C2F CONNECTED TO THE FUTURE

# Evaluation of Wireless Technology

## Wireless in Medical Environment

12/8/2015

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# Evaluation of Wireless Technology

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| Testing | Inspecting | Certifying | Qualifying | Consulting |
|---|---|---|---|---|

| Products | Systems | Processes | People |
|---|---|---|---|

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## Wireless in General

- Frequency spectrum
  - Low frequency (ELF-VF)
    - Inductive systems
    - 100 Hz – 10 kHz
  - Radio frequency (VLF-LF-MF-HF-VHF)
    - Transmitters
    - 10 (9) kHz – 1 GHz
  - Ultra high frequency
    - 1 GHz - 100 GHz
- Depending purpose of use
  - Near field communication
  - Far field communication

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## Wireless in General

- Wireless in medical environment
  - Fast growing market
- Advantage compared with wired technology
  - Ease of use
  - Reduction of discomfort
    - No bed-bound
  - Healthcare efficiency
  - Remote monitoring
- Extending healthcare
  - Anywhere
  - Anytime
- Many techniques and systems
  - Constant new developments and improvements



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## Wireless in Medical Environment

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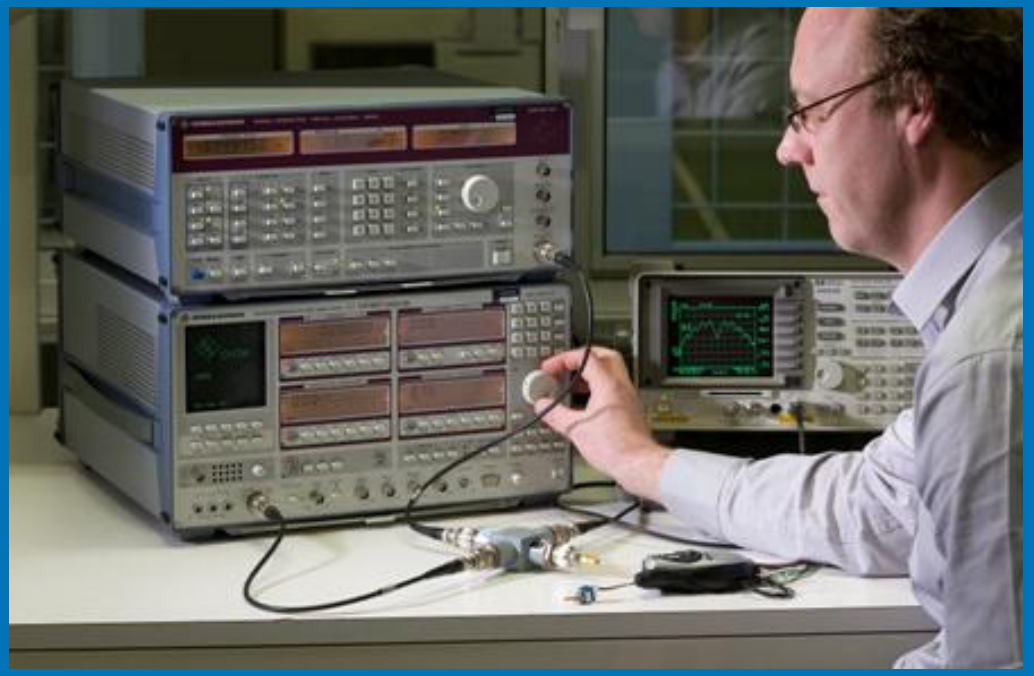
## Wireless in Medical Environment (cont.)

- **Controlling medical devices**:
  - ***Directly to medical device only***
    - Adjusting to needs
    - Read measured data
    - Read stored memory
    - System configurations
  - ***Essential performance***
    - see regulations
  - ***At anyplace, anywhere***
    - Using all possible wireless media



**Open media: Cyber Security!**



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## Wireless in Medical Environment (cont.)

- **Controlling patient data**:
  - **WAN** (wide area networks)
    - GSM: 10 to >100 Mbps
    - WiMAX: up to 70 Mbps
  - **WLAN** (WHAN) (wireless local area networks)
    - IEEE802.11abgn: up to 100 Mbps
  - **WPAN** (Wireless Personal Area Network)
    - ZigBee: up to 250 kbps
    - Bluetooth: up to 720 kbps
  - **WBAN** (Wireless Body Area Network)
    - ZigBee
    - UWB: 100 - 400Mbps
  - WiGig: up to 7 Gb/s

**Open media: Cyber Security!**

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## Wireless and regulations

- Medical devices are subject to MED 93/42/EEC however:
  - All wireless products in MED are within the scope of the Radio and Telecommunication Directive (R&TTE) 1999/5/EG
  - This Directive will be replaced next year by the new RED (Radio Equipment Directive) 2014/53/EU on 13-06-2016
    - 1 year transition (13-06-2017)
  - Definition of “Radio waves” changes from:
    - 9kHz – 300GHz into
    - *waves of frequencies below 3000GHz*
  - Receiver requirements will be in
    - More M2M requirements
    - Adaptivity (LBT)
  - Channel access requirements



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## Wireless and regulations (cont.)

- Medical devices are subject to MED 93/42/EEC
- All wireless products in MED subject to R&TTE 1999/5/EG
  - RED 2014/53/EU on 13-06-2017
- R&TTE (and RED) has three essential requirements:
  - Art. 3.1(a): Safety as for LVD (no voltage limits)
    - EMF exposure (SAR)!
  - Art. 3.1(b) EMC (not specific related to safety)
  - Art. 3.2 efficient use of spectrum to avoid interference
- MED has also EMC and Safety requirements
  - EMC and Safety requirements of MED are leading
    - Aspects of specific radio behavior need to be assessed
  - All related to Essential Performance



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## Wireless and testing

- **Legal testing**
  - Market access and usage
    - CE Directives
    - Many new Standards needed for RED
    - EN 303 660: Radio equipment operating < 9kHz
    - EN 303 348: Inductive loop for hearing impaired in 0-20 kHz
    - Etc
- **Voluntary testing**
  - Functional testing
  - Interoperability testing
    - Protocol testing
      - Use of Logo's



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