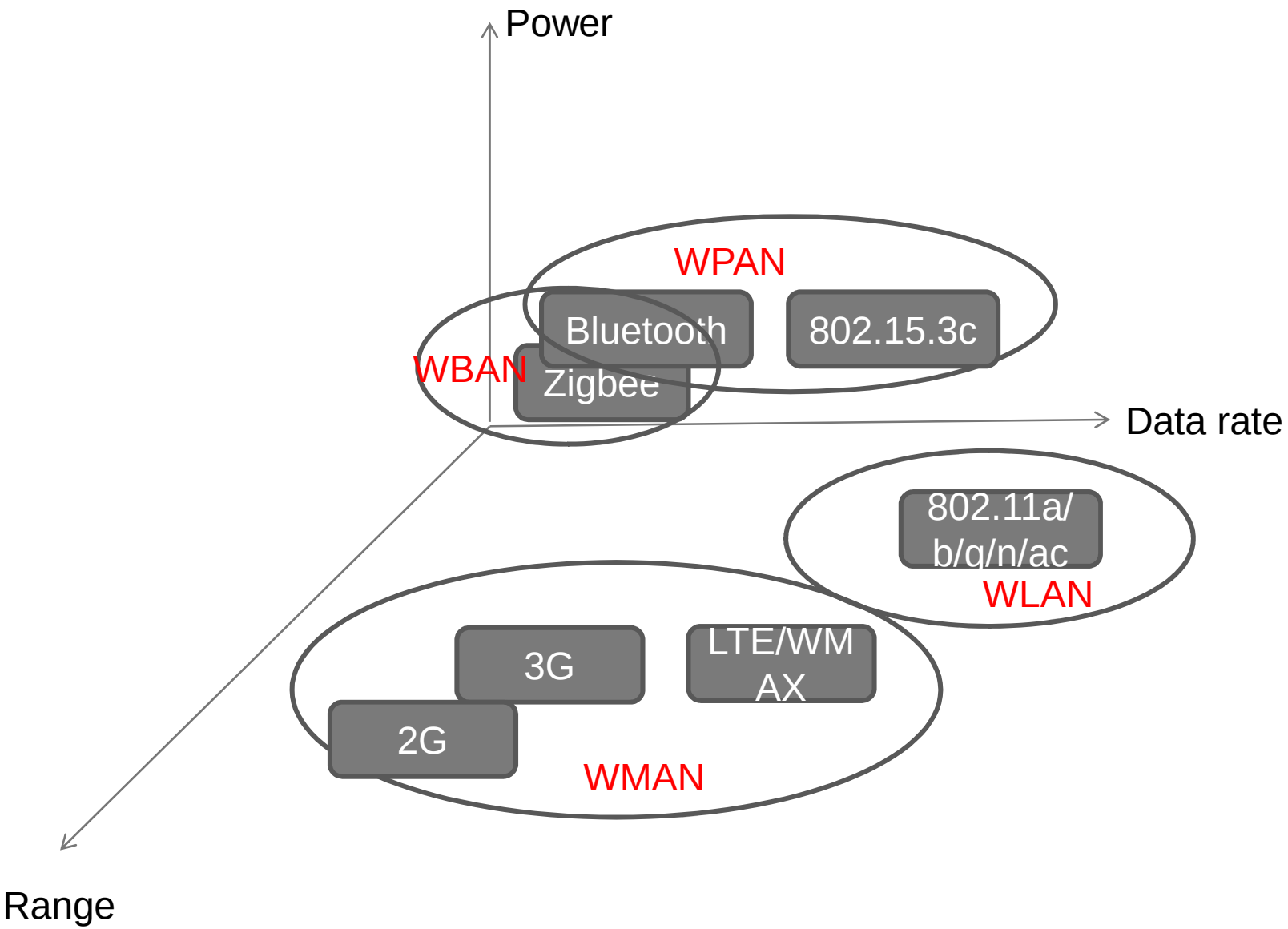
- WiFi @ 1+ Gbps standards being defined
- LTE/4G @ 100Mbps over wide-area
- Billion+ devices with wireless access

INCREASING DATA RATES

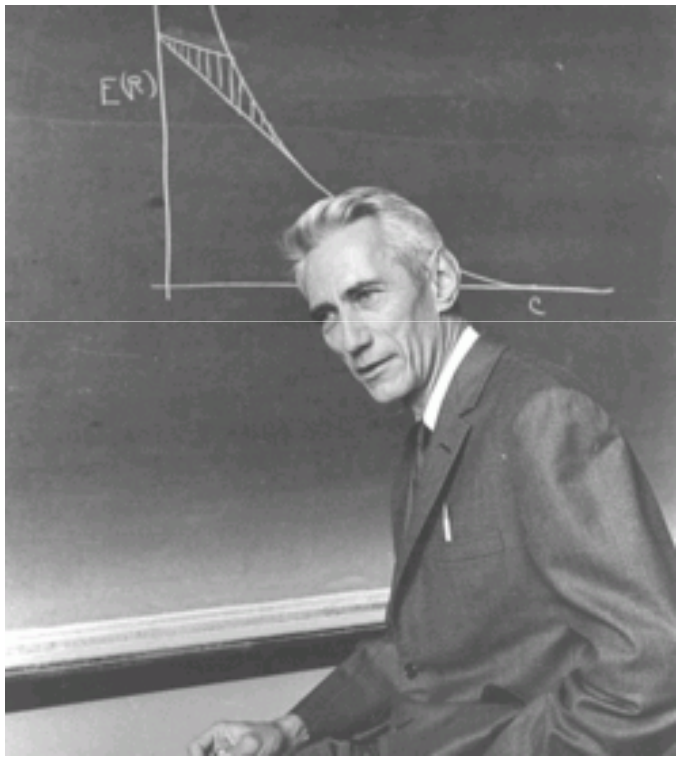


Evolution of WiFi

DIVERSE RANGE AND POWER CONSUMPTION



HOW MUCH FASTER/FURTHER/ENERGY EFFICIENT CAN WE GET?

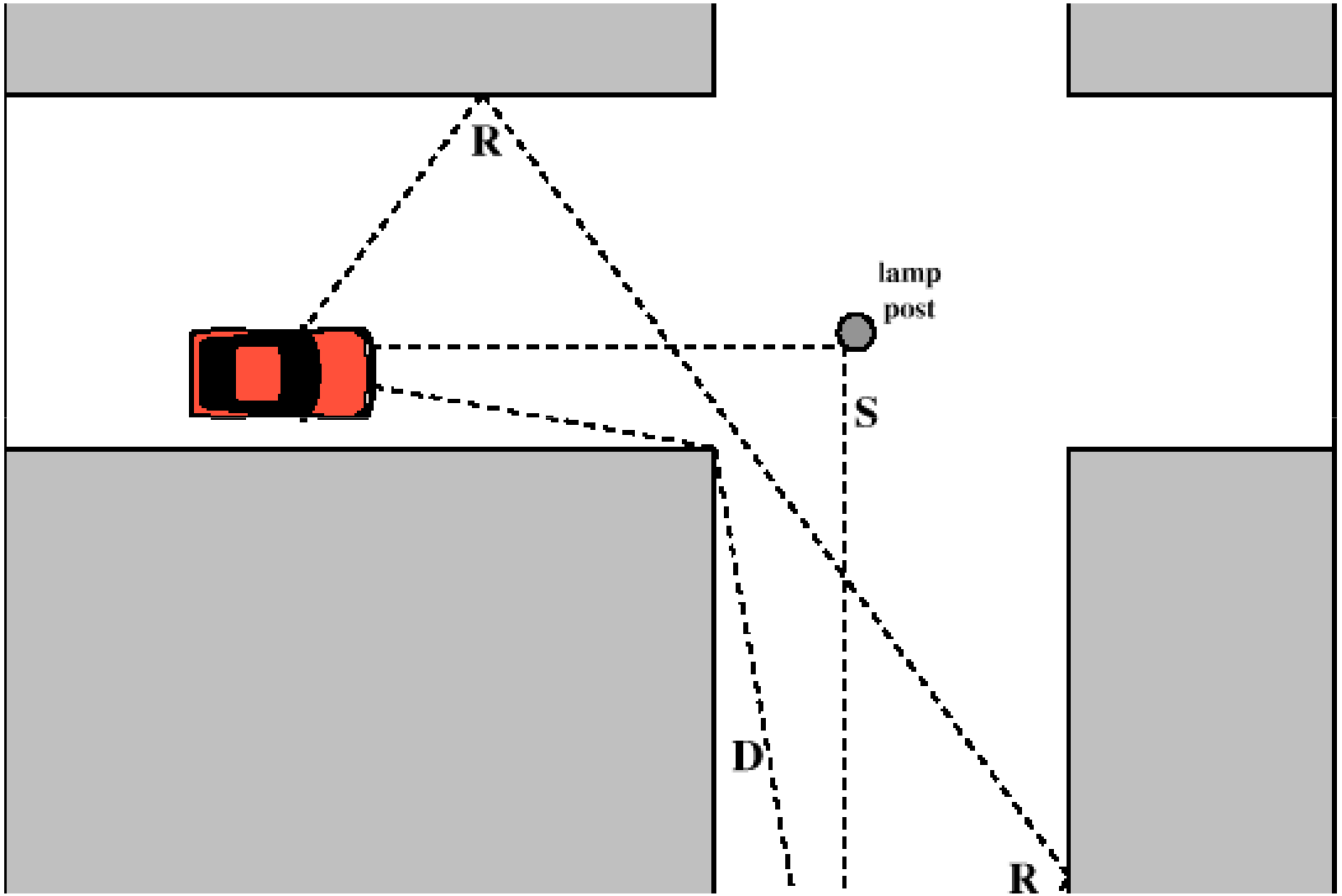


$$C = B\log_2\left(1+\frac{P_s}{N_o B}\right)$$

C is the capacity in bits per second, B is the bandwidth in Hertz, P_s is the signal power and N_0 is the noise spectral density.

RADIO PROPAGATION

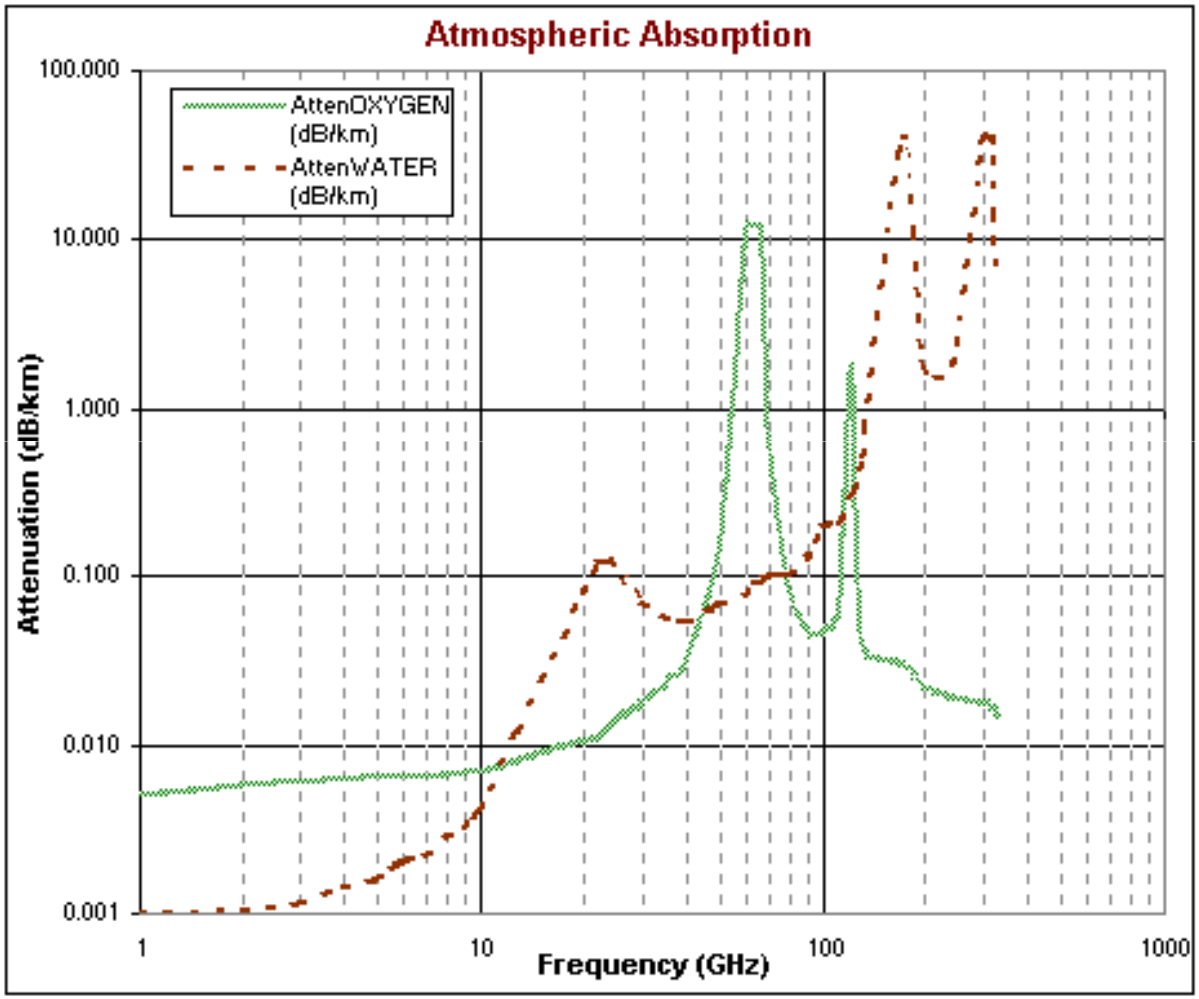
R: reflection
D: diffraction
S: Scattering



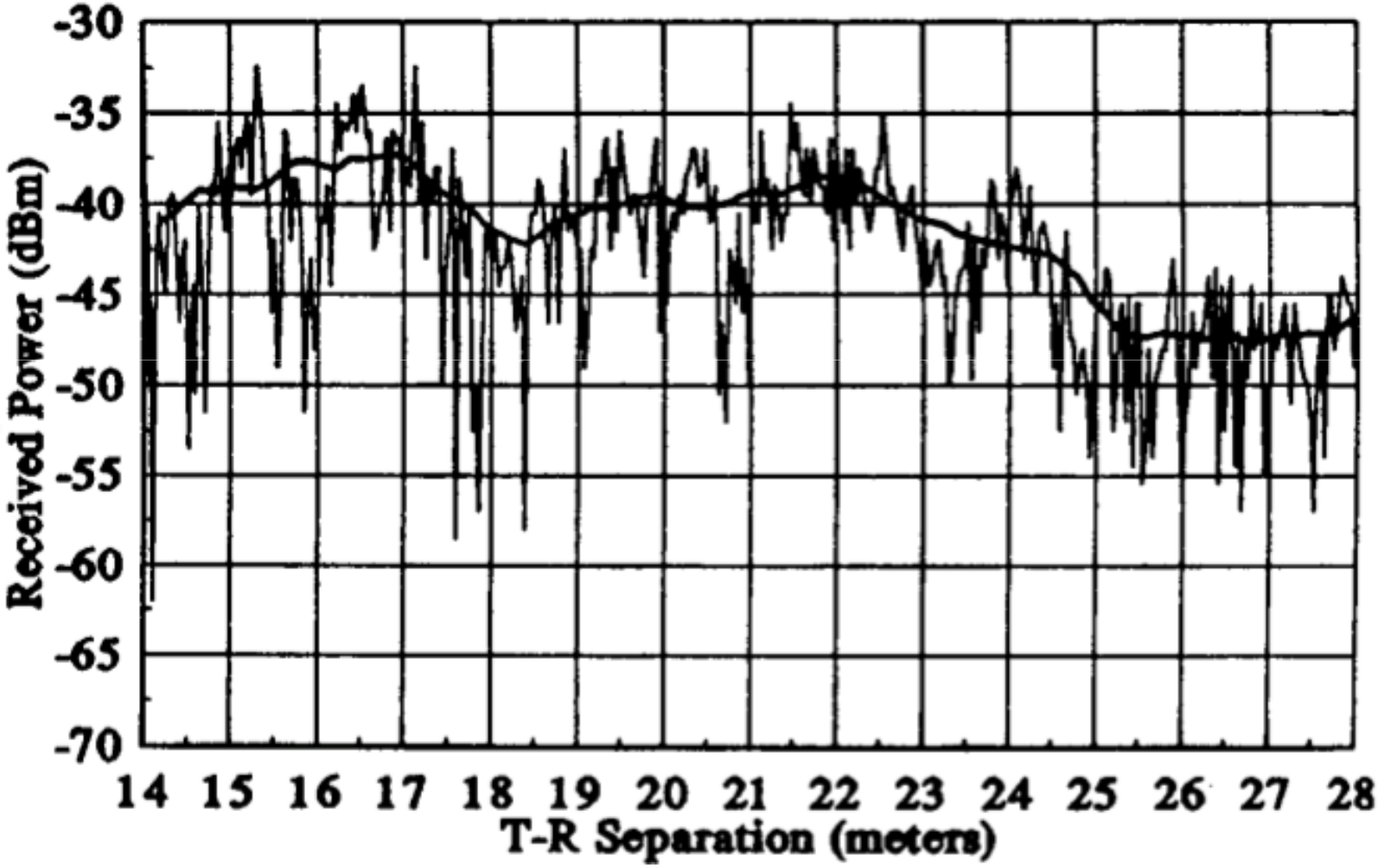
$\lambda = C / f$

Ex: $3e^8/2.4e^9 = 12.5cm$

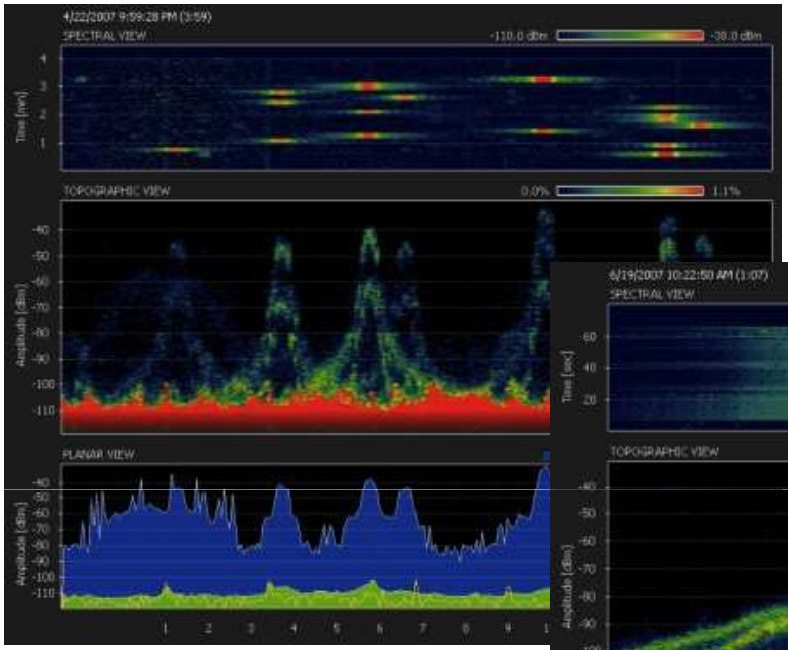
RF ABSORPTION



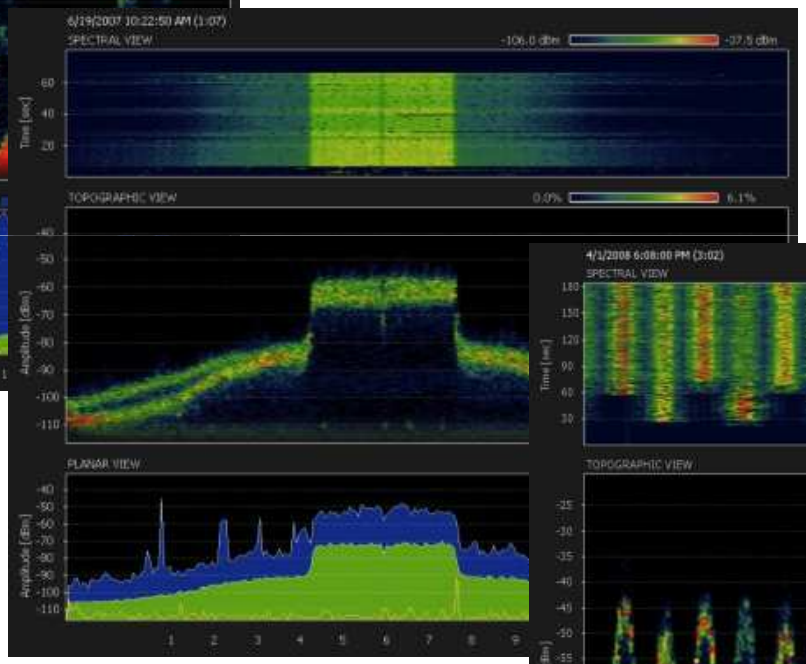
LARGE SCALE AND SMALL SCALE FADING



SPECTRUM USAGE

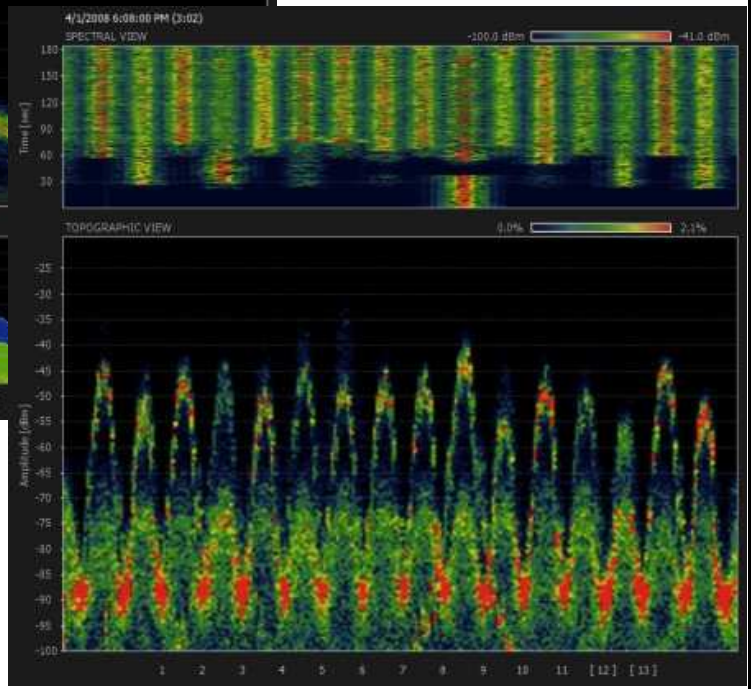


Cellphone

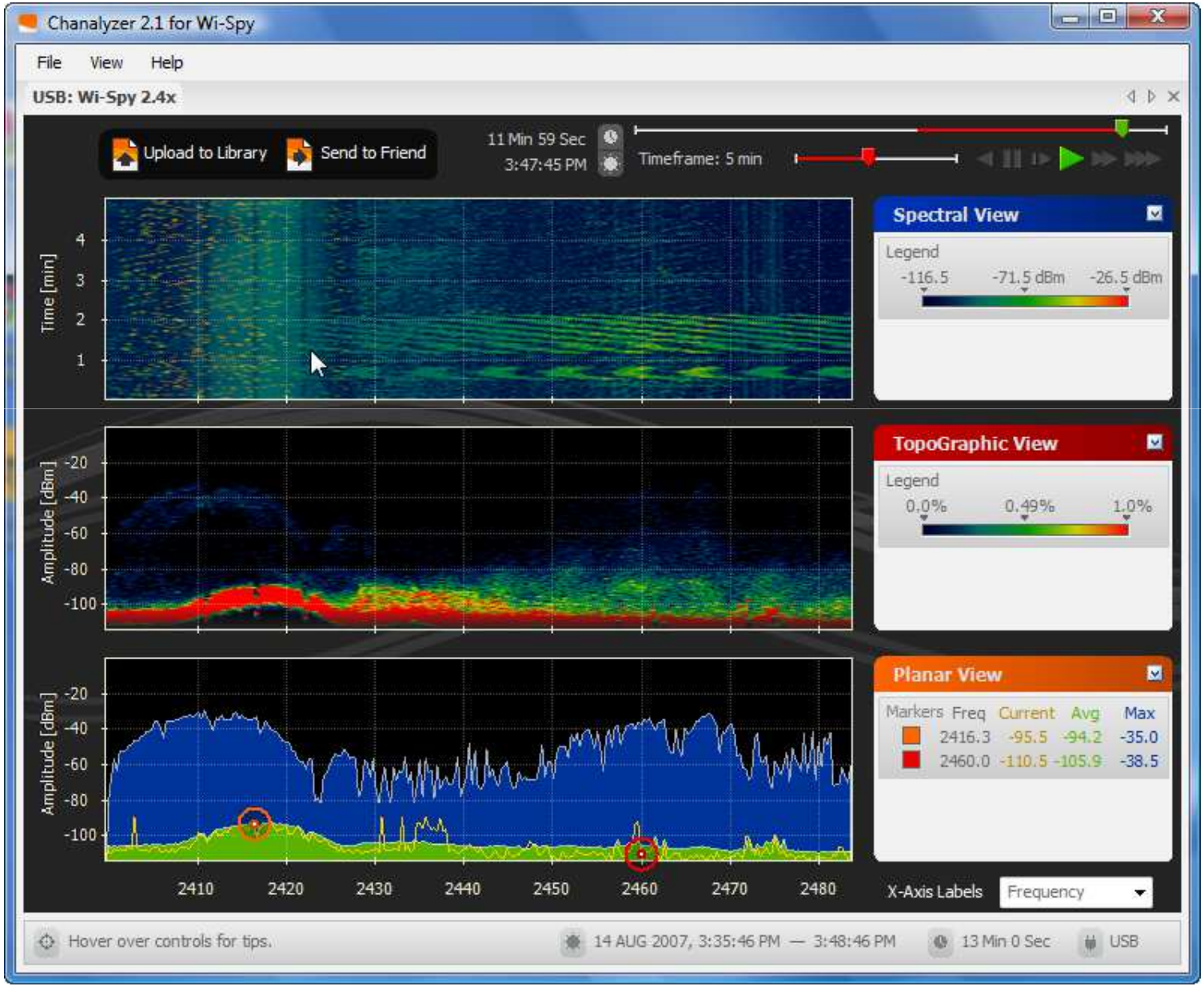


WiFi

Zigbee



EFFECTS OF MICROWAVE OVEN



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Wireless body area networks (WBANs)

Wireless Co-existence

US FREQUENCY ALLOCATION

UNITED STATES FREQUENCY ALLOCATIONS

THE RADIO SPECTRUM

RADIO SERVICES COLOR LEGEND

- AERONAUTICAL MOBILE
- AERONAUTICAL MOBILE SATELLITE
- AERONAUTICAL RADIONAVIGATION
- AMATEUR
- AMATEUR SATELLITE
- BROADCASTING
- BROADCASTING SATELLITE
- EARTH EXPLORATION SATELLITE
- FIXED
- FIXED SATELLITE
- INTER-SATELLITE
- LAND MOBILE
- LAND MOBILE SATELLITE
- MARITIME MOBILE
- MARITIME MOBILE SATELLITE
- MARITIME RADIONAVIGATION
- METEOROLOGICAL AIDS
- METEOROLOGICAL SATELLITE
- MOBILE
- MOBILE SATELLITE
- RADIO ASTRONOMY
- RADIODETERMINATION SATELLITE
- RADIOLOCATION
- RADIOLOCATION SATELLITE
- RADIONAVIGATION
- RADIONAVIGATION SATELLITE
- SPACE OPERATION
- SPACE RESEARCH
- STANDARD FREQUENCY AND TIME SIGNAL
- STANDARD FREQUENCY AND TIME SIGNAL SATELLITE

ACTIVITY CODE

- GOVERNMENT EXCLUSIVE
- GOVERNMENT/ NON-GOVERNMENT SHARED
- NON-GOVERNMENT EXCLUSIVE

ALLOCATION USAGE DESIGNATION

SERVICE	EXAMPLE	DESCRIPTION
Primary	FIXED	Capital Letters
Secondary	Mobile	1st Capital with lower case letters

This chart is a graphic single-point-in-time portrayal of the Table of Frequency Allocations used by the FCC and NTIA. As such, it does not completely reflect all aspects, i.e., footnotes and recent changes made to the Table of Frequency Allocations. Therefore, for complete information, users should consult the Table to determine the current status of U.S. allocations.

U.S. DEPARTMENT OF COMMERCE
National Telecommunications and Information Administration
Office of Spectrum Management

October 2003

* EXCEPT AERO MOBILE (R)

** EXCEPT AERO MOBILE

PLEASE NOTE: THE SPACING ALLOTTED THE SERVICES IN THE SPECTRUM SEGMENTS SHOWN IS NOT PROPORTIONAL TO THE ACTUAL AMOUNT OF SPECTRUM OCCUPIED.

SPECTRUM ALLOCATION FOR MEDICAL DEVICES (US)

Medical Device Radiocommunications Service (MedRadio)

- 401 – 406, 413 – 419, 426 – 432, 438 – 444, and 451 – 457 MHz range
- diagnostic and therapeutic purposes for implant and on-body device
- Secondary status

Wireless Medical Telemetry Service (WMTS)

- 608 – 614 (radio astronomy), 1395 – 1400, and 1427 – 1432 MHz (primary) range
- remote monitoring of a patient's health

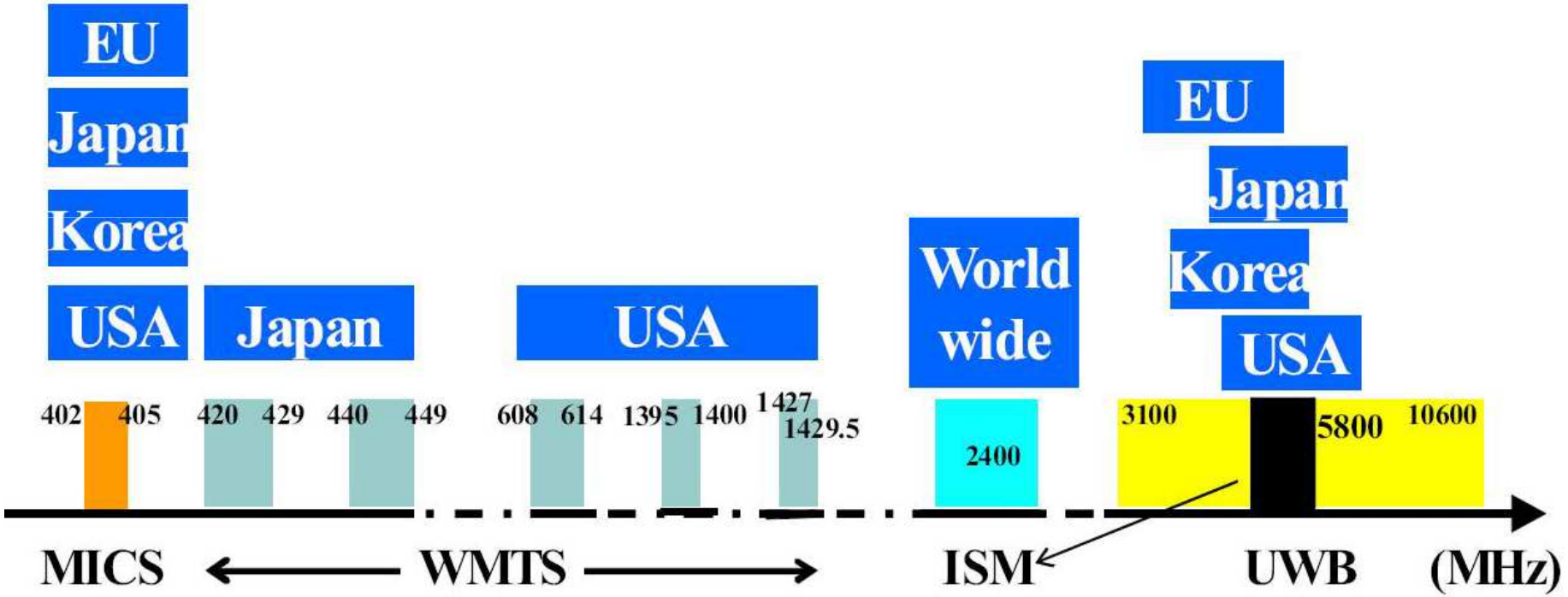
Industrial, scientific and medical (ISM) radio bands

- 6.765 - 6.795 MHz, 13.553 MHz - 13.567 MHz, 26.957 MHz - 27.283 MHz, 40.660 MHz - 40.700 MHz, 433.050 MHz - 434.790 MHz, 902.000 MHz - 928.000 MHz, 2.4GHz – 2.5GHz, 5.725 GHz - 5.875 GHz, 24GHz – 24.25GHz, 61-61.5 GHz, 122 – 123GHz, 244 – 246GHz

Medical BAN

- 2360-2400 MHz (2390-2400 MHz not require registration and coordination)

SPECTRUM ALLOCATION FOR MEDICAL DEVICES IN DIFFERENT REGIONS



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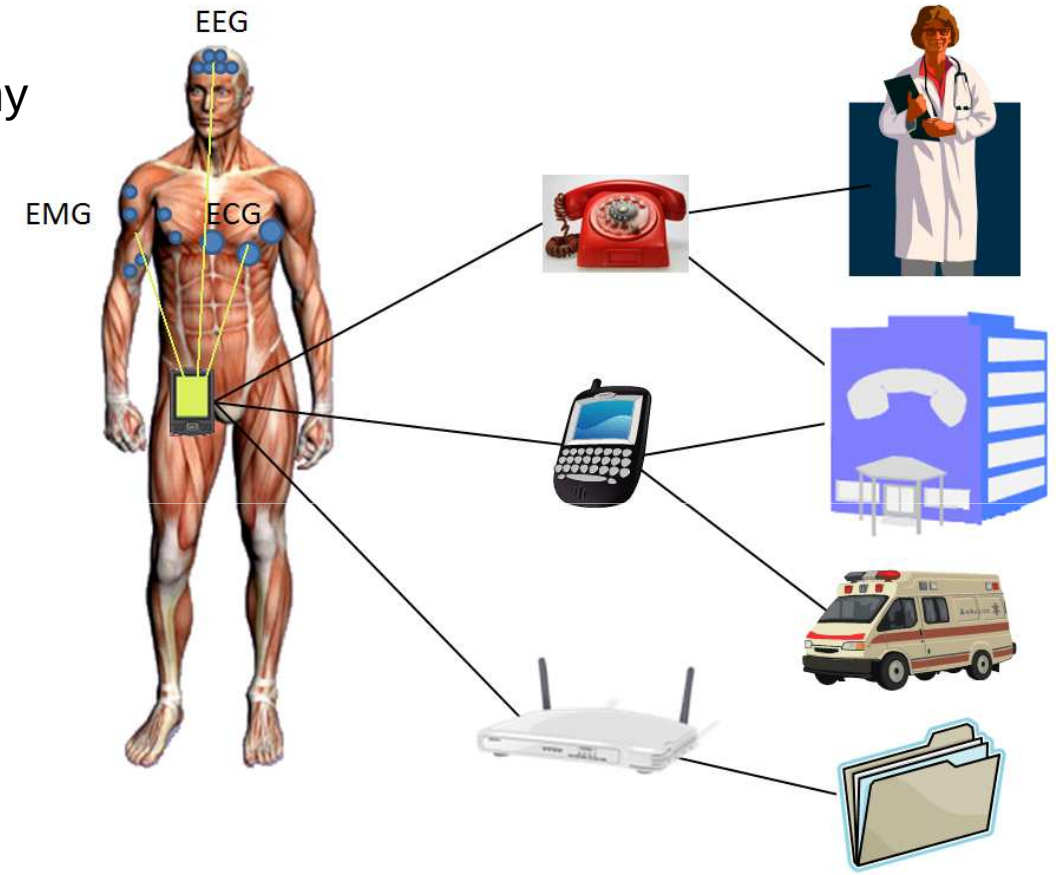
MEDICAL BODY AREA NETWORKS (mBAN)

- **Bio-Medical**
  - EEG Electroencephalography
  - ECG Electrocardiogram
  - EMG Electromyography (muscular)
  - Blood pressure
  - Blood SpO2
  - Blood pH
  - Glucose sensor
  - Respiration
  - Temperature
  - Fall detection
- **Sports performance**
  - Distance
  - Speed
  - Posture (Body Position)
  - Sports training aid



WEARABLE VS IMPLANT

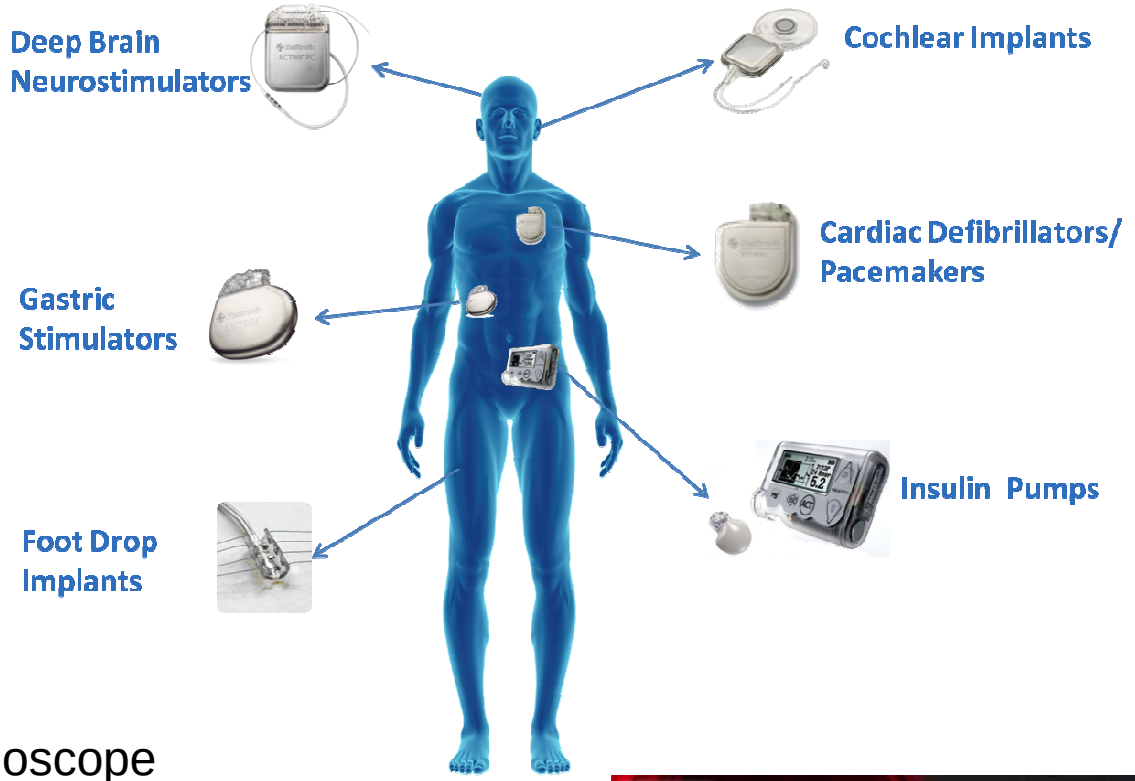
Wearable mBAN

- Tele-metering or sensing vita signs available
- On-body
- Frequency less constrained
- Short ranged

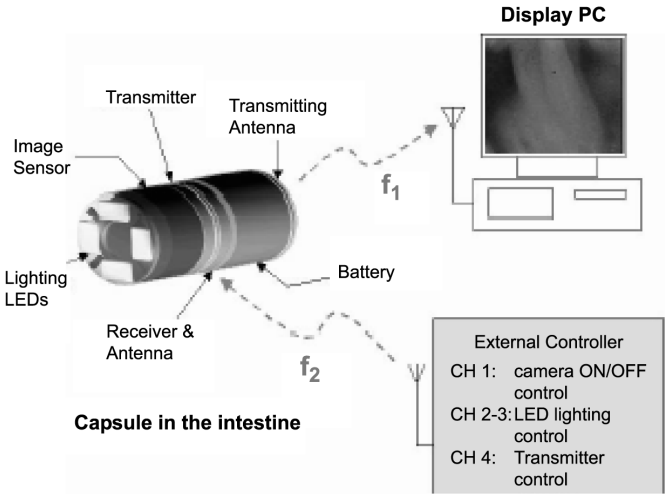
Implant mBAN

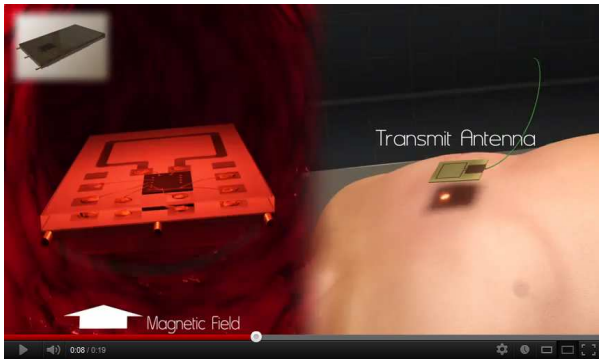
- Tele-control of (implanted) medical equipment and devices
- Typically in the MCIS band (~400MHz)
- Short ranged

WIRELESS IMPLANTABLE MEDICAL DEVICES



Wireless Endoscope





http://www.youtube.com/watch?v=oVCeGlrRGeY&feature=player_embedded

WIRELESS AREA NETWORK STANDARD

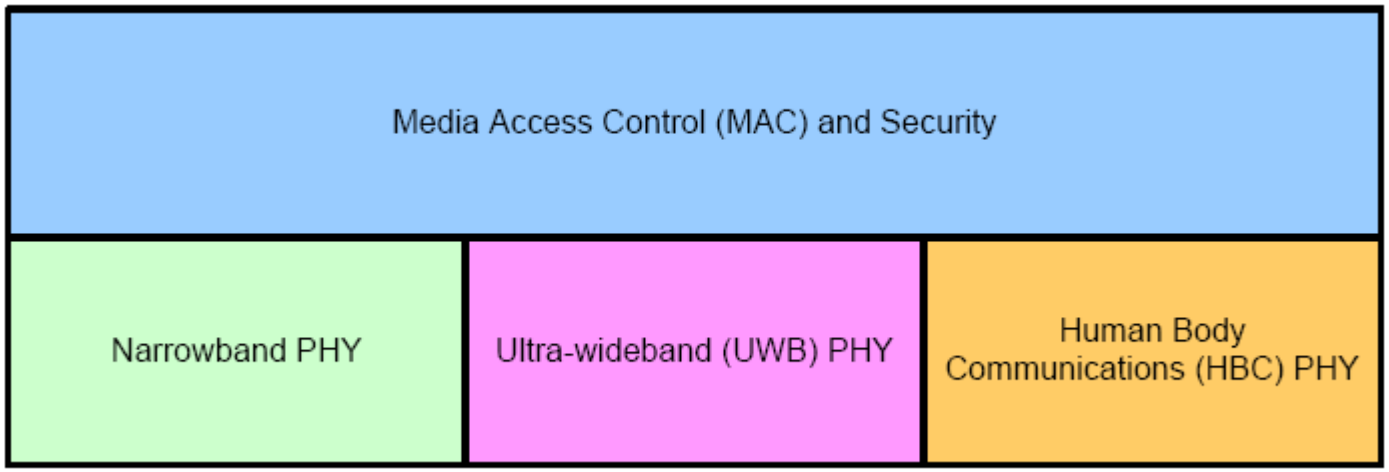
A Body Area Network (BAN) is defined as:

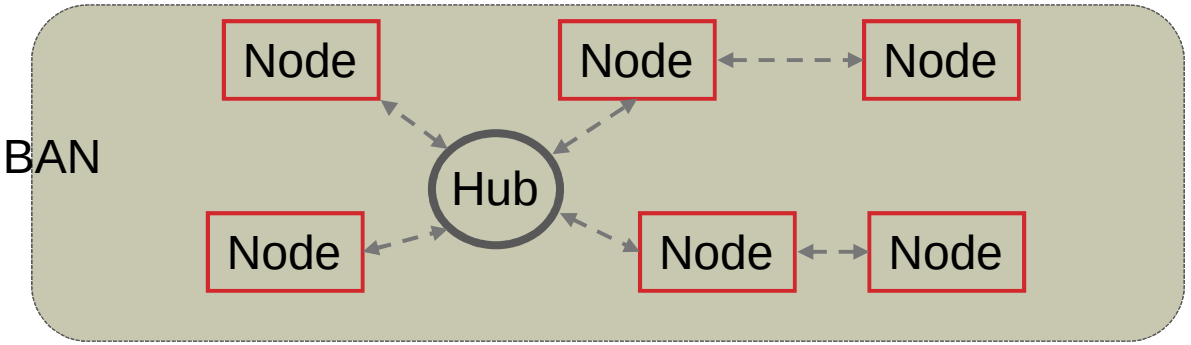
- “A communications technology that is optimized for low power consumption and operates in, on or around the human body to enable a variety of applications including medical, consumer electronics and personal entertainment”

IEEE 802.15.6 defines the Physical (PHY) and Medium access control (MAC) layers

- Short-range, low-power, Quality of Service (QoS) support in the vicinity of, or insides, a human body (but not limited to humans)

ARCHITECTURE



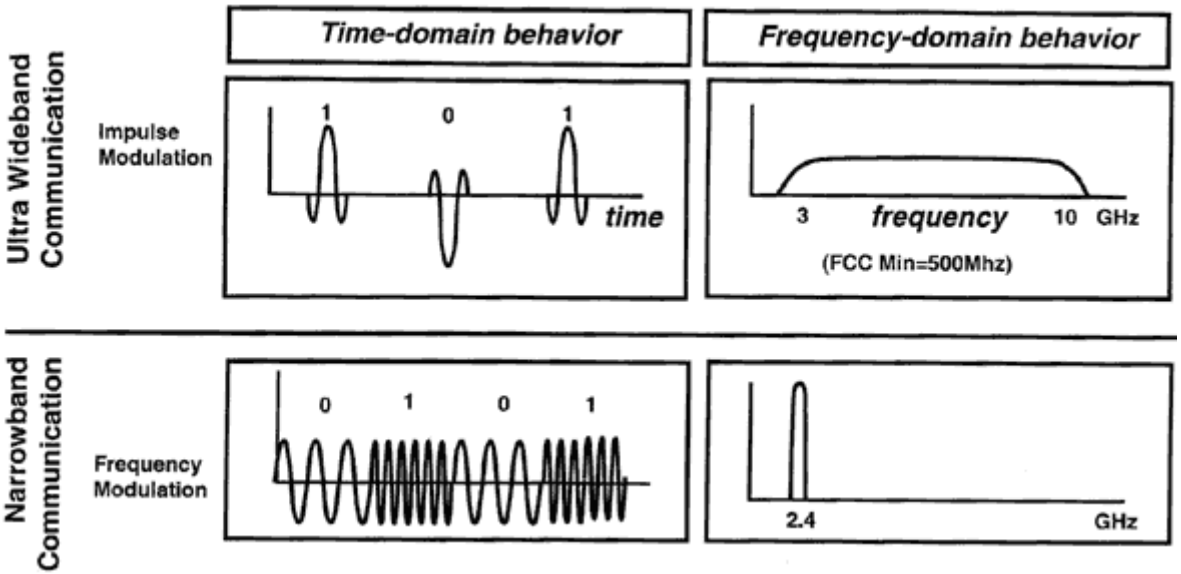


NARROWBAND PHY

Band (MHz)	Number of Channels	Modulation	Symbol Rate (ksps)	Code Rate (k/n)	Spreading Factor (S)	Pulse Shape	Information Data Rate (kbps)	Support
402 – 405	10	π/2-DBPSK	187.5	51/63	2	SRRC	75.9	Mandatory
		π/4-DQPSK			1		151.8	
		π/8-D8PSK					303.6	
							455.4	Optional
863 – 870 902 – 928 950 – 956	14 60 16	π/2-DBPSK	250	51/63	2	SRRC	101.2	Mandatory
		π/4-DQPSK			1		202.4	
		π/8-D8PSK					404.8	
							607.1	Optional
2360 – 2400 2400 – 2483.5	39 79	π/2-DBPSK	600	51/63	4	SRRC	121.4	Mandatory
					2		242.9	
		π/4-DQPSK			1		485.7	
							971.4	

- low peak-power consumption (≤ 3 mA)
- Scalable data rates: 100 –1000 kbps
- Support for 10+ simultaneously operating networks

UWB PHY



Impulse radio (IR-UWB) and wideband FM (FM-UWB)

Low interference

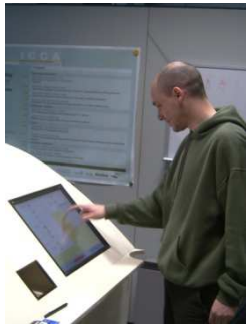
Bit rate up to 12Mbps

Band group	Channel number	Central frequency (MHz)	Bandwidth (MHz)	Channel attribute
Low band	1	3494.4	499.2	Optional
	2	3993.6	499.2	Mandatory
	3	4492.8	499.2	Optional
High band	4	6489.6	499.2	Optional
	5	6988.8	499.2	Optional
	6	7488.0	499.2	Optional
	7	7987.2	499.2	Mandatory
	8	8486.4	499.2	Optional
	9	8985.6	499.2	Optional
	10	9484.8	499.2	Optional
	11	9984.0	499.2	Optional

HUMAN BODY COMMUNICATION (HBC)

Designed for exchanging data between devices by touching

- The electrode in contact with the body is used for transmitting or receiving an electrical signal through the body to a device (e.g. smartphone)



e-Payment via touch screen

Exchange e-business cards via handshake

HBC uses 21MHz band

Data Rate (21MHz)
164 kbps
328 kbps
656 kbps
1.3125 Mbps

MAC LAYER

Supports Quality of Service (QoS)

Supports MICS band communication support

Supports Emergency Communications

Supports hub to node as well as hub to node to node

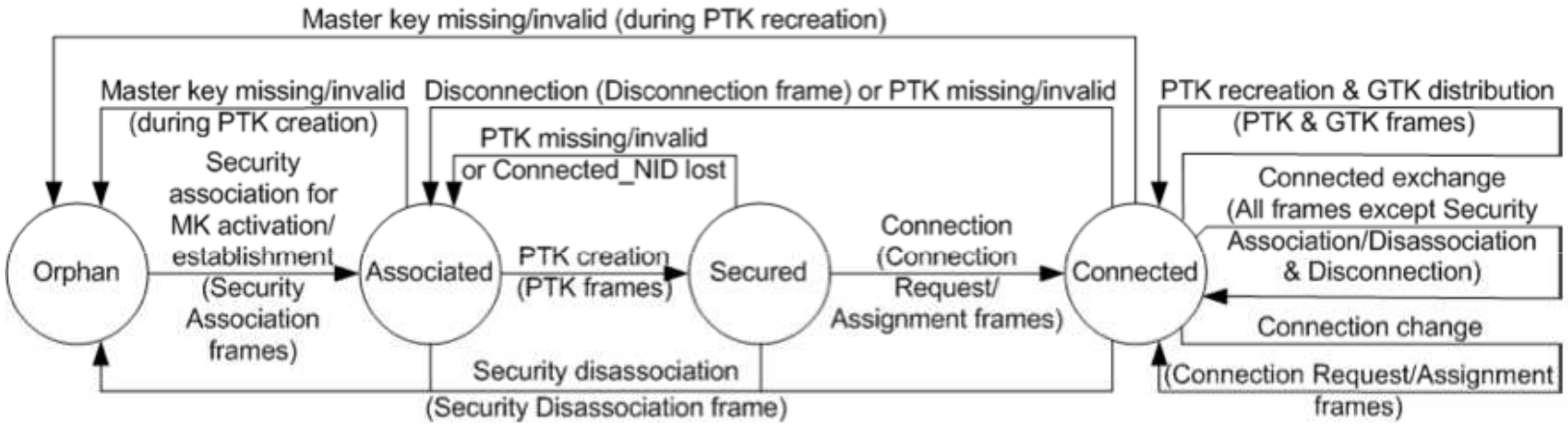
Strong Security

Macroscopic and microscopic power management

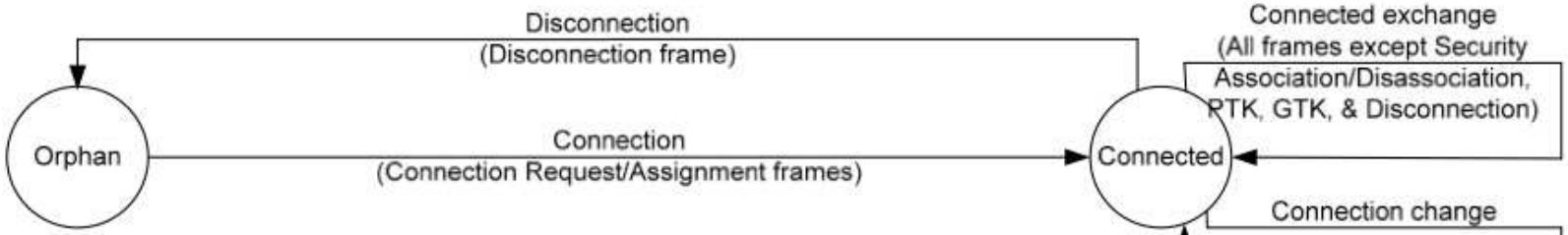
Coexistence and interference mitigation

SECURED COMMUNICATION

Can choose from 1) unsecured communication 2) authentication but not encryption and 3) authentication and encryption



(a) Secured communication



(b) Unsecured communication

MAC SUPPORT OF PRIORITY

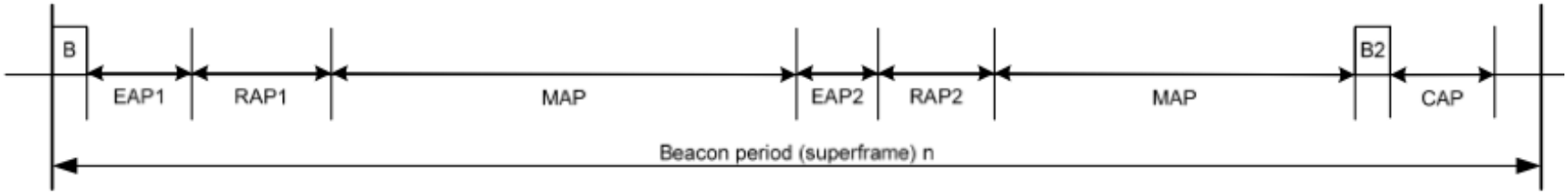
BAN Priority field encoding

Field value in decimal	BAN services
0	Non-medical services
1	Mixed medical and non-medical services
2	General health services
3	Highest priority medical services

User priority mapping

Priority	User Priority	Traffic designation	Frame type	Contention windows in CSMA/CA
Lowest	0	Background (BK)	Data	[16. 64]
]	1	Best effort (BE)	Data	[16, 32]
	2	Excellent effort (EE)	Data	[8, 32]
	3	Video (VI)	Data	[8, 16]
	4	Voice (VO)	Data	[4, 16]
	5	Medical data or network control	Data or management	[4, 8]
	6	High priority medical data or network control	Data or management	[2, 8]
Highest	7	Emergency or medical event report	Data	[1, 4]

MEDIUM ACCESS



Beacon mode with beacon periods (superframe)

- B -- beacon
- Exclusive access phase 1 (EAP1), exclusive access phase 2 (EAP2)
  - for highest priority data
- Random access phase 1 (RAP1), random access phase 2 (RAP2)
  - (can be combined with EAPs)
- Managed access phase (MAP), and
  - Scheduled up/down link transmissions
  - Suitable for periodic traffic
- Contention access phase (CAP) (optional)

CSMA/CA

8

Node A

Inter-frame spacing

Node B

Inter-frame spacing

Inter-frame spacing

16

OTHER FEATURES

Power management

- Node can perform macroscopic power management by sleeping more than one beacon period, or
- Microscopic power management within a beacon period

Coexistence and interference mitigation among multiple BANs

- Beacon shifting
- Channel hopping (after dwelling in the current channel for a fixed number of beacon periods)
- Active superframe interleaving

Two-hop star topology extension

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MEDICAL DEVICE

Definition: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is

- Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

CLASSIFICATION OF MEDICAL DEVICES

Classification I – III: low to high risk to the patient/users

- Consult classification database

How did the AED industry get into this state? It has to do with a quirk in the law regulating medical devices. If you count AEDs as Class III devices—those intended to support and sustain life—then manufacturers must produce extensive efficacy, safety, and reliability data, usually provided by large-scale clinical trials. This process can cost upward of US $800 000 and take two years.

Manufacturers can, however, get around those requirements, thanks to what's called the 510(k) process, which effectively removes AEDs from Class III. The process requires merely that a new AED be "substantially equivalent" to any AED on the market. The 510(k) system was originally intended as a temporary measure to grandfather in devices already on the market in 1976. More than 30 years later, the process is still being used to clear AEDs, as well as 25 other high-risk products, including implantable pacemakers, ventricular bypass devices, and systems for electroconvulsive therapy. Meanwhile, external defibrillators have graduated from manual operation that requires some

from *The Shocking Truth About Defibrillators – IEEE Spectrum*

RADIO-FREQUENCY WIRELESS TECHNOLOGY IN MEDICAL DEVICES (FDA)

Electromagnetic compatibility (EMC) — the ability of a device to function (a) properly in its intended electromagnetic environment, and (b) without introducing excessive electromagnetic energy that may interfere with other devices

Wireless coexistence -- The ability of one wireless system to perform a task in a given shared environment where other systems (in that environment) have an ability to perform their tasks and may or may not be using the same set of rules

ETSI EN 301 839 (EUROPEAN STANDARD)

Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz;

- Test procedures and testing equipment (e.g., human toso emulator) requirements
- Normal and extreme conditions
- Transmitter and receiver requirements: freq drifts, bandwidth, spurious emissions/radiation, duty cycle
- Listen before talk (LBT) and 30 seconds per hour for Medical Implant Event

IEC 60601-1-2:2001 (INTERNATIONAL STANDARD)

Medical Electrical Equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

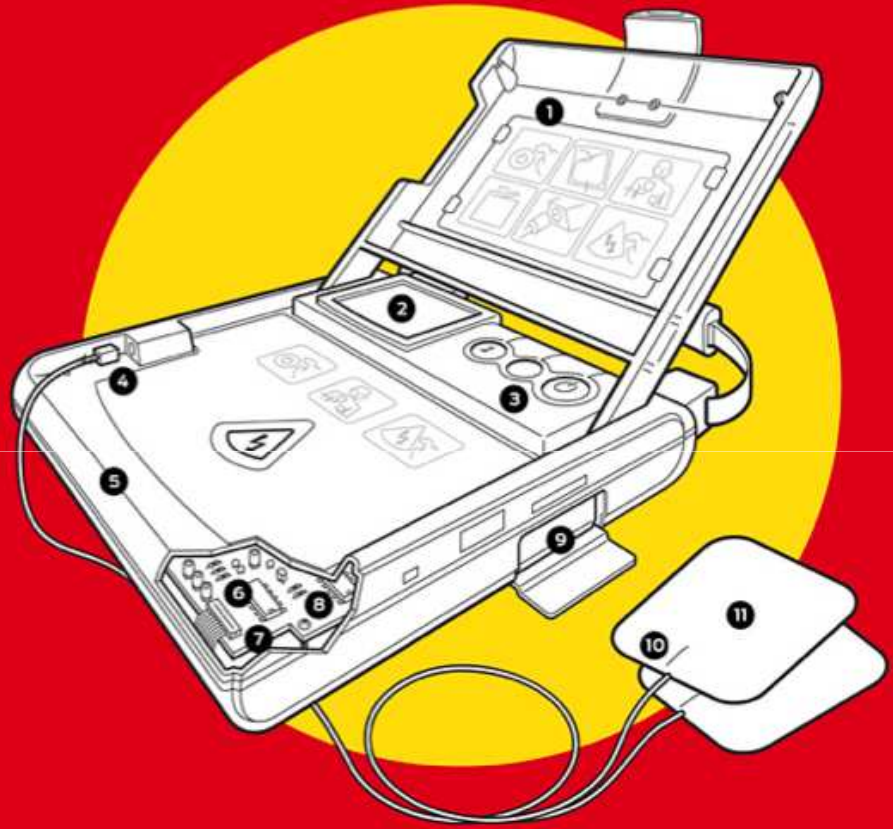
- Specifies testing limits for electrostatic discharge (ESD), radiated radio-frequency (RF) immunity, surge immunity, and electrical fast transients (EFTs)
- Test procedure for conducted RF immunity, magnetic field immunity, voltage dips, harmonic distortion, and voltage flicker.

ANYTHING THAT CAN GO WRONG WILL GO WRONG

from *The Shocking Truth About Defibrillators – IEEE Spectrum*

If It Can Go Wrong...

it will—unless engineers can design AEDs that work without fail after sitting in a box for years at a stretch



1 **USER INTERFACE** Controls can be confusing; voice prompts may refer to buttons that are not visible.

2 **LCD** Information on displays can be difficult to read, particularly in bright light or from a wide angle.

3 **STATUS INDICATOR** An unexpected shutdown can result from component failures or poor design.

4 **CABLES AND CONNECTORS** Incompatible or damaged cables can lead to serious malfunctions.

5 **CASING AND CONSTRUCTION** Cases may not sufficiently protect the device from humid conditions and minor knocks.

6 **VOLTAGE MONITORING CIRCUIT** If this draws power from the source it monitors, a false alert can cause a shutdown.

7 **CIRCUIT BOARDS** Faulty circuit boards are the main cause of repairs on malfunctioning AEDs.

8 **RESISTORS** The wrong resistor can lead to misdiagnosis of the ECG waveform.

9 **BATTERIES** Problems with power management, recharging, or accidental discharge can make AEDs cancel shocks.

10 **ELECTRODES** These can dry out if not maintained and regularly replaced.

11 **PADDLES** Skin burns may occur at the electrode sites, particularly during repeated defibrillation attempts.

12 **SOFTWARE** Bugs cause error messages or malfunctions.

13 **POWER-UP SELF-TEST** If tests miss component defects, the device may fail.

14 **LOCATION AND DISPLAY** Many units are inaccessible or marked "For use by trained personnel only."

SUMMARY

Medical wireless body area networks are happening

Subject to extensive testing and regulations

From EMC to wireless co-existence