Body Area Networks Standardization

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Challenges in Healthcare

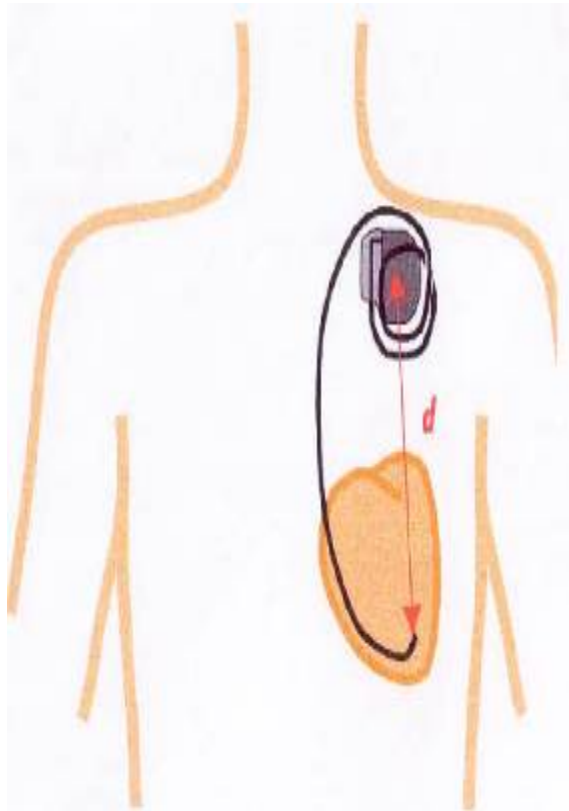
Skill Labor is Becoming Scare	• *Registered nurse shortage*: Projected to be 1 million in the US by 2020 [1] • *Short supply of specialized doctors in the US*: Aging population => increase in critically ill [2]
Reporting Requirements are Significant	• *More than 300 external reporting requirements* • *Manual recording of patient information*: 40% of patient care time for each active bed [3]
Next Generation Patient Monitoring Systems are Needed	• *ICU monitoring*: 10% of all US hospital beds with significant monitoring of the patient [4] • *Medical errors*: More people die from them than from breast cancer, AIDS, or vehicle accidents • *Demand for automated patient monitoring in the US*: Increase by 5.4% annually through 2010 [5]

Need Low-Power, Low-Cost, Wireless Sensors (Wireless Body Area Networks)

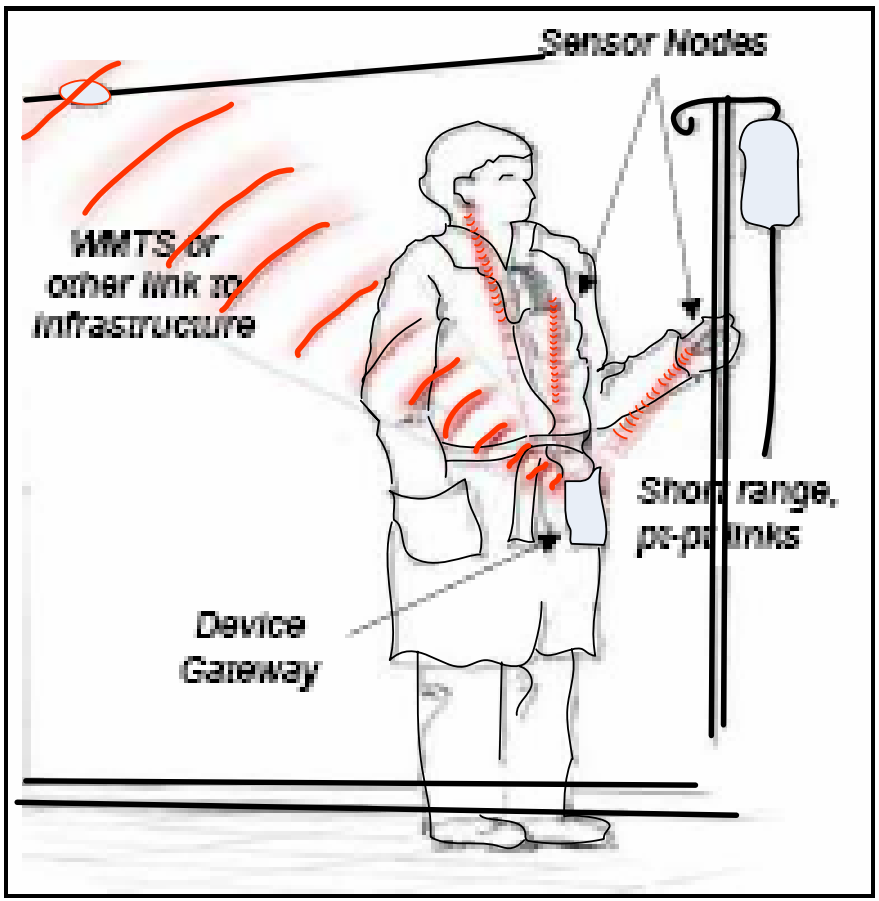
[1] U.S. Department of Health and Human Services
[2] "The Critical Care Workforce: A Study of the Supply and Demand for Critical Care Physicians," Health Resources and Service Administration, 22 May 2008
[3] "ICU Data Center, Inc.", University of Florida Office and Technology Licensing October 2006
[4] D. Davenport, "Medical Body Area Network Application," GE Global Research, IEEE 802.15-08-0108-00-006
[5] "Patient Monitoring Systems to 2010," The Freedonia Group, 1 May 2006

Applications: Implantables

- Different types of implantables
  - Neuro stimulators, Cardiac pacemekers, defibrillators, Cochlear implants, Drug delivery (eg. Diabetes) etc.
- Different usage scenarios
  - Surgical scenario, Doctors office, Home monitoring
- Two way communication
  - Record and transmit data
  - Receive commands and programming
- Few meters of range



Applications: Patient Monitoring



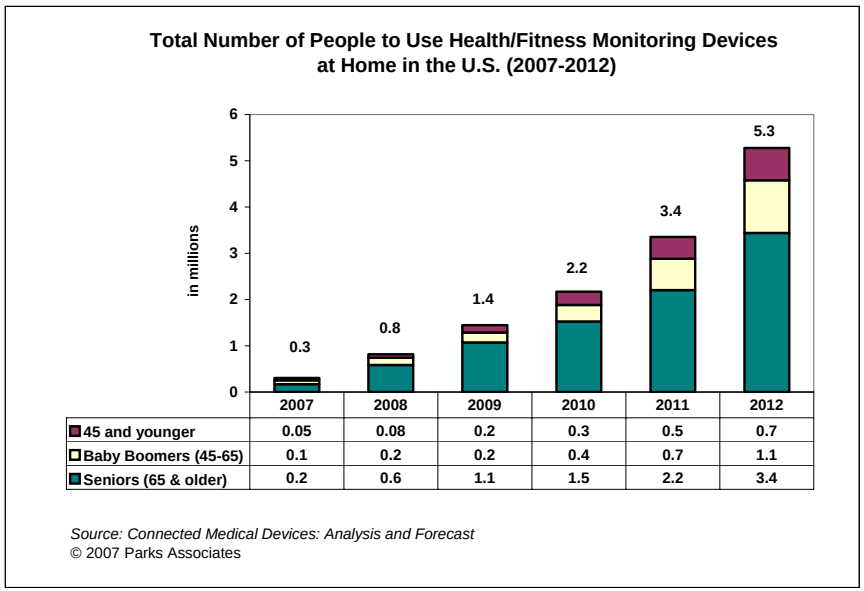
- Monitoring of patient vitals
  - ECG, EEG, PulseOx, blood sugar, temperature etc.
- Different environments
  - Home, Hospital, Ambulance etc.
- Wearable sensors
  - Patient mobility, comfort, infection control
  - Monitoring flexibility and scalability

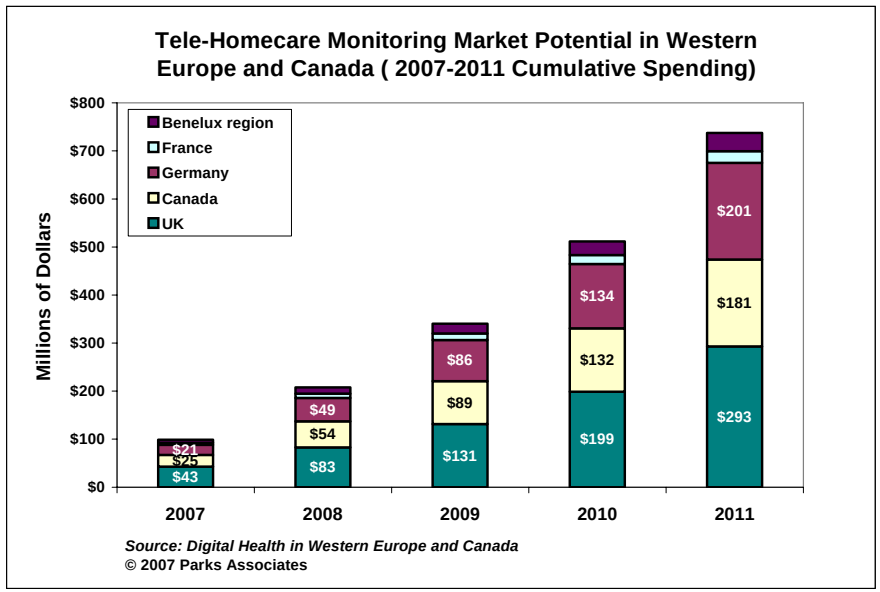
Other Applications

- Wireless Capsule endoscopy
  - Patient takes a pill with digital camera
  - Wireless transmission of endoscopy data to a gateway device
- Health and Fitness
  - Heart rate monitor, Weighing scale, Thermometer, Cardiovascular fitness and activity monitor, Strength fitness equipment
- Independent Living for Aged
  - Disease management devices, Medication monitor

Need Low-Power, Low-Cost, Wireless Sensors (Wireless Body Area Networks)

Market Size for Monitoring





- Consumer/Government/Corporations and Insurance companies will also drive the adoption
- Baby boomers are expected to double home monitoring market year over year
- Significant market growth even among 45 and younger

What are Body Area Networks

- Wireless network of sensors
- Sensors can be located both inside and on the body
- Implantable sensors communicate with gateways just outside the body
- On-body sensors communicate with gateways at short ranges of up to 3m
- Devices must be able to support different types of sensors
- Sensors must be able to work in different environments
  - Hospitals, at home/work, ambulance etc.
- Must be ultra low power, frequency band agnostic, with varying duty cycles
- Devices must support scalable data rates from 10bps to 10Mbps
- Sensors need to protect privacy and should have simple setup with short access times
- BANs need to coexist with legacy networks/devices, primary users of the spectrum

Need for a New BAN Standard

- Proprietary solutions are available
  - No interoperability between vendors
  - Focus is on niche markets $\Rightarrow$ low volumes
- Standards based solutions help create interoperable solutions, a larger market and lower cost solutions, all of which leads to wide spread adoption
- Current standard based solutions are optimized for other applications
  - Bluetooth is optimized for supporting voice links
  - Zigbee is optimized for industrial sensor applications
  - Wi-Fi for data networks etc.
- Modifications to current standards based solutions are a short term solution
  - Are possible but not optimal
  - Carry a significant overhead as they were designed with other applications in mind
- IEEE Standards Process
  - New standards are initiated only when existing standards are found lacking
  - IEEE 802.15.6 started specifically for Wireless Body Area Network

Need for BAN Standardization

"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."

BAN Standardization

- Standardization will occur in IEEE 802.15.6: Define both PHY and MAC layers

- 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.

Application Requirements

Application	Target data rate	Latency	BER
Drug Delivery	< 16 Kbps	< 250 ms	< 10^{-10}
Deep Brain Stimulation	< 320 Kbps	< 250 ms	< 10^{-10}
Capsule Endoscope	>1 Mbps		< 10^{-10}
ECG	192 Kbps (6 Kbps, 32 channels)	< 250 ms	< 10^{-10}
EEG	86.4 Kbps (300Hz sample, 12-bit ADC, 24 channels)	< 250 ms	< 10^{-10}
EMG	1.536 Mbps (8kHz sample, 16-bit ADC, 12 channels)	< 250 ms	< 10^{-10}
Glucose level monitor	< 1 Kbps	< 250 ms	< 10^{-10}
Audio	1 Mbps	< 20ms	< 10^{-5}
Video / Medical imaging	< 20 Mbps (e.g., Standard Video, HD video)	< 100ms	< 10^{-3}
Voice	50 – 100 Kbps per flow	< 10ms	< 10^{-3}

Taken from IEEE 802.15-07-0564-0ban: “Use Cases, Applications and Requirements for BANs” by C. Cordeiro

Traffic, Data Rate and Packet Types

- Traffic type:
  - Highly directed for medical applications are point-to-multipoint and multipoint-to-point medical or a mix of them.
  - Unlikely to have redundant medical sensors for vital information collection.
  - Non-medical applications are generally point-to point
  - Most of traffic is upstream from sensors to access point very little downstream traffic (commands)
  - Close loop control has a latency requirement that can be 100ms to seconds

- Data rates and packet types:
  - Most biomedical and vital signals are of low frequency and period
  - Packet samples are generated continuously with rates are from 1/ms to 1000/s.
  - Some sensors can be event/bursty (e.g. fall detection sensors for elderly).
  - Time crucial alarm packets are expected to have higher priority and low latency than sensor data.
  - The mean-time between missing of alarm packet should be over years.
  - If packets do not arrive within the specified interval, the system will enter an emergency alarm state, often with life or dead indication.

BAN Requirements

	Requirement	Details
Operating space	In, on, or around the body	Up to 3 m
Data rate	Scalable	Up to 10Mbps
Target bands	Unlicensed and Medical approved bands	MICS, MEDS, WMTS, ISM
Device duty cycle	Scalable	Up to 100% For example, between 0.001-1% in stand-by mode up to 100% in fully active mode
Peak Power consumption	Scalable	Up to 40mW For example, between 0.01-0.1mW in stand-by mode up to 40mW in fully active mode Ability to be switched-off completely
Coexistence	Coexistence with legacy devices, primaries, and self-coexistence	Simultaneous nearby operation of hundreds devices belonging to different BANs
Security	High	Authentication, privacy, encryption, etc.
Safety	High	Meet regulation requirements for SAR
Topology	Multiple simultaneous links	Tens of simultaneous links, no single point of failure, and multi-hop support
Network Setup	Required	Secure and under a few seconds
Cost	Low cost disposable	Disposable for monitoring, Different for implantable
Location information	Desirable	Localization within a radius of a few centimeters

Ref: IEEE 802.15-07-0564-0ban: “Use Cases, Applications and Requirements for BANs” by C. Cordeiro

Detailed Requirements (1)

- Low complexity, low cost and ultra low power
  - Capable of energy scavenging / battery-less operation
  - Disposable sensors operate for days between battery replacement/charges
  - Implantables have to operate for years
- High reliability
  - Need to have failsafe operation
- Operation in close proximity to or inside a human body
  - Specific FDA/FCC requirements have to be met in terms of currents induced in the body, SAR etc.
- Supports sensor, control and peripheral networks
- Compliant with co-located systems and addresses coexistence
  - Interference in a dense BAN environment should be managed through co-existence protocols etc.
- Support different classes of QoS for high reliability
  - Guaranteed bandwidth depending on application

Detailed Requirements (2)

- Graceful degradation of services
- Asymmetric traffic, power constrained
  - Sensors devices have different power constraints as compared to gateways
  - Traffic flows maximally from sensor device to gate way
- Needs optimized, low complexity MAC and Networking layer
  - MAC could also be asymmetric in complexity for low power
- High number of simultaneously operating piconets required
  - For hospital/healthcare facility environments
- Application specific, security/privacy required
- Small form factor for the whole radio, antenna, power supply system
- Locating radios (" find me") mode
- Concurrent availability of asynchronous and isochronous channels

BAN Challenges and Solutions

Challenges

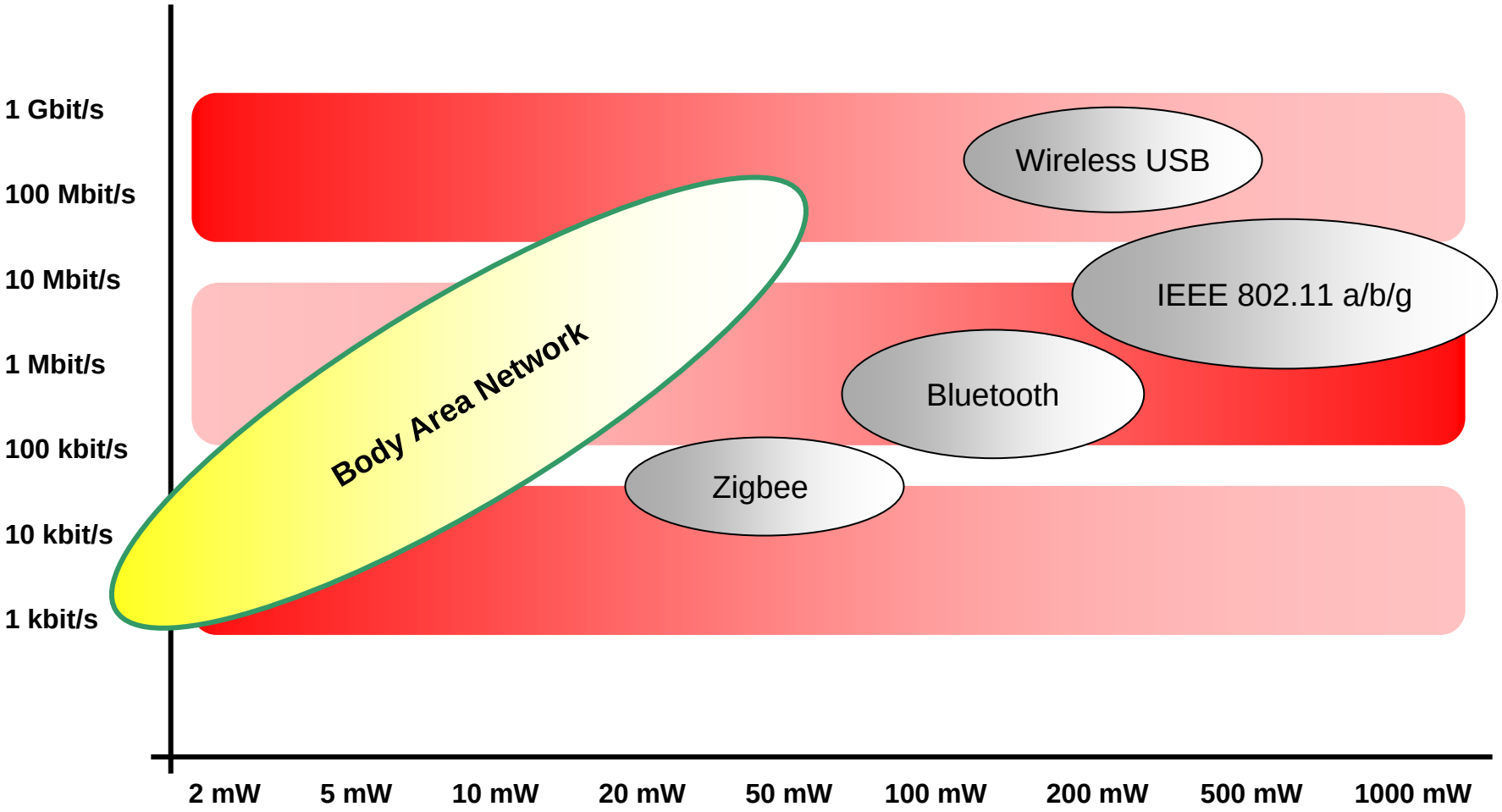
- Robust wireless link and bounded latency
- Capacity for patient and sensor density
- Ease of setup and use
- Security
- Coexist with other radios
- Battery life for days of continuous operation
- Small form factor for body worn devices
- Must be robust to interference
- Low power sleep modes

Solutions

- Error correcting code, spreading, diversity schemes, ARQ, low BER
- Advanced, simple media access protocols – contention or polled
- Exploit limited data rate by using low duty cycle TDMA
- Small, efficient antennas
- Reuse existing radios, if possible
- Higher complexity at BS, multiple antennas/radios
- AES encryption
- Unified MAC architecture – supports multiple frequency bands

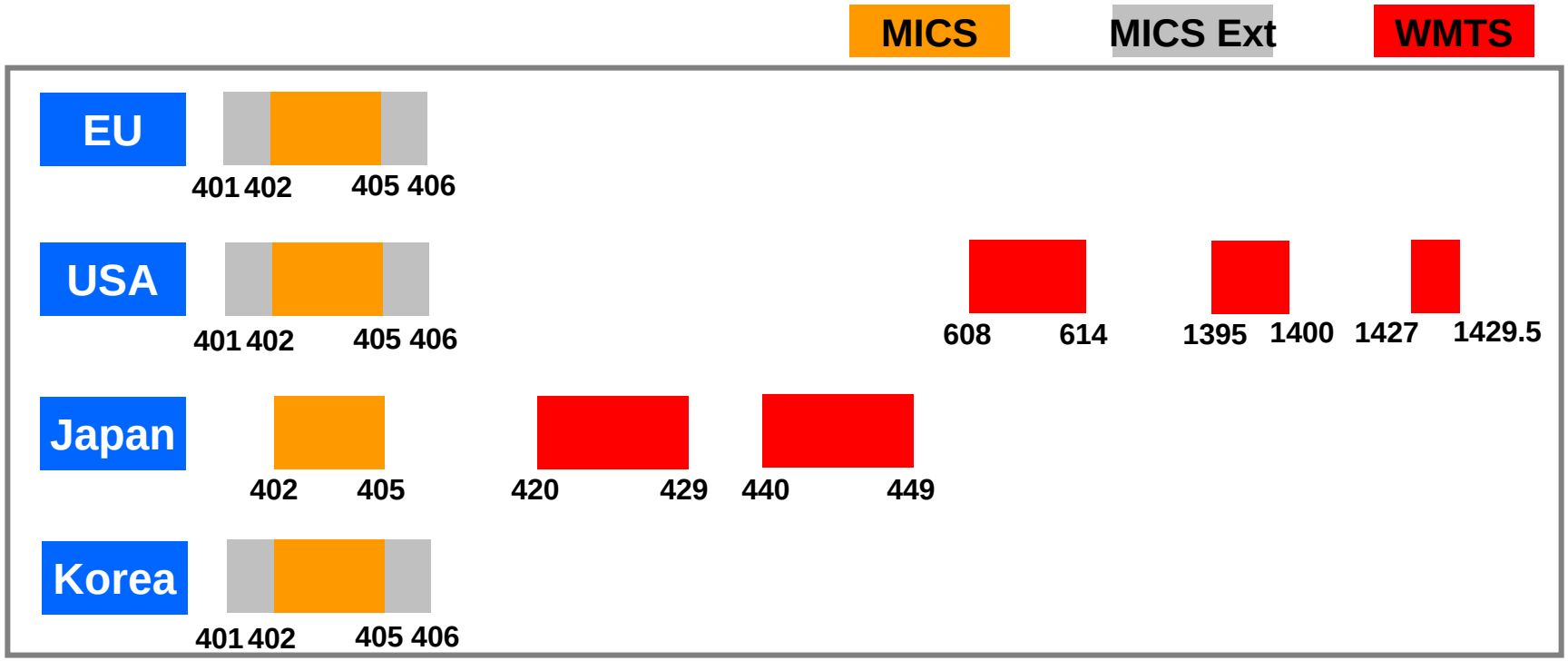
From IEEE 802.15-08-0108-0006: “Medical Body Area Network Application” by D. Davenport

Average Power Consumption & Data Rate Target



From IEEE 802.15-06-0331-00ban: “Tutorial on BAN” by S. Drude

Potential Spectrum (1)



MICS: Output power: 25μW ⇔ 9.1mV/m @ 3m, Signal BW = 300 KHz, Listen before talk (LBT)
MICS Ext: (1) Transmit only: Output power: -36 dBm, Signal BW = 100 kHz, < 0.1% duty cycle;
(2) Output power: -16 dBm, LBT with AFA
US WMTS: 608-614 MHz, Output power: 200 mW/m, Signal BW = 1.5 MHz, only data, no voice or video
US WMTS: 1395-1400, 1427-1429.5 MHz, Output power: 740 mW/m, only data, no voice or video
Japan WMTS: 420-429 MHz, 440-449 MHz, Output power: 0.001 W for BW ≤ 64 kHz, 0.01W for BW > 64 kHz,
Signal BW = 8.5, 16, 32, 64, 320 kHz, only simplex communication

From IEEE 802.15-07-0871-0ban: “Frequency Allocation Status of BAN” by Y. Yoon et al.

Potential Spectrum (2)

- Unlicensed bands: 900 MHz, 2.4 GHz and 5 GHz
  - Very crowded
  - Already used by hospitals (WLAN) for mission critical applications

- 400 MHz MedRadio or Medical Data Service (MEDS):
  - Duty cycle limits forces networks to center 3 MHz of band
  - 3 MHz bandwidth insufficient for entire patient population within hospital

- WMTS:
  - Limited and disjointed spectrum bands
  - Heavily utilized by hospital for existing telemetry applications
  - “Command and control” channel coordination
  - Use in ambulance, home and office is prohibited

From IEEE 802.15-08-0108-0006: “Medical Body Area Network Application” by D. Davenport

New Spectrum? (1)

- Proposed Part 95 Rules for BAN
  - Licenses for authorized health care professionals or by persons with prescriptions from health care professionals
  - Limited to transmission of data (no voice) – used for monitoring, diagnosing or treating patients
- Frequency range:
  - 2370 – 2390 MHz: limited to health care facilities and other environments where health care professionals monitor, diagnose or treat patients (including ambulances)
  - 2360 – 2370, 2390 – 2400 MHz: operations permitted anywhere CBs can operate
- Technical specifications:
  - All stations must access spectrum via a contention protocol
  - Maximum emissions bandwidth = 1 MHz
  - Maximum EIRP shall not exceed the lesser of [0, $10\log_{10}$(20-dB BW)] dBm
  - Same out-of-band (> 500 kHz outside of band) field strength limits as apply to MICS

New Spectrum? (2)

- Medtronic petitioned FCC in 2005 for body-area networks
  - FCC initiated a rulemaking in July, 2006
  - Want to extend band by adding 401-402MHz, 405-406MHz
  - New BW = 6 MHz

- Two access types defined:
  - Transmit only:
    - Power limited to 250nW (-36 dBm) EIRP with < 0.1% duty cycle
    - No Listen Before Transmit (LBT)
    - 100kHz/channel
  - LBT – same as MICS

Benefits of New Spectrum

- More bandwidth at 400 MHz (3 MHz → 6 MHz)
  - Better propagation characteristics
- 2360 – 2400 MHz is close to 2.4 GHz ISM band
  - Can leverage existing radio designs
  - Spectrum permits small, efficient antennas
- Larger BW can potentially supports high density requirements at hospitals: Can support multiple uncoordinated networks
- Notice of Proposed Rule Making (NPRM) can take up to 1 – 2 years depending on the level of contention

Coordination with IEEE 11073 (1)

- IEEE 11073 has defined a Medical Information Bus (MIB)
  - Between bedside medical device associated with a patient
  - Between bedside environment and a patient care information system

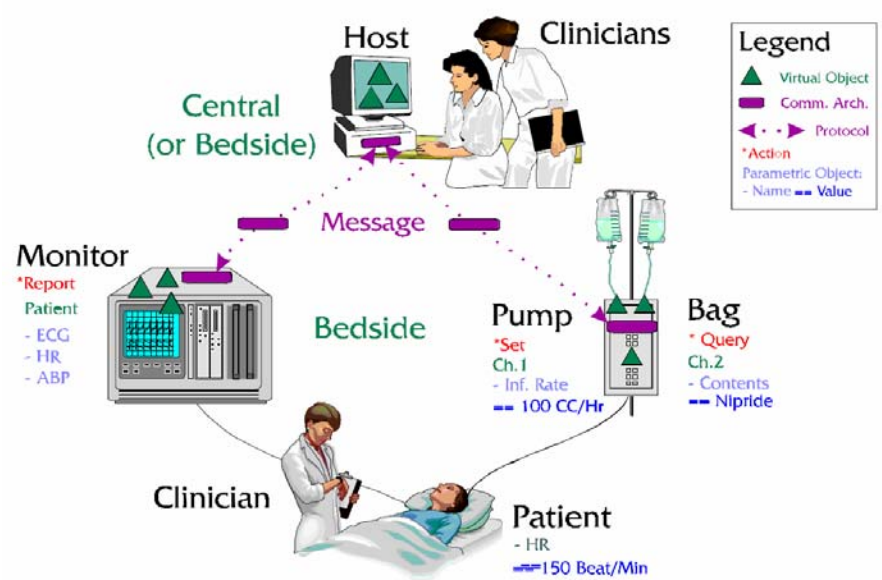
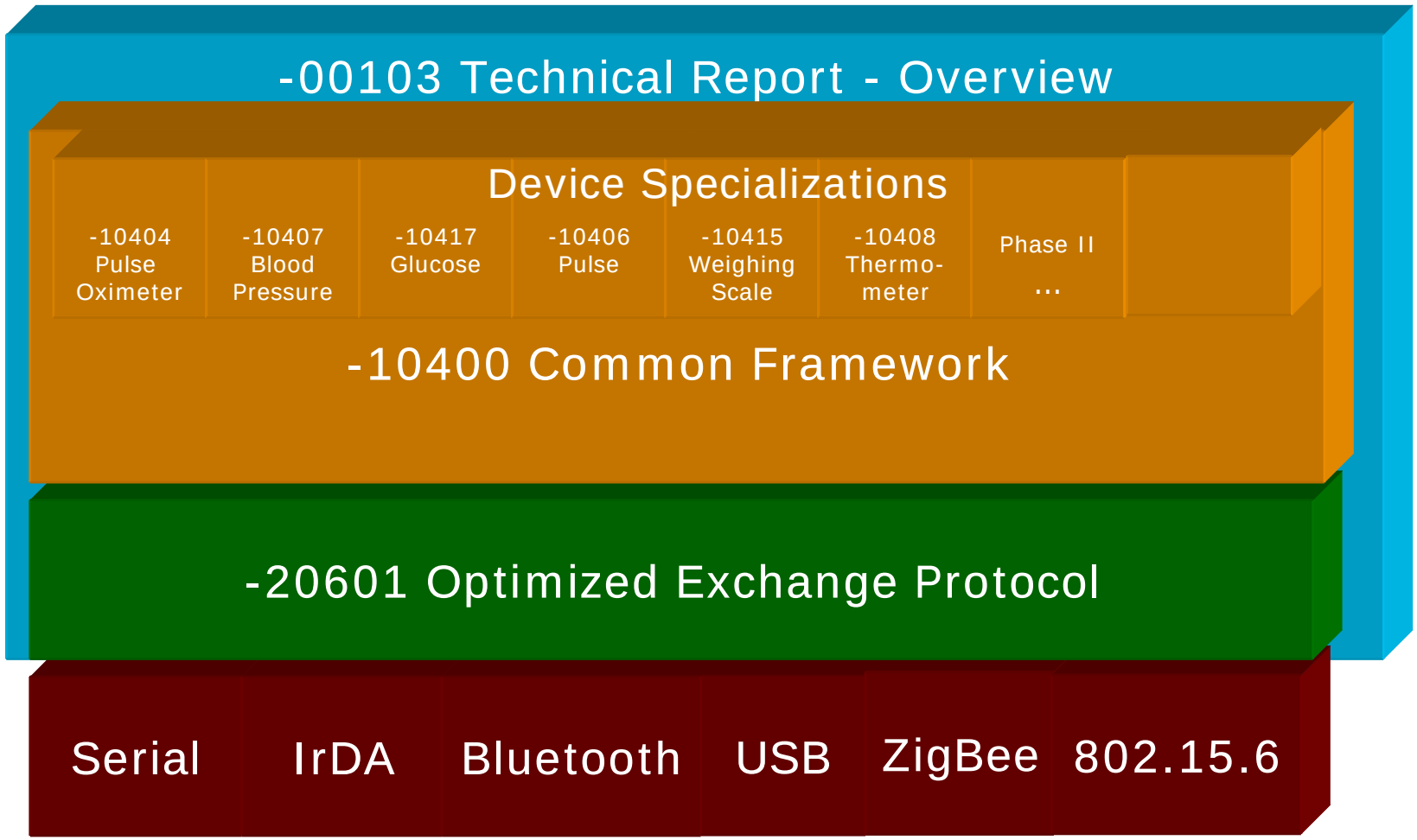


Figure 1—Conceptual bedside environment

Taken from IEEE 802.15-07-0725-0ban: “Coomunication Requirements from IEEE 1073” by B. Zhen et al.

IEEE 11073 Protocols



Coordination with IEEE 11073 (2)

- IEEE 11073 Requirements:
  - Used in a clinical environment, the transport must be robust, reliable and adaptable to changing conditions
  - Be suitable for a small single-bed systems with a local host at bedside to a lager multi-bed system with hosts and instrument throughout clinical facility
  - A MDS shall be unambiguously associated with a patient
  - Ease of use (“plug it in and walk away”)
  - QoS requirement: Delay < 300ms, determine by human response time
  - FER<10-6, in some cases, data cannot be lost
  - Mobility: patient, doctor, nurse can be moving

- IEEE 11073 guarantees the plug-and-play interoperability in upper layers:
  - Until now point-point cable connections have been defined
  - Data rate required is pretty low
  - QoS is provided by point-point connection

Taken from IEEE 802.15-07-0725-0ban: “Coomunication Requirements from IEEE 1073” by B. Zhen et al.

Timeline

- IEEE 802.15.6 – Formed in November 2007
- Call for applications: due March 2008
- Initial Sponsor Ballot submission: November 2009
- Submission to RevCom: March 2010

Conclusion

- Body area networking is needed *today* in the medical field
  - Demand for monitoring will grow 5.4% annually through 2010
- Needs to be a low cost, low power solution and fast deployment
- Must support low power media access protocols, guaranteed latency (QoS), security (privacy), easy setup and must be tolerant to disappearance of devices
- Standardization will occur in IEEE 802.15.6