Introduction to Standardization of Smart Body Area Networks in EU

Medical Device Regulatory Science Panel

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The need and focus

- As the world’s population ages, the need for solutions, such as eHealth, that help people live longer at home and with a better quality of life increases.
- eHealth is one such solution. It is a broad topic with many facets. Solutions may be used at home, in the hospital or on the move.
- For the purposes of this presentation, the focus is on **Body Area Networks (BAN)** in support of “Health” related applications and services such as:
  - Health and wellness monitoring
  - Personalised Medicine
  - Assisted living (including social networks)
  - Sports training and rehabilitation
  - Safety / emergency

*From devices to applications and services*
Body Area Network

Definition of a Body Area Network (BAN)

- BAN consists of one or more body sensor devices connected in a short range communication network about the body.
- Wireless body sensor devices may be wearable or implantable.
- Connectivity within a BAN may be wired, wireless or a combination.
- Devices may include: biomedical sensors, watches, handsets, hearing aids, necklaces…
- A BAN may be a stand-alone solution or part of a larger system connected via a wide area network (e.g. the Internet)

BAN may be viewed as a kind of access network. Communication may be machine-to-machine (M2M), person-to-machine, person-to-person…

Potential applications include Health, Wellness, Medical, safety, gaming and more.

Our focus is on Wireless BAN for «Health» applications
Health BAN applications

**Bio-Medical** (with average data rate)
- Blood pressure (0.01-0.1 kbps)
- SpO2, CO2, pH (0.01 – 0.1 kbps)
- Glucose sensor (0.01 – 0.1 kbps)
- Temperature (0.01 – 0.1 kbps)
- EEG (10-100 kbps)
- ECG (2-8kbps/lead)
- Respiration, fall detection...

**Sports performance**
- Distance
- Speed
- Posture (Body Position)
- Sports training aid

*Not only measurements, but increasingly towards continuous updates of data for tracking performance and conditions as well as better diagnosis*
Market growth projections for wireless enabled monitoring devices in kilo units (KU)

Exponential growth on the device side. Similar growth on the application-service side, perhaps especially given continuous monitoring systems.
## Snapshot of applications

<table>
<thead>
<tr>
<th>Category</th>
<th>Application</th>
<th>Metrics, sensors, actuators</th>
<th>Nature of devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assisted living</td>
<td>Alzheimers / dementia</td>
<td>Localization of persons, memory aids</td>
<td>Wearable</td>
</tr>
<tr>
<td></td>
<td>Assistance</td>
<td>Remote personal assistant, Social Network support group</td>
<td>Wearable, portable</td>
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<tr>
<td></td>
<td>Fall alarm</td>
<td>Fall detection and alarm</td>
<td>Wearable, portable</td>
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<tr>
<td></td>
<td>Medication compliance</td>
<td>Dosage, vital signs monitoring, reminders</td>
<td>Dispenser, wearable sensors</td>
</tr>
<tr>
<td>Fitness</td>
<td>Activity and metabolism</td>
<td>Activity detection (e.g. accelerometer), heat flux (calories)</td>
<td>Wearable, portable</td>
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<tr>
<td></td>
<td>Weight and body fat</td>
<td>Weight and calorie management, body fat analyzer (BMI), scale</td>
<td>Portable</td>
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<tr>
<td></td>
<td>Rehabilitation</td>
<td>Motion, posture, stress</td>
<td>Wearable devices</td>
</tr>
<tr>
<td></td>
<td>Sports training</td>
<td>Motion, pulse, temperature, heat flux, GSR</td>
<td>Wearable devices</td>
</tr>
<tr>
<td>Hospital</td>
<td>Vital signs / eICU</td>
<td>Real-time vital sign monitoring</td>
<td>Wearable</td>
</tr>
<tr>
<td></td>
<td>Location</td>
<td>Patients, new born babies</td>
<td>Wearable</td>
</tr>
<tr>
<td>Medical</td>
<td>Bowels, colon, esophagus</td>
<td>Camera pill, endoscopy</td>
<td>Swallowable capsule</td>
</tr>
<tr>
<td></td>
<td>Diabetes</td>
<td>Blood glucose level monitor, insulin delivery monitor</td>
<td>Wearable, portable</td>
</tr>
<tr>
<td></td>
<td>Enhanced diagnostics</td>
<td>Various, sensors and vital signs monitoring</td>
<td>Wearable, portable</td>
</tr>
<tr>
<td></td>
<td>Heart / vital signs</td>
<td>Pulse, ECG, blood pressure, respiration, temp, SpO2</td>
<td>Wearable, portable</td>
</tr>
<tr>
<td></td>
<td>Heart arrhythmia</td>
<td>Heart rhythm monitoring and defibrillator</td>
<td>Implant, portable</td>
</tr>
<tr>
<td></td>
<td>Parkinsons</td>
<td>Deep brain stimulator</td>
<td>Implant</td>
</tr>
<tr>
<td>Wellbeing</td>
<td>Sleep</td>
<td>EEG monitor</td>
<td>Wearable</td>
</tr>
<tr>
<td></td>
<td>Stress / emotion</td>
<td>Heat rate, muscle tension, GSR (skin conductance)</td>
<td>Wearable, portable</td>
</tr>
</tbody>
</table>

Tip of the iceberg! And most either use or could benefit from wireless
# Overview of technical requirements

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Wearable BAN Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coexistence/robustness</td>
<td>Good (low interference to other systems, high tolerance to interference)</td>
</tr>
<tr>
<td>Data Rates</td>
<td>Nominally 1-100 kbps (vital sign monitoring)</td>
</tr>
<tr>
<td>(De-) insertion</td>
<td>&lt; 3 seconds</td>
</tr>
<tr>
<td>Network topology</td>
<td>Star (mandatory), mesh (optional)</td>
</tr>
<tr>
<td>Power consumption</td>
<td>Low, autonomy &gt; 1 yr (1% duty cycle, MAC sleep modes, 500 mAh battery)</td>
</tr>
<tr>
<td>QoS (Medical BAN)</td>
<td>PER &lt; 10%, delay &lt; 125 ms</td>
</tr>
<tr>
<td>Reliability</td>
<td>Robust to multipath interference (&gt; 99% link success/availability)</td>
</tr>
<tr>
<td>SAR regulations</td>
<td>&lt; 1.6 mW (US) / &lt; 2.0 mW (EU)</td>
</tr>
<tr>
<td>Scalability</td>
<td>High, up to 256 devices</td>
</tr>
<tr>
<td>Range</td>
<td>≥ 3m</td>
</tr>
<tr>
<td>Security / privacy</td>
<td>3-level: 1) unsecured, 2) authentication, 3) authentication and encryption</td>
</tr>
</tbody>
</table>

Source: IEEE802.15.6

*Body sensor devices are typically miniature and low power*
The future?

- Heterogeneous networks

100's of millions to billions of devices

Many millions of users

- Multi-radio, multi-protocol
  - WBAN

Cloud

Massive volumes of personal data

- Mobile
- Scalable
- Trusted
- Dependable
- Cooperative
- Smart (yet simple)

- Personal healthcare and fitness communities
  - Doctors, hospitals, continuous diagnostics…
  - Caregivers, relatives, support groups…
  - Fitness, training and gaming communities…
  - Interaction and more…

Data, any time, any where, the ability to share and to correlate with context…
Illustration of a multi-radio / multi-protocol BAN using a wristband relay – possible early SmartBAN realization

- Network topology
  - Star and relay
- Multi-radio sensor connectivity
  - e.g. BT LE, SmartBAN, MBAN, 802.15.6...
- WAN connectivity
  - Mobile gateway (e.g. commercial handset)
- Relay (amplifier)
  - Around body (hidden devices)
  - Through body (implants)
- Bridge (multi-radio / protocol)
  - Optimized BAN (ULP, robustness, coexistence)
  - Enhanced connectivity / interoperability e.g.: BTLE, MBAN, SmartBAN, 802.15.6 (NB and UWB), MICS, 868MHz, proprietary solutions...

From a few stand-alone sensor devices to multiple devices in a heterogeneous BAN integrated in the IoT...
WBAN and the IoT...

- The IoT is rapidly expanding and untethered wireless connectivity is an essential feature, with Wireless Sensor Networks (WSN) and Wireless Body Area Networks (WBAN) at the forefront. Yet, the IoT can mean different things to different people. Many questions, issues and challenges remain:
  - All IP (each device an IP address)?
  - Personal data and trust, security and privacy
  - Operation over heterogeneous networks?
  - Interaction / coordination with other devices in the IoT? What level?
  - Scalability → 100s -1000s of nodes for higher device densities and larger scale networks?
  - Enhanced co-existence and dependability of wireless devices?
  - What are the standards / protocols for WBAN in the IoT? Semantic interface?

In the IoT, perhaps more than ever, **interoperability is a key!**
Open Issues

- Wireless body networks for measuring and transmitting human bio-potential signals.

- Patients’ frequency of monitoring could be very high
  - Cloud storage, Big data analysis

- Systems (and communications) must be dependable
  - Interference, coexistence, multiple access, backup routes, …

- BAN must work anywhere, anytime

- Solutions must be standardized (!)
General issues and limitations of BAN today

- Available frequency bands vary around the world
- Today’s solutions are too large & power consuming - not BAN optimized.
- Solutions for monitoring exercise a few hours / week fall far short of the requirements for unobtrusive 24/7 monitoring (e.g. heart patients at home)
- Solutions must be robust, generally based on standards (incl. defacto IND standards), support worldwide operation, compatible with existing solutions, simple and low cost.
- Miniature, ULP wireless solutions tailored to the unique requirements of BAN are needed.
- At the same time, we must gain user acceptance and confidence.
- Additionally, the business case may need to be clarified
Worldwide frequency band overview

BAN devices may operate in various frequency bands. The spectrum is crowded and differences exist in worldwide allocations.

Source: Huan-Bang Li, NICT, TG 15.6 Regulation summary, IEEE 802.15-08-0348-00-0006
# World Class Standards

## Medical Body Area Network Systems (MBANS) in Europe

<table>
<thead>
<tr>
<th>Frequency Band</th>
<th>Power / Magnetic Field</th>
<th>Spectrum access and mitigation requirements</th>
<th>Modulation / maximum occupied bandwidth</th>
<th>ECC/ERC Deliverable</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>d1 2483.5-2500 MHz</td>
<td>1 mW e.i.r.p.</td>
<td>Adequate spectrum sharing mechanisms (e.g. Listen-Before-Talk and Adaptive Frequency Agility) shall be implemented by the equipment and ≤ 10% duty cycle</td>
<td>≤ 3 MHz</td>
<td></td>
<td>The frequency band is also identified in Annex 12. The application is for MBANS, indoor only within healthcare facilities</td>
</tr>
<tr>
<td>d2 2483.5-2500 MHz</td>
<td>10 mW e.i.r.p.</td>
<td>Adequate spectrum sharing mechanisms (e.g. Listen-Before-Talk and Adaptive Frequency Agility) shall be implemented by the equipment and ≤ 2% duty cycle</td>
<td>≤ 3 MHz</td>
<td></td>
<td>The frequency band is also identified in Annex 12. The application is for MBANS, indoor only within the patient’s home</td>
</tr>
</tbody>
</table>

**MBANS Spectrum**

- **2360MHz**
- **2483.5 MHz**

Low power non-voice data networks for healthcare facilities and homes. Use of the same frequency band as in the US is not possible due to Wideband Data (4G / LTE)
Key technical / R&D subjects for BAN today

- Radio co-existence, robustness, QoS, security
- ULP multi-radio PHY and enhancements
- Low complexity, ULP MAC
- Multi-layer solutions (PHY-MAC through API and applications)
- Heterogeneous networks
- End-to-end system, handling and presentation of data
- Interoperability
- Security / privacy (low complexity means)
- Smart control, coordination and management
- Implant communication

Use what exists, fill in the gaps, and make it work better.
This is the mission of the new ETSI TC SmartBAN
ETSIS Technical Committee (TC) SmartBAN was approved on March 2013

- Responsible for development and maintenance of ETSI standards, specifications, reports, etc…

- Support development and implementation of SmartBAN network technologies (Wireless BAN, Personal BAN, Personal Networks etc.) in health, wellness, leisure, sport and more.

- Initial ETSI members supporting SmartBAN
  - CNIT (University of Florence)
  - CSEM
  - Cybernetic Medical Systems
  - CWC Oulu
  - IMEC
  - iMinds
  - Medtronic Bakken Research
  - IMT/Telecom Sud Paris
  - Toshiba Research Europe
ETSI TC SmartBAN organization

- At the SmartBAN workshop held at BodyNETS 2012 in Oslo, key technical challenges for SmartBAN were identified.
- These were refined at the ETSI eHealth meeting held in Geneva on 23 November 2012 and organized according to six main tracks or projects:
  1. Heterogeneity management, data representation and transfer
  2. Smart control, network management, interoperability & security
  3. Multi-layer, co-existence and dependability for SmartBAN
  4. Low complexity MAC and routing for SmartBAN
  5. Enhanced, ultra-low power PHY for SmartBAN
  6. SmartBAN implant communication

These projects are included in the Terms of Reference (ToR) which defines the basis for TC SmartBAN
Concluding Remarks

- The potential market for BAN is huge. Today, a number of issues still remain to be resolved:
  
  ➢ Further *regulation* is needed for *interoperability* and to help open the market.
    ➢ *Regulatory Science is essential* (!)
  
  ➢ Technical advances are also needed to make BAN devices and solutions that are *unobtrusive*, more *convenient* to the user and *dependable*.
  
  ➢ To *coexist* with potentially massive numbers of devices in the IoT including new types
  
  ➢ Increasingly *miniature, low power, adaptable, flexible / stretchable*
  
  ➢ *Scalable* to large numbers of devices (e.g. in a HD-BSN), from single radio BANs to *multi- radio* solutions with *flexible* topologies, ideally *batteryless*.

*Wireless BAN in the IoT, only the beginning...*
Thank you for your attention